Review
STATISTICAL ISSUES IN OBESITY RESEARCH

Obesity

Weight Change Among People Randomized to Minimal Intervention Control Groups in Weight Loss Trials

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Objective: Evidence on the effectiveness of behavioral weight management programs often comes from uncontrolled program evaluations. These frequently make the assumption that, without intervention, people will gain weight. The aim of this study was to use data from minimal intervention control groups in randomized controlled trials to examine the evidence for this assumption and the effect of frequency of weighing on weight change.

Methods: Data were extracted from minimal intervention control arms in a systematic review of multicomponent behavioral weight management programs. Two reviewers classified control arms into three categories based on intensity of minimal intervention and calculated 12-month mean weight change using baseline observation carried forward. Meta-regression was conducted in STATA v12.

Results: Thirty studies met the inclusion criteria, twenty-nine of which had usable data, representing 5,963 participants allocated to control arms. Control arms were categorized according to intensity, as offering leaflets only, a single session of advice, or more than one session of advice from someone without specialist skills in supporting weight loss. Mean weight change at 12 months across all categories was −0.8 kg (95% CI −1.1 to −0.4). In an unadjusted model, increasing intensity by moving up a category was associated with an additional weight loss of −0.53 kg (95% CI −0.96 to −0.09). Also in an unadjusted model, each additional weigh-in was associated with a weight change of −0.42 kg (95% CI −0.81 to −0.03). However, when both variables were placed in the same model, neither intervention category nor number of weigh-ins was associated with weight change.

Conclusions: Uncontrolled evaluations of weight loss programs should assume that, in the absence of intervention, their population would weigh up to a kilogram on average less than baseline at the end of the first year of follow-up.

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Introduction

Evidence from randomized controlled trials shows that behavioral weight management programs involving diet, exercise, and behavioral counselling can lead to significant weight loss in adults with overweight or obesity (1). However, many programs have not been evaluated in randomized trials due to the complexity and costs associated with trial design, conduct, and analysis (2,3). In the absence of a control group, these observational reports (4-7) leave either readers to make their own judgement on the weight of a population left untreated or the investigators to make explicit assumptions about

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See Commentary, pg. 767.

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what would happen to the population had they not received the intervention being evaluated.

For example, a cost-effectiveness analysis of a primary care-based behavioral weight management program assumed that, had participants not enrolled in the intervention, they would have gained 1 kg $year^{-1}$ (8). Two other evaluations used data from the CARDIA cohort ($n = 5{,}115$; age: 18-30 years; mean baseline BMI: 24.4 ± 3.9 kg m^{-2}) to suggest that, if untreated, individuals would steadily gain weight over time, though neither paper quantified the rate of weight gain (9,10). Yet analysis of a large, pooled multi-cohort database suggests such assumptions are unwarranted. The collaborative analysis of 57 prospective cohort studies found that, although participants who were classified as overweight (BMI ≥ 25 and <30 kg m^{-2}) at baseline gained 0.9 kg after 10 or more years, participants with a baseline BMI of 30-50 kg m^{-2} lost an average of -0.4 kg over the same period (11). However, using data from population cohort studies is not appropriate for investigating what may happen to people who are aiming to lose weight because the population was enrolled without this being an inclusion criterion. There is no data on what a group of people with the desire to enroll in a weight management program might achieve without a formal program. As such, it is difficult to evaluate the effectiveness of weight loss programs when tested in uncontrolled evaluations.

In addition, the control arm in an randomized controlled trial may contain elements that constitute an effective intervention since the process of recruitment to a trial and measurement of body weight might motivate weight loss. For example, cross-sectional studies show an association between doctors' advice to lose weight and their patients' attempts to do so (12), and in qualitative research many people report the regular weigh-in as an important aspect of weight management programs (13). This suggests that it would be helpful for physicians to raise the issue of weight, weigh people, and remind their patients that they will check their weight again in the future. Such interventions may have important public health benefits because of their low cost and high reach but any randomized trial to examine the efficacy of such minimal interventions with very small effect sizes would have to be very large and perhaps impractical as a result. Nonetheless, formal weight management programs need to demonstrate efficacy over and above this "brief intervention."

Here we aimed to examine the weight loss achieved during the first 12 months of follow-up by people enrolled in randomized trials who were assigned to minimal intervention control groups in order to inform future uncontrolled program evaluations. Additionally, in order to inform the development and provision of brief interventions, we used meta-regression to provide observational evidence on the potential value of both advice on weight loss from someone without special knowledge of how to achieve it and of scheduled weigh-ins for weight management.

Methods

Search and inclusion criteria

We identified the studies included in this review from those in a large systematic review of the effectiveness of multicomponent behavioral weight management programs. The review of multicomponent weight management programs has been published elsewhere, along with a full account of its methods (14).

To be included in the review of multicomponent weight management programs, studies had to recruit adults ($\geq$18 years) with a BMI of ≥ 25 kg m^{-2} (or a BMI of ≥ 23 kg m^{-2} in Asian populations). Interventions had to involve multiple contacts with the provider and be clearly defined as multicomponent weight management programs. Studies in women who were pregnant, people with eating disorders, and those where the weight loss program was used specifically to treat a medical condition, such as sleep apnea or diabetes, were excluded. Studies were required to include a measure of weight change at 12 months or greater from baseline.

Definitions of control intensity

To be included in this analysis of weight change in control groups, trials had to have a minimal contact control arm, which ranged from no intervention to multiple contacts with someone without specific training in weight management. Often, these were described as "usual care" in the included studies, but given the variation in these definitions, we established criteria to define control group intensity. Control groups were coded as:

A. No intervention at all; self-help material only (including leaflets and static websites); or seeing someone more than once for discussion of something other than weight management;
B. Single weight management session including discussion/advice/counseling ±self-help material; or
C. Seeing a professional (e.g., general practitioner [GP], practice nurse) without specific training in delivering weight management advice and without a defined program to follow, more than once for weight management, ± self-help material.

Statistical analysis

We calculated mean weight change from baseline to 3, 6, and 12 months. Weight was extracted or calculated from complete case data (15) as baseline observation carried forward (BOCF). Where 12-month data were not available, we used data at up to 18 months in their place. Mean difference in weight change between the intervention and control groups has been evaluated elsewhere (14).

This was an exploratory not confirmatory analysis so all nominally statistically significant P values should be interpreted as indicative and not confirmation of a hypothesis. We used random effects meta-analysis to calculate mean weight change for all studies combined. We used the methods described by Riley et al. to calculate 95% prediction intervals (16). Random effects analysis assumes that there is not a single underlying mean but rather that means from studies vary, in this case as a function of the population enrolled. The prediction intervals give the range of weights within which 95% of control population means would be expected to lie.

Random effects meta-regression was conducted using STATA v12 for all studies with usable data. Control group categories A, B, and C were of increasing intensity, with A the lowest and C the highest, and therefore we tested for a linear trend. A second meta-regression investigated all categories as binary variables with control category A as the reference group. Finally, we examined the association between number of weigh-ins during 12 months and weight loss, so we added this variable and other potential study level confounders to the model using a stepwise method.

Results

Of the 37 studies included in the review of behavioral weight management programs, 30 met our inclusion criteria for this analysis, 29 of which had sufficient outcome data to be included in the analysis.

Characteristics of included studies

An overview of the 30 included studies can be seen in Table 1. Half of the studies were conducted in the USA, and all but three of the remaining studies were conducted in Europe. One multicenter study was conducted in the UK, Germany, and Australia (42).

The studies included 14,169 participants in total. Of these, 5,953 were allocated to control arms. As is common in weight loss studies, the majority of participants were female (69%). Two studies recruited men only and six studies recruited only women. All studies required that participants be at least 18 years or older. The mean age across studies was 49, ranging from 32 to 70 years old. Five studies were aimed at diabetes prevention and required some measure of elevated risk for developing type 2 diabetes beyond overweight/obesity. In two, there was no lower BMI limit, but reported data indicated that >80% of participants in each study arm had overweight or obesity at baseline (31,40). All other studies had overweight or obesity as an inclusion criterion. The mean BMI across all studies at baseline was 33 (the median was also 33), ranging from 29 to 40. Thirteen of the 30 included studies had a maximum BMI cutoff at baseline; this ranged from 35 to 50 (average 40). The other 17 included studies had no maximum cutoff for baseline BMI.

Thirteen studies had control arms consisting of no additional weight-related contact (Category A); of these, three received no intervention at all, six received written information only, and four received sessions discussing health issues other than weight loss. One of these studies, Jeffrey and Wing 1995, could not be included in the meta-regression due to insufficient data with which to calculate BOCF. In nine studies, control arms received one-off weight management advice (Category B), and in the remaining eight studies, control arms received multiple contacts regarding weight management, delivered by someone without specific training in delivering a weight management program (Category C).

The median number of weight measures in the first year across all studies was three, ranging from two to six weigh-ins. Table 2 provides further details of the nature of the contact and information provided to the control group in each included study, as well as on the number of weight measures over 12 months.

Weight change

Figures 1–3 display weight curves for control groups in studies where weight was reported at more than one follow-up point. The weighted average of weight change for all control groups combined was −1.0 kg (95% CI −1.77 to −0.23, $P = 0.011$) at 3 months; −0.72 (95% CI −1.17 to −0.27, $P = 0.002$) at 6 months; and −0.76 kg (95% CI −1.14 to −0.39, $P < 0.001$) at 12 months. The 95% prediction intervals were wide, encompassing modest weight gain and substantial weight loss (Figure 4).

Using meta-regression we looked for evidence of a linear trend in weight loss with increasing intensity of intervention. At 12 months, increasing intensity was associated with an additional weight loss of −0.53 kg (95% CI −0.96 to −0.09, $P = 0.017$) per category in an unadjusted model.

At 12 months, we found that each additional weigh-in was associated with a weight change of −0.42 kg (95% CI −0.81 to −0.03, $P = 0.035$) in an unadjusted model. No other study characteristics were associated with significant weight change in these control groups.

When both variables were placed in the same model neither intervention category (−0.39 kg; 95% CI −0.86 to 0.08, $P = 0.104$) nor number of weigh-ins (−0.28 kg; 95% CI −0.69 to 0.13, $P = 0.181$) was associated with weight change.

We investigated whether a single session of advice (B) was associated with a greater weight loss than a leaflet or non-weight-related contacts (A) at 12 months. There was no evidence of a significant difference in an unadjusted model (−0.25 kg; 95% CI −0.83 to 0.32, $P = 0.394$) or in one adjusted for the number of weigh-ins (−0.29 kg; 95% CI −0.91 to 0.33, $P = 0.359$).

There was a significant difference in 12-month weight loss between groups having a regular contact with an untrained professional (C) and those having one-off advice or regular non-weight-related contacts (A) in unadjusted (−1.19 kg; 95% CI −2.32 to −0.06, $P = 0.039$) but not adjusted models (−1.03 kg; 95% CI −2.49 to 0.41, $P = 0.164$).

None of the findings was qualitatively affected by excluding one study in control category C in which the description of the control intervention was unclear (40).

Discussion

People who volunteered for randomized trials to test the effectiveness of weight loss programs and who were allocated to the control group were about 1 kg lighter on average at the first year of follow-up. Weight change during that year varied greatly between studies but most studies would be predicted to see weight loss in the control group. There was a suggestion that greater intensity of brief advice on weight loss was associated with greater weight loss but the evidence for this was not strong. Each additional weigh-in was associated with greater weight loss, but the association was attenuated and not significant when adjusted for intensity of advice given.

The validity of these analyses rests on the comprehensive search for trials of interventions that delivered combined dietary and physical activity interventions. It is possible that interventions we excluded because they involved dietary advice only as the “active” treatment, for example, may have observed different weight loss in control groups, but it is difficult to see a reason why this might be so. We also excluded studies enrolling people who were being treated for a particular medical condition and studies of more intensive interventions and it is perhaps more plausible that people randomized to control groups in these studies may have had greater weight loss

TABLE 1 Characteristics of included studies: Participants[a]

Study ID	Country	Total *N*	% Female	Mean age	BMI, mean (SD)	Participant inclusion criteria[b]	Control *N*
Control group category A *(Leaflet/advice only and/or non-weight-related follow-up)*							
Bertz 2012 (17)	Sweden	68	100%	32	30.2 (3.4)	Women 8-12 weeks post-partum	17
Fitzgibbon 2010 (18)	USA	213	100%	46	39.8 (5.8)	African-American women	106
Foster-Schubert 2012 (19)	USA	439	100%	58	30.7 (3.9)	Post-menopausal women	87
Jeffrey and Wing 1995 (20)[c]	USA	202	50%	37	31.1[d]		40
Jolly 2011 (21)	UK	640	71%	49	33.9 (4.4)		100
Kuller 2012 (22)	USA	508	100%	57	30.9 (3.8)	Post-menopausal women	255
Nanchahal 2011 (23)	UK	381	73%	49	33.9 (5.6)		190
Patrick 2011 (24)	USA	441	0%	44	34.3 (4.0)	Men	217
Rejeski 2011 (25)	USA	288	67%	67	32.6 (3.5)	Older adults, evidence of CVD or metabolic syndrome, self-reported mobility limitation	93
Silva 2010 (26)	Portugal	239	100%	38	31.3 (4.0)	Pre-menopausal women	116
Stevens 1993 (27)	USA	564	79%	43	29.5 (2.8)	Baseline blood pressure in high normal range	256
Stevens 2001 (28)	USA	1191	34%	43	30.9 (3.2)	As above	596
Vissers 2010 (29)	Belgium	79	NR	45	30.8 (3.4)		21
Control group category B *(Single weight management session)*							
Appel 2011 (30)	USA	415	64%	54	36.8 (5.1)	One or more CVD risk factors	138
Eriksson 2009 (31)	Sweden	151	57%	54	29.4 (5.1)	Additional risk factor for type 2 diabetes	76
Hersey 2012 (32)	USA	1755	74%	NR	33.6[e]		598
Lindstrom 2003 (33)	Finland	522	67%	55	31.1 (4.5)	High risk for type 2 diabetes	257
Mensink 2003 (34)	Netherlands	114	43%	57	29.3 (3.1)	Elevated fasting glucose	59
Morgan 2011 (35)	Australia	65	0%	36	30.5 (3.0)	Men	31
Penn 2009 (36)	UK	102	60%	57	33.5 (4.6)	Impaired glucose tolerance	51
Ross 2012 (37)	Canada	490	71%	52	32.0 (4.2)		208
Vermunt 2011 (38)	Netherlands	925	60%	58	28.5 (4.1)	Elevated risk of developing type 2 diabetes	444
Control group category C *(Seeing a professional without specific training)*							
Dale 2008 (39)	New Zealand	79	67%	46	36.5 (4.3)	Impaired insulin sensitivity	23
DPP (40)	USA	2161	69%	50	34.2 (6.7)	Impaired glucose tolerance	1082
Heshka 2006 (41)	USA	433	82%	45	33.6 (3.7)		212
Jebb 2011 (42)	UK, Germany, and Australia	772	87%	47	31.3 (2.6)		395
Munsch 2003 (43)	Switzerland	122	75%	46	32.6 (1.8)		17
Rock 2010 (44)	USA	442	100%	44	34.0 (3.2)	Women	111
Villareal 2011 (45)	USA	107	63%	70	37.3 (4.7)	Aged 65 years or older, mild to moderate frailty	27
Wadden 2011 (46)	USA	261	80%	52	39.0 (4.8)	Have $\geq$ 2 criteria for metabolic syndrome	130

[a]NR: not reported.
[b]Beyond being adults of both genders with overweight/obesity.
[c]Did not contribute to weight change analyses due to insufficient data.
[d]SD not available.
[e]Across all arms, SD not available.

than the people in the studies included here. However, participants in the control group of trials of these more intensive interventions are usually randomized to a behavioral program of the kind that represent the "active" intervention of these trials here. In summary, we believe the data show that most populations, and by extension, most people, who would have joined a weight loss program but were randomized to a minimal intervention lose weight and are also at a lower weight at 1 year of follow-up than at baseline.

TABLE 2 Characteristics of included studies: Contact and information offered to control participants

Study ID	Control condition	Study weight measures over 12 months
Control group category A *(Initial contact with leaflet/advice only and/or non-weight-related follow-up)*		
Bertz 2012 (17)	No additional contact or information	3
Fitzgibbon 2010 (18)	Regular newsletters covering general health information; phone call from staff member every month relating to newsletter information	3
Foster-Schubert 2012 (19)	No additional contact or information	2
Jeffrey and Wing 1995 (20)[a]	No additional contact or information	3
Jolly 2011 (21)	Offered voucher for 12 free entries to local sports center; no additional contact	3
Kuller 2012 (22)	Six general health education sessions in year one and several times over following years to discuss women's health	3
Nanchahal 2011 (23)	Weight management booklet at baseline; no additional contact	3
Patrick 2011 (24)	Offered access to website with general health information; no additional contact.	3
Rejeski 2011 (25)	18 sessions over 18 months covering general topics related to aging and health	3
Silva 2010 (26)	29 face-to-face health education sessions in thematic courses; weight loss not focus	3
Stevens 1993 (27)	No additional contact or information	3
Stevens 2001 (28)	No additional contact or information	3
Vissers 2010 (29)	No additional contact or information	4
Control group category B *(Single weight management session)*		
Appel 2011 (30)	Session with weight loss coach; received brochures and list of recommended websites promoting weight loss	3
Eriksson 2009 (31)	Education session by doctor, physiotherapist, and dietician	2
Hersey 2012 (32)	Advice session; provided with a booklet about encouraging exercise and weight loss and access to a basic (non-interactive) website	3
Lindstrom 2003 (33)	General lifestyle weight management information provided at baseline in an individual or group session lasting 30-60 minutes	2
Mensink 2003 (34)	One-off, oral and written information on diet, weight loss, and physical activity	2
Morgan 2011 (35)	Group information session regarding weight loss at baseline, plus program booklet	4
Penn 2009 (36)	Advice session from dietician and physiotherapist; leaflets	2
Ross 2012 (37)	One-off general advice from physicians on merits of physical activity as strategy for obesity reduction	3
Vermunt 2011 (38)	Session of advice from GP about benefits of healthy diet and exercise	3
Control group category C *(Seeing a professional without specific training)*		
Dale 2008 (39)	At 8 and 12 months, some advice regarding lifestyle changes; provider not specified	4
DPP (40)	Placebo controlled with written lifestyle advice provided at baseline and alongside an annual individual session	3
Heshka 2006 (41)	Two consultations with a dietician (baseline and 12 weeks); included as control as authors state dietician provided basic, publicly available information and did not use training to personalize or help set individual goal	4
Jebb 2011 (42)	Weight loss advice from primary care professional at local GP practice (minimum six visits over 12 months)	5
Munsch 2003 (43)	Non-specific comments about general measures to lose weight from GP on multiple occasions; no specific technique, tools, or written material were used	3
Rock 2010 (44)	Consultation at baseline with research staff where given written information; monthly check-ins by email or phone	3
Villareal 2011 (45)	General information about a healthy diet provided during monthly visits with the staff	3
Wadden 2011 (46)	Quarterly primary care visits over 24 months to address coexisting illnesses; at each visit, primary care practitioner spent 5-7 minutes reviewing weight change and discussing info in handouts; given pedometer and calorie counting book.	6

[a]Did not contribute to weight change analyses due to insufficient data.

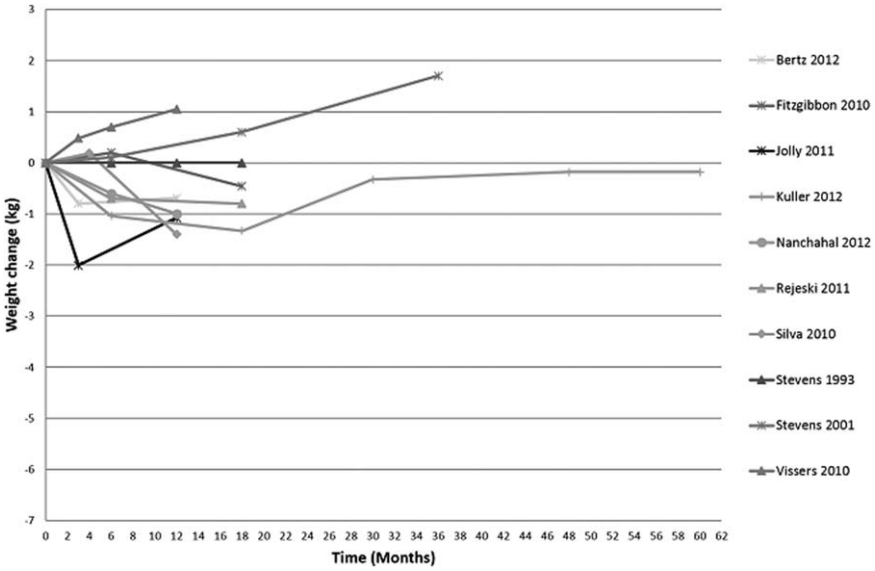

Figure 1 Weight change over time, control group category A.

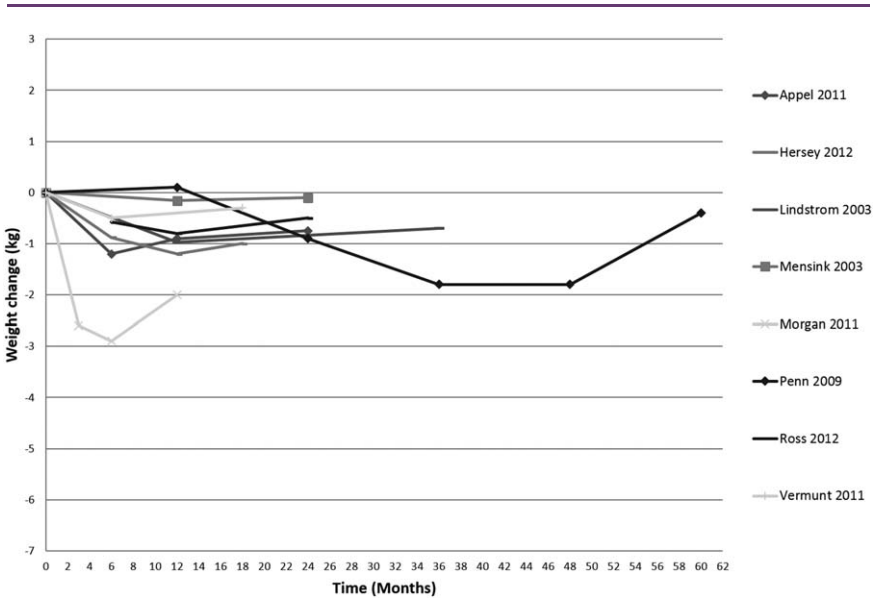

Figure 2 Weight change over time, control group category B.

Our analysis has several strengths and limitations. The studies we reviewed all suffered loss to follow-up and presented their results using a variety of methods of imputation or using complete cases only. By standardizing the way statistics were presented, we removed spurious variation due to this. There are two main assumptions that underlie methods to deal with missing data, which are that data are missing at random or they are missing non-randomly, most probably because people with a "bad" outcome are less willing to attend for follow-up. Analyzing only those with follow-up data or multiple imputation assumes data are missing at random. It would have been possible to use either approach here although, for multiple imputation, this would have had to be done at the study level.

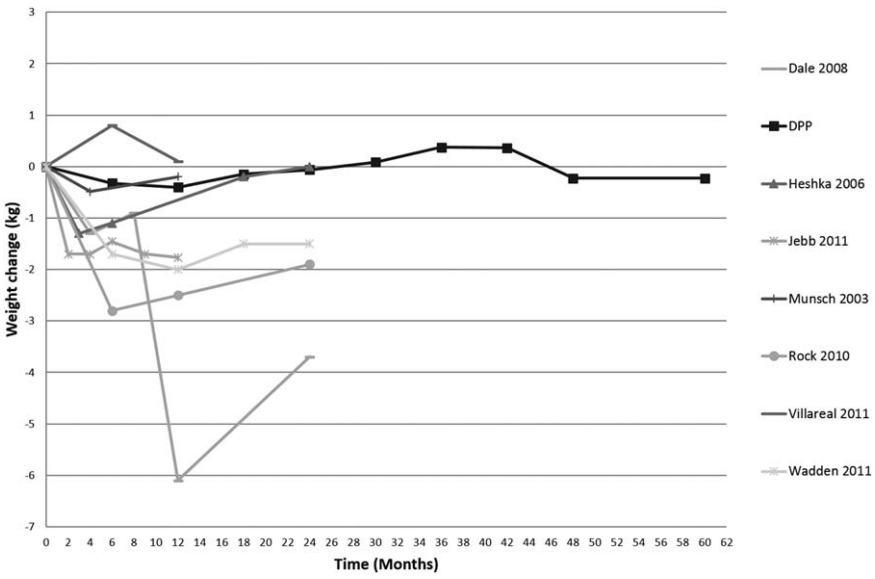

Figure 3 Weight change over time, control group category C.

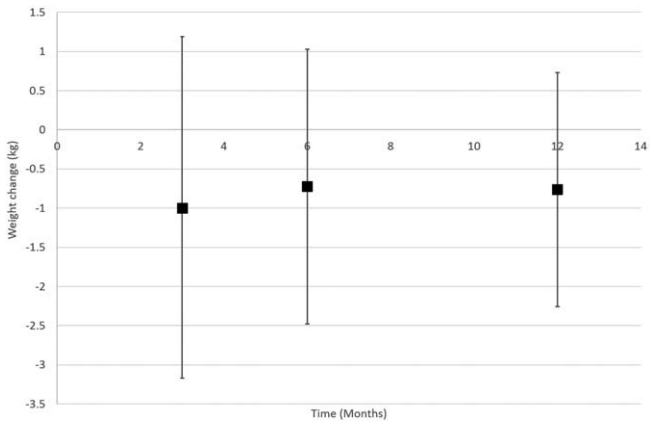

Figure 4 95% prediction intervals for weight loss at 3, 6, and 12 months.

Multiple imputation at the study level is unlikely to have changed the results because the characteristics of participants in the studies were largely similar (14). Normally, multiple imputation is done at the individual level but this requires access to the full data from the trial. It is conceivable that multiple imputation at the individual level could be more conservative than BOCF, but a study that used several methods of imputing for missing weight data in trials of interventions for weight loss found no great differences between complete case data only and multiple imputation for missing data (47). In this review, we imputed missing data assuming they were not missing at random using BOCF. In the context of a review, this can only move the weight change towards the null, whether it showed mean weight increase or mean weight decrease. Mean weight loss at 12 months was observed in the control group in 90% of studies.

As might be expected, studies in which participants were offered multiple contacts with a health professional who gave untrained and non-programmatic advice on how to manage weight had a greater number of weigh-ins. Consequently, when terms reflecting both the intensity of advice and the number of weigh-ins were added to the equation, none was significant. It is therefore unclear whether the unstructured advice or the simple act of weighing without advice might be contributing to the apparently greater weight loss observed in programs of this type. Previous literature has observed greater weight loss in people trying to lose weight who weigh themselves more frequently (48). In our analysis, the process of being weighed by an independent investigator also includes contact with an external party which may provide tacit accountability and increase motivation. There remains an opportunity to develop regular weighing as a routine intervention in primary care. Perhaps surprisingly, beyond the number of weigh-ins, there were no differences in outcomes between our different categories of intensity, but this may reflect the difficulties in capturing the relevant aspects of care, for example specific elements of advice provided or the type of professional delivering the advice, which were often not reported in detail. However, we are not aware of other systematic reviews that specifically report on the weight loss in control groups or of evidence testing the differences between these relatively minimal interventions.

By summarizing and comparing weight loss achieved from different trials, our analysis is effectively based on observational data. A summary of weight lost in control groups could only ever be obtained from observational data, and data on the effect of such minimal and tacit interventions as reweighing people might never be the subject of randomized trials because of the very large sample size required. In our study we observed that control groups who received more

advice or counseling lost more weight but meta-regression was unable to exclude chance as the cause of this apparent association.

Our results have important implications for the interpretation of data from uncontrolled evaluations of weight loss interventions, in particular, evaluations that assume weight gain in a comparable but untreated population. Indeed, prospective cohort studies indicate a trend towards weight loss over time in those with obesity (11). However, the reliance on data from cohort studies aiming to establish the natural weight history of the general population may be problematic in uncontrolled program evaluations. Program evaluations include only individuals who want to lose weight and thus have a greater motivation than the general population. This is also the case for participants who volunteer to take part in research to test weight loss interventions but are assigned to a control group. The estimate of weight loss observed here may enable researchers presenting results of uncontrolled evaluations of treatment programs to put the weight loss achieved in context.

In summary, uncontrolled evaluations of weight loss programs should assume that, in the absence of intervention, their population would weigh up to a kilogram less than baseline at 1-year follow-up. The variation between studies was great meaning that even 2-3 kg of weight loss might be observed without a behavioral weight loss program. There is a suggestion, but insufficient evidence to be sure, that regular reweighing and brief advice on how to lose weight may create additional weight loss. O

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