

Behavioral Counseling to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors

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

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IMPORTANCE Cardiovascular disease is the leading cause of death in the US, and poor diet and lack of physical activity are major factors contributing to cardiovascular morbidity and mortality.

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

DATA SOURCES MEDLINE, PubMed, PsycINFO, and the Cochrane Central Register of Controlled Trials through September 2019; literature surveillance through July 24, 2020.

STUDY SELECTION English-language randomized clinical trials (RCTs) of behavioral counseling interventions to help people with elevated blood pressure or lipid levels improve their diet and increase physical activity.

DATA EXTRACTION AND SYNTHESIS Data were extracted from studies by one reviewer and checked by a second. Random-effects meta-analysis and qualitative synthesis were used.

MAIN OUTCOMES AND MEASURES Cardiovascular events, mortality, subjective well-being, cardiovascular risk factors, diet and physical activity measures (eg, minutes of physical activity, meeting physical activity recommendations), and harms. Interventions were categorized according to estimated contact time as low (≤ 30 minutes), medium (31-360 minutes), and high (>360 minutes).

RESULTS Ninety-four RCTs were included (N = 52 174). Behavioral counseling interventions involved a median of 6 contact hours and 12 sessions over the course of 12 months and varied in format and dietary recommendations; only 5% addressed physical activity alone. Interventions were associated with a lower risk of cardiovascular events (pooled relative risk, 0.80 [95% CI, 0.73-0.87]; 9 RCTs [n = 12 551]; $I^2 = 0\%$). Event rates were variable; in the largest trial (Prevención con Dieta Mediterránea [PREDIMED]), 3.6% in the intervention groups experienced a cardiovascular event, compared with 4.4% in the control group. Behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure, low-density lipoprotein cholesterol levels, fasting glucose levels, and adiposity at 12 to 24 months' follow-up. Measurement of diet and physical activity was heterogeneous, and evidence suggested small improvements in diet consistent with the intervention recommendation targets but mixed findings and a more limited evidence base for physical activity. Adverse events were rare, with generally no group differences in serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, or withdrawals due to adverse events.

CONCLUSIONS AND RELEVANCE Medium- and high-contact multisession behavioral counseling interventions to improve diet and increase physical activity for people with elevated blood pressure and lipid levels were effective in reducing cardiovascular events, blood pressure, low-density lipoproteins, and adiposity-related outcomes, with little to no risk of serious harm.

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Risk factors for cardiovascular disease (CVD), such as high blood pressure and high cholesterol and lipid levels, are common in the US and contribute to excess mortality.¹ Counseling to encourage a healthy diet and physical activity in populations with CVD risk factors can improve blood pressure, cholesterol levels, and other outcomes.² While observational evidence shows associations between lower levels of CVD risk factors and lower cardiovascular-related mortality,³⁻⁵ trial evidence regarding the effectiveness of behavioral counseling on reducing CVD events and mortality is sparse.

This systematic review was conducted to provide updated evidence on the benefits and harms of behavioral counseling for healthy diet and physical activity in adults with CVD risk factors to inform an update of the 2014 US Preventive Services Task Force (USPSTF) recommendation.⁶ In 2014, the task force recommended offering or referring adults who were overweight or had obesity and had additional CVD risk factors to intensive behavioral counseling interventions to promote a healthy diet and physical activity for CVD prevention (B recommendation). This review was conducted in parallel with a review addressing abnormal blood glucose levels⁷ and complements other USPSTF reviews related to primary prevention of CVD.⁸⁻¹³

Methods

Scope of Review

This review addressed 4 key questions (KQs) (Figure 1). 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.¹⁵

Data Sources and Searches

MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials were searched to identify literature published after the previous review for the USPSTF.¹⁶ Searches covered literature published January 2013 through September 2019 (eMethods in the Supplement). All studies in the prior review¹⁶ were also evaluated, as well as reference lists of related systematic reviews.^{9,17}

ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform were searched for relevant ongoing trials. Active surveillance was conducted through July 24, 2020, via article alerts and targeted journal searches to identify major studies that might affect the conclusions or understanding of the evidence. None were identified.

Study Selection

Investigators reviewed 14 409 unique citations and 466 full-text articles against a priori inclusion criteria (Figure 2; eTable 1 in the Supplement). Disagreements were resolved via discussion and consultation with another reviewer. Eligible studies were fair- and good-quality RCTs that evaluated the effectiveness of primary care-relevant interventions of behavioral counseling for diet and nutrition, physical activity (including sedentary behavior), or both in adults with CVD risk factors. Studies had to target populations at increased risk of CVD due to hypertension or elevated

blood pressure, dyslipidemia, or through examination of multiple risk factors. These could include estimated 10-year CVD risk of 7.5% or higher (eg, using the Pooled Cohort Equations¹⁸ or Framingham risk calculators¹⁹), presence of metabolic syndrome, or having any of multiple CVD risk factors as long as hypertension/elevated blood pressure and dyslipidemia were among them. In contrast to the review to support the 2014 recommendation, the current review excluded studies limited to or predominantly in populations with diabetes or prediabetes because a separate systematic review will address these populations.⁷ In addition, weight loss trials targeting people with relevant CVD risk factors were included in this review but not in the previous review.

Interventions could be delivered alone or as part of a larger intervention that also addressed other health behaviors (eg, smoking cessation). Additionally, interventions had to have been conducted in countries with "very high" human development according to the United Nations²⁰ and take place or be feasible in a health care setting. Studies had to report a 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 related to the intervention. Comparative effectiveness trials without a true control group were excluded.

Data Extraction and Quality Assessment

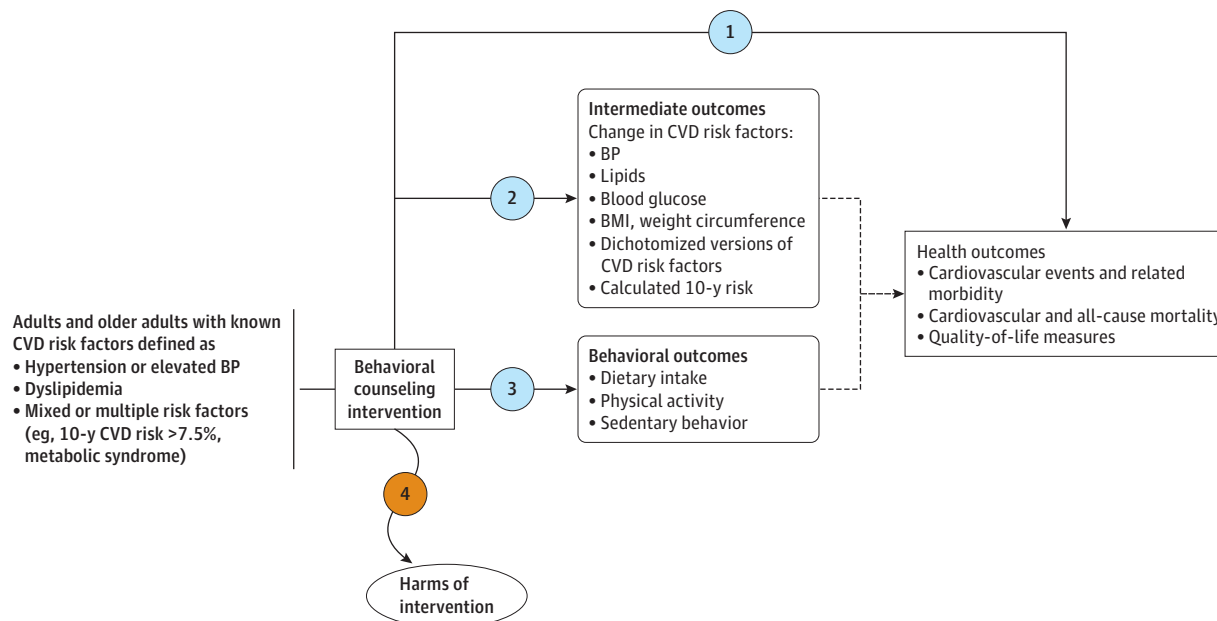
Two reviewers independently assessed the methodological quality of eligible studies using criteria outlined by the USPSTF (eTable 2 in the Supplement).¹⁴ Each study was assigned a quality rating of "good," "fair," or "poor," and disagreements between investigators were resolved through consensus after discussion with additional investigators. Studies rated as poor were excluded.¹⁴ Poor-quality studies typically had several major risks of bias, including very high attrition (generally >40%), differential attrition between intervention groups (generally >20%), substantial lack of baseline comparability between groups without adjustment for those variables, or other issues judged to considerably bias the results (eg, possible selective reporting, inappropriate exclusion of participants from analyses, questionable validity of randomization and allocation concealment procedures). One reviewer abstracted descriptive and outcome data from each included study into standardized evidence tables; a second checked for accuracy and completeness.

Data Synthesis and Analysis

Summary tables were created for study characteristics, population characteristics, intervention characteristics, and outcomes. Methods consistent with the previous review were used to estimate and categorize the total contact time of each intervention group as low (≤ 30 minutes), medium (31-360 minutes [6 hours]), or high (>360 minutes).

All outcomes were quantitatively pooled except for patient-reported measures of subjective well-being (KQ1), dietary pattern scores (KQ3), and adverse events (KQ4), which were summarized descriptively. For mortality and cardiovascular event outcomes (KQ1), results for multiple intervention groups were combined because the absolute number of events was generally small.

Figure 1. Analytic Framework: Behavioral Counseling to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors



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

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. Details available in the USPSTF Procedure Manual.¹⁴ BMI indicates body mass index; BP, blood pressure; CVD, cardiovascular disease.

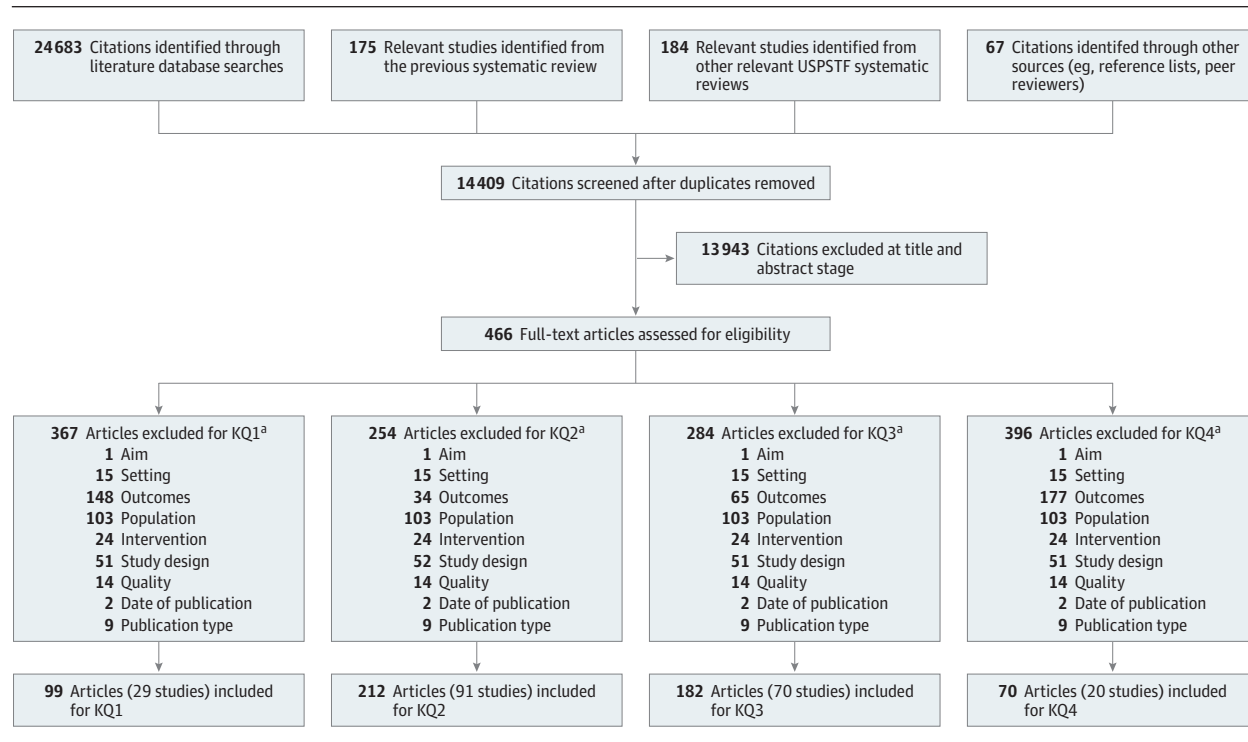
Meta-analyses for intermediate (KQ2) and behavioral (KQ3) outcomes were conducted using the most comprehensive or highest-contact intervention group if a study had multiple intervention groups and using the follow-up time point closest to 12 months if there were multiple follow-up assessments. Adjusted effect estimates reported by primary studies were used over unadjusted values, and crude effect estimates were calculated if between-group results were not reported. For pooling, the Restricted Maximum Likelihood model with the Knapp-Hartung correction^{21,22} was used. The presence of statistical heterogeneity among the studies was assessed using standard χ^2 tests, and the magnitude of heterogeneity 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 commonly reported outcomes of systolic blood pressure (SBP), total cholesterol, and weight. In addition, small-study effects were evaluated using funnel plots and the Egger test.²³

Stata version 15.1 (StataCorp) and R version 3.5.2 (R Foundation for Statistical Computing) were used for all quantitative analyses. All significance testing was 2-sided, and results were considered statistically significant at $P < .05$.

The aggregate strength of evidence was assessed for each KQ using the approach described in the Methods Guide for Effectiveness and Comparative Effectiveness Reviews,²⁴ based on the number, quality, and size of studies and the consistency and precision of results between studies.

Figure 2. Literature Search Flow Diagram: Behavioral Counseling to Promote a Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors



KQ indicates key question.

^a Reasons for exclusion: Aim: Study aim not relevant. Setting: Study was not conducted in a country relevant to US practice or study was conducted in intermediate care facility or otherwise unrepresentative setting. Outcomes: Study did not report relevant outcomes. Population: Symptomatic, 50% or more with coronary heart disease or diabetes; 50% or more with prediabetes;

age not 18 years or older. Intervention: Study used an excluded intervention or intervention aim was irrelevant. Study design: Not an included study design. Comparative effectiveness: follow-up 6 months or less. Quality: Study did not meet criteria for fair or good quality. Publication type: Ancillary study to excluded primary study.

Results

Ninety-four randomized and cluster-randomized clinical trials reported in 227 publications were included (N = 52 174) (Figure 2; eTable 3 in the Supplement).²⁵⁻²⁵⁰ Fifty-two trials were carried forward from the previous review^{30,31,35,37,40-42,45,53,55,56,61-63,72,74,80,87,90,99,121,123,130,131,134,138,145,147,149,155,174,176-178,180,181,192,193,208,210,215,217,223,225,227,229,231,234,238,242,244,247} and were synthesized with 42 newly identified trials.^{36,46-48,51,69-71,73,92,97,110,111,115,118,124,127,132,139,142,144,148,152,158,163,165,182,183,187,190,194,196,200,203,205,207,216,220,221,237,241,245} Of 94 studies, 32 (34.0%) were limited to people with hypertension or elevated blood pressure, 16 (17.0%) were limited to those with dyslipidemia or elevated lipid levels, and the remaining 46 (49.0%) included people with any of multiple risk factors (Table 1). Most participants were overweight or had obesity, and the mean baseline body mass index (BMI) was 29.8 (calculated as weight in kilograms divided by height in meters squared) (eTable 4 in the Supplement). Forty-three trials (45.7%) were conducted in the US; of these, 16 trials appeared to include majority Hispanic or non-White samples. The majority of trials recruited participants from health care settings, but most interventions did not involve a primary care clinician. Almost all trials addressed diet, with or without physical activity, and had at least 30 minutes of contact time (eTable 5

in the Supplement). Very few intervention groups (6/120 [5.0%]) addressed physical activity alone. The median number of contacts was 12 (interquartile range [IQR], 5-27), with an estimated 6 (IQR, 2.2-15.8) hours of contact over 12 (IQR, 6-18) months. Interventions varied widely in format and dietary recommendations, and 23 (19.2%) also included medication management.

Benefits of Interventions

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 outcomes (eg, morbidity, mortality) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [eg, 10-year CVD risk >7.5%, metabolic syndrome])?

Twenty-nine of the 94 studies reported health outcomes. Of these, 12 trials reported CVD events, with follow-up ranging from 6 months to 16 years.^{37,46,47,55,97,99,124,127,220,221,241,242} All had medium or high intervention contact time. Behavioral counseling was associated with lower risk of the composite outcomes of any CVD events (risk ratio [RR], 0.80 [95% CI, 0.73 to 0.87]; 9 RCTs [n = 12 551]; *I*² = 0%), myocardial infarction (RR, 0.85 [95% CI, 0.70 to 1.02]; 6 RCTs [n = 10 375]; *I*² = 0%), and stroke (RR, 0.52 [95% CI, 0.25 to 1.10]; 4 RCTs [n = 9800]; *I*² = 0%), although the pooled

Table 1. Summary of Study Characteristics of All Included Studies (94 Studies, N = 52 174), Overall and by Risk Focus

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

Abbreviations: IQR, interquartile range; RCT, randomized clinical trial; SBP, systolic blood pressure.

^a Includes trials limited to persons with hypertension or elevated blood pressure.

^b Includes trials limited to persons with dyslipidemia or elevated lipid levels.

^c Twelve additional studies were rated as poor quality and excluded from the review; the remainder were rated fair quality.

effect size showed a statistically significant association only for the composite outcome of any CVD events (Figure 3). Only 3 of these trials were included in the previous review.^{37,99,242} The newly included Prevención con Dieta Mediterránea (PREDIMED) study⁹⁷ was heavily weighted in this analysis because of its large sample size; however, the association remained statistically significant in a sensitivity analysis excluding PREDIMED (RR, 0.79 [95% CI, 0.70 to 0.90]; 8 RCTs [n = 5104]). Event rates were variable; in PREDIMED 3.6% in the intervention groups experienced a cardiovascular event, compared with 4.4% in the control group.

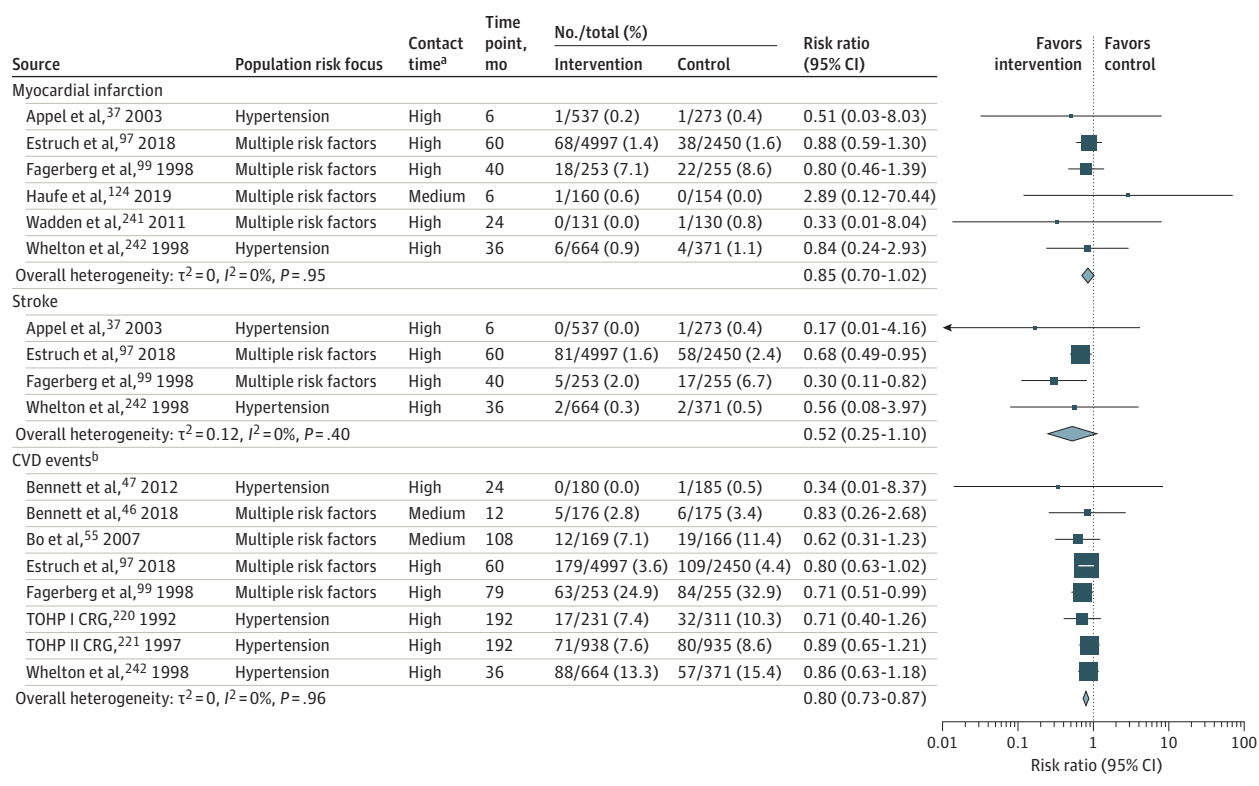
Few studies were powered for mortality, and neither individual large studies nor the pooled estimate showed a beneficial association with all-cause mortality (RR, 0.89 [95% CI, 0.71 to 1.11]; 18 RCTs [n = 17 939]; I² = 0%) with follow-up of 6 months to 16 years. Among 3 large trials,^{97,99,221} findings for both all-cause and cardiovascular mortality indicated greater benefit for intervention participants relative to control participants; however, results were statistically significant in only 1 trial.⁹⁹ Patient-reported well-being

measures were reported in 11 trials,^{36,37,42,62,99,110,115,124,148,200,231} but group differences were generally very small and statistically nonsignificant.

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, body mass index) in adults with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [eg, 10-year CVD risk >7.5%, metabolic syndrome])?

All but 3 trials reported intermediate outcomes.^{87,180,231} Behavioral counseling interventions were associated with small, statistically significant reductions in continuous measures of blood pressure, low-density lipoprotein cholesterol (LDL-C) and total cholesterol levels, fasting glucose levels, and adiposity-related outcomes at 12 to 24 months' follow-up (Table 2).

Figure 3. CVD Events (Key Question 1)



CVD indicates cardiovascular disease; RR, risk ratio; TOHP I CRG, Trials of Hypertension Prevention-Phase I Collaborative Research Group; TOHP II CRG, Trials of Hypertension Prevention-Phase II Collaborative Research Group. Random-effects restricted maximum likelihood model with Knapp-Hartung confidence intervals. Size of data markers indicates weight of each study in the analysis.

^a Intervention contact time defined as low (0-30 minutes), medium (31-360 minutes), or high (>360 minutes).

^b Hinderliter et al¹²⁷ reported no CVD events in both groups (not shown on plot).

There was a mean 1.8-mm Hg/1.2-mm Hg greater reduction in blood pressure in intervention groups vs control groups after 12 to 24 months (pooled SBP mean difference, -1.8 [95% CI, -2.5 to -1.1]; 42 RCTs [44 effects, n = 14 580]; $I^2 = 37.3\%$; pooled diastolic blood pressure mean difference, -1.2 [95% CI, -1.6 to -0.8]; 38 RCTs [40 effects, n = 13 098]; $I^2 = 32.5\%$). In addition, in trials reporting incidence of hypertension, intervention groups had a 26% lower risk of onset (pooled RR, 0.74 [95% CI, 0.58 to 0.94]; 5 RCTs [n = 2707]; $I^2 = 12\%$).

For lipid levels, the pooled mean difference in change between groups was -3.5 mg/dL for total cholesterol, -2.1 mg/dL for LDL-C, and 0.6 mg/dL for high-density lipoprotein cholesterol (pooled total cholesterol mean difference, -3.5 [95% CI, -5.6 to -1.4]; 36 RCTs [38 effects, n = 11 414]; $I^2 = 65.9\%$; pooled LDL-C mean difference, -2.1 [95% CI, -4.1 to -0.2]; 30 RCTs [32 effects, n = 8894]; $I^2 = 55.9\%$; pooled high-density lipoprotein cholesterol mean difference, 0.6 [95% CI, 0.2 to 1.0]; 32 RCTs [34 effects, n = 8974]; $I^2 = 33.7\%$). Among 20 trials reporting fasting glucose levels, there was a mean 2.3-mg/dL greater reduction in fasting blood glucose in the intervention groups compared with the control groups at 12 to 24 months' follow-up (mean difference, -2.3 [95% CI, -3.6 to -1.0]; 20 RCTs [22 effects, n = 5950]; $I^2 = 82.5\%$).

At 12 to 24 months, the intervention groups showed slightly greater reductions in all 3 adiposity-related measures: pooled BMI mean difference, -0.5 (95% CI, -0.7 to -0.3); 30 RCTs (n = 9909); $I^2 = 83.3\%$; pooled weight mean difference, -1.6 kg (95% CI, -2.1 to -1.1); 37 RCTs (n = 16 345); $I^2 = 88.1\%$; pooled waist circumference mean difference, -1.7 cm (95% CI, -2.4 to -1.1); 23 RCTs (n = 11 708); $I^2 = 87.3\%$. Incidence of diabetes and metabolic syndrome were sparsely reported; findings usually favored the intervention group, although they were generally not statistically significant (eTable 6 in the Supplement).

Very few intervention or population characteristics were clearly associated with effect size consistently across outcomes. Meta-regression and stratified analyses were conducted for the most commonly reported outcomes: SBP, total cholesterol level, and weight. Total cholesterol was chosen over LDL-C because it was more commonly reported; however, absolute effect sizes were typically very similar between these 2 outcomes, suggesting that most of the change in total cholesterol was due to changes in LDL-C. In these analyses, there was no clear indication for any outcome that high-contact (>360-minute) trials showed larger effects than medium-contact (31- to 360-minute) trials, nor was there an association between continuous measures of contact

Table 2. Pooled Difference in Mean Change for Blood Pressure, Lipid Levels, Glucose Levels, and Adiposity-Related Outcomes at 12 to 24 Months' Follow-up

Outcome	Study population risk focus	Effect size (95% CI) ^a	No. of effects analyzed	No. of participants analyzed	I ² , %	Median (IQR) change	
						Intervention group	Control group
SBP, mm Hg	All available trials	-1.81 (-2.49 to -1.13)	44	14 580	37.3	-5.1 (-7.6 to -1.7)	-2.9 (-6.0 to -0.2)
	Hypertension ^b	-1.97 (-2.59 to -1.36)	16	5769	7.8	-5.8 (-8.6 to -3.9)	-3.1 (-7.5 to -1.8)
DBP, mm Hg	All available trials	-1.16 (-1.57 to -0.75)	40	13 098	32.5	-3.4 (-4.6 to -0.7)	-1.6 (-3.7 to -0.2)
	Hypertension ^b	-1.06 (-1.75 to -0.38)	15	5461	43.4	-4.4 (-6.0 to -2.2)	-3.2 (-5.0 to -0.3)
Total cholesterol, mg/dL	All available trials	-3.48 (-5.57 to -1.38)	38	11 414	65.9	-7.1 (-12.4 to -2.3)	-4.4 (-6.6 to 0)
	Dyslipidemia ^c	-3.80 (-7.23 to -0.37)	9	2001	24.0	-8.8 (-15.8 to -7.6)	-8.6 (-12.8 to -5.0)
LDL-C, mg/dL	All available trials	-2.14 (-4.08 to -0.21)	32	8894	55.9	-4.8 (-11.2 to -1.5)	-3.9 (-7.7 to 0.1)
	Dyslipidemia ^c	-4.12 (-8.81 to 0.57)	7	1271	36.3	-11.0 (-19.6 to -7.3)	-10.4 (-15.4 to -4.6)
HDL-C, mg/dL	All available trials	0.58 (0.19 to 0.98)	34	8974	33.7	0.8 (0.3 to 2.6)	0.5 (0 to 1.7)
	Dyslipidemia ^c	-0.44 (-1.26 to 0.37)	6	1033	0.0	0.4 (0 to 3.1)	1.0 (0.4 to 2.7)
Fasting blood glucose, mg/dL	All available trials	-2.33 (-3.64 to -1.02)	22	5950	82.5	-2.9 (-5.7 to -0.4)	0.2 (-2.0 to 3.6)
Weight, kg	All available trials	-1.59 (-2.06 to -1.12)	37	16 345	88.1	-1.5 (-2.8 to -0.8)	-0.3 (-1.0 to 0)
	Weight loss trials ^d	-2.55 (-3.40 to -1.70)	12	3193	66.9	-1.9 (-3.6 to -1.2)	-0.6 (-1.1 to 0)
BMI ^e	All available trials	-0.46 (-0.66 to -0.26)	30	9909	83.3	-0.5 (-0.9 to -0.2)	-0.1 (-0.4 to 0)
	Weight loss trials ^d	-0.91 (-1.43 to -0.40)	7	1520	78.0	-1.0 (-1.6 to -0.6)	-0.3 (-0.4 to -0.2)
Waist circumference, cm	All available trials	-1.75 (-2.44 to -1.06)	23	11 708	87.3	-2.2 (-3.7 to -0.8)	-0.9 (-1.8 to -0.2)
	Weight loss trials ^d	-2.50 (-3.97 to -1.03)	8	1654	85.4	-2.9 (-4.6 to -1.4)	-1.2 (-2.3 to -0.7)

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; HDL-C, high-density lipoprotein cholesterol; IQR, interquartile range; LDL-C, low-density lipoprotein cholesterol.

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

^a Between-group mean difference in change unless otherwise specified.

^b Includes trials limited to persons with hypertension or elevated blood pressure.

^c Includes trials limited to persons with dyslipidemia or elevated lipid levels.

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

^e Calculated as weight in kilograms divided by height in meters squared.

(number of sessions, total estimated minutes of contact) and effect size. However, very few trials offered low-contact (<30-minute) interventions. The analyses of SBP demonstrated generally consistent effects among studies with various characteristics, including study quality, setting, baseline weight selection and weight loss approach, some key intervention characteristics, and socioeconomic status (eFigure 1 in the Supplement).

For total cholesterol, a number of study characteristics showed statistically significant bivariate associations (eFigure 2 in the Supplement); however, multivariable models suggested only larger reductions in trials with medication management components ($P = .003$) and those focusing on older adults ($P = .03$).

While several characteristics showed statistically significant bivariate associations with the effect size for weight (eFigure 3 in the Supplement), the correlated nature of these characteristics made it difficult to disentangle the results; a multivariable model suggested larger effects were found in weight loss trials ($P < .03$). The test of small-study effects was statistically significant for only the outcome of weight (Egger test of bias, -2.8 ; $P < .001$), indicating that smaller trials tended to have larger effects. Weight loss trials tended to be smaller (mean sample size, 461, compared with 585 in non-weight loss trials). Four trials had multiple intervention groups that allowed for the direct comparison of weight loss vs other messages to improve intermediate outcomes.^{132,158,220,221} All 4 were trials among people with hypertension that had both weight loss and sodium reduction (without weight loss) interven-

tions; blood pressure consistently improved even without encouragement to lose weight. Based on direct within-study comparisons using study-reported subgroup analyses, there was no indication that any demographic subpopulations consistently benefited more or less than others.^{37,47,62,63,69,70,74,97,99,121,130,134,147,155,158,181,183,193,194,200,216,217,220,221}

No single optimal or representative intervention was identified, and a wide range of behavioral counseling approaches improved health profiles. Among programs that showed a clear benefit, group-based programs generally offered 5 to 12 sessions over 4 to 12 months or, if weight loss was a primary focus, 20 to 30 sessions over 24 months.

One-on-one interventions were generally shorter than group-based interventions, and individually delivered interventions usually fell into the medium contact category, while high-contact trials usually involved groups, often in addition to individual contact.

Among interventions showing a benefit, motivational interviewing was often used, and common behavior-change techniques included goal setting, active self-monitoring, and addressing barriers related to diet, physical activity, or weight change.

Key Question 3. Do primary care-relevant behavioral counseling interventions to improve diet, increase physical activity, and reduce sedentary behavior improve behavioral outcomes (eg, diet, physical activity, sedentary behavior) in adults with known CVD risk factors (hypertension or elevated blood pressure,

Table 3. Pooled Difference in Mean Change for Dietary Fats, Fruit Vegetable, Urinary Sodium Levels, and Physical Activity Outcomes at 12 to 24 Months' Follow-up

Outcome	Unit	Effect size (95% CI) ^a	No. of effects analyzed	No. of participants analyzed	I ² , %	Median (IQR) change	
						Intervention group	Control group
Saturated fat	% of energy	-1.5 (-1.9 to -1.1)	15	6229	72	-1.9 (-3.0 to -1.4)	-0.6 (-1.0 to -0.1)
Saturated fat (fat-modified diet interventions only)	% of energy	-1.5 (-2.3 to -0.8)	8	3951	72	-2.2 (-3.0 to -1.6)	-0.5 (-1.0 to -0.01)
Polyunsaturated fat	% of energy	-0.4 (-1.0 to 0.3)	7	2032	90	-0.9 (-1.2 to -0.1)	0 (-0.3 to 0)
Monounsaturated fat	% of energy	-1.7 (-2.5 to -0.9)	7	1827	83	-2.0 (-2.1 to -1.9)	-0.2 (-0.4 to 0)
Fruits and vegetables	Servings/d	0.7 (0.1 to 1.3)	11	4310	90	0.5 (-0.01 to 1.2)	0.1 (0 to 0.3)
Fruits	Servings or pieces/d	0.2 (0.04 to 0.3)	9	3698	71	0.2 (0.1 to 0.5)	0 (0 to 0.1)
Vegetables	Standardized mean difference	0.1 (0.02 to 0.2)	9	3555	50	Servings/d: 0.5 (0 to 0.8) g/d: 11 (9 to 16)	Servings/d: 0.3 (0.2 to 0.3) g/d: 2 (-3 to 12)
Fiber	g/d	1.3 (0.1 to 2.6)	5	1350	42	1.7 (0 to 3.0)	0.1 (-0.7 to 0.2)
Urinary sodium	mmol/L	-18.0 (-34.8 to -1.2)	9	3583	89	-18.4 (-45.4 to -5.3)	-6.0 (-10.0 to -3.4)
Physical activity	Standardized mean difference	0.06 (-0.03 to 0.14)	32	19 834	64	-	-
	min/wk	9.1 (-4.6 to 22.8)	11	9746	48	44.4 (-2.5 to 97.0)	31.2 (-13.0 to 74.7)
	MET-min/wk	83 (-83 to 249)	7	4958	62	130 (33 to 289)	70 (-16 to 112)
	% Meeting physical activity goal	RR, 1.22 (1.00 to 1.50)	11	5887	91	36.0 (28.1 to 52.8) ^b	23.8 (22.9 to 50.8) ^b

Abbreviations: IQR, interquartile range; MET, metabolic equivalent; RR, risk ratio.

^a Between-group mean difference in change unless otherwise specified.

^b Median (IQR) percent meeting physical activity goal.

dyslipidemia, or mixed or multiple risk factors [eg, 10-year CVD risk >7.5%, metabolic syndrome])?

Seventy of the 94 included trials reported some type of behavioral outcome (n = 43 243).^{30,31,35,37,40,41,45-48,51,53,55,61,63,70-72,74,80,87,90,92,97,110,115,121,123,124,127,130-132,142,145,148,149,152,155,158,163,165,174,177,180,182,190,193,196,200,205,207,208,210,215-217,220,221,223,225,229,231,234,237,238,241,244,245,247} Specific behavioral outcomes were typically reported by fewer than 15 trials per outcome, and there was substantial variability in measurement for most. Overall, behavioral counseling interventions were associated with dietary improvements, including reductions in saturated fat consumption and increases in the consumption of fruits, vegetables, and fiber (Table 3). The mean difference in reduction in the percentage of calories from saturated fat was 1.5% after 12 to 24 months (pooled mean difference, -1.5% [95% CI, -1.9% to -1.1%]; 15 RCTs [17 effects, n = 6229]; I² = 72%). For fruits and vegetables, the intervention groups increased consumption by a mean of 0.7 servings per day more than the control groups (pooled mean difference, 0.7 [95% CI, 0.1 to 1.3]; 11 RCTs [n = 4310]; I² = 90%). The mean increase in fiber consumption was 1.3 g per day (95% CI, 0.1 to 2.6; 5 RCTs [n = 1350]; I² = 42%) more than control groups. In addition, trials among people with hypertension or elevated blood pressure who were counseled to reduce sodium consumption did show reduced urinary sodium levels (pooled mean difference, -18.0 mmol/L [95% CI, -34.8 to -1.2]; 9 RCTs [n = 3583]; I² = 89%). Dietary pattern scores generally showed statistically significantly greater improvement in intervention groups, but measurement was heterogeneous and interpretation of effect sizes was unclear.

Physical activity outcomes were highly variable in terms of both measurement and results, with minimal evidence to suggest that in-

terventions were associated with increased physical activity. In the 50 trials reporting some type of physical activity outcome, the reported measures and the units of measure were disparate, and almost all outcomes were self-reported. Pooled analyses of continuous physical activity outcomes did not show statistically significant association, with high statistical heterogeneity (pooled standardized mean difference, 0.06 [95% CI, -0.03 to 0.14]; 30 RCTs [32 effects, n = 19 834]; I² = 64%), and a pooled estimate of physical activity minutes per week showed an increase of 9.1 minutes in intervention groups compared with control groups that was not statistically significant (pooled minutes per week mean difference, 9.1 [95% CI, -4.6 to 22.8]; 10 RCTs [11 effects, n = 9746]; I² = 48%). Dichotomous outcome reporting in terms of meeting study-defined physical activity goals occurred in a small subset of 11 trials, and the pooled effect size suggested a statistically significant benefit associated with intervention groups (pooled RR, 1.22 [95% CI, 1.00 to 1.50]; 11 RCTs [n = 5887]; I² = 91%).

Harms of Interventions

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 with known CVD risk factors (hypertension or elevated blood pressure, dyslipidemia, or mixed or multiple risk factors [eg, 10-year CVD risk >7.5%, metabolic syndrome])?

Twenty of the 94 included trials reported harms (n = 18 263).^{36,37,46,47,55,63,87,97,118,152,187,193,194,200,241,242,247} Seven of these 20 trials reported that there were no adverse events or no serious adverse events,^{55,87,97,118,148,152,247} and other trials reported 1 or more of the following: serious adverse events, any adverse events,

hospitalizations, musculoskeletal injuries, withdrawals due to adverse events, gallbladder disease, and headaches. Adverse events related to diet and physical activity counseling were exceedingly rare, with generally no statistically significant differences in any study for harms outcomes. There was no consistent evidence of paradoxical effects for intermediate or behavioral outcomes.

Discussion

Consistent with the prior review that was conducted to support the 2014 USPSTF recommendation,¹⁶ this review found that medium- and high-contact behavioral counseling interventions in people with cardiovascular risk factors were associated with improvements in intermediate and behavioral outcomes. The evidence is summarized in **Table 4**. No single optimal or representative intervention was identified; a wide range of behavioral counseling approaches improved health profiles. Similar effect sizes were found for most outcomes, compared with the previous review. This was observed despite the inclusion of weight loss studies in adults with relevant CVD risk factors and the exclusion of studies conducted predominantly in adults with prediabetes or diabetes (the latter are addressed in a separate USPSTF review).⁷

The finding that behavioral counseling interventions were associated with a lower likelihood of CVD events is new since the previous review. The overall pooled effect size showed a 20% lower risk of CVD events, which translates to a number needed to treat of 100 (95% CI, 74 to 154) to prevent 1 CVD event, assuming a baseline rate of 5%. Population risks of 7.5% and 10% translate to numbers needed to treat of 67 (95% CI, 49 to 103) and 50 (95% CI, 37 to 77), respectively.

The largest study was PREDIMED, which accounted for more than one-half of the participants in the analysis and was not included in the previous review.⁹⁷ PREDIMED investigators issued a retraction of the original publication after the discovery of protocol violations regarding enrollment of household members without randomization and inconsistent use of randomization tables. The published updated analyses, including extensive sensitivity analyses to explore the effect of the violations, found that effect sizes were only minimally affected. Results reported here are from the updated version of the results. The association was still statistically significant in a sensitivity analysis excluding this study. The finding of no consistent evidence of benefit for physical activity outcomes is surprising and may reflect limitations in the evidence. The difference in results between continuous outcomes showing no benefit and dichotomous outcomes showing marked improvement suggests that physical activity reporting is not representative in this body of literature, which included few trials exclusively addressing physical activity. The results of this review stand in contrast to those of another commissioned by the USPSTF that addressed behavioral counseling for diet and physical activity in adults *without* CVD risk factors.

That review found that behavioral counseling was associated with approximately 35 more minutes per week of physical activity.⁸ That review also included substantially more trials only addressing physical activity. Indeed, studies whose primary inclusion criterion was suboptimal physical activity were included in that review and not in the present review. The clinical significance of modest

improvements in intermediate and behavioral outcomes is challenging to quantify, given that behavioral changes may not be maintained. This may be particularly true for dietary outcomes for which the effect of individual diet components is difficult to evaluate and there is sparse reporting on overall dietary patterns. Regardless, there is observational evidence linking lower levels of CVD risk factors as well as improved diet and physical activity behaviors to better cardiovascular and mortality outcomes. Such evidence is reinforced by trial data suggesting that behavioral counseling for healthy diet and physical activity in adults with CVD risk factors is associated with lower risk of CVD events and by data that suggest little to no harm.

Further understanding is needed regarding the contribution of weight loss in the context of complex behavioral interventions targeting CVD risk factors. Robust analyses of the importance of weight loss on intermediate outcomes are best provided by individual patient-level data and direct within-study comparisons of interventions with and without weight loss goals, both of which are sparse. While many interventions in this review had weight loss goals for all or some participants, some within-study comparisons suggested that CVD risk reduction can occur in the absence of weight loss,^{132,158,220,221} consistent with a recent comparative effectiveness trial not included in this review because it did not include a true control group.²⁵¹ While evidence from clinical trials remains limited, observational evidence also supports the benefits of a healthy diet and physical activity for people with excess weight, even in the absence of weight loss. The Nurses' Health Study and the Health Professionals Follow-up Study²⁵² found that all-cause mortality was lower in people with BMIs of 30.0 to 39.9 who had engaged in at least 3 healthy behaviors (including healthy diet, physical activity, moderate alcohol consumption, and not smoking) than in people of healthy weight who reported only 1 of these behaviors. Thus, for people with excess weight, particularly those with a history of unsuccessful or unhealthy weight loss approaches, promoting diet and physical activity goals without targeting weight loss is likely to improve health.

There are important limitations in the research that should be considered. First, only a small proportion of trials had sufficient sample size and follow-up time to evaluate CVD events and mortality. Continued follow-up and large replication studies are needed.

Second, there was highly variable reporting of behavioral outcomes, particularly for physical activity. The variability in specific measures, as well as the lack of behavioral outcomes in studies reporting intermediate outcomes, make it difficult to interpret pooled effect sizes. Third, for dietary outcomes it is difficult to understand the clinical importance of changes in a single aspect of diet. Given the importance of substitutions when modifying diet,²⁵³ validated measures of overall diet pattern would be a more valuable outcome; however, the field lacks a consistent measure of overall optimal diet pattern. The Healthy Eating Index is a validated measure of overall diet quality that assesses alignment with the Dietary Guidelines for Americans and is associated with all-cause, CVD, and cancer mortality.²⁵⁴ However, only 2 included studies reported this measure,^{215,216} and the field would benefit from a set of core outcome measures of diet and physical activity. Fourth, data were very limited for persons 75 years and older. The PREDIMED study had a mean age of 67 years, however, supporting the benefits of dietary counseling adults 65 years and older.

Table 4. Summary of Evidence

No. of studies (No. of observations) study designs	Summary of findings and related health outcomes	Consistency and precision	Other limitations	Strength of evidence	Applicability
KQ1: Benefits of interventions on CVD and related health outcomes CVD events: 12 RCTs (15 107) Mortality: 18 RCTs (18 146) Subjective well-being: 11 RCTs (5684)	CVD events were reported in 12 trials of medium- or high-contact interventions, and pooled analyses showed lower rates of total CVD events (pooled RR, 0.80 [95% CI, 0.73 to 0.87]; 9 studies) and fairly large but statistically nonsignificant associations with myocardial infarction (pooled RR, 0.85 [95% CI, 0.70 to 1.02]; 6 studies) and stroke (RR, 0.52 [95% CI, 0.25 to 1.10]; 4 studies). Event rates were variable, but the largest trial reported that 3.6% of intervention participants had CVD events, compared with 4.4% of control participants. Few studies were powered for mortality; neither those few large studies nor the pooled estimate clearly demonstrated an effect on mortality (pooled RR, 0.89 [95% CI, 0.71 to 1.11]). Patient-reported measures of subjective well-being were sparsely reported and showed no clear pattern of clinically important benefit.	Mortality: Reasonably consistent, imprecise CVD events: reasonably consistent, reasonably precise Subjective well-being: inconsistent, imprecise	Sparsely reported, few trials had sufficient power and length of follow-up for mortality and CVD events Trial with the strongest evidence had protocol violations in allocation; however, extensive sensitivity analyses showed limited effect on results	CVD events: moderate for benefit Mortality: low for small to no benefit Subjective well-being: insufficient	CVD events: Most trials conducted in the US; however, the largest trial providing the strongest evidence was conducted in Spain Most participants across all trials were middle-aged and older adults who were predominantly White and not socioeconomically disadvantaged
KQ2: Benefits of interventions on intermediate outcomes associated with CVD Continuous clinical measures: 89 RCTs (46 354) Hypertension incidence: 5 RCTs (2707) Diabetes incidence: 4 RCTs (6701) Metabolic syndrome: 5 RCTs (3103)	Behavioral counseling interventions were associated with small, statistically significant reductions in blood pressure, total cholesterol and LDL-C, fasting glucose, and adiposity-related outcomes at 12 to 24 mo follow-up. Hypertension incidence was lower with interventions designed to prevent hypertension in those who did not have it already (pooled RR, 0.74 [95% CI, 0.58 to 0.94]; 5 RCTs [n = 2707]; I ² = 12%). No intervention factors were clearly associated with effect size, but among trials with the largest effects across multiple domains, most offered more than 6 h of intervention contact and many offered group as well as individual contact. Selected pooled mean differences: SBP, -1.8 (95% CI, -2.5 to -1.1); 44 studies DBP, -1.2 (95% CI, -1.6 to -0.8); 40 studies Total cholesterol, -3.5 (95% CI, -5.6 to -1.4); 38 studies LDL-C, -2.1 (95% CI, -4.1 to -0.2); 32 studies fasting blood glucose, -2.3 (95% CI, -3.6 to -1.0); 22 studies BMI, -0.5 (95% CI, -0.7 to -0.2); 30 studies Evidence primarily in medium- and high-contact interventions	Reasonably consistent, reasonably precise	Hypertension prevalence, diabetes, and metabolic syndrome were reported in very few trials, raising concerns about reporting bias	High for benefit	Substantial number of trials conducted in the US and conducted in or recruited from primary care Most participants across all trials were middle-aged and older adults who were predominantly White and not socioeconomically disadvantaged

(continued)

Table 4. Summary of Evidence (continued)

No. of studies (No. of observations) study designs	Summary of findings	Consistency and precision	Other limitations	Strength of evidence	Applicability
<p>KQ3: Benefits of interventions in behavioral outcomes</p> <p>70 RCTs (43 243)</p>	<p>Interventions were associated with small reductions in saturated fat and small increases in fruit, vegetable, and fiber consumption; for example, fruit and vegetables consumption increased by a mean of 0.7 servings/d more in the intervention than in the control groups (pooled mean difference, 0.7 [95% CI, 0.1 to 1.3]; 14 effects [11 RCTs] [n = 4310]; $I^2 = 90%$)</p> <p>The mean increase in fiber consumption was 1.3 g/d (95% CI, 0.1 to 2.6; 5 trials [n = 1350]; $I^2 = 42%$)</p> <p>In addition, trials of persons with hypertension or elevated blood pressure who were counseled to reduce sodium consumption showed greater reductions in urinary sodium (pooled mean difference, -18.0 [95% CI, -34.8 to -1.2]; 9 RCTs [n = 3583]; $I^2 = 89%$)</p> <p>Findings were mixed for physical activity</p> <p>Most trials included medium- or high-contact interventions</p>	<p>Diet: reasonably consistent, imprecise</p> <p>Physical activity: inconsistent, imprecise</p>	<p>Sparse reporting, with substantial variability in measures used, particularly for physical activity</p> <p>Clinical importance of effect sizes could not be clearly determined</p>	<p>Diet: low for benefit</p> <p>Physical activity: low for no benefit</p>	<p>Substantial number of trials conducted in the US and conducted in or recruited from primary care</p> <p>Most participants across all trials were middle-aged and older adults who were predominantly White and not socioeconomically disadvantaged</p>
<p>KQ4: Harms of interventions</p> <p>20 RCTs (18 263)</p>	<p>Adverse events related to diet and physical activity counseling were very rare, with generally no statistically significant differences in any study for serious adverse events, any adverse events, hospitalizations, musculoskeletal injuries, withdrawals due to adverse events, gallbladder disease, and headaches</p> <p>There was no consistent evidence of paradoxical effects for intermediate or behavioral outcomes</p>	<p>Reasonably consistent, imprecise</p>	<p>Sparsely reported, ascertainment typically not described</p>	<p>Low for no harms</p>	<p>Substantial number of trials conducted in the US and conducted in or recruited from primary care</p> <p>Most participants across all trials were middle-aged and older adults who were predominantly White and not socioeconomically disadvantaged</p>

Abbreviations: BMI, body mass index; CVD, cardiovascular disease; DBP, diastolic blood pressure; KQ, key question; LDL-C, low-density lipoprotein cholesterol; RCT, randomized clinical trial; RR, risk ratio; SBP, systolic blood pressure.

Limitations

This review has several limitations. First, the review included studies conducted over approximately 30 years, a range of time over which the clinical context has changed. Changes in eating patterns, treatment guidelines, and understanding of nutrition science increase the clinical heterogeneity of participants and the interventions used in these trials. Treatment guidelines for hypertension and dyslipidemia have changed, generally recommending treatment at lower lipid and blood pressure levels. Rates of smoking have declined. Dietary messages and technology platforms have changed, yet evidence for technology-driven interventions without support from a health care professional is scarce. Moreover, the sparse reporting of baseline estimated 10-year CVD risk—coupled with the rarity of trials powered for CVD events—makes it difficult to characterize the risk levels of participants in terms consistent with treatment guidelines informed by 10-year risk.

Second, the wide-ranging study populations and sparsity of within-study subgroup analyses precluded robust analysis of differ-

ential effectiveness across patient characteristics. Meta-analytic techniques were used to address effect modification when possible, but such analyses were limited because of the risk of ecological bias; the best analysis of effect modification across patient subpopulations uses individual-level data. Similarly, controlling for the confounding effects of medication use is best addressed in individual-level analyses. Individual studies rarely controlled for this potentially important confounding variable.

Third, statistical heterogeneity was high in many of the included meta-analyses. This likely reflected the underlying clinical and methodological heterogeneity in the included studies.

Conclusions

Medium- and high-contact multisession behavioral counseling interventions to improve diet and increase physical activity for people with elevated blood pressure and lipid levels were effective in reducing cardiovascular events, blood pressure, low-density lipoproteins, and adiposity-related outcomes, with little to no risk of serious harm.

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Concept and design: O'Connor, Evans, Rushkin, Lin.

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