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## Randomized Clinical Trials of Weight-Loss Maintenance: A Review

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### Abstract

The problem of overweight and obesity has reached epidemic proportions in the U.S. and globally, and the high prevalence is due in part to the recidivism associated with weight-loss treatment. Approximately one third of lost weight is often regained in the first year after treatment and, at times, continues. Because a plethora of co-morbid diseases are associated with obesity, in particular, cardiovascular disease, hypertension and hyperlipidemia, clinicians and researchers have attempted to find useful strategies for maintaining weight loss. This review presents the findings from 42 randomized clinical trials of weight-loss maintenance from 1984 through 2007 utilizing interventions that include 1) the Internet, 2) strategies after a very-low-calorie diet, 3) pharmacotherapy, 4) behavioral strategies, 5) physical activity, and 6) alternative strategies. The results of the reviewed trials revealed that treatment with orlistat or sibutramine combined with dietary modification, caffeine or protein supplementation, consuming a diet lower in fat, adherence to physical activity routines, prolonged contact with participants, problem-solving therapy and the alternative treatment acupuncture were efficacious in reducing weight regain after weight-loss treatment. The limitations of some studies may reduce the robustness of their findings, and future studies are necessary to replicate and support these results so that individuals are able to maintain weight loss and retain the health benefits associated with a lower weight.

### Keywords

weight loss maintenance; weight loss; obesity; overweight

Overweight and obesity are worldwide, chronic health problems that are associated with heart disease and stroke,<sup>1</sup> and 66.3% of the U.S. population falls into one of these two weight categories.<sup>2</sup> Overweight and obesity are measured by body mass index (BMI), i.e., weight in kilograms divided by height in meters squared. Overweight is defined as a BMI between 25.0 kg/m<sup>2</sup> and 29.9 kg/m<sup>2</sup> and obesity as a BMI > 30 kg/m<sup>2</sup>. Obesity is categorized further by obesity I (BMI between 30.0 kg/m<sup>2</sup> and 34.9 kg/m<sup>2</sup>), obesity II (35.0 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>), and a BMI greater than 40.0 kg/m<sup>2</sup> is obesity III or extreme obesity.<sup>3</sup> With increasing levels of BMI, the associated level of risk for cardiovascular disease (CVD) and development of type 2 diabetes increases; a BMI  $\geq$  30 kg/m<sup>2</sup> is an independent risk factor for CVD.<sup>4</sup> Moreover, central adiposity, mainly visceral fat, is a strong risk factor for hypertension, dyslipidemia, and insulin resistance.<sup>5</sup>

The usual course of weight-loss therapy shows that weight is lost quickly at first, and the point of greatest loss occurs 6 months after beginning treatment; then weight is slowly regained until weight returns near the original level.<sup>6</sup> Often, 30–35% of the weight a person loses is regained during the first year after treatment,<sup>7</sup> and weight gain frequently persists with an average loss of about 1.8 kg remaining at four years after treatment.<sup>8</sup> Approximately 20% of individuals could be considered successful when *successful* weight-loss maintenance is defined as intentionally losing at least 10% of one's weight and maintaining that loss for a minimum of one year.<sup>9</sup> While weight-loss treatment programs have succeeded at assisting people to lose weight, helping to maintain the loss has remained an elusive endeavor despite the use of multiple behavioral change strategies.

Investigations into how to best promote weight-loss maintenance have examined several strategies e.g., ongoing therapist contact, training in relapse prevention, problem-solving therapy, providing prepackaged foods, incorporating support from peers and including multifaceted programs after weight-loss treatment.<sup>10</sup> Relapse prevention training involves instruction in recognizing high-risk circumstances for potential lapses, practicing dealing with high-risk circumstances like eating at parties or restaurants, and restructuring negative thoughts to cope with guilt related to a lapse or failure.<sup>11</sup> The application of problem solving involves a 5-step process that includes having the individual identify the problem, formulate alternative solutions, make decisions, and test and evaluate those decisions until the problem is resolved.<sup>12</sup> Yet even with interventions targeting relapse, the issue of poor maintenance of lost weight remains, causing some to question whether maintenance programs are helpful or only postpone weight regain at an added cost.<sup>13</sup>

Weight loss and maintenance can improve or even prevent risk factors for CVD and the development of co-morbidities related to obesity.<sup>4</sup> Modest weight loss (5–10% of initial weight) is associated with an improvement in several established risk factors for CVD e.g., hypertension,<sup>14–16</sup> dyslipidemia,<sup>4</sup> reduced incidence of type 2 diabetes mellitus,<sup>17–19</sup> as well as improvement in control of diabetes.<sup>20</sup> A meta-analysis of 25 randomized controlled trials examining blood pressure found that a weight loss of 5.1 kg resulted in a 4.44 mm Hg reduction in systolic blood pressure and a 3.57 mm Hg decrease in diastolic blood pressure; significantly greater reductions in blood pressure were seen when the average weight loss was greater than 5 kg.<sup>16</sup> However, the positive effects of weight loss on CVD risk factors do not remain unless weight loss is maintained. While serum triglyceride and LDL cholesterol levels typically decrease during the first two months of weight loss, a weight regain causes lipids to return to former levels,<sup>21</sup> making the prevention of weight regain imperative.

The National Weight Control Registry is an ongoing registry of individuals who have been successful at losing and maintaining a minimum of 13.6 kg for at least 1 year.<sup>22</sup> Many descriptive studies of this cohort have reported on behavioral strategies used by these successful individuals, including increasing physical activity, consuming a low-fat diet, regularly self-

monitoring foods eaten and body weight,<sup>9</sup> restricting the variety of foods eaten,<sup>23</sup> consuming a consistent weekly diet,<sup>24</sup> eating breakfast,<sup>25</sup> and limiting the amount of time spent watching television.<sup>26</sup> The generalizability of this information is limited, however, by the descriptive nature of the studies and the demographics of the sample, which is 77% female and 95% Caucasian with 82% having a college education.<sup>27</sup> Because of the rigorous methodology, the most robust empirical evidence comes from the randomized clinical trial (RCT), which is considered the second strongest level in the hierarchy of evidence, after meta-analyses of controlled trials.<sup>28</sup> Therefore, the purpose of this paper is to summarize for clinicians and researchers the findings of RCTs that tested strategies for weight-loss maintenance and the efficacy of these interventions.

## Methods

In order to assess what methods have been reported as beneficial for maintaining weight loss, the existing literature was searched electronically using the databases of Medline, Allied and Complementary Medicine (AMED), Cumulative Index to Nursing & Allied Health Literature (CINAHL), and PsycINFO using the keywords *weight loss maintenance*, *weight loss*, *obesity*, *overweight*, and *long-term weight loss*. In addition, a hand search of pertinent articles was conducted for other relevant articles. The criteria for inclusion in the review were 1) a randomized clinical trial of a weight-loss maintenance intervention after an initial weight loss, 2) adult population (18 years of age, 1 trial > 17 years old), and 3) English language. In order to isolate the specific effect on weight-loss maintenance, only trials that used a true experimental design and randomly assigned participants to an intervention for maintenance were included. Thus, weight-loss trials with a maintenance phase that did not randomly assign participants to the maintenance intervention were excluded. Because some early papers were identified as important in the development of knowledge related to weight-loss maintenance, papers from 1984 to 2007 were included. Subsequent articles reporting on the same intervention study were excluded. Four-hundred and eighty-two relevant articles were initially identified. Most were excluded because they did not report on a randomized clinical trial of weight-loss maintenance (n = 314). Others were excluded because the main outcome was not weight-loss maintenance, e.g. short-term weight loss, metabolic syndrome, diabetes (n = 126). Thus, 42 articles on weight-loss maintenance were included in the review. Findings from the studies were organized according to the types of interventions used for weight-loss maintenance, and six categories of studies were found, those using 1) the Internet, 2) maintenance strategies after a very-low-calorie diet, 3) pharmacotherapy, 4) behavior therapy, 5) physical activity, and 6) alternative therapies. Most trials required that participants lost at least 5% of initial body weight during the weight-loss period before being randomized to the weight-loss maintenance intervention, although one medication trial required only a 2% weight loss.<sup>29</sup> Measures of the principal outcome of interest, weight change (continued loss, maintenance, or regain), were expressed in 1) absolute weight change (kg or lbs) or percentage of weight loss from the completion of the weight-loss period to the completion of the maintenance intervention or 2) from prior to weight-loss treatment to the end of maintenance or follow up based on the reporting of the article. In order to determine the magnitude of the treatment effect for each study, effect sizes (ES) were calculated by converting the p-value to a z-score and using the equation,  $ES = \Phi = Z / n^{1/2}$ , unless a p-value was not reported, then the Cohen's *d* was determined from the difference between the two group means divided by the pooled standard deviation for those means.<sup>30</sup>

## Findings

### Internet

Technological advances have permitted the use of less traditional methods for encouraging weight-loss maintenance. The four randomized trials listed in Table 1 used the Internet as an innovative strategy to assist participants in sustaining their lost weight. In general, these studies compared the use of an Internet-based weight-loss maintenance intervention with online chat room sessions to in-person group behavioral therapy sessions after a behavioral weight-loss trial.<sup>31–34</sup> Results were mixed, and two studies found no difference in weight-loss maintenance between groups, suggesting that a behavioral intervention conducted over the Internet may be as effective as in-person without the higher cost of conducting face-to-face treatment.<sup>31, 33</sup> Harvey-Berino et al<sup>31</sup> found the program via the Internet resulted in long-term weight losses similar to in-person programs. In an earlier trial by this group, all persons continued to lose weight during weight maintenance despite no significant differences between groups.<sup>33</sup> However, a comparison of Internet treatment to minimal and frequent in-person treatment found that the Internet group maintained significantly less weight at the end of the trial than the in-person groups,  $p < .05$ ; weight maintenance differences were observed between the different types of participant contact rather than the different intensities of contact.<sup>32</sup> Similarly, after controlling for percent weight loss during the weight-loss trial, an Internet chat room intervention was found to be less effective in preventing weight regain than the in-person, group behavioral treatment,  $p = .02$ ; yet, adherence to the self-regulatory behavior of weighing oneself was significantly related to maintaining weight loss,  $p < .001$ .<sup>34</sup>

### Very-Low-Calorie Diet (VLCD)

Nineteen reviewed studies examined weight-loss maintenance trials after a VLCD and have included additional intervention strategies such as 1) medications, 2) meal replacements, macronutrient and other dietary intervention or supplementation, 3) periodic use of the VLCD or prepackaged foods, and 4) exercise. A VLCD usually provides less than 800 kcal/day in a liquid form, is medically supervised to monitor electrolyte balance, includes vitamin and mineral supplementation and has been shown to produce rapid, substantial weight loss.<sup>35</sup> However, sizable weight regain after these diets is also typical,<sup>36</sup> and they may offer no long-term benefit over traditional reduced-calorie diets.<sup>37, 38</sup> The reviewed studies began with a VLCD for varying lengths of time (4 to 16 weeks) using caloric intakes ranging from 220 to 1000 kcal/day, and then participants were randomized to a weight-loss maintenance intervention. See Table 2.

**VLCD followed by medications in maintenance**—In seven trials of weight-loss maintenance after a VLCD, four types of medications were administered— orlistat, sibutramine, acarbose, or sertraline. Three studies examined orlistat,<sup>39–41</sup> a lipase inhibitor that decreases absorption of dietary fat in the gastrointestinal tract.<sup>42</sup> Two trials investigated sibutramine,<sup>43, 44</sup> which suppresses appetite by inhibiting the reuptake of norepinephrine and serotonin.<sup>45</sup> The effect on weight-loss maintenance of acarbose, an oral medication to treat type 2 diabetes, and sertraline, a serotonin reuptake inhibitor, was evaluated in one study each.<sup>46, 47</sup> One trial using orlistat versus placebo<sup>39</sup> and one examining orlistat versus meal replacements<sup>40</sup> found no difference in weight regain between groups at completion of the intervention. Laaksonen and colleagues found that those who lost and maintained a loss of  $\geq 10\%$  regained less weight during weight maintenance than those who lost less.<sup>39</sup> In a 3-year study where participants received orlistat or placebo, the orlistat group maintained 2.4 kg more lost weight than those receiving placebo; 67% in the orlistat group compared to 56% in the placebo group were 5% or more below baseline weight at 3 years,  $p = .037$ .<sup>41</sup> While all three orlistat studies used some form of a reduced-calorie diet for all participants, only the 3-year study resulted in significant differences between groups. Both sibutramine interventions were

of a sizable length and found weight-loss maintenance to be superior in the sibutramine groups versus placebo,<sup>43, 44</sup> with a greater proportion of the sibutramine group in one trial<sup>43</sup> maintaining a higher percentage of lost weight than the other.<sup>44</sup> Weight loss by VLCD was better sustained with sibutramine and reduced-calorie diet than with placebo and reduced-calorie diet.<sup>44</sup> Apfelbaum et al<sup>43</sup> found that those who received sibutramine continued to lose weight in the weight maintenance period while those who received a placebo regained. (Table 2). In terms of weight regain, there was no difference between acarbose and placebo, with both groups remaining relatively weight stable and no observed benefit from acarbose.<sup>46</sup> Wadden and colleagues found that the sertraline group regained more of their lost weight than placebo,  $p = NS$ , but that both groups maintained more than 8% of their original weight loss.<sup>47</sup>

**VLCD followed by a dietary component in maintenance**—Table 2 also lists seven trials after a VLCD that evaluated the use of a dietary intervention, macronutrients, and other dietary supplements. Treatments used included an ad lib, high-carbohydrate low-fat diet versus a calorie-restricted diet,<sup>48</sup> green tea use,<sup>49, 50</sup> increasing protein intake,<sup>51, 52</sup> adding fiber,<sup>53</sup> and supplementing carbohydrate intake.<sup>54</sup> One study tested the effect of an ad lib, high-carbohydrate, low-fat diet compared to a reduced-calorie diet (1875 kcal/day) that utilized color-coded cards to represent food groups and calorie content; the ad lib group regained less weight. Consumed calories from fat were higher in the reduced-calorie group compared to the ad-lib group, suggesting that eating a lower-fat diet could be important in weight-loss maintenance.<sup>48</sup> The effect of a green tea-caffeine mixture on weight-loss maintenance appears to be contingent upon the individual's baseline level of caffeine intake. For example, Kovacs et al<sup>49</sup> found no difference in weight regain between the green tea and placebo groups until the sample was divided into low (< 300 mg) and high (> 300 mg) caffeine consumers for the analysis; the high caffeine consumers regained more weight than the low caffeine consumers,  $p < .05$ .<sup>49</sup> A later study by the same investigators reported that the percentage of weight regained was significantly less in the group who received the green tea mixture & had consumed low levels of caffeine at baseline,  $p < .01$ , suggesting a possible maximum effect of caffeine on weight management and thermogenesis.<sup>50</sup> Increased protein intake resulted in less weight regain in two studies testing the effect of 30 g/day<sup>51</sup> and 42.8 g/day<sup>52</sup> of added protein. Although both studies were relatively short in duration (see Table 2), both reported increased satiety in the participants receiving additional protein, with those who received the higher amount of protein regaining 50% less weight than the placebo group.<sup>52</sup> In both studies, the actual consumption of protein was 18% of calories in the protein groups compared to 15% of calories from protein in the control groups.<sup>51, 52</sup> Neither the trial examining the effect of supplementing fiber<sup>53</sup> nor the evaluation of added carbohydrate with fiber, caffeine, and chromium picolinate<sup>54</sup> found any difference in amount of weight regained between the intervention and control groups.

**VLCD followed by VLCD use in maintenance**—The results of three studies that included the occasional use of a VLCD during maintenance or provided foods after VLCD-induced weight loss indicated that weight regain was similar among the randomized groups.<sup>55–57</sup> For example, the group who received a late afternoon 239 kcal reconstituted drink, as part of a reduced-calorie diet to prevent overeating in the evening, regained a similar amount of weight as the reduced-calorie diet only group. Weight maintenance after 24 months was the same for all groups whether or not a VLCD was included in the maintenance phase.<sup>57</sup> An examination of two methods of using a VLCD for weight maintenance determined that weight regain was similar between those who used a VLCD intermittently and those who used a VLCD as needed, i.e., when their weight exceeded the end of weight-loss treatment weight by 3 kg; yet, clinically significant weight losses were maintained in a majority of both groups after two years of continued VLCD use.<sup>56</sup> Table 2 shows that participants randomized to one of four treatment groups to examine the effect of limiting food variety with prepackaged meals and

individualizing the pace of solid food reintroduction after a VLCD were not significantly different in weight-loss maintenance at the end the trial.<sup>55</sup>

**VLCD followed by physical activity in maintenance**—Two randomized trials of weight-loss maintenance explored the role of physical activity after a VLCD.<sup>58, 59</sup> The trial conducted in only women compared a control group (no increase in exercise) to a walking group with a caloric expenditure goal of 1,000 kcal/week and a walking group with a goal of expending 2,000 kcal/week.<sup>59</sup> The other trial enrolled only male participants and randomized participants to resistance training, or walking, or control.<sup>58</sup> Both studies offered counseling to follow a low-fat diet. Although neither study found a difference between groups in weight regain at the completion of the trial (Table 2), adherence to the exercise prescription was negatively correlated with weight gain ( $r = -0.43, p < .01$ ), and resistance training reduced the regain of body fat mass in the sample of men.<sup>58</sup> In the trial with women, a higher number of daily steps was significantly associated with weight-loss maintenance, and slightly better maintenance in the 1,000 kcal/week group suggests that a moderate exercise prescription was easier to follow.<sup>59</sup>

### Pharmacotherapy

Table 3 lists the seven trials that used medication, either sibutramine<sup>29, 60, 61</sup> or orlistat,<sup>62–65</sup> with dietary instructions or dietary support in randomized maintenance interventions following a drug therapy weight-loss trial. Two sibutramine studies compared a 15mg/day dose to placebo,<sup>29, 60</sup> and one trial used 10 mg/day, which could be increased to a maximum of 20 mg/day if additional weight gain occurred.<sup>61</sup> All three sibutramine studies found the drug to be superior in sustaining weight loss when compared to placebo.<sup>29, 60, 61</sup> No difference was found between groups who received a continuous or periodically interrupted dose,  $p = .28$ .<sup>29</sup> However, one trial compared sibutramine and meal replacements to placebo and a traditional, reduced-calorie diet, making it difficult to discern which element of the drug therapy arm contributed to the efficacy of the intervention. Of note, a higher proportion of black participants in this trial failed to meet the eligibility criteria for the maintenance phase of a  $\geq 5\%$  weight loss.<sup>60</sup> The four orlistat studies all used 1-year maintenance interventions and found the medication to be more efficacious for promoting weight-loss maintenance than placebo.<sup>62–65</sup> Participants who received continuous treatment with orlistat 120 mg/TID for 2 years (during weight loss and during weight maintenance) experienced the least amount of regain.<sup>64</sup> Administering higher doses resulted in less regain.<sup>62, 63</sup> In fact, Hill and colleagues found that a higher proportion of the group that received orlistat 120 mg TID regained  $\leq 25\%$  of their body weight compared to placebo,  $p < .001$ .<sup>63</sup>

### Behavior Therapy

Ten studies used some form of a behavioral therapy in randomized trials for weight-loss maintenance. (Table 4). Perri and colleagues conducted five such studies between 1984 and 2001 in an effort to improve maintenance after behavioral weight-loss treatment. Early research by these researchers found weight regain to be attenuated by forming peer social support groups and receiving weekly therapist phone calls,  $p < .01$ ,<sup>66</sup> continued interventionist contact via mail and telephone,  $p < .05$ ,<sup>67</sup> particularly when combined with behavioral and problem-solving therapy during weight loss compared to behavior therapy only,  $p < .05$ ,<sup>68</sup> and including more treatment components in the intervention, i.e., behavior therapy, therapist contact, aerobic exercise, and social support  $p < .01$ .<sup>69</sup> More recent findings by Perri et al<sup>70</sup> indicate that problem-solving therapy is significantly better at promoting weight maintenance compared to a no-contact control condition over a 1-year maintenance period,  $p < .05$ . These results also suggest that problem-solving therapy may be superior to relapse-prevention training in longer-term maintenance (11–17 months),  $p = .013$ .<sup>70</sup> The sessions for the relapse-prevention training groups included didactic lectures designed to train participants in specific maintenance skills.

The problem-solving therapy group meetings did not include didactic material but centered on therapist-led group discussions about solutions to participant-introduced weight management issues. The finding of an improved outcome in the problem-solving therapy group suggests that participants may have benefited more from the group discussions and less instructive methods.

Building on the results of Perri and colleagues, other researchers have investigated continued participant contact for weight maintenance with less definitive results after inpatient weight-loss treatment,<sup>71</sup> using phone contact or optional prepackaged meals,<sup>72</sup> and mailing personalized reports.<sup>73</sup> In the maintenance study following 10 weeks of inpatient weight-loss treatment, the group randomized to the control condition did receive detailed materials to support long-term behavior change; some individuals also formed peer support groups.<sup>71</sup> Riebe et al<sup>73</sup> mailed to the treatment group additional reports, individualized to the person's stage of change in the Transtheoretical Model of Health Behavior Change, but this did not influence weight maintenance as the treatment and control groups both regained about 3 kg. See Table 4. Two studies by Wing and colleagues were published together.<sup>72</sup> In the first study, weekly phone calls to the treatment group inquiring about self-weighing and self-monitoring food and exercise behaviors did not influence weight regain; however, calls were made by individuals who were unknown to the participant.<sup>72</sup> In the second study, participants randomly assigned to the treatment group were required to purchase prepackaged meals if they wished to use them. No difference in weight regain was observed between the treatment and control groups. Of those who chose to purchase the food boxes, weight regain was no different,  $p = .11$ .<sup>72</sup> A study examining financial incentives for maintaining weight or for participating in weight-maintenance behaviors found that the two treatment groups were not different from the controls in the amount of weight they regained; all participants sustained about half of their lost weight.<sup>74</sup> A study with African Americans that used a culturally-tailored intervention did not find a difference in weight regain between the clinic-visit-only usual care group and the two intervention arms, group counseling and staff-assisted self-help.<sup>75</sup> The average regain for all participants was minimal, but the initial weight loss achieved was only 1.2 kg. Being in the highest tertile of weight loss during the weight-loss treatment phase was the strongest predictor of overall loss and maintenance,  $p = .002$ .<sup>75</sup>

### Physical Activity and Alternative Therapies

Only two studies examined either the effect of a physical activity intervention or an alternative therapy method in randomized trials of weight-loss maintenance and are not represented in a table. While research has documented the importance of physical activity in weight loss and maintenance,<sup>76-82</sup> only one trial, not conducted after a VLCD, randomized participants to a weight-loss maintenance intervention that focused on the effect of physical activity in preventing weight regain. Leermakers and colleagues randomly assigned 67 participants to either an exercise-centered intervention or a weight-centered intervention after a behavioral weight-loss study.<sup>83</sup> The weight-centered treatment focused on dealing with participant-introduced barriers to weight-loss maintenance, and the exercised-centered intervention focused on sustaining physical activity, e.g., organized biweekly exercise sessions, incentives for meeting exercise goals, and problem-solving for handling exercise lapses. While both groups regained weight during the trial and 6-month follow-up, the weight-centered group regained less weight,  $p < .01$  (effect size = .31), and ate fewer calories from fat,  $p < .05$  (effect size = .24), suggesting that the exercised-centered intervention might not have included enough emphasis on controlling dietary intake.<sup>83</sup> The 12-week alternative therapy trial included 10 hours of group meetings and explored the effects of randomly assigning 92 participants to *qigong*, Tapas Acupressure Technique<sup>R</sup> (TAT), or a support group.<sup>84</sup> *Qigong* is an ancient Chinese healing discipline that consists of a combination of breathing, mental exercises, and physical movements. TAT merges acupressure with mental focusing to change stored energy

patterns in the body. The support group reviewed handouts related to weight-loss maintenance. At the 3-month follow-up, the TAT group had regained significantly less weight (+0.1 kg) than the *qigong* group (+2.8 kg),  $p < .01$  (effect size = .36), and marginally less than the support group (+1.2 kg),  $p = .09$  (effect size = .24).<sup>84</sup>

## Summary of Study Effect Sizes

Of the studies examined, 39% had fewer than 100 participants and might have been underpowered to detect a difference in treatment effect. Only the phone intervention study by Wing and colleagues reported a small-medium effect size of 0.30 for the difference between the treatment and control groups.<sup>72</sup> Effect sizes noted in the tables ranged from a very small .01<sup>57</sup> to a medium-large effect of .60 for the study comparing the medication sertraline to placebo.<sup>47</sup> This latter study reported that the difference between groups in weight regain was non-significant, although a medium-large effect size was found suggesting that a sample size of 30 participants was not large enough to detect the effect.

## Discussion

The findings from this review show that a limited number of interventions tested in randomized clinical trials have been successful in assisting individuals to maintain their initial weight loss after treatment. The reviewed studies suggest that promising methods for reducing weight regain include some medications, inclusion of caffeine, added dietary protein, adherence to physical activity, continued weight-loss therapist contact, consuming fewer calories from fat, and alternative strategies such as acupuncture. A small number of studies detected a significant influence on weight regain. Table 5 presents a summary of the strategies from this review noted to be beneficial for weight-loss maintenance. According to the levels of evidence established by the American College of Cardiology and American Heart Association,<sup>85</sup> most strategies listed would meet the level of evidence B, as data are from relatively few trials that are smaller in size, indicating that the evidence is limited regarding these strategies. Maintenance of lost weight is a complex undertaking, and long-term data on weight-loss maintenance are still lacking. Over time, it becomes increasingly difficult for persons to continue to follow the weight-management strategies learned during the course of weight-loss treatment. Ongoing weight management may require the use of a continuous care model<sup>86</sup> in order to help individuals sustain the lifestyle changes that promoted the initial weight loss.

Methodological limitations of the reported studies, e.g., small sample size, participant attrition, short treatment duration, and sample characteristics that limit generalizability, (e.g., mostly women, mostly White), suggest that replication of these clinical trials with attention to their methodological limitations is needed. Many trials were limited by a lack of male and minority representation in the study sample. With the exception of one trial,<sup>58</sup> the reviewed studies consisted of mostly or all women, limiting the generalizability of findings to women. One trial that enrolled nearly 50% men found that the effect of orlistat versus placebo was significant in women, but not in men over the 3 years.<sup>41</sup> Few studies even reported on the ethnicity of participants, and all but one included predominantly white individuals. Early et al<sup>60</sup> found that a higher proportion of Blacks and African Americans failed to meet the eligibility criteria for randomization to the weight-maintenance intervention,  $\geq 5\%$  weight loss. The study that included only African American participants reported an overall small weight loss from pre-treatment through weight maintenance.<sup>75</sup> These two trials attest to potential ethnic differences in weight management that are not explored in trials with nearly all white participants. Another limitation of all but one of these trials<sup>34</sup> is that there was no specific identification of a theory-base for the RCT. The study by Wing and colleagues utilized self-regulation theory in the design of their intervention using the Internet to promote weight maintenance,<sup>34</sup> but otherwise the lack of theory-based interventions is a notable limitation to these trials.



Ten reviewed trials had attrition rates of more than 35%, complicating the interpretability of the findings and introducing the possibility of a selection bias,<sup>87</sup> particularly in weight management studies where participants who have not lost/maintained weight may be more likely to drop out.<sup>88</sup> A strength of the randomized clinical trial is the intention-to-treat analysis, which incorporates all participants according to their randomized group assignment without consideration to withdrawal or departure from treatment.<sup>89</sup> However, a true intention-to-treat analysis requires that all participants be followed to the end of the trial, which is often very difficult in longitudinal studies.

Nearly half the studies included in this review examined the efficacy of an intervention after a very-low-calorie diet. Perhaps because these diets result in greater initial weight losses in the short-term,<sup>37</sup> several researchers have attempted to identify strategies for maintaining these significant weight reductions long term. A larger weight loss with VLCD has been found to be associated with a higher percentage of weight-loss maintenance after more than 2 years,<sup>90</sup> but some evidence suggests that there is a sizable variation in the percent of weight regained from initial losses at one-year (-7% to 122%) and five-year follow-up (26% to 121%).<sup>36</sup> Pharmacotherapy trials found sibutramine and orlistat to improve weight maintenance after VLCD as well as after initial treatment with the drug and a reduced-caloric intake. These medications may indeed be helpful tools in weight-loss maintenance when combined with an adjustment in dietary intake. It is important to recognize the role of lifestyle modification with reduced caloric intake and increased activity in obesity treatment in combination with orlistat and sibutramine, and that these medications are not without side effects. Sibutramine is associated with elevations in blood pressure and heart rate. Orlistat, which has recently become available as an over-the-counter medication (Alli), has gastrointestinal side effects like oily stools, fecal urgency and incontinence, or reduced fat-soluble vitamin absorption.<sup>91</sup> Additionally, these medications are only approved for up to two years of ongoing use,<sup>91</sup> and weight regain occurs after the medication is stopped.<sup>43</sup> A recent population-based Canadian study found that discontinuation rates in the community were much higher for both drugs than rates observed in clinical trials, and 98% of individuals had stopped taking the medication at 2 years.<sup>92</sup>

Other treatments noted to be effective after a VLCD included a green-tea mixture, additional dietary protein, and physical activity adherence. Because the efficacy of a green-tea mix was found in only one study and only the group of participants who tended to consume lower levels of caffeine, these results should be interpreted cautiously. However, a large observational study over 12 years recently found increases in caffeine consumption to be associated with less weight gain.<sup>93</sup> The positive<sup>94-96</sup> and negative effects<sup>95, 97, 98</sup> of caffeine on health have been debated. Consequently, the use of increased caffeine for weight-loss maintenance may be controversial.

The addition of protein to dietary intake resulted in less body weight regain, consisting of only fat-free mass, even when physical activity levels were similar between groups. The level of satiety was also higher in the group that consumed more protein, although actual dietary intake did not differ.<sup>52</sup> While others have documented that higher protein diets resulted in greater weight loss in the short term,<sup>99-101</sup> the long-term effectiveness of this eating plan has not been well documented. The two protein trials examined here were 3 or 6 months in length; thus, additional exploration of the role of higher protein intake in the long-term is necessary.

The reviewed studies of physical activity and weight maintenance after weight loss via VLCD did not report a difference in regain between randomized treatment groups. However, higher levels of physical activity, i.e., estimated total energy expenditure<sup>58</sup> and daily steps taken,<sup>59</sup> were associated with improved maintenance. The exercised-focused intervention that followed behavioral weight-loss treatment found the exercise-group had a poorer outcome compared to

the weight-focused group; however, there were no differences between the two groups in 24-hour estimated energy expenditure, as measured by accelerometer.<sup>83</sup> This suggests that the group that was intended to have a greater emphasis on exercise perhaps, in reality, did not. In fact, inadequate adherence to the physical activity protocol may be a key reason why randomized trials frequently fail to find a relationship between physical activity and weight maintenance.<sup>102</sup> The important role of physical activity in weight maintenance has been well documented,<sup>79, 81, 82, 103, 104</sup> with particular emphasis placed on the value of long-term adherence to physical activity.<sup>105</sup> Current recommendations for maintaining lost weight in adults include participation in a minimum of 60 to 90 minutes of moderate-intensity activity each day,<sup>106</sup> a level of physical activity that may be difficult for many individuals to achieve and or maintain.

The reviewed behavioral weight-loss maintenance interventions showed that maintaining contact with participants was influential in reducing weight regain. While ongoing communication with participants is beneficial for sustaining weight loss,<sup>66, 68</sup> the method of the continued contact could be important to the participants' success. For example, the telephone calls made by interviewers unknown to the participants, not the participant's interventionist, did not result in an improved outcome.<sup>72</sup> Additionally, using the Internet as a means of continued contact had mixed results with two studies reporting that Internet support was as effective in preventing regain as in-person contact,<sup>31, 33</sup> and two studies reporting that the Internet groups regained more weight than in-person groups.<sup>32, 34</sup> In fact, 70% of persons in one Internet group indicated at the 12-month assessment that they would have preferred to be in the group that met in-person,<sup>32</sup> demonstrating the importance of participant acceptability of the intervention.

The findings of one reviewed study revealed that the more successful group had a lower intake of calories from fat.<sup>48</sup> These results are supported by much of the weight-management literature.<sup>107-111</sup> Yet, a recent 14-month study comparing the effects of a moderate-fat intake (30% of calorie intake) to a diet low in fat (20% of calorie intake) found improved long-term weight losses in the moderate-fat intake group; the authors indicated that dietary adherence in the moderate-fat group might have been easier to attain, and thus, more successful weight-loss outcomes resulted.<sup>112</sup> Others have noted improved adherence and weight loss with a moderate-fat intake in an 18-month trial.<sup>113</sup> A Cochrane Review of randomized controlled weight-loss trials of low-fat diets compared to other diets found no significant benefit of low-fat diets over other types of weight-loss diets in maintaining long-term weight loss.<sup>114</sup> Future research should explore the role of enhanced dietary adherence and low-fat versus moderate-fat intake for weight management.

Acupressure was shown to have efficacy as an alternative treatment for weight-loss maintenance.<sup>84</sup> However, this study included only 43 participants and was just 12 weeks in length after 12 weeks of weight-loss treatment, a time period that coincides with typical peak weight-loss.<sup>6</sup> Another trial that examined acupressure for weight loss found no significant effect.<sup>115</sup> This area of treatment for weight-loss maintenance is relatively unexplored and might warrant further research in larger and long-term trials.<sup>116, 117</sup>

## Implications for Nursing

Medical care of the obese patient often includes treating obesity-related conditions like hypertension, hyperlipidemia, or type 2 diabetes mellitus without equal attention to the underlying contributing factor of weight. Assisting patients with weight-loss maintenance remains a formidable challenge for nurses as well as all health care professionals. It is imperative for nurses to understand that the clinical benefits of weight loss are only transient if the reduced weight is not maintained. Health care providers need to emphasize the favorable

health effects that result from losing and maintaining a moderate 10% weight loss, and help each individual to have a realistic weight-loss goal.<sup>4</sup> The National Heart, Lung, and Blood Institute and North American Association for the Study of Obesity have specified that a program of weight maintenance should be implemented after 6 months of weight-loss treatment and that the practitioner has a responsibility for following the patient long term to encourage the maintenance of lost weight.<sup>118</sup> Because ongoing contact with persons was found to be beneficial for weight-loss maintenance,<sup>66–68</sup> nurses can make follow-up phone calls to stay in contact with and monitor the patient's weight management efforts. By learning about the strategies that are effective for weight-loss maintenance, nurses can contribute significantly as supportive clinicians to addressing this major health problem.

## Conclusion

The lack of prolonged success in behavioral therapy for weight loss has been recognized for approximately 30 years.<sup>119–121</sup> Longer weight-loss trials have helped individuals lose more weight initially,<sup>6</sup> but extended maintenance of the weight loss is not necessarily realized. The reviewed studies found that weight-loss maintenance treatment with orlistat or sibutramine and dietary modification, supplementing caffeine or protein, following a lower-fat diet, adherence to physical activity, continued participant contact, problem-solving therapy, and the alternative treatment acupuncture were effective in reducing weight regain after weight-loss treatment. Additional studies are needed to confirm and expand upon these findings. Future research should explore the safety and efficacy of orlistat and sibutramine beyond the 2-year time period currently approved by the Food and Drug Administration. Further investigation of innovative strategies to promote adherence to a lower dietary fat intake and increased physical activity will likely be beneficial in assisting with weight maintenance. Future research should determine the most appropriate, cost-effective ways to maintain contact with and provide support to individuals in their weight maintenance efforts. Finally, the development of unexplored, novel strategies to promote weight-loss maintenance is also imperative so that individuals are able to sustain the weight loss they work so hard to achieve.

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Table 1

## Internet

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Harvey-Berino et al <sup>33</sup>	46 (37 women) 41 at end of trial 4% attrition "mostly White"	<b>3-GROUP DESIGN:</b> Control -no treatment <i>In-person therapist-led Internet therapist-led</i> Biweekly meetings in person or chat session with same behavioral content, self-monitoring diet & physical activity. Call or e-mail on alternate weeks.	22-week WM after 15 weeks of behavioral WL	<i>During WM:</i> All groups lost an average of 1.6 kg additional weight during the 22 weeks of WM with no between group differences, $p = .83$ .	25% of total weight loss experienced by the total sample during the trial was lost during 15 weeks of WM	.03
Harvey-Berino et al <sup>32</sup>	122 (104 women) 90 at end of trial 26% attrition > 96% White	<b>3-GROUP DESIGN:</b> <i>Frequent in-person (FIP)</i> biweekly meetings <i>Minimal in-person (MIP)</i> monthly meetings for 6 months, then no contact <i>Internet support (IS)</i> biweekly chat sessions Same behavioral content, self-monitoring diet & physical activity. Call or e-mail on alternate weeks, FIP & IS.	1-year WM after 24 weeks behavioral WL	<i>Prior to WL Rx through WM:</i> <i>Frequent in-person</i> -10.4 ± 6.3 kg <i>Minimal in-person</i> -10.4 ± 9.3 kg <i>Internet</i> -5.7 ± 5.9 kg $p < .05$ for between group differences. IS group sustained less WL than FIP & MIP.	More of the FIP & MIP groups maintained a ≥ 5% WL, $p < .02$ . FIP: 84% MIP: 81.3% IS: 44.4%	.20
Harvey-Berino et al <sup>31</sup>	232 (194 women) 176 at end of trial 24% attrition 100% White	<b>3-GROUP DESIGN</b> <i>Frequent in-person (FIP)</i> biweekly meetings at local interactive T.V. (ITV) studio <i>Minimal in-person (MIP)</i> monthly meetings at ITV studio for 6 months, then no contact <i>Internet support (IS)</i> biweekly chat sessions Same behavioral content, self-monitoring diet & physical activity. Call or e-mail on "off" weeks, FIP & IS.	1-year WM after 6 months behavioral WL via ITV (live group members with a televised therapist)	<i>Prior to WL Rx through WM:</i> <i>Frequent in-person</i> -5.1 ± 6.5 kg <i>Minimal in-person</i> -5.5 ± 8.9 kg <i>Internet</i> -7.6 ± 7.3 kg $p = .22$ for between group differences.	<i>Percent who maintained a ≥ 5% WL:</i> FIP: 46% MIP: 49% IS: 62% $p = .23$ for between group differences.	.08
Wing et al <sup>34</sup>	314 (255 women) 291 at end of trial 7% attrition Ethnicity not reported	<b>3-GROUP DESIGN:</b> <i>Control</i> monthly informational newsletter <i>In-person</i> weekly group meetings for 1 <sup>st</sup> month, then monthly; submitted weekly weights via telephone system <i>Internet</i> weekly group meetings for 1 <sup>st</sup> month, then monthly via chat room; submitted weekly weights online	18-month WM- subjects had lost ≥ 10% of body weight in the previous 2 years	<i>During WM:</i> <i>Control</i> +4.9 ± 6.5 kg <i>In-person</i> +2.5 ± 6.7 kg <i>Internet</i> +4.7 ± 8.6 kg $p = .05$ for difference between in-person and control groups	<i>Percent who regained ≥ 2.3 kg:</i> <i>Control</i> 72.4% <i>In-person</i> 45.7% <i>Internet</i> 54.8% $p = .008$ and $p < .001$ for difference between control & Internet and control & in-person, respectively.	.11

Abbreviations: WL, weight loss; WM, weight maintenance; Tx, treatment.

$\alpha$  mean  $\pm$  standard deviation.

## Treatment after a Very-Low-Calorie-Diet

Table 2

Study	N	Treatment	Medication Use			Effect Size
			Length of WM Tx	Results	% Weight Change	
Richelsen et al <sup>41</sup>	309 (157 women) 200 at end of trial 35% attrition Ethnicity not reported	2-GROUP DESIGN: Orlistat 120mg TID Placebo Both groups were prescribed a reduced calorie diet (-600 kcal/d); visits with dietary and lifestyle counseling every mo for 18 mo then every 3 mo thereafter	3-year WM after 8- week VLCD	During WM <sup>a</sup> : Orlistat +4.6 ± 8.6kg Placebo +7.0 ± 7.1kg p < .02 for group differences	After 3 years: Men Orlistat: -8.3% Placebo: -7.5%, p = NS Women Orlistat: -8.4% Placebo: -5.3%, p < .02	.13
Laaksonen et al <sup>39</sup>	41 (20 women) 34 at end of trial 17% attrition Ethnicity not reported	2-GROUP DESIGN: Orlistat 120mg TID Placebo Both followed a reduced-calorie and fat diet of at least 1200 kcal/d personalized according to estimated energy expenditure	1-year WM after 9- week VLCD	Prior to WL Rx through WM <sup>a</sup> : -12.6 ± 7.4 kg for entire sample with no difference between groups, p- value not reported	Those who lost ≥ 10% <sup>a</sup> : Weight change in the last 6 months was +0.6 ± 2.3 kg	Unable to determine from data provided.
LeCheminant et al <sup>40</sup>	147 (107 women) 92 at end of trial 41% attrition Ethnicity not reported	2-GROUP DESIGN: 2 meal replacements daily + meal plan Orlistat 120 mg BID + meal plan In both groups the meal plan was to maintain weight; weekly group meetings in lifestyle modification until 26 weeks then biweekly thereafter.	36-week WM after 12-week VLCD & 4 weeks of solid foods	Weight after WL <sup>a</sup> : Meal replacements 85.4 ± 14.3 kg Orlistat 120 mg 85.7 ± 17.9 kg Weight after WM <sup>a</sup> : Meal replacements 88.1 ± 16.5 kg Orlistat 120 mg 88.5 ± 20.5 kg	During WM: Men 4.9% increase in body weight, p < .05 Women 2.4% increase in body weight, p = NS	.02
Mathus-Vliegen et al <sup>44</sup>	189 (162 women) 119 at end of trial 37% attrition >98% White	2-GROUP DESIGN: Sibutramine 10mg/d- could increase to 15 mg after 6 mo if weight gain of > 3 kg Placebo Both groups had biweekly meetings with GP and dietitian for 2 mo, monthly until 12 mo & bi-monthly thereafter; 600 calorie- deficit/d	18-month WM after 10-week VLCD & 2 weeks of solid foods	Prior to WL Rx through WM <sup>a</sup> : Sibutramine -10.7 ± 0.5 kg or -10.3 ± 7.0% Placebo -8.5 ± 8.1 kg or -7.9 ± 7.3%	During WM: Sibutramine +4.1 kg or 4.5% Placebo +6.7 kg or 7.6% p = .004 for between group differences	.21
Apfelbaum et al <sup>43</sup>	160 (127 women) 108 at end of trial 32% attrition Ethnicity not reported	2-GROUP DESIGN: Sibutramine 10mg/d Placebo Both groups had dietary counseling to consume 20-30% less total calories than pre-weight loss intake; individual meeting with	1-year WM after 4-week VLCD	During WM <sup>a</sup> : Sibutramine 10mg/d -5.2 ± 7.5 kg Placebo +0.5 ± 5.7 kg p = .004 for group differences	Sibutramine 75% of group sustained ≥ 100% of lost weight Placebo 42% of group sustained ≥ 100% of lost weight p = .004 for group differences	.23

Study	N	Treatment	Medication Use		Results	% Weight Change	Effect Size
			Length of WM Tx	Results			
Hauner et al <sup>46</sup>	110 (84 women) 75 at end of trial 29% attrition 100% White	dietician every 3 months; assessments monthly <i>2-GROUP DESIGN:</i> <i>Acarbose</i> 50–300 mg/d (titrated weekly; 59.3% of group took 300 mg <i>Placebo</i> Both groups were advised to follow a personalized WM diet	26-week WM after 12-week VLCD	<i>During WM:</i> <i>Acarbose</i> no weight gain <i>Placebo</i> +0.6 kg $p = .38$ for group differences	<i>Acarbose</i> No weight change <i>Placebo</i> 6% regain of lost weight	.09	
Wadden et al <sup>47</sup>	53 (all women) 30 at end of trial 43% attrition Ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Serrtraline</i> 200mg/d <i>Placebo</i> Both groups received a relapse prevention training program in weekly group meetings for 4 weeks & biweekly for 50 weeks	54-week WM after 26-week WL Rx with VLCD and behavior therapy	<i>During WM<sup>a</sup>:</i> <i>Serrtraline</i> +17.7 ± 10.6 kg regained of the 26.3 ± 7.6 kg original loss <i>Placebo</i> +11.8 ± 9.0 kg regained of the 23.4 ± 7.8 kg original loss $p = NS$ for between group differences	<i>Serrtraline</i> 70.9 ± 41.7% <sup>a</sup> of lost weight regained <i>Placebo</i> 46.5 ± 34.6% <sup>a</sup> of lost weight regained	.60	
Toubro & Astrup <sup>48</sup>	43 (39 women) 37 eligible for WM 34 at end of trial 21% attrition Ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Ad lib</i> 55% carb, 20–25% fat diet; 24-pg dietary booklet <i>Reduced-calorie</i> 7.8 MJ/d (1875 kcal) using 144 color-coded cards to represent foods, each card = 65.2 kcal Both groups had 2–3 group meetings a month for 6 mo, then monthly	1-year WM after 8 weeks VLCD with 1 year follow-up	<i>During WM:</i> <i>Ad lib</i> +0.3 (95% CI, -3.0 to 3.6) kg regained <i>Reduced-calorie</i> +4.1 (95% CI, 1.2 to 6.9) kg regained $p = .08$ for a group difference	<i>After 1 yr lib:</i> <i>Ad lib</i> +5.4 (95% CI, 2.3 to 8.6) kg of initial 13.5 kg WL regained (40%) <i>Reduced-calorie</i> +11.3 (95% CI, 7.1 to 15.5) kg of initial 13.8 kg WL regained (82%) $p = .03$ for a group difference	.29	
Pasman et al <sup>53</sup>	39 (all women) 31 at end of trial 20% attrition Ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Fiber</i> 10 mg BID 10 g guar gum BID <i>Control</i> Both groups had no dietary restrictions or physical activity advise; assessments at 2, 8 & 14 months with 3-day food diaries of food intake	14-month WM after 2-month VLCD	<i>During WM<sup>a</sup>:</i> <i>Group A</i> (consumed > 80% of fiber) +65 ± 65% regain of lost weight <i>Group B</i> (consumed 50–80% of fiber) +123 ± 63% regain of lost weight <i>Control</i> +61 ± 66% regain of lost weight	<i>Group A</i> 6/10 persons regained ≥ 50% <i>Group B</i> 9/10 persons regained ≥ 50% <i>Control</i> 7/11 persons regained ≥ 50%	.33	
Pasman et al <sup>54</sup>	39 (all women) 33 at end of trial 15% attrition Ethnicity not reported	<i>3-GROUP DESIGN:</i> 50 g carbohydrate + 200 µg chromium-picolinate + 20 g fiber + 100 mg caffeine ( <i>CHO</i> +) 50 g carbohydrate ( <i>CHO</i> ) <i>Control</i> Both groups followed an ad lib diet; assessments at 4, 10 & 16 mo with 3-day food diaries of food intake	16-month WM after 2-month VLCD	<i>During WM<sup>a</sup>:</i> ( <i>CHO</i> +) 51.1 ± 109.0% regain of lost weight ( <i>CHO</i> ) 68.1 ± 55.2% regain of lost weight <i>Control</i> 85.5 ± 55.8% regain of lost weight	( <i>CHO</i> +) 31% regained < 50% of lost weight ( <i>CHO</i> ) 36% regained < 50% of lost weight <i>Control</i> 21% regained < 50% of lost weight <i>CHO</i> vs. <i>Control</i> = .40 <i>CHO</i> vs. <i>CHO</i> = .31 <i>CHO</i> vs. <i>Control</i> = .20		

Study	N	Treatment	Medication Use		Results	% Weight Change	Effect Size
			Length of WM Tx	Results			
Kovaacs et al <sup>49</sup>	104 (78 women) 104 at end of trial No attrition Ethnicity not reported	2-GROUP DESIGN: Green tea 450 mg/d 2 capsules with each meal Placebo No dietary or activity instructions specified	13-week WM after 4-week VLCD	During WM <sup>a</sup> ; Green tea 450 mg/d 30.5 ± 61.8% regain of lost weight Placebo 19.7 ± 56.9% regain of lost weight p = NS for group differences	High-caffeine consumer who received green tea +39 ± 17% <sup>a</sup> Low-caffeine consumer who received green tea +16 ± 11% <sup>a</sup> p < .05 for group differences	.18	
Westerterp-Plantenga et al <sup>50</sup>	76 (53 women) 76 at end of trial No attrition Ethnicity not reported	2-GROUP DESIGN: Green tea-caffeine mix (150 mg caffeine/d) 2 capsules with each meal Placebo Randomized after stratification for high caffeine (HC) intake (> 300 mg/d) and low caffeine (LC) intake (< 300 mg/d); food intake not assessed	3-month WM after 4-week WL	During WM: Weight loss continued in the green-tea group with low caffeine intake and increased in both the placebo group with low caffeine intake as well as the green-tea group with high caffeine intake. p < .01 for group differences.	Green tea + LC -11.1 ± 24.3% <sup>a</sup> weight loss Placebo + LC +40.8 ± 38.9% <sup>a</sup> weight regain Green tea + HC +24.4 ± 18.7% <sup>a</sup> weight regain	.30	
Westerterp-Plantenga et al <sup>52</sup>	148 ("women & men") 148 at end of trial No attrition Ethnicity not reported	2-GROUP DESIGN: Added protein 48.2 g/d as 2 drinks Control Both groups followed an ad lib diet, counseling as needed from dietitian	3-month WM after 4-week VLCD	During WM <sup>a</sup> ; Added protein 17.3 ± 60.3% regain of lost weight Control 36.6 ± 46.8% regain of lost weight p < .05 for group differences	50% less weight regained in added protein group compared to control	.16	
Lejeune et al <sup>51</sup>	120 ("women & men") 113 at end of trial 6% attrition Ethnicity not reported	2-GROUP DESIGN: Added protein 30 g/d as 1 drink Control Both groups had monthly visits for 6 mo; allowed to eat usual diet; counseling as requested from dietitian	6-month WM after 4-week VLCD	During WM <sup>a</sup> ; Added protein 19.6 ± 82.1% regain of lost weight Control 54.9 ± 65.8% regain of lost weight p < .05 for group differences	Net weight loss after WM compared to pre-VLCD: Added protein -6.7 ± 7.2% <sup>a</sup> Control -3.8 ± 4.8% <sup>a</sup> p < .05 for group differences	.18	
Ryttig et al <sup>57</sup>	81 (44 women) 76 eligible for WM 42 at end of trial 45% attrition Ethnicity not reported	3-GROUP DESIGN: 1600 kcal/d diet for WL & WM (A) 1600 kcal/d diet with 239 kcal of VLCD in WM (B) 1600 kcal/d diet in WM (C) All were instructed to maintain same level of physical activity; monthly assessments for 7 months then every 7 weeks	VLCD Use 24-month WM after 2-month VLCD or 1600 kcal/d diet	Prior to WL Rx to trial end <sup>a</sup> ; -10.9 ± 10.2 kg in all groups Weight at end of Rx: <sup>a</sup> Group A 110.7 ± 17.4 kg Group B 107.3 ± 15.1 kg Group C 107.5 ± 16.9 kg NS group differences	Group A -7% overall Group B -10% overall Group C -9.5% overall	A vs. B = .21 A vs. C = .19 B vs. C = .01	
Lantz et al <sup>56</sup>	334 (248 women) 117 at end of trial	3-GROUP DESIGN: Intermittent VLCD Repeat VLCD for 2 weeks every 3 <sup>rd</sup> month	2-year WM after 16-week VLCD	Prior to WL Rx to trial end <sup>a</sup> ; Intermittent VLCD -6.2 ± 9.5%	Intermittent VLCD 44% maintained a ≥ 5% weight loss	.17	

Study	N	Treatment	Medication Use		Results	% Weight Change	Effect Size
			Length of WM Tx	Results			
Agras et al <sup>55</sup>	65% attrition Ethnicity not reported 194 (all women) 174 at end of trial 10% attrition Ethnicity not reported	<i>On-demand VLCD</i> Use VLCD when weight surpasses 3 kg above weight after VLCD Both had appointments biweekly for 6 months then monthly thereafter <i>4-GROUP DESIGN: Standard food + time dependent (S + T)</i> Regular food started 1 meal at a time at set intervals over 4 weeks <i>Standard food + weight dependent (S + W)</i> Regular food started only when weight stable over 1–3 months <i>Prepackaged food + time dependent (P + T)</i> Prepackaged meals started 1 meal at a time at set intervals over 4 weeks <i>Prepackaged food + weight dependent (P + W)</i> Prepackaged meals started only when weight stable over 1–3 months All received group behavior therapy in weekly meetings for 3 months, biweekly meetings for 3 months and monthly thereafter	9-month WM after 12-week VLCD with follow up 9 months after WM	<i>On-demand VLCD</i> $-7.7 \pm 8.4\%$ $p < 0.001$ for significant loss over time; $p = NS$ for group differences <i>Prior to WL Rx to trial end</i> $a$ : $S + T - 8.2 \pm 12.3$ kg $S + W - 8.6 \pm 11.4$ kg $P + T - 6.0 \pm 11.1$ kg $P + W$ $-2.8 \pm 18.3$ kg $p = NS$ for group differences	<i>On-demand VLCD</i> 62% maintained a $\geq 5\%$ weight loss No significant differences in percent weight regain among the 4 groups after VLCD.	$S+T$ vs. $S+W = .03$ $S+T$ vs. $P+T = .19$ $S+T$ vs. $P+W = .35$ $S+W$ vs. $P+T = .23$ $S+W$ vs. $P+W = .38$ $P+T$ vs. $P+W = .21$	
Fogelholm et al <sup>59</sup>	82 (all women) 80 at end of trial 2% attrition Ethnicity not reported	<i>3-GROUP DESIGN: Walk 1</i> Use 1000 kcal/week walking <i>Walk 2</i> Use 2000 kcal/week walking <i>Control</i> No walking program All receive a low-fat diet, weekly group meetings, monthly materials on a healthy diet, pedometers	<i>Physical Activity</i> 40-week WM after 12-week VLCD	<i>During WM</i> $a$ : $Walk 1 -0.7$ (1.0) kg $Walk 2 +0.2$ (0.9) kg $Control +1.7$ (0.8) kg $p = .18$ for group differences	Not reported	.15	
Borg et al <sup>58</sup>	90 (all men) 82 at end of trial 9% attrition Ethnicity not reported	<i>3-GROUP DESIGN: Walking</i> 45-min sessions 3 times/week <i>Resistance training</i> 45-min sessions 3 times/week <i>Control</i> No increase in activity All received a low-fat, ad-lib diet, weekly group meetings, food and exercise diaries	6-month WM after 2- month VLCD with 23- month follow up	<i>During WM adjusted mean difference to control:</i> <i>Walking</i> $+0.3$ kg (95% CI, $-2.2$ to $2.8$ ) <i>Resistance training</i> $-1.3$ kg (95% CI, $-3.8$ to $1.1$ ) $p = .25$ for group differences	<i>At 23-month follow-up:</i> 47.5% of all participants regained $> 10\%$ compared to weight after WL Rx	.13	

Abbreviations: CI, confidence interval; GP, general practitioner; NS, non-significant; Tx, treatment; VLCD, very-low-calorie diet; WL, weight loss; WM, weight maintenance.

<sup>a</sup> mean ± standard deviation.

<sup>b</sup> mean ± stand error of the mean.



Pharmacotherapy

Table 3

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Early et al <sup>60</sup>	148 (126 women) 133 eligible for WM 60 at end of trial 55% attrition 48% White 40% Black 9% Hispanic 1.5% Asian 1.5% Other	<b>2-GROUP DESIGN:</b> Sibutramine 15 mg/d + 1 meal replacement & 2 low-calorie meals (~1500 kcal/d) Placebo 3 low-calorie meals (~1500 kcal/d) Both received behavior therapy with self-monitoring, problem solving, social support	9-month WM after 3 months WL with sib, 10 mg/d and low-calorie diet	<u>During WM<sup>b</sup>, Sibutramine</u> -2.5 ± 0.6 kg <u>Placebo</u> +2.9 ± 0.6 kg <i>p</i> < .001 for group difference	<u>During WM<sup>b</sup>,</u> Sibutramine -2.9 ± 0.7% <u>Placebo</u> +3.3 ± 0.7% <i>p</i> < .001 for group difference	.28
Wirth & Krause <sup>29</sup>	1102 1001 eligible for WM (768 women) 787 at end of trial 21% attrition 99.5% White	<b>3-GROUP DESIGN:</b> Sibutramine ongoing 15mg/d for 44 wks Sibutramine periodic: 15mg/d except for weeks 13-18 and 31-36 when placebo was received Placebo All received dietary advice; no formal dietary or behavior therapy	44-week WM after 4 weeks WL with sib, 15 mg/d	<u>During WM, Sib. ongoing</u> -3.8 kg (95% CI, -4.4 to -3.2) <u>Sib. periodic</u> -3.3 kg (95% CI, -3.9 to -2.6) <u>Placebo</u> +0.2 kg (95% CI, -0.6 to 0.94)	<u>During WM, Sib. ongoing</u> Lost an additional 4% <u>Sib. periodic</u> Lost an additional 3.5% <u>Placebo</u> Regained 0.2%	.10
James et al <sup>61</sup>	605 467 eligible for WM (390 women) 261 at end of trial 44% attrition 96.5% White	<b>2-GROUP DESIGN:</b> Sibutramine 10mg/d (increased up to 20mg/d if regain) Placebo Both groups received dietary counseling each month or every 2 weeks if desired	18-month WM after 6-month WL with sib, 10 mg/d	<u>Prior to WL Rx to trial end</u> <u>a. Sibutramine</u> -8.9 ± 8.1 kg <u>Placebo</u> -4.9 ± 5.9 kg <i>p</i> < .001 for group difference	Sibutramine 43% sustained at least 80% of lost weight. Placebo 16% sustained ≥ 80% of lost weight <i>p</i> < .001 for group difference	.15
Sjostrom et al <sup>65</sup>	688 (567 women) 526 eligible for WM 435 at end of trial 17% attrition Ethnicity not reported	<b>2-GROUP DESIGN:</b> Orlistat 120 mg/TID Placebo Both groups were to follow a weight-maintenance diet; received either orlistat or placebo during WL	1-year WM after 1-year WL with orlistat 120 mg/TID or placebo	<u>During WM, Orlistat in WL</u> orlistat regained 2.4 [SE 0.6] kg less than placebo, <i>p</i> < .001 <u>Placebo in WL</u> orlistat lost 3.6 [SE 0.6] kg versus placebo, <i>p</i> < .001	<u>After 2 years: Continuous orlistat</u> 57.1% maintained a WL > 5% <u>Continuous placebo</u> 37.4% maintained a WL > 5%	.14
Davidson et al <sup>62</sup>	1187 880 eligible for WM (741 women) 403 at end of trial 54% attrition 81% White 15% Black 4% Hispanic	<b>4-GROUP DESIGN:</b> Orlistat-treated group rerandomized for WM Orlistat 120 mg TID Orlistat 60 mg TID Placebo All followed a WM diet; 4 seminars on strategies for WM; instruction in self-monitoring food intake and activity	1-year WM after 1-year WL with orlistat 120 mg/TID or placebo	<u>During WM<sup>b</sup>, Orlistat 120 mg</u> +3.2 ± 0.45kg <u>Orlistat 60 mg</u> +4.3 ± 0.57kg <u>Placebo</u> +5.6 ± 0.42kg Orlistat 120 mg regained less weight than other groups, <i>p</i> < .001	<u>During WM: Orlistat 120 mg</u> 35.2% of lost weight regained <u>Orlistat 60 mg</u> 51.3% of lost weight regained <u>Placebo</u> 63.4% of lost weight regained	.11
Hill et al <sup>63</sup>	1313 (605 women)	<b>4-GROUP DESIGN:</b> Orlistat 120 mg TID	1-year WM after 1-year	<u>Prior to WL Rx to trial end</u> <u>b. Orlistat 120 mg</u> -8.20 ±	<u>Percent who regained</u> ≤ 25% of lost weight: Orlistat 120 mg 47.5%	.12

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Karthunen et al <sup>64</sup>	726 eligible for WM 537 at end of trial 26% attrition 88% White 6% Black 5% Hispanic 1% Other	<i>Orlistat 60 mg TID</i> <i>Orlistat 30mg TID</i> <i>Placebo</i> All followed a WM diet; behavioral & dietary counseling; visits biweekly for 1 mo, monthly until month 5, & bimonthly thereafter.	WL with a 1000 kcal/d deficit diet	0.5% <i>Orlistat 60 mg</i> -6.66 ± 0.5% <i>Orlistat 30 mg</i> -5.94 ± 0.6% <i>Placebo</i> -6.42 ± 0.7%	<i>Orlistat 60 mg</i> 30.4% <i>Orlistat 30 mg</i> 32.3% <i>Placebo</i> 29.9%	
	96 88 eligible for WM 72 at end of trial (59 women) 18% attrition Ethnicity not reported	<b>2-GROUP DESIGN:</b> <i>Orlistat (O)</i> 120 mg TID <i>Placebo (P)</i> TID Groups were prescribed a WM diet; because of assignment during WL, 4 groups resulted after WL & WM: O+O, O+P, P+O, P+P	1-year WM after 1-year WL with either <i>orlistat</i> 120 mg TID or <i>placebo</i> TID	<u>Weight after WL<sup>a</sup>:</u> O+O 82.6 ± 11.4kg O+P 87.7 ± 14.2kg P+O 89.2 ± 19.0kg P+P 88.2 ± 15.8kg <u>Weight after WM<sup>a</sup>:</u> O+O 85.7 ± 12.4kg O+P 94.0 ± 16.6kg P+O 89.7 ± 19.9kg P+P 91.7 ± 16.0kg	<i>During WM:</i> O+O 24% of lost weight regained O+P 48% of lost weight regained P+O 69% of lost weight regained P+P 37% of lost weight regained	.27

Abbreviations: CI, confidence interval; TID, three times a day; Tx, treatment; WL, weight loss; WM, weight maintenance. <sup>a</sup>mean ± standard deviation.

<sup>b</sup> mean ± standard error of the mean.

Behavior Therapy

Table 4

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Perri et al <sup>66</sup>	56 (45 women) 43 at end of trial 25% attrition Ethnicity not reported	<b>2-GROUP DESIGN: Booster</b> review of WL Rx strategies <b>Multicomponent</b> Self-help groups, use problem-solving; weekly therapist calls and mailed in postcards of food intake/weight Both groups received 6 biweekly group sessions	1-year WM after 14-week WL with behavior therapy; follow up 6 months later	<i>During WM</i> <sup>a</sup> : <i>Booster</i> -4.6 ± 11.1 lbs <i>Multicomponent</i> -12.8 ± 16.0 lbs <i>WL at follow up</i> <i>Booster</i> -0.8 ± 7.9 lbs <i>Multicomponent</i> -10.0 ± 15.3 lbs	<i>Booster</i> 94% of lost weight regained <i>Multicomponent</i> 25% of lost weight regained	.39
Perri et al <sup>67</sup>	129 (115 women) 99 at end of trial 25% attrition Ethnicity not reported	<b>2-GROUP DESIGN: Phone &amp; mail contact (P)</b> therapist calls, mailed postcards of food intake, exercise & weight for 6 months <b>No-contact control (C)</b> Initial WL Rx: randomization to non-behavioral therapy (NB), behavior therapy (B) or behavior therapy + relapse-prevention training (B+R) resulting in 6 groups after WM, these 3 WL groups plus either contact or control in WM.	6-month WM after 15-week WL with behavior therapy; follow up 6 months later	<i>WL at follow up</i> <sup>a</sup> : <i>B+R: P</i> -22.7 ± 25.1 lbs <i>B+R: C</i> -6.5 ± 7.9 lbs <i>B: P</i> -12.7 ± 9.2 lbs <i>B: C</i> -13.8 ± 13.4 lbs <i>NB: P</i> -13.6 ± 11.0 lbs <i>NB: C</i> -6.9 ± 10.5 lbs	<i>Attained a net loss of</i> ≥20 lbs <i>at follow-up</i> <i>Phone &amp; mail contact</i> 33.3% <i>No-contact control</i> 13.7% <i>p</i> <.05 for group differences	.17
Perri et al <sup>68</sup>	90 (76 women) 67 at end of trial 25% attrition Ethnicity not reported	<b>2-GROUP DESIGN: Multicomponent (M)</b> taught to form peer groups, problem solve; mailed weekly postcards of food intake/weight; weekly call from therapist <b>No-contact control (C)</b> Initial WL Rx included randomization to behavior therapy (B) or behavior therapy + aerobic exercise (B+A) resulting in 4 groups: B+A:M, B:M, B+A:C, B:C	1-year WM after 20-week WL with behavior therapy; follow up 6 months later	<i>Weight at end of WM</i> <sup>a</sup> : <i>B</i> +A:M 82.8±13.2 kg <i>B:M</i> 85.5±16.5 kg <i>B+A: C</i> 86.2±18.5 kg <i>B:C</i> 91.6±20.1 kg <i>Weight at 6-mo</i> <i>follow up</i> <sup>a</sup> : <i>B+A:M</i> 84.8±13.3 kg <i>B:M</i> 86.8±17.6 kg <i>B+A: C</i> 88.3±19.4 kg <i>B:C</i> 91.3±18.7 kg	Unable to determine from information provided.	.24
Kramer et al <sup>74</sup>	87 (36 women) 85 at end of treatment 2% attrition Ethnicity not reported	<b>3-GROUP DESIGN: Skills, focus</b> + \$ eating/exercise skills practice <i>Weight focus</i> + \$ general problem-solving, \$10 withheld if any weight regain <b>No-contact control</b> For two intervention groups, \$10 return of deposited money at monthly meeting.	1-year WM after 15-week WL with behavior therapy	<i>During WM</i> <sup>a</sup> : <i>Skills focus</i> + \$ +13.4 ± 10.4 lbs <i>Weight focus</i> + \$ +11.9 ± 12.8 lbs <i>No-contact control</i> +10.3 ± 14.5 lbs (5 lbs added to 6 self-reported weights)	% of WL maintained <sup>a</sup> : <i>Skills focus</i> + \$ 50.0 ± 38.3% <i>Weight focus</i> + \$ 59.4 ± 44.5% <i>Control</i> 48.2 ± 90.1%	Skill focus+ \$ vs. Weight focus+ \$ = .13 Skill focus+ \$ vs. Control = .25 Weight focus+ \$ vs. Control = .12

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Perri et al <sup>69</sup>	123 (97 women) 91 at end of treatment 26% attrition Ethnicity not reported	5-GROUP DESIGN: Therapist contact (TC) biweekly group sessions TC + social influence (SI) added peer-support and incentives for adherence TC + aerobic exercise (AE) added up to 180 min/week of aerobic activity TC + SI + AE all of the above No-contact control	1-year WM after 1-year WL with behavior therapy; follow up 6 months later	Prior to WL Rx through $f/u^a$ : TC -11.4 ± 12.1 kg TC + SI -8.4 ± 7.5 kg TC + AE -9.1 ± 6.4 kg TC + SI + AE -13.5 ± 15.2 kg No-contact control -3.6 ± 6.2 kg	% of WL maintained: 4 Rx groups 82.7% No-contact control 33.3%	.27
Perri et al <sup>70</sup>	88 80 at end of trial (all women) 9% attrition Ethnicity not reported	3-GROUP DESIGN: Relapse-prevention training recognizing high-risk times, coping, practicing handling challenging situations Problem-solving therapy orienting self to problem, generating alternatives, decision making, evaluation No-contact control Two intervention groups attended biweekly meetings	1-year WM after 5-month WL with behavior therapy	Prior to WL Rx through WM <sup>a</sup> : Relapse-prevention training (RPT) -5.9 ± 6.4 kg Problem-solving therapy (PST) -10.8 ± 8.7 kg No-contact control (C) -4.1 ± 4.9 kg	% who lost and maintained ≥ 10% RPT 21.4% PST 35.3% C 5.6%	.22
Wing et al <sup>72</sup>	Study 1 53 (all women) 50 at end of trial 6% attrition Study 2 57 (no gender data) 48 at end of trial 16% attrition Ethnicity not reported	2-GROUP DESIGN: Study 1: Telephone Phone weekly calls re: self-weight or self-monitor foods and exercise Control no contact Study 2: Food Provision Optional foods monthly group meetings + optional food boxes for a fee during 4 months of WM Control monthly group meetings	1-year WM after 6-month WL with behavior therapy	During WM <sup>a</sup> : Study 1 Phone +3.9 ± 1.1 kg Control +5.6 ± 1.0 kg Study 2 Optional foods +4.2 ± 1.0 kg Control +4.3 ± 1.1 kg $p$ 's > .28 for group differences	Study 1 25% less weight regained in phone group compared to control Study 2 32% of lost weight regained in both groups	Study 1 = .30 Study 2 = .16
Liebbrand & Fichter <sup>71</sup>	109 91 at end of trial (all women) 16% attrition Ethnicity not reported	2-GROUP DESIGN: Maintenance Eight 45-min phone calls from therapist in 1 <sup>st</sup> 9 months; 4 calls during 2 <sup>nd</sup> 9 months Control no support after discharge	18-month WM after 10-week inpatient WL Rx	Weight after WL <sup>a</sup> : Maintenance 120.9 ± 23.4 kg Control 118.3 ± 24.4 kg Weight after WM <sup>a</sup> : Maintenance 118.7 ± 26.0 kg Control 118.2 ± 24.0 kg	6.3% of weight was lost and maintained by the total sample during WL and WM with no difference between groups	.02
Riebe et al <sup>73</sup>	144 (112 women) 104 at end of trial 28% attrition 97% White	2-GROUP DESIGN: Extended care received 2 personalized reports in the mail at 9 and 12 mo Control received general materials about diet and exercise at 9 and 12 mo All received the same anthropometric, biochemical,	18-month WM after 6-month WL with behavior therapy	Weight at end of WL <sup>a</sup> : Extended care 87.6 ± 15.9 kg Control 84.1 ± 14.1 kg Weight at end of WM <sup>a</sup> : Extended care 90.5 ± 16.9 kg Control 86.9 ± 15.4 kg	The total sample maintained 48% of lost weight.	.22

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Kumanyika et al <sup>75</sup>	128 (116 women) 87 at end of trial 32% attrition 100% African American	and dietary reports at 12 and 24 mo  3-GROUP DESIGN: Group counseling 6 meetings biweekly then monthly; reviewed topics and > focus on group discussion Staff-assisted self-help resources to promote self-directed WM-pedometer, peer support, monthly calls Clinic visits only No intervention, only brief advice from MD as requested	8- to 18-month WM after 10-week WL with behavior therapy adapted for culture	During WM: Group counseling -0.02 kg (95% CI, -1.7 to 1.8 kg) Staff-assisted self-help +1.1 kg (95% CI, -0.3 to 2.5 kg) Clinic visits only -0.04 kg (95% CI, -1.9 to 1.8 kg) p =.55 for group differences	25% of the total sample lost and maintained ≥ 5% of initial weight	.05

Abbreviations: CI, confidence interval; M, mean; Tx, treatment; WL, weight loss; WM, weight maintenance.

<sup>a</sup> mean ± standard deviation.

**Table 5**  
Strategies Found to be Beneficial for Weight-Loss Maintenance

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- Medications (orlistat, sibutramine) + dietary modification<sup>29, 41, 43, 44, 60–65</sup>
  - Following a lower-fat diet<sup>48</sup>
  - Adherence to physical activity<sup>58, 59</sup>
  - Continued contact with individuals<sup>31, 33, 66–69</sup>
  - Problem-solving therapy<sup>70</sup>
  - Increased protein intake<sup>51, 52</sup>
  - Increased caffeine intake for those consuming < 300 mg/day<sup>49, 50</sup>
  - Acupressure<sup>84</sup>
-