

SUPPLEMENTARY REPORT
on evidence from studies of
MAINTENANCE of WEIGHT LOSS

Supplemental to:
Treatment of Overweight/Obesity in Adult Populations:
A Systematic Review with Meta-analyses

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Introduction

In the review *Treatment of Overweight/Obesity in Adult Populations: A Systematic Review with Meta-analyses* (available on the CTFPHC website <http://canadiantaskforce.ca/>), Key Question 1d was: *How well is weight loss or health outcomes maintained after an intervention is completed?* The search resulted in a group of studies that answered a slightly different question, which was: ***What is the effectiveness of weight maintenance interventions on weight related outcomes?*** The Canadian Task Force on Preventive Health Care Adult Obesity Working Group agreed this question should be addressed as a supplemental question.

Methods

See the main document, *Treatment of Overweight/Obesity in Adult Populations: A Systematic Review with Meta-analyses* (<http://canadiantaskforce.ca/>) for details. Methods were identical with the exception of the inclusion in this report of papers that randomized people to weight maintenance interventions following initial successful weight loss. PROSPERO registration #: CRD42012002753

Results

Supplemental Question: What is the effectiveness of weight maintenance interventions on weight related outcomes?

The search for the adult obesity reviews (<http://canadiantaskforce.ca/>) found eight studies (11 papers) concerning weight maintenance interventions following weight loss (see Figure 1 for Flow Diagram).¹⁻⁸ In every instance, participants had completed an active weight loss phase, then were assigned to an intervention aimed at maintaining their weight loss or to a control group. These eight studies were used to answer the supplemental question addressed in this report.

Study populations were predominantly mixed gender^{2,4-8} with one exclusively involving rural women³ and one study not reporting gender.¹ Mean age ranged from 42.6 to 59.2 years. The interventions in the eight studies were classified as behavioural¹⁻³ or pharmacological plus behavioural.⁴⁻⁸ The former were all lifestyle interventions and the latter all included a group that received 120 mg orlistat three times daily plus a weight maintenance diet. The weight maintenance interventions lasted between six and 36 months, with most interventions running for one year. In all studies outcomes were assessed at the post intervention point. Five studies were conducted in the US,²⁻⁶ with the other studies coming from the UK,¹ various Scandinavian countries,⁷ and European centres.⁸ The studies were published between 1998 and 2011; half were published between 1998 and 2000,^{4-6,8} and half after 2007.^{1-3,7} Summary characteristics of the included studies are provided in Table 1. Table 2 presents the risk of bias ratings for individual studies. Detailed characteristics for each of the eight studies are reported in Table 3.

Maintaining Weight (kg) – Overall and by Primary Focus of Intervention

The Evidence Set provides the GRADE Evidence Profile (Table 3), the GRADE Summary of Findings Table (Table 4), and the forest plot (Figure 2) for the outcome of weight in kg

comparing the intervention participants with usual care, no intervention or placebo groups. An overall analysis was performed using six of the seven studies that reported data for weight in kg. Findings from the seventh study¹ could not be pooled as the outcome was reported as median weight loss, and is reported narratively below.

Overall

Six RCTS (n=2,386) of moderate GRADE quality (downgraded for risk of bias) were included in the meta-analysis assessing weight maintenance as measured in kg.²⁻⁷ All six studies included adults aged 18 to 64 years. Most studies (n=5) included mixed gender samples and one included only women. In one study the participants had a high risk of T2D and dyslipidemia. In terms of primary focus of intervention, two used behavioural (lifestyle) strategies, and four used pharmacological (orlistat) plus behavioural approaches. Control participants in the behavioural intervention studies engaged in self-directed weight maintenance or minimal contact through mail. Control participants in pharmacological studies received placebo instead of orlistat plus the same behavioural components as the intervention group. The duration of the weight maintenance intervention was six months in one study, 12 months in three studies, 30 months in one study and 36 months in the final study. Five studies were conducted in the US and one was located in various Scandinavian countries. Two studies were published between 2007 and 2011 and four studies were published between 1999 and 2000. At the post intervention assessment point, there was a mean difference of -1.44 kg (95% CI -2.42, -0.47; $I^2=67\%$) between intervention and control groups. In all studies except one,⁵ participants in both groups gained weight during the maintenance phase, with less weight gain in the intervention group than in the control. In Hauptman et al.'s study, the intervention group regained more weight than the control group, although there was no statistically significant difference.⁵ There was no evidence that the effect of treatment differed based on primary focus of intervention [behavioural (lifestyle) versus pharmacological (orlistat) plus behavioural] [test for subgroup differences: $\text{Chi}^2=0.02$ df=1 (P=0.88) $I^2=0\%$].

Behavioural Interventions

Two RCTs (n=1,215) of moderate GRADE quality (downgraded for risk of bias) were included in the meta-analysis assessing weight maintenance as measured in kg.^{2,3} Both studies included adults aged 18 to 64 years. One study included a mixed gender sample while the other included only women. In both studies the type of behavioural intervention was lifestyle. Control participants engaged in self-directed weight maintenance in one study and minimal contact through mail in the other study. Intervention duration was six months in one study and 30 months in the other. Both US-based studies were published in 2011. At the post intervention assessment point, mean difference favored the intervention [MD (95% CI) -1.56 kg (-3.10, -0.02) $I^2=63\%$]; which, in this case, meant less weight regain in the intervention group compared to controls.

One behavioural RCT provided data for this outcome that could not be incorporated in the meta-analysis.¹ This fairly recent, small (n=55), UK-based study reported the effect of diet support by email contact over six months for adults who had already achieved $\geq 5\%$ body weight loss. The

intervention group maintained a median of 9.6 kg weight loss (interquartile range 10.9) compared with control participants who maintained a median weight loss of 7.8 kg (interquartile range 5.9).

Pharmacological plus Behavioural Interventions

Four pharmacological plus behavioural RCTs (n=1,171) of low GRADE quality (downgraded for risk of bias and imprecision) were included in the meta-analysis assessing weight maintenance as measured in kg.⁴⁻⁷ All four studies included adults aged 18 to 64 years and mixed gender samples. In one study the participants had a high risk of T2D and dyslipidemia. In all four studies the pharmacological intervention was 120 mg orlistat taken three times daily. Control participants followed the same maintenance diet and exercise instructions as the intervention participants but they received placebos instead of the active medication. Intervention duration was 12 months in three studies and 36 months in one study. Three studies were conducted in the US and one was located in various Scandinavian countries. One study was published in 2007 and the other three were published in 1999 and 2000. There was no difference in weight maintenance between the intervention and control groups [MD (95% CI) -1.39 kg (-2.86, 0.08) $I^2=76\%$].

Other Primary Weight Outcomes

The Evidence Set also provides the GRADE Evidence Profile (Table 5), the GRADE Summary of Findings Table (Table 6), and the forest plots (Figures 3 to 6) for the outcomes of maintaining loss of $\geq 5\%$ initial body weight, maintaining loss of $\geq 10\%$ initial body weight, maintaining waist circumference, and maintaining BMI for the comparison between intervention participation and usual care, no intervention or placebo.

Maintenance of Loss of $\geq 5\%$ Initial Body Weight

Three RCTs (n=987) of moderate GRADE quality (downgraded for risk of bias) were included in the meta-analysis assessing maintenance of loss of $\geq 5\%$ initial body weight.^{5,7,8} All three studies included adults aged 18 to 64 years and mixed gender samples. In one study the participants had a high risk of T2D and dyslipidemia. All three studies compared the effects of a pharmacological intervention (120 mg orlistat three times daily) plus a weight maintenance diet against a placebo plus the same weight maintenance diet. Intervention duration was 12 months in two studies and 36 months in one study. One study was conducted in the US, one in 15 European centres and one in various Scandinavian countries. One study was published in 2007; the other two studies were published in 1998 and 2000. At the post intervention assessment point, intervention participants were significantly more likely to have maintained the loss of $\geq 5\%$ of their initial body weight as compared to control participants [RR (95% CI) 1.33 (1.15, 1.54) $I^2=14\%$]. The number needed to treat (NNT) for one participant to maintain the loss of $\geq 5\%$ of their initial body weight was 8 (95% CI 5, 18).

Maintenance of Loss of $\geq 10\%$ Initial Body Weight

Two RCTs (n=731) of low GRADE quality (downgraded for risk of bias and imprecision) were included in the meta-analysis assessing maintenance of loss of $\geq 10\%$ initial body weight.^{5,7} Both studies included adults aged 18 to 64 years and mixed gender samples. In one study the participants

had a high risk of T2D and dyslipidemia. Both studies compared the effects of a pharmacological intervention (120 mg orlistat three times daily) plus a weight maintenance diet against a placebo plus the same weight maintenance diet. Intervention duration was 12 months in one study and 36 months in the other. One study was conducted in the US and the other was located in various Scandinavian countries. One study was published in 2007 and the other in 2000. At the post intervention assessment point, there was no difference between intervention and control participants in terms of maintaining the loss of $\geq 10\%$ of their initial body weight [RR (95% CI) 1.76 (0.75, 4.12) $I^2=85\%$].

Maintaining Waist Circumference

A single RCT (n=306) of moderate GRADE quality (downgraded for risk of bias) provided data for the outcome of maintaining waist circumference.⁷ The study included a mixed gender sample of adults aged 18 to 64 who had identified metabolic risk factors such as dyslipidemia, impaired fasting glucose and diet treated T2D. The 36 month intervention involved pharmacological (120 mg orlistat three times daily) plus behavioural (standard energy restricted diet and dietary and lifestyle counseling) components. Control participants were administered placebo and received the same diet and lifestyle strategies as the intervention participants. The study was conducted in a number of Scandinavian countries and was published in 2007. At the post intervention assessment point, both groups had an increase in their waist circumference, but a smaller increase was observed in the intervention participants compared to control [MD (95% CI) -2.3 cm (-3.45, -1.15)].

Maintaining BMI

A single US-based RCT (n=234) of moderate GRADE quality (downgraded for risk of bias) provided data for the outcome of maintaining BMI.³ The study included rural women aged 50 to 75. The six month behavioural intervention used counseling approaches to support women in making lifestyle changes. Control participants had minimal contact by mail. The study was published in 2011. At the post intervention assessment point, intervention participants remained at a lower BMI (i.e., they had a smaller increase in BMI) compared to the control group [MD (95% CI) -0.95 kg/m² (-1.67, -0.23)].

Discussion, Limitations and Conclusion

There was a limited body of evidence on the effectiveness of weight maintenance interventions. Four of the six studies reporting on weight as measured in kg included orlistat (120 mg three times daily). Overall, the six studies were rated as moderate GRADE quality evidence. Interventions showed a significant effect for maintaining the loss of $\geq 5\%$ initial body weight, lower weight (kg), smaller waist circumference and lower BMI compared to control group. When only the studies of orlistat were analyzed, there was no overall benefit on weight maintenance. There was no significant effect for the outcome of maintaining the loss of $\geq 10\%$ initial body weight; however there were only two studies (both about orlistat) for this outcome and overall quality of this evidence was rated low with high observed heterogeneity. The maintenance of loss of $\geq 5\%$ initial body weight [NNT 8 (95% CI 5, 18)] would be clinically meaningful at a population level. Other outcomes are difficult to interpret clinically, as all interventions resulted in small benefits in terms of weight maintenance.

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Figure 1: Search and Selection Flow Diagram

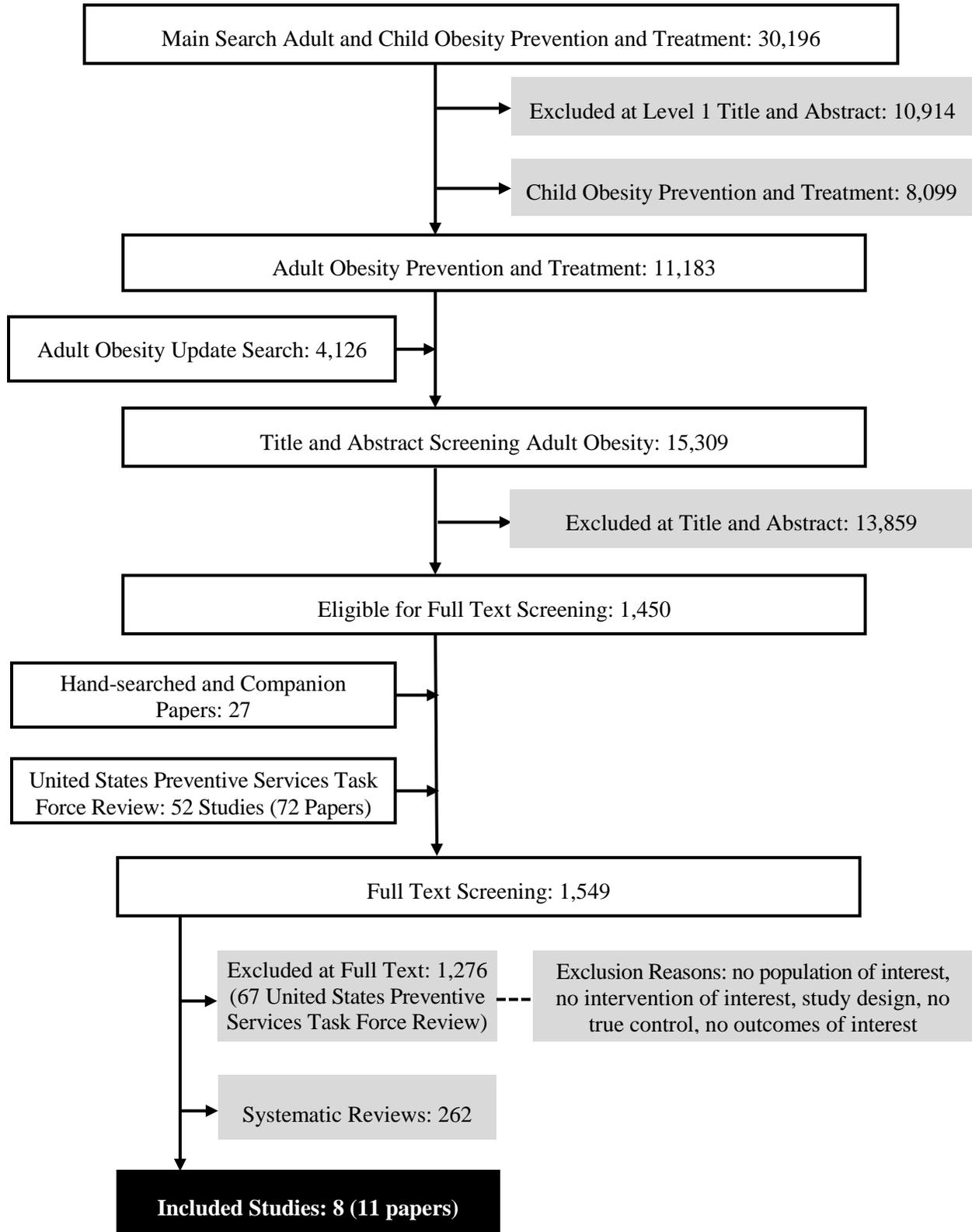


Table 1: Summary of Characteristics of Included Studies

Study	Gender	Mean Age	Sample Size*	Prior Weight Loss Intervention Type	Intervention Type	Comparator	Intervention Length (months)	Location	Date	Study Risk of Bias
Champagne ^{2,9}	mixed	55	1,032	6 month diet plus group based support	lifestyle (delivery strategies: internet or personal contact)	self-directed	30	United States	2011	Unclear
Davidson ⁴	mixed	43	306	1 year 120 mg orlistat 3x/day plus controlled energy diet	120 mg orlistat 3x/day plus weight maintenance diet	placebo plus same weight maintenance diet	12	United States	1999	Unclear
Hauptman ⁵	mixed	42	273	1 year of 120 mg orlistat 3x/day plus energy reduced diet	120 mg orlistat 3x/day plus weight maintenance diet	placebo plus same weight maintenance diet	12	United States	2000	Unclear
Hill ⁶	mixed	46	369	6 month hypo-energetic diet plus encouraged to exercise	120 mg orlistat 3x/day plus dietary and behavioural counselling	placebo plus same diet and behavioural components	12	United States	1999	Unclear
Richelsen ⁷	mixed	47	309	8 weeks very low energy diet	120 mg orlistat 3x/day plus energy restricted diet and dietary and lifestyle counselling	placebo plus same diet and behavioural components	36	Scandinavian Countries	2007	Unclear
Rickel ^{3,10,11}	female	59	234	6 month group based lifestyle program	6 month group based lifestyle program	newsletters with tips and recipes	6	United States	2011	Unclear
Sjöström ⁸	mixed	45	261	1 year of 120 mg orlistat 3x/day plus hypo-caloric diet	120 mg orlistat 3x/day plus weight maintenance diet	placebo plus weight maintenance diet	12	European Countries	1998	Unclear
Thomas ¹	not reported	45	55	not reported (recruited from a weight loss clinic)	weekly emails from dietician with dietary, behavioural and exercise advice	no contact	6	United Kingdom	2011	Unclear

* If a study included multiple treatment arms with varied orlistat doses, we included only the 120 mg group.

Table 2: Summary of Risk of Bias Assessment for Included Studies

Study	Sequence Generation	Allocation Concealment	Blinding of Participants/ Personnel	Blinding of Outcome Assessors	Incomplete Reporting	Selective Reporting	Other Bias
Champagne ^{2,9}	U	L	H	L	L	L	L
Davidson ⁴	U	U	U	U	H	L	H
Hauptman ⁵	U	U	U	U	H	H	U
Hill ⁶	U	U	U	U	L	L	H
Richelsen ⁷	L	L	U	U	L	L	H
Rickel ^{3,10,11}	U	U	H	L	L	L	L
Sjöström ⁸	L	U	U	U	L	L	H
Thomas ¹	L	L	H	U	L	L	L

L (green) = Low Risk of Bias; U (yellow) = Unclear Risk of Bias; H (red) = High Risk of Bias

Table 3: Detailed Characteristics of Included Studies

Study/Location	Champagne 2011 ² US; Companion paper: Svetkey ⁹
Objective	To compare 2 weight loss maintenance interventions with a self-directed control group
Methods	<p>Design: RCT</p> <p>Selection: recruited from 4 medical centre/health research sites in the US; 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 Technology) 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 ⁴ US

Objective	To test whether orlistat plus a dietary intervention is more effective than placebo plus diet for weight loss and maintenance over 2 years
Methods	<p>Design: RCT</p> <p>Selection: recruited at 18 clinical research centers in the US</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 ⁵ US
Objective	To evaluate the long-term efficacy and tolerability of orlistat for the treatment of obesity within primary care settings

Methods	<p>Design: RCT</p> <p>Selection: recruited from 17 primary care centers in the US</p> <p>Inclusion Criteria: >18 years; BMI 30 to 44</p> <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 \geq10% 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</p>
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 ⁶ US
Objective	To test the effectiveness of orlistat against placebo in preventing weight regain

Methods	<p>Design: RCT</p> <p>Selection: recruited at 17 clinical research centers in the US</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, 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</p>
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 ⁷ 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: RCT</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</p>

	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
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 ³ US; Companion papers: Perri, ¹⁰ Radcliff ¹¹
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: RCT</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> <p>Loss to follow-up: no loss</p>
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 ⁸ 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: RCT</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:</p>

	284 (82.8%); Control: 283 (83.2%) Loss to follow-up: Intervention n=2; Control n=3
Intervention	Description of pre-intervention run-in: 4 weeks of placebo taken 3 times daily plus hypocaloric diet Description of one-year weight loss intervention: 120 mg of orlistat three times daily plus continuation of hypocaloric diet Description of weight maintenance intervention: 120 mg orlistat three times daily plus eucaloric (weight maintenance) diet Description of control: placebo plus eucaloric diet Duration of intervention: 12 months Length of follow-up: immediate post
Study/Location	Thomas 2011 ¹ UK
Objective	To assess the effects of diet support via e-mail on weight loss maintenance
Methods	Design: RCT Selection: recruited directly from a weight loss clinic led by a dietician (within a Hospital Trust) twice a week Inclusion Criteria: already lost $\geq 5\%$ initial body weight; access to e-mail Exclusion Criteria: applying for bariatric surgery; no e-mail access; taking weight loss medication; binge eating disorder; learning difficulties
Participants	Sample: 55 Intervention n=28; Control n=27 Age, Mean (SD) years: Intervention: 43.2 (15.2); Control: 46.2 (12.0) Gender: not reported Loss to follow-up: Intervention n=3; Control n=3
Intervention	Description of weight maintenance intervention: weekly e-mails from dietitian with dietary, behavioural and exercise advice Description of weight maintenance control: no contact with the dietician Duration of weight maintenance intervention: 6 months Length of follow-up: immediate post

Evidence Set: What is the effect of weight maintenance interventions on weight related outcomes?

- Summary of Weight Related Outcome Evidence
- Table 3: GRADE Evidence Profile - Effect of Weight Maintenance Interventions on Maintaining Weight (kg)
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- Figure 1: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining Weight (kg)
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- Figure 4: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining Waist Circumference
- Figure 5: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining BMI

Summary of Weight Related Outcome Evidence

Maintaining Weight (kg) - Overall

- 6 studies; 2,386 participants
- Intervention participants had less regain than controls [MD (95% CI) -1.44 kg (-2.42, -0.47)]
- Moderate heterogeneity across studies [$\text{Chi}^2=15.21$, $\text{df}=5$ ($P=0.010$), $I^2=67\%$]

There was no evidence that the effect of treatment differed based on primary focus of intervention [behavioural (lifestyle), pharmacological (orlistat) plus behavioural] [test for subgroup differences: $\text{Chi}^2=0.02$, $\text{df}=1$ ($P=0.88$), $I^2=0\%$].

Maintaining Weight (kg) - Behavioural Interventions (Lifestyle Only)

- 2 studies; 1,215 participants
- Intervention participants had less regain than controls [MD (95% CI) -1.56 kg (-3.10, -0.02)]
- Moderate heterogeneity across studies [$\text{Chi}^2=2.70$, $\text{df}=1$ ($P=0.10$), $I^2=63\%$]

Maintaining Weight (kg) - Pharmacological (Orlistat) plus Behavioural Interventions

- 4 studies; 1,171 participants
- No statistically significant effect of orlistat [MD (95% CI) -1.39 kg (-2.86, 0.08)]
- High heterogeneity across studies [$\text{Chi}^2=12.50$, $\text{df}=3$ ($P=0.006$), $I^2=76\%$]

Maintaining Loss of $\geq 5\%$ Initial Body Weight

- 3 studies; 987 participants
- Intervention participants were significantly more likely to maintain the loss of $\geq 5\%$ of their initial body weight as compared to controls [RR (95% CI) 1.33 (1.15, 1.54)]
- Low heterogeneity across studies [$\text{Chi}^2=2.32$, $\text{df}=2$ ($P=0.31$), $I^2=14\%$]

Maintaining Loss of $\geq 10\%$ Initial Body Weight

- 2 studies; 731 participants
- No difference in maintaining the loss of $\geq 10\%$ of initial body weight [RR (95% CI) 1.76 (0.75, 4.12)]
- High heterogeneity across studies [$\text{Chi}^2=6.52$, $\text{df}=1$ ($P=0.01$), $I^2=85\%$]

Maintaining Waist Circumference (cm)

- 1 study; 306 participants
- Intervention participants had less of an increase in their waist circumference than control participants [MD (95% CI) -2.3 cm (-3.45, -1.15)]

Maintaining BMI (kg/m^2)

- 1 study; 234 participants
- Intervention participants had a smaller increase in their BMI than control participants [MD (95% CI) -0.95 kg/m^2 (-1.67, -0.23)]

Table 4: GRADE Evidence Profile - Effect of Weight Maintenance Interventions on Maintaining Weight (kg) *

Quality Assessment							No. of Participants		Effect	Quality	Importance
No. of Studies	Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Considerations	Treatment	Control	Mean Difference (95% CI)		
Maintaining Weight (kg): Overall [interventions 6-36 months; immediate post assessment] (better indicated by lower values)											
6	randomized trials ¹	serious risk ²	no serious inconsistency ³	no serious indirectness ⁴	no serious imprecision ⁵	none ⁶	1,401	985	1.4444 lower (2.4183 to 0.4706 lower)	⊕⊕⊕○ MODERATE	CRITICAL
Maintaining Weight (kg): by Primary Focus of Intervention - Behavioural (Lifestyle Only) [interventions 6-30 months; immediate post assessment] (better indicated by lower values)											
2	randomized trials ⁷	serious risk ⁸	no serious inconsistency ⁹	no serious indirectness ¹⁰	no serious imprecision ¹¹	none ⁶	816	399	1.5601 lower (3.1039 to 0.0163 lower)	⊕⊕⊕○ MODERATE	CRITICAL
Maintaining Weight (kg): by Primary Focus of Intervention - Pharmacological (Orlistat) plus Behavioural (intervention 12-36 months; immediate post assessment) (better indicated by lower values)											
4	randomized trials ¹²	serious risk ¹³	no serious inconsistency ¹⁴	no serious indirectness ¹⁵	serious imprecision ¹⁶	none ⁶	585	586	1.3902 lower (2.8632 lower to 0.0827 higher)	⊕⊕○○ LOW	CRITICAL

* Footnotes appear after the Summary of Findings Table

Table 5: GRADE Summary of Findings - Effect of Weight Maintenance Interventions on Maintaining Weight (kg)

Outcome: Maintaining Weight (kg)	Compared to the control group, the mean weight in kg (95% CI) in the intervention groups was	No. of Participants (Studies)	Quality of the Evidence (GRADE)
Overall [intervention 6-36 months; immediate post assessment]	1.4444 lower (2.4183 to 0.4706 lower)	2,386 (6 studies ¹)	⊕⊕⊕○ moderate ^{2,3,4,5,6}
By Primary Focus of Intervention – Behavioural (Lifestyle Only) [intervention 6-30 months; immediate post assessment]	1.5601 lower (3.1039 to 0.0163 lower)	1,215 (2 studies ⁷)	⊕⊕⊕○ moderate ^{6,8,9,10,11}
By Primary Focus of Intervention - Pharmacological (Orlistat) plus Behavioural (intervention 12-36 months; immediate post assessment)	1.3902 lower (2.8632 lower to 0.0827 higher)	1,171 (4 studies ¹²)	⊕⊕○○ low ^{6,13,14,15,16}

Footnotes for GRADE Evidence Profile and Summary of Findings Tables for Effect of Weight Maintenance Interventions on Maintaining Weight (kg)

¹ Champagne et al. 2011; ² Rickel et al. 2011; ³ Davidson et al. 1999; ⁴ Hauptman et al. 2000; ⁵ Hill et al. 1999; ⁶ Richelsen et al. 2007

² Using Cochrane's Risk of Bias tool, for this outcome all studies were rated as unclear risk. Across studies, there was a lack of certainty (unclear ratings) regarding risk of bias associated with sequence generation (83%), allocation concealment (67%), blinding of participants and/or personnel (67%), and blinding of outcome assessors (67%); identified risks (high ratings) were located in the domains of blinding of participants and personnel (33%), incomplete reporting (33%), and other sources of bias (50%; i.e., industry funding and/or insufficient power). Given that all of the information for this outcome is from studies at moderate risk of bias, this body of evidence was downgraded for serious study limitations.

³ Although the statistical heterogeneity is moderate [$\text{Chi}^2=15.21$, $\text{df}=5$ ($p<0.01$); $I^2=67\%$] the direction of the effect is consistent across most studies and the confidence intervals overlap. The test for subgroup differences (behavioural, pharmacological plus behavioural) was not significant [$\text{Chi}^2=0.02$, $\text{df}=1$ ($p=0.88$), $I^2=0\%$]. The statistical heterogeneity is most likely due to small versus large treatment effects observed across studies. This body of evidence was not downgraded for inconsistency.

⁴ All 6 studies included adults aged 18-64 years. Five studies included mixed gender samples and one included only women. In one study the participants had a high risk of T2D and dyslipidemia. In terms of intervention type, 2 were behavioural (lifestyle), and 4 were pharmacological (orlistat) plus behavioural. Control participants in behavioural intervention studies engaged in self-directed weight maintenance or had minimal contact through mail. Control participants in pharmacological studies received placebo instead of active medication plus the same behavioural components as the intervention group. Maintenance intervention duration was 12 months or less in 4 studies and more than 12 months in 2 studies. Five studies were conducted in the US and one across various Scandinavian countries. Two studies were published in the last 5 years (2009-2013); 4 studies were published between 1999 and 2008. There were no serious concerns regarding indirectness for this body of evidence.

⁵ The sample size is adequate (1,401 intervention arm, 985 control arm) and the pooled effect estimate is precise with a narrow confidence interval [MD (95% CI) -1.4444 kg (-2.4183, -0.4706)]. This body of evidence was not downgraded for imprecision.

⁶ There were too few studies ($n<10$) to assess publication bias.

⁷ Champagne et al. 2011;² Rickel et al. 2011³

⁸ Using Cochrane's Risk of Bias tool, for this outcome both studies were rated as unclear risk. There was a lack of certainty (unclear ratings) regarding risk of bias associated with sequence generation in both studies and allocation concealment in one study; identified risks (high ratings) were located in the domain of blinding of participants and personnel in both studies. Given that all of the information for this outcome is from studies at moderate risk of bias, this body of evidence was downgraded for serious study limitations.

⁹ Although the statistical heterogeneity is moderate [$\text{Chi}^2=2.70$, $\text{df}=1$ ($p=0.10$); $I^2=63\%$] the direction of the effect is consistent across studies and the confidence intervals overlap. The statistical heterogeneity is most likely due to small versus large treatment effects observed across studies. This body of evidence was not downgraded for inconsistency.

¹⁰ Both studies included adults aged 18-64 years. One included a mixed gender sample while the other included only women. In both studies the main focus of behavioural intervention was lifestyle. Control participants engaged in self-directed weight maintenance in one study and had minimal contact through mail in the other study. Intervention duration was 12 months or less in one study and more than 12 months in the other. Both studies were conducted in the US and published in 2011. There were no serious concerns regarding indirectness for this body of evidence.

¹¹ The sample size is adequate (816 intervention arm, 399 control arm) and the pooled effect estimate is precise with a narrow confidence interval [MD (95% CI) -1.5601 kg (-3.1039, -0.0163)]. This body of evidence was not downgraded for imprecision.

¹² Davidson et al. 1999;⁴ Hauptman et al. 2000;⁵ Hill et al. 1999;⁶ Richelsen et al. 2007⁷

¹³ Using Cochrane's Risk of Bias tool, for this outcome all studies were rated as unclear risk. Across studies, there was a lack of certainty (unclear ratings) regarding risk of bias associated with sequence generation (75%), allocation concealment (75%), blinding of participants and/or personnel (100%), and blinding of outcome assessors (100%); identified risks (high ratings) were located in the domains of incomplete reporting (50%), and other sources of bias (75%; i.e., industry funding and/or insufficient power). Given that all of the information for this outcome is from studies at moderate risk of bias, this body of evidence was downgraded for serious study limitations

¹⁴ Although the statistical heterogeneity is high [$\text{Chi}^2=12.50$, $\text{df}=3$ ($p<0.006$); $I^2=76\%$] the direction of the effect is consistent across most studies and the confidence intervals overlap. The statistical heterogeneity is most likely due to small versus large treatment effects observed across studies. This body of evidence was not downgraded for inconsistency.

¹⁵ All 4 studies included adults aged 18-64 years and mixed gender samples. In one study the participants had a high risk of T2D and dyslipidemia. In all 4 studies the pharmacological intervention was orlistat. Control participants followed the same diet and exercise instructions as the intervention participants but they received placebo instead of active medication. Intervention duration was 12 months or less in 3 studies and more than 12 months in one study. Three studies were conducted in the US and one was conducted in various Scandinavian countries. One study was published in 2007; the remaining 3 were published between 1999 and 2000. There were no serious concerns regarding indirectness for this body of evidence.

¹⁶ The sample size is adequate (585 intervention arm, 586 control arm) but the pooled effect estimate is not precise with a confidence interval that includes the no effect value [MD (95% CI) -1.3902 (-2.8632, 0.0827)]. This body of evidence was downgraded for serious concerns regarding imprecision.

Figure 2: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining Weight (kg) – Overall and by Primary Focus of Intervention [Behavioural (Lifestyle), Pharmacological (Orlistat) plus Behavioural]

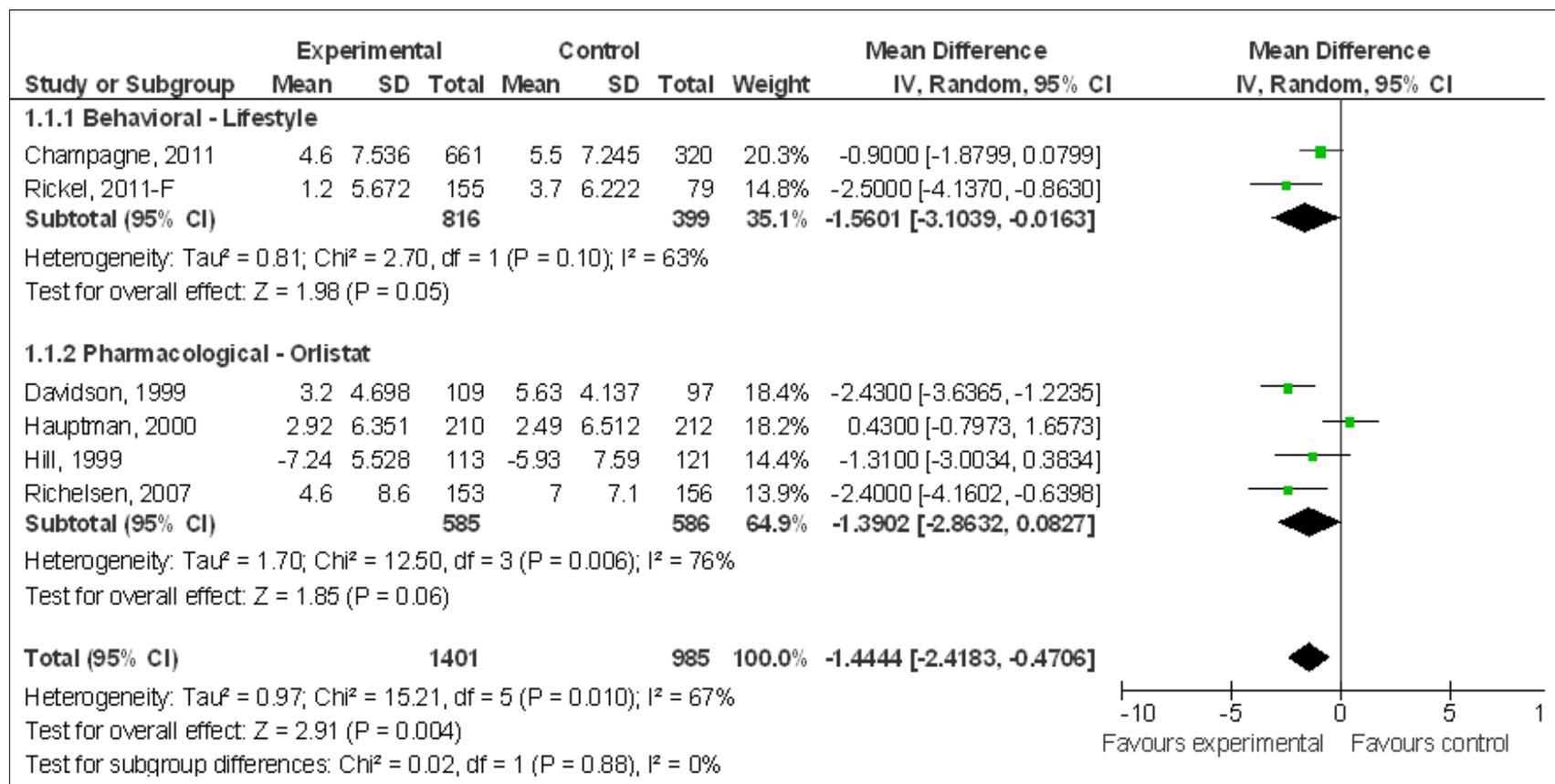


Figure 2 notations: -F extension indicates data is for women only

Table 6: GRADE Evidence Profile - Effect of Weight Maintenance Interventions on Other Weight Outcomes *

Quality Assessment							No. of Participants		Effect				Quality	Importance	
No. of Studies	Design	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other	Treatment	Control	Relative (95% CI)	Absolute per Million (Range)	ARR	NNT (95% CI)			
Maintaining ≥5% Weight Loss: Pharmacological (Orlistat) plus Behavioural (intervention duration 12-36 months; immediate post assessment)															
3	randomized trials ¹	serious risk ²	no serious inconsistency ³	no serious indirectness ⁴	no serious imprecision ⁵	none ⁶	251/496 (50.6048%)	184/491 (37.4745%)	RR 1.3301 (1.1472 to 1.5421)	123,703 more (from 55,163 more to 203,149 more)	12.37%	8 (5,18)	⊕⊕⊕O MODERATE	CRITICAL	
Maintaining ≥10% Weight Loss: Pharmacological (Orlistat) plus Behavioural (intervention duration 12-36 months; immediate post assessment)															
2	randomized trials ⁷	serious risk ⁸	no serious inconsistency ⁹	no serious indirectness ¹⁰	serious imprecision ¹¹	none ⁶	91/363 (25.0689%)	59/368 (16.0326%)	RR 1.7595 (0.7521 to 4.1165)	121,768 more (from 39,745 fewer to 499,656 more)	█	█	⊕⊕OO LOW	CRITICAL	
										Mean Difference (95% CI)					
Maintaining Waist Circumference (cm) - Pharmacological (Orlistat) plus Behavioural (intervention duration 36 months; immediate post assessment) (better indicated by lower values)															
1	randomized trial ¹²	serious risk ¹³	no serious inconsistency ¹⁴	no serious indirectness ¹⁵	no serious imprecision ¹⁶	none ⁶	153	153	2.3000 lower (3.4540 to 1.1460 lower)			⊕⊕⊕O MODERATE	CRITICAL		
Maintaining BMI (kg/m²) – Behavioural (Lifestyle Only) (intervention duration 6 months; immediate post assessment) (better indicated by lower values)															
1	randomized trial ¹⁷	serious risk ¹⁸	no serious inconsistency ¹⁴	no serious indirectness ¹⁹	no serious imprecision ²⁰	none ⁶	155	79	0.9500 lower (1.6700 to 0.2300 lower)			⊕⊕⊕O MODERATE	CRITICAL		

* Footnotes appear after the Summary of Findings Table

Table 7: GRADE Summary of Findings - Effect of Maintenance Interventions on Other Primary Outcomes

Outcome	Illustrative Comparative Risks* (95% CI)		Relative Effect (95% CI)	No. of Participants (Studies)	Quality of the Evidence (GRADE)
	Assumed Risk Number per Million Control	Corresponding Risk Number per Million Treatment			
Maintaining Loss of $\geq 5\%$ Initial Body Weight – Pharmacological (Orlistat) plus Behavioural (intervention duration 12-36 months; immediate post assessment)	374,745	498,449 (429,908 to 577,895)	RR 1.3301 (1.1472 to 1.5421)	987 (3 studies ¹)	⊕⊕⊕⊖ moderate ^{2,3,4,5,6}
Maintaining Loss of $\geq 10\%$ Initial Body Weight – Pharmacological (Orlistat) plus Behavioural (intervention duration 12-36 months; immediate post assessment)	160,326	282,094 (120,581 to 659,982)	RR 1.7595 (0.7521 to 4.1165)	731 (2 studies ⁷)	⊕⊕⊖⊖ low ^{6,8,9,10,11}
Compared to the control group, the mean change (95% CI) in the intervention groups was					
Maintaining Waist Circumference (cm) – Pharmacological (Orlistat) plus Behavioural (intervention duration 36 months; immediate post assessment)	2.3000 lower (3.4540 to 1.1460 lower)			306 (1 study ¹²)	⊕⊕⊕⊖ moderate ^{6,13,14,15,16}
Maintaining BMI (kg/m ²) – Behavioural (Lifestyle Only) (intervention duration 6 months; immediate post)	0.9500 lower (1.6700 to 0.2300 lower)			234 (1 study ¹⁷)	⊕⊕⊕⊖ moderate ^{6,14,18,19,20}

*The assumed risk is the mean control group risk across studies. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

Footnotes for GRADE Evidence Profile and Summary of Findings Tables for Effect of Weight Maintenance Interventions on Other Weight Outcomes

¹ Hauptman et al. 2000;⁵ Richelsen et al. 2007;⁷ Sjöström et al. 1998⁸

² Using Cochrane's Risk of Bias tool, for this outcome all 3 studies were rated as having unclear risk. Across the 3 studies, there was a lack of certainty (unclear ratings) regarding risk of bias associated with sequence generation (33%), allocation concealment (67%), blinding of participants and/or personnel (100%), and blinding of outcome assessors (100%); identified risks (high ratings) were located in the domains of incomplete reporting (33%), and other sources of bias (67%; i.e., industry funding and/or insufficient power). Given that all of the information for this outcome is from studies at moderate risk of bias, this body of evidence was downgraded for serious study limitations.

³ The statistical heterogeneity is minimal [Chi²=2.32, df=2 (p=0.31); I²=14%] and the direction of the effect is consistent across studies and the confidence intervals overlap. This body of evidence was not downgraded for inconsistency.

⁴ Only 3 pharmacological plus behavioural intervention studies provided data for this outcome. All 3 studies included adults aged 18-64 years and mixed gender samples. In one study the participants had a high risk of T2D and dyslipidemia. In all 3 studies the pharmacological intervention was orlistat. Control participants followed the same diet and/or exercise instructions as the intervention participants but they received placebo instead of active medication. Intervention duration was 12 months or less in 2 studies and more than 12 months in one study. One study was conducted in the US, one in 15 European centres and one in various Scandinavian countries. One study was published in 2007; the other 2 studies were published between 1998 and 2000. There were no serious concerns regarding indirectness for this body of evidence.

⁵ The sample size is adequate (496 intervention arm, 491 control arm) and the pooled effect estimate is precise with a narrow confidence interval [RR (95% CI) 1.3301 (1.1472, 1.5421)]. This body of evidence was not downgraded for imprecision

⁶ There were too few studies (n<10) to assess publication bias.

⁷ Hauptman et al. 2000;⁵ Richelsen et al. 2007⁷

⁸ Using Cochrane's Risk of Bias tool, for this outcome both studies were rated as having unclear risk. Across studies, there was a lack of certainty (unclear ratings) regarding risk of bias associated with sequence generation (50%), allocation concealment (50%), blinding of participants and/or personnel (100%), and blinding of outcome assessors (100%); identified risks (high ratings) were located in the domains of incomplete reporting (50%), and other sources of bias (50%; i.e., industry funding and/or insufficient power). Given that all of the information for this outcome is from studies at moderate risk of bias, this body of evidence was downgraded for serious study limitations.

⁹ Although the statistical heterogeneity is high [$\text{Chi}^2=6.52$, $\text{df}=1$ ($p=0.01$); $I^2=85\%$] the direction of the effect is consistent across studies. The statistical heterogeneity is most likely due to small versus large treatment effects observed across studies. This body of evidence was not downgraded for inconsistency.

¹⁰ Only two pharmacological plus behavioural intervention studies provided data for this outcome. Both studies included adults aged 18-64 years and mixed gender samples. In one study the participants had a high risk of T2D and dyslipidemia. In both studies the pharmacological intervention was orlistat. Control participants followed the same diet and/or exercise instructions as the intervention participants but they received placebo instead of active medication. Intervention duration was 12 months or less in one study and more than 12 months in the other study. One study was conducted in the US and one was conducted in various Scandinavian countries. One study was published in 2007 and the other was published in 2000. There were no serious concerns regarding indirectness for this body of evidence.

¹¹ The sample size is adequate (363 intervention arm, 368 control arm) but the pooled effect estimate is not precise with a confidence interval that includes the no effect value [RR (95% CI) 1.7595 (0.7521, 4.1165)]. This body of evidence was downgraded for serious concerns regarding imprecision.

¹² Richelsen et al. 2007⁷

¹³ Using Cochrane's Risk of Bias tool, for this outcome the study was rated as having unclear risk. There was a lack of certainty (unclear ratings) regarding risk of bias associated with blinding of participants and/or personnel and blinding of outcome assessors; identified risks (high ratings) were located in the domain of other sources of bias (i.e., industry funding and/or insufficient power). Given that all of the information for this outcome is from a study at moderate risk of bias, this body of evidence was downgraded for serious study limitations.

¹⁴ Inconsistency could not be assessed as only study provided the data for this outcome.

¹⁵ Only one pharmacological plus behavioural intervention study provided data for this outcome. The study included a mixed gender population aged 18-64 years with identified metabolic risk factors such as dyslipidemia, impaired fasting glucose and diet treated T2D. The 36 month intervention involved pharmacological (120 mg orlistat three times daily) plus behavioural (standard energy restricted diet) components. Control participants were administered placebo and followed the same diet as intervention participants. The study was conducted in a number of Scandinavian countries and was published in 2007. There were no serious concerns regarding indirectness for this body of evidence.

¹⁶ Although the sample size is less than adequate (153 intervention arm, 153 control arm) the effect estimate is precise with a narrow confidence interval [MD (95% CI) -2.3000 (-3.4540, -1.1460)]. This body of evidence was not downgraded for imprecision.

¹⁷ Rickel et al. 2011³

¹⁸ Using Cochrane's Risk of Bias tool, for this outcome the study was rated as having unclear risk. There was a lack of certainty (unclear ratings) regarding risk of bias associated with sequence generation and allocation concealment; identified risks (high ratings) were located in the domain of blinding of participants and personnel. Given that all of the information for this outcome is from a study at moderate risk of bias, this body of evidence was downgraded for serious study limitations

¹⁹ Only one behavioural intervention study provided data for this outcome. The study included women aged 18-64 years. The 6 month behavioural intervention involved lifestyles changes. Control participants had minimal contact by mail. The study was conducted in the US and was published in 2011. There were no serious concerns regarding indirectness for this body of evidence.

²⁰ Although the sample size is less than adequate (155 intervention arm, 79 control arm) the effect estimate is precise with a narrow confidence interval [MD (95% CI) -0.9500 (-1.6700, -0.2300)]. This body of evidence was not downgraded for imprecision.

Figure 3: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining Loss of $\geq 5\%$ Initial Body Weight

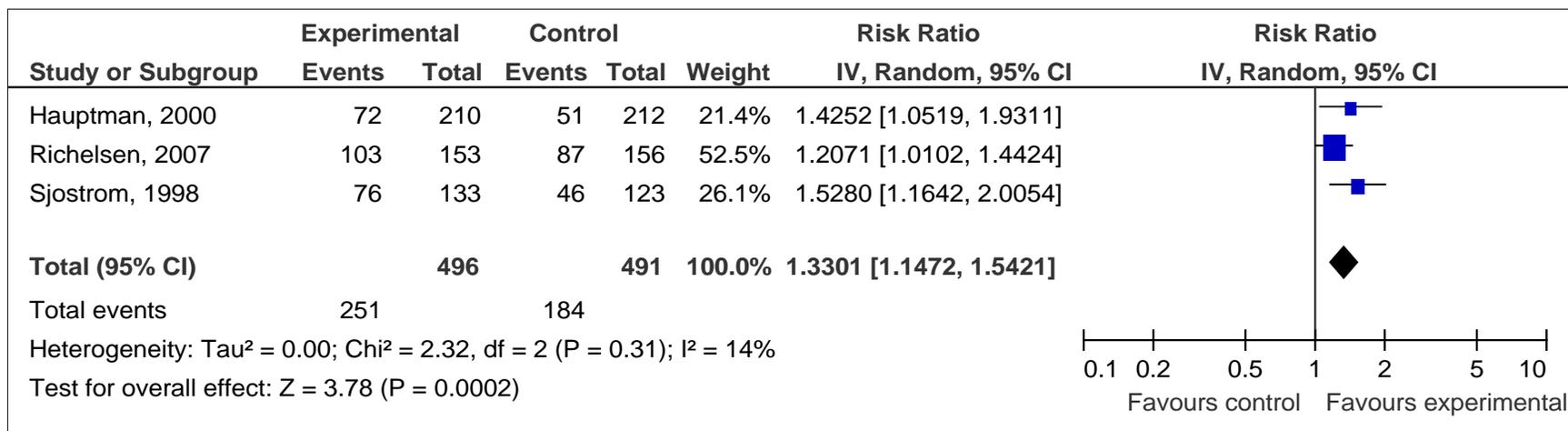


Figure 4: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining Loss of $\geq 10\%$ Initial Body Weight

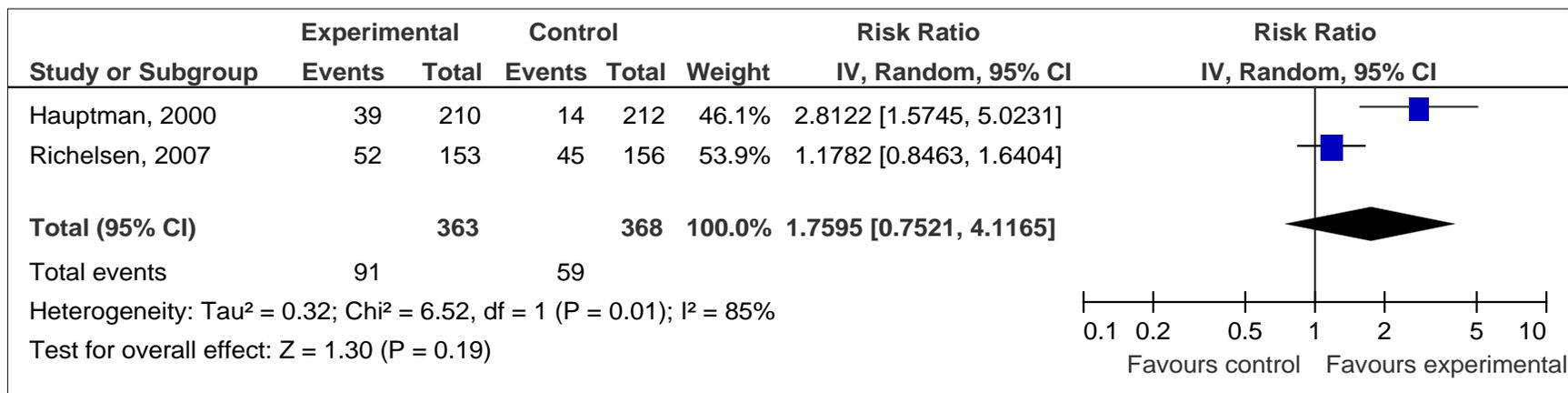


Figure 5: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining Waist Circumference (cm)

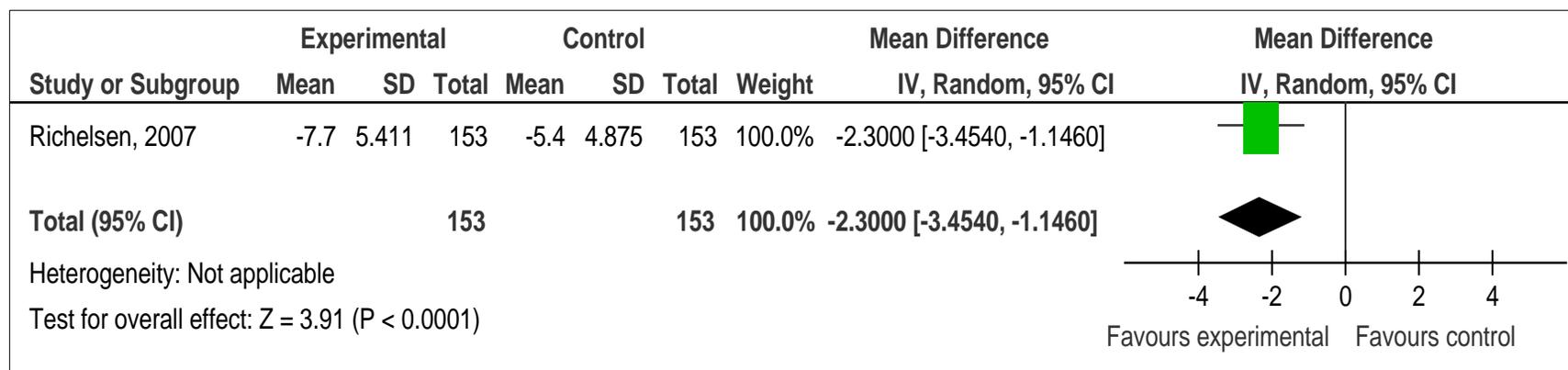


Figure 6: Forest Plot - Effect of Weight Maintenance Interventions on Maintaining BMI (kg/m²)

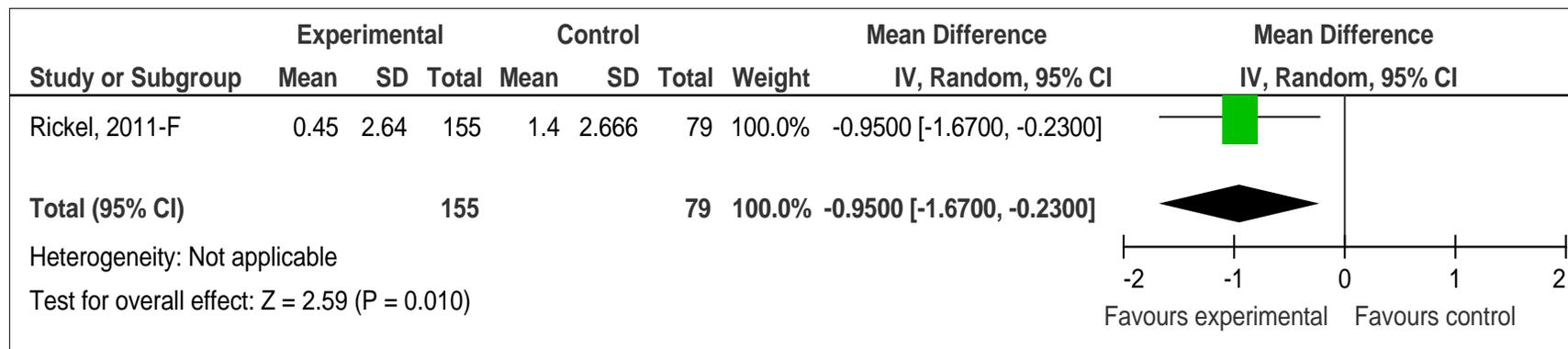


Figure 6 notations: -F extension indicates data is for women only