A feasibility randomised controlled trial of a motivational interviewing-based intervention for weight loss maintenance in adults

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Scientific summary

Trial of a motivational interviewing-based intervention for weight loss

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Background

Over one-quarter of adults in the UK are obese. Obesity is associated with increased health risks and reduced life expectancy and has a significant impact on NHS costs. The underlying causes are complex, and tackling obesity is challenging. Evidence suggests that relatively small reductions in weight (5–10% of body weight) can lead to clinically significant health benefits. Interventions tackling lifestyle changes have been effective for weight loss. However, maintaining weight loss in the longer term remains a challenge. Lifestyle and behavioural interventions are likely to be important. Reviews of factors associated with weight loss maintenance (WLM) have identified a number of key features, including physical activity, low-calorie and low-fat foods, tailoring of advice, self-monitoring, social support, internal motivation and self-efficacy.

Motivation is crucial to maintenance of behaviour change. Motivational interviewing (MI) is a counselling technique that emphasises personal autonomy and enhances motivation for change. Some studies have explored MI for weight loss, but none have used it to support WLM. The evidence suggests that relatively brief contact and use of MI in weight loss can be effective. However, we do not know if MI may be useful for WLM or the required treatment intensity.

The intervention tested in this trial comprised MI, incorporating goal-setting, planning and self-monitoring. This study was originally designed as an effectiveness trial with the primary outcome, body mass index (BMI), assessed 3 years post randomisation. However, owing to lower than anticipated recruitment, the trial was closed to recruitment early and became a feasibility study. The results of the feasibility study are reported here in addition to both the original and modified design.

Objectives

The primary objectives were to assess the feasibility, acceptability, compliance and delivery of a 12-month multicomponent intervention based on MI, as well as recruitment and retention. The impact of the intervention on participants' BMI was evaluated 1 year from randomisation. We also assessed the impact of the intervention on a number of secondary outcomes including physical activity, diet, alcohol, smoking status, health-related quality of life, binge eating, psychological well-being and resource use. Furthermore, we aimed to assess key mediators associated with successful change, including self-efficacy, social support, self-monitoring, implementation intentions, habit formation and intrinsic motivation.

Process and cost-effectiveness evaluations were also undertaken.

Methods

Study design

Three-arm individually randomised controlled trial.

Participant recruitment and baseline data collection

Participants were recruited in South Wales and the East Midlands, from general practitioner (GP) practice, exercise referral schemes, a commercial weight loss programme (Slimming World) and the community (via advertising). Individuals were approached either face to face or record searches or self-referred. They were provided with an information sheet and expression of interest (EOI) form. Participants were screened for eligibility, based on age (18–70 years), current or previous BMI ($\geq 30\ kg/m^2$), intentional weight loss of at least

5% body weight during the previous 12 months and independent verification of weight loss. Participants were not eligible if they had previously undergone bariatric surgery, were terminally ill, had poor competence in English, lived with another study participant or were pregnant. On fulfilment of eligibility criteria, potential participants were invited to a baseline meeting. If participants did not meet or could not provide verification of 5% weight loss, they were invited to recontact the research team when they had achieved this.

Eligibility was confirmed at baseline by the researcher. Participants were consented and randomised to one of three arms: intensive intervention, less intensive intervention or control. Participants completed baseline questionnaires and had their weight, height, and waist and hip circumference measured. On completion of the baseline assessments, intervention participants were invited to the MI sessions and all participants were followed up at 6 months (postal questionnaire) and 12 months (face to face) post randomisation. Those unable or unwilling to attend the 12-month assessment were offered the opportunity to complete a shorter version of the questionnaires over the telephone and self-report their weight.

Trial intervention

Intervention participants received an individually tailored MI counselling intervention. Participants in the intensive arm received six 1-hour face-to-face sessions during the first 3 months followed by nine 20-minute telephone sessions during the remaining 9 months of the intervention period. Participants in the less intensive arm received two 1-hour face-to-face sessions during the first month followed by two 20-minute telephone sessions at 6 and 12 months post randomisation. Originally, the intervention included a group-based peer support element; however, this was not delivered when the study design changed because of feasibility issues relating to recruitment and attendance at the groups. Participants in the control group received a leaflet advising them on healthy eating and lifestyle along with usual care.

Outcome measures

Outcome measures were self-reported with the exception of height, weight, and waist and hip circumference. Secondary outcomes and mediators were measured with validated instruments. All outcomes were recorded on study-specific case report forms (CRFs).

Quantitative analysis

Feasibility outcomes included number recruited, retention and adherence. The main effectiveness analysis was intention to treat and complete case, comparing BMI at 12 months in the intensive intervention arm and the control arm using analysis of covariance controlling for age, gender, ethnicity, source of recruitment and percentage weight lost.

Secondary outcomes included waist circumference, waist-to-hip ratio, physical activity, proportion maintaining weight loss (defined as having a weight at follow-up the same as or lower than their baseline weight), dietary intake, health-related quality of life, health service and weight control resource use, binge eating, alcohol consumption, smoking, psychological well-being, duration of participation and dropout from the intervention. Binary outcomes were analysed using logistic regression and continuous outcomes using linear regression. Mediation analyses were conducted for self-efficacy, social support, intrinsic motivation, habits and self-monitoring as measured at 6 months using a hierarchical model and controlling for baseline randomisation variables. The Consolidated Standards of Reporting Trials – Patient-Reported Outcomes guidelines are referenced for reporting patient-reported outcomes. Exploratory subgroup analyses investigated WLM in binge eaters, gender and source of recruitment.

Process evaluation

We conducted a process evaluation with the aims of assessing delivery of the intervention, establishing the level of participant adherence to the intervention, exploring participants' views of and satisfaction with the intervention, exploring motivational interviewing practitioners' (MIPs) experiences of delivering the intervention and testing the intervention theory. A process evaluation framework was devised to focus on eight key components (context, reach, fidelity, exposure, recruitment, retention, contamination and theory testing). This was used to frame the analysis. Mixed methods were employed.

Audio-recordings of face-to-face sessions were analysed to assess fidelity of intervention delivery and session CRFs were analysed to determine participant adherence. Participants' use of the website for self-monitoring was analysed for frequency of use. Focus groups were conducted with MIPs to gather their views on training received, practicalities of delivering the intervention and suggested improvements. Participants were interviewed to gather their views on the intervention, and barriers and facilitators to weight maintenance. Potential mediators and moderators were also explored, including those specifically being tested in the process evaluation as well as the impact of life events, environmental influences, social support, coping and response to relapse. Focus groups and interviews were analysed using thematic analysis.

Health economic analysis

The change to a feasibility study meant that definitive cost-effectiveness results were unlikely given the reduced sample size and shortened follow-up period. Nevertheless, the costs of delivering the MIP training and intervention delivery were determined, subsequent costs of NHS and non-NHS weight loss/maintenance were estimated and, after adjusting for baseline differences in key variables and for skewness, total costs were assessed against effects in terms of quality-adjusted life-years (QALYs) derived from the European Quality of Life-5 Dimensions health-related quality-of-life data and against BMI.

Results

Quantitative analysis

A total of 1284 EOIs were received and 170 participants recruited. The most common reason for ineligibility was an inability to verify 5% weight loss. The most efficient recruitment route was through the commercial weight loss programme. Adherence to the face-to-face element was excellent in both arms (intensive, 83%; less intensive, 91%). The overall withdrawal and non-responder rates were very low, at 10% and 7%, respectively. The three arms were broadly similar with regard to key demographics and comorbidities. Overall, more women than men ($n = 141$) were recruited.

Although not statistically significant, the between-group difference in mean BMI at 12 months indicated the intensive arm had BMIs 1.0 kg/m^2 lower than the controls [95% confidence interval (CI) –2.2 kg/m^2 to 0.2 kg/m^2]. Mean BMI was also lower in the less intensive group, but the difference was not at a level considered clinically significant. A similar effect was found when considering weight, with the intensive arm weighing an average of 2.8 kg lower than the control (95% CI –6.1 kg to 0.5 kg) and the less intensive group an average of 0.7 kg lower (95% CI –4.1 kg to 2.7 kg). These differences from control were not statistically significant but for the intensive arm would be of clinical importance if shown to be true differences. A difference in waist measurement was also found, with the intensive participants having an average of 0.8 cm lower waist circumference than control (95% CI –4.2 cm to 2.6 cm), while those in less intensive group had an average of 0.2 cm smaller waist circumference (95% CI –3.3 cm to 3.7 cm). In addition, although neither difference was statistically significant, participants in the intensive arm had, on average, a 43% higher chance of maintaining weight loss [odds ratio (OR) 1.4, 95% CI 0.6 to 3.5] than controls, whereas participants in the less intensive arm were, on average, 40% less successful than controls at maintaining weight loss (OR 0.6, 95% CI 0.2 to 1.6).

The other secondary outcomes showed limited evidence of differences between groups. Analysis on the Dietary Instrument for Nutrition Education (DINE) fat scale showed that fat intake was significantly lower in the intensive arm (adjusted mean difference –4.7, 95% CI –7.4 to –2.3). The DINE healthy eating score also showed some evidence of effect in the intensive arm (adjusted mean 4.16, 95% CI –1.8 to 10.1). A statistically significant reduction in binge eating was observed in the intensive arm (mean binge eating rate 0.6 days, 95% CI 0.4 days to 0.9 days). Further analyses controlling for level of adherence indicated that average BMI was 1.2 kg/m^2 lower in the intensive arm than in the control arm (95% CI –2.5 kg/m^2 to 0.0 kg/m^2). The intensive intervention led to a statistically significant difference in weight (mean –3.7 kg, 95% CI –7.1 kg to –0.3 kg) relative to controls.

The mediation analysis showed that 5 out of the 10 mediators were statistically significantly associated with lower BMI. However, this analysis was largely unable to determine the causal mechanisms underlying these associations. The results do not show any impact of the intervention on the mediators tested.

Process evaluation

The intervention was successfully delivered in the community by trained counsellors. Adherence was good, although there were some issues with telephone delivery, including low acceptability to some counsellors and participants. Use of the website for self-monitoring was quite low, with a median number of 26 logins. The face-to-face MI was delivered with good fidelity, and contamination between arms was minimal.

Motivational interviewing practitioners were positive about the intervention, although they would have preferred the number of sessions to be based on need rather than chance (i.e. randomisation). They preferred face-to-face delivery and felt that participants benefited from the supportive ongoing relationship. They reflected positively on the possibilities of implementing the intervention in 'the real world' and commented on wider social and environmental factors and their impacts.

Participants appreciated the counselling as it provided a safe, caring and non-judgemental environment. They valued the psychological expertise and support of the counsellors. They felt that it provided increased insight into their weight-related behaviours, as well as encouragement to find their own solutions, which helped boost feelings of control in relation to weight management. They also suggested that long-term support was important for maintenance. Most preferred the face-to-face sessions, although telephone sessions were seen as useful for 'checking in'. Some participants reported that they had shared information with family and friends and that, in some cases, this led to behaviour change. Participants described a number of barriers to managing their weight, which included cultural attitudes around food and eating, and significant life events.

The qualitative data provided insights into the mediators of intervention effect. The most important was ongoing motivation, which was strongly influenced by the support of family, friends, peers and professionals. Other factors described as important included positive reinforcement, self-monitoring and habit formation.

Economic analysis

The total cost per person of the intensive and less intensive interventions was £510 and £168, respectively. The cost–utility analysis indicated a small QALY gain for the intensive group (0.001) and a small QALY loss (0.032) for the less intensive group compared with controls, but neither difference was statistically significant. As total NHS costs for both intervention groups were higher than for controls, the less intensive intervention was dominated (i.e. unambiguously not cost-effective) and the intensive intervention produced an incremental cost-effectiveness ratio well above the willingness-to-pay threshold used by the National Institute for Health and Care Excellence. The cost-effectiveness analyses (CEAs) using BMI as the outcome indicated that both interventions were more effective than the control, with the intensive intervention being the most effective, although neither difference was statistically significant.

Conclusions

This is the first trial of an intervention for WLM in the UK. Although recruitment was challenging and problems with verification of weight loss, and governance and infrastructure support issues led to the trial becoming a feasibility study, the results look promising. The intervention is feasible and acceptable, and retention and adherence were high. The qualitative work indicates that both counsellors and participants were happy with the delivery of the intervention and the participants particularly appreciated the support. The effectiveness outcomes showed promising mean differences and CIs for the intensive arm, which would be considered clinically significant; however, the reduced sample size limits our ability to draw

definitive conclusions from the quantitative, mediation and CEAs. Outcomes in the less intensive and control arms appear similar; therefore, we do not recommend the less intensive arm for further investigation. Based on current research evidence, it is likely that more intensive interventions with longer-term support are needed to facilitate long-term weight maintenance.

Motivational interviewing appears to be a promising approach for behaviour modification leading to WLM and, therefore, further testing in an effectiveness trial may be indicated. However, significant resources are required to deliver this intervention at an appropriate level. This intervention could be implemented in a community setting and may prove cost-effective to deliver, particularly if viewed as part of a broader strategy to support healthy choices.

Weight loss maintenance research is still relatively undeveloped. There is a need for future research improving our understanding of WLM and expanding theory to inform the development of interventions, which should then be tested in rigorously designed randomised controlled trials with cost-effectiveness assessed.

Trial registration

This trial is registered as ISRCTN35774128.

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