Text messaging and financial incentives to encourage weight loss in men with obesity: the Game of Stones feasibility RCT

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Scientific summary

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Background

In 2016, an estimated 26% of UK men were classified as obese. In the UK, men are less likely than women to be a healthy weight. Obesity results in an increased risk of serious health conditions, such as cardiovascular disease, cancer and diabetes mellitus, and is a major public health priority.

Men are an underserved population in current evidence-based weight management programmes, particularly those living in areas of deprivation. Systematic review evidence suggests that men often require different interventions from women. Effective strategies to recruit and retain men in weight management programmes are required to provide evidence-based weight loss and weight loss maintenance support.

This feasibility study examined two intervention components to support men with obesity to lose weight and to maintain weight loss: (1) narrative short message service (SMS) and (2) a financial incentive.

The narrative SMS are story-based SMS written and scheduled to be sent automatically from a computer and received by study participants on their mobile phones. Evidence suggests that narrative SMS may be an engaging way to deliver a health behaviour change intervention, covering sensitive health issues such as obesity and alcohol use in men.

Financial incentives have shown promise to change weight-related behaviour. Current systematic review evidence of financial incentives for habitual behaviour change highlights the potential for incentives to change behaviours and help reduce health inequalities. The evidence of financial incentives for weight loss in men is uncertain. Economic theory suggests that financial incentives framed as losses through endowment incentives (where participants receive a promise of money at the start for achieving target outcomes) have the potential to be more motivating. Endowment incentives draw on loss aversion, as people are more motivated to avoid losses than they are to achieve similarly sized gains.

Aim and objectives

The overall aim was to co-produce, with patient and public involvement, an acceptable and feasible randomised controlled trial design with broad reach to test a narrative theory-based SMS intervention with embedded behaviour change techniques and key messages, with and without an endowment incentive, compared with waiting list control, to inform a future full trial.

Objectives phase 1: trial design

- To collaborate with a charity for men and men with obesity to minimise inequalities and maximise the intervention's appeal and reach.
- To refine the theoretical basis of the intervention by integrating systematic review findings and National Institute for Health and Care Excellence evidence for reducing diets, physical activity, behaviour change techniques and theory to refine a logic model.
- To operationalise acceptable and effective behaviour change techniques so that these can be embedded in a novel narrative SMS delivery form, which builds on existing National Institute for Health Research-funded narrative SMS alcohol interventions.

- To identify acceptable ways to provide a menu of information resources on, for example, diet and physical activity, visual feedback of self-report weight and waist circumference, and pedometer readings using our own or other available open-source websites.
- To optimise an endowment incentive to motivate behaviour change by applying insights from behavioural economics and a survey/discrete choice experiment with men who are obese to define the frequency, constant or varying values and contingency of incentives on targets met for (1) initial weight loss and (2) weight loss maintenance.
- To select acceptable and valid outcome and cost-effectiveness measures that have potential for future long-term data linkage.
- To produce a library of SMS content, recruitment materials and a phase 2 protocol.

Objectives phase 2: feasibility trial to refine approach, recruitment, randomisation, intervention delivery, engagement, retention and follow-up processes

- To assess the acceptability and willingness to be randomised to (1) SMS, (2) SMS and an endowment incentive or (3) waiting list for SMS.
- To assess the acceptability and feasibility of recruiting from general practice obesity registers and community venues identified in phase 1.
- To determine the acceptability of the intervention content, delivery and attendance levels for objective weight measures at baseline and at 3, 6 and 12 months, and any unintended consequences.
- To assess the likely impact of the intervention on the percentage of weight lost at 12 months and on health inequalities using an assessment of differential uptake and potential effectiveness by socioeconomic group.
- To assess if alternative SMS based on mixed-methods data analysis are acceptable and more likely to improve trial retention at 3 months than the narrative SMS intervention. This objective was added to the protocol following an approved study extension request.

Methods

Design

This was a two-phase feasibility study. Phase 1 consisted of developing the intervention components (narrative SMS and financial incentives), study procedures and materials. This included a discrete choice experiment with a survey to ascertain the most acceptable incentive strategy, with the survey questions designed to inform trial procedures, and patient and public involvement, with a stakeholder workshop to help make decisions about protocol uncertainties. Phase 2 was an individually randomised three-arm feasibility trial over 12 months. Narrative SMS development took place iteratively over the 12 months taking into consideration the SMS replies received from engaged participants and also patient and public involvement. Qualitative interviews were conducted at 3 months ($n = 50$) and 12 months ($n = 33$). After an approved study extension, an alternative style of SMS focused on weight management in waiting list control participants was developed and was tested for 3 months. The alternative SMS were informed by an analysis of the qualitative data collected from trial participants and by patient and public involvement feedback. Further qualitative interviews ($n = 14$) were conducted after the alternative SMS had been sent for 3 months.

Setting

The survey/discrete choice experiment was conducted online by Ipsos MORI (London, UK; www.ipsos.com/ipsos-mori/en-uk). The feasibility randomised controlled trial was conducted in two sites in Scotland that had disadvantaged urban and rural areas and that differed in employment level and ethnic groups.

Participants

Phase 1 participants were 1045 men with obesity, representative of the UK population, who were recruited by Ipsos MORI. Men, including many in the target population, were involved in patient and public involvement activities.

Phase 2 participants were adult men ($n = 105$) with obesity, which was defined as having a body mass index of ≥ 30 kg/m^2 and/or a waist measurement of ≥ 40 inches (102 cm), who were recruited in the community or through general practitioners' obesity registers.

Interventions and comparator

Men were randomly assigned to one of three arms: (1) narrative SMS for 12 months (SMS only); (2) financial endowment incentive informed by loss aversion and linked to achievement of weight loss targets plus narrative SMS for 12 months (SMS + I) (men could secure up to £400 by meeting weight loss targets); and (3) waiting list control arm for 12 months followed by 3 months of alternative SMS that were developed based on the analysis of men's feedback in interviews undertaken at the 3-month trial assessments. All participants received access to a study web page containing existing online resources that offered a choice of evidence-based diets, physical activity approaches, hints and tips. Additional web pages were specific to each intervention arm. Both SMS-only and SMS + I participants could self-monitor their step counts, weight, waist circumference and belt notches, and they could access a brief biography and images of the characters featured in the narrative SMS. The SMS + I arm had access to additional web pages describing the financial incentives and a visual progress chart of money they had secured or lost in relation to weight loss targets, which was populated automatically following their weight assessment appointments.

Main outcome measures

The primary outcome was the acceptability and feasibility of recruitment, retention, the intervention components and the trial procedures. The outcomes were assessed by examining procedural, quantitative and qualitative data at 3, 6 and 12 months, and at 3 months following alternative SMS.

An independent Study Steering Committee advised whether or not the following prespecified progression criteria were met sufficiently to proceed to a full trial:

- Acceptability of the intervention and of the control arm (by the majority of the target group), and willingness to be randomised. This was evidenced by quantitative and qualitative data on satisfaction, recruitment and intervention engagement.
- Feasibility of recruiting 105 men in 4 months.
- Twelve-month outcomes on at least 72% of men randomised per arm, consistent with a recent UK weight management trial in men and systematic reviews of male obesity literature.
- Evidence of mean weight loss of at least 3% of baseline weight at 12 months in any intervention arm; the National Institute for Health and Care Excellence defines 3% as clinically significant.
- An independent study steering committee will decide whether or not the findings support a two- or three-arm trial.
- Commitment by, for example, government or NHS/local authorities to fund the incentive intervention, if it shows positive indicative effects, to ensure translation and sustainability.

Results

Overall, this mixed-methods feasibility study developed intervention components specifically for men with men, which showed overall acceptability and feasibility for delivery and should be taken forward to a definitive trial, with minor modifications to improve study retention.

Based on the discrete choice experiment results, the most acceptable incentive strategy in the discrete choice experiment was to meet researcher-verified weight loss from baseline of 5% at 3 months and of 10% at 6 months and to maintain weight loss of 10% at 12 months. This strategy was subsequently implemented in the feasibility trial.

Recruiting 105 men with obesity within 4 months was feasible through both community outreach and general practices. More participants were recruited from the community ($n = 60$) than from general practices ($n = 45$). Researchers spent an average of around 2 hours at community venues per participant randomised via this route. General practice recruitment required a longer set-up period to recruit practices and for clinical staff to screen practice lists.

Differences in sample composition emerged between the two recruitment channels. Compared with community recruits, those recruited via general practice obesity registers were more likely to live in deprived areas (community, 56%; general practice, 64%), to be older (community, 48.3 years; general practice, 57.1 years) and to report having a comorbidity (community, 44%; general practice, 87%) and had a lower body mass index (community, 36.2 kg/m^2; general practice, 35.0 kg/m^2). The employment status of the two cohorts was broadly comparable, potentially reflecting that recruitment activity was undertaken in the evenings and at weekends to ensure that men in full-time employment would be represented in the study. The qualitative findings suggested that both recruitment channels were acceptable to men.

Retention levels were acceptable, with 74% of the 105 men completing the 12 months' follow-up. Differential dropout rates between the study arms were observed, with fewer SMS + I participants completing the study (64%) than SMS-only (79%) or control arm participants (83%). A total of 12 men withdrew from the study and gave the following reasons: disliked the narrative SMS intervention component ($n = 4$), health ($n = 3$), family ($n = 1$), unknown ($n = 1$), dissatisfied with arm allocation ($n = 1$), appointment logistics ($n = 1$) and multiple reasons ($n = 1$). Retention differed slightly by recruitment channel. Of the 45 participants recruited from general practices, 36 (80%) completed the 12-month follow-up assessment, 6 (13%) withdrew from the study and 3 (7%) were lost to follow-up. Of the 60 participants recruited from the community, 43 (71%) completed the 12-month follow-up assessment, 6 (10%) withdrew and 11 (18%) were lost to follow-up.

The majority of appointments with participants recruited from general practices were held in the practice, a familiar environment for patients. Study data, patient and public involvement and stakeholder feedback suggested that the difference in site retention might be due to many factors, such as population composition, number of local research activities or familiarity with the institutions conducting the research.

Small differences emerged between participants who completed the 12-month assessment and those who withdrew or did not return for an assessment. Non-completers ($n = 26$) were heavier (non-completers, 37.5 kg/m^2; completers, 35.1 kg/m^2) and intended to lose more weight through the programme (non-completers, 19.2 kg; completers, 16.9 kg). More participants from more deprived backgrounds remained in the study, suggesting that the intervention has the potential to make a positive impact on health inequalities.

Acceptability of the intervention components was generally demonstrated, with some variation between the different study aspects. Narrative SMS were acceptable to most participants. A few men had negative reactions and withdrew from the study because they disliked the narrative SMS ($n = 4$), or they requested that the SMS be stopped while they continued trial participation ($n = 11$).

The endowment incentives were acceptable, with no strong negative reactions, although few participants explicitly reported being motivated by them. Overall, 12 men secured money and, of those, three achieved the full £400 endowment. Two out of three men failed to reach 5% weight loss at any time point and, therefore, did not secure any money. Interviews revealed a complexity related to incentives that went

beyond simple statements of acceptability. The intervention website was acceptable, and some men used it to self-monitor behaviour and weight (0–3 months, 27%; 3–6 months, 16%; 6–12 months, 13%), but most did not engage with this component. The study pedometer given to all participants was the most popular intervention component.

There was high intervention fidelity and no major technical errors occurred. Both the measurement of weight for securing the incentive and the delivery of incentives were feasible. Two men reported that they had met other men in the programme, suggesting no evidence that individual-level randomisation would lead to significant levels of contamination in a full trial.

Indicative effectiveness was established for weight measures, with participants demonstrating small changes in weight and weight-related outcomes (mean percentage weight change at 12 months for completers: SMS + I −3.51%, standard deviation 5.83%; SMS only −1.51%, standard deviation 4.65%; control −1.00%, standard deviation 5.31%). SMS + I participants showed the highest level of weight loss, including when accounting for differential dropout. The SMS + I arm showed no increase in average levels of controlled regulation (i.e. performing behaviours for external reasons), and levels of autonomous regulation (i.e. performing behaviours for internal reasons) remained high and stable, suggesting no evidence that the endowment incentive undermined the quality and strength of participants' motivation to lose weight in the SMS + I arm.

Outcome measures collected with questionnaires were acceptable to men, with numbers of missing data acceptable and comparable with those in other studies. Health, well-being and body image were identified in the qualitative interviews as the key outcome domains that matter most to men. The acceptability of gaining consent for future follow-up and data linkage to health and well-being outcomes for a future cost effectiveness trial was demonstrated. Publicly available videos helped men to understand the issues and improved acceptability.

Outcome assessment was not blind; however, a small feasibility test of 11 assessments suggests that blinding would be possible in a future trial. Quantitative and qualitative data analysis about receiving 3 months of the alternative SMS showed acceptability, with no strong negative reactions.

No adverse events or evidence of gaming incentives were identified.

An independent Study Steering Committee agreed that the Game of Stones study had demonstrated acceptability and feasibility, showed promise for addressing health inequalities and had a broad reach. The committee agreed that, overall, the prespecified progression criteria were sufficiently met and that findings would support a full three-arm multisite randomised controlled trial, maintaining both community and general practice recruitment channels.

Conclusions

The men-only weight management interventions consisting of narrative SMS and financial incentives were both feasible to deliver as a randomised controlled trial and acceptable. SMS-tailoring options may improve acceptability. Minor refinements will be made to the intervention components and study processes in the light of the findings of this study and prior to testing in a multisite definitive randomised controlled trial.

Trial registration

This trial is registered as ClinicalTrials.gov NCT03040518.

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