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Behavioral Treatment of Obesity in Patients Encountered in Primary Care Settings: A Systematic Review

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Abstract

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

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

EVIDENCE REVIEW—We searched PubMed, CINAHL, and EMBASE for randomized controlled trials (January 1980–June 2014) which: recruited overweight/obese patients from primary care; provided behavioral counseling (i.e., diet, exercise, and behavior therapy) for 3 months, with 6 months post-randomization follow-up; included 15 participants/treatment group and objectively measured weights; and had a comparator, an intention-to-treat analysis, and attrition <30% at 1 year or <40% at longer follow-up.

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FINDINGS—Review of 3,304 abstracts yielded 12 trials (with 3,893 total participants) that met inclusion/exclusion criteria and pre-specified quality ratings. No studies were found in which PCPs delivered counseling following CMS guidelines (14 sessions in 6 months). Mean 6-month weight changes (relative to baseline) in the intervention group ranged from -0.3 to -6.6 kg, with corresponding values of +0.9 to -2.0 kg in control group. Weight loss in both groups generally declined with longer follow-up (12–24 months). Interventions that prescribed both reduced energy intake (e.g., 500 kcal/day deficit) and increased physical activity (e.g., 150 minutes/week of walking), with traditional behavior therapy, generally produced larger weight loss than interventions without all three specific components. In the former trials, more treatment sessions, delivered in person or by phone by trained interventionists, were associated with greater mean weight loss and likelihood of losing 5% of baseline weight.

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

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 again in 2011) the U.S. 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 and Medicaid Services approved the provision of intensive behavioral counseling (~14 face-to-face visits in 6 months) to obese beneficiaries in primary care practice, when delivered by physicians and other select practitioners (Box 1).^{4,5}

Box 1

Centers for Medicare and Medicaid Services' Requirements for Intensive Behavioral Therapy for Obesity

Treatment Components

- Measurement of BMI
- 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 behavior change advice

Frequency of Contact

A maximum of 22 sessions in a 12-month period, as follows:

- One face-to-face visit each week for the first month
- One face-to-face visit every other week for months 2–6
- One face-to-face visit every month for months 7–12, if weight loss goal is met

Eligible Providers

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

Qualified non-physician primary care practitioner:^a 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 7–12, weight loss of 3 kg or greater must be achieved during the first 6 months of therapy

Note: USPSTF = U.S. Preventive Services Task Force

^aServices 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 (see reference 5).

The frequency of behavioral counseling prescribed by CMS is generally consistent with conclusions of a review commissioned by the U.S. Preventive Services Task Force⁶ and with recommendations of the recently published Obesity Guidelines.⁷ The latter guidelines, based on findings of a systematic review, advise primary care practitioners to prescribe overweight/obese individuals a high intensity (i.e., 14 sessions in 6 months) comprehensive lifestyle intervention, delivered by a trained interventionist.⁶ 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.⁶ Comprehensive behavioral interventions, as defined by the Obesity Guidelines, include the prescription of: 1) a reduced calorie diet (typically to induce an energy deficit 500 kcal/d); 2) 150 min/week of aerobic physical activity (typically walking); and 3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations.^{6,8}

The present systematic review examines the evidence to support the behavioral treatment of obesity in patients encountered in primary care settings. The review summarizes the results of randomized controlled trials conducted with patients recruited from primary care, in which CMS-defined primary care practitioners, working alone or with trained interventionists, delivered behavioral weight loss counseling. The review also examines randomized trials of patients recruited from primary care in which trained interventionists (who were not primary care practitioners) delivered behavioral counseling, including by telephone and Internet.⁸ These latter interventionists are not currently recognized by CMS as independent providers of behavioral counseling, although they may potentially provide services incident to eligible practitioners (see Box 1).⁵ This review does not include trials such as the Diabetes Prevention Program⁹ or Look AHEAD study¹⁰ in which behavioral counseling was provided to highly-selected volunteers, recruited outside of primary care.

METHODS

This review used methods similar to those employed in developing the recent Obesity Guidelines⁶ (which updated those from 1998¹¹). The present authors used the PICOTS¹² (i.e., population, interventions, comparators, outcomes, timing, setting) approach to establish inclusion/exclusion criteria and searched PubMed, CINAHL, and EMBASE (January 1, 1980–June 30, 2014) using terms including "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) overweight or obese adults (i.e., body mass index [BMI] 25 kg/m²) recruited from primary care settings; 2) participants received behavioral weight loss counseling (also referred to as lifestyle intervention) consisting of diet, physical activity, and behavioral strategies (all three components); 6 3) behavioral counseling 3 months, with 6 months post-randomization follow-up; 4) intervention delivered by CMS-defined primary care practitioners, working alone or with trained interventionists, or by trained interventionists alone who provided behavioral counseling in person or remotely (e.g., telephone); 5) a comparator intervention was included; 6) outcomes included objectively measured change in weight (reported in kg, BMI units, or % change); and 7) randomized sample size 15 per treatment group. (This review did not include trials of weight gain prevention or pharmacologic agents.) The search resulted in 3,304 articles (Figure 1). It was supplemented by examination of prior reviews $^{7,13-15}$ and a search of Cochrane Central Registry of Controlled Trials.

Titles and abstracts of all papers were reviewed independently by two authors to exclude non-relevant articles. The full text of each remaining article was similarly reviewed to determine if it met inclusion/exclusion criteria. As shown in Figure 1, 27 studies^{16–42} (3 of which published additional follow-up data^{43–45}) met all criteria and were subjected to quality rating (i.e., *poor, fair*, or *good*) by two authors who used criteria similar to those employed by the Obesity Guidelines.⁶ Fifteen studies were excluded from further consideration because they were rated *poor* or had one or more fatal flaws: 1) high attrition (average 30% at 6 or 12 months or 40% thereafter);^{29,30,33,35,37–39,41,42} 2) differential attrition between treatment groups >15% at any time;^{31,34,36,40} or 3) failure to report results of an intention-to-treat analysis (unless attrition was <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 rated *good*, were divided into two categories following preliminary examination. The first category was whether the weight loss program prescribed all three components of a comprehensive lifestyle intervention as operationalized by the Obesity Guidelines.⁶ Seven trials, for example, encouraged participants to change components of their diet but did not specifically prescribe a reduced-calorie diet (i.e., deficit

500 kcal/d).^{21–27} Six^{21,23–27} of these seven 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 (i.e., 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 two interventions.⁴⁸ (Two studies in this review used elements of motivational interviewing within a primarily behavioral approach.^{19,22}) 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, the two 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 (i.e., 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 CMS coverage requirements.

RESULTS

Participant Characteristics

The 12 identified studies included a total of 3,893 participants, with a range of 50–665 persons per study.^{16–27} Across trials, mean baseline BMIs ranged from 32.0 to 38.5 kg/m² and ages from 49.4 to 55.7 years. The percentage of female participants ranged from 46.5% to 100% (see Table 1).

Traditional Behavioral Counseling: Primary Care Practitioners/Trained Interventionists

Three studies assessed behavioral counseling delivered in person by CMS-defined primary care practitioners (PCPs), working alone or with trained interventionists.^{16–18} Kumanyika et al¹⁶ compared participants randomly assigned to "Basic" lifestyle intervention (i.e., PCP visits every four months) or "Basic Plus," which included the PCP meetings plus monthly brief (10–15 minute) individual sessions with a trained interventionist (typically a medical assistant) who delivered counseling following a modified version of the Diabetes Prevention Program⁹ (see Table 2 for details). At month 12, mean weight losses in Basic and Basic Plus were 0.6 and 1.6 kg, respectively (P=.15) (Table 1). Significantly more participants in the latter group lost 5% of baseline weight (10.2% vs 22.5%, P=.022).

Tsai et al¹⁷ randomly allocated participants to Usual Care (quarterly medical visits with a PCP) or Brief Counseling, which included PCP visits plus 8 brief individual counseling visits with a trained interventionist (i.e., medical assistant) during the first 6 months. Brief Counseling produced significantly greater mean weight loss than Usual Care at month 6 (4.4 vs 0.9 kg), with 47.8% and 0% of participants, respectively, losing 5% of baseline weight (P<.0001 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 al¹⁸ compared Usual Care (i.e., quarterly PCP visits) to Brief Lifestyle Counseling, consisting of PCP visits plus brief monthly individual sessions with a trained interventionist (medical assistant). (The trial included a third group, Enhanced Brief Lifestyle Counseling, which is not described here because it included pharmacotherapy as a

treatment option.) At month 6, participants in Usual Care and Brief Lifestyle Counseling lost a mean of 2.0 and 3.5 kg, respectively (P<.05). Weight losses at month 24 (1.7 and 2.9 kg, respectively) did not differ significantly.

Summary—No studies were found in which PCPs, working alone or with trained interventionists, provided intensive behavioral counseling as recommended by CMS (i.e., 14 sessions in 6 months). Trials by Tsai et al¹⁷ and Wadden et al¹⁸ both provided 3 PCP visits combined with 8 counseling sessions with a trained interventionist during the first 6 months. The interventions produced mean weight losses of 4.4 and 3.5 kg, respectively, at this time, which would meet 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 minutes/week of activity, and instructed participants to monitor these goals daily (Table 2). Kumanyika et al¹⁶ 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 African-American women, who typically lose less weight in the first year than non-Hispanic white females.^{49–50} All three studies found that quarterly or less frequent behavioral counseling by PCPs alone induced mean losses of only 0.6 to 1.7 kg in 6 to 24 months.^{16–18}

Traditional Behavioral Counseling: Trained Interventionists

In two trials, ^{19,20} behavioral counseling was delivered by trained interventionists who (with one exception) were not employees of the primary care practices from which participants were recruited and who had limited or no direct collaboration with patients' PCPs (Table 2). The studies differed in the frequency of intervention contact, as well as in the method of treatment delivery (i.e., face-to-face vs. remote delivery). Appel et al¹⁹ compared three interventions: Control; Remote-Support Only; or In-Person Support. Participants in Remote-Support Only initially were provided 12 brief weekly individual telephone sessions with trained interventionists (lifestyle coaches at a disease-management call center), followed by monthly calls through month 24 (i.e., 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 off-site (at an academic medical center) followed by an additional 45 meetings (some potentially by phone) through month 24 (Table 2). Participants in the two intervention groups also were provided a web-based program that included a curriculum of behavior change and encouraged self-monitoring of food intake and physical activity. Mean weight losses at month 6 were 0.4, 6.1, and 5.8 kg, respectively, with 14.2%, 52.7%, and 46.0% of participants, respectively, losing 5% (P<.001 for both interventions versus control for both outcomes). Weight losses were generally well maintained at month 24 (Table 1).

Ma et al²⁰ randomly assigned participants to: Usual Care; a Coach-Led version of the Diabetes Prevention Program,⁹ delivered in weekly group sessions the first 3 months by a trained registered dietitian and a fitness instructor (with monthly to twice monthly phone or e-mail support thereafter); or a Self-Directed version of the same program in which participants were given 12 DVD sessions of the Diabetes Prevention Program. Mean weight losses at month 6 were 0.7, 6.6, and 4.3 kg, respectively, with 8.2%, 65.0%, and 44.5% of participants, respectively, losing 5% of baseline weight (P<.001 for both intervention

groups versus Usual Care for both outcomes). Similar weight losses were maintained at month $24.^{43}$

Summary—Both Appel et al¹⁹ and Ma et al^{20,43} employed 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 (in 6 months) proposed by CMS (and the Obesity Guidelines⁶), were delivered following well-established behavioral protocols (e.g., Diabetes Prevention Program), and produced mean 6-month weight losses >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' PCPs and were not, at least in one study,¹⁹ at the same physical location as PCPs. These practices likely would prevent coverage of the services under current CMS regulations.

Alternative Behavioral Counseling: Primary Care Practitioners/Trained Interventionists

The seven trials^{21–27} that follow did not prescribe both a reduced calorie diet (500 kcal/d deficit) and physical activity 150 minutes/week.⁶ In addition, in six^{21,23–27} of seven studies, behavioral counseling was guided principally by motivational interviewing⁴⁶ or stages of change.⁴⁷

A trial by Christian et al²¹ was the only one of the seven in which PCPs 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 and PCPs to review during two counseling visits (Table 2). At month 12, the control group gained a mean of 0.2 kg and the intervention group lost 1.5 kg (P=.002), with 8.5% and 26.3% of participants, respectively, losing 5% (P<.01).

Alternative Behavioral Counseling: Trained Interventionists

Bennett et al²² assigned participants to usual care or a behavioral intervention that was delivered by trained interventionists (i.e., community health educators) using brief monthly telephone calls the first year and bi-monthly calls in year 2. 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 al²³ compared participants 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 20 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=.014), with significantly more participants in the latter group losing 5% (11.0% vs. 18.7%, P<.027).

Greaves et al²⁴ allocated participants to a control group or a motivational-interviewingbased 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 losses in the control and intervention groups were 1.8 and 0.3 kg, respectively (P<.05 in favor of the control group). However, more intervention than control participants lost 5% of baseline weight (7.2% vs 23.6%, P<.05). Hardcastle et al²⁵ compared usual care to a motivational-interviewing-based intervention that offered up to five 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 (following 12 months of no-treatment follow-up), both groups exceeded their baseline weight (by 1.4 kg and 0.5 kg, respectively; P>.05).²⁵

Logue et al²⁶ compared augmented usual care (i.e., control), which included four in-person semi-annual meetings with a trained registered dietitian over 24 months, to a more intensive program based on a transtheoretical model-chronic disease approach. The latter intervention included the four dietitian meetings plus monthly brief (15 minute) phone calls with a trained weight loss adviser (supervised by a psychologist) who reviewed participants' stage of change with each of five targeted behaviors for the month. At month 24, participants in control and intervention groups lost a mean of 0.2 and 0.4 kg, respectively (P=.5).

Ross et al²⁷ randomly assigned participants to usual care or a motivational-interviewingbased intervention that included 15 1-hour, in-person individual sessions in the first 6 months, 6 additional sessions from months 7–12, and variable contact from months 13–24 (based on participants' 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 and 2.4 kg, respectively (P<.002) and at month 24 were 0.6 and 1.2 kg, respectively (P=.33).

Summary—None of the trials of alternative behavioral counseling achieved a mean 6month weight loss 3 kg, despite the provision during this time in one study²⁷ of 15 inperson, 1 hour individual sessions. The provision of low intensity (< monthly) counseling^{2,3} in two trials^{21,25} and approximately moderate intensity (monthly) in a third,²⁶ 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 (i.e., treatment – control) ranged from -1.5 kg (i.e., 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 Figure 2.

Four studies of traditional behavioral counseling prescribed participants an energy-restricted diet and specific physical activity goals (as recommended by the Obesity Guidelines⁶), were delivered using person-to-person counseling (i.e, face-to-face or by telephone), and reported weight losses at month $6.^{17-20}$ These trials are the most relevant for evaluating the intensity of treatment recommended by CMS (and the Obesity Guidelines⁶) 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 sessions¹⁸ to 6.6 kg with 15 contacts.²⁰ The alternative behavioral counseling trials that provided 6-month data did not reveal as clear a dose-response relationship.

DISCUSSION

This review found no studies that evaluated the efficacy of intensive behavioral weight loss counseling (14 in-person sessions in 6 months) delivered by physicians and other CMS-eligible PCPs. Three trials^{16–18} provided approximately monthly brief counseling visits, which were delivered by trained medical assistants in collaboration with PCPs. Mean weight losses at 6 months ranged from 3.5 to 4.4 kg,^{17,18} with 48% of participants in one study losing 5% of baseline weight.¹⁷ Mean weight losses in these two trials^{17,18} declined over follow-up, and smaller 12-to 24-month losses (-0.6 to -1.7 kg) were observed when PCPs, working alone, provided quarterly or less frequent weight loss counseling.^{16–18}

Two trials strongly supported the frequency of intervention contact recommended during the first 6 months by both CMS and the Obesity Guidelines⁶. Ma et al²⁰ found that 12 weekly (face-to-face) group lifestyle modification sessions, followed by phone or e-mail contact every 2 to 4 weeks, produced a 6-month loss of 6.6 kg, with 65% of participants losing 5% of baseline weight. Appel et al¹⁹ observed that 15 brief phone sessions (with trained interventionists at a call center) yielded a loss of 6.1 kg at 6-months, with 52.7% of participants losing 5% weight, outcomes comparable to 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,⁶ which includes a reduced calorie diet (e.g., 500 kcal/day deficit), 150 minutes/week of physical activity (e.g., brisk walking), and behavioral strategies to reach these targets.^{6,8–10} Smaller weight losses generally were observed in trials^{21–27} in this review that did not provide specific recommendations for both reducing energy intake and increasing expenditure, as well as offer behavioral strategies to achieve these goals. While 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 specific goals for energy restriction and expenditure.

There is a pressing need to identify the professional qualifications and training needed to provide effective behavioral weight loss counseling in primary care and other settings. Controlled trials are needed to compare the efficacy and costs of having behavioral counseling delivered by PCPs, other primary care staff (e.g., medical assistants, nurses), registered dietitians, other health professionals (e.g., health counselors, exercise specialists, psychologists), and potentially evidenced-based commercial programs.^{52,54} The Obesity

Guidelines observed that behavioral weight loss counseling could be provided by trained interventionists (following structured protocols) from a variety of educational backgrounds.⁶ 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/obese patients encountered in primary care. This research likely will include the use of web- or smartphone-based applications,^{56,57} as well as cellular-connected smart scales,⁵⁸ data from which potentially could be integrated into patients' electronic health records.^{5,8}

The CMS decision to provide intensive behavioral counseling for obese beneficiaries in primary care settings is a major advancement in the treatment of a disease that has long been overlooked. While this review found limited data to support the delivery of intensive behavioral weight loss counseling by physicians and other PCPs, these health professionals will continue to play a critical role in diagnosing obesity, evaluating its causes (including medications associated with weight gain), assessing and treating weight-related co-morbid conditions, and monitoring changes in health that occur with weight loss (including the need for medication adjustment). PCPs undoubtedly can learn to provide intensive behavioral counseling, like the other trained interventionists described in this review. However, ever increasing demands on PCPs' time may favor their referring patients for behavioral counseling, an option suggested by the U.S. Preventive Services Task Force.^{2,3} This review, along with the Obesity Guidelines,⁶ has identified options for referring patients to trained interventionists who work in primary care, as well as a variety of other settings.

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JAMA. Author manuscript; available in PMC 2015 May 26.

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Figure 1.

Organization and flow of the literature search. ^a Quality ratings were made following the procedures used by the American Heart Association American College of Cardiology Obesity Society in developing the Guidelines for the Management of Overweight and Obesity.⁶ Two of the original 14 items (#3 and #4) for quality rating were not used because they were not applicable to behavioral treatment studies. Studies were rated on a 12-point scale comprised of the remaining items. Studies with a score <6 were rated "poor," those with scores of 6–8 were rated "fair," and those with scores 9 as "good." A study also was rated "poor" if it had a fatal methodological flaw, as described in the Methods section. RCT = randomized controlled trial.



Figure 2.

The figure shows mean weight losses (in kg, with 95% confidence intervals) for intervention and control groups in each trial, as measured at the final assessment. Values to the left of "0" indicate weight loss. PCPs = primary care practitioners as defined by the Centers for Medicare and Medicaid Services. Citations for each study, (Shown in parentheses) may be found in the references.

JAMA. Author manuscript; available in PMC 2015 May 26.

Study	Sample Characteristics	Interventions, Number (N) Randomized	Number of Treatment Sessions	Mo. of Post- Baseline Up	Weight Change at Mo. 6, kg (95% Confidence Interval)	Weight Change at Follow-up, kg (95% Confidence Interval)	5% Weight Loss at Follow-Up, no. (%)	Attrition at follow- up, no. (%)
TRADITIONAL I	3EHAVIORAL COUNSELING							
Primary Care Pra	ctitioners/Trained Interventionists							
Kumanyika et	Age, 47.2 y; BMI, 37.2; 84.3% Women;	1. Basic, N = 137	3	12	Not Reported (NR)	$-0.6 (-1.4, 0.2)^{a}$	$10(10.2)^{a}$	39 (28.5)
al, ¹⁰ 2012	16.0% White, 05.0% Black	2. Basic Plus, N = 124	15		NR	$-1.6 (-2.8, -0.4)^{a}$	20 (22.5) ^b	35 (28.2)
Tsai et al, ¹⁷ 2010	Age, 49.4 y; BMI, 36.5; 88.0% Women;	1. Control, $N = 26$	4	12	$-0.9 (-2.1, 0.3)^{a}$	$-1.1 (-2.7, 0.5)^{a}$	3 (12.0) ^a	1 (3.8)
	ZU.U% WILLE, OU.U% DIACK	2. Brief Counseling, N = 24	12		-4.4 (-5.6, -3.2) ^b	-2.3 (-4.1, -0.5) ^a	$4 (18.0)^{a}$	2 (8.3)
Wadden et al, ¹⁸ 2011	Age, 51.9 yr; ** BMI, 38.7; ** 79.7% Women ^{-**} 59.8% White ** 37.5%	1. Usual Care, N = 130	8	24	$-2.0 (-3.0, -1.0)^{a}$	$-1.7 (-3.1, -0.3)^{a}$	28 (21.5) ^a	20 (15.4)
	Black; ** 2 or more components of metabolic syndrome	2. Brief Lifestyle Counseling, N = 131	33		-3.5 (-4.5, -2.5) ^b	-2.9 (-4.3, -1.5) ^a	34 (26.0) ^a	19 (14.5)
Trained Intervent	ionists							
Appel et al, ¹⁹	Age, 54.0 y; BMI, 36.6; 63.6% Women;	1. Control, N= 138	2	24	$-1.4 (-2.2, -0.6)^{a}$	$-0.8(-2.0, 0.4)^{a}$	24 (18.8) ^a	10 (7.2)
1107	JOLTS WITTE, 41.0% DIACK, 1 CVD IISK factors	2. Remote support, N = 139	33		-6.1 (-7.1, -5.1) ^b	-4.6 (-6.0, -3.2) ^b	50 (38.2) ^b	8 (5.8)
		3. In person support N= 138	57		-5.8 (-7.0, -4.6) ^b	-5.1 (-6.7, -3.5) ^b	55 (41.4) ^b	5 (3.6)
Ma et al, 20 2013	Age, 52.9 y; BMI, 32.0; 46.5% Women;	1. Usual Care, $N = 81$	0	24	$-0.7 (-2.5, 1.1)^{a}$	$-2.4 (-4.2, -0.6)^{a}$	17 (25.3) ^a	21 (25.9)
Xiao et al, ⁴⁵ 2013	7.0.0% while, 17.0% Asian/Facine Islander; pre-diabetes or metabolic syndrome	2. Coach-led, $N = 79$	12		$-6.6 (-8.2, -5.0)^{\rm b}$	-5.4 (-7.2, -3.6) ^b	39 (59.1) ^b	20 (25.3)
		3. Self-directed N = 81	1		-4.3 (-5.9, -2.7) ^b	-4.5 (-6.3, -2.7) ^b	26 (43.6) ^b	29 (35.8)
ALTERNATIVE	BEHAVIORAL COUNSELING							
Primary Care Pra	ctitioners/Trained Interventionists							
Christian et al. ²¹	Age, 49.6 y; BMI, 34.3; ** 68.4% Women;	1. Control, $N = 139$	1	12	NR	$0.15 \ (-0.65, \ 0.95)^{a}$	11 (8.5) ^a	9 (6.5)
1102	50.6% White; two or more features of metabolic syndrome	2. Intervention, N = 140	2		NR	–1.5 (–2.5, –0.5) ^b	35 (26.3) ^b	7 (5.0)

Trained Interventionists

JAMA. Author manuscript; available in PMC 2015 May 26.

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Participants' Mean Baseline Characteristics and Mean Changes in Weight (Relative to Baseline Weight) at Month 6 and Follow-Up.

Table 1

Study	Sample Characteristics	Interventions, Number (N) Randomized	Number of Treatment Sessions	Mo. of Post- Baseline Follow- Up	Weight Change at Mo. 6, kg (95% Confidence Interval)	Weight Change at Follow-up, kg (95% Confidence Interval)	5% Weight Loss at Follow-Up, no. (%)	Attrition at follow- up, no. (%)*
Bennett et al, ²² 2012	Age, 49.6 y; BMI, 37.0; 68.5% Women; 3.6% White, 71.2% Black; antihypertensive	1. Usual care, N = 185	0	24	$-0.1 (-0.8, 0.6)^{a}$	-0.5 (-1.3, 0.3) ^a	36 (19.5) ^a	19 (10.3)
	medication use	2. Intervention, N = 180	30		-1.3 (-2.1, -0.5) ^b	-1.5 (-2.3, -0.7) ^b	$36(20.0)^{a}$	31 (17.2)
de Vos et al, ²³	Age, 55.7 y; BMI, 32.4; 100% Women;	1. Control, $N = 204$	0	12	$0.9 (0.3, 1.5)^{a}$	$0.6 (-0.2, 1.4)^{a}$	$20(11.0)^{a}$	23(11.3)
2014 ⁸	92.0% write; 0.0% biack; 1.1% South American; 1.1% Asian; 4.5% Other	2. Intervention, N = 203	26		-0.9 (-1.5, 0.3) ^b	-0.6 (-1.4, 0.2) ^b	35 (18.7) ^b	16 (7.9)
Greaves et al, ²⁴	Age, 53.9 y; Weight, 93.0 kg; 63.8% Women: Baca/Ethnicity Mot renorad.	1. Control, $N = 69$	0	6	$-1.8^{a^{***}}$	NR	5 (7.2) ^a	12 (17.4)
0007	without diabetes or heart disease	2. Intervention, N = 72	11		-0.3 ^b ***	NR	17 (23.6) ^b	14 (19.4)
Hardcastle et al, ²⁵ 2008; Hardcastle	Age, 50.2 y; BMI, 33.7; Gender Not reported; Race/Ethnicity Not reported; 1	1. Minimal intervention, $N = 131$	0	18	$0.1 (-0.5, 0.7)^a$	1.4 ^{a ***}	NR	38 (29.0)
et al, 2013 ⁴³	CVD risk factor	2. Motivational Interviewing, N = 203	S		-0.7 (-1.3, -0.1) ^b	0.5 ^{a***}	NR	78 (38.4)
Logue et al, ²⁶ 2005	Ages 40–69 y; BMI 27 or WHR > 0.95 (men) or > 0.8 (women); 68.5 % Women;	1. Augmented Usual Care, N = 336	4	24	NR	$-0.2 (-1.0, 0.6)^{a}$	NR	70 (20.8)
	Kace/Ethnicity not reported	2. Trans-theoretical Model, N = 329	28		NR	$-0.4 (-1.2, 0.4)^{a}$	NR	58 (17.6)
Ross et al, ²⁷ 2012	Age, 51.8 y. ^e BMI, 27–39; 70.2% Women; Rece/Ethnicity Not reported; sedentary;	1. Usual Care, N = 241	0	24	-0.7 (-1.3, -0.1) ^a	$-0.6 (-1.4, 0.2)^{a}$	NR	35 (14.5)
	abdominally obese	2. Behavioral Intervention, $N = 249$	33		-2.4 (-3.0, -1.8) ^b	$-1.2 (-2.0, -0.4)^{a}$	NR	59 (23.7)
Note: BMI = body m	ass index, CVD = cardiovascular disease, PI = P	<pre>>acific Islander, TM-CD =</pre>	transtheoretical	model-chronic	disease, NR = not report	ted.		

Values shown for age and BMI are means.

JAMA. Author manuscript; available in PMC 2015 May 26.

For each study, under "weight change" (at month 6 and at follow-up) values within columns labeled with different letters (a, b) are significantly different from each other at P<05. For example, in the Tsai et al. study, the mean 6-month weight loss of -0.9 (-2.1, 0.3)^a for the control group differs significantly from the -4.4 (-5.6, -3.2)^b loss for the brief counseling. Values with the same letter (a) are not significantly different, as for example, with the 12-month control and brief counseling weight losses in the Tsai et al. study.

Within each study, all treatment groups had the same number of months of post-baseline follow-up.

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

** Calculated mean;

*** Variance not reported.

Wadden et al.

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 $\frac{8}{8}$ Weights were measured at 30 months but are not included in this review since they were only provided in a figure in the paper. In addition, this paper reported on percentage of participants who lost 5kg or 5% of baseline body weight.

Description of Inte	rvention Components and	d Providers.			
Study	Intervention Group	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Provider (PCP)	Components of Diet, Physical Activity (PA), and Behavior Therapy (BT)
TRADITIONAL BEH	IAVIORAL COUNSELING				
Primary Care Practit	ioners/Trained Interventionists				
Kumanyika et al, ¹⁶ 2012	I. Basic	Counseling every 4 mo with the PCP based on Diabetes Prevention Program (DPP) materials. PCPs completed 3 hr training.	On-site visits with PCP.	Provided brief counseling during visits every 4 mo.	Diet: 1200–1499 kcal/day with 30 g fat (if weight <100 kg) or 1500–1800 kcal/day with 40 g fat (100 kg); provided calorie counter. PA: 150 min of moderate PA/week, typically walking. BT: Prescribed DPP behavior change program, including self-monitoring of diet and PA; goal setting.
	2. Basic Plus	Visits every 4 mo with PCP; 10–15 min monthly individual sessions with a lifestyle coach, usually a medical assistant (MA). MAs completed 3 hr training.	On-site visits with PCP and lifestyle coach.	Same as for Basic.	Diet: Same as for Basic. PA: Same as for Basic. BT: Same as for Basic.
Tsai et al, ¹⁷ 2010	1. 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 healthy diet; provided calorie counter and meal plans. PA: Standard advice to exercise more; provided pedometer. BT: 1–2 page handouts from NH/Weight- Control Information Network, including healthy behaviors.
	2. Brief Counseling	Quarterly usual care meetings with PCP (weight management, ~2–3 min); 8 brief (10–15 min) individual meetings with MAs at weeks 0, 2, 4, 8, 12, 16, 20, 24. MAs completed 3 hr training.	On-site visits with PCP or MA (with occasional phone counseling by MAs for missed visits).	Same as for Control group.	Received same materials as control group. Diet: 1200–1499 kcal/day (<250 lb) or 1500–1800 kcal/day (<250 lb). PA: gradual increase to 175 min/week, typically walking. BT: Prescribed DPP behavior 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, ¹⁸ 2011	1. Usual Care	Quarterly usual care visits with PCP (weight management, ~5-7 min). PCP completed 6-8 hr training at baseline.	On-site, routine clinical visits with physician.	Discussed handouts; reviewed participants' weight change;	Diet: 1200–1500 kcal/day (<113.4 kg) or 1500–1800 kcal/day (<113.4 kg); received calorie counting book and pedometer. PA: Gradual increase to 180 min/week, typically walking. BT: Handouts from NHLBI's "Aim for a Healthy Weight".
	2. Brief Lifestyle Counseling	Quarterly usual care visits with PCP (weight	On-site, individual visits with PCP and MA. In year 2 counseling visits	Same as for Usual Care.	Diet: Same prescription and materials as Usual Care.

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Table 2

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Study	Intervention Group	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Provider (PCP)	Components of Diet, Physical Activity (PA), and Behavior Therapy (BT)
		management, -5-7 min); month management, -5-7 min); month	Jycindidi hdural impetiting a (enj0offffernin) wi lyniodidi hdural impetiting a ($\sim 10-15$ min) wi ly individual meetings ($\sim 10-15$ min) wi	th a lifestyle coach, usuall th a lifestyle coach, usuall	RAA Saftweith Avgressistip simom was this tight KlaAs. complete B-shr training / BTM Rressifthead ORPH the law month shares with the second set of the second rest of the second rest of the second set of the se
Trained Intervention	nists				
Appel et al, ¹⁹ 2011	1. Control	One session with weight loss coach (a university employee) at randomization and, if desired, one after final data collection visit.	On-site, individual visit with staff member.	None	Received brochures and a list of recommended websites promoting weight loss.
	2. Remote Support Only	Individual, 20-min phone calls weekly for 12 weeks, 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/day. PA: Increase to 180 min/week of moderate intensity. BT: Self-monitoring of diet and PA; problem solving and social support; study website; motivational interviewing elements.
	3. In-Person Support	Combination of 9 group (90 min) and 3 individual (20 min) contacts for 12 weeks, then 2–3 such contacts per moth. 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, ²⁰ 2013;	1. Usual Care	None	None	None	No materials provided.
Xiao et al. ⁴⁵ 2013	2. Coach-Led, Intervention	12 in-person, group sessions (90–120 min) in mo 1–3; contact every 2–4 weeks 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/day energy deficit. PA: 150 min of moderate PA/week; 30– 45 min of supervised PA at weekly class during mo 1–3. BT: DPP Group Lifestyle Balance BT: DPP Group Lifestyle Balance physical activity and goal setting; weight scale and pedometer for self-monitoring and goal setting.
	3. Self-directed DVD intervention	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	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.
		during mo 1–10.			e î

JAMA. Author manuscript; available in PMC 2015 May 26.

Study	Intervention Group	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Provider (PCP)	Components of Diet, Physical Activity (PA), and Behavior Therapy (BT)
ALTERNATIVE BE.	HAVIORAL COUNSELING				
Primary Care Practi	tioners/Trained Interventionists				
Christian et al, ²¹ 2011	1. 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.
	2. Intervention	Twice-yearly counseling with PCP during routine visits. Clinic staff administered one computer-based assessment session prior to baseline visit and one session at 6 mo. PCP completed 3-hr training in motivational interviewing.	On-site; computer assessment, physician feedback.	Received computer- generated report with summary of each patients were provided recommendations for behavior 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 interviewing to reduce calorie intake and interease 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 Intervention	ists				
Bennett et al, ²² 2012	1. Control	Initial visit with program staff.	Self-help booklet.	None	NHLBI's "Aim for a Healthy Weight" booklet provided.
	2. 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 behavior change goals to create an energy deficit. PA: Walk 10,000 steps/day, 20 min/day brisk walking, strength training 2 days/ week. BT: Goal prescriptions; self-monitoring; tailored skills training; problem solving; motivational interviewing elements.
de Vos et al, ²³ 2014	1. Control	None	None	None	No materials provided.
	2. Intervention	Referral to registered diettian for up to 4 hr of counseling in year 1; up to 20, 1-hr 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 physical activity; physical activity classes offered. BT: Motivational interviewing; goal setting.
Greaves et al, ²⁴ 2008	1. 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.
	2. Intervention	Up to 11 individual visits (~30 min) in-person or by telephone for 6 mo.	On-site, individual consultations and telephone contacts.	None	Diet: Reduce calories, fat, and portion size; increase fiber.

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Study	Intervention Group	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Provider (PCP)	Components of Diet, Physical Activity (PA), and Behavior Therapy (BT)
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Hardcastle et al, 2008; ²⁵ 2013 ⁴⁴	I. 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/day of PA. BT: None
	2. Motivational Interviewing	One consultation with PA specialist or registered dietitian with opportunity to meet 4 more times (20–30 min) following 6 mo. PA specialist and registered dietitian participated in two 4 hr training sessions focused on MI.	On-site, individual consultation.	None	Diet: Motivational interviewing to improve diet. PA: Motivational interviewing to increase physical activity. BT: Motivational interviewing integrated with a stage-matched approach; agenda setting: exploration of the pros and cons, importance and confidence unlers, strengthening commitment to change and negotiating a change plan.
Logue et al. ²⁶ 2005	1. Augmented Usual Care	Semi-annual 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.
	2. Trans-theoretical Model	Same dietitian visits as Usual Care; monthly 15-min telephone calls with a weight- loss advisor, conducted "stage-of-change" (SOC) assessments for five 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 with respect to 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, 27 2012	1. Usual Care	Routine visit with physician.	Usual schedule of meetings with physicians.	Provide general advice during routine office visit (typically once a year).	Diet, PA, and BT: Advice regarding benefits of PA for obesity reduction; at end of intervention, patients Invited to attend workshop on strategies to integrate PA and healthy eating into lifestyle.

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Study	Intervention Group	Intervention Frequency and Provider	Method of Intervention Delivery	Role of Primary Care Provider (PCP)	Components of Diet, Physical Activity (PA), and Behavior Therapy (BT)
	2. Behavioral Intervention	Health educators (in kinesiology) provided 15, 1 hr 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/day of moderate PA. BT: Motivational interviewing (mo 1–6); individually tailored counseling based on transtheoretical model and social cognitive theory; goal setting.

BT= behavior therapy; MA= medical assistant; PA= physical activity; PCP= primary care provider; SOC= stage of change; NHLBI= National Heart, Lung, and Blood Institute.