Effectiveness of behavioral weight loss interventions delivered in a primary care setting: A Systematic Review and Meta-analysis

SUPPORTING INFORMATION

Authors:

Miss Helen P. Booth[1], BSc MSc

Professor A. Toby Prevost[1], BSc MSc PhD

Dr Alison J. Wright[1], BSc MSc PhD

Professor Martin C. Gulliford[1], FFPH FRCP

[1]Department of Primary Care and Public Health Sciences, King's College London

Search terms used in for the electronic database search

((‘anti-obesity agents’ OR ‘appetite depressants’ OR ‘sibutramine’ OR ‘orlistat’) OR (‘cognitive therapy’ OR ‘behavior therapy’)) AND (‘obesity’ OR ‘obesity, morbid’ OR ‘overweight’ OR ‘weight loss’) AND (‘clinical trial’ OR ‘controlled clinical trial’ OR ‘meta-analysis’ OR ‘randomized controlled trial’ OR ‘RCT’) AND ‘limit to year =’1990’ to present’

Table S1: Risk of bias using the Cochrane Risk of Bias Tool

Study	Sequence generation	Allocation concealment	Blinding of ppts, personnel & outcome assessors	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Appel (2011)	NO "randomization was stratified according to sex and was generated in blocks of 3 and 6 with the use of a Web-based program."	UNCLEAR	UNCLEAR Blinding not discussed. Likely that no blinding was in place which could lead to observation bias	UNCLEAR 89% completion in both intervention groups, 78% in control at 12m. 100% in remote GP, 96% in in-person & 93% in control at 24m. Drop-out bigger in control groups and reasons for drop-out not given.	YES Only weight reported in the main paper. Secondary outcomes reported in the supplementary appendix. Protocol states that Framingham Risk Score, HOMA-IR & insulin will be reported but don't appear to be.	NO No obvious issues around bias not addressed elsewhere
Bennett (2012)	NO "Participants were randomized to treatment arm using computer-generated allocations, blocked by clinic and sex"	UNCLEAR "computer-generated" - no further information	YES "The trial design precluded blinding either patients or interventionists to treatment assignment" Further details of intervention in Greaney (2009). PCP heightened awareness in control group?	UNCLEAR Limited information on drop-out in Figure 1. Completion 80% in intervention, 75% in control at 12m. 92% in intervention & 80% in control at 24m. Drop-out higher in control group. No significant differences found on group drop-out	UNCLEAR No protocol available. Weight and SBP reported as primary & secondary outcomes in method but DBP also mentioned in results.	NO No obvious issues around bias not addressed elsewhere
Christian (2008)	NO "Assignments to 1 of these 2 groups [control or intervention] were	UNCLEAR "Assignment was concealed to the RA by a padded envelope that also	YES "Neither physicians nor patients could be blinded to the intervention	UNCLEAR 91% of intervention & 85% of control group completed 12m. Description of reasons	NO Protocol not available. Primary endpoint was weight loss (mean &	NO No obvious issues around bias not addressed elsewhere

	based on a computer-generated random number sequence"	contained a kit of baseline enrollment materials." Not clear whether these were sequentially numbered and whether the number sequence could be seen in advance	assignment". Physicians had training then saw both control and intervention participants, treatment bias risk?	behind loss restricted to 'dropped out' and 'eliminated by Data Safety and Monitoring Board'.	fraction reaching 5% loss). Secondary was change in physical activity, energy intake, & lipid and HBA1c levels. Results on these outcomes are reported.	
Cohen (1991)	UNCLEAR "The residents were stratified by residency year and randomly assigned to either control or experimental groups"	UNCLEAR No information given	UNCLEAR No information given	NO No missing outcome data. 15 patients in each group and all completed	UNCLEAR No protocol available. "At six and 12 months, the patients were weighed, their blood pressures were measured, and the number of antihypertensive agents prescribed was noted by the trained nurse." These outcomes are covered in results.	YES Trial was a cluster RCT, no obvious tailoring of the analysis to account for this. The sample sizes were very small for a cluster trial.
Jalkanen (1991)	UNCLEAR No information given on randomization process	UNCLEAR No information given	UNCLEAR No information given	NO 96% of intervention & 100% of control group completed (only 50ppts).	UNCLEAR No protocol available. Study tested an intervention for "treatment of cardiovascular risk factors, especially overweight, hypertension and high serum lipids". Outcomes not	NO No obvious issues around bias not addressed elsewhere

					specified clearly.	
Karvetti (1992)	UNCLEAR No information given on randomization process. "[Patients] selected for the study were randomly assigned to a treatment group and a control group"	UNCLEAR No information given	UNCLEAR No information given	UNCLEAR 74% of treatment & 82% of control group completed at 12m. "Reasons for drop-out included refusal to enter the study, loss of interest during the intervention year and relocation outside the city of Turku". Differences between groups not clear.	UNCLEAR No protocol available. Outcomes not specified, but significance of changes in food & nutrient intake, weight, blood pressure and serum cholesterol reported in results.	NO No obvious issues around bias not addressed elsewhere
Kumanyika (2012)	NO "A randomization algorithm provided by a study biostatistician was electronically administered by assigning treatment group after key eligibility data were entered." Taken from Kumanyika, 2011	UNCLEAR "Random assignments were concealed from both participant and study staff prior to implementation." Doesn't explain how.	UNCLEAR No information given	UNCLEAR 79% of treatment & 65% of control group completed 12m. Only 7 patients reported as withdrawals from each treatment group (see figure 2).	UNCLEAR No protocol available. Outcomes not specifically mentioned but weight change discussed and reported.	NO No obvious issues around bias not addressed elsewhere
Logue (2005)	NO "Participants were randomized by opening an envelope with a set of ordered tickets indicating “TM-CD” or “Traditional” care. The (NEOUCOM)	NO "Participants and research staff at each practice were blind to the assignment of patients while obtaining baseline measures, because	YES "Participants were randomized by opening an envelope with a set of ordered tickets indicating “TM-CD” or “Traditional” care." Not blinded and all	UNCLEAR 89% of treatment and 85% of control completed 12m. 82% of treatment & 79% control completed 24m. “The majority of missing values occurred because	UNCLEAR No protocol available. "The main outcome measure was weight" "Other biological risk measurements included waist girths, blood	NO No obvious issues around bias not addressed elsewhere

	Office of Biostatistics prepared the ordered randomization tickets using permuted blocks of 10."	assignment envelopes were not opened until the end of the visit."	patients seen by PCPs which may have affected care of control group.	participants declined further participation when an effort was made to schedule a follow-up appointment."	lipids (from a central laboratory), and blood pressures." All discussed in results but non-significant results reported without numerical data.	
Martin (2008)	UNCLEAR "Physicians were randomly assigned to provide either a tailored weight loss intervention or standard care."	UNCLEAR No information given	UNCLEAR No information given	UNCLEAR 71% of treatment and 88% of control completed 12m. Poor description of the withdrawals but higher number in treatment group.	NO No protocol available. Weight at follow-up visits was primary outcome.	NO Clustering as a result of physician-randomisation was considered in the statistical analyses. Sample sizes were small for a cluster trial.
Mayer-Davis (2004)	UNCLEAR No information given on the randomization process. "Of the 664 potential participants contacted by phone, 143 (21.5%) were randomized into the study"	UNCLEAR No information given	UNCLEAR No information given	UNCLEAR "Of the 187 participants, 152 (81%) were retained through the 12-month end-of-study measurement visit." No information how many from each group withdrew.	NO No protocol available. "The primary outcome was weight loss." "Secondary outcomes included HbA1c (marker of glycemic control), lipid profile, and blood pressure." All presented in results.	NO No obvious issues around bias not addressed elsewhere
Moore (2003)	NO "patient level characteristics (body mass index at recruitment, age, and sex) and practice	UNCLEAR No information given	YES "Patients were not aware of the intervention status of their practice, and researchers collecting	UNCLEAR 67% of treatment and control groups completed to 12m. Reasons for withdrawal not	NO No protocol available. "The primary outcome measure was difference in mean	NO Cluster RCT "We analysed change [in outcomes] to account for both within cluster and

	level characteristics (practice size, socioeconomic status, and existence of dietetic service) were used to inform randomisation."		outcome measurements from patients were blind to the intervention status of the practices, both before and after the intervention. Double blinding was not possible in this trial." Control practice staff may have treated patients differently.	discussed.	weight of patients." Also measured "knowledge of obesity management and self-reported behaviour in consultations by staff."	between cluster variation"
Munsch (2003)	UNCLEAR "Patients from general practices (n =70) were randomised into either treatment (GP BASEL) or control (GP control) groups with a ratio of 3 to 2."	UNCLEAR No information given	UNCLEAR No information given	YES 77% of treatment group & 47% of control completed to 12m. Reasons for withdrawal not discussed.	UNCLEAR No protocol available. Outcome not specifically outlined though a list of instruments is given specifying that BMI was measured at baseline and endpoint.	NO No obvious issues around bias not addressed elsewhere
Rapoport (2000)	YES "In the first cohort, allocation of the groups to M-CBT or S-CBT was by the toss of a coin, and in the subsequent cohorts the allocation alternated, to ensure that both treatment types were represented at both times of day"	UNCLEAR No information given	UNCLEAR Not clear whether leaders of the intervention and control group sessions are the same people.	UNCLEAR 81% of treatment & 74% of control group completed 12m. Reasons for withdrawal only given up to 24 week assessment not 12m.	NO No protocol available. Outcomes were weight & body fat, fasting lipids & glucose, blood pressure, psychological measures, eating behaviour & body image, diet & activity, and acceptability of treatment. All	NO No obvious issues around bias not addressed elsewhere

					reported in results.	
Ross (2012)	NO "Eligible participants were randomized on the basis of a computer-automated randomization sequence after the acquisition of primary outcome data. Randomization was stratified by sex, age, and WC"	UNCLEAR No information given	YES "It was not possible to conceal the group assignment from the patients or the physicians." Intervention delivered by health educators but PCP's knew which group their patients were in which may have influenced care.	NO 76% of treatment group & 85% of control completed 24m. Reasons for withdrawal presented in Figure 1 and seem broadly similar.	UNCLEAR No protocol available. Primary outcome was waist circumference. Secondary outcomes were "common metabolic risk factors".	NO No obvious issues around bias not addressed elsewhere
Wadden (2011)	NO "Participants were randomly assigned to interventions (in equal numbers) with the use of a computer-generated algorithm that was operated by the Investigational Drug Service at the University of Pennsylvania."	UNCLEAR No information given	UNCLEAR No information given	UNCLEAR At 12m 85% & 86% of treatment groups & 84% of control groups completed. At 24m 85% & 88% of treatment groups & 85% of control groups completed. Withdrawal reasons not separated by treatment group.	NO Protocol states weight as primary outcome. Secondary outcomes are waist circumference, blood pressure & pulse & biochemical measurements. Reported in results	NO No obvious issues around bias not addressed elsewhere