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Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults Without Known Cardiovascular Disease Risk Factors: Updated Systematic Review for the U.S. Preventive Services Task Force

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Structured Abstract

Objective: We conducted this systematic review to support the U.S. Preventive Services Task Force (USPSTF) in updating its 2012 recommendation on behavioral counseling to promote a healthful diet and physical activity for the primary prevention of cardiovascular disease (CVD) in adults without known CVD risk factors. Our review addressed four key questions: 1) Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve health outcomes in adults? 2) Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve intermediate outcomes associated with CVD in adults? 3) Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve associated health behaviors in adults? 4) What adverse events are associated with primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior in adults?

Data Sources: We performed a search of MEDLINE, PubMed (publisher-supplied), PsycINFO, and the Cochrane Central Register of Controlled Trials for studies published through May 25, 2016. Studies included in the 2010 USPSTF review were re-evaluated for potential inclusion. We supplemented searches by examining reference lists from related articles and expert recommendations and searched federal and international trial registries for ongoing trials.

Study Selection: Two researchers reviewed 10,045 titles and abstracts and 351 full-text articles against prespecified inclusion criteria. Eligible studies were those that evaluated the effectiveness of a behavioral intervention targeting improved diet, increased physical activity, decreased sedentary time, or a combination of these targets among adults without known hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors. Studies among adults without these risk factors but with other characteristics that may still put them at elevated risk for CVD (e.g., being overweight or having obesity, having a family history of CVD or diabetes, having high-normal blood pressure) were included. Studies focused on the primary prevention of CVD among persons with traditional CVD risk factors or weight loss were excluded from this review, as they were the focus of other USPSTF reviews and recommendations. Studies that recruited participants from primary care or the broader health care system, took place in primary care or included primary care staff, or were deemed to be potentially feasible for primary care were eligible for inclusion. Studies had to take place in a developed country and be published in the English language to be included. We conducted dual independent critical appraisal of all provisionally included studies and abstracted all important study details and results from all studies rated fair or good quality. Data were abstracted by one reviewer and confirmed by another.

Data Analysis: Data on health outcomes and harms were sparsely reported, and the specific outcomes measured differed across trials, precluding meta-analysis, so we summarized those data in tables and narratively. For intermediate health outcomes and physical activity behavioral outcomes, we ran random effects meta-analyses using the DerSimonian and Laird method to calculate the pooled differences in mean changes (for continuous data) and pooled odds ratio (for binary data). We examined statistical heterogeneity among the pooled studies using standard chi-

squared tests and estimated the proportion of total variability in point estimates using the I^2 statistic. Meta-analyses for each dietary outcome found considerable statistical heterogeneity ($I^2 > 88\%$) that could not be adequately explained. Thus, we did not present the pooled estimates for these outcomes. We used meta-regression to explore potential effect modification by various study, population, and intervention characteristics, such as study quality, link to primary care, intervention focus, intervention intensity, and baseline characteristics. We generated funnel plots and conducted tests for small-study effects for all pooled analyses. Using established methods, we assessed the strength of evidence for each key question.

Results: We included 88 trials reported in 145 publications. We carried forward 50 trials from our previous review; 38 new trials were added. Of the 88 included trials, 12 reported health outcomes (KQ 1) (e.g., CVD events, self-reported quality of life), 34 reported intermediate health outcomes (KQ 2) (e.g., lipid, blood pressure, and glucose levels; weight measures), 86 reported behavioral outcomes (KQ 3) (i.e., objective or self-reported measures of diet, physical activity, or sedentary time), and 14 reported harms (or lack thereof) of a counseling intervention (KQ 4). The majority of the trials took place in the United States and were conducted within or recruited from a primary care setting. There was great diversity in the interventions that were tested; 23 trials focused on healthful diet and physical activity, another 24 on healthful diet only, and 44 on physical activity only. Intervention intensity (total minutes of contact) ranged from 3 to 2,340 minutes (39 hours), with a mean of 6 hours and 11 minutes. Low-intensity interventions were mostly mailed, print-based interventions, whereas medium- and high-intensity interventions involved one-on-one individual and telephone counseling and group sessions.

Health outcomes. Four trials (all in the original review) of high-intensity diet-only interventions reported no differences in all-cause or CVD-related mortality between intervention and control groups at 3 to 15 years of followup. Also, there were no consistent findings for the effects on CVD events over 8 to 15 years of followup. Results of 10 trials (mostly physical activity interventions) showed general improvements in quality of life over 6 to 12 months among intervention groups, but there was no consistent benefit of the intervention compared with control conditions.

Intermediate outcomes. There was evidence of small, statistically significant improvements in systolic blood pressure (mean difference [MD], -1.26 mm Hg [95% confidence interval (CI), -1.77 to -0.75]; k=22), diastolic blood pressure (MD, -0.49 mm Hg [95% CI, -0.82 to -0.16]; k=23), low-density lipoprotein cholesterol level (MD, -2.58 mg/dL [95% CI, -4.30 to -0.85]; k=13), and total cholesterol level (MD, -2.85 mg/dL [95% CI, -4.95 to -0.75]; k=19) at 6 to 12 months associated with healthful diet and/or physical activity interventions. For adiposity outcomes, interventions were associated with improvements in body mass index (MD, -0.41 kg/m² [95% CI, -0.62 to -0.19]; k=20), weight (MD, -1.04 kg [95% CI, -1.56 to -0.13]; k=20), and waist circumference (MD, -1.19 cm [95% CI, -1.79 to -0.59]; k=17) although there was considerable statistical heterogeneity ($I^2 > 90\%$) in all of these analyses, and therefore pooled results should be interpreted with caution. Very few studies reported the effects of the interventions beyond 12 months. There was evidence of a dose-response effect, with an association between increasing intervention intensity and larger improvements in intermediate outcomes, but insufficient evidence to assess the effects of low-intensity interventions alone on intermediate outcomes. There was no evidence of an association with high-density lipoprotein

cholesterol, triglycerides, or fasting glucose level and limited evidence on the effects of interventions on incident hypertension, dyslipidemia, and diabetes.

Behavioral outcomes. There was consistent evidence that behavioral interventions generally improved participants' dietary intake and physical activity levels at 6 to 12 months of followup. Between-group differences for dietary outcomes were in the magnitude of 65 kcal/day (favoring the control group) to -500 kcal/day (favoring the intervention group) in total energy intake (k=11), 0.8 to -11 percentage points in the percent of calories from fat (k=15), -0.3 to -4.1 percentage points in the percent of calories from saturated fat (k=9), and approximately -380 to nearly -1,400 mg/day of sodium (k=6). Effects on fruit and vegetable intake ranged from between-group differences of -0.2 servings/day (favoring the control group) to 2.2 servings/day (favoring the intervention group) (k=16); between-group differences in grams of fiber per day ranged from 1 to 2.5 g/day in favor of the intervention group (k=6). Persistent effects of the interventions were seen over time for all dietary outcomes among studies that reported multiple time points. Physical activity interventions (with or without dietary messages) resulted in an approximate 35-minute increase in physical activity per week compared with control groups (k=27). Additionally, intervention group participants had a 32-percent higher odds of meeting physical activity recommendations compared with those in the control group (k=16). Studies that limited enrollment to participants with suboptimal levels of physical activity at baseline (generally below the recommended level of 150 minutes/week) resulted in greater increases in physical activity compared with those that did not limit enrollment based on baseline physical activity levels. In contrast to findings for intermediate outcomes, there was no evidence of effect modification based on intervention intensity.

Adverse events. Across 14 trials, there were no serious adverse events related to counseling, although we did not hypothesize that these counseling interventions would result in serious harms (i.e., unexpected or unwanted medical attention). There was no consistent evidence that the incidence of injuries, falls, or adverse cardiovascular events were different among participants in physical activity interventions and those in control groups.

Limitations: Our focus on counseling interventions that take place in or were considered feasible for primary care among adults without risk factors for CVD or known CVD is relatively narrow. This systematic review represents only a subset of a much larger body of literature on diet and physical activity interventions. There was very limited evidence on the effectiveness of interventions aimed at reducing time spent in sedentary behaviors.

Conclusions: The results of our updated systematic review are generally consistent in magnitude with our 2010 review on this topic. In general, diet and physical activity behavioral interventions for generally unselected adults who were not targeted for counseling based on their CVD risk resulted in consistent modest benefits across a variety of important intermediate health outcomes, including blood pressure, low-density lipoprotein, and total cholesterol levels as well as adiposity, with evidence of a dose-response effect with higher intensity interventions resulting in greater improvements. Small-to-moderate improvements were also seen in dietary and physical activity behaviors. Very limited evidence exists on health outcomes or harmful effects of these interventions. The improvements we saw, however, in intermediate and behavioral health outcomes could translate into long-term reduction in CVD-related events, with minimal to no

harms, if such changes were maintained over time.

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Chapter 1. Introduction

Purpose

The U.S. Preventive Services Task Force (USPSTF) requested an updated evidence report on primary care–relevant behavioral counseling interventions to promote healthful diet and physical activity for the primary prevention of cardiovascular disease (CVD) in adults without known CVD or CVD risk factors (i.e., hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors). This report will be used by the USPSTF to update its 2012 recommendation.¹

Condition Definition

Healthful Diet

A healthful eating pattern is comprised of foods and beverages in quantities, proportions, or combinations that assist persons in achieving and maintaining a healthy weight, reducing the risk of chronic disease, and promoting overall health and well-being.^{2,3} For the purposes of this review, we included any dietary counseling that focused on improving dietary patterns, consuming more of certain foods and nutrients (e.g., fruits, vegetables, whole grains, fat-free and low-fat dairy, lean proteins), and consuming less foods with sodium, saturated fat, trans fat, cholesterol, added sugar, or refined grains. This guidance is generally consistent with major dietary recommendations, including the “2015–2020 Dietary Guidelines for Americans.”²

Physical Activity

Physical activity is generally defined as any physical movement produced by the contraction of skeletal muscle that leads to an increase in energy expenditure above being at rest.^{4,5} Prominent national and international guideline bodies recommend that adults age 18 years or older engage in at least 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity, or an equivalent combination of moderate- and vigorous-intensity physical activity per week, as well as strengthening activities at least twice per week.^{5,6}

Sedentary Behavior

Sedentary behaviors are those that involve sitting and require a low level of energy expenditure (1.0 to 1.5 metabolic equivalents of task [METs]), such as watching television, using a computer, playing an electronic game, and sitting in an automobile.⁷ Sedentary behavior is not simply the absence of physical activity; rather, it is a unique set of behaviors. There are currently no specific U.S.-based recommendations for decreasing sedentary time. In addition to their physical activity guidelines, the governments of Australia and the United Kingdom recommend minimizing the amount of time spent in prolonged sitting and breaking up long periods of sitting as often as

possible.^{8, 9}

Burden and Prevalence of CVD and Risk Factors

Diseases associated with modifiable risk factors are the primary cause of morbidity and mortality in the United States.¹⁰ CVD is the chief contributor to this trend and remains the leading cause of death for men and women in the United States, despite the overall reductions in death from coronary heart disease and stroke over the last decade.^{11, 12} In 2013, the overall mortality rate associated with CVD was 222.9 deaths per 100,000 persons, or more than 2,200 deaths each day.¹² Treatment of CVD-related morbidity represents a significant burden to the U.S. health care system; in 2010, the estimated direct and indirect costs of CVD were approximately \$444 billion, and the direct and indirect costs of high blood pressure alone were \$93.5 billion.¹³

The American Heart Association's concept of "cardiovascular health" is characterized by seven health behaviors and measures, each of which is known to substantially reduce the risk of CVD: normal blood pressure, cholesterol, and fasting glucose levels; normal body weight; healthy dietary pattern; sufficient physical activity; and not smoking.¹² Based on 2011–2012 National Health and Nutrition Examination Survey (NHANES) data, only about 13 percent of U.S. adults met five measures of ideal cardiovascular health, 5 percent met six criteria, and almost none met all seven criteria. The prevalence of cardiovascular health across these measures varied considerably; among adults age 50 years or older, 1.8 percent met criteria for an ideal dietary pattern, 19.6 percent had a blood pressure level of less than 120/80 mm Hg, 24.2 percent had a total cholesterol level of less than 200 mg/dL, 26.7 percent had a body mass index (BMI) less than 25 kg/m², 35.1 percent had a fasting glucose level of less than 100 mg/dL, 37.1 percent got at least 150 minutes per week of moderate physical activity or at least 75 minutes of vigorous physical activity, and 82.1 percent were never smokers or quit a year or more ago. The proportion of adults meeting the ideal level for each of these measures was generally higher among those ages 20 to 49 years than among older adults, with the exception of smoking (74.5% vs. 82.1% were never smokers or quit a year or more ago) and healthful diet (1.3% vs. 1.8%) (**Table 1**).¹² In addition to these risk factors, a greater amount of sedentary behavior— independent of regular moderate- to vigorous-intensity physical activity—is associated with higher cardiovascular morbidity and mortality.^{14–16} Current estimates based on NHANES objective measures indicate that adults spend approximately 8 hours per day of approximately 15 waking hours engaged in sedentary behavior.¹⁷

In this review, "known CVD risk factors" specifically refers to known hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors. Although being overweight or having obesity is associated with higher CVD risk,^{18, 19} in this review, it was not used as a criterion for high CVD risk given the high prevalence in the U.S. population²⁰ and because it is not included in CVD risk assessment models (e.g., Framingham,^{21–23} American Heart Association/American College of Cardiology pooled cohort equations^{24, 25}). Likewise, although poor dietary patterns, low levels of physical activity, and high levels of sedentary behavior are associated with increased CVD risk, participants selected based on these factors were included in this review. Due to the high prevalence of these behaviors, and the high prevalence of being overweight or having obesity, we considered adults with these

characteristics to be part of a generally unselected population as opposed to being selected for counseling based on high CVD risk.

Cardiovascular risk factors and the burden of CVD are not equally distributed across adults in the United States. Specific subpopulations that experience a higher prevalence of CVD risk factors and rates of avoidable death from CVD include older adults, racial/ethnic minority groups, and persons of lower socioeconomic status.^{12, 26-28} Additionally, CVD develops about 7 to 10 years earlier in men than in women, with men experiencing the first myocardial infarction (MI) at an average age of 65.1 years and women at 72.0 years.¹² Of note, rates of controlled blood pressure and cholesterol are considerably lower among older adults (**Table 1**).¹²

Hispanic and black adults are less likely than white adults and other racial/ethnic groups to have measures of cardiovascular health at ideal levels. Based on 2011–2012 NHANES data, 19.6 percent of white adults age 20 years or older met five or more criteria for ideal cardiovascular health compared with only 14.4 percent of Hispanic and 10.5 percent of black adults age 20 years or older.¹² These disparities begin early in the life course, with racial/ethnic differences in cardiovascular health measures beginning to appear in childhood.¹²

Complex health behaviors, such as healthful diet, physical activity, and sedentary behavior also vary by important subpopulations. Persons of lower socioeconomic status or those with lower educational attainment tend to be less active, eat fewer fruits and vegetables, and eat fewer foods rich in dietary fiber compared with persons in a higher socioeconomic position or with higher educational attainment.^{29, 30} Nonwhite adults tend to be less active than white adults and consume fewer servings of fruits and vegetables.³⁰ Physical activity rates are lower in older persons and women than in younger persons and men.³⁰ Moreover, older adults and women spend more of their waking time engaged in sedentary behaviors than do their younger and male counterparts, whereas Mexican American adults are significantly less sedentary than adults from other racial/ethnic groups.¹⁷

Commonly cited barriers to healthful eating include the cost of healthful foods, lack of accessible and accurate information on what constitutes a healthful diet, poor accessibility to affordable healthful foods, time constraints due to work and family demands, and sociocultural factors (e.g., family or cultural food norms, family resistance, and lack of support).³¹⁻³⁴ Major barriers to physical activity include time constraints due to work and family demands; high cost of exercise facilities, exercise equipment, and sports teams; existence of physical ailments or chronic conditions; poor access to facilities; and unsafe or unsupportive environments.^{32, 35-37} Psychosocial barriers to physical activity include lack of social support for exercise, low self-efficacy for maintaining an exercise program, anxiety about unfamiliar settings for exercise, poor body image, and fatigue.^{32, 36, 37} Additionally, environmental barriers such as the nonavailability of healthy eating establishments or grocery stores, parks, sidewalks, bicycle trails, or safe and pleasant walking paths close to home or the workplace; traffic; the availability of public transportation; crime; and pollution may affect individuals' perceived or real ability to be more active and adopt healthful eating behaviors.^{38, 39}

Behavioral Counseling Interventions for CVD Primary Prevention

Behavioral interventions to improve diet and physical activity encompass a wide range of strategies that may be available within, feasible for, or referable from primary care. These interventions 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; or computer-based interventions, including Web-based sessions, email, or mobile technology. Behavioral counseling interventions can be delivered by a primary care provider, health educator or behavioral health specialist, nutritionist or dietitian, exercise specialist, or “coaches.” Behavior change techniques employed in these interventions can include a broad range of activities, including goal-setting and planning, monitoring and feedback through food and activity logs or pedometers, increasing efficacy and motivation for behavior change (including using motivational interviewing), addressing barriers to change, social support, and general education and advice regarding the benefits of healthy eating or physical activity.⁴⁰

Other interventions for CVD prevention include tobacco cessation, weight loss, aspirin use, and screening for and treatment of high or abnormal levels of blood pressure, cholesterol, and glucose. These interventions are the focus of other reports commissioned by the USPSTF.⁴¹⁻⁴⁶

Recommendations From Other Groups on Healthful Diet and Physical Activity Counseling

The American Academy of Family Physicians fully adopted the specific recommendations of the USPSTF to selectively counsel patients not at risk for CVD (2012) and to offer or refer adults who are overweight or have obesity and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity.⁴⁷ The American Heart Association (2013), American College of Cardiology (2013), and American College of Preventive Medicine (2006) recommend that clinicians provide nutritional assessment and physical activity counseling to their adult patients.^{48, 49} The “Exercise Is Medicine” initiative, which was developed by the American College of Sports Medicine and American Medical Association⁵⁰ and is endorsed by the American Heart Association,⁵¹ calls for health care providers to review and assess every patient’s physical activity level (e.g., physical activity as a vital sign), with office visits concluding with an exercise prescription or referral to a qualified health and fitness professional for further counseling. The Community Preventive Services Task Force (2001) recommends implementing behavioral and social interventions such as individually-adapted health behavior change programs and social support interventions in community settings to increase physical activity.⁵² Through its Healthy People 2020 objectives, the U.S. Department of Health and Human Services also encourages health care providers to counsel patients on nutrition, diet, and physical activity.⁵³

Current Clinical Practice in the United States

In 2012 in the United States, 61.4 percent of preventive care visits were made to office-based physicians per 100 persons, and 58.2 percent of those visits were made to primary care physicians.⁵⁴ Although patients perceive family doctors as one of the most reliable sources for health and medical information,⁵⁵ and specifically for food and nutrition advice,⁵⁶ few adults report receiving any advice on diet or exercise. In a 2000 survey of U.S. adults, only 21.3 and 24.5 percent of respondents reported receiving advice by a physician in the past year to modify their diet or exercise, respectively.⁵⁷ There are no updated data for dietary counseling, but the percentage of patients who had been seen by a health professional in the previous year and were advised to begin or continue physical activity rose from 22.6 percent in 2001 to 36.6 percent in 2012.⁵⁸ A majority (70% to 97%) of physicians endorse physical activity or lifestyle counseling as important to very important, and most report that they consider it their role to provide such counseling.⁵⁹ Frequently cited barriers to physical activity counseling by primary care providers include the lack of time, knowledge, or training about physical activity counseling, or lack of success with changing patients' behaviors.⁵⁹

Previous USPSTF Recommendations

In 2012, the USPSTF concluded with moderate certainty that in a primary care setting, medium- or high-intensity behavioral counseling interventions to promote a healthful diet and physical activity have a small net benefit for adults *without* known CVD risk factors.¹ Therefore, it issued a C recommendation, meaning that clinicians may choose to selectively counsel patients rather than incorporate counseling into the care of all adults in the general population. The body of evidence related to this recommendation represented generally unselected adults who were not targeted for counseling based on their risk for CVD (i.e., having hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors).

In 2014, the USPSTF issued a separate recommendation regarding behavioral counseling interventions to promote healthful diet and physical activity in adults *with* known CVD risk factors.⁶⁰ It recommended that clinicians offer intensive behavioral counseling interventions to adults who are overweight or have obesity and who have additional CVD risk factors, or refer these patients to such interventions (B recommendation). The evidence review to support this recommendation included studies in which participants were selected on the basis of their CVD risk, including those with hypertension, dyslipidemia, impaired fasting glucose, or a combination of these factors. Although that recommendation is specifically for adults who are overweight or have obesity and who have additional CVD risk factors, the evidence review was not limited to such adults. The recommendation specified this population because all but two included studies were among adults who were overweight or had obesity.

Two other USPSTF recommendations relate to the current update. In 2015, the USPSTF recommended screening for abnormal blood glucose as part of cardiovascular risk assessment in adults ages 40 to 70 years who are overweight or have obesity and offering or referring patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity (B recommendation).⁶¹ Similarly, in 2012, the USPSTF

recommended screening all adults for obesity and offering or referring patients with a BMI of 30 kg/m² or higher to intensive, multicomponent behavioral interventions (B recommendation).⁶²

Chapter 2. Methods

Scope of Review

The current review is an update of the 2010 review⁴⁰ and focuses on the effectiveness of behavioral counseling interventions to promote a healthful diet and physical activity and/or reduce sedentary behavior for the primary prevention of CVD among adults *without* known CVD or those not at high risk for CVD (i.e., with known hypertension, dyslipidemia, or impaired fasting glucose).

Key Questions and Analytic Framework

We developed an Analytic Framework (**Figure 1**) and four Key Questions (KQs) to guide the literature search, data abstraction, and data synthesis.

KQs

1. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve health outcomes in adults?
2. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve intermediate outcomes associated with CVD in adults?
3. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve associated health behaviors in adults?
4. What adverse events are associated with primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior in adults?

Data Sources and Searches

We designed this review as an extension of two of our prior systematic reviews on behavioral counseling for the primary prevention of CVD. The first was a review of adults not at high risk of CVD and was published in 2010 (encompassing literature through 2009).^{40, 63} The second review focused on studies among high-risk adults and was published in 2014 (encompassing literature through October 2013).^{64, 65} Regardless of the focus on high-risk persons in the 2014 review, our search strategy for that review was designed to encompass all adults regardless of risk level and was identical to the search performed for the original 2010 review. During the search process for the 2014 review, we purposefully coded studies that did not include a high-risk population but that might otherwise be included for evaluation in our updated review. As such, we re-evaluated all of these records as well as the 73 studies included in the 2010 review for potential inclusion. We then searched for new primary published literature from January 2013 through May 25, 2016. We searched the following databases: MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials. We

worked with a research librarian to develop our search strategy, which was peer reviewed by a second research librarian (**Appendix A**). All searches were limited to articles published in the English language. Collectively, the literature searches encompassed literature published from 1966 through May 25, 2016.

Because the scope of this current review was expanded to include sedentary behavior as an independent intervention target and behavioral outcome, the updated search included specific search terms to locate this literature. We also reviewed all of the studies included in a recent systematic review of literature published through October 2013 on the effectiveness of physical activity and sedentary behavior interventions in reducing sedentary time in adults.⁶⁶

In addition to these database searches, we searched ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform (www.who.int/ictrp) for ongoing trials through January 2016. We also examined the reference lists of previously published reviews, meta-analyses, and primary studies to identify any 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.⁶⁷ We managed the literature search results using version X7 of EndNote® (Thomson Reuters, New York, NY), a bibliographic management software database.

Study Selection

We developed specific inclusion criteria to guide our study selection (**Appendix A Table 1**). For all KQs, we included randomized, controlled trials (RCTs), including cluster randomized trials; nonrandomized, controlled trials; and systematic reviews of trials that evaluated the effectiveness of primary care–relevant interventions focused on improving dietary habits, increasing physical activity, and/or reducing sedentary time with the primary aim of CVD primary prevention. We excluded studies with a primary aim of weight loss or weight management as this evidence is covered by a separate systematic review conducted for the USPSTF.⁴² Similarly, we excluded studies primarily aimed at falls prevention or improving cognitive function rather than CVD prevention. Studies had to report a behavioral outcome (i.e., diet, physical activity, sedentary time), intermediate outcome (e.g., blood pressure, lipid levels, weight), or health outcome (i.e., morbidity, mortality, health-related quality of life [HrQOL]) or report adverse events related to the intervention.

We included studies if they were among adults age 18 years or older *without* known CVD, diabetes, or CVD risk factors. The evidence on CVD prevention among adults *with* known cardiovascular risk factors is covered by a separate systematic review.^{64, 65} As such, we excluded studies that 1) targeted persons with known CVD, hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors; 2) targeted persons categorized as high risk based on a cardiovascular risk assessment tool; or 3) generically stated that participants must have one or more CVD risk factors to be included. We included studies with persons that may be at elevated risk for CVD based on factors such as age, race/ethnicity, family history of CVD, overweight or obesity, high-normal blood pressure (i.e., systolic blood pressure [SBP] of 120 to 139 mm Hg or diastolic blood pressure [DBP] of 80 to 89 mm Hg), or

history of gestational diabetes. We also included studies among unselected samples (e.g., a general population, recruited on the basis of age or sex only) or samples that were selected because of suboptimal behavior (e.g., did not meet national physical activity guidelines). Within these samples, we examined the baseline characteristics to determine whether a sample could be considered high risk based on mean baseline values or the proportion of participants taking medications for a CVD risk factor (e.g., antihypertensive agents, statins, or hypoglycemic agents) and excluded studies that generally indicated a high-risk population. We also excluded studies of persons with other known chronic diseases, such as cancer (including studies targeting cancer survivors) or severe mental illness, as well as pregnant women.

We included interventions that were conducted in or recruited from primary care or a health care system or that we judged could feasibly be implemented in or referred from primary care. For example, we included studies relying on virtual-, computer-, or telephone-based programs or those that exclusively used print or mailed materials, as we judged these all to be potentially feasible for a primary care office or a large health system to implement. We excluded studies that took place exclusively in or in conjunction with worksites, churches, or other settings that are not generalizable to primary care given pre-existing social ties that are not easily reproducible in primary care. Behavioral counseling was broadly defined to include interventions such as counseling or education that included but was not limited to assessment with feedback, motivational interviewing, advice, collaborative goal-setting, and exercise prescriptions. Interventions could be delivered in various modes, including in person, with print materials, or by telephone or computer and could be delivered by a number of potential interventionists, such as physicians, nurses, exercise specialists, dietitians, nutritionists, or behavioral health specialists. We excluded interventions focused on supervised exercise or controlled diets as well as those that focused on stress management techniques, such as meditation or yoga. We included only studies that included the following controls: no intervention (e.g., wait list or usual care), minimal intervention (e.g., usual care limited to ≤ 15 minutes of contact or generic brochures), or attention controls (e.g., similar format and intensity but different content). We excluded studies that evaluated the comparative effectiveness of two active interventions without the addition of a true control group. For the greatest applicability to U.S. primary care practice, we included only studies conducted in developed countries, as defined by “very high” development according to the 2014 United Nations Human Development Index.⁶⁸ Finally, due to resource constraints, we included only studies that published their results in English.

On the basis of these inclusion criteria, one investigator re-evaluated the 73 studies included in our original 2010 review for potential inclusion; studies proposed for exclusion were reviewed by a second investigator, and any disagreements were reconciled through consensus. For the new body of evidence, two reviewers independently reviewed titles and abstracts for potential inclusion, and two reviewers reviewed the full-text articles. Discrepancies were resolved by discussion and third party consultation as needed.

Quality Assessment and Data Abstraction

For the new literature, two reviewers applied USPSTF design-specific criteria (**Appendix A Table 2**)⁶⁷ to assess the methodological quality of all eligible studies. We assigned each study a

quality rating of “good,” “fair,” or “poor.” Discordant quality ratings were reviewed and discussed; a third reviewer adjudicated as needed. 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 $\geq 80\%$), whereas fair-quality studies did not meet these criteria but did not have serious threats to their internal validity related to the design, execution, or reporting of the study. Studies rated as poor quality 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 $>20\%$); 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, and questionable validity of randomization and allocation concealment procedures). Studies rated as poor quality were excluded from the review. As the quality assessment was an update of our own work, we did not repeat critical appraisal of the original studies through full dual-quality rating; rather, we confirmed the quality rating during data abstraction. In one case⁶⁹ where we questioned the original quality rating, we re-rated the quality of the study through dual review. This one study was subsequently excluded for poor quality given serious concerns about an imbalance between treatment groups at baseline (nonrandomized trial in which intervention and control groups were selected based on different criteria) and lack of reporting on differential attrition and handling of missing data.

For all of the included studies, one reviewer extracted key elements into standardized abstraction forms in Microsoft Access® 2010 (Microsoft, Redmond, WA). A second reviewer checked the data for accuracy. For each study, we abstracted general characteristics of the study (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), analytic methods, and results. For intervention characteristics, we abstracted detailed information about specific components: duration, number, and length of sessions; group or one-on-one delivery; mode of delivery (i.e., in person, telephone, electronic, or print); providers and provider training; and setting. We used methods consistent with the previous reviews on this topic to estimate and categorize the intensity of each intervention. To calculate the total intensity of an intervention, we multiplied the number of sessions by the length of the respective sessions and estimated the total number of minutes. For example, a 12-month intervention consisting of eight 1-hour group sessions would have been calculated as $8 \times 60 = 480$ minutes. We categorized an intervention as low intensity if the number of minutes was estimated to be 30 or fewer, medium intensity if the number of minutes was 31 to 360, and high intensity if the number of minutes was greater than 360. Interventions that consisted of only print materials were categorized as low intensity. We abstracted the number of sessions and length of sessions according to what was planned (and not necessarily implemented). When reported, we abstracted actual adherence or implementation of the intervention and documented that as well. If a study did not report the length of sessions, we estimated a session described as “brief” to be 15 minutes, 5 minutes for telephone sessions, 30 minutes for individual face-to-face sessions or Web-based sessions that were not described as “brief”, and 60 minutes for group sessions. Mailings and print materials were not included in the estimated number of sessions or session length. If the intervention consisted of only mailings or print materials, it was categorized as low intensity (i.e., <30 minutes). We noted the theoretical basis of the intervention where reported and used the description of the intervention to judge the specific behavior change techniques that were used (e.g., goals and planning, feedback and

monitoring, self-belief) according to the taxonomy of Michie et al⁷⁰ for behavior change techniques.

Data Synthesis and Analysis

We synthesized data separately for each KQ. The data on health outcomes (KQ 1) and adverse events (KQ 4) did not allow for quantitative pooling due to the limited number of contributing studies and the variability in outcomes measured, so we summarized those data in tables and narratively. For intermediate health outcomes (KQ 2) and behavioral outcomes (KQ 3), we ran random effects meta-analyses using the method of DerSimonian and Laird to calculate the pooled differences in mean changes (for continuous data) and pooled odds ratio (OR) (for binary data).⁷¹ Details of our data analysis methods are included in **Appendix B**. Briefly, we used the between-group differences for each outcome as reported by each respective study and favored adjusted over unadjusted effect estimates. If a between-group effect estimate and variance were not provided, we calculated a crude effect estimate. Within each study, we chose 52-week (1-year) outcome data if available; if they were not available we chose the time point closest to 52 weeks, and favored 78 weeks over 26 weeks. We presented the results of other time points in tabular format. For intermediate outcomes, we conducted sensitivity analyses in which we removed the one study⁷² that reported outcomes at 104 weeks (2 years) to investigate whether the longer followup altered the effect estimate. The pooled result, including precision of the estimate, was nearly identical when this study was removed. Thus, we present the results with this study included but report followup generally as 6 to 12 months. If a trial had more than one active intervention arm, we plotted the most intensive arm or the arm that was the most similar with other interventions included in the analysis.

We examined statistical heterogeneity among the pooled studies using standard chi-squared tests and estimated the proportion of total variability in point estimates using the I^2 statistic.⁷³ We applied the Cochrane Collaboration's rules of thumb for interpreting heterogeneity: less than 40 percent likely represents unimportant heterogeneity, 30 to 65 percent moderate heterogeneity, 50 to 90 percent substantial heterogeneity, and more than 75 percent considerable heterogeneity.⁷⁴ We ran sensitivity analyses for selected intermediate outcomes (e.g., SBP, DBP, total cholesterol) using a restricted maximum likelihood model with the Knapp-Hartung modification (using the `metareg` command in version 13.1 of Stata [StataCorp, College Station, TX]), which is a more conservative approach when there is substantial heterogeneity or the number of studies is small.⁷⁵ All statistically significant results remained within the restricted maximum likelihood model, so we show results using the method of DerSimonian and Laird.⁷¹ In addition, we generated funnel plots to evaluate small-study effects (a possible indication of publication bias) and ran the Egger's or Peters' test to assess the statistical significance of imbalance in study size as well as findings that suggest a pattern.^{76, 77}

We used visual displays and tables grouped and sorted by potentially important characteristics to investigate whether variability among the results was associated with any prespecified study, population, or intervention characteristics. Specifically, we examined study quality (good vs. fair), link to primary care (conducted in or recruited from primary care vs. not), population at elevated cardiovascular risk (yes vs. no), mean age, baseline mean BMI, intervention focus

(healthful diet only, physical activity only, healthful diet and physical activity), intervention intensity (as continuous minutes; high vs. medium and low intensity), intervention duration (as continuous weeks), number of intervention sessions, and group sessions (yes vs. no). On the basis of this initial assessment, we used meta-regression to examine whether the effects were different in specific subgroups or by specific variables, namely study quality, link to primary care, intervention intensity, and intervention duration. There was some evidence that intervention intensity was correlated with the effect estimates; therefore, we stratified the studies according to their intensity category (high, medium, or low) and sorted studies within these groups by intervention focus.

Stata was applied for all quantitative analyses.

Grading the Strength of the Body of Evidence

We graded the strength of the overall body of evidence for each KQ. We adapted the Evidence-based Practice Center approach,⁷⁸ which is based on a system developed by the Grading of Recommendations Assessment, Development, and Evaluation Working Group.⁷⁹ 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 (study limitations). We did not address the fifth required domain—directness—as it is implied in the structure of the KQs (i.e., whether the evidence links the interventions directly to a health outcome). We supplemented the four domains with the additional domain of dose-response association given our a priori hypothesis that larger effects may be seen with greater intensity (or exposure) of interventions. Evidence of a dose-response association either across or within studies may warrant increasing the overall strength of evidence.

Consistency was rated as reasonably consistent, inconsistent, or not applicable (e.g., single study). Precision was rated as reasonably precise, imprecise, or not applicable (e.g., no evidence). Reporting bias was rated as suspected, undetected, or not applicable (e.g., when there is insufficient evidence for a particular outcome). 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 KQ (e.g., lack of replication of interventions, nonreporting of outcomes important to patients).

We graded the overall strength of evidence as high, moderate, or low. “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 effect. “Moderate” suggests 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 is likely to change the estimate. A grade of “insufficient” indicates that evidence is either unavailable or does not permit estimate of an effect. Two independent

reviewers rated each KQ according to consistency, precision, reporting bias, and overall strength of evidence grade. We resolved discrepancies through consensus discussion involving more reviewers.

Expert Review and Public Comment

A draft research plan was posted on the USPSTF Web site for public comment from February 19 to March 18, 2015. The USPSTF received comments from 27 individuals and organizations, with some comments reflecting the input of many individuals. We made two changes to the research plan based on these comments. The first was to include reduction of sedentary behavior, independently of physical activity, as an intervention target and behavioral outcome. The second was to explicitly acknowledge the inclusion of studies among persons who are overweight or have obesity and who do not have CVD risk factors. Other minor changes and clarifying text was added as appropriate. A final research plan was posted on the USPSTF Web site on May 14, 2015. This full draft report was shared with invited expert reviewers and federal partners. We compiled and addressed (where appropriate) the comments received from these invited experts. Additionally, a draft of the full report was posted for public comment on the USPSTF Web site from November 29, 2016 through January 2, 2017. A few comments were received during this public comment period; no changes were made to the report based on these comments.

USPSTF Involvement

We worked with three USPSTF members at key points throughout this review, particularly when determining the scope and methods for this review and developing the Analytic Framework and KQs. After revisions reflecting the public comment period, the USPSTF members approved the final analytic framework, KQs, and inclusion and exclusion criteria. The Agency for Healthcare Research and Quality funded this review under a contract to support the work of the USPSTF. An Agency Medical Officer provided project oversight, reviewed the draft report, and assisted in the external review of the report.

Chapter 3. Results

Description of Included Studies

Our literature search yielded 10,045 unique citations. From these, we provisionally accepted 351 articles for review based on titles and abstracts (**Appendix A Figure 1**). After reviewing the full-text articles and performing critical appraisal, we included 88 studies that were reported in 145 publications.^{72, 80-221} **Appendix C** contains a full list of included studies. We carried forward 50 studies from our prior review; 38 new studies were added.

For the 351 articles that were reviewed in full, the most common reasons for exclusion were: not an included population (i.e., studies were among adults at high risk for CVD, who had CVD, or who had other known chronic disease; k=60), not an included study design (i.e., not an RCT or controlled clinical trial for KQs 1–3; k=53), and not a relevant study aim (k=28) or relevant outcome (k=28). **Appendix D** contains a list of all excluded trials and their reasons for exclusion.

Of the 88 included studies, 12 trials reported health outcomes (KQ 1) (e.g., CVD events, self-reported quality of life), 34 trials reported intermediate health outcomes (KQ 2) (e.g., lipid, blood pressure, and glucose levels; weight measures), and 86 trials reported behavioral outcomes (KQ 3) (objective or self-reported measures of diet, physical activity, or sedentary time). Fourteen trials explicitly reported on harms (or the lack thereof) of a counseling intervention (KQ 4) (**Table 2**).

Study Characteristics

All of the included studies were RCTs, with the exception of one study that was a nonrandomized controlled clinical trial (**Table 2**).²⁰³ Fourteen trials were cluster RCTs with randomization of physicians, clinics, or health care centers.^{81, 92, 102, 111, 120, 122, 132, 148, 179, 188, 189, 211, 214, 218} The majority of the studies (k=52) took place in the United States. The remaining studies were conducted in Europe (k=23), Australia (k=7), New Zealand (k=4), Canada (k=1), and Japan (k=1). Samples sizes for the included studies ranged from 49 to 48,835 participants, and the median sample size was 332. Study duration ranged from 6 months (minimum followup required per inclusion criteria) to 6 years, with the majority reporting outcomes at 6 or 12 months. Half of the studies were conducted within or recruited participants from primary care or the broader health care system (k=44). The remaining studies recruited community volunteers through mass media, targeted recruitment, or larger population-based cohorts (e.g., registered voters, research cohorts).

Included Populations

Trials included a wide range of populations in terms of age, sociodemographic features, and clinical characteristics (**Table 2**). The mean age of the samples ranged from 19.0 to 79.5 years (interquartile range, 40.7 to 57.9 years). Fifteen trials specifically targeted older adults age 60

years or older; the mean age in those trials ranged from 63.2 to 79.5 years.^{93, 94, 100, 117, 125, 128, 132, 146, 155, 186, 201, 208, 212, 218, 220} All but three of these trials among older adults focused solely on increasing physical activity. The remaining three focused on improving diet^{93, 125} or improving both diet and physical activity.¹⁰⁰ Most of the studies (k=71) included both men and women, but one study was limited to men only¹³⁵ and 18 studies were limited to women only.^{83, 91, 106, 113, 119, 126, 160, 164, 166, 177, 184, 194, 197, 203, 207, 209, 211, 219} Many of the studies limited to women were further restricted to specific racial/ethnic subgroups (i.e., American Indian,²⁰⁷ Hispanic/Latina,^{126, 166, 184} black⁹¹), age groups (college age^{211, 219}), and postpartum status^{83, 203} or mothers of young children.^{113, 164} Of the 53 studies that reported race/ethnicity, the percentage of nonwhite participants ranged from 2.2 to 100 percent; in only 15 of these studies was more than two thirds of the sample nonwhite. For studies that reported the education level of participants, the proportion of participants with more than a high school education (i.e., some college, vocational or technical school, or more) ranged from 16.8 to 93.0 percent (**Table 2**).

Among the 88 trials, 37 studies limited inclusion to persons with suboptimal levels of physical activity (e.g., <150 minutes of moderate- to vigorous-intensity physical activity per week), inadequate dietary habits (e.g., suboptimal intake of fruits, vegetables, red and processed meats, whole-fat dairy foods, or whole grains), or both. Thirteen of the 88 trials were specifically among persons at higher risk for CVD (but without levels of traditional CVD risk factors reaching diagnostic thresholds), including those with high-normal blood pressure (e.g., DBP of 80 to 89 mm Hg);^{137, 140, 204, 205} men with moderately elevated cholesterol, fasting blood glucose, triglyceride, and blood pressure levels¹³⁵; those with a family history of type 2 diabetes^{97, 154, 210} or CVD¹⁷⁶; women who were overweight or had obesity and a history of gestational diabetes¹⁹⁷; black women who were overweight or had obesity⁹¹; and adults age 60 years or older who were overweight or had obesity.^{117, 146} In the remaining 38 studies, participants were not chosen on the basis of their baseline behavior or cardiovascular risk but instead represented a general, unselected population. While we excluded trials conducted exclusively among persons with hypertension, dyslipidemia, or impaired fasting glucose, a few of the studies included some participants with hypertension (2.8% to 70.7%), dyslipidemia (11.3% to 27.4%), impaired fasting glucose (13.0% to 21.0%), or diabetes (6.5% to 12.0%). Of the 62 studies that reported baseline mean BMI, the range was 22.0 to 32.9 kg/m² (mean, 27.7 kg/m²). The mean BMI was in the overweight range (i.e., 25.0 to 29.9 kg/m²) in nearly half of the studies (k=42) and in the obese range (≥ 30 kg/m²) in 12 studies. The proportion of current smokers included in the studies ranged from 3.5 to 38 percent (**Table 2**).

Included Interventions

Within the 88 trials there were 121 distinct intervention arms (**Table 3**). Twenty-three trials focused on both healthful diet and physical activity, 24 focused on healthful diet only, and 44 focused on physical activity only. (Two trials contributed to more than one intervention category;^{97, 135} hence, the number of trials does not equal 88 across these groups.) Most of the newly added trials (published from 2010 to the present) focused on physical activity (20 of 38 new trials); only five new trials focused on healthful diet only. Fourteen new trials had intervention components aimed at improving both healthful diet and physical activity. Across all 121 intervention arms, 40 arms were low intensity (≤ 30 minutes of estimated contact time), 55 were medium intensity (31 to 360 minutes), and 26 were high intensity (> 360 minutes [6 hours]).

Intervention intensity ranged from 3 to 2,340 minutes (39 hours) (mean, 371 minutes [6 hours and 11 minutes]) (Figure 2). Details of all of the interventions are provided in Table 4 and Appendix E Table 1.

Within the **low-intensity interventions** (40 arms), the majority were mailed, print-based interventions in which participants received tailored feedback regarding their dietary and/or physical activity behaviors and specific recommendations and tools for behavior change. A higher proportion of the low-intensity trials focused on physical activity only (k=16) as opposed to healthful diet (k=7) or healthful diet and physical activity (k=5). Frequency of mailings ranged from once to 36 monthly mailings over 3 years. Many of these interventions involved individually tailored print materials that were generated by a computer expert system and often included self-help materials or a self-directed written plan for increasing physical activity and/or changing eating patterns. A minority of the low-intensity interventions (k=7) included brief in-person or telephone counseling or “endorsements” on behalf of the primary care provider^{81, 92, 120, 122, 135, 190} or “coach.”²¹² Counseling ranged from 3 to 15 minutes and generally included individualized prescriptions for changing behavior or encouragement to use self-help materials. Five low-intensity interventions relied on Web- or text-based messages for intervention delivery.^{119, 149, 169, 189, 219}

The **medium-intensity interventions** (55 arms) were more variable than the low- and high-intensity interventions in terms of the number of sessions and modes of delivery. The duration of the interventions ranged from 1 day to 2 years, with most taking place over the course of 6 to 12 months. The total intensity of the interventions ranged from 40 minutes to approximately 5 hours of contact time (median, 2.25 hours). In general, most of the medium-intensity interventions consisted of at least one face-to-face individual counseling session lasting from 20 to 60 minutes followed by booster telephone counseling calls, emails, or text messages. Several of the medium-intensity physical activity–only interventions consisted solely of telephone-based counseling and involved no face-to-face sessions. The majority of counseling sessions and telephone calls were provided by research staff (i.e., study personnel), health educators, dietitians or nutritionists, or exercise specialists; nine trials (10 arms)^{90, 111, 117, 132, 135, 146, 160, 179, 186} included intervention components delivered by a primary care provider.

Within the **high-intensity interventions** (26 arms), most provided healthful diet counseling, with or without physical activity messages; only five high-intensity interventions focused solely on increasing physical activity with no healthful diet messages. The high-intensity interventions were typically provided through group sessions ranging from 45 minutes to 2.5 hours in length, with more than 15 group sessions in most studies. Interventions spanned 4 weeks to 6 years in total duration, with the bulk of the active (vs. maintenance) phase of the intervention lasting around 6 months. The high-intensity physical activity interventions were quite variable and included physician training,¹⁴⁸ individual face-to-face and telephone counseling,^{154, 172, 208} and group workshops.²⁰¹ With the exception of one study,²⁰³ the high-intensity interventions did not involve primary care staff. Most of the interventions were delivered by dietitians or nutritionists, behavioral health specialists, or research staff. As such, very few took place in primary care and were instead usually conducted in research clinics or at home, or the setting was not described. The one intervention delivered by primary care staff targeted women at 0 to 1 months postpartum; diet and physical activity counseling was provided by a pediatric primary care

provider and a health educator through individualized counseling calls and included optional group sessions on parenting skills.²⁰³

Similar messages and behavior change techniques were used across all of the interventions (**Appendix E Table 1**). Diet messages typically focused on general heart-healthy eating patterns, including increased fruit and vegetable intake (specifically 5 to 9 servings/day), decreased fat consumption and salt intake, and increased fiber consumption; fewer mentioned specific messages about increasing intake of whole grains, reducing consumption of red and processed meats, or increasing intake of calcium-rich foods. Two studies specifically encouraged the Dietary Approaches to Stop Hypertension (DASH) diet,^{101, 137} and three studies (the Hypertension Prevention Trial¹⁴⁰ and the Trials of Hypertension Prevention [TOHP] phases I²⁰⁴ and II²⁰⁵) focused exclusively on decreasing sodium intake to approximately 1,400 to 1,600 mg or less per day, with or without a simultaneous increase in potassium intake of 3,900 mg or more per day. Four of these five studies were conducted among adults with high-normal blood pressure (i.e., SBP of 130 to 159 mm Hg, DBP of 80 to 99 mm Hg).^{137, 140, 204, 205} The largest trial, the Women's Health Initiative (WHI) Dietary Modification Trial (n=48,835), focused on a 20-percent low-fat dietary pattern with no focus on specific subtypes of fat. Only three studies specifically mentioned encouraging an energy deficit (e.g., reducing total energy intake by 200 kcal each day, following a 1,300- or 1,500-kcal meal plan) to prevent weight gain^{91, 194} or to help those who were overweight to lose weight.¹⁸⁸ One study included regular weigh-ins to monitor participants' weight and suggested dietary adjustments to maintain weight.¹³⁷

Physical activity messages emphasized gradually increasing aerobic activities to recommended levels (i.e., 150 minutes of moderate-intensity physical activity per week), with many interventions emphasizing walking. Only one study focused on decreasing sedentary behavior (e.g., reducing television viewing, substituting sitting with standing).⁸⁰

Many interventions provided counseling related to reading food labels; planning, purchasing, and preparing foods and meals; finding local physical activity opportunities; and overcoming barriers related to desired behavior changes. Optional activities included group exercise classes, free memberships to community exercise facilities, weight loss materials or courses, grocery shopping trips with a dietitian, and cooking demonstrations. Additionally, many interventions included tangible tools to facilitate behavior change, such as pedometers, resistance bands, and log books or diaries for self-monitoring. Almost all of the interventions distributed print materials to participants; some materials were standard educational information only while others were tailored with normative or motivational feedback. Thirteen of the interventions, regardless of intervention focus or intensity, relied on computer-based counseling or included email or other mobile health technology to deliver the main components of the intervention.^{86, 94, 113, 115, 119, 141, 147, 169, 189, 198, 217, 219} Only one study incorporated ongoing measurement and feedback regarding specific CVD risk factors, such as lipid levels.¹⁷⁶

Of those trials that reported the theoretical basis of the intervention, the majority were based on principles of the transtheoretical model (i.e., stages of change), social cognitive theory, or both (**Appendix E Table 1**). As such, most interventions included behavior change techniques focused on the broad areas of goals and planning, monitoring and feedback (e.g., through the use of food logs, dietary analysis with feedback, pedometers, and activity logs), increasing efficacy

and motivation for healthy eating or physical activity, improving social support, and general education and advice regarding the benefits of specific behavioral changes. Eleven studies specifically mentioned using principles of motivational interviewing^{80, 83, 86, 91, 125, 146, 148, 149, 155, 203, 212} and five studies based their counseling, at least in part, on the “5 A’s” model (assess, advise, agree, assist, and arrange).^{81, 112, 120, 146, 176}

Intervention Fidelity and Participant Adherence

Most of the studies reported some minimal information on participant adherence to the planned interventions (**Appendix E Table 1**). For those that reported adherence, rates of participation were generally high, particularly for the low- and medium-intensity interventions. Across these studies, approximately 70 to 98 percent of participants reported reading most of the print materials provided, taking part in face-to-face individual counseling sessions, or participating in most or all planned counseling telephone calls. There did not appear to be any differences in the level of adherence between the healthful diet and physical activity versus healthful diet-only or physical activity-only interventions. Only one study had exceptionally low intervention adherence; in one medium-intensity physical activity intervention, only 38 percent of participants randomized to receive the intervention took part in the intervention, which consisted of three monthly telephone counseling calls and mailed print materials.¹²³ As is shown later, despite the low participation rate, this study reported a statistically significant between-group difference in levels of self-reported physical activity at 6 months, after controlling for baseline levels of physical activity among both the full randomized sample and the reduced sample of only those who participated in the intervention.

Adherence to high-intensity interventions, especially the group-based interventions, was generally a little lower than adherence to the low- and medium-intensity interventions. For example, in one study, only 61.5 percent of participants attended all 12 planned weekly group sessions.¹⁴⁰ Similarly, in a study that offered five 2- to 2.5-hour group sessions, half of all participants attended three sessions or fewer.²⁰⁷

Very few studies reported adherence to optional activities such as group exercise classes. For example, in a study that offered supervised exercise, only 26 percent of trial participants reported participating in an exercise class each week.¹³⁵ In another study, 70.3 percent of intervention participants activated their free membership to a community exercise facility, of which only 40.7 percent visited more than once over the course of the year-long intervention.⁹¹

Control Arms

Just more than half of the studies (k=44) employed a no-intervention, usual care, or waitlist control arm for the control group. Usual care was generally described as “routine” or “standard” care that included standard prevention messages or generic print materials or was otherwise not described. In one study,¹³⁵ the usual care control group participants were specifically told to maintain their normal diet and physical activity levels. The remaining studies employed minimal intervention (k=25) or attention control groups (k=19). Minimal intervention groups typically consisted of brief print materials regarding the benefits and recommendations of healthful diet and/or physical activity, such as the “Dietary Guidelines for Americans.” A few of the minimal

intervention groups were more intensive and provided specific recommendations (e.g., increase physical activity by 2 hours a week) or self-help materials, including pedometers and tracking logs, although these were still less intensive than interventions categorized as low intensity. The attention control groups usually followed the same intervention schedule as the study's intervention group but focused on a different health topic (e.g., stress management, general health and wellness, women's health).

Study Quality

We rated 19 of the 88 trials as good quality and the remaining 69 as fair quality (**Table 2**). Twenty trials were excluded for poor quality (**Appendix D**). Common threats to internal validity of these poor-quality studies included very high attrition (generally >40%), with differential attrition between intervention arms (>20%); lack of baseline comparability between groups without adjustment; and 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). In general, the 19 trials rated as good quality were characterized by appropriate randomization procedures; comparable groups at baseline (or adequate adjustment for known baseline differences in the analysis); high followup rate (i.e., ≥85% retention at 6 months); the use of reliable and valid measurement instruments applied equally across arms and blinding of outcome assessors for nonobjective measures; well-described interventions with high fidelity and good adherence to the intervention; no evidence of selective reporting; and appropriate analyses, including intention-to-treat principles using multiple imputation or other conservative data imputation procedures for missing data. Some common limitations of the fair-quality studies included lack of reporting details about allocation concealment, small differences in baseline characteristics between treatment arms, no or unclear blinding for outcomes assessment (particularly for interviewer-administered questionnaires), relatively higher attrition (i.e., >20%) and differential attrition between groups, and no attempt (or lack of reporting) to account for missing data or conducting completers-only analyses.

KQ 1. Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Health Outcomes in Adults?

Summary of Results

Twelve of the 88 included trials reported health outcomes.^{111, 122, 128, 135, 140, 154, 155, 179, 204, 205, 209, 212} Only two of these trials^{121, 212} were newly identified as part of our update, and both reported quality-of-life outcomes (**Table 2**). Four trials reported all-cause or CVD-related mortality,^{140, 204, 205, 209} of which three also reported CVD-related events.^{204, 205, 209} All four of these trials were high-intensity diet-focused trials. Overall, few deaths were reported, and no differences were observed between treatment and control groups over 3 to 15 years of followup. Trials reporting cardiovascular events and composite CVD outcomes showed some beneficial results, although results were mixed. Ten trials (of which seven were physical activity-only interventions) reported HrQOL outcomes, with the majority using the 36-Item Short-Form Health Survey (SF-

36) to measure quality of life.^{89, 111, 121, 128, 135, 154, 155, 179, 204, 213} Results showed general improvements in quality of life at 6 and 12 months among intervention participants, although there was no consistent benefit of the intervention compared with control conditions.

Detailed Results by Outcome

CVD and Mortality

Four trials (n=51,356) of high-intensity diet-only interventions reported CVD-related health outcomes; three were good quality and one was fair quality (**Appendix F Table 1**).^{140, 204, 205, 209} All of these trials reported all-cause mortality. Two additionally reported CVD deaths^{205, 209} and three reported CVD events.^{204, 205, 209}

Overall, few deaths occurred in each trial, and mortality was comparable between the intervention and control groups. In the WHI Dietary Modification Trial (n=48,835), postmenopausal women randomized to intensive low-fat dietary counseling showed no difference in deaths from all causes (hazard ratio [HR], 0.98 [95% confidence interval [CI], 0.91 to 1.07) or CVD (HR, 1.01 [95% CI, 0.81 to 1.27) compared with women randomized to the usual diet group after approximately 8.1 years of followup.²⁰⁹ Similarly, long-term observational followup combining the results from two hypertension prevention trials, TOHP phases I and II (n=3,126), which randomized persons with high-normal blood pressure to intensive sodium restriction counseling or usual care, found no difference in all-cause mortality (HR, 0.80 [95% CI, 0.51 to 1.26]) or deaths from cardiovascular causes (HR, 0.62 [95% CI, 0.28 to 1.40]) after 10 to 15 years of followup.¹⁰⁷ Lastly, a trial of 587 participants aimed at preventing hypertension among adults with high-normal DBP found no difference in all-cause mortality among those randomized to intensive diet counseling focused on either increased potassium intake and decreased sodium intake or decreased sodium intake alone compared with usual care, with each group experiencing a single death over 3 years of followup.¹⁴⁰

Results for cardiovascular events reported in three trials were mixed.^{204, 205, 209} The WHI Dietary Modification Trial (n=48,835) showed no difference in major coronary heart disease events (i.e., nonfatal MI or coronary heart disease death) (adjusted HR, 0.93 [95% CI, 0.83 to 1.05]) or fatal and nonfatal stroke (adjusted HR, 1.02 [95% CI, 0.90 to 1.17]) among women without a history of CVD who were randomized to low-fat diet counseling or the usual diet group over 8.1 years of followup.¹³⁹ Similarly, a broader composite CVD outcome comprised of nonfatal MI, coronary heart disease death, and coronary artery bypass/percutaneous coronary interventions showed no significant difference between treatment groups (adjusted HR, 0.94 [95% CI, 0.86 to 1.02]).¹³⁹ In contrast to the results from the WHI Dietary Modification Trial, long-term observational followup from the TOHP phase I and II trials (n=2,415) showed a significant difference in CVD (defined as MI, stroke, revascularization, or CVD death) between treatment groups over 10 to 15 years of followup (HR, 0.70 [95% CI, 0.53 to 0.94]).¹⁰⁷ When revascularization was excluded from the definition, however, significance was lost (adjusted HR, 0.72 [95% CI, 0.50 to 1.03]). Exploratory subgroup analyses of demographic and clinical characteristics in these three trials showed no evidence of effect modification.^{107, 138}

HrQOL

Ten fair- to good-quality trials (n=52,423) reported the effect of a healthful diet and/or physical activity intervention on HrQOL,^{89, 111, 121, 128, 135, 154, 155, 179, 204, 213} of which seven focused on physical activity only. The SF-36 was used to measure HrQOL in seven of the 10 trials; the Louvain Well-Being scale,²¹³ the Psychological General Well-Being scale,²⁰⁴ and the Minor Symptoms Evaluation survey¹³⁵ were used in the other three trials.

Overall, self-reported measures of HrQOL appeared to generally improve more among intervention than control participants over 6 to 12 months, although the specific HrQOL domains that were measured and the results of the individual trials were mixed. In the WHI Dietary Modification Trial, global quality of life (as measured by a single item) improved by a small but statistically significant amount in the intervention group compared with the control group at 1 year. On a 10-point scale, the mean score in the intervention group decreased from 8.20 to 8.19 (-0.01) and from 8.18 to 8.11 (-0.07) in the control group (p<0.001). Similarly, small statistically significant differences in favor of the intervention group were seen on seven of the eight SF-36 subscales.⁸⁹ Only one low-intensity physical activity trial reported results according to the two summary scores of the SF-36 (mental health component and physical component) rather than the eight individual subscales, finding small improvements in the mental health component scores for both groups over 24 months but no differences between groups at any time point.¹²¹ The remaining five physical activity trials^{111, 128, 154, 155, 179} that used the SF-36 instrument to measure HrQOL reported results according to the eight domain-specific subscales; three of these trials focused specifically on older adults.^{128, 155, 179} While self-reported improvements were generally seen for one or more of the HrQOL subscales for intervention participants, there was no consistent effect of the interventions on any subscale. Similarly, the remaining three trials that used other measures of HrQOL reported no consistent effect of the interventions on HrQOL or well-being.^{135, 204, 213}

KQ 2. Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Intermediate Outcomes Associated With CVD in Adults?

Summary of Results

Thirty-four of the included studies reported the effects of behavioral interventions on at least one intermediate outcome; nearly half were of good quality (**Table 2**).^{72, 80, 85, 90, 91, 97, 98, 106, 111, 122, 126, 130, 135, 137, 140, 143, 144, 146, 147, 149, 154, 156, 160, 176, 188, 190, 194, 204, 205, 207-209, 211, 219} Only 10 of the 34 studies were newly identified as part of our update;^{80, 91, 98, 126, 130, 137, 147, 149, 208, 211, 219} the remaining 24 were included in our original review.⁴⁰ Most of these 34 studies were of medium- or high-intensity interventions and focused on healthful diet, with or without physical activity messages. When studies of all levels of intensity were pooled, healthful diet and/or physical activity interventions were associated with small but statistically significant improvements in blood pressure, low-density lipoprotein (LDL) cholesterol, total cholesterol, and adiposity

measures compared with controls at 6 months or more (**Table 5**). Average effects were between-group mean differences (MDs) of -1.26 mm Hg (95% CI, -1.77 to -0.75) for SBP, -0.49 mm Hg (95% CI, -0.82 to -0.16) for DBP, -2.58 mg/dL (95% CI, -4.30 to -0.85) for LDL cholesterol, and -2.85 mg/dL (95% CI, -4.95 to -0.75) for total cholesterol—all in favor of intervention versus control arms, with general followup times from 6 months or more. For adiposity outcomes, interventions were associated with improvements in BMI (MD, -0.41 kg/m² [95% CI, -0.62 to -0.19]), weight (MD, -1.04 kg [95% CI, -1.56 to -0.51]), and waist circumference (MD, -1.19 cm [95% CI, -1.79 to -0.59]), although there was considerable statistical heterogeneity ($I^2 > 90%$) in all analyses of adiposity, so the pooled results should be interpreted with caution. There was no evidence of an association between healthful diet and/or physical activity counseling and high-density lipoprotein (HDL) cholesterol, triglycerides, or fasting glucose when trials including all levels of intervention intensity were pooled (**Table 5**).

Among the intermediate outcomes showing a positive association, dose-response effects were evident, with increasing intervention intensity associated with larger improvements in intermediate outcomes. High-intensity interventions (i.e., ≥ 6 hours total) were consistently associated with statistically significant benefit on intermediate outcomes, and the effect sizes were slightly higher in analyses limited to the subset of high-intensity interventions compared with the results of combining trials of all level of intensity (**Table 5**). The effects of medium-intensity interventions (i.e., 31 minutes to 6 hours total) on intermediate outcomes were less consistent and generally showed no benefit, with the exception of the outcome of weight. There was insufficient evidence (only one to four trials per outcome) to assess the effects of low-intensity interventions (i.e., ≤ 30 minutes total) on intermediate outcomes. When we stratified meta-analyses by a focus on diet and/or physical activity, results were consistent with those seen in analyses stratified by intensity (**Appendix F Table 2**). That is, healthful diet interventions (with or without physical activity messages), which were mostly high-intensity interventions, consistently showed statistically significant favorable associations with intermediate outcomes. No such benefit was seen when limiting the analyses to physical activity-only trials, which were largely of low intensity, although there were far fewer trials included in these analyses (four to eight trials per outcome), and results should be interpreted accordingly.

Just more than half of the 34 trials that reported intermediate outcomes took place in the United States.^{85, 91, 98, 106, 126, 137, 140, 143, 147, 156, 176, 194, 204, 205, 207-209, 219} Ten of the trials were limited to populations with elevated CVD risk, including persons with high-normal blood pressure;^{137, 140, 204, 205} persons with a family history of type 2 diabetes^{97, 154} or CVD;¹⁷⁶ men with moderately elevated DBP, cholesterol, and glucose levels;¹³⁵ older adults who were overweight;¹⁴⁶ and black women who were overweight.⁹¹ Two of the trials were limited to older adults (age ≥ 60 years);^{146, 208} in one of these trials, the mean age of the sample was 79.5 years. Only 14 of the 34 trials took place in or recruited from primary care; of those, four took place in the United States.^{91, 137, 156, 176} The remaining 20 trials recruited volunteers through community venues (e.g., advertising, community events) or other convenience or random samples (e.g., existing research cohorts or databases, registered voters). These studies evaluated almost exclusively high-intensity interventions and showed concordant findings with the analysis that was limited strictly to high-intensity interventions. That is, subgroup analyses that included only trials that did *not* recruit from or occur in the primary care setting found similarly statistically significant positive associations with blood pressure, LDL cholesterol, total cholesterol, fasting blood glucose, and

waist circumference, but no association was seen with these outcomes in the subgroup of trials that were conducted in or recruited from primary care, which were primarily of medium and low intensity (data not shown). Pooled results were statistically significant for both subgroups of studies (those conducted in and not conducted in primary care) for BMI and weight measures. Meta-regression results showed a statistically significant difference between trials conducted in and not conducted in primary care for DBP and total cholesterol in bivariate analyses, but significance was lost after controlling for intervention intensity. Given the confounding of intervention intensity and the statistically significant dose-response relationship with intensity, differences seen between trials conducted in and not conducted in primary care could be a reflection of intensity rather than the recruitment or intervention setting.

On the basis of the Egger's test and visual inspection of funnel plots, we found no evidence of small-study effects (an indicator of publication bias) for any of the intermediate outcomes.

Detailed Results by Outcome

Blood Pressure

Meta-analyses from more than 20 trials of mostly good quality found that healthful diet and physical activity counseling interventions were associated with a decrease in SBP and DBP of -1.26 mm Hg (95% CI, -1.77 to -0.75; k=22; n=57,953) (**Figure 3**) and -0.49 mm Hg (95% CI, -0.82 to -0.16; k=23; n=58,022) (**Figure 4**), respectively, at approximately 6 to 12 months compared with controls (**Table 5**). We were able to pool all 23 trials that reported a blood pressure outcome.^{72, 85, 91, 106, 111, 122, 130, 135, 137, 140, 144, 146, 154, 160, 176, 188, 190, 194, 204, 205, 207-209} Within these 23 trials, most participants were normotensive or had high-normal blood pressure; mean blood pressure across trials was 127/78 mm Hg. The largest reductions in blood pressure were seen in the 12 high-intensity interventions (MD in change for SBP, -1.55 mm Hg [95% CI, -2.21 to -0.89; n=47,630; $I^2=48.1\%$]; MD in change for DBP, -0.67 mm Hg [95% CI, -0.98 to -0.37; n=47,625; $I^2=17.5\%$]) (**Appendix F Table 3**). These high-intensity interventions included four trials enrolling persons with high-normal blood pressure (DBP, approximately 80 to 89 mm Hg), which focused on decreasing dietary salt intake and resulted in intervention group reductions ranging from -3.4 to -9.5 mm Hg for SBP and from -3.7 to -4.6 mm Hg for DBP at 6 to 18 months of followup.^{137, 140, 204, 205} A sensitivity analysis in which we removed the two studies conducted among older adults^{146, 208} showed no appreciable difference in the average intervention effect for DBP overall or within intensity subgroups. For SBP, however, the pooled result for medium-intensity interventions showed a small improvement (MD, -1.34 [95% CI, -2.48 to -0.20]; k=7; $I^2=39.5\%$), which was not significant in analyses that included one trial that recruited older adults exclusively (MD, -1.10 [95% CI, -2.38 to 0.15]; k=8; $I^2=48.7\%$).

Within the 23 trials that were pooled, 16 included healthful diet messages with (k=7) or without (k=9) physical activity messages and seven focused exclusively on physical activity messages. When we stratified the meta-analyses by a focus on diet, physical activity, or both, the results were consistent with those seen in analyses stratified by intensity (**Appendix F Table 2**). That is, healthful diet interventions (with or without physical activity messages), which were mostly high-intensity interventions, consistently showed statistically significant favorable associations with blood pressure. No such benefit was seen when limiting the analyses to physical activity–

only trials, which were generally of medium intensity. For example, the MD in change for SBP for healthful diet interventions, with or without physical activity interventions, was -1.53 mm Hg (95% CI, -2.14 to -0.93) in favor of the intervention, whereas it was -0.36 mm Hg (95% CI, -1.17 to 0.44) for the physical activity-only trials.

There was no consistent pattern in the effects of the interventions on blood pressure over time (**Appendix F Table 3**). Eight studies reported additional measures of SBP and DBP after 1 year of followup.^{91, 160, 194, 204, 205, 207, 209} Mean between-group reductions in blood pressure remained statistically significant in the TOHP phase I and II trials from 6 months to 1.5 years²⁰⁴ and 2.5 years,²⁰⁵ respectively, whereas they attenuated and lost significance in two other long-term trials of 1.5¹⁹⁴ and 6 years.²⁰⁹ In the U.S.-based good-quality Women's Healthy Lifestyle Project, women (mean age, 47.1 years) in the intervention group took part in 15 healthful diet and physical activity group counseling sessions in the first 5 months of the intervention, which was followed by six booster group sessions and followup telephone calls and mailings for 4.5 years.¹⁹⁴ Statistically significant reductions in both SBP (MD, -2.00 mm Hg [95% CI, -3.86 to -0.14]) and DBP (MD, -2.20 mm Hg [95% CI, -3.39 to -1.10]) were seen at 6 months. The effects remained statistically significant for SBP but not DBP at 1.5 years and were attenuated by the end of the intervention at 4.5 years (MD for SBP, -0.32 mm Hg; MD for DBP, -0.70 mm Hg [significance level not reported]). Likewise, in the largest trial, the good-quality WHI Dietary Modification Trial (n=48,435), significant effects on blood pressure were found at 1 year, after the most intensive phase of the intervention (i.e., 18 group sessions), but were no longer evident at 6 years when the intervention was less intensive (approximately four group sessions per year).²⁰⁹

Five studies reported the prevalence or incidence of hypertension in addition to continuous measures of blood pressure (**Appendix F Table 3**).^{85, 88, 140, 204, 205} The findings were mixed. In the TOHP phase I²⁰⁴ and II²⁰⁵ trials (which enrolled persons with high-normal blood pressure), despite small statistically significant differences in the improvement of continuous measures of SBP and DBP among participants receiving low-sodium dietary counseling versus control participants at up to 1.5 and 2.5 years, respectively, there was no statistically significant difference in incident hypertension (defined as average DPB \geq 90 mm Hg or average SBP of 140 mm Hg) and no significant difference in diagnosis and drug treatment of hypertension over the course of 1.5 to 3 years. In the TOHP phase I trial, 8.6 percent of intervention participants and 11.3 percent of control participants developed hypertension (risk ratio [RR], 0.84 [95% CI, 0.62 to 1.13]) over 1.5 years.²⁰⁴ In the TOHP phase II trial, in which participants were overweight in addition to having high-normal blood pressure, a small statistically significant relative effect was seen for incident hypertension at 6 months. Incident hypertension was present in 4.5 and 7.3 percent of intervention and control participants, respectively, at 6 months (RR, 0.61 [95% CI, 0.38 to 0.98]); however, the relative risk diminished over time. At 3 years, 34.4 and 39.2 percent of intervention and control participants, respectively, had incident hypertension (RR, 0.88 [95% CI, 0.75 to 1.02]) at 3 years. In contrast to the TOHP phase I and II trials, the earlier Hypertension Prevention Trial, which also enrolled persons with high-normal blood pressure, showed no statistically significant differences in continuous SBP and DBP between the intervention and control groups; however, a statistically significant difference in the incidence of hypertension was found between the sodium plus potassium arm and the control arm. During 3 years of followup, 24.6 percent of the intervention participants randomized to a sodium-only arm

and 21.7 percent randomized to a sodium plus potassium arm developed hypertension compared with 33.5 percent of control participants (RR for sodium-only group vs. control, 0.73 [95% CI, 0.53 to 1.01]; RR for sodium plus potassium, 0.65 [95% CI, 0.46 to 0.90]).¹⁴⁰ In the WHI Dietary Modification Trial, women in the intervention group had a 4 percent lower overall risk of developing incident hypertension than women in the control group (HR, 0.96 [95% CI, 0.93 to 0.99]) over 8 years of followup. This effect, however, diminished over time and showed no reduced risk after 5 years.⁸⁸ The final trial, among generally normotensive adults (mean blood pressure, 129/77 mm Hg), reported slight improvements in continuous measures of blood pressure and a decrease in the prevalence of high blood pressure among both intervention and control groups at 6 months, but no statistically significant difference between groups.⁸⁵

Lipids

Nineteen trials reported at least one lipid measure, including LDL, total, and HDL cholesterol and triglyceride levels (**Appendix F Table 4**).^{72, 80, 85, 90, 91, 97, 111, 122, 130, 135, 144, 146, 154, 160, 176, 188, 194, 207, 208} We were able to pool all 19 trials in at least one meta-analysis for these respective outcomes. Baseline levels of cholesterol were generally optimal or near-optimal among these samples; mean LDL and total cholesterol levels were 127 and 201 mg/dL, respectively. For LDL cholesterol, meta-analysis of 13 trials (seven of good quality) resulted in a statistically significant decrease in LDL cholesterol level (MD, -2.58 mg/dL [approximately 0.067 mmol/L]) at 6 to 12 months of followup (95% CI, -4.30 to -0.85; n=5,554; $I^2=19.6\%$) (**Figure 5**). When stratified by intervention intensity, this decrease was significant only among the six high-intensity interventions, with an average effect of -4.51 mg/dL (95% CI, -6.85 to -2.16; n=1,381; $I^2=0\%$) (**Table 5**); results from meta-regression confirmed a statistically significant dose-response effect with more benefit seen as intensity increased (p=0.036).

Results for total cholesterol were concordant with findings for LDL cholesterol. A pooled analysis of 19 trials (n=9,325) showed an average intervention effect of a decrease in total cholesterol level of -2.85 mg/dL (0.074 mmol/L) (95% CI, -4.95 to -0.75), with substantial statistical heterogeneity ($I^2=50.8\%$) (**Figure 6**). A larger effect was seen among the high-intensity interventions (MD, -5.32 mg/dL [95% CI, -8.84 to -1.81]; k=7; n=1,429; $I^2=36.7\%$) (**Figure 6; Table 5**), and a dose-response effect was present, with increasing intensity related to larger reductions (p=0.017). All but one of the high-intensity interventions focused on both dietary and physical activity messages. Dietary goals within these interventions focused on reducing total energy intake in addition to a specific emphasis on decreasing total and saturated fat intake and, in some cases, dietary cholesterol level. The remaining trial focused on increasing physical activity among older adults. After we limited the analysis to the eight trials that had combined diet and physical activity messages, a similarly large effect was seen (MD, -4.00 mg/dL [95% CI, -7.94 to -0.63]), although substantial heterogeneity remained ($I^2=54.8\%$) (**Appendix F Table 2**).

One trial showed consistent beneficial effects of the intervention for both LDL and total cholesterol (**Appendix F Table 4**). In the good-quality Women's Healthy Lifestyle Project by Simkin-Silverman et al,¹⁹⁴ relatively large statistically significant differences in changes in LDL and total cholesterol levels were seen between women receiving the high-intensity group counseling intervention and women in the control group at 6 months and 1.5 years, as well as 4.5

years for LDL cholesterol. For example, at 6 months, LDL cholesterol level declined by -11.3 mg/dL among women in the intervention group but by only -0.1 mg/dL among women in the control group, resulting in an MD in change of -11.20 mg/dL (95% CI, -14.75 to -7.65) in favor of the intervention group.¹⁹⁴ For HDL cholesterol, a statistically significant larger benefit was seen for the *control* group compared with the intervention group. MDs in change in LDL cholesterol level were slightly attenuated but remained statistically significant at 1.5 and 4.5 years of followup. Three other trials reported followup beyond 12 months for one or more lipid outcomes; none found an effect of the intervention on lipid outcomes at 6 months to 2 years.^{91, 160, 207} In addition, none of the included trials reported the between-group difference in the proportion of participants with high cholesterol after the intervention.

There was no evidence of an association between healthful diet and/or physical activity interventions and levels of HDL cholesterol (**Figure 7**) or triglycerides (**Figure 8**) in pooled analyses. Mean between-group differences in change in HDL cholesterol level were generally inconsistent, ranging from absolute differences of 2.7 mg/dL in favor of the control group to 5.8 mg/dL in favor of the intervention group at 6 months to 2 years of followup (mean HDL cholesterol level at baseline, 56 mg/dL). Only three studies reported effect estimates indicating potential benefit of interventions on HDL cholesterol,^{97, 122, 176} although only two of them were statistically significant. Large variation was also seen in the effects of the intervention on triglyceride levels; only one small study (n=115) among college students (mean age, 19.7 years) in Canada reported a borderline statistically significant effect of a high-intensity intervention on triglyceride levels.⁷²

Fasting Glucose Level

Fourteen trials reported the effect of a counseling intervention on one or more indicators of diabetes, including fasting blood glucose level, hemoglobin A1c (HbA1c) level, and incident diabetes.^{80, 85, 91, 97, 106, 122, 146, 154, 160, 176, 194, 207-209} There were inconsistent results across studies that reported MDs in changes in fasting glucose (**Appendix F Table 5**). Our meta-analysis of 13 trials (n=7,274) found no evidence of an effect on fasting glucose at 6 months to 1.5 years (MD, -0.36 mg/dL [0.02 mmol/L] [95% CI, -1.22 to 0.50]; $I^2=42.4\%$). There was, however, evidence of a beneficial association when looking only at the high-intensity interventions (MD, -1.35 mg/dL [95% CI, -2.24 to -0.45]; k=7; n=2,381), and statistical heterogeneity was reduced to zero (**Figure 9; Table 5**). All but two of these seven high-intensity interventions included both healthful diet and physical activity messages; the remaining trial focused only on healthful diet. Consistent with the results for blood pressure and LDL cholesterol, the Women's Healthy Lifestyle Project again showed a statistically significant benefit of the high-intensity intervention on fasting glucose at both 6 months and 1.5 years, with a slight attenuation in the effect over time.¹⁹⁴ No other individual trial reported a statistically significant benefit of the intervention (**Figure 9**).

Across all trials, mean baseline fasting glucose level generally ranged from 87.3 to 104.4 mg/dL (mean, 97.3 mg/dL). The largest changes in fasting glucose level were seen in a small trial of adults with a family history of type 2 diabetes.⁹⁷ Participants randomized to a high-intensity counseling intervention focused on healthful diet plus physical activity (n=24) or to a high-intensity healthful diet-only intervention (n=25) experienced larger reductions in fasting glucose

levels at 1 year than the minimal intervention group (n=19) (reductions of -7.7, -5.9, and -3.8 mg/dL, respectively). However, there were no statistically significant differences between groups.

Five of these trials also reported the effects of the interventions on HbA1c (not pooled).^{80, 146, 154, 160, 208} Results were similarly inconsistent, with only one trial among older adults who were overweight suggesting a benefit of the intervention on HbA1c level (MD, -0.25 mg/dL [95% CI, -0.37 to -0.12]) (**Appendix F Table 5**).¹⁴⁶ Only two trials reported the prevalence or incidence of diabetes.^{85, 209} In the U.S.-based Coronary Health Improvement Project, small improvements in continuous fasting glucose were seen in both the counseling intervention group (mean change, -3.0 mg/dL [95% CI, -5.9 to -0.1]) and the control group (mean change, -1.0 mg/dL [95% CI, -3.6 to 1.6]), and the between-group difference was not statistically significant.⁸⁵ The proportion of participants with diabetes (defined as fasting glucose ≥ 126 mg/dL) decreased from 12.1 to 9.8 percent in the intervention group ($p < 0.0001$) and increased slightly (from 4.0% to 5.2%) in the control group. Again, the between-group difference was not statistically significant. In the very large WHI Dietary Modification Trial, which focused on low-fat dietary patterns, 7.1 versus 7.4 percent of intervention and control participants, respectively, reported incident diabetes after 8.1 years of followup (HR, 0.96 [95% CI, 0.90 to 1.03]). This study did not report continuous measures of blood glucose.²⁰⁹

Adiposity

Thirty-one trials reported an adiposity-related outcome, such as BMI, weight, waist circumference, or percent body fat (**Appendix F Table 6**).^{72, 80, 85, 91, 97, 98, 106, 111, 122, 126, 135, 140, 143, 144, 146, 147, 149, 154, 156, 160, 176, 188, 190, 194, 204, 205, 207-209, 211, 219} Given the number of trials that reported each respective outcome, we were able to pool the results for BMI, weight, and waist circumference separately. Although the included trials did not address weight loss as a direct goal of the interventions (by virtue of our inclusion criteria), they were associated with small improvements in BMI, weight, and waist circumference (**Table 5**). The results of each meta-analysis showed small but statistically significant associations between healthful diet and/or physical activity interventions and reductions in BMI, weight, and waist circumference at approximately 6 months to 1 year (**Figures 10–12**). However, considerable statistical heterogeneity ($I^2 > 90\%$) was present in these analyses due to wide variation in effect estimates and precision around those estimates, which likely reflects clinical variability among the included studies, particularly in the samples' baseline characteristics and the studies' aims. Thus, the average intervention effects (MDs) should be interpreted with caution.

Thirteen trials presented both BMI and weight outcomes and were included in both meta-analyses;^{72, 85, 91, 97, 106, 126, 146, 147, 149, 154, 188, 194, 209} seven additional studies were unique to each respective plot. Thus, these two outcomes represent slightly different sets of studies. The meta-analysis of BMI measures showed a pooled MD of -0.41 kg/m^2 (95% CI, -0.62 to -0.19 ; $k=20$; $n=55,059$; $I^2=95.8\%$) related to healthful diet and physical activity interventions (**Figure 10**). The range in between-group differences in change in BMI was 0.6 kg/m^2 in favor of the control group and 2.1 kg/m^2 in favor of the intervention group (**Appendix F Table 6**). The subset of nine high-intensity interventions consistently showed benefit of the interventions on BMI, with a pooled MD in change of -0.81 kg/m^2 supporting the intervention (95% CI, -0.99 to -0.63)

(**Figure 10; Table 5**); no such benefit was seen among the subsets of medium- or low-intensity interventions, although the number of studies contributing to these subgroups was smaller (seven and four studies for medium- and low-intensity subgroups, respectively). A dose-response effect was seen, with increasing intensity being statistically significantly associated with increasing effect estimates ($p=0.004$). Two trials reported large, nearly statistically significant effects in an unexpected direction (i.e., favoring the control group).^{98, 154} Sensitivity analyses excluding those trials resulted in a slightly larger pooled effect estimate for BMI (MD, -0.50 kg/m^2 [95% CI, -0.72 to -0.27]) but did not improve the statistical heterogeneity ($I^2=96.1\%$). The same sensitivity analyses for weight and waist circumference showed a similar pattern.

A separate meta-analysis showed a statistically significant association with weight in favor of behavioral interventions over control conditions, although again the statistical heterogeneity was considerable (MD, -1.04 kg [95% CI, -1.56 to -0.51]; $k=20$; $n=51,401$; $I^2=92.4\%$) (**Figure 11**). This finding translates into an MD of -2.3 lb (95% CI, -3.4 to -1.1). The dose-response effect of intervention intensity with weight was also evident (meta-regression, $p=0.035$).¹⁴³ Nine trials reported adiposity outcomes over time; consistent or slightly attenuated effects were seen for BMI or weight outcomes from 6 months to 6 years of followup across trials.^{72, 91, 140, 143, 160, 194, 205, 207, 209}

There was no trend in the effect estimates for BMI or weight according to the samples' mean BMI or weight at baseline. For example, while the largest difference in BMI reduction was seen among the sample with the highest BMI at baseline—the Aldana study, in which the mean baseline BMI was 32.3 kg/m^2 and the MD in change was -1.3 kg/m^2 at 6 months⁸⁵—relatively large differences were also seen among samples with a mean BMI reflecting normal or borderline overweight status (e.g., studies by Brekke,⁹⁷ Simkin-Silverman,¹⁹⁴ and Hellenius¹³⁵). Across adiposity outcomes, only three studies required participants to be overweight or have obesity upon study entry.^{91, 146, 205}

Five trials could not be included in the meta-analyses for BMI^{211, 219} or weight^{156, 204, 207} because of limitations in data reporting (e.g., no measure of dispersion). Results of these trials were mixed, with two trials generally showing no change in adiposity within or between groups,^{207, 211} two trials showing a difference in mean weight change in favor of the intervention versus control group but no estimate in the confidence of the effect,^{156, 204} and one trial showing a slightly better improvement in BMI among control group participants (-1.3 kg/m^2) versus those participating in a Web-based intervention (-0.6 kg/m^2).²¹⁹

Seventeen studies (all of which also reported BMI or weight outcomes) presented a measure of waist circumference at 6 months to 2 years of followup (**Appendix F Table 6**). Pooled analyses suggested a reduction of approximately -1.19 cm (0.5 in) in waist circumference related to a diet and/or physical activity intervention (95% CI, -1.79 to -0.59 ; $k=17$; $n=50,500$; $I^2=91.8\%$) (**Figure 12**). Mean baseline waist circumference ranged considerably, from 72 cm in a sample of young adults (mean age, 19.7 years)⁷² to 105 cm among samples of older adults.^{146, 208} Eight studies also reported the percentage of body fat of participants before and after the intervention (**Appendix F Table 6**). Two trials suggested a benefit of the intervention on percent body fat;^{85, 194} the remaining trials were inconsistent in the direction and magnitude of effect on percent body fat.^{80, 146, 154, 207, 208, 219}

There was very little evidence to indicate that interventions resulting in the greatest between-group changes in adiposity outcomes (BMI, weight, or waist circumference) were the most beneficial in affecting other intermediate outcomes. For example, in the Coronary Health Improvement Project, primarily among adults with obesity, statistically significant benefits of the healthful diet and physical activity intervention were seen for both BMI (MD, -1.30 kg/m^2 [95% CI, -1.65 to -0.96]) and weight (MD, -3.90 kg [95% CI, -5.00 to -2.80]) outcomes at 6 months, but no such between-group differences were seen for blood pressure, lipid, or glucose outcomes.⁸⁵ Likewise, the Shape Program, a weight gain prevention program among black women who were overweight or had obesity, reported larger 12- and 18-month weight changes among intervention versus control participants (MD at 12 months, -1.4 kg [95% CI, -2.8 to 0.1]), but reported no such differences in treatment arms for change in blood pressure, lipid, or glucose levels at any time point.⁹¹ Other studies that reported statistically significant benefits on adiposity outcomes reported no statistically significant benefits on other intermediate outcomes^{80, 135, 190} or only one other intermediate outcome (e.g., SBP,¹⁰⁶ DBP,²⁰⁹ total cholesterol,^{146, 188} HDL cholesterol,⁹⁷ and triglycerides⁷²) and no apparent pattern in effects across trials. Only one trial, the Women's Healthy Lifestyle Project, showed a consistent benefit of the high-intensity intervention across adiposity and other cardiometabolic intermediate outcomes.¹⁹⁴ These interventions, however, were not necessarily designed to induce greater weight loss among intervention versus control group participants; rather, the goal was to prevent weight gain.

Cardiovascular Risk Status

Four trials used the Framingham risk equation to report the effects of a diet or physical activity intervention on multivariate cardiovascular risk status.^{111, 118, 135, 176} The results for this outcome were consistent with the results of other intermediate outcomes reported by each respective trial. Despite seeing reductions in 4- or 10-year risk of coronary heart disease among intervention group participants at 6 to 12 months, there was no statistically significant difference compared with control groups. For instance, in the U.S.-based primary care study Family Intervention Trial for Heart Health, there was no statistically significant difference in the proportion of participants with a Framingham absolute risk of less than 10 percent between the intervention and control groups (90% vs. 92%) ($p=0.51$).¹⁷⁶ Likewise, in an older trial by Hellenius et al, a significant reduction in 10-year CVD risk was seen among all three intervention arms after 6 months (a reduced risk of 12% to 14%), but there were no differences in between-group comparisons with the control group.

Effect Modifiers, Including Intervention Components

We explored potential differences in the effects of the interventions on intermediate outcomes as they related to specific study, population, and intervention characteristics. Specifically, we examined possible effect modification using meta-regression for five prespecified variables: study quality (good vs. fair), link to primary care (yes vs. no), intervention intensity (as a continuous variable in minutes and categorical as high- vs. medium- or low-intensity), duration of the intervention (continuous in weeks) and, for adiposity outcomes, mean baseline BMI or weight. Other prespecified variables, including population risk for CVD, number of intervention sessions, offers of group sessions, and a focus on diet (messages regarding a general heart-healthy diet, sodium reduction, increased intake of fruits and vegetables, and/or low-fat diet

patterns) showed no apparent relationship with the effects on any of the intermediate outcomes after visual inspection of plots and tables. Therefore, we did not conduct meta-regression to explore effect modification for these variables.

Of all these factors, only intervention intensity (evaluated either continuously in estimated minutes or categorically as high- vs. medium- and low-intensity) and whether the studies recruited participants from or were conducted in primary care were consistently associated with pooled effect estimates across outcomes ($p < 0.05$). Across the intermediate outcomes, larger effects were seen with increasing intensity of the intervention (**Table 5**). Intervention intensity, as measured by the estimated total minutes of contact, ranged from 15 to 2,340 minutes (39 hours) among the studies that reported at least one intermediate outcome. The range of estimated contact time was 40 to 240 minutes (4 hours) for medium-intensity interventions and 420 minutes (7 hours) to 2,340 minutes (39 hours) for high-intensity interventions. This estimate of intensity included only sessions that were conducted face-to-face with an interventionist, by telephone, or using a computer. Print-based materials and mailings did not contribute to the intensity value. Interventions that were solely print-based were always categorized as low intensity. Our estimates of intensity were based on the planned (vs. actual) number and length of sessions; in several cases, we made assumptions and provided estimates regarding the number and length of sessions based on details provided in each article. Our methods for estimating intensity are described in detail in Chapter 2. Intensity appears to be confounded by several factors. In general, interventions of higher intensity focused on healthful diet messages and may or may not have included physical activity messages. Very few interventions of higher intensity focused on physical activity only. In addition, higher intensity interventions were generally longer in duration (e.g., ≥ 1 year), although the bulk of the intensive phase of these interventions generally occurred in the first 6 months. Lastly, almost all of the high-intensity interventions relied on volunteer or other convenience samples and did not occur in a primary setting. Across the 30 studies that reported an intermediate outcome, only two studies in primary care were categorized as high intensity.

Nine studies had more than one active intervention arm designed to contrast specific approaches; four included multiple interventions of the same intensity but with different behavior change messages,^{97, 135, 169, 220} one compared diet messages,¹⁴⁰ and four others tested the effects of varying intervention components and delivery modes on intermediate outcomes.^{143, 149, 154, 198} There was no consistent pattern within or across these studies that suggested that diet-only, physical activity-only, or diet plus physical activity messages (particularly behavior change techniques or dietary messages) or specific intervention strategies were preferable across intermediate outcomes.

Subpopulations

Direct within-study analyses of particular subpopulations of interest (i.e., age, race/ethnicity, and sex) were sparse, often not prespecified, and rarely included interaction testing, so we could draw no definitive conclusions about differential effectiveness on intermediate outcomes. Only one trial reported varying effects of the intervention based on age subgroups; in the large WHI Dietary Modification Trial ($n=45,887$), there was no interaction between the effect of the intervention and age group (50 to 59, 60 to 69, and 70 to 79 years) for incidence of diabetes at up

to 8 years of followup.²⁰⁹ Two trials reporting intermediate outcomes by race/ethnicity showed no consistent evidence of effect modification for blood pressure,^{158, 159} weight,¹³⁸ or incidence of diabetes.²⁰⁹ Four studies reported effects by sex.^{90, 149, 159, 188} In the TOHP phase I trial (n=744), no significant differences in treatment effectiveness were found between men and women in changes in DBP, but there was a significant difference for SBP, with an adjusted treatment effect of -1.23 mm Hg (95% CI not reported) for men and -4.44 mm Hg (95% CI not reported) for women (p=0.02 for interaction).¹⁵⁹ Three other studies reported the effects of the intervention on lipids^{90, 188} or adiposity outcomes¹⁴⁹ for men and women separately, but they did not report interaction testing, and MDs appeared similar across subgroups.^{90, 188}

Given the high potential for confounding by clinical differences in these samples and from other sources of clinical heterogeneity, such as intervention intensity, we did not perform indirect comparisons of subpopulation effects across trials (e.g., trials of women vs. men)

Reporting Bias

Overall, there was no evidence of small-study effects for any of the intermediate outcomes based on visual inspection of funnel plots and Egger's test.

KQ 3. Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Associated Health Behaviors in Adults?

Summary of Results

All but two^{91, 211} of the 88 included studies reported the effects of a behavioral intervention on dietary, physical activity, and/or sedentary behavior outcomes. Of these 86 studies, we rated 18 as good quality and the remaining 68 as fair quality. More than one third of the studies that reported behavioral outcomes (36 of 86 studies) were newly identified as part of our update. Almost all of the behavioral outcomes were based on self-report; three trials measured urinary sodium excretion and 11 trials used accelerometers or pedometers to capture objective measures of physical activity. The instruments, modes of administration, and summary measures were highly variable across trials that measured behavioral outcomes through self-report.

Overall, there was evidence that behavioral interventions generally improved participants' dietary intake and physical activity levels (**Table 6**). Mean between-group differences for dietary outcomes generally showed consistent benefit of the intervention versus control groups, but the precision in the magnitude of effects was quite variable across the trials that reported each respective outcome, and each meta-analysis found considerable statistical heterogeneity ($I^2=88\%$ to 99% in each analysis). We examined a number of clinical and study characteristics across the trials (e.g., study quality, intervention intensity, intervention focus [diet messages only vs. diet plus physical activity messages], broad population characteristics, specific dietary messages, and baseline dietary intake) in an attempt to help explain the heterogeneity. We also conducted

sensitivity analyses as appropriate. Although a meta-regression for continuous intensity was statistically significant for some dietary outcomes, statistical heterogeneity remained considerable within groups when stratified by intensity. Given the considerable statistical heterogeneity within each meta-analysis, we do not present the pooled effect estimate for any dietary outcome, as we do not feel confident that these effects reflect the average effects. Rather, we present forest plots to illustrate the range of effects seen across studies. In general, healthful diet interventions (with or without physical activity messages) were associated with reduced total energy, fat, saturated fat, and sodium intake and increased fiber and fruit and vegetable intake compared with control arms. Between-group differences for dietary outcomes were in the magnitude of 65 kcal/day (favoring the control group) to -500 kcal/day (favoring the intervention group) in total energy intake (k=11), 0.8 to -11 percentage points in the percent of calories from fat (k=15), and -0.3 to -4.1 percentage points in the percent of calories from saturated fat (k=9). Effects on fruit and vegetable intake ranged from between-group differences of -0.2 servings/day (favoring the control group) to 2.2 servings/day (favoring the intervention group) (k=16); between-group differences in grams of fiber per day ranged from 1 to 2.5 g/day in favor of the intervention group (k=6). Reductions in sodium ranged from -380 to -1,380 mg/day (k=6). Consistent effects of the interventions were seen over time for all dietary outcomes among studies that reported multiple time points.

Physical activity interventions (with or without dietary messages) resulted in an approximate 35-minute increase in physical activity per week compared with controls (k=27). Additionally, intervention group participants had a 32 percent higher odds of meeting physical activity recommendations compared with those in the control group (k=16). Studies that limited enrollment to participants with suboptimal levels of physical activity at baseline (generally below the recommended level of 150 minutes per week) resulted in greater increases in physical activity compared with those that did not limit enrollment based on baseline physical activity levels. In contrast to findings for intermediate outcomes, there was no evidence of effect modification based on intervention intensity. Likewise, there was no evidence of a difference in effects for interventions focused only on physical activity messages versus those focused on both physical activity and healthful diet messages.

Among trials that reported both intermediate and behavioral outcomes (k=32), findings were generally concordant within studies (**Table 7**). That is, trials that reported a statistically significant benefit of the intervention on one or more intermediate outcomes also reported statistically significant benefit on dietary and/or physical activity behaviors at each given time point. Furthermore, the specific intermediate outcome showing benefit within each trial generally reflected the specific behavior changes targeted in that trial. For example, trials that reported significant reductions in measures of blood pressure as a result of the interventions generally also found significant reductions in measures of sodium intake.^{137, 204, 205} Studies finding differences in between-group mean BMI and/or weight reductions also reported large between-group reductions in total caloric intake (e.g., studies by Aldana,⁸⁵ Coates,¹⁰⁶ Simkin-Silverman,¹⁹⁴ and Tinker²⁰⁹). The limited number of studies that reported a statistically significant benefit of the intervention on LDL or total cholesterol reported concordant significant between-group reductions in total fat and saturated fat intake.^{188, 194} In many instances in which trials did not find any benefit in intermediate outcomes, the trials demonstrated statistically significant improvements in dietary intake and/or physical activity.^{90, 98, 111, 126, 130, 140, 147, 156, 160} Among the

physical activity—only interventions that reported increased physical activity levels as a result of the interventions, statistically significant effects on intermediate outcomes were limited to waist circumference,^{80, 135} HDL cholesterol level,¹²² or BMI or weight.¹⁴⁶ There was only one trial that reported statistically significant improvements in intermediate outcomes in the absence of concurrent improvements in behaviors; in the weight gain prevention trial by Hivert et al¹⁷² among 115 college students, a difference of 1.4 kg in weight change was found between groups, despite no obvious differences between groups in dietary intake or physical activity levels.

Detailed Results by Outcomes

Diet

Forty-one studies reported one or more dietary outcomes, including total energy and intake of fat and saturated fat, fruits and vegetables, fiber, and sodium.^{72, 85, 86, 90, 92, 93, 97, 100, 101, 106, 109, 115, 116, 125, 126, 135, 137, 140, 141, 143, 144, 147, 149, 152, 156, 162, 176, 181, 188-190, 194, 197, 198, 203-205, 207, 209, 210, 217} Only six of the 41 studies were rated as good quality. Furthermore, only 14 were newly identified as part of our update. We limited our abstraction and analyses to these six specific dietary outcomes for consistency with the original review and to focus our results. Many trials, however, reported the effects of the interventions on other important dietary outcomes, such as intake of carbohydrates, protein, cholesterol, milk/dairy, potassium, and whole grains. With the exception of three studies that assessed sodium intake based on urine sodium excretion, the studies relied on self-reported dietary intake. The instruments to assess dietary intake were extremely heterogeneous and evidence of validity and reliability varied. Recall periods ranged from 1 to 7 days, with many studies not reporting the specific recall period.

Within these 41 studies, there were 56 unique intervention arms aimed at improving dietary intake, with or without physical activity messages. Most of the interventions were of medium or high intensity. The specific dietary aims, and the reporting of these details, varied widely across trials (**Table 4; Appendix E Table 1**). Most of the interventions centered dietary messages on general heart-healthy eating patterns that included limiting fat intake, decreasing intake of saturated and trans fat, eating a variety of fruits and vegetables, limiting intake of sodium, and emphasizing whole grains. Six studies specifically emphasized increasing fruit and vegetable intake^{86, 93, 125, 144, 162, 189} while another five studies focused only on reducing fat intake.^{92, 106, 116, 141, 217} The four trials focused on decreased sodium intake enrolled persons with above-normal blood pressure.^{137, 140, 204, 205} Most of the trials that reported a dietary outcome were conducted in the United States (26 of 41 trials), and nearly half of them were recruited from or took place in a primary care setting. Additional characteristics of these interventions are described above (Intervention Characteristics).

Total Energy

Thirteen trials reported self-reported total energy intake in terms of kilocalories per day at 6 months to 6 years of followup (n=46,955) (**Appendix F Table 7**).^{72, 85, 93, 97, 106, 126, 135, 143, 194, 197, 207, 209, 210} Baseline energy intake ranged from approximately 1,450 to 2,500 kcal/day among the included trials. Nearly all of the trials reported greater reductions in total energy intake among intervention versus control participants; seven of the 13 studies reported statistically significant

greater benefit at 6 months to 1.5 years (**Figure 13**).^{85, 106, 126, 194, 197, 209, 210} Across the trials, participants in the intervention groups generally decreased their total energy intake by approximately -13 to more than -550 kcal/day, whereas the control groups ranged from a reduction of -25 to -243 kcal/day (range of between-group differences, 65 kcal/day in favor of the control group, 500 kcal/day in favor of the intervention group). For example, at 1 year in the WHI Dietary Modification Trial, women taking part in the high-intensity group counseling intervention (n=17,117) reported a decrease that was 94 kcal/day (95% CI, -106.15 to -81.85) greater than that of women in the control group (n=25,182). An even greater between-group difference was seen at the end of the 6-year intervention (MD, -115 kcal/day [95% CI, -128.28 to -101.72]).²⁰⁹ Persistent effects of the interventions on total energy intake were seen over time in all of the trials that reported multiple timepoints.^{72, 143, 194, 207}

Fat and Saturated Fat

All but one of the studies that reported total energy intake and an additional 14 studies reported the effects of a healthful diet intervention (with or without physical activity messages) on self-reported fat and/or saturated fat intake (k=25; n=54,897 for fat and n=49,463 for saturated fat) (**Appendix F Table 7**).^{72, 85, 92, 97, 100, 101, 106, 109, 115, 116, 126, 135, 141, 143, 147, 152, 156, 176, 188, 194, 197, 198, 207,}

^{209, 217} Fat intake outcomes varied across trials and included fat reported as percent of energy, grams of fat per day, or a study-defined score. There was consistent evidence of an effect of the interventions on both total fat (**Figure 14**) and saturated fat intake (**Figure 15**) at 6 months to 1.5 years of followup. Looking specifically at the 15 trials that reported the daily percent of energy from fat, the magnitude of between-group differences was generally from approximately 0.8 percentage points (favoring the control group) to -11 percentage points (favoring the intervention group) of total energy from fat, with mean baseline percent of energy from fat ranging from approximately 30 to 40 percent (**Appendix F Table 7**).^{72, 85, 92, 97, 106, 115, 126, 135, 143, 147, 176, 188, 194,}

^{209, 217} For saturated fat, mean between-group differences ranged from about -0.3 to -4.1 percentage points in the reduction of saturated fat intake, in favor of the intervention groups. For example, a trial by King et al¹⁵² of a 1-year telephone counseling intervention reported mean changes in the percent of energy from saturated fat ranging from -1.8 to -2.5 percentage points within three active intervention arms, while the control arm experienced a decrease of only -1.2 percentage points (a statistically significant between-group difference for the active intervention arm focusing simultaneously on diet and physical activity and the arm focusing on messages sequentially, with diet messages first). Additionally, a greater proportion of intervention participants were meeting recommendations for less than 10 percent of calories from saturated fat among the three active intervention arms (40% to 59%) versus the control arm (31%). Among trials that reported both total fat and saturated fat outcomes, consistent results were seen across these outcomes within each trial.

Fruits and Vegetables

Twenty-six studies reported fruit and vegetable intake and found that healthful diet interventions generally resulted in small increases in fruit and vegetable intake compared with controls (n=67,821) (**Figure 16; Appendix F Table 7**).^{85, 86, 93, 100, 101, 106, 109, 115, 125, 126, 141, 144, 147, 149, 152, 156,}

^{162, 176, 181, 188-190, 198, 203, 207, 209} Again, the meta-analysis of trials reporting servings per day of fruit and vegetables found considerable heterogeneity ($I^2=95.6%$); thus, we do not present the pooled

estimate. Between-group differences in the mean change of fruit and vegetable intake ranged from -0.2 servings/day (favoring the control group) to 2.2 servings/day (favoring the intervention group) at 6 months to 1 year of followup; baseline servings of fruits and vegetables were between 3 and 6 servings/day. All six trials that focused dietary messages exclusively on increased fruit and vegetable intake found statistically significantly greater benefit among intervention versus control participants.^{86, 93, 125, 144, 162, 189} For example, the U.S.-based Making Effective Nutritional Choices study by Alexander et al⁸⁶ (n=2,540) found a statistically significantly greater increase in the number of fruit and vegetable servings per day for the intervention group randomized to the use of a tailored Web-based intervention plus email counseling (+2.8 servings/day [95% CI, 2.6 to 3.0]) compared with a control arm randomized to a generic nutrition Web site (+2.3 servings/day [95% CI, 2.1 to 2.5]). Likewise, another computer-tailored Web-based intervention—the Family Healthware Impact Trial (n=3,389)—found that intervention participants were more likely to increase daily fruit and vegetable consumption from 5 or fewer servings/day to 5 or more servings/day after 6 months (adjusted OR, 1.29 [95% CI, 1.05 to 1.58]). The intervention itself was generally low intensity in that it involved no face-to-face contact with an interventionist; participants could complete the intervention in one Web-based session or through multiple sessions over the course of 6 months.¹⁸⁹

Fiber

Fewer trials (k=11; n=47,218) reported the effects of interventions on fiber intake.^{90, 92, 93, 97, 100, 109, 116, 176, 188, 197, 209} Six of the trials reported fiber intake in terms of grams per day, whereas the remaining five trials reported grams per 1,000 kilocalories per day or a study-defined fiber score (**Appendix F Table 7**). All but one of the 11 trials are shown in the forest plot that presents the standardized MD (SMD) in fiber intake (**Figure 17**). The remaining trial¹⁰⁹ did not present within-group variance but reported a statistically significantly greater increase in grams of fiber per day among intervention versus control participants (adjusted MD, 1.00 g/day [95% CI, 0.40 to 1.60]). In general, all but one of the trials suggested a benefit of the intervention on fiber intake but only four of the individual trials reported statistically significantly greater benefit versus the control group.^{90, 97, 109, 209} Among studies reporting change in fiber intake as grams per day, the magnitude of between-group difference was approximately 1 to 2.5 g/day at 6 months to 1 year in favor of the intervention groups. The baseline levels of fiber intake were quite low in these samples, ranging from 6 to 25 g/day.

Sodium

Six trials, all of which were conducted in the United States, reported sodium outcomes (n=2,572) (**Appendix F Table 7**).^{85, 101, 137, 140, 204, 205} All of the interventions included specific messages about decreasing salt or sodium intake, including counseling on the DASH diet,^{101, 137} specific goals for decreasing sodium intake to approximately 1,400 to 1,600 mg or less per day,^{140, 204, 205} or general messages about reducing dietary salt intake.⁸⁵ We did not pool these studies given the small number of trials and extensive variability in the populations and measurement of sodium (i.e., self-reported vs. 8- to 24-hour urine collection). All but one of the trials reported statistically significantly greater reductions in sodium among intervention versus control group participants. The one trial that found no benefit was one of the two trials reporting this outcome

that included general heart healthy dietary messages, including limiting salt intake, but did not focus on salt intake alone.¹⁰¹ The remaining trials reported quite large differences in sodium (mg/day) or urinary sodium output (mmol/8 or 24 hours) between intervention and control participants, with evidence of persistence in the effects up to 3 years of followup (**Appendix F Table 7**). For example, in the trial by Aldana et al.,⁸⁵ which included general messages about decreasing salt intake, intervention group participants reduced their sodium intake on average from a baseline of 2,941 to 2,332 mg/day at 6 months (MD, -609 mg/day [95% CI, -817 to -401]), whereas control group participants decreased intake from 2,712 to 2,486 mg/day over this same period (MD, -226 mg/day [95% CI, -402 to -50]), for a statistically significant between-group difference of -383 mg/day (95% CI, -590 to -176) in favor of the intervention group. The TOHP phase I and phase II trials among adults with high-normal blood pressure indicated statistically significant between-group differences in urinary sodium output, which ranged from approximately -40 mmol/24 hours (-920 mg/day) to -60 mmol/24 hours (-1,380 mg/day) at up to 3 years of followup. The most intensive phases of these two interventions occurred within the first 3 and 4 months of the studies, with refresher or booster sessions occurring up to 1.5 to 3 years, respectively.^{204, 205}

Physical Activity

Sixty-three trials reported the effects of a behavioral intervention on participants' physical activity levels (**Appendix F Table 8**).^{72, 81, 83, 85, 94, 97, 98, 100, 102, 103, 108, 111, 112, 115, 120, 122, 123, 128, 131, 132, 135, 141, 143, 146, 148, 152-155, 160, 161, 166, 167, 170, 172, 176, 177, 179, 181, 184-186, 189, 194, 197, 201, 203, 207, 208, 210, 212, 214, 217-219} Within these 63 trials, 14 trials were of good quality and the remaining 49 trials of fair quality. Physical activity was the primary outcome in 41 trials.^{81, 83, 94, 98, 100, 102, 103, 108, 111, 112, 115, 120, 122, 123, 131, 132, 141, 146, 148, 152-155, 160, 161, 166, 167, 170, 172, 177, 179, 181, 184-186, 189, 197, 201, 203, 207, 208, 210, 212, 214, 217-219}

Thirty trials were newly identified as part of this update and 33 were included in the original review. Most of the studies relied on self-reported measures of physical activity (e.g., 7-day physical activity recall, International Physical Activity Questionnaire); only 11 studies used accelerometers^{113, 132, 164, 169, 194, 197, 208} or pedometers^{94, 119, 130, 212} to capture an objective measure of physical activity. The specific physical activity outcomes were highly variable across studies and included continuous measures such as total physical activity, moderate- to vigorous-intensity physical activity, walking, study-defined physical activity scores, and a binary measure of the number of participants meeting physical activity recommendations (≥ 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week). Likewise, the unit of measurement for each of these outcomes was very diverse (e.g., minutes/week, metabolic equivalent of task [MET]-minutes/week, days/week, steps/day, kcal/kg/day).

Across the 87 intervention arms included in these 63 trials, most were of low or medium intensity and focused on physical activity alone. Additional characteristics of these interventions are described above (see Intervention Characteristics). Low-intensity interventions were mostly print-, Web-, or text-based interventions whereby participants received tailored information to set appropriate behavior change goals and monitor their progress and which were typically based on the stages of change (transtheoretical) model. Medium-intensity interventions typically included at least one face-to-face session and followup with several telephone counseling calls. High-intensity interventions often included group sessions. Almost half of the trials that reported a physical activity outcome were conducted in the United States (35 of 63 trials); however, only

six of these U.S.-based studies were conducted in a primary care setting or included intervention components delivered by primary care staff.^{117, 120, 148, 179, 186, 203}

Continuous Levels of Physical Activity

Overall, there was evidence that behavioral interventions increased participants' physical activity levels (**Table 6**). The meta-analysis of the SMD in change in continuous measures of physical activity (e.g., minutes/week, kcal/kg/day, steps/day) showed a small but statistically significant association between physical activity interventions (with or without healthful diet messages) and an increase in physical activity levels compared with controls at 6 to 12 months of followup (SMD, 0.20 [95% CI, 0.14 to 0.26]; k=46; n=16,948; $I^2=60.2\%$) (**Figure 18**). Meta-regression revealed no evidence of effect modification based on study quality, intervention intensity, intervention focus (physical activity only vs. physical activity and healthful diet), mean age, or link to primary care. In addition, there was no evidence that the effectiveness varied by intensity or that the effects differed between the subgroup of interventions focused only on increasing physical activity (SMD, 0.23 [95% CI, 0.16 to 0.31]; k=34; n=12,588; $I^2=58.9\%$) versus those that focused on both physical activity and healthful diet goals (SMD, 0.11 [95% CI, 0.02 to 0.20]; k=12; n=4,360; $I^2=51.0\%$) ($p=0.09$).

There was evidence, however, of an interaction between intervention effectiveness and physical activity outcomes according to whether the sample was selected on the basis of suboptimal behavior (i.e., not meeting physical activity recommendations or a specific threshold of physical activity). The pooled effect size for studies that limited enrollment to participants with suboptimal levels of physical activity (SMD, 0.28 [95% CI, 0.18 to 0.38]; k=24; n=8,211; $I^2=64.4\%$) was statistically significantly higher than for those that did not limit enrollment based on baseline physical activity levels (SMD, 0.12 [95% CI, 0.05 to 0.19]; k=22; n=8,737; $I^2=44.9\%$) (meta-regression, $p=0.012$). Review of the baseline levels of physical activity within each sample confirmed lower levels of baseline physical activity in general among participants selected for low levels of physical activity compared with those not selected on the basis of their baseline levels of physical activity (**Appendix F Table 8**). In most of the studies in which participants were selected on the basis of suboptimal behavior, participants were well below the recommended levels of physical activity at baseline (from 2.5 to 99 minutes/week), whereas studies in which participants were enrolled regardless of their baseline physical activity levels had higher baseline values (from 257 to 620 minutes/week). All but one of the studies that selected participants with suboptimal baseline physical activity were physical activity-only trials. Most interventions were of medium or low intensity.

To assist with interpretation of our findings, we also conducted an analysis limited to studies that reported minutes per week of physical activity (as opposed to measures such as MET-minutes or scale scores). Among the 27 trials that reported minutes per week of physical activity, this change amounted to approximately 35 additional minutes of physical activity per week for the intervention group compared with the control group (MD, 34.5 minutes/week [95% CI, 22.0 to 47.0]; n=11,289) (**Figure 19**). Statistical heterogeneity was still substantial within this meta-analysis ($I^2=67.7\%$), which was likely due to the clinical heterogeneity of the populations and interventions and the specific measurement of physical activity (i.e., total physical activity, moderate- to vigorous-intensity physical activity, and moderate physical activity). There was

considerable variation in the level of baseline physical activity across the studies. Physical activity ranged from 2 minutes/week among a sample of Hispanic/Latina women to 621 minutes/week (nearly 1.5 hours/day) among older adults (mean age, 64.5 years) in the Netherlands. Absolute differences between groups at 6 months to 1 year ranged from approximately 14 minutes/week more in favor of the control group to 106 minutes/week in favor of the intervention group.

Thirteen of the 27 trials reported statistically significant benefit of the intervention on minutes per week of physical activity at 6 to 12 months of followup;^{83, 98, 103, 111, 112, 132, 152, 153, 155, 161, 166, 186, 214} nine of these trials were newly identified in our update. For instance, in the trial by Lewis et al,¹⁶¹ 448 healthy, sedentary adults (70% white and 87% women) were randomly assigned to either a low-intensity, tailored, print-based physical activity or a minimal contact arm focused on general wellness over 6 months. Greater increases in self-reported physical activity were seen in the print intervention versus control arm at both 6 months (MD, 31.3 minutes/week) and 12 months (MD, 39.1 minutes/week). A few of these studies focused on specific subpopulations for which the prevalence of physical activity is generally low. For example, in the U.S.-based Nā Mikimiki Project by Albright et al,⁸³ 311 postpartum women from Honolulu with infants generally around age 6 months were randomized to receive up to 17 tailored telephone counseling calls and access to a “momcentric” Web site focused on increasing physical activity or a standard physical activity Web site over the course of 1 year. Women in the intervention group reported an average increase of 202 minutes/week of moderate- to vigorous-intensity physical activity, whereas women in the control group reported an average increase of 110 minutes/week, up from baseline values of 44 and 46 minutes/week, respectively (MD, 92 minutes/week [95% CI, 64 to 120]).

Nine studies that reported a physical activity outcome were not included in any of the physical activity meta-analyses due to a lack of reporting of detailed results (e.g., no within-group data, no variance) (**Appendix F Table 8**).^{94, 100, 115, 128, 131, 146, 201, 203, 210} Results of these studies were mixed. Five studies reported no statistically significant effect of the intervention on levels of moderate- to vigorous-intensity physical activity or total physical activity at 6 months to 1 year,^{94, 115, 131, 203, 210} whereas four trials reported beneficial effects of the intervention on at least one physical activity outcome.^{100, 128, 146, 201} For example, one study among sedentary older adults found a statistically significant benefit of a self-help booklet and telephone and email counseling on self-reported walking at 6 months but not on moderate- or vigorous-intensity physical activity.¹⁰⁰ Conversely, another study among older adults found a benefit of a primary care counseling intervention on vigorous-intensity physical activity but not on walking.¹²⁸

Among the trials that reported a continuous measure of physical activity, 18 trials included more than one active intervention arm of varying intensities, components, modes of delivery, or timing of messages.^{81, 103, 108, 115, 131, 135, 143, 152-154, 167, 169, 177, 181, 212, 214, 217, 220} There was no consistent evidence to suggest that certain intervention characteristics were more favorable than others in increasing participants’ levels of physical activity.

Meeting Physical Activity Recommendations

Sixteen trials, seven of good quality, reported the proportion of participants meeting

recommended levels of physical activity at 6 months to 1.5 years of followup (**Appendix F Table 8**).^{111, 113, 117, 120, 122, 152, 155, 160, 166, 167, 170, 172, 181, 185, 189, 218} The definition of meeting physical activity recommendations was generally the same in all of the trials—at least 150 minutes of moderate-intensity physical activity per week. The meta-analysis of all 16 studies showed that participants in the intervention groups had a 32-percent higher odds of meeting physical activity recommendations at 6 to 18 months of followup compared with those in the control group (pooled OR, 1.32 [95% CI, 1.12 to 1.56]; k=16; n=14,899; $I^2=70.3\%$) (**Figure 20**), which represents an RR of 1.22 when using a prevalence of 25 percent as the referent, based on the proportion of control group participants meeting recommendations or a number needed to treat of 17 for one additional person to meet physical activity guidelines. Despite nearly all of the trials generally showing higher rates of meeting recommendations among those receiving the intervention compared with those in the control groups, only five trials found a statistically significant benefit.^{117, 155, 160, 166, 189} Across all of the trials, the absolute difference in the percentage of participants meeting physical activity recommendations ranged from -4.1 percentage points (in favor of the control group)²¹⁸ to 19 percentage points (in favor of the intervention group).¹⁵⁵ When just the 12 trials that focused exclusively on physical activity messages were pooled, the relative association was slightly higher (pooled OR, 1.40 [95% CI, 1.13 to 1.75]; n=8,720). Five trials reported this outcome at multiple time points; there was no pattern across studies in the persistence of effect over time.^{117, 122, 160, 166, 167}

Cardiorespiratory Fitness

In addition to physical activity levels, measures of cardiorespiratory fitness were reported in seven trials with eight unique intervention arms. Five interventions focused on increasing physical activity only, while three focused on improving both physical activity and diet (**Appendix F Table 8**).^{72, 98, 122, 135, 154, 167, 207} Most of the studies reported maximal oxygen capacity ($VO_2\text{max}$) at baseline and followup (6 months to 2 years) based on maximal or submaximal treadmill or cycle ergometer tests. The effects of the interventions on cardiorespiratory fitness were generally consistent with those seen for self-reported physical activity. Those trials that reported statistically significant benefit of the intervention on self-reported minutes of physical activity per week also reported greater improvement in cardiorespiratory fitness among intervention versus control group participants, although these differences were not statistically significant.^{98, 122, 167} For example, the Colorado Stride trial found a statistically significant beneficial effect of its low-intensity, print-based physical activity intervention on self-reported physical activity (difference of approximately 33 minutes/week between groups) at 1 year. Mean $VO_2\text{max}$ improved slightly more in the intervention group (34.07 to 34.92 mL/kg/minute) than in the control group (33.23 to 33.39 mL/kg/minute), but there was no significant time-by-group interaction ($p=0.55$).⁹⁸ Three other studies found no appreciable differences between treatment groups in either self-reported physical activity or cardiorespiratory fitness at 1 to 2 years of followup.^{72, 154, 207} In the study by Thompson et al²⁰⁷ among women, there was a slight improvement in cardiorespiratory fitness in the control group but not the intervention group at 6 months, 1 year, or 1.5 years, although this difference was reported as not statistically significant (**Appendix F Table 8**). One other study found a small, statistically significant difference in self-reported physical activity sessions per month and minutes per session for the combined healthful diet and physical activity intervention arm (approximately five more sessions a month) versus the control group at 6 months but reported no

difference in cardiorespiratory fitness in any group.¹³⁵

Sedentary Behavior

Four trials reported measures of sedentary behavior independent of physical activity behavior.^{80, 100, 148, 169} One of these trials, the good-quality study by Aadahl et al⁸⁰ (n=149), designed its intervention specifically to reduce daily television viewing and minimize sitting time. At 6 months, objectively measured sitting time decreased in the intervention group (from 9.29 to 9.02 hours/day) and increased in the control group (from 9.78 to 9.84 hours/day), but the between-group difference in change (-0.32 hours/day) was not significantly significant (95% CI, -0.87 to 0.24). Changes in self-reported leisure sitting were statistically significantly different (5.3 to 4.4 hours/day and 5.0 to 4.9 hours/day in the intervention and control groups, respectively); the difference in change was -0.81 hours/day (95% CI, -1.36 to -0.27). The trial by Katz et al¹⁴⁸ that focused on primary care provider training to encourage and facilitate increases in physical activity among primary care patients found no effect of the intervention on sitting time after 6 or 12 months. Likewise, the trial by Marsaux et al¹⁶⁹ found no difference in change in minutes per week of sedentary time following a tailored Web-based intervention. In contrast, the study by Burke et al¹⁰⁰ found a statistically significant group-by-time effect on self-reported minutes per week of sitting time when comparing older adults randomized to a home-based self-help diet and physical activity intervention versus a no-intervention control group.

Reporting Bias

There was no evidence of small-study effects for either dietary or physical activity outcomes based on Egger's test (for continuous data) or Peters' test (for percent meeting physical activity recommendations).

KQ 4. What Adverse Events Are Associated With Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior in Adults?

Summary of Results

We narrowly looked at the harms of counseling interventions themselves rather than the harms of dietary or physical activity changes. We examined the 88 trials included for KQs 1 to 3 for any reported harms, as defined by the study authors. Generally, the harms of included counseling interventions were sparsely reported and were inconsistently defined, which precluded pooling. Fourteen of the included trials specifically mentioned the occurrence of harms or lack of harms (**Table 2**).^{81, 91, 94, 100, 103, 111, 132, 137, 153, 155, 160, 179, 190, 208} Across these studies, there were no serious adverse events related to counseling, although we did not hypothesize that these counseling interventions would result in serious harms (i.e., unexpected or unwanted medical attention). Eight trials reported adverse events of any kind or serious adverse events, with the majority reporting no differences between intervention and control participants. Similarly, eight trials

reported the incidence of important patient events, including injuries, falls, or adverse cardiovascular events, and found primarily no differences between treatment groups.

Detailed Results

Five trials (n=4,483) reported adverse events of any kind,^{81, 94, 100, 132, 190} while three trials (n=470) reported serious adverse events or cardiovascular adverse events.^{91, 103, 137} Three of these trials (one healthful diet plus physical activity, one healthful diet only, and one physical activity only) reported “no adverse events”^{100, 190} or “no serious adverse events”;¹⁰³ however, no additional details were provided. There was no consistent evidence of harms of the interventions in the remaining five trials. The medium-intensity PACE-LIFT trial focused on increasing physical activity among adults ages 60 to 75 years and found nearly identical rates of adverse events of any kind (e.g., falls, fractures, injuries, and deterioration in health problems) between treatment groups at 12 months (55% vs. 56%; p=0.90).¹³² Similarly, a brief physical activity counseling trial found no statistically significant difference in self-reported adverse events among participants randomized to the intervention versus usual care; at 2 months, 24 percent of participants reported some adverse effects, such as musculoskeletal pain.⁸¹ Conversely, another medium-intensity physical activity trial in older adults (mean age, 71.3 years) reported a higher rate of adverse events that were attributed to participation in the trial over 12 months (8 vs. 2 events in the control vs. the intervention group [7% vs. 1.8%], respectively).⁹⁴ A high-intensity diet and physical activity intervention that focused on weight gain prevention among black women who were overweight or had mild obesity reported the occurrence of six “serious” adverse events (2 cases of gynecological surgery, 1 case each of knee replacement, breast abscess, musculoskeletal injury, and cancer diagnosis) in the intervention group over 12 months of followup.⁹¹ It was unclear, however, if any of these events were related to study participation, and no information was reported for the women receiving usual care. Finally, one diet-focused trial, which included inactive men and women who were overweight or had obesity and above-normal blood pressure, reported that no participants experienced adverse cardiovascular events.¹³⁷

Seven physical activity–only trials (n=3,565) reported the incidence of injuries, fractures, or falls and found primarily no differences between treatment groups.^{111, 132, 153, 155, 160, 179, 208} Three out of four studies that recorded injuries sustained by participants during the course of the trial found no significant difference between those randomized to the physical activity intervention and those randomized to usual care or an attention control in injuries reported over 12 months of followup,^{111, 132, 153} whereas one trial comprised of women ages 40 to 74 years reported significantly more injuries among participants in the intervention group than in the control group over 24 months of followup (19% vs. 14%; p=0.03).¹⁶⁰ Two trials among older adults reported the incidence of fractures; one reported a single foot fracture in the intervention group (none in the control group)²⁰⁸ and the other found no significant difference in fractures between treatment groups (4% vs. 3% in intervention vs. control groups, respectively; p=0.74).¹³² Of the five trials that reported the occurrence of falls during the course of followup, only one trial reported more falls among intervention participants than among those receiving usual care; this was the same trial of women ages 40 to 74 years in which 37 percent of the intervention group versus 29 percent of the control group experienced a fall over 24 months of followup (p<0.001).¹⁶⁰ The other four trials—two in older adults and two in general, primary care populations—reported no

differences in falls between intervention and control participants over 12 months of followup.^{111,}
132, 155, 179

Chapter 4. Discussion

Summary of Evidence

We conducted this systematic review to assist the USPSTF in updating its 2012 recommendation on healthful diet and physical activity counseling for the primary prevention of CVD.¹ The current review focused specifically on the effectiveness and harms of primary care–relevant interventions in persons without known CVD or CVD risk factors. We included 88 unique trials, nearly a half of which (k=38) were published since the previous USPSTF review in 2010. The pooled effect estimates found in our updated systematic review are generally consistent in magnitude with the 2010 review on this topic⁴⁰ and slightly lower in magnitude than the effects seen with our 2014 review among persons at high risk for CVD.⁶⁵ The number of studies that contributed to each meta-analysis generally stayed the same or increased slightly but included higher quality and more relevant literature. Most of the new evidence (28 of 38 trials) focused on increasing physical activity among persons with low levels of physical activity and found consistent evidence of small to moderate increases in physical activity.

Table 8 summarizes the findings for this evidence review. We found that healthful diet and physical activity behavioral interventions in persons generally without traditional CVD risk factors were associated with modest reductions in blood pressure, total and LDL cholesterol, and adiposity measures at approximately 6 to 12 months of followup compared with control conditions. Given the consistency in the effect estimates and precision in those estimates over time for each intermediate outcome, we are moderately confident that our pooled estimates lie close to the true effects, although the body of evidence is still fairly small (<20 trials for most outcomes) and there is considerable variation in the interventions. Pooled analyses resulted in moderate or substantial statistical heterogeneity, reflecting the clinical heterogeneity across studies. There was evidence of a dose-response relationship, with increasing intervention intensity being associated with larger improvements in intermediate outcomes, but there was insufficient evidence to assess the effects of low-intensity interventions alone on intermediate outcomes. Most of the medium- to high-intensity interventions for which we saw a benefit on intermediate outcomes included healthful diet messages, with or without physical activity messages, and recruited persons outside of the primary care setting; thus, these interventions may have limited applicability to a general, unselected population. There was considerably more evidence for behavioral outcomes, with 86 trials reporting the effects of counseling interventions on dietary intake, physical activity, and/or sedentary behaviors. The directions of effects for all behavioral outcomes were reasonably consistent and suggested generally a small benefit for dietary outcomes and a moderate benefit for physical activity. However, there was substantial variation in outcomes measures and insufficient evidence on the effects of interventions on sedentary behaviors. Moreover, data on the long-term effects of the interventions on behavioral or intermediate health outcomes were limited.

We have limited certainty in the evidence for the effects on longer-term health outcomes, including all-cause and CVD-specific mortality, CVD events, and HrQOL. The evidence for these outcomes was sparse and inconsistent in the effects and reporting of health outcomes, precluding a robust conclusion. No new studies were included for mortality or CVD events.

Though the studies reporting these outcomes were generally large and of good quality, most were conducted in a selected population (persons with high-normal blood pressure). These studies consistently showed no difference in all-cause or CVD mortality and showed mixed findings for CVD events. Studies reporting quality of life showed small benefits for participants in intervention groups and no consistent benefit compared with controls. Overall, a limited number of trials reported on harms of physical activity interventions and none reported harms related to dietary interventions; none of these studies reported any serious adverse events related to the interventions. Only one trial among women found a statistically significantly greater incidence of injuries and falls related to a physical activity intervention. Despite a relatively smaller body of evidence related to harms, we are moderately confident that there are no serious adverse events associated with behavioral counseling for healthful diet and physical activity as we did not hypothesize any serious harm from counseling interventions.

Comparison With Findings From Other Systematic Reviews

The findings of our review are generally concordant with other systematic reviews that synthesized the evidence of healthful diet and physical activity interventions for the primary prevention of CVD. This includes a number of diet-related reviews by the Cochrane Collaboration focused on general dietary advice,²²² fruit and vegetable intake,²²³ reductions in fat²²⁴ and saturated fat,²²⁵ fiber intake,²²⁶ and adherence to a Mediterranean diet,²²⁷ as well as reviews focused on increasing physical activity.²²⁸⁻²³¹ Similar to our review, findings of other existing diet-focused reviews suggested that persons randomized to receive dietary advice experienced statistically significant higher reductions in SBP (MD, 2.61 mm Hg [95% CI, 1.31 to 3.91]), DBP (MD, 1.45 mm Hg [95% CI, 0.68 to 2.22]), LDL cholesterol (MD, 0.16 mmol/L [6.2 mg/dL] [95% CI, 0.08 to 0.24]), and total cholesterol (MD, 0.15 mmol/L [5.8 mg/dL] [95% CI, 0.06 to 0.23]) after 3 to 36 months, whereas mean changes in HDL cholesterol and triglyceride levels were not different between groups.²²² Also concordant with our review, there was significant heterogeneity in the analyses for self-reported dietary intake, but the results generally suggested improvements in fruit and vegetable, fiber, sodium, fat, and saturated fat intake with dietary advice.^{222, 223} Among those reviews, there was no clear effect of any dietary intervention compared with usual care or control diet on total or CVD mortality. One review, however, reported a reduction in cardiovascular events for dietary fat interventions compared with usual diets (pooled RR, 0.86, [95% CI, 0.77 to 0.96]; n=65,508) among persons at high or low risk for CVD.²²⁴

The National Institute for Health and Care Excellence performed two separate reviews of the literature to determine the effectiveness of brief advice^{231, 232} and exercise referral schemes^{230, 233} in increasing physical activity. In the first review, moderate evidence from 15 trials suggested an increase in self-reported physical activity among participants who received brief advice or who were seen by primary care professionals trained to deliver brief advice. Brief advice was defined as interventions delivered in one session or in fewer than 30 minutes. There was weak evidence, however, of a benefit of exercise referral schemes in increasing the number of participants who achieved 90 to 150 minutes of at least moderate-intensity physical activity per week at 6 to 12 months of followup (pooled RR, 1.11 [95% CI, 0.99 to 1.25]) versus usual care.

Observational Evidence on the Association Between Differences in Intermediate and Behavioral Outcomes and Health Outcomes

Due to sparse direct RCT evidence on the effect of healthful diet and physical activity counseling interventions on health outcomes, we present observational evidence to contextualize our results. This evidence likely represents an upper bound of potential benefit due to a broader inclusion of studied populations, including those at higher CVD risk, as well as an optimistic assumption that behavior modification, and hence subsequent differences in intermediate outcomes, are maintained over time.

Overall, observational data from very large individual participant data (IPD) meta-analyses of prospective cohort studies show that small differences in intermediate outcomes translate into small differences in important health outcomes, with greater proportional (though not absolute) benefit occurring at progressively younger ages (**Table 9**).^{19, 234, 235} The relationships between blood pressure (>115/75 mm Hg) and death from ischemic heart disease or stroke and between cholesterol and death from ischemic heart disease or stroke are generally log-linear. These associations are stronger than the association between fasting glucose and death from ischemic heart disease or stroke—a relationship that exhibits a nonlinear pattern and a threshold around 100 mg/dL, below which increases do not raise vascular risk. The relationship between BMI and ischemic heart disease and stroke death is also nonlinear, existing only above a BMI of 25 kg/m². However, BMI is highly correlated with other intermediate outcomes.

Blood Pressure

Our review found that primary care–relevant healthful diet and physical activity counseling can decrease SBP and DBP by approximately 1.3 and 0.5 mm Hg, respectively, at 6 to 12 months of followup compared with usual care. Within the included evidence, most participants were normotensive or had high-normal blood pressure, with a mean blood pressure across trials of 127/78 mm Hg. Epidemiologic data suggest that even small differences in blood pressure may decrease the risk for CVD-related mortality (**Table 9**). An IPD meta-analysis of nearly 1 million adults without CVD studied in 61 prospective observational cohorts found a strong and direct relationship between blood pressure and age-specific mortality for stroke, ischemic heart disease, and other vascular causes; this relationship persisted after adjustment for lipid levels, diabetes, weight, alcohol intake, and smoking.²³⁴ The continuous and positive association found in this analysis existed across a wide range of blood pressures, including the normotensive range; there was no evidence of a threshold for which lower blood pressure was not associated with lower CVD risk, down to levels of 115/75 mm Hg. When associations from this analysis, expressed as hazard ratios per 20-mm Hg difference in SBP and per 10-mm Hg difference in DBP, were converted into smaller increments more consistent with our results, the findings suggested that even a small blood pressure difference in SBP of 2 mm Hg in adults ages 40 to 49 years was associated with a stroke mortality reduction of 10 percent (HR, 0.90 [95% CI, 0.89 to 0.91]) and an ischemic heart disease mortality reduction of 7 percent (HR, 0.93 [95% CI, 0.92 to 0.94]) (**Table 9**).²³⁴ These associations were similar in magnitude for DBP when estimated for increments of 1 mm Hg.¹⁰⁷ An IPD meta-analysis of trial data of all classes of antihypertensive

medications offered support for the generalizability of the benefits of blood pressure lowering across a spectrum of overall risk and risk factor levels.^{236, 237}

Lipids

Our meta-analyses of lipid outcomes suggested that diet and physical activity counseling interventions decrease LDL cholesterol level by approximately 2.6 mg/dL and total cholesterol level by approximately 2.8 mg/dL at 6 to 12 months of followup compared with usual care. High-intensity interventions resulted in greater benefit: a reduction of nearly 4.5 and 5.3 mg/dL for LDL and total cholesterol, respectively. There was no evidence of an effect of interventions on HDL cholesterol or triglyceride level. Most studies reported mean levels of LDL cholesterol below 129 mg/dL, below 200 mg/dL for total cholesterol, and above 50 mg/dL for HDL cholesterol. The relationship between cholesterol and health outcomes is complicated by lipid components that work in different directions and varying strengths of association across different outcomes. Based on a related IPD meta-analysis of about 900,000 individuals without CVD, there is evidence of a strong positive relationship between non-HDL cholesterol level (reported instead of LDL cholesterol in the IPD meta-analysis) and ischemic heart disease mortality and a strong inverse relationship between HDL cholesterol level and this outcome.²³⁵ These associations were seen for all age groups, with no evidence of thresholds above or below which these relationships did not persist; the proportional strength of association, however, became weaker with increasing age. On average, a difference in non-HDL cholesterol level of 3 mg/dL was associated with a 4 percent reduction in fatal ischemic heart disease risk at ages 40 to 59 years (HR, 0.96 [95% CI, 0.95 to 0.96]) and a 3 percent reduction (HR, 0.97 [95% CI, 0.96 to 0.97]) at ages 60 to 69 years (**Table 9**).²³⁵ There was no statistically significant association between non-HDL cholesterol level and stroke mortality, although analyses were limited by fewer events for this outcome.²³⁵

Fasting Glucose

Our pooled analysis of interventions of all levels of intensity did not find a significant effect for diet or physical activity counseling interventions on fasting glucose; analyses restricted to high-intensity interventions found a small effect of -1.4 mg/dL. Our review excluded adults with diabetes as well as those with impaired fasting glucose, and the mean baseline value of fasting glucose was 97 mg/dL for persons included in our pooled analysis. Epidemiologic evidence does not suggest that lowering blood glucose level in persons with normal glucose levels imparts benefit. In an IPD meta-analysis of 284,686 individuals without CVD from 54 prospective studies, fasting glucose levels between 70 and 100 mg/dL were not associated with excess vascular or all-cause mortality risk in analyses adjusted for age, smoking, and BMI²³⁸; similar results were found for coronary heart disease and stroke outcomes inclusive of nonfatal events in a related IPD meta-analysis.²³⁹ At levels above 100 mg/dL, however, an increment of 2 mg/dL was associated with a 1 percent increase in fatal plus nonfatal coronary heart disease risk (HR, 1.01 [95% CI, 1.01 to 1.02]) (**Table 9**).²³⁹ At the same glucose concentration, this same 2 mg/dL increment increase had a similar effect on vascular death (HR, 1.01 [95% CI, 1.01 to 1.02]) and an increase of 1 percent for all-cause mortality (HR, 1.01 [95% CI, 1.01 to 1.01]).²³⁸ There is a well-established link between the presence of diabetes and the incidence of cardiovascular events

that roughly doubles the risk for both fatal and nonfatal coronary heart disease and stroke.²³⁹ This link highlights the importance of preventing progression to diabetes in persons at highest risk. Our separate review focused on persons with known CVD risk factors, including those with impaired fasting glucose or glucose tolerance, found that counseling interventions in high-risk populations substantially reduced the risk of progression to diabetes at 12 to 24 months (pooled RR, 0.58 [95% CI, 0.37 to 0.89]; k=8; $I^2=32\%$).⁶⁵

Adiposity

By design, the included trials in our review did not explicitly focus on weight loss. Nevertheless, small improvements in BMI, weight, and waist circumference were found to be associated with diet and physical activity interventions at 6 to 12 months of followup. The statistical heterogeneity for these pooled effects was considerable, however, and therefore some uncertainty in the average effects remains. The between-group differences found in our included trials suggested a reduction in BMI of approximately -0.41 kg/m^2 (95% CI, -0.62 to -0.10), a decrease in weight of approximately -1.0 kg (2.3 lb) (95% CI, -1.56 to -0.51), and a decrease in waist circumference of -1.19 cm (0.5 in) (95% CI, -1.79 to -0.59). These effects are slightly lower than those seen for our separate review focused on persons with increased CVD risk⁶⁵ and for our review on behavioral weight loss interventions.⁴² Within these reviews, a between-group difference in weight loss of approximately 3 kg was seen. The average BMI of participants within these two reviews was also slightly higher (29.8 and 31.9 kg/m^2 , respectively) than that of the current review (27.7 kg/m^2).

An IPD meta-analysis of 57 prospective studies with nearly 900,000 adults without CVD found that all-cause mortality was lowest in BMI ranges of 22.5 to 25 kg/m^2 ; above this level, increases of 1 kg/m^2 were associated with an 8 percent increase in the risk of ischemic heart disease death (HR, 1.08 [95% CI, 1.07 to 1.10]) and a 12 percent increase in the risk of fatal stroke (HR, 1.12 [95% CI, 1.09 to 1.15]) at ages 35 to 59 years, with progressively weaker associations at older ages (**Table 9**).¹⁹ These estimates were not adjusted for blood pressure level, lipid levels, or diabetes, as these are the mechanisms through which BMI affects vascular mortality.¹⁹ A 2016 analysis of a recent Danish cohort suggests that the association between BMI and mortality is changing over time, perhaps due to greater effects of improved treatment of cardiovascular risk factors among persons with a higher BMI. Data from a 2003–2013 Danish cohort found that the BMI value associated with the lowest all-cause mortality was 27.0 kg/m^2 and that associations between BMI higher than 30 kg/m^2 and all-cause mortality have decreased over time (2003–2013: HR, 0.99 [95% CI, 0.92 to 1.07]; 1991–1994: HR, 1.13 [95% CI, 1.04 to 1.22]; 1976–1978: HR, 1.31 [95% CI, 1.23 to 1.39]).²⁴⁰ Because of the strong associations between BMI and known cardiovascular risk factors, including blood pressure level, lipid levels, and diabetes,¹⁹ the clinical significance of changes in weight should also consider the accompanying changes in these outcomes.

Diet

Our review of the evidence found that healthful diet interventions were associated with reduced intake of total energy, fat, saturated fat, and sodium intake and increased intake of fiber and

fruits and vegetables compared with control arms. Between-group differences for dietary outcomes were in the magnitude of 65 kcal/day (favoring the control group) to -500 kcal/day (favoring the intervention group) in total energy intake, 0.8 to -11 percentage points in the percent of calories from fat, -0.3 to -4 percentage points in the percent of calories from saturated fat, and approximately -380 to nearly -1,400 mg/day of sodium. Effects on fruit and vegetable intake ranged from between-group differences of -0.2 servings/day (favoring the control group) to 2.2 servings/day (favoring the intervention group); between-group differences in grams of fiber per day ranged from 1 to 2.5 g in favor of the intervention group. Persistent effects of the interventions were seen over time for all dietary outcomes among studies that reported multiple time points. Observational data offer support that small changes such as these may be associated with important health benefits. A 2014 meta-analysis of prospective cohort studies by Wang et al,²⁴¹ for example, found that an additional serving of fruit and vegetables per day was associated with a 4 percent reduction in cardiovascular mortality (HR, 0.96 [95% CI, 0.92 to 0.99]; k=4) and a 5 percent reduction in all-cause mortality (HR, 0.95 [95% CI, 0.92 to 0.98]; k=7). Although we did not pool our estimates due to high heterogeneity (which was also present for some outcomes in the meta-analysis of Wang et al), increases in fruit and vegetable consumption from our review are likely consistent with this magnitude. Baseline servings of fruits and vegetables in our included studies that reported this outcome ranged from about 1.5 to more than 5.5 servings/day. Further, a 2015 analysis using two very large U.S.-based prospective cohort studies (the Nurses' Health Study and the Health Professionals Followup Study) found that an isocaloric replacement of 5 percent of total energy from saturated fat with energy from polyunsaturated fatty acids, monounsaturated fatty acids, or whole grain-based carbohydrates was associated with statistically significant reductions in risk for coronary heart disease of 25, 15, and 9 percent, respectively (HR, 0.75 [95% CI, 0.67 to 0.84]; HR, 0.85 [95% CI, 0.74 to 0.97]; and HR, 0.91 [95% CI, 0.85 to 0.98], respectively).²⁴² Mean between-group decreases in percent energy from saturated fat in our included studies were consistently less than 5 percent but greater than 3 percent in four trials,^{97, 106, 194, 209} and statistically significantly reduced in all but one trial.¹⁷⁶ Our results related to decreases in total fat intake should be interpreted in light of increasing evidence (including from the large WHI Dietary Modification Trial included in this review²⁰⁹) that low-fat dietary patterns may not assist with weight loss or be protective for CVD and several types of cancer.^{138, 139, 243, 244} Recent guidance² has moved away from advocating low fat intake in general to an emphasis on the type of fat (e.g., increasing monounsaturated and polyunsaturated fats).

Finally, a 2015 model based on data from NHANES and the same two very large prospective cohort studies estimated that modest improvements in the quality of the U.S. diet from 1999 to 2012 were associated with a sizeable reduction in disease burden and prevented as many as 1.1 million premature deaths and 8.6 percent fewer cases of CVD.²⁴⁵ These diet improvements were measured by the Alternate Healthy Eating Index, which increased from 39.9 to 48.2 (perfect score=110) during this time period. The improvements were driven largely by reduced consumption of trans fat (which has been a target of government regulation) but also by modest improvements in the intake of fruit, whole grains, nuts and legumes, polyunsaturated fats, sugar-sweetened beverages and juices, and red and processed meat. Despite these temporal improvements in diet quality, however, the U.S. diet remains poor, and socioeconomic disparities in diet quality persist.

Physical Activity

The bulk of the included literature (63 of 88 studies) and, in particular, the newly added trials (28 of 38 studies), evaluated the effects of counseling interventions on physical activity behaviors. Very few of these studies (k=17) reported the effects of the interventions on intermediate cardiometabolic outcomes or health outcomes; those that did were generally limited to measures of adiposity and quality of life. Instead, the primary outcome within most of these trials was self-reported physical activity. Our pooled analyses of these trials indicated a fairly large increase in physical activity participation, although there was some imprecision in the magnitude of effects across studies. Physical activity interventions, with or without components focused on dietary improvements, resulted in an increase of approximately 35 minutes of physical activity per week compared with control conditions. Studies among persons with low levels of baseline physical activity resulted in greater increases in physical activity compared with persons at levels above recommendations. Additionally, intervention participants had a 32-percent higher odds of meeting physical activity recommendations (150 minutes of moderate-intensity or 75 minutes of vigorous-intensity physical activity per week) compared with controls. The baseline level of physical activity in trials in our meta-analyses varied from 12 to 519 minutes/week among control groups (mean, 124 minutes/week). The dose-response pattern shown in observational evidence suggests that as long as changes persist and regardless of baseline physical activity level, our findings of an increase of about 35 minutes/week from behavioral counseling interventions could translate into additional benefit for cardiovascular and all-cause mortality.

Observational data consistently show that physical activity reduces the risk of cardiovascular and all-cause mortality in a dose-response fashion and that substantial benefits accrue even when physical activity is performed in amounts less than the nationally recommended 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity activity per week (approximately 500 to 1,000 MET-minutes/week).²⁴⁶ Activity less than the recommended minimum (<450 MET-minutes/week) is associated with a 20 percent reduction in cardiovascular death (HR, 0.80 [95% CI, 0.77 to 0.84]) and a similar reduction in all-cause mortality (HR, 0.80 [95% CI, 0.78 to 0.82]) compared with no activity (adjusted for clinical and demographic characteristics, including BMI).²⁴⁷ Levels at national recommendations (approximately 500 to 1,000 MET-minutes/week) are associated with further reductions in cardiovascular and all-cause mortality risk of 33 and 31 percent, respectively (HR, 0.67 [95% CI, 0.65 to 0.70] and HR, 0.69 [95% CI, 0.67 to 0.70], respectively). Further, the benefit of physical activity appears broadly generalizable, with reasonably consistent point estimates across subpopulations defined by age, sex, race/ethnicity, BMI, smoking, and history of heart disease. These findings are supported by a large Taiwanese prospective cohort study of more than 400,000 individuals which also found that even low levels of activity below recommendations, characterized by about 90 minutes/week or 15 minutes/day, were associated with a 19 percent reduction in the risk of cardiovascular mortality (HR, 0.81 [95% CI, 0.71 to 0.93]) and 14 percent reduction in the risk of all-cause mortality (HR, 0.86 [95% CI, 0.81 to 0.91]), with additional benefit accruing at progressively higher levels of activity.²⁴⁸ Furthermore, this analysis found that additional increments of 15 minutes/day (beyond a minimum of 15 minutes/day) were associated with an all-cause mortality risk reduction of 4 percent (95% CI, 2.5 to 7.0).²⁴⁸

Large cross-sectional analyses show that physical activity is associated with better overall quality

of life and perceived health status, independent of BMI.^{249, 250} Results of longitudinal analyses are mixed, with some showing that increases in physical activity over 3 to 4 years of followup are associated with improvements in a range of quality-of-life domains with either substantial²⁵¹ or limited clinical impact;²⁵² other studies show that cross-sectional associations are not confirmed by longitudinal analyses.²⁵³ These mixed results are echoed by our results from intervention studies of 6 to 12 months' duration.

Harms

Very few of the included trials reported on adverse effects of interventions, and only two trials found more harms among intervention versus control participants. These harms were categorized as “mild” or “moderate” within the trials and included falls and injuries related to increased physical activity; the mean age of the participants in these trials was 59 years¹⁶⁰ and 71 years,⁹⁴ respectively. We did not, however, hypothesize any serious harm from diet and physical activity counseling. Observational data suggest that the rate of adverse cardiovascular events in generally healthy adults is extremely low during and immediately after physical activity of varying types and levels of intensity and is significantly lower among those with a history of being active.²⁵⁴ Increasing age and physical activity intensity are related to greater risk of adverse cardiovascular events. Risk of musculoskeletal injury varies substantially across different activities; activities with limited or no contact (e.g., baseball, walking, running, biking) carry the lowest risk of injury. Consensus exists that the benefits of regular physical activity outweigh the inherent risk of adverse events.²⁴⁶ The possible harms of dietary counseling have not been well defined or measured. There is potential that focusing counseling on, for example, reducing total fat intake but not reducing caloric intake, might lead to an increased intake of carbohydrates (in the form of reduced-fat or low-fat food products), which could result in weight gain and decrements in other cardiometabolic indicators. Likewise, unsupervised behavior changes to extreme levels (e.g., very-low-fat or low-calorie “diets”) could cause nutrient inadequacy or other adverse effects.

Considerations for Applicability of Findings

By design, the current review included unselected adults or those generally at low risk for CVD. Otherwise, the persons represented in the trials exhibited a broad range of sociodemographic and behavioral characteristics. A number of studies were limited to specific subpopulations for which particular CVD risk factors and dietary and activity habits may differ from their counterparts, including women (in particular, the large WHI trial [n=48,835]), older adults, racial/ethnic minority groups, persons with high-normal blood pressure, persons with a family history of CVD or diabetes, and persons who are overweight or have obesity. Likewise, nearly half of the studies limited enrollment to persons with suboptimal levels of physical activity, inadequate dietary habits, or both. The remaining studies were conducted among unselected adults with varying sociodemographic and clinical characteristics. Across all of the studies, baseline dietary and physical activity behaviors were highly variable. For instance, minutes of physical activity per week ranged from 2 to more than 600. Likewise, baseline daily servings of fruits and vegetables ranged from 1.5 to 5.5.

Although the majority of studies recruited participants directly (via invitations through primary

care, the broader health care system, or some other convenience sample rather than relying on community volunteers), the adults who took part in these studies are likely to have been more motivated to change their behaviors than those not represented in these trials. Indeed, we saw generally high rates of retention (>85% at 12 months) over the course of the studies and good adherence to the interventions—rates which may not be seen in real-world scenarios. Regardless, given the broad representation across population characteristics and the fact that most of the studies took place in the United States, we believe the findings of this review are generalizable to a U.S. primary care population, although the magnitude of the effects may be slightly lower when applied to general practice.

There was some evidence, at least for intermediate outcomes, that increasing intervention intensity was related to greater benefit. It is difficult to disentangle differences in the various intervention, population, and broader study characteristics, however, when attempting to explain the effectiveness of the interventions on these outcomes. Most of the studies that reported intermediate outcomes were of medium- or high-intensity interventions that often were conducted among persons with slightly higher risk for CVD. Additionally, most of these interventions focused messages on dietary changes and may or may not have included messages about increasing physical activity. Even within the high-intensity interventions, the estimated intervention contact (minutes of counseling) ranged considerably—from 420 minutes (7 hours) to 2,340 minutes (39 hours) over the course of 4 weeks to 6 years. Furthermore, most of these high-intensity interventions took place outside of the primary care setting and may represent persons with higher motivation to change their behaviors. Similarly, the effects seen for dietary outcomes were mostly for medium- or high-intensity interventions, whereas the effects for physical activity outcomes included trials testing mostly low- and medium-intensity interventions. There was no evidence of a dose-response relationship with intervention intensity, but there was evidence that trials targeting persons with baseline activity below recommended levels saw larger improvements in physical activity participation than trials in which participants were already achieving higher levels of physical activity. These latter studies, however, emphasized both dietary changes and, to a lesser extent, changes in physical activity.

Based on the included literature, we are not able to define either the minimum necessary intervention components for an effective intervention or identify a representative intervention. No two studies had exactly the same goals, modes of delivery, or delivery schedule, although some explicitly built off of learnings from earlier trials (for example, the STRIDE,¹⁶⁷ COSTRIDE,⁹⁸ and VA-STRIDE¹¹⁷ trials). Using qualitative analyses and meta-regression, we did not find that the intervention focus (healthful diet alone, physical activity alone, or healthful diet plus physical activity), format (group vs. individual, phone, print), number of sessions, person delivering the intervention, or duration of the intervention significantly affected the direction or magnitude of the benefit. Though we broadly focused on studies related to the primary prevention of CVD among healthy adults, the specific aims of each trial differed (e.g., prevention of hypertension, weight gain prevention, increasing physical activity) and appropriately resulted in different intervention goals and components. For instance, the trials targeting persons with high-normal blood pressure focused the interventions on reducing dietary sodium, whereas the trials aimed at increasing physical activity among persons with very low levels of physical activity included highly tailored written and verbal messages and tools for self-monitoring physical activity. Across all of the interventions, most included tailored advice and

materials and encouraged goal setting and self-monitoring. Therefore, the ideal counseling intervention for any given person will depend on consideration of their specific clinical characteristics, including existing diet and physical activity behaviors, and the larger context of other prevention or screening priorities, given the limited time for a typical primary care encounter.

Limitations of Our Approach

There are limitations of this review that arise from scoping and analytic decisions that should be acknowledged. First, this updated review represents only a subset of the literature focused on dietary and physical activity counseling. To be consistent with the scope and mission of the USPSTF and to avoid duplication of literature addressed in other reviews for the USPSTF, we excluded some related bodies of evidence, including studies focused on persons with known disease (e.g., coronary heart disease, diabetes, impaired fasting glucose, hypertension, dyslipidemia), trials focused on weight loss or weight management, and trials focused on dietary or physical activity counseling to prevent or manage other health risks and conditions (e.g., falls, cognitive impairment, cancer) or for general health promotion. In addition, a wide variety of interventions are available for primary prevention of CVD; we excluded trials evaluating other (not dietary or physical activity counseling) interventions, such as stress management interventions (e.g., yoga, tai chi, low-dose aspirin, statins, and tobacco cessation). Many of these topics are the focus of other USPSTF reviews and recommendations.^{41, 43, 45, 64, 255}

Although we focused this review specifically on adults “without known CVD risk factors,” precisely defining a level of CVD risk is difficult given the multifactorial and continuous nature of cardiometabolic indicators, some of which (e.g., LDL cholesterol) have no threshold for which lower levels are not associated with lower risk.^{234, 235} Moreover, exceptionally few studies performed cardiovascular risk assessment using a multivariate tool. We excluded studies that explicitly enrolled participants on the basis of known hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors. Additionally, we examined the baseline characteristics of each sample and excluded studies for which the sample mean for one or more risk factors was “high” (i.e., mean SBP >140 mm Hg or DBP >90 mm Hg, total cholesterol >240 mg/dL, LDL cholesterol >160 mg/dL, impaired fasting glucose >110 mg/dL). We did, however, include studies among adults who may otherwise be at increased risk for CVD due to being overweight or having obesity, family history, having high-normal blood pressure, or suboptimal dietary or physical activity behavior at baseline. Despite these operational criteria, there was still some subjectivity in determining risk and deciding which review (or reviews) each trial best fit (i.e., the current review, which focused on adults not at high risk, and/or our separate review, which focused on high-risk adults). Two trials are included in this current update as well as our review among high-risk adults.⁶⁵ Most of the studies included in this review represented an unselected population or persons selected on the basis of suboptimal behaviors, but did not report baseline values of blood pressure, lipid levels, glucose levels, current smoking, or adiposity.

Our review was limited to interventions that were conducted in primary care or those that we felt may be feasible for primary care. Only 23 of the 88 trials, however, actually took place in a

primary care setting or involved primary care staff in the delivery of the intervention. An additional 21 studies recruited participants through mailings or phone calls from their primary care office or health insurance provider, but the interventions themselves were delivered in a research setting, at home, or elsewhere and did not include primary care staff. The remaining 44 studies had no connection to the primary care setting; however, we judged them to be potentially feasible for implementation in a primary care setting given the nature of the intervention components (e.g., print material, telephone counseling, computer based) or interventionists (e.g., health educators, trained staff). Many of these latter studies recruited participants through community venues, including mass advertising or through existing convenience lists (e.g., existing research cohorts), and therefore may represent populations with higher levels of motivation to change their behaviors or participate in research. Defining what interventions are “feasible for” or “referable from” primary care is an ongoing challenge as it applies to USPSTF-related behavioral counseling interventions.²⁵⁶⁻²⁵⁹ In addition, because our focus was on primary care–conducted or referable interventions, our review excluded interventions delivered through worksites, churches, and other community organizations as well as interventions that focused on environmental and policy changes that may not be easily replicated or implemented solely through primary care. For these interventions, we refer to the Community Preventive Services Task Force²⁶⁰ and the National Cancer Institute’s Research-Tested Intervention Programs.²⁶¹ Additionally, our review focused on *counseling* to improve dietary habits and did not review the evidence on the relationship between particular dietary patterns (e.g., Mediterranean-style, DASH-style, vegetarian) and health outcomes. The Scientific Report of the 2015 Dietary Guidelines Advisory Committee provides a thorough review of this evidence.³ Likewise, our review excluded observational studies that have shown that including physical activity as a vital sign within health systems’ electronic medical records increases the documentation of exercise behaviors and referrals for lifestyle-related counseling (e.g., Grant et al²⁶²).

We also excluded studies without a true control and thus did not address the comparative effectiveness of different types of behavioral interventions. Our requirement was that the control group receive counseling that was no longer than 15 minutes, which we deemed to be equivalent to usual care for persons at low risk for CVD. This criterion led to the exclusion of a number of high-profile trials that otherwise would have been included in this review, such as PREMIER²⁶³ and the Activity Counseling Trial.²⁶⁴ In the PREMIER trial, adults (n=810) with untreated high-normal blood pressure or stage I hypertension (SBP, 120 to 159 mm Hg; DBP, 80 to 90 mm Hg) were randomized to an advice-only group (print materials plus a 30-minute counseling session), a group focused on established recommendations for blood pressure control (i.e., sodium reduction, weight loss, and increased physical activity), or an established plus DASH group that combined the established recommendations with the DASH diet. Among all participants, compared with the advice-only arm, mean SBP was 3.7 and 4.3 mm Hg lower in the established and established plus DASH groups, respectively (p<0.001). Likewise, at both 6 and 18 months, a greater reduction in the median 10-year CVD risk was seen among the established and established plus DASH groups compared with the advice-only arm; this finding was true among the subset of participants with high-normal blood pressure as well as the subset of participants with stage 1 hypertension.²⁶⁵ The multisite Activity Counseling Trial (n=874) compared the effects of three physical activity counseling interventions within the primary care setting: 1) advice that included brief physician advice, written educational materials, and referral to a health educator; 2) advice plus counseling with the health educator and followup telephone calls,

tailored mailings, and self-monitoring; or 3) advice, counseling, plus more intense telephone counseling and group sessions over the course of the 2-year intervention. All three groups emphasized increasing physical activity to 30 minutes of moderate-intensity physical activity for 5 or more days per week or 30 minutes of vigorous-intensity physical activity for 3 or more days per week. At 2 years, no differences in self-reported physical activity were found between groups, among both men and women. Among women, however, cardiorespiratory fitness was statistically significantly higher in both the advice plus counseling and counseling plus arms compared with the advice-only arm.²⁶⁴

With complex interventions such as these, describing and synthesizing intervention characteristics is difficult. The included interventions varied considerably in terms of the nature of the advice, mode of delivery, and delivery schedule. We diligently abstracted as much detail as possible about each intervention, used an established taxonomy for describing the behavior change techniques used in the interventions,⁷⁰ and carefully summarized this detail in tabular and narrative format. We used consistent rules for estimating the total minutes of contact (i.e., intensity) across studies and used our established^{40, 65} cutpoints to categorize each intervention arm as low intensity (≤ 30 minutes), medium intensity (31 to 360 minutes), or high intensity (> 360 minutes). Despite this consistency, the rules are still somewhat arbitrary, and many medium-intensity interventions were quite intensive in terms of participant contact (e.g., nearly 5 hours of participation). Furthermore, in many cases, detailed reporting of the number and length of sessions was lacking, so we had to make several assumptions. Our analysis of the effect of intensity (both as a continuous variable and when comparing high- vs. medium- and low-intensity interventions) provided some evidence that higher intensity interventions are associated with larger improvements in intermediate outcomes, although there were very few low-intensity (≤ 30 minutes) interventions that reported intermediate outcomes. There was no evidence of a specific threshold of intensity (i.e., a certain number of sessions, number of minutes, or duration) that resulted in greater benefit. There is clearly a need to continue evaluating the effect of lower intensity interventions that take place in or involve primary care staff on intermediate health outcomes in addition to behavioral outcomes. Additionally, we did not collect or evaluate any data on costs or cost-effectiveness of the interventions given resource limitations, although such information could be useful for decisionmakers.

Finally, we purposefully pooled across a body of literature that was heterogeneous with respect to clinical and demographic characteristics, interventions, and settings. For most outcomes, the statistical heterogeneity was unimportant ($I^2 < 40\%$) or moderate ($I^2 = 30\%$ to 60%) and therefore still reasonable to allow for interpreting of pooled estimates. However, given the clinical heterogeneity, looking at the confidence intervals for each point estimate helps us to understand the true magnitude of effects on the individual outcomes. There was considerable heterogeneity ($I^2 > 90\%$) in the meta-analyses of adiposity and dietary outcomes, which is consistent with both the clinical variability of included populations and the variability in interventions among the included studies as well as the continuous nature of the data. Nevertheless, the high statistical heterogeneity may indicate that the pooled average effect of the interventions should be interpreted with caution. In light of the considerable heterogeneity and relatively few studies within each analysis, we chose not to present the pooled effects for any of the dietary outcomes.

Other potential sources of risk of bias in our review include limiting the search to English-only

publications and published trials.

Limitations of the Studies and Future Research Needs

A number of limitations related to the included studies should be noted. Most of the included evidence recruited participants more than a decade ago, many did not report measures of intermediate cardiometabolic outcomes, and even fewer reported longer term health outcomes. As the prevalence and rate of these health outcomes are lower in lower risk groups (by definition), these studies require larger sample sizes and longer followup to observe an effect of an intervention in a low-risk group of participants.²⁵⁷ As such, enhanced methods for using observational data to understand the effect of small differences in intermediate outcomes from these interventions on long-term health outcomes are needed; some methods are used herein. Additionally, patient-centered outcomes, namely HrQOL measures, were also rarely reported in this literature base; future research should consistently measure and report quality of life and other related patient-centered outcomes. Additional studies should also determine if less intensive interventions are as effective as higher intensity interventions for these intermediate and health outcomes.

It is clear that healthful diet and physical activity behaviors both contribute to good cardiovascular and overall health. Additional research on the additive or differential benefit of different counseling foci (i.e., diet, physical activity, or both) in different populations would be helpful in determining whether clinical scenarios focusing on diet alone or physical activity alone is advisable (or preferable) to combined counseling. Likewise, there is a need for more data from well-designed pragmatic trials and better reporting of intervention characteristics to facilitate evaluation and dissemination of evidence-based practices. As outlined by Krist et al,²⁵⁸ research on behavioral counseling interventions such as the type synthesized here would benefit from application of checklists and frameworks such as the Template for Intervention Description and Replication (TIDierR); Research, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM); and the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) to assess the feasibility and applicability of interventions as well as to improve replication and dissemination. Our review found no evidence of a difference in effects by the focus of the message, but analyses were highly confounded by the intensity of interventions (i.e., healthful diet interventions were mainly medium or high intensity, whereas physical activity interventions were mainly low or medium intensity). Also, only one of the included studies targeted reductions in sedentary behavior (i.e., sitting time) as the main focus of the trial and only three trials reported the outcomes of sedentary behavior. More research on the effects of counseling to reduce sedentary behavior on behavioral and intermediate health outcomes is warranted. Very few studies explored whether effectiveness of the intervention varied among important subpopulations (including the prespecification of such analyses). Such analyses could assist in identifying groups of adults who might benefit more from such interventions.

Additionally, most of the trials relied on self-reported dietary and physical activity measures with variable levels of evidence of the reliability and validity of the measures. Dietary intake was generally measured by food frequency questionnaires (such as the full-length or shorter versions of the Block Food Frequency Questionnaire^{266, 267}), entries in food diaries, or 24-hour food

recalls. The tools and summary variables used to measure physical activity were even more inconsistent. Physical activity was summarized in terms of total physical activity, leisure-specific physical activity, moderate- and/or vigorous-intensity physical activity, walking behaviors, and multiple other indicators; in addition, the results were expressed in different units across studies (e.g., minutes/week, MET-minutes/week, steps/day, summary “scores”). Each of these methods can be prone to bias.²⁶⁸ While researchers must fit the specific measurement instruments and summary variables to the needs of their particular study aims, research protocols, and sample characteristics, it is clear we could benefit from more standardization of behavioral outcome measurement.²⁵⁷ Only three trials measured urinary sodium excretion, and six trials used accelerometers or pedometers to objectively measure physical activity.

We identified 14 trials, including seven conducted in the United States, currently under way that may contribute to this evidence base (**Appendix G**).

Conclusions

The beneficial effects of healthful diet and physical activity interventions on physiologic and behavioral outcomes that we observed in our updated systematic review are generally consistent in direction and magnitude with our 2010 review on this topic. Healthful diet and physical activity behavioral interventions for persons not at risk for CVD resulted in small but statistically significant benefits across a variety of important intermediate health outcomes, including blood pressure, LDL and total cholesterol levels, and adiposity, with evidence of a dose-response effect with higher intensity interventions resulting in greater improvements. Small and moderate changes in self-reported dietary and physical activity behaviors were also evident. Very limited evidence exists regarding the health outcomes or harmful effects of these interventions. However, the improvements we saw in intermediate and behavioral health outcomes could translate into long-term reduction in CVD-related events. Future research on behavioral counseling in this population should focus on the effectiveness of lower intensity, primary care–conducted interventions and consistently include measures of intermediate cardiometabolic health outcomes and patient-centered outcomes such as HrQOL.

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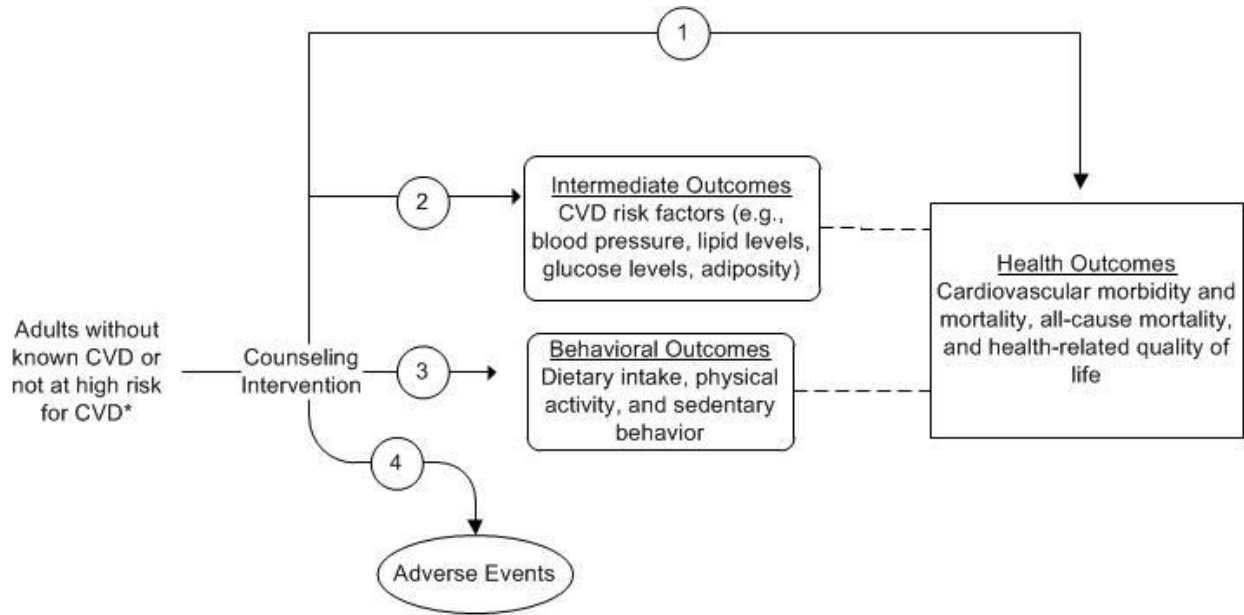
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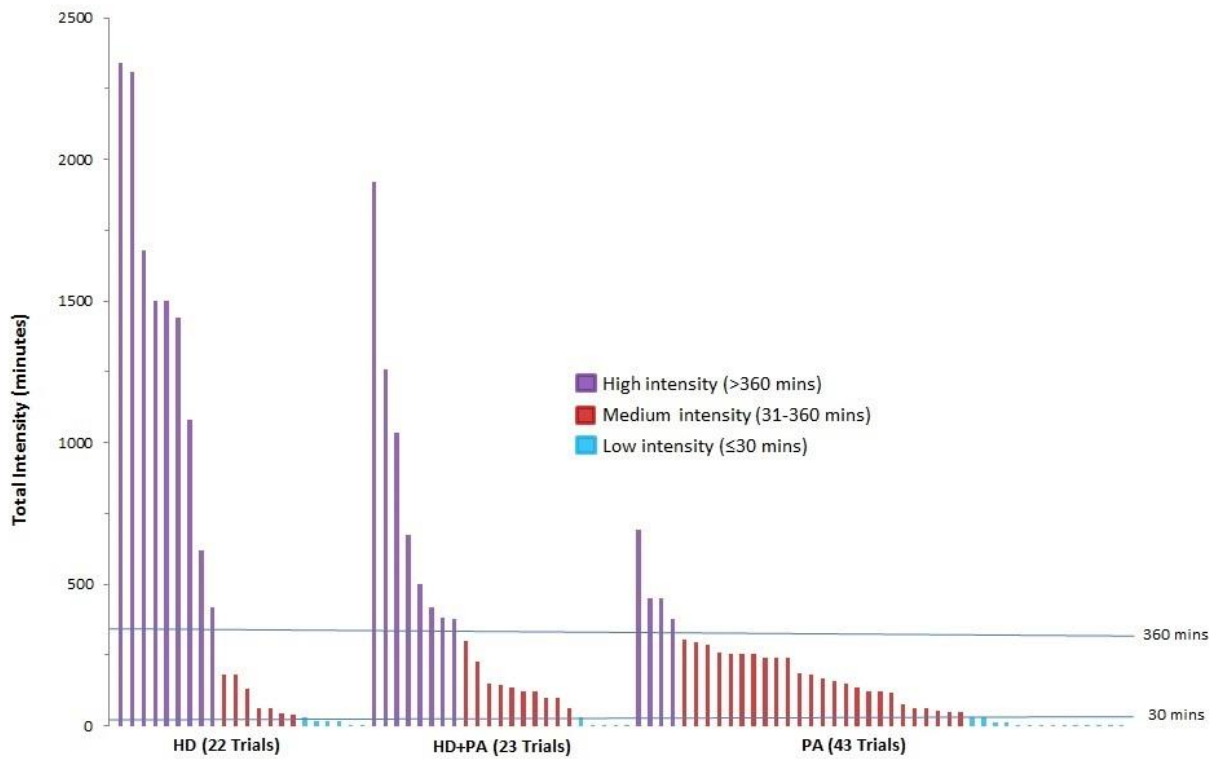
Figure 1. Analytic Framework



* High risk of CVD includes adults with hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors.

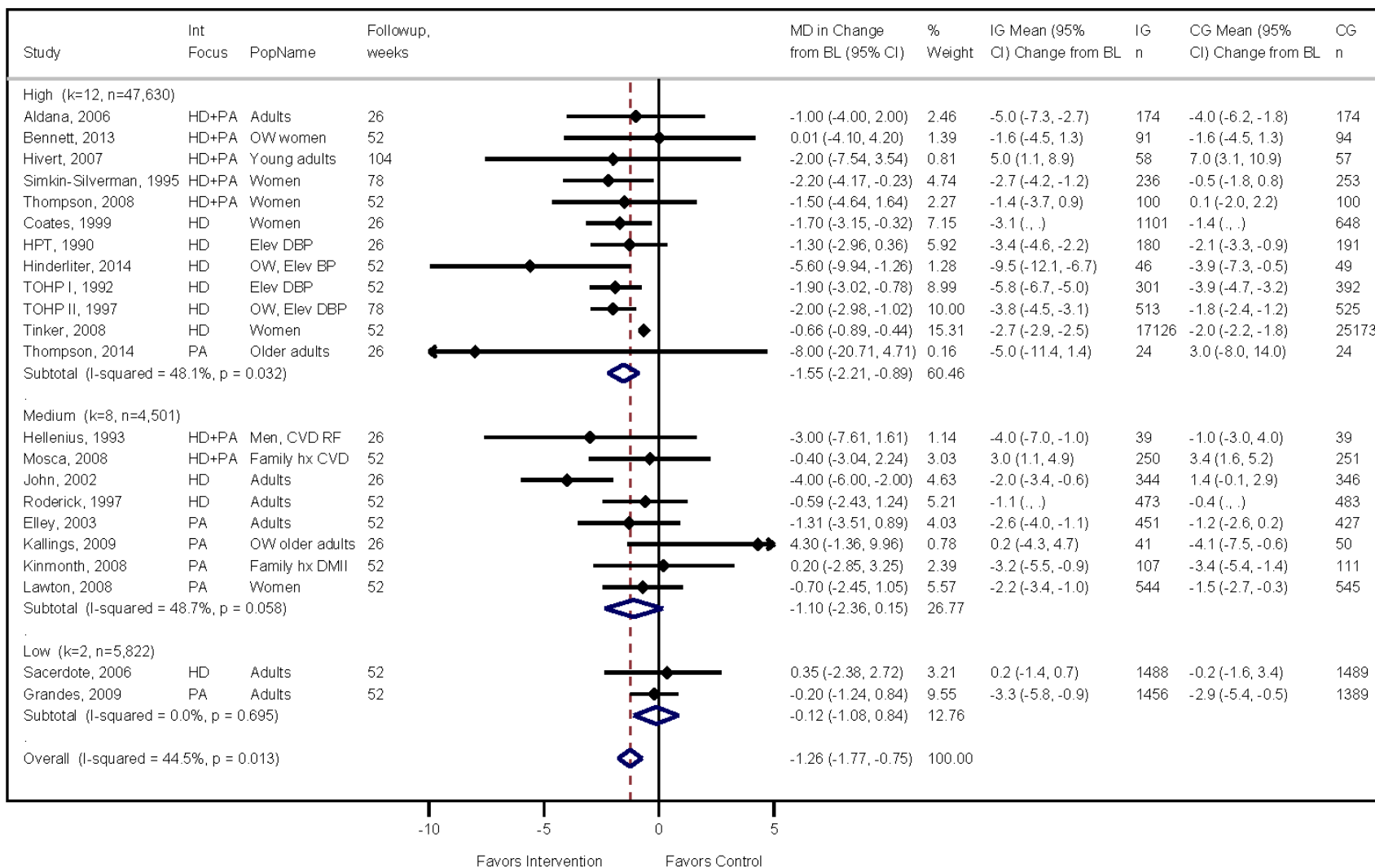
Abbreviation: CVD=cardiovascular disease.

Figure 2. Estimated Intervention Intensity for Each Included Trial, by Intervention Focus



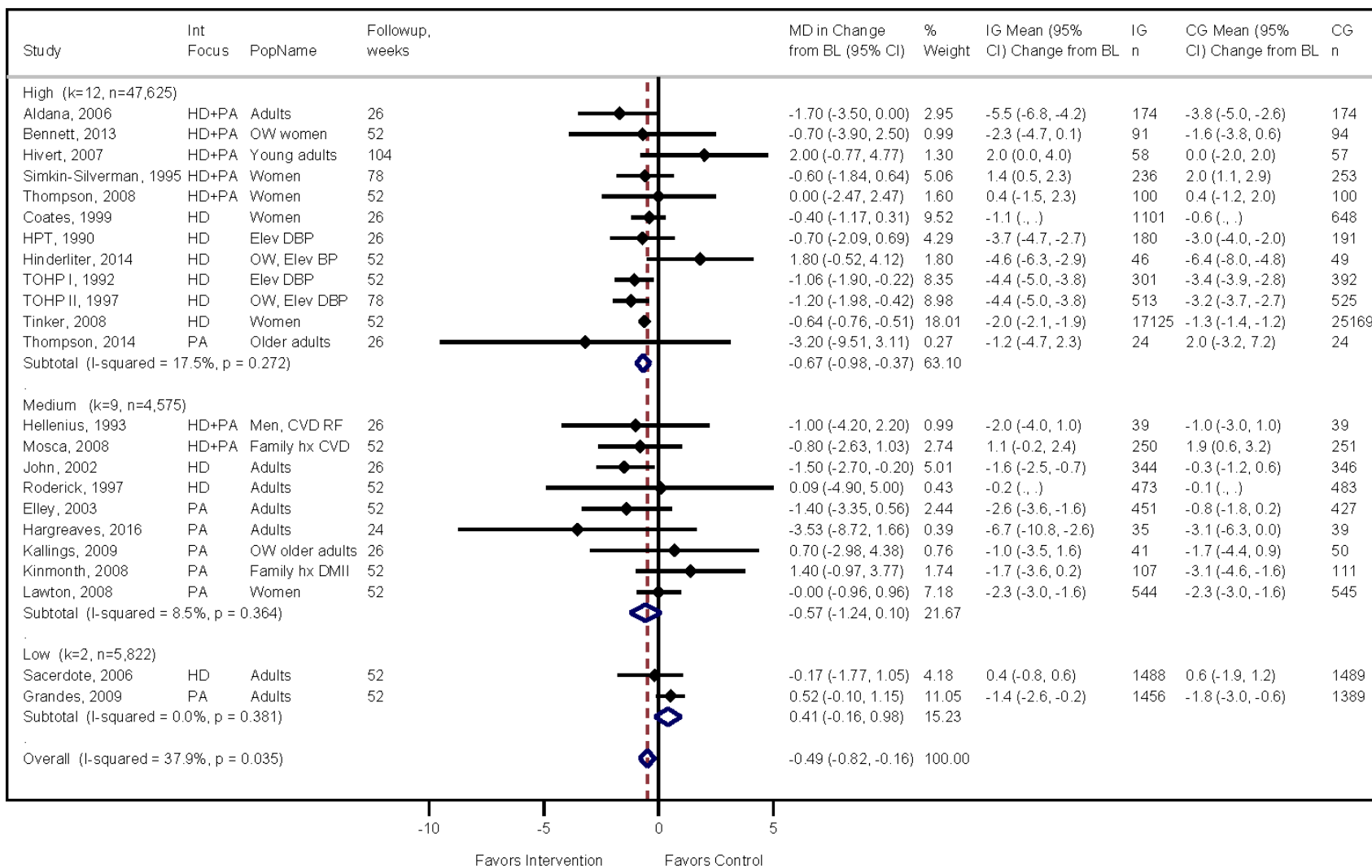
Abbreviations: HD=healthful diet; HD+PA=healthful diet and physical activity; PA=physical activity.

Figure 3. Pooled Analysis of Change in Systolic Blood Pressure in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



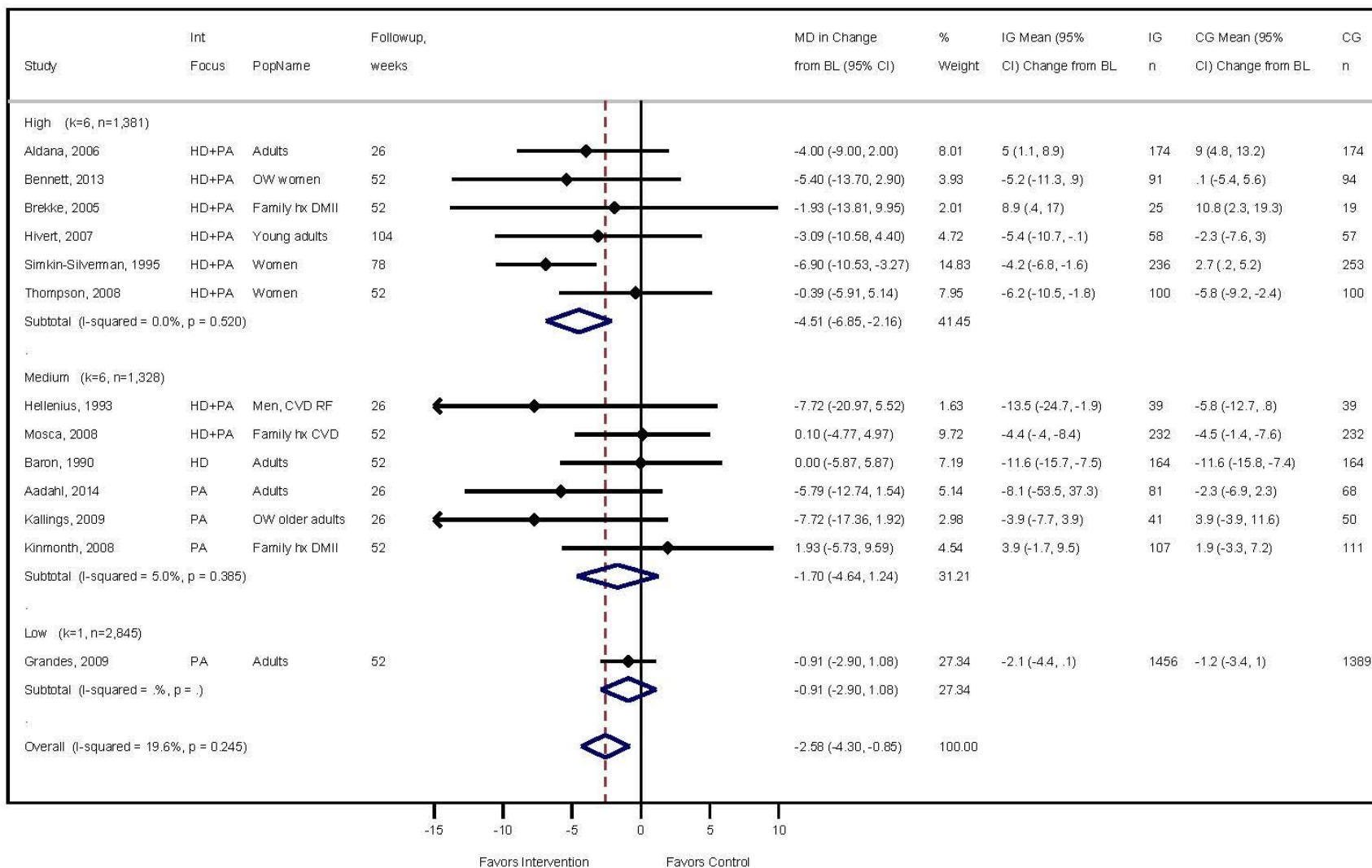
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 4. Pooled Analysis of Change in Diastolic Blood Pressure in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



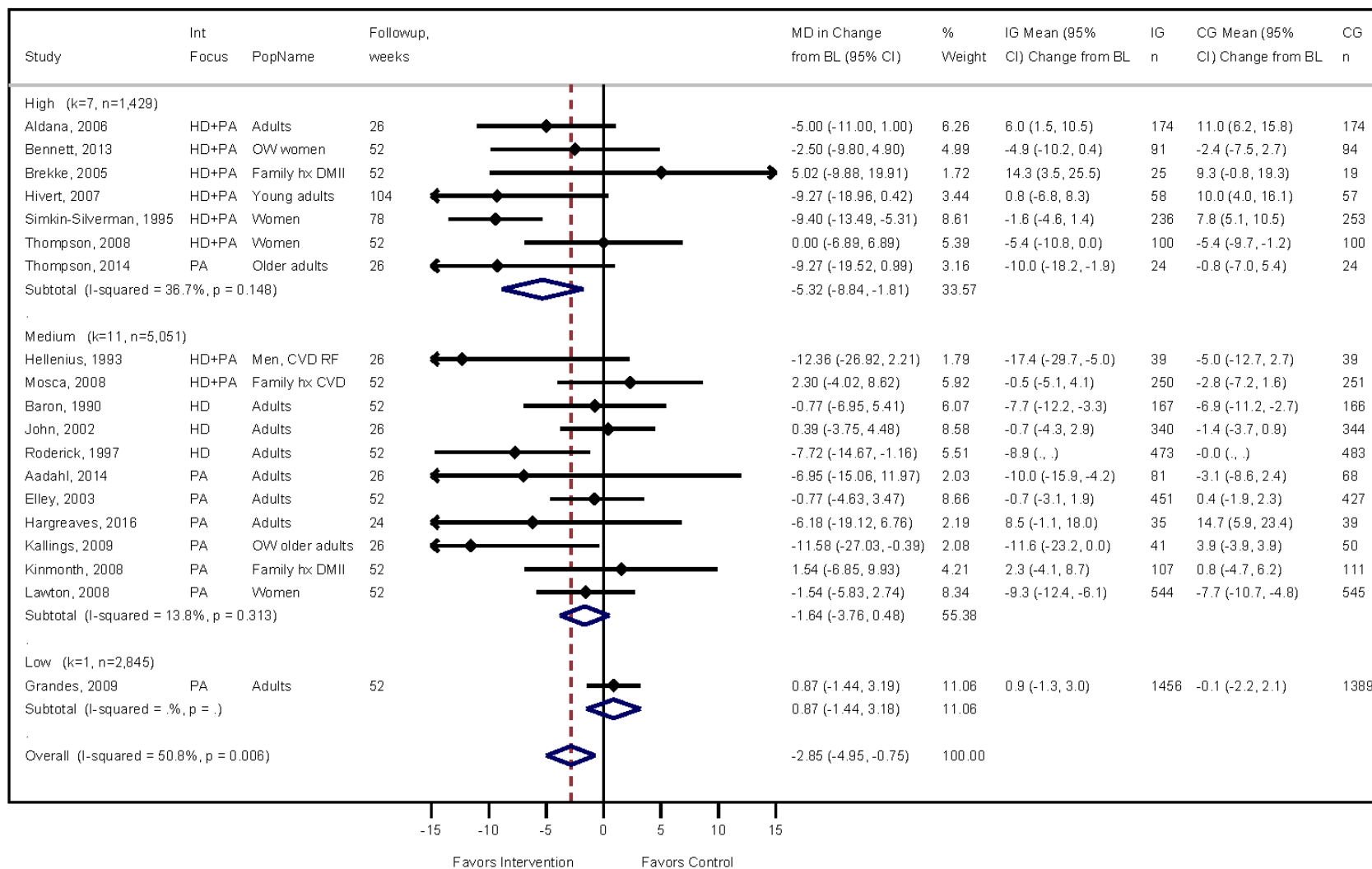
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 5. Pooled Analysis of Change in Low-Density Lipoprotein Cholesterol in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



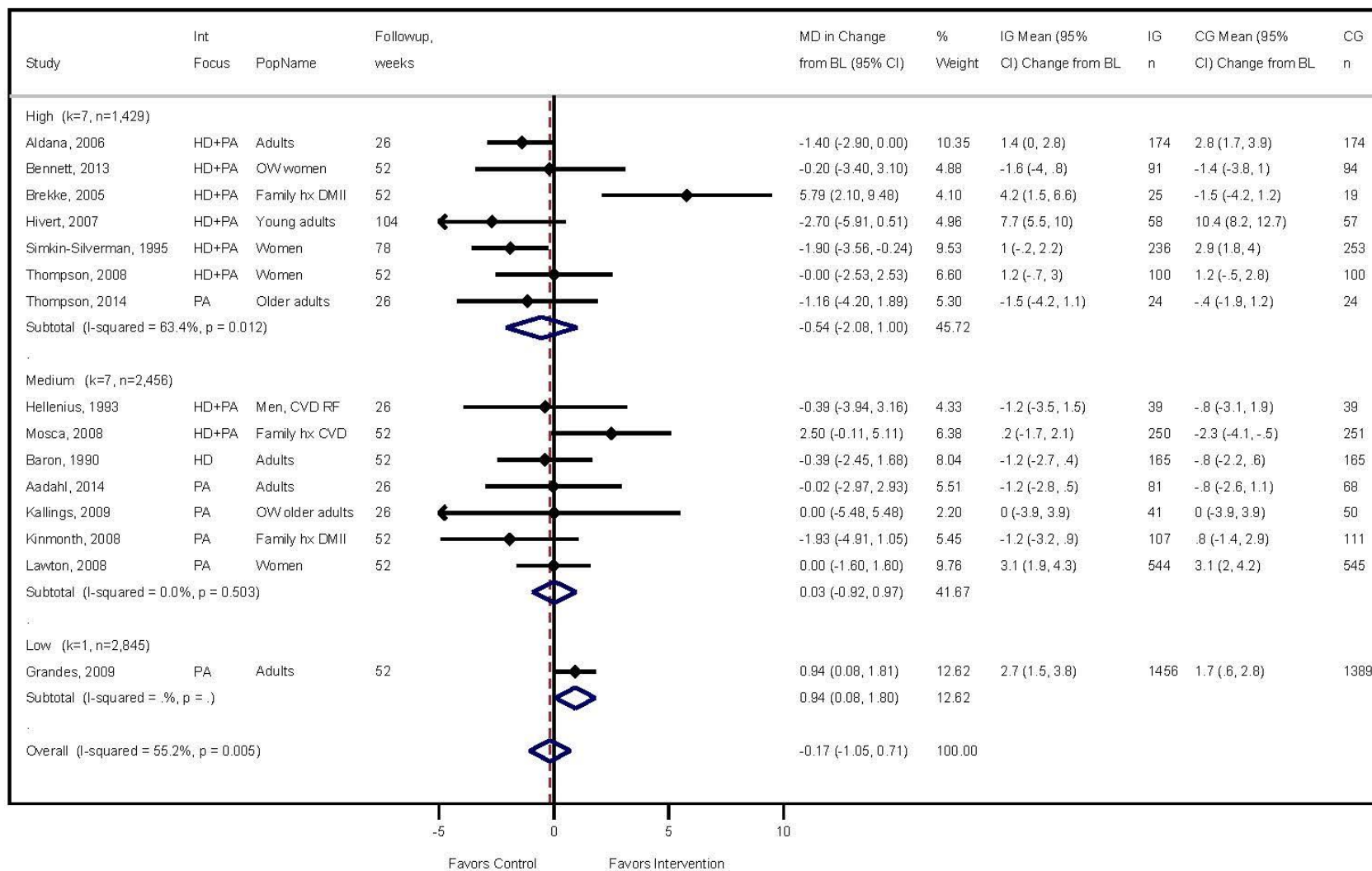
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 6. Pooled Analysis of Change in Total Cholesterol in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



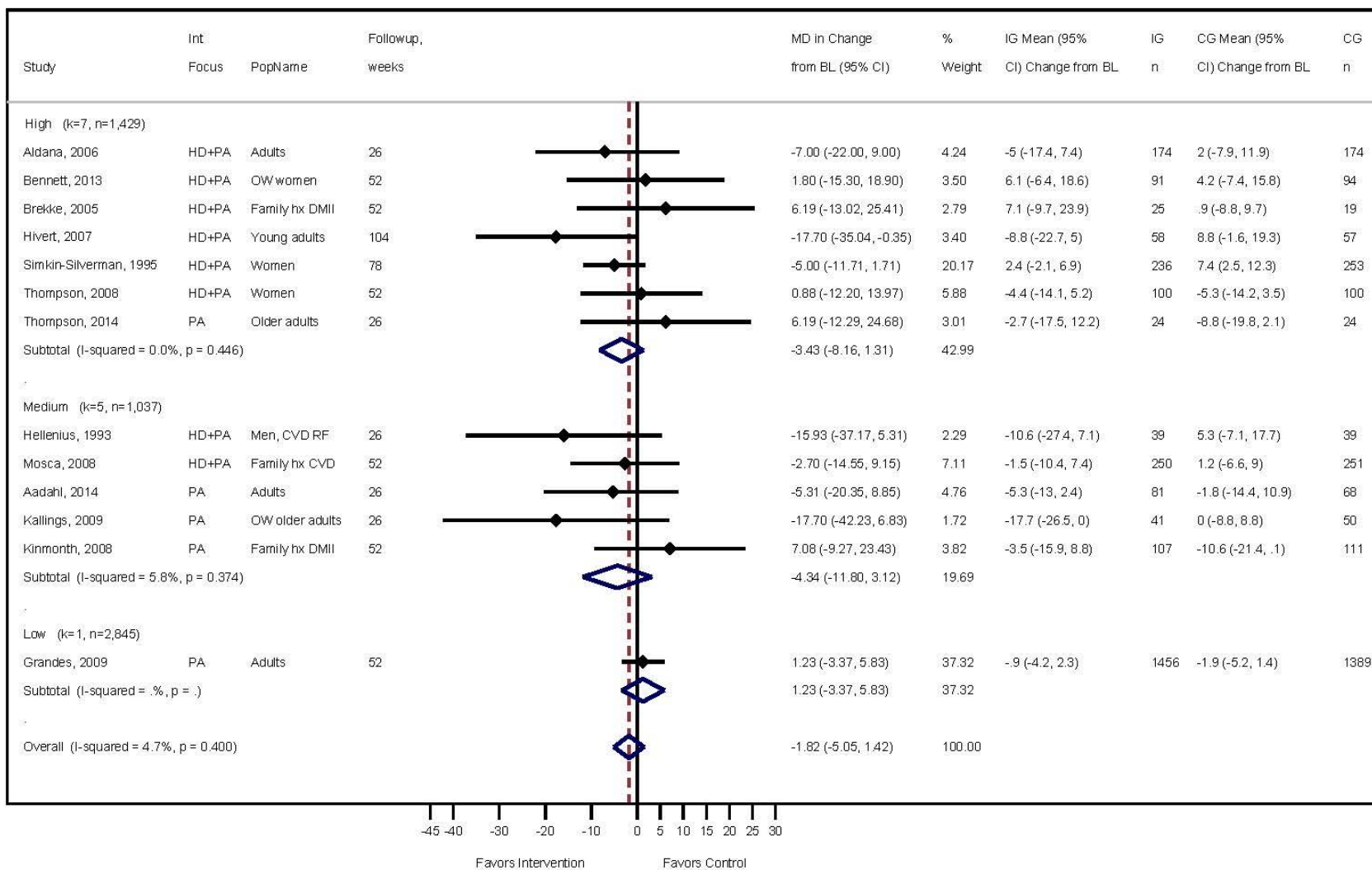
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 7. Pooled Analysis of Change in High-Density Lipoprotein Cholesterol in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



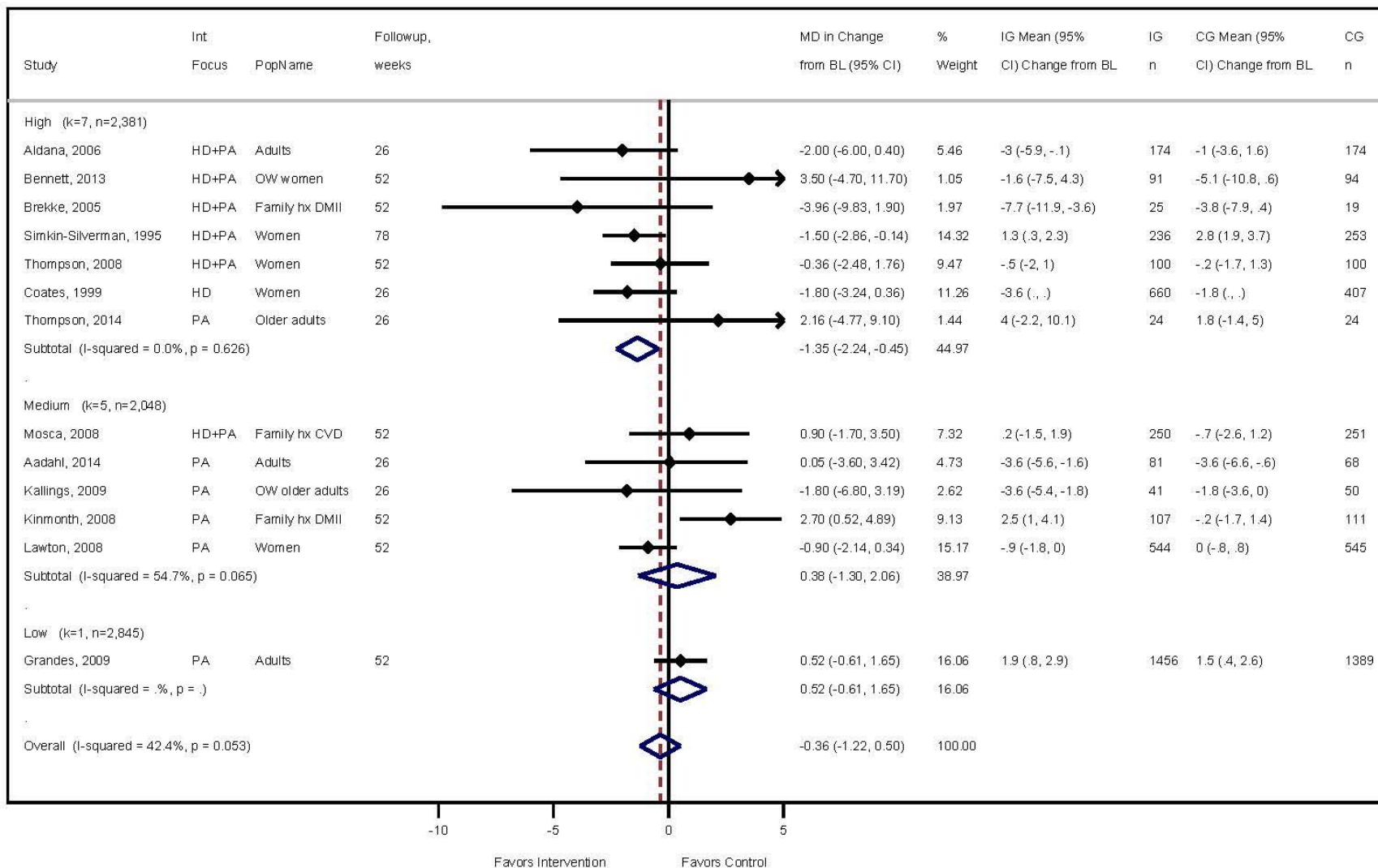
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 8. Pooled Analysis of Change in Triglycerides in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



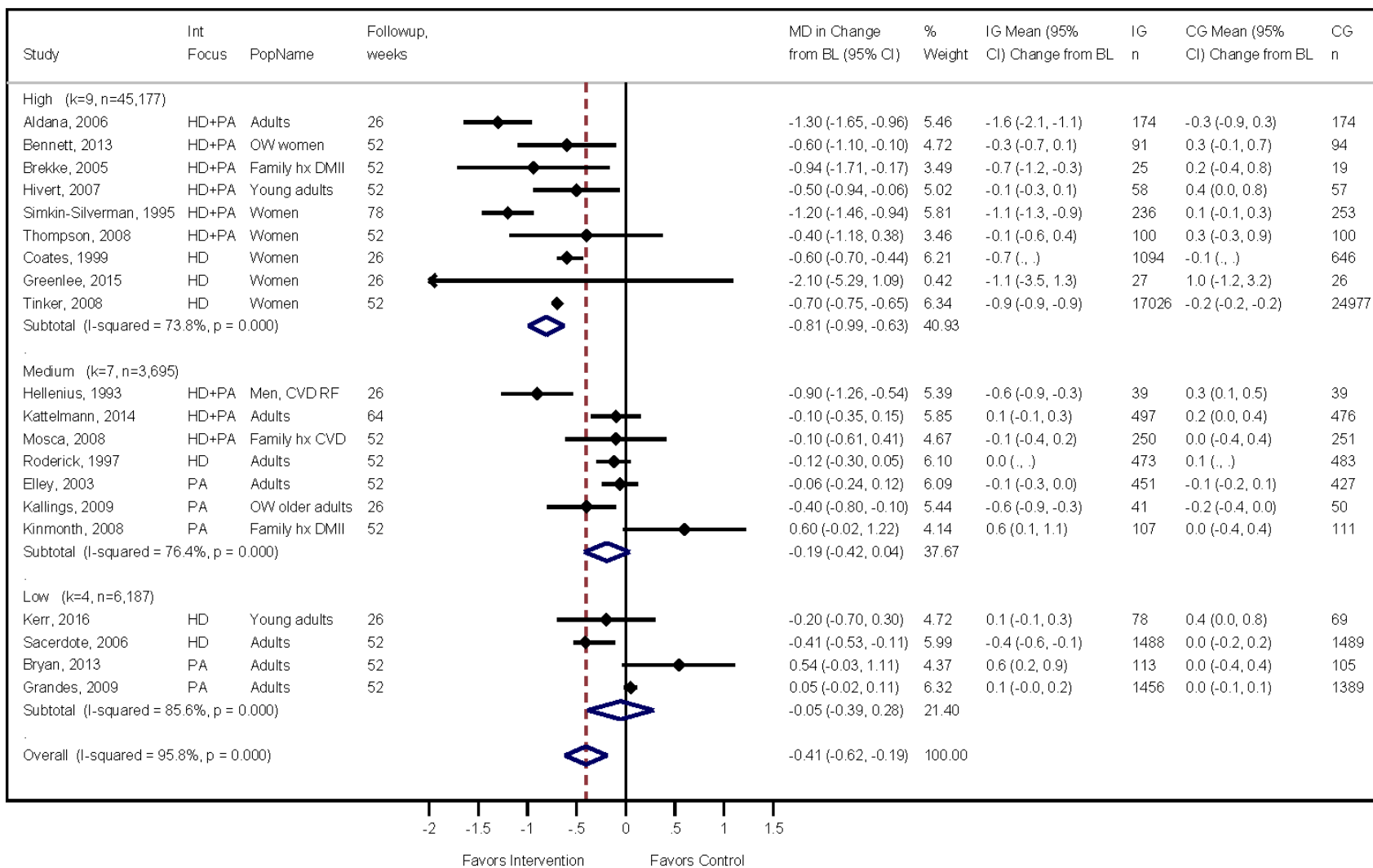
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 9. Pooled Analysis of Change in Fasting Glucose in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



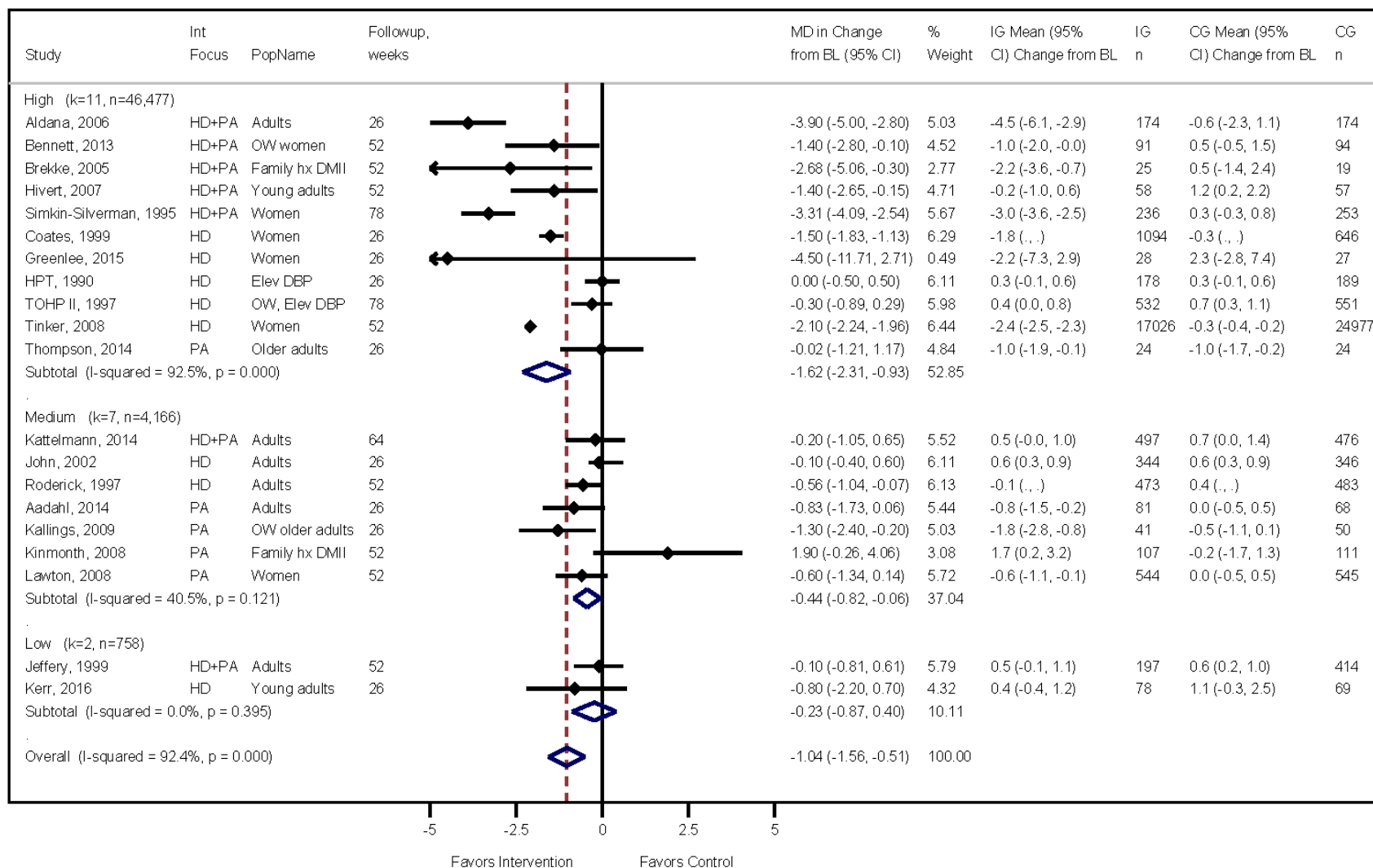
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 10. Pooled Analysis of Change in Body Mass Index in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



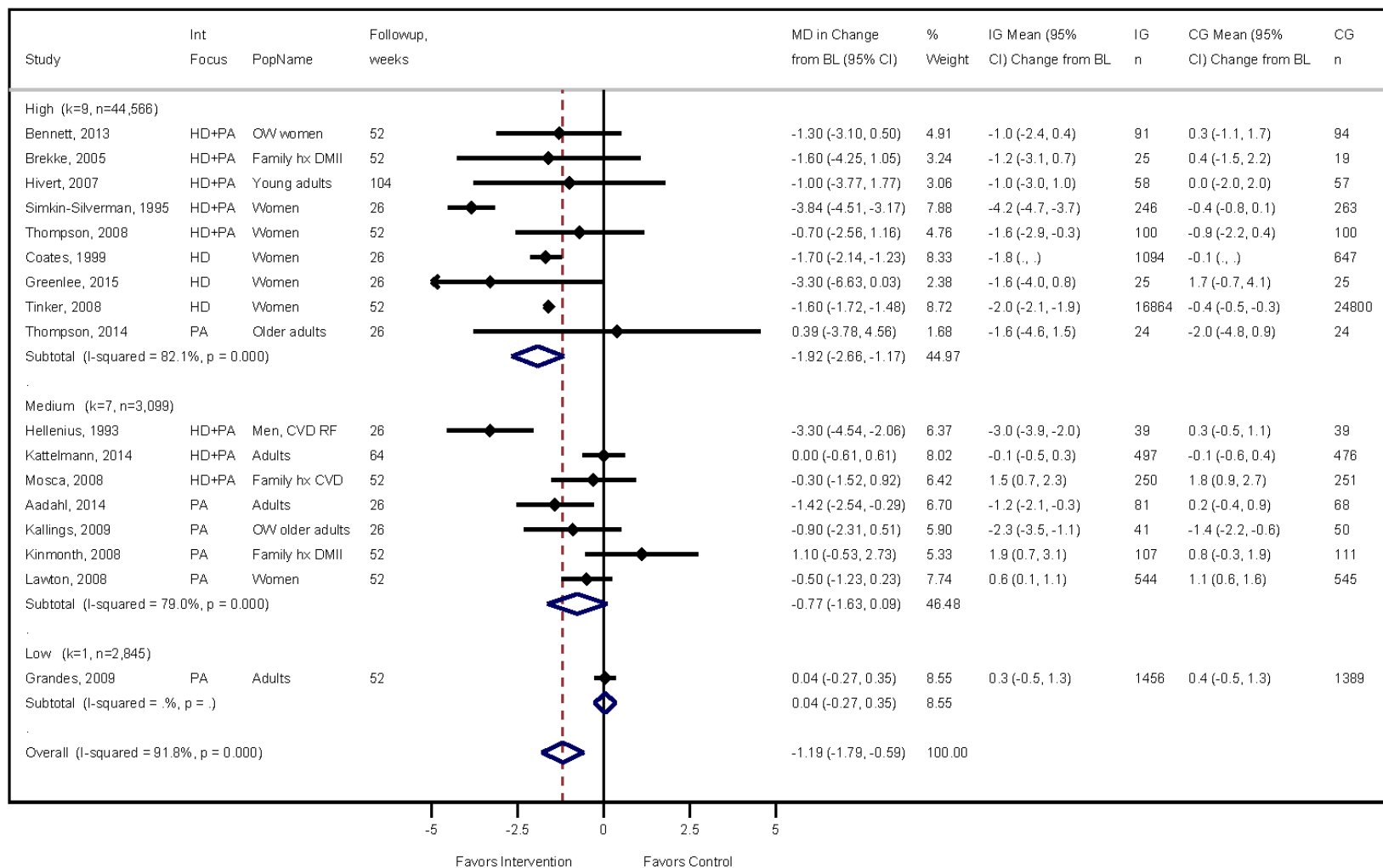
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 11. Pooled Analysis of Change in Weight in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



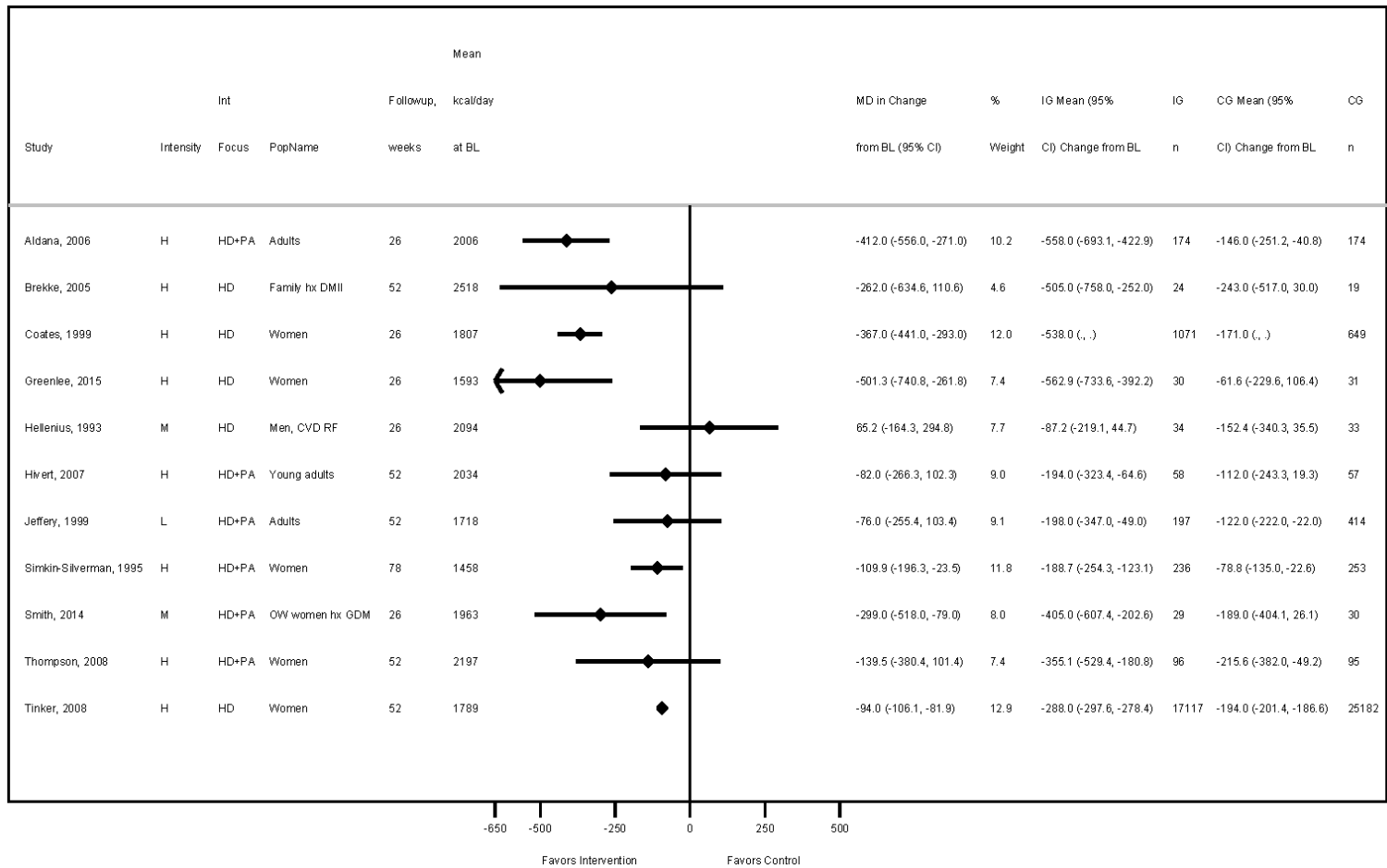
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

Figure 12. Pooled Analysis of Change in Waist Circumference in Healthful Diet and/or Physical Activity Interventions Compared With Controls, by Intervention Intensity



Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DBP=diastolic blood pressure; DM=diabetes mellitus; Elev=elevated; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

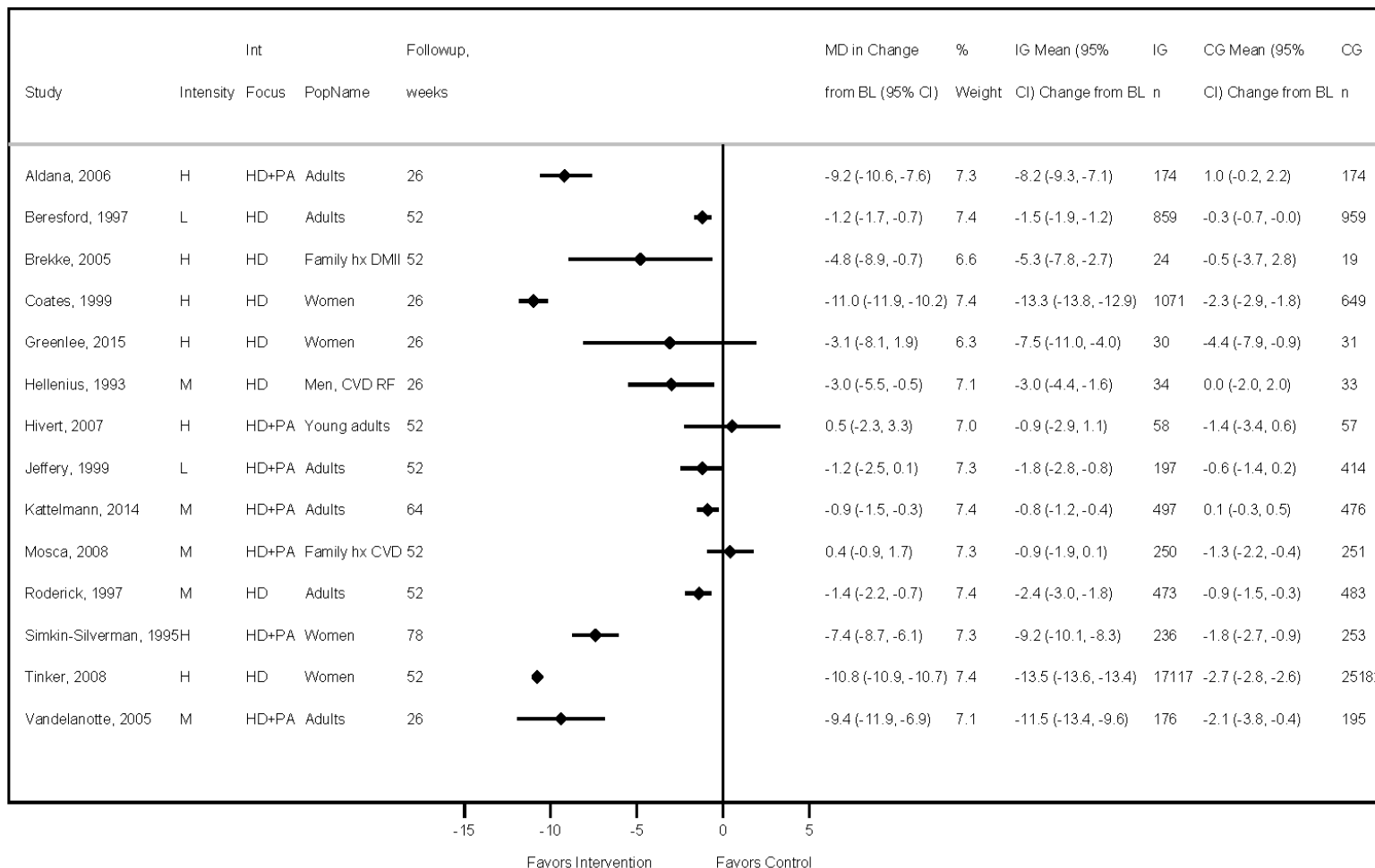
Figure 13. Change in Total Energy Intake in Healthful Diet Interventions (With or Without Physical Activity) Compared With Controls*



* Pooled estimate not presented given considerable statistical heterogeneity in meta-analysis.

Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DM=diabetes mellitus; Elev=elevated; GDM=gestational diabetes mellitus; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

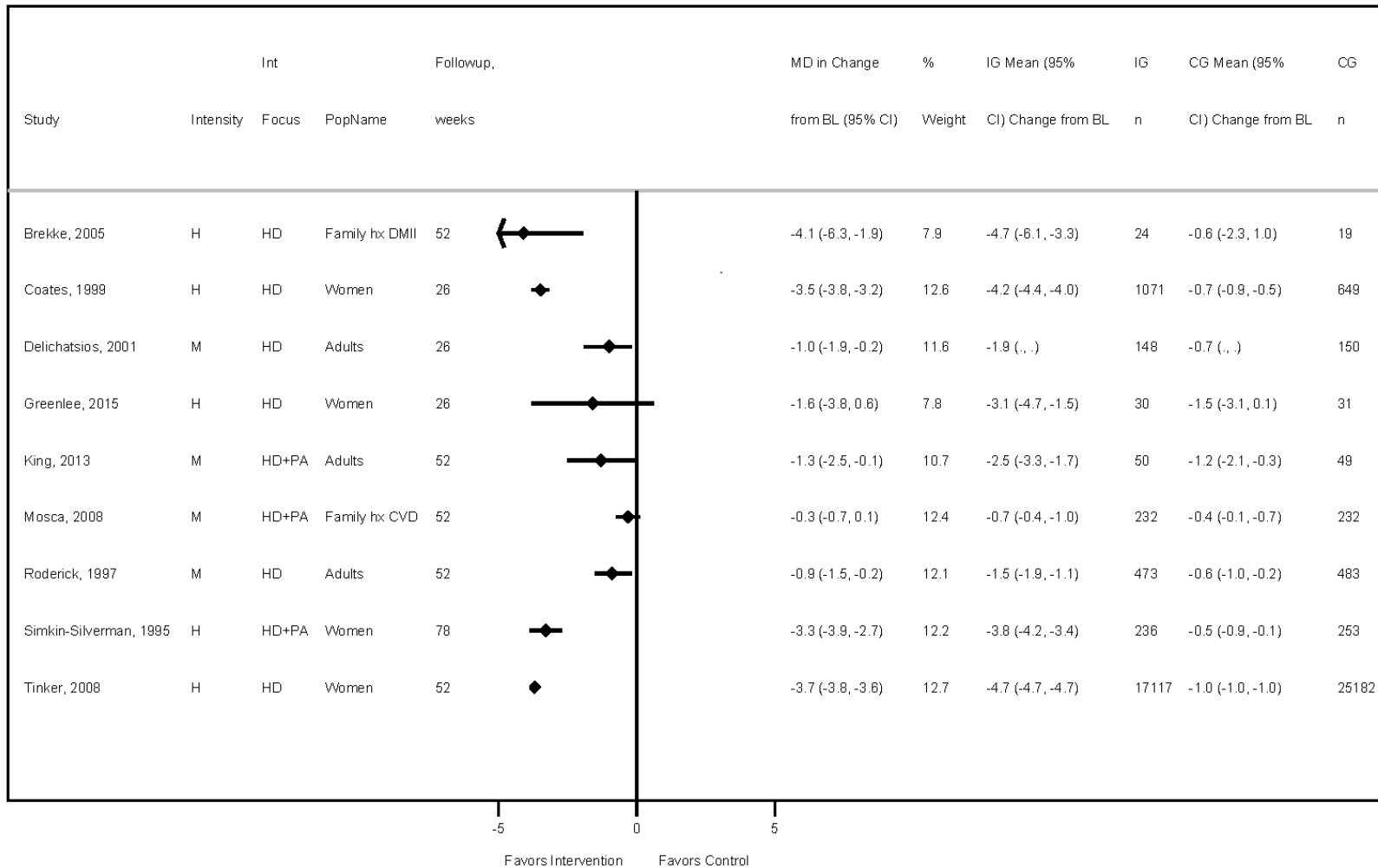
Figure 14. Change in Fat Intake in Healthful Diet Interventions (With or Without Physical Activity) Compared With Controls*



* Pooled estimate not presented given considerable statistical heterogeneity in meta-analysis.

Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DM=diabetes mellitus; Elev=elevated; GDM=gestational diabetes mellitus; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

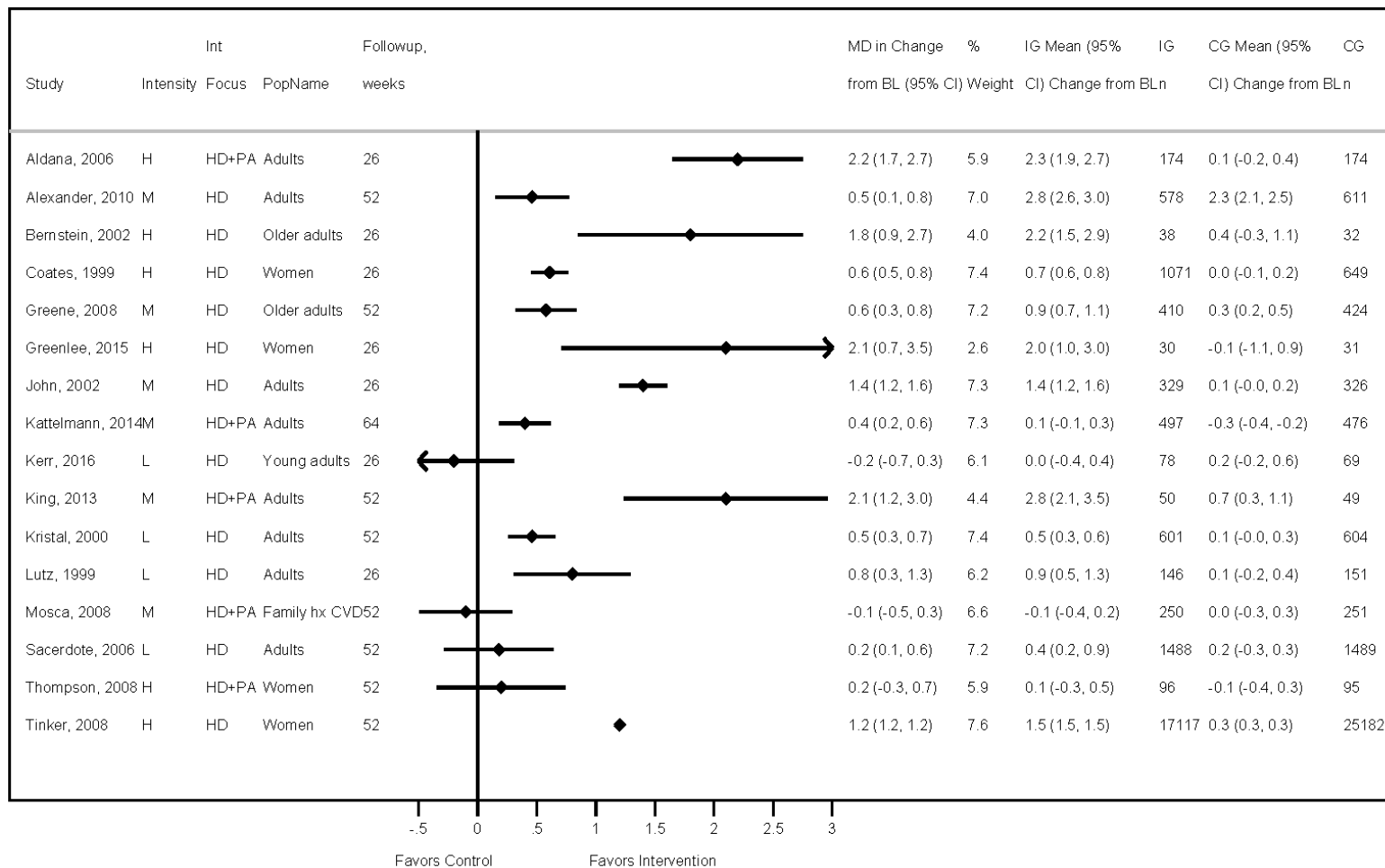
Figure 15. Change in Saturated Fat Intake in Healthy Diet Interventions (With or Without Physical Activity) Compared With Controls*



* Pooled estimate not presented given considerable statistical heterogeneity in meta-analysis.

Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DM=diabetes mellitus; Elev=elevated; GDM=gestational diabetes mellitus; HD=healthy diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

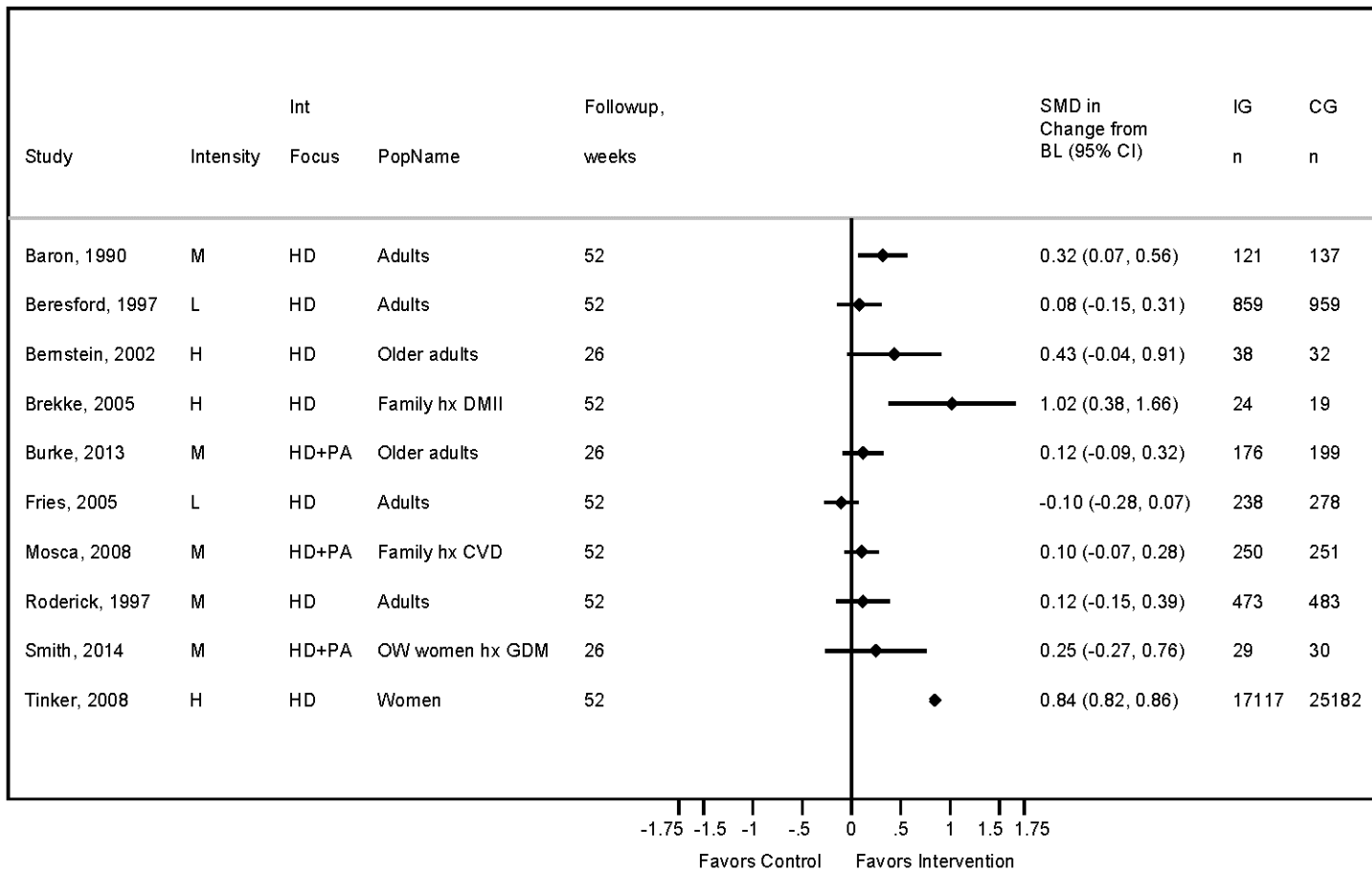
Figure 16. Change in Fruit and Vegetable Intake in Healthful Diet Interventions (With or Without Physical Activity) Compared With Controls*



* Pooled estimate not presented given considerable statistical heterogeneity in meta-analysis.

Abbreviations: BL=baseline; CG=control group; CI=confidence interval; CVD=cardiovascular disease; DM=diabetes mellitus; Elev=elevated; GDM=gestational diabetes mellitus; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity; RF=risk factor.

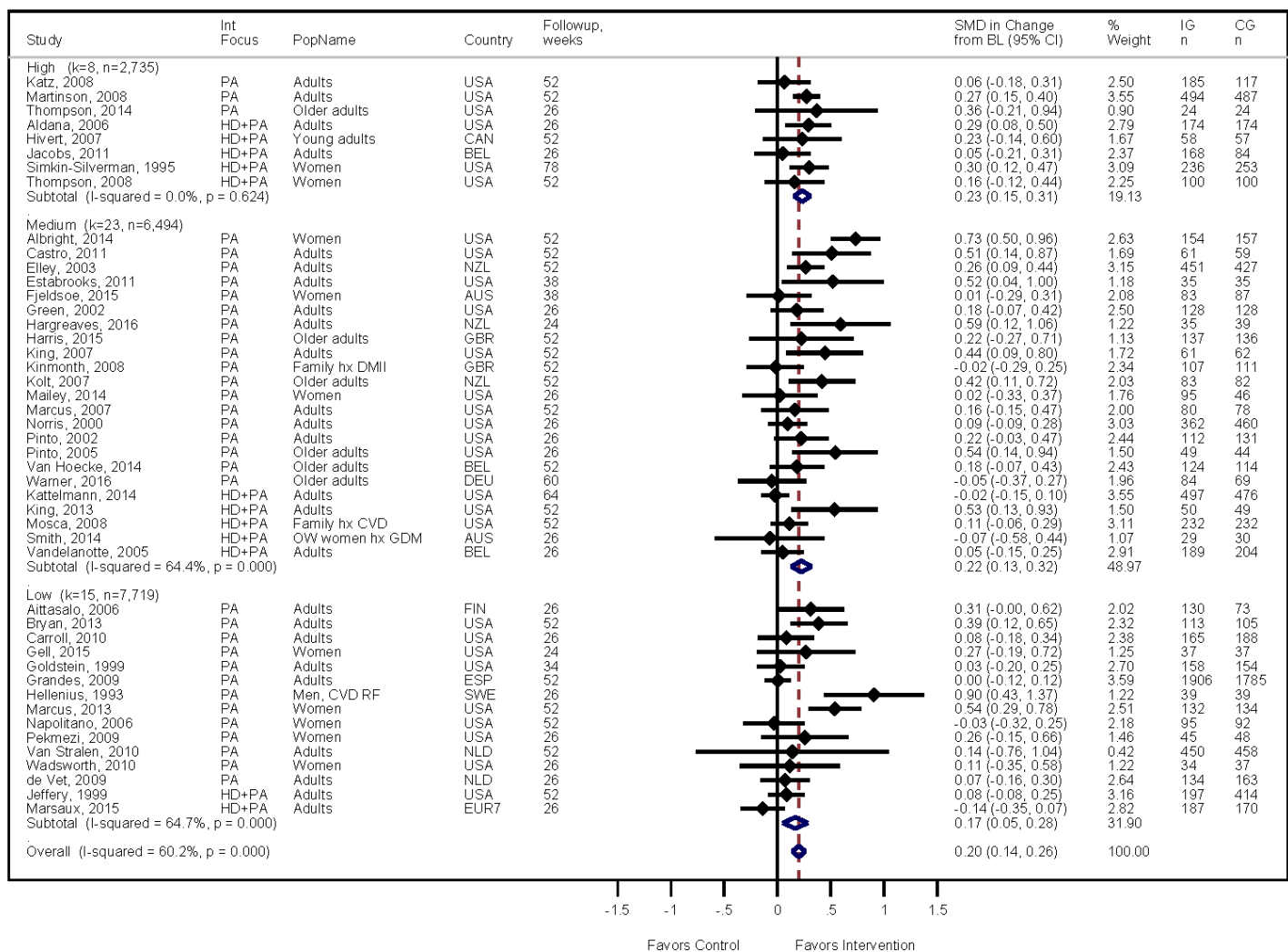
Figure 17. Change in Fiber Intake in Healthful Diet Interventions (With or Without Physical Activity) Compared With Controls*



* Pooled estimate not presented given considerable statistical heterogeneity in meta-analysis.

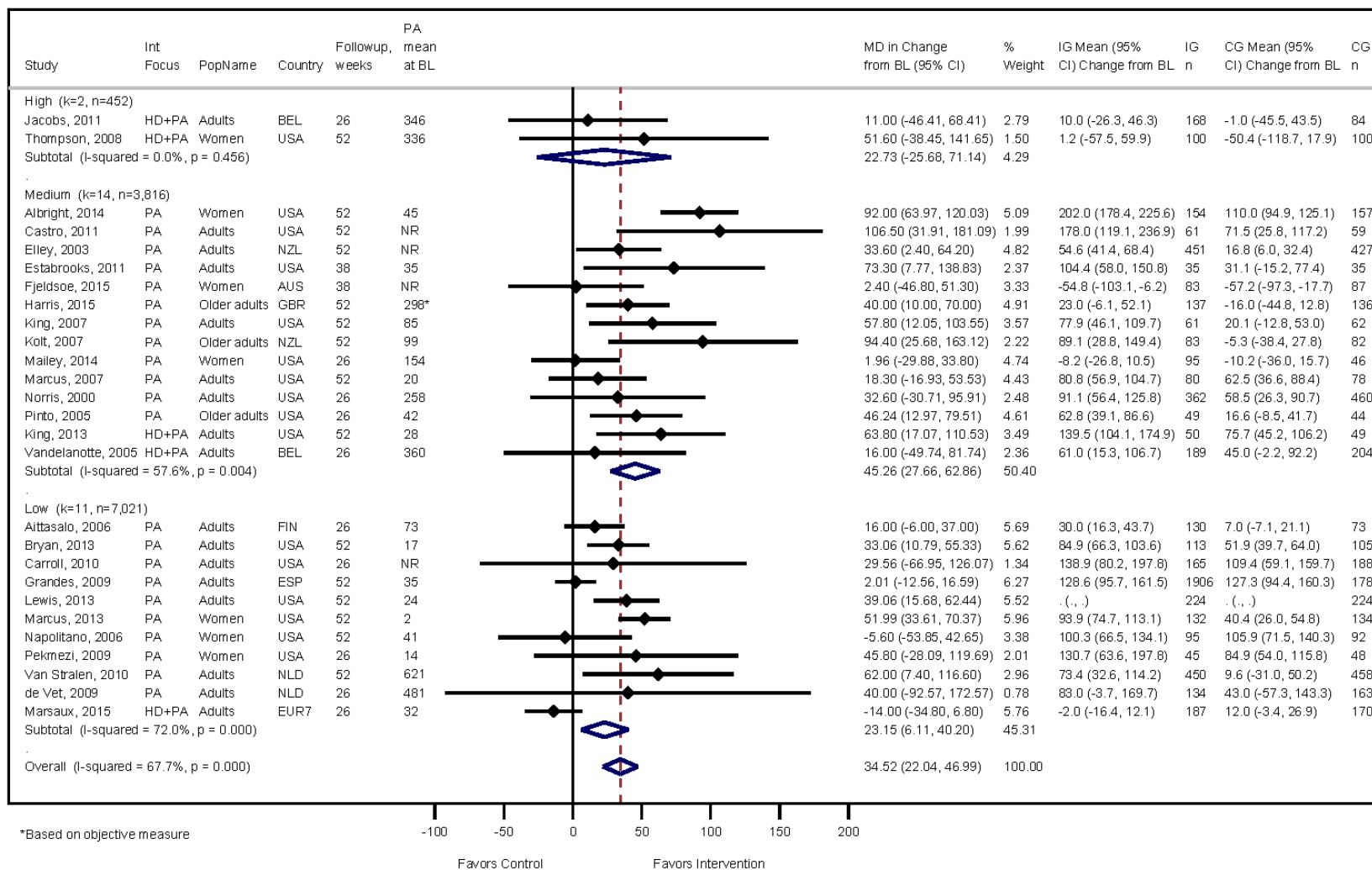
Abbreviations: BL=baseline; CG=control group; CI=confidence interval; DM=diabetes mellitus; Elev=elevated; GDM=gestational diabetes mellitus; HD=healthful diet; hx=history; IG=intervention group; Int=intervention; MD=mean difference; OW=overweight; Pop=population; PA=physical activity.

Figure 18. Pooled Analysis of Change in Physical Activity (Standardized Mean Difference) in Physical Activity Interventions (With or Without Healthful Diet) Compared With Controls, by Intervention Intensity



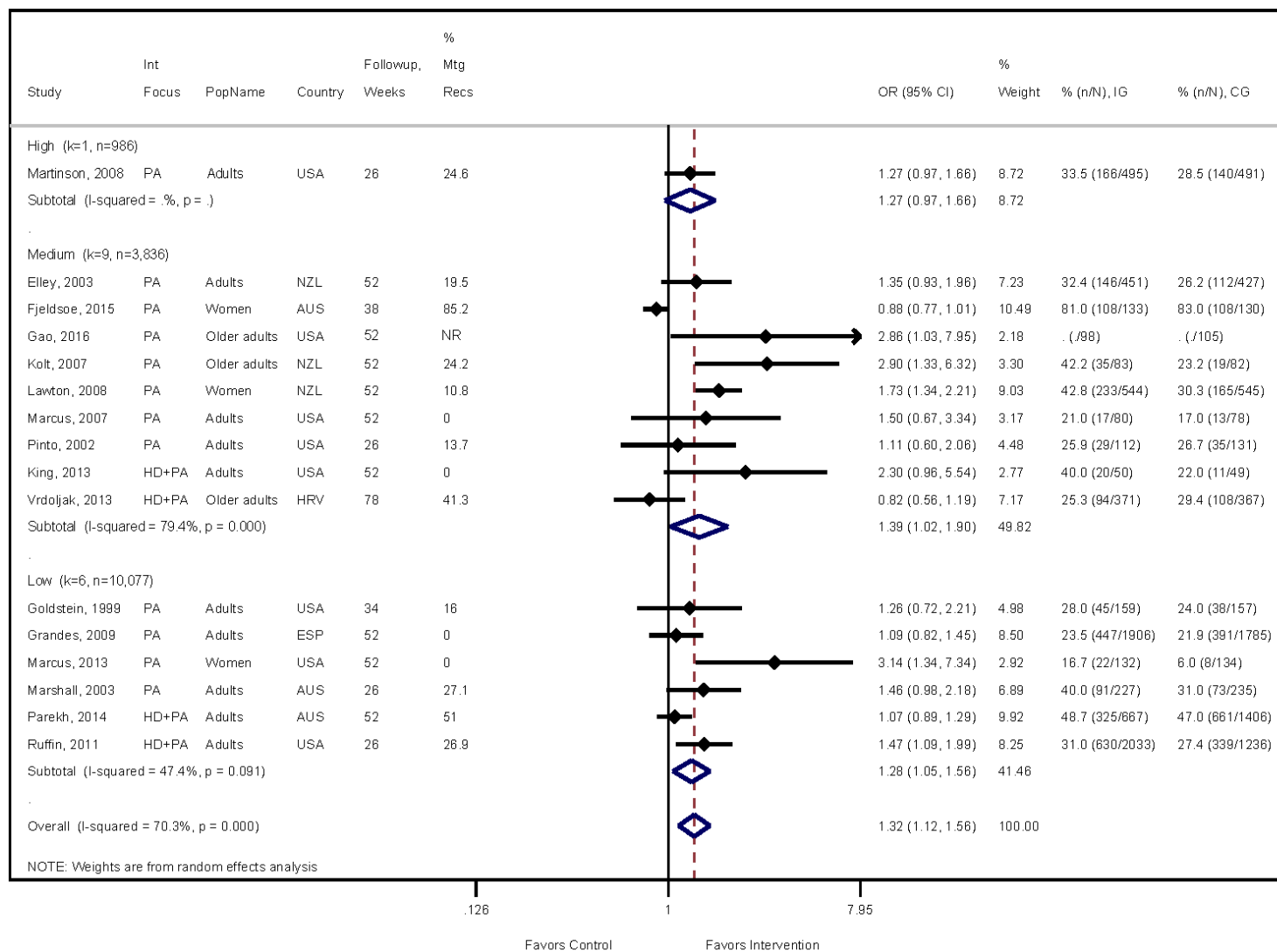
Abbreviations: AUS=Australia; BEL=Belgium; BL=baseline; CAN=Canada; CG=control group; CI=confidence interval; DEU=Germany; DNK=Denmark; ESP=Spain; EUR7=7 European countries; FIN=Finland; GBR=United Kingdom; HD=healthful diet; HRV=Croatia; IG=intervention group; Int=intervention; ITA=Italy; JPN=Japan; NLD=Netherlands; NZL=New Zealand; PA=physical activity; Pop=population; SMD=standardized mean difference; SWE=Sweden; USA=United States.

Figure 19. Pooled Analysis of Change in Physical Activity (Minutes/Week) in Physical Activity Interventions (With or Without Healthful Diet) Compared With Controls, by Intervention Intensity



Abbreviations: AUS=Australia; BEL=Belgium; BL=baseline; CAN=Canada; CG=control group; CI=confidence interval; DNK=Denmark; ESP=Spain; EUR7=7 European countries; FIN=Finland; GBR=United Kingdom; HD=healthful diet; HRV=Croatia; IG=intervention group; Int=intervention; ITA=Italy; JPN=Japan; MD=mean difference; NLD=Netherlands; NZL=New Zealand; PA=physical activity; Pop=population; SWE=Sweden; USA=United States.

Figure 20. Pooled Analysis of Odds of Meeting Physical Activity Recommendations in Physical Activity Interventions (With or Without Healthful Diet) Compared With Controls, by Intervention Intensity



Abbreviations: AUS=Australia; BEL=Belgium; BL=baseline; CAN=Canada; CG=control group; CI=confidence interval; DNK=Denmark; ESP=Spain; FIN=Finland; GBR=United Kingdom; HD=healthful diet; HRV=Croatia; IG=intervention group; ITA=Italy; JPN=Japan; NLD=Netherlands; NZL=New Zealand; OR=odds ratio; PA=physical activity; Pop=population; SWE=Sweden; USA=United States.

Table 1. Prevalence Estimates of Ideal Cardiovascular Health for Each of the Seven Metrics of Cardiovascular Health in the AHA 2020 Goals Among U.S. Adults

Measure	Definition of ideal cardiovascular health	Prevalence among adults ages 20-49 years, %	Prevalence among adults age ≥50 years, %
Current smoking	Never or quit >12 months ago	74.5	82.1
BMI	<25 kg/m ²	34.6	26.7
Physical activity	≥150 min/wk moderate-intensity or ≥75 min/wk vigorous-intensity	49.3	37.1
Healthy diet score	AHA Diet Score of 4 to 5*	1.3	1.8
Total cholesterol	<200 mg/dL	61.1	24.2
Blood pressure	<120/<80 mm Hg	57.2	19.6
Fasting plasma glucose	<100 mg/dL	64.6	35.1

* Meeting 4 to 5 of the following dietary targets: ≥4.5 cups/day fruits and vegetables, ≥2 3.5-oz servings/wk fish and shellfish, ≤1,500 mg/day sodium, ≤36 oz/wk sugar-sweetened beverages, ≥3 1-oz servings/day whole grains.

Abbreviations: AHA=American Heart Association; BMI=body mass index; min=minute; wk=week.

Adapted from Mozaffarian, 2016.¹²

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Aadahl, 2014 ⁸⁰ (Sedentary Intervention Trial [SIT]) Good	Denmark 2010-2011		X	X		166	Adults	X		52.0 (18-69)	57.2	NR	45.8	NR	27.3	15.7	
Aittasalo, 2006 ⁸¹ Fair	Finland 2003-2004			X	X	265	Adults	X		47.0 (20-65)	75.8	NR	NR	NR	NR	NR	X
Albright, 2014 ⁸³ (Nā Mikimiki) Fair	US 2008-2010			X		311	Postpartum women*	X		31.8 (18-45)	100	White: 15.1 Hisp: 17.4 Asian: 65.3	64.0	77.8	27.9	3.5	X
Aldana, 2006 ⁸⁵ (Coronary Health Improvement Project [CHIP]) Fair	US 2003		X	X		348	Adults			50.5 (24-81)	71.8	White: 94.0 Black: 4.0	NR	72.0	32.4	NR	
Alexander, 2010 ⁸⁶ (Making Effective Nutritional Choices [MENU]) Fair	US 2005-2006			X		2540	Adults			46.3 (21-65)	68.8	Black: 23.3 Hisp: 7.6	NR	91.0	NR	NR	X
Baron, 1990 ⁹⁰ Fair	UK NR		X	X		368	Adults			41.7 (25-60)	48.6	NR	NR	NR	24.5	34.5	X
Bennett, 2013 ⁹¹ (Shape Program) Good	US 2009-2011		X		X	194	Overweight or obese black women [†]		X	35.4 (25-44)	100	Black: 100	71.4	65.4	30.2	NR	X
Beresford, 1997 ⁹² (Eating Patterns Study) Fair	US 1990-1992			X		4778	Adults			NR (NR)	68.0	White: 91.0	NR	73.0	NR	NR	X
Bernstein, 2002 ⁹³ Fair	US 1994-1996			X		70	Older adults	X		77.9 (≥70)	80.0	White: 97.1 Black: 2.9	NR	NR	28.5	NR	

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Bickmore, 2013 ⁹⁴ Fair	US 2009-2011			X	X	263	Older adults	X		71.3 (≥65)	61.2	White: 28.5 Black: 62.7 Hisp: 7.6	NR	48.7	29.5	8.7	X
Brekke, 2005 ^{97f} Fair	Sweden 1997-1999		X	X		77	Adults with family history of type 2 diabetes [§]		X	42.6 (25-55)	36.8	NR	NR	NR	25.7	38	
Bryan, 2013 ⁹⁸ (Colorado Stride [COSTRIDE]) Fair	US NR		X	X		238	Adults	X		28.2 (18-45)	80.4	White: 67.1	NR	NR	25.2	NR	
Burke, 2013 ¹⁰⁰ (Physical Activity and Nutrition for Seniors [PANS]) Fair	Australia 2010			X	X	478	Older adults	X		65.8 (60-70)	48.3	NR	NR	47.2	NR	5.6	
Carpenter, 2004 ¹⁰¹ Fair	US NR			X		98	Adults			49.6 (29-71)	64.3	White: 86.7 Black: 8.2 Hisp: 2	NR	82.7	NR	NR	
Carroll, 2010 ¹⁰² (Computerized Health Improvement Project [CHIP]) Fair	US 2004-2007			X		394	Adults			46.4 (≥18)	69.0	White: 36.0 Black: 59.0	79.0	80.0	30.4	NR	X
Castro, 2011 ¹⁰³ (Telephone Advice and Mentoring [TEAM]) Fair	US NR			X	X	181	Adults	X		59.1 (≥50)	65.8	White: 67.4 Hisp: 15.2 Asian: 13.5	70.8	NR	NR	NR	

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Coates, 1999 ¹⁰⁶ (Women's Health Trial Feasibility Study in Minority Populations [WHT:FSMP]) Fair	US 1991-1995		X	X		2208	Post-menopausal women [†]	X		60.0 (50-79)	100	White: 54.6 Black: 28.2 Hisp: 16	NR	68.0	28.8	9.3	
de Vet, 2009 ¹⁰⁸ Fair	Netherlands 2003-2004			X		709	Adults			45.9 (18-65)	67.3	NR	NR	66.0	NR	NR	
Delichatsios, 2001 ¹⁰⁹ Fair	US NR			X		298	Adults	X		45.9 (≥25)	72.1	White: 44.9 Black: 44.6	85.2	71.0	28.7	18.5	X
Elley, 2003 ¹¹¹ Good	New Zealand 2000-2001	X	X	X	X	878	Adults [#]	X		57.9 (40-79)	66.3	NR	NR	25.9	30.0	17.5	X
Estabrooks, 2011 ¹¹² Fair	US 2004			X		115	Adults	X		48.8 (≥18)	61.0	White: 60.0 Black: 22.0 Hisp: 13.0	NR	62.0	NR	NR	X
Fjeldsoe, 2015 ¹¹³ (MobileMums) Fair	Australia NR			X		263	Women with young children			31.9 (NR)	100	NR	NR	NR	28.1	NR	
Franko, 2008 ¹¹⁵ Fair	US 2005			X		476	College students			20.1 (18-24)	56.3	White: 58.2 Black: 14.1 Asian: 14.9 AI/NA: 6.1	NR	NR	NR	NR	
Fries, 2005 ¹¹⁶ (Rural Physician Cancer Prevention Project) Fair	US 1999-2003			X		754	Adults			47.3 (18-72)	64.1	White: 59.5 Black: 37.7	NR	49.8	NR	NR	X
Gao, 2016 ¹¹⁷ (VA-STRIDE) Fair	US 2010-2012			X		261	Older adults	X		63.2 (NR)	17.2	White: 74.6 Black: 23.3 Hisp: 3.1	30.2	63.8	31.8	NR	X

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Gell, 2015 ¹¹⁹ Fair	US 2010			X		87	Women			47.2 (NR)	100	NR	NR	NR	29.2	NR	
Goldstein, 1999 ¹²⁰ (Physically Active for Life [PAL]) Fair	US NR			X		355	Adults	X		65.6 (≥50)	64.5	White: 95.8	36.0	NR	NR	NR	X
Grandes, 2009 ¹²² Good	Spain 2003-2004	X	X	X		4,317	Adults**	X		50.0 (20-80)	65.6	NR	50.6	16.8	27.3	30.4	X
Green, 2002 ¹²³ Fair	US 1997-1998			X		316	Adults	X		44.0 (18-65)	52.5	White: 91.5 Black: 1.6 Hisp: 0.6 Asian: 4.4	NR	NR	NR	NR	X
Greene, 2008 ¹²⁵ (Study of Exercise and Nutrition in Older Rhode Islanders [SENIOR]) Fair	US NR			X		1,280	Older adults			75 (≥60)	69.6	White: 77.1 Black: 2.1 Hisp: 14.2	NR	39.0	27.2	NR	
Greenlee, 2015 ¹²⁶ (¡Cocinar Para Su Salud!) Fair	US 2011-2012		X	X		70	Breast cancer survivors	X		56.6 (36-81)	100	White: 40 Black: 25.7 Hisp: 100	40.0	38.6	30.9	NR	
Halbert, 2000 ¹²⁸ Fair	Australia 1996	X		X		299	Older adults	X		67.6 (≥60)	54.5	NR	37.5	NR	27.1	7.4	X
Hargreaves, 2016 ¹³⁰ (StepWise) Fair	New Zealand 2012		X	X		97	Adults	X		46.2 (NR)	84.5	NR	76.2	86.6	31.1	NR	
Harland, 1999 ¹³¹ Fair	UK 1995-1996			X		523	Adults	X		NR (40-64)	58.3	NR	51.6	NR	NR	NR	X

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Harris, 2015 ¹³² (Pedometer Acelerometer Consultation Evaluation [PACE-LIFT]) Good	UK 2011-2012			X	X	298	Older adults			NR (60-75)	53.7	White: 97.3	NR	NR	NR	5.4	X
Hellenius, 1993 ^{135††} Fair	Sweden 1990	X	X	X		158	Men with moderately elevated CVD risk factors ^{††}		X	46.0 (35-60)	0	NR	NR	NR	25.3	26	X
Hinderliter, 2014 ¹³⁷ (Exercise and Nutrition Interventions for Cardiovasc- ular Health [ENCORE]) Good	US 2003-2008		X	X	X	95	Overweight or obese adults with above- normal BP ^{§§}		X	51.8 (NR)	66.3	White: 54.7 Black: 43.2 Hisp: 3.2 Asian: 2.1 AI/NA: 0	NR	48.4	32.9	8.4	X
Hivert, 2007 ¹² Fair	Canada 2002-2003		X	X		115	College students			19.7 (NR)	81.7	White: 93.0	NR	NR	22.4	NR	
HPT, 1990 ¹⁴⁰ (Hypertension Prevention Trial [HPT]) Good	US 1982-1986	X	X	X		587	Adults with high- normal DBP		X	38.6 (25-49)	36.8	White: 83.8	NR	56.1	26.3	15.0	
Jacobs, 2011 ¹⁴¹ Fair	Belgium 2007			X		314	Adults			40.5 (25-75)	66.6	NR	NR	NR	25.2	21.3	
Jeffery, 1999 ¹⁴³ (Pound of Prevention) Fair	US NR		X	X		1,226	Adults			38.3 (20-45)	80.2	White: 89.6	NR	88.9	26.6	16.4	
John, 2002 ¹⁴⁴ Fair	UK 1997-1998		X	X		729	Adults			45.9 (25-64)	51.0	NR	NR	NR	25.8	16.5	X

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Kallings, 2009 ¹⁴⁶ Good	Sweden 1997-1999		X	X		101	Overweight or obese older adults ^{††}		X	NR (≥60)	57.4	NR	NR	NR	30.1	6.9	X
Kattelman, 2014 ¹⁴⁷ (Young Adults Eating and Active for Health [YEAH]) Fair	US 2011		X	X		1639	Young adults			19.3 (18-24)	67.2	White: 72.1 Black: 13.1 Hisp: 5.7 Asian: 9.9 AI/NA: 0.7	NR	NR	24.1	NR	
Katz, 2008 ¹⁴⁸ Fair	US 2001-2002			X		316	Adults			NR (≥18)	67.1	White: 35.4 Black: 29.1 Hisp: 20.6	NR	30.0	NR	NR	X
Kerr, 2016 ¹⁴⁹ (Connecting Health and Technology [CHAT]) Fair	Australia NR		X	X		247	Young adults			24.3 (18-30)	65.6	White: 77.3 Black: 0.4 Asian: 16.6	NR	NR	24.4	5.3	
King, 2007 ¹⁵³ (Community Health Advice by Telephone [CHAT]) Fair	US NR			X	X	218	Adults	X		60.8 (≥55)	69.8	White: 87.3	64.0	NR ^{###}	29.5	NR	
King, 2013 ¹⁵² (Counseling Advice for Lifestyle Management [CALM]) Good	US NR			X		200	Adults	X		55.2 (≥45)	51.3	White: 70.6	68.0	NR ^{***}	29.2	NR	
Kinmonth, 2008 ¹⁵⁴ Fair	UK 2001-2003	X	X	X		365	Adults with family history of type 2 diabetes ^{†††}		X	40.6 (30-50)	62.0	NR	NR	NR	27.8	NR	X
Kolt, 2007 ¹⁵⁵ Good	New Zealand 2003-2004	X		X	X	186	Older adults	X		74.2 (≥65)	66.1	NR	NR	44.1	NR	NR	X

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Kristal, 2000 ¹⁵⁶ (Puget Sound Eating Patterns [PEP]) Fair	US 1997-1998		X	X		1,459	Adults			44.9 (18-69)	49.1	White: 85.9 Black: 4.5 Hisp: 3.0 Asian: 5.8	NR	NR	26.5	14.1	X
Lawton, 2008 ¹⁶⁰ Good	New Zealand 1999-2002, 2004-2005		X	X	X	1,089	Women	X		58.9 (40-74)	100	White: 77.7 Asian: 13.1	NR	NR	29.2	12.6	X
Lewis, 2013 ¹⁶¹ Good	US 2005-2008			X		448	Adults	X		42.6 (≥18)	87.1	White: 69.9 Black: 25.4	88.0	57.8	NR	13.6	
Lutz, 1999 ¹⁶² Fair	US 1995			X		710	Adults			39.3 (≥18)	64.4	White: 77.9 Black: 19.3	NR	60.0	NR	NR	X
Mailey, 2014 ¹⁶⁴ Fair	US 2011			X		141	Women	X		37.3 (25-52)	100	White: 80.1 Black: 9.2 Asian: 7.1	100	87.2	NR	NR	
Marcus, 2007 ¹⁶⁷ (Project STRIDE) Fair	US NR			X		239	Adults	X		44.5 (18-65)	82.0	White: 90.3	90.4	70.6	28.1	12.6	
Marcus, 2013 ¹⁶⁶ (Seamos Saludable Trial) Good	US 2009-2013			X		292	Hispanic/ Latina women	X		40.7 (18-65)	100	Hisp: 100	53.0	46.2	29.4	NR	
Marsaux, 2015 ¹⁶⁹ (Food4Me) Fair	Europe***** 2012-2013			X		1,067	Adults			39.9 (18-79)	58.4	White: 96.8 Black: 0.1 Asian: 0.7	NR	NR	25.5	12.1	
Marshall, 2003 ¹⁷⁰ Fair	Australia 1997			X		462	Adults			49.0 (40-60)	57.6	NR	NR	NR	26.4	NR	

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Martinson, 2008 ¹⁷² (Keep Active Minnesota) Good	US 2004-2005			X		1,049	Adults			57.1 (50-70)	72.4	White: 94.0 Black: 3.3 Hisp: 1.8 Asian: 0.9 AI/NA: 0.2	NR	66.7	27.6	NR	X
Mosca, 2008 ¹⁷⁶ (Family Interv- ention Trial for Heart Health [FIT Heart]) Good	US 2005-2007		X	X		501	Adults with family history of CVD ⁺⁺⁺		X	48 (20-79)	66.3	White: 64.5	74.0	78.0	28.1	10.2	X
Napolitano, 2006 ¹⁷⁷ Fair	US 2002-2005			X		280	Women	X		47.2 (18-65)	100	White: 94.6 Hisp: 27.9	81.4	54.5	28.7	NR	
Norris, 2000 ¹⁷⁹ Fair	US NR	X		X	X	847	Adults			54.9 (≥30)	52.1	White: 90.9	NR	82.2	NR	19.3	X
Parekh, 2014 ¹⁸¹ (10 Small Steps Study) Fair	Australia 2008			X		4,676	Adults			46.9 (18-70)	69.2	NR	65.2	58.7	NR	NR	X
Pekmezi, 2009 ¹⁸⁴ (Seamos Activas [Let's Be Active]) Fair	US 2007-2008			X		93	Hispanic/ Latina women	X		41.4 (18-65)	100	Hisp: 100	NR	52.0	NR	NR	
Pinto, 2002 ¹⁸⁵ Fair	US NR			X		298	Adults	X		45.9 (≥25)	72.1	White: 44.9 Black: 44.6	85.2	71.0	28.7	18.5	X
Pinto, 2005 ¹⁸⁶ (Physically Active for Life 2 [PAL2]) Fair	US 2000-2002			X		100	Older adults	X		68.5 (≥60)	65.0	White: 81.0 Black: 14.0	30.1	57.9	29.2	NR	X
Roderick, 1997 ¹⁸⁸ Fair	UK 1991-1993		X	X		956	Adults			47.3 (35-59)	50.0	NR	NR	NR	26.1	28	X

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Ruffin, 2011 ¹⁸⁹ (Family Healthware Impact Trial) Fair	US 2005-2007			X		4,248	Adults			50.6 (35-65)	69.7	White: 91.2 Black: 3.2 Hispanic: 2.3 Asian: 2.8 AI/NA: 0.1	NR	NR	27.3	7.7	X
Sacerdote, 2006 ¹⁹⁰ Fair	Italy NR		X	X	X	3,179	Adults			44.4 (18-65)	50.0	NR	NR	NR	NR	NR	X
Simkin- Silverman, 1995 ¹⁹⁴ (Women's Healthy Life- style Project [WHLP]) Good	US 1992-1994		X	X		535	Pre- menopausal women			47.1 (44-50)	100	White: 97.8	86.0	85.0	25.1	9	
Smith, 2014 ¹⁹⁷ Fair	Australia NR			X		59	Overweight or obese women with history of gestational diabetes ^{§§§}		X	35.4 (NR)	100	NR	49.0	59.3	30.5	NR	X
Springvloed, 2015 ¹⁹⁸ Fair	Netherlands 2012			X		1,349	Adults			49.4 (20-65)	64.6	NR	NR	45.7	25.6	NR	
Stewart, 2001 ²⁰¹ (Community Healthy Activities Model Program for Seniors [CHAMPS II]) Fair	US NR			X		173	Older adults	X		74.4 (65-90)	65.9	NR	NR	56.1	NR	NR	X
Taveras, 2011 ^{203¶¶¶} Fair	US 2008			X		84	Postpartum women ^{###}			32.9 (NR)	100	White: 74.0	NR	93.0	23.5	NR	X
Thompson, 2008 ²⁰⁷ Fair	US 2002-2006		X	X		200	American Indian women ^{****}			29.2 (18-40)	100	AI/NA: 100	NR	84.6	29.4	NR	

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Thompson, 2014 ²⁰⁸ (Go4Life) Good	US NR		X	X	X	49	Older adults	X		79.5 (≥65)	81.2	NR	NR	NR	NR		
Tinker, 2008 ²⁰⁹ (Women's Health Initiative Dietary Modifi- cation Trial [WHI DMT]) Good	US 1993-1998	X	X	X		48,835	Post- menopausal women ^{††††}	X		62.2 (50-79)	100	White: 82.4 Black: 10 Hisp: 3.7 Asian: 2.2 AI/NA: 0.4	NR	NR	28.9	6.7	
TOHP I, 1992 ²⁰⁴ (Trials of Hypertension Prevention, Phase 1 [TOHP-I]) Fair	US 1987-1988	X	X	X		744	Adults with high-normal DBP ^{††††}		X	43.0 (30-54)	28.6	White: 77.2 Black: 20.3	91.8	55.3	27.1	10.9	
TOHP II, 1997 ²⁰⁵ (Trials of Hypertension Prevention, Phase 2 [TOHP-II]) Good	US 1990-1992	X	X	X		1190	Moderately overweight adults with high-normal DBP ^{§§§§}		X	43.7 (30-54)	33.4	White: 80.3 Black: 17.1	88.2	52.4	30.9	8.9	
Tokunaga- Nakawatase, 2014 ²¹⁰ (Lifestyle Intervention Support Software for Diabetes Prevention [LISS-DP]) Fair	Japan 2010			X		216	Adults with family history of type 2 diabetes		X	45.2 (30-60)	34.8	NR	49.0	39.0	22.7	NR	X
Valve, 2013 ²¹¹ (LINDA) Fair	Finland 2006		X			3059	College-age women			19.0 (17-21)	100	NR	NR	47.8	22.0 FN: Median	NR	

Table 2. Study and Population Characteristics for All Studies, by Author

Author, year (Study name) Quality	Country Date	KQ 1	KQ 2	KQ 3	KQ 4	N Rand	Population description	Subopt behavior	Elev CVD risk	Mean age (range)	% Female	Race/ ethnicity, %	% Empl	% >HS	Mean BMI	% Smoking	PCP####
Van Hoecke, 2014 ²¹² Fair	Belgium NR	X		X		442	Older adults	X		69.5 (60-93)	66.7	NR	NR	32.6 ^{††††}	27.1	NR	
Van Stralen, 2010 ²¹⁴ Fair	Netherlands 2007			X		8,500	Adults			64.0 (≥50)	57.0	NR	45.0	52.0	25.5	NR	X
Vandelanotte, 2005 ²¹⁷ Fair	Belgium NR			X		1,023	Adults			39.1 (20-60)	64.5	NR	86.3	69.6	24.5	NR	
Vrdoljak, 2013 ²¹⁸ Fair	Croatia 2008			X		738	Older adults			72.3 (≥65)	61.2	NR	NR	NR	NR	6.8	X
Wadsworth, 2010 ²¹⁹ Fair	US NR		X	X		91	College-age women	X		NR (NR)	100	NR	NR	NR	27.5	NR	
Warner, 2016 ²²⁰ (Active Retirement) Fair	Germany 2012			X		360	Older adults	X		70.3 (64-92)	75.2	NR	NR	NR	NR	NR	

* 2-12 months postpartum.

† Study inclusion criteria required BMI of 25-34.9 kg/m²; at baseline, 36.4% with hypertension and 6.5% with diabetes.

‡ Includes both combined and healthful diet-only intervention arms.

§ Study inclusion criteria required 2 first-degree relatives or 1 first-degree and ≥2 second-degree relatives with type 2 diabetes; at baseline, 13% had impaired fasting glucose.

|| 15.8 mean years of education.

¶ 38.9% with hypertension and 24.5% taking medication for hypertension at baseline.

52.4% with hypertension, 10.5% with diabetes, and 19.0% with previous CVD at baseline.

** 24.4% with hypertension and 8.2% with diabetes at baseline.

†† Includes combined, healthful diet-only, and physical activity-only intervention arms.

‡‡ Study inclusion criteria required serum cholesterol of 5.2-7.8 mmol/L, FBG ≤6.7 mmol/L, fasting triglycerides ≤5.6 mmol/L, and DBP ≤100 mm Hg.

§§ Study inclusion criteria required BMI of 25-39.9 kg/m² and SBP of 130-159 mm Hg or DBP of 80-99 mm Hg.

||| Study inclusion criteria required DBP of 76-99 mm Hg at baseline and DBP of 78-89 mm Hg 7-30 days later.

¶¶ Study inclusion criteria required BMI of 25-40 kg/m² and abdominal obesity of ≥88 cm for women or ≥102 cm for men.

16.2 mean years of education.

*** 15.8 mean years of education.

††† Study inclusion criteria required parental history of type 2 diabetes.

‡‡‡ Study inclusion criteria required that participants had a blood relative, spouse, or cohabitant who had acute atherosclerotic CVD; at baseline, 34.1% with hypertension and 21% were taking medication for hypertension.

§§§ Study inclusion criteria required diagnosis with gestational diabetes within the past 4 years, BMI not reported.

|||| 39.6% with hypertension and 7.3% with diabetes at baseline.

Table 2. Study and Population Characteristics for All Studies, by Author

¶¶¶ Nonrandomized clinical controlled trial.

0-1 month postpartum.

**** 21.0% with impaired fasting glucose at baseline.

††† 37.7% with hypertension at baseline.

‡‡‡ Study inclusion criteria required average DBP of 80-89 mm Hg after 3 visits.

§§§§ Study inclusion criteria required BMI of 26.1-37.4 kg/m² for men and 24.4-37.4 kg/m² for women and average DBP of 83-89 mm Hg and SBP <140 mm Hg.

|||| Study inclusion criteria required 1 first-degree relative with type 2 diabetes.

¶¶¶¶ ≥15 mean years of education.

PCP=conducted in or recruited from primary care setting (X=yes).

***** 7 European countries (Germany, Greece, Ireland, the Netherlands, Poland, Spain, and the United Kingdom).

Abbreviations: AI=American Indian; BMI=body mass index; BP=blood pressure; CVD=cardiovascular disease; DBP=diastolic blood pressure; elev=elevated; empl=employed; FBG=fasting blood glucose; Hisp=hispanic; HS=high school education; KQ=key question; NA=Native American; NR=not reported; PCP=primary care provider; rand=randomized; SBP=systolic blood pressure; Subopt=suboptimal; US=United States, UK=United Kingdom; yr=year; zBMI=body mass index z score.

Table 3. List of Study-Specific Intervention Arms, by Intervention Focus and Intensity (121 Arms in 88 Trials*)

	Healthful Diet + Physical Activity 32 arms (23 trials)	Healthful Diet 31 arms (24 trials)	Physical Activity 58 arms (44 trials)
Low intensity (≤30 min) 41 arms (29 trials)	9 arms (5 trials)	10 arms (7 trials)	21 arms (16 trials)
	Jeffery, 1999 ¹⁴³ (IG1)	Beresford, 1997 ⁹² (IG1)	Aittasalo, 2006 ⁸¹ (IG1)
	Jeffery, 1999 ¹⁴³ (IG2)	Carpenter, 2004 ¹⁰¹ (IG2)	Aittasalo, 2006 ⁸¹ (IG2)
	Marsaux, 2015 ¹⁶⁹ (IG1) [§]	Fries, 2005 ¹¹⁶ (IG1)	Bryan, 2013 ⁹⁸ (IG1) [§]
	Marsaux, 2015 ¹⁶⁹ (IG2) [§]	Kerr, 2016 ¹⁴⁹ (IG1) [§]	Carroll, 2010 ¹⁰² (IG1) [§]
	Marsaux, 2015 ¹⁶⁹ (IG3) [§]	Kerr, 2016 ¹⁴⁹ (IG2) [§]	de Vet, 2009 ¹⁰⁸ (IG1)
	Parekh, 2014 ¹⁸¹ (IG1) [§]	Kristal, 2000 ¹⁵⁶ (IG1)	de Vet, 2009 ¹⁰⁸ (IG2)
	Parekh, 2014 ¹⁸¹ (IG2) [§]	Lutz, 1999 ¹⁶² (IG1)	de Vet, 2009 ¹⁰⁸ (IG3)
	Ruffin, 2011 ¹⁸⁹ (IG1) [§]	Lutz, 1999 ¹⁶² (IG2)	Gell, 2015 ¹¹⁹ (IG1) [§]
	Tokunaga-Nakawatase, 2014 ²¹⁰ (IG1) [§]	Lutz, 1999 ¹⁶² (IG3)	Goldstein, 1999 ¹²⁰ (IG1)
		Sacerdote, 2006 ¹⁹⁰ (IG1)	Grandes, 2009 ¹²² (IG1)
			Hellenius, 1993 ¹³⁵ (IG2)
			Lewis, 2013 ¹⁶¹ (IG1) [§]
			Marcus, 2013 ¹⁶⁶ (IG1) [§]
			Marshall, 2003 ¹⁷⁰ (IG1)
			Napolitano, 2006 ¹⁷⁷ (IG1)
			Napolitano, 2006 ¹⁷⁷ (IG2)
		Pekmezi, 2009 ¹⁸⁴ (IG1)	
		Van Hoecke, 2014 ²¹² (IG2) [§]	
		Van Stralen, 2010 ²¹⁴ (IG1) [§]	
		Van Stralen, 2010 ²¹⁴ (IG2) [§]	
		Wadsworth, 2010 ²¹⁹ (IG1) [§]	
Medium intensity (31-360 min) 55 arms (42 trials)	13 arms (10 trials)	10 arms (8 trials)	32 arms (25 trials)
	Burke, 2013 ¹⁰⁰ (IG1) [§]	Alexander, 2010 ⁸⁶ (IG1) [§]	Aadah, 2014 ⁸⁰ (IG1) ^{†§}
	Franko, 2008 ¹¹⁵ (IG1)	Alexander, 2010 ⁸⁶ (IG2) [§]	Albright, 2014 ⁸³ (IG1) [§]
	Franko, 2008 ¹¹⁵ (IG2)	Baron, 1990 ⁹⁰ (IG1)	Bickmore, 2013 ⁹⁴ (IG1) [§]
	Hellenius, 1993 ¹³⁵ (IG3)	Delichatsios, 2001 ¹⁰⁹ (IG1)	Castro, 2011 ¹⁰³ (IG1) [§]
	Kattelman, 2014 ¹⁴⁷ (IG1) [§]	Greene, 2008 ¹²⁵ (IG1)	Castro, 2011 ¹⁰³ (IG2) [§]
	King, 2013 ¹⁵² (IG1) [§]	Hellenius, 1993 ¹³⁵ (IG1)	Elley, 2003 ¹¹¹ (IG1)
	Mosca, 2008 ¹⁷⁶ (IG1)	John, 2002 ¹⁴⁴ (IG1)	Estabrooks, 2011 ¹¹² (IG1) [§]
	Smith, 2014 ¹⁹⁷ (IG1) [§]	Roderick, 1997 ¹⁸⁸ (IG1)	Fjeldsoe, 2015 ¹¹³ (IG1) [§]
	Valve, 2013 ²¹¹ (IG1) [§]	Springvloet, 2015 ¹⁹⁸ (IG1) [§]	Gao, 2016 ¹¹⁷ (IG1) [§]
	Vandelanotte, 2005 ²¹⁷ (IG1)	Springvloet, 2015 ¹⁹⁸ (IG2) [§]	Green, 2002 ¹²³ (IG1)
	Vandelanotte, 2005 ²¹⁷ (IG2)		Halbert, 2000 ¹²⁸ (IG1)
	Vandelanotte, 2005 ²¹⁷ (IG3)		Hargreaves, 2016 ¹³⁰ (IG1) [§]
	Vrdoljak, 2013 ²¹⁸ (IG1) ^{‡§}		Harland, 1999 ¹³¹ (IG1)
			Harland, 1999 ¹³¹ (IG2)
			Harland, 1999 ¹³¹ (IG3)
			Harland, 1999 ¹³¹ (IG4)
		Harris, 2015 ¹³² (IG1) [§]	
		Kallings, 2009 ¹⁴⁶ (IG1)	
		King, 2007 ¹⁵³ (IG1)	
		King, 2007 ¹⁵³ (IG2)	
		Kinmonth, 2008 ¹⁵⁴ (IG1)	
		Kolt, 2007 ¹⁵⁵ (IG1)	
		Lawton, 2008 ¹⁶⁰ (IG1)	
		Mailey, 2014 ¹⁶⁴ (IG1) [§]	
		Marcus, 2007 ¹⁶⁷ (IG1)	
		Marcus, 2007 ¹⁶⁷ (IG2)	
		Norris, 2000 ¹⁷⁹ (IG1)	
		Pinto, 2002 ¹⁸⁵ (IG1)	
		Pinto, 2005 ¹⁸⁶ (IG1)	
		Van Hoecke, 2014 ²¹² (IG1) [§]	
		Warner, 2016 ²²⁰ (IG1) [§]	
		Warner, 2016 ²²⁰ (IG2) [§]	

Table 3. List of Study-Specific Intervention Arms, by Intervention Focus and Intensity (121 Arms in 88 Trials*)

	Healthful Diet + Physical Activity 32 arms (23 trials)	Healthful Diet 31 arms (24 trials)	Physical Activity 58 arms (44 trials)
Low intensity (≤30 min)	9 arms (5 trials)	10 arms (7 trials)	21 arms (16 trials)
41 arms (29 trials)	Jeffery, 1999 ¹⁴³ (IG1)	Beresford, 1997 ⁹² (IG1)	Aittasalo, 2006 ⁸¹ (IG1)
	Jeffery, 1999 ¹⁴³ (IG2)	Carpenter, 2004 ¹⁰¹ (IG2)	Aittasalo, 2006 ⁸¹ (IG2)
	Marsaux, 2015 ¹⁶⁹ (IG1) [§]	Fries, 2005 ¹¹⁶ (IG1)	Bryan, 2013 ⁹⁸ (IG1) [§]
	Marsaux, 2015 ¹⁶⁹ (IG2) [§]	Kerr, 2016 ¹⁴⁹ (IG1) [§]	Carroll, 2010 ¹⁰² (IG1) [§]
	Marsaux, 2015 ¹⁶⁹ (IG3) [§]	Kerr, 2016 ¹⁴⁹ (IG2) [§]	de Vet, 2009 ¹⁰⁸ (IG1)
	Parekh, 2014 ¹⁸¹ (IG1) [§]	Kristal, 2000 ¹⁵⁶ (IG1)	de Vet, 2009 ¹⁰⁸ (IG2)
	Parekh, 2014 ¹⁸¹ (IG2) [§]	Lutz, 1999 ¹⁶² (IG1)	de Vet, 2009 ¹⁰⁸ (IG3)
	Ruffin, 2011 ¹⁸⁹ (IG1) [§]	Lutz, 1999 ¹⁶² (IG2)	Gell, 2015 ¹¹⁹ (IG1) [§]
	Tokunaga-Nakawatase, 2014 ²¹⁰ (IG1) [§]	Lutz, 1999 ¹⁶² (IG3)	Goldstein, 1999 ¹²⁰ (IG1)
		Sacerdote, 2006 ¹⁹⁰ (IG1)	Grandes, 2009 ¹²² (IG1)
			Hellenius, 1993 ¹³⁵ (IG2)
			Lewis, 2013 ¹⁶¹ (IG1) [§]
			Marcus, 2013 ¹⁶⁶ (IG1) [§]
		Marshall, 2003 ¹⁷⁰ (IG1)	
		Napolitano, 2006 ¹⁷⁷ (IG1)	
		Napolitano, 2006 ¹⁷⁷ (IG2)	
		Pekmezi, 2009 ¹⁸⁴ (IG1)	
		Van Hoecke, 2014 ²¹² (IG2) [§]	
		Van Stralen, 2010 ²¹⁴ (IG1) [§]	
		Van Stralen, 2010 ²¹⁴ (IG2) [§]	
		Wadsworth, 2010 ²¹⁹ (IG1) [§]	
High intensity (>360 min)	10 arms (9 trials)	11 arms (10 trials)	5 arms (5 trials)
26 arms (23 trials)	Aldana, 2006 ⁸⁵ (IG1)	Bernstein, 2002 ⁹³ (IG1)	Katz, 2008 ¹⁴⁸ (IG1) [‡]
	Aldana, 2006 ⁸⁵ (IG1)	Brekke, 2005 ⁹⁷ (IG1)	Kinmonth, 2008 ¹⁵⁴ (IG2)
	Bennett, 2013 ⁹¹ (IG1) [§]	Carpenter, 2004 ¹⁰¹ (IG1)	Martinson, 2008 ¹⁷² (IG1)
	Brekke, 2005 ⁹⁷ (IG2)	Coates, 1999 ¹⁰⁶ (IG1)	Stewart, 2001 ²⁰¹ (IG1)
	Hivert, 2007 ⁷² (IG1)	Hinderliter, 2014 ¹³⁷ (IG1) [§]	Thompson, 2014 ²⁰⁸ (IG1) [§]
	Jacobs, 2011 ¹⁴¹ (IG1) [§]	HPT, 1990 ¹⁴⁰ (IG1)	
	King, 2013 ¹⁵² (IG2) [§]	HPT, 1990 ¹⁴⁰ (IG2)	
	King, 2013 ¹⁵² (IG3) [§]	Greenlee, 2015 ¹²⁶ (IG1) [§]	
	Simkin-Silverman, 1995 ¹⁹⁴ (IG1)	Tinker, 2008 ²⁰⁹ (IG1)	
	Taveras, 2011 ²⁰³ (IG1) [§]	TOHP I, 1992 ²⁰⁴ (IG1)	
Thompson, 2008 ²⁰⁷ (IG1)	TOHP II, 1997 ²⁰⁵ (IG1)		

* 25 trials had more than one intervention arm (Aittasalo, Alexander, Brekke, Carpenter, Castro, De Vet, Franko, Harland, Hellenius, HPT, Jeffery, Kerr, King 2007, King 2013, Kinmonth, Lutz, Marcus, Marsaux, Napolitano, Parekh, Springvloed, Van Hoecke, Van Stralen, Vandelotte, Warner).

† Intervention focused on reducing sedentary time (Aadah).

‡ Intervention focused on provider training (Katz and Vrdoljak).

§ Trial identified in update.

Abbreviations: IG=intervention group; min=minute.

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
Aadahl, 2014 ⁸⁰	PA* M	IG1	Counseling	Four 30- to 45-min individual theory-based face-to-face sessions and written materials summarizing the sessions and reiterating key messages.		26	4	40	160	Research clinic	X			X		Research nurse	None
Aittasalo, 2006 ⁸¹	PA L	IG1	Brief counseling	One 5- to 10-min PCP prescription-based counseling session. Optional self-monitoring with PA log and referral to PA expert.		0.14	1	10	10	Primary care	X					PCP	UC
Aittasalo, 2006 ⁸¹	PA L	IG2	Self-monitoring	Pedometer and PA log for self-monitoring and tailored feedback via mail.		1	NA	NA	NA	Primary care				X		NA	UC
Albright, 2014 ⁸³	PA M	IG1	Tailored phone counseling plus web site	17 15-min phone counseling calls plus a tailored web site addressing key mediators of PA.		52	17	15	255	Home		X	X			Health educator/counselor	MI
Aldana, 2006 ⁸⁵	HD+PA H	IG1	Group counseling	16 2-hr group education sessions.	G	4	16	120	1920	NR	X			X	X	Dietetic and medical professional	W
Alexander, 2010 ⁸⁶	HD M	IG1	Tailored web-based + email counseling	4 tailored web sessions and 4 email counseling sessions aimed at increasing fruit and vegetable intake.	F&V	52	8	Web: 30 Email: 15	180	Home			X			Research assistant	MI
Alexander, 2010 ⁸⁶	HD M	IG2	Tailored web-based counseling	4 tailored web sessions (no email sessions) aimed at increasing fruit and vegetable intake.	F&V	52	4	30	120	Home			X			NA	MI

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
Baron, 1990 ⁹⁰	HD M	IG1	Counseling	One 30-min individual or small-group dietary counseling session with 2 followup visits and print materials.	G	12	3	Initial sess: 30 FU sess: NR	60	Primary care	X			X	X	Nurse	UC
Bennett, 2013 ⁹¹	HD+PA H	IG1	Counseling, tailored print materials and self-monitoring	Behavior change goals assigned at baseline and months 2 and 4, with pedometers and logs to track daily activity, brief 5-min weekly calls with interactive phone system, 12 monthly 20-min counseling calls with RD, and 12-month membership to YMCA.	G	52	64	IVR calls: 5 RD calls: 20	500	Primary care	X	X		X		RD	UC
Beresford, 1997 ⁹²	HD L	IG1	Brief counseling and self-help material	Self-help booklet and a 3-min motivational endorsement from PCP.	LF	2	1	3	3	Primary care	X			X		PCP	UC
Bernstein, 2002 ⁹³	HD H	IG1	Home-based education	Home-based nutrition education including 8 home visits, 12 phone calls, and monthly print materials.	F&V	26	20	NR	420	Home	X	X		X		NR	AC
Bickmore, 2013 ⁹⁴	PA M	IG1	Computer-based counseling	Daily 5-min conversations with virtual coach on home computer tablet for 2 months and continued use of electronic counseling interface at clinic kiosk when attending routine		52	61	5	305	Home			X			Computer	MI

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
				appointments over remaining 10 months.													
Brekke, 2005 ⁹⁷	HD H	IG1	Group counseling (diet)	2 60- to 120-min initial group education sessions, 8 followup phone calls in first 4 months, and then every 10 weeks for 2 years.	F&V, LF	104	18	Group sess: 90 Calls: 15	420	NR	X	X			X	Dietician	MI
Brekke, 2005 ⁹⁷	HD+PA H	IG2	Group counseling (diet and PA)	2 60- to 120-min initial group education sessions, 8 followup phone calls in first 4 months, and then every 10 weeks for 2 years.	F&V, LF	104	18	Group sess: 90 Calls: 15	420	NR	X	X			X	Dietician	MI
Bryan, 2013 ⁹⁸	PA L	IG1	Tailored print mailings	14 individually-tailored mailings with information on increasing PA delivered at varying frequencies over 12 months, with self-help manual and series of tip sheets.		52	NA	NA	NA	Home				X		Computer expert system	AC
Burke, 2013 ¹⁰⁰	HD+PA M	IG1	Self-help booklet and phone and email counseling	Booklet designed to motivate and improve PA and nutrition, 6 to 10 phone calls, 2 to 5 email contacts, bimonthly newsletters, resistance band and pedometer.	G	26	8	15	120	Home		X	X	X		Senior university health science student	None

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
Carpenter, 2004 ¹⁰¹	HD H	IG1	Group counseling	20 75-min group counseling sessions.	F&V, LF, S	24	20	75	1500	Research clinic	X			X	X	Research staff	MI
Carpenter, 2004 ¹⁰¹	HD L	IG2	Mailed materials and web site	Mailed curriculum and access to web site for posting questions and weekly online chat session.	F&V, LF, S	24	NA	NA	NA	Home			X	X		NA	MI
Carroll, 2010 ¹⁰²	PA L	IG1	Tailored print mailings	4 tailored feedback reports based on preceding PA survey mailed to participants over 6 months.		26	NA	NA	NA	Home				X		NA	AC
Castro, 2011 ¹⁰³	PA M	IG1	Counseling	1 in-person session with professional followed by 14 phone counseling calls, supplemented with monthly newsletter mailings and tip sheets.		52	15	Initial sess: 30 Calls: 15	240	Home	X	X		X		Professional staff member	AC
Castro, 2011 ¹⁰³	PA M	IG2	Peer counseling	1 in-person session with peer mentor followed by 14 phone counseling calls, supplemented with monthly newsletter mailings and tip sheets.		52	15	Initial sess: 30 Calls: 15	240	Home	X	X		X		Peer mentor	AC
Coates, 1999 ¹⁰⁶	HD H	IG1	Group counseling	Up to 18 group counseling sessions.	LF	52	18	60	1080	Research clinic	X				X	Nutritionist	MI
de Vet, 2009 ¹⁰⁸	PA L	IG1	Self-directed and self-selected activity plan (with repeat planning)	Self-directed written plan for increasing self-selected PA by 2 hr/week, written at 3 different time points over 6 months.		26	NA	NA	NA	Home				X		NA	MI

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
de Vet, 2009 ¹⁰⁸	PA L	IG2	Self-directed and self-selected activity plan (1-time plan)	Self-directed written plan for increasing self-selected PA by 2 hr/week.		26	NA	NA	NA	Home				X		NA	MI
de Vet, 2009 ¹⁰⁸	PA L	IG3	Self-directed walking plan (1-time plan)	Self-directed written plan for increasing walking by 2 hr/week.		26	NA	NA	NA	Home				X		NA	MI
Delichatsios, 2001 ¹⁰⁹	HD M	IG1	Automated phone counseling	26 5- to 7-min calls with an automated phone-linked communication system providing dietary counseling, advice, and feedback over 6 months, with additional written reports to supplement calls.	G	26	26	5	130	Other		X				Expert system with digitized human speech	AC
Elley, 2003 ¹¹¹	PA M	IG1	Counseling with tailored prescription	One 10-min PCP prescription-based counseling session with three 15-min followup phone calls from exercise physiologists over 3 months and 4 newsletters over 12 months.		52	4	Initial sess: 10 Calls: 15	55	Primary care	X	X		X		PCP, Exercise physiologists	UC
Estabrooks, 2011 ¹¹²	PA M	IG1	Group counseling	Two 2-hr group sessions, 1 phone contact, and handouts on how to complete a PA plan.		12	3	Group sess: 120 Calls: 15	255	Research clinic	X	X		X	X	Health educator	MI
Fjeldsoe, 2015 ¹¹³	PA M	IG1	Counseling and regular text messages	1 face-to-face counseling session, 12 weeks of tailored text messages, and 1 followup phone call.		12	2	35	50	Home	X	X	X	X		Behavioral counselor	MI

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
Franko, 2008 ¹¹⁵	HD+PA M	IG1	Web-based intervention + booster session	Two 45-min computer-based interactive sessions plus 1 booster session.	G	5	3	45	135	University computer lab and home			X			Research assistant: oversaw web sessions + answered questions	AC
Franko, 2008 ¹¹⁵	HD+PA M	IG2	Web-based intervention	Two 45-min computer-based interactive sessions.	G	2	2	45	90	University computer lab			X			Research assistant: oversaw web sessions + answered questions	AC
Fries, 2005 ¹¹⁶	HD L	IG1	Tailored print mailing and brief counseling call	1 mailing of individually-tailored fat + fiber feedback with physician endorsement, minimal brief counseling call, and 5 low-literacy self-help booklets.	LF	6	1	NR	15	Home		X		X		Research staff	WL
Gao, 2016 ¹¹⁷	PA M	IG1	Individual counseling and tailored print materials	Initial 60-min counseling session followed by 14 expert computer-tailored print mailings.		52	1	60	60	Home	X		X			PCP, expert computer system	AC
Gell, 2015 ¹¹⁹	PA L	IG1	Targeted text messages	3 targeted text messages per week for 24 weeks plus walking maps and informational web site.		24	NA	NA	NA	Other		X	X			NA	MI
Goldstein, 1999 ¹²⁰	PA L	IG1	Brief counseling with tailored prescription	One 5-min PCP prescription-based counseling session with one 5-min followup session over 4 weeks plus 9 mailings over 26		26	2	5	10	Primary care	X			X		PCP	UC

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
				weeks.													
Grandes, 2009 ¹²²	PA L	IG1	Brief counseling	1 brief (assumed <15 min) counseling session with PCP using web-based software + optional 15-min followup session to develop a prescription-based action plan, plus a 4-page pamphlet.		NR	2	15	30	Primary care	X			X		PCP	UC
Green, 2002 ¹²³	PA M	IG1	Phone counseling	Mailed self-help workbook and three 20- to 30-min counseling phone calls. [†]		12	3	25	75	Home		X		X		Behavioral health specialists	MI
Greene, 2008 ¹²⁵	HD M	IG1	Tailored print mailings and counseling phone calls	12 monthly tailored mailings and three 15-min coaching phone calls.	F&V	52	3	15	45	Home		X		X		Counselor, Computer expert system	AC
Greenlee, 2015 ¹²⁶	HD H	IG	Group counseling	Nine 1.5- to 3.5-hr group sessions.	F&V, L	12	9	160	1440	Research clinic	X			X	X	Registered dietitian	MI
Halbert, 2000 ¹²⁸	PA M	IG1	Counseling	One 20-min counseling session and print materials on increasing PA at initial visit and two 15-min followup visits.		26	3	20	50	Primary care	X			X		Exercise physiologist	AC
Hargreaves, 2016 ¹³⁰	PA M	IG1	Tailored walking program	Tailored pedometer- and web-based walking program.		12	13	Initial sess: 30 Web sess: 10	150	Home	X		X			NR	MI
Harland, 1999 ¹³¹	PA M	IG1	Counseling and PA vouchers	1 brief informational and advice session followed by six 40-min motivational interviews plus 30 vouchers for PA		12	7	Initial sess: 15 MI: 40	255	Primary care	X			X		Health visitor	MI

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Harland, 1999 ¹³¹	PA M	IG2	Counseling	1 brief informational and advice session followed by six 40-min motivational interviews.		12	7	Initial sess: 15 MI: 40	255	Primary care	X			X		Health visitor	MI
Harland, 1999 ¹³¹	PA M	IG3	Brief counseling and PA vouchers	1 brief informational and advice session followed by one 40-min motivational interview plus 30 vouchers for PA facilities.		2	2	Initial sess: 15 MI: 40	55	Primary care	X			X		Health visitor	MI
Harland, 1999 ¹³¹	PA M	IG4	Brief counseling	1 brief informational and advice session followed by one 40-min motivational interview.		2	2	Initial sess: 15 MI: 40	55	Primary care	X			X		Health visitor	MI
Harris, 2015 ¹³²	PA M	IG1	Counseling and self-monitoring	1 initial 45-min PA consultation session followed by three 30-min sessions with pedometers, accelerometers, and a PA log to track activity.		52	4	Initial sess: 45 FU sess: 30	135	Primary care	X					Nurse	UC
Hellenius, 1993 ¹³⁵	HD M	IG1	Counseling (diet)	1 dietary advice session with physician (assumed 30-min) followed by 1 advice session 2 weeks later with dietitian.	G	2	2	30	60	Primary care	X			X		PCP, Dietician	UC
Hellenius, 1993 ¹³⁵	PA L	IG2	Brief counseling (PA)	1 PA advice session with physician (assumed 30-min).		0.14	1	30	30	Primary care	X					PCP	UC
Hellenius, 1993 ¹³⁵	HD+PA M	IG3	Counseling (diet + PA)	1 dietary and PA advice session with physician (assumed 30-min) followed by 1 advice session 2 weeks later with	G	2	2	30	60	Primary care	X					Dietician, PCP	UC

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Hinderliter, 2014 ¹³⁷	HD H	IG1	Group counseling on DASH diet	2 weeks of a DASH-controlled feeding period with 4 counseling sessions followed by 14 weekly 30- to 45-min small group sessions with nutritionist; participants were asked not to exercise or attempt to lose weight.	G	16	18	Indiv sess: NR Group sess: 30-45	620	Research clinic	X				X	Nutritionist	MI
Hivert, 2007 ⁷²	HD+PA H	IG1	Group counseling	23 45-min small-group interactive seminars over 2 years.	G	104	23	45	1035	Other	X				X	Endocrinology resident and physical education graduate student	None
HPT, 1990 ¹⁴⁰	HD H	IG1	Group counseling (potassium and sodium focus)	12 weekly 60-min group counseling sessions in first 4 months followed by 16 group counseling sessions for up to 3 years in maintenance phase to increase potassium and reduce sodium intake.	S	156	28	60	1680	Research clinic	X	X		X	X	Nutritionists and behavioral specialists	None
HPT, 1990 ¹⁴⁰	HD H	IG2	Group counseling (sodium focus)	12 weekly 60-min group counseling sessions in first 4 months followed by 16 group counseling sessions for up to 3 years in maintenance phase to reduce sodium intake (potassium intake not	S	156	28	60	1680	Research clinic	X	X		X	X	Nutritionists and behavioral specialists	None

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Jacobs, 2011 ¹⁴¹	HD+PA H	IG1	Counseling	discussed) Received individually tailored PA + diet counseling via delivery mode of participant's choice, including email, phone, or face-to-face sessions over 1 year.	LF	52	15	30	380 [‡]	Research clinic	X	X	X			Health psychologist	UC
Jeffery, 1999 ¹⁴³	HD+PA L	IG1	Nontailored print mailings	36 monthly newsletters mailed to encourage paying attention to weight, diet, and exercise habits plus optional intervention sessions every 6 months up to 3 years.	F&V, LF	156	NA	NA	NA	Home				X		NA	None
Jeffery, 1999 ¹⁴³	HD+PA L	IG2	Nontailored print mailings plus incentives	36 monthly newsletters mailed to encourage paying attention to weight, diet, and exercise habits plus optional intervention sessions every 6 months up to 3 years, plus an incentive lottery to encourage reading the newsletters.	F&V, LF	156	NA	NA	NA	Home				X		NA	None
John, 2002 ¹⁴⁴	HD M	IG1	Counseling	One 25-min counseling session and one 15-min followup call to encourage increased consumption of fruits and vegetables and recipe book,	F&V	12	2	25	40	Research clinic	X	X		X		Research nurse	WL

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				portion guide, and record book.													
Kallings, 2009 ¹⁴⁶	PA M	IG1	Counseling with tailored prescription	Two 30-min individualized patient-centered counseling sessions and PA prescriptions delivered at baseline and 6 months, with one 60-min group session at 1 month focused on PA and health and 3 to 5 short followup calls.		NR	3	Individ sess: 30 Group sess: 60	120	Primary care	X			X	X	Health care professional, PCP	UC
Kattelmann, 2014 ¹⁴⁷	HD+PA M	IG1	Web-based intervention	Tailored emails 4 times per week plus weekly web-based sessions.	F&V	64	21	NR	150	Home			X			NA	WL
Katz, 2008 ¹⁴⁸	PA H	IG1	Provider training	Physicians participated in 5 interactive group sessions and were trained in how to apply the Pressure System Model to overcome common PA barriers, identify opportunities for PA, and specify a plan for followup during existing appointments.		26	5	75	375	Primary care	X					PA and preventive medicine specialist	UC
Kerr, 2016 ¹⁴⁹	HD L	IG1	Tailored text messages (with booster messages)	2 tailored text messages over 1 week and weekly text messages for 6 months.	F&V	24	32	NR	30	Other			X			NA	None
Kerr, 2016 ¹⁴⁹	HD L	IG2	Tailored text messages	2 tailored text messages.	F&V	1	2	NR	2	Other			X			NA	None

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King, 2007 ¹⁵³	PA M	IG1	Automated phone counseling	Initial 30- to 40-min individualized session with health educator, 15 brief individualized structured calls with automated phone-linked counseling system biweekly and then monthly over 1 year, pedometer and PA log to track activity and allow feedback on progress, and supplemental mailings.		52	16	Initial sess: 35 Calls: 15	260	Home	X	X		X		Health educator	AC
King, 2007 ¹⁵³	PA M	IG2	Human phone counseling	Initial 30- to 40-min individualized session with health educator, 15 brief individualized structured calls with health educator biweekly and then monthly over 1 year, pedometer and PA log to track activity and allow feedback on progress, and supplemental mailings.		52	16	Initial sess: 35 Calls: 15	260	Home	X	X		X		Health educator	AC
King, 2013 ¹⁵²	HD+PA M	IG1	Phone counseling with self-monitoring (PA + diet together)	1 individual in-person session followed by 15 30- to 40-min phone counseling sessions. PA + diet were addressed simultaneously, half of each call covered each topic;	F&V, LF	52	15	20	300 ^s	Home	X	X		X		Health educator	AC

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				supplemental mailings and homework and pedometer for logging and reporting progress.													
King, 2013 ¹⁵²	HD+PA H	IG2	Phone counseling with self-monitoring (diet discussions first)	1 individual in-person session followed by 21 phone sessions; topics introduced sequentially, beginning with diet for first 4 months, then both PA + diet in the remaining 8 months; supplemental mailings and homework and pedometer for logging and reporting progress.	F&V, LF	52	21	20	420 [¶]	Home	X	X		X		Health educator	AC
King, 2013 ¹⁵²	HD+PA H	IG3	Phone counseling with self-monitoring (PA discussions first)	1 individual in-person session followed by 21 phone sessions; topics introduced sequentially, beginning with PA for first 4 months, then both PA + diet in the remaining 8 months; supplemental mailings and homework and pedometer for logging and reporting progress.	F&V, LF	52	21	20	420 [¶]	Home	X	X		X		Health educator	AC

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Kinmonth, 2008 ¹⁵⁴	PA M	IG1	Phone counseling	Initial in-home PA counseling session followed by four 45-min support calls and two 15-min support calls over 5-month intensive phase, followed by 7 monthly mailings.		52	7	Initial sess: 30 Calls: 45 FU calls: 15	240	Home	X	X		X		Trained facilitators from a range of health professions	MI
Kinmonth, 2008 ¹⁵⁴	PA H	IG2	In-home counseling	Initial in-home PA counseling session followed by four 60-min in-home visits and two 15-min support calls over 5-month intensive phase, followed by seven 30-min monthly followup phone calls.		52	14	Initial sess: 30 Home visit: 60 Support call: 15 FU call: 30	510	Home	X	X		X		Trained facilitators from a range of health professions	MI
Kolt, 2007 ¹⁵⁵	PA M	IG1	Phone counseling	Eight 10- to 16-min phone counseling sessions occurring weekly for 4 weeks and biweekly for 8 weeks focused on stages of behavior change in relation to increasing PA, and supplementary mailings, including an exercise log and informational pamphlets.		12	8	15	120	Home		X		X		Exercise counselor	None
Kristal, 2000 ¹⁵⁶	HD L	IG1	Tailored print mailings and counseling call	Tailored self-help dietary materials and 1 followup call focused on lowered fat intake and increased fruit and vegetable intake.	F&V, LF	52	1	15	15	Home		X		X		Health educator	None

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Lawton, 2008 ¹⁶⁰	PA M	IG1	Counseling with tailored prescription	Brief 10-min session with primary care nurse plus green prescription to increase PA, followed by five 15-min followup calls over 9 months and one 30-min followup visit.		38	7	Initial sess: 10 FU calls: 15 FU sess: 30	115	Primary care	X	X				Primary care nurse	UC
Lewis, 2013 ¹⁶¹	PA L	IG1	Tailored print mailings	11 individually-tailored PA print mailings plus stage-matched manuals, tip sheets, and PA logs.		26	NA	NA	NA	Home				X		Computer expert system	AC
Lutz, 1999 ¹⁶²	HD L	IG1	Tailored print mailings with tailored prescription	Tailored nutrition newsletters and tailored goal-setting information for increasing fruit and vegetable intake.	F&V	16	NA	NA	NA	Home				X		Computer expert system	None
Lutz, 1999 ¹⁶²	HD L	IG2	Tailored print mailings	Tailored newsletters with nutrition information for increasing fruit and vegetable intake (no tailored goal-setting).	F&V	16	NA	NA	NA	Home				X		Computer expert system	None
Lutz, 1999 ¹⁶²	HD L	IG3	Nontailored print mailings	Nontailored newsletters about increasing fruit and vegetable intake (no tailored newsletters or tailored goal-setting).	F&V	16	NA	NA	NA	Home				X		NA	None
Mailey, 2014 ¹⁶⁴	PA	IG1	Group counseling	Two 90- to 120-min group counseling sessions, one 60-min personal training session, and five 5-min		26	7	Group: 105 Trainer: 60 Calls: 5	295	NR	X	X			X	Research staff	WL

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				followup phone calls.													
Marcus, 2007 ¹⁶⁷	PA M	IG1	Phone counseling	Initial 45-min session followed by fourteen 13-min phone calls at decreasing frequency over 12 months and supplemented with a monthly PA log and brief questionnaire.		52	14	10	185	Home		X				Health educator	AC
Marcus, 2007 ¹⁶⁷	PA M	IG2	Tailored print materials	Initial 45-min session followed by fourteen individually-tailored printed reports with decreasing frequency over 12 months and supplemented with a monthly PA log and brief questionnaire.		52	1	45	45	Home				X		Computer expert system	AC
Marcus, 2013 ¹⁶⁶	PA L	IG1	Tailored print mailings and self-monitoring	14 culturally adapted, Spanish-language, individually-tailored PA print mailings and pedometers and PA logs for self-monitoring.		52	NA	NA	NA	Home				X		Computer expert system	AC
Marsaux, 2015 ¹⁶⁹	HD+PA L	IG1	Tailored web-based advice (diet, PA, and phenotype)	Tailored web-based advice based on diet, PA, and phenotype.	F&V	26	NR	NR	NA	NR			X			NA	MI
Marsaux, 2015 ¹⁶⁹	HD+PA L	IG2	Tailored web-based advice (diet + PA)	Tailored web-based advice based on diet and PA.	F&V	26	NR	NR	NA	NR			X			NA	MI

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Marsaux, 2015 ¹⁶⁹	HD+PA L	IG3	Tailored web-based advice (diet, PA, phenotype, and genotype)	Tailored web-based advice based on diet, PA, phenotype, and genotype.	F&V	26	NR	NR	NA	NR			X			NA	MI
Marshall, 2003 ¹⁷⁰	PA L	IG1	Tailored print mailing	1-time mailing of letter tailored to individual stage of change and Active Living booklets corresponding to stage of change, and additional booklets aimed at higher stages of change.		0.14	NA	NA	NA	Home				X		NA	None
Martinson, 2008 ¹⁷²	PA H	IG1	Counseling	One 60-min in-person group orientation session, followed by seven 20-min individualized sessions occurring twice a month with activity coach, and monthly followup calls for 8 months and bimonthly for subsequent year. Additional materials included a PA log, course workbook, and pedometer, with optional library of PA informational resources and 4 in-person support sessions held over 2-year intervention period.		104	26	Initial group sess: 60 Indiv sess: 20 Calls: 20	450	Home		X		X		Activity coaches	MI

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Mosca, 2008 ¹⁷⁶	HD+PA M	IG1	Counseling	Five 30- to 60-min individual education and lifestyle counseling sessions to reduce LDL-C and change diet, lifestyle, and other CVD risk factors.	G	38	5	45	225	Research clinic	X	X		X		Health educator, registered dietitian, + physician specializing in CVD prevention	MI
Napolitano, 2006	PA L	IG1	Tailored print mailings	4 individually-tailored feedback letters based on PA readiness plus 1 stage-matched booklet and letter explaining how to use materials.		26	NA	NA	NA	Home				X		Computer expert system	AC
Napolitano, 2006	PA L	IG2	Nontailored print mailings	1-time mailing of AHA Choose to Move booklet and letter explaining how to use materials.		12	NA	NA	NA	Home				X		NA	AC
Norris, 2000	PA M	IG1	Counseling	1-time individually-tailored counseling session with PCP based on PACE questionnaire responses and relevant to stage of change, followed by ≥1 followup calls and optional 1-time educational mailing.		20	4	Initial sess: 30 FU calls: 15	60	Primary care	X	X		X		PCP	UC
Parekh, 2014	HD+PA L	IG1	Computer-tailored print mailings (2 contacts)	2 mailed personalized, computer-tailored feedback letters and health promotion information sheets at baseline and 3 months.	F&V, LF	12	NA	NA	NA	Home				X		Computer expert system	AC

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Parekh, 2014	HD+PA	IG2	Computer-tailored print mailing (1 contact)	1 mailed personalized, computer-tailored feedback letter and health promotion information sheets at baseline.	F&V, LF	0.14	NA	NA	NA	Home				X		Computer expert system	AC
Pekmezi, 2009	PA L	IG1	Tailored print mailings and self-monitoring	6 monthly mailings of individually-tailored PA manuals on increasing PA, with activity logs and pedometers to track and monitor progress toward PA goals, plus tip sheets on related topics.		26	NA	NA	NA	Home				X		NA	AC
Pinto, 2002 ¹⁸⁵	PA M	IG1	Automated phone counseling	Weekly 10-min counseling calls with phone-linked communication system for 12 weeks and then biweekly for 3 months, and 7 monthly reports providing feedback and advice toward PA goals, with activity logs and pedometers to track and monitor progress.		26	18	10	180	Other		X				Expert system with digitized human speech	AC
Pinto, 2005 ¹⁸⁶	PA M	IG1	Counseling with tailored prescription	Three 30- to 40-min face-to-face counseling sessions in first 3 months, with twelve 10- to 15-min counseling phone calls weekly for 3 months and then biweekly for 3 months, and 12 tip		26	15	Individ sess: 35 Calls: 15	285	Primary care	X	X		X		PCP, Health educator	MI

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				sheets mailed at same time phone calls occurred.													
Roderick, 1997 ¹⁸⁸	HD M	IG1	Counseling	1 dietary advice session (assumed 30-min) and 1 followup session aimed at changing serum cholesterol, weight, and diet plus print materials.	G	5	2	30	60	Primary care	X					Research nurse	MI
Ruffin, 2011 ¹⁸⁹	HD+PA L	IG1	Computer-tailored web-based intervention	Family Healthware tool and surveys completed online that provided personalized familial risk assessment and tailored prevention messages via computer or print. Could be completed in 1 or multiple sessions (assumed 30 min total).	F&V	26	1	NR	30	Home			X	X		Computer expert system	UC
Sacerdote, 2006 ¹⁹⁰	HD L	IG1	Brief counseling	One 15-min counseling session with PCP to encourage increased fruit and vegetable intake and improve dietary habits.	G	1	1	15	15	Primary care	X			X		PCP	UC
Simkin-Silverman, 1995 ¹⁹⁴	HD+PA H	IG1	Group counseling	15 group sessions (assumed 60-min) over 20 weeks followed by 6 booster group sessions. Then contacted via group, mail, and phone on average every 2 to 3 months over 4.5	G	234	21	60	1260	Other	X	X		X	X	Behavioral and nutritional intervention-ists	None

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Smith, 2014 ¹⁹⁷	HD+PA M	IG1	Counseling	Two 60-min face-to-face counseling sessions and 1 phone session in first month followed by 4 monthly booster calls and text messages in months 2 through 6.	G	26	7	Individ sess: 60 Calls: 5 min	145	Research clinic	X	X				NR	None
Springvloed, 2015 ¹⁹⁸	HD M	IG1	Web-based tailored education plus feedback	4 web-based, tailored nutrition modules plus environmental-level feedback on the availability and prices of healthy foods nearby.	F&V, L	6	12	15	180	Home			X			NA	MI
Springvloed, 2015 ¹⁹⁸	HD M	IG2	Web-based tailored education	4 web-based computer-tailored nutrition education modules.	F&V, L	6	12	15	180	Home			X			NA	MI
Stewart, 2001 ²⁰¹	PA H	IG1	Group counseling	1 group informational meeting, 1 individual planning session, and 10 monthly group workshops, with PA diaries, monthly newsletters, functional fitness assessments, and 2 booklets focused on PA and benefits of PA.		52	12	NR	690	Research clinic	X	X		X	X	Program staff	WL

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Taveras 2011 ²⁰³	HD+PA H	IG1	Postpartum counseling	5 brief sessions (assumed 15-min) with pediatric PCP, four 15- to 20-min individualized sessions with health educator at 3, 6, 12, and 20 weeks postpartum, invitation to 4 group sessions, and comprehensive educational materials delivered over 6 months.	G	26	13	Brief sess: 15 Calls: 15 Group sess: 60	375	Primary care	X	X		X	X	PCP, Health educator	UC
Thompson, 2008 ²⁰⁷	HD+PA H	IG1	Group counseling	5 monthly 2- to 2.5-hr group sessions on decreasing dietary fat, increasing fruit and vegetable intake, and increasing PA.	F&V, LF	20	5	135	675	NR	X			X	X	American Indian health educators	WL
Thompson, 2014 ²⁰⁸	PA H	IG1	Counseling and self-monitoring	Participants wore Fitbit accelerometers for 24 weeks with feedback from the device and 24 weekly counseling calls, with 3 face-to-face counseling sessions with a counselor every 2 months.		24	27	Calls: 15 Indiv sess: 30	450	Home	X	X				Counselor	WL
Tinker, 2008 ²⁰⁹	HD H	IG1	Group counseling	18 group sessions (assumed 60-min) and 1 individual session during first year focused on decreasing fat and increasing fruit and vegetable intake, followed by up to 20	F&V, LF	312	39	60	2310	Research clinic	X				X	Nutritionist and peers (optional)	MI

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				group sessions, including optional peer-led sessions, over 6 years.													
TOHP I, 1992 ²⁰⁴	HD H	IG1	Group counseling	Ten 90-min initial sessions (8 group and 2 individual) in first 3 months and subsequent monthly in-person group or individual meetings up to 1.5 years.	S	78	26	90	2340	Research clinic	X	X		X	X	Nutritionist, psychologist, or experienced counselor	None
TOHP II, 1997 ²⁰⁵	HD H	IG1	Group counseling	Ten 60- to 90-min individual and group counseling sessions in first 3 months and subsequent monthly meetings for 4 months and 3 to 6 refresher sessions over up to 3 years.	S	156	20	75	1500	Research clinic	X	X			X	Centrally trained staff (dietitians, psychologist or health counselors)	None
Tokunaga-Nakawatase, 2014 ²¹⁰	HD+PA L	IG1	Computer-tailored print mailings	3 computer-tailored print mailings with dietary and PA recommendations.	G	26	NA	NA	NA	Home			X	X		Computer expert system	UC
Valve, 2013 ²¹¹	HD+PA M	IG1	Counseling	1 initial 20-min counseling session with 3 to 5 followup sessions plus print materials.	G	104	5	20	100	NR	X			X		Research nurse	None
Van Hoecke, 2014 ²¹²	PA M	IG1	Counseling	One 60-min PA coaching session and six 30-min booster contacts or phone calls.		10	7	Initial sess: 60 FU sess: 30	240	NR	X	X		X		Coach	MI
Van Hoecke, 2014 ²¹²	PA L	IG2	Tailored prescription	One 15-min contact with coach, self-help booklet, and individualized, written walking program.		10	1	15	15	NR	X			X		Coach	MI

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
Van Stralen, 2010 ²¹⁴	PA L	IG1	Tailored print mailings with environmental focus	3 mailed computer-tailored letters targeting psychosocial and environmental mediators of PA, plus web site access to induce changes in PA.		14	NA	NA	NA	Home			X	X		Computer expert system	WL
Van Stralen, 2010 ²¹⁴	PA L	IG2	Tailored print mailings	3 mailed computer-tailored letters targeting psychosocial mediators to induce changes in PA.		14	NA	NA	NA	Home				X		Computer expert system	WL
Vandelanotte, 2005 ²¹⁷	HD+PA M	IG1	Computer-based sessions with tailored feedback (PA + diet together)	One 100-min session completing 2 computer-tailored interventions.	LF	0.14	1	100	100	Research clinic			X			Computer	WL
Vandelanotte, 2005 ²¹⁷	HD+PA M	IG2	Computer-based sessions with tailored feedback (PA first)	Two 50-min individual interactive computer-tailored intervention sessions (PA first, diet second).	LF	12	2	50	100	Research clinic			X			Computer	WL
Vandelanotte, 2005 ²¹⁷	HD+PA M	IG3	Computer-based sessions with tailored feedback (diet first)	Two 50-min individual interactive computer-tailored intervention sessions (diet first, PA second).	LF	12	2	50	100	Research clinic			X			Computer	WL
Vrdoljak, 2013 ²¹⁸	HD+PA M	IG1	Provider training	Provider training (assumed two 60-min sessions) on counseling patients on healthy lifestyle over 1 year with use of intervention booklet, patient	G	52	2	60	120	Primary care	X				X	NR	None

Table 4. Intervention Characteristics for All Studies, by Author

Author, year	Int focus Intensity	Grp	Name	Brief description	Diet focus	Dur (wks)	No. sess	Length sess (min)	Est total intensity (min)	Setting	In person	Phone	Elec	Print	Grp sess	Provider	CG
				education flyers, and protocol monitoring.													
Wadsworth, 2010 ²¹⁹	PA L	IG1	Web-based intervention	1 orientation session, 6 weekly emails, web site, access to an e-counselor, and access to computer-mediated exercise materials and 4 monthly booster emails.		26	1	30	30	Other	X		X	X		Exercise physiologist	MI
Warner, 2016 ²²⁰	PA M	IG1	Group counseling with views-on-aging component	One 2.75-hr group session focused on increasing PA plus focus on aging.		0.14	1	166	166	NR	X				X	Psychologist	AC
Warner, 2016 ²²⁰	PA M	IG2	Group counseling	One 2.75-hr group session focused on increasing PA.		0.14	1	170	170	NR	X				X	Psychologist	AC

* Intervention focused on reducing sedentary time.

† Only 38% of IG received the intervention as planned.

‡ Weighted mean intensity based on self-selected dose of intervention.

§ Actual=244 mins.

|| Actual=278 mins.

¶ Actual=270 mins.

Abbreviations: AC=attention control; AHA=American Heart Association; CG=control group; CVD=cardiovascular disease; Dur=duration; Elec=electronic; Est=estimated; FU=followup; Grp=group; H=high; HD=healthful diet; hr=hour; IG=intervention group; Indiv=individual; Int=intervention; IVR=interactive voice response; L=low; LDL-C=low-density lipoprotein cholesterol; LF=low fat; M=medium; MI=motivational interviewing; min=minute; NR=not reported; PA=physical activity; PACE=Physician-based Assessment & Counseling for Exercise; PCP=primary care provider; RD=registered dietician; SD=standard deviation; sess=session; UC=usual care; YMCA=Young Men's Christian Association.

Table 5. Pooled Results of Intermediate Outcomes for All Interventions and by Intervention Intensity

Outcome	All interventions			High-intensity interventions (>360 min)			Medium-intensity interventions (31-360 min)			Low-intensity interventions (≤30 min)		
	Mean difference in change (95% CI)	Trials, k	I ² , %	Mean difference in change (95% CI)	Trials, k	I ² , %	Mean difference in change (95% CI)	Trials, k	I ² , %	Mean difference in change (95% CI)	Trials, k	I ² , %
SBP, mm Hg	-1.26 (-1.77 to -0.75)	22	44.5	-1.55 (-2.21 to -0.89)	12	48.1	-1.10 (-2.38 to 0.15)	8	48.7	-0.12 (-1.08 to 0.84)	2	0
DBP, mm Hg	-0.49 (-0.82 to -0.16)	23	37.9	-0.67 (-0.98 to -0.37)	12	17.5	-0.57 (-1.24 to 0.10)	9	8.5	0.41 (-0.16 to 0.98)	2	0
Low-density lipoprotein cholesterol, mg/dL*	-2.58 (-4.30 to -0.85)	13	19.6	-4.51 (-6.85 to -2.16)	6	0	-1.70 (-4.64 to 1.24)	6	5.0	-0.91 (-2.90 to 1.08)	1	--
Total cholesterol, mg/dL*	-2.85 (-4.95 to -0.75)	19	50.8	-5.32 (-8.84 to -1.81)	7	36.7	-1.64 (-3.76 to 0.48)	11	13.8	0.87 (-1.44 to 3.18)	1	--
High-density lipoprotein cholesterol, mg/dL*	-0.17 (-1.05 to 0.71)	15	55.2	-0.54 (-2.08 to 1.00)	7	63.4	0.03 (-0.92 to 0.97)	7	0	0.94 (0.08 to 1.80)	1	--
Triglycerides, mg/dL [†]	-1.82 (-5.05 to 1.42)	13	4.7	-3.43 (-8.16 to 1.31)	7	0	-4.34 (-11.80 to 3.12)	5	5.8	1.23 (-3.37 to 5.83)	1	--
Fasting glucose, mg/dL [‡]	-0.36 (-1.22 to 0.5)	13	42.4	-1.35 (-2.24 to -0.45)	7	0	0.38 (-1.30 to 2.06)	5	54.7	0.52 (-0.61 to 1.65)	1	--
BMI, kg/m ²	-0.41 (-0.62 to -0.19)	20	95.8	-0.81 (-0.99 to -0.63)	9	73.8	-0.19 (-0.42 to 0.04)	7	76.4	-0.05 (-0.39 to 0.28)	4	85.6
Weight, kg [§]	-1.04 (-1.56 to -0.51)	20	92.4	-1.62 (-2.31 to -0.93)	11	92.5	-0.44 (-0.82 to -0.06)	7	40.5	-0.23 (-1.56 to 0.40)	2	0
Waist circumference, cm	-1.19 (-1.79 to -0.59)	17	91.8	-1.92 (-2.66 to -1.17)	9	82.1	-0.77 (-1.63 to 0.09)	7	79.0	0.04 (-0.27 to 0.35)	1	--

* To convert mg/dL to mmol/L, multiply by 0.0259.

† To convert mg/dL to mmol/L, multiply by 0.0113.

‡ To convert mg/dL to mmol/L, multiply by 0.0555.

§ To convert kg to lb, multiply by 2.205.

|| To convert cm to in, multiply by 0.394.

Abbreviations: BMI=body mass index; CI=confidence interval; DBP=diastolic blood pressure; min=minute(s); SBP=systolic blood pressure.

Table 6. Results of Behavioral Outcomes for All Interventions

Outcome	Mean difference in change (95% CI)*	Trials, k	I ² , %
Total energy (kcal/day) [†]	Range: 65 to -500	11	NA
Fat (% of energy from fat)	Range: 0.8 to -11.0	23 [‡]	NA
Saturated fat (% of energy from fat)	Range: -0.3 to 4.1	15 [§]	NA
Fruits and vegetables (servings/day)	Range: -0.2 to 2.2	26	NA
Fiber (g/day)	Range: 1 to 2.5	11 [¶]	NA
Sodium (mg/day)	Range: -380 to -1380	6	NA
Physical activity (standardized mean difference)	0.20 (0.14 to 0.26)	46	60.2
Physical activity (min/week)	34.5 (22.0 to 47.0)	27	67.7
Meeting physical activity recommendations	1.32 (1.12 to 1.56) [#]	16	70.3

* Pooled results for dietary outcomes are not presented given considerable statistical heterogeneity in all analyses ($I^2 > 88\%$). Instead, we present the range of between-group differences observed in trials reporting each respective outcome.

[†] To convert kcal to kJ, multiply by 0.239.

[‡] 15/23 trials reported daily percent of energy from fat.

[§] 9/15 trials reported daily percent of energy from saturated fat.

^{||} 20/26 trials reported servings/day.

[¶] 6/11 trials reported g/day.

[#] Odds ratio (95% CI).

Abbreviations: CI=confidence interval; min=minute; NA=not applicable.

Table 7. Summary of Findings Across Intermediate and Behavioral Outcomes, by Author

Author, Year	Int focus	KQ 2: Intermediate outcomes											KQ 3: Behavioral outcomes	
		SBP	DBP	LDL-C	TC	HDL-C	TG	Glucose	BMI	Weight	WC	CVD Risk	Diet*	PA
Aadahl, 2014 ⁸⁰	PA			↑	↑	↔	↑	↔		↑	↑↑		NA	↑↑ [†]
Aldana, 2006 ⁸¹	HD+PA	↑	↑	↑	↑	↓	↑	↑	↑↑	↑↑			↑↑	↑↑
Baron, 1990 ⁹⁰	HD			↔	↔	↔							↑↑	NA
Bennett, 2013 ⁹¹	HD+PA	↔	↑	↑	↑	↔	↓	↓	↑↑	↑↑	↑			
Brekke, 2005 ⁹⁷	HD+PA			↑	↓	↓↓	↓	↑	↑↑	↑↑	↑		↑↑	↑ ^{‡§}
Bryan, 2013 ⁹⁸	PA								↓				NA	↑↑
Coates, 1999 ¹⁰⁶	HD	↑↑	↔					↑	↑↑	↑↑	↑↑		↑↑	NA
Elley, 2003 ¹¹¹	PA	↑	↑		↔				↔			↑	NA	↑↑
Grandes, 2009 ¹²²	PA	↔	↓	↑	↔	↑↑	↓	↔	↔		↔	↑	NA	↑↑
Greenlee, 2015 ¹²⁶	HD							↑	↑	↑			↑↑	NA
Hargreaves, 2016 ¹³⁰	PA		↑		↑								NA	↑↑
Hellenius, 1993 ¹³⁵	HD+PA	↑	↑	↑	↑	↔	↑		↑↑		↑↑	↑	↔	↑↑
Hinderliter, 2014 ¹³⁷	HD	↑↑	↓										↑↑	NA
Hivert, 2007 ⁷²	HD+PA	↑	↓	↑	↑	-	↑↑		↑↑	↑↑	↑		↔	↑
HPT, 1990 ¹⁴⁰	HD	↑	↑							↔			↑↑	NA
Jeffery, 1999 ¹⁴³	HD+PA								↔	↔			↔	↔
John, 2002 ¹⁴⁴	HD	↑↑	↑↑		↔				↔				↑↑	NA
Kallings, 2009 ¹⁴⁶	PA	↓	↓	↑	↑	↔	↑	↑	↑↑	↑↑	↑		NA	↑↑
Kattelman, 2014 ¹⁴⁷	HD+PA								↑	↑	↔		↑↑	↔
Kerr, 2016 ¹⁴⁹	HD								↑	↑			↔	NA
Kinmonth, 2008 ¹⁵⁴	PA	↔	↓	↓	↓	↓	↓	↓↓	↓	↓	↓		NA	↔
Kristal, 2000 ¹⁵⁶	HD									↑‡			↑↑	NA
Lawton, 2008 ¹⁶⁰	PA	↑	↔		↑	↔		↔		↑	↑		NA	↑↑ [§]
Mosca, 2008 ¹⁷⁶	HD+PA	↔	↑	↔	↓	↑	↑	↔	↔		↔	↑	↔	↑
Roderick, 1997 ¹⁸⁸	HD	↑	↔		↑↑				↔	↑↑			↑↑	NA
Sacerdote, 2006 ¹⁹⁰	HD	↔	↔						↑↑	↑↑			↑↑	NA
Simkin-Silverman, 1995 ¹⁹⁴	HD+PA	↑↑	↑	↑↑	↑↑	↓↓	↑↑	↑↑	↑↑	↑↑	↑↑		↑↑	↑↑
Thompson, 2008 ²⁰⁷	HD+PA	↑	↔	↔	↔	↔	↔	↔	↑	↔‡	↑		↔	↑
Thompson, 2014 ²⁰⁸	PA	↑	↑		↑	↓	↓	↓		↔	↔		NA	↑
Tinker, 2008 ²⁰⁹	HD	↑↑	↑↑						↑↑	↑↑	↑↑		↑↑	NA
TOHP I, 1992 ²⁰⁴	HD	↑↑	↑↑							↑ [‡]			↑↑	NA
TOHP II, 1997 ²⁰⁵	HD	↑↑	↑↑							↔			↑↑	NA
Valve, 2013 ²¹¹	HD+PA								↔ [‡]					
Wadsworth, 2010 ²¹⁹	PA								↓ [‡]				NA	↑

Symbol Legend:

↑↑ = Statistically significant between-group difference in favor of intervention group.

↑ = Between-group difference in favor of intervention group, but not statistically significantly different.

↔ = No clear between-group difference. For blood pressure, between-group change <0.5 mm Hg. For cholesterol and glucose, between-group change of <1.0 mg/dL. For BMI, between-group change of <0.25 kg/m². For weight and waist circumference, between-group change of <0.5 kg or cm, respectively. For dietary outcomes, total energy intake <100 kcal/day, percent energy from total fat and saturated fat <1%, fiber <0.10 standardized mean difference, and fruits and vegetables <0.5 serving/day. For physical activity, standardized mean difference <0.10.

Table 7. Summary of Findings Across Intermediate and Behavioral Outcomes, by Author

↓ = Between-group difference in favor of control group, not statistically significantly different.

↓↓ = Statistically significant between-group difference in favor of control group.

* For majority of reported dietary outcomes. See Appendix F Table 7 for detailed dietary outcome results.

† Self-reported sitting time.

‡ Not included in meta-analysis.

§ For percent meeting physical activity recommendations.

Abbreviations: BMI=body mass index; CVD=cardiovascular disease; CVD risk=Multivariate risk status; DBP=diastolic blood pressure; HD=healthful diet; HD+PA=healthful diet and physical activity; HDL-C=high-density lipoprotein cholesterol; Int=intervention; KQ=key question; LDL-C=low-density lipoprotein cholesterol; PA=physical activity; NA=not applicable; SBP=systolic blood pressure; TC=total cholesterol; TG=triglycerides; WC=waist circumference.

Table 8. Summary of Evidence, by Key Question

No. of RCTs (k), No. of obs (n)	Summary of findings by outcome	Consistency/precision	Reporting bias	Study quality	Body of evidence limitations	EPC assessment of strength of evidence	Applicability
KQ 1. Health outcomes							
k=12 n=58,848 (2/12 trials identified in update; both new studies reported QOL outcomes)	No difference in all-cause or CVD-related mortality in high-intensity diet-only interventions at 3 to 15 years FU (k=4, n=51,356). Mixed findings for effects on CVD events in 3 high-intensity diet-only interventions at 8 to 15 years FU. Largest trial in postmenopausal women (n=48,835) found no difference in major CVD events or stroke among women without a history of CVD over 8.1 years FU. No consistent benefit of interventions on QOL at 6 to 12 months (k=10, n=52,423).	Reasonably consistent* Imprecise	Undetected for mortality and CVD events Suspected for QOL [†]	Good: 5 Fair: 7	Data from 2 trials based on observational FU after trials were completed. Few studies reported QOL measures; most reported domain-specific QOL instead of summary scores.	Low	Mortality and CVD event data limited to high-intensity diet-only interventions and most studies were among adults with high-normal BP. Largest trial in postmenopausal women. QOL data limited to mostly physical activity trials.
KQ 2. Intermediate outcomes							
k=34 n=75,793 (10/34 trials identified in update)	Small, statistically significant improvements in systolic (-1.26 mm Hg [95% CI, -1.77 to -0.76], k=22) and diastolic blood pressure (-0.49 mm Hg [95% CI, -0.82 to -0.16], k=23), LDL cholesterol (-2.58 mg/dL [95% CI, -4.30 to -0.85], k=13), total cholesterol (-2.85 mg/dL [95% CI, -4.95 to -0.75], k=19), and adiposity outcomes (BMI, -0.41 kg/m ² [95% CI, -0.62 to -0.19], k=20) at 6 to 12 months associated with healthful diet and/or physical activity interventions. Evidence of dose-response effect with increasing intervention intensity associated with larger improvements in intermediate outcomes. Insufficient evidence to assess the effects of low-intensity interventions alone. No evidence of an association with HDL cholesterol, triglycerides, or fasting glucose.	Consistency and precision varied across intermediate outcomes; more consistent and precise for blood pressure and LDL cholesterol [‡]	Undetected	Good: 13 Fair: 21	Considerable statistical heterogeneity ($I^2 > 90%$) for meta-analyses of adiposity outcomes. Limited evidence beyond 12 months or for incidence of hypertension, dyslipidemia, or diabetes.	Moderate	Generally applicable to adults not at risk for CVD. Intensity of intervention confounded with setting; high-intensity interventions were more likely to take place outside of primary care and show effectiveness. Few physical activity-focused trials reported intermediate outcomes.

Table 8. Summary of Evidence, by Key Question

No. of RCTs (k), No. of obs (n)	Summary of findings by outcome	Consistency/precision	Reporting bias	Study quality	Body of evidence limitations	EPC assessment of strength of evidence	Applicability
KQ3. Behavioral outcomes							
<p>k=86^s n=117,589 (36/86 trials identified in update)</p>	<p>Magnitude and precision in differences for dietary outcomes were quite variable across studies and resulted in considerable heterogeneity in meta-analysis. Between-group differences for dietary outcomes were in the magnitude of 65 (favoring the control group) to -500 kcal/day (favoring the intervention group) in total energy intake (k=11), 0.8 to -11 percentage points in the percent of calories from fat (k=15) and -0.3 to -4.1 percentage points in the percent of calories from saturated fat (k=9), and approximately -380 to nearly -1,400 mg/day of sodium (k=6). Effects on fruit and vegetable intake ranged from between-group differences of -0.2 servings/day (favoring the control group) to 2.2 servings/day (favoring the intervention group) (k=16); between-group differences in grams of fiber per day ranged from 1 to 2.5 g/day in favor of the intervention group (k=6).</p> <p>Small, statistically significant association with behavioral interventions and physical activity in favor of interventions over controls (SMD, 0.20 [95% CI, 0.14 to 0.26], k=46). An analysis of minutes per week of physical activity found difference of approximately 35 min/week of physical activity between groups (MD, 34.5 min/week [95% CI, 22.0 to 47.0], k=27). Significantly higher odds of meeting PA recommendations (150 min/week of PA) among intervention vs. control group participants (OR, 1.32 [95% CI, 1.12 to 1.64], k=16). Effects on cardiorespiratory fitness were generally consistent with results for self-reported physical activity.</p> <p>Insufficient evidence for sedentary behaviors.</p>	<p>Reasonably consistent</p> <p>Imprecise</p>	<p>Undetected</p>	<p>Good: 18 Fair: 68</p>	<p>Almost all outcomes based on self-report. Instruments, recall periods, and summary measures were extremely heterogeneous, with varying evidence of validity and reliability.</p> <p>Few interventions incorporated messages to decrease sedentary behavior.</p>	<p>Low</p>	<p>Generally applicable to adults not at risk for CVD.</p> <p>Larger effect sizes for physical activity outcomes were seen for persons with lower levels of physical activity at baseline.</p> <p>Most trials that reported a physical activity outcome were of low or medium intensity.</p>

Table 8. Summary of Evidence, by Key Question

No. of RCTs (k), No. of obs (n)	Summary of findings by outcome	Consistency/precision	Reporting bias	Study quality	Body of evidence limitations	EPC assessment of strength of evidence	Applicability
KQ 4. Harms							
k=14 n=8,220	No serious adverse events related to behavioral interventions (k=8).	Reasonably consistent	Undetected	Good: 7 Fair: 7	Harms sparsely reported for included trials. Few details provided about how harms were recorded and specific events that occurred.	Moderate	Applicable to physical activity interventions.
(7/14 trials identified in update)	Seven physical activity trials generally found no differences in rates of injuries, fractures, falls, or CV events. Only one trial among women ages 40-74 years found significantly more injuries and falls among intervention vs. control group participants.	Precise					Did not include observational evidence on harms related to changes in diet or physical activity.

* Inconsistent in direction and magnitude of effects for QOL outcomes.

† Possible selective reporting or selective analysis bias.

‡ Reasonably consistent and reasonably precise for SBP; reasonably consistent and imprecise for DBP and LDL cholesterol; inconsistent and imprecise for TC, HDL cholesterol, and TG; and inconsistent and reasonably precise for adiposity outcomes.

§ All but one study was a randomized, controlled trial; the one remaining study was a nonrandomized controlled trial.

|| Despite the relatively limited number of studies that reported harms related to interventions, we are moderately confident that there are no serious harms related to behavioral counseling interventions for healthful diet and physical activity.

Abbreviations: BMI=body mass index; CI=confidence interval; CV=cardiovascular; EPC=evidence-based practice center; FU=followup; HDL=high-density lipoprotein; k=number of trials; KQ=key question; MD=mean difference; min=minute; obs=observations; OR=odds ratio; PA=physical activity; QOL=quality of life; RCT=randomized, controlled trial; SBP=systolic blood pressure; SMD=standardized mean difference; TC=total cholesterol.

Table 9. Association of Differences in Intermediate Outcomes With Relevant Health Outcomes

Intermediate outcome	Original increment difference	HR (95% CI) for health outcome for original increment change in intermediate outcome	Converted increment difference	Age, years	Mortality outcome	HR (95% CI) for health outcome for converted increment change in intermediate outcome
SBP ^{234*}	↓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)
Non-HDL-C ^{235†}	↓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)
HDL-C ^{235‡}	↑0.33 mmol/L	0.61 (0.54 to 0.69)	↑1 mg/dL	40-59	IHD	0.96 (0.95 to 0.97)
	↑0.33 mmol/L	0.55 (0.49 to 0.61)	↑1 mg/dL	60-69	IHD	0.95 (0.95 to 0.96)
TC ^{235§}	↓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)
TC ²³⁵	↓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)
	↓1 mmol/L	1.12 (1.08 to 1.15)	↓3 mg/dL	60-69	Stroke	1.00 (1.00 to 1.01)
FBG ^{238, 239}	↑1 mmol/L	1.12 (1.08 to 1.15)	↑2 mg/dL	56 [#]	F+NF CHD	1.01 (1.01 to 1.02)
	↑18.02 mg/dL	1.13 (1.11 to 1.15)	↑2 mg/dL	53 [#]	Vascular	1.01 (1.01 to 1.02)
	↑18.02 mg/dL	1.10 (1.09 to 1.11)	↑2 mg/dL	53 [#]	All-cause	1.01 (1.01 to 1.01)
BMI ^{19**}	↑5 kg/m ²	1.50 (1.39 to 1.62)	↑1 kg/m ²	35-59	IHD	1.08 (1.07 to 1.10)
	↑5 kg/m ²	1.40 (1.32 to 1.49)	↑1 kg/m ²	60-69	IHD	1.07 (1.06 to 1.08)
	↑5 kg/m ²	1.76 (1.52 to 2.04)	↑1 kg/m ²	35-59	Stroke	1.12 (1.09 to 1.15)
	↑5 kg/m ²	1.49 (1.34 to 1.67)	↑1 kg/m ²	60-69	Stroke	1.08 (1.06 to 1.11)

* For SBP >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 ages 40-59 years only.

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

Mean age.

** For BMI >25 kg/m². Adjusted for sex and smoking.

Abbreviations: BMI=body mass index; CHD=coronary heart disease; CI=confidence interval; F+NF=fatal plus nonfatal; FBG=fasting blood glucose; HDL-C=high-density lipoprotein cholesterol; HR=hazard ratio; IHD=ischemic heart disease; NS=not significant; SBP=systolic blood pressure; TC=total cholesterol.

Literature Search Strategies for Primary Literature

Key:

/ = MeSH subject heading
\$ = truncation
* = truncation
? = wildcard
ab = word in abstract
adj# = adjacent within x number of words
ae = adverse effects
hw = subject heading word
id = identifier
kw = keyword
md = methodology
near/# = adjacent within x number of words
ti = word in title

Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

Issue 3 of 12, May 2016

- #1 diet:ti
- #2 diets:ti
- #3 dietary:ti
- #4 exercis*:ti
- #5 "physical activity":ti,ab,kw
- #6 fruit*:ti,ab,kw
- #7 vegetable*:ti,ab,kw
- #8 sedentary:ti,ab,kw next (lifestyle* or (life next style*) or behavior* or behaviour* or time):ti,ab,kw
- #9 (sitting or lying):ti,ab,kw near/2 time:ti,ab,kw
- #10 "screen time":ti,ab,kw
- #11 (television or tv):ti,ab,kw next viewing:ti,ab,kw
- #12 (watch* or view*):ti,ab,kw next (television or tv):ti,ab,kw
- #13 (computer or internet):ti,ab,kw next (time or use or usage):ti,ab,kw
- #14 (computer or video):ti,ab,kw next game*:ti,ab,kw
- #15 (screen or screen-based):ti,ab,kw next (entertainment or behavior* or behaviour* or use or usage):ti,ab,kw
- #16 (low next energy next expenditure*):ti,ab,kw
- #17 (physical* next inactiv*):ti,ab,kw
- #18 #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
- #19 counsel*:ti,ab,kw
- #20 (Behavio* next therap*):ti,ab,kw
- #21 (cognitive next therap*):ti,ab,kw
- #22 advice:ti,ab,kw
- #23 (Behavio* next chang*):ti,ab,kw
- #24 (Behavio* next modification*):ti,ab,kw
- #25 Referral:ti,ab,kw
- #26 "life style":ti,ab,kw
- #27 lifestyle:ti,ab,kw
- #28 #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27
- #29 #18 and #28 Publication Year from 2013 to 2016, in Trials

Appendix A. Detailed Methods

Medline (via Ovid)

Database: Ovid MEDLINE(R) <1946 to May Week 1 2016>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations < May 25, 2016>, Ovid MEDLINE(R) Daily Update <May 25, 2016>

- 1 Diet, Reducing/
- 2 Diet, Fat-Restricted/
- 3 Diet, Mediterranean/
- 4 Diet, Sodium-Restricted/
- 5 Diet, Carbohydrate-Restricted/
- 6 Caloric Restriction/
- 7 Fruit/
- 8 Vegetables/
- 9 Diet Therapy/
- 10 Food Habits/
- 11 Exercise/
- 12 Exercise Therapy/
- 13 Motor Activity/
- 14 Physical Fitness/
- 15 Walking/
- 16 (diet or dietary).ti.
- 17 (fruit\$ or vegetable\$).ti.
- 18 (exercise or physical activity).ti.
- 19 walking.ti.
- 20 Sedentary lifestyle/
- 21 (sedentary adj (lifestyle\$ or life style\$ or behavio\$ or time)).ti.
- 22 ((sitting or lying) adj2 time).ti.
- 23 Screen time.ti.
- 24 Television/
- 25 Computers/
- 26 Video games/
- 27 ((television or TV) adj viewing).ti.
- 28 ((watch\$ or view\$) adj (television or TV)).ti.
- 29 ((computer or internet) adj (time or "use" or usage)).ti.
- 30 ((computer or video) adj game\$).ti.
- 31 (screen adj (entertainment or behavio\$ or "use" or usage)).ti.
- 32 low energy expenditure\$.ti.
- 33 physical\$ inactiv\$.ti.
- 34 or/1-33
- 35 Counseling/
- 36 Directive Counseling/
- 37 "Behavior-Therapy"/
- 38 Cognitive Therapy/
- 39 "Referral and Consultation"/
- 40 Persuasive Communication/
- 41 Social Control, Informal/
- 42 Risk Reduction Behavior/
- 43 Life Style/
- 44 Motivation/
- 45 Social Support/
- 46 Feedback, Psychological/
- 47 Self Efficacy/
- 48 Health Knowledge, Attitudes, Practice/

Appendix A. Detailed Methods

49 Health Behavior/
50 Health Education/
51 Health Promotion/
52 Patient Education as Topic/
53 counsel\$.ti,ab.
54 advice.ti,ab.
55 (behavio\$ adj (therap\$ or chang\$ or modification\$)).ti,ab.
56 referral.ti,ab.
57 (life style or lifestyle).ti,ab.
58 motivation\$.ti,ab.
59 health behavio\$.ti,ab.
60 health education.ti,ab.
61 health promotion.ti,ab.
62 patient education.ti,ab.
63 nonpharmacologic intervention\$.ti,ab.
64 non pharmacologic intervention\$.ti,ab.
65 or/35-64
66 34 and 65
67 limit 66 to (clinical trial or controlled clinical trial or meta analysis or randomized controlled trial)
68 clinical trials as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ (
69 Meta-Analysis as Topic/
70 (control\$ adj3 trial\$).ti,ab.
71 random\$.ti,ab.
72 clinical trial\$.ti,ab.
73 meta analy\$.ti,ab.
74 68 or 69 or 70 or 71 or 72 or 73
75 66 and 74
76 67 or 75
77 limit 76 to english language
78 limit 77 to yr="2013 - Current"
79 remove duplicates from 78
80 (harm or harms or harmful or harmed).ti,ab.
81 (risky behavior\$ or risky behaviour\$).ti,ab.
82 (adverse effects or mortality).fs.
83 Mortality/
84 Morbidity/
85 death/
86 Athletic injuries/
87 Malnutrition/
88 nutritional defici\$.ti,ab.
89 (death or deaths).ti,ab.
90 fracture\$.ti,ab,hw.
91 80 or 81 or 82 or 83 or 84 or 85 or 86 or 87 or 88 or 89 or 90
92 66 and 91
93 case-control studies/ or cohort studies/ or longitudinal studies/ or follow-up studies/ or prospective
studies/
94 case control\$.ti,ab.
95 cohort.ti,ab.
96 longitudinal.ti,ab.
97 (follow-up or followup).ti,ab.
98 prospective\$.ti,ab.

Appendix A. Detailed Methods

99 (comparison group\$ or control group\$.ti,ab.
100 observational.ti,ab.
101 retrospective studies/
102 retrospective\$.ti,ab.
103 database\$.ti,ab.
104 nonrandomi\$.ti,ab.
105 population\$.ti,ab.
106 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105
107 92 and 106
108 limit 107 to english language
109 limit 108 to yr="2013 - Current"
110 remove duplicates from 109
111 79 or 110
112 limit 111 to "all child (0 to 18 years)"
113 limit 111 to "all adult (19 plus years)"
114 112 not 113
115 111 not 114
116 Animals/ not (Humans/ and Animals/
117 115 not 116

PsycInfo (via Ovid)

Database: PsycINFO <1806 to May Week 3 2016>

1 Diets/
2 Dietary Restraint/
3 Eating Behavior/
4 fruit\$.ti,ab,id,hw.
5 vegetable\$.ti,ab,id,hw.
6 Exercise/
7 Physical Activity/
8 Aerobic Exercise/
9 Walking/
10 physical activity.ti,ab,id,hw.
11 Activity Level/
12 (sedentary adj (lifestyle\$ or life style\$ or behavio\$ or time)).ti,ab,id,hw.
13 ((sitting or lying) adj2 time).ti,ab,id,hw.
14 Television/
15 Television Viewing/
16 Computers/
17 Computer Games/
18 Role Playing Games/
19 Simulation Games/
20 ((television or TV) adj viewing).ti,ab,id,hw.
21 ((watch\$ or view\$) adj (television or TV)).ti,ab,id,hw.
22 ((computer or internet) adj (time or "use" or usage)).ti,ab,id,hw.
23 ((computer or video) adj game\$.ti,ab,id,hw.
24 (screen adj (entertainment or behavio\$ or "use" or usage)).ti,ab,id,hw.
25 low energy expenditure\$.ti,ab,id,hw.
26 physical\$ inactiv\$.ti,ab,id,hw.
27 or/1-26
28 behavior therapy/
29 cognitive behavior therapy/

Appendix A. Detailed Methods

30 cognitive therapy/
31 Cognitive Techniques/
32 Behavior Modification/
33 Behavior Change/
34 Lifestyle Changes/
35 Lifestyle/
36 Persuasive Communication/
37 Motivation/
38 Motivational Interviewing/
39 Self Efficacy/
40 Health Knowledge/
41 Health Behavior/
42 Health Education/
43 Health Promotion/
44 Client Education/
45 counseling/
46 counseling.id.
47 counselling.id.
48 advice.ti,ab,id,hw.
49 or/28-48
50 27 and 49
51 controlled trial\$.ti,ab,id,hw.
52 clinical trial\$.ti,ab,id,hw.
53 random\$.ti,ab,id,hw.
54 treatment outcome clinical trial.md.
55 or/51-54
56 50 and 55
57 (harm or harms or harmful or harmed).ti,ab,id,hw.
58 (risky behavior\$ or risky behaviour\$).ti,ab,id,hw.
59 adverse effect\$.ti,ab,id,hw.
60 mortality.ti,ab,id,hw.
61 morbidity.ti,ab,id,hw.
62 death.ti,ab,id,hw.
63 Nutritional Defici\$.ti,ab,id,hw.
64 fracture\$.ti,ab,id,hw.
65 cardiovascular.ti,ab,id,hw.
66 injur\$.ti,ab,id,hw.
67 or/57-66
68 50 and 67
69 case control\$.ti,ab,id,hw.
70 cohort.ti,ab,id,hw.
71 longitudinal.ti,ab,id,hw.
72 (follow-up or followup).ti,ab,id,hw.
73 prospective\$.ti,ab,id,hw.
74 (comparison group\$ or control group\$).ti,ab,id,hw.
75 observational.ti,ab,id,hw.
76 retrospective\$.ti,ab,id,hw.
77 database\$.ti,ab,id,hw.
78 nonrandomi\$.ti,ab,id,hw.
79 population\$.ti,ab,id,hw.
80 or/69-79

Appendix A. Detailed Methods

- 81 68 and 80
- 82 56 or 81
- 83 limit 82 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>)
- 84 limit 82 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>")
- 85 83 not 84
- 86 82 not 85
- 87 limit 86 to (english language and yr="2013 -Current")

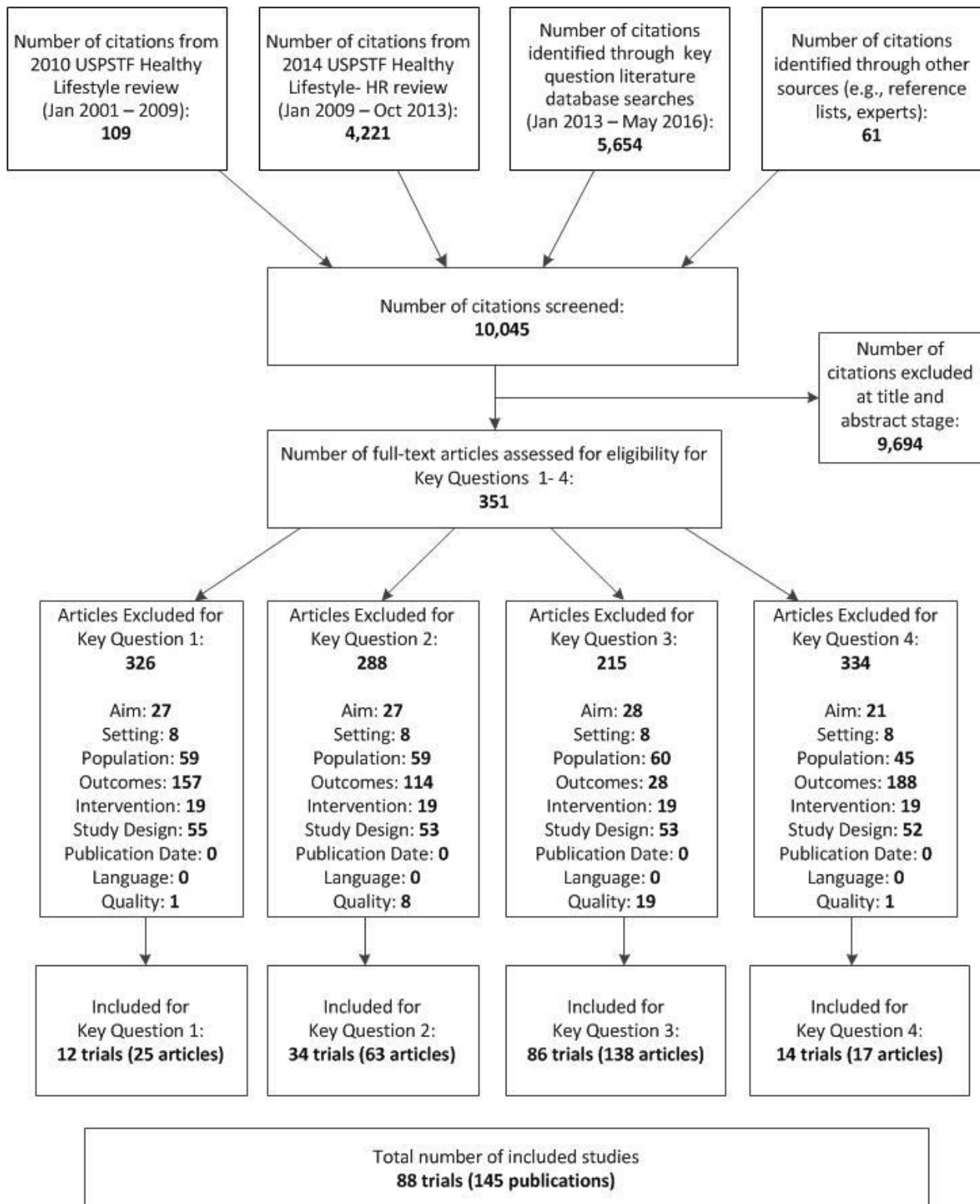
PubMed, publisher-supplied records

- #44 Search #43 AND publisher[*sb*] AND English[*Language*] AND ("2013"[*Date - Publication*] : "3000"[*Date - Publication*])
- #43 Search #33 OR #42
- #42 Search #31 AND #41
- #41 Search #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40
- #40 Search fracture*[*tiab*]
- #39 Search death[*tiab*] OR deaths[*tiab*]
- #38 Search nutritional defici*[*tiab*]
- #37 Search injury[*tiab*] OR injuries[*tiab*]
- #36 Search risky behavio*[*tiab*]
- #35 Search complication*[*tiab*]
- #34 Search (harm*[*tiab*] OR adverse event*[*tiab*] OR adverse effect*[*tiab*] OR adverse outcome*[*tiab*])
- #33 Search #31 AND #32
- #32 Search trial[*tiab*] OR trials[*tiab*] OR random*[*tiab*] OR metaanaly*[*tiab*] OR "meta analysis"[*tiab*] OR "meta analyses"[*tiab*] OR "meta analytic"[*tiab*] OR systematic[*tiab*]
- #31 Search #14 AND #30
- #30 Search #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
- #29 Search "patient education" [*tiab*]
- #28 Search "health promotion" [*tiab*]
- #27 Search "health education" [*tiab*]
- #26 Search "health behaviours" [*tiab*]
- #25 Search "health behaviour" [*tiab*]
- #24 Search "health behaviors" [*tiab*]
- #23 Search "health behavior" [*tiab*]
- #22 Search motivation* [*tiab*]
- #21 Search "life style"[*tiab*] OR lifestyle[*tiab*]
- #20 Search referral[*tiab*]
- #19 Search behavio*[*tiab*] AND modification*[*tiab*]
- #18 Search behavio*[*tiab*] AND change[*tiab*]
- #17 Search behavio*[*tiab*] AND therapy[*tiab*]
- #16 Search advice[*tiab*]
- #15 Search counsel*[*tiab*]
- #14 Search #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
- #13 Search physical* inactiv*[*ti*]
- #12 Search energy expenditure*[*ti*]
- #11 Search screen[*ti*] AND (entertainment[*ti*] OR behavio*[*ti*] OR use[*ti*] OR usage[*ti*])

Appendix A. Detailed Methods

- #10 Search (computer[ti] OR video[ti]) AND game*[ti]
- #9 Search (computer[ti] OR internet[ti]) AND (time[ti] OR use[ti] OR usage[ti])
- #8 Search (television[ti] OR tv[ti]) AND (watch*[ti] OR view*[ti])
- #7 Search “screen time”[ti]
- #6 Search ((sitting[ti] OR lying[ti]) AND time[ti])
- #5 Search sedentary[ti]
- #4 Search walking[ti]
- #3 Search exercise[ti] OR "physical activity"[ti]
- #2 Search fruit*[ti] OR vegetable*[ti]
- #1 Search diet[ti] OR dietary[ti]

Appendix A Figure 1. Literature Flow Diagram



Appendix A Table 1. Inclusion and Exclusion Criteria

	Include	Exclude
Study aim	Primary prevention of CVD	<ul style="list-style-type: none"> • Secondary or tertiary prevention of CVD • Weight loss* • Cancer prevention or treatment • Prevention of cognitive decline • Prevention of falls • Smoking cessation
Condition definition	<ul style="list-style-type: none"> • A healthful diet includes dietary patterns that emphasize vegetables, fruits, whole grains, legumes, and nuts; include low-fat dairy products and seafood; limit sodium, saturated fat, refined grains, and sugar-sweetened foods and beverages; and have lower in amounts of red and processed meats. • Physical activity is defined as any bodily movement produced by the contraction of skeletal muscle that increases energy expenditure. For the purposes of this review, physical activity includes aerobic and muscle-strengthening physical activity. • Sedentary behavior refers to behavior characterized by minimal energy expenditure while in a sitting or reclining posture. 	<p>Aspects of a healthful diet that are out of scope include:</p> <ul style="list-style-type: none"> • Dietary calcium and other vitamin, micronutrient, and antioxidant supplementation • Alcohol moderation <p>Aspects of physical activity that are out of scope include:</p> <ul style="list-style-type: none"> • Balance • Flexibility • Gait
Populations	<p>Adults age >18 years without known CVD, hypertension, dyslipidemia, impaired fasting glucose/glucose tolerance, and/or smoking, or those who are high risk based on a cardiovascular risk assessment tool, including:</p> <ul style="list-style-type: none"> • Persons who are unselected • Persons who have suboptimal behavior (e.g., poor dietary intake, not meeting recommended levels of physical activity, high levels of sedentary time) • Persons who are at increased risk for CVD (e.g., due to family history, overweight [BMI of 25.0 to 29.9 kg/m²] or obesity [BMI of ≥30 kg/m²], high-normal blood pressure) 	<p>Studies limited to:</p> <ul style="list-style-type: none"> • Adults with known CVD or diabetes mellitus • Adults with other known chronic diseases (e.g., cancer, chronic kidney disease, severe mental illness, cognitive impairment) • Adults with known traditional, modifiable CVD risk factors (i.e., hypertension, dyslipidemia, impaired fasting glucose/ glucose tolerance, smoking); adults at high risk for CVD based on a cardiovascular risk assessment tool; or trial inclusion criteria specifies that the population has ≥1 CVD risk factors • Children and adolescents • Parents (if intended behavior change is directed toward children) • Pregnant women • Institutionalized adults
Settings	Conducted in or recruited from primary care or a health care system or could feasibly be implemented in or referred from primary care	Conducted in or recruited from settings not generalizable to primary care (e.g., worksites, university classrooms, institutional settings, community-wide settings) or in a population with pre-existing social ties (e.g., from the same worksite or church), or in a setting that could not be reproduced in primary care or within a broader health system

Appendix A Table 1. Inclusion and Exclusion Criteria

	Include	Exclude
Interventions	<ul style="list-style-type: none"> Behavioral counseling intervention alone or as part of a larger multicomponent intervention on healthful diet and nutrition, physical activity, sedentary behavior, or a combination, including but not limited to: assessment with feedback, advice, collaborative goal-setting, assistance, exercise prescriptions (referral to exercise facility or program), or arranging further contacts Interventions may be delivered via face-to-face contact, telephone, print materials, or technology (e.g., computer-based, text messages) and can be delivered by a number of potential interventionists, including but not limited to: physicians, nurses, exercise specialists, dietitians, nutritionists, and behavioral health specialists 	<ul style="list-style-type: none"> Supervised exercise Controlled diet (i.e., feeding trials or providing food to participants) Dietary supplements Stress management interventions (e.g., meditation, yoga, tai chi) Prenatal or postnatal dietary counseling Broader community-based programs (e.g., mass media, social marketing, changes to the community built environment, legislation)
Comparisons	<ul style="list-style-type: none"> No intervention (e.g., wait-list control, usual care) Minimal intervention (e.g., usual care limited to ≤15 minutes of information or pamphlets) Attention control (e.g., similar format and intensity of intervention on a different content area) 	<ul style="list-style-type: none"> Active comparators without a control (as defined above) Studies in which the control group is instructed not to exercise
Outcomes	<p>KQ 1: Health outcomes (i.e., CVD events [stroke, myocardial infarction], cardiovascular and all-cause mortality, health-related quality of life [physical and mental health–related quality of life])</p> <p>KQ 2: Intermediate outcomes (e.g., blood pressure, lipid levels, glucose levels, weight, BMI, waist circumference)</p> <p>KQ 3: Behavioral outcomes (i.e., physical activity, dietary intake or patterns, sedentary behavior)</p> <p>KQ 4: Adverse outcomes, including any harms requiring unexpected or unwanted medical attention (e.g., nutritional deficiencies, musculoskeletal injuries, cardiovascular events)</p>	Knowledge, attitudes, and self-efficacy
Timing of outcome assessment	<p>KQs 1–3: ≥6 months after baseline</p> <p>KQ 4: No minimum followup</p>	KQs 1–3: <6 months after baseline
Countries	Studies conducted in countries categorized as “Very High” on the 2014 Human Development Index (as defined by the United Nations Development Programme)	Studies conducted in countries that are not categorized as “Very High” on the 2014 Human Development Index
Study designs	<p>KQs 1–3: Systematic reviews, individual and cluster RCTs, nonrandomized CCTs</p> <p>KQ 4: Systematic reviews, RCTs, CCTs, large comparative cohort or case-control studies with appropriate comparison group, large event-monitoring studies</p>	<p>KQs 1–3: Any observational studies</p> <p>KQ 4: Ecological studies, case-series, case reports</p>
Publication date	Trials whose primary results were published from 1990 to present	Trials whose primary results were published prior to 1990
Publication language	English	Non-English
Study quality	Fair or good	Poor (according to design-specific USPSTF criteria)

* Studies that focus on the effectiveness of primary care interventions for weight management are included in a separate review commissioned by the USPSTF on screening for and management of adult obesity.

Abbreviations: CCT=controlled clinical trial; CVD=cardiovascular disease; RCT=randomized, controlled trial; USPSTF=U.S. Preventive Services Task Force.

Appendix A Table 2. Quality Assessment Criteria of Randomized, Controlled Trials

USPSTF Quality Rating Criteria
<ul style="list-style-type: none">• Initial assembly of comparable groups employs adequate randomization, including first concealment and whether potential confounders were distributed equally among groups• Maintenance of comparable groups (includes attrition, crossovers, adherence, contamination)• Important differential loss to followup or overall high loss to followup• Measurements are equal, reliable, and valid (includes masking of outcome assessment)• Clear definition of the interventions• All important outcomes considered• Intention-to-treat analysis

Appendix B. Detailed Data Analysis Methods

We ran random effects meta-analyses using the DerSimonian and Laird method to calculate the pooled differences in means for intermediate outcomes (systolic and diastolic blood pressure, low-density lipoprotein cholesterol, total cholesterol, high-density lipoprotein cholesterol, triglycerides, glucose, and measures of adiposity) and behavioral outcomes (self-reported or objectively-measured physical activity, intake of total energy, fat, saturated fat, fruits and vegetables, and fiber).⁷¹ We used the between-group differences for each outcome as reported by each respective study and favored adjusted effect estimates over unadjusted. If a between group effect estimate and variance were not provided, we calculated a crude effect estimate.

We converted certain International System of Units/Système International (SI) values to conventional units for ease of interpretation. **Appendix B Table 1** presents conversion factors for the units that we converted.

In cases where a cluster randomized trial was used but the analysis did not account for the nested nature of the data (as was the case in 11 trials^{81, 92, 102, 111, 122, 132, 148, 179, 188, 214, 218}), we adjusted for the clustering effect by applying a design effect, which was based on an estimated average cluster size (the total number of randomized participants divided by the total number of clusters) and multiplied by an estimated intraclass correlation. We estimated the intraclass correlation to be 0.032 for meeting physical activity recommendations, 0.033 for continuous physical activity outcomes, and 0.03 for fat, saturated fat, and fiber based on existing literature.^{122, 269}

Within each study, we chose 52-week (1 year) outcome data if available. If not, we chose the time point closest to 52 weeks and favored 78 weeks over 26 weeks where provided. We describe the results generally as 6 to 12-months followup. If a trial had more than one active intervention arm, we plotted the most intensive arm or the arm that was the most similar with other interventions included in that respective analysis. WebPlotDigitizer© version 3.10 was used to extract data from four figures within three trials to provide estimates of the within-group means and 95% confidence intervals at followup for the following outcome measures: diastolic blood pressure¹³⁷, moderate-to-vigorous physical activity (95% confidence interval at 52 weeks)¹⁶⁵, moderate physical activity¹⁶⁹, and sedentary time.¹⁶⁹

Because we included different measures in the pooled analyses for continuous measures of physical activity, fat, saturated fat, and fiber, we pooled *standardized* mean differences in change between groups. We also conducted analyses limited to only studies that reported similar measures (e.g., minutes per week of physical activity, percent of energy from fat) and found that the standardized pooled effects were very similar to analyses that included trials reporting other measures, indicating that confounding by measurement is minimal or absent.

We used standard calculations to convert standard errors and 95% confidence intervals to standard deviations:

$$\begin{aligned}SD_{\text{mean}} &= SE_{\text{mean}} * \text{sqrt}(n) \text{ or} \\SD_{\text{mean}} &= (CI_{\text{upper}} - CI_{\text{lower}}) * \text{sqrt}(n) / 3.92\end{aligned}$$

If reported, within-group change from baseline was used for analysis. Where change scores were not available, they were calculated from baseline and followup measures if possible, using an outcome-specific correlation (**Appendix B Table 2**). This correlation was used to estimate the standard deviation in the following formula:⁷⁴

$$SD_{\text{change}} = \text{Sqrt}(SD_{\text{base}}^2 + SD_{\text{post}}^2 - 2 * SD_{\text{base}} * SD_{\text{post}} * r_{\text{base,post}})$$

Appendix B. Detailed Data Analysis Methods

In one study,⁹⁰ results were presented separately for males and females. We used the following formula to calculate a combined mean and standard deviation by group:⁷⁴

$$\text{Mean}_{\text{combined}} = N_1M_1 + N_2M_2 / N_1 + N_2$$

$$\text{SD}_{\text{combined}} = \sqrt{\frac{(N_1 - 1)SD_1^2 + (N_2 - 1)SD_2^2 + \frac{N_1N_2}{N_1 + N_2}(M_1^2 + M_2^2 - 2M_1M_2)}{N_1 + N_2 - 1}}$$

The only non-continuous outcome for which we performed meta-analysis was the proportion of people meeting the recommended level physical activity. Because half of the studies that reported this outcome reported adjusted odds ratios and their corresponding 95% confidence interval, we opted to use study-reported adjusted odds ratios as reported. When not reported, we calculated an odds ratio and 95% confidence interval using the raw numbers of participants meeting recommendations at followup. After calculating a pooled odds ratio, we estimated the risk ratio (relative risk) based on the formula:

$$\text{RR} = \text{OR}(1 - P_{\text{ref}}) + (P_{\text{ref}} * \text{OR})$$

where P_{ref} equaled the prevalence of meeting physical activity recommendations in the control group (or referent).

In one case,²⁰⁷ the standard deviation of the triglycerides in the control group at baseline was approximately five times larger than all other standard deviations, so we assume that was a typo and substituted baseline intervention group standard deviation instead.

We ran sensitivity analyses for selected intermediate outcomes (systolic and diastolic blood pressure and total cholesterol) using a restricted maximum likelihood model with the Knapp-Hartung modification (using the `metareg` command in Stata), which is a more conservative approach than the DerSimonian and Laird method when there is substantial heterogeneity or the number of studies is small.^{75, 270} All statistically significant results remained within the restricted maximum likelihood model, so we show results using the DerSimonian and Laird method.⁷¹ For intermediate outcomes, we also ran sensitivity analyses whereby we removed two trials among older adults;^{146, 208} differences in the results of these sensitivity analyses are noted in the results.

We generated funnel plots to evaluate small-study effects (a possible indication of publication bias) and ran the Egger's test⁷⁷ (for continuous data) and Peters' test⁷⁶ (for binary data) to assess statistical significance of imbalance in study size and findings that suggest a pattern.

We investigated whether variability among the results was associated with any pre-specified study, population, or intervention characteristics first qualitatively, using visual displays and tables grouped and sorted by these potentially important characteristics. Specifically, we examined study quality (good versus fair), link to primary care (conducted in or recruited from primary care versus not), population at elevated cardiovascular risk (yes/no), mean age, baseline mean body mass index, intervention focus (healthful diet *and* physical activity, healthful-diet only, physical activity-only), intervention intensity (as continuous minutes and high-intensity versus medium- and low-intensity), intervention duration (continuous weeks), number of intervention sessions, and whether the intervention included group sessions (yes/no). Based on this initial assessment, we ran a series of meta-regressions to examine the effects of study, populations, and intervention characteristics on effect size. Specifically, we included a single factor of interest (study quality [good versus fair], link to primary care [Y/N], intervention intensity [continuous and high- versus medium- and low-intensity], and intervention duration [continuous]) in each meta-regression model.

Appendix B. Detailed Data Analysis Methods

Two-level variables were entered as 1/0 dummy variables and 3-level variables were converted to two 1/0 dummy variables with reference groups selected on the basis of interpretability of results. There was some evidence that intervention intensity was correlated with the effect estimates; therefore, we stratified the studies according to their intensity category (high, medium, or low) and sorted studies within these groups by intervention focus.

To estimate the relationship between differences in intermediate outcomes and associated health outcomes, we relied upon estimates from very large individual participant data meta-analyses of observational studies (IPA MA).^{19, 234, 235, 238, 239} These analyses reported the difference in risk for a relevant health outcome (e.g., ischemic heart disease or stroke death), consistently expressed as HRs, for given increments of difference in an intermediate outcome (e.g., 20 mm Hg, 5 kg/m²). Reported increments of difference for intermediate outcomes were much larger than changes in our pooled analyses, so we converted these to smaller increments more comparable with our results. Conversions were made using the formula:

$$\text{HRc}=\exp(\ln(\text{HRo})/\text{Io}*\text{Ic})$$

where HRc is the converted HR, HRo is the originally reported HR, Io is the original increment for HR calculation, and Ic is the increment to which the HR was converted. The CIs were also converted accordingly using the formula $\text{LBC}=\exp(\ln(\text{LBo})/\text{Io}*\text{Ic})$ and $\text{UBc}=\exp(\ln(\text{UBo})/\text{Io}*\text{Ic})$, where LBo and LBC are the original and converted lower bounds of the CI and UBo and UBc are the original and converted upper bounds of the CI, respectively. To ensure face validity we cross-checked our formula by applying it to any additional reported increments and associated HRs in the source IPD MA.

We used Stata version 13.1 (Stata Corp LP, College Station, TX) for all quantitative analyses. All significance testing was two-sided and results were considered statistically significant if the p-value was 0.05 or less.

Appendix B Table 1. Factors Used to Convert International System (SI) Units to Conventional Units of Measure

Measure	SI Unit	Conventional Unit	Conversion Factor²⁷¹	Reverse Conversion Factor (SI to Conventional, 1/x)
Total cholesterol	mmol/l	mg/dL	0.0259	38.61
Low-density lipoprotein cholesterol	mmol/l	mg/dL	0.0259	38.61
High-density lipoprotein cholesterol	mmol/l	mg/dL	0.0259	38.61
Triglycerides	mmol/l	mg/dL	0.0113	88.496
Glucose	mmol/l	mg/dL	0.0555	18.02
Weight	kg	lb	0.4535	2.205
Length	cm	in	0.3937	2.54
Energy	kJ	kcal	0.2389	4.186

Appendix B Table 2. Estimated Correlations Between Baseline and Followup Values, by Outcome

Outcome (treatment group)	Correlation used in data calculations for meta-analysis
Systolic BP (CG)	0.65
Systolic BP (IG)	0.60
Diastolic BP (CG)	0.65
Diastolic BP (IG)	0.60
LDL Cholesterol (CG)	0.65
LDL Cholesterol (IG)	0.60
Total Cholesterol (CG)	0.65
Total Cholesterol (IG)	0.60
HDL Cholesterol (CG)	0.75
HDL (Cholesterol (IG)	0.70
Triglycerides (CG)	0.65
Triglycerides (IG)	0.60
Adiposity (CG)	0.90
Adiposity (IG)	0.90
Total Energy (CG)	0.60
Total Energy (IG)	0.50
Fat/Saturated Fat (CG)	0.50
Fat/Saturated Fat (IG)	0.40
Fruits and Vegetables (CG)	0.70
Fruits and Vegetables (IG)	0.55
Fiber (CG)	0.50
Fiber (IG)	0.40

Abbreviations: BP=blood pressure; CG=control group; IG=intervention group; HDL=high-density lipoprotein; LDL=low-density lipoprotein.

Appendix C. Included Studies

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

1. Aadahl M, Linneberg A, Moller TC, et al. Motivational counseling to reduce sitting time: a community-based randomized controlled trial in adults. *Am J Prev Med.* 2014;47(5):576-86. PMID: 25113139.
2. Aittasalo M, Miilunpalo S, Kukkonen-Harjula K, et al. A randomized intervention of physical activity promotion and patient self-monitoring in primary health care. *Prev Med.* 2006;42(1):40-6. PMID: 16297442.
3. Albright CL, Steffen AD, Wilkens LR, et al. Effectiveness of a 12-month randomized clinical trial to increase physical activity in multiethnic postpartum women: Results from Hawaii's N Mikimiki Project. *Prev Med.* 2014;69:214-23. PMID: 25285751.
 - a. Albright CL, Saiki K, Steffen AD, et al. What barriers thwart postpartum women's physical activity goals during a 12-month intervention? A process evaluation of the Na Mikimiki Project. *Women & Health.* 2015;55(1):1-21. PMID: 25402618.
 - b. Albright CL, Steffen AD, Novotny R, et al. Baseline results from Hawaii's Na Mikimiki Project: a physical activity intervention tailored to multiethnic postpartum women. *Women & Health.* 2012;52(3):265-91. PMID: 22533900.
4. Aldana SG, Greenlaw RL, Diehl HA, et al. The behavioral and clinical effects of therapeutic lifestyle change on middle-aged adults. *Prev Chronic Dis.* 2006;3(1):A05. PMID: 16356358.
 - a. Aldana SG, Greenlaw RL, Diehl HA, et al. Effects of an intensive diet and physical activity modification program on the health risks of adults. *J Am Diet Assoc.* 2005;105(3):371-81. PMID: 15746824.
5. Alexander GL, McClure JB, Calvi JH, et al. A randomized clinical trial evaluating online interventions to improve fruit and vegetable consumption. *American journal of public health.* 2010;100(2):319-26. PMID: 20019315.
 - a. Stopponi MA, Alexander GL, McClure JB, et al. Recruitment to a randomized web-based nutritional intervention trial: characteristics of participants compared to non-participants. *J Med Internet Res.* 2009;11(3):e38. PMID: 19709990.
6. Baron JA, Gleason R, Crowe B, et al. Preliminary trial of the effect of general practice based nutritional advice. *Br J Gen Pract.* 1990;40(333):137-41. PMID: 2115348.
7. Bennett GG, Foley P, Levine E, et al. Behavioral treatment for weight gain prevention among black women in primary care practice: A randomized clinical trial. *JAMA Intern Med.* 2013;173(19):1770-7. PMID: 23979005.
 - a. Foley P, Levine E, Askew S, et al. Weight gain prevention among black women in the rural community health center setting: the Shape Program. *BMC Public Health.* 2012;12:305. PMID: 22537222.
8. Beresford SA, Curry SJ, Kristal AR, et al. A dietary intervention in primary care practice: the Eating Patterns Study. *Am J Public Health.* 1997;87(4):610-6. PMID: 9146440.
9. Bernstein A, Nelson ME, Tucker KL, et al. A home-based nutrition intervention to increase consumption of fruits, vegetables, and calcium-rich foods in community dwelling elders. *J Am Diet Assoc.* 2002;102(10):1421-7. PMID: 12396159.
10. Bickmore TW, Silliman RA, Nelson K, et al. A Randomized Controlled Trial of an Automated Exercise Coach for Older Adults. *J Am Geriatr Soc.* 2013;61(10):1676-83. PMID: 24001030.

Appendix C. Included Studies

11. Brekke HK, Jansson PA, Lenner RA. Long-term (1- and 2-year) effects of lifestyle intervention in type 2 diabetes relatives. *Diabetes Res Clin Pract.* 2005;70(3):225-34. PMID: 15885845.
12. Bryan AD, Magnan RE, Hooper AE, et al. Colorado stride (COSTRIDE): testing genetic and physiological moderators of response to an intervention to increase physical activity. *Int J Behav Nutr Phys Act.* 2013;10:139. PMID: 24359456.
13. Burke L, Lee AH, Jancey J, et al. Physical activity and nutrition behavioural outcomes of a home-based intervention program for seniors: a randomized controlled trial. *Int J Behav Nutr Phys Act.* 2013;10:14. PMID: 23363616.
 - a. Burke L, Jancey J, Howat P, et al. Physical activity and nutrition program for seniors (PANS): protocol of a randomized controlled trial. *BMC Public Health.* 2010;10:751. PMID: 21129226.
14. Carpenter RA, Finley C, Barlow CE. Pilot test of a behavioral skill building intervention to improve overall diet quality. *J Nutr Educ Behav.* 2004;36(1):20-4. PMID: 14756978.
15. Carroll JK, Lewis BA, Marcus BH, et al. Computerized tailored physical activity reports. A randomized controlled trial. *Am J Prev Med.* 2010;39(2):148-56. PMID: 20621262.
16. Castro CM, Pruitt LA, Buman MP, et al. Physical activity program delivery by professionals versus volunteers: the TEAM randomized trial. *Health Psychol.* 2011;30(3):285-94. PMID: 21553972.
17. Coates RJ, Bowen DJ, Kristal AR, et al. The Women's Health Trial Feasibility Study in Minority Populations: changes in dietary intakes. *Am J Epidemiol.* 1999;149(12):1104-12. PMID: 10369504.
 - a. Bowen D, Clifford CK, Coates R, et al. The Women's Health Trial Feasibility Study in Minority Populations: design and baseline descriptions. *Ann Epidemiol.* 1996;6(6):507-19. PMID: 8978881.
 - b. Hall WD, Feng Z, George VA, et al. Low-fat diet: effect on anthropometrics, blood pressure, glucose, and insulin in older women. *Ethn Dis.* 2003;13(3):337-43. PMID: 12894958.
18. De Vet E, Oenema A, Sheeran P, et al. Should implementation intentions interventions be implemented in obesity prevention: the impact of if-then plans on daily physical activity in Dutch adults. *Int J Behav Nutr Phys Act.* 2009;6:11. PMID: 19267889.
19. Delichatsios HK, Friedman RH, Glanz K, et al. Randomized trial of a "talking computer" to improve adults' eating habits. *Am J Health Promot.* 2001;15(4):215-24. PMID: 11349340.
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 - a. Kerse N, Elley CR, Robinson E, et al. Is physical activity counseling effective for older people? A cluster randomized, controlled trial in primary care. *J Am Geriatr Soc.* 2005;53(11):1951-6. PMID: 16274377
21. Estabrooks PA, Smith-Ray RL, Almeida FA, et al. Move More: Translating an efficacious group dynamics physical activity intervention into effective clinical practice. *Int J Sport Exerc Psychology.* 2011;9(1):4-18. PMID: None.
22. Fjeldsoe BS, Miller YD, Graves N, et al. Randomized Controlled Trial of an Improved Version of MobileMums, an Intervention for Increasing Physical Activity in Women with Young Children. *Ann Behav Med.* 2015;49(4):487-99. PMID: 25582987.

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- a. Marshall AL, Miller YD, Graves N, et al. Moving MobileMums forward: protocol for a larger randomized controlled trial of an improved physical activity program for women with young children. *BMC Public Health*. 2013;13(1):593. PMID: None.
23. Franko DL, Cousineau TM, Trant M, et al. Motivation, self-efficacy, physical activity and nutrition in college students: Randomized controlled trial of an internet-based education program. *Prev Med*. 2008;47(4):369-77. PMID: 18639581.
24. Fries E, Edinboro P, McClish D, et al. Randomized trial of a low-intensity dietary intervention in rural residents: the Rural Physician Cancer Prevention Project. *Am J Prev Med*. 2005;28(2):162-8. PMID: 15710271.
25. Gao S, Stone RA, Hough LJ, et al. Physical activity counseling in overweight and obese primary care patients: Outcomes of the VA-STRIDE randomized controlled trial. *Prev Med Rep*. 2016;3:113-20. PMID: 26844197.
26. Gell NM, Wadsworth DD. The use of text messaging to promote physical activity in working women: A randomized controlled trial. *J Phys Act Health*. 2015;12(6):756-63. PMID: 25110303.
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 - a. Garcia-Ortiz L, Grandes G, Sanchez-Perez A, et al. Effect on cardiovascular risk of an intervention by family physicians to promote physical exercise among sedentary individuals. *Rev Esp Cardiol*. 2010;63(11):1244-52. PMID: 21070720.
 - b. Grandes G, Sanchez A, Montoya I, et al. Two-year longitudinal analysis of a cluster randomized trial of physical activity promotion by general practitioners. *PLoS One*. 2011;6(3):e18363. PMID: 21479243.
29. Green BB, McAfee T, Hindmarsh M, et al. Effectiveness of telephone support in increasing physical activity levels in primary care patients. *Am J Prev Med*. 2002;22(3):177-83. PMID: 11897462.
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 - a. Clark PG, Nigg CR, Greene G, et al. The Study of Exercise and Nutrition in Older Rhode Islanders (SENIOR): translating theory into research. *Health Educ Res*. 2002;17(5):552-61. PMID: 12408200.
 - b. Clark PG, Rossi JS, Greaney ML, et al. Intervening on exercise and nutrition in older adults: the Rhode Island SENIOR Project. *J Aging Health*. 2005;17(6):753-78. PMID: 16377771.
31. Greenlee H, Gaffney AO, Aycinena AC, et al. Cocinar Para Su Salud!: Randomized Controlled Trial of a Culturally Based Dietary Intervention among Hispanic Breast Cancer Survivors.[Reprint in *J Acad Nutr Diet*. 2015 May;115(5 Suppl):S42-S56.e3; PMID: 25911520]. *J Acad Nutr Diet*. 2015;115(5):709-23.e3. PMID: 25578926.

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32. Halbert JA, Silagy CA, Finucane PM, et al. Physical activity and cardiovascular risk factors: effect of advice from an exercise specialist in Australian general practice. *Med J Aust*. 2000;173(2):84-7. PMID: 10937036.
 - a. Halbert JA, Silagy CA, Finucane P, et al. Recruitment of older adults for a randomized, controlled trial of exercise advice in a general practice setting. *J Am Geriatr Soc*. 1999;47(4):477-81. PMID: 10203125.
33. Hargreaves EA, Mutrie N, Fleming JD. A Web-Based Intervention to Encourage Walking (StepWise): Pilot Randomized Controlled Trial. *JMIR Res Protoc*. 2016;5(1):e14. PMID: 26810251.
34. Harland J, White M, Drinkwater C, et al. The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *BMJ*. 1999;319(7213):828-32. PMID: 10496829.
35. Harris T, Kerry SM, Victor CR, et al. A primary care nurse-delivered walking intervention in older adults: PACE (pedometer accelerometer consultation evaluation)-Lift cluster randomised controlled trial. *PLoS Med*. 2015;12(2):e1001783. PMID: 25689364.
 - a. Harris T, Kerry S, Victor C, et al. Randomised controlled trial of a complex intervention by primary care nurses to increase walking in patients aged 60-74 years: protocol of the PACE-Lift (Pedometer Accelerometer Consultation Evaluation - Lift) trial. *BMC Public Health*. 2013;13:5. PMID: 23289648.
36. Hellenius ML, de FU, Berglund B, et al. Diet and exercise are equally effective in reducing risk for cardiovascular disease. Results of a randomized controlled study in men with slightly to moderately raised cardiovascular risk factors. *Atherosclerosis*. 1993;103(1):81-91. PMID: 8280188.
 - a. Hellenius ML, Dahlof C, Aberg H, et al. Quality of life is not negatively affected by diet and exercise intervention in healthy men with cardiovascular risk factors. *Qual Life Res*. 1995;4(1):13-20. PMID: 7711685.
37. Hinderliter AL, Sherwood A, Craighead LW, et al. The long-term effects of lifestyle change on blood pressure: One-year follow-up of the ENCORE study. *Am J Hypertens*. 2014;27(5):734-41. PMID: 24084586.
 - a. Blumenthal JA, Babyak MA, Hinderliter A, et al. Effects of the DASH diet alone and in combination with exercise and weight loss on blood pressure and cardiovascular biomarkers in men and women with high blood pressure: the ENCORE study. *Arch Intern Med*. 2010;170(2):126-35. PMID: 20101007.
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39. Hypertension Prevention Trial Research Group. The Hypertension Prevention Trial: three-year effects of dietary changes on blood pressure. *Arch Intern Med*. 1990;150(1):153-62. PMID: 2404477.
 - a. Meinert CL, Borhani NO, Langford HG. Design, methods, and rationale in the Hypertension Prevention Trial. Hypertension Prevention Trial Research Group. *Control Clin Trials*. 1989;10(3 Suppl):1S-29S. PMID: 2680271.
 - b. Shah M, Jeffery RW, Laing B, et al. Hypertension Prevention Trial (HPT): food pattern changes resulting from intervention on sodium, potassium, and energy intake. Hypertension Prevention Trial Research Group. *J Am Diet Assoc*. 1990;90(1):69-76. PMID: 2404050.

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 - a. Jacobs N, De BI, Thijs H, et al. Effect of a cardiovascular prevention program on health behavior and BMI in highly educated adults: a randomized controlled trial. *Patient Educ Couns*. 2011;85(1):122-6. PMID: 20888728.
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42. John JH, Ziebland S, Yudkin P, et al. Effects of fruit and vegetable consumption on plasma antioxidant concentrations and blood pressure: a randomised controlled trial. *Lancet*. 2002;359(9322):1969-74. PMID: 12076551.
43. Kallings LV, Sierra JJ, Fisher RM, et al. Beneficial effects of individualized physical activity on prescription on body composition and cardiometabolic risk factors: results from a randomized controlled trial. *Eur J Cardiovasc Prev Rehabil*. 2009;16(1):80-4. PMID: 19237997.
 - a. Kallings LV. Physical activity on prescription: studies on physical activity level, adherence, and cardiovascular risk factors [Doctoral]. Stockholm, Sweden: Karolinska Institute; 2008. PMID: None.
44. Kattelman KK, Bredbenner CB, White AA, et al. The effects of Young Adults Eating and Active for Health (YEAH): A theory-based web-delivered intervention. *J Nutr Educ Behav*. 2014;46(6):S27-S41. PMID: None.
45. Katz DL, Shuval K, Comerford BP, et al. Impact of an educational intervention on internal medicine residents' physical activity counselling: the Pressure System Model. *J Eval Clin Pract*. 2008;14(2):294-9. PMID: 18324934.
46. Kerr DA, Harray AJ, Pollard CM, et al. The connecting health and technology study: A 6-month randomized controlled trial to improve nutrition behaviours using a mobile food record and text messaging support in young adults. *Int J Behav Nutr Phys Act*. 2016;13(1):52. PMID: 27098449.
 - a. Kerr DA, Pollard CM, Howat P, et al. Connecting Health and Technology (CHAT): protocol of a randomized controlled trial to improve nutrition behaviours using mobile devices and tailored text messaging in young adults. *BMC Public Health*. 2012;12:477. PMID: None.
47. King AC, Castro CM, Buman MP, et al. Behavioral Impacts of Sequentially versus Simultaneously Delivered Dietary Plus Physical Activity Interventions: the CALM Trial. *Ann Behav Med*. 2013;46(2):157-68. PMID: 23609341.
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49. Kinmonth AL, Wareham NJ, Hardeman W, et al. Efficacy of a theory-based behavioural intervention to increase physical activity in an at-risk group in primary care (ProActive UK): a randomised trial. *Lancet*. 2008;371(9606):41-8. PMID: 18177774.
 - a. Williams K, Prevost AT, Griffin S, et al. The ProActive trial protocol - a randomised controlled trial of the efficacy of a family-based, domiciliary intervention programme to increase physical activity among individuals at high risk of diabetes [ISRCTN61323766]. *BMC Public Health*. 2004;4:48. PMID: 15491494.

Appendix C. Included Studies

50. Kolt GS, Schofield GM, Kerse N, et al. Effect of telephone counseling on physical activity for low-active older people in primary care: a randomized, controlled trial. *J Am Geriatr Soc.* 2007;55(7):986-92. PMID: 17608869.
51. Kristal AR, Curry SJ, Shattuck AL, et al. A randomized trial of a tailored, self-help dietary intervention: the Puget Sound Eating Patterns study. *Prev med.* 2000;31(4):380-9. PMID: 11006063.
52. Lawton BA, Rose SB, Elley CR, et al. Exercise on prescription for women aged 40-74 recruited through primary care: two year randomised controlled trial. *BMJ.* 2008;337:a2509. PMID: 19074218.
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54. Lutz SF, Ammerman AS, Atwood JR, et al. Innovative newsletter interventions improve fruit and vegetable consumption in healthy adults. *J Am Diet Assoc.* 1999;99(6):705-9. PMID: 10361533.
55. Mailey EL, McAuley E. Impact of a brief intervention on physical activity and social cognitive determinants among working mothers: a randomized trial. *J Behav Med.* 2014;37(2):343-55. PMID: 23338616.
56. Marcus BH, Dunsiger SI, Pekmezi DW, et al. The Seamos Saludables study: A randomized controlled physical activity trial of Latinas. *Am J Prev Med.* 2013;45(5):598-605. PMID: 24139773.
 - a. Marcus BH, Dunsiger SI, Pekmezi D, et al. Twelve-month physical activity outcomes in Latinas in the Seamos Saludables trial. *Am J Prev Med.* 2015;48(2):179-82. PMID: 25442225.
 - b. Pekmezi D, Dunsiger S, Gans K, et al. Rationale, design, and baseline findings from Seamos Saludables: a randomized controlled trial testing the efficacy of a culturally and linguistically adapted, computer- tailored physical activity intervention for Latinas. *Contemp Clin Trials.* 2012;33(6):1261-71. PMID: 22789455.
57. Marcus BH, Napolitano MA, King AC, et al. Telephone versus print delivery of an individualized motivationally tailored physical activity intervention: Project STRIDE. *Health Psychol.* 2007;26(4):401-9. PMID: 17605559.
 - a. Magnan RE, Nilsson R, Marcus BH, et al. A transdisciplinary approach to the selection of moderators of an exercise promotion intervention: baseline data and rationale for Colorado STRIDE. *J Behav Med.* 2013;36(1):20-33. PMID: 22083142.
 - b. Marcus BH, Napolitano MA, King AC, et al. Examination of print and telephone channels for physical activity promotion: Rationale, design, and baseline data from Project STRIDE. *Contemp Clin Trials.* 2007;28(1):90-104. PMID: 16839823.
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60. Martinson BC, Crain AL, Sherwood NE, et al. Maintaining physical activity among older adults: six-month outcomes of the Keep Active Minnesota randomized controlled trial. *Prev med.* 2008;46(2):111-9. PMID: 17904629.

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- a. Martinson BC, Sherwood NE, Crain AL, et al. Maintaining physical activity among older adults: 24-month outcomes of the Keep Active Minnesota randomized controlled trial. *Prev Med*. 2010. PMID: 20382179.
- b. Sherwood NE, Martinson BC, Crain AL, et al. A new approach to physical activity maintenance: rationale, design, and baseline data from the Keep Active Minnesota Trial. *BMC Geriatrics*. 2008;8:17. PMID: 18655709.
61. Mosca L, Mochari H, Liao M, et al. A novel family-based intervention trial to improve heart health: FIT Heart: results of a randomized controlled trial. *Circ Cardiovasc Qual Outcomes*. 2008;1(2):98-106. PMID: 20031796.
 - a. Greenberger HM. Modifiers of the effectiveness of a diet intervention in family members of cardiovascular disease patients [Dissertation Research]. UMI Dissertation Publishing: Columbia University; 2010. PMID: None.
 - b. Mochari-Greenberger H, Terry MB, Mosca L. Sex, age, and race/ethnicity do not modify the effectiveness of a diet intervention among family members of hospitalized cardiovascular disease patients. *J Nutr Educ Behav*. 2011;43(5):366-73. PMID: 21906549.
62. Napolitano MA, Whiteley JA, Papandonatos G, et al. Outcomes from the women's wellness project: a community-focused physical activity trial for women. *Prev Med*. 2006;43(6):447-53. PMID: 16919322.
 - a. Dutton GR, Napolitano MA, Whiteley JA, et al. Is physical activity a gateway behavior for diet? Findings from a physical activity trial. *Prev Med*. 2008;46(3):216-21. PMID: 18234327.
63. Norris SL, Grothaus LC, Buchner DM, et al. Effectiveness of physician-based assessment and counseling for exercise in a staff model HMO. *Prev Med*. 2000;30(6):513-23. PMID: 10901494.
64. Parekh S, King D, Boyle FM, et al. Randomized controlled trial of a computer-tailored multiple health behaviour intervention in general practice: 12-month follow-up results. *Int J Behav Nutr Phys Act*. 2014;11(1):41. PMID: 24646165.
 - a. Parekh S, Vandelanotte C, King D, et al. Design and baseline characteristics of the 10 Small Steps Study: a randomised controlled trial of an intervention to promote healthy behaviour using a lifestyle score and personalised feedback. *BMC Public Health*. 2012;12:179. PMID: 22405027.
65. Pekmezi DW, Neighbors CJ, Lee CS, et al. A culturally adapted physical activity intervention for Latinas: a randomized controlled trial. *Am J Prev Med*. 2009;37(6):495-500. PMID: 19944914.
66. Pinto BM, Friedman R, Marcus BH, et al. Effects of a computer-based, telephone-counseling system on physical activity. *Am J Prev Med*. 2002;23(2):113-20. PMID: 12121799.
67. Pinto BM, Goldstein MG, Ashba J, et al. Randomized controlled trial of physical activity counseling for older primary care patients. *Am J Prev Med*. 2005;29(4):247-55. PMID: 16242586.
68. Roderick P, Ruddock V, Hunt P, et al. A randomized trial to evaluate the effectiveness of dietary advice by practice nurses in lowering diet-related coronary heart disease risk. *Br J Gen Pract*. 1997;47(414):7-12. PMID: 9115804.
69. Ruffin MT, Nease DE, Jr., Sen A, et al. Effect of preventive messages tailored to family history on health behaviors: the Family Healthware Impact Trial. *Ann Fam Med*. 2011;9(1):3-11. PMID: 21242555.

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 - a. Kuller LH, Simkin-Silverman LR, Wing RR, et al. Women's Healthy Lifestyle Project: A randomized clinical trial: results at 54 months. *Circulation.* 2001;103(1):32-7. PMID: 11136682.
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 - a. Springvloet L, Lechner L, de Vries H, et al. Long-term efficacy of a Web-based computer-tailored nutrition education intervention for adults including cognitive and environmental feedback: a randomized controlled trial. *BMC Public Health.* 2015;15:372. PMID: 25887891.
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76. The Trials of Hypertension Prevention Collaborative Research Group. The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels. Results of the Trials of Hypertension Prevention, Phase I. *JAMA.* 1992;267(9):1213-20. PMID: 1586398.
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Appendix C. Included Studies

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Appendix D. Excluded Studies

Reason for Exclusion	
E1.	Study aim: not focused on cardiovascular disease primary prevention
E2a.	Setting: Not conducted in 'very high' HDI country
E2b.	Setting: Not conducted in, recruited from, or feasible for primary care or a health care system
*E3a.	Population: Adults at high-risk for CVD
E3b.	Population: Adults with known CVD or diabetes mellitus
E3c.	Population: Adults with other known chronic disease (e.g., cancer, chronic kidney disease, severe mental illness)
E3d.	Population: Other excluded population (i.e., children and adolescents, parents, pregnant women, institutionalized adults)
E4.	Outcomes: No relevant outcomes
E5a.	Interventions: Intervention out-of-scope
E5b.	Interventions: Stress reduction-focused intervention (e.g., Yoga, Tai Chi)
E6a.	Study design: Not RCT, CCT for KQ1-3; not RCT, CCT, large comparative cohort or case-control or event monitoring study for KQ4
E6b.	Study design: Less than 6 months f/u (for KQ1-3)
E6c.	Study design: Not an included comparator/comparative effectiveness
E7.	Publication date: primary results published prior to 1990
E8.	Language: Publication not in English
E9.	Study quality: Poor quality rating

* Assigned at abstract and full-text phase.

Abbreviations: CCT=controlled clinical trial; CVD=cardiovascular disease; f/u=follow-up; E=exclude; HDI=human development index; KQ=key question; RCT=randomized, controlled trial.

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- Aggarwal B, Liao M, Allegrante JP, et al. Low social support level is associated with non-adherence to diet at 1 year in the Family Intervention Trial for Heart Health (FIT Heart). *J Nutr Educ Behav.* 2010;42(6):380-8. PMID: 20696617. KQ1E4, KQ2E4, KQ3E4, KQ4E4.
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- Albert CM, Mittleman MA, Chae CU, et al. Triggering of sudden death from cardiac causes by vigorous exertion. *N Engl J Med.* 2000;343(19):1355-61. PMID: 11070099. KQ1E5a, KQ2E5a, KQ3E5a, KQ4E5a.
- Albright CL, Saiki K, Steffen AD, et al. What barriers thwart postpartum women's physical activity goals during a 12-month intervention? A process evaluation of the Nā Mikimiki Project. *Women Health.* 2015;55(1):1-21. PMID: 25402618. KQ1E4, KQ2E4, KQ3E4, KQ4E4.

Appendix D. Excluded Studies

9. Andersen E, Burton NW, Anderssen SA. Physical activity levels six months after a randomised controlled physical activity intervention for Pakistani immigrant men living in Norway. *Int J Behav Nutr Phys Act*. 2012;9:47. PMID: 22537281. KQ1E5a, KQ2E5a, KQ3E5a, KQ4E5a.
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Appendix D. Excluded Studies

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46. De Cocker K, Spittaels H, Cardon G, et al. Web-based, computer-tailored, pedometer-based physical activity advice: development, dissemination through general practice, acceptability, and preliminary efficacy in a randomized controlled trial. *J Med Internet Res*. 2012;14(2):e53. PMID: 22532102. KQ1E6b, KQ2E6b, KQ3E6b, KQ4E6b.
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Appendix D. Excluded Studies

52. Eaton CB, Hartman S, Risica PM, et al. P119: tailored lifestyle intervention for obese, sedentary patients in primary care: Choose to Lose study. American Heart Association's Epidemiology and Prevention/Lifestyle and Cardiometabolic Health 2015 Scientific Sessions. 2015;131. PMID: None. KQ1E3a, KQ2E3a, KQ3E3a, KQ4E3a.
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60. Fjeldsoe B, Phongsavan P, Bauman A, et al. "Get Healthy, Stay Healthy": protocol for evaluation of a lifestyle intervention delivered by text-message following the Get Healthy Information and Coaching Service. *BMC Public Health*. 2014;14:112. PMID: 24495781. KQ1E4, KQ2E4, KQ3E4, KQ4E4.
61. Friederichs SA, Oenema A, Bolman C, et al. Long term effects of self-determination theory and motivational interviewing in a web-based physical activity intervention: randomized controlled trial. *Int J Behav Nutr Phys Act*. 2015;12(101). PMID: 26283094. KQ1E4, KQ2E4, KQ3E9, KQ4E4.
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Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Aadahl, 2014 ⁸⁰	PA M	IG1	Counseling	4 individual behavioral choice theory-based face-to-face sessions, 30- to 45-min, at 6-week intervals during a 6-month period. Sessions incorporated individual behavior goal-setting, self-efficacy, and MI techniques. Participants set specific, individual goals for change in sedentary behavior by identifying adequate behavior substitutes or choices and initiating small changes in availability and access to sedentary behavior in their daily lives; behavior goals were reviewed and evaluated. Each session also focused on 1 of the 4 key messages: 1) reduce daily TV viewing; 2) substitute sitting with standing when possible, at work and at home (no time restrictions); 3) break up prolonged sitting by standing up frequently; and 4) 30-min maximum of sitting per episode. Written materials containing these key messages, including strategies and suggestions for reduction of sitting time, were given to participants at each session in purposefully developed booklets and on postcards and stickers.	97.5% of participants nearly completed all 4 intervention sessions (2/81 unable to attend last session; received materials via mail)	BCT	X	X			X	X			None
Aittasalo, 2006 ⁸¹	PA L	IG1	Brief counseling	One 5- to 10-min prescription-based counseling session with PCP using the 5As. Key issues of counseling were: 1) patients' current PA level, their readiness to increase PA, and PA preferences; 2) patient-centered goal-setting; 3) emphasis on lifestyle activities, which may have more long-term effects than structured exercise; and 4) agreement on control visits, most preferably with a preset date. Evidence about the health benefits of PA also presented. Optional activities included PA log for self-monitoring and referral to PA experts.	NR	NR							X		UC: Appointment with physician carried out as usual
Aittasalo, 2006 ⁸¹	PA L	IG2	Self-monitoring	Pedometer and PA log for monitoring 5 days of activity. Received feedback and personal PA recommendations based on PA log by mail.	NR	NR		X							

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Albright, 2014 ⁸³	PA L	IG1	Tailored phone counseling plus website	17 phone calls with counselor who used MI techniques to problem-solve barriers using culturally sensitive techniques and set future PA goals (incrementally building up to 150 min/week of MVPA), with a pedometer to track and set goals (10,000 steps/day). Participants were referred to a condition-specific, tailored website that included tailored “mom-centric” PA “resource directories,” such as information on parks with paved paths for a stroller; newsletters that included personal factors of self-regulatory behavioral skills and self-efficacy to do regular PA; and enlisting social support for PA from family and friends.	Mean, 12.7 min per call Out of 17 planned calls, 70% received ≥13 calls 23% did not visit website 6% visited once 31% visited 2 to 10 times 18% visited 11 to 20 times 22% visited ≥21 times	NR	X	X	X		X	X			MI: Information on PA benefits via standard website and print materials.
Aldana, 2006 ⁸⁵	HD+PA H	IG1	Group counseling	16 2-hr group education sessions over 4 weeks addressing various diet, exercise, lifestyle, and health topics. Participants encouraged to follow preset dietary and exercise goals. Dietary goal was a more plant-based food diet that was low in fat, animal protein, sugar, and salt; very low in cholesterol; and high in fiber. Exercise goal was walking ≥30 min/day. Participants also received a workbook with assignments, a pedometer, and were encouraged to keep an exercise log and had access to shopping trips with dietitians and cooking demonstrations.	Average of 89% of classes attended	NR		X						X	WL

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Alexander, 2010 ⁸⁶	HD M	IG1	Tailored web-based + email counseling	4 tailored web sessions offered 1, 3, 13, and 15 weeks after enrollment. 4 sets of email counseling sessions based on MI, initiated by a study counselor within a week following a new web session visit. Counseling was linked to the most current session and included feedback on current intake levels and reflection on participant's plan. Behavioral web sessions were tailored to the participant's stage of change and designed to increase motivation and self-efficacy for eating fruits and vegetables, including expanded goal intake of 5 to 9 daily servings, and a goal-setting tool was available to aid in planning for change. Each session included 4 to 5 pages of core content, illustrations, optional links to more detailed explanations, and special features designed to supplement session content. Once available, all program components were accessible throughout the 12-month study period. Optional features: individually tailored menus; 60-second video clips of recipe preparation; create own menus from the recipe library.	Counselor-initiated emails ranged from 0 to 17 emails per participant (mean, 6). Participation rate in email support: 22% had no exchanges, 29% had 1 to 3, 17% had 4 to 8, 33% had ≤9.	SCT, TTM, HBM	X	X		X	X	X			MI: 4 nontailored web sessions provided general fruit and vegetable nutrition information.
Alexander, 2010 ⁸⁶	HD M	IG2	Tailored web-based counseling	4 tailored web sessions offered 1, 3, 13, and 15 weeks after enrollment. Behavioral web sessions were tailored to the participant's stage of change and designed to increase motivation and self-efficacy for eating fruits and vegetables, including expanded goal intake of 5 to 9 daily servings, and a goal-setting tool was available to aid in planning for change. Each session included 4 to 5 pages of core content, illustrations, optional links to more detailed explanations, and special features designed to supplement session content. Once available, all program components were accessible throughout the 12-month study period. Optional features: individually tailored menus; 60-second video clips of recipe preparation; create own menus from the recipe library.	NR		X	X		X	X				

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Baron, 1990 ⁹⁰	HD M	IG1	Counseling	Participants completed a self-administered questionnaire concerning general health, smoking habits, and present diet and given instruction on optimal body weight and diet by a nurse in the practice. Counseling sessions were done individually or in small groups and lasted about 30 min per session; dietary advice was focused on making modest decreases in total fat intake from an expected level of >40% of calories to 30% to 35% of calories, increase in ratio of polyunsaturated to saturated fats to about 0.4 from an expected level of <0.3, and stressed the value of increased dietary fiber, including soluble fiber. Potential benefits of PA and moderation of salt, alcohol, and tobacco intake were also mentioned but not emphasized. A booklet was given that summarized basic ideas of diet, provided recipes, and offered advice concerning local restaurants. Study nurse also provided support and encouragement on dietary modification at 2 brief FU counseling sessions. Promotional materials were also on display at the practice.	NR	NR								X	UC: Participants were told they were part of a nutrition survey and were followed up on the same schedule by the same nurse, but without dietary advice
Bennett, 2013 ⁹¹	HD+PA H	IG1	Counseling, tailored print materials, and self-monitoring	Goal was slight (<200 kcal) daily energy deficit to offset weight gain. 3 behavior change goals were assigned using the interactive obesity treatment approach (iOTA) at baseline and new goals at months 2 and 4; each goal assignment included printed personalized feedback reports with previous goal results and tailored prescriptions for new goals. Pedometers and tracking logs were used daily and reported during weekly interactive voice response (IVR) calls. Individually tailored intervention materials were delivered 22 times over 1 year, including 1 initial set at baseline followed by 5 bimonthly mailings during months 3 to 12 and quarterly newsletters. Also 12 monthly 20-min counseling calls with a registered dietician trained in MI and 12-month membership to local YMCA.	81.9% completed counseling calls during 12-month period, IVR call completion rate ranged from 65.2% to 89.5% per week with a mean (SD) of 72% (28%). 70.3% initiated free YMCA membership and 40.7% visited more than once.	SCT	X	X	X		X			X	UC: 3 newsletters covering general wellness topics, not including weight, nutrition, or PA, sent every 6 months

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Beresford, 1997 ⁹²	HD L	IG1	Brief counseling and self-help material	Self-help booklet and brief physician endorsement of dietary change at routine scheduled medical appointment. Physicians introduced the booklet to the participant in a standardized fashion, taking <3 min during the encounter. The booklet contained a brief self-test of current dietary behavior, suggestions for small, sequential behavior change, self-assessment questionnaires, and sections for recording short- and long-term goals. 2 weeks later, a reminder letter signed by the physician was mailed to participants. Booklet and script to introduce it were placed in patient chart.	95% of participants who attended their appointment received their booklet	SCT	X								UC: Not described
Bernstein, 2002 ⁹³	HD H	IG1	Home-based education	In-depth, home-based, personalized education program that stressed increasing fruit and vegetable intake to a minimum of 5 servings/day and calcium-rich foods to a minimum of 3 servings/day. Provided through 8 home visits, biweekly phone contacts, and monthly letters over 6 months. Subjects were given an education book. Topics included good nutrition at any age, health benefits of eating more fruits and vegetables, importance of calcium-rich foods and risk factors for osteoporosis, what constitutes a serving, grocery shopping tips, and nutrient dense recipes. Behavior modification techniques such as goal setting, rewards, food log recording, role-playing games, and trouble shooting were included in home visit sessions.	NR	NR	X	X		X					AC: Home-based exercise program

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Bickmore, 2013 ⁹⁴	PA M	IG1	Computer-based counseling	2-month intensive intervention phase delivered on take-home computer tablets followed by 10-month maintenance phase delivered on outpatient waiting room kiosk computers. Intervention used an embodied conversational agent (ECA) exercise coach. ECAs are animated computer characters that simulate face-to-face conversation using voice, hand gesture, and gaze cues and other nonverbal behavior to make the computer interface as acceptable and intuitive as possible for people who may have no prior experience with computers and for those with low health literacy. At baseline, participants were instructed on how to use the tablets and to conduct daily 5-min conversations with the ECA for 2 months, focused on increasing walking. The virtual coach reviewed individual progress relative to short- and long-term goals, provided positive reinforcement, problem solving to overcome barriers to PA, and goal setting. Pedometer tracked steps and participants downloaded their data to the virtual system to aid in feedback during conversations. Tablets were returned at 2 months and participants were instructed on how to use an identical computer kiosk program in clinic waiting room when they were attending a routine appointment for the remaining 10 months.	Mean number of interactions with take-home tablet (SD): 35.8 (19.7) out of 60 days. Use decreased after first week from average of 4.7 to 4.0 sessions per week and then declined to 3.3 sessions per week at end of 2-month period. Mean (SD): 1.0 (2.9) interaction with outpatient kiosk over 10-month period.	NR	X	X							MI: Pedometers and monthly activity logs to track step counts

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Brekke, 2005 ⁹⁷	HD H	IG1	Group counseling (diet)	Two 60- to 120-min dietary group education sessions given 1 to 2 weeks apart at start of study; participants were asked to bring another member in their household, preferably the meal preparer. Sessions addressed general dietary advice, food examples, meal patterns and regular meal frequency, and side effects of increased fiber intake. Time was provided to discuss questions and food choices. Dietary advice aimed to reduce saturated fat (10% energy); increase monounsaturated fat and omega-3 fatty acids; increase vegetable, fruit, and fiber intake; increase intake of low glycemic index (GI) foods and reduce intake of high GI foods. For first 4 months, 7 to 9 unannounced phone interviews were performed using 24-hr dietary recall as basis for discussion. After 4 months, phone interviews were conducted every 10 weeks.	NR	NR			X						MI: UC for the first year. At 1 year, dietary counseling (minimal intervention with lower intensity FU)

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Brekke, 2005 ⁹⁷	HD+PA H	IG2	Group counseling (diet and PA)	Two 60- to 120-min dietary group education sessions given 1 to 2 weeks apart at start of study; participants were asked to bring another member in their household, preferably the meal preparer. Sessions addressed general dietary advice, food examples, meal patterns and regular meal frequency, and side effects of increased fiber intake. Time was provided to discuss questions and food choices. Dietary advice aimed to reduce saturated fat (10% energy); increase monounsaturated fat and omega-3 fatty acids; increase vegetable, fruit, and fiber intake; and increase intake of low glycemic index (GI) foods and reduce intake of high GI foods. Also, sessions included exercise advice and discussion of benefits of PA and how to increase PA. Participants could decide how to personally achieve their goals for ≥30 min of PA 4 or 5 times per week. For first 4 months, 7 to 9 unannounced phone interviews were performed using 24-hr dietary recall and 72-hr PA recall as basis for discussion. After 4 months, phone interviews were conducted every 10 weeks.	NR	NR	X		X						
Bryan, 2013 ⁹⁸	PA L	IG1	Tailored print mailings	14 individually tailored mailings with information based on current perceived barriers and level of motivation for increasing PA over 1 year, with weekly mailings during month 1, biweekly during months 2 and 3, monthly during months 4 to 6, and bimonthly during months 7 to 12. Mailings included questionnaires and printed feedback reports based on questionnaire results generated by a computer expert system, a self-help manual matched to current stage of motivational readiness, and a series of tip sheets. Participants were told that their goal was to increase PA to 30 min/day, 5 days/week.	NR	SCT, TTM	X	X		X	X				AC: 14 mailings with general health and wellness information

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Burke, 2013 ¹⁰⁰	HD+PA M	IG1	Self-help booklet and phone and email counseling	1 booklet designed for seniors that provided PA and nutrition recommendations and encouraged goal setting. Booklet was supported by an exercise chart, calendar, 3 bimonthly newsletters, resistance band and pedometer, along with 6 to 10 motivational phone calls and/or 2 to 5 email contacts with program guides.	NR	Precede Proceed Model, SCT	X	X	X		X				None
Carpenter, 2004 ¹⁰¹	HD H	IG1	Group counseling	Twenty 75-min group (13 to 15 people) counseling sessions with 2 staff facilitators (weekly for first 16 weeks and biweekly for last 8 weeks). Sessions included a brief check-in, session topic and review of materials, interactive learning strategies to personalize the topic to participants' respective lives, and review of homework. Participants were encouraged to turn in weekly food logs for feedback. Curriculum focused on process of behavior change; facilitators stressed 4 main dietary changes: decreasing fats, increasing whole grains, dairy products, and other calcium-rich foods, and fruits and vegetables. Also received a copy of the American Dietetic Association's Complete Food & Nutrition Guide and contact information of study staff for any questions.	NR	SCT, TTM	X	X	X	X					MI: Booklet on healthy diet
Carpenter, 2004 ¹⁰¹	HD L	IG2	Mailed materials and web site	Received 2 weekly print curriculum sessions twice a month via regular mail with weekly reminders, which focused on teaching the process of behavior change. In addition, had access to a web site through which they could post questions and review responses, read restaurant critiques, obtain recipes, and participate in a weekly live online chat session. Curriculum focused on process of behavior change and focused on 4 main dietary changes: decreasing fats, increasing whole grains, dairy products, and other calcium-rich foods, and fruits and vegetables. Also received a copy of the American Dietetic Association's Complete Food & Nutrition Guide and contact information of study staff for any questions.	NR	SCT, TTM	X	X	X	X					

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Carroll, 2010 ¹⁰²	PA L	IG1	Tailored print mailings	Participants completed PA surveys mailed to them at baseline, 1, 3, and 6 months. Surveys asked about current PA habits, self-efficacy, decisionmaking about PA, health status, and chronic conditions. After completing and returning each PA survey, a tailored ipsative feedback report was mailed to the participant, designed to motivate them to increase PA personalized to their needs. Reports were based on both psychosocial measure (stage of change, process of change, self-efficacy, and pros and cons) and the reported amount of PA. The tailored reports provided congratulatory messages for participants obtaining the recommended PA, and tips on increasing activity for those not meeting the recommendations. The reports also contained an activity prescription (in which physicians could prescribe a type of activity, intensity [moderate/hard], frequency, and duration), with instructions to bring the prescription to their next physician visit.	89% received the intervention materials; 86.2% reported reading all or most of the materials.	TTM	X	X		X	X				AC: 4 feedback reports containing information on recommended preventive and screening tests.

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Castro, 2011 ¹⁰³	PA M	IG1	Counseling	1 initial face-to-face session with professional staff member to discuss health history and motivation for changing behavior, set initial goals, and establish phone counseling appointment times. 14 phone counseling calls over 12 months by a trained professional, twice per month for first 2 months and then monthly for remaining 10 months, in which the Active Choices Program (ACP), a guided self-management program, was delivered. ACP focused on increasing leisure PA to moderate- or vigorous-intensity PA to achieve recommendations of ≥150 min/week. Phone counseling calls were supplemented with monthly newsletter mailings and tip sheets.	Across both intervention groups, average of 11/14 (78.6%) calls completed (15 to 16 min per call)	SCT, TTM	X	X		X	X				AC: 1 face-to-face session, followed by 14 FU calls focused on adopting a heart-healthy diet by reducing saturated fat and increasing fruits and vegetables. Participants were asked to track food intake and behavior change efforts, and to maintain usual patterns of PA.
Castro, 2011 ¹⁰³	PA M	IG2	Peer counseling	1 initial face-to-face session with peer mentor to discuss health history and motivation for changing behavior, set initial goals, and establish phone counseling appointment times. 14 phone counseling calls over 12 months by a peer mentor, occurring twice per month for first 2 months and then monthly for remaining 10 months, in which the Active Choices Program (ACP), a guided self-management program, was delivered. ACP focused on increasing leisure PA to moderate- or vigorous-intensity PA to achieve recommendations of ≥150 min/week. Phone counseling calls were supplemented with monthly newsletter mailings and tip sheets.		SCT, TTM	X	X	X	X	X				

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Coates, 1999 ¹⁰⁶	HD H	IG1	Group counseling	Up to 18 group (8 to 15 people per group) counseling sessions with research nutritionist. Groups met weekly for first 6 weeks, biweekly for next 6 weeks, and monthly thereafter for an additional 9 months or until end of the study. Each session integrated nutritional and behavioral change strategies. Nutritionists encouraged participants to substitute low-fat for high-fat foods and recipes. Group members shared experiences, role played, provided support, and helped each other solve problems. Sessions incorporated regional and ethnic foods and local terminology. Groups reinforced success in changing eating patterns and in bringing interesting low-fat dishes to sessions. Nutritionists invited family members to selected sessions and encouraged a friendly group environment. Each participant monitored dietary intake with a goal for grams of fat equivalent to ~20% of total energy, using self-monitoring tools. For individuals having difficulty making changes or continuing participation, nutritionists provided individualized attention.	96% attended at least 1 session 83% attended sessions for ≥6 months 79% attended sessions for ≥12 months Adherence was somewhat lower among Hispanic women	NR	X	X	X						MI: Received copy of Dietary Guidelines for Americans
de Vet, 2009 ¹⁰⁸	PA L	IG1	Self-directed and self-selected activity plan (with repeat planning)	All participants asked to increase PA level by 2 hr/week and to explicitly decide and write down their plan (i.e., implementation intentions) for what activity, when, where, and how long they would do it. This group self-selected up to 3 activities and made repeated plans after 2 weeks and 3 months. The plan was set autonomously with no help of an interventionist.	Of respondents asked to form implementation intentions, 89%, 89%, and 86% did so at baseline, 2 weeks, and 3 months, respectively	NR	X								MI: Questionnaire with information about benefits of exercise and recommended increase in activity level by 2 hr/week
de Vet, 2009 ¹⁰⁸	PA L	IG2	Self-directed and self-selected activity plan (one-time plan)	All participants asked to increase PA level by 2 hr/week and to explicitly decide and write down their plan (implementation intentions) for what activity, when, where, and how long they would do it. This group self-selected up to 3 activities. Plan was set autonomously with no help of an interventionist.			X								

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de Vet, 2009 ¹⁰⁸	PA L	IG3	Self-directed walking plan (one-time plan)	All participants asked to increase PA level by 2 hr/week and to explicitly decide and write down their plan (implementation intentions) for what activity, when, where, and how long they would do it. This group was assigned their activity (walking). Plan was set autonomously with no help of an interventionist.			X								
Delichatsios 2001 ¹⁰⁹	HD M	IG1	Automated phone counseling	Home monitoring, education, and counseling delivered via a phone-linked communication system (TLC-Eat) once a week for 6 months, lasting 5 to 7 min, focused on specific food groups or eating behaviors. TLC-Eat monitored the participants' behaviors and health conditions and provided education and behavioral reinforcement for targeted behaviors, such as diet. It focused on fruits, vegetables, red and processed meats, whole-fat dairy foods, and whole grain foods using SCT as a guide to behavior change, focusing on intrapersonal factors linking eating behaviors to personally valued outcomes. Responses were compared between conversations and provided feedback on change, along with education, advice, and counseling tailored to the participants reported eating behaviors, and FU on goals set in previous conversations. Data were also used to generate written reports for participants and their health care providers as needed.	24% never called the system 36% called 1 to 10 times 23% called 11 to 19 times 18% called >20 times	SCT	X	X		X	X				AC: PA counseling using the same TLC automated technology

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Elley, 2003 ¹¹¹	PA M	IG1	Counseling with tailored prescription	One 10-min consultation with PCP discussing increasing PA and goal setting. Goals, usually home-based PA or walking, were written on a standard green prescription and given to participants. This was followed by three 10- to 20-min phone calls over 3 months from exercise physiologists to encourage and support participants, including MI, and specific advice about exercise or community groups was provided if appropriate. Quarterly newsletters were sent over the course of a year, containing information about community exercise initiatives and motivational material.	95% of participants who attended FU recalled receiving a green prescription	TTM	X			X					UC: Not described
Estabrooks, 2011 ¹¹²	PA M	IG1	Group counseling	The Move More intervention consisted of two 2-hr group sessions (average 8 participants/group, 4 weeks apart) and 1 phone contact (12 weeks after randomization). Group dynamic principles were used in each session: providing team points and rewards for class attendance, completion of activities between sessions, and tracking behaviors; creating small teams and team goals; discussing barriers of behavior change; identifying strategies to overcome barriers; presenting resources, such as supportive people to achieve their goals; and discussing personal benefits of PA as well as the components of an effective PA plan. In addition, handouts were provided on how to determine exercise intensity and complete stretches and strength training at home, and personal action plan. Instructors led each small team through a series of group strength, flexibility, and cardiovascular exercises that could be completed at home. 8 weeks after second group session, participants received a FU phone call where counselors used the 5As to assess, advise, agree, assist, and arrange strategies for increasing or maintaining PA.	NR	Group Dynamics Model	X	X	X		X		X		MI: 2 print mailings and 1 phone contact

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Fjeldsoe, 2015 ¹¹³	PA M	IG1	Counseling and regular text messages	Intervention began with one 24- to 45-min face-to-face counseling session with a trained MobileMums behavioral counselor, after which participants received 12 weeks of individually tailored theory-based text messages (52 total) and a FU phone counseling session with behavioral counselor at 6 weeks. Participants also received supplementary resources, including a MobileMums participant handbook, a MobileMums goal tracking refrigerator magnet, and standard PA information brochures, as well as details for joining a dedicated Facebook group and web site with a searchable online exercise directory. Each participant was asked to identify a support person who also received 12 weeks of individually tailored, theory-based text messages.	98% completed face-to-face counseling session (mean duration, 50 min); 83% completed phone FU (mean duration, 14 min). On average, 58 text messages were sent per participant and 33 sent per support person.	SCT	X	X	X	X	X				MI: PA brochures, information-only website and Facebook group, 1-page summary of accelerometer-derived PA
Franco, 2008 ¹¹⁵	HD+PA M	IG1	Web-based intervention + booster session	Used MyStudentBody.com-Nutrition (MSB-N) for two 45-min web sessions plus a subsequent booster session. This interactive, web-based program specifically targets the needs of college students and aims to improve nutrition behaviors, increase nutritional knowledge, and increase PA. MSB-N is comprised of: 1) 3 information links (Ask the Expert, Student Voices, College News); 2) Rate Myself assessment (questions that are used to provide feedback to the user); 3) 4 main topic pages (Nutrition 101, Eating on the Run, Weighing In, Fitness); and 4) Resources. Participants were instructed to log into the site and begin by completing the Rate Myself questionnaires, which assessed current dietary intake and patterns as well as PA levels and beliefs. Participants were then directed to visit the 4 main topic pages, which contained text-based and audio information, interactive activities, and goal-setting areas.	NR	TTM	X	X		X	X				AC: Interactive website on anatomy

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group	
Franko, 2008 ¹¹⁵	HD+PA M	IG2	Web-based intervention	Used MyStudentBody.com-Nutrition (MSB-N) for two 45-min web sessions. This interactive, web-based program specifically targets the needs of college students and aims to improve nutrition behaviors, increase nutritional knowledge, and increase PA. MSB-N is comprised of: 1) 3 information links (Ask the Expert, Student Voices, College News); 2) Rate Myself assessment (questions that are used to provide feedback to the user); 3) 4 main topic pages (Nutrition 101, Eating on the Run, Weighing In, Fitness); and 4) Resources. Participants were instructed to log into the site and begin by completing the Rate Myself questionnaires, which assessed current dietary intake and patterns as well as PA levels and beliefs. Participants were then directed to visit the 4 main topic pages, which contained text-based and audio information, interactive activities, and goal-setting areas.			X	X		X	X					
Fries, 2005 ¹¹⁶	HD L	IG1	Tailored print mailing and brief counseling call	1 individually-tailored fat and fiber feedback mailing with physician endorsement, minimal brief counseling call, and 5 low-literacy self-help booklets. Tailored mailing consisted of 2 feedback forms and 2 recommendation forms (1 each for fat and fiber) based on baseline fat and fiber questionnaire plus physician endorsement letter. Feedback categorized into STOP (poor eating habits), YIELD (needs improvement), and GO (good habits) messages. Participants received minimal brief counseling call 2 weeks after mailing; call was designed to remind and reinforce and offer to answer questions. 5 low-literacy self-help booklets mailed during weeks 2 to 6 focused on behavior and skills for healthy eating; booklets adapted from the Eating Patterns Study (Beresford, 1997). Community advisory board provided input for tailoring intervention to rural audience.	82% of participants received 1 FU call. 74% reported receiving materials and 63.9% feedback; materials resent to all participants not receiving them.	SCT, TTM	X			X	X				WL	

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Gao, 2016 ¹¹⁷	PA M	IG1	Individual counseling and tailored print materials	Participants attended one 60-min individually-tailored counseling session based on medical conditions identified in their medical record and their baseline assessment. Session included guided goal setting to gradually increase moderate-intensity PA to ≥150 min/week. Subsequently, they received 14 expert system-tailored mailings weekly.	NR	SCT, TTM		X							AC: 14 mailed wellness newsletters
Gell, 2015 ¹¹⁹	PA L	IG1	Targeted text messages	Participants received 3 text messages per week on personal cell phone via SMS for 24 weeks. While messages were not sent at a specific time each day, the majority were sent based on optimal time availability for PA planning, such as early morning for time management of the day, in the hour prior to the lunch break, which was standard across campus, and in the hour prior to the official close of university offices. All participants received the same content and number of messages. Content included the following: 1) recommended amounts of PA needed to meet guidelines; 2) specific suggestions for ways to meet the guidelines; 3) self-regulation strategies such as goal setting, relapse prevention, engaging social support, self-monitoring, time management and reinforcement; and 4) strategies to address the most common barriers identified from baseline and mid-point self-efficacy instrument. Content was adjusted for weather conditions. In addition, all participants were provided with 3 maps displaying walking routes of 1, 2, and 3 miles from each subject's worksite location and a fourth map provided an alternative 1-mile route or a parking option about 1 mile from work site. All participants were also provided a link to the intervention web site, which included PA guidelines, PDF versions of all campus walking maps, and links and suggestions on ways to begin an exercise program and increase PA levels.	NR	Behavior Choice Theory	X		X		X				MI: Walking maps and educational website

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Goldstein, 1999 ¹²⁰	PA L	IG1	Brief counseling with tailored prescription	One 5-min patient-centered counseling session with PCP based on stages of change with matched written exercise prescription and patient manual, plus one 5-min FU visit for additional PA counseling and a new exercise prescription. Also received 5 monthly mailings, including another copy of the manual, and 4 newsletters providing information on specific exercise activities appropriate for older adults, local resources, quizzes, and tips.	93% reported receiving PA counseling at initial visit 67% recalled receiving exercise prescription	SCT, TTM, theory of health education	X						X		UC: UC from primary care physicians
Grandes, 2009 ¹²²	PA L	IG1	Brief counseling	1 brief (assumed <15 min) counseling session with PCP using web-based software primarily discussing the benefits of PA and risks of inactivity, including a 4-page nontailored brochure. Patients then offered an optional 15-min FU session to develop a 3-month prescription-based action plan.	69.6% received advice only 30.4% received advice plus prescription	HBM, SCT	X	X							UC: UC from primary care physicians
Green, 2002 ¹²³	PA M	IG1	Phone counseling	1 nontailored letter from PCP encouraging PA, including reading materials on fitness and a workbook containing self-help materials on how to get 30 min of moderate PA, setting targets, ways to overcome barriers, and measuring progress. Print materials were followed by three 20- to 30-min phone calls with behavioral specialists monthly for 3 months to assess current exercise status and motivational stage, to assist in making a reasonable and measurable goal, to identify and problem solve barriers, and to identify resources and support.	Only 38% of intervention participants received the intervention. Of those, 77% received all 3 self-management support calls, 9 (15%) received 2 calls, 3 (5%) received 1 call, and 2 (3%) received no calls.	TTM	X	X							MI: One-time delivery of print materials on improving overall health and preventive practices, including PA
Greene, 2008 ¹²⁵	HD M	IG1	Tailored print mailings and counseling phone calls	Monthly print or phone contact over 12 months focused on increasing fruit and vegetable intake, including a tailored manual; 9 monthly mailings of stage-specific tailored newsletters; 3 computer-based expert system generated tailored reports; and three 15-min coaching calls from trained counselors to reinforce the expert systems reports, including MI.	NR	TTM	X					X			AC: Falls prevention manual or PA intervention.

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Greenlee, 2015 ¹²⁶	HD H	IG1	Group counseling	9 culturally tailored nutritional intervention group sessions (4 to 12 participants per group) conducted entirely in Spanish for 12 weeks for total of 24 hr. Sessions ranged from 1.5 to 3.5 hr. Sessions included 4 interactive nutrition education classes to promote dietary changes, provide information about the potential benefits of dietary change, and improve health literacy; 3 hands-on cooking classes to show new cooking methods of familiar and unfamiliar foods; and 2 field trips to teach how to shop for healthy foods in their neighborhoods. Target behaviors were identified based on the ACS and AICR dietary recommendations for cancer survivors. Targeted behaviors included eating more fruits and vegetables and decreasing fat intake through fewer and leaner meats; fewer and lower-fat dairy products; and using less fat during cooking. Participants also received a 22-page Spanish-language booklet on healthy eating for breast cancer survivors.	Out of 9 sessions: 38% attended all 9, 26% attended 7 to 8, 18% attended 1 to 6, 18% attended 0	SCT, TTM	X		X	X	X				MI: Booklet on healthful eating
Halbert, 2000 ¹²⁸	PA M	IG1	Counseling	1 session with exercise physiologist discussing the benefit of PA, individualized advice, and a pamphlet containing a PA plan for next 3 months. Focus was on incorporating PA into participants' usual activities and on increasing self-efficacy. Spouses were invited to attend initial session. Individualized advice was also given at 3- and 6-month in-person FU visits to discuss progress.	NR	NR	X				X				AC: Visit with exercise physiologist discussing nutrition pamphlet

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Hargreaves, 2016 ¹³⁰	PA M	IG1	Tailored walking program	Intervention consisted of 2 components: 1) individualized pedometer-based walking program with weekly step goals, and 2) website where individuals entered their step counts; received goal feedback, their next weekly goal (from the walking program), and tailored motivational feedback; and created a PA plan. At 1 face-to-face session, intervention components were discussed with each participant and each was given an information sheet summarizing the discussion. The walking program was structured around each participant's baseline step counts and designed so that PA increased gradually. By week 7, participants had a goal of walking an extra 3000 steps/day over their baseline and meeting the PA guidelines. In addition, participants were sent an email at the end of each week prompting them to log into the website and enter their weekly step counts (read from the pedometer memory). The website algorithm calculated whether they had achieved their weekly step goal and generated a motivational message relating to whether they had been successful or not in achieving their goal. Finally, participants were prompted to use the diary feature to write an action plan for how they would achieve their step goals and a coping plan to overcome any barriers they might face in trying to achieve that plan.	82% logged into the website weekly	SCT, Self-Regulation Theory	X	X			X				MI: Pedometer plus information on PA guidelines, access to a noninteractive PA website, and weekly emails about PA and encouragement to visit the website

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Harland, 1999 ¹³¹	PA M	IG1	Counseling and PA vouchers	1 initial brief session where participants received their baseline test results, brief advice comparing their test results with recommended levels, and print materials on the benefits of PA, recommended activity levels, and 19 brochures on leisure facilities and activities available locally. Initial brief session was followed by six 40-min MIs plus offered 30 PA vouchers valid during intervention period for use at local authority leisure center, swimming pool, or other voluntary or leisure center.	Among all intervention participants, 82% attended at least 1 interview. Median number of interviews attended was 3 (of 6). Within this group, 44% used the vouchers.	TTM	X			X					MI: Brief information and advice on benefits of PA.
Harland, 1999 ¹³¹	PA M	IG2	Counseling	1 initial brief session where participants received their baseline test results, brief advice comparing their test results with recommended levels, and print materials on the benefits of PA, recommended activity levels, and 19 brochures on leisure facilities and activities available locally. Initial brief session was followed by six 40-min MIs.	Among all intervention participants, 82% attended at least 1 interview. Median number attended was 3 (of 6).		X			X					
Harland, 1999 ¹³¹	PA M	IG3	Brief counseling and PA vouchers	1 initial brief session where participants received their baseline test results, brief advice comparing their test results with recommended levels, and print materials on the benefits of PA, recommended activity levels, and 19 brochures on leisure facilities and activities available locally. Initial brief session was followed by one 40-min in-person MI within 2 weeks to promote safe and effective PA plus offered 30 PA vouchers valid during intervention period for use at local authority leisure center, swimming pool, or other voluntary or leisure center.	Among all intervention participants, 82% attended at least 1 interview. Within this group, 27% used vouchers.		X			X					
Harland, 1999 ¹³¹	PA M	IG4	Brief counseling	1 initial brief session where participants received their baseline test results, brief advice comparing their test results with recommended levels, and print materials on the benefits of PA, recommended activity levels, and 19 brochures on leisure facilities and activities available locally. Initial brief session was followed by one 40-min in-person motivational interview within 2 weeks to promote safe and effective PA.	Among all intervention participants, 82% attended at least 1 interview.		X			X					

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Harris, 2015 ¹³²	PA M	IG1	Counseling and self-monitoring	One 45-min initial PA consultation session with a nurse focused on individual walking/PA plan to encourage adding both steps and time spent walking in moderate-intensity PA in bouts of ≥10 min, followed by three 30-min sessions occurring at weeks 3, 7, and 11, with a nurse focused on feedback from pedometer, activity logs, and accelerometer data. Also, participants wore pedometers and kept activity logs for entire intervention period of 12 weeks, participants also wore an accelerometer for 7 days before each FU session to monitor progress and aid in feedback by relating specific PA log activities to accelerometer-recorded PA intensity. Participants wore an accelerometer for 7 days and completed a questionnaire at 12 months to assess maintenance of PA levels achieved at 3 months.	86% attended all 4 nurse-led sessions; accelerometer was worn 98% of requested time before sessions occurred	BCT	X	X	X		X				UC: Received UC from general practice
Hellenius, 1993 ¹³⁵	HD M	IG1	Counseling (diet)	1 session with physician with verbal and written dietary advice followed by 1 session with a dietitian at 2 weeks. Wives/partners could be present. Dietary advice was in accordance with National Cholesterol Education Program Step 1 diet: total fat <30%, saturated fat <10%, polyunsaturated fat ≤10%, monounsaturated fat 10% to 15%, carbohydrates 50% to 60%, protein 10% to 20%, cholesterol <300 mg/day.	NR	NR								X	UC: Participants were told to maintain normal diet and PA levels.
Hellenius, 1993 ¹³⁵	PA L	IG2	Brief counseling (PA)	1 session with physician with verbal and written information regarding PA, including advice to gradually increase amount of exercise. Advice on shoes and stretching was given, also told to maintain prepared activity logs specifying date, type of activity, duration, and mean Borg intensity; recommended aerobic exercise at 60% to 80% max HR for 30 to 45 min, 2 to 3 times/week, and given opportunity to take part in supervised aerobic exercise sessions.	54% participated in aerobic training session each week and 80% maintained PA logs			X							

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Hellenius, 1993 ¹³⁵	HD+PA M	IG3	Counseling (Diet and PA)	1 session with physician with verbal and written dietary advice and advice about PA followed by 1 session with a dietitian at 2 weeks. Wives/partners could be present. Dietary advice was in accordance with National Cholesterol Education Program Step 1 diet: total fat <30%, saturated fat <10%, polyunsaturated fat ≤10%, monounsaturated fat 10% to 15%, carbohydrates 50% to 60%, protein 10% to 20%, cholesterol <300 mg/day. Participants were advised to gradually increase amount of exercise and advice on shoes and stretching was given, also told to maintain prepared activity logs specifying date, type of activity, duration, and mean Borg intensity; recommended aerobic exercise at 60% to 80% max HR for 30 to 45 min, 2 to 3 times/week, given opportunity to take part in supervised aerobic exercise sessions.	26% participated in aerobic training session each week and 44% maintained PA logs			X							
Hinderliter, 2014 ¹³⁷	HD H	IG1	Group counseling on DASH diet	2 weeks controlled feeding period followed by 14 weekly 30- to 45-min small group sessions with nutritionist; participants 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 diet (assumed individual session). 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.	Median attendance was 12/14 weekly small group sessions	NR	X	X							MI: 2-week controlled feeding period followed by maintenance of usual diet and exercise for 4 months; weight and BP monitored and health habits assessed on biweekly basis.

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Hivert, 2007 ⁷²	HD+PA H	IG1	Group counseling	23 45-min small-group interactive seminars over 2 years for undergraduate students aimed to educate and introduce behavioral modification methods to prevent weight gain. Seminars offered every 2 weeks for first 2 months of the academic calendar and every month thereafter for the remaining 2 years. First 3 seminars aimed at increasing knowledge about weight gain and its complications, national dietary recommendations, exercise categories, and expected benefits and recommendations for the maintenance of health. Remaining seminars were designed to introduce behavioral modification methods such as problem solving, goal setting, and monitoring. Role models introduced to promote a positive image of a healthy lifestyle.	53% attended >60% of seminars during the first year and 26% attended >60% in the second year	SCT	X	X		X					None

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HPT, 1990 ¹⁴⁰	HD H	IG1	Group counseling (potassium and sodium focus)	Initial phase consisted of 12 weekly group sessions (60 min; 7 to 22 participants per group) held during a 4-month period. Sessions were conducted by trained nutritionists and behaviorists who provided dietary counseling specific to increasing potassium intake to $\geq 3,900$ mg/day and reducing sodium intake to $\leq 1,600$ mg/day (individual goal: urine sodium excretion ≤ 70 mmol/day and urine potassium excretion ≥ 100 mmol/day). Participants received counseling related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Based on daily food records, participants were encouraged to make further changes or maintain their dietary changes. Maintenance phase continued to end of the study and consisted of 16 group sessions (60 min) every other month and periodic individual counseling sessions. Participants who did not attend the group sessions were contacted by phone. Phone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Participants also received a bimonthly newsletter containing relevant dietary information and recipes.	61.5% attended all 12 sessions during the initial phase; maintenance phase NR	NR	X	X						X	None

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
HPT, 1990 ¹⁴⁰	HD H	IG2	Group counseling (sodium focus)	Initial phase consisted of 12 weekly group sessions (60 min; 7 to 22 participants per group) held during a 4-month period. Sessions were conducted by trained nutritionists and behaviorists who provided dietary counseling specific to reducing sodium intake to ≤1,600 mg/day (individual goal: urine sodium excretion ≤70 mmol/day). Counseling sessions were related to meal planning and preparation, food purchasing, and label reading to assist them in making the required changes. Based on daily food records, participants were encouraged to make further changes or maintain their dietary changes. Maintenance phase continued to end of the study and consisted of 16 group sessions (60 min) every other month and periodic individual counseling sessions. Participants who did not attend the group sessions were contacted by phone. Phone contact included a qualitative assessment of the participant's dietary compliance based on self-report. Participants also received a bimonthly newsletter containing relevant dietary information and recipes.	59.6% attended all 12 sessions during the initial phase; maintenance phase NR	NR	X	X						X	
Jacobs, 2011 ¹⁴¹	HD+PA H	IG1	Counseling	Initial phone session with a health psychologist to individually tailor each participant's intervention and determine delivery mode (email, phone, or face-to-face). Additional access to a tailored web site and 1-on-1 coaching was available. Intervention intensity varied and the delivery mode of coaching was self-selected by participants to allow for a combination of different target behaviors and delivery modes. Counseling sessions were mainly delivered via email (100%) or phone (97%), and less face-to-face (10%), with a mean of 13.7 (22-min) diet sessions and 15.5 (37-min) PA coaching sessions. Intensity varied by dose groups; low (<5 hr, mean 227.8 min), medium (5 to 7 hr, mean 343.7 min), and high (>7 hr, mean 727.0 min).	By design, frequency and delivery mode of intervention was self-selected and half of participants chose no- or low-dose (<5 hr). Weighted mean intensity was 380.6 min.	SCT, TPB	X	X			X				UC: Not described

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Jeffery, 1999 ¹⁴³	HD+PA L	IG1	Nontailored print mailings	Intervention delivered educational messages in 36 monthly newsletters, 2 to 4 pages in length, that encouraged paying attention to weight and making small changes in diet and exercise habits. Education messages emphasized 5 major themes: 1) weighing self regularly (at least once a week); 2) eating more fruit (2 servings/day), 3) eating more vegetables (3 servings/day); 4) reducing consumption of high-fat foods, and 5) increasing exercise, with a particular emphasis on walking. Reduction in energy intake was not specifically recommended. Educational messages also included practical guides for behavior (recipes and locations in the community for walking or other types of PA). Once every 6 months, intervention participants were offered the opportunity to participate in additional low-cost intervention activities. Activities offered during the 3-year study included: 1) 4-session weight control classes staffed by nutritionists at local health departments; 2) educational seminars on PA; 3) aerobics dance; 4) free 1 month membership to a community exercise facility; 5) walking group; 6) mail-based weight loss course; and 7) home-based walking competition.	Across both intervention groups, 80% reported having read most or all newsletters and 25% participated in ≥1 of the extra activities that were offered	NR								X	None

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Jeffery, 1999 ¹⁴³	HD+PA L	IG2	Nontailored print mailings plus incentives	Intervention delivered educational messages in 36 monthly newsletters, 2 to 4 pages in length, that encouraged paying attention to weight and making small changes in diet and exercise habits. Education messages emphasized 5 major themes: 1) weighing self regularly (at least once a week), 2) eating more fruit (2 servings/day), 3) eating more vegetables (3 servings/day), 4) reducing consumption of high-fat foods, and 5) increasing exercise, with a particular emphasis on walking. Reduction in energy intake was not specifically recommended. Educational messages also included practical guides for behavior (recipes and locations in the community for walking or other types of PA). Once every 6 months, intervention participants were offered the opportunity to participate in additional low-cost intervention activities. Activities offered during the 3-year study included: 1) 4-session weight control classes staffed by nutritionists at local health departments, 2) educational seminars on physical activity, 3) aerobics dance, 4) free 1 month membership to a community exercise facility, 5) walking group, 6) mail-based weight loss course, and 7) home-based walking competition. In addition, participants were asked to return monthly postcards monitoring behavior, and these were used for a \$100 lottery drawing each month. The intent of the incentive lottery was to encourage participants to open and read their newsletters and thus to learn more about weight gain prevention.		NR								X	

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John, 2002 ¹⁴⁴	HD M	IG1	Counseling	25-min dietary intervention with research nurse presenting the benefits of eating more fruit and vegetables with a pictorial portion guide; eliciting meal and snack patterns with an eating pattern assessment questionnaire to show where increases in consumption might be made; using the brief negotiation method to encourage participants to identify specific and practical ways that were consistent with their habits and preferences of eating more fruit and vegetables; and discussing possible barriers to eating more fruit and vegetables. 2 weeks after initial intervention, a research nurse phoned participants to reinforce the message and discuss any problems. At 3 months, a letter was sent reinforcing the 5-a-day message, together with a booklet of seasonal recipes and a strategy check list suggesting various ways of incorporating additional portions of fruit and vegetables into the diet. As needed, participants received prepared leaflets that addressed these difficulties. Participants also received a copy of their action plan, a magnet with the 5-a-day logo, a portion guide, and a 2-week self-monitoring record book.	96.4% completed the initial session	NR	X							X	WL
Kallings, 2009 ¹⁴⁶	PA M	IG1	Counseling with tailored prescription	One 30-min individualized patient-centered counseling session based on individual readiness to change and the 5As and written prescription of PA. Participants were provided pedometers, encouraged to keep a PA log for at least 3 months, given written materials on PA and health, and a booklet with ideas for everyday activities. Within 1 month of initial session, one 60-min group session was offered, an individualized letter with advice from PCP on increasing PA, and short FU 3- to 5-min phone call. One 30-min individualized patient-centered counseling session and written PA prescription delivered at the 6 month FU.	NR; 65% adhered to the PA prescription	SCT, TTM	X		X	X	X	X	X		UC: UC and 1-time written information about importance of PA for health

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Kattelmann, 2014 ¹⁴⁷	HD+PA M	IG1	Web-based intervention	First 10 weeks of intervention consisted of 3 stages-of-change tailored emails with motivational messages. 1 of the 3 weekly emails encouraged participants to visit a tailored website to view a “mini” educational session. Within the website, participants were asked to set goals for 1 to 3 targeted behaviors (eating behavior, PA, stress management); within their personal Web portal, participants could see their progress toward their goal. In weeks 10 to 64 (15 months), the frequency of emails was reduced to 4 per month. The website remained active, but no new lessons were added.	NR	TTM	X								WL
Katz, 2008 ¹⁴⁸	PA H	IG1	Provider training	Physicians were trained on the Pressure System Model (PSM), covering a decision algorithm, MI, decisional balance, strategies for overcoming barriers, and role play. Physicians participated in 5 interactive group sessions lasting 1.5 hr over 5 to 6 months led by physician assistant and preventive medicine specialist, with mock patient encounters. Providers applied the PSM during existing patient appointments focused on overcoming barriers to PA with varied patient session frequency.	NR	NR	X			X		X			UC: Providers received their usual residency curriculum

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Kerr, 2016 ¹⁴⁹	HD L	IG1	Tailored text messages (with booster messages)	Participants recorded their food intake for 4 consecutive days, including taking pictures of their meals, using an app on their mobile device. After an analysis of their food intake, they received 2 tailored dietary feedback text messages 1 week apart. 1 text message focused on fruits and vegetables and the other focused on energy-dense, nutrient-poor foods and beverages. Participants also received 32 text messages once or twice weekly for 24 weeks including motivational and informational messages focused on fruits, vegetables, and junk foods and beverages. The messages used an autonomous supportive style of communication using MI principles. Messages also included web links to recipes and nutrition information. Messages were delivered between 4 and 6 pm on different days of the week. Participants were able to stop receiving text messages at any point by replying "stop."	NR	SDT		X		X		X			None
Kerr, 2016 ¹⁴⁹	HD L	IG2	Tailored text messages	Participants recorded their food intake for 4 consecutive days, including taking pictures of their meals, using an app on their mobile device. After an analysis of their food intake, they received 2 tailored dietary feedback text messages 1 week apart. 1 text message focused on fruits and vegetables and the other on energy-dense, nutrient-poor foods and beverages.											

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
King, 2007 ¹⁵³	PA M	IG1	Automated phone counseling	Initial in-person 30- to 40-min health educator led session, including individualized plan development focused on gradually increasing frequency, duration, and intensity of PA toward goal of ≥30 min moderate-intensity PA on most days of the week. Followed by brief individualized structured phone calls delivered by automated telephone-linked counseling (TLC) system occurring biweekly and monthly, with each participant receiving 15 total calls over 1 year focused on support and problem solving around barriers to PA based on participant's ongoing reports of PA levels, goals, and problem areas. Phone calls were supplemented with mailings and pedometer and PA log to track activity and allow feedback provided to participants.	11.8 (out of 15 planned) average calls completed; average call length was 6.6 min	SCT, TTM	X	X		X	X				AC: Offered 50 weekly health education classes focused on non-PA topics and not asked to change their usual PA patterns.
King, 2007 ¹⁵³	PA M	IG2	Human phone counseling	Initial in-person 30- to 40-min health educator led session, including individualized plan development focused on gradually increasing frequency, duration, and intensity of PA toward goal of ≥30 min moderate-intensity PA on most days of the week. Followed by brief individualized structured phone calls delivered by health educator occurring biweekly and monthly, with each participant receiving 15 total calls over 1 year focused on support and problem solving around barriers to PA based on participant's ongoing reports of PA levels, goals, and problem areas. Phone calls were supplemented with mailings and pedometer and PA log to track activity and allow feedback provided to participants.	13.1 (out of 15 planned) average calls completed; average call length was 10.7 min		X	X		X	X				

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King, 2013 ¹⁵²	HD+PA M	IG1	Phone counseling with self-monitoring (PA and Diet simultaneous)	1 individual in-person introductory session followed by 15 30- to 40-min phone counseling sessions over 12 months. PA and diet were addressed simultaneously, with half of each call covering each topic. PA goal was to meet national guidelines of ≥150 min/week of MVPA, diet goals were to reduce saturated fat intake and increase fruits and vegetables to 9 servings/day. PA component included mailings and pedometer where participants recorded PA and reported it to advisor during calls. Diet component included recording dietary intake and reporting back during calls; participants given homework and reading materials such as recipes. Intervention focused on facilitating mastery through self-regulatory skill building (social support, realistic expectations, cognitive and behavioral processes of change, problem solving).	11.6 (out of 15 planned) average calls completed	SCT, TTM	X	X	X	X	X				AC: 15 30- to 40-min phone counseling calls focused on stress management
King, 2013 ¹⁵²	HD+PA H	IG2	Phone counseling with self-monitoring (Diet discussions first)	1 individual in-person introductory session followed by 21 phone counseling sessions over 12 months. Counseling topics introduced sequentially, beginning with diet for first 4 months (six 15- to 20-min calls). Both diet and PA addressed in remaining 8 months in longer counseling calls (nine 30- to 40-min calls), with six 15- to 20- min booster calls focused on PA to ensure equivalent exposure to each behavior target. PA goal was to meet national guidelines of ≥150 min/week of MVPA, diet goals were to reduce saturated fat intake and increase fruits and vegetables to 9 servings/day. PA component included mailings and pedometer where participants recorded PA and reported it to advisor during calls. Diet component included recording of dietary intake and reporting back during calls; participants given homework and reading materials such as recipes. Intervention focused on facilitating mastery through self-regulatory skill building (social support, realistic expectations, cognitive and behavioral processes of change, problem solving).	15.5 (out of 21 planned) average calls completed		X	X	X	X	X				

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King, 2013 ¹⁵²	HD+PA H	IG3	Phone counseling with self-monitoring (PA discussions first)	1 individual in-person introductory session followed by 21 phone counseling sessions over 12 months. Counseling topics introduced sequentially, beginning with PA for first 4 months (six 15- to 20-min calls). Both PA and diet addressed in remaining 8 months in longer counseling calls (nine 30- to 40-min calls), with six 15- to 20-min booster calls focused on diet to ensure equivalent exposure to each behavior target. PA goal was to meet national guidelines of ≥150 min/week of MVPA, diet goals were to reduce saturated fat intake and increase fruits and vegetables to 9 servings/day. PA component included mailings and pedometer where participants recorded PA and reported it to advisor during calls. Diet component included recording dietary intake and reporting back during calls; participants given homework and reading materials such as recipes. Intervention focused on facilitating mastery through self-regulatory skill building (social support, realistic expectations, cognitive and behavioral processes of change, problem solving).	15.1 (out of 21 planned) average calls completed		X	X	X	X	X				
Kinmonth, 2008 ¹⁵⁴	PA M	IG1	Phone counseling	Initial counseling session in participant's home focused on increasing opportunities and reducing barriers to becoming more physically active using 8 self-regulatory techniques for behavioral change, including goal setting, action planning, self-monitoring, using rewards, goal review, using prompts, building social supports, and prevention of relapses. Four 45-min phone support calls and two 15-min support calls over 5-month intensive phase, followed by monthly mailings for 7 months.	88% completed all "core" counseling sessions	TPB	X	X	X		X				MI: 1-time leaflet by mail with brief motivational advice on benefits of PA.

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Kinmonth, 2008 ¹⁵⁴	PA H	IG2	In-home counseling	Initial counseling session in participant's home focused on increasing opportunities and reducing barriers to becoming more physically active using 8 self-regulatory techniques for behavioral change, including goal setting, action planning, self-monitoring, using rewards, goal review, using prompts, building social supports, and prevention of relapses. Four 60-min home visits and two 15-min support calls over 5-month intensive phase, followed by monthly 30-min FU phone calls for the remaining 7 months.	83% completed all "core" counseling sessions		X	X	X		X				
Kolt, 2007 ¹⁵⁵	PA M	IG1	Phone counseling	8 individualized phone counseling sessions ranging 10 to 17 min over 12 weeks, occurring weekly for first 4 weeks and then biweekly for remaining 8 weeks. Phone calls followed a script based on the appropriate stage of change for each individual in relation to adoption of PA and drew on earlier calls and MI techniques and set PA goals with an exercise counselor to assess progress toward goals. In addition, supplementary mailings, including a walking log and pamphlets to support counseling.	NR	TTM	X		X	X	X	X			None

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Kristal, 2000 ¹⁵⁶	HD L	IG1	Tailored print mailings and counseling call	Computer-generated, tailored self-help intervention with 4 components: 1) package of self-help materials, sent within a week of randomization (including “Help-Yourself: A Smart and Simple Guide for Healthy Eating” manual with skills for implementing and maintaining dietary changes, decreasing fat and increasing fruits and vegetables, and modifying specific meals to reduce fat and increase fruits and vegetables); 2) dietary analysis with behavioral feedback, available any time participants returned a food frequency questionnaire, providing positive feedback on current food choices, quantitative goals to reach 30% energy from fat and 5 servings/day of fruits and vegetables, and food sources of fat and fruits and vegetables and recommendations for change; 3) 1 motivational phone call, completed within a month of randomization by a trained health educator; and 4) twice monthly newsletters, sent until 1 year post-randomization to maintain salience of intervention messages; additional, seasonal information on food purchasing and preparation; enhance and reinforce motivation through use of personal stories. Computer programs generated instructions to mailing staff on where to place flags, write notes, and place highlights on intervention materials that were particularly relevant to each participant.	90.3% reported reading some to more than half of the print materials 90.8% reported receiving FU counseling call	SCT, TTM	X	X							None

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Lawton, 2008 ¹⁶⁰	PA M	IG1	Counseling with tailored prescription	Brief, 7- to 13-min counseling session with primary care nurse using MI techniques to increase PA. Green prescription was given to participants with individualized exercise advice with goal of achieving 30 min of moderate-intensity exercise, such as brisk walking, 5 days/week, and sent to a community-based exercise facilitator who provided phone counseling and support focused on activity choice, goal setting, and overcoming barriers to PA. Average of 5 calls lasting 15 min over 9 months as FU, and 1 additional 30-min visit with the primary care nurse at 6 months occurred.	NR	NR	X								UC: Not described
Lewis, 2013 ¹⁶¹	PA L	IG1	Tailored print mailings	11 individually-tailored PA print mailings plus stage-matched manuals, tip sheets, and PA logs. Mailings were weekly in first month, biweekly in months 2 and 3, and monthly in months 4 to 6. PA mailings were 3 pages and computer-tailored based on responses to monthly questionnaires about cognitive and behavioral processes, self-efficacy, and decisional balance. Mailings included motivational, educational, and normative feedback. 14-page stage-matched manual provided at start of intervention and additional manuals given if participant moved to a different stage of change. Participants also given 14 tip sheets covering various PA topics (rewarding yourself, exercising in bad weather) and PA logs.	NR	SCT, TTM	X	X		X	X				AC: 11 health and wellness mailings as contact control over 6 months

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group	
Lutz, 1999 ¹⁶²	HD L	IG1	Tailored print mailings with tailored prescription	4 monthly newsletters with tailored nutrition and goal-setting information based on the baseline survey (intake, eating behaviors, nutrition-related activities, psychosocial factors). Tailored messages determined from a computer algorithm were delivered based on baseline response. Newsletters also provided 3 tailored subgoals to achieve the goal of 5-a-day, based on the baseline survey. Participants were given a specific goal of "increasing fruit and vegetable intake to 5 or more servings each day."	Across all 3 intervention groups, among those who remembered receiving at least 3 newsletters, 71% reported reading most or all 3 newsletters	SCT, TTM, HBM	X									None
Lutz, 1999 ¹⁶²	HD L	IG2	Tailored print mailings	4 monthly newsletters with tailored information and no goal-setting component based on the baseline survey (intake, eating behaviors, nutrition-related activities, psychosocial factors). Tailored messages determined from a computer algorithm were delivered based on baseline response. Given the vague goal of "eating more fruits and vegetables."												
Lutz, 1999 ¹⁶²	HD L	IG3	Nontailored print mailings	4 monthly traditional newsletters with nontailored nutrition information. Participants were given the vague goal of "eating more fruits and vegetables."												

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Mailey, 2014 ¹⁶⁴	PA M	IG1	Group counseling	Intervention consisted of 2 interactive 1.5- to 2-hr group-based sessions, 3 weeks apart, which taught participants behavior modification strategies based on social cognitive principles. Participants in the “intervention only” and “intervention plus” groups were scheduled to attend separate sessions to avoid contamination between groups but each group received identical content, and group results were combined for analyses. Sessions were interactive and incorporated small and large group discussions and problem solving activities. They also received a pedometer and an electronic log for tracking their daily steps to facilitate goal setting and self-monitoring. All participants received a 1-hr session with a personal trainer, who worked with them to devise an exercise program that could be completed at home. All received a handbook containing information, worksheets, and resources that complemented the topics addressed during the workshop sessions. Participants assigned to the intervention plus FU support group received monthly phone support calls from a study investigator to monitor their progress following the structured intervention. These contacts were brief (3 to 8 min) and designed to provide support, feedback, and active problem solving strategies that were individualized based on the participant’s current activity level and goal adherence. Phone calls were semistructured in that they focused on topics specified in an interview guide (barriers encountered or anticipated, pedometer use, goals for the following month) but were flexible to accommodate participants’ individual needs.	NR	SCT	X					X				WL

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Marcus, 2007 ¹⁶⁷	PA M	IG1	Phone counseling	Initial 45-min session with health educator, then 14 13-min phone calls over 12 months with a counselor-guided, tailored message generated by an expert system report, stage-matched manual, and tip sheets focused on the goal of increasing moderate-intensity PA to meet CDC/ACSM recommendation of ≥30 min of moderate activity 5 days/week. Phone calls occurred weekly for first month, biweekly for months 2 and 3, monthly for months 4 to 7, and bimonthly for months 8 to 12. Participants also completed a PA log and brief questionnaire each month.	90.5% of all scheduled calls were completed	SCT, TTM	X	X		X	X				AC: General health information pamphlets via mail during the intervention period.
Marcus, 2007 ¹⁶⁷	PA M	IG2	Tailored print materials	Initial 45-min session with health educator, then 14 individually tailored printed reports focused on increasing PA to meet CDC/ACSM recommendation of ≥30 min of moderate-intensity exercise 5 days/week. Reports were based on feedback generated by a computer expert system along with manuals matched to participant's stage of motivational readiness for PA adoption, and supplementary materials included stage-targeted booklets and PA-related sheets over 12 months. Mailings occurred weekly for first month, biweekly for months 2 and 3, monthly for months 4 to 7, and bimonthly for months 8 to 12. Participants completed a monthly PA log and brief questionnaire each month.	NR		X	X		X	X				

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Marcus, 2013 ¹⁶⁶	PA L	IG1	Tailored print mailings and self-monitoring	14 culturally adapted, Spanish-language, individually-tailored PA print mailings matched to motivational readiness based on monthly questionnaires and generated by a computer expert system. Mailings were weekly first month, biweekly in months 2 and 3, monthly in months 4 to 6, with booster mailings in months 8, 10, and 12. Intervention emphasized behavioral strategies for increasing activity levels, including: goal setting, self-monitoring, problem solving barriers, increasing social support, and rewarding oneself for meeting PA goals. Mailings included normative feedback and feedback on progress over time. Pedometers and PA logs provided to encourage self-monitoring. Cultural adaptation based on formative research that included modification of intervention based on PA barriers identified by Latinas in focus groups.	86.4% reported reading most or all of the print materials	SCT, TTM	X	X	X	X	X				AC: 14 Spanish-language pamphlets on wellness, including heart-healthy behaviors (but not PA) developed by NHLBI
Marsaux, 2015 ¹⁶⁹	HD+PA L	IG1	Tailored web-based advice (diet, PA, and phenotype)	Web-based personalized advice provided for weight, waist circumference, PA, dietary intake, and blood markers (phenotypic data). Participants received feedback at 4, 8, and 12 weeks on how their intake of specific food groups compared with guideline amounts, as well as tailored advice to increase or maintain PA based on current PA level and BMI and tips on how to be more physically active. Additional information about PA and tips were provided on participant's web account and hyperlinks were included in the tailored report and encouraged to visit website.	NR	NR		X							MI: Non-personalized dietary and PA advice

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Marsaux, 2015 ¹⁶⁹	HD+PAL	IG2	Tailored web-based advice (diet and PA)	Web-based personalized advice provided for weight, PA, and dietary intake (no phenotypic or genotypic data). Participants received feedback at 4, 8, and 12 weeks on how their intake of specific food groups compared with guideline amounts, as well as tailored advice to increase or maintain PA based on current PA level and BMI and tips on how to be more physically active. Additional information about PA and tips were provided on participant's web account and hyperlinks were included in the tailored report and encouraged to visit website.											
Marsaux, 2015 ¹⁶⁹	HD+PAL	IG3	Tailored web-based advice (diet, PA, phenotype, and genotype)	Web-based personalized advice provided for weight, waist circumference, PA, dietary intake, and blood markers (phenotypic data) plus specific information about whether the participant carried the risk allele for the FTO (fat mass and obesity associated) gene (genotypic data). Participants received feedback at 4, 8, and 12 weeks on how their intake of specific food groups compared with guideline amounts, as well as tailored advice to increase or maintain PA based on current PA level and BMI and tips on how to be more physically active. Additional information about physical activity and tips were provided on participant's web account and hyperlinks were included in the tailored report and encouraged to visit website.											
Marshall, 2003 ¹⁷⁰	PAL	IG1	Tailored print mailing	1-time mailing of a personally addressed letter tailored to individual's stage of change, and the corresponding Active Living booklet for the individual's current stage of change, plus any booklets aimed at the higher stages of change.	81.5% recalled receiving the print materials; of those, 87% reported reading the materials related to their stage of change	TTM	X			X	X				None

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Martinson, 2008 ¹⁷²	PA H	IG1	Counseling	One 60-min in-person group orientation session to meet activity coach and review goals and materials, including a course workbook, PA log for recording activity, and pedometer. Initial session was followed by seven 20-min individualized course sessions twice a month delivered over the phone with assigned activity coach focused on current PA level, PA goals, and barriers to PA. Following completion of the 7-session course, participants received monthly FU calls for 8 months, then bimonthly FU calls for the subsequent year. In addition, a lending library of PA books, videos, and DVDs were available, motivational contests, and 4 optional in-person support sessions over 24 months were provided.	Out of 7 main intervention sessions, 92% completed ≥1 phone session and 39.8% completed all 7 sessions (mean, 5.12 sessions).	SCT	X	X	X						MI: Information about the 10,000 steps PA program offered by the health plan, and 4 newsletters focused on general health and wellness

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Mosca, 2008 ¹⁷⁶	HD+PA M	IG1	Counseling	Regular contact between participant and health educator was in person or over phone at 2 weeks, 6 weeks, 3 months, 6 months, and 9 months (30 to 60 min). At each FU, lifestyle changes were reinforced and potential barriers to attaining risk factor goals were discussed. At the 6-week and 6-month FU, a validated dietary assessment of adherence to a therapeutic lifestyle change diet was administered, and results were used to counsel subjects. In addition, at 3, 6, and 9 months, participants with previously abnormal lipid panels were offered testing and immediate feedback of lipid levels. Risk factor results were given to participants' PCPs in the form of progress reports sent via fax to physician offices. Education focused on avoiding foods that contain saturated fat, cholesterol, partially hydrogenated fats, trans fats, and refined sugars, as well as recommendations to eat ≥2 servings of fruits, ≥3 servings of vegetables, and ≥20 g/day of fiber. Counseling focused on foods and encouraged moderate PA for ≥30 min daily (60 min if weight loss was desired). Smokers were given educational handouts, encouraged to stop smoking, and referred to a hospital-based smoking-cessation program. All participants received a 1-page handout to 1) avoid tobacco, 2) choose good nutrition, and 3) be more active. A report was sent to their health care providers if a critical threshold value for a CVD risk factor was determined (BP ≥140/90 mm Hg, LDL-C ≥190 mg/dL, HDL-C <25 mg/dL, triglycerides ≥500 mg/dL, TC >300 mg/dL).	NR	TTM	X	X		X	X		X		MI: 1-page handout on tobacco, nutrition, and PA. Report sent to PCP if high risk for CVD risk factor.

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Napolitano, 2006 ¹⁷⁷	PA	IG1	Tailored print mailings	Completion of Jumpstart 65-item questionnaire related to PA readiness; responses were entered into an expert system computer program that generated tailored feedback letters sent to participants. Questionnaire and feedback letters were delivered once at baseline, and months 1, 3, and 6. Tailored feedback letters addressed self-efficacy, barriers, benefits, social support, and goal setting; in addition, a stage-matched booklet and letter explaining how to use materials was included.	NR	TTM	X	X		X	X				AC: 1 mailing of women's health information
	L														
Napolitano, 2006 ¹⁷⁷	PA	IG2	Nontailored print mailings	1-time mailing of American Heart Association's Choose to Move booklet and letter explaining how to use the materials. Choose to Move is a 12-week program targeted to women, with each week covering a topic of relevance from SCT and TTM.		SCT, TTM	X			X	X				
Norris, 2000 ¹⁷⁹	PA	IG1	Counseling	1-time completion of PACE questionnaire to determine baseline PACE score, followed by receipt of PA information relevant to individual's stage of change containing tips on overcoming barriers to PA. 1-time PCP counseling session using PACE protocol appropriate for stage of change, reviewed informational sheet, and gave written exercise prescription. At 4 weeks, one 15-min FU phone call with research assistant to reinforce counseling, identify any barriers to PA regimen, and arrange mailing of educational materials if requested. One-third of intervention patients were randomly selected to receive booster phone calls at 2, 3, 4, and 5 months; no significant increases were found in PA measures among those receiving booster calls (enhanced PACE protocol).	Within the subset of participants scheduled to receive FU phone calls, 64% received ≥3 calls	TTM	X		X	X	X				UC: Not described

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Parekh, 2014 ¹⁸¹	HD+PA L	IG1	Computer-tailored print mailings (2 contacts)	1-page, personalized, computer-tailored feedback letter was mailed after completion of the assessment questionnaire at baseline and at 3 months. Feedback letter was printed on PCP's letterhead and encouraged the participant to improve at least 1 behavior not adhering to health recommendation guidelines by the National Health and Medical Research Council and the National Heart Foundation of Australia. Guidelines focused on 6 dietary behaviors: meat, fish, vegetables and fruits, use of unsaturated fats as spreads, avoidance of added salt, as well as responses to smoking behavior, alcohol intake, PA, and BMI. In addition, 1-page health promotion information sheets were mailed to participants only for behaviors not meeting national guidelines.	NR	NR	X	X							AC: Mailed 1 to 2 personalized, computer-tailored feedback letters and health promotion information sheets at baseline and/or at 3 months.
Parekh, 2014 ¹⁸¹	HD+PA L	IG2	Computer-tailored print mailing (1 contact)	1-page, personalized, computer-tailored feedback letter was mailed after completing the assessment questionnaire at baseline only. Feedback letter was printed on the PCP's letterhead and encouraged the participant to improve at least 1 behavior not adhering to health recommendation guidelines by the National Health and Medical Research Council and the National Heart Foundation of Australia. Guidelines focused on 6 dietary behaviors: meat, fish, vegetables and fruits, use of unsaturated fats as spreads, avoidance of added salt, as well as responses to smoking behavior, alcohol intake, PA, and BMI. In addition, 1-page health promotion information sheets were mailed to participants only for behaviors not meeting national guidelines.			X	X							

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Pekmezi, 2009 ¹⁸⁴	PA L	IG1	Tailored print mailings and self-monitoring	6 monthly mailings of PA manuals matched to participant's current level of readiness and individually-tailored computer expert-system feedback reports based on monthly questionnaire responses focused on goal setting, self-monitoring, problem solving, barriers, increasing social support, and rewarding self for meeting PA goals. Participants received PA logs and pedometers to track and monitor progress, along with tip sheets on related topics such as stretching.	85% reported reading most or all of the print materials 72% reported wearing pedometers	SCT, TTM	X	X	X	X	X				AC: General nutrition and CVD risk brochures
Pinto, 2002 ¹⁸⁵	PA M	IG1	Automated phone counseling	Weekly 10-min phone calls for 12 weeks with a phone-linked communication system (TLC-PA) focused on activity counseling and promoting moderate-intensity PA, followed by bimonthly calls for 3 months. Responses from phone conversations generated 1 initial and 6 monthly individualized printed reports with text and graphs showing PA level based on data collected during phone calls with TLC-PA and pedometer readings. Reports were also sent to PCP with expectation it would prompt PCPs to reinforce the value of PA.	24% never called the system 36% called 1 to 10 times 23% called 11 to 20 times 18% called >20 times	SCT, TTM	X	X		X	X				AC: Dietary counseling using the same TLC automated technology
Pinto, 2005 ¹⁸⁶	PA M	IG1	Counseling with tailored prescription	Three 30- to 45-min face-to-face counseling sessions with health educator at 0, 1, and 3 months; 1-time individually tailored PA prescription, along with 12 10- to 15-min PA counseling phone calls weekly for 3 months and biweekly for next 3 months; and 12 PA tip sheets mailed at the same time as phone calls. All materials and sessions were tailored to the participant's individual stage of readiness to change PA levels.	47% received brief advice from their physician. 100% went to first in-person counseling session, 83% went to second, and 78% went to third. 86% of scheduled calls were completed; mean length of calls was 14.8 min	TTM	X			X	X				MI: Brief physician counseling

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Roderick, 1997 ¹⁸⁸	HD M	IG1	Counseling	1 dietary advice session (assumed 30 min) based on negotiated change, which aimed for food substitution (nurse and patient negotiated and agreed on up to 5 changes) after review of the type, quantity, and frequency of key foods consumed. Specially designed dietary sheets were given out according to whether weight loss was required; all foods were classified as “to eat plentifully,” “in moderation,” or “on special occasions only.” Special leaflets covering, for example, snacking, were given out when appropriate. Patients who were overweight (BMI > 25 kg/m ²) were given special advice, including a self-monitoring chart and choice of a calorie-restricted diet. At 4 to 6 weeks, progress with dietary change was assessed, weight remeasured, and further changes made if appropriate. Patients (n=NR) who had a high baseline serum cholesterol (>6.5 mmol/L in men or >7.0 mmol/L in women) or BMI >27.5 kg/m ² or ≥2 other CHD risk factors (male sex, smoking, hypertension, family or past history of CHD) were asked to return at 3 and 6 months for further assessment. Leaflets of standard health education were given to all participants: “Guide to Healthy Eating,” “Giving Up Smoking,” “Look After Your Heart,” “Heart Disease,” and “Exercise, Why Bother?”	NR	NR								X	MI: Standard health education leaflets
Ruffin, 2011 ¹⁸⁹	HD+PA L	IG1	Computer-tailored web-based intervention	Participants completed an online baseline survey, followed by Family Healthware tool. Participants could log on any time to complete the instruments over multiple sessions. Familial risk assessments and tailored prevention messages were instantly received on-screen that were based on familial risk for CHD; stroke; diabetes; and colorectal, breast, and ovarian cancer. Some participants responded by phone with data entered online by study personnel. Printed reports were either mailed or given to the participants at their scheduled PCP appointment.	91% viewed their risk report and messages online	TTM	X	X			X				UC: Standard prevention messages

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Sacerdote, 2006 ¹⁹⁰	HD L	IG1	Brief counseling	One 15-min personalized nutrition counseling session, based on a brochure about diet and health and a short explanation by the PCP. Intervention focused on the importance of more consumption of fruits, vegetables, fish, and olive oil and less consumption of red meat, snacks, and sweets and was modulated on the basis of sex- and age-specific energy consumption and on unbalanced nutritional habits of each subject.	NR	NR	X								UC: Simple and non-personalized conversation without use of brochure with PCP at the first visit.

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Simkin-Silverman, 1995 ¹⁹⁴	HD+PA H	IG1	Group counseling	Participants attended 15 group sessions (assume 60 min each) held weekly for 10 weeks, then biweekly for remaining 10 weeks. Trained nutritional and behavioral interventionists educated and encouraged participants to lower intake of total fat to 25% of daily calories, saturated fat to 7%, and total cholesterol to 100 mg/day and prevent future weight gain by achieving a modest weight loss goal. Participants were asked to follow a 1300 or 1500 kcal meal plan for 4 weeks, and subsequently encouraged to modify or adapt the meal plan to include favorite foods while still maintaining dietary and caloric goals. Participants kept a dietary log throughout the 20 weeks using a 7-day pocket diary. Participants were given education and guidance on gradually increasing PA level to 1000 kcal/week (walking 10 miles/week over 3 to 5 days). Behavioral strategies, including problem solving, stimulus control, goal setting, assertiveness training, relapse prevention, and cognitive techniques to help implement and maintain dietary and exercise changes. Following 20-week intensive period, participants entered the maintenance phase, which consisted of 6 bimonthly meetings (assume 60 min each). Thereafter, participants were provided group, mail, or phone contact on average every 2 to 3 months. All participants were invited to 6-week refresher programs (between months 14 and 54) and received quarterly newsletters. Social and educational gatherings were held for all participants 2 to 3 times a year. Additional consultation was available to participants who could not attend group meetings and consisted of instruction on additional skills, support, and motivation to help with maintenance of behavior change.	Participants attended on average 11.4 of 15 sessions during initial 20-week phase of intervention	NR	X	X	X	X	X				None

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Smith, 2014 ¹⁹⁷	HD+PA M	IG1	Counseling	One 1-hr face-to-face counseling session, followed by phone support at 2 weeks, and a second face-to-face counseling session at 4 weeks. An additional 4 monthly short phone calls were made, supplemented by text messages and mailed postcards. Participants were also given pedometers, logbooks, and dietary journals.	93.1% received both face-to-face sessions 89.7% received 4 phone contacts 86.2% received 4 postcard and 4 FU text messages	NR	X	X		X	X					None

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Springvloet, 2015 ¹⁹⁸	HD M	IG1	Web-based tailored education plus feedback	4 web-based tailored nutrition modules (fruit, vegetables, high-energy snacks, and fat) structured to target knowledge, awareness, intention, attitude, self-efficacy, goal setting, and action and coping plans, except for the fat module (did not contain methods to target attitude and self-efficacy to limit participant burden). Each module had 3 sessions to be worked during 6 consecutive weeks. Each session arranged according to the self-regulation phases: pre-action, action, and evaluation of the behavioral change. Before first session, participants could choose which behavior(s) they wanted to receive feedback and guidance on and say which supermarket they use. First session (20-40 min) provided tailored feedback on self-selected potential barriers, difficult situations, and availability and price of products in their supermarket. Participants could set a goal and formulate an implementation intention for when, where, and how to make the behavior change, as well as start enacting their plans and performing their new behavior for 2 weeks. Second and third sessions (10-20 min) provided opportunity to evaluate progress of the behavior change. Participants monitored their goal achievement in the past week and provided with feedback on their progress. When the goal was not achieved, attitude and self-efficacy were targeted to stimulate a second attempt. All participants were stimulated to formulate coping plans for expected difficult situations. If necessary, goals could be adapted to make them more achievable or challenging. Third session was on how to maintain the behavior change over time. Completion of all 4 modules took about 160 min. Email reminders sent to prompt returning to the intervention program. Also, environmental-level feedback on the availability and prices of healthy foods nearby was provided.	NR	TPB, Self regulation theory	X	X			X					MI: 4 web-based, nontailored nutrition education modules

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Springvloed, 2015 ¹⁹⁸	HD M	IG2	Web-based tailored education	4 web-based computer-tailored nutrition education modules (fruit, vegetables, high-energy snacks, and fat) structured to target knowledge, awareness, intention, attitude, self-efficacy, goal setting, and action and coping plans, except for the fat module (did not contain methods to target attitude and self-efficacy to limit participant burden). Each contained 3 sessions to be worked during 6 consecutive weeks. Each session arranged according to the self-regulation phases: pre-action, action, and evaluation of the behavioral change. Before first session, participants could choose which behavior(s) they wanted to receive feedback and guidance on. First session (20-30 min) provided tailored feedback on self-selected potential barriers and difficult situations. Participants could set a goal and formulate an implementation intention for when, where, and how to make the behavior change, as well as start enacting their plans and performing their new behavior for 2 weeks. Second and third sessions (10-20 min) provided the opportunity to evaluate progress of the behavior change. Participants monitored their goal achievement in the past week and provided with feedback on their progress. When the goal was not achieved, attitude and self-efficacy were targeted to stimulate a second attempt. All participants were stimulated to formulate coping plans for expected difficult situations. If necessary, goals could be adapted to make them more achievable or challenging. Third session additionally provided information on how to maintain the behavior change over time. Completion of all 4 modules took about 160 min. Email reminders were sent to prompt returning to the intervention program.		TPB, Self regulation theory	X	X			X				

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Stewart, 2001 ²⁰¹	PA H	IG1	Group counseling	1 informational meeting, 1 individual planning session, and 10 monthly group workshops focused on discussing participant's readiness to increase PA, ways to overcome barriers to PA, how to exercise safely and avoid injury, and how to engage in appropriate levels of PA given individual health conditions. Participants kept PA diaries, received monthly newsletters, and functional fitness assessments. 2 booklets were provided on PA and benefits of PA and heart health.	NR	SCT	X				X				WL
Taveras, 2011 ²⁰³	HD+PA H	IG1	Postpartum counseling	5 brief, focused negotiation sessions with a pediatric PCP using MI to encourage healthful behavior change; four 15- to 20-min individualized coaching and motivational counseling phone calls with a health educator at 3, 6, 12, and 20 weeks postpartum focused on healthful eating, PA, sleep, and TV; invitation to 4 group parenting skills training sessions led by pediatric PCPs and health educators to promote peer support and social networking, in addition to comprehensive educational materials that were individually tailored.	NR	NR			X			X			UC: Routine standard care for postpartum women
Thompson, 2008 ²⁰⁷	HD+PA H	IG1	Group counseling	5 group sessions of 2 to 2.5 hr (1 per month for 5 months) using social cognitive theory strategies. Sessions involved written and oral didactic material and small-group discussions; topics included learning to read food labels, strategies for healthy food choices when eating out, taste-testing healthy meals, and recipes to support study goals. 15-min outdoor walk was conducted at the beginning of each session. In all sessions, goal setting, feasible action steps, addressing barriers, enhancing behavior change through nonfood rewards were emphasized, and discussion of how strategy implementation proceeded during previous month. For missed sessions, participants received didactic materials and a brief review of content prior to the subsequent session.	53% attended ≤3 (of the 5) group sessions	SCT, TTM	X			X	X				WL

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Thompson, 2014 ²⁰⁸	PA H	IG1	Counseling and self-monitoring	Participants wore Fitbit accelerometers for 24 weeks with feedback from the device and 24 weekly exercise counseling calls with a counselor, along with 3 face-to-face counseling sessions every 2 months. Counselors worked with subjects to increase PA using Go4Life materials developed by the National Institute on Aging at NIH. The Go4Life curriculum focuses on exercise that promotes endurance, strength, balance, and flexibility, with overall goal of increasing activity level by 20%.	NR	NR	X	X							WL
Tinker, 2008 ²⁰⁹	HD H	IG1	Group counseling	Group sessions (assumed 60 min) of 10 to 12 participants met weekly with a trained nutrition interventionist for 6 weeks, every other week for an additional 6 weeks, and then monthly for the course of the first year (18 group sessions in first year). Each participant had 1 individual dietary counseling session (assumed 30 min) with interventionist in first 12 to 16 weeks to ensure nutritional balance of new dietary pattern. Dietary maintenance group sessions occurred quarterly after the first year, along with optional peer-led monthly meetings. Relative focus on nutrition highest in earlier sessions during the time of most intensive dietary change, while later emphasis was on maintenance of dietary change. Participants received individualized fat gram goal estimating 20% of energy from fat and a common goal of ≥5 daily servings of vegetables and fruits and ≥6 daily servings of grains (whole grains encouraged). Participants encouraged to maintain usual energy intake by replacing fat calories with calories from other sources (mainly carbohydrates).	At 3 years, 43% participated in ≥9 (of 18) sessions and ≥2 (of 4) maintenance sessions.	NR	X	X	X		X				MI: Received copy of "Dietary Guidelines for Americans"

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TOHP I, 1992 ²⁰⁴	HD H	IG1	Group counseling	Lifestyle interventions consisted of group educational sessions, supplemented by individual counseling. Demonstrations and practice were incorporated into each meeting. 3-month initial (intensive) sessions were weekly; 10 sessions (8 group and 2 individual) of 90 min each. Interventions focused on shopping, cooking, and food selection behaviors aimed at reducing sodium intake. Individual counseling goal was to reduce 24-hr sodium intake to 60 mmol (1400 mg). Food diaries used to facilitate self-monitoring of sodium intake; intervention staff reviewed and commented on food diaries. 16 F/U sessions offered after intensive intervention. FU implemented to provide continued information, support, and counseling through phone, mail, and, at minimum, bimonthly in-person group or individual meetings (90 min each) throughout the trial.	80.7% of scheduled sessions completed and 18.4 mean sessions attended (range 1 to 26 visits)	NR	X	X	X						None

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TOHP II, 1997 ²⁰⁵	HD H	IG1	Group counseling	Based on behavior change principles, an intensive intervention phase during which groups of 11 to 34 participants were counseled weekly (10 weeks, 60 to 90 min each). During this phase, primary goal was to provide participants with core knowledge and behavioral skills necessary to make and maintain reductions in sodium intake. Progress monitored by frequent measurement of overnight sodium excretion; diet and activity diaries were also kept. A transitional phase consisting of 4 monthly sessions (intensity NR) was designed to prevent relapse and ease transition from weekly to less frequent contacts. The final extended phase was to maintain participants' behavior changes. As a routine, this included 1 or 2 monthly contacts and a series of 3 to 6 refresher sessions (intensity NR) offered on intervention-related topics to promote contact and adherence with the intervention. Group goal was average sodium intake ≤80 mmol/24h; individual goal was sodium intake ≤70 mmol/24h. 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.	72.7% went to at least half of the counseling sessions in first 6 months. 30.1% went to at least half of the counseling sessions in months 6 to 18. 11.3% went to at least half of counseling sessions in months 18 to 36. Black participants had lower attendance than whites (40% vs. 60% went to ≥9 face-to-face sessions, respectively)	NR	X	X	X						None

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Tokunaga-Nakawatase 2014 ²¹⁰	HD+PAL	IG1	Computer-tailored print mailings	Over 6 months, 3 tailored, concrete lifestyle recommendations were generated using a computer-tailored system (Lifestyle Intervention Support Software for Diabetes Prevention) and mailed to participants. Each mailing included a free comment section for the clinical diabetes educator to add additional advice. Also, participants received a pamphlet about general information on diabetes prevention with regard to favorable behavior related to diet and PA.	NR	NR	X	X							UC: Pamphlet and routine care
Valve, 2013 ²¹¹	HD+PALM	IG1	Counseling	1 initial one-on-one 20-min solution-focused individualized lifestyle counseling session with a study nurse where a behavioral change goal focused on PA, diet, or sleep was set, along with printed materials covering the topics discussed. Details of the discussion were determined by the participants' needs, interests, and current life circumstances. Initial session was followed by 3 to 5 FU support sessions up to 1.5 to 2.5 years to revisit behavioral goals. Both treatment groups received counseling on sexual health as part of the HPV vaccination study.	Median duration of initial counseling session was 15 min. 47% chose to discuss PA, 36% dietary behaviors, and 20% sleeping behaviors. 71% chose any of the target behaviors.	NR	X	X	X		X				None

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Van Hoecke, 2014 ²¹²	PA M	IG1	Counseling	Participants first attended a 15-min informative session in which a fitness coach referred them to locally organized PA opportunities and distributed a self-help booklet and pedometer. Self-help booklet included detailed practical information of local PA opportunities for older adults, recommendations to achieve 30 min/day of moderate-intensity PA, and how to integrate more PA into their daily routines. Then, over 10 weeks, regular contact between the coach and participant took place, including an initial 60-min face-to-face, individually-tailored PA coaching session and six 30-min booster contacts or phone calls. Coaching sessions were based on self-determination theory and designed to determine individual PA goals according to the participant's preferences and abilities. Goals, which were specified by PA type, location, time frame, company, possible barriers, and solutions, were written down in a personal weekly schedule. Besides endurance activities like walking, the coach provided home-based exercises to improve the participant's strength, flexibility, and balance. Every 10 days, participants were supported through face-to-face contacts or booster phone calls (max 30 min). PA goals were evaluated and modified if necessary, barriers were identified, and participants were stimulated to persist in PA by using behavior change techniques and applying MI.	NR	SCT	X				X	X			MI: One 15-min informative session and received a self-help booklet and pedometer.

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Van Hoecke, 2014 ²¹²	PA L	IG2	Tailored prescription	Participants first attended a 15-min informative session in which a fitness coach referred them to locally organized PA opportunities and distributed a self-help booklet and pedometer. Self-help booklet included detailed practical information of local PA opportunities for older adults, recommendations to achieve 30 min/day of moderate-intensity PA, and how to integrate more PA into their daily routines. In addition, participants were given an individualized walking program based on their baseline walking level (based on the 6-min walk test). Written program consisted of structured weekly schedules of uninterrupted walks (described as number of steps) on most days of the week. Walking volume and intensity increased gradually and participants were encouraged to progress through the different levels of the walking program according to their individual abilities. Participants could accomplish the program on their own or in a social context (e.g., with significant others, in a social organization).	NR	NR									

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Van Stralen, 2010 ²¹⁴	PA L	IG1	Tailored print mailings with environmental focus	3 motivationally and environmentally focused computer-tailored letters mailed to each participant including personalized PA advice. First and second letters were based on personal data gathered at baseline and sent 2 weeks and 2 months after baseline, respectively. Third letter sent 2 weeks after receiving the 3-month questionnaire and was based on data gathered at baseline and 3 months; it addressed any changes undertaken during these 3 months. Several psychosocial determinants that underlie PA behavior change (e.g., awareness, attitude, social influence, self-efficacy, intention, and self-regulation skills) were targeted. Environmental information comprised handouts on walking and cycling routes in their neighborhood, examples of exercises to do at home, and contact information for local sports clubs matching their interests and abilities combined with access to a forum and ebuddy system on a website to increase social and environmental determinants. Letters comprised between 3 and 11 pages depending on (changes in) PA level and determinant scores.	Across both intervention groups, 98% read tailored letters 68% saved the letters 37% discussed letters with others	TTM	X	X	X		X				WL
Van Stralen, 2010 ²¹⁴	PA L	IG2	Tailored print mailings	3 motivationally focused computer-tailored letters mailed to each participant including personalized PA advice. First and second letters were based on personal data gathered at baseline and sent 2 weeks and 2 months after baseline, respectively. Third letter was sent 2 weeks after receiving the 3-month questionnaire and was based on data gathered at baseline and 3 months; it addressed any changes undertaken during these 3 months. Several psychosocial determinants that underlie PA behavior change (e.g., awareness, attitude, social influence, self-efficacy, intention, and self-regulation skills) were targeted. Letters comprised between 3 and 11 pages depending on (changes in) PA level and determinant scores.			X	X	X		X				

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Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Vandelanote, 2005 ²¹⁷	HD+PA	IG1	Computer-based sessions with tailored feedback (PA and diet simultaneous)	At 1 session, participants completed 2 interactive computer-tailored interventions (about 50 min each) targeted at increasing PA and reducing fat intake that were delivered at a local university computer lab at baseline. After reading the purpose of the intervention, participants filled out an electronic questionnaire consisting of demographics, health behavior, and psychosocial variables. Tailored feedback was displayed immediately, based on the theory of planned behavior and the stages of change concept from the transtheoretical model. Feedback consisted of normative feedback, which related participants' PA or fat intake to current recommendations (30 min/day of moderate PA and consume <30% energy from fat) and tips and suggestions on how to increase PA or decrease fat intake. Tailored advice was printed and taken home.	Across all intervention groups, 95.3% read the PA advice and 96.2% read the diet advice	TPB, TTM	X	X			X				WL
	M														
Vandelanote, 2005 ²¹⁷	HD+PA	IG2	Computer-based sessions with tailored feedback (PA feedback first)	Participants completed 2 interactive computer-tailored interventions (about 50 min each) targeted at increasing PA and reducing fat intake delivered at a local university computer lab. Tailored PA intervention was delivered at baseline and tailored fat intake intervention at 3 months postbaseline. After reading the purpose of the intervention, participants filled out an electronic questionnaire consisting of demographics, health behavior, and psychosocial variables. Tailored feedback was displayed immediately, based on the theory of planned behavior and the stages of change concept from the transtheoretical model. Feedback consisted of normative feedback, which related participants' PA or fat intake to current recommendations (30 min/day of moderate PA and consume <30% energy from fat) and tips and suggestions on how to increase PA or decrease fat intake. Tailored advice was printed and taken home.			X	X			X				
	M														

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Vandelanote, 2005 ²¹⁷	HD+PA M	IG3	Computer-based sessions with tailored feedback (Diet feedback first)	Participants completed 2 interactive computer-tailored interventions (about 50 min each) targeted at increasing PA and reducing fat intake t delivered at a local university computer lab. Tailored fat-intake intervention was delivered at baseline and tailored PA intervention at 3 months postbaseline. After reading the purpose of the intervention, participants filled out an electronic questionnaire consisting of demographics, health behavior, and psychosocial variables. Tailored feedback was displayed immediately, based on the theory of planned behavior and the stages of change concept from the transtheoretical model. Feedback consisted of normative feedback, which related participants' PA or fat intake to current recommendations (30 min/day of moderate PA and consume <30% energy from fat) and tips and suggestions on how to increase PA or decrease fat intake. Tailored advice was printed and taken home.			X	X			X				
Vrdoljak, 2013 ²¹⁸	HD+PA M	IG1	Provider training	PCPs received instructions for helping patients fill out questionnaires on adherence to the traditional Mediterranean diet, PA, smoking, and alcohol use and received training on using nonpharmacological and/or pharmacological interventions in accordance with recommendations when suboptimal behavior was reported. In addition, PCPs received a booklet on the intervention, patient education flyers, and precise protocols for monitoring participants. PCPd received repeated group training over 1 year.	NR	NR									None: Providers were not instructed to perform any specific interventions for patients and did not receive any training or materials

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Wadsworth, 2010 ²¹⁹	PA L	IG1	Web-based intervention	Attended 1 orientation face-to-face session (assume 30 min) that provided written information regarding exercise: terminology, recommendations, safety precautions, and campus PA opportunities, as well as encouraging the participant to begin a moderate exercise program and ask any questions about their exercise program. Results from the DXA scan given to each participant and shown how they compare to others of same age and sex. 6 weekly emails directed participants to web pages that targeted goal settings, time management, self-monitoring, social support, reinforcements, relapse prevention, realistic expectations of exercise, expectancies of exercise, overcoming barriers to exercise, anticipation of exercise relapse, natural history of exercise, and building of exercise self-efficacy. Each web page directed the subject to complete a short survey at the end. Access to an ecounselor who was a trained exercise physiologist provided. In addition, a web site that contained discussion boards, exercise information, exercise suggestions, sample workouts, and community events tailored to the campus community was accessible. In addition, 4 monthly booster emails sent to prevent relapse and overcome barriers to exercise.	55% did not initiate contact with ecounselor. Of those who did, 69% responded to all 6 weekly emails, 11% to 5, 2% to 4, 2% to 3, and 9% to 2. 90% accessed the web site weekly. 4% accessed the web site monthly. 6% did not access the web site.	SCT	X	X	X	X	X				MI: 1 orientation session with printed materials that included brief information about exercise and encouraged PA.
Warner, 2016 ²²⁰	PA	IG1	Group counseling with views-on-aging component	One 170-min interactive group session (3 to 8 participants/group) designed to increase PA through social support and ongoing goal setting plus targeting positive views-on-aging. Information on PA opportunities for older adults (for all city districts where participants lived) was available for free in the intervention room. Participants also informed that they should consult their physician to clarify what kind of PA would be suitable for their health status.	Group sessions averaged 166 min, with 5.9 participants on average per group session	Health Action Process Approach (HAPA)	X	X	X		X				AC: One 165-min group session focused on volunteering

Appendix E Table 1. Intervention Details

Author, Year	Int Focus Intensity	IG	Intervention	Detailed Description	Adherence/ Intervention Fidelity	Theory	Goals	FB	Social Support	Compares Outcomes	Self-Belief	MI	5As	Other	Control Group
Warner, 2016 ²²⁰	PA	IG2	Group counseling	One 170-min interactive group session (3 to 8 participants/group) designed to increase PA through social support and ongoing goal setting plus targeting positive views-on-aging. Instead, this group received 1 extra action planning sheet to increase PA. Information on PA opportunities for older adults (for all city districts where participants lived) was available for free in the intervention room. Participants also informed that they should consult their physician to clarify what kind of PA would be suitable for their health status.	Group sessions averaged 170 min, with 6.3 participants on average per group session										

Abbreviations: AC=attention control; ACP=Active Choices Program; BCT=behavior choice theory; CHD=coronary heart disease; CG=control group; CVD=cardiovascular disease; ECA=embodied conversational agent; FB=feedback; FU=followup; GI=glycemic index; H=high; HBM=health belief model; HD=healthful diet; hr=hour; IG=intervention group; Int=intervention; IVR=interactive voice response; L=low; LDL-C=low-density lipoprotein cholesterol; HDL-C=high-density lipoprotein cholesterol; M=medium; MI=motivational interviewing; min=minute; MVPA=moderate-to-vigorous physical activity; NR=not reported; PA=physical activity; PCP=primary care provider; SCT=social cognitive theory; SD=standard deviation; TLC=telephone-linked communication; TTM=transtheoretical model; UC=usual care; WL=waitlist.

Appendix F Table 1. Cardiovascular Disease Health Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	FU, weeks	Outcome	IG N	IG N (%)	CG N	CG N (%)	Study-reported between- group difference HR (95% CI)
HPT, 1990 ¹⁴⁰ Good	HD	IG1	Group counseling (potassium and sodium focus)	156	All-cause mortality	195	1 (0.5)	196	1 (0.5)	NR
	H									
	HD	IG2	Group counseling (sodium focus)	156	All-cause mortality	196	1 (0.5)	196	1 (0.5)	NR
	H									
Tinker, 2008 ²⁰⁹ Good	HD	IG1	Group counseling	421.2	All-cause mortality	19,541	950 (0.6)*	29,294	1454 (0.6)*	0.98 (0.91 to 1.07) [†]
	H			421.2	Composite CHD (nonfatal MI, CHD death, CABG/PCI)	18,633	806 (0.5)*	27,925	1292 (0.6)*	0.94 (0.86 to 1.02) [‡]
				421.2	CVD mortality	18,633	124 (0.1)*	27,925	185 (0.1)*	1.01 (0.81 to 1.27) [‡]
				421.2	Major CHD (nonfatal MI or CHD death)	18,633	452 (0.3)*	27,925	733 (0.3)*	0.93 (0.83 to 1.05) [‡]
				421.2	MI (nonfatal)	18,633	353 (0.2)*	27,925	581 (0.3)*	0.91 (0.80 to 1.04) [‡]
				421.2	Stroke (fatal)	18,633	46 (0.03)*	27,925	73 (0.03)*	0.94 (0.65 to 1.35); NR [‡]
				421.2	Stroke (fatal + nonfatal)	18,633	384 (0.2)*	27,925	564 (0.2)*	1.02 (0.90 to 1.17) [‡]
				421.2	Stroke (nonfatal)	18,633	338 (0.2)*	27,925	491 (0.2)*	1.04 (0.90 to 1.19) [‡]
421.2	Total CVD (MI, CHD death, CABG/PCI, stroke)	18,633	1132 (0.7)*	27,925	1777 (0.8)*	0.96 (0.89 to 1.03) [‡]				
TOHP I, 1992 ²⁰⁴ Fair	HD	IG1	Group counseling	520	All-cause mortality	327	10 (3.1)	417	14 (3.4)	0.76 (0.33 to 1.74) [§]
	H				520	Cardiovascular disease (MI, stroke, revascularization, or CVD death)	231	17 (7.4)	311	32 (10.3)
TOHP II, 1997 Good	HD	IG1	Group counseling	520	All-cause mortality	1,518	35 (2.3)	1,608	42 (2.6)	0.80 (0.51 to 1.26)
	H			520	CVD Events (MI, stroke, CV death)	NR	NR (NR)	NR	NR (NR)	0.72 (0.50 to 1.03)
				520	CVD Events (MI, stroke, revascularization, or CV death)	1,169	88 (7.5)	1,246	112 (9.0)	0.70 (0.53 to 0.94)
				520	CVD mortality	1,169	10 (0.8)	1,246	15 (1.2)	0.62 (0.28 to 1.40)

* Annualized percentage.

† Stratified by prevalent condition, age, and randomization group.

‡ Stratified by prevalent condition, age, and hormone therapy randomization group.

§ Adjusted by baseline weight and sodium excretion.

|| Adjusted by clinic, age, race, sex, weight loss intervention, baseline weight, and sodium excretion.

Abbreviations: CABG=coronary artery bypass graft; CG=control group; CHD=coronary heart disease; CV=cardiovascular; CVD=cardiovascular disease; FU=followup; H=high; HD=healthful diet; HR=hazard ratio; IG=intervention group; Int=intervention; MI=myocardial infarction; N=number analyzed; NR=not reported; PCI=percutaneous coronary intervention.

Appendix F Table 2. Pooled Results of Intermediate Outcomes for All Interventions and by Intervention Focus

Outcome	Healthful Diet (± Physical Activity)			Healthful Diet + Physical Activity			Healthful Diet			Physical Activity		
	Mean Difference in Change (95% CI)	Trials, k	I ² , %	Mean Difference in Change (95% CI)	Trials, k	I ² , %	Mean Difference in Change (95% CI)	Trials, k	I ² , %	Mean Difference in Change (95% CI)	Trials, k	I ² , %
SBP, mm Hg	-1.53 (-2.15 to -0.91)	16	52.2	-1.46 (-2.61 to -0.30)	7	0	-1.60 (-2.40 to -0.80)	9	71.5	-0.36 (-1.17 to 0.44)	6	1.4
DBP, mm Hg	-0.66 (-0.79 to -0.52)	16	0.6	-0.62 (-1.37 to 0.14)	7	0	-0.70 (-0.99 to -0.41)	9	18.8	0.10 (-0.62 to 0.82)	7	23.7
Low-density lipoprotein cholesterol, mg/dL*	-3.21 (-5.32 to -1.11)	9	8.4	-3.68 (-5.85 to -1.50)	8	4.7	0.00 (-5.87 to 5.87)	1	--	-1.92 (-5.08 to 1.23)	4	26.0
Total cholesterol, mg/dL*	-3.44 (-6.49 to -0.40)	11	55.1	-4.00 (-7.94 to -0.63)	8	54.8	-2.17 (-6.80 to 2.46)	3	51.4	-1.19 (-3.51 to 1.13)	8	21.3
High-density lipoprotein cholesterol, mg/dL*	-0.11 (-1.47 to 1.26)	9	64.4	-0.02 (0.161 to 1.57)	8	68.8	-0.39 (-2.54 to 1.68)	1	--	0.38 (-0.36 to 1.12)	6	3.4
Triglycerides, mg/dL [†]	-4.42 (-8.85 to 0.01)	8	0	-4.42 (-8.85 to 0.01)	8	0	--	--	--	0.80 (-3.27 to 4.88)	5	0
Fasting glucose, mg/dL [‡]	-1.15 (-2.02 to -0.29)	7	1.0	-0.92 (-1.99 to 0.15)	6	7.9	1.80 (-3.60 to 0.00)	1	0	0.37 (-0.89 to 1.63)	6	46.1
BMI, kg/m ²	-0.58 (-0.76 to -0.40)	15	86.7	-0.68 (-1.04 to -0.32)	9	85.8	-0.45 (-0.67 to -0.22)	6	89.6	0.03 (-0.18 to 0.24)	5	70.1
Weight, kg [§]	-1.25 (-1.86 to -0.64)	15	93.7	-1.81 (-3.09 to -0.53)	7	90.6	-0.82 (-1.61 to -0.03)	8	95.6	-0.49 (-1.17 to 0.20)	5	49.2
Waist circumference, cm	-1.67 (-2.37 to -0.98)	11	87.9	-1.54 (-3.00 to -0.08)	8	91.4	-1.61 (-1.72 to -1.49)	3	0	-0.33 (-0.93 to 0.27)	6	52.7

* To convert mg/dL to mmol/L, multiply by 0.0259.

† To convert mg/dL to mmol/L, multiply by 0.0113.

‡ To convert mg/dL to mmol/L, multiply by 0.0555.

§ To convert kg to lb, multiply by 2.205.

|| To convert cm to in, multiply by 0.394.

Abbreviations: BMI=body mass index; CI=confidence interval; DBP=diastolic blood pressure; SBP=systolic blood pressure.

Appendix F Table 3. Blood Pressure Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Aldana, 2006 ⁸⁵ Fair	HD+PA	IG1	Group counseling	X	26	SBP	174	129 (16)	-5 (-7.3 to -2.7)	174	128 (17)	-4 (-6.2 to -1.8)	-1.00 (-4.00 to 2.00)
				X	26	DBP	174	78.3 (9.2)	-5.5 (-6.8 to -4.2)	174	76.7 (9.6)	-3.8 (-5.0 to -2.6)	-1.7 (-3.5 to -0.0)
	H		26	% with HTN*	174	43 (24.7) [†]	-9 (-5.2) [†]	174	45 (25.9) [†]	-16 (-9.2) [†]	7 (4.0) ^{††}		
Bennett, 2013 ⁹¹ Good	HD+PA	IG1	Counseling, tailored print materials, and self-monitoring		26	SBP	91	123.2 (15.3)	-1.7 (-4.2 to 0.8)	94	122.9 (14.5)	-1.2 (-3.7 to 1.3)	-0.50 (-4.20 to 3.20)
				X	52	SBP	91	123.2 (15.3)	-1.6 (-4.5 to 1.3)	94	122.9 (14.5)	-1.6 (-4.5 to 1.3)	0.01 (-4.10 to 4.20)
					78	SBP	90	123.2 (15.3)	-3.0 (-5.7 to -0.3)	94	122.9 (14.5)	0.8 (-1.7 to 3.3)	-3.80 (-7.60 to 0.20)
					26	DBP	91	80.9 (10.7)	-2.5 (-4.5 to -0.5)	94	80.4 (11.3)	-1.3 (-3.3 to 0.7)	-1.1 (-4.0 to 1.7)
				X	52	DBP	91	80.9 (10.7)	-2.3 (-4.7 to 0.1)	94	80.4 (11.3)	-1.6 (-3.8 to 0.6)	-0.7 (-3.9 to 2.5)
					78	DBP	90	80.9 (10.7)	-1.9 (-4.1 to 0.3)	94	80.4 (11.3)	-1.0 (-3.2 to 1.2)	-0.9 (-3.9 to 2.2)
Coates, 1999 ¹⁰⁶ Fair	HD	IG1	Group counseling	X	26	SBP	1101	127.1 (19.1)	-3.1 (NR to NR)	648	127.3 (18.3)	-1.4 (NR to NR)	-1.7 (-3.15 to -0.32)
				X	26	DBP	1101	76.3 (9.7)	-1.1 (NR to NR)	648	76.9 (9.5)	-0.6 (NR to NR)	-0.4 (-1.17 to 0.31)
Elley, 2003 ¹¹¹ Good	PA	IG1	Counseling with tailored prescription	X	52	SBP	451	135.1 (19.6)	-2.6 (-4.0 to -1.1)	427	135.4 (17.9)	-1.2 (-2.6 to 0.2)	-1.31 (-3.51 to 0.89) [§]
				X	52	DBP	451	82.4 (12.2)	-2.6 (-3.6 to -1.6)	427	81.8 (12.1)	-0.8 (-1.8 to 0.2)	-1.40 (-3.35 to 0.56) [§]
Grandes, 2009 ¹²² Good	PA	IG1	Brief counseling	X	52	SBP	1456	130.03 (18.43)	-3.3 (-5.8 to -0.9)	1389	129.92 (19.21)	-2.9 (-5.4 to -0.5)	-0.20 (-1.24 to 0.84) [§]
				X	52	DBP	1456	78.49 (10.67)	-1.4 (-2.6 to -0.21)	1389	78.08 (10.59)	-1.81 (-3 to -0.61)	0.52 (-0.1 to 1.15) [§]
Hargreaves, 2016 ¹³⁰ Fair	PA	IG1	Tailored walking program	X	24	DBP	35	76.6 (9.4)	-6.7 (-10.8 to -2.6)	39	76.1 (13.2)	-3.1 (-6.3 to 0.0)	-3.53 (-8.72 to 1.66) [‡]
				M									
Hellenius, 1993 ¹³⁵ Fair	HD	IG1	Counseling (diet)		26	SBP	40	130 (16.2)	-7 (-10 to -3)	39	130 (12.2)	-1 (-3 to 4)	-6.00 (-10.95 to -1.05) [‡]
				M									
	PA	IG2	Brief counseling (PA)		26	SBP	39	133 (18.0)	-5 (-9 to -0.3)	39	130 (12.2)	-1 (-3 to 4)	-4.00 (-9.58 to 1.58) ^{‡†}
				L									
	C	IG3	Counseling (Diet & PA)	X	26	SBP	39	129 (12.6)	-4 (-7 to -1)	39	130 (12.2)	-1 (-3 to 4)	-3.00 (-7.61 to 1.61) [‡]
				M									
	HD	IG1	Counseling (diet)		26	DBP	40	82 (7.9)	-6 (-8 to -4)	39	82 (8.3)	-1 (-3 to 1)	-5.00 (-7.83 to -2.17) [‡]
M													
PA	IG2	Brief counseling (PA)		26	DBP	39	82 (9.6)	-4 (-7 to -2)	39	82 (8.3)	-1 (-3 to 1)	-3.00 (-6.20 to 0.20) ^{‡†}	
			L										
HD+PA	IG3	Counseling (Diet & PA)	X	26	DBP	39	81 (7.7)	-2 (-4 to 1)	39	82 (8.3)	-1 (-3 to 1)	-1.00 (-4.20 to 2.20) [‡]	
			M										
Hinderliter, 2014 ¹³⁷ Good	HD	IG1	Group counseling on DASH diet	X	52	SBP	46	138 (9)	-9.5 (-12.1 to -6.7)	49	138 (9)	-3.9 (-7.3 to -0.5)	-5.60 (-9.94 to -1.26) [‡]
					52	DBP	46	86 (6)	-4.6 (-6.3 to -2.9)	49	86 (6)	-6.4 (-8.0 to -4.8)	1.80 (-0.52 to 4.12) [‡]
Hivert, 2007 ¹² Fair	HD+PA	IG1	Group counseling	X	104	SBP	58	111 (7.62)	5.0 (1.1 to 8.9)	57	110 (15.1)	7.0 (3.1 to 10.9)	-2.00 (-7.54 to 3.54) [‡]
				X	104	DBP	58	70 (7.62)	2.0 (0.0 to 4.0)	57	71 (7.55)	0.0 (-2.0 to 2.0)	2.00 (-0.77 to 4.77) [‡]
	H												

Appendix F Table 3. Blood Pressure Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
HPT, 1990 ¹⁴⁰ Good	H	IG1	Group counseling (potassium and sodium focus)	X	26	SBP	180	124.1 (NR)	-3.4 (-4.6 to -2.2)	191	123.9 (NR)	-2.1 (-3.3 to -0.9)	-1.30 (-2.96 to 0.36) [‡]
		IG2	Group counseling (sodium focus)		26	SBP	173	124.0 (NR)	-3.8 (-5.0 to -2.6)	191	123.9 (NR)	-2.1 (-3.3 to -0.9)	-1.70 (-3.46 to 0.06) [§]
		IG1	Group counseling (potassium and sodium focus)		156	SBP	178	124.1 (NR)	-4.1 (-5.5 to -2.7)	177	123.9 (NR)	-2.9 (-4.3 to -1.5)	-1.20 (-3.14 to 0.74) [‡]
		IG2	Group counseling (sodium focus)		156	SBP	174	124.0 (NR)	-2.8 (-4.2 to -1.4)	177	123.9 (NR)	-2.9 (-4.3 to -1.5)	0.10 (-1.86 to 2.06) [§]
		IG1	Group counseling (potassium and sodium focus)	X	26	DBP	180	82.3 (NR)	-3.7 (-4.7 to -2.7)	191	83.0 (NR)	-3.0 (-4.0 to -2.0)	-0.70 (-2.09 to 0.69) [‡]
		IG2	Group counseling (sodium focus)		26	DBP	173	82.6 (NR)	-3.4 (-4.4 to -2.4)	191	83.0 (NR)	-3.0 (-4.0 to -2.0)	-0.4 (-1.77 to 0.97) [§]
		IG1	Group counseling (potassium and sodium focus)		156	DBP	178	82.3 (NR)	-3.7 (-4.7 to -2.7)	177	83.0 (NR)	-3.0 (-4.0 to -2.0)	-0.70 (-2.09 to 0.69) [‡]
		IG2	Group counseling (sodium focus)		156	DBP	174	82.6 (NR)	-2.8 (-3.8 to -1.8)	177	83.0 (NR)	-3.0 (-4.0 to -2.0)	0.2 (-1.37 to 1.77) [§]
		IG1	Group counseling (potassium and sodium focus)		156	Incident HTN [¶]	189	0 (0.0) [†]	41 (21.7) [†]	194	0 (0.0) [†]	65 (33.5) [†]	0.65 (0.46 to 0.90) ^{‡¶}
		IG2	Group counseling (sodium focus)		156	Incident HTN [¶]	187	0 (0.0) [†]	46 (24.6) [†]	194	0 (0.0) [†]	65 (33.5) [†]	0.73 (0.53 to 1.01) ^{‡¶}
John, 2002 ¹⁴⁴ Fair	HD	IG1	Counseling	X	26	SBP	344	130.2 (19.7)	-2.0 (-3.4 to -0.6)	346	129.3 (19.6)	1.4 (-0.1 to 2.9)	-4.00 (-6.0 to -2.0) [§]
				X	26	DBP	344	79.2 (11.4)	-1.6 (-2.5 to -0.7)	346	79.9 (11.9)	-0.3 (-1.2 to 0.6)	-1.5 (-2.7 to -0.2) [§]
Kallings, 2009 ¹⁴⁶ Good	PA	IG1	Counseling with tailored prescription	X	26	SBP	41	137.6 (2.2)	0.2 (-4.3 to 4.7)	50	142.3 (2.6)	-4.1 (-7.5 to -0.6)	4.30 (-1.36 to 9.96) [‡]
	M			X	26	DBP	41	79.9 (1.5)	-1.0 (-3.5 to 1.6)	50	81.6 (1.3)	-1.7 (-4.4 to 0.9)	0.70 (-2.98 to 4.38) [‡]
Kinmonth, 2008 ¹⁵⁴ Fair	PA	IG1	Telephone counseling	X	52	SBP	107	124.2 (13.0)	-3.2 (-5.5 to -0.9)	111	122.6 (12.6)	-3.4 (-5.4 to -1.4)	0.20 (-2.85 to 3.25) [‡]
	PA	IG2	In-home counseling		52	SBP	103	122.6 (12.6)	-3.0 (-5.2 to -0.8)	111	122.6 (12.6)	-3.4 (-5.4 to -1.4)	0.40 (-2.55 to 3.35) [‡]

Appendix F Table 3. Blood Pressure Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
	PA	IG1	Telephone counseling	X	52	DBP	107	79.1 (10.6)	-1.7 (-3.6 to 0.2)	111	78.2 (9.0)	-3.1 (-4.6 to -1.6)	1.40 (-0.97 to 3.77) [‡]
	M												
	PA	IG2	In-home counseling		52	DBP	103	77.9 (9.0)	-1.7 (-3.3 to -0.1)	111	78.2 (9.0)	-3.1 (-4.6 to -1.6)	1.40 (-0.77 to 3.57) [‡]
	H												
Lawton, 2008 ¹⁶⁰ Good	PA	IG1	Counseling with tailored prescription	X	52	SBP	544	122.8 (16.3)	-2.2 (-3.4 to -1.0)	545	123.4 (18.7)	-1.5 (-2.7 to -0.3)	-0.70 (-2.45 to 1.05) [‡]
					104	SBP	544	122.8 (16.3)	-3.7 (-4.9 to -2.5)	545	123.4 (18.7)	-3.9 (-5.1 to -2.7)	0.20 (-1.55 to 1.95) [§]
	M			X	52	DBP	544	73.8 (9.3)	-2.3 (-3.0 to -1.6)	545	74.7 (9.3)	-2.3 (-3.0 to -1.6)	0.00 (-0.96 to 0.96) [‡]
					104	DBP	544	73.8 (9.3)	-2.2 (-2.9 to -1.5)	545	74.7 (9.3)	-3.3 (-4.0 to -2.6)	1.10 (0.14 to 2.06) [‡]
Mosca, 2008 ¹⁷⁶ Good	HD+PA	IG1	Counseling	X	52	SBP	250	126.7 (15.33)	3.0 (1.1 to 4.9)	251	126.4 (16.17)	3.4 (1.6 to 5.2)	-0.40 (-3.04 to 2.24) [‡]
	M			X	52	DBP	250	77.9 (11.29)	1.1 (-0.2 to 2.4)	251	77.0 (11.72)	1.9 (0.6 to 3.2)	-0.80 (-2.63 to 1.03) [‡]
Roderick, 1997 ¹⁸⁸ Fair	HD	IG1	Counseling	X	52	SBP	473	124.4 (18.0)	-1.1 (NR to NR)	483	125.2 (15.9)	-0.4 (NR to NR)	-0.59 (-2.43 to 1.24) [§]
				X	52	DBP	473	77.8 (11.8)	-0.2 (NR to NR)	483	77.1 (11.7)	-0.1 (NR to NR)	0.09 (-4.9 to 5.0) [§]
Sacerdote, 2006 ¹⁹⁰ Fair	HD	IG1	Brief counseling	X	52	SBP	1488	128.7 (14.5)	0.2 (-1.4 to 0.7)	1489	128.8 (19.4)	-0.2 (-1.6 to 3.4)	0.35 (-2.38 to 2.72) [§]
	L				52	DBP	1488	78.5 (8.6)	0.4 (-0.7 to 0.6)	1489	78.7 (8.1)	0.6 (-1.9 to 1.2)	-0.17 (-1.77 to 1.05) [§]
Simkin-Silverman, 1995 ¹⁹⁴ Good	HD+PA	IG1	Group counseling		26	SBP	236	110.0 (12.5)	-3.4 (-4.7 to -2.1)	253	110.1 (13.0)	-1.4 (-2.7 to -0.1)	-2.00 (-3.86 to -0.14) [‡]
				X	78	SBP	236	110.0 (12.5)	-2.7 (-4.2 to -1.2)	253	110.1 (13.0)	-0.5 (-1.8 to 0.8)	-2.20 (-4.17 to -0.23) [‡]
	H				234	SBP	246	110.0 (12.5)	-0.12 (NR to NR)	263	110.1 (13.0)	0.20 (NR to NR)	-0.32 (NR to NR) [‡]
					26	DBP	236	68.5 (7.6)	-2.5 (-3.3 to -1.7)	253	67.9 (8.5)	-0.3 (-1.2 to 0.6)	-2.20 (-3.39 to -1.01) [‡]
				X	78	DBP	236	68.5 (7.6)	1.4 (0.5 to 2.3)	253	67.9 (8.5)	2.0 (1.1 to 2.9)	-0.60 (-1.84 to 0.64) [‡]
					234	DBP	246	68.5 (7.6)	1.5 (NR to NR)	263	67.9 (8.5)	2.2 (NR to NR)	-0.7 (NR to NR) [‡]
Thompson, 2008 ²⁰⁷ Fair	HD+PA	IG1	Group counseling		26	SBP	100	115.8 (13.2)	-0.5 (-2.9 to 1.9)	100	116.6 (11.2)	0.3 (-1.9 to 2.5)	-0.80 (-4.00 to 2.40) [‡]
				X	52	SBP	100	115.8 (13.2)	-1.4 (-3.7 to 0.9)	100	116.6 (11.2)	0.1 (-2.0 to 2.2)	-1.50 (-4.64 to 1.64)
	H				78	SBP	100	115.8 (13.2)	-0.9 (-3.1 to 1.3)	100	116.6 (11.2)	0.4 (-1.7 to 2.5)	-1.30 (-4.38 to 1.78) [‡]
					26	DBP	100	67.6 (10.8)	-1.5 (-3.3 to 0.3)	100	68.7 (9.4)	1.2 (-0.5 to 2.9)	-2.70 (-5.17 to -0.23) [‡]
				X	52	DBP	100	67.6 (10.8)	0.4 (-1.5 to 2.3)	100	68.7 (9.4)	0.4 (-1.2 to 2.0)	0.00 (-2.47 to 2.47) [‡]
					78	DBP	100	67.6 (10.8)	0.3 (-1.5 to 2.1)	100	68.7 (9.4)	0.1 (-1.5 to 1.7)	0.20 (-2.17 to 2.57) [‡]
Thompson, 2014 ²⁰⁸ Good	PA	IG1	Counseling and self-monitoring	X	26	SBP	24	138.8 (17.2)	-5.0 (-11.4 to 1.4)	24	137.0 (20.0)	3.0 (-8.0 to 14.0)	-8.00 (-20.71 to 4.71) [‡]
	H			X	26	DBP	24	72.5 (11.4)	-1.2 (-4.7 to 2.3)	24	75.4 (9.4)	2.0 (-3.2 to 7.2)	-3.20 (-9.51 to 3.11) [‡]
Tinker, 2008 ²⁰⁹ Good	HD	IG1	Group counseling	X	52	SBP	17,126	127.1 (17.2)	-2.7 (-2.9 to -2.5)	25,173	127.4 (17.1)	-2.0 (-2.2 to -1.8)	-0.66 (-0.89 to -0.44) [§]
					312	SBP	14,543	127.1 (17.2)	-2.6 (-2.8 to -2.4)	22,532	127.4 (17.1)	-2.8 (-3.0 to -2.6)	0.20 (-0.11 to 0.51) [‡]
	H			X	52	DBP	17,125	75.9 (9.1)	-2 (-2.1 to -1.9)	25,169	76.0 (9.0)	-1.3 (-1.4 to -1.2)	-0.64 (-0.76 to -0.51) [§]
					312	DBP	14,540	75.9 (9.1)	-4.2 (-4.3 to -4.1)	22,532	76.0 (9.0)	-4.1 (-4.2 to -4)	-0.10 (-0.27 to 0.07) [‡]
					432	Incident HTN	12,566	NR (NR)	NR (NR)	18,580	NR (NR)	NR (NR)	0.96 (0.93 to 0.99) ^{§§}

Appendix F Table 3. Blood Pressure Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
TOHP I, 1992 ²⁰⁴ Fair	HD H	IG1	Group counseling		26	SBP	305	124.8 (8.5)	-5.9 (-6.8 to -5.0)	397	125.1 (8.1)	-3.8 (-4.7 to -3.0)	-2.03 (-3.26 to -0.80) [§]
				X	52	SBP	301	124.8 (8.5)	-5.8 (-6.7 to -5.0)	392	125.1 (8.1)	-3.9 (-4.7 to -3.2)	-1.90 (-3.02 to -0.78) [§]
					78	SBP	304	124.8 (8.5)	-5.1 (-6.0 to -4.2)	395	125.1 (8.1)	-3.0 (-3.8 to -2.2)	-2.06 (-3.28 to -0.84) [§]
					26	DBP	305	83.7 (2.7)	-3.9 (-4.6 to -3.2)	397	83.9 (2.8)	-2.9 (-3.5 to -2.3)	-1.00 (-1.95 to -0.04) [§]
				X	52	DBP	301	83.7 (2.7)	-4.4 (-5.0 to -3.8)	392	83.9 (2.8)	-3.4 (-3.9 to -2.8)	-1.06 (-1.90 to -0.22) [§]
					78	DBP	304	83.7 (2.7)	-4.3 (-5.0 to -3.7)	395	83.9 (2.8)	-3.2 (-3.8 to -2.6)	-1.17 (-2.03 to -0.31) [§]
					78	Incident HTN	327	0 (0)*	28 (8.6) ^{††}	417	0 (0) [†]	47 (11.3) ^{††}	0.84 (0.62 to 1.13) ^{**}
TOHP II, 1997 ²⁰⁵ Good	HD H	IG1	Group counseling		26	SBP	529	127.7 (6.6)	-5.1 (-5.8 to -4.4)	538	127.3 (6.4)	-2.2 (-2.9 to -1.5)	-2.90 (-3.88 to -1.92)
				X	78	SBP	513	127.7 (6.6)	-3.8 (-4.5 to -3.1)	525	127.3 (6.4)	-1.8 (-2.4 to -1.2)	-2.00 (-2.98 to -1.02)
					156	SBP	515	127.7 (6.6)	-0.7 (-1.5 to 0.1)	514	127.3 (6.4)	0.6 (-0.1 to 1.3)	-1.20 (-2.18 to -0.22)
					26	DBP	529	86.1 (1.9)	-4.4 (-5.0 to -3.8)	538	85.8 (1.9)	-2.8 (-3.3 to -2.3)	-1.6 (-2.38 to -0.82)
				X	78	DBP	513	86.1 (1.9)	-4.4 (-5.0 to -3.8)	525	85.8 (1.9)	-3.2 (-3.7 to -2.7)	-1.2 (-1.98 to -0.42)
					156	DBP	515	86.1 (1.9)	-3.0 (-3.6 to -2.4)	514	85.8 (1.9)	-2.4 (-3.0 to -1.8)	-0.7 (-1.48 to 0.08)
					26	Incident HTN	578	0 (0)*	26 (4.5) ^{††}	589	0 (0) [†]	43 (7.3) ^{††}	0.61 (0.38 to 0.98) ^{††}
					78	Incident HTN	581	0 (0)*	108 (18.6) ^{††}	588	0 (0) [†]	124 (21.1) ^{††}	0.88 (0.70 to 1.11) ^{††}
					156	Incident HTN	576	0 (0)*	198 (34.4) ^{††}	584	0 (0) [†]	229 (39.2) ^{††}	0.88 (0.75 to 1.02) ^{††}
	208	Incident HTN	554	0 (0)*	211 (38.1) ^{††}	558	0 (0) [†]	248 (44.4) ^{††}	0.86 (0.74 to 0.99) ^{††}				

* Defined as SBP ≥140 mm Hg.

† n (%).

‡ Calculated.

§ Adjusted between-group difference.

|| Reported as significantly different based on post hoc comparisons.

¶ DBP ≥90 mm Hg or SBP ≥140 mm Hg or treatment for HTN.

RR.

** Relative risk; HTN defined as mean of 9 DBP readings ≥90 mm Hg at either 12- or 18-month followup or ever on anti-HTN medication during followup.

†† Relative risk; HTN defined as average DBP ≥90 mm Hg or average SBP ≥140 mm Hg or diagnosis and drug treatment of HTN.

‡‡ Hazard ratio, adjusted for age and hormone therapy group; HTN defined as self-report of treated HTN or blood pressure ≥140/90 mm Hg at one of the annual followup visits.

Abbreviations: CG=control group; CI=confidence interval; DBP=diastolic blood pressure; FU=followup; H=high; HD=healthful diet; HTN=hypertension; IG=intervention group; Int=intervention; L=low; M=medium; MA=meta-analysis; N=number analyzed; NR=not reported; PA=physical activity; RR=risk ratio; SBP=systolic blood pressure; SD=standard deviation; wk=week.

Appendix F Table 4. Lipid Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between-group difference Mean (95% CI)
Aadahl, 2014 ⁹⁰ Good	PA M	IG1	Counseling	X	26	LDL-C*	81	123.6 (34.7)	-8.1 (-53.5 to 37.3)	68	123.6 (38.6)	-2.3 (-6.9 to 2.3)	-5.79 (-12.74 to 1.54) [†]
				X	26	TC*	81	204.6 (34.7)	-10.0 (-15.9 to -4.2)	68	204.6 (42.5)	-3.1 (-8.6 to 2.4)	-6.95 (-15.06 to 11.97) [†]
				X	26	HDL-C*	81	61.8 (15.4)	-1.2 (-2.8 to 0.5)	68	57.9 (15.4)	-0.8 (-2.6 to 1.1)	-0.02 (-2.97 to 2.93) [†]
				X	26	TG [‡]	81	100.0 (44.2)	-5.3 (-13.0 to 2.4)	68	118.6 (510.8)	-1.8 (-14.4 to 10.9)	-5.31 (-20.35 to 8.85) [†]
Aldana, 2006 ⁹⁵ Fair	HD+PA H	IG1	Group counseling	X	26	LDL-C	174	122.0 (29.0)	5.0 (1.1 to 8.9)	174	121.0 (33.0)	9.0 (4.8 to 13.2)	-4.00 (-9.00 to 2.00)
				X	26	TC	174	193.0 (33.0)	6.0 (1.5 to 10.5)	174	190.0 (39.0)	11.0 (6.2 to 15.8)	-5.00 (-11.00 to 1.00)
				X	26	HDL-C	174	45.0 (12.2)	1.4 (0.0 to 2.8)	174	45.0 (10.4)	2.8 (1.7 to 3.9)	-1.40 (-2.90 to 0.00)
				X	26	TG	174	133.0 (102.0)	-5.0 (-17.4 to 7.4)	174	115.0 (86.0)	2.0 (-7.9 to 11.9)	-7.00 (-22.00 to 9.00)
Baron, 1990 ⁹⁰ Fair	HD M	IG1	Counseling	X	52	LDL-C	164	109.3 (30.5)	-11.6 (-15.7 to -7.5)	164	108.5 (33.6)	-11.6 (-15.8 to -7.4)	0.00 (-5.87 to 5.87) [§]
				X	52	TC	167	187.6 (31.7)	-7.7 (-12.2 to -3.3)	166	186.9 (33.2)	-6.9 (-11.2 to -2.7)	-0.77 (-6.95 to 5.41) [§]
				X	52	HDL-C	165	57.1 (13.9)	-1.2 (-2.7 to 0.4)	165	58.7 (13.9)	-0.8 (-2.2 to 0.6)	-0.39 (-2.45 to 1.68) [§]
Bennett, 2013 ⁹¹ Good	HD+PA H	IG1	Counseling, tailored print materials, and self- monitoring		26	LDL-C	91	107.3 (34.6)	-0.8 (-6.9 to 5.3)	94	106.8 (34.3)	2.6 (-3.1 to 8.3)	-3.40 (-11.70 to 4.90)
				X	52	LDL-C	91	107.3 (34.6)	-5.2 (-11.3 to 0.9)	94	106.8 (34.3)	0.1 (-5.4 to 5.6)	-5.40 (-13.70 to 2.90)
					78	LDL-C	90	107.3 (34.6)	-3.3 (-9.4 to 2.8)	94	106.8 (34.3)	-1.6 (-7.3 to 4.1)	-1.70 (-10.00 to 6.70)
					26	TC	91	176.4 (36.4)	-1.5 (-6.6 to 3.6)	94	181.3 (38.6)	0.9 (-4.2 to 6.0)	-2.40 (-9.70 to 4.80)
				X	52	TC	91	176.4 (36.4)	-4.9 (-10.2 to 0.4)	94	181.3 (38.6)	-2.4 (-7.5 to 2.7)	-2.50 (-9.80 to 4.90)
					78	TC	90	176.4 (36.4)	-4.3 (-9.8 to 1.2)	94	181.3 (38.6)	-4.5 (-9.8 to 0.8)	0.10 (-7.60 to 7.80)
					26	HDL-C	91	53.7 (15.8)	-3.2 (-5.4 to -1.0)	94	53.9 (16.4)	-3.2 (-5.4 to -1.0)	-0.03 (-3.10 to 3.00)
				X	52	HDL-C	91	53.7 (15.8)	-1.6 (-4.0 to 0.8)	94	53.9 (16.4)	-1.4 (-3.8 to 1.0)	-0.20 (-3.40 to 3.10)
					78	HDL-C	90	53.7 (15.8)	-1.2 (-3.6 to 1.2)	94	53.9 (16.4)	-1.6 (-4.0 to 0.8)	0.40 (-3.00 to 3.80)
					26	TG	91	99.6 (38.1)	8.9 (-5.2 to 23.0)	94	105.0 (54.6)	16.2 (2.9 to 29.5)	-7.40 (-26.80 to 12.10)
				X	52	TG	91	99.6 (38.1)	6.1 (-6.4 to 18.6)	94	105.0 (54.6)	4.2 (-7.4 to 15.8)	1.80 (-15.30 to 18.90)
	78	TG	90	99.6 (38.1)	0.2 (-11.0 to 11.4)	94	105.0 (54.6)	1.8 (-8.6 to 12.2)	-1.60 (-16.90 to 13.80)				
Brekke, 2005 ⁹⁷ Fair	HD, HD+PA H	IG1	Group counseling (diet)		52	LDL-C	24	118.1 (23.2)	0.4 (-9.3 to 10.0)	19	124.7 (39.0)	10.8 (2.3 to 19.3)	-10.42 (-23.28 to 2.43) [§]
				X	52	LDL-C	25	105.4 (34.0)	8.9 (0.4 to 17.0)	19	124.7 (39.0)	10.8 (2.3 to 19.3)	-1.93 (-13.81 to 9.95) [§]
	HD, HD+PA H	IG1	Group counseling (diet)		52	TC	24	186.9 (27.8)	3.9 (-5.8 to 13.9)	19	194.2 (44.4)	9.3 (-0.8 to 19.3)	-5.41 (-19.47 to 8.66) [§]
				X	52	TC	25	183.0 (29.0)	14.3 (3.5 to 25.5)	19	194.2 (44.4)	9.3 (-0.8 to 19.3)	-5.02 (-9.88 to 19.91) [§]
	HD, HD+PA H	IG1	Group counseling (diet)		52	HDL-C	24	48.6 (10.4)	3.1 (-0.8 to 7.3)	19	50.6 (10.4)	-1.5 (-4.2 to 1.2)	4.63 (-0.24 to 9.51) [§]
				X	52	HDL-C	25	44.8 (10.4)	4.2 (1.5 to 6.6)	19	50.6 (10.4)	-1.5 (-4.2 to 1.2)	5.79 (2.10 to 9.48) [§]

Appendix F Table 4. Lipid Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between-group difference Mean (95% CI)
	HD, HD+PA H	IG1	Group counseling (diet)		52	TG	24	102.7 (44.2)	2.7 (-12.4 to 17.7)	19	97.3 (45.1)	0.9 (-8.8 to 9.7)	1.77 (-15.91 to 19.45) [§]
	HD, HD+PA H	IG2	Group counseling (diet and PA)	X	52	TG	25	111.5 (56.6)	7.1 (-9.7 to 23.9)	19	97.3 (45.1)	0.9 (-8.8 to 9.7)	6.19 (-13.02 to 25.41) [§]
Elley, 2003 ¹¹¹ Good	PA M	IG1	Counseling with tailored prescription	X	52	TC	451	223.2 (38.6)	-0.7 (-3.1 to 1.9)	427	217.8 (38.6)	0.4 (-1.9 to 2.3)	-0.77 (-4.63 to 3.47) [†]
Grandes, 2009 ¹²² Good	PA L	IG1	Brief counseling	X	52	LDL-C	1456	134.2 (33.2)	-2.1 (-4.4 to 0.1)	1389	133.5 (32.7)	-1.2 (-3.4 to 1.0)	-0.91 (-2.90 to 1.08) [†]
				X	52	TC	1456	213.9 (38.6)	0.9 (-1.3 to 3.0)	1389	213.6 (36.3)	-0.1 (-2.2 to 2.1)	0.87 (-1.44 to 3.19) [†]
				X	52	HDL-C	1456	57.6 (14.7)	2.7 (1.5 to 3.8)	1389	58.3 (14.8)	1.7 (0.6 to 2.8)	0.94 (0.08 to 1.81) [†]
				X	52	TG	1456	118.0 (72.1)	-0.9 (-4.2 to 2.3)	1389	114.8 (66.2)	-1.9 (-5.2 to 1.4)	1.23 (-3.37 to 5.83) [†]
Hargreaves, 2016 ¹³⁰ Fair	PA M	IG1	Tailored walking program	X	24	TC	35	180.3 (32.4)	8.5 (-1.1 to 18.0)	39	189.6 (34.8)	14.7 (5.9 to 23.4)	-6.18 (-19.12 to 6.76) [§]
Hellenius, 1993 ¹³⁵ Fair	PA M	IG1	Counseling (diet)		26	LDL-C	40	165.6 (26.3)	-11.6 (-20.8 to -2.3)	39	159.8 (29.0)	-5.8 (-12.7 to 0.8)	-5.79 (-17.26 to 5.68) [§]
	HD L	IG2	Brief counseling (PA)		26	LDL-C	39	156.4 (25.5)	-3.5 (-9.3 to 2.7)	39	159.8 (29.0)	-5.8 (-12.7 to 0.8)	2.32 (-6.71 to 11.34) [§]
	HD+PA M	IG3	Counseling (diet & PA)	X	26	LDL-C	39	179.9 (33.2)	-13.5 (-24.7 to -1.9)	39	159.8 (29.0)	-5.8 (-12.7 to 0.8)	-7.72 (-20.97 to 5.52) [§]
	HD M	IG1	Counseling (diet)		26	TC	40	234.7 (30.9)	-7.3 (-18.9 to 4.2)	39	230.5 (34.7)	-5.0 (-12.7 to 2.7)	-2.32 (-16.24 to 11.60) [§]
	PA L	IG2	Brief counseling (PA)		26	TC	39	230.9 (24.7)	-4.6 (-13.5 to 4.2)	39	230.5 (34.7)	-5.0 (-12.7 to 2.7)	0.39 (-11.38 to 12.15) [§]
	HD+PA M	IG3	Counseling (diet & PA)	X	26	TC	39	252.1 (35.9)	-17.4 (-29.7 to -5.0)	39	230.5 (34.7)	-5.0 (-12.7 to 2.7)	-12.36 (-26.92 to 2.21) [§]
	HD M	IG1	Counseling (diet)		26	HDL-C	40	54.4 (15.1)	0.4 (-1.9 to 2.7)	39	52.5 (10.8)	-0.8 (-3.1 to 1.9)	1.16 (-2.26 to 4.57) [§]
	PA L	IG2	Brief counseling (PA)		26	HDL-C	39	51.7 (8.9)	0.4 (-1.5 to 2.7)	39	52.5 (10.8)	-0.8 (-3.1 to 1.9)	1.16 (-2.13 to 4.45) [§]
	HD+PA M	IG3	Counseling (diet & PA)	X	26	HDL-C	39	51.4 (13.5)	-1.2 (-3.5 to 1.5)	39	52.5 (10.8)	-0.8 (-3.1 to 1.9)	-0.39 (-3.94 to 3.16) [§]
	HD M	IG1	Counseling (diet)		26	TG	40	112.4 (41.6)	2.7 (-8.0 to 13.3)	39	117.7 (46.9)	5.3 (-7.1 to 17.7)	-2.65 (-18.97 to 13.66) [§]

Appendix F Table 4. Lipid Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between-group difference Mean (95% CI)
	PA	IG2	Brief counseling (PA)		26	TG	39	131.0 (90.3)	-8.8 (-30.1 to 11.5)	39	117.7 (46.9)	5.3 (-7.1 to 17.7)	-14.16 (-38.37 to 10.05) [§]
	HD+PA M	IG3	Counseling (Diet & PA)	X	26	TG	39	138.9 (61.9)	-10.6 (-27.4 to 7.1)	39	117.7 (46.9)	5.3 (-7.1 to 17.7)	-15.93 (-37.17 to 5.31) [§]
Hivert, 2007 ⁷² Fair	HD+PA H	IG1	Group counseling	X	104	LDL-C	58	103.5 (29.4)	-5.4 (-10.7 to -0.1)	57	97.3 (23.3)	-2.3 (-7.6 to 3.0)	-3.09 (-10.58 to 4.40) [§]
	HD+PA H	IG1	Group counseling	X	104	TC	58	175.7 (35.3)	0.8 (-6.8 to 8.3)	57	167.2 (29.1)	10.0 (4.0 to 16.1)	-9.27 (-18.96 to 0.42) [§]
	HD+PA H	IG1	Group counseling	X	104	HDL-C	58	50.2 (8.8)	7.7 (5.5 to 10.0)	57	50.6 (11.7)	10.4 (8.2 to 12.7)	-2.70 (-5.91 to 0.51) [§]
	HD+PA H	IG1	Group counseling	X	104	TG	58	109.7 (53.9)	-8.8 (-22.7 to 5.0)	57	98.2 (33.4)	8.8 (-1.6 to 19.3)	-17.70 (-35.04 to -0.35) [§]
John, 2002 ¹⁴⁴ Fair	HD M	IG1	Counseling	X	26	TC	340	194.5 (37.1)	-0.7 (-4.3 to 2.9)	344	197.8 (39.4)	-1.4 (-3.7 to 0.9)	0.39 (-3.75 to 4.48) [†]
	Kallings, 2009 ¹⁴⁶ Good	PA M	Counseling with tailored prescription	X	26	LDL-C	41	131.3 (4.6)	-3.9 (-7.7 to 3.9)	50	123.6 (3.5)	3.9 (-3.9 to 11.6)	-7.72 (-17.36 to 1.92) [§]
X				26	TC	41	216.2 (3.9)	-11.6 (-23.2 to 0.0)	50	212.4 (3.9)	3.9 (-3.9 to 3.9)	-11.58 (-27.03 to -0.39)	
X				26	HDL-C	41	65.6 (2.7)	0.0 (-3.9 to 3.9)	50	65.6 (1.9)	0.0 (-3.9 to 3.9)	0.00 (-5.48 to 5.48)	
X				26	TG	41	123.9 (8.8)	-17.7 (-26.5 to 0.0)	50	115.0 (8.8)	0.0 (-8.8 to 8.8)	-17.70 (-42.23 to 6.83) [§]	
Kinmonth, 2008 ¹⁵⁴ Fair	PA M	IG1	Telephone counseling	X	52	LDL-C	107	117.8 (32.8)	3.9 (-1.7 to 9.5)	111	124.3 (32.8)	1.9 (-3.3 to 7.2)	1.93 (-5.73 to 9.59) [§]
	PA H	IG2	In-home counseling		52	LDL-C	103	121.2 (38.2)	7.3 (0.7 to 14.0)	111	124.3 (32.8)	1.9 (-3.3 to 7.2)	5.41 (-3.05 to 13.86) [§]
	PA M	IG1	Telephone counseling	X	52	TC	107	194.2 (36.7)	2.3 (-4.1 to 8.7)	111	204.2 (35.1)	0.8 (-4.7 to 6.2)	1.54 (-6.85 to 9.93) [§]
	PA H	IG2	In-home counseling		52	TC	103	198.1 (39.8)	8.9 (1.9 to 15.9)	111	204.2 (35.1)	0.8 (-4.7 to 6.2)	8.11 (-0.73 to 16.95) [§]
	PA M	IG1	Telephone counseling	X	52	HDL-C	107	54.1 (14.3)	-1.2 (-3.2 to 0.9)	111	56.4 (15.8)	0.8 (-1.4 to 2.9)	-1.93 (-4.91 to 1.05) [§]
	PA H	IG2	In-home counseling		52	HDL-C	103	56.4 (15.8)	0.0 (-2.3 to 2.3)	111	56.4 (15.8)	0.8 (-1.4 to 2.9)	-0.77 (-3.93 to 2.38) [§]
	PA M	IG1	Telephone counseling	X	52	TG	107	119.5 (70.8)	-3.5 (-15.9 to 8.8)	111	119.5 (72.6)	-10.6 (-21.4 to 0.1)	7.08 (-9.27 to 23.43) [§]

Appendix F Table 4. Lipid Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between-group difference Mean (95% CI)
	PA	IG2	In-home counseling		52	TG	103	108.9 (55.8)	5.3 (-5.6 to 16.2)	111	119.5 (72.6)	-10.6 (-21.4 to 0.1)	15.93 (0.60 to 31.25) [§]
	H												
Lawton, 2008 ¹⁶⁰ Good	PA	IG1	Counseling with tailored prescription	X	52	TC	544	235.5 (45.2)	-9.3 (-12.4 to -6.1)	545	232.8 (45.2)	-7.7 (-10.7 to -4.8)	-1.54 (-5.83 to 2.74) [§]
					104	TC	544	235.5 (45.2)	-17.4 (-20.5 to -14.2)	545	232.8 (45.2)	-17.0 (-19.9 to -14.1)	-0.39 (-4.67 to 3.90) [§]
				X	52	HDL-C	544	63.7 (18.1)	3.1 (1.9 to 4.3)	545	62.9 (18.1)	3.1 (2.0 to 4.2)	0.00 (-1.60 to 1.60) [§]
					104	HDL-C	544	63.7 (18.1)	0.4 (-0.8 to 1.6)	545	62.9 (18.1)	1.2 (0.1 to 2.2)	-0.77 (-2.37 to 0.83) [§]
Mosca, 2008 ¹⁷⁶ Good	HD+PA	IG1	Counseling	X	52	LDL-C	232	128.5 (34.2)	-4.4 (-0.4 to -8.4)	232	130.6 (35.0)	-4.5 (-1.4 to -7.6)	0.10 (-4.77 to 4.97) [§]
				X	52	TC	250	202.7 (38.3)	-0.5 (-5.1 to 4.1)	251	205.9 (40.4)	-2.8 (-7.2 to 1.6)	2.30 (-4.02 to 8.62) [§]
				X	52	HDL-C	250	58.5 (18.2)	0.2 (-1.7 to 2.1)	251	59.9 (19.4)	-2.3 (-4.1 to -0.5)	2.50 (-0.11 to 5.11) ^{§¶}
				X	52	TG	250	115.0 (67.0)	-1.5 (-10.4 to 7.4)	251	118.0 (67.9)	1.2 (-6.6 to 9.0)	-2.70 (-14.55 to 9.15) [§]
Roderick, 1997 ¹⁸⁸ Fair	HD	IG1	Counseling	X	52	TC	473	235.5 (NR)	-8.9 (NR to NR)	483	235.5 (NR)	0.0 (NR to NR)	-7.72 (-14.67 to -1.16) [†]
	M												
Simkin-Silverman, 1995 ¹⁹⁴ Good	HD+PA	IG1	Group counseling		26	LDL-C	236	114.7 (21.8)	-11.3 (-13.9 to -8.7)	253	116.3 (21.8)	-0.1 (-2.5 to 2.3)	-11.20 (-14.75 to -7.65) [§]
				X	78	LDL-C	236	114.7 (21.8)	-4.2 (-6.8 to -1.6)	253	116.3 (21.8)	2.7 (0.2 to 5.2)	-6.90 (-10.53 to -3.27) [§]
					234	LDL-C	246	114.7 (21.8)	3.5 (NR to NR)	263	116.3 (21.8)	8.9 (NR to NR)	-5.40 (NR) ^{§¶}
					26	TC	236	189.7 (24.5)	-13.8 (-16.8 to -10.8)	253	189.6 (24.3)	0.9 (-1.7 to 3.5)	-14.70 (-18.70 to -10.70) [§]
				X	78	TC	236	189.7 (24.5)	-1.6 (-4.6 to 1.4)	253	189.6 (24.3)	7.8 (5.1 to 10.5)	-9.40 (-13.49 to -5.31) [§]
					26	HDL-C	236	59.7 (13.0)	-2.4 (-3.6 to -1.2)	253	58.4 (12.1)	-0.2 (-1.2 to 0.8)	-2.20 (-3.82 to -0.58) [§]
				X	78	HDL-C	236	59.7 (13.0)	1.0 (-0.2 to 2.2)	253	58.4 (12.1)	2.9 (1.8 to 4.0)	-1.90 (-3.56 to -0.24) [§]
					234	HDL-C	246	59.7 (13.0)	2.3 (NR to NR)	263	58.4 (12.1)	3.1 (NR to NR)	-0.80 (NR) [§]
					26	TG	236	82.2 (38.2)	-4.5 (-8.7 to -0.3)	253	78.2 (42.4)	5.5 (0.2 to 10.8)	-10.00 (-16.79 to -3.21) [§]
				X	78	TG	236	82.2 (38.2)	2.4 (-2.1 to 6.9)	253	78.2 (42.4)	7.4 (2.5 to 12.3)	-5.00 (-11.71 to 1.71) [§]
	234	TG	246	82.2 (38.2)	18.2 (NR to NR)	263	78.2 (42.4)	29.9 (NR to NR)	-11.70 (NR) ^{§¶}				
Thompson, 2008 ²⁰⁷ Fair	HD+PA	IG1	Group counseling		26	LDL-C	100	93.4 (25.1)	-5.4 (-9.8 to -1.0)	100	91.9 (20.1)	-3.9 (-7.1 to -0.6)	-1.54 (-7.05 to 3.96) [§]
				X	52	LDL-C	100	93.4 (25.1)	-6.2 (-10.5 to -1.8)	100	91.9 (20.1)	-5.8 (-9.2 to -2.4)	-0.39 (-5.91 to 5.14) [§]
					78	LDL-C	100	93.4 (25.1)	-5.4 (-9.7 to -1.1)	100	91.9 (20.1)	-4.2 (-7.7 to -0.8)	-1.16 (-6.66 to 4.34) [§]
					26	TC	100	167.6 (31.3)	-5.4 (-10.8 to 0.0)	100	168.3 (25.1)	-3.1 (-7.1 to 0.9)	-2.32 (-9.04 to 4.41) [§]
				X	52	TC	100	167.6 (31.3)	-5.4 (-10.8 to 0.0)	100	168.3 (25.1)	-5.4 (-9.7 to -1.2)	0.00 (-6.89 to 6.89) [§]
					78	TC	100	167.6 (31.3)	-6.2 (-11.6 to -0.8)	100	168.3 (25.1)	-3.5 (-7.6 to 0.6)	-2.70 (-9.46 to 4.06) [§]
					26	HDL-C	100	48.6 (12.0)	0.0 (-1.8 to 1.8)	100	50.6 (12.0)	-0.4 (-2.0 to 1.2)	0.39 (-2.00 to 2.77) [§]
				X	52	HDL-C	100	48.6 (12.0)	1.2 (-0.7 to 3.0)	100	50.6 (12.0)	1.2 (-0.5 to 2.8)	0.00 (-2.53 to 2.53) [§]
					78	HDL-C	100	48.6 (12.0)	0.0 (-1.8 to 1.8)	100	50.6 (12.0)	-0.4 (-2.0 to 1.2)	0.39 (-2.00 to 2.78) [§]
					26	TG	100	129.2 (56.6)	-1.8 (-12.0 to 8.5)	100	129.2 (56.6)	5.3 (-4.3 to 14.9)	-7.08 (-21.13 to 6.97) [§]
X	52	TG	100	129.2 (56.6)	-4.4 (-14.1 to 5.2)	100	129.2 (56.6)	-5.3 (-14.2 to 3.5)	0.88 (-12.20 to 13.97) [§]				
	78	TG	100	129.2 (56.6)	-5.3 (-15.6 to 4.9)	100	129.2 (56.6)	5.3 (-4.6 to 15.3)	-10.62 (-24.91 to 3.67) [§]				
Thompson, 2014 ²⁰⁸ Good	PA	IG1	Counseling and self-monitoring	X	26	TC	24	202.3 (31.3)	-10.0 (-18.2 to -1.9)	24	194.2 (29.3)	-0.8 (-7.0 to 5.4)	-9.27 (-19.52 to 0.99) [§]
	X			26	HDL-C	24	59.1 (11.6)	-1.5 (-4.2 to 1.1)	24	54.4 (15.4)	-0.4 (-1.9 to 1.2)	-1.16 (-4.20 to 1.89) [§]	
	X			26	TG	24	136.3 (46.0)	-2.7 (-17.5 to 12.2)	24	144.2 (55.8)	-8.8 (-19.8 to 2.1)	6.19 (-12.29 to 24.68) [§]	

* mg/dL. To convert to mmol/L, multiply by 0.0259.

† Adjusted.

‡ mg/dL. To convert to mmol/L, multiply by 0.0113.

§ Calculated.

¶ Mean HDL-C % change between groups reported as significantly different.

¶ Reported as statistically significant.

Appendix F Table 4. Lipid Outcomes

Abbreviations: C=counseling; CG=control group; CI=confidence interval; FU=followup; H=high; HD=healthful diet; HDL-C=high-density lipoprotein cholesterol; HTN=hypertension; IG=intervention group; Int=intervention; L=low intensity; LDL-C=low-density lipoprotein cholesterol; M=medium; MA=meta-analysis; N=number analyzed; NR=not reported; PA=physical activity; SD=standard deviation; TC=total cholesterol; TG=triglycerides; wk=week.

Appendix F Table 5. Glucose Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Aadahl, 2014 ⁸⁰ Good	PA	IG1	Counseling	X	26	Fasting glucose*	81	99.1 (16.2)	-3.6 (-5.6 to -1.6)	68	104.5 (19.8)	-3.6 (-6.6 to -0.6)	0.05 (-3.60 to 3.42) [†]
	M				26	HbA1c [‡]	81	5.6 (0.5)	0.1 (0.0 to 0.1)	66	5.6 (0.6)	0.1 (0.0 to 0.1)	0.01 (-0.07 to 0.09) [†]
Aldana, 2006 ⁸⁵ Fair	C	IG1	Group counseling	X	26	Fasting glucose	174	103.0 (23.0)	-3.0 (-5.9 to -0.1)	174	100.0 (19.0)	-1.0 (-3.6 to 1.6)	-2.00 (-6.00 to 0.40)
	H				26	Percent with diabetes [§]	174	21.0 (12.1)	-4.0 (-2.3)	174	7.0 (4.0)	2.0 (1.2)	-6 (-3.5) [‡]
Bennett, 2013 ⁹¹ Good	HD+PA	IG1	Counseling, tailored print materials, and self-monitoring		26	Fasting glucose	91	103.4 (35.5)	5.8 (-1.5 to 13.1)	94	105.4 (49.8)	5.7 (-1.4 to 12.8)	0.10 (-10.20 to 10.30)
	H			X	52	Fasting glucose	91	103.4 (35.5)	-1.6 (-7.5 to 4.3)	94	105.4 (49.8)	-5.1 (-10.8 to 0.6)	3.50 (-4.70 to 11.70)
						78	Fasting glucose	90	103.4 (35.5)	-3.1 (-9.4 to 3.2)	94	105.4 (49.8)	-7.4 (-13.7 to -1.1)
Brekke, 2005 ⁹⁷ Fair	HD, HD+PA	IG1	Group counseling (diet)		52	Fasting glucose	24	86.9 (9.0)	-5.9 (-9.7 to -2.0)	19	87.6 (8.5)	-3.8 (-7.9 to 0.4)	-2.16 (-7.84 to 3.51) [‡]
	H												
	HD, HD+PA	IG2	Group counseling (diet and PA)	X	52	Fasting glucose	25	87.8 (8.8)	-7.7 (-11.9 to -3.6)	19	87.6 (8.5)	-3.8 (-7.9 to 0.4)	-3.96 (-9.83 to 1.90) [‡]
Coates, 1999 ¹⁰⁶ Fair	HD	IG1	Group counseling	X	26	Fasting glucose	660	95.5 (27.0)	-3.6 (NR to NR)	407	95.5 (28.8)	-1.8 (NR to NR)	-1.80 (-3.24 to 0.36)
	H												
Grandes, 2009 ¹²² Good	PA	IG1	Brief counseling	X	52	Fasting glucose	1456	98.1 (22.1)	1.9 (0.8 to 2.9)	1389	99.2 (23.6)	1.5 (0.4 to 2.6)	0.52 (-0.61 to 1.65) [†]
	L												
Kallings, 2009 ¹⁴⁶ Good	PA	IG1	Counseling with tailored prescription	X	26	Fasting glucose	41	99.1 (1.8)	-3.6 (-5.4 to -1.8)	50	97.3 (1.8)	-1.8 (-3.6 to 0.0)	-1.80 (-6.80 to 3.19) [‡]
	M				26	HbA1c	41	5.0 (0.1)	-0.1 (-0.2 to 0.0)	50	4.8 (0.1)	0.2 (0.1 to 0.3)	-0.25 (-0.37 to -0.12)
Kinmonth, 2008 ¹⁵⁴ Fair	PA	IG1	Telephone counseling	X	52	Fasting glucose	107	86.5 (9.2)	2.5 (0.8 to 4.3)	111	88.1 (10.3)	-0.2 (-2.0 to 1.7)	2.70 (0.17 to 5.23) [†]
	M												
	PA	IG2	In-home counseling		52	Fasting glucose	103	87.2 (9.7)	0.7 (-1.2 to 2.6)	111	88.1 (10.3)	-0.2 (-2.0 to 1.7)	0.90 (-1.72 to 3.53) [‡]
	H												
	PA	IG1	Telephone counseling		52	HbA1c	107	5.2 (0.4)	0.2 (0.1 to 0.3)	111	5.2 (0.4)	0.1 (0.0 to 0.2)	0.10 (0.00 to 0.20) [‡]
	M												
PA	IG2	In-home counseling		52	HbA1c	103	5.2 (0.4)	0.2 (0.1 to 0.3)	111	5.2 (0.4)	0.1 (0.0 to 0.2)	0.09 (-0.01 to 0.19) [‡]	
H													

Appendix F Table 5. Glucose Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Lawton, 2008 ¹⁶⁰ Good	PA	IG1	Counseling with tailored prescription	X	52	Fasting glucose	544	90.5 (12.6)	-0.9 (-2.0 to 0.2)	545	89.4 (8.4)	0.0 (-0.9 to 0.9)	-0.90 (-2.31 to 0.51)
	M				104	Fasting glucose	544	90.5 (12.6)	-1.8 (-2.9 to -0.7)	545	89.4 (8.4)	-1.6 (-2.3 to -0.9)	-0.18 (-1.45 to 1.09)
					52	HbA1c	544	5.6 (0.5)	0.1 (0.1 to 0.2)	545	5.5 (0.7)	0.2 (0.1 to 0.2)	0.00 (-0.07 to 0.07)
					104	HbA1c	544	5.6 (0.5)	0.2 (0.2 to 0.2)	545	5.5 (0.7)	0.2 (0.2 to 0.3)	-0.04 (-0.11 to 0.03)
Mosca, 2008 ¹⁷⁶ Good	HD+PA	IG1	Counseling	X	52	Fasting glucose	250	97.9 (15.3)	0.2 (-1.5 to 1.9)	251	99.3 (19.4)	-0.7 (-2.6 to 1.2)	0.90 (-1.70 to 3.50)
	M												
Simkin-Silverman, 1995 ¹⁹⁴ Good	HD+PA	IG1	Group counseling		26	Fasting glucose	236	98.1 (8.0)	-1.0 (-1.9 to -0.1)	253	97.8 (8.3)	0.9 (0.1 to 1.7)	-1.90 (-3.13 to -0.67)
	H			X	78	Fasting glucose	236	98.1 (8.0)	1.3 (0.3 to 2.3)	253	97.8 (8.3)	2.8 (1.9 to 3.7)	-1.50 (-2.86 to -0.14)
					234	Fasting glucose	246	98.1 (8.0)	1.6 (NR to NR)	263	97.8 (8.3)	3.3 (NR to NR)	-1.70 (NR to NR)
Thompson, 2008 ²⁰⁷ Fair	HD+PA	IG1	Group counseling	X	26	Fasting glucose	100	93.7 (8.3)	-1.1 (-2.5 to 0.3)	100	93.0 (9.0)	0.9 (-0.6 to 2.4)	-1.98 (-4.06 to 0.09)
	H												
Thompson, 2014 ²⁰⁸ Good	PA	IG1	Counseling and self-monitoring	X	26	Fasting glucose	24	94.1 (11.5)	4.0 (-2.2 to 10.1)	24	92.4 (15.0)	1.8 (-1.4 to 5.0)	2.16 (-4.77 to 9.10)
	H				26	HbA1c	24	5.6 (0.4)	-0.1 (-0.1 to 0.0)	24	5.8 (0.5)	-0.1 (-0.2 to -0.0)	0.04 (-0.05 to 0.13)
Tinker, 2008 ²⁰⁹ Good	HD	IG1	Group counseling		421.2	Incident diabetes	18,376	NR (NR)	1303 (7.1) [¶]	27,511	NR (NR)	2039 (7.4) [¶]	0.96 (0.90 to 1.03) ^{†**}

* mg/dL. To convert to mmol/L, multiply by 0.0555.

† Adjusted.

‡ %.

§ n (%). Defined as fasting glucose ≥126 mg/dL.

|| Calculated.

¶ Reported as statistically significant.

¶ n (%). Defined as self-reported incident diabetes treated with oral agents or insulin.

** Hazard ratio.

Abbreviations: CG=control group; CI=confidence interval; DBP=diastolic blood pressure; FU=followup; H=high; HbA1c=hemoglobin A1C; HD=healthful diet; HTN=hypertension; IG=intervention group; Int=intervention; L=low; M=medium; MA=meta-analysis; N=number analyzed; NR=not reported; PA=physical activity; SBP=systolic blood pressure; SD=standard deviation; wk=week.

Appendix F Table 6. Adiposity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference
Aadahl, 2014 ⁸⁰ Good	PA	IG1	Counseling	X	26	Weight*	81	79.7 (15.7)	-0.8 (-1.5 to -0.2)	68	82.1 (17.6)	0.0 (-0.5 to 0.5)	-0.83 (-1.73 to 0.06) [†]
				26	WC [‡]	81	93.5 (12.9)	-1.2 (-2.1 to -0.3)	68	95.5 (14.5)	0.2 (-0.4 to 0.9)	-1.42 (-2.54 to -0.29) [†]	
	M			26	Body fat [§]	81	32.9 (8.9)	-0.5 (-1.1 to 0.1)	67	31.4 (9.7)	0.2 (-0.4 to 0.8)	-0.74 (-1.55 to 0.07) [†]	
Aldana, 2006 ⁸⁵ Fair	HD+PA	IG1	Group counseling	X	26	BMI	174	33.3 (8.0)	-1.6 (-2.1 to -1.1)	174	31.4 (9.0)	-0.3 (-0.9 to 0.3)	-1.30 (-1.65 to -0.96)
				26	Weight	174	93.3 (24.1)	-4.5 (-6.1 to -2.9)	174	87.7 (25.9)	-0.6 (-2.3 to 1.1)	-3.90 (-5.00 to -2.80)	
	H			26	Body fat	174	40.6 (8.8)	-2.4 (-3.0 to -1.8)	174	37.9 (10.3)	-0.8 (-1.5 to -0.1)	-1.60 (-2.30 to -0.90)	
Bennett, 2013 ⁹¹ Good	HD+PA	IG1	Counseling, tailored print materials, and self-monitoring		26	BMI	91	30.1 (2.7)	-0.3 (-0.7 to 0.1)	94	30.2 (2.4)	0.1 (-0.3 to 0.5)	-0.40 (-0.80 to 0.03)
	H			X	52	BMI	91	30.1 (2.7)	-0.3 (-0.7 to 0.1)	94	30.2 (2.4)	0.3 (-0.1 to 0.7)	-0.60 (-1.10 to -0.10)
					78	BMI	90	30.1 (2.7)	-0.2 (-0.6 to 0.2)	94	30.2 (2.4)	0.4 (0.0 to 0.8)	-0.60 (-1.20 to -0.10)
				26	Weight	91	81.3 (8.8)	-1.0 (-1.8 to -0.2)	94	81.0 (8.8)	0.1 (-0.7 to 0.9)	-1.10 (-2.30 to 0.04)	
	X			52	Weight	91	81.3 (8.8)	-1.0 (-2.0 to 0.0)	94	81.0 (8.8)	0.5 (-0.5 to 1.5)	-1.40 (-2.80 to -0.10)	
				78	Weight	90	81.3 (8.8)	-0.9 (-2.1 to 0.3)	94	81.1 (8.8)	0.8 (-0.4 to 2.0)	-1.70 (-3.30 to -0.20)	
				26	WC	91	98.2 (8.5)	-1.4 (-2.8 to 0.0)	94	97.3 (8.0)	-0.8 (-2.0 to 0.4)	-0.60 (-2.40 to 1.20)	
				52	WC	91	98.2 (8.5)	-1.0 (-2.4 to 0.4)	94	97.3 (8.0)	0.3 (-1.1 to 1.7)	-1.30 (-3.10 to 0.50)	
	78	WC	90	98.2 (8.5)	-1.4 (-3.0 to 0.2)	94	97.3 (8.0)	-0.2 (-1.8 to 1.4)	-1.20 (-3.40 to 1.00)				
Brekke, 2005 ⁹⁷ Fair	HD, HD+PA	IG1	Group counseling (diet)		52	BMI	24	25.0 (3.3)	-0.2 (-0.5 to 0.2)	19	26.1 (2.5)	0.2 (-0.4 to 0.8)	-0.37 (-1.07 to 0.33)
	H												
	HD, HD+PA	IG2	Group counseling (diet and PA)	X	52	BMI	25	26.1 (3.1)	-0.7 (-1.2 to -0.2)	19	26.1 (2.5)	0.2 (-0.4 to 0.8)	-0.94 (-1.71 to -0.17)
	H												
	HD, HD+PA	IG1	Group counseling (diet)		52	Weight	24	78.7 (12.6)	-0.4 (-1.6 to 0.7)	19	78.0 (12.0)	0.5 (-1.4 to 2.4)	-0.97 (-3.16 to 1.22)
	H												
	HD, HD+PA	IG2	Group counseling (diet and PA)	X	52	Weight	25	79.8 (10.3)	-2.2 (-3.6 to -0.7)	19	78.0 (12.0)	0.5 (-1.4 to 2.4)	-2.68 (-5.06 to -0.30)
H													
HD, HD+PA	IG1	Group counseling (diet)		52	WC	24	88.7 (10.6)	-1.2 (-2.5 to 0.1)	19	90.6 (10.6)	0.4 (-1.5 to 2.2)	-1.60 (-3.86 to 0.66)	
H													
HD, HD+PA	IG2	Group counseling (diet and PA)		52	WC	25	90.9 (8.9)	-1.2 (-3.1 to 0.7)	19	90.6 (10.6)	0.4 (-1.5 to 2.2)	-1.60 (-4.25 to 1.05)	
H													

Appendix F Table 6. Adiposity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference
Bryan, 2013 ⁹⁸ Fair	PA	IG1	Tailored print mailings	X	52	BMI	113	25.0 (4.5)	0.6 (0.2 to 0.9)	105	25.5 (5.1)	0.0 (-0.4 to 0.4)	0.54 (-0.03 to 1.11) [¶]
	L												
Coates, 1999 ¹⁰⁶ Fair	HD	IG1	Group counseling	X	26	BMI	1094	28.7 (4.6)	-0.7 (NR to NR)	646	29.1 (4.8)	-0.1 (NR to NR)	-0.60 (-0.70 to -0.44)
	X			26	Weight	1094	75.1 (12.5)	-1.8 (NR to NR)	646	75.8 (12.7)	-0.3 (NR to NR)	-1.50 (-1.83 to -1.13)	
				26	WC	1094	86.1 (10.8)	-1.8 (NR to NR)	647	86.4 (10.8)	-0.1 (NR to NR)	-1.70 (-2.14 to -1.23)	
Elley, 2003 ¹¹¹ Good	PA	IG1	Counseling with tailored prescription	X	52	BMI	451	30.0 (6.7)	-0.1 (-0.2 to 0.0)	427	29.9 (6.4)	-0.1 (-0.2 to 0.1)	-0.06 (-0.24 to 0.12) [†]
	M												
Grandes, 2009 ¹²² Good	PA	IG1	Brief counseling	X	52	BMI	1456	27.7 (4.6)	0.1 (-0.0 to 0.2)	1389	27.6 (4.7)	0.0 (-0.1 to 0.1)	0.05 (-0.02 to 0.11) [†]
	L						52	WC	1456	93.4 (13.1)	0.3 (-0.5 to 1.3)	1389	93.1 (13.0)
Greenlee, 2015 ¹²⁶ Fair	HD H	IG1	Group counseling	X	26	BMI	27	30.1 (5.5)	-1.1 (-3.5 to 1.3)	26	31.1 (5.3)	1.0 (-1.2 to 3.2)	-2.10 (-5.29 to 1.09) ^{¶¶}
				X	26	Weight	28	74.0 (15.3)	-2.2 (-7.3 to 2.9)	27	78.4 (15.4)	2.3 (-2.8 to 7.4)	-4.50 (-11.71 to 2.71) ^{¶¶}
				X	26	WC	25	93.1 (13.4)	-1.6 (-4.0 to 0.8)	25	97.5 (13.4)	1.7 (-0.7 to 4.1)	-3.30 (-6.63 to 0.03) ^{¶¶}
Hellenius, 1993 ¹³⁵ Fair	HD	IG1	Counseling (diet)		26	BMI	40	25.2 (2.9)	-0.3 (-0.6 to 0.0)	39	24.5 (3.0)	0.3 (0.1 to 0.5)	-0.60 (-0.97 to -0.23) [¶]
	M												
	PA	IG2	Brief counseling (PA)		26	BMI	39	25.3 (2.9)	-0.3 (-0.5 to -0.0)	39	24.5 (3.0)	0.3 (0.1 to 0.5)	-0.60 (-0.92 to -0.28) [¶]
	L												
	HD+PA	IG3	Counseling (Diet & PA)	X	26	BMI	39	26.1 (3.7)	-0.6 (-0.9 to -0.3)	39	24.5 (3.0)	0.3 (0.1 to 0.5)	-0.90 (-1.26 to -0.54) [¶]
	M												
	HD	IG1	Counseling (diet)		26	WC	40	91.3 (10.8)	-1.3 (-2.5 to -0.1)	39	89.8 (11.0)	0.3 (-0.5 to 1.1)	-1.60 (-3.04 to -0.16) [¶]
M													
PA	IG2	Brief counseling (PA)		26	WC	39	93.3 (9.1)	-2.2 (-3.2 to -1.3)	39	89.8 (11.0)	0.3 (-0.5 to 1.1)	-2.50 (-3.74 to -1.26) [¶]	
L													
HD+PA	IG3	Counseling (Diet & PA)		26	WC	39	95.9 (9.0)	-3.0 (-3.9 to -2.0)	39	89.8 (11.0)	0.3 (-0.5 to 1.1)	-3.30 (-4.54 to -2.06) [¶]	
M													
Hivert, 2007 ⁷² Fair	HD+PA	IG1	Group counseling	X	52	BMI	58	22.4 (3.0)	-0.1 (-0.3 to 0.1)	57	22.4 (2.3)	0.4 (0.0 to 0.8)	-0.50 (-0.94 to -0.06) [¶]
					104	BMI	58	22.4 (3.0)	-0.3 (-0.7 to 0.1)	57	22.4 (2.3)	0.2 (-0.2 to 0.6)	-0.50 (-1.05 to 0.05) ^{¶¶}
	H	X	52	Weight	58	62.9 (10.7)	-0.2 (-1.0 to 0.6)	57	63.5 (9.8)	1.2 (0.2 to 2.2)	-1.40 (-2.65 to -0.15) [¶]		
			104	Weight	58	62.9 (10.7)	-0.6 (-1.6 to 0.4)	57	63.5 (9.8)	0.7 (-0.5 to 1.9)	-1.30 (-2.83 to 0.23) ^{¶¶}		
		X	52	WC	58	72.0 (7.6)	-1.0 (-1.0 to -1.0)	57	72.0 (7.5)	0.0 (0.0 to 0.0)	-1.00 (NR to NR) [¶]		
			104	WC	58	72.0 (7.6)	-1.0 (-3.0 to 1.0)	57	72.0 (7.5)	0.0 (-2.0 to 2.0)	-1.00 (-3.77 to 1.77) [¶]		

Appendix F Table 6. Adiposity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference
HPT, 1990 ¹⁴⁰ Good	HD	IG1	Group counseling (potassium and sodium focus)	X	26	Weight	178	78.5 (NR)	0.3 (-0.1 to 0.6)	189	77.5 (NR)	0.3 (-0.1 to 0.6)	0.00 (-0.50 to 0.50) [†]
	H												
	HD	IG2	Group counseling (sodium focus)		26	Weight	170	79.5 (NR)	0.0 (-0.4 to 0.4)	189	77.5 (NR)	0.3 (-0.1 to 0.6)	-0.27 (-0.72 to 0.18) ^{†**}
	H												
HD	IG1	Group counseling (potassium and sodium focus)		156	Weight	176	78.5 (NR)	1.1 (0.6 to 1.7)	175	77.5 (NR)	1.6 (1.1 to 2.1)	-0.46 (-1.21 to 0.29) ^{††}	
H													
HD	IG2	Group counseling (sodium focus)		156	Weight	172	79.5 (NR)	0.9 (0.4 to 1.5)	175	77.5 (NR)	1.6 (1.1 to 2.1)	-0.64 (-1.35 to 0.07) [†]	
H													
Jeffery, 1999 ¹⁴³ Fair	HD+PA	IG1	Nontailored print mailings	X	52	Weight	197	NR (NR)	0.5 (-0.1 to 1.1)	414	NR (NR)	0.6 (0.2 to 1.0)	-0.10 (-0.81 to 0.61) ^{†††}
	L												
	HD+PA	IG2	Nontailored print mailings plus incentives		52	Weight	198	NR (NR)	0.4 (-0.2 to 1.0)	414	NR (NR)	0.6 (0.2 to 1.0)	-0.20 (-0.91 to 0.51) ^{††}
	L												
	HD+PA	IG1	Nontailored print mailings		104	Weight	197	NR (NR)	1.3 (0.5 to 2.1)	414	NR (NR)	1.4 (0.8 to 2.0)	-0.10 (-1.08 to 0.88) ^{††}
	L												
HD+PA	IG2	Nontailored print mailings plus incentives		104	Weight	198	NR (NR)	1.2 (0.4 to 2.0)	414	NR (NR)	1.4 (0.8 to 2.0)	-0.20 (-1.18 to 0.78) ^{††}	
L													
John, 2002 ¹⁴⁴ Fair	HD	IG1	Counseling	X	26	Weight	344	76.1 (13.8)	0.6 (0.3 to 0.9)	346	75.6 (14.9)	0.6 (0.3 to 0.9)	-0.10 (-0.40 to 0.60) [†]
	M												
Kallings, 2009 ¹⁴⁶ Good	PA	IG1	Counseling with tailored prescription	X	26	BMI	41	29.7 (3.4)	-0.6 (-0.9 to -0.3)	50	30.4 (2.9)	-0.2 (-0.4 to 0.0)	-0.40 (-0.80 to -0.10)
				X	26	Weight	41	88.0 (14.2)	-1.8 (-2.8 to -0.8)	50	88.3 (11.1)	-0.5 (-1.1 to 0.1)	-1.30 (-2.40 to -0.20)
	M				26	WC	41	105.2 (9.2)	-2.3 (-3.5 to -1.1)	50	106.4 (7.8)	-1.4 (-2.2 to -0.6)	-0.90 (-2.31 to 0.51) ^{††}
					26	Body fat	41	36.0 (7.1)	-1.2 (-2.0 to -0.5)	50	37.4 (7.3)	-0.5 (-1.0 to 0.0)	-0.70 (-1.58 to 0.18) ^{††}
Kattelman, 2014 ¹⁴⁷ Fair	HD+PA	IG1	Web-based intervention	X	64	BMI	497	23.9 (3.9)	0.1 (-0.1 to 0.3)	476	24.4 (4.9)	0.2 (0.0 to 0.4)	-0.10 (-0.35 to 0.15) ^{††}
				X	64	Weight	497	68.6 (14.0)	0.5 (-0.0 to 1.0)	476	69.9 (16.2)	0.7 (0.0 to 1.4)	-0.20 (-1.05 to 0.65) ^{††}
	M				X	64	WC	497	82.0 (10.3)	-0.1 (-0.5 to 0.3)	476	83.1 (11.6)	-0.1 (-0.6 to 0.4)

Appendix F Table 6. Adiposity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference
Kerr, 2016 ¹⁴⁹ Fair	HD L	IG1	Tailored text messages (with booster messages)	X	26	BMI	78	23.8 (4.1)	0.1 (-0.1 to 0.3)	69	24.6 (5.6)	0.4 (0.0 to 0.8)	-0.20 (-0.70 to 0.30)
				X	26	Weight	78	67.9 (14.1)	0.4 (-0.4 to 1.2)	69	71.9 (17.6)	1.1 (-0.3 to 2.5)	-0.80 (-2.20 to 0.70)
	HD L	IG2	Text messages		26	BMI	72	24.7 (6.2)	-0.3 (-0.7 to 0.1)	69	24.6 (5.6)	0.4 (0.0 to 0.8)	-0.60 (-1.10 to -0.10)
					26	Weight	72	70.4 (17.7)	-0.6 (-1.6 to 0.4)	69	71.9 (17.6)	1.1 (-0.3 to 2.5)	-1.70 (-3.20 to -0.30)
Kinmonth, 2008 ¹⁵⁴ Fair	PA M	IG1	Telephone counseling	X	52	BMI	107	27.8 (5.2)	0.6 (0.1 to 1.1)	111	27.8 (5.2)	0.0 (-0.4 to 0.4)	0.60 (-0.02 to 1.22) [¶]
					52	BMI	103	27.7 (4.6)	0.0 (-0.4 to 0.4)	111	27.8 (5.2)	0.0 (-0.4 to 0.4)	0.00 (-0.58 to 0.58) [¶]
	PA M	IG1	Telephone counseling	X	52	Weight	107	79.9 (18.0)	1.7 (0.2 to 3.2)	111	80.3 (18.5)	-0.2 (-1.7 to 1.3)	1.90 (-0.26 to 4.06) [¶]
					52	Weight	103	78.6 (15.6)	0.5 (-0.9 to 1.9)	111	80.3 (18.5)	-0.2 (-1.7 to 1.3)	0.70 (-1.34 to 2.74) [¶]
	PA M	IG1	Telephone counseling		52	WC	107	92.7 (13.4)	1.9 (0.7 to 3.1)	111	93.0 (13.9)	0.8 (-0.3 to 1.9)	1.10 (-0.53 to 2.73) [¶]
					52	WC	103	92.4 (12.8)	1.2 (0.1 to 2.3)	111	93.0 (13.9)	0.8 (-0.3 to 1.9)	0.40 (-1.20 to 2.00) [¶]
	PA M	IG1	Telephone counseling		52	Body fat	107	31.0 (8.1)	0.4 (-0.3 to 1.1)	111	31.3 (7.9)	-0.2 (-0.9 to 0.5)	0.60 (-1.51 to 2.71) [¶]
					52	Body fat	103	31.5 (7.9)	-0.4 (-1.1 to 0.3)	111	31.3 (7.9)	-0.2 (-0.9 to 0.5)	-0.20 (-2.32 to 1.92) [¶]
	PA M	IG2	In-home counseling		52	Weight	103	78.6 (15.6)	0.5 (-0.9 to 1.9)	111	80.3 (18.5)	-0.2 (-1.7 to 1.3)	0.70 (-1.34 to 2.74) [¶]
					52	WC	103	92.4 (12.8)	1.2 (0.1 to 2.3)	111	93.0 (13.9)	0.8 (-0.3 to 1.9)	0.40 (-1.20 to 2.00) [¶]
PA M	IG2	In-home counseling		52	Weight	103	78.6 (15.6)	0.5 (-0.9 to 1.9)	111	80.3 (18.5)	-0.2 (-1.7 to 1.3)	0.70 (-1.34 to 2.74) [¶]	
				52	WC	103	92.4 (12.8)	1.2 (0.1 to 2.3)	111	93.0 (13.9)	0.8 (-0.3 to 1.9)	0.40 (-1.20 to 2.00) [¶]	
Kristal, 2000 ¹⁵⁶ Fair	HD L	IG1	Tailored print mailings and counseling telephone call		52	Weight	601	NR (NR)	0.1 (NR to NR)	604	NR (NR)	0.4 (NR to NR)	-0.34 (NR to NR)
					52	Weight	601	NR (NR)	0.1 (NR to NR)	604	NR (NR)	0.4 (NR to NR)	-0.34 (NR to NR)
Lawton, 2008 ¹⁶⁰ Good	PA M	IG1	Counseling with tailored prescription	X	52	Weight	544	73.2 (14.0)	-0.6 (-1.1 to -0.1)	545	72.7 (14.0)	0.0 (-0.5 to 0.5)	-0.60 (-1.34 to 0.14) [¶]
					104	Weight	544	73.2 (14.0)	-0.6 (-1.1 to -0.1)	545	72.7 (14.0)	-0.2 (-0.7 to 0.3)	-0.40 (-1.14 to 0.34) [¶]
	PA M	IG1	Counseling with tailored prescription		52	WC	544	86.7 (14.0)	0.6 (0.1 to 1.1)	545	86.2 (14.0)	1.1 (0.6 to 1.6)	-0.50 (-1.23 to 0.23) [¶]
					104	WC	544	86.7 (14.0)	2.0 (1.5 to 2.5)	545	86.2 (14.0)	2.5 (2.0 to 3.0)	-0.50 (-1.24 to 0.24) [¶]
Mosca, 2008 ¹⁷⁶ Good	HD+PA M	IG1	Counseling	X	52	BMI	250	27.8 (5.6)	-0.1 (-0.4 to 0.2)	251	28.4 (6.5)	0.0 (-0.4 to 0.4)	-0.10 (-0.61 to 0.41) [¶]
					52	WC	250	90.4 (14.5)	1.5 (0.7 to 2.3)	251	91.2 (15.4)	1.8 (0.9 to 2.7)	-0.30 (-1.52 to 0.92) [¶]
Roderick, 1997 ¹⁸⁸ Fair	HD M	IG1	Counseling	X	52	BMI	473	26.3 (4.4)	0.0 (NR to NR)	483	25.9 (4.7)	0.1 (NR to NR)	-0.12 (-0.30 to 0.05) [†]
				X	52	Weight	473	NR (NR)	-0.1 (NR to NR)	483	NR (NR)	0.4 (NR to NR)	-0.56 (-1.04 to -0.07) [†]

Appendix F Table 6. Adiposity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference
Sacerdote, 2006 ¹⁹⁰ Fair	HD	IG1	Brief counseling	X	52	BMI	1488	24.8 (4.2)	-0.4 (-0.6 to -0.1)	1489	24.3 (3.5)	0.0 (-0.2 to 0.2)	-0.41 (-0.53 to -0.11) [†]
	L												
Simkin-Silverman, 1995 ¹⁹⁴ Good	HD+PA	IG1	Group counseling		26	BMI	236	24.9 (3.2)	-1.8 (-2.0 to -1.6)	253	25.1 (3.3)	-0.1 (-0.3 to 0.1)	-1.70 (-1.96 to -1.44) [‡]
				X	78	BMI	236	24.9 (3.2)	-1.1 (-1.3 to -0.9)	253	25.1 (3.3)	0.1 (-0.1 to 0.3)	-1.20 (-1.46 to -0.94) [‡]
				234	BMI	246	24.9 (3.2)	0.1 (-0.2 to 0.3)	263	25.1 (3.3)	1.0 (0.7 to 1.2)	-0.91 (-1.24 to -0.58) [‡]	
				26	Weight	236	67.1 (9.7)	-4.9 (-5.5 to -4.4)	253	67.0 (9.9)	-0.4 (-0.9 to 0.2)	-4.58 (-5.35 to -3.81) [‡]	
	X			78	Weight	236	67.1 (9.7)	-3.0 (-3.6 to -2.5)	253	67.0 (9.9)	0.3 (-0.3 to 0.8)	-3.31 (-4.09 to -2.54) [‡]	
				234	Weight	246	67.1 (9.7)	-0.1 (NR to NR)	263	67.0 (9.9)	2.4 (NR to NR) ^{†††}	-2.44 (NR to NR) ^{†††}	
				26	WC	246	78.6 (8.1)	-4.2 (-4.7 to -3.7)	263	78.4 (9.0)	-0.4 (-0.8 to 0.1)	-3.84 (-4.51 to -3.17) [‡]	
				78	WC	246	78.6 (8.1)	-3.5 (NR to NR)	263	78.4 (9.0)	-0.7 (NR to NR)	-2.82 (NR to NR) ^{†††}	
				234	WC	246	78.6 (8.1)	-2.9 (NR to NR)	263	78.4 (9.0)	-0.5 (NR to NR)	-2.44 (NR to NR) ^{†††}	
				26	Body fat	236	33.2 (4.3)	-4.9 (-5.4 to -4.4)	253	33.0 (4.5)	-0.9 (-1.4 to -0.6)	-3.95 (-4.61 to -3.29) [‡]	
	234	Body fat	246	33.2 (4.4)	-0.5 (-1.0 to 0.0)	263	33.0 (4.6)	1.1 (0.6 to 1.6)	-1.60 (-2.30 to -0.90) [‡]				
Thompson, 2008 ²⁰⁷ Fair	HD+PA	IG1	Group counseling		26	BMI	100	29.5 (5.9)	-0.1 (-0.6 to 0.4)	100	29.2 (6.7)	0.1 (-0.5 to 0.7)	-0.20 (-0.97 to 0.57) [‡]
	H			X	52	BMI	100	29.5 (5.9)	-0.1 (-0.6 to 0.4)	100	29.2 (6.7)	0.3 (-0.3 to 0.9)	-0.40 (-1.18 to 0.38) [‡]
					78	BMI	100	29.5 (5.9)	-0.1 (-0.6 to 0.4)	100	29.2 (6.7)	0.4 (-0.2 to 1.0)	-0.50 (-1.28 to 0.28) [‡]
				26	Weight ^{††}	100	NR (NR)	-2.1 (-2.7 to -1.5)	100	NR (NR)	-1.7 (-2.5 to -0.9)	-0.40 (-1.39 to 0.59) [‡]	
				78	Weight ^{††}	100	NR (NR)	-4.7 (-5.5 to -3.9)	100	NR (NR)	-4.8 (-5.6 to -4.0)	0.10 (-1.04 to 1.24) [‡]	
				26	WC	100	93.3 (14.7)	-1.2 (-2.5 to 0.1)	100	91.8 (15.6)	-1.0 (-2.3 to 0.3)	-0.20 (-2.04 to 1.64) [‡]	
				52	WC	100	93.3 (14.7)	-1.6 (-2.9 to -0.3)	100	91.8 (15.6)	-0.9 (-2.2 to 0.4)	-0.70 (-2.56 to 1.16) [‡]	
				78	WC	100	93.3 (14.7)	-1.4 (-2.7 to -0.1)	100	91.8 (15.6)	-1.3 (-2.7 to 0.1)	-0.10 (-1.98 to 1.78) [‡]	
				26	Body fat	100	41.6 (6.3)	0.2 (-0.4 to 0.8)	100	40.8 (6.6)	0.4 (-0.2 to 1.0)	-0.20 (-1.97 to 1.57) [‡]	
				52	Body fat	100	41.6 (6.3)	0.5 (-0.1 to 1.1)	100	40.8 (6.6)	0.7 (0.1 to 1.3)	-0.20 (-1.96 to 1.56) [‡]	
	78	Body fat	100	41.6 (6.3)	0.7 (0.1 to 1.3)	100	40.8 (6.6)	0.8 (0.2 to 1.4)	-0.10 (-1.87 to 1.67) [‡]				
Thompson, 2014 ²⁰⁸ Good	PA	IG1	Counseling and self-monitoring		26	Weight	24	75.7 (13.4)	-1.0 (-1.9 to -0.1)	24	81.0 (13.6)	-1.0 (-1.7 to -0.2)	-0.02 (-1.21 to 1.17) [‡]
	H				26	WC	24	102.7 (10.8)	-1.6 (-4.6 to 1.5)	24	107.2 (11.8)	-2.0 (-4.8 to 0.9)	0.39 (-3.78 to 4.56) [‡]
					26	Body fat	24	42.0 (6.4)	0.0 (-0.6 to 0.6)	24	45.0 (6.2)	-0.3 (-1.0 to 0.5)	0.27 (-0.68 to 1.22) [‡]
Tinker, 2008 ²⁰⁹ Good	HD	IG1	Group counseling	X	52	BMI	17,026	28.9 (5.8)	-0.90 (-0.94 to -0.86) ^{§§}	24,977	28.9 (5.8)	-0.20 (-0.23 to -0.17) ^{§§}	-0.70 (-0.75 to -0.65) [‡]
	H				312	BMI	14,409	28.9 (5.8)	-0.10 (-0.14 to -0.06) ^{§§}	22,321	28.9 (5.8)	0.20 (0.16 to 0.23) ^{§§}	-0.30 (-0.35 to -0.25) [‡]
				X	52	Weight	17,026	76.4 (16.5)	-2.4 (-2.5 to -2.3)	24,977	76.2 (16.3)	-0.3 (-0.4 to -0.2)	-2.10 (-2.42 to -1.96) [‡]
				312	Weight	14,409	76.4 (16.5)	-0.8 (-0.9 to -0.7)	22,321	76.2 (16.3)	0.0 (-0.1 to 0.1)	-0.80 (-0.96 to -0.64) [‡]	
				52	WC	16,864	88.3 (13.6)	-2.0 (-2.1 to -1.9)	24,800	88.3 (13.4)	-0.4 (-0.5 to -0.3)	-1.60 (-1.72 to -1.48) [‡]	
TOHP I, 1992 ²⁰⁴ Fair	HD	IG1	Group counseling		26	Weight	327	82.7 (14.3)	NR (NR to NR)	417	82.8 (14.0)	NR (NR to NR)	-1.23 (NR to NR) ^{††}
	H				52	Weight	327	82.7 (14.3)	NR (NR to NR)	417	82.8 (14.0)	NR (NR to NR)	-0.82 (NR to NR) ^{††}
TOHP II, 1997 ²⁰⁵ Good	HD	IG1	Group counseling		26	Weight	539	94.0 (14.3)	-1.1 (-1.4 to -0.8)	561	93.6 (13.5)	0.1 (-0.2 to 0.4)	-1.20 (-1.59 to -0.81)
	H			X	78	Weight	532	94.0 (14.3)	0.4 (0.0 to 0.8)	551	93.6 (13.5)	0.7 (0.3 to 1.1)	-0.30 (-0.89 to 0.29)
					156	Weight	549	94.0 (14.3)	1.7 (1.3 to 2.1)	554	93.6 (13.5)	1.8 (1.4 to 2.2)	0.00 (-0.59 to 0.59)

Appendix F Table 6. Adiposity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Intervention	MA	FU, wks	Outcome	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference
Valve, 2013 ²¹¹ Fair	HD+PA M	IG1	Counseling		104	BMI ^{¶¶}	1244	22.0 (18.0 to 26.0)	0.6 (-1.0 to 2.1)	1294	22.3 (18.2 to 26.4)	0.5 (-1.2 to 2.2)	0.04 (NR to NR) ^{¶¶}
					104	Percent obese ^{¶¶}	1243	66 (4.9)	9 (1.1)	1293	72 (5.4)	29 (2.4)	-20 (-1.3) ^{¶¶}
					104	Percent overweight ^{¶¶}	1243	202 (15.0)	43 (4.7)	1293	222 (16.6)	39 (3.6)	4 (1.1) ^{¶¶}
Wadsworth, 2010 ²¹⁹ Fair	PA L	IG1	Web-based intervention		26	BMI	34	26.9 (NR)	-0.6 (NR to NR)	37	28.0 (NR)	-1.3 (NR to NR)	0.72 (NR to NR) ^{¶¶}
					26	Body fat	34	35.8 (7.0)	-0.1 (-1.2 to 1.1)	37	36.9 (7.4)	-1.1 (-2.2 to -0.1)	1.05 (-2.36 to 4.46) ^{¶¶}
					26	Percent obese ^{¶¶}	34	12 (26.0)	-5 (-5.0)	37	14 (30.0)	-5 (-6.7)	0 (1.7) ^{¶¶}
					26	Percent overweight ^{¶¶}	34	12 (26.0)	-5 (-4.6)	37	14 (30.0)	-7 (-10.0)	2 (5.4) ^{¶¶}

* Weight in kg. To convert kg to lb, multiply by 2.205.

† Adjusted.

‡ Waist circumference in cm. To convert cm to in, multiply by 0.394.

§ Body fat %.

|| kg/m².

¶ Calculated.

¶¶ Reported as significantly different based on mixed model repeated measures ANOVA with time, group, and time x group as independent variables.

** Reported as significantly different based on linear regression substituting rank transformations of the changes and measured covariates.

†† Reported as significantly different in unadjusted analyses.

‡‡ % of baseline.

§§ Additional decimal places shown to show small differences.

||| Median (IQR).

¶¶¶ n (%).

Abbreviations: ANOVA= analysis of variance; BMI=body mass index; CG=control group; CI=confidence interval; FU=followup; H=high; IQR=interquartile range; HD=healthful diet; IG=intervention group; Int=intervention; L=low; M=medium; MA=meta-analysis; N=number analyzed; NR=not reported; PA=physical activity; SD=standard deviation; WC=waist circumference; wk=week.

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Aldana, 2006 ⁸⁵ Fair	HD+PA H	IG1	Group counseling	X					26	Total energy	kcal/day	174	2092.0 (1030.0)	-558.0 (-693.1 to -422.9)	174	1919.0 (805.0)	-146.0 (-251.2 to -40.8)	-412.00 (-556.00 to -271.00)
					X				26	Fat	% energy	174	36.7 (6.9)	-8.2 (-9.3 to -7.1)	174	34.6 (7.4)	1.0 (-0.2 to 2.2)	-9.20 (-10.60 to -7.60)
								26	Fat	g/day	174	88.6 (55.3)	-38.0 (-45.2 to -30.8)	174	76.8 (42.9)	-4.9 (-11.1 to 1.3)	-33.10 (-40.60 to -25.70)	
						X		26	Saturated fat	g/day	174	26.3 (17.3)	-13.0 (-15.4 to -10.6)	174	21.8 (12.1)	-1.3 (-3.3 to 0.7)	-11.60 (-13.90 to -9.30)	
								26	Fruit	servings/day	174	1.3 (1.0)	0.9 (0.7 to 1.1)	174	1.6 (1.1)	0.0 (-0.2 to 0.2)	0.90 (0.60 to 1.10)	
								26	Vegetables	servings/day	174	3.3 (2.1)	1.4 (1.0 to 1.8)	174	3.4 (2.2)	0.1 (-0.2 to 0.4)	1.30 (0.90 to 1.90)	
								26	Sodium	mg/d	174	2941.0 (1530.0)	-609.0 (-817.0 to -401.0)	174	2712.0 (1233.0)	-226.0 (-402.4 to -49.6)	-383.00 (-590.00 to -176.00)	
			X	26	F&V*	servings/day	174	4.6 (2.7)	2.3 (1.9 to 2.7)	174	5.0 (2.9)	0.1 (-0.2 to 0.4)	2.20 (1.65 to 2.75) [†]					
Alexander, 2010 ⁸⁶ Fair	HD M	IG1	Tailored Web based+email counseling				X		52	F&V	servings/day	578	4.5 (2.7)	2.8 (2.6 to 3.0)	611	4.6 (2.9)	2.3 (2.1 to 2.5)	0.46 (0.15 to 0.77) ^{††}
	HD M	IG2	Tailored Web-based counseling						52	F&V	servings/day	599	4.2 (2.7)	2.7 (2.4 to 2.9)	611	4.6 (2.9)	2.3 (2.1 to 2.5)	0.34 (0.02 to 0.66) [†]
Baron, 1990 ⁹⁰ Fair	HD M	IG1	Counseling					X	52	Fiber	g/day	121	19.7 (7.3)	2.4 (0.9 to 3.8)	137	17.9 (6.8)	-0.1 (-1.3 to 1.1)	2.47 (0.54 to 4.40) [†]
Beresford, 1997 ⁹² Fair	HD L	IG1	Brief counseling and self-help material		X				52	Fat	% energy	859	37.6 (8.8)	-1.5 (-1.9 to -1.2)	959	37.5 (9.3)	-0.3 (-0.7 to 0.0)	-1.20 (-1.68 to -0.73) [§]
							X	52	Fiber	g/1000 kcal	859	10.0 (2.9)	0.6 (0.3 to 0.8)	959	10.0 (3.1)	0.2 (0.0 to 0.5)	0.32 (-0.06 to 0.70) [§]	
Bernstein, 2002 ⁹³ Fair	HD H	IG1	Home-based education						26	Fruit	servings/day	38	2.8 (1.8)	1.1 (0.7 to 1.5)	32	3.0 (1.3)	0.1 (-0.3 to 0.5)	1.00 (0.44 to 1.56) [†]
								26	Vegetables	servings/day	38	2.3 (0.8)	1.1 (0.7 to 1.5)	32	2.8 (1.2)	0.1 (-0.3 to 0.5)	1.00 (0.49 to 1.51) [†]	
						X	26	Fiber	g/day	38	17.0 (6.0)	4.0 (2.4 to 5.6)	32	18.0 (7.0)	2.0 (0.6 to 3.4)	2.00 (-0.11 to 4.11) [†]		
						X	26	F&V*	servings/day	38	5.1 (2.3)	2.2 (1.5 to 2.9)	32	5.8 (2.2)	0.4 (-0.3 to 1.1)	1.80 (0.85 to 2.75) [†]		

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Brekke, 2005 ⁹⁷	HD	IG1	Group counseling (diet)	X					52	Total energy	kcal/day	24	2547.0 (690.0)	-505.0 (-758.0 to -252.0)	19	2482.0 (740.0)	-243.0 (-517.0 to 30.0)	-262.00 (-634.57 to 110.57) [†]
	H																	
Fair	HD+PA	IG2	Group counseling (diet and PA)						52	Total energy	kcal/day	25	2341.0 (600.0)	-323.0 (-551.0 to -96.0)	19	2482.0 (740.0)	-243.0 (-517.0 to 30.0)	-80.00 (-435.74 to 275.74) [†]
	H																	
	HD	IG1	Group counseling (diet)		X				52	Fat	% energy	24	35.8 (5.4)	-5.3 (-7.8 to -2.7)	19	34.7 (5.3)	-0.5 (-3.7 to 2.8)	-4.80 (-8.93 to -0.67) [†]
	H																	
	HD+PA	IG2	Group counseling (diet and PA)						52	Fat	% energy	25	34.9 (5.7)	-5.1 (-7.6 to -2.6)	19	34.7 (5.3)	-0.5 (-3.7 to 2.8)	-4.60 (-8.70 to -0.50) [†]
	H																	
	HD	IG1	Group counseling (diet)			X			52	Saturated fat	% energy	24	15.0 (3.6)	-4.7 (-6.1 to -3.3)	19	14.1 (3.9)	-0.6 (-2.3 to 1.0)	-4.10 (-6.26 to -1.94) [†]
	H																	
HD+PA	IG2	Group counseling (diet and PA)						52	Saturated fat	% energy	25	13.8 (3.5)	-3.9 (-5.4 to -2.3)	19	14.1 (3.9)	-0.6 (-2.3 to 1.0)	-3.30 (-5.56 to -1.04) [†]	
H																		
HD	IG1	Group counseling (diet)					X	52	Fiber	g/1000 kcal	24	9.3 (3.2)	3.5 (1.7 to 5.4)	19	9.7 (2.7)	-0.5 (-1.6 to 0.7)	4.00 (1.82 to 6.18) [†]	
H																		
HD+PA	IG2	Group counseling (diet and PA)						52	Fiber	g/1000 kcal	25	8.6 (3.0)	2.5 (1.0 to 4.0)	19	9.7 (2.7)	-0.5 (-1.6 to 0.7)	3.00 (1.11 to 4.89) [†]	
H																		
Burke, 2013 ¹⁰⁰	HD+PA	IG1	Self-help booklet and phone and email counseling	X					26	Fat	score [¶]	176	1.8 (2.0)	-0.2 (-0.5 to 0.1)	199	1.5 (1.6)	0.1 (-0.1 to 0.4)	-0.34 (-0.70 to 0.02) [†]
	M							26	Fruit	n (%) eating ≥2 servings 3-7 day/wk	176	153 (86.9)	11 (6.3) [†]	199	167 (83.9)	-4 (-2.0) [†]	15 (8.3) ^{†¶}	
								26	Vegetables	n (%) eating ≥2 servings 3-7 day/wk	176	155 (88.1)	10 (5.7) [†]	199	170 (85.4)	7 (3.5) [†]	3 (2.2) [†]	
							X	26	Fiber	score [¶]	176	16.8 (5.6)	1.3 (0.4 to 2.2)	199	16.1 (6.1)	0.6 (-0.2 to 1.4)	0.70 (-0.52 to 1.92) [†]	

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Carpenter, 2004 ¹⁰¹ Fair	HD	IG1	Group counseling		X				26	Fat	score**	28	6.3 (3.5)	-2.0 (-3.2 to -0.7)	33	5.6 (3.3)	0.4 (-0.8 to 1.6)	-2.35 (-4.10 to -0.60) ^{†,††}
	H																	
	HD	IG2	Mailed materials and website						26	Fat	score**	32	6.5 (3.4)	-0.8 (-2.0 to 0.4)	33	5.6 (3.3)	0.4 (-0.8 to 1.6)	-1.20 (-2.90 to 0.50) [†]
	L																	
	HD	IG1	Group counseling			X			26	Saturated fat	score**	28	7.3 (3.5)	-1.2 (-2.5 to 0.0)	33	6.8 (3.5)	-0.6 (-1.8 to 0.6)	-0.65 (-2.36 to 1.06) ^{†††}
	H																	
	HD	IG2	Mailed materials and website						26	Saturated fat	score**	32	7.3 (3.4)	-0.1 (-1.3 to 1.1)	33	6.8 (3.5)	-0.6 (-1.8 to 0.6)	0.50 (-1.15 to 2.15) [†]
	L																	
	HD	IG1	Group counseling						26	Fruit	score ^{SS}	28	4.9 (3.5)	2.2 (1.2 to 3.2)	33	4.3 (3.5)	-0.5 (-1.5 to 0.4)	2.74 (1.40 to 4.08) [†]
	H																	
	HD	IG2	Mailed materials and website						26	Fruit	score ^{SS}	32	4.9 (3.4)	-0.2 (-1.1 to 0.7)	33	4.3 (3.5)	-0.5 (-1.5 to 0.4)	0.36 (-0.94 to 1.66) [†]
	L																	
HD	IG1	Group counseling						26	Vegetables	score ^{SS}	28	6.8 (2.8)	-0.2 (-1.3 to 0.8)	33	7.8 (2.5)	-1.1 (-2.1 to -0.1)	0.88 (-0.55 to 2.31) [†]	
H																		
HD	IG2	Mailed materials and website						26	Vegetables	score ^{SS}	32	6.8 (2.7)	0.1 (-0.9 to 1.0)	33	7.8 (2.5)	-1.1 (-2.1 to -0.1)	1.17 (-0.21 to 2.55) [†]	
L																		
HD	IG1	Group counseling						26	Sodium	score ^{SS}	28	7.5 (2.8)	1.2 (0.2 to 2.2)	33	7.0 (3.0)	0.4 (-0.5 to 1.4)	0.74 (-0.66 to 2.14) [†]	
H																		
HD	IG2	Mailed materials and website						26	Sodium	score ^{SS}	32	7.2 (2.9)	1.4 (0.4 to 2.3)	33	7.0 (3.0)	0.4 (-0.5 to 1.4)	0.93 (-0.42 to 2.28) [†]	
L																		
Coates, 1999 ¹⁰⁶ Fair	HD	IG1	Group counseling	X					26	Total energy	kcal/day	1071	1834.0 (927.0)	-538.0 (NR to NR)	649	1766.0 (836.0)	-171.0 (NR to NR)	-367.00 (-441.00 to -293.00)
	H				X				26	Fat	% energy	1071	39.7 (7.1)	-13.3 (-13.8 to -12.9)	649	39.1 (7.0)	-2.3 (-2.9 to -1.8)	-11.01 (-11.85 to -10.17)
					X				26	Saturated fat	% energy	1071	13.3 (2.8)	-4.2 (-4.4 to -4.0)	649	13.0 (2.8)	-0.7 (-0.9 to -0.5)	-3.49 (-3.80 to -3.18)
									26	Saturated fat	g/day	1071	27.8 (17.2)	-14.4 (NR to NR)	649	26.3 (15.8)	NR (NR to NR)	-10.70 (-12.10 to -9.20)
									26	Fruit	servings/day	1071	1.5 (1.1)	0.4 (0.3 to 0.5)	649	1.5 (1.1)	0.0 (-8.3 to 8.4)	0.37 (0.26 to 0.48)
									26	Vegetables	servings/day	1071	1.6 (1.1)	0.3 (0.2 to 0.3)	649	1.6 (1.1)	0.0 (-0.1 to 0.1)	0.24 (0.13 to 0.35)
								X		26	F&V *	servings/day	1071	3.2 (1.9)	0.7 (0.6 to 0.8)	649	3.2 (1.9)	0.0 (-0.1 to 0.2)

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Delichatsios, 2001 ¹⁰⁹ Fair	HD M	IG1	Automated telephone counseling						26	Saturated fat	% energy	148	12.6 (NR)	-1.9 (NR to NR)	150	12.2 (NR)	-0.7 (NR to NR)	-1.00 (-1.90 to -0.20) [§]
									26	Fruit	servings/day	148	1.1 (NR)	0.4 (NR to NR)	150	1.2 (NR)	0.0 (NR to NR)	0.40 (0.20 to 0.60) [§]
									26	Vegetables	servings/day	148	1.3 (NR)	0.2 (NR to NR)	150	1.2 (NR)	0.2 (NR to NR)	0.10 (-0.10 to 0.30) [§]
									26	Fiber	g/day	148	6.2 (NR)	1.1 (NR to NR)	150	6.0 (NR)	0.2 (NR to NR)	1.00 (0.40 to 1.60) [§]
Franko, 2008 ¹¹⁵ Fair	HD+PA M	IG1	Web-based intervention + booster session						26	Fat	% energy	148	31.4 (5.1)	-0.4 (NR to NR)	135	31.9 (4.8)	-0.5 (NR to NR)	0.09 (NR to NR) [†]
									26	Fat	% energy	139	30.7 (5.1)	0.3 (NR to NR)	135	31.9 (4.8)	-0.5 (NR to NR)	0.81 (NR to NR) [†]
									26	F&V	servings/day	148	5.2 (2.6)	-0.2 (NR to NR)	135	5.1 (2.4)	-0.2 (NR to NR)	0.02 (NR to NR) [†]
									26	F&V	servings/day	139	5.4 (2.6)	-0.3 (NR to NR)	135	5.1 (2.4)	-0.2 (NR to NR)	-0.17 (NR to NR) [†]
Fries, 2005 ¹¹⁶ Fair	HD L	IG1	Tailored print mailings and brief counseling call						26	Fat	score ^{¶¶}	221	2.0 (0.3)	-0.2 (-0.2 to -0.1)	249	2.0 (0.3)	-0.1 (-0.1 to -0.0)	-0.08 (-0.14 to -0.02) [†]
					X				52	Fat	score ^{¶¶}	238	2.0 (0.3)	-0.2 (-0.2 to -0.1)	278	2.0 (0.3)	-0.1 (-0.1 to -0.1)	-0.06 (-0.12 to -0.00) ^{†††}
									26	Fiber	score ^{¶¶}	221	2.2 (0.3)	-0.2 (-0.2 to -0.1)	249	2.2 (0.4)	-0.1 (-0.1 to -0.0)	-0.09 (-0.16 to -0.02) [†]
							X		52	Fiber	score ^{¶¶}	238	2.2 (0.3)	-0.1 (-0.2 to -0.1)	278	2.2 (0.4)	-0.1 (-0.1 to -0.0)	-0.04 (-0.11 to 0.03) [†]
Greene, 2008 ¹²⁵ Fair	HD M	IG1	Tailored print mailings and counseling telephone calls				X		52	F&V	servings/day	410	5.7 (2.2)	0.9 (0.7 to 1.1)	424	5.5 (2.2)	0.3 (0.2 to 0.5)	0.58 (0.32 to 0.84) [†]
									104	F&V	servings/day	410	5.7 (2.2)	1.0 (0.8 to 1.2)	424	5.5 (2.2)	0.8 (0.6 to 0.9)	0.23 (-0.03 to 0.49) ^{††}
Greenlee, 2015 ¹²⁶ Fair	HD H	IG1	Group counseling	X					26	Total energy	kcal/day	30	1573.8 (415.2)	-562.9 (-733.6 to -392.2)	31	1611.7 (415.2)	-61.6 (-229.6 to 106.4)	-501.30 (-740.79 to -261.81) ^{†§}
					X				26	Fat	% energy	30	28.5 (7.6)	-7.5 (-11.0 to -4.0)	31	26.9 (7.8)	-4.4 (-7.9 to -0.9)	-3.10 (-8.09 to 1.89) ^{†§}
						X			26	Saturated fat	% energy	30	9.9 (3.5)	-3.1 (-4.7 to -1.5)	31	8.9 (3.6)	-1.5 (-3.1 to 0.1)	-1.60 (-3.82 to 0.62) ^{†§}
							X		26	F&V	servings/day	30	4.7 (2.9)	2.0 (1.0 to 3.0)	31	5.8 (3.0)	-0.1 (-1.1 to 0.9)	2.10 (0.71 to 3.49) ^{†§}

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Hellenius, 1993 ¹³⁵ Fair	HD	IG1	Counseling (diet)	X					26	Total energy	kcal/day	34	1949.4 (418.3)	-87.2 (-219.1 to 44.7)	33	2243.5 (650.5)	-152.4 (-340.3 to 35.5)	65.22 (-164.32 to 294.76) [†]
	M																	
	HD+PA	IG3	Counseling (Diet & PA)						26	Total energy	kcal/day	31	2062.9 (490.9)	-222.2 (-381.4 to -62.9)	33	2243.5 (650.5)	-152.4 (-340.3 to 35.5)	-69.76 (-316.04 to 176.52) [†]
	M																	
Hinderliter, 2014 ¹³⁷ Good	HD	IG1	Group counseling on DASH diet						52	Sodium	mg/d	36	NR (NR)	NR (NR to NR)	37	NR (NR)	NR (NR to NR)	NR (NR to NR) ^{¶¶}
	H																	
	HD+PA	IG1	Group counseling	X					52	Total energy	kcal/day	58	2051.0 (586.4)	-194.0 (-323.4 to -64.6)	57	2016.0 (581.3)	-112.0 (-243.3 to 19.3)	-82.00 (-266.33 to 102.33) [†]
	H								104	Total energy	kcal/day	58	NR (NR)	-224.0 (-367.1 to -80.9)	57	NR (NR)	-229.0 (-385.8 to -72.2)	5.00 (-207.27 to 217.27) [†]
Hivert, 2007 ⁷² Fair									52	Fat	% energy	58	29.5 (6.1)	-0.9 (-2.9 to 1.1)	57	30.1 (6.0)	-1.4 (-3.4 to 0.6)	0.50 (-2.27 to 3.27) [†]
									104	Fat	% energy	58	NR (NR)	0.6 (-1.8 to 3.0)	57	NR (NR)	0.0 (-2.0 to 2.0)	0.60 (-2.46 to 3.66) [†]
HPT, 1990 ¹⁴⁰ Good	HD	IG1	Group counseling (potassium and sodium focus)						26	Sodium	Urinary sodium, mmol/8hr	170	42.1 (NR)	-11.4 (-13.9 to -8.9)	185	43.4 (NR)	-3.9 (-6.4 to -1.4)	-7.50 (-11.10 to -3.90) [†]
	H																	
	HD	IG2	Group counseling (sodium focus)						26	Sodium	Urinary sodium, mmol/8hr	165	42.8 (NR)	-9.4 (-11.9 to -6.9)	185	43.4 (NR)	-3.9 (-6.4 to -1.4)	-5.50 (-9.22 to -1.78) [§]
	H																	
HPT, 1990 ¹⁴⁰ Good	HD	IG1	Group counseling (potassium and sodium focus)						156	Sodium	Urinary sodium, mmol/8hr	151	42.1 (NR)	-5.8 (-8.7 to -2.9)	155	43.4 (NR)	0.0 (-2.9 to 2.9)	-5.80 (-9.96 to -1.64) [†]
	H																	
	HD	IG2	Group counseling (sodium focus)						156	Sodium	Urinary sodium, mmol/8hr	143	42.8 (NR)	-4.2 (-7.1 to -1.3)	155	43.4 (NR)	0.0 (-2.9 to 2.9)	-4.20 (-8.32 to -0.08) ^{***}
	H																	

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Jacobs, 2011 ¹⁴¹ Fair	HD+PA	IG1	Counseling		X				26	Fat	g/day	168	106.0 (39.0)	-6.0 (-11.8 to -0.2)	84	107.0 (36.0)	-2.0 (-9.8 to 5.8)	-4.00 (-13.70 to 5.70) [†]
	H						52	Saturated fat	g/day	194	41.4 (17.5)	-0.54 (34.25) ^{†††}	93	40.1 (14.7)	0.32 (27.18) ^{†††}	NR (NR to NR) ^{†††}		
							52	F&V	servings/day	194	1.5 (1.1)	23.93 (105.62) ^{†††}	93	1.5 (1.1)	16.62 (95.50) ^{†††}	NR (NR to NR) ^{†††}		
Jeffery, 1999 ¹⁴³ Fair	HD+PA	IG1	Nontailored print mailings	X					52	Total energy	kcal/day	197	1753.0 (NR)	-198.0 (-347.0 to -49.0)	414	1702.0 (NR)	-122.0 (-222.0 to -22.0)	-76.00 (-255.39 to 103.39) [†]
	L							52	Total energy	kcal/day	198	1682.0 (NR)	-88.0 (-237.0 to 61.0)	414	1702.0 (NR)	-122.0 (-222.0 to -22.0)	34.00 (-145.39 to 213.39) [†]	
	HD+PA	IG1	Nontailored print mailings						104	Total energy	kcal/day	197	1753.0 (NR)	-142.0 (-287.0 to 3.0)	414	1702.0 (NR)	-172.0 (-272.0 to -72.0)	30.00 (-146.15 to 206.15) [†]
	L							104	Total energy	kcal/day	198	1682.0 (NR)	-158.0 (-303.0 to -13.0)	414	1702.0 (NR)	-172.0 (-272.0 to -72.0)	14.00 (-162.15 to 190.15) [†]	
	HD+PA	IG2	Nontailored print mailings plus incentives						156	Total energy	kcal/day	197	1753.0 (NR)	-213.0 (-365.9 to -60.1)	414	1702.0 (NR)	-130.0 (-235.8 to -24.2)	-83.00 (-268.94 to 102.94) [†]
	L							156	Total energy	kcal/day	198	1682.0 (NR)	-183.0 (-335.9 to -30.1)	414	1702.0 (NR)	-130.0 (-235.8 to -24.2)	-53.00 (-238.94 to 132.94) [†]	
	HD+PA	IG1	Nontailored print mailings		X				52	Fat	% energy	197	33.9 (NR)	-1.8 (-2.8 to -0.8)	414	34.0 (NR)	-0.6 (-1.4 to 0.2)	-1.20 (-2.45 to 0.05) [†]
	L							52	Fat	% energy	198	34.0 (NR)	-1.7 (-2.7 to -0.7)	414	34.0 (NR)	-0.6 (-1.4 to 0.2)	-1.10 (-2.35 to 0.15) [†]	
	HD+PA	IG2	Nontailored print mailings plus incentives						104	Fat	% energy	197	33.9 (NR)	-1.5 (-2.7 to -0.3)	414	34.0 (NR)	-0.7 (-1.5 to 0.1)	-0.80 (-2.21 to 0.61) [†]
	L							104	Fat	% energy	198	34.0 (NR)	-1.1 (-2.3 to 0.1)	414	34.0 (NR)	-0.7 (-1.5 to 0.1)	-0.40 (-1.81 to 1.01) [†]	
	HD+PA	IG1	Nontailored print mailings						156	Fat	% energy	197	33.9 (NR)	-1.3 (-2.5 to -0.1)	414	34.0 (NR)	-1.1 (-1.9 to -0.3)	-0.20 (-1.61 to 1.21) [†]
	L							156	Fat	% energy	198	34.0 (NR)	-1.4 (-2.6 to -0.2)	414	34.0 (NR)	-1.1 (-1.9 to -0.3)	-0.30 (-1.71 to 1.11) [†]	

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
	L		plus incentives															
John, 2002 ¹⁴⁴ Fair	HD M	IG1	Counseling				X		26	F&V	servings/day	329	3.4 (1.7)	1.4 (1.2 to 1.6)	326	3.4 (1.5)	0.1 (0.0 to 0.2)	1.40 (1.20 to 1.60) [§]
Kattelman 2014 ¹⁴⁷ Fair	HD+PA M	IG1	Web-based intervention		X				64	Fat	% energy	497	31.3 (5.2)	-0.8 (-1.2 to -0.4)	476	30.9 (5.2)	0.1 (-0.3 to 0.5)	-0.90 (-1.50 to -0.30) ^{†§}
							X		64	F&V	cups/day	497	2.6 (2.1)	0.1 (-0.1 to 0.3)	476	2.7 (1.9)	-0.3 (-0.4 to -0.2)	0.40 (0.18 to 0.62) ^{†§}
Kerr, 2016 ¹⁴⁹ Fair	HD L	IG1	Tailored text messages (with booster messages)						26	Fruit	servings/day	78	1.1 (1.1)	-0.2 (-0.4 to 0.0)	69	0.9 (0.8)	-0.2 (-0.4 to -0.0)	-0.10 (-0.40 to 0.20)
		IG2	Text messages						26	Fruit	servings/day	72	1.0 (1.1)	-0.1 (-0.3 to 0.1)	69	0.9 (0.8)	-0.2 (-0.4 to -0.0)	0.10 (-0.20 to 0.40)
		IG1	Tailored text messages (with booster messages)						26	Vegetables	servings/day	78	2.0 (1.0)	0.2 (0.0 to 0.4)	69	1.9 (1.1)	0.4 (0.2 to 0.6)	-0.10 (-0.50 to 0.20)
		IG2	Text messages						26	Vegetables	servings/day	72	1.7 (0.9)	0.4 (0.2 to 0.6)	69	1.9 (1.1)	0.4 (0.2 to 0.6)	0.10 (-0.30 to 0.40)
		IG1	Tailored text messages (with booster messages)				X		26	F&V *	servings/day	78	3.1 (1.9)	0.0 (-0.4 to 0.4)	69	2.8 (1.8)	0.2 (-0.2 to 0.6)	-0.20 (-0.71 to 0.31) [†]
		IG2	Text messages						26	F&V *	servings/day	72	2.7 (1.9)	0.3 (-0.1 to 0.7)	69	2.8 (1.8)	0.2 (-0.2 to 0.6)	0.10 (-0.41 to 0.61) [†]
King, 2013 ¹⁵² Good	HD+PA M	IG1	Telephone counseling with self-monitoring (PA and Diet simultaneous)			X			52	Saturated fat	% energy	50	12.0 (2.8)	-2.5 (-3.3 to -1.7)	49	12.6 (3.4)	-1.2 (-2.1 to -0.3)	-1.30 (-2.51 to -0.09) [†]
	HD+PA H	IG2	Telephone counseling with self-monitoring (diet first)						52	Saturated fat	% energy	48	12.0 (1.8)	-2.3 (-2.9 to -1.7)	49	12.6 (3.4)	-1.2 (-2.1 to -0.3)	-1.10 (-2.22 to 0.02) ^{†††}
	HD+PA H	IG3	Telephone counseling with self-monitoring (PA first)						52	Saturated fat	% energy	50	12.2 (3.3)	-1.8 (-2.7 to -0.9)	49	12.6 (3.4)	-1.2 (-2.1 to -0.3)	-0.60 (-1.92 to 0.72) [†]

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI) [†]	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI) [†]	Study-reported between group difference Mean (95% CI)
	HD+PA M	IG1	Telephone counseling with self-monitoring (PA and Diet simultaneous)						52	Saturated fat	n (%) with <10% calories from SF	50	0 (0.0)	29 (57.0) [†]	49	0 (0.0)	15 (31.0) [†]	14 (26.0) ^{†††}
	HD+PA H	IG2	Telephone counseling with self-monitoring (diet first)						52	Saturated fat	n (%) with <10% calories from SF	48	0 (0.0)	27 (57.0) [†]	49	0 (0.0)	15 (31.0) [†]	12 (26.0) ^{†††}
	HD+PA H	IG3	Telephone counseling with self-monitoring (PA first)						52	Saturated fat	n (%) with <10% calories from SF	50	0 (0.0)	20 (40.0) [†]	49	0 (0.0)	15 (31.0) [†]	5 (9.0) ^{†††}
	HD+PA M	IG1	Telephone counseling with self-monitoring (PA and Diet simultaneous)						52	F&V	n (%) with 5-9 F&V servings/day	50	0 (0.0)	29 (59.0) [†]	49	0 (0.0)	16 (33.0) [†]	13 (26.0) ^{†††}
	HD+PA H	IG2	Telephone counseling with self-monitoring (diet first)						52	F&V	n (%) with 5-9 F&V servings/day	48	0 (0.0)	39 (78.0) [†]	49	0 (0.0)	16 (33.0) [†]	23 (45.0) ^{†††}
	HD+PA H	IG3	Telephone counseling with self-monitoring (PA first)						52	F&V	n (%) with 5-9 F&V servings/day	50	0 (0.0)	27 (54.0) [†]	49	0 (0.0)	16 (33.0) [†]	11 (21.0) ^{††††}
	HD+PA M	IG1	Telephone counseling with self-monitoring (PA and Diet simultaneous)				X		52	F&V	servings/day	50	3.5 (1.9)	2.8 (2.1 to 3.5)	49	3.5 (1.6)	0.7 (0.3 to 1.1)	2.10 (1.24 to 2.96) [†]
	HD+PA H	IG2	Telephone counseling with self-monitoring (diet first)						52	F&V	servings/day	48	3.9 (2.1)	3.7 (2.9 to 4.5)	49	3.5 (1.6)	0.7 (0.3 to 1.1)	3.00 (2.06 to 3.94) [†]

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
	HD+PA H	IG3	Telephone counseling with self-monitoring (PA first)						52	F&V	servings/day	50	3.6 (2.1)	3.0 (2.2 to 3.8)	49	3.5 (1.6)	0.7 (0.3 to 1.1)	2.30 (1.38 to 3.22) [†]
Kristal, 2000 ¹⁵⁶	HD L	IG1	Tailored print mailings and counseling call		X				52	Fat	score	601	2.3 (0.5)	-0.1 (-0.1 to -0.1)	604	2.3 (0.5)	0.0 (0.0 to 0.0)	-0.10 (-0.14 to -0.06) [§]
Fair							X		52	F&V	servings/day	601	3.6 (1.5)	0.5 (0.3 to 0.6)	604	3.5 (1.4)	0.1 (0.0 to 0.3)	0.46 (0.26 to 0.66) [§]
Lutz, 1999 ¹⁶²	HD L	IG1	Tailored print mailings with tailored prescription				X		26	F&V	servings/day	146	3.5 (2.5)	0.9 (0.5 to 1.3)	151	3.5 (2.5)	0.1 (-0.2 to 0.4)	0.80 (0.31 to 1.29) [†]
Fair									26	F&V	servings/day	136	3.3 (2.2)	0.8 (0.4 to 1.2)	151	3.5 (2.5)	0.1 (-0.2 to 0.4)	0.70 (0.22 to 1.18) [†]
	HD L	IG3	Nontailored print mailings						26	F&V	servings/day	140	3.4 (2.1)	0.7 (0.4 to 1.0)	151	3.5 (2.5)	0.1 (-0.2 to 0.4)	0.60 (0.15 to 1.05) [†]
Mosca, 2008 ¹⁷⁶	HD+PA M	IG1	Counseling		X				52	Fat	% energy	250	37.7 (6.9)	-0.9 (-1.9 to 0.1)	251	37.8 (6.9)	-1.3 (-2.2 to -0.4)	0.40 (-0.94 to 1.74) [†]
Good						X			52	Saturated fat	% energy	232	10.7 (2.4)	-0.7 (-0.4 to -1.0)	232	10.7 (2.8)	-0.4 (-0.1 to -0.7)	-0.31 (-0.74 to 0.12) [†]
							X		52	F&V	servings/day	250	4.8 (2.4)	-0.1 (-0.4 to 0.2)	251	4.9 (2.8)	0.0 (-0.3 to 0.3)	-0.10 (-0.49 to 0.29) [†]
								X	52	Fiber	g/day	250	18.3 (9.3)	-0.1 (-1.4 to 1.2)	251	18.8 (8.9)	-1.1 (-2.2 to 0.0)	1.00 (-0.69 to 2.69) [†]
Parekh, 2014 ¹⁸¹	HD+PA L	IG1	Computer-tailored print mailings (2 contacts)						52	F&V	n (%) meeting F&V recs	667	79 (11.9)	62 (9.2)	1406	163 (11.6)	8 (0.6)	54 (8.6) [†]
Fair									52	F&V	n (%) meeting F&V recs	800	111 (13.9)	39 (4.9)	1406	163 (11.6)	8 (0.6)	31 (4.3) [†]
	HD+PA L	IG2	Computer-tailored print mailing (1 contact)															
Roderick, 1997 ¹⁸⁸	HD M	IG1	Counseling		X				52	Fat	% energy	473	34.3 (6.3)	-2.4 (-3.0 to -1.8)	483	34.2 (6.7)	-0.9 (-1.5 to -0.3)	-1.40 (-2.20 to -0.70) [§]
Fair						X			52	Saturated fat	% energy	473	13.7 (3.6)	-1.5 (-1.9 to -1.1)	483	14.0 (3.9)	-0.6 (-1.0 to -0.2)	-0.90 (-1.50 to -0.20) [§]
									52	Fruit	servings/week	473	NR (NR)	0.8 (NR to NR)	483	NR (NR)	0.3 (NR to NR)	0.44 (-0.24 to 1.11) [§]
									52	Vegetables	servings/week	473	NR (NR)	0.3 (NR to NR)	483	NR (NR)	-0.3 (NR to NR)	0.50 (-0.90 to 1.90) [§]
								X	52	Fiber	g/day	473	23.3 (8.0)	0.9 (0.1 to 1.6)	483	23.2 (9.3)	-0.2 (-1.0 to 0.6)	1.02 (-0.20 to 2.23) [§]

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Ruffin, 2011 ¹⁸⁹ Fair	HD+PA L	IG1	Computer-tailored web-based intervention						26	F&V	% meeting F&V recs	2111	388.0 (17.0)	NR (NR to NR)	1278	160.0 (16.0)	NR (NR to NR)	1.29 (1.05 to 1.58) ^{§§§}
Sacerdote, 2006 ¹⁹⁰ Fair	HD L	IG1	Brief counseling				X		52	F&V	servings/day	1488	2.7 (1.2)	0.4 (0.2 to 0.9)	1489	2.8 (1.2)	0.2 (-0.3 to 0.3)	0.18 (-0.28 to 0.64) [†]
Simkin-Silverman, 1995 ¹⁹⁴ Good	HD+PA H	IG1	Group counseling						26	Total energy	kcal/day	236	1491.3 (562.6)	-195.3 (-261.4 to -129.2)	253	1427.2 (544.3)	-22.1 (-79.0 to 34.8)	-173.20 (-260.40 to -86.00) [†]
				X					78	Total energy	kcal/day	236	1491.3 (562.6)	-188.7 (-254.3 to -123.1)	253	1427.2 (544.3)	-78.8 (-135.0 to -22.6)	-109.90 (-196.28 to -23.52) [†]
									234	Total energy	kcal/day	246	1491.3 (562.6)	-159.6 (-217.7 to -101.5)	263	1427.2 (544.3)	-24.8 (-92.5 to 42.9)	-134.80 (-223.99 to -45.61) [†]
									26	Fat	% energy	236	32.5 (7.0)	-9.7 (-10.6 to -8.8)	253	32.4 (7.4)	-0.6 (-1.5 to 0.3)	-9.10 (-10.41 to -7.79) [†]
					X				78	Fat	% energy	236	32.5 (7.0)	-9.2 (-10.1 to -8.3)	253	32.4 (7.4)	-1.8 (-2.7 to -0.9)	-7.40 (-8.71 to -6.09) [†]
									26	Saturated fat	% energy	236	11.8 (3.0)	-4.0 (-4.4 to -3.6)	253	11.4 (3.0)	-0.2 (-0.6 to 0.2)	-3.80 (-4.37 to -3.23) [†]
Smith, 2014 ¹⁹⁷ Fair	HD+PA M	IG1	Counseling	X					26	Total energy	kcal/day	29	1859.0 (627.0)	-405.0 (-607.4 to -202.6)	30	2063.0 (679.0)	-189.0 (-404.1 to 26.1)	-299.00 (-518.00 to -79.00) [§]
					X				26	Fat	g/day	29	62.8 (27.5)	-19.6 (-28.4 to -10.8)	30	74.8 (41.9)	-8.0 (-22.3 to 6.3)	-16.80 (-28.50 to -5.00) [§]
						X			26	Saturated fat	g/day	29	22.3 (12.7)	-8.6 (-12.9 to -4.3)	30	26.9 (17.7)	-3.3 (-10.2 to 3.6)	-7.20 (-12.20 to -2.10) [§]
								X	26	Fiber	g/day	29	24.8 (8.4)	0.4 (-2.9 to 3.7)	30	25.5 (10.4)	-1.9 (-5.3 to 1.5)	2.10 (-1.10 to 5.20) [§]
Springvloet, 2015 ¹⁹⁸ Fair	HD M	IG1	Web-based tailored education plus feedback						26	Saturated fat	score	459	18.1 (6.2)	-1.4 (-2.0 to -0.9)	434	18.0 (6.0)	0.8 (-1.3 to -0.3)	-0.59 (-1.32 to 0.14) [†]
									26	Saturated fat	score	456	17.6 (6.2)	-1.8 (-2.8 to -1.3)	434	18.0 (6.0)	0.8 (-1.3 to -0.3)	-0.94 (-1.87 to -0.01) [†]
		IG1	Web-based tailored education plus				X		48	Saturated fat	score	459	18.1 (6.2)	-1.9 (-2.5 to -1.4)	434	18.0 (6.0)	-1.2 (-1.7 to -0.7)	-0.74 (-1.50 to 0.02) [†]

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
			feedback															
		IG2	Web-based tailored education						48	Saturated fat	score	456	17.6 (6.2)	-1.8 (-2.3 to -1.2)	434	18.0 (6.0)	-1.2 (-1.7 to -0.7)	-0.58 (-1.33 to 0.17) [†]
		IG1	Web-based tailored education plus feedback						26	Fruit	pieces/day	459	1.8 (1.3)	0.3 (0.2 to 0.5)	434	1.8 (1.2)	0.2 (0.0 to 0.3)	0.16 (-0.05 to 0.37) [†]
		IG2	Web-based tailored education						26	Fruit	pieces/day	456	1.9 (1.3)	0.2 (0.1 to 0.3)	434	1.8 (1.2)	0.2 (0.0 to 0.3)	0.01 (-0.20 to 0.22) [†]
		IG1	Web-based tailored education plus feedback						48	Fruit	pieces/day	459	1.8 (1.3)	0.2 (0.0 to 0.3)	434	1.8 (1.2)	0.1 (-0.1 to 0.2)	0.09 (-0.08 to 0.26) [†]
		IG2	Web-based tailored education						48	Fruit	pieces/day	456	1.9 (1.3)	0.2 (0.0 to 0.3)	434	1.8 (1.2)	0.1 (-0.1 to 0.2)	0.09 (-0.08 to 0.26) [†]
		IG1	Web-based tailored education plus feedback						26	Vegetables	g/day	459	159.0 (69.2)	8.7 (1.6 to 15.7)	434	158.9 (69.0)	-0.3 (-6.9 to 6.4)	8.93 (-0.79 to 18.56) [†]
		IG2	Web-based tailored education						26	Vegetables	g/day	456	163.2 (68.8)	10.0 (3.2 to 16.9)	434	158.9 (69.0)	-0.3 (-6.9 to 6.4)	10.30 (0.73 to 19.87) ^{††††}
		IG1	Web-based tailored education plus feedback						48	Vegetables	g/day	459	159.0 (69.2)	8.3 (-2.0 to 18.5)	434	158.9 (69.0)	-1.2 (-11.0 to 8.6)	9.44 (-4.71 to 23.59) [†]
		IG2	Web-based tailored education						48	Vegetables	g/day	456	163.2 (68.8)	10.4 (0.3 to 20.5)	434	158.9 (69.0)	-1.2 (-11.0 to 8.6)	11.59 (-2.44 to 25.62) [†]
Taveras, 2011 ²⁰³ Fair	HD+PA H	IG1	Postpartum counseling						26	F&V	servings/day	58	NR (NR)	NR (NR to NR)	22	NR (NR)	NR (NR to NR)	NR ^{†††}
Thompson, 2008 ²⁰⁷ Fair	HD+PA H	IG1	Group counseling						26	Total energy	kcal/day	96	2201.3 (971.8)	-279.8 (-457.1 to -102.5)	95	2191.8 (978.2)	-238.0 (-400.9 to -75.1)	-41.80 (-282.54 to 198.94) [†]
				X					52	Total energy	kcal/day	96	2201.3 (971.8)	-355.1 (-529.4 to -180.8)	95	2191.8 (978.2)	-215.6 (-382.0 to -49.2)	-139.50 (-380.44 to 101.44) [†]

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
									78	Total energy	kcal/day	96	2201.3 (971.8)	-318.0 (-489.6 to -146.4)	95	2191.8 (978.2)	-497.0 (-664.8 to -329.2)	179.00 (-61.02 to 419.02) [†]
									26	Fat	g/day	96	94.9 (44.5)	-12.5 (-20.7 to -4.3)	95	96.6 (49.6)	-11.2 (-20.5 to -1.9)	-1.30 (-13.71 to 11.11) [†]
				X					52	Fat	g/day	96	94.9 (44.5)	-14.7 (-22.8 to -6.6)	95	96.6 (49.6)	-8.8 (-18.3 to 0.7)	-5.90 (-18.40 to 6.60) [†]
									78	Fat	g/day	96	94.9 (44.5)	-13.9 (-21.9 to -5.9)	95	96.6 (49.6)	-10.3 (-19.8 to -0.8)	-3.60 (-16.04 to 8.84) [†]
									26	Saturated fat	g/day	96	29.7 (14.2)	-4.0 (-6.9 to -1.1)	95	30.0 (15.2)	-3.8 (-6.9 to -0.7)	-0.20 (-4.41 to 4.01) [†]
					X				52	Saturated fat	g/day	96	29.7 (14.2)	-4.7 (-7.5 to -1.9)	95	30.0 (15.2)	-3.6 (-6.7 to -0.5)	-1.10 (-5.27 to 3.07) [†]
									78	Saturated fat	g/day	96	29.7 (14.2)	-4.8 (-7.5 to -2.1)	95	30.0 (15.2)	-3.6 (-6.8 to -0.4)	-1.20 (-5.40 to 3.00) [†]
									26	Fruit	servings/day	96	1.0 (0.7)	0.2 (0.1 to 0.4)	95	1.1 (0.9)	0.0 (-0.1 to 0.2)	0.19 (-0.05 to 0.43) [†]
									52	Fruit	servings/day	96	1.0 (0.7)	0.2 (0.0 to 0.4)	95	1.1 (0.9)	0.0 (-0.2 to 0.1)	0.24 (0.00 to 0.48) [†]
									78	Fruit	servings/day	96	1.0 (0.7)	0.3 (0.1 to 0.4)	95	1.1 (0.9)	0.0 (-0.2 to 0.2)	0.28 (0.03 to 0.53) [†]
									26	Vegetables	servings/day	96	2.9 (1.7)	0.3 (-0.1 to 0.7)	95	2.7 (1.7)	0.1 (-0.2 to 0.5)	0.18 (-0.39 to 0.75) [†]
									52	Vegetables	servings/day	96	2.9 (1.7)	-0.1 (-0.4 to 0.2)	95	2.7 (1.7)	0.0 (-0.4 to 0.3)	-0.04 (-0.52 to 0.44) [†]
									78	Vegetables	servings/day	96	2.9 (1.7)	0.3 (-0.1 to 0.7)	95	2.7 (1.7)	0.1 (-0.3 to 0.5)	0.17 (-0.36 to 0.70) ^{†****}
									26	F&V*	servings/day	96	3.9 (2.2)	0.5 (0.0 to 1.1)	95	3.8 (2.2)	0.2 (-0.2 to 0.6)	0.37 (-0.26 to 1.00) [†]
					X	52	F&V*	servings/day	96	3.9 (2.2)	0.1 (-0.3 to 0.5)	95	3.8 (2.2)	-0.1 (-0.4 to 0.3)	0.20 (-0.34 to 0.74) [†]			
						78	F&V *	servings/day	96	3.9 (2.2)	0.5 (0.1 to 1.0)	95	3.8 (2.2)	0.1 (-0.3 to 0.5)	0.45 (-0.15 to 1.05) [†]			
Tinker, 2008 ²⁰⁹	HD	IG1	Group counseling	X					52	Total energy	kcal/day	17,117	1790.0 (709.0)	-288.0 (-297.6 to -278.4)	25182	1788.0 (699.0)	-194.0 (-201.4 to -186.6)	-94.00 (-106.15 to -81.85) [†]
Good	H								312	Total energy	kcal/day	14,117	1790.0 (709.0)	-355.0 (-365.6 to -344.4)	21759	1788.0 (699.0)	-240.0 (-248.0 to -232.0)	-115.00 (-128.28 to -101.72) [†]
				X					52	Fat	% energy	17,117	37.7 (5.0)	-13.5 (-13.6 to -13.4)	25,182	37.7 (5.0)	-2.7 (-2.8 to -2.6)	-10.80 (-10.93 to -10.67) [†]
									312	Fat	% energy	14,117	37.7 (5.0)	-9.1 (-9.2 to -9.0)	21,759	37.7 (5.0)	-0.8 (-0.9 to -0.7)	-8.30 (-8.45 to -8.15) [†]
					X				52	Saturated fat	% energy	17,117	12.7 (2.5)	-4.7 (-4.7 to -4.7)	25,182	12.7 (2.5)	-1.0 (-1.0 to -1.0)	-3.70 (-3.76 to -3.64) [†]

Appendix F Table 7. Dietary Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
									312	Saturated fat	% energy	14,117	12.7 (2.5)	-3.2 (-3.3 to -3.1)	21,759	12.7 (2.5)	-0.3 (-0.3 to -0.3)	-2.90 (-2.97 to -2.83) [†]
							X		52	F&V	servings/day	17,117	3.6 (1.8)	1.5 (1.5 to 1.5)	25,182	3.6 (1.8)	0.3 (0.3 to 0.3)	1.20 (1.16 to 1.24) [†]
									312	F&V	servings/day	14,117	3.6 (1.8)	1.4 (1.4 to 1.4)	21,759	3.6 (1.8)	0.2 (0.2 to 0.2)	1.20 (1.16 to 1.24) [†]
								X	52	Fiber	g/1000 kcal	17,117	8.8 (2.4)	3.5 (3.4 to 3.6)	25,182	8.8 (2.4)	0.9 (0.9 to 0.9)	2.60 (2.54 to 2.66) [†]
									312	Fiber	g/1000 kcal	14,117	8.8 (2.4)	3.2 (3.1 to 3.3)	21,759	8.8 (2.4)	0.8 (0.8 to 0.8)	2.40 (2.33 to 2.47) [†]
TOHP I, 1992 ²⁰⁴ Fair	HD H	IG1	Group counseling						26	Sodium	Urinary sodium, mmol/24hr	228	154.6 (59.9)	-55.7 (-65.6 to -45.8)	323	156.4 (60.5)	2.8 (-6.0 to 11.5)	-58.45 (-71.80 to -45.09)
									52	Sodium	Urinary sodium, mmol/24hr	244	154.6 (59.9)	-54.4 (-62.0 to -46.8)	342	156.4 (60.5)	-4.3 (-11.5 to 2.9)	-50.10 (-60.56 to -39.64) [†]
									78	Sodium	Urinary sodium, mmol/24hr	232	154.6 (59.9)	-55.2 (-65.1 to -45.3)	330	156.4 (60.5)	-11.3 (-19.7 to -2.9)	-43.86 (-56.88 to -30.84)
TOHP II, 1997 ²⁰⁵ Good	HD H	IG1	Group counseling						78	Sodium	Urinary sodium, mmol/24hr	450	186.1 (80.7)	-59.5 (-68.0 to -51.0)	467	188.0 (80.9)	-16.8 (-25.4 to -8.2)	-42.70 (-54.80 to -30.60)
									156	Sodium	Urinary sodium, mmol/24hr	470	NR (NR)	-50.9 (-58.7 to -43.1)	482	NR (NR)	-10.5 (-18.4 to -2.6)	-40.40 (-51.50 to -29.30)
Tokunaga-Nakawatase 2014 ²¹⁰ Fair	HD+PA L	IG1	Computer-tailored print mailings						26	Total energy	kcal/day	52	1689.9 (335.5)	-118.3 (NR to NR)	50	1867.7 (493.6)	-24.8 (NR to NR)	-93.52 (NR to NR) ^{†‡‡}
									52	Total energy	kcal/day	47	1689.9 (335.5)	-13.1 (NR to NR)	50	1867.7 (493.6)	-75.1 (NR to NR)	61.96 (NR to NR) [†]

Appendix F Table 7. Dietary Outcomes

Author, Year, Quality	Int Focus Intensity	IG	Int	Total Energy MA	Fat MA	SF MA	F&V MA	Fiber MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Vandelanotte, 2005 ²¹⁷ Fair	HD+PA	IG1	Computer-based sessions with tailored feedback (PA and diet simultaneous)		X				26	Fat	% energy	176	40.8 (13.2)	-11.5 (-13.4 to -9.6)	195	35.3 (12.2)	-2.1 (-3.8 to -0.4)	-9.40 (-11.93 to -6.87) [†]
	M								26	Fat	% energy	194	38.0 (12.7)	-8.6 (-10.4 to -6.8)	195	35.3 (12.2)	-2.1 (-3.8 to -0.4)	-6.50 (-8.99 to -4.01) [†]
	HD+PA	IG3	Computer-based sessions with tailored feedback (diet first)						26	Fat	% energy	194	38.0 (12.7)	-8.6 (-10.4 to -6.8)	195	35.3 (12.2)	-2.1 (-3.8 to -0.4)	-6.50 (-8.99 to -4.01) [†]
	M								26	Fat	% energy	194	38.0 (12.7)	-8.6 (-10.4 to -6.8)	195	35.3 (12.2)	-2.1 (-3.8 to -0.4)	-6.50 (-8.99 to -4.01) [†]

* Fruits and Vegetables combined for MA.

† Calculated.

‡ Reported as p=0.05 in adjusted analyses with correction for multiple comparisons.

§ Adjusted.

|| Fat intake score (range, 0-21) computed based on consumption behavior questions from fat and fiber questionnaire.

¶ Reported as statistically significant.

¶¶ Fiber intake score (range, 0-28) computed based on consumption behavior questions from fat and fiber questionnaire.

** Score from 0 to 10, with higher score more closely following dietary recommendations. For the MA, sign was changed from positive to negative for consistent interpretation of directionality with other studies.

†† Reported as not statistically significant in adjusted analyses.

‡‡ Reported as statistically significant in adjusted analyses.

§§ Score from 0 to 10, with higher score more closely following dietary recommendations.

||| Score of 0 to 3, based on fat and fiber questionnaire, where a lower score indicated lower fat.

¶¶¶ Score of 0 to 3, based on fat and fiber questionnaire, where a lower score indicated higher fiber.

¶¶¶ Statistically significant for this intervention group combined with an active weight management group (not included in this review due to aim) vs. control.

*** Reported as p=0.053 in adjusted analyses.

††† Mean percent (SD).

‡‡‡ Reported as not statistically significant.

§§§ p=0.05 in adjusted analyses.

|||| Score from a 21-item scale, scored from 1.0 (low fat) to 4.0 (high fat).

¶¶¶¶ Defined as ≥5 vegetable servings/day and ≥2 fruit servings/day.

¶¶¶¶ Adjusted OR.

**** Reported as statistically significant in repeated measures ANOVA.

Abbreviations: ANOVA=analysis of variance; CG=control group; CI=confidence interval; d=day; FU=followup; F&V=fruits and vegetables; H=high; HD=healthful diet; hr=hour; IG=intervention group; int=intervention; L=low; M=medium; MA=meta-analysis; min=minute; PA=physical activity; OR=odds ratio; N=number analyzed; NR=not reported; NS=not significant; OR=odds ratio; SD=standard deviation; SF=saturated fat; wk=week.

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Aittasalo, 2006 ⁸¹ Fair	PA	IG1	Brief counseling	X	X		26	Mod PA	min/wk	130	69.0 (57.0)	30.0 (16.3 to 43.7)	73	81.0 (51.3)	7.0 (-7.1 to 21.1)	16.00 (-6.00 to 37.00)*
	L															
	PA	IG2	Self-monitoring				26	Mod PA	min/wk	62	84.0 (55.1)	10.0 (-6.0 to 26.0)	73	81.0 (51.3)	7.0 (-7.1 to 21.1)	6.00 (-20.00 to 31.00)*
	L															
	PA	IG1	Brief counseling				26	Total PA	min/wk	130	344.0 (331.0)	182.0 (107.6 to 256.4)	73	430.0 (701.0)	50.0 (-91.6 to 191.6)	79.00 (-28.00 to 186.00)*
L																
PA	IG2	Self-monitoring				26	Total PA	min/wk	62	419.0 (512.0)	136.0 (17.2 to 254.8)	73	430.0 (701.0)	50.0 (-91.6 to 191.6)	79.00 (-46.00 to 205.00)*	
L																
Albright, 2014 ⁸³ Fair	PA	IG1	Tailored telephone counseling plus web site	X	X		52	MVPA	min/wk	154	44.0 (19.0)	202.0 (178.4 to 225.6)	157	46.0 (22.4)	110.0 (94.9 to 125.1)	92.00 (63.97 to 120.03) [†]
	M															
Aldana, 2006 ⁸⁵ Fair	HD+PA	IG1	Group counseling	X			26	Total PA	steps/wk	174	40,579.0 (22,631.0)	12,372.0 (8883.6 to 15,860.4)	174	43,869.0 (23,466.0)	5661.0 (2240.7 to 9081.3)	6711.00 (30,26.00 to 10,396.00)
	H															
Bickmore, 2013 ⁸⁴ Fair	PA	IG1	Computer-based counseling				52	Total PA [‡]	steps/d	55	NR (NR)	NR (NR to NR)	73	NR (NR)	NR (NR to NR)	NR [§]
	M															
Brekke, 2005 ⁹⁷ Fair	HD+PA	IG2	Group counseling (diet and PA)				104	Leisure PA	MET-min/wk	24	700 (0 to 2920)	330 (-1435 to 1325)	16	780 (0 to 4180)	105 (-2315 to 4195)	NR
	H															
Bryan, 2013 ⁹⁸ Fair	PA	IG1	Tailored print mailings	X	X		52	Total PA	min/wk	113	18.1 (24.5)	84.9 (66.3 to 103.6)	105	16.5 (27.5)	51.9 (39.7 to 64.0)	33.06 (10.79 to 55.33) [†]
	L						52	PA score	Study defined [¶]	113	-0.1 (0.8)	0.2 (0.1 to 0.4)	105	0.1 (0.9)	-0.3 (-0.4 to -0.1)	0.51 (0.28 to 0.74) [†]
							52	CRF	VO ₂ max	113	34.1 (8.2)	0.8 (-0.7 to 2.4)	105	33.2 (7.1)	0.2 (-1.2 to 1.6)	0.69 (-1.39 to 2.77) [†]
Burke, 2013 ¹⁰⁰ Fair	HD+PA	IG1	Self-help booklet and phone and email counseling				26	Mod PA	n (%) participating ≥10 mins/wk	176	124 (70.5)	21 (11.9) [†]	199	143 (71.9)	11 (5.5) [†]	NR, p=0.229
	M					26	Vig PA	n (%) participating ≥10 min/wk	176	33 (18.8)	16 (9.0) [†]	199	55 (27.6)	-4 (-2.0) [†]	NR, p=0.629	
						26	Walking	n (%) participating ≥10 min/wk	176	152 (86.4)	14 (7.9) [†]	199	171 (85.9)	2(1.0) [†]	NR, p=0.015	

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Carroll, 2010 ¹⁰² Fair	PA	IG1	Tailored print mailings				26	Mod PA	min/wk	165	NR (NR)	106.6 (53.3 to 159.8)	188	NR (NR)	83.6 (37.7 to 129.6)	22.92 (-64.84 to 110.68) [†]
	L			X	X		26	MVPA	min/wk	165	NR (NR)	138.9 (80.2 to 197.8)	188	NR (NR)	109.4 (59.1 to 159.7)	29.56 (-66.95 to 126.07) ^{††}
							26	Vig PA	min/wk	165	NR (NR)	33.0 (14.0 to 52.0)	188	NR (NR)	28.5 (11.9 to 45.1)	4.52 (-26.95 to 35.99) [†]
Castro, 2011 ¹⁰³ Fair	PA	IG1	Counseling	X	X		52	MVPA	min/wk	61	NR (NR)	178.0 (119.1 to 236.9)	59	NR (NR)	71.5 (25.8 to 117.2)	106.50 (31.91 to 181.09) [†]
	M															
	PA	IG2	Peer counseling				52	MVPA	min/wk	61	NR (NR)	216.2 (126.9 to 305.5)	59	NR (NR)	71.5 (25.8 to 117.2)	144.70 (44.42 to 244.98) [†]
de Vet, 2009 ¹⁰⁸ Fair	PA	IG1	Self-directed and self-selected activity plan (with repeat planning)	X	X		26	Mod PA	min/wk	134	435.0 (475.0)	83.0 (-3.7 to 169.7)	163	519.0 (657.0)	43.0 (-57.3 to 143.3)	40.00 (-92.57 to 172.57) [†]
	L															
	PA	IG2	Self-directed and self-selected activity plan (1-time plan)				26	Mod PA	min/wk	136	441.0 (544.0)	24.0 (-61.1 to 109.1)	163	519.0 (657.0)	43.0 (-57.3 to 143.3)	-19.00 (-150.58 to 112.58) [†]
	L															
	PA	IG3	Self-directed walking plan (1-time plan)				26	Mod PA	min/wk	127	500.0 (490.0)	62.0 (-25.6 to 149.6)	163	519.0 (657.0)	43.0 (-57.3 to 143.3)	19.00 (-114.17 to 152.17) [†]
	L															
	PA	IG1	Self-directed and self-selected activity plan (with repeat planning)				26	Total PA	min/wk	134	2745.0 (1237.0)	-16.0 (-226.9 to 194.9)	163	2789.0 (1163.0)	81.0 (-126.4 to 288.4)	-97.00 (-392.80 to 198.80) [†]
L																
PA	IG2	Self-directed and self-selected activity plan (1-time plan)				26	Total PA	min/wk	136	2777.0 (1118.0)	-70.0 (-268.9 to 128.9)	163	2789.0 (1163.0)	81.0 (-126.4 to 288.4)	-151.00 (-438.40 to 136.40) [†]	
L																
PA	IG3	Self-directed walking plan (1-time plan)				26	Total PA	min/wk	127	2748.0 (1076.0)	-3.0 (-205.9 to 199.9)	163	2789.0 (1163.0)	81.0 (-126.4 to 288.4)	-84.00 (-374.15 to 206.15) [†]	
L																
PA	IG1	Self-directed and self-selected activity plan (with repeat planning)				26	Walking	min/wk	134	127.0 (226.0)	4.0 (-30.5 to 38.5)	163	124.0 (161.0)	59.0 (6.7 to 111.3)	-55.00 (-117.60 to 7.60) [†]	
L																

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
	PA L	IG2	Self-directed and self-selected activity plan (1-time plan)				26	Walking	min/wk	136	140.0 (208.0)	49.0 (-30.0 to 128.0)	163	124.0 (161.0)	59.0 (6.7 to 111.3)	-10.00 (-104.69 to 84.69) [†]
	PA L	IG3	Self-directed walking plan (1-time plan)				26	Walking	min/wk	127	146.0 (232.0)	26.0 (-14.7 to 66.7)	163	124.0 (161.0)	59.0 (6.7 to 111.3)	-33.00 (-99.23 to 33.23) [†]
Elley, 2003 ¹¹¹ Good	PA M	IG1	Counseling with tailored prescription				52	MVPA	kcal/kg/wk	451	6.0 (12.2)	4.3 (3.3 to 5.4)	427	6.5 (11.1)	1.3 (0.1 to 2.5)	2.67 (0.48 to 4.86)*
				X	X		52	MVPA	min/wk	451	NR (NR)	54.6 (41.4 to 68.4)	427	NR (NR)	16.8 (6.0 to 32.4)*	33.60 (2.40 to 64.20)*
					X		52	Mtg PA recs	n (%)	451	80 (18.0)	66 (14.4) [†]	427	91 (21.0)	21 (5.2) [†]	1.35 (0.93 to 1.96)** ^{††}
Estabrooks, 2011 ¹¹² Fair	PA M	IG1	Group counseling	X	X		38	Mod PA	min/wk	35	28.3 (55.4)	104.4 (58.0 to 150.8)	35	42.1 (56.1)	31.1 (-15.2 to 77.4)	73.30 (7.77 to 138.83) [†]
Fjeldsoe, 2015 ¹¹³ Fair	PA M	IG1	Counseling and regular text messages	X	X		38	MVPA [‡]	min/wk	83	402.0 (218.8 to 636.5) ^{††}	-54.8 (-103.1 to -6.2)	87	358.0 (203.9 to 565.0) ^{††}	-57.2 (-97.3 to -17.7)	2.40 (-46.80 to 51.30)*
					X		38	Mtg PA recs [‡]	n (%)	133	113 (85.0)	-5 (-4.0) [†]	130	111 (85.0)	-3 (-2.0) [†]	0.88 (0.77 to 1.01) [†]
Franko, 2008 ¹¹⁵ Fair	HD+PA M	IG1	Web-based intervention + booster session				26	Total PA	MET-min/wk	148	1718.0 (909.2)	133.4 (NR to NR)	135	1820.0 (982.1)	-68.0 (NR to NR)	201.41 (NR) [†]
	HD+PA M			IG2	Web-based intervention				26	Total PA	MET-min/wk	139	1878.0 (1027.6)	112.8 (NR to NR)	135	1820.0 (982.1)
Gao, 2016 ¹¹⁷ Fair	PA M	IG1	Individual counseling + tailored print materials				26	Mtg PA recs	n (%)	101	NR (NR)	NR (NR to NR)	107	NR (NR)	NR (NR to NR)	1.54 (0.56 to 4.23)**
					X		52	Mtg PA recs	n (%)	98	NR (NR)	NR (NR to NR)	105	NR (NR)	NR (NR to NR)	2.86 (1.03 to 7.96)**
Gell, 2015 ¹¹⁹ Fair	PA L	IG1	Targeted text messages	X			24	Total PA [‡]	steps/day	37	6752.1 (2653.3)	115.6 (-679.6 to 910.8)	37	6737.9 (2619.3)	-548.9 (-1346.1 to 248.3)	664.50 (-461.46 to 1790.46) ^{†*****}
Goldstein, 1999 ¹²⁰ Fair	PA L	IG1	Brief counseling with tailored prescription	X			34	PA score	PASE ^{‡‡}	158	108.5 (68.8)	4.1 (-7.0 to 15.1)	154	108.8 (65.1)	2.2 (-8.4 to 12.8)	1.84 (-13.47 to 17.15) [†]
					X		34	Mtg PA recs	n (%)	159	26 (15.0)	19 (13.0) [†]	157	29 (17.0)	9 (7.0) [†]	1.26 (0.72 to 2.22) ^{***}

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Grandes, 2009 ¹²² Good	PA L	IG1	Brief counseling				26	MVPA	MET-hr/wk	2248	2.4 (6.0)	5.7 (4.1 to 7.3)	2069	2.4 (5.9)	4.4 (2.8 to 6.1)	1.27 (0.38 to 2.16)*
							26	MVPA	min/wk	2248	34.4 (90.9)	82.6 (59.9 to 105.2)	2069	33.2 (79.5)	65.1 (42.4 to 87.9)	18.15 (5.66 to 30.65)*
							52	MVPA	MET-hr/wk	1906	2.5 (6.1)	7.8 (5.5 to 10.0)	1785	2.4 (5.9)	7.3 (5.0 to 9.5)	0.49 (-0.60 to 1.59)*
				X	X		52	MVPA	min/wk	1906	35.9 (94.8)	128.6 (95.7 to 161.5)	1785	33.5 (77.8)	127.3 (94.4 to 160.3)	2.01 (-12.56 to 16.59)*
							104	MVPA	MET-hr/wk	1906	2.5 (6.1)	9.1 (6.8 to 11.4)	1785	2.4 (5.9)	8.3 (6.0 to 10.6)	0.62 (-0.62 to 1.86)
							104	MVPA	min/wk	1906	35.9 (94.8)	148.8 (115.4 to 182.2)	1785	33.5 (77.8)	140.0 (106.5 to 173.5)	7.33 (-9.75 to 24.42)*
							26	Mtg PA recs	n (%)	2248	0 (0.0)	423 (18.8) [†]	2069	0 (0.0)	310 (15.0) [†]	1.30 (1.10 to 1.60)**
						X	52	Mtg PA recs	n (%)	1906	0 (0.0)	447 (23.5) [†]	1785	0 (0.0)	391 (21.9) [†]	1.09 (0.82 to 1.45)** ^{†§§}
							104	Mtg PA recs	n (%)	1906	0 (0.0)	531 (27.8) [†]	1785	0 (0.0)	459 (25.7) [†]	1.12 (0.85 to 1.46)** [†]
							26	CRF	VO ₂ max (mL/kg/min)	1598	24.3 (8.1)	1.6 (1.1 to 2.1)	1491	24.6 (8.4)	1.4 (0.9 to 1.9)	0.24 (-0.14 to 0.61)*
							52	CRF	heart rate	1456	75.8 (11.4)	-0.5 (-1.8 to 0.7)	1389	75.4 (11.0)	-0.5 (-1.8 to -0.7)	-0.05 (-0.59 to 0.48)*
							52	CRF	VO ₂ max (mL/kg/min)	1598	24.3 (8.1)	1.1 (0.6 to 1.6)	1491	24.6 (8.4)	1.2 (0.7 to 1.8)	-0.11 (-0.53 to 0.31)*
							104	CRF	VO ₂ max (mL/kg/min)	1598	24.3 (8.1)	1.1 (0.5 to 1.6)	1491	24.6 (8.4)	0.9 (0.3 to 1.4)	0.18 (-0.28 to 0.64) [†]
Green, 2002 ¹²³ Fair	PA M	IG1	Telephone counseling	X			26	PA score	PACE	128	5.0 (2.0)	0.4 (0.1 to 0.7)	128	4.7 (2.1)	0.1 (-0.2 to 0.4)	0.32 (-0.12 to 0.76) [†]
Halbert, 2000 ¹²⁸ Fair	PA M	IG1	Counseling				52	Vig PA	min/session	149	0 (0 to 0)	NR (NR to NR)	150	0 (0 to 0)	NR (NR to NR)	NR, p<0.05
							52	Walking	min/session	149	0 (0 to 25)	NR (NR to NR)	150	0 (0 to 20)	NR (NR to NR)	NR, p=NS
Hargreaves, 2016 ¹³⁰ Fair	PA M	IG1	Tailored walking program	X			24	Walking [†]	steps/week	35	50,971.0 (19,229.0)	18,258.0 (11,959.0 to 24,557.0)	39	53,480.0 (19,426.7)	6810.0 (741.9 to 12878.1)	11,448.00 (2701.73 to 20,194.27) [†]

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)	
Harland, 1999 ¹³¹ Fair	PA	IG1	Counseling and PA vouchers				52	Mod PA	n (%) increased total sessions of MPA	79	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	0.00 (-12.00 to 12.00)***	
	M																
	PA	IG2	Counseling				52	Mod PA	n (%) increased total sessions of MPA	88	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	8.00 (-5.00 to 20.00)***	
	M																
	PA	IG3	Brief counseling and PA vouchers				52	Mod PA	n (%) increased total sessions of MPA	88	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	23.00 (-10.00 to 14.00)***	
	M																
	PA	IG4	Brief counseling				52	Mod PA	n (%) increased total sessions of MPA	96	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	22.00 (-9.00 to 14.00)***	
	M																
	PA	IG1	Counseling and PA vouchers				52	Vig PA	n (%) increased total sessions of MPA	79	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	6.00 (-5.00 to 16.00)***	
	M																
PA	IG2	Counseling				52	Vig PA	n (%) increased total sessions of MPA	88	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	10.00 (-12.00 to 21.00)***		
M																	
PA	IG3	Brief counseling and PA vouchers				52	Vig PA	n (%) increased total sessions of MPA	88	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	10.00 (-1.00 to 21.00)***		
M																	
PA	IG4	Brief counseling				52	Vig PA	n (%) increased total sessions of MPA	96	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	6.00 (-5.00 to 16.00)***		
M																	
PA	IG1	Counseling and PA vouchers				52	PA score	n (%) participants increasing ≥ 1 PA level ^{†††}	79	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	4.00 (-10.00 to 17.00)***		
M																	
PA	IG2	Counseling				52	PA score	n (%) participants increasing	88	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	8.00 (-5.00 to 21.00)***		
M																	

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
									≥1 PA level ^{†††}							
	PA M	IG3	Brief counseling and PA vouchers				52	PA score	n (%) participants increasing ≥1 PA level ^{†††}	88	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	3.00 (-10.00 to 15.00) ^{***}
	PA M	IG4	Brief counseling				52	PA score	n (%) participants increasing ≥1 PA level ^{†††}	96	NR (NR)	NR (NR to NR)	91	NR (NR)	NR (NR to NR)	0.00 (-12.00 to 12.00) ^{***}
Harris, 2015 ¹³² Good	PA M	IG1	Counseling and self-monitoring	X	X		52	MVPA [‡]	min/wk	137	296.0 (154.0)	23.0 (-6.1 to 52.1)	136	301.0 (169.0)	-16.0 (-44.8 to 12.8)	40.00 (10.00 to 70.00) [*]
Hellenius, 1993 ¹³⁵ Fair	PA L	IG2	Brief counseling (PA)				26	Total PA	min/session	39	39.0 (50.0)	14.0 (0.4 to 27.6)	39	30.0 (32.0)	-1.0 (-10.7 to 8.7)	15.00 (-1.73 to 31.73) [†]
	PA L	IG2	Brief counseling (PA)	X			26	Total PA	sessions/month	39	5.1 (7.3)	6.6 (4.4 to 8.8)	39	5.3 (7.1)	0.1 (-2.2 to 2.4)	6.50 (3.33 to 9.67) [†]
	HD+PA M	IG3	Counseling (Diet & PA)				26	Total PA	min/session	39	30.0 (35.0)	26.0 (14.9 to 37.1)	39	30.0 (32.0)	-1.0 (-10.7 to 8.7)	27.00 (12.20 to 41.80) [†]
	HD+PA M	IG3	Counseling (Diet & PA)				26	Total PA	sessions/month	39	5.1 (7.3)	4.8 (2.6 to 7.0)	39	5.3 (7.1)	0.1 (-2.2 to 2.4)	4.70 (1.52 to 7.88) [†]
	PA L	IG2	Brief counseling (PA)				26	CRF	HR at 150 W	39	NR (NR)	NR (NR to NR)	39	NR (NR)	NR (NR to NR)	NR [§]
	HD+PA M	IG3	Counseling (Diet & PA)				26	CRF	HR at 150 W	39	NR (NR)	NR (NR to NR)	39	NR (NR)	NR (NR to NR)	NR [§]
Hivert, 2007 ⁷² Fair	HD+PA H	IG1	Group counseling	X			52	Total PA	kcal/kg/yr	58	1216.0 (853.0)	-81.0 (-261.3 to 99.3)	57	1378.0 (1094.7)	-260.0 (-477.6 to -42.4)	179.00 (-103.57 to 461.57) [†]
							104	Total PA	kcal/kg/yr	58	1216.0 (853.0)	-89.0 (-337.9 to 159.9)	57	1378.0 (1094.7)	-292.0 (-507.6 to -76.4)	203.00 (-126.30 to 532.30) [†]
							52	CRF [‡]	ml/kg/min (VO ₂ max)	58	39.0 (4.6)	-0.3 (-1.0 to 0.4)	57	38.8 (4.5)	-1.0 (-1.9 to -0.1)	0.65 (-0.47 to 1.77) [†]
							104	CRF [‡]	ml/kg/min (VO ₂ max)	58	39.0 (4.6)	0.3 (-0.4 to 0.9)	57	38.8 (4.5)	0.3 (-0.5 to 1.1)	-0.03 (-1.09 to 1.03) [†]

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)	
Jacobs, 2011 ¹⁴¹ Fair	HD+PA	IG1	Counseling	X	X		26	Total PA	min/wk	168	343.0 (234.0)	10.0 (-26.3 to 46.3)	84	352.0 (215.0)	-1.0 (-45.5 to 43.5)	11.00 (-46.41 to 68.41) [†]	
	H						52	Total PA	min/wk	194	351.0 (241.0)	NR (NR to NR)	93	350.0 (212.0)	NR (NR to NR)	NR ^s	
Jeffery, 1999 ¹⁴³ Fair	HD+PA	IG1	Nontailored print mailings	X			52	PA score	Study defined ⁺⁺⁺	197	42.9 (NR)	1.4 (-2.9 to 5.7)	414	46.6 (NR)	-1.2 (-4.1 to 1.7)	2.60 (-2.62 to 7.82) [†]	
	L																
	HD+PA	IG2	Nontailored print mailings plus incentives				52	PA score	Study defined ⁺⁺⁺	198	48.0 (NR)	-0.3 (-4.6 to 4.0)	414	46.6 (NR)	-1.2 (-4.1 to 1.7)	0.90 (-4.32 to 6.12) [†]	
	L																
	HD+PA	IG1	Nontailored print mailings				104	PA score	Study defined ⁺⁺⁺	197	42.9 (NR)	0.4 (-3.5 to 4.3)	414	46.6 (NR)	-1.9 (-4.6 to 0.8)	2.30 (-2.48 to 7.08) [†]	
	L																
Kallings, 2009 ¹⁴⁶ Good	PA	IG1	Counseling with tailored prescription				26	MVPA	min/wk	41	120 (0 to 220) ^{††}	NR (NR to NR)	54	130 (40 to 215) ^{††}	NR (NR to NR)	NR, p<0.05	
	M																
	HD+PA	IG1		Web-based intervention	X			64	Total PA	MET-min/wk	497	2212.0 (1639.0)	56.0 (-88.9 to 200.9)	476	2136.0 (1668.0)	94.0 (-54.2 to 242.2)	-38.00 (-245.27 to 169.27) [†]
	M																
	PA	IG1		Provider training				26	Vig PA	score	185	9.9 (15.2)	1.5 (-0.0 to 3.0)	117	9.3 (16.3)	0.6 (-1.3 to 2.4)	0.90 (-1.63 to 3.43) [†]
	H																
Katz, 2008 ¹⁴⁸ Fair	PA	IG1	Provider training				52	Vig PA	score	185	9.9 (15.2)	2.3 (0.4 to 4.1)	117	9.3 (16.3)	1.8 (-1.0 to 4.5)	0.54 (-2.98 to 4.06) [†]	
	H																
	PA	IG1	Provider training				26	Total PA	score	185	27.1 (18.9)	1.8 (0.1 to 3.4)	117	28.1 (19.3)	0.3 (-1.6 to 2.3)	1.42 (-1.30 to 4.14) [†]	
	H																
	PA	IG1	Provider training	X			52	Total PA	score	185	27.1 (18.9)	1.9 (0.0 to 3.9)	117	28.1 (19.3)	1.0 (-2.0 to 4.0)	0.95 (-2.81 to 4.71) ^{†§§§}	
H																	
PA	IG1	Provider training				26	Leisure walking	score	185	11.4 (13.5)	-0.2 (-1.6 to 1.2)	117	13.4 (13.0)	-1.4 (-2.9 to 0.1)	1.16 (-1.03 to 3.35) [†]		
H																	

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)	
	H																
	PA	IG1	Provider training				52	Leisure walking	score	185	11.4 (13.5)	0.2 (-1.6 to 2.0)	117	13.4 (13.0)	-1.8 (-3.7 to 0.2)	1.97 (-0.80 to 4.74) [†]	
	M																
	PA	IG1	Automated telephone counseling				26	MVPA	kcal/kg/d	61	0.8 (1.2)	0.7 (0.3 to 1.1)	62	0.9 (1.3)	0.0 (-0.3 to 0.4)	0.69 (0.16 to 1.22) [†]	
	M																
	PA	IG1	Automated telephone counseling				26	MVPA	min/wk	61	78.4 (113.3)	107.0 (72.3 to 141.7)	62	92.2 (126.7)	19.1 (-16.4 to 54.6)	87.90 (38.25 to 137.55) [†]	
King, 2007 ¹⁵³ Fair	PA	IG2	Human telephone counseling				26	MVPA	kcal/kg/d	66	0.9 (1.0)	0.8 (0.5 to 1.2)	62	0.9 (1.3)	0.0 (-0.3 to 0.4)	0.80 (0.33 to 1.27) [†]	
	M																
	PA	IG2	Human telephone counseling				26	MVPA	min/wk	66	99.7 (147.6)	69.4 (32.3 to 106.5)	62	92.2 (126.7)	19.1 (-16.4 to 54.6)	50.30 (-1.03 to 101.63) ^{††††}	
	M																
	PA	IG1	Automated telephone counseling				52	MVPA	kcal/kg/d	61	0.8 (1.2)	0.8 (0.3 to 1.2)	62	0.9 (1.3)	0.3 (-0.1 to 0.6)	0.50 (-0.09 to 1.09) [†]	
	M																
	PA	IG1	Automated telephone counseling	X	X		52	MVPA	min/wk	61	78.4 (113.3)	77.9 (46.1 to 109.7)	62	92.2 (126.7)	20.1 (-12.8 to 53.0)	57.80 (12.05 to 103.55) ^{††††}	
King, 2013 ¹⁵² Good	PA	IG2	Automated telephone counseling				52	MVPA	min/wk	66	99.7 (147.6)	66.1 (31.7 to 100.5)	62	92.2 (126.7)	20.1 (-12.8 to 53.0)	46.00 (-1.56 to 93.56) ^{††††}	
	M																
	PA	IG2	Human telephone counseling				52	MVPA	kcal/kg/d	66	0.9 (1.0)	0.8 (0.4 to 1.2)	62	0.9 (1.3)	0.3 (-0.1 to 0.6)	0.53 (0.01 to 1.05) [†]	
	M																
	HD+PA	IG1	Telephone counseling with self-monitoring (PA and Diet simultaneous)	X	X		52	MVPA	min/wk	50	30.1 (40.6)	139.5 (104.1 to 174.9)	49	24.9 (40.1)	75.7 (45.2 to 106.2)	63.80 (17.07 to 110.53) [†]	
	M																
	HD+PA	IG2	Telephone counseling with self-monitoring (diet first)				52	MVPA	min/wk	48	26.9 (33.5)	106.3 (81.3 to 131.3)	49	24.9 (40.1)	75.7 (45.2 to 106.2)	30.60 (-8.87 to 70.07) [†]	
	H																
	HD+PA	IG3	Telephone counseling with self-monitoring (PA first)				52	MVPA	min/wk	50	49.7 (85.8)	133.2 (93.8 to 172.6)	49	24.9 (40.1)	75.7 (45.2 to 106.2)	57.50 (7.65 to 107.35) [†]	
	H																
	HD+PA	IG1	Telephone counseling with self-			X	52	Mtg PA recs	n (%)	50	0 (0.0)	20 (40.0) [†]	49	0 (0.0)	11 (22.0) [†]	2.30 (0.96 to 5.54) ^{**†}	
M																	

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
			monitoring (PA and Diet simultaneous)													
	HD+PA H	IG2	Telephone counseling with self-monitoring (diet first)				52	Mtg PA recs	n (%)	48	0 (0.0)	18 (38.0) [†]	49	0 (0.0)	11 (22.0) [†]	2.07 (0.85 to 5.05) ^{**†}
	HD+PA H	IG3	Telephone counseling with self-monitoring (PA first)				52	Mtg PA recs	n (%)	50	0 (0.0)	24 (48.0) [†]	49	0 (0.0)	11 (22.0) [†]	3.19 (1.34 to 7.62) ^{**†}
Kinmonth, 2008 ¹⁵⁴	PA M	IG1	Telephone counseling				26	Total PA	MET-hr/wk	107	89.3 (52.1)	14.9 (5.0 to 24.8)	111	84.4 (55.7)	14.7 (4.2 to 25.2)	0.20 (-14.18 to 14.58) [†]
Fair	PA H	IG2	In-home counseling				26	Total PA	MET-hr/wk	103	87.4 (47.2)	10.4 (1.2 to 19.6)	111	84.4 (55.7)	14.7 (4.2 to 25.2)	-4.30 (-18.23 to 9.63) [†]
	PA M	IG1	Telephone counseling	X			52	Total PA	MET-hr/wk	107	89.3 (52.1)	15.9 (6.1 to 25.7)	111	84.4 (55.7)	17.0 (6.4 to 27.6)	-1.10 (-15.60 to 13.40) [†]
	PA M	IG1	Telephone counseling				52	Total PA [‡]	Ratio to REE	107	1.8 (0.6)	0.1 (-0.0 to 0.2)	111	1.9 (0.5)	0.1 (0.0 to 0.3)	-0.03 (-0.19 to 0.13) [†]
	PA H	IG2	In-home counseling				52	Total PA	MET-hr/wk	103	87.4 (47.2)	9.7 (0.7 to 18.7)	111	84.4 (55.7)	17.0 (6.4 to 27.6)	-7.30 (-21.22 to 6.62) [†]
	PA H	IG2	In-home counseling				52	Total PA [‡]	Ratio to REE	103	1.9 (0.7)	0.0 (-0.1 to 0.2)	111	1.9 (0.5)	0.1 (0.0 to 0.3)	-0.12 (-0.28 to 0.04) [†]
	PA M	IG1	Telephone counseling				52	CRF [‡]	VO ₂ max (L/min)	107	3.2 (1.0)	0.1 (-0.0 to 0.3)	111	3.2 (0.9)	0.0 (-0.2 to 0.2)	0.13 (-0.13 to 0.39) [†]
	PA H	IG2	In-home counseling				52	CRF [‡]	VO ₂ max (L/min)	103	3.2 (0.9)	0.1 (-0.1 to 0.3)	111	3.2 (0.9)	0.0 (-0.2 to 0.2)	0.08 (-0.17 to 0.33) [†]

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Kolt, 2007 ¹⁵⁵ Good	PA M	IG1	Telephone counseling				26	Mod PA	min/wk	86	108.6 (163.8)	45.3 (5.8 to 84.8)	83	88.6 (168.2)	8.8 (-25.6 to 43.2)	36.50 (-15.83 to 88.83) [†]
				X	X		52	Mod PA	min/wk	83	108.6 (163.8)	89.1 (28.8 to 149.4)	82	88.6 (168.2)	5.3 (-38.4 to 27.8)	94.40 (25.68 to 163.12) [†]
							26	Leisure PA	min/wk	86	165.5 (220.4)	33.6 (-13.1 to 80.3)	83	121.0 (172.6)	1.8 (-36.6 to 33.0)	35.40 (-22.79 to 93.59) [†]
							52	Leisure PA	min/wk	83	165.5 (220.4)	78.5 (9.9 to 147.1)	82	121.0 (172.6)	3.7 (-38.0 to 30.6)	82.20 (5.50 to 158.90) [†]
							26	Leisure walking	min/wk	86	72.4 (85.3)	16.2 (-2.1 to 34.5)	83	59.2 (74.6)	4.7 (-12.3 to 21.7)	11.50 (-13.52 to 36.52) [†]
							52	Leisure walking	min/wk	83	72.4 (85.3)	19.0 (-0.1 to 38.1)	82	59.2 (74.6)	4.5 (-13.2 to 22.2)	14.50 (-11.56 to 40.56) [†]
						X	52	Mtg PA recs	n (%)	83	24 (25.8)	11 (16.4) [†]	82	21 (22.6)	-2 (0.6) [†]	2.90 (1.33 to 6.32) ^{***,*}
Lawton, 2008 ¹⁶⁰ Good	PA M	IG1	Counseling with tailored prescription				52	Total PA	min/wk	544	30 (0 to 90) ^{†††}	NR (NR to NR)	545	30 (0 to 90) ^{†††}	NR (NR to NR)	NR (NR to NR)
							104	Total PA	min/wk	544	30 (0 to 90) ^{†††}	NR (NR to NR)	545	30 (0 to 90) ^{†††}	NR (NR to NR)	NR (NR to NR) ^{††††}
						X	52	Mtg PA recs	n (%)	544	56 (10.3)	177 (32.5) [†]	545	62 (11.4)	103 (18.9) [†]	1.73 (1.34 to 2.21) ^{***†}
							104	Mtg PA recs	n (%)	544	56 (10.3)	158 (29.0) [†]	545	62 (11.4)	117 (21.4) [†]	1.33 (1.03 to 1.70) ^{***†}
Lewis, 2013 ¹⁶¹ Good	PA L	IG1	Tailored print mailings				26	Total PA	min/wk	224	24.5 (27.7)	NR (NR to NR)	224	22.7 (27.0)	NR (NR to NR)	31.26 (8.70 to 53.82) [*]
					X		52	Total PA	min/wk	224	24.5 (27.7)	NR (NR to NR)	224	22.7 (27.0)	NR (NR to NR)	39.06 (15.68 to 62.44) [*]
Mailey, 2014 ¹⁶⁴ Fair	PA M	IG1	Group counseling	X	X		26	MVPA [‡]	min/wk ^{§§§§§}	95	157.2 (93.1)	-8.2 (-26.8 to 10.5)	46	146.1 (95.2)	-10.2 (-36.0 to 15.7)	1.96 (-29.88 to 33.80) [†]
							26	Total PA [‡]	counts/day	95	21,7591.0 (74,418.0)	5599.0 (-9115.2 to 20313.2)	46	22,2057.0 (64,031.0)	-4818.0 (-22,424.6 to 12,788.6)	10,417 (-12,528.18 to 33,362.18) [†]
							26	PA score	score	95	19.0 (17.1)	14.7 (10.6 to 18.8)	46	16.9 (19.3)	8.4 (3.0 to 13.8)	6.35 (-0.46 to 13.16) ^{†,††}
Marcus, 2007 ¹⁶⁷ Fair	PA M	IG1	Telephone counseling				26	Total PA	min/wk	80	19.8 (26.6)	103.5 (84.3 to 122.7)	78	19.4 (24.5)	58.3 (37.9 to 78.7)	45.20 (17.20 to 73.20) [†]
							26	Total PA	min/wk	81	20.2 (24.2)	109.3 (77.5 to 141.1)	78	19.4 (24.5)	58.3 (37.9 to 78.7)	51.00 (13.23 to 88.77) [†]
	PA M	IG1	Telephone counseling	X	X		52	Total PA	min/wk	80	19.8 (26.6)	80.8 (56.9 to 104.7)	78	19.4 (24.5)	62.5 (36.6 to 88.4)	18.30 (-16.93 to 53.53) [†]
							52	Total PA	min/wk	81	20.2 (24.2)	142.2 (108.5 to 175.9)	78	19.4 (24.5)	62.5 (36.6 to 88.4)	79.70 (37.22 to 122.18) [†]

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)		
	PA	IG1	Telephone counseling				26	Mtg PA recs	n (%)	80	0 (0.0)	34 (42.0) [†]	78	0 (0.0)	14 (18.0) [†]	3.30 (1.66 to 7.22) ^{***}		
	M																	
	PA	IG2	Tailored print materials				26	Mtg PA recs	n (%)	81	0 (0.0)	32 (40.0) [†]	78	0 (0.0)	14 (18.0) [†]	2.95 (1.41 to 6.19) ^{***}		
	M																	
	PA	IG1	Telephone counseling			X	52	Mtg PA recs	n (%)	80	0 (0.0)	17 (21.0) [†]	78	0 (0.0)	13 (17.0) [†]	1.50 (0.67 to 3.33) ^{***}		
	M																	
	PA	IG2	Tailored print materials				52	Mtg PA recs	n (%)	81	0 (0.0)	40 (49.0) [†]	78	0 (0.0)	13 (17.0) [†]	5.31 (2.47 to 11.39) ^{***}		
	M																	
	PA	IG1	Telephone counseling				26	CRF [†]	VO ₂ max	80	25.3 (7.0)	1.8 (0.2 to 3.4)	78	25.6 (5.6)	1.3 (-0.1 to 2.6)	0.53 (-1.55 to 2.61) [†]		
M																		
PA	IG2	Tailored print materials				26	CRF [†]	VO ₂ max	81	26.0 (6.4)	1.3 (-0.2 to 2.8)	78	25.6 (5.6)	1.3 (-0.1 to 2.6)	0.04 (-1.98 to 2.06) [†]			
M																		
PA	IG1	Telephone counseling				52	CRF [†]	VO ₂ max	80	25.3 (7.0)	1.9 (0.3 to 3.4)	78	25.6 (5.6)	0.8 (-0.5 to 2.0)	1.09 (-0.94 to 3.12) [†]			
M																		
PA	IG2	Tailored print materials				52	CRF [†]	VO ₂ max	81	26.0 (6.4)	1.2 (-0.3 to 2.6)	78	25.6 (5.6)	0.8 (-0.5 to 2.0)	0.40 (-1.52 to 2.32) [†]			
M																		
Marcus, 2013 ¹⁶⁶ Good	PA	IG1	Tailored print mailings and self-monitoring				26	MVPA	min/wk	132	1.9 (6.9)	71.5 (56.7 to 86.2)	134	3.0 (10.3)	30.0 (16.7 to 43.2)	41.36 (25.82 to 56.90) [*]		
	L			X	X		52	MVPA	min/wk	132	1.9 (6.9)	93.9 (74.7 to 113.1)	134	3.0 (10.3)	40.4 (26.0 to 54.8)	51.99 (33.61 to 70.37) [*]		
							26	Mtg PA recs	n (%)	132	0 (0.0)	15 (11.4) [†]	134	0 (0.0)	8 (6.0) [†]	2.34 (0.96 to 5.72) ^{***†}		
					X		52	Mtg PA recs	n (%)	132	0 (0.0)	22 (16.7) [†]	134	0 (0.0)	8 (6.0) [†]	3.14 (1.34 to 7.34) ^{***†}		
Marsaux, 2015 ¹⁶⁹ Fair	HD+PA	IG1	Tailored web-based advice (diet, PA, and phenotype)	X	X		26	Mod PA ^{****}	min/wk	187	NR	-2.0 (-16.4 to 12.1)	170	NR	12.0 (-3.4 to 26.9)	-14.00 (-34.80 to 6.80) ^{*†}		
	L			IG2	Tailored web-based advice (diet & PA only)				26	Mod PA ^{****}	min/wk	174	NR	-3.0 (-17.3 to 12.2)	170	NR	12.0 (-3.4 to 26.9)	-15.00 (-36.14 to 6.14) ^{*†}
				IG3	Tailored web-based advice (diet, physical activity, phenotype, & genotype)				26	Mod PA ^{****}	min/wk	195	NR	14.0 (-0.2 to 27.7)	170	NR	12.0 (-3.4 to 26.9)	2.00 (-18.59 to 22.59) ^{*†}

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
		IG1	Tailored web-based advice (diet, PA, and phenotype)				26	Sedentary time ^{****}	min/wk	187	NR	-176.0 (-216.0 to -138.0)	170	NR	-190.0 (-225.0 to -149.0)	14.00 (-40.45 to 68.45) ^{*†}
		IG2	Tailored web-based advice (diet & PA only)				26	Sedentary time ^{****}	min/wk	174	NR	-151.0 (-192.0 to -111.0)	170	NR	-190.0 (-225.0 to -149.0)	39.00 (-16.54 to 94.54) ^{*†}
		IG3	Tailored web-based advice (diet, physical activity, phenotype, & genotype)				26	Sedentary time ^{****}	min/wk	195	NR	-138.0 (-176.0 to -100.0)	170	NR	-190.0 (-225.0 to -149.0)	52.00 (-1.74 to 105.74) ^{*†}
Marshall, 2003 ¹⁷⁰ Fair	PA	IG1	Tailored print mailing				26	Total PA	min/wk	227	180.0 (204.0)	18.0 (NR to NR)	235	198.0 (246.0)	-12.0 (NR to NR)	30 (NR to NR) ^{†, ††}
	L				X	26	Mtg PA recs	n (%)	227	59 (26.0)	32 (14.0) [†]	235	66 (28.0)	7 (3.0) [†]	1.46 (0.98 to 2.18) ^{**}	
Martinson, 2008 ¹⁷² Good	PA H	IG1	Counseling				26	MVPA	kcal/wk	493	1907.0 (1415.2)	101.0 (-32.8 to 234.8)	490	2141.0 (1810.1)	-377.0 (-532.8 to -221.2)	241.00 (35.00 to 447.00) ^{****}
				X			52	MVPA	kcal/wk	494	1907.0 (1415.2)	239.0 (101.7 to 376.3)	487	2141.0 (1810.1)	-207.0 (-359.7 to -54.3)	224.00 (18.00 to 430.00) ^{****}
							104	MVPA	kcal/wk	487	1907.0 (1415.2)	273.0 (130.5 to 415.5)	475	2141.0 (1810.1)	-238.0 (-396.1 to -79.9)	273.00 (66.00 to 481.00) ^{****}
							26	Total PA	kcal/wk	492	3822.0 (1940.2)	26.0 (-154.4 to 206.4)	491	3998.0 (2176.7)	-440.0 (-636.3 to -243.7)	321.00 (50.00 to 593.00) ^{****}
							52	Total PA	kcal/wk	494	3822.0 (1940.2)	341.0 (157.4 to 524.6)	487	3998.0 (2176.7)	-57.0 (-245.9 to 131.9)	243.00 (-28.00 to 515.00) ^{****}
							104	Total PA	kcal/wk	490	3822.0 (1940.2)	487.0 (287.0 to 687.0)	475	3998.0 (2176.7)	-94.0 (-291.9 to 103.9)	415.00 (142.00 to 688.00) ^{****}
						X	26	Mtg PA recs ^{†††}	n (%)	495	112 (21.4)	54 (12.1) [†]	491	146 (27.8)	-6 (0.7) [†]	1.27 (0.97 to 1.66) ^{**†, ††}
							26	Mtg PA recs ^{****}	n (%)	495	192 (36.7)	42 (10.6) [†]	491	184 (35.0)	25 (7.5) [†]	1.21 (0.94 to 1.56); 0.52 ^{§§§§}
Mosca, 2008 ¹⁷⁶ Good	HD+PA M	IG1	Counseling	X			52	MVPA	d/wk	232	1.9 (2.0)	0.6 (0.3 to 0.9)	232	1.6 (2.0)	0.3 (0.1 to 0.6)	0.24 (-0.14 to 0.62) [†]

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)	
Napolitano, 2006 ¹⁷⁷	PA	IG1	Tailored print mailings	X	X		52	MVPA	min/wk	95	48.6 (141.2)	100.3 (66.5 to 134.1)	92	33.6 (51.2)	105.9 (71.5 to 140.3)	-5.60 (-53.85 to 42.65) [†]	
	L																
Fair	PA	IG2	Nontailored print mailings				52	MVPA	min/wk	93	50.7 (79.4)	103.8 (70.6 to 137.0)	92	33.6 (51.2)	105.9 (71.5 to 140.3)	-2.10 (-49.94 to 45.74) [†]	
	L																
Norris, 2000 ¹⁷⁹	PA	IG1	Counseling				26	Total PA	kcal/wk	362	1571.9 (2422.1)	536.2 (NR to NR)	460	1681.2 (2470.3)	366.4 (NR to NR)	169.80 (NR to NR) [†]	
	Fair	M		X	X		26	Total PA	min/wk	362	240.0 (336.4)	91.1 (56.4 to 125.8)	460	272.2 (352.4)	58.5 (26.3 to 90.7)	32.60 (-30.71 to 95.91) ^{††}	
								26	Walking	min/wk	362	148.1 (206.5)	38.8 (NR to NR)	460	163.1 (232.2)	38.7 (NR to NR)	0.10 (NR to NR) [†]
Parekh, 2014 ¹⁸¹	HD+PA	IG1	Computer-tailored print mailings (2 contacts)			X	52	Mtg PA recs	n (%)	667	333 (49.9)	-8 (-1.2) [†]	1406	725 (51.6)	-64 (-4.6) [†]	1.07 (0.89 to 1.29) ^{***†}	
	L																
Fair	HD+PA	IG2	Computer-tailored print mailing (1 contact)				52	Mtg PA recs	n (%)	800	419 (52.4)	-4 (-0.6) [†]	1406	725 (51.6)	-64 (-4.6) [†]	1.21 (1.02 to 1.45) ^{***†}	
	L																
Pekmezi, 2009 ¹⁸⁴	PA	IG1	Tailored print mailings and self-monitoring	X	X		26	MVPA	min/wk	45	16.6 (25.8)	130.7 (63.6 to 197.8)	48	11.9 (22.0)	84.9 (54.0 to 115.8)	45.80 (-28.09 to 119.69) [†]	
	L																
Fair	PA	IG1	Automated telephone counseling	X			26	Mod PA	kcal/kg/d	112	1.5 (2.5)	0.5 (-0.1 to 1.1)	131	2.0 (3.4)	-0.2 (-0.7 to 0.3)	0.70 (-0.10 to 1.50) [†]	
	M						26	Vig PA	kcal/kg/d	112	0.1 (0.7)	0.4 (0.2 to 0.6)	126	0.2 (0.6)	0.2 (0.0 to 0.4)	0.20 (-0.11 to 0.51) [†]	
								26	Total PA	kcal/kg/d	112	33.2 (1.9)	0.6 (0.2 to 1.0)	126	33.5 (2.0)	0.1 (-0.3 to 0.5)	0.50 (-0.07 to 1.07) [†]
					X			26	Mtg PA recs	n (%)	112	12 (10.7)	17 (15.2) [†]	131	24 (16.2)	11 (10.5) [†]	1.11 (0.60 to 2.06) ^{***†}
Fair	PA	IG1	Counseling with tailored prescription				26	Mod PA	kcal/kg/wk	49	2.5 (4.3)	4.2 (2.6 to 5.8)	44	3.0 (5.0)	1.1 (-0.6 to 2.8)	3.08 (0.86 to 5.30) [†]	
	M	X		X			26	Mod PA	min/wk	49	38.1 (64.8)	62.8 (39.1 to 86.6)	44	45.3 (74.6)	16.6 (-8.5 to 41.7)	46.24 (12.97 to 79.51) [†]	
								26	Vig PA	kcal/kg/wk	49	0.8 (3.5)	-0.4 (-0.5 to -0.4)	44	0.0 (0.2)	-0.4 (-0.5 to -0.4)	-0.03 (-0.08 to 0.02) [†]
								26	Vig PA	min/wk	49	7.8 (35.1)	-4.5 (-4.9 to -4.0)	44	0.3 (2.2)	-4.2 (-4.7 to -3.7)	-0.22 (-0.85 to 0.41) [†]
								26	Total PA	kcal/kg/d	49	32.2 (0.9)	-0.8 (-2.2 to 0.6)	44	32.1 (1.1)	-0.1 (-1.5 to 1.4)	-0.76 (-2.71 to 1.19) [†]
Ruffin, 2011 ¹⁸⁹	HD+PA	IG1	Computer-tailored web-based intervention			X	26	Mtg PA recs	n (%)	2033	620 (27.0)	10 (4.0) [†]	1236	397 (29.0)	-58 (-1.6) [†]	1.47 (1.08 to 1.98) ^{****}	
Fair	L																

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Simkin-Silverman, 1995 ¹⁹⁴ Good	HD+PA H	IG1	Group counseling				26	Total PA [‡]	counts/hr	236	18.3 (6.7)	3.2 (2.1 to 4.3)	253	19.9 (8.9)	0.1 (-0.9 to 1.1)	3.12 (1.62 to 4.62) [†]
							26	Total PA	kcal/wk	236	1216.6 (1026.0)	402.1 (269.2 to 535.0)	253	1389.1 (1352.2)	-48.0 (-216.5 to 120.5)	450.10 (235.53 to 664.67) [†]
				X			78	Total PA	kcal/wk	236	1216.6 (1026.0)	431.7 (272.0 to 591.4)	253	1389.1 (1352.2)	43.4 (-125.3 to 212.1)	388.30 (155.98 to 620.62) [†]
							234	Total PA [‡]	counts/hr	246	18.3 (6.7)	2.3 (1.2 to 3.4)	263	19.9 (8.9)	-0.3 (-1.2 to 0.7)	2.56 (1.08 to 4.04) [†]
							234	Total PA	kcal/wk	246	1216.6 (1026.0)	274.9 (128.3 to 421.5)	263	1389.1 (1352.2)	-113.3 (-265.7 to 39.1)	388.20 (176.76 to 599.64) [†]
Smith, 2014 ¹⁹⁷ Fair	HD+PA M	IG1	Counseling	X			26	MVPA [‡]	min/d	29	19.0 (14.0)	0.0 (-4.8 to 4.8)	30	16.0 (13.0)	1.0 (-3.8 to 5.8)	-0.10 (-4.70 to 4.50) [*]
							26	Total PA [‡]	steps/d	29	7170.0 (2973.0)	-153.0 (-1149.3 to 843.3)	30	7152.0 (2171.0)	-111.0 (-881.9 to 659.9)	-38.00 (-732.00 to 657.00) [*]
Stewart, 2001 ²⁰¹ Fair	PA H	IG1	Group counseling				52	MVPA	kcal/wk	81	1052.0 (NR)	487.0 (NR to NR)	83	1185.0 (NR)	5.0 (NR to NR)	482.00 (NR to NR) ^{†,††}
							52	Total PA	kcal/wk	81	1935.0 (NR)	687.0 (NR to NR)	83	2057.0 (NR)	-10.0 (NR to NR)	697.00 (NR to NR) ^{†,††}
Taveras, 2011 ²⁰³ Fair	HD+PA H	IG1	Postpartum counseling				26	Total PA	hr/d	58	NR (NR)	NR (NR to NR)	22	NR (NR)	NR (NR to NR)	NR (NR to NR) ^{††††}
Thompson, 2008 ²⁰⁷ Fair	HD+PA H	IG1	Group counseling				26	Leisure PA	min/wk	100	303.6 (289.8)	9.6 (-45.7 to 64.9)	100	367.8 (384.0)	-27.6 (-103.9 to 48.7)	37.2 (-57.06 to 131.46) [†]
				X	X		52	Leisure PA	min/wk	100	303.6 (289.8)	1.2 (-57.5 to 59.9)	100	367.8 (384.0)	-50.4 (-118.7 to 17.9)	51.60 (-38.45 to 141.65) [†]
							78	Leisure PA	min/wk	100	303.6 (289.8)	-7.2 (-64.4 to 50.0)	100	367.8 (384.0)	-54.6 (-122.9 to 13.7)	47.48 (-41.65 to 136.45) [†]
							26	CRF [‡]	Peak VO ₂ L/min	98	2.1 (0.4)	0.0 (-0.1 to 0.1)	99	1.2 (0.4)	0.7 (0.7 to 0.8)	-0.77 (-0.89 to -0.65) [†]
							52	CRF [‡]	Peak VO ₂ L/min	99	2.1 (0.4)	0.0 (-0.1 to 0.1)	99	1.2 (0.4)	0.8 (0.7 to 0.9)	-0.80 (-0.92 to -0.68) [†]
							78	CRF [‡]	Peak VO ₂ L/min	99	2.1 (0.4)	0.0 (-0.1 to 0.1)	99	1.2 (0.4)	0.7 (0.7 to 0.8)	-0.77 (-0.88 to -0.66) ^{†††††}
Thompson, 2014 ²⁰⁸ Good	PA H	IG1	Counseling and self-monitoring	X			26	Total PA [‡]	Activity units	24	4255.0 (1480.0)	-217.8 (-630.8 to 195.2)	24	4668.0 (2121.0)	-583.6 (-959.8 to -207.4)	365.80 (-192.85 to 924.45) [†]

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Tokunaga-Nakawatase, 2014 ²¹⁰	HD+PA	IG1	Computer-tailored print mailings				26	Total PA	kcal/d	52	243.0 (296.6)	-15.8 (NR to NR)	50	379.8 (816.6)	-28.8 (NR to NR)	13.02 (NR to NR) ^{TS}
	L						52	Total PA	kcal/d	47	243.0 (296.6)	-4.7 (NR to NR)	50	379.8 (816.6)	-70.3 (NR to NR)	65.61 (NR to NR) ^{TS}
Fair																
Van Hoecke, 2014 ²¹²	PA	IG1	Counseling	X			52	Total PA [†]	steps/d	124	5734.3 (2565.4)	460.6 (42.6 to 878.6)	114	5877.5 (2542.0)	39.8 (-379.3 to 458.8)	420.41 (-166.39 to 1007.21)*
	M															
Fair																
Van Hoecke, 2014 ²¹²	PA	IG2	Tailored prescription				52	Total PA [†]	steps/d	110	5923.2 (2578.0)	538.9 (116.6 to 961.1)	114	5877.5 (2542.0)	39.8 (-379.3 to 458.8)	499.10 (-92.89 to 1091.08)*
	L															
	PA	IG1	Counseling				52	PA score	Study defined ^{††††}	124	12.1 (11.8)	20.0 (17.1 to 22.9)	114	14.9 (11.6)	13.6 (10.7 to 16.6)	6.40 (2.05 to 10.76)*
	M															
Van Stralen, 2010 ²¹⁴	PA	IG1	Tailored print mailings with environmental focus				26	Total PA	d/wk	481	4.2 (2.2)	0.7 (0.5 to 0.9)	486	4.0 (2.2)	0.2 (0.0 to 0.4)	0.54 (0.28 to 0.80)*
	L															
Fair	PA	IG2	Tailored print mailings				26	Total PA	d/wk	444	4.2 (2.2)	0.6 (0.4 to 0.8)	486	4.0 (2.2)	0.2 (0.0 to 0.4)	0.59 (0.32 to 0.85)*
	L															
	PA	IG1	Tailored print mailings with environmental focus				52	Total PA	d/wk	450	4.2 (2.2)	0.5 (0.3 to 0.7)	458	4.0 (2.2)	0.3 (0.1 to 0.5)	0.28 (0.04 to 0.52)*
	L															
	PA	IG2	Tailored print mailings				52	Total PA	d/wk	418	4.2 (2.2)	0.5 (0.3 to 0.7)	458	4.0 (2.2)	0.3 (0.1 to 0.5)	0.39 (0.15 to 0.62)*
	L															
	PA	IG1	Tailored print mailings with environmental focus	X	X		52	Total PA	min/wk	450	629.8 (440.9)	73.4 (32.6 to 114.2)	458	610.4 (438.2)	9.6 (-31.0 to 50.2)	62.00 (7.40 to 116.60)*
	L															
PA	IG2	Tailored print mailings				52	Total PA	min/wk	418	662.8 (474.6)	7.9 (-35.9 to 51.7)	458	610.4 (438.2)	9.6 (-31.0 to 50.2)	13.50 (-42.40 to 69.40)*	
L																
PA	IG1	Tailored print mailings with environmental focus				52	Leisure walking	min/wk	450	162.2 (186.5)	20.9 (2.8 to 39.0)	458	149.9 (181.8)	-2.5 (-18.6 to 13.6)	21.90 (1.00 to 42.90)*	
L																
PA	IG2	Tailored print mailings				52	Leisure walking	min/wk	418	178.6 (206.6)	-5.3 (-24.2 to 13.6)	458	149.9 (181.8)	-2.5 (-18.6 to 13.6)	5.90 (-15.60 to 27.40)*	
L																

Appendix F Table 8. Physical Activity Outcomes

Author, Year Quality	Int Focus Intensity	IG	Int	Std MA	Un Std MA	Mtg Recs MA	FU, wks	Outcome	Unit	IG N	IG Mean (SD) Baseline	IG Mean change (95% CI)	CG N	CG Mean (SD) Baseline	CG Mean change (95% CI)	Study-reported between group difference Mean (95% CI)
Vandelanotte, 2005 ²¹⁷ Fair	HD+PA	IG1	Computer-based sessions with tailored feedback (PA and diet simultaneous)	X	X		26	MVPA	min/wk	189	325.0 (312.0)	61.0 (15.3 to 106.7)	204	392.0 (340.0)	45.0 (-2.2 to 92.2)	16.00 (-49.74 to 81.74) [†]
	M															
	HD+PA	IG2	Computer-based sessions with tailored feedback (PA first)				26	MVPA	min/wk	180	295.0 (249.0)	93.0 (51.8 to 134.2)	204	392.0 (340.0)	45.0 (-2.2 to 92.2)	48.00 (-14.65 to 110.65) [†]
	M															
Vrdoljak, 2013 ²¹⁸ Fair	HD+PA	IG1	Provider training			X	78	Mtg PA recs	n (%)	371	158 (42.6)	-64 (-17.3) [†]	367	147 (40.1)	-39 (-10.7) [†]	0.82 (0.56 to 1.19) ^{***††}
	M															
Wadsworth, 2010 ²¹⁹ Fair	PA	IG1	Web-based intervention	X			26	Mod PA	sessions/wk	34	2.3 (2.0)	0.8 (0.0 to 1.5)	37	1.5 (1.4)	0.5 (0.0 to 1.1)	0.22 (-0.67 to 1.11) [†]
Warner, 2016 ²²⁰ Fair	PA	M	IG1	Group counseling with views-on-aging component			42	Total PA	Met-min/wk	86	219.1 (31.8)	-10.8 (-16.8 to -4.9)	80	222.6 (27.2)	-9.2 (-15.3 to -3.1)	-1.67 (-10.19 to 6.85) [†]
			IG2		Group counseling			42	Total PA	Met-min/wk	27	214.82 (28.8)	-1.2 (-12.4 to 9.9)	80	222.6 (27.2)	-9.2 (-15.3 to -3.1)
			IG1	Group counseling with views-on-aging component		X		60	Total PA	Met-min/wk	84	219.1 (31.8)	-5.2 (-11.6 to 1.2)	69	222.6 (27.2)	-3.7 (-9.8 to 2.4)
			IG2		Group counseling			60	Total PA	Met-min/wk	25	214.8 (28.8)	14.2 (1.9 to 26.6)	69	222.6 (27.2)	-3.7 (-9.8 to 2.4)

Appendix F Table 8. Physical Activity Outcomes

* Adjusted.

† Calculated.

‡ Based on objective measurement.

§ Reported as not significant (NS).

|| Median (range).

¶ Participants indicated how often they engaged in aerobic activity in past 3 months (1= never, 7=often), the average number of days/week engaged in aerobic exercise in past 3 months (0-7 days), and number of days engaged in aerobic exercise in past week (0-7 days); items were standardized and averaged.

¶ Applied ICC=0.033 per Grandes, 2009 for MA.

** OR.

†† Reported as statistically significant.

‡‡ The PASE is an 11-item self-report measure of PA defined in terms of 3 dimensions: leisure time, household, and occupational activity performed within the past week. For leisure time activity, subjects are asked to recall the frequency, duration, and type of leisure time activity they engaged in over the past 7 days. For household activity, subjects are asked to indicate whether or not they engaged in light or heavy housework, home repairs, lawn work, gardening, or caregiving activity. Occupational activity is defined in terms of the occurrence, duration, and type of volunteer or paid work.

§§ Reported adjusted RR=1.80 (-1.97 to 5.85).

||| Reported adjusted RR=2.14 (-1.81 to 6.32).

¶¶ Interviewer-administered 11-item instrument that takes into account the stage of change for persons who do little or no activity and the level of activity for those who are active.

¶¶ Median (IQR).

*** % difference.

††† PA score based on number of sessions of moderate and vigorous activity lasting a minimum of 20 min in the previous 4 weeks; levels of PA were defined by the number of PA sessions reported (Level 0 equated to no sessions and Level 5 was defined by 12 or more sessions of vigorous activity).

‡‡‡ Frequency per week of each of 13 activities multiplied by intensity in METs and summed across 13 activity items.

§§§ Applied ICC=0.033 per Grandes, 2009 for MA.

|||| Reported as statistically significant in analyses adjusted for baseline values.

¶¶¶ Reported as p=0.056 in analyses adjusted for baseline values.

¶¶¶ Reported as statistically significant in analyses adjusted for repeated measures and baseline values; data were log transformed due to skewed nature.

**** Least squares mean difference.

†††† Mod PA 5+ days/week.

‡‡‡† Vig PA 3+ days/week.

§§§§ Calculated OR.

||||| Reported as not statistically significant.

¶¶¶¶ Reported as not statistically significant in repeated measures ANOVA.

¶¶¶¶ Frequency of mild, moderate, and strenuous 20-min PA bouts in the past week weighted by METs and summed.

***** Reported as p=0.06 in adjusted analyses.

††††† Statistical significance for this comparison not tested in primary paper.

‡‡‡‡† Estimated from figure; vigorous PA also reported, but not estimated from figure.

§§§§§ Calculated from min/day.

Abbreviations: ANOVA=analysis of variance; BMI=body mass index; CG=control group; CI=confidence interval; CRF=cardiorespiratory fitness; d=day; FU=followup; H=high; HD=healthful diet; hr=hour; ICC=intracenter correlation; IG=intervention group; Int=intervention; IQR=interquartile range; L=low; M=medium; MA=meta-analysis; min=minute; Mod=moderate; MPA=moderate physical activity; Mtg Recs= meeting PA recommendations; MVPA=moderate to vigorous physical activity; OR=odds ratio; N=number analyzed; NR=not reported; NS=not significant; PA=physical activity; REE=ratio to resting energy expenditure; RR=risk ratio; SD=standard deviation; Std=standardized; UnStd=unstandardized; Vig=vigorous; VO₂=volume of oxygen; WC=waist circumference; wk=week.

Appendix G. Ongoing Studies

Study Reference Trial Identifier	Study Name	Location	Estimated N	Description	2016 Status
NCT02367963	Peer-group-based Intervention Program (Fifty-Fifty)	Spain	600	A multicenter, randomized control trial scheme was adopted. A peer-group based intervention approach in which community members support each other to promote health-enhancing changes was chosen.	Completed: Dec 2015
NCT02553980	Virtual Trainer System (3rd Version) for Physical Activity Promotion in Middle-aged Hong Kong Adults	Hong Kong	200	IT- instruction based lifestyle intervention program, with the purpose to improve PA level and health status in a sample of middle-aged Hong Kong adults.	Ongoing: Est. Completion Date Aug 2016
NCT02016014	Effectiveness of the Use of a Mobile Tool in Improving Lifestyles	Spain	1200	To develop and validate a mobile tool for use in Smartphone supports as a first step, and to evaluate the effect of adding this new tool of information and communication technologies (ICT), to a standardized intervention to increase adherence to nutritional recommendations of the Mediterranean diet and increase physical activity as primary endpoint	Ongoing: Est Completion Date Jul 2016
NCT02686502	Motivation Makes the Move! (MoMaMo!)	Finland	120	This study evaluates the effect and usability of mobile and cloud technology -based intervention on lifestyle modification in 18-40 year obese and overweight subjects.	Ongoing: Est completion Date May 2019
NCT02136381	Lifestyle Interventions at Retirement	UK	90	This study is an RCT with two intervention arms: Internet-based lifestyle programme (Living, Eating, Activity and Planning through retirement (LEAP)) that promotes three key health and social behaviours; 1) healthy eating by adopting a Mediterranean diet, 2) increasing physical activity with the use of a step-counter, and 3) improving social connectedness.	Recruiting Participants
NCT02111213	Virtual Advisors for Physical Activity Promotion in Underserved Communities (COMPASS2)	US	530	Study will evaluate the effectiveness of a computer-based 'virtual lay advisor' compared to a proven human lay advisor/promotora to promote regular walking among inactive midlife and older Latino adults.	Ongoing: Est. Completion Date Jun 2017
NCT01975181	Cardiovascular Prevention Program Registry	US	5000	The Cardiovascular Prevention Program (CPP) Registry seeks to improve the cardiovascular disease (CVD) risk profile of subjects through therapeutic lifestyle change using an integrative model of medicine.	Ongoing: Est. Completion Date Oct 2020
NCT02648360	Text Messaging for Physical Activity & Healthy Eating	US	300	This project will design, implement and evaluate the delivery and effectiveness of an existing health promotion text messaging program focused on increasing physical activity and improving dietary behaviors among medically underserved Hispanic patients.	Ongoing: Est. Completion Date Aug 2016

Appendix G. Ongoing Studies

Study Reference Trial Identifier	Study Name	Location	Estimated N	Description	2016 Status
NCT02247219	Promoting Health in Healthy Living Centres - a Clinical Study Among Adults	Norway	200	Evaluate the effect of behavior change intervention programs across different domains; the programs will specifically target the underlying causes of chronic disease. Map the distribution of lifestyle habits among individuals and families; explore how lifestyle habits relate to known determinants of social health inequality; study if socioeconomic differences are of importance for entering or dropping out of HLC interventions, and the ability to sustain lifestyle changes.	Ongoing: Est. Completion Date Sep 2017
NCT02645071	Brief Program in Reducing Sedentary Behavior and Promoting Physical Exercise	Hong Kong	400	This study will focus on reduction of sedentary behavior and increasing physical activity in daily life. The intervention is a 15- to 20- minute interactive session program, which aims to reduce participants' sedentary behavior and increase physical activity by increasing their motivation, self-efficacy and knowledge of different types of easy movements (Zero-time exercises).	Ongoing: Est. Completion Date Jul 2017
NCT02204176	Exercise Behavior Among Young Adults Study (EBYA)	US	200	Compare three training approaches (& control) for college students to increase exercise behavior. (1) provide general information on the different types of exercises and benefits of engaging in exercise behavior after an initial questionnaire assessment session. (2) general exercise information and questionnaire assessment as well as training on how to create specific goal intentions (i.e., implementation intentions) to aid in exercise initiation. (3) All the components of the second approach but also tests the utility of a personality-informed module by incorporating concepts from the theory of learned industriousness.	Ongoing: Est. Completion Date Dec 2016
NCT02632487	Wearable Technology to Reduce Sedentary Behavior and CVD Risk in Older Adults	US	40	This study will evaluate the feasibility and efficacy of combining a traditional, structured exercise intervention with an innovative intervention designed to decrease sedentary behavior and increase non-exercise physical activity (NEPA).	Ongoing: Est. Completion Date Dec 2017
NCT02467881	Physical Activity and Sedentary Behavior Change; Impact on Lifestyle Intervention Effects for Diabetes Translation	US	321	This study proposes to examine the impact of a modified version of the Group Lifestyle Balance (GLB) program, which will focus on decreasing sedentary/sitting behaviors. The results of this project will provide information regarding best options for physical activity within lifestyle intervention programs, focusing both on verifying the current role of physical activity in lifestyle intervention using an objective measure and on examining an alternative intervention option for translation efforts.	Ongoing: Est. Completion Date: Dec 2018

Appendix G. Ongoing Studies

Study Reference Trial Identifier	Study Name	Location	Estimated N	Description	2016 Status
NCT01997021	Effects of Interrupting Sedentary Time on Glycemic Control in Older Overweight and Obese Adults (B-WELL)	US	25	The purpose of this project is to determine how interrupting sedentary time with short bouts of moderate intensity walking affects important metabolic outcomes in older, overweight adults. It would also be of interest to compare the effects of short, frequent interruptions in sedentary behavior to a traditional exercise prescription (continuous 30 min walking bout) on metabolic outcomes (e.g., glycemic control, insulin sensitivity, and 24 h fat oxidation). Thus, the overall aims of the proposed research are to 1) Determine the effect of performing short bouts of moderate-intensity intermittent walking (IW) on glucose and insulin metabolism compared to uninterrupted sitting (US) in older overweight and obese adults. 2) To compare the effects of interrupting sedentary time (IW) vs. a traditional exercise prescription (continuous 30 m walk (CW)) on metabolism.	Ongoing: Est. Completion Date: May 2016
NHS HTA (project number 10/32/32)	Pedometer and Consultation Evaluation – UP (PACE-UP)	UK	1023	This trial aims to evaluate whether a postal pedometer-based walking intervention can increase step-counts and moderate-to-vigorous physical activity in inactive adults aged 45-75 years. Additionally, it will evaluate whether physical activity consultations delivered by a nurse increases the effectiveness of the intervention.	Ongoing: Est. Completion Date: October 2016