JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Behavioral Counseling Interventions to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults Without Known Cardiovascular Disease Risk Factors

Updated Evidence Report and Systematic Review for the US Preventive Services Task Force

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IMPORTANCE Unhealthful dietary patterns, low levels of physical activity, and high sedentary time increase the risk of cardiovascular disease.

OBJECTIVE To synthesize the evidence on benefits and harms of behavioral counseling interventions to promote a healthy diet and physical activity in adults without known cardiovascular disease (CVD) risk factors to inform a US Preventive Services Task Force recommendation.

DATA SOURCES MEDLINE, PsycINFO, and the Cochrane Central Register of Controlled Trials through February 2021, with ongoing surveillance through February 2022.

STUDY SELECTION Randomized clinical trials (RCTs) of behavioral counseling interventions targeting improved diet, increased physical activity, or decreased sedentary time among adults without known elevated blood pressure, elevated lipid levels, or impaired fasting glucose.

DATA EXTRACTION AND SYNTHESIS Independent data abstraction and study quality rating and random effects meta-analysis.

MAIN OUTCOMES AND MEASURES CVD events, CVD risk factors, diet and physical activity measures, and harms.

RESULTS One-hundred thirteen RCTs were included (N = 129 993). Three RCTs reported CVD-related outcomes: 1 study (n = 47 179) found no significant differences between groups on any CVD outcome at up to 13.4 years of follow-up; a combined analysis of the other 2 RCTs (n = 1203) found a statistically significant association of the intervention with nonfatal CVD events (hazard ratio, 0.27 [95% CI, 0.08 to 0.88]) and fatal CVD events (hazard ratio, 0.31 [95% CI, 0.11 to 0.93]) at 4 years. Diet and physical activity behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure (systolic mean difference, −0.8 [95% CI, −1.3 to −0.3]; 23 RCTs [n = 57 079]; diastolic mean difference, −0.4 [95% CI, −0.8 to −0.0]; 24 RCTs [n = 57 148]), low-density lipoprotein cholesterol level (mean difference, 2.2 mg/dL [95% CI, −3.8 to −0.6]; 15 RCTs [n = 6350]), adiposity-related outcomes (body mass index mean difference, −0.3 [95% CI, −0.5 to −0.1]; 27 RCTs [n = 59 239]), dietary outcomes, and physical activity at 6 months to 1.5 years of follow-up vs control conditions. There was no evidence of greater harm among intervention vs control groups.

CONCLUSIONS AND RELEVANCE Healthy diet and physical activity behavioral counseling interventions for persons without a known risk of CVD were associated with small but statistically significant benefits across a variety of important intermediate health outcomes and small to moderate effects on dietary and physical activity behaviors. There was limited evidence regarding the long-term health outcomes or harmful effects of these interventions.

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Despite evidence that healthy dietary patterns, physical activity, and limited sedentary time are associated with reduced cardiovascular morbidity and mortality, most US adults do not meet national recommendations for these behaviors.[1-3] Behavioral interventions occurring in or referred from primary care may be one strategy to improve these behaviors and subsequently prevent poor cardiovascular outcomes.

The US Preventive Services Task Force (USPSTF) has several recommendations related to preventing cardiovascular disease (CVD), including guidance on healthy lifestyle counseling,[4,5] tobacco cessation,[6] weight loss,[7] aspirin use,[8] statin use,[9] and screening for and treatment of high or abnormal levels of blood pressure[10] and glucose.[11] In a 2017 recommendation statement, the USPSTF provided a C recommendation that clinicians may choose to selectively counsel adults without known cardiovascular risk factors about healthful diet and physical activity for the primary prevention of CVD.[4] The purpose of this review was to update the previous review[12,13] on the benefits and harms of behavioral counseling interventions for healthy diet, physical activity, or sedentary behavior to inform an updated USPSTF recommendation statement on this topic. For the purposes of this review, cardiovascular risk factors included elevated blood pressure, elevated lipid levels, or impaired fasting glucose.

Methods

Scope of Review

This review addressed 4 key questions (KQs) (**Figure 1**). A full research plan was published prior to conducting the review.[15] Methodological details including study selection, a list of excluded studies, additional data analysis methods, detailed study-level results for all outcomes, and contextual observational data are available in the full evidence report.[16]

Data Sources and Searches

To identify studies published since the previous review,[12] literature searches were conducted from 2016 through February 2021 in MEDLINE, PsycINFO, and the Cochrane Central Register of Controlled Trials (eMethods in the Supplement). Additional studies were sought by reviewing reference lists of other systematic reviews. Ongoing surveillance was conducted to identify newly published studies that might affect the findings of the review. This was accomplished through article alerts and targeted searches of select clinical journals.[17] The last surveillance on February 9, 2022, identified no new studies.

Study Selection

Two reviewers independently evaluated citations and full-text articles against prespecified inclusion criteria (eTable 1 in the Supplement). Disagreements were resolved by discussion and consensus. The review was limited to fair- and good-quality randomized clinical trials (RCTs) that evaluated the effectiveness of primary care–relevant interventions of behavioral interventions focused on healthy diet, physical activity, sedentary behavior, or a combination of these behaviors. RCTs were included if they were conducted among adults 18 years or older without known CVD, diabetes, or CVD risk factors. As such, trials were excluded that (1) targeted persons with known CVD, hypertension or elevated blood pressure (high blood pressure stage 1 [systolic blood pressure [SBP] 130 mm Hg or diastolic blood pressure [DBP] 80-89 mm Hg]), 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 1 or more CVD risk factors to be included. Trials were included if they were among persons who may be at elevated risk for CVD based on factors such as age, race and ethnicity, family history of CVD, overweight or obesity, or history of gestational diabetes. Studies with a primary aim of weight loss or weight management were excluded, because this evidence is covered by a separate systematic review conducted for the USPSTF.[18] Studies had to report at least 1 health outcome (eg, CVD events, mortality), intermediate outcome (eg, blood pressure, lipid levels, glucose levels, adiposity), or behavioral outcome (eg, dietary intake, physical activity) or report adverse events (eg, serious harm, injury) related to the intervention. Comparative effectiveness trials without a true control group were excluded.

Data Extraction and Quality Assessment

Two reviewers independently assessed the methodological quality of each study as good, fair, or poor using predefined criteria developed by the USPSTF (eTable 2 in the Supplement). Discrepancies were resolved through consensus. Poor-quality studies with critical methodological limitations were excluded and typically had several major risks of bias, including very high or differential attrition between groups, substantial lack of baseline comparability between groups without adjustment for those variables, possible selective reporting, or inappropriate exclusion of participants from analyses.

One reviewer abstracted data about each study's design, population, interventions, and outcomes and a second checked data abstraction for accuracy.

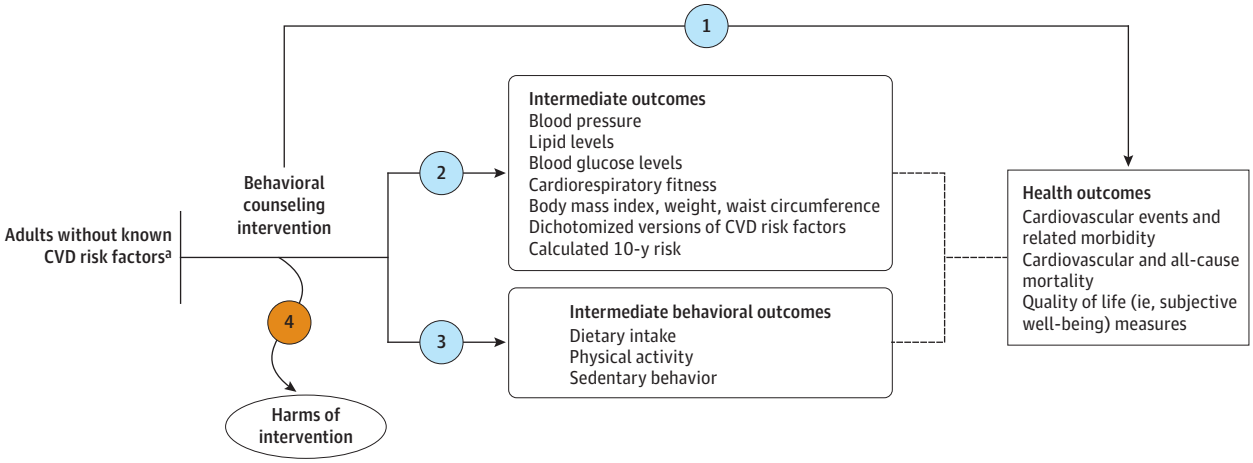
Data Synthesis and Analysis

The strength of evidence was rated for each KQ using the approach described in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*,[19] based on the number, quality, and size of studies as well as the consistency (similarity of effect direction and size) and precision (degree of certainty around an estimate) of the results between studies.

Data were synthesized separately for each KQ. The data on health outcomes (KQ1) and adverse events (KQ4) did not allow for quantitative pooling because of the limited number of contributing studies, so those data were summarized in tables and narratively. For intermediate health outcomes (KQ2) and behavioral outcomes (KQ3), random-effects meta-analyses were performed to account for the variability of the studies.[20] The restricted maximum likelihood method with the Knapp-Hartung correction was applied in meta-analyses.[21,22] Crude effect estimates were calculated if between-group results were not reported and adjusted effect estimates were favored over unadjusted. Within each study, the follow-up time point closest to 12 months was pooled. The results of other time points are presented in tabular format in the full report.[16]

The presence of statistical heterogeneity among the studies was assessed using standard χ^2 tests, and the magnitude of heterogeneity

Figure 1. Analytical Framework: Behavioral Counseling Interventions to Promote Behaviors for CVD Prevention



Key questions

1. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve cardiovascular disease (CVD) and related health outcomes (eg, morbidity and mortality) in adults without known CVD risk factors?
2. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve intermediate outcomes associated with CVD (eg, blood pressure, lipid levels, blood glucose levels, and body mass index) in adults without known CVD risk factors?
3. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve intermediate behavioral outcomes (eg, diet, physical activity, and sedentary behavior) in adults without known CVD risk factors?
4. What are the harms of primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior in adults without known CVD risk factors?

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. A dashed line indicates a health outcome that immediately follows an intermediate outcome. CVD indicates cardiovascular disease. Refer to the USPSTF Procedure Manual for interpretation of the analytic framework.[14]

[a] CVD risk factors include hypertension or elevated blood pressure, dyslipidemia or elevated lipid levels, impaired fasting glucose or impaired glucose tolerance, and mixed or multiple risk factors (eg, 10-year CVD risk ≥7.5%, metabolic syndrome).

was estimated using the I^2 statistic. Meta-regression and stratified analyses were conducted to explore whether there were methodologic, population, or intervention characteristics at the study level that were associated with effect size for the most-reported outcomes of SBP and DBP, low-density lipoprotein cholesterol (LDL-C), fasting glucose, body mass index (BMI, calculated as weight in kilograms divided by square of height in meters), weight, and physical activity. The distribution of trial results was examined with funnel plots, and the Egger test (for continuous data) or Peters test (for binary data) was run to assess whether there was evidence of small-study effects.[23,24]

Stata version 16.1 (StataCorp) was used for all analyses. All significance testing was 2-sided, and results were considered statistically significant if $P < .05$.

Results

Two reviewers evaluated 7485 citations and 411 full-text articles against inclusion criteria, and 113 RCTs[25-137] (204 articles) met inclusion criteria (**Figure 2**). A full list of the included studies, including ancillary publications, can be found in the full evidence report.[16]

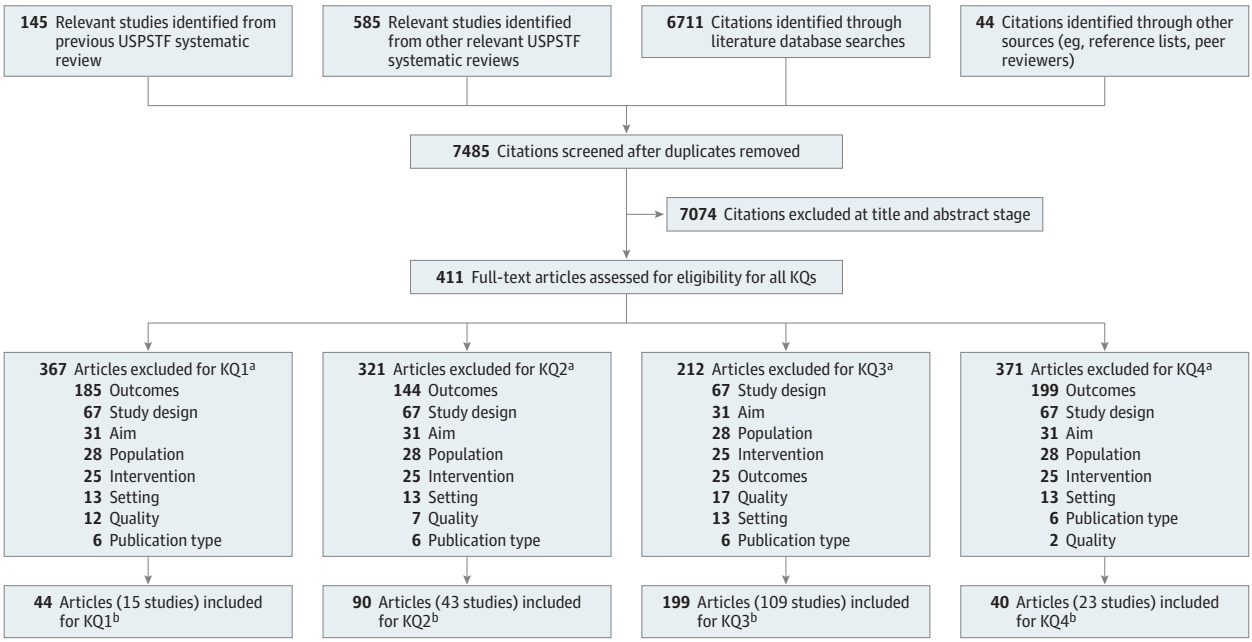
Of the RCTs, 60 took place in the US; sample sizes ranged from 32 to 48 835 participants. The mean age of the samples ranged from 18.5 to 79.5 years, and most trials included both men and women. A summary of the study and population characteristics can be found in **Table 1**. Details of each included study can be found in eTable 3 in the Supplement.

The interventions were variable with 33% focusing on both healthy diet and physical activity, 19% focusing on healthy diet only, and 48% focusing on physical activity alone. Most interventions took place for 6 months or less, and the median number of contacts was 7. A summary of the interventions is available in eTable 4 in the Supplement, and detailed intervention characteristics for each trial are reported in eTable 5 in the Supplement and in the full report.[16]

Benefits on Health Outcomes

Key Question 1. Do primary care–relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve CVD and related health

Figure 2. Literature Search Flow Diagram: Behavioral Counseling Interventions to Promote Behaviors for CVD Prevention



CVD indicates cardiovascular disease; KQ, key question; RCT, randomized clinical trial.

[a] Reason for exclusion: Outcomes: Study did not report relevant outcomes. Study design: Study was not an RCT or controlled intervention. Aim: Study aim not relevant. Population: Study not limited to adults older than 18 years without known CVD risk factors. Intervention: Study did not include a behavioral counseling intervention alone or as part of a larger multicomponent intervention on diet and nutrition, physical activity, sedentary behavior, or a combination of these. Setting: Study was not conducted in a country with a "very high" Human Development Index score; not relevant to US practice; or study was not conducted in a setting generalizable to primary care (eg, workplace, inpatient hospital units, nursing homes). Quality: Study was of poor quality. Publication type: Was not a peer-reviewed article (eg, editorial, conference proceeding) or was not available in English language.

[b] Included studies may appear in more than 1 KQ.

outcomes (eg, morbidity and mortality) in adults without known CVD risk factors?

Fifteen of the 113 included trials reported health outcomes (n = 58 286). Three good-quality trials (n = 48 382) (with relevant results in 8 publications) reported CVD-related health outcomes.[29,82,121,138-142] The 3 trials included the very large Women's Health Initiative Dietary Modification Trial (WHI-DMT) that tested the effects of a high-intensity (6 or more hours of intervention time) low-fat dietary group counseling intervention among postmenopausal women (n = 47 179 without a history of CVD)[121] and the PACE-UP[29] and PACE-Lift[82] physical activity trials by Harris et al (n = 1203 participants without a previous CVD diagnosis).

Within the WHI-DMT, among women without a history of CVD (96.6% of the full sample), total mortality was not statistically significantly different between intervention and control groups over a median cumulative follow-up of 8.5 years (hazard ratio [HR], 0.96 [95% CI, 0.88 to 1.04]) or 13.4 years (HR, 0.97 [95% CI, 0.94 to 1.01]).[140] Likewise, time-to-event analyses did not show significant differences between intervention and comparison groups for coronary heart disease (CHD, defined as nonfatal myocardial infarction plus CHD death), total stroke (ischemic plus hemorrhagic stroke), or total CVD events (CHD plus coronary artery bypass graft surgery or percutaneous coronary intervention plus stroke), either over the intervention period (8.5 years) or over longer follow-up (13.4 years).[140]

When data from both the PACE-UP and PACE-Lift trials were combined, there was a statistically significant intervention association with nonfatal CVD events (HR, 0.27 [95% CI, 0.08 to 0.88]; *P* = .03). When fatal cardiovascular events were included and trial data were combined, results were similar (HR, 0.31 [95% CI, 0.11 to 0.93]; *P* = .04).[139]

Fifteen trials reported health-related quality of life outcomes, using various measures.[28,29,34,48,68,76,79,82,93,94,107,124,130,136,143] While many studies showed improvements in quality of life among intervention participants, only 3 trials demonstrated statistically significant differences between intervention and control groups on at least 1 quality of life subscale at 6 months' or more follow-up.[68,93,143] In most cases, very small improvements (eg, less than a 1-point improvement on the SF-36 [36-Item Short Form Health Survey] score) were seen in both intervention and control groups.

Benefits on Intermediate CVD Outcomes

Key Question 2. Do primary care–relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve intermediate outcomes associated with CVD (eg, blood pressure, lipid levels, blood glucose levels, and body mass index) in adults without known CVD risk factors?

Forty-three of the included trials (n = 77 965) reported the effects of a behavioral intervention on at least 1 intermediate health outcome at 6 months or more of follow-up. When results of these

trials were pooled in meta-analyses, healthy diet and physical activity interventions were associated with small but statistically significant improvements in blood pressure, LDL-C level, and all measures of adiposity (BMI, weight, waist circumference) compared with controls at 6 months or more (**Table 2**).

Individually, very few of the trials found statistically significant differences in changes in SBP or DBP between intervention and control groups. However, the pooled mean difference between groups in blood pressure reductions showed statistically significant associations with mean differences of −0.80 mm Hg for SBP (95% CI, −1.30 to −0.31; 23 RCTs [n = 57 079]; I^2 = 11.3%) (eFigure 1 in the Supplement) and −0.42 mm Hg for DBP (95% CI, −0.80 to −0.04; 24 RCTs [n = 57 148]; I^2 = 35.8%) (eFigure 2 in the Supplement), respectively, at 6 to 18 months compared with controls. Results of meta-regressions and subgroup analyses based on various study, population, and intervention characteristics showed that there were consistent intervention effects on SBP and DBP regardless of these varying characteristics.

For LDL-C, meta-analysis of 15 trials resulted in a statistically significant association, with a mean difference in change of −2.20 mg/dL (approximately 0.057 mmol/L) between groups at 6 to 18 months of follow-up (95% CI, −3.80 to −0.60; n = 6350; I^2 = 25.7%) (eFigure 3 in the Supplement). When stratified by intervention intensity, this decrease was significant only among the 8 high-intensity interventions, with a mean difference of −3.88 mg/dL (95% CI, −6.15 to −1.61) between groups. Similarly, a dose-response association was seen, with greater effect sizes associated with increasing duration of the intervention, the number of total intervention sessions, and the number of in-person sessions. There was no significant association between healthy diet, physical activity interventions, or both and levels of total cholesterol or high-density lipoprotein cholesterol in pooled analyses.

There were inconsistent results across studies that reported mean differences in changes in fasting glucose levels, and with few exceptions[93,115] none of the individual trials reported statistically significant differences in fasting glucose changes at 6 months or more follow-up. Furthermore, a meta-analysis of 14 trials found no significant association between interventions and changes in fasting glucose levels vs control groups at 6 to 12 months (mean difference, −0.34 mg/dL [95% CI, −1.24 to 0.55] [0.02 mmol/L {95% CI, −0.07 to 0.03 mmol/L}]; n = 7468; I^2 = 42.7%).

Although trials that addressed weight loss as a direct goal of the interventions were excluded, the included trials reported small improvements in BMI, weight, and waist circumference (Table 2). Considerable statistical heterogeneity (I^2 > 90%) was present in all analyses because of wide variation in effect estimates and precision around those estimates, which likely reflects clinical variability among the included studies. The meta-analysis of BMI measures showed a pooled difference in mean change of −0.32 (95% CI, −0.51 to −0.13; 27 RCTs [n = 59 239]; I^2 = 94.6%) related to healthy diet and physical activity interventions (eFigure 4 in the Supplement). The subset of 12 high-intensity interventions consistently showed benefit of the interventions on BMI, with a pooled difference in mean change of −0.69 supporting the intervention (95% CI, −0.99 to −0.40); no such benefit was seen among the subsets of medium- or low-intensity interventions (eFigure 4 in the Supplement). Furthermore, a dose-response association was seen, with increasing intensity (ie, total minutes of intervention contact) and the total number

Table 1. Summary of Study and Population Characteristics

Characteristics	RCTs, No. (%)
All studies	113 (100)
KQ[a]	
1: Health outcomes	15 (13)
2: Intermediate outcomes	43 (38)
3: Behavioral outcomes	109 (97)
4: Harms	23 (20)
Study design	
RCT	93 (82)
Cluster RCT	20 (18)
New study	33 (29)
Good-quality rating	23 (20)
Conducted in the US	60 (53)
Sample size, median (IQR) [range]	314 (200-710) [32-48 835]
Follow-up at 12 mo or closest, median (IQR) [range], %	86 (77-91) [38-100]
Population selection[b]	
Unselected	53 (47)
Suboptimal behavior	46 (41)
Elevated risk	14 (12)
Recruitment setting	
Primary care	37 (33)
Community volunteer	23 (20)
Direct mailing	15 (13)
Mixed	20 (18)
Other	17 (15)
Not reported	1 (1)
Age (105 studies), weighted mean (SD)	54 (12)
Trials restricted to older adults (≥60 y), No./total (%)	15/113 (13)
Female (113 studies), % (SD)[c]	80 (20)
Current smokers (41 studies), % (SD)	10 (7)
BMI (79 studies), weighted mean (SD)[d]	28 (2)
Trials restricted to persons with excess weight, No./total (%)	11/113 (10)
Trials majority Hispanic or non-White, No./total (%)[e,f,g]	20/60 (33)
Trials targeted low socioeconomic status population, No./total (%)[h]	14/113 (12)

Abbreviations: BMI, body mass index; KQ, key question; RCT, randomized clinical trial.

[a] Total percentage does not equal 100 because studies could be included for more than 1 KQ.

[b] According to trial eligibility criteria. "Unselected" includes a general population sample representing "all comers" or those recruited based on a sociodemographic characteristic alone; "suboptimal behavior," samples selected because they were not meeting specific thresholds for dietary or physical activity behaviors; "elevated risk," samples selected because they may have elevated risk for cardiovascular disease (CVD) based on family history, personal history (eg, gestational diabetes), or being overweight or having obesity. Trials limited to persons with CVD risk factors (eg, elevated blood pressure, dyslipidemia or elevated lipid levels, impaired fasting glucose or impaired glucose tolerance, or multiple risk factors) were excluded.

[c] Twenty-six trials were limited to women.

[d] Calculated as weight in kilograms divided by height in meters squared.

[e] Thirteen trials were limited to Hispanic or non-White persons.

[f] Limited to trials in the US (60 trials).

[g] Where more than 50% of sample was non-White or Hispanic; assumed majority White, non-Hispanic if race and ethnicity not reported.

[h] Study described targeting a low-resource community or recruitment resulted in a sample with high unemployment, low educational attainment, or very low income.

Table 2. Pooled Results of Intermediate Outcomes

Outcome	Difference in mean changes (95% CI)	RCTs (No. of participants enrolled)	I^2, %
Blood pressure, mm Hg			
Systolic	−0.80 (−1.30 to −0.31)	23 (57 079)	11.3
Diastolic	−0.42 (−0.80 to −0.04)	24 (57 148)	35.8
Total cholesterol, mg/dL	−1.58 (−4.21 to 1.04)	21 (10 122)	68.8
LDL-C, mg/dL	−2.20 (−3.80 to −0.60)	15 (6350)	25.7
HDL-C, mg/dL	−0.12 (−1.04 to 0.80)	17 (7527)	51.4
Fasting plasma glucose, mg/dL	−0.34 (−1.24 to 0.55)	14 (7468)	42.7
BMI[a]	−0.32 (−0.51 to −0.13)	27 (59 239)	94.6
Weight, kg	−1.07 (−1.62 to −0.52)	24 (51, 812)	91.2
Waist circumference, cm	−0.81 (−1.32 to −0.30)	23 (52 128)	96.1

Abbreviations: BMI, body mass index; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; RCT, randomized clinical trial.

SI conversion factors: To convert total cholesterol, LDL-C, and HDL-C values to mmol/L, multiply by 0.0259; fasting plasma glucose values to mmol/L, multiply by 0.0555.

[a] Calculated as weight in kilograms divided by the square of height in meters.

Table 3. Pooled Results of Behavioral Outcomes

Outcome	Effect size (95% CI)	No. of RCTs (No. of participants enrolled)[a]	I^2, %
Saturated fat			
SMD	−0.53 (−0.78 to −0.27)	16 (48 661)	97.4
Mean difference in % of energy from fat	−2.01 (−3.19 to −0.84)	9 (46 772)	98.1
Fruits and vegetables, mean difference in servings/d	1.11 (0.41 to 1.81)	17 (53 711)	99.3
Fiber			
SMD	0.24 (0.05 to 0.43)	13 (47 571)	93.9
g/d	1.05 (0.59 to 1.51)	8 (2414)	0
Sodium, mg/d[b]	Range, −4.9 to −383.0	4 (1444)	NA
Physical activity			
SMD	0.19 (0.14 to 0.25)	59 (20 801)	65.4
Mean difference, min/wk	33.0 (21.9 to 44.2)	37 (15 015)	76.0
Meeting physical activity recommendations	OR, 1.41 (1.18 to 1.67)	24 (17 338)	55.1
Sedentary behavior, SMD	−0.22 (−0.47 to 0.03)	15 (3479)	89.9

Abbreviations: OR, odds ratio; RCT, randomized clinical trial; SMD, standardized mean difference.

[a] Number of trials included in meta-analyses. Not all trials reporting each outcome could be included in meta-analyses given units or data reported. Total number of trials and observations reporting outcome were: dietary fat (17 trials, n = 57 470), fruits and vegetables (35 trials, n = 80 366), fiber (14 trials, n = 58 541), sodium (4 trials, n = 1444), physical activity (85 trials, n = 52 838), and sedentary behavior (16 trials, n = 5867).

[b] Not meta-analyzed, given few trials reporting this outcome.

of in-person intervention sessions being statistically significantly associated with increasing effect estimates in meta-regression. 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 (mean difference, −1.07 kg [95% CI, −1.62 to −0.52]; 24 RCTs [n = 51 812]; I^2 = 91.2%) (eFigure 5 in the Supplement). This finding translates into a mean difference of −2.4 lb (95% CI, −3.6 to −1.1).

Benefits on Health Behaviors

Key Question 3. Do primary care–relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve intermediate behavioral outcomes (eg, diet, physical activity, and sedentary behavior) in adults without known CVD risk factors?

All but 4[26,47,123,134] of the 113 included trials were included for KQ3 (n = 125 878); 45 trials (n = 89 140) reported 1 or more dietary outcomes and 87 trials (n = 54 534) reported 1 or more measures of physical activity. The specific behavioral outcomes, measures, and units of measurement were highly variable across the included trials.

Between-group differences in mean change for dietary outcomes showed consistent benefit of the intervention vs control groups, but the precision in the magnitude of effects was variable across the trials that reported each respective outcome (**Table 3**). Furthermore, there was considerable statistical heterogeneity (I^2 > 90%) present in most meta-analyses. Nevertheless, meta-analysis indicated statistically significant associations between healthy diet counseling interventions and measures of saturated fat (standardized mean difference [SMD], −0.53 [95% CI, −0.78 to −0.27]; 16 RCTs [n = 48 661]; I^2 = 97.4%), fruit and vegetables (mean difference, 1.11 servings/d [95% CI, 0.41 to 1.81]; 17 RCTs [n = 53 711]; I^2 = 99.3%), and fiber (SMD, 0.24 [95% CI, 0.05 to 0.43]; 13 RCTs [n = 47 571]; I^2 = 93.9%) intake.

The meta-analysis of the SMD in change in continuous measures of physical activity (eg, minutes per week, kcal/kg per day, steps per day) showed a small but statistically significant association between physical activity interventions and an increase in physical activity levels compared with controls at 6 to 12 months of follow-up (SMD, 0.19 [95% CI, 0.14 to 0.25]; 59 RCTs [n = 20 801]; I^2 = 65.4%) (Table 3). Among the 37 trials that reported minutes per week of physical activity, this change amounted to approximately 33 additional minutes of physical activity per week for the intervention group compared with the control group (mean difference, 33.0 min/wk [95% CI, 21.9 to 44.2]; n = 15 015; I^2 = 76.0%).

Twenty-four trials reported the proportion of participants meeting recommended levels of physical activity (at least 150 minutes of moderate to vigorous–intensity physical activity) at 6 months to 2 years of follow-up. The meta-analysis of all 24 trials showed that physical activity interventions were associated with a higher odds of meeting physical activity recommendations at 6 to 12 months of follow-up compared with control interventions (pooled odds ratio, 1.41 [95% CI, 1.18 to 1.67]; 24 RCTs [n = 17 338]; I^2 = 55.1%).

Sixteen trials (n = 5867) reported measures of sedentary behavior, independent of physical activity.[29,33,34,39-41,46,50,62,82,89,102,116,119,130,136] The measures and results were highly variable. When measures were combined, the standardized effect of the interventions did not show a statistically significant difference between groups at 6 to 12 months of follow-up, although the effect was in the direction of intervention benefit (SMD, −0.22 [95% CI, −0.47 to 0.03]; 15 trials [n = 3479]; I^2 = 89.9%).

Harms

Key Question 4. What are the harms of primary care–relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior in adults without known CVD risk factors?

Twenty-three of the 113 included trials specifically mentioned the occurrence of adverse events or lack of adverse events (n = 12 452). Thirteen trials reported adverse events or serious adverse events of any kind,[29-31,33,41,48,51,56,62,82,114,132,136] although 7 of these trials only stated that no adverse events were reported or that no adverse events related to the trial were evident but no additional details were provided.[33,41,51,62,114,132,136] The other 6 trials found that rates of adverse events were relatively similar across groups (ranging from 22.6% to 80% of intervention group participants and 25.4% to 71% of control group participants), and none reported rates of any adverse events to be statistically significantly different between groups.[29-31,48,56,82] Twelve trials reported the incidence of musculoskeletal injuries, fractures, or falls and found primarily no differences between treatment groups.[29,42,59,68,82,92,94,96,107,120,130,134]

Discussion

This review included 113 unique trials, of which 33 (29%) were published since the 2017 USPSTF review.[12] The pooled effect estimates found in the updated systematic review are consistent in magnitude with those from the 2017 review on this topic[12] and lower in magnitude than the effects seen with the 2020 review among persons at high risk for CVD.[144] The evidence is summarized in **Table 4**.

By design, the current review excluded studies that recruited individuals at high risk of CVD—defined only by the presence of elevated blood pressure, elevated lipid levels, or impaired fasting glucose. In all other ways, the persons represented in the trials exhibited a broad range of sociodemographic and behavioral characteristics. Very few trials reported the underlying CVD risk of participants at baseline (ie, the proportion of participants with existing hypertension or dyslipidemia). While this review was designed to represent persons not at risk of CVD, it is possible that not all participants within the included evidence were of average CVD risk; at best, it is known that they were not recruited into these trials because of an underlying risk.

Although most studies recruited participants directly (via invitations through primary care, the broader health care system, or some other convenience sample), the adults who took part in these studies may have been more motivated to change their behaviors than those in the general community. Given the broad representation across population characteristics and that most of the studies took place in the US, the findings of this review are likely generalizable to a US primary care population, although the magnitude of the effects may be lower when applied to general practice.

Based on the included literature, it is not possible to define either the minimum necessary intervention components for an effective intervention or identify a single optimal or representative intervention. No two studies had the same goals, behavior change messages, modes of delivery, or delivery schedule. Across all interventions, most included tailored advice and materials and encouraged goal setting and self-monitoring. A substantial number of the trials, including many of the newer studies, used interventions that were administered completely remotely—either via telephone or printed materials—or were computer- or e-mail-based.

Although there was general consistency in the direction of beneficial effects among all the trials, there was variation in the magnitude of the effects, and there was often wide variation within studies. This variation likely reflects that even within studies, some participants can achieve greater change while others may not. Most likely, 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. Furthermore, it is likely that there are many social determinants of health at play (eg, food insecurity, low-income status) that may affect the size of the effects seen. Very limited data were provided on the underlying social conditions (ie, risks and inequities) present among the included samples.

Limitations

This review has several limitations. First, few studies were included that reported measures of intermediate cardiometabolic outcomes, and even fewer were included that reported longer term health outcomes. Because the prevalence and rate of these health outcomes are lower in lower-risk groups (by definition), these studies require larger sample sizes and longer follow-up to observe an effect of an intervention in a low-risk group of participants.[145] Second, very few of the included trials explored whether effectiveness of the interventions varied among important populations. Such analyses could assist in identifying groups of adults who might benefit more and help reduce disparities that exist related to cardiovascular-related health. Third, given that behavioral outcomes were the primary outcomes in almost all the included studies, there is a need for better standardization related to the collection and reporting of these outcomes. Fourth, given the strong evidence that greater time spent in sedentary behavior is independently associated with all-cause and CVD mortality[146] and clear guidance that individuals should limit the amount of time spent being sedentary,[147] there is a need for trials evaluating interventions designed to reduce sedentary behaviors.

Table 4. Summary of Evidence, by Key Question

No. of RCTs	Summary of findings	Consistency and precision	Other limitations	Strength of evidence	Applicability
KQ1: Benefits on health outcomes					
15 RCTs (n = 58 286) (6/15 trials identified in update)	Three good-quality trials (n = 48 382) reported CVD-related health outcomes at up to 4 y and 13.4 y of follow-up Largest trial (n = 47 179) among postmenopausal women found no difference in all-cause or CVD-related mortality or CVD events between women in dietary counseling group vs control group over median follow-up of 8.5 and 13.4 y Two other trials of 12-wk pedometer-based physical activity interventions found low CVD event rates for all participants, with statistically significant intervention effects on nonfatal and fatal CVD events at 4 y when the data from both trials were combined (n = 1203) Patient-reported QOL measures were sparsely reported and showed no clear pattern of clinically important benefit at 6 to 12 mo of follow-up (15 trials [n = 58 286])	Mortality and CVD events: inconsistent, imprecise QOL: inconsistent, imprecise	Sparsely reported outcomes High variability in measures and reporting of QOL outcomes, with possible selective reporting bias	Mortality and CVD events: low for no benefit QOL: low for no benefit	Mortality and CVD event data limited to 1 large trial among postmenopausal women in the US and 2 primary care–based trials in the UK Most participants were middle-aged (>45 y) and older (>60 y) adults who were predominantly White females, without a history of CVD QOL data limited to mostly physical activity trials
KQ2: Benefits on intermediate CVD outcomes					
43 RCTs (n = 77 898) (14/43 trials identified in update)	Healthy diet and physical activity behavioral interventions were associated with small, statistically significant reductions in blood pressure, LDL-C level, and measures of adiposity at 6 to 12 mo of follow-up Pooled differences in mean changes: SBP: −0.80 mm Hg (95% CI, −1.30 to −0.31); 23 RCTs (n = 57 079) DBP: −0.42 mm Hg (95% CI, −0.80 to −0.04); 24 RCTs (n = 57 148) LDL-C: −2.20 mg/dL (95% CI, −3.80 to −0.60); 15 RCTs (n = 6350) BMI: −0.32 (95% CI, −0.51 to −0.13); 27 RCTs (n = 59 239) Weight: −1.07 kg (95% CI, −1.62 to −0.52); 24 RCTs (n = 51 812) Evidence of dose-response effect with increasing intervention contact and duration associated with larger improvements in intermediate outcomes No evidence of an association with total cholesterol, HDL-C, or FBG	Reasonably consistent, reasonably precise	Evidence for each intermediate outcome drawn from subsample of full body of evidence Limited evidence beyond 12 mo or for incidence of hypertension, dyslipidemia, or diabetes Considerable statistical heterogeneity (I^2 > 90%) for meta-analyses of adiposity outcomes	Moderate for benefit	Generally applicable to adults not at risk for CVD High-intensity interventions were more likely to include both healthy diet and physical activity messages and take place outside of primary care

(continued)

Table 4. Summary of Evidence, by Key Question (continued)

No. of RCTs	Summary of findings	Consistency and precision	Other limitations	Strength of evidence	Applicability
KQ3: Benefits on Health Behaviors					
109 RCTs (n = 125 878) (30/109 trials identified in update)	Magnitude and precision in differences for dietary outcomes were variable across studies and resulted in considerable heterogeneity in meta-analysis Pooled analyses indicated statistically significant associations between healthy diet interventions (with or without physical activity messages) and measures of saturated fat (SMD, 0.53 [95% CI, −0.78 to −0.27]; 16 RCTs), fiber (SMD, 0.24 [95% CI, 0.05 to 0.43]; 13 RCTs), and fruit and vegetable (mean difference, 1.11 [95% CI, 0.41 to 1.81] intake; 17 RCTs) at 6 to 12 mo of follow-up Sodium intake was infrequently reported Small, statistically significant association with behavioral interventions and physical activity in favor of interventions over controls (SMD, 0.19 [95% CI, 0.14 to 0.25]; 59 RCTs [n = 20 801]), or a mean difference of approximately 33 min of physical activity per wk between groups (mean difference, 33.0 min [95% CI, 21.9 to 44.2]; 37 RCTs) Additionally, intervention participants had significantly higher odds of meeting physical activity recommendations (150 min/wk of physical activity) vs control group participants (OR, 1.41 [95% CI, 1.18 to 1.67]; 24 RCTs) No clear evidence of an association between interventions and sedentary behaviors, though few studies included messages regarding changes in sedentary behaviors (15 RCTs)	Reasonably consistent, reasonably precise	Almost all outcomes based on self-report Instruments, recall periods, and summary measures were extremely heterogeneous, with varying evidence of validity and reliability	Diet: low for benefit Physical activity: moderate for benefit Sedentary behavior: low for no benefit	Generally applicable to adults not at risk for CVD Larger effect sizes for physical activity outcomes were seen for persons with lower levels of physical activity at baseline Few interventions explicitly mentioned targeting changes in sedentary behaviors
KQ4: Harms					
23 RCTs (n = 12 452) (12/23 trials identified in update)	Adverse events related to diet and physical activity interventions were very rare, with generally no statistically significant increased risk of harm Twelve trials (n = 5771) including physical activity counseling reported generally no differences in rates of musculoskeletal injuries or falls between intervention and control groups	Reasonably consistent, reasonably precise	Harms were sparsely reported, and few details were provided about how harms were recorded and specific events that occurred	Moderate for no harms[a]	Applies to harms related to counseling interventions and to any subsequent behavior changes that occurred Most trials reporting harms included physical activity messages

Abbreviations: BMI, body mass index; CVD, cardiovascular disease; DBP, diastolic blood pressure; FBG, fasting blood glucose; HDL-C, high-density lipoprotein cholesterol; KQ, key question; LDL-C, low-density lipoprotein cholesterol; OR, odds ratio; QOL, quality of life; RCT, randomized clinical trial; SBP, systolic blood pressure; SMD, standardized mean difference.

SI conversion factor: To convert LDL-C values to mmol/L, multiply by 0.0259.

[a] Despite the relatively limited number of studies that reported harms related to interventions, there is moderate confidence that there are no serious harms related to behavioral counseling interventions for healthful diet and physical activity.

Conclusions

Healthy diet and physical activity behavioral interventions for persons without a known risk of CVD were associated with small but statistically significant benefits across a variety of important intermediate health outcomes and small to moderate effects on dietary and physical activity behaviors. There was limited evidence regarding the long-term health outcomes or harmful effects of these interventions.

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Concept and design: Patnode.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Patnode, Iacocca.
Critical revision of the manuscript for important intellectual content: Patnode, Redmond, Henninger.
Statistical analysis: Patnode, Redmond.
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