RUNNING HEAD: Active ingredients in complex RCTs

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Identifying active ingredients in complex behavioural interventions for obese adults with obesity-related co-morbidities or additional risk factors for co-morbidities: A systematic review

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ABSTRACT

Reducing obesity is an important preventive strategy for people who are at increased risk of major disabling or life-threatening conditions. Behavioural treatments for obesity are complex and involve several components aiming to facilitate behaviour change. Systematic reviews need to assess the components that moderate intervention effects.

Electronic databases and journals were searched for randomised controlled trials (RCTs) of behavioural interventions targeting dietary and/or physical activity change for obese adults (mean BMI ≥30, mean age ≥40 years) with risk factors and follow-up data ≥12 weeks. A reliable taxonomy of theory-congruent behaviour change techniques (BCTs) (Abraham & Michie, 2008) was used to identify programme components.

Meta-regression suggested that increasing numbers of identified BCTs are not necessarily associated with better outcomes. The BCTs provision of instructions (β=-2.69, p=.0.02), self-monitoring (β=-3.37, p<.001), relapse prevention (β=-2.63, p=0.02), and prompting practice (β=-3. 63, p<0.001) could be linked to more successful interventions. Studies including more BCTs congruent with Control Theory for dietary change were associated with greater weight loss (β=-1.13; p=0.04).

Post-hoc ratings of intervention components in published trials can lead to the identification of components and theories for behaviour change practice and research.

Key words*:* systematic review, obesity, behavioural interventions, behaviour change techniques, meta-regression

INTRODUCTION

The rising level of obesity and associated diseases has reached epidemic proportions (WHO, 2000). Behavioural factors, i.e. poor diet and physical inactivity are among the main proximal causes linked to obesity (Haslam & James, 2005), obesity-related morbidity (Alley & Chang, 2007) and mortality (Flegal, Graubard, Williamson, & Gail, 2007). In clinical populations at increased risk of diseases (compared with the general population) obesity management is an important component in preventing or delaying the onset of ill health and death (Adams et al., 2006; Goldstein, 1992). Given the growing prevalence of obesity, health services will be likely to prioritise treatments of obese people with additional risk factors for obesity related co-morbidities or those with the presence of co-morbidities already to optimise the treatment impact for allocated resources. Patients with additional risk factors are more likely to be seen by health professionals (Maaten, Kephart, Kirkland, & Andreou, 2008) and successful treatments for weight reduction will reduce both risk factors and secondary disease (Goldstein, 1992).

Changing dietary and physical activity (PA) behaviours constitutes the main obesity treatment (Foster, Makris, & Bailer, 2005; Wadden & Stunkard, 2002). Identifying effective and efficient intervention components facilitating diet and PA change is vital. This is of particular importance for obese populations with additional risk factors or co-morbidities – one of the fastest growing patient populations facing health services.

Pragmatic evidence for behaviour change intervention practice and research is urgently required (NICE, 2006). Interventions for obesity are typically complex featuring multiple components. Two broad component categories have been identified (Collins, Murphy, Nair, & Strecher, 2005): *intervention programme* (e.g. employed behaviour change techniques [BCTs]), and *intervention delivery* (e.g. intervention provider, format, setting, recipient, intensity, duration

and fidelity of the intervention (Davidson et al., 2003)).

Systematic reviews commonly attest overall effectiveness of behavioural interventions in reducing weight and changing obesity relevant behaviours (Abraham & Graham-Rowe, 2009; Annesi, Marti, & Stice, 2010; Avenell et al., 2004; Brunner, Rees, Ward, Burke, & Thorogood, 2007; Dansinger, Tatsioni, Wong, Chung, & Balk, 2007) but often fall short of exploring associations between potential 'active ingredients' and intervention effectiveness (Avenell et al., 2004; Michie & Abraham, 2004). For example, combining interventions according to behavioural targets (e.g. diet and or exercise) or delivery method (e.g. group based vs. individually delivered) might leave the potential intervention programme effects unexplored. Moreover, significant heterogeneity within pooled outcome data is commonly reported (e.g. Avenell et al., 2004), suggesting further investigation of associations between intervention programme and relevant outcomes.

Previous systematic reviews have started examining specific intervention components, including a mixture of intervention programme and delivery features (Ellis et al., 2004; Hardeman, Griffin, Johnston, Kinmonth, & Wareham, 2000). The recent development of a reliable, comprehensive and theory-linked taxonomy of BCTs facilitates the categorisation of published interventions and allows for the systematic examination of intervention programme components (Abraham & Michie, 2008). A systematic review of behaviour change interventions (Michie, Abraham, Wittington, McAteer, & Gupta, 2009) has demonstrated the feasibility of using this taxonomy for in-depth analyses of behaviour change interventions. The current systematic review extends this research by focusing on obese adults with additional risk factors for obesity related co-morbidities or presence of co-morbidities, scrutinising specific behaviours separately and examining the effects of modes of delivery and BCTs on health outcomes (i.e. weight change).

Several issues are of importance when examining intervention programme effects within systematic reviews of the available evidence. First, the number of intervention BCTs might be associated with superior intervention effects. The question of the optimum number of techniques is currently unclear and has important implications for intervention design. Some evidence to date has indicated that *fewer* techniques might be associated with more successful interventions in terms of behaviour change in low income groups (Michie, Jochelson, Markham, & Bridle, 2009). Second, in addition to quantity, it could be that the quality of specific BCTs affects outcomes. Thus, it might be possible to detect specific single BCTs associated with more effective intervention. Identifying BCTs (e.g. goal setting, barrier identification) with a greater probability of intervention success aids intervention development, ensures efficient use of limited resources and guides the prioritisation of future research. Third, besides understanding how behaviour changed, it is also important to understand why behaviour changed (Hagger, 2010; Michie & Abraham, 2004). Theories of behaviour and behaviour change provide the frameworks to understand intervention effects (M. Johnston, 1995; Sniehotta, 2009) and insight into which particular BCT combinations might lead to better outcomes. To date, there has been contradictory evidence regarding the reporting of theory underpinning interventions and effectiveness (Michie & Prestwich, 2010; Webb, Joseph, Yardley, & Michie, 2010). Assessing associations between programme components congruent with theory at the level of intervention delivery presents a further avenue to advance our understanding as to which theories might be useful for intervention development (Abraham & Michie, 2008).

Thus, the current systematic review examines behaviour change interventions for obese adults with additional risk factors or co-morbidities, specifically focusing on two key questions:

First, what are the intervention delivery (i.e. mode of delivery) and programme (i.e. BCTs) components of behaviour change interventions for obese adults with additional risk

factors?

Second, what are the associations between (a) the mode of delivery, (b) the number of BCTs, (c) the type of BCTs and (d) theory-congruent[1] clusters of BCTs on changes in behaviour and/or weight?

METHOD

Study inclusion criteria

Types of studies. Randomised controlled trials (RCTs) providing ≥12 weeks follow-up data after the point of randomisation to allow time for weight loss following behaviour change and assessment of persistence of behaviour change while enabling inclusion of as many studies as possible. All studies under consideration had to be published.

Types of participants. Adults with a mean/median age of ≥40. The lower age limit was chosen as there is a rapid increase in obesity-related diseases including the metabolic syndrome (Eckel, Grundy, & Zimmet, 2005) and type 2 diabetes (Gill, Ismail, Beeching, Macfarlane, & Bellis, 2003) in middle age. Studies had to include participants with a mean/median BMI ≥30, in order to conform to the current standard definitions of obesity (WHO, 2000). At least one additional risk factor for morbidity or an already present co-morbidity was required as this population is in great need of behaviour change to prevent long-term morbidity.

Types of interventions. Behavioural interventions aimed at changing diet and/or PA compared to usual care (UC), waiting list control (WLC) or less intensive intervention groups. There was no restriction on the type of intervention setting.

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[1] Theory-congruence refers to the link between BCTs and a particular theory of behaviour or behaviour change. Note that the concept of 'theory-congruence' is thus less restrictive than the concept of 'theory-base' as it does not necessarily assume a theory as the underlying basis for intervention development, but still notes overlap between the design of an intervention and the mechanisms of action as specified by a theory. There are different ways in which one can determine theory-congruence between BCTs including previously established evidence, using expert agreement methods (e.g. Michie, Johnston, Francis, Hardeman, & Eccles, 2008) or creative linkage (e.g. Ajzen, 2006). For the purpose of the current paper, theory congruence is defined by the published linkage between BCTs and theories as published in the Abraham & Michie (2008) taxonomy.

Types of outcome measures. The main outcomes are behaviour and weight change. Secondary descriptive outcome are identified modes of intervention delivery and BCTs. Reporting of behaviour change data for diet and PA including both self-report (e.g. questionnaire items, food diaries) and objective measures (e.g. step count), measured at both baseline and follow-up, was specified as inclusion criterion.

Search strategy for identification of studies

The databases MEDLINE, EMBASE and PsycInfo were searched using a comprehensive search strategy, based on previous systematic reviews in the area (Avenell et al., 2004; Shaw, O'Rourke, Del Mar, & Kenardy, 2005) (search strategy available on request from the authors). Three journals were hand searched: the *International Journal of Obesity*, the *International Journal of Behavioural Medicine* and *Obesity Research*. Reference lists of relevant review articles and of all included studies were searched for further studies.

Methods of the review

Identification of RCTs. The first 200 references of RCTs were independently screened by two researchers (AA and SUD) and differences were resolved in discussion. Thereafter, the identification of studies was completed by one researcher (SUD).

Quality assessment of studies. A standard set of criteria for RCTs from Avenell et al. (2004) was used by two researchers (SUD and VAS) to appraise the methodological quality of studies (Kappas .59 – .78) and disagreements were resolved by discussion.

Data extraction. Two researchers (SUD and JP) extracted data from 25% of studies with good agreement (Kappas 0.73 – 1) and disagreements resolved in discussion. Remaining data were extracted by one researcher (SUD) for diet (i.e. kilocalories/day), PA (e.g. questionnaire scales, measures of energy expenditure, measures of time spent physically active and objective behavioural outcome measures) weight outcomes, and modes of delivery (i.e. delivery format

[group, individual, or group and individual format], contact frequency, and recruitment setting [community, general practice, or clinical setting]).

BCTs were extracted by two researchers (SUD and VAS) using Abraham and Michie's (2008) taxonomy. Ratings were made independently for techniques targeting diet and PA change and were based on the most comprehensive published intervention descriptions. Freely available published protocols and full manuals were used for the rating procedures when available. Following initial ratings on a small set of studies, common interpretations were agreed and studies were re-rated. Remaining disagreements between presence/absence of a technique were resolved by a third researcher (FFS).

Data analysis. Outcomes were quantitatively combined in random effects meta-analyses using RevMan (Version 4.3). Random effects models were chosen due to the considerable heterogeneity for various outcomes. Outcomes were combined at the end of the active intervention period. For all effect sizes, 95% percent confidence intervals (CIs) were derived. Degree of inconsistency across studies was assessed using I^2 (Higgins, Thompson, Deeks, & Altman, 2003). I^2 levels of ≥25% and ≥50% were interpreted as an indicator for moderate and substantial heterogeneity respectively. Intention-to-treat data were used wherever available (Higgins & Green, 2006). All inter-rater reliabilities were estimated using Cohen's (1960) Kappa statistic.

In line with Cochrane recommendations (Higgins & Green, 2006) two different effect sizes were calculated depending on the outcomes under investigation. Kilocalorie and weight outcomes were reported on the same scales and thus combined as mean differences (MD). Weight was analysed as change scores (Avenell et al., 2004) and a mix of change scores and final value scores was used to assess the MD for kilocalorie consumption (cf. Higgins & Green, 2006). PA outcomes were reported on different scales and thus combined as standardised mean

differences (SMD), also known as Hedges' (adjusted) *g*. PA effects were calculated from final value scores only (cf. Higgins & Green, 2006).

Publication bias was assessed by means of Egger's regression test using the 'metabias' and 'metafunnel' macros in STATA 11 (Thompson & Higgins, 2002).

To explore heterogeneity within main effects meta-analyses, moderator effects of BCTs were explored using random effects models subgroup analyses in RevMan (Higgins & Green, 2006). This subgroup analysis was performed using studies that compared an intervention against a control group (i.e. either 'waiting list control', 'usual care' or 'standard care'). Differences of BCT subgroups were explored by means of a restricted maximum likelihood meta-regression using the using the 'metareg' macro in STATA 11 (Thompson & Higgins, 2002). A meta-regression extends subgroup analyses allowing further investigation of associations between treatment effects and study characteristics (Sutton & Higgins, 2008). Meta-regression thus applies regression principles in a meta-analysis context by predicting pooled intervention outcome variables (e.g. mean difference of weight loss) using an explanatory variable (e.g. behaviour change technique). Random effects meta-regression models were used to allow for the residual heterogeneity among intervention effects not modelled by the explanatory variables (Higgins & Green, 2006). Meta-regressions were performed using MD for weight and kilocalories, accordingly giving rise to unstandardised regression coefficients. Moreover, meta-regressions were performed using SMD for PA, accordingly giving rise to standardised regression coefficients. Meta-regressions were only performed if evidence for substantial heterogeneity was found (I^2 levels $\geq$50%) and $\geq$10 RCTs were present for a particular BCT (Higgins & Green, 2006). Meta-regressions were only examined when at least 3 trials were identified to have used a BCT, to minimise chance impact of single trials. Adjusted R^2 was used as a measure of the proportion of variance accounted for by the covariate, which is calculated by

subtracting the heterogeneity accounted for by the covariate regression model τ^2_b from the heterogeneity of the baseline model (τ^2_a) in the following way: $([\tau^2_a - \tau^2_b]/ \tau^2_a) \times 100$.

Univariate meta-regressions were performed to assess the effects of modes of intervention delivery, number of BCTs, individual BCTs, and the number of theory-congruent BCTs in interventions on weight and behaviour.

Missing data. Weight outcomes were analysed as change scores only with 45% of missing data imputed using previously described methods (Avenell et al., 2004). Where weight was presented as actual values rather than changes, change scores were derived by subtracting the endpoint values from the value at baseline. Where only BMI was reported, weight was calculated using the average heights reported by Avenell et al., (2004). Missing standard deviations for change scores were calculated using a linear regression equation.

RESULTS

---------- Figure 1 ----------

---------- Table 1 ----------

Forty-four studies met inclusion criteria (Figure 1, Table 1). Studies were published between 1985 and 2008 with the majority conducted in the USA (k = 27). The mean number of participants randomised to treatments across studies was 240 (*SD* = 502; range = 26 to 3234) with a mean dropout at study completion of 16% (*SD* = 10.2; range = 0 to 47.1). The active intervention phases lasted an average of 6.2 (*SD*=3.2; range = 1 to 14) months. Contact intensity was a median of 4 days per month.

The mean average age of participants across all included studies was 55.0 (*SD*=6.8; range = 40.0 to 70.3), and the mean average BMI was 33.1 (*SD*=2.2, range = 30.1 to 38.8), mean proportion of female participants was 55%; eleven studies sampled only women and one study exclusively recruited men. The samples were taken from a range of at risk populations. The

majority of studies (k = 21) examined individuals diagnosed with type 2 diabetes. Risk factors included impaired glucose tolerance (k = 3), hypertension (k = 4), or co-morbidities such as breast cancer (k = 2).

Twenty-seven of the 44 trials allowed comparison between a combined diet and PA intervention against UC or WLC group for at least one intervention phase. Six comparisons between diet only as well as PA only interventions against UC or WLC groups were possible, respectively. Altogether seven trials allowed comparisons of more intensive against less intensive treatments for diet and PA, and a further four comparisons of more intensive against less intensive dietary interventions.

Quality of trials

Randomisation. Nineteen (44%) trials were identified as having made a good attempt at concealment of randomisation, not allowing disclosure of assignment. The remaining 25 studies (56%) stated that there was random allocation without providing descriptions of randomisation procedures.

Description of withdrawals. 21 studies provided numbers and reasons for study participant dropouts and 20 studies mentioned the numbers of withdrawals only. Three studies stated withdrawals but did not provide further details regarding numbers and reasons.

Intention to treat. Twenty-five studies described using intention-to-treat (ITT) analysis with 13 studies not stating ITT procedures. For six studies descriptions were ambiguous.

Blinding of participants. The majority of studies did not mention blinding of study participants to treatment status (k=36). Two studies specifically stated that participants were not blinded, five studies described blinding procedures of participants and one study described that participants were blinded without giving specific details.

Blinding of intervention providers. As can be expected in behavioural interventions,

not many studies mentioned blinding of intervention providers with 38 studies failing to mention blinding of interveners altogether. One study specifically stated that no blinding was undertaken. A further three studies mentioned blinding, but did not state any description and two studies mentioned blinding and provided details of utilised procedures.

Blinding of outcome assessors. The majority of trials (*k*=32) did not report details on blinding of outcome assessors. Three studies stated blinding of assessors but did not provide further detail and 9 studies described blinding.

Ratings and description of intervention programme features

Cohen's (1960) Kappa statistic was calculated to estimate inter-rater reliability of identified BCTs used to change dietary as well as PA behaviours (Table 2). Altogether 48 different intervention arms were included in this descriptive analysis with 42 intervention arms for each target behaviour (Table 1). With regard to changing both diet and PA behaviours, there were two techniques that were not identified in intervention descriptions (T3 *provide information about others' approval*, T21 *prompt identification as role model*), one technique was identified for changing dietary but not for PA behaviour (T16 *agree behavioural contract*) and one technique was identified by one researcher only (T22 *prompt self talk*). Most Kappas indicated moderate to good reliabilities and the majority of dietary (78%) and PA (64%) Kappas were above 0.7, a cut-off point generally regarded as indicative of good agreement. Techniques that were not reliably identified between the two raters (defined as Kappas below 0.4) included T18 (*use follow up prompts*) for both diet and PA, as well as T6 (*provide general encouragement*) and T15 (*teach to use prompts/ cues*) for PA behaviour change. Furthermore, codings for T11 (*prompt review of behavioural goals*) fell below 0.7 for both behaviours (0.65 and 0.54 for dietary and PA behaviours respectively) indicating only moderate agreement for this technique.

---------- Table 2 ----------

Interventions were typically complex with the number of identified techniques used per study ranging from 1 to 16 for dietary interventions and 1 to 14 for PA interventions. Studies were found to use more techniques to change dietary compared to PA behaviours (*Mdn* = 7 and 6, respectively). The most popular BCTs to change dietary behaviour were T4 (*prompt intention formation*), T8 (*provide instruction*), T12 (*prompt self-monitoring of behaviour*) and T5 (*prompt barrier identification*) (Table 2). Changing PA behaviour was most readily attempted through T19 (*provide opportunities for social comparison*), T4 (*prompt intention formation*), T12 (*prompt self-monitoring of behaviour*) and T20 (*plan social support/ social change*).

Combinations of techniques

Overall, it was rare that set combinations of techniques were used between studies. When examining set technique combinations it was found that no two of the 42 different intervention arms aiming to change diet were identified as using the same combination of BCTs. Of the 42 intervention arms targeting changes in PA, two different BCT combinations were employed by more than one study. Two studies (Laitinen et al., 1993; Logue et al., 2005) were identified to use technique combination T8 (*provide instruction*) and T12 (*self-monitoring of behaviour*), and two other studies (Blumenthal et al., 2000; Tessier et al., 2000) were identified to use technique combination T8 (*provide instruction*), T17 (*prompt practice*) and T19 (*provide opportunities for social comparisons*).

In order to scrutinise theoretically congruent combinations of BCTs independent of any other techniques employed within intervention arms, the provided links of BCTs and theoretical models as provided by Abraham and Michie's (2008) taxonomy was used (see Table 1). Technique combinations matching the Information-Motivation-Behavioural Skills model (IMB, (Fisher & Fisher, 1992) and the Theory of Planned Behaviour (TPB, (Ajzen, 1991)) could not be fully examined as no instances of T3 (*provide information about others' approval*) were

identified in the reviewed trials. One study (Keyserling et al., 2002) was identified for having employed all Social Cognitive Theory (SCogT, (Bandura, 1997)) BCTs to change dietary behaviour. Control Theory (CT, (Carver & Scheier, 1982)) congruent BCTs were found in one intervention aimed at changing diet (Glasgow, Toobert, & Hampson, 1996) and one PA intervention (Mefferd, Nichols, Pakiz, & Rock, 2007) respectively. The final theory that was found to be congruent with more than one BCT is Operant Theory (OT, (Skinner, 1974)). None of the intervention arms was found to use all four BCTs congruent with OT (i.e. T14 *provide contingent rewards*, T15 *teach to use prompts/ cues*, T16 *agree behavioural contract*, and T17 *prompt practice*).

Four theories were defined as congruent with a single BCT. These include social comparison theory (T19 *provide opportunities for social comparison*, (Festinger, 1954)), social support theory (T20 *plan social support/ social change*, (Berkman & Syme, 1979)), and relapse prevention therapy (T23 *relapse prevention*, (Marlatt & Donovan, 2005)) and stress theory (T24 *stress management*, (D. W. Johnston, 1991)) (see Table 1 for details on these BCTs).

Intervention Impact

Weight. The MD of weight loss between intervention and control groups was -3.0 kg (95% CI -4.3, -1.8 kg) with heterogeneity in the outcome data (I^2 = 94%) (Table 3). Egger's test suggested a slight tendency for publication bias, p=0.045. There was some evidence of greater MD in weight loss in studies not mentioning blinding of assessors compared to those mentioning blinding (-1.3 [CI -2.9, 0.4] vs. -3.8 [CI – 5.3, -2.3], p=0.023). All other quality assessment criteria yielded non-significant weight loss differences in subgroup analyses.

---------- Table 3 ----------

Kilocalorie intake. The MD of reported kilocalorie intake was -112 kcal (95% CI -217, -7 kcal) with evidence of heterogeneity (I^2 = 64%) (Table 3). There was no evidence of

publication bias (p=0.13)

PA. SMD of PA was 0.3, (95% CI 0.2, 0.5) with evidence for heterogeneity present (I^2 = 65%). There was evidence of publication bias (Egger's test, p<0.001) with visual inspection of the forest plot suggesting that small studies with negative findings remained unpublished.

For all three outcomes significant heterogeneity of effectiveness was detected suggesting further investigation of moderating factors that might have influenced outcomes. This finding warrants a systematic examination of moderator effects of programme components.

Moderator analysis of Intervention Delivery Features

Delivery format and the timing of the active intervention period were not significantly related to weight loss (ps>0.25). Contact frequency was significantly related to weight loss, with interventions with higher contact frequency related to greater weight loss (β =-0.39 [CI –0.65, -0.12; p=0.005]) explaining 35.1% of the variance. Recruitment setting led to differing MDs in weight between community (MD = -4.7 [CI -5.0, -4.4]), general practice (WM = -1.2 [CI -1.9, -0.5]) and clinical setting (MD = -0.3 [CI -1.5, 1.3]). This difference was significant when comparing community against clinical settings (p=0.023) and approaching significance comparing community against general practice (p=0.063) explaining 25.5% of the variance.

Moderator Analysis of Intervention Programme Features

Effect of number of BCTs

We explored whether interventions that were identified for having used more techniques were associated with more successful outcomes. Inspecting the number of BCTs detected to change diet, there was suggestive evidence for an association between greater numbers of BCTs and greater weight loss, β =-0.30 (CI -0.64, 0.03; p=0.076) with number of dietary BCTs explaining 16% of the between study heterogeneity. No significant association was found between the number of BCTs used to change PA and weight loss, p=0.67. Moreover, no

significant associations were detected between the number of BCTs and kilocalorie intake (p=0.49) and PA (p=0.51).

As an increase in the number of identified BCTs was not necessarily associated with a corresponding increase in the effect magnitude for weight and behaviour change we examined which specific BCTs were associated with more successful interventions.

Effects of specific BCTs

Weight effects for specific dietary BCTs. Subgroup analyses were conducted of studies reporting weight after the active intervention phase (k = 23). They revealed significant associations between BCTs and more successful interventions in terms of inducing MD in weight loss between intervention and control groups. Three BCTs showed significant moderator effects: T8 (*provision of instructions*; β=-2.69, p=.0.02), T12 (*prompt self-monitoring of behaviour;* β=-3.37, p<.001), and T23 (*relapse prevention;* β=-2.63, p=0.02) individually explaining 26.2%, 39.9% and 24.3% of the between-study heterogeneity respectively (Table 4).

---------- Table 4 ----------

Weight effects for specific PA BCTs. One BCT aimed at changing behaviour showed significant positive moderator effects on weight (Table 4): T17 (*prompt practice*) individually explaining 47.9% of heterogeneity. Two BCTs showed negative moderator effects: T1 (*provide general information*) and T2 (*provide information on consequences*).

Kilocalorie intake effects for specific dietary BCTs: Subgroup analyses of 13 studies reporting kilocalorie intake were conducted. T10 (*provide instructions;* β=-240.0, p=0.02 individually explaining 65.1% of between-study heterogeneity) was significantly associated with greater effects on MDs of kilocalorie intake between intervention and control groups in interventions identified as having employed the technique compared to those that had not.

PA behaviour effects for specific PA BCTs. No significant effects were detected.

Effects of theory congruent BCT clusters on weight

In order to examine whether RCTs using technique combinations congruent with theory lead to more beneficial intervention outcomes, we scrutinised MDs of weight loss by the number of theory congruent BCTs utilised for changes in dietary behaviours. As none of the studies used an application of BCTs that was fully congruent with a theory outlined by Abraham and Michie (2008) it was examined whether using more BCTs congruent with a theory leads to greater weight outcomes. Only BCTs congruent with Control Theory (CT) showed an increase in MD of weight loss with inclusion of more theory congruent techniques. This increase was significant (β = -1.1 [CI -2.26, -0.01], p=0.047) suggesting that an increase in CT related BCTs was associated with an increase in weight loss, explaining 21.4% of between study variance (Figure 2). No other theory congruent BCT combinations showed trends across weight outcomes. Furthermore, irrespective of the employed theory-congruent BCTs, those studies which stated a theory as the foundation of the intervention showed no greater weight losses compared to studies that did not state theoretical underpinnings (-3.4 [CI -3.8, -1.0] vs. -3.8 [CI -5.5, -1.8], p=0.3).

---------- Figure 2 ----------

DISCUSSION

The current systematic review is the first to investigate effective intervention components within complex behavioural interventions for weight loss amongst obese adults with additional risk factors for obesity-related co-morbidities or the presence of co-morbidities already, using reliable methods to identify specific programme components. In order to move beyond establishing that interventions have significant average effect sizes, we focused on trial level covariates to try and explain some of the heterogeneity and point to components which might improve outcomes of future interventions. Using a reliable taxonomy of BCTs (Abraham & Michie, 2008) allowed accurate mapping of the intervention content, and to scrutinise whether

the quantity of BCTs, specific BCTs and/or theory-congruent clusters of BCTs would moderate intervention effects on weight and behavioural outcomes

In line with other reviews (Hardeman et al., 2000; Michie et al., 2009; Michie, Jochelson et al., 2009) we found behaviour change interventions to be heterogeneous with regard to delivery and programme features as well as behavioural and weight outcomes. Complex interventions in this field are composed of multiple features, with few interventions consisting of common sets of intervention ingredients. Consequently, main effects of behavioural interventions show significant heterogeneity.

This systematic review examined whether a dose-response relationship exists between the quantity of BCTs and obesity relevant outcomes. This question has important implications for intervention development and delivery and it is currently unclear whether using more techniques leads to better outcomes. One possibility might be that employing more intervention BCTs leads to better results, as for example the chances that participants will find suitable 'tools' for their own behaviour change increases. On the other hand, it might be that interventions offering more BCTs are less effective (e.g. Michie, Jochelson et al., 2009) due to issues such as dilution of effective BCTs within those offered, difficulty of intervention delivery leading to low fidelity, low adherence and/or participant confusion. This study found that the number of BCTs employed to change dietary behaviour was positively related to weight loss effects. However, despite this trend, there was still considerable variation in terms of outcomes even in studies identified as using the most BCTs to change diet. In addition, no effects of number of dietary BCTs on kilocalorie intake, or PA BCTs on weight or PA change were detected. The issue of quantity effects of BCTs on obesity related outcomes needs additional investigation in RCTs as well as systematic reviews.

Moderator analyses of individual BCTs found that three BCTs aimed at changing dietary

behaviours led to significant moderator effects: the *provision of dietary instructions* (T8), *self-monitoring of dietary behaviour* (T12) and *relapse prevention* (T23). *Provision of instructions* (T10) also showed significant moderator effects on kilocalorie intake. This suggests that interventions aimed at changing dietary behaviours might benefit from including specific instructions as to *how* one should go about changing one's diet, ask participants to self-monitor their dietary intake and help to maintain initially achieved behaviour change by anticipating potential lapses, and outlining ways to cope with lapses. The finding of *self-monitoring* (T12) as a significant moderator of intervention effectiveness on weight is in line with recent findings associating this BCT with changes in behaviour in a systematic review of healthy eating and physical activity studies (Michie et al., 2009). One technique aimed at changing PA was found to significantly moderate intervention effects on weight: *prompting practice* (T17), suggesting that an essential component of a PA change intervention might be to prompt participants to practice the target behaviour.

The BCTs identified as leading to more beneficial outcomes in the current review can be linked to different phases of the process of behaviour change. The provision of instruction on how to perform the behaviour and the prompting of practice to change the behaviour enable the initiation of behaviour change, the self-monitoring of behaviour facilitates the maintenance of behaviour change and relapse prevention aims to achieve maintenance of behaviour change in challenging circumstances. None of the techniques associated with successful interventions were aimed at enhancing motivation to change (Abraham et al., 1999; D. W. Johnston, Johnston, Pollard, Mant, & Kinmonth, 2004). This suggests that, in line with current theorising, interventions incorporating post-motivational or volitional behaviour change strategies seem to be more effective compared to merely motivational interventions (Darker, French, Eves, & Sniehotta, 2010; Sniehotta, Scholz, & Schwarzer, 2005).

Moreover, results on delivery features found that contact frequency and the community as recruitment setting significantly moderated weight loss outcomes. This might suggest that weight loss focused behaviour change interventions targeting obese adults with additional risk factors for co-morbidities or the presence of co-morbidities already could benefit from providing regular meetings, as well as recruiting participants from the community. A potential reason might be that community participants volunteering for behaviour change interventions have high levels of initial motivation and need the intervention structure in the form of regular meetings, as well as the tools, in the form of BCTs for translating motivation into behaviour in a sustainable manner, which subsequently leads to greater weight loss outcomes. Further research would need to clarify these relations between recruitment settings, contact frequency and motivational vs. volitional BCTs.

Moderator analyses of individual BCTs does not account for the fact that most interventions are complex. The current review therefore attempted to investigate whether interventions employing specific sets of BCTs congruent with particular theories would lead to better outcomes. In line with previous research, we found that many interventions did not explicitly report a theoretical basis for intervention development (Michie & Prestwich, 2010). Furthermore, none of the identified BCT clusters were fully congruent with the theories outlined by Abraham and Michie's taxonomy (2008). Therefore, it was tested whether using more techniques for dietary change associated with a specific theory would lead to greater weight loss outcomes. Control Theory (Carver & Scheier, 1982) was associated with a significant but consistent increase in weight effects with increasing numbers of theory congruent BCTs employed, suggesting that the inclusion of Control Theory congruent BCTs (goal setting, self-monitoring, review of behavioural goals etc) might increase the intervention effectiveness when attempting to change dietary behaviour in an obese population with additional risk factors for

disease or obesity-related morbidities already. This is in line with recently emerging evidence of the usefulness of this particular theory (Michie et al., 2009). All other models showed either inconsistent trends, and/or could not be tested due to a lack of data.

Several issues need to be considered when interpreting the findings of the current review. Multiple and potentially interacting factors lead to effects in reported studies. RCTs are seldom designed to test isolated or interactive influence of single factors. Consequently pooling such studies in meta-analysis will only yield associative findings without controlling for potential confounders or moderators. Ideally, systematic reviews should strive to take into account and control for as many potentially relevant factors as possible. However, the current body of evidence does not allow for such complex analyses.

We detected evidence for publication bias and some indication that methodological features might have impacted on study outcomes overall. The taxonomy of BCTs used is the first published comprehensive taxonomy with established inter-rater reliability (Abraham & Michie, 2008). The current taxonomy specifies 26 BCTs, however, these 26 techniques do not cover all established techniques to change individual behaviour and future research will be needed to include additional techniques. The taxonomy represents a first attempt to standardise technique labels and definitions. It is clear that such pioneering work will not be perfect from the start and requires optimisation as usage of this tool increases. This need for optimisation is reflected in some of the modest inter-rater reliability scores which we obtained in our current review. Additionally, the coding of BCTs in intervention descriptions was often limited by the lack of precision and/or detail provided in reports, a problem previously reported in the literature (Dombrowski, Sniehotta, Avenell, & Coyne, 2007; Ellis et al., 2004). Consequently it was only possible to code BCTs that were explicitly referred to in the intervention description. Further developments of relevant taxonomies are needed to extend the comprehensiveness and improve

the reliability of the Abraham and Michie taxonomy. Recently, emphasis has been placed on descriptions of RCTs in all the necessary details (Moher, Jones, & Lepage, 2001). An equal emphasis should be placed on the provision of details of actual intervention components. A recent study used the BCT taxonomy to describe a complex behavioural intervention in an original report which helps to provide the necessary clarity about the intervention *a priori* rather than relying on *post hoc* ratings (Araújo-Soares, McIntyre, MacLennan, & Sniehotta, 2009). Moreover, when a BCT has been mentioned in a study report, this does not automatically equate to the technique having been used or taught by interveners and participants (Hardeman et al., 2008). Few studies used fidelity checks (e.g. Hardcastle, Taylor, Bailey, & Castle, 2008) and we can only code what was planned to be delivered to the intervention participants. We were also unable to systematically code control groups as trial reports due to a lack of information that would allow to confidently determine whether a BCT had also been used within the control condition. However, it should be noted that systematic reviews should always attempt to make the most of any descriptions of control conditions where possible.(de Bruin, Viechtbauer, Hospers, Schaalma, & Kok, 2009; de Bruin et al., 2010)

In the current systematic review various techniques were associated with more successful interventions in terms of behaviour and weight change. However, two important issues need to be taken into consideration when interpreting such findings. First, the finding of a lack of significant effect of BCTs does not imply a lack of effect of the specific technique. Non-significant findings regarding specific BCTs might be due to a number of reasons, such as neutral effects, no effects, counterbalanced effects (e.g. due to other intervention components) or masked positive effects. Second, the identification of positive significant associations between BCTs and outcomes in the context of a systematic review does not imply that better outcomes were caused by a particular technique. Such a finding could be due to chance, especially when

considering multiple tests being conducted for each individual technique, for multiple outcomes. This methodology does not replace full factorial randomised tests of the effectiveness of the BCT under study (Collins et al., 2005). In the current analyses, participants are not randomly assigned to BCTs, therefore, no causality can be concluded. Such causal inferences cannot be made because of a) a main effect of these techniques, b) an interaction effect with other techniques, or c) co-occurrence with other features of the intervention. The methodology employed in this review allows us to utilise the available evidence base to identify techniques that are likely to be useful in behavioural treatments for obese adults and should be prioritised in future research. Therefore, this review has to be seen as hypothesis generating, rather than hypothesis testing. It provides a tool to improve behavioural science based on systematic reviewing, rather than just accepting inconclusive evidence with heterogeneous effects without any indication for improvements. Accordingly, this systematic review is limited by the limitations of the available evidence on which it draws its conclusions.

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* indicates studies included in the systematic review

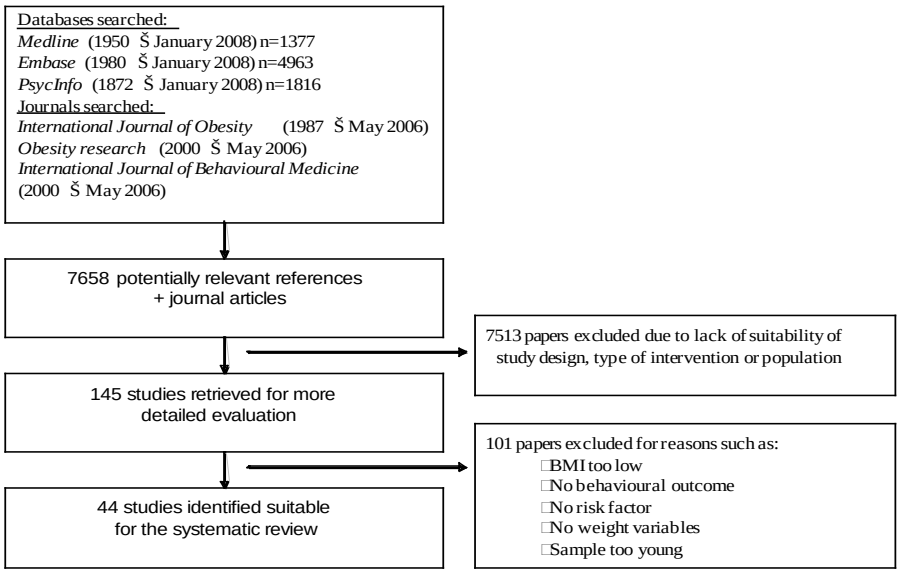

Figure 1 Flow diagram for locating RCTs for systematic review

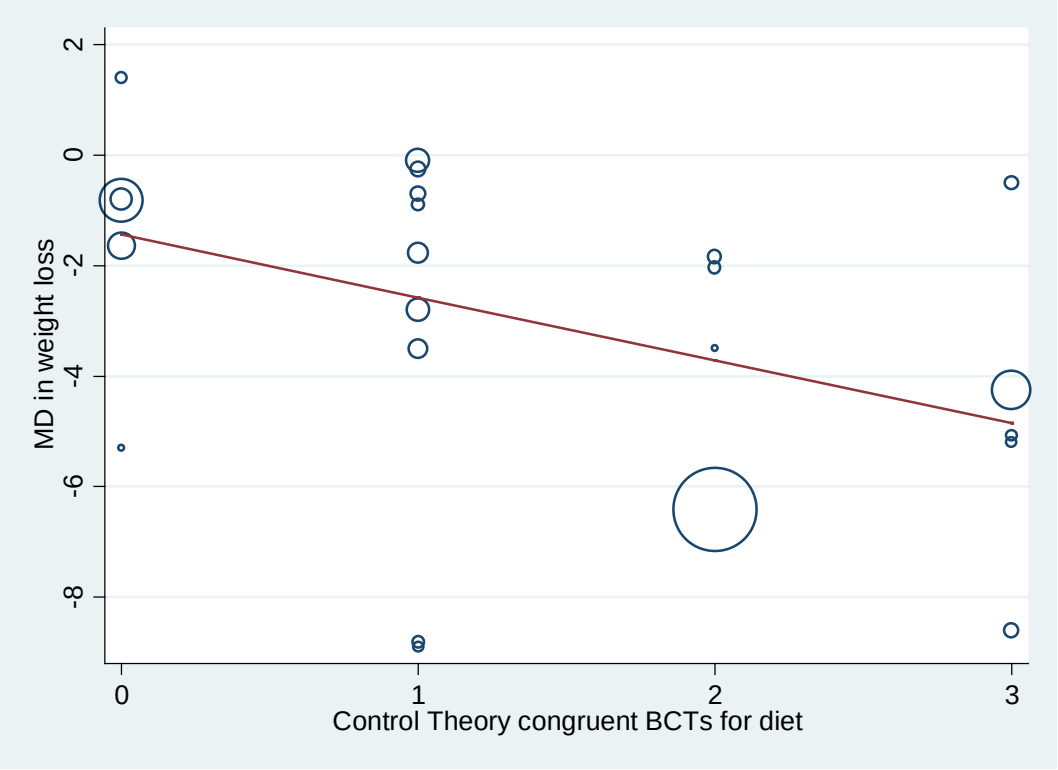

Figure 2 Meta regression of mean differences (MD) in weight loss on number of behaviour change techniques congruent with Control Theory. Circle size symbolises the inverse of the within-study variance and indicates weight assigned within the meta-regression

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Table 1 Details of included randomised controlled trials.

Study ID	*Country*	*Risk-factor*	*N*	*Active phase (weeks)*	*Delivery format*	*Intervener*	*Setting*	*Comparisons*	*Outcome(s)*
Argus-Collins	USA	T2D	64	12	GF & IF	HP	CS	D-PA vs. UC	weight, kcal, PA (subj.)
Ash	Australia	T2D	51	12	IF.	HP	Com	D vs. UC	weight, kcal
Blonk	Netherlands	T2D	53	24	GF & IF	HP	GP	Int. vs. less int. (D-PA).	weight, kcal
Blumenthal	USA	HT	133	24	GF	HP	Com	D-PA vs. WLC; PA vs. WLC.	weight, kcal, PA (obj.)
Burke	Australia	HT	241	16	GF & IF	non-HP	Com	D-PA vs. UC	weight, kcal, PA (subj.)
Carels	USA	PM	44	24	GF	HP & non-HP	Com	Int. vs. less int. (D-PA).	weight, kcal, PA (obj.)
Clark	UK	T2D	100	12	IF	non-HP	CS	D-PA vs. UC.	weight, PA (subj.)
Deakin	UK	T2D	314	16	GF	HP	GP	D-PA vs. UC.	weight, kcal, PA (subj.)
DPP	USA	EPG	2161	24	GF & IF	non-HP	Com	D-PA vs. UC	weight, kcal
Djuric	USA	BC	48	12	GF & IF	HP & non-HP	Com	D-PA vs. UC., Int. vs. less int. (D-PA, D only)	weight, kcal
Edelman	USA	Multiple	154	16	GF & IF	non-HP	CS	D-PA vs. UC.	weight , PA (subj.)
Evangelista	USA	AHF	110	24	GF	HP	Com	PA vs. UC.	weight, PA (obj.)
FDP	Finland	IGT	522	48	GF & IF	HP	Com	D-PA vs. UC.	Weight, kcal, PA (subj.)
Glasgow	USA	T2D	200	12	IF	non-HP	GP	D vs. UC; Int. vs. less int. (D only).	weight, kcal
Glasgow	USA	T1D or T2D	320	12	IF	HP & non-HP	GP	D only vs. UC.	weight, kcal
Goodrick	USA	BED	219	24	GF	HP	Com	D-PA vs. UC.	weight, kcal/kg/day
Grilo	USA	BED	90	12	IF	non-HP	Com	Int. vs. less int. (D-PA).	weight
Hardcastle	UK	CHD risk	334	24	IF	HP & non-	Com	D-PA vs. UC.	Weight, PA (subj.)

Study ID	*Country*	*Risk-factor*	*N*	*Active phase (weeks)*	*Delivery format*	*Intervener*	*Setting*	*Comparisons*	*Outcome(s)*
		factors				HP			
Jehn	USA	HT	43	48	GF	non-HP	Com	D-PA vs. UC.	weight
Jones	Canada	T1D or T2D	1119	48	IF	HP & non-HP	Com	D only vs. UC.	weight
Keyserling	USA	T2D	200	24	GF & IF	non-HP	GP	D-PA vs. UC; Int. vs. less int. (D-PA).	weight, kcal, PA (obj.)
Kirk	UK	T2D	70	24	IF	non-HP	CS	PA only vs. UC.	Weight, PA (obj.)
Kirkman	USA	T2D	156	48	IF	HP	CS	D-PA vs. UC.	weight
Laitinen	Finland	T2D	86	12	GF	HP	CS	D-PA vs. UC	weight, kcal
Logue	USA	Multiple	665	24	IF	HP & non-HP	GP	Int. vs. less int. (D-PA).	weight, kcal, PA (subj.)
Mefferd	USA	BC	85	16	IF	non-HP	Com	D-PA vs. UC.	weight, PA (subj.)
Menard	Canada	T2D	72	24	IF	non-HP	CS	D-PA vs. UC.	Weight, kcal, PA (obj.)
Metz	USA	1. HT/DL 2. T2D	1. 183 2. 119	48	IF	HP	CS	D only vs. UC.	weight, kcal
Oldroyd	UK	IGT	78	24	IF	HP	GP & CS	D-PA vs. UC.	weight, kcal, PA (subj.)
Pascale	USA	1. T2D 2. family history T2D	1. 44 2. 46	16	GF	HP	Com	Int. vs. less int. (D only).	weight, kcal
Pendelton	Australia	BED	110	16	GF	HP	Com	Int. vs. less int. (D-PA).	weight
PREMIER trial	USA	HT	810	24	GF & IF	non-HP	Com	D-PA vs. UC, Int. vs. less int. (D-PA)	weight, kcal, PA (subj.)
Reeves	USA	BED	98	24	GF	HP	Com	D-PA vs. WLC.	weight, kcal
Samaras	Australia	T2D	26	24	GF	HP	CS	PA vs. UC	Weight, PA (obj.)
Southard	Canada	CVD	104	24	IF	HP & non-HP	CS & GP	D-PA vs. UC	weight, PA (subj.)

Study ID	*Country*	*Risk-factor*	*N*	*Active phase (weeks)*	*Delivery format*	*Intervener*	*Setting*	*Comparisons*	*Outcome(s)*
Tate	USA	Multiple	92	48	IF	HP & non-HP	CS	Int. vs. less int. (D-PA)	weight
Tessier	Canada	T2D	45	16	GF	non-HP	CS	PA only vs. UC	weight, PA (obj.)
Tudor-Locke	Canada	T2D	60	16	GF	non-HP	CS	PA only vs. WLC	Weight, PA (obj.).
Toobert 2000	USA	CHD	28	16	GF	HP	Com	D-PA vs. UC	weight, kcal, PA (subj.)
Toobert 2005	USA	T2D	279	24	GF	HP	GP	D-PA vs. UC	weight, PA (subj.)
Villareal	USA	MS	27	24	GF	HP	Com	D-PA vs. UC	weight, PA (obj.)
Wing 1985	USA	T2D	53	12	GF	HP	Com	D-PA vs. UC	weight
Wing 1991	USA	T2D	45	20	GF	HP	Com	Int. vs. less int. (D-PA).	weight
Wing 1998	USA	T2D	154	24	GF	HP	Com	D-PA vs. UC, D only vs. UC, PA only vs. UC	weight, kcal, PA (subj.)

Note. AHF = advanced heart failure, BC = breast cancer, BED = binge eating disorder, CHD = coronary heart disease, CVD = cardiovascular disease, D-PA = diet and physical activity intervention, CS = community setting, Com = community, D only = diet only intervention, GP = general practice, DL = dyslipidemia, HP = health professional, HT = hypertension, Int. vs. less int. = Intensive compared to less intensive intervention, EPG = elevated plasma glucose, GF = group format, IF = individual format, MS = metabolic syndrome, N = numbers randomised, PM = postmenopause, T1D = type 1 diabetes, T2D = type 2 diabetes, UC = usual care, WLC = waiting list control group

Table 2 Reliability estimates (Kappa) of technique identification and numbers of studies identified as having used a behaviour change technique.

	Diet		*PA*	
Behaviour Change Technique (associated theory)	*Kappa*	*k*	*Kappa*	*k*
1 Provide general information (IMB)	.79	11	.72	8
2 Provide information on consequences (TRA, TPB, SCogT, IMB)	.78	14	.84	12
3 Provide information about others' approval (TRA, TPB, IMB)	N/A	0	N/A	0
4 Prompt intention formation (TRA, TPB, SCogT, IMB)	.74	30	.90	24
5 Prompt barrier identification (SCogT)	.89	26	.90	21
6 Provide general encouragement (SCogT)	.59	10	.47	11
7 Set graded tasks (SCogT)	.90	7	.68	12
8 Provide Instruction (SCogT)	.70	27	.65	23
9 Model/ demonstrate the behaviour (SCogT)	.72	3	.89	5
10 Prompt specific goal setting (CT)	.84	8	.68	4
11 Prompt review of behavioural goals (CT)	.65	7	.54	7
12 Prompt self-monitoring of behaviour (CT)	.84	26	.80	24
13 Provide feedback on performance (CT)	.79	16	.79	12
14 Provide contingent rewards (OC)	.59	9	.75	9
15 Teach to use prompts/ cues (OC)	1	4	.47	5
16 Agree behavioural contract (OC)	1	1	N/A	0
17 Prompt practice (OC)	.93	10	.90	17
18 Use follow up prompts (OC)	.13	4	-.07	2
19 Provide opportunities for social comparison (SCompT)	.80	24	.79	28
20 Plan social support/ social change (social support theories)	.85	19	.70	22
21 Prompt identification as role model	N/A	0	N/A	0
22 Prompt self talk	N/A	3	N/A	2
23 Relapse prevention (Relapse Prevention Therapy)	.84	15	.69	12
24 Stress management (stress theories)	.89	6	.80	6
25 Motivational interviewing	.53	3	.78	2
26 Time Management	1	2	.78	3

Note. k = number of studies, PA = physical activity, N/A = not applicable, IMB = Information-Motivation-Behavioural Skills model., TRA = Theory of Reasoned Action, TPB = Theory of Planned Behaviour, SCogT = social cognitive theory, CT = Control Theory, OC = operant conditioning, SCompT = theories of social comparison.

Table 3 Main effects of intervention compared to usual care/waiting list control groups.

Variable	*Effect*	*CI*	*k*	*N*
weight [a]	-3.0**	-4.3, -1.8	23	5020
Kilocalorie intake [a]	-112**	-217, -7	13	1686
Physical activity [b]	0.4**	0.3, 0.5	21	3048

Note. I^2 * >25%, ** >50%

[a] mean difference (MD), [b] standardised mean difference (SMD),

CI = 95% Confidence Interval; k = number of studies; N = number of participants.

Table 4 Meta-regression results for comparison of intervention effects on weight and kilocalorie consumption for studies using or not using a particular behaviour change technique.

	BCT included				*BCT not included*							
BCT	*MD*	*CI*	*k*	*N*	*MD*	*CI*	*k*	*N*	*β*	*p*	*CI*	*adj.* R^2
Weight (BCTs targeting diet)												
Provide Instruction	-4.3**	-5.8, -2.8	12	3327	-1.5**	-2.3, -0.6	12	1693	-2.69	0.023	-0.93, -0.14	26.2
Self-monitoring	-4.2**	-5.5, -2.9	15	3844	-0.8*	-1.4, -0.2	8	1176	-3.37	0.005	-0.98, -0.18	39.9
Relapse prevention	-4.5**	-6.2, -2.8	10	3221	-1.7**	-2.4, -0.9	13	1799	-2.63	0.028	-0.92, -0.09	24.3
Weight (BCTs targeting PA)												
General info	-0.7	-1.6, 0.3	5	505	-3.7**	-5.2, -2.3	18	4515	3.13	0.031	0.11, 1.09	18.0
Info on consequences	-1.2*	-2.0, -0.4	8	1344	-3.9**	-5.4, -2.5	15	3676	2.56	0.04	0.10, 0.94	19.2
Prompt practice	-4.8**	-6.2, -3.4	12	3584	-1.2*	-1.9, -0.4	11	1436	-3.6	0.001	-0.95, -0.19	47.9
Kilocalorie intake												
Provide Instruction	-196**	-309, -83	9	1102	71	-21, 163	4	584	-240	0.02	-440 -39	61.5

Note. I^2 * >25%, ** >50%, BCT = behaviour change technique, MD = mean difference in kg, CI = 95% Confidence Interval; k = number of studies; N = number of participants, Δ kg = difference in MDs in kg, β = Meta-regression coefficient, adj. R^2 = proportion of variance accounted for by covariate, $([\tau^2_a - \tau^2_b]/ \tau^2_a) \times 100$.