

Appendix 2 (as supplied by authors): Details of included studies

Study/Location	Champagne 2011 [1] United States; Companion paper: Svetkey [2]
Objective	To compare two weight loss maintenance interventions with a self-directed control group
Methods	<p>Design: randomized controlled trial</p> <p>Selection: recruited from 4 medical centres/health research sites in the United States; recruitment included mass mailing, posted flyers, radio advertisements, and print media</p> <p>Inclusion Criteria: ≥ 4 kg weight loss during phase 1 (weight loss) of the intervention</p> <p>Exclusion Criteria: medication-treated diabetes; recent cardiovascular event; medical or psychiatric conditions preventing full participation; weight loss ≥ 9 kg in past 3 months; recent use of weight loss medications; prior weight loss surgery</p>
Participants	<p>Sample: 1,032 (weight maintenance study)</p> <p>Intervention 1 (Internet) n=348; Intervention 2 (Personal Contact) n=342; Control n=342</p> <p>Age, Mean (SD) years (at beginning of weight maintenance study): Intervention 1: 55.7 (8.5); Intervention 2: 55.4 (9.1); Control: 55.8 (8.5)</p> <p>Gender [Female n (%)] (at beginning of weight maintenance study): Intervention 1: 220 (63.2%); Intervention 2: 213 (62.3%); Control: 221 (64.6%)</p> <p>Race/Ethnicity (African American) (at beginning of weight maintenance study): 37.5%</p> <p>SES (Education) (at beginning of weight maintenance study): Some college or less: 37.7%; College: 22.5%; Post-college: 39.9%</p> <p>SES (Income) (at beginning of weight maintenance study): <\$30,000: 7.3%; \$30-59,000: 35.4%; \$60-89,999: 31.3%; \geq\$90,000: 26.1%</p> <p>Loss to follow-up: Intervention 1 n=15; Intervention 2 n=14; Control n=22</p>
Intervention	<p>Description of prior weight loss intervention: followed DASH diet for 6 months (increase intake of fruits, vegetables, low-fat dairy, whole grains); program support delivered in 20 group sessions</p> <p>Description of weight maintenance intervention: 2 strategies for delivering program support: one group received personal contact and the second group received support via interactive technology; both groups encouraged to continue the DASH diet</p> <p>Description of weight maintenance control: self-directed</p> <p>Duration of weight maintenance intervention: 30 months</p> <p>Length of follow-up: immediate post</p>
Study/Location	Davidson 1999 [3] United States
Objective	To test whether orlistat plus a dietary intervention is more effective than placebo plus diet for weight loss and maintenance over two years
Methods	Design: randomized controlled trial

	<p>Selection: recruited at 18 clinical research centers in the United States</p> <p>Inclusion Criteria (for weight loss phase): >18 years; BMI 30 to 43; adequate contraception in women of childbearing potential; ≤0.4 kg weight loss in past 3 months</p> <p>Exclusion Criteria: frequently changed smoking habits or stopped smoking in the past 6 months; history or presence of substance abuse or excessive intake of alcohol; significant cardiac, renal, hepatic, gastrointestinal, psychiatric, or endocrine disorders; drug-treated T2D; use of medications that alter appetite or lipid levels</p>
Participants	<p>Sample: 576 (weight loss maintenance portion of study) (ITT population randomized in initial weight loss study n=880)</p> <p>Intervention 1 (60 mg orlistat) n=152; Intervention 2 (120 mg orlistat) n=153; Control n=153</p> <p>Age, Mean (SD) years (orlistat recipients at start of weight loss study run-in): 43.3 (0.6)</p> <p>Gender [Female n (%)] (orlistat recipients at start of weight loss study run-in): 544 (82.8%)</p> <p>Race/Ethnicity [n (%)] (orlistat recipients at start of weight loss study run-in): White 534 (81.3%); Black 88 (13.4%); Hispanic 28 (4.3%)</p> <p>Loss to follow-up (over weight loss and weight loss maintenance phases): Intervention 1 n=44; Intervention 2 n=50; Control n=43</p>
Intervention	<p>Description of prior weight loss intervention: placebo plus a controlled-energy diet during a 4-week lead-in; on day 1 of weight loss study, diet continued and participants randomized to intervention received 120 mg dose of orlistat 3 times a day for 52 weeks; participants randomized to control also continued with the diet but were administered a placebo 3 times daily for 52 weeks</p> <p>Description of weight maintenance intervention: participants previously treated with 120 mg orlistat were randomized to one of two intervention groups (or the control group); intervention group 1 received a 60 mg dose of orlistat 3 times daily plus they followed a weight-maintenance diet; intervention group 2 continued to receive a 120 mg dose of orlistat taken 3 times daily and followed the weight maintenance diet</p> <p>Description of weight maintenance control: control group of patients previously treated with orlistat received placebo plus followed the weight-maintenance diet</p> <p>Duration of weight maintenance intervention: 12 months</p> <p>Length of follow-up: immediate post</p>
Study/Location	Hauptman 2000 [4] United States
Objective	To evaluate the long-term efficacy and tolerability of orlistat for the treatment of obesity within primary care settings
Methods	<p>Design: randomized controlled trial</p> <p>Selection: recruited from 17 primary care centers in the United States</p> <p>Inclusion Criteria: >18 years; BMI 30 to 44</p>

	Exclusion Criteria: pregnant, lactating or women not using adequate contraception; weight loss >4 kg during past 3 months; history of significant cardiac, renal, hepatic, or gastrointestinal disorders; uncontrolled hypertension other clinically significant condition; gastrointestinal surgery for weight-reducing purposes; bulimia or laxative and/or substance abuse; abnormal laboratory measures (values $\geq 10\%$ reference value for normal range and requiring medical follow-up); changes in smoking habits in past 6 months; drugs that could affect body weight or food intake 8 weeks prior to screening
Participants	<p>Sample: 427 (weight maintenance portion of study)</p> <p>Intervention 1 (60 mg orlistat) n=154; Intervention 2 (120 mg orlistat) n=151; Control n=122</p> <p>Age, Mean (SD) years (prior to run in of weight loss portion of study): Intervention 1: 42.6 (0.8); Intervention 2: 43.2 (0.7); Control: 41.6 (0.7)</p> <p>Gender [Female n (%)] (prior to run in of weight loss portion of study): Intervention 1: 166 (77.9%); Intervention 2: 166 (79.0%); Control: 165 (77.8%)</p> <p>Race/Ethnicity (prior to run in of weight loss portion of study): Intervention 1: White n=200, Black n=9, Hispanic n=2, Other n=2; Intervention 2: White n=184, Black n=19, Hispanic n=6, American Indian n=1; Control: White n=193, Black n=15, Hispanic n=4</p> <p>Loss to follow-up (weight maintenance portion): Intervention 1 n=34; Intervention 2 n=34; Control n=31</p>
Intervention	<p>Description of prior weight loss intervention: after a 4-week single-blind, placebo run-in participants randomized to placebo, 60 mg of orlistat, or 120 mg of orlistat, all 3 times daily for 52 weeks; followed a reduced-energy diet from beginning of the run-in and throughout the 52 weeks of treatment; participants in all groups were encouraged to engage in physical activities (e.g., brisk walking 20-30 minutes 3-5 times a week)</p> <p>Description of weight maintenance intervention: participants received the same placebo or drug treatment for a second year in combination with a weight maintenance diet intended to prevent weight regain rather than induce further weight loss</p> <p>Description of weight maintenance control: placebo plus weight maintenance diet (same control group as weight loss)</p> <p>Duration of weight maintenance intervention: 12 months</p> <p>Length of follow-up: immediate post</p>
Study/Location	Hill 1999 [5] United States
Objective	To test the effectiveness of orlistat against placebo in preventing weight regain
Methods	<p>Design: randomized controlled trial</p> <p>Selection: recruited at 17 clinical research centers in the United States</p> <p>Inclusion Criteria: lost $\geq 8\%$ baseline body weight during run-in period</p> <p>Exclusion Criteria: history of significant medical disorders (uncontrolled hypertension, recurrent nephrolithiasis, symptomatic cholelithiasis, active gastrointestinal disorders,</p>

	T2D, pancreatic disease, cancer); pregnant or lactating; history or presence of substance abuse or excessive alcohol intake; eating disorders; significantly abnormal laboratory test results; previous gastrointestinal surgery for weight reduction; history of postsurgical adhesions
Participants	<p>Sample: 729 (weight maintenance period)</p> <p>Intervention 1 (30 mg orlistat) n=187; Intervention 2 (60 mg orlistat) n=173; Intervention 3 (120 mg orlistat) n=181; Control (placebo) n=188</p> <p>Age Mean (SD) years (at start of 6 month lead in weight loss period): Intervention 1: 46.8 (0.8); Intervention 2: 46.1 (0.7); Intervention 3: 45.9 (0.7); Control: 46.4 (0.7)</p> <p>Gender [Female n (%)] (at start of 6 month lead in weight loss period): Intervention 1: 157 (84.4%); Intervention 2: 136 (79.5%); Intervention 3: 156 (87.1%); Control: 156 (84.8%)</p> <p>Race/Ethnicity (White) (at start of 6 month lead in weight loss period): Intervention 1: n=164; Intervention 2: n=155; Intervention 3: n=153; Control: n=164</p> <p>Loss to follow-up: Intervention 1 n=47; Intervention 2 n=40; Intervention 3 n=55; Control n=50</p>
Intervention	<p>Description of previous weight loss intervention: 6 month dietary intervention involving nutritionally balanced, hypoenergetic diet with a deficit of 4,180 kJ/d; encouraged to engage in physical activity (brisk walking 20-30 minutes 5 times/week)</p> <p>Description of weight maintenance intervention: 3 intervention groups: group 1 30 mg orlistat 3 times/day, group 2 60 mg orlistat 3 times/day, group 3 120 mg orlistat 3 times/day; dietary and behavioural counseling provided throughout treatment period</p> <p>Description of weight maintenance control: placebo and same behavioural components as intervention</p> <p>Duration of weight maintenance intervention: 12 months</p> <p>Length of follow-up: immediate post</p>
Study/Location	Richelsen 2007 [6] Scandinavian Countries
Objective	To investigate the efficacy of orlistat on the maintenance of weight following a major diet induced weight loss in obese patients with metabolic risk factors
Methods	<p>Design: randomized controlled trial</p> <p>Selection: recruited at 9 clinical research centers across Scandinavia</p> <p>Inclusion Criteria: 18-65 years; BMI 30-45; waist circumference ≥ 102 cm (men) or ≥ 92 cm (women); ≥ 1 identified risk factors [impaired fasting glucose (plasma glucose ≥ 6.1 mmol/L), diet-treated T2D (plasma glucose ≥ 7.0 mmol/L), dyslipidemia (HDL cholesterol ≤ 0.9 mmol/L [men] or ≤ 1.1 [women]), serum triglycerides ≥ 2.0 mmol/L but < 10.0 mmol/L]; loss of $\geq 5\%$ baseline body weight during run-in period</p>
Participants	<p>Sample: 309 (weight maintenance study)</p> <p>Intervention n=153; Control n=156</p>

	<p>Age, Mean (range) years (after run-in and at randomization for weight maintenance): Intervention: 47.2 (20-64); Control: 46.7 (19-63)</p> <p>Gender [Female n (%)] : Intervention: 77 (50.3%); Control: 80 (51.3%)</p> <p>Loss to follow-up: not reported</p>
Intervention	<p>Description of run-in weight loss intervention: 8 weeks on a very low energy diet of 600 to 800 kcal/day</p> <p>Description of weight maintenance intervention: 120 mg orlistat three times daily; standard energy restricted diet (600 kcal daily deficit); dietitian provided dietary (reduce fat, increase fruit and vegetable intake) and lifestyle (increase physical activity) counseling (monthly for first 18 months, every 3 months thereafter)</p> <p>Description of weight maintenance control: placebo plus the same behavioural components as intervention</p> <p>Duration of weight maintenance intervention: 36 months</p> <p>Length of follow-up: immediate post</p>
Study/Location	Rickel 2011 [7] United States; Companion papers: Perri [8], Radcliff [9]
Objective	To examine ethnic differences in patterns of weight loss and regain in response to an initial behavioural weight loss intervention followed by extended-care maintenance
Methods	<p>Design: randomized controlled trial</p> <p>Selection: study brochures mailed to 15,000 households in 6 rural counties where program offered; using US Census data mailing list included households with women in the designated age range; those interested invited to orientation session</p> <p>Inclusion Criteria: rural women aged 50 to 75 years; reside in rural counties designated as health professional shortage areas in Florida; BMI >30; weighed <159.1 kg; no uncontrolled hypertension or diabetes; no diagnosis in past year of cardiovascular, cerebrovascular, renal or hepatic disease; completed 6 month initial lifestyle program</p>
Participants	<p>Sample: 234 (weight maintenance period)</p> <p>Intervention 1 (Telephone Counselling) n=72; Intervention 2 (Face-to-face Counselling) n=83; Control (Education) n=79</p> <p>Age, Mean (SD) years (at start of 6 month weight loss intervention): Intervention 1: 59.8 (6.2); Intervention 2: 59.2 (6.2); Control: 58.6 (6.0)</p> <p>Gender (Female): 100%</p> <p>Race/Ethnicity (Black, Hispanic, White, Asian/Native American/Pacific Islander): Intervention 1: 29.2%, 1.4%, 66.7%, 2.8%; Intervention 2: 15.7%, 1.2%, 83.1%, 0%; Control: 11.4%, 3.8%, 81.0%, 3.8%</p> <p>SES (Household Income): Intervention 1: <\$35K 48.6%; \$35>50K 16.7%; \$50>75K 13.9%; ≥\$75K 13.9%; Intervention 2: <\$35K 53%; \$35<50K 21.7%; \$50<75K 16.9%; ≥\$75K 7.2%; Control: <\$35K 31.6%; \$35<50K 26.6%; \$50<75K 22.8%; ≥\$75K 17.7%</p>

	Loss to follow-up: no loss
Intervention	<p>Description of previous weight loss intervention: 6 month group based lifestyle program (modelled after the Diabetes Prevention Program) including low calorie diet, increased physical activity, goal setting, self-monitoring of food intake, cooking demonstrations, support strategies, techniques for eating healthy away from home</p> <p>Description of weight maintenance interventions: group 1: 26 biweekly face-to-face group counseling sessions lasting 60 minutes each and addressing barriers to diet and exercise behaviours required for weight maintenance; group 2: 26 biweekly one-on-one telephone counseling sessions lasting 15 to 20 minutes each also addressing barriers</p> <p>Description of weight maintenance control: 26 biweekly newsletters containing tips and recipes to help maintain weight loss, sent by mail</p> <p>Duration of weight maintenance intervention: 6 months</p> <p>Length of follow-up: 12 months post intervention completion</p>
Study/Location	Sjöström 1998 [10] European Countries
Objective	To assess the efficacy and tolerability of orlistat in promoting weight loss and preventing weight regain in obese patients
Methods	<p>Design: randomized controlled trial</p> <p>Selection: recruitment from hospital waiting lists and local advertising</p> <p>Inclusion Criteria: BMI 28-47; ≥ 18 years; women using adequate contraception; for weight maintenance phase those demonstrating $>75\%$ compliance with treatment</p> <p>Exclusion Criteria: serious diseases (e.g., uncontrolled hypertension, pharmacologically treated diabetes); weight loss >4 kg in past 3 months; surgery for weight reduction; history of post-surgical adhesions, bulimia, laxative or drug or alcohol abuse; use of drugs that might have influenced weight or plasma lipids in past month</p>
Participants	<p>Sample: 261</p> <p>Intervention n=133; Control n=126</p> <p>Age, Mean (range) years (at randomization for weight loss intervention): Intervention: 45.2 (20-76); Control: 44.3 (18-77)</p> <p>Gender [Female n (%)] (at randomization for weight loss intervention): Intervention: 284 (82.8%); Control: 283 (83.2%)</p> <p>Loss to follow-up: Intervention n=2; Control n=3</p>
Intervention	<p>Description of pre-intervention run-in: 4 weeks of placebo taken 3 times daily plus hypocaloric diet</p> <p>Description of one-year weight loss intervention: 120 mg of orlistat three times daily plus continuation of hypocaloric diet</p> <p>Description of weight maintenance intervention: 120 mg orlistat three times daily plus eucaloric (weight maintenance) diet</p>

	<p>Description of control: placebo plus eucaloric diet</p> <p>Duration of intervention: 12 months</p> <p>Length of follow-up: immediate post</p>
Study/Location	Thomas 2011 [11] United Kingdom
Objective	To assess the effects of diet support via e-mail on weight loss maintenance
Methods	<p>Design: randomized controlled trial</p> <p>Selection: recruited directly from a weight loss clinic led by a dietician (within a Hospital Trust) twice a week</p> <p>Inclusion Criteria: already lost $\geq 5\%$ initial body weight; access to e-mail</p> <p>Exclusion Criteria: applying for bariatric surgery; no e-mail access; taking weight loss medication; binge eating disorder; learning difficulties</p>
Participants	<p>Sample: 55</p> <p>Intervention n=28; Control n=27</p> <p>Age, Mean (SD) years: Intervention: 43.2 (15.2); Control: 46.2 (12.0)</p> <p>Gender: not reported</p> <p>Loss to follow-up: Intervention n=3; Control n=3</p>
Intervention	<p>Description of weight maintenance intervention: weekly e-mails from dietitian with dietary, behavioural and exercise advice</p> <p>Description of weight maintenance control: no contact with the dietician</p> <p>Duration of weight maintenance intervention: 6 months</p> <p>Length of follow-up: immediate post</p>

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