

## Interventions to Promote Physical Activity and Dietary Lifestyle Changes for Cardiovascular Risk Factor Reduction in Adults

### A Scientific Statement From the American Heart Association

*Endorsed by the Preventive Cardiovascular Nurses Association and the Society of Behavioral Medicine*

Nancy T. Artinian, PhD, RN, FAHA, Chair; Gerald F. Fletcher, MD, FAHA, Co-Chair;  
Dariush Mozaffarian, MD, DrPH, FAHA; Penny Kris-Etherton, PhD, RD, FAHA;  
Linda Van Horn, PhD, RD, FAHA; Alice H. Lichtenstein, DSc, FAHA;  
Shiriki Kumanyika, PhD, MPH, FAHA; William E. Kraus, MD, FAHA; Jerome L. Fleg, MD, FAHA;  
Nancy S. Redeker, PhD, RN, FAHA; Janet C. Meininger, PhD, RN; JoAnne Banks, RN, PhD;  
Eileen M. Stuart-Shor, PhD, ANP, FAHA; Barbara J. Fletcher, RN, MN, FAHA;  
Todd D. Miller, MD, FAHA; Suzanne Hughes, MSN, RN, FAHA; Lynne T. Braun, PhD, CNP, FAHA;  
Laurie A. Kopin, MS, RN, ANP, FPCNA; Kathy Berra, MSN, ANP, FAHA;  
Laura L. Hayman, PhD, RN, FAHA; Linda J. Ewing, PhD, RN; Philip A. Ades, MD;  
J. Larry Durstine, PhD; Nancy Houston-Miller, BSN, FAHA;  
Lora E. Burke, PhD, MPH, FAHA, Steering Committee Co-Chair; on behalf of the American Heart Association Prevention Committee of the Council on Cardiovascular Nursing

Approximately 79 400 000 American adults, or 1 in 3, have cardiovascular disease (CVD).<sup>1</sup> CVD accounts for 36.3% or 1 of every 2.8 deaths in the United States and is the leading cause of death among both men and women in the United States, killing an average of 1 American every 37 seconds.<sup>1</sup> Older adults, some ethnic minority populations, and socioeconomically disadvantaged individuals have an increased prevalence of CVD and vascular/metabolic risk factors such as hypertension, dyslipidemia, and diabetes; are more likely to have  $\geq 2$  risk factors; and are at increased risk of being sedentary, overweight or obese, and having unhealthy dietary habits.<sup>2–10</sup> Black and Hispanic immigrants are initially at lower risk for vascular/metabolic risk factors and CVD than US-born black and Hispanic individuals,<sup>2</sup> but as they adapt to the diet and activity habits of this country,

the prevalence of vascular/metabolic risk factors increases.<sup>3</sup> Each of these issues emphasizes the importance of interventions to promote physical activity (PA) and healthy diets in all American adults.

Even modest sustained lifestyle changes can substantially reduce CVD morbidity and mortality. Because many of the beneficial effects of lifestyle changes accrue over time, long-term adherence maximizes individual and population benefits. Interventions targeting dietary patterns, weight reduction, and new PA habits often result in impressive rates of initial behavior changes, but frequently are not translated into long-term behavioral maintenance.<sup>4</sup> Both adoption and maintenance of new cardiovascular risk-reducing behaviors pose challenges for many individuals. According to the National Center for Health Statistics, life expectancy could increase by

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almost 7 years if all forms of major CVD were eliminated.<sup>5</sup> Improvements in morbidity and quality of life would also be substantial. In order to achieve these goals, healthcare providers must focus on reducing CVD risk factors such as overweight and obesity, poor dietary habits, and physical inactivity by helping individuals begin and maintain dietary and PA changes. Each year >\$44 billion, including \$33 billion in medical costs and \$9 billion in lost productivity due to heart disease, cancer, stroke, and diabetes, is attributable to poor nutrition.<sup>6</sup> In the year 2000, the annual estimated direct medical cost of physical inactivity was \$76.6 billion.<sup>1</sup>

There are considerable published data to strongly support the benefits of PA and dietary changes as a means to decrease the morbidity and mortality of CVD and stroke in adults. Such data are presented and discussed in detail in the statements from the American Heart Association (AHA)<sup>7</sup> and other sources. Notable statements and studies include, but are not limited to, the statement on exercise (AHA),<sup>8</sup> the statement on PA intervention studies (AHA),<sup>9</sup> the statement on diet and lifestyle recommendations (AHA),<sup>10</sup> the 2005 *Dietary Guidelines for Americans*,<sup>11</sup> and the recommendation on PA and public health.<sup>12</sup> Despite the abundance of data supporting the benefits of lifestyle changes for CVD, it is striking that Americans are increasingly more challenged with the growing burdens of excess body weight, limited PA, and suboptimal dietary habits. These lifestyle problems are also associated with many chronic diseases other than CVD and stroke, including type 2 diabetes, osteoporosis, depression, and many cancers.

Cardiovascular risk factors can be combated and controlled by adherence to current lifestyle recommendations. One important example of success achieved in improving lifestyle habits is the achieved decline in prevalent tobacco use from 42.4% to 20.5% of American adults between 1965 and 2007.<sup>13</sup> Although work remains in this regard, the success of tobacco cessation efforts provides a strong basis for optimism that a concerted evidence-based program of education, policy change, and individual interventions could successfully improve dietary and PA habits in the United States.

The purpose of this scientific statement is to provide evidence-based recommendations on implementing PA and dietary interventions among adult individuals, including adults of racial/ethnic minority and/or socioeconomically disadvantaged populations. The most efficacious and effective strategies are summarized, and guidelines are provided to translate these strategies into practice. Individual, provider, and environmental factors that may influence the design of the interventions, as well as implications for policy and for future research, also are briefly addressed.

**Description of Data Search Strategies and Evidence Rating System**

To identify articles concerned with diet and PA behavior change interventions in individuals, literature searches were performed in 5 databases; MEDLINE, CINAHL, Cardiosource Clinical Trials, Cochrane Library, and PsycINFO. Included studies were limited to adult humans (defined as ≥18 years of age); English language; randomized controlled or quasi-experimental designs or meta-analyses; focused on the effects of diet or PA interventions on weight, blood pressure (BP), PA level, aerobic resis-

**Table 1. Definition of Classes and Levels of Evidence Used in Dietary and Physical Activity Lifestyle Changes Recommendations<sup>226</sup>**

Class I	Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective.
Class II	Conditions for which there is conflicting evidence and/or divergence of opinion about the usefulness/efficacy of a procedure or treatment.
Class IIa	Weight of evidence or opinion is in favor of the procedure or treatment.
Class IIb	Usefulness/efficacy is less well established by evidence or opinion.
Class III	Conditions for which there is evidence and/or general agreement that the procedure or treatment is not useful/effective and in some cases may be harmful.
Level of Evidence A	Data derived from multiple randomized clinical trials.
Level of Evidence B	Data derived from a single randomized trial or nonrandomized studies.
Level of Evidence C	Expert opinion or case studies.

tance exercise, fitness, or consumption of calories, fruits, vegetables, fiber, total fat, saturated fat, cholesterol or salt; and published between January 1997 and May 2007. A few landmark studies that predate 1997 publication were included in our review. Despite extensive search efforts, all relevant studies may not have been identified; overall studies are representative and capture the state of the field.

Unpublished reports or reports published only in abstract form were not included. There was considerable variation in the direction and strength of findings within the studies reviewed; however, an effect of bias against publication of studies with null results cannot be ruled out. Studies were restricted to those conducted in the United States because societal and cultural factors can affect feasibility and success of particular intervention strategies; nonetheless, most of the findings may be generalizable to other developed nations. Feeding trials, observational studies of specific nutrients, and observational studies of aerobic capacity were excluded. Given the varying goals and outcomes of the different identified intervention studies, when possible we used a common measure of effect size (ES) to quantify and compare the success of each intervention.<sup>14</sup> Recommendations follow the AHA and the American College of Cardiology methods of classifying the evidence (Table 1).

**Findings**

Details of studies of behavioral change interventions and related PA and dietary outcomes are presented in Tables 2 and 3. Because cognitive-behavioral strategies for promoting change are integrated across all reports, the studies in Tables 2 and 3 are organized according to the format of the intervention delivery. The majority of studies assessed changes in body weight and/or specific eating patterns (fruits/vegetables, dietary fat). Except for studies using standard behavioral interventions for weight loss, in which daily calorie and fat gram goals are provided, most studies did not target total energy intake. As shown in Tables 2 and 3, the ES for the between-

**Table 2. RCTs of Interventions to Promote PA and Dietary Lifestyle Change: Nonminority Samples**

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes		
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight
Print-only delivery strategies					
Hunt et al, <sup>118</sup> 2004, 2-group RCT/12 mo (N=5473)	Primary care practice subjects with mildly controlled HTN, 58% women, mean age 69 y, =90% white. Retention: 52%.	<p>1: 2 educational packets sent 3 mo apart; first focused on HTN and lifestyle, second on medication adherence and home BP monitoring with BP log; both included letter from PCP.</p> <p>2: complete survey. Intervention group scored higher on HTN knowledge quiz (7.48±1.6 vs 7.06±1.6, <i>P</i>=0.019).</p> <p>3: Subjects received usual care.</p>	...	...	BP: C 137/77 vs I 135/77, <i>P</i> =0.229.
Marcus et al, <sup>79</sup> 1998, 2-group RCT/6 mo (N=194)	76% female, mean age 44.3 y, 93.8% white, 82% employed, mean 12.5 min of moderate level PA at baseline.	<p>C: 4 self-help booklets promoting PA mailed to subjects.</p> <p>I: Computer-generated, individually tailored reports and self-help manuals matched to stage of motivational readiness. Reports consisted of feedback about (1) stage of readiness for PA; (2) level of self-efficacy, decisional balance, and use of cognitive-behavioral processes; (3) comparative feedback; and (4) progress since last assessment. Motivationally matched manuals accompanied reports; sent by mail.</p>	...	...	...
Group-based intervention delivery strategies					
Aldana et al, <sup>113</sup> 2006, 2-group RCT/6 mo (N=348)	70% women, mean age 50 y, 93% white, BMI 31–33. Retention: 88%, intervention 95%.	<p>I: 40-lecture course over 4 wks, focus on nutrition and PA. Textbook and workbook followed curriculum topics provided, included assignments. Only within-group changes reported, all <i>P</i> values significant.</p> <p>C: Not described.</p>	...	...	Weight loss: C -0.5 vs I -4.5 kg, <i>P</i> <0.0001. SBP/DBP mm Hg: -5/-5.5 vs -4/-3.8, <i>P</i> <0.0001 Cholesterol: -6 vs -11, <i>P</i> =0.004 Glucose: -3 vs -1, <i>P</i> =0.005. SBP, cholesterol improvement within groups ( <i>P</i> <0.001) at 16 wks, NSD between groups.
Andersen et al, <sup>56</sup> 1999, 2-group RCT/1 y (N=40)	Women, mean age 43 y; BMI 32.9. Retention: 98% at 16 wks, 82.5% at 68 wks.	<p>Structured aerobic exercise (SAE) + low-fat diet: weekly aerobic exercise classes for 16 wks.</p> <p>Moderate lifestyle activity + low-fat diet: weekly group sessions focused on moderate PA, kept daily records, wore pedometers, received graphs of PA and feedback.</p>	...	...	Weight loss: SAE group -8.3 kg vs -7.9 kg at 16 wks, <i>P</i> =0.08; ES=-0.57. At 1 year, SAE regained 1.6 vs 0.08 kg.
Burke et al, <sup>24</sup> 2006, 4-group RCT/18 mo (N=182)	87% women, mean age 44 y, 29.7% minority, BMI 34. Retention: 86%.	<p>Standard behavioral weight loss treatment (SBT) delivered to all 4 groups: (1) SBT+lacto-ovo-veg (LOV) diet/not preferred, (2) SBT+LOV diet/preferred, (3) SBT+standard weight loss diet/not preferred, (4) SBT+standard weight loss diet/preferred.</p> <p>SBT includes goal setting, self-monitoring, and feedback.</p> <p>Intervention 12 mo, study gives 6-mo report.</p>	...	...	Weight loss by diet groups: -7.0–7.5 kg, NSD by diet or preference group; ES=0.03. LDL: SBT 0.05 vs SBT+LOV -0.16, <i>P</i> =0.013.
Carais et al, <sup>23</sup> 2004, 2-group RCT/1 y (N=44)	100% women, mean age 54.7 y, race not reported, 44.5% college degree, 33.3% income <\$30 000, mean BMI 36.4.	<p>Lifestyle change (LC): 24 group sessions to change weight and PA: 5 components: lifestyle, exercise, attitudes, relationships, and nutrition. Focused on self-monitoring, controlling stimuli, PA, nutrition education, modifying self-defeating thoughts and negative emotions, setting realistic goals, relationships, relapse prevention, and weight maintenance.</p> <p>Lifestyle change+self-control skills training: Lifestyle change as above plus a combination of didactic instruction, individual activities, and weekly out-of-class assignments to strengthen self-control.</p>	...	...	Weight loss: Mean weight loss in both groups was 6.2 kg, <i>P</i> <0.05. NSD between groups. BP: Both groups had a mean decrease in SBP of 8 mm Hg and in DBP of 7.9 mm Hg, <i>P</i> <0.05. NSD between groups. Chol: For both groups LDL decreased an average of 10.6 mg/dL. NSD between groups.

(Continued)

Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	
Heshika et al, <sup>123,124</sup> 2003, 2-group, multicenter RCT/2 y (N=423)	>80% women, age 44–45 y, BMI 34	Self-help program (SH): two 20-min counseling sessions with nutritionist and provision of self-help resources. Commercial weight loss program: food and activity plans, cognitive restructuring behavior modification plan, weekly meetings over 104 wks.	...	...	Weight loss: SH group –1.3 vs Commercial group –4.3 kg, $P<0.001$ at 12 mo; –0.2 vs –2.9 kg at 2 y, $P<0.001$ ; ES=0.16.	BP/Cholesterol/Glucose/ Hemoglobin A1c
Jakicic et al, <sup>109</sup> 1999, 3-group RCT/18 mo (N=148)	Women, mean age 37 y, BMI 32.8. Retention: 78%.	Behavioral weight control program combined with (1) Long-bout exercise (LB); (2) multiple short-bout exercise (SB); or (3) multiple short-bout exercise with home exercise equipment (SBEQ) (provided treadmill).	...	...	Weight loss in SBEQ –7.4 kg vs SB –3.7, $P<0.05$ ; NSD from LB group –5.8; ES=16.	...
Jeffery et al, <sup>25</sup> 1998, 5-group RCT/18 mo (N=193)	≈80% female, age ≈40 y, ≈80% white, BMI 31. Retention: 78%.	(1) Standard behavioral therapy for weight loss (SBT); (2) SBT+supervised walks (SW), 3/wk; (3) SBT+SW+personal trainer (PT) worked with 2–3 subjects during walks; (4) SBT+SW+monetary incentives (I) paid \$1–\$5 for walks (In); and (5) SBT+SW+PT+In received all of the above. SBT= weekly group sessions ×24, monthly thereafter for 1 y. Daily calorie/fat goals, PA 250–1000 kcal/wk.	...	...	Weight loss in all groups achieved study goal of 1000 kcal/wk. PA: subjects in all groups achieved study goal of 1000 kcal/wk.	...
Writing Group of the PREMIER Collaborative Research Group, <sup>26</sup> 2003, 3-group RCT/6 mo (N=810)	Adults with stage 1 hypertension or optimal BP, 34% black, 62% women, mean age 50 years, approximately 10% <\$30 000 annual income.	Subjects' goals for EST and EST+DASH were weight loss $\geq 15$ lb for subjects with BMI $\geq 25$ , $\geq 180$ minutes/wk moderate intensity PA, daily intake of $\leq 100$ mEq Na, daily intake $\leq 1$ oz alcohol for men and $\frac{1}{2}$ oz for women. Established (EST): 18 face-to-face contacts (14 group meetings and 4 individual sessions). Diaries used to record PA, calories, and Na. Established plus DASH (EST+DASH): Subjects received all in EST plus instruction and counseling about DASH diet; dietary goals for F/V, low-fat dairy, saturated fat, and total fat. Diaries used to record PA, calorie, Na, F/V, dairy, and fat. Advice only (A): Dietitian provided a 30-min individual session on nonpharmacological factors that affect BP and provided printed educational materials. Counseling on behavior change not provided but had 4 individual counseling sessions on lifestyle change. DASH diet included 9–12 servings F/V per day, low-fat dairy 2–3 servings/d, <7% energy saturated fat, and <25% energy total fat.	F/V servings/d: Change from baseline, 0.5 for A, 0.5 for EST, 3.0 for EST+DASH. EST vs A, $P=0.79$ ; all other comparisons $P<0.001$ . Total fat, % kcal: –1.0 for A, –3.9 for EST, –9.5 EST+DASH. All comparisons $P<0.001$ .	PA kcal/kg/d: NSD.	Weight loss: Change from baseline: –1.1 kg in A, –4.9 kg in EST, –5.8 kg in EST+DASH; EST vs A and EST+DASH vs A, $P<0.001$ ; EST vs EST+DASH, $P=0.07$ . Prevalence of high BP at 6 mo: 26% in A group, 17% in EST group, 12% in EST+DASH group (difference between A and EST, $P=0.01$ ; between A and EST+DASH, $P=0.12$ ).	...
McManus et al, <sup>27</sup> 2001, 2-group RCT/18 mo (N=101)	≈90% female, mean age 44 y, ≈88% white, BMI 34. Retention: 20% vs 54% at 18 mo.	Low-fat (LF) diet: 20% of kcal. Moderate fat (MF): 35% of kcal, Mediterranean diet. Both groups: weekly group educational classes to address behavioral modification skills and PA; self-monitored in weekly diaries, feedback provided.	Total fat (% kcal): LF 30% vs MF 35%, $P=0.03$ .	...	Weight loss: LF –2.9 vs MF 4.8 kg at 18 mo, $P<0.001$ ; ES=0.33.	...
Sinkin-Silverman et al, <sup>66</sup> 2003, 2-group RCT/4.5 y (N=635)	Women (per- to postmenopausal), predominantly white, 35.5% overweight, 11% obese. Retention at 5 y: 95%.	C: Health education pamphlet and assessment only at 6, 18, 30, 42, and 54 mo. Lifestyle intervention (LI): Phase 1: 15 group meetings/20 wks, lifestyle changes, modest weight loss, and PA; Phase 2: 6 group meetings in mo 6–54; mail and telephone F/U. Individual nutrition consultation offered to lower LDL cholesterol.	Kcal: C –24.8 vs LI –159.6 kcal, $P<0.01$ ; ES=0.11.	Energy expenditure: C –113.3 vs 274.9 kcal, $P<0.001$ ; ES=0.14.	Weight loss: 55% of LI group were at or below baseline weight compared with 26% of C group, $P<0.001$ . Mean weight change in LI group was 0.1 kg below baseline compared with mean weight gain of 2.4 kg in C group.	...

(Continued)

**Table 2. Continued**

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/Hemoglobin A1c
Toobert et al. <sup>67</sup> 2005, 2-group RCT/6 mo (N=279)	Postmenopausal women with type 2 DM, >90% white, BMI 35. Retention: 88%.	UC: ongoing diabetes care from MD Mediterranean Lifestyle Program (MLP): lifestyle change aimed at behavioral risk factors affecting CHD; 2.5-d retreat followed by weekly 4-h meetings for 6 mo. Focus: diet, PA, stress management, social support.	Total fat (g): UC 162.1 vs MLP 46.6 g, <i>P</i> <0.001; ES=20. Fruit servings/d: UC 1.6 vs 2.2, <i>P</i> <0.001 Vegetable servings/d: UC 2.0 vs 2.6, <i>P</i> <0.001.	PA (METs)×duration(×days): 55.9 UC vs 80.9 MLP, <i>P</i> <0.009.	Weight: UC 93.4 vs MLP 91.7 kg, <i>P</i> =0.004.	...
Wadden et al. <sup>72</sup> 1998, 4-group RCT/1 y (N=99)	Women, mean age 42 y, BMI 36. Retention: 60.2%.	Cognitive-behavioral treatment for weight loss delivered in 28 weekly sessions followed by 10 biweekly sessions combined with caloric-restricted diet plus 1 of 4 exercise groups: (1) aerobic exercise, (2) strength training+aerobic, (3) strength training, or (4) no exercise beyond lifestyle activity.	...	...	Weight loss: 4 groups 10.6–11.4 kg, NSD; at 1 y 35%–55% of weight regained, NSD.	...
Wadden et al. <sup>28</sup> 2005, 4-group RCT/1 y (N=224)	Men & women, mean age 43.6 y, 65% white, BMI 37.8.	All subjects had diet of 1200–1500 kcal/d and exercise 30 min/d most days of the week. Sibutramine Alone (SibA): 8 brief visits with PCP at 1, 3, 6, 10, 18, 40, 52 wks. Received dose of sibutramine at wk 1; received print materials about fitness. Lifestyle Modification Alone (LMA): Wkly group meetings from wks 1–19, every 2 wks from wks 20–40, follow-up visit wk 52. Daily self-monitoring of food intake and PA, which were reviewed at wkly meetings. Combined Therapy (CT): Same 2 treatments as groups above. Sibutramine plus Brief Therapy. (Sib+BT): Sibutramine as in group 1 and met with PCP 10–15 min. on same schedule as group meetings.	...	...	Weight loss: CT 12.1±9.8 kg vs SibA 5.0±7.4 kg vs LMA 6.7±7.9 kg vs Sib+BT, 7.5±8.0 kg, <i>P</i> <0.001. Subjects in CT group who self-monitored frequently: weight loss 18.1±9.8 kg vs 7.7±7.5 kg, <i>P</i> =0.04.	...
Wing et al. <sup>29</sup> 1999, 4-group RCT/10 mo (N=166)	Women and men, age ≈42 y, >90% white, BMI 31.2. Retention: 75%–95%.	(1) Recruited alone and standard behavioral therapy for weight loss [SBT]; (2) recruited alone and SBT+social support; (3) recruited with friends and SBT; (4) recruited with friends & SBT+social support. SBT includes group sessions; self-monitoring calories, fat, and PA in weekly diaries; and feedback. Social support: included intragroup activities and intergroup competition for groups 2 and 4.	...	...	Weight loss: Recruited with friends –7.7 kg, recruited alone –4.3 kg, <i>P</i> <0.001; ES=0.26.	...
Yeh et al. <sup>68</sup> 2003, 2-group RCT/2 y (N=80)	Women, age 30–60 y, BMI 36.3 and 37.9. Retention: 33% SBI, 35% CB.	Office-based counseling with dietitian (OBC); 6 intervention sessions over 6 mo+offer of 6 more. Skills based intervention (SBI): two 90-min didactic sessions related to diet and behavior; additional sessions for technical skill building (supermarket, restaurants); telephone and E-mail access to dietitian for rest of 12 mo.	Saturated fat (g): OBC –0.08 vs SBI –4.2 g at 24 mo, <i>P</i> =0.07.	...	Weight loss: OBC –4.0 vs SBI –1.7 at 6 mo, <i>P</i> <0.05; 1.1 vs –0.6 at 24 mo. NS.	...

(Continued)

Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	
Individual-based intervention delivery strategies						
Ammerman et al, <sup>98</sup> 2003, 2-group cluster randomized trial, 8 rural health departments/12 mo (N=468)	71% female, mean age 55 y, 80% white, 75% HS education.	Subjects in both groups were informed of cholesterol results by letter; if lipids high, they were informed they needed treatment. <u>Special intervention (SI)</u> : (1) Public health nurse directed component using Food for Health Program during 3 counseling visits; (2) referral to a local nutritionist if lipids remained elevated at 3 mo F/U; (3) a reinforcement program during 2nd half of intervention—1 telephone call from nurse and 2 newsletters. Structured, individually tailored dietary counseling by nurse facilitated by a dietary risk assessment, illustrated goal sheets, and a Southern style cookbook. <u>Minimal intervention (MI)</u> : Other than initial letter about cholesterol results, other intervention activities not described.	Dietary Risk Assessment Score 2.1 units better in the SI vs MI, $P=0.005$ .	...	NSD in weight loss.	Reduction in total cholesterol similar in both groups: 18.4 mg/dL in SI vs 15.6 mg/dL in MI, $P=0.006$ .
Burke et al, <sup>30</sup> 2005, 2-group RCT/14 wks (N=65)	>60% male, 94% white, BMI 38–45. Retention: 98%.	<u>UC</u> : Usual clinical care. <u>I</u> : Telephone-delivered, self-efficacy-based counseling to improve adherence to a cholesterol-lowering diet, 6 sessions over 12 wks, included goal setting, self-monitoring with feedback, self-efficacy enhancement.	Fat change score: UC 2.3 vs I -10.4 g $P=0.035$ ; ES=0.29. Saturated fat change score: UC 0.18 vs I -23 g, $P=0.045$ ; ES=0.28.	...	...	LDL-C change score: UC 0.25 vs I 0.42 mg/dL, $P=0.013$ ; ES=0.30.
Delichatsios et al, <sup>130</sup> 2001, 2-group cluster randomized trial/3 mo (N=504)	70% female, 91% white, mean age 54 y.	<u>C</u> : Usual PCP practice <u>I</u> : 3 components—personalized diet recommendations and stage-matched diet-related educational booklets by mail, provider endorsement of the recommendations, and 2 motivational interview counseling sessions by telephone. Counseling encouraged goal-setting and stage of change messages.	FV: Change in FV intake in I group was 0.6 (CI, 0.3–0.8) servings/d higher than control group.	...	...	...
Elliot et al, <sup>71</sup> 2007, 3-group cluster randomized trial/12 mo (N=599)	97% male firefighters, mean age 41 y, 91% white, income $\geq$ \$50 000.	Both intervention groups received a Health and Fitness guide. <u>Team centered</u> : Work groups with designated leader met for 11 45-min sessions and followed scripted lesson plans on nutrition, PA, energy balance, stress, sleep, and dietary supplements. Members received baseline PA, dietary, and lab assessment results followed by goal setting. <u>Motivational interviewing (MI)</u> : Participants randomly assigned to 1 of 6 MI counselors; 4 meetings with MI counselor with possibility of 5 hours of additional in person or telephone contact. <u>Control</u> : Received only test results with explanation of normal values; free to use own initiative to alter lifestyle.	FV: Both Team and MI had increased FV intake ( $P<0.05$ ).	PA: Team and MI increased no. of sit-ups in 1 min, $P<0.05$ .	Weight: Both Team and MI gained weight, but less gain than UC, $P<0.05$ .	...

(Continued)

Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	
Keyserling et al, <sup>227</sup> 2-group RCT, randomization of clinician-patient groups/1 y (N=372)	42 physicians, ≈66% patient participants with high cholesterol were female, 40% black, 11% Native American, Mean age 55.9 y, 10.6 mean y education.	3 components—(1) clinician-directed dietary component; (2) referral to a local dietitian if LDL-C remained elevated at 4 mo follow-up with ≥2 risk factors or CHD; (3) a prompt for the clinician to consider drug treatment based on LDL-C at 7 mo follow-up. <u>UC</u> : Physicians were advised to manage their subjects hypercholesterolemia according to their usual practices.	...	...	...	BP/Cholesterol/Glucose/ Hemoglobin A1c Total cholesterol: At 4-mo follow-up, total cholesterol decreased 0.33 mmol/L in the I group vs 0.21 mmol/L in the C group (90% CI, -0.02–0.24 mmol/L). The mean reduction at 1-y follow-up was 0.09 greater in the I group (90% CI, -0.01–0.19 mmol/L). Changes in LDL-C were similar.
Marcus et al, <sup>69</sup> 2007, 3-group RCT/12 mo (N=239)	82% female, 90.3% white, mean age 44.5 y, mean BMI 28.5, 60% with household income >\$50 000.	<u>C</u> : Health education material mailed on same schedule as print and telephone; subjects completed PA log each month. <u>Telephone I</u> : Subjects received PA intervention materials through telephone contact with a health educator. Educator incorporated individually tailored feedback generated by an expert computer system and provided counseling using a motivation staged-matched manual. Mean length of calls was 13 min; 90% of calls were completed, 14 contacts over the course of 12 mo. Completed PA log each month. <u>Print I</u> : Subjects received individually tailored printed reports of PA, feedback generated by expert computer system, along with manuals matched to their stage of readiness and tip sheets, 14 contacts. Completed PA log each month.	...	PA: At 6 mo, subjects in T group (123.3±97.6) and P group (129.5±156.5) reported larger increase in min of PA/wk than subjects in C group (M=77.7±101.89), P=0.02. At 12 mo, P group reported greater moderate-intensity PA compared with C group, NSD between T and P groups.	...	...
Green et al, <sup>31</sup> 2002, 2-group RCT/6 mo (N=316)	52.5% female, 91.5% white, median age 44.5 y.	<u>UC</u> : No telephone calls. <u>I</u> : 3 20–30 min telephone calls monthly for 3 mo from behavioral health specialists who provided motivational counseling in accordance with stages-of-change model, goal setting, assistance with problem-solving barriers, and identify resources for support.	...	PA: Higher PA level per PACE score for I 5.37 vs 4.98 in UC, P<0.05.	...	...
Omish et al, <sup>222</sup> 1998, 2-group randomized invitation design/ 5 y (N=35)	91% male with moderate to severe CHD, Mean age 59.6 y, mean 15 y of education.	<u>I</u> : Intensive lifestyle change, 10% fat, vegetarian diet, aerobic exercise, stress management, smoking cessation, group psychosocial support for 5 years. <u>C</u> : Follow advice of physician regarding lifestyle changes.	Fat intake: I group fat intake decreased 30% to 8.5%, decreased 211 to 18.6 mg/d, P=0.002 C group decreased fat intake 30% to 25%. Fat %kcal: Group 1 vs 2 vs 3 -0.7% vs -1.0% vs -2.3%, P=0.11. Saturated fat (% kcal): 0.0 vs -0.4 vs -1.1%, P=0.01; ES=0.10.	Weight: I group 12.8 lb loss vs no change in C group, P<0.001.	LDL-C: I group decreases 20% vs 19.3% in C group, NSD between groups. Arterial stenosis decreased from baseline in I group, P=0.001 between groups.	...
Ockene et al, <sup>95</sup> 1999, 3-group RCT/1 y	927 primary care subjects, 45 primary care internists, 66% female, >90% white, BMI 29. Retention not reported.	<u>UC</u> : Usual clinical care in primary care setting. <u>Physician nutrition counseling training, 2 sessions, a 2.5-h small group session and a 30-min individualized tutorial; included didactic instruction, videotape observation, and role-playing.</u> <u>Physician nutrition counseling training+office-support program: As above+office-support program designed to assist MD in carrying out counseling sequence, eg, patient completed Dietary Risk Assessment in waiting room, lipid results flagged. Note: counseling took 8.2 min, 5.5 min more than control condition.</u>	...	Weight loss: Group 1 vs 2 vs 3 0.0 vs -1.0 vs -2.3 kg, P<0.001.	LDL-C: -0.01 vs 0.02 vs -0.11 mmol/L, P=0.10. Total cholesterol: HDL ratio: 0.1 vs 0.1 vs -0.1 mg/dL, P=0.004.	...

(Continued)

Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/ Hemoglobin A1c
Pinto et al, <sup>125</sup> 2005, 2 group/6 mo (N=100)	85% white, 63% female BMI 29. Retention: EA 46, BA 44.	Brief advice (BA): Brief advice to exercise by a clinician alone. Extended advice (EA): Brief advice to exercise from a clinician supplemented by telephone-based counseling by health educators, counseling tailored to subject's readiness to increase PA levels as well as their conviction and confidence; used motivational interviewing techniques.	...	Energy expenditure: BA +0.83 vs EA +3.8 kcal/wk 3 mo, P=0.03; ES=0.23; 6 mo, P<0.05, ES=0.20.	...	...
Richards et al, <sup>104</sup> 2006, 2-group RCT/74 mo (N=437)	100% college students; mean age 20.4 y, 75% women, 96% white.	I: Subjects received a personalized letter to stage of change, a series of 4 stage-based newsletters specific to their stage of change at baseline, 1 motivational interviewing session, referral to a nutrition Web site, and a minimum of 2 E-mail contacts over a 4-mo period. C: Subjects completed baseline and following surveys with no additional contact from study personnel.	...	FV: Consumption increased by 1 serving/d in I group as measured by a 26-item FFQ and a 1-item FFQ vs 0.4 servings/d in C group per the 1-item FFQ and no change per the 26-item FFQ. P<0.001 Fat (%): C 38.6% vs 34.9%, P<0.001 FV (servings): C 3.4 vs 4.3, P<0.001; ES=0.13.	...	...
Stevens et al, <sup>22</sup> 2003, 2-group RCT/12 mo (N=616)	Women, mean age 54.4 y, 91% white, BMI 30.2±7.1. Retention I: 89%, Con: 85%.	C: Focused on breast self-examination, individual session+videotape, and 2 F/U telephone calls. I: Two 45-min diet counseling sessions+2 brief F/U telephone contacts, with goal setting, feedback, problem-solving, and motivational interviewing strategies; delivered by master's prepared health counselors.	...	...	...	...
Computer/Internet- based intervention delivery strategies						
Anderson et al, <sup>33</sup> 2001, 2-group RCT/6 mo (N=277)	96% female, 96% white, median income ≈\$35 000.	C: No exposure to supermarket kiosks. I: Subjects used supermarket kiosk-based self-administered, computer-based SCT intervention; provided personalized info, behavioral strategies, incentives for change, and feedback on personal goals. Program guide increase fiber, FV, and reduced fat in food purchases through 15 weekly segments; offered food coupons of \$8-\$12/wk.	...	Fat, fiber, FV: I group more likely than C group to attain goals for fat, fiber, FV.	...	...
Delichatsios et al, <sup>17</sup> 2001, 2-group RCT/6 mo (N=298)	72% female, 45% white, 45% black, mean age 45.95 y, BMI 28.7, 85% employed.	C: Used an interactive, computer-based system to serve as an at-home monitor, educator, and counselor regarding diet. Subjects called system 1/wk for 6 mo; received reminder call if subject did not call system in 2 wks. I: Used same system as C except conversation focused on PA.	...	FV: I group raised no. of servings of fruit compared with C group (C, 4-1.7). No differences for vegetables. Dietary fiber raised by 4.0 g/d compared with C group (C, 1-7.8).	...	...
Gold et al, <sup>122</sup> 2007, 2-group RCT/12 mo (N=124)	98% women, 98% white, age 47 y, BMI 32. Retention: 65% in VTrim, 77% in eDiets.	VTrim: Access to therapist-led structured behavioral weight loss program delivered online. eDiets.com: Access to self-help commercial weight loss program Web site.	...	Weight loss: VTrim -8.3 kg vs eDiet -4.1 kg at 6 mos, P=0.004, ES=0.21; at 12 mo, -7.8 vs -3.4, P=0.002, ES=0.16.	...	...
Marcus et al, <sup>108</sup> 2007, 3-group RCT/12 mo (N=249)	83.7% female, mean age=44.5±9.3 y, BMI 29.4, Retention: 87.1%.	Tailored Internet. Motivationally tailored Internet materials. Tailored print: Motivationally tailored print materials. Researcher-selected Web sites: available to the public.	...	PA (min): NSD among 3 groups; within group increase at 6 mo (5.2%), 12 mo (5.9%).	...	...

(Continued)



Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/Hemoglobin A1c
Napolitano et al. <sup>34</sup> 2003, 2-group RCT (N=65)	86% women, mean age 42.8 y, 91% white, 55% >\$50 000 income/y, BMI 26.4, 88% retention 3 mo.	C: Received 1 after 3-mo wait. I: Received access to Web site for 3 mo along with weekly E-mail tip sheets. Web site based on SCT, targeted stages of motivational readiness, and provided PA information to help reach goal (eg, use of social support, rewards, planning in activity).	...	PA: At 1 mo, subjects in I group had higher levels of moderate min/wk and walking min/wk vs C group ( $P<0.05$ , $<0.001$ , respectively); At 3 mo, only walking min were higher compared with C group ( $P<0.05$ ).	...	...
Miccio et al. <sup>35</sup> 2007, 2-group RCT/12 mo (N=123)	83% female, 96% white, mean age 46.8 y, BMI 31.7, 74% with college degrees.	Internet: 12-mo SBT weight loss program taught through series of online lessons. Subjects met weekly in online chat rooms. Homework assignments submitted electronically before meeting. Prescribed diet of 1200–2100 cal/d. Emphasized diet abundant in FV and whole grains and moderate in fat, sugar, and salt; emphasized exercising 5–7 days/wk. Online meetings addressed self-monitoring and setting calorie and PA goals; journals provided basis for feedback. Internet plus in-person: Subjects received same Internet program plus met once a month as a group in person. In-person meetings took the place of online chat sessions, led by different facilitator (dietitian) than online chats.	...	Weight loss: No significant group×time difference in weight loss at 6 or 12 mo. Completers lost mean 7.5±6.4 kg at 6 mo and 6.6±6.6 kg over 12 mo.	...	...
Pinto et al. <sup>32</sup> 2002, 2-group RCT/6 mo (N=298)	72% female, 45% white, mean age 45.9 y, BMI 28–30. Retention: TLC-PA 75%, TLC-Eat 89%.	Telephone-linked communication (TLC)-Eat: Promoted healthy eating, comparison group. TLC-PA: Promoted regular moderate intensity (MI) PA; TLC computer technology, and digitized human speech to converse through totally automated telephone conversations.	NSD	Energy expenditure: TLC-E 2.0 vs TLC-PA 2.3 kcal/kg/d at 3 mo, $P=0.02$ ; ES=0.23; NSD at 6 mo, ES=0.02.	...	...
Tate et al. <sup>36</sup> 2003, 2-group RCT/1 y (N=92)	90% female, 89% white, BMI 33. Retention: 85%.	All subjects attended group session: oriented to Internet; instructed on calorie, fat restriction, PA goals; how to self-monitor. Basic Internet (BI): Web site tutorial on weight loss, weekly tip and link, directory of Internet resources, weekly E-mail reminder to submit weight and given weight loss info. Internet weight loss program+behavioral E-counseling (I+Be): E-mail communication with counselor, submit calorie/fat intake, PA on Web-based diary daily for 1 mo, daily or weekly for 11 mo; weekly counselor E-mail gave feedback.	Fat (% kcal): -1% in BI group vs -4% in I+Be, $P=0.06$ .	Increases in energy expenditure: +63 in BI vs +342 kcal in I+Be, $P=0.26$ . Weight loss: BI -2.0 kg vs -4.4 kg in I+Be, $P=0.04$ ; ES=0.21.	...	...
Tate et al. <sup>37</sup> 2006, 3-group RCT/6 mo (N=192)	>80%, ≥90% white, BMI 33. Retention: 82% at 3 mo, 80% at 6 mo.	All subjects received 1 group session, meal replacement coupons, access to an interactive Web site. No counseling (NC) Computer-automated feedback (AF): Access to electronic diary for self-monitoring foods, PA, weight; message board; weekly E-mail reminder to self-monitor, behavioral lesson, and feedback from preprogrammed computer. Human E-mail Counseling (HC): AF except feedback delivered via E-mail from human weight loss counselor.	Kcal: NSD Fat intake (%/d): NC 37.2 vs AF 34.0 vs HC 33.1%/d, $P=0.004$ .	NSD Weight loss: NC -2.6 vs AF -4.9 vs HC -7.2 kg, $P=0.001$ ; ES=0.29.	...	...

(Continued)

Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes		
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight
Wylie-Rosett et al, <sup>37</sup> 2001, 3-group RCT/12 mo (N=588 from HMO)	82% female, mean age 52 y, 83% white, 84% ≥1 y of college, mean BMI 35.6. Retention: 81%.	3 incremental levels of weight loss intervention intensity: (1) Workbook alone (W); (2) addition of computerized tailoring using on-site computer screens with touchscreen monitors (W+C); (3) addition of both computers and staff consultation (ie, 6 closed-group sessions and up to 18 telephone or in-person consultations). (W+C+S). All 3 interventions used cognitive behavioral approach for tailoring goals and principles of transtheoretical model of behavioral change.	Mean energy intake and percent energy from fat decreased from baseline in all 3 groups (P<0.01). MSD in mean nutrient intake by group.	All groups reported a mean increase in walking time and number of blocks walked each day (P<0.01). NSD by intervention group.	All groups lost weight. W+C+S lost significantly more weight than W only, P=0.02. W+C did not lose was significantly greater weight than W only.
Multicomponent intervention delivery strategies Carels et al, <sup>15</sup> 2007, RCT/6 mo (N=55)	87% women, obese BMI not provided. Retention: 79–81%. Across both trials: 68.5% men, ≈78% white, ≈17% black, mean age 43.3 y, mean BMI=29.	Behavior weight loss program (BWLP); 20 sessions based on LEARN program. BWLP+stepped care (SC): Individuals in the BWLP+SC group who did not meet weight loss goal received motivational interviewing strategies (MI). TOHP trial: Tested nonpharmacological interventions (ie, weight loss, Na+ reduction, stress management, and nutritional supplements) in reducing BP in subjects with high normal BP. Of 2182 TOHP I subjects, 327 were randomized to Na+ reduction and 417 were assigned to UC. Individual and weekly group sessions offered for 3 mo; lifestyle interventions were offered for 18 mo. Compared with UC, Na+ and BP significantly decreased.	Total calories: BWLP -380 kcal vs BWLP+SC -358 kcal, ES=0.11 (P values not reported).	VO <sub>2</sub> , BWLP+2.3 vs BWLP+SC +1.7, ES=0.12.	Weight loss: BWLP -2.1 vs BWLP+SC -4.5, ES=0.84.
Cook et al, <sup>21</sup> 2007, long-term follow-up 10–15 y after TOHP I and TOHP II trials (N=744 in TOHP I; N=2382 TOHP II)			...	...	...
Diabetes Prevention Program Research Group, <sup>38,28</sup> 2004, 3-group RCT/average 2.8 y (N=3234)	ILI group was 68% female, 46.3% minority, BMI 34. Retention: 92.5%. Mean age 43.3 y, mean BMI=29.	Standard: standard lifestyle placebo group Metformin: 850 mg twice daily. Intensive Lifestyle Intervention (ILI): Main goal: lose 7% of baseline weight and achieve 150 min/wk of PA; individual case manager for full time of study—16 sessions in core curriculum covered basic skills related to nutrition, exercise, and behavior change. Diet ≤25% fat+calorie restriction. Self-monitored min of PA and fat g consumed every day during core curriculum, then 1 wk/mo remainder of trial. Note: Incidence of diabetes reduced significantly greater in the LI group than in the standard and metformin groups.	For ILI group: Kcal/d: -452 at 1 y Total fat/d (g): -30.3 at 1 y % of cal from fat: -6.6% at 1 y.	PA (METS): +6.6 at 1 y, +4.3 METS at 3 y.	Weight loss: -4.2 kg in ILI group vs 0.8 kg in standard group, P<0.05 at 12 mo. In ILI, -4.1 kg at 3 y.
Glasgow et al, <sup>39</sup> 1997, 2-group RCT/12 mo (N=206)	Adults with DM, >60% female, mean age 62 y, 77% overweight or obese, race not reported. Retention: 83.3%; UC: 84.7%.	UC: Quarterly medical care and F/U of risk factors+touch-screen computer assessment in medical office. Brief Intervention (BI): Single session, touch-screen computer-assisted assessment, immediate feedback on key barriers to dietary self-management, goal setting, and problem-solving counseling; additional video intervention based on self-efficacy score (>85 vs ≤85). Telephone calls/videotapes 1 and 3 wks; intervention repeated at 3 mo; telephone call at 6 mo, DM book at 12 mo.	Kcal: UC 1659 vs BI 1547 kcal, P=0.05; ES=0.14 Fat (%): UC 32.0% vs 30.5%, P=0.023; ES=0.16.	...	BMI: NSD. Cholesterol: UC 226 vs BI 208, P=0.002 HbA <sub>1c</sub> : NSD.

(Continued)

Table 2. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	
Glasgow, <sup>80</sup> 2000, 2×2 Factorial RCT/6 mo (N=320)	Adults with type 2 DM, mean age 59 y. BMI not reported. Retention: 84%–94% for 4 groups.	Subjects received Basic Intervention (BI): health counselor meeting, dietary goals set with aid of touch-screen computer, feedback on dietary pattern. Tailored dietary fat reduction goal. 4 groups: (1) BI; (2) BI+TF (3–4 telephone follow-up calls/6 mo for ongoing support, reinforcement, and problem-solving); (3) BI+Community Resources (CR) Enhancement; (4) Combined Conditions. CR Enhancement: binder of resources, 4 newsletters, goal setting, and FFO completed/given tailored feedback.	Fat: NSD; ES=0.19. Fat/fiber behaviors: TF groups better, P=0.017.	...	NSD	BP/Cholesterol/Glucose/Hemoglobin A1c Cholesterol: CR>phase P=0.010 HbA <sub>1c</sub> , NSD
Howard et al, <sup>58</sup> 2006, WHI: Dietary Modification Trial 2-group RCT/7.5 y (N=48 835)	Postmenopausal women, 81% white, BMI 29. Retention: 96%.	C: Usual diet, received diet-related education materials ( <i>Dietary Guidelines for Americans</i> ) I: Group (18 sessions in first year, 4/y afterward) and individual sessions to promote decrease in fat intake, increase in FV and grain intake; maintain usual energy intake (no weight loss or calorie restriction goals). Three individual sessions that used reflective listening. Self-monitored dietary fat, FV, grain intake throughout study.	Kcal: C vs I: -240.8 vs -361.4, P<0.001; ES=0.02 % fat: -0.6 vs -8.8% P<0.001 FV: 0.2 vs 1.4 servings, P<0.001 Fiber: -0.2 vs 2.2, P<0.001.	PA (METS): Con vs I 0.9 vs 1.1 METs, P=0.07.	Weight change difference C and I groups at 12 mo, 1.9 kg, P<0.001; at 7 y, 0.4 kg, P=0.01.	...
Look AHEAD Research Group, <sup>111</sup> 2007, 2-group RCT/12 mo (N=5145)	Adults with T2DM, 59% female, 63% white, mean age 59 y, BMI 35–36. Retention at 1 y: ~96%	Diabetes support and education condition (DSE); 4 sessions on topics related to diet and PA, no counseling, not weighed. Intensive lifestyle intervention (ILI): Group and individual meetings to achieve/maintain 7% weight loss via decreased caloric intake (30% fat) and portion-controlled diets; increased PA (175 min/wk); 3 group meetings+1 individual meeting monthly during mo 1–6, 2 group meetings+1 individual meeting monthly for 7–12 mo.	...	Cardiorespiratory fitness: Fitness increases 10.8% in DSE vs 15.9% in ILI, P<0.001.	Weight loss: 0.7% vs 8.6% of initial body weight, P<0.0001.	DSE vs ILI: SBP -2.8 vs -6.8, P<0.001; DBP -1.8 vs -3.0, P<0.001; HDL +1.4 vs +3.4, P<0.001; glucose -7.2 vs 21.5, P<0.001.
Perry et al, <sup>40</sup> 2007, 2-group RCT/12 wk (N=46)	100% rural women, 95% white, mean age 45 y, mean education =15 y.	HTH: Individual+group components. Individual component included motivational interviewing for 30 min at baseline followed by weekly 10-min booster calls. Women asked to set goals and monitor progress and received individualized exercise prescription. Group component included a nurse led 1-h weekly group walk to promote support and self-efficacy. Comparison: Subjects received a brief 10-min individual private advice session, a monthly 5-min reinforcement call, an individualized exercise prescription, and a logbook to record walking.	...	Cardiorespiratory fitness per distance walked in 12-min walk test: Women in HTH had greater improvement in fitness, P=0.057 vs comparison group.	...	...
Stevens et al, <sup>41</sup> 2001, 4-group RCT (TOHP II)/36 mo (N=1191)	66% male, mean age 43 years, 79% white; BMI 31. Retention: 92% and 93% for weight loss, 89% and 86% for BP measure.	Weight loss intervention (WL): Individual counseling followed by 14 weekly group meetings; thereafter, 6 biweekly group meetings. After 18 mo, options included individual or group sessions on selected weight-loss topics. Focus on behavioral self-management, social support; included self-monitoring, goal setting, developing action plans, and problem solving. Weight loss goal of ~4.5 kg, PA 30–45 minutes, 4–5/wk. Advice (AD): Includes physician advice and written educational materials (recommended care). Assistance (AS): Components of AD group+interactive mail and behavioral counseling at physician visits. Counseling (Coun): All of AD and AS components+regular telephone counseling and behavioral classes.	...	...	Weight loss: UC vs WL: -0.1 vs -4.4, 0.7 vs -2.0, and 1.8 vs -0.2 kg at 6, 18, 36 mo, P<0.001; ES=0.10.	Difference in scores: SBP -3.7, -1.8, -1.3 mm Hg at 6, 18, 36 mo, P<0.01. DBP -2.7, -3.5, -2.0 mm Hg at 6, 18, 36 mo, P<0.001–0.05; P<0.001–P<0.05.
Writing Group for Activity Counseling Trial, <sup>135</sup> 2001, RCT/24 mo (N=874)	55% males, mean age 51 y, >60% white; BMI 29–30. Retention: 91.4% completed PA, 77.6% VO <sub>2</sub> max.	...	...	VO <sub>2</sub> max: Significantly higher in AS than AD group (80.8 mL), higher in Coun than in AD group (73.9 mL); NSD in men; ES=0.07–0.08.	...	...

RCT indicates randomized controlled trial; I, intervention group; BP, blood pressure; PCP, primary care provider; C, control or comparison group; SBP, systolic blood pressure; DBP, diastolic blood pressure; NSD, no significant difference; ES, effect size; LDL-C, low-density lipoprotein cholesterol; F/U, follow-up; DM, diabetes mellitus; UC, usual care; METs, metabolic equivalents; UC, usual care; METs, metabolic equivalents; HS, high school; FV, fruits and vegetables; HDL, high-density lipoprotein; FFO, Food Frequency Questionnaire; SCT, social cognitive theory; HMO, health maintenance organization; CVD, cardiovascular disease; and Hb, hemoglobin.

Table 3. RCTs of Interventions to Promote PA and Dietary Lifestyle Change: Minority Samples

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/ Hemoglobin A1c
Group-based intervention delivery strategies						
Elder et al, <sup>110</sup> 1998, 2-group cluster randomized parallel group trial/3-mo posttest and 6 mo (N=408)	Adults enrolled in English as second language classes, mean age 28.7 y, ~50% female, in US <3 y, 87% Hispanic, 66% monthly income <\$1099.	<u>Nutrition Heart-Health Education:</u> Five 3-h group classes on nutrition/heart health; culturally sensitive classes conducted in English and Spanish. <u>Stress-management Education:</u> Five 3-h group classes on stress management.	...	...	Weight loss: Nutrition group: No loss, gain of 2.5 lb at 6 mo vs 0.66 lb gain in Stress group, 141.65 lb (no between-group differences).	Total cholesterol, mg/dL: Nutrition group 178.94 at baseline, 169.88 at 6 mo. Stress group 177.03 at baseline, 166.18 at 6 mo. Within group difference, $P<0.01$ . NSD between groups. HDL cholesterol, mg/dL: NSD within or between groups. BP mm Hg: significant within-group changes, $P<0.001$ . NSD between groups.
Hartman et al, <sup>96</sup> 1997, quasi- experimental design/8 wks (N=204)	Low literacy adults nutrition education program for the low income, 94% female, 32% black, 57% income <\$10 000/y.	I: Received low-fat nutrition education "Help Yourself to Health" in fun and entertaining format; 10 sessions on low-fat nutrition, taught by Nutrition Education Assistants who lived in the community. Groups met at community sites; literacy level addressed. C: Received usual Expanded Food and Nutrition Education Program—food budgeting, food safety, and healthy eating.	Calories: per 24-h recall. Energy/kcal: NSD within or between groups. Total fat (kcal): NSD within or between groups.	...	...	Total cholesterol (mg/dL), treatment group: NSD within or between groups.
Howard-Pitney et al, <sup>54</sup> 2-group cluster RCT/≈5 mo (N=351)	Adults recruited from adult education classes. 59% Hispanic, 85% women, 66% had reading level at sixth grade level or below, 65% family income <\$10 000/y.	I: A dietary fat curriculum offered over 20 mo; 2 parts, 6 wks in classroom followed by a 12-wk maintenance intervention; taught by nutrition educators; six 90-min, which were interactive with few written materials, plus skill building, food tastings, and demonstrations of low-fat goals set by participants. 12-wk maintenance intervention (ie, contact every 2 wks by telephone or mail for 6 contacts (to provide support and encouragement); methods and materials tailored for adult with low literacy. C: General nutrition classes taught by paraprofessional education; designed to improve knowledge and nutrition choices. Addressed food pyramid, food safety and meal planning.	Total fat: per FFQ %cals from fat, change from baseline, $I=37.1\%$ – $33.2\%$ ; vs $O=36.4\%$ – $35.2\%$ . Significant within-group difference, for I: $P=0.01$ . No between-group differences. Total fat (g/d): NSD within or between groups.	...	BMI: change from baseline. NSD within group or between groups.	Cholesterol (mg/dL): change from baseline. NSD within group or between groups.
Kumanyika et al, <sup>42</sup> 2005, 2-phase trial, phase 1 all received group classes; phase II 2-group RCT/12 mo (N=87 completed phase II)	100% black, 90% female, mean age ≈44.4 y, ≈67% education >12 y, mean BMI 37.5.	Phase I—Group counseling program (HELP); All interested participants enrolled in 10 weekly group weight loss classes; no specific diet or caloric intake specified; subjects encouraged to set personal goals and to self-monitor diet; advice to increase PA was individually tailored to ability and preference. 3 mo after enrollment subjects randomized to phase II interventions: Classes: HELP classes+group counseling offered biweekly, then monthly vs weekly. Enhanced self-help: Staff facilitated self-help; subjects received a personalized calendar, a packets describing local resources, a personal diary, a pedometer, and ad hoc telephone support. UC: No further counseling outside brief counseling at semiannual clinic visits.	...	...	Weight loss (kg): $-1.2\pm 5.2$ over entire study period, $P<0.05$ . Neither HELP classes nor self-help was superior to UC during phase II.	SBP (mm Hg): $-6.5\pm 11$ over entire study period, $P<0.01$ ; DBP (mm Hg): $-4.9\pm 6.8$ . No significant changes in total cholesterol, triglycerides, or blood glucose.

(Continued)

Table 3. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes		
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight BP/Cholesterol/Glucose/ Hemoglobin A1c
McNabb et al, <sup>43</sup> 1997, 2-group RCT/1 wk after I finished (N=39)	Women recruited from 3 urban black churches. Mean age 56 y. BMI $\geq 30$ , 13% < HS education, approximately 54% employed	I: PATHWAYS program: 14-wk, small lay-led culturally sensitive group sessions at church on diet that included goal setting, problem solving, and instructions to engage in recreational walking administered by lay facilitators at the churches; included use of ethnic foods. C: Wait-list control.	...	...	Weight loss (lb): $-10.0 \pm 10.28$ vs C $+1.9 \pm 4.25$ , $P < 0.0001$ . BMI ( $\text{kg}/\text{m}^2$ ): I group $-1.4 \pm 1.61$ vs C group $0.6 \pm 0.73$ , $P < 0.0001$ , ES=0.65.
Individual-based intervention delivery strategies					
Ahluwalia et al, <sup>93</sup> 2007, cluster randomized trial of 20 public housing developments/6 mo (N=173)	100% smokers, mean age 45.5 y. 81.3% black, $\approx 38\%$ HS education, 42% unemployed, $\approx 73\%$ monthly income $\leq \$800$ .	Both arms received 5 sessions of motivational interviewing counseling for FV or smoking cessation. Self-efficacy and balancing pros and cons of change and 2-dimensional model of cultural sensitivity guided interventions. Fruit and vegetable intervention (FV): Received a bag of fresh FVs, a cookbook of healthy recipes, dietary education materials, and 2 videos on FVs. Smoking cessation intervention (SC): Received an 8-week supply of nicotine gum and instructions about quitting.	FV: At 8 weeks and 6 mo, the FV group consumed 1.58 ( $P < 0.001$ ) and 0.78 ( $P = 0.04$ ), respectively, more FV servings per day than SC. Completing more motivational interview sessions ( $P = 0.02$ ) and trying more recipes ( $P = 0.02$ ) led to significantly greater increase of FVs in the FV group.	...	...
Eakin et al, <sup>44</sup> 2007, 2-group RCT/6 mo (N=200)	Adults with $\geq 1$ chronic conditions. Mean age 49.5 y, 75% Hispanic, $< 5$ y in US, 79% female, $\approx 36\%$ $< \$10\,000/\text{y}$ .	I: Bilingual health educator provided 2-individual sessions on PA and dietary recommendations (60–90 min) 3 mo apart at home or clinic; feedback on baseline assessment; participants chose PA and diet goal; goal setting, feedback and problem solving plus ID of multilevel community supports for health behavior change emphasized. 3 follow-up telephone calls during 6-mo intervention; low-literacy letters reminded participants of goals, addressed barriers, and suggested resources; all activities adapted to literacy level (visual aids) and culture; interventions translated into Spanish and validated. UC: Subjects were mailed a local community resources guide and 3 newsletters on financial management.	Fat/fiber intake per self-report questionnaire: At 6-month the I group had significantly better Fat/fiber intake compared with UC group, $P < 0.05$ .	PA: Change from B in minutes walked, NSD within or between groups.	...
Elder et al, <sup>144</sup> 2006, 3-group RCT/12 mo (N=367)	Latina women, mean age $39.7 \pm 9.9$ y, BMI 28.9–30.4. Retention 76%–82% for 3 groups.	Tailored (T): 12 tailored print newsletters with homework assignments mailed weekly. Promotora (P): Weekly home visits or telephone calls by lay advisor over 14 wks + 12 tailored newsletters and homework. Assessment at baseline, 12 wks, and 6 and 12 mo. C: 12 off-the-shelf materials mailed weekly to home.	Kcal: Promotora 1288.7 vs Tailored 1420.6 vs C 1430.5; $P = 0.018$ at 12 wks, NSD at 6 and 12 mo. Fat: Promotora 43.1 g vs Tailored 49.8 g, C 49.1 g; $P = 0.028$ at 12 wks, NSD at 6 and 12 mo; ES=0.14.	...	...

(Continued)

Table 3. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/Hemoglobin A1c
Jacobs et al, <sup>45</sup> 2004, cluster randomized trial of 22 health departments/12 mo (N=421)	100% low-income female, mean age 59 y, 51% <HS education, 44% from ethnic minority groups.	All subjects previously participated in a 1-y diet and PA behavior change program (phase II); North Carolina WISEWOMAN, in which health departments were randomized to the enhanced intervention or the minimal intervention. In phase III, of the 22 health departments who had received the enhanced intervention in phase II, 11 were randomized to Maintenance Special Intervention and 11 were randomized to Maintenance Usual Care. <u>Maintenance Special Intervention (MSI)</u> : Subjects were mailed 6 bimonthly computer-tailored health messages and received 2 telephone calls from health department staff. Intervention materials were based on social cognitive theory, relapse prevention theory, and the transtheoretical model. Tailoring was according to goals, stage of change, knowledge, social support systems, high-risk situations for relapse, and perceived benefits and barriers. Messages were designed for low-literate and low-income. <u>Maintenance Usual Care (MUC)</u> : Received usual follow-up services at the discretion of the health departments. Basic nutrition and PA counseling pamphlets were available.	Both groups maintained low reported intake levels of dietary saturated fat and cholesterol.	Both groups maintained low levels of self-reported PA. Subjects in MSI were more likely to move forward into more advanced stages of PA, $P=0.02$ .	...	...
Resnicow et al, <sup>103</sup> 2005, 3-group cluster randomized trial/1 y (N=906)	Mean age 46.3 y, 76.2% female, 100% black, 60% income $\geq$ \$40 000/y, >70% some college.	<u>C</u> : Standard commercial self-help videos and brochures matched for intensity and type with group 2 materials. <u>Culturally targeted self-help nutrition and PA</u> : Culturally tailored nutrition video, cookbook, exercise video, exercise guide, and audio cassette. <u>Motivational Interview (MI) plus group 2 intervention</u> : 4 MI sessions delivered by telephone at 4, 12, 26, and 40 wks. Two calls address FV and 2 call addressed PA. Self-help materials reviewed during calls.	FV: MI increased F&V intake compared with other 2 groups, $P<0.05$ .	PA: Total min/wk of PA increased in Cultural and MI groups compared with C, $P<0.05$ . NSD between culture and MI.	...	...
Multicomponent intervention delivery strategies						
Albright et al, <sup>46</sup> 2005, 2-group RCT/10 wks, 6 mo, and 1 y (N=72)	Sedentary low-income women recruited from adult education sites, mean age 32 y, 73% Hispanic, $\approx$ 70% income <\$20 000/y.	All received 8 weekly 1-h PA skill-building classes taught by ethnically matched educators; included small group discussions and Q&A; Goal 30 min of moderate PA 5 days/wk. After classes, subjects randomized to: <u>Home-based telephone+mail support (P+MS)</u> : Weekly telephone counseling for first 4 wks, biweekly for 8 wks, then monthly, calls 10 mo; pedometers, accompanied by counseling and provision of feedback; women provided large magnetic, erasable monthly calendar to attach to refrigerator and record number of steps. <u>Home-based mail support (MS)</u> : Monthly newsletters with postage paid mail-back card to report number of steps and PA in last week; feedback sheets were sent from health educator based on responses; prizes earned for mailing back (eg, pens, waist packs, mugs). Both groups incorporated people, places, language, and clothing familiar to culture; addressed core values.	PA: AT 10-wk P+MS+263 kcal/wk vs MS 294 kcal/wk, NSD between or within groups. 10-week to 12 mo change, P+MS: added increase of 52 kcal/wk vs MS: 1014 kcal/wk less, between group difference, $P<0.045$ , ES=0.24.	...	...	...

(Continued)

Table 3. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	
Buller et al, <sup>74</sup> 1999, 2-group RCT/6 and 18 mo (N=766)	Employees from 93 work groups. Mean age 43 y, 43% Hispanic, 6% black, 75% men, ≈13% ≤11th grade education.	All received general 5-a-day info over 18 mo. Peer Education (PE): last 9 months of the general program. Subjects had individual sessions with peer leader and peer-led group discussions about FV; activities for children; print materials about FV. Materials to support behavioral skills (ie, FV calendar, recipes); addressed cultural trends in diet, low-literacy graphics, and stories. General Education only: No peer education during last 9 mo. I: 5-a-day program—20-mo individual, social network and community-level activities emphasizing FV ≥2 educational sessions regarding modifying cooking methods, served more FV at church functions; community coalitions included church members, local agencies, grocers, and farmers to plan community events; church-initiated activities. Materials promoted locally grown produce; lay health advisors attended bimonthly training sessions to provide social support and advance stage of change; pastors promoted project. C: Delayed intervention—no program until the final follow-up.	FV: in PE group at 18 mo, 0.77 and 0.46 increases in daily FV servings per FFQ, and recall $P<0.001$ , $P=0.002$ , respectively.	...	...	BP/Cholesterol/Glucose/ Hemoglobin A1c
Campbell et al, <sup>76</sup> 1999, cluster randomized 2-group RCT/2 y (N=2519)	Recruited from 50 black churches in 10 rural North Carolina counties. 98% black, mean age 53.8 y, 73% female, 59% income <\$20 000, 67% ≥HS education.	I: Vanguard Women's Health Trial modified to include additional goals. A nutritionist assigned personal fat g goals and delivered ≈10 group sessions with decreasing frequency over 2-y period. For individuals having difficulty, nutritionists provided individualized sessions; each session included nutrition and behavior change strategies, cultural (regional/ethnic foods), language and low-literacy sensitive information was used; sessions included regional and ethnic foods. Staff from varied racial/ethnic backgrounds. C: Subjects received package of standard materials on good dietary practices including the <i>Dietary Guidelines for Americans</i> .	FV servings per FFQ: at 2-y follow-up, the 5-a-day group consumed 0.85 FV servings more than the delayed intervention group, $P<0.001$ .	...	...	...
Coates et al, <sup>47</sup> 1999, 2-group RCT/6, 12, 18 mos (N=2208)	100% female, mean age 60 y, 28% black, 16% Hispanic, recruited from clinics located in 3 southern states, 16% <\$15 000 income, 11% <HS education.	I: Tailored feedback plus self-help. Feedback mailed and included a PCP letter, 2 feedback forms (fat and fiber), and 2 recommendation forms (fat/fiber). Structured telephone counseling within 2 wks to reinforce mailed feedback, address needs of low literate. Low-literacy self-help booklets mailed weekly ×4. A cultural, community advisory board made decisions about content and pictures in intervention material. C: Delayed intervention.	Cal Energy (kcal): At 18 mo, between-group (I vs C) difference of -233 (-355, -111); Fruits (servings): I-C difference of 0.53 (0.33, 0.73); Vegetables (servings): I-C difference of 0.27 (0.07, 0.47); Fat (% of energy): I-C difference of -11.62 (-13.07, -10.17); Sat Fat % of energy: I-C difference of -3.54 (-4.09, -2.99); cholesterol (mg): -74.1 (-100.5, -47.6).	...	...	...
Fries et al, <sup>81</sup> 2005, 2-group RCT/1, 6, and 12 mo (N=622)	Individuals from 3 rural Virginia physician practices. 36.7% black, mean age 46 y, 65% female, 17% <\$20 000/y income.	I: Tailored feedback plus self-help. Feedback mailed and included a PCP letter, 2 feedback forms (fat and fiber), and 2 recommendation forms (fat/fiber). Structured telephone counseling within 2 wks to reinforce mailed feedback, address needs of low literate. Low-literacy self-help booklets mailed weekly ×4. A cultural, community advisory board made decisions about content and pictures in intervention material. C: Delayed intervention.	Fiber: per fat and fiber questionnaire, higher scores=more fiber. I group: 2.24 (0.35) at baseline, 2.07 (.37) at 6 mo 2.12 (0.39) at 12 mo vs C group: 2.24 (0.36) at baseline, 2.16 (0.37) at 6 mo, and 2.16 (0.38) at 12 mo. Fat per questionnaire, lower scores=less dietary fat. I group: 0.203 (0.35) at baseline, 1.85 (0.34) at 6 mo, 1.87 (0.35) at 12 mo, vs C group: 2.05 (0.33) at baseline, 1.97 (0.34) at 6 mo, 1.95 (0.34) at 12 mo. For fat and fiber, I group significant improvement over time $P<0.05$ ; interaction between condition and time significant $P<0.05$ .	...	...	...

(Continued)

Table 3. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/ Hemoglobin A1c
Havas et al, <sup>48</sup> 1998, 2-group randomized crossover design/8 mo and 1 y (N= 3122)	Women served by 16 WIC programs in Maryland. 52% black, ≈66% age <30 y, 19% <HS education, approximately 44% using food stamps.	I: 3 components—(1) Stage of change–based nutrition sessions conducted by peer educators; (2) printed materials and visual reminders; (3) direct mail. Three peer-led 45-min group discussions over 6-mo period, goal-based. Story-based print materials and videotapes about FV were used. C: Intervention delayed.	FV: Change between baseline and 8 mo, 1 group +0.56±0.11 servings vs C group +0.13±0.17, between group P=0.002. At 1 y, 1 group added increase of +0.27±0.09 servings vs C group +0.27±0.06 servings; between-group difference, P=0.004 ES=0.05.	...	...	...
Keyserling et al, <sup>49</sup> 2002, 3-group RCT/12 mo (N= 167)	100% women with type 2 DM, 100% black, mean age 59 y, ≈33% income <\$10 000/y	A. Clinic and community: In clinic—4 monthly visits with a nutritionist who counseled about diet and PA and tailored it to baseline practices and attitudes. In community—3 group sessions and 12 monthly telephone calls from a peer counselor who provided social support and reinforced behavior change goals. B. Clinic only: Same as clinic described above. C. Minimal intervention: Educational pamphlets mailed to subjects.	...	PA per accelerometer: A vs C groups, the difference in adjusted mean for PA was 44.1 kcal/d, P=0.005. B vs C, the difference was 33.1 kcal/d, P=0.029.	...	...
Kumanyika, <sup>75</sup> 1999, 2-group RCT/1 y (N=330)	Black adults recruited from supermarket BP screenings aged 40–70 y. ≈72% female, 47% literacy less than eighth grade 52% <\$15 000/y.	All subjects to reduce fat, cholesterol, and Na in diet by a nutritionist every 4 mo at office visits. All subjects received some CARDES materials that consisted of (a) food cards with photos of common foods and coded with symbols to indicate low, medium, or high fat, cholesterol, or Na content; (b) a 42-page nutrition guide; (c) 25-min video to motivate and support change; and (d) 12, 10–15-min audiotapes and accompanying worksheets to provide info. CARDES materials were at fifth to eighth grade reading levels. Full Instruction (F): Subjects participated in monthly nutrition classes for 4 mo after enrollment in which a CARDES video was viewed; guidance provided about audiotapes and worksheets, and discussion of themes in audio programs. Video portrayed African American family. Self-Help (SH): In addition to counseling every 4 mo, subjects received self-help materials including food cards and nutrition guide.	...	...	...	All NSD between groups. Change from baseline: Total cholesterol (mmol/L): F –0.41±0.07 female, –0.50±0.12 male, P=0.0001, vs SH –0.43±0.07 F, –0.36±0.13 mol/L, P=0.006. HDL-C (mmol/L): F 0.3 (0.03) female, 0.01 (0.04) male vs SH –0.02 (0.03) female, –0.03 (0.05) male. NSD within-group difference. LDL-C (mmol/L): F –0.34 (0.07) female, –0.36 (0.11) male, within group P<0.001, vs SH –0.35 (0.07) female, –0.31 (0.12) male; within group P=0.009. SBP (mm Hg): F –7.4 (1.9) vs SH –10.6 (1.9), within-group difference, P=0.0001. DBP (mm Hg): F –3.7 (1.1), P=0.0007 vs SH group –6.6 (1.1), P=0.0001.

(Continued)



Table 3. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/ Hemoglobin A1c
Racette et al, <sup>51</sup> 2001, quasi- experimental/1 y (N=69)	100% black, employees of the University of Washington medical center at risk for type 2 DM, 86% female, education and income not reported.	I: Assigned diet goals (ie, decrease fat ≈14g/d). Subjects received a 1-wk energy- and fat-restricted diet prepared by a metabolic kitchen followed by a lifestyle program and increased PA for 1 year. Subjects received PA prescription and help about how to meet goals, 7-d food diaries every 4 mo and exercise logbooks. There were: individual meetings on request over 1-y period; optional bimonthly group meetings; monthly telephone calls to maintain contact. C: Subjects matched for age, body weight, body composition, and glucose tolerance. Subjects were invited to enroll in the intervention on completion of the study.	...	...	Weight loss: -4.6 kg in I vs + 0.3 kg in C, <i>P</i> <0.001.	Total cholesterol (mmol/L): -0.3 in I vs +0.4 in C, <i>P</i> <0.001. Glucose tolerance (GT): At baseline 13 in I had impaired GT, and 6 had diabetic GT; at 1 y, 10 had normal GT, 4 had impaired GT, and 5 had diabetic GT. Control: no difference from baseline.
Resnicow et al, <sup>102</sup> 2001, cluster randomized trial/12 mo (N=861)	100% black church members, mean age 43.9 y, 73.3% female, ≈45% had income >\$40 000, >50% had at least some college.	A. Comparison: Standard nutrition and culturally sensitive FV education materials. B. Self-help+1 cue call: Self-help materials included a video, cookbook, printed education materials, quarterly newsletters, and other cues (magnet, pot-holder, erasable writing tablet). Calls provided cues to use intervention materials. C. Multicomponent: Multicomponent self-help materials with 1 cue call and 3 motivational interviewing counseling calls.	FV: Change in FV was significantly greater in group C vs group A or B. The net difference between group A and C was 1.38, 1.03, and 1.21 servings of FV per day for the 2-, 7-, and 36-item FFOs, respectively. The net difference between group A and B was 1.14, 1.10, and 0.97.	...	...	...
Rosal et al, <sup>52</sup> 2005, 2-group RCT/3 and 6 mo (N=25)	Adults with type 2 DM recruited from a community, 100% Hispanic, 80% female, mean age 62.6 y, 84% ≈\$10 000/y, 74% less than or equal to eighth grade.	All participants received a booklet describing importance of lifestyle factors in DM and providing recommendations for diet, PA, and SMBG. I: Initial 1-h individual session plus two 15-min individual sessions, followed by 10 weekly 2.5-3 h group sessions and two 15-min individual sessions on diabetes; tailored to literacy level and culture, included: self-monitoring logs, step counters. A bilingual nurse, nutritionist, and an assistant. Interventionist bilingual and known in community.	NSD in increased PA between or within groups.	...	BMI: NSD.	HbA1c: decrease at 6 months in I was -0.85% vs -0.12%, <i>P</i> <0.01. Total cholesterol (mg/dL): -2.0 in I, +11.2 in C at 6 mo, NSD. LDL (mg/dL): +3.2 in I vs +12.5 in C at 6 mo, NSD. SBP and DBP: NSD.
Staten et al, <sup>53</sup> Arizona WISEWOMAN, 2004, 3-group RCT/12 mo (N=217)	Women recruited from 2 Tucson clinics, mean age 57.2 y, 75% Hispanic, income \$9737/y.	Active control—provider counseling (AC-PC): At each clinic visit, NPs provided health education brochures, discussed benefits and barriers to increasing PA and FV, gave behavior change prescription; suggested goals 150+ min/wk of PA and 5+ servings FV per day. Provider counseling+health ed classes (PC+HE): Counseling plus subjects referred to 2 education classes on diet and PA; also a monthly health newsletter for 12 mo. Provider counseling+health education classes+CHW provided social support (PC+HE+CHW): Counseling and health education classes plus subjects received semiweekly to monthly telephone calls from CHWs to provide info regarding benefits of PA and FV, how to modify behavior, bimonthly walks provided encouragement to find walking partners and support.	FV: Change at 12 mo, PC+HE+CHW: +0.26±-0.5, 1.0 vs PC+HE -0.23±-1.0, 0.5 vs PC -0.59±-1.2, 0.1, NSD all comparisons. -7.4% more women who received PC+HE+CHW progressed to eating ≥5 FV/d than in PC+HE (-8.3%) or PC (-5.2%), <i>P</i> =0.05, ES=0.07.	PA min/wk: Change from baseline, PC+HE+CHW: 0.1 (-0.3, 0.6) vs PC+HE: +0.7 (-0.1, +22.8 (6.0, 39.6), <i>P</i> ≤0.01, vs PC+HE: +22.6 (2.2, 43.0), <i>P</i> ≤0.05, vs PC: +15.1 (0.5, 29.8), <i>P</i> ≤0.01, ES=0.03.	BMI: Change from baseline, PC+HE+CHW: 0.1 (-0.3, 0.6) vs PC+HE: +0.7 (-0.1, 1.4) vs PC: -0.1 (-0.6, 0.5), NSD all comparisons.	Total cholesterol (mg/dL): Change from baseline, PC+HE+CHW: -8.3 (-16.0, -0.7) vs PC+HE: -10.9 (-19.9, -1.8) <i>P</i> ≤0.05 vs PC: -6.1 (-13.7, 1.4). SBP (mm Hg): PC+HE+CHW: -5.1 (-8.9, -1.2) <i>P</i> ≤0.01 NSD in other 2 groups. DBP (mm Hg): PC+HE+CHW: +1.3 (-0.8, 3.3) vs PC+HE: 43 (-1.6, 2.5) vs PC+3.4 (1.5, 5.2).

(Continued)

Table 3. Continued

Reference(s), Year, Study Design/ Duration (N)	Population/Sample	Intervention	Outcomes			
			Calories/Fat/Fruits and Vegetables/Fiber/Sodium	PA	Weight	BP/Cholesterol/Glucose/Hemoglobin A1c
Stoddard et al, <sup>11</sup> 2004, MA WISEWOMAN Project, 2-group RCT/12 mo (N=1443)	Women, mean age 58 y, 79% black, 70% with BMI $\geq$ 25, all uninsured or underinsured, retention: 80% for EI, 73% for MI.	All participants received low-literacy fact sheets on CVD risks, nutrition, and PA; also a follow-up screening at 12 mo. <u>Minimum Intervention (MI)</u> : Subjects received comprehensive CVD risk assessment, on-site counseling, education, referral, and follow-up as needed. <u>Enhanced Intervention (EI)</u> : Subjects received same as MI plus group education, one-on-one dietary and PA counseling, group activities such as walking.	FV: 80% MI vs 82% EI >5 servings/d, $P=0.12$ .	Proportion with increased PA: 6% MI vs 18% EI, $P=0.04$ .	...	Proportion with normal BP: 73% MI vs 82% EI, $P=0.80$ ; normal total cholesterol: 74.6% in MI vs 81% in EI, $P=0.63$ .
Yancey et al, <sup>59</sup> 2006, 2-group RCT/2-, 6-, and 12-mo (N=366)	Obese black women attending a black-owned gym. Mean age 45.5 y, income \$40,000-\$59,000/y.	A 1-y gym membership was offered to all participants as an incentive to participate in study. I: Subjects participated in 8 weekly 2-h interactive group sessions including PA and dietary education promoting low-fat complex CHO rich diet; pedometers and exercise bands provided; dietary recalls done by dietitian 3 or 4 times, provided feedback. To provide social support, subjects invited to come to gym with a friend. Instructors were culturally/ ethnically matched to subjects. C: Subjects received 8 weekly, 2-h interactive sessions on black women's health topics without the social support component.	...	Fitness, within group: I group and C group fitness levels (per 1-mile run/walk) improved by 1.9 and 2.3 min, respectively at 12 mo. Within group differences, $P=0.0001$ for both I and C; NSD between groups.	Weight (kg): Both groups significantly heavier at 12 mo, $P=0.001$ .	...
Yanek et al, <sup>55</sup> 2001, 2-group cluster RCT/1 y (N=529)	All black women, mean age 53 y, income $\approx$ \$36,000/y.	Note: Ultimately the standard and spiritual interventions operated identically (SI) since women did not believe there could be a church-based program without spirituality. <u>Standard behavioral intervention (SBI)</u> : Subjects attended kick-off retreat for 1.5 days, received feedback on baseline data; also received 20 weekly group sessions on diet and PA focusing on building self-efficacy and skills; each session included weigh-ins, taste tests, cooking demos, and 30 min of moderate-intensity PA. After 20 wks, lay-led weekly sessions provided info/support for rest of year. Church sponsored yearly events. <u>Spiritual Intervention</u> : Weekly sessions included prayer and health messages enriched with scripture, aerobics to gospel music, or praise and worship dance. <u>Self-help control intervention (SH)</u> : Subjects received AHA materials on healthy eating and PA and information targeted to subjects' personal screening results.	Energy intake (kcal/d): Change at 1 y, $-117$ for SI vs $-7$ for SH. Within group $P=0.0001$ for SI vs $P=0.8190$ for SH. Between group $P<0.004$ . Na (mg/d): $-145$ in SI vs $-8$ SH, within group $P=0.0001$ and between group $P=0.02$ . Total fat (g/d): Change at 1 y, $-8.1$ in SI vs $-2.3$ in SI, within group $P=0.0001$ for SI and $0.2374$ for SH, Btw group $P=0.03$ .	...	Weight loss (lb): Change at 1 y, $-1.1$ SI vs $+0.83$ in SH, w/group $P=0.009$ between group $P=0.0008$ .	BP (mmHg): Change at 1 y, SBP $-1.6$ and DBP $-0.36$ in SI vs SBP $-0.95$ and DBP $+0.22$ in SH; within group $P=0.004$ for SBP and $0.21$ for DBP in SI; NS for SH; NSD between groups.

WIC indicates Women, Infants, and Children; NP, nurse practitioner; and CHO, carbohydrates.

group differences for the majority of studies was small, ranging from 0.00 to 0.33, except for the preliminary study of Carels et al,<sup>15</sup> that used motivational interviewing to augment behavioral intervention and reported an ES of 0.84.

### **Cognitive-Behavioral Strategies for Promoting Behavior Change**

Cognitive-behavioral strategies are an essential component of behavior change interventions. These strategies focus on changing how an individual thinks about themselves, their behaviors, and surrounding circumstances and how to modify their lifestyle. As illustrated in Tables 2 and 3, at least 2 or more strategies were incorporated in studies that yielded favorable outcomes.

#### **Goal Setting**

Several lines of evidence indicate that setting goals at the outset of the program is important to achieve the desired behavior change. Under most circumstances, setting specific goals leads to higher performance compared with no goals or vague goals.<sup>16</sup> Compared with individuals who have vague or absent goals, individuals who target a specific behavior change are more likely to be successful.<sup>17,18</sup> Such goals may vary by degree of difficulty, specificity, and complexity; for example, making some dietary changes can be complex and requires several intended outcomes.<sup>19</sup> The use of goals is more successful when the goals are specific in outcome, proximal in terms of attainment, and realistic in terms of the individual's capability.<sup>20</sup> Goals that focus on behavior (eg, increasing whole grain intake) rather than a physiological target (eg, improving low-density lipoprotein [LDL] cholesterol or glucose levels) are preferable because behaviors are under a person's more direct control and also observable by the individual, whereas several factors (eg, genetics) can influence physiological targets.<sup>16,19,21,22</sup>

Setting appropriately ambitious goals is also important. Goals that are too difficult may not be attempted, whereas those viewed as too easy may not be taken seriously or provide a sense of satisfaction once achieved. Providing regular feedback on goal attainment is important to instill a sense of learning and mastery.<sup>16</sup> Of the 74 trials described in Tables 2 and 3, 31 trials (42%) included goal-based diet and/or PA strategies.<sup>23–53</sup> Positive dietary or PA behavior changes were observed in all but 2<sup>35,46</sup> of the trials. Goals either set by participants<sup>43,44,46,48,54</sup> or assigned by the healthcare provider can lead to desired outcomes (eg, weight loss).<sup>26,38,53,55</sup>

#### **Self-Monitoring**

The purpose of self-monitoring is to increase one's awareness of physical cues and/or behaviors and to identify the barriers to changing a behavior. Self-monitoring facilitates recognition of progress made toward the identified goal (eg, minutes of PA or number of calories consumed per day), thus providing direct feedback. Self-based monitoring allows the individual to assess progress with the program on his/her terms, removing barriers such as travel or scheduling constraints associated with structured group programs. Self-monitoring interventions can be simple, such as pencil-and-paper logs of PA or dietary intake or charting of weight lost, steps taken, or distance walked.<sup>23,26,27,29,35,36,38,40,42,46,50–52,56–59</sup> Self-monitoring strategies can be provided and then left to the

discretion of the individual or applied in conjunction with external prompts incorporated into the behavior-change strategy. For example, such prompts can include scripted telephone messages or Internet e-mail reminders, specialized personal digital assistant (PDA) programs for monitoring dietary intake and PA, as well as both commercial and free-of-charge Internet-based programs.<sup>35,36,57</sup> Studies to date suggest that electronic self-monitoring systems can be effective for monitoring behavior changes. An advantage of electronic monitoring systems is their mobility, decreasing cost, and increasing availability; a potential limitation is the absence of human interaction.

Both observational data<sup>60–64</sup> and evidence from clinical trials<sup>26–28,30,36,38,50,52</sup> demonstrate the importance of self-monitoring in achieving behavior change. A recent meta-analysis found that PA intervention studies using self-monitoring demonstrated larger effect sizes than studies without self-monitoring.<sup>65</sup> In a recent trial of weight loss, participants who self-monitored their food intake lost twice as much weight as those who did not self-monitor.<sup>62</sup> Frequency of self-monitoring, as well as detail and proximity in time to the recorded behavior, can influence efficacy of self-monitoring.<sup>62</sup> In a study testing interventions to promote weight loss, individuals in a combined therapy group who frequently recorded their weight achieved more than twice the weight loss than those who recorded their weight infrequently.<sup>28</sup> In the Women's Health Initiative Dietary Modification Trial, a randomized controlled trial in nearly 50 000 postmenopausal women, independent predictors of dietary change at 1 year included younger age, more education, having a more optimistic personality, attending more intervention sessions, and submitting more self-monitoring records.<sup>64</sup> Notably, at 3 years, the only predictors of continued dietary maintenance were attending more sessions and submitting more self-monitoring records.<sup>63,64</sup> Among the 25 trials with sizable minority representation in Table 3, only 6 included interventions that described self-monitoring.<sup>42,46,50–52,59</sup> Five of these 6 trials that included self-monitoring<sup>42,46,50–52</sup> led to positive lifestyle behavior changes, compared with 13 of the 19 trials that did not include self-monitoring. Thus, both in whites and minority populations, self-monitoring appears to be an effective complement to behavioral intervention strategies.

#### **Frequent and Prolonged Contact**

Compared with single-session interventions, the evidence suggests that programs that incorporate scheduled follow-up sessions as a core component are generally more effective.<sup>25,26,28,41,43,47,52,55,66–69</sup> Frequent contact with individuals helps establish trust between the provider and individual, a component of care especially important among racial/ethnic minority groups.<sup>70</sup> Ongoing contacts can be delivered by various modes, including face-to-face, telephone, email or through the Internet.<sup>27,36,68,69,71</sup> When combined with the use of group-based interventions, scheduled follow-up sessions provide several advantages, including social support from the peer group, an increased desire to succeed due to a sense of commitment to the group, and an opportunity to modify the program based on feedback from group members or the program leaders.

Across all behavioral domains, it is well-established that adherence to any new behavior will often decline as the

intervention is reduced or withdrawn. Evidence suggests that as the frequency of contact decreases, achievement of initial behavior change also decreases.<sup>72</sup> Further, any already achieved behavior change often diminishes over time as frequency of the follow-up decreases, and particularly so when the intervention ceases entirely.<sup>41,59,68</sup> Greater numbers and more prolonged time courses of follow-up sessions facilitate success across sequential stages of behavior change, such as new learning of diet and/or PA behavior change skills, practicing of these skills, problem solving and finding solutions to overcome relapse, integrating new diet and PA behavioral skills into one's daily routine, and learning skills to facilitate maintenance of new behaviors.<sup>73</sup> Among the trials reviewed (Tables 2 and 3), the majority of interventions that led to dietary or PA changes that lasted  $\geq 12$  months included follow-up contacts over at least 4 months.<sup>26,38,46,48,51,53,55,74-76</sup>

There are few data on critical time points for follow-up. Expert opinion suggests that 6 months is a critical time to assess maintenance, but no data are available that compare this period with others between 3 and 12 months. Initial intervention and follow-up should be early and often, incorporating the expectation of self-monitoring and deliberate follow-up. In the absence of conclusive data, expert opinion suggests that follow-up beyond the initial visit could include visits at 6 weeks; then at 3, 6, 9, and 12 months; and then every 6 months thereafter if behavior change adherence is successful. Lack of adherence should prompt more frequent follow-up, whether in person, by telephone, or electronically. Further research is needed to confirm the feasibility and effectiveness of this suggested time frame versus other alternatives.

### **Feedback and Reinforcement**

Healthcare provider feedback helps individuals learn new dietary or PA behavioral skills by providing an external measuring stick against which to assess their progress.<sup>77</sup> Feedback about behavior performance can illuminate consequences of diet and PA behavior for an individual, which may motivate individuals to continue a certain behavior or provide direction for adjusting behavior to reach a targeted goal.<sup>78</sup> When goal setting is combined with receipt of performance feedback, individuals can use information about their current level of performance to set realistic goals for improvement.<sup>78</sup> Evidence in Table 2 suggests that feedback is frequently included in successful behavior change interventions.<sup>24,27,29,30,32,33,36,44,46,52,55,57,69,71,79-81</sup> Six of the 25 trials listed in Table 3 described provision of feedback as part of the intervention. Five of these studies resulted in positive lifestyle changes.<sup>44,46,52,55,81</sup> Of the successful trials, all interventions included provision of feedback about the initial baseline screening results, and several included further feedback during follow-up assessments. Feedback based on initial screening can help individuals become aware of the need for behavior change, and feedback during follow-up provides updated information about ongoing behavior change efforts.

### **Self-Efficacy Enhancement**

Self-efficacy, a component of social cognitive theory, describes an individual's perception regarding his/her abilities to carry out actions necessary to perform certain behaviors (eg, making changes in diet or lifestyle).<sup>20</sup> Perceived self-efficacy is a major

determinant of performance independent of an individual's actual underlying skill.<sup>20</sup> The strength of perceived self-efficacy is particularly important, as individuals are more likely to both initiate a behavior and continue their efforts until success is achieved if their perceived self-efficacy is higher.<sup>20</sup> Thus enhancement of an individual's perceived self-efficacy can be incorporated into interventions to improve the likelihood of successful behavior change. Bandura's theory suggests 4 sources of self-efficacy that can be drawn on and incorporated into intervention strategies to enhance self-efficacy.<sup>82</sup> The source with the greatest potential for increasing self-efficacy, mastery experiences, entails having a person successfully achieve a goal that is reasonable and proximal; for example, substituting fruit for a high-calorie dessert or being able to walk 1 mile. A second source, vicarious experience, consists of the individual witnessing someone who is similar in capability successfully perform the desired task; for example, observing patients exercise and improve their physical function in cardiac rehabilitation or watching a nonprofessional prepare a healthy meal. A third source, verbal persuasion, entails the provider persuading the person that he/she believes in the person's capability to perform the task. This is the weakest source for improving self-efficacy, but can be implemented via telephone or other electronic modes. The fourth source, physiological feedback, entails interpreting to the individual the meaning of different symptoms associated with behavior change. Examples include explaining that experiencing fewer symptoms with exertion is related to regular participation in a physical activity program or that feeling less fatigued or more comfortable is related to weight loss.<sup>20</sup> An extensive body of evidence indicates that self-efficacy influences behavior change across all the behavior domains related to CVD risk reduction.<sup>83-92</sup> Self-efficacy enhancements were incorporated into the interventions of several of the studies that yielded favorable outcomes.<sup>30,39,40,46,54,55,68,79,93</sup>

### **Incentives**

The efficacy of incentive programs to induce or support behavioral change has been most extensively studied at the workplace. The most commonly used incentives have been financial, such as health premium reductions or direct cash payments/bonuses for specific changes.<sup>94</sup> Few interventions described in this review included incentives,<sup>34,57,76</sup> and the return on investment from them has not been widely assessed. Novel but untested incentive strategies include rewards for employees frequently parking in the spaces located furthest away from the work site in the company parking lot or lowering the charge for use of on-site fitness facilities when frequency of use is higher.

### **Modeling**

Modeling is a behavior change strategy that consists of having the person observe another individual perform behaviors (eg, engaging in PA or preparing healthy food) that are related to his/her goal. Among interventions described in Tables 2 and 3, several incorporated modeling, including use of in-person or video cooking demonstrations and personal PA training (having credible individuals demonstrate how to exercise and have the individual practice with them if possible).<sup>25,43,54,55,75,95,96</sup> Another modeling approach is to have a person speak with someone who has been successful in making behavior changes (eg, maintained weight loss or a

PA program). Exposure to models that are credible to participants can be an effective strategy to enhance skills for changing behavior and enhancing self-efficacy.<sup>82</sup>

### **Problem Solving**

Problem solving consists of 5 steps: identifying and defining the problem, brainstorming solutions, evaluating the pros and cons of potential solutions, implementing the solution plan, and evaluating its success.<sup>97</sup> Problem solving can be used to help an individual navigate barriers to behavior change (eg, negotiating support from the family when attempting dietary change). It is important to have the individual do the brainstorming when developing solutions and, when possible, to have the person practice the skill.<sup>97</sup> Tables 2 and 3 describe several studies that included problem solving as a part of interventions that led to positive behavior change.<sup>31,32,39,41,43–45</sup>

### **Relapse Prevention**

Relapse prevention is an approach that makes a person aware that it is normal to deviate episodically from the goal behavior, such as missing some scheduled exercise sessions or giving up on the program due to lapses. Individuals are taught to recognize past situations that have placed them at risk for lapses from their dietary or PA behavior change program (eg, vacations or calendar holidays) and how to use behavioral and cognitive strategies for handling these situations.<sup>30</sup> Although few interventions reviewed specifically addressed relapse prevention as a strategy,<sup>23,30,45</sup> others may have indirectly addressed relapse prevention through the inclusion of social support,<sup>29,35,41,47,53,55,76,80</sup> through problem solving to reduce barriers,<sup>31,32,39,41,44</sup> or through a reinforcement program.<sup>98</sup>

### **Motivational Interviewing**

Motivational interviewing is a directive, individual-centered counseling style for eliciting behavior change with a central purpose of helping individuals to explore and resolve their ambivalence (ie, lack of readiness toward changing their behavior).<sup>99</sup> Briefly, the 7 key principles that characterize the nature of motivational interviewing include the following: (1) motivation to change is elicited from the individual, rather than imposed from without; (2) it is the person's task, not the counselor's, to articulate and resolve his or her ambivalence; (3) direct persuasion is not an effective method for resolving ambivalence<sup>100,101</sup>; (4) the counseling style is generally a quiet and eliciting one; (5) the counselor is directive in helping the person to examine and resolve ambivalence; (6) readiness to change is not a person trait, but a fluctuating product of interpersonal interaction; and (7) the therapeutic relationship is more like a partnership than one in which there are expert/recipient roles.<sup>100</sup>

Interventionist behaviors that are characteristic of motivational interviewing include seeking to understand the person's frame of reference, particularly via reflective listening, and expressing acceptance and affirmation; eliciting and selectively reinforcing the person's own self-motivational statements, expressions of problem recognition, concern, desire and intention to change, and ability to change; monitoring the person's degree of readiness to change; ensuring that resistance is not generated by jumping ahead of the individual; and affirming the person's freedom of choice and self-direction. Training and certification of the interventionist

is necessary to achieve optimal results. There are several print and electronic resources to help clinicians wanting to learn more about motivational interviewing,<sup>101</sup> including the following Web site: <http://www.motivationalinterview.org/training/trainers.html>. Referral to allied professionals trained in motivational interviewing is also an excellent option for individuals ambivalent about behavior change.

Evidence suggests that motivational interviewing can facilitate behavior change. A 2003 meta-analysis<sup>19</sup> was conducted on controlled clinical trials investigating interventions that primarily implemented motivational interviewing principles. Four studies demonstrated a combined ES of 0.53 (95% CI, 0.32 to 0.74) for diet and exercise, thereby indicating moderate efficacy. Additional motivational interviewing studies reported increased fruit and vegetable consumption as part of general lifestyle change in whites and blacks,<sup>32,102,103</sup> firefighters,<sup>71</sup> smokers,<sup>93</sup> and college students.<sup>104</sup> Other studies demonstrated that motivational interviewing increased PA among women and/or individuals with diabetes or obesity<sup>15,40,105</sup> and black individuals with hypertension.<sup>106</sup> An array of studies have reported improved body mass index or weight loss using motivational interviewing in workers in Oregon,<sup>107</sup> other occupational settings,<sup>105</sup> black individuals with hypertension,<sup>106</sup> and white females.<sup>15</sup> Overall, there is general consensus that motivational interviewing offers an evidence-based approach for enhancing adherence to behavioral interventions, including dietary and PA change.

## **Intervention Processes or Delivery Strategies**

### **Targeting Single Behaviors Versus Multiple Behaviors**

Evidence described in Tables 2 and 3 shows that interventions may focus on changing only PA,<sup>34,46,69,108,109</sup> only dietary behaviors,<sup>17,24,30,32,33,39,47,48,54,68,74–76,80,81,96,110</sup> or both.<sup>26–29,35,36,38,43,44,50,51,53,55,57,66,67,111–113</sup> Studies that focus on multiple behaviors have generally applied the same type of intervention strategy (eg, provision of education materials, counseling sessions, follow-up monitoring) to change each specific behavior. Results of these studies have been variable. Most reported positive results (ie, the desired change in both PA and dietary behaviors). However, studies have not consistently resulted in improvements in related metabolic/vascular biomarkers (eg, serum lipids, blood pressure). The results of a meta-analysis of studies testing interventions to increase PA among older adults indicated that interventions targeting only PA resulted in higher ES than studies designed to change multiple health behaviors.<sup>65</sup>

There is limited knowledge about the relative benefits of simultaneous versus sequential delivery of multiple PA and dietary behavior change interventions in adults. In a randomized trial of 289 blacks with hypertension, participants were randomized to 1 of 3 groups: (1) an in-clinic counseling session every 6 months on smoking, reduced dietary salt intake, and PA, supplemented by use of motivational interviewing strategies by telephone for 18 months; (2) a similar protocol that introduced 1 behavior every 6 months; or (3) a 1-time referral to existing group classes.<sup>106</sup> When examining individual target behaviors at 6 months, 29.6% in the simultaneous, 16.5% in the sequential, and 13.4% in the usual care arms had reached the urine sodium goal ( $P=0.01$  for the simultaneous versus the usual care group and  $P<0.05$  for the simultaneous versus the sequential group).

At 18 months, 20.3% in the simultaneous, 16.9% in the sequential, and 10.1% in the usual care arms were negative for urinary cotinine ( $P=0.06$  for the simultaneous group versus the usual care group and  $P=0.08$  for the overall trend in smoking cessation), whereas 6.5% in the simultaneous arm, 5.2% in the sequential arm, and 6.5% in the usual care arm were adherent to  $\geq 2$  target behaviors (all statistical contrasts resulted in  $P>0.05$ ). In contrast, findings from another trial among 315 female smokers supported a sequential over simultaneous approach to multiple behavior changes, including diet, exercise, and smoking cessation.<sup>114</sup>

It is worth noting that additional studies published later than our time window or performed outside the United States have also shown mixed results for superiority of sequential versus simultaneous intervention strategies.<sup>115,116</sup> In 1 trial, at 6 months, the simultaneous strategy was superior for a fat intake intervention and for a subgroup of participants who did not meet physical activity recommendations at baseline.<sup>115</sup> However, the sequential intervention resulted in better maintenance of intervention effects at 2 years.<sup>117</sup> Thus, the relative merits of simultaneous versus sequential intervention are unresolved, and more studies comparing these intervention modes are needed.

#### **Print- or Media-Only Delivery Strategies**

Media messages, printed materials, and other nonindividualized strategies may be used to provide information to individuals to encourage PA and dietary change. In a study involving individuals with mild hypertension, the use of nonindividualized educational mailers did not significantly decrease BP.<sup>118</sup> Overall, self-help approaches that provide nonindividualized brochures and other behavioral learning tools without any additional personal counseling appear to produce little benefit.<sup>55</sup>

In contrast, in a study comparing the efficacy of nonindividualized self-help manuals versus motivationally matched reports and manuals to promote PA adoption, both groups showed significant improvement in PA at 6 months, but the increase was 50% greater among participants receiving motivationally matched materials.<sup>79</sup> The mode of delivery may also influence efficacy. In a study comparing the effects of motivationally matched print materials versus motivationally matched telephone counseling, both groups had significantly increased PA at 6 months, but participants receiving the print materials were more likely to maintain PA change at 12 months.<sup>69</sup> Thus, whereas further research on optimal modes of delivery is needed, the evidence suggests that individualized print or media material are more effective than nonindividualized ones.

#### **Group, Individual, Technology, and Multicomponent-Based Delivery Strategies**

Four general approaches can characterize interventions to modify dietary intake and increase PA, including (1) group-based interventions, (2) individual-based interventions, (3) computer/technology-based (interactive session, personal or automated telephone calls) interventions, and (4) multicomponent interventions.

#### **Group-Based Interventions**

Group-based interventions are characterized by opportunities for social interaction, support from others who are experiencing similar challenges in modifying their lifestyle, role

modeling, and positive observational learning.<sup>29</sup> Group-based approaches are commonly used in randomized clinical trials employing standard behavioral interventions for weight loss,<sup>24,25,28,29,66,72,109</sup> as well as in other trials using diet and PA changes to target CVD risk factors such as BP or blood cholesterol.<sup>23,26,27,56,66,67,113</sup> In a meta-analysis of studies that tested interventions to increase PA among older adults, group-based intervention delivery resulted in larger ES than individual-based interventions.<sup>65</sup>

Group-based interventions have been successful in both white<sup>28</sup> and minority populations.<sup>76</sup> The majority of studies with minority populations (18/25) included group-based intervention strategies.<sup>42,43,46–48,51–55,59,74–76,96,110,112</sup> Minority populations ranged from being 100% black,<sup>42,43,51,55,75,76,102,103,119</sup> 73% to 100% Hispanic,<sup>44,46,52,53,110</sup> to smaller subsamples of blacks and/or Hispanics.<sup>26,45,47,48,50,54,74,93,96,112,113</sup>

Typically, group interventions are administered in a small, closed group format (eg, 7 to 10 members). Groups initially meet as often as weekly, with meeting frequency often decreasing over time.<sup>28,43</sup> Sessions may be led by a lay person or a professional.<sup>43,46,56,58,76,113</sup> Successful group-based interventions incorporate didactic education, counseling strategies, and multiple behavior change strategies such as goal setting and self-monitoring.<sup>26,38</sup> Some group-based programs have included skill-building sessions such as food label reading; grocery shopping; methods for healthy cooking; practice using pedometers, exercise bands, or other exercise equipment; and walking groups.<sup>24,68</sup> Of the trials in Table 3 with a group-based intervention delivery, approximately one third ( $n=9$ ) incorporated the use of skill-building strategies.<sup>43,46,47,54,55,59,74,76,112</sup> Among these, all but 1 study<sup>46</sup> demonstrated at least within-group positive changes in dietary or PA behaviors or improved CVD risk factors.

In group-based weight loss interventions, the greatest weight loss usually occurs within the first 6 months of the study.<sup>15,30,120</sup> Regardless of type of diet or activity, investigators typically report that many individuals find it challenging to maintain the reduced caloric intake and/or PA plan, and weight is often regained by many individuals as early as 4 to 6 months into the program. A major challenge in weight management is identifying strategies to assist individuals in maintaining long-term weight loss.<sup>24,121</sup> To achieve this, investigators have tried supplementing the group-based approach by recruiting participants with friends and enhancing social support,<sup>29</sup> providing home exercise equipment,<sup>109</sup> using aerobic or strength-training exercises,<sup>72</sup> providing improved access to counselors through the Internet,<sup>36,57,122</sup> and using a stepped-care approach and motivational interviewing for those who did not meet their weight loss goals.<sup>15</sup> The studies found improvements in all groups, with small between-group differences in energy and fat consumption or PA changes, suggesting that supplementary strategies to most basic group-based approaches do not have a major effect on efficacy; however, most approaches that include the basic elements of standard behavioral treatment will have a positive effect on eating and PA habits and will result in weight loss, at least for the short term.

Commercial programs that use the group approach and a self-monitoring system to guide food restrictions (eg, Weight Watchers) appear to be more effective than self-help approaches.

For example, in a trial among 212 adults,<sup>123,124</sup> greater weight reductions were observed at both 1 and 2 years in the commercial group compared with the self-help group, with accompanying improvements in BP, blood lipids, insulin, and glucose levels. Although such commercial programs have many similarities to the empirically tested noncommercial ones described above, having access to continued group support and ongoing contact for 2 years may be the salient features of these programs compared with a self-help approach. However, due to their cost, commercial programs may be less available to socioeconomically disadvantaged populations.

### **Individual-Focused Interventions**

Individual-focused interventions allow tailoring or personalization of healthcare recommendations to the learner's particular health concerns and life context. Individualized counseling has been effectively provided by health educators and/or counselors,<sup>31,32,125</sup> physicians,<sup>95</sup> and/or other healthcare professionals.<sup>30</sup> A meta-analysis of randomized clinical trials testing interventions to promote PA among older adults found that individualized interventions consisting of a health risk appraisal, activity counseling, and/or cognitive-behavioral strategies resulted in increased PA levels for at least short term (<1 year), compared with a control group.<sup>126</sup>

A wide range of individual-based strategies have been tested, including in-person, telephone, electronic, and combined approaches. For example, among the studies reviewed, individual-only approaches included 6 biweekly telephone sessions,<sup>30</sup> 3 monthly telephone sessions,<sup>31</sup> one 8-minute physician-provided counseling session during a clinic visit,<sup>95</sup> three 30- to 45-minute face-to-face counseling sessions followed by 12 counseling telephone calls,<sup>125</sup> and 2 face-to-face 45-minute counseling sessions followed by two 5- to 10-minute telephone calls 3 and 6 weeks after the sessions.<sup>32</sup>

Combined individual-based approaches appear to be successful in creating behavior change. For example, the use of personal goal setting and self-monitoring via individual telephone counseling improved adherence to a cholesterol-lowering diet and reduced serum cholesterol compared with usual care.<sup>30</sup> In another trial, supplementing clinician advice with telephone counseling by a health educator was more effective in improving levels of PA than clinician advice alone.<sup>125</sup> In a study comparing physician-delivered nutrition counseling alone versus physician counseling combined with in-office prompts to usual care,<sup>95</sup> only the combined program decreased participants' saturated fat intake, weight, and LDL cholesterol. The average counseling time was 8.2 minutes, 5.5 minutes more than in the control group.<sup>95</sup> No studies were identified that examined the effects of in-office prompts only, in-office reminders only, or in-office dietary and/or PA assessment tools only on diet and/or PA behavior change; more research is needed in these areas.

Three studies that addressed individual-based CVD risk reduction in the practice setting were published earlier than our time window of published articles or were performed outside the United States but warrant mentioning here.<sup>127–129</sup> In 1 study, nurses initiated interventions for smoking cessation, exercise, and diet and drug therapies for hyperlipidemia among hospitalized individuals who had suffered an acute

myocardial infarction.<sup>127</sup> They followed the study participants after hospital discharge by telephone and mail contact. Compared with usual care, the intervention group reported higher functional capacity at 6 months and higher smoking cessation rates and lower LDL cholesterol at 12 months.<sup>127</sup> A second study delivered a 4-year intervention to assist individuals with coronary artery disease in meeting several CVD risk reduction goals through improving diet and PA, smoking cessation, and drug therapy.<sup>128</sup> After an individualized session with a nurse at baseline, individuals were followed-up by mail and telephone contact and seen every 3 months in the clinic. Compared with usual care, the intervention group had less progression of coronary atherosclerosis and decreased hospitalizations for cardiac events.<sup>128</sup> This is one of the few trials of sufficient size and follow-up duration to demonstrate that PA and dietary changes lead to reductions in clinical end points. A third trial, EUROACTION, investigated the efficacy of a nurse-coordinated multidisciplinary, family-based (rather than individual-based) preventive cardiology program conducted in 8 European countries for both primary and secondary prevention.<sup>129</sup> Compared with usual care, more individuals and their partners in the intervention group achieved recommended targets for PA and for fruit, vegetable, saturated fat, and oily fish consumption. Central obesity was also reduced. These findings indicate that a nurse-led multidisciplinary team approach, coupled with support and involvement of an individual's partner and family, can yield significant lifestyle improvements and cardiovascular risk factor reductions.

Because the studies described here utilized interventions that were delivered at the individual level, cognitive-behavioral intervention strategies may also have been incorporated and improved efficacy. For example, some studies incorporated motivational interviewing strategies<sup>32,93,103,125</sup>; some used goal setting, feedback, and/or self-efficacy enhancement<sup>30,79</sup>; and others used readiness to change<sup>31,45,69,104,125,130</sup> or problem-solving<sup>31,32,44</sup> strategies. Overall, individual-based interventions have been shown to be successful, at least for the short term (up to 1 year). In studies with minority samples (Table 3), individual intervention approaches to promoting change seem to result in smaller or fewer changes in total diet or PA compared with group-only<sup>55</sup> or combined individual- and group-based approaches.<sup>26,38,47,51</sup> Research has yet to establish when and for whom individual-only approaches are most appropriate.

Further investigation should better quantify the processes and comparative effects of specific individual interventions. Key questions include whether the type of provider (eg, nurse, physician) influences efficacy; what specific combination of cognitive, behavioral, and informational strategy is most effective; and what are optimal strategies for including family members.

### **Computer/Technology-Based Interventions**

With the growth of computer technology and the Internet, health interventions are increasingly delivered online or with the use of technology. Several advantages of Internet-based interventions have been cited,<sup>131</sup> including ability to reach many people with a single posting; easy storage of large amounts of information; ease of updating information; ability to provide personalized feedback; cost effectiveness and

convenience for users; ability to reach people suffering from isolation or conditions that cause them to feel embarrassed or stigmatized; timeliness of access; user control of the intervention; supplier control of the intervention; and ease of adapting information for specific populations.<sup>36,57,108,122,132</sup>

Several studies have employed the use of the Internet or computer-based programs to deliver education and counseling interventions for weight loss and dietary change.<sup>17,33–36,57,108,122,132</sup> (Table 2). Three studies demonstrated that the combination of an Internet program (eg, weekly reporting and graphs of weight, recipes, and weight loss tips) plus E-counseling (eg, automated praise or feedback) resulted in greater weight loss than use of the Internet program alone.<sup>36,57,122</sup> Another study found that Internet-only counseling was as effective for weight loss at 6 or 12 months as Internet-only counseling plus monthly in-person counseling.<sup>35</sup> A strategy of interactive, computer-controlled telephone systems for educating participants about a healthy diet resulted in some improvements in fruit, fiber, and saturated fat intake.<sup>17</sup> A supermarket kiosk program providing onsite nutrition information also resulted in improvements in fat, fiber, fruit, and vegetable purchases and intake.<sup>33</sup>

A few US trials have evaluated the efficacy of Internet or computer-delivered interventions to increase PA.<sup>34,108,132</sup> In 1 small trial (N=65), use of a PA Web site and 12 weekly E-mail tip sheets resulted in increased total minutes of walking, but not time spent in moderate PA at 1 and 3 months, compared with a control group.<sup>34</sup> In a larger and longer randomized clinical trial, investigators compared a motivationally tailored Internet intervention to motivationally tailored print material and to publicly available PA Internet sites; at 6 and 12 months, there were no significant differences in minutes of PA among the 3 groups.<sup>108</sup>

Few Internet studies have been conducted among minority and/or socioeconomically disadvantaged populations. Investigators have reported that low-literacy individuals may have difficulty accessing information through the Internet because of suboptimal searching strategies (eg, use of nonspecific search terms), unwillingness to click on links, accessing Web sites written at or above the 10th grade reading level, and perceived higher quantity and complexity of the information.<sup>133,134</sup> An understanding of the target population appears essential to optimize delivery of Internet-based diet and PA behavior change interventions.

Overall, the results of these trials are mixed, but at least in some scenarios, the use of Web-based and computerized materials appears to improve weight loss and certain dietary behaviors; fewer studies have evaluated PA. Combinations of technology-based approaches may be more effective than single interventions; for example, the addition of E-counseling appeared to improve efficacy of Internet-based programs for weight loss.<sup>35</sup> The use of the Internet can allow healthcare providers to reach a greater number of sedentary adults in a cost-effective manner, but several important questions remain unanswered, including effectiveness in low-income and minority samples, utility for increasing PA, long-term sustainability, optimal components of Internet interventions (eg, number of log-ins, E-mails, online chats) and relative efficacy versus traditional printed material.

### **Multicomponent Intervention Delivery Strategies**

In contrast to single strategies, most trials have evaluated multicomponent interventions (Tables 2 and 3). Multicomponent programs include combinations of technology/media; group or individual-based delivery strategies such as interactive computer-based programs plus telephone follow-up and community resource enhancement<sup>80</sup>; computerized assessment and feedback plus videotapes, telephone follow-up, or individual counseling<sup>32,39</sup>; physician advice plus motivational videotapes, telephone calls, and interactive mail<sup>135</sup>; group sessions plus individual motivational interviewing<sup>15,40</sup>; or individual plus group sessions.<sup>38,41,58,111</sup> In most multicomponent studies, various behavioral strategies were also included, including goal setting, self-monitoring, feedback,<sup>38–41,46,49–53,55,58,59,80,81,111</sup> social support,<sup>49,76</sup> problem solving,<sup>39,41</sup> or motivational interviewing.<sup>15,40,102</sup>

Among nonminority populations (Table 2), all 10 multicomponent intervention trials reviewed demonstrated positive dietary and/or PA outcomes. Among the 16 multicomponent intervention trials involving minority populations (Table 3), most<sup>47–53,55,74–76,81,102,112</sup> demonstrated some positive changes in either dietary and/or PA behavior. The 2 trials of multicomponent interventions that did not lead to dietary or PA changes<sup>46,59</sup> may have been limited by insufficient duration or lack of effective combination of behavior change strategies. The optimal combination of behavior change strategies in multicomponent interventions has yet to be determined.

As part of a personalized, medical office-based intervention focused on dietary self-management for individuals with type 1 or 2 diabetes, a computerized assessment of potential dietary barriers was used to immediately generate 2 printed feedback forms that were provided in combination with personalized counseling and other self-help materials.<sup>39</sup> One year later, significant decreases were observed in total fat intake and serum cholesterol levels, but not hemoglobin A1c levels. One of the most successful multicomponent studies has been the Diabetes Prevention Program (DPP).<sup>38</sup> The DPP used individual counseling in the intensive lifestyle intervention arm of the trial, with goals of 7% weight loss and 150 minutes per week of PA.<sup>38</sup> Compared with a control group that received some group education, participants assigned to the lifestyle intervention had greater dietary changes, increased levels of leisure-time PA, and greater weight loss. Incidence of diabetes and metabolic syndrome were reduced by 58% and 41% in the lifestyle and control groups, respectively. Notably, the effects of the intensive lifestyle treatment did not differ significantly by sex, race, or ethnicity. The Look Ahead Trial,<sup>111</sup> an ongoing, multicenter randomized clinical trial of participants with type 2 diabetes mellitus, combined individual and group sessions. At 1 year, the trial reported significantly greater weight loss, improved fitness, and lower mean hemoglobin A1c in the combined group compared with those who received diabetes support and education through a limited number of group-only meetings.

### **Special Considerations for Interventions With Minority and Socioeconomically Disadvantaged Populations**

In the United States, numerous racial and ethnic groups exist with diverse cultural norms, values, attitudes, beliefs, and



lifestyle patterns. Interventions designed to change dietary and/or PA behavior in 1 population group may be less effective in another group, especially when the population is educationally or economically disadvantaged or differs in cultural health beliefs or practices from the population in which the intervention was initially tested. Optimally, methods to design or adapt interventions should be directly assessed in diverse populations and settings. Relatively fewer studies ( $n=25$ ) within the specified time period for this review (1997 to 2007) evaluated samples other than white middle- or upper middle-class Americans. The most commonly studied minorities were blacks and Hispanics. Studies in Hispanic populations often did not adequately address linguistic competency. Although intervention studies have been conducted that included Asian American and Native American populations, in most, numbers were insufficient to conduct ethnic-specific subgroup analyses. Table 3 displays the 25 studies that included ethnic minorities or low-income participants that were reviewed and that provide the basis for additional discussion about implementing dietary and PA change interventions in these population subgroups. It is important to recognize that additional diversity occurs within racial/ethnic groups, so that intervention designs should consider the potentially diverse values, beliefs, and socioeconomic characteristics within each group.

#### ***Setting in Which Healthcare Is Delivered***

For interventions in minority or socially and/or economically disadvantaged populations, an important consideration is identifying a setting to minimize the barriers to access the intervention. Once access is established, Table 3 indicates that interventions conducted in work sites, clinics, communities, and churches can lead to improved dietary intake and PA levels among blacks and/or Hispanics.

#### ***Peer/Lay Led Versus Professionally Led***

Research suggests that people are more likely to hear and personalize messages, and thus to change their attitudes and behaviors, if they believe the messenger is similar to them and faces the same concerns and pressures.<sup>136</sup> It is therefore important to consider when a person may be more likely to believe a lay health advisor versus health professional thought to be an authority figure. Lay health advisors, peer educators, or community health workers are trusted community members and usually live in the same communities, speak the same language, have similar values and beliefs, and understand the cultural context of the minority target population.<sup>137,138</sup> Lay leaders can improve the quantity of messages about healthy behavior and tailor messages to the unique needs and culture of the target population.<sup>74</sup> The homophily for ethnicity (ie, the tendency of individuals to associate and bond with similar others) is important and may affect whether lay advisors or healthcare professionals are more effective.

Of the 25 trials reviewed (Table 3), 3 tested lay-led group or individual-level interventions,<sup>43,48,74</sup> and 4 tested interventions that combined professional and lay educators.<sup>52,53,55,76</sup> All these trials generally showed some positive changes related to diet and or weight. The trials using both professionals and lay leaders also further led to positive outcomes in diet,<sup>55,76</sup> blood chole-

sterol and BP,<sup>53,55</sup> PA,<sup>53</sup> and hemoglobin A1c at follow-up.<sup>52</sup> It is also important to note that several studies demonstrated that professional-only led interventions can also lead to improved diet and PA changes in minorities.<sup>42,45–47,93,103</sup> Given the well-documented history of discrimination toward minorities in healthcare settings, and a greater awareness of historical discrimination against blacks,<sup>70,139–141</sup> expert opinion agrees that provider capacity for trust building, communication skills, and cultural sensitivity are important ingredients of professional-led interventions.

#### ***Cultural Sensitivity***

Cultural sensitivity in health promotion interventions refers to designing and delivering interventions that are relevant and acceptable within the cultural framework of the target population.<sup>142</sup> Development of culturally sensitive interventions depends on knowledge of the history, values, belief systems, and behaviors of the members of the target minority group. The ability to overcome language barriers faced by non-English-speaking immigrants is also necessary.<sup>143</sup> Of the 25 trials reviewed (Table 3), 18 designed culturally sensitive interventions and had mixed results.<sup>43–47,52,55,59,74–76,81,93,96,102,103,110,144</sup> In comparison, the results of the trials not including culturally sensitive interventions<sup>42,48,49,51,53,54,112</sup> demonstrated within- and/or between-group differences in diet, PA, or related metabolic/vascular biomarkers. Thus cultural sensitivity alone is not sufficient and needs to be combined with essential behavior change strategies to produce positive outcomes.

#### ***Literacy Level Sensitivity***

Without adequate literacy skills, individuals cannot read health-related materials. When working with persons of lower educational levels, literacy assessment and modification of methods for providing health information are useful. Effective strategies include use of audiovisual and interactive multimedia rather than print media; use of simple messages with short sentences, 1- or 2-syllable words, and large print with lots of space; and nonreliance on the Internet for provision of information.<sup>54,110,145,146</sup> Seven of the 25 studies described in Table 3 used interventions sensitive to literacy levels<sup>44,45,47,52,54,74,81</sup>; 6 of these<sup>44,45,47,52,74,81</sup> resulted in some positive outcomes. The trial with null outcomes<sup>54</sup> lacked other intervention components such as specific behavioral goals, self-monitoring, or feedback that may have lessened the efficacy of the intervention.

#### ***Barriers to Behavior Change***

Reported barriers to healthy eating among the disadvantaged and/or minority groups include poor dental health, lack of access to quality produce at affordable prices, inability to find ethnically preferred fruits and vegetables in local markets, transportation problems, family customs/habits, social and cultural symbolism of certain foods, and low price and easy access to snack foods.<sup>147–152</sup> Neighborhoods in which lower socioeconomic status individuals often live may not be conducive to exercise due to high traffic, poor lighting, waste sites, infrastructure deterioration, high crime rates,<sup>151,153</sup> and lack of availability of facilities that enable and promote PA.<sup>154,155</sup> Thus assessment of barriers to behavior change should be part of interventions targeting these population groups.

### Acculturation

Evidence supports that acculturation of immigrants to the United States negatively influences healthy dietary patterns.<sup>156,157</sup> For example, highly acculturated Hispanics ate fewer servings of fruits and vegetables per day compared with those not highly acculturated, suggesting that healthcare providers need to encourage immigrants to retain traditional healthful eating patterns. Thus assessment of acculturation may be helpful in designing and implementing interventions to improve dietary habits in immigrant groups.

### Fostering Initiation and Maintenance of Behavior Change

Several factors influence the design of optimal interventions and may influence a person's ability to adopt and maintain new lifestyle behaviors. First, various psychological factors enable individuals to adopt as well as sustain new behaviors long term. For initiating a behavior, persons' consideration of the anticipated benefits must compare favorably to their current situation, and they need to hold favorable expectancies regarding future outcomes.<sup>4,158</sup> The decision to maintain a behavior is dependent, at least in part, on whether the achieved outcomes associated with the new behavior pattern are sufficiently desirable to sustain the behavior (ie, on the individual's *perceived satisfaction* with the outcomes of that behavior change). Most individuals have clear expectations about what a new lifestyle will provide; if their experiences do not meet those expectations, they will be dissatisfied and less motivated to maintain it, particularly in environments that are frequently not supportive of healthy choices.

Other factors that may influence adoption and maintenance of new PA or dietary behavior include:

- Age—Evidence suggests that older age per se does not significantly reduce the response to PA or dietary interventions. Older age may be associated with more healthful dietary patterns and better adherence, such as higher consumption of fruits.<sup>159–163</sup> In the DPP trial, the greatest risk reduction in response to the lifestyle intervention was seen in the oldest age group, suggesting better adherence and/or efficacy in this group. However, although older adults on average may have better adherence, some may have barriers to overcome to achieve this adherence. For example, some older adults may be at particular risk for poor dietary habits, especially if they live alone and/or have low incomes. Although younger adults are more likely to cite time as the main constraint to exercise,<sup>164</sup> older adults most frequently cite poor health, including pain, reduced mobility, and low endurance.<sup>165</sup>
- Sex—Lower PA levels in women than men are generally reported.<sup>166–168</sup> Women, however, are reported to have better eating habits than men.<sup>169–174</sup>
- Better health status has been associated with greater levels of PA.<sup>175–177</sup>
- Obesity, higher body mass index, and smoking are associated with lower PA levels.<sup>175,177–179</sup>
- Presence of comorbid conditions and depression negatively impact adherence to most lifestyle change regimens.<sup>180–183</sup>

- Deficits in cognitive processing and memory can reduce adherence, particularly for complex regimens.<sup>184,185</sup>
- Individual differences in perception and assessment of costs and benefits of behavior change, when different from provider expectations, may alter responsiveness to interventions.<sup>186</sup>
- Conscientiousness and self-efficacy each have been reported to favorably impact adherence.<sup>187</sup>
- Somatic factors related to side effects negatively impact adherence to most regimens.<sup>180,181,188</sup>
- Availability of social support positively influences PA and healthy food choices.<sup>29,189–192</sup>
- It is important to consider the above-listed factors as well as the knowledge levels and skills of the individual before implementing therapeutic lifestyle changes.

### Recommendations

Table 4 provides evidence-based and expert opinion recommendations on designing and implementing PA and dietary interventions in adults. Recommendations are organized to aid clinicians: to use cognitive-behavioral strategies to assist adults to adopt and maintain healthy dietary and PA targets; to make decisions about behavior change intervention processes and delivery strategies; and to modify interventions for addressing cultural and social context variables that influence behavioral change. The level of evidence base for these different recommendations varies; a few are supported more strongly by expert opinion or case study rather than direct research findings. The strength and types of evidence used to derive each recommendation are indicated in Table 4.

Subsequent to May 2007, when the literature review was completed for this publication, results from a few landmark studies conducted in large study populations were published. These include the POUNDS Lost Study (N=811), which compared 4 diets for weight loss, and the 1-year weight loss data from the Look AHEAD Study (N=5145).<sup>193–195</sup> In each case, weight loss itself, however it was achieved, was associated with reduced CVD risk. In addition to a specified dietary intervention, these studies included behavioral counseling strategies that are described in detail in this article, which were implemented to promote behavior modification for weight loss and to complement the dietary and/or physical activity components of the intervention. Consistent with the recommendations made in Table 4 in the present article, weight loss success was attributed to the best adherence to behavior and dietary recommendations.<sup>193–195</sup> The results of these studies add further and consistent support for the recommendations made herein that include state of the art behavior change strategies to counsel individuals in order to promote weight loss as needed along with the dietary and physical activity changes to maximize reduction in CVD risk.

### Implications for Healthcare Policy and for Other Policy

Changes in healthcare policies are needed to make it more feasible to follow the recommendations made in this statement. Providers face numerous barriers to assessment and counseling for therapeutic lifestyle change. Although a major provider barrier to adherence in the acute *inpatient* setting is a focus on the acuity of the presenting problem, the major

**Table 4. Recommendations for Counseling Individuals to Promote Dietary and PA Changes to Reduce Cardiovascular Disease Risk**

## Cognitive-behavioral strategies for promoting behavior change

## Class I

- Design interventions to target dietary and PA behaviors with specific, proximal goals [goal setting]. (Level of evidence: A)
- Provide feedback on progress toward goals. (Level of evidence: A)
- Provide strategies for self-monitoring. (Level of evidence: A)
- Establish a plan for frequency and duration of follow-up contacts (eg, in-person, oral, written, electronic) in accordance with individual needs to assess and reinforce progress toward goal achievement. (Level of evidence: A)
- Utilize motivational interviewing strategies, particularly when an individual is resistant or ambivalent about dietary and PA behavior change. (Level of evidence: A)
- Provide for direct or peer-based long-term support and follow-up, such as referral to ongoing community-based programs, to offset the common occurrence of declining adherence that typically begins at 4–6 months in most behavior change programs. (Level of evidence: B)
- Incorporate strategies to build self-efficacy into the intervention. (Level of evidence: A)
- Use a combination of  $\geq 2$  of the above strategies (eg, goal setting, feedback, self-monitoring, follow-up, motivational interviewing, self-efficacy) in an intervention. (Level of evidence: A)

## Class II

- Use incentives, modeling, and problem solving strategies. (Level of evidence: B)

## Intervention processes and/or delivery strategies

## Class I

- Use individual- or group-based strategies. (Level of evidence: A)
- Use individual-oriented sessions to assess where the individual is in relation to behavior change, to jointly identify the goals for risk reduction or improved cardiovascular health, and to develop a personalized plan to achieve it. (Level of evidence: A)
- Use group sessions with cognitive-behavioral strategies to teach skills to modify the diet and develop a PA program, to provide role modeling and positive observational learning, and to maximize the benefits of peer support and group problem solving. (Level of evidence: A)
- For appropriate target populations, use Internet- and computer-based programs to target dietary and PA change; evidence is less for targeting PA alone; adding a form of E-counseling improves outcomes. (Level of evidence: B)

## Class IIa

- Use individualized rather than nonindividualized print- or media-only delivery strategies. (Level of evidence: A)

## Addressing cultural and social context variables that influence behavioral change

## Class IIa

- Utilize church, community, work, or clinic settings for delivery of interventions. (Level of evidence: B)
- Use a multiple-component delivery strategy that includes a group component rather than individual-only or group-only approaches. (Level of evidence: A)
- Use culturally adapted strategies, including use of peer or lay health advisors to increase trust; tailor health messages and counseling strategies to be sensitive to the cultural beliefs, values, language, literacy, and customs of the target population. (Level of evidence: A)
- Use problem solving to address barriers to PA and dietary change, such as lack of access to affordable healthier foods, lack of resources for PA, transportation barriers, and poor local safety. (Level of evidence: B)

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PA indicates physical activity.

provider barrier in the *outpatient* ambulatory setting is limited resources for counseling and sustained follow-up support.<sup>196</sup> Across all settings are the persistent and ever-growing issues of provider time restraints, lack of financial incentives or reimbursement for health promotion, skepticism regarding whether health promotion counseling will result in behavior change, insufficient information about the most effective counseling strategies, lack of skills necessary to provide positive individualized counseling using both verbal and non-verbal communication skills, and doubts about the likelihood of lifestyle changes resulting in the desired outcome.<sup>197–199</sup> Physicians and nurses often cite their own lack of confidence in a person's ability to use preventive strategies for long-term behavior change.<sup>200–205</sup>

Healthcare delivery systems need to address policy to ensure an environment that supports preventive interventions.<sup>206</sup> Examples of healthcare system policies needed to strengthen the provider's ability to promote PA and dietary lifestyle changes include: use of tracking, reporting, and feedback systems; assessment of practice goals and benchmarks; availability of toolkits containing assessment tools and diet and PA behavior change guidelines; education and training for providers, including cultural sensitivity training; provision of incentives that are tied to desired individual and provider outcomes; and development of mechanisms for obtaining data on diet and PA behavior before a provider visit. It is encouraging that the American College of Cardiology Foundation/AHA's 2009 performance measures for primary prevention of CVD in adults include lifestyle counseling.<sup>207</sup> Performance measures for diet and PA intervention are critical to improve the value placed on these interventions by the reimbursement system.<sup>207</sup>

It is important to note that other factors not included in this review will affect whether our evidence-informed recommendations are feasible for implementation, will result in improved levels of cardiovascular risk factors, and will prevent clinical events. Policies that foster individual healthy lifestyle choices are needed. For example, insurance premiums could be lowered for those who participate in programs around healthy diet and PA behaviors. Legislative initiatives geared toward providing more complete and accessible information to the general public or limiting the use of certain food components in the food supply, coupled with guidance on how to use that information or implement the policy, has been shown to positively influence food choices and foods available. For example, mandatory calorie labeling at point of purchase enacted by the New York City Health Department has provided expanded information for individuals about their food choices.<sup>208</sup> This legislatively mandated regulation has been coupled with large-scale education initiatives on how to use the information. An environmental legislative initiative also championed by New York City is the staged phase-out of partially hydrogenated fat by food purveyors.<sup>209,210</sup> Extensive support systems to the food producers to provide advice and assistance in how to make the change and where to obtain the alternate fats were key ingredients in the success of the program. Many other cities have adopted or have legislative efforts underway to mandate law that food purveyors phase out industrially produced trans fats. As of October 2009, California passed legislation to limit trans fats, and numerous

other states have similar legislation under review (<http://www.ncsl.org/default.aspx?tabid=14362>). These types of approaches, if enacted in a collaborative fashion, can serve to shape an environment where optimal lifestyle choices are available and in some cases are the “default” options.

Community environments have been extensively investigated in relation to PA and diet.<sup>9,211–216</sup> Special efforts by community groups, businesses, and government to increase the availability of healthier food and PA choices will complement provider interventions to implement lifestyle changes. Policies for providing wide and safe routes for walking and biking in communities and along state and federal roads, maintaining public parks, reducing exposure to unhealthy fast food or to high-calorie/low-nutrient foods, menu labeling, and increasing access and availability to healthy foods appear crucial.

Workplace policies designed to engage employees to achieve optimal health, as well as provide opportunities for organized PA (eg, lunch hour walking programs, instructor-led group exercise) and more healthy eating options (eg, cafeterias, vending machines, healthy taste clubs) will complement provider efforts to implement lifestyle change. A synthesis of older studies indicated that a point-of-decision prompt to use the stairs instead of an elevator or escalator resulted in a median increase in stair climbing of 53.9%.<sup>189</sup> More recent studies have confirmed the positive effects of signage on stair usage in public buildings<sup>190</sup> and have shown that experimentally reducing the availability of escalators and modeling more active behaviors increase stair use.<sup>217,218</sup> In summary, healthcare system policy and other policy changes are needed to increase the effectiveness of our evidence-based recommendations to improve diet and PA behaviors.

### Where Do We Go From Here? Implications for Future Research

Evidence suggests that cognitive-behavioral strategies are an essential component of interventions targeting dietary and PA behavior change. We know that individual, group, and multicomponent intervention delivery strategies are effective; however, we need comparative studies to demonstrate the relative strengths and weaknesses of implementing multicomponent strategies versus any single strategy. We also know that computer/Internet-based delivery strategies are effective for selected populations. However, the ability for newer technologies such as text messaging and social networking tools such as Health Vault, Twitter, and Facebook to facilitate dietary and PA change needs to be determined.

There are many other gaps in our current knowledge about promoting lifestyle change. Comparative studies evaluating the effectiveness and intensity of diverse interventions are needed to identify the interventions most likely to succeed in both initiation and maintenance of diet and PA lifestyle changes. Optimal follow-up strategies to maximize the duration of change needs to be addressed in future studies. We do not know the specific design features that determine which interventions are most effective for whom (eg, young-old, male-female, high-low socioeconomic status) and at what cost. More knowledge about treatment receptivity or efficacy across different sex, racial, ethnic, or socioeconomic groups is needed. Many of the studies

reviewed included samples of predominantly well-educated whites, and several studies targeted blacks and Hispanics; more studies that target other racial and ethnic minorities such as Asians, Native Americans, or Arab Americans are needed because these groups are also at risk for CVD.<sup>219</sup> The majority of studies reviewed ( $\approx 57\%$ ) contained samples that were predominantly ( $\geq 70\%$ ) female. Although this representation of women is an improvement from that reported in an earlier review of 49 studies of compliance to pharmacological, exercise, nutritional, and smoking cessation therapies (85% male),<sup>187</sup> we still do not know the extent to which lifestyle change interventions should be tailored to sex. The absence of males in most of the weight loss trials may reflect reluctance of some investigators to mix sexes,<sup>29,36,57,109</sup> as well as lower numbers of males who seek weight loss treatment or respond to recruitment efforts for studies that include men.<sup>24,62</sup> More research is needed on weight loss interventions in men, among whom the obesity epidemic is similarly rampant.<sup>220</sup>

Although the studies reviewed examined the influence of behavior change on surrogate end points such as lipid or BP changes, few examined the influence of behavior change on CVD events, mortality, hospitalizations, or quality of life.<sup>221,222</sup> More studies with longer-term follow-up of individuals who are able to maintain behavior change are needed to allow evaluation of these clinical end points.

The next generation of studies should also investigate how individual interventions interact with the multiple levels of environmental influences on PA and dietary behavior change. Both increased scope and detail of investigation are needed to understand the combined effects of individual behavior, healthcare system, and sociocultural and environmental factors. Health-promoting community design,<sup>223</sup> active-living communities,<sup>224</sup> and providing a healthier food environment should be incorporated into future studies to investigate multiple levels of environmental influences on health behavior.

Lifestyle interventions often target constructs based on social cognitive theory (eg, self-efficacy, self-regulation [self-monitoring, goal-setting, feedback], social support, observational learning) or the trans-theoretical model of change (eg, stages of motivational readiness). More evidence is needed to determine whether one or the other theoretical approach may be better in specific circumstances.

Lack of reimbursement for therapies targeting dietary and PA lifestyle change is a barrier for healthcare providers. In order to establish a case for reimbursement, we need to better understand the expected costs and cost-effectiveness of such interventions in the community. Future research must more carefully examine effectiveness of behavior change strategies in routine clinical practice, as opposed to efficacy trials that examine interventions under more structured ideal conditions. The efficacy of different behavior change strategies should also be assessed in diverse practice settings with diverse populations to understand generalizability and factors that influence it. Finally, we need to understand how to translate and feasibly deliver these evidenced-based strategies into health practice, through delivery, dissemination, and diffusion research.

The AHA's 2020 Goals include a new concept of cardiovascular health that directly incorporates metrics of lifestyle behav-

iors, including diet and PA habits, as defining health.<sup>225</sup> Whereas further research is needed on several aspects of individual- and group-based interventions to improve diet and PA, a sufficient evidence base now exists to incorporate several specific strat-

egies, as outlined in Table 4, into clinical practice. The promotion of these interventions should form a key component of strategies to achieve the AHA's 2020 Goals and improve the cardiovascular health of the population.

## Disclosures

### Writing Group Disclosures

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Nancy T. Artinian	Wayne State University	None	None	None	None	None	None	None
Gerald F. Fletcher	Mayo Clinic	None	None	None	None	None	None	None
Philip A. Ades	University of Vermont	None	None	None	None	None	None	None
JoAnne Banks	Winston-Salem State	None	None	None	None	None	None	None
Kathy Berra	Stanford University	None	None	Boehringer Ingelheim*; Gilead*	None	None	Knowledgepoint360 2009 Lipids Online Contributing Author*; Aspirin Measurement Advisory Panel NCCA/CPM/HEDIS 2009*; NHLBI Implementation Workshop 2009*	None
Lynne T. Braun	Rush University	None	None	None	None	None	AHA Learning Library*; Heart Profilers*	None
Lora E. Burke	University of Pittsburgh	NIH†	None	Novo Nordisk*	None	None	None	None
J. Larry Durstine	University of South Carolina	None	None	None	None	None	None	None
Linda J. Ewing	University of Pittsburgh	NHLBI*; NIDDK*; NIH†; Pennsylvania Tobacco Fund†	None	None	None	None	None	None
Jerome L. Fleg	NIH	None	None	None	None	Bristol-Myers Squibb*	None	None
Barbara J. Fletcher	University of North Florida	None	None	None	None	None	None	Pritchett and Hull Associates†
Laura L. Hayman	University of Massachusetts-Boston	None	None	None	None	None	None	None
Nancy Houston-Miller	Stanford University	None	None	Gilead*; Pfizer*; Boehringer-Ingelheim*	None	None	None	None
Suzanne Hughes	Robinson Memorial Hospital	None	None	None	None	None	None	Associate Editor, <i>Cardiosource</i> (ACC)†
Laurie A. Kopin	University of Rochester	None	None	Bristol-Myers Squibb*; Sanofi-Aventis*	None	None	None	None
William E. Kraus	Duke University	None	None	None	None	None	None	None
Penny Kris-Etherton	Penn State University	None	California Pistachio Commission†; General Mills†; Hershey Foods†; National Cancer Institute†; National Cattlemen's Beef Association†; Tomato Wellness Council†; Unilever†; United Soybean Board†; US Department of Agriculture†	None	None	None	Health Fitness Corp*; Heinz*; Merck*; Shaping America Health*; Unilever*	None

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Writing Group Member	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Shiriki Kumanyika	University of Pennsylvania	None	None	None	None	None	Weight Watchers, Inc*	None
Alice H. Lichtenstein	Tufts University	None	None	None	None	None	None	None
Janet C. Meininger	University of Texas Health Science Center–Houston	NIH†	None	None	None	None	Center for Health Promotion Research–University of Texas School of Nursing Austin, TX*	None
Todd D. Miller	Mayo Clinic	Lantheus Medical Imaging†; Molecular Insight Pharmaceuticals†	None	None	None	None	TherOx, Inc.*; The Medicines Company*	None
Dariusz Mozaffarian	Harvard University	In discussions with Sigma Tau, GlaxoSmithKline, and Pronova for an investigator-initiated trial of fish oil and cardiac disease	None	None	None	None	None	None
Nancy S. Redeker	Yale University	None	None	None	None	None	None	None
Eileen M. Stuart-Shor	University of Massachusetts Boston/Beth Israel Deaconess Medical Center	NIH†	None	None	None	None	None	None
Linda Van Horn	Northwestern University	NIH†	None	None	None	None	None	None

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\*Modest.  
†Significant.

Reviewer Disclosures

Reviewer	Employment	Research Grant	Other Research Support	Speakers' Bureau/Honoraria	Expert Witness	Ownership Interest	Consultant/Advisory Board	Other
Vera Bittner	University of Alabama at Birmingham	NHLBI-HF ACTION Study (Multicenter Trial of Exercise Training in Heart Failure)†	None	American Heart Association*	None	None	None	None
Timothy S. Church	Pennington Biomedical Research Center	None	None	None	None	None	None	None
Barry Franklin	William Beaumont Hospital	None	None	None	None	None	Smart Balance*	None
Bonnie J. Spring	Northwestern University	NIH†	None	None	None	None	None	None

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\*Modest.  
†Significant.

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KEY WORDS: AHA Scientific Statements ■ diet ■ lifestyle ■ activity, physical ■ skills, behavior change ■ reduction, cardiovascular risk ■ modification, lifestyle

**Interventions to Promote Physical Activity and Dietary Lifestyle Changes for  
Cardiovascular Risk Factor Reduction in Adults: A Scientific Statement From the  
American Heart Association**

Nancy T. Artinian, Gerald F. Fletcher, Dariush Mozaffarian, Penny Kris-Etherton, Linda Van Horn, Alice H. Lichtenstein, Shiriki Kumanyika, William E. Kraus, Jerome L. Fleg, Nancy S. Redeker, Janet C. Meininger, JoAnne Banks, Eileen M. Stuart-Shor, Barbara J. Fletcher, Todd D. Miller, Suzanne Hughes, Lynne T. Braun, Laurie A. Kopin, Kathy Berra, Laura L. Hayman, Linda J. Ewing, Philip A. Ades, J. Larry Durstine, Nancy Houston-Miller and Lora E. Burke  
on behalf of the American Heart Association Prevention Committee of the Council on  
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