

Review

Behavioral Treatment of Obesity in Patients Encountered in Primary Care Settings

A Systematic Review

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IMPORTANCE In 2011, the Centers for Medicare & Medicaid Services (CMS) approved intensive behavioral weight loss counseling for approximately 14 face-to-face, 10- to 15-minute sessions over 6 months for obese beneficiaries in primary care settings, when delivered by physicians and other CMS-defined primary care practitioners.

OBJECTIVE To conduct a systematic review of behavioral counseling for overweight and obese patients recruited from primary care, as delivered by primary care practitioners working alone or with trained interventionists (eg, medical assistants, registered dietitians), or by trained interventionists working independently.

EVIDENCE REVIEW We searched PubMed, CINAHL, and EMBASE for randomized controlled trials published between January 1980 and June 2014 that recruited overweight and obese patients from primary care; provided behavioral counseling (ie, diet, exercise, and behavioral therapy) for at least 3 months, with at least 6 months of postrandomization follow-up; included at least 15 participants per treatment group and objectively measured weights; and had a comparator, an intention-to-treat analysis, and attrition of less than 30% at 1 year or less than 40% at longer follow-up.

FINDINGS Review of 3304 abstracts yielded 12 trials, involving 3893 participants, that met inclusion-exclusion criteria and prespecified quality ratings. No studies were found in which primary care practitioners delivered counseling that followed the CMS guidelines. Mean 6-month weight changes from baseline in the intervention groups ranged from a loss of 0.3 kg to 6.6 kg. In the control group, mean change ranged from a gain of 0.9 kg to a loss of 2.0 kg. Weight loss in both groups generally declined with longer follow-up (12-24 months). Interventions that prescribed both reduced energy intake (eg, ≥ 500 kcal/d) and increased physical activity (eg, ≥ 150 minutes a week of walking), with traditional behavioral therapy, generally produced larger weight loss than interventions without all 3 specific components. In the former trials, more treatment sessions, delivered in person or by telephone by trained interventionists, were associated with greater mean weight loss and likelihood of patients losing 5% or more of baseline weight.

CONCLUSIONS AND RELEVANCE Intensive behavioral counseling can induce clinically meaningful weight loss, but there is little research on primary care practitioners providing such care. The present findings suggest that a range of trained interventionists, who deliver counseling in person or by telephone, could be considered for treating overweight or obesity in patients encountered in primary care settings.

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Obesity has been the subject of increasing professional attention in the past decade, including the American Medical Association's declaration that it is a disease.¹ In 2003 and 2012, the US Preventive Services Task Force recommended that primary care practitioners screen all adults for obesity and offer intensive behavioral counseling to affected individuals, either by providing such treatment themselves or by referral.^{2,3} In 2011, the Centers for Medicare & Medicaid Services (CMS) approved the provision of intensive behavioral counseling for obese beneficiaries seen in primary care practices for approximately 14 face-to-face sessions over 6 months when delivered by physicians and other select practitioners (Box).^{4,5}

The frequency of behavioral counseling prescribed by the CMS is generally consistent with conclusions of a review commissioned by the US Preventive Services Task Force⁶ and with recommendations of the recently published Guidelines for the Management of Overweight and Obesity in Adults.⁷ The latter guidelines, based on findings of a systematic review, advise primary care practitioners to prescribe overweight and obese patients with a high-intensity (ie, ≥ 14 sessions in 6 months) comprehensive lifestyle intervention, delivered by a trained interventionist.⁷ Interventionists in the studies reviewed included registered dietitians, psychologists, exercise specialists, health counselors, medical assistants, and laypersons, all of whom delivered counseling following structured protocols.⁷ Comprehensive behavioral interventions, as defined by the obesity guidelines,⁷ include the prescription of (1) a reduced calorie diet, typically to induce an energy deficit of 500 kcal/d or more; (2) 150 minutes or more a week of aerobic physical activity, typically walking; and (3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations.⁸

This systematic review summarizes the results of randomized controlled trials involving patients recruited from a primary care setting, in which CMS-defined primary care practitioners, working alone or with trained interventionists, delivered behavioral weight loss counseling. It also examines randomized trials involving patients recruited from primary care who were counseled by trained interventionists alone, working without primary care practitioners, who delivered treatment in person, by telephone, and via the Internet rather than counseled by physicians.⁸ These interventionists are not currently recognized by the CMS as independent providers of behavioral counseling, although they may potentially provide services incident to eligible practitioners (Box).⁴ This review does not include trials such as the Diabetes Prevention Program⁹ or the Look AHEAD study¹⁰ in which behavioral counseling was provided to highly selected volunteers recruited outside of primary care.

Methods

For this systematic review, we followed methods similar to those used to conduct the literature review for the 2013 obesity guidelines,⁷ updated from 1998.¹¹ We used the PICOTS¹² (ie, population, interventions, comparators, outcomes, timing, setting) approach to establish inclusion and exclusion criteria and searched PubMed, CINAHL, and EMBASE from January 1, 1980, through June 30, 2014, using the following terms: *obesity, primary care, weight loss, counseling, diet, exercise, behavior modification, and lifestyle counseling*. Studies included were randomized trials that were published in the English language and had the following characteristics: (1) recruited from pri-

Box. Centers for Medicare & Medicaid Services' Requirements for Intensive Behavioral Therapy for Obesity

Treatment Components

Measurement of body mass index

Dietary assessment

Behavioral counseling to promote weight loss through high-intensity interventions on diet and exercise, using the USPSTF 5 A's approach, which includes clear, specific, and personalized behavioral change advice

Frequency of Contact

A maximum of 22 face-to-face sessions over a 12-month period, as follows:

One each week for the first month

One every other week for months 2 through 6

One every month for months 7 through 12, if weight loss goal is met

Eligible Providers

Qualified primary care practitioner, ie, physician who has a primary specialty designation of family practice, general practice, geriatric medicine, internal medicine, obstetrics/gynecology, or pediatric medicine

Qualified nonphysician primary care practitioners³ are defined as certified clinical nurse specialist, nurse practitioner, or physician assistant

Eligible Settings

Setting in which there is a provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community

Eligible settings include independent clinic, outpatient hospital, physician office, or public health clinic

Weight Loss Assessment

At the 6-month visit, weight loss must be assessed

To be eligible for continued visits in months 7 through 12, weight loss of 3 kg or more must be achieved during the first 6 months of therapy

Abbreviation: USPSTF, US Preventive Services Task Force.

^a Services also may be provided by auxiliary personnel incident to a physician or other primary care practitioner's professional service, when directly supervised by the physician or other practitioner.⁴

mary care settings overweight or obese adults whose body mass index (BMI) was 25 or higher [BMI is calculated as weight in kilograms divided by height in meters squared]; (2) included behavioral weight loss counseling, also referred to as lifestyle intervention, consisting of the following 3 components: diet, physical activity, and behavioral strategies⁷; (3) offered behavioral counseling for at least 3 months and with at least 6 months' follow-up after randomization; (4) delivered the intervention using CMS-defined primary care practitioners, working alone or with trained interventionists, or by trained interventionists alone who provided behavioral counseling in person or remotely (eg, telephone); (5) included a comparator intervention; (6) included objectively measured change in weight, reported in kilograms, BMI units, or percent change; and (7) had randomized sample size of 15 or more participants per treatment group. Our review did not include trials of weight gain prevention or use of pharmacological agents. The search

fielded 3304 articles (eFigure in the Supplement). It was supplemented by examination of prior reviews^{6,13-15} and a search of the Cochrane Central Registry of Controlled Trials.

Titles and abstracts of all articles were reviewed independently by pairs of authors (T.A.W. and P.S.H.; M.L.B. and A.G.T.) to exclude nonrelevant articles. The full text of each remaining article was similarly reviewed to determine whether it met inclusion and exclusion criteria. As shown in the eFigure in the Supplement, 27 studies,¹⁶⁻⁴² 3 of which published additional follow-up data,⁴³⁻⁴⁵ met all criteria and were subjected to a quality rating of *poor*, *fair*, or *good* by 2 authors who used criteria similar to those of the obesity guidelines.⁷ Fifteen studies were excluded from further consideration because they were rated *poor* or had one or more fatal flaws: (1) high attrition (average $\geq 30\%$ at 6 or 12 months or $\geq 40\%$ thereafter)^{29,30,33,35,37-39,41,42}; (2) differential attrition between treatment groups of more than 15% at any time^{31,34,36,40}; or (3) failure to report results of an intention-to-treat analysis, unless attrition was less than 10% at the time for which data were reported in a completers-only analysis.^{28,29,32,37-39,42}

The 12 remaining studies, all with a good rating, were divided into 2 categories following preliminary examination. The first category was whether the weight loss program prescribed all 3 components of a comprehensive lifestyle intervention as operationalized by the obesity guidelines.⁷ Seven trials, for example, encouraged participants to change components of their diet but did not specifically prescribe a reduced-calorie diet (eg, deficit ≥ 500 kcal/d).^{16,22-27} Six^{16,22,24-27} of these 7 trials similarly did not provide primarily behavioral counseling, as identified by the obesity guidelines, but instead included instruction guided principally by motivational interviewing⁴⁶ or stages of change theory (ie, the transtheoretical model).⁴⁷ Motivational interviewing typically is less prescriptive than traditional behavioral weight loss counseling and encourages exploration of ambivalence about change.⁴⁶ This approach may conflict with more directive behavioral counseling, although some investigators have successfully combined the 2 interventions.⁴⁸ Two studies in this review used elements of motivational interviewing within a primarily behavioral approach.^{20,23} The stages-of-change model seeks to match interventions to participants' readiness to change.⁴⁷ This approach, like motivational interviewing, often avoids prescribing specific energy intake and expenditure goals on a set schedule. As shown in Table 1 and Table 2, the 2 different groups of studies are referred to as traditional behavioral counseling ($n = 5$) and alternative behavioral counseling ($n = 7$), respectively.

Within each group of studies, the trials were further divided (ie, second category) according to whether behavioral counseling was delivered by CMS-defined primary care practitioners (working alone or with a trained interventionist) or by a trained interventionist alone, without personal collaboration with participants' primary care practitioners. Studies in the former category were more likely to meet current the CMS coverage requirements.

Results

Participant Characteristics

The 12 identified studies included a total of 3893 participants, with a range of 50 to 665 persons per study.¹⁶⁻²⁷ Across trials, mean baseline BMIs ranged from 32.0 to 38.5 and ages from 49.4 to 55.7 years. The percentage of women ranged from 46.5% to 100% (Table 1 and Table 2).

Traditional Behavioral Counseling

Primary Care Practitioners and Trained Interventionists

Three studies assessed behavioral counseling delivered in person by CMS-defined primary care practitioners, working alone or with trained interventionists.¹⁷⁻¹⁹ Kumanyika et al¹⁷ compared participants randomly assigned either to basic lifestyle intervention (ie, primary care practitioner visits every 4 months) or to the basic plus intervention, which included the practitioner meetings plus monthly 10- to 15-minute individual sessions with a trained interventionist, typically a medical assistant, who delivered counseling following a modified version of the Diabetes Prevention Program⁹ (Table 1). At month 12, mean weight loss in the basic intervention was 0.6 kg and was 1.6 kg in the basic plus group ($P = .15$). Significantly more participants in the latter group lost at least 5% of baseline weight (10.2% vs 22.5%, $P = .02$).

Tsai et al¹⁸ randomly allocated participants to usual care, consisting of quarterly medical visits with a primary care practitioner, or to brief counseling, which included visiting their practitioner plus attending 8 brief individual counseling sessions with trained interventionist (ie, medical assistant) during the first 6 months. At 6 months, those in the brief counseling lost 4.4 kg with 47.8% losing 5% or more of their baseline weight, whereas those in the usual care group lost a mean of 0.9 kg with none losing 5% or more of their baseline weight ($P < .001$ for both outcomes). Neither mean nor categorical weight losses differed significantly at month 12 after a no-treatment follow-up period. Building on the prior study, Wadden et al¹⁹ compared 3 groups: usual care, which involved quarterly primary care practitioner visits; a brief lifestyle counseling intervention, consisting of practitioner visits plus brief monthly individual sessions with a trained medical assistant interventionist; and an enhanced brief lifestyle counseling intervention, which we did not include in our analysis because it included the option of taking weight loss medication. At month 6, participants in the usual care group lost a mean of 2.0 kg and the brief lifestyle counseling group lost a mean of 3.5 kg ($P < .05$). Weight losses at month 24 were 1.7 kg in the usual care group and 2.9 kg in the brief counseling group.

Summary

We found no trials in which a primary care practitioner alone or with a trained interventionist followed the CMS recommendations of providing intensive behavioral counseling of 14 sessions over 6 months. Trials by Tsai et al¹⁸ and Wadden et al¹⁹ both included a combination of 3 visits with the primary care practitioner and 8 counseling sessions with a trained interventionist over 6 months vs usual care of 3 primary care practitioner visits alone. The interventions produced mean weight losses of 4.4 kg in the study by Tsai et al and 3.5 kg in the study by Wadden et al. Both of these studies would have met the CMS's 3-kg criterion on average. Both studies used a modified version of the Diabetes Prevention Program protocol,⁹ included prescriptions for reduced calorie intake and 150 or more minutes a week of physical activity and instructions for monitoring these goals daily (Table 2). In another study, Kumanyika et al¹⁷ used a similar protocol but achieved a smaller mean weight loss, which may have been attributable, in part, to the study's inclusion of primarily black women, who typically lose less weight in the first year than non-Hispanic white women.^{49,50} All 3 studies found that quarterly or less frequent behavioral counseling by a primary care practitioner alone induced mean losses of only 0.6 to 1.7 kg in 6 to 24 months.¹⁷⁻¹⁹

Table 1. Participants in Traditional Behavioral Counseling: Mean Baseline Characteristics and Mean Changes in Weight at Month 6 and Follow-up

Source	Sample Characteristics ^a	Treatment Type	No. of Participants (n=3893)	No. of Treatment Sessions	Months of Follow-up	Weight Change (95% CI), kg		No. (%) of Participants	
						Month 6	Follow-up	≥5% Weight Loss at Follow-up	Attrition at Follow-up ^b
Primary care practitioners/ trained interventionists									
Kumanyika et al, ¹⁷ 2012	Age, 47.2 y; BMI, 37.2; Women, 84.3%; White, 18.0%; Black, 65.0%	Basic	137	3	12	NR	-0.6 (-1.4 to 0.2) ^c	10 (10.2) ^c	39 (28.5)
		Basic plus	124	15		NR	-1.6 (-2.8 to -0.4) ^c	20 (22.5) ^d	35 (28.2)
Tsai et al, ¹⁸ 2010	Age, 49.4 y; BMI, 36.5; Women, 88.0%; White, 20.0%; Black, 80.0%	Control	26	4	12	-0.9 (-2.1 to 0.3) ^c	-1.1 (-2.7 to 0.5) ^c	3 (12.0) ^c	1 (3.8)
		Brief counseling	24	12		-4.4 (-5.6 to -3.2) ^d	-2.3 (-4.1 to -0.5) ^c	4 (18.0) ^c	2 (8.3)
Wadden et al, ¹⁹ 2011 ^e	Age, 51.9 y; BMI, 38.7; Women, 79.7%; White, 59.8%; Black, 38.5%; ≥2 Metabolic syndrome conditions	Usual care	130	8	24	-2.0 (-3.0 to -1.0) ^c	-1.7 (-3.1 to -0.3) ^c	28 (21.5) ^c	20 (15.4)
		Brief lifestyle counseling	131	33		-3.5 (-4.5 to -2.5) ^d	-2.9 (-4.3 to -1.5) ^c	34 (26.0) ^c	19 (14.5)
Trained interventionists									
Appel et al, ²⁰ 2011	Age, 54.0 y; BMI, 36.6; Women, 63.6%; White, 56.1%; Black, 41.0%; ≥1 CVD risk factors	Usual care	138	2	24	-1.4 (-2.2 to -0.6) ^c	-0.8 (-2.0 to 0.4) ^c	24 (18.8) ^c	10 (7.2)
		Remote support	139	33		-6.1 (-7.1 to -5.1) ^d	-4.6 (-6.0 to -3.2) ^d	50 (38.2) ^d	8 (5.8)
		In-person support	138	57		-5.8 (-7.0 to -4.6) ^d	-5.1 (-6.7 to -3.5) ^d	55 (41.4) ^d	5 (3.6)
Ma et al, ²¹ 2013 Xiao et al, ⁴³ 2013	Age, 52.9 y; BMI, 32.0; Women, 46.5%; White, 78.0%; Asian/Pacific Islander, 17.0%; Prediabetes or metabolic syndrome	Usual care	81	0	24	-0.7 (-2.5 to 1.1) ^c	-2.4 (-4.2 to -0.6) ^c	17 (25.3) ^c	21 (25.9)
		Coach-led	79	12		-6.6 (-8.2 to -5.0) ^d	-5.4 (-7.2 to -3.6) ^d	39 (59.1) ^d	20 (25.3)
		Self-directed	81	1		-4.3 (-5.9 to -2.7) ^d	-4.5 (-6.3 to -2.7) ^d	26 (43.6) ^d	29 (35.8)

Abbreviations: BMI, body mass index; CVD, cardiovascular disease; CI, confidence interval; PI, Pacific Islander, TM-CD; transtheoretical model-chronic disease; NR, not reported.

^a Values shown for age and BMI, calculated as weight in kilograms divided by height in meters squared, are means.

^b Attrition is defined as the percentage of participants who did not contribute an in-person weight at the end of the study.

^c For each study, under "weight change," values within columns for each trial that are labeled with c and d, as with different letters represent a significant

difference of $P < .05$. For example, in the Tsai et al study, the mean 6-month weight loss: "-0.9 (-2.1 to 0.3)^c" for the control group differs significantly from the "-4.4 (-5.6 to -3.2)^d" loss for the brief counseling group.

^d Values with the same letter in the column for a single trial (c) are not significantly different. For example, the 12-month weight losses for the control and brief counseling group in the Tsai et al study are not significantly different. Within each study, all treatment groups had the same number of months of postbaseline follow-up.

^e Estimated mean.

Traditional Behavioral Counseling

Trained Interventionists

Two trials^{20,21} evaluated the efficacy of behavioral counseling delivered by trained interventionists who had limited or no direct collaboration with patients' primary care practitioners (Table 3). The studies differed in the frequency of intervention contact, as well as in the method of treatment delivery (ie, face to face vs remote delivery). Appel et al²⁰ included 3 interventions: control, remote support only, or in-person support. Participants in the remote-support only group initially were provided 12 brief weekly individual telephone sessions with trained interventionist, lifestyle coaches at a disease-management call center, followed by monthly calls through month 24, for a total of 33 calls. Those assigned to in-person support were offered 12 weekly group or individual meetings the first 3

months, delivered by trained interventionists at an academic medical center, followed by an additional 45 meetings (some by telephone if desired) through month 24 (Table 2). Both intervention groups had access to a web-based program that included a curriculum of behavioral change and encouraged self-monitoring of food intake and physical activity. At 6 months, the usual care group lost 0.4 kg with 14.2% losing at least 5% of their baseline weight; the remote-support group, 6.1 kg with 52.7% losing at least 5%; and the in-person support group, 5.8 kg with 46.0% losing at least 5% of their baseline weight ($P < .001$ for both interventions vs control for both outcomes). Weight losses were generally well maintained at month 24 (Table 1).

Ma et al²¹ randomly assigned participants to usual care; a coach-led version of the Diabetes Prevention Program,⁹ delivered

Table 2. Participants in Alternative Behavioral Counseling: Mean Baseline Characteristics and Mean Changes in Weight at Month 6 and Follow-up

Source	Sample Characteristics ^a	Treatment Type	No. of Participants (n=3893)	No. of Treatment Sessions	Months of Follow-up	Weight Change (95% CI), kg		No. (%) of Participants	
						Month 6	Follow-up	≥5% Weight Loss at Follow-up	Attrition at Follow-up ^b
Primary care practitioners/ trained interventionists									
Christian et al, ²² 2011 ^c	Age, 49.6 y; BMI, 34.3; Women, 68.4%; White, 50.6%; ≥2 Metabolic syndrome conditions	Control	139	1	12	NR	0.2 (−0.7 to 1.0) ^d	11 (8.5) ^d	9 (6.5)
		Intervention	140	2		NR	−1.5 (−2.5 to −0.5) ^e	35 (26.3) ^e	7 (5.0)
Trained interventionists									
Bennett et al, ²³ 2012	Age, 49.6 y; BMI, 37.0; Women, 68.5%; White, 3.6%; Black, 71.2%; Antihypertensive medication use	Usual care	185	0	24	−0.1 (−0.8 to 0.6) ^d	−0.5 (−1.3 to 0.3) ^d	36 (19.5) ^d	19 (10.3)
		Intervention	180	30		−1.3 (−2.1 to −0.5) ^d	−1.5 (−2.3 to −0.7) ^e	36 (20.0) ^d	31 (17.2)
de Vos et al, ²⁴ 2014 ^f	Age, 55.7 y; BMI, 32.4; Women, 100%; White, 92.6% Black, 0.6% South American, 1.1%; Asian, 1.1%; Other, 4.5%	Control	204	0	12	0.9 (0.3 to 1.5) ^d	0.6 (−0.2 to 1.4) ^d	20 (11.0) ^d	23(11.3)
		Intervention	203	26		−0.9 (−1.5 to 0.3) ^e	−0.6 (−1.4 to 0.2) ^e	35 (18.7) ^e	16 (7.9)
Greaves et al, ²⁵ 2008	Age, 53.9 y; weight, 93.0 kg; Women, 63.8%; race/ethnicity NR; without diabetes or heart disease	Control	69	0	6	−1.8 ^{d,g}	NR	5 (7.2) ^d	12 (17.4)
		Intervention	72	11		−0.3 ^{e,g}	NR	17 (23.6) ^e	14 (19.4)
Hardcastle et al, ²⁶ 2008	Age, 50.2 y; BMI, 33.7;	Minimal intervention	131	0	18	0.1 (−0.5 to 0.7) ^d	1.4 ^{d,g}	NR	38 (29.0)
Hardcastle et al, 2013 ⁴³	Sex, NR; Race/ethnicity, NR; ≥1 CVD risk factor	Motivational interviewing	203	5		−0.7 (−1.3 to −0.1) ^e	0.5 ^{d,g}	NR	78 (38.4)
Logue et al, ²⁷ 2005	Ages 40-69 y; BMI≥27 or WHR>0.95 cm, men WHR>0.8 cm Women, 68.5%; Race/ethnicity, NR	Augmented usual care	336	4	24	NR	−0.2 (−1.0 to 0.6) ^d	NR	70 (20.8)
		Transtheoretical model	329	28		NR	−0.4 (−1.2 to 0.4) ^d	NR	58 (17.6)
Ross et al, ¹⁶ 2012 ^h	Age, 51.8 y; BMI, 27-39; Women, 70.2%; Race/ethnicity, NR; sedentary; Abdominally obese	Usual care	241	0	24	−0.7 (−1.3 to −0.1) ^d	−0.6 (−1.4 to 0.2) ^d	NR	35 (14.5)
		Behavioral intervention	249	33		−2.4 (−3.0 to −1.8) ^e	−1.2 (−2.0 to −0.4) ^d	NR	59 (23.7)

Abbreviations: BMI, body mass index; CVD, cardiovascular disease; CI, confidence interval; PI, Pacific Islander; TM-CD, transtheoretical model-chronic disease; NR, not reported; WHR, waist-hip ratio.

^a Values shown for age and BMI, calculated as weight in kilograms divided by height in meters squared, are means.

^b Attrition is defined as the percentage of participants who did not contribute an in-person weight at the end of the study.

^c Estimated mean for BMI.

^d For each study, under “weight change,” values within columns for each trial that are labeled with *c* and *d*, as with different letters represent a significant difference of $P < .05$. For example, in the Tsai et al study, the mean 6-month weight loss: “−0.9 (−2.1 to 0.3)^c” for the control group differs significantly from the “−4.4 (−5.6 to −3.2)^d” loss for the brief counseling group.

^e Values with the same letter in the column for a single trial (*c*) are not significantly different. For example, the 12-month weight losses for the control and brief counseling group in the Tsai et al study are not significantly different. Within each study, all treatment groups had the same number of months of postbaseline follow-up.

^f Weights were measured at 30 months but are not included in this review because they were only provided in a Figure in the article.²⁴ In addition, the article reported on percentage of participants who lost at least 5 kg or at least 5% of baseline body weight.

^g Variance not reported.

^h Estimated mean for age.

Table 3. Description of Intervention Among Trials Assessing Traditional Behavioral Counseling

Source	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Practitioner	Components of Diet, Physical Activity, and Behavioral Therapy
Primary care practitioners/ trained interventionists				
Kumanyika et al, ¹⁷ 2012				
Basic	Every 4 mo with the PCP based on DPP materials Practitioners completed 3-h training	On-site visits	Brief counseling	Diet: 1200-1499 kcal/d with 30 g fat if weight <100 kg or 1500-1800 kcal/d with 40 g fat ≥100 kg; provided calorie counter. PA: weekly 150 min of moderate exercise, typically walking BT: Prescribed DPP behavior change program, including self-monitoring of diet and physical activity; Goal setting
Basic plus	Visits every 4 mo with PCP; 10-15 min monthly individual sessions with a lifestyle coach, usually an MA MAs completed 3-h training	On-site visits	Same as for basic	Diet: Same as for basic PA: Same as for basic BT: Same as for basic
Tsai et al, ¹⁸ 2010				
Control	Quarterly usual care meetings with PCP (weight management, ≈2-3 min) PCPs trained in use of weight loss handouts	On-site visits with physician	Regular medical care with weight management as part of visit PCPs reviewed weight loss handouts at quarterly visits	Diet: Standard advice to eat healthful diet; provided calorie counter and meal plans PA: standard advice to exercise more; provided pedometer BT: 1-2 page handouts from NIH Weight-Control Information Network, including healthful behaviors
Brief counseling	Quarterly usual care meetings with PCP (weight management, ≈2-3 min); 8 brief (10-15 min) individual meetings with MAs at wk 0, 2, 4, 8, 12, 16, 20, 24; MAs completed 3-h training	On-site visits, occasional telephone counseling by MAs for missed visits	Same as for Control group	Received same materials as control group Diet: 1200-1499 kcal/d (<250 lb) or 1500-1800 kcal/d (≥250 lb) PA: gradual increase to 175 min/wk, typically walking BT: prescribed DPP behavioral change program, including self-monitoring of diet and PA; handouts at each visit; weighed at each visit and reviewed food records with MA
Wadden et al, ¹⁹ 2011				
Usual care	Quarterly routine usual care visits with PCP (weight management, ≈5-7 min) PCP completed 6-8 h training at baseline	On-site	Discussed handouts; reviewed participants' weight change	Diet: 1200-1500 kcal/d (<113.4 kg) or 1500-1800 kcal/d (≥113.4 kg); received calorie-counting book and pedometer PA: gradual increase to 180 min/wk, typically walking BT: handouts from NHLBI's "Aim for a Healthy Weight"
Brief lifestyle counseling	Quarterly usual care visits with PCP (weight management, ≈5-7 min); monthly individual meetings (≈10-15 min) with a lifestyle coach, usually an MA, with 2 visits in mo 1; MAs completed 8-h training at baseline and received monthly group supervision thereafter	On-site, individual visits with PCP and MA; In year 2, counseling visits could be completed every other month by telephone	Same as for usual care	Diet: Same prescription and materials as usual care; PA: Same PA prescription as usual care; BT: Prescribed DPP behavioral change program, including self-monitoring of diet and PA, handouts at each visit, weighed at each visit, and reviewed food records with MA

(continued)

Table 3. Description of Intervention Among Trials Assessing Traditional Behavioral Counseling (continued)

Source	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Practitioner	Components of Diet, Physical Activity, and Behavioral Therapy
Trained Interventionists				
Appel et al, ²⁰ 2011				
Control	1 Session with weight loss coach (a university employee) at randomization and, if desired, 1 after final data collection visit	On-site	None	Received brochures and a list of recommended websites promoting weight loss
Remote support only	20-Min telephone calls weekly for 12 wk, then monthly Coaches were trained employees from a disease management company	Telephone and web-based counseling	Reviewed progress reports at routine office visits; encouraged participation and engagement in intervention	Diet: DASH diet with 1200-2200 kcal/d PA: Increase to 180 min/wk of moderate intensity BT: Self-monitoring of diet and PA; problem solving and social support; study website; motivational interviewing elements
In-person support	Combination of 9 group (90 min) and 3 individual (20 min) contacts for 12 wks, then 2-3 such contacts per mo Coaches were trained university employees.	Off-site counseling at academic medical center; also telephone and web-based support	Same as for remote support only	Diet: same as for remote support only PA: same as for remote support only BT: same as for remote support only
Ma et al, ²¹ 2013 Xiao et al, ⁴³ 2013				
Usual care	None	None	None	No materials provided.
Coach-led	12 In-person, group sessions (90-120 min) in mo 1-3; contact every 2-4 wk by e-mail or telephone in mo 4-15 Registered dietitian (certified to deliver the DPP) and a fitness instructor jointly taught all classes	On-site, group classes during mo 1-3; e-mail or telephone contacts thereafter	None	Diet: low-fat diet to induce 500-1000 kcal/d energy deficit PA: ≥150 min of moderate PA/wk; 30-45 min of supervised PA at weekly class during mo 1-3 BT: DPP Group Lifestyle Balance program; AHA Heart 360 website for physical activity and goal setting; weight scale and pedometer for self-monitoring and goal setting
Self-directed DVD	Orientation class in-person plus instruction to watch 12 DPP lifestyle sessions (90-120 min) via DVD at home during mo 1-3; lifestyle coach sent standardized bi-weekly reminder messages during mo 1-15	On-site orientation session; intervention delivered via home-based DVD; e-mail messages (standardized) during maintenance	None	Diet, PA, and BT: DPP on DVD; use of AHA Heart 360 website for physical activity and goal setting; given weight scale and pedometer for self-monitoring and goal setting

Abbreviations: AHA, American Heart Association; BT, behavior therapy; DASH, Dietary Approaches to Stop Hypertension; DPP, Diabetes Prevention Program;

MA, medical assistant; PA, physical activity; PCP, primary care provider; NHLBI, National Heart, Lung, and Blood Institute.

in weekly group sessions for the trial's first 3 months by a trained registered dietitian and a fitness instructor followed by monthly or twice monthly telephone or e-mail support; or a self-directed version of the same program in which participants were given 12 recorded DVD sessions of the Diabetes Prevention Program. Mean weight losses at month 6 were 0.7 kg with 8.2% losing at least 5% of their baseline weight in the usual care group; 6.6 kg with 65% losing at least 5% of their baseline weight in the coach-led group; and 4.3 kg with 44.5% losing at least 5% of their baseline weight in the self-directed group ($P < .001$ for both intervention groups vs usual care for both outcomes). Similar weight losses were maintained at month 24.⁴³

Summary

Both Appel et al²⁰ and Ma et al²¹ included trained interventionists to provide high-intensity behavioral counseling during the first 6 months, either in person or by telephone. Both interventions appeared to meet the 14 treatment contacts over 6 months as proposed by the CMS and the obesity guidelines,⁷ were delivered following well-established behavioral protocols (eg, Diabetes Prevention Program), and produced mean 6-month weight losses of at least 5 kg that were generally well maintained at month 24. In the Appel et al study, the potential contribution of the web-based program to the favorable results cannot be determined. In both trials, the trained interventionists worked largely independently

of the patients' primary care practitioners and were not housed, at least in the Appel study,²⁰ in the same place as the practitioners. These practices likely would prevent coverage of the services under current CMS regulations.

Alternative Behavioral Counseling

Primary Care Practitioners

The 7 trials^{16,22-27} that follow did not prescribe both a reduced calorie diet of at least 500 kcal/d and physical activity of at least 150 minutes a week.⁶ In 6^{16,22,24-27} of the 7 studies, behavioral counseling was guided principally by motivational interviewing⁴⁶ or stages of change.⁴⁷

A trial by Christian et al²² was the only 1 of the 7 in which primary care practitioners delivered behavioral counseling. The study allocated participants to usual medical care or to a computer-based assessment that obtained diet and physical activity histories, assessed patients' motivations for weight loss, and provided a tailored report for patients that was reviewed during 2 counseling visits (Table 4). At month 12, the control group gained a mean of 0.2 kg with 8.5% losing at least 5% of their baseline weight, and the intervention group lost a mean of 1.5 kg, with 26.3% losing at least 5% of their baseline weight ($P = .002$ for weight loss; $P < .01$ for $\geq 5\%$ of baseline weight loss; Table 4).

Alternative Behavioral Counseling

Trained Interventionists

Bennett et al²³ assigned participants to usual care or a behavioral intervention that was delivered by community health educators (who were trained interventionists) using brief monthly telephone calls the first year and bimonthly calls in the second year. Participants were encouraged to monitor their progress using a study website or a telephone-based interactive voice response system. At month 6, usual care participants gained an average of 0.1 kg compared with a loss of 1.3 kg in the intervention ($P < .05$). Similar weight changes were observed at month 24 (Table 1). de Vos et al²⁴ compared participants who were assigned to a control group or to a tailor-made intervention that provided up to 4 hours of individual counseling with a registered dietitian, trained in motivational interviewing, and up to twenty 1-hour group exercise classes, supervised by a physical therapist. Patients were referred to these interventionists in the community. At month 12, the control group gained an average of 0.6 kg compared with a loss of 0.6 kg in the intervention ($P = .02$), with significantly more participants in the latter group losing at least 5% of their baseline weight (11.0% vs 18.7%, $P < .03$).

Greaves et al²⁵ allocated participants to a control group or a motivational-interviewing-based intervention that provided up to 11 individual counseling sessions, delivered by a combination of in-person and telephone contacts. Trained interventionists included a registered nurse and graduate students in exercise science. At month 6, mean weight loss in the control group was 1.8 kg and 0.3 kg in the intervention group ($P < .05$ in favor of the control group). However, more intervention than control participants lost at least 5% of their baseline weight (7.2% vs 23.6%, $P < .05$). Hardcastle et al²⁶ compared usual care with a motivational-interviewing-based intervention that offered up to 5 in-person, individual sessions with a trained exercise specialist

or registered dietitian. At month 6, usual-care participants gained an average of 0.1 kg compared with a loss of 0.7 kg in the intervention group ($P < .05$). At month 18, after 12 months without treatment, participants exceeded their baseline weight by 1.4 kg in the usual care group and 0.5 kg in the intervention group ($P > .05$).²⁶

Logue et al²⁷ compared augmented usual care (ie, control), which included 4 in-person semiannual meetings over 24 months from a trained registered dietitian, with a more intensive program based on a transtheoretical model-chronic disease approach. The latter intervention included 4 sessions with a dietitian plus monthly 15-minute telephone calls with a trained weight loss advisor, under supervision of a psychologist. The advisor reviewed participants' stage of change with each of 5 targeted behaviors for the month. At month 24, participants in the control group lost a mean of 0.2 kg, and the intervention group lost a mean of 0.4 kg ($P = .50$).

Ross et al¹⁶ randomly assigned participants to usual care or a motivational-interviewing-based intervention that included fifteen 1-hour, in-person individual sessions in the first 6 months, 6 additional sessions from months 7 through 12, and variable contact from months 13 through 24, based on participant needs. The intervention, delivered by trained exercise specialists, focused principally on increasing energy expenditure rather than restricting intake. Mean losses at month 6 were 0.7 kg in the control group and 2.4 kg in the intervention group ($P < .002$) and at month 24 were 0.6 kg and 1.2 kg, respectively ($P = .33$).

Summary

None of the trials of alternative behavioral counseling achieved a mean 6-month weight loss of at least 3 kg, despite the provision during this time in 1 study¹⁶ of 15 in-person, 1-hour individual sessions. The provision of low-intensity (<monthly) counseling^{2,3} in 2 trials^{22,26} and approximately moderate intensity (monthly) in a third²⁷ may have contributed to the small mean losses observed in these studies.

Intervention Effects and Relation of Treatment Intensity to Weight Loss

Across all 12 studies, the difference in weight loss between treatment and control groups (ie, treatment – control) ranged from –1.5 kg (ie, 1.5 kg greater weight loss in the control group) to 4.3 kg. The weight losses relative to baseline in each group of each trial are presented in the Figure.

Four studies of traditional behavioral counseling prescribed participants an energy-restricted diet and specific physical activity goals—as recommended by the obesity guidelines⁷—were delivered using person-to-person counseling (ie, face-to-face or by telephone), and reported weight losses at month 6.¹⁸⁻²¹ These trials are the most relevant for evaluating the intensity of treatment recommended by the CMS and by the obesity guidelines during the first 6 months. The provision of more counseling sessions appeared to be associated with greater weight loss, ranging from 3.5 kg with 8 sessions¹⁹ to 6.6 kg with 15 contacts.²¹ The alternative behavioral counseling trials that provided 6-month data did not reveal as clear a dose-response relationship.

Table 4. Description of Intervention Among Trials Assessing Alternative Behavioral Counseling

Source	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Practitioner	Components of Diet, Physical Activity, and Behavioral Therapy
Primary care practitioners/ trained interventionists				
Christian et al, ²² 2011				
Control	Clinic staff provided education packet prior to baseline visit	Written materials	None	Packet of health education materials at baseline visit addressing diabetes, diet, and exercise
Intervention	Twice-y counseling with PCP during routine visits; clinic staff administered 1 computer-based assessment session prior to baseline visit and 1 session at 6 mo; PCP completed 3-h training in motivational interviewing	On-site; computer assessment, physician feedback	Received computer-generated report with summary of each patient's assessment; Patients were provided recommendations for behavioral change following stages of change and motivational interviewing	Diet, PA, and BT: individualized, computer-generated report addressing participant-identified barriers to making lifestyle changes; motivational interviewing to reduce calorie intake and increase PA; increase self-efficacy to make lifestyle changes; 30-page guide providing general supplemental information on diabetes prevention and achieving dietary and physical activity goals
Trained interventionists				
Bennett et al, ²³ 2012				
Control	Initial visit with program staff	Self-help booklet.	None	NHLBI's "Aim for a Healthy Weight" booklet provided
Intervention	12 monthly and 6 bimonthly calls (15-20 min) 12 Optional, monthly group sessions 1 Brief standardized message from PCP Trained community health educators	Telephone, study website, interactive voice response system	Delivered at least 1 message about importance of intervention; electronic signature included on behavior change prescription	Diet: tailored behavioral change goals to create an energy deficit PA: walk 10 000 steps/d, 20 min/d brisk walking, strength training 2 d/wk BT: goal prescriptions, self-monitoring, tailored skills training, problem solving, motivational interviewing elements
de Vos et al, ²⁴ 2014				
Control	None	None	None	No materials provided
Intervention	Referral to registered dietitian for up to 4 h of counseling in year 1; up to 20, 1-h group exercise classes with physical therapist in first 6 mo; Dietitians trained in motivational interviewing	Off-site individualized meetings and physical activity courses	None	Diet: tailored advice for a low-fat or low-calorie diet; PA: increased PA, PA classes offered; BT: motivational interviewing, goal setting
Greaves et al, ²⁵ 2008				
Control	Written guidelines at study outset; 2 individual sessions with counselors at study end; clinic staff	Received standardized information packet promoting diet and physical activity	None	Diet, PA, and BT: British Heart Foundation health-promotion materials; National Health Service Smoking Cessation Service Green Book; locally produced information on walk-and-talk activities
Intervention	≤11 individual visits (≈30 min) in-person or by telephone for 6 mo Health promotion counselors, including 1 nurse and 3 postgraduate students, completed 2-d course in motivational interviewing	On-site, individual consultations and telephone contacts	None	Diet: reduce calories, fat, and portion size; increase fiber PA: increase overall PA within existing lifestyle BT: motivational interviewing, relapse prevention, self-monitoring
Hardcastle et al, ²⁶ 2008; Hardcastle et al, ⁴⁴ 2013				
Minimal intervention	Clinic staff provided written materials	Written materials	None	Diet: written materials encouraging increased fruit and vegetable intake and reduced fat PA: written materials encouraging 30 min/d of PA BT: none
Motivational interviewing	Consultation with MA specialist or registered dietitian with opportunity to meet >4 times (20-30 min) following 6 mo MA specialist and registered dietitian participated in two 4-h training sessions focused on MI	On-site, individual consultation	None	Diet: motivational interviewing to improve diet PA: motivational interviewing to increase PA; BT: motivational interviewing integrated with a stage-matched approach; agenda setting; exploration of the pros and cons, importance and confidence rulers, strengthening commitment to change and negotiating a change plan

(continued)

Table 4. Description of Intervention Among Trials Assessing Alternative Behavioral Counseling (continued)

Source	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Practitioner	Components of Diet, Physical Activity, and Behavioral Therapy
Logue et al, ²⁷ 2005				
Augmented usual care	Semiannual meeting with registered dietitian for 10-min sessions based on the USDA Food Guide Pyramid or a Soul Food Guide Pyramid	On-site, individual meeting	None	Diet: recommendations based on dietary recalls and standard dietetic practice (Dietary Guidelines for America) PA: recommendations based on exercise recalls BT: Counseling based on either USDA Food Guide Pyramid (Dietary Guidelines for Americans) or a Soul Food Guide Pyramid; behavioral self-monitoring
Transtheoretical model	Same dietitian visits as usual care; monthly 15-min telephone calls with a weight-loss advisor, conducted SOC assessments for 5 target behaviors every month; mailed SOC and target behavior-matched workbooks Weight loss advisor trained in SOC, supervised by psychologist	On-site, individual meeting, mailings, telephone support	Discussion with patient during routine visits, facilitated by SOC pocket card; received periodic reports summarizing patient progress on target behaviors	Diet: counseling based on standard dietetic practice (Dietary Guidelines for America) PA: counseling to increase physical activity BT: SOC assessment every 2 mo for target behaviors; stage- and behavior-matched workbooks; assessment for depression, anxiety, and binge eating disorder every 6 mo
Ross et al, ¹⁶ 2012				
Usual care	Routine visit with PCP	Usually scheduled visits	Provide general advice during routine office visit (typically once a year)	Diet, PA, and BT: advice on benefits of PA for obesity reduction; at end of intervention, patients invited to attend workshop on strategies to integrate PA and healthful eating into lifestyle
Behavioral intervention	Health educators (in kinesiology) provided 15, 1-h sessions during mo 1-6; monthly, 30-60 min sessions during mo 7-24, based on participants' progress	On-site, individual, tailored counseling	None	Diet: promote daily consumption of whole-grain foods, fruits, vegetables, legumes, and low-fat dairy products PA: 45-60 min/d of moderate PA BT: motivational interviewing (mo 1-6); individually tailored counseling based on transtheoretical model and social cognitive theory; goal setting

Abbreviations: BT, behavior therapy; DASH, Dietary Approaches to Stop Hypertension; MA, medical assistant; MI, myocardial infarction; PA, physical

activity; PCP, primary care provider; SOC, stage of change; NHLBI, National Heart, Lung, and Blood Institute; USDA, US Department of Agriculture.

Discussion

This review found no studies that evaluated the efficacy of intensive behavioral weight loss counseling (14 in-person sessions over 6 months) delivered by physicians and other CMS-eligible primary care practitioners. Three trials¹⁷⁻¹⁹ provided approximately monthly brief counseling visits, which were delivered by trained medical assistants in collaboration with primary care practitioners. Mean weight losses at 6 months ranged from 3.5 kg to 4.4 kg,^{18,19} with 48% of participants in 1 study losing at least 5% of baseline weight.¹⁸ Mean weight losses in these 2 trials^{18,19} declined during the follow-up period, and smaller 12- to 24-month losses, from -0.6 kg to -1.7 kg, were observed when primary care practitioners, working alone, provided quarterly or less frequent weight loss counseling sessions.¹⁷⁻¹⁹

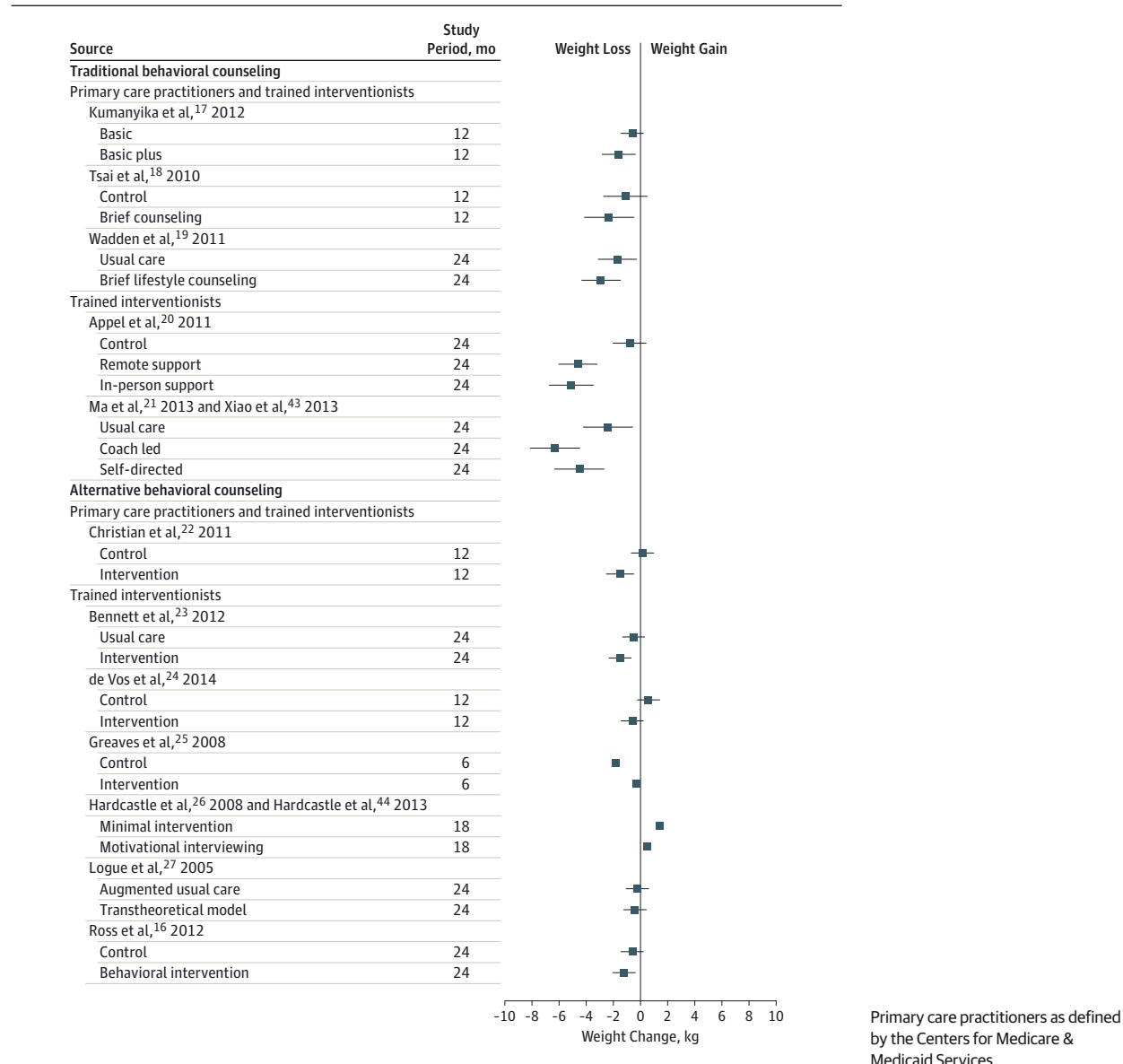
Two trials strongly supported the frequency of intervention contact recommended during the first 6 months by both the CMS and the obesity guidelines.⁷ Ma et al²¹ found that 12 weekly (face-to-face) group lifestyle modification sessions, followed by telephone or e-mail contact every 2 to 4 weeks, produced a 6-month loss of 6.6 kg, with 65% of participants losing at least 5% of baseline weight. Appel et al²⁰ observed that 15 brief telephone sessions (with trained interventionists at a call center) yielded a loss of 6.1 kg at 6 months, with 52.7% of participants losing at least 5% of baseline weight, out-

comes comparable with those produced by a more intensive face-to-face intervention. The obesity guidelines⁶ preferentially recommend face-to-face counseling, given its large evidence base of support.⁶ However, a growing literature suggests that telephone-delivered counseling is generally as effective as traditional face-to-face contact,⁵¹⁻⁵³ potentially is more convenient and less costly for patients, and can reach more individuals in underserved areas.⁵¹

Results of this review also confirm the prescription of a comprehensive lifestyle intervention, recommended by the obesity guidelines, which includes a reduced calorie diet (eg, ≥ 500 kcal/d deficit), at least 150 minutes a week of physical activity (eg, brisk walking), and behavioral strategies to reach these targets.⁷⁻¹⁰ Smaller weight losses generally were observed in trials^{16,22-27} that did not provide specific recommendations for both reducing energy intake and increasing expenditure, as well as offer behavioral strategies to achieve these goals. Although alternative counseling approaches, such as motivational interviewing, have been shown to enhance weight loss when added to traditional behavioral counseling,⁴⁸ results of this review underscore the importance of providing patients with specific goals for energy restriction and expenditure.

There is a need to identify the professional qualifications and training required to provide effective behavioral weight loss counseling in primary care and other settings. Controlled trials are needed

Figure. Mean Weight Losses From Baseline to Follow-up for Intervention and Control Groups in Each Trial



to compare the efficacy and costs of having behavioral counseling delivered by primary care practitioners, other primary care staff (eg, medical assistants, nurses), registered dietitians, other health professionals (eg, health counselors, exercise specialists, psychologists), and potentially commercial programs that use successful evidenced-based strategies, as demonstrated by randomized controlled trials.^{52,54} The obesity guidelines⁷ observed that behavioral weight loss counseling could be provided by trained interventionists, following structured protocols, from a variety of educational backgrounds. A recent initiative from the Patient Centered Outcomes Research Institute⁵⁵ should advance practice in this area by assessing different methods, including community-based programs, of providing behavioral counseling to overweight and obese patients encountered in primary care. This research likely will include the use of web-based or smartphone-based applications,^{56,57} as well as cellular-connected smart scales,⁵⁸ data from which could be potentially integrated into patients' electronic health records.^{4,8}

Although this review found limited data to support the delivery of intensive behavioral weight loss counseling by physicians and other primary care practitioners, these health professionals are likely to continue to play a critical role in diagnosing obesity; evaluating its causes, including medications associated with weight gain; assessing and treating weight-related comorbid conditions; and monitoring changes in health that occur with weight loss, including the need for medication adjustment. Primary care practitioners can be trained to provide intensive behavioral counseling, like the other trained interventionists described in this review. However, ever increasing demands on practitioners' time may favor their referring patients for behavioral counseling, an option suggested by the US Preventive Services Task Force.^{2,3} This review, along with the obesity guidelines,⁷ has identified options for referring patients to trained interventionists who work in primary care, as well as a variety of other settings.

ARTICLE INFORMATION

Author Contributions: Drs Wadden, Butryn, and Tsai had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Wadden, Tsai.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: All authors.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Butryn, Tsai.

Obtained funding: Wadden.

Administrative, technical, or material support: Hong. **Study supervision:** Wadden.

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Submissions: We encourage authors to submit papers for consideration as a Review. Please contact Mary McGrae McDermott, MD, at mdm608@northwestern.edu.

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