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Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: US Preventive Services Task Force Recommendation Statement.

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# Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults

## US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

**IMPORTANCE** More than 35% of men and 40% of women in the United States are obese. Obesity is associated with health problems such as increased risk for coronary heart disease, type 2 diabetes, various types of cancer, gallstones, and disability. Obesity is also associated with an increased risk for death, particularly among adults younger than 65 years.

**OBJECTIVE** To update the US Preventive Services Task Force (USPSTF) 2012 recommendation on screening for obesity in adults.

**EVIDENCE REVIEW** The USPSTF reviewed the evidence on interventions (behavioral and pharmacotherapy) for weight loss or weight loss maintenance that can be provided in or referred from a primary care setting. Surgical weight loss interventions and nonsurgical weight loss devices (eg, gastric balloons) are considered to be outside the scope of the primary care setting.

**FINDINGS** The USPSTF found adequate evidence that intensive, multicomponent behavioral interventions in adults with obesity can lead to clinically significant improvements in weight status and reduce the incidence of type 2 diabetes among adults with obesity and elevated plasma glucose levels; these interventions are of moderate benefit. The USPSTF found adequate evidence that behavior-based weight loss maintenance interventions are of moderate benefit. The USPSTF found adequate evidence that the harms of intensive, multicomponent behavioral interventions (including weight loss maintenance interventions) in adults with obesity are small to none. Therefore, the USPSTF concludes with moderate certainty that offering or referring adults with obesity to intensive behavioral interventions or behavior-based weight loss maintenance interventions has a moderate net benefit.

**CONCLUSIONS AND RECOMMENDATION** The USPSTF recommends that clinicians offer or refer adults with a body mass index of 30 or higher to intensive, multicomponent behavioral interventions. (B recommendation)

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**Group Information:** The US Preventive Services Task Force (USPSTF) members are listed at the end of this article.

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**T**he US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient

or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

### Summary of Recommendation and Evidence

The USPSTF recommends that clinicians offer or refer adults with a body mass index (BMI) of 30 or higher (calculated as weight in kilograms divided by height in meters squared) to intensive, multicomponent behavioral interventions (B recommendation) (Figure 1).

Figure 1. USPSTF Grades and Levels of Evidence

What the USPSTF Grades Mean and Suggestions for Practice		
Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit	
Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as the number, size, or quality of individual studies. inconsistency of findings across individual studies. limited generalizability of findings to routine primary care practice. lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of the limited number or size of studies. important flaws in study design or methods. inconsistency of findings across individual studies. gaps in the chain of evidence. findings not generalizable to routine primary care practice. lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.
The USPSTF defines certainty as “likelihood that the USPSTF assessment of the net benefit of a preventive service is correct.” The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.	

USPSTF indicates US Preventive Services Task Force.

## Rationale

### Importance

More than 35% of men and 40% of women in the United States are obese.<sup>1,2</sup> Obesity is associated with health problems such as increased risk for coronary heart disease, type 2 diabetes, various types of cancer, gallstones, and disability.<sup>1,3-7</sup> Obesity is also associated with an increased risk for death, particularly among adults younger than 65 years.<sup>1</sup> The leading causes of death among adults with obesity include ischemic heart disease, type 2 diabetes, respiratory

diseases, and cancer (eg, liver, kidney, breast, endometrial, prostate, and colon cancer).<sup>1,3,8-12</sup>

### Benefits of Behavioral Counseling Interventions

The USPSTF found adequate evidence that behavior-based weight loss interventions in adults with obesity can lead to clinically significant improvements in weight status and reduced incidence of type 2 diabetes among adults with obesity and elevated plasma glucose levels. The USPSTF found adequate evidence that behavior-based weight loss maintenance interventions are associated with less weight gain after the cessation of interventions,

Figure 2. Clinical Summary: Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults

Population	Adults with a BMI ≥30 <sup>a</sup>
Recommendation	Offer or refer to intensive, multicomponent behavioral interventions. Grade: B
Risk Assessment	More than 35% of men and 40% of women in the United States have obesity. Obesity is associated with health problems such as increased risk for coronary heart disease, type 2 diabetes, various types of cancer, gallstones, and disability. Obesity is also associated with an increased risk for death, particularly among adults younger than 65 years.
Interventions	<ul style="list-style-type: none"> <li>• Effective intensive behavioral interventions were designed to help participants achieve or maintain a ≥5% weight loss through a combination of dietary changes and increased physical activity</li> <li>• Most interventions lasted for 1 to 2 years, and the majority had ≥12 sessions in the first year</li> <li>• Most behavioral interventions focused on problem solving to identify barriers, self-monitoring of weight, peer support, and relapse prevention</li> <li>• Interventions also provided tools to support weight loss or weight loss maintenance (eg, pedometers, food scales, or exercise videos)</li> </ul>
Relevant USPSTF Recommendations	The USPSTF has made recommendations on screening for abnormal blood glucose levels and type 2 diabetes, screening for high blood pressure, statin use in persons at risk for cardiovascular disease, counseling for tobacco smoking cessation, aspirin use in certain persons for prevention of cardiovascular disease, behavioral counseling interventions to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with and without common risk factors, and screening for obesity in children and adolescents.

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to <https://www.uspreventiveservicestaskforce.org>.



USPSTF indicates US Preventive Services Task Force.

<sup>a</sup> Calculated as weight in kilograms divided by height in meters squared.

compared with control groups. The magnitude of these benefits is moderate.

### Harms of Behavioral Counseling Interventions

The USPSTF found adequate evidence to bound the harms of intensive, multicomponent behavioral interventions (ie, behavior-based weight loss and weight loss maintenance interventions) in adults with obesity as small to none, based on the absence of reported harms in the evidence and the noninvasive nature of the interventions. When direct evidence is limited, absent, or restricted to select populations or clinical scenarios, the USPSTF may place conceptual upper or lower bounds on the magnitude of benefit or harms.

### USPSTF Assessment

The USPSTF concludes with moderate certainty that offering or referring adults with obesity to intensive, multicomponent behavioral interventions (ie, behavior-based weight loss and weight loss maintenance interventions) has a moderate net benefit.

### Clinical Considerations

#### Patient Population Under Consideration

This recommendation applies to adults 18 years or older (Figure 2). The USPSTF uses the following terms to define categories of

increased BMI: "overweight" is a BMI of 25 to 29.9 and "obesity" is a BMI of 30 or higher. Obesity can be categorized as class 1 (BMI of 30.0 to 34.9), class 2 (BMI of 35.0 to 39.9), or class 3 (BMI of ≥40) (see the Table for other USPSTF recommendations related to weight).

#### Behavioral Counseling Interventions

Many of the effective intensive behavioral interventions considered by the USPSTF were designed to help participants achieve or maintain a 5% or greater weight loss through a combination of dietary changes and increased physical activity. The US Food and Drug Administration considers a weight loss of 5% as clinically important.<sup>1</sup>

Most of the intensive behavioral weight loss interventions considered by the USPSTF lasted for 1 to 2 years, and the majority had 12 or more sessions in the first year.<sup>1</sup> One-third of the interventions had a "core" phase (ranging from 3-12 months) followed by a "support" or "maintenance" phase (ranging from 9-12 months).<sup>1</sup> Most behavioral interventions encouraged self-monitoring of weight and provided tools to support weight loss or weight loss maintenance (eg, pedometers, food scales, or exercise videos).<sup>1</sup> Similar behavior change techniques and weight loss messages were used across the trials.<sup>1</sup> Some trials provided interventions modeled after the Diabetes Prevention Program lifestyle intervention for use in a primary care or community setting.<sup>1</sup> Study heterogeneity, trial quality, and differences in populations and settings made it difficult to identify the most

Table. Summary of Related USPSTF Recommendations

Risk Factors	Normal Weight (BMI 18.5 to <25) <sup>a</sup>	Overweight (BMI 25 to <30) <sup>a</sup>	Obese (BMI ≥30) <sup>a</sup>
No hypertension, dyslipidemia, or abnormal blood glucose levels	Individualize the decision to provide or refer to behavioral counseling	Individualize the decision to provide or refer to behavioral counseling	Provide or refer to intensive behavioral counseling
Hypertension, dyslipidemia, or both	Individualize the decision to provide or refer to behavioral counseling	Provide or refer to intensive behavioral counseling	Provide or refer to intensive behavioral counseling
Abnormal blood glucose levels or diabetes	Provide or refer to intensive behavioral counseling <sup>b</sup>	Provide or refer to intensive behavioral counseling	Provide or refer to intensive behavioral counseling

Abbreviation: BMI, body mass index.

<sup>a</sup> BMI calculated as weight in kilograms divided by height in meters squared.

<sup>b</sup> The USPSTF recommends screening for abnormal blood glucose levels as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or have obesity. Patients with certain risk factors (family history of diabetes, personal history of gestational diabetes or polycystic ovarian

syndrome, or being a member of certain racial/ethnic groups [African American, American Indian or Alaskan Native, Asian American, Hispanic or Latino, or Native Hawaiian or Pacific Islander]) may also be at increased risk of diabetes at a younger age or at a lower BMI and should be considered for screening.<sup>13</sup>

effective intervention characteristics (eg, number of sessions, in-person vs remote sessions, or group- vs individual-based).<sup>1</sup> Benefits may depend on tailoring interventions to social, environmental, and individual factors.

Interventionists varied across the trials, and interventions included varied interactions with a primary care clinician. Primary care clinician involvement ranged from limited interactions with participants in interventions conducted by other practitioners or individuals (ie, group-based interventions conducted by lifestyle coaches or registered dietitians) to reinforcing intervention messages through brief counseling sessions.<sup>1</sup> Few interventions included a primary care clinician as the primary interventionist over 3 to 12 months of individual counseling. In the trials not involving a primary care clinician, the interventionists were highly diverse and included behavioral therapists, psychologists, registered dietitians, exercise physiologists, lifestyle coaches, and other staff. The majority of the trials focused on individual participants, but a few interventions invited family members to participate.<sup>1</sup>

Trials used various delivery methods (group, individual, mixed, and technology- or print-based). Group-based interventions ranged from 8 group sessions over 2.5 months to weekly group sessions over 1 year (median, 23 total sessions in the first year). These interventions consisted of classroom-style sessions lasting 1 to 2 hours.<sup>1</sup> Within the group-based interventions, some trials offered supplemental support with 1 brief individual counseling session, while other trials provided referral and free access to commercially available group-based weight loss programs.

Most of the individual-based interventions provided individual counseling sessions, with or without ongoing telephone support.<sup>1</sup> The remaining interventions were provided remotely through telephone counseling calls (average time, 15-30 minutes) and web-based self-monitoring and support. The median number of sessions in the first year for individual-based interventions was 12.<sup>1</sup>

Mixed interventions included comparatively equal numbers of group- and individual-based counseling sessions, with or without other forms of support (eg, telephone-, print-, or web-based). Most of these interventions took place for more than 1 year and involved more than 12 sessions (median, 23 total sessions in the first year).

Among technology-based interventions, intervention components included computer- or web-based intervention modules,<sup>1</sup>

web-based self-monitoring, mobile phone-based text messages, smartphone applications, social networking platforms, or DVD learning. Only 1 trial delivered its intervention through print-based tailored materials.<sup>1</sup>

Rates of participant adherence were generally high.<sup>1</sup> More than two-thirds of study participants completed interventions. In addition, all study participants completed more than two-thirds of the intervention. Participation rates did decline over time.<sup>1</sup>

Behavior-based weight loss maintenance trials were designed to maintain weight loss by continuing dietary changes and physical activity.<sup>1</sup> Interventions included group interventions, technology-based individual counseling sessions, or a combination of individual and group counseling. Most weight loss maintenance interventions lasted for 12 to 18 months; the majority of interventions had more than 12 sessions in the first year.<sup>1</sup> Intervention components focused on nutrition, physical activity, self-monitoring, identifying barriers, problem solving, peer support, and relapse prevention.<sup>1</sup> Participants used tools such as food diaries and pedometers to help maintain weight loss.<sup>1</sup>

Interventions that combined pharmacotherapy with behavioral interventions reported greater weight loss and weight loss maintenance over 12 to 18 months compared with behavioral interventions alone.<sup>1</sup> However, the participants in the pharmacotherapy trials were required to meet highly selective inclusion criteria, including adherence to taking medications and meeting weight loss goals before enrollment. These trials also had high attrition.<sup>1</sup> Therefore, it is unclear how well patients tolerate these medications and whether the findings from these trials are applicable to the general US primary care population. In addition, data were lacking about the maintenance of improvement after discontinuation of pharmacotherapy.<sup>1</sup> As a result, the USPSTF encourages clinicians to promote behavioral interventions as the primary focus of effective interventions for weight loss in adults.

### Additional Approaches to Prevention

The USPSTF has made recommendations on screening for abnormal blood glucose levels and type 2 diabetes,<sup>13</sup> screening for high blood pressure,<sup>14</sup> statin use in persons at risk for cardiovascular disease,<sup>15</sup> counseling for tobacco smoking cessation,<sup>16</sup> aspirin use in certain persons for prevention of cardiovascular disease,<sup>17</sup> and behavioral counseling interventions to promote a healthful diet and physical activity for cardiovascular disease prevention in adults with and without common risk factors<sup>18,19</sup> (Table). The USPSTF

recommends that clinicians screen for obesity in children 6 years or older and offer or refer them to a comprehensive, intensive behavioral intervention (B recommendation).<sup>20</sup>

### Useful Resources

The Community Preventive Services Task Force recommends multicomponent interventions that use technology-supported coaching or counseling to help adults lose weight and maintain weight loss.<sup>21</sup>

## Other Considerations

### Research Needs and Gaps

Further research is needed to examine the effects of interventions for obesity on longer-term weight and health outcomes (eg, cardiovascular outcomes), including data on important subpopulations (eg, older adults, racial/ethnic groups, or persons who are overweight). Psychosocial, quality of life, and patient-centered outcomes should continue to be evaluated in future studies. Well-designed pragmatic trials and improved reporting of intervention characteristics to enable evaluation and dissemination of interventions in primary care settings are needed. Future research is needed on factors (eg, genetics or untreated medical or psychological conditions) that may be barriers to weight loss during behavioral interventions. Trials are needed that examine whether interventions that focus on both weight loss and support of persons living with obesity improve patient-centered outcomes. Comparative effectiveness trials would provide more evidence about the components of effective interventions.

## Discussion

### Burden of Disease

From 2013 to 2014, the prevalence of obesity in the United States was greater than 35% among men and 40% among women.<sup>2</sup> One in 13 Americans has a BMI higher than 40 (class 3 obesity).<sup>22</sup> According to 2011-2014 data, the age-adjusted prevalence of persons who are overweight or obese is 72.8% among men and 66.2% among women.<sup>23</sup>

The prevalence of overweight and obesity varies across race/ethnicity. The age-adjusted prevalence of obesity is higher among non-Hispanic black (57.2%) and Hispanic (46.9%) women than among non-Hispanic white (38.2%) women. Among men, obesity prevalence is 38.0% in non-Hispanic black, 37.9% in Hispanic, and 34.7% in non-Hispanic white men.<sup>24</sup> Obesity rates among Asian Americans are lower than among other racial/ethnic groups (12.6% and 12.4% in men and women, respectively). However, Asian Americans have higher body fat at a given BMI than other racial/ethnic groups. When using an adjusted cut point of greater than 25, obesity prevalence is higher among US-born Asian Americans (43%) than among non-Hispanic whites (36%).<sup>25</sup>

### Scope of Review

The USPSTF commissioned a systematic evidence review to update its 2012 recommendation on screening for obesity in

adults.<sup>1,26</sup> Because screening for obesity is now part of routine clinical practice, it was not a focus of this review. The USPSTF reviewed evidence on interventions (behavioral counseling and pharmacotherapy) for weight loss or weight loss maintenance that can be provided in or referred from a primary care setting. Waist circumference may be an acceptable alternative to BMI measurement in some patient subpopulations. Surgical weight loss interventions and nonsurgical weight loss devices (eg, gastric balloons) are considered to be outside the scope of the primary care setting.

### Effectiveness of Behavioral Counseling and Pharmacotherapy Interventions

The USPSTF reviewed the evidence on 4 types of interventions: behavior-based weight loss (80 trials), behavior-based weight loss maintenance (9 trials), pharmacotherapy-based weight loss (32 trials), and pharmacotherapy-based weight loss maintenance (3 trials). In the weight loss maintenance trials, patient randomization occurred after prior weight loss.<sup>1</sup>

#### Behavioral Counseling Interventions

The USPSTF identified 89 behavior-based weight loss and weight loss maintenance trials, 26 of which were good quality and 63 of which were fair quality. Eighty trials focused on behavior-based weight loss interventions.<sup>1</sup> The majority of behavior-based weight loss intervention trials (47 trials) were conducted in the United States; other study sites included Europe (15 trials), the United Kingdom (11 trials), Japan (3 trials), Australia (2 trials), and Canada (2 trials). In more than half of the trials (40 trials), participants came from an unselected population of adults who were overweight or had obesity. In the remaining trials, enrolled participants had elevated clinical or subclinical risk of cardiovascular disease or cancer.<sup>1</sup> Trial sample sizes ranged from 30 to 2161. The mean baseline BMI ranged from 25 to 39.2 (median, 33.4), and the mean age ranged from 22 to 66 years (median, 50.3 years). Fourteen trials were limited to women, and 4 trials were restricted to men.<sup>1</sup> Eleven trials focused on specific racial/ethnic groups (eg, African American, Asian and South Asian, American Indian, or Hispanic). Socioeconomic status was not well reported in trials; however, when described, most participants were of medium to high socioeconomic status. Most trials did not stratify results by BMI or BMI category, age, race/ethnicity, or health status.<sup>1</sup>

Although some trials included participants who were overweight, the average BMI in the majority of trials was in the obese range (median BMI, >33).<sup>1</sup> Therefore, the USPSTF was unable to examine the differential effects of interventions among participants who were overweight or had obesity.

Nine trials focused on behavior-based weight loss maintenance.<sup>1</sup> Study sites were in the United States, the United Kingdom, Finland, and Australia. In most trials (8 trials), participants came from an unselected population of adults who were overweight or had obesity. One trial enrolled participants with cardiovascular risk factors.<sup>1</sup> Trial sample sizes ranged from 92 to 1032. Participants were required to meet weight loss goals before enrollment. The mean BMI at enrollment ranged from 28.4 to 41.7 and the mean age ranged from 46.4 to 61.8 years (median, 49.2 years).<sup>1</sup> One trial was limited to women, and 1 trial was limited to men.

The majority of trials did not report information regarding race/ethnicity or socioeconomic status. When this information was reported, participants were mostly white and of medium to high socioeconomic status.<sup>1</sup>

#### Behavior-Based Weight Loss and Weight Loss Maintenance Interventions

Few health outcomes were identified in the behavior-based weight loss and weight loss maintenance trials (20 trials [n = 9910]). There were no significant differences in mortality between intervention and control groups (4 trials [n = 4442]). There were also no significant differences in cardiovascular events between intervention and control groups (2 trials [n = 2666]).<sup>1</sup> Trials that examined health-related quality of life (17 trials [n = 7120]) mostly demonstrated a lack of statistically significant differences between intervention and control groups.

Intermediate outcomes (eg, prevalence of high blood pressure or the metabolic syndrome, use of cardiovascular disease medications, or estimated 10-year risk of cardiovascular disease) were seldom reported. Effects of interventions on cardiovascular disease risk, the metabolic syndrome, hypertension or hyperlipidemia diagnoses, and medication use were mixed.

Thirteen behavior-based weight loss trials (n = 4095) evaluated incident type 2 diabetes in intervention vs control groups. Twelve of the 13 trials enrolled participants with impaired fasting glucose or increased risk for type 2 diabetes (ie, persons with a family history of diabetes or personal history of gestational diabetes or the metabolic syndrome). In the good-quality Diabetes Prevention Program trial (n = 1295), the estimated cumulative incidence of type 2 diabetes at 3 years was 14.4% vs 28.9% in the intervention vs placebo groups, respectively, and the number needed to treat to prevent 1 case of diabetes was 6.8. The good-quality Finnish Diabetes Prevention Study (n = 523) demonstrated that participants in the intervention group were significantly less likely to develop type 2 diabetes than those in the control group after 9 years (40.0% vs 54.5%, respectively; hazard ratio, 0.4 [95% CI, 0.3 to 0.7]). In the remaining trials, the differences between the intervention and control groups were not statistically significant. However, these trials were smaller and shorter than the larger trials. Pooling the trials (9 studies; n = 3140) showed a significant reduction in the risk of developing type 2 diabetes over 1 to 9 years (pooled risk ratio, 0.67 [95% CI, 0.51 to 0.89];  $I^2 = 49.2\%$ ).<sup>1,27-29</sup>

Participants in behavior-based weight loss intervention groups demonstrated greater weight loss and decreased waist circumference compared with those in control groups at 24 months of follow-up. At 12 to 18 months, pooled results showed greater weight loss among intervention participants (-2.39 kg [-5.3 lb] [95% CI, -2.86 to -1.93]; 67 trials [n = 22 065];  $I^2 = 90.0\%$ ).<sup>1</sup> The mean absolute change in weight ranged from -0.5 kg (-1.1 lb) to -9.3 kg (-20.5 lb) among intervention groups and from 1.4 kg (3.1 lb) to -5.6 (-12.3 lb) among control groups. At 12 to 18 months, intervention participants were more likely to lose 5% of their initial weight compared with control participants (risk ratio, 1.94 [95% CI, 1.70 to 2.22]; 38 trials [n = 12 231];  $I^2 = 67.2\%$ ; number needed to treat = 8).<sup>1</sup> Participants in weight loss maintenance interventions had less weight gain compared with participants in control groups (pooled mean difference in weight change,

-1.59 kg [-3.5 lb] [95% CI, -2.38 to -0.79]; 8 studies [n = 1408];  $I^2 = 26.8\%$ ).<sup>1</sup>

#### Pharmacotherapy-Based Weight Loss and Weight Loss Maintenance Interventions

Pharmacotherapy trials evaluated liraglutide (4 trials), lorcaserin (4 trials), naltrexone and bupropion (3 trials), orlistat (21 trials), and phentermine-topiramate (3 trials) in combination with behavioral counseling.<sup>1</sup> The review of pharmacotherapy-based trials focused on trials that used dosages approved by the US Food and Drug Administration. All trials were fair quality. Across all trials, both study groups (ie, placebo and pharmacotherapy groups) received the same behavioral interventions. The trials were conducted in the United States, Europe, Australia, New Zealand, and other regions. Participant characteristics were similar to those in the behavioral intervention trials. Many trials required participants to demonstrate medication adherence, meet weight loss goals before enrollment, or both. The more narrowly defined inclusion criteria of these trials resulted in more selective populations enrolled as study participants.<sup>1</sup> Meta-analyses could not be conducted because of the few number of trials for each drug or variability in outcome reporting.<sup>1</sup> The rate of trial completion in the medication and placebo groups ranged from 10% to 93% (most ranged from 50% to 70%).<sup>1</sup>

Ten trials of pharmacotherapy-based interventions (n = 13 145) examined quality of life outcomes.<sup>1</sup> Many trials showed improvement in obesity-specific quality of life measures among participants receiving pharmacotherapy compared with placebo. However, these outcomes are difficult to interpret because of high dropout rates ( $\geq 35\%$  in half of the included trials), the small differences between study groups, and the unclear clinical significance of improved quality of life scores.<sup>1</sup> Trials that reported cardiovascular events found few events in any group (2 trials [n = 6210]). Pharmacotherapy-based weight loss maintenance trials did not report any health outcomes.<sup>1</sup>

Limited data from 4 trials examined weight loss medication and incident diabetes (n = 9763) and found a reduced risk of diabetes. However, these trials were limited by high dropout rates.<sup>1,26</sup> Other intermediate outcomes (use of lipid-lowering and antihypertensive medications, prevalence of the metabolic syndrome, and 10-year risk of cardiovascular disease) were sparsely reported and had mixed findings.<sup>1</sup>

At 12 to 18 months, participants in pharmacotherapy-based weight loss trials (32 trials) had more weight loss compared with placebo groups (mean or least squares mean difference in weight change, -1.0 kg [-2.2 lb] to -5.8 kg [-12.8 lb]).<sup>1,26</sup> Participants also experienced a greater decrease in waist circumference and a greater likelihood of losing 5% of their initial weight compared with placebo groups. Three pharmacotherapy-based weight loss maintenance trials showed that participants receiving the intervention had better weight loss maintenance compared with placebo groups over 12 to 36 months (mean difference, -0.6 to -3.5 kg).<sup>1</sup>

#### Potential Harms of Behavioral Counseling Interventions

##### Behavior-Based Weight Loss and Weight Loss Maintenance Interventions

The USPSTF looked for evidence on potential harms of behavioral weight-loss interventions, including increased risk for

fractures, serious injuries resulting from increased physical activity, and an increased risk for eating disorders, weight stigma, and weight fluctuation. Thirty trials (n = 12 824) examined the harms of behavior-based weight loss and weight loss maintenance interventions. Fifteen trials were good quality and 15 trials were fair quality. Intervention harms were sparsely reported. Overall, the trials showed no serious harms, and most trials observed no difference in the rate of adverse events between intervention and control groups. Three trials demonstrated mixed results for musculoskeletal problems.

#### Pharmacotherapy-Based Weight Loss and Weight Loss Maintenance Interventions

Pharmacological agents for weight loss have multiple potential harms, including anxiety, pancreatitis, and gastrointestinal symptoms with liraglutide; dizziness and cognitive impairment with lorcaserin; nausea, constipation, headache, and dry mouth with naltrexone and bupropion; cramps, flatulence, fecal incontinence, and oily spotting with orlistat; and mood disorders, elevated heart rate, and metabolic acidosis with phentermine-topiramate. These harms have not been well studied. Thirty-three trials and 2 observational studies (n = 239 428), all fair quality, assessed the harms of pharmacotherapy-based weight loss and weight loss maintenance interventions. Serious adverse events were uncommon and similar between groups.<sup>1</sup> Adverse event rates were high in both intervention and placebo groups by 12 months, with 80% to 96% of participants experiencing an adverse event in the medication group compared with 63% to 94% in the placebo group. The higher rate of adverse events in the medication groups resulted in higher dropout rates than in the placebo groups.<sup>1</sup> Other limitations of the pharmacotherapy studies include a small number of trials for each medication, methodological variability, missing data, poor follow-up, and limited applicability (participants met narrowly defined inclusion criteria).<sup>26</sup>

#### Estimate of Magnitude of Net Benefit

The USPSTF found adequate evidence that intensive, multicomponent behavioral interventions in adults with obesity can lead to clinically significant improvements in weight status and reduce the incidence of type 2 diabetes among adults with obesity and elevated plasma glucose levels; these interventions are of moderate benefit. The USPSTF found adequate evidence that behavior-based weight loss maintenance interventions are of moderate benefit. The USPSTF found adequate evidence that the harms of intensive, multicomponent behavioral interventions (including weight loss maintenance interventions) in adults with obesity are small to none.

Therefore, the USPSTF concludes with moderate certainty that offering or referring adults with obesity to intensive behavioral in-

terventions or behavior-based weight loss maintenance interventions has a moderate net benefit.

#### How Does Evidence Fit With Biological Understanding?

Various environmental and genetic factors play an important role in the development of obesity. After obesity has developed, an individual's biological mechanisms work to sustain the body's weight gain.<sup>30</sup> Changes in neuronal signaling decrease satiety and perceptions of the amount of food eaten. As a result, weight loss can be challenging.<sup>31</sup> Weight gain can progressively increase over the life span of an adult until later in life. Weight declines after the sixth decade of life.<sup>32</sup> An increasing BMI may lead to increased long-term health risks. Losing weight may reduce the risk for illness and mortality and improve overall health.

#### Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from February 20 to March 19, 2018. In response to comments, the USPSTF expanded the description of behavioral counseling interventions in the Clinical Considerations section. In the Discussion section, the USPSTF clarified why persons who are overweight were not included in the recommendation statement, expanded the description on harms of behavioral counseling interventions and pharmacotherapy, and added the limitations of pharmacotherapy trials.

#### Update of Previous USPSTF Recommendation

This recommendation updates the 2012 USPSTF recommendation statement on screening for obesity in adults (B recommendation).<sup>33</sup>

#### Recommendations of Others

The Canadian Task Force on Preventive Health Care recommends screening for obesity in adults with BMI at primary care visits.<sup>34</sup> The Academy of Nutrition and Dietetics, American College of Cardiology, American Heart Association, and the Obesity Society recommend screening for obesity in adults with BMI and waist circumference.<sup>35,36</sup> The American Association of Clinical Endocrinologists, American College of Endocrinology, and the National Institute for Health and Care Excellence recommend screening for obesity with BMI and using waist circumference as a supplement in adults with a BMI higher than 35.<sup>37,38</sup> The American Academy of Family Physicians recommends screening for obesity in all adults and offering or referring patients with a BMI of 30 or higher to intensive, multicomponent behavioral interventions.<sup>39</sup>

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