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Behavioral Counseling Interventions to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: Updated Systematic Review for the U.S. Preventive Services Task Force

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Structured Abstract

Objective: To review the benefits and harms of behavioral counseling interventions to improve diet and increase physical activity in adults with cardiovascular risk factors.

Data Sources: We performed a search of MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials for relevant English-language studies published between January 2013 and September 2019. Additionally, we reevaluated all studies included in the 2014 USPSTF review and related USPSTF systematic reviews. We conducted ongoing surveillance for relevant literature through January 4, 2020.

Study Selection: Two investigators independently reviewed 14,409 unique citations and 466 full-text articles against a priori inclusion criteria. We included English-language randomized clinical trials of behavioral counseling interventions to help people with elevated blood pressure or lipids improve their diet and increase physical activity. Critical appraisal was completed independently by two investigators. Data were extracted from studies by one reviewer and checked by a second.

Data Analysis: Random effects meta-analysis was used to examine outcomes with sufficient evidence to warrant pooled analyses, including all-cause mortality, cardiovascular events, blood pressure, lipids, adiposity-related outcomes, glucose-related outcomes, dietary measures, and physical activity. Subgroup analyses and meta-regression were used to explore effect modification for systolic blood pressure, total cholesterol, and weight.

Results: Ninety-four randomized trials were included (N=52,174). Behavioral counseling interventions were associated with a lower risk of cardiovascular events (pooled relative risk [RR]=0.80 [95% confidence interval (CI), 0.73 to 0.87]; 9 randomized controlled trials [RCTs] [n=12,551]; I²=0%), myocardial infarction (MI) (pooled RR=0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n=10,375]; $I^2=0\%$) and stroke (RR=0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n=9,800]; $I^2=0\%$), although the pooled effect was not statistically significant for stroke or MI. Event rates were variable; in the largest trial (Prevención con Dieta Mediterránea [PREDIMED]) 3.6 percent in the intervention groups experienced a cardiovascular event, compared with 4.4 percent in the control group. In addition, behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure, total cholesterol, fasting glucose, and adiposity-related outcomes at 12 to 24 months' followup. Blood pressure in intervention groups was reduced by a greater amount than in control groups—by a mean 1.8/1.2 mm Hg—after 12 to 24 months (pooled systolic blood pressure [SBP]=-1.8 [95% CI, -2.5 to -1.1]; 44 RCTs [n=14,580]; I²=37%; pooled diastolic blood pressure [DBP]=-1.2 [95% CI, -1.6 to -0.8]; 40 RCTs [n=13,098]; I²=32%). Total cholesterol was reduced by 3.5 mg/dL (95% CI, -5.6 to -1.4; 38 RCTs [n=11,414]; I²=66%) and low-density lipoprotein cholesterol was reduced by 2.1 mg/dL (95% CI, -4.1 to -0.2; 32 RCTs [n=8,894]; I²=56%). Intervention groups also showed slightly greater reductions in three adiposity-related measures: pooled body mass index=-0.5 kg/m^2 (95% CI, -0.7 to -0.3); 30 RCTs (n=9,909); I^2 =83%; pooled weight=-1.6 kg (95% CI, -2.1 to -1.1); 37 RCTs (n=16,345); I²=88%; and pooled waist circumference=-1.8 cm (95% CI, -2.4 to -1.1); 23 RCTs (n=11,708); I²=87%. Reporting of diet and physical activity was very heterogeneous, and evidence suggested small mean improvements in dietary intake consistent

with the intervention targets but small to no impact on physical activity. Results for blood pressure, lipid, and adiposity-related measures were generally consistent with the previous review despite some modifications to the review scope.

Limitations: Health outcomes were reported in a small proportion of the included trials, and many had very few events. Measurement of behavioral outcomes was extremely heterogeneous, and the clinical importance of measures of a single aspect of participants' diet is limited.

Conclusions: Medium- and high-contact multi-session behavioral counseling interventions to improve diet and increase physical activity provided to people with hypertension, dyslipidemia, or elevated blood pressure and lipid levels are effective in reducing CVD events, blood pressure, total cholesterol, and adiposity-related outcomes, with little to no risk of serious harm.

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Chapter 1. Introduction

Purpose

This report will be used by the United States Preventive Services Task Force (USPSTF) to update its 2014 recommendation on behavioral counseling to promote a healthy diet and physical activity for cardiovascular disease (CVD) prevention in adults with cardiovascular risk factors.¹

Condition Background

Condition Definition

CVD Risk Factors

For the purposes of this review, adults with CVD risk factors are defined as individuals with hypertension, dyslipidemia, impaired fasting glucose/impaired glucose tolerance, metabolic syndrome, or calculated 10-year CVD risk of 7.5 percent or greater. Because of the broad and multicomponent nature of cardiovascular risk, not all features of elevated risk are captured by this definition.

Diet

Healthy eating includes a balance and variety of foods and beverages that assist people in achieving and maintaining a healthy weight, supporting health, and preventing disease. For the purposes of this review, we consider any dietary counseling that focuses on increasing consumption of fruits, vegetables, whole grains, fat-free or low-fat dairy, lean proteins, and oils, and decreasing consumption of foods with high sodium levels, saturated- or *trans* fats, and added sugars, as recommended by the United States Department of Agriculture (USDA).² This guidance is generally consistent with dietary recommendations of a number of professional medical organizations as well as the USDA (**Table 1**).³⁻⁸

Physical Activity

Physical activity is broadly defined as any bodily activity that enhances or maintains overall health and physical fitness. Prominent organizations have most recently recommended that adults 18 years and older engage in at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity per week in addition to engaging in strengthening activities at least twice per week.^{3,9} These guidelines emphasize that some physical activity is better than none.

Burden of Preventable Illness

CVD is the leading cause of death in the United States for both men and women, and most ethnicities, including Hispanics, African Americans, and whites. ^{10, 11} In 2016, CVD was the underlying cause of 840,678—or 1 in 3—deaths. ¹² CVD prevalence is higher in males (51.2%) than females (44.7%), and is higher for African Americans (60.1% for males, 57.1% for females) than whites (50.6% for males, 43.4% for females among non-Hispanic whites; prevalence is comparable or lower for Hispanics and Asians). Between 2008 and 2010, CVD death rates in the United States were highest in the South and lowest in the West. ¹⁰ The American Heart Association (AHA) estimates that by 2035, over 130 million adults in the US will have some form of CVD. ¹³

Risk Factors

Risk factors for CVD are well-established, multicomponent, and common in adults. Modifiable risk factors include dyslipidemia or hyperlipidemia (referred to as dyslipidemia in this report), hypertension, diabetes, overweight and obesity, smoking, lack of physical activity, and unhealthy diet. Nonmodifiable risk factors include age, sex, and family history. The CDC estimates that nearly half of all U.S. adults age 20 years or older have at least one of the following CVD risk factors: uncontrolled hypertension; uncontrolled, elevated low-density lipoprotein (LDL) cholesterol level; or use of tobacco. Prevalence of risk factors defined by the AHA's "Life's Simple 7" similarly show the pervasiveness of modifiable risk factors (**Table 2**). 12

Cardiovascular risk can be characterized as the elevation of a single risk factor or can be quantitatively estimated from multivariate risk tools that are readily available in primary care. The most recent of these are the Pooled Cohort Equations, which estimate the 10-year risk of a cardiovascular event through application of the variables of age, sex, race, total and high-density lipoprotein cholesterol, blood pressure (including treatment status), current smoking, and diabetes. Thresholds for pharmacologic treatment with statins are recommended as 10 percent by the USPSTF and 7.5 percent by the American College of Cardiology/American Heart Association (ACC/AHA) (and considered when risk is 5 to 7.5% in the presence of risk-enhancing factors). Recent guidance for adults from the AHA/ACC recommends lifestyle modification when BP is 130–139/80–89 mm Hg and estimated risk is less than 10 percent, and blood pressure-lowering medication when blood pressure is greater than 130/80 mm Hg and 10-year risk is greater than 10 percent. Treatment thresholds recommended by guidelines and definitions around elevated values have generally decreased over time.

Dietary and Physical Activity Behaviors: Association With Health Outcomes and Prevalence in the United States

Large observational studies show that healthy diet and physical activity are associated with lower cardiovascular and all-cause mortality. The U.S. Burden of Disease Collaborators found that poor diet was the leading risk factor contributing to death in the United States in 2016—even greater than tobacco smoking; physical inactivity and low physical activity were also among the leading risk factors for death. A risk assessment study utilizing National Health and Nutrition

Examination Survey (NHANES) data estimated that dietary factors were associated with 45.4 percent of deaths due to heart disease, stroke, or diabetes; high sodium, high intake of processed meats, and low fruit and vegetable intake were the dietary components conferring the highest risk.²⁶

Despite observational evidence for associations between these behaviors and outcomes, current diet and physical activity behaviors in the United States are suboptimal. Data from the 2015 Behavioral Risk Factor Surveillance System (BRFSS) found only 12.2 percent of adults meet the daily recommendation of 1.5 to 2.0 cups of fruit each day and 9.3 percent of adults met the vegetable consumption target of 2.0 to 3.0 cups per day. ²⁷. Based on 2013 BRFSS data, an estimated 36.8 percent of U.S. adults met the criteria for the 2014 USPSTF recommendation for intensive behavioral counseling for CVD prevention in adults with risk factors, based on selfreported BMI of 25 or greater and the presence of hypertension, dyslipidemia, or impaired fasting glucose. 28 Adults \geq 65 years (56.4%), non-Hispanic blacks (43.3%), and men (40%) were most likely to meet criteria for behavioral counseling according to the existing USPSTF recommendation.²⁸ Of the AHA's seven components of ideal cardiovascular health—smoking, BMI, physical activity, healthy diet, total cholesterol, blood pressure, and fasting plasma glucose—the proportion of Americans meeting targets for a healthy diet is consistently the lowest among all age groups (**Table 2**). 11 There are some indications of progress, however, as NHANES data show that overall dietary pattern score improved between 1999 and 2016, with slight increases in carbohydrates from high quality sources, including whole grains (+2.95 g/day, p<.001), whole fruits (1.21 g/day, p<.001), non-starchy vegetables (0.44 g/day, p<.001); protein from nuts (+0.44 g/day, p<.001) and legumes (+0.13 g/day, p<.001); and decreased consumption of added sugar (-7.0 g/day, p<.001).²⁹ Progress was uneven, however²⁷. The largest improvements in Healthy Eating Index scores were among younger adults and those with high income and education; no differences in eating trends were found by sex or race/ethnicity²⁷.

More U.S. adults are meeting physical activity guidelines than dietary recommendations; however, the proportion is still low. As of 2018, 54.2 percent of U.S. adults \geq 18 years are meeting leisure-time aerobic physical activity goals. ³⁰ However, only 24.0 percent are meeting both the aerobic and muscle-strengthening guidelines. ³⁰ Older people, women of any age, and Hispanics are less likely to meet either of these guidelines. ³⁰ Fortunately, recent trends suggest physical activity among adults in the United States is improving ^{31, 32}.

Behavioral Counseling Approaches

Most behavioral counseling interventions to reduce cardiovascular risk among those with elevated blood pressure or lipids address both diet and physical activity, although some focus on only one of these. The interventions can include goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, modeling, problem-solving, and motivational interviewing. These interventions are typically delivered by specially trained health professionals (e.g., health educator, dietitian) and can take different formats, including brief counseling by a primary care provider, with or without accompanying materials or followup counseling; mailed, print-based interventions with tailored feedback; individual or group counseling; telephone counseling with no face-to-face contact; and computer-based interventions, including web-based sessions, email, or mobile technology. Additionally, support

that addresses barriers to change, social support, and general education and advice regarding the benefits of healthy eating or physical activity can be provided.⁴ Some interventions included addition of cardiovascular-related components such as smoking cessation support and stress management. Most interventions also encourage weight loss among patients with excess weight.

Current Clinical Practice in the United States and Recent Recommendations

Numerous organizations, including the AHA, Academy of Nutrition and Dietetics, and Department of Veterans Affairs, recommend that all adults adhere to a healthy lifestyle, which includes a balanced diet low in sodium and saturated fats, and regular exercise. Lifestyle counseling for weight loss is additionally recommended for people with overweight or obesity. Details of these and other recommendations appear in **Table 3**.

The 2018 U.S. physical activity guidelines recommend that all adults engage in at least 150–300 minutes of moderate-intensity or 75-150 minutes a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity in addition to engaging in strengthening activities at least twice per week. For adults with chronic conditions, including hypertension, who are not able to meet the key guidelines for general adult populations, the guideline recommends they engage in regular physical activity according to their abilities and should avoid inactivity.⁹

Despite these recommendations, counseling referral rates in primary care remain low and there are a number of barriers to referral from the clinician's perspective. A 2015 survey of U.S. primary care providers found that 58.6 percent discussed physical activity with most of their patients with CVD risk factors.³³ Nearly all providers that reported discussing physical activity with their patients reported encouraging increased physical activity (98.5%), but only 8.1 percent actually referred at-risk patients to intensive behavioral counseling. A major barrier to low rates of referral included attitudes and beliefs of providers that "patients won't do it" (53.4% of providers) and that "counseling is ineffective" (10%).³³ With respect to system-level barriers, "not enough time during visit" (60.9%), "insurance doesn't cover it" (12.1%) and "referral services aren't available" (11.4%) were among the barriers cited.

These findings are supported by other studies assessing treatment of at-risk patients in primary care. A 2014 review of physicians' use of the 5 A's model for weight loss counseling (Assess, Advise, Agree, Assist and Arrange) found that physicians frequently asked about or assessed patients' behavioral habits and readiness for change and provided behavior change advice, but rarely assisted patients in achieving goals or arranging support or referral to more intensive treatment.³⁴ Another review found that general practitioners tended to provide very little combined diet and physical activity advice to patients who were overweight or had obesity.³⁵ A survey of practitioners found that while 70 percent encountered conditions related to nutrition on a daily or weekly basis, only 25 percent felt "very confident" in providing nutrition advice.³⁶ It was also found that physicians infrequently referred patients to specialists such as dietitians for tailored interventions and advice.³⁵

Previous USPSTF Recommendation

In 2014, the Task Force recommended offering or referring adults who were overweight or had obesity and had additional CVD risk factors to intensive behavioral counseling interventions to promote a healthy diet and physical activity for CVD prevention (Grade: B recommendation).¹ Specific guidance was not provided on what constituted an "intensive" intervention, but the recommendation statement noted that effective interventions involved multiple contacts over an extended period of time, typically 5 to 16 contacts over 9 to 12 months. This recommendation applied to adults age 18 years or older in primary care settings who were overweight or had obesity and known CVD risk factors, defined as hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome. The USPSTF maintains reviews and recommendations for a number of other conditions associated with increased cardiovascular risk, including obesity, smoking, diabetes, lipids, peripheral artery disease, carotid artery stenosis, and nontraditional risk factors.³⁷⁻⁴³ Because these risk factors and conditions frequently coexist with those encompassed in this review, there exists some overlap of included populations and interventions. The recommendations related to behavioral counseling in adults without risk factors, those with abnormal blood glucose levels or diabetes, and those with obesity are particularly inter-related and are shown in Table 4. The recommendation on screening and treatment of adults for abnormal blood glucose is being updated concurrently with this recommendation.

Chapter 2. Methods

Scope and Purpose

This review is an update of the systematic review⁴⁴ that supported the 2014 USPSTF recommendation on this topic.¹ In contrast to the previous review, the current review excluded studies limited to or predominantly in populations with diabetes or prediabetes. This change was made because the USPSTF has commissioned a companion, concurrent systematic review to support the update of the recommendation on screening for abnormal blood glucose in adults that will include the evidence on behavioral counseling in populations with diabetes or prediabetes.⁴⁵ Thus, that population will be addressed in the separate diabetes screening review. In addition, weight loss trials that specifically targeted people with relevant cardiovascular risk factors were included in this review but were not included in the previous review.

Analytic Framework and Key Questions

With input from the USPSTF, we developed an Analytic Framework (**Figure 1**) and four Key Questions (KQs) to guide the literature search and selection of studies, data abstraction, and data synthesis.

Key Questions

- 1. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve <u>cardiovascular disease (CVD)</u> and related health outcomes (e.g., morbidity, mortality) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?
- 2. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve <u>intermediate outcomes</u> associated with CVD (e.g., blood pressure, lipid levels, blood glucose, body mass index) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?
- 3. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve <u>behavioral outcomes</u> (e.g., diet, physical activity, sedentary behavior) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?
- 4. What are the <u>harms</u> of primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior in adults with known CVD risk factors (e.g., hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [e.g., 10-year CVD risk >7.5%, metabolic syndrome])?

Data Sources and Searches

In addition to evaluating all studies that were included in the previous review of lifestyle counseling in populations with CVD risk factors,⁴⁴ we conducted a search to find studies published since the previous review, covering literature published from January 2013 through September 5, 2019. Additionally, to identify studies published during the search window of the previous review that might meet our updated inclusion criteria, we also evaluated selected studies *excluded* from the previous review and studies that were included in related reviews.^{46, 47} The search strategy was developed by a research librarian and was peer-reviewed by a second research librarian (**Appendix A**). It included searches of MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials. All searches were limited to articles published in the English language.

In addition to these database searches, we examined the reference lists of other previously published reviews, meta-analyses, and primary studies to identify additional potential studies for inclusion. We supplemented our searches with suggestions from experts and articles identified through news and table-of-content alerts such as those produced by the USPSTF Scientific Resource Center LitWatch activity. We also searched ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform (www.who.int/ictrp) for ongoing trials through August 2019. We managed the literature search results using version X9 of EndNote® (Thomson Reuters, New York, NY), a bibliographic management software database.

Study Selection

Two reviewers independently reviewed 14,409 unique citations and 466 full-text articles against a priori inclusion and exclusion criteria (**Appendix A Table 1, Appendix B**). We included studies that targeted populations at increased risk of cardiovascular disease due to hypertension or elevated blood pressure, dyslipidemia, or through examination of multiple risk factors. Examination of multiple risk factors may include estimated 10-year CVD risk of >7.5 percent or higher (e.g., using the Pooled Cohort Equations¹⁷ or Framingham risk calculators¹⁵), presence of the metabolic syndrome, or having any of multiple risk CVD factors (as long as hypertension/elevated blood pressure and dyslipidemia are among the eligible risk factors). For all key questions, we included randomized controlled trials (RCTs), including clusterrandomized trials, as well as nonrandomized controlled trials of behavioral counseling interventions to improve diet and increase physical activity in people with CVD risk factors. In addition, we allowed inclusion of systematic reviews, comparative cohort studies, and population-based case-control studies for assessments of harms of lifestyle counseling (KQ4).

We excluded studies that targeted populations with known CVD, diabetes, or chronic kidney disease; and studies that targeted populations with prediabetes. We also excluded studies of behavioral counseling interventions that targeted prevention or management of other medical conditions, such as cognitive impairment, serious mental health conditions, arthritis, falls, chronic pain, and cancer. We included trials whose primary aim was weight loss if the study targeted people with CVD risk factors and involved a behavioral counseling intervention. We

limited inclusion to studies in adult populations in countries rated as "Very High" on the human development index according to the UN, based on 2015 indicators.⁴⁸

We included studies of behavioral counseling interventions on diet and nutrition, physical activity (including sedentary behavior), or a combination thereof. Interventions could be delivered alone or as part of a larger multicomponent intervention that also addressed other health behaviors (e.g., smoking cessation, medication adherence). There were no restrictions on the contact time or duration of the interventions for inclusion, however, 6 months after randomization or the baseline assessment was the required minimum followup time for outcome assessment. Interventions had to have been conducted in a healthcare setting or be feasible for a healthcare setting to implement, meaning that the intervention could be "referable" from primary care were it to be implemented in a healthcare system. Thus, we excluded interventions with components that were not feasible for implementation in healthcare settings (e.g., interventions conducted within existing social networks, media campaigns, environmental interventions, public policy interventions). We also excluded studies conducted in settings that were not generalizable to primary care, such as inpatient facilities, emergency departments, nursing homes or other institutional settings, classrooms, and occupational settings. Comparative effectiveness studies were excluded, and allowable control groups included no intervention (e.g., usual care, wait list), a minimal intervention (e.g., pamphlets, links to preexisting internet resources, brief counseling of no more than an estimated 60 minutes annually), and attention controls with similar format and intensity but a different content area.

For the main search results, pairs of independent reviewers assessed a sample of 1,500 abstracts for inclusion, and discrepancies were resolved by discussion and consultation with the larger review team as needed. An artificial intelligence (AI) program embedded in the DistillerSR platform (Evidence Partners, Ottawa, Canada) then "trained" on these 1,500 abstracts and the abstracts of other known included studies from the previous review and related reviews. For the remaining abstracts, we conducted dual human review (if the AI score was equivocal for inclusion; 2,241 abstracts) or used the AI program in place of one of two human reviewers (if the AI score indicated a low probability of inclusion; 4,217 abstracts). Every abstract was assessed by at least one human reviewer. All abstracts identified in subsequent updating bridge searches (6,451 abstracts) were reviewed only by human reviewers. Discrepancies between any two reviewers (either two human reviewers or the AI and a human reviewer) were resolved by a different human reviewer or consultation with the larger team. Two independent (human) reviewers assessed full-text articles against our inclusion criteria and discrepancies were resolved by discussion or consultation with the larger review team as necessary.

Quality Assessment and Data Abstraction

Two reviewers independently rated the studies' methodological quality using USPSTF design-specific criteria (**Appendix A Table 2**).⁴⁹ Studies were rated as "good," "fair," or "poor," and discrepancies between raters were resolved by discussion or consultation with the larger review team. Good-quality studies were those that met nearly all of the specified quality criteria (e.g., comparable groups were assembled initially and maintained throughout the study and followup was approximately 90% or higher), whereas fair-quality studies did not meet these criteria but

did not have serious threats to their internal validity related to their design, execution, or reporting. Poor-quality studies typically had several important limitations, including at least one of the following risks of bias: very high attrition (generally >40%), differential attrition between intervention arms (generally >20%); substantial lack of baseline comparability between groups without adjustment; or issues in trial conduct, analysis, or reporting of results (e.g., possible selective reporting, inappropriate exclusion of participants from analyses, questionable validity of randomization and allocation concealment procedures). Studies rated as "poor" quality were excluded from the review. For studies that had been included in the previous review on this topic or the recent USPSTF review of weight management interventions, we did not repeat critical appraisal of the original studies since we were updating our own work.

For all of the included studies, one reviewer extracted key elements into standardized abstraction forms in DistillerSR (Evidence Partners, Ottawa, Canada). A second reviewer checked the data for accuracy. For each study, we abstracted general characteristics (e.g., author, year, study design), clinical and demographic characteristics of the sample and setting (e.g., age, race/ethnicity, baseline clinical characteristics, setting, country), intervention details, and results. Outcomes of interest included health outcomes (cardiovascular events and related morbidity, including myocardial infarction [MI], stroke, coronary event, transient ischemic attack, arrhythmia, incident peripheral artery disease, angina, claudication, congestive heart failure, any CVD event); mortality; quality-of-life and related measures), intermediate outcomes (blood pressure, lipids, glucose, adiposity-related measures, 10-year CVD risk, cardiorespiratory fitness), and behavioral outcomes (dietary intake, physical activity, sedentary behavior). We abstracted objectively measured weight loss outcomes (weight, BMI, waist circumference) instead of self-reported weight or energy intake. We required that all outcomes were measured 6 months or more after baseline assessment.

For population risk factors, we categorized studies based on the risk factors required by the studies' inclusion criteria. We labeled trials limited to people with hypertension or elevated blood pressure as "Hypertension," even if the trial was limited to people with elevated blood pressure and excluded those meeting criteria for hypertension. Similarly, the label "Dyslipidemia" was used for trials that required all participants to have lipid levels outside of the optimal range, including both borderline and high LDL (or low for HDL) levels. Trials that included participants with any of multiple risk factors are labeled as "Multiple." Trials are described as "weight loss" trials if the study required all participants to have a specified level of excess weight at study entry and had an explicit goal of weight loss for all participants. Trials were categorized as targeting low socioeconomic status (SES) populations if the community in which recruitment took place was described as low-income by the authors, or if any of the following were true: there was 20 percent or higher unemployment among participants, or 30 percent or more of participants were either unemployed or disabled, among working-age populations; fewer than 70 percent or participants were high school graduates (U.S. studies only); more than 20 percent of participants were at or below the 100 percent of federal poverty limit; more than 30 percent of participants were on Medicaid; or all participants were recruited from Federally Qualified Health Centers (designed to serve low-income individuals).

For intervention characteristics, we abstracted a detailed description of the interventions and information on the setting, format, mode of delivery (i.e., in-person, telephone, electronic, or

print), dietary approach (Dietary Approaches to Stop Hypertension [DASH], fat-modified [low in saturated fat, low in all fats, or moderate levels of fats], low sodium, Mediterranean), duration, number and length of sessions, providers and provider training, and adherence. We estimated the total hours of interventionist contact based on the planned number and length of contacts. If a study did not report the length of sessions, we estimated session length as follows: a session described as "brief" was assumed to last 15 minutes if there was face-to-face, individual contact and 5 minutes if it was a phone session and for sessions that were not described as "brief," individual face-to-face or interactive web-based sessions were assumed to last 30 minutes and group sessions was assumed to last for 60 minutes. Consistent with the previous review, we grouped the studies into three levels of contact dose (referred to as "intensity" in the previous review): low (estimated ≤30 minutes of phone or in-person contact), medium (31–360 minutes), and high (>360 minutes). Interventions that consisted of only print materials were categorized as low contact. Mailings and print materials were not included in the estimated of number of sessions or session length.

During data abstraction, we catalogued the availability and characteristics of subgroup analyses by age, sex, race/ethnicity, and other characteristics of interest (e.g., BMI or weight status). We noted whether subgroup analyses were prespecified or post-hoc and whether interaction testing was reported.

Data Synthesis and Analysis

We created summary tables for all KQs showing study, population, intervention characteristics, and outcomes for qualitative evidence synthesis. For both continuous and dichotomous outcomes, adjusted effect estimates reported by primary studies were used over unadjusted values. Crude effect estimates were calculated if between-group results were not reported. For pooling, we used the Restricted Maximum Likelihood model with the Knapp-Hartung correction for small numbers of studies.^{50, 51} We chose this method because there was either a small number of trials to be pooled or high statistical heterogeneity (commonly $I^2 > 50\%$, often > 80%) for most analyses.⁵² We generated analyses that included all available intervention groups for each study and that were limited to the single most intensive or comprehensive intervention group per study (termed primary intervention group). Effect sizes were generally slightly larger when limited to the primary intervention group, with slightly larger confidence intervals, but statistical significance was almost always consistent between the two approaches. Meta-analyses limited to the primary intervention group are presented for all intermediate (KQ2) and behavioral (KQ3) outcomes except diabetes incidence and metabolic syndrome, where we included results for both groups from the Prevención con Dieta Mediterránea (PREDIMED) study, since a substantial proportion of the evidence would have been lost if one PREDIMED arm was excluded. However, for mortality and cardiovascular event outcomes, for which the absolute number of events was generally small, results for multiple intervention groups were combined. For pooled analyses of intermediate (KQ2) and behavioral (KQ3) outcomes, the followup time point closest to 12 months was selected if there were multiple followup assessments. For systolic blood pressure, total cholesterol, and weight outcomes, we generated funnel plots and ran Egger's test to explore small-study effects, which can be related to publication bias.⁵³

Additionally, we conducted meta-regression and subgroup analyses to explore whether there were study, population, or intervention characteristics that were associated with effect size for systolic blood pressure, total cholesterol, and weight. These outcomes were selected for prespecified subgroup and meta-regression analyses because they were the most commonly reported outcome in each of the three main intermediate outcome domains. Characteristics explored were: intervention contact (number of sessions, estimated contact hours, high-vs. medium- vs. low-contact category, duration [in weeks]); diet recommendation (fat-modified, low-sodium); delivery (group, in-person contact); weight loss approach (recommended for all participants, recommended for the subset of participants with overweight or obesity); use of motivational interviewing; active medication management; provision of pedometers; provision of blood pressure monitors; primary care staff involvement; population targets (older adults, CVD risk factor selection, low SES), U.S. setting; and indicators of study quality (quality rating, time to followup, sample size, year of publication). Initially we also planned to explore whether trials with majority nonwhite samples differed from those that did not; however, almost all trials with high race/ethnic minority representation were in economically disadvantaged populations, so we were unable to disentangle these effects and instead focused on socioeconomic status.

The availability of subgroup analyses within individual studies was audited to determine the proportion of studies reporting outcomes according to various subgroups. Subgroup analyses were sparsely and inconsistently conducted in included studies and thus were not quantitatively pooled. Analyses were qualitative and aimed to determine whether interventions were broadly effective among various subpopulations.

We used Stata 15.1 (StataCorp LLC, College Station, TX) and R 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria). All significance testing was 2-sided, and results were considered statistically significant if the p-value was 0.05 or less.

Grading the Strength of the Body of Evidence

We graded the strength of the overall body of evidence for each key question. We adapted the Evidence-based Practice Center approach,⁵⁴ which is based on a system developed by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group.⁵⁵ Our method explicitly addresses four of the five Evidence-based Practice Center-required domains: consistency (similarity of effect direction and size), precision (degree of certainty around an estimate), reporting bias (potential for bias related to publication, selective outcome reporting, or selective analysis reporting), and study quality (i.e., study limitations). We did not address the fifth required domain—directness—as it is implied in the structure of the key questions (i.e., pertains to whether the evidence links the interventions directly to a health outcome).

The domain of consistency was rated as reasonably consistent, inconsistent, or not applicable (e.g., single study). The domain of precision was rated as reasonably precise, imprecise, or not applicable (e.g., no evidence). Study quality reflects the quality ratings of the individual trials and indicates the degree to which the included studies for a given outcome have a high likelihood of adequate protection against bias. The body-of-evidence limitations field highlights important

restrictions in answering the overall key question (e.g., evidence of reporting bias, lack of replication of interventions, nonreporting of outcomes important to patients).

At least two independent reviewers rated the overall strength of evidence for each intervention type. We resolved discrepancies through consensus discussion with the full review team, consulting with outside reviewers as needed. We graded the overall strength of evidence as high, moderate, low, or insufficient. "High" indicates high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effects. "Moderate" indicates moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of effect and may change the estimate. "Low" indicates low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of effect and to change the estimate. A grade of "insufficient" indicates that evidence is either unavailable or does not permit an estimate of an effect.

Expert Review and Public Comment

The draft Research Plan was posted from June 14 to July 17, 2018. Comments addressed the types of eligible interventions, selection of outcomes, eligible settings, clarity about included populations, and integration of findings with the diabetes review. Clarifying text was added to the intervention inclusion and exclusion criteria. Waist circumference was added as an outcome, and cardiorespiratory fitness was explicitly listed as an included intermediate outcome. The setting description was broadened to include the term primary care-referable in addition to primary care-generalizable. With respect to included populations, language in the KQs was clarified, and the condition definition in the inclusion and exclusion criteria table was modified to explicitly define the included populations; newly included in this update are populations with elevated blood pressure in addition to populations with hypertension. The draft version of this report was reviewed by three invited experts and 9 individuals at 5 USPSTF Federal Partner agencies. Experts were selected based on their expertise with fundamental methodologic and content aspects of the review (i.e., nutrition, physical activity, hypertension, and dyslipidemia, CVD epidemiology, and population health) and were selected to obtain diverse informed perspectives. All expert comments were considered, and selected comments from experts were used to clarify and extend the synthesis of evidence to ensure accuracy and address scientifically relevant concerns. All comments were shared with members of the USPSTF and the Agency for Healthcare Research and Quality (AHRQ).

USPSTF Involvement

This systematic review was funded by AHRQ under contract to support the USPSTF. We consulted with USPSTF liaisons at key points in the review regarding the development of the research plan (i.e., KQs, analytic framework, and inclusion and exclusion criteria) and the finalization of the systematic review. An AHRQ Medical Officer provided project oversight, reviewed the draft and final versions of the review, and assisted with public comment on the

research plan and draft review. The USPSTF and AHRQ had no role in the study selection, quality assessment, or writing of the systematic review.

Chapter 3. Results

Description of Included Studies

Ninety-four randomized and cluster-randomized trials $^{56-149}$ (N=52,174) of diet and physical activity counseling, reported in 227 publications $^{56-282}$ (**Appendix B**), met our inclusion criteria. Twenty-nine trials reported a health (KQ1) outcome (n=23,854), 91 reported an intermediate (KQ2) outcome (n=47,951), 70 reported a behavioral (KQ3) outcome (n=43,243), and 20 reported on harms or potential harms (n=18,263). Forty-two trials were newly identified in this update. $^{108-137,\ 139-144,\ 261}$

Of all included studies, 32 (34.0%) were limited to people with hypertension or elevated blood pressure, 16 (17.0%) were limited to those with dyslipidemia, and the remaining 46 (49.0%) included people with any of multiple risk factors, typically including excess weight, impaired glucose tolerance, metabolic syndrome, type 2 diabetes, smoking, and/or elevated 10-year cardiovascular risk in addition to hypertension and dyslipidemia (**Table 5**). Most trials recruited participants from healthcare settings: 38 (40.4%) in primary care settings and 20 (21.3%) in similar settings, such as community health clinics or health plan membership databases. Forty-three (45.7%) of the trials were conducted in the United States. The median (interquartile range [IQR]) sample size was 314 (154 to 601). One of the newly published trials was the PREDIMED trial, a large (n=7,447) multisite trial with long-term (5-year) followup conducted by Estruch and colleagues. ¹³¹

Included Populations

Across all trials, 49.5 percent of the participants were female and the mean (SD) age was 56.0 (8.3) years; 11 trials had a minimum age of 50 or higher (**Table 6**). Among the trials reporting baseline CVD risk factor status, 62.0 percent of the participants had hypertension, 70.3 percent had dyslipidemia, 20.2 percent had diabetes, 2.8 percent had known cardiovascular disease, and 22.7 percent were current smokers. Twenty-one trials were limited to individuals with excess weight, ^{58, 60, 69, 84, 98, 109, 116, 119-121, 123-130, 134, 141, 144} and although this was not an inclusion requirement for the remaining trials, most participants in the included trials were overweight or had obesity; the mean (SD) baseline BMI was 29.8 (2.6) kg/m². Of the 43 trials conducted in the United States, 16 trials (37.2%) appeared to include majority Hispanic or nonwhite samples. Overall, 19 (20.2%) focused on low-SES populations. Detailed population characteristics are available in **Appendix F Table 1**.

Among the 32 trials that were limited to people with hypertension or elevated blood pressure , the mean (SD) baseline systolic and diastolic blood pressure values were 136 (10) and 86 (6) mm Hg, respectively, with 61.1 percent of participants meeting diagnostic criteria for hypertension according to study criteria. Nine of these studies (28.1%) were limited to patients taking antihypertensive medications, and nine other trials (28.1%) excluded patients taking antihypertensive medications. Four trials (n=4,659) excluded people with hypertension and limited participation to those with elevated blood pressure , with the goal of preventing progression to hypertension. $^{120,\,122,\,133,\,138}$

For the 16 trials limited to patients with dyslipidemia, baseline mean (SD) total cholesterol was 254 (20.2) mg/dL and LDL cholesterol was 160 (22) mg/dL. Ten (62.5%) of the trials in populations with dyslipidemia excluded patients who were taking lipid-lowering medications, and the remaining trials had no restrictions related to medication use. Among the 46 trials that recruited patients with any of multiple CVD risk factors, 42 (91.3%) had no restrictions related to medication use.

Included Interventions

The 94 included trials had 120 active intervention arms (**Table 7**). Eighty-one (67.5%) of the interventions provided counseling that encompassed both diet and physical activity, 33 (27.5%) addressed only diet, and six (5.0%) addressed only physical activity. None of the physical activity trials focused exclusively on reducing sedentary behavior. The median (IQR) number of contacts was 12 (5–27), with an estimated 6 (2.2–15.8) hours of contact over 12 (6–18) months. Fifty-four (45.0%) of the interventions offered high-contact interventions, that is, over 6 hours of contact time with an interventionist (in person or over the phone), 59 (49.2%) offered mediumcontact interventions, or an estimated 31 minutes to 6 hours of contact, and only 7 (5.8%) were low-contact interventions with 30 minutes or less of direct contact. The trials that only addressed physical activity had relatively low contact time, ranging up to an estimated 4.5 hours of contact at most. ^{61, 87, 90, 94, 132, 140} See **Figure 2** for a graph showing the distribution of contact time by intervention target. Almost all of the interventions involved some one-on-one time with an interventionist; however, nine (7.5%) were limited to group sessions and four (3.3%) were entirely computer- and/or print-based, 97, 103, 123, 142 including one that tested an online training module for primary care physicians without any specific patient-facing components. 97 The use of motivational interviewing was described in 43 (35.8%) interventions. Other common elements included typical behavior change techniques such as goal setting, problem solving, and selfmonitoring. Primary care clinicians were involved in delivering 27 (22.5%) of the interventions, and delivered all or most of the interventions in eight (6.7%) trials. ^{77, 80, 83, 97, 102, 119, 128, 129} Other interventionists included nutritionists, registered dieticians, exercise specialists, nurses, master'sand doctoral-level counselors trained in behavioral methods, and lifestyle coaches.

Among the trials targeting people with hypertension or elevated blood pressure, the most commonly used dietary approaches were a low-sodium diet (29 of 50 groups [58.0%]) and the DASH diet (11 of 50 groups [22.0%]), which also recommends moderate or restricted sodium intake. Eighteen of these trials (36.0%) included management of antihypertensive medications, and five (10.0%) provided blood pressure monitors. Of the interventions limited to people with dyslipidemia or suboptimal lipid levels, 12 (60%) recommended a fat modified diet. Of all studies, the approach for weight loss was variable: 29 (24.2%) interventions were limited to people with excess weight and explicitly recommended weight loss for all participants, 31 (25.8%) interventions recommended weight loss for those in the sample with excess weight, and 11 interventions (9.2%) focused on improving diet and physical activity without explicitly promoting weight loss. The remaining 49 (40.8%) interventions did not report whether or for whom weight loss was promoted. Usual care was the most common type of control group (73 [77.7%] of the trials), but 7 trials instructed control group participants to maintain their usual habits. ^{57, 58, 72, 87, 95, 121, 148} For detailed information about intervention characteristics for each

trial, see **Appendix F Tables 2 and 3**. **Table 8** lists recommended eating plans for two diets used in the included trials, the DASH diet and the Mediterranean diet.

The PREDIMED trial was a large trial conducted in Spain among middle-aged and older adults who had any of a number of CVD risk factors and did not score as "unlikely to change" according to the Stages of Change model. The trial is an important addition to this literature base, given its large sample size and length of followup. Participants in both active intervention groups first met with a dietitian to discuss individual recommendations to help them adopt the Mediterranean diet based on a dietary assessment. Next, they participated in a group educational session covering dietary goals, meal plans, shopping lists, and questions they had about the recommended diet. Participants then had quarterly visits with the dietitian, who assessed their progress, discussed dietary goals, and offered support for an estimated 20 sessions of individual diet counseling. Throughout the program, interventionists emphasized the holistic approach to lifestyle change in order to tailor the intervention to nutritional assessment and individual needs, instill a sense of empowerment, and support a sense of accomplishment for each upward step in the 14-point Mediterranean diet score. Interventionists used cognitive behavioral techniques such as goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, problem solving, relapse prevention, and motivational interviewing in individual and group sessions. In addition, participants received either 20 1.5-liter allotments of extra virgin olive oil (intervention group 1 [IG1]) or 20 allotments of 2,700–3,700 grams of mixed nuts (intervention group 2 [IG2]). The dietary recommendations are listed in **Table 8**. Also, dietitians insisted that two main meals per day should be eaten seated at a table and last more than 20 minutes. Control group participants received a brief counseling session promoting a low-fat diet and annual leaflets, and in the fourth year of the study and beyond, received quarterly invitations to individual and group-based sessions focused on low-fat diets.

Study Quality

Among all trials, 19 (20.2%) were rated as "good" quality, and the remaining were rated as "fair." The median (IQR) study retention was 86 percent (79%–92%) at 12 months' followup or the closest to 12 months reported by the trial. Among those that did not receive the "good" rating, attrition was typically 15 percent or greater; important methodologic information was often missing, such as blinding of allocation and outcomes assessment, and, particularly for smaller trials, groups were not clearly comparable at baseline. The PREDIMED trial received a "fair" rating primarily due to noted protocol violations regarding enrollment of household members without randomization and inconsistent use of randomization tables. The study investigators issued a retraction of the original publication after violations were discovered with updated analyses, ¹⁹³ including extensive sensitivity analyses to explore the impact of the violations (e.g., dropping sites in which the violations had occurred) and found that effect sizes were only minimally affected. Results reported here are from the updated version of the results. Eleven trials were excluded due to quality concerns; most had either very high attrition (>40%) or very differential attrition between groups (>20%), or we had serious concerns about the baseline comparability of the groups and usually other concerns as well (e.g., failure to report randomization methods and blind, lack of information about outcomes assessment).

Adherence to the interventions was variable and reporting of adherence was very heterogeneous. In general, most trials providing data indicated that a very high proportion (typically >90%) engaged in the intervention at least minimally, and that roughly 60 to 80 percent of participants participated in more than half of the offered sessions. A few trials reported attendance rates that exceeded ~80 percent of all sessions, for all participants, for interventions involving two, ¹⁴³ three, ⁸¹ five, ^{63, 65, 80} six, ⁶⁷ and nine sessions. ¹⁰⁴

KQ1. Do Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity Improve CVD and Related Health Outcomes in Adults With Known CVD Risk Factors?

Summary of Results

Only 29 of the 94 included studies reported health outcomes. Twelve trials 59, 65, 75, 105, 116, 120, 121, 125, 131, 138, 141, 148 reported CVD events with followup ranging from six months to sixteen years, and medium- or high-contact behavioral counseling was associated with lower risk of any CVD event (RR=0.80 [95% CI, 0.73 to 0.87]; 9 RCTs [n=12,551]; I²=0%), myocardial infarction (MI, RR=0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n=10,375]; I²=0%), and stroke (RR=0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n=9,800]; I²=0%), although the pooled effect was only statistically significant for the composite CVD events outcome (Figure 3, Table 9). Only three of these trials were included in the previous review. 59,75,105 The PREDIMED study reported a number of cardiovascular outcomes at 5-year followup, with statistically significant reductions in stroke, incident peripheral artery disease (PAD), and all CVD events combined, but not MI (Table 10). Overall, 3.6 percent (179/4997) of PREDIMED intervention participants, compared with 4.4 percent (109/2450) of control participants, experienced a CVD event, for a 30 percent reduction in risk (HR=0.70 [95% CI, 0.55 to 0.89]). ¹³¹ Few studies were powered for mortality, and neither individual large studies nor the pooled estimate showed a beneficial effect on mortality (pooled RR=0.89 [95% CI, 0.71 to 1.11]; 18 RCTs [n=17,939], I²=0%, **Figure 4**) at followup ranging from 6 months to 16 years. Among three large trials, 75, 131, 138 all findings for both all-cause and cardiovascular-related mortality were in the direction of a greater benefit for intervention participants relative to control participants; however, results were statistically significant in only one trial.⁷⁵ This trial was limited to men with treated hypertension and offered seven diet and physical activity counseling sessions for all participants as well as smoking cessation counseling to the 29 percent of participants who were smokers (estimated 11.5 hours of interventionist contact for non-smokers and 17.5 hours for smokers). Both all-cause mortality (RR=0.62 [95%] CI, 0.42, 0.92]) and cardiovascular mortality (RR=0.56 [95% CI, 0.34, 0.92]) were reduced at 6.6-year followup. 75 A variety of patient-reported subjective well-being measures were reported in eleven trials, but group differences were generally very small and statistically nonsignificant.

Detailed Results by Outcome

CVD Events

CVD events were reported in 12 trials (**Figure 3, Appendix G Figures 1 and 2, Appendix H Table 1**). ^{59, 75, 105, 116, 120, 121, 125, 131, 138, 141, 148} Only three of these trials were included in the previous review. 59, 75, 105 Among the eight trials reporting a composite outcome of any CVD event, the pooled effect showed lower risk among those participating in a behavioral counseling intervention (pooled RR=0.80 [95% CI, 0.73 to 0.87]; 9 RCTs [n=12,551]; $I^2=0\%$, Figure 3, **Table 9**). A sensitivity analysis dropping outcomes assessed prior to 2 years of followup showed almost identical results (pooled RR=0.80 [95% CI, 0.72 to 0.88]; 7 RCTs [n=12,105]; I²=0%). Populations in these trials were recruited based on hypertension or the presence of multiple risk factors, and control group event rates suggest that these trials included populations with a broad range of underlying CVD risk. For example, in PREDIMED, 4.4 percent of the control group experienced an event over 5-year followup. Considering that 49 percent of participants had diabetes and 47 percent were obese, event rates may be lower than expected; however, 49 percent were on antihypertensive medication and 40 percent were on statin-lowering medication at baseline. 131 On the other hand, in the trial by Fagerberg, 32.9 percent of the control group experienced a CVD event over 6.6 years of followup. Thirteen percent of participants in this study had a history of a prior CVD event, 29 percent were smokers, and mean BP was 155/91 mm Hg despite participants having taken multiple antihypertensive medications for a decade or more.⁷⁵ The behavioral counseling interventions employed in these trials reporting CVD events were heterogeneous in terms of dietary messages and did not consistently include a PA component. For example, the PREDIMED trial¹³¹ was based on the Mediterranean diet, and the Fagerberg trial⁷⁵ promoted a fat-modified diet consistent with older NCEP guidelines at the time; additionally, it offered a robust 6-session smoking cessation component. In contrast, two of three intervention groups in the TONE trial involved sodium reduction. Among trials reporting CVD events, three 105, 116, 141 were weight loss trials, three 120, 121, 131 made no mention of weight loss (although one of these had no observed CVD events¹²¹), and two recommended weight loss for participants with excess weight. 75, 138

Pooled analysis of MI (RR=0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n=10,375]; I²=0%) and stroke (RR=0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n=9,800]; I²=0%) showed a statistically non-significant lower risk of events in the intervention groups. The PREDIMED trial accounted for approximately two-thirds of the individuals included in these analyses, and reported hazard ratios for a number of cardiovascular outcomes at 5-year followup (**Table 10**). PREDIMED reported statistically significant reductions in stroke (1.6% in intervention group vs. 2.4% in control group, HR=0.58 [95% CI, 0.42 to 0.82]), incident PAD (0.7 to 1.1% in the intervention groups vs. 1.8% in the control group, HR=0.36 to 0.52, [95% CI, range 0.20 to 0.86 for both intervention groups), and all CVD events combined (3.6% in the intervention groups vs. 4.4% in the control group, HR=0.70 [95% CI, 0.55 to 0.89]), but not MI (1.4% in the intervention groups vs. 1.6% in the control group, HR=0.80 [95% CI, 0.53 to 1.21]). ¹³¹ The overall beneficial effect on any CVD event was maintained in a sensitivity analysis dropping the PREDIMED trial from the meta-analysis (pooled RR=0.79 [95% CI, 0.70 to 0.90], 8 RCTs [n=5,104], **Table 9**). Of all trials reporting CVD outcomes, other outcomes reported included transient ischemic attacks, arrhythmias, angina, claudication, congestive heart failure, and "other CVD event." Most of

these outcomes were hampered by small numbers of events, however, and results were wideranging, typically very imprecise (i.e., very wide confidence intervals), and usually not statistically significant.

PREDIMED also reported on the consistency of effects on any CVD event (their primary endpoint) among a number of patient subgroups. ¹³¹ They found that the effect was larger for people with a baseline BMI of 30 or more (HR=0.51 [95% CI, 0.37 to 0.71]) than those with a BMI of 25 to 30 (HR=1.04 [95% CI, 0.71 to 1.54]) or less than 25 (HR=0.69 [95% CI, 0.29 to 1.67], interaction p=0.05). In addition, intervention effects were larger for those with hypertension (HR=0.65 [95% CI, 0.50 to 0.84]) and dyslipidemia (HR=0.60 [95% CI, 0.44 to 0.80]) at baseline compared with their counterparts (no baseline hypertension HR=1.25 [95% CI, 0.64 to 2.45], no baseline dyslipidemia HR=0.95 [95% CI, 0.64 to 1.42], interaction p=0.06 for both). They found no differences in the impact of the intervention on effect size by sex, age (<70 vs. ≥70), presence of diabetes at baseline, smoking status (never vs. ever smokers), family history of premature CHD, waist circumference (<median vs. ≥median), or baseline Mediterranean diet adherence score (<10 vs. ≥10).

Mortality

Eighteen trials of medium and high-contact interventions reported all-cause mortality (**Figure 4**, **Appendix H Table 2**), and the pooled effect did not demonstrate a benefit (pooled RR=0.89 [95% CI, 0.71 to 1.11], 18 RCTs [n=17,939], I^2 =0%) at followup ranging from 6 months to 16 years. Among these 18 studies are three that reported that there were no deaths, $I^{110, 126, 127}$ and other studies had a limited number of deaths, likely due to trial duration and sample sizes. Only three had sufficient sample size and time to followup to have more than 10 deaths per study group. A sensitivity analysis dropping mortality outcomes assessed prior to 2 years of followup showed similar results (pooled RR=0.85 [95% CI, 0.67 to 1.07]; 10 RCTs [n=14,017]; I^2 =3%).

The most recent of the large trials was PREDIMED. 131 PREDIMED found no difference between groups in all-cause mortality after 5 years, but did show slightly reduced cardiovascular-related mortality, with 1.1 percent of intervention participants dying (57/4,997), compared with 1.2 percent of control participants (30/2,450). However, this difference was not statistically significant (HR=0.83 [95% CI, 0.54 to 1.29]). 131 The trial with the largest effect, offering a highcontact intervention limited to 508 men with treated hypertension, found statistically significant reductions in mortality after 6.6 years for both all causes (16.2% [41/253] of intervention participants vs. 25.1% [64/255] of control participants, RR=0.62 [95% CI, 0.42 to 0.92]) and cardiovascular-related mortality (9.5% [24/253] vs. 16.5% [42/255], RR=0.56 [95% CI, 0.34 to 0.92]), but smaller statistically nonsignificant findings at 3.3 years' followup. ⁷⁵ This trial also offered smoking cessation counseling to the 29 percent of participants who were smokers. The third large trial to examine mortality was the Trial of Hypertension Prevention-II (TOHP-II) trial among adults younger than age 50 with elevated blood pressure who were 110 to 165 percent of their ideal weight, offering sodium reduction and/or weight loss interventions in a 2x2 factorial design. 138 TOHP-II found no group differences for all-cause mortality at 16-year followup (RR=0.90 [95% CI, 0.52 to 1.52], 2.1% [25/1,191] deaths in the intervention group vs. 2.4% [28/1,191] in the control group) comparing sodium reduction vs. no sodium reduction.

Patient-Reported Outcomes of Subjective Well-Being

Eleven^{59, 62, 68, 75, 103, 109, 114, 126, 148, 149, 224} trials reported some type of patient-reported health outcome, including SF-36 or SF-12 scores;^{59, 68, 126, 148, 224} Minor Symptoms Evaluation Profile measures of vitality, contentment, and sleep;⁷⁵ the General Health Questionnaire;⁶² the EQ-5D quality of life measure;^{109, 114, 224} the European Quality of Life instrument,¹⁴⁹ and quality-adjusted life years (**Appendix H Table 3**).¹⁰³ Although most results favored the intervention groups in absolute differences, very few differences were statistically significant and most group differences in change were less than one point. The single measure that showed a benefit among multiple intervention groups or timepoints was the SF-36 vitality score in a single study of a 33-session intervention promoting either the DASH diet or a low-sodium diet for patients with untreated elevated blood pressure or hypertension.⁵⁹ This trial reported 1.8- to 3.6-point greater improvement in the intervention groups on a 100-point scale at 6- and 18-month followup.

KQ2. Do Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity Improve Intermediate Outcomes in Adults With Known CVD Risk Factors?

Summary of Results

Behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure, total cholesterol, fasting glucose, and adiposity-related outcomes at 12 to 24 months' followup. There was a mean 1.8/1.2 mm Hg greater reduction in blood pressure in intervention than control groups after 12 to 24 months (pooled systolic blood pressure [SBP]=-1.8 [95% CI, -2.5 to -1.1]; 42 RCTs [44 effects, n=14.580]; I²=37%; pooled diastolic blood pressure [DBP]=-1.2 [95% CI, -1.6 to -0.8]; 38 RCTs [40 effects, n=13,098]; I²=33%; **Figure 5, Table 11**). In addition, in trials reporting incidence of hypertension, intervention groups had a 26 percent lower risk of onset (pooled RR=0.74 [95%] CI, 0.58 to 0.94]; 5 RCTs [n=2,707]; $I^2=12\%$) (**Table 12**). For lipids, the pooled average mg/dL difference in change between groups was -3.5 for total cholesterol, -2.1 for LDL, and 0.6 for HDL (total cholesterol MD=-3.5 [95% CI, -5.6 to -1.4]; 36 RCTs [38 effect, n=11,414]; I²=66%; LDL=-2.1 [95% CI, -4.1 to -0.2]; 30 RCTs [32 effects, n=8,894]; I²=56%; HDL= 0.6 [95% CI, 0.2 to 1.0]; 32 RCTs [34 effects, n=8.974]; $I^2=34\%$; **Figures 9 and 10, Table 11**). The impact on diabetes was mixed in four trials and the pooled effect was not statistically significant (RR=0.82) [95% CI, 0.66 to 1.03]; 5 effects [4 RCTs, n=7,848]; I²=19%; **Figure 13, Table 12**). Among 20 trials reporting on fasting glucose, there was an average 2.3 mg/dL greater reduction in fasting blood glucose in the intervention than the control groups at 12 to 24 months' followup (MD=-2.3 [95% CI, -3.6 to -1.0]; 20 RCTs [22 effects, n=5.950]; I^2 =82%, **Figure 12**, **Table 11**). At 12 to 24 months, the intervention groups showed slightly greater reductions in all three adiposityrelated measures examined: pooled BMI MD=-0.5 kg/m² (95% CI, -0.7 to -0.3); 30 RCTs (n=9,909); $I^2=83\%$; pooled weight=-1.6 kg (95% CI, -2.1 to -1.1); 37 RCTs (n=16,345); $I^2=88\%$; pooled waist circumference=-1.7 cm (95% CI, -2.4 to -1.1); 23 RCTs (n=11,708); I²=87%; Figure 15, Table 11). Very few trials offered low-contact interventions, and there was no clear difference in effect size between medium- and high-contact interventions.

Detailed Results by Outcome

Blood Pressure

Some type of blood pressure outcome was reported by 67 trials (n=36,079), most commonly mean change in systolic and diastolic blood pressure (**Appendix H Tables 5 and 6**). Among all trials reporting these outcomes at 12 to 24 months, the pooled average difference between groups in blood pressure reductions was 1.8/1.2 mm Hg (pooled SBP mean difference between groups [MD]=-1.8] [95% CI, -2.5 to -1.1]; 42 RCTs [44 effects, n=14,580]; I²=37%; pooled DBP=-1.2 [95% CI, -1.6 to -0.8]; 38 RCTs [40 effects, n=13,098]; I²=33%; **Figure 5, Table 11, Appendix G Figures 3 and 4**). Among all intervention arms and timepoints in the 12- to 24-month range, the median reductions in blood pressure at 12 to 24 months were 5.1/3.4 mm Hg in the intervention groups and 2.9/1.6 mm Hg in control groups, with a baseline mean blood pressure of 139/84 mm Hg. Effects were similar when limited to studies that only recruited participants with hypertension or elevated blood pressure, which also had similar mean baseline blood pressure (136/86 mm Hg).

Meta-regressions and subgroup analyses on SBP (the most commonly reported blood pressure outcome) demonstrated generally consistent effects among studies with various characteristics, including study quality, setting, baseline weight selection and weight loss approach, some key intervention characteristics, and socioeconomic status (**Figure 6**). There was no indication that smaller studies were associated with larger effect sizes (Egger's test of bias=0.01, p=0.99).

Some trials reported the number of participants who met the blood pressure goal established for the study (typically SBP<140 mm Hg, DBP<90 mm Hg, or both) or the percent meeting criteria for hypertension at followup (**Table 12**). For incidence of hypertension, the pooled RR reflected a 26 percent lower likelihood of hypertension onset at 6 to 36 months' followup (RR=0.74 [95% CI, 0.58 to 0.94]; 5 RCTs [n=2,707]; I²=12%). Three^{120, 122, 138} of the five^{59, 62, 120, 122, 138} trials reporting hypertension incidence were limited to people with elevated blood pressure (without hypertension) with the goal of preventing progression, and the other trials included both patients who did and did not meet criteria for hypertension.^{59, 62} Of all available timepoints and intervention groups, the median (interquartile range [IQR]) percent with incident hypertension was 21.7 percent (8.0% to 31.9%) in the intervention groups and 21.1 percent (11.2% to 39.2%) in the control groups. The median (IQR) absolute risk difference was -5.3 (-6.4 to -3.1).

Similarly, there was a 14 percent higher likelihood of meeting the study BP goal at followup among intervention participants (pooled RR=1.13 [95% CI, 1.04 to 1.23]; 13 RCTs [n=6,485]; I^2 =70%). The median (IQR) percent meeting the study goal at followup was 64.9 percent (48.6% to 79.4%) in the intervention groups and 60.9 percent (43.0% to 75.0%) in the control groups with a median (IQR) absolute risk difference of 5.0 (1.0 to 8.1). Most of the trials reporting this outcome were limited to patients with existing hypertension and included medication management as an intervention component. Thus, the blood pressure goal was achieved through a combination of lifestyle modification and optimized medication use for most of these trials. The pooled effect for five trials reporting the *prevalence* of hypertension at 12 to 60 months' followup (as opposed to the *incidence* of hypertension) did not show group differences (pooled RR=0.98 [95% CI, 0.89 to 1.08]; 5 RCTs [n=5.633]; I^2 =56%).

Lipids

Total cholesterol, LDL, or HDL were reported by 59 trials (n=30,245; **Appendix H Tables 7 and 8**). Among all trials reporting these outcomes at 12 to 24 months, the pooled average mg/dL difference in change between groups was -3.5 for total cholesterol, -2.1 for LDL, and 0.6 for HDL (total cholesterol MD=-3.5 [95% CI, -5.6 to -1.4]; 36 RCTs [38 effects, n=11,414]; I²=66%; LDL=-2.1 [95% CI, -4.1 to -0.2]; 30 RCTs [32 effects, n=8,894]; I²=56%; HDL= 0.6 [95% CI, 0.2 to 1.0]; 32 RCTs 34 effect, [n=8,974]; I²=34%; **Figures 9 and 10, Table 11**). Among all intervention arms and timepoints in the 12- to 24-month range, the median (IQR) reduction in total cholesterol at 12 to 24 months was 7.1 (12.4 to 2.3) mg/dL in the intervention groups and 4.4 (6.6 to 0) in control groups, from an average baseline of 217 mg/dL. Effects were similar when limited to studies that only recruited participants with dyslipidemia. Pooled effects for LDL change were slightly smaller than for total cholesterol and not statistically significant in the near-term (<12 months followup) nor when limited to studies that only recruited participants with dyslipidemia. Most pooled effects did not show group differences in HDL change from baseline to followup and were generally of a magnitude that is unlikely to be of clinical importance.

Meta-regressions and subgroup analyses of total cholesterol (the most commonly reported lipid outcome [46 RCTs]) identified some statistically significant or nearly statistically significant bivariate relationships, with larger effects found in trials that were conducted in older adults (p<0.01), were conducted outside of the United States (p=0.04), and included medication management as an intervention component (p=0.06); smaller effects were found in weight loss trials (p=0.01) and those that targeted low-income populations (p=0.01) (**Figure 11**). However, only medication management (p=0.003) and older adult population (p=0.03) were statistically significant in models controlling for the other population or intervention characteristics showing bivariate relationships. Larger effects were seen when medication management was included and trials were limited to older adults. There was no indication that small studies were associated with larger effect sizes (Egger's test of bias=-0.7, p=0.29).

Glucose and Metabolic Outcomes

The proportion of participants with diabetes in the included trials ranged from 0 (in 27 trials) to 49 percent. Per our inclusion and exclusion criteria, we excluded trials if 50 percent or more of participants had impaired glucose tolerance or diabetes. Fasting glucose, diabetes incidence, or metabolic syndrome was reported by 31 of the included trials (n=21,521; **Appendix H Tables 9 and 10**). There was an average 2.3 mg/dL greater reduction in fasting blood glucose in the intervention than the control groups at 12 to 24 months' followup (MD=-2.3 [95% CI, -3.6 to -1.0]; 20 RCTs [22 effects, n=5,950]; I²=82%, **Figure 12**, **Table 11**). Four trials reported diabetes incidence, ^{62,65,100,131} and the pooled effect using calculated RRs did not show an association between behavioral counseling and reduced diabetes onset (pooled RR=0.82 [95% CI, 0.66 to 1.02]; 5 effects [4 RCTs, n=7,848]; I²=0%, **Figure 13**, **Table 12**). However, interventions in two trials reduced diabetes incidence, either as calculated based on unadjusted results as shown in the forest plot ^{65,131} or in study-reported adjusted analyses. ¹³¹ PREDIMED reported a 40 percent reduction in the risk of incident diabetes in the intervention group that was given olive oil (HR=0.60 [95% CI, 0.43 to 0.85]; 6.9% in the intervention group, 8.8% in the control group), but

the effect was slightly smaller and not statistically significant for the group that was given nuts (HR=0.82 [95% CI, 0.61 to 1.10]; 7.4% in the intervention group, 8.8% in the control group) after 48 months of observation. Another small trial found a large effect after only 12 months (OR=0.23 [95% CI, 0.06 to 0.85]; 1.8% in the intervention group, 7.2% in the control group), but included a total of only 15 cases of incident diabetes. Calculated RRs in the other trials showed no impact: 0.98 (95% CI, 0.47 to 0.07) and 1.03 (95% CI, 0.67 to 1.59). Metabolic syndrome incidence or prevalence was reported in five trials; the effects were wide-ranging, PREDIMED showed no benefit, and the pooled effect did not demonstrate an association (pooled RR=0.78 [95% CI, 0.53 to 1.16]; 5 effects [5 RCTs, n=1,847]; I^2 =85%) (Figure 14, Table 12).

Weight/Adiposity

Weight, BMI, or waist circumference was reported by 72 trials (n=35,228; Appendix H Tables 11 and 12). At 12 to 24 months, the intervention groups were associated with slightly greater reductions in all three measures: pooled BMI MD=-0.5 kg/m² (95% CI, -0.7 to -0.3); 30 RCTs (n=9,909); $I^2=83\%$; pooled weight=-1.6 kg (95% CI, -2.1 to -1.1); 35 RCTs (37 effects, n=16,345); I²=88%; pooled waist circumference=-1.8 cm (95% CI, -2.4 to -1.1); 22 RCTs (23 effects, n=11,708); I²=87%; **Figure 15, Table 11**). Among all intervention arms and timepoints in the 12- to 24-month range, the median (IQR) change in BMI at 12 to 24 months was -0.5 kg/m² (-0.9 to -0.2) in the intervention groups and -0.1 (-0.4 to 0) in control groups. For weight, median (IQR) intervention group effect wase -1.5 kg (-2.8 to -0.8), compared with -0.3 (-1.0, 0.0) in the control groups. The median (IQR) change in waist circumference was -2.2 cm (-3.7 to -0.8) in the intervention groups and -0.9 (-1.8 to -0.2) in the control groups (**Table 11**). Effects were larger in weight loss trials (that is, trials in which participants were only included if they had excess weight and weight loss was an explicit goal of the trial), where the pooled mean between-group difference in weight change was -2.6 kg (95% CI, -3.4 to -1.7; 12 RCTs [n=3,193]; $I^2=67\%$), BMI was -0.9 kg/m² (95% CI, -1.4 to -0.4; 7 RCTs [n=1,520]; $I^2=78\%$), and waist circumference was -2.5 cm (95% CI, -4.0 to -1.0; 8 RCTs [n=1,654]); I²=85%) (**Table 11**). Effects were intermediate among those that had a mix of people with and without excess weight and only recommended weight loss for those with excess weight (e.g., weight change: -1.4 kg (95% CI, -2.0 to -0.7); 15 RCTs [n=6,486]; I^2 =73%). Five^{57, 98, 122, 131, 148} trials appeared to focus only on behavior change without directly assigning a weight loss goal for participants, and did not result in greater weight loss than control groups (pooled MD=-1.1 [95% CI, -2.5to 0.4]; 6 RCTs [n=6124]: $I^2=90\%$).

In addition, 11 trials reported the proportion of participants who lost at least 5 percent of their weight or had a 5 percent reduction in BMI. 82, 107, 110, 116, 123, 125, 126, 129, 132, 134, 141 Behavioral counseling interventions were associated with a 86 percent increase in the likelihood of losing 5 percent of baseline weight or BMI (pooled RR=1.86 [95% CI, 1.33 to 2.60]; 11 RCTs [n=3,970]; I²=68%, **Figure 16**). Other than one small trial that focused only on increasing physical activity, 132 all trials reporting this outcome were either weight loss trials 116, 123, 125, 129, 134, 141 or explicitly stated that weight loss was recommended for all participants with overweight or obesity. 82, 107, 110, 126 Three trials also reported the proportion who lost 10 percent or more of their baseline weight and all found an increased probability of this level of weight loss at one or more followup timepoints (percent with 10% weight loss ranged from 7.5% to 25.0% in the intervention groups and 2.3% to 8.6% in the control groups). 125, 126, 129

Meta-regressions and subgroup analyses on weight (the most commonly reported adiposity-related outcome) identified some statistically significant bivariate relationships, with larger effects being found in trials conducted in the United States (p=0.01), those that were limited to individuals with obesity or who were overweight (p=0.04), and in weight loss trials (p<0.03) (i.e., trials that recruited people with excess weight and had an explicit weight loss goal for all participants), but no effect modification based on intervention contact, age group, socioeconomic status, and whether a fat-modified diet was recommended (**Figure 17**). Most weight loss trials were conducted in the USA and all were limited to individuals with obesity or who were overweight, so we were unable to disentangle the relative impacts of these factors. The test of small study effects was statistically significant (Egger's test of bias=-2.8, p<0.001), indicating that smaller trials tended to have larger effects. Weight loss trials tended to be smaller studies: the average sample size in weight loss trials was 461, compared with 585 in non-weight loss trials. Thus, small studies effects may be related to intervention content and target population rather than publication bias.

Cardiovascular Risk

Twelve trials used published models or calculators to calculate 5- or 10-year risk of CVD or CHD events^{68, 70, 77, 106, 109, 142, 144, 224} or mortality^{84, 85, 98, 99} (**Appendix H Table 13**). Two trials found statistically significant reductions in 10-year CVD risk after 1 year, reporting reductions of 1.8 (95% CI, -3.0 to -0.6)¹⁰⁶ and 2.1 (95% CI, -4.1 to -0.1)¹⁴² percentage points, although the pooled effect was not statistically significant when combining all trials reporting 8- or 10-year CVD risk outcomes (pooled MD=-0.5 percentage points [95% CI, -1.3 to 0.3]; 7 RCTs [n=2,533]; I²=53%, **Figure 18**). None of the trials reporting the 10-year CVD *mortality* risk found group differences, nor was the pooled effect statistically significant (pooled MD=-0.1 percentage points (95% CI, -0.3 to 0.2); 5 effects [4 RCTs, n=1,764]; I²=0%).

Impact of Population, Study, and Intervention Characteristics on Effect Size

Based on direct within-study comparisons using study-reported subgroup analyses, we found no indication that any demographic subgroups consistently benefited more or less than others. Sixteen trials examined variability in effects by sex, ^{59, 69, 85, 91, 98, 114, 116, 120, 123, 127, 129-131, 138, 142, 144} and while some showed larger effects for some outcomes in men than women (overall^{69, 98, 127, 142} or among African-American participants only⁵⁹), one showed larger effects in women for some outcomes¹³⁰ and the remaining reported no differential effect by sex. Some trials found that effect sizes increased with age for weight loss^{59, 123, 138} and blood pressure, ^{59, 93} but other trials found no association between intermediate outcomes and age. 91, 114, 130, 131 Most trials examining interactions by race or ethnicity reported no differential effectiveness; 120, 123, 129, 144 however, TOHP II reported a larger effect for weight loss in white participants than African-American participants. ¹³⁸ Risk factor status was associated with effect size in several trials: people with hypertension experienced a greater reduction in blood pressure than those without hypertension,⁵⁹ those with the highest 10-year CVD risk had the greatest reductions in future CVD risk, ^{68, 71} and people with dyslipidemia had the greatest reductions in lipids. ⁷⁶ However, other trials did not show an association between baseline risk and improvement in intermediate outcomes. 75, 130, 131 Effects on lipids were not moderated by medication status in three trials. 78, 80,

As described under the outcome-specific results, we found very few intervention or population characteristics that were clearly associated with effect size. In meta-regressions examining the association between study and intervention characteristics and effect size, we did not see a clear indication that high-contact (>360 min) trials showed larger effects than medium-contact trials, nor was there an association between continuous measures of contact (number of sessions, total estimated minutes of contact) and effect size. However, very few trials offered low-contact (<30 min) interventions (**Figure 2**). See the Methods section for the full list of characteristics explored.

While there were no differences in effect size between interventions that counseled people only to change their diet compared with those that addressed both diet and physical activity, evidence was limited on interventions that only addressed physical activity. Only five studies^{61, 87, 94, 132, 140} with interventions that addressed physical activity alone reported intermediate outcomes. Among these 5 trials, sample sizes were generally very small and outcome reporting was inconsistent.

We attempted to identify common intervention elements of effective trials by examining trials that showed the largest beneficial effects on intermediate outcomes. For this exercise, we limited to trials that randomized at least 150 participants to limit the risk of spurious findings. We focused on four intermediate outcome domains of blood pressure, lipids, fasting glucose, and weight. Then we identified studies with the 10 largest absolute effect sizes for outcomes in each domain. Sixteen trials had relatively large effects in at least two of the four intermediate outcome domains. 65, 69, 75, 76, 79, 92, 95, 98, 99, 106, 107, 113, 120, 126, 139, 141 Five of these trials had relatively large effects in the three 92, 106, 107, 141 or four 65 domains and are listed in **Table 13**. Each of these five trials selected participants based on having any of multiple CVD risk factors or metabolic syndrome and included counseling for both diet and physical activity. Interventions in these 5 trials are described below.

One of these successful trials was a good-quality, U.S.-based weight-loss trial that was part of the NHLBI-funded Practice-Based Opportunity for Promotion of Weight Reduction Trials (POWER) project. This intervention included 18 10–15 minute coaching sessions by phone, a median of three brief counseling visits with the primary care provider, and 52 brief interactive voice recognition calls. Intervention participation in this study was generally good: participants completed a median of 89 percent of the coaching calls and a median of 93 percent of their weekly self-monitoring forms. Another successful trial was a good-quality Canadian trial that recruited participants with a 10-year CVD risk of 10 percent or more based on the Framingham model. The intervention involved two 30-minute phone sessions 6 months apart, a CVD risk "report card" sent to each participant and their provider, and two additional mailings after each call summarizing the counseling sessions and including education materials addressing smoking, diet, physical activity, weight management, and stress management as appropriate to the participant's profile. Smokers were eligible for four additional smoking-cessation phone counseling sessions.

The other three trials—which were given fair-quality ratings—were conducted in Europe among Italians with metabolic syndrome, ⁶⁵ Spaniards with moderate or high Framingham CHD risk (specific thresholds not reported) and elevated fibrinogen levels, ⁹² and Europeans from six countries with a 10-year CVD mortality risk score of 5 percent or higher. ¹⁰⁷ While none of these

was a weight loss trial, specifically, all promoted weight loss for participants who were overweight or with obesity. The Italian trial involved one individual and four group sessions lasting 1 hour each, covering diet and physical activity, with participants attending an average of 4.1 to 4.5 of the five sessions.⁶⁵ The Spanish trial included 12 individual sessions with the primary care provider and 12 follow-up phone sessions with a psychologist covering diet, physical activity, medication management, and smoking cessation (if applicable).⁹² The multicountry European trial included family members in the intervention and involved an individual nurse assessment with a personal "report card," a family support pack, and eight group workshops on diet, physical activity, and risk factor management. ¹⁰⁷ Intervention adherence was not reported in either of these trials. ^{92, 107}

The range of average between-group difference in change for blood pressure in these five trials was -0.9 (-4.9 to 3.1)¹⁴¹ to -6.8 (-10.7 to -2.8)⁹² SBP and -1.0 (-3.5 to 1.5)¹⁴¹ to -4.4 (-6.8 to -2.0)⁹² DBP (**Table 13**). Differences in total cholesterol change ranged from +3.1 mg/dL (-4.7 to 10.9)¹⁴¹ to -19.2 mg/dL (-25.6 to -12.7),⁹² and BMI change differences ranged from -0.1 kg/m² (-0.6 to 0.3)¹⁰⁶ to -1.7 kg/m² (-2.2 to -1.1).⁹²

Role of Weight Management

We were unable to provide a robust analysis of the importance of weight loss on the impact of intermediate outcomes, since this question is better approached with individual patient data. Weight loss interventions did have a larger pooled effect on weight change than interventions that did not promote weight loss (**Figure 17**). There was no bivariate or multivariate association between weight loss promotion and SBP, and an inverse association with total cholesterol such that smaller reductions in total cholesterol were seen in weight loss trials, however this effect disappeared when controlling for medication management and older adult populations.

We examined trials with multiple intervention arms with direct comparison of weight-loss versus other messages to evaluate the role of weight loss on intermediate outcomes. Four trials had this design. ^{120, 122, 138, 144} All of these trials targeted people with hypertension and the diet-only intervention arms (with no explicit mention of weight loss) encouraged either sodium reduction or sodium reduction and an increase in potassium intake. Effect sizes were generally slightly larger in intervention arms that promoted weight loss, however the intervention conditions encouraging sodium reduction without apparent encouragement to lose weight also had statistically larger reductions in blood pressure than control groups for three of these trials. 120, 122, 138 One small (n=95) trial of people with untreated elevated blood pressure who were either overweight or had obesity explicitly instructed participants to focus on adopting the DASH diet without changing their weight or physical activity level. 121 The intervention involved four inperson individual instructional sessions and 14 30- to 45-minute group sessions, and was effective in reducing systolic but not diastolic blood pressure. At 12-month followup, there was a 5.6 (95% CI, -9.8 to -1.4) mm Hg greater reduction in systolic blood pressure in the intervention group: a 9.5 (SD 9.1) mm Hg reduction in the intervention group compared with a 3.9 (SD 11.8) mm Hg reduction in the control group. 121

KQ3. Do Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity Improve Behavioral Outcomes in Adults With Known CVD Risk Factors?

Summary of Results

Altogether, 70 of the included trials reported some type of behavioral outcome (n=43,243); however, most specific outcomes were reported by fewer than 15 trials, and there was substantial variability in measurement for most of these outcomes. Behavioral counseling interventions were associated with dietary improvements, including reductions in saturated fat consumption and increases in the consumption of fruits, vegetables, and fiber (Table 14). The average difference in reduction in the percent of calories from saturated fat was 1.5 percentage points after 12 to 24 months (pooled MD=-1.5 [95% CI, -1.9 to -1.1]; 15 RCTs [17 effects, n=6,229]; I²=72%). The median (IOR) reduction in the intervention groups was -1.9 (-3.0 to -1.4), compared with -0.6 (-1.0 to -0.1) in the control groups. For fruits and vegetables, the intervention groups increased consumption by an average of 0.7 servings per day more than the control groups (pooled MD=0.7 [95% CI, 0.1 to 1.3]; 11 RCTs [n=4,310]; I²=90%). The average increase in fiber consumption was 1.3 grams per day (95% CI, 0.1 to 2.6, 5 RCTs [n=1,350], $I^2=42\%$) more than control groups. In addition, trials among people with hypertension or elevated blood pressure who were counseled to reduce sodium consumption did show reduced urinary sodium (pooled MD=-18.0 [95% CI, -34.8 to -1.2]; 9 RCTs [n=3,583]; I²=89%). Dietary pattern scores, arguably the better measures of dietary improvement than those that capture only a single aspect of diet, generally showed greater improvement in intervention groups, but measurement was heterogeneous and interpretation of effect sizes was unclear. Physical activity outcomes were highly variable in terms of both measurement and results, with minimal evidence to suggest that interventions were associated with increased physical activity. Trials that had relatively large benefits for intermediate outcomes also tended to report mean differences in change in behavioral outcomes that were at or above the means for the full body of evidence.

Detailed Results by Outcome

Dietary Fat Intake

Behavioral counseling interventions were associated with small reductions in saturated fat: the average difference in reduction in the percent of calories from saturated fat was 1.5 percentage points after 12 to 24 months (pooled MD=-1.5 [95% CI, -1.9 to -1.1]; 17 effects [15 RCTs] [n=6,229]; I²=72%; **Table 14, Appendix G Figure 12**). The median (IQR) reduction in the intervention groups was -1.9 (-3.0 to -1.4), compared with -0.6 (-1.0 to -0.1) in the control groups. Effects were similar in trials that specifically encouraged people to adopt a fat-modified diet (pooled MD=-1.5 [95% CI, -2.3 to -0.8]; 10 effects [8 RCTs] [n=3,951]; I²=72%). Polyunsaturated fat intake did not change (**Table 14, Appendix G Figure 13**), and monounsaturated fat (MUFA) intake was reduced on average (pooled MD=-1.7 [95% CI, -2.5 to -0.9]; 8 effects [7 RCTs] [n=1,827]; I²=83%; **Table 14, Appendix G Figure 14**). However, in PREDIMED, which encouraged a Mediterranean diet and supplied participants with either olive

oil or nuts, MUFA increased by 1.9 (95% CI, 1.4 to 2.3) percentage points more in the group receiving nuts and 3.0 (95% CI, 2.6 to 3.5) percentage points in the olive oil group, compared with the control group. ¹³¹ All other trials reporting MUFA and most reporting polyunsaturated fat intake found reductions in intake. Trials reporting other fat-related outcomes (grams per day, score on a dietary fat scale) generally found group differences in the direction of greater reductions in the intervention groups, with most reporting only saturated fat (**Appendix H Tables 15 and 16**).

Fruits and Vegetables

Behavioral counseling interventions were also associated with an average 0.7 greater increase in servings per day of fruits and vegetables compared with control groups after 12 to 24 months (pooled MD=0.7 [95% CI, 0.1 to 1.3]; 11 RCTs [n=4,310]; I²=90%, **Table 14, Appendix G** Figure 15). The median (IQR) increase in fruit and vegetable servings per day was 0.5 (0 to 1.2) in the intervention groups, compared with 0.1 (0 to 0.3) in the control groups. Fruit consumption was typically reported as servings or pieces per day, and there was in average 0.2 greater increase in servings per day for intervention than the control groups (pooled MD=0.2 [95% CI, 0.0 to 0.3]; 9 RCTs [n=3,698]; $I^2=72\%$, **Table 14, Appendix G Figure 16**). The two most common vegetable-specific outcomes were servings per day and grams per day, which were combined into a single meta-analysis of standardized mean differences (SMD). The results indicated a very small effect in the direction of benefit (SMD=0.12 [95% CI, 0.02 to 0.21]; 9 RCTs [n=3,555]; I²=50%, **Table 14, Appendix G Figure 17**). Intervention groups increased consumption by a median (IOR) of 0.5 (0 to 0.8) servings or 11 (9 to 16) grams per day, while the control groups increased consumption by 0.3 (0.2 to 0.3) servings or 2 (-3 to 12) grams per day. Interestingly, the effect measured in grams/day appears to be smaller; one serving (0.5 cup of cooked vegetables) is approximately 75g, so 11 grams is equivalent to approximately 1 tablespoon, while 0.5 of a serving is 4 tablespoons. Data were insufficient to determine whether this was due to random chance or related to the measurement approach. At 12 to 24 months' followup, the median (IQR) consumption of fruits and vegetables was 5.1 (4.3 to 6.4) servings per day in the intervention groups and 4.6 (3.4 to 6.2) servings per day in the control groups.

Fiber

Seven trials reported change in grams per day of fiber (**Appendix H Table 15**).^{57, 65, 69, 72, 82, 104, 131} Most trials reported group differences in change that ranged up to 5 grams per day, and most differences were not statistically significant. At 12-24 months' followup, the pooled mean difference in change was 1.3 grams per day (95% CI, 0.1 to 2.6, 5 trials [n=1,350], I²=42.4%, **Table 14, Appendix G Figure 18**). The USDA recommends eating 28 grams per day for a hearthealthy diet, for a 2,000-calorie-per-day diet.²

Sodium

Twelve trials in populations with hypertension or elevated blood pressure reported urinary sodium to determine whether participants had reduced sodium intake as encouraged by their interventions. ^{59, 61, 63, 69, 79, 82, 97, 111, 120, 122, 138, 144} Most trials reported greater reductions in 24-hour urinary sodium excretion in intervention groups that were coached to reduce their sodium intake

than control groups (pooled MD=-18.0 [95% CI, -34.8 to -1.2]; 9 RCTs [n=3,583]; I²=89%; **Appendix G Figure 19**); at 12 to 24 months' followup, the median (IQR) change in the interventions groups was -18.4 mmol/L (-45.4 to -5.3) and was -6 mmol/L (-10 to -3.4) in the control groups. The largest reduction seen in any control group was 16.8 mmol/L, while reductions in the intervention group ranged up to 72 mmol/L (**Appendix H Table 15**). In addition, trials that had separate intervention arms that did and did not promote a low-sodium diet saw reductions in the low-sodium diet intervention arms but not the other intervention arms. The typical American diet includes approximately 150 mmol per day of sodium, while the recommended intake is below 100 mmol per day. See Province 1.22, 138 mmol/L (1.22, 1.33 mmol/L) mmol per day.

Dietary Pattern

Ten trials reported some type of dietary pattern or quality measure (**Appendix H Table 15**).^{58, 70, 86, 97, 106, 109, 114, 131, 137, 143} For most of these outcomes, dietary patterns improved in intervention participants and showed very little change in control group participants, and quite a few group differences were statistically significant, although the clinical importance of the effects are difficult to interpret. For example, two trials ^{131, 137} (one of them PREDIMED) reported MEDAS-14 scores, which measures adherence to the Mediterranean diet. Considering all available followup assessments and intervention groups in both studies, intervention groups generally improved their adherence scores by 1.4 to 2.0 points on a 14-point scale. Intervention groups showed greater improvements than the control group that were statistically significant at all timepoints in PREDIMED. No other instrument was used in more than one trial.

Physical Activity

Altogether, 50 trials reported some type of physical activity outcome (n=34,028), and no consistent evidence of benefit emerged using a variety of self-report measures (Appendix H Tables 17 and 18). Outcome reporting was highly variable both in the measure reported (e.g., any, moderate, moderate-to-vigorous, leisure physical activity, meeting goal) and unit of measurement (e.g., minute/week, MET-hours/week, sessions/week, kJ/kg/day, steps/day). When standardized mean differences of the continuous outcomes were examined, effect sizes were very heterogeneous and inconsistent, with a number of effects favoring control groups, although those were typically not statistically significant. The pooled effect was not statistically significant, represented an effect size well below what would typically be considered a "small" effect, and had high statistical heterogeneity (pooled SMD=0.06 [95% CI, -0.03 to 0.14]; 32 effects [30 RCTs, n=19.834]; $I^2=64\%$) (**Appendix G Figure 20**). When similar outcomes were isolated, there was an average 9.1 additional minutes' increase in physical activity per week in the intervention groups compared with the control groups (pooled MD=9.1 minutes/week [95% CI, -4.6 to 22.8]; 11 effects [10 RCTs, n=9,746]; I²=48%), and 83 MET-minutes per week (pooled MD=83 [95% CI, -83 to 249]; 7 effects [6 RCTs, n=4.958]; I²=62%), however neither of these findings were statistically significant. For comparison, an hour of walking briskly expends approximately 200 MET-minutes, so the pooled effect is roughly equivalent to an additional 25 minutes of walking per week. Again, the discrepancy in effect sizes using different measures is puzzling.

Of the six^{61, 87, 90, 94, 132, 140} trials with intervention arms that addressed only physical activity (and not diet), four^{61, 90, 132, 140} found greater improvements in physical activity in the intervention groups and one reported only intermediate outcomes.⁸⁷ Of those reporting physical activity outcomes, no two studies used the same measure and the clinical significance of the effects was difficult to understand. Results included:

- 17 kJ/kg/d greater total energy expenditure (95% CI, 5.6 to 28.4)⁶¹
- 6-fold increase in the risk of increasing physical activity over baseline levels (RR=6.13 [95% CI, 3.07 to 12.23], 52.7% in the intervention group vs. 8.6% in the control group)¹⁴⁰
- 29 percent increase in the odds of increasing by one of five levels on a measure of total physical activity (95% CI, 1.04 to 1.60)⁹⁰
- 1,400 additional kcal/week (95% CI, -1299 to 4100) of moderate to vigorous physical activity (p=0.03 in an adjusted analysis)¹³²
- No difference in the likelihood of meeting physical activity guideline recommendations (OR=0.99 [95% CI, 0.62 to 1.57])⁹⁴

Intervention groups had a higher likelihood of meeting the study-defined physical activity goal, which typically was 90–180 minutes per week of moderate to vigorous physical activity (pooled RR=1.22 [95% CI, 1.00 to 1.50]; 11 RCTs [n=5,887]; I²=91%, **Appendix G Figure 21**). The median (IQR) percent meeting the study goal was 36 percent (28.1% to 52.8%) in the intervention groups and 23.8 percent (22.9% to 50.8%) in the control groups, with median (IQR) absolute risk differences of 3.7 percent (0.4% to 10.1%).

Two trials reported change in resting heartbeat, with greater reductions representing improved cardiorespiratory fitness (**Appendix H Table 17**).^{59, 69} Both found greater reductions in the intervention groups. For example, one of these reported 8 and 9 beat-per-minute reductions in intervention groups at stage 2 of a submaximal exercise test, compared with 5.3 beats per minute reduction in the control group at 6 months' followup.⁵⁹ This study reported a slightly smaller difference after 18 months, when the control group average had dropped 2 more beats per minute, but the intervention groups maintained the previous changes.⁵⁹ In the other trial, the intervention group saw a 1-beat-per-minute increase in 24-hour heart rate after 16 months, while the control group had increased by 7 beats per minute, but there was no difference between groups after 40 months (2 years after the intervention had ended).⁶⁹ Three trials explored sedentary time using a variety of measures but found no group differences on any measure.^{85, 109, 135}

Consistency With Intermediate and Health Outcomes

We addressed the issue of consistency between the intermediate and behavioral outcomes in two ways. First, we examined subgroup analyses reported by the included trials and noted whether participant subgroups with large behavioral effects also had large effects on intermediate outcome within the same study. Some trials reported that subgroups with the largest changes in behavioral outcomes also showed the largest improvements in intermediate outcomes. ^{59, 64, 69, 73}

Next, we examined behavior change in the trials with relatively large intermediate and health outcome effects, and found that behavior change in these trials tended to be higher than the

pooled average effects. Of the five trials that had relatively large effects in three or four domains of intermediate outcomes; two also reported behavioral outcomes. After 12 months, the Italian trial reported greater reductions in saturated fat percent of energy in the intervention group (MD in change=-1.8 percentage points [95% CI, -2.6 to -1.0]) and increases in polyunsaturated fatty acids (PUFA) (MD in change=1.0 percentage point [95% CI, 0.6 to 1.4]), fiber intake (MD in change=1.5 g/day [95% CI, 0.8 to 2.3]), and physical activity (MD in change=5.0 MET-hours/week [95% CI, 3.0 to 6.9], roughly equivalent to 1.5 additional hours of brisk walking per week) (**Appendix H Tables 15 and 17**). The multi-country European study reported that after 12 months, intervention participants were more likely to have consumed 400 or more grams of fruits and vegetables per day (78.4% in the intervention group vs. 38.8% in the control group, difference in probability= 39.7 [95% CI, 18.1 to 61.3]) and to have reported 30 or more minutes of physical activity on 4 or more days per week (50.3% in the intervention group vs. 22.1% in the control group, difference in probability=29.4 [95% CI, 10.7 to 48.0]).

In addition, the PREDIMED trial had relatively large beneficial effects on health outcomes. It also showed improvements in both intervention groups at all follow-up assessments on the MEDAS-14, a measure of adherence to the Mediterranean diet, on the order of 1.3 to 1.6-point greater increases on a 14-point scale. Regarding specific dietary components, PREDIMED intervention participants reported greater increases in MUFA, PUFA, saturated fat (for the olive oil supplementation group only), and fiber (for the nuts supplementation group only), but did not differ from the control group on fruit and vegetable consumption. 131

Several additional trials with relatively large effects in two domains of intermediate outcomes also reported behavioral outcomes, with findings that were generally in the direction of benefit for the intervention group, often at or above the pooled mean difference, but with mixed findings in terms of statistical significance. ^{69, 76, 79, 95, 98, 106, 131} For example, relative to change in control groups, fruit and vegetable consumption increased in intervention groups by 0.8 servings per day (95% CI, 0.3 to 1.3)⁶⁹ after 16 months, 0.70 servings per day (95% CI, -0.18 to 1.58)⁷⁶ after 18 months, 23.5 g/day (95% CI, -15.0 to 62.0) after 12 months, 98 and 0.07 (95% CI, -0.11 to 0.25, study-reported p<0.05) and 0.18 servings per day (95% CI, 0.00 to 0.36 study-reported p<0.05) after 5 years (**Appendix H Table 15**). ¹³¹ Of the four trials^{69, 76, 79, 98} reporting the percent meeting physical activity goals, most did not find that the groups differed, with absolute risk differences generally on the order of 0.2 to 10 percent (**Appendix H Table 18**). These same four trials also reported a continuous measure of change in physical activity, with mixed findings. Differences in change in these trials included: 53 minutes per week vigorous activity (95% CI, 15 to 91, study-reported p=0.007) at 40 months' followup, but a smaller, statistically nonsignificant difference at 16 months; ⁶⁹ 3.1 MET-hours per week walking (95% CI, -2.2 to 8.3, study-reported p<0.01) at 18 months, but no statistically significant findings for either moderate- or vigorousintensity physical activity; ⁷⁶ 723 steps per day (95% CI, -519 to 1966, p not reported) at 18 months;⁷⁹ and 38.0 minutes per day walking (95% CI, 0.2 to 75.8, p=0.05) at 12 months, but no differences in minutes per week of moderate to vigorous or total physical activity, or in any physical activity outcomes at 36-month followup (**Appendix H Table 17**). 98 The PREDIMED intervention did not discuss physical activity and found no group differences in leisure physical activity. 131

KQ4. What Are the Harms of Behavioral Counseling Interventions to Improve Diet and Increase Physical Activity in Adults With Known CVD Risk Factors?

Summary of Results

We narrowly focused this question on harms of counseling interventions, rather than broadly on harms of dietary or physical activity changes themselves. We examined the 94 trials included for KQs 1 through 3 for harms, as defined by the study authors, or any paradoxical change in outcomes (e.g., worsening of blood pressure, lipids, glucose, measures of weight, dietary intake, physical activity). We searched for additional studies examining harms of healthy lifestyle counseling interventions but did not find any such studies.

The reporting of adverse events was sparse and variable. A subset of 20 of the 94 included trials reported one or more adverse events. Adverse events related to diet and physical activity counseling appear to be exceedingly rare, with generally no statistically significant differences in any study for: serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, or withdrawals due to adverse events. There was no consistent evidence of paradoxical effects for intermediate or behavioral outcomes. There were occasional instances of control groups showing more improvement than intervention groups, but this was usually not statistically significant and was often accompanied by greater improvement for the intervention group for other outcomes.

Detailed Results for Harms

Twenty trials reported harms (N=18,263), ^{59, 65, 69, 73, 93, 105, 107, 112, 114, 116, 125-127, 131, 134, 139, 141, 148, 149, ²²⁴ (**Appendix H Table 19**). Seven of these 20 trials reported that there were no adverse events or no serious adverse events, ^{65, 73, 107, 131, 134, 139, 224} and other trials reported one or more of the following: serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, withdrawals due to adverse events, gallbladder disease, and headaches.}

Serious Adverse Events

Three trials reported serious adverse events, all of which included medium- to high-intensity diet and physical activity counseling interventions. 112, 114, 125 While serious adverse events were not rare—occurring in 6.8 to 15.3 percent of intervention group participants and 7.6 to 12.3 percent of control group participants—serious adverse events attributed to interventions were exceedingly rare. In a U.K. primary-care based telephone and web-based intervention study of adults with multiple risk factors, one serious adverse event was potentially associated with the intervention: hospitalization due to low blood pressure. This could have been related to antihypertensive drug dose not being reduced after weight loss, according to the trial authors. 114 In the Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP) trial of weight loss in participants with CVD risk factors, three serious adverse events—two cholecystectomies and one case of syncope—were determined to be related to the

intervention.¹²⁵ In the Counseling African Americans to Control Hypertension (CAATCH) trial, which recruited African Americans with hypertension, one serious adverse event in the intervention group was considered possibly related to the intervention and two serious adverse events, one in the intervention group and one in the control group, were considered definitely related; however, the nature of these events was not reported.¹¹² Differences in serious adverse events were not statistically significant between groups in any study.

Any Adverse Events

Seven trials reported that no adverse events occurred, ^{65, 73, 107, 131, 134, 139, 224} and three trials reported a general measure of "any adverse events." ^{93, 112, 114} In these three trials, the rates of any adverse events among intervention group participants ranged from 0 to 11.7 percent and from 0 to 12.0 among control group participants. Differences in any adverse events were not statistically significant in any study, and details were not described in any reporting study.

Withdrawal Due to Adverse Events

Only two trials explicitly mentioned withdrawals due to adverse events. The study by Rodriguez⁹³ noted that nine participants were withdrawn by study staff due to an adverse event that would affect study participation, but events by group are not reported. The CAATCH trial reported that no individuals terminated study participation due to adverse events.¹¹²

Hospitalizations

Five trials reported hospitalizations. ^{112, 116, 126, 127, 141} In four of these trials, there were no statistically significant differences between groups, and the nature of the hospitalizations was not further specified. ^{112, 116, 126, 127} A study of the Track intervention—a medium-intensity diet and physical activity intervention with weight loss focus that was conducted in obese adults with at least one risk factor—reported 11 hospitalizations in the intervention group and one in the control group (6.3% vs. 0.6%). ¹⁴¹ Hospitalizations were for causes other than CVD, cancer, or musculoskeletal injury, and authors reported that no events were deemed to be related to the trial. The study by Rosas et al additionally reported emergency department visits, which occurred in 35.4 percent and 27.4 percent of the two intervention arms and 41.5 percent in the control arm. ¹²⁷

Musculoskeletal Injuries

Six trials reported musculoskeletal injuries or serious musculoskeletal injuries, all of which were trials of medium- to high-intensity diet and physical activity counseling interventions. ^{59, 116, 126, 141, 148, 149} Rates of injuries ranged from 0.0 to 6.3 percent in intervention groups and 0.0 to 7.3 percent in control groups, with no statistically significant differences in any study. Two trials reported one case each of musculoskeletal injury related to the intervention, one as the result of an assault while exercising, ¹²⁶ and the other a twisted ankle sustained while running. ¹⁴⁸

Other Outcomes

Other adverse events were variably reported among trials, with no between-group differences noted (**Appendix H Table 19**). 105, 116, 131

Paradoxical Changes

There was little evidence to suggest any paradoxical changes in intermediate outcomes. For each continuous intermediate outcome, there were a few studies in which the control group performed better than the intervention group, but in only one case was this statistically significant and it was offset by benefit for other outcomes. This occurred for the outcome of total cholesterol in the POWER study at 12-24 months (between-group difference of 7.80 mg/dL favoring the control group [95% CI, 0.39 to 15.21]), but LDL was not statistically significantly worsened (5.70 mg/dL favoring the control group [95% CI, -1.00 to 12.40]). ¹²⁶ However, weight loss was the primary outcome of this study, which had an impressive between-group difference favoring the intervention group of -4.30 kg (95% CI, -6.30 to -2.30)—one of the largest weight-loss effects in this body of literature. The study by Liira showed nonstatistically significant poorer outcomes in the intervention group (IG) for several intermediate outcome categories (blood pressure, lipids, adiposity), yet had a statistically significant improvement in fasting blood glucose favoring the IG at 12-24 months (-5.41 mg/dl [95% CI, -9.76 to -1.06]). This was a small Finnish study of adults with multiple risk factors who received a one-time 90-minute risk assessment and counseling intervention from a public health nurse. ¹¹⁷

With respect to behavioral outcomes, a small number of studies showed greater control group improvements for some dietary intake outcomes compared with intervention groups, but none was statistically significant in adjusted analyses. Authors of the Activity, Diet, and Blood Pressure Trial (ADAPT) study noted that there was a reported decrease in the consumption of high-fat dairy that wasn't necessarily replaced with low-fat dairy and considered a potential reduction in calcium intake a possible harm. ⁶⁹ For physical activity, effects favored control groups in a few studies, although those were typically not statistically significant in analyses reported by authors.

Chapter 4. Discussion

Summary of Evidence

Consistent with our prior review to support the previous recommendation, this review found that medium- and high-contact behavioral counseling interventions to improve diet and physical activity in people with cardiovascular risk factors was associated with improvements spanning a range of intermediate and behavioral outcomes, including blood pressure; lipids; adiposity; blood glucose; and intake of saturated fat, fruits and vegetables, fiber, and sodium. We found very similar effect sizes for most of these outcomes compared with the previous review (**Table 15**), despite the change in the composition of the evidence. Unlike the previous review, the current review included weight loss trials (as long as the trial was limited to people with CVD risk factors) and trials in people with elevated blood pressure and lipids (rather than requiring participants to meet criteria for hypertension or dyslipidemia), and excluded diabetes prevention trials that required all or most participants to have impaired fasting glucose. Thus, the current review was more heavily weighted toward populations with hypertension, dyslipidemia, and obesity, and de-emphasized diabetes prevention, which is addressed in a separate, concurrent USPSTF review.

Unlike the previous review, the current review found that behavioral counseling interventions were associated with a lower likelihood of CVD events, based on 12 trials reporting CVD event outcomes. Nine of these trials were new in this update. The overall pooled effect showed a 20 percent lower risk of CVD events with behavioral counseling interventions (pooled RR=0.80 [95% CI, 0.73 to 0.87], 9 RCTs [n=12,551]). This translates to a number needed to treat (NNT) of 100 (95% CI, 74 to 154) to prevent one CVD event, assuming a baseline rate of 5 percent. Population risks of 7.5 percent and 10 percent translate to NNTs of 67 (95% CI, 49 to 103) and 50 (95% CI, 37 to 77), respectively. This evidence is based largely on the strength of PREDIMED, a recently completed large trial conducted in Spain that was not included in the previous review. The PREDIMED study reduced stroke, PAD, and total CVD events. Total CVD events were reduced from 4.4 percent in the control group to 3.6 percent in the intervention group after 5 years. The PREDIMED findings were supported by a number of additional trials targeting patients with hypertension or selected based on having any of multiple CVD risk factors, and the effect was still statistically significant in a sensitivity analysis excluding PREDIMED (pooled RR=0.79 [95% CI, 0.70 to 0.90], 8 RCTs [n=5,104]) (**Table 9**).

Applicability of Findings

We considered this evidence to generally have good applicability to most U.S. primary care settings. Many of the trials were conducted in or recruited from primary care settings or other related healthcare settings (e.g., enrollment records from health clinics or systems), and almost half were conducted in the United States. Most interventions were delivered by professionals of the type embedded in large health systems (e.g., registered dieticians, nurses, health educators) and 25 (22%) of the included trials involved the primary care provider or their staff directly. However, we acknowledge that access to these professionals may not be widely available in all

primary care settings, and there may be more opportunities in large healthcare delivery systems. Additionally, recruitment from most studies (63%) was not self-selected or volunteer-based, improving the generalizability to primary care.

While PREDIMED was conducted in primary care settings, two factors limit the generalizability of its results: first, it excluded patients who were not ready to change according to the Stages of Change model, and second, it provided nuts or olive oil to all participants on a weekly basis. Indeed, some commenters have suggested that the results of PREDIMED might largely reflect the impact of supplemental food rather than overall dietary pattern. ²⁸⁴ Given evidence to support the benefits of food subsidies for low-income families, ^{285, 286} food provision may be a powerful intervention that could reduce socioeconomic health disparities. However, it does likely limit generalizability since most primary care settings are unlikely to distribute food directly. An additional limitation to the generalizability of PREDIMED is that it was conducted in Spain, where the typical diet already has Mediterranean elements. One group has noted that the typical U.S. diet would probably score 1 to 2 on the MEDAS, based largely on NHANES data, ²⁸⁷ in contrast to the baseline score in PREDIMED of approximately 8.5. The typical diet in the United States includes a substantial quantity of prepared and processed foods, and cooking from scratch is relatively rare. Thus, a 2-point increase on the MEDAS from 8.5, as was seen in the PREDIMED study, may not have the same health impact as a 2-point increase from a score of 1.5. It is plausible that the effect could be larger from such a different starting point.

Importantly, we found that behavioral counseling interventions appear to be effective in low-SES populations as well as those with more ample resources, which may provide an opportunity to help reduce income-related health disparities. There is a body of literature demonstrating an association between low socioeconomic status and unhealthy diet, which relates to the relatively higher burden of obesity and other cardiovascular risk factors among low-income individuals.²⁸⁸²⁸⁹ These groups therefore have the potential for substantial benefit from these interventions. A number of mechanisms have been suggested as reasons economically disadvantaged individuals have poorer quality diets: such diets cost less per calorie and people with very limited funds may need to prioritize price over healthfulness; knowledge is lacking about what constitutes a healthy diet and how to prepare foods to maximize their healthful qualities; and environmental factors may play a role, including limited access to fresh fruits and vegetables and greater access to fast-food outlets. ²⁸⁸ A systematic review of 35 RCTs examined factors associated with greater effectiveness of healthy lifestyle behavioral interventions in lowincome individuals.²⁹⁰ It found that self-monitoring, targeting multiple behaviors, and delivery through personal contact were all associated with greater improvement in healthy eating for people with low incomes. Features that were associated with more limited benefits included providing feedback on their eating, providing information about the emotional consequences of an unhealthy diet, and encouraging participants to use prompts and cues to be meeting dietary goals. They also found that physical activity interventions that included behavioral practice or instruction on how to perform the activity tended to report larger improvements in physical activity in low-income individuals.²⁹⁰

Comparisons with Other Reviews and Implementation Studies

Our findings were consistent with another recent review of 36 trials of multifactorial (primarily diet and physical activity) lifestyle interventions.²⁹¹ At 12-month followup among trials it categorized as being in "moderate" risk populations (generally meaning participants had one or more CVD risk factors but not CVD), it reported findings that were very similar to ours for blood pressure, (-2.48 mm Hg [95% CI, -4.34 to -0.62]/ -1.66 mm Hg [95% CI, -2.17 to -1.14], SBP/DBP change), and slightly larger for lipids (total cholesterol=-8.8 mg/dL [95% CI, -17.0 to -0.1], LDL=-4.2 mg/dL [95% CI, -8.5 to -0.0]) and adiposity (BMI=-0.8 kg/m² [95% CI, -1.8 to 0.2], waist circumference=-2.4 cm [95% CI, -5.4 to 0.6]). However, unlike our review, this review included trials with supervised physical activity. Similarly, USPSTF reviews^{47, 292} on adult obesity also found larger mean differences between groups in adiposity-related outcomes (e.g., BMI: -1.0 [95% CI, -1.2 to -0.7], **Table 15**), and LDL (-4.9 [95% CI, -7.3 to -2.6]), but had similar SBP results (SBP=-2.0 [95% CI, -2.9 to -1.2]), with 13 trials appearing in both reviews. 109, 116, 119, 120, 123-130, 138 The USPSTF review on diet and physical activity counseling in people who do not have CVD risk factors reported slightly smaller pooled effects for most intermediate outcomes and minimal evidence on the impact in CVD events but larger increases in physical activity than our review.²⁹³ It found approximately 35 more minutes per week of physical activity with lifestyle counseling interventions, and that USPSTF review included 43 trials of interventions that only addressed physical activity, many of which recruited adults with low levels of physical activity. ²⁹³ Indeed, studies whose primary inclusion criterion was suboptimal physical activity (without reference to CVD risk factors) were included in that review and not the present review.

Large implementation trials may provide insight into how well review results will generalize to real-life settings. A retrospective cohort study of the Veterans Administration MOVE! weight loss program included 1,463,003 veterans with obesity or overweight with weight-related health conditions and no baseline CVD, of whom 169,248 participated in the MOVE! program.²⁹⁴ The MOVE! program involves group-based educational sessions on nutrition, physical activity, and goal-setting. After a mean of 4.9 years of followup, participants in the MOVE! program had lower incidence of total CVD (hazard ratio [HR]=0.83 [95% CI, 0.80 to 0.86]), coronary artery disease (HR=0.81 [95% CI=0.77, 0.86]), cerebrovascular disease (HR=0.87 [95% CI, 0.82 0.92]), peripheral vascular disease (HR=0.89 [95% CI, 0.83 to 0.94]), and heart failure (HR=0.78 [95% CI, 0.74 to 0.83]), all controlling for age, race, sex, BMI, statin use, and baseline comorbidities. These results held up when examined for the categories of race/ethnicity, BMI, diabetes, hypertension, smoking status, and statin use. These effect sizes are consistent with our observed 19 percent reduction in CVD events. In this study, 49 percent had hypertension, 19 percent had diabetes, and 41 percent had dyslipidemia at baseline.

Another implementation study included 12,513 patients with multiple cardiovascular risk factors or history of atherosclerotic disease who were followed for 5 years in primary care clinics in Italy that implemented a program of annual screening and counseling by primary care providers for cardiovascular risk factors, including hypertension, hypercholesterolemia, diabetes, obesity, smoking, unhealthy diet, and physical inactivity.²⁹⁵ If control of any major modifiable cardiovascular risk factors was suboptimal, general practitioners use a brief checklist to develop

action plans to improve the patients' global risk profile. From the first to the last year of the program, control of all major modifiable risk factors except physical inactivity improved (p<0.0001). The improvement in the global cardiovascular risk profile during the first year was associated with a lower rate of major cardiovascular events in the following years (HR=0.94 [95% CI, 0.88 to 0.99]).

Intervention Approach

We identified no single optimal or representative intervention, but rather found that a wide range of approaches improve health profiles (**Table 16**). A number of effective trials used group-based counseling, and almost all of these also provided at least one individual support or assessment session as well. Quite a few interventions only provided individual contact, either in person or over the phone. Interestingly, an evaluation of participation in a health coaching program in a large integrated delivery system found that 80 percent of patients who participated in their program opted to receive one-on-one counseling over the phone rather than in-person individual or group sessions. ²⁹⁶

In the included trials, the intervention contact time required to show a benefit was as low as 1 hour over two sessions, although not all interventions with this level of contact were beneficial. In addition, weight loss interventions tended to offer more contact time than general diet and physical activity interventions. Most effective group-based programs offered five to 12 sessions over 4 to 12 months, or if weight loss was a primary focus, 20 to 30 sessions over 24 months. One-on-one interventions were generally briefer, typically four to 17 sessions over 6 to 16 months, and up to 32 or more sessions over 24 months for interventions focusing on weight loss. Medium contact interventions were typically delivered individually while high contact trials usually involved groups, often in addition to individual contact. Two trials included interventions both with and without human contact, using technology¹²³ or print-based¹⁰³ approaches for one of the intervention groups. Compared with a high-contact intervention, an online-only intervention resulted in less weight loss but no clear differences in diet composition or physical activity, ¹²³ and the four-session medium contact intervention showed comparable levels of behavior change as four tailored letters. ¹⁰³

In general, the interventions involved both physical activity and dietary counseling, which typically advised participants to reduce saturated fat; reduce sodium intake to below 1,500 or 2,300 mg/day for hypertension prevention and management; increase consumption of fruits, vegetable, whole grains, healthy fats, and fish; and reduce consumption of sweets and added sugar. The DASH diet and the Mediterranean diet were both employed by multiple interventions. A recently published diet described as optimal for both human and planetary health similarly emphasizes fish, vegetables, fruit, legumes, whole grains, and nuts. ²⁹⁷

Among interventions showing a benefit, common behavior-change techniques included goal setting, active use of self-monitoring, and addressing barriers related to diet, physical activity, or weight change. Some of the interventions offered smoking cessation support to smokers. Motivational interviewing was commonly employed. The most common type of provider to deliver the bulk of the interventions was a registered dietician, but a wide range of providers

were employed, such as health educators, nurses, lifestyle coaches, psychologists or psychology graduate students, and exercise physiologists. Few of the included interventions were primarily or wholly delivered through the computer or other electronic means, and a systematic review of lifestyle counseling to improve components of metabolic syndrome found that while technology could be a useful tool, interventions with personal contact were most effective. This approach was employed by an included U.S.-based trial that supplemented 18 phone-based coaching sessions with interactive voice recognition calls. It found relatively large benefits on lipids, fasting blood glucose, and weight. The same review found that team-based, interactive approaches with high-frequency contact with patients who were motivated found the largest effects. Page 198

Most of the interventions had weight loss goals for all or some of the participants. Consistent with our review, another review found that explicitly targeting weight loss in behavioral counseling interventions was associated with greater weight loss. ²⁹⁹ This review also found that providing dietary goals or meal plans and feedback on behavior change were associated with greater weight loss. ²⁹⁹ A comparative effectiveness study compared the effects of a weight loss intervention against a weight-neutral approach for health promotion in 80 women with BMI \geq 30 and age 30–45. ³⁰⁰ At postintervention, the weight-neutral program had larger reductions in LDL cholesterol and greater improvements in intuitive eating, while the weight loss program had larger reductions in BMI, weight, and (in the short-term only) larger decreases in a dietary risk score. Both groups improved on waist-to-hip ratio, total cholesterol, physical activity, fruit and vegetable intake, self-esteem, and quality of life at the 24-month followup. These findings highlight that important health benefits can accrue for people with excess weight even in the absence of weight loss or encouragement to lose weight. This trial was not limited to people with CVD risk factors, however, so generalizability to this group is unclear.

Further arguing for the benefits of improved diet and physical activity even without weight loss are the results from a large epidemiologic study combining participants from the Nurses' Health Study and the Health Professionals Follow-up Study. After 32 years, it found that all-cause mortality was lower in people with BMIs between 30 and 39.9 kg/m² who had engaged in at least three of the following healthy behaviors: healthy diet, physical activity, moderate alcohol consumption, and not smoking (incidence rate [IR]=51.7/10,000 person-years for BMI 30.0 to 34.9; IR=81.1/10,000 person-years for BMI 35.0 to 39.9) than people of healthy weight who reported engaging in only one of these four healthy behaviors (IR=96.5/10,000 person-years for BMI 22.5 to 24.9). Thus, for people with excess weight, particularly for those with a history of unsuccessful weight loss, unhealthy weight loss approaches, or disordered eating, promoting diet and physical activity goals without targeting weight loss is likely to improve their health status.

We did not find that physical activity consistently increased with lifestyle counseling for patients with CVD risk factors, despite evidence that suggests physical activity can improve cardiometabolic profiles among people with CVD risk factors. 9, 302, 303 In contrast, the USPSTF-commissioned systematic review of behavioral counseling for diet and physical activity in adults without CVD risk factors found a statistically significant 35-minute increase in physical activity per week and 32 percent higher odds of meeting physical activity recommendations. Like the current review, it also excluded trials with supervised physical activity. In both reviews, only a small subset of trials reported physical activity outcomes, although reporting was even more

sparse in our review. It is possible that supervised activity is an important factor in helping adults with CVD risk factors increase and maintain physical activity regimens. Indeed, semi-structured interviews of participants who had declined participation in an intervention to increase walking identified existing medical conditions as one of the more common reasons for declining,³⁰⁴ so people with CVD risk factors may similarly prefer to undertake physical activity under the supervision of a health or exercise professional. However, it remains unclear why improvements in physical activity were consistent and statistically significant in one review and not another. While we theorize that differences may be due to differing needs of patients with cardiovascular risk factors, we were unable to provide a clear explanation and other hypotheses cannot be ruled out, including reporting issues in primary trials.

Observational Evidence on the Association Between Differences in Intermediate and Behavioral Outcomes and Health Outcomes (Contextual Question)

Observational data from very large individual participant data (IPD) meta-analyses of prospective cohort studies show that small differences in blood pressure, non-HDL cholesterol, fasting glucose, and adiposity translate into small reductions in the risk of cardiovascular-related mortality (**Table 17**). 305-307 In our review we found that behavioral counseling interventions in persons with CVD risk factors had a pooled effect size of 1.9 mm Hg greater reduction in SBP. Using observational data, an effect of 2 mm Hg was associated with reductions of 6 percent or more in the risk of cardiovascular-related mortality, and the effect appears to hold down to blood pressure levels of 115/75 mm Hg.³⁰⁵ A recent analysis extended these findings to show that important associations between blood pressure and CVD events exist regardless of threshold (e.g., 140/90 mm Hg vs 130/90 mm Hg) and when using real-world clinical databases that do not use research-quality blood pressure measurements. ³⁰⁸ An average decrease in non-HDL cholesterol of 3 mg/dL (slightly smaller than the 3.7 mg/dL greater reduction in total cholesterol found in our review) was associated with a 4 percent reduction in IHD mortality in adults ages 40 to 49 years old (HR=0.96 [95% CI, 0.95 to 0.96]. 305 An incremental 2 mg/dL decrease in fasting blood glucose above 100 mg/dL was associated with an estimated 1 percent decreased risk of fatal plus nonfatal coronary heart disease (HR=0.99 [95% CI, 0.98 to 0.99]), 309 vascular deaths (HR=0.99 [95% CI, 0.98 to 0.99]),³¹⁰ and all-cause mortality (HR=0.99 [95% CI, 0.99 to 0.99]).³¹⁰ The relationship between BMI and cardiovascular-related mortality is found only above a BMI of 25 kg/m². A BMI decrease of 0.4 kg/m² (the effect size found in our pooled analysis) was associated with an estimated 3 percent decreased risk of death caused by ischemic heart disease (HR=0.97 [95% CI, 0.96 to 0.97]) and fatal strokes (HR=0.97 [95% CI, 0.97 to 0.98]) among adults with a BMI above 25 kg/m² and ranging from ages 35 to 59 years.³⁰⁷ Based on data pooled from multiple prospective cohort studies, we estimated that a 1.7 cm decline in waist circumference could be associated with a 5 percent lower risk of ischemic heart disease events (HR=0.95 [95% CI, 0.95 to 0.98])³¹¹ and a 1 to 3 percent lower risk of all-cause mortality (men: HR=0.97 [95% CI, 0.96 to 0.98] for a 2 cm decline; women: HR=0.99 [95% CI, 0.98 to 0.99] for a 1 cm decline).³¹²

For dietary outcomes, the impact of individual diet components is difficult to evaluate, as the totality of the diet is most important.²⁸⁸ One meta-analysis of 16 cohort studies found a 5 percent

lower risk of all-cause mortality for an increment of one serving of fruit and vegetables per day (pooled HR=0.95 [95% CI, 0.92 to 0.98]),²⁰ although our analysis found a mean difference in change of less than one serving. The effect of a 17.9 mmol/L greater reduction in sodium is unclear. Meta-analyses of cohort studies indicate that a 40 mmol/L reduction was associated with reduced incidence of stroke and fatal coronary heart disease events, but some other cardiovascular-related outcomes did not show a clear association.³¹³ The DASH feeding study found that a reduction in urinary sodium of approximately 50 mmol per day (a level of change consistent with someone who eats a typical American diet reducing their intake to meet current recommendations) was associated with approximately 2 mm Hg reduction in SBP,³¹³ which is the effect we found in this review.

The findings on intake of different types of dietary fats are less clear, although evidence suggests that a fat-modified diet may not assist with weight loss or decrease CVD and cancer mortalities. 314-317 Evidence suggests that replacing 5 percent of energy from saturated fats with other types of fats or whole-grain carbohydrates is associated with health benefits, 21 but not all researchers agree with this conclusion. 318-320 Further, a 5 percent change is larger than the 1.5 percent difference in change that we found in this review.

There is a strong body of evidence showing substantial health benefits associated with physical activity, and current evidence suggests that there is no threshold that must be exceeded before benefits can occur. Thus, despite the small, statistically nonsignificant findings for minutes and MET-minutes per week of exercise, any increase in physical activity is likely beneficial.

See **Appendix E** for a more detailed description of observational evidence supporting the link between changes in behavior and intermediate outcomes of the magnitude found in this review and long-term cardiovascular health outcomes. However, it is always worth emphasizing that observational evidence may overestimate the benefits of behavior change due to the inherent difficulty in controlling for confounding factors in non-randomized studies. Biases in observational results may be even more pronounced when long-term adherence to drug or behavioral change is assumed in order to maintain benefits. Some have noted that this concern is particularly important for applying effects of observational evidence to preventive interventions in primary care settings. ³²¹ Moreover, observational evidence does not reflect changes in intermediate or behavioral outcomes based on counseling interventions.

Limitations of Our Approach

This review addressed a subset of a larger body of literature on behavioral counseling interventions to promote a healthy diet and increase physical activity to encourage health and wellness more broadly. We focused narrowly on CVD prevention, limited further to patients with problematic blood pressure or lipids, to complement related USPSTF-sponsored reviews surrounding CVD prevention^{45, 46, 322}. Interventions targeting other health conditions are not represented, such as those focused on reducing or managing chronic pain, stress, limiting disability/frailty in older adults, improving mental health, or myriad other conditions that may be affected by diet and physical activity. We also did not include studies limited to some important underrepresented populations, such as those with physical or intellectual disabilities, and some of

the included trials specifically excluded these individuals from their studies, although these interventions are relevant to these populations.³²³

In addition, we limited our definition of high risk to hypertension, dyslipidemia, and any of multiple risk factors (including estimated 10-year risk). However, increasing age is a primary risk factor for CVD and studies restricted to older adults but without 10-year CVD risk inclusion requirements were excluded. In addition, we did not include studies focused on persons with mild chronic kidney disease, many of whom also have hypertension and dyslipidemia and who may also benefit from behavioral counseling for diet and physical activity.

Our search did not comprehensively address weight loss for trials published prior to 2016. Since the previous review did not include weight loss trials, the previous search did not include weight loss terms. We used the USPSTF review on weight management interventions to identify weight loss trials in people with CVD risk factors that were published prior to 2016.³²² In addition, we searched the excluded studies lists from the previous on lifestyle counseling for people with CVD risk factors to identify studies that had been excluded because they were considered to be weight loss studies.³²⁴

Additionally, we excluded populations with prediabetes or identified with a diabetes risk score. A concurrent companion systematic review is addressing behavioral counseling interventions to prevent diabetes in those at increased risk of diabetes. While we are confident that this targeted approach will not miss any literature, we acknowledge that prediabetes commonly coexists in adults with obesity, hypertension, and dyslipidemia.

Limitations of the Studies and Future Research Needs

Although the evidence base for the impact of diet and physical activity counseling on health outcomes has improved since the previous review, one limitation of the literature is that only a small proportion of trials had sufficient sample size and length of followup to explore the impact of their interventions on important health outcomes such as stroke, MI, and mortality. Continued long-term followup presents a valuable opportunity to assess the impact on these important outcomes.

Another important limitation of this literature is the highly variable reporting of behavioral outcomes, particularly physical activity outcomes. The variability in specific measures used, as well as the general lack of reporting of behavioral outcomes in studies reporting intermediate outcomes, made it very difficult to understand the range of effects and to interpret the pooled effects. In addition, for dietary outcomes, it is difficult to understand the clinical importance of changes in a single aspect of diet, particularly in the area of fat consumption, because recommendations have changed over the past decades and controversy remains over the role of saturated fats in the development of heart disease. Given the importance of substitutions when modifying diet, validated measures of overall diet pattern would be a more valuable outcome; however, the field has not converged on a consistent measure of overall optimal diet pattern. The Healthy Eating Index (HEI), for example, is a validated measure of overall diet quality assessing alignment with the Dietary Guidelines for Americans, and is associated with

all-cause, CVD, and cancer mortality.³²⁶ Yet, only two included studies reported this measure.^{97,} This field would benefit from establishing a set of core outcome measures of optimal diet and physical activity.

Additionally, changes over time in eating patterns, treatment guidelines, and our understanding of the science of nutrition increase the clinical heterogeneity of participants as well as the interventions used in these trials. Treatment guidelines for hypertension and dyslipidemia have changed over time, generally becoming more aggressive. At the same time, rates of smoking have declined. Dietary messages as well as technology platforms available to deliver interventions have similarly undergone rapid change. While we restricted our included literature to trials published from 1990 to present, this review encompasses nearly 30 years of literature, during which the clinical context of behavioral counseling for individuals with CVD risk factors has changed. The sparse reporting of baseline estimated 10-year CVD risk—coupled with the rarity of trials powered for CVD events—makes it difficult to characterize the risk levels of participants in terms consistent with treatment guidelines that are informed by 10-year risk levels.

The wide-ranging clinical characteristics of the study populations also made it difficult to generalize from study-reported subgroup analyses, which were rarely available from more than one or two studies for any given outcome for a given patient subpopulation. Thus, we were not able to provide a robust analysis of differential effectiveness across patient characteristics. While we conducted meta-regression and subgroup analysis in our meta-analyses to address effect modification to the extent possible, these analyses were very limited due to the risk of ecological bias, and the best analysis of effect modification across patient subpopulations is with individual-level data. Another analysis issue that is best addressed in individual-level analyses is controlling for the confounding effects of medication use. Medication use may have systematically differed between groups if control participants had a greater need for medication use due to poorer lifestyle behaviors. Individual studies rarely controlled for this potentially important confounding variable.

In addition, there was little literature on the use of technology, online resources, or other low-contact approaches, which may be valuable in settings with very limited resources. Relatedly, there was very limited use of modern wearable activity trackers in the included interventions, but these may be useful tools to increase engagement in physical activity as well as to provide objective physical activity outcomes. Research suggests that these devices can even be acceptable to adults over the age of 50 with chronic illnesses. 327

Despite the large number of included trials in this review, there were few replication studies, unlike DPP in the diabetes prevention literature. Large replication studies of interventions showing reduction in CVD events are urgently needed. Given the recency and magnitude of benefit from PREDIMED, it would be of great value to determine if these findings could be replicated in the United States. Our review includes only one U.S.-based trial explicitly stating that a Mediterranean diet message was evaluated. This 12-month trial of 184 participants showed statistically significant improvement in blood pressure, adiposity, and saturated fat outcomes; however, it was too small to assess impact on CVD events.

The PREDIMED-Plus (ISRCTN89898870) trial currently underway in Spain intends to build upon the findings of PREDIMED. PREDIMED-Plus, for which 6,874 individuals were recruited, will compare a Mediterranean diet (with supplemental olive oil and nuts given at no cost) to a Mediterranean diet (with the same supplemental foods) together with promotion of physical activity, behavioral support, and weight loss goals. The primary outcome of this trial is a CVD event composite, and the anticipated trial completion date is 2020. Many behavioral counseling trials are currently in progress, with many being conducted in the United States (**Appendix I**). The trials are evaluating different intervention formats in both general and targeted populations with CVD risk factors. With the exception of PREDIMED-Plus, none of the trials appear to be powered for CVD events.

Finally, we agree with the Hypertension Canadian Priority Setting Partnership Group that more research is needed to determine the combinations of healthy lifestyle modifications that are necessary and sufficient to reduce the need for medications to manage CVD risk factors, and the optimal use of educational tools and technologies to improve patient motivation and health behavior change. While great strides have been made in developing and testing numerous interventions, it is still unclear exactly which intervention components and messages are most effective, how much contact time is required, and who should deliver these interventions to help most individuals substantially improve their diet or increase physical activity, and to maintain the changes for the long term. Comparative effectiveness studies are the best vehicle for addressing these types of questions; however, they fall outside the scope of the current review.

Thus, with the caveats surrounding the need to standardized measures, future research needs include:

- Replication of effective studies (e.g., PREDIMED, others showing reductions in CVD events or relatively large effects on intermediate outcomes) in the current US environment with respect to clinical care, dietary recommendations, and food intake patterns
- Long-term followup on previously completed studies examining CVD and mortality outcomes
- Large-scale implementation studies of effective interventions in health systems

Conclusions

Medium- and high-contact multisession behavioral counseling interventions to improve diet and increase physical activity provided to people with hypertension or dyslipidemia, or who have elevated blood pressure and lipid levels, are effective in reducing CVD events, blood pressure, total cholesterol, and adiposity-related outcomes, with little to no risk of serious harm.

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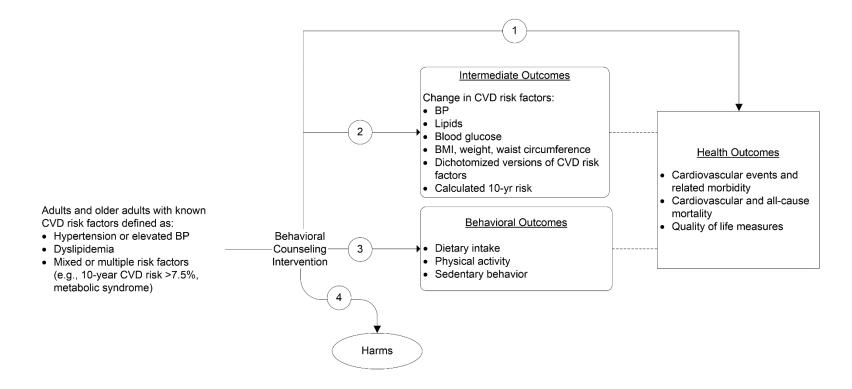
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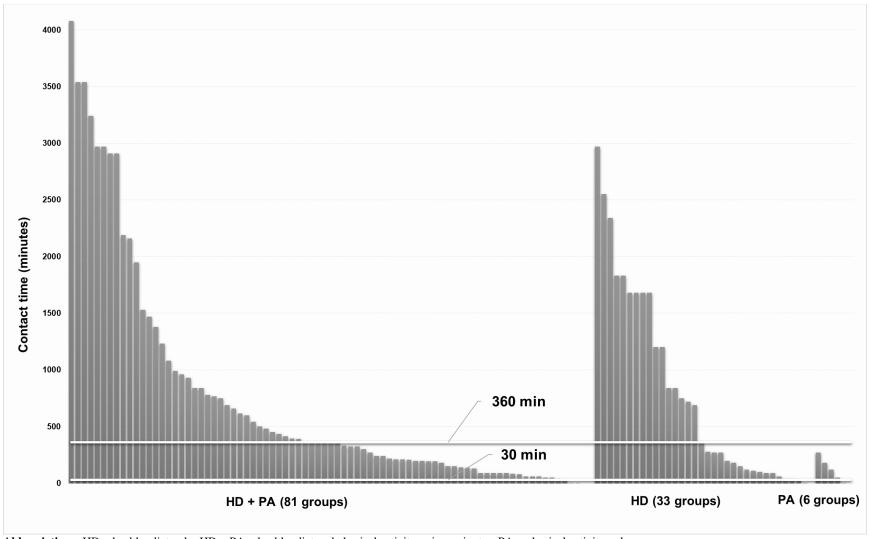
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Figure 1. Analytic Framework



Abbreviations: BP = blood pressure, BMI = body mass index, CVD = cardiovascular disease

Figure 2. Distribution of Intervention Arms by Contact Time* and Focus



Abbreviations: HD = healthy diet only; HD + PA = healthy diet and physical activity; min = minutes; PA = physical activity only

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 3. CVD Events (KQ1)

Study	Population risk focus	Contact time*	Timepoint (months)	IG n/N (%)	CG n/N (%)		cv	D Events		RR	95	% CI
Stroke												
Appel, 2003	Hypertension	High	6	0/537 (0.0)	1/273 (0.4)	-				0.17	[0.01;	4 161
Estruch, 2018	Multiple risk factors		60	81/4997 (1.6)	58/2450 (2.4)					0.68	[0.49;	
Fagerberg, 1998	Multiple risk factors		40	5/253 (2.0)	17/255 (6.7)					0.30	[0.43,	
Whelton, 1998	Hypertension	High	36	2/664 (0.3)	2/371 (0.5)						[0.08;	
Overall (REML + KH)		riigii	50	2/004 (0.3)	2/3/1 (0.5)						[0.25;	
Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$.										0.02	[0.20,	
notorogonoxy. 7 570, 1 6.	12, p 0.40											
МІ												
Appel, 2003	Hypertension	High	6	1/537 (0.2)	1/273 (0.4)	-		+		0.51	[0.03;	8.03]
Estruch, 2018	Multiple risk factors	High	60	68/4997 (1.4)	38/2450 (1.6)			-		0.88	[0.59;	1.30]
Fagerberg, 1998	Multiple risk factors	High	40	18/253 (7.1)	22/255 (8.6)			-		0.80	[0.46;	1.39]
Haufe, 2019	Multiple risk factors	Medium	6	1/160 (0.6)	0/154 (0.0)					2.89	[0.12; 7	0.44]
Wadden, 2011	Multiple risk factors	High	24	0/131 (0.0)	1/130 (0.8)	_	+	+-		0.33	[0.01;	8.04]
Whelton, 1998	Hypertension	High	36	6/664 (0.9)	4/371 (1.1)		_	-		0.84	[0.24;	2.93]
Overall (REML + KH)								•		0.85	[0.70;	1.02]
Heterogeneity: $t^2 = 0\%$, $\tau^2 = 0$,	p = 0.95											
CVD events												
Bennett, 2012	Hypertension	High	24	0/180 (0.0)	1/185 (0.5)	5	-	_		0.34	[0.01;	8.37]
Bennett, 2018	Multiple risk factors			5/176 (2.8)	6/175 (3.4)		-	+		0.83		
Bo, 2007	Multiple risk factors			12/169 (7.1)	19/166 (11.4)		_	•			[0.31;	Nation - Colombia
Estruch, 2018	Multiple risk factors	-	60	, ,	109/2450 (4.4)			-		0.80	[0.63;	(0.5) (1.5) (1.5)
Fagerberg, 1998	Multiple risk factors		79	63/253 (24.9)	84/255 (32.9)			-		0.71	[0.51;	0.99]
Hinderliter, 2014	Hypertension	High	12	0/46 (0.0)	0/49 (0.0)							
TOHP I CRG, 1992	Hypertension	High	192	17/231 (7.4)	32/311 (10.3)			•		0.71	[0.40;	20 Page 1970
TOHP II CRG, 1997	Hypertension	High	192	71/938 (7.6)	80/935 (8.6)			*		0.89	[0.65;	
Whelton, 1998	Hypertension	High	36	88/664 (13.3)	57/371 (15.4)			-		0.86	[0.63;	
Overall (REML + KH)								•		0.80	[0.73;	0.87]
Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$,	p = 0.96											
						0.01	0.1	1 .	10 100			
							Favors	IG Favors C	G			

Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; KH = Knapp-Hartung adjustment; MI = myocardial infarction; REML = restricted maximum likelihood; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 4. All-Cause Mortality (KQ1)

	Population	Contact	Timepoint							
Study	risk focus	time*	(months)	IG n/N (%)	CG n/N (%)		All-Cause	Mortality	RR	95% CI
Annal 2011	Multiple viels feetens	I II ala	24	0/077 /0 0\	0/439 (0.0)		1			
Appel, 2011	Multiple risk factors		24	0/277 (0.0)	0/138 (0.0)					
Bennett, 2018	Multiple risk factors			1/176 (0.6)	0/175 (0.0)					[0.12; 72.58]
Bo, 2007	Multiple risk factors	Medium	108	21/169 (12.4)	28/166 (16.9)		-	-	0.73	[0.43; 1.25]
Bosworth, 2009	Hypertension	Medium	24	7/319 (2.2)	5/159 (3.1)		-		0.70	[0.22; 2.17]
Eakin, 2009	Multiple risk factors	Medium	18	3/231 (1.3)	2/208 (1.0)		-	•	1.35	[0.23; 8.03]
Estruch, 2018	Multiple risk factors	High	60	234/4997 (4.7)	114/2450 (4.7)		+	1.01	[0.81; 1.25]
Fagerberg, 1998	Multiple risk factors	High	79	41/253 (16.2)	64/255 (25.1)		-		0.62	[0.42; 0.92]
Greaves, 2015	Multiple risk factors	High	12	2/55 (3.6)	0/53 (0.0)		-	•	4.81	[0.23; 98.33]
HPT, 1990	Hypertension	High	36	3/645 (0.5)	1/196 (0.5)				0.91	[0.10; 8.71]
Kandula, 2015	Multiple risk factors	High	6	0/31 (0.0)	0/32 (0.0)					
Keyserling, 1997	Dyslipidemia	Medium	24	4/184 (2.2)	1/188 (0.5)		_		- 4.10	[0.47; 36.07]
Niiranen, 2014	Hypertension	Medium	12	1/117 (0.9)	0/112 (0.0)					
Ogedegbe, 2014	Hypertension	Medium	12	8/529 (1.5)	3/510 (0.6)		-	•	2.56	[0.69; 9.52]
Rosas, 2015	Multiple risk factors	High	24	0/166 (0.0)	0/41 (0.0)		į			
Salisbury, 2016	Multiple risk factors	Medium	12	0/325 (0.0)	2/316 (0.6)	8	+		0.19	[0.01; 4.05]
Svetkey, 2008	Multiple risk factors	High	30	2/690 (0.3)	1/342 (0.3)			-	0.99	[0.09; 10.82]
TOHP CRG, 1992	Hypertension	High	18	1/635 (0.2)	1/417 (0.2)	10	*	, a	0.66	[0.04; 10.42]
TOHP II CRG, 1997	Hypertension	High	192	25/1191 (2.1)	28/1191 (2.4)		-	-	0.90	[0.53; 1.52]
Overall (REML + KH)									0.89	[0.71; 1.11]
Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$.	02, p = 0.48						8			
						0.01	0.1	1 10	100	
							Favors IG	Favors CG		

Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 5. Systolic and Diastolic Blood Pressure Summary (KQ2)

Outcome	Population risk focus	K	Ţ	Diff. in change	95% CI I^2
SBP (mm Hg)	Hypertension <12 months 12-24 months >24 months	16 16 4	•	-2.84 -1.97 -1.11	[-4.38; -1.29] 70% [-2.59; -1.36] 8% [-1.71; -0.51] 0%
	Dyslipidemia 12-24 months	3	-	-0.57	[-3.90; 2.75] 0%
	Multiple risk factors <12 months 12-24 months >24 months	14 25 2	-		[-2.20; -0.60] 0% [-2.91; -0.55] 51% [-36.77; 28.02] 76%
	All studies <12 months 12-24 months >24 months	30 44 6	* *	-2.25 -1.81 -1.84	[-3.12; -1.37] 58% [-2.49; -1.13] 37% [-4.12; 0.44] 55%
DBP (mm Hg)	Hypertension <12 months 12-24 months >24 months	14 15 4			[-2.51; -0.80] 68% [-1.75; -0.38] 43% [-2.50; 2.44] 77%
	Dyslipidemia 12-24 months	2	•	-1.40	[-2.67; -0.13] 0%
	Multiple risk factors <12 months 12-24 months >24 months	12 23 2		-0.85 -1.22 -1.43	[-1.40; -0.30] 0% [-1.82; -0.61] 33% [-6.42; 3.57] 0%
	All studies <12 months 12-24 months >24 months	26 40 6	-30-20-10 0 10 20 30	-1.35 -1.16 -0.45	
			Favors IG Favors CG		

Abbreviations: CI = confidence interval; DBP = diastolic blood pressure; Diff. = difference; studies (including studies reported by subgroups); mm Hg = millimeter of mercury; SBP = systolic blood pressure

Figure 6. Systolic Blood Pressure Subgroup Analyses (KQ2)

Subgroup	К	P*	SBP (mm Hg)	Diff. in change†	95% CI 1^2
Study quality Good Fair	18 39	0.74			[-2.40; -1.44] 0% [-3.14; -1.08] 59%
USA-based Yes No	23 34	0.69			[-2.71; -1.22] 44% [-3.14; -1.26] 51%
Age group General/younger adult focus Older adult focus	49 8	0.13	-		[-2.40; -1.24] 33% [-7.45; -0.66] 71%
100% overweight or obese Yes No NR	17 13 27	0.97	#	-2.05	[-2.83; -1.11] 10% [-3.40; -0.70] 57% [-3.40; -0.91] 57%
Weight loss approach Promoted for all participants Promoted for subset of participants Not promoted NR	14 17 7 19	0.62		-1.96 -2.72	[-2.67; -1.05] 5% [-3.23; -0.69] 47% [-4.06; -1.38] 20% [-3.73; -0.36] 66%
Contact time High (>360 min) Medium (31-360 min) Low (0-30 min)	27 27 3	0.84 ←		-2.05	[-2.59; -1.37] 27% [-3.13; -0.97] 48% -17.22; 9.66] 90%
Medication management Yes No	15 42	0.77	=		[-4.01; -0.50] 54% [-2.74; -1.23] 45%
Low sodium diet Yes No	13 44	0.80			[-2.73; -1.20] 35% [-2.97; -1.24] 51%
BP monitor provided Yes No	6 51	0.26	-		[-3.90; -1.49] 0% [-2.78; -1.26] 51%
Socioeconomic status Low SES Average	11 46	0.42			[-3.53; 0.79] 50% [-2.93; -1.49] 46%
Overall (REML + KH) Heterogeneity: $I^2 = 47\%$, $\tau^2 = 2.50$, $\rho < 0.01$		-15	-10 -5 0 5 10 Favors IG Favors CG	- 2.08 [-2.76; -1.39]

Abbreviations: BP = blood pressure; CI = confidence interval; Diff. = difference; K = number of studies (including studies reported by subgroups); KH = Knapp-Hartung adjustment; mm Hg = millimeters of mercury; NOS = not otherwise specified; NR = not reported; REML = restricted maximum likelihood; SES = socioeconomic status

^{*}Bivariate P-values derived from Q test of between-subgroups heterogeneity (based on random effects model)

†For this analysis, the most comprehensive or highest dose intervention group was selected if a study had multiple intervention groups, and the followup timepoint closest to 12 months was selected of there were multiple followup assessments

Figure 7. Hypertension Incidence and Prevalence (KQ2)

Study	Population risk focus	Intervention focus	Contact time*	Timepoint (months)	IG n/N (%)	CG n/N (%)		Inc	10000		ension Preva			RR	95	5% CI
Hypertension inciden	ICA															
Appel, 2003	Hypertension	HD + PA	High	6	9/156 (5.8)	18/160 (11.3)		_						0.51	[0.24;	1 101
Babazono, 2007	Multiple risk factors		Medium		10/46 (21.7)	6/41 (14.6)									[0.59;	
HPT, 1990	Hypertension	HD only		36	41/189 (21.7)	65/194 (33.5)									[0.33,	
		-	High	18	, ,	, ,										1,00
TOHP I CRG, 1992	Hypertension	HD only	High		28/327 (8.6)	47/417 (11.3)									[0.63;	
TOHP II CRG, 1997	Hypertension	HD + PA	High	18	88/589 (14.9)	124/588 (21.1)			7						[0.55;	5. 4 .5
Overall (REML + KH)										•				0.74	[0.58;	0.94]
Heterogeneity: $I^2 = 12\%$, $\tau^2 = <$	0.01, p = 0.34															
Hypertension prevale	ence															
Appel, 2003	Hypertension	HD + PA	High	18	57/258 (22.1)	82/257 (31.9)			-	1				0.69	[0.51;	0.93]
Bo, 2007	Multiple risk factors	HD + PA	Medium	12	143/169 (84.6)	148/166 (89.2)				+				0.95	[0.88;	1.03]
Cochrane, 2012	Multiple risk factors	HD + PA	Medium	12	43/236 (18.2)	53/365 (14.5)				+	-			1.26	[0.87;	1.83]
Estruch, 2018	Multiple risk factors	HD only	High	60	1938/2032 (95.4)	1899/1990 (95.4)			+				1.00	[0.98;	1.02]
Muhlhauser, 1993	Hypertension	HD + PA	Medium	18	73/86 (84.9)	64/74 (86.5)				7				0.97	[0.81;	1.16]
Overall (REML + KH)	30 1 30 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				()	,				•					[0.89;	
Heterogeneity: $I^2 = 56\%$, $\tau^2 = <$															•	
y y								ı	1			1				
							0.1	0.2	0.5	1	2	5	10			
									Favors	IG	Favors	s CG				

Abbreviations: CI = confidence interval; HD = healthy diet; HD + PA = healthy diet and physical activity; K = number of studies (including studies reported by subgroups); KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 8. Blood Pressure at Goal (KQ2)

	Planned	Contact	Population	Med				1	Blood	Press	ure			
Study	FUP, mo.	hrs	risk focus	mgmt	IG n/N (%)	CG n/N (%)			at	Goal			RR	95% CI
										1207				
Appel, 2003	18	59	Hypertension	No	62/258 (24.0)	46/257 (17.9)					-		1.34	[0.96; 1.86]
Bennett, 2012	12	18	Hypertension	Yes	129/180 (71.7)	120/185 (64.9)				+			1.11	[0.96; 1.27]
Beune, 2014	6	2	Hypertension	Yes	34/71 (47.9)	29/68 (42.6)			-				1.13	[0.78; 1.64]
Edelman, 2006	10	68	Multiple risk factors	No	63/77 (81.8)	53/77 (68.8)							1.19	[0.99; 1.41]
Fagerberg, 1998	12	12	Multiple risk factors	No	188/239 (78.7)	175/238 (73.5)				+			1.07	[0.97; 1.18]
Jones, 1999	12	12	Hypertension	Yes	44/51 (86.3)	42/51 (82.4)							1.05	[0.88; 1.25]
Khanji, 2019	6	0	Multiple risk factors	No	158/194 (81.4)	142/184 (77.2)				+			1.05	[0.95; 1.16]
Langford, 1991	6	14	Hypertension	Yes	228/265 (86.0)	220/264 (83.3)				+			1.03	[0.95; 1.11]
Niiranen, 2014	12	3	Hypertension	Yes	59/112 (52.7)	65/108 (60.2)				-			0.84	[0.47; 1.52]
Ogedegbe, 2014	12	6	Hypertension	Yes	261/529 (49.3)	227/510 (44.5)				+			1.11	[0.96; 1.27]
Rodriguez, 2012	6	2	Hypertension	Yes	114/176 (64.8)	81/177 (45.8)				-			1.42	[1.17; 1.73]
Schoenthaler, 2016	6	16	Hypertension	Yes	36/97 (37.1)	42/97 (43.3)			-	 			0.86	[0.60; 1.22]
Wood, 2008	12	8	Multiple risk factors	Yes	586/1016 (57.7)	407/1004 (40.5)			+			1.42	[1.29; 1.57]
										İ				
Overall (REML + KH)										•			1.13	[1.04; 1.23]
Heterogeneity: $I^2 = 70\%$, $\tau^2 = 0$.	01, <i>p</i> < 0.01						I	1	J.	1	Ţ	Ţ		
							0.1	0.2	0.5	19	2	5	10	
								Fav	ors CG	Fav	ors IG			

 $\textbf{Abbreviations:} \ CG = control \ group; \ CI = confidence \ interval; \ FUP = followup; \ hrs = hours; \ IG = intervention \ group; \ K = number \ of \ studies; \ KH = Knapp-Hartung \ adjustment; \ Med \ mgmt. = medication \ management; \ mo. = months; \ REML = restricted \ maximum \ likelihood; \ RR = risk \ ratio$

Figure 9. Total Cholesterol and Low-Density Lipoprotein Cholesterol Summary (KQ2)

Population Outcome risk focus		K	ı	Diff. in change				
TC (mg/dL)	Dyslipidemia <12 months 12-24 months	6 9	-	-3.84 -3.80	[-9.44; 1.76] 32% [-7.23; -0.37] 24%			
	Multiple risk factors <12 months 12-24 months >24 months	9 22 2	-	-2.64 -4.06 → -6.07				
	Hypertension <12 months 12-24 months >24 months	4 7 1	-	-8.11 -0.72 -7.72	[-27.16; 10.93] 88% [-3.17; 1.73] 18% [-17.36; 1.92]			
	All studies <12 months 12-24 months >24 months	19 38 3		-4.03 -3.47 -6.64	The state of the s			
LDL-C (mg/dL)	Dyslipidemia <12 months 12-24 months	5 7	-	-0.95 -4.12	[-6.74; 4.85] 45% [-8.81; 0.57] 36%			
	Multiple risk factors <12 months 12-24 months >24 months	8 20 1		-1.73 -1.71 -14.67	[-4.34; 0.88] 0% [-4.64; 1.22] 62% [-21.43; -7.91]			
	Hypertension <12 months 12-24 months	3 5	-	-2.66 -1.57	[-13.68; 8.36] 65% [-4.78; 1.65] 56%			
	All studies <12 months 12-24 months >24 months	16 32 1	-20 -10 0 10 20	-2.14 -14.67	[-3.52; 0.30] 17% [-4.08; -0.21] 56% [-21.43; -7.91]			
			Favors IG Favors CG					

Abbreviations: CI = confidence interval; Diff. = difference; K = number of studies (including studies reported by subgroups); LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; TC = lotal cholesterol

Figure 10. High-Density Lipoprotein Cholesterol (KQ2)

Population risk focus	K	HDL (mg/dL)	Diff. in change	95% CI I^2
Dyslipidemia <12 months 12-24 months	3 6		-	-1.19; -1.14] 0% -1.26; 0.37] 0%
Multiple risk factors <12 months 12-24 months >24 months	10 23 2		0.81	0.07; 0.89] 0% 0.30; 1.32] 39% -1.42; 3.21] 0%
Hypertension <12 months 12-24 months >24 months	2 5 1		0.69 [-8.87; 9.61] 64% 0.00; 1.38] 0% -2.31; 3.09]
All studies <12 months 12-24 months >24 months	15 34 3	-5 0 5	0.58	-0.15; 0.69] 0% 0.19; 0.98] 34% 0.05; 1.57] 0%
		Favors CG Favors IG		

 $\label{eq:Abbreviations: CI = confidence interval; Diff. = difference; HDL = high-density lipoprotein cholesterol; K = number of studies (including studies reported by subgroups); mg/dL = milligrams per deciliter$

Figure 11. Total Cholesterol Subgroup Analyses (KQ2)

Subgroup	K	P*	TC (mg/dL)	Diff. in change†	95% CI I^2
Study quality Good Fair	13 33	0.07	-		[-5.20; 2.94] 73% [-7.35; -2.73] 60%
USA-based Yes No	18 28	0.04	-		[-4.14; 1.23] 39% [-8.02; -2.49] 72%
Age group General/younger adult focus Older adult focus	41 5	0.00		-3.09 -10.08 [-	[-5.18; -1.00] 63% -15.92; -4.23] 34%
100% overweight or obese Yes No NR	11 12 23	0.02	-	-6.05 [-	[-3.21; 3.51] 34% -11.87; -0.23] 85% [-6.86; -2.33] 44%
Weight loss approach Promoted for all participants Promoted for subset of participants Not promoted NR	10 17 4 15	0.01		-4.72 -6.40 [-	[-1.96; 3.70] 11% [-8.26; -1.18] 76% -17.56; 4.75] 64% [-9.06; -1.50] 60%
Contact time High (>360 min) Medium (31-360 min) Low (0-30 min)	20 24 2	0.00	-	-3.52	[-8.12; -0.84] 78% [-5.87; -1.16] 41% [-6.10; 7.64] 0%
Medication management Yes No	6 40	0.06 —	-		-20.97; -0.05] 88% [-4.52; -0.91] 51%
Fat modified Yes No	15 31	0.63	-		[-7.88; -1.17] 59% [-6.18; -0.94] 70%
Socioeconomic status Low SES Average	9 37	0.01	-		[-2.73; 2.35] 0% [-6.97; -2.31] 71%
Overall (REML + KH) Heterogeneity: $I^2 = 66\%$, $\tau^2 = 28.48$, $\rho < 0.01$		-20	-10 0 10 Favors IG Favors CG	-3.86 [20	-5.87; -1.85]

Abbreviations: CI = confidence interval; CG = control group; Diff. = difference; IG = intervention group; K = number of studies (including studies reported by subgroups); KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SES = socioeconomic status; TC = total cholesterol

^{*}Bivariate P-values derived from Q test of between-subgroups heterogeneity (based on random effects model)

†For this analysis, the most comprehensive or highest dose intervention group was selected if a study had multiple intervention groups, and the followup timepoint closest to 12 months was selected of there were multiple followup assessments

Figure 12. Fasting Blood Glucose (KQ2)

Population risk focus	к	FBG (mg/dL)	Diff. in change	95% CI I^2
Dyslipidemia 12-24 months	3	-	-2.97	[-7.01; 1.06] 0%
Multiple risk factors <12 months 12-24 months >24 months	8 18 3		-2.47	[-3.53; 0.19] 69% [-4.12; -0.82] 85% [-14.08; 7.52] 90%
Hypertension <12 months 12-24 months >24 months	2 1 1	••••••••••••••••••••••••••••••••••••••	-0.18	[-21.84; 27.17] 0% [-1.20; 0.84] [-1.80; 1.80]
All studies <12 months 12-24 months >24 months	10 22 4	-20 -10 0 10 20	-1.38 -2.33 -2.27	[-3.64; -1.03] 83%
		Favors IG Favors CG		

Abbreviations: CI = confidence interval; Diff. = difference; FBG = fasting blood glucose; K = number of studies (including studies reported by subgroups); mg/dL = milligrams per deciliter

Figure 13. Incident Diabetes (KQ2)

		Population	Contact	Timepoint					
Study	Int arm	risk focus	time*	(months)	IG n/N (%)	CG n/N (%)	Incident Diabetes	RR	95% CI
Bo, 2007	IG1	Multiple risk factors	Medium	108	14/169 (8.3)	27/166 (16.3)	10	0.51	[0.28; 0.94]
Estruch, 2018	IG1	Multiple risk factors	High	48	80/1154 (6.9)	101/1147 (8.8)	-	0.79	[0.60; 1.03]
Estruch, 2018	IG2	Multiple risk factors	High	48	92/1240 (7.4)	101/1147 (8.8)		0.84	[0.64; 1.11]
Babazono, 2007	' IG1	Multiple risk factors	Medium	12	11/46 (23.9)	10/41 (24.4)		0.98	[0.47; 2.06]
Toft, 2008	IG1	Multiple risk factors	High	60	187/2454 (7.6)	21/284 (7.4)		1.03	[0.67; 1.59]
Overall (REML	+ KH)						<u> </u>	0.82	[0.66; 1.03]
Heterogeneity: $I^2 = 0\%$	ρ , τ^2 < 0.01, p = 0.44								
							0.5 1 2		
							Favors IG Favors CG		

Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; Int arm = intervention arm; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 14. Metabolic Syndrome Incidence and Prevalence (KQ2)

	Population Contact			Timepoint			Metabolic	Metabolic Syndrome					
Study	risk focus	time*	Outcome	(months)	IG n/N (%)	CG n/N (%)	Incidence &	Prevalence	RR	95% CI			
				100			_						
Anderssen, 1995 (Males)	Multiple risk factors	Medium	METS prevalence	12	22/34 (64.7)	23/26 (88.5)	-		0.73	[0.55; 0.98]			
Bo, 2007	Multiple risk factors	Medium	METS incidence	12	59/169 (34.9)	109/166 (65.7)	-		0.53	[0.42; 0.67]			
Estruch, 2018	Multiple risk factors	High	METS incidence	38	329/663 (49.6)	298/594 (50.2)	-		0.99	[0.88; 1.11]			
Greaves, 2015	Multiple risk factors	High	METS prevalence	12	21/54 (38.9)	32/53 (60.4)			0.64	[0.44; 0.95]			
Liira, 2014	Multiple risk factors	Medium	METS prevalence	12	27/46 (58.7)	21/42 (50.0)	ļ——	-	1.17	[0.79; 1.74]			
Overall (REML + KH)									0.78	[0.53; 1.16]			
Heterogeneity: $I^2 = 85\%$, $\tau^2 = 0.08$, μ	< 0.01							Į.	7				
· , , , , , , , , , , , , , , , , , , ,							0.5	1	2				
							Favors IG	Favors CG					

Abbreviations: CG = control group; CI = confidence interval; Int arm = intervention arm; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; METS = metabolic syndrome; REML = restricted maximum likelihood; RR = risk ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Figure 15. Weight, BMI, WC Summary Plot (KQ2)

Outcome	Population risk focus	ĸ	1	Diff. in change	95% CI 1^2
вмі	Dyslipidemia				
	<12 months	2	 	-0.18	[-2.04; 1.67] 51%
(kg/m2)	12-24 months	2	-	0.10	[-1.24; 1.43] 0%
	Multiple risk factors				
	<12 months	12	-	-0.72	[-1.10; -0.33] 88%
	12-24 months	22	-	-0.60	[-0.83; -0.37] 82%
	>24 months	2		-0.59	[-3.12; 1.95] 71%
	Hypertension				
	<12 months	4	-		[-1.02; 0.33] 67%
	12-24 months	6	7	-0.14	[-0.63; 0.36] 66%
	All studies				
	<12 months	18	+	-0.57	[-0.86; -0.29] 87%
	12-24 months	30	-	-0.46	[-0.67; -0.26] 83%
	>24 months	2	-		[-3.12; 1.95] 71%
	Dyslipidemia				
WC	<12 months	1		0.10	[-1.59; 1.79]
(cm)		2	=		[-2.97; 3.03] 0%
, ,	12-24 months	2	T	0.03	[-2.97, 3.03] 0%
	Multiple risk factors		19679		
	<12 months	11		-2.26	[-3.19; -1.33] 77%
	12-24 months	18	-	-1.83	[-2.63; -1.03] 85%
	>24 months	1	=	-0.54	[-1.07; -0.01]
	Hypertension				
	<12 months	1	-	-3.20	[-4.26; -2.14]
	12-24 months	3		-2.14	[-6.14; 1.85] 80%
	>24 months	1		-0.30	[-1.65; 1.05]
	All studies				
	<12 months	13			[-3.04; -1.29] 78%
	12-24 months	23	-		[-2.44; -1.06] 87%
	>24 months	2		-0.51	[-1.54; 0.53] 0%
Weight	Dyslipidemia				F 4 00 0 001 004
(kg)	<12 months	4			[-1.38; -0.38] 0%
(Ng)	12-24 months	6	-	-1.40	[-3.17; 0.38] 86%
	Multiple risk factors	2020	_		
	<12 months	16	<u> </u>		[-3.06; -1.33] 86%
	12-24 months	22			[-2.22; -0.90] 87%
	>24 months	5	-	-0.84	[-1.50; -0.17] 57%
	Hypertension				
	<12 months	10		-2.64	[-3.79; -1.50] 95%
	12-24 months	9	-		[-2.64; -1.01] 81%
	>24 months	3	-		[-3.40; 1.13] 85%
	All studies				
	<12 months	30	=		[-2.76; -1.60] 91%
	12-24 months	37	-		[-2.06; -1.13] 88%
	>24 months	8			[-1.54; -0.43] 78%
					erre in the state of the state
			-6 -4 -2 0 2 4 6		
			Favors IG Favors CG		

Abbreviations: BMI = body mass index; CI = confidence interval; cm = centimeters; Diff. = difference; IG = intervention group; $K = number of studies (including studies reported by subgroups); <math>kg = kilograms; kg/m^2 = kilograms per meter squared; WC = waist circumference$

Figure 16. ≥5% Reduction in Weight or BMI (KQ2)

Study	Population risk focus	Intervention focus	Contact time*	Timepoint (months)	IG n/N (%)	CG n/N (%)	≥	5% Weight or BMI Reduc	tion RR	95% CI
Appel, 2011	Multiple risk factors	HD + PA	High	24	55/133 (41.4)	24/128 (18.8)		-	2.20	[1.46; 3.33]
Bennett, 2012	Hypertension	HD + PA	High	24	36/180 (20.0)	36/185 (19.5)			1.03	[0.68; 1.56]
Bennett, 2018	Multiple risk factors	HD + PA	Medium	12	69/170 (40.6)	28/167 (16.8)		-	2.41	[1.63; 3.57]
Christian, 2011	Multiple risk factors	HD + PA	Medium	12	35/133 (26.3)	11/130 (8.5)		-	4.01	[0.50; 32.06]
Kandula, 2015	Multiple risk factors	HD + PA	High	6	6/31 (19.4)	3/32 (9.4)			2.05	[0.56; 7.49]
Kastarinen, 2002†	Hypertension	HD + PA	High	12	55/294 (18.7)	26/279 (9.3)		-	2.01	[1.31; 3.10]
Kramer, 2018	Multiple risk factors	HD + PA	High	6	45/81 (55.6)	4/43 (9.3)		-	5.99	[2.29; 15.65]
Scott, 2018	Multiple risk factors	PA only	Medium	6	3/17 (17.6)	0/18 (0.0)			7.39	[0.41; 134.39]
Svetkey, 2008	Multiple risk factors	HD + PA	High	30	144/341 (42.2)	116/341 (34.0)		+	1.25	[1.02; 1.52]
Wadden, 2011	Multiple risk factors	HD + PA	High	12	38/131 (29.0)	32/130 (24.6)			1.17	[0.78; 1.77]
Wood, 2008	Multiple risk factors	HD + PA	High	12	134/814 (16.5)	13/192 (6.8)		 	2.44	[1.41; 4.22]
Overall (REML + KH) Heterogeneity: $I^2 = 68\%$, $\tau^2 = 68\%$							0.01	0.1 1 10 Favors CG Favors IG	1.86	[1.33; 2.60]

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; Int arm = intervention arm; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Reflects ≥5% BMI reduction; all other studies reflect ≥5% weight reduction

Figure 17. Weight Subgroup Analyses (KQ2)

Subgroup	K	P*	Weight (kg)	Diff. in change†	95% CI I^2
Study quality Good Fair	17 33	0.60	+		[-2.10; -0.91] 79% [-2.25; -1.17] 89%
USA-based Yes No	23 27	0.01	-	-2.21 -1.21	[-2.78; -1.63] 76% [-1.71; -0.70] 87%
Age group General/younger adult focus Older adult focus	45 5	0.11	-		[-2.13; -1.26] 83% [-2.01; -0.02] 84%
100% overweight or obese Yes No NR	17 11 22	0.04		-1.03	[-3.05; -1.48] 80% [-1.70; -0.35] 91% [-2.09; -0.92] 77%
Weight loss approach Promoted for all participants Promoted for subset of participants Not promoted NR	16 15 7 12	0.03		-1.35 -1.11	[-3.28; -1.73] 86% [-1.97; -0.73] 73% [-2.27; 0.04] 89% [-2.00; -0.33] 65%
Contact time High (>360 min) Medium (31-360 min) Low (0-30 min)	26 22 2	0.00 -		-1.51	[-2.32; -1.25] 90% [-2.18; -0.85] 82% [-2.17; 1.24] 0%
Medication management Yes No	7 43	0.97 —	-		[-3.02; -0.29] 87% [-2.06; -1.20] 87%
Fat modified Yes No	11 39	0.66 —	-		[-2.96; -0.70] 84% [-2.02; -1.16] 88%
Socioeconomic status Low SES Average	8 42	0.29	-		[-2.21; -0.21] 71% [-2.16; -1.27] 89%
Overall (REML + KH) Heterogeneity: $I^2 = 88\%$, $\tau^2 = 1.48$, $p < 0.01$		-3	-2 -1 0 1 2 Favors IG Favors CG	-1.64	[-2.03; -1.24]

Abbreviations: CI = confidence interval; Diff. = difference; K = number of studies (including studies reported by subgroups); kg = kilograms; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SES = socioeconomic status

^{*}P-values derived from Q test of between-subgroups heterogeneity (based on random effects model)

[†]For this analysis, the most comprehensive or highest dose intervention group was selected if a study had multiple intervention groups, and the followup timepoint closest to 12 months was selected of there were multiple followup assessments

Figure 18. 10-Year CVD Risk and 10-Year CVD Mortality Risk (KQ2)

Study		Population risk focus	Intervention focus	Contact time*	•		IG mean change (SD)	CG N analyzed	CG mean change (SD)	CVD Risk & CVD Mortality Risk	Diff. in change	95% CI
10-year CVI	D risk											
Bruckert, 20	08	Dyslipidemia	HD + PA	Medium	6	274	-0.7 (8.4)	199	0.1 (8.0)		-0.72	[-4.42; 2.98]
Cochrane, 2	012	Multiple risk factors	HD + PA	Medium	12	236	-2.8 (6.2)	365	-3.1 (6.5)		0.30	[-0.72; 1.32]
Greaves, 20	15	Multiple risk factors	HD + PA	High	12	55	NR (NR)	51	NR (NR)	· · · · · · · ·	-0.76	[-2.19; 0.67]
Khanji, 2019)	Multiple risk factors	HD + PA	Low	6	194	-1.2 (8.9)	183	-1.4 (9.8)		0.14	[-0.92; 1.20]
Langford, 19	991†	Hypertension	HD + PA	High	6	235	0.9 (0.3)	229	1 (0.3)	•	-0.09	[-0.15; -0.03]
Nolan, 2018		Hypertension	HD + PA	High	12	100	-1.9 (7.1)	97	0.2 (7.3)		-2.10	[-4.12; -0.08]
Wister, 2007	7	Multiple risk factors	HD + PA	Medium	12	157	-3.1 (5.6)	158	-1.3 (5.6)	· 	-1.80	[-3.03; -0.57]
Overall (RE	ML + KH)										-0.49	[-1.32; 0.33]
Heterogeneity: I ²	2 = 53%, τ^2 = 0.41, p	= 0.05										
10-year CVI	D mortality ris	k										
Koelewijn-va	an Loon, 2009	Multiple risk factors	HD + PA	Medium	12	286	-0.5 (4.6)	261	-0.7 (5.9)		0.20	[-0.70; 1.10]
Lakerveld, 2	013	Multiple risk factors	HD + PA	Medium	12	314	0 (3.0)	308	-0.1 (4.0)	-	0.10	[-0.47; 0.67]
Ter Bogt, 20	009 (Females)	Multiple risk factors	HD + PA	High	12	103	0.1 (1.7)	114	0.5 (4.3)		-0.36	[-1.22; 0.50]
Ter Bogt, 20	009 (Males)	Multiple risk factors	HD + PA	High	12	98	-0.2 (2.8)	101	-0.1 (1.3)		-0.16	[-0.77; 0.45]
Tiessen, 201	12	Multiple risk factors	HD + PA	Medium	12	89	-1.8 (2.9)	90	-1.6 (2.9)		-0.20	[-1.04; 0.64]
Overall (RE	ML + KH)									•	-0.07	[-0.32; 0.19]
Heterogeneity: I ²	$r^2 = 0\%, \ \tau^2 = 0, \ \rho = 0$	86										
										-4 -2 0 2 4		

Favors IG Favors CG

Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; RR = risk ratio; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

^{†8-}year CVD risk

Table 2. Prevalence of Risk Factors Defined by the AHA's Life's Simple $7^{\star 12}$

Recommendations category	Category	Amount
	Fiber	28 g/day
Diotom/2	Vegetables	2.5 c-eq
	Fruits	2 c-eq
Dietary ²	Saturated fat	<20 g/day
	Sodium	<2,300 mg/day
	Potassium	4,700 mg/day
	Sedentary behavior	All adults should avoid inactivity. Some physical activity is better than none, and adults who participate in any amount of physical activity gain some health benefits.
Physical activity ⁹	Moderate-to-vigorous physical activity	≥150 minutes per week of moderate-intensity, or ≥75 minutes per week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity.
		≥2 days per week muscle-strengthening activities that involve all major muscle groups.

Abbreviations: c-eq = cup equivalents; g/day = grams per day; mg/day = milligrams per day

Table 2. Prevalence of Risk Factors Defined by the AHA's Life's Simple 7*12

Risk factor	Definition of Intermediate or Poor	Age 20-39 (%)	Age 40-59 (%)	Age ≥60 (%)
Smoking	Smoker or quit <12 months ago	25.0	23.0	13.5
Body mass index	BMI ≥25 kg/m ²	63.7	74.6	74.4
Physical activity	<150 mins/week moderate or <75 mins/week vigorous or equivalent combination of moderate and vigorous	55.0	65.8	73.3
Healthy diet score	<4–5 Diet goals met [†]	100	99.8	99.6
Total cholesterol	≥200 mg/dL or not reaching treatment goal	27.1	61.0	74.8
Blood pressure	SBP ≥120 mm Hg or DBP ≥80 mm Hg or not reaching treatment goal	38.3	65.9	74.8
Fasting plasma glucose	≥100 mg/dL or not reaching treatment goal	21.5	42.3	64.6

Abbreviations: BMI = body mass index; DBP = diastolic blood pressure; kg/m² = kilograms per meter squared; mg/dL = milligrams per deciliter; mins = minutes; mm Hg = millimeters of mercury; SBP = systolic blood pressure

^{*}Percentages represent those with intermediate or poor cardiovascular health

 $^{^{\}dagger}$ In the context of a healthy dietary pattern that is consistent with a Dietary Approaches to Stop Hypertension (DASH)—type eating pattern, with goals to: (1) consume \geq 4.5 cups/day of fruits and vegetables, (2) \geq 2 servings/wk of fish, and (3) \geq 3 servings/day of whole grains, (4) and no more than 36 ounces/week of sugar-sweetened beverages and (5) 1500 mg/day of sodium.

Table 3. Other Relevant Guidelines on Diet and Physical Activity for CVD Risk Reduction

	Recommendation(s)
Management of Blood Cholesterol	The AAFP refer to and affirm the ACC/AHA 2018 guideline on management of blood cholesterol ⁸ which recommends that a heart-healthy lifestyle should be emphasized for all individuals. Lifestyle therapy should be the primary intervention for metabolic syndrome.
$(2019)^{329}$	·
Cardiology/American Heart Association Guideline on the Primary Prevention	All adults should consume a diet emphasizing intake of vegetables, fruits, legumes, nuts, whole grains and fish; replacement of saturated fat with dietary monounsaturated and polyunsaturated fats; reduced amounts of cholesterol and sodium; minimized intake of processed meats, refined carbohydrates, and sweetened beverages; and intake of trans fats avoided.
	For adults with overweight and obesity, counseling and comprehensive lifestyle interventions, including caloric restriction are recommended for achieving and maintaining weight loss.
	Adults should be routinely counseled in healthcare visits to optimize a physically active lifestyle and should engage in at least 150 minutes per week of accumulated moderate-intensity or 75 minutes per week of vigorous-intensity aerobic physical activity (or an equivalent combination of moderate and vigorous activity). For adults unable to meet the minimum physical activity recommendations, engaging in some moderate- or vigorous-intensity physical activity, even if less than this recommended amount, can be beneficial. Decreasing sedentary behavior in adults may be reasonable to reduce ASCVD risk.
	In adults with elevated blood pressure (BP) or hypertension, including those requiring antihypertensive medications, nonpharmacological interventions are recommended to reduce BP. These include: • weight loss • a heart-healthy dietary pattern • sodium reduction • dietary potassium supplementation
	increased physical activity with a structured exercise program; and limited algebra.
Human Services Physical Activity Guidelines for Americans, 2 nd edition, 2018 ⁹	 limited alcohol For the general adult population: Adults should move more and sit less throughout the day. Some physical activity is better than none. Adults who sit less and do any amount of moderate-to-vigorous physical activity gain some health benefits. For substantial health benefits, adults should do at least 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes (2 hours and 30 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Preferably, aerobic activity should be spread throughout the week. Additional health benefits are gained by engaging in physical activity beyond the equivalent of 300 minutes (5 hours) of moderate-intensity physical activity a week. Adults should also do muscle-strengthening activities of moderate or greater intensity and that involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits PA in adults with chronic health conditions: When adults with chronic conditions or disabilities are not able to meet
	the above key guidelines, they should engage in regular physical activity according to their abilities and should avoid inactivity. •

Table 3. Other Relevant Guidelines on Diet and Physical Activity for CVD Risk Reduction

Organization Title (year)	Recommendation(s)
American Association of Clinical Endocrinologists and American College of Endocrinology	A comprehensive strategy to control lipid levels and address associated metabolic abnormalities and modifiable risk factors is recommended primarily using lifestyle changes and patient education with pharmacotherapy as needed to achieve evidence-based targets. A reasonable and feasible approach to
Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease, 2017 ⁵	fitness therapy (i.e., exercise programs that include at least 30 minutes of moderate-intensity physical activity [consuming 4-7 kcal/min] 4 to 6 times weekly, with an expenditure of at least 200 kcal/day) is recommended; suggested activities include brisk walking, riding a stationary bike, water aerobics, cleaning/scrubbing, mowing the lawn, and sporting activities. Daily physical activity goals can be met in a single session or in multiple sessions throughout the course of a day (10 minutes minimum per session); for some individuals, breaking activity up throughout the day may help improve adherence with physical activity programs. In addition to aerobic activity, muscle-strengthening activity is recommended at least 2 days a week. For adults, a reduced-calorie diet consisting of fruits and vegetables (combined ≥5 servings/day), grains (primarily whole grains), fish, and lean meats is recommended. For adults, the intake of saturated fats, transfats, and cholesterol should be limited, while LDLC-lowering macronutrient intake should include plant stanols/sterols (~2 g/day) and soluble fiber (10-25 g/day).
American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of	Patients with overweight or obesity and dyslipidemia (elevated triglycerides and reduced HDL-c) should be treated with lifestyle therapy to achieve 5 to 10% weight loss or more as needed to achieve therapeutic targets. The lifestyle intervention should include a physical activity program and a reduced-calorie healthy meal plan that minimizes sugars and refined carbohydrates, avoids
Patients with Obesity, 2017 ⁶	trans fats, limits alcohol use, and emphasizes fiber. Patients with overweight or obesity and elevated blood pressure or hypertension should be treated with lifestyle therapy to achieve 5 to 15% weight loss or more as necessary to achieve blood pressure reduction goals in a program that includes caloric restriction and regular physical activity.
Academy of Nutrition and Dietetics Hypertension evidence-based nutrition practice guideline, 2015 ³³⁰	Medical Nutrition Therapy (MNT) provided by a registered dietitian nutritionist (RDN) is recommended to reduce blood pressure (BP) in adults with hypertension (HTN). To reduce BP in adults with HTN, the RDN should provide MTN encounters at least monthly for the first year. After the first year, the RDN should schedule follow-up sessions at least two to three times per year to maintain reductions in BP. The RDN should counsel on a DASH dietary pattern plus reduced sodium intake for BP reduction in adults with HTN. The RDN should encourage adults with HTN to engage in regular aerobic activity to lower BP. Physical activity should be of moderate intensity to vigorous intensity three to four times per week for an average of 40 minutes per session.
Department of Veterans Affairs / Department of Defense VA/DoD Clinical Practice Guideline for the diagnosis and management of hypertension in the primary care	Offer lifestyle modification interventions for patients with prehypertension or hypertension based on patient indications and preferences as well as assessment of available local resources. Discuss healthy weight range and advising overweight or obese hypertensive patients to reduce their body mass index to below 25; if a normal body mass index (<25) cannot be achieved, advise patients that a weight reduction of at least 10 pounds can achieve a
setting, 2014 ³³¹	decrease in blood pressure. Target aerobic exercise at 30 to 45 minutes per session, at least four times per week and the use of a self-monitoring device
Update in Progress	(e.g., pedometer, mobile apps, etc.) to increase adherence to physical activity. Recommend a dietitian-led Dietary Approaches to Stop Hypertension (DASH) Diet for the treatment and/or prevention of hypertension for patients with hypertension and/or interested patients with prehypertension and other cardiovascular risk factors. In patients with additional cardiovascular risk factors, such as dyslipidemia, we suggest considering a dietitian-led Mediterranean Diet as an alternative to the DASH Diet. Recommend against the use of soy protein supplements for the treatment of hypertension. In patients with hypertension or prehypertension, sodium intake should be limited to no more than 2300 mg/day (100 mmol/day), with referral to a dietitian or other support as appropriate.

Table 3. Other Relevant Guidelines on Diet and Physical Activity for CVD Risk Reduction

Organization Title (year)	Recommendation(s)
	Advise hypertensive and prehypertensive patients to limit alcohol intake to no more than 1 oz per day for men or 0.5 oz of alcohol per day for women.
Department of Veterans Affairs / Department of Defense	Recommend all adults adopt healthy lifestyles to reduce CVD risk, including Therapeutic Lifestyle Changes (TLC) diet to optimize nutrition and optimal physical activity per the 2008 physical activity guidelines.
VA/DoD Clinical Practice Guideline	
for the management of dyslipidemia for cardiovascular risk reduction, 2014 ³³²	Suggest offering high-risk patients a dietitian-monitored Mediterranean diet supplemented with either extra-virgin olive oil or mixed nuts for the reduction of CVD events.
Update in Progress	Suggest that each patient's diet be individualized based on a nutrition assessment other CVD risk factors, other disease conditions, and lifestyle.
American Academy of Family Physicians	The AAFP refer to and endorse the AHA/ACC 2014 guideline on lifestyle management to reduce cardiovascular risk ³³³ which recommends the following:
Lifestyle Management to Reduce Cardiovascular Risk (2014) ⁷	Adults who would benefit from lowering of LDL-C and/or lowering of blood pressure should consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, non-tropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages and red meats. Adults who would benefit from lowering of LDL-C should reduce the percent of calories in their diet that come from saturated- and trans-fat, and should aim for a dietary pattern that achieves 5-6% of calories from saturated fat.
	Adults who would benefit from lowering of their blood pressure should lower their sodium intake, consuming no more than 2,400 mg of sodium per day. Further reduction of sodium to 1,500 mg/day is associated with an even greater reduction in blood pressure. Reducing intake of sodium by at least 1,000 mg/day will decrease blood pressure, even if the desired daily sodium intake is not achieved.
	Adults should engage in aerobic physical activity to reduce LDL-C and non-HDL-C and to lower blood pressure. This should include 3-4 sessions per week lasting an average of 40 minutes per session and involving moderate-to-vigorous intensity physical activity.

Table 4. Related USPSTF Behavioral Counseling Recommendations

Risk Factors	Normal Weight (BMI 18.5	Overweight (BMI 25 to <30)*‡	Obese (BMI ≥30) ^{*‡}
	to <25)*		
No hypertension,	Individualize the decision	Individualize the decision to	Provide or refer to intensive
dyslipidemia, or abnormal	to provide or refer to	provide or refer to behavioral	behavioral counseling ³³⁵
blood glucose levels	behavioral counseling ³³⁴	counseling ³³⁴	
Hypertension, dyslipidemia,			Provide or refer to intensive
or both	to provide or refer to	behavioral counseling ¹	behavioral counseling ^{1, 335}
	behavioral counseling ^{334†}	-	-
Abnormal blood glucose	Provide or refer to	Provide or refer to intensive	Provide or refer to intensive
levels or diabetes	intensive behavioral	behavioral counseling ^{1, 43}	behavioral counseling ^{1, 43, 335}
	counseling ⁴³		

Abbreviations: BMI = body mass index; USPSTF = US Preventive Services Task Force

^{*}BMI calculated as weight in kilograms divided by the square of height in meters.

[†]From the "Other Considerations" section of the referenced recommendation statement

[‡]The 2015 USPSTF recommendation also recommends screening for abnormal blood glucose levels as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or have obesity. Patients with certain risk factors (family history of diabetes, personal history of gestational diabetes or polycystic ovarian syndrome, or being a member of certain racial/ethnic groups [African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders]) may also be at increased risk of diabetes at a younger age or at a lower BMI and should be considered for earlier screening. ⁴³

Table 5. Summary of Study Characteristics of All Included Studies (94 Studies, n=52,174), Overall and by Risk Focus

	All stu	dies	Hyperte	ension	Dyslipio	lemia	Mixed Risk Factors	
Characteristics	No. studies	%	No. studies	%	No. studies	%	No. studies	%
All studies	94	100	32	100	16	100	46	100
Study design								
RCT	78	83.0	27	84.4	11	68.8	40	87.0
Cluster RCT	16	17.0	5	15.6	5	31.2	6	13.0
Good quality rating*	19	20.2	9	28.1	1	6.2	10	21.7
Conducted in the US	43	45.7	19	59.4	9	56.2	15	32.6
Recruitment setting								
Primary care	38	40.4	12	37.5	5	31.2	21	45.6
Other health care	20	21.3	3	9.4	5	31.2	12	26.1
Other (e.g., media, community settings, research center, epidemiologic surveys, etc.)	36	38.3	17	53.1	6	37.5	13	28.3
Risk group								
Hypertension	32	34.0						
Dyslipidemia	16	17.0						
Multiple risk factors	46	48.9						
Medication use restrictions								
Limited to those taking medications to manage risk factors	11	11.7	9	28.1	0	0	2	4.4
Excluded those taking medications to manage risk factors	21	22.3	9	28.1	10	62.5	2	4.4
No restrictions	62	66.0	14	43.8	6	37.5	42	91.3
Control Group								
No intervention/usual care	73	77.7	22	68.8	14	87.5	37	80.4
Minimal intervention	19	20.2	9	28.1	1	6.2	9	19.6
Attention control	2	2.1	1	3.1	1	6.2	0	0
Control group instructed to maintain typical habits	7	7.4	2	6.3	3	18.8	2	4.4
Median sample size (IQR), Range	314 (154 – 601)	24 – 7447	272 (197 – 762)	24– 2382	222 (133 – 420)	80 – 1197	342 (154 – 601)	37 – 7447
Median % followup at 12 months or closest (IQR), Range	86 (79 – 92)	63 – 100	88 (80– 92)	69– 100	88 (78– 96)	73 – 99	84 (78 – 91)	63 – 100

Abbreviations: IQR = Interquartile range; No. = Number; RCT = Randomized controlled trial; US = United States

^{*12} additional studies were rated as poor quality and excluded from the review

Table 6. Summary of Population Characteristics of All Included Studies (94 Studies), Overall and by Risk Factor Focus

	All stu-		Hyperter (k=32		Dyslipid (k=16		Mixed R Factors (I	
Baseline Characteristic (No. studies reporting)	Weighted Mean or Percent*	SD or k/K	Weighted Mean or Percent*	SD or k/K	Weighted Mean or Percent*	SD or k/K	Weighted Mean or Percent*	SD or k/K
Age; Mean (k=92)	56.0	8.3	52.9 (31)	7.9	57.6 (16)	8.5	57.3 (45)	8.0
% of trials restricted to older adults (minimum age ≥50)	11.7	11/94	15.6	5/32	6.2	1/16	10.9	5/46
Female; % (k=90)	49.5	20.5	45.1 (31)	18.0	57.2 (15)	23.6	50.6 (44)	20.7
Hypertension; % (k=61)	62.0	35.5	62.7 (30)	44.2	30.9 (8)	21.3	67.0 (23)	24.2
Systolic blood pressure; Mean (k=63)	138.6	10.3	135.5 (28)	10.3	115.0 (2)	2.8	140.8 (33)	9.5
Diastolic blood pressure; Mean (k=62)	83.8	5.3	85.6 (30)	5.5	76.0 (2)	1.4	82.3 (30)	4.4
Dyslipidemia; % (k=39)	70.3	23.7	32.2 (5)	10.8	100 (16)	0	65.9 (18)	17.3
Total cholesterol; Mean mg/dL (k=50)	217.4	21.4	218.7 (9)	16.7	254.5 (12)	20.2	210.7 (29)	14.5
Low-density lipoprotein; Mean mg/dL (k=39)	135.9	18.6	132.0 (4)	8.0	160.4 (10)	22.4	131.3 (25)	14.1
Diabetes; % (k=60)	20.2	18.5	13.1 (17)	16.1	7.5 (11)	6.7	25.3 (32)	18.8
Fasting blood glucose; Mean mg/dL (k=33)	110.0	12.0	105.3 (5)	9.4	115.7 (2)	8.2	110.0 (26)	12.3
Cardiovascular disease; % (k=51)	2.8	6.1	3.2 (18)	5.1	13.3 (10)	8.8	0.6 (23)	3.0
Current smokers; % (k=62)	22.7	17.6	17.5 (25)	17.0	17.7 (10)	7.1	26.6 (27)	18.0
BMI; Mean kg/m ² (k=77)	29.8	2.6	29.8 (26)	2.9	27.9 (11)	1.9	30.0 (40)	2.5
% of trials restricted to persons with excess weight	22.3	21/94	25.0%	8/32	0	0/16	28.3%	13/46
% of trials majority Hispanic or non-white ^{††}	37.2	16/43	36.8	7/19	22.2	2/9	46.7	7/15
% of trials targeted low socioeconomic status population§	20.2	19/94	25.0	8/32	25.0	4/16	17.4	8/46

Abbreviations: IQR = Interquartile range; k = number of trials with the stated characteristics; K = total number of trials in the analysis; SD = Standard deviation; US = United States

^{*}Mean or percent across all trials, weighted by number randomized in each trial; numbers in parentheses are the numbers of trials reporting on the pertinent characteristics

[†]Limited to trials conducted in the US (43 trials)

[‡]Assuming majority white, non-Hispanic if race and ethnicity were not reported

 $^{^{\$}}$ Described as targeting a low-resource community or any of the following (or equivalent): >20% unemployment, >30% combination of unemployed or disabled (among the working-age population), <70% high school graduates, >20% \leq 100% of federal poverty level, >30% in Medicaid, recruited from a Federally Qualified Healthcare Clinic

Table 7. Summary of Intervention Characteristics of All Included Studies (94 Studies, 120 Intervention Groups), Overall and by Risk Factor Focus

Characteristics	All studies (120 groups)		Hypertension (50 groups)		Dyslipidemia (20 groups)		Mixed Risk Factors (50 groups)	
	No.	%	No.	%	No.	%	No.	%
Behavioral target								
Diet and Physical Activity	81	67.5	33	66.0	6	30.0	42	84.0
Diet only	33	27.5	14	28.0	14	70.0	5	10.0
Physical Activity only	6	5.0	3	6.0	0	0	3	6.0
Contact time								
Low (0-30 minutes)	7	5.8	6	12.0	0	0	1	2.0
Medium (31-360 minutes)	59	49.2	18	36.0	17	85.0	24	48.0
High (>360 minutes)	54	45.0	26	52.0	3	15.0	25	50.0
Intervention directed at								
Patient (only)	115	95.8	47	94.0	19	95.0	49	98.0
Provider (only)	1	0.8	1	2.0	0	0	0	0
Both	4	3.3	2	4.0	1	5.0	1	2.0
Primary care clinician involvement								
Delivered all/most	8	6.7	2	4.0	3	15.0	3	6.0
Delivered part	19	15.8	7	14.0	2	10.0	10	20.0
No involvement	84	70.0	34	68.0	15	75.0	35	70.0
Not described	9	7.5	7	14.0	0	0	2	4.0
Type of sessions								
Individual session (only)	63	52.5	19	38.0	13	65.0	31	62.0
Group sessions (only)	9	7.5	5	10.0	1	5.0	3	6.0
Both individual and group	44	36.7	23	46.0	6	30.0	15	30.0
Tech or print-based (only)	4	3.3	3	6.0	0	0	1	2.0
Included family members	11	9.2	4	8.0	2	10.0	5	10.0
Motivational Interviewing	43	35.8	14	28.0	2	10.0	27	54.0
Dietary recommendation*								
General heart healthy, or not described	59	49.2	19	38.0	8	40.0	32	64.0
Low sodium	31	25.8	29	58.0	0	0	2	4.0
Fat modified	23	19.2	5	10.0	12	60.0	6	12.0
DASH	14	11.7	11	22.0	0	0	3	6.0
Mediterranean	5	4.2	0	0	0	0	5	10.0
DPP-based approach	5	4.2	0	0	0	0	5	10.0
Weight loss approach			-	_	_	-		3.3
Promoted for all	29	24.2	13	26.0	0	0	16	32.0
Promoted if excess weight	31	25.8	13	26.0	4	20.0	14	28.0
Not promoted	11	9.2	5	10.0	2	10.0	4	8.0
Not described	49	40.8	19	38.0	14	70.0	16	32.0
Equipment/Services								
Pedometer	22	18.3	7	14.0	0	0	15	30.0

Table 7. Summary of Intervention Characteristics of All Included Studies (94 Studies, 120 Intervention Groups), Overall and by Risk Factor Focus

Characteristics	All studies (120 groups)		Hypertension (50 groups)		Dyslipidemia (20 groups)		Mixed Risk Factors (50 groups)	
	No.	%	No.	%	No.	%	No.	%
Blood pressure monitor	7	5.8	5	10.0	0	0	2	4.0
Medication management	23	19.2	18	36.0	1	5.0	4	8.0
Intervention Contact	Median (IQR)	Range	Median (IQR)	Range	Median (IQR)	Range	Median (IQR)	Range
Intervention duration, months	12 (6–18)	1 day – 60 mo.	14 (6-24)	1 day-36 mo.	8.5 (6-12)	2-12	12 (6-24)	1 day – 60 mo.
Est. contact hours	6 (2.2- 15.8)	0-68	9.9 (3.2-28)	0-59	2.8 (1.8-4.2)	0.7-20	5.4 (2.1- 12.8)	0-68
Number of contacts [†]	12 (5-27)	0-73	18 (8-32)	0-60	6 (4-13)	2-28	9 (5-20)	0-73

Abbreviations: DASH = Dietary Approaches to Stop Hypertension; DPP = Diabetes Prevention Program; IQR = Interquartile range; SD = Standard deviation; US = United States

^{*}Interventions may advocate multiple diet approaches (e.g., low sodium and low fat)

[†]Contacts involving a live interventionist; excludes print, text message, technology-only contacts

Table 8. Daily and Weekly DASH and Mediterranean Eating Plan Goals for a 2,000-Calorie-a-Day Diet*

Food Group	DASH ³³⁶	Mediterranean ¹³¹		
	Servings	Servings		
Grains	6–8 per day	(not specified)		
Vegetables	4-5 per day	≥2 (≥1 fresh vegetables)		
Fruit	4-5 per day	≥2 to 3		
Low-fat or fat-free dairy products	2–3 per day	(not specified)		
Fats and oils	2–3 per day	Abundant use of olive oil for cooking and		
		dressing dishes; minimize food products		
		high in saturated fats		
Sodium	≤2,300 mg per day	(not specified)		
	(1,500 mg for even greater blood-			
	pressure lowering benefits)			
Alcohol		≤300 ml/day, primarily wine		
Meats, poultry, and fish	6 or less per week	≥3 of fish or seafood per week, use chicken		
		or rabbit rather than other red or processed		
		meats		
Nuts, seeds, dry beans, and peas	4–5 per week	≥3 of legumes per day		
		≥1 of nuts or seeds per day		
Sweets	5 or less per week	Minimize consumption of sweets and		
		simple carbohydrates		
Other		Cook at least twice per week with tomato,		
		garlic, and onion with other aromatic herbs;		
		dress vegetables, pasta, and rice with		
		tomato, garlic, and onion.		

Abbreviations: DASH = Dietary Approaches to Stop Hypertension; mg = milligrams; ml = milliliters

^{*}Adapted from https://www.nhlbi.nih.gov/health-topics/dash-eating-plan. This is the reduced-sodium version of the DASH diet plan; the initial DASH diet included 3,000 mg/day of sodium (and demonstrated efficacy in reducing blood pressure in the original DASH feeding study).

Table 9. Summary of Pooled Analyses of CVD Events

CVD Outcome	Pooled RR (95% CI)	N	No.	l ²	Tau ²
			Studies		
Stroke	0.52 (0.25, 1.10)	9,800	4	0	0.1
Myocardial Infarction	0.85 (0.70, 1.02)	10,375	6	0	0.0
CVD Events	0.80 (0.73, 0.87)	12,551	9	0	0.0
CVD Events sensitivity analysis:	0.79 (0.70, 0.90)	5,104	8	0	0.0
Dropping PREDIMED					

Abbreviations: CI = confidence interval; CVD = cardiovascular disease; No. = number; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RR = risk ratio

Table 10. PREDIMED CVD Events: Hazard Ratios and Number of CVD Events for Each Group Reported by the PREDIMED131 Study (n=7,447)

Outcome	Group	Intervention	Control	HR (95% CI)
		n/N (%)	n/N (%)	
Stroke	Both	81/4997 (1.6)	58/2450 (2.4)	0.58 (0.42 to 0.82)
Myocardial Infarction	Both	68/4997 (1.4)	38/2450 (1.6)	0.80 (0.53 to 1.21)
Incident PAD	Olive oil	18/2539 (0.7)	45/2444 (1.8)	0.36 (0.20 to 0.62)
Incident PAD	Nuts	26/2452 (1.1)	45/2444 (1.8)	0.52 (0.32 to 0.86)
Total CVD Events	Both	179/4997 (3.6)	109/2450 (4.4)	0.70 (0.55 to 0.89)

Abbreviations: CI = confidence interval; CVD = cardiovascular disease; HR = hazard ratio; PAD = peripheral artery disease

Table 11. Pooled Difference in Mean Change for Blood Pressure, Lipids, Glucose, and Adiposity-Related Outcomes at 12 to 24 Months' Followup

Outcome	Study population	Effect size (95% CI)*	K	N	P	Median (IQR)	Median (IQR)
	risk focus					change, IG	change, CG
SBP (mm Hg)	All available trials	-1.81 (-2.49, -1.13)	44	14580	37.3%	-5.1 (-7.6, -1.7)	-2.9 (-6.0, -0.2)
	Hypertension	-1.97 (-2.59, -1.36)	16	5769	7.8%	-5.8 (-8.6, -3.9)	-3.1 (-7.5, -1.8)
DBP (mm Hg)	All available trials	-1.16 (-1.57, -0.75)	40	13098	32.5%	-3.4 (-4.6, -0.7)	-1.6 (-3.7, -0.2)
	Hypertension	-1.06 (-1.75, -0.38)	15	5461	43.4%	-4.4 (-6.0, -2.2)	-3.2 (-5.0, -0.3)
TC (mg/dL)	All available trials	-3.48 (-5.57, -1.38)	38	11414	65.9%	-7.1 (-12.4, -2.3)	-4.4 (-6.6, 0)
	Dyslipidemia	-3.80 (-7.23, -0.37)	9	2001	24.0%	-8.8 (-15.8, -7.6)	-8.6 (-12.8, -5.0)
LDL-C (mg/dL)	All available trials	-2.14 (-4.08, -0.21)	32	8894	55.9%	-4.8 (-11.2, -1.5)	-3.9 (-7.7, 0.1)
	Dyslipidemia	-4.12 (-8.81, 0.57)	7	1271	36.3%	-11.0 (-19.6, -7.3)	-10.4 (-15.4, -4.6)
HDL-C (mg/dL)	All available trials	0.58 (0.19, 0.98)	34	8974	33.7%	0.8 (0.3, 2.6)	0.5 (0, 1.7)
	Dyslipidemia	-0.44 (-1.26, 0.37)	6	1033	0.0%	0.4 (0, 3.1)	1.0 (0.4, 2.7)
FBG (mg/dL)	All available trials	-2.33 (-3.64, -1.02)	22	5950	82.5%	-2.9 (-5.7, -0.4)	0.2 (-2.0, 3.6)
Weight (kg)	All available trials	-1.59 (-2.06, -1.12)	37	16345	88.1%	-1.5 (-2.8, -0.8)	-0.3 (-1.0, 0)
	Weight loss trials†	-2.55 (-3.40, -1.70)	12	3193	66.9%	-1.9 (-3.6, -1.2)	-0.6 (-1.1, 0)
BMI (kg/m²)	All available trials	-0.46 (-0.66, -0.26)	30	9909	83.3%	-0.5 (-0.9, -0.2)	-0.1 (-0.4, 0)
	Weight loss trials†	-0.91 (-1.43 to -0.40)	7	1520	78.0%	-1.0 (-1.6, -0.6)	-0.3 (-0.4, -0.2)
Waist	All available trials	-1.75 (-2.44, -1.06)	23	11708	87.3%	-2.2 (-3.7, -0.8)	-0.9 (-1.8, -0.2)
circumference (cm)	Weight loss trials†	-2.50 (-3.97 to -1.03)	8	1654	85.4%	-2.9 (-4.6, -1.4)	-1.2 (-2.3, -0.7)

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; DBP = diastolic blood pressure; FBG = fasting blood glucose; IG = intervention group; IQR = interquartile range; HDL-C = high-density lipoprotein cholesterol; K = number of effects analyzed; N = number of participants analyzed; kg = kilograms; kg/m² = kilograms per meter squared; LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; mm Hg = millimeters of mercury; TC = total cholesterol

^{*} Between-group mean difference in change unless otherwise specified

[†]Weight loss trials are those that required all participants to have a specified level of excess weight at baseline and had an explicit goal of weight loss for all participants.

Table 12. Pooled Results for Group Differences in the Proportion With Hypertension, Meeting Blood Pressure Goal, Diabetes, and Metabolic Syndrome, for All Trials Reporting Each Outcome

Outcome	RR (95% CI)	K	N	P	Median (IQR) percent, IG	Median (IQR) percent, CG	Median (IQR) Absolute risk difference
Hypertension incidence	0.74 (0.58, 0.94)	5	2707	12%	21.7 (8.0, 31.9)	21.1 (11.2, 39.2)	-5.3 (-6.4, -3.1)
Hypertension prevalence	0.98 (0.89, 1.08)	5	5633	56%	24.1 (18.2, 84.9	31.9 (26.1, 89.2)	-4.5 (-8.9, -0.6)
Meeting blood pressure goal	1.13 (1.04, 1.23)	13	6485	70%	64.9 (48.6, 79.4)	60.9 (43.0, 75.0)	5.0 (1.0, 8.1)
Diabetes incidence	0.82 (0.66, 1.03)	5	7848	0%	7.4 (6.9, 8.3)	8.8 (7.4, 16.3)	-1.6 (-5.5, -0.5)
Metabolic syndrome	0.78 (0.53, 1.16)	5	1847	85%	54.5 (44.3, 64.8)	63.0 (50.2, 68.6)	-2.8 (-22.6, -0.2)

Abbreviations: CG = control group; CI = confidence interval; cm = centimeters; IG = intervention group; IQR = interquartile range; K = number of effects analyzed; N = number of participants analyzed

Table 13. Results in Trials With Relatively Large Effects* Across Multiple Domains of Blood Pressure, Lipids, Fasting Glucose, or Weight

Outcome	Measure	Bennett, 2018 ¹⁴¹	Bo, 2007 ⁶⁵	Rodriguez-Cristobal, 2012 ⁹²	Wister, 2007 ¹⁰⁶	Wood, 2008 ¹⁰⁷
		18 phone, 3 PCP weight loss counseling sessions, 52 IVR calls (est 324 min)	1 individual, 4 group 60 min sessions, 3 mailings (est 300 min)	24 individual in-person and phone sessions (est 540 min)		Individual assessment, 8 group sessions (est 480 min)
SBP (mm Hg)	Mean difference in change (95% CI)	-0.9 (-4.9 to 3.1)	-6.8 (-10.6 to -3.0)	-6.8 (-10.7 to -2.8)	-3.9 (-7.4 to -0.4)	-4.8 (-10.2 to 0.6)
	IG mean change (SD)	-8.4 (20.3)	-2.0 (18.8)	-4.2 (17.2)	-7.5 (15.9)	-7.6 (NR)
	CG mean change (SD)	-7.5 (19.5)	4.8 (17.0)	2.2 (17.4)	-3.6 (16.0)	-2.8 (NR)
DBP (mm Hg)	Mean difference in change (95% CI)	-1.0 (-3.5 to 1.5)	-2.3 (-4.4 to -0.2)	-4.4 (-6.8 to -2.0)	NR	-2.7 (-5.9 to 0.6)
	IG mean change (SD)	-5.2 (12.6)	-2.6 (9.3)	-5.2 (10.2)	NR	-4.1 (NR)
	CG mean change (SD)	-4.2 (12.2)	-0.3 (10.0)	-1.3 (9.5)	NR	-1.6 (NR)
TC (mg/dL)	Mean difference in change (95% CI)	3.1 (-4.7 to 10.9)	-2.3 (-9.6 to 4.9)	-19.2 (-25.6 to -12.7)	-10.4 (-20.2 to -0.6)	-13.1 (-20.9 to -5.8)
	IG mean change (SD)	-3.5 (41.7)	0.0 (33.2)	-6.7 (24.2)	-15.8 (44.4)	-14.7 (NR)
	CG mean change (SD)	-6.6 (41.4)	2.3 (34.4)	14.2 (24.8)	-5.4 (44.4)	0.0 (NR)
LDL (mg/dL)	Mean difference in change (95% CI)	-3.2 (-10.5 to 4.1)	NR	1.9 (-6.0 to 9.9)	NR	-13.1 (-20.1 to -6.2)
	IG mean change (SD)	-5.0 (37.6)	NR	-3.5 (23.0)	NR	-15.8 (NR)
	CG mean change (SD)	-1.8 (38.0)	NR	-4.7 (25.2)	NR	-1.2 (NR)
HDL (mg/dL)	Mean difference in change (95% CI)	3.5 (1.1 to 5.9)	3.5 (2.2 to 4.7)	2.1 (-0.9 to 5.1)	0.4 (-1.2 to 2.0)	NR
	IG mean change (SD)	3.2 (12.6)	0.8 (5.4)	7.5 (8.0)	1.5 (7.3)	NR
	CG mean change (SD)	-0.3 (12.4)	-2.7 (6.2)	5.1 (7.7)	1.2 (7.3)	NR
FBG (mg/dL)	Mean difference in change (95% CI)	-8.1 (-17.1 to 0.9)	-5.9 (-8.4 to -3.5)	NR	-6.8 (-18.3 to 4.6)	-2.0 (-13.5 to 9.6)
	IG mean change (SD)	-4.9 (48.2)	-4.7 (11.9)	NR	-6.7 (55.3)	-8.3 (NR)
	CG mean change (SD)	3.2 (48.0)	1.3 (10.6)	NR	0.2 (48.5)	-5.1 (NR)
BMI (kg/m²)	Mean difference in change (95% CI)	-1.4 (-1.8 to -0.9)	-0.9 (-1.3 to -0.5)	-1.7 (-2.2 to -1.1)	-0.1 (-0.6 to 0.3)	-0.6 (-0.9 to -0.2)
	IG mean change (SD)	-1.4 (2.3)	-0.3 (1.8)	-0.7 (2.0)	-0.5 (2.0)	-0.5 (NR)
	CG mean change (SD)	0.0 (2.0)	0.6 (2.0)	1.3 (1.6)	-0.3 (1.8)	0.1 (NR)
Weight (kg)	Mean difference in change (95% CI)	-3.8 (-5.1 to -2.5)	-2.4 (-3.5 to -1.3)	NR	NR	-1.5 (-2.5 to -0.5)

Table 13. Results in Trials With Relatively Large Effects* Across Multiple Domains of Blood Pressure, Lipids, Fasting Glucose, or Weight

Outcome	Measure	Bennett, 2018 ¹⁴¹		Rodriguez-Cristobal, 2012 ⁹²	Wister, 2007 ¹⁰⁶	Wood, 2008 ¹⁰⁷
		18 phone, 3 PCP weight loss counseling sessions, 52 IVR calls (est 324 min)		and phone sessions (est	1	Individual assessment, 8 group sessions (est 480 min)
	IG mean change (SD)	-4.0 (6.3)	-0.7 (4.9)	NR	NR	NR
	CG mean change (SD)	-0.1 (5.9)	1.6 (5.2)	NR	NR	NR
WC (cm)	Mean difference in change (95% CI)	-3.6 (-5.0 to -2.1)	-4.5 (-5.8 to -3.2)	NR	-0.5 (-2.1 to 1.1)	-1.6 (-2.6 to -0.6)
	IG mean change (SD)	-2.9 (7.0)	-2.5 (5.2)	NR	-2.8 (7.0)	-1.7 (NR)
	CG mean change (SD)	0.6 (6.6)	2.0 (6.7)	NR	-2.3 (7.1)	-0.2 (NR)

Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; DBP = diastolic blood pressure; est = estimated; FBG = fasting blood glucose; HDL = high-density lipoprotein cholesterol; IG = intervention group; IVR = interactive voice recognition; kg = kilograms; kg/m² = kilograms per meter squared; LDL = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; min = minutes; mm Hg = millimeters of mercury; NR = not reported; PCP = primary care provider; SD = standard deviation; SBP = systolic blood pressure; TC = total cholesterol; WC = waist circumference

^{*}One of the 10 largest absolute effect sizes for the specified outcome, at 12 to 24 months' followup

Table 14. Pooled Difference in Mean Change for Dietary Fats, Fruit Vegetable, Urinary Sodium, and Physical Activity Outcomes at 12 to 24 Months' Followup

Outcome	Unit	Effect size (95% CI)*	K	N	P	Median (IQR) change, IG	Median (IQR) change, CG
Saturated fat	% of energy	-1.5 (-1.9, -1.1)	15	6229	72%	-1.9 (-3.0, -1.4)	-0.6 (-1.0, -0.1)
Saturated fat (Fat	% of energy	-1.5 (-2.3, -0.8)	8	3951	72%	-2.2 (-3.0, -1.6)	-0.5 (-1.0, -0.01)
modified diet							
interventions							
only)							
Polyunsaturated	% of energy	-0.4 (-1.0, 0.3)	7	2032	90%	-0.9 (-1.2, -0.1)	0 (-0.3, 0)
fat							
Monounsaturated	% of energy	-1.7 (-2.5, -0.9)	7	1827	83%	-2.0 (-2.1, -1.9)	-0.2 (-0.4, 0)
fat							
Fruits and	Servings/day	0.7 (0.1, 1.3)	11	4310	90%	0.5 (-0.01, 1.2)	0.1 (0, 0.3)
vegetables							
Fruits	Servings or pieces/day	0.2 (0.04, 0.3)	9	3698	71%	0.2 (0.1, 0.5)	0 (0, 0.1)
Vegetables	Standardized	0.1 (0.02, 0.2)	9	3555	50%	s/d: 0.5 (0, 0.8)	s/d: 0.3 (0.2, 0.3)
	mean difference					g/d: 11 (9, 16)	g/d: 2 (-3, 12)
Fiber	Grams/day	1.3 (0.1, 2.6)	5	1350	42%	1.7 (0, 3.0)	0.1 (-0.7, 0.2)
Urinary Sodium	mmol/L	-18.0 (-34.8 to -1.2)	9	3583	89%	-18.4 (-45.4, -5.3)	-6 (-10.0, -3.4)
Physical activity	Standardized	0.1 (-0.03 to 0.1)	30	19834	64%		
	mean difference						
Physical activity	Minutes/week	9.1 (-4.6 to 22.8)	13	10758	48%	44.4 (-2.5, 97.0)	31.2 (-13.0, 74.7)
Physical activity	MET-min/week	83 (-101 to 267)	7	5580	62%	130 (33, 289)	70 (-16, 112)
,	% Meeting PA goal	RR=1.22 (1.00, 1.50)	11	5887	91%	36.0 (28.1, 52.8) [†]	23.8 (22.9, 50.8)†

Abbreviations: CG = control group; CI = confidence interval; g/d = grams/day; IG = intervention group; IQR = interquartile range; K = number of studies; MET = metabolic equivalent; mmol/L = millimoles per liter; N = number of participants analyzed; PA = physical activity; RR = risk ratio; s/d = servings per day

^{*}Between-group mean difference in change unless otherwise specified

[†]Median (IQR) percent meeting physical activity goal

Table 14. Pooled Difference in Mean Change for Dietary Fats, Fruit Vegetable, Urinary Sodium, and Physical Activity Outcomes at 12 to 24 Months' Followup

Outcome	Current Review	Previous Review ⁴⁴	2017 Adult Obesity review* ⁴⁷ , 2011 Adult Obesity review ²⁹² , behavioral counseling interventions [†]
Mortality	17 trials, no clear benefit (Pooled RR NSD, mixed findings in 3 adequately powered trials)	3 trials, no benefit	4 trials, small number of deaths, no benefit
CVD events	12 trials, reduced MI, total events; pooled RRs (95% CI): Total: 0.80 (0.73 to 0.87), k=9 MI: 0.85 (0.70 to 1.02), k=6 Stroke: 0.52 (0.25 to 1.10), k=4	5 trials, no benefit, low event rates	2 trials in persons with prediabetes, no differences in CVD events.
Blood	Pooled MD (95% CI):	Pooled MD (95% CI):	Pooled MD (95% CI):
Pressure	SBP: -1.8 (-2.5 to -1.1), k=44 DBP: -1.2 (-1.6 to -0.8), k=40 HTN Incidence: 0.74 (0.58, 0.94), k=5	SBP: -2.0 (-2.9 to -1.2), k=48 DBP: -1.4 (-1.9 to -0.8), k=24 HTN Incidence: Not examined	SBP: -2.0 (-2.9 to -1.2), k=48
Lipids	Pooled MD (95% CI): TC: -3.5 (-5.6 to -1.4), k=38 LDL: -2.1 (-4.1 to -0.2), k=32 HDL: 0.6 (0.2, 1.0), k=34	Pooled MD (95% CI): TC: -4.5 (-6.4 to -2.6), k=34 LDL: -3.4 (-5.4 to -1.5), k=25 HDL: 0.7 (0.1, 1.3), k=19	Pooled MD (95% CI): LDL: -4.9 (-7.3 to -2.6), k=8
Glucose	Pooled MD (95% CI): FBG: -2.3 (-3.6 to -1.0), k=22 DM Incidence: 0.82 (0.66, 1.03), k=5 (4 trials)	Pooled MD (95% CI): FBG: -2.1 (-3.3 to -0.9), k=22 DM Incidence: 0.58 (0.37, 0.89), k=8	2 trials in persons with prediabetes, 30% to 50% reductions in diabetes incidence
Weight	Pooled MD (95% CI): BMI: -0.5 (-0.7 to -0.3), k=30 Weight: -1.6 (-2.1, -1.1), k=37 WC: -1.8 (-2.4, -1.1), k=23	Pooled MD (95% CI): Hedge's g (BMI or weight): -0.26 (-0.35 to -0.16), k=34	Pooled MD (95% CI), 12-18 months: BMI: -1.0 (-1.2 to -0.7), k=40 Weight: -2.4 (-2.9, -1.9), k=67 WC: -2.5 (-3.2, -1.9), k=41

Abbreviations: BMI = body mass index; CI = confidence interval; CVD = cardiovascular disease; DBP = diastolic blood pressure; DM = diabetes mellitus; FBG = fasting blood glucose; HTN = hypertension; HDL = high-density lipoprotein cholesterol; LDL = low-density lipoprotein cholesterol; MD = mean difference; MI = myocardial infarction; NSD = no statistically significant difference; RR = risk ratio; SBP = systolic blood pressure; TC = total cholesterol; WC = waist circumference

^{*}For mortality, CVD events, and weight outcomes

[†]For blood pressure, lipids, and glucose outcomes

Table 16. Behavioral Intervention Implementation Table: Summary and Examples of Included Interventions

Primary Population	overweight or with obesity (mean BMI=29.8)					
Primary Outcomes Measured	Cardiovascular events (stroke,	myocardial infarction, any CVD even	t); blood pressure; lipids; weight			
Study Findings	Intervention groups had fewer cardiovascular events at 1 to 16 years' followup (pooled RR=0.81 (0.74 to 0.88), with 10 trials reporting. At 12 to 24 months, the intervention groups showed greater reductions in blood pressure (SBP=-1.8 [-2.5 to -1.2] / DBP=-1.2 [-1.6 to -0.7] mm Hg), total cholesterol (-3.7 mg/dL [-5.9 to -1.5]), low-density lipoproteins (-2.3 mg/dL [-4.3 to -0.2]), BMI (-0.4 kg/m² [-0.7 to -0.2]), weight (-1.5 kg [-2.1 to -1.1]), and waist circumference (-1.6 [-2.3 to -0.9]).					
Behavior change goals and techniques	Designed to help participants improve dietary intake (e.g., reduce saturated fat; reduce sodium intake to below 1500-2300 mg/day; increase consumption of fruits, vegetable, whole grains, healthy fats, fish; reduce sweets and added sugar) and increase physical activity. Many interventions also had weight loss goals for all or some of the participants, some also offered smoking cessation support. Behavior change techniques included goal setting, active use of self-monitoring, and addressing barriers related to diet, physical activity, or weight change. Motivational interviewing commonly employed. A small number of trials in each category below included family members as well as the individual with CVD risk factors themselves.					
Duration of interventions	Typically 6 to 18 months					
Settings of Studies	Most took place in primary care	settings, 46% took place in the Unit	ed States.			
To Whom is Intervention Targeted?	Adults with hypertension, prehy overweight or with obesity (mea		nultiple cardiovascular disease risk fact	ors; most participants were		
INTERVENTION TYPE	Group-based counseling with individual support, broadly targeted intervention	Individual-based support only, broadly targeted intervention	Hypertension prevention or management	Dyslipidemia management		
Mode and intensity of delivery	for each session, typically with an additional single individual meeting for each person. Number of sessions typically ranged from 20-30 over 24 months (~16-36 contact hours) for weight loss interventions and 5-12 sessions over 4-12 months (~6-13 contact hours)	support. Some also used web- based programs or other technology-enhanced components. Number of sessions typically ranged from 2-32 over 9-24 months (~1-7 contact hours) for weight loss interventions and 4-17 sessions	only seeing participants individually. Number of sessions typically ranged from 28-53 over 18-36 months (~28-42 contact hours) for hypertension prevention interventions and 5-24	Number of sessions typically ranged from 4-12 over 6-12 months (~2-4 contact hours), most commonly delivered during individual face-to-face sessions. Typically recommended limiting overall fat intake or limiting saturated fat intake.		

Table 16. Behavioral Intervention Implementation Table: Summary and Examples of Included Interventions

Example	General: Bo 2007; RIS	General: Hardcastle 2008;	Prevention: TOHP I & II (TOHP I	DEER (Stefanick 1998) [†]
interventions*			CRG, 1992 & TOHP II CRG, 1997)†;	,
	EUROACTION (Wood 2008)	Rodriguez-Cristobol 2012; SPRING	Management: ADAPT (Burke 2006);	
	Weight loss: POWER Hopkins	(Tiessen 2012); Wister 2008	Hyman 2007 [†]	
		Weight loss: GOAL (Ter Bogt 2009)		
	2018) [†]	,		
	,			
Materials Provided	Track:	PREDIMED:	TOHP II:	‡
for Practice	https://www.ncbi.nlm.nih.gov/p	https://www.nejm.org/doi/suppl/10.1	https://www.ncbi.nlm.nih.gov/pubmed/	
(Materials for	mc/articles/PMC4885789/	056/NEJMoa1800389/suppl_file/nej	7795834 (study protocol)	
specific cited	(study protocol)	moa1800389_appendix.pdf (pages		
programs)		20-24, study protocol)		
Evidence of effect	Larger weight loss effects were	evident in weight loss trials. No patte	ern of effects was based on intensity of	f the intervention, duration of the
modification	intervention, whether there as in	n-person support, whether individual	in-person or telephone sessions were	offered, whether medication
	management was offered, or wl	nether blood pressure monitors or pe	edometers were provided.	
Comparison group	Typically usual care consisting	of brief messages from the primary of	care provider.	
Interventionist and	Many trials used Registered Die	eticians as interventionists, but other	common providers were health educate	tors, nurses, lifestyle coaches,
Training Required	psychologists or psychology gra	aduate students, and exercise physic	ologists. Brief (60-90 minute) training w	as typically provided to primary
			y of the intervention (22% of trials inclu	
	staff), and 2- to 5-day intensive	training sessions were typically requ	ired for other front-line interventionists	, as well as regular check-ins or
	supervised sessions to ensure t	idelity to intervention protocol.		
Reported adherence	Relatively high adherence with	most studies reporting more than two	o-thirds of the intervention participants	at least half of the intervention
to	sessions. Participation rates de	clined over time, especially as interv	ention intensity lessened.	
Intervention				
All '4' ADADT	A .: '. D' . 1D1 1D	TO I DEED D' LE ' C I	There is a District COAL Consider Constitution Constitution	' 1. II'C . I DDEDIMED

Abbreviations: ADAPT = Activity, Diet, and Blood Pressure Trial; DEER = Diet and Exercise for Elevated Risk; GOAL = Groningen Overweight and Lifestyle; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RIS = Risk Factor Intervention Study; TOHP I = Trials of Hypertension Phase 1; TOHP II = Trials of Hypertension Phase 2

^{*}Primarily focused on trials that had one of the top 10 largest absolute effect sizes across 2 more of the four intermediate outcome domains of blood pressure, lipids, fasting glucose, and weight.

[†]Study conducted in US

DEER intervention materials not provided, based on out-of-date guidance

Table 17. Association Between Changes in Intermediate Outcomes and Mortality Outcomes, Based on Individual Patient Data Meta-Analysis of Epidemiological Studies

Intermediate Outcome	Original Increment Difference	HR (95% CI) for Health Outcome for Original Increment Change in Intermediate Outcome	Converted Increment Difference	Age, years	Mortality Outco	meHR (95% CI) for Health Outcome for Converted Increment Change in Intermediate Outcome
SBP ³⁰⁵ *	↓20 mm Hg	0.49 (0.45 to 0.53)	↓2 mm Hg	40-49	IHD	0.93 (0.92 to 0.94)
	↓20 mm Hg	0.54 (0.53 to 0.55)	↓2 mm Hg	60-69	IHD	0.94 (0.94 to 0.94)
	↓20 mm Hg	0.36 (0.32 to 0.40)	↓2 mm Hg	40-49	Stroke	0.90 (0.89 to 0.91)
	↓20 mm Hg	0.43 (0.41 to 0.45)	↓2 mm Hg	60-69	Stroke	0.92 (0.91 to 0.92)
	↑14 mm Hg ³³⁷ ABPM	1.58 (1.55 to 1.60)	↓2 mm Hg	58.4#	CVD	0.94 (0.93 to 0.94)
	↑19 mm Hg ³³⁷ clinic- based	1.54 (1.52 to 1.56)	↓2 mm Hg	58.4#	CVD	0.96 (0.95 to 0.96)
Non-HDL-C306†	↓1 mmol/L	0.57 (0.52 to 0.62)	↓3 mg/dL	40-59	IHD	0.96 (0.95 to 0.96)
	↓1 mmol/L	0.66 (0.61 to 0.71)	↓3 mg/dL	60-69	IHD	0.97 (0.96 to 0.97)
「C ^{306§}	↓1 mmol/L	0.44 (0.42 to 0.48)	↓3 mg/dL	40-49	IHD	0.94 (0.93 to 0.94)
	↓1 mmol/L	0.72 (0.69 to 0.74)	↓3 mg/dL	60-69	IHD	0.97 (0.97 to 0.98)
C306II	↓1 mmol/L	0.90 (0.84 to 0.97)	↓3 mg/dL	40-59	Stroke	0.99 (0.99 to 1.00)
	↓1 mmol/L	1.02 (0.97 to 1.08)	↓3 mg/dL	60-69	Stroke	1.00 (1.00 to 1.01)
BG ^{309, 310¶}	↑1 mmol/L	1.12 (1.08 to 1.15)	↓2 mg/dL	56 [#]	F+NF CHD	0.99 (0.98 to 0.99)
	↑18.02 mg/dL	1.13 (1.11 to 1.15)	↓2 mg/dL	53 [#]	Vascular	0.99 (0.98 to 0.99)
	18.02 mg/dL	1.10 (1.09 to 1.11)	↓2 mg/dL	53#	All-cause	0.99 (0.99 to 0.99)
BMI ³⁰⁷ **	↑5 kg/m²	1.50 (1.39 to 1.62)	↓0.4 kg/m ²	35-59	IHD	0.97 (0.96 to 0.97)
	↑5 kg/m²	1.40 (1.32 to 1.49)	↓0.4 kg/m²	60-69	IHD	0.97 (0.97 to 0.98)
	↑5 kg/m²	1.76 (1.52 to 2.04)	↓0.4 kg/m²	35-59	Stroke	0.94 (0.94 to 0.97)
	↑5 kg/m²	1.49 (1.34 to 1.67)	↓0.4 kg/m ²	60-69	Stroke	0.97 (0.96 to 0.98)

Abbreviations: BMI = body mass index; CHD = coronary heart disease; CI = confidence interval; dL = deciliter; F+NF = fatal plus nonfatal; FBG = fasting blood glucose; HDL-C = high-density lipoprotein cholesterol; Hg = mercury; HR = hazard ratio; IHD = ischemic heart disease; kg = kilogram(s); m = meter(s); mg = milligram(s); mm = millimeter(s); mmol = millimole(s); NS = not significant; SBP = systolic blood pressure; TC = total cholesterol.

^{*}For SBPs above 115 mm Hg. Adjusted for age (within range being considered), sex, and study. Adjustments for lipids, diabetes, weight, alcohol, and smoking did not change results

[†]Adjusted for age (within range being considered), sex, and study. Formal test for heterogeneity NS for sex (significant for age)

[‡]Directionality inverted from negative to positive

[§]Adjusted for age (within range being considered), sex, and study. Result slightly attenuated by adjustment for SBP and unaltered by adjustment for smoking. Formal test for heterogeneity NS for sex for age <69 years; formal test for heterogeneity significant for age

Adjusted for age (within range being considered), sex, and study. Result attenuated with adjustment for SBP and minimal increase in HR with further adjustment for smoking for 40-59-year group only

For FBG above 100 mg/dL and assuming log-linear association. Adjusted for age, smoking, BMI, SBP

[#]Mean age

^{**}For BMI above 25 kg/m². Adjusted for sex and smoking

Table 18. Summary of Evidence

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
KQ1	CVD events: 12 RCTs (15,107)	trials of medium or high-contact interventions and pooled	, ,	few trials had sufficient power and		CVD events: Most trials conducted in the US, however, the largest trial
	Mortality: 18 RCTs (18,146)	total CVD events (pooled	CVD events: Reasonably consistent,	length of followup for mortality and CVD events; trial		providing the strongest evidence was conducted in Spain. Most participants
	Subjective well- being: 11 RCTs (5684)	statistically non-significant associations with myocardial			for small to no benefit	across all trials were middle aged and older adults who were predominantly white and
			Imprecise	allocation, however extensive sensitivity analyses showed limited impact on results.	Subjective well-	not socioeconomically disadvantaged.
KQ2	Continuous clinical measures: 89 RCTs (46,354)		Reasonably consistent, Reasonably precise	Hypertension prevalence, diabetes and metabolic syndrome		Substantial number of trials conducted in the US and in conducted in or recruited from primary
	Hypertension incidence: 5 RCTs (2707)	total and LDL cholesterol, fasting glucose, and adiposity-related outcomes at 12 to 24 months' followup. Hypertension incidence		were reported in very few trials, raising concerns about reporting bias		care. Most participants across all trials were middle aged and older adults who were
	Diabetes incidence: 4 RCTs (6701)	was lower with interventions designed to prevention hypertension in those who did		, 1 7 9 144		predominantly white and not socioeconomically disadvantaged.
	Metabolic syndrome: 5 RCTs (3103)	not have it already (pooled RR=0.74 [95% CI 0.58 to 0.94]; 5 RCTs, [n=2707]; I ² =12%). No				

Table 18. Summary of Evidence

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
		intervention factors were clearly associated with effect size, but among trials with the largest effects across multiple domains, most offered more than 6 hours of intervention contact and offered group as well as individual contact. Selected Pooled MDs were as follows: SBP= -1.8 (95% CI -2.5 to -1.1), k=44 DBP= -1.2 (95% CI -1.6 to -0.8), k=40 TC= -3.5 (95% CI -5.6 to -1.4), k=38 LDL= -2.1 (95% CI -4.1 to -0.2), k=32 FBG=-2.3 (95% CI -3.6 to -1.0), k=22 BMI=-0.5 (95% CI -0.7 to -0.2), k=30 Evidence primarily in medium and high-contact interventions.				
KQ3	70 RCTs (43,243)	Interventions were associated with small reductions in saturated fat and small increases in fruit, vegetable, and fiber consumption. For example, fruit	Diet: Reasonably consistent, imprecise Physical activity: inconsistent, imprecise	with substantial variability in measures used,	benefit Physical activity: Low for no benefit	Substantial number of trials conducted in the US and in conducted in or recruited from primary care. Most participants across all trials were middle aged and older adults who were predominantly white and not socioeconomically disadvantaged.

Table 18. Summary of Evidence

Key Question	No. of Studies (No. of observations) Study Designs	Summary of Findings	Consistency and Precision	Other Limitations	Strength of Evidence	Applicability
		were counseled to reduce sodium consumption showed greater reductions in urinary sodium (pooled MD=-18.0 [95% CI -34.8 to -1.2]; 9 RCTs [n=3583]; I ² =89%). Findings were mixed for physical activity. Most trials included medium or high-contact interventions.				
KQ4	20 RCTs (18,263)		, г	Sparsely reported, ascertainment typically not described.	Low for no harms	Substantial number of trials conducted in the US and in conducted in or recruited from primary care. Most participants across all trials were middle aged and older adults who were predominantly white and not socioeconomically disadvantaged.

Abbreviations: BMI = body mass index; CI = confidence interval; CVD = cardiovascular disease; DBP = diastolic blood pressure; FBG = fasting blood glucose; k = number of studies analyzed; KQ = key question; LDL = low-density lipoprotein cholesterol; MD = mean difference; No. = number; RCT = randomized controlled trial; RR = risk ratio; SBP = systolic blood pressure; TC = total cholesterol

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Kev:
/ = MeSH subject heading
$ = truncation
* = truncation
? = wildcard
ab = word in abstract
adj\# = adjacent\ within\ x\ number\ of\ words
bt = book title
fs= floating subheading
hw = subject heading word
id =key phrase identifier
kf= keyword heading [word not phrase indexed]
kw = keyword
md = methodology
near/\# = adjacent\ within\ x\ number\ of\ words
pt = publication type
ti = word in title
```

Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

```
#1
       diet:ti
#2
       diets:ti
#3
       dietary:ti
#4
        (fruit* or vegetable*):ti
#5
        exercis*:ti
#6
        walking:ti
#7
        "physical activity":ti,ab,kw
#8
       pedometer*:ti,ab,kw
#9
       fitbit*:ti,ab,kw
        "steps per":ti,ab,kw
#10
#11
       distance walked:ti,ab,kw
       (measuring next step*):ti,ab,kw
#12
#13
       (step next count*):ti,ab,kw
#14
        (activity or fitness):ti,ab,kw near/1 track*:ti,ab,kw
        sedentary:ti,ab,kw next (lifestyle* or (life next style*) or behavior* or behaviour* or
#15
time):ti,ab,kw
#16
       (sitting or lying):ti,ab,kw near/2 time:ti,ab,kw
        "screen time":ti,ab,kw
#17
#18
       (television or tv):ti,ab,kw next viewing:ti,ab,kw
#19
       (watch* or view*):ti,ab,kw next (television or tv):ti,ab,kw
       (computer or internet):ti,ab,kw next (time or use or usage):ti,ab,kw
#20
#21
        (computer or video):ti,ab,kw next game*:ti,ab,kw
#22
        (screen or screen-based):ti,ab,kw next (entertainment or behavior* or behaviour* or use or
usage):ti,ab,kw
       (low next energy next expenditure*):ti,ab,kw
#23
#24
       (physical* next inactiv*):ti,ab,kw
#25
       {or #15-#24}
       (reduce* or reduction* or decrease* or change* or target*):ti,ab
#26
       #25 and #26
#27
#28
        {or #1-#14, #27}
```

#29 counsel*:ti,ab,kw #30 (advice or advise or consultation*):ti,ab,kw #31 Behavio*:ti,ab,kw near/2 (therap* or chang* or modification* or improv*):ti,ab,kw #32 referral*:ti,ab,kw #33 (set* near/2 goal*):ti,ab,kw #34 (action next plan*):ti,ab,kw #35 (self next monitor*):ti,ab,kw #36 "follow up feedback":ti,ab,kw #37 (assessment near/5 feedback):ti,ab,kw #38 "support planning":ti,ab,kw #39 "risk factor management":ti,ab,kw #40 "life style":ti,ab,kw #41 lifestyle:ti,ab,kw #42 motivation*:ti,ab,kw #43 health:ti,ab,kw next (coach* or behavio* or education):ti,ab,kw #44 (education* next program*):ti,ab,kw #45 "patient education":ti,ab,kw #46 "health promotion":ti,ab,kw promot*:ti,ab,kw near/3 (exercise or physical activit* or weight loss):ti,ab,kw #47 #48 (nonpharmacologic or "non pharmacologic"):ti,ab,kw next intervention*:ti,ab,kw #49 intervention*:ti #50 {or #29-#49} #51 (cardiovascular or cardiometabolic):ti #52 #28 and (#50 or #51) (lifestyle near/2 intervention*):ti,ab,kw or ("life style" near/2 intervention*):ti,ab,kw or ((health* #53 next lifestyle) or (health* next "life style")):ti,ab,kw #54 (cardiovascular or cardiometabolic or coronary or heart):ti,ab,kw #55 (insulin or glucose or diabet*):ti,ab,kw #56 (lipoprotein* or lipid* or triglyceride* or hyperlipidemia* or cholesterol):ti,ab,kw #57 (bmi or body mass index or body weight):ti,ab,kw #58 (hypertension or "blood pressure"):ti,ab,kw #59 {or #54-#58} #53 and #59 #60 #52 or #60 Publication Year from 2016 to 2018 #61

Ovid Medline, Ovid MEDLINE In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily Update

Diet, Reducing/
 Caloric Restriction/
 Diet, Fat-Restricted/
 Diet, Mediterranean/
 Diet, Sodium-Restricted/
 Diet, Carbohydrate-Restricted/
 Diet, Carbohydrate Loading/
 Diet, High-Protein Low-Carbohydrate/
 Diet, Ketogenic/
 Diet, Gluten-Free/
 Diet, High-Protein/

- 13 Diet, High-Protein Low-Carbohydrate/
- 14 Diet, Paleolithic/
- 15 Diet, Protein-Restricted/
- 16 Diet, Vegetarian/
- 17 Diet, Macrobiotic/
- 18 Diet, Vegan/
- 19 Fruit/
- 20 Vegetables/
- 21 Functional food/
- 22 Feeding behavior/
- 23 Healthy diet/
- 24 Healthy lifestyle/
- 25 Weight Reduction Programs/
- 26 Exercise/
- 27 physical conditioning, human/
- 28 circuit-based exercise/
- 29 high-intensity interval training/
- 30 plyometric exercise/
- 31 resistance training/
- 32 running/
- 33 jogging/
- 34 swimming/
- 35 walking/
- 36 stair climbing/
- 37 Fitness trackers/
- 38 Accelerometry/
- 39 Actigraphy/
- 40 Exercise Therapy/
- 41 Physical Fitness/
- 42 (diet or diets or dietary).ti,bt,kf.
- 43 (fruit* or vegetable*).ti,bt,kf.
- 44 (exercise or physical activity).ti,bt,kf.
- 45 walking.ti,bt,kf.
- 46 pedometer*.ti,ab,kf.
- 47 fitbit*.ti,ab,kf.
- 48 steps per.ti,ab,kf.
- 49 distance walked.ti,ab,kf.
- 50 measuring step*.ti,ab,kf.
- 51 step count*.ti,ab,kf.
- 52 ((activity or fitness) adj1 track*).ti,ab,kf.
- 53 Sedentary lifestyle/
- 54 (sedentary adj (lifestyle* or life style* or behavio* or time)).ti,ab,kf.
- 55 ((sitting or lying) adj2 time).ti,ab,kf.
- 56 Screen time.ti,ab,kf.
- 57 ((television or TV) adj viewing).ti,ab,kf.
- 58 ((watch* or view*) adj (television or TV)).ti,ab,kf.
- 59 ((computer or internet) adj (time or "use" or usage)).ti,ab,kf.
- 60 ((computer or video) adj game*).ti,ab,kf.
- 61 ((screen or screen based) adj (entertainment or behavio* or "use" or usage)).ti,ab,kf.
- 62 low energy expenditure*.ti,ab,kf.
- 63 physical* inactiv*.ti,ab,kf.

64 or/54-63 65 (reduce* or reduction* or decrease* or change* or target*).ti,ab. 66 64 and 65 67 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 66 68 Counseling/ 69 Directive Counseling/ 70 "Behavior-Therapy"/ 71 Cognitive Therapy/ 72 "Referral and Consultation"/ 73 Persuasive Communication/ 74 Social Control, Informal/ 75 Risk Reduction Behavior/ 76 Life Style/ 77 Healthy aging/ 78 Motivation/ 79 Social Support/ 80 Feedback, Psychological/ 81 Self Efficacy/ 82 Health Knowledge, Attitudes, Practice/ 83 Health Behavior/ 84 Health Education/ 85 Health Promotion/ 86 Patient Education as Topic/ 87 counsel*.ti,ab,kf. 88 (advice or advise or consultation*).ti,ab,kf. 89 (behavio* adj2 (therap* or chang* or modification* or improv*)).ti,ab,kf. 90 referral*.ti,ab,kf. 91 (set* adj2 goal*).ti,ab,kf. 92 action plan*.ti,ab,kf. 93 self monitor*.ti,ab,kf. 94 follow-up feedback.ti,ab,kf. 95 (assessment adj5 feedback).ti,ab,kf. 96 support planning.ti,ab,kf. 97 risk factor management.ti,ab,kf. 98 (life style or lifestyle).ti,ab,kf. 99 motivation*.ti,ab,kf. 100 health coach*.ti,ab,kf. 101 health behavio*.ti,ab,kf. 102 health education.ti,ab,kf. 103 education* program*.ti,ab,kf. 104 patient education.ti,ab,kf. 105 health promotion.ti,ab,kf. 106 (promot* adj3 (exercise or physical activit* or weight loss)).ti,ab,kf. 107 nonpharmacologic intervention*.ti,ab,kf. 108 non pharmacologic intervention*.ti,ab,kf. 109 intervention*.ti,bt.

110 or/68-109

- 111 (cardiovascular or cardiometabolic).ti,bt.
- 112 67 and (110 or 111)
- 113 Healthy lifestyle/ or Healthy diet/
- 114 ((lifestyle adj2 intervention*) or (life style adj2 intervention*) or health* lifestyle or health* life style).ti,ab,kf.
- 115 113 or 114
- 116 (cardiovascular or coronary or cardiometabolic or heart).ti,ab,kf,hw.
- 117 (insulin or glucose or diabet*).ti,ab,kf,hw.
- 118 (lipoprotein* or lipid* or triglyceride* or hyperlipidemia* or cholesterol).ti,ab,kf,hw.
- 119 (bmi or body mass index or body weight).ti,ab,kf,hw.
- 120 (hypertension or blood pressure).ti,ab,kf,hw.
- 121 or/116-120
- 122 115 and 121
- 123 112 or 122
- 124 limit 123 to "all child (0 to 18 years)"
- 125 limit 123 to "all adult (19 plus years)"
- 126 124 not 125
- 127 123 not 126
- 128 Animals/ not (Humans/ and Animals/)
- 129 127 not 128
- 130 (clinical trial or controlled clinical trial or randomized controlled trial or adaptive clinical trial or equivalence

clinical trial or pragmatic clinical trial or meta analysis).pt.

131 clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or adaptive

clinical trials as topic/ or equivalence clinical trials as topic/ or pragmatic clinical trials as topic/

- 132 Meta-Analysis as Topic/
- 133 Random allocation/
- 134 clinical trial*.ti,ab,kf.
- 135 (control* adj3 (study or studies or trial*)).ti,ab,kf.
- 136 random*.ti,ab,kf.
- 137 trial.ti.
- 138 or/130-137
- 139 129 and 138
- 140 (harm or harms or harmful or harmed).ti,ab,kf.
- 141 (risky behavior* or risky behaviour*).ti,ab,kf.
- 142 (adverse effects or mortality).fs.
- 143 Mortality/
- 144 Morbidity/
- 145 death/
- 146 Athletic injuries/
- 147 Malnutrition/
- 148 nutritional defici*.ti,ab,kf.
- 149 (death or deaths).ti,ab,kf.
- 150 fracture*.ti,ab,hw.
- 151 or/140-150
- 152 129 and 151
- 153 observational study/ or clinical study/ or case-control studies/ or cohort studies/ or longitudinal studies/ or

follow-up studies/or prospective studies/

154 case control*.ti,ab,kf.

- 155 cohort.ti,ab,kf.
- 156 longitudinal.ti,ab,kf.
- 157 (follow-up or followup).ti,ab,kf.
- 158 prospective*.ti,ab,kf.
- 159 (comparison group* or control group*).ti,ab,kf.
- 160 observational.ti,ab,kf.
- 161 retrospective studies/
- 162 retrospective*.ti,ab,kf.
- 163 database*.ti,ab,kf.
- 164 nonrandomi*.ti,ab,kf.
- 165 population.ti,ab.
- 166 or/153-165
- 167 152 and 166
- 168 139 or 167
- 169 limit 168 to (english language and yr="2016 -Current")

PsycInfo

- 1 Diets/
- 2 Dietary Restraint/
- 3 Eating Behavior/
- 4 fruit*.ti,ab,id.
- 5 vegetable*.ti,ab,id.
- 6 (diet or diets or dietary).ti,ab,id.
- 7 Exercise/
- 8 Physical Activity/
- 9 Aerobic Exercise/
- 10 Walking/
- 11 (exercise or physical activity).ti,ab,id.
- 12 walking.ti,ab,id.
- 13 (pedometer* or fitbit* or steps per or distance walked or measuring step* or step count*).ti,ab,id.
- 14 ((activity or fitness) adj1 track*).ti,ab,id.
- 15 Activity Level/
- 16 Sedentary behavior/
- 17 (sedentary adj (lifestyle* or life style* or behavio* or time)).ti,ab,id.
- 18 ((sitting or lying) adj2 time).ti,ab,id.
- 19 Screen time/
- 20 Television/
- 21 Television Viewing/
- 22 Computers/
- 23 Computer Games/
- 24 Role Playing Games/
- 25 Simulation Games/
- 26 screen time.ti,ab,id.
- 27 ((television or TV) adj viewing).ti,ab,id.
- 28 ((watch* or view*) adj (television or TV)).ti,ab,id.
- 29 ((computer or internet) adj (time or "use" or usage)).ti,ab,id.
- 30 ((computer or video) adj game*).ti,ab,id.
- 31 ((screen or screen based) adj (entertainment or behavio* or "use" or usage)).ti,ab,id.
- 32 low energy expenditure*.ti,ab,id.
- 33 physical* inactiv*.ti,ab,id.

- 34 or/1-33
- 35 behavior therapy/
- 36 cognitive behavior therapy/
- 37 cognitive therapy/
- 38 Cognitive Techniques/
- 39 Behavior Modification/
- 40 Behavior Change/
- 41 Lifestyle Changes/
- 42 Lifestyle/
- 43 Persuasive Communication/
- 44 Motivation/
- 45 Motivational Interviewing/
- 46 Self Efficacy/
- 47 Health Knowledge/
- 48 Health Behavior/
- 49 Health Education/
- 50 Health Promotion/
- 51 Client Education/
- 52 counseling/
- 53 counsel*.ti,ab,id,hw.
- 54 (advice or advise or consultation*).ti,ab,id,hw.
- 55 (behavio* adj2 (therap* or chang* or modification* or improv*)).ti,ab,id.
- 56 referral*.ti,ab,id.
- 57 (set* adj2 goal*).ti,ab,id.
- 58 action plan*.ti,ab,id.
- 59 self monitor*.ti,ab,id.
- 60 follow-up feedback.ti,ab,id.
- 61 (assessment adj5 feedback).ti,ab,id.
- 62 support planning.ti,ab,id.
- 63 risk factor management.ti,ab,id.
- 64 (life style or lifestyle).ti,ab,id.
- 65 motivation*.ti,ab,id.
- 66 (health adj (coach* or behavio* or education)).ti,ab,id.
- 67 education* program*.ti,ab,id.
- 68 patient education.ti,ab,id.
- 69 health promotion.ti,ab,id.
- 70 (promot* adj3 (exercise or physical activit* or weight loss)).ti,ab,id.
- 71 nonpharmacologic intervention*.ti,ab,id.
- 72 non pharmacologic intervention*.ti,ab,id.
- 73 intervention.ti.
- 74 or/35-73
- 75 (cardiovascular or cardiometabolic).ti.
- 76 34 and (74 or 75)
- 77 ((lifestyle adj2 intervention*) or (life style adj2 intervention*) or health* lifestyle or health* life style).ti,ab,id.
- 78 (cardiovascular or coronary or cardiometabolic or heart).ti,ab,id.
- 79 (insulin or glucose or diabet*).ti,ab,id.
- 80 (lipoprotein* or lipid* or triglyceride* or hyperlipidemia* or cholesterol).ti,ab,id.
- 81 (bmi or body mass index or body weight).ti,ab,id.
- 82 (hypertension or blood pressure).ti,ab,id.
- 83 or/78-82

84 77 and 83 85 76 or 84 86 (control* adj3 (study or studies or trial*)).ti,ab,id,hw. 87 clinical trial*.ti,ab,id,hw. 88 random*.ti.ab.id.hw. 89 trial.ti. 90 (treatment outcome or clinical trial).md. 91 or/86-89 92 85 and 91 93 (harm or harms or harmful or harmed).ti,ab,id,hw. 94 (risky behavior* or risky behaviour*).ti,ab,id,hw. 95 adverse effect*.ti,ab,id,hw. 96 mortality.ti,ab,id,hw. 97 morbidity.ti,ab,id,hw. 98 death.ti,ab,id,hw. 99 nutritional defici*.ti,ab,id,hw. 100 fracture*.ti,ab,id,hw. 101 or/93-100 102 85 and 101 103 case control*.ti,ab,id,hw. 104 cohort.ti,ab,id,hw. 105 longitudinal.ti,ab,id,hw. 106 (follow-up or followup).ti,ab,id,hw. 107 prospective*.ti,ab,id,hw. 108 (comparison group* or control group*).ti,ab,id,hw. 109 observational.ti,ab,id,hw. 110 retrospective*.ti,ab,id,hw. 111 database*.ti,ab,id,hw. 112 nonrandomi*.ti,ab,id,hw. 113 population*.ti,ab,id,hw. 114 or/103-113 115 102 and 114 116 92 or 115 117 limit 116 to (100 childhood
 birth to age 12 yrs> or 120 neonatal
 birth to age 1 mo> or 140 *infancy* <2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>) 118 limit 116 to ("300 adulthood <age 18 yrs and older>" or 320 young adulthood <age 18 to 29 yrs> or 340 thirties <age 30 to 39 yrs> or 360 middle age <age 40 to 64 yrs> or "380 aged <age 65 yrs and older>" or "390 very old <age 85 yrs and older>") 119 117 not 118 120 116 not 119 121 limit 120 to animal 122 limit 120 to human 123 121 not 122 124 120 not 123

125 limit 124 to (english language and yr="2016 -Current")

	Include	Exclude
Condition	The current review will target populations at	Increased risk of cardiovascular disease solely
definition	increased risk of cardiovascular disease due to hypertension or elevated blood pressure, dyslipidemia, or through examination of	due to prediabetes (trials in this population will be included in a concurrent review of screening for abnormal blood glucose and type 2 diabetes mellitus).
Populations	Adults age >18 with known hypertension or elevated blood pressure, dyslipidemia, the metabolic syndrome, or with 10-year CVD risk of 7.5% or greater based on a CVD risk assessment tool, or trial inclusion criteria specifies that population has one or more CVD risk factors	 Trials limited to or predominantly: Children and adolescents Parents (if intended behavior change is directed towards children) Persons with prediabetes Persons with known CVD or diabetes mellitus such that >50% of participants have known CVD, severe chronic kidney disease, or diabetes (including gestational diabetes) Persons with medical conditions limiting their generalizability to primary care-based populations of persons with CVD risk factors (e.g., acute illness, cognitive impairment, severe and persistent mental illness, cancer, chronic pain) Institutionalized persons
Settings	 Conducted in or recruited from primary care or a health care system or could feasibly be implemented in or referred from primary care. Trials in countries rated as "very high" on the UN Human Development Index (based on 2015 indicators): Andorra, Argentina, Australia, Austria, Bahrain, Belgium, Brunei Darussalam, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russia, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, 	Settings not generalizable to primary care (e.g., inpatient hospital units, emergency departments, nursing home and other institutionalized settings, school classroom- based programs, occupational settings,

	Include	Exclude
	United Arab Emirates, United Kingdom,	
	United States	
Interventions	le a action is the contract of	 incentives, supervised exercise with the goal of assessing effects of exercise); Interventions providing controlled diets; counseling interventions aimed at diabetes prevention, falls prevention, depression, cognitive functioning, or disease prevention other than CVD Prenatal or post-natal dietary counseling; Counseling interventions with components that are not feasible for implementation in healthcare settings, e.g., occupational/worksite, church, or school-based interventions that are conducted within existing social networks; social marketing (e.g., media campaigns); or policy (e.g., local or state public/health policy); Stress management interventions (e.g., meditation; yoga or tai chi-based interventions that have minimal aerobic or strength-building activities) Dietary counseling solely focused on increasing specific vitamins, micronutrients or anti-oxidants through dietary change or supplementation or on alcohol moderation.

	Include	Exclude
Comparisons	 No intervention (e.g., wait-list, usual care) Minimal intervention (e.g., pamphlets, links to general information web sources, in-person counseling of no more than an estimated 60 minutes annually, presenting information similar to what individuals can receive through usual care in a primary care setting, but without personalized prescription based on standardized assessment) Attention control (e.g., similar format and intensity intervention on a different content area) 	 Comparative-effectiveness trials without a control (as defined in inclusion column) PA only: studies in which the control group is instructed not to exercise
Outcomes	 KQ1: Health outcomes Cardiovascular events and related morbidity (e.g., stroke, myocardial infarction, heart failure, heart failure) Cardiovascular and all-cause mortality Quality of life measures and related outcomes (e.g., functioning, well-being) KQ2: Intermediate outcomes Blood pressure TC, LDL and HDL cholesterol Hba1c, fasting glucose, 1- and 2-hr glucose tolerance BMI, weight, waist circumference Dichotomized versions of CVD risk factors (hypertension, dyslipidemia, diabetes, overweight or obesity, incidence of metabolic syndrome) Calculated 10-year CVD risk Cardiorespiratory fitness (e.g., VO2max, heart rate, exercise tolerance, 6 minute walk) KQ 3: Behavioral outcomes Dietary intake or patterns Physical activity Sedentary behavior KQ4: Adverse outcomes Harms requiring medical attention (e.g., nutritional deficiencies, musculoskeletal 	 Initiation or withdrawal of medication Knowledge, attitudes, self-efficacy, Mental health symptom scores Balance, flexibility Less than 6 months Less than 60% followup
Timing of outcome	injuries, cardiovascular events) ≥6 months post-baseline	<6 months post-baseline
assessment		

	Include	Exclude
Study Designs	 Fair to good quality studies KQ1, 2, 3: RCT, CCT (Prior to 2001: RCTs only) KQ4: systematic reviews, RCT, CCT, comparative cohort, population-based case-control studies 	 Poor quality studies KQ1, 2: any observational studies KQ3: ecological studies, case-series, case reports
Publication Date	Trials published from 1990 to present	• Trials whose primary results were published prior to 1990

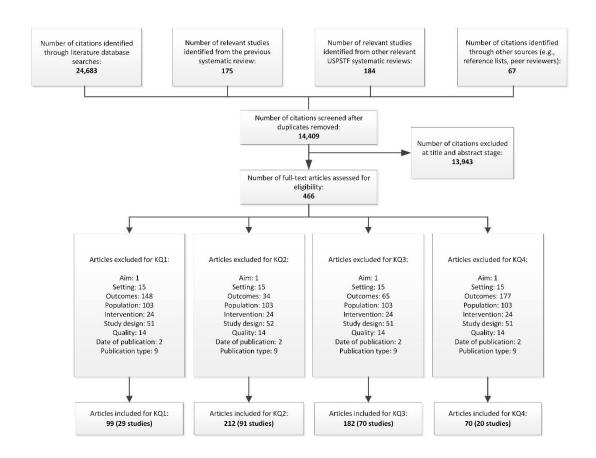
Abbreviations: CCT = controlled clinical trial; CVD = cardiovascular disease; HDL = high-density lipoprotein; HTN = hypertension; KQ = key question; LDL = low-density lipoprotein; RCT = randomized, controlled trial; TC = total cholesterol; USPSTF = United States Preventive Services Task Force

Study Design	Adapted Quality Criteria
	Bias arising in the randomization process or due to confounding
	• Valid random assignment/random sequence generation method used
U.S. Preventive	Allocation concealed
	Balance in baseline characteristics
Manual ¹	Bulance in Suscimo characterístics
	Bias in selecting participants into the study
	• CCT only: No evidence of biased selection of sample
	Bias due to departures from intended interventions
	• Fidelity to the intervention protocol
	• Low risk of contamination between groups
	Participants were analyzed as originally allocated
	Bias from missing data
	• No, or minimal, post-randomization exclusions
	• Outcome data are reasonably complete and comparable between groups
	• Reasons for missing data are similar across groups
	Missing data are unlikely to bias results
	Bias in measurement of outcomes
	Blinding of outcome assessors
	 Outcomes are measured using consistent and appropriate procedures and
	instruments across treatment groups
	No evidence of biased use of inferential statistics
	The evidence of blused use of inferential statistics
	Bias in reporting results selectively
	• No evidence that the measures, analyses, or subgroup analyses are selectively
	reported
Cohort studies,	Bias arising in randomization process or due to confounding
adapted from	Balance in baseline characteristics
Newcastle-Ottawa	No baseline confounding
Scale ²	No time-varying confounding
	Bias in selecting participants into the study
	• No evidence of biased selection of sample
	Start of followup and start of intervention coincide
	Discolus de descriptions from index de la linde constitue
	Bias due to departures form intended interventions Destinant intervention status is clearly and available defined and massayed
	• Participant intervention status is clearly and explicitly defined and measured
	• Classification of intervention status is unaffected by knowledge of the outcome or risk of the outcome
	TISK OF the outcome
	Bias in classifying interventions
	• Fidelity to intervention protocol
	Participants were analyzed as originally allocated
	Bias from missing data
	Outcome data are reasonably complete and comparable between groups
	• Confounding variables that are controlled for in analysis are reasonably complete
	• Reasons for missing data are similar across groups

Study Design	Adapted Quality Criteria
	Missing data are unlikely to bias results
	Bias in measurement of outcomes
	Blinding of outcome assessors
	 Outcomes are measured using consistent and appropriate procedures and
	instruments across treatment groups
	No evidence of biased use of inferential statistics
	Bias in reporting results selectively
	No evidence that the measures, analyses, or subgroup analyses are selectively
	reported

^{*} All randomized clinical trials were classified as good, fair, or poor according to the USPSTF Procedure Manual¹

Appendix B. Literature Flow Diagram



Below is a list of included studies and their ancillary publications (indented below main results publication):

- 1. Ammerman AS, Keyserling TC, Atwood JR, et al. A randomized controlled trial of a public health nurse directed treatment program for rural patients with high blood cholesterol. Prev Med. 2003;36(3):340-51. PMID: 12634025.
 - a. Keyserling TC, Ammerman AS, Atwood JR, et al. A cholesterol intervention program for public health nurses in the rural southeast: description of the intervention, study design, and baseline results. Public Health Nurs. 1999;16(3):156-67. PMID: 10388332. http://dx.doi.org/10.1046/j.1525-1446.1999.00156.x
- 2. Anderson JW, Garrity TF, Wood CL, et al. Prospective, randomized, controlled comparison of the effects of low-fat and low-fat plus high-fiber diets on serum lipid concentrations. Am J Clin Nutr. 1992;56(5):887-94. PMID: 1329482.
- 3. Anderssen SA, Haaland A, Hjerman I, et al.. Oslo diet and exercise study: a one year randomized intervention trial. Efect on Haemostatic variables and other coronary risk factors. Nutr Metab Cardiovasc Dis. 1995;5:189-200. PMID: 8339552. http://dx.doi.org/10.1016/0197-2456(93)90005-X
 - a. Anderssen SA, Carroll S, Urdal P, et al. Combined diet and exercise intervention reverses the metabolic syndrome in middle-aged males: results from the Oslo Diet and Exercise Study. Scand J Med Sci Sports. 2007;17(6):687-95. PMID: 17331082. http://dx.doi.org/10.1111/j.1600-0838.2006.00631.x
 - b. Anderssen SA, Hjermann I, Urdal P, et al. Improved carbohydrate metabolism after physical training and dietary intervention in individuals with the "atherothrombogenic syndrome'. Oslo Diet and Exercise Study (ODES). A randomized trial. J Intern Med. 1996;240(4):203-9. PMID: None. http://dx.doi.org/10.1046/j.1365-2796.1996.22848000.x
 - c. Anderssen S, Holme I, Urdal P, et al. Diet and exercise intervention have favourable effects on blood pressure in mild hypertensives: the Oslo Diet and Exercise Study (ODES). Blood Press. 1995;4(6):343-9. PMID: None. http://dx.doi.org/10.1111/j.1365-2796.1994.tb00858.x
 - d. Jacobs DR, Jr., Sluik D, Rokling-Andersen MH, et al. Association of 1-y changes in diet pattern with cardiovascular disease risk factors and adipokines: results from the 1-y randomized Oslo Diet and Exercise Study. Am J Clin Nutr. 2009;89(2):509-17. PMID: 19116328. http://dx.doi.org/10.3945/ajcn.2008.26371
 - e. Odes Investigators. The Oslo Diet and Exercise Study (ODES): design and objectives. Control Clin Trials. 1993;14(3):229-43. PMID: 8339552. http://dx.doi.org/10.1016/0197-2456(93)90005-X
 - f. Reseland JE, Anderssen SA, Solvoll K, et al. Effect of long-term changes in diet and exercise on plasma leptin concentrations. Am J Clin Nutr. 2001;73(2):240-5. PMID: 11157319. http://dx.doi.org/10.1093/ajcn/73.2.240\
 - g. Torjesen PA, Birkeland KI, Anderssen SA, et al. Lifestyle changes may reverse development of the insulin resistance syndrome. The Oslo Diet and Exercise Study: a randomized trial. Diabetes Care. 1997;20(1):26-31. PMID: 9028689.
- 4. Appel L, Clark J, Yeh H, et al. Comparative effectiveness of weight-loss interventions in clinical practice. N Engl J Med. 2011;365(21):1959-68. PMID: 22085317. http://dx.doi.org/10.1056/NEJMoa1108660
 - a. Jerome GJ, Dalcin A, Coughlin JW, et al. Longitudinal accuracy of web-based self-reported weights: results from the Hopkins POWER Trial. J Med Internet Res. 2014;16(7):e173. PMID: 25042773. http://dx.doi.org/10.2196/jmir.3332
 - b. Rubin RR, Peyrot M, Wang NY, et al. Patient-reported outcomes in the practice-based opportunities for weight reduction (POWER) trial. Qual Life Res. 2013;22(9):2389-98. PMID: 23515902. http://dx.doi.org/10.1007/s11136-013-0363-3

- 5. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. JAMA. 2003;289(16):2083-93. PMID: 12709466. http://dx.doi.org/10.1001/jama.289.16.2083
 - a. Crist LA, Champagne CM, Corsino L, et al. Influence of change in aerobic fitness and weight on prevalence of metabolic syndrome. Prev Chronic Dis. 2012;9:E68. PMID: 22405475. http://dx.doi.org/10.5888/pcd9.110171
 - b. Elmer PJ, Obarzanek E, Vollmer WM, et al. Effects of comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control: 18-month results of a randomized trial. Ann Intern Med. 2006;144(7):485-95. PMID: 16585662. http://dx.doi.org/10.7326/ACPJC-2006-145-2-042
 - c. Funk KL, Elmer PJ, Stevens VJ, et al. PREMIER--a trial of lifestyle interventions for blood pressure control: intervention design and rationale. Health Promot Pract. 2008;9(3):271-80. PMID: 16803935. http://dx.doi.org/10.1177/1524839906289035
 - d. Lien LF, Brown AJ, Ard JD, et al. Effects of PREMIER lifestyle modifications on participants with and without the metabolic syndrome. Hypertension. 2007;50(4):609-16. PMID: 17698724. http://dx.doi.org/10.1161/HYPERTENSIONAHA.107.089458
 - e. Lin PH, Appel LJ, Funk K, et al. The PREMIER intervention helps participants follow the Dietary Approaches to Stop Hypertension dietary pattern and the current Dietary Reference Intakes recommendations. J Am Diet Assoc. 2007;107(9):1541-51. PMID: 17761231. http://dx.doi.org/10.1016/j.jada.2007.06.019
 - f. Maruthur NM, Wang NY, Appel LJ. Lifestyle interventions reduce coronary heart disease risk: results from the PREMIER Trial. Circulation. 2009;119(15):2026-31. PMID: 19349322. http://dx.doi.org/10.1161/CIRCULATIONAHA.108.809491
 - g. Svetkey LP, Erlinger TP, Vollmer WM, et al. Effect of lifestyle modifications on blood pressure by race, sex, hypertension status, and age. J Hum Hypertens. 2005;19(1):21-31. PMID: 15385946. http://dx.doi.org/10.1038/sj.jhh.1001770
 - h. Young DR, Coughlin J, Jerome GJ, et al. Effects of the PREMIER interventions on health-related quality of life. Ann Behav Med. 2010;40(3):302-12. PMID: 20799005. http://dx.doi.org/10.1007/s12160-010-9220-6
 - i. Young DR, Vollmer WM, King AC, et al. Can individuals meet multiple physical activity and dietary behavior goals? Am J Health Behav. 2009;33(3):277-86. PMID: 19063649. http://dx.doi.org/10.5993/AJHB.33.3.6
- 6. Applegate WB, Miller ST, Elam JT, et al. Nonpharmacologic intervention to reduce blood pressure in older patients with mild hypertension. Arch Intern Med. 1992;152(6):1162-6. PMID: 1599343. http://dx.doi.org/10.1001/archinte.1992.00400180034005
- 7. Arroll B, Beaglehole R. Salt restriction and physical activity in treated hypertensives. N Z Med J. 1995;108(1003):266-8. PMID: 7637923.
- 8. Babazono A, Kame C, Ishihara R, et al. Patient-motivated prevention of lifestyle-related disease in Japan: A randomized, controlled clinical trial. Dis Manage Health Outcomes. 2007;15(2):119-26. PMID: None. http://dx.doi.org/10.2165/00115677-200715020-00007
- 9. Beckmann SL, Os I, Kjeldsen SE, et al. Effect of dietary counselling on blood pressure and arterial plasma catecholamines in primary hypertension. Am J Hypertens. 1995;8(7):704-11. PMID: 7546496.
- 10. Bennett GG, Steinberg D, Askew S, et al. Effectiveness of an App and Provider Counseling for Obesity Treatment in Primary Care. Am J Prev Med. 2018. PMID: 30361140. http://dx.doi.org/10.1016/j.amepre.2018.07.005
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- b. Steinberg D, Kay M, Burroughs J, et al. The Effect of a Digital Behavioral Weight Loss Intervention on Adherence to the Dietary Approaches to Stop Hypertension (DASH) Dietary Pattern in Medically Vulnerable Primary Care Patients: Results from a Randomized Controlled Trial. J Acad Nutr Diet. 2019;119(4):574-84. PMID: 30905430. http://dx.doi.org/10.1016/j.jand.2018.12.011
- 11. Bennett GG, Warner ET, Glasgow RE, et al. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. Arch Intern Med. 2012;172(7):565-74. PMID: 22412073 http://dx.doi.org/10.1001/archinternmed.2012.1
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 - a. Haafkens JA, Beune EJ, Moll van Charante EP, et al. A cluster-randomized controlled trial evaluating the effect of culturally-appropriate hypertension education among Afro-Surinamese and Ghanaian patients in Dutch general practice: study protocol. BMC Health Serv Res. 2009;9:193. PMID: 19849857. http://dx.doi.org/10.1186/1472-6963-9-193
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 - b. Blackford K, Jancey J, Lee AH, et al. A randomised controlled trial of a physical activity and nutrition program targeting middle-aged adults at risk of metabolic syndrome in a disadvantaged rural community. BMC Public Health. 2015;15:284. PMID: 25885657. http://dx.doi.org/10.1186/s12889-015-1613-9
 - c. Blackford K, Lee A, James AP, et al. Process evaluation of the Albany Physical Activity and Nutrition (APAN) program, a home-based intervention for metabolic syndrome and associated chronic disease risk in rural Australian adults. Health Promot J Austr. 2017;28(1):8-14. PMID: 27426475. http://dx.doi.org/10.1071/HE16027
- 14. Bloemberg BP, Kromhout D, Goddijn HE, et al. The impact of the Guidelines for a Healthy Diet of The Netherlands Nutrition Council on total and high density lipoprotein cholesterol in hypercholesterolemic free-living men. Am J Epidemiol. 1991;134(1):39-48. PMID: 1853859.
- 15. Bo S, Ciccone G, Baldi C, et al. Effectiveness of a lifestyle intervention on metabolic syndrome. A randomized controlled trial. J Gen Intern Med. 2007;22(12):1695-703. PMID: 17922167. http://dx.doi.org/10.1007/s11606-007-0399-6
 - a. Ponzo V, Gentile L, Gambino R, et al. Incidence of diabetes mellitus, cardiovascular outcomes and mortality after a 12-month lifestyle intervention: A 9-year follow-up. Diabetes Metab. 2018;44(5):449-51. PMID: 29773350. http://dx.doi.org/10.1016/j.diabet.2018.04.008
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Exclusion Code and Definition*

E1. Study relevance

E1c. Not CVD focused

E2. Setting

E2a. Not a "very high" development country

E2b. Not generalizable to primary care

E3. Population

E3a. Symptomatic, \geq 50% with CHD or DM

E3b. Participants not selected for CVD high-risk criteria

E3c. Other (e.g., children, pregnant, etc.)

E3d. \geq 50% with pre-DM

E4. Outcomes: No relevant outcomes

E5. Intervention: Not an included intervention

E5a. Yoga or tai chi

E5b. Supervised PA too extensive

E5c. Food provision too extensive

E6. Study design

E6a. Not a trial

E6b. Less than 6 months followup

E6c. Comparative effectiveness

E6d. Control group told not to change diet or PA

E7. Study quality

E7a. High or differential attrition

E8. Main outcomes published prior to 1990

E9 Publication not in English

E9a. Publication type (e.g., conference abstract)

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Building on the methods used in the recent USPSTF of lifestyle counseling in adults without CVD risk factors,³ we looked for new observational evidence to support the association between effects of the size seen in the included studies and health outcomes, and updated this evidence where it was available. However, it is always worth noting that observational evidence may overestimate the benefits of behavior change, due to the inherent difficulty in controlling for confounding factors in non-randomized studies. Biases in observational results may be even more pronounced when long-term adherence to drug or behavioral change is assumed in order to maintain benefits. Some have noted that this concern is particularly important for applying effects of observational evidence to preventive interventions in primary care settings.⁴ Moreover, observational evidence does not reflect changes in intermediate or behavioral outcomes based on counseling interventions.

Blood Pressure

Overall, we found that behavioral counseling was associated with a greater decrease in SBP/DBP by 1.9/1.2 mm Hg after 12 to 24 months follow-up compared to individuals in control groups, which was typically usual care. In trials that were limited to persons with hypertension or prehypertension, there was an average greater reduction of 2.0/1.1 mm Hg SBP/DBP, compared to control participants. Median reductions in SBP/DBP were 5.1/3.4 mm Hg in the intervention groups and 2.9/1.6 mm Hg in the control groups for all included trials at 12-24 months, from a mean baseline SBP/DBP of 139/84 mm Hg.

Blood pressure declines of this magnitude have been associated with decreased risk of CVD-related mortality in epidemiologic literature. ^{5,6} An IPD meta-analysis of 61 prospective observational cohort studies with nearly 1 million adults without CVD revealed a strong relationship between blood pressure and age-specific stroke deaths and ischemic heart disease deaths which persisted after adjusting for lipid levels, diabetes, weight, alcohol intake, and smoking. ⁶ The positive associations between lowering blood pressures down to 115/75 mm Hg and outcomes were apparent through all age groups categorized by each decade of life. The hazard ratios were originally reported in incremental decreases in 20 mm Hg in SBP and 10 mm Hg in DBP. To allow for comparability to our results, we converted the blood pressures to smaller incremental decreases of 2 mm Hg in SBP and 1 mm Hg in DBP, respectively (**Table 17**). In adults between ages 40-49, a 2 mm Hg decrease in SBP was associated with lower mortality due to stroke by 10 percent (HR, 0.90 [95% CI, 0.89 to 0.91]) and mortality due to ischemic heart disease by 7 percent (HR, 0.93 [95% CI, 0.92 to 0.94]).

Similarly, a prospective cohort study of 63,000 patients with suspected hypertension found an association between increased in-clinic and ambulatory blood pressure measurements (ABPM) and increased cardiovascular mortality. The average age of the subjects was 58.4 years old and the results were adjusted for age, sex, smoking status, BMI, diabetes, dyslipidemia, history of CVD and number of antihypertensive drugs used. The study results reported hazard ratios per 1-SD (14 mm Hg) SBP increase in ABPM and 1-SD (19 mm Hg) SBP increase in the clinic. To comparably assess the effects of decreased SBP, the inverse of the HRs were calculated and converted to incremental 2 mm Hg decreases (**Table 17**). This resulted in a 6 percent (HR, 0.94 [95% CI, 0.93 to 0.94]) and a 4 percent (HR, 0.96 [95% CI, 0.95 to 0.96]) reduction in CVD mortality for ABPM and clinical BP measurements, respectively. Further, a IPD meta-analyses of randomized controlled trials and prospective studies supported the overall benefits of a broad class of antihypertensives in lowering blood pressure decreasing cardiovascular mortality risks. For example, one of these found that among trials with baseline SBP between 130 and 139 mm Hg, a 10 mm Hg reduction was associated with a 13% reduction in major CVD events (RR=0.87 [95% CI 0.82 to 0.92]), 27% reduction in strokes (RR=0.73 [95% CI 0.62 to 0.85]) and a 11% reduction in all-cause mortality (RR=0.89 [95% CI 0.82 to 0.98]).

Similarly, CVD events were reduced in a combined analysis of long-term followup of the two TOHP trials, in which the average change in blood pressure was a 1.2/0.7 mm Hg greater reduction than control groups after 36 months, presumably due to restricted sodium intake found by the TOHP trials. In this follow-up study, risk of a cardiovascular event was 25% lower among those in the intervention group (RR= 0.75 [95% CI 0.57 to 0.99]), adjusted for trial, clinic, age, race, and sex, and was 30% lower after further adjustment for baseline sodium excretion and weight (RR=0.70 [95% CI 0.53 to 0.94]). This was after approximately 10 years for TOHP I and 5 years for TOHP II. However, there was not a statistically significant reduction in all-cause mortality in this combined analysis (RR=0.80 [95% CI 0.51 to 1.26]; 67 deaths total).

Lipids

We found that behavioral counseling interventions were associated with a 3.7 mg/dL greater reduction in total cholesterol than control groups and a 2.3 mg/dL greater reduction in LDL compared to the control groups after 12 to 24 months of follow-up. Individuals with dyslipidemia experienced similar outcome in TC levels, decrease by 3.8 mg/dL and a decrease of 4.1 for LDL. The mean baseline LDL levels were 136 mg/dL across all included studies, and 160 in trials that were limited to persons with dyslipidemia or levels that were outside the optimal range. Median reductions in LDL were 4.8 mg/dL in the intervention groups and 4.2 mg/dL in the control groups for all studies, and absolute reductions were larger in trials limited to participants selected for lipid levels (median 11.0 and 10.4 mg/dL reductions in the intervention and control groups, respectively). There was a minimal impact on HDL.

The variety in lipid components and their interactions with each other creates complications when determining the health impact of cholesterol levels, but epidemiologic evidence suggests that decreases in LDL can lead to decrease in cardiovascular mortality. 10, 11 However, evidence is mixed on the likelihood that changes of the magnitude found in our review are associated with long-term health benefits. In an IPD meta-analysis of 61 prospective observational studies consisting of 900,000 adults without a history of known diseases revealed a positive relationship between non-HDL cholesterol levels and IHD mortality after a median 13 years followup. This trend persisted through each decade of life beginning at age 40 but weakened through subsequent decades. An average decrease in non-HDL cholesterol of 3 mg/dL was associated with a 4 percent reduction in IHD mortality in adults ages 40 to 49 years old (HR, 0.96 [95% CI, 0.95 to 0.96]) (**Table 17**). This study did not find a relationship between non-HDL cholesterol levels and stroke mortality (e.g., HR=0.99 [95% CI 0.99 to 1.00] for adults ages 40 to 49 years). A separate meta-analysis of 34 trials with 135,000 subjects supported the usage of intensive statin therapy to decrease all-cause mortality and CVD mortality over less-intensive. ¹⁰ For example, among persons with a baseline LDL between 100 and 129 mg/dL, 48 weeks of LDL lowering therapy was associated with a 12% lower risk of all-cause mortality (RR=0.88 [95% CI 0.79 to 0.98]). However, this analysis found that there was no benefit in trials with average absolute reductions of less than 35 mg/dL (RR=0.98 [95% CI 0.94 to 1.01]).

Fasting Glucose

We excluded trials if 50% or more of participants had diabetes or prediabetes, but nevertheless found that behavioral counseling interventions were associated with a 2.4 mg/dL greater reduction in FBG and control groups after 12 to 24 months of follow-up. The mean baseline FBG levels were 86 mg/dL across all included studies, and the median change was a 2.9 mg/dL reduction in the intervention groups and 0.2 mg/dL increase in the control groups. The percent with diabetes at baseline ranged from 0 to 49 percent, with 12.7 percent of all participants having diabetes across all studies reporting diabetes prevalence.

Epidemiologic evidence suggests that maintaining a normoglycemic level is associated with the best cardiovascular outcomes and incremental increases beyond normoglycemia increases cardiovascular mortality. In an IPD meta-analysis of 54 prospective studies that included 284,686 individuals without known CVD, all-cause mortality and vascular death was not associated with a fasting blood glucose level between 70 and 100 mg/dL adjusted for age, smoking, and BMI.¹² A different IPD meta-analysis generated similar results for coronary heart disease and stroke events, both fatal and nonfatal. An incremental 2 mg/dL increases in fasting blood glucose above 100 mg/dL was associated with a 1 percent decreased risk of fatal plus nonfatal coronary heart disease (HR, 0.99 [95% CI, 0.98 to 0.99]), ¹² vascular deaths (HR, 0.99 [95% CI, 0.98 to 0.99]), ¹² and all-cause mortality (HR, 0.99 [95% CI, 0.99 to 0.99]). ¹² The link between diabetes and cardiovascular events is well-established; the incidence rate is doubled for fatal and nonfatal coronary heart disease and stroke. The previous review on this topic found that counseling individuals with known impaired fasting glucose or glucose intolerance about interventions reduced their risk of progressing to diabetes by 42 percent in 12 to 24 months (pooled RR, 0.58 [95% CI, 0.37 to 0.89]; k=8; I^2 =32%). ¹³ These results demonstrate the importance of preventing the progression to diabetes in risk populations.

Adiposity

We found that behavioral counseling interventions were associated with a 0.4 kg/m² greater reduction in BMI than control groups and a 1.6 cm greater reduction in waist circumference compared to the control groups after 12 to 24 months of follow-up. Among the weight loss trials in this review, the average BMI and waist circumference reductions were 0.9 kg/m² and 2.5 cm, respectively. The mean baseline BMI was 29.8 across all included studies, 89.3% of all participants were either overweight or had obesity across all studies reporting the prevalence of excess weight. Median reductions in BMI were 0.5 kg/m² in the intervention groups and 0.1 kg/m² in the control groups, and absolute reductions were larger in weight loss trials (i.e., participants were selected on the basis of excess weight and all were given a weight loss goal: median 1.0 and 0.3 kg/m² reductions in the intervention and control groups, respectively).

We found data to support that even modest changes in BMI may be associated with small reductions in cardiovascular related mortality. An IPD meta-analysis of 57 prospective studies that included 900,000 individuals found that all-cause mortality was lowest in BMI ranges between 22.5 to 25 kg/m² in adults without CVD. 14 Applying conversions to determine the impact of a BMI change comparable to that found in our review, a BMI decrease of 0.4 kg/m² was associated with a 3 percent lower risk of death caused ischemic heart disease (HR, 0.97 [95% CI, 0.96 to 0.97]) and fatal strokes (HR, 0.97 [95% CI, 0.97 to 0.981), among adults with a BMI above 25 kg/m² and ranging from ages 35 to 59 years. These results were not adjusted for mechanisms which affect vascular mortality such as blood pressure levels, lipid levels, or diabetes. 14 A Danish study published in 2016 investigated the relationship between BMI and mortality over time from three different cohorts and found smaller associations between BMI and mortality over time.¹⁵ In the most recent cohort, a BMI greater than 30 kg/m² was not associated with an increased risk of all-cause mortality relative to a BMI of 18.5 to 24.9 (HR, 0.99 [95% CI, 0.92 to 1.07]), in contrast to earlier cohorts (1991–1994: HR, 1.13 [95% CI, 1.04 to 1.22]; 1976–1978: HR, 1.31 [95% CI, 1.23 to 1.39]). An analysis of the most recent cohort (2003-2013) revealed a BMI of 27.0 kg/m² to have the lowest all-cause mortality, which is 3.3 kg/m² higher than at was in the earliest cohort. They hypothesized that improved treatment for cardiovascular risk factors and CVD complications may have had a greater impact at higher BMI levels than at lower BMI levels. Body mass index is known to be associated with other cardiovascular risk factors such as blood pressure, lipid levels and diabetes and therefore the clinical significance of weight loss should also be considered when examining these outcomes.15

Evidence was not as extensive for waist circumference, however we did find prospective observational studies to support the association between waist circumference and future all-cause mortality¹⁶ and ischemic heart disease events.¹⁷ A pooled analysis of 11 prospective cohort studies (n=650,386) with mean followup of 9 years reported a 7% increase in the risk of all-cause mortality in men (HR=1.07 [95% CI 1.06 to 1.08]) and 9% increase in women (HR=1.09 [95% CI 1.08 to 1.09]) associated with a 5 cm increment in waist circumference. We inverted these figures and calculated the decline in risk associated with a 2 cm reduction in men and a 1 cm reduction in women, consistent with our findings; the result was a 3% lower risk for men (HR=0.97 [95% CI 0.96 to 0.98]) and a 1% lower risk for women (HR=0.99 [95% CI 0.98 to 0.99]).¹⁶ Similar calculations based on a pooled analysis of 6 prospective cohort studies from China and Australia (n=45,988) with a mean 6 years followup results in a 5% reduction in the risk of ischemic heart disease events (HR=0.95 [95% CI 0.95 to 0.98)] being associated with a 1.7 cm decrease in waist circumference.¹⁷

Diet

We found that dietary counseling was associated with decrease in percentage of energy from saturated fats and monounsaturated fats and had no statistically significant effect on the percentage of energy coming from polyunsaturated fats. Between-group differences included a decrease in 1.5 percent and 1.7 percent of total energy consumed in saturated fats and mono-unsaturated fats, respectively. We also found that dietary counseling increased the consumption of fruits and vegetable combined by 0.7 servings a day more than control groups and consumption of fiber increased by 1.4 grams per day more than control groups. Urinary sodium was also decreased by 17.9 mmol/L more in the intervention groups than the control groups. In addition, several trials improved overall indices of diet, and two reported increased adherence with the Mediterranean diet.

There is some observational data to support the benefits of a healthful diet on cardiovascular and all-cause mortality. A 2014 study meta-analysis of 95 cohort studies with up to 2 million participants found that an increase in fruit and vegetable consumption of 200 g/d was associated with an decreased relative risk of cardiovascular disease by 8 percent (RR, 0.92 [95% CI, 0.90 to 0.95]), strokes by 16% (RR, 0.84 [95% CI, 0.76 to 0.92]), and all-cause mortality by 10% (RR, 0.90 [95% CI, 0.87 to 0.93]). However, 200 g/d is a considerably larger between-group effect than we found, which is more on the order of 30 g/day or less. A separate meta-analysis of 16 cohort studies that included over 800,000 individuals and 56,423 deaths found a 5 percent lower risk of all-cause mortality for an increment of one serving of fruit and vegetables per day (pooled HR=0.95 [95% CI 0.92 to 0.98]). 19

Evidence also support increased fiber consumption. Incremental consumptions of 10 gram of dietary fiber per day has also been shown to decrease the all-cause mortality risk ratio by 11 percent [RR, 0.89 (95% CI 0.85 to 0.92)] according to a meta-analysis from 2014.²⁰ Again, however, this was a nearly 10 times larger change in fiber consumption than the between-group differences that was observed in the included studies.

The findings on intake of different types of dietary fat are less clear, although evidence suggest that a low-fat diet may not assist with weight loss or decrease CVD and cancer mortalities. ²¹⁻²⁴ The results of a meta-analysis of two U.S.-based prospective cohort studies (the Nurses' Health Study and the Health Professionals Followup Study) of individuals without diabetes, cardiovascular disease and cancer at baseline found that a replacement of 5 percent of energy from saturated fats to polyunsaturated fats, monounsaturated fats, or whole grain carbohydrates was associated with a 25 (HR, 0.75 [95% CI, 0.67 to 0.84]), 15 (HR, 0.85 [95% CI, 0.74 to 0.97]), and 8 percent (HR, 0.91 [95% CI, 0.85 to 0.98]) reduction in coronary heart disease, respectively. ²⁵ The reduction in saturated fat was substantially lower in the

included studies, and it was unlikely that these calories were replaced with MUFA or PUFA, since those also either declined or health steady in the included studies. A 2017 publication from the American Heart Association's review of the current evidence concluded that replacing saturated fats with unsaturated fats in lowers the incidences of cardiovascular disease, however some disagreement in the field remains. The U.S. Department of Health and Human Service has also began recommending substitution of saturated fats for poly- and monounsaturated fats.

Physical Activity

Our analysis found that physical activity counseling was associated with statistically nonsignificant increases in physical activity of 9.1 minutes per week and 83 MET-minutes per week compared to the control group. We also found that 22 percent of individuals were able to meet the set physical activity recommendation (150 minutes of moderate-intensity or 75 minutes of vigorous physical activity per week) compared to the control. However, there was substantial level of heterogeneity in our pooled analysis for this outcome.

The broader body of observational and trial literature support the benefits of exercise in decreasing cardiovascular disease even at levels below the national standard. The Physical Activity Guidelines for Americans, second edition, reaffirmed the strong evidence to support the benefits of physical activity on all-cause mortality.²⁹ They recommend a minimum of 150 minutes of moderate intensity exercise or 75 minutes of vigorous-intensity exercise per week (approximately 500 to 1,000 MET-minutes/week). However, even physical activities below what is recommended show significant benefits,²⁹ and the current guide states that the is no threshold that must be exceeded before benefits begin to occur. Compared to no activity, activity below the recommended 450-MET-minutes/week reduced both cardiovascular death and all-cause mortality by 20 percent (HR, 0.80 [95% CI, 0.77 to 0.84]), HR, 0.80 [95% CI, 0.78 to 0.82] respectively) after adjusting for clinical and demographic characteristics, including BMI. Physical activity at the level of the national recommendation (500 to 1000 MET-minute/week) is associated with a 33 percent reduction in the risk of cardiovascular mortality (HR, 0.67 [95% CI, 0.65 to 0.70]) and all-cause mortality is reduced by 31 percent (HR, 0.69 [95% CI, 0.67 to 0.70]).³⁰ The benefits are observed regardless of whether the physical activity is recreational or non-recreational (e.g., housework, transportation and occupational).³¹ The benefits of physical activities are generalizable across subpopulations of age, sex, race/ethnicity, BMI smoking and history of heart disease according to a Taiwanese prospective cohort study of more than 400,000 individuals. The study found that low levels of activity (90 min/week or 15/min/day) was associated with a 19 percent reduction in cardiovascular mortality (HR, 0.81 [95% CI, 0.71 to 0.93]) and a 14 percent reduction in risk of all-cause mortality (HR, 0.86 [95% CI, 0.81 to 0.91]). Furthermore, additional 15 minutes/day was associated with a 4 percent risk reduction in all-cause mortality (95% CI, 2.5 to 7.0).³²

Large cross-sectional studies have associated better quality of life and perceived health status with physical activity regardless of BMI, 33, 34 while results of longitudinal analyses showed a mixture of substantial improvements in the range of quality-of-life domains, 35 and others showed limited impact. 36 The results of cross-sectional associations were not reproducible by longitudinal analysis, however. 37

Appendix F Table 1. Population Characteristics

(Study name)	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
Ammerman, 2003 ³⁸ Fair	US Mixed		Residents of rural areas, age 20 to 70, with untreated hypercholesterole mia		3, 6, 12 (75)	55 (20-70)		29 NR	HTN: 41 Dys: 100 PreDM: NR DM: 3 CVD: 10 Smoking: 21	% unemployed: 44 % education <high 30<="" school:="" td=""></high>
Anderson, 1992 ³⁹ Fair	US Community		Age 30 to 50 with moderate untreated hypercholesterole mia and without obesity or hypertension	177	4, 8, 12 (82)	41 (30-50)	40		HTN: 0 Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: 12	Mean education, years: 16
Anderssen, 1995 ⁴⁰ (Oslo Diet and Exercise Study (ODES)) Fair	•	factors	Age ≥40 with untreated elevated BP/hypertension and lipids, physically inactive and BMI >24	98	12 (97)	45 (41-50)	NR		HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR
Appel, 2003 ⁴¹ (PREMIE R) Good	US Mixed		Age ≥25 with untreated elevated BP/hypertension	810	6, 18 (94)	50 (≥25)			HTN: 38 Dys: 24 PreDM: NR DM: 0 CVD: 0 Smoking: 5	No. (%) ≤ High school: 74 (9) No. (%) some college: 476 (59) No. (%) some graduate school: 260 (32) No. (%) No. (%) \$30-60k annual income: 256 (32) No. (%) >\$60k annual income: 441 (54)
Appel, 2011 ⁴² (POWER Hopkins (Practice Based		factors	Age ≥21 with obesity and any of multiple risk factors	415	6, 12, 24 (95)	54 (≥21)	64		HTN: 76 Dys: 68 PreDM: NR DM: 23	Education, %: -HS grad or less, 10.6% -Some college, 30.1% -College grad, 59.3%

Appendix F Table 1. Population Characteristics

Author, year	Country	Population	Population	N	All F/U	Mean age	%	Mean BMI	CVD risk	Socioeconomic status
(Study name) Quality	Recruitment setting		_	rand	timepoints (months) (% available at main F/U timepoint)		Female		factors	
Opportunities for Weight Reduction)) Good									-	Household income, %: -\$50,000-\$99,000, 37.3% -≥\$100,000, 40.7% Employment status, %: -Employed, 75.2% -Retired, 15.7% -Other, 9.2% Insurance status: -Private, HMO, Medicare: 98.5% -Medicaid, uninsured: 1.5%
Applegate, 1992 ⁴³ Fair	US Community		Age 60 to 85 at ≥115% of ideal body weight, with hypertension	56	1, 2, 3, 4, 5, 6 (84)	64 (60-85)	55	NR 100	HTN: 100 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 13	Education (yrs): 12 Employment (Full time or part time): 30%
Arroll, 1995 ⁴⁴ Fair	New Zealand Mixed		Age 20 to 69 with treated hypertension and sedentary		3, 6 (87)	55 (20-69)		NR NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: NR	NR
Babazono, 2007 ⁴⁵ (PHPP) Fair	Japan Health Care	factors	with elevated BP, hypertension or prediabetes	99	4, 6, 12 (88)		58		HTN: 30 Dys: NR PreDM: NR DM: 17 CVD: NR Smoking: NR	
Beckmann, 1995 ⁴⁶ Fair	Norway NR		Men, age 40 to 56, with untreated mild-to-moderate hypertension	64	3, 6, 12 (100)	NR (40- 56)	0			NR

Appendix F Table 1. Population Characteristics

	Country Recruitment setting		_	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
									CVD: NR	
Bennett, 2012 ⁴⁷ (Be Fit, Be Well [POWER]) Good		Hypertension	Age ≥21 with obesity and treated hypertension	365	6, 12, 18, 24 (69)	55 (≥21)	68	37 100	Smoking: 22 HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	Educational level, n (%) High school/GED, 109 (30) Some college/AD, 86 (24) Bachelor's degree, 50 (14) Income, n (%) \$10,000 to \$25,000 to \$50 000, 56 (15) Employment, n (%) Employed, 192 (53) Unemployed, 50 (14) Retired, 43 (12) Disabled, 80 (22) Health insurance, n (%) Medicaid, 123 (34) Medicare, 75 (21) Private insurance, 137 (38) Other, 30 (8)
Bennett, 2018 ⁴⁸ (Track) Good	US Health Care	Multiple risk factors	Age 21 to 65 with obesity and any of multiple CVD risk factors		6, 12 (90)	51 (21-65)	68	36 100	HTN: 82 Dys: 55 PreDM: NR DM: 42 CVD: 0 Smoking: NR	Education: HS grad: 36% Some college or vocational: 40% 4-year college degree or higher: 10% Annual household income: 0-\$11,999: 20% \$12,000-\$24,999: 31% \$25,000-\$34,999: 16% \$35,000-\$49,999: 13%

(Study name)	Country Recruitment setting		_	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
										≥\$50,000: 7% Living under US poverty threshold: Below: 30% Borderline: 16% Above: 41% Current employment: Full- or part-time: 67% Unemployed: 31%
Beune, 2014 ⁴⁹ (Culturally Adapted Hypertension Education (CAHE)) Fair	The Netherlands Primary Health Care	Hypertension	Surinamese and Ghanaian immigrants, age ≥20, with hypertension	146	6 (95)	54 (≥20)	53	31 94	Dys: NR PreDM: NR	Education: Low: 50% Middle: 30% High: 19% Employment: Paid work: 64% Unpaid work: 1% Unemployed/disabled: 24% Retired: 11%
Blackford, 2016 ⁵⁰ (Albany Physical Activity and Nutrition (APAN)) Fair	Australia Health Care	Multiple risk factors	Age 50 to 69 with or at risk of metabolic syndrome	401	6 (78)	61 (50-69)	66	31 NR		Employment: Full time: 46% Part time: 17% Unemployed: 4% Retired: 33% Education: Primary: 2% Secondary: 41% Technical/diploma: 32% University: 26%

Author, year (Study name) Quality	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
Bloemberg, 1991 ⁵¹ Fair	The Netherlands Other		Men, age 30 to 60, with untreated dyslipidemia	80	6 (99)	47 (30-60)	0		HTN: 0 Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR
Bo, 2007 ⁵² Fair	Primary Health Care	factors	Age 45 to 64 with metabolic syndrome		12 (89)	56 (45-64)			HTN: 94 Dys: NR PreDM: 38 DM: 0 CVD: 0 Smoking: 22	Education level, %: - Primary, 79 - Secondary, 16 - University, 5
Bosworth, 2009 ⁵³ (Take Control of Your Blood pressure (TCYB)) Fair	Primary	Hypertension	Adults with treated hypertension	478	12, 24 (76)	61 (NR)		NR	HTN: 100 Dys: NR PreDM: NR DM: 36 CVD: NR Smoking: 17	% completed ≤12 years education: 35 % employed: 40 % inadequate income: 19
Broekhuizen, 2012 ⁵⁴ (PRO- FIT) Fair	The Netherlands Other		Age 18 to 70 with familial hypercholesterole mia	340	12 (94)	45 (18-70)	57	NR	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: 17	Education, %: - Low, 3 - Medium, 60 - High, 36
Bruckert, 2008 ⁵⁵ (PEGASE (Effect of an Education Program)) Fair	France Health Care		Age ≥18 with elevated LDL and additional CVD risk factor (unless LDL very high)	640	6 (74)	57 (≥18)	40		HTN: 34 Dys: 100 PreDM: NR DM: 9 CVD: 23 Smoking: 21	Education, %: - No education, 10 - HS grad, 14 - Tech school, 49 - Higher education, 24 Employed, %: 42 Retired,%: 47 Unemployed, %: 2

(Study name)	Country Recruitment setting			N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
Burke, 2006 ⁵⁶ (ADAPT) Fair	Australia NR		Age 40 to 70 with treated hypertension and overweight or obese	241		56 (40-70)	NR	30 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Chirinos, 2016 ⁵⁷ (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS))	Health Care	Multiple risk factors	Low-income adults, age 30 to 70, with metabolic syndrome and BMI ≥25	120	6, 12 (78)	52 (30-70)	56	NR 100	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: NR	Education, mean: 13 years Income, %: - \$20,000-\$40,000: 22 - >\$40,000: 4
Christian,	US Primary Health Care	Multiple risk factors	Age 18 to 75 with BMI >25 and ≥2 components of the metabolic syndrome		12 (94)	50 (18-75)	68	34 100	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: NR Smoking: NR	100% uninsured, Medicaid- eligible, or Medicare 60% at or below 100% of federal poverty level among entire patient population
	Italy Primary Health Care	Hypertension	Adults with treated hypertension	203	3, 6 (98)	59 (NR)	NR	29 NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 62	NR
	UK Primary Health Care	Multiple risk factors	Age 35 to 74 with Framingham 10- year CVD risk ≥20%	601	12 (81)	64 (35-74)	11	28 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 53	SES based on IMD deciles: - Deprived, n (%): 282 (48) - Intermediate, n (%): 189 (32) - More affluent, n (%): 112 (19)

(Study name)	Country Recruitment setting		-	rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
Cohen, 1991 ⁶¹ Fair	US Primary Health Care		Age 20 to 75 with BMI ≥27.8 and hypertension	30	6, 12 (100)	60 (20-75)	73	100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Coleman, 2012 ⁶² (Wisewoman California) Fair			Low-income Hispanic females, age 40 to 64, with hypertension or hypercholesteremi a		12 (80)	52 (40-64)		90		Education, %: Some HS, 10 ≥HS, 20
Delahanty, 2001 ⁶³ Good	US Primary Health Care		Age 21 to 65 with untreated dyslipidemia	90	3, 6, 12 (97)	49 (21-65)		NR	HTN: NR Dys: 100 PreDM: NR DM: 0 CVD: NR Smoking: 8	% education < college grad: 33
Eakin, 2009 ⁶⁴ (Logan Healthy Living) Fair			Age ≥30 with diabetes or hypertension	434	4, 12, 18 (79)	58 (≥30)		31 NR	HTN: 86 Dys: NR PreDM: NR DM: 45 CVD: NR Smoking: 14	% ≥ high school graduate: 45 % retired: 36 % employed: 46
Edelman, 2006 ⁶⁵ Fair	Primary Health Care	factors	Age ≥45 with one or more CVD risk factors		5, 10 (79)		80	34 NR	HTN: 38 Dys: NR PreDM: NR DM: 16 CVD: 0 Smoking: 10	Education, n (%): - completed college, 104 (68) Family income, n (%): - \$40,000 to \$59,999, 16 (10) - >\$60,000, 85 (55)
Ellsworth, 2016 ⁶⁶ Fair		factors	Age ≥18 with any of multiple risk factors	184	12 (80)	61 (34-86)		85	HTN: 43 Dys: 33 PreDM: NR	NR

(Study name)	Country Recruitment setting			N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
									DM: 24 CVD: 22 Smoking: NR	
	Spain Primary Health Care	Multiple risk factors	Men, age 55 to 80, and women, age 60 to 80, with any of multiple CVD risk factors, who did not score as unlikely to change according to the Stages of Change model	7447	12, 24, 36, 48, 60, 72 (93)	67 (55-80)	43	30 93	PreDM: NR DM: 49 CVD: 0 Smoking: 14	Employment status: Working: 13% Housewife: 32% Unemployed: 1% Retired: 52% Education: University graduate: 4% Some college: 4% Secondary education: 16% Primary education: 74% Illiterate: 2%
1998 ⁶⁸ (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)	Sweden Mixed	factors	72, with treated hypertension and any of high total cholesterol, diabetes, or current smoking	508	12, 40, 79 (94)	66 (50-72)		27 NR	HTN: 100 Dys: 74 PreDM: NR DM: 22 CVD: 13 Smoking: 29	NR
Challenge - First Responders) Fair	US Other	Multiple risk factors	Adults, aged 18 to 65, with low HDL or high waist circumference	175	3, 6, 12 (78)	42 (18-65)	NR	32 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Gill, 2019 ⁷⁰ (HealtheSteps) Fair	Canada Mixed		Adults, aged 18 to 85 years, with BMI >25 kg/m2 and any of	118	6 (75)	58 (18-85)	79	31 100	HTN: 28 Dys: 28 PreDM: 16 DM: 15	Education, n (%): ≤High school, 35 (30) >High school, 83 (70)

(Study name)	Country Recruitment setting		description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
			multiple risk						CVD: NR	
	UK Primary Health Care	Multiple risk factors	factors Age 40 to 74 with BMI ≥28 and ≥1 additional CV risk factor	108	4, 12 (89)	65 (40-74)	31	33 100	Smoking: 8 HTN: NR Dys: NR PreDM: 8 DM: 0 CVD: NR Smoking: NR	Education, n (%): - Up to age 16, 50 (46.3) - Up to age 18, 8 (7.4) - Some additional, 23 (21.3) - ≥Undergraduate, 27 (25.0) Area deprivation (Index of Multiple Deprivation [IMD] score): 11.9
Groeneveld, 2010 ⁷² (Health Under Construction) Fair	The Netherlands Health Care	Multiple risk factors	Males in the construction industry, age 18 to 65, with higher than moderate (thresholds not defined) Framingham 10-yr CVD risk and any of multiple risk factors		6, 12 (72)	47 (18-65)	0	28 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 52	% blue-collar workers (performing the construction vs. white-collar workers involved in admin and supervision): 74
Hardcastle, 2008 ⁷³ Fair	UK Primary Health Care	Multiple risk factors	Age 18 to 65 with BMI ≥28, hypertension, or hypercholesterole mia	334	6, 18 (63)	50 (18-65)	67	34 99	HTN: 35 Dys: 57 PreDM: NR DM: NR CVD: NR Smoking: 16	NR
Harris, 2012 ⁷⁴ (Health Improvement and Prevention	Australia Health Care	factors	Age 40 to 55 with hypertension or dyslipidemia; age 56 to 64 with or	814	6, 12 (80)	NR (40- 64)	57	29 56	HTN: 9 Dys: 88 PreDM: NR DM: 0	% employed: 68 % tertiary educated (college of technical and further education or university): 47

(Study name)	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
Study (HIPS))			without recorded						CVD: 0	% Socioeconomic Indexes for
Fair			risk factors						Smoking: 13	Areas score in lowest quintile: 2
Haufe, 2019 ⁷⁵	Germany	Multiple risk	Age >18 years	314	6 (87.3)	48 (>18)	14	33	HTN: NR	Type of work:
Fair	Other	factors	with ≥ 3 of 5		, ,	, ,		NR	Dys: NR	Manual: 36%
			components of						PreDM: NR	Office: 52%
			metabolic							Unclassified: 12%
			syndrome						CVD: NR	
									Smoking: NR	
Hinderliter,	US	Hypertension	U —	95	4,12 (86)	52 (≥35)	66	33	HTN: NR	Education: n (%)
2014 ⁷⁶ (Exercise	Mixed		untreated above-					100	Dys: 27	High school, 34 (36%)
and Nutrition			normal blood						PreDM: NR	Completed college, 23 (24%)
interventions for			pressure and BMI						DM: 0	Income: n (%)
CardiOvasculaR			between 25 and						CVD: 0	
hEalth			39.9						Smoking: 8	
(ENCORE)) Good										
HPT, 1990 ⁷⁷	US	Lyportonsion	Age 25 to 49 with	Q / 1	6, 12, 18, 24,	30 (25 40)	25	27	HTN: 0	College graduate, %: 54
	Community	Trypertension	untreated high	041	30, 36 (90)	39 (23-49)	55	75	Dys: NR	College graduate, %. 34
Prevention Trial	Community		normal DBP		50, 50 (70)			73	PreDM: NR	
(HPT))			normar BB1						DM: NR	
Good									CVD: NR	
									Smoking: 17	
Hyman, 1998 ⁷⁸	US	Dyslipidemia	Low-income	123	6 (80)	56 (18-65)	75	31	HTN: NR	≤ High school education, %: 89
	Health Care		patients, age 18 to			, ,		NR	Dys: 100	Income level \le \$1000/month, %:
			65, with untreated						PreDM: NR	78
			hypercholesterole						DM: NR	
			mia						CVD: NR	
									Smoking: NR	
Hyman, 2007 ⁷⁹	US	Hypertension	Sedentary African	281	6, 18 (82)	53 (45-65)	67	32	HTN: 100	Recruited from facility that
Fair	Primary		Americans adults,					NR	Dys: NR	serves medically indigent,
	Health Care		age 45 to 60, with						PreDM: NR	"most" patients ≤100% FPL
			hypertension and						DM: 18	
			current smoking							

(Study name)	Country Recruitment setting		-		All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
									CVD: 0	
100280	TIG	D 1: :1 :	D 11 (C 1	1107	20 (77)	71 (65 70)	<i></i>	NID	Smoking: 100 HTN: 18	D. 6. 1 11
Ives, 1993 ⁸⁰ (Rural Health Promotion Project (RHPP) Trial) Fair	US Community	Dysiipidemia	Residents of rural areas, age 65 to 79, with TC ≥240 mg/dL	1197	50 (77)	71 (65-79)	57	NR NR	Dys: 100 PreDM: NR DM: 16 CVD: 20 Smoking: 12	Mean education, years: 11 Completed school; 60.1% completed HS or above Mean annual household income: \$15,500
Johnston, 1995 ⁸¹ Fair	Australia Health Care	Dyslipidemia	Adults with elevated total cholesterol	179	2, 6 (73)	57 (24-81)	NR	25 NR	HTN: NR Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR
Optimal Treatment (HOT)) Fair	NR		Age 50 to 80 with BMI ≥27 and hypertension		6, 12,18, 24, 30 (91)	58 (50-80)	NR	34 100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Heart Lifestyle Intervention (SAHELI)) Fair	Community	factors	Pakistani immigrants, age 30 to 59, with at least one ASCVD risk factor	63		50 (30-59)		30 NR	Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: NR	Born outside of the US: 100% Limited English proficiency: 36%
Kanke, 2015 ⁸⁴ Fair	Japan Primary Health Care	Multiple risk factors	Age 30 to 69 with obesity (per Japanese cutpoints) and hypertension, dyslipidemia,	50	6, 12 (80)	55 (30-69)	36	28 100	Dys: 38	Education n (%): >HS: 14 (28.0%) ≥HS: 36 (72.0%)

Author, year (Study name) Quality	Country Recruitment setting	risk focus	description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
			and/or type 2 diabetes							
Kastarinen, 2002 ⁸⁵ (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF)) Fair		• 1	Age 25 to 74 with hypertension	715	12, 24 (83)	54 (25-74)	53	80	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 4 Smoking: 8	NR
Keyserling, 1997 ⁸⁶ (Southeast Cholesterol Project) Fair	US Health Care		Low-income adults, age 20 to 75, with elevated cholesterol	372	4, 7, 12, 24 (92)	56 (20-75)	67	NR	HTN: 60 Dys: 100 PreDM: NR DM: 0 CVD: 10 Smoking: 18	Education, mean grade: 11 Employed full-time, %: 36
Khanji, 2019 ⁸⁷ (HAPPY London) Good		factors	Age 40 to 74 with QRISK2 10-year CVD risk score ≥10%	402	6 (93.8)	65 (40-74)	37	NR	HTN: NR Dys: NR PreDM: NR DM: 14 CVD: 0 Smoking: 8	NR
Loon, 2009 ⁸⁸ (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Netherlands Primary Health Care	factors	Adults with one or more CVD risk factors	615	3, 12 (79)	57 (NR)	55	NR	HTN: 65 Dys: 43 PreDM: NR DM: 14 CVD: 0 Smoking: 26	SES level, n (%): -High, 134 (23) -Intermediate, 228 (39) -Low, 204 (35)
		factors	Age ≥18 with any of multiple risk factors	134	6 (92)	62 (28-88)	67	100	HTN: NR Dys: NR PreDM: NR	Median income for the three communities: \$62,058

	Country Recruitment setting			N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
Project) Fair									DM: 0 CVD: NR Smoking: NR	\$45,099 \$38,811
Lakerveld, 2013 ⁹⁰ (HOORN) Fair	The Netherlands Primary Health Care	factors	Age 30 to 50 with any of multiple CVD risk factors	622	6, 12, 24 (81)	44 (30-50)	58	29 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 21	% employed: 85 % below average income: 37 % average income: 18 % above average income: 30 % ≤ primary education: 23 % secondary education: 46 % college/university: 21
Langford, 1991 ⁹¹ (Trial of Antihypertensiv e Interventions and Management (TAIM)) Fair	US Mixed		Age 21 to 65 at 110-160% of ideal body weight and untreated hypertension	878	6 (90)	49 (21-65)	44	100	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 16	% employed (FT or PT): 79 % education ≥college: 61
Lee, 2007 ⁹² Fair	Taiwan Other		Older adults, age ≥60, with hypertension	202	6 (91)		42	25 NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 22	Education level: 4-7 yrs: 39% >7 yrs: 18%
Liira, 2014 ⁹³ Fair	Finland Mixed	factors	Sedentary men, age 35 to 45, with at least 2 CVD risk factors		3, 12 (77)	40 (35-45)		NR NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	
Migneault, 2012 ⁹⁴ Fair	US Health Care		African-American adults, age ≥35,	337	4, 8, 12 (77)	56 (≥35)	70	34 NR	HTN: 100 Dys: NR PreDM: NR	Median household income: 10- 20k/year % Employed full or part-time:

(Study name)	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
			with treated hypertension						DM: 38 CVD: 8 Smoking: NR	39.7 Education, mean years: 12.2
Moreau, 2001 ⁹⁵ Fair	US NR	Hypertension	Postmenopausal women, age 52 to 56, with borderline to stage 1 hypertension	24	3, 6 (100)	54 (53-55)	100	NR NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 0	NR
Moy, 2001 ⁹⁶ Fair	US Health Care	Multiple risk factors	Siblings of persons with CHD onset prior to age 60, age 30 to 59, with elevated LDL, hypertension, or current smoking	235	24 (76)	46 (30-59)	48	29 NR	HTN: 57 Dys: 79 PreDM: NR DM: NR CVD: NR Smoking: 46	Education, mean years: 12
Muhlhauser, 1993 ⁹⁷ (Hypertension Treatment and Teaching Program (HTTP)) Fair	Germany Primary Health Care	Hypertension	Age 30 to 60 with hypertension	200	18 (80)	51 (30-60)	NR	NR NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Murphy, 2012 ⁹⁸	UK Health Care	Multiple risk factors	Age >16 with ≥1 CHD risk factors or a mental health condition and sedentary	2160	12 (68)	52 (16-88)	66	NR NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	Welsh deprivation index: % low: 35 % mild: 34 % high: 31 Education beyond min school leaving age, %: 52.7 Employment: % Employed: 31

Author, year (Study name) Quality	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
										% Retired: 34 % Housework: 19 % Other: 16 % Missing: 0
Neil, 1995 ⁹⁹ Fair	UK Primary Health Care	Dyslipidemia	European adults, age 35 to 64, with untreated hypercholesterole mia	309	6 (97)	55 (35-64)	47	26 59	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: 22	NR
Niiranen, 2014 ¹⁰⁰ Fair	Finland Primary Health Care	Hypertension	Age 35 to 74 with hypertension	229	12 (96)	62 (35-74)	50	28 NR	HTN: 100 Dys: 43 PreDM: NR DM: 11 CVD: NR Smoking: 11	>8 yrs education: 38%
Nolan, 2018 ¹⁰¹ (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH))	Canada Other	Hypertension	Age 35 to 74 with hypertension	264	4, 12 (74)	58 (35-74)	58	31 NR	HTN: 100 Dys: NR PreDM: NR DM: 7 CVD: 5 Smoking: 9	Mean years education: 16
Ogedegbe, 2014 ¹⁰² (Counseling African Americans to Control Hypertension	US Health Care	Hypertension	Black adults, age ≥18, with treated, uncontrolled hypertension	1039	3, 6, 9, 12 (71)	56 (≥18)	72	33 86	HTN: 100 Dys: NR PreDM: NR DM: 36 CVD: 9 Smoking: 51	Education: ≤HS: 72% Some college: 26% Some graduate school: 2% Annual household income < \$20k: 72%

Author, year	Country	Population	Population	N	All F/U	Mean age	%	Mean BMI	CVD risk	Socioeconomic status
(Study name) Quality	Recruitment setting		description	rand	timepoints (months) (% available at main F/U timepoint)		Female		factors	
(CAATCH)) Fair										Employment status: Unemployed: 11% Retired or homemaker: 55% Employed part time: 14% Employed full time: 20%
Reid, 2014 ¹⁰³ Fair	Canada Health Care		Family members of patients with CAD with ≥1 modifiable risk factor	426	3, 12 (74)	52 (NR)	61	29 NR	HTN: NR Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 9	Education, mean years: 14.7
Rodriguez, 2012 ¹⁰⁴ Fair	US Primary Health Care	Hypertension	Veterans, age ≥21, with treated uncontrolled hypertension	533	6, 12 (90)	66 (≥21)	1	30 NR	HTN: 100 Dys: 24 PreDM: NR DM: 44 CVD: 13 Smoking: 19	Employed full-time, %: 14 Employed (unspecified), %: 21 College graduate, %: 22 ≤High school graduate, %: 46
Rodriguez- Cristobal, 2012 ¹⁰⁵ Fair	Spain Primary Health Care	Multiple risk factors	Age 30 to 75, with elevated fibrinogen levels and estimated moderate or high Framingham CHD risk (thresholds not defined)	436	24 (69)	58 (30-75)	63	30 NR	HTN: 42 Dys: NR PreDM: NR DM: 14 CVD: 0 Smoking: 29	NR
Rosas, 2015 ¹⁰⁶ (Vivamos Activos Fair Oaks (VAFO)) Good	US Health Care	factors	Latino adults, age ≥18, with BMI 30-60 and 1 or more additional CHD risk factors	207	6, 12, 24 (84)	47 (≥18)	77	36 100	HTN: NR Dys: NR PreDM: NR DM: 43 CVD: NR Smoking: NR	Food insecure, %: 51 Education n (%): ≤8th grade: 140 (67.6%) Some HS: 24 (11.3%) ≥HS: 43 (20.8%)

Author, year (Study name) Quality	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
										Employment status n (%) Employed: 97 (46.9%) Unemployed: 21 (10.1%) Not working: 89 (43.0%) Annual income n (%): < \$10,000: 58 (28.0%) \$10,000 - \$20,000: 92 (44.4%) > \$20,000: 56 (27.1%)
Rubinstein, 2016 ¹⁰⁷ Good	Argentina Mixed	Hypertension	Latino adults, age 30 to 60, with untreated prehypertension	212	12 (90)	43 (30-60)	54	29 NR	HTN: 0 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 19	Years education, mean: 11 Employment status: Employee: 42% Independent worker: 29% Housewife: 25% Other: 4% Income: First quintile: 9% Fifth quintile: 23%
Salisbury, 2016 ¹⁰⁸ Good	UK Primary Health Care	Multiple risk factors	Age 40 to 74 with 10 year CVD risk ≥20% and any of: SBP ≥140 mm Hg, BMI ≥30, or current smoking	641	6, 12 (91)	67 (40-74)	20	31 NR	HTN: NR Dys: NR PreDM: NR DM: 22 CVD: NR Smoking: 18	Employment status: Full time: 15% Part time: 11% Unemployed: 1% Unable to work: 2% Retired: 65% Homemaker: 1% Other: 4% College degree or higher: 22%

Author, year (Study name) Quality	Country Recruitment setting		_	rand	All F/U timepoints (months) (% available at main F/U timepoint)			Mean BMI % overweight or obese	factors	Socioeconomic status
Schoenthaler, 2016 ¹⁰⁹ (Individual Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	US Primary Health Care	• •	Black adults, age ≥18, with hypertension	194	1, 3, 6 (80)	57 (≥18)	50	NR	Dys: NR PreDM: NR	Highest degree or level of education: < HS: 19% HS diploma/GED: 47% ≥ Some college: 34% Current employment status: Employed/self-employed: 27% Retiree: 20% On disability: 14% Unemployed/not working: 39% Annual income < \$20k: 69%
Scott, 2018 ¹¹⁰ Fair		factors	Age ≥18 with any of multiple risk factors and completed previous exercise referral program	37	3, 6 (94)	59 (≥18)		94	DM: NR CVD: 6	Employment: Full-time: 6% Part-time: 17% Full-time caregiver: 6% Unemployed: 11% Incapacity benefit: 14% Retired: 46%
Soto Rodriguez, 2016 ¹¹¹ Fair	Health Care	factors	Women, age 45 to 60, with any of diabetes, dyslipidemia, or hypertension		12 (72)	53 (45-60)		NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: NR	NR
Stefanick, 1998 ¹¹² (Diet and Exercise for Elevated Risk (DEER)) Fair	Mixed		Postmenopausal women, age 45 to 64, and men, aged 30 to 64, with untreated dyslipidemia or	189	12 (98)	52 (30-64)		NR	HTN: NR Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: NR	NR

Author, year (Study name) Quality	Country Recruitment setting		description	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	% Female	Mean BMI % overweight or obese	CVD risk factors	Socioeconomic status
			mildly elevated lipids							
Stevens, 2003 ¹¹³ Fair	US Health Care	Dyslipidemia		616	12 (87)	54 (40-70)	100	NR	HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: NR	% college grad or more: 40
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM)) Good		factors	Age ≥25 with previous weight loss and pharmacologically treated for hypertension and/or dyslipidemia	1032	12, 18, 24, 30, 60 (95)	56 (28-83)	63		HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: NR	Household income/y: ≥\$60,000: 57.4% Education: ≤Some college: 38.4% College degree: 61.6%
Svetkey, 2009 ¹¹⁵ (Hypertension Improvement Project (HIP)) Fair	US Primary Health Care		Age ≥25 with hypertension	574	6, 18 (88)	60 (28-94)	61	NR	HTN: 97 Dys: 48 PreDM: NR DM: 30 CVD: 16 Smoking: 9	% % inadequate income: 15
Ter Bogt, 2009 ¹¹⁶ (Groningen Overweight and Lifestyle (GOAL)) Good	Netherlands Primary	factors	Age 40 to 70 with BMI 25-40 and hypertension or dyslipidemia	457	12, 36 (91)	56 (40-70)	52	30 100	HTN: 62 Dys: 39 PreDM: NR DM: 0 CVD: NR Smoking: 19	% low education: 32
Tiessen, 2012 ¹¹⁷ (SPRING (Selfmonitoring and Prevention of		factors	Age 50 to 75 with any of multiple CVD risk factors	201	12 (89)	65 (50-75)	31	NR	HTN: 76 Dys: 79 PreDM: NR DM: 0	% no education or primary education: 10 % lower secondary education: 42

(Study name)	Country Recruitment setting		-		All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
RIsk Factors by Nurse practitioners in the region of Groningen)) Fair									CVD: 0 Smoking: 32	% higher secondary education: 27 % college or university: 22
Toft, 2008 ¹¹⁸ (Inter99) Fair	Research Center	factors	Age 30 to 60 with any of multiple CVD risk factors		12, 36, 60 (64)	47 (30-60)		NR	HTN: NR Dys: NR PreDM: NR DM: 11 CVD: NR Smoking: 59	% employed: 83 % no vocational education: 19
TOHP I CRG, 1992 ¹¹⁹ (Trials of Hypertension Prevention Phase I (TOHP I)) Good	Research		Overweight or obese adults age 30 to 54 with prehypertension	1224	3, 6, 12, 18, 192 (93)	43 (30-54)	28	100	HTN: 0 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 12	College graduates: 54% FT employment: 92%
			Age 30 to 54 with untreated prehypertension and 110 to 165% of ideal body weight	2382	6, 18, 36, 48 (88)	44 (30-54)	34		HTN: 0 Dys: NR PreDM: NR DM: 0 CVD: 0 Smoking: 9	Education: Some college: 35% College graduate: 21% Postgraduate: 30% Employed full time: 88%
Tomson, 1995 ¹²¹ Fair	Sweden Primary Health Care		Age 25 to 54 with dyslipidemia	92	12 (83)	42 (25-54)	NR	NR	HTN: 0 Dys: 100 PreDM: NR DM: 0 CVD: 0 Smoking: 54	NR

Author, year (Study name) Quality	Country Recruitment setting			rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)		Mean BMI % overweight or obese	factors	Socioeconomic status
van der Veen, 2002 ¹²² (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	Netherlands Primary		Age 40 to 70 with dyslipidemia, high dietary fat intake, and hypertension or diabetes	143		58 (40-70)	73	29 NR	HTN: 92 Dys: 100 PreDM: NR DM: 6 CVD: 0 Smoking: 22	Education, %: - Low, 68 - Intermediate, 19 - High, 14
van Keulen, 2011 ¹²³ (Vitalum) Fair	The Netherlands Primary Health Care		Age 45 to 70 with or without hypertension, not meeting Dutch diet and PA guidelines	1629	6, 11, 17 (74)	57 (45-70)	45		HTN: 52 Dys: NR PreDM: NR DM: 10 CVD: NR Smoking: 22	% low education: 54 % with paying job: 48
van Sluijs, 2005 ¹²⁴ (Physician- based Assessment and Counseling for Exercise (PACE)) Fair	Netherlands Primary Health Care	factors	Age 18 to 70 with hypertension, hypercholesterole mia, or non- insulin dependent diabetes		2, 6, 12 (86)			29 NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: NR Smoking: 25	% low level of education: 36 % medium level of education: 43 % high level of education: 20 % employed full time: 30 % employed part time: 24 % unemployed: 46 (but average age is 55, unclear how many of these retired)
Viglione, 2019 ¹²⁵ (Goals for Eating and Moving (GEM)) Fair	Primary Health Care	factors	Veterans, age 18 to 69, with obesity or overweight and multiple risk factors		3, 6, 12 (84.4)	54 (18-69)	33	NR NR	HTN: 40 Dys: 28 PreDM: NR DM: NR CVD: NR Smoking: NR	Annual household income: <\$24,999: 27% \$25,000-49,999: 29% \$50,000-99,000: 31% \$≥100,000: 9% Household food security: Food secure: 72% Food insecure: 21% Hunger: 7%

(Study name) Quality	Recruitment setting	risk focus	description		timepoints (months) (% available at main F/U timepoint)		% Female	Mean BMI % overweight or obese	factors	Socioeconomic status
Voils, 2013 ¹²⁶ (CouPLES) Fair	US Primary Health Care		Veterans with dyslipidemia and their spouses	255	6, 11 (89)	61 (NR)	NR		HTN: NR Dys: 100 PreDM: NR DM: NR CVD: NR Smoking: NR	≤High School 24%; FT employment 41%
	Primary Health Care	factors	Age ≥21 with obesity and two or more CVD risk factors	261	6, 12, 18, 24 (85)	52 (≥21)	80	39 100	HTN: 71 Dys: 66 PreDM: NR DM: 21 CVD: 0	Education n (%): Less than HS: 5.7% HS: 19.9% Some college/associate's: 35.6% BA: 21.0% Graduate/professional degree: 17.6%
	Mixed		Age 60 to 80 with treated hypertension	975	36 (92)	66 (60-80)		NR	HTN: 100 Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 5	No. (%) ≥11th grade: 107 (11) No. (%) College grad: 322 (33) No. (%) Unemployed: 29 (3) No. (%) Retired: 575 (59)
Good	Mixed	factors	Age 45 to 64 with 10-yr CVD risk ≥10% based on Framingham risk score		12 (88)	55 (45-64)	58	NR	HTN: NR Dys: NR PreDM: NR DM: NR CVD: 0 Smoking: 13	NR
Wong, 2015 ¹³⁰ Good	Hong Kong Mixed		Age 40 to 70 with untreated newly- diagnosed Grade I hypertension		6, 12 (87)	55 (40-70)	51	NR	HTN: 100 Dys: NR PreDM: NR DM: 0	Employment: % unemployed: 43 % employed: 57

Author, year (Study name) Quality	Country Recruitment setting		-	N rand	All F/U timepoints (months) (% available at main F/U timepoint)	Mean age (range)	Female	Mean BMI % overweight or obese	factors	Socioeconomic status
									CVD: NR Smoking: 9	Monthly household income: % on comprehensive social security assistance: 2 % % \$1290-2579: 24 % \$2580-3869: 19 % \$3870-5159: 18 % ≥\$5160: 25 Education: % illiterate/kindergarten/primary: 19 % secondary: 64 % ≥undergraduate: 15 % other:
Wood, 2008 ¹³¹ (EUROACTIO N) Fair	_	Multiple risk factors	Age 50 to 80 with 10-yr SCORE CVD risk score ≥5%	2385	12 (85)	62 (50-80)	NR	NR	HTN: 63 Dys: 75 PreDM: NR DM: 30 CVD: 0 Smoking: 31	NR

Abbreviations: ASCVD = atherosclerotic cardiovascular disease; BMI = body mass index; CAD = coronary artery disease; CHD = coronary heart disease; CVD = cardiovascular disease; DBP = diastolic blood pressure; DM = diabetes mellitus; Dys = dyslipidemia; F/U = followup; FPL = federal poverty line; GED = general education diploma; HMO = health management organization; HS = high school; HTN = hypertension; LDL = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter; mm Hg; millimeters of mercury; N rand = number of participants randomized; No. = number; NR = not reported; PA = physical activity; PHPP = Patient-motivated Health Promotion Program; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; PreDM = prediabetes mellitus; SBP = systolic blood pressure; TC = total cholesterol; yrs = years

/ •	Int arm	Focus	description		Weight loss approach	t		Int	PCP (Staff involved?)	Ö	Control Group
Ammerman,	IG1	HD	7 sessions of dietary	Total: 9			In-person		None (No)	Nurse, nutritionist	UC
2003^{38}			\mathcal{E} \		NR		Phone			Health department	
Fair			, 1	Other: 2			Print				
				Est Tot Hr: 3.2							
			referred]) and 2 newsletters	Category: Medium							
A 1 1000339	TC1	TID	Total duration: 12 months	T 1 26	T C.	т 1:	T		NI (NI)	D: .:.:	TIC
Anderson, 1992 ³⁹	IG1	HD	10 60-min group dietary	Total: 26			In-person		None (No)	Dietitian, project	UC
Fair						Group	Phone			staff	
				Other: 0 Est Tot Hr: 20	promoted					NR, home	
			consultation; 4 home visits								
			(min NR); 12 monthly	Category, riigii							
			phone calls (min NR)								
			Total duration: 12 months								
Anderson, 1992 ³⁹	IG2	HD	10 60-min group dietary	Total: 26	Low-fat	Indiv	In-person		None (No)	Dietitian, project	UC
Fair	102		counseling sessions (AHA			Group	Phone		110110 (110)	staff	
			Diet) with 30-min	Other: 0	promoted	Group	none			NR, home	
			· · · · · · · · · · · · · · · · · · ·	Est Tot Hr: 20	F						
			consultation; 4 home visits								
			(min NR); 12 monthly								
			phone calls (min NR)								
			Total duration: 12 months								
	IG1	HD	3 individual sessions diet	Total: 3			In-person		NR (NR)	NR	WL
(Oslo Diet and			\mathcal{E}	Interactive: 3	Low sodium						
Exercise Study			Total duration: 9 months	Other: 0	Promoted for	•					
(ODES))					all						
Fair				Category: Medium							
Appel,	IG1	HD +	33 DASH diet and physical				In-person	X	None (No)	Master's degree-	UC
2003 ⁴¹ (PREMIER		PA			Low sodium		Print			level counselors	
)			8		Promoted for					(dietitians and	
Good				Est Tot Hr: 59	subset of					health educators	
			sessions and 7 30-60 min	Category: High	participants					trained in	
			individual sessions using							behavioral	
			motivational interviewing							methods)	
A mm o 1	IG2	IID :	Total duration: 18 months 33 sessions of low sodium	Total: 33	Low sodium	India	In none	v	Mona (Na)	Clinical centers	UC
Appel, 2003 ⁴¹ (PREMIER	102	HD +					In-person	Λ	None (No)	Master's degree- level counselors	UC
ZUUD (PKEMIEK		PA	diet and physical activity	Interactive: 33	Promoted for	Group	riiii			never counselors	

/ •	Int arm	Focus	description		Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	` /	Control Group
) Good			90-120 min group	Other: 0 Est Tot Hr: 59 Category: High	subset of participants					(dietitians and health educators trained in behavioral methods) Clinical centers	
Appel, 2011 ⁴² (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	IG1	HD + PA	sessions (90 min), 12 individual counseling sessions (20 min), 15	Interactive: 58 Other: 0	DASH Promoted for all participants	Indiv Group	In-person Tech- based Phone	X	Deliver part (NR)	Lifestyle coach Research clinic and home (web-based)	UC
Appel, 2011 ⁴² (POWER Hopkins (Practice Based Opportunities for Weight Reduction)) Good	IG2	HD + PA	weekly web-based modules, PCP counseling	Interactive: 34 Other: 0	DASH Promoted for all participants	Indiv	Tech- based Phone	X	Deliver part (NR)	PCP, lifestyle coach Home (web-based)	UC
	IG1	HD + PA	sessions of weight management, sodium restriction, and PA	Other: 0	Low sodium Promoted for all participants		In-person		None (No)	Registered dietitians Clinic	None
Arroll, 1995 ⁴⁴ Fair	IG1	HD + PA	Number/duration of sessions NR. Total duration: 6 months	Interactive: Other: 0 Est Tot Hr: Category: Low	Low sodium NR	Indiv	In-person Print		NR (NR)	GP "community setting"	Min
Arroll, 1995 ⁴⁴ Fair	IG2	PA	Advised to walk briskly 40mins, 3 days per week.	Total: Interactive:	NR	Indiv	In-person Print		NR (NR)	Research staff and GP	Min

/ •	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)		Control Group
				Other: 0 Est Tot Hr: Category: Low						"community setting"	
Arroll, 1995 ⁴⁴ Fair	IG3	HD	sessions NR. Total duration: 6 months	Total: Interactive: Other: 0 Est Tot Hr: Category: Low	Low sodium NR	Indiv	In-person Print		NR (NR)	Research staff and GP "community setting"	Min
Babazono, 2007 ⁴⁵ (PHPP) Fair	IG1	HD + PA	3 sessions of diet and physical activity counseling (length of sessions: NR), 1 at health			Indiv	In-person		None (No)	Dietitians, health exercise instructors, public health nurses Medical center, home visits	
Beckmann, 1995 ⁴⁶ Fair	IG1	HD	dietary counseling sessions Total duration: 12 months		Low sodium Promoted for subset of		In-person		None (No)	Nutritionist Outpatient clinic	WL
Bennett, 2012 ⁴⁷ (Be Fit, Be Well [POWER]) Good	IG1	HD + PA	counseling calls (20 min	Total: 31 Interactive: 30 Other: 0 Est Tot Hr: 18	Promoted for	Indiv Group	In-person Tech- based Phone Print	X	Deliver part (Yes)	Community health educator and PCP endorsement Home (web-based or print and phone) and community health center	UC
Bennett, 2018 ⁴⁸ (Track) Good	IG1	HD + PA	18 10-15 min telephone coaching sessions of diet and physical activity counseling, 3 PCP 2 min	Interactive: 21	Promoted for all participants	Indiv	In-person Tech- based Phone Print	X	Deliver part (Yes)	PCP, dietitian, psychology graduate students Primary care and home (coaching calls)	UC

(Study name) Quality	Int arm	Focus	description		Weight loss approach	Forma t	Delivery	Int	PCP (Staff involved?)	Setting	Control Group
Beune, 2014 ⁴⁹ (Culturally Adapted Hypertension Education (CAHE)) Fair	IG1	HD + PA	counseling and culturally- specific written materials	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 1.5 Category: Medium			In-person Print		None (Yes)	Practice Nurse Primary care	UC
Blackford, 2016 ⁵⁰ (Albany Physical Activity and Nutrition (APAN)) Fair	IG1	HD + PA	calls, 3 newsletters, and	Total: 9 Interactive: 6 Other: 0 Est Tot Hr: 1.5 Category: Medium			Tech- based Phone Print	X	None (No)	Research assistants Home	WL
Bloemberg, 1991 ⁵¹ Fair	IG1	HD	and 5 mailers	Total: 8 Interactive: 3 Other: 5 Est Tot Hr: 1 Category: Medium	NR		In-person Phone Print		None (No)	Dietitian NR	None
Bo, 2007 ⁵² Fair	IG1	HD + PA	5 sessions of diet and physical activity counseling (1 60-min individual session and 4 60-min interactive group sessions) and printed materials Total duration: 12 months	Total: 5 Interactive: 5 Other: 0	NR Promoted for subset of participants		In-person Print		None (Yes)	Nutritionists, specialists in endocrinology, and internal medicine Assumed health clinic	UC
Bosworth, 2009 ⁵³ (Take Control of Your Blood pressure (TCYB)) Fair	IG1	HD + PA	12 16-min phone sessions of diet and physical activity counseling and	Interactive: 12	Low sodium Promoted for subset of		Phone		None (No)	Nurse Home	UC
Bosworth, 2009 ⁵³ (Take Control of Your Blood	IG2	HD + PA	12 16-min phone sessions	Interactive: 12	DASH Low sodium Promoted for		Phone		None (No)	Nurse Home	UC

/ •	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach		Delivery	Int	Role of PCP (Staff involved?)		Control Group
pressure (TCYB)) Fair				Est Tot Hr: 3.2 Category: Medium	subset of participants						
Broekhuizen, 2012 ⁵⁴ (PRO-FIT) Fair	IG1	HD + PA	counsellor-initiated booster	Total: 6 Interactive: 6 Other: 0	NR	Indiv	In-person Tech- based Phone	X	None (No)	Trained lifestyle coach Participants' home	UC
Bruckert, 2008 ⁵⁵ (PEGASE (Effect of an Education Program)) Fair	IG1	HD + PA	6 sessions of diet and physical activity counseling (4 45-min group sessions, 2 in-person	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 4 Category: Medium	NR		In-person Print		None (No)	Physician, nurse, nutritionist Medical centers specializing in CVD prevention	UC
Burke, 2006 ⁵⁶ (ADAPT) Fair	IG1	HD + PA	6 group sessions of diet and physical activity counseling accompanied by 5 printed modules and 4 newsletters Total duration: 16 months	Total: 10 Interactive: 6 Other: 4 Est Tot Hr: 6 Category: Medium	DASH Promoted for all participants	Indiv Group Family	In-person Phone Print		None (No)	Dietitian, program coordinators Medical center	AC
Chirinos, 2016 ⁵⁷ (Community Health and Risk- reduction for Metabolic Syndrome (CHARMS)) Fair	IG1	HD + PA	17 (90-min) diet and physical activity group counseling sessions	Total: 17 Interactive: 17 Other: 0 Est Tot Hr: 25.5 Category: High	DPP Promoted for all participants		In-person		None (No)	Master and doctoral level clinicians Research clinic	UC
Christian, 2011 ⁵⁸ Fair	IG1	HD + PA	(10 min) and 2 physician motivational feedback	Total: 4 Interactive: 2 Other: 0 Est Tot Hr: 0.8 Category: Medium	NR Promoted for all participants	r	In-person Tech- based Print		Deliver all/most (Yes)	Computer expert system and PCP Community health center	UC

(Study name) Quality	Int arm		Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)		Control Group
Cicolini, 2014 ⁵⁹ Fair	IG1	HD + PA	session on healthy lifestyle and hypertension	Total: 27 Interactive: 1 Other: 0 Est Tot Hr: 1 Category: Medium	Low sodium NR		Tech- based Phone Print		None (NR)	Nurse care manager Home	UC
Cochrane, 2012 ⁶⁰ Fair	IG1	HD + PA	lifestyle counseling/motivational	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 3.5 Category: Medium	Promoted for subset of participants		In-person Phone	X	None (No)	Lifestyle coach Medical center	Min
Cohen, 1991 ⁶¹ Fair	IG1	HD	12 monthly diet counseling visits with family practice resident	Interactive: 12 Other: 0	Promoted for all participants		In-person		Deliver all/most (Yes)	Family practice resident Primary care	UC
Coleman, 2012 ⁶² (Wisewoman California) Fair	IG1	HD + PA	physical activity counseling (averaged 50		NR		In-person Phone Print		None (No)	Bilingual (English/Spanish) community health workers (from same community as participants) medical center (4 sites)	UC
Delahanty, 2001 ⁶³ Good	IG1		counseling	Other: 0	Promoted for subset of participants		In-person			Registered dietitian Medical center	UC

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Eakin, 2009 ⁶⁴	IG1	HD +	18 (average 18-min)	Total: 19	Low-fat			X	None (No)	Graduate-level	Min
(Logan Healthy		PA		Interactive: 18	NR		Print			counselors	
Living)			physical activity telephone							Home	
Fair			<u>U</u>	Est Tot Hr: 5.4							
			workbook	Category: Medium	L						
			Total duration: 12 months								
Edelman, 2006 ⁶⁵	IG1	HD +	52 total sessions of diet,	Total: 52	NR		In-person		None (No)	Master's level	UC
Fair		PA	μ 5	Interactive: 52		Group	Phone			trained health	
			mind-body approaches to	Other: 0						coaches,	
			`	Est Tot Hr: 68						nutritionists,	
				Category: High						physician,	
			30 min individual sessions)							physician assistant	
			Total duration: 10 months							Academic	
										"integrative"	
										medical center	
	IG1	HD +	22 diet and physical	Total: 22	Mediter	Indiv	In-person		None (No)	Registered	UC
Fair		PA		Interactive: 22	NR					dietitian, exercise	
			sessions (1 240-min	Other: 0						physiologist, stress	
				Est Tot Hr: 20.5						management	
			individual counseling	Category: High						instructor,	
			sessions with each of							psychologist, and	
			registered dietitian,							integrative health	
			exercise physiologist,							coach	
			stress management							NR	
			instructor, and								
			psychologist (time NR); 9								
			individual counseling								
			sessions with integrative health coach (time NR))								
			Total duration: 12 months								
Estruch, 2018 ⁶⁷	IG1	HD	21 sessions of diet	Total: 21	Mediter	Indiv	In-person	v	None (No)	Registered	Min
(Primary	101	מוו		Interactive: 21	Not	l l	Print	Λ	None (No)	dietitians	IVIIII
Prevention of			session with dietitian, 20	Other: 0	promoted	Group	111111			Primary care	
Cardiovascular				Est Tot Hr: 30.5	promoted					centers, university	
Disease with a			motivational interview and							health care centers,	
Mediterranean			group session), print	Category, ringil						hospitals	
Diet			materials (shopping list,							nospitais	
שוכו		1	materiais (snopping list,			1	l			1	

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	` /	Control Group
(PREDIMED)) Fair			weekly meal plans, recipes), and 20 15-liter allotments of extra-virgin olive oil Total duration: 60 months								
Estruch, 2018 ⁶⁷ (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	IG2	HD	21 sessions of diet counseling (1 individual session with dietitian, 20	Interactive: 21 Other: 0 Est Tot Hr: 30.5			In-person Print	X	None (No)	Registered dietitians Primary care centers, university health care centers, hospitals	Min
Fagerberg, 1998 ⁶⁸ (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)		HD + PA	7 sessions of diet and physical activity counseling (1 group informational session, five	Category: High	participants		In-person		None (No)	Physician, nurses, and dietitian Hypertension outpatient clinic	UC
Gill, 2019 ⁶⁹ (Heartmatters Challenge - First Responders) Fair	IG1	HD + PA	Total duration: 12 months	Interactive: 30 Other: 0 Est Tot Hr: 10	DASH Mediter Promoted for subset of participants		Tech- based Phone		None (No)	Registered dietitian Home	Min
Gill, 2019 ⁷⁰ (HealtheSteps) Fair	IG1	HD + PA	4 in-person individual sessions of diet and physical activity counseling (4 35-min			Indiv	In-person Tech- based		None (No)	Health coach Primary care community clinic sites	WL

/ •	Int arm	Focus	description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)		Control Group
			sessions), print materials, and health technology tools and resources (e.g., phone coaching, online HealtheSteps social network, smartphone app, HealtheSteps website) Total	Est Tot Hr: 2.3 Category: Medium			Phone Print				
Greaves, 2015 ⁷¹ (Waste the Waist) Fair		HD + PA	diet and physical activity counseling, 5 90-min group maintenance support	Interactive: 9 Other: 0	Low-fat Promoted for all participants		In-person Print	X	None (No)	Lifestyle coach Community	UC
Groeneveld, 2010 ⁷² (Health Under Construction) Fair		HD + PA	for weight loss or smoking counseling (4 45-60 min in-person counseling	Interactive: 7	participants	Indiv Family	In-person Phone Print	X	None (No)	Occupational physicians and occupational nurses in the role of lifestyle counselors Ocupational health clinic	UC
Hardcastle, 2008 ⁷³ Fair	IG1	HD + PA	1 3			Indiv	In-person Print	Х	None (No)	Physical activity specialist and a registered dietician Primary care	UC
Harris, 2012 ⁷⁴ (Health Improvement and Prevention Study (HIPS)) Fair		HD + PA	of diet and physical activity counseling and 6	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 10.2 Category: High	Promoted for subset of participants	Indiv Group	In-person		Deliver all/most (Yes)	GP and practice nurse, dietitian or exercise physiologist, intervention officer Primary care	WL

/ •	Int arm	Focus	description	Contacts	Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
			sessions Total duration: 12 months								
Haufe, 2019 ⁷⁵ Fair	IG1	HD + PA	session of diet counseling Total duration: 6 months	Total: 7 Interactive: 7 Other: 0 Est Tot Hr: 3.5 Category: Medium	Not promoted	Indiv	Tech- based Phone		None (No)	Exercise scientist Community/home	WL
Hinderliter, 2014 ⁷⁶ (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE))	IG1	HD	diet and 14 (30-45 min) in- person group sessions of	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 11.5 Category: High	DASH Not promoted	Indiv Group	In-person		None (No)	Nutritionist Medical research center	UC
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT)) Good	IG1	HD	28 60-min group dietary counseling sessions and 16 bimonthly newsletters Total duration: 36 months	Total: 28 Interactive: 28 Other: 0 Est Tot Hr: 28 Category: High	Low sodium Not promoted		In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT)) Good	IG2	HD	28 60-min group diet counseling sessions and 16 bimonthly newsletters Total duration: 36 months	Total: 28	Low sodium Promoted for subset of participants		In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT)) Good	IG3	HD	loss counseling sessions and 16 bimonthly newsletters	Total: 28 Interactive: 28 Other: 0 Est Tot Hr: 28 Category: High	NR Promoted for all participants	Group	In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT)) Good	IG4	HD	28 60-min group weight loss and sodium reduction counseling sessions and 16 bimonthly newsletters	Total: 28 Interactive: 28	Low sodium Promoted for all participants		In-person Print		None (No)	Nutritionists and behavioral specialists Research clinic	None

(Study name) Quality	Int arm	Focus	description		Weight loss approach	t	Delivery	Int	PCP (Staff involved?)	Setting	Control Group
Hyman, 1998 ⁷⁸ Fair	IG1	HD	of dietary education and behavioral changes, 12 mailed individualized diet	Other: 12		Group	In-person Phone Print		None (No)	Registered dietitian CHC	UC
Fair	IG1	HD + PA	smoking cessation, sodium reduction, and physical		Low sodium NR		In-person Phone Print	X	None (No)	Health educator Primary care clinic, home (phone sessions)	Min
Hyman, 2007 ⁷⁹ Fair	IG2	HD + PA	smoking cessation, sodium		Low sodium NR		In-person Phone Print	X	None (No)	Health educator Primary care clinic, home (phone sessions)	Min
Ives, 1993 ⁸⁰ (Rural Health Promotion Project (RHPP) Trial) Fair	IG1	HD + PA	5 visits of diet and physical activity counseling for cholesterol reduction Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2.5 Category: Medium		Indiv	In-person		None (No)	Hospital staff Hospital	UC
Ives, 1993 ⁸⁰ (Rural Health Promotion Project (RHPP) Trial) Fair	IG2	HD + PA	5 visits of diet and physical activity counseling for cholesterol reduction Total duration: 12 months	Total: 5 Interactive: 5 Other: 0 Est Tot Hr: 2.5 Category: Medium	NR		In-person		Deliver all/most (Yes)	Primary care clinic	UC
Johnston, 1995 ⁸¹ Fair	IG1	HD	\mathcal{E}	Total: 3 Interactive: 3 Other: 0	NR	Group	In-person Print		None (No)	Dietitian/nutritionis t NR	UC

/ •	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	\ \ /	Control Group
				Est Tot Hr: 4.5 Category: Medium							
Fair	IG2	HD		Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 1.5 Category: Medium		Indiv	In-person Print		None (No)	Dietitian/nutritionis t NR	UC
Jones, 1999 ⁸² (Hypertension Optimal Treatment (HOT)) Fair	IG1	HD	1.1	Total: 13 Interactive: 13 Other: 0 Est Tot Hr: 12 Category: High	NR Promoted for all participants	Indiv Group	In-person		NR (No)	Registered dietitian NR	UC
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	IG1	HD + PA	group classes about diet, physical activity, and stress reduction; 6 15-min	Total: 14 Interactive: 14 Other: 0 Est Tot Hr: 12.5 Category: High	NR Promoted for subset of participants		In-person Phone	X	None (No)	Health educators Community (classes and melas), home (phone calls)	UC
Kanke, 2015 ⁸⁴ Fair	IG1	HD + PA	12 7-min sessions of weight loss, diet, and physical activity counseling (1 introductory	Total: 12 Interactive: 12 Other: 0 Est Tot Hr: 1.4 Category: Medium	Promoted for all participants		In-person Print		Deliver all/most (Yes)	PCP Primary care	Min
Kastarinen, 2002 ⁸⁵ (Lifestyle Intervention against Hypertension in Eastern Finland	IG1	HD + PA	7 individual sessions of	Total: 9 Interactive: 9 Other: 0 Est Tot Hr: 7.5 Category: High	Low sodium Promoted for subset of participants		In-person		(Yes)	Public health nurses Primary health care center	UC

(Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)		Control Group
(LIHEF)) Fair Keyserling, 1997 ⁸⁶ (Southeast	IG1	HD	3 5-10 min in-person individual diet counseling	Total: 7 Interactive: 6	NR		In-person Print		all/most	PCPs; dieticians; health educators	UC
Cholesterol Project) Fair			visits with PCP, referral to 3 30-min in-person individual diet counseling with dietician, 1 mailing Total duration: 12 months	Other: 4 Est Tot Hr: 2 Category: Medium						Community and rural health centers, local health department, hospital outpatient services	
Khanji, 2019 ⁸⁷ (HAPPY London) Good	IG1	HD + PA	physician-delivered	Total: 1 Interactive: 1 Other: 0 Est Tot Hr: 0.4 Category: Low	Promoted for all participants		In-person Tech- based			Study physician Primary care, home	UC
Koelewijn-van Loon, 2009 ⁸⁸ (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair		HD + PA	2 (15-20 min) in-person individual diet and physical activity counseling sessions with practice nurse, 1 (10-min) follow-up telephone call, and printed materials Total duration: 1 months	Total: 3 Interactive: 3 Other: 0 Est Tot Hr: 0.8 Category: Medium			In-person Phone Print	X	None (Yes)	Nurses General practice	UC
Kramer, 2018 ⁸⁹ (Healthy Lifestyle Project) Fair	IG1	HD + PA	8	Other: 0 Est Tot Hr: 16 Category: High	DPP Promoted for all participants	Group	In-person Tech- based Phone Print			Registered dietitians and exercise specialist Senior community centers	WL

/ •	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)		Control Group
			pedometer and exercise bands. Total duration: 6 months								
Lakerveld, 2013 ⁹⁰ (HOORN) Fair	IG1	HD + PA	Nine sessions of diet and physical activity counseling (6 30-min individual counseling sessions and 3 30-min booster phone calls) Total duration: 16 months	Total: 9 Interactive: 9 Other: 0 Est Tot Hr: 4.5 Category: Medium		Indiv	In-person Phone	X	None (Yes)	Practice nurses Diabetes research center	UC
Langford, 1991 ⁹¹ (Trial of Antihypertensive Interventions and Management (TAIM)) Fair	IG1	HD + PA	10 group sessions and 2 individual sessions of lifestyle counseling for weight loss and 6 individual BP medication management visits Total duration: 6 months	Interactive: 18 Other: 0	NR Promoted for all participants	Indiv Group	In-person		NR (NR)	Nutritionists and therapists (nutritional intervention); NR (medical intervention) NR	Min
	IG2	HD	10 group sessions and 2 individual sessions of nutrition counseling for reducing sodium intake and increasing potassium intake and 6 individual BP medication management visits Total duration: 6 months	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 14 Category: High	Low sodium Not promoted	Indiv Group	In-person		NR (NR)	Nutritionists and therapists (nutritional intervention); NR (medical intervention) NR	Min
Lee, 2007 ⁹² Fair	IG1	PA	Median of 6 sessions of individual in-person and	Interactive: 6		Indiv	In-person Phone		None (No)	Public health nurse Community centers, home	UC
Liira, 2014 ⁹³ Fair	IG1	HD + PA	1 90-min in-person diet and physical activity counseling session Total duration: 0.03 months		NR	Indiv	In-person		None (No)	Public health nurses Primary care	UC

(Study name) Quality	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	PCP (Staff involved?)	Setting	Control Group
Fair	IG1	HD + PA	and one 20-min in-home health education session	Est Tot Hr: 8.3 Category: High	DASH Low sodium NR		In-person Phone Print	X	Deliver part (Yes)	phone system), PCP Home	Min
Moreau, 2001 ⁹⁵ Fair	IG1	PA	walking program	Total: 0 Interactive: 0 Other: 0 Est Tot Hr: 0 Category: Low	NR	Indiv	In-person		NR (No)	NR Home	None
Moy, 2001 ⁹⁶ Fair	IG1	HD	13 sessions of individual and family dietary counseling (1 120-min sessions and 12 60-min sessions) Total duration: 24 months	Total: 13		Indiv Family	In-person Phone		None (No)	Nurse NR	UC
Muhlhauser, 1993 ⁹⁷ (Hypertension Treatment and Teaching Program (HTTP)) Fair	IG1	HD + PA	4 60-90 min group counseling sessions on diet, exercise, and self- monitoring of blood pressure Total duration: 1 months	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 6 Category: Medium	NR		In-person Print		Deliver part (Yes)	Physicians and practice staff Primary health care	Min
Murphy, 2012 ⁹⁸ (National Exercise Referral Scheme (NERS)) Fair	IG1	PA	3 individual in-person sessions of physical activity counseling with 2 telephone calls focused on relapse prevention and discounted access to 1-on- 1 exercise instruction or group classes Total duration: 12 months	Interactive: 5 Other: 0		Indiv Group	In-person Phone	Х	None (No)	Exercise professional Leisure centre, home (phone)	WL
Neil, 1995 ⁹⁹ Fair	IG1	HD		Interactive: 2 Other: 0	Promoted for subset of participants	Indiv	In-person		None (No)	Dietitian General practice clinic	UC

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Setting	Control Group
Neil, 1995 ⁹⁹ Fair	IG2	HD	Total duration: 2 months	Interactive: 2	NR		In-person		None (No)	Nurse General practice clinic	UC
Niiranen, 2014 ¹⁰⁰ Fair	IG1	HD + PA	counseling (2 30-min individual counseling	Total: 8 Interactive: 8 Other: 0 Est Tot Hr: 3.2 Category: Medium	Low sodium Promoted for subset of participants	1	In-person Print		Deliver part (Yes)	PCPs and nurses Primary care, home	UC
Nolan, 2018 ¹⁰¹ (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH))	IG1	HD + PA	sessions including videos on diet, exercise, and BP	Total: 28 Interactive: 0 Other: 0 Est Tot Hr: NA Category: High	NR	Indiv	Tech- based	X	None (No)	NA (counseling fully automated) Home	Min
Ogedegbe, 2014 ¹⁰² (Counseling African Americans to Control Hypertension (CAATCH)) Fair		HD + PA	and physical activity counseling, four interactive computerized educational modules, and home BP monitoring Total duration: 6 months	Interactive: 6 Other: 0 Est Tot Hr: 6 Category: Medium	Low sodium Promoted for subset of participants	Group	In-person Tech- based	X	Deliver part (Yes)	nurses, and health educators (from study and community health center), physicians Community health center	Min
Reid, 2014 ¹⁰³ Fair	IG1	HD + PA	physical activity	Interactive: 17 Other: 0	NR Promoted for subset of participants		In-person Phone Print		None (No)	Health educators Tertiary care cardiac center	UC

/ •	Int arm	Focus	description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	\ /	Control Group
			1 45-min phone counseling session, and 15 15-20 min phone counseling sessions) and print materials on smoking cessation, healthy eating, weight mgmt, and physical activity Total duration: 12 months	Est Tot Hr: 6.5 Category: High							
Rodriguez, 2012 ¹⁰⁴ Fair	IG1	HD + PA	medication, and physical		Low sodium NR	Indiv	Phone		None (No)	Counselors (Master's degree or higher in psychology or social work) Home	UC
Rodriguez- Cristobal, 2012 ¹⁰⁵ Fair	IG1	HD + PA	24 sessions of individual lifestyle counseling on diet, PA, and smoking cessation (12 physician-delivered inperson sessions and 12 psychologist follow-up calls) Total duration: 24 months	Interactive: 24 Other: 0	NR Promoted for subset of participants		In-person Phone		Deliver part (Yes)	Physician, psychologist Primary care	UC
(Vivamos Activos Fair Oaks (VAFO)) Good	IG1	HD + PA	20 weight loss counseling sessions (15 120-min group sessions and 5 30- min individual counseling	Interactive: 27 Other: 0	DPP Promoted for all participants		In-person	X	None (No)	Research staff & community health workers Community health center, home	UC
Rosas, 2015 ¹⁰⁶ (Vivamos Activos Fair Oaks	IG2	HD + PA	20 weight loss counseling sessions (15 120-min		DPP Promoted for		In-person	X	None (No)	Research staff Community health center	UC

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
(VAFO)) Good			min individual counseling sessions) and take home items (pedometers, exercise CDs, and free weights) Total duration: 24 months		all participants						
Rubinstein, 2016 ¹⁰⁷ Good	IG1	HD + PA	physical activity	Total: 60 Interactive: 12 Other: 0 Est Tot Hr: 6 Category: Medium			Tech- based Phone Print	X	None (No)	Nutritionists Home	None
Salisbury, 2016 ¹⁰⁸ Good	IG1	HD + PA	activity, and blood pressure management counseling	Interactive: 12 Other: 0	Promoted for subset of participants		Tech- based Phone	X	None (No)	Health advisors Home	UC
Schoenthaler, 2016 ¹⁰⁹ (Individual Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	IG1	HD + PA	13 sessions of diet and physical activity counseling (10 60-90 min	Other: 0		Group	In-person Phone	X	None (No)	Health educators Hospital, home	Min
Scott, 2018 ¹¹⁰ Fair	IG1	PA	7 sessions of physical activity counseling (2 1-hr in-person sessions and 5 15-30 min phone sessions) Total duration: 3 months	Interactive: 7 Other: 0			In-person Phone	X	None (No)	PhD-level psychologist NR (in-person sessions), home (phone sessions)	UC

/ U	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Soto Rodriguez, 2016 ¹¹¹ Fair	IG1	HD	Three 90-min group sessions of CVD prevention counseling Total duration: 0.25 months			Group	In-person		NR (NR)	NR Health care	None
Stefanick, 1998 ¹¹² (Diet and Exercise for Elevated Risk (DEER)) Fair		HD	17 sessions of dietary counseling (1 individual session, eight 60-min group sessions, and 6-8 maintenance sessions) Total duration: 11 months	Total: 17	Low-fat	Group	In-person Phone Print		None (No)	Registered dietitians Research clinic, home	None
Stevens, 2003 ¹¹³ Fair	IG1	HD	2 45-min sessions of individual diet counseling (including 20-min computer assessment) and 2 10-min followup phone calls Total duration: 2 months	Other: 0	NR	Indiv	In-person Tech- based Phone Print	X	None (No)	Health counselors Research clinic	AC
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM)) Good	IG1	HD + PA	30 sessions of weight loss maintenance counseling (23 5-15 min phone sessions and 45-60 min individual in-person sessions); participants in extended followup received 4 in-person group sessions and an additional 29 5-15 min phone calls) Total duration: 60 months	Other: 0	NR Promoted for all participants		In-person Phone	X	None (No)	Research interventionist NR	Min
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM)) Good	IG2	HD + PA	Access to weight-loss maintenance support website, email reminders for weekly use for 30 months (median 107 log- ins) Total duration: 30 months	Interactive: 0 Other: 0	NR Promoted for all participants	1	Tech- based		None (No)	NA Home	Min

/ v	Int arm	Focus	Brief intervention description		Diet Weight loss	Forma t	Delivery		Role of PCP (Staff		Control Group
Quality			•		approach				involved?)	8	•
3 /		HD +	Physicians received 2 45-	Total: 39			In-person	X	Deliver part		UC
(Hypertension		PA	\mathcal{C}		Low sodium		Phone		(Yes)	interventionists and	
Improvement			modules, a pocket	Other: 4	Promoted for		Print			community health	
Project (HIP))			· · · · · · · · · · · · · · · · · · ·		subset of					advisors, PCP	
Fair			quarterly feedback reports.	Category: High	participants					Physician: Clinic,	
			Patients received 20							Patients: At or near	
			weekly group sessions of							participant's clinic	
			diet and physical activity							site	
			counseling followed by 12								
			monthly individual phone								
			sessions								
g 4 2000115	7.00	***	Total duration: 18 months	T 1 22	D + GYY	· ·	_			5.1.1.1	77.0
J /		HD +	20 weekly group sessions	Total: 32			In-person	X	None (No)		UC
(Hypertension		PA		Interactive: 32	Low sodium		Phone			interventionists and	
Improvement			activity counseling		Promoted for		Print			community health	
Project (HIP))			3	Est Tot Hr: 23	subset of					advisors	
Fair			individual phone sessions Total duration: 18 months	Category: High	participants					At or near	
			Total duration: 18 months							participant's clinic site	
Svetkey, 2009 ¹¹⁵	IG3	HD +	2 45-min online training	Total: 7	NR		Tech-		Deliver		UC
(Hypertension		PA	modules, pocket reference	Interactive: 0	111		based		all/most	trained)	
Improvement			care, and quarterly	Other: 0			Print		(Yes)	Clinic	
Project (HIP))				Est Tot Hr: 1.5					()		
Fair				Category: Medium							
Ter Bogt, 2009 ¹¹⁶	IG1	HD+	7 sessions of individual	_ ,		Indiv	In-person		Deliver part	General	UC
(Groningen		PA	diet and physical activity	Interactive: 12	Not		Tech-		(Yes)	practitioner, nurse	
Overweight and			counseling (1 GP session	Other: 0	promoted		based			practitioner	
Lifestyle (GOAL))				Est Tot Hr: 7.2			Phone			Primary care, home	
Good			followup calls over 3 years	Category: High							
			(estimated 245 mins of								
			contact in year 1)								
			Total duration: 36 months								
/		HD +	1 20-min individual		Promoted for	Indiv	In-person	X	None (Yes)		Min
(SPRING (Self-		PA		Interactive: 5	subset of					Primary care	
monitoring and			<u> </u>		participants						
Prevention of RIsk			T	Est Tot Hr: 2.1							
Factors by Nurse			based on self-monitoring	Category: Medium							

(Study name) Quality	Int arm		description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	\ \ /	Control Group
practitioners in the region of Groningen)) Fair			feedback with the number of follow-up visits determined by the presence of risk factors Total duration: 12 months								
(Inter99) Fair		PA	sessions of smoking cessation/reduction and diet and physical activity counseling and 6 120-min group sessions of diet and physical activity counseling Total duration: 60 months	Interactive: 10 Other: 0 Est Tot Hr: 14 Category: High	Low-fat Low sodium Promoted for subset of participants	Group	In-person	X	,	and dietitians Research center	Min
TOHP I CRG, 1992 ¹¹⁹ (Trials of Hypertension Prevention Phase I (TOHP I)) Good	IG1	HD	counseling (8 group counseling sessions and 2	Interactive: 26	Low sodium Not promoted	Indiv Group	In-person		None (No)	Registered dietitian and psychologist or exercise psychologist Research center	
1992 ¹¹⁹ (Trials of Hypertension Prevention Phase I (TOHP I)) Good		HD + PA	loss counseling (1 individual session and 29 group sessions) and optional individual check- in sessions Total duration: 18 months	Interactive: 30 Other: 0 Est Tot Hr: 36.5 Category: High	Promoted for all participants	Group	In-person		, ,	Registered dietitian and psychologist or exercise psychologist Clinical center	
TOHP II CRG, 1997 ¹²⁰ (Trial of Hypertension Prevention II (TOHP II)) Good		HD + PA	sessions (1 individual introductory session, 14	Interactive: 57 Other: 0	Low sodium Promoted for all participants		In-person Phone Print		None (No)	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	None

Author, year (Study name) Quality	Int arm	Focus	Brief intervention description	Contacts	Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Quanty			biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions) Total duration: 36 months		арргоасп				involved:)		
TOHP II CRG, 1997 ¹²⁰ (Trial of Hypertension Prevention II (TOHP II)) Good	IG2	HD + PA	57 weight loss counseling sessions (1 individual introductory session, 14 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions) Total duration: 36 months	Total: 57 Interactive: 57 Other: 0 Est Tot Hr: 48.5 Category: High	NR Promoted for all participants		In-person Phone Print		None (No)	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	None
TOHP II CRG, 1997 ¹²⁰ (Trial of Hypertension Prevention II (TOHP II)) Good	IG3	HD	53 sodium reduction counseling sessions (1 individual introductory	Total: 53 Interactive: 53 Other: 0 Est Tot Hr: 42.5 Category: High	Low sodium Not promoted		In-person Phone Print		None (No)	Centrally trained staff (dietitians, psychologists, or health counselors) Research clinic	None

(Study name) Quality	Int arm	Focus	Brief intervention description		Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Provider(s) Setting	Control Group
Tomson, 1995 ¹²¹ Fair	IG1	HD	6 sessions diet counseling, including 3 sessions with primary care physician and 3 sessions with dietician (1 individual, 1 with spouse, and 1 group session with trip to grocery store) Total duration: 12 months		Promoted for subset of participants		In-person		Deliver part (Yes)	PCP, dietician Medical center	UC
van der Veen, 2002 ¹²² (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	IG1	HD	counseling sessions with	Total: 6 Interactive: 6 Other: 0 Est Tot Hr: 1.7 Category: Medium	Promoted for subset of participants		In-person		Deliver all/most (Yes)	Family physician; dietician Family practice	UC
van Keulen, 2011 ¹²³ (Vitalum) Fair	IG1	HD + PA	physical activity counseling	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 1.3 Category: Medium		Indiv	Phone	X	None (No)	Counselors (students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	UC
van Keulen, 2011 ¹²³ (Vitalum) Fair	IG2	HD + PA	sessions of diet and physical activity counseling and 2 tailored letters Total duration: 10 months	Interactive: 2 Other: 2 Est Tot Hr: 0.7 Category: Medium			Print		None (No)	Counselors (students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	UC
van Keulen, 2011 ¹²³ (Vitalum) Fair	IG3	HD + PA	Four tailored letters addressing physical activity and consumption	Total: 4 Interactive: 0 Other: 4	NR	Indiv	Print		None (No)		UC

/ •	Int arm	Focus	description	Contacts	Diet Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)		Control Group
			\mathcal{E}	Est Tot Hr: 0							
G1 :: 2007124	TC1	D.4		Category: Low	NID	T 1'	T		D 1:	CDAID 1 DA	TIC
van Sluijs, 2005 ¹²⁴ (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	IG1	PA	Two GP/NP sessions of physical activity counseling (10-min consultation followed by a counseling appointment) and two phone sessions with physical activity	Total: 4 Interactive: 4 Other: 0 Est Tot Hr: 0.8 Category: Medium			In-person Phone		Deliver part (Yes)	GP/NP and PA counselor Clinic, home (phone)	UC
			counselors Total duration: 2 months								
Viglione, 2019 ¹²⁵ (Goals for Eating and Moving (GEM)) Fair	IG1	HD + PA	counseling delivered by	Total: 15 Interactive: 15 Other: 0 Est Tot Hr: 6.6 Category: High	Promoted for all participants		In-person Tech- based Phone Print	X		Health coaches (trained students), PC team Primary care (baseline and PCP visits), home (calls)	UC
Voils, 2013 ¹²⁶ (CouPLES) Fair	IG1	HD + PA	9 phone counseling sessions for the patient and 9 phone counseling sessions for their spouse	Total: 18 Interactive: 18 Other: 0 Est Tot Hr: 3.4 Category: Medium		Indiv Family	Phone Print		None (No)	Research nurse Home	Min
Wadden, 2011 ¹²⁷ (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	IG1	HD + PA	32 sessions of diet and lifestyle counseling (8 5-7 min individual sessions	Total: 32 Interactive: 32 Other: 0 Est Tot Hr: 6.9 Category: High			In-person Phone Print		Deliver part (Yes)	Medical assistant (lifestyle coach) and PCP Primary care	Min
Whelton, 1998 ¹²⁸	IG1	HD +	53 sessions of sodium	Total: 53	Low sodium	Indiv	In-person		None (No)	Nutritionists and	Min
(Trial of		PA	reduction and weight loss	Interactive: 53	Promoted for		•		` ′	exercise counselors	

(Study name) Quality	Int arm	Focus	description		Weight loss approach	Forma t	Delivery	Int	Role of PCP (Staff involved?)	Setting	Control Group
Nonpharmacologi c Interventions in the Elderly (TONE)) Good			counseling, including 7 individual and 46 group sessions. (Limited to pts with obesity) Total duration: 36 months		all participants					Academic health center	
(Trial of Nonpharmacologi c Interventions in the Elderly (TONE)) Good	IG2	HD + PA	53 sessions of weight loss counseling, including 7 individual and 46 group sessions. (Limited to pts with obesity) Total duration: 36 months		NR Promoted for all participants	Indiv Group	In-person		None (No)	Nutritionists and exercise counselors Academic health center	Min
Whelton, 1998 ¹²⁸ (Trial of Nonpharmacologi c Interventions in the Elderly (TONE)) Good	IG3	HD	53 sessions of sodium reduction counseling, including 7 individual and 46 group sessions Total duration: 36 months	Other: 0	Low sodium Promoted for subset of participants		In-person		None (No)	Nutritionists and exercise counselors Academic health center	Min
Wister, 2007 ¹²⁹ Good	IG1	HD + PA	2 30-min phone sessions (4 additional 20-30 min sessions for smokers) and 3 mailings, targeting smoking, diet, physical activity, weight management and/or stress management Total duration: 12 months	Interactive: 2 Other: 1 Est Tot Hr: 1 Category: Medium	Promoted for subset of participants		Phone Print	X	None (No)	Clinical lifestyle counselors (were also kinesiologists) Home	UC
Wong, 2015 ¹³⁰ Good	IG1	HD	1 3-5 min physiciandelivered UC session and 1 25-min dietitian-delivered DASH diet counseling session Total duration: 0.03 months		Low-fat DASH Low sodium NR		In-person Print			Physician and dietitian Primary care	UC

Author, year	Int	Focus	Brief intervention	Contacts	Diet	Forma	Delivery	Motiv	Role of	Provider(s)	Control
(Study name)	arm		description		Weight loss	t		Int	PCP (Staff	Setting	Group
Quality					approach				involved?)		
Wood, 2008 ¹³¹	IG1	HD +	Individual nurse	Total: 8	NR	Indiv	In-person	X	Deliver part	Nurses; family	UC
(EUROACTION)		PA	assessment with personal	Interactive: 8	Promoted for	Group			(Yes)	doctors	
Fair			report card and family	Other: 0	subset of	Family				General practice	
			support pack plus 8 group	Est Tot Hr: 8	participants					center	
			workshops of diet, PA, and	Category: High							
			risk factor counseling								
			Total duration: 4 months								

Abbreviations: AC = attention control; AHA = American Heart Association; DASH = Dietary Approaches to Stop Hypertension; DPP = Diabetes Prevention Program diet; Est Tot Hr = estimated total intervention contact hours; GP = general practitioner; HD = healthy diet only; HD = healthy diet and physical activity; IG = intervention group; Indiv = intervention delivered individually; Int arm = intervention arm; IVR = Interactive Voice Response; Mediter = Mediterranean diet; mgmt = management; Min = minimal intervention; min = minutes; Motiv Int = motivational interviewing; NR = not reported; PA = physical activity only; PCP = primary care provider; UC = usual care; WL = waitlist

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration		Control group description
Ammerman,	IG1	Participants received an intervention with 3 components: (1) Public	HD only	Nurse,	Usual care: Nurses
2003^{38}		health nurse-directed Food For Heart Program (FFHP) during three	Total contact hrs: 3.25	nutritionist	were instructed to
Fair		tailored counseling sessions, (2) referral to local nutritionist if lipids	Total duration: 12	Health	provide counseling for
		remained elevated at 3 month followup, and (3) a reinforcement	months	department	high cholesterol as
		program during the second half of the intervention (phone call, two			usual. Participants were
		newsletters focusing on seasonal tips for food preparation and			instructed to see their
		strategies to enhance dietary change). The FFHP is a theory-based			physician if total
		dietary assessment and tailored counseling program for lower income			cholesterol remained
		patients with high blood cholesterol who reside in the southeastern			high.
		United States. The FFHP is initiated and guided by the Dietary Risk			
		Assessment (DRA) instrument, a validated food frequency			
		instrument. The primary nutritional goals of the FFHP are aimed to			
		reduce consumption of foods high in saturated fat and increase fruit			
		and vegetable intake and complex carbohydrates. The nurse provided			
		structured, individually tailored dietary counseling with illustrated			
		goal sheets, educational pamphlets and southern-style cookbooks.			
		Behavior change recommendations were broken into small,			
		achievable steps, and specific strategies were recommended that			
		addressed barriers to dietary change. The DRA was used to monitor			
		progress and facilitate reinforcement during a followup counseling			
		session. Participants were also referred to a nutritionist for three			
		counseling visits if their 3-month lipid levels remained above the			
		NCEP cutpoints for nutritional counseling. Nutritionist reviewed			
		progress, helped address problems related to dietary change, and			
		worked with participants to set new goals.			
Anderson, 1992 ³⁹	IG1	Participants attended 10-weekly 1- hour group sessions; and after	HD only		Usual care: Participants
Fair		each session 30-min individual session with dietitian to discuss	Total contact hrs: 20	staff	were directed to
		dietary progress and set achievable goals. Each session followed	Total duration: 12	NR, home	maintain current
		recommended nutritional targets derived from the American Heart	months		dietary behaviors.
		Association Phase II guidelines: 55% carbohydrate energy, 20%			
		protein energy, 25% fat energy, ≤200 mg dietary cholesterol per day,			
		and dietary fiber was 50 g. Individually tailored preplanned meal			
		patterns with daily goal of 3 servings each of fruits and vegetables, 4			
		starches/breads (which always included 1 serving each of beans and			
		a cereal), 2 low-fat dairy, ≤198.5 g lean meat, poultry or seafood, no			
		egg yolks, fat servings based on energy content. Optional sweets and			
		alcohol servings available. No additional recommendations regarding			

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		modification of other risk-relevant behaviors (e.g., smoking, exercise). Encouraged to attend sessions with spouse/close friend; included demonstrations, problem solving, individual counseling (problems, questions about diet; goals). Home visits (4/year) by dietitian who provided further instruction and problem solving; also dietitian made monthly phone calls to check progress and problem solve.			
Anderson, 1992 ³⁹ Fair	IG2	Participants attended 10-weekly 1- hour group sessions; and after each session 30-min individual session with dietitian. Each session followed recommended nutritional targets derived from the American Heart Association Phase II guidelines: 55% carbohydrate energy, 20% protein energy, 25% fat energy, ≤ 200 mg dietary cholesterol per day, 15 g fiber. Individually tailored preplanned meal patterns for daily pattern with 3 servings each of fruits and vegetables, 4 starches/breads, 2 low-fat dairy, ≤ 198.5 g lean meat, poultry or seafood, no egg yolks, fat servings based on energy content. Optional sweets and alcohol servings available. No additional recommendations regarding modification of other risk-relevant behaviors (e.g., smoking, exercise). Encouraged to attend sessions with spouse/close friend; included demonstrations, problem solving, individual counseling (problems, questions about diet; goals). Home visits (4/year) by dietitian who provided further instruction and problem solving; also dietitian made monthly phone calls to check progress and problem solve.	HD only Total contact hrs: 20 Total duration: 12 months	Dietitian, project staff NR, home	Usual care: Participants were directed to maintain current dietary behaviors.
Anderssen, 1995 ⁴⁰ (Oslo Diet and Exercise Study (ODES)) Fair	IG1	3 individual sessions diet counseling. Diet counseling was individualized and included spouse at the initial session, with additional sessions at 3 and 9 months followup without spouse. Diet messages were to decrease total calories, increase fish, reduce total and saturated fat, increase vegetables, and reduce sugar. Participants with elevated BP were advised to reduce salt. A target body weight reduction goal was set during counseling (typically 0.5 to 1 kg per month).	HD only Total contact hrs: 1.5 Total duration: 9 months	NR NR	Waitlist: Participants were offered dietary advice and physical training after 1 year. CG were told not to change their lifestyle during the trial but were advised against smoking.
Appel, 2003 ⁴¹ (PREMIER) Good	IG1	Same goals as IG2 plus instruction and counseling on the Dietary Approaches to Stop Hypertension (DASH) diet. Goals related to DASH diet were: increased consumption of fruits and vegetables (9-12 servings/day) and low-fat dairy products (2-3 servings/d), and	HD + PA Total contact hrs: 59 Total duration: 18 months	level counselors (dietitians and	Usual care: Interventionist discussed nonpharmacological

Author, year (Study name) Quality	Int arm Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
· · · · · · · · · · · · · · · · · · ·	reduced intake of saturated fat (≤7% of energy) and total fat (≤25% of energy). To achieve weight loss, increased physical activity and reduced total energy intake was emphasized (as in IG2) but DASH intervention also emphasized substitution of fruits and vegetables for high-fat, high-calorie foods. In addition to food diaries, recording physical activity, and monitoring calorie and sodium intake (as with IG2), DASH intervention participants also monitored intake of fruits, vegetables, and dairy products and monitored their intake of fat. The individual 30-60 minute sessions focused on the participant's specific concerns, behavior change goals, and ways to maintain motivation during challenging situations. Interventionists used motivational enhancement techniques to assess the participant's current stage of change relative to dietary and physical activity behavior. Participants received individualized graphs of attendance, weight change, physical activity, and dietary goals to use as resources for goal setting and problem solving. The 90-120 minute group sessions were interactive, with group activities to foster problem solving, support, and program ownership. Behavior-change techniques (checking progress, problem solving, action planning, goal setting, and self-monitoring) occurred at each session. PA was incorporated into group sessions where participants exercised along with videos, took group walks, and watched demonstrations of stretching, weight training, and aerobics. Print materials contained information on physical activity, sodium, alcohol, weight loss, and DASH dietary recommendations The intervention was composed of 3 phases. The Intensive Phase I consisted of 3 months of weekly contacts (8 group and 3 individual). The Intermediate Phase II consisted of 3 months of biweekly contacts (6 group and 1 individual) and the Maintenance Phase III consisted of 12 months of monthly group sessions supplemented with 3 individual visits.		trained in behavioral methods) Clinical centers	factors that affect blood pressure (weight, sodium intake, physical activity, and the DASH diet) and provided printed educational materials. Counseling on behavior change not provided. Advice provided in two 30-minute individual sessions, 1 immediately after random assignment and 1 after 6-month data collection visit.
	The link provided for publicly available curriculum no longer works: http://www.kpchr.org/public/premier/intervention/			

Author, year (Study name) Quality	Intervention description	Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Appel, 2003 ⁴¹ (PREMIER) Good	with BMI ≥25, (2) ≥180 minutes/week moderate-intensity physical activity, (3) daily intake ≤2400 mg dietary sodium, and (4) daily intake ≤1 oz alcohol (2 drinks) for men and ½ oz of alcohol (1 drink) for women. No goals for fruit, vegetable, or dairy intake; saturated fat goal ≤10%, total fat goal ≤30% of energy. To achieve weight loss, increased physical activity and reduced total energy intake was emphasized. Participants kept food diaries, recorded physical activity, and monitored calorie and sodium intake. The individual 30-60 minute sessions focused on the participant's specific concerns, behavior change goals, and ways to maintain motivation during challenging situations. Interventionists used motivational enhancement techniques to assess the participant's current stage of change relative to dietary and physical activity behavior. Participants received individualized graphs of attendance, weight change, physical activity, and dietary goals to use as resources for goal setting and problem solving. The 90-120 minute group sessions were interactive, with group activities to foster problem solving, support, and program ownership. Behavior-change techniques (checking progress, problem solving, action planning, goal setting, and self-monitoring) occurred at each session. Physical activity was incorporated into group sessions where participants exercised along with videos, took group walks, and watched demonstrations of stretching, weight training, and aerobics. Print materials contained information on physical activity, sodium, alcohol, and weight loss. The intervention was composed of 3 phases. The Intensive Phase I consisted of 3 months of weekly contacts (8 group and 3 individual). The Intermediate Phase II consisted of 3 months of biweekly contacts (6 group and 1 individual) and the Maintenance Phase III consisted of 12 months of monthly group sessions supplemented with 3 individual visits.	Total contact hrs: 59 Total duration: 18 months	Master's degree- level counselors (dietitians and health educators trained in behavioral methods) Clinical centers	Usual care: Interventionist discussed nonpharmacological factors that affect blood pressure (weight, sodium intake, physical activity, and the DASH diet) and provided printed educational materials. Counseling on behavior change not provided. Advice provided in two 30- minute individual sessions, 1 immediately after random assignment and 1 after 6-month data collection visit.
	http://www.kpchr.org/public/premier/intervention/			

Author, year (Study name) Quality		·	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Appel, 2011 ⁴²	IG1		HD + PA	Lifestyle coach	Usual care: At
(POWER		phone sessions, and PCP counseling at routine visits, including	Total contact hrs: 54	Research clinic	randomization,
Hopkins (Practice		weekly web-based modules and monthly e-mail messages.	Total duration: 24	and home (web-	participant met with a
Based			months	based)	weight-loss coach for
Opportunities for		designed to help participants set weight-related goals, self-monitor			brief orientation to the
Weight		weight and weight-related behaviors, increase self-efficacy and			static website and, if
Reduction))		support, and solve problems. Motivational interviewing was the			desired, after
Good		primary approach to interactions with participants. Participants were			participant's 24-month
		encouraged to lose 5% of their weight within 6 months and maintain			follow up visit, can
		reduced weight through end of study at 2 years. Participants were			meet again to discuss
		encouraged to log on to the study-specific Web site weekly that			weight management
		contained learning modules and opportunities for self-monitoring of			guidelines. Received
		weight, calorie intake, and exercise. Monthly e-mail messages were			NHLBI "Aim for a
		sent to provide tailored feedback. In addition, participants received			Healthy Weight"
		in-person contact with lifestyle coaches to encourage completing			brochure and a list of
		web-based module and reinforce key behaviors. In-person support			recommended Web
		included weekly contact in months 1-3 (9 group sessions plus 3			sites promoting weight
		individual sessions), monthly contact in months 4-6 (1 group session			loss.
		plus 2 individual sessions), and two monthly contacts in months 7-24			
		(1 group and 1 individual session [in-person or via phone per month).			
		Group sessions were 90 minutes and individual and telephone calls			
		were approximately 20 minutes. At routine medical visits, PCP			
		encouraged participant to actively engage in the intervention and			
		reviewed one-page report on patients' weight-loss progress at routine			
		office visits.			
Appel, 2011 ⁴²	IG2		HD + PA	PCP, lifestyle	Usual care: At
(POWER		and PCP counseling at routine visits. Intervention focused on	Total contact hrs: 11	coach	randomization,
Hopkins (Practice		behavioral self-management approaches designed to help participants	Total duration: 24	Home (web-	participant met with a
Based		set weight-related goals, self-monitor weight and weight-related	months	based)	weight-loss coach for
Opportunities for		behaviors, increase self-efficacy and support, and solve problems.			brief orientation to the
Weight		Motivational interviewing was the primary approach to interactions			static website and, if
Reduction))		with participants. Participants were encouraged to lose 5% of their			desired, after
Good		weight within 6 months and maintain reduced weight through end of			participant's 24-month
		study at 2 years. Participants were encouraged to log on to the study-			follow up visit, can
		specific Web site weekly that contained learning modules and			meet again to discuss
		opportunities for self-monitoring of weight, calorie intake, and			weight management
		exercise. Monthly e-mail messages were sent to provide tailored			guidelines. Received

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		feedback. In the first 3 months, participants received 12 weekly coaching calls with lifestyle coaches to encourage completing webbased module and reinforce key behaviors. In months 7-24, monthly coaching calls were received. Telephone calls were approximately 20 minutes. At routine medical visits, PCP encouraged participant to actively engage in the intervention.			NHLBI "Aim for a Healthy Weight" brochure and a list of recommended Web sites promoting weight loss.
Applegate, 1992 ⁴³ Fair	IG1		HD + PA Total contact hrs: 13 Total duration: 6 months	Registered dietitians Clinic	No advice: Received no treatment; if DBP exceeded 105 mm Hg, participants were placed on meds and removed from trial. At the end of the trial, any participant with DBP >90 mm Hg placed on open-label medication
Arroll, 1995 ⁴⁴ Fair	IG1	Exercise and salt interventions: Advised to walk 40mins 3 times per week, 1 page pamphlet, general article on BP/salt reduction, book containing salt content of common foods. Number and duration of sessions NR, but state that "The interventions were very simple and based on written and verbal information that could be easily used in a primary care setting. There was no intensive dietary advice" All participants kept a weekly diary tracking injuries or health problems and medication compliance.	HD + PA Total contact hrs: NR Total duration: 6 months	Research staff and GP "community setting"	Minimal intervention: Usual care; weekly diary of health problems and medication changes.
Arroll, 1995 ⁴⁴ Fair	IG2	Participants advised to walk briskly for 40 minutes 3 days a week. A plan to build up to this amount of exercise was determined by the patient's doctor. Number and duration of sessions NR, but state that "The interventions were very simple and based on written and verbal information that could be easily used in a primary care setting. There was no intensive dietary advice" All participants kept a weekly diary tracking injuries or health problems and medication compliance.	PA only Total contact hrs: NR Total duration: 6 months	Research staff and GP "community setting"	Minimal intervention: Usual care; weekly diary of health problems and medication changes.
Arroll, 1995 ⁴⁴ Fair	IG3	Participants advised to decrease their use of high salt foods and added salt when cooking and eating. Each person received a simple pamphlet, a general article about salt and BP, and an in depth book	HD only Total contact hrs: NR Total duration: 6 months	Research staff and GP	Minimal intervention: Usual care; weekly diary of health

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		with information about salt content of common foods. Number and duration of sessions NR, but state that "The interventions were very simple and based on written and verbal information that could be easily used in a primary care setting. There was no intensive dietary advice" All participants kept a weekly diary tracking injuries or health problems and medication compliance.		"community setting"	problems and medication changes.
Babazono, 2007 ⁴⁵ (PHPP) Fair	IG1	Team encouraged patients to set their own goals & to select lifestyle improvements that they were interested in making; choose and prioritize physical activity to achieve goals; provided advice about	Total contact hrs: 3 Total duration: 12 months	Dietitians, health exercise instructors, public health nurses Medical center, home visits	Usual care: Asked to return to the medical center 1 month after baseline assessments, where they received results and were given instructions on how to enhance physical activity via leaflets only.
Beckmann, 1995 ⁴⁶ Fair	IG1	adding salt at table or while cooking, avoiding sodium-rich foods, processed food; bake own bread, use oil, salt-free margarine and	HD only Total contact hrs: 2.5 Total duration: 12 months	Nutritionist Outpatient clinic	Waitlist: At 12 months, participants were given dietary advice similar to that given to the intervention group.
Bennett, 2012 ⁴⁷ (Be Fit, Be Well [POWER]) Good	IG1	min each); 12 optional group sessions; PCP endorsement message; and self-monitoring using study website or interactive voice response	HD + PA Total contact hrs: 18 Total duration: 24 months	Community health educator and PCP endorsement Home (web- based or print and phone) and	Usual care: Received NHLBI self-help booklet, "Aim for a Healthy Weight."

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration		Control group description
		self-monitored behavioral goals via the study website or printed logs which were then entered into an interactive voice response system. Trained community health educators delivered monthly 15-20-min telephone counseling calls in the first year and bimonthly during the second year (18 telephone calls total) that covered data from self-monitoring, problem solving and behavioral skills training. Twelve optional bimonthly group sessions were also offered including interactive skills training and a physical activity component (e.g., group walk), and promoting social support for behavioral change. PCP delivered at least 1 brief, standardized message about the importance of intervention participation. Participants were provided behavior change "prescription" that included PCP's electronic signature, as well as tailored information on community resources (e.g., public parks, walking groups, and farmers' market) and		community health center	
Bennett, 2018 ⁴⁸ (Track) Good	IG1	received a walking kit with a pedometer. Weight-loss intervention informed by social cognitive theory, and had a weight loss goal of 7% weight reduction. The Track intervention contained five components: (1) tailored physical activity- and diet-related behavioral goals; (2) self-monitoring of behavioral goals via interactive voice response (IVR) phone calls and SMS text messages with automated, tailored feedback; (3) daily self-weighing via a cellular connected scale; (4) skills training materials in print and video; (5) 18 weight loss counseling 10-15 min coaching calls (weekly for calls 1-4; biweekly for calls 5-10; and monthly for calls 11-18), during which registered dietitians and psychology graduate students (i) reviewed self-monitoring data (behavioral goals and daily weights) and reinforced its importance, (ii) discussed barrier reduction strategies, (iii) delivered skills training content, and (iv) discussed community resources; and (6) brief PCP-delivered weight-loss counseling at medical visits. To facilitate PCP counseling, regular participant progress reports were delivered to PCPs through the EHR that include the participant's status on behavioral change goals, weight change data, and feedback regarding the participant's adherence to self-monitoring. Clinicians are alerted to their updates through pop-ups that display upon opening an intervention participant's EHR. PCPs also received quarterly reports with feedback on their individual counseling rates. PCPs also			Usual care: Participants received current standard of care offered by their primary care providers, as well as self-help materials (NHLBI "Aim for a Healthy Weight") and a collated list of community resources for healthful eating, physical activity, and weight management. Participants also received quarterly newsletters that included seasonal-related health tips, and financial and safety information.

Author, year	Int arm	Intervention description	Intervention focus	Provider(s) Setting	Control group description
(Study name) Quality			Total contact (hrs) Total duration	Setting	description
Quanty		received annual in-service trainings and period presentations at staff meetings showing clinic-level data. Four individualized behavior change goals were selected among 24 dietary and PA goals, rotating every 8 weeks, based on a self-administered survey. Each person was assigned their top 3 goals based on a computer algorithm, and plus a rotating 4th goal which was the same for all participants. The 4th goal also changed every 8 weeks and were: (1) "no red zone foods" [red zone foods are commonly eaten high-calorie foods and beverages (sodas, sweet teas, desserts, potato chips, pizza, hamburgers) that the participant typically eats 3 times per week or more], (2) practice portion control,			
		(3) walk 7000-10000 steps per day.			
Beune, 2014 ⁴⁹ (Culturally Adapted Hypertension Education (CAHE)) Fair	IG1	Participants received three 30-minute culturally-appropriate hypertension education (CAHE) sessions adapting the "5As" model (ask, assess, advise, assist, arrange) over a period of 4.5 months, conducted by a trained practice nurse. During the first session, the PN educated the participant about hypertension and discussed hypertension treatment goals for the next 3 months, as well as potential barriers/facilitators in achieving treatment goals. During the second and third sessions, the PN discussed with the participant their experiences of culturally-specific barriers/enables in achieving their hypertension treatment goals, such as medication use and lifestyle changes. PNs also discussed the participant's current BP measurement; self-reported medication and lifestyle adherence; goals for the next 3 months; potential barriers/facilitators in achieving treatment goals; and feasible steps needed to maintain/achieve treatment goals. In addition to the CAHE sessions, participants received culturally-specific, educational written material, and if necessary, referrals to neighborhood facilities (e.g., walking clubs or health food stores) that could help Surinamese and Ghanaian patients adopt healthier lifestyles.		Practice Nurse Primary care	Usual care: Participants received standard hypertension care and education following the recommendations in the Dutch clinical guidelines.
Blackford, 2016 ⁵⁰ (Albany Physical Activity and Nutrition	IG1		HD + PA Total contact hrs: 1.5 Total duration: 6 months	Research assistants Home	Waitlist: Participants received the intervention after completing post-test data collection.

Author, year (Study name) Quality	Int arm	, and the second	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(APAN)) Fair		weighing. The package contained a booklet, exercise chart, calendar, resistance bands, and nutrition panel wallet cards. The educational			
		materials provide illustrations and tips on how to perform exercises safely. The PA component will use accelerometers to measure PA at			
		baseline and posttest for the IG group only, with graphical feedback			
		provided to participants at baseline. A resistance band was provided			
		for strength training exercises. The nutrition component consists of			
		suggested meal plans, recipes, and tips on healthy eating,			
		encouraging a higher consumption of fruits and vegetables and fiber			
		while reducing intake of fat and sugar. The package materials were			
		adapted from PANS study materials for a rural context. The booklet			
		had materials based on the Australian Dietary Guidelines and			
		Australia's Physical Activity and Sedentary Behavior Guidelines,			
		which participants used to set their diet and PA goals for the duration			
		of the intervention. The calendar was used to support goal setting by			
		providing a resource for their planning and recording their PA and			
		eating habits and supplemented the program booklet as a quick and			
		convenient reference. In addition to the package materials,			
		participants received 6 motivational telephone calls (weeks 3, 6, 12, 18, and 24) utilizing strategies such as empathy, shared decision-			
		making, and reflective listening and followup emails from research			
		assistants, which were used to support goal setting and use of the			
		program resources. Participants chose their own goals. Participants			
		had the option to contact the research assistant they had been			
		allocated to throughout the course of the intervention. Participants			
		also received a bimonthly newsletter and had access to a website that			
		included diet and PA information and links, a blog for program news			
		and updates, and a daily and weekly progress tracker to PA, diet			
		behaviors, and weight.			
Bloemberg,	IG1	Participants received individualized dietary advice based on their	HD only	Dietitian	No advice: Did not
1991 ⁵¹		habitual food intake and the "Guidelines for a Healthy Diet" of	Total contact hrs: 1	NR	receive any advice to
Fair		Netherlands Nutrition Council. The aim of the advice was to lower	Total duration: 6 months		improve diet during the
		plasma total cholesterol level without lowering the HDL cholesterol			study period.
		level. With the aid of a study-created computer program, the study			
		dietitian examined data on participant baseline habitual food intake			
		and checked the effect of changes on the energy and nutrient content.			
		The computer program was also able to estimate the expected			

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		decrease of plasma total cholesterol level due to changes in fatty acid and cholesterol content of their diet. The aim of the dietary advice was to reduce total cholesterol by 1 mmol/L. One week after examination, dietitian counseled participants on their diet and tried to convince them to adhere to their advice. In addition, participants received an average of two telephone calls in which the dietitian inquired about possible problems related to their dietary advice. Five mailers with information on healthy diets were sent to participants.			
Bo, 2007 ⁵² Fair	IG1	Trained interventionists delivered the following: 1 individual session prescribing diet tailored to participants' current weight and dietary intake (normo- or hypocaloric); general dietary recommendations about cooking, reducing fat, sugar, and salt intake, and tips for dining out; discussion about behavior modifications; written recommendations for physical activity; a brief written guide on behavioral change; a copy of the food pyramid; explanations about the benefits of using diet and exercise to control metabolic abnormalities; and individualized diet and physical activity goals; and 4 group sessions for each different topics: food composition; portion control, strategies for dining out; and physical activity benefits. In addition, PCP delivered a brief general healthy lifestyle advice according to their usual practice to participants in both groups.	Total contact hrs: 5 Total duration: 12	Nutritionists, specialists in endocrinology, and internal medicine Assumed health clinic	Usual care: General information on the importance of a healthy lifestyle was given from participants' physicians according to their usual practice.
Bosworth, 2009 ⁵³ (Take Control of Your Blood pressure (TCYB)) Fair		Participants received a tailored behavioral self-management intervention, delivered by one nurse via bi-monthly telephone calls. Information was presented in an easily understood format with a		Nurse Home	Usual care: Participants received usual hypertension care from their primary care provider.

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration		Control group description
		same time of day. The trial nurse was not aware of home monitored			
Bosworth, 2009 ⁵³ (Take Control of Your Blood pressure (TCYB)) Fair		intervention, delivered by one nurse via bi-monthly telephone calls. Information was presented in an easily understood format with a readability score of 9th grade or less. Factors targeted in calls were: perceived risk for HTN, memory, literacy, social support, patients' relationships with their healthcare provider, and side effects of medication. The intervention also focused on improving adherence to the DASH diet, weight loss, reduced sodium intake, regular moderate intensity PA, smoking cessation, and moderation of alcohol intake. Each encounter included a core group of modules potentially		Home	Usual care: Participants received usual hypertension care from their primary care provider.
Broekhuizen, 2012 ⁵⁴ (PRO- FIT) Fair	IG1	one face-to-face counselling complemented with 1 to 5 telephone booster sessions (PRO-FIT*coach). The goal was to: 1) improve	HD + PA Total contact hrs: 2.25 Total duration: 11 months	Trained lifestyle coach Participants' home	Usual care: Usual care (no intervention)
		specifically with regard to physical activity, saturated fat intake, fruit and vegetables intake, smoking and compliance to statin therapy, and 4) lower the level of LDL-C and other biological CVD risk indicators and thereby reducing the CVD risk. Thus, the intervention was a personalized health counseling intervention that included the use of a website on CVD risk communication and how to change these risks; and access to online PRO-FIT advice account, which had tailored advice regarding positive behaviors such as food intake, smoking, and compliance to statin therapy, presented according to the individual participants risk profile; and a lifestyle coach who delivered personal feedback and worked with participants to make action plans using motivational interviewing techniques.			
Bruckert, 2008 ⁵⁵ (PEGASE (Effect of an Education	IG1		HD + PA Total contact hrs: 4 Total duration: 6 months	nutritionist	Usual care: Physicians received no training;

(Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Program)) Fair		action, maintain action. Group sessions included self-reflection on risks and threats to health, physical activity & healthy diet education, and information on cholesterol management and barriers to drug adherence, plus written materials. Educational messages were reinforced during individual sessions, along with focusing on translating individual goals into small, achievable steps and actions related to healthy behaviors.		specializing in CVD prevention	patients received usual care
Burke, 2006 ⁵⁶ (ADAPT) Fair	IG1	6 group workshops with printed materials for behavioral self-management of nutrition, physical activity and weight loss with emphasis on barriers, costs and benefits of a healthy lifestyle, goal setting, and time management. The DASH diet was the model for dietary advice with the following goals: sodium intake <2 g per day, increased intake of fruit, vegetables, and low-fat dairy, reduced intake of total and saturated fats, sweets, and sugary drinks; eating ≥4 fish meals per week; participating in ≥30 min of physical activity most days and increasing incidental activity; weight loss of ≥5%; reduced alcohol (consuming ≤2 drinks per day), and smoking cessation. Social support was encouraged by allowing a partner, relative, or friend to accompany participants during group sessions and involving them in grocery shopping, meal prep, and physical activity. Diet and physical activity calendars were used to track behaviors. Individual counselling sessions with dietician or program coordinator were offered, but few participated (5 individuals attended with 2 sessions each). A newsletter was issued every 3 months. Participants with 24-hr ambulatory BP <130/85 mm Hg at the end of 4 months had anti-HTN medications withdrawn; these participants then measured their BP using a home monitor with regular phone contact with study facilitators to report results of home-monitored BP.	HD + PA Total contact hrs: 6 Total duration: 16 months	Dietitian, program coordinators Medical center	Attention control: Usual care; publications from the National Heart Foundation of Australia & the Health Department of Australia; attention control with 4 seminars on topics unrelated to ADAPT were held as well.
Chirinos, 2016 ⁵⁷ (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	IG1		HD + PA Total contact hrs: 25.5 Total duration: 12 months	Master and doctoral level clinicians Research clinic	Usual care: At baseline and 6 months, received detailed description of their lab values and met with a medical provider for lifestyle modification advice, which is recommended

Author, year (Study name) Quality	Int arm	*	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		participants were not prescribed a structured dietary program. Unsupervised exercise, which consisted of brisk walking, was initiated at week 1, starting with four 15-min weekly sessions, increasing progressively to five 30-min weekly sessions by week 5. Dietary and exercise goals were aligned to national recommendations. Participants were asked to record their food intake in food logs and wear a pedometer for at least one week prior to each sessions. Sessions targeted a broad range of material related to diet,			management of the metabolic syndrome.
Christian, 2011 ⁵⁸ Fair	IG1	motivational readiness to increase physical activity and make dietary		Computer expert system and PCP Community health center	Usual care: Given a packet of health education materials addressing diabetes, diet, and exercise before completing their usual care visit
Cicolini, 2014 ⁵⁹ Fair	IG1		HD + PA Total contact hrs: 1 Total duration: 6 months	Nurse care manager Home	Usual care: Received 1-hour educational session on healthy lifestyle and

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		healthy lifestyle. And, in case of no read receipt, nurse care manage phoned participants to press for reading. The attached program to the emails contained recommendations on healthy lifestyle, including a diet high in vegetables and low in salt, saturated fat intake and cholesterol, moderate aerobic exercise, smoking cessation and/or replacement with nicotine/bupropion, moderate alcohol consumption, blood pressure self-monitoring (with instructions) and medication adherence.			hypertension management.
Cochrane, 2012 ⁶⁰ Fair		Health check plus 1 individual 45-60 minute lifestyle counseling/motivational interviewing session with lifestyle coach. The coach offered an additional maximum of 6 hours of support over 6 months and a final review at 12 months; subsequent contacts could be face-to-face, by telephone, or text message based on patient preference. Initial consultation session was used to discuss, develop, and negotiate a personalized health improvement plan and lifestyle improvement priorities identified by the patient. Referrals to free support sessions were offered, including PA sessions (free 20-week program), weight management support (free Weight Watchers vouchers), cooking and eating and positive thinking sessions, and access to smoking cessation support. Primary care toolkit publicly available at: https://www.healthcheck.nhs.uk/		Lifestyle coach Medical center	Minimal intervention: NHS health check plus usual general practice care, including medication or treatment for raised BP and/or cholesterol and newly diagnosed diabetes and referral to smoking cessation services, but did not receive additional lifestyle support. May have received lifestyle advice from the GP team.
Cohen, 1991 ⁶¹	IG1		HD only	Family practice	Usual care: Physicians
Fair		goal of the dietary advice was to reduce the caloric content of the die without radically changing the patient's lifestyle; suggested diets were not specifically intended to be salt-reducing. At the initial visit, the resident reviewed the patient's diet using a questionnaire. Information was provided about the calorie content of foods and suggestions for changes made as appropriate. Patients were encouraged to use a diet history sheet to evaluate and modify diet. At each visit the patient's weight was recorded and any weight change noted, and dietary analysis and advice repeated. Short-term goals were set for the patient to meet by the next visit. The amount of weight gained or lost at each visit was used as feedback.	Total duration: 12 months	resident Primary care	received no special instructions or materials. Participants received usual care; physicians could provide or refer participants for dietary advice. Participants were instructed about the importance of blood pressure control.

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		Management of the patient's hypertension medication was left to the PCP.			
Coleman, 2012 ⁶² (Wisewoman California) Fair	IG1		HD + PA Total contact hrs: 3.25 Total duration: 6 months) community health workers (from same community as participants)	Usual care: Usual care for elevated blood pressure and cholesterol. May have included brief healthy behavior education, healthy lifestyle handouts (general, related to hypertension/hyperlipid emia), and/or referral to education classes. Received incentives during assessments.
Delahanty, 2001 ⁶³ Good	IG1	Participants received cholesterol lowering nutritional counseling and treatment according to NCEP-based cholesterol lowering protocol (e.g., progressively reducing intake of saturated fat and cholesterol and to promote weight loss for participants who are overweight by eliminating excess total calories and increasing physical activity). Participants were required to meet with a registered dietitian for a minimum of 2 to 3 visits over a 2- to 3-month period (average 90-min/session, range 60-140 min, average of 2.5 sessions), followed by an additional 2-3 visit over the next 3 months of lipids were not in the target range, average 30 min/session, average of 1.5 sessions). The number of visits each participant received was based on an assessment of each volunteer's eating habits, lifestyle, capabilities, and motivation for change, in addition to usual care from PCPs.	HD + PA Total contact hrs: 4 Total duration: 6 months	Registered dietitian Medical center	Usual care: Participants received usual care and were instructed not to use lipid-lowering drugs or to seek additional dietary counseling.
Eakin, 2009 ⁶⁴ (Logan Healthy Living) Fair	IG1	The intervention was delivered over 18 months with 18 phone calls (10 over 12-month implementation period and 8 over 8-month maintenance period), during which participants received counseling	HD + PA Total contact hrs: 5.4 Total duration: 12 months	Graduate-level counselors Home	Minimal intervention: After each assessment, participants received a brief and tailored letter with feedback on their results. They also received generic

Author, year	Int arm	Intervention description	Intervention focus	Provider(s)	Control group
(Study name)			Total contact (hrs)	Setting	description
Quality			Total duration		
Quality		were guided through a series of steps, beginning with a detailed assessment of their current physical activity and dietary behaviors, followed by feedback on their health behaviors in relation to national recommendations. The feedback highlighted the discrepancy between their health goals and current health behaviors. Participants set collaborative goals for PA and dietary change with their telephone counselor, which was incorporated into a behaviorally-specific action plan specifying exactly what was to be done and when. Discussions included barriers and supports to behavior change, confidence in ability to change, and problem-solving as needed. Other components covered included goal setting, problem-solving, self-rewards, social support, positive self-talk, relapse, and action plans. Counseling followed the 4As approach: assessment,			brochures on a variety of health topics, including physical activity and diet, and a project newsletter with general health tips.
		advice, assistance, and arranging followup. Participants were encouraged to meet the Australian dietary recommendations (5 servings/day of vegetables, 2 servings/day of fruit,			
Fair		52 total sessions of diet, physical activity, and mind-body approaches to reduce CVD risk (2 individual in-person sessions providing feedback on CVD risk assessment results, 28 120-min group sessions, 20 20-30 min phone calls, and 2 individual nutrition counseling sessions). Baseline CVD risk assessment using "Know Your Number" with individualized feedback at baseline and 5-months from physician or physician assistant. With support of health coach, participants prioritized 1-3 goals for behavior change, and new goals were added once previous goals were achieved. Group sessions included mind-body approaches to self-care, nutrition education, physical activity education, and strategies for behavior change such as goal-setting, communication skills, and relapse prevention. Every two weeks, participants had individual telephone sessions (20-30 min) with their coach to reinforce group session techniques, to clarify priorities and set or update goals, and enhance motivation. Participants had 2 opportunities to meet with a nutritionist for individualized support and recommendations.	Total contact hrs: 68 Total duration: 10 months	trained health coaches, nutritionists, physician, physician assistant Academic "integrative" medical center	Usual care: The group received a mailed report including their health assessment and baseline blood test results.
Ellsworth, 2016 ⁶⁶ Fair	IG1	Participants first received a 3-month therapeutic education and lifestyle workshop in which they developed individualized lifestyle plans to reduce metabolic risk. Lifestyle plans focused on a Mediterranean-style diet that included moderate carbohydrate and	HD + PA Total contact hrs: 20.5 Total duration: 12 months	dietitian, exercise physiologist,	Usual care: Participants received standard care from their PCPs, but did not participate in

Author, year (Study name) Quality		•	Intervention focus Total contact (hrs) Total duration		Control group description
		animal/vegetable fat, weight loss, strength and endurance, and stress reduction. Participants first attended a 4-h orientation that outlined objectives, requirements and expectations and then met individually with a registered dietitian, exercise physiologist, stress management instructor and psychologist to learn effective strategies for integrating healthy changes into their current lifestyle. Subjects met monthly with each specialty provider to receive reinforcement for implementing recommended lifestyle changes and guidance for maintaining success on their own. Over the next 9 months, participants received additional instruction for integrating healthy behaviors into daily life through monthly contact with an integrative health coach.		instructor, psychologist, and integrative health coach NR	any component of the lifestyle programs or receive any advice or counseling beyond routine care information regarding healthy lifestyle behaviors.
Estruch, 2018 ⁶⁷ (Primary Prevention of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	1	Following randomization, all participants met with a dietitian to complete a questionnaire regarding adherence to the Mediterranean diet and discussed individual recommendations for changes to their		dietitians Primary care centers, university health care centers, hospitals	Minimal intervention: During the first three years, participants received one dietary counseling session with a dietitian at baseline and an annual leaflet explaining the low-fat diet. Thereafter, participants had quarterly individual and group sessions with the delivery of food descriptions, shopping lists, meal plans and recipes (adapted to the low-fat diet) in such a way that the intensity of the intervention was similar to that of the Mediterranean diet groups, except for the provision of free

Author, year (Study name) Quality	Int arm	*	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		emphasized the holistic approach to lifestyle change in order to tailor			supplemental olive oil
		the intervention to nutritional assessment and individual needs,			or nuts.
		encourage adherence to the MedDiet, transmit a sense of			
		empowerment, and, importantly, feel a self-reward for each upward			
		step in the 14-point MedDiet score. The focus was shifted from			
		changing portion sizes to changing frequency of intake or to changes			
		in cooking methods. Accomplishments in the previous months, even			
		if minor, are considered as support to provide further empowerment			
		and self-reward. The general guidelines to follow the Mediterranean			
		diet included: a) abundant use of olive oil for cooking and dressing			
		dishes; b) consumption of ≥2 daily servings of vegetables (at least			
		one of them as fresh vegetables in a salad), discounting side dishes;			
		c) \geq 2-3 daily servings of fresh fruits (including natural juices); d) \geq 3			
		weekly servings of legumes; e) \geq 3 weekly servings of fish or			
		seafood (at least one serving of fatty fish); f) ≥ 1 weekly serving of			
		nuts or seeds; g) select white meats (poultry without skin or rabbit)			
		instead of red meats or processed meats (burgers, sausages); h) cook			
		regularly (at least twice a week) with tomato, garlic and onion adding			
		other aromatic herbs, and dress vegetables, pasta, rice and other			
		dishes with tomato, garlic and onion. Participants were encouraged			
		to eliminate or limit the consumption of food products high in			
		saturated fat, simple carbohydrates, and sugar. The dietitians insisted			
		that two main meals per day should be eaten (seated at a table,			
		lasting more than 20 minutes). For usual drinkers, the dietitian's			
		advice was to use wine as the main source of alcohol (maximum 300			
		ml, 1-3 glasses of wine per day)			
		Interventionists applied common cognitive behavioral techniques,			
		including goal setting, self-monitoring, feedback and reinforcement,			
		self-efficacy enhancement, incentives, problem solving, relapse			
		prevention, and motivational interviewing in individual and group			
		sessions. Measurable realistic goals easily identifiable by the			
		participant and attainable in specified time frames were set.			
Estruch, 2018 ⁶⁷	IG2	Following randomization, all participants met with a dietitian to	HD only	Registered	Minimal intervention:
(Primary		complete a questionnaire regarding adherence to the Mediterranean	Total contact hrs: 30.5	dietitians	During the first three
Prevention of	1	diet and discussed individual recommendations for changes to their	Total duration: 60	Primary care	years, participants
Cardiovascular		diet in order to achieve a personalized goal depending on group	months	centers,	received one dietary
Disease with a		assignment. The dietitian provided reasons to adopt a Mediterranean		university health	counseling session with

Author, year (Study name)	Int arm Intervention description	Intervention focus Total contact (hrs)	Provider(s) Setting	Control group description
Quality		Total duration		
Mediterranean	diet, highlighting the advantages of following this diet rather than the		care centers,	a dietitian at baseline
Diet	risks of not adhering to it, and transmitting a positive message		hospitals	and an annual leaflet
(PREDIMED))	emphasizing the benefits for the high CV risk of the participants. The			explaining the low-fat
Fair	dietitian personalized the message by adapting it to the participant's			diet. Thereafter,
	clinical condition, preferences, and beliefs. The visit ended with an			participants had
	agreement to participate in the group session, which was scheduled			quarterly individual
	in the next 1-2 weeks. The group sessions were facilitated by the			and group sessions
	dietitians and were scheduled regularly and attended by ≤20			with the delivery of
	participants per session. During the group sessions, the dietitian gave			food descriptions,
	an informative talk regarding dietary goals, description and			shopping lists, meal
	clarification of written materials (descriptions of 4 to 5 foods typical			plans and recipes
	of the high-nut dietary pattern), a quantitative 1-week shopping list			(adapted to the low-fat
	of food items according to the season of the year, a weekly plan of			diet) in such a way that
	meals (with detailed menus) corresponding to the shopping list, and			the intensity of the
	the recipes for preparing the meals of the suggested menus),			intervention was
	allotments of supplemental foods (3-month supply of nuts consisting			similar to that of the
	of 1350 g walnuts, 675 g hazelnuts, 675 g hazelnuts [additional 1000			Mediterranean diet
	g packs of mixed nuts provided to each family unit]), and an			groups, except for the
	agreement to participate in the next visit 3 months later.			provision of free
	The individual motivational interviews and group sessions were			supplemental olive oil
	repeated every 3 months with the same content. Each visit included			or nuts.
	three steps: assessment, intervention, and future directions. The			
	general guidelines to follow the Mediterranean diet included: a)			
	abundant use of olive oil for cooking and dressing dishes; b)			
	consumption of ≥2 daily servings of vegetables (at least one of them			
	as fresh vegetables in a salad), discounting side dishes; c) $\geq 2-3$ daily			
	servings of fresh fruits (including natural juices); d) ≥ 3 weekly			
	servings of legumes; e) ≥ 3 weekly servings of fish or seafood (at			
	least one serving of fatty fish); f) ≥ 1 weekly serving of nuts or seeds;			
	g) select white meats (poultry without skin or rabbit) instead of red			
	meats or processed meats (burgers, sausages); h) cook regularly (at			
	least twice a week) with tomato, garlic and onion adding other			
	aromatic herbs, and dress vegetables, pasta, rice and other dishes			
	with tomato, garlic and onion. Participants were encouraged to			
	eliminate or limit the consumption of food products high in saturated			
	fat, simple carbohydrates, and sugar. The dietitians insisted that two			
	main meals per day should be eaten (seated at a table, lasting more			

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Fagerberg, 1998 ⁶⁸ (Risk Factor Intervention Study (RIS)) Good (KQ1); Fair (KQ2)		than 20 minutes). For usual drinkers, the dietitian's advice was to use wine as the main source of alcohol (maximum 300 ml, 1-3 glasses of wine per day). Interventionists applied common cognitive behavioral techniques, including goal setting, self-monitoring, feedback and reinforcement, self-efficacy enhancement, incentives, problem solving, relapse prevention, and motivational interviewing in individual and group sessions. Measurable realistic goals easily identifiable by the participant and attainable in specified time frames were set. Aims to reduce total cholesterol to <6.0 mmol/L, help current smokers quit, prevent nonsmokers from starting, reduce hemoglobin A1c to <6.0% in those with diabetes, and lower DBP to <90 mm Hg. Dietary advice was consistent with NCEP guidelines. After an initial informational group meeting, weekly group lessons for 5 weeks for 10-20 patients (and spouses) to change eating habits. Basic nutrition, purchase and preparation of food discussed using a slide series, a specially developed textbook and food/beverage exhibition. Overweight patients set a weight goal and restriction of alcohol intake encouraged for high consumers. Those with diabetes taught self-monitoring of glucose. Information provided about physical activity. At 4 months, individual follow-up visit with nurse to discuss results and further changes in dietary habits. Smoking cessation program consisting of 1 physician visit and weekly 1-hour group sessions were offered to smokers. Sessions included discussion of smoking habits, symptoms and diseases secondary to nicotine usage, psychological and social factors, and motivation for quitting. Nicotine gum was offered. At the 6 month visit, physicians started treatment with lipid lowering drugs and diabetes drugs if TC and/or HbA1c goals were not met.	HD + PA Total contact hrs: 11.5 Total duration: 4 months	Physician, nurses, and dietitian Hypertension outpatient clinic	Usual care: Usual care. Primary care provider treated hypercholesterolemia, diabetes, and smoking according to normal practice. Similar to IG, goal was to reduce DBP to <90 mm Hg so that differences in endpoint rates were not attributable to difference in BP.
Gill, 2019 ⁶⁹ (Heartmatters Challenge - First Responders) Fair	IG1		HD + PA Total contact hrs: 10 Total duration: 12 months	Registered dietitian Home	Minimal intervention: Completed 3-day food journals prior to each blood draw at FUP timepoints.

Author, year (Study name) Quality	Int arm	·	Intervention focus Total contact (hrs) Total duration		Control group description
		waist to height ratio. Carbohydrates recommendation were based on the severity of metabolic syndrome, and promoted unrefined natural sources such as vegetables, legumes, fruits, low-fat dairy, and whole grains. Dietary cholesterol was limited to 300 mg/dL, or 200 mg/dL for subjects with CVD, LDL ≥160 mg/dL or abnormally high cholesterol absorption. A 30% reduction in total energy intake was recommended to those requiring weight loss. Online food journals were reviewed during 20-minute one-on-one telephone lifestyle coaching sessions.			
Gill, 2019 ⁷⁰ (HealtheSteps) Fair	IG1	4 in-person individual sessions of diet and physical activity counseling (4 35-min sessions), print materials, and health technology tools and resources (e.g., phone coaching, online HealtheSteps social network, smartphone app, HealtheSteps website). Participants received 'Eating Well with Canada's Food Guide' and the 'Canadian Physical Activity Guidelines for Adults' and met with their coach to set their exercise (moderate to vigorous intensity), physical activity (steps/day) and healthy eating prescriptions and discuss strategies to achieve their goals. Specifically, sessions were personalized to the participant focusing on setting S.M.A.R.T. (specific, measurable, attainable, realistic, and timely) goals. For the exercise prescription, participants completed a validated Step and Exercise Prescription providing a personalized target heart rate to measure and assist participants meeting their personal recommendations for moderate to vigorous activity. Coaches also discussed and encouraged strategies with participants on how to increase the amount of time that they spent exercising at their target heart rate. For the physical activity prescription, participants used a pedometer to record their average daily step count for 1 week (baseline). A paper chart was used to guide participants to incrementally increase their step count up to 10,000 steps per day. For aiding in further reducing sedentary behaviour, participants were instructed to reduce their sitting time in addition to increasing their step count daily. Lastly, a heathy eating prescription was planned so that the participant would increase (or decrease) their intake of fruits and vegetables, fats, carbohydrates and protein until they met the recommendations set out by Health Canada through Eating Well with Canada's Food Guide.		Primary care community clinic sites	Waitlist: At allocation, participants were provided with copies of 'Eating Well with Canada's Food Guide' and the 'Canadian Physical Activity Guidelines for Adults'.

(Study name)	Int arm	Intervention description	Intervention focus Total contact (hrs)		Control group description
Quality	TO 1		Total duration	T. C 1 1	T. 1 D : C
			HD + PA	,	Usual care: Brief
(Waste the Waist)			Total contact hrs: 15.5	•	advice from usual PCP
Fair		1.5, 2, 4, 6, and 9 months. Goals included increasing PA, reducing	Total duration: 9 months		care. Received standard
		intake of total and saturated fat, increasing fiber intake, and other			pack of written
		dietary changes to achieve 5% weight loss, although specific goals			information on
		were chosen by each participant. Participants were invited to bring			cardiovascular risk and
		along a partner if they wished. Each session comprised a series of			the effects of diet and
		short sections to elicit and exchange ideas (e.g., about the importance			physical activity on
		of exercise, risks of excess weight, healthy eating etc.), learn key			such risk. After 12
		facts about diet and physical activity and skills of action/coping			months, participants
		planning, self-monitoring and problem-solving. Early sessions			were offered condense
		focused on the skills and information required to adopt a new			(two sessions) version
		behavior, and later sessions introduced discussions more relevant to			of the intervention.
		the maintenance of behavior, such as dealing with stress and			
		challenging situations, and how to maintain motivation if weight loss			
		'plateaus'. Sessions also encouraged emotional self-regulation, and			
		included a cognitive behavioral therapy technique for impulse			
		control. The main focus of sessions was to equip participants with a			
		better understanding of what a healthy lifestyle is and it is			
		importance, as well as to encourage them towards the continued use			
		of self-regulatory activities (goal-setting, self-monitoring of behavior			
		and weight, reviewing progress, problem-solving and review of			
		goals) and to help them to better understand the process of behavior			
		change over the long term. At the start and end of each session			
		participants were reminded of the program's two key messages			
		designed to encourage sustainable lifestyle change; (i) small changes			
		can make a big difference to their weight and your health, and (ii)			
		aim for a lifestyle that is both healthy and enjoyable (make changes			
		that they can live with). Participants were provided with a handbook			
		including information for reference, and were given tasks each week;			
		these usually included implementing action plans set during session			
G 11	7.01	time.	****		** 1 ** **
			HD + PA		Usual care: Participants
2010 ⁷² (Health			Total contact hrs: 5.5		received usual care in
Under		trained to be lifestyle counselors. Using MI, the counselors guided	Total duration: 6 months		which an occupational
Construction)		participants through the process of becoming aware of their CVD		nurses in the role	
Fair		risk, changing their behavior, and maintaining the changed behavior		of lifestyle	informed them of their

Author, year (Study name) Quality	Int arm	Intervention description			Control group description
		delivered in three 45-60 minute in-person counseling sessions and four 15-30 minute telephone counseling sessions. Participants' wives or partners were invited to accompany them to the in-person sessions. During the first in-person session, the counselor explained the goals and procedure of the intervention and discussed the participant's knowledge about CVD risk factors and health consequences, their personal risk profile, current lifestyle, and family history. Also during the first session, participants were offered two types of interventions: (1) Energy balance - Both diet and PA were addressed. Depending on the current PA and dietary behavior of the participant, the focus was on both diet and daily PA; (2) smoking cessation. After choosing the intervention type, pros and cons of behavior change, and willingness, readiness, and perceived confidence in the ability to change were discussed. Last, the participant set long- and short-term goals, and formulated implementation intentions. In subsequent sessions, progress and barriers were discussed and short-term goals could be adjusted. No specific weight loss advice was given. In addition to the in-person and telephone sessions, counselors provided several brochures to each participant containing educational materials on lifestyle risk factors for CVD, smoking cessation, PA, healthy diet, and dietary guidelines of the Dutch Nutrition Center. Participants were also provided a leaflet describing products high in saturated fat and low-fat alternatives, a leaflet with caloric values of common food		counselors Occupational health clinic	CVD risk profile in person or by mail. In some cases the OP provided brochures about CVD risk factors and/or lifestyle. The OP could provide advice on the participant's lifestyle or refer them to a general practitioner, depending on the seriousness of the risk and the OP's usual practice.
Hardcastle, 2008 ⁷³ Fair	IG1	products, and a brochure with recipes for healthy meals. I motivational interviewing session of diet and/or physical activity counseling (20-30 mins) with up to 4 optional MI sessions offered over the following 6 months (20-30 mins per session); average 2.0 sessions attended. MI sessions conducted by a registered dietician and/or physical activity specialist. Stage-matched motivational interviewing approach in which the focus on diet or physical activity depended on the participant's priorities and readiness to change. Techniques included agenda setting, exploring pros and cons, exploring concerns/building confidence, providing information, asking key questions, and negotiating a change plan. Standard leaflet about exercise and nutrition provided at baseline assessment.	Total contact hrs: 1 Total duration: 6 months	Physical activity specialist and a registered dietician Primary care	Usual care: Standard leaflet about exercise and nutrition provided at baseline assessment; included food and activity quiz which advice depending on score.

(Study name) Quality		•	Total contact (hrs) Total duration	Setting	Control group description
Harris, 2012 ⁷⁴ (Health Improvement and Prevention Study (HIPS)) Fair	IG1	This brief intervention with the PCP was modeled on the 5As framework (ask, advise, assess, assist, arrange). At the patient's health-check visit, the GP and practice nurse reviewed behavioral and physiological risk factors and provided brief lifestyle counseling. Patients were referred to the lifestyle-modification program if they were found to be at high risk, defined as including one or more of the following characteristics: (1) a history of gestational diabetes mellitus, or impaired glucose tolerance or impaired fasting glycemia; (2) hypertension (blood pressure [BP] ≥140/90 mm/Hg on two occasions) or already treated for hypertension; (3) dyslipidemia (any of: TC >4.5 mmol/L, LDL >2.5 mmol/L, TG >2.0 mmol/L, or already treated for dyslipidemia); (4) overweight (BMI ≥kg/m²); (5) waist circumference >102 cm in males or >88 cm in females; (6) current smoker. The lifestyle program included an initial visit with a dietitian or exercise physiologist for an assessment and individual goal setting, followed by attendance at a group education program, "CHANGE for HIPS", adapted from the patient education component of the Counterweight program. This comprised four 1.5-hour sessions over the first 3 months and a further two follow-up sessions at 6 and 9 months. Group sessions included education, physical activity (20−30 minutes of walking or resistance exercise) and self-management strategies (goal setting, self-monitoring, developing practical skills and problem solving) aimed at promoting positive dietary and physical activity changes and weight loss. Patients were encouraged to keep a food and physical activity diary and use a pedometer between sessions.		nurse, dietitian or exercise physiologist,	Waitlist: After 12 months of usual care, control practices were offered to join intervention.
Haufe, 2019 ⁷⁵ Fair	IG1	6 sessions of physical activity counseling and 1 session of diet counseling. Based on data from initial exercise tests, activity	HD + PA Total contact hrs: 3.5 Total duration: 6 months	Community/hom e	Waitlist: Participants were instructed to maintain their current lifestyle and were offered the intervention following the completion of the study.

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration		Control group description
		and to wear the monitors throughout the duration of the intervention. The smartphone application provided general information about the study, individual training goals, recommended heart rates for endurance activities, tips for increased physical activity in everyday life, and the exercise scientist's contact information. The exercise scientist monitored participants' physical activity levels using data from the application and provided feedback and adaptations to their further training schedule during monthly meetings. Participants were free to contact the exercise scientist by telephone or email at any time with questions. Adherence to the goal of 150 min of activity per week was assessed from self-started activities using the provided activity monitor. In addition to the exercise intervention, participants received nutritional counseling, which provided background			
		information on healthy food choices based on general recommendations issued by the German Society for Nutrition.			
Hinderliter, 2014 ⁷⁶ (Exercise and Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good		4 in-person individual instructional sessions on diet and 14 (30-45 min) group sessions of diet counseling. Intervention began with 2 week controlled feeding period followed by 14 weekly 30-45 minute small group sessions with nutritionist. Participants were asked not to exercise or attempt to lose weight. During controlled feeding period, provided study meals were isocaloric to prevent weight gain or loss and participant met twice weekly with nutritionist to learn about the DASH dietary pattern. Following feeding period, participants instructed to maintain DASH diet on their own. The goal of weekly group counseling sessions was to assist participants in learning how to buy and prepare appropriate foods, to enhance motivation to choose to eat those foods, and to overcome obstacles to following the diet. Participants weighed each week to monitor weight and make adjustments in the recommended servings so that weight would remain stable during the intervention period.		Medical research center	Usual care: Asked to maintain their usual dietary and exercise habits
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT)) Good	IG1	28 60-min group diet counseling sessions and 16 bimonthly newsletters: The HPT dietary intervention consisted of two phases: initial and maintenance. The initial phase consisted of 12 group sessions held during a 4-month period. Participants were given a goal to increase potassium intake to approximately 3,900 mg or more per day and reduce daily sodium intake to approximately 1,600 mg or less per day. Participants received counseling related to meal	HD only Total contact hrs: 28 Total duration: 36 months	Nutritionists and behavioral specialists Research clinic	No advice: No dietary counseling

Author, year (Study name) Quality	Int arm	•	Total contact (hrs) Total duration	Control group description
		planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Behavioral strategies included: (1) setting realistic daily and weekly goals for diet change; (2) assessing your diet at regular intervals to track your progress; (3) rewarding yourself for adhering to your diet; (4) Planning ahead, especially for meals away from home; (5) discussing your diet with family and friends and enlisting their help; (6) asking, when eating out, what is being served and request modifications as needed; (7) recognizing negative moods and thoughts that interfere with diet adherence and practicing a positive attitude; and (8) analyzing causes of recurrent dietary mistakes and taking steps to minimize them. Other specific content included building motivation, social eating strategies, assertiveness, problem solving, food cues, maintenance/relapse prevention strategies. The maintenance phase followed the initial phase and continued to the end of the study. It consisted of group sessions every second month. Participants who did not attend the group sessions were contacted by telephone and were provided a makeup with an individual session. The telephone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and		
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT)) Good	IG2	recipes. 28 60-min group diet counseling sessions and 16 bimonthly newsletters: The HPT dietary intervention consisted of two phases: initial and maintenance. The initial phase consisted of 12 group sessions held during a 4-month period. Participants were given a goal to reduce daily sodium intake to approximately 1,600 mg or less per day (individual goal: urine sodium excretion ≤70 mmol/d). Participants received counseling related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Same behavioral	Total contact hrs: 28 Total duration: 36 months	No advice: No dietary counseling

Author, year (Study name)	Int arm	Intervention description	Intervention focus Total contact (hrs)	Provider(s) Setting	Control group description
Quality			Total duration	F g	
		components as IG1. The maintenance phase followed the initial phase and continued to			
		the end of the study. It consisted of group sessions every second			
		month. Participants who did not attend the group sessions were			
		contacted by telephone and were provided a makeup with an			
		individual session. The telephone contact included a qualitative			
		assessment of the participant's dietary compliance based on self-			
		report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and			
		recipes.			
HPT, 1990 ⁷⁷	IG3		HD only		No advice: No dietary
(Hypertension		newsletters: The HPT dietary intervention consisted of two phases:	Total contact hrs: 28	behavioral	counseling
Prevention Trial		initial and maintenance. The initial phase consisted of 12 group	Total duration: 36	specialists	
(HPT))		sessions held during a 4-month period. Participants were given a goal	months	Research clinic	
Good		to reduce their weight by 5% through calorie restriction. Participants			
		received counseling related to meal planning and preparation, food			
		purchasing, and label reading to assist them in making the required			
		changes. Participants were asked to complete daily food records for			
		the basis to encourage participants to make further changes or to maintain their dietary changes. Same behavioral components as IG1.			
		inanitam their dietary changes. Same behavioral components as 161.			
		The maintenance phase followed the initial phase and continued to			
		the end of the study. It consisted of group sessions every second			
		month. Participants who did not attend the group sessions were			
		contacted by telephone and were provided a makeup with an			
		individual session. The telephone contact included a qualitative			
		assessment of the participant's dietary compliance based on self-			
		report. Throughout the maintenance phase, participants also received a bimonthly newsletter containing relevant dietary information and			
		recipes.			
HPT, 1990 ⁷⁷	IG4		HD only	Nutritionists and	No advice: No dietary
(Hypertension		newsletters: The HPT dietary intervention consisted of two phases:	Total contact hrs: 28	behavioral	counseling
Prevention Trial		initial and maintenance. The initial phase consisted of 12 group	Total duration: 36	specialists	
(HPT))		sessions held during a 4-month period. Participants were given a goal		Research clinic	
Good		to reduce their weight by 5% through calorie restriction and reduce			
		daily sodium intake to approximately 1,600 mg or less per day.			

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		Participants received counseling related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Participants were asked to complete daily food records for the basis to encourage participants to make further changes or to maintain their dietary changes. Same behavioral components as IG1. The maintenance phase followed the initial phase and continued to the end of the study. It consisted of group sessions every second month. Participants who did not attend the group sessions were contacted by telephone and were provided a makeup with an individual session. The telephone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Throughout the maintenance phase, participants also received			
100070		a bimonthly newsletter containing relevant dietary information and recipes.			
Hyman, 1998 ⁷⁸ Fair	IG1	dietary changes to reduce cholesterol levels. Intervention focused on improving practical skills like reading labels, eating out, modifying recipes and self-monitoring, while being practical for primary care. Phone calls included 1 to 4 questions asking about recent dietary behaviors, goals, intentions, or nutritional knowledge, and received an appropriate pre-recorded message. Class components included videos featuring practical skills to reduce fat and cholesterol intake and included cooking and tasting, recipe modification, role playing to restaurant ordering and dealing with pressure to eat high-fat meals.	Total contact hrs: 4.59999990463257 Total duration: 6 months	Registered dietitian CHC	Usual care: Usual care by primary care physician, hypercholesterolemic patients could be referred to clinic registered dieticians. After trial, offered the series of classes (waitlist control)
Hyman, 2007 ⁷⁹ Fair	IG1	Simultaneous counseling addressed smoking cessation, sodium reduction, and increasing PA during each of 3 brief individual inclinic counseling sessions held every 6 months. Each counseling visit was followed by 7 15-minute motivational interviewing telephone counseling sessions scheduled 2, 4, 6, 8, 12, 16, and 20 weeks later. Participants also received home-based instructional materials including a printed manual and motivational videotape. Primary goals for target areas included: stop smoking, reduce sodium levels	HD + PA Total contact hrs: 6 Total duration: 18 months	Health educator Primary care clinic, home (phone sessions)	Minimal intervention: Brief educational session on 3 target behaviors (smoking cessation, sodium intake reduction, increased physical activity). Postcards

Author, year (Study name) Quality	Int arm	<u> </u>	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		to 10,000 per week) where were all measured objectively. After each 6-month measurement visit, a postcard was mailed to participants to report how their measures compared to goals.			mailed after each 6- month measurement to report how measures compared to goals.
Hyman, 2007 ⁷⁹ Fair	IG2	(smoking cessation, sodium reduction, or increasing PA) during each of 3 brief individual in-clinic counseling sessions held every 6 months. Each counseling visit was followed by 7 15-minute motivational interviewing telephone counseling sessions scheduled 2, 4, 6, 8, 12, 16, and 20 weeks later. Participants also received home-based instructional materials including a printed manual and motivational videotape. Primary goals for target areas included: stop smoking, reduce sodium levels to 10,000 per week) where were all measured objectively. After each 6-month measurement visit, a postcard was mailed to participants to report how their measures compared to goals.	Total duration: 18 months	Health educator Primary care clinic, home (phone sessions)	Minimal intervention: Brief educational session on 3 target behaviors (smoking cessation, sodium intake reduction, increased physical activity). Postcards mailed after each 6- month measurement to report how measures compared to goals.
Ives, 1993 ⁸⁰ (Rural Health Promotion Project (RHPP) Trial) Fair	IG1	Appraisal and review of risk factors identified by the appraisal. Participants received 5 vouchers redeemable for cholesterol-lowering	HD + PA Total contact hrs: 2.5 Total duration: 12 months	Hospital staff Hospital	Usual care: Usual care; completed Health Risk Appraisal but results were not reviewed and not offered vouchers for screening or health education
Ives, 1993 ⁸⁰ (Rural Health Promotion Project (RHPP) Trial) Fair	IG2	5 visits of diet and physical activity counseling. Health Risk Appraisal and review of risk factors identified by the appraisal. Participants received 5 vouchers redeemable for cholesterol-lowering	months	PCP Primary care clinic	Usual care: Usual care; completed Health Risk Appraisal but results were not reviewed and not offered vouchers for screening or health education

(Study name) Quality		·	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Johnston, 1995 ⁸¹ Fair	IG1	3 90-min group sessions of diet counseling in groups of 2 to 6. Content included source and function of dietary cholesterol, risk associated with high cholesterol intake, debunking of dietary misconceptions, advice for eating out, and benefits of exercise. Partners invited to attend. At study entry, all patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 minutes) and a pamphlet about diet modification, cooking methods and physical exercise.	HD only Total contact hrs: 4.5 Total duration: 6 months	nist	Usual care: All patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 mins) and a pamphlet about diet modification, cooking methods and physical exercise. No further counseling. Incidental queries from the subjects were answered briefly on their return to clinic.
Johnston, 1995 ⁸¹ Fair	IG2	3 in-person individual sessions of diet counseling. Content included detailed diet history, food planning, cooking methods, recipe modification, shopping for food and exercise. At study entry, all patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 mins) and a pamphlet about diet modification, cooking methods and physical exercise.	HD only Total contact hrs: 1.5 Total duration: 6 months	nist NR	Usual care: All patients completed a simple health questionnaire which included basic info on diet and exercise; received verbal advice (~3 mins) and a pamphlet about diet modification, cooking methods and physical exercise. No further counseling. Incidental queries from the subjects were answered briefly on their return to clinic.
Jones, 1999 ⁸² (Hypertension Optimal Treatment	IG1	2 in-person individual counseling sessions on diet and 11 in-person group support sessions. Intervention began with two individual counseling sessions on food selection and preparation and establishment of weight reduction goals. Total caloric restriction and reduction of fat intake were the only methods used for weight	HD only Total contact hrs: 12 Total duration: 30 months	Registered dietitian NR	Usual care: Research nurse informed participants to lose weight but no

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(HOT))		reduction. Six group support sessions in first 3 months and then			counseling or group
Fair		every 3 to 6 months for duration of the study. Participants were not			support provided.
		counseled to exercise.			
Kandula, 2015 ⁸³	IG1		HD + PA		Usual care: After
(South Asian		referral by CBO staff. Following the primary care referral,	Total contact hrs: 12.5	Community	randomization, all
Heart Lifestyle		participants received a 16-week lifestyle intervention that included	Total duration: 4 months	`	participants were given
Intervention		group classes, experiential activities, behavior change counseling,		melas), home	a primary care referral
(SAHELI))		and telephone support. The 60-90 minute group classes were held		(phone calls)	by CBO staff. In
Fair		weekly for 6 weeks. Each class covered a different topic (#1: What is			addition to the primary
		Heart Disease and Understanding Your Risk Factors; #2: How to Get			care referral,
		More Exercise; #3: Eat Less Fat and Salt; #4: Enjoy Fruits,			participants received
		Vegetables, & Grains; #5: Maintain A Healthy Weight; #6: Taking			their baseline screening
		Care of Stress and Tension). During the classes, participants watched			results and monthly
		a video pertaining to the class topic, followed by a discussion,			mailing of National
		experiential activities, goal-setting, and closing review. Participants			Heart, Lung, and Blood
		were taught about national physical activity guidelines (e.g. 150			Institute's print
		minutes of moderate intensity physical activity per week) and diet			education materials on
		(e.g. 7 servings of fruits and vegetables per day) recommendations			heart disease, diet,
		and were encouraged to set a realistic goal based on their current			exercise, and weight
		behaviors using the recommendations as a guide. Individual			(translated into Hindi
		telephone support started after the group classes ended and ran to 10			and Urdu by academic
		weeks, biweekly and then monthly (6 total calls). The 15-min phone			and CBO staff).
		counseling used a motivational interviewing framework to focus on			Participants were
		self-reflection, behavior goals, and problem-solving. In addition to			advised to followup
		the group classes and phone support calls, participants had to option			with their PCP for
		to attend 4 heart healthy "melas" (festive gatherings) over the course			further advice.
		of 12 months that incorporated culturally-salient activities (yoga,			
		healthy cooking with a South Asian chef, aerobic exercise that built			
		on South Asian folk dance, and competitions with prices), which			
		were designed to reinforce healthy behaviors and increase group			
		cohesion and support. Melas were offered over 12 months to capture			
		multiple intervention group cohorts, we assumed only two of the			
		melas occurred prior to the final (6 month) followup for any given			
		intervention cohort.			
Kanke, 2015 ⁸⁴	IG1		HD + PA	PCP	Minimal intervention:
Fair		introductory session followed by 11 monthly or bimonthly routine	Total contact hrs: 1.4	Primary care	Participants received
		consultations). At the first consultation, the PCP counseled			same initial

Author, year	Int arm	Intervention description	Intervention focus		Control group
(Study name)			Total contact (hrs)	Setting	description
Quality			Total duration		
			Total duration: 12		intervention as IG1 at first consultation and
		reduction target (5% of baseline body weight), as well as the positive effect of weight reduction for the participant's specific disease	monus		usual care was
		(dyslipidemia, hypertension, or T2DM). In addition to the			provided at subsequent
		counseling, the PCP provided participants with an informational			(every 1-2 month)
		leaflet. Following the first consultation, participants received routine			consultations. The
		consultations every 1 or 2 months for the participant's specific			physician was not
		disease based on the Japanese guidelines. During these visits, the			required to measure
		PCP questioned the participant on key lifestyle factors for weight			body weight or discuss
		reduction (i.e., eating, exercising, and weight monitoring) and			weight reduction at
		provided the participant with information on the standard lifestyle			every consultation.
		changes: (1) reduce calorie intake to 25 kcal/kg ideal body			
		weight/day; (2) eat a well-balanced diet (calorie balance: protein, 10-			
		15%; fat, 20-25%; carbohydrate, 60%); (3) exercise for 20-30 min at			
		least 3 times per week. The physician advice focused on weight			
		reduction adjusted to each participant's circumstances and lifestyle.			
		Participants were weighed at all consultations.			
Kastarinen,	IG1		HD + PA	Public health	Usual care: Participants
2002 ⁸⁵ (Lifestyle		counseling and 2 120-minute group counseling sessions. Intervention		nurses	were instructed to see
Intervention		goals were to achieve a normal weight (BMI <25 kg/m ²), sodium	Total duration: 21	Primary health	their primary care
against		intake <5 g daily, <2 alcoholic drinks per day, moderate intensity	months	care center	providers according to
Hypertension in		exercise ≥ 3 times per week for 30 minutes, and to stop smoking if a			usual care practice.
Eastern Finland		smoker. During individual counseling visits with nurses, participants			
(LIHEF))		were instructed to change health behaviors on the basis of their			
Fair		individual situation. At each counseling visit, BP and weight were			
		measured and the values, as well as changes in lifestyle factors to be			
		reached before the next study visit, were written down in a followup card. The 2 120-minute group sessions focused on advice targeting			
		reduction of salt intake and overweight.			
Keyserling,	IG1		HD only	PCPs; dieticians;	Usual care: Usual care
1997 ⁸⁶ (Southeast		referral to 3 30-min in-person individual diet counseling with	Total contact hrs: 2	health educators	clinicians were advised
Cholesterol			Total duration: 12	Community and	to manage their
Project)			months	rural health	patient's
Fair		Assessment (DRA), a color and number-coded educational strategy		centers, local	hypercholesterolemia
		corresponding to the DRA to guide clinician counseling without		health	according to usual
		requiring extensive knowledge of behavior-change theory or food		department,	practices.
		composition, and easy-to-read illustrated patient educational		hospital	1

Author, year (Study name) Quality	Int arm		Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		materials that are culturally and regionally specific to the population. Includes identification of major sources of saturated fat and cholesterol and rates the atherogenicity of individual foods, weekly consumption for each food or preparation practice. If LDL-C remained elevated at 4 months, participants were referred to dietician or health educator for up to 3 30-minute sessions where the Food for Heart Program materials were used in greater depth along with other materials as appropriate. If LDL remained elevated at 7 months, the clinician received a prompt (a letter) to consider initiation of drug therapy. A mailing was sent to participants with recipes and health tips at 7 months.		outpatient services	
Khanji, 2019 ⁸⁷ (HAPPY London) Good	IG1	Diet and physical activity counseling (1 25-min physician-delivered counseling and instructional session and auto-generated personalized web-based counseling). At baseline participants received a 10-15 min physician-delivered personalized face-to-face counseling session on suboptimal lifestyle and cardiovascular risk factors based on guideline recommendations. The counseling was based on a lifestyle questionnaire and baseline measurements, and included advice on factors including blood pressure, cholesterol, glucose readings, smoking, weight, physical activity, fruit and vegetable intake, alcohol intake, and stress. During the same visit, participants received instructions on how to use the website for the HAPPY London web-based tool (5-10 min). The web-based tool provided a personalized score for the participant's lifestyle, 10-year risk score, and tailored advice and information specifically for the participant's relevant suboptimal risk factors. Ideal targets were highlighted as goals and updated during the 3 and 6-month visits. Additional regular email reminders were sent to encourage achievement of goals.	Total contact hrs: 0.42 Total duration: 6 months	Study physician Primary care, home	Usual care: Participants received a 10-15 min physician-delivered personalized face-to-face counseling session on suboptimal lifestyle and cardiovascular risk factors based on guideline recommendations during the baseline visit. The counseling was based on a lifestyle questionnaire and baseline measurements, and included advice on factors including blood pressure, cholesterol, glucose readings, smoking, weight, physical activity, fruit and vegetable intake, alcohol intake, and stress.

(Study name)	Int arm	Intervention description	Total contact (hrs)		Control group description
Quality Koelewijn-van Loon, 2009 ⁸⁸ (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair		2 (15-20 min) in-person individual diet and physical activity counseling sessions with practice nurse, 1 (10-min) follow-up telephone call, and printed materials. During the first meeting with the practice nurse, a risk communication tool was used with patients to explain 10-year CVD mortality risk. Options for risk reduction were presented to patients with increased risk and a decision aid was provided for review at home. During the second meeting approximately 2 weeks later, the nurse asked questions about the decision aid and asked the patient what they wanted to discuss with the help of an agenda-setting chart. Nurses guided patients in formulating personal goals for lifestyle change, focusing on one or more of smoking, physical exercise, dietary behavior (fruits and vegetables, fat intake), alcohol consumption, and adherence to medical treatment. A follow-up phone call using motivational interviewing was made approximately 2 weeks later to explore the	Total duration HD + PA Total contact hrs: 0.83 Total duration: 1 months	1	Usual care: Patients received usual care after risk assessment step. [Nurses received a 2-hour training session on risk assessment.]
(Healthy Lifestyle Project) Fair	IG1	importance of the lifestyle goal, increase patient confidence, and refer to local facilities as necessary. Participant could choose between 16 (1-hr) group lifestyle counseling sessions or 12 (1-hr) individually-viewed lifestyle DVD sessions followed by brief telephone sessions (5-min); both options included health-related handouts, self-monitoring logs, a fat and calorie counter, a pedometer and exercise bands. DVD sessions were made available to participants who missed a group session. Intervention was DPP-based and adapted to a group format with goals to achieve and maintain 7% weight loss and safely and progressively increase to 150 min/wk of moderately intense PA. Participants who chose face-to-face group delivery attended 12 weekly 1-hour sessions; followed by biweekly and then monthly meetings. Participants who chose the DVD watched 1 session each week for 12 weeks and received a brief weekly telephone call to assess weight and PA and ascertain understanding of the program content; these participants were also invited to attend monthly group meetings.		dietitians and exercise specialist Senior community centers	Waitlist: Received periodic health-related handouts via mail; will begin intervention in 6 months.
Lakerveld, 2013 ⁹⁰ (HOORN) Fair		Participants received a cognitive behavioral program, which combined several elements of both the theory of planned behavior & self-regulation. The intervention was provided by practice nurses in the participating general practices and consisted of six individual 30-	Total duration: 16	Diabetes research center	Usual care: Participants received written information about their risk of developing

Author, year (Study name) Quality	Int arm	Intervention description			Control group description
		min counseling sessions followed by three monthly booster sessions by phone over the period of one year. The counseling techniques included motivational interviewing and problem-solving treatment, with development of SMART goals and implementation plans. The aim of counseling was to increase motivation & ability to change dietary (fruit, vegetable, fiber, alcohol consumption, saturated fat), PA, & smoking behaviors (participants chose which behavior[s] they wanted to focus on). Motivational interviewing & problem-solving treatment were used to help patients find solutions to overcoming barriers & increase perceived control.			T2DM and CVD, and existing brochures containing health guidelines regarding physical activity, a healthy diet, and how to stop smoking. Patients with SBP >160 mm Hg and/or hypercholesterolemia (>8 mmol/L) were referred to their GP for additional medication.
Langford, 1991 ⁹¹ (Trial of Antihypertensive Interventions and Management (TAIM)) Fair		10 group sessions and 2 individual sessions of lifestyle counseling for weight loss and 6 individual BP medication management visits. Participants additionally randomized to either a diuretic (chlorthalidone 25 mg), a beta-blocker (atenolol 50 mg), or a placebo, as well as counseling for weight loss, consisting of 10 weekly group sessions followed by individual sessions every 6-12 weeks. The weight loss goal was a reduction of 10% of baseline weight or 4.54 kg. In addition, participants had monthly BP management clinical visits, which included (1) blood pressure and weight measurements; (2) review of interim history and symptoms, treatment status, compliance; and (3) dispensing of study drugs. Participants who failed to achieve adequate blood pressure control were stepped up to additional therapy at 6 months or sooner if emergency failure criteria were met. The additional step-up therapy included either 25 mg chlorthalidone or 50 mg atenolol for placebo failures; combined 25 mg chlorthalidone-50 mg atenolol therapy was given to the chlorthalidone or atenolol failures. Medication was increased during the first 6 months if DBP was ≥100 mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a week apart; or ≥115 mm Hg at any visit. If the additional step-up therapy did not adequately control DBP, open-label therapy (antihypertensive medication) was used.	Total contact hrs: 14 Total duration: 6 months	therapists (nutritional intervention); NR (medical intervention) NR	Minimal intervention: No further nutritional counseling beyond the initial explanation of the allocation and general consultation provided to all participants. Participants additionally randomized to either a diuretic (chlorthalidone 25 mg), a beta-blocker (atenolol 50 mg), or a placebo. In addition, participants had monthly BP management clinical visits, which included (1) blood pressure and weight measurements; (2) review of interim history and symptoms, treatment status,

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Control group description
				compliance; and (3)
				dispensing of study
				drugs. Participants who
				failed to achieve
				adequate blood
				pressure control were
				stepped up to
				additional therapy at 6 months or sooner if
				emergency failure criteria were met. The
				additional step-up
				therapy included either
				25 mg chlorthalidone
				or 50 mg atenolol for
				placebo failures;
				combined 25 mg
				chlorthalidone-50 mg
				atenolol therapy was
				given to the
				chlorthalidone or
				atenolol failures.
				Medication was
				increased during the
				first 6 months if DBP
				was ≥100 mm Hg for
				three visits at 2-wk
				intervals, ≥105 mm Hg
				at two visits a week
				apart; or ≥115 mm Hg
				at any visit. If the
				additional step-up
				therapy did not
				adequately control
				DBP, open-label
				 therapy

Author, year (Study name) Quality	Int arm	•			Control group description
					(antihypertensive
					medication) was used.
Langford, 1991 ⁹¹			HD only		Minimal intervention:
(Trial of		for reducing sodium intake and increasing potassium intake and 6	Total contact hrs: 14	1	No further nutritional
Antihypertensive		individual BP medication management visits. Participants			counseling beyond the
Interventions and		additionally randomized to either a diuretic (chlorthalidone 25 mg), a			initial explanation of
Management		beta-blocker (atenolol 50 mg), or a placebo, as well as nutritional		(medical	the allocation and
(TAIM))		counseling for reducing sodium intake and increasing potassium		intervention)	general consultation
Fair		intake, consisting of 10 weekly group sessions followed by		NR	provided to all
		individual sessions every 6-12 weeks. Sodium and potassium goals			participants.
		were individualized by weight and ranged from 52-100 mmol/day for			Participants
		sodium (average 87 mmol/day), and from 62-115 mmol/day for			additionally
		potassium (average 103 mmol/day). In addition, participants had			randomized to either a
		monthly BP management clinical visits, which included (1) blood			diuretic (chlorthalidone
		pressure and weight measurements; (2) review of interim history and			25 mg), a beta-blocker
		symptoms, treatment status, compliance; and (3) dispensing of study			(atenolol 50 mg), or a
		drugs. Participants who failed to achieve adequate blood pressure			placebo. In addition,
		control were stepped up to additional therapy at 6 months or sooner			participants had
		if emergency failure criteria were met. The additional step-up			monthly BP
		therapy included either 25 mg chlorthalidone or 50 mg atenolol for			management clinical
		placebo failures; combined 25 mg chlorthalidone-50 mg atenolol			visits, which included
		therapy was given to the chlorthalidone or atenolol failures.			(1) blood pressure and
		Medication was increased during the first 6 months if DBP was ≥100			weight measurements;
		mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a			(2) review of interim
		week apart; or ≥115 mm Hg at any visit. If the additional step-up			history and symptoms,
		therapy did not adequately control DBP, open-label therapy			treatment status,
		(antihypertensive medication) was used.			compliance; and (3)
					dispensing of study
					drugs. Participants who
					failed to achieve
					adequate blood
					pressure control were
					stepped up to
					additional therapy at 6
					months or sooner if
					emergency failure
					criteria were met. The

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
					additional step-up therapy included either 25 mg chlorthalidone or 50 mg atenolol for placebo failures; combined 25 mg chlorthalidone-50 mg atenolol therapy was given to the chlorthalidone or atenolol failures. Medication was increased during the first 6 months if DBP was ≥100 mm Hg for three visits at 2-wk intervals, ≥105 mm Hg at two visits a week apart; or ≥115 mm Hg at any visit. If the additional step-up therapy did not adequately control DBP, open-label therapy (antihypertensive medication) was used.
Lee, 2007 ⁹² Fair	IG1	Median of 6 sessions of individual in-person and telephone physical activity counseling. Six-month community-based walking intervention delivered by a public health nurse. The intervention involved a series of regular individual contacts, provided through telephone and face-to-face visits in both local community activity centers and participants' homes according to their preference. The first intervention contact occurred within one month of randomization. The primary aim of the intervention was to increase the frequency and time participants spent walking. Participants were provided with a pedometer, walking log, and advice about regular	PA only Total contact hrs: 3 Total duration: 6 months	Public health nurse Community centers, home	Usual care: Participants received usual primary health care involving self-initiated contact with health services as required.

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		walking based on established PA guidelines. The intervention was individualized according to each participant's baseline exercise stage of change. Content areas for discussion for each participant varied, but mainly included perceived benefits of increased walking, ideas for overcoming perceived barriers and sharing practical information gleaned from others about pleasant walking routes and pedometer usage. More frequent contacts were arranged during the first three months of the intervention period in order to facilitate and reinforce regular walking and less frequently during the last three months.			
Liira, 2014 ⁹³ Fair	IG1		HD + PA Total contact hrs: 1.5 Total duration: 0.03 months	Public health nurses Primary care	Usual care: Participants received usual care at a municipal public primary care unit where, if necessary, they were referred to a PCP. Participants were offered the health counseling intervention after the study period.
Migneault, 2012 ⁹⁴ Fair	IG1			NA (automated phone system), PCP Home	Minimal intervention: Prior to randomization, participants had an in- home visit for health education, which consisted of a 75-page resource manual that described hypertension, listed dietary recommendations, heart healthy food recipes, and local resources for exercise, and provided information to support

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration		Control group description
		forces relevant to African American populations. The first three calls introduced targeted behaviors, how they help with blood pressure control, and oriented users to the system. Subsequent calls were modules on medication adherence (8 calls), physical activity (12 calls), and diet (9 calls, covering fruits and vegetables, fiber, sodium, and fat). Each call consisted of a (1) introduction; (2) section for reporting health information collected on study-issued home measurement devices (pedometers, sphygmomanometers, weight scales); (3) theory-based interactive education and counseling on the targeted behavior. The physical activity module focused on increasing moderate or greater intensity physical activity. The diet module focused on fruits/vegetables, fiber, sodium, and fat and intended to promote the Dietary Approaches to Stop Hypertension (DASH) diet. Participants and their primary care providers received printouts of their tracked health behaviors, which were sent at the beginning and end of each of the three behavioral modules and were			antihypertensive medication adherence. In addition to the resource manual, participants received a 20-minute education session based on the content of the manual and were given a pedometer and digital weight scale.
Moreau, 2001 ⁹⁵ Fair	IG1	designed to reinforce the intervention. Participants were given a pedometer to wear throughout the day for a 1- to 2-wk period before beginning the 24-wk walking program in order to document preintervention daily lifestyle walking activity. Participants wore the pedometer on their belt or waistband as soon as they awoke in the morning, removed it before going to bed each night, and recorded the number of steps they accumulated each day. Participants were provided with a target number of steps that could lead to a 3-km increase in daily walking. The target steps were added onto their baseline step value to prevent a decline in their current daily lifestyle activity. Initially, all women were prescribed a distance of 1.4 km per day above their baseline walking during week 1. Distance was then increased by 0.5 km per day until the desired walking distance was achieved by the third week. Participants were instructed to walk at a self-selected comfortable pace and were allowed to accumulate their steps in whatever pattern best fit their lifestyle. Other than walking, subjects were asked not to make any changes in their current lifestyle activities.	Total contact hrs: 0 Total duration: 6 months	Home	No advice: Participants were given a pedometer to wear throughout the day for a 1- to 2-wk period before beginning the 24-wk walking program in order to document preintervention daily lifestyle walking activity. Participants were asked not to change daily activity and subsequently wore a pedometer 1 wk each month to document their walking.
Moy, 2001 ⁹⁶ Fair	IG1	Participants received individualized instructions to lower fat intake (based on Adult Treatment Panel III guidelines), focusing on total fat	HD only Total contact hrs: 14	Nurse	Usual care: Participants received usual care

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
	IG1	consumption and daily monitoring (usually a goal <40 g total fat). Participants were initially given a total "fat allowance" based on their intake at baseline and were taught how to read food labels, use fat counter to monitor and record total daily fat intake. Self-monitoring logs were used to record daily fat intake. Participants were seen individually and with family members every 6-8 weeks to reinforce the diet, evaluate dietary compliance, and measure lipids. Physicians were asked to explicitly not to manage dietary interventions as recommended based on results and feedback from baseline screening. At each visit, a dietary fat screening instrument was used to identify potential problems. Counseling was individualized based on initial dietary habits, lifestyles, and progress. Participants received 4 consecutive weekly group 60-90 min	HD + PA	Physicians and	from a primary care physician. Physicians received patient-specific recommendations from results and feedback from the baseline screening for risk factor management on three occasions. Minimal intervention:
1993 ⁹⁷ (Hypertension Treatment and Teaching Program (HTTP)) Fair		counseling sessions, for groups of 4-6 participants. The objectives of the intervention were: assumption of greater responsibility for disease management, including blood pressure self-monitoring and treatment decision making; confirming the diagnosis of hypertension and treatment using at home blood pressure monitoring; and emphasis on non-pharmacological treatments. The first session focused on group discussions and patients were provided with blood pressure monitors and logbooks. During the second session, blood pressure monitoring and logbooks were assessed, as well as strategies for achieving blood pressure control (including dietary and physical activity recommendations; details of dietary advice NR). The last two sessions began with a presentation and discussion about participants' experiences with nutrition, weight change, and blood pressure self-monitoring. Participants discussed their experiences and fears related to the side effects of antihypertensive drug therapy during the third session. Information leaflets about drugs currently used by the participants were discussed, as well as possibilities of avoiding side effects of blood pressure lowering therapy. Participants following non-drug treatment regimens were encouraged to try to reduce the dosages of their antihypertensive drugs. If indicated, drug therapy was started by the physician at the end of the third session. During the fourth session, the effects of antihypertensive drug therapy on blood pressure control was discussed, as well as psychological aspects and smoking.	Total duration: 1 months	practice staff Primary health care	Physicians and staff at CG practices received the same training on BP measurement as those in IG practices but did not deliver HTTP intervention. Additionally, 20 patients at each CG site had their medical files marked with a red dot to remind clinic staff to take BP, weight, and medication information at each visit.

(Study name) Quality		·	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Murphy, 2012 ⁹⁸ (National Exercise Referral Scheme (NERS)) Fair	IG1	to 1-on-1 exercise instruction or group classes. The initial	PA only Total contact hrs: 2 Total duration: 12 months	Exercise professional Leisure center, home (phone)	Waitlist: Usual care and a leaflet highlighting the benefits of exercise and including a website address listing locations of local leisure facilities.
Neil, 1995 ⁹⁹ Fair	IG1		HD only Total contact hrs: 0.67 Total duration: 2 months	Dietitian General practice clinic	Usual care: Participants received a pamphlet containing dietary guidance consistent with advice provided by dietitian. Additional written advice was provided after 2 months.
Neil, 1995 ⁹⁹ Fair	IG2	1 11	HD only Total contact hrs: 0.67 Total duration: 2 months		Usual care: Participants received a pamphlet containing dietary guidance consistent with advice provided by dietitian. Additional written advice was provided after 2 months.

Author, year (Study name)	Int arm	Intervention description		Provider(s) Setting	Control group description
Quality			Total duration	s	P
Niiranen, 2014 ¹⁰⁰ Fair		individual counseling sessions and 1 60-min group session) and 5 PCP BP medication management calls that included individualized lifestyle advice. Lifestyle guidance from nurse during two 30-min individual counseling sessions held at 4-week intervals and at a 60-min group session of 10-12 participants held 4 weeks later. In addition, written instructions were distributed to the participants. During the counseling sessions, participants were instructed to avoid added salt, use low-salt food ingredients, increase intake of fruits, vegetables, and berries, favor unsaturated fat over saturated fat, use low-fat dairy products, eat fish for 1−2 meals per week, exercise at least 3 hours per week, lose weight if necessary, and use no more than moderate amounts of alcohol. The lifestyle goals were: (i) BMI 5% among the obese (body mass index ≥30 kg/m²); (ii) >180 minutes per week of moderate-intensity physical activity; (iii) daily intake of 3/3.5 grams of dietary potassium for women/men; (v) smoking cessation; (vi) 1% of daily energy intake from omega-3 fatty acids; and (viii) daily intake of ≤3 drinks of alcohol for men and ≤2 drinks for women. In addition to the lifestyle counseling, the participants' antihypertensive treatment was guided by systematic home BP measurements. The target BP was home BP <135/83 mm Hg. Participants self-measured their BP at 0, 3, 6, 9, and 12 months and additionally 1 month after any changes in their medication. The BP readings were mailed to the treating physician, and the participant was contacted by phone. During the calls, results of the participant was contacted by phone. During the calls, results of the participant was contacted by phone. During the calls, results of the participant was contacted by phone. During the calls, results of the participant's lifestyle questionnaire (on exercise, nutrition, alcohol use, and smoking; administered at 0, 3, 6, 9, and 12 months) were examined at the same time, and lifestyle guidance was given. Faceto-face PCP appointments were scheduled if de	HD + PA Total contact hrs: 3.25 Total duration: 12 months	Primary care, home	Usual care: No intervention was offered to patients or staff at the control site. No contact between the control group and the study organization occurred between the baseline examinations and the follow-up examinations at 12 months, and hypertension treatment continued according to conventional practice.
Nolan, 2018 ¹⁰¹	IG1	combinations. Participants were contacted by email weekly for months 1 to 4,	HD + PA	NA (counseling	Minimal intervention:
(Reducing Risk		biweekly for months 5 to 8, and monthly for months 9 to 12. Each	Total contact hrs:		Participants received
with E-based		email contained an e-link to lifestyle counseling activities including	Total duration: 12	Home	the same amount of
Support for			months		automated emails as

(Study name) Quality	Int arm	•		Provider(s) Setting	Control group description
Adherence to		with blood pressure management. Initially, participants assessed their			intervention group
Lifestyle Change		stage of readiness to adhere to self-care according to the			participants, but were
in Hypertension		Transtheoretical Model. Then they selected their behavior change			instead linked to
(REACH))		priority from a list that included exercise, diet, smoke-free living,			publicly available
Fair		and adherence to antihypertensive medications. Motivational			content on self-help
		components helped participants by validating their initial stage of			skills for managing BP
		readiness, build their readiness by guiding them to select a goal that			from the resource
		matched their readiness stage, reinforcing their active and			section of the Blood
		collaborative role in the intervention, and helping them resolve			Pressure Action Plan of
		ambivalence for change by linking their behavior change goal to a			the Heart and Stroke
		salient personal priority. For participants with elevated readiness,			Foundation of Canada.
		cognitive-behavioral strategies reinforced their efficacy for initiating			Participants were also
		and sustaining change by (1) educating them about how to set			permitted to log into
		manageable behavioral goals for self-care adherence, (2) outlining			the Heart and Stroke
		progressive steps in the change plan for self-care, (3) facilitating			Foundation website to
		performance-based feedback with self-monitoring tools for BP and			access heart healthy
		self-care behavior, (4) providing rewarding feedback about progress			recipes, as well as e-
		in initiating or sustaining behavior change, (5) maintaining virtual			tools and self-
		peer support and positive behavioral modeling via video material,			monitoring forms to
		and (6) reviewing guidelines to manage stress to sustain therapeutic			track BP and changes
		change in self-care. The 14 intervention videos developed for the e-			in self-care behaviors.
		counseling sessions included (1) expert-type presentations with self-			
		help guidelines for adhering to self-care behavior; (2) an unscripted			
		discussion among peers that provided positive role modeling and			
		guidance as they spoke about how heart healthy living was connected			
		to their personal priorities and how they managed barriers to change;			
		and (3) dramatic vignettes that reflected and validated participant			
		experiences as fictional characters learned to accept the diagnosis of			
		hypertension and then as they planned and carried out lifestyle			
		changes with the support of a healthcare professional or peer.			
Ogedegbe,	IG1		HD + PA	Nutritionists,	Minimal intervention:
2014^{102}		computerized self-paced programmed instruction (4 modules) for	Total contact hrs: 6	nurses, and	Participants received a
(Counseling		, 1	Total duration: 6 months		single HTN patient
African		HTN; expected side effects of medications, and methods for adoption			education session plus
Americans to		of lifestyle changes; (2) home BP monitoring; and (3) individual and		community	printed versions of the
Control		group behavioral counseling sessions on the adoption of lifestyle		health center),	NHLBI patient
Hypertension		modifications conducted by trained study staff, community health		physicians	education material,

Author, year (Study name) Quality	Int arm	Intervention description			Control group description
(CAATCH))		center dieticians and health educators. The content of the computer		Community	"Your Guide to
Fair		tutorial is based on two NHLBI publications, "Your Guide to		health center	Lowering Blood
		Lowering Blood Pressure" and "Facts about the DASH Eating Plan".			Pressure" and "Facts
		The tutorial is broken down into several modules that are written at			about the DASH Eating
		an appropriate reading level. The computer program gives patients			Plan". Primary care
		control of the pace of learning and they are asked questions on the			providers received print
		material and given feedback to verify their understanding of the			versions of the Seventh
		material. For home BP monitoring, participants received an			Report of the Joint
		automated home BP monitor and instructions on its use. Participants			National Committee on
		were encouraged to record their weekly BP readings (twice daily,			Prevention, Detection,
		three times per week) in a diary that they brought with them to each			Evaluation, and
		study visit. The behavioral counseling involved six monthly group			Treatment of High
		behavioral counseling sessions on adoption of recommended lifestyle			Blood Pressure
		modifications conducted by trained community health center staff			guidelines.
		and/or study staff (nutritionists, nurses, and health educators).			
		Behavior change strategies involved motivational interviewing, goal			
		setting, problem solving, stimulus control, cognitive strategies, and			
		self-monitoring. The specific behavior goals set in collaboration with			
		the patients included dietary changes, weight loss, reduction of			
		sodium intake, increased physical activity, moderation of alcohol			
		intake, and adherence to prescribed BP medications. In addition to			
		the patient intervention, their primary care providers received			
		monthly onsite continuing medical education based on the Seventh			
		Report of the Joint National Committee on Prevention, Detection,			
		Evaluation, and Treatment of High Blood Pressure guidelines; HTN			
		case rounds; and quarterly chart audits of their patient office BP			
		readings. They were also provided quarterly feedback on the values			
		of their patient's home BP readings, which were obtained from the			
		patient diaries.			
Reid, 2014 ¹⁰³	IG1	The heart health intervention included feedback about the results of	HD + PA	Health educators	Usual care: Participants
Fair		the baseline and 3 month assessments; goal setting; 17 counseling	Total contact hrs: 6.5	Tertiary care	received printed
		sessions with a health educator; and the communication of reports	Total duration: 12	cardiac center	materials about
		and recommendations to the participant's PCP. Counseling sessions	months		smoking cessation,
		occurred weekly for the first 12 weeks, and then at weeks 16, 20, 26,			healthy eating, weight
		39, and 52. The first 2 counseling sessions were 45-min; the			management, and
		remaining 15 were 15-20-min long. All counseling sessions were			physical activity. A
		delivered via phone except for the second counseling session, which			report was sent to their

Author, year (Study name) Quality	Int arm	<u>*</u>	Intervention focus Total contact (hrs) Total duration		Control group description
		was delivered in-person. During the first two sessions, participants			PCP if the critical
		received feedback about their risk levels relative to			thresholds for BP or
		recommendations. The health educators helped participants set goals for reducing their risks and create action plans. An assessment			lipids were exceeded.
		summary and indications for the participant's medical care were			
		mailed to their PCP. Medical care was suggested if the participant's			
		BP or lipid levels exceeded threshold values (BP >140/90 mm Hg;			
		LDL-C > 2.0 mmol/L and Framingham Risk Score (FRS) 20%; LDL-			
		C 3.5 mmol/L and FRS 10-19%; or LDL-C >5.0 mmol/L and FRS			
		<10%). Participants received printed materials about smoking			
		cessation, healthy eating, weight management, and physical activity.			
		During sessions 3-12, 16, 20, 26, 39, and 52, the health educators			
		engaged participants in a dialog about progress toward their goals			
		and recommended strategies to overcome any barriers. During the			
		week 16 session, participants received results from their 3 month			
		assessment. The summary of this assessment and recommendations			
		for medical care were mailed to the participant's PCP.			
Rodriguez,	IG1	6 monthly telephone sessions of diet, medication, and physical	HD + PA	Counselors	Usual care: Participated
2012^{104}		activity counseling individualized based on stage of change. Stage of	Total contact hrs: 1.5	(Master's degree	in in-person assessment
Fair		change, decisional balance, and self-efficacy was evaluated at each	Total duration: 6 months		visits only
		session for diet, physical activity, and medication adherence, and a		psychology or	
		computer system was used to deliver standardized interventions.		social work)	
		Calls covered problem solving; tips and information for each		Home	
		behavior; and review of a medication log (participants used a			
		calendar to track medication use). Diet counseling focused on low			
		sodium and total fat intake, high intake of fruits and vegetables and			
		low or nonfat dairy products.			
	IG1		HD + PA		Usual care: Participants
Cristobal, 2012 ¹⁰⁵		smoking cessation (12 physician-delivered in-person sessions and 12		, ,	received standard
Fair		psychologist follow-up calls). Psychologists made phone calls to	Total duration: 24	,	advice from their
			months		physician about their
		months) and to provide encouragement about maintaining lifestyle			lifestyle (diet, physical
		changes. Participants who smoked were motivated to give up			activity, smoking
		smoking and received clear and tailored advice as well as medication			cessation) according to
		when indicated. For physical activity, participants received advice to			current practice
		start, maintain, or increase their current level of physical activity.			guidelines.
		Participants with overweight or obesity (BMI 25-30 and ≥30 kg/m ² ,			

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Rosas, 2015 ¹⁰⁶	IG1	respectively) received advice on gradual weight loss (0.51 kg per week) and maintaining a healthy diet after healthy weight achieved with the objective of achieving a BMI 20-25 kg/m ² . Participants with hypertension received dietary and pharmacological treatment according to guidelines with the objective of achieving BP <7%. Participants received a case management intervention based on DPP	HD + PA	Research staff &	Usual care: Routine
(Vivamos Activos Fair Oaks (VAFO)) Good		and Heart to Heart trial tailored to local population plus home visits by community health workers. Intervention consisted of 12 group sessions (2 hrs) and 4 individual (30 min) sessions in the intensive phase (12 months) followed by 3 group sessions and 1 individual session in the maintenance phase (months 13-24). Key intervention components included motivational interviewing, building self-management and goal setting skills, proving hands-on cooking and physical activity demonstrations, fostering self-efficacy, leveraging group-based social support, identifying community resources, and coordinating with primary care providers. Take-home items included pedometers, exercise CDs, and free weights. Individual sessions focused on individualized goal setting based on the patient's stage of behavior change, problem solving, medical and social service referrals. Participants also received 5 community health worker (CHW) home visits in the intensive phase and 2 CHW visits in the maintenance phase. Visits were semi-structured to allow the CHW to facilitate behavioral changes relevant to participant and their household, family, and neighborhood (e.g., navigating an obesogenic environment, fostering family support, enhancing participant success in food negotiations, mapping out neighborhood walking routes, using participant-taken photos of food/PA as triggers for goal setting	Total contact hrs: 36 Total duration: 24 months	community health workers Community health center, home	primary care follow- ups with potential for referral to lifestyle counseling within a specialized diabetes clinic.
Rosas, 2015 ¹⁰⁶ (Vivamos Activos Fair Oaks (VAFO)) Good	IG2	and problem-solving. Participants received a case management intervention based on DPP and Heart to Heart trial tailored to the local population. The intervention consisted of 12 group sessions (2 hrs) and 4 individual (30 min) sessions in the intensive phase (12 months) followed by 3 group sessions and 1 individual session in the maintenance phase (months 13-24). Key intervention components included motivational interviewing, building self-management and goal setting skills, proving hands-on cooking and physical activity demonstrations, fostering self-efficacy, leveraging group-based social support,	HD + PA Total contact hrs: 32.5 Total duration: 24 months	Research staff Community health center	Usual care: Routine primary care follow-ups with potential for referral to lifestyle counseling within a specialized diabetes clinic.

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		identifying community resources, and coordinating with primary care providers. Take-home items included pedometers, exercise CDs, and free weights. Individual sessions focused on individualized goal setting based on the patient's stage of behavior change, problem solving, medical and social service referrals.			
Rubinstein, 2016 ¹⁰⁷ Good	IG1	12 20-30 min telephone sessions of diet and physical activity counseling, 48 followup text messages, and an informational leaflet about healthy lifestyles. After a short introductory call, each		Nutritionists Home	No advice: Participants received a leaflet with written information about the adoption of healthy lifestyles. No further information was provided.
Salisbury, 2016 ¹ Good	⁰⁸ IG1	In addition to usual NHS care, participants received support from the Healthlines service, which is a multifaceted intervention incorporating a range of strategies to address the various components	Total contact hrs: 3.6	Health advisors Home	Usual care: Participants continued to receive care normally provided by the NHS (management of CVD risk factors by primary care clinicians, including, in some

Author, year (Study name) Quality	Int arm	*	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		coordination of care between providers, and methods designed to			cases, referral to
		enhance engagement of patients and GP. The intervention was based			community services for
		around regular telephone calls form a health advisor, supported by			advice about smoking
		patient-specific tailored algorithms and standardized scripts			cessation and weight
		generated through a computerized behavioral management program.			management).
		The program included the following series of modules: knowledge			
		about CVD risk and healthy lifestyles; review of drugs and side			
		effects; optimization of drugs for BP lowering; home BP monitoring;			
		review of statins; support for drug adherence; smoking and nicotine			
		replacement therapy; healthy eating; weight loss and Orlistat; alcohol			
		use; and exercise. The standardized scripts generated by the software			
		were based on principles of behavior change (e.g., stimulus control,			
		problem solving, cognitive restructuring, and goal setting). During			
		the first call, health advisors discussed with participants their health			
		needs and agreed on specific goal. Thereafter, participants received			
		one call monthly for one year. Participants were also provided with			
		access to a Healthlines web portal where they could obtain further			
		information about CVD, access other online resources, request a call-			
		back from Healthlines staff, see copies of letters sent to their GP, and			
		use a BP monitoring system. Participants with baseline SBP ≥140			
		mm Hg were offered a validated home BP monitor by their practice			
		nurse, requested to take their BP twice daily for the first week and			
		weekly thereafter, and to upload their readings to the Healthlines			
		portal. Using these readings, participants were automatically advised			
		by the portal whether their BP was too high or too low. At each			
		telephone contact, health advisors reviewed average BP meetings,			
		and participants with above target readings were instructed to see			
		their doctor to review their treatment. Advisors sent an email to the			
		GP, attaching details of the participant's recent BP readings and a			
		summary of guidelines from NICE about recommended steps for			
		intensifying treatment.			
Schoenthaler,	IG1	13 sessions of diet and physical activity counseling (10 60-90 minute		Health educators	Minimal intervention:
2016^{109}		group sessions and 3 30-min individual phone sessions). In addition	Total contact hrs: 16.5	Hospital, home	In addition to standard
(Individual		to standard treatment recommendations as determined by their	Total duration: 6 months		treatment
Motivational		physicians, participants received an intervention based on established			recommendations as
Interviewing -		clinical practice guidelines for prevention and treatment of			determined by their
Therapeutic		hypertension, which recommends weight loss (if overweight),			physicians, participants

(Study name) Quality		Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Lifestyle Changes		regular physical activity, limiting and/or reducing sodium and			received a 30-minute
(MINT-TLC))		alcohol intake, and eating a low-fat diet that is rich in fruit and			individual counseling
Fair		vegetables. Stress management and medication adherence were also			session on lifestyle
		addressed. Participants attended 10 weekly classes over 12 weeks			modification, as well as
		(intensive phase) followed by monthly, individual telephone-based			content on stress
		motivational interviewing sessions for 3 months (maintenance			management and
		phase). The intensive phase involved 60-90 minute group classes			medication adherence.
		conducted by health educators, focusing on developing skills, goal-			Participants also
		setting and generating strategies for behavior change as well as			received printed
		support for relapse prevention. Each session followed a similar			versions of the MINT-
		structure and included the following components: 1) Overview of			TLC intervention
		HTN and antihypertensive medications; 2) DASH eating plan 3)			material.
		Goal setting and healthy living diaries; 4) Serving sizes, portion			
		control and food labels (with emphasis on sodium monitoring); 5)			
		Physical activity; 6) Building skills for meal planning and shopping;			
		7) Recipe modification and eating away from the home; 8) Stress			
		Management; 9) Eating triggers and mindful eating; and 10)			
		Planning for lasting change. The monthly 30-minute individual			
		telephone-based sessions were also conducted by health educators			
		with the purpose of helping participants focus on problem-solving,			
		goal setting, and prevention of relapse with regard to each of the			
		therapeutic lifestyle changes adopted during the intensive phase. The			
		sessions focused on tailoring the intervention strategies to the			
		participant's individual needs and consisted of: 1) assessing the			
		participant's motivation and confidence in engaging in a given			
		behavior; 2) eliciting barriers and concerns about adoption of each			
		lifestyle modification; 3) summarizing in a non-threatening manner			
		the pros and cons of the participant's concerns; 4) providing a menu			
		of options to the patient based on the nature of the barriers elicited by			
		the patient; 5) assessing each participant's values and goals. Each			
		session ended with a global summary of what was discussed and a			
		clarification of an agreed upon action plan.			
Scott, 2018 ¹¹⁰	IG1		PA only	PhD-level	Usual care: Participants
Fair			Total contact hrs: 4.5	psychologist	received usual care and
			Total duration: 3 months	` *	no additional PA
	1	6, and 8. During the sessions, eight theory-derived determinants were		sessions), home	support throughout the
		targeted: PA outcome expectations, PA outcome experiences, PA		(phone sessions)	study. Usual care

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		outcome expectations—experiences discrepancy, values, exercise barrier self-efficacy, social support and coping skills. MI was the underpinning counseling approach used to influence motivation, self-efficacy and discrepancies/ambivalence. A toolkit of 36 cognitive behavioral techniques derived from a taxonomy and a previous study were tailored to the individual. These included: providing information on consequences of behavior in general and to the individual; providing information about others' approval; goal setting (behavior); goal setting (outcome); action planning; setting graded tasks; prompt review of behavioral goals; prompt review of outcome goals; prompt rewards contingent on effort or progress toward behavior; providing rewards contingent on successful behavior; shaping; prompt generalization of a target behavior; prompt self-monitoring of behavioral outcome; prompting focus on past success; providing feedback on performance; providing information on where and when to perform the behavior; providing instruction on how to perform the behavior; model/demonstrate the behavior; teach to use prompt cues; environmental restructuring; behavioral contract; prompt practice; use of follow-up prompts; facilitating social comparison; plan social support/social change; prompt identification as role mode/position advocate; prompt anticipated regret; fear arousal; prompt self-talk; prompt use of imagery; relapse prevention/coping planning; and			participants received a one-hour feedback session on questionnaire results after the study ended.
Soto Rodriguez, 2016 ¹¹¹ Fair	IG1	stress management/emotional control training. Three 90-min interactive group educational workshops on the prevention of CVD, recommending the adoption and maintenance of healthy habits that favor a change in lifestyle. The importance of following a Mediterranean diet was emphasized, reducing consumption of saturated fats, sugar and alcohol, and increasing consumption of plant foods and foods rich in polyunsaturated fats. The three workshops were held over one week in groups of 15 participants.	HD only Total contact hrs: 4.5 Total duration: 0.25 months	NR Health care	No advice: Participants received a brochure mailed to their address with the information on the same subjects covered in the intervention group.
Stefanick, 1998 ¹¹² (Diet and Exercise for Elevated Risk	IG1		HD only Total contact hrs: 12.5 Total duration: 11 months	Registered dietitians Research clinic, home	No advice: Participants were instructed to maintain usual diet and exercise.

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(DEER)) Fair		followed by eight one-hour, mixed-sex group lessons on replacing dietary sources of saturated fat with complex carbohydrates, low-fat dairy foods, and other alternatives, including lean meats. Weight loss was not emphasized in the group sessions, which averaged 15 persons per group. A six-to-eight-month maintenance phase consisted of monthly contacts with study dietitians, by mail or telephone or in group or private meetings.			
Stevens, 2003 ¹¹³ Fair	IG1	2 45-min sessions of individual diet counseling (including 20-min computer assessment) and 2 10-min followup phone calls. The intervention combined motivational interviewing, problem-solving and social cognitive theory strategies. The first session described the overall goals: reduction in dietary fat and increased consumption of fruits, vegetables, and whole grains. Feedback was provided on baseline fat, fruit, and vegetable consumption relative to goals and participants were asked to select one or two goals for the first session. If dietary fat was selected, then a 20-minute touch-screen computer-assisted assessment provided feedback on fat intake and other dietary patterns based upon the modified Fat and Fiber Behavior Questionnaire. Participants then answered questions about their personal barriers to dietary change and were helped to select tailored strategies to address those barriers. An automated touch-screen program produced a personalized printout which the interventionist then reviewed with the participant. The participant took the printout with them in addition to nutrition education materials. Participants not selecting dietary fat at the first session received an individually tailored counseling session focused on increasing consumption of fruits, vegetables, and whole grains. At the second visit 2–3 weeks later, participants reported on their progress toward achieving their goals. If they had not selected dietary fat as a target in the first intervention session, they then completed the automated program described above. Those who completed the automated program described above. Those who completed the automated program described above. Those who completed the automated program in the first session were encouraged to focus on increasing fruit and vegetable consumption. The focus was on the parts of their personal eating pattern they were most willing to change, and on the barriers encountered. During this session, participants had made commitments to work on several dietary changes and identified	HD only Total contact hrs: 1.83 Total duration: 2 months	Health counselors Research clinic	Attention control: Participants received an intervention focused on breast self-exam, which included a 9 minute American Cancer Society video, self-help pamphlets, barriers-based problem solving counseling regarding interest and motivation for conducting regular breast self-exam.

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		strategies for each. Two 5- to 10-min calls after the second session provided ongoing support and checks on participants' behavior change plans.			
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM)) Good	IG1	All participants had successfully lost ≥4 kg in phase 1 of a 6-month nonrandomized initial weight loss intervention prior to enrollment. Phase 2, the maintenance portion, included monthly 5-15 minute	HD + PA Total contact hrs: 12.75 Total duration: 60 months	Research interventionist NR	Minimal intervention: Printed lifestyle guidelines with diet and physical activity recommendations at randomization and met briefly with a study interventionist after 12- month data collection visit.
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM)) Good	IG2	Unlimited access to a website designed to support weight loss maintenance and were encouraged to log in at least once per week. Participants were required to record their weight upon logging into the website. The website provided a number of intervention elements, including social support using a bulletin board feature,	HD + PA Total contact hrs: 0 Total duration: 30 months	NA Home	Minimal intervention: Printed lifestyle guidelines with diet and physical activity recommendations at
		record-keeping tools, tracking options, accountability, diet and exercise information, and tailored feedback. The website also			randomization and met briefly with a study

Author, year (Study name) Quality	Int arm	·	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		included interactive training modules that addressed problem solving and motivation. If participants missed a self-scheduled contact, they were sent an email reminder that was repeated after another week of no contact. If there was no response to the 2 email prompts, participants received 2 weekly automated telephone calls. If participants didn't log into the website after that, they were contacted by study staff, who encouraged them to return to the website.			interventionist after 12- month data collection visit.
		IG2 participants were not part of the phase 3 extended F/U.			
Svetkey, 2009 ¹¹⁵ (Hypertension Improvement Project (HIP)) Fair	IG1	Participants received both the physician intervention (MD-I) and the patient intervention (Pt-I). For the MD-I, physicians received two 45-minute online training modules (Continuing Medical Education)	Total contact hrs: 24.5 Total duration: 18 months	Behavioral interventionists and community health advisors, PCP Physician: Clinic, Patients: At or near participant's clinic site	Usual care: Participants had a brief PC visit after randomization during which they received advice and brochures on lifestyle modification for blood pressure control consistent with Joint National Committee-7.

Author, year (Study name) Quality	Int arm	<u> </u>	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		sessions and the participant manual emphasized diet, physical activity, and changing behaviors. Community health advisors attended and helped to lead group sessions and also provided one-on-one monthly telephone counseling during and after the group session period.			
Svetkey, 2009 ¹¹⁵ (Hypertension Improvement Project (HIP)) Fair	IG2		HD + PA Total contact hrs: 23 Total duration: 18 months	Behavioral interventionists and community health advisors At or near participant's clinic site	Usual care: Participants had a brief PC visit after randomization during which they received advice and brochures on lifestyle modification for blood pressure control consistent with Joint National Committee-7.
Svetkey, 2009 ¹¹⁵ (Hypertension Improvement Project (HIP)) Fair	IG3	Physicians received two 45-minute online training modules (Continuing Medical Education) aimed at Joint National Committee-7 guidelines and lifestyle modification for blood pressure control. An evaluation and treatment algorithm summarizing the major Joint National Committee-7 guidelines and formatted as a decision tree (laminated, color-coded, pocket-sized) was provided to each physician. Assessment and quarterly feedback was provided to physicians on their adherence to guidelines, including lifestyle counseling that assessed the proportion of patients with hypertension whose blood pressure was controlled, proportion not at goal, the proportion that received lifestyle counseling, the proportion with diabetes or chronic kidney disease who were at goal blood pressure and prescribed a thiazide diuretic or angiotensin-converting enzyme inhibitor/angiotensin receptor blocker, and comparisons of physicians with peers.		NA (Physicians trained) Clinic	Usual care: Participants had a brief PC visit after randomization during which they received advice and brochures on lifestyle modification for blood pressure control consistent with Joint National Committee-7.

Author, year (Study name) Quality		•	Intervention focus Total contact (hrs) Total duration	Setting	Control group description
Ter Bogt, 2009 ¹¹⁶	IG1	1 1 1 1	HD + PA	General	Usual care: Participants
(Groningen		visit with their general practitioner (GP) to discuss results of the	Total contact hrs: 7.25		were offered one GP
Overweight and		baseline assessment and start treatment according to the GP's	Total duration: 36		consultation to discuss
Lifestyle			months	,	the results of their
(GOAL))		physical activity and healthy diet counseling consisting of individual			baseline measurements
Good		sessions focused on self-awareness, lifestyle education, individual			and thereafter received
		motivation, and goal-setting. During the four individual sessions, the			usual care by a GP
		NP was guided by a standardized computer program that contained			according to national
		instructions on lifestyle counseling defined by international			GP guidelines.
		guidelines and allowed data entry of the measurements. The aim of			
		the intervention was to achieve persistent lifestyle changes and			
		prevent weight gain. Participants developed a tailored treatment plan			
		based on goals. Ongoing evaluation of goals by nurse practitioners			
		during sessions; modification of goals, as needed, as well as possible			
		referral to dietician. Diet was assessed via food diaries and physical			
		activity was measured using pedometers. Following the in-person			
		sessions, the NP called participants to give them feedback on their			
		lifestyle by critiquing their food diary, physical activity (pedometer),			
		baseline questionnaires, and discussed finishing their treatment plan.			
		During the second and third year, participants had one individual			
		session with the NP and received two feedback phone calls per year.			
Tiessen, 2012 ¹¹⁷	IG1	1 6	HD + PA		Minimal intervention: 1
(SPRING (Self-		motivational interviewing and 6-12 follow-up visits with the number		,	20-minute individual
monitoring and		of follow-up visits determined by the presence of risk factors.	Total duration: 12		session with nurse
Prevention of			months		using motivational
RIsk Factors by		BP device). The first session was based on SCORE risk assessment,			interviewing. The first
Nurse		present risk factors and corresponding treatment goals. The number,			session was based on
practitioners in		length, and interval of follow-up visits was tailored to participants			SCORE risk
the region of		risk factors and the order in which risk factors were addressed			assessment, present
Groningen))		depended on the participant's preference and stage of change.			risk factors and
Fair		Quitting smoking was the first treatment goal if applicable. Adapted			corresponding
		motivational interviewing was used to help participants recognize			treatment goals.
		and change unhealthy behavior. Overweight participants received a			Standard information
		food diary, home weight scale, step diary, and pedometer, and were			leaflets were given to
		followed up three times at monthly intervals followed by 3-monthly			participants based on
		intervals. Participants with low physical activity received a step diary			overweight, smoking,
		and pedometer and were followed up three times at monthly intervals			and physical activity

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		followed by 3-monthly intervals. Participants with hypertension received home blood pressure monitoring and medication with monthly follow-up. Participants with dyslipidemia received medication and follow-up at three-month intervals. Participants with current smoking were followed up monthly until planned date of quitting, and after that at increasing intervals. Any medication adjustments were made by nurse under supervision of GP.			status. More counseling or referral for these risk factors given only on patient's request. After the initial visit, participants had follow-up visits based on the Dutch HTN and hypercholesterolemia guidelines if these risk
Toft, 2008 ¹¹⁸ (Inter99)	IG1	Participants were offered three types of counseling: a smoking cessation course, a smoking reduction course, and a course on diet	HD + PA Total contact hrs: 14	Doctors, nurses, and dietitians	factors were present. Minimal intervention: Assessment and
Fair			Total duration: 60 months	Research center	individual counseling at baseline, 1, 3, and 5 years. Based on a personal risk assessment, each participant received an individual 'lifestyle counseling talk' focusing on smoking, PA, diet and alcohol. Counseling addressed all individuals who smoked, had 14 drinks/week for women and >21 for men. Written materials provided as appropriate. Overall goal was to achieve small but sustained dietary changes. Specifically, decreasing total SF intake, substituting SF for

Author, year (Study name) Quality	Int arn	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		Participants also received same health assessment and 45-min (baseline) or 15-min (years 1,3,5) individual counseling session provided to control participants.			unsaturated fat, and increasing intake of F/V and fish. Participants advised to aim for 4 hours/week PA (some papers report 30 mins/day); only minimal counseling time spent on PA. Participants were reinvited after 1 and 3 years for risk assessment and counseling and at 5 years for a short finishing lifestyle counseling.
TOHP I CRG, 1992 ¹¹⁹ (Trials of Hypertension Prevention Phase I (TOHP I)) Good	IG1	The intervention consisted of group educational sessions supplemented by individual counseling. Demonstrations and practice were incorporated into each meeting. There was a 3-month initial (intensive) period consisting of 10 weekly sessions (8 group and 2 individual) lasting 90 minutes each. Interventions focused on shopping, cooking, and food selection behaviors aimed at reducing sodium intake. The individual sessions focused on a goal to reduce 24-hour sodium intake to 60 mmol (1400 mg). Food diaries were provided to participants and used to facilitate self-monitoring of sodium intake; intervention staff reviewed and commented on food diaries. 16 followup sessions offered after intensive intervention. Followup was implemented to provide continued information, support, and counseling through telephone, mail and at minimum, bimonthly in-person group or individual meetings (90 minutes each) throughout the trial. Participants were guided through a behavioral change process that focused on action goals and implementation steps specific to social, emotional, or practical problems encountered in sodium reduction. Group meetings included discussions to generate peer support and	HD only Total contact hrs: 39 Total duration: 18 months	Registered dietitian and psychologist or exercise psychologist Research center	Usual care: Participants received usual care.

Author, year (Study name) Quality	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
TOUR LORG TO	share effective strategies for achieving sodium-related behavior changes. Additional motivational strategies included special presentations about the importance of and rationale for the study and incentives in the form of food products and cooking demonstrations, and as some sites, contests (low-sodium "cook-offs") or door prizes at group meetings.	WD - DA	District	W. L. D. C. C.
TOHP I CRG, 1992 ¹¹⁹ (Trials of Hypertension Prevention Phase I (TOHP I)) Good	Participants attended an individual counseling session followed by 14 weekly 90 minute group sessions (intensive phase), which were followed by monthly group meetings (extended intervention). Sessions presented information basic nutrition, social eating, self-management techniques, exercise demonstrations, supervised exercise, and relapse prevention. Participants reviewed progress and made plans for the next week. During the extended intervention participants had the option of monthly group sessions, group weighin session, individual weigh-in sessions, and individual counseling sessions according to individual needs. Food diaries were kept for the first 14 weeks and reviewed by nutrition staff who provided comments. Participants were asked to make a moderate reduction in total energy intake with the goal of achieving gradual weight loss not to exceed 0.9 kg (2 lb) a week with intake to not to fall below 1200 kcal. After reaching weight loss goal they were asked to adjust intake to maintain weight. Participants were encouraged maintain a graph of weight change from baseline and record daily exercise time as a bar graph. Participants were encouraged to increase activity, principally through walking at least 20 minutes 3 times per week. As intervention progressed, they were asked to adopt moderate exercise of 4 to 5 days per week between 30-45 minutes with an intensity of 40-55% of heart rate reserve. Behavioral self-management strategies employed included setting reasonable short-term goals, formulating specific plans of action to achieve these goals, developing reinforcement and social support for each major element of the plan, keeping records to assess progress, and regularly evaluating and modifying action plans. Small group sessions took place at every group where participants shared their		Registered dietitian and psychologist or exercise psychologist Clinical center	Usual care: Participants received usual care.

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration		Control group description
		detailed goals for the following week. Relapse prevention was also discussed and strategies developed.			
TOHP II CRG,	IG1		HD + PA	Centrally trained	No advice: Assessment
1997 ¹²⁰ (Trial of			Total contact hrs: 48.5		only, received no
Hypertension		90-min biweekly group sessions and 3-6 "minimodules" consisting	Total duration: 36	psychologists, or	further intervention.
Prevention II		, , , ,	months	health	
(TOHP II))		participant-initiated individual counseling sessions. Goal was to		counselors)	
Good		achieve ≥4.5 kg weight loss and mean sodium intake of ≤80 mmol/L		Research clinic	
		with the aim to achieve goals during initial 6 months and to maintain			
		goal thereafter. Behavioral objectives for weight loss intervention			
		emphasized reducing caloric intake by decreasing consumption of			
		excess fat, sugar, and alcohol and included daily food diaries and			
		encouragement of moderately increasing physical activity. The			
		physical activity goal was to gradually increase moderate intensity			
		activity to 30-45 min per day, four to five days per week.			
		Intervention was delivered in four phases. The pre-intensive phase			
		consisted of one individual counseling session to prevent weight gain			
		prior to initiation of group sessions. The intensive phase followed			
		with 14 weekly 90-min group meetings led by dietitians or health			
		educators and focused on core knowledge and skills for weight loss			
		and sodium reduction. After the 14-week intensive phase, the			
		transitional phase consisted of participants attending 6 biweekly			
		group meetings and then monthly group meetings. Beginning in the			
		18th month, participants were offered optional individual counseling			
		sessions and special group sessions focused on selected weight loss			
		and sodium reduction topics. The program covered behavioral self-			
		management, nutrition education, information on PA, social support,			
		self-monitoring (food diaries and graphs of PA), goal-setting with			
		action plans, strategies for situations that trigger problem eating.			
TOHP II CRG,	IG2		HD + PA	•	No advice: Assessment
1997 ¹²⁰ (Trial of			Total contact hrs: 48.5		only, received no
Hypertension		sessions and 3-6 "minimodules" consisting of up to 6 sessions each	Total duration: 36		further intervention.
Prevention II			months	health	
(TOHP II))		counseling sessions). Goal was to achieve ≥4.5 kg weight loss with		counselors)	
Good		the aim to achieve goal during initial 6 months and to maintain goal		Research clinic	
		thereafter. Behavioral objectives for weight loss intervention			
		emphasized reducing caloric intake by decreasing consumption of			

Author, year (Study name) Quality	Int arm	Intervention description	Provider(s) Setting	Control group description
		excess fat, sugar, and alcohol and included daily food diaries and encouragement of moderately increasing physical activity. The physical activity goal was to gradually increase moderate intensity activity to 30-45 min per day, four to five days per week. Intervention was delivered in four phases. The pre-intensive phase consisted of one individual counseling session to prevent weight gain prior to initiation of group sessions. The intensive phase followed with 14 weekly 90-min group meetings led by dietitians or health educators and focused on core knowledge and skills for weight loss. After the 14-week intensive phase, the transitional phase consisted of participants attending 6 biweekly group meetings and then monthly group meetings. Beginning in the 18th month, participants were offered optional individual counseling sessions and special group sessions focused on selected weight loss topics. The program covered behavioral self-management, nutrition education, information on PA, social support, self-monitoring (food diaries and graphs of PA), goal-setting with action plans, strategies for situations		
TOHP II CRG, 1997 ¹²⁰ (Trial of Hypertension Prevention II (TOHP II)) Good	IG3	that trigger problem eating. 53 sodium reduction counseling sessions (1 individual introductory session, 10 90-min weekly group sessions, 6 90-min biweekly group sessions and 3-6 "minimodules" consisting of up to 6 sessions each [36 available sessions], and optional participant-initiated individual counseling sessions). The group goal was average sodium intake ≤80 mmol/24h, and the individual goal was sodium intake ≤70 mmol/24h with the aim to achieve goals during initial 6 months and to maintain goal thereafter. Intervention focused on identifying sodium content of foods, preparing lower sodium foods, modifying recipes, and making lower sodium food selections at and between meals and when eating out; taste-testing, making small, progressive sodium intake changes; alternatives to high-sodium eating behaviors; general behavioral modification and relapse prevention techniques, including self-monitoring of sodium intake; and feedback on food records and urinary sodium excretion. Intervention was delivered in four phases. The pre-intensive phase consisted of one individual counseling session. During this phase, the primary goal was to provide participants with core knowledge and behavioral skills necessary to	staff (dietitians,	No advice: Assessment only, received no further intervention.

Author, year (Study name) Quality	Int arm	•	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		followed with 10 weekly 90-min group meetings led by dietitians or health educators and focused on core knowledge and skills for reducing dietary sodium. After the 10-week intensive phase, the transitional phase consisted of participants attending 6 biweekly group meetings and then monthly group meetings. A transitional phase consisting of 4 monthly sessions was designed to prevent relapse and to ease transition from weekly to less frequent contacts. The final extended phase was to maintain participants' behavior changes. As a routine, this included 1 to 2 monthly contacts and a series of 3 to 6 refresher sessions that was offered on intervention-related topics to promote contact and adherence with the intervention.			
Tomson, 1995 ¹²¹ Fair	IG1	6 sessions diet counseling, including 3 sessions with primary care physician and 3 sessions with dietician (1 individual, 1 with spouse, and 1 group session with trip to grocery store). Counseling	HD only Total contact hrs: 3 Total duration: 12 months	PCP, dietician Medical center	Usual care: Results of screening were communicated to participant by letter from GP explaining that cholesterol values were too high and therapy is to modify diet. A booklet with diet information was sent with the letter and dietary recommendations based on the patient's weight were included. For those who were overweight: increase fiber and decrease fat intake to 30% of total daily calories. For those of healthy weight: focus on switching to mono and polyunsaturated fats. If participant had to visit

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration		Control group description
					health center for other reasons during the intervention period, there was no restriction on discussion of hypercholesterolemia.
van der Veen, 2002 ¹²² (Nijmegen Family Practices Monitoring Project (NFPMP)) Fair	IG1	sessions with referral to dietician for 3 sessions (initial consultation of 30-40 minutes and 10-15 minutes for second and third		Family	Usual care: No details provided
van Keulen, 2011 ¹²³ (Vitalum) Fair	IG1	motivational interviewing on physical activity, and fruit/vegetable consumption. During each call, the counselor assessed the		(students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	Usual care: After the intervention period, participants received one tailored letter addressing physical activity and fruit/vegetable consumption based on results from previous followup questionnaire.

(Study name) Quality		•	Total contact (hrs) Total duration	Setting	Control group description
van Keulen, 2011 ¹²³ (Vitalum) Fair	IG2	minute telephone-based motivational interviewing calls. One letter and 1 call focused on physical activity; the other two focused on	HD + PA Total contact hrs: 0.67 Total duration: 10 months	(students of Health Education and Health Promotion, Mental Health Sciences, or Psychology) Home	Usual care: After the intervention period, participants received one tailored letter addressing physical activity and fruit/vegetable consumption based on results from previous followup questionnaire.
van Keulen, 2011 ¹²³ (Vitalum) Fair	IG3	Participants received four tailored letters based on baseline and followup survey data (variables included current behavior, awareness, age, gender, stage of change, attitude, self-efficacy expectations, and action plans): letters 1 & 3 focused on physical activity (3-6 pages) and letters 2 & 4 focused on fruit and vegetable consumption (4-6 pages). Letters included feedback on the targeted behavior and stage-matched advice to change behavior. Letters 3 and 4 reinforced tailored feedback on behavioral progress based on intermediate survey data. Half of the participants in each group received pedometers at week 29 (along with instructions to gradually increase their number of steps to 10,000 per day) and the remainder received one after the last followup.	HD + PA Total contact hrs: 0 Total duration: 10 months	NA Home	Usual care: After the intervention period, participants received one tailored letter addressing physical activity and fruit/vegetable consumption based on results from previous followup questionnaire.
van Sluijs, 2005 ¹²⁴ (Physician-based Assessment and Counseling for Exercise (PACE)) Fair	IG1	Participants had 2 visits with their provider and 2 "booster" followup phone calls with a PACE counselor. At the initial visit patients met with their general practitioner or nurse practitioner for a 10-minute consultation to discuss the patients' medical condition(s), to offer advice about becoming more physically active, and to assess their stage of change for physical activity, using the PACE physical activity program materials, which included a stage-specific protocol to guide the clinician. The goal of PACE intervention was to "promote long-term participation in regular physical activity by altering social and psychological factors known to influence physical activity, such as social support, increased self-efficacy, reduced perceived barriers, and increased awareness of the benefits of physical activity". After initial visit, 1 follow-up visit with provider (4 weeks), where they focused on stage-specific protocols and checked in on participant progress. At 4 wk visit physical activity	Total contact hrs: 0.83 Total duration: 2 months	counselor Clinic, home (phone)	Usual care: GPs discussed patient's current level of physical activity and, as appropriate, encouraged patient to become more active. Standard text on physical activity promotion was provided.

Author, year Int (Study name) Quality	t arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Wi-li 2010125 IC		counselors offered new counseling protocol for those who had either progressed or regressed through stages of change. PACE physical activity counselors (separate from general practitioner/nurse practitioner) provided 2 "booster" phone call consultations (2 and 8 weeks after initial provider visit), to offer support and resolve possible problems or questions.	HD - DA	I Tankhana dan	Haralana Participant
Viglione, 2019 ¹²⁵ IG (Goals for Eating and Moving (GEM)) Fair		13 sessions of diet and physical activity counseling delivered by health coaches (1 60-min in-person counseling session and 12 25-min coaching calls) and an average of 2.3 counseling sessions with PCP. Participants attended an hour-long baseline visit with a health coach, in which the health coach provided an overview of the tablet-delivered GEM tool, as well as instructions for using the pedometer and food/physical activity diary. Health coaches also used the baseline visit to counsel participants, using motivational interviewing techniques, to explore motivation and barriers for losing weight, increasing physical activity, and making dietary changes. Participants were encouraged to attend MOVE! Sessions (weight management program comprised of support and skill-building lessons focused on self-monitoring, diet, physical activity, and weight loss for veterans seen at the VA). Participants used the GEM tool at baseline to answer a series of questions and complete a goal-setting algorithm, which the tool used to generate tailored educational materials (SMART goal worksheets, standardized MOVE! Handouts, information on health resources, GEM summary report), which were given to participants in a binder as a personalized care plan. Following the baseline visit, participants received up to 12 25-minute coaching calls in which health coaches reminded them to use food records and pedometers three days prior to each coaching session. Health coaches documented their encounters in the participant's medical record with a note to generate a clinical reminder for the PCP. PCPs were trained on the GEM tool, supporting participant goals and addressing barriers, the role of the health coach, and the electronic clinical reminders. PCPs were asked to discuss goal and address barriers, communicate with health	HD + PA Total contact hrs: 6.6 Total duration: 12 months	Health coaches (trained students), PC team Primary care (baseline and PCP visits), home (calls)	Usual care: Participants received a printed flyer about MOVE! and a "VA Healthy Living" brochure from a health coach. The pamphlet covered screening tests and immunizations, stress management, tobacco and alcohol use, and physical activity. Handouts encouraged participants to discuss goals with their PCPs.

(Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration		Control group description
Voils, 2013 ¹²⁶	IG1		HD + PA		Minimal intervention:
(CouPLES)		sessions for their spouse. Patient phone sessions addressed goal-	Total contact hrs: 3.5		Clinical management
Fair		setting and problem solving and the topic was selected by the patient	Total duration: 11		of lipid disorders using
		at the beginning of the call from among: diet, physical activity,	months		Adult Treatment Panel
		patient-physician communication, and medication adherence. In the			III guidelines.
		first session, patients and spouses received information about			Reminders for
		hypercholesterolemia and an overview of self-management			physicians were
		principles. Spouses also received an orientation on strategies to			embedded in 11 emails,
		support patient goal achievement. Subsequent phone sessions			electronic medical
		allowed each patient to choose a behavior on which to focus and set			records, and
		their own goals and action plans according to what they felt they			performance measures.
		could accomplish. Spouse calls occurred within one week of patient			Emails emphasized the
		calls and included a review of patients' success in meeting previous			use of lipid lowering
		goals; spouses were asked to create a behavior plan for supporting			medications.
		achievement of new goals. For diet and physical activity goals,			Physicians also had
		spouses were asked if they planned to make the same changes that			access to 2 referral
		patients planned to make. Patients selected diet for 51% of calls and			clinics: a subspecialty
		physical activity for 49% of calls. Spouses agreed to make the same			lipid clinic for difficult
		changes as patients in 97% of calls in which the patient sets dietary			to manage cases and a
		change goals and 65% of calls in which the patient set exercise goals.			subspecialty risk factor
		The patient–physician communication topic was only selected for 2			management clinic that
		calls, and the medication management topic was never selected.			enrolled high-risk
					patients whose LDL-C
					was above goal. These
					clinics provided
					lifestyle behavior
					counseling, medication
					management, and
777 44 2044127					followup.
,	IG1		HD + PA		Minimal intervention:
(Practice-based		balanced diet of 1200 to 1500 kcal per day (1500 to 1800 kcal per	Total contact hrs: 6.9		Participants attended
Opportunities for		day for participants who weighed 113.4 or more), which consisted of			eight quarterly 5-7 min
Weight Reduction	l	approximately 15 to 20% kcal from protein, 20 to 35% kcal from fat,	months	•	PCP visits to review
at the University		and the remainder from carbohydrates. All participants were			their weight change
of Pennsylvania		instructed to gradually increase their PA to 180 min/week and were			and to discuss
(POWER-UP))		given a pedometer, a calorie-counting book, and handouts from Aim			information in the Aim
Good		for a Healthy Weight. Attended quarterly 10-15 min PCP visits, at			for a Healthy Weight

Author, year (Study name) Quality	Int arm	*	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
		which they reviewed their health status and were provided handouts from Aim for a Healthy Weight. In addition, participants attended monthly visits with a medical assistant (referred to as lifestyle coach [LC]), who delivered abbreviated DPP treatment. Participants attended 14 LC visits in year 1, followed by 12 LC visits in year 2. During month 1, this included 2 counseling visits to learn how record food and calorie intake in diaries provided. Visits began with a weigh-in and then a review of food intake, PA and other goals prescribed in monthly handouts. In year 2, they were permitted, every other month, to complete counseling visits by telephone			handouts. Same dietary and PA goals as IG.
		(although <5% of visits were made by telephone). The intervention views participants as active problem solvers who are capable of regulating their affect, behavior, and cognition. Selfmonitoring is used to identify times, places, emotions, people, and events associated with eating (or exercising) appropriately or inappropriately. Goal setting is facilitated by specifying behaviors to be adapted and when, where, how, and with whom they will be performed. Behavior change is reinforced by increased self-efficacy, by the inherent rewards in reaching a goal (i.e., weight loss or improved fitness), by social support (including encouragement from medical personnel) or by the use of external rewards.			
		The intervention will include other traditional lifestyle modification topics (e.g., challenging negative thoughts, obtaining social support), most of which will be accompanied by a homework assignment to be completed before the next visit with the Lifestyle Coach. An important behavior will be having participants weigh themselves at least once a week and record their weight. Participants who do not have access to a scale for weekly weigh-ins will be provided an inexpensive bathroom scale.			
Whelton, 1998 ¹²⁸ (Trial of Nonpharmacologi c Interventions in the Elderly		(Limited to patients with obesity) 25 sessions of individual and group counseling over 8 months, followed by 28 monthly maintenance sessions, focused on reducing dietary sodium intake to ≤1800 mg per	Total contact hrs: 49.5	exercise counselors	Minimal intervention: Usual care groups received no study- related counseling in lifestyle change techniques but were

Author, year (Study name) Quality	Int arn	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
(TONE)) Good		medication was a goal for all participants and was initiated 3 months after the first group counseling session. Counseling interventionists provided information using both centrally and locally prepared materials, motivated participants to make and sustain long-term lifestyle changes, monitored individual and group progress at frequent intervals, and helped participants customize intervention to meet individual needs. Centrally prepared materials included food counters, scorekeepers, manuals, and audiovisual aides. Intervention consisted of 3 phases (intensive, extended, and maintenance). Primary goal during intensive phase was to provide core knowledge and behavior skills necessary to achieve and maintain reductions in sodium reduction and body weight. During extended phase, focus was on problem solving and relapse prevention. During maintenance phase, continued attempts were made to maintain or re-engage participant interest in the intervention. Telephone and mail contacts			invited to meetings on topics unrelated to diet, physical activity, and cardiovascular disease.
Whelton, 1998 ¹²⁸ (Trial of Nonpharmacologi c Interventions in the Elderly (TONE)) Good		are suggested in the protocol during the maintenance phase without specific details provided. (Limited to patients with obesity) 25 sessions of individual and group counseling over 8 months, followed by 28 monthly maintenance sessions, focused on achieving weight loss of ≥10 lbs. Weight loss was to be achieved by a caloric deficit from both dietary restriction and increased physical activity. Withdrawal of antihypertensive medication was a goal for all participants and was initiated 3 months after the first group counseling session. Counseling interventionists provided information using both centrally and locally prepared materials, motivated participants to make and sustain long-term lifestyle changes, monitored individual and group progress at frequent intervals, and helped participants customize intervention to meet individual needs. Centrally prepared materials included food counters, scorekeepers, manuals, and audiovisual aides. Weight loss group received information on techniques and group practice in safe low-level exercise. Intervention consisted of 3 phases (intensive, extended, and maintenance). Primary goal during intensive phase was to provide core knowledge and behavior skills necessary to achieve and maintain reductions in body weight. During extended phase, focus was on problem solving and relapse prevention. During maintenance phase, continued attempts were made to maintain or re-	Total contact hrs: 49.5 Total duration: 36 months	exercise counselors	Minimal intervention: Usual care groups received no study- related counseling in lifestyle change techniques but were invited to meetings on topics unrelated to diet, physical activity, and cardiovascular disease.

Author, year (Study name) Quality	Int arm	Intervention description			Control group description
		engage participant interest in the intervention. Telephone and mail contacts are suggested in the protocol during the maintenance phase without specific details provided.			
Whelton, 1998 ¹²⁸ (Trial of Nonpharmacologi c Interventions in the Elderly (TONE)) Good		25 sessions of individual and group counseling over 8 months focused on reducing dietary sodium intake to ≤1800 mg per day, followed by 28 monthly maintenance sessions. Withdrawal of antihypertensive medication was a goal for all participants and was initiated 3 months after the first group counseling session. Counseling interventionists provided information using both centrally and locally prepared materials, motivated participants to make and sustain long-term lifestyle changes, monitored individual and group progress at frequent intervals, and helped participants customize intervention to meet individual needs. Centrally prepared materials included food counters, scorekeepers, manuals, and audiovisual aides. Intervention consisted of 3 phases (intensive, extended, and maintenance). Primary goal during intensive phase was to provide core knowledge and behavior skills necessary to achieve and maintain reductions in sodium and body weight. During extended phase, focus was on problem solving and relapse prevention. During maintenance phase, continued attempts were made to maintain or re-engage participant interest in the intervention. Telephone and mail contacts are suggested in the protocol during the maintenance phase without specific details provided.		exercise counselors Academic health center	Minimal intervention: Usual care groups received no study- related counseling in lifestyle change techniques but were invited to meetings on topics unrelated to diet, physical activity, and cardiovascular disease.
Wister, 2007 ¹²⁹ Good		smokers) of diet and physical activity counseling and 3 mailings. The	HD + PA Total contact hrs: 1 Total duration: 12 months	counselors (were also kinesiologists)	Usual care: Participants received usual care from their physicians, based on their own determination of the need for visits.

Author, year (Study name) Quality	Int arm	Intervention description	Intervention focus Total contact (hrs) Total duration	Provider(s) Setting	Control group description
Wong, 2015 ¹³⁰ Good	IG1	comparisons with previous report cards were discussed with the participant to set new goals. Smokers prepared to quit received additional 20- to 30-minute sessions at 2, 4, 8 and 12 weeks according to US and Canadian guidelines. Summaries of each counseling session and supporting evidence-based educational materials were mailed to the participants. 1 3-5 min physician-delivered usual care session and 1 25-min dietitian-delivered DASH diet counseling session. Usual care	HD only Total contact hrs: 0.5	Physician and dietitian	Usual care: Participants received usual care
Good		consisted of a 3-5 minute physician-delivered counseling session based on a standard pamphlet for hypertensive patients used in all public primary care clinics in Hong Kong. Participants were educated on (i) the definition and nature of hypertension; (ii) the diagnosis of Grade 1 hypertension with its associated complications; (iii) causes of hypertension; the clinical tests needed for annual assessment; and (iv) non-pharmacological approaches to control BP (i.e., smoking cessation, reduction in alcohol use, maintenance of body weight, regular PA, balanced diet [low salt and low fat], and adequate rest). The DASH diet counseling session was delivered by a dietitian and included information about the nature of DASH, benefits, major components, and individualized meal plan tailored to Chinese culture. Participants were encouraged to achieve individualized DASH diet goals, with regard to higher intake of fruits (4–5 serves/day) and vegetables (4–5 serves/day), low-fat dairy products (2–3 serves/day), lean meats, poultry, and fish (≤6 serves/day), and nuts, seeds, and legumes (4–5 serves/week), while limiting the intake of sweets and added sugars (≤5 serves/week), and fats and oils (2–3 serves/day). Practical tips for decreasing salt intake were also emphasized, and participants were given an educational pamphlet on the DASH diet. Dietician checked all patients for comprehension of DASH advice offered and provided clarification to hose with inquires.	Total duration: 0.03 months	Primary care	consisting of a 3-5 minute physician- delivered counseling session based on a standard pamphlet for hypertensive patients used in all public primary care clinics in Hong Kong. Participants were educated on (i) the definition and nature of hypertension; (ii) the diagnosis of Grade 1 hypertension with its associated complications; (iii) causes of hypertension; the clinical tests needed for annual assessment; and (iv) non- pharmacological approaches to control BP (i.e., smoking cessation, reduction in alcohol use, maintenance of body weight, regular PA, balanced diet [low salt

Author, year	Int arm	Intervention description	Intervention focus	Provider(s)	Control group
(Study name)			Total contact (hrs)	Setting	description
Quality			Total duration		
					and low fat], and
					adequate rest). No
					advice was given on
					the DASH diet.
Wood, 2008 ¹³¹	IG1	Individual nurse assessment with personal report card and family	HD + PA	Nurses; family	Usual care: Centers
(EUROACTION)		support pack plus 8 group workshops of diet, PA, and risk factor	Total contact hrs: 8	doctors	randomized to usual
Fair			Total duration: 4 months	General practice	care were informed that
		support were used to help participants and their partners achieve risk		center	they would be audited.
		factor and lifestyle targets which included: not smoking, saturated fat			No other details
		400 g/day, fish >20 g/day, oily fish >3 times/week, alcohol < 6.1			reported.
		mmol/L (good glycemic control in diabetics); those with BMI >25			
		kg/m ² had a goal to reduce weight by 5% in 1 year. A pedometer was			
		used to motivate PA. Nurse monitored BP, lipids, and glucose and			
		reviewed results with physicians to treat to targets. Nurses educated			
		families about medications to improve adherence.			

Abbreviations: DPP = Diabetes Prevention Program; F/U = followup; g = grams; GP = general practitioner; HD = healthy diet only; HD + PA = healthy diet and physical activity; HDL = high-density lipoprotein cholesterol; hrs = hours; HTN = hypertension; IG = intervention group; Int arm = intervention arm; kg = kilograms; kg/m² = kilograms per meter squared; LDL = low-density lipoprotein cholesterol; mg = milligrams; MI = motivational interviewing; min = minutes; ml = milliliters; mm Hg = millimeters of mercury; mmol/L = millimoles per liter; NCEP = National Cholesterol Education Program; NHLBI = National Heart, Lung, and Blood Institute; NHS = National Health Service (UK); NR = not reported; PA = physical activity only; PCP = primary care provider; PN = practice nurse; TC = total cholesterol; TG = triglycerides; wk = week

Appendix G Figure 1. All CVD Events by Study

		Population	Timepoint						
Study	Int arm	risk focus	(months)	Outcome	IG n/N (%)	CG n/N (%)	CVD events	RR	95% CI
100000									
Appel, 2003	IG1	Hypertension	6	MI	1/269 (0.4)	1/273 (0.4)	-	1.01	[0.06; 16.02]
Appel, 2003	IG2	Hypertension	6	MI	0/268 (0.0)	1/273 (0.4)		0.34	[0.01; 8.29]
Appel, 2003	IG1	Hypertension	6	Stroke	0/269 (0.0)	1/273 (0.4)	•	0.34	[0.01; 8.29]
Appel, 2003	IG2	Hypertension	6	Stroke	0/268 (0.0)	1/273 (0.4)	•	0.34	[0.01; 8.29]
Bennett, 2012	IG1	Hypertension	24	CVD events	0/180 (0.0)	1/185 (0.5)		0.34	[0.01; 8.37]
Bennett, 2018	IG1	Multiple risk factors	12	CVD events	5/176 (2.8)	6/175 (3.4)	· · · · · · · · · · · · · · · · · · ·	0.83	[0.26; 2.68]
Bo, 2007	IG1	Multiple risk factors	108	CVD events	12/169 (7.1)	19/166 (11.4)	-	0.62	[0.31; 1.23]
Bo, 2007	IG1	Multiple risk factors	108	CVD Mortality	5/169 (3.0)	11/166 (6.6)	-	0.44	[0.16; 1.26]
Estruch, 2018	IG1	Multiple risk factors	60	CVD events	96/2543 (3.8)	109/2450 (4.4)		0.85	[0.65; 1.12]
Estruch, 2018	IG2	Multiple risk factors	60	CVD events	83/2454 (3.4)	109/2450 (4.4)	-	0.76	[0.58; 1.00]
Estruch, 2018	IG1	Multiple risk factors	60	CVD Mortality	26/2543 (1.0)	30/2450 (1.2)	- 	0.84	[0.49; 1.42]
Estruch, 2018	IG2	Multiple risk factors	60	CVD Mortality	31/2454 (1.3)	30/2450 (1.2)	-	1.03	[0.63; 1.68]
Estruch, 2018	IG1	Multiple risk factors	60	MI	37/2543 (1.5)	38/2450 (1.6)	-	0.94	[0.60; 1.48]
Estruch, 2018	IG2	Multiple risk factors	60	MI	31/2454 (1.3)	38/2450 (1.6)	-	0.81	[0.51; 1.30]
Estruch, 2018	IG1	Multiple risk factors	60	Stroke	49/2543 (1.9)	58/2450 (2.4)	-	0.81	[0.56; 1.18]
Estruch, 2018	IG2	Multiple risk factors	60	Stroke	32/2454 (1.3)	58/2450 (2.4)	-	0.55	[0.36; 0.84]
Fagerberg, 1998	IG1	Multiple risk factors	79	Coronary deaths	17/253 (6.7)	23/255 (9.0)	-	0.72	[0.38; 1.37]
Fagerberg, 1998	IG1	Multiple risk factors	79	Coronary events	44/253 (17.4)	50/255 (19.6)	-	0.86	[0.57; 1.30]
Fagerberg, 1998	IG1	Multiple risk factors	79	CVD events	63/253 (24.9)	84/255 (32.9)	-	0.71	[0.51; 0.99]
Fagerberg, 1998	IG1	Multiple risk factors	40	CVD Mortality	12/253 (4.7)	13/255 (5.1)	-	0.90	[0.41; 1.96]
Fagerberg, 1998	IG1	Multiple risk factors	79	CVD Mortality	24/253 (9.5)	42/255 (16.5)	-	0.56	[0.34; 0.91]
Fagerberg, 1998	IG1	Multiple risk factors	79	MI fatal	7/253 (2.8)	10/255 (3.9)	-	0.70	[0.28; 1.81]
Fagerberg, 1998	IG1	Multiple risk factors	79	MI nonfatal	22/253 (8.7)	25/255 (9.8)	_	0.89	[0.51; 1.54]
Fagerberg, 1998	IG1	Multiple risk factors	40	MI	18/253 (7.1)	22/255 (8.6)		0.80	[0.46; 1.39]
Fagerberg, 1998	IG1	Multiple risk factors	79	Stroke fatal	3/253 (1.2)	4/255 (1.6)	-	0.76	[0.17; 3.35]
Fagerberg, 1998	IG1	Multiple risk factors	79	Stroke nonfatal	13/253 (5.1)	25/255 (9.8)	-	0.52	[0.27; 1.00]
Fagerberg, 1998	IG1	Multiple risk factors	40	Stroke	5/253 (2.0)	17/255 (6.7)	-	0.30	[0.11; 0.82]
Fagerberg, 1998	IG1	Multiple risk factors	79	Stroke	16/253 (6.3)	29/255 (11.4)	-	0.53	[0.29; 0.98]
Haufe, 2019	IG1	Multiple risk factors	6	MI nonfatal	1/160 (0.6)	0/154 (0.0)	-		[0.12; 70.44]
Hinderliter, 2014	IG1	Hypertension	12	CVD events	0/46 (0.0)	0/49 (0.0)	- Mar		
TOHP I CRG, 1992	IG1	Hypertension	192	CVD events	17/231 (7.4)	32/311 (10.3)		0.71	[0.40; 1.26]
TOHP II CRG, 1997	IG0	Hypertension	192	CVD events	71/938 (7.6)	80/935 (8.6)	-	0.89	[0.65; 1.21]
Wadden, 2011	IG1	Multiple risk factors	24	MI	0/131 (0.0)	1/130 (0.8)	<u> </u>	0.33	[0.01; 8.04]
Whelton, 1998	IG1	Hypertension	36	CVD events	23/147 (15.6)		-		[0.65; 1.60]
Whelton, 1998	IG2	Hypertension	36	CVD events	21/147 (14.3)	57/371 (15.4)	-	0.93	[0.58; 1.49]
Whelton, 1998	IG3	Hypertension	36	CVD events	44/370 (11.9)	57/371 (15.4)			[0.53; 1.12]
Whelton, 1998	IG1	Hypertension	36	MI nonfatal	2/147 (1.4)	4/371 (1.1)		1.26	[0.23; 6.79]
Whelton, 1998	IG2	Hypertension	36	MI nonfatal	2/147 (1.4)	4/371 (1.1)		1.26	[0.23; 6.79]
Whelton, 1998	IG3	Hypertension	36	MI nonfatal	2/370 (0.5)	4/371 (1.1)		0.50	[0.09; 2.71]
Whelton, 1998	IG1	Hypertension	36	Stroke nonfatal	1/147 (0.7)	2/371 (0.5)		1.26	[0.12; 13.75]
Whelton, 1998	IG2	Hypertension	36	Stroke nonfatal	0/147 (0.0)	2/371 (0.5)	•		[0.02; 10.46]
Whelton, 1998	IG3	Hypertension	36	Stroke nonfatal	1/370 (0.3)	2/371 (0.5)			[0.05; 5.48]
						, ,			
							0.1 0.5 1 2 10		
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Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; Int arm = intervention arm; MI = myocardial infarction; RR = risk ratio; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

Appendix G Figure 2. Other CVD Events by Study

Study	Int arm	Population risk focus	Timepoint (months)	Outcome	IG n/N (%)	CG n/N (%)	Other CVD events	RR	95% CI
Annal 2002	IG1	Hypertension	6	Transient Ischemic Attack	0/260 (0.0)	1/272 (0.4)		0.34	[0.04- 9.20]
Appel, 2003	IG2	Hypertension	6	Transient Ischemic Attack	,	1/273 (0.4)		0.34	[0.01; 8.29]
Appel, 2003 Estruch, 2018	IG2					1/273 (0.4)			[0.01; 8.29]
		Multiple risk factors		Arrhythmia	3 2		·	0.78	[0.57; 1.07]
Estruch, 2018	IG2	Multiple risk factors		Arrhythmia	92/2210 (4.2)	\$1.00 miles \$1		1.03	[0.77; 1.38]
Estruch, 2018	IG1	Multiple risk factors		Incident PAD	18/2539 (0.7)		·		[0.22; 0.67]
Estruch, 2018	IG2	Multiple risk factors		Incident PAD	26/2452 (1.1)	and the second second second	-		[0.36; 0.92]
Fagerberg, 1998	IG1	Multiple risk factors		Angina	7/253 (2.8)	12/255 (4.7)			[0.20; 1.80]
Fagerberg, 1998	IG1	Multiple risk factors	40	Claudication	7/253 (2.8)	10/255 (3.9)		0.70	[0.28; 1.72]
Wadden, 2011	IG1	Multiple risk factors	24	Angina	5/131 (3.8)	1/130 (0.8)	-	4.95	[0.58; 41.95]
Wadden, 2011	IG1	Multiple risk factors	24	Congestive Heart Failure	0/131 (0.0)	2/130 (1.5)		0.20	[0.01; 4.05]
Whelton, 1998	IG1	Hypertension	36	Angina	10/147 (6.8)	19/371 (5.1)	-	1.32	[0.63; 2.79]
Whelton, 1998	IG2	Hypertension	36	Angina	10/147 (6.8)	19/371 (5.1)	- 1	1.32	[0.63; 2.79]
Whelton, 1998	IG3	Hypertension	36	Angina	10/370 (2.7)	19/371 (5.1)	-	0.53	[0.25; 1.11]
Whelton, 1998	IG1	Hypertension	36	Arrhythmia	1/147 (0.7)	4/371 (1.1)		0.63	[0.07; 5.56]
Whelton, 1998	IG2	Hypertension	36	Arrhythmia	2/147 (1.4)	4/371 (1.1)	-	1.26	[0.23; 6.79]
Whelton, 1998	IG3	Hypertension	36	Arrhythmia	6/370 (1.6)	4/371 (1.1)		1.51	[0.43; 5.28]
Whelton, 1998	IG1	Hypertension	36	Congestive Heart Failure	0/147 (0.0)	1/371 (0.3)	•	- 0.84	[0.03; 20.38]
Whelton, 1998	IG2	Hypertension	36	Congestive Heart Failure	1/147 (0.7)	1/371 (0.3)	-	2.53	[0.16; 40.19]
Whelton, 1998	IG3	Hypertension	36	Congestive Heart Failure	4/370 (1.1)	1/371 (0.3)	-	4.01	[0.45; 36.06]
Whelton, 1998	IG1	Hypertension	36	Other CVD events	8/147 (5.4)	19/371 (5.1)	-	1.06	[0.48; 2.37]
Whelton, 1998	IG2	Hypertension	36	Other CVD events	6/147 (4.1)	19/371 (5.1)		0.79	[0.32; 1.96]
Whelton, 1998	IG3	Hypertension	36	Other CVD events	13/370 (3.5)	19/371 (5.1)	-	0.68	[0.34; 1.36]
Whelton, 1998	IG1	Hypertension	36	Transient Ischemic Attack	1/147 (0.7)	8/371 (2.2)		0.32	[0.04; 2.53]
Whelton, 1998	IG2	Hypertension	36	Transient Ischemic Attack	0/147 (0.0)	8/371 (2.2)	.	0.15	[0.01; 2.54]
Whelton, 1998	IG3	Hypertension	36	Transient Ischemic Attack	8/370 (2.2)	8/371 (2.2)	_	1.00	[0.38; 2.61]
		95b/sm:			a 5	8 48		1	10 W 5
							0.01 0.1 0.5 1 2 10	100	

Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; IG = intervention group; Int arm = intervention arm; PAD = peripheral artery disease; RR = risk ratio

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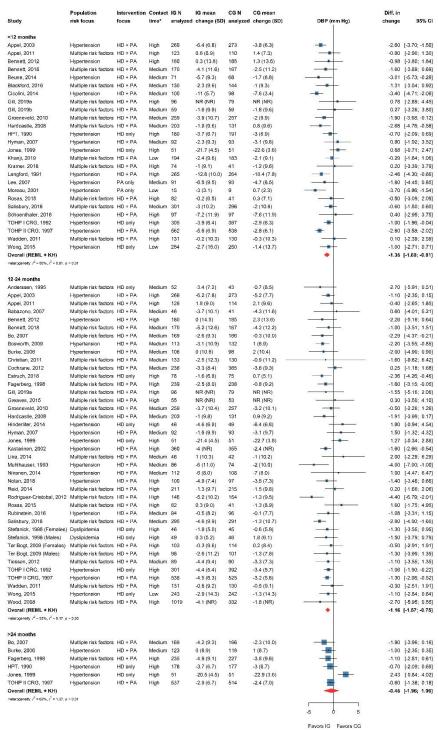
Appendix G Figure 3. Systolic Blood Pressure by Study and Followup Category

Study	Population risk focus	Intervention focus	Contact time*		IG mean change (SD)	CG N analyzed	CG mean change (SD)	SBP (mm Hg)	Diff. in change	95
<12 months										
Appel, 2003	Hypertension	HD + PA	High	269	-11.1 (9.9)	273	-6.6 (9.2)		-4.30	[-5.85; -
opel, 2011	Multiple risk factors		High	123	0.7 (13.3)	110	2.1 (11.5)			[-4.59:
lennett, 2012	Hypertension	HD + PA	High	180	0.5 (21.5)	185	1.8 (21.1)	-	-1.30	[-5.67:
ennett. 2018	Multiple risk factors		Medium	170	-4.6 (19.3)	167	-3.4 (18.8)		-1.20	[-5.00:
eune. 2014	Hypertension Multiple risk factors	HD + PA	Medium		-9.9 (14.5)	68	-6.3 (13.6)		-1.69	[-6.00: [-6.70:
lackford, 2016	Multiple risk factors Hypertension	HD + PA			-5.2 (15.2)	144	-2.2 (16.0)	-		
ilcolini, 2014 illi, 2019a		30,070 2000	Medium	96	-14.9 (8.1)	79	-10 (11.6)			[-7.68;
iii, 2019a iii. 2019b	Multiple risk factors Multiple risk factors		High Medium		NR (NR) -6.4 (15.5)	59	NR (NR) -6.6 (15.0)			[-5.02:
roeneveld, 2010	Multiple risk factors		Medium		-5.2 (16.7)	257	-2.1 (16.1)			[-5.92;
lardcastle, 2008	Multiple risk factors		Medium		-2.9 (17.0)	131	-0.6 (18.2)		-2.27	[-6.17:
aufe, 2019	Multiple risk factors		Medium		-6 (12.7)	154	-3 (13.7)			[-4.95;
PT. 1990	Hypertension	HD only	High	180	-3.4 (8.1)	191	-2.1 (8.3)			1-2.97
yman, 2007	Hypertension	HD + PA	Medium		-5.8 (19.4)	93	-3.3 (19.1)	-	-2.50	[-8.05:
ones, 1999	Hypertension	HD only	High	51	-32 (15.0)	51	-32.9 (10.7)		0.88	[-4.18:
andula, 2015	Multiple risk factors		High	31	-3.6 (11.5)	32	-3.4 (11.6)	· · · · · · · · · · · · · · · · · · ·	-0.20	[-5.41:
hanji, 2019	Multiple risk factors	HD + PA	Low	194	-3.2 (14.1)	183	-1.7 (15.5)		-1.50	[4.20:
ramer. 2018	Multiple risk factors	HD + PA	High	74	-3.4 (11.2)	41	0.3 (10.3)		-3.10	[-7.16:
angford, 1991	Hypertension	HD + PA	High	265	-17 (15.9)	264	-14.2 (15.9)		-2.80	[-5.52;
ee. 2007	Hypertension	PA only	Medium	91	-16.2 (14.8)	93	-8.1 (14.3)		-8.10	[-12.75;
loreau, 2001	Hypertension	PA only	Low	15	-11 (4.9)	9	-0.8 (4.3)		-10.20	[-13.96;
odriguez, 2012	Hypertension	HD + PA	Medium	176	-4.7 (14.9)	177	-2.7 (3.4)		-2.00	[-4.25:
tosas, 2015	Multiple risk factors	HD + PA	High	82	-1.8 (11.1)	41	-2.2 (13.3)		0.40	[-4.32:
alisbury, 2016	Multiple risk factors		Medium		-6.6 (16.4)	296	-6.7 (17.4)			[-1.90:
choenthaler, 2016	Hypertension	HD + PA	High	97	-9.5 (15.6)	97	-12.9 (15.0)		3.40	[-0.91;
vetkey. 2009	Hypertension	HD + PA	High	132	-9.7 (12.7)	132	-6.7 (12.8)			[-6.08:
OHP I CRG, 1992	Hypertension	HD only	High	305	-5.9 (7.9)	397	-3.8 (8.5)	-		[-3.26;
OHP II CRG, 1997	Hypertension	HD + PA	High	562	-6.2 (8.6)	538	-2.2 (8.1)	-		[-4.98;
Vadden, 2011	Multiple risk factors		High	131	0.3 (14.9)	130	-0.7 (14.8)			[-2.61:
Vong, 2015	Hypertension	HD only	Low	254	-8.9 (18.3)	250	-8.3 (17.3)	-		[-2.95;
verall (REML + KH) serogeneity 12 - 63%, 13 - 2.38, p	×0.01							•	-2.25	[-3.12;
2-24 months										
anderssen, 1995	Multiple risk factors	HD only	Medium	52	-6.4 (10.1)	43	-0.5 (11.2)		-5.90	[-10.21;
ppel, 2003	Hypertension	HD + PA	High	269	-9.5 (10.8)	273	-7.4 (10.8)	-		[-3.70;
appel, 2011	Multiple risk factors	HD + PA	High	126	2.6 (12.3)	114	3.6 (14.9)			[-4.65]
abazono, 2007	Multiple risk factors	HD + PA	Medium	46	-5.2 (16.8)	41	-8.7 (17.5)			[-3.71:
ennett, 2012	Hypertension	HD + PA	High	180	-1.4 (22.5)	185	3.3 (21.2)	-	-4.73	[-9.24;
ennett, 2018	Multiple risk factors		Medium		-8.4 (20.3)	167	-7.5 (19.5)		-0.90	[-4.90]
a, 2007	Multiple risk factors	HD + PA	Medium	169	-2 (18.8)	186	4.8 (17.0)		-6.78	[-10 62;
lasworth, 2009	Hypertension	HD + PA	Medium	113	-5.2 (19.0)	132	0.7 (16.1)		-3.30	[-5.75;
roekhuizen, 2012	Dyslipidemia	HD + PA	Medium	169	0 (14.9)	143	-1.1 (15.8)		1.10	[-2.33;
urke, 2006	Hypertension	HD + PA	Medium		2 (10.8)	98	4 (10.4)	_ 	-2.00	[-4.90;
Christian, 2011	Multiple risk factors	HD + PA	Medium	133	-2.2 (14.8)	130	-0.5 (18.4)		-1.70	[-13.15;
Ochrane, 2012	Multiple risk factors	HD + PA	Medium	236	-5.6 (14.8)	365	-6.7 (16.7)		1.01	[-1.54;
struch, 2018	Multiple risk factors	HD only	High	78	-2.9 (10.6)	75	2.4 (8.1)		-6.30	[-8.28;
agerberg, 1998	Multiple risk factors	HD + PA	High	239	-3 (16.0)	238	-2 (20.0)		-2.00	[-5.51;
Bill, 2019a	Multiple risk factors	HD + PA	High	96	NR (NR)	79	NR (NR)		0.05	[-3.99;
ireaves, 2015	Multiple risk factors	HD + PA	High	55	NR (NR)	53	NR (NR)		1.09	[-3.67;
iroeneveld, 2010	Multiple risk factors	HD + PA	Medium	259	-4.9 (17.0)	257	-3.8 (16.3)	-	-1.10	[-3.98;
lardcastle, 2008	Multiple risk factors	HD + PA	Medium	203	-4.1 (16.3)	131	-2.5 (18.4)		-1.69	[-6.55;
finderliter, 2014	Hypertension	HD only	High	46	-9.5 (9.1)	49	-3.9 (11.8)	·	-6.60	[-9.83;
lyman, 2007	Hypertension	HD + PA	Medium	92	-6.5 (19.6)	93	-2.9 (18.7)			[-9.13;
ones, 1999	Hypertension	HD only	High	51	-30 (14.7)	51	-33 (10.7)			[-2.00;
lasterinen, 2002	Hypertension	HD + PA	High	360	-4.7 (NR)	355	-3.4 (NR)	-	-1.30	[-3.20;
delewijn-van Loon, 2009	Multiple risk factors	HD + PA	Medium	286	-6 (18.5)	281	-8 (1B.5)		2.00	[-1.12;
iira, 2014	Multiple risk factors	HD + PA	Medium		3 (13.8)	42	-2 (13.8)		5.00	[-0.78; 1
Juhlhauser, 1993	Hypertension	HD + PA	Medium		-8 (17.0)	74	-3 (18.0)			[-10.00;
liranen, 2014	Hypertension	HD + PA	Medium		-8 (17.0)	108	-11 (17.0)	× ***		[-8.60;
lolan, 2018	Hypertension	HD + PA	High	100	-10.1 (12.5)	97	-6 (12.6)	-		[-7.61;
teid, 2014	Multiple risk factors		High	211	-3.3 (15.6)	215	-2.9 (16.7)			[-3.46;
todriguez-Cristobal, 2012	Multiple risk factors	HD + PA	High	146	-4.2 (17.2)	154	2.2 (17.4)		-6.BD	[-10.76;
todriguez, 2012	Hypertension	HD + PA	Medium		-5.4 (14.8)	157	-4.1 (15.0)		-1.33	[-4.66;
tosas, 2015	Multiple risk factors		High	82	-1.3 (13.6)	41	-3 (15.1)		1.70	[-3.77;
tubinstein, 2016	Hypertension	HD + PA	Medium		-4 (9.4)	96	-2.2 (11.0)		-1.77	[-5.06;
lalisbury, 2016	Multiple risk factors	HD + PA	Medium	295	-8 (15.9)	291	-5.9 (17.7)		-2.70	[-4.76;
tefanick, 1998 (Females)		HD only	High	46	-3.5 (9.2)	45	-2.4 (7.8)			[-4.57;
tefanick, 1998 (Males)	Dyslipidemia	HD only	High	49	-1.7 (6.4)	46	-0.3 (7.9)	-		[-4.30;
er Bogt, 2009 (Females)	Multiple risk factors		High	103	-5.3 (20.1)	114	-2.2 (16.5)		-3.10	[-8.02;
er Bogt, 2009 (Males)	Multiple risk factors		High	98	-8.5 (16.8)	101	-5.3 (12.7)	(-3.20	[-7.36;
iessen, 2012	Multiple risk factors		Medium		-6.8 (17.1)	90	-5.6 (14.3)	-	-1.20	[-5.81;
OHP I CRG, 1992	Hypertension	HD only	High	301	-5.8 (7.5)	392	-3.9 (7.4)			[-3.02;
OHP II CRG, 1997	Hypertension	HD + PA	High	538	-3.9 (8.3)	525	-1.8 (7.0)		-2.00	[-2.98;
Vadden, 2011	Multiple risk factors		High	131	0.8 (14.9)	130	1.2 (14.8)	-		[-4.01;
Vister, 2007	Multiple risk factors		Medium		-7.5 (15.8)	158	-3.6 (16.0)			[-7.44;
Vong, 2015	Hypertension	HD only	Low	243	-9 (18.3)	242	-8.7 (17.1)			[-2.39;
food, 2008	Multiple risk factors	HD + PA	High	1019	-7.6 (NR)	332	-2.8 (NR)		-4.80	[-10.21;
verall (REML + KH)	<0.01							•		[-2.49;
24 months a, 2007	Multiple risk factors	HD + PA	Medium	189	-4.6 (15.2)	166	2.3 (16.7)	W	,e o^	[-10.31,
	Multiple risk factors Hypertension							The second secon		
urke, 2006		HD + PA	Medium		-1 (11.9)	118	1 (11.6)			[-3.50,
agerberg, 1998	Multiple risk factors	HD + PA HD only	High	235	-2 (18.4)	227	-0.2 (20.5)	M.	-1.80	[-5.35,
PT, 1990 ones, 1999		HD only	High	178 51	-4.1 (9.3)	177	-2.9 (9.3) -33.9 (10.7)			[-3.14;
	Hypertension		High High	537	-33.1 (14.7)	514				[-4.20;
OHP II CRG, 1997 Overall (REML + KH)	Hypertension	HD + PA	High	331	-0.5 (9.0)	317	0.6 (8.5)			[-4.12;
mongonary (* 100%, * 1100, p	# Q EG									
								-10 -5 0 5 10		
								Favors IG Favors CG		
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Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; HPT = Hypertension Prevention Trial; KH = Knapp-Hartung adjustment; mm + Hg = millimeters of mercury; REML = restricted maximum likelihood; SBP = systolic blood pressure; SD = standard deviation; $TOHP \ I \ CRG = The$ Trials of Hypertension Prevention - Phase I Collaborative Research Group; $TOHP \ II \ CRG = The$ Trials of Hypertension Prevention - Phase II Collaborative Research Group

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

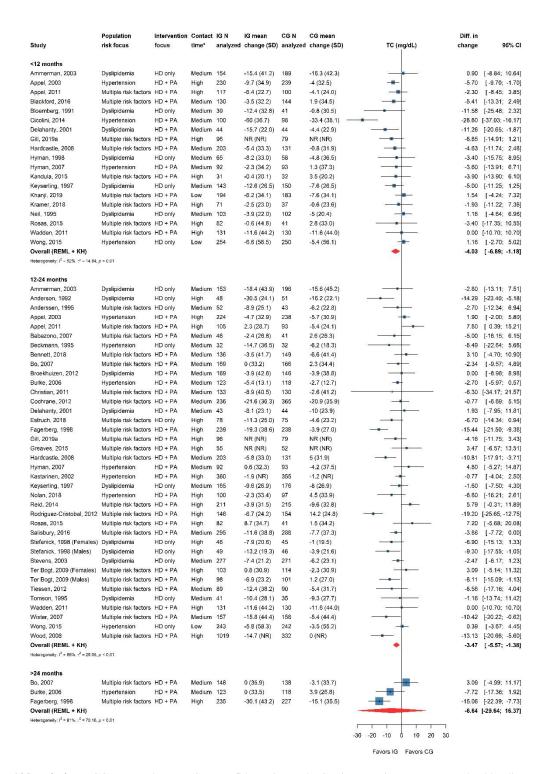
Appendix G Figure 4. Diastolic Blood Pressure by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; DBP = diastolic blood pressure; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; HPT = Hypertension Prevention Trial; KH = Knapp-Hartung adjustment; mm Hg = millimeters of mercury; REML = restricted maximum likelihood; SD = standard deviation; TOHP I CRG = The Trials of Hypertension Prevention – Phase I Collaborative Research Group; TOHP II CRG = The Trials of Hypertension Prevention – Phase II Collaborative Research Group

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

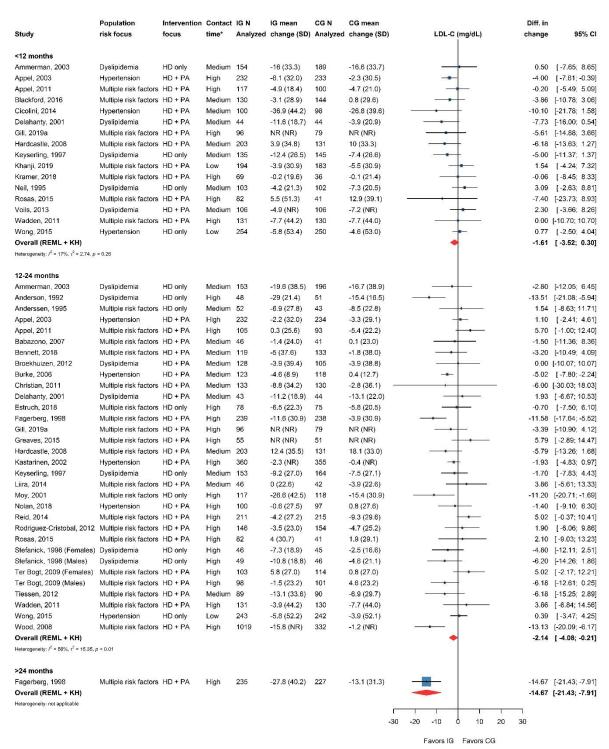
Appendix G Figure 5. Total Cholesterol by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; TC = total cholesterol

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

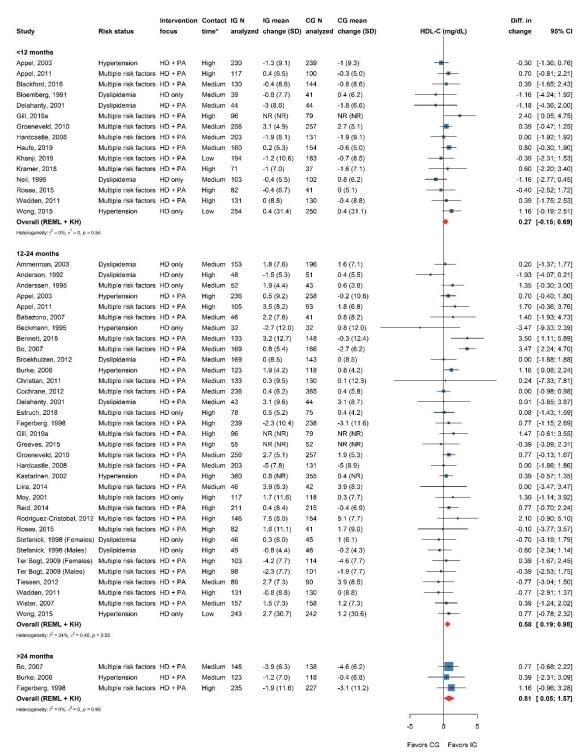
Appendix G Figure 6. LDL Cholesterol by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; CI = confidence interval; CI = confidence i

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

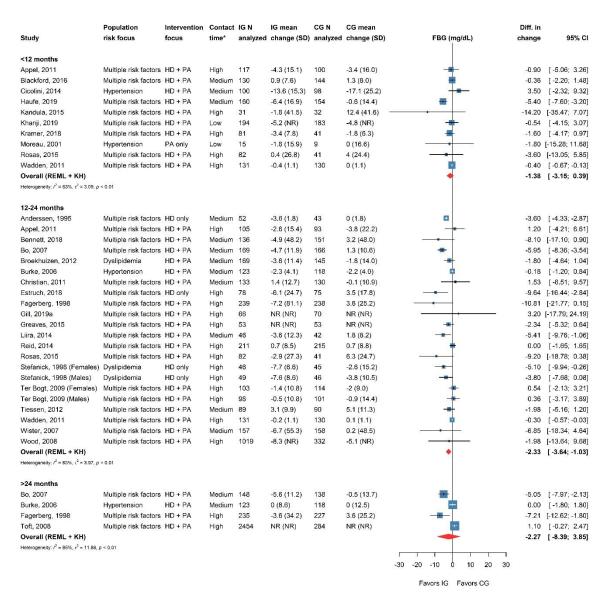
Appendix G Figure 7. HDL Cholesterol by Study and Followup Category



Abbreviations: $CG = control\ group;\ CI = confidence\ interval;\ IG = intervention\ group;\ HD = healthy\ diet;\ HD + PA = healthy\ diet\ and\ physical\ activity;\ HDL-C = low-density\ lipoprotein\ cholesterol;\ KH = Knapp-Hartung\ adjustment;\ mg/dL = milligrams\ per\ deciliter;\ REML = restricted\ maximum\ likelihood;\ SD = standard\ deviation$

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

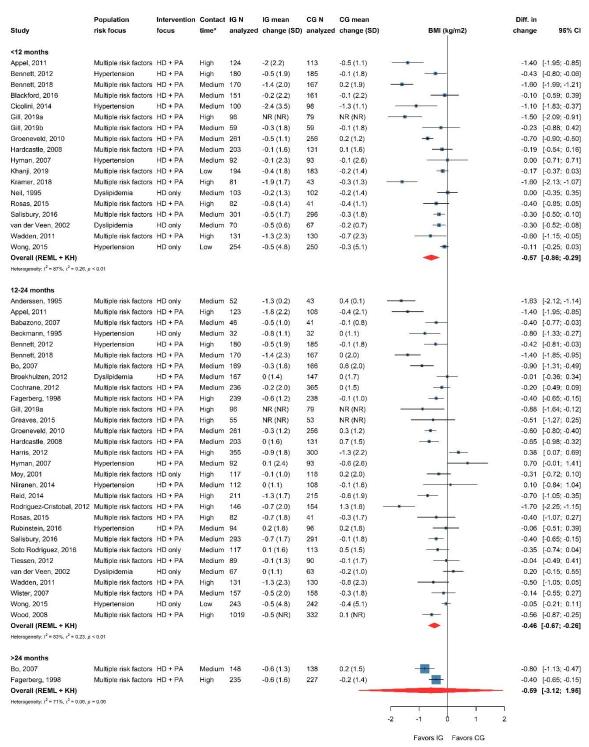
Appendix G Figure 8. Fasting Blood Glucose by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FBG = fasting blood glucose; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; mg/dL = milligrams per deciliter; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

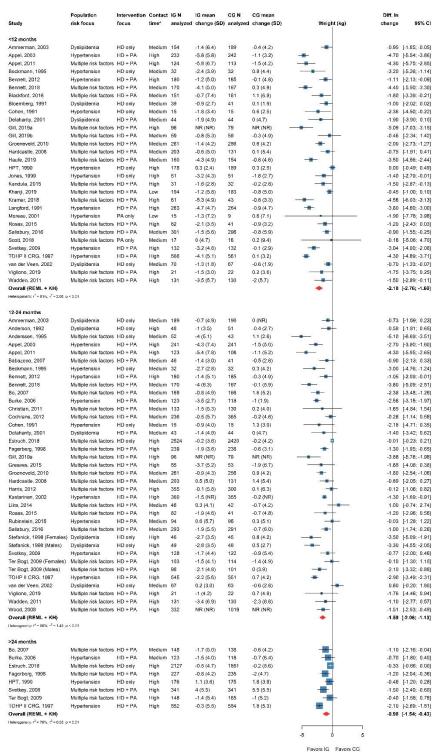
Appendix G Figure 9. Body Mass Index by Study and Followup Category



Abbreviations: BMI = body mass index; CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; kg/m² = kilograms per meter squared; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

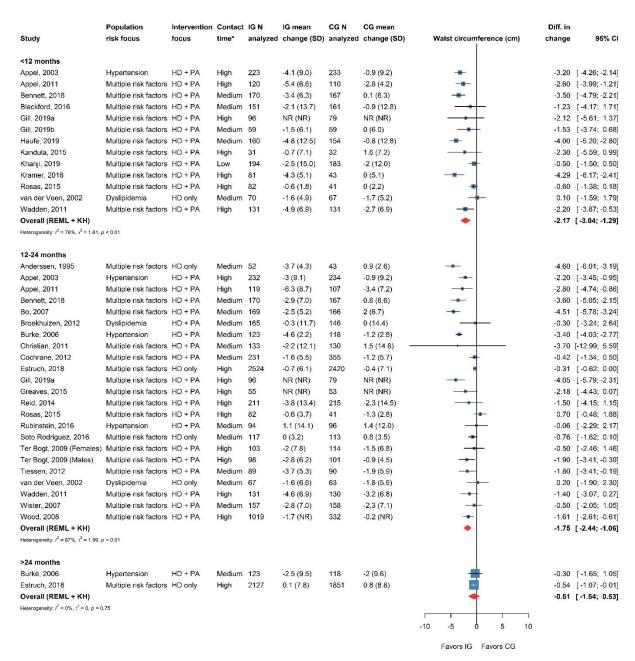
Appendix G Figure 10. Weight by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; kg = kilograms; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

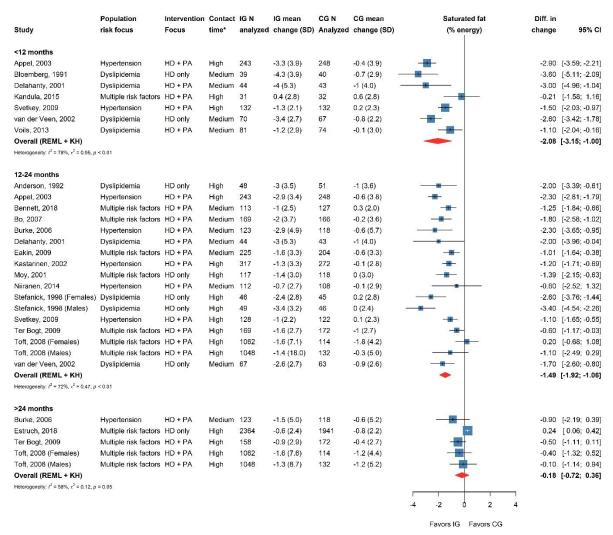
Appendix G Figure 11. Waist Circumference by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; cm = centimeters; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

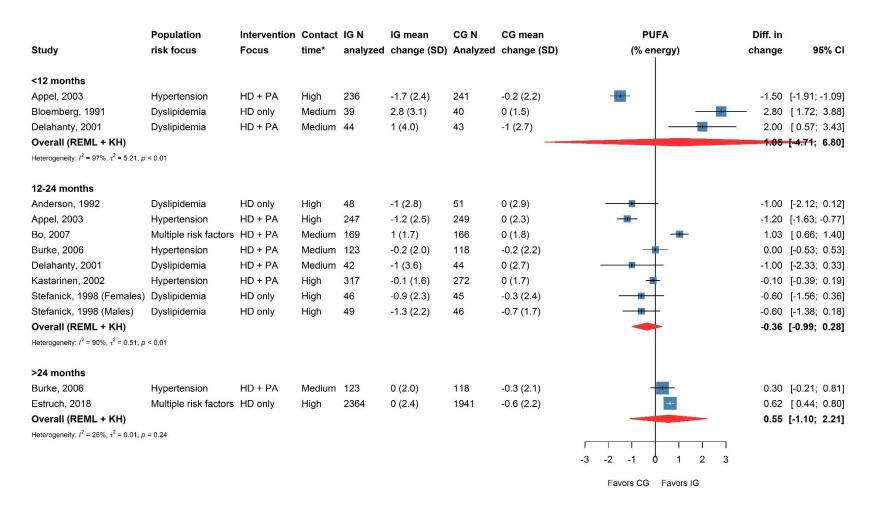
Appendix G Figure 12. Saturated Fat by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

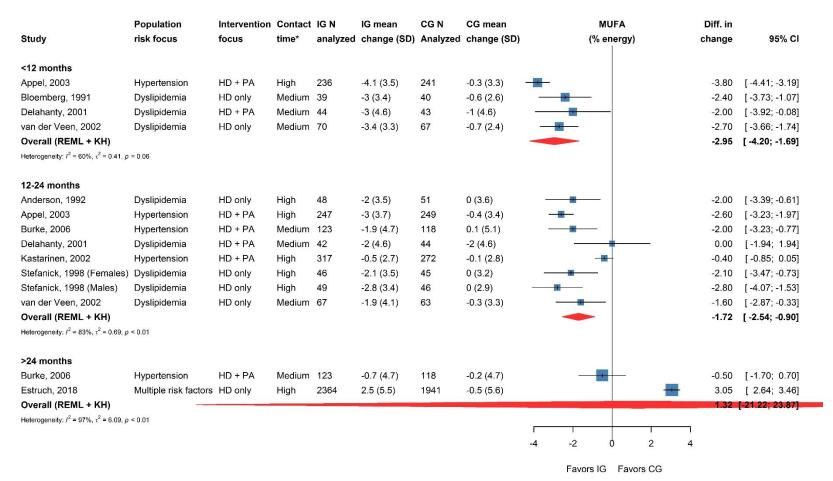
Appendix G Figure 13. Polyunsaturated Fat by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; PUFA = polyunsaturated fatty acids; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

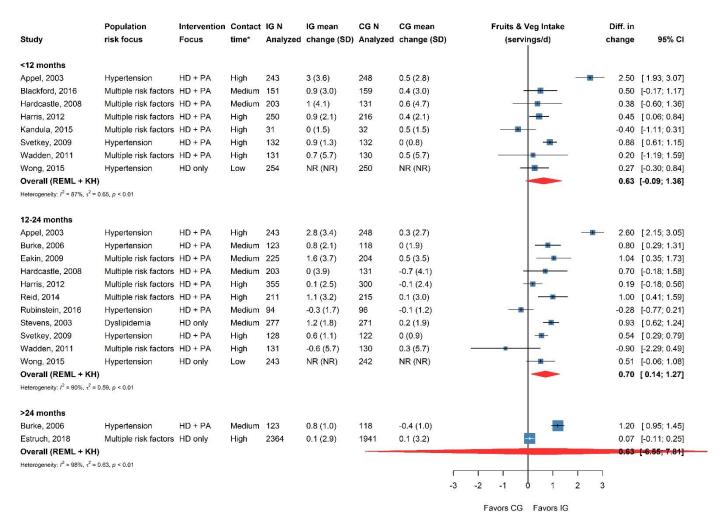
Appendix G Figure 14. Monounsaturated Fat by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; IG = intervention group; HD = healthy diet; HD + PA = healthy diet and physical activity; KH = Knapp-Hartung adjustment; MUFA = monounsaturated fatty acids; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

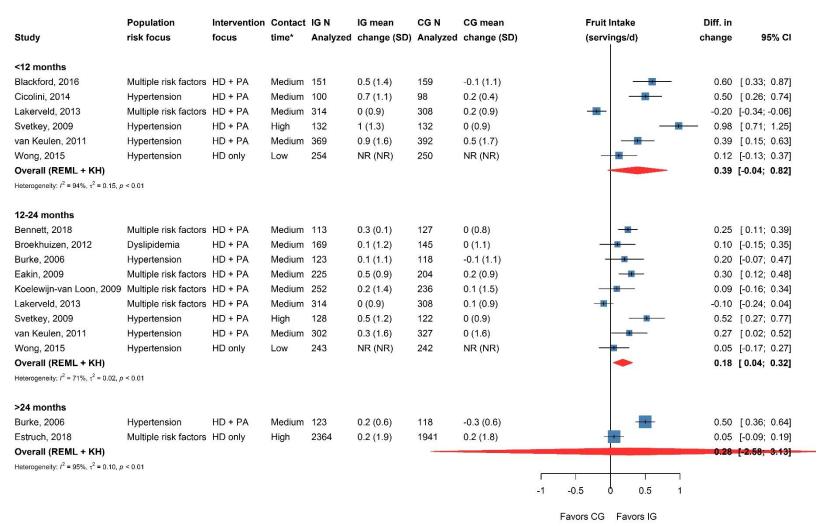
Appendix G Figure 15. Fruit and Vegetable Intake by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; servings/d = servings per day

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 16. Fruit Intake by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; servings/d = servings per day

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 17. Vegetable Intake by Study and Followup Category

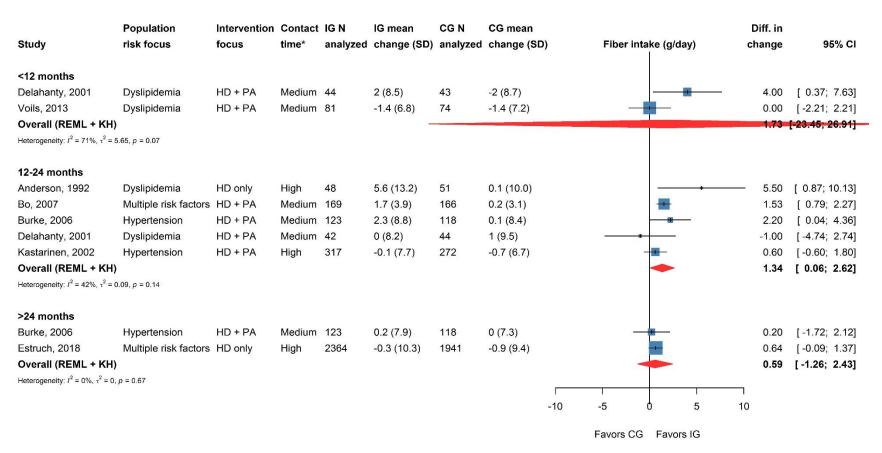
Study	•	Intervention focus	Contact time*	Unit	IG N Analyzed	IG mean change (SD)	CG N Analyzed	CG mean change (SD)	Vegetable Intake	Hedges g	95% CI
<12 months											
Blackford, 2016	Multiple risk factors	HD + PA	Medium	servings/d	151	0.4 (2.1)	159	0.5 (2.2)	-	-0.05	[-0.27; 0.18]
Lakerveld, 2013	Multiple risk factors	HD + PA	Medium	g/day	314	13 (109.8)	308	1 (69.5)	 -	0.13	[-0.03; 0.29]
Svetkey, 2009	Hypertension	HD + PA	High	servings/d	132	1 (2.5)	132	0.1 (1.7)	-	0.42	[0.18; 0.66]
van Keulen, 2011	Hypertension	HD + PA	Medium	g/day	369	26 (78.2)	392	16 (80.0)	-	0.13	[-0.02; 0.27]
Overall (REML + KH)									•	0.15	[0.00; 0.30]
Heterogeneity: $I^2 = 62\%$, $\tau^2 = 0.01$, ρ	= 0.05										
12-24 months											
Bennett, 2018	Multiple risk factors	HD + PA	Medium	servings/d	113	0.2 (1.8)	127	0.1 (1.8)	-	0.06	[-0.20; 0.31]
Broekhuizen, 2012	Dyslipidemia	HD + PA	Medium	g/day	169	9.4 (76.2)	146	12.2 (77.5)		-0.04	[-0.26; 0.19]
Burke, 2006	Hypertension	HD + PA	Medium	servings/d	123	0.7 (1.3)	118	0.1 (1.1)		0.50	[0.24; 0.75]
Eakin, 2009	Multiple risk factors	HD + PA	Medium	servings/d	225	1.1 (3.2)	204	0.3 (3.0)	-	0.26	[0.07; 0.45]
Koelewijn-van Loon, 2009	Multiple risk factors	HD + PA	Medium	Tbsp/d	252	0.3 (1.7)	236	0.1 (1.9)	-	0.11	[-0.07; 0.29]
Lakerveld, 2013	Multiple risk factors	HD + PA	Medium	g/day	314	8 (72.2)	308	7 (81.9)	-	0.01	[-0.14; 0.17]
Svetkey, 2009	Hypertension	HD + PA	High	servings/d	128	0.3 (2.5)	122	0.3 (2.5)		0.00	[-0.25; 0.25]
Ter Bogt, 2009	Multiple risk factors	HD + PA	High	g/day	169	16.1 (65.0)	172	13.6 (77.9)	- -	0.03	[-0.18; 0.25]
van Keulen, 2011	Hypertension	HD + PA	Medium	g/day	302	11 (84.7)	327	-3 (80.5)	- - M -	0.17	[0.01; 0.33]
Overall (REML + KH)									•	0.12	[0.02; 0.21]
Heterogeneity: $I^2 = 50\%$, $\tau^2 = 0.01$, ρ	= 0.04										
>24 months											
Burke, 2006	Hypertension	HD + PA	Medium	servings/d	123	0.6 (0.6)	118	-0.1 (0.6)	-	1.16	[0.89; 1.44]
Estruch, 2018	Multiple risk factors	HD only	High	servings/d	2364	-0.1 (1.5)	1941	-0.1 (1.9)	+	0.00	[-0.06; 0.06]
Ter Bogt, 2009	Multiple risk factors	HD + PA	High	g/day	158	11.7 (74.1)	172	18.2 (86.7)		-0.08	[-0.30; 0.14]
Overall (REML + KH)										0.35	[-0.25; 0.95]
Heterogeneity: $I^2 = 97\%$, $\tau^2 = 0.27$, p	< 0.01										
									1 05		
									-1 -0.5 0 0.5 1		

Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; NR = not reported; REML = restricted maximum likelihood; SD = standard deviation; SD = s

Favors CG Favors IG

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

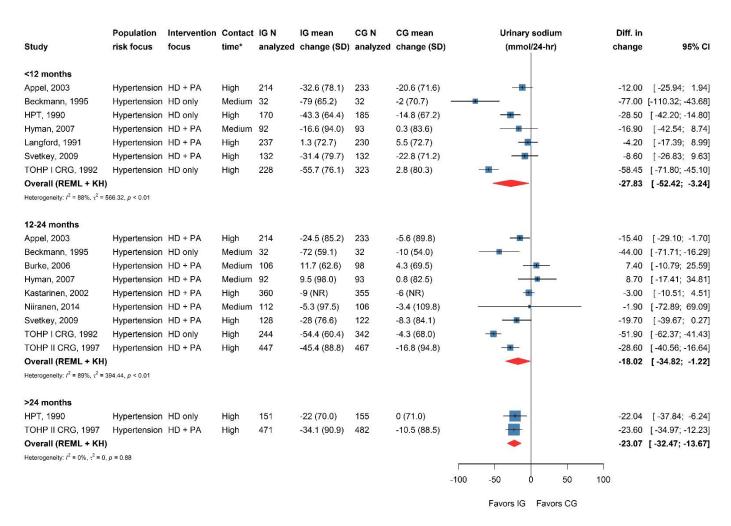
Appendix G Figure 18. Fiber Intake by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 19. Urinary Sodium by Study and Followup Category



Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; mmol/24-hr = millimoles per 24 hours; REML = restricted maximum likelihood; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Appendix G Figure 20. Physical Activity at 12 to 24 Months' Followup

	Intervention	Contact			IG N	IG mean	CG N	CG mean				
Study	focus	time*	Outcome	Unit	Analyzed	change (SD)	Analyzed	change (SD)	BG p-value	Physical Activity	Hedges g	95% CI
Anderson, 1992	HD only	High	Total energy expenditure	kJ/kg/d	48	0.1 (16.9)	51	13.7 (28.2)	<0.05			[-0.98; -0.17]
Appel, 2003	HD + PA	High	Total PA	kcal/kg	240	0.8 (3.4)	242	0.6 (3.6)	NSD	_		[-0.12; 0.24]
Babazono, 2007	HD + PA		Total PA	steps/d	46	3028 (3993.2)	41	-381 (3558.7)	≤0.001	_		[0.45; 1.33]
Bo, 2007	HD + PA		Total PA	MET-min/wk		283.8 (724.3)	166	-15.6 (260.3)	<0.001		0.55	[0.33; 0.77]
Broekhuizen, 2012	HD + PA		Moderate to vigorous intensity PA	min/wk	171	79 (NR)	146	64.9 (NR)	NSD			
Burke, 2006	HD + PA		Moderate to vigorous intensity PA	min/wk	123	41 (124.5)	118	20 (119.2)	0.185			[-0.08; 0.42]
Christian, 2011	HD + PA		Total PA	MET-min/wk		288.8 (659.0)	130	112.3 (1216.4)	0.07	+	0.18	[-0.06; 0.42]
Cochrane, 2012	HD + PA		Total PA	score	236	0.1 (NR)	365	0.2 (NR)	NSD			
Delahanty, 2001	HD + PA	Medium	Total PA	min/wk	43	29 (115.9)	44	43 (160.3)	NSD	-	-0.10	[-0.52; 0.32]
Eakin, 2009	HD + PA	Medium	Moderate to vigorous intensity PA	min/wk	225	71.2 (213.0)	204	82.2 (213.0)	0.589		-0.05	[-0.24; 0.14]
Estruch, 2018 (w/ METS)	HD only	High	Leisure PA	MET-min/wk	1236	133 (1946.2)	1094	77 (1890.0)	NSD		0.03	[-0.05; 0.11]
Estruch, 2018 (w/o METS)	HD only	High	Leisure PA	MET-min/wk	663	126 (1977.1)	594	63 (1871.4)	NSD		0.03	[-0.08; 0.14]
Greaves, 2015	HD + PA	High	Moderate to vigorous intensity PA	min/wk	53	-3.6 (104.2)	53	22.9 (131.7)	0.291	-	-0.22	[-0.60; 0.16]
Hardcastle, 2008	HD + PA	Medium	Total PA	MET-min/wk	203	1299.6 (2977.6)	131	993.5 (3470.0)	NSD	- - - - - - - - - - 	0.10	[-0.12; 0.32]
Harris, 2012	HD + PA	High	PA score	score	355	0.9 (2.5)	300	0.7 (2.5)	0.005	-	0.08	[-0.07; 0.23]
Hyman, 2007	HD + PA	Medium	Total PA	steps/d	92	127 (2813.7)	93	-284.5 (3906.7)	NSD	-	0.12	[-0.17; 0.41]
Koelewijn-van Loon, 2009	HD + PA	Medium	Moderate to vigorous intensity PA	min/wk	252	55 (352.9)	236	2 (355.4)	0.74	 -	0.15	[-0.03; 0.33]
Lakerveld, 2013	HD + PA	Medium	Vigorous intensity PA	MET-min/wk	314	NR (NR)	308	NR (NR)	NSD			
Migneault, 2012	HD + PA	High	Moderate to vigorous intensity PA	min/wk	169	-21.3 (NR)	168	7.3 (NR)	NSD			
Niiranen, 2014	HD + PA	Medium	Leisure PA	MJ/d	112	0 (0.4)	108	0.1 (0.3)	0.15		-0.28	[-0.55; -0.02]
Reid, 2014	HD + PA	High	Total PA	min/wk	211	50.8 (113.5)	215	29.9 (104.7)	0.03	-	0.19	[0.00; 0.38]
Rodriguez, 2012	HD + PA	Medium	Total PA	min/wk	151	-60.6 (412.7)	155	31.2 (420.7)	NSD		-0.22	[-0.44; 0.01]
Rubinstein, 2016	HD + PA	Medium	Total PA	MET-min/wk	94	-348.9 (1345.5)	96	-188.5 (842.2)	0.22		-0.14	[-0.43; 0.14]
Salisbury, 2016	HD + PA	Medium	PA score	score	297	NR (NR)	294	NR (NR)	0.003			
Svetkey, 2009	HD + PA	High	Moderate to vigorous intensity PA	min/wk	128	-0.7 (112.3)	122	-13 (145.7)	NSD		0.09	[-0.15; 0.34]
Ter Bogt, 2009	HD + PA	High	Total PA	MET-min/wk	120	-126 (997.6)	129	-68 (909.8)	0.52		-0.06	[-0.31; 0.19]
Toft, 2008 (Males)	HD + PA	High	Moderate to vigorous intensity PA	min/wk	2965	-2.5 (359.4)	337	-18.9 (361.6)	NSD	-	0.05	[-0.07; 0.16]
Toft, 2008 (Females)	HD + PA	High	Moderate to vigorous intensity PA	min/wk	3126	-1.8 (380.2)	356	-38.8 (358.5)	NSD		0.10	[-0.01; 0.21]
van Keulen, 2011	HD + PA	Medium	Moderate intensity PA	min/wk	302	44.4 (255.0)	327	45.6 (249.2)	NSD	-	-0.00	[-0.16; 0.15]
van Sluijs, 2005	PA only	Medium	Moderate intensity energy expenditure	min/wk	171	NR (NR)	187	NR (NR)	0.38			
Wadden, 2011	HD + PA	High	Moderate to vigorous intensity PA	kcal/wk	131	415.4 (2060.2)	130	-70.4 (2120.7)	0.037	<u> </u>	0.23	[-0.01; 0.48]
Wister, 2007	HD + PA	Medium	PA score	score	157	0.2 (1.5)	158	0.2 (1.5)	NSD		0.00	[-0.22; 0.22]
										T		
Overall (REML + KH)											0.06	[-0.03; 0.14]
Heterogeneity: $I^2 = 64\%$, $\tau^2 = 0.02$, p	< 0.01											
										-1 -0.5 0 0.5 1		
										Favors CG Favors IG		

Abbreviations: BG = between-group; CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = intervention group; KH = Knapp-Hartung adjustment; kcal/kg = kilocalories per kilogram; kcal/wk = kilocalories per week; kJ/kg/d = kilojoules per kilogram per day; MET-min/wk = metabolic equivalent of task minutes per week; METS = metabolic syndrome; min/wk = minutes per week; NR = not reported; NSD = no statistically significant difference; PA = physical activity; REML = restricted maximum likelihood; steps/d = steps per day

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

	Intervention	Contact				Meeti	ng PA		
Study	focus	time*	IG n/N (%)	CG n/N (%)		Recomm	endations	s RI	R 95% CI
Appel, 2003	HD + PA	High	130/240 (54.2)	123/242 (50.8)		<u> </u>	1	1.0	6 [0.89; 1.27]
Burke, 2006	HD + PA	Medium	76/123 (61.8)	68/118 (57.6)		-	1	1.0	7 [0.86; 1.33]
Eakin, 2009	HD + PA	Medium	101/225 (44.9)	71/204 (34.8)				1.2	8 [1.01; 1.62]
Hyman, 2007	HD + PA	Medium	31/92 (33.7)	22/93 (23.7)		-		1.4	2 [0.89; 2.27]
Kastarinen, 2002	HD + PA	High	60/173 (34.7)	41/171 (24.0)				- 1.4	5 [1.04; 2.02]
Koelewijn-van Loon, 2009	HD + PA	Medium	163/252 (64.7)	153/236 (64.8)		+		1.0	0 [0.87; 1.15]
Lakerveld, 2013	HD + PA	Medium	162/314 (51.6)	160/308 (51.9)		4	- -	0.9	9 [0.85; 1.16]
Liira, 2014	HD + PA	Medium	7/46 (15.2)	7/42 (16.7)	_	-	i	 0.9	1 [0.35; 2.39]
van Keulen, 2011	HD + PA	Medium	72/302 (23.8)	75/327 (22.9)		(C	-	1.0	4 [0.79; 1.37]
van Sluijs, 2005	PA only	Medium	./171 (.)	./187 (.)					
Wood, 2008	HD + PA	High	512/1018 (50.3)	222/1003 (22.1))			2.2	7 [1.98; 2.60]
								_	
Overall (REML + KH)								1.2	2 [1.00; 1.50]
Heterogeneity: $I^2 = 91\%$, $\tau^2 = 0.07$, p	< 0.01					5 8			
					0.3	0.5	1	2 3	
						Favors CG	Favors IC	3	

Abbreviations: CG = control group; CI = confidence interval; FUP = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; IG = confidence intervention group; IG = confidence i

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

Author, year (Study name)		Contact time*	Outcome	Int arm		IG n/N (%)		RR [†] (95% CI), p-
Quality	risk focus	Intervention focus			(months)			value
Appel, 2003 ⁴¹ (PREMIER) Good	HTN	High HD + PA	Myocardial Infarction	IG1	6	1/269 (0.4)	1/273 (0.4)	1.01 (0.06 to 16.14), NR
	HTN	High	Myocardial	IG2	6	0/268 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.30), NR
	TITTAL	HD + PA	Infarction	TC1		0/260 (0.0)	1/072 (0.4)	0.24 (0.01 (0.27) ND
	HTN	High HD + PA	Stroke	IG1	6	0/269 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.27), NR
	HTN	High HD + PA	Stroke	IG2	6	0/268 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.30), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG1	6	0/269 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.27), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG2	6	0/268 (0.0)	1/273 (0.4)	0.34 (0.01 to 8.30), NR
Bennett, 2012 ⁴⁷ (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	CVD events	IG1	24	0/180 (0.0)	1/185 (0.5)	0.34 (0.01 to 8.35), NR
Bennett, 2018 ⁴⁸ (Track)	Multiple	Medium	CVD events	IG1	12	5/176 (2.8)	6/175 (3.4)	0.83 (0.26 to 2.67), NR
Good		HD + PA						
Bo, 2007 ⁵² Fair	Multiple	Medium HD + PA	CVD events	IG1	108	12/169 (7.1)	19/166 (11.4)	HR=0.60 (0.29 to 1.24), 0.17
	Multiple	Medium HD + PA	CVD Mortality	IG1	108	5/169 (3.0)	11/166 (6.6)	HR=0.42 (0.15 to 1.23), 0.11
Estruch, 2018 ⁶⁷ (Primary Prevention of	Multiple	High HD only	Arrhythmia	IG1	72	72/2292 (3.1)	89/2203 (4.0)	HR=0.62 (0.44 to 0.85), <0.05
Cardiovascular Disease with a Mediterranean Diet	Multiple	High HD only	Arrhythmia	IG2	72	92/2210 (4.2)	89/2203 (4.0)	HR=0.86 (0.63 to 1.17), NSD
(PREDIMED)) Fair	Multiple	High HD only	CVD events	IG1	60	96/2543 (3.8)	, , ,	HR=0.69 (0.53 to 0.91), <0.05
	Multiple	High HD only	CVD events	IG2	60	83/2454 (3.4)		HR=0.72 (0.54 to 0.95), <0.05
	Multiple	High HD only	CVD Mortality	IG1	60	26/2543 (1.0)	30/2450 (1.2)	HR=0.62 (0.36 to 1.06), NSD
	Multiple	High HD only	CVD Mortality	IG2	60	31/2454 (1.3)	30/2450 (1.2)	HR=1.02 (0.63 to 1.67), NSD
	Multiple	High HD only	Myocardial Infarction	IG1	60	37/2543 (1.5)	38/2450 (1.6)	HR=0.82 (0.52 to 1.30), NSD
	Multiple	High HD only	Myocardial Infarction	IG2	60	31/2454 (1.3)	38/2450 (1.6)	HR=0.76 (0.47 to 1.25), NSD

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Quanty	Multiple	High HD only	Stroke	IG1		49/2543 (1.9)	58/2450 (2.4)	HR=0.65 (0.44 to 0.95), <0.05
	Multiple	High HD only	Stroke	IG2	60	32/2454 (1.3)	58/2450 (2.4)	HR=0.54 (0.35 to 0.82), <0.05
Fagerberg, 1998 ⁶⁸ (Risk Factor Intervention Study	Multiple	High HD + PA	Angina	IG1	40	7/253 (2.8)	12/255 (4.7)	0.60 (0.20 to 1.80), 0.36
(RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	Claudication	IG1	40	7/253 (2.8)	10/255 (3.9)	0.70 (0.30 to 1.80), 0.63
	Multiple	High HD + PA	Coronary deaths	IG1	79	17/253 (6.7)	23/255 (9.0)	0.72 (0.39 to 1.40), NSD
	Multiple	High HD + PA	Coronary events	IG1	79	44/253 (17.4)	50/255 (19.6)	0.86 (0.57 to 1.28), NSD
	Multiple	High HD + PA	CVD events	IG1	79	63/253 (24.9)	84/255 (32.9)	0.71 (0.51 to 0.99), 0.041
	Multiple	High HD + PA	CVD Mortality	IG1	40	12/253 (4.7)	13/255 (5.1)	0.90 (0.40 to 1.90), 0.98
	Multiple	High HD + PA	CVD Mortality	IG1	79	24/253 (9.5)	42/255 (16.5)	0.56 (0.34 to 0.92), 0.021
	Multiple	High HD + PA	Myocardial Infarction	IG1	40	18/253 (7.1)	22/255 (8.6)	0.80 (0.50 to 1.50), 0.64
	Multiple	High HD + PA	Myocardial Infarction fatal	IG1	79	7/253 (2.8)	10/255 (3.9)	0.71 (0.27 to 1.82), NR
	Multiple	High HD + PA	Myocardial Infarction nonfatal	IG1	79	22/253 (8.7)	25/255 (9.8)	0.89 (0.51 to 1.53), NR
	Multiple	High HD + PA	Stroke	IG1	40	5/253 (2.0)	17/255 (6.7)	0.30 (0.11 to 0.81), 0.017
	Multiple	High HD + PA	Stroke	IG1	79	16/253 (6.3)	29/255 (11.4)	0.53 (0.29 to 0.97), <0.05
	Multiple	High HD + PA	Stroke fatal	IG1	79	3/253 (1.2)	4/255 (1.6)	0.76 (0.17 to 3.34), NR
	Multiple	High HD + PA	Stroke nonfatal	IG1	79	13/253 (5.1)	25/255 (9.8)	0.52 (0.27 to 1.00), NR
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	MI nonfatal	IG1	6	1/160 (0.6)	0/154 (0.0)	2.89 (0.12 to 70.36), NS

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Ouality	ear (Study name) Population Contact time* Outcome risk focus Intervention focus			Int arm	Timepoint IG n/N (%) (months)		CG n/N (%)	RR [†] (95% CI), p-
Hinderliter, 2014 ⁷⁶ (Exercise		High	CVD events	IG1	12	0/46 (0.0)	0/49 (0.0)	value NR, NSD
and Nutrition interventions	11111	HD only	CVD events	101	12	0/40 (0.0)	0/49 (0.0)	NK, NSD
for CardiOvasculaR hEalth		TID OHLY						
(ENCORE))								
Good								
TOHP I CRG, 1992 ¹¹⁹	HTN	High	CVD events	IG1	192	17/231 (7.4)	32/311 (10.3)	HR=0.48 (0.25 to
(Trials of Hypertension		HD only	0 12 0 10 1115	101	172	1,7201 (,1.1)	02,011 (10.0)	0.92), 0.027
Prevention Phase I (TOHP								,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
I))								
Good								
Wadden, 2011 ¹²⁷ (Practice-	Multiple	High	Angina	IG1	24	5/131 (3.8)	1/130 (0.8)	4.96 (0.59 to 41.89),
based Opportunities for	1	HD + PA				, í	, ,	NR
Weight Reduction at the	Multiple	High	Congestive Heart	IG1	24	0/131 (0.0)	2/130 (1.5)	0.20 (0.01 to 4.09), NR
University of Pennsylvania	-	HD + PA	Failure					
(POWER-UP))	Multiple	High	Myocardial	IG1	24	0/131 (0.0)	1/130 (0.8)	0.33 (0.01 to 8.05), NR
Good		HD + PA	Infarction					
	Multiple	High	Transient Ischemic	IG1	24	0/131 (0.0)	0/130 (0.0)	NR, NSD
		HD + PA	Attack					
	HTN	High	Angina	IG1	36	10/147 (6.8)	19/371 (5.1)	1.33 (0.63 to 2.79), NR
		HD + PA						
	HTN	High	Angina	IG2	36	10/147 (6.8)	19/371 (5.1)	1.33 (0.63 to 2.79), NR
		HD + PA						
	HTN	High	Angina	IG3	36	10/370 (2.7)	19/371 (5.1)	0.53 (0.25 to 1.12), NR
		HD only						
	HTN	High	Arrhythmia	IG1	36	1/147 (0.7)	4/371 (1.1)	0.63 (0.07 to 5.60), NR
		HD + PA						
	HTN	High	Arrhythmia	IG2	36	2/147 (1.4)	4/371 (1.1)	1.26 (0.23 to 6.82), NR
		HD + PA						
	HTN	High	Arrhythmia	IG3	36	6/370 (1.6)	4/371 (1.1)	1.50 (0.43 to 5.29), NR
	*****	HD only	G	T.C.1	2.5	0.44.57.40.00	1 (271 (2.2)	0.04 (0.02
	HTN	High	Congestive Heart	IG1	36	0/147 (0.0)	1/371 (0.3)	0.84 (0.03 to 20.45),
	TITTAL	HD + PA	Failure	100	26	1 /1 47 (0.7)	1/271 (0.2)	NR
	HTN	High	Congestive Heart Failure	IG2	36	1/147 (0.7)	1/371 (0.3)	2.52 (0.16 to 40.08),
	LITNI	HD + PA		IC2	36	4/270 (1.1)	1/271 (0.2)	NR
	HTN	High	Congestive Heart Failure	IG3	30	4/370 (1.1)	1/371 (0.3)	4.01 (0.45 to 35.71),
		HD only	ranure					NR

Appendix H Table 1. CVD Events + CVD Mortality (KQ1)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
	HTN	High HD + PA	CVD events	IG1	36	23/147 (15.6)	57/371 (15.4)	1.02 (0.65 to 1.59), NR
	HTN	High HD + PA	CVD events	IG2	36	21/147 (14.3)	57/371 (15.4)	0.93 (0.59 to 1.48), NR
	HTN	High HD only	CVD events	IG3	36	44/370 (11.9)	57/371 (15.4)	0.77 (0.54 to 1.12), NR
	HTN	High HD + PA	Myocardial Infarction nonfatal	IG1	36	2/147 (1.4)	4/371 (1.1)	1.26 (0.23 to 6.82), NR
	HTN	High HD + PA	Myocardial Infarction nonfatal	IG2	36	2/147 (1.4)	4/371 (1.1)	1.26 (0.23 to 6.82), NR
	HTN	High HD only	Myocardial Infarction nonfatal	IG3	36	2/370 (0.5)	4/371 (1.1)	0.50 (0.09 to 2.72), NR
	HTN High HD + PA		Other CVD events	IG1	36	8/147 (5.4)	19/371 (5.1)	1.06 (0.48 to 2.37), NR
	HTN	High HD + PA	Other CVD events	IG2	36	6/147 (4.1)	19/371 (5.1)	0.80 (0.32 to 1.96), NR
	HTN	High HD only	Other CVD events	IG3	36	13/370 (3.5)	19/371 (5.1)	0.69 (0.34 to 1.37), NR
	HTN	High HD + PA	Stroke nonfatal	IG1	36	1/147 (0.7)	2/371 (0.5)	1.26 (0.12 to 13.81), NR
	HTN	High HD + PA	Stroke nonfatal	IG2	36	0/147 (0.0)	2/371 (0.5)	0.50 (0.02 to 10.41), NR
	HTN	High HD only	Stroke nonfatal	IG3	36	1/370 (0.3)	2/371 (0.5)	0.50 (0.05 to 5.51), NR
	HTN High HD + PA		Transient Ischemic Attack	IG1	36	1/147 (0.7)	8/371 (2.2)	0.32 (0.04 to 2.50), NR
	HTN	High HD + PA	Transient Ischemic Attack	IG2	36	0/147 (0.0)	8/371 (2.2)	0.15 (0.01 to 2.55), NR
Abbreviations CC - control or	HTN	High HD only	Transient Ischemic Attack	IG3			8/371 (2.2)	1.00 (0.38 to 2.64), NR

Abbreviations: CG = control group; CI = confidence interval; CVD = cardiovascular disease; Dys = dyslipidemia; F/U = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; HR = hazard ratio; IG = intervention group; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; RR = risk ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

Appendix H Table 2. All-Cause Mortality (KQ1)

name) Quality	risk focus	Contact time* Intervention focus		(months)	, ,	CG n/N (%)	RR [†] (95% CI), p-value
Appel, 2011 ⁴² (POWER Hopkins (Practice Based	1	High HD + PA	IG1	24	0/138 (0.0)	0/138 (0.0)	NR, NSD
Opportunities for Weight Reduction)) Good	Multiple	High HD + PA	IG2	24	0/139 (0.0)	0/138 (0.0)	NR, NSD
Good	Multiple	Medium HD + PA	IG1	12	1/176 (0.6)	0/175 (0.0)	2.98 (0.12 to 72.73), NSD
Fair	Multiple	Medium HD + PA	IG1		, , ,	28/166 (16.9)	HR=0.71 (0.40 to 1.26), 0.24
Bosworth, 2009 ⁵³ (Take Control of Your Blood	HTN	Medium HD + PA	IG1	24	2/159 (1.3)	5/159 (3.1)	0.40 (0.08 to 2.03), NSD
Fair	HTN	Medium HD + PA	IG2	24	5/160 (3.1)	5/159 (3.1)	0.99 (0.29 to 3.37), NSD
Eakin, 2009 ⁶⁴ (Logan Healthy Living) Fair	Multiple	Medium HD + PA	IG1	18	3/231 (1.3)	2/208 (1.0)	1.35 (0.23 to 8.00), NSD
Estruch, 2018 ⁶⁷ (Primary Prevention of	Multiple	High HD only	IG1	60	118/2543 (4.6)	114/2450 (4.7)	HR=0.90 (0.69 to 1.18), NSD
with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	IG2	60	116/2454 (4.7)	114/2450 (4.7)	HR=1.12 (0.86 to 1.47), NSD
Fagerberg, 1998 ⁶⁸ (Risk Factor Intervention Study		High HD + PA	IG1	12	5/253 (2.0)	6/255 (2.4)	0.84 (0.26 to 2.72), NSD
(RIS)) Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	IG1	40	14/253 (5.5)	21/255 (8.2)	0.70 (0.40 to 1.30), 0.3
	Multiple	High HD + PA	IG1	79	41/253 (16.2)	64/255 (25.1)	0.62 (0.42 to 0.92), 0.016
the Waist) Fair		High HD + PA	IG1	12	2/55 (3.6)	0/53 (0.0)	4.82 (0.24 to 98.13), NSD
HPT, 1990 ⁷⁷ (Hypertension Prevention	HTN	High HD only	IG1	36	1/195 (0.5)	1/196 (0.5)	1.01 (0.06 to 15.96), NSD
	HTN	High HD only	IG2	36	1/196 (0.5)	1/196 (0.5)	1.00 (0.06 to 15.87), NSD

Author, year (Study name) Quality		Contact time* Intervention focus	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
	HTN	High HD only	IG3	36	0/125 (0.0)	1/196 (0.5)	0.52 (0.02 to 12.69), NSD
	HTN	High HD only	IG4	36	1/129 (0.8)	1/196 (0.5)	1.52 (0.10 to 24.08), NSD
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	IG1	6	0/31 (0.0)	0/32 (0.0)	NR, NSD
Keyserling, 1997 ⁸⁶ (Southeast Cholesterol	Dys	Medium HD only	IG1	12	2/184 (1.1)	0/188 (0.0)	5.11 (0.25 to 105.68), NR
Project) Fair	Dys	Medium HD only	IG1	24	4/184 (2.2)	1/188 (0.5)	4.09 (0.46 to 36.22), NR
Niiranen, 2014 ¹⁰⁰ Fair	HTN	Medium HD + PA	IG1	12	1/117 (0.9)	0/112 (0.0)	NR, NSD
Ogedegbe, 2014 ¹⁰² (Counseling African Americans to Control Hypertension (CAATCH)) Fair	HTN	Medium HD + PA	IG1	12	8/529 (1.5)	3/510 (0.6)	2.57 (0.69 to 9.64), 0.22
Rosas, 2015 ¹⁰⁶ (Vivamos Activos Fair Oaks	Multiple	High HD + PA	IG1	24	0/82 (0.0)	0/41 (0.0)	NR, NSD
(VAFO)) Good	Multiple	High HD + PA	IG2	24	0/84 (0.0)	0/41 (0.0)	NR, NSD
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	IG1	12	0/325 (0.0)	2/316 (0.6)	0.19 (0.01 to 4.03), NSD
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance	Multiple	High HD + PA	IG1	30	1/342 (0.3)	1/342 (0.3)	1.00 (0.06 to 15.92), NSD
(WLM)) Good	Multiple	High HD + PA	IG2	30	1/348 (0.3)	1/342 (0.3)	0.98 (0.06 to 15.65), NSD
	Multiple	High HD + PA	IG1	60	3/244 (1.2)	1/247 (0.4)	3.04 (0.32 to 28.99), NR
(Trials of Hypertension	HTN	High HD only	IG1	18	0/327 (0.0)	1/417 (0.2)	0.42 (0.02 to 10.39), NSD
Prevention Phase I	HTN	High HD + PA	IG2	18	1/308 (0.3)	1/256 (0.4)	0.83 (0.05 to 13.22), NSD

Appendix H Table 2. All-Cause Mortality (KQ1)

	risk focus	Contact time* Intervention focus	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
(TOHP I))	HTN	High	IG1	180	10/327 (3.1)	14/417 (3.4)	HR=0.76 (0.33 to 1.74), 0.52
Good		HD only					
TOHP II CRG, 1997 ¹²⁰	HTN	High	IG1	48	2/597 (0.3)	2/596 (0.3)	1.00 (0.14 to 7.06), NSD
(Trial of Hypertension		HD + PA					
Prevention II (TOHP II))	HTN	High	IG2	48	5/595 (0.8)	2/596 (0.3)	2.50 (0.49 to 12.86), NSD
Good		HD + PA					
		High HD only	IG3	48	3/594 (0.5)	2/596 (0.3)	1.51 (0.25 to 8.97), NSD

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; F/U = followup timepoint; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; HR = hazard ratio; IG = intervention group; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RR = risk ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

Author, year	Population	Contact time*	Outcome	Int	Timepoint	IG N	IG baseline	IG mean	CG	CG baseline	CG mean	Between-group
(Study name)	risk focus	Intervention		arm	(months)		mean (SD)	change	N	mean (SD)		difference,† p-
Quality		focus						(SD)				value
Appel, 2003 ⁴¹	HTN	High	SF-36 Bodily	IG1	6	219	53.8 (7.4)	0.1 (7.4)	219	54.6 (5.92)	-0.5 (7.4)	0.60 (-0.79 to 1.99),
(PREMIER)		HD + PA	pain									NSD
Good	HTN	High	SF-36 Bodily	IG2	6	221	54.2 (5.95)	0.4 (7.43)	219	54.6 (5.92)	-0.5 (7.4)	
		HD + PA	pain									NSD
	HTN	High	SF-36 Bodily	IG1	18	219	53.8 (7.4)	0.6 (7.4)	219	54.6 (5.92)	0 (7.4)	0.60 (-0.79 to 1.99),
		HD + PA	pain									NSD
	HTN	High	SF-36 Bodily	IG2	18	221	54.2 (5.95)	-0.7 (7.43)	219	54.6 (5.92)	0 (7.4)	-0.70 (-2.09 to
		HD + PA	pain									0.69), NSD
	HTN	High		IG1	6	219	50.5 (7.4)	0.9 (7.4)	219	51.7 (7.4)	-1 (7.4)	1.90 (0.51 to 3.29),
		HD + PA	health problems									< 0.05
	HTN	High		IG2	6	221	50.8 (7.43)	0.1 (7.43)	219	51.7 (7.4)	-1 (7.4)	1.10 (-0.29 to 2.49),
		HD + PA	health problems									NSD
	HTN	High			18	219	50.5 (7.4)	1.3 (7.4)	219	51.7 (7.4)	-1.3 (7.4)	2.60 (1.21 to 3.99),
		HD + PA	health problems									< 0.05
	HTN	High			18	221	50.8 (7.43)	0.1 (7.43)	219	51.7 (7.4)	-1.3 (7.4)	1.40 (0.01 to 2.79),
		HD + PA	health problems									< 0.1
	HTN	High		IG1	6	219	52.4 (7.4)	0.4 (7.4)	219	53.5 (7.4)	-0.2 (7.4)	0.60 (-0.79 to 1.99),
		HD + PA	mental health									NSD
	HTN	High	SF-36 General	IG2	6	221	52.7 (7.43)	-0.2 (7.43)	219	53.5 (7.4)	-0.2 (7.4)	0.00 (-1.39 to 1.39),
		HD + PA	mental health									NSD
	HTN	High	SF-36 General	IG1	18	219	52.4 (7.4)	0.1 (7.4)	219	53.5 (7.4)	0.2 (7.4)	-0.10 (-1.49 to
		HD + PA	mental health									1.29), NSD
	HTN	High		IG2	18	221	52.7 (7.43)	-0.3 (7.43)	219	53.5 (7.4)	0.2 (7.4)	-0.50 (-1.89 to
		HD + PA	mental health						<u> </u>			0.89), NSD
	HTN	High	SF-36 MCS	IG1	6	219	51.5 (8.88)	0.9 (8.88)	219	52.6 (7.4)	0.1 (8.88)	0.80 (-0.86 to 2.46),
		HD + PA							<u> </u>			<0.1
	HTN	High	SF-36 MCS	IG2	6	221	52 (7.43)	-1 (8.92)	219	52.6 (7.4)	0.1 (8.88)	-1.10 (-2.76 to
		HD + PA							<u> </u>			0.56), NSD
	HTN	High	SF-36 MCS	IG1	18	219	51.5 (8.88)	0.2 (8.88)	219	52.6 (7.4)	0.1 (8.88)	0.10 (-1.56 to 1.76),
		HD + PA										NSD
	HTN	High	SF-36 MCS	IG2	18	221	52 (7.43)	-0.3 (8.92)	219	52.6 (7.4)	0.1 (8.88)	-0.40 (-2.06 to
		HD + PA							<u> </u>		<u> </u>	1.26), NSD
	HTN	High	SF-36 PCS	IG1	6	219	52 (7.4)	0.2 (7.4)	219	52.3 (5.92)	-1 (7.4)	1.20 (-0.19 to 2.59),
		HD + PA							<u> </u>		1	NSD
		High	SF-36 PCS	IG2	6	221	51.8 (5.95)	0.8 (7.43)	219	52.3 (5.92)	-1 (7.4)	1.80 (0.41 to 3.19),
		HD + PA										< 0.05

Author, year		Contact time*	Outcome				IG baseline			CG baseline		Between-group
(Study name) Quality		Intervention focus			(months)		mean (SD)	(SD)	N	mean (SD)	(SD)	difference,† p- value
		High HD + PA	SF-36 PCS	IG1	18	219	52 (7.4)	0.5 (7.4)	219	52.3 (5.92)		1.10 (-0.29 to 2.49), NSD
Appel, 2003 ⁴¹ (PREMIER) Good	HTN	High HD + PA	SF-36 PCS	IG2	18	221	51.8 (5.95)	0.1 (7.43)	219	52.3 (5.92)		0.70 (-0.69 to 2.09), NSD
Good		High HD + PA	SF-36 Physical functioning				, ,	, ,		52.1 (5.92)		1.60 (0.21 to 2.99), <0.1
		High HD + PA	SF-36 Physical functioning				51.9 (5.95)			52.1 (5.92)	, í	0.80 (-0.59 to 2.19), NSD
		High HD + PA	SF-36 Physical functioning				, ,	, ,		52.1 (5.92)	, í	0.70 (-0.69 to 2.09), NSD
		High HD + PA	SF-36 Physical functioning				51.9 (5.95)	, ,		52.1 (5.92)	, ,	0.40 (-0.99 to 1.79), NSD
		High HD + PA	SF-36 Role limitations - emotional	IG1	6	219	51.6 (8.88)	0.5 (8.88)	219	52.3 (7.4)	0.9 (8.88)	-0.40 (-2.06 to 1.26), NSD
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG2	6	221	52.2 (7.43)	-1.5 (8.92)	219	52.3 (7.4)	, , ,	-2.40 (-4.06 to - 0.74), <0.05
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG1	18	219	51.6 (8.88)	0 (10.36)	219	52.3 (7.4)	0.3 (10.36)	-0.30 (-2.24 to 1.64), NSD
	HTN	High HD + PA	SF-36 Role limitations - emotional	IG2	18	221	52.2 (7.43)	-0.3 (10.41)	219	52.3 (7.4)	0.3 (10.36)	-0.60 (-2.54 to 1.34), NSD
	HTN	High HD + PA	SF-36 Role limitations - physical	IG1	6	219	51.9 (7.4)	-0.6 (8.88)	219	52 (7.4)	0 (8.88)	-0.60 (-2.26 to 1.06), NSD
		High HD + PA	SF-36 Role limitations - physical	IG2	6	221	51.3 (7.43)	0.7 (8.92)	219	52 (7.4)		0.70 (-0.96 to 2.36), NSD
	HTN	High HD + PA	SF-36 Role limitations - physical	IG1	18	219	51.9 (7.4)	-0.4 (10.36)	219	52 (7.4)	0 (10.36)	-0.40 (-2.34 to 1.54), NSD

Author, year	Population	Contact time*	Outcome	Int	Timepoint	IG N	IG baseline	IG mean	CG	CG baseline	CG mean	Between-group
(Study name) Quality	risk focus	Intervention focus			(months)		mean (SD)	(SD)		mean (SD)	change (SD)	difference,† p- value
	HTN	High	SF-36 Role	IG2	18	221	51.3 (7.43)	0.4 (10.41)	219	52 (7.4)	0 (10.36)	0.40 (-1.54 to 2.34),
		HD + PA	limitations -									NSD
			physical									
	HTN	High	SF-36 Social	IG1	6	219	52.9 (7.4)	0.6 (8.88)	219	53.2 (7.4)	-0.3	0.90 (-0.76 to 2.56),
		HD + PA	functioning								(8.88)	NSD
	HTN	High	SF-36 Social	IG2	6	221	53.2 (7.43)	-0.2 (8.92)	219	53.2 (7.4)	-0.3	0.10 (-1.56 to 1.76),
		HD + PA	functioning								(8.88)	NSD
	HTN	High	SF-36 Social	IG1	18	219	52.9 (7.4)	0.3 (10.36)	219	53.2 (7.4)	0.4	-0.10 (-2.04 to
41		HD + PA	functioning								(10.36)	1.84), NSD
I I		High	SF-36 Social	IG2	18	221	53.2 (7.43)		219	53.2 (7.4)	0.4	-1.10 (-3.04 to
(PREMIER) Good		HD + PA	functioning					(10.41)			(10.36)	0.84), NSD
	HTN	High	SF-36 Vitality	IG1	6	219	49.7 (8.88)	1.7 (8.88)	219	51.2 (8.88)	-1.9	3.60 (1.94 to 5.26),
		HD + PA									(8.88)	< 0.05
	HTN	High	SF-36 Vitality	IG2	6	221	49.7 (8.92)	0.1 (8.92)	219	51.2 (8.88)	-1.9	2.00 (0.34 to 3.66),
		HD + PA									(8.88)	< 0.05
	HTN	High	SF-36 Vitality	IG1	18	219	49.7 (8.88)	0.6 (8.88)	219	51.2 (8.88)	-1.2	1.80 (0.14 to 3.46),
		HD + PA									(8.88)	<0.1
	HTN	High	SF-36 Vitality	IG2	18	221	49.7 (8.92)	0.7 (8.92)	219	51.2 (8.88)	-1.2	1.90 (0.24 to 3.56),
		HD + PA									(8.88)	< 0.05
	Multiple	High	SF-12 MCS	IG1	24	100	52.16 (9.6)	-0.5 (7.6)	88	51.06 (8.71)	0.62	-1.12 (-3.52 to
(POWER Hopkins		HD + PA									(8.91)	1.27), NSD
	Multiple	High	SF-12 MCS	IG2	24	115	52.53 (7.4)		88	51.06 (8.71)	0.62	-1.70 (-3.99 to
Opportunities for		HD + PA						(7.29)			(8.91)	0.60), NSD
	Multiple	High	SF-12 PCS	IG1	24	100		2.23 (7.5)	88	46.83 (7.95)	-0.29	2.52 (0.11 to 4.93),
Reduction))		HD + PA					(8.92)				(9.1)	< 0.05
Good	Multiple	High	SF-12 PCS	IG2	24	115		1.16 (8.26)	88	46.83 (7.95)	-0.29	1.45 (-0.99 to 3.90),
45		HD + PA					(8.42)				(9.1)	NSD
Babazono, 2007 ⁴⁵												-1.30 (-2.91 to
, ,	Multiple	HD + PA	GHQ-30	IG1	12	46	4.4 (4.1)	-1.3 (3.8)	41	4 (3.3)	0 (3.83)	0.31), NSD
Fair	-		GE 24 B 111	7.01	-	221	, m, a, m,	2.5.6.0 m)	100	, m, a, m)	0.05	·
	Dys	Medium	SF-36 Bodily	IG1	6	221	NR (NR)	2.76 (NR)	188	NK (NR)	-0.95	NR, NSD
(PEGASE (Effect	D	HD + PA	pain	TG:		221	AID (AID)	0.01.070	1.00	AID (AID)	(NR)	ND NGD
of an Education	Dys	Medium			6	221	NR (NR)	2.81 (NR)	188	NK (NR)	-0.64	NR, NSD
		HD + PA	health problems								(NR)	

Author, year (Study name) Quality	risk focus	Contact time* Intervention focus	Outcome		(months)		IG baseline mean (SD)	change (SD)	N	CG baseline mean (SD)	change (SD)	Between-group difference,† p- value
Program)) Fair	Dys	Medium HD + PA	SF-36 General mental health	IG1	6	221	NR (NR)	1.79 (NR)	188	NR (NR)	0.13 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 MCS	IG1	6	221	NR (NR)	0.53 (NR)	188	NR (NR)	0.69 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 PCS	IG1	6	221	NR (NR)	2.57 (NR)	188	NR (NR)	-0.5 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Physical functioning	IG1	6	221	NR (NR)	6.72 (NR)	188	NR (NR)	-0.63 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Role limitations – emotional	IG1	6	221	NR (NR)	2.22 (NR)	188	NR (NR)	3.55 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Role limitations - physical	IG1	6	221	NR (NR)	7.91 (NR)	188	NR (NR)	1.08 (NR)	NR, NSD
Bruckert, 2008 ⁵⁵ (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	SF-36 Social functioning	IG1	6	221	NR (NR)	2.09 (NR)	188	NR (NR)	0.73 (NR)	NR, NSD
	Dys	Medium HD + PA	SF-36 Vitality	IG1	6	221	NR (NR)	3.43 (NR)	188	NR (NR)	-1.47 (NR)	NR, NSD
Fagerberg, 1998 ⁶⁸ (Risk Factor Intervention Study (RIS))	_	High HD + PA	MSEP – Contentment (No. deteriorated)	IG1	40	176	NA	28 (15.9)		NA	24 (15.3)	RR=1.04 (0.63 to 1.72)
Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	MSEP – Contentment (No. improved)		40	176	NA	14 (8.0)‡	157	NA	` /	RR=1.39 (0.62 to 3.12)
	Multiple	High HD + PA	MSEP – Sleep (No. deteriorated)	IG1	40	176	NA	32 (18.2)‡	157	NA	32 (20.4)‡	RR=0.89 (0.57 to 1.39)
	Multiple	High HD + PA	MSEP – Sleep (No. deteriorated)	IG1	40	176	NA	39 (22.2)‡	157	NA	31 (19.7)‡	RR=1.12 (0.74 to 1.71)
	Multiple	High HD + PA	MSEP – Vitality	IG1	40	176	NA	22 (12.5) [‡]	157	NA	27 (17.2)‡	RR=0.73 (0.43 to 1.22)

Author, year	Population	Contact time*	Outcome	Int	Timepoint	IG N	IG baseline	IG mean	CG	CG baseline	CG mean	Between-group
	risk focus	Intervention		arm	(months)		mean (SD)		N	mean (SD)	change	difference,† p-
Quality		focus						(SD)			(SD)	value
			(No.									
			deteriorated)									
	Multiple	High		IG1	40	176	NA	25 (14.2)‡	157	NA	19 (12.1)‡	RR=1.17 (0.67 to
		HD + PA	Vitality (No. improved)									2.05)
Gill, 2019b ⁷⁰			European								4.37	1.55 (-3.25 to 6.35)
(HealtheSteps) Fair	Multiple	HD + PA	Quality of Life	IG1	6	59	NR (NR)	5.92 (NR)	59	NR (NR)	(13.85)	0.52
Greaves, 2015 ⁷¹	Multiple	High	EQ-5D VAS	IG1	12	55	77 (14.9)	NR (NR)	53	76.4 (17)	NR (NR)	1.36 (-3.37 to 6.04)
(Waste the Waist) Fair		HD + PA										NSD
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	SF-36 MCS	IG1	6	160	49.2 (9.4)	4.1 (8.55)	154	49.9 (9.7)	1.6 (9.2)	2.20 (0.70 to 3.70), 0.005
i un	Multiple	Medium HD + PA	SF-36 PCS	IG1	6	160	48.3 (1.8)	2.6 (6.98)	154	49.1 (7.6)	0.8 (7.65)	1.00 (-0.50 to 2.50) 0.201
Khanji, 2019 ⁸⁷	Multiple	Low	EQ-5D VAS	IG1	6	194	NR (NR)	NR (NR)	183	NR (NR)	0.01 (NR)	-0.01 (-0.02 to
(HAPPY London)	rrunipic	HD + PA	EQ 3D VAS	101	O	174	1111 (1111)	111(111)	103	ruc (ruc)	0.01 (1111)	0.05), 0.44
Good	Multiple	Low HD + PA	SF-36 (Overall)	IG1	6	194	NR (NR)	4.8 (NR)	183	NR (NR)	5.6 (NR)	-0.77 (-6.50 to 4.90), 0.79
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	EQ-5D-3L	IG1	12	295	NR (NR)	NR (NR)	297	NR (NR)	NR (NR)	MD=0.01 (-0.01 to 0.03), 0.41
van Keulen,	HTN	Medium		IG1	17	407	NR (NR)	NR (NR)	409	NR (NR)	NR (NR)	MD=0.02 (0.00 to
2011 ¹²³ (Vitalum) Fair		HD + PA	(quality- adjusted life years)									0.04), 0.07
	HTN	Medium		IG2	17	408	NR (NR)	NR (NR)	409	NR (NR)	NR (NR)	MD=0.01 (-0.01 to
		HD + PA	(quality-					() 9				0.03), 0.32
			adjusted life									<i>''</i>
			years)									
	HTN	Low	QALYs	IG3	17	405	NR (NR)	NR (NR)	409	NR (NR)	NR (NR)	MD=0.02 (0.00 to
		HD + PA	(quality- adjusted life									0.04), 0.09
			years)									

Abbreviations: CG = control group; CI = confidence interval; Dys = dyslipidemia; EQ-5D-3L = EuroQol 5 Dimensions, 3 Levels; EQ-5D VAS = EuroQol 5 Dimensions Visual Analog Scale; F/U = followup timepoint; GHQ-30 = General Health Questionnaire – 30 items; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; MCS = Mental Component Summary; MSEP = Minor symptoms evaluation profile; NR = not reported; NSD =

no statistically significantly difference; PCS = Physical Component Summary; QALYs = quality-adjusted life years; RR = risk ratio; SD = standard deviation; SF-36 = Short Form Healthy Survey - 12 items; SF-36 = Short Form Healthy Survey - 36 items

*Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

[‡]No. (%)

Appendix H Table 4. Meta-Analysis Summary of Pooled Intermediate Outcomes

Outcome (unit)	Population risk focus	Followup category	Effect size (95% CI)*	K	N	I^2
SBP (mm Hg)	Dyslipidemia	<12 months				
		12-24 months	-0.57 (-3.90, 2.75)	3	498	0.0%
		>24 months				
	Hypertension	<12 months	-2.84 (-4.38, -1.29)	16	5756	70.0%
		12-24 months	-1.97 (-2.59, -1.36)	16	5769	7.8%
		>24 months	-1.11 (-1.71, -0.51)	4	1749	0.0%
	Multiple risk factors	<12 months	-1.40 (-2.20, -0.60)	14	3837	0.0%
		12-24 months	-1.73 (-2.91, -0.55)	25	8313	51.0%
		>24 months	-4.37 (-36.77, 28.02)	2	797	75.8%
	All available studies	<12 months	-2.25 (-3.12, -1.37)	30	9523	57.9%
		12-24 months	-1.81 (-2.49, -1.13)	44	14580	37.3%
		>24 months	-1.84 (-412, 0.44)	6	2546	55.3%
DBP (mm Hg)	Dyslipidemia	<12 months				
		12-24 months	-1.40 (-2.67, -0.13)	2	186	0.0%
		>24 months				
	Hypertension	<12 months	-1.66 (-2.51, -0.80)	14	5139	67.8%
		12-24 months	-1.06 (-1.75, -0.38)	15	5461	43.4%
		>24 months	-0.03 (-2.50, 2.44)	4	1749	77.4%
	Multiple risk factors	<12 months	-0.85 (-1.40, -0.30)	12	3460	0.0%
		12-24 months	-1.22 (-1.82, -0.61)	23	7451	32.7%
		>24 months	-1.43 (-6.42, 3.57)	2	797	0.0%
	All available studies	<12 months	-1.35 (-1.88, -0.81)	26	8599	55.9%
		12-24 months	-1.16 (-1.57, -0.75)	40	13098	32.5%
		>24 months	-0.45 (-1.96, 1.06)	6	2546	68.7%
TC (mg/dL)	Dyslipidemia	<12 months	-3.84 (-9.44, 1.76)	6	1132	32.4%
_		12-24 months	-3.80 (-7.22, -0.37)	9	2001	24.0%
		>24 months				
	Hypertension	<12 months	-8.11 (-27.16, 10.93)	4	1356	88.3%
		12-24 months	-0.72 (-3.17, 1.73)	7	2349	18.3 %
		>24 months	-7.72 (-17.36, 1.92)	1	241	
	Multiple risk factors	<12 months	-2.64 (-4.88, -0.39)	9	1932	0.0%
		12-24 months	-4.06 (-7.38, -0.74)	22	7064	73.9%
		>24 months	-6.07 (-121.37, 109.24)	2	748	90.6%
	All available studies	<12 months	-4.03 (-6.89, -1.18)	19	4420	52.0%
		12-24 months	-3.48 (-5.57, -1.38)	38	11414	65.9%
		>24 months	-6.64 (-29.64, 16.37)	3	989	81.2%
LDL-C (mg/dL)	Dyslipidemia	<12 months	-0.95 (-6.74, 4.85)	5	1128	44.9%
_		12-24 months	-4.12 (-8.81, 0.57)	7	1271	36.3%
		>24 months				
	Hypertension	<12 months	-2.66 (-13.68, 8.36)	3	1167	65.1%
		12-24 months	-1.57 (-4.78, 1.65)	5	2104	55.6%
		>24 months				
	Multiple risk factors	<12 months	-1.73 (-4.34, 0.88)	8	1866	0.0%
		12-24 months	-1.71 (-4.64, 1.22)	20	5519	61.8%
		>24 months	-14.67 (-21.43, -7.91)	1	462	
	All available studies	<12 months	-1.61 (-3.52, 0.30)	16	4161	17.0%
		12-24 months	-2.14 (-4.08, -0.21)	32	8894	55.9%
		>24 months	-14.67 (-21.43, -7.91)	1	462	
HDL-C (mg/dL)	Dyslipidemia	<12 months	-1.16 (-1.19, -1.15)	3	373	0.0%
		12-24 months	-0.44 (-1.26, 0.37)	6	1033	0.0%
		>24 months				
	Hypertension	<12 months	0.37 (-8.87, 9.61)	2	973	64.0

Appendix H Table 4. Meta-Analysis Summary of Pooled Intermediate Outcomes

Outcome (unit)	Population risk focus	Followup category	Effect size (95% CI)*	K	N	I^2
		12-24 months	0.69 (0.00, 1.38)	5	1979	0.0%
		>24 months	0.39 (-2.31, 3.09)	1	241	
	Multiple risk factors	<12 months	0.48 (0.07, 0.89)	10	2696	0.0%
		12-24 months	0.81 (0.30, 1.32)	23	5962	39.4%
		>24 months	0.89 (-1.42, 3.21)	2	748	0.0%
	All available studies	<12 months	0.27 (-0.15, 0.69)	15	4042	0.0%
		12-24 months	0.58 (0.19, 0.98)	34	8974	33.7%
		>24 months	0.81 (0.05, 1.57)	3	989	0.0%
FBG (mg/dL)	All available studies	<12 months	-1.38 (-3.15, 0.39)	10	1973	62.9%
` ` ` ` ` ` `		12-24 months	-2.33 (-3.64, -1.02)	22	5950	82.5%
		>24 months	-2.27 (-8.39, 3.85)	4	3727	85.4%
DM Incidence	All available studies	All available (12-60	RR=0.82 (0.66, 1.03)	5	7848	0.0%
		months)				
Weight (kg)	Dyslipidemia	<12 months	-0.88 (-1.38, -0.38)	4	648	0.0%
		12-24 months	-1.40 (-3.17, 0.38)	6	887	86.0%
		>24 months				
	Hypertension	<12 months	-2.64 (-3.79, -1.50)	10	3345	95.1%
		12-24 months	-1.82 (-2.64, -1.01)	9	3433	81.3%
		>24 months	-1.13 (-3.40, 1.13)	3	1698	84.7%
	Multiple risk factors	<12 months	-2.19 (-3.06, -1.33)	16	3967	85.8%
		12-24 months	-1.56 (-2.22, -0.90)	22	12025	86.7%
		>24 months	-0.84 (-1.50, 0.17)	5	5721	56.8%
	All available studies	<12 months	-2.18 (-2.76, -1.60)	30	7960	91.0%
		12-24 months	-1.59 (-2.06, -1.13)	37	16345	88.1%
		>24 months	0.98 (-1.54, -0.43)	8	7419	77.5%
BMI (kg/m²)	Dyslipidemia	<12 months	-0.18 (-2.04, 1.67)	2	342	50.6%
```		12-24 months	0.10 (-1.24, 1.43)	2	444	0.0%
		>24 months				
	Hypertension	<12 months	-0.35 (-1.02, 0.33)	4	1252	67.2%
	71	12-24 months	-0.14 (-0.63, 0.36)	6	1509	66.2%
		>24 months				
	Multiple risk factors	<12 months	-0.72 (-1.10, -0.33)	12	3512	88.2%
		12-24 months	-0.60 (-0.83, -0.37)	22	7956	81.9%
		>24 months	-0.58 (-3.12, 1.95)	2	748	71.4%
	All available studies	<12 months	-0.57 (-0.86, -0.29)	18	5106	86.7%
		12-24 months	-0.46 (-0.66, -0.26)	30	9909	83.3%
		>24 months	-0.58 (-3.12, 1.95)	2.	748	71.4%
WC (cm)	Dyslipidemia	<12 months	0.10 (-1.59, 1.79)	1	137	
,, e (em)	D J Simpracinia	12-24 months	0.03 (-2.97, 3.03)	2	441	0.0%
		>24 months		- <u>-</u> -		
	Hypertension	<12 months	-3.20 (-4.26, -2.14)	1	456	<del> </del>
	rrypertension	12-24 months	-2.14 (-6.14, 1.85)	3	897	79.5%
		>24 months	-0.30 (-1.65, 1.05)	1	241	
	Multiple risk factors	<12 months	-2.26 (-3.19, -1.33)	11	2435	77.0%
	aviditipie fisk factors	12-24 months	-1.83 (-2.63, -1.03)	18	10370	85.3%
		>24 months	-0.54 (-1.07, -0.01)	10	3978	05.570
	All available studies			12	_	78 00/
	An available studies	<12 months	-2.16 (-3.04, -1.29)	13	3028	78.0%
		12-24 months	-1.75 (-2.44, -1.06)	23	11708	87.3%
		>24 months	-0.51 (-1.54, 0.53)	2	4219	0.0%

**Abbreviations:** BMI = body mass index; cm = centimeters; CI = confidence interval; DBP = diastolic blood pressure; DM = diabetes mellitus; FBG = fasting blood glucose; HDL-C = high-density lipoprotein cholesterol; K = number of studies; kg = kilograms; kg/m² = kilograms per meter squared; LDL-C = low-density lipoprotein cholesterol; mg/dL = milligrams per deciliter;

### Appendix H Table 4. Meta-Analysis Summary of Pooled Intermediate Outcomes

 $mm\ Hg = millimeters\ of\ mercury;\ N = number\ of\ participants\ analyzed;\ SBP = systolic\ blood\ pressure;\ TC = total\ cholesterol;\ WC = waist\ circumference$ 

*Between-group mean difference in change unless otherwise specified

Author, year (Study name) Quality		time* Intervention focus	Outcome (mm Hg)		(months)			change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
Anderssen, 1995 ⁴⁰ (Oslo Diet and	Multiple	Medium HD only	DBP	IG1	12	52	87.5 (8.65)	-3.4 (7.21)	43	87 (7.21)	-0.7 (8.52)	-2.70 (-5.91 to 0.51), NSD
Exercise Study (ODES)) Fair	Multiple	Medium HD only	SBP	IG1	12	52	132.8 (15.14)	-6.4 (10.1)	43	128.7 (9.84)	-0.5 (11.15)	-5.90 (-10.22 to - 1.58), <0.05
Appel, 2003 ⁴¹ (PREMIER)	HTN	High HD + PA	DBP	IG1	6	269	84.6 (4)	-6.4 (6.8)	273	84.8 (4.3)		-2.60 (-3.70 to - 1.50), <0.001
Good	HTN	High HD + PA	DBP	IG2	6	268	85 (4.1)	-5.5 (6.7)	273	84.8 (4.3)	` /	-1.70 (-2.80 to - 0.60), 0.002
	HTN	High HD + PA		IG2 (HTN subgroup)		97	NR (NR)	-7.4 (7.1)		NR (NR)	, ,	-3.60 (-5.34 to - 1.86), <0.05
	HTN	High HD + PA				269	84.6 (4)	-6.2 (7.8)	273	84.8 (4.3)	, , ,	-1.10 (-2.30 to 0.20), NSD
	HTN	High HD + PA		IG2			85 (4.1)	, , ,		84.8 (4.3)		-0.60 (-1.90 to 0.60), NSD
	HTN	High HD + PA		IG2 (HTN subgroup)			87.2 (4)	-7.4 (8.8)		87.8 (4.5)		-1.00 (-3.00 to 1.00),
	HTN	High HD + PA			6	269	134.9 (9.4)	(9.9)	273	134.2 (10.1)	` ′	-4.30 (-5.90 to - 2.80), <0.001
	HTN	High HD + PA		IG2		268	135.5 (9.2)	(10.1)	273	134.2 (10.1)	, ,	-3.70 (-5.30 to - 2.10), <0.001
	HTN	High HD + PA		IG2 (HTN subgroup)		97	NR (NR)	(10.1)	97		` ′	-6.30 (-8.85 to - 3.75), <0.05
	HTN	High HD + PA		IG1		269	134.9 (9.4)	(10.8)	273	134.2 (10.1)		-1.90 (-3.70 to - 0.10), NSD
	HTN	High HD + PA		IG2		268	, ,	(11.6)	273		-7.4 (10.8)	-0.90 (-2.70 to 0.90), NSD
	HTN	High HD + PA		IG2 (HTN subgroup)	18	96	144.1 (7.1)	-11 (13)	97	143.5 (8.2)	-9.9 (13.2)	-1.00 (-3.96 to 1.96), NR, NSD
Appel, 2011 ⁴² (POWER Hopkins (Practice Based	Multiple	High HD + PA	DBP	IG1	6	123	71.7 (9.36)	0.6 (8.87)	110	73.3 (9.36)		-0.80 (-2.90 to 1.30), 0.44
Opportunities for	Multiple	High HD + PA	DBP	IG2	6	129	72.5 (9.43)	-0.6 (9.09)	110	73.3 (9.36)		-2.00 (-4.10 to 0.20), 0.069

Author, year	Population		Outcome		Timepoint	IG N	IG baseline	IG mean	CG N	CG	CG	Between-group
Quality	risk focus	Intervention focus	(mm Hg)		(months)			(SD)		mean (SD)	change (SD)	difference,† p-value
Weight Reduction)) Good	Multiple	High HD + PA	DBP	IG1	24	126	71.7 (9.36)	1.8 (8.98)	114	73.3 (9.36)	2.1 (9.61)	-0.40 (-2.60 to 1.90), 0.75
	Multiple	High HD + PA	DBP	IG2	24	122	72.5 (9.43)	1.6 (9.94)	114	73.3 (9.36)	2.1 (9.61)	-0.60 (-2.90 to 1.80), 0.65
	Multiple	High HD + PA	SBP	IG1	6	123	118.3 (12.88)	0.7 (13.31)	110	120.2 (11.7)	2.1 (11.54)	-1.40 (-4.60 to 1.80), 0.39
	Multiple	High HD + PA	SBP	IG2	6	129	119.2 (14.15)		110	120.2 (11.7)	2.1 (11.54)	-3.40 (-6.80 to 0.00), 0.048
	Multiple	High HD + PA	SBP	IG1	24	126			114		3.6 (14.95)	-1.10 (-4.60 to 2.50), 0.55
	Multiple	High HD + PA	SBP	IG2	24	122	119.2 (14.15)		114	120.2 (11.7)	3.6	MD=-2.00 (-5.60 to 1.60), 0.28
Applegate, 1992 ⁴³ Fair	HTN	High HD + PA	DBP	IG1	6	21	` '	-6.8 (NR)	26	88.4 (3.6)	-1.9 (NR)	
	HTN	High HD + PA	SBP	IG1	6	21	142.6 (11.7)	-8.7 (NR)	26	144.5 (9.7)	-4.5 (NR)	NR, 0.22
Arroll, 1995 ⁴⁴ Fair	HTN	Low HD + PA	DBP	IG1	6	48	` /	-2.2 (NR)	43	94 (NR)	-4.8 (NR)	NR, NSD
	HTN	Low PA only	DBP	IG2	6	46	88.4 (NR)	-2.1 (NR)	43	94 (NR)	-4.8 (NR)	NR, NSD
	HTN	Low HD only	DBP	IG3	6	44	86.4 (NR)	-1.7 (NR)	43	94 (NR)	-4.8 (NR)	NR, NSD
	HTN	Low HD + PA	SBP	IG1	6	48	145 (NR)	-5.2 (NR)	43	145.3 (NR)	-6.2 (NR)	NR, NSD
	HTN	Low PA only	SBP	IG2	6	46	142.9 (NR)	-9 (NR)	43	145.3 (NR)	-6.2 (NR)	NR, NSD
	HTN	Low HD only	SBP	IG3	6	44	145.4 (NR)	-9.1 (NR)	43	145.3 (NR)	-6.2 (NR)	NR, NSD
Babazono, 2007 ⁴⁵ (PHPP)	Multiple	Medium HD + PA	DBP	IG1	12	46	78.2 (9)	-3.7 (10.12)	41	79.3 (11.8)	-4.3 (11.62)	0.60 (-4.00 to 5.20), NSD
Fair	Multiple	Medium HD + PA	SBP	IG1	12	46	127.6 (15.7)		41	132 (17.8)	-8.7 (17.45)	3.50 (-3.72 to 10.72), NSD
Beckmann, 1995 ⁴⁶ Fair	HTN	Medium HD only	MAP (mean	IG1	12	32	102.9		32	102.5 (8.49)	-0.4	-8.40 (-12.33 to - 4.47), <0.001

			Outcome (mm Hg)	Int arm	Timepoint (months)		IG baseline mean (SD)		CG N	baseline		Between-group difference,† p-value
			arterial									
Bennett, 2012 ⁴⁷ (Be Fit, Be Well	HTN	High HD + PA	pressure) DBP	IG1	6	180	79.34 (12.73)	0.3 (13.82)	185	77.45 (13.77)	1.28 (13.6)	-0.98 (-3.80 to 1.83), NSD
[POWER]) Good	HTN		DBP	IG1	12	180		0.04 (14.49)	185			-2.26 (-5.15 to 0.64), NSD
	HTN	High HD + PA	DBP	IG1	18	180	79.34 (12.73)	0.49 (14.62)	185	77.45 (13.77)	2.73 (13.87)	-2.24 (-5.16 to 0.69), NSD
	HTN	High HD + PA	DBP	IG1	24	180	79.34 (12.73)	0.56 (13.28)	185	77.45 (13.77)	2 (12.79)	-1.44 (-4.13 to 1.24), NSD
	HTN	High HD + PA	SBP	IG1	6	180	130.22 (18.89)	0.49 (21.47)	185	128.55 (19.73)	1.78 (21.08)	-1.30 (-5.67 to 3.08), NSD
	HTN	High HD + PA	SBP	IG1	12	180	130.22 (18.89)	-1.38 (22.54)	185	128.55 (19.73)	3.35 (21.22)	-4.73 (-9.23 to - 0.22), <0.05
	HTN	High HD + PA	SBP	IG1	18	180	130.22 (18.89)	-0.22 (22.67)	185	128.55 (19.73)	5.61 (21.49)	-5.83 (-10.38 to - 1.28), <0.05
	HTN	High HD + PA	SBP	IG1	24	180	130.22 (18.89)	1.56 (20.66)	185	(19.73)	5.3 (19.99)	-3.73 (-7.91 to 0.45), NSD
Bennett, 2018 ⁴⁸ (Track)	Multiple	Medium HD + PA	DBP	IG1	6	170	82.1 (11.6)	-4.1 (11.64)	167	81.9 (11.8)	-2.5 (11.21)	-1.60 (-3.90 to 0.70), 0.16
Good	Multiple	Medium HD + PA	DBP	IG1	12	170	82.1 (11.6)	-5.2 (12.64)	167	81.9 (11.8)	-4.2 (12.2)	-1.00 (-3.50 to 1.50), 0.43
	1	Medium HD + PA	SBP	IG1	6	170	130.1 (17.4)	-4.6 (19.29)	167	130 (17.6)	-3.4 (18.79)	-1.20 (-5.00 to 2.60), 0.54
	Multiple	HD + PA	SBP	IG1	12	170	130.1 (17.4)	-8.4 (20.29)	167	130 (17.6)	-7.5 (19.45)	-0.90 (-4.90 to 3.10), 0.65
Beune, 2014 ⁴⁹ (Culturally Adapted	HTN l	Medium HD + PA	DBP	IG1	6	71	91.02 (9.61)	-5.73 (9.33)		89.6 (9.36)	-1.7 (8.77)	-3.01 (-5.73 to - 0.30), 0.032
Hypertension Education (CAHE)) Fair	HTN	Medium HD + PA	SBP	IG1	6	71	156.73 (12.26)	-9.95 (14.53)	68	155.19 (10.69)	-6.26 (13.61)	-1.69 (-6.01 to 2.62), 0.444
Blackford, 2016 ⁵⁰ (Albany Physical	1	Medium HD + PA		IG1	6	130	87.21 (9.02)	-2.34 (9.55)	144	85.99 (8.75)	-1.03 (9.32)	-1.31 (-3.55 to 0.93), 0.18
Activity and	Multiple	Medium HD + PA	SBP	IG1	6	130	138.54 (14.05)	-5.24 (15.17)	144	138.56 (14.36)	-2.24 (16.04)	-3.00 (-6.70 to 0.70), 0.06

(Study name) Quality			Outcome (mm Hg)	Int arm	Timepoint (months)		IG baseline mean (SD)			baseline	CG mean change (SD)	Between-group difference,† p-value
Nutrition (APAN)) Fair												
Bo, 2007 ⁵² Fair	Multiple	Medium HD + PA	DBP	IG1	12	169	88.2 (8.8)	-2.57 (9.32)	166	87.8 (9.5)	-0.28 (9.99)	-2.29 (-4.36 to - 0.22), 0.03
	Multiple	Medium HD + PA	DBP	IG1	108	169	88.2 (8.8)	-4.2 (9.28)	166	87.8 (9.5)	-2.3 (9.96)	-1.90 (-3.96 to 0.16), 0.17
	Multiple		SBP	IG1	12	169	142.6 (14.1)	-1.99 (18.77)	166	141.5 (15.2)	4.79 (16.99)	-6.78 (-10.61 to - 2.95), <0.001
	Multiple		SBP	IG1	108	169	142.6 (14.1)	-4.6 (15.22)	166	141.5 (15.2)	2.3 (16.66)	-6.90 (-10.32 to - 3.48), 0.002
Bosworth, 2009 ⁵³ (Take Control of	HTN	Medium HD + PA	DBP	IG1	12	113	72 (12)	-3.1 (10.89)	132	70 (10)	1 (8.93)	-2.20 (-3.50 to - 0.80), 0.001
Your Blood pressure (TCYB))	HTN	Medium HD + PA	DBP	IG2	12	127	71 (10)	-1.4 (9.33)	132	70 (10)	1 (8.93)	-1.40 (-2.60 to - 0.10), 0.03
Fair	HTN	Medium HD + PA	DBP	IG1	24	113	72 (12)	-3.2 (11.29)	132	70 (10)	1 (8.93)	-2.20 (-3.80 to - 0.60), 0.009
	HTN	Medium HD + PA	DBP	IG2	24	127	71 (10)	0.4 (9.96)	132	70 (10)	1 (8.93)	0.40 (-1.10 to 1.90), 0.61
	HTN	Medium HD + PA	SBP	IG1	12	113	126 (20)	-5.2 (18.99)	132	124 (18)	0.7 (16.11)	-3.30 (-5.70 to - 0.80), 0.009
	HTN	Medium HD + PA	SBP	IG2	12	127	124 (18)	-0.9 (16.71)	132	124 (18)	0.7 (16.11)	-1.60 (-3.90 to 0.70), 0.174
	HTN	Medium HD + PA	SBP	IG1	24	113	126 (20)	-4.5 (18.2)	132	124 (18)	0.7 (16.08)	-3.90 (-6.90 to - 0.90), 0.01
	HTN	HD + PA	SBP	IG2	24	127	124 (18)	1.2 (17.71)	132	124 (18)	0.7 (16.08)	0.60 (-2.20 to 3.40), 0.67
Broekhuizen, 2012 ⁵⁴ (PRO-FIT) Fair	Dys	Medium HD + PA	SBP	IG1	12	169	123 (14.4)	0 (14.95)	143	126.3 (15.7)	-1.1 (15.82)	1.10 (-2.34 to 4.54), NSD
Bruckert, 2008 ⁵⁵ (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	SBP	IG1	6	274	\ /	-0.63 (NR)	199	NR (NR)	0.34 (NR)	NR, NSD

Quality	Population risk focus	time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)		` /	change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
Burke, 2006 ⁵⁶ (ADAPT)	HTN	Medium HD + PA	DBP	IG1	16	106	77 (10.3)	0 (10.8)	98	76 (9.9)	, ,	-2.00 (-4.91 to 0.91), 0.62
Fair	HTN	Medium HD + PA	DBP	IG1	40	123	77 (8.49)	0 (8.9)	118	76 (8.31)	1 (8.72)	-1.00 (-2.40 to 0.30), 0.146
	HTN	Medium HD + PA	SBP	IG1	16	106	128 (10.3)	2 (10.8)	98	126 (9.9)		-2.00 (-4.91 to 0.91), 0.729
	HTN	Medium HD + PA	SBP	IG1	40	123	128 (11.32)	-1 (11.87)	118	125 (11.08)		-1.40 (-3.50 to 0.70), 0.373
Chirinos, 2016 ⁵⁷ (Community Health	Multiple	High HD + PA	DBP	IG1	6	60	79.35 (9.49)	-3.02 (NR)	60	79.27 (9.57)	-2.54 (NR)	NR
and Risk-reduction for Metabolic	Multiple	High HD + PA	DBP	IG1	12	60	79.35 (9.49)	-0.93 (NR)	60	79.27 (9.57)	-3.8 (NR)	NR, NSD
Syndrome (CHARMS))	Multiple	High HD + PA		IG1		60	124.85 (16.46)	(NR)	60	125.45 (17.31)	-4.8 (NR)	
Fair	Multiple	High HD + PA	SBP	IG1	12	60	124.85 (16.46)	-0.64 (NR)	60	125.45 (17.31)	-6.32 (NR)	NR, NSD
Christian, 2011 ⁵⁸ Fair	Multiple	Medium HD + PA	DBP	IG1	12	133	83.2 (10.73)	-2.5 (12.26)	130	80.4 (10.23)	-0.9 (11.23)	-1.60 (-9.62 to 6.42), 0.13
	Multiple	Medium HD + PA	SBP	IG1	12	133	130.2 (14.3)	-2.2 (14.78)	130	129.9 (17.95)	-0.5 (18.43)	-1.70 (-13.14 to 9.74), 0.2
Cicolini, 2014 ⁵⁹ Fair	HTN	Medium HD + PA	DBP	IG1	6	100	87.5 (5.7)		98	88.6 (2.3)		-3.40 (-4.70 to - 2.10), <0.001
	HTN	Medium HD + PA	SBP	IG1	6	100	150 (11)	-14.9 (8.1)	98	153 (12)	, í	-4.90 (-7.69 to - 2.11), <0.001
Cochrane, 2012 ⁶⁰ Fair	Multiple	Medium HD + PA		IG1		236	85.3 (9.6)	-3.31 (8.35)	365	84.9 (9.5)	-3.56 (9.31)	0.25 (-1.18 to 1.68), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	236	144.4 (16.2)	-5.64 (14.85)	365	146 (17)	-6.65 (16.67)	1.01 (-1.54 to 3.56), NSD
Cohen, 1991 ⁶¹ Fair	HTN	Medium HD only	MAP (mean arterial pressure)	IG1	6	15	105.6 (NR)		15	105.9 (NR)	-2.3 (7.5)	3.50 (-4.40 to 11.40), >0.1
	HTN	Medium HD only	MAP (mean	IG1	12	15	105.6 (NR)	3 (14.2)	15	105.9 (NR)		3.70 (-5.48 to 12.88), >0.1

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)		IG baseline mean (SD)	IG mean change (SD)		baseline		Between-group difference,† p-value
			arterial pressure)									
Coleman, 2012 ⁶² (Wisewoman	Multiple	Medium HD + PA	DBP	IG1	12	433	76.6 (8.46)	-3.8 (NR)	436	77.2 (9.3)	-2.5 (NR)	NR, 0.103
California) Fair	Multiple	Medium HD + PA	SBP	IG1	12	433	124.9 (13.39)	-5.9 (NR)	436	125.5 (13.96)	-3.7 (NR)	NR, 0.038
Ellsworth, 2016 ⁶⁶ Fair	Multiple	High HD + PA	DBP	IG1	12	89	80 (11.5)	-6.3 (14.2)	58	78.9 (11)	-1.6 (NR)	NR, 0.047
Estruch, 2018 ⁶⁷ (Primary	Multiple	High HD only	DBP	IG1	12	78	74.9 (6.98)	-1.63 (6.78)	75	73.6 (7.95)		-2.36 (-4.25 to - 0.47), <0.05
Prevention of Cardiovascular	Multiple	High HD only	DBP	IG2	12	82	74.2 (7.85)	-1.51 (5.52)	75	73.6 (7.95)	0.73 (5.08)	-2.24 (-3.90 to - 0.58), <0.05
Disease with a Mediterranean Diet	Multiple	High HD only	SBP	IG1	12	78	130.5 (14.42)	-2.94 (10.61)	75	126.4 (13.26)	2.36 (8.09)	-5.30 (-8.28 to - 2.32), <0.05
(PREDIMED)) Fair	Multiple	High HD only	SBP	IG2	12	82	128.9 (13.63)	-3.12 (9.33)	75	126.4 (13.26)		-5.48 (-8.21 to - 2.75), <0.05
Fagerberg, 1998 ⁶⁸ (Risk Factor	Multiple	High HD + PA	DBP	IG1	12	239	91 (8)	-2.5 (8)	238	91 (9)	-0.8 (9.2)	-1.60 (-3.15 to - 0.05), 0.039
Intervention Study (RIS))	Multiple	High HD + PA	DBP	IG1	40	235	91 (8)	-4.9 (9.1)	227	91 (9)	, ,	MD=-1.10 (-2.80 to 0.60), 0.2
Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	DBP	IG1	79	248	91 (8)	-4 (6.43)	252	91 (9)	-3 (7.69)	-1.00 (-2.29 to 0.29),
	Multiple	High HD + PA	SBP	IG1	12	239	155 (18)	-3 (16)	238	155 (20)	-2 (20)	-2.00 (-5.51 to 1.51), 0.34
	Multiple	High HD + PA	SBP	IG1	40	235	155 (18)	-2 (18.4)	227	155 (20)	-0.2 (20.5)	MD=-1.80 (-5.40 to 1.70), 0.31
	Multiple	High HD + PA	SBP	IG1	79	248	155 (18)	-1 (15.27)	252	155 (20)	1 (17.01)	-2.00 (-4.80 to 0.80),
Gill, 2019 ⁶⁹ (Heartmatters	Multiple	High HD + PA	DBP	IG1	6	96	85.99 (10.23)	NR (NR)	79	84.32 (8.85)	NR (NR)	0.78 (-2.89 to 4.45), 0.69
Challenge - First Responders)	Multiple	High HD + PA	DBP	IG1	12	96	85.99 (10.23)	NR (NR)	79	84.32 (8.85)	NR (NR)	-1.55 (-5.16 to 2.06), 0.43
Fair	Multiple	High HD + PA	SBP	IG1	6	96		NR (NR)	79	` /		-1.46 (-5.58 to 2.66), 0.51

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)		Timepoint (months)		IG baseline mean (SD)	change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	SBP	IG1	12	96	128.03 (14.06)	NR (NR)	79	129.49 (15.28)		0.05 (-3.99 to 4.09), 0.98
Gill, 2019 ⁷⁰ (HealtheSteps)	Multiple	Medium HD + PA	DBP	IG1	6	59	NR (NR)	-1.57 (9.86)	59	NR (NR)		0.27 (-3.26 to 3.81), 0.88
Fair	Multiple	Medium HD + PA	SBP	IG1	6	59	NR (NR)	-6.38 (15.54)	59	NR (NR)	-6.61 (15)	0.23 (-5.02 to 5.48), 0.93
Greaves, 2015 ⁷¹ (Waste the Waist)	Multiple	High HD + PA	DBP	IG1	12	55	79.8 (13.7)	NR (NR)	53	84.3 (9.3)		0.30 (-3.50 to 4.09), NSD
Fair	Multiple	High HD + PA	SBP	IG1	12	55	137.7 (15.7)	NR (NR)	53	139.5 (16.4)		1.09 (-3.67 to 5.85), NSD
Groeneveld, 2010 ⁷² (Health Under	Multiple	Medium HD + PA	DBP	IG1	6	259	89.1 (9.7)	-3.9 (10.73)	257	88.5 (9.4)	` ′	-1.90 (-3.68 to - 0.12), <0.05
Construction) Fair	Multiple	Medium HD + PA	DBP	IG1	12	259	89.1 (9.7)	-3.7 (10.44)	257	88.5 (9.4)	-3.2 (10.07)	-0.50 (-2.27 to 1.27), NSD
	Multiple	Medium HD + PA	SBP	IG1	6	259	143 (15.8)	-5.2 (16.68)	257	141 (14.8)	-2.1 (16.07)	-3.10 (-5.93 to - 0.27), NSD
	Multiple	Medium HD + PA	SBP	IG1	12	259	143 (15.8)	-4.9 (17)	257	141 (14.8)	-3.8 (16.3)	-1.10 (-3.97 to 1.77), NSD
Hardcastle, 2008 ⁷³ Fair	Multiple	Medium HD + PA	DBP	IG1	6	203	83.42 (9.63)	-1.9 (9.59)	131	81.92 (9.27)	0.78 (9.57)	-2.68 (-4.78 to - 0.58), <0.05
	Multiple	Medium HD + PA	DBP	IG1	18	203	83.42 (9.63)	-1.02 (9.8)	131	81.92 (9.27)	0.89 (9.18)	-1.91 (-3.98 to 0.16), <0.01
	Multiple	Medium HD + PA	SBP	IG1	6	203	133.12 (16.53)	-2.87 (16.96)	131	132.41 (17.33)	-0.6 (18.24)	-2.27 (-6.17 to 1.63), NSD
	Multiple	Medium HD + PA	SBP	IG1	18	203	133.12 (16.53)	-4.14 (16.33)	131	132.41 (17.33)	-2.45 (18.4)	-1.69 (-5.56 to 2.18), NSD
Harris, 2012 ⁷⁴ (Health Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	SBP	IG1	12	355		NR (NR)	300	NR (NR)	NR (NR)	NR, 0.9
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	SBP	IG1	6	160	138 (13)	-6 (12.7)	154	138 (14)	` /	-2.70 (-4.90 to - 0.40), 0.020

(Study name) Quality		time* Intervention focus	Outcome (mm Hg)		(months)			change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
Hinderliter, 2014 ⁷⁶ (Exercise and	HTN	High HD only	DBP	IG1	12	46	86 (6)	-4.6 (6.81)	49	86 (6)	-6.4 (6.85)	1.80 (-0.95 to 4.55), NSD
Nutrition interventions for CardiOvasculaR hEalth (ENCORE)) Good	HTN	High HD only	SBP	IG1	12	46	138 (9)	-9.5 (9.09)	49	138 (9)	-3.9 (11.84)	-5.60 (-9.83 to - 1.37), <0.05
HPT, 1990 ⁷⁷ (Hypertension	HTN	High HD only	DBP	IG1	6	180	82.3 (NR)	-3.7 (6.71)	191	83 (NR)	-3 (6.91)	-0.70 (-2.09 to 0.69), <0.05
Prevention Trial (HPT))	HTN	High HD only	DBP	IG2	6	173	82.6 (NR)	-3.4 (6.58)	191	83 (NR)	-3 (6.91)	-0.40 (-1.77 to 0.97), 0.664
Good	HTN	High HD only	DBP	IG3	6	112	83 (NR)	-5.3 (7.41)	121	83.3 (NR)	l , ,	-2.80 (-4.76 to - 0.84), 0.01
	HTN	High HD only		IG4	6		82.6 (NR)	, ,		83.3 (NR)	, , ,	-1.50 (-3.44 to 0.44), <0.05
	HTN	High HD only		IG1	36		` /	-3.7 (6.67)		83 (NR)	, ,	-0.70 (-2.09 to 0.69), <0.05
	HTN	High HD only	DBP	IG2	36	174	82.6 (NR)	-2.8 (6.6)	177	83 (NR)	-3 (6.65)	-0.90 (-2.27 to 0.47), 0.398
	HTN	High HD only		IG3	36	117	83 (NR)	-4.2 (8.65)		83.3 (NR)	-2.4 (8.58)	-1.80 (-3.96 to 0.36), 0.045
	HTN	High HD only	DBP	IG4	36	115	82.6 (NR)	-3.7 (8.58)	115	83.3 (NR)	-2.4 (8.58)	-1.30 (-3.52 to 0.92), <0.05
	HTN	High HD only	SBP	IG1	6	180	124.1 (NR)	-3.4 (8.05)	191	123.9 (NR)	-2.1 (8.29)	-1.30 (-2.96 to 0.36), <0.05
	HTN	High HD only	SBP	IG2	6	173	124 (NR)	-3.8 (7.89)	191	123.9 (NR)	-2.1 (8.29)	-1.70 (-3.46 to 0.06), 0.126
	HTN	High HD only	SBP	IG3	6	112	125.3 (NR)	(7.41)	121	124.7 (NR)	-1.8 (7.7)	-5.10 (-7.06 to - 3.14), <0.001
H	HTN	High HD only	SBP	IG4	6	113	124.4 (NR)	-5.8 (7.44)	121	124.7 (NR)	-1.8 (7.7)	-4.00 (-5.94 to - 2.06), <0.05
	HTN	High HD only		IG1	36	178	124.1 (NR)	(9.34)	177	123.9 (NR)	-2.9 (9.31)	-1.20 (-3.14 to 0.74), <0.05
	HTN	High HD only	SBP	IG2	36	174	124 (NR)	-2.8 (9.23)	177	123.9 (NR)	-2.9 (9.31)	0.10 (-1.86 to 2.06), 0.885

Author, year (Study name) Quality		time* Intervention focus	Outcome (mm Hg)		(months)		IG baseline mean (SD)	change (SD)		baseline mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	HTN	High HD only	SBP	IG3	36	117	125.3 (NR)	-5 (9.73)	115	124.7 (NR)	-2.6 (9.65)	-2.40 (-4.95 to 0.15), 0.031
	HTN	High HD only	SBP	IG4	36	115	124.4 (NR)	-3.6 (9.65)	115	124.7 (NR)	-2.6 (9.65)	-1.00 (-3.49 to 1.49), NSD
Hyman, 2007 ⁷⁹ Fair	HTN	Medium HD + PA	DBP	IG1	6	92	83.7 (9.1)	-2.3 (9.34)	93	84.8 (8.9)	-3.1 (9.61)	0.80 (-1.93 to 3.53), NSD
	HTN	Medium HD + PA	DBP	IG2	6	96	87.4 (9.5)	-4.1 (11.82)	93	84.8 (8.9)	-3.1 (9.61)	-1.00 (-4.07 to 2.07), NSD
	HTN	Medium HD + PA	DBP	IG1	18	92	83.7 (9.1)	-1.6 (9.93)	93	84.8 (8.9)	-3.1 (9.72)	1.50 (-1.33 to 4.33), NSD
	HTN	Medium HD + PA	DBP	IG2	18	96	87.4 (9.5)	-3.9 (10.95)	93	84.8 (8.9)	-3.1 (9.72)	-0.80 (-3.75 to 2.15), NSD
	HTN	Medium HD + PA	SBP	IG1	6	92	137.4 (19.1)	-5.8 (19.38)	93	137.2 (17.2)	-3.3 (19.1)	-2.50 (-8.05 to 3.05), NSD
	HTN	Medium HD + PA	SBP	IG2	6	96	142 (18)	-7.6 (21.12)	93	137.2	-3.3 (19.1)	-4.30 (-10.04 to 1.44), NSD
	HTN	Medium HD + PA	SBP	IG1	18	92	137.4 (19.1)	-6.5 (19.62)	93	137.2	-2.9 (18.7)	-3.60 (-9.12 to 1.92), NSD
	HTN	Medium HD + PA	SBP	IG2	18	96	142 (18)	-7.9 (20.06)	93	137.2	-2.9 (18.7)	-5.00 (-10.53 to 0.53), <0.05
Jones, 1999 ⁸² (Hypertension	HTN	High HD only	DBP	IG1	6	51	105 (5)		51	105 (4)	-22.59 (3.61)	0.88 (-0.70 to 2.46), NSD
Optimal Treatment (HOT))	HTN	High HD only	DBP	IG1	12	51	105 (5)	-21.41 (4.48)	51	105 (4)	-22.68 (3.8)	1.27 (-0.34 to 2.88), NSD
Fair	HTN	High HD only	DBP	IG1	18	51	105 (5)		51	105 (4)	-21.71 (3.94)	-0.33 (-1.96 to 1.30), NSD
	HTN	High HD only	DBP	IG1	24	51	105 (5)	-21.94 (4.47)	51	105 (4)	-22.9 (3.68)	0.96 (-0.63 to 2.55), NSD
	HTN	High HD only	DBP	IG1	30	51	105 (5)	-20.47 (4.52)	51	105 (4)	-22.9 (3.61)	2.43 (0.84 to 4.02), NSD
	HTN	High HD only	SBP	IG1	6	51	165 (16)	-32 (15.02)	51	167 (12)	-32.88 (10.72)	0.88 (-4.18 to 5.94), NSD
	HTN	High HD only	SBP	IG1	12	51	165 (16)	-29.96 (14.72)	51	167 (12)	-32.96 (10.73)	3.00 (-2.00 to 8.00), NSD

	Population risk focus	Contact time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)		IG baseline mean (SD)			baseline		Between-group difference,† p-value
	HTN	High HD only	SBP	IG1	18	51	165 (16)	-32.43 (14.94)	51	167 (12)	-31.35 (10.75)	-1.08 (-6.13 to 3.97), NSD
	HTN	High HD only	SBP	IG1	24	51	165 (16)		51	167 (12)	-34.17	2.11 (-2.86 to 7.08), NSD
	HTN	High HD only	SBP	IG1	30	51	165 (16)	-33.14 (14.71)	51	167 (12)	-33.94 (10.74)	0.80 (-4.20 to 5.80), NSD
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	SBP	IG1	6	31	127 (17)	-3.6 (11.52)	32	130 (17)	-3.4 (11.58)	-0.20 (-5.43 to 5.00), NSD
Kanke, 2015 ⁸⁴ Fair	Multiple	Medium HD + PA	DBP	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	DBP	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	SBP	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	SBP	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, NSD
Kastarinen, 2002 ⁸⁵ (Lifestyle	HTN	High HD + PA	DBP	IG1	12	360	91 (9)	-4 (NR)	355	91 (8)	-2.4 (NR)	MD=-1.60 (-2.70 to -0.60), <0.05
Intervention against Hypertension in	HTN	High HD + PA	DBP	IG1	24	360	91 (9)	-4.3 (NR)	355	91 (8)	-3.2 (NR)	-1.10 (-2.40 to 0.20), <0.05
Eastern Finland (LIHEF))	HTN	High HD + PA	SBP	IG1	12	360	149 (16)	-4.7 (NR)	355	148 (16)	, ,	MD=-1.30 (-3.20 to 0.60), <0.05
Fair	HTN	High HD + PA	SBP	IG1	24	360	149 (16)	-6.2 (NR)	355	148 (16)		-2.00 (-4.30 to 0.30), <0.05
Khanji, 2019 ⁸⁷ (HAPPY London)	Multiple	Low HD + PA	DBP	IG1	6	194	79.2 (9.2)	-2.37 (9.6)	183	80 (8.6)	-2.08 (9.07)	-0.29 (-1.60 to 1.10), 0.67
Good	Multiple	Low HD + PA	SBP	IG1	6	194	132.5 (13.3)	-3.18 (14.11)	183	132.3 (14.8)	-1.69 (15.47)	-1.50 (-4.20 to 1.20), 0.27
Koelewijn-van Loon, 2009 (Improving Patient	Multiple	Medium HD + PA	SBP	IG1	12	286	144 (19)	-6 (18.53)	261	150 (19)	-8 (18.53)	2.00 (-1.11 to 5.11), 0.004

Author, year (Study name)	Population risk focus	time*	Outcome (mm Hg)	Int arm	Timepoint (months)		IG baseline mean (SD)	change		baseline	mean	Between-group difference,† p-value
Quality		Intervention focus						(SD)			change (SD)	
Adherence to Lifestyle Advice (IMPALA)) Fair												
Kramer, 2018 ⁸⁹ (Healthy Lifestyle	Multiple	High HD + PA	DBP	IG1	6	74	72.3 (8.8)	-1 (9.1)	41	73.2 (11.5)		0.20 (-3.40 to 3.80), 0.88
Project) Fair	Multiple	High HD + PA	SBP	IG1	6	74	118.2 (11.7)	-3.4 (11.2)	41	119.1 (12.2)	-0.3 (10.3)	-3.10 (-7.16 to 0.96), 0.13
Langford, 1991 ⁹¹ (Trial of	HTN	High HD + PA	DBP	IG1	6	265	93.8 (NR)	-12.84 (10.02)	264	93.6 (NR)	-10.36 (7.81)	-2.48 (-4.30 to - 0.66), 0.001
Antihypertensive Interventions and	HTN	High HD only		IG2	6	258	94 (NR)	(8.89)		93.6 (NR)	-10.36 (7.81)	-0.71 (-2.53 to 1.11), 0.347
Management (TAIM))	HTN	High HD + PA		IG1		265	142.3 (NR)	(15.95)	264	, ,	-14.2 (15.95)	-2.80 (-5.52 to - 0.08), <0.05
Fair	HTN	High HD only	SBP	IG2	6	258	144.8 (NR)	-15.8 (15.95)	264	143.1 (NR)	-14.2 (15.95)	-1.60 (-4.34 to 1.14), NSD
Lee, 2007 ⁹² Fair	HTN	Medium PA only		IG1	6	91	83.5 (11.2)	-6.47 (9.5)			-4.71 (8.5)	-1.80 (-4.40 to 0.90), 0.19
	HTN	Medium PA only	SBP	IG1	6	91	152 (10.5)	-16.2 (14.8)	93	152.4 (11.1)	-8.1 (14.3)	-8.10 (-12.00 to - 2.70), 0.002
Liira, 2014 ⁹³ Fair	Multiple	Medium HD + PA		IG1		46	82 (9.5)	1 (10.35)	42	84 (9.7)		2.00 (-2.29 to 6.29), NSD
	Multiple	Medium HD + PA		IG1	12	46	, ,	3 (13.85)	42	136 (13.9)		5.00 (-0.77 to 10.77), NSD
Migneault, 2012 ⁹⁴ Fair	HTN	High HD + PA		IG1	8		` ′	-1.28 (NR)		80.3 (11.8)	, ,	-1.18 (NR), NSD
	HTN	High HD + PA		IG1	12	169	, , ,	-0.4 (NR)	168	, , ,	-0.5 (NR)	NR, NSD
	HTN	High HD + PA		IG1	8	169	130.6 (19.8)	-2.06 (NR)	168	(18.6)	0.25 (NR)	-2.31 (NR), NSD
	HTN	High HD + PA		IG1	12	169	130.6 (19.8)	0.9 (NR)		131.8 (18.6)	, ,	NR, NSD
Moreau, 2001 ⁹⁵ Fair	HTN	Low PA only	DBP	IG1	6	15	84 (3.87)	-3 (3.07)	9	86 (6)		-3.70 (-5.85 to - 1.55), NSD

Author, year (Study name) Quality	Population risk focus	time* Intervention focus	Outcome (mm Hg)		Timepoint (months)			change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
	HTN	Low PA only	SBP	IG1	6	15	142 (11.62)	-11 (4.94)	9	142 (9)	-0.8 (4.29)	-10.20 (-13.96 to - 6.44), <0.05
Muhlhauser, 1993 ⁹⁷ (Hypertension	HTN	Medium HD + PA	DBP	IG1	18	86	100 (7)	-6 (11)	74	98 (7)	-2 (10)	-4.00 (1.00 to 7.00), 0.018
Treatment and Teaching Program (HTTP)) Fair	HTN	Medium HD + PA	SBP	IG1	18	86	162 (14)	-8 (17)	74	161 (13)	-3 (18)	-5.00 (0.00 to 10.00), 0.071
Niiranen, 2014 ¹⁰⁰ Fair	HTN	Medium HD + PA	DBP	IG1	12	112	87 (9)	-6 (8)	108	87 (8)	-7 (8)	1.00 (-4.46 to 6.46), 0.16
	HTN	Medium HD + PA	SBP	IG1	12	112	146 (19)	-8 (17)	108	148 (20)		3.00 (-8.61 to 14.61), 0.25
Nolan, 2018 ¹⁰¹ (Reducing Risk	HTN	High HD + PA	DBP	IG1	12	100	87.3 (8.83)	-4.9 (7.4)	97	87.3 (8.76)		-1.40 (-3.45 to 0.65), 0.17
with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	HTN	High HD + PA	SBP	IG1	12	100	141.5 (11.77)	-10.1 (12.5)	97	140.6 (11.68)		-4.10 (-7.60 to - 0.60), 0.02
	HTN	Medium HD + PA	DBP	IG1	6	529	91 (10)	-9 (NR)	510	91 (11)	-8.3 (NR)	NR, 0.6
African Americans to Control	HTN	Medium HD + PA	DBP	IG1	9	529	91 (10)	-9.9 (NR)	510	91 (11)	-9.9 (NR)	NR, 0.86
Hypertension (CAATCH))	HTN	Medium HD + PA	DBP	IG1	12	529	91 (10)	-9.9 (NR)	510	91 (11)	-9.1 (NR)	NR, 0.46
Fair	HTN	Medium HD + PA	SBP	IG1	6	529	150 (17)	-16 (NR)	510	153 (17)	-15.7 (NR)	NR, 0.82
	HTN	Medium HD + PA	SBP	IG1	9	529	150 (17)	(NR)	510	153 (17)	-18 (NR)	NR, 0.62
	HTN	Medium HD + PA	SBP	IG1	12	529	150 (17)	(NR)	510	153 (17)	-16.6 (NR)	NR, 0.96
Reid, 2014 ¹⁰³ Fair	Multiple	High HD + PA	DBP	IG1	12	211	76.8 (9)	-1.3 (9.71)	215	76.3 (9.9)		0.20 (-1.65 to 2.05), 0.4

Author, year (Study name) Quality	Population risk focus	time* Intervention focus	Outcome (mm Hg)	Int arm	Timepoint (months)		IG baseline mean (SD)	change (SD)	CG N	baseline	mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	SBP	IG1	12	211	121.8 (15.3)	-3.3 (15.55)	215	120.4 (16.9)	-2.9 (16.68)	-0.40 (-3.46 to 2.66), 0.9
Rodriguez, 2012 ¹⁰⁴ Fair	HTN	Medium HD + PA	SBP	IG1	6	176	135.96 (13.78)		177	137 (14.86)		-2.00 (-4.26 to 0.26), 0.007
	HTN	Medium HD + PA	SBP	IG1	12	151	135.96 (13.78)	-5.38 (14.78)	157	137 (14.86)	-4.05 (15.03)	-1.33 (-4.66 to 2.00), NSD
Rodriguez- Cristobal, 2012 ¹⁰⁵	Multiple	High HD + PA	DBP	IG1	24	146	80.7 (9.8)	-5.2 (10.23)	154	81.7 (9.4)	-1.3 (9.51)	MD=-4.40 (-6.80 to -2.00), 0.0001
Fair	Multiple	High HD + PA	SBP	IG1	24	146	133.8 (17.4)	-4.2 (17.16)	154	134.7 (18)	2.2 (17.41)	MD=-6.80 (-10.70 to -2.80), 0.0001
Rosas, 2015 ¹⁰⁶ (Vivamos Activos	Multiple	High HD + PA	DBP	IG1	6	82	74.1 (7.2)	-0.2 (6.47)	41	73.8 (8.6)	0.3 (7.13)	-0.50 (-3.09 to 2.09), 0.72
Fair Oaks (VAFO)) Good	Multiple	High HD + PA	DBP	IG2	6	84	73 (7.6)	-0.1 (6.55)	41	73.8 (8.6)	0.3 (7.13)	-0.40 (-2.99 to 2.19), 0.73
	Multiple	High HD + PA	DBP	IG1	12	82	74.1 (7.2)	0.3 (9.01)	41	73.8 (8.6)	-1.3 (8.87)	1.60 (-1.74 to 4.94), 0.4
	Multiple	High HD + PA	DBP	IG2	12	84	73 (7.6)	-0.6 (7.95)	41	73.8 (8.6)	-1.3 (8.87)	0.70 (-2.50 to 3.90), 0.62
	Multiple	High HD + PA	DBP	IG1	24	82	74.1 (7.2)	0.9 (8.32)	41	73.8 (8.6)	-0.2 (6.34)	1.10 (-1.55 to 3.75), 0.46
	Multiple	High HD + PA	DBP	IG2	24	84	73 (7.6)	1.2 (7.95)	41	73.8 (8.6)	-0.2 (6.34)	1.40 (-1.18 to 3.98), 0.33
	Multiple	High HD + PA	SBP	IG1	6	82	114.8 (12.7)	-1.8 (11.09)	41	117.2 (13.9)	-2.2 (13.31)	0.40 (-4.33 to 5.13), 0.87
	Multiple	High HD + PA	SBP	IG2	6	84	114.5 (13)	(13.09)	41	117.2 (13.9)	-2.2 (13.31)	2.10 (-2.84 to 7.04), 0.41
	Multiple	High HD + PA	SBP	IG1	12	82	114.8 (12.7)	-1.3 (13.63)	41	117.2 (13.9)	-3 (15.05)	1.70 (-3.77 to 7.17), 0.57
	Multiple	High HD + PA	SBP	IG2	12	84	114.5 (13)	-2.2 (13.33)	41	117.2 (13.9)	-3 (15.05)	0.80 (-4.62 to 6.22), 0.77
	Multiple		SBP	IG1	24	82	114.8 (12.7)		41	117.2 (13.9)	-0.2 (12.83)	0.70 (-4.46 to 5.86), 0.79
	Multiple	High HD + PA	SBP	IG2	24	84	114.5 (13)		41	117.2 (13.9)	-0.2 (12.83)	0.80 (-4.08 to 5.68), 0.74

Author, year (Study name) Quality		time* Intervention focus	Outcome (mm Hg)		(months)		, ,	change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
Rubinstein, 2016 ¹⁰⁷ Good	HTN	Medium HD + PA	DBP	IG1	12	94	77 (7.2)	-0.5 (8.24)	96	77.6 (6.4)	-0.1 (7.67)	-1.08 (-3.32 to 1.15), 0.32
	HTN	Medium HD + PA	SBP	IG1	12	94	128.9 (5.5)	-4 (9.41)	96	128 (6)	-2.2 (10.99)	-1.77 (-5.06 to 1.52), 0.29
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	DBP	IG1	6	301	81.2 (9.6)	-3 (10.23)	296	80 (10.4)	-2 (10.56)	MD=-0.60 (-1.80 to 0.60), 0.34
	Multiple	Medium HD + PA	DBP	IG1	12	295	81.2 (9.6)	-4.6 (9.86)	291	80 (10.4)	-1.3 (10.65)	MD=-2.80 (-4.00 to -1.60), <0.001
	Multiple	Medium HD + PA	SBP	IG1	6	301	147.6 (16.2)	-6.6 (16.44)	296	148.1 (17.6)		MD=0.00 (-1.90 to 1.90), 0.1
	Multiple	Medium HD + PA	SBP	IG1	12	295	147.6 (16.2)	-8 (15.95)	291	148.1 (17.6)	-5.9 (17.72)	MD=-2.70 (-4.70 to -0.60), 0.01
Schoenthaler, 2016 ¹⁰⁹ (Individual	HTN	High HD + PA	DBP	IG1	6	97	88.2 (10.83)	-7.2 (11.91)	97	90.1 (10.83)		0.40 (-2.95 to 3.75), 0.7921
Motivational Interviewing - Therapeutic Lifestyle Changes (MINT-TLC)) Fair	HTN	High HD + PA	SBP	IG1	6	97	145.4 (13.79)	-9.5 (15.58)	97	147.2 (13.79)	` /	3.40 (-0.90 to 7.70), 0.1819
Stefanick, 1998 ¹¹² (Diet and Exercise	Dys	High HD only		IG1 (Females)	12	46	NR (NR)	-1.9 (5)	45	NR (NR)	-0.6 (5.9)	-1.30 (-3.55 to 0.95), NSD
for Elevated Risk (DEER))	Dys	High HD only		IG1 (Males)	12	49	NR (NR)	0.3 (5.2)	46	NR (NR)	1.8 (6.1)	-1.50 (-3.79 to 0.79), NSD
Fair	Dys	High HD only		IG1 (Females)	12	46	NR (NR)	-3.5 (9.2)	45	NR (NR)	-2.4 (7.6)	-1.10 (-4.56 to 2.36), NSD
	Dys	High HD only		IG1 (Males)	12	49	NR (NR)	-1.7 (6.4)	46	NR (NR)	-0.3 (7.9)	-1.40 (-4.30 to 1.50), NSD
Svetkey, 2009 ¹¹⁵ (Hypertension	HTN	High HD + PA	DBP	IG1	6	132	75.3 (11.1)	-5.4 (NR)	132	73.3 (10.5)	-3.6 (NR)	NR, NSD
Improvement Project (HIP))	HTN	High HD + PA	DBP	IG2	6	124	73.3 (12.6)	-3.4 (NR)	132	73.3 (10.5)	-3.6 (NR)	NR, NSD
Fair	HTN	Medium HD + PA	DBP	IG3	6	137	74.3 (11)	-3.2 (NR)	132	73.3 (10.5)	-3.6 (NR)	NR, NSD

Author, year (Study name) Quality		time* Intervention focus	Outcome (mm Hg)		(months)			change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
	HTN	HD + PA	DBP	IG1	18	128	75.3 (11.1)	-5.3 (NR)		, , ,	, ,	NR, NSD
	HTN	High HD + PA	DBP	IG2	18	124	73.3 (12.6)	-3.4 (NR)	122	73.3 (10.5)	-4.9 (NR)	NR, NSD
	HTN	Medium HD + PA	DBP	IG3	18	134	74.3 (11)	-4.6 (NR)	122	73.3 (10.5)	-4.9 (NR)	NR, NSD
	HTN		SBP	IG1	6	132	133.8 (16.3)	-9.7 (12.7)	132	131.6 (14.6)	-6.7 (12.8)	-3.00 (-6.08 to 0.08), NSD
	HTN		SBP	IG2	6	124	132.1 (17.6)		132	131.6 (14.6)	-6.7 (12.8)	-0.40 (-3.45 to 2.65), NSD
	HTN		SBP	IG3	6	137	134.6 (15.7)		132	131.6 (14.6)	-6.7 (12.8)	1.40 (-1.58 to 4.38), NSD
	HTN	High HD + PA	SBP	IG1	18	128	133.8 (16.3)	-8.6 (NR)	122	131.6 (14.6)	-7.5 (NR)	NR, NSD
	HTN	High HD + PA	SBP	IG2	18	124	132.1 (17.6)	-6.8 (NR)	122	131.6 (14.6)	-7.5 (NR)	NR, NSD
	HTN	Medium HD + PA	SBP	IG3	18	134	134.6 (15.7)	-7.5 (NR)	122	131.6 (14.6)	-7.5 (NR)	NR, NSD
Ter Bogt, 2009 ¹¹⁶ (Groningen	Multiple		DBP	IG1 (Females)	12	103	NR (NR)	-0.3 (9.6)	114		0.2 (8.4)	-0.50 (-2.91 to 1.91), NSD
Overweight and Lifestyle (GOAL))	Multiple		DBP	IG1 (Males)	12	98	NR (NR)	-2.6 (11.2)	101	NR (NR)	-1.3 (7.8)	-1.30 (-3.99 to 1.39), NSD
Good	Multiple	High HD + PA	SBP	IG1 (Females)	12	103	NR (NR)		114	NR (NR)	-2.2 (16.5)	-3.10 (-8.02 to 1.82), NSD
	Multiple		SBP	IG1 (Males)	12	98	NR (NR)	-8.5 (16.8)	101	NR (NR)	-5.3 (12.7)	-3.20 (-7.35 to 0.95), NSD
Tiessen, 2012 ¹¹⁷ (SPRING (Self-	Multiple	Medium HD + PA	DBP	IG1	12	89	92 (9.5)	-4.4 (9.39)	90	91 (8.5)	-3.3 (7.26)	-1.10 (-3.50 to 1.40), NSD
monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	Multiple		SBP	IG1	12	89	158 (17.1)		90	158 (16.3)	-5.6 (14.28)	-1.20 (-5.80 to 3.40), NSD

Author, year (Study name) Quality		time* Intervention focus	Outcome (mm Hg)		(months)			change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
TOHP I CRG,	HTN	_ <i>U</i>	DBP	IG1	6	305	83.7 (2.7)		397	83.9 (2.8)	-2.88	-1.00 (-1.95 to -
1992 ¹¹⁹ (Trials of	T TOO Y	HD only	DDD	T.C.2	-	200	00.7 (0.6)	(6.42)	220	0.4.(2)		0.04), <0.05
Hypertension Prevention Phase I	HTN	High HD + PA	DBP	IG2	6	299	83.7 (2.6)	-6.3 (6.92)	239	84 (3)	-3.7 (6.18)	-2.50 (-3.68 to - 1.32), <0.001
(TOHP I))	HTN		DBP	IG1	12	301	83.7 (2.7)	` '	392	83.9 (2.8)	-3.37	-1.06 (-1.90 to -
Good	11111	HD only	DDI	101	12	501	03.7 (2.7)	(5.38)	372	03.7 (2.0)	(5.74)	0.22), <0.05
	HTN		DBP	IG2	12	287	83.7 (2.6)		237	84 (3)	-3.8	-2.00 (-2.98 to -
		HD + PA					, ,	(6.78)			(6.16)	1.02), <0.001
	HTN	High	DBP	IG1	18	304	83.7 (2.7)	-4.35	395	83.9 (2.8)	-3.18	-1.17 (-2.03 to -
		HD only						(5.65)			(5.8)	0.31), < 0.01
	HTN	High	DBP	IG2	18	295	83.7 (2.6)	-6.2	236	84 (3)	-3.8	-2.40 (-3.38 to -
		HD + PA						(6.87)			(6.14)	1.42), < 0.001
	HTN	High	SBP	IG1	6	305	124.8 (8.5)		397	125.1 (8.1)	-3.83	-2.03 (-3.26 to -
		HD only						(7.95)			(8.46)	0.80), < 0.01
	HTN	_ <i>U</i>	SBP	IG2	6	299	124.3 (8.4)		239	124.6 (8.1)	-2.7	-3.80 (-5.17 to -
		HD + PA						(8.65)				2.43), 0.001
	HTN	$\mathcal{C}$	SBP	IG1	12	301	124.8 (8.5)		392	125.1 (8.1)	-3.93	-1.90 (-3.02 to -
		HD only						(7.46)				0.78), <0.01
	HTN		SBP	IG2	12	287	124.3 (8.4)		237	124.6 (8.1)	-3.1 (7.7)	-2.30 (-3.67 to -
		HD + PA						(8.47)				0.93), 0.001
	HTN	U	SBP	IG1	18	304	124.8 (8.5)		395	125.1 (8.1)	-3.02	-2.06 (-3.28 to -
		HD only						(7.94)			(8.31)	0.84), < 0.01
	HTN	0	SBP	IG2	18	295	124.3 (8.4)		236	124.6 (8.1)	-2.3	-2.90 (-4.27 to -
TOWN W CD C	* * * * * * * * * * * * * * * * * * *	HD + PA	D D D	7.01	-	~ - 0	0.5 (4.0)	(6.87)	<b>70</b> 0	0.7.0 (4.0)	(7.68)	1.53), <0.001
TOHP II CRG,	HTN		DBP	IG1	6	562	86 (1.9)	-5.6 (6.9)	538	85.8 (1.9)	-2.8 (6.1)	-2.80 (-3.58 to -
1997 ¹²⁰ (Trial of	T TOTAL	HD + PA	DDD	TCO		C C 1	0.6 (1.0)	<i>5.5.(6.0)</i>	<b>520</b>	07.0 (1.0)	20(61)	2.02), <0.001
Hypertension Prevention II	HTN	_ <i>U</i>	DBP	IG2	6	561	86 (1.9)	-5.5 (6.9)	538	85.8 (1.9)	-2.8 (6.1)	-2.70 (-3.48 to -
(TOHP II))	TITAL	HD + PA	DBP	IG3	(	520	061(10)	4.4.(6.7)	520	05.0 (1.0)	20 (6.1)	1.92), <0.001
Good	HTN	High HD only	אמע	103	6	529	86.1 (1.9)	-4.4 (6.7)	J38	85.8 (1.9)	-2.8 (0.1)	-1.60 (-2.38 to - 0.82), <0.001
	HTN		DBP	IG1	18	538	86 (1.9)	-4.5 (6.3)	525	85.8 (1.9)	-3 2 (5 8)	-1.30 (-2.08 to -
	1111	HD + PA		101		230	00 (1.7)	1.5 (0.5)	525	05.0 (1.7)		0.52), <0.001
	HTN		DBP	IG2	18	533	86 (1.9)	-4.5 (6.1)	525	85.8 (1.9)		-1.30 (-2.08 to -
		HD + PA								. ,		0.52), <0.001

		time* Intervention focus	Outcome (mm Hg)		(months)		, ,	change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p-value
	HTN	High HD only	DBP	IG3	18	513	86.1 (1.9)	-4.4 (6.5)	525	85.8 (1.9)	, ,	-1.20 (-1.98 to - 0.42), 0.002
	HTN	High HD + PA	DBP	IG1	36	537	86 (1.9)	-2.9 (6.7)	514	85.8 (1.9)	-2.4 (7)	-0.60 (-1.38 to 0.18), 0.19
	HTN	High HD + PA	DBP	IG2	36	527	86 (1.9)	-3.2 (6.5)	514	85.8 (1.9)	-2.4 (7)	-0.90 (-1.68 to - 0.12), 0.04
	HTN	High HD only	DBP	IG3	36	515	86.1 (1.9)	-3 (6.5)	514	85.8 (1.9)	-2.4 (7)	-0.70 (-1.48 to 0.08), 0.1
	HTN	High HD + PA	SBP	IG1	6	562	127.4 (6.5)	-6.2 (8.6)	538	127.3 (6.4)	, ,	-4.00 (-4.98 to - 3.02), <0.001
	HTN	High HD + PA	SBP	IG2	6	561	127.6 (6.1)	-6 (8.1)	538	127.3 (6.4)	-2.2 (8.1)	-3.70 (-4.68 to - 2.72), <0.001
	HTN	High HD only	SBP	IG3	6	529	127.7 (6.6)	-5.1 (8.6)	538	127.3 (6.4)	-2.2 (8.1)	-2.90 (-3.88 to - 1.92), <0.001
	HTN	High HD + PA	SBP	IG1	18	538	127.4 (6.5)	-3.9 (8.3)	525	127.3 (6.4)	-1.8 (7)	-2.00 (-2.98 to - 1.02), <0.001
	HTN	High HD + PA	SBP	IG2	18	533	127.6 (6.1)	-3.6 (7.9)	525	127.3 (6.4)		-1.80 (-2.78 to - 0.82), <0.001
	HTN	High HD only	SBP	IG3	18	513	127.7 (6.6)	-3.8 (8.2)	525	127.3 (6.4)	-1.8 (7)	-2.00 (-2.98 to - 1.02), <0.001
	HTN	High HD + PA	SBP	IG1	36	537	127.4 (6.5)	-0.5 (9)	514	127.3 (6.4)		-1.10 (-2.08 to - 0.12), 0.05
	HTN	High HD + PA	SBP	IG2	36	527	127.6 (6.1)	-0.8 (8.7)	514	127.3 (6.4)	0.6 (8.5)	-1.30 (-2.28 to - 0.32), 0.01
	HTN	High HD only	SBP	IG3	36	515	127.7 (6.6)	-0.7 (9)	514	127.3 (6.4)	0.6 (8.5)	-1.20 (-2.18 to - 0.22), 0.02
Wadden, 2011 ¹²⁷ (Practice-based	Multiple	High HD + PA	DBP	IG1	6	131	75.9 (11.3)	-0.2 (10.3)	130	76 (10.4)	-0.3 (10.26)	0.10 (-2.39 to 2.59), 0.941
Opportunities for Weight Reduction	Multiple	High HD + PA	DBP	IG1	12	131	75.9 (11.3)	-0.8 (9.16)	130	76 (10.4)	-0.5 (9.12)	-0.30 (-2.52 to 1.92), 0.828
at the University of Pennsylvania	Multiple	High HD + PA	DBP	IG1	24	131	75.9 (11.3)		130	76 (10.4)	0.2	-0.40 (-2.89 to 2.09), 0.974
(POWER-UP)) Good	Multiple	High HD + PA	SBP	IG1	6	131	122.8 (15.6)	0.3 (14.88)	130	120.9 (18.4)	-0.7	1.00 (-2.60 to 4.60), 0.567

### Appendix H Table 5. Blood Pressure, Continuous (KQ2)

, •		Contact time* Intervention focus	Outcome (mm Hg)		Timepoint (months)		, ,	IG mean change (SD)		baseline mean (SD)		Between-group difference,† p-value
	Multiple	High HD + PA	SBP	IG1	12	131		0.8 (14.88)	130	120.9	1.2	-0.40 (-4.00 to 3.20), 0.849
	Multiple	High HD + PA	SBP	IG1	24	131		1.5 (18.31)	130	120.9	1.5 (18.24)	0.00 (-4.43 to 4.43), 0.998
Wister, 2007 ¹²⁹ Good	Multiple	Medium HD + PA	SBP	IG1	12	157	139 (15.2)	-7.49 (15.85)	158	136.1 (14.3)	-3.58 (16.03)	-3.91 (-7.43 to - 0.39), <0.05
Wong, 2015 ¹³⁰ Good	HTN	Low HD only	DBP	IG1	6	254	90.5 (7.1)	-2.7 (15.04)	250	89.9 (6.6)	-1.4 (13.71)	-1.00 (-2.70 to 0.70), 0.24
	HTN	Low HD only	DBP	IG1	12	243	90.5 (7.1)	-2.9 (14.32)	242	89.9 (6.6)	-1.3 (14.29)	-1.10 (-2.90 to 0.60), 0.2
	HTN	Low HD only	SBP	IG1	6	254	145.2 (7.8)	-8.9 (18.3)	250	144.9 (7.3)	-8.3 (17.34)	-0.70 (-3.00 to 1.50), 0.54
	HTN	Low HD only	SBP	IG1	12	243	145.2 (7.8)	-9 (18.29)	242	144.9 (7.3)	-8.7 (17.06)	-0.10 (-2.40 to 2.20), 0.94
Wood, 2008 ¹³¹ (EUROACTION)	Multiple	High HD + PA	DBP	IG1	12	1019	NR (NR)	-4.1 (NR)	332	NR (NR)	-1.6 (NR)	-2.70 (-5.90 to 0.60), 0.09
Fair	Multiple	High HD + PA	SBP	IG1	12	1019	NR (NR)	-7.6 (NR)	332	NR (NR)		-4.80 (-10.20 to 0.60), 0.07

**Abbreviations:** CG = control group; CI = confidence interval; DBP = diastolic blood pressure; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; mm Hg = millimeters of mercury; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SBP = systolic blood pressure; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	(months)	, ,	CG n/N (%)	RR [†] (95% CI), p-value
Appel, 2003 ⁴¹ (PREMIER)	HTN	High	BP at goal	IG1	6	89/253	49/257 (19.1)	1.85 (1.36 to 2.50),
Good		HD + PA	(<120/80 mm Hg)			(35.2)	10/2 (10 1)	<0.001
	HTN	High	BP at goal	IG2	6	75/251	49/257 (19.1)	1.57 (1.14 to 2.15),
		HD + PA	(<120/80 mm Hg)		1.0	(29.9)		<0.005
	HTN	High	BP at goal	IG1	18	62/258	46/257 (17.9)	OR=1.17 (0.84 to 1.63),
	X X (77) X	HD + PA	(<120/80 mm Hg)	7.00	1.0	(24.0)	1.5/2.55 (1.5.0)	NSD
	HTN	High	BP at goal	IG2	18	60/249	46/257 (17.9)	OR=1.25 (0.91 to 1.72),
		HD + PA	(<120/80 mm Hg)		_	(24.1)		NSD
	HTN	High HD + PA	Hypertension incidence	IG1	6	9/156 (5.8)	, ,	0.51 (0.24 to 1.11), 0.12
	HTN	High HD + PA	Hypertension incidence	IG2	6	13/162 (8.0)	18/160 (11.3)	0.71 (0.36 to 1.41), 0.42
	HTN	High	Percent with	IG1	6	30/253	67/257 (26.1)	0.45 (0.31 to 0.67),
	пти	HD + PA	hypertension	IGI	О	(11.9)	07/237 (20.1)	<0.001
	HTN	High	Percent with	IG2	6	43/251	67/257 (26.1)	0.66 (0.47 to 0.92), 0.01
	пти	HD + PA	hypertension	102	О	(17.1)	07/237 (20.1)	0.00 (0.47 to 0.92), 0.01
	HTN	High	Percent with	IG1	18	57/258	82/257 (31.0)	OR=0.77 (0.62 to 0.97),
	1111	HD + PA	hypertension	101	10	(22.1)	02/237 (31.9)	<0.05
	HTN	High	Percent with	IG2	18	60/249	82/257 (31.9)	OR=0.83 (0.67 to 1.04),
		HD + PA	hypertension	102		(24.1)	02/237 (31.7)	NSD
Babazono, 2007 ⁴⁵ (PHPP)	Multiple	Medium	Hypertension	IG1	12	10/46 (21.7)	6/41 (14.6)	1.49 (0.59 to 3.73),
Fair		HD + PA	incidence					NSD
Bennett, 2012 ⁴⁷ (Be Fit, Be	HTN	High	BP at goal	IG1	6	117/180	129/185	OR=1.02 (0.58 to 1.79),
Well [POWER])		HD + PA	(<140/90 mm Hg)			(65.0)	(69.7)	NSD
Good	HTN	High	BP at goal	IG1	12	129/180	120/185	OR=1.39 (0.98 to 1.98),
		HD + PA	(<140/90 mm Hg)			(71.7)	(64.9)	NSD
	HTN	High	BP at goal	IG1	18	121/180	107/185	OR=1.28 (0.90 to 1.82),
		HD + PA	(<140/90 mm Hg)			(67.2)	(57.8)	NSD
	HTN	High	BP at goal	IG1	24	116/180	108/185	OR=1.52 (1.01 to 2.30),
		HD + PA	(<140/90 mm Hg)			(64.4)	(58.4)	< 0.05
Beune, 2014 ⁴⁹ (Culturally	HTN	Medium	BP at goal (SBP	IG1	6	34/71 (47.9)	29/68 (42.6)	OR=0.42 (0.11 to 1.54),
Adapted Hypertension		HD + PA	reduction ≥10 mm					0.19
Education (CAHE))			Hg)					
Fair				<u> </u>	1	1		
Bo, 2007 ⁵²	Multiple	Medium	Percent with	IG1	12	143/169	148/166	OR=0.67 (0.35 to 1.29),
Fair		HD + PA	hypertension			(84.6)	(89.2)	0.23

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	(months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Bosworth, 2009 ⁵³ (Take Control of Your Blood pressure (TCYB)) Fair	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	12	./159 (.)	./159 (.)	Risk difference in change=5.60 (0.90 to 10.20), NSD
	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG2	12	./160 (.)	./159 (.)	Risk difference in change=2.10 (-2.20 to 6.20), NSD
	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	24	./159 (.)	./159 (.)	Risk difference in change=11.00 (1.90 to 19.80), 0.012
	HTN	Medium HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG2	24	./160 (.)	./159 (.)	Risk difference in change=4.30 (-4.50 to 12.90), 0.34
Edelman, 2006 ⁶⁵ Fair	Multiple	High HD + PA	BP at goal (<140/90 mm Hg (<130/80 mm Hg if diabetic))	IG1	10	63/77 (81.8)	53/77 (68.8)	1.19 (0.99 to 1.43), 0.34
Estruch, 2018 ⁶⁷ (Primary Prevention of Cardiovascular	Multiple	High HD only	Percent with hypertension	IG1	60	1938/2032 (95.4)	1899/1990 (95.4)	1.00 (0.99 to 1.01),
Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Percent with hypertension	IG2	60	1833/1934 (94.8)	1899/1990 (95.4)	0.99 (0.98 to 1.01),
Fagerberg, 1998 ⁶⁸ (Risk Factor Intervention Study (RIS))	Multiple	High HD + PA	BP at goal (DBP <90 mm Hg)	IG1	12	188/239 (78.7)	175/238 (73.5)	1.07 (0.97 to 1.18), 0.23
Good (KQ1); Fair (KQ2)	Multiple	High HD + PA	BP at goal (DBP <90 mm Hg)	IG1	40	151/235 (64.3)	140/227 (61.7)	1.04 (0.91 to 1.20), 0.63
HPT, 1990 ⁷⁷ (Hypertension Prevention Trial (HPT))	HTN	High HD only	Hypertension incidence	IG1	36	41/189 (21.7)	65/194 (33.5)	0.65 (0.46 to 0.91),
Good	HTN	High HD only	incidence	IG2	36	46/187 (24.6)	, ,	0.73 (0.53 to 1.01),
	HTN	High HD only	Hypertension incidence	IG3	36	35/124 (28.2)	, , ,	0.84 (0.60 to 1.19),
	HTN	High HD only	Hypertension incidence	IG4	36	39/125 (31.2)	65/194 (33.5)	0.93 (0.67 to 1.29),

## Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	, ,		RR [†] (95% CI), p-value
Jones, 1999 ⁸² (Hypertension	HTN	High	BP at goal (DBP	IG1	6	44/51 (86.3)	44/51 (86.3)	1.00 (0.86 to 1.17), NSD
Optimal Treatment (HOT)) Fair	HTN	HD only High	80-90 mm Hg) BP at goal (DBP	IG1	12	44/51 (86.3)	42/51 (92.4)	1.05 (0.89 to 1.24),
ran	пти	HD only	80-90 mm Hg)	IGI	12	44/31 (60.3)	42/31 (82.4)	NSD
	HTN	High	BP at goal (DBP	IG1	18	41/51 (80.4)	30/51 (76.5)	1.05 (0.86 to 1.29),
	11111	HD only	80-90 mm Hg)	101	10	71/31 (60.4)	37/31 (70.3)	NSD
	HTN	High	BP at goal (DBP	IG1	24	38/51 (74.5)	41/51 (80.4)	0.93 (0.75 to 1.14),
	11111	HD only	80-90 mm Hg)	101	2-7	30/31 (74.3)	71/31 (00.4)	NSD
	HTN	High	BP at goal (DBP	IG1	30	37/51 (72.5)	36/51 (70.6)	1.03 (0.80 to 1.31),
		HD only	80-90 mm Hg)				, ,	NSD
Khanji, 2019 ⁸⁷ (HAPPY	Multiple	Low	DBP at Goal (<90	IG1	6	178/194	164/184	1.03 (0.96 to 1.10), 0.39
London)		HD + PA	mm Hg)			(91.8)	(89.1)	
Good	Multiple	Low	SBP at Goal (<140	IG1	6	158/194	142/184	1.06 (0.95 to 1.17), 0.31
		HD + PA	mm Hg)			(81.4)	(77.2)	
Langford, 1991 ⁹¹ (Trial of	HTN	High	BP at goal (DBP	IG1	6	228/265	220/264	1.03 (0.96 to 1.11),
Antihypertensive Interventions		HD + PA	<90 mm Hg)			(86.0)	(83.3)	
and Management (TAIM))	HTN	High	BP at goal (DBP	IG2	6	207/258	220/264	0.96 (0.89 to 1.04),
Fair		HD only	<90 mm Hg)			(80.2)	(83.3)	
Migneault, 2012 ⁹⁴	HTN	High	BP at goal	IG1	8	./169 (.)	./168 (.)	Risk difference in
Fair		HD + PA	(<140/90 mm Hg					change=0.80 (NR),
			(<130/80 mm Hg if					NSD
			diabetic))					
	HTN	High	BP at goal (DBP	IG1	8	./169 (.)	./168 (.)	Risk difference in
		HD + PA	<90 mm Hg (<80					change=1.30 (NR),
	T TOTAL	XX' 1	mm Hg if diabetic)		0	(1.60.()	(1.60.()	NSD Did 1966
	HTN	High	BP at goal (SBP	IG1	8	./169 (.)	./168 (.)	Risk difference in
		HD + PA	<140 mm Hg					change=-1.20 (NR),
			(<130 mm Hg if diabetic))					NSD
Muhlhauser, 1993 ⁹⁷	HTN	Medium	Percent with	IG1	18	73/86 (84.9)	61/71 (96.5)	0.97 (0.81 to 1.16),
(Hypertension Treatment and	пти	HD + PA	hypertension	IGI	10	73/80 (84.9)	04/ /4 (80.3)	0.97 (0.81 to 1.16), NSD
Teaching Program (HTTP))		IID + FA	hypertension					NSD
Fair								
Niiranen, 2014 ¹⁰⁰	HTN	Medium	BP at goal	IG1	12	59/112	65/108 (60.2)	0.85 (0.47 to 1.52), 0.26
Fair		HD + PA	(<140/85 mm Hg)			(52.7)		

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	BP outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Ogedegbe, 2014 ¹⁰² (Counseling	HTN	Medium	BP at goal	IG1	12	261/529	227/510	OR=1.21 (0.90 to 1.63),
African Americans to Control		HD + PA	(<140/90 mm Hg			(49.3)	(44.5)	0.21
Hypertension (CAATCH))			(<130/80 mm Hg					
Fair Rodriguez, 2012 ¹⁰⁴	HTN	Medium	for DM or CKD))	IG1		114/176	01/177 (45.0)	1.40 (1.17.4. 1.70)
Fair	HIN	Medium HD + PA	BP at goal (<140/90 mm Hg	IGI	6	(64.8)	81/1// (45.8)	1.42 (1.17 to 1.72), 0.001
rair		пр + РА	(<130/80 mm Hg			(04.8)		0.001
			for DM or CKD))					
Schoenthaler, 2016 ¹⁰⁹	HTN	High	BP at goal	IG1	6	36/97 (37.1)	42/97 (43.3)	0.86 (0.61 to 1.21),
(Individual Motivational		HD + PA	(<140/90 mm Hg					0.437
Interviewing - Therapeutic			(<130/80 mm Hg					
Lifestyle Changes (MINT-			for DM or CKD))					
TLC))								
Fair								
TOHP I CRG, 1992 ¹¹⁹ (Trials of	HTN	High	Hypertension	IG1	18	28/327 (8.6)	47/417 (11.3)	0.84 (0.62 to 1.13),
Hypertension Prevention Phase		HD only	incidence					NSD
I (TOHP I))	HTN	High	Hypertension	IG2	18	20/308 (6.5)	34/256 (13.3)	0.66 (0.46 to 0.94),
Good	Y Y Y Y	HD + PA	incidence	701		1.5/505./2.5	10 (500 (500)	<0.05
TOHP II CRG, 1997 ¹²⁰ (Trial of	HTN	High	Hypertension	IG1	6	16/597 (2.7)	43/592 (7.3)	0.37 (NR), <0.001
Hypertension Prevention II (TOHP II))		HD + PA	incidence					
Good	HTN	High	Hypertension	IG2	6	25/595 (4.2)	43/592 (7.3)	0.58 (0.36 to 0.94), 0.02
Good		HD + PA	incidence				(,,,,,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	HTN	High	Hypertension	IG3	6	26/576 (4.5)	43/592 (7.3)	0.61 (NR), 0.04
		HD only	incidence			, , ,		, , , , ,
	HTN	High	Hypertension	IG1	18	88/589	124/588	0.71 (NR), 0.006
		HD + PA	incidence			(14.9)	(21.1)	
	HTN	High	Hypertension	IG2	18	97/584		0.78 (0.62 to 1.00), 0.05
		HD + PA	incidence			(16.6)	(21.1)	
	HTN	High	Hypertension	IG3	18	108/581	124/588	0.88 (NR), 0.28
		HD only	incidence			(18.6)	(21.1)	
	HTN	High	Hypertension	IG1	36	191/582	229/584	0.84 (NR), 0.02
	T TOO I	HD + PA	incidence	TCO	26	(32.8)	(39.2)	0.01 (0.70 ( 0.05)
	HTN	High	Hypertension	IG2	36	185/580		0.81 (0.70 to 0.95),
	HTN	HD + PA	incidence	IG3	36	(31.9) 198/575	(39.2) 229/584	0.009 0.88 (NR), 0.09
	HIN	High HD only	Hypertension incidence	103	90	(34.4)	(39.2)	0.88 (NK), 0.09
		ину ошу	ристаенсе			(34.4)	(37.4)	

### Appendix H Table 6. Blood Pressure, Dichotomous (KQ2)

Author, year (Study name)	Population	Contact time*	BP outcome	Int	Timepoint	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Quality	risk focus	Intervention		arm	(months)			
		focus						
	HTN	High	Hypertension	IG1	48	213/566	248/558	0.85 (NR), 0.02
		HD + PA	incidence			(37.6)	(44.4)	
	HTN	High	Hypertension	IG2	48	211/548	248/558	0.87 (NR), 0.06
		HD + PA	incidence			(38.5)	(44.4)	
	HTN	High	Hypertension	IG3	48	211/554	248/558	0.86 (NR), 0.04
		HD only	incidence			(38.1)	(44.4)	
Wood, 2008 ¹³¹	Multiple	High	BP at goal	IG1	12	586/1016	407/1004	Difference in
(EUROACTION)		HD + PA	(<140/90 mm Hg			(57.7)	(40.5)	probability=16.90 (2.00
Fair			(<135/85 mm Hg if					to 31.80), 0.03
			diabetic))					

**Abbreviations:** BP = blood pressure; CG = control group; CI = confidence interval; Dys = dyslipidemia; DM = diabetes mellitus; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio; PREDIMED = Primary Prevention of Cardiovascular Disease with a Mediterranean Diet; RR = risk ratio; TONE = Trial of Nonpharmacologic Interventions in the Elderly

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

Author, year (Study name) Quality	Population risk focus	time* Intervention focus	(mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)		Between-group difference,† p- value
Ammerman, 2003 ³⁸	Dys	Medium HD only	HDL-C	IG1	6	154	45 (12.93)	-0.3 (NR)	189	43 (12.86)	1 (NR)	NR, NSD
Fair	Dys	Medium HD only	HDL-C	IG1	12	153	45 (12.93)	1.8 (7.57)	196	43 (12.86)	1.6 (7.14)	0.20 (-1.36 to 1.76), NSD
	Dys	Medium HD only	LDL-C	IG1	6	154	181 (33.8)	-16 (33.35)	189	179 (33.34)	-16.6 (33.67)	0.50 (-7.60 to 8.70), NSD
	Dys	Medium HD only	LDL-C	IG1	12	153	181 (33.8)	-19.6 (38.45)	196	179 (33.34)	-16.7 (38.93)	-2.80 (-12.10 to 6.40), 0.5
	Dys	Medium HD only	TC	IG1	6	154	258 (45.56)	-15.4 (41.2)	189	256 (46.04)	-16.3 (42.34)	0.90 (-8.90 to 10.60), NSD
	Dys	Medium HD only	TC	IG1	12	153	258 (45.56)	-18.4 (43.91)	196	256 (46.04)	-15.6 (45.22)	-2.80 (-13.70 to 7.50), 0.6
Anderson, 1992 ³⁹ Fair	Dys	High HD only	HDL-C	IG1	12	48	49.03 (13.37)	-1.54 (5.35)	51	46.33 (11.03)		-1.93 (-4.07 to 0.21), NSD
	Dys	High HD only	HDL-C	IG2	12	47	50.97 (10.59)	0.39 (5.29)	51	46.33 (11.03)	0.39 (5.51)	0.00 (-2.14 to 2.14), NSD
	Dys	High HD only	LDL-C	IG1	12	48	161.78 (21.4)	-28.96 (21.4)	51	154.44 (19.3)	-15.44 (16.54)	-13.51 (-21.08 to -5.95), <0.002
	Dys	High HD only	LDL-C	IG2	12	47	159.46 (21.18)	-21.62 (21.18)	51	154.44 (19.3)	-15.44 (16.54)	-6.18 (-13.75 to 1.39), NSD
	Dys	High HD only	TC	IG1	12	48	235.13 (21.4)	-30.5 (24.07)	51	228.57 (19.3)	-16.22 (22.06)	-14.29 (-23.40 to -5.17), <0.01
	Dys	High HD only	TC	IG2	12	47	235.13 (18.53)	-22.78 (23.82)	51	228.57 (19.3)	-16.22 (22.06)	-6.56 (-15.68 to 2.55), NSD
Anderssen, 1995 ⁴⁰ (Oslo Diet and	Multiple	Medium HD only	HDL-C	IG1	12	52	39 (8.49)	1.93 (4.44)	43	40.15 (7.72)	0.58 (3.78)	1.35 (-0.30 to 3.01), NSD
Exercise Study (ODES))	Multiple	Medium HD only	LDL-C	IG1	12	52	164.86 (33.59)	-6.95 (27.8)	43	176.45 (32.82)	-8.49 (22.78)	1.54 (-8.63 to 11.72), NSD
Fair	Multiple	Medium HD only	TC	IG1	12	52	245.95 (36.29)	-8.88 (25.1)	43	254.05 (32.82)	-6.18 (22.78)	-2.70 (-12.34 to 6.94), NSD
Appel, 2011 ⁴² (POWER Hopkins	Multiple	High HD + PA	HDL-C	IG1	6	117	51.2 (14.05)	0.4 (6.49)	100	50.5 (11.66)	-0.3 (5)	0.70 (-0.80 to 2.20), 0.35
(Practice Based Opportunities for	Multiple	High HD + PA	HDL-C	IG2	6	121	53.5 (12.97)	1 (6.6)	100	50.5 (11.66)	-0.3 (5)	1.30 (-0.10 to 2.80), 0.07

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)		Between-group difference,† p- value
Weight Reduction))	Multiple	High HD + PA	HDL-C	IG1	24	105	51.2 (14.05)	3.5 (8.2)	93	50.5 (11.66)	1.8 (6.75)	1.70 (-0.40 to 3.70), 0.11
Good	Multiple	High HD + PA	HDL-C	IG2	24	110	53.5 (12.97)	2.2 (8.39)	93	50.5 (11.66)	1.8 (6.75)	0.30 (-1.70 to 2.30), 0.74
	Multiple	High HD + PA	LDL-C	IG1	6	117	106 (31.6)	-4.9 (18.39)	100	109.5 (32.65)	-4.7 (21)	-0.20 (-5.50 to 5.10), 0.93
	Multiple	High HD + PA	LDL-C	IG2	6	120	107.4 (30.65)	-3.2 (23)	100	109.5 (32.65)	-4.7 (21)	1.50 (-4.40 to 7.40), 0.62
	Multiple	High HD + PA	LDL-C	IG1	24	105	106 (31.6)	0.3 (25.62)	93	109.5 (32.65)	-5.4 (22.18)	5.70 (-1.00 to 12.40), 0.097
	Multiple	High HD + PA	LDL-C	IG2	24	110	107.4 (30.65)	-4.5 (31.46)	93	109.5 (32.65)		0.90 (-6.60 to 8.30), 0.82
	Multiple	High HD + PA	TC	IG1	6	117	181.7 (35.11)	-6.4 (22.71)	100	187.3 (36.28)	-4.1 (24)	-2.30 (-8.50 to 3.80), 0.46
	Multiple	High HD + PA	TC	IG2	6	121	187.1 (36.55)	-6 (26.4)	100	187.3 (36.28)	-4.1 (24)	-1.90 (-8.50 to 4.80), 0.58
	Multiple	High HD + PA	TC	IG1	24	105	181.7 (35.11)	2.3 (28.69)	93	187.3 (36.15)	-5.4 (24.11)	7.80 (0.40 to 15.20), 0.039
	Multiple	High HD + PA	TC	IG2	24	110	187.1 (36.55)	-4.6 (35.66)	93	187.3 (36.15)		0.80 (-7.50 to 9.10), 0.85
Babazono, 2007 ⁴⁵ (PHPP)	Multiple	Medium HD + PA	HDL-C	IG1	12	46	54.5 (13.4)	2.2 (7.6)	41	55.7 (12.9)	0.8 (8.23)	1.40 (-1.94 to 4.74), NSD
Fair	Multiple	Medium HD + PA	LDL-C	IG1	12	46	121 (29.2)	-1.4 (23.95)	41	123.8 (28.2)	0.1 (22.97)	-1.50 (-11.37 to 8.37), NSD
	Multiple	Medium HD + PA	TC	IG1	12	46	204.3 (31.8)	-2.4 (26.78)	41	207 (30.2)	2.6 (26.26)	-5.00 (-16.16 to 6.16), NSD
Beckmann, 1995 ⁴⁶ Fair	HTN	Medium HD only	HDL-C	IG1	12	32	49.81 (21.84)	-2.7 (11.96)	32	48.26 (21.84)	0.77 (11.96)	-3.47 (-9.34 to 2.39), NSD
	HTN	Medium HD only	TC	IG1	12	32	242.47 (43.68)	-14.67 (36.55)	32	236.29 (21.84)	-6.18 (18.27)	-8.49 (-22.65 to 5.66), NSD
Bennett, 2018 ⁴⁸ (Track)	Multiple	Medium HD + PA	HDL-C	IG1	12	133	44.7 (14.1)	` /	148	43.6 (13.8)	-0.3	3.50 (1.10 to 5.90), 0.005
Good	Multiple	Medium HD + PA	LDL-C	IG1	12	119	109.8 (31.7)	-5 (37.57)	133	111.7 (34.1)	-1.8 (37.95)	-3.20 (-10.50 to 4.10), 0.39

Author, year (Study name) Quality			Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)	change	Between-group difference,† p- value
		Medium HD + PA	TC	IG1	12	136	185.9 (35)	-3.5 (41.65)	149	188.6 (40.9)	(41.42)	3.10 (-4.70 to 10.90), 0.44
Blackford, 2016 ⁵⁰ (Albany		Medium HD + PA	HDL-C	IG1	6	130	56.37 (16.22)	-0.39 (8.64)	144	56.37 (16.22)		0.39 (-1.66 to 2.43), 0.93
Physical Activity and Nutrition		Medium HD + PA	LDL-C	IG1	6	130	132.05 (31.27)	-3.09 (28.85)	144	128.19 (35.91)	0.77 (29.58)	-3.86 (-10.78 to 3.06), 0.13
(APAN)) Fair		HD + PA		IG1	6	130	214.67 (37.45)	-3.47 (32.19)		208.49 (42.47)	1.93 (34.49)	-5.41 (-13.30 to 2.49), 0.02
Bloemberg, 1991 ⁵¹ Fair	•	HD only		IG1	6	39	45.95 (9.27)	-0.77 (7.72)		, ,	0.39 (6.18)	-1.16 (-4.23 to 1.92), 0.27
	,	HD only		IG1	6	39	270.66 (39.77)	(32.82)		269.88 (45.17)		-11.58 (-25.48 to 2.32), <0.05
Bo, 2007 ⁵² Fair		HD + PA		IG1	12	169	, , ,	, ,		57.92 (11.58)	(6.18)	3.47 (2.23 to 4.72), <0.001
	1	Medium HD + PA	HDL-C	IG1	108	148	54.05 (11.58)	-3.86 (6.34)	138	54.05 (11.58)		0.77 (-0.69 to 2.23), 0.56
		Medium HD + PA	TC	IG1	12	169	223.94 (42.47)	-0.02 (33.2)	166	231.66 (42.47)	2.32 (34.36)	-2.34 (-9.58 to 4.90), 0.55
		Medium HD + PA	TC	IG1	108	148	223.94 (42.47)	0 (35.86)	138	231.66 (42.47)		3.09 (-4.98 to 11.16), 0.34
Broekhuizen, 2012 ⁵⁴ (PRO-FIT)		Medium HD + PA	HDL-C	IG1	12	169	46.33 (15.44)	0 (8.46)	143	46.33 (15.44)	0 (8.46)	0.00 (-1.88 to 1.88), NSD
Fair	-	HD + PA		IG1	12	128	139 (50.19)	-3.86 (39.39)	105	142.86 (46.33)	-3.86 (38.76)	0.00 (-10.08 to 10.08), NSD
	,	HD + PA		IG1	12	169	204.63 (54.05)	-3.86 (42.58)		200.77 (46.33)		0.00 (-8.99 to 8.99), NSD
Bruckert, 2008 ⁵⁵ (PEGASE (Effect		HD + PA		IG1	6	274	NR (NR)	0.87 (NR)	199	NR (NR)	0.38 (NR)	NR, NSD
of an Education Program))		HD + PA		IG1	6	274	NR (NR)	2 (NR)	199	NR (NR)	, ,	-8.00 (NR), 0.032
Fair	-	Medium HD + PA	TC	IG1	6	274	NR (NR)	-7.64 (NR)	199	NR (NR)	-3.4 (NR)	NR, NSD
		Medium HD + PA	HDL-C	IG1	16	123	52.12 (11.97)	1.93 (4.25)	118	51.35 (11.58)		1.16 (0.09 to 2.23), NSD

# Appendix H Table 7. Lipids, Continuous (KQ2)

Author, year (Study name) Quality			Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)	change (SD)	Between-group difference,† p- value
Burke, 2006 ⁵⁶ (ADAPT)		Medium HD + PA	HDL-C	IG1	40	123	52.12 (11.97)	-1.16 (6.96)	118	51.35 (11.58)		0.39 (-2.32 to 3.09), 0.803
Fair		Medium HD + PA	LDL-C	IG1	16	123	NR (NR)	-4.63 (8.88)	118	NR (NR)		-5.02 (-7.80 to - 2.24), <0.05
		Medium HD + PA	TC	IG1	16	123	196.91 (43.63)	-5.41 (13.13)	118	200.77 (32.05)	-2.7 (12.74)	-2.70 (-5.97 to 0.56), NSD
		HD + PA		IG1	40	123	196.91 (43.63)	0 (33.45)	118	200.77 (32.05)	3.86 (26.81)	-7.72 (-15.44 to 3.86), 0.04
Chirinos, 2016 ⁵⁷ (Community Health and Risk-		High HD + PA	HDL-C	IG1	6	60	37.77 (7.39)	1.53 (NR)	60	40.98 (10.19)	1.08 (NR)	NR, NSD
reduction for Metabolic Syndrome (CHARMS)) Fair		High HD + PA	HDL-C	IG1	12	60	37.77 (7.39)	2.04 (NR)	60	40.98 (10.19)	0.45 (NR)	NR, NSD
Christian, 2011 ⁵⁸ Fair	1	Medium HD + PA	HDL-C	IG1	12	133	45.3 (13.85)	0.32 (9.54)	130	43.9 (12.93)		0.24 (-7.32 to 7.80), 0.43
	1	Medium HD + PA	LDL-C	IG1	12	133	125.3 (40.75)	-8.8 (34.23)	130	129.2 (40.99)		-6.00 (-30.02 to 18.02), 0.08
	1	Medium HD + PA	TC	IG1	12	133	203.9 (45.67)	-8.9 (40.45)	130	207.9 (49.81)		-6.30 (-34.17 to 21.57), 0.11
Cicolini, 2014 ⁵⁹ Fair		HD + PA		IG1	6	100	144 (67)	-36.9 (44.2)		134 (60)	-26.8 (39.6)	-10.10 (-21.78 to 1.58), <0.001
		Medium HD + PA		IG1	6	100	265 (64)	, ,		251 (59)	(38.1)	-26.60 (-37.02 to -16.18), <0.001
Cochrane, 2012 ⁶⁰ Fair	1	HD + PA		IG1	12	236	46.33 (11.58)	, ,		46.33 (11.58)	(5.79)	0.00 (-0.99 to 0.99), NSD
	1	Medium HD + PA		IG1	12	236	220.08 (34.75)	-21.62 (36.29)		220.08 (34.75)		-0.77 (-6.69 to 5.14), NSD
Coleman, 2012 ⁶² (Wisewoman	1	Medium HD + PA		IG1	12	433	45.1 (12.45)	2.6 (NR)	436	44.9 (13.72)	2 (NR)	NR, 0.285
California) Fair	1	Medium HD + PA	TC	IG1	12	433	198.2 (36.18)	1.9 (NR)	436	197.8 (37.68)	1.1 (NR)	NR, 0.906

(Study name) Quality	Population risk focus	time* Intervention focus	(mg/dL)		Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)			change	Between-group difference,† p- value
Delahanty, 2001 ⁶³ Good	Dys	Medium HD + PA	HDL-C	IG1	6	44	47.1 (16.22)	-3 (8.55)	44	44.02 (11.97)		-1.18 (-4.36 to 2.00), NSD
	Dys	Medium HD + PA	HDL-C	IG1	6	44	47.1 (16.22)	-3.09 (8.54)	44	44.02 (11.97)		-1.16 (-4.34 to 2.02), NSD
	Dys	Medium HD + PA	HDL-C	IG1	12	43	47.1 (16.22)	3.09 (9.59)	44	44.02 (11.97)	3.08	0.01 (-3.85 to 3.87), NSD
	Dys		HDL-C	IG1	12	43	47.1 (16.22)	3.09 (9.59)	44	44.02 (11.97)	3.09	0.00 (-3.86 to 3.86), NSD
	Dys	Medium HD + PA	LDL-C	IG1	6	44	165.64 (23.17)	-11.64 (18.68)	44	163.71 (26.25)	-3.91	-7.73 (-16.01 to 0.55), NSD
	Dys	Medium HD + PA	LDL-C	IG1	6	44	165.64 (23.17)	-11.97 (18.66)	44	163.71 (26.25)	-4.25 (20.86)	-7.72 (-15.99 to 0.55), NSD
	Dys	Medium HD + PA	LDL-C	IG1	12	43	165.64 (23.17)	-11.2 (18.93)	44	163.71 (26.25)	-13.13 (21.96)	1.93 (-6.68 to 10.54), NSD
	Dys	Medium HD + PA	LDL-C	IG1	12	43	165.64 (23.17)	-11.2 (18.93)	44	163.71 (26.25)	-13.13 (21.97)	1.93 (-6.68 to 10.54), NSD
	Dys		TC	IG1	6	44	239 (28.19)	-16.22 (21.96)	44	237.84 (28.96)	-5.02 (22.88)	-11.20 (-20.57 to -1.83), <0.05
	Dys		TC	IG1	6	44	239 (28.19)	-15.7 (21.97)	44	237.84 (28.96)	-4.44 (22.91)	-11.26 (-20.64 to -1.88), <0.05
	Dys		TC	IG1	12	43	239 (28.19)	-8.11 (23.12)	44	237.84 (28.96)	-10.04	1.93 (-7.95 to 11.81), NSD
	Dys	Medium HD + PA	TC	IG1	12	43	239 (28.19)	-8.11 (23.12)	44	237.84 (28.96)	-10.04	1.93 (-7.96 to 11.82), NSD
Edelman, 2006 ⁶⁵ Fair	Multiple	High HD + PA	LDL-C	IG1	10	77	132.4 (35.1)	-11.3 (NR)	77	137.1 (35.6)	-4 (NR)	NR, 0.25
Ellsworth, 2016 ⁶⁶ Fair	Multiple	High HD + PA	HDL-C	IG1	12	89	47.8 (12.3)	0.2 (NR)	58	50.2 (14.5)	-2.3 (NR)	NR, 0.102
	Multiple		LDL-C	IG1	12	89	111 (31)	-3.8 (NR)	58	116 (30)	-4.8 (NR)	NR, 0.761
	Multiple	High HD + PA	TC	IG1	12	89	185 (39)	-3.6 (NR)	58	192 (36)	-4.3 (NR)	NR, 0.921
Estruch, 2018 ⁶⁷ (Primary	Multiple	High HD only	HDL-C	IG1	12	78	52.2 (12.17)	0.48 (5.23)	75	53.4 (13.26)		0.08 (-1.43 to 1.59), NSD

		Contact time* Intervention focus	(mg/dL)	Int arm	Timepoint (months)	IG N		IG mean change (SD)			change	Between-group difference,† p- value
Prevention of Cardiovascular	Multiple	High HD only	HDL-C	IG2	12	82	53.7 (12.47)	0.36 (4.11)	75	53.4 (13.26)	0.4 (4.24)	-0.04 (-1.35 to 1.27), NSD
Disease with a Mediterranean	Multiple	High HD only	LDL-C	IG1	12	78	138.2 (35.82)	-6.5 (22.3)	75	129.9 (32.48)	(20.55)	-0.70 (-7.49 to 6.09), NSD
Diet (PREDIMED))	Multiple	High HD only	LDL-C		12	82	135.7 (33.26)	-11.3 (21.48)	75	129.9 (32.48)	-5.8 (20.55)	-5.50 (-12.08 to 1.08), NSD
Fair	Multiple	HD only	TC		12	78	223.4 (50.47)	-11.3 (25.01)		208.1 (37.56)	(23.2)	-6.70 (-14.34 to 0.94), NSD
	Multiple	High HD only	TC	IG2	12	82	214.7 (38.35)	-13.6 (21.48)		208.1 (37.56)	(23.2)	-9.00 (-16.01 to - 1.99), <0.05
Fagerberg, 1998 ⁶⁸ (Risk Factor	1	HD + PA	HDL-C		12	239	50.19 (15.44)	-2.32 (10.42)		46.33 (15.44)	(11.58)	0.77 (-1.16 to 2.70), 0.43
Intervention Study (RIS))		HD + PA	HDL-C		40	235	50.19 (15.44)	-1.93 (11.58)		46.33 (15.44)	(11.2)	MD=1.16 (-1.16 to 3.09), 0.3
Good (KQ1); Fair (KQ2)	1	HD + PA	HDL-C		79	248	50.19 (15.44)	-2.32 (9.27)			(9.27)	0.77 (-0.74 to 2.29),
	Multiple	High HD + PA	LDL-C		12	239	177.61 (38.61)	-11.58 (30.89)		(42.47)	-3.86 (30.89)	-11.58 (-17.64 to -5.53), 0.000
	Multiple	High HD + PA	LDL-C	IG1	40	235	177.61 (38.61)	-27.8 (40.15)	227			MD=-14.67 (- 21.24 to -7.72), 0.0001
	Multiple	High HD + PA	LDL-C	IG1	79	248	177.61 (38.61)	-27.03 (30.89)	252	173.74 (42.47)	-7.72 (31.27)	-15.44 (-21.50 to -9.39),
	Multiple	HD + PA	TC		12	239	258.69 (46.33)	-19.31 (38.61)		(46.33)	-3.86 (27.03)	-15.44 (-21.50 to -9.39), 0.000
	Multiple	High HD + PA	ТС	IG1	40	235	258.69 (46.33)	-30.12 (43.24)	227		-15.06 (35.52)	MD=-15.06 (- 22.39 to -7.72), 0.0001
	Multiple	High HD + PA	TC	IG1	79	248	258.69 (46.33)	-27.03 (30.89)			-7.72 (31.27)	-19.31 (-25.36 to -13.25),
Gill, 2019 ⁶⁹ (Heartmatters		HD + PA	HDL-C	IG1	6	96	, , ,	NR (NR)		42.72 (10.37)		2.40 (0.05 to 4.75), 0.08
Challenge - First	Multiple	High HD + PA	HDL-C	IG1	12	96	45.58 (12.13)	NR (NR)	79	42.72 (10.37)	NR (NR)	1.47 (-0.61 to 3.55), 0.20

	Population risk focus	Contact time* Intervention focus	(mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)		Between-group difference,† p- value
Responders) Fair	Multiple	High HD + PA	LDL-C	IG1	6	96	130.64 (30.55)	NR (NR)	79	135.1 (31.87)	NR (NR)	-5.61 (-14.88 to 3.66), 0.28
ran	Multiple	High HD + PA	LDL-C	IG1	12	96	130.64 (30.55)	NR (NR)	79	135.1 (31.87)	NR (NR)	-3.39 (-10.90 to 4.12), 0.40
	Multiple	High HD + PA	TC	IG1	6	96	197.09 (36.23)	NR (NR)	79	202.17 (35.11)	` ′	-6.85 (-14.91 to 1.21), 0.14
	Multiple	High HD + PA	TC	IG1	12	96	197.09 (36.23)	NR (NR)		(35.11)		-4.16 (-11.75 to 3.43), 0.32
Greaves, 2015 ⁷¹ (Waste the Waist)	Multiple	High HD + PA	HDL-C	IG1	12	55	52.51 (13.13)	, ,		53.67 (15.06)		-0.39 (-3.09 to 2.32), NSD
Fair	Multiple	High HD + PA	LDL-C	IG1	12	55	123.17 (36.68)	NR (NR)		(38.22)	, ,	5.79 (-3.09 to 14.29), NSD
	Multiple	High HD + PA	TC	IG1	12	55	204.25 (40.54)	NR (NR)		(49.03)		3.47 (-6.56 to 13.51), NSD
Groeneveld, 2010 ⁷² (Health	Multiple	Medium HD + PA	HDL-C	IG1	6	256	43.63 (7.72)	3.09 (4.88)			2.7 (5.09)	0.39 (-0.48 to 1.25), NSD
Under Construction) Fair	Multiple	Medium HD + PA	HDL-C	IG1	12	256	43.63 (7.72)	2.7 (5.11)	257	` /	1.93 (5.31)	0.77 (-0.13 to 1.67), NSD
Hardcastle, 2008 ⁷³ Fair	Multiple	Medium HD + PA	HDL-C	IG1	6	203	56.37 (14.67)	-1.93 (8.15)	131	58.69 (16.6)	-1.93 (9.09)	0.00 (-1.92 to 1.92), NSD
	Multiple	HD + PA	HDL-C	IG1	18	203	56.37 (14.67)	-5.02 (7.8)	131	58.69 (16.6)	-5.02 (8.91)	0.00 (-1.87 to 1.87), NSD
	Multiple	Medium HD + PA	LDL-C	IG1	6	203	114.29 (44.02)	3.86 (34.8)	131	116.22 (41.7)	10.04 (33.33)	-6.18 (-13.63 to 1.27), NSD
	Multiple	Medium HD + PA	LDL-C	IG1	18	203	114.29 (44.02)	12.36 (35.51)	131	116.22 (41.7)	18.15 (32.99)	-5.79 (-13.26 to 1.68), NSD
	Multiple	HD + PA	TC	IG1	6	203	212.74 (39)	-5.41 (33.3)	131	208.11 (35.91)	-0.77 (31.85)	-4.63 (-11.76 to 2.49), NSD
	Multiple	Medium HD + PA	TC	IG1	18	203	212.74 (39)	-5.79 (32.96)	131	208.11 (35.91)	5.02 (31.85)	-10.81 (-17.90 to -3.72), <0.01
Harris, 2012 ⁷⁴ (Health	Multiple	High HD + PA	HDL-C	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.7
Improvement and Prevention Study	Multiple	High HD + PA	LDL-C	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.6

			Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)	change	Between-group difference,† p- value
(HIPS)) Fair												
Haufe, 2019 ⁷⁵ Fair	1	Medium HD + PA	HDL-C	IG1	6	160	45.1 (10)	0.2 (5.33)	154	44.1 (9.2)		0.80 (-1.90 to 0.30), 0.13
Hyman, 1998 ⁷⁸ Fair	Dys	Medium HD only	TC	IG1	6	65	273.2 (40.3)	-8.2 (33)	58	272.4 (42.3)	-4.8 (36.5)	-3.40 (-15.75 to 8.95), 0.58
Hyman, 2007 ⁷⁹ Fair		Medium HD + PA	TC	IG1	6	92	194.9 (36.5)	-2.3 (34.24)	93	192.8 (46.7)	1.3 (37.32)	-3.60 (-13.92 to 6.72), NSD
	I .	Medium HD + PA	TC	IG2	6	96	200.4 (34.5)	-7.3 (30.6)	93	192.8 (46.7)	1.3 (37.32)	-8.60 (-18.35 to 1.15), NSD
	HTN	Medium HD + PA	TC	IG1	18	92	194.9 (36.5)	0.6 (32.26)	93	192.8 (46.7)		4.80 (-5.27 to 14.87), NSD
	HTN	Medium HD + PA	TC	IG2	18	96	200.4 (34.5)	-13.4 (30.24)	93	192.8 (46.7)	-4.2	-9.20 (-18.93 to 0.53), <0.05
Ives, 1993 ⁸⁰ (Rural Health Promotion		Medium HD + PA	TC	IG1	30	332	267.8 (NR)		258	264.7 (NR)		NR,
Project (RHPP) Trial) Fair	Dys	Medium HD + PA	ТС	IG2	30	311	267.8 (NR)	-17.7 (NR)	258	264.7 (NR)		NR,
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	1	High HD + PA	тс	IG1	6	31	185 (32)	-0.4 (20.13)	32	185 (32)	3.5 (20.18)	-3.90 (-13.88 to 6.12), NSD
Kastarinen, 2002 ⁸⁵ (Lifestyle		High HD + PA	HDL-C	IG1	12	360	50.97 (12.74)	0.77 (NR)	355	52.51 (14.67)		MD=0.39 (-0.39 to 1.54), NSD
Intervention against		High HD + PA	HDL-C	IG1	24	360	50.97 (12.74)	3.86 (NR)	355	52.51 (14.67)		1.16 (0.00 to 2.70), NSD
Hypertension in Eastern Finland	HTN		LDL-C	IG1	12	360	140.54 (31.27)	-2.32 (NR)	355	137.45 (30.5)	-0.39	MD=-1.93 (-4.63 to 1.16), NSD
(LIHEF)) Fair	HTN		LDL-C	IG1	24	360	140.54 (31.27)	-4.25 (NR)	355	137.45 (30.5)	1.54 (NR)	-5.79 (-8.88 to - 1.93), <0.05
	HTN	High HD + PA	TC	IG1	12	360	218.53 (35.14)	-1.93 (NR)		215.83 (35.91)	-1.16	MD=-0.77 (-4.25 to 2.32), NSD

			(mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		mean (SD)	change	Between-group difference,† p- value
		High HD + PA	ТС	IG1	24	360	218.53 (35.14)	-1.16 (NR)	355	215.83 (35.91)		-4.25 (-7.72 to -
Keyserling, 1997 ⁸⁶ (Southeast	Dys		LDL-C	IG1	7	135	182.3 (NR)	-12.4 (26.49)	145	178.6 (NR)	-7.4 (26.61)	0.39), <0.05 -5.00 (-11.37 to 1.37), NSD
Cholesterol Project)	Dys	Medium HD only		IG1	12	153	182.3 (NR)	-9.2 (26.97)		178.6 (NR)	-7.5 (27.15)	-1.70 (-7.84 to 4.44), NSD
Fair	,	HD only		IG1	7	143	256.6 (NR)	-12.6 (26.55)		252.7 (NR)	-7.6 (26.45)	-5.00 (-11.26 to 1.26), NSD
	,	Medium HD only		IG1	12	165	256.6 (NR)	-9.6 (26.85)		252.7 (NR)		-1.60 (-7.50 to 4.30), NSD
Khanji, 2019 ⁸⁷ (HAPPY London)	1	HD + PA		IG1	6	194		(10.57)		61.78 (15.44)	(8.46)	-0.39 (-3.86 to 0.00), 0.64
Good	1	HD + PA		IG1	6	194	108.11 (38.61)	-3.86 (30.89)		111.97 (38.61)		1.54 (-3.86 to 7.72), 0.56
	1	Low HD + PA	TC	IG1	6	194	189.19 (42.47)	-6.18 (34.1)		196.91 (42.47)	-7.61 (34.1)	1.54 (-3.86 to 7.72), 0.60
Kramer, 2018 ⁸⁹ (Healthy Lifestyle		High HD + PA	HDL-C	IG1	6	71	50.8 (14.4)	-1 (7)	37	49.2 (12.4)	` /	0.60 (-2.21 to 3.41), 0.19
Project) Fair	-	High HD + PA	LDL-C	IG1	6	69	115.2 (33.3)	-0.2 (19.6)	36	113.6 (41.5)	-0.14 (21.4)	-0.06 (-8.44 to 8.32), 0.94
		HD + PA		IG1	6	71	194.4 (37.8)	-2.5 (23)	37	192.7 (43.9)		-1.93 (-11.23 to 7.37), 0.68
Langford, 1991 ⁹¹ (Trial of Antihypertensive Interventions and		High HD + PA	TC	IG1	6	235	NR (NR)	4.25 (NR)	229	NR (NR)		Regression parameter=- 174.90 (-358.04 to 8.24), 0.0617
Management (TAIM)) Fair		High HD only	TC	IG2	6	228	NR (NR)	8.88 (NR)	229	NR (NR)	8.11 (NR)	Regression parameter=-32.82 (-218.98 to 153.34), 0.7296
Liira, 2014 ⁹³ Fair	1	Medium HD + PA	HDL-C	IG1	12	46	50.19 (15.44)	3.86 (8.28)	42	54.05 (11.58)		0.00 (-3.46 to 3.46), NSD
		Medium HD + PA	LDL-C	IG1	12	46	142.86 (27.03)	0 (22.61)	42	135.13 (27.03)		3.86 (-5.60 to 13.32), NSD

(Study name) Quality	Population risk focus	time* Intervention focus	(mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)				Between-group difference,† p- value
Moy, 2001 ⁹⁶ Fair	Multiple	High HD only	HDL-C	IG1	24	117	NR (NR)	1.7 (11.58)	118	NR (NR)	0.31 (7.72)	1.39 (-1.13 to 3.91), 0.24
	Multiple	High HD only	LDL-C	IG1	24	117	181.47 (54.05)	-26.64 (42.47)	118	166.02 (46.33)	-15.44 (30.89)	-11.20 (-20.70 to -1.70), 0.0223
Neil, 1995 ⁹⁹ Fair	Dys		HDL-C	IG1	6	103		-0.39 (5.5)	102	47.49 (10.81)		-1.16 (-2.76 to 0.44), NSD
	Dys		HDL-C	IG2	6	104	47.49 (10.42)	1.93 (6.13)	102	47.49 (10.81)	. /	1.16 (-0.52 to 2.84), NSD
	Dys	Medium HD only	LDL-C	IG1	6	103	197.3 (23.17)	-4.25 (21.29)	102	202.7 (25.1)	-7.34 (20.54)	3.09 (-2.64 to 8.82), NSD
	Dys	Medium HD only	LDL-C	IG2	6	104	199.61 (25.87)	-6.95 (21.98)	102	202.7 (25.1)	-7.34 (20.54)	0.39 (-5.42 to 6.19), NSD
	Dys	Medium HD only	TC	IG1	6	103	270.66 (23.55)	-3.86 (22.05)	102	279.15 (24.32)	-5.02 (20.35)	1.16 (-4.65 to 6.97), NSD
	Dys	Medium HD only	TC	IG2	6	104	276.06 (25.1)	-6.95 (22.67)		279.15 (24.32)	-5.02 (20.35)	-1.93 (-7.81 to 3.95), NSD
Nolan, 2018 ¹⁰¹ (Reducing Risk	HTN	High HD + PA	LDL-C	IG1	12	100	116.7 (38.25)	-0.6 (27.55)	97	118.6 (35.04)	0.8 (27.64)	-1.40 (-9.11 to 6.31), 0.68
with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH)) Fair	HTN	High HD + PA	ТС	IG1	12	100	195.6 (44.13)	-2.3 (33.42)	97	195.8 (37.96)	(33.92)	-6.80 (-16.21 to 2.61), 0.11
Reid, 2014 ¹⁰³ Fair	Multiple	High HD + PA	HDL-C	IG1	12	211	51.35 (14.67)	0.39 (8.43)	215	50.19 (13.13)	-0.39 (6.93)	0.77 (-0.69 to 2.24), 0.7
	Multiple	High HD + PA	LDL-C	IG1	12	211	124.32 (33.2)	-4.25 (27.17)	215	126.64 (35.14)	-9.27 (29.56)	5.02 (-0.37 to 10.41), 0.6
	Multiple		TC	IG1	12	211	198.07 (37.45)	-3.86 (31.5)	215	200 (39.38)	-9.65 (32.79)	5.79 (-0.31 to 11.90), 0.7
Rodriguez- Cristobal, 2012 ¹⁰⁵	Multiple		HDL-C	IG1	24	146	54.2 (12)	7.5 (8)	154	55.2 (13.1)	5.1 (7.72)	MD=2.10 (-0.90 to 5.10), 0.171
Fair	Multiple	High HD + PA	LDL-C	IG1	24	146	134.6 (26.9)	-3.5 (22.99)	154	134.3 (28.6)	-4.7 (25.23)	MD=1.90 (-6.00 to 9.90), 0.633

			Outcome (mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)			change	Between-group difference,† p- value
		HD + PA		IG1	24	146	211.1 (26.7)	-6.7 (24.18)		210.2 (25.5)	(24.77)	MD=-19.20 (- 25.60 to -12.70), 0.0001
(Vivamos Activos	1	HD + PA		IG1	6	82	47.2 (9.4)	` ′		44.9 (8.9)	` ′	-0.40 (-2.52 to 1.72), 0.76
(VAFO))	1	HD + PA		IG2	6	84	44.3 (12.7)	-1.4 (8.88)		44.9 (8.9)		-1.40 (-3.85 to 1.05), 0.29
Good	1	HD + PA		IG1	12	82	47.2 (9.4)	1.6 (11.09)	41	44.9 (8.9)	` /	-0.10 (-3.76 to 3.56), 0.98
		High HD + PA	HDL-C	IG2	12	84	44.3 (12.7)	0.6 (11.69)	41	44.9 (8.9)		-1.10 (-4.83 to 2.63), 0.59
		High HD + PA	HDL-C	IG1	24	82	47.2 (9.4)	0.3 (16.17)	41	44.9 (8.9)		-1.10 (-5.56 to 3.36), 0.62
		High HD + PA	HDL-C	IG2	24	84	44.3 (12.7)	-0.2 (16.37)	41	44.9 (8.9)		-1.60 (-6.06 to 2.86), 0.46
		High HD + PA	LDL-C	IG1	6	82	107.8 (39.2)	5.5 (51.28)	41	107.8 (33.5)	12.9 (39.13)	-7.40 (-23.73 to 8.93), 0.39
		High HD + PA	LDL-C	IG2	6	84	100.6 (30.8)	16.3 (106.15)	41	107.8 (33.5)		3.40 (-22.27 to 29.07), 0.79
		High HD + PA	LDL-C	IG1	12	82	107.8 (39.2)	4 (30.72)	41	107.8 (33.5)		2.10 (-9.03 to 13.23), 0.72
		High HD + PA	LDL-C	IG2	12	84	100.6 (30.8)	2.9 (27.12)	41	107.8 (33.5)	1.9 (29.15)	1.00 (-9.64 to 11.64), 0.86
	1	High HD + PA	LDL-C	IG1	24	82	107.8 (39.2)	4.8 (39.73)	41	107.8 (33.5)	4 (33.11)	0.80 (-12.49 to 14.09), 0.91
		High HD + PA	LDL-C	IG2	24	84	100.6 (30.8)	5.8 (32.97)	41	107.8 (33.5)	4 (33.11)	1.80 (-10.55 to 14.15), 0.77
	Multiple		TC	IG1	6	82	181.6 (46)	-0.6 (44.58)	41	188 (40.4)	2.8 (32.95)	-3.40 (-17.36 to 10.56), 0.64
	Multiple		TC	IG2	6	84	178.5 (38.7)	1.7 (29.23)	41	188 (40.4)	2.8 (32.95)	-1.10 (-12.97 to 10.77), 0.86
	Multiple		TC	IG1	12	82	181.6 (46)	8.7 (34.65)	41	188 (40.4)	1.5	7.20 (-5.68 to 20.08), 0.3
	Multiple		TC	IG2	12	84	178.5 (38.7)	1.8 (32.73)	41	188 (40.4)	1.5	0.30 (-12.30 to 12.90), 0.96

		time* Intervention focus			(months)	IG N	IG baseline mean (SD)	change (SD)		mean (SD)	change (SD)	Between-group difference,† p- value
		High HD + PA	TC	IG1	24	82	181.6 (46)	10.8 (46.43)	41	188 (40.4)		5.20 (-8.80 to 19.20), 0.48
	Multiple		TC	IG2	24	84	178.5 (38.7)		41	188 (40.4)	5.6	1.40 (-11.73 to 14.53), 0.82
Salisbury, 2016 ¹⁰⁸ Good		Medium HD + PA	TC	IG1	12	295	189.19 (46.33)	-11.58 (38.76)	288	189.19 (46.33)	(37.31)	MD=-3.86 (-7.72 to 0.00), 0.17
Stefanick, 1998 ¹¹² (Diet and Exercise		HD only		IG1 (Females)	12	46	NR (NR)	, ,	45	NR (NR)		-0.70 (-3.19 to 1.79), NSD
(DEER))		HD only		IG1 (Males)	12	49	NR (NR)	` ′	46	NR (NR)		-0.60 (-2.35 to 1.15), NSD
Fair	•	HD only		IG1 (Females)	12	46	NR (NR)	, ,		NR (NR)		-4.80 (-12.10 to 2.50), NSD
		HD only		IG1 (Males)	12	49	NR (NR)	-10.8 (18.8)		NR (NR)	-4.6 (21.1)	-6.20 (-14.26 to 1.86), NSD
		HD only		IG1 (Females)	12	46	NR (NR)	-7.9 (20.6)	45	NR (NR)		-6.90 (-15.14 to 1.34), NSD
	Dys	High HD only	TC	IG1 (Males)	12	49	NR (NR)	-13.2 (19.3)	46	NR (NR)	-3.9 (21.6)	-9.30 (-17.56 to - 1.04), NSD
Fair	2	Medium HD only	TC	IG1	12	277	230.81 (23.17)	-7.39 (21.16)	271	232.08 (25.18)	-6.19 (23.06)	-2.47 (-4.91 to 2.51), 0.4
Ter Bogt, 2009 ¹¹⁶ (Groningen		High HD + PA	HDL-C	IG1 (Females)	12	103	NR (NR)	-4.25 (7.72)	114	NR (NR)		0.39 (-1.67 to 2.44), NSD
Overweight and Lifestyle (GOAL))		High HD + PA	HDL-C	IG1 (Males)	12	98	NR (NR)	-2.32 (7.72)	101	NR (NR)	-1.93 (7.72)	-0.39 (-2.53 to 1.76), NSD
Good		High HD + PA	LDL-C	IG1 (Females)	12	103	NR (NR)	5.79 (27.03)	114	NR (NR)	0.77 (27.03)	5.02 (-2.18 to 12.22), NSD
		High HD + PA		IG1 (Males)	12	98	NR (NR)	-1.54 (23.17)	101	NR (NR)	4.63 (23.17)	-6.18 (-12.62 to 0.26), NSD
		High HD + PA		IG1 (Females)	12	103	NR (NR)	0.77 (30.89)	114	NR (NR)		3.09 (-5.14 to 11.32), NSD
	Multiple	High HD + PA	TC	IG1 (Males)	12	98	NR (NR)	-6.95 (23.17)	101	NR (NR)	1.16	-8.11 (-15.10 to - 1.12), NSD
Tiessen, 2012 ¹¹⁷ (SPRING (Self-	Multiple		HDL-C	ÌG1	12	89	50.19 (11.2)	2.7 (7.34)	90	50.19 (13.13)	3.86	-0.77 (-3.09 to 1.54), NSD

	Population risk focus	time* Intervention focus	(mg/dL)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)			change	Between-group difference,† p- value
monitoring and Prevention of RIsk	Multiple	Medium	LDL-C	IG1	12	89	139 (30.12)	-13.13 (33.59)	90	139 (31.27)	-6.95	-6.18 (-15.06 to
	Multiple	HD + PA Medium HD + PA	ТС	IG1	12	89	216.22 (32.82)	-12.36 (38.22)		216.22 (36.29)	(29.73) -5.41 (31.66)	3.09), NSD -6.56 (-16.99 to 3.47), NSD
Tomson, 1995 ¹²¹ Fair	Dys	Medium HD only	HDL-C	IG1	12	41	NR (NR)	NR (NR)	35	NR (NR)	NR (NR)	NR, <0.05
	Dys		TC	IG1	12	41	281.08 (9.27)	-10.42 (28.08)	35	281.85 (9.27)	-9.27 (27.71)	-1.16 (-13.73 to 11.42), NSD
van der Veen, 2002 ¹²² (Nijmegen	Dys	Medium HD only	HDL-C	IG1	12	67	NR (NR)	3.9 (NR)	63	NR (NR)	2.7 (NR)	NR, NSD
Family Practices Monitoring	Dys	Medium HD only	LDL-C	IG1	12	67	NR (NR)	-6.2 (NR)	63	NR (NR)	-7.7 (NR)	NR, NSD
Project (NFPMP)) Fair	Dys	Medium HD only	TC	IG1	12	67	NR (NR)	-2.3 (NR)	63	NR (NR)	-6.2 (NR)	NR, NSD
Voils, 2013 ¹²⁶ (CouPLES)	Dys		LDL-C	IG1	6	103	126.2 (NR)	-2.1 (NR)	100	126.2 (NR)	-0.9 (NR)	NR,
Fair	Dys	Medium HD + PA	LDL-C	IG1	11	106	126.2 (NR)	-4.9 (NR)	106	126.2 (NR)	-7.2 (NR)	2.30 (-3.60 to 8.30), 0.44
Wadden, 2011 ¹²⁷ (Practice-based	Multiple	High HD + PA	HDL-C	IG1	6	131	42.47 (11.58)	0 (0)	130	42.47 (11.58)	-0.39 (0)	NR, 0.643
Opportunities for Weight Reduction	Multiple	High HD + PA	HDL-C	IG1	12	131	42.47 (11.58)	-0.77 (0)	130	42.47 (11.58)	0 (0)	NR, 0.502
at the University of Pennsylvania	Multiple	High HD + PA	HDL-C	IG1	24	131	42.47 (11.58)	0.77 (0)	130	42.47 (11.58)	0.39 (0)	NR, 0.851
(POWER-UP)) Good	Multiple		LDL-C	IG1	6	131	111.97 (30.89)	-7.72 (44.19)	130		-7.72 (44.02)	0.00 (-10.70 to 10.70), 0.095
	Multiple	High HD + PA	LDL-C	IG1	12	131	111.97 (30.89)	-3.86 (44.19)	130		-7.72 (44.02)	3.86 (-6.84 to 14.56), 0.428
	Multiple	High HD + PA	LDL-C	IG1	24	131	111.97 (30.89)	-11.58 (44.19)	130	108.11		0.00 (-10.70 to 10.70), 0.972
	Multiple		TC	IG1	6	131	177.61 (34.75)	-11.58 (44.19)		181.47	-11.58	0.00 (-10.70 to 10.70), 0.971

#### Appendix H Table 7. Lipids, Continuous (KQ2)

				Int arm	Timepoint (months)	IG N		IG mean change (SD)		CG baseline mean (SD)	change	Between-group difference,† p- value
	Multiple	High HD + PA	TC	IG1	12	131	177.61 (34.75)	-11.58 (44.19)	130	181.47 (46.33)	-11.58 (0)	NR, 0.801
	Multiple	High HD + PA	TC	IG1	24	131	177.61 (34.75)	-15.44 (44.19)	130	181.47 (46.33)		0.00 (-10.70 to 10.70), 0.597
Wister, 2007 ¹²⁹ Good	Multiple	Medium HD + PA	HDL-C	IG1	12	157	50.19 (11.58)	1.54 (7.34)	158	50.19 (11.58)		0.39 (-1.23 to 2.01), NSD
	Multiple	Medium HD + PA	TC	IG1	12	157	223.94 (50.19)	-15.83 (44.4)	158	216.22 (46.33)	-5.41 (44.4)	-10.42 (-20.23 to -0.62), <0.05
Wong, 2015 ¹³⁰ Good	HTN	Low HD only	HDL-C	IG1	6	254	59.85 (16.6)	0.39 (31.4)	250	59.85 (16.6)	0.39 (31.15)	1.16 (-0.39 to 2.32), 0.1
	HTN	Low HD only	HDL-C	IG1	12	243	59.85 (16.6)	2.7 (30.71)	242	59.85 (16.6)		0.77 (-0.77 to 2.32), 0.34
	HTN	Low HD only	LDL-C	IG1	6	254	130.89 (31.27)	-5.79 (53.37)	250	125.48 (29.34)		0.77 (-2.70 to 3.86), 0.7
	HTN	Low HD only	LDL-C	IG1	12	243	130.89 (31.27)	-5.79 (52.2)	242	125.48 (29.34)		0.39 (-3.47 to 4.25), 0.88
	HTN	Low HD only	TC	IG1	6	254	215.06 (33.2)	-6.56 (56.51)	250	208.49 (32.43)	-5.41 (56.06)	1.16 (-2.70 to 5.02), 0.55
	HTN	Low HD only	TC	IG1	12	243	215.06 (33.2)	-5.79 (58.34)	242	208.49 (32.43)		0.39 (-3.86 to 4.25), 0.91
Wood, 2008 ¹³¹ (EUROACTION)	Multiple	High HD + PA	LDL-C	IG1	12	1019	NR (NR)	-15.83 (NR)	332	NR (NR)	-1.16 (NR)	-13.13 (-20.08 to -6.18), 0.004
Fair		HD + PA	TC	IG1	12	1019	NR (NR)	-14.67 (NR)		NR (NR)	0 (NR)	-13.13 (-20.85 to -5.79), 0.006

**Abbreviations:**  $CG = control \ group; CI = confidence \ interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HDL-C = high-density lipoprotein cholesterol; HTN = hypertension; <math>IG = confidence$ ; Intervention group; Int arm = intervention arm; IG = confidence; IG = confi

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

#### Appendix H Table 8. Lipids, Dichotomous (KQ2)

, •	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Estruch, 2018 ⁶⁷ (Primary Prevention of		High HD only	C	IG1	60	694/1985 (35.0)	(34.3)	1.02 (0.93 to 1.11),
Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Percent with low HDL-C	IG2	60	656/1886 (34.8)	668/1946 (34.3)	1.01 (0.93 to 1.11),
Fagerberg, 1998 ⁶⁸ (Risk Factor	Multiple	High HD + PA	TC at goal (<6.0 mmol/L)	IG1	40	120/235 (51.1)	88/227 (38.8)	1.32 (1.07 to 1.62), 0.01
(RIS))	Multiple	High HD + PA	TC at goal (<6.0 mmol/L)	IG1	79	114/248 (46.0)		1.49 (1.18 to 1.87), 0.0007
(KQ2)	Multiple	High HD + PA	TC at goal (<6.0 mmol/L)	IG1	12	87/239 (36.4)	(28.6)	1.27 (0.98 to 1.66), 0.084
Khanji, 2019 ⁸⁷ (HAPPY London)	Multiple	Low HD + PA	LDL at goal (LDL <3 mmol/L)	IG1	6	121/194 (62.4)	108/184 (58.7)	1.06 (0.90 to 1.25), 0.51
	Multiple	Low HD + PA	TC at goal (TC <5 mmol/L)	IG1	6	116/194 (59.8)	101/184 (54.9)	1.09 (0.91 to 1.30), 0.37
Voils, 2013 ¹²⁶ (CouPLES) Fair	Dys	Medium HD + PA	LDL-C at goal (<100 mg/dL [high risk], <130 mg/dL [moderate risk], <160 [low-risk])	IG1	11	58/106 (54.7)		OR=0.95 (0.60 to 1.70), 0.87
	Dys	Medium HD + PA	LDL-C at goal (<100 mg/dL [high risk], <130 mg/dL [moderate risk], <160 [low-risk])	IG1	6	59/106 (55.7)	45/100 (45.0)	1.24 (0.94 to 1.63),
Wood, 2008 ¹³¹ (EUROACTION) Fair	Multiple	High HD + PA	TC at goal (<5 mmol/L)	IG1	12	345/965 (35.8)	(31.5)	Difference in probability=2.40 (-9.90 to 14.80), 0.64
	Multiple	High HD + PA	LDL-C at goal (<3 mmol/L)	IG1	12	419/936 (44.8)	(35.2)	Difference in probability=8.70 (-5.20 to 22.70), 0.17

**Abbreviations:** CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HDL-C = high-density lipoprotein cholesterol; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; LDL-C = low-density lipoprotein cholesterol; mmol/L = millimoles per liter; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio; TC = total cholesterol

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
Anderssen, 1995 ⁴⁰ (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	FBG (mg/dL)	IG1	12	52	101.81 (14.6)		43	97.49 (9.37)	0 (1.8)	-3.60 (-4.33 to - 2.88), <0.05
Appel, 2011 ⁴²	Multiple	High	FBG	IG1	6	117	103.9	-4.3	100	107.1	-3.4 (16)	-0.90 (-5.10 to
(POWER Hopkins		HD + PA	(mg/dL)				(21.07)	(15.14)		(30.32)		3.20), 0.66
(Practice Based	Multiple	High	FBG	IG2	6	121	104.8	-2.5 (20.9)	100	107.1	-3.4 (16)	0.90 (-3.90 to
Opportunities for		HD + PA	(mg/dL)				(23.58)			(30.32)		5.70), 0.71
Weight Reduction))	Multiple	High	FBG	IG1	24	105	103.9	-2.6	93	107.1	-3.8	1.20 (-4.20 to
Good		HD + PA	(mg/dL)				(21.07)	(15.37)		(30.32)	(22.18)	6.60), 0.66
	Multiple	High	FBG	IG2	24	110	104.8	-5.7	93	107.1	-3.8	-1.80 (-7.50 to
		HD + PA	(mg/dL)				(23.58)	(17.83)		(30.32)	(22.18)	3.80), 0.52
Babazono, 2007 ⁴⁵ (PHPP) Fair	Multiple	Medium HD + PA	HbA1c (%)	IG1	12	46	5.5 (0.6)	0 (0.53)	41	5.4 (0.4)	0 (0.4)	0.00 (-0.20 to 0.20), NSD
Bennett, 2018 ⁴⁸ (Track)	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	136	119.4 (52.1)	-4.9 (48.19)	151	115.7 (46)	3.2 (47.96)	-8.10 (-17.10 to 0.90), 0.08
Good	Multiple	Medium HD + PA	HbA1c (%)	IG1	12	129	6.6 (1.7)	-0.3 (0.87)	146	6.5 (1.6)	-0.2 (0.12)	-0.20 (-0.40 to 0.04), 0.11
Blackford, 2016 ⁵⁰ (Albany Physical Activity and Nutrition (APAN)) Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	6	130	90.28 (8.29)	0.9 (7.55)	144	90.82 (8.83)	1.26 (8)	-0.36 (-2.20 to 1.48), 0.79
Bo, 2007 ⁵²	Multiple	Medium	FBG	IG1	12	169	104.52	-4.69	166	104.52	1.26	-5.95 (-8.36 to -
Fair	•	HD + PA	(mg/dL)				(14.42)	(11.89)		(12.61)	(10.63)	3.53), <0.001
	Multiple	Medium	FBG	IG1	108	148	104.52	-5.59	138	104.52	-0.54	-5.05 (-7.97 to -
		HD + PA	(mg/dL)				(14.42)	(11.24)		(12.61)	(13.72)	2.13), 0.004
Broekhuizen, 2012 ⁵⁴ (PRO-FIT) Fair	Dys	Medium HD + PA	FBG (mg/dL)	IG1	12	169	88.3 (14.42)	-3.6 (11.43)	145	88.3 (18.02)	-1.8 (13.96)	-1.80 (-4.65 to 1.05), NSD
Burke, 2006 ⁵⁶ (ADAPT)	HTN	Medium HD + PA	FBG (mg/dL)	IG1	16	123	90.1 (10.27)	-2.34 (4.14)	118	90.1 (14.96)	-2.16 (3.96)	-0.18 (-1.20 to 0.84), NSD
Fair	HTN	Medium HD + PA	FBG (mg/dL)	IG1	40	123	90.1 (10.27)	0 (8.59)	118	90.1 (14.96)	0 (12.51)	0.00 (-1.80 to 1.80), 0.981
Chirinos, 2016 ⁵⁷ (Community Health	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	60	88.83 (10.9)	-2.38 (NR)	60	86.66 (9.47)	1.84 (NR)	NR, <0.05
and Risk-reduction for Metabolic Syndrome	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	60	88.83 (10.9)	-0.4 (NR)	60	86.66 (9.47)	4.02 (NR)	NR, <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
(CHARMS)) Fair												
Christian, 2011 ⁵⁸ Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	133	95.1 (11.6)	1.41 (12.65)		97.4 (10.76)	(10.86)	1.53 (-6.50 to 9.56), 0.85
Cicolini, 2014 ⁵⁹ Fair	HTN	Medium HD + PA	FBG (mg/dL)	IG1	6	100	119 (29)	-13.6 (15.3)		127 (38)	-17.1 (25.2)	3.50 (-2.32 to 9.32), 0.9
Estruch, 2018 ⁶⁷ (Primary Prevention	Multiple	High HD only	FBG (mg/dL)	IG1	12	78	123.1 (38.3)	-6.13 (24.74)	75	113.8 (33.8)	3.51 (17.78)	-9.64 (-16.45 to -2.83), <0.05
of Cardiovascular Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	FBG (mg/dL)	IG2	12	82	119.6 (36.04)	-4.61 (24.07)	75	113.8 (33.8)	3.51 (17.78)	-8.12 (-14.70 to -1.54), NSD
Fagerberg, 1998 ⁶⁸ (Risk Factor	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	239	104.52 (43.25)	-7.21 (81.09)	238	104.52 (36.04)	3.6 (25.23)	-10.81 (-21.62 to 0.00), 0.051
Intervention Study (RIS)) Good (KQ1); Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	40	235	104.52 (43.25)	-3.6 (34.24)	227		3.6 (25.23)	MD=-7.21 (- 12.61 to -1.80), 0.011
(KQ2)	Multiple	High HD + PA	FBG (mg/dL)	IG1	79	248	104.52 (43.25)	-3.6 (26.13)	252	104.52 (36.04)	0 (21.08)	-3.60 (-8.47 to - 0.18), NSD
Gill, 2019 ⁶⁹ (Heartmatters	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	66	100.66 (21.54)	NR (NR)	70	103.5 (9.19)	NR (NR)	3.20 (-17.79 to 24.19), 0.77
Challenge - First Responders)	Multiple	High HD + PA	HbA1c (%)	IG1	6	96	5.48 (0.39)	NR (NR)	79	5.64 (0.4)	NR (NR)	-0.12 (-0.20 to - 0.04), 0.01
Fair	Multiple	High HD + PA	HbA1c (%)	IG1	12	96	5.48 (0.39)	NR (NR)	79	5.64 (0.4)	NR (NR)	0.04 (-0.02 to 0.10), 0.17
Greaves, 2015 ⁷¹ (Waste the Waist)	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	53	93.88 (9.01)	NR (NR)	53	96.59 (10.81)	NR (NR)	-2.34 (-5.23 to 0.72), NSD
Fair	Multiple	High HD + PA	HbA1c (mmol/L)	IG1	12	54	38.1 (3.5)	NR (NR)	52	39.1 (5)	NR (NR)	-0.84 (-1.89 to 0.21), NSD
Groeneveld, 2010 ⁷² (Health Under	Multiple	Medium HD + PA	HbA1c (%)	IG1	6	250	5.66 (0.41)	0.04 (0.4)	255	5.66 (0.41)	0.04 (0.37)	0.00 (-0.07 to 0.07), NSD
Construction) Fair	Multiple	Medium HD + PA	HbA1c (%)	IG1	12	2560	5.66 (0.41)	0.08 (0.37)	255	5.66 (0.41)	0.12 (0.4)	-0.04 (-0.09 to 0.01), NSD
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	6	160	110.4 (22.1)	-6.4 (16.94)	154	109.4 (17.8)	-0.6 (14.36)	-5.40 (-7.60 to - 3.20), <0.0001
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	31	109 (21)	-1.8 (41.49)	32	114 (44)	12.4 (41.56)	-14.20 (-35.47 to 7.05), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change		CG baseline mean (SD)	CG mean change	Between-group difference,† p-
,	118K TOCUS	focus			(months)		illean (SD)	(SD)			(SD)	value
Khanji, 2019 ⁸⁷ (HAPPY London) Good	Multiple	Low HD + PA	FBG (mg/dL)	IG1	6	194	NR (NR)	-5.23 (NR)		NR (NR)	-4.79 (NR)	-0.54 (-3.60 to 3.60), 0.77
Kramer, 2018 ⁸⁹ (Healthy Lifestyle	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	81	96 (10.3)	-3.4 (7.8)	41	95.9 (13.1)	-1.8 (6.3)	-1.60 (-4.17 to 0.97), 0.24
Project) Fair	Multiple	High HD + PA	HbA1c (%)	IG1	6	81	5.8 (0.32)	-0.15 (0.17)	41	5.76 (0.33)	-0.02 (0.17)	-0.13 (-0.19 to -0.07), 0.0002
Liira, 2014 ⁹³ Fair	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	46	104.52 (16.22)	-3.6 (12.33)	42	100.91 (7.21)	1.8 (8.22)	-5.41 (-9.75 to - 1.06), NSD
Moreau, 2001 ⁹⁵ Fair	HTN	Low PA only	FBG (mg/dL)	IG1	6	15	100.91 (20.9)	-1.8 (15.89)	9	102.71 (21.62)	0 (16.57)	-1.80 (-15.29 to 11.69), NSD
Reid, 2014 ¹⁰³ Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	211	92.26 (9.37)			(10.63)	, ,	0.00 (-1.64 to 1.64), 0.3
Rosas, 2015 ¹⁰⁶ (Vivamos Activos	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	82	111.9 (31.7)		41		4 (24.39)	-3.60 (-13.06 to 5.86), 0.47
Fair Oaks (VAFO)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG2	6	84	116.6 (37.5)	,			4 (24.39)	-3.30 (-13.23 to 6.63), 0.52
	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	82	111.9 (31.7)	(27.26)	41		, ,	-9.20 (-18.79 to 0.39), 0.07
	Multiple	High HD + PA	FBG (mg/dL)	IG2	12	84		(38.58)	41		, , ,	-7.90 (-19.09 to 3.29), 0.18
	Multiple	High HD + PA	FBG (mg/dL)	IG1	24	82	, ,	-1.9 (46.43)	41		, ,	-6.50 (-21.09 to 8.09), 0.34
	Multiple	High HD + PA	FBG (mg/dL)	IG2	24	84	116.6 (37.5)	,			, ,	-1.90 (-17.30 to 13.50), 0.81
Stefanick, 1998 ¹¹² (Diet and Exercise for		High HD only	FBG (mg/dL)	IG1 (Females)	12	46	NR (NR)	, ,	45	NR (NR)	, ,	-5.10 (-9.93 to - 0.27), NSD
Elevated Risk (DEER)) Fair	Dys	High HD only	FBG (mg/dL)	IG1 (Males)	12	49		-7.6 (8.6)	46	NR (NR)	, , ,	-3.80 (-7.67 to 0.07), NSD
Ter Bogt, 2009 ¹¹⁶ (Groningen	Multiple	High HD + PA	FBG (mg/dL)	IG1 (Females)	12	103	NR (NR)	-1.44 (10.81)	114	NR (NR)	-1.98 (9.01)	0.54 (-2.12 to 3.20), NSD
Overweight and Lifestyle (GOAL)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG1 (Males)	12	98	NR (NR)	-0.54 (10.81)	101	NR (NR)	-0.9 (14.42)	0.36 (-3.17 to 3.89), NSD
Tiessen, 2012 ¹¹⁷ (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	89	97.31 (9.01)	3.06 (9.91)	90		5.05 (11.35)	-1.98 (-5.05 to 1.26), NSD

	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	1 1	IG mean change (SD)			change	Between-group difference,† p- value
region of Groningen))												
Fair Toft, 2008 ¹¹⁸ (Inter99) Fair	Multiple	High HD + PA	FBG (mg/dL)	IG1	60	2454	NR (NR)	NR (NR)	284	NR (NR)	` /	1.10 (-0.28 to 2.48), 0.116
Wadden, 2011 ¹²⁷ (Practice-based	Multiple	High HD + PA	FBG (mg/dL)	IG1	6	131	106.3 (32.4)	-0.4 (1.14)	130	111.7 (39.6)	` '	-0.40 (-0.68 to - 0.12), <0.05
Opportunities for Weight Reduction at	Multiple	High HD + PA	FBG (mg/dL)	IG1	12	131	106.3 (32.4)	-0.2 (1.14)	130	111.7 (39.6)		-0.30 (-0.58 to - 0.02), NSD
the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	FBG (mg/dL)	IG1	24	131	106.3 (32.4)	0 (2.29)	130	111.7 (39.6)	` /	0.00 (-0.55 to 0.55), NSD
Wister, 2007 ¹²⁹ Good	Multiple	Medium HD + PA	FBG (mg/dL)	IG1	12	157		-6.67 (55.32)	158			-6.85 (-18.34 to 4.64), NSD
Wood, 2008 ¹³¹ (EUROACTION) Fair	Multiple	High HD + PA		IG1	12	1019	NR (NR)	-8.29 (NR)	332	NR (NR)	-5.05 (NR)	-1.98 (-13.52 to 9.55), 0.67

**Abbreviations:** BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; Dys = dyslipidemia; FBG = fasting blood glucose; HbA1c = glycated hemoglobin; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; mg/dL = milligrams per deciliter; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

### Appendix H Table 10. Glucose and Metabolic Syndrome, Dichotomous (KQ2)

name) Quality	Population risk focus	Contact time* Intervention focus		Int arm	Timepoint (months)			RR† (95% CI), p- value
Anderssen, 1995 (Oslo Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	METS prevalence (Males with METS at baseline only)	IG1	12	22/34 (64.7)		0.73 (0.55 to 0.97), 0.023
(PHPP) Fair	Multiple	Medium HD + PA	Diabetes incidence	IG1	12	11/46 (23.9)		0.98 (0.47 to 2.07), NSD
Bo, 2007 ⁵² Fair	Multiple	Medium HD + PA	Diabetes incidence	IG1	12	3/169 (1.8)	` ′	OR=0.23 (0.06 to 0.85), 0.03
	Multiple	Medium HD + PA	Diabetes incidence	IG1	108	14/169 (8.3)		HR=0.47 (0.24 to 0.89), 0.021
	Multiple	Medium HD + PA	Percent with Hyperglycemia	IG1	12			OR=0.19 (0.11 to 0.32), <0.001
	Multiple	Medium HD + PA	IFG incidence	IG1	12			OR=0.22 (0.13 to 0.39), <0.001
	Multiple	Medium HD + PA	METS incidence	IG1	12	59/169 (34.9)	(65.7)	OR=0.28 (0.18 to 0.44), <0.001
Chirinos, 2016 (Community Health and Risk-reduction for Metabolic Syndrome (CHARMS)) Fair	Multiple	High HD + PA	METS prevalence	IG1	6	1320/1982 (66.6)		0.97 (0.93 to 1.01), NSD
Estruch, 2018 ⁶⁷ (Primary Prevention of	Multiple	High HD only	Diabetes incidence	IG1	48	80/1154 (6.9)		HR=0.60 (0.43 to 0.85), <0.05
Cardiovascular Disease with a Mediterranean	Multiple	High HD only	Diabetes incidence	IG2	48	92/1240 (7.4)	101/1147 (8.8)	HR=0.82 (0.61 to 1.10), NSD
Diet (PREDIMED)) Fair	Multiple	High HD only	METS incidence	IG2	38	333/662 (50.3)		HR=1.08 (0.92 to 1.27), NSD
Greaves, 2015 (Waste the Waist) Fair	Multiple	High HD + PA	METS prevalence	IG1	12	21/54 (38.9)		0.64 (0.43 to 0.96), 0.034
Khanji, 2019 ⁸⁷ (HAPPY London) Good	Multiple	Low HD + PA	FBG at goal	IG1	6	162/194 (83.5)		1.03 (0.94 to 1.13), 0.60
Liira, 2014 Fair	Multiple	Medium HD + PA	METS prevalence	IG1	12	27/46 (58.7)	, , ,	1.17 (0.80 to 1.73), 0.33

#### Appendix H Table 10. Glucose and Metabolic Syndrome, Dichotomous (KQ2)

Toft, 2008 ¹¹⁸ (Inter99)	Multiple	High	Diabetes incidence	60	187/2454	21/284 (7.4)	1.03 (0.67 to 1.59),
Fair	_	HD + PA			(7.6)		0.892

**Abbreviations:** CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HR = hazard ratio; HTN = hypertension; IG = intervention group; IFG = impaired fasting glucose; Int arm = intervention arm; KQ = key question; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
Ammerman,	Dys	Medium	Weight (kg)	IG1	6	154	79.5	-1.41	189	80 (30.16)		-0.95 (-1.86 to -
$2003^{38}$		HD only					(29.39)	(6.37)			(4.17)	0.05), 0.04
Fair	Dys	Medium HD only	Weight (kg)	IG1	12	189	79.5 (29.39)	-0.73 (4.91)	196	80 (30.16)	0 (NR)	-0.73 (-1.68 to 0.23), 0.13
Anderson, 1992 ³⁹ Fair	Dys	High HD only	Weight (kg)	IG1	12	48	71.08 (12.7)	-1.02 (3.54)	51	71.44 (9.91)	-0.44 (2.68)	-0.58 (-1.82 to 0.66), <0.05
	Dys	High HD only	Weight (kg)	IG2	12	47	72.04 (8.69)		51	71.44 (9.91)	-0.44	-0.62 (-1.64 to 0.40), <0.05
Anderssen, 1995 ⁴⁰ (Oslo Diet and	Multiple	Medium HD only	BMI (kg/m²)	IG1	12	52	29.7 (4.2)	-1.3 (0.2)		28.3 (3.1)	0.4 (0.1)	-1.63 (-2.12 to - 1.14), <0.05
Exercise Study (ODES)) Fair	Multiple	Medium HD only	Waist circumference (cm)	IG1	12	52	105 (9.37)	-3.7 (4.33)	43	102.3 (9.18)		-4.60 (-6.01 to - 3.19), <0.05
	Multiple	Medium HD only	Weight (kg)	IG1	12	52	93.4 (12.98)	-4 (5.05)		89.3 (13.77)	` ′	-5.10 (-6.68 to - 3.52), <0.05
Appel, 2003 ⁴¹ (PREMIER)	HTN	High HD + PA	Weight (kg)	IG1	6	233	98.8 (19.3)	, ,		95.8 (17)	` ′	-4.70 (-5.55 to - 3.85), <0.001
Good	HTN	High HD + PA	Weight (kg)	IG2	6	238	96.2 (17.8)	-4.9 (5.5)	242	95.8 (17)	-1.1 (3.2)	-3.80 (-4.61 to - 2.99), <0.001
	HTN	High HD + PA	Weight (kg)	IG2 (HTN subgroup)	6	97	98.1 (18.4)	-5.9 (5.9)	97	94.7 (16)	-1.3 (3.4)	-4.60 (-5.96 to - 3.24), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	18	241	98.6 (19.1)	-4.3 (7.4)	241	96 (17.2)	-1.5 (5)	-2.70 (-3.80 to - 1.60), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	18	235	95.7 (17.6)	-3.8 (6.1)	241	96 (17.2)	-1.5 (5)	-2.20 (-3.30 to - 1.10), <0.001
Appel, 2011 ⁴² (POWER	Multiple	High HD + PA	BMI (kg/m ² )	IG1	6	124	36.8 (16.45)	-2 (2.23)	113	36.8 (4.7)	-0.5 (1.06)	-1.40 (-2.00 to - 0.90), <0.001
Hopkins (Practice Based	Multiple	High HD + PA	BMI (kg/m ² )	IG2	6	129	36.1 (4.72)	-2.1 (2.27)	113	36.8 (4.7)	-0.5 (1.06)	-1.60 (-2.00 to - 1.10), <0.001
Opportunities for Weight	Multiple	High HD + PA	BMI (kg/m ² )	IG1	12	123	36.8 (16.45)	-1.8 (2.22)	108	36.8 (4.7)	-0.4	-1.40 (-1.90 to - 0.80), <0.001
_	Multiple	High HD + PA	BMI (kg/m ² )	IG2	12	124	36.1 (4.72)		108	36.8 (4.7)	-0.4	-1.50 (-2.10 to - 0.90), <0.001
	Multiple	High HD + PA	BMI (kg/m²)	IG1	24	133	36.8 (16.45)	-1.7 (3.46)	129	36.8 (4.7)	-0.4 (2.27)	-1.30 (-2.10 to - 0.60), <0.001

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
	Multiple	High HD + PA	BMI (kg/m ² )	IG2	24	139	36.1 (4.72)	-1.7 (3.54)	129	36.8 (4.7)	-0.4 (2.27)	-1.30 (-2.00 to - 0.60), <0.001
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	120	118.3 (14.1)	-5.4 (6.57)	110	118.5 (12.92)	. ,	-2.60 (-4.00 to - 1.20), <0.001
	Multiple	High HD + PA	Waist circumference (cm)	IG2	6	127	117.8 (12.97)	-6.4 (6.76)	110	118.5 (12.92)		-3.50 (-5.00 to - 2.00), <0.001
	Multiple	High HD + PA	Waist circumference (cm)	IG1	24	119	118.3 (14.1)	-6.3 (8.73)	107	118.5 (12.92)	-3.4 (7.24)	-2.80 (-4.80 to - 0.90), 0.005
	Multiple	High HD + PA	Waist circumference (cm)	IG2	24	119	117.8 (12.97)	-6.7 (9.82)	107	118.5 (12.92)	-3.4 (7.24)	-3.30 (-5.40 to - 1.20), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	6	124	104.9 (18.8)	-5.8 (6.68)	113	104.2 (15.27)	-1.5 (4.25)	-4.30 (-5.80 to - 2.90), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	6	129	102.5 (14.15)	-6 (5.68)	113	104.2 (15.27)	-1.5 (4.25)	-4.50 (-5.80 to - 3.20), <0.001
	Multiple	High HD + PA	Weight (kg)	IG1	12	123	104.9 (18.8)	-5.4 (7.76)	108	104.2 (15.27)	-1.1 (5.2)	-4.30 (-5.90 to - 2.60), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	12	124	102.5 (14.15)	-5.7 (7.79)	108	104.2 (15.27)		-4.50 (-6.10 to - 2.90), <0.001
	Multiple	High HD + PA	Weight (kg)	IG1	24	133	104.9 (18.8)	-5.1 (9.23)	129	104.2 (15.27)	-0.8 (7.95)	-4.30 (-6.30 to - 2.30), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	24	139	102.5 (14.15)	-4.5 (8.25)	129	104.2 (15.27)	-0.8 (7.95)	-3.80 (-5.60 to - 1.90), <0.001
Applegate, 1992 ⁴³ Fair	HTN	High HD + PA	Weight (kg)	IG1	6	21	88.7 (NR)	-2.1 (NR)	26	79.7 (NR)	0.3 (NR)	NR, 0.0001
Arroll, 1995 ⁴⁴ Fair	HTN	Low HD + PA	Weight (kg)	IG1	6	48	NR (NR)	0.3 (NR)	43	NR (NR)	0.8 (NR)	NR
	HTN	Low PA only	Weight (kg)	IG2	6	46	NR (NR)	-0.7 (NR)	43	NR (NR)	0.8 (NR)	NR
	HTN	Low HD only	Weight (kg)	IG3	6	44	NR (NR)	-0.6 (NR)	43	NR (NR)	0.8 (NR)	NR

### Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
Babazono, 2007 ⁴⁵	Multiple	Medium	BMI (kg/m ² )	IG1	12	46	23.6 (3.2)	-0.5	41	24 (2.5)	-0.1	-0.40 (-0.78 to -
(PHPP)	7.6.1.1.1	HD + PA	TT 1 1 (1 )	TC1	1.2	4.6	50.5 (0.5)	(1.01)	4.1	50.6 (0.1)	(0.78)	0.02), NSD
Fair	Multiple	Medium HD + PA	Weight (kg)	IG1	12	46	58.5 (9.7)	-1.4 (3.04)	41	58.6 (9.1)	-0.5 (2.85)	-0.90 (-2.14 to 0.34), NSD
Beckmann, 1995 ⁴⁶	HTN	Medium HD only	BMI (kg/m²)	IG1	12	32	27.9 (3.39)	)-0.8 (1.07)	32	26.7 (3.39)		-0.80 (-1.33 to - 0.27), <0.05
Fair	HTN	Medium HD only	Weight (kg)	IG1	6	32	87.2 (12.45)	-2.4 (3.92)	32	83.6 (13.01)	0.8 (4.44)	-3.20 (-5.25 to - 1.15), <0.05
	HTN	Medium HD only	Weight (kg)	IG1	12	32	87.2 (12.45)	-2.7 (2.83)	32	83.6 (13.01)	0.3 (4.24)	-3.00 (-4.77 to - 1.23), <0.05
Bennett, 2012 ⁴⁷ (Be Fit, Be Well	HTN	High HD + PA	BMI (kg/m²)	IG1	6	180	37.04 (4.96)	-0.48 (1.88)	185	36.99 (5.24)	-0.05 (1.77)	-0.43 (-0.80 to - 0.05), <0.05
[POWER]) Good	HTN	High HD + PA	BMI (kg/m²)	IG1	12	180	37.04 (4.96)	-0.54 (1.88)	185	36.99 (5.24)	-0.12 (1.77)	-0.42 (-0.80 to - 0.03), <0.05
	HTN	High HD + PA	BMI (kg/m²)	IG1	18	180	37.04 (4.96)	-0.5 (2.01)	185	36.99 (5.24)	-0.15 (1.9)	-0.35 (-0.75 to 0.06), <0.05
	HTN	High HD + PA	BMI (kg/m ² )	IG1	24	180	37.04 (4.96)	-0.58 (1.88)	185	36.99 (5.24)	-0.2 (1.77)	-0.38 (-0.75 to 0.00), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	6	180	99.7 (16.29)	-1.25 (4.96)	185	100.61 (18.67)	-0.13	-1.11 (-2.12 to - 0.10), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	12	180	99.7 (16.29)	-1.37 (5.1)	185	100.61 (18.67)	-0.32 (4.9)	-1.05 (-2.09 to - 0.01), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	18	180	99.7 (16.29)	-1.28 (5.37)	185	100.61 (18.67)	-0.33 (5.17)	-0.95 (-2.03 to 0.14), <0.05
	HTN	High HD + PA	Weight (kg)	IG1	24	180	99.7 (16.29)	-1.53 (4.96)	185	100.61 (18.67)	-0.5 (4.76)	-1.03 (-2.03 to - 0.03), <0.05
Bennett, 2018 ⁴⁸ (Track)	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	6	170	35.9 (4.1)	-1.4 (2)	167	35.9 (3.7)		-1.60 (-2.00 to - 1.20), <0.0001
Good	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	12	170	35.9 (4.1)	-1.4 (2.33)	167	35.9 (3.7)	-0.01 (1.98)	-1.40 (-1.80 to - 0.90), <0.0001
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	170	114.4 (10.2)	-3.4 (6.32)	167	115 (10.2)	0.1 (6.26)	-3.50 (-4.80 to - 2.20), <0.0001

### Appendix H Table 11. Adiposity, Continuous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	170	114.4 (10.2)	-2.9 (6.98)	167	, , ,		-3.60 (-5.00 to - 2.10), <0.0001
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	170	98.9 (14.4)	(4.99)	167	99.7 (13.8)		-4.40 (-5.50 to - 3.30), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	170	98.9 (14.4)	-4 (6.32)	167	99.7 (13.8)		-3.80 (-5.10 to - 2.50), <0.001
Blackford, 2016 ⁵⁰ (Albany Physical	Multiple	Medium HD + PA	BMI (kg/m ² )	IG1	6	151	29.55 (6.93)	-0.2 (2.2)	161	29.8 (7.05)		-0.10 (-0.59 to 0.39), <0.001
Activity and Nutrition (APAN))	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	151	102.67 (13.58)	-2.11 (13.71)	161	101.41 (12.93)	-0.88 (12.81)	-1.23 (-4.18 to 1.72), 0.03
Fair	Multiple	Medium HD + PA	Weight (kg)	IG1	6	151	85.2 (22.6)	-0.7 (7.4)	161	85.3 (21.9)	, ,	-1.80 (-3.39 to - 0.21), 0.01
Bloemberg, 1991 ⁵¹ Fair	Dys	Medium HD only	Weight (kg)	IG1	6	39	80.8 (9.9)	-0.94 (2.68)	41	83.3 (8.6)	0.06 (1.86)	-1.00 (-2.02 to 0.02), 0.03
Bo, 2007 ⁵² Fair	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	12	169	29.7 (4.1)	-0.29 (1.79)	166	29.8 (4.6)	0.61 (1.97)	-0.90 (-1.30 to - 0.50), <0.001
	Multiple	Medium HD + PA	BMI (kg/m ² )	IG1	108	148	29.7 (4.1)	-0.6 (1.34)	138	29.8 (4.6)	` ′	-0.80 (-1.13 to - 0.47), 0.12
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	169	99.6 (11.6)		166	99.8 (10.6)	1.96	-4.51 (-5.79 to - 3.23), <0.001
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	169	81.7 (14.9)	)-0.75 (4.93)	166	81.3 (13.5)	1.63 (5.23)	-2.38 (-3.47 to - 1.29), <0.001
	Multiple	Medium HD + PA	Weight (kg)	IG1	108	148	81.7 (14.9)	)-1.7 (4.97)	138	81.3 (13.5)	-0.6 (4.22)	-1.10 (-2.17 to - 0.03), 0.69
Broekhuizen, 2012 ⁵⁴ (PRO-FIT)	Dys	Medium HD + PA	BMI (kg/m²)	IG1	12	167	25.9 (4.5)	-0.01 (1.41)	147	27.1 (5.4)	0 (1.69)	-0.01 (-0.36 to 0.34), NSD
Fair	Dys	Medium HD + PA	Waist circumference (cm)	IG1	12	165	86.4 (11.9)		146	89.9 (14.5)	0 (14.4)	-0.30 (-3.24 to 2.64), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	mean	Between-group difference,† p- value
Burke, 2006 ⁵⁶ (ADAPT) Fair	HTN	Medium HD + PA	Waist circumference (cm)	IG1	16	123	96.6 (9.3)	-4.62 (2.21)	118	93.8 (8.4)	, ,	-3.40 (-4.03 to - 2.77), <0.001
	HTN	Medium HD + PA	Waist circumference (cm)	IG1	40	123	96.6 (9.3)	-2.5 (9.46)	118	93.8 (8.4)	-2 (9.64)	-0.30 (-1.70 to 1.00), 0.930
	HTN	Medium HD + PA	Weight (kg)	IG1	16	123	86.5 (12.73)	-3.52 (2.72)	118	84.4 (6.1)	-0.96 (1.88)	-2.56 (-3.15 to - 1.97), <0.001
	HTN	Medium HD + PA	Weight (kg)	IG1	40	123	86.5 (12.73)	-1.5 (4.03)	118	84.4 (6.1)	-0.7 (6.41)	-0.70 (-1.80 to 0.40), 0.273
Chirinos, 2016 ⁵⁷ (Community Health and Risk-	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	60	104.58 (9.05)	(NR)	60	105.21 (9.22)		NR, NSD
reduction for Metabolic Syndrome	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	60	104.58 (9.05)	-0.84 (NR)	60	105.21 (9.22)	-1.13 (NR)	NR
(CHARMS)) Fair	Multiple	High HD + PA	Weight (kg)	IG1	6	60	87.75 (12.85)	-2.84 (NR)	60	88.03 (13.02)	-0.46 (NR)	NR, <0.05
	Multiple	High HD + PA	Weight (kg)	IG1	12	60	87.75 (12.85)	-2.36 (NR)	60	88.03 (13.02)	-0.54 (NR)	NR, <0.05
Christian, 2011 ⁵⁸ Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	133	116.7 (14.91)	-2.2 (12.12)	130	113.8 (14.7)	1.5 (14.85)	-3.70 (-12.98 to 5.58), 0.01
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	133	93.92 (19.92)	-1.5 (5.27)	130	92.02 (22.6)	0.15 (4.02)	-1.65 (-4.83 to 1.54), 0.002
Cicolini, 2014 ⁵⁹ Fair	HTN	Medium HD + PA	BMI (kg/m²)	IG1	6	100	29 (6.7)	-2.4 (3.5)	98	29 (5.1)		-1.10 (-1.82 to - 0.38), <0.001
Cochrane, 2012 ⁶⁰ Fair	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	12	236	28.7 (5)	-0.22 (1.96)	365	27.5 (4.1)		-0.20 (-0.49 to 0.09), NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	231	101.3 (11.2)	-1.61 (5.51)	355	99.5 (11.8)		-0.42 (-1.34 to 0.50), NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	236	85 (14.5)	-0.51 (5.68)	365	82.6 (13.8)		-0.28 (-1.14 to 0.58), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
Cohen, 1991 ⁶¹	HTN	Medium	Weight (kg)	IG1	6	15	91.8 (NR)	-1.8 (3.4)	15	91.7 (NR)	0.56 (2.5)	-2.36 (-4.50 to -
Fair	HTN	HD only Medium	Weight (kg)	IG1	12	15	91.8 (NR)	-0.88 (4)	15	91.7 (NR)	1.3 (3)	0.22), 0.04 -2.18 (-4.71 to
		HD only										0.35), <0.1
Coleman, 2012 ⁶² (Wisewoman California)	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	12	433	31.7 (5.87)	)-0.2 (NR)	436	32.1 (6.28)	00 (NR)	NR, 0.321
Delahanty, 2001 ⁶³ Good	Dys	Medium HD + PA	Weight (kg)	IG1	6	44	79.6 (15.4)	)-1.9 (4.87)	44	83.2 (15)	0 (4.74)	-1.90 (-3.91 to 0.11), <0.001
	Dys	Medium HD + PA	Weight (kg)	IG1	12	43	79.6 (15.4)		44	83.2 (15)	0 (4.74)	-1.40 (-3.42 to 0.62), NSD
Edelman, 2006 ⁶⁵ Fair	Multiple	High HD + PA	BMI (kg/m ² )	IG1	10	77	33.3 (7.8)	-1.2 (NR)	77	34.1 (7.7)	-0.6 (NR)	NR, 0.11
Ellsworth, 2016 ⁶⁶ Fair	Multiple	High HD + PA	BMI (% change)	IG1	12	89	31.5 (6.5)	-2.8 (4.57)	58	31.1 (6.5)	0 (NR)	NR, <0.001
	Multiple	High HD + PA	Weight (% change)	IG1	12	89	89.1 (21)	-2.8 (4.57)	58	86.5 (20)	0 (NR)	NR, <0.001
Estruch, 2018 ⁶⁷ (Primary Prevention of	Multiple	High HD only	Waist circumference (cm)	IG1	12	2524	100.2 (10.4)	-0.66 (6.14)	2420	100.9 (10.8)	-0.45 (7.07)	-0.35 (-0.70 to 0.00), 0.05
Cardiovascular Disease with a Mediterranean	Multiple	High HD only	Waist circumference (cm)	IG2	12	2433	100.2 (10.5)	-0.41 (6.27)	2420	100.9 (10.8)	-0.45 (7.07)	-0.08 (-0.45 to 0.29), 0.671
Diet (PREDIMED)) Fair	Multiple	High HD only	Waist circumference (cm)	IG1	36	2127	100.2 (10.4)	0.14 (7.79)	1851	100.9 (10.8)	0.81 (8.79)	-0.71 (-1.16 to - 0.25), 0.002
	Multiple	High HD only	Waist circumference (cm)	IG2	36	2114	100.2 (10.5)	0.44 (8.23)	1851	100.9 (10.8)	0.81 (8.79)	-0.37 (-0.86 to 0.11), 0.133
	Multiple	High HD only	Waist circumference (cm)	IG1	60		100.2 (10.4)	0.85 (8.38)	1243	100.9 (10.8)		-0.55 (-1.16 to - 0.06), 0.048
	Multiple	High HD only	Waist circumference (cm)	IG2	60	1241	100.2 (10.5)	0.37 (8.91)	1243	100.9 (10.8)	1.2 (9.37)	-0.94 (-1.60 to - 0.27), 0.006

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
	Multiple	High	Weight (kg)	IG1	12	2524	76.7 (11.8)		2420	77 (12.2)	-0.23	-0.02 (-0.23 to
		HD only			1			(3.63)			(4.19)	0.20), 0.876
	Multiple	High	Weight (kg)	IG2	12	2433	76.6 (11.9)	0.01 (3.9)	2420	77 (12.2)	-0.23	0.14 (-0.09 to
		HD only									(4.19)	0.36), 0.231
	Multiple	High	Weight (kg)	IG1	36	2127	76.7 (11.8)		1851	77 (12.2)	-0.24	-0.36 (-0.68 to -
		HD only						(4.71)			(5.62)	0.04), 0.026
	Multiple	High	Weight (kg)	IG2	36	2114	76.6 (11.9)		1851	77 (12.2)	-0.24	-0.06 (-0.40 to
		HD only						(5.07)			(5.62)	0.28), 0.712
	Multiple	High	Weight (kg)	IG1	60	1501	76.7 (11.8)		1243	77 (12.2)		-0.43 (-0.86 to -
		HD only						(5.31)				0.01), 0.044
	Multiple	High	Weight (kg)	IG2	60	1241	76.6 (11.9)		1243	77 (12.2)		-0.08 (-0.50 to
		HD only	_					(5.28)				0.35), 0.73
Fagerberg, 1998 ⁶⁸	Multiple	High	BMI $(kg/m^2)$	IG1	12	239	27.3 (3.9)	-0.6 (1.2)	238	26.9 (3.5)	-0.1 (1)	MD=-0.40 (-0.70
(Risk Factor		HD + PA										to -0.20), 0.000
Intervention	Multiple	High	BMI $(kg/m^2)$	IG1	40	235	27.3 (3.9)	-0.6 (1.6)	227	26.9 (3.5)	-0.2 (1.4)	MD=-0.40 (-0.60
Study (RIS))		HD + PA										to -0.10), 0.0007
Good (KQ1); Fair	Multiple	High	Weight (kg)	IG1	12	239	83.4 (14.1)	-1.9 (3.6)	238	82.1 (11.9)	-0.6 (3.1)	-1.30 (-1.95 to -
(KQ2)		HD + PA										0.65), 0.000
	Multiple	High	Weight (kg)	IG1	40	227	83.4 (14.1)	0.8 (4.2)	235	82.1 (11.9)	-2 (4.7)	MD=-1.20 (-2.00
		HD + PA										to -0.30), 0.006
	Multiple	High	Weight (kg)	IG1	79	248	83.4 (14.1)		252	82.1 (11.9)		-1.50 (-2.21 to -
		HD + PA						(4.42)				0.79),
Gill, 2019 ⁶⁹	Multiple	High	BMI (kg/m2)	IG1	6	96	31.8 (5.01)	NR (NR)	79	31.57		-1.50 (-2.09 to -
(Heartmatters		HD + PA								(4.48)		0.91), 0.001
Challenge - First	Multiple	High	BMI (kg/m2)	IG1	12	96	31.8 (5.01)	NR (NR)	79	31.57	NR (NR)	-0.88 (-1.64 to -
Responders)		HD + PA								(4.48)		0.12), 0.06
Fair	Multiple	High	Waist	IG1	6	96	104.59	NR (NR)	79	106.5		-2.12 (-5.61 to
		HD + PA	circumference				(12.75)			(12.87)		1.37), 0.27
			(cm)									
	Multiple	High	Waist	IG1	12	96	104.59	NR (NR)	79	106.5	NR (NR)	-4.05 (-5.79 to -
		HD + PA	circumference				(12.75)			(12.87)		2.31), 0.003
			(cm)									
	Multiple	High	Weight (kg)	IG1	6	96	NR (NR)	NR (NR)	79	NR (NR)		-5.09 (-7.03 to -
		HD + PA										3.15), 0.001

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		(SD)	mean change (SD)	Between-group difference,† p- value
	Multiple	High HD + PA	Weight (kg)	IG1	12	96	NR (NR)	NR (NR)	79	NR (NR)	NR (NR)	-3.88 (-5.78 to - 1.98), 0.006
Gill, 2019 ⁷⁰ (HealtheSteps)	Multiple	Medium HD + PA	BMI (kg/m2)	IG1	6	59	NR (NR)	-0.34 (1.84)	59	NR (NR)	-0.1 (1.75)	-0.23 (-0.89 to 0.42), <0.05
Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	59	103.4 (17.1)		59	102.8 (15.7)	0.01 (6.04)	-1.53 (-3.74 to 0.69), 0.17
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	59	84.2 (20.6)	-0.81 (5.26)	59	86.1 (23.6)	-0.35 (4.95)	-0.46 (-2.35 to 1.42), 0.63
Greaves, 2015 ⁷¹ (Waste the Waist)	Multiple	High HD + PA	BMI (kg/m²)	IG1	12	55	33 (3.2)	NR (NR)	53	32.3 (3)	NR (NR)	-0.51 (-1.28 to 0.26), NSD
Fair	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	55	110 (10.7)	NR (NR)	53	110 (8.8)	NR (NR)	-2.18 (-4.43 to 0.06), 0.06
	Multiple	High HD + PA	Weight (kg)	IG1	12	55	96.6 (14)	-3.65 (5.22)	53	97.6 (12.8)	-1.9 (6.69)	-1.85 (-4.08 to 0.38), 0.103
Groeneveld, 2010 ⁷² (Health	Multiple	Medium HD + PA	BMI (kg/m ² )	IG1	6	261	28.8 (3.5)	-0.5 (1.11)	256	28.2 (3.6)	0.2 (1.19)	-0.70 (-0.90 to - 0.50), <0.05
Under Construction)	Multiple	Medium HD + PA	BMI (kg/m ² )	IG1	12	261	28.8 (3.5)	-0.3 (1.16)	256	28.2 (3.6)	0.3 (1.22)	-0.60 (-0.81 to - 0.39), <0.05
Fair	Multiple	Medium HD + PA	Weight (kg)	IG1	6	261	93.1 (13.2)	-1.4 (4.16)	256	92 (12.8)	0.6 (4.18)	-2.00 (-2.72 to - 1.28), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	261	93.1 (13.2)	-0.9 (4.28)	256	92 (12.8)	0.9 (4.25)	-1.80 (-2.54 to - 1.06), <0.05
Hardcastle, 2008 ⁷³	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	6	203	33.66 (5.12)	-0.13 (1.62)	131	33.37 (4.47)	0.06 (1.62)	-0.19 (-0.55 to 0.17), <0.05
Fair	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	18	203	33.66 (5.12)	0.02 (1.6)	131	33.37 (4.47)	0.67 (1.53)	-0.65 (-0.99 to - 0.31), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	203	93.64 (15.93)	-0.62 (4.99)	131	91.38 (16.88)	0.13 (5.45)	-0.75 (-1.91 to 0.41), <0.05
	Multiple	Medium HD + PA	Weight (kg)	IG1	18	203	93.64 (15.93)	0.48 (5)	131	91.38 (16.88)	1.37 (5.44)	-0.89 (-2.05 to 0.27), NSD
Harris, 2012 ⁷⁴ (Health	Multiple	High HD + PA	BMI (kg/m²)	IG1	12	355	28.97 (5.58)	-0.91 (1.76)	300	29.68 (6.9)	-1.29 (2.24)	0.38 (0.07 to 0.69), 0.5

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
Improvement and Prevention Study (HIPS))		High HD + PA	Waist circumference (cm)	IG1 (Females)	12	232	NR (NR)	NR (NR)		NR (NR)	NR (NR)	·
Fair	Multiple	High HD + PA	Waist circumference (cm)	IG1 (Males)	12	152	NR (NR)	NR (NR)	146	NR (NR)	NR (NR)	NR, 0.7
	Multiple	High HD + PA	Weight (kg)	IG1	12	355	NR (NR)	-0.07 (5.77)	300	NR (NR)	0.05 (6.3)	-0.12 (-1.05 to 0.81), 0.7
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	160	115.6 (12.1)	-4.8 (12.46)	154	114.6 (12.6)	-0.8 (12.8)	-4.00 (-5.20 to - 2.80), <0.0001
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	160	107.4 (18.2)	-4.3 (4.9)	154	106.1 (20.3)	-0.8 (4.6)	-3.50 (-4.55 to - 2.45), <0.0001
HPT, 1990 ⁷⁷ (Hypertension	HTN	High HD only	Weight (kg)	IG1	6	178	78.5 (NR)	, ,		` ′	0.27 (2.47)	0.00 (-0.50 to 0.50), <0.05
Prevention Trial (HPT))	HTN	High HD only	Weight (kg)	IG2	6	170	79.5 (NR)	, ,	189	77.5 (NR)	0.27 (2.47)	-0.27 (-0.72 to 0.18), 0.025
Good	HTN	High HD only	Weight (kg)	IG3	6	112	87.4 (NR)	(2.86)	119	83.4 (NR)	0.18 (2.95)	-5.76 (-6.56 to - 4.96), <0.001
	HTN	High HD only	Weight (kg)	IG4	6	111	84.1 (NR)	-3.9 (2.84)	119	83.4 (NR)	0.18 (2.95)	-4.08 (-4.83 to - 3.33), <0.05
	HTN	High HD only	Weight (kg)	IG1	36	176	, ,	1.13 (3.58)	175	77.5 (NR)	1.59 (3.57)	-0.46 (-1.21 to 0.29), <0.05
	HTN	High HD only	Weight (kg)	IG2	36	172	79.5 (NR)	0.95 (3.54)	175	77.5 (NR)	1.59 (3.57)	0.64 (-0.07 to 1.35), 0.179
	HTN	High HD only	Weight (kg)	IG3	36	117	87.4 (NR)	NR (NR)	113	83.4 (NR)	1.86 (4.36)	-3.49 (-4.65 to - 2.33), <0.001
	HTN	High HD only	Weight (kg)	IG4	36	114	84.1 (NR)	-0.14 (4.38)	113	83.4 (NR)	1.86 (4.36)	-2.00 (-3.14 to - 0.86), <0.05
Hyman, 1998 ⁷⁸ Fair	Dys	Medium HD only	Weight (kg)	IG1	6	65	86.64 (19.53)	-1.09 (NR)	58	87.37 (20.25)	-0.77 (NR)	-0.32 (NR), 0.53
Hyman, 2007 ⁷⁹ Fair	HTN	Medium HD + PA	BMI (kg/m²)	IG1	6	92	31.8 (7.5)	-0.1 (2.35)	93	33.4 (8.2)	-0.1 (2.58)	0.00 (-0.71 to 0.71), <0.05
	HTN	Medium HD + PA	BMI (kg/m²)	IG2	6	96	31.9 (7.8)	0 (2.51)	93	33.4 (8.2)	-0.1 (2.58)	0.10 (-0.63 to 0.83), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
	HTN	Medium HD + PA	BMI (kg/m²)	IG1	18	92	` '	0.1 (2.37)		33.4 (8.2)	-0.6 (2.57)	0.70 (-0.01 to 1.41), NSD
	HTN	Medium HD + PA	BMI (kg/m²)	IG2	18	96	31.9 (7.8)	0.3 (2.8)	93	33.4 (8.2)	-0.6 (2.57)	0.90 (0.13 to 1.67), NSD
Johnston, 1995 Fair	Dys	Medium HD only	Weight (kg)	IG1	6	40	NR (NR)	NR (NR)	47	NR (NR)	NR (NR)	NR, NSD
	Dys	Medium HD only	Weight (kg)	IG2	6	43	NR (NR)	NR (NR)	47	NR (NR)	NR (NR)	NR, NSD
Jones, 1999 ⁸² (Hypertension	HTN	High HD only	Weight (kg)	IG1	6	51	97 (18)	-3.2 (4.3)	51	92 (18)	-1.8 (2.7)	-1.40 (-2.79 to - 0.01), 0.05
Optimal Treatment	HTN	High HD only	Weight (kg)	IG1	12	51	97 (18)	-1.61 (NR)	51	92 (18)	-1.28 (NR)	NR, NSD
(HOT)) Fair	HTN	High HD only	Weight (kg)	IG1	18	51	97 (18)	-1.82 (NR)	51	92 (18)	-1.44 (NR)	NR, NSD
	HTN	High HD only	Weight (kg)	IG1	24	51	97 (18)	-1.74 (NR)	51	92 (18)	-1.99 (NR)	NR, NSD
	HTN	High HD only	Weight (kg)	IG1	30	51	97 (18)	-1.26 (NR)	51	92 (18)	-2.22 (NR)	NR, NSD
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	31	95 (13)	-0.7 (7.13)	32	98 (11)	1.6 (7.16)	-2.30 (-5.61 to 0.96), NSD
Intervention (SAHELI)) Fair	Multiple	High HD + PA	Weight (kg)	IG1	6	31	72.6 (10.9)	)-1.6 (2.78)	32	77.1 (14.5)	)-0.2 (2.83)	-1.50 (-2.81 to - 0.07), <0.05
Kanke, 2015 ⁸⁴ Fair	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	25	NR (NR)	NR (NR)	19	NR (NR)	NR (NR)	NR, NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	22	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	NR, 0.68

(Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	mean change (SD)	Between-group difference,† p- value
Kastarinen, 2002 ⁸⁵ (Lifestyle	HTN	High HD + PA	Weight (kg)	IG1	12	360	81.1 (15.7)	-1.5 (NR)	355	80 (14.8)	` /	MD=-1.30 (-1.70 to -0.90), <0.05
Intervention against Hypertension in Eastern Finland (LIHEF)) Fair	HTN	High HD + PA	Weight (kg)	IG1	24	360	81.1 (15.7)	-1.5 (NR)	355	80 (14.8)	-0.3 (NR)	-1.20 (-1.70 to - 0.70), <0.05
Khanji, 2019 ⁸⁷ (HAPPY London)	Multiple	Low HD + PA	BMI (kg/m2)	IG1	6	194	28.1 (5.6)	-0.42 (1.75)	183	27.4 (4.4)	-0.25 (1.39)	-0.17 (-0.40 to 0.00), 0.07
'	Multiple	Low HD + PA	Waist circumference (cm)	IG1	6	194	95.8 (15.2)		183	95.4 (12)	-2.05 (12)	-0.50 (-1.50 to 0.50), 0.31
	Multiple	Low HD + PA	Weight (kg)	IG1	6	194	80.7 (18.4)	-1.22 (5.78)	183	79.7 (16)	-0.76 (5.03)	-0.45 (-1.00 to 0.10), 0.10
Kramer, 2018 ⁸⁹ (Healthy Lifestyle	Multiple	High HD + PA	BMI (kg/m ² )	IG1	6	81	34.9 (6.7)	-1.9 (1.7)	43	33.4 (4.9)	-0.3 (1.3)	-1.60 (-2.14 to - 1.06), <0.0001
	Multiple	High HD + PA	Waist circumference (in)	IG1	6	81	108.2 (14.73)	-4.32 (5.08)	43	105.66 (11.94)	-0.03 (5.08)	-4.29 (-6.17 to - 2.41), <0.0001
	Multiple	High HD + PA	Weight (kg)	IG1	6	81	96.32 (21)	-5.35 (4.94)	43	91.38 (16.82)	-0.77 (3.27)	-4.58 (-6.03 to - 3.13), <0.0001
Langford, 1991 ⁹¹ (Trial of	HTN	High HD + PA	Weight (kg)	IG1	6	263	87.5 (NR)		264	87.9 (NR)	-0.9	-3.80 (-4.60 to - 3.00), <0.05
Antihypertensive Interventions and Management (TAIM)) Fair	HTN	High HD only	Weight (kg)	IG2	6	257	87.9 (NR)		264	87.9 (NR)	-0.9	0.60 (-0.20 to 1.40), NSD
Lee, 2007 ⁹² Fair	HTN	Medium PA only	BMI (kg/m²)	IG1	6	91	25.4 (3.8)	-0.03 (NR)	93	25.31 (3.5)	-0.21 (NR)	NR, NSD
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	46	89.3 (12.9)		42	86.2 (11.4)	-0.7	1.00 (-0.74 to 2.74), NSD
Moreau, 2001 ⁹⁵ Fair	HTN	Low PA only	Weight (kg)	IG1	6	15	81.1 (22.85)	-1.3 (7.17)	9	79.1 (22.2)	0.6 (7.07)	-1.90 (-7.78 to 3.98), NSD

# Appendix H Table 11. Adiposity, Continuous (KQ2)

(Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N		IG mean change (SD)	CG N	CG baseline mean (SD)	mean	Between-group difference,† p- value
Moy, 2001 ⁹⁶ Fair	Multiple	High HD only	BMI (kg/m ² )	IG1	24	117	28.5 (5)	-0.1 (1)	118	29.5 (7)	0.21 (2)	-0.31 (-0.71 to 0.09), 0.164
Neil, 1995 ⁹⁹ Fair	Dys	Medium HD only	BMI (kg/m ² )	IG1	6	103	26.64 (4.06)	-0.24 (1.28)	102	26.32 (4.32)	-0.24 (1.36)	0.00 (-0.36 to 0.36), NSD
	Dys	Medium HD only	BMI (kg/m ² )	IG2	6	104	26.31 (3.93)	-0.07 (1.32)	102	26.32 (4.32)	-0.24 (1.36)	0.17 (-0.20 to 0.54), NSD
Fair	HTN	Medium HD + PA	BMI (kg/m²)	IG1	12	112		0 (1.08)	108	28.4 (4.1)	-0.1 (1.59)	0.10 (-0.83 to 1.03), 0.86
Reid, 2014 ¹⁰³ Fair	Multiple	High HD + PA	BMI (kg/m²)	IG1	12	211	29.2 (5.4)	-1.3 (1.72)	215	29.6 (6)	-0.6 (1.92)	-0.70 (-1.05 to - 0.35), 0.9
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	211	96.3 (13.5)	-3.8 (13.45)	215	97.4 (15.1)		-1.50 (-4.15 to 1.15), 0.9
Rodriguez- Cristobal, 2012 ¹⁰⁵ Fair	Multiple	High HD + PA	BMI (kg/m²)	IG1	24	146	30.3 (5.8)	-0.7 (1.95)	154	30.5 (5.1)	1.3 (1.59)	MD=-1.70 (-2.20 to -1.10), 0.0001
Rosas, 2015 ¹⁰⁶ (Vivamos Activos	Multiple	High HD + PA	BMI (kg/m ² )	IG1	6	82	35.5 (5.1)	-0.8 (1.39)	41	34.9 (4.4)	-0.4 (1.11)	-0.40 (-0.85 to 0.05), 0.07
Fair Oaks (VAFO))	Multiple	High HD + PA	BMI (kg/m ² )	IG2	6	84	36 (5.7)	-0.6 (1.64)	41	34.9 (4.4)	-0.4 (1.11)	-0.20 (-0.69 to 0.29), 0.27
Good	Multiple	High HD + PA	BMI (kg/m ² )	IG1	12	82	35.5 (5.1)	-0.7 (1.85)	41	34.9 (4.4)	-0.3 (1.74)	-0.40 (-1.07 to 0.27), 0.2
	Multiple	High HD + PA	BMI (kg/m²)	IG2	12	84	36 (5.7)	-0.6 (2.1)	41	34.9 (4.4)	-0.3 (1.74)	-0.30 (-1.00 to 0.40), 0.39
	Multiple	High HD + PA	BMI (kg/m²)	IG1	24	82	35.5 (5.1)	-0.4 (2.54)	41	34.9 (4.4)	-0.2 (2.85)	-0.20 (-1.23 to 0.83), 0.72
	Multiple	High HD + PA	BMI (kg/m ² )	IG2	24	84	36 (5.7)	-0.4 (2.81)	41	34.9 (4.4)	-0.2 (2.85)	-0.20 (-1.26 to 0.86), 0.67
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	82	NR (NR)	-0.6 (1.85)	41	NR (NR)		-0.60 (-1.39 to 0.19), 0.14
	Multiple	High HD + PA	Waist circumference (cm)	IG2	6	84	NR (NR)	-0.7 (2.57)	41	NR (NR)		-0.70 (-1.57 to 0.17), 0.11

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	82	NR (NR)	-0.6 (3.7)		NR (NR)	-1.3 (2.85)	0.70 (-0.48 to 1.88), 0.26
	Multiple	High HD + PA	Waist circumference (cm)	IG2	12	84	NR (NR)	-1.5 (3.27)	41	NR (NR)	-1.3 (2.85)	-0.20 (-1.32 to 0.92), 0.76
	Multiple	High HD + PA	Waist circumference (cm)	IG1	24	82	NR (NR)	-0.8 (3.23)	41	NR (NR)	-0.7 (3.01)	-0.10 (-1.26 to 1.06), 0.95
	Multiple	High HD + PA	Waist circumference (cm)	IG2	24	84	NR (NR)	-1.4 (3.27)	41	NR (NR)	-0.7 (3.01)	-0.70 (-1.86 to 0.46), 0.24
	Multiple	High HD + PA	Weight (% change)	IG1	6	82	NR (NR)	-0.02 (0.05)	41	NR (NR)	-0.01 (0.03)	-0.01 (-0.02 to 0.00), 0.24
	Multiple	High HD + PA	Weight (% change)	IG2	6	84	NR (NR)	-0.02 (0.05)	41	NR (NR)	-0.01 (0.03)	-0.01 (-0.02 to 0.00), 0.5
	Multiple	High HD + PA	Weight (% change)	IG1	12	82	NR (NR)	(0.07)	41	NR (NR)	-0.01 (0.06)	-0.01 (-0.03 to 0.01), 0.92
	Multiple	High HD + PA	Weight (% change)	IG2	12	84	NR (NR)	(0.07)	41	NR (NR)	-0.01 (0.06)	0.00 (-0.02 to 0.02), 0.96
	Multiple	High HD + PA	Weight (% change)	IG1	24	82	NR (NR)	(0.07)	41	NR (NR)	0 (0.08)	-0.02 (-0.05 to 0.01), 0.72
	Multiple	High HD + PA	Weight (% change)	IG2	24	84	NR (NR)	(0.49)	41	, , ,	0 (0.08)	-0.01 (-0.12 to 0.10), 0.92
	Multiple	High HD + PA	Weight (kg)	IG1	6	82	89.3 (15.9)	(3.47)	41	88.6 (15.2)	(3.17)	-1.20 (-2.43 to 0.03), 0.05
	Multiple	High HD + PA	Weight (kg)	IG2	6	84	89.3 (15.9)	(3.97)	41	88.6 (15.2)	(3.17)	-0.70 (-1.99 to 0.59), 0.28
	Multiple	High HD + PA	Weight (kg)	IG1	12	82	89.3 (15.9)	(4.62)	41	88.6 (15.2)	(4.75)	-1.20 (-2.97 to 0.57), 0.21
	Multiple	High HD + PA	Weight (kg)	IG2	12	84	89.3 (15.9)	(4.91)	41	88.6 (15.2)	(4.75)	-0.70 (-2.49 to 1.09), 0.49
	Multiple	High HD + PA	Weight (kg)	IG1	24	82	89.3 (15.9)	1 (6.47)	41	88.6 (15.2)	-0.6 (6.81)	-0.40 (-2.91 to 2.11), 0.76

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)		Between-group difference,† p- value
	Multiple	High HD + PA	Weight (kg)	IG2	24	84	89.3 (15.9)	-1 (7.95)	41	88.6 (15.2)		-0.40 (-3.09 to 2.29), 0.78
Rubinstein, 2016 ¹⁰⁷	HTN	Medium HD + PA	BMI (kg/m ² )	IG1	12	94	28.7 (5.4)	0.2 (1.75)	96	30 (5.6)	0.2 (1.77)	-0.06 (-0.50 to 0.39), 0.81
Good	HTN	Medium HD + PA	Waist circumference (cm)	IG1	12	94	96.3 (13.8)	1.1 (14.06)	96	97.6 (12.5)		-0.06 (-2.29 to 2.16), 0.95
	HTN	Medium HD + PA	Weight (kg)	IG1	12	94	79.8 (17.3)	0.6 (5.71)	96	82.9 (16.3)	0.3 (5.09)	-0.03 (-1.28 to 1.23), 0.97
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	6	301	31.2 (5.4)	-0.5 (1.73)	296	30.9 (5.7)	-0.3 (1.78)	MD=-0.30 (-0.50 to -0.10), 0.006
	Multiple	Medium HD + PA	BMI (kg/m²)	IG1	12	293	31.2 (5.4)	-0.7 (1.71)	291	30.9 (5.7)	\ /	MD=-0.40 (-0.60 to -0.10), 0.008
	Multiple	Medium HD + PA	Weight (kg)	IG1	6	301	93.2 (17.3)	-1.5 (5.55)	296	91.9 (18.9)	-0.8	MD=-0.90 (-1.50 to -0.20), 0.006
	Multiple	Medium HD + PA	Weight (kg)	IG1	12	293	93.2 (17.3)	-1.9 (5.51)	291	91.9 (18.9)		MD=-1.00 (-1.80 to -0.30), 0.008
Scott, 2018 ¹¹⁰ Fair	Multiple	Medium PA only	BMI (kg/m ² )	IG1	6	17	NR (NR)	NR (NR)	18	NR (NR)	NR (NR)	Hedges g=0.02 (- 0.64 to 0.69), 0.961
	Multiple	Medium PA only	Weight (kg)	IG1	6	17	89.59 (12.13)	0 (4.65)	18	89.21 (17.2)	0.18 (9.44)	-0.18 (-5.07 to 4.71), 0.925
Soto Rodriguez, 2016 ¹¹¹	Multiple	Medium HD only	BMI (kg/m ² )	IG1	12	117	27.57 (5.52)	0.12 (1.57)	113	27.34 (5.3)		-0.35 (-0.75 to 0.04), 0.018
Fair	Multiple	Medium HD only	Waist circumference (cm)	IG1	12	117	105.3 (10.6)	0.03 (3.16)	113	106 (9.87)		-0.76 (-1.62 to 0.10), 0.034
Stefanick, 1998 ¹¹² (Diet and	Dys	High HD only	Weight (kg)	IG1 (Females)	12	46	NR (NR)	-2.7 (3.5)	45	NR (NR)	` ′	-3.50 (-5.09 to - 1.91), <0.001
Exercise for Elevated Risk (DEER)) Fair	Dys	High HD only	Weight (kg)	IG1 (Males)	12	49	NR (NR)	-2.8 (3.5)	46	NR (NR)	0.5 (2.7)	-3.30 (-4.55 to - 2.05), <0.001
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance	Multiple	High HD + PA	Percent weight change (% change)	IG1	30	341	NR (NR)	NR (NR)	341	NR (NR)	NR (NR)	LS Mean change=-1.80 (NR), <0.001

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
(WLM)) Good	Multiple	High HD + PA	Percent weight change (% change)	IG2	30	347	NR (NR)	NR (NR)		NR (NR)		LS Mean change=-0.40 (NR), 0.5
	Multiple	High HD + PA	Weight (kg)	IG1	6	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-0.90 (NR), 0.001
	Multiple	High HD + PA	Weight (kg)	IG2	6	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-0.80 (NR), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	12	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-1.60 (NR), <0.001
	Multiple	High HD + PA	Weight (kg)	IG2	12	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	
	Multiple	High HD + PA	Weight (kg)	IG1	18	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	
	Multiple	High HD + PA	Weight (kg)	IG2	18	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	LS Mean change=-1.10 (NR), 0.003
	Multiple	High HD + PA	Weight (kg)	IG1	24	341	88.7 (16.9)	NR (NR)	341	87.4 (15.3)	NR (NR)	
	Multiple	High HD + PA	Weight (kg)	IG2	24	347	88.6 (15.4)	NR (NR)	341	87.4 (15.3)	NR (NR)	
	Multiple	High HD + PA	Weight (kg)	IG1	30	341	88.7 (16.9)	4 (5.54)	341	87.4 (15.3)	5.5 (5.54)	
	Multiple	High HD + PA	Weight (kg)	IG2	30	347	88.6 (15.4)	5.2 (5.59)	341	87.4 (15.3)	5.5 (5.54)	

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)		Between-group difference,† p- value
	Multiple	High	Weight (kg)	IG1	60	243	88.3 (16.7)	NR (NR)	246	87.3 (15.4)	NR (NR)	-1.60 (-3.10 to -
		HD + PA										0.10), < 0.05
Svetkey, 2009 ¹¹⁵	HTN	High	Weight (kg)	IG1	6	132	91.83	-3.17	132	91.65	-0.14	-3.04 (-4.00 to -
(Hypertension		HD + PA					(17.01)	(4.85)		(17.96)	(2.86)	2.08), <0.05
Improvement	HTN	High	Weight (kg)	IG2	6	124	87.21	-2.36	132	91.65	-0.14	-2.22 (-3.21 to -
Project (HIP))		HD + PA					(17.23)	(4.85)		(17.96)	(2.86)	1.24), <0.05
Fair	HTN	Medium	Weight (kg)	IG3	6	137	90.25	0.05	132	91.65	-0.14	0.18 (-0.80 to
		HD + PA					(17.41)	(5.08)		(17.96)	(2.86)	1.16), NSD
	HTN	High	Weight (kg)	IG1	18	128	91.83	-1.72	122	91.65	-0.95	-0.77 (-2.01 to
		HD + PA					(17.01)	(4.44)		(17.96)	(5.44)	0.46), $< 0.05$
	HTN	High	Weight (kg)	IG2	18	124	87.21	-1.18	122	91.65	-0.95	-0.23 (-1.60 to
		HD + PA					(17.23)	(5.53)		(17.96)	(5.44)	1.14), NSD
	HTN	Medium	Weight (kg)	IG3	18	134	90.25	-0.18	122	91.65	-0.95	0.77 (-0.64 to
		HD + PA					(17.41)	(6.08)		(17.96)	(5.44)	2.18), NSD
Ter Bogt, 2009 ¹¹⁶	Multiple	High	Waist	IG1	12	103	97 (9.8)	-2 (7.8)	114	97 (11.8)	-1.5 (6.8)	-0.50 (-2.46 to
(Groningen Overweight and		HD + PA	circumference (cm)	(Females)								1.46), NSD
Lifestyle	Multiple	High	Waist	IG1	12	98	104 (7.8)	-2.8 (6.2)	101	105 (9.5)	-0.9 (4.5)	-1.90 (-3.41 to -
(GOAL)) Good		HD + PA	circumference (cm)	(Males)								0.39), <0.05
	Multiple	High	Weight (kg)	IG1	12	169	88.3 (12.1)		172	87.6 (13.7)	$-0.9(5)^{\ddagger}$	-1.00 (-2.05 to
		HD + PA						$(4.9)^{\ddagger}$				0.05), <0.05
	Multiple	High	Weight (kg)	IG1	12	103	NR (NR)	-1.5 (4.1)	114	NR (NR)	-1.4 (4.9)	-0.10 (-1.30 to
		HD + PA		(Females)								1.10), NSD
	Multiple	High	Weight (kg)	IG1	12	98	NR (NR)	-2.1 (4.8)	101	NR (NR)	0 (3.9)	-2.10 (-3.32 to -
		HD + PA		(Males)								0.88), <0.05
	Multiple	High HD + PA	Weight (kg)	IG1	36	148	88.3 (12.1)	-1.4 (5.4)	165	87.6 (13.7)	-1 (5.2)	-0.40 (-1.58 to 0.78), 0.726
Tiessen, 2012 ¹¹⁷	Multiple	Medium	BMI (kg/m ² )	IG1	12	89	28 (3.3)	-0.1	90	29 (4)	-0.1	-0.04 (-0.50 to
(SPRING (Self-		HD + PA						(1.32)			(1.67)	0.40), NSD
monitoring and	Multiple	Medium	Waist	IG1	12	89	101 (8)	-3.7	90	102 (10.8)	-1.9	-1.80 (-3.40 to -
Prevention of	_	HD + PA	circumference					(5.29)			(5.88)	0.20), < 0.05
RIsk Factors by			(cm)									
Nurse												
practitioners in												
the region of												

(Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N		IG mean change (SD)	CG N	baseline		Between-group difference,† p- value
Groningen)) Fair												
TOHP I CRG, 1992 ¹¹⁹ (Trials of	HTN	High HD only	Weight (kg)	IG1	6	327	82.7 (14.3)	NR (NR)	417	82.8 (14)	NR (NR)	-1.23 (NR), <0.0001
,	HTN	High HD + PA	Weight (kg)	IG2	6	294	90.2 (13.3)	-5.68 (5.74)	237	89.3 (13)	-0.01 (3.24)	-5.67 (-6.45 to - 4.90), <0.01
	HTN	High HD only	Weight (kg)	IG1	12	327	82.7 (14.3)		417	82.8 (14)		-0.82 (NR), 0.002
	HTN	High HD only	Weight (kg)	IG1	18	327	82.7 (14.3)	NR (NR)	417	82.8 (14)	NR (NR)	-0.39 (NR), 0.19
	HTN	High HD + PA	Weight (kg)	IG2	18	293	90.2 (13.3)	-3.83 (6.12)	235	89.3 (13)	0.07 (4.01)	-3.90 (-4.77 to - 3.03), <0.01
TOHP II CRG, 1997 ¹²⁰ (Trial of	HTN	High HD + PA	Weight (kg)	IG1	6	566	93.6 (14.2)	-4.1 (5.1)	561	93.6 (13.5)	0.1 (3.2)	-4.30 (-4.89 to - 3.71), <0.001
Prevention II	HTN	High HD + PA	Weight (kg)	IG2	6	565	93.4 (14.1)	-4.4 (5.2)	561	93.6 (13.5)	0.1 (3.2)	-4.50 (-5.09 to - 3.91), <0.001
(TOHP II)) Good	HTN	High HD only	Weight (kg)	IG3	6	539	94 (14.3)	-1.1 (3.7)	561	93.6 (13.5)	0.1 (3.2)	-1.20 (-1.59 to - 0.81), <0.001
	HTN	High HD + PA	Weight (kg)	IG1	18	545	93.6 (14.2)	-2.2 (5.6)	551	93.6 (13.5)	0.7 (4.2)	-2.90 (-3.49 to - 2.31), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	18	545	93.4 (14.1)	-2 (5.8)	551	93.6 (13.5)	0.7 (4.2)	-2.70 (-3.30 to - 2.10), <0.001
	HTN	High HD only	Weight (kg)	IG3	18	532	94 (14.3)	0.4 (4.3)	551	93.6 (13.5)	0.7 (4.2)	-0.30 (-0.89 to 0.29), 0.19
	HTN	High HD + PA	Weight (kg)	IG1	36	552	93.6 (14.2)	-0.3 (5.5)	554	93.6 (13.5)	1.8 (5.3)	-2.10 (-2.69 to - 1.51), <0.001
	HTN	High HD + PA	Weight (kg)	IG2	36	547	93.4 (14.1)	-0.2 (5.9)	554	93.6 (13.5)	1.8 (5.3)	-1.90 (-2.60 to - 1.30), <0.001
	HTN	High HD only	Weight (kg)	IG3	36	549	94 (14.3)	1.7 (5.2)	554	93.6 (13.5)	1.8 (5.3)	0.00 (-0.59 to 0.59), 0.92
van der Veen, 2002 ¹²²	Dys	Medium HD only	BMI (kg/m²)	IG1	6	70	28.1 (4.3)	-0.5 (0.6)	67	29.2 (4.8)	-0.2 (0.7)	-0.30 (-0.52 to - 0.08), 0.01
(Nijmegen Family Practices	Dys	Medium HD only	BMI (kg/m ² )	IG1	12	67	28.1 (4.3)	0 (1.1)	63	29.2 (4.8)	-0.2 (1)	0.20 (-0.16 to 0.56), 0.03

	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)			mean	Between-group difference,† p- value
Monitoring Project (NFPMP)) Fair	Dys )	Medium HD only	Waist circumference (cm)	IG1	6	70	94.3 (12.1)	-1.6 (4.9)	67	97.7 (10.3)	-1.7 (5.2)	0.10 (-1.59 to 1.79), 0.43
	Dys	Medium HD only	Waist circumference (cm)	IG1	12	67	94.3 (12.1)	-1.6 (6.6)	63	97.7 (10.3)		0.20 (-1.90 to 2.30), 0.61
	Dys	Medium HD only	Weight (kg)	IG1	6	70	79.2 (14.9)	-1.3 (1.8)	67	80.3 (12)	-0.6 (1.9)	-0.70 (-1.32 to - 0.08), 0.01
	Dys	Medium HD only	Weight (kg)	IG1	12	67	79.2 (14.9)	, ,	63	80.3 (12)	, , ,	0.80 (-0.20 to 1.80), 0.02
van Sluijs, 2005 ¹²⁴ (Physician-based Assessment and	Multiple	Medium PA only	BMI (kg/m²)	IG1	12	171	29.3 (5.7)	NR (NR)	187	28.6 (4.2)	NR (NR)	Beta coefficient=0.21 (-0.14 to 0.55), 0.24
Counseling for Exercise (PACE)) Fair	Multiple	Medium PA only	Waist circumference (cm)	IG1	12	171	97.9 (14.1)	NR (NR)	187	98.3 (12.1)	NR (NR)	Beta coefficient=2.00 (0.92 to 3.07), <0.001
	Multiple	Medium PA only	Weight (kg)	IG1	12	171	85.8 (17.9)	NR (NR)	187	85.1 (15.2)	NR (NR)	Beta coefficient=0.27 (-0.45 to 1.00), 0.46
Viglione, 2019 ¹²⁵ (Goals for Eating	Multiple	High HD + PA	Weight (kg)	IG1	6	21	NR (NR)	-1.52 (3.05)	22	NR (NR)	0.23 (3.64)	-1.75 (-3.75 to 0.25), 0.08
and Moving (GEM)) Fair	Multiple	High HD + PA	Weight (kg)	IG1	12	21	NR (NR)	-1.02 (4.16)	22	NR (NR)	0.74 (4.9)	-1.76 (-4.47 to 0.95), 0.40
Wadden, 2011 ¹²⁷ M. (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-LIP))	Multiple	High HD + PA	BMI (kg/m²)	IG1	6	131	38.5 (4.6)	-1.3 (2.29)	130	39 (4.8)	-0.7 (2.28)	-0.60 (-1.15 to - 0.05), 0.02
		High HD + PA	BMI (kg/m ² )	IG1	12		38.5 (4.6)	-1.3 (2.29)	130	39 (4.8)	-0.8 (2.28)	-0.50 (-1.05 to 0.05), 0.18
	Multiple	High HD + PA	BMI (kg/m²)	IG1	18	131	38.5 (4.6)	-1.1 (2.29)	130	39 (4.8)		-0.40 (-0.95 to 0.15), 0.17
	Multiple	High HD + PA	BMI (kg/m²)	IG1	24	131	38.5 (4.6)	-0.9 (2.29)	130	39 (4.8)	-0.6 (2.28)	-0.30 (-0.85 to 0.25), 0.27

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
	Multiple	High HD + PA	Percent weight change (% change)		6		NR (NR)	-3.5 (5.72)	130	NR (NR)		-1.70 (-3.09 to - 0.31), 0.005
	Multiple	High HD + PA	Percent weight change (% change)		12		NR (NR)	-3.5 (6.87)	130	NR (NR)	-2.1 (6.84)	-1.40 (-3.06 to 0.26), 0.08
	Multiple	High HD + PA	Percent weight change (% change)	IG1	18	131	NR (NR)	-3.1 (8.01)	130	NR (NR)	-1.7 (7.98)	-1.40 (-3.34 to 0.54), 0.1
	Multiple	High HD + PA	Percent weight change (% change)	IG1	24	131	NR (NR)	-2.9 (8.01)	130	NR (NR)	-1.6 (6.84)	-1.30 (-3.11 to 0.51), 0.12
	Multiple	High HD + PA	Waist circumference (cm)	IG1	6	131	117.1 (11.9)	-4.9 (6.87)	131	119.8 (13.9)	-2.7 (6.87)	-2.20 (-3.86 to - 0.54), 0.002
	Multiple	High HD + PA	Waist circumference (cm)	IG1	12	131	117.1 (11.9)	-4.6 (6.87)	130	119.8 (13.9)	-3.2 (6.84)	-1.40 (-3.06 to 0.26), 0.089
	Multiple	High HD + PA	Waist circumference (cm)	IG1	24	131	117.1 (11.9)	-4 (8.01)	130	119.8 (13.9)	-2.3 (7.98)	-1.70 (-3.64 to 0.24), 0.056
	Multiple	High HD + PA	Weight (kg)	IG1	6	131	106.3 (17.3)	-3.5 (5.72)	130	111.2 (20)	-2 (5.7)	-1.50 (-2.89 to - 0.11), 0.03
	Multiple	High HD + PA	Weight (kg)	IG1	12	131	106.3 (17.3)	-3.4 (6.87)	130	111.2 (20)	-2.3 (6.84)	-1.10 (-2.76 to 0.56), 0.23
	Multiple	High HD + PA	Weight (kg)	IG1	18	131	106.3 (17.3)	-3 (8.01)	130	111.2 (20)		-1.10 (-3.04 to 0.84), 0.22
	Multiple	High HD + PA	Weight (kg)	IG1	24	131	106.3 (17.3)	-2.9 (8.01)	130	111.2 (20)	-1.7 (7.98)	-1.20 (-3.14 to 0.74), 0.22
Wister, 2007 ¹²⁹ Good	Multiple	Medium HD + PA	BMI (kg/m ² )	IG1	12	157	31.8 (6.9)	-0.47 (1.95)	158	33.2 (7.6)	-0.33 (1.8)	-0.14 (-0.55 to 0.27), NSD
	Multiple	Medium HD + PA	Waist circumference (cm)	IG1	12	157	105.7 (17.2)	-2.81 (7.03)	158	108.1 (17.7)	-2.31 (7.05)	-0.50 (-2.06 to 1.06), NSD
Wong, 2015 ¹³⁰ Good	HTN	Low HD only	BMI (kg/m²)	IG1	6	254	24.17 (2.83)	-0.49 (4.8)	250	24.23 (3.06)	-0.33 (5.08)	-0.11 (-0.24 to 0.02), 0.08

#### Appendix H Table 11. Adiposity, Continuous (KQ2)

/ <b>V</b>	Population				Timepoint	IG N		IG mean				Between-group
` '	risk focus	time*	(Unit)		(months)			change		baseline	mean	difference,† p-
Quality		Intervention					mean	(SD)		mean	change	value
		focus					(SD)			(SD)	(SD)	
	HTN	Low	BMI (kg/m ² )	IG1	12	243	24.17	-0.52	242	24.23	-0.39	-0.05 (-0.20 to
		HD only					(2.83)	(4.77)		(3.06)	(5.08)	0.10), 0.49
Wood, 2008 ¹³¹	Multiple	High	BMI (kg/m ² )	IG1	12	1019	NR (NR)	-0.47	332	NR (NR)	0.13	-0.56 (-0.86 to -
(EUROACTION)		HD + PA						(NR)			(NR)	0.25), 0.005
Fair	Multiple	High	Waist	IG1	12	1019	NR (NR)	-1.66	332	NR (NR)	-0.21	-1.61 (-2.61 to -
		HD + PA	circumference					(NR)			(NR)	0.61), 0.009
			(cm)									
	Multiple	High	Weight (kg)	IG1	12	332	NR (NR)	NR (NR)	1019	NR (NR)	NR (NR)	-1.51 (-2.53 to -
		HD + PA										0.50), 0.01

**Abbreviations:** BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; kg = kilograms; kg/m² = kilograms per meter squared; KQ = key question; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

[‡]Mean percent change in weight (kg)

#### Appendix H Table 12. Adiposity, Dichotomous (KQ2)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention	Outcome	Int arm	Timepoint (months)	IG n/N (%)		RR [†] (95% CI), p- value
1 201142 (DOWED	N	focus	100/ 11/	TC1		21/124	4/112 (2.5)	7.06 (2.57 + 10.20)
Appel, 2011 ⁴² (POWER	Multiple	High	≥10% weight	IG1	6		4/113 (3.5)	7.06 (2.57 to 19.38), <0.001
Hopkins (Practice Based Opportunities for Weight	M14:1-	HD + PA	loss	ICO	6	(25.0)	4/112 (2.5)	
Reduction))	Multiple	High	≥10% weight	IG2	0		4/113 (3.5)	6.57 (2.39 to 18.08),
Good	N ( 1 ( 1 . 1 .	HD + PA	loss	IG1	2.4	(23.3)	11/120 (0.6)	<0.001
Good	Multiple	High	≥10% weight	IGI	24		11/128 (8.6)	2.27 (1.17 to 4.41),
	N # 1.1 1	HD + PA	loss	100	2.4	(19.5)	11/120 (0.6)	0.01
	Multiple	High	≥10% weight	IG2	24		11/128 (8.6)	2.13 (1.09 to 4.17),
	N # 1.1 1	HD + PA	loss	IC1		(18.3)	1.6/1.10	0.02
	Multiple	High	≥5% weight loss	IGI	6	57/124		3.25 (1.98 to 5.31),
	N # 1.1 1	HD + PA	50/ : 1.1	100		(46.0)	(14.2)	<0.001
	Multiple	High	≥5% weight loss	IG2	6	68/129		3.72 (2.30 to 6.03),
	3.6.1.1.1	HD + PA	50/ 1.1	TC1	2.4	(52.7)	(14.2)	<0.001
	Multiple	High	≥5% weight loss	IGI	24			2.21 (1.46 to 3.34),
		HD + PA	50/ 11/1	7.00	2.4	(41.4)	(18.8)	<0.001
	Multiple	High	≥5% weight loss	IG2	24		24/128	2.04 (1.34 to 3.10),
201247		HD + PA	50/ 1.1.1			(38.2)	(18.8)	<0.001
Bennett, 2012 ⁴⁷ (Be Fit, Be	HTN	High	≥5% weight loss	IG1	24	36/180	36/185	1.03 (0.68 to 1.55),
Well [POWER])		HD + PA				(20.0)	(19.5)	
Good								
Bennett, 2018 ⁴⁸ (Track)	Multiple	Medium	≥5% weight loss	IG1	6	73/170	10/167 (6.0)	6.80 (3.60 to 12.70),
Good		HD + PA				(42.9)		< 0.001
	Multiple	Medium	≥5% weight loss	IG1	12		28/167	2.40 (1.60 to 3.50),
		HD + PA				(40.6)	(16.8)	< 0.001
Bo, 2007 ⁵²	Multiple	Medium	BMI $\geq$ 25 kg/m ²	IG1	12	141/169	149/166	OR=0.58 (0.30 to 1.10),
Fair		HD + PA				(83.4)	(89.8)	0.1
Christian, 2011 ⁵⁸	Multiple	Medium	≥10% weight	IG1	12	10/133 (7.5)	3/130 (2.3)	OR=3.40 (NR), 0.024
Fair		HD + PA	loss					
	Multiple	Medium	≥5% weight loss	IG1	12		11/130 (8.5)	OR=3.86 (NR), 0.001
		HD + PA				(26.3)		
Cicolini, 2014 ⁵⁹	HTN	Medium	Percent obese	IG1	6		25/98 (25.5)	0.90 (0.55 to 1.48), 0.7
Fair		HD + PA				(23.0)		
Kandula, 2015 ⁸³ (South Asian	Multiple	High	≥5% weight loss	IG1	6	6/31 (19.4)	3/32 (9.4)	2.06 (0.57 to 7.54),
Heart Lifestyle Intervention		HD + PA						0.26
(SAHELI))								
Fair								

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p- value
Kastarinen, 2002 ⁸⁵ (Lifestyle Intervention against Hypertension in	HTN	High HD + PA		IG1	12			Difference in probability=3.90 (0.10 to 7.70), NSD
Eastern Finland (LIHEF)) Fair	HTN	High HD + PA		IG1	24	24/294 (8.2)	, ,	Difference in probability=4.60 (1.00 to 8.40), <0.05
	HTN	High HD + PA	BMI loss ≥5%	IG1	12	55/294 (18.7)		Difference in probability=9.40 (3.80 to 15.00), <0.05
	HTN	High HD + PA	BMI loss ≥5%	IG1	24	65/294 (22.1)	29/279 (10.4)	Difference in probability=11.70 (5.80 to 17.70), <0.05
Khanji, 2019 ⁸⁷ (HAPPY London)	Multiple	Low HD + PA	BMI ≤25 kg/m ²	IG1	6	74/194 (38.1)	66/184 (35.9)	1.06 (0.82 to 1.38), 0.65
Good	Multiple	Low HD + PA	WC at goal (WC <102 cm for males; <88 cm for females)	IG1	6	127/194 (65.5)	119/184 (64.7)	1.01 (0.87 to 1.17), 0.87
Kramer, 2018 ⁸⁹ (Healthy Lifestyle Project)	Multiple	High HD + PA	≥5% weight loss	IG1	6	45/81 (55.6)	4/43 (9.3)	5.97 (2.30 to 15.50), <0.001
Fair	Multiple	High HD + PA	≥7% weight loss	IG1	6	32/81 (39.5)	2/43 (4.7)	8.49 (2.14 to 33.76), <0.001
Scott, 2018 ¹¹⁰ Fair	Multiple	Medium PA only	≥5% weight loss	IG1	6		0/18 (0.0)	7.39 (0.41 to 133.24), NSD
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM))	Multiple	High HD + PA	≥5% weight loss	IG1	30	144/341 (42.2)	116/341 (34.0)	1.24 (1.02 to 1.51), 0.02
Good	Multiple	High HD + PA	≥5% weight loss	IG2	30	122/347 (35.2)	116/341 (34.0)	1.03 (0.84 to 1.27), NSD
	Multiple	High HD + PA	≥5% weight loss	IG1	60	72/194 (37.1)	59/218 (27.1)	1.37 (1.03 to 1.82), 0.052
Wadden, 2011 ¹²⁷ (Practice- based Opportunities for	Multiple	High HD + PA	≥10% weight loss	IG1	12	14/131 (10.7)	5/130 (3.8)	2.78 (1.03 to 7.49), 0.04
Weight Reduction at the University of Pennsylvania	Multiple	High HD + PA	≥10% weight loss	IG1	24	13/131 (9.9)	` ′	1.61 (0.69 to 3.76), NSD
(POWER-UP)) Good	Multiple	High HD + PA	≥5% weight loss	IG1	12	38/131 (29.0)	32/130 (24.6)	1.18 (0.79 to 1.76), NSD

#### Appendix H Table 12. Adiposity, Dichotomous (KQ2)

, , , , , , , , , , , , , , , , , , , ,	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)		RR [†] (95% CI), p- value
	Multiple	High HD + PA	≥5% weight loss	IG1	24	34/131 (26.0)		1.21 (0.78 to 1.87), NSD
Wood, 2008 ¹³¹ (EUROACTION) Fair	Multiple  Multiple	High HD + PA High	_	IG1 (Overweight subgroup) IG1	12	134/814 (16.5) 230/1018		Difference in probability=10.40 (4.70 to 16.10), 0.005 Difference in
	Munipic	HD + PA	Divir 325 kg/m	101	12	(22.6)	(22.0)	probability=0.60 (-6.90 to 8.00), 0.85
	Multiple	High HD + PA	Percent obese	IG1	12	355/1018 (34.9)	291/1002 (29.0)	1.20 (1.06 to 1.36), <0.05
	Multiple	High HD + PA	Waist circumference	IG1	12	234/1009 (23.2)	(15.2)	Difference in probability=7.90 (-2.30 to 18.10), 0.1

**Abbreviations:** CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = control group; Int arm = intervention arm; Intervention

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

# Appendix H Table 13. CVD Risk Score Outcomes (KQ2)

(Study name) Quality	Population risk focus	focus	(Instrument)		Timepoint (months)	IG N	baseline mean (SD)	, ,		baseline mean (SD)	change (SD)	Between-group difference,† p- value
Bruckert, 2008 ⁵⁵ (PEGASE (Effect of an Education Program)) Fair	Dys	Medium HD + PA	10-year CVD risk (Modified Framingham Anderson model)	IG1	6	274	13.6 (8.48)	-0.66 (8.35)	199	12.4 (7.81)		-0.72 (-4.43 to 2.99), 0.08
Burke, 2006 ⁵⁶ (ADAPT) Fair	HTN	Medium HD + PA	10-year CHD risk (Wilson, 1998 model)	(Females)	40	67	2.8 (NR)	0.7 (NR)		2.5 (NR)		NR, 0.560
	HTN	Medium HD + PA	10-year CHD risk (Wilson, 1998 model)	IG1 (Males)	40	56	10.2 (NR)	2 (NR)	51	8.9 (NR)	3.2 (NR)	NR, 0.748
Cochrane, 2012 ⁶⁰ Fair	Multiple	Medium HD + PA	10-year CVD risk (Framingham Anderson Model)	IG1	12	236	\ /	-2.8 (6.15)	365	32.9 (9.7)		0.30 (-0.73 to 1.33), NSD
Coleman, 2012 ⁶² (Wisewoman California) Fair	Multiple	Medium HD + PA	10-year CHD risk (Framinghan Anderson model)	IG1	12	433	0.07 (0.05)	-0.01 (NR)	436	0.07 (0.05)	0 (NR)	NR, 0.51
Edelman, 2006 ⁶⁵ Fair	Multiple	High HD + PA	10-year CHD risk (Framingham, Wilson 1998 model)	IG1	10	77	9.3 (NR)	16 (NR)	77	11.1 (NR)	12 (NR)	NR, 0.04
Greaves, 2015 ⁷¹ (Waste the Waist) Fair	Multiple	High HD + PA	10-year CVD risk (QRISK2)	IG1	12	55	23.6 (9.8)	NR (NR)	51	22.5 (10.4)		-0.76 (-2.19 to 0.66), NSD
	Multiple	High HD + PA	5-year CVD risk (Absolute 5-yr CVD risk)	IG1	12	355	NR (NR)	NR (NR)	300	NR (NR)	NR (NR)	NR, 0.1

# Appendix H Table 13. CVD Risk Score Outcomes (KQ2)

(Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Instrument)	Int arm	Timepoint (months)		baseline mean (SD)	. ,	CG N		change (SD)	Between-group difference,† p- value
Khanji, 2019 ⁸⁷ (HAPPY London) Good	Multiple	Low HD + PA	10-year CVD risk (Framingham)	IG1	6	194	16 (9)	-1.23 (8.95)	183	17.8 (10)	(9.76)	0.14 (-0.90 to 1.20), 0.79
	Multiple	Low HD + PA	10-year CVD risk (QRISK2)	IG1	6	194	NR (NR)	0.14 (NR)	183	NR (NR)		0.24 (-0.40 to 0.60), 0.63
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE w/o DM; UKPDS w/ DM)	IG1	12	286	` /	-0.5 (4.55)	261	5.4 (6.3)		0.20 (-0.69 to 1.09), 0.023
Lakerveld, 2013 ⁹⁰ (HOORN) Fair	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE)	IG1	6			0 (3)	308	3.8 (2.9)	(2.95)	0.10 (-0.37 to 0.57), NSD
	Multiple	Medium HD + PA	10-year CVD mortality risk (SCORE)	IG1	12	314	4 (3)	0 (3)	308	3.8 (2.9)		0.10 (-0.46 to 0.66), NSD
Langford, 1991 ⁹¹ (Trial of Antihypertensive Interventions and	HTN	High HD + PA	8-year CVD risk (Framingham Risk Score)	IG1	6	235		0.89 (0.33)	229	NR (NR)		-0.09 (-0.15 to - 0.03), <0.05
(TAIM)) Fair	HTN	High HD only	8-year CVD risk (Framingham Risk Score)	IG2	6			0.93 (0.3)			(0.33)	-0.05 (-0.11 to 0.01), <0.05
Nolan, 2018 ¹⁰¹ (Reducing Risk with E-based Support for Adherence to Lifestyle Change in Hypertension (REACH))	HTN	High HD + PA	10-year CVD risk (Framingham risk index for CVD)	IG1	12	100	16.5 (8.83)	-1.9 (7.14)	97	14.6 (8.76)		-2.10 (-4.12 to -0.08), 0.02

#### Appendix H Table 13. CVD Risk Score Outcomes (KQ2)

, v	Population risk focus	Contact time* Intervention focus			Timepoint (months)			IG mean change (SD)	CG N		change	Between-group difference,† p- value
Salisbury, 2016 ¹⁰⁸	Multiple			IG1	6		31.1 (10.2)	0.3	296	30.8 (9.5)	0.2 (9.5)	MD=0.10 (-0.20
Good			risk (QRISK2)					(10.25)				to 0.40), 0.49
	Multiple		10-year CVD	IG1	12	295	31.1 (10.2)		291	30.8 (9.5)	, ,	MD=-0.40 (-1.20
			risk (QRISK2)					(10.46)				to 0.30), 0.27
Ter Bogt, 2009 ¹¹⁶	Multiple	_	10-year CVD	IG1	12	103	NR (NR)	0.1(1.7)	114	NR (NR)		-0.36 (-1.21 to
(Groningen			mortality risk	(Females)								0.49), NSD
Overweight and			(SCORE)									
Lifestyle	Multiple	_	10-year CVD	IG1 (Males)	12	98	NR (NR)	-0.23	101	NR (NR)		-0.16 (-0.77 to
(GOAL))			mortality risk					(2.8)			(1.3)	0.45), NSD
Good			(SCORE)									
	Multiple		10-year CVD	IG1	12	89	NR (NR)		90	NR (NR)		-0.20 (-1.10 to
(SPRING (Self-			mortality risk					(2.89)				0.60), NSD
monitoring and			(SCORE)									
Prevention of												
RIsk Factors by												
Nurse												
practitioners in the												
region of												
Groningen))												
Fair							4.5.7.7.00					1.00 ( 5.04
Wister, 2007	Multiple		10-year CVD	IG1	12	157	12.5 (5.9)	-3.1	158	11 (6)	-1.3	-1.80 (-3.04 to -
Good			risk					(5.63)			(5.64)	0.56), <0.01
			(Framingham									
			global risk									
			score)									

**Abbreviations:** CG = control group; CHD = coronary heart disease; CI = confidence interval; CVD = cardiovascular disease; DM = diabetes mellitus; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; MD = mean difference; NR = not reported; NSD = no statistically significantly difference; SD = standard deviation; UKPDS = UK Prospective Diabetes Study; w/o = without

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

#### Appendix H Table 14. Other Intermediate Outcomes (KQ2)

Author, year (Study name)	Population risk	Contact time*	Outcome	Int arm	Timepoint	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-
Quality		Intervention focus			(months)			value
Anderssen, 1995 ⁴⁰ (Oslo Diet and	Multiple	Medium	METS	IG1 (Males	12	22/34 (64.7)	23/26 (88.5)	0.73 (0.55 to 0.97),
Exercise Study (ODES))		HD only	prevalence	w/METS at				0.023
Fair				BL)				
Bo, 2007 ⁵²	Multiple	Medium	METS	IG1	12	59/169 (34.9)	109/166	OR=0.28 (0.18 to
Fair		HD + PA	incidence				(65.7)	0.44), < 0.001
Chirinos, 2016 ⁵⁷ (Community	Multiple	High	METS	IG1	6	NR	NR	NR, NSD
Health and Risk-reduction for		HD + PA	prevalence					
Metabolic Syndrome	Multiple	High	METS	IG1	12	NR	NR	NR, NSD
(CHARMS))		HD + PA	prevalence					
Fair								
Estruch, 2018 ⁶⁷ (Primary	Multiple	High	METS	IG1	60	1320/1982	1326/1934	0.97 (0.93 to 1.01),
Prevention of Cardiovascular		HD only	prevalence			(66.6)	(68.6)	
Disease with a Mediterranean	Multiple	High	Incident PAD	IG2	60	26/2452 (1.1)	45/2444 (1.8)	HR=0.52 (0.32 to
Diet (PREDIMED))		HD only						0.86), $< 0.05$
Fair	Multiple	High	METS	IG2	60	1223/1885	1326/1934	0.95 (0.90 to 0.99),
		HD only	prevalence			(64.9)	(68.6)	
	Multiple	High	Incident PAD	IG1	60	18/2539 (0.7)	45/2444 (1.8)	HR=0.36 (0.20 to
		HD only						0.62), < 0.05
	Multiple	High	METS	IG2	38	333/662	298/594	HR=1.08 (0.92 to
		HD only	incidence			(50.3)	(50.2)	1.27), NSD
	Multiple	High	METS	IG1	38	329/663	298/594	HR=1.10 (0.94 to
		HD only	incidence			(49.6)	(50.2)	1.30), NSD
Greaves, 2015 ⁷¹ (Waste the	Multiple	High	METS	IG1	12	21/54 (38.9)	32/53 (60.4)	0.64 (0.43 to 0.96),
Waist)		HD + PA	prevalence					0.034
Fair								
Liira, 2014 ⁹³	Multiple		METS	IG1	12	27/46 (58.7)	21/42 (50.0)	1.17 (0.80 to 1.73),
Fair		HD + PA	prevalence					0.33

**Abbreviations:** BL = baseline; CG = control group; CI = confidence interval; Dys = dyslipidemia; HD = healthy diet; HD + PA = healthy diet and physical activity; HR = hazard ratio; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; METS = metabolic syndrome; NR = not reported; NSD = no statistically significantly difference; OR = odds ratio; PAD = peripheral artery disease; RR = risk ratio

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	change	Between-group difference,† p- value
Anderson, 1992 ³⁹ Fair	Dys	High HD only	Fiber (g/day)	IG1	12	48	19 (11.09)	5.6 (13.16)	51	17 (10)	0.1 (10)	5.50 (0.87 to 10.13), <0.05
	Dys	High HD only	Fiber (g/day)	IG2	12	47	17 (7.54)	3 (8.91)	51	17 (10)	0.1 (10)	2.90 (-0.84 to 6.64), NSD
	Dys	High HD only	MUFA (% energy)	IG1	12	48	12 (2.77)	-2 (3.46)	51	11 (2.86)	0 (3.57)	-2.00 (-3.39 to - 0.61), <0.05
	Dys	High HD only	energy)	IG2	12	47	12 (3.43)	-2 (3.43)	51	11 (2.86)	0 (3.57)	-2.00 (-3.39 to - 0.61), <0.05
	Dys	High HD only	energy)	IG1	12	48	8 (2.08)	-1 (2.77)	51	7 (2.86)	0 (2.86)	-1.00 (-2.11 to 0.11), NSD
	Dys	High HD only	PUFA (% energy)	IG2	12	47	8 (2.74)	0 (3.43)	51	7 (2.86)	0 (2.86)	0.00 (-1.25 to 1.25), NSD
	Dys	High HD only	Saturated fat (% energy)	IG1	12	48	11 (2.77)	-3 (3.46)	51	11 (3.57)	-1 (3.57)	-2.00 (-3.39 to - 0.61), <0.05
	Dys	High HD only	Saturated fat (% energy)	IG2	12	47	11 (3.43)	-2 (2.74)	51	11 (3.57)	-1 (3.57)	-1.00 (-2.25 to 0.25), <0.05
Anderssen, 1995 ⁴ (Oslo Diet and Exercise Study	Multiple	Medium HD only	Dietary pattern score (score)	IG1 (Males)	12	45	30.7 (6.5)	1.2 (6.2)	36	29.6 (7.1)	-1.7 (5.1)	2.90 (0.44 to 5.36), <0.05
(ODES)) Fair	Multiple	Medium HD only	MUFA (g/day)	IG1 (Males)	12	43	37.2 (13.6)	-12.3 (11.3)	36	33.1 (9.9)	-1.6 (11.2)	-10.70 (-15.68 to -5.72), <0.001
	Multiple	Medium HD only	PUFA (g/day)	IG1 (Males)	12	43	18.8 (8)	-4.9 (6.6)	36	16 (5.8)	-0.5 (5.7)	-4.40 (-7.11 to - 1.69), ≤0.05
	Multiple	Medium HD only	Saturated fat (g/day)	ÌG1	12	52	NR (NR)	-14 (12.98)	43	NR (NR)	-1.9 (13.11)	-12.10 (-17.37 to -6.83), <0.05
Appel, 2003 ⁴¹ (PREMIER) Good	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	243	4.7 (2.5)	3 (3.6)	248	4.4 (2.3)	` /	2.50 (1.93 to 3.07), <0.001
H	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	6	237	4.6 (2.3)	0.5 (2.6)	248	4.4 (2.3)	` /	0.00 (-0.48 to 0.48), 0.79
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	18	243	4.7 (2.5)	2.8 (3.4)	248	4.4 (2.3)	0.3 (2.7)	2.60 (2.20 to 3.10), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	18	237	4.6 (2.3)	0.1 (2.7)	248	4.4 (2.3)		-0.10 (-0.50 to 0.40), NSD
	HTN	High HD + PA	MUFA (% energy)	IG1	6	236	12.8 (3.5)	, ,		, í	, ,	-3.80 (-4.42 to - 3.18), <0.0001
	HTN	High HD + PA	energy)	IG2	6	233	, ,	-1.8 (3.6)		12.4 (3.2)	, ,	-1.50 (-2.12 to - 0.88), <0.0001
	HTN	High HD + PA	energy)	IG1	18	247	12.8 (3.5)	` ′	249	12.4 (3.2)	` ′	-2.60 (-3.22 to - 1.98), <0.0001
	HTN	High HD + PA	energy)	IG2	18	241	, ,	-1.2 (3.7)		12.4 (3.2)	` ′	-0.80 (-1.43 to - 0.17), NSD
	HTN	High HD + PA	(mmol/L)	IG1	6	214	, ,	19.3 (32.1)	233	, ,	, ,	20.60 (14.94 to 26.26), <0.001
	HTN	High HD + PA	(mmol/L)	IG2	6	223	66.6 (23.9)	, , ,		Ì	, ,	2.20 (-2.51 to 6.91), 0.35
	HTN	High HD + PA	(mmol/L)	IG1	18	214	68.1 (27)	, , ,		Ì	, ,	12.70 (7.80 to 17.70), <0.05
	HTN	High HD + PA	(mmol/L)	IG2	18	233	66.6 (23.9)	` /		, ,		2.70 (-2.20 to 7.60), NSD
	HTN	High HD + PA	energy)	IG1	6	236	` ′	-1.7 (2.42)		6.7 (2.3)	, ,	-1.50 (-1.92 to - 1.08), <0.0001
	HTN	High HD + PA	energy)	IG2	6	233	` ′	-0.6 (2.51)		6.7 (2.3)	, í	-0.40 (-0.83 to 0.03), NSD
	HTN	High HD + PA	energy)	IG1	18	247	` ′	-1.2 (2.51)		6.7 (2.3)	, í	-1.20 (-1.63 to - 0.77), <0.01
	HTN	High HD + PA	energy)	IG2	18	241	7 (2.6)	-0.4 (2.65)		6.7 (2.3)		-0.40 (-0.84 to 0.04), NSD
	HTN	High HD + PA	Saturated fat (% energy)		6	243		-3.3 (3.9)		10.9 (3.3)	` ′	-2.90 (-3.59 to - 2.21), <0.001
	HTN	High HD + PA	Saturated fat (% energy)		6	237	10.9 (3.1)	` '	248	, í	, ,	-1.10 (-1.80 to - 0.40), <0.001
	HTN	High HD + PA	Saturated fat (% energy)		18	243	10.9 (3)	-2.9 (3.4)		, í	` ′	-2.30 (-2.80 to - 1.80), <0.05
	HTN	High HD + PA	Saturated fat (% energy)	IG2	18	237	10.9 (3.1)	-1.1 (3.7)	248	10.9 (3.3)	, ,	-0.60 (-1.10 to 0.00), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	change (SD)	CG N		change	Between-group difference,† p- value
	HTN	High		IG1	6	214	177.3 (80)		233	173.2	-20.6	-12.00 (-25.93 to
	T TOTAL	HD + PA	(mmol/24-hr)	100		222	1.67.4	(78.1)	222	(69.5)	(71.6)	1.93), 0.12
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	6	223	165.4 (70.1)	-31.6 (74.7)	233	173.2 (69.5)	-20.6 (71.6)	-11.00 (-24.44 to 2.44), 0.01
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	18	214	177.3 (80)	-24.5 (85.2)	233	173.2 (69.5)	-5.6 (89.8)	-15.40 (-29.10 to -1.70), <0.05
	HTN	High HD + PA		IG2	18	223	165.4 (70.1)		233	173.2 (69.5)	-5.6 (89.8)	-16.70 (-30.30 to -3.20), <0.05
Arroll, 1995 ⁴⁴ Fair	HTN	Low HD + PA		IG1	6	48			43		NR (NR)	
	HTN	Low PA only	Sodium (mmol/24-hr)	IG2	6	46	NR (NR)	NR (NR)	43	NR (NR)	NR (NR)	NR
	HTN	Low HD only	Sodium (mmol/24-hr)	IG3	6	44	NR (NR)	NR (NR)	43	NR (NR)	NR (NR)	NR
	HTN	Low HD + PA	Sodium (score)	IG1	6	48	21.3 (9.01)	-7 (8.17)	43	21.2 (8.52)	` ′	-6.10 (-9.41 to - 2.79), <0.05
	HTN	Low PA only	Sodium (score)	IG2	6	46	22 (8.82)	-1.4 (8)	43	21.2 (8.52)		-0.50 (-3.81 to 2.81), NSD
	HTN	Low HD only	Sodium (score)	IG3	6	44	22.3 (8.62)	-7.1 (8.04)	43	21.2 (8.52)	, ,	-6.20 (-9.56 to - 2.84), <0.05
Beckmann, 1995 ⁴ Fair	HTN	Medium HD only		IG1	6	32	195 (67.88)	-79 (65.24)	32	177 (56.57)	-2 (70.65)	-77.00 (-110.32 to -43.68), <0.05
	HTN	Medium HD only		IG1	12	32	195 (67.88)	-72 (59.06)	32	177 (56.57)	-10	MD=-44.00 (- 89.72 to -34.28),
Bennett, 2012 ⁴⁷ (Be Fit, Be Well [POWER]) Good	HTN	High HD + PA	(score, subscale of Hill-Bone Instrument)	IG1	6	180	5.52 (1.58)	,		5.23 (1.5)	-0.15 (1.09)	-0.45 (-0.68 to - 0.21), <0.001
	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	12	180	5.52 (1.58)	-0.64 (1.21)	185	5.23 (1.5)		-0.51 (-0.76 to - 0.27), <0.001

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	change (SD)	CG N	baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	18	180	5.52 (1.58)	-0.57 (1.21)	185	5.23 (1.5)	-0.18 (1.22)	-0.39 (-0.63 to - 0.14), 0.002
	HTN	High HD + PA	Sodium (score, subscale of Hill-Bone Instrument)	IG1	24	180	5.52 (1.58)	-0.61 (1.21)	185	5.23 (1.5)	-0.27 (1.09)	-0.33 (-0.56 to - 0.11), 0.004
Bennett, 2018 ⁴⁸ (Track) Good	Multiple	Medium HD + PA		IG1	12	113	2.35 (0.66)	-0.06 (0.71)	127	2.4 (0.75)	0.05 (0.72)	-0.11 (-0.29 to 0.07), 0.10
	Multiple	Medium HD + PA	Dietary pattern score (DASH nutrients score)	IG1	12	113	1.74 (1.38)	1.28 (1.51)	127	1.89 (1.46)	0.2 (1.32)	1.08 (0.72 to 1.44), <0.001
	Multiple	Medium HD + PA	Fiber (g/1000 kcal)	IG1	12	113	9.08 (3.25)	2.54 (3.38)	127	9.07 (3.22)		2.08 (1.27 to 2.89), <0.001
	Multiple	Medium HD + PA		IG1	12	113	0.91 (0.74)		127	1.01 (0.82)	0.02	0.25 (0.11 to 0.39), 0.06
	Multiple	Medium HD + PA	Potassium (mg/1000 kcal)	IG1	12	113		279.2 (350.02)	127	1355.5 (338.03)	48.38 (296.14)	230.82 (148.25 to 313.39), <0.001
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	12	113	12.31 (2.4)	-0.99 (2.55)	127	12.05 (2.28)	0.26 (2.03)	-1.25 (-1.84 to - 0.66), <0.001
	Multiple	Medium HD + PA	Sodium (mg/d)	IG1	12	113	3315.94 (1463.31)	-977.86 (1229.09)	127	3204.67 (1237.42)	-240.72	-737.14 (- 1036.87 to - 437.41), <0.001
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	12	113	3.12 (2.07)	0.17 (1.83)	127	2.87 (1.87)	0.1 (1.82)	0.07 (-0.39 to 0.53), 0.51
Beune, 2014 ⁴⁹ (Culturally Adapted	HTN	Medium HD + PA	Meeting diet and PA recs (score,	IG1	6	52	2.74 (0.73)		45	2.98 (0.7)	-0.13 (0.67)	0.34 (0.12 to 0.55), 0.003

(Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
Hypertension Education (CAHE)) Fair			Morisky scale)									
Blackford, 2016 ⁵⁰ (Albany Physical Activity and	Multiple	Medium HD + PA	Fiber (score, Fat and Fiber Barometer)	IG1	6	151	23.3 (4.2)	1.6 (4.15)	159	23.4 (4)	0.2 (3.9)	1.40 (0.50 to 2.30), <0.001
(APAN))	Multiple	Medium HD + PA	(servings/d)	IG1	6	151	1.5 (1.3)	0.5 (1.35)	159	1.5 (1.2)	-0.1 (1.15)	0.60 (0.32 to 0.88), 0.106
Fair	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	6	151	4.5 (3.16)	0.9 (3.03)	159	4 (2.99)	0.4 (3)	0.50 (-0.17 to 1.17), NSD
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	6	151	3 (2.3)	0.4 (2.13)	159	2.5 (2.2)	0.5 (2.25)	-0.10 (-0.59 to 0.39), 0.002
Bloemberg, 1991 ⁵¹	Dys	Medium HD only	Fiber (g/MJ)	IG1	6	39	2.4 (0.7)	0.6 (0.9)	40	2.5 (0.7)	0.1 (0.8)	0.50 (0.12 to 0.88), <0.01
Fair	Dys	Medium HD only	energy)	IG1	6	39	14.2 (3.2)	, ,	40	14 (3.2)	-0.6 (2.6)	-2.40 (-3.74 to - 1.06), <0.01
	Dys	Medium HD only	energy)	IG1	6	39	6.8 (2.4)	2.8 (3.1)	40	6.6 (2.9)	0 (1.5)	2.80 (1.72 to 3.88), <0.01
	Dys	Medium HD only	Saturated fat (% energy)		6	39	, í	-4.3 (3.9)		16.3 (4.7)	, ,	-3.60 (-5.12 to - 2.08), <0.01
Bo, 2007 ⁵² Fair	Multiple	Medium HD + PA	Fiber (g/day)	IG1	12	169	19.2 (6.4)	1.7 (3.91)	166	19.4 (7.8)	0.17 (3.09)	1.53 (0.78 to 2.28), <0.001
	Multiple	Medium HD + PA	energy)	IG1	12	169	4.3 (1.3)	0.99 (1.72)	166	4.1 (1.2)	-0.04 (1.84)	1.03 (0.65 to 1.41), <0.001
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	12	169	12.3 (2.6)	-1.97 (3.71)	166	12 (2.6)	-0.17 (3.62)	-1.80 (-2.58 to - 1.02), <0.001
Broekhuizen, 2012 ⁵⁴ (PRO-FIT)	Dys	Medium HD + PA	Fruit (servings/d)	IG1	12	169	1.5 (1.3)	0.1 (1.21)	145	1.4 (1.1)	0 (1.1)	0.10 (-0.16 to 0.36), NSD
Fair	Dys	Medium HD + PA	Saturated fat (g/day)	IG1	12	171	30.8 (9.6)	-2.8 (9.81)	146	28.6 (9.8)	-1.2 (9.51)	-1.60 (-3.73 to 0.53), NSD
	Dys	Medium HD + PA		IG1	12	169	162.1 (75.8)	9.4 (76.2)	146	151.2 (77.8)	12.2 (77.5)	-2.80 (-19.83 to 14.23), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	change (SD)	CG N	CG baseline mean (SD)	change	Between-group difference,† p- value
Burke, 2006 ⁵⁶ (ADAPT)	HTN	Medium HD + PA	Fiber (g/day)	IG1	16	123	24 (7.64)	2.3 (8.8)	118	24.1 (7.2)	0.1 (8.35)	2.20 (0.04 to 4.36), <0.05
Fair	HTN	Medium HD + PA	Fiber (g/day)	IG1	40	123	24 (7.64)	0.2 (7.94)	118	24.1 (7.2)	` ′	0.20 (-1.73 to 2.13), NSD
	HTN	Medium HD + PA	Fruit (servings/d)	IG1	16	123	1.7 (1.13)	0.1 (1.13)	118	1.9 (1.11)	-0.1 (1.11)	0.20 (-0.08 to 0.48), NSD
	HTN	Medium HD + PA		IG1	40	123	1.7 (1.13)	0.2 (0.57)	118	1.9 (1.11)	-0.3 (0.55)	0.50 (0.36 to 0.64), 0.147
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	16	123	4.3 (1.96)	0.8 (2.1)	118	4.6 (1.91)	0 (1.91)	0.80 (0.29 to 1.31), NSD
	HTN	Medium HD + PA		IG1	40	123	4.3 (1.96)	0.8 (1.01)	118	4.6 (1.91)	-0.4 (0.96)	1.20 (0.95 to 1.45), NSD
	HTN	Medium HD + PA		IG1	16	123	10.6 (5.38)	-1.9 (4.66)	)118	10.7 (5.27)	0.1 (5.13)	-2.00 (-3.24 to - 0.76), <0.001
	HTN	Medium HD + PA		IG1	40	123	10.6 (5.38)	-0.7 (4.71)	118	10.7 (5.27)	0.2 (4.73)	-0.50 (-1.69 to 0.69), NSD
	HTN	Medium HD + PA		IG1	16	123	3.3 (1.13)	0 (1.13)	118	3.4 (0.83)	-0.2 (0.83)	0.20 (-0.05 to 0.45), NSD
	HTN	Medium HD + PA		IG1	40	123	3.3 (1.13)	0 (1.02)	118	3.4 (0.83)	-0.1 (1)	0.10 (-0.15 to 0.35), NSD
	HTN	Medium HD + PA		IG1	16	106	79.3 (24.71)	3.8 (27.01)	98	85.4 (20.79)	-2.9 (21.85)	6.70 (-0.02 to 13.42), 0.826
	HTN	Medium HD + PA	PUFA (% energy)	IG1	16	123	4.6 (1.98)	-0.2 (1.98)	118	4.8 (2.22)	-0.2 (2.22)	0.00 (-0.53 to 0.53), NSD
	HTN	Medium HD + PA		IG1	40	123	4.6 (1.98)	0 (1.98)	118	4.8 (2.22)	` ′	0.30 (-0.21 to 0.81), NSD
	HTN	Medium HD + PA	Saturated fat (% energy)	IG1	16	123	12.3 (5.66)	-2.9 (4.91)	118	12 (5.82)	` /	-2.30 (-3.64 to - 0.96), <0.001
	HTN	Medium HD + PA	Saturated fat (% energy)	IG1	40	123	12.3 (5.66)	-1.5 (5.03)	)118	12 (5.82)		-0.90 (-2.19 to 0.39), 0.008
	HTN	Medium HD + PA		IG1	16	123	2.7 (0.85)	-0.4 (0.85)	)118	2.8 (0.83)	-0.2 (1)	-0.20 (-0.43 to 0.03), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	IG baseline mean (SD)	change (SD)		CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
	HTN	Medium		IG1	40	123	2.7 (0.85)	-0.2 (0.85)	118	2.8 (0.83)	-0.1 (0.83)	-0.10 (-0.31 to
		HD + PA	(g/day)									0.11), NSD
	HTN	Medium	Sodium	IG1	16	123	NR (NR)	-156 (312)	118	NR (NR)	-78 (390)	-78.00 (-167.40
		HD + PA	(mg/d)									to 11.40), NSD
	HTN	Medium	Sodium	IG1	40	123	NR (NR)	-78 (312)	118	NR (NR)	-39 (312)	-39.00 (-117.80
		HD + PA	(mg/d)									to 39.80), NSD
	HTN	Medium		IG1	16	106	151.8	11.7	98	160.8	4.3	7.40 (-10.80 to
		HD + PA	(mmol/24-hr)				(50.45)	(62.57)		(66.33)	(69.49)	25.60), 0.896
	HTN	Medium	Vegetables	IG1	16	123	2.6 (1.13)	0.7(1.3)	118	2.7 (1.11)	0.1 (1.11)	0.60 (0.30 to
		HD + PA	(servings/d)									0.90), < 0.001
	HTN	Medium	Vegetables	IG1	40	123	2.6 (1.13)	0.6 (0.61)	118	2.7 (1.11)	-0.1 (0.55)	0.70 (0.55 to
		HD + PA	(servings/d)									0.85), 0.147
Cicolini, 2014 ⁵⁹	HTN	Medium		IG1	6	100	2 (0.9)	0.7 (1.1)	98	1.9 (0.7)	0.2 (0.4)	0.50 (0.27 to
Fair		HD + PA	(servings/d)									0.73), <0.001
	Multiple	Medium	-	IG1	12	236	2.2 (NR)	0.25 (NR)	365	2.1 (NR)	0.3 (NR)	NR
Fair		HD + PA	pattern score									
			(score)									
Delahanty, 2001 ⁶³	Dys	Medium	Fiber (g/day)	IG1	6	44	16 (9)	2 (8.54)	43	18 (10)	-2 (8.72)	4.00 (0.37 to
Good		HD + PA										7.63), NSD
	Dys	Medium	Fiber (g/day)	IG1	12	42	16 (9)	0 (8.19)	44	18 (10)	1 (9.54)	-1.00 (-4.75 to
		HD + PA		7.01		-	10 (5)	2 (4 50)	1.0	10 (5)	1 (1 70)	2.75), NSD
	Dys	Medium	`	IG1	6	44	12 (5)	-3 (4.58)	43	12 (5)	-1 (4.58)	-2.00 (-3.93 to -
		HD + PA	energy)	TO 1	1.2	10	10 (5)	2 (4 50)	1.4	10 (5)	2 (4.50)	0.07), <0.01
	Dys	Medium	`	IG1	12	42	12 (5)	-2 (4.58)	44	12 (5)	-2 (4.58)	0.00 (-1.94 to
	<b>D</b>	HD + PA	energy)	TC 1	-	4.4	C (4)	1 (4)	12	(2)	1 (0 (5)	1.94), NSD
	Dys	Medium	`	IG1	6	44	6 (4)	1 (4)	43	6 (3)	-1 (2.65)	2.00 (0.58 to
	D .	HD + PA	energy)	IG1	12	42	C (1)	1 (2 (1)	44	(2)	0 (2 (5)	3.42), NSD
	Dys	Medium	`	IGI	12	42	6 (4)	-1 (3.61)	44	6 (3)	0 (2.65)	-1.00 (-2.34 to
	<b>D</b>	HD + PA	energy)	TC 1	-	4.4	11 (6)	4 (5 20)	12	11 (4)	1 (4)	0.34), NSD
	Dys	Medium HD + PA	Saturated fat (% energy)	IGI	6	44	11 (6)	-4 (5.29)	43	11 (4)	-1 (4)	-3.00 (-4.97 to - 1.03), <0.001
	Drie	Medium	Saturated fat	IC1	12	44	11 (6)	-3 (5.29)	43	11 (4)	-1 (4)	-2.00 (-3.97 to -
	Dys	HD + PA	(% energy)	IGI	12	44	11 (0)	-3 (3.29)	+3	11 (4)	-1 (4)	0.03), NSD
Eakin, 2009 ⁶⁴	Multiple	Medium		IG1	12	225	1.6 (1)	0.5 (0.9)	204	1.5 (1.3)	0.2 (0.86)	0.30 (0.13 to
(Logan Healthy	riampic	HD + PA	(servings/d)	101	12	223	1.0 (1)	0.5 (0.7)	204	1.5 (1.5)	0.2 (0.00)	0.47), <0.001

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	CG baseline mean (SD)		Between-group difference,† p- value
Living)	Multiple	Medium	Fruit	IG1	18	225	1.6(1)	0.47 (0.9)	204	1.5 (1.3)	0.24	0.22 (0.05 to
Fair		HD + PA	(servings/d)								(0.86)	0.40), 0.01
	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	12	225		1.57 (3.68)	204	4.5 (2.61)	0.53 (3.51)	1.04 (0.36 to 1.72), NSD
	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	18	225	4.6 (2.36)	1.24 (3.68)	204	4.5 (2.61)	0.42 (3.51)	0.82 (0.14 to 1.50), NSD
	Multiple	Medium HD + PA	Saturated fat (% energy)	IG1	12	225	14.5 (3.3)	-1.58 (3.3)	204	14.2 (3.4)	-0.57 (3.29)	-1.01 (-1.64 to - 0.37), 0.002
	Multiple	Medium HD + PA	Saturated fat (% energy)		18	225	14.5 (3.3)	-1.58 (3.3)	204	14.2 (3.4)	-0.52 (3.29)	-1.06 (-1.70 to - 0.43), 0.001
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	12	225	3 (1.7)	1.07 (3.15)	204	3 (1.7)	0.33 (3)	0.73 (0.13 to 1.31), 0.015
	Multiple	Medium HD + PA	Vegetables (servings/d)	IG1	18	225	3 (1.7)	0.77 (3.15)	204	3 (1.7)	0.18 (3)	0.59 (-0.01 to 1.17), 0.051
Ellsworth, 2016 ⁶⁶ Fair	Multiple	High HD + PA	Saturated fat (% change)	IG1	12	89	19.7 (9.1)	-10.4 (NR)	58	22.3 (11)	-1.8 (NR)	NR, 0.02
Estruch, 2018 ⁶⁷ (Primary Prevention of Cardiovascular	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	12	941	8.77 (1.91)	1.81 (1.79)	754	8.4 (1.92)	0.44 (1.81)	1.37 (1.20 to 1.54), <0.01
Disease with a Mediterranean Diet (PREDIMED))	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	12	939	` /	1.98 (1.81)	754	8.4 (1.92)	0.44 (1.81)	1.54 (1.37 to 1.71), <0.01
Fair	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG1	24	935	8.77 (1.91)	1.97 (1.82)	630	8.4 (1.92)	0.53 (1.78)	1.44 (1.26 to 1.62), <0.01
	Multiple	High HD only	Dietary pattern score (score, MEDAS-14)	IG2	24	890		2.14 (1.76)	630	8.4 (1.92)	0.53 (1.78)	1.61 (1.43 to 1.79), <0.01
	Multiple	High HD only	Dietary pattern score	IG1	36	723	8.77 (1.91)	1.85 (1.82)	433	8.4 (1.92)	0.58 (1.84)	1.27 (1.05 to 1.49), <0.01

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	CG baseline mean (SD)	change	Between-group difference,† p- value
			(score, MEDAS-14)									
	Multiple	High HD only		IG2	36	624	8.8 (1.88)	2.12 (1.75)	433	8.4 (1.92)	0.58 (1.84)	1.54 (1.32 to 1.76), <0.01
	Multiple	High HD only		IG1	48	594	8.77 (1.91)	2.03 (1.83)	300	8.4 (1.92)	0.65 (1.83)	1.38 (1.13 to 1.63), <0.01
	Multiple	High HD only		IG2	48	489	8.8 (1.88)	2.23 (1.79)	300	8.4 (1.92)	0.65 (1.83)	1.58 (1.32 to 1.84), <0.01
	Multiple	High HD only		IG1	60	557	8.77 (1.91)	1.97 (1.83)	305	8.4 (1.92)	0.86 (1.8)	1.11 (0.86 to 1.36), <0.01
	Multiple	High HD only		IG2	60	438	8.8 (1.88)	2.24 (1.78)	305	8.4 (1.92)	0.86 (1.8)	1.38 (1.12 to 1.64), <0.01
	Multiple	High HD only		IG1	72	367	8.77 (1.91)	2.02 (1.86)	202	8.4 (1.92)	0.84 (1.82)	1.18 (0.86 to 1.50), <0.01
	Multiple	High HD only		IG2	72	281	8.8 (1.88)	2.32 (1.78)	202	8.4 (1.92)	0.84 (1.82)	1.48 (1.15 to 1.81), <0.01
	Multiple	High HD only	Fiber (g/day)	IG1	60	2364	25.7 (9.1)	-0.29 (10.29)	1941	24.7 (8.4)	-0.93 (9.44)	0.64 (-0.08 to 1.36), 0.1
	Multiple	High HD only	Fiber (g/day)		60	2108	25.7 (8.6)	(10.07)	1941	24.7 (8.4)	(9.44)	2.29 (1.56 to 3.03), <0.001
	Multiple	High HD only	Fruit (servings/d)	IG1	60	2364	3 (1.7)	0.21 (1.86)	1941	2.8 (1.6)		0.05 (-0.09 to 0.19), 0.75

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N		IG mean change (SD)	CG N	CG baseline mean (SD)	change	Between-group difference,† p- value
	Multiple	High		IG2	60	2108	3 (1.6)	0.25	1941	2.8 (1.6)	0.15 (1.8)	0.10 (-0.04 to
		HD only	(servings/d)					(1.87)				0.24), 0.25
	Multiple	High HD only	Fruits and Vegetables (servings/d)	IG1	60	2364	5.8 (2.5)	0.13 (2.91)	1941	5.4 (2.4)		0.07 (-0.11 to 0.25), <0.05
	Multiple	High HD only	Fruits and Vegetables (servings/d)	IG2	60	2108	5.7 (2.4)	0.24 (2.75)	1941	5.4 (2.4)		0.18 (0.00 to 0.36), <0.05
	Multiple	High HD only	MUFA (% energy)	IG1	60	2364	19.6 (4.6)	2.52 (5.46)	1941	19.3 (4.7)	-0.53 (5.62)	3.05 (2.65 to 3.46), <0.001
	Multiple	High HD only	MUFA (% energy)	IG2	60	2108	19.6 (4.3)	1.32 (5.15)	1941	19.3 (4.7)	-0.53 (5.62)	1.89 (1.45 to 2.26), <0.001
	Multiple	High HD only	PUFA (% energy)	IG1	60	2364	6.1 (2.1)	-0.03 (2.36)	1941	6.2 (2.1)	-0.65 (2.25)	0.62 (0.45 to 0.79), <0.001
	Multiple	High HD only	PUFA (% energy)	IG2	60	2108	6.4 (2)	1.31 (2.46)	1941	6.2 (2.1)	-0.65 (2.25)	1.96 (1.77 to 2.14), <0.001
	Multiple	High HD only	Saturated fat (% energy)	IG1	60	2364	10 (2.2)	-0.56 (2.36)	1941	10 (2.3)		0.24 (0.06 to 0.41), 0.004
	Multiple	High HD only	Saturated fat (% energy)	IG2	60	2108	10 (2.1)	-0.67 (2.34)	1941	10 (2.3)		0.12 (-0.06 to 0.30), 0.3
	Multiple	High HD only	Vegetables (servings/d)	IG1	60	2364	2.8 (1.2)	-0.08 (1.49)	1941	2.6 (1.1)		0.01 (-0.08 to 0.11), 0.98
	Multiple	High HD only	Vegetables (servings/d)	IG2	60	2108	2.7 (1.2)	-0.01 (1.29)	1941	2.6 (1.1)	-0.09 (1.91)	0.08 (-0.01 to 0.18), 0.12
Gill, 2019 ⁷⁰ (HealtheSteps) Fair	Multiple	Medium HD + PA	Dietary pattern score (score)	IG1	6	59	6.7 (2.6)	-1.84 (2.74)	59	6.4 (2.7)	-0.35 (2.63)	-1.50 (-2.42 to - 0.58), 0.002
	Multiple	Medium HD + PA	Fats or sweets (score)	IG1	6	59	21.1 (6.2)	-1.38 (5.58)	59	19.7 (5.2)	-0.7 (5.39)	-0.68 (-2.55 to 1.19), 0.47
Greaves, 2015 ⁷¹ (Waste the Waist) Fair	Multiple	High HD + PA	Dietary pattern score (Fat score of DINE questionnaire )	IG1	12	54	30 (9.1)	-5 (7.97)	52	32.2 (10.9)		-2.22 (-5.12 to 0.68), 0.132

(Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
	Multiple	High HD + PA	Dietary pattern score (Fruit and vegetable score of DINE questionnaire	IG1	12	54	21.6 (7.3)	2.39 (7.08)	51	21.1 (6.6)		2.91 (0.65 to 5.16), 0.012
	Multiple	High HD + PA	Fiber score (Fiber score of DINE questionnaire	IG1	12	54	36.7 (11.6)	2.94 (10.87)	51	37 (10)		5.33 (1.83 to 8.82), 0.003
Hardcastle, 2008 ⁷³ Fair	Multiple	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	6	203	6.31 (4.02)	1.02 (4.14)	131	6.94 (4.48)	0.64 (4.68)	0.38 (-0.60 to 1.36), NSD
	Multiple	Medium HD + PA		IG1	18	203	6.31 (4.02)	-0.01 (3.9)	131	6.94 (4.48)	-0.71 (4.1)	0.70 (-0.18 to 1.58), NSD
Harris, 2012 ⁷⁴ (Health Improvement and	Multiple	High HD + PA		IG1	6	250	4.73 (2.12)	0.85 (2.07)	216	4.59 (2.08)	0.4 (2.13)	0.45 (0.07 to 0.83), 0.002
	Multiple	High HD + PA		IG1	12	355	4.73 (2.12)	0.12 (2.52)	300	4.59 (2.08)		0.19 (-0.18 to 0.56), 0.47
Hinderliter, 2014 ⁷⁶ (Exercise	HTN	High HD only	Potassium (mg/d)	IG1	12	36	NR (NR)	NR (NR)	37	NR (NR)	NR (NR)	NR
`	HTN	High HD only		IG1	12	36	NR (NR)	NR (NR)	37	NR (NR)	NR (NR)	NR
	HTN	High HD only	Potassium (mmol/24-hr)	IG1	6	170		5.88 (25.56)	185	65.66 (NR)	-0.49 (26.66)	6.37 (0.94 to 11.80), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	IG baseline mean (SD)	change (SD)		CG baseline mean (SD)	change (SD)	Between-group difference,† p- value
Prevention Trial	HTN	High		IG2	6	165	64.19	0.98	185	65.66	-0.49	1.47 (-4.29 to
(HPT))		HD only	(mmol/24-hr)				(NR)	(25.18)		(NR)	(26.66)	7.23), 0.994
Good	HTN	High		IG3	6	102	67.13	-5.39	116	67.62	1.47	-6.86 (-14.54 to
		HD only	(mmol/24-hr)				(NR)	(29.69)		(NR)	(26.39)	0.82), 0.066
	HTN	High		IG4	6	104	69.09	-0.49	116	67.62	1.47	-1.96 (-8.75 to
		HD only	(mmol/24-hr)				(NR)	(24.99)		(NR)	(26.39)	4.83), NSD
	HTN	High		IG1	36	151	64.68	4.41	155	65.66	-1.96	6.37 (-1.13 to
		HD only	(mmol/24-hr)				(NR)	(36.13)		(NR)	(30.5)	13.87), NSD
	HTN	High		IG2	36	144	64.19	4.41	155	65.66	-1.96	6.37 (-1.31 to
		HD only	(mmol/24-hr)				(NR)	(35.28)		(NR)	(30.5)	14.05), 0.044
	HTN	High	Potassium	IG3	36	101	67.13	5.88	102	67.62	0.49	5.39 (-4.21 to
		HD only	(mmol/24-hr)				(NR)	(34.47)		(NR)	(34.64)	14.99), 0.328
	HTN	High	Potassium	IG4	36	96	69.09	-3.92	102	67.62	0.49	-4.41 (-13.92 to
		HD only	(mmol/24-hr)				(NR)	(33.61)		(NR)	(34.64)	5.10), NSD
	HTN	High	Sodium	IG1	6	170	159.98	-43.32	185	164.92	-14.82	-28.50 (-42.19 to
		HD only	(mmol/24-hr)				(NR)	(64.41)		(NR)	(67.19)	-14.81), <0.05
	HTN	High	Sodium	IG2	6	165	162.64	-35.72	185	164.92	-14.82	-20.90 (-35.05 to
		HD only	(mmol/24-hr)				(NR)	(63.46)		(NR)	(67.19)	-6.75), 0.002
	HTN	High	Sodium	IG3	6	102	174.04	-15.96	116	174.42	-17.1	1.14 (-18.22 to
		HD only	(mmol/24-hr)				(NR)	(72.92)		(NR)	(73.67)	20.50), 0.922
	HTN	High	Sodium	IG4	6	104	173.28	-31.92	116	174.42	-17.1	-14.82 (-33.78 to
		HD only	(mmol/24-hr)				(NR)	(69.75)		(NR)	(73.67)	4.14), NSD
	HTN	High	Sodium	IG1	36	151	159.98	-22.04	155	164.92	0 (70.96)	-22.04 (-37.84 to
		HD only	(mmol/24-hr)				(NR)	(70.04)		(NR)		-6.24), <0.05
	HTN	High	Sodium	IG2	36	143	162.64	-15.96	155	164.92	0 (70.96)	-15.96 (-31.60 to
		HD only	(mmol/24-hr)				(NR)	(68.16)		(NR)		-0.32), 0.053
	HTN	High	Sodium	IG3	36	101	174.04	-1.52	102	174.42	8.36	-9.88 (-29.99 to
		HD only	(mmol/24-hr)				(NR)	(72.56)		(NR)	(72.92)	10.23), 0.114
	HTN	High	Sodium	IG4	36	96	173.28	-34.96	102	174.42	8.36	-43.32 (-63.33 to
		HD only	(mmol/24-hr)				(NR)	(70.74)		(NR)	(72.92)	-23.31), <0.05
Hyman, 2007 ⁷⁹	HTN	Medium		IG1	6	92	185.8	-16.6	93	189 (71)	0.3	-16.90 (-42.54 to
Fair		HD + PA	(mmol/24-hr)				(77.9)	(93.99)		` ′	(83.57)	8.74), NSD
	HTN	Medium		IG2	6	96	200.7	-0.3	93	189 (71)	0.3	-0.60 (-25.60 to
		HD + PA	(mmol/24-hr)				(88.2)	(91.68)		` ′		24.40), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)		CG baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	Medium		IG1	18	92	185.8	9.5	93	189 (71)	0.8 (82.5)	8.70 (-17.41 to
		HD + PA	(mmol/24-hr)				(77.9)	(97.98)				34.81), NSD
	HTN	Medium		IG2	18	96	200.7	7.9	93	189 (71)	0.8 (82.5)	7.10 (-18.30 to
		HD + PA	(mmol/24-hr)				(88.2)	(95.37)				32.50), NSD
Kandula, 2015 ⁸³	Multiple	High		IG1	6	31	3 (2)	0.04	32	2(1)	0.5 (1.53)	-0.40 (-1.15 to
(South Asian		HD + PA	Vegetables					(1.53)				0.26), NSD
Heart Lifestyle			(servings/d)									
Intervention	Multiple	High	Saturated fat	IG1	6	31	7.7 (1.9)	0.37	32	7.9 (2.5)	0.58	-0.21 (-1.59 to
(SAHELI))		HD + PA	(% energy)					(2.77)			(2.79)	1.17), NSD
Fair												
Kastarinen,	HTN	High	Fiber (g/day)	IG1	12	317	22.8 (8.6)	-0.1 (7.7)	272	22.9 (8.4)	-0.7 (6.7)	0.60 (-0.60 to
2002 ⁸⁵ (Lifestyle		HD + PA										1.80), 0.349
Intervention	HTN	High	Fiber (g/day)	IG1	24	275	22.8 (8.6)	0.8 (7.3)	233	22.9 (8.4)	-1.4 (6.9)	2.20 (1.00 to
against		HD + PA										3.50), <0.001
Hypertension in	HTN	High	- (	IG1	12	317	11.8 (2.5)	-0.5 (2.7)	272	11.7 (2.8)	-0.1 (2.8)	-0.40 (-0.90 to
Eastern Finland		HD + PA	energy)				110(5.5)	0.0 (2.5)			0.0 (0.0)	0.00), 0.054
(LIHEF))	HTN	High	`	IG1	24	275	11.8 (2.5)	-0.9 (2.7)	233	11.7 (2.8)	-0.2 (3.2)	-0.70 (-1.20 to -
Fair		HD + PA	energy)									0.20), <0.008
	HTN	High		IG1	12	360	83 (27)	1 (NR)	355	83 (28)	1 (NR)	0.00 (-4.00 to
		HD + PA	(mmol/d)									4.00), NSD
	HTN	High		IG1	24	360	83 (27)	3 (NR)	355	83 (28)	1 (NR)	2.00 (-2.00 to
		HD + PA	(mmol/d)				<u> </u>					5.00), NSD
	HTN	High	`	IG1	12	317	5.5 (1.5)	-0.1 (1.6)	272	5.3 (1.5)	0 (1.7)	-0.10 (-0.40 to
		HD + PA	energy)				<u> </u>					0.20), 0.512
	HTN	High	`	IG1	24	275	5.5 (1.5)	-0.1 (1.7)	233	5.3 (1.5)	0.1 (1.5)	-0.20 (-0.50 to
		HD + PA	energy)									0.00), 0.105
	HTN	High	Saturated fat	IG1	12	317	13.6 (3.1)	-1.3 (3.3)	272	13.6 (3.2)	-0.1 (2.8)	-1.20 (-1.70 to -
		HD + PA	(% energy)									0.70), < 0.0005
	HTN	High	Saturated fat	IG1	24	275	13.6 (3.1)	-1.8(0.3)	233	13.6 (3.2)	-0.1 (3.3)	-1.70 (-2.30 to -
		HD + PA	(% energy)					0.07				1.10), <0.0005
	HTN	High		IG1	12	360	146 (56)	-9 (NR)	355	142 (56)	-6 (NR)	-3.00 (-10.00 to
		HD + PA	(mmol/24-hr)								<u> </u>	5.00), NSD
	HTN	High		IG1	24	360	146 (56)	-7 (NR)	355	142 (56)	-2 (NR)	-5.00 (-14.00 to
		HD + PA	(mmol/24-hr)									3.00), NSD

	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	baseline	change	Between-group difference,† p- value
	Multiple	Medium		IG1	12	252	1.73 (1.31)		236	1.87 (1.5)		0.09 (-0.17 to
Loon, 2009		HD + PA	(pieces/d)					(1.36)				0.34), 0.7
(Improving Patient Adherence to Lifestyle Advice	Multiple	Medium HD + PA	Saturated fat (Dutch Fat Questionnair e)		12	252	16.6 (5.7)	-2.2 (5.56)	236	17.2 (5.3)		-0.40 (-1.37 to 0.57), 0.034
(IMPALA))	Multiple	Medium	Vegetables	IG1	12	252	3.39 (1.6)	0.26	236	3.24 (1.84)	0.1 (1.87)	0.16 (-0.16 to
Fair		HD + PA	(Tbsp/d)					(1.72)				0.48), 0.09
Lakerveld, 2013 ⁹⁰ (HOORN)	Multiple	Medium HD + PA	(pieces/d)	IG1	6	314	1.1 (0.9)	0 (0.9)	308	1.1 (0.8)	0.2 (0.92)	-0.20 (-0.34 to - 0.06), NSD
Fair	Multiple	Medium HD + PA	Fruit (pieces/d)	IG1	12	314	1.1 (0.9)	0 (0.9)	308	1.1 (0.8)		-0.10 (-0.24 to 0.04), NSD
	Multiple	Medium HD + PA	Vegetables (g/day)	IG1	6	314	148 (69.5)	13 (109.81)	308	150 (70.4)	, ,	12.00 (-2.41 to 26.41), NSD
	Multiple	Medium HD + PA		IG1	12	314	148 (69.5)	8 (72.19)	308	150 (70.4)	7 (81.91)	1.00 (-11.14 to 13.14), NSD
Langford, 1991 ⁹¹ (Trial of	HTN	High HD + PA	Potassium (mmol/d)	IG1	6	237	57.4 (NR)	2.2 (30.36)	230	55.1 (NR)		-1.60 (-7.11 to 3.91), NSD
Antihypertensive Interventions and	HTN	High HD only	Potassium (mmol/d)	IG2	6	214	58.3 (NR)	10.9 (30.36)	230	55.1 (NR)	3.8 (30.36)	7.10 (1.45 to 12.75), <0.05
Management (TAIM))	HTN	High HD + PA	Sodium (mmol/24-hr)	IG1	6	237	134.4 (NR)	1.3 (72.68)	230	129.6 (NR)	5.5 (72.68)	-4.20 (-17.39 to 8.99), NSD
Fair	HTN	High HD only		IG2	6	214	135.9 (NR)	-27.4 (72.68)	230	129.6 (NR)	5.5 (72.68)	-32.90 (-46.43 to -19.37), <0.05
Migneault, 2012 ⁹⁴ Fair	HTN	High HD + PA	Dietary quality score (Overall Diet Quality)	IG1	8	169	53.9 (17.6)	2.8 (NR)	168	55.8 (17)	-0.74 (NR)	3.54 (NR), <0.03
	HTN	High HD + PA		IG1	12	169	53.9 (17.6)	2.2 (NR)	168	55.8 (17)	1.4 (NR)	NR, NSD
Moy, 2001 ⁹⁶ Fair	Multiple	High HD only	Saturated fat (% energy)	IG1	24	117	NR (NR)	-1.4 (3)	118	NR (NR)	-0.01 (3)	-1.39 (-2.16 to - 0.63), 0.0005

	Population risk focus	Contact time* Intervention focus	Outcome (Unit)		Timepoint (months)	IG N	IG baseline mean (SD)	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
	Multiple	High	Saturated fat	IG1	24	117	30.2 (16)	-4.9 (12)	118	29.7 (15)	1.9 (16)	-6.80 (-10.41 to -
100		HD only	(g/day)			1						3.19), 0.0002
Niiranen, 2014 ¹⁰⁰ Fair	HTN	Medium HD + PA	(mEq/8h)		12	107	` ′	1.2 (8.71)		19.1 (7.9)		0.90 (-5.73 to 7.53), 0.49
	HTN	Medium HD + PA	Saturated fat (% energy)	IG1	12	112	13 (2.8)	-0.7 (2.7)	108	12.5 (2.9)	-0.1 (2.92)	1.32), 0.11
	HTN	Medium HD + PA		IG1	12	112	176.7 (97.28)	-5.32 (97.46)	106	184.68 (93.1)	-3.42 (109.79)	-1.90 (-72.89 to 69.09), 0.91
Reid, 2014 ¹⁰³ Fair	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	12	211	6.3 (3)	1.1 (3.22)	215	6.5 (3.1)		1.00 (0.40 to 1.60), 0.5
Rubinstein, 2016 ¹⁰⁷ Good	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG1	12	94	2.12 (1.8)	-0.28 (1.67)	96	1.79 (1.2)	-0.12 (1.25)	-0.28 (-0.78 to 0.21), 0.26
	HTN	Medium HD + PA	Sodium (servings/d)	IG1	12	94	1.16 (0.9)	-0.27 (1.01)	96	1.17 (0.7)	-0.27 (0.7)	0.31), 0.92
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	Dietary pattern score (Starting the Conversation questionnaire		12	300	NR (NR)	NR (NR)	299	NR (NR)	NR (NR)	MD=0.60 (0.40 to 0.90), <0.001
Soto Rodriguez, 2016 ¹¹¹ Fair	Multiple	Medium HD only	Dietary pattern score (MEDAS-14)		12	117	7.06 (2.02)	2.31 (1.91)	113	6.96 (2.15)	0.23 (1.85)	2.08 (1.59 to 2.56), 0.000
Stefanick, 1998 ¹¹² (Diet and Exercise for Elevated Risk		High HD only	energy)	IG1 (Females )	12	46	NR (NR)	-2.1 (3.5)	45	NR (NR)	0 (3.2)	-2.10 (-3.48 to - 0.72), <0.05
(DEER)) Fair	Dys	High HD only	energy)	IG1 (Males)	12	49	NR (NR)	-2.8 (3.4)	46	NR (NR)	0 (2.9)	-2.80 (-4.07 to - 1.53), <0.001
	Dys	High HD only	PUFA (% energy)	IG1 (Females )	12	46	NR (NR)	-0.9 (2.3)	45	NR (NR)	-0.3 (2.4)	-0.60 (-1.57 to 0.37), NSD
	Dys	High HD only	PUFA (% energy)	IG1 (Males)	12	49	NR (NR)	-1.3 (2.2)	46	NR (NR)	-0.7 (1.7)	-0.60 (-1.39 to 0.19), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	CG baseline mean (SD)	CG mean change (SD)	Between-group difference,† p- value
	Dys	High HD only	Saturated fat (% energy)	IG1 (Females	12	46	NR (NR)	-2.4 (2.8)	45	NR (NR)	0.2 (2.8)	-2.60 (-3.75 to - 1.45), <0.001
	Dys	High HD only	Saturated fat (% energy)	IG1 (Males)	12	49	NR (NR)	-3.4 (3.2)	46	NR (NR)	0 (2.4)	-3.40 (-4.53 to - 2.27), <0.001
Stevens, 2003 ¹¹³	Dys	Medium HD only	Fruits and Vegetables (servings/d)	IG1	12	277	3.09 (1.76)	1.24 (1.83)	271	3.21 (1.97)	0.19 (1.94)	0.93 (0.73 to 1.37), <0.001
	Dys	Medium HD only		IG1	12	277	15.2 (NR)	-2.1 (NR)	271	14.8 (NR)	-0.8 (NR)	NR, <0.001
	Dys	Medium HD only	energy)	IG1	12	277	8.3 (NR)	-1.6 (NR)	271	8.1 (NR)	-0.6 (NR)	NR, <0.001
	Dys	Medium HD only	Saturated fat (% energy)		12	277	14 (NR)	-1.6 (NR)	271		, ,	NR, <0.001
Svetkey, 2009 ¹¹⁵ (Hypertension Improvement Project (HIP))	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG1	6	132	3.41 (1.38)	0.68 (1.29)	132	3.37 (1.24)	-0.04 (1.09)	0.72 (0.43 to 1.01), NSD
Fair	HTN	High HD + PA		IG1	6	132	61.3 (12.8)	8.9 (11.5)	132	60.9 (11.7)	0-0.2 (9.4)	9.10 (6.57 to 11.63), <0.05
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG2	6	124	3.21 (1.36)	0.06 (1.2)	132	3.37 (1.24)		0.10 (-0.18 to 0.38), <0.05
	HTN	High HD + PA		IG2	6	124	60.8 (12.2)	0.9 (10.5)	132	60.9 (11.7)	0-0.2 (9.4)	1.10 (-1.35 to 3.55), NSD
	HTN	Medium HD + PA		IG3	6	137	3.34 (1.26)	0.41 (1.45)	132	3.37 (1.24)	)-0.04 (1.09)	0.45 (0.14 to 0.76), <0.05
	HTN	Medium HD + PA		IG3	6	137	59.6 (12.1)	5 (12.2)	132	60.9 (11.7)	-0.2 (9.4)	5.20 (2.60 to 7.80), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	CG baseline mean (SD)	change	Between-group difference,† p- value
			(Healthy Eating Index)									
	HTN	High HD + PA	Dietary quality score (Healthy Eating Index)	IG1	18	128	3.41 (1.38)	0.27 (1.4)	122	3.37 (1.24)		0.24 (-0.10 to 0.58), <0.05
	HTN	High HD + PA		IG1	18	128	61.3 (12.8)	4.6 (11.6)	122	60.9 (11.7)		6.20 (3.47 to 8.93), <0.05
	HTN	High HD + PA		IG2	18	124	3.21 (1.36)	0.07 (1.21)	122	3.37 (1.24)		0.04 (-0.28 to 0.36), <0.05
	HTN	High HD + PA		IG2	18	124	60.8 (12.2)	-0.03 (10.4)	122	60.9 (11.7)		1.57 (-1.03 to 4.17), NSD
	HTN	Medium HD + PA		IG3	18	134	59.6 (12.1)	3.7 (10.8)	122	60.9 (11.7)	-1.6 (10.4)	5.30 (2.70 to 7.90), <0.05
	HTN	Medium HD + PA	Dietary quality score (Healthy Eating Index)	IG3	18	134	3.34 (1.26)	0.16 (1.12)	122	3.37 (1.24)		0.13 (-0.18 to 0.44), <0.05
	HTN	High HD + PA	Fats or sweets (servings/d)	IG1	6	132	3 (1.7)	-0.9 (1.4)	132	2.9 (1.5)		-0.50 (-0.81 to - 0.19), <0.05
	HTN	High HD + PA		IG2	6	124	2.8 (1.4)	-0.2 (1.3)	132	2.9 (1.5)		0.20 (-0.11 to 0.51), <0.05
	HTN	Medium HD + PA		IG3	6	137	2.8 (1.6)	-0.6 (1.4)	132	2.9 (1.5)	` /	-0.20 (-0.51 to 0.11), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	CG baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	High HD + PA	Fats or sweets (servings/d)	IG1	18	128	3 (1.7)	-0.6 (1.6)	122	2.9 (1.5)		-0.50 (-0.88 to - 0.12), <0.05
	HTN	High HD + PA	Fats or sweets (servings/d)	IG2	18	124	2.8 (1.4)	-0.1 (1.4)	122	2.9 (1.5)		0.00 (-0.36 to 0.36), <0.05
	HTN	Medium HD + PA	Fats or sweets (servings/d)	IG3	18	134	2.8 (1.6)	-0.2 (1.4)	122	2.9 (1.5)		-0.10 (-0.46 to 0.26), <0.05
	HTN	High HD + PA	Fruit (servings/d)	IG1	6	132	1.4 (1.1)	1 (1.3)	132	1.3 (0.9)	0.02 (0.9)	0.98 (0.71 to 1.25), NSD
	HTN	High HD + PA	Fruit (servings/d)	IG2	6	124	1.3 (0.9)	0.1 (0.7)	132	1.3 (0.9)	0.02 (0.9)	0.08 (-0.12 to 0.28), <0.05
	HTN	Medium HD + PA	Fruit (servings/d)	IG3	6	137	1.3 (1)	0.6 (1.3)	132	1.3 (0.9)		0.58 (0.31 to 0.85), <0.05
	HTN	High HD + PA	Fruit (servings/d)	IG1	18	128	1.4 (1.1)	0.5 (1.2)	122	1.3 (0.9)		0.52 (0.26 to 0.78), <0.05
	HTN	High HD + PA	Fruit (servings/d)	IG2	18	124	1.3 (0.9)	0.01 (0.8)	122	1.3 (0.9)	` /	0.03 (-0.18 to 0.24), <0.05
	HTN	Medium HD + PA	Fruit (servings/d)	IG3	18	134	1.3 (1)	0.4 (1.1)	122	1.3 (0.9)		0.42 (0.17 to 0.67), <0.05
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	132	1.42 (1.13)	(1.34)	132	1.28 (0.9)		0.88 (0.61 to 1.15), NSD
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	6	124	1.33 (0.99)	0.59 (1.27)	132	1.28 (0.9)		0.55 (0.29 to 0.81), <0.05
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG3	6	137	1.23 (0.88)	0.09 (0.72)	132	1.28 (0.9)		0.05 (-0.13 to 0.23), <0.05
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG1	18	128	1.42 (1.13)	0.55 (1.13)	122	1.28 (0.9)		0.54 (0.29 to 0.79), <0.05
	HTN	High HD + PA	Fruits and Vegetables (servings/d)	IG2	18	124	1.33 (0.99)	0.41 (1.13)	122	1.28 (0.9)		0.40 (0.14 to 0.66), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	Medium HD + PA	Fruits and Vegetables (servings/d)	IG3	18	134	1.23 (0.88)	-0.03 (0.87)	122	1.28 (0.9)		-0.04 (-0.26 to 0.18), <0.05
	HTN	High HD + PA		IG1	6	132	2621 (1079)	152 (942)	132	2662 (1127)		405.00 (182.27 to 627.73), <0.05
	HTN	High HD + PA	(mg)	IG2	6	124	2470 (925)	(657)	132	2662 (1127)		219.10 (26.34 to 411.86), <0.05
	HTN	Medium HD + PA	(mg)	IG3	6	137	2475 (1212)	-19.5 (874)	132	2662 (1127)	, ,	233.50 (20.89 to 446.11), <0.05
	HTN	High HD + PA	(mg)	IG1	18	128	2621 (1079)	-49.4 (1007)	122	2662 (1127)	-205 (1078)	155.60 (-103.29 to 414.49), NSD
	HTN	High HD + PA	(mg)	IG2	18	124	2470 (925)	(781)	122	2662 (1127)		178.60 (-56.96 to 414.16), NSD
	HTN	Medium HD + PA	(mg)	IG3	18	134	2475 (1212)	, ,	122	2662 (1127)		133.00 (-101.49 to 367.49), NSD
	HTN	High HD + PA	(mg/dL)	IG1	6	132	61.2 (27.9)	, ,		, ,	, ,	7.90 (1.41 to 14.39), <0.05
	HTN	High HD + PA	(mg/dL)	IG2	6	124	61.3 (22.8)	, ,		` ′	` ′	5.00 (-1.21 to 11.21), NSD
	HTN	Medium HD + PA	(mg/dL)	IG3	6	137	51.7 (23)		132	, ,	, , ,	12.80 (7.13 to 18.47), <0.05
	HTN	High HD + PA	(mg/dL)	IG1	18	128	61.2 (27.9)	` ′	122	` ′	, ,	1.80 (-4.18 to 7.78), NSD
	HTN	High HD + PA	(mg/dL)	IG2	18	124	61.3 (22.8)	, ,	122	, ,	, ,	8.70 (-0.10 to 17.50), NSD
	HTN	Medium HD + PA	(mg/dL)	IG3	18	134	, ,	8.4 (22.4)		, í	, ,	14.10 (8.25 to 19.95), <0.05
	HTN	High HD + PA	Saturated fat (% energy)		6	132		-1.3 (2.1)	132	10.6 (2.5)		-1.50 (-2.03 to - 0.97), <0.05
	HTN	High HD + PA	Saturated fat (% energy)		6	124	10.9 (2.7)		132	10.6 (2.5)	, ,	-1.20 (-1.82 to - 0.58), <0.05
	HTN	Medium HD + PA	Saturated fat (% energy)		6	137	11 (2.3)	-0.2 (2)	132	10.6 (2.5)	` ′	-0.40 (-0.92 to 0.12), <0.05
	HTN	High HD + PA	Saturated fat (% energy)	IG1	18	128	10.5 (2.4)	-1 (2.2)	122	10.6 (2.5)	, ,	-1.10 (-1.66 to - 0.54), <0.05

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	High	Saturated fat	IG2	18	124	10.9 (2.7)	-0.9 (2.1)	122	10.6 (2.5)	, ,	-1.00 (-1.55 to -
	HTN	HD + PA Medium	(% energy) Saturated fat	IC2	18	134	11 (2.2)	0.2 (2)	122	10 ( (2.5)		0.45), <0.05
	HIN	HD + PA	(% energy)	163	18	134	11 (2.3)	-0.2 (2)	122	10.6 (2.5)	, ,	-0.30 (-0.83 to 0.23), <0.05
	HTN	High	Saturated fat	IG1	6	132	21.5 (12.6)	-5.9 (10.2)	132	20.9 (11.6)		-4.20 (-6.30 to -
	11111	HD + PA	(g/day)	101	Ö	132	21.3 (12.0)	3.7 (10.2)	132	20.5 (11.0)	1.7 (0.5)	2.10), <0.05
	HTN	High	Saturated fat	IG2	6	124	19.9 (10.6)	-1 (6.8)	132	20.9 (11.6)	-1.7 (6.9)	0.70 (-0.98 to
		HD + PA	(g/day)					()				2.38), NSD
	HTN	Medium	Saturated fat	IG3	6	137	20.5 (12)	-4.7 (9.6)	132	20.9 (11.6)		-3.00 (-4.99 to -
		HD + PA	(g/day)									1.01), <0.05
	HTN	High HD + PA	Saturated fat (g/day)	IG1	18	128	21.5 (12.6)	-4.7 (11.6)	122	20.9 (11.6)	-1.1 (9)	-3.60 (-6.17 to - 1.03), <0.05
	HTN	High HD + PA	Saturated fat (g/day)	IG2	18	124	19.9 (10.6)	-1.2 (8)	122	20.9 (11.6)		-0.10 (-2.23 to 2.03), NSD
	HTN	Medium HD + PA	Saturated fat (g/day)	IG3	18	134	20.5 (12)	-3.4 (8.3)	122	20.9 (11.6)	, ,	-2.30 (-4.43 to - 0.17), <0.05
	HTN	High HD + PA		IG1	6	132	2346 (1170)	-338 (1051)	132	2345 (1114)	-217 (792)	-121.00 (-345.50 to 103.50), NSD
	HTN	High HD + PA		IG2	6	124	2249 (968)	` /	132	2345 (1114)	-217 (792)	103.00 (-80.21 to 286.21), NSD
	HTN	Medium HD + PA		IG3	6	137	2134 (1215)	-234 (902)	132	2345 (1114)	-217 (792)	-17.00 (-219.65 to 185.65), NSD
	HTN	High HD + PA		IG1	18	128	2346	-352 (1107)	122	2345 (1114)	-163 (968)	-189.00 (-446.45 to 68.45), NSD
	HTN	High HD + PA		IG2	18	124	2249 (968)		122	2345 (1114)	-163 (968)	49.00 (-179.71 to 277.71), NSD
	HTN	Medium HD + PA		IG3	18	134	2134 (1215)	-145 (828)	122	2345 (1114)	-163 (968)	18.00 (-203.72 to 239.72), NSD
	HTN	High HD + PA		IG1	6	132	170.3 (76.2)	-31.4 (79.7)	132	174.7 (77)	-22.8	-8.60 (-26.83 to 9.63), NSD
	HTN	High HD + PA		IG2	6	124	150.9 (68)		132	174.7 (77)	-22.8	9.70 (-6.65 to 26.05), NSD
	HTN	Medium HD + PA		IG3	6	137	175.2 (82.9)	-23.6 (75.2)	132	174.7 (77)		-0.80 (-18.30 to 16.70), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	High		IG1	18	128	170.3	-28 (76.6)	122	174.7 (77)	, ,	-19.70 (-39.67 to
	* ***** *	HD + PA	(mmol/24-hr)	7.00	1.0	101	(76.2)	24 (07.2)	100	1545 (55)		0.27), <0.05
	HTN	High HD + PA	Sodium (mmol/24-hr)	IG2	18	124	150.9 (68)	-24 (85.2)	122	174.7 (77)	-8.3 (84.1)	-15.70 (-36.86 to 5.46), NSD
	HTN	Medium HD + PA	Sodium (mmol/24-hr)	IG3	18	134	175.2 (82.9)	-1.4 (69.9)	122	174.7 (77)	-8.3 (84.1)	6.90 (-12.15 to 25.95), NSD
	HTN	High HD + PA		IG1	6	132		1 (2.5)	132	2.9 (1.9)	0.1 (1.7)	0.90 (0.38 to 1.42), NSD
	HTN	High HD + PA		IG2	6	124	2.8 (1.6)	0.2 (1.6)	132	2.9 (1.9)	0.1 (1.7)	0.10 (-0.30 to 0.50), <0.05
	HTN	Medium HD + PA	Vegetables (servings/d)	IG3	6	137	3 (2.2)	0.5 (2.4)	132	2.9 (1.9)	0.1 (1.7)	0.40 (-0.10 to 0.90), <0.05
	HTN	High HD + PA	(servings/d)	IG1	18	128	3.1 (2.4)	0.3 (2.5)	122	2.9 (1.9)	, ,	0.00 (-0.62 to 0.62), <0.05
	HTN	High HD + PA	(servings/d)	IG2	18	124	2.8 (1.6)	0.04 (1.8)	122	2.9 (1.9)	0.3 (2.5)	-0.26 (-0.81 to 0.29), <0.05
	HTN	Medium HD + PA	Vegetables (servings/d)	IG3	18	134	3 (2.2)	0.03 (1.8)	122	2.9 (1.9)	` /	-0.27 (-0.81 to 0.27), <0.05
Ter Bogt, 2009 ¹¹⁶ (Groningen	Multiple	High HD + PA	Fruit (g/day)	IG1	12	169	130.5 (108.11)	85.1 (130)	172	137 (118.77)		21.00 (-7.62 to 49.62), 0.27
Overweight and Lifestyle	Multiple	High HD + PA	Fruit (g/day)	IG1	36	158	130.5 (108.11)	84 (174.9)	172	137 (118.77)	63 (165.9)	21.00 (-15.86 to 57.86), 0.468
(GOAL)) Good	Multiple	High HD + PA	Fruits and Vegetables (g/day)	IG1	12	169	275.7 (153.6)	101.2 (172)	172	295.6 (171.1)	77.7 (190.9)	23.50 (-15.05 to 62.05), NSD
	Multiple	High HD + PA	Fruits and Vegetables (g/day)	IG1	36	158		95.7 (221.5)	172	295.6 (171.1)	81.2 (222.3)	14.50 (-33.42 to 62.42), NSD
	Multiple	High HD + PA	Saturated fat (% energy)	IG1	12	169	12.9 (2.98)	-1.6 (2.65)	172	12.5 (3.01)	-1 (2.68)	-0.60 (-1.17 to - 0.03), 0.16
	Multiple	High HD + PA	Saturated fat (% energy)	IG1	36	158	12.9 (2.98)	-0.9 (2.9)	172	12.5 (3.01)	-0.4 (2.7)	-0.50 (-1.11 to 0.11), 0.164
	Multiple	High HD + PA		IG1	12	169	145.2 (67.65)	16.1 (65)	172	158.6 (77.28)	13.6 (77.95)	2.50 (-12.72 to 17.72), 0.87

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	IG mean change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
	Multiple	High		IG1	36	158		11.7	172	158.6	18.2	-6.50 (-23.86 to
110		HD + PA	(g/day)				(67.65)	(74.1)		(77.28)	(86.7)	10.86), 0.556
Toft, 2008 ¹¹⁸ (Inter99) Fair	Multiple	High HD + PA	Fruit (g/day)	IG1 (Females )	60	1062	NR (NR)	NR (NR)	114	NR (NR)	NR (NR)	NR, NSD
	Multiple	High HD + PA	Fruit (g/day)	IG1 (Males)	60	1048	NR (NR)	NR (NR)	132	NR (NR)	NR (NR)	NR, NSD
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Females )	12	1062	11.5 (6.65)	-1.6 (7.1)	114	11.5 (4.09)	-1.8 (4.23)	0.20 (-0.69 to 1.09), 0.65
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Males)	12	1048	12.8 (8.26)	-1.4 (18)	132	12.8 (4.69)		-1.10 (-2.48 to 0.28), 0.002
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Females	36	1062	11.5 (6.65)	-1.6 (7.62)	114	11.5 (4.09)	` ′	-0.40 (-1.33 to 0.53), 0.26
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Males)	36	1048	12.8 (8.26)	-1.3 (8.7)	132	12.8 (4.69)	-1.2 (5.19)	-0.10 (-1.13 to 0.93), 0.63
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Females )	60	1062	11.5 (6.65)	-1.5 (7.1)	114	11.5 (4.09)	, ,	-0.20 (-1.14 to 0.74), 0.59
	Multiple	High HD + PA	Saturated fat (% energy)	IG1 (Males)	60	1048	12.8 (8.26)	-1 (8.7)	132	12.8 (4.69)	-0.5 (5.19)	-0.50 (-1.53 to 0.53), 0.1
	Multiple	High HD + PA	0	IG1 (Females )	60	1062	NR (NR)	NR (NR)	114	NR (NR)	NR (NR)	NR, NSD
	Multiple	High HD + PA		IG1 (Males)	60	1048	NR (NR)	NR (NR)	132	NR (NR)	NR (NR)	NR, NSD
TOHP I CRG, 1992 ¹¹⁹ (Trials of	HTN	High HD only	(mmol/24-hr)	IG1	6	228	154.6 (59.9)	-55.68 (76.06)	323	156.4 (60.5)	2.77 (80.33)	-58.45 (-71.80 to -45.09), <0.01
Hypertension Prevention Phase I (TOHP I))	HTN	High HD only	(mmol/24-hr)	IG1	12	244	154.6 (59.9)	-54.4 (60.41)	342	156.4 (60.5)	-4.3 (68)	MD=-51.90 (- 60.56 to -39.64), <0.001
Good	HTN	High HD only	Sodium (mmol/24-hr)	IG1	18	232	154.6 (59.9)	-55.19 (76.93)	330	156.4 (60.5)	-11.33 (77.68)	-43.86 (-56.88 to -30.84), <0.01

(Study name) Quality	Population risk focus	Contact time* Intervention focus	(Unit)		Timepoint (months)	IG N	baseline mean (SD)	change (SD)		baseline mean (SD)	change (SD)	Between-group difference,† p- value
TOHP II CRG,	HTN	High		IG1	18	447			467	188 (80.9)		-28.60 (-40.56 to
1997 ¹²⁰ (Trial of		HD + PA	(mmol/24-hr)					(88.8)			(94.8)	-16.64), <0.001
V 1	HTN	High		IG2	18	460			467	188 (80.9)		5.20 (-6.56 to
Prevention II		HD + PA	(mmol/24-hr)					(86.2)			(94.8)	16.96), 0.39
	HTN	High		IG3	18	450			467	188 (80.9)		-42.70 (-54.85 to
Good		HD only	(mmol/24-hr)					(91.7)			(94.8)	-30.55), <0.001
	HTN	High		IG1	36	471			482	188 (80.9)		-23.60 (-34.97 to
		HD + PA	(mmol/24-hr)					(90.9)			(88.5)	-12.23), <0.001
	HTN	High	Sodium	IG2	36	475	180.9	-9 (87.1)	482	188 (80.9)		1.50 (-9.67 to
		HD + PA	(mmol/24-hr)				(72.4)				(88.5)	12.67), 0.79
	HTN	High	Sodium	IG3	36	470	186.1	-50.9	482	188 (80.9)	-10.5	-40.40 (-51.57 to
		HD only	(mmol/24-hr)					(86.3)			(88.5)	-29.23), <0.001
van der Veen,	Dys	Medium	MUFA (%	IG1	6	70	14.6 (3.3)	-3.4 (3.3)	67	14.9 (2.6)	-0.7 (2.4)	-2.70 (-3.66 to -
$2002^{122}$		HD only	energy)									1.74), 0.000
(Nijmegen Family	Dys	Medium	MUFA (%	IG1	12	67	14.6 (3.3)	-1.9 (4.1)	63	14.9 (2.6)	-0.3 (3.3)	-1.60 (-2.88 to -
Practices		HD only	energy)									0.32), 0.01
Monitoring	Dys	Medium	Saturated fat	IG1	6	70	15.2 (2.6)	-3.4 (2.7)	67	15.5 (2.3)	-0.8 (2.2)	-2.60 (-3.42 to -
Project (NFPMP))		HD only	(% energy)									1.78), 0.000
Fair	Dys	Medium	Saturated fat	IG1	12	67	15.2 (2.6)	-2.6 (2.7)	63	15.5 (2.3)	-0.9 (2.6)	-1.70 (-2.61 to -
		HD only	(% energy)									0.79), 0.000
	HTN	Medium		IG1	6	369	2.04 (1.55)	0.86 (1.6)	392	2.1 (1.69)	0.47	0.39 (0.16 to
2011 ¹²³ (Vitalum)		HD + PA	(servings/d)								(1.67)	0.62), < 0.01
Fair	HTN	Medium	Fruit	IG2	6	369	2.04 (1.63)	0.55	392	2.1 (1.69)	0.47	0.08 (-0.16 to
		HD + PA	(servings/d)					(1.66)			(1.67)	0.32), < 0.05
	HTN	Low		IG3	6	376	2.16 (1.69)		392	2.1 (1.69)		0.27 (0.03 to
		HD + PA	(servings/d)					(1.73)			(1.67)	0.51), <0.05
	HTN	Medium	Fruit	IG1	11	307	2.04 (1.55)	0.74 (1.9)	326	2.1 (1.69)	0.26	0.48 (0.19 to
		HD + PA	(servings/d)								(1.79)	0.77), < 0.01
	HTN	Medium	Fruit	IG2	11	284	2.04 (1.63)	0.66(1.9)	326	2.1 (1.69)	0.26	0.40 (0.11 to
		HD + PA	(servings/d)								(1.79)	0.69), < 0.05
	HTN	Low	Fruit	IG3	11	267	2.16 (1.69)		326	2.1 (1.69)	0.26	0.60 (0.29 to
		HD + PA	(servings/d)					(2.01)			(1.79)	0.91), < 0.001
	HTN	Medium	Fruit	IG1	17	302	2.04 (1.55)		327	2.1 (1.69)	-0.01	0.27 (0.02 to
		HD + PA	(servings/d)					(1.57)			(1.64)	0.52), < 0.01

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline mean (SD)	change (SD)	CG N	CG baseline mean (SD)	change (SD)	Between-group difference,† p- value
	HTN	Medium	Fruit	IG2	17	285	2.04 (1.63)	0.24	327	2.1 (1.69)	-0.01	0.25 (-0.01 to
		HD + PA	(servings/d)					(1.61)			(1.64)	0.51), < 0.05
	HTN	Low HD + PA	Fruit (servings/d)	IG3	17	272	2.16 (1.69)	0.52 (1.75)	327	2.1 (1.69)	-0.01 (1.64)	0.53 (0.26 to 0.80), <0.001
	HTN	Medium HD + PA	Meeting diet and PA recs (score)	IG1	17	407	0.7 (0.7)	0.4 (1.01)	409	0.8 (0.7)	0.26 (1.01)	0.14 (0.02 to 0.26), 0.02
	HTN	Medium HD + PA	Meeting diet and PA recs (score)	IG2	17	408	0.7 (0.7)	0.5 (1.21)	409	0.8 (0.7)	0.26 (1.01)	0.24 (0.10 to 0.38), <0.001
	HTN	Low HD + PA	Meeting diet and PA recs (score)	IG3	17	405		0.62 (1.21)	409	0.8 (0.7)	0.26 (1.01)	0.36 (0.22 to 0.50), <0.001
	HTN	Medium HD + PA	Vegetables (g/day)	IG1	6	369	164 (81)	26 (78.17)	392	167 (80)	16 (80)	10.00 (-1.24 to 21.24), <0.05
	HTN	Medium HD + PA		IG2	6	370	163 (81)	18 (80.02)	392	167 (80)	16 (80)	2.00 (-9.37 to 13.37), NSD
	HTN	Low HD + PA	Vegetables (g/day)	IG3	6	376	166 (88)	25 (84.72)	392	167 (80)	16 (80)	9.00 (-2.66 to 20.66), <0.05
	HTN	Medium HD + PA		IG1	11	310	164 (81)	19 (83.61)	332	167 (80)	9 (81.54)	10.00 (-2.79 to 22.79), NSD
	HTN	Medium HD + PA		IG2	11	290	163 (81)	25 (83.61)	332	167 (80)	9 (81.54)	16.00 (2.98 to 29.02), <0.05
	HTN	Low HD + PA	Vegetables (g/day)	IG3	11	267	166 (88)	39 (92.26)	332	167 (80)	9 (81.54)	30.00 (15.88 to 44.12), <0.001
	HTN	Medium HD + PA	Vegetables (g/day)	IG1	17	302	164 (81)	11 (84.72)	327	167 (80)	-3 (80.5)	14.00 (1.06 to 26.94), <0.05
	HTN	Medium HD + PA	(g/day)	IG2	17	285	, ,	11 (83.07)		167 (80)	-3 (80.5)	14.00 (0.99 to 27.01), NSD
	HTN	Low HD + PA	(g/day)	IG3	17	272	166 (88)	21 (90.07)	327	167 (80)	, , ,	24.00 (10.19 to 37.81), <0.01
Voils, 2013 ¹²⁶ (CouPLES)	Dys	Medium HD + PA	Fiber (g/day)	IG1	6	81	14.8 (6.8)	-1.4 (6.75)	74	13.9 (6.7)	-1.4 (7.25)	0.00 (-2.21 to 2.21), NSD
Fair	Dys	Medium HD + PA	Fiber (g/day)	IG1	11	88	14.8 (6.8)	-1.6 (6.56)	80	13.9 (6.7)	-2 (6.26)	0.40 (-1.54 to 2.34), 0.26

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Timepoint (months)	IG N	baseline	IG mean change (SD)	CG N	CG baseline mean (SD)		Between-group difference,† p- value
	Dys	Medium	Saturated fat	IG1	6	81	12.3 (2.9)	-1.2 (2.9)	74	12.6 (2.7)	-0.1 (3.04)	-1.10 (-2.04 to -
		HD + PA	(% energy)									0.16), < 0.05
	Dys	Medium HD + PA	Saturated fat (% energy)	IG1	11	88	12.3 (2.9)	-0.9 (2.85)	80	12.6 (2.7)	-0.3 (2.81)	0.26), 0.09
	Dys	Medium HD + PA	Saturated fat (g/day)	IG1	6	81	22.5 (14.8)	-6.7 (13.14)	74	21.3 (12.6)	-4.1 (11.4)	)-2.60 (-6.46 to 1.26), NSD
	Dys	Medium HD + PA	Saturated fat (g/day)		11	88	22.5 (14.8)		80	21.3 (12.6)	-3.9 (11.46)	-3.50 (-7.18 to 0.18), 0.02
Wadden, 2011 ¹²⁷ (Practice-based Opportunities for	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	6	131	6.1 (3.9)	0.7 (5.72)	130	5.6 (4.1)	0.5 (5.7)	0.20 (-1.19 to 1.59), NSD
Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	Fruits and Vegetables (servings/d)	IG1	24	131	6.1 (3.9)	-0.6 (5.72)	130	5.6 (4.1)	0.3 (5.7)	-0.90 (-2.29 to 0.49), 0.195
Wister, 2007 ¹²⁹ Good	Multiple	Medium HD + PA	Dietary pattern score (score)	IG1	12	157	NR (NR)	0.3 (1.09)	158	NR (NR)	-0.05 (1.09)	0.35 (0.11 to 0.59), <0.01
Wong, 2015 ¹³⁰ Good	HTN	Low HD only	Dietary pattern score (score)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	NR, 0.036
	HTN	Low HD only	Fruit (servings/d)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	MD=0.12 (-0.14 to 0.38), 0.352
	HTN	Low HD only	Fruit (servings/d)	IG1	12	243	NR (NR)	NR (NR)	242	NR (NR)	NR (NR)	MD=0.05 (-0.16 to 0.26), 0.643
	HTN	Low HD only	Fruits and Vegetables (servings/d)	IG1	6	254	NR (NR)	NR (NR)	250	NR (NR)	NR (NR)	MD=0.27 (-0.30 to 0.84), <0.05
	HTN	Low HD only	Fruits and Vegetables (servings/d)	IG1	12	243	NR (NR)	NR (NR)	242	NR (NR)	NR (NR)	MD=0.51 (-0.05 to 1.07), NSD
	HTN	Low HD only	Vegetables (servings/d)	IG1	6	254	, , ,	NR (NR)		NR (NR)	, ,	MD=0.15 (-0.24 to 0.54), 0.442
	HTN	Low HD only	Vegetables (servings/d)	IG1	12	243	NR (NR)	NR (NR)	242	NR (NR)	NR (NR)	MD=0.46 (0.04 to 0.88), 0.032

**Abbreviations:** BMI = body mass index; CG = control group; CI = confidence interval; cm = centimeters; Dys = dyslipidemia; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; KQ = key question; mg/d = milligrams per day; MD = mean difference; mmol/24-hr = millimoles per 24 hours; mmol/L = millimoles per liter; mmol/L = millimoles per liter

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

# Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)		RR [†] (95% CI), p- value
Appel, 2003 ⁴¹	HTN	High	Meeting diet recs (Met goal of	IG1	6		43/219	1.47 (1.05 to 2.06),
(PREMIER)		HD + PA	≤100 mmol/L sodium intake/d)			(28.8)	(19.6)	< 0.05
Good	HTN	High	Meeting diet recs (Met goal of	IG2	6	81/220	43/219	1.88 (1.36 to 2.58),
		HD + PA	≤100 mmol/L sodium intake/d)			(36.8)	(19.6)	< 0.05
	HTN	High	Meeting diet recs (Met goal of	IG1	18	57/227	49/235	1.20 (0.86 to 1.68),
		HD + PA	≤100 mmol/L sodium intake/d)			(25.1)	(20.9)	NSD
	HTN	High	Meeting diet recs (Met goal of	IG2	18	69/225	49/235	1.47 (1.07 to 2.02),
		HD + PA	≤100 mmol/L sodium intake/d)			(30.7)	(20.9)	< 0.05
	HTN	High	Meeting diet recs (Met goal of	IG1	6	79/236	16/243 (6.6)	5.08 (3.06 to 8.44),
		HD + PA	≥9 F/V servings/d)			(33.5)		< 0.05
	HTN	High	Meeting diet recs (Met goal of	IG2	6	14/233 (6.0)	16/243 (6.6)	0.91 (0.46 to 1.83),
		HD + PA	≥9 F/V servings/d)					NSD
	HTN	High	Meeting diet recs (Met goal of	IG1	18	74/247	13/252 (5.2)	5.81 (3.31 to 10.19),
		HD + PA	≥9 F/V servings/d)			(30.0)		< 0.05
	HTN	High	Meeting diet recs (Met goal of	IG2	18	13/241 (5.4)	13/252 (5.2)	1.05 (0.49 to 2.21),
		HD + PA	≥9 F/V servings/d)					NSD
	HTN	High	Meeting diet recs (Met goal of	IG1	6	182/230	103/232	1.78 (1.52 to 2.09),
		HD + PA	saturated fat ≤10% kcal/d)			(79.1)	(44.4)	< 0.001
	HTN	High	Meeting diet recs (Met goal of	IG2	6	139/227	103/232	1.38 (1.16 to 1.65),
		HD + PA	saturated fat ≤10% kcal/d)			(61.2)	(44.4)	< 0.001
	HTN	High	Meeting diet recs (Met goal of	IG1	6	107/230	36/232	3.00 (2.15 to 4.17),
		HD + PA	saturated fat ≤7% kcal/d)			(46.5)	(15.5)	< 0.001
	HTN	High	Meeting diet recs (Met goal of	IG2	6	60/227	36/232	1.70 (1.18 to 2.47),
		HD + PA	saturated fat ≤7% kcal/d)			(26.4)	(15.5)	0.004
Babazono, 2007 ⁴⁵ (PHPP)	Multiple	Medium	Vegetables (≤1 meals/day	IG1	12	6/46 (13.0)	11/41 (26.8)	0.49 (0.20 to 1.20),
Fair		HD + PA	w\vegetable servings)					NSD
	Multiple	Medium	Vegetables (≥2 meals/day	IG1	12	40/46 (87.0)	30/41 (73.2)	OR=3.80 (1.00 to
		HD + PA	w\vegetable servings)					14.00), < 0.05
Eakin, 2009 ⁶⁴ (Logan	Multiple	Medium	Meeting diet recs (% meeting	IG1	12	179/225	55/204	OR=1.99 (1.33 to
Healthy Living)		HD + PA	guidelines for fruit intake (≥2			(79.6)	(27.0)	2.99), <0.05
Fair			servings/d))	<u> </u>				
	Multiple	Medium	Meeting diet recs (% meeting	IG1	18	162/225	121/204	OR=1.65 (0.94 to
		HD + PA	guidelines for fruit intake (≥2 servings/d))			(72.0)	(59.3)	2.91), NSD

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR† (95% CI), p- value
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for sat fat intake (≤10% of total calorie intake))	IG1	12	52/223 (23.3)	30/201 (14.9)	OR=1.79 (0.85 to 3.78), NSD
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for sat fat intake (≤10% of total calorie intake))	IG1	18	41/223 (18.4)	21/201 (10.4)	OR=2.34 (0.86 to 6.35), NSD
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for vegetable intake (≥5 servings/d))	IG1	12	95/225 (42.2)	41/204 (20.1)	OR=2.35 (1.43 to 3.88), <0.05
	Multiple	Medium HD + PA	Meeting diet recs (% meeting guidelines for vegetable intake (≥5 servings/d))	IG1	18	73/225 (32.4)	36/204 (17.6)	OR=2.37 (1.48 to 3.80), <0.05
Hyman, 2007 ⁷⁹ Fair	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG1	6	27/92 (29.3)	12/93 (12.9)	2.27 (1.23 to 4.21), 0.01
	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG2	6	16/96 (16.7)	12/93 (12.9)	1.29 (0.65 to 2.58), NSD
	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG1	18	9/92 (9.8)	16/93 (17.2)	0.57 (0.26 to 1.22), 0.06
	HTN	Medium HD + PA	Meeting diet recs (Prop. meeting goal of Na levels <100 mEq/L per day)	IG2	18	12/96 (12.5)	16/93 (17.2)	0.73 (0.36 to 1.45), NSD
Koelewijn-van Loon, 2009 (Improving Patient	Multiple	Medium HD + PA	Fruit (Meeting national recommendation)	IG1	12	114/252 (45.2)	108/236 (45.8)	0.99 (0.81 to 1.20), 0.91
Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	Vegetables (Meeting national recommendation)	IG1	12	93/252 (36.9)	65/236 (27.5)	1.34 (1.03 to 1.74), 0.045
Lakerveld, 2013 ⁹⁰ (HOORN)	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for fruit intake (≥2 pieces/day))		6	57/314 (18.2)	70/308 (22.7)	OR=1.60 (0.90 to 2.60), NSD
Fair	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for fruit intake (≥2 pieces/day))	IG1	12	58/314 (18.5)	68/308 (22.1)	OR=1.40 (0.90 to 2.40), NSD
	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for vegetable intake (200 g/day))		6		57/308 (18.5)	OR=1.10 (0.70 to 1.70), NSD

### Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
	Multiple	Medium HD + PA	Meeting diet recs (Meeting rec for vegetable intake (200 g/day))		12	62/314 (19.7)	56/308 (18.2)	OR=0.90 (0.60 to 1.50), NSD
Moy, 2001 ⁹⁶ Fair	Multiple	High HD only	Meeting diet recs (% meeting the National Cholesterol Education Program Adult Treatment Panel II (ATP II) guidelines (≤30%))	IG1	24	35/117 (29.9)	20/118 (16.9)	1.76 (1.09 to 2.87), 0.019
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM))	Multiple	High HD + PA	Fruits and Vegetables (Number of participants who have increased their F&V intake)	IG1	30	257/292 (88.0)	230/287 (80.1)	1.10 (1.02 to 1.18), <0.1
Good	Multiple	High HD + PA	Fruits and Vegetables (Number of participants who have increased their F&V intake)	IG2	30	245/301 (81.4)	230/287 (80.1)	1.02 (0.94 to 1.10), NSD
Ter Bogt, 2009 ¹¹⁶ (Groningen Overweight	Multiple	High HD + PA	Meeting diet recs (Percent meeting rec for fruit (200 g/d))	IG1	36	76/158 (48.1)	89/172 (51.7)	0.93 (0.75 to 1.15), 0.77
and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Meeting diet recs (Percent meeting rec for saturated fat (10% of total energy intake/d))	IG1	36	34/158 (21.5)	32/172 (18.6)	1.16 (0.75 to 1.78), 0.35
	Multiple	High HD + PA	Meeting diet recs (Percent meeting rec for vegetables (200 g/d))	IG1	36	32/158 (20.3)	37/172 (21.5)	0.94 (0.62 to 1.43), 0.95
van Keulen, 2011 ¹²³ (Vitalum) Fair	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for fruit (≥2 servings/day))	IG1	17	151/302 (50.0)	144/327 (44.0)	OR=1.44 (NR), NSD
	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for fruit (≥2 servings/day))	IG2	17	137/285 (48.1)	144/327 (44.0)	OR=1.17 (NR), NSD
	HTN	Low HD + PA	Meeting diet recs (Meeting guidelines for fruit (≥2 servings/day))	IG3	17	166/272 (61.0)	144/327 (44.0)	OR=1.78 (NR), NSD
	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for vegetables (≥200 g/day))	IG1	17	109/302 (36.1)	92/327 (28.1)	OR=1.32 (NR), NSD
	HTN	Medium HD + PA	Meeting diet recs (Meeting guidelines for vegetables (≥200 g/day))	IG2	17	97/285 (34.0)	92/327 (28.1)	OR=1.31 (NR), NSD

### Appendix H Table 16. Dietary, Dichotomous Outcomes (KQ3)

Author, year (Study	Population	Contact time*	Outcome	Int	Timepoint	IG n/N (%)	CG n/N	RR [†] (95% CI), p-
name) Quality	risk focus	Intervention		arm	(months)		(%)	value
		focus						
	HTN	Low	Meeting diet recs (Meeting	IG3	17	109/272	92/327	OR=1.73 (NR), NSD
		HD + PA	guidelines for vegetables (≥200			(40.1)	(28.1)	
			g/day))					
Wood, 2008 ¹³¹	Multiple	High	Fruits and Vegetables (Goal	IG1	12	799/1019	388/1001	Difference in
(EUROACTION)		HD + PA	≥400 g/day)			(78.4)	(38.8)	probability=39.70
Fair								(18.10 to 61.30), 0.005

Abbreviations: BL = baseline; CG = control group; CI = confidence interval; F/V = fruit and vegetable; g/day = grams per day; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; mEq/L = milliequivalents per liter; min(s) = minutes; mmol/L = millimoles per liter; NR = not reported; NSD = no statistically significant difference; OR = odds ratio; prop = proportion; recs = recommendations; RR = risk ratio; servings/d = servings per day; wk = week

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)		point (mont hs)		` ,	change (SD)		mean (SD)	change (SD)	Between-group difference,† p-value
Anderson, 1992 ³⁹ Fair	Dys		expenditure (kJ/kg/d)	IG1			, ,	0.08 (16.9)				-13.62 (-22.72 to - 4.52), NSD
	Dys	High HD only	Total energy expenditure (kJ/kg/d)	IG2	12	47	155.5 (22.5)	-5.73 (19)	51			-19.43 (-28.89 to - 9.97), NSD
Anderssen, 1995 ⁴⁰ (Oslo	Multiple	Medium HD only	Cardiorespiratory fitness (min)	IG1	12	52	NR (NR)	56.6 (121.87)	43	NR (NR)	8.2 (91.8)	48.40 (5.39 to 91.41), <0.05
Diet and Exercise Study (ODES)) Fair	Multiple	Medium HD only	Cardiorespiratory fitness (mL/kg/min)	IG1	12	52	34.4 (5.05)	-0.3 (3.61)	43	34.3 (5.25)	-2 (3.28)	-1.70 (-1.90 to -1.50), <0.05
Appel, 2003 ⁴¹ (PREMIER) Good	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG1	6	225	130 (14.6)	-9 (10.7)	233	129.8 (14.6)	-5.3 (9.7)	-3.70 (-5.57 to -1.83), <0.001
	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG2	6	225	130.5 (14.1)	-8 (11.1)	233	129.8 (14.6)	-5.3 (9.7)	-2.70 (-4.61 to -0.79), 0.005
	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG1	18	225	130 (14.6)	-9.5 (11)	233	129.8 (14.6)	` /	-2.10 (-4.00 to -0.10), 0.035
	HTN	High HD + PA	Cardiorespiratory fitness (beats/min)	IG2	18	225	130.5 (14.1)	-8.2 (11.2)	233	129.8 (14.6)	-7.4 (10.4)	-0.80 (-2.70 to 1.20), NSD
	HTN	High HD + PA	Total PA (kcal/kg)	IG1	6	240	33.6 (2.4)	0.6 (2.4)	242	33.7 (2.5)	0.3 (2.9)	0.30 (-0.18 to 0.78), 0.1
	HTN		Total PA (kcal/kg)	IG2	6	232	33.8 (2.6)	0.4 (2.9)	242	33.7 (2.5)		0.10 (-0.42 to 0.62), 0.66
	HTN	High HD + PA	Total PA (kcal/kg)	IG1	18	240	33.6 (2.4)	0.8 (3.4)	242	33.7 (2.5)	0.6 (3.6)	0.10 (-0.30 to 0.60), NSD
	HTN	High HD + PA	(kcal/kg)	IG2	18	232	33.8 (2.6)	0.3 (2.6)	242	33.7 (2.5)	0.6 (3.6)	-0.20 (-0.70 to 0.30), NSD
Arroll, 1995 ⁴⁴ Fair	HTN	HD + PA	Moderate intensity energy expenditure (kJ/kg/d)	IG1	6	48	15.7 (27.02)	27.8 (42.09)	43	13.5 (26.23)	7.5 (40.97)	20.30 (3.22 to 37.38), <0.05

Author, year		Contact	Outcome (Unit)	Int arm	Time	IG N	IG baseline		CG N			Between-group
(Study name) Quality		time* Intervention focus			point (mont hs)		mean (SD)	change (SD)		, ,	(SD)	difference,† p-value
	HTN	Low PA only	Moderate intensity energy expenditure (kJ/kg/d)	IG2	6	46	15.1 (4)	38.3 (46.28)	43	13.5 (26.23)		30.80 (12.67 to 48.93), <0.05
	HTN	Low HD only	Moderate intensity energy expenditure (kJ/kg/d)	IG3	6	44	10.6 (26.53)	27.4 (40.9)	43	13.5 (26.23)	7.5 (40.97)	19.90 (2.70 to 37.10), <0.05
	HTN	Low HD + PA	Total energy expenditure (kJ/kg/d)	IG1	6	48	145.2 (18.71)	16.2 (27.74)	43	145.5 (18.36)		9.20 (-2.02 to 20.42), NSD
	HTN	Low PA only	Total energy expenditure (kJ/kg/d)	IG2	6	46	145.2 (18.99)	24 (27.77)	43	145.5 (18.36)	7 (26.85)	17.00 (5.65 to 28.35), <0.05
	HTN	Low HD only	Total energy expenditure (kJ/kg/d)	IG3	6	44	143 (18.57)	14.9 (27.16)	43	145.5 (18.36)	` /	7.90 (-3.45 to 19.25), NSD
Babazono, 2007 ⁴⁵ (PHPP) Fair	Multiple	Medium HD + PA	Total PA (steps/d)	IG1	12	46	7345 (3890)	3028 (3993.22)	41			3409.00 (1822.12 to 4995.88), ≤0.001
Blackford, 2016 ⁵⁰ (Albany Physical	Multiple	Medium HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	6	151	300 (585)	180 (753.31)	159	,	, ,	180.00 (24.21 to 335.79), 0.049
Nutrition	Multiple	Medium HD + PA	Strength exercise (min/wk)		6		39.2 (168.9)	(151.58)		, ,	(68.67)	17.40 (-9.03 to 43.83), 0.653
Fair	Multiple	Medium HD + PA	min/wk)	IG1	6		807.5 (1486.9)	524.5 (1560.48)		990 (1357.5)	(1582.44)	541.50 (191.57 to 891.43), 0.335
	Multiple	Medium HD + PA	intensity PA (MET-min/wk)	IG1	6		181.5 (479.4)	36 (470.09)		, ,	(446.21)	59.50 (-42.64 to 161.64), 0.537
	Multiple	Medium HD + PA	min/wk)	IG1	6		396 (561)	181.5 (670.44)		, ,	(659.07)	115.50 (-32.59 to 263.59), 0.524
Bo, 2007 ⁵² Fair	Multiple	Medium HD + PA	Total PA (MET- min/wk)	IG1	12	169	1134 (798)	283.8 (724.29)	166	1086 (960)		299.40 (183.24 to 415.56), <0.001

Author, year		Contact	Outcome (Unit)	Int arm	Time	IG N	IG baseline		CG N			Between-group
(Study name) Quality		time* Intervention focus			point (mont hs)		mean (SD)	change (SD)		, ,	(SD)	difference,† p-value
Broekhuizen, 2012 ⁵⁴ (PRO- FIT) Fair	Dys	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	171	422 (NR)	79 (NR)	146	363.1 (NR)	64.9 (NR)	Beta coefficient=1.11 (-0.12 to 0.33), NSD
Burke, 2006 ⁵⁶ (ADAPT) Fair	HTN	Medium HD + PA	Cardiorespiratory fitness (beats/min)	IG1	16	106	74 (10.3)	1 (10.3)	98	71 (9.9)	` /	-6.00 (-9.92 to -2.08), 0.044
	HTN	Medium HD + PA	Cardiorespiratory fitness (beats/min)		40	123	73 (11.32)	-1 (10.2)	118	71 (8.31)		-0.70 (-2.00 to 0.70), 0.675
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	16	123	162 (169.75)	41 (124.49)	118	174 (116.39)		21.00 (-9.76 to 51.76), 0.185
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	40	123	162 (169.75)	66 (169.75)	118	174 (116.39)		53.00 (15.00 to 91.00), 0.007
Christian, 2011 ⁵⁸ Fair	Multiple	Medium HD + PA	Total PA (MET- min/wk)	IG1	12	133	271.9 (424.8)	288.8 (659)	130	395.9 (552.31)		176.50 (-496.83 to 849.83), 0.07
Cicolini, 2014 ⁵⁹ Fair	HTN	Medium HD + PA	Total PA (min/wk)	IG1	6	100	47.6 (56)	113.4 (63)	98	56.7 (65.8)		79.10 (61.74 to 96.46), <0.001
Cochrane, 2012 ⁶⁰ Fair	Multiple	Medium HD + PA	Total PA (NHS Primary Prevention Toolkit)	IG1	12	236	2.67 (NR)	0.14 (NR)	365	2.65 (NR)	0.15 (NR)	NR, NSD
Delahanty, 2001 ⁶³ Good	Dys	Medium HD + PA	Total energy expenditure (min/wk)	IG1	6	44	119 (126)	25 (128.05)	44	92 (97)		9.00 (-39.65 to 57.65), NSD
	Dys	Medium HD + PA		IG1	12	43	119 (126)	29 (115.88)	44	( )		-14.00 (-72.67 to 44.67), NSD
Eakin, 2009 ⁶⁴ (Logan Healthy	Multiple	Medium HD + PA		IG1	12	225	142.5 (226.2)	71.19 (213)	204			-11.14 (-51.56 to 29.28), 0.589

Author, year (Study name) Quality	Population risk focus	time* Intervention	Outcome (Unit)	Int arm	point (mont		IG baseline mean (SD)	IG mean change (SD)	CG N		CG mean change (SD)	Between-group difference,† p-value
Living)	Multiple	focus Medium	Moderate to	IG1	<b>hs</b> )	225	142.5	62.19 (213)	204	142.4	74.73	-12.54 (-52.95 to
Fair	Multiple		vigorous intensity	-	10	223	(226.2)	02.19 (213)	204	(197.3)		27.88), 0.543
			PA (min/wk)				(220.2)			(177.3)	(212.70)	27.86), 0.343
	Multiple			IG1	12	225	2.9 (3.8)	2.61 (4.95)	204	2.9 (3.5)	2.22 (5)	0.39 (-0.55 to 1.33),
			vigorous intensity	,								0.491
			PA (sessions/wk)									
	Multiple			IG1	18	225	2.9 (3.8)	2.24 (4.95)	204	2.9 (3.5)	2.13 (5)	0.11 (-0.83 to 1.05),
			vigorous intensity	r								0.815
E 1 1	N		PA (sessions/wk) Total PA	TC1	10	77	1.6 (MD)	2.1 (AID)	77	1.4.(ND)	1 (NID)	NID. 0.002
Edelman, 2006 ⁶⁵	Multiple	High HD + PA	Total PA (days/wk)	IG1	10	77	1.6 (NR)	2.1 (NR)	77	1.4 (NR)	1 (NR)	NR, 0.002
Fair		пр+га	(days/wk)									
Estruch,	Multiple	High	Leisure PA	IG1	12	1236	1533	133	1094	1344	77	56.00 (-99.93 to
2018 ⁶⁷	iviumpie	HD only	(MET-min/wk)	(Participa		1230	(1632.28)	(1946.18)	1074	(1771.91)		211.93), NSD
(Primary			(IVIZI IIIII VIK)	nts			(1032.20)	(1) (0.10)		(17,71.51)	(10)0.01)	211.53), 1182
Prevention of				w/METs)								
Cardiovascula	Multiple	High	Leisure PA	IG1	12	663	1890	126	594	1750	63	63.00 (-149.84 to
r Disease with		HD only	(MET-min/wk)	(Participa			(1701.26)	(1977.14)		(1784.39)	(1871.43)	275.84), NSD
a				nts w/out								
Mediterranean				METs)								
Diet	Multiple	High	Leisure PA	IG2	12	1062		42	1094	1344	77	-35.00 (-179.31 to
(PREDIMED)		HD only	(MET-min/wk)	(Participa			(1571.22)	(1513.03)		(1771.91)	(1890.04)	109.31), NSD
) Fair				nts								
rair	M14:1-	TT: -1-	Leisure PA	w/METs) IG2	12	662	2079	-56	594	1750	63	110.00 / 226.94 +-
	Multiple	High HD only	(MET-min/wk)	1G2 (Participa		002	(1883.76)	(2067.54)	594	(1784.39)		-119.00 (-336.84 to 98.84), NSD
		HD only		nts w/out			(1003.70)	(2007.34)		(1704.39)	(16/1.43)	90.04), NSD
				METs)								
	Multiple	High	Leisure PA	IG1	36	1236	1533	140	1094	1344	91	49.00 (-117.27 to
			(MET-min/wk)	(Participa			(1632.28)	(1946.18)		(1771.91)		215.27), NSD
				nts			,	,		,	,	,,
				w/METs)								
	Multiple	High	Leisure PA	IG1	36	663	1890		594	1750		0.00 (-281.57 to
		HD only	(MET-min/wk)	(Participa			(1701.26)	(2115.08)		(1784.39)	(2872.43)	281.57), NSD
				nts w/out								
				METs)								

Author, year (Study name)		time*	Outcome (Unit)	Int arm	point		IG baseline mean (SD)	change			change	Between-group difference,† p-value
Quality		Intervention focus			(mont hs)			(SD)			(SD)	
	Multiple	High	Leisure PA	IG2	36	1062		112	1094	1344		21.00 (-151.35 to
		HD only	(MET-min/wk)	(Participa nts w/METs)			(1571.22)	(1955.3)		(1771.91)	(2126.29)	193.35), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participa nts w/out METs)		662	2079 (1883.76)	-7 (2205.37)	594	1750 (1784.39)	126 (2872.43)	-133.00 (-418.63 to 152.63), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participa nts w/METs)	60	1236	1533 (1632.28)	203 (2197.3)	1094	1344 (1771.91)	35 (2716.93)	168.00 (-34.30 to 370.30), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG1 (Participa nts w/out METs)	60	663	1890 (1701.26)	-49 (2666.84)	594	1750 (1784.39)	28 (2828.91)	-77.00 (-381.90 to 227.90), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participa nts w/METs)	60	1062	1561 (1571.22)	49 (2502.32)	1094	1344 (1771.91)	35 (2716.93)	14.00 (-206.38 to 234.38), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participa nts w/out METs)		662	2079 (1883.76)	-35 (2756.72)	594	1750 (1784.39)	28 (2828.91)	-63.00 (-372.60 to 246.60), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	(Participa nts w/METs)		1236	(1632.28)	77 (4269.04)		1344 (1771.91)	(4547.9)	91.00 (-268.54 to 450.54), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	(Participa nts w/out METs)		663	1890 (1701.26)	-154 (5195.74)	594	1750 (1784.39)	-483 (6106.09)	329.00 (-301.50 to 959.50), NSD
	Multiple	High HD only	Leisure PA (MET-min/wk)	IG2 (Participa nts w/METs)		1062	1561 (1571.22)	-77 (5121.02)	1094	1344 (1771.91)	-14 (4547.9)	-63.00 (-472.25 to 346.25), NSD

Author, year (Study name)		time*	Outcome (Unit)	Int arm	point		IG baseline mean (SD)	change	CG N		change	Between-group difference,† p-value
Quality		Intervention focus			(mont hs)			(SD)			(SD)	
	Multiple	High		IG2	84	662	2079		594	1750	-483	196.00 (-447.88 to
		HD only		(Participa			(1883.76)	(5467.49)		(1784.39)	(6106.09)	839.88), NSD
				nts w/out								
201070				METs)								0.71/0.77
Gill, 2019 ⁷⁰	Multiple	Medium	`	IG1	6	59	NR (NR)		59	NR (NR)	1.37	0.76 (-8.52 to 10.04),
(HealtheSteps)	N	HD + PA	min/wk)	TC1	_	50	AID (AID)	(25.79)	50	NID (NID)	(25.67)	0.87
Fair	Multiple	Medium HD + PA	Walking (steps/d)		6	59	NR (NR)	(3301.98)	59	NR (NR)	-1485 (3171.51)	3132.00 (1969.00 to 4294.00), <0.001
Greaves,	Multiple	High		IG1	12	53	157.5		53	151.2	22.89	-0.64 (-1.83 to 0.56),
2015 ⁷¹ (Waste the Waist)		HD + PA	vigorous intensity PA (min/wk)				(156.1)	(104.16)		(115.5)	(131.74)	0.291
Fair	Multiple	High	Sedentary time	IG1	12	53	4121.6	-31.64	53	3824.8	-81.2	113.40 (-44.10 to
	_	HD + PA	(min/wk)				(520.8)	(392.35)		(619.5)	(429.8)	270.20), 0.156
	Multiple	High HD + PA	Walking (steps/d)	IG1	12	53	6420 (3016)	-141 (1903)	53	6551 (2499)	166.1 (2291)	-345.00 (-1100.00 to 410.00), 0.367
Hardcastle,	Multiple	Medium	Moderate	IG1	6	203	440.69	91.03	131	576.15	-62.13	153.16 (-87.32 to
2008 ⁷³ Fair	_	HD + PA	intensity PA (MET-min/wk)				(1091.22)	(1122.29)		(1159.23)	(1076.72)	393.64), NSD
	Multiple	Medium	Moderate	IG1	18	203	440.69	420.92	131	576.15	510.09	-89.17 (-404.67 to
	_	HD + PA	intensity PA (MET-min/wk)				(1091.22)	(1361.82)		(1159.23)	(1482.49)	226.33), NSD
	Multiple	Medium	Total PA (MET-	IG1	6	203	1854.08	497.16	131	2278.56	-13.41	510.57 (-63.20 to
	_	HD + PA	min/wk)				(2174.67)	(2377.06)		(2820.37)		1084.34), NSD
	Multiple	Medium	`	IG1	18	203	1854.08	1299.59	131	2278.56	993.54	306.05 (-415.66 to
		HD + PA	min/wk)				(2174.67)	(2977.57)		(2820.37)		1027.76), NSD
	Multiple	Medium		IG1	6	203	590.05	146.67	131	746.55	-1.77	148.44 (-180.38 to
		HD + PA	intensity PA (MET-min/wk)				(1294.38)	(1356.16)		(1672.04)		477.26), NSD
	Multiple	Medium	0	IG1	18	203	590.05	470.69	131	746.55	225.49	245.20 (-164.23 to
		HD + PA	intensity PA (MET-min/wk)				(1294.38)	(1850.51)		(1672.04)	(1872.6)	654.63), NSD
	Multiple	Medium	Walking (MET-	IG1	6	203	996.07	199.47	131	1242.45	-191.96	391.43 (101.27 to
		HD + PA	min/wk)				(1116.59)	(1205.19)		(1432.69)		681.59), < 0.05
	Multiple	Medium	<i>U</i> \	IG1	18	203	996.07	269.07	131	1242.45	85.25	183.82 (-132.22 to
		HD + PA	min/wk)				(1116.59)	(1251.18)		(1432.69)	(1547.86)	499.86), < 0.01

(Study name) Quality		Contact time* Intervention focus	Outcome (Unit)	Int arm	point (mont hs)		IG baseline mean (SD)	change (SD)		mean (SD)	change (SD)	Between-group difference,† p-value
Harris, 2012 ⁷⁴ (Health	1	High HD + PA	PA score (score)				3.71 (2.38)	0.88 (2.36)		3.38 (2.4)	, ,	0.37 (-0.07 to 0.81), 0.002
Improvement and Prevention Study (HIPS)) Fair	Multiple	High HD + PA	PA score (score)	IG1	12	355	3.71 (2.38)	0.89 (2.49)	300	3.38 (2.4)	0.71 (2.49)	0.18 (-0.20 to 0.56), 0.005
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	Cardiorespiratory fitness (W/kg)	IG1	6	160	0.83 (1.26)	1.06 (1.1)	154	0.93 (1.37)	0.84 (1.2)	0.22 (-0.03 to 0.47), <0.0001
	Multiple	Medium HD + PA	min/wk)	IG1			384 (822)	180.0 (1187.9)		390 (540)	-144.0 (838.5)	324.00 (97.24 to 550.76), 0.010
Hyman, 2007 ⁷⁹	HTN	Medium HD + PA	(steps/d)	IG1			3624.4 (2917.5)	525 (3215)		3933 (3363.6)	·	606.00 (-366.77 to 1578.77), NSD
Fair	HTN	Medium HD + PA	(steps/d)	IG2			3306 (2785.3)	(3570.83)		3933 (3363.6)		490.00 (-522.39 to 1502.39), NSD
	HTN	Medium HD + PA	(steps/d)	IG1			3624.4 (2917.5)	(2813.74)	93	3933 (3363.6)	(3906.66)	411.50 (-568.80 to 1391.80), NSD
	HTN	Medium HD + PA	(steps/d)	IG2			3306 (2785.3)	(4776.82)	93	3933 (3363.6)		723.40 (-518.97 to 1965.77), NSD
Kandula, 2015 ⁸³ (South Asian Heart Lifestyle Intervention (SAHELI)) Fair	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	6	31	56 (114)	9.5 (79.09)			4.4 (76.15)	5.10 (-32.98 to 43.26), NSD
Khanji, 2019 ⁸⁷ (HAPPY London) Good		Low HD + PA	(min/wk)	IG1			495.6 (529.2)	175.7 (882.27)	183	454.3 (643.3)	59.14 (674.62)	116.55 (-72.10 to 305.20), 0.23
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice	Multiple	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	12	252	405 (343)	55 (352.88)	236	447 (345)	2 (355.42)	53.00 (-9.88 to 115.88), 0.74

Author, year (Study name) Quality		Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (mont hs)		IG baseline mean (SD)	IG mean change (SD)	CG N			Between-group difference,† p-value
(IMPALA)) Fair												
Kramer, 2018 ⁸⁹	Multiple	High HD + PA	Leisure PA (MET-min/wk)	IG1	6	81	NR (NR)	996 (1224)	43	NR (NR)	432 (996)	564.00 (164.41 to 963.59), 0.007
(Healthy Lifestyle Project) Fair	Multiple	High HD + PA	Total PA (min/wk)	IG1	6	81	NR (NR)	35.6 (224.7)	43	NR (NR)	29.7 (367)	5.90 (-114.21 to 126.01), 0.05
Lakerveld, 2013 ⁹⁰ (HOORN) Fair	Multiple	Medium HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	6	314	NR (NR)	NR (NR)	308	NR (NR)	, ,	Beta coefficient=- 66.50 (-156.10 to 22.40), NSD
	Multiple	Medium HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	12	314	NR (NR)	NR (NR)	308	NR (NR)	NR (NR)	Beta coefficient=- 65.80 (-154.00 to 22.40), NSD
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	6	314	NR (NR)	NR (NR)	308	NR (NR)	NR (NR)	Beta coefficient=- 5.60 (-23.10 to 12.60), NSD
	Multiple	Medium HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	12	314	NR (NR)	NR (NR)	308	NR (NR)	, ,	Beta coefficient=- 0.70 (-23.10 to 21.70), NSD
Migneault, 2012 ⁹⁴ Fair	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1	8	169	162.4 (169)	-3.44 (NR)	168	126.3 (144.3)	2.77 (NR)	-6.21 (NR), NSD
	HTN	High HD + PA		IG1	12	169	162.4 (169)	-21.3 (NR)	168	126.3 (144.3)	7.3 (NR)	NR, NSD
	HTN	High HD + PA		IG1	8	169	3234.7 (860.7)	43.8 (NR)	168	3188.5 (820.3)	-36.2 (NR)	80.00 (NR), 0.02
	HTN	High HD + PA		IG1	12	169	3234.7 (860.7)	-49.1 (NR)	168	3188.5 (820.3)	-5.2 (NR)	NR, NSD

Author, year (Study name) Quality	risk focus	Contact time* Intervention focus	Outcome (Unit)		point (mont hs)		IG baseline mean (SD)	change (SD)	CG N	mean (SD)	change (SD)	Between-group difference,† p-value
Niiranen, 2014 ¹⁰⁰ Fair	HTN	Medium HD + PA	Leisure PA (MJ/d)	IG1	12	112	0.49 (0.45)	0 (0.4)	108	0.51 (0.44)	0.07 (0.32)	-0.07 (-0.32 to 0.18), 0.15
Fair	Multiple	High HD + PA	(min/wk)	IG1			91.7 (102.5)	(113.51)	215	, ,	(104.72)	MD=23.90 (3.90 to 44.00), 0.03
2012104	HTN	Medium HD + PA	Total PA (min/wk)	IG1	6		315.6 (453)	-17.4 (568.56)	177	, ,	`	8.40 (-94.83 to 111.63), 0.88
	HTN	Medium HD + PA	Total PA (min/wk)	IG1	12		315.6 (453)	-60.6 (412.69)	155	, ,		-91.80 (-185.17 to 1.57), NSD
Rubinstein, 2016 ¹⁰⁷ Good	HTN	Medium HD + PA	min/wk)	IG1	12	94	971.5 (1544.1)	-348.9 (1345.49)	96	566.4 (779.9)	-188.5 (842.22)	-229.10 (-595.10 to 136.80), 0.22
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	PA score (score, heiQ health directed behavior subscale)	IG1	12	297	NR (NR)	NR (NR)	294	NR (NR)	NR (NR)	MD=0.10 (0.00 to 0.20), 0.003
Fair	Multiple	Medium PA only	vigorous intensity PA (kcal/wk)				4799.73 (3450.16)	86.18 (4126.59)	18	,	(4015.56)	1400.95 (-1298.90 to 4100.80), 0.027
	Multiple	Medium PA only	(steps/d)	IG1			5638.29 (3063.19)	-5.04 (2850.35)	18	5530.4 (3142.14)		429.55 (-1468.08 to 2327.18), 0.382
2008 ¹¹⁴ (Weight Loss	Multiple	High HD + PA	vigorous intensity PA (min/wk)	IG1		342	172 (173.3)	NR (NR)	342	(141.8)	NR (NR)	-5.00 (-24.00 to 14.00), NSD
(WLM)) Good	Multiple	High HD + PA	vigorous intensity PA (min/wk)	IG2		348	159.1 (136.6)	NR (NR)	342	(141.8)	NR (NR)	-8.00 (-27.00 to 12.00), NSD
2009 ¹¹⁵ (Hypertension	HTN	High HD + PA	vigorous intensity PA (min/wk)				, ,	28.4 (134.9)	132		` /	44.10 (13.07 to 75.13), <0.05
Project (HIP)) Fair	HTN	High HD + PA	vigorous intensity PA (min/wk)		6			6.2 (103.2)	132		(122)	21.90 (-5.72 to 49.52), NSD
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG3	6	137	36.4 (127.1)	18.5 (297.8)	132	` /	-15.7 (122)	34.20 (-19.84 to 88.24), NSD

Author, year	Author, year Population Contact			, ,				IG mean	CG N	CG baseline	CG mean	an Between-group	
(Study name) Quality		time* Intervention focus			point (mont hs)		mean (SD)	change (SD)		, ,	(SD)	difference,† p-value	
	HTN	High HD + PA	vigorous intensity PA (min/wk)	IG1	18	128	28.8 (106.7)		122	43.9 (122.5)		12.30 (-20.06 to 44.66), NSD	
	HTN	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG2	18	124	37.9 (89.1)	-21.5 (138.8)	122	43.9 (122.5)		-8.50 (-44.07 to 27.07), NSD	
	HTN	Medium HD + PA	Moderate to vigorous intensity PA (min/wk)	IG3	18	134	36.4 (127.1)	5 (95.1)	122	\ /		18.00 (-12.46 to 48.46), NSD	
Ter Bogt, 2009 ¹¹⁶ (Groningen Overweight	Multiple	High HD + PA	Moderate intensity energy expenditure (MET-min/wk)	IG1	36	111	424 (532)	16 (633)	137	467 (510)		-57.00 (-216.67 to 102.67), 0.166	
and Lifestyle (GOAL)) Good	Multiple	High HD + PA	Moderate to vigorous intensity PA (MET- min/wk)	IG1	12	135	596 (589.84)	97 (572.06)	140	720 (624.81)		119.00 (-12.95 to 250.95), 0.24	
	Multiple	High HD + PA	Total PA (MET- min/wk)	IG1	12	120	2304 (1168.1)	-126 (997.64)	129	2026 (921.37)	-68 (909.78)	-58.00 (-295.72 to 179.72), 0.52	
	Multiple	High HD + PA	Total PA (MET- min/wk)	IG1	36	111	2304 (1168.1)	-167 (1321)	97	2026 (921.37)		-75.00 (-420.17 to 270.17), 0.387	
	Multiple	High HD + PA	Vigorous intensity PA (MET-min/wk)	IG1	36	111	217 (233)	59 (288)	137	237 (290)		14.00 (-59.79 to 87.79), 0.85	
	Multiple	High HD + PA	min/wk)	IG1	12		174 (213.63)	, , , ,	162	183 (191.57)	(149.36)	38.00 (0.20 to 75.80), 0.05	
	Multiple	High HD + PA	Walking (MET- min/wk)	IG1	36	139	174 (213.63)	25 (253)	153	183 (191.57)		2.00 (-56.32 to 60.32), 0.875	
Toft, 2008 ¹¹⁸ (Inter99) Fair	Multiple	High HD + PA	vigorous intensity PA (min/wk)	<u></u>		3126	291 (167.73)	-1.8 (380.19)	356	327 (175.47)		37.00 (-2.55 to 76.55), NSD	
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Males)	12	2 <mark>965</mark>	286 (168.8)	-2.5 (359.38)	337	304 (167.05)		16.40 (-24.32 to 57.12), NSD	

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome (Unit)	Int arm	Time point (mont hs)		IG baseline mean (SD)	IG mean change (SD)	CG N	mean (SD)	CG mean change (SD)	Between-group difference,† p-value
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)				291 (167.73)	(385.78)	356		(371.7)	10.70 (-30.21 to 51.61), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	, ,			286 (168.8)	-5.3 (359.38)	337	304 (167.05)	(357.97)	-3.20 (-43.55 to 37.15), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Females)		3126	291 (167.73)	-3.8 (363.42)	356	327 (175.47)	-21.9 (356.6)	18.10 (-21.07 to 57.27), NSD
	Multiple	High HD + PA	Moderate to vigorous intensity PA (min/wk)	IG1 (Males)	60	2965	286 (168.8)	1.4 (359.38)	337	304 (167.05)	-20.4 (350.63)	21.80 (-17.81 to 61.41), NSD
van Keulen, 2011 ¹²³ (Vitalum)	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	6	369	290.4 (237.6)	114.6 (281.02)	392		78.6 (256.01)	36.00 (-2.27 to 74.27), NSD
Fair	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG2	6	370	258.6 (223.8)	142.8 (278.15)	392		78.6 (256.01)	64.20 (26.18 to 102.22), <0.05
	HTN	Low HD + PA	Moderate intensity PA (min/wk)	IG3	6		291.6 (238.8)	123.6 (290.91)	392	(217.8)	78.6 (256.01)	45.00 (6.18 to 83.82), <0.01
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	11		(237.6)	49.8 (252.88)	331	(217.8)	42.6 (249.23)	7.20 (-31.80 to 46.20), NSD
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG2			258.6 (223.8)	109.2 (246.37)		(217.8)	42.6 (249.23)	66.60 (27.37 to 105.83), <0.01
	HTN	Low HD + PA	Moderate intensity PA (min/wk)	IG3			291.6 (238.8)	119.4 (283.42)		(217.8)	42.6 (249.23)	76.80 (33.43 to 120.17), <0.001
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	17		(237.6)	44.4 (254.99)		(217.8)	45.6 (249.23)	-1.20 (-40.66 to 38.26), NSD
	HTN	Medium HD + PA	Moderate intensity PA (min/wk)	IG2	17	285	258.6 (223.8)	96 (252.03)	327		45.6 (249.23)	50.40 (10.58 to 90.22), <0.01

Author, year (Study name) Quality	risk focus	Contact time* Intervention focus	Outcome (Unit)		point (mont hs)		IG baseline mean (SD)	change (SD)		mean (SD)	change (SD)	Between-group difference,† p-value
	HTN	Low HD + PA	intensity PA (min/wk)	IG3			291.6 (238.8)	52.2 (263.07)	327	276.6 (217.8)		6.60 (-34.72 to 47.92), NSD
van Sluijs, 2005 ¹²⁴ (Physician- based	Multiple	Medium PA only	Moderate intensity energy expenditure (min/wk)	IG1	6	171	NR (NR)	NR (NR)	187	NR (NR)	NR (NR)	NR, NSD
Assessment and Counseling for Exercise (PACE)) Fair	Multiple	Medium PA only	Moderate intensity energy expenditure (min/wk)	IG1	12	171	NR (NR)	NR (NR)	187	NR (NR)	NR (NR)	Beta coefficient=- 34.17 (-110.91 to 42.56), 0.38
Voils, 2013 ¹²⁶ (CouPLES) Fair	Dys	Medium HD + PA	Moderate intensity PA (freq/wk)	IG1	6	96	8.3 (NR)	2.2 (NR)	94	8.3 (NR)	0.6 (NR)	NR, NSD
	Dys	Medium HD + PA		IG1	11	100	8.3 (NR)	1.8 (NR)	98	8.3 (NR)	0.1 (NR)	IRR=1.20 (1.00 to 1.50), 0.06
	Dys	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	6	96	414 (NR)	36 (NR)	94	414 (NR)	-12 (NR)	NR
	Dys	Medium HD + PA	Moderate intensity PA (min/wk)	IG1	11	100	414 (NR)	24 (NR)	98	414 (NR)	-18 (NR)	IRR=66.00 (54.00 to 84.00), 0.37
Wadden, 2011 ¹²⁷	Multiple	High HD + PA	(kcal/wk)	IG1			1074.9 (1070.7)	113.7 (2140.31)	130	1153.4 (1536.4)		163.30 (-352.26 to 678.86), NSD
(Practice- based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-	Multiple	High HD + PA	Total PA (kcal/wk)	IG1	24		1074.9 (1070.7)	415.4 (2060.19)	130	1153.4 (1536.4)	-70.4 (2120.73)	485.80 (-21.51 to 993.11), 0.037

Author, year (Study name) Quality	risk focus	time* Intervention	Outcome (Unit)	Int arm	Time point (mont		` /	IG mean change (SD)		mean (SD)		Between-group difference,† p-value
		focus			hs)							
UP))												
Good												
	Multiple	Medium	PA score (score,	IG1	12	157	NR (NR)	0.17 (1.47)	158	NR (NR)	0.16 (1.54)	0.01 (-0.32 to 0.34),
$2007^{129}$		HD + PA	5-pt scale based									NSD
Good			on ACSM									
			guidelines)									

**Abbreviations:** ACSM = American College of Sports Medicine; BG = between-group; CG = control group; CI = confidence interval; DS = dyslipidemia; EI = followup timepoint; EI = healthy diet; EI + EI = healthy diet and physical activity; EI = intervention group; EI = incident rate ratio; EI = kilocalories per kilogram; kcal/wk = kilocalories per week; EI = kilojoules per kilogram per day; EI = not reported; EI = not statistically significant difference; EI = physical activity; EI = point; steps/d = steps per day

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Between-group mean difference in change unless otherwise specified

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus		Int arm	Timepoint (months)	IG n/N (%)		RR† (95% CI), p- value
Appel, 2003 ⁴¹ (PREMIER) Good	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG1	6	149/237 (62.9)	123/241 (51.0)	1.23 (1.05 to 1.44),
	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG2	6	139/232 (59.9)	123/241 (51.0)	1.17 (1.00 to 1.38),
	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG1	18	130/240 (54.2)	123/242 (50.8)	1.07 (0.90 to 1.26),
	HTN	High HD + PA	Meeting PA recs (Met goal of ≥180 min/wk of moderate-to-vigorous PA)	IG2	18	127/235 (54.0)	123/242 (50.8)	1.06 (0.90 to 1.26),
Burke, 2006 ⁵⁶ (ADAPT) Fair	HTN	Medium HD + PA	Meeting PA recs (At least 30 mins/day 5 days/wk)	IG1	16	76/123 (61.8)	68/118 (57.6)	1.07 (0.87 to 1.32),
Coleman, 2012 ⁶² (Wisewoman California) Fair	Multiple	Medium HD + PA	Moderate intensity PA (yes/no)	IG1	12	365/433 (84.3)	335/435 (77.0)	1.09 (1.03 to 1.17),
Coleman, 2012 ⁶² (Wisewoman California) Fair	Multiple	Medium HD + PA	Vigorous intensity PA (yes/no)	IG1	12	143/433 (33.0)	75/435 (17.2)	1.92 (1.50 to 2.45),
Eakin, 2009 ⁶⁴ (Logan Healthy Living) Fair	Multiple	Medium HD + PA	Meeting PA recs (% meeting PA guidelines (≥150 mins, ≥5 sessions/wk)	IG1	12	101/225 (44.9)	71/204 (34.8)	OR=1.34 (0.90 to 2.00), NSD
	Multiple	Medium HD + PA	Meeting PA recs (% meeting PA guidelines (≥150 mins, ≥5 sessions/wk)	IG1	18	84/225 (37.3)	79/204 (38.7)	OR=0.96 (0.64 to 1.45), NSD
Hardcastle, 2008 ⁷³ Fair	Multiple	Medium HD + PA	Meeting PA recs (≥600 MET min/wk)	IG1	6	152/203 (74.9)	96/131 (73.3)	1.02 (0.90 to 1.16),
	Multiple	Medium HD + PA	Not meeting PA recs, inactive	IG1	6	51/203 (25.1)	35/131 (26.7)	0.94 (0.65 to 1.36), 0.005
Hyman, 2007 ⁷⁹ Fair	HTN	Medium HD + PA		IG1	6			1.33 (0.87 to 2.06), NSD
	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG2	6	27/96 (28.1)	25/93 (26.9)	1.05 (0.66 to 1.66), NSD

	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)		RR† (95% CI), p- value
	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG1	18	31/92 (33.7)	22/93 (23.7)	1.42 (0.90 to 2.27), NSD
	HTN	Medium HD + PA	Meeting PA recs (Prop. mtg goal to increase PA by 1500 steps/d (or >10,000/wk))	IG2	18	26/96 (27.1)		1.14 (0.70 to 1.87), NSD
Khanji, 2019 ⁸⁷ (HAPPY London) Good	Multiple	Low HD + PA	Meeting PA recs (PA >150 min/wk)	IG1	6	109/194 (56.2)	104/184 (56.5)	0.99 (0.83 to 1.19), 0.36
Kastarinen, 2002 ⁸⁵ (Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF))	HTN	High HD + PA	Meeting PA recs (30 mins moderate intensity PA 3x week, among not meeting at BL)	IG1	12	60/173 (34.7)	41/171 (24.0)	Difference in probability=10.70 (1.20 to 20.30),
Fair	HTN	High HD + PA	Meeting PA recs (30 mins moderate intensity PA 3x week, among not meeting at BL)	IG1	24	59/173 (34.1)	39/171 (22.8)	Difference in probability=11.30 (1.80 to 20.80),
Koelewijn-van Loon, 2009 (Improving Patient Adherence to Lifestyle Advice (IMPALA)) Fair	Multiple	Medium HD + PA	Meeting PA recs	IG1	12	163/252 (64.7)	153/236 (64.8)	1.00 (0.88 to 1.14), 0.97
Lakerveld, 2013 ⁹⁰ (HOORN) Fair	Multiple	Medium HD + PA	Meeting PA recs (Meeting rec for PA (≥30 min moderate-intensity PA ≥5 days/wk))	IG1	6	161/314 (51.3)	167/308 (54.2)	OR=0.70 (0.50 to 1.10), NSD
	Multiple	Medium HD + PA	Meeting PA recs (Meeting rec for PA (≥30 min moderate-intensity PA ≥5 days/wk))	IG1	12	162/314 (51.6)	160/308 (51.9)	OR=0.90 (0.60 to 1.40), NSD
Lee, 2007 ⁹² Fair	HTN	Medium PA only	Walking (No change in walking frequency)	IG1	6			0.62 (0.48 to 0.79),
	HTN	Medium PA only	Walking (Walking less compared w/BL)	IG1	6			0.15 (0.03 to 0.62),
	HTN	Medium PA only	Walking (Walking more compared w/BL)	IG1	6	48/91 (52.7)	8/93 (8.6)	6.13 (3.07 to 12.23),

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p- value
Liira, 2014 ⁹³ Fair	Multiple	Medium HD + PA	Meeting PA recs (PA ≥3 times per week)	IG1	12	7/46 (15.2)	7/42 (16.7)	0.91 (0.35 to 2.39), NSD
Migneault, 2012 ⁹⁴ Fair	HTN	High HD + PA	Leisure PA (>150 min/wk moderate-or-greater PA recs)	IG1	8	NR	NR	NR, NSD
Murphy, 2012 (National Exercise Referral Scheme (NERS)) Fair	Multiple	Medium PA only	Total PA (7D-PAR)	IG1	12	NR	NR	OR=1.29 (1.04 to 1.60), <0.05
Svetkey, 2008 ¹¹⁴ (Weight Loss Maintenance (WLM)) Good	Multiple	High HD + PA	Total PA (Number of participants who have increased their PA)	IG1	30	228/292 (78.1)	207/287 (72.1)	1.08 (0.99 to 1.19), <0.1
	Multiple	High HD + PA	Total PA (Number of participants who have increased their PA)	IG2	30	201/301 (66.8)	207/287 (72.1)	0.93 (0.83 to 1.03), NSD
Ter Bogt, 2009 ¹¹⁶ (Groningen Overweight and Lifestyle (GOAL)) Good		High HD + PA	Meeting PA recs (Percent meeting rec for 150 mins/week PA (National Dutch recs)	IG1	36	82/111 (73.9)	101/137 (73.7)	1.00 (0.86 to 1.16), 0.28
	Multiple	High HD + PA	Meeting PA recs (Percent meeting rec for 60 min/week vigorous PA (ACSM fit guideline)	IG1	36	71/111 (64.0)	84/137 (61.3)	1.04 (0.86 to 1.27), 0.99
Tiessen, 2012 ¹¹⁷ (SPRING (Self-monitoring and Prevention of RIsk Factors by Nurse practitioners in the region of Groningen)) Fair	Multiple	Medium HD + PA	Not meeting PA recs, inactive	IG1	12	NR	NR	Risk difference in change=-7.30 (-15.40 to 0.80), NSD
van Keulen, 2011 ¹²³ (Vitalum) Fair	HTN	Medium HD + PA	Meeting PA recs (Meeting guidelines for PA (≥5 days/wk for ≥30 min/day)	IG1	17	72/302 (23.8)	75/327 (22.9)	OR=1.57 (NR), <0.05
	HTN	Medium HD + PA	Meeting PA recs (Meeting guidelines for PA (≥5 days/wk for ≥30 min/day)	IG2	17	83/285 (29.1)	75/327 (22.9)	OR=2.08 (NR), <0.05
	HTN	Low HD + PA	Meeting PA recs (Meeting guidelines for PA (≥5 days/wk for ≥30 min/day)	IG3	17	73/272 (26.8)	75/327 (22.9)	OR=1.82 (NR), <0.05

Author, year (Study name)	Population	Contact time*	Outcome	Int	Timepoint	IG n/N (%)	CG n/N	RR [†] (95% CI), p-
Quality	risk focus	Intervention		arm	(months)		(%)	value
		focus						
van Sluijs, 2005 ¹²⁴	Multiple	Medium	Meeting PA recs (Meets	IG1	12	NR	NR	OR=0.99 (0.62 to
(Physician-based Assessment		PA only	ACSM/CDC guidelines)					1.57), 0.95
and Counseling for Exercise								
(PACE))								
Fair								
Wood, 2008 ¹³¹	Multiple	High	Meeting PA recs (≥30 mins,	IG1	12	512/1018	222/1003	Difference in
(EUROACTION)	_	HD + PA	≥4 times/week)			(50.3)	(22.1)	probability=29.40
Fair			·					(10.70 to 48.00), 0.01

**Abbreviations:** 7D-PAR = Standard 7-day Physical Activity Recall; ACSM = American College of Sports Medicine; BL = baseline; CG = control group; CI = confidence interval; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; MET = metabolic equivalent of task; min(s) = minutes; mtg = meeting; NR = not reported; NSD = no statistically significant difference; OR = odds ratio; PA = physical activity; prop = proportion; recs = recommendations; RR = risk ratio; wk = week

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

# Appendix H Table 19. Harms Outcomes (KQ4)

	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Appel, 2003 ⁴¹ (PREMIER) Good	HTN	High HD + PA	Serious musculoskeletal injuries	IG1	6	16/269 (5.9)	20/273 (7.3)	0.81 (0.43 to 1.53), NSD
	HTN	High HD + PA	Serious musculoskeletal injuries	IG2	6	17/268 (6.3)	20/273 (7.3)	0.87 (0.46 to 1.62), NSD
Appel, 2011 ⁴² (POWER Hopkins (Practice Based Opportunities for		High HD + PA	Hospitalizations	IG1	24	18/138 (13.0)	15/138 (10.9)	1.20 (0.63 to 2.28), NSD
Weight Reduction)) Good	Multiple	High HD + PA	Hospitalizations	IG2	24	15/139 (10.8)	15/138 (10.9)	0.99 (0.51 to 1.95), NSD
	Multiple	High HD + PA	Musculoskeletal injuries	IG1	24	1/138 (0.7)	0/138 (0.0)	3.00 (0.12 to 73.01), NSD
	Multiple	High HD + PA	Musculoskeletal injuries	IG2	24	0/139 (0.0)	0/138 (0.0)	NR, NSD
Bennett, 2012 ⁴⁷ (Be Fit, Be Well [POWER])	HTN	High HD + PA	Gallbladder disease	IG1	24	0/180 (0.0)	2/185 (1.1)	0.21 (0.01 to 4.25), NSD
Good	HTN	High HD + PA	Hospitalizations	IG1	24	36/180 (20.0)	35/185 (18.9)	1.06 (0.70 to 1.61), NSD
	HTN	High HD + PA	Musculoskeletal injuries	IG1	24	1/180 (0.6)	0/185 (0.0)	3.08 (0.13 to 75.18), NSD
Bennett, 2018 ⁴⁸ (Track) Good	Multiple	Medium HD + PA	Hospitalizations	IG1	12	11/176 (6.3)	1/175 (0.6)	10.94 (1.43 to 83.81), <0.05
	Multiple	Medium HD + PA	Musculoskeletal injuries	IG1	12	1/176 (0.6)	1/175 (0.6)	0.99 (0.06 to 15.77), NSD
Eakin, 2009 ⁶⁴ (Logan Healthy Living) Fair	Multiple	Medium HD + PA	SAEs	IG1	18	0/228 (0.0)	0/206 (0.0)	NR, NSD
Estruch, 2018 ⁶⁷ (Primary Prevention of Cardiovascular	Multiple	High HD only	Any adverse events	IG1	60	0/2543 (0.0)	0/2450 (0.0)	NR, NSD
Disease with a Mediterranean Diet (PREDIMED)) Fair	Multiple	High HD only	Any adverse events	IG2	60	0/2454 (0.0)	0/2450 (0.0)	NR, NSD
Gill, 2019 ⁷⁰ (HealtheSteps) Fair	Multiple	Medium HD + PA	Any adverse events	IG1	6	4/59 (6.8)	0/59 (0.0)	9.00 (0.50 to 163.53), NR
	Multiple	Medium HD + PA	SAEs	IG1	6	0/59 (0.0)	0/59 (0.0)	NR

### Appendix H Table 19. Harms Outcomes (KQ4)

Author, year (Study name) Quality	Population risk focus	Contact time* Intervention focus	Outcome	Int arm	Timepoint (months)	IG n/N (%)	CG n/N (%)	RR [†] (95% CI), p-value
Groeneveld, 2010 ⁷² (Health Under Construction) Fair	Multiple	Medium HD + PA	Any adverse events	IG1	12	0/408 (0.0)	0/408 (0.0)	NR, NSD
Haufe, 2019 ⁷⁵ Fair	Multiple	Medium HD + PA	Any adverse events	IG1	6	11/160 (6.9)	1/154 (0.6)	10.59 (1.38 to 81.03), 0.004
	Multiple	Medium HD + PA	Musculoskeletal injuries	IG1	6	1/160 (0.6)	0/154 (0.0)	2.89 (0.12 to 70.36), NR
Ogedegbe, 2014 ¹⁰² (Counseling African Americans to Control	HTN	Medium HD + PA	Any adverse events	IG1	12	0.189 [‡]	0.216 [‡]	NR, 0.34
Hypertension (CAATCH)) Fair	HTN	Medium HD + PA	Hospitalizations	IG1	12	54/529 (10.2)	66/510 (12.9)	0.79 (0.56 to 1.11), 0.16
	HTN	Medium HD + PA	SAEs	IG1	12	0.115‡	0.139‡	NR, 0.28
Rodriguez, 2012 ¹⁰⁴ Fair	HTN	Medium HD + PA	Any adverse events	IG1	6	2/176 (1.1)	3/177 (1.7)	0.67 (0.11 to 3.96), NSD
Rosas, 2015 ¹⁰⁶ (Vivamos Activos Fair Oaks (VAFO))	Multiple	High HD + PA	ED Visits	IG1	24	29/82 (35.4)	17/41 (41.5)	0.85 (0.53 to 1.36), NSD
Good	Multiple	High HD + PA	ED Visits	IG2	24	23/84 (27.4)	17/41 (41.5)	0.66 (0.40 to 1.09), NSD
	Multiple	High HD + PA	Hospitalizations	IG1	24	5/82 (6.1)	1/41 (2.4)	2.50 (0.30 to 20.70), NSD
	Multiple	High HD + PA	Hospitalizations	IG2	24	5/84 (6.0)	1/41 (2.4)	2.44 (0.29 to 20.22), NSD
Salisbury, 2016 ¹⁰⁸ Good	Multiple	Medium HD + PA	Any adverse events	IG1	12	38/325 (11.7)	38/316 (12.0)	0.97 (0.64 to 1.48), NSD
	Multiple	Medium HD + PA	SAEs	IG1	12	22/325 (6.8)	24/316 (7.6)	0.89 (0.51 to 1.56), NSD
Wadden, 2011 ¹²⁷ (Practice-based Opportunities for Weight Reduction at the University of Pennsylvania (POWER-UP)) Good	Multiple	High HD + PA	SAEs	IG1	24	20/131 (15.3)	16/130 (12.3)	
Wood, 2008 ¹³¹ (EUROACTION) Fair	Multiple	High HD + PA	Any adverse events	IG1	12 DA L	0/1019 (0.0)	0/1005 (0.0)	NR, NSD

**Abbreviations:** CG = control group; CI = confidence interval; ED = emergency department; HD = healthy diet; HD + PA = healthy diet and physical activity; HTN = hypertension; IG = intervention group; Int arm = intervention arm; NR = not reported; NSD = no statistically significant difference; RR = risk ratio; SAEs = serious adverse events

### Appendix H Table 19. Harms Outcomes (KQ4)

^{*}Intervention contact time defined as: Low = 0-30 min, Medium = 31-360 min, High = >360 min

[†]Risk ratio unless otherwise specified

[‡]Mean number per 100 participants

### Appendix I. Ongoing Studies

Trial Identifier	Principal Investigator	Study Name	Country	Estimated N		Estimated Completion Date
NCT02342808	James A. Blumenthal, PhD	Lifestyle Interventions in Treatment-Resistant Hypertension (TRIUMPH)	US	150	To examine the effects of a lifestyle intervention on fitness, dietary habits, and body weight in patients with resistant hypertension	December 2019
NCT01180673	Olugbenga Ogedegbe, MD	Counseling Older Adults to Control Hypertension (COACH)	US	251	To evaluate the effect of a senior center- based comprehensive therapeutic lifestyle intervention delivered through group-based counseling and motivational interviewing among hypertensive African American or Latino seniors aged ≥60 years	Completed as of March 2019. Awaiting publication of results.
ISRCTN18008011	Oliver Peacock, PhD	Multidimensional Individualized Physical Activity profiles for behavior Change using Technology (MiPACT)	UK	216	To examine whether personalized multidimensional physical activity feedback and self-monitoring using a webbased platform alongside in-person advice supports an increase in physical activity and weight loss in men and women at risk for future chronic disease	publication of results.
ACTRN126130007157 74	Julie Redfern, PhD	Consumer Navigation of electronic cardiovascular Tools (CONNECT)	AUS	934	To test whether a consumer-focused e- health strategy provided to Aboriginal and Torres Strait Islander and non-indigenous adults, recruited through primary care, at moderate-to-high risk of a cardiovascular disease event will improve risk factor control when compared with usual care	NR – Ongoing as of August, 2018
NCT02283697	Marcel Ruzicka, MD, PhD	Dietary Counseling to Reduce Salt Intake in Patients With High Blood Pressure	CAN	120	To test the efficacy of a structured counseling session by a registered dietitian in addition to usual care on sodium intake and blood pressure compared with usual care alone	December 2019
NCT02551640	Kamal Jethwani, MD	Improving Physical Activity Through a mHealth Intervention in Cardio-metabolic Risk Patients	US	300	To examine the effects of a smartphone- based physical activity-focused application in patients with cardiometabolic risk factors compared with usual care	December 2018. Awaiting publication of results.
NCT01838226	David Edelman, MD	Randomized Controlled Trial of Group Prevention Coaching	US	401	To test the effectiveness of a group prevention coaching (GPC) intervention in improving cardiovascular risk	Completed June, 2019. Awaiting publication of results

# **Appendix I. Ongoing Studies**

Trial Identifier	Principal Investigator	Study Name	Country	Estimated N	- I ( I	Estimated Completion Date
NCT03052959	Lawrence Paszat, MD	BETTER HEALTH: Durham	US	120	To examine the effectiveness of supportive meetings between a specially trained prevention practitioner nurse and individuals aged 40-64 years to review recommended chronic disease prevention and screening activities (CDPS)	
NCT03164499	Sara Mora Simón, PhD	Intensive Intervention to Improve Lifestyles in Subjects With Intermediate Cardiovascular Risk	ESP	203	To evaluate the effectiveness of an intensive intervention to modify lifestyles of subjects with intermediate cardiovascular risk	Completed March 2019. Awaiting publication of results.
NCT03092960	Lisa Goldman Rosas, PhD	Comparing Two Innovative Approaches to Reduce Chronic Disease Risk Among Latino Men (HOMBRE)	US	424	To test a flexible lifestyle program designed to help Latino men make healthy lifestyle changes to lower their risk of developing diabetes and heart disease	July 2020
ISRCTN76069254	Aina Riera, PhD	Effectiveness of a brief multifactorial intervention in adherence to physical exercise prescription of moderate to high cardiovascular risk patients	ESP	616	To evaluate the effectiveness of a brief multifactorial intervention designed to improve the adherence to physical exercise prescription of moderate to high cardiovascular risk patients	Completed December 2017. Awaiting publication of results.
NCT02725203	Marieke J. Schuurmans, PhD	Unravelling Effectiveness of a Nurse-led Behavior Change Intervention to Enhance Physical Activity in Patients		195	To evaluate the effectiveness of the Active intervention, consisting of four nurse-led consultations over 3-months in patients at risk for cardiovascular disease	Completed October 2018. Awaiting publication of results.
<u>ISRCTN54638034</u>	Varun Anand, MBChB, BMedSc	Communicating cardiovascular disease risk in UK primary care	UK	60	To investigate the effects of GPs using heart age to communicate the risk of CVD to patients	Completed 2018. Awaiting publication of results.
ISRCTN89898870	Jordi Salas-Salvadó, MD, PhD	PREDIMED-Plus	ESP	6874	To evaluate whether intensive interventions involving an energy-restricted Mediterranean diet, promotion of physical activity, and behavioral support are likely to result in long-term weight loss, reduced	May 2020

# **Appendix I. Ongoing Studies**

Trial Identifier	Principal Investigator	Study Name	Country	Estimated	Purpose (as reported)	Estimated
				N		Completion Date
					CVD risk, and greater quality of life for	
					older people with metabolic syndrome.	
NCT03577990	Willie M Abel, PhD	Interactive Technology-	US	90	To evaluate the effectiveness of a	May 2022
		Enhanced Coaching			technology coaching Intervention for black	
		(ITEC)			women with hypertension.	
NCT02499731	Rebecca A. Seguin-Fowler,	Strong Hearts: Rural CVD	US	194	To evaluate the efficacy of the Strong	February 2022
	<u>PhD</u>	Prevention			Hearts Healthy Communities (SHHC)	
					curriculum in a 24-week community based	
					randomized controlled intervention trial in	
					an underserved rural population.	

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