JAMA | US Preventive Services Task Force | EVIDENCE REPORT

Behavioral Counseling to Promote a Healthful 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 systematically review the evidence on the benefits and harms of behavioral counseling for the primary prevention of cardiovascular disease in adults without known cardiovascular risk factors to inform the US Preventive Services Task Force.

DATA SOURCES MEDLINE, PubMed, Cochrane Central Register of Controlled Trials, and PsycINFO for studies published in the English language between January 1, 2013, and May 25, 2016, and ongoing surveillance in targeted publications through March 24, 2017. Studies included in the previous review were reevaluated for inclusion.

STUDY SELECTION Randomized clinical trials of behavioral interventions targeting improved diet, increased physical activity, decreased sedentary time, or a combination of these among adults without known hypertension, dyslipidemia, diabetes, or impaired fasting glucose.

DATA EXTRACTION AND SYNTHESIS Independent critical appraisal and data abstraction by 2 reviewers.

MAIN OUTCOMES AND MEASURES Cardiometabolic health and intermediate outcomes, behavioral outcomes, and harms related to interventions.

RESULTS Eighty-eight studies (N = 121 190) in 145 publications were included. There was no consistent benefit of the interventions on all-cause or cardiovascular mortality or morbidity (4 trials [n = 51 356]) or health-related quality of life (10 trials [n = 52 423]). There was evidence of small, statistically significant between-group mean differences for systolic blood pressure (−1.26 mm Hg [95% CI, −1.77 to −0.75]; 22 trials [n = 57 953]), diastolic blood pressure (−0.49 mm Hg [95% CI, −0.82 to −0.16]; 23 trials [n = 58 022]), low-density lipoprotein cholesterol level (−2.58 mg/dL [95% CI, −4.30 to −0.85]; 13 trials [n = 5554]), total cholesterol level (−2.85 mg/dL [95% CI, −4.95 to −0.75]; 19 trials [n = 9325]), and body mass index (−0.41 [95% CI, −0.62 to −0.19]; 20 trials [n = 55 059]) at 6 to 12 months as well as small-to-modest associations with dietary and physical activity behaviors. There was no evidence of greater incidence of serious adverse events, injuries, or falls in intervention vs control participants.

CONCLUSIONS AND RELEVANCE Diet and physical activity behavioral interventions for adults not at high risk for cardiovascular disease result in consistent modest benefits across a variety of important intermediate health outcomes across 6 to 12 months, including blood pressure, low-density lipoprotein and total cholesterol levels, and adiposity, with evidence of a dose-response effect, with higher-intensity interventions conferring greater improvements. There is very limited evidence on longer-term intermediate and health outcomes or on harmful effects of these interventions.

JAMA. 2017;318(2):175-193. doi:10.1001/jama.2017.3303

Editorial page 130

Related article page 167 and JAMA Patient Page page 210

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Despite evidence that healthful dietary patterns, physical activity, and limited sedentary time are associated with reduced cardiovascular morbidity and mortality,[1-4] most US adults are not meeting national recommendations for these behaviors.[5] Counseling within primary care and interventions referred through 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 cardiovascular disease (CVD) prevention, including guidance on healthy lifestyle counseling[6,7]; screening and treatment for obesity,[8] hypertension,[9] and abnormal blood glucose levels[10]; aspirin[11] and statin[12] use; and tobacco cessation interventions.[12] The purpose of this review was to update the USPSTF review on the benefits and harms of behavioral counseling interventions for healthful diet, physical activity, and/or sedentary behavior for the primary prevention of cardiovascular disease among adults without known CVD or those with known hypertension, dyslipidemia, diabetes, or impaired fasting glucose. This review will help the USPSTF update their 2012 C grade recommendation that clinicians may choose to selectively counsel adults about healthful diet and physical activity.[7]

Methods

Scope of Review

This review addressed 4 key questions (KQs) as shown in **Figure 1**. Methodological details (including study selection, a list of excluded studies, and description of data analyses), as well as more detailed results (including detailed descriptions of all of the interventions and data on effect modification and subpopulation results), are publicly available in the full evidence report at https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/healthful-diet-and-physical-activity-for-cardiovascular-disease-prevention-in-adults-without-known-risk-factors-behavioral-counseling.

Data Sources and Searches

This review was designed as an extension of 2 prior systematic reviews conducted by the Kaiser Permanente Research Affiliates Evidence-based Practice Center for the USPSTF that focused on healthful diet and physical activity counseling for cardiovascular disease prevention among individuals with[14] and without[15] known CVD risk factors (ie, hypertension, dyslipidemia, diabetes, or impaired fasting glucose). As such, relevant studies from those reviews were reevaluated for potential inclusion. Then, the following databases were searched for new relevant English-language literature published between January 1, 2013, and May 25, 2016: MEDLINE, PubMed (publisher-supplied records only), PsycINFO, and the Cochrane Central Register of Controlled Trials (eMethods in the Supplement). Collectively, the literature searches encompassed literature published from 1966 through May 25, 2016. The database searches were supplemented by reviewing bibliographies from other relevant literature and from expert suggestions. ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform were searched for ongoing trials. Since May 2016, ongoing surveillance was conducted using searches of a subset of core clinical journals identified by the USPSTF to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on March 24, 2017, and identified no new studies.

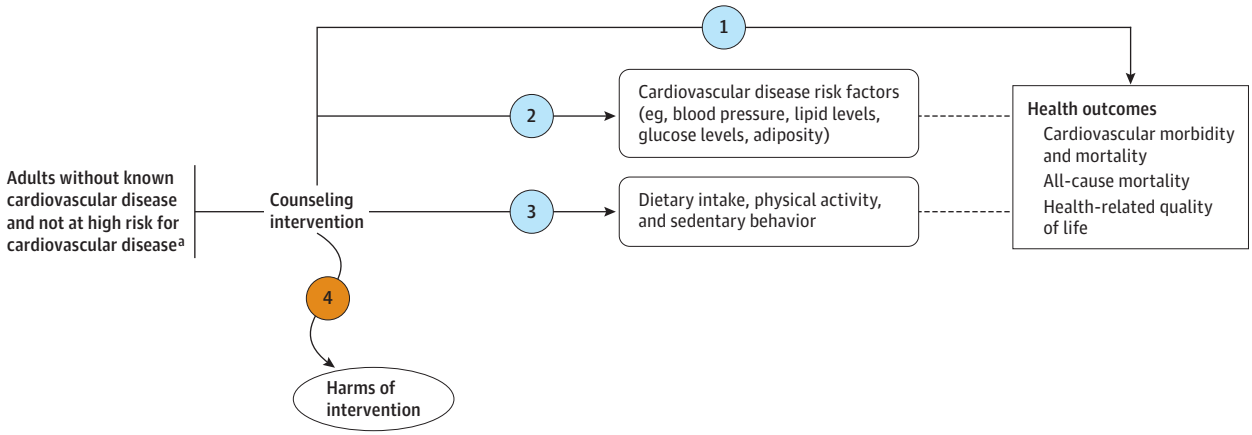
Study Selection

Two reviewers independently reviewed all identified titles and abstracts and relevant full-text articles against prespecified inclusion and exclusion criteria (eTable 1 in the Supplement). Discrepancies were resolved through discussion and consensus. Eligible studies were fair- and good-quality randomized clinical trials that evaluated the effectiveness of primary care–relevant interventions focused on improving dietary habits, increasing physical activity, and/or reducing sedentary time with the primary aim of CVD primary prevention among adults 18 years or older. Studies were excluded from this review if they (1) targeted persons with known CVD, hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors; (2) targeted persons categorized as high risk based on a cardiovascular risk–assessment tool; or (3) generically stated that participants must have 1 or more CVD risk factors to be included. In contrast, studies in adults who may be at elevated risk for CVD based on factors such as age, race/ethnicity, family history of CVD, overweight or obesity, high-normal blood pressure, or history of gestational diabetes, as well as those conducted among unselected samples or samples selected because of suboptimal behavior (eg, did not meet national physical activity guidelines) were included. Eligible interventions were those conducted in primary care or referred from primary care, or those deemed feasible for primary care or referral given the nature of the intervention delivery (eg, face-to-face counseling, telephone support), behavior change techniques (eg, goal setting, self-monitoring), or setting (eg, home, community). Studies had to report a behavioral outcome (ie, diet-, physical activity–, sedentary time–related measure), intermediate outcome (eg, blood pressure, lipid levels, weight, incidence of hypertension), or health outcome (ie, morbidity, mortality, health-related quality of life) or report adverse events related to the intervention.

Data Extraction and Quality Assessment

Two reviewers independently assessed the methodological quality of all eligible studies, using criteria outlined by the USPSTF (eTable 2 in the Supplement).[13] Each study was assigned a final quality rating of good, fair, or poor; disagreements between the investigators were resolved through consensus after discussion and consultation with additional investigators. Studies were rated as poor quality and excluded if they had several important major risks of bias, including very high attrition at 6 to 12 months (eg, greater than 40%), differential attrition between intervention groups (eg, greater than 20%), lack of baseline comparability between groups without adjustment for those variables, or other issues in the conduct, analysis, or reporting of results of the trial that were judged to considerably bias the results (eg, possible selective reporting, inappropriate exclusion of participants from analyses, and questionable validity of randomization and allocation concealment procedures). One reviewer completed primary data abstraction, and a second reviewer checked all data for accuracy and completeness.

Figure 1. Analytic Framework



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 relationship between an intermediate outcome and a health outcome that is presumed to describe the natural progression of the disease. Further details are available in the USPSTF procedure manual.[13]

[a] High risk of cardiovascular disease includes adults with hypertension, dyslipidemia, diabetes, impaired fasting glucose or glucose tolerance, or a combination of these factors.

Data Synthesis and Analysis

Summary tables were created for study characteristics, population characteristics, intervention characteristics, and outcomes. The data on health outcomes (KQ1) and adverse events (KQ4) did not allow for pooled analyses and so were summarized descriptively. For intermediate health outcomes (KQ2) and behavioral outcomes (KQ3), random-effects meta-analyses using the method of DerSimonian and Laird were run to calculate the pooled differences in mean changes (for continuous data) and pooled odds ratio (for binary data).[16] The between-group difference for each outcome as reported by each respective study was pooled favoring adjusted over unadjusted reported effect estimates. If a between-group effect estimate and variance were not provided, a crude effect estimate was calculated. Within each study, 1-year outcome data were chosen for meta-analyses if available; otherwise, the point closest to 1 year was chosen. If a trial had more than 1 active intervention group, data for the most intensive group or the group that was the most similar with other interventions included in the analysis were plotted. Methods consistent with the previous review[15] were used to estimate and categorize the intensity (total contact in minutes) of each intervention group as low (≤30 minutes), medium (31-360 minutes), or high (>360 minutes). Results at all other points and for all intervention groups within each trial were reported in tabular format.

Statistical heterogeneity among the pooled studies was examined using standard χ^2 tests, and the proportion of total variability in point estimates was approximated using the I^2 statistic.[17]

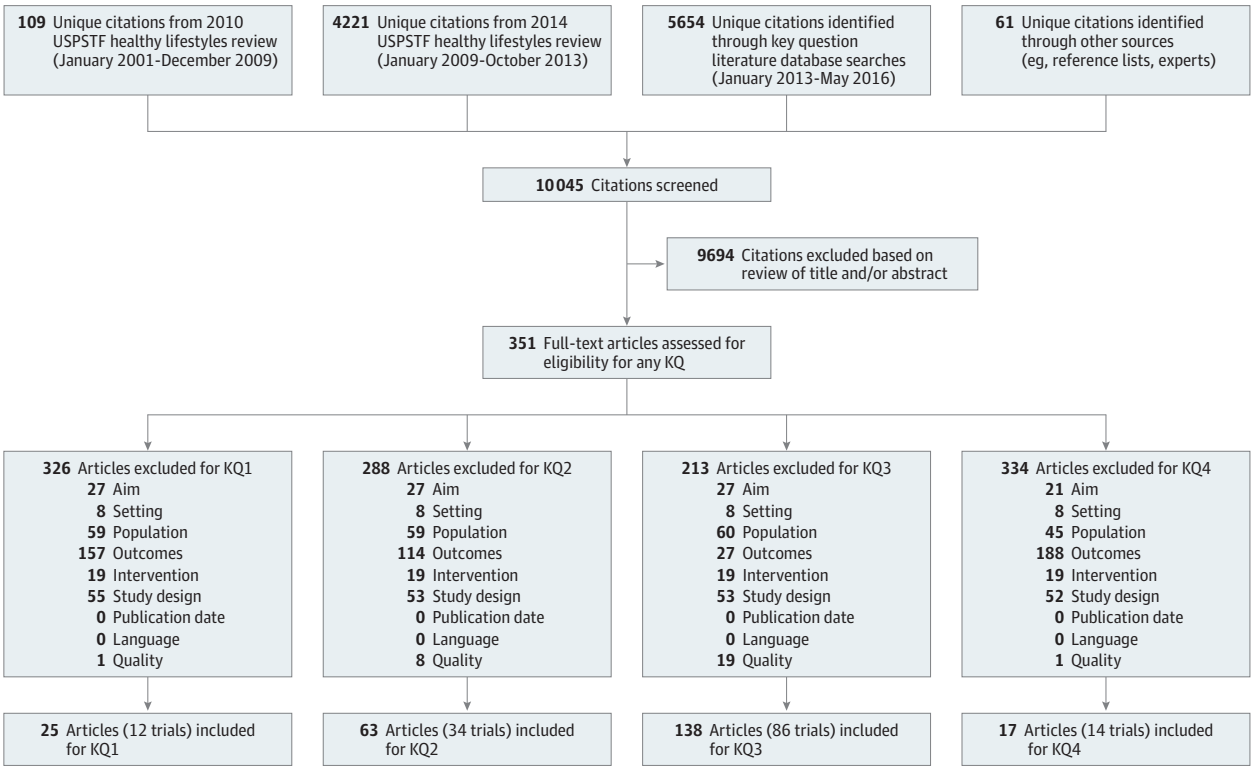
Visual displays were first used to investigate whether the heterogeneity among the results was associated with any prespecified population or intervention characteristics; meta-regression was then used when indicated. To evaluate small-study effects, funnel plots and the Egger test[18] (for continuous outcomes) or Peters test[19] (for dichotomous outcomes) were used. Stata version 13.1 (Stata Corp) was used for all quantitative analyses. All significance testing was 2-sided, and results were considered statistically significant at $P < .05$.

The strength of the overall body of evidence for each KQ was graded as high, moderate, low, or insufficient based on established methods[20] and addressed the consistency, precision, reporting bias, study quality, and dose response related to each outcome.

Results

A total of 10 045 titles and abstracts and 351 articles were reviewed to determine if they met the prespecified inclusion criteria, and 88 trials (87 randomized clinical trials [n = 121 106] and 1 nonrandomized clinical trial [n = 84]) reported in 145 publications were

Figure 2. Literature Search Flow Diagram



Reasons for exclusion: Aim: Study aim was not relevant. Setting: Study was not conducted in a country relevant to US practice or not conducted in, recruited from, or feasible for primary care or a health system. Population: Study was not conducted in an included population. Outcomes: Study did not have relevant outcomes or had incomplete outcomes. Intervention: Intervention was out of scope. Design: Study did not use an included design. Publication Date: primary results published prior to 1990. Language: Publication not in English. Quality: Study was poor quality. USPSTF indicates US Preventive Services Task Force.

included (**Figure 2**).[21-165] Fifty trials were carried forward from the previous review[22,26,31,33,34,38,42,47,49,50,52,56,57,61,63,64,66,69,72,76,79,82,85,86,88,90,95-98,102,104,109,112,114,118,119,121,126-128,130,132,136,143,146,147,149,151,159] and were synthesized with 38 newly identified trials.[21,24,27,32,35,39,41,43,44,53,54,58,60,67,71,73,78,83,89,91,94,103,106,108,111,123,131,139,140,145,150,152-154,156,160-162] The included trials were highly variable in terms of their study populations, interventions, and specific outcome measures (**Table 1**). The majority of the trials took place in the United States and were conducted within or recruited from a primary care setting. There was great diversity in the interventions tested: 23 trials focused on healthful diet and physical activity, another 24 on healthful diet only, and 44 on physical activity only. Intervention intensity (total minutes of contact) ranged from 3 minutes to 2340 minutes (39 hours), with a mean of 6 hours and 11 minutes. Low-intensity interventions were mostly mailed, print-based interventions, whereas medium- and high-intensity interventions involved one-on-one individual and telephone counseling and group sessions.

Effects of Interventions on Health Outcomes

Key Question 1. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve health outcomes in adults?

Twelve of the 88 included trials reported health outcomes.[52,63,69,76,82,96,97,121,146,147,151,154] Only 2 of these trials[62,154] were identified as part of the update, and both reported quality-of-life outcomes. Four trials (n = 51 356) reported all-cause or CVD-related mortality,[82,146,147,151] of which 3 also reported cardiovascular events.[146,147,151] All 4 of these trials focused on high-intensity diet interventions. Overall, few deaths were reported, and no differences were observed between treatment and control groups over 3 to 15 years of follow-up. The 3 trials that reported cardiovascular events or composite CVD outcomes showed some beneficial results, although results were mixed. The Women's Health Initiative dietary modification trial (n = 48 835) showed no difference in major coronary heart disease events (ie, nonfatal myocardial infarction [MI] or coronary heart disease death) (adjusted hazard ratio [HR], 0.93 [95% CI, 0.83 to 1.05]) or fatal and nonfatal stroke (adjusted HR, 1.02 [95% CI, 0.90 to 1.17]) among women without a history of CVD between those randomized to low-fat diet counseling and those in a usual-care diet group over 8.1 years of follow-up.[81] Similarly, a broader composite CVD outcome comprising nonfatal MI, coronary heart disease death, and coronary artery bypass graft surgery/percutaneous coronary intervention showed no significant difference between treatment groups (adjusted HR, 0.94 [95% CI, 0.86 to 1.02]).[81] In contrast, long-term observational follow-up from the Trial of Hypertension Prevention (TOHP) phase I and II (n = 2415) showed a significant difference in CVD (defined as MI, stroke, revascularization, or CVD death) between treatment groups over 10 to 15 years of follow-up (HR, 0.70 [95% CI, 0.53 to 0.94]).[48] When revascularization was excluded from the definition, however, significance was lost (adjusted HR, 0.72 [95% CI, 0.50 to 1.03]).

Table 1. Characteristics of All Included Trials

Source	Study Quality[a]	Country	Sample Size, Population Description (% Women)	Age, Mean, y	Intervention	Intervention Focus	Duration, wk	Intervention Intensity[b]	Setting	PCC[c]
Aadahl et al,[21] 2014	Good	Denmark	166 adults (57.2)	52.0	Counseling	PA[d]	26	Medium	Research clinic	
Aittasalo et al,[22] 2006	Fair	Finland	265 adults (75.8)	47.0	Brief counseling	PA	0.14	Low	Primary care	✓
					Self-monitoring	PA	1	Low		
Albright et al,[24] 2014	Fair	United States	311 postpartum women (100)	31.8	Tailored telephone counseling plus website	PA	52	Medium	Home	✓
Aldana et al,[26] 2006	Fair	United States	348 adults (71.8)	50.5	Group counseling	HD + PA	4	High	NR	
Alexander et al,[27] 2010	Fair	United States	2540 adults (68.8)	46.3	Tailored web-based + email counseling	HD	52	Medium	Home	✓
					Tailored web-based counseling	HD	52	Medium		
Baron et al,[31] 1990	Fair	United Kingdom	368 adults (48.6)	41.7	Counseling	HD	12	Medium	Primary care	✓
Bennett et al,[32] 2013	Good	United States	194 overweight or obese black women (100)[e]	35.4	Counseling, tailored print materials, and self-monitoring	HD + PA	52	High	Primary care	✓
Beresford et al,[33] 1997	Fair	United States	4778 adults (68.0)	NR	Brief counseling and self-help material	HD	2	Low	Primary care	✓
Bernstein et al,[34] 2002	Fair	United States	70 older adults (80.0)	77.9	Home-based education	HD	26	High	Home	
Bickmore et al,[35] 2013	Fair	United States	263 older adults (61.2)	71.3	Computer-based counseling	PA	52	Medium	Home	✓
Brekke et al,[38] 2005	Fair	Sweden	77 adults with family history of type 2 diabetes (36.8)	42.6	Group counseling (diet)	HD	104	High	NR	
					Group counseling (diet and PA)	HD + PA	104	High		
Bryan et al,[39] 2013	Fair	United States	238 adults (80.4)	28.2	Tailored print mailings	PA	52	Low	Home	
Burke et al,[41] 2013	Fair	Australia	478 older adults (48.3)	65.8	Self-help booklet and phone and email counseling	HD + PA	26	Medium	Home	
Carpenter et al,[42] 2004	Fair	United States	98 adults (64.3)	49.6	Group counseling	HD	24	High	Research clinic	
					Mailed materials and website	HD	24	Low		
Carroll et al,[43] 2010	Fair	United States	394 adults (69.0)	46.4	Tailored print mailings	PA	26	Low	Home	✓
Castro et al,[44] 2011	Fair	United States	181 adults (65.8)	59.1	Counseling	PA	52	Medium	Home	
					Peer counseling	PA	52	Medium		
Coates et al,[47] 1999	Fair	United States	2208 postmenopausal women (100)[f]	60.0	Group counseling	HD	52	High	Research clinic	
De Vet et al,[49] 2009	Fair	Netherlands	709 adults (67.3)	45.9	Self-directed and self-selected activity plan (with repeat planning)	PA	26	Low	Home	
					Self-directed and self-selected activity plan (1-time plan)	PA	26	Low		
					Self-directed walking plan (1-time plan)	PA	26	Low		
Delichatsios et al,[50] 2001	Fair	United States	298 adults (72.1)	45.9	Automated telephone counseling	HD	26	Medium	Other	✓
Elley et al,[52] 2003	Good	New Zealand	878 adults (66.3)[g]	57.9	Counseling with tailored prescription	PA	52	Medium	Primary care	✓
Estabrooks et al,[53] 2011	Fair	United States	115 adults (61.0)	48.8	Group counseling	PA	12	Medium	Research clinic	✓
Fjeldsoe et al,[54] 2015	Fair	Australia	263 women with young children (100)	31.9	Counseling and regular text messages	PA	12	Medium	Home	
Franko et al,[56] 2008	Fair	United States	476 college students (56.3)	20.1	Web-based intervention + booster session		5	Medium	University computer laboratory and home	
					Web-based intervention	HD + PA	2	Medium		

(continued)

Table 1. Characteristics of All Included Trials (continued)

Source	Study Quality[a]	Country	Sample Size, Population Description (% Women)	Age, Mean, y	Intervention	Intervention Focus	Duration, wk	Intervention Intensity[b]	Setting	PCC[c]
Fries et al,[57] 2005	Fair	United States	754 adults (64.1)	47.3	Tailored print mailing and brief counseling call	HD	6	Low	Home	✓
Gao et al,[58] 2015	Fair	United States	261 older adults (17.2)	63.2	Individual counseling and tailored print materials	PA	52	Medium	Home	✓
Gell and Wadsworth,[60] 2015	Fair	United States	87 women (100)	47.2	Targeted text messages	PA	24	Low	Other	
Goldstein et al,[61] 1999	Fair	United States	355 adults (64.5)	65.6	Brief counseling with tailored prescription	PA	26	Low	Primary care	✓
Grandes et al,[63] 2009	Good	Spain	4317 adults (65.6)[h]	50.0	Brief counseling	PA	NR	Low	Primary care	✓
Green et al,[64] 2002	Fair	United States	316 adults (52.5)	44.0	Telephone counseling	PA	12	Medium	Home	✓
Greene et al,[66] 2008	Fair	United States	1280 older adults (69.6)	75.0	Tailored print mailings and counseling telephone calls	HD	52	Medium	Home	
Greenlee et al,[67] 2015	Fair	United States	70 Hispanic breast cancer survivors (100)	56.6	Group counseling	HD	12	High	Research clinic	
Halbert et al,[69] 2000	Fair	Australia	299 older adults (54.5)	67.6	Counseling	PA	26	Medium	Primary care	✓
Hargreaves et al,[71] 2016	Fair	New Zealand	97 adults (84.5)	46.2	Tailored walking program	PA	12	Medium	Home	
Harland et al,[72] 1999	Fair	United Kingdom	523 adults (58.3)	NR	Counseling and PA vouchers	PA	12	Medium	Primary care	✓
					Counseling	PA	12	Medium		
					Brief counseling and PA vouchers	PA	2	Medium		
					Brief counseling	PA	2	Medium		
Harris et al,[73] 2015	Good	United Kingdom	298 older adults (53.7)	NR	Counseling and self-monitoring	PA	52	Medium	Primary care	✓
Hellénius et al,[76] 1993	Fair	Sweden	158 men with moderately elevated CVD risk factors (0)[i]	46.0	Counseling (diet)	HD	2	Medium	Primary care	✓
					Brief counseling (PA)	PA	0.14	Low		
					Counseling (diet and PA)	HD + PA	2	Medium		
Hinderliter et al,[78] 2014	Good	United States	95 overweight or obese adults with above-normal BP (66.3)	51.8	Group counseling on DASH diet	HD	16	High	Research clinic	✓
Hivert et al,[79] 2007	Fair	Canada	115 college students (81.7)	19.7	Group counseling	HD + PA	104	High	Other	
HPT Research Group,[82] 1990	Good	United States	587 adults with high-normal DBP (36.8)	38.6	Group counseling (potassium and sodium focus)	HD	156	High	Research clinic	
					Group counseling (sodium focus)	HD	156	High		
Jacobs et al,[83] 2011	Fair	Belgium	314 adults (66.6)	40.5	Counseling	HD + PA	52	High	Research clinic	
Jeffery and French,[85] 1999	Fair	United States	1226 adults (80.2)	38.3	Nontailored print mailings	HD + PA	156	Low	Home	
					Nontailored print mailings + incentives	HD + PA	156	Low		
John et al,[86] 2002	Fair	United Kingdom	729 adults (51.0)	45.9	Counseling	HD	12	Medium	Research clinic	✓
Kallings et al,[88] 2009	Good	Sweden	101 overweight or obese older adults (57.4)	NR	Counseling with tailored prescription	PA	NR	Medium	Primary care	✓
Kattelmann et al,[89] 2014	Fair	United States	1639 young adults (67.2)	19.3	Web-based intervention	HD + PA	64	Medium	Home	
Katz et al,[90] 2008	Fair	United States	316 adults (67.1)	NR	Provider training	PA	26	High	Primary care	✓

(continued)

Table 1. Characteristics of All Included Trials (continued)

Source	Study Quality[a]	Country	Sample Size, Population Description (% Women)	Age, Mean, y	Intervention	Intervention Focus	Duration, wk	Intervention Intensity[b]	Setting	PCC[c]
Kerr et al,[91] 2016	Fair	Australia	247 young adults (65.6)	24.3	Tailored text messages (with booster messages)	HD	24	Low	Other	
					Tailored text messages	HD	1	Low		
King et al,[95] 2007	Fair	United States	218 adults (69.8)	60.8	Automated telephone counseling	PA	52	Medium	Home	
					Human telephone counseling	PA	52	Medium		
King et al,[94] 2013	Good	United States	200 adults (51.3)	55.2	Telephone counseling with self-monitoring (PA and diet simultaneous)	HD + PA	52	Medium	Home	
					Telephone counseling with self-monitoring (diet discussions first)	HD + PA	52	High		
					Telephone counseling with self-monitoring (PA discussions first)	HD + PA	52	High		
Kinmonth et al,[96] 2008	Fair	United Kingdom	365 adults with family history of type 2 diabetes (62.0)	40.6	Telephone counseling	PA	52	Medium	Home	✓
					In-home counseling	PA	52	High		
Kolt et al,[97] 2007	Good	New Zealand	186 older adults (66.1)	74.2	Telephone counseling	PA	12	Medium	Home	✓
Kristal et al,[98] 2000	Fair	United States	1459 adults (49.1)	44.9	Tailored print mailings and counseling call	HD	52	Low	Home	✓
Lawton et al,[102] 2008	Good	New Zealand	1089 women (100)	58.9	Counseling with tailored prescription	PA	38	Medium	Primary care	✓
Lewis et al,[103] 2013	Good	United States	448 adults (87.1)	42.6	Tailored print mailings	PA	26	Low	Home	
Lutz et al,[104] 1999	Fair	United States	710 adults (64.4)	39.3	Tailored print mailings with tailored prescription	HD	16	Low	Home	✓
					Tailored print mailings	HD	16	Low		
					Nontailored print mailings	HD	16	Low		
Mailey and McAuley,[106] 2014	Fair	United States	141 women (100)	37.3	Group counseling	PA	26	Medium	NR	
Marcus et al,[109] 2007	Fair	United States	239 adults (82.0)	44.5	Telephone counseling	PA	52	Medium	Home	
					Tailored print materials	PA	52	Medium		
Marcus et al,[108] 2013	Good	United States	292 Hispanic/Latina women (100)	40.7	Tailored print mailings and self-monitoring	PA	52	Medium	Home	
Marsaux et al,[111] 2015	Fair	Europe[j]	1067 adults (58.4)	39.9	Tailored web-based advice (diet, physical activity, and phenotype)	HD + PA	26	Low	NR	
					Tailored web-based advice (diet and physical activity)	HD + PA	26	Low		
					Tailored web-based advice (diet, physical activity, phenotype, and genotype)	HD + PA	26	Low		
Marshall et al,[112] 2003	Fair	Australia	462 adults (57.6)	49.0	Tailored print mailing	PA	0.14	Low	Home	
Martinson et al,[114] 2008	Good	United States	1049 adults (72.4)	57.1	Counseling	PA	104	High	Home	✓
Mosca et al,[118] 2008	Good	United States	501 adults with family history of CVD (66.3)	48.0	Counseling	HD + PA	38	Medium	Research clinic	✓
Napolitano et al,[119] 2006	Fair	United States	280 women (100)	47.2	Tailored print mailings	PA	26	Low	Home	
					Nontailored print mailings	PA	12	Low		
Norris et al,[121] 2000	Fair	United States	847 adults (52.1)	54.9	Counseling	PA	20	Medium	Primary care	✓

(continued)

Table 1. Characteristics of All Included Trials (continued)

Source	Study Quality[a]	Country	Sample Size, Population Description (% Women)	Age, Mean, y	Intervention	Intervention Focus	Duration, wk	Intervention Intensity[b]	Setting	PCC[c]
Parekh et al,[123] 2014	Fair	Australia	4676 adults (69.2)	46.9	Computer-tailored print mailings (2 contacts)	HD + PA	12	Low	Home	✓
					Computer-tailored print mailing (1 contact)	HD + PA	0.14	Low		
Pekmezi et al,[126] 2009	Fair	United States	93 Hispanic/Latina women (100)	41.4	Tailored print mailings and self-monitoring	PA	26	Low	Home	
Pinto et al,[127] 2002	Fair	United States	298 adults (72.1)	45.9	Automated telephone counseling	PA	26	Medium	Other	✓
Pinto et al,[128] 2005	Fair	United States	100 older adults (65.0)	68.5	Counseling with tailored prescription	PA	26	Medium	Primary care	✓
Roderick et al,[130] 1997	Fair	United Kingdom	956 adults (50.0)	47.3	Counseling	HD	5	Medium	Primary care	✓
Ruffin et al,[131] 2011	Fair	United States	4248 adults (69.7)	50.6	Computer-tailored web-based intervention	HD + PA	26	Low	Home	✓
Sacerdote et al,[132] 2006	Fair	Italy	3179 adults (50.0)	44.4	Brief counseling	HD	1	Low	Primary care	✓
Simkin-Silverman et al,[136] 1995	Good	United States	535 premenopausal women (100)	47.1	Group counseling	HD + PA	234	High	Other	
Smith et al,[139] 2014	Fair	Australia	59 overweight or obese women with history of gestational diabetes (100)	35.4	Counseling	HD + PA	26	Medium	Research clinic	✓
Springvloet et al,[140] 2015	Fair	Netherlands	1349 adults (64.6)	49.4	Web-based tailored education-plus feedback	HD	6	Medium	Home	
					Web-based tailored education	HD	6	Medium		
Stewart et al,[143] 2001	Fair	United States	173 older adults (65.9)[k]	74.4	Group counseling	PA	52	High	Research clinic	✓
Taveras et al,[145] 2011[l]	Fair	United States	84 postpartum women (100)	32.9	Postpartum counseling	HD + PA	26	High	Primary care	✓
Thompson et al,[149] 2008	Fair	United States	200 American Indian women (100)	29.2	Group counseling	HD + PA	20	High	NR	
Thompson et al,[150] 2014	Good	United States	49 older adults (81.2)	79.5	Counseling and self-monitoring	PA	24	High	Home	
Tinker et al,[151] 2008	Good	United States	48 835 postmenopausal women (100)[m]	62.2	Group counseling	HD	312	High	Research clinic	
TOHP Collaborative Research Group (Phase I),[146] 1992	Fair	United States	744 adults with high-normal DBP (28.6)	43.0	Group counseling	HD	78	High	Research clinic	
TOHP Collaborative Research Group (Phase II),[147] 1997	Good	United States	1190 moderately overweight adults with high-normal DBP (33.4)	43.7	Group counseling	HD	156	High	Research clinic	
Tokunaga-Nakawatase et al,[152] 2014	Fair	Japan	216 adults with family history of type 2 diabetes (34.8)	45.2	Computer-tailored print mailings	HD + PA	26	Low	Home	✓
Valve et al,[153] 2013	Fair	Finland	3059 college-aged women (100)	19.0	Counseling	HD + PA	104	Medium	NR	
Van Hoecke et al,[154] 2014	Fair	Belgium	442 older adults (66.7)	69.	Counseling	PA	10	Medium	NR	
					Tailored prescription	PA	10	Low		
van Stralen et al,[156] 2010	Fair	Netherlands	8500 adults (57.0)	64.0	Tailored print mailings with environmental focus	PA	14	Low	Home	✓
					Tailored print mailings	PA	14	Low		

(continued)

Table 1. Characteristics of All Included Trials (continued)

Source	Study Quality[a]	Country	Sample Size, Population Description (% Women)	Age, Mean, y	Intervention	Intervention Focus	Duration, wk	Intervention Intensity[b]	Setting	PCC[c]
Vandelanotte et al,[159] 2005	Fair	Belgium	1023 adults (64.5)	39.1	Computer-based sessions with tailored feedback (PA and diet simultaneous)	HD + PA	0.14	Medium	Research clinic	
					Computer-based sessions with tailored feedback (PA feedback first)	HD + PA	12	Medium		
					Computer-based sessions with tailored feedback (diet feedback first)	HD + PA	12	Medium		
Vrdoljak et al,[160] 2013	Fair	Croatia	738 older adults (61.2)	72.3	Provider training	HD + PA	52	Medium	Primary care	✓
Wadsworth and Hallam,[161] 2010	Fair	United States	91 college-aged women (100)	NR	Web-based intervention	PA	26	Low	Other	
Warner et al,[162] 2016	Fair	Germany	360 older adults (75.2)	70.3	Group counseling with views-on-aging component	PA	0.14	Medium	NR	
					Group counseling	PA	0.14	Medium		

Abbreviations: BMI, body mass index; BP, blood pressure; CVD, cardiovascular disease; DASH, Dietary Approaches to Stop Hypertension; DBP, diastolic blood pressure; HD, healthy diet; HPT, Hypertension Prevention Trial; NR, not reported; PA, physical activity; PCC, primary care clinician; TOHP, Trials of Hypertension Prevention; USPSTF, US Preventive Services Task Force.

[a] Quality assessed using criteria specific for randomized clinical trials outlined in the USPSTF procedure manual.[13]

[b] Low intervention intensity indicates 30 minutes or less of total contact time; medium intensity, 31 to 360 minutes; high intensity, 360 minutes or more.

[c] Conducted in or recruited from primary care setting.

[d] Intervention focused on reducing sedentary time.

[e] Study inclusion criteria required BMI of 25 to 34.9 (calculated as weight in kilograms divided by height in meters squared); at baseline, 36.4% with hypertension and 6.5% with diabetes.

[f] Included 38.9% with hypertension and 24.5% taking medication for hypertension at baseline.

[g] Included 52.4% with hypertension, 10.5% with diabetes, and 19.0% with previous CVD at baseline.

[h] Included 24.4% with hypertension and 8.2% with diabetes at baseline.

[i] Study inclusion criteria required serum cholesterol level 5.2 to 7.8 mmol/L (200.8-301.2 mg/dL), fasting blood glucose level 6.7 mmol/L (120.7 mg/dL) or less, fasting triglycerides level 5.6 mmol/L (495.6 mg/dL) or less, and DBP 100 mm Hg or less.

[j] Seven European countries (Germany, Greece, Ireland, the Netherlands, Poland, Spain, and the United Kingdom).

[k] Included 39.6% with hypertension and 7.3% with diabetes at baseline.

[l] Nonrandomized clinical controlled trial.

[m] Included 37.7% with hypertension at baseline.

Ten trials reported quality-of-life outcomes and reported modest improvements at 6 and 12 months among intervention participants but no consistent benefit of the intervention compared with control conditions.[30,52,62,69,76,96,97,121,146,155]

Effects of Interventions on Intermediate Health Outcomes

Key Question 2. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve intermediate outcomes associated with cardiovascular disease (CVD) in adults?

Thirty-four of the included trials (n = 75 793) reported the effects of behavioral interventions on at least 1 intermediate outcome (ie, blood pressure, lipid levels, glucose levels, or adiposity measures); nearly half of the trials were of good quality.[21,26,31,32,38,39,47,52,63,67,71,76,78,79,82,85,86,88,89,91,96,98,102,118,130,132,136,146,147,149-151,153,161] When trials were pooled, healthful diet, physical activity interventions, or both were associated with small but statistically significant improvements in systolic blood pressure (22 trials), diastolic blood pressure (23 trials), low-density lipoprotein cholesterol (LDL-C) level (13 trials), total cholesterol level (19 trials), and adiposity measures (20 trials), compared with controls at 6 months or more (Table 1). Pooled between-group mean differences were −1.26 mm Hg (95% CI, −1.77 to −0.75) for systolic blood pressure, −0.49 mm Hg (95% CI, −0.82 to −0.16) for diastolic blood pressure, −2.58 mg/dL (95% CI, −4.30 to −0.85) for LDL-C level, and −2.85 mg/dL (95% CI, −4.95 to −0.75) for total cholesterol level—all in favor of intervention vs control groups with follow-up times of 6 months or more. For adiposity outcomes, interventions were associated with improvements in body mass index (mean difference, −0.41 [95% CI, −0.62 to −0.19]; calculated as weight in kilograms divided by height in meters squared), weight (mean difference, −1.04 kg [95% CI, −1.56 to −0.51]), and waist circumference (mean difference, −1.19 cm [95% CI, −1.79 to −0.59]), with considerable statistical heterogeneity (I^2 > 90%) in all analyses. There was no evidence of an association between healthful diet, physical activity counseling, or both and levels of high-density lipoprotein cholesterol, triglycerides, or fasting glucose in pooled analyses (**Table 2**).

Among the intermediate outcomes showing a positive association, dose-response effects were evident, with increasing intervention intensity associated with larger improvements in intermediate outcomes (Table 2). High-intensity interventions were consistently associated with statistically significant benefit on intermediate outcomes, and the effect sizes were slightly higher in analyses limited to the subset of high-intensity interventions (6-12 trials per outcome), compared with the results of combining trials of all intensities. The associations between medium-intensity interventions (5-9 trials per outcome) and intermediate outcomes were less

Table 2. Pooled Results of Intermediate Outcomes for All Interventions and by Intervention Intensity

Outcome	All Interventions			Intervention Intensity								
				High (>360 min)[a]			Medium (31-360 min)[a]			Low (≤30 min)[a]		
	No. of Trials	Mean Difference in Change (95% CI)	I^2, %	No. of Trials	Mean Difference in Change (95% CI)	I^2, %	No. of Trials	Mean Difference in Change (95% CI)	I^2, %	No. of Trials	Mean Difference in Change (95% CI)	I^2, %
Blood pressure, mm Hg												
Systolic	22	−1.26 (−1.77 to −0.75)	44.5	12	−1.55 (−2.21 to −0.89)	48.1	8	−1.10 (−2.38 to 0.15)	48.7	2	−0.12 (−1.08 to 0.84)	0
Diastolic	23	−0.49 (−0.82 to −0.16)	37.9	12	−0.67 (−0.98 to −0.37)	17.5	9	−0.57 (−1.24 to 0.10)	8.5	2	0.41 (−0.16 to 0.98)	0
Lipids, mg/dL												
LDL-C	13	−2.58 (−4.30 to −0.85)	19.6	6	−4.51 (−6.85 to −2.16)	0	6	−1.70 (−4.64 to 1.24)	5.0	1	−0.91 (−2.90 to 1.08)	NA
Total cholesterol	19	−2.85 (−4.95 to −0.75)	50.8	7	−5.32 (−8.84 to −1.81)	36.7	11	−1.64 (−3.76 to 0.48)	13.8	1	0.87 (−1.44 to 3.18)	NA
HDL-C	15	−0.17 (−1.05 to 0.71)	55.2	7	−0.54 (−2.08 to 1.00)	63.4	7	0.03 (−0.92 to 0.97)	0	1	0.94 (0.08 to 1.80)	NA
Triglycerides	13	−1.82 (−5.05 to 1.42)	4.7	7	−3.43 (−8.16 to 1.31)	0	5	−4.34 (−11.80 to 3.12)	5.8	1	1.23 (−3.37 to 5.83)	NA
Fasting glucose, mg/dL	13	−0.36 (−1.22 to 0.5)	42.4	7	−1.35 (−2.24 to −0.45)	0	5	0.38 (−1.30 to 2.06)	54.7	1	0.52 (−0.61 to 1.65)	NA
BMI[b]	20	−0.41 (−0.62 to −0.19)	95.8	9	−0.81 (−0.99 to −0.63)	73.8	7	−0.19 (−0.42 to 0.04)	76.4	4	−0.05 (−0.39 to 0.28)	85.6
Weight, kg	20	−1.04 (−1.56 to −0.51)	92.4	11	−1.62 (−2.31 to −0.93)	92.5	7	−0.44 (−0.82 to −0.06)	40.5	2	−0.23 (−1.56 to 0.40)	0
Waist circumference, cm	17	−1.19 (−1.79 to −0.59)	91.8	9	−1.92 (−2.66 to −1.17)	82.1	7	−0.77 (−1.63 to 0.09)	79.0	1	0.04 (−0.27 to 0.35)	NA

Abbreviations: BMI, body mass index; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NA, not applicable.

SI conversion factors: To convert LDL-C, total cholesterol, and HDL-C values to mmol, multiply by 0.0259; triglyceride values to mmol/L, multiply by 0.0113; glucose values to mmol/L, multiply by 0.0555.

[a] Minutes indicate total contact time for intervention.

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

consistent and generally showed no benefit, with the exception of the outcome of weight. There was insufficient evidence (only 1-4 trials per outcome) to assess the association between low-intensity interventions and intermediate outcomes.

Meta-analyses stratified by diet-only messages, physical activity–only messages, or combined diet and physical activity messages were consistent with those seen in analyses stratified by intensity (results available in the full evidence report). Healthful diet interventions (with or without physical activity messages) (7-16 trials per outcome), which were mostly high-intensity interventions, consistently showed statistically significant favorable associations with intermediate outcomes. No such benefit was seen when limiting the analyses to physical activity–only trials, which were largely of low intensity, although there were far fewer trials included in these analyses (4-8 trials per outcome). There was no evidence of effect modification based on whether the intervention was linked to primary care (independent of intervention intensity), the number of intervention sessions, the duration of the intervention, whether the intervention included group sessions, the focus of the intervention message (eg, specific dietary message), the population risk for CVD, or study quality. Very few trials reported longer-term effects (ie, greater than 12 months of follow-up) on intermediate outcomes, and there was no consistent pattern in the effects over time among those that did. In addition, there was no evidence of small-study effects for any of the intermediate outcomes.

Effects of Interventions on Behavioral Outcomes

Key Question 3. Do primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior improve associated health behaviors in adults?

All but 2[32,153] of the 88 included studies (n = 117 589) reported the effects of a behavioral intervention on dietary, physical activity, and/or sedentary behavior outcomes. More than one-third of the studies that reported behavioral outcomes (36/86 studies) were newly identified as part of this update. Almost all of the behavioral outcomes were based on self-report; 3 trials measured urinary sodium excretion, and 11 trials used accelerometers or pedometers to capture objective measures of physical activity. The instruments, modes of administration, and summary measures were highly variable across trials that measured behavioral outcomes through self-report.

Overall, there was evidence that behavioral interventions generally improved participants' dietary intake and physical activity levels. Mean between-group differences for dietary outcomes showed consistent benefit for healthful diet interventions (with or without physical activity messages) vs control groups at 6 months' or greater follow-up, but the precision in the magnitude of effects was highly

variable across trials; thus, pooled results are not presented. Between-group differences for dietary outcomes were in the magnitude of 65 kcal/d (favoring the control group) to −500 kcal/d (favoring the intervention group) in total energy intake (11 trials), 0.8 to −11 percentage points in the percentage of calories from fat (15 trials), and −0.3 to −4.1 percentage points in the percentage of calories from saturated fat (9 trials). Effects on fruit and vegetable intake ranged from between-group differences of −0.2 serving/d (favoring the control group) to 2.2 servings/d (favoring the intervention group) (16 trials); between-group differences in grams of fiber per day ranged from 1 g to 2.5 g in favor of the intervention group (6 trials). Reductions in sodium (urinary sodium excretion or self-reported dietary intake) ranged from −380 mg/d to −1380 mg/d (6 trials). Only 9 trials reported the effects of the interventions on dietary outcomes at greater than 12 months of follow-up (ie, 1.5 to 6 years of follow-up), with a lack of effect or slightly attenuated effect being seen over time.

Physical activity interventions (with or without dietary messages) were associated with a 35-minute (95% CI, 22.0 to 47.0) increase in physical activity per week compared with controls in pooled analyses at 6 to 12 months of follow-up (27 trials). The standardized effect size when pooling 46 trials that reported any continuous measure of physical activity (eg, minutes per day, minutes per week, metabolic-equivalent minutes per week, score) was a mean difference of 0.20 (95% CI, 0.14 to 0.26) in favor of the intervention group. Additionally, meta-analysis indicated that intervention group participants had an odds ratio of 1.32 (95% CI, 1.12 to 1.56) for meeting physical activity recommendations, compared with those in the control group (16 trials). Data on physical activity outcomes beyond 12 months were sparsely reported. Studies that limited their inclusion to participants with suboptimal levels of physical activity at baseline (eg, below the recommended level of 150 minutes per week) resulted in greater increases in physical activity compared with those that did not limit inclusion based on baseline physical activity levels. In contrast to findings for intermediate outcomes, there was no evidence of effect modification based on intervention intensity. Likewise, there was no evidence of a difference in effects for interventions focused only on physical activity messages vs those focused on both physical activity and healthful diet messages.

Only 4 trials reported measures of sedentary behavior independent of physical activity behavior. Of these 4 trials, 2 found statistically significant group × time effects on self-reported minutes of sitting, including 1 trial that specifically targeted reductions in daily television viewing and total sitting time.

Harms of Interventions

Key Question 4. What adverse events are associated with primary care behavioral counseling interventions to improve diet, increase physical activity, and/or reduce sedentary behavior in adults?

Harms of included interventions were sparsely reported and were inconsistently defined. Fourteen of the included trials (n = 8220) specifically mentioned the occurrence of harms or lack of harms.[22,32,35,41,44,52,73,78,95,97,102,121,132,150] Across these studies, there were no serious adverse events related to the interventions reported, although none were hypothesized. Seven physical activity–focused trials (n = 3565) reported the incidence of injuries, fractures, or falls; only 1 trial among women aged 40 to 74 years reported significantly more injuries (19% vs 14%, $P = .03$) and falls (37% vs 29%, $P < .001$) among participants in the intervention group than in the control group, respectively, over 24 months of follow-up.[102]

Discussion

This systematic review was conducted to assist the USPSTF in updating its 2012 recommendation on healthful diet and physical activity counseling for the primary prevention of CVD in persons without CVD risk factors (ie, hypertension, dyslipidemia, diabetes, or impaired fasting glucose). Eighty-eight unique trials, nearly one-half of which (38 trials) were published since the previous USPSTF review, were included. The pooled estimates found in this updated systematic review were generally consistent in magnitude with the 2010 review on this topic[15] and slightly lower in magnitude compared with the associations seen in the 2014 review among persons at high risk for CVD[14] (eTable 3 in the Supplement).

Table 3 summarizes the findings for this evidence review. Healthful diet and physical activity behavioral interventions in persons without traditional CVD risk factors were associated with modest reductions in blood pressure, levels of total cholesterol and LDL-C, and adiposity measures at approximately 6 to 12 months of follow-up, compared with control conditions. The interventions varied considerably across the studies, such as in their behavioral focus (diet only, physical activity only, or diet plus physical activity messages), their delivery mode (group and individual in-person counseling, telephone counseling, print-based, or technology-based), and their intensity (number of sessions, length of sessions, and duration of the intervention). There was evidence of a dose-response relationship, with increasing intervention intensity being associated with larger improvements in intermediate outcomes, but there was insufficient evidence to assess the effects of low-intensity interventions alone on intermediate outcomes. There was considerably more evidence for behavioral outcomes, with 86 trials reporting the effects of counseling interventions on dietary intake, physical activity, and/or sedentary behaviors. The direction of effects for all behavioral outcomes were reasonably consistent and suggested generally a small benefit for dietary outcomes and a moderate benefit for physical activity. However, there was substantial variation in outcome measures and insufficient evidence on the effects of interventions on sedentary behaviors.

The evidence for the effects of interventions on longer-term health outcomes, including all-cause and CVD-specific mortality, CVD events, and health-related quality of life, as well as intermediate cardiometabolic outcomes past 1 year, was sparse and inconsistent, precluding a robust conclusion. Likewise, a limited number of trials reported on harms of the interventions, and none of these studies found any serious adverse events related to the interventions.

In the context of sparse randomized clinical trial evidence for the effect of healthful diet and physical activity interventions on health outcomes, observational evidence from very large, individual participant–data meta-analyses of prospective cohort studies can be used to estimate and bound the potential benefit of proportional differences in intermediate outcomes on the risk of morbidity and mortality. Such evidence suggests that small differences in blood pressure, blood cholesterol levels, and body mass index can translate into small differences in important health outcomes (see full evidence report).[166-168]

Table 3. Summary of Evidence, by Key Question

No. of RCTs, No. of Observations	Study Quality	Body of Evidence Limitations	Consistency/Precision	Applicability	Summary of Findings by Outcome	Reporting Bias	EPC Assessment of Strength of Evidence
KQ1: Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Health Outcomes in Adults?							
12 RCTs n = 58 848 (2/12 trials identified in update; both new studies reported QOL outcomes)	Good: 5 Fair: 7	Data from 2 trials based on observational follow-up after trials were completed. Few studies reported QOL measures; most reported domain-specific QOL instead of summary scores.	Reasonably consistent[a] Imprecise	Mortality and CVD event data limited to high-intensity diet-only interventions, and most studies were among individuals with high-normal BP. Largest trial in postmenopausal women. QOL data limited to mostly physical activity trials.	No difference in all-cause or CVD-related mortality in high-intensity diet-only interventions at 3 to 15 y of follow-up (4 studies, n = 51 356). Mixed findings for effects on CVD events in 3 high-intensity diet-only interventions at 8 to 15 y follow-up. Largest trial in postmenopausal women (n = 48 835) found no difference in major CVD events or stroke among women without a history of CVD over 8.1 y of follow-up. No consistent benefit of interventions on QOL at 6-12 mo (10 studies, n = 52 423).	Undetected for mortality and CVD events Suspected for QOL[b]	Low
KQ2: Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Intermediate Outcomes Associated With CVD in Adults?							
34 RCTs n = 75 793 (10/34 trials identified in update)	Good: 13 Fair: 21	Considerable statistical heterogeneity (I^2 > 90%) for meta-analyses of adiposity outcomes. Limited evidence beyond 12 mo or for incidence of hypertension, dyslipidemia, or diabetes.	Consistency and precision varied across intermediate outcomes; more consistent and precise for blood pressure and LDL-C.[c]	Generally applicable to adults not at risk for CVD. Intensity of intervention confounded with setting; high-intensity interventions were more likely to take place outside of primary care and show effectiveness. Few physical activity–focused trials reported intermediate outcomes.	Small, statistically significant improvements in SBP (−1.26 mm Hg [95% CI, −1.77 to −0.76], 22 studies) and DBP (−0.49 mm Hg [95% CI, −0.82 to −0.16], 23 studies), LDL-C (−2.58 mg/dL [95% CI, −4.30 to −0.85], 13 studies), total cholesterol (−2.85 mg/dL [95% CI, −4.95 to −0.75], 19 studies), and adiposity outcomes (BMI, −0.41 [95% CI, −0.62 to −0.19], 20 studies) at 6-12 mo associated with healthful diet, physical activity interventions, or both. Evidence of dose-response effect with increasing intervention intensity associated with larger improvements in intermediate outcomes. Insufficient evidence to assess the effects of low-intensity interventions alone. No evidence of an association with levels of HDL-C, triglycerides, or FBG.	Undetected	Moderate

(continued)

Table 3. Summary of Evidence, by Key Question (continued)

No. of RCTs, No. of Observations	Study Quality	Body of Evidence Limitations	Consistency/Precision	Applicability	Summary of Findings by Outcome	Reporting Bias	EPC Assessment of Strength of Evidence
KQ3: Do Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior Improve Associated Health Behaviors in Adults?							
86 studies[d] n = 117 589 (36/86 trials identified in update)	Good: 18 Fair: 68	Almost all outcomes based on self-report. Instruments, recall periods, and summary measures were extremely heterogeneous, with varying evidence of validity and reliability. Few interventions incorporated messages to decrease sedentary behavior.	Reasonably consistent Imprecise	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. Most trials that reported a physical activity outcome were of low or medium intensity.	Magnitude and precision in differences for dietary outcomes were quite variable across studies and resulted in considerable heterogeneity in meta-analysis. Between-group differences for dietary outcomes were in magnitude of 65 (favoring the control group) to −500 kcal/d (favoring the intervention group) in total energy intake (11 studies), 0.8 to −11 points in percentage of calories from fat (15 studies), and −0.3 to −4.1 points in percentage of calories from saturated fat (9 studies), and approximately −380 to nearly −1400 mg/d of sodium (6 studies). Effects on fruit and vegetable intake ranged from between-group differences of −0.2 servings/d (favoring control group) to 2.2 servings/d (favoring intervention group) (16 studies); between-group differences in grams of fiber per day ranged from 1 to 2.5 g in favor of intervention group (6 studies). Small, statistically significant association with behavioral interventions and physical activity in favor of interventions over controls (SMD, 0.20 [95% CI, 0.14 to 0.26]; 46 studies). An analysis of physical activity found difference of approximately 35 min of physical activity per wk between groups (mean difference, 34.5 min/wk [95% CI, 22.0 to 47.0]; 27 studies). Significantly higher odds of meeting PA recommendations (150 min/wk of PA) among intervention vs control group participants (OR, 1.32 [95% CI, 1.12 to 1.64]; 16 studies). Effects on cardiorespiratory fitness were generally consistent with results for self-reported physical activity. Insufficient evidence for sedentary behaviors.	Undetected	Low

(continued)

Table 3. Summary of Evidence, by Key Question (continued)

No. of RCTs, No. of Observations	Study Quality	Body of Evidence Limitations	Consistency/Precision	Applicability	Summary of Findings by Outcome	Reporting Bias	EPC Assessment of Strength of Evidence
KQ4: What Adverse Events Are Associated With Primary Care Behavioral Counseling Interventions to Improve Diet, Increase Physical Activity, and/or Reduce Sedentary Behavior In Adults?							
14 RCTs n = 8220 (7/14 trials identified in update)	Good: 7 Fair: 7	Harms sparsely reported for included trials. Few details provided about how harms were recorded and specific events that occurred.	Reasonably consistent Precise	Applicable to physical activity interventions. Did not include observational evidence on harms related to changes in diet or physical activity.	No serious adverse events related to behavioral interventions (8 studies). Seven PA trials generally found no differences in rates of injuries, fractures, falls, or CV events. Only 1 trial among women aged 40-74 y found significantly more injuries and falls among intervention vs control group participants.	Undetected	Moderate[e]

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

SI conversion factors: To convert LDL-C and total cholesterol values to mmol/L, multiply by 0.0259.

[a] Inconsistent in direction and magnitude of effects for QOL outcomes.

[b] Possible selective reporting or selective analysis bias.

[c] Reasonably consistent and reasonably precise for SBP; reasonably consistent and imprecise for DBP and LDL-C; inconsistent and imprecise for total cholesterol, HDL-C, and triglycerides; and inconsistent and reasonably precise for adiposity outcomes.

[d] All but 1 study was a randomized clinical trial; the 1 remaining study was a nonrandomized clinical trial.

[e] 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.

This review represents only a subset of the literature on dietary and physical activity counseling. Trials focused on dietary or physical activity counseling in persons with known cardiovascular risk factors or to prevent or manage other health risks and conditions (eg, falls, cognitive impairment, cancer), as well as those focused on weight loss or weight management, were excluded. Many of these topics are the focus of other USPSTF reviews and recommendations.[169-173]

Limitations

With complex interventions such as these, describing and synthesizing intervention characteristics is difficult. The included interventions varied considerably in terms of the nature of the advice, mode of delivery, and delivery schedule. Details of each intervention were abstracted, and an established taxonomy for describing the behavior change techniques used in the interventions[174] was used. Consistent rules were used to estimate the total minutes of contact and to categorize each intervention group by intensity. Despite these attempts, there is a need for better reporting of intervention characteristics to facilitate evaluation and dissemination of evidence-based practices. As outlined by Krist et al,[175] research on behavioral counseling interventions such as the type synthesized here would benefit from an application of checklists and frameworks, such as the Template for Intervention Description and Replication (TIDierR); Research, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM); and the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS), to assess the feasibility and applicability of interventions as well as to improve replication and dissemination.

This review found no evidence of a difference in effects by the focus of the message, but analyses were highly confounded by the intensity of interventions. Also, only 1 of the included studies targeted reductions in sedentary behavior (ie, sitting time) as the main focus of the trial, and only 3 trials reported the outcomes of sedentary behavior. More research on the effects of counseling to reduce sedentary behavior in adults on behavioral and intermediate health outcomes is warranted. Very few studies explored whether effectiveness of the intervention varied among important subpopulations (older adults, racial and ethnic minority groups, and those with lower socioeconomic status). Such a priori analyses could assist in identifying groups of adults who might benefit more from such interventions.

Additionally, most of the trials relied on self-reported dietary and physical activity measures, with variable levels of evidence of the reliability and validity of the measures. Dietary intake was most often measured by food frequency questionnaires (such as the full-length or shorter versions of the Block food frequency questionnaire[176,177]), entries in food diaries, or 24-hour food recalls. The tools and summary variables used to measure physical activity were even more inconsistent. Physical activity was summarized in terms of total physical activity, leisure-specific physical activity, moderate- and/or vigorous-intensity physical activity, walking behaviors, and multiple other indicators; in addition, the results were expressed in different units across studies (eg, minutes per week, metabolic equivalent task-minutes per week, steps per day, summary "scores"). Each of

these methods can be prone to bias.[178] While researchers must fit the specific measurement instruments and summary variables to the needs of their particular study aims, research protocols, and sample characteristics, the field ofresearch could benefit from more standardization of behavioral outcome measurement.[179]

Studies that were heterogeneous with respect to clinical and demographic characteristics, interventions, and settings were intentionally pooled. For most outcomes, the statistical heterogeneity of pooled analyses was unimportant (I^2 < 40%) or moderate (I^2 = 30%-60%) and therefore still reasonable to allow for interpreting of pooled estimates. However, given the clinical heterogeneity, interpreting the 95% confidence intervals instead of the summary estimate helps inform the true magnitude of effects on the individual outcomes.

Conclusions

Diet and physical activity behavioral interventions for adults not at high risk for cardiovascular disease result in consistent modest benefits across a variety of important intermediate health outcomes across 6 to 12 months, including blood pressure, low-density lipoprotein and total cholesterol levels, and adiposity, with evidence of a dose-response effect, with higher-intensity interventions conferring greater improvements. There is very limited evidence on longer-term intermediate and health outcomes or on harmful effects of these interventions.

ARTICLE INFORMATION

Accepted for Publication: March 10, 2017.

Author Contributions: Dr Patnode had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Patnode, Evans.
Acquisition, analysis, or interpretation of data: Patnode, Evans, Senger, Redmond.
Drafting of the manuscript: Patnode, Evans, Redmond.
Critical revision of the manuscript for important intellectual content: Patnode, Senger.
Statistical analysis: Patnode, Redmond.
Administrative, technical, or material support: Patnode, Evans, Senger.
Supervision: Patnode.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Funding/Support: This research was funded under contract number HHSA-290-2012-00015-I, Task Order 6, from the Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services, under a contract to support the USPSTF.

Role of the Funder/Sponsor: Investigators worked with USPSTF members and AHRQ staff to develop the scope, analytic framework, and key questions for this review. AHRQ had no role in study selection, quality assessment, or synthesis. AHRQ staff provided project oversight, reviewed the report to ensure that the analysis met methodological standards, and distributed the draft for peer review. Otherwise, AHRQ had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript findings. The opinions expressed in this document are those of the authors and do not reflect the official position of AHRQ or the US Department of Health and Human Services.

Additional Contributions: We gratefully acknowledge the following individuals for their contributions to this project: the AHRQ staff; the US Preventive Services Task Force; EPC staff members Keshia Bigler, MPH, Erin Coppola, BS, Smyth Lai, MLS, Elizabeth O'Connor, PhD, Ning Smith, PhD, and Elizabeth Hess, MA, ELS(D). USPSTF members, peer reviewers, and federal partner reviewers did not receive financial compensation for their contributions.

Additional Information: A draft version of this evidence report underwent external peer review from 7 content experts: David Brown, PhD (Centers for Disease Control and Prevention), Janet de Jesus, MS (National Heart, Lung, and Blood Institute), Paul James, MD (University of Iowa), Sarah Lewington, DPhil (University of Oxford), Alice Lichtenstein, DSc (Tufts University), JoAnn Manson, MD (Harvard University and Brigham and Women's Hospital), and Deborah Young, PhD (Kaiser Permanente) and 4 federal partners: the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Indian Health Service (IHS), and the Department of Veterans Affairs. Comments were presented to the USPSTF during its deliberation of the evidence and were considered in preparing the final evidence review.

Editorial Disclaimer: This evidence report is presented as a document in support of the accompanying USPSTF Recommendation Statement. It did not undergo additional peer review after submission to *JAMA*.

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