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# BMJ Open

## Game of Stones: Feasibility randomised controlled trial of how to engage men with obesity in text message and incentive interventions for weight loss

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4 **Game of Stones: Feasibility randomised controlled trial of how to engage men with**  
5 **obesity in text message and incentive interventions for weight loss**  
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## ABSTRACT

### Objectives

To examine the acceptability and feasibility of narrative text messages with or without financial incentives to support weight loss for men.

### Design

Individually randomised three-arm feasibility trial with 12 months' follow-up.

### Setting

Two sites in Scotland with high levels of disadvantage according to Scottish Index for Multiple Deprivation (SIMD).

### Participants

Men with obesity (n=105) recruited through community outreach and general practitioner registers.

### Interventions

Participants randomised to a) narrative text messages plus financial incentive for 12 months (SMS+I), b) narrative text messages for 12 months (SMS only), or c) waiting list control.

### Outcomes

Acceptability and feasibility of recruitment, retention, intervention components and trial procedures assessed by analysing quantitative and qualitative data at three, six and 12 months.

### Results

105 men were recruited, 60% from more disadvantaged areas (SIMD quintiles 1 or 2). Retention at 12 months was 74%. Fewer SMS+I participants group (64%) completed 12-month assessments compared to SMS only (79%) and control (83%). Narrative texts were acceptable to many men, but some reported negative reactions. No evidence emerged that level of disadvantage was related to acceptability of narrative texts. Eleven SMS+I participants (31%) successfully met or partially met weight loss targets. The cost of the incentive per participant was £81.94 (95% CI £34.59-£129.30). Incentives were acceptable, but improving health was reported as the key motivator for weight loss. All groups lost

1  
2  
3 weight (SMS+I -2.51kg (SD=4.94); SMS only -1.29kg (SD=5.03); control -0.86kg  
4 (SD=5.64) at 12 months).  
5  
6

### 7 **Conclusions**

8  
9 This weight management intervention recruited and retained men from across the  
10 socioeconomic spectrum with the majority from areas of disadvantage, was broadly  
11 acceptable to most participants and indicated some weight loss benefits.  
12  
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14

### 15 **Trial registration**

16  
17 ClinicalTrials.gov Identifier: NCT03040518  
18

### 19 **Funding details**

20  
21 Funded by the National Institute for Health Research Public Health Research Programme  
22 (14/185).  
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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This weight management study for men with obesity recruited men across the socio-economic spectrum, with a specific focus on more disadvantaged areas, to a randomised controlled feasibility study examining SMS with or without endowment incentives.
- Acceptability and feasibility was established using a multi-lens perspective drawing on quantitative, qualitative and trial procedure data.
- Effectiveness of intervention components will need to be established in a full multi-centre trial.



## BACKGROUND

Obesity is associated with an increased risk of serious health conditions such as type 2 diabetes, cardiovascular disease and some cancers.<sup>1</sup> In 2016, 26% of men in the UK were classified as obese, and men were less likely to be a healthy weight than women (31% of men compared with 35% of women).<sup>2,3</sup>

Despite the growing prevalence of obesity, men contribute a disproportionately low number of participants to evidence-based weight management programmes.<sup>4</sup> Most interventions are designed for mixed sex populations, but systematic review evidence suggests that, compared to women, men often benefit from different ways of providing interventions.<sup>4</sup>

### Text message interventions

The evidence for text message interventions supporting changes in lifestyle behaviours, including behaviour change for weight loss, is promising.<sup>5-7</sup> However, systematic reviews<sup>4-7</sup> report no text message delivered trials that target weight loss designed for men only. Text-based interventions can reach large numbers of people, including men from disadvantaged backgrounds,<sup>8</sup> and mobile technologies such as standard mobile phones allow delivery of evidence-based strategies anywhere and anytime.

Narrative approaches to promoting behaviour change have been suggested as a tool for communication-based interventions.<sup>9</sup> Narrative SMS can be broadly defined as interactive life stories, which are based around a group of characters with whom recipients can identify.<sup>10</sup> Text message based interventions using narratives have been used to engage hard to reach men in moderating their alcohol consumption, and were found to be acceptable.<sup>11-13</sup> Narrative approaches to weight management in men may be a promising tool to support behaviour and weight change.

### Financial incentive interventions

Systematic review evidence of financial incentives for behaviour change highlights the potential for incentives to change behaviours and help reduce health inequalities.<sup>14</sup> A discrete choice experiment found that paying people (£10-£30/week varying by age and weight) to take part in diet and physical activity (PA) interventions is likely to improve uptake, adherence and maintenance of behaviour change.<sup>15</sup> Moreover, the evidence for financial incentives for weight loss is growing.<sup>16-19</sup> In particular, deposit contracts, where participants deposit their own money and are reimbursed only if they achieve the target weight loss, are effective whilst the incentives are in place.<sup>4,20</sup> Deposit contracts draw on loss aversion where

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3 people are more motivated to avoid losses than they are to achieve similarly sized gains.<sup>21 22</sup>  
4  
5 However, deposit contracts may not be not equitable, as committing one's own money up  
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7 front may not be possible, particularly for individuals with lower income.

8  
9 Endowment incentive contracts may overcome limitations of deposit contracts. Endowment  
10  
11 incentive contracts are financial incentives where a person is endowed with a (hypothetical)  
12  
13 amount of money which they either 'secure' or 'lose' depending on achieving certain targets.  
14  
15 A trial that framed financial incentives in this way found these incentives were effective for  
16  
17 achieving PA goals in the short term.<sup>23</sup>

## 18 **Aim**

19  
20 The aim of the Game of Stones feasibility trial was to examine the acceptability and  
21  
22 feasibility of a men-only weight management intervention consisting of narrative text  
23  
24 messages, with and without an endowment incentive, compared to waiting list control. The  
25  
26 objectives were to:

- 27  
28 1. Assess the acceptability and willingness to be randomised to: i) narrative text message  
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30 and endowment incentives; ii) narrative text messages only; or iii) waiting list for text  
31  
32 messages (control).
- 33  
34 2. Assess the feasibility of recruiting from general practitioner (GP) practice obesity  
35  
36 registers and community venues.
- 37  
38 3. Determine the acceptability of intervention content, feasibility of delivery, fidelity and  
39  
40 any unintended consequences.
- 41  
42 4. Assess indicative effects on weight change and progression criteria for a full trial.

## 43 **METHODS**

### 44 **Trial design**

45  
46 A three-arm individually randomised parallel-group controlled feasibility trial was  
47  
48 conducted. Participants were randomised to receive narrative text messages and endowment  
49  
50 incentives (SMS+I), narrative text messages only (SMS only), or a waiting list for text  
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52 messages (Control). The protocol and the a priori progression criteria for the full trial are  
53  
54 available: <https://www.journalslibrary.nihr.ac.uk/programmes/phr/1418509/#/>

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56 Ethical approval for the study was obtained from the North of Scotland Research Ethics  
57  
58 Service (Ref: 16/NS/0120).

## Setting

Two Health Board areas in Scotland (Sites A and B) with high levels of disadvantage.

## Eligibility criteria

Participants met the following eligibility criteria: men over 18 years old; BMI  $\geq 30$  kg/m<sup>2</sup> and/or a waist circumference of  $\geq 40$  inches (102 cm); owned a mobile phone capable of receiving text messages; could understand English language text messages; not already taking part in a weight loss study; not planning or waiting to have bariatric surgery; not planning to move within the next 12 months; considered by practice clinical staff as suitable for participation (GP practice recruitment only), for example, no severe medical, terminal or psychiatric illness (in patient or close family member) or no significantly impaired cognitive function.

## Sample size

This study aimed to randomise 105 men, 35 to each arm, in line with recent recommendations for pilot trials as sufficient to estimate key parameters for a full trial.<sup>24</sup> A sample size of 35 per arm is sufficient to allow the population variance to be estimated (e.g. the SD in weight loss) with enough precision to deliver at least 80% power and 90% confidence in a full trial, with a standardised effect size between 0.2 and 0.5.<sup>24</sup>

## Participant recruitment

Participants were recruited via: 1) community outreach, and 2) GP practice obesity registers.

### *Community outreach*

Community recruitment strategies that report success for recruiting men in disadvantaged areas were used.<sup>11-13</sup> This included researchers working on stands with study information leaflets and table banners in supermarkets, fitness centres, hospital foyers, health centres, council workplaces and community centres across both sites. Eleven of the 13 recruitment venues were within more disadvantaged areas based on the Scottish Index of Multiple Deprivation (SIMD quintiles 1 and 2).<sup>25</sup> Men who showed interest were given study information and asked to leave their contact details with researchers.

In addition, some men were recruited through word of mouth. This included researcher discussions with family, friends, colleagues and local workers who passed on study information to eligible men they knew. Information leaflets were distributed across localities

1  
2  
3 in shops, libraries, barbers and community centres. Interested men then contacted researchers  
4 to get more information.  
5

#### 6 7 *GP practice obesity register letters* 8

9 Practices within more disadvantaged areas (SIMD quintiles 1 or 2) were invited to participate  
10 in the study. Of the 33 practices invited (n= 13 in Site A, n=20 in Site B), five practices  
11 participated (n=4 in Site A, n=1 in Site B).  
12

13 Practice database searches identified potentially eligible men with a documented BMI of at  
14 least 30kg/m<sup>2</sup>. Lists were screened by clinical practice staff and details passed to the Health  
15 Informatics Centre at the University of Dundee who sent out GP-headed study invitation  
16 letters and information leaflets. Interested men contacted the research team or returned an  
17 'opt-in' card.  
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#### 20 21 22 23 24 *Baseline Appointment* 25

26 Men interested in participating were invited to attend a face-to-face appointment. Detailed  
27 study information was discussed and written informed consent provided. Anthropometric  
28 measurements were conducted and eligibility assessed. Participants then completed a baseline  
29 questionnaire, and were randomised. Group-specific post-randomisation information was  
30 provided and discussed with the participant.  
31  
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#### 33 34 35 36 *Randomisation* 37

38 At the baseline appointment, independent randomisation was performed by the researcher  
39 using the clinical trials unit's secure remote web-based system, stratifying by recruitment  
40 method (GP and community) and recruitment site (Site A and Site B).  
41  
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#### 43 44 45 46 *Blinding* 47

48 The two recruitment researchers who also assessed outcomes and conducted qualitative  
49 interviews were mostly not blinded to group allocations. All other study team members were  
50 blinded. A demonstration of the feasibility for researcher outcome assessors to be blind to  
51 group allocation was conducted with eleven participants at the six month assessment. In this  
52 case, a researcher who had not previously met the participant arranged and undertook the  
53 assessment. These participants all complied with the request not to reveal their group  
54 allocation.  
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3 The trial statistician was fully blinded to intervention groups, and partially blinded for the  
4 control group due to the different response schedule (control participants were only assessed  
5 at baseline months and 12 months to reflect “usual life”).  
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## 8 **Intervention components**

### 9 *Narrative text messages*

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11 A narrative text message library consisting of 604 texts was written by a professional  
12 scriptwriter/researcher (MG). Full details of the narrative texts development process are  
13 available elsewhere.<sup>10</sup> Narrative texts were sent to participants over the course of 12 months  
14 and were written from the point of view of a fictional character aiming to lose weight over 12  
15 months. Narrative texts were written to appeal to men from disadvantaged backgrounds. All  
16 participants in the SMS+I and SMS only groups received automated texts according to a pre-  
17 determined schedule. Participants could reply to texts but did not receive a response. Texts  
18 were sent between 8:00AM and 10:00PM and ranged from 0-5 texts per day. Some texts  
19 were personalised including participants’ names and men could select whether weight  
20 information should be presented in kilogrammes or stones and pounds. No further  
21 personalisation and tailoring options were offered. Texts were delivered by the Health  
22 Information Centre in Dundee using existing automated technology linked to a clinical trials  
23 unit database.  
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### 36 *Endowment incentive*

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38 The incentive strategy was informed by existing evidence and men’s preferences elicited  
39 using a Discrete Choice Experiment completed by 1,045 men with obesity and reported  
40 elsewhere.<sup>10</sup> SMS+I participants were ‘endowed’ with a £400 incentive at baseline which was  
41 placed into a hypothetical personal account at the University of Stirling and given a mock-up  
42 personalised cheque. The full £400 could be secured by meeting weight loss targets at  
43 researcher assessments: 5% of body weight lost since baseline at three months (£50  
44 secured/lost), 10% lost since baseline at six months (£150 secured/lost) and 10% lost since  
45 baseline at 12 months (£200 secured/lost) (online supplement 1). Weight loss was verified at  
46 all face-to-face appointments. At six and 12 months, men lost a proportion of the money for  
47 each % weight loss not attained between 5-10%. Weight at 12 months had to be less than at  
48 baseline to receive any money, regardless of whether interim weight loss targets had been  
49 met. Men received the money by direct bank transfer after the 12-month assessment.  
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3 Feedback on meeting incentive targets was sent by automated text message and displayed on  
4 the personalised SMS+I webpage.  
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### 6 *Website*

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9 All trial participants were provided with a unique login ID for the Game of Stones website.  
10 The front page was accessible to all participants and included trial information and links to  
11 existing evidence-based online weight management resources. SMS +I and SMS only  
12 webpages had a brief biography and images of the fictional characters featured in narrative  
13 texts. Participants could enter their weight, pedometer steps, waist circumference and belt  
14 notches, which were displayed as basic visual progress charts. Only individual performance  
15 was displayed on the webpage, and no group averages were shown for social comparison.  
16 SMS+I webpages described the financial incentives and a visual progress chart of money  
17 secured/lost.  
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### 25 *Printed information*

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27 All participants received a weight loss fact sheet (British Dietetic Association, Weight Loss  
28 Food Fact Sheet) and a small card which could be carried in their wallet for noting website  
29 details and their appointment weight, weight loss targets and appointments.  
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### 33 *Pedometer*

34  
35 All participants received a study pedometer (3DFitBud, A420S, manufactured by 3DActive).  
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### 38 **Comparator group**

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40 At baseline, participants received access to the information section of the webpage, printed  
41 information (i.e. a weight loss fact sheet) and a pedometer. They attended a baseline and 12-  
42 month appointment only. Control group participants were offered texts for three months  
43 commencing after the 12 month data collection point.  
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### 47 **Outcome assessment**

48  
49 Outcomes were assessed at baseline, three, six and 12 months for intervention participants  
50 (SMS+I and SMS only), and at baseline and 12 months for control participants. Individual  
51 appointments were at community centres, universities, NHS clinical research facilities,  
52 voluntary sector organisations, GP practice premises, or the participant's home if no suitable  
53 alternative venue could be found. At the 12 month appointment, all participants received a  
54 £20 voucher as reimbursement for their time. No travel expenses were provided.  
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3 The text message delivery system automatically the frequency of responses received to the  
4 texts. The website automatically recorded engagement with self-monitoring tools.

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7 Self-report questionnaires were completed during appointments and measured socio-  
8 demographics, co-morbidities, disability, ethnicity, and perceptions on intervention  
9 acceptability. Overall satisfaction with the intervention was assessed with the item: “*On a*  
10 *scale from 0 (not satisfied at all) to 100 (completely satisfied). How satisfied are you with the*  
11 *Game of Stones programme?*”. Acceptability of the intervention was assessed with the stem  
12 “*Overall the Game of Stones programme has been...*” followed by options ‘*understandable*’,  
13 ‘*useful*’, ‘*helpful*’, ‘*interesting*’ and ‘*relevant*’, with responses captured on a 5-point scale  
14 ranging from ‘*totally disagree*’ to ‘*totally agree*’. Helpfulness of the intervention was  
15 assessed with the item “*How helpful have you found the following in helping you lose*  
16 *weight?*” followed by options ‘*text messages*’, ‘*website*’, and ‘*pedometer*’, with responses  
17 captured on a 5-point scale ranging from ‘*totally unhelpful*’ to ‘*totally helpful*’. Measures of  
18 overall satisfaction, acceptability and helpfulness were adapted from Dombrowski et al.,  
19 (2012).<sup>26</sup>

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22 Anthropometry measures included height measured at baseline using a portable standing  
23 stadiometer (Seca 217, Birmingham, UK) to the nearest 0.1cm. Prior to weight  
24 measurements, participants removed shoes and bulky clothing and items from their pockets.  
25 Weight was recorded using portable calibrated electronic scales (Marsden M420, Rotherham,  
26 UK) to the nearest 0.01kg and waist circumference using a tape measure (Seca 203,  
27 Birmingham, UK) to the nearest 0.1cm.

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30 Information on possible adverse events was recorded at assessment visits via open questions  
31 and through automatic monitoring of text message replies including words like ‘suicide’,  
32 ‘die’, and ‘death’ indicative of potential adverse events, which were notified to the research  
33 team by email.

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36 Interviews took place during three and 12 month appointments and were conducted face-to-  
37 face and detailed methods are described elsewhere.<sup>10</sup> All audio recorded interviews were  
38 transcribed verbatim and anonymised. At three months, all SMS+I and SMS only men were  
39 invited to participate in either a brief feedback or an in-depth interview (participant choice).  
40 The three month topic guide focussed on the early acceptability of the intervention  
41 components in order to identify any refinements required over the remaining nine month  
42 intervention. For the 12 month qualitative interviews, separate topic guides for the three trial  
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3 groups were informed by the analysis of the three-month interviews, researcher field notes  
4 and to gain information power<sup>27</sup> to address the study objectives. Purposive sampling from the  
5 three trial groups was informed by the three month interview data and researcher field notes  
6 to provide diversity of perspectives. Researcher field notes taken at all assessments were  
7 referred to when interpreting interview data.  
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12 Qualitative interviews were conducted face-to-face with 50 of 58 men who attended the three  
13 month assessment (7-61 minutes, median=23 minutes). At 12 months, interviews were  
14 conducted with 14 participants from SMS+I (13-65 minutes, median=33 minutes), 13 from  
15 SMS only (10-59 minutes, median=28 minutes) and six from the control group (7-18  
16 minutes, median=11 minutes). Fourteen interviews at 12 months lasted <20 minutes, mostly  
17 for control participants who had received no contact from the research team between baseline  
18 and 12 months.  
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## 24 **Analysis**

### 25 *Quantitative analysis*

26  
27 All continuous variables were summarised and tabulated using the following descriptive  
28 statistics: N (number of valid non-missing responses), mean, standard deviation (SD). Likert-  
29 scale variables were treated as continuous measures. The frequency and percentages (based  
30 on the non-missing sample size) of observed levels are reported for all categorical measures.  
31 The proportion of individuals contacted who were recruited and the proportions retained and  
32 withdrawn at each assessment by group was determined. Missing weight data are presented  
33 as baseline observation carried forward (BOCF) and last observation carried forward (LOCF)  
34 in addition to observed cases only.  
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43 CONSORT guidance for reporting randomised pilot and feasibility studies was followed<sup>28</sup>.

### 44 *Qualitative and mixed method data analysis*

45  
46 Anonymised transcripts of interviews together with: attributes for recruitment channel;  
47 attendance at assessments, trial group and participant characteristics and weight loss  
48 outcomes were entered into NVivo12 software for analysis guided by the framework  
49 approach.<sup>29</sup> Reference to researcher field notes contributed to interview data interpretation.  
50 Iterative data collection and analysis were driven by the key feasibility and acceptability  
51 research questions and objectives. A coding frame was developed by three researchers  
52 independently reading a diverse sample of six interviews, followed by a team discussion to  
53 finalise the coding frame and identify key themes. Independent coding was conducted by four  
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3 researchers (EC, NG, MM and RS) and checked for consistency by FH. Two independent  
4 researchers (EC and NG) who were not involved in any other aspect of the study, assisted  
5 with coding and analysis to enhance rigour and reliability of data analysis. Emergent themes  
6 and interpretive analysis were discussed at weekly researcher meetings and at two Co-  
7 Investigator qualitative interpretation meetings.  
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12 At the final stage of mixed methods data interpretation, the quantitative attributes on NVivo  
13 were drawn on to triangulate the analysis and suggest further avenues for interrogation.  
14 Matrix coding queries in NVivo were generated to cross-reference attributes for trial group,  
15 participant SIMD and weight loss outcome at 12 months, with nodes coded for views of  
16 incentives and texts messages respectively. Credibility and reliability of qualitative analysis  
17 was enhanced by independent coding, use of memos to ensure transparency of interpretation,  
18 and interpretive charting conducted with input from the wider study team.  
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### 25 **Patient and Public Involvement**

26  
27 A continuous and responsive approach to patient and public involvement (PPI) was adopted  
28 to prepare the grant application and throughout the study, as described by Gamble and  
29 colleagues.<sup>30</sup>  
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31

32  
33 Continuous PPI was provided by a Co-Investigator partnership with the Charities Men's  
34 Health Forum GB and Men's Health Forum in Ireland. The partnership commenced in 2011  
35 with the ROMEO evidence syntheses of weight loss interventions for men with obesity.<sup>4</sup>  
36  
37

38  
39 During the study, Co-Investigators from each of the Men's Health Forum charities attended  
40 trial management meetings to contribute to decisions, intervention development, data  
41 analysis, interpretation of findings and reporting. They provided feedback on the grant  
42 application, protocol, text messages, information materials and engaged wider involvement of  
43 men from their organisation to assist with appropriate language.<sup>31</sup>  
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46

47  
48 Continuous PPI at the study oversight level was provided by two independent lay members of  
49 the study steering committee which met on three occasions.  
50

51  
52 Responsive PPI occurred at the study funding application stage. Co-Investigator CG engaged  
53 men who provided PPI input in the FFIT Trial.<sup>32</sup> During the study, relevant members of the  
54 public were identified through several sources including: Men's Health Forum GB, Men's  
55 Health Forum in Ireland, Scottish Community Health Councils, Men's Sheds, University of  
56 Stirling PPI group, Alliance Scotland and other Co-Investigator contacts. Effort was made to  
57 engage men from more disadvantaged communities. A total of 121 PPI contributors were  
58  
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60

involved in a range of study activities, including finding a study name, helping with wording of information material, and helping with designing the intervention content. For full details see the report to the funder.<sup>10</sup>

## RESULTS

### Recruitment and retention

Recruitment was completed in four months between March to June 2017 meeting the target number of 105 men randomised (Figure 1).

Overall, 177 men expressed an interest in the study. Baseline appointments were attended by 111 (63%), of which six (5%) were ineligible. All 105 men consented to be randomised to the SMS+I (n=36), SMS only (n=33) and control (n=36) groups.

GP practice recruitment was undertaken in five GP practices (Site A n=4, Site B n=1) with 45 men recruited and randomised through GP practices. The additional 60 men were recruited through community outreach.

--- Figure 1 ---

The 12 month assessment was completed by 79/105 participants (75%). One of the 79 participants (control group) could not attend and provided self-reported information because he was out of the region due to work commitments, which means that 74% (78/105) of participants were retained for weight assessments at 12 months. Overall 12 month retention differed by group (SMS+I=23/36, 64%; SMS only=26/33, 79%; control=30/36, 83%). Fourteen participants (13%) were lost to follow-up, and 12 participants (11%) withdrew. Reasons for withdrawal were dislike of narrative texts (n=4), health (n=3), family (n=1), unknown (n=1), dissatisfaction with group allocation (n=1), appointment logistics (n=1) and multiple reasons (n=1).

### Baseline characteristics

Baseline characteristics are displayed in Table 1. On average, participants were 52.2 (SD=13.1) years old, had a BMI of 35.7 (SD=5.9) and a waist circumference of 116.8 cm (SD=11.8). BMI ranged from 27.5 kg/m<sup>2</sup> to 62.5kg/m<sup>2</sup>. Twelve participants (11%) had a baseline BMI less than 30 kg/m<sup>2</sup> due to the additional weight circumference entry criterion of  $\geq 40$  inches (102 cm).

The majority of men lived in disadvantaged areas defined as SIMD quintiles 1 or 2 (n=62/104; 60%). Most participants were married (58%), reported at least one co-morbidity

(63%), were of white ethnicity (91%), reported having children (76%), and were in full-time employment (48%).

--- Table 1 ---

### **Intervention fidelity**

The intervention components were feasible to deliver with fidelity. The majority (95.4%) of the 38,214 text messages sent to the two intervention groups were delivered to the mobile phone, with 1,782 (4.6%) having no delivery status (i.e. lack of response from the mobile phone provider after 48 hrs and invalid phone numbers). No major technical errors occurred. All participants who secured financial incentives were paid by direct bank transfer, in line with their stated preference.

### **Acceptability of intervention components**

#### *Overall acceptability ratings and contamination*

Table 2 displays intervention satisfaction indicators over the course of the study for participants attending assessments. Overall mean study satisfaction at 12 months was 81%, 77% and 87% for the SMS+I, SMS only and control groups respectively. Satisfaction over time was comparable between both intervention groups. For scores on specific programme attributes see Table 2.

Helpfulness ratings of the narrative texts, webpage and pedometer were highest for the pedometer and relatively stable throughout the measurement time points. At 12 months, helpfulness ratings (out of 5) for the pedometer were 3.9, 4.0, and 3.7 for the SMS+I, SMS only and control groups respectively. The narrative texts (SMS+I=3.4; SMS only=3.3) and the webpage (SMS+I=3.6; SMS only=3.4; control=3.5) were perceived as somewhat helpful on average at 12 months.

Minimal contamination between intervention groups was observed, with one participant at six and 12 months (SMS+I group) and another at 12 months (control group) reporting meeting other men in the study.

--- Table 2 ---

#### *Acceptability of narrative text messages*

Some men sent spontaneous replies to the narrative texts (0-3 months n=25/69, 36%; 3-6 months n=8/69, 12%, 6-12 months n=13/69, 19%; see online supplement 2). Most

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3 spontaneous replies were received between 0-3 months (n=370 replies) and decreased at 3-6  
4 months (n=16 replies) and 6-12 months (n=39 replies).

7 Eleven participants (11/69, 16%) requested to no longer receive texts but asked to remain in  
8 the trial. Requests to stop narrative texts were similar in both groups (SMS+I=5/36, 14%;  
9 SMS only=6/33, 18%), and occurred throughout the study. Four participants (4/69, 6%)  
10 withdrew due to dislike of narrative texts between baseline and three months, two in each  
11 intervention group.

16 Qualitative interviews at three and 12 months demonstrated varied views on the narrative  
17 texts. Participants' views ranged from positive to indifferent to negative. Those who liked the  
18 narrative texts found the storyline entertaining, engaging and some participants felt a certain  
19 camaraderie for the main character:  
20  
21

23 *You get involved in the content and you start following the script, they're very funny*  
24 *and me being a [from city name] you can see the funny side and you can see the wit in*  
25 *that, .... and that's what keeps you reading them. (210010, SMS only, 12m)*

29 For other participants, the frequency of texts became a source of irritation, the storyline did  
30 not resonate with their own experience nor could they empathise with the fictional characters:  
31

33 *I'm not a lover of chocolate, biscuits, cake, ice cream, I hardly ever touch them, hardly*  
34 *ever, so hearing about somebody eating pizza or sweets means nothing to me because I*  
35 *don't eat them anyway (120002, SMS+I, 12m)*

39 Some were uncertain of the role of the texts in helping to support weight loss. Others  
40 expressed an indifference towards the texts, and a decreasing interest in the story over time  
41 leading to infrequent engagement with text content. However, the regular reminder of being a  
42 participant in a weight loss programme through receiving texts was seen as important:  
43  
44

46 *I often wonder, do they relate to myself here. And the only commonality is both trying*  
47 *to lose weight. So in that respect it's just a reminder all the time, you should be*  
48 *reviewing your weight and watching what you're eating, so...from that it's a positive,*  
49 *yeah. (220017, SMS+I, 3m)*

53 A matrix coding query and analysis of the quotations generated from the NVivo qualitative  
54 and demographic data suggested no obvious relationships between the participant SIMD level  
55 and the qualitative accounts of acceptability of the narrative texts. This is in line with  
56 quantitative data showing similar acceptability ratings for overall programme satisfaction and  
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3 helpfulness ratings of the narrative texts across SIMD levels (see online supplement 3). Some  
4 men would have liked more interactivity built into the texts, however, the text message  
5 system was set up for uni-directional messaging only.  
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7

#### 8 9 *Acceptability of endowment incentive*

10  
11 At three months, 31/36 SMS+I participants attended the appointment, with eight men losing  
12 5% or more of their baseline weight and securing £50. Attendance at six months was lower  
13 (n=23/36), with five participants achieving the weight loss target of >10% weight loss  
14 securing £150 each, and a further three participants losing between ≥5-10% of weight  
15 securing between £75-150. At 12 months, 23/36 participants attended the appointment, with  
16 three achieving >10% weight loss securing £200, and a further seven losing between ≥5-10%  
17 of weight securing between £100-200.  
18  
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21 Overall, £2,955 was paid in total to the 11 participants (11/36, 31%) successfully meeting or  
22 partially meeting weight loss targets. The full £400 was secured by three participants (3/36,  
23 8%). The cost of the incentive per participant was £81.94 (95% CI £34.59-£129.30). No  
24 participant secured money at three or six months which was then lost due to weight regain to  
25 baseline weight at 12 months.  
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29 No negative views were expressed about the incentives in qualitative interviews. Only one  
30 man reported being motivated by the financial incentive, and many expressed indifference.  
31 Participants reported the weight loss and health benefits as sufficiently rewarding.  
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*The money's not that much of an issue. I think the incentive for me is the health that, at the end of the day, your health improves. That's the most important incentive. The money, it's fine, it's there, but it's not the incentive (120022, SMS+I, 3m)*

Some interpreted the incentives as a final reward linked to their weight loss targets, whereas others fully understood the intended use of the loss aversion concept:

*[W]e all know how much more distress it causes you to lose money than the pleasure of finding a fiver down the back of the couch, you know, so I think if you lose something it almost has a bigger impact on you than if you gain. (220040, SMS+I, 3m)*

### *Acceptability of study webpages and pedometer*

Some participants used the self-monitoring features on the webpage (see online supplement 3) and reported valuing the ability to visually track their weight in interviews. However, most did not access the website. The majority (77%) did not own a pedometer at baseline, and pedometers were highly acceptable to participants.

### **Acceptability of Control Group**

Most control group participants (30/26, 83%) attended the 12 month appointment and many reported being pleased to be involved in a research study. One participant had a strong negative reaction to being randomised to the control group and subsequently withdrew when invited to the 12 month assessment.

### **Weight outcomes**

Table 3 displays weight change outcomes at three, six, and 12 months. The difference in mean percentage weight loss at 12 months for observed cases was -2.51% (95% CI -6.03 to 1.01) for SMS+I v control and -0.51% (95% CI -3.91 to 2.89) for SMS only v control. The difference in absolute weight loss at 12 months was -2.87kg (95% CI -6.82 to 1.08) for SMS+I v control and -0.57kg (95% CI -4.40 to 3.25) for SMS only v control.

---Table 3 ---

The SMS+I group displayed mean weight loss of over 3% at 12 months (-3.51%, SD=5.83). The SMS only and control groups remained below 3% weight loss on average (SMS only=-1.51%, 4.65; control=-1.00%, SD=5.31). The highest mean percentage weight loss at 12 months for BOCF was -2.24% (SD=4.93) in the SMS+I group, followed by -1.19% (SD=4.16) and -0.80% (SD=4.77) in the SMS only and control groups respectively.

### **Harms and unintended consequences**

No harms or unintended consequences were reported.

## **DISCUSSION**

### **Principal findings**

This study successfully recruited 105 men from across the socioeconomic spectrum to a three-armed RCT and overall achieved 74% retention at 12 months' follow-up. Men living in more disadvantaged areas formed 60% of the sample. Narrative texts were broadly acceptable, but some participants disengaged or withdrew from the study due to dislike of

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3 texts. The endowment incentives were acceptable, and improving health was reported as a  
4 key motivator for weight loss. Positive indicative effects of weight loss were found in  
5 intervention and control groups.  
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### 8 9 **Strengths and weaknesses of the study**

10  
11 This study was underpinned by the ROMEO systematic reviews and qualitative evidence  
12 synthesis of weight loss interventions for men with obesity<sup>33 34</sup>, with a continuing PPI  
13 partnership with the Men's Health Forum GB and Ireland charities. Mixed methods research  
14 combined quantitative and qualitative data which, together with patient, public and  
15 stakeholder involvement, provided a multi-lens perspective on this study.  
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18  
19 Most assessments were not blind to group allocation. Researchers were unable to collect data  
20 via qualitative interviews, questionnaires and anthropometric measures with men who  
21 withdrew from the study or were lost to follow-up at the 12 month appointment. Those  
22 providing a withdrawal reason may have provided socially desirable responses. Text  
23 messages were personalised by including the participant's name and weight unit preference,  
24 but no tailoring or interactivity were possible due to technical limitations of the delivery  
25 system. This study was not powered to detect effects on weight loss; study and weight  
26 outcomes should be interpreted with caution.  
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### 34 **Relation to other studies**

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36 The Game of Stones study adds to the evidence base demonstrating the feasibility of  
37 recruiting men for research on sensitive subjects, such as obesity, through community  
38 outreach and GP practice lists.<sup>11-13</sup>  
39  
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41  
42 The average BMI and age of the study participants of around 35kg/m<sup>2</sup> and 50-55 years is  
43 similar to UK weight management trials recruiting in the community<sup>32</sup>, primary care<sup>35</sup>, or a  
44 combination of community and primary care.<sup>12</sup> Three international text message based  
45 weight management studies examining outcomes after 12 months recruited younger  
46 participants with lower BMI.<sup>36-38</sup> However, three mixed sex weight management studies with  
47 financial incentives (two including text message components) reported broadly similar  
48 participant demographics to this study.<sup>39-41</sup>  
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55 Retention levels of 74% were acceptable and are similar to systematic review evidence of  
56 men-only weight loss interventions which found an average retention of 78%, ranging from  
57 44% to 100%.<sup>34</sup> International text message studies with mixed sex participants report similar  
58 retention rates at 12 months of 70.3%<sup>37</sup> and 73%<sup>36</sup>, with one study conducted in Latvia  
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3 reporting 93% retention<sup>38</sup>. Two large UK studies recruiting mixed sex participants with  
4 obesity to weight management in primary care reported 75%<sup>35</sup> and 81%<sup>42</sup> retention at 12  
5 months.  
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8  
9 Two previous narrative text message intervention studies in men targeting alcohol reduction  
10 reported high acceptability levels and no negative reactions.<sup>12 13</sup> However, these studies were  
11 only 12 weeks in duration and overall contained fewer texts. The narrative texts in this study  
12 were broadly acceptable, although some negative reactions were reported. Study withdrawal  
13 due to texts and requests to stop texts suggest that the current narrative texts may not be  
14 universally acceptable to men. The text messages were designed by a professional  
15 scriptwriter/researcher with PPI input from the target population of men from disadvantaged  
16 backgrounds, but the narrative texts were similarly acceptable across the socio-economic  
17 spectrum. Intervention fidelity was high with the majority of sent texts successfully delivered  
18 and no adverse events were encountered, similar to previous text message-based intervention  
19 studies.<sup>11-13</sup>  
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28 The use of a financial incentive strategy for weight loss in men with obesity across the  
29 socioeconomic spectrum was feasible and acceptable. Two previous incentive studies used  
30 text messages to inform participants about their incentive achievement of weight loss targets,  
31 and found it acceptable.<sup>39 40</sup> This extends the evidence base on the use of financial incentives  
32 as a complementary behaviour change strategy alongside other components.<sup>19 43</sup>  
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37 The financial incentive strategy was designed with future sustainability in mind and to be  
38 attractive to public sector funders. The text messages and incentive components are mostly  
39 automated, encourage self-management of weight and have a low administrative burden with  
40 one bank transfer pay out after 12 months, and verification of weight loss at three, six and 12  
41 months. Yancy et al. similarly provided incentives at three and six months for their six  
42 months' incentive intervention<sup>39</sup>. John et al. asked participants to be weighed monthly, for  
43 which they received \$20 per visit.<sup>40</sup> Few RCTs examine financial incentive strategies that are  
44 delivered for at least 12 months.<sup>43</sup> Two other studies providing financial incentives for 12  
45 months provided an intensive financial incentive schedule either weekly<sup>44</sup> or monthly<sup>45</sup>.  
46 Previous studies typically provided participants with weekly weight loss goals such as 1lb  
47 (0.45kg) per week, on which financial incentives were contingent.<sup>43</sup> Whilst these goals are  
48 similar to the weight loss targets in the current study, there were no intermittent or weekly  
49 targets. A balance needs to be struck between having more regular weight measurements and  
50 more immediate pay-outs, costs and future sustainability.  
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3 Patel et al. applied a similar framing which they called a loss incentive<sup>23</sup>. University  
4 employees were allocated a monthly hypothetical incentive of \$42 upfront and \$1.40 was  
5 taken away each time their daily goal of 7000 steps was not met. The current study adds to  
6 the evidence base demonstrating the acceptability and feasibility of loss framed interventions  
7 for weight loss and in settings outside workplaces.  
8  
9

## 10 11 12 **Conclusion**

13  
14 This weight management intervention recruited men from across the socioeconomic spectrum  
15 with the majority coming from disadvantaged areas, had an acceptable retention rate, and was  
16 broadly acceptable to most participants, with some weight loss benefits. A full trial of the  
17 study is warranted.  
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Fiona Hogarth, Director Tayside Clinical Trials Unit, oversaw randomisation, data management and the running of the study from a Clinical Trials Unit perspective.

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The Study Steering Committee:

Associate Professor Ed Juszcak, Director, NPEU Clinical Trials Unit, Nuffield Department of Population Health, University of Oxford (Chair).

Professor Kate Jolly, Professor of Public Health & Primary Care, University of Birmingham.

Mr Mark Kelvin, Programme Director (until 2018), Health and Social Care Alliance Scotland (the ALLIANCE).

Mr Andrew Shanahan, Director MAN v FAT - the weight loss website for men

1  
2  
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4  
5 Miss Joyce Thompson Dietetic Consultant in Public Health Nutrition and Tayside Nutrition  
6  
7 MCN Lead Clinician, NHS Tayside.  
8

### 9 **AUTHOR CONTRIBUTIONS**

10  
11 SD co-led the study with PH as joint Chief-Investigator and co-led the design and overall  
12  
13 conduct of the study and led the writing of the manuscript, overseen by PH.  
14

15  
16 MM undertook the study set up, recruitment and data collection, co-ordinated various PPI  
17  
18 activities, contributed substantially to qualitative and quantitative data analysis and  
19  
20 interpretation. MvdP was a co-investigator, contributed to the design and the interpretation of  
21  
22 findings and led the DCE and health economic analysis. MG was a co-investigator,  
23  
24 contributed to the design and the interpretation of findings and led the development of the  
25  
26 narrative SMS component, the related PPI. AA was a co-investigator, contributed to the  
27  
28 design and the interpretation of findings. PC and MT linked to PPI networks, contributed to  
29  
30 the design, and interpretation of the findings. AE was a co-investigator, contributed to the  
31  
32 design and the interpretation of findings and oversaw the statistical analysis. NG and EC  
33  
34 contributed to the analysis and interpretation of the qualitative data. CG was a co-  
35  
36 investigator, facilitated PPI, contributed to the design, and interpretation of findings. FH was  
37  
38 a co-investigator, oversaw the qualitative data collection and analysis and contributed to the  
39  
40 interpretation of findings. AH undertook the statistical analysis at Tayside Clinical Trials  
41  
42 Unit. CJ was a co-investigator, contributed to the design and the interpretation of findings  
43  
44 and oversaw the automated SMS delivery system, recruitment tracking, the study website and  
45  
46 integration of data with databases at Tayside Clinical Trials Unit. FK and MMcK were co-  
47  
48 investigators and contributed to the design and the interpretation of findings. RS contributed  
49  
50 to recruitment, data collection and undertaking qualitative interviews and contributed to the  
51  
52 interpretation of findings.

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54  
55 This report presents independent research commissioned by the NIHR. The views and  
56  
57 opinions expressed by authors in this publication are those of the authors and do not  
58  
59 necessarily reflect those of the NHS, the NIHR, MRC, CCF, NETSCC, the Public Health  
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61 Research programme or the Department of Health. The views and opinions expressed by the  
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63 interviewees in this publication are those of the interviewees and do not necessarily reflect

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4 Research programme or the Department of Health.  
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11

## 12 **COMPETING INTERESTS**

13  
14  
15 Dr Grindle is Director of Eos Digital Health Ltd which holds all rights to DNA - The Digital  
16 Narrative Approach deployed to design and write the narrative text intervention.  
17

18  
19 No other competing interests were declared.  
20

## 21 **DATA AVAILABILITY**

22  
23 Access to data can be arranged through the Co-PIs of the study: Prof. Pat Hoddinott,  
24 (University of Stirling, p.m.hoddinott@stir.ac.uk) and Dr. Stephan Dombrowski (University  
25 of New Brunswick, stephan.dombrowski@unb.ca) to discuss data sharing, data requirements  
26 and conflicts of interest, in line with any EU and other regulations, including ethics  
27 approvals.  
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**Table 1 Participant baseline characteristics**

	<b>SMS + I</b>	<b>SMS only</b>	<b>Control</b>	<b>Total</b>
	<b>N=36</b>	<b>N=33</b>	<b>N=36</b>	<b>N=105</b>
Age (years), mean (SD)	50.9 (14.2) <sup>a</sup>	52.5 (15.1) <sup>b</sup>	53.1 (10.1)	52.2 (13.1) <sup>c</sup>
Waist circumference (cm), mean SD	115.8 (10.0)	114.9 (12.7)	119.5 (12.2)	116.8 (11.8)
Weight (kg), mean (SD)	108.6 (16.4)	107.8 (20.2)	110.7 (19.0)	109.1 (18.4)
Height (cm), mean (SD)	175.9 (6.6)	175.2 (6.7)	173.8 (5.9)	175.0 (6.4)
BMI (kg/m <sup>2</sup> ), mean (SD)	35.1 (5.3)	35.1 (5.9)	36.7 (6.5)	35.7 (5.9)
<b>BMI (kg/m<sup>2</sup>) categories, n (%)</b>				
<30	5 (13.9)	3 (9.1)	3 (8.3)	11 (10.5)
≥30->35	16 (44.4)	19 (57.6)	14 (38.9)	49 (46.7)
≥35->40	10 (27.8)	6 (18.2)	7 (19.4)	23 (21.8)
≥40->45	4 (11.1)	2 (6.1)	10 (27.8)	16 (15.2)
≥45->50	0 (0.0)	2 (6.1)	1 (2.8)	3 (2.9)
≥50	1 (2.8)	1 (3.0)	1 (2.8)	3 (2.9)
<b>SIMD deprivation category, n (%)</b>				
SIMD 1 (most disadvantaged)	11 (31.4) <sup>a</sup>	12 (36.4)	15 (41.7)	38 (36.5) <sup>d</sup>
SIMD 2	8 (22.9) <sup>a</sup>	9 (27.3)	7 (19.4)	24 (23.1) <sup>d</sup>
SIMD 3	6 (17.1) <sup>a</sup>	3 (9.1)	3 (8.3)	12 (11.5) <sup>d</sup>
SIMD 4	4 (11.4) <sup>a</sup>	4 (12.1)	6 (16.7)	14 (13.5) <sup>d</sup>
SIMD 5 (least disadvantaged)	6 (17.5) <sup>a</sup>	5 (15.2)	5 (13.9)	16 (15.4) <sup>d</sup>

**Marital status, n (%)**

Cohabiting	4 (11.1)	2 (6.3) <sup>e</sup>	5 (13.8)	11 (10.6) <sup>d</sup>
Divorced	2 (5.6)	0 (0.0) <sup>e</sup>	2 (5.6)	4 (3.9) <sup>d</sup>
Married	22 (61.1)	21 (65.6) <sup>e</sup>	17 (47.2)	60 (57.7) <sup>d</sup>
Separated	1 (2.8)	3 (9.4) <sup>e</sup>	2 (5.6)	6 (5.8) <sup>d</sup>
Single	7 (19.4)	5 (15.6) <sup>e</sup>	8 (22.2)	20 (19.2) <sup>d</sup>
Widowed	0 (0)	1 (3.1) <sup>e</sup>	1 (2.8)	2 (19.2) <sup>d</sup>
Prefer not to say	0 (0.0)	0 (0.0) <sup>e</sup>	1 (2.8)	1 (1.0) <sup>d</sup>

**Comorbidities, n (%)**

Arthritis	11 (30.6)	3 (9.1)	8 (22.2)	22 (21.0)
Cancer	0 (0.0)	0 (0.0)	1 (2.8)	1 (1.0)
Diabetes	4 (11.1)	5 (15.2)	6 (16.7)	15 (14.3)
Myocardial infarction	2 (5.6)	1 (3.0)	0 (0.0)	3 (2.9)
Hypertension	7 (19.4)	8 (24.2)	7 (19.4)	22 (21.0)
Stroke (including TIA)	1 (2.8)	1 (3.0)	0 (0.0)	2 (1.9)

**Ethnic group, n (%)**

Asian	2 (5.6)	1 (3.1) <sup>e</sup>	1 (2.8)	4 (3.8) <sup>d</sup>
Black	2 (5.6)	1 (3.1) <sup>e</sup>	1 (2.8)	4 (3.8) <sup>d</sup>
White	32 (88.8)	29 (90.7) <sup>e</sup>	34 (94.4)	95 (91.4) <sup>d</sup>
Prefer not to say	0 (0.0)	1 (3.1) <sup>e</sup>	0 (0.0)	1 (1.0) <sup>d</sup>

**Education**

Bachelor Degree (=SVQ5)	7 (19.4)	6 (19.5) <sup>b</sup>	11 (30.6)	24 (23.3) <sup>f</sup>
HNC/ HND (=SVQ4)	4 (11.1)	6 (19.5) <sup>b</sup>	2 (5.6)	12 (11.6) <sup>f</sup>
Higher Grade/ Advanced Higher/ A-Level or equivalent (=SVQ3)	3 (8.3)	5 (16.1) <sup>b</sup>	1 (2.8)	9 (8.7) <sup>f</sup>
Masters/ PhD or equivalent	1 (2.8)	1 (3.2) <sup>b</sup>	3 (8.3)	5 (4.8) <sup>f</sup>
No formal qualifications	7 (19.4)	3 (9.7) <sup>b</sup>	10 (27.8)	20 (19.4) <sup>f</sup>
Standard Grade/GCSE/ Intermediate 1 or 2	6 (16.7)	7 (22.6) <sup>b</sup>	4 (11.1)	17 (16.5) <sup>f</sup>
Still studying	2 (5.6)	1 (3.2) <sup>b</sup>	3 (8.3)	6 (5.8) <sup>f</sup>
Vocational qualifications (=SVQ1+2)	4 (11.1)	1 (3.2) <sup>b</sup>	0 (0.0)	5 (4.8) <sup>f</sup>
Other	0 (0.0)	1 (3.2) <sup>b</sup>	0 (0.0)	1 (1.0) <sup>f</sup>
Prefer not to say	2 (5.6)	0 (0.0) <sup>b</sup>	2 (5.6)	4 (3.9) <sup>f</sup>
<b>Working status, n (%)</b>				
Full time student	4 (11.1)	2 (6.3) <sup>e</sup>	1 (2.8)	7 (6.7) <sup>d</sup>
Employed - Full time (30+ hours per week)	16 (44.4)	16 (50.0) <sup>e</sup>	18 (50.0)	50 (48.1) <sup>d</sup>
Employed - Part time (8-29 hours per week)	3 (8.3)	3 (9.4) <sup>e</sup>	0 (0.0)	6 (5.8) <sup>d</sup>
Self-employed	3 (8.3)	3 (9.4) <sup>e</sup>	1 (2.8)	7 (6.7) <sup>d</sup>
Not in paid work	2 (5.6)	2 (6.2) <sup>e</sup>	12 (33.3)	16 (15.4) <sup>d</sup>
Retired	8 (22.2)	6 (18.7) <sup>e</sup>	4 (11.1)	18 (17.3) <sup>d</sup>
Household size, mean (SD)	2.6 (1.3)	2.6 (1.0)	2.4 (1.4)	2.5 (1.3)

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3 *Note:* <sup>a</sup> N=35, <sup>b</sup> N=31, <sup>c</sup> N=102, <sup>d</sup> N=104, <sup>e</sup> N=32, <sup>f</sup> N=103; BMI = Body Mass Index, CM =  
4 centimetres, GCSE = General Certificate of Secondary Education, kg = kilogram, N = overall  
5 participants, n = participants within specific category, SD = Standard Deviation, SIMD =  
6 Scottish index of multiple deprivation 1 represents the most disadvantaged area; quintile  
7 SIMD 5 represents the least disadvantaged area, SVQ = Scottish Vocational Qualification  
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**Table 2 Programme satisfaction, and contamination at three, six and 12 months**

	3 months		6 months		12 months		
	SMS + I (N=31)	SMS only (N=27)	SMS + I (N=23)	SMS only (N=21)	SMS + I (N=22)	SMS only (N=26)	Control (N=30)
Programme satisfaction (0-100), mean (SD)	80.3 (21.1)	75.0 (22.2)	76.2 (29.6)	79.0 (20.7)	80.9 (20.0)	77.0 (20.8)	87.3 (17.5) <sup>a</sup>
<b>Programme has been... (1 = low, 5 = high), mean (SD)</b>							
understandable	4.5 (0.9)	4.4 (0.8) <sup>b</sup>	4.4 (1.2) <sup>c</sup>	4.4 (1.2)	4.6 (1.1) <sup>d</sup>	4.6 (1.1) <sup>e</sup>	4.6 (0.9) <sup>a</sup>
useful	4.4 (0.9)	4.0 (1.0)	4.1 (1.3)	4.1 (1.1) <sup>d</sup>	4.1 (1.2)	4.0 (1.0)	4.3 (0.9)
helpful	4.3 (0.9) <sup>f</sup>	3.9 (1.0)	4.1 (1.3)	4.1 (1.1) <sup>d</sup>	4.1 (1.10)	4.0 (1.0)	4.3 (0.9)
interesting	4.3 (1.0)	4.2 (1.1)	4.2 (1.1)	4.4 (1.3) <sup>d</sup>	4.3 (0.8)	4.3 (1.2)	4.5 (1.0)
relevant	4.2 (1.1)	3.9 (1.2)	4.0 (1.3)	4.3 (1.1) <sup>d</sup>	4.1 (1.1)	4.2 (1.1)	4.5 (1.0)
<b>Helpfulness (1 = low, 5 = high), mean (SD)</b>							
Text messages	3.4 (1.5)	3.1 (1.3)	3.1 (1.3)	3.6 (1.3)	3.4 (1.3)	3.3 (1.4)	n/a

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Website	3.3 (1.2) <sup>g</sup>	3.3 (0.9) <sup>b</sup>	3.3 (1.2)	3.2 (0.8) <sup>d</sup>	3.6 (1.0)	3.4 (0.7) <sup>h</sup>	3.5 (1.1) <sup>b</sup>
Pedometer	4.1 (1.2) <sup>f</sup>	4.1 (0.9)	3.7 (1.4)	4.0 (1.0)	3.9 (1.2) <sup>i</sup>	4.0 (1.0) <sup>e</sup>	3.7, (1.4)
<b>Met other men in programme, n (%)</b>							
Yes	0 (0.0)	0 (0.0)	1 (4.3)	0 (0.0)	1 (4.5)	0 (0.0)	1 (3.3)

Note. <sup>a</sup> N=29, <sup>b</sup> N=26, <sup>c</sup> N=22, <sup>d</sup> N=20, <sup>e</sup> N=25, <sup>f</sup> N=30, <sup>g</sup> N=28, <sup>h</sup> N=24, SD = Standard Deviation.

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**Table 3 Weight change at three, six, and 12 months**

	3 months		6 months		12 months		
	SMS + I	SMS only	SMS + I	SMS only	SMS + I	SMS only	Control
	N=36	N=33	N=36	N=33	N=36	N=33	N=36
<b>Weight change (kg), mean (SD)</b>							
Observed cases only	2.79 (3.50) <sup>a</sup>	-1.97 (3.97) <sup>b</sup>	-4.59 (5.62) <sup>c</sup>	-3.30 (4.92) <sup>d</sup>	-3.93 (5.74) <sup>c</sup>	-1.64 (5.64) <sup>b</sup>	-1.06 (6.29) <sup>e</sup>
BOCF	-2.40 (3.38)	-1.55 (3.60)	-2.93 (4.98)	-2.10 (4.21)	-2.51 (4.94)	-1.29 (5.03)	-0.86 (5.64)
LOCF	-2.40 (3.38)	-1.86 (3.88)	-3.38 (4.92)	-2.21 (4.39)	-2.98 (4.91)	-1.33 (5.04)	-0.86 (5.64)
<b>Weight change (%), mean (SD)</b>							
Observed cases only	-2.54 (3.47) <sup>a</sup>	-1.95 (3.72) <sup>b</sup>	-4.20 (5.54) <sup>c</sup>	-3.02 (4.22) <sup>d</sup>	-3.51 (5.83) <sup>c</sup>	-1.51 (4.65) <sup>b</sup>	-1.00 (5.31) <sup>e</sup>
BOCF	-2.18 (3.33)	-1.53 (3.39)	-2.69 (4.84)	-1.92 (3.65)	-2.24 (4.93)	-1.19 (4.16)	-0.80 (4.77)
LOCF	-2.18 (3.33)	-1.53 (3.39)	-3.11 (4.80)	-2.06 (3.85)	-2.68 (4.92)	-1.22 (4.16)	-0.80 (4.77)
<b>Weight change categories (observed cases only), n (%)</b>							



weight gain	6 (19.4) <sup>a</sup>	8 (30.8) <sup>b</sup>	2 (8.7) <sup>c</sup>	6 (28.6) <sup>d</sup>	5 (21.7) <sup>c</sup>	10 (38.5) <sup>b</sup>	14 (48.3) <sup>e</sup>
0-<3% weight loss	13 (41.9) <sup>a</sup>	10 (38.5) <sup>b</sup>	10 (43.5) <sup>c</sup>	7 (33.3) <sup>d</sup>	5 (21.7) <sup>c</sup>	9 (34.6) <sup>b</sup>	7 (24.1) <sup>e</sup>
≥3-<5% weight loss	4 (12.9) <sup>a</sup>	4 (15.4) <sup>b</sup>	3 (13.0) <sup>c</sup>	2 (9.5) <sup>d</sup>	3 (13.0) <sup>c</sup>	4 (15.4) <sup>b</sup>	0 (0.0) <sup>e</sup>
≥5-<10% weight loss	8 (25.8) <sup>a</sup>	2 (7.7) <sup>b</sup>	3 (13.0) <sup>c</sup>	4 (19.1) <sup>d</sup>	7 (30.4) <sup>c</sup>	2 (7.7) <sup>b</sup>	6 (20.7) <sup>e</sup>
≥10% weight loss	0 (0.0) <sup>a</sup>	2 (7.7) <sup>b</sup>	5 (21.7) <sup>c</sup>	2 (9.5) <sup>d</sup>	3 (13.0) <sup>c</sup>	1 (3.9) <sup>b</sup>	2 (6.9)

#### BMI change, mean (SD)

Observed cases only	-0.89 (1.1) <sup>a</sup>	-0.73 (1.32) <sup>b</sup>	-1.45 (1.79) <sup>c</sup>	-1.04 (1.49) <sup>d</sup>	-1.24 (1.89) <sup>c</sup>	-0.49 (1.68) <sup>b</sup>	-0.47 (2.13) <sup>e</sup>
BOCF	-0.75 (1.07)	-0.59 (1.22)	-0.92 (1.58)	-0.66 (1.28)	-0.78 (1.60)	-0.37 (1.50)	-0.37 (1.96)
LOCF	-0.75 (1.07)	-0.59 (1.22)	-0.93 (1.56)	-0.69 (1.34)	-0.93 (1.59)	-0.38 (1.50)	-0.37 (1.96)

#### Waist circumference change (cm), mean (SD)

Observed cases only	-3.74 (4.62) <sup>a</sup>	-3.14 (4.3) <sup>b</sup>	-4.70 (6.29) <sup>c</sup>	-3.14 (4.34) <sup>d</sup>	-4.40 (6.08) <sup>c</sup>	-2.30 (4.37) <sup>b</sup>	-2.26 (4.97) <sup>e</sup>
BOCF	-3.22 (4.47)	-2.49 (3.9)	-3.00 (5.49)	-2.00 (3.76)	-2.81 (5.82)	-1.82 (3.98)	-1.82 (4.53)
LOCF	-3.22 (4.47)	-2.49 (3.9)	-3.71 (5.76)	-2.23 (4.03)	-3.51 (4.48)	-1.85 (3.97)	-1.82 (4.53)

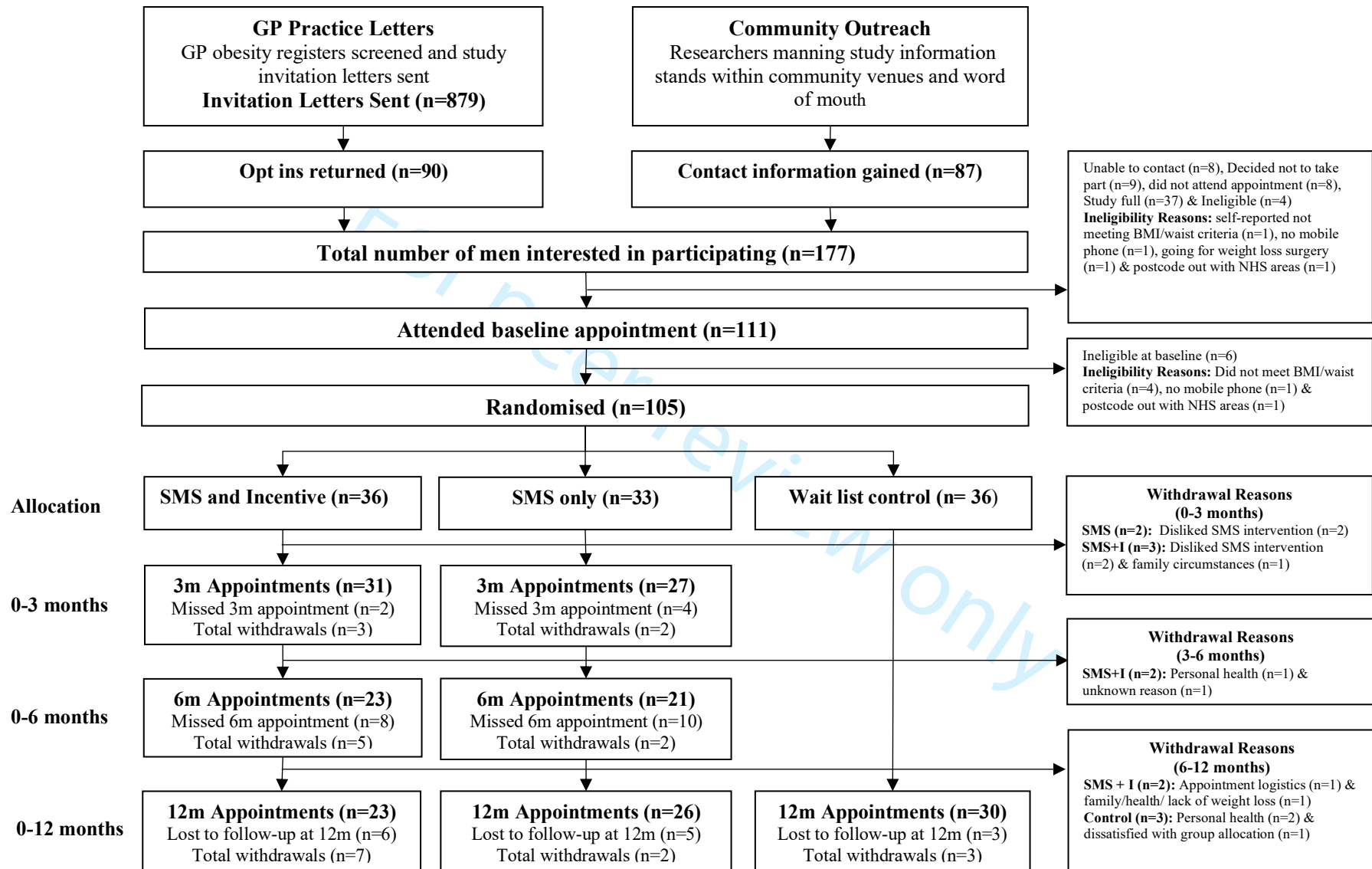
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3 *Note.* <sup>a</sup> N=31, <sup>b</sup> N=26, <sup>c</sup> N=23, <sup>d</sup> N=21, BOCF = baseline observation carried forward, cm = centimetres, LOCF = last observation carried  
4 forward, kg = kilogram, M = mean, SD = Standard Deviation.  
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**Figure 1 Consort flow diagram**

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**Online supplement 1: Incentive strategy contingent on meeting weight loss targets over 12 months**

	Money secured	Money lost
3 months: £50 – target 5% weight loss		
<5%	£0	£50
≥5%	£50	£0
6 months: £150 – target 10%		
<5%	£0	£150
5%	£75	£75
6%	£90	£60
7%	£105	£45
8%	£120	£30
9%	£135	£15
≥10%	£150	£0
12 months: £200 – target 10%		
<5%	£0	£200
5%	£100	£100
6%	£120	£80
7%	£140	£60
8%	£160	£40
9%	£180	£20
≥10%	£200	£0

**Online supplement 2 Intervention engagement over time for narrative texts and study webpage**

	0-3 months		3-6 months		6-12 months	
	SMS + I	SMS only	SMS + I	SMS only	SMS + I	SMS only
	N=36	N=33	N=36	N=33	N=36	N=33
Replies to texts, count	289	81	10	6	28	11
Replies to texts, mean (SD)	8.0 (24.2)	2.5 (7.9)	0.3 (0.7)	0.3 (1.0)	0.8 (3.3)	0.3 (1.0)
<b>Text replies, n (%)</b>						
0 replies	21 (58.3)	23 (69.7)	30 (83.3)	31 (93.9)	28 (77.8)	28 (84.8)
1-5 replies	9 (25.0)	7 (22.3)	6 (16.7)	2 (6.1)	7 (19.4)	5 (15.2)
6-10 replies	2 (5.6)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
11-15 replies	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
16-20 replies	1 (2.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>20 replies	3 (8.3)	1 (3.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)

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Stopping texts, n (%)	1 (2.8)	2 (6.1)	3 (8.3)	3 (9.1)	1 (2.8)	1 (3.0)
Withdrawal due to texts (self-report)	2 (5.6)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Participants using website self-monitoring features, n (%)</b>						
Weight	8 (22.2)	5 (15.2)	6 (16.7)	3 (9.1)	4 (11.1)	3 (9.1)
Steps	10 (27.8)	6 (18.2)	7 (19.4)	2 (6.1)	3 (8.3)	2 (6.1)
Waistline	4 (11.1)	3 (9.1)	3 (8.3)	0 (0.0)	1 (2.8)	0 (0.0)
Belt notches	2 (5.6)	0 (0.0)	2 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Number self-monitoring features used, n (%)</b>						
None	24 (66.7)	26 (78.8)	28 (77.8)	30 (90.1)	31 (86.1)	29 (87.9)
One	5 (13.9)	2 (6.1)	2 (5.6)	1 (3.1)	3 (8.3)	3 (9.1)
Two	3 (8.3)	3 (9.1)	3 (8.3)	2 (6.1)	1 (2.8)	1 (3.0)

Three	3 (8.3)	2 (6.1)	2 (5.6)	0 (0.0)	1 (2.8)	0 (0.0)
Four	1 (2.8)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)

**Number of entries on self-monitoring feature, count**

Weight	69	115	45	23	42	46
Steps	419	296	350	102	397	74
Waistline	4	7	5	0	2	0
Belt notches	8	0	4	0	0	0

*Note.* M = mean, SD = Standard Deviation.



**Online supplement 3 Satisfaction and helpfulness ratings for overall programme and narrative texts at 12 months by deprivation status**

	SMS+I		SMS only		Total	
	SIMD 1, 2	SIMD 3+	SIMD 1, 2	SIMD 3+	SIMD 1, 2	SIMD 3+
	(n=14)	(n=7)	(n=16)	(n=10)	(n=30)	(n=17)
Satisfaction programme <sup>a</sup>	81.8, 21.7	79.9, 19.2	74.6, 23.5	81.0, 16.0	77.9, 22.6	80.5, 16.8
Helpfulness programme <sup>b</sup>	4.2, 1.1	3.9, 1.1	3.9, 1.1	4.2, 1.0	4.1, 1.1	4.1, 1.0
Helpfulness of narrative texts <sup>b</sup>	3.4, 1.3	3.4, 1.4	3.0, 1.5	3.8, 1.2	3.2, 1.4	3.6, 1.3

*Note.* All data mean (SD), <sup>a</sup> scored 0-100 (higher = more satisfied), <sup>b</sup> scored 1-5 (1 = low, 5 = high), SIMD = Scottish index of multiple deprivation 1 represents the most disadvantaged area; quintile SIMD 5 represents the least disadvantaged area SMS = Short message service, SMS+I = SMS plus incentive group.



## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3, 4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6, 7
	2b	Specific objectives or research questions for pilot trial	7
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8,9
	4c	How participants were identified and consented	8,9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10, 11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	7
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
2	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
3		11b	If relevant, description of the similarity of interventions	n/a
4	Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	11-13
5	<b>Results</b>			
6	Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	40
7		13b	For each group, losses and exclusions after randomisation, together with reasons	40
8	Recruitment	14a	Dates defining the periods of recruitment and follow-up	15
9		14b	Why the pilot trial ended or was stopped	15
10	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	31-33
11	Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	31-45
12	Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-19
13	Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
14	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19
15		19a	If relevant, other important unintended consequences	n/a
16	<b>Discussion</b>			
17	Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	20
18	Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	22
19	Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22
20		22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	22
21	<b>Other information</b>			
22	Registration	23	Registration number for pilot trial and name of trial registry	4
23	Protocol	24	Where the pilot trial protocol can be accessed, if available	7
24	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24,25
25		26	Ethical approval or approval by research review committee, confirmed with reference number	7

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

2 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important  
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological  
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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# BMJ Open

## Game of Stones: Feasibility randomised controlled trial of how to engage men with obesity in text message and incentive interventions for weight loss

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<b>Primary Subject Heading</b>:	Public health
Secondary Subject Heading:	Public health
Keywords:	obesity, men, feasibility, trial, SMS, weight loss

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4 **Game of Stones: Feasibility randomised controlled trial of how to engage men with**  
5 **obesity in text message and incentive interventions for weight loss**  
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15  
16 Word count: 5624  
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18 **Key words:** obesity, men, feasibility, trial, SMS, weight loss, behaviour change, financial  
19 incentives  
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## ABSTRACT

### Objectives

To examine the acceptability and feasibility of narrative text messages with or without financial incentives to support weight loss for men.

### Design

Individually randomised three-arm feasibility trial with 12 months' follow-up.

### Setting

Two sites in Scotland with high levels of disadvantage according to Scottish Index for Multiple Deprivation (SIMD).

### Participants

Men with obesity (n=105) recruited through community outreach and general practitioner registers.

### Interventions

Participants randomised to a) narrative text messages plus financial incentive for 12 months (SMS+I), b) narrative text messages for 12 months (SMS only), or c) waiting list control.

### Outcomes

Acceptability and feasibility of recruitment, retention, intervention components and trial procedures assessed by analysing quantitative and qualitative data at three, six and 12 months.

### Results

105 men were recruited, 60% from more disadvantaged areas (SIMD quintiles 1 or 2). Retention at 12 months was 74%. Fewer SMS+I participants group (64%) completed 12-month assessments compared to SMS only (79%) and control (83%). Narrative texts were acceptable to many men, but some reported negative reactions. No evidence emerged that level of disadvantage was related to acceptability of narrative texts. Eleven SMS+I participants (31%) successfully met or partially met weight loss targets. The cost of the incentive per participant was £81.94 (95% CI £34.59-£129.30). Incentives were acceptable, but improving health was reported as the key motivator for weight loss. All groups lost

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3 weight (SMS+I -2.51kg (SD=4.94); SMS only -1.29kg (SD=5.03); control -0.86kg  
4 (SD=5.64) at 12 months).  
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### 6 7 **Conclusions**

8  
9 This three-arm weight management feasibility trial recruited and retained men from across  
10 the socioeconomic spectrum with the majority from areas of disadvantage, was broadly  
11 acceptable to most participants and feasible to deliver.  
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### 14 15 **Trial registration**

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17 ClinicalTrials.gov Identifier: NCT03040518  
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### 19 20 **Funding details**

21  
22 Funded by the National Institute for Health Research Public Health Research Programme  
23 (14/185).  
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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This weight management study for men with obesity recruited men across the socio-economic spectrum, with a specific focus on more disadvantaged areas, to a randomised controlled feasibility study examining SMS with or without endowment incentives.
- Acceptability and feasibility were established using a multi-lens perspective drawing on quantitative, qualitative and trial procedure data.
- Effectiveness of intervention components will need to be established in a full multi-centre trial.

## BACKGROUND

Obesity is associated with an increased risk of serious health conditions such as type 2 diabetes, cardiovascular disease and some cancers.<sup>1</sup> In 2016, 26% of men in the UK were classified as obese, and men were less likely to be a healthy weight than women (31% of men compared with 35% of women).<sup>2,3</sup>

Despite the growing prevalence of obesity, men contribute a disproportionately low number of participants to evidence-based weight management programmes.<sup>4</sup> Most interventions are designed for mixed sex populations, but systematic review evidence suggests that, compared to women, men often benefit from different ways of providing interventions.<sup>4</sup>

### Text message interventions

The evidence for text message interventions supporting changes in lifestyle behaviours, including behaviour change for weight loss, is promising.<sup>5-7</sup> However, systematic reviews<sup>4-7</sup> report no text message delivered trials that target weight loss designed for men only. Text-based interventions can reach large numbers of people, including men from disadvantaged backgrounds,<sup>8</sup> and mobile technologies such as standard mobile phones allow delivery of evidence-based strategies anywhere and anytime.

Narrative approaches to promoting behaviour change have been suggested as a tool for communication-based interventions.<sup>9</sup> Narrative SMS can be broadly defined as interactive life stories, which are based around a group of characters with whom recipients can identify.<sup>10</sup> Text message based interventions using narratives have been used to engage hard to reach men in moderating their alcohol consumption, and were found to be acceptable.<sup>11-13</sup> Narrative approaches to weight management in men may be a promising tool to support behaviour and weight change.

### Financial incentive interventions

Systematic review evidence of financial incentives for behaviour change highlights the potential for incentives to change behaviours in low-income adults<sup>14</sup> and help reduce health inequalities.<sup>15</sup> However, little evidence exists that focuses on using financial incentives to support weight management in individuals from disadvantaged backgrounds<sup>16,17</sup>, particularly for men<sup>4</sup>. A discrete choice experiment found that paying people (£10-£30/week varying by age and weight) to take part in diet and physical activity (PA) interventions is likely to improve uptake, adherence and maintenance of behaviour change.<sup>18</sup> Moreover, the evidence for financial incentives for weight loss is growing.<sup>19-22</sup> In particular, deposit contracts, where

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3 participants deposit their own money and are reimbursed only if they achieve the target  
4 weight loss, are effective whilst the incentives are in place.<sup>4 23</sup> Deposit contracts draw on loss  
5 aversion where people are more motivated to avoid losses than they are to achieve similarly  
6 sized gains.<sup>24 25</sup> However, deposit contracts may not be not equitable, as committing one's  
7 own money up front may not be possible, particularly for individuals with lower income.  
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10 Endowment incentive contracts may overcome limitations of deposit contracts. Endowment  
11 incentive contracts are financial incentives where a person is endowed with a (hypothetical)  
12 amount of money which they either 'secure' or 'lose' depending on achieving certain targets.  
13 A trial that framed financial incentives in this way found these incentives were effective for  
14 achieving PA goals in the short term.<sup>26</sup>  
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## 21 **Aim**

22 The aim of the Game of Stones feasibility trial was to examine the acceptability and  
23 feasibility of a men-only weight management intervention consisting of narrative text  
24 messages, with and without an endowment incentive, compared to waiting list control. The  
25 objectives were to:  
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- 30 1. Assess the acceptability and willingness to be randomised to: i) narrative text message  
31 and endowment incentives; ii) narrative text messages only; or iii) waiting list for text  
32 messages (control).  
33
- 34 2. Assess the feasibility of recruiting from general practitioner (GP) practice obesity  
35 registers and community venues.  
36
- 37 3. Determine the acceptability of intervention content, feasibility of delivery, fidelity and  
38 any unintended consequences.  
39
- 40 4. Assess indicative effects on weight change and progression criteria for a full trial.  
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## 45 **METHODS**

### 46 **Trial design**

47 A three-arm individually randomised parallel-group controlled feasibility trial was conducted  
48 with an integrated qualitative and quantitative mixed methods approach<sup>27</sup>. Informed by MRC  
49 guidance on the evaluation of complex interventions, the study included an integrated mixed  
50 methods process evaluation<sup>28 29</sup>. Drawing on both qualitative and quantitative approaches  
51 allows the team to explore participants views (acceptability) of the intervention with  
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3 participants as well as explore implementation processes such as recruitment, retention and  
4 barriers and facilitators to these.  
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6  
7 Participants were randomised to receive narrative text messages and endowment incentives  
8 (SMS+I), narrative text messages only (SMS only), or a waiting list for text messages  
9 (Control). The protocol the full study are available:  
10

11 <https://www.journalslibrary.nihr.ac.uk/programmes/phr/1418509/#/>  
12

13  
14 Ethical approval for the study was obtained from the North of Scotland Research Ethics  
15 Service (Ref: 16/NS/0120).  
16

### 17 **Setting**

18  
19 Two Health Board areas in Scotland (Sites A and B) with high levels of disadvantage were  
20 the setting for this study (see participant recruitment section for additional details).  
21

### 22 **Eligibility criteria**

23  
24 Participants met the following eligibility criteria: men over 18 years old; BMI  $\geq 30$  kg/m<sup>2</sup>  
25 and/or a waist circumference of  $\geq 40$  inches (102 cm); owned a mobile phone capable of  
26 receiving text messages; could understand English language text messages; not already taking  
27 part in a weight loss study; not planning or waiting to have bariatric surgery; not planning to  
28 move within the next 12 months; considered by practice clinical staff as suitable for  
29 participation (GP practice recruitment only), for example, no severe medical, terminal or  
30 psychiatric illness (in patient or close family member) or no significantly impaired cognitive  
31 function.  
32

### 33 **Sample size**

34  
35 This study aimed to randomise 105 men, 35 to each arm, in line with recent recommendations  
36 for pilot trials as sufficient to estimate key parameters for a full trial.<sup>30</sup> A sample size of 35  
37 per arm is sufficient to allow the population variance to be estimated (e.g. the SD in weight  
38 loss) with enough precision to deliver at least 80% power and 90% confidence in a full trial,  
39 with a standardised effect size between 0.2 and 0.5.<sup>30</sup>  
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### 41 **Participant recruitment**

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43 Participants were recruited via: 1) community outreach, and 2) GP practice obesity registers.  
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### *Community outreach*

Community recruitment strategies that report success for recruiting men in disadvantaged areas were used.<sup>11-13</sup> This included researchers working on stands with study information leaflets and table banners in supermarkets, fitness centres, hospital foyers, health centres, council workplaces and community centres across both sites. Eleven of the 13 recruitment venues were within more disadvantaged areas based on the Scottish Index of Multiple Deprivation (SIMD quintiles 1 and 2).<sup>31</sup> Men who showed interest were given study information and asked to leave their contact details with researchers.

In addition, some men were recruited through word of mouth. This included researcher discussions with family, friends, colleagues and local workers who passed on study information to eligible men they knew. Information leaflets were distributed across localities in shops, libraries, barbers and community centres. Interested men then contacted researchers to get more information.

### *GP practice obesity register letters*

Practices within more disadvantaged areas (SIMD quintiles 1 or 2) were invited to participate in the study. Of the 33 practices invited (n= 13 in Site A, n=20 in Site B), five practices participated (n=4 in Site A, n=1 in Site B).

Practice database searches identified potentially eligible men with a documented BMI of at least 30kg/m<sup>2</sup>. Lists were screened by clinical practice staff and details passed to the Health Informatics Centre at the University of Dundee who sent out GP-headed study invitation letters and information leaflets. Interested men contacted the research team or returned an 'opt-in' card.

### *Baseline Appointment*

Men interested in participating were invited to attend a face-to-face appointment. Detailed study information was discussed and written informed consent provided. Anthropometric measurements were conducted and eligibility assessed. Participants then completed a baseline questionnaire, and were randomised. Group-specific post-randomisation information was provided and discussed with the participant.

### *Randomisation*

At the baseline appointment, independent randomisation was performed by the researcher using the clinical trials unit's secure remote web-based system, stratifying by recruitment method (GP and community) and recruitment site (Site A and Site B).

### *Blinding*

The two recruitment researchers who also assessed outcomes and conducted qualitative interviews were mostly not blinded to group allocations. All other study team members were blinded. A demonstration of the feasibility for researcher outcome assessors to be blind to group allocation was conducted with eleven participants at the six month assessment. In this case, a researcher who had not previously met the participant arranged and undertook the assessment. These participants all complied with the request not to reveal their group allocation.

The trial statistician was fully blinded to intervention groups, and partially blinded for the control group due to the different response schedule (control participants were only assessed at baseline months and 12 months to reflect "usual life").

## **Intervention components**

### *Narrative text messages*

A narrative text message library consisting of 604 texts was written by a professional scriptwriter/researcher (MG) who designed the overall narrative with enough interlinked stories to engage participants over 12 months. Full details of the narrative texts development process are available elsewhere.<sup>10</sup> Narrative texts were sent to participants over the course of 12 months and were written from the point of view of a fictional character aiming to lose weight over 12 months. Narrative texts were written to appeal to men from disadvantaged backgrounds. All participants in the SMS+I and SMS only groups received automated texts according to a pre-determined schedule. Participants could reply to texts but did not receive a response. Texts were sent between 8:00AM and 10:00PM and ranged from 0-5 texts per day. Some texts were personalised including participants' names and men could select whether weight information should be presented in kilogrammes or stones and pounds. No further personalisation and tailoring options were offered. Texts were delivered by the Health Information Centre in Dundee using existing automated technology linked to a clinical trials unit database.



### *Endowment incentive*

The incentive strategy was informed by existing evidence and men's preferences elicited using a Discrete Choice Experiment completed by 1,045 men with obesity and reported elsewhere.<sup>10</sup> SMS+I participants were 'endowed' with a £400 incentive at baseline which was placed into a hypothetical personal account at the University of Stirling and given a mock-up personalised cheque. The full £400 could be secured by meeting weight loss targets at researcher assessments: 5% of body weight lost since baseline at three months (£50 secured/lost), 10% lost since baseline at six months (£150 secured/lost) and 10% lost since baseline at 12 months (£200 secured/lost) (online supplement 1). Weight loss was verified at all face-to-face appointments. At six and 12 months, men lost a proportion of the money for each % weight loss not attained between 5-10%. Weight at 12 months had to be less than at baseline to receive any money, regardless of whether interim weight loss targets had been met. Men received the money by direct bank transfer after the 12-month assessment. Feedback on meeting incentive targets was sent by automated text message and displayed on the personalised SMS+I webpage.

### *Website*

All trial participants were provided with a unique login ID for the Game of Stones website. The front page was accessible to all participants and included trial information and links to existing evidence-based online weight management resources. SMS +I and SMS only webpages had a brief biography and images of the fictional characters featured in narrative texts. Participants could enter their weight, pedometer steps, waist circumference and belt notches, which were displayed as basic visual progress charts. Only individual performance was displayed on the webpage, and no group averages were shown for social comparison. SMS+I webpages described the financial incentives and a visual progress chart of money secured/lost.

### *Printed information*

All participants received a weight loss fact sheet (British Dietetic Association, Weight Loss Food Fact Sheet) and a small card which could be carried in their wallet for noting website details and their appointment weight, weight loss targets and appointments.

### *Pedometer*

All participants received a study pedometer (3DFitBud, A420S, manufactured by 3DActive).

## Comparator group

At baseline, participants received access to the information section of the webpage, printed information (i.e. a weight loss fact sheet) and a pedometer. They attended a baseline and 12-month appointment only. Control group participants were offered texts for three months commencing after the 12 month data collection point.

## Outcomes

The outcomes for this study related to whether the design of Game of Stones was both acceptable and feasible to deliver as a full scale randomised controlled trial. An independent study steering committee advised whether the following pre-specified progression criteria in the study protocol were met sufficiently to proceed to a full trial.

1. Acceptability of the intervention and the control group (by the majority of the target group); willingness to be randomised.
2. Feasibility of recruiting 105 men in four months.
3. 12-month outcomes on at least 72% of men randomised per group.
4. Evidence of mean weight loss of at least 3% of baseline weight at 12 months in any intervention group.
5. Commitment by, for example, government or NHS/local authorities to fund the incentive intervention to ensure translation and sustainability.

## Outcome assessment

Outcomes were assessed at baseline, three, six and 12 months for intervention participants (SMS+I and SMS only), and at baseline and 12 months for control participants. Individual appointments were at community centres, universities, NHS clinical research facilities, voluntary sector organisations, GP practice premises, or the participant's home if no suitable alternative venue could be found. At the 12 month appointment, all participants received a £20 voucher as reimbursement for their time. No travel expenses were provided.

The text message delivery system automatically the frequency of responses received to the texts. The website automatically recorded engagement with self-monitoring tools.

Self-report questionnaires were completed during appointments and measured socio-demographics, co-morbidities, disability, ethnicity, and perceptions on intervention acceptability. Overall satisfaction with the intervention was assessed with the item: "*On a scale from 0 (not satisfied at all) to 100 (completely satisfied). How satisfied are you with the*

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3 *Game of Stones programme?*". Acceptability of the intervention was assessed with the stem  
4 "Overall the Game of Stones programme has been..." followed by options 'understandable',  
5 'useful', 'helpful', 'interesting' and 'relevant', with responses captured on a 5-point scale  
6 ranging from 'totally disagree' to 'totally agree'. Helpfulness of the intervention was  
7 assessed with the item "How helpful have you found the following in helping you lose  
8 weight?" followed by options 'text messages', 'website', and 'pedometer', with responses  
9 captured on a 5-point scale ranging from 'totally unhelpful' to 'totally helpful'. Measures of  
10 overall satisfaction, acceptability and helpfulness were adapted from Dombrowski et al.,  
11 (2012).<sup>32</sup>

12  
13 Anthropometry measures included height measured at baseline using a portable standing  
14 stadiometer (Seca 217, Birmingham, UK) to the nearest 0.1cm. Prior to weight  
15 measurements, participants removed shoes and bulky clothing and items from their pockets.  
16 Weight was recorded using portable calibrated electronic scales (Marsden M420, Rotherham,  
17 UK) to the nearest 0.01kg and waist circumference using a tape measure (Seca 203,  
18 Birmingham, UK) to the nearest 0.1cm.

19  
20 Information on possible adverse events was recorded at assessment visits via open questions  
21 and through automatic monitoring of text message replies including words like 'suicide',  
22 'die', and 'death' indicative of potential adverse events, which were notified to the research  
23 team by email.

24  
25 Any negative participant reactions to their randomised group were recorded in researcher  
26 field notes to assess willingness to be randomised.

27  
28 Interviews took place during three and 12 month appointments and were conducted face-to-  
29 face and detailed methods are described elsewhere.<sup>10</sup> All audio recorded interviews were  
30 transcribed verbatim and anonymised. At three months, all SMS+I and SMS only men were  
31 invited to participate in either a brief feedback or an in-depth interview (participant choice).  
32 The three month topic guide focussed on the early acceptability of the intervention  
33 components in order to identify any refinements required over the remaining nine month  
34 intervention. For the 12 month qualitative interviews, separate topic guides for the three trial  
35 groups were informed by the analysis of the three-month interviews, researcher field notes  
36 and to gain information power<sup>33</sup> to address the study objectives. Purposive sampling from the  
37 three trial groups was informed by the three month interview data and researcher field notes  
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3 to provide diversity of perspectives. Researcher field notes taken at all assessments were  
4 referred to when interpreting interview data.  
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7 Qualitative interviews were conducted face-to-face with 50 of 58 men who attended the three  
8 month assessment (7-61 minutes, median=23 minutes). At 12 months, interviews were  
9 conducted with 14 participants from SMS+I (13-65 minutes, median=33 minutes), 13 from  
10 SMS only (10-59 minutes, median=28 minutes) and six from the control group (7-18  
11 minutes, median=11 minutes). Fourteen interviews at 12 months lasted <20 minutes, mostly  
12 for control participants who had received no contact from the research team between baseline  
13 and 12 months.  
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## 19 **Analysis**

### 20 *Quantitative analysis*

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22 All continuous variables were summarised and tabulated using the following descriptive  
23 statistics: N (number of valid non-missing responses), mean, standard deviation (SD). Likert-  
24 scale variables were treated as continuous measures. The frequency and percentages (based  
25 on the non-missing sample size) of observed levels are reported for all categorical measures.  
26 The proportion of individuals contacted who were recruited and the proportions retained and  
27 withdrawn at each assessment by group was determined. Missing weight data are presented  
28 as baseline observation carried forward (BOCF) and last observation carried forward (LOCF)  
29 in addition to observed cases only.  
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38 CONSORT guidance for reporting randomised pilot and feasibility studies was followed<sup>34</sup>.

### 39 *Qualitative and mixed method data analysis*

40  
41 Anonymised transcripts of interviews together with: attributes for recruitment channel;  
42 attendance at assessments, trial group and participant characteristics and weight loss  
43 outcomes were entered into NVivo12 software for analysis guided by the framework  
44 approach.<sup>35</sup> Reference to researcher field notes contributed to interview data interpretation.  
45 Iterative data collection and analysis were driven by the key feasibility and acceptability  
46 research questions and objectives. A coding frame was developed by three researchers  
47 independently reading a diverse sample of six interviews, followed by a team discussion to  
48 finalise the coding frame and identify key themes. Independent coding was conducted by four  
49 researchers (EC, NG, MM and RS) and checked for consistency by FH. Two independent  
50 researchers (EC and NG) who were not involved in any other aspect of the study, assisted  
51 with coding and analysis to enhance rigour and reliability of data analysis. Emergent themes  
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3 and interpretive analysis were discussed at weekly researcher meetings and at two Co-  
4 Investigator qualitative interpretation meetings.  
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7 At the final stage of mixed methods data interpretation, the quantitative attributes on NVivo  
8 were drawn on to triangulate the analysis and suggest further avenues for interrogation.  
9 Matrix coding queries in NVivo were generated to cross-reference attributes for trial group,  
10 participant SIMD and weight loss outcome at 12 months, with nodes coded for views of  
11 incentives and texts messages respectively. Credibility and reliability of qualitative analysis  
12 was enhanced by independent coding, use of memos to ensure transparency of interpretation,  
13 and interpretive charting conducted with input from the wider study team.  
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### 19 **Patient and Public Involvement**

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21 A continuous and responsive approach to patient and public involvement (PPI) was adopted  
22 to prepare the grant application and throughout the study, as described by Gamble and  
23 colleagues.<sup>36</sup>  
24  
25  
26

27 Continuous PPI was provided by a Co-Investigator partnership with the Charities Men's  
28 Health Forum GB and Men's Health Forum in Ireland. The partnership commenced in 2011  
29 with the ROMEO evidence syntheses of weight loss interventions for men with obesity.<sup>4</sup>  
30  
31

32 During the study, Co-Investigators from each of the Men's Health Forum charities attended  
33 trial management meetings to contribute to decisions, intervention development, data  
34 analysis, interpretation of findings and reporting. They provided feedback on the grant  
35 application, protocol, text messages, information materials and engaged wider involvement of  
36 men from their organisation to assist with appropriate language.<sup>37</sup>  
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41 Continuous PPI at the study oversight level was provided by two independent lay members of  
42 the study steering committee which met on three occasions.  
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45

46 Responsive PPI occurred at the study funding application stage. Co-Investigator CG engaged  
47 men who provided PPI input in the FFIT Trial.<sup>38</sup> During the study, relevant members of the  
48 public were identified through several sources including: Men's Health Forum GB, Men's  
49 Health Forum in Ireland, Scottish Community Health Councils, Men's Sheds, University of  
50 Stirling PPI group, Alliance Scotland and other Co-Investigator contacts. Effort was made to  
51 engage men from more disadvantaged communities. A total of 121 PPI contributors were  
52 involved in a range of study activities, including finding a study name, helping with wording  
53 of information material, and helping with designing the intervention content. For full details  
54 see the report to the funder.<sup>10</sup>  
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## RESULTS

### Recruitment and retention

Recruitment was completed in four months between March to June 2017 meeting the target number of 105 men randomised (Figure 1).

Overall, 177 men expressed an interest in the study. Baseline appointments were attended by 111 (63%), of which six (5%) were ineligible. All 105 men consented to be randomised to the SMS+I (n=36), SMS only (n=33) and control (n=36) groups.

GP practice recruitment was undertaken in five GP practices (Site A n=4, Site B n=1) with 45 men recruited and randomised through GP practices. The additional 60 men were recruited through community outreach.

--- Figure 1 ---

The 12 month assessment was completed by 79/105 participants (75%). One of the 79 participants (control group) could not attend and provided self-reported information because he was out of the region due to work commitments, which means that 74% (78/105) of participants were retained for weight assessments at 12 months. Overall 12 month retention differed by group (SMS+I=23/36, 64%; SMS only=26/33, 79%; control=30/36, 83%). Fourteen participants (13%) were lost to follow-up, and 12 participants (11%) withdrew. Reasons for withdrawal were dislike of narrative texts (n=4), health (n=3), family (n=1), unknown (n=1), dissatisfaction with group allocation (n=1), appointment logistics (n=1) and multiple reasons (n=1).

### Baseline characteristics

Baseline characteristics are displayed in Table 1. On average, participants were 52.2 (SD=13.1) years old, had a BMI of 35.7 (SD=5.9) and a waist circumference of 116.8 cm (SD=11.8). BMI ranged from 27.5 kg/m<sup>2</sup> to 62.5kg/m<sup>2</sup>. Twelve participants (11%) had a baseline BMI less than 30 kg/m<sup>2</sup> due to the additional weight circumference entry criterion of  $\geq 40$  inches (102 cm).

The majority of men lived in disadvantaged areas defined as SIMD quintiles 1 or 2 (n=62/104; 60%). Most participants were married (58%), reported at least one co-morbidity (63%), were of white ethnicity (91%), reported having children (76%), and were in full-time employment (48%).

--- Table 1 ---

## Intervention fidelity

The intervention components were feasible to deliver with fidelity. The majority (95.4%) of the 38,214 text messages sent to the two intervention groups were delivered to the mobile phone, with 1,782 (4.6%) having no delivery status (i.e. lack of response from the mobile phone provider after 48 hrs and invalid phone numbers). No major technical errors occurred. All participants who secured financial incentives were paid by direct bank transfer, in line with their stated preference.

## Acceptability of intervention components

### *Overall acceptability ratings and contamination*

Table 2 displays intervention satisfaction indicators over the course of the study for participants attending assessments. Overall mean study satisfaction at 12 months was 81%, 77% and 87% for the SMS+I, SMS only and control groups respectively. Satisfaction over time was comparable between both intervention groups. For scores on specific programme attributes see Table 2.

Helpfulness ratings of the narrative texts, webpage and pedometer were highest for the pedometer and relatively stable throughout the measurement time points. At 12 months, helpfulness ratings (out of 5) for the pedometer were 3.9, 4.0, and 3.7 for the SMS+I, SMS only and control groups respectively. The narrative texts (SMS+I=3.4; SMS only=3.3) and the webpage (SMS+I=3.6; SMS only=3.4; control=3.5) were perceived as somewhat helpful on average at 12 months.

Minimal contamination between intervention groups was observed, with one participant at six and 12 months (SMS+I group) and another at 12 months (control group) reporting meeting other men in the study.

--- Table 2 ---

### *Acceptability of narrative text messages*

Some men sent spontaneous replies to the narrative texts (0-3 months n=25/69, 36%; 3-6 months n=8/69, 12%, 6-12 months n=13/69, 19%; see online supplement 2). Most spontaneous replies were received between 0-3 months (n=370 replies) and decreased at 3-6 months (n=16 replies) and 6-12 months (n=39 replies).

Eleven participants (11/69, 16%) requested to no longer receive texts but asked to remain in the trial. Requests to stop narrative texts were similar in both groups (SMS+I=5/36, 14%;

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3 SMS only=6/33, 18%), and occurred throughout the study. Four participants (4/69, 6%)  
4 withdrew due to dislike of narrative texts between baseline and three months, two in each  
5 intervention group.  
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8  
9 Qualitative interviews at three and 12 months demonstrated varied views on the narrative  
10 texts. Participants' views ranged from positive to indifferent to negative. Those who liked the  
11 narrative texts found the storyline entertaining, engaging and some participants felt a certain  
12 camaraderie for the main character:  
13  
14

15  
16 *You get involved in the content and you start following the script, they're very funny*  
17 *and me being a [from city name] you can see the funny side and you can see the wit in*  
18 *that, .... and that's what keeps you reading them. (210010, SMS only, 12m)*  
19  
20

21  
22 For other participants, the frequency of texts became a source of irritation, the storyline did  
23 not resonate with their own experience nor could they empathise with the fictional characters:  
24

25  
26 *I'm not a lover of chocolate, biscuits, cake, ice cream, I hardly ever touch them, hardly*  
27 *ever, so hearing about somebody eating pizza or sweets means nothing to me because I*  
28 *don't eat them anyway (120002, SMS+I, 12m)*  
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31  
32 Some were uncertain of the role of the texts in helping to support weight loss. Others  
33 expressed an indifference towards the texts, and a decreasing interest in the story over time  
34 leading to infrequent engagement with text content. However, the regular reminder of being a  
35 participant in a weight loss programme through receiving texts was seen as important:  
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37

38  
39 *I often wonder, do they relate to myself here. And the only commonality is both trying*  
40 *to lose weight. So in that respect it's just a reminder all the time, you should be*  
41 *reviewing your weight and watching what you're eating, so...from that it's a positive,*  
42 *yeah. (220017, SMS+I, 3m)*  
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46  
47 A matrix coding query and analysis of the quotations generated from the NVivo qualitative  
48 and demographic data suggested no obvious relationships between the participant SIMD level  
49 and the qualitative accounts of acceptability of the narrative texts. This is in line with  
50 quantitative data showing similar acceptability ratings for overall programme satisfaction and  
51 helpfulness ratings of the narrative texts across SIMD levels (see online supplement 3). Some  
52 men would have liked more interactivity built into the texts, however, the text message  
53 system was set up for uni-directional messaging only.  
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### *Acceptability of endowment incentive*

At three months, 31/36 SMS+I participants attended the appointment, with eight men losing 5% or more of their baseline weight and securing £50. Attendance at six months was lower (n=23/36), with five participants achieving the weight loss target of >10% weight loss securing £150 each, and a further three participants losing between  $\geq 5$ -10% of weight securing between £75-150. At 12 months, 23/36 participants attended the appointment, with three achieving >10% weight loss securing £200, and a further seven losing between  $\geq 5$ -10% of weight securing between £100-200.

Overall, £2,955 was paid in total to the 11 participants (11/36, 31%) successfully meeting or partially meeting weight loss targets. The full £400 was secured by three participants (3/36, 8%). The cost of the incentive per participant was £81.94 (95% CI £34.59-£129.30). All participants who completed the study and secured money at three or six months received it at the end of the study. No participant lost previously secured money due to weight regain to baseline weight at 12 months. One participant secured money at an early appointment but withdrew from the study, did not attend at 12 months, and did not receive any money.

No negative views were expressed about the incentives in qualitative interviews. Only one man reported being motivated by the financial incentive, and many expressed indifference. Participants reported the weight loss and health benefits as sufficiently rewarding.

*The money's not that much of an issue. I think the incentive for me is the health that, at the end of the day, your health improves. That's the most important incentive. The money, it's fine, it's there, but it's not the incentive (120022, SMS+I, 3m)*

Some interpreted the incentives as a final reward linked to their weight loss targets, whereas others fully understood the intended use of the loss aversion concept:

*[W]e all know how much more distress it causes you to lose money than the pleasure of finding a fiver down the back of the couch, you know, so I think if you lose something it almost has a bigger impact on you than if you gain. (220040, SMS+I, 3m)*

### *Acceptability of study webpages and pedometer*

Some participants used the self-monitoring features on the webpage (see online appendix 3) and reported valuing the ability to visually track their weight in interviews. However, most

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3 did not access the website. The majority (77%) did not own a pedometer at baseline, and  
4 pedometers were highly acceptable to participants.  
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### 7 **Acceptability of Control Group**

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9 Most control group participants (30/36, 83%) attended the 12 month appointment. Six  
10 qualitative interviews were conducted with men in the control group covering topics  
11 including acceptability of waiting 12 months for text messages, views about the study and  
12 improvement suggestions. Many reported being pleased to be involved in a research study.  
13 One participant had a strong negative reaction to being randomised to the control group and  
14 subsequently withdrew when invited to the 12 month assessment.  
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### 20 **Weight outcomes**

21  
22 Table 3 displays weight change outcomes at three, six, and 12 months. The difference in  
23 mean percentage weight loss at 12 months for observed cases was -2.51% (95% CI -6.03 to  
24 1.01) for SMS+I v control and -0.51% (95% CI -3.91 to 2.89) for SMS only v control. The  
25 difference in absolute weight loss at 12 months was -2.87kg (95% CI -6.82 to 1.08) for  
26 SMS+I v control and -0.57kg (95% CI -4.40 to 3.25) for SMS only v control.  
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32 ---Table 3 ---

33  
34 The SMS+I group displayed mean weight loss of over 3% at 12 months (-3.51%, SD=5.83).  
35 The SMS only and control groups remained below 3% weight loss on average (SMS only=-  
36 1.51%, 4.65; control=-1.00%, SD=5.31). The highest mean percentage weight loss at 12  
37 months for BOCF was -2.24% (SD=4.93) in the SMS+I group, followed by -1.19%  
38 (SD=4.16) and -0.80% (SD=4.77) in the SMS only and control groups respectively.  
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### 43 **Harms and unintended consequences**

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45 No harms or unintended consequences were reported.  
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### 48 **Progression to full trial**

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50 An independent study steering committee agreed that the Game of Stones study had  
51 demonstrated acceptability and feasibility agreeing that overall the pre-specified progression  
52 criteria were sufficiently met to support a full three-arm multi-site RCT.  
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## DISCUSSION

### Principal findings

This study successfully recruited 105 men from across the socioeconomic spectrum to a three-armed RCT and overall achieved 74% retention at 12 months' follow-up. Men living in more disadvantaged areas formed 60% of the sample. Narrative texts were broadly acceptable, but some participants disengaged or withdrew from the study due to dislike of texts. The endowment incentives were acceptable, and improving health was reported as a key motivator for weight loss. Positive indicative effects of weight loss were found in intervention and control groups.

### Strengths and weaknesses of the study

This study was underpinned by the ROMEO systematic reviews and qualitative evidence synthesis of weight loss interventions for men with obesity<sup>39 40</sup>, with a continuing PPI partnership with the Men's Health Forum GB and Ireland charities. Mixed methods research combined quantitative and qualitative data which, together with patient, public and stakeholder involvement, provided a multi-lens perspective on this study.

Most assessments were not blind to group allocation. The difference in assessment schedules for intervention and control groups meant that study staff were only partially blind. A full trial should ensure full blinding of all outcome assessments. Researchers were unable to collect data via qualitative interviews, questionnaires and anthropometric measures with men who withdrew from the study or were lost to follow-up at the 12 month appointment. Those providing a withdrawal reason may have provided socially desirable responses. Text messages were personalised by including the participant's name and weight unit preference, but no tailoring or interactivity were possible due to technical limitations of the delivery system. This feasibility trial was not powered to detect effects on weight loss and, in line with recommendations<sup>41</sup>, no p-values are reported. Weight outcomes should be interpreted with caution.

### Relation to other studies

The Game of Stones study adds to the evidence base demonstrating the feasibility of recruiting men for research on sensitive subjects, such as obesity, through community outreach and GP practice lists.<sup>11-13</sup>

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3 The average BMI and age of the study participants of around 35kg/m<sup>2</sup> and 50-55 years is  
4 similar to UK weight management trials recruiting in the community<sup>38</sup>, primary care<sup>42</sup>, or a  
5 combination of community and primary care.<sup>12</sup> Three international text message based  
6 weight management studies examining outcomes after 12 months recruited younger  
7 participants with lower BMI.<sup>43-45</sup> However, three mixed sex weight management studies with  
8 financial incentives (two including text message components) reported broadly similar  
9 participant demographics to this study.<sup>46-48</sup>

10 Retention levels of 74% were acceptable and are similar to systematic review evidence of  
11 men-only weight loss interventions which found an average retention of 78%, ranging from  
12 44% to 100%.<sup>40</sup> International text message studies with mixed sex participants report similar  
13 retention rates at 12 months of 70.3%<sup>44</sup> and 73%<sup>43</sup>, with one study conducted in Latvia  
14 reporting 93% retention<sup>45</sup>. Two large UK studies recruiting mixed sex participants with  
15 obesity to weight management in primary care reported 75%<sup>42</sup> and 81%<sup>49</sup> retention at 12  
16 months.

17 Two previous narrative text message intervention studies in men targeting alcohol reduction  
18 reported high acceptability levels and no negative reactions.<sup>12 13</sup> However, these studies were  
19 only 12 weeks in duration and overall contained fewer texts. The narrative texts in this study  
20 were broadly acceptable, although some negative reactions were reported. Study withdrawal  
21 due to texts and requests to stop texts suggest that the current narrative texts may not be  
22 universally acceptable to men. The text messages were designed by a professional  
23 scriptwriter/researcher with PPI input from the target population of men from disadvantaged  
24 backgrounds, but the narrative texts were similarly acceptable across the socio-economic  
25 spectrum. Intervention fidelity was high with the majority of sent texts successfully delivered  
26 and no adverse events were encountered, similar to previous text message-based intervention  
27 studies.<sup>11-13</sup>

28 The use of a financial incentive strategy for weight loss in men with obesity across the  
29 socioeconomic spectrum was feasible and acceptable. Two previous incentive studies used  
30 text messages to inform participants about their incentive achievement of weight loss targets,  
31 and found it acceptable.<sup>46 47</sup> This extends the evidence base on the use of financial incentives  
32 as a complementary behaviour change strategy alongside other components.<sup>22 50</sup>

33 The financial incentive strategy was designed with future sustainability in mind and to be  
34 attractive to public sector funders. The text messages and incentive components are mostly  
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3 automated, encourage self-management of weight and have a low administrative burden with  
4 one bank transfer pay out after 12 months, and verification of weight loss at three, six and 12  
5 months. Yancy et al. similarly provided incentives at three and six months for their six  
6 months' incentive intervention<sup>46</sup>. John et al. asked participants to be weighed monthly, for  
7 which they received \$20 per visit.<sup>47</sup> Few RCTs examine financial incentive strategies that are  
8 delivered for at least 12 months.<sup>50</sup> Two other studies providing financial incentives for 12  
9 months provided an intensive financial incentive schedule either weekly<sup>51</sup> or monthly<sup>52</sup>.  
10 Previous studies typically provided participants with weekly weight loss goals such as 11lb  
11 (0.45kg) per week, on which financial incentives were contingent.<sup>50</sup> Whilst these goals are  
12 similar to the weight loss targets in the current study, there were no intermittent or weekly  
13 targets. A balance needs to be struck between having more regular weight measurements and  
14 more immediate pay-outs, costs and future sustainability.

15 Patel et al. applied a similar framing which they called a loss incentive<sup>26</sup>. University  
16 employees were allocated a monthly hypothetical incentive of \$42 upfront and \$1.40 was  
17 taken away each time their daily goal of 7000 steps was not met. The current study adds to  
18 the evidence base demonstrating the acceptability and feasibility of loss framed interventions  
19 for weight loss and in settings outside workplaces.

## 30 **Conclusion**

31 This three-arm weight management feasibility trial recruited men from across the  
32 socioeconomic spectrum with the majority coming from disadvantaged areas, had an  
33 acceptable retention rate, and was broadly acceptable to most participants, and feasible to  
34 deliver. A full trial of the study is warranted.  
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1  
2  
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9 MCN Lead Clinician, NHS Tayside.  
10

## 11 **AUTHOR CONTRIBUTIONS**

12  
13 SD co-led the study with PH as joint Chief-Investigator and co-led the design and overall  
14  
15 conduct of the study and led the writing of the manuscript, overseen by PH.  
16

17  
18 MM undertook the study set up, recruitment and data collection, co-ordinated various PPI  
19  
20 activities, contributed substantially to qualitative and quantitative data analysis and  
21  
22 interpretation. MvdP was a co-investigator, contributed to the design and the interpretation of  
23  
24 findings and led the DCE and health economic analysis. MG was a co-investigator,  
25  
26 contributed to the design and the interpretation of findings and led the development of the  
27  
28 narrative SMS component, the related PPI. AA was a co-investigator, contributed to the  
29  
30 design and the interpretation of findings. PC and MT linked to PPI networks, contributed to  
31  
32 the design, and interpretation of the findings. AE was a co-investigator, contributed to the  
33  
34 design and the interpretation of findings and oversaw the statistical analysis. NG and EC  
35  
36 contributed to the analysis and interpretation of the qualitative data. CG was a co-  
37  
38 investigator, facilitated PPI, contributed to the design, and interpretation of findings. FH was  
39  
40 a co-investigator, oversaw the qualitative data collection and analysis and contributed to the  
41  
42 interpretation of findings. AH undertook the statistical analysis at Tayside Clinical Trials  
43  
44 Unit. CJ was a co-investigator, contributed to the design and the interpretation of findings  
45  
46 and oversaw the automated SMS delivery system, recruitment tracking, the study website and  
47  
48 integration of data with databases at Tayside Clinical Trials Unit. FK and MMcK were co-  
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50 investigators and contributed to the design and the interpretation of findings. RS contributed  
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52 to recruitment, data collection and undertaking qualitative interviews and contributed to the  
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54 interpretation of findings.

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13  
14  
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16 Narrative Approach deployed to design and write the narrative text intervention.  
17

18  
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20

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22  
23 Access to data can be arranged through the Co-PIs of the study: Prof. Pat Hoddinott,  
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27 approvals.  
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**Table 1 Participant baseline characteristics**

	<b>SMS + I</b>	<b>SMS only</b>	<b>Control</b>	<b>Total</b>
	<b>N=36</b>	<b>N=33</b>	<b>N=36</b>	<b>N=105</b>
Age (years), mean (SD)	50.9 (14.2) <sup>a</sup>	52.5 (15.1) <sup>b</sup>	53.1 (10.1)	52.2 (13.1) <sup>c</sup>
Waist circumference (cm), mean SD	115.8 (10.0)	114.9 (12.7)	119.5 (12.2)	116.8 (11.8)
Weight (kg), mean (SD)	108.6 (16.4)	107.8 (20.2)	110.7 (19.0)	109.1 (18.4)
Height (cm), mean (SD)	175.9 (6.6)	175.2 (6.7)	173.8 (5.9)	175.0 (6.4)
BMI (kg/m <sup>2</sup> ), mean (SD)	35.1 (5.3)	35.1 (5.9)	36.7 (6.5)	35.7 (5.9)
<b>BMI (kg/m<sup>2</sup>) categories, n (%)</b>				
<30	5 (13.9)	3 (9.1)	3 (8.3)	11 (10.5)
≥30->35	16 (44.4)	19 (57.6)	14 (38.9)	49 (46.7)
≥35->40	10 (27.8)	6 (18.2)	7 (19.4)	23 (21.8)
≥40->45	4 (11.1)	2 (6.1)	10 (27.8)	16 (15.2)
≥45->50	0 (0.0)	2 (6.1)	1 (2.8)	3 (2.9)
≥50	1 (2.8)	1 (3.0)	1 (2.8)	3 (2.9)
<b>SIMD deprivation category, n (%)</b>				
SIMD 1 (most disadvantaged)	11 (31.4) <sup>a</sup>	12 (36.4)	15 (41.7)	38 (36.5) <sup>d</sup>
SIMD 2	8 (22.9) <sup>a</sup>	9 (27.3)	7 (19.4)	24 (23.1) <sup>d</sup>
SIMD 3	6 (17.1) <sup>a</sup>	3 (9.1)	3 (8.3)	12 (11.5) <sup>d</sup>
SIMD 4	4 (11.4) <sup>a</sup>	4 (12.1)	6 (16.7)	14 (13.5) <sup>d</sup>
SIMD 5 (least disadvantaged)	6 (17.5) <sup>a</sup>	5 (15.2)	5 (13.9)	16 (15.4) <sup>d</sup>

**Marital status, n (%)**

Cohabiting	4 (11.1)	2 (6.3) <sup>e</sup>	5 (13.8)	11 (10.6) <sup>d</sup>
Divorced	2 (5.6)	0 (0.0) <sup>e</sup>	2 (5.6)	4 (3.9) <sup>d</sup>
Married	22 (61.1)	21 (65.6) <sup>e</sup>	17 (47.2)	60 (57.7) <sup>d</sup>
Separated	1 (2.8)	3 (9.4) <sup>e</sup>	2 (5.6)	6 (5.8) <sup>d</sup>
Single	7 (19.4)	5 (15.6) <sup>e</sup>	8 (22.2)	20 (19.2) <sup>d</sup>
Widowed	0 (0)	1 (3.1) <sup>e</sup>	1 (2.8)	2 (19.2) <sup>d</sup>
Prefer not to say	0 (0.0)	0 (0.0) <sup>e</sup>	1 (2.8)	1 (1.0) <sup>d</sup>

**Comorbidities, n (%)**

Arthritis	11 (30.6)	3 (9.1)	8 (22.2)	22 (21.0)
Cancer	0 (0.0)	0 (0.0)	1 (2.8)	1 (1.0)
Diabetes	4 (11.1)	5 (15.2)	6 (16.7)	15 (14.3)
Myocardial infarction	2 (5.6)	1 (3.0)	0 (0.0)	3 (2.9)
Hypertension	7 (19.4)	8 (24.2)	7 (19.4)	22 (21.0)
Stroke (including TIA)	1 (2.8)	1 (3.0)	0 (0.0)	2 (1.9)

**Ethnic group, n (%)**

Asian	2 (5.6)	1 (3.1) <sup>e</sup>	1 (2.8)	4 (3.8) <sup>d</sup>
Black	2 (5.6)	1 (3.1) <sup>e</sup>	1 (2.8)	4 (3.8) <sup>d</sup>
White	32 (88.8)	29 (90.7) <sup>e</sup>	34 (94.4)	95 (91.4) <sup>d</sup>
Prefer not to say	0 (0.0)	1 (3.1) <sup>e</sup>	0 (0.0)	1 (1.0) <sup>d</sup>

**Education**



Bachelor Degree (=SVQ5)	7 (19.4)	6 (19.5) <sup>b</sup>	11 (30.6)	24 (23.3) <sup>f</sup>
HNC/ HND (=SVQ4)	4 (11.1)	6 (19.5) <sup>b</sup>	2 (5.6)	12 (11.6) <sup>f</sup>
Higher Grade/ Advanced Higher/ A-Level or equivalent (=SVQ3)	3 (8.3)	5 (16.1) <sup>b</sup>	1 (2.8)	9 (8.7) <sup>f</sup>
Masters/ PhD or equivalent	1 (2.8)	1 (3.2) <sup>b</sup>	3 (8.3)	5 (4.8) <sup>f</sup>
No formal qualifications	7 (19.4)	3 (9.7) <sup>b</sup>	10 (27.8)	20 (19.4) <sup>f</sup>
Standard Grade/GCSE/ Intermediate 1 or 2	6 (16.7)	7 (22.6) <sup>b</sup>	4 (11.1)	17 (16.5) <sup>f</sup>
Still studying	2 (5.6)	1 (3.2) <sup>b</sup>	3 (8.3)	6 (5.8) <sup>f</sup>
Vocational qualifications (=SVQ1+2)	4 (11.1)	1 (3.2) <sup>b</sup>	0 (0.0)	5 (4.8) <sup>f</sup>
Other	0 (0.0)	1 (3.2) <sup>b</sup>	0 (0.0)	1 (1.0) <sup>f</sup>
Prefer not to say	2 (5.6)	0 (0.0) <sup>b</sup>	2 (5.6)	4 (3.9) <sup>f</sup>
<b>Working status, n (%)</b>				
Full time student	4 (11.1)	2 (6.3) <sup>e</sup>	1 (2.8)	7 (6.7) <sup>d</sup>
Employed - Full time (30+ hours per week)	16 (44.4)	16 (50.0) <sup>e</sup>	18 (50.0)	50 (48.1) <sup>d</sup>
Employed - Part time (8-29 hours per week)	3 (8.3)	3 (9.4) <sup>e</sup>	0 (0.0)	6 (5.8) <sup>d</sup>
Self-employed	3 (8.3)	3 (9.4) <sup>e</sup>	1 (2.8)	7 (6.7) <sup>d</sup>
Not in paid work	2 (5.6)	2 (6.2) <sup>e</sup>	12 (33.3)	16 (15.4) <sup>d</sup>
Retired	8 (22.2)	6 (18.7) <sup>e</sup>	4 (11.1)	18 (17.3) <sup>d</sup>
Household size, mean (SD)	2.6 (1.3)	2.6 (1.0)	2.4 (1.4)	2.5 (1.3)

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3 *Note:* <sup>a</sup> N=35, <sup>b</sup> N=31, <sup>c</sup> N=102, <sup>d</sup> N=104, <sup>e</sup> N=32, <sup>f</sup> N=103; BMI = Body Mass Index, CM =  
4 centimetres, GCSE = General Certificate of Secondary Education, kg = kilogram, N = overall  
5 participants, n = participants within specific category, SD = Standard Deviation, SIMD =  
6 Scottish index of multiple deprivation 1 represents the most disadvantaged area; quintile  
7 SIMD 5 represents the least disadvantaged area, SVQ = Scottish Vocational Qualification  
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**Table 2 Programme satisfaction, and contamination at three, six and 12 months**

	3 months		6 months		12 months		
	SMS + I (N=31)	SMS only (N=27)	SMS + I (N=23)	SMS only (N=21)	SMS + I (N=22)	SMS only (N=26)	Control (N=30)
Programme satisfaction (0-100), mean (SD)	80.3 (21.1)	75.0 (22.2)	76.2 (29.6)	79.0 (20.7)	80.9 (20.0)	77.0 (20.8)	87.3 (17.5) <sup>a</sup>
<b>Programme has been... (1 = low, 5 = high), mean (SD)</b>							
understandable	4.5 (0.9)	4.4 (0.8) <sup>b</sup>	4.4 (1.2) <sup>c</sup>	4.4 (1.2)	4.6 (1.1) <sup>d</sup>	4.6 (1.1) <sup>e</sup>	4.6 (0.9) <sup>a</sup>
useful	4.4 (0.9)	4.0 (1.0)	4.1 (1.3)	4.1 (1.1) <sup>d</sup>	4.1 (1.2)	4.0 (1.0)	4.3 (0.9)
helpful	4.3 (0.9) <sup>f</sup>	3.9 (1.0)	4.1 (1.3)	4.1 (1.1) <sup>d</sup>	4.1 (1.10)	4.0 (1.0)	4.3 (0.9)
interesting	4.3 (1.0)	4.2 (1.1)	4.2 (1.1)	4.4 (1.3) <sup>d</sup>	4.3 (0.8)	4.3 (1.2)	4.5 (1.0)
relevant	4.2 (1.1)	3.9 (1.2)	4.0 (1.3)	4.3 (1.1) <sup>d</sup>	4.1 (1.1)	4.2 (1.1)	4.5 (1.0)
<b>Helpfulness (1 = low, 5 = high), mean (SD)</b>							
Text messages	3.4 (1.5)	3.1 (1.3)	3.1 (1.3)	3.6 (1.3)	3.4 (1.3)	3.3 (1.4)	n/a

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Website	3.3 (1.2) <sup>g</sup>	3.3 (0.9) <sup>b</sup>	3.3 (1.2)	3.2 (0.8) <sup>d</sup>	3.6 (1.0)	3.4 (0.7) <sup>h</sup>	3.5 (1.1) <sup>b</sup>
Pedometer	4.1 (1.2) <sup>f</sup>	4.1 (0.9)	3.7 (1.4)	4.0 (1.0)	3.9 (1.2) <sup>i</sup>	4.0 (1.0) <sup>e</sup>	3.7, (1.4)
<b>Met other men in programme, n (%)</b>							
Yes	0 (0.0)	0 (0.0)	1 (4.3)	0 (0.0)	1 (4.5)	0 (0.0)	1 (3.3)

Note. <sup>a</sup> N=29, <sup>b</sup> N=26, <sup>c</sup> N=22, <sup>d</sup> N=20, <sup>e</sup> N=25, <sup>f</sup> N=30, <sup>g</sup> N=28, <sup>h</sup> N=24, SD = Standard Deviation.

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**Table 3 Weight change at three, six, and 12 months**

	3 months		6 months		12 months		
	SMS + I	SMS only	SMS + I	SMS only	SMS + I	SMS only	Control
	N=36	N=33	N=36	N=33	N=36	N=33	N=36
<b>Weight change (kg), mean (SD)</b>							
Observed cases only	2.79 (3.50) <sup>a</sup>	-1.97 (3.97) <sup>b</sup>	-4.59 (5.62) <sup>c</sup>	-3.30 (4.92) <sup>d</sup>	-3.93 (5.74) <sup>c</sup>	-1.64 (5.64) <sup>b</sup>	-1.06 (6.29) <sup>c</sup>
BOCF	-2.40 (3.38)	-1.55 (3.60)	-2.93 (4.98)	-2.10 (4.21)	-2.51 (4.94)	-1.29 (5.03)	-0.86 (5.64)
LOCF	-2.40 (3.38)	-1.86 (3.88)	-3.38 (4.92)	-2.21 (4.39)	-2.98 (4.91)	-1.33 (5.04)	-0.86 (5.64)
<b>Weight change (%), mean (SD)</b>							
Observed cases only	-2.54 (3.47) <sup>a</sup>	-1.95 (3.72) <sup>b</sup>	-4.20 (5.54) <sup>c</sup>	-3.02 (4.22) <sup>d</sup>	-3.51 (5.83) <sup>c</sup>	-1.51 (4.65) <sup>b</sup>	-1.00 (5.31) <sup>c</sup>
BOCF	-2.18 (3.33)	-1.53 (3.39)	-2.69 (4.84)	-1.92 (3.65)	-2.24 (4.93)	-1.19 (4.16)	-0.80 (4.77)
LOCF	-2.18 (3.33)	-1.53 (3.39)	-3.11 (4.80)	-2.06 (3.85)	-2.68 (4.92)	-1.22 (4.16)	-0.80 (4.77)

**Weight change categories (observed cases only), n (%)**

weight gain	6 (19.4) <sup>a</sup>	8 (30.8) <sup>b</sup>	2 (8.7) <sup>c</sup>	6 (28.6) <sup>d</sup>	5 (21.7) <sup>c</sup>	10 (38.5) <sup>b</sup>	14 (48.3) <sup>e</sup>
0-<3% weight loss	13 (41.9) <sup>a</sup>	10 (38.5) <sup>b</sup>	10 (43.5) <sup>c</sup>	7 (33.3) <sup>d</sup>	5 (21.7) <sup>c</sup>	9 (34.6) <sup>b</sup>	7 (24.1) <sup>e</sup>
≥3-<5% weight loss	4 (12.9) <sup>a</sup>	4 (15.4) <sup>b</sup>	3 (13.0) <sup>c</sup>	2 (9.5) <sup>d</sup>	3 (13.0) <sup>c</sup>	4 (15.4) <sup>b</sup>	0 (0.0) <sup>e</sup>
≥5-<10% weight loss	8 (25.8) <sup>a</sup>	2 (7.7) <sup>b</sup>	3 (13.0) <sup>c</sup>	4 (19.1) <sup>d</sup>	7 (30.4) <sup>c</sup>	2 (7.7) <sup>b</sup>	6 (20.7) <sup>e</sup>
≥10% weight loss	0 (0.0) <sup>a</sup>	2 (7.7) <sup>b</sup>	5 (21.7) <sup>c</sup>	2 (9.5) <sup>d</sup>	3 (13.0) <sup>c</sup>	1 (3.9) <sup>b</sup>	2 (6.9)

#### BMI change, mean (SD)

Observed cases only	-0.89 (1.1) <sup>a</sup>	-0.73 (1.32) <sup>b</sup>	-1.45 (1.79) <sup>c</sup>	-1.04 (1.49) <sup>d</sup>	-1.24 (1.89) <sup>c</sup>	-0.49 (1.68) <sup>b</sup>	-0.47 (2.13) <sup>e</sup>
BOCF	-0.75 (1.07)	-0.59 (1.22)	-0.92 (1.58)	-0.66 (1.28)	-0.78 (1.60)	-0.37 (1.50)	-0.37 (1.96)
LOCF	-0.75 (1.07)	-0.59 (1.22)	-0.93 (1.56)	-0.69 (1.34)	-0.93 (1.59)	-0.38 (1.50)	-0.37 (1.96)

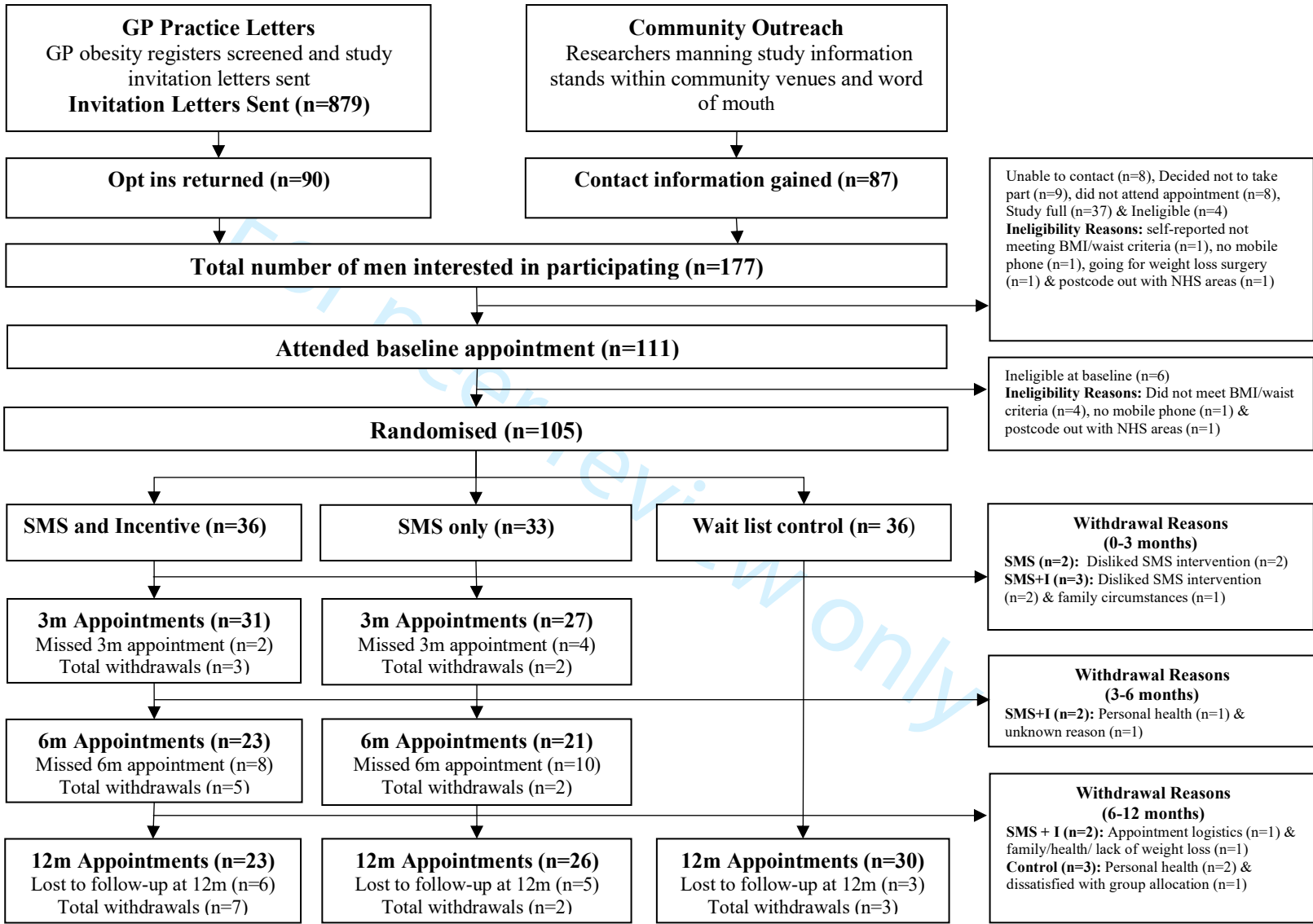
#### Waist circumference change (cm), mean (SD)

Observed cases only	-3.74 (4.62) <sup>a</sup>	-3.14 (4.3) <sup>b</sup>	-4.70 (6.29) <sup>c</sup>	-3.14 (4.34) <sup>d</sup>	-4.40 (6.08) <sup>c</sup>	-2.30 (4.37) <sup>b</sup>	-2.26 (4.97) <sup>e</sup>
BOCF	-3.22 (4.47)	-2.49 (3.9)	-3.00 (5.49)	-2.00 (3.76)	-2.81 (5.82)	-1.82 (3.98)	-1.82 (4.53)
LOCF	-3.22 (4.47)	-2.49 (3.9)	-3.71 (5.76)	-2.23 (4.03)	-3.51 (4.48)	-1.85 (3.97)	-1.82 (4.53)

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3 *Note.* <sup>a</sup> N=31, <sup>b</sup> N=26, <sup>c</sup> N=23, <sup>d</sup> N=21, BOCF = baseline observation carried forward, cm = centimetres, LOCF = last observation carried  
4 forward, kg = kilogram, M = mean, SD = Standard Deviation.  
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**Online supplement 1: Incentive strategy contingent on meeting weight loss targets over 12 months**

	Money secured	Money lost
3 months: £50 – target 5% weight loss		
<5%	£0	£50
≥5%	£50	£0
6 months: £150 – target 10%		
<5%	£0	£150
5%	£75	£75
6%	£90	£60
7%	£105	£45
8%	£120	£30
9%	£135	£15
≥10%	£150	£0
12 months: £200 – target 10%		
<5%	£0	£200
5%	£100	£100
6%	£120	£80
7%	£140	£60
8%	£160	£40
9%	£180	£20
≥10%	£200	£0

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3 **Online supplement 2 Intervention engagement over time for narrative texts and study webpage**  
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	0-3 months		3-6 months		6-12 months	
	SMS + I	SMS only	SMS + I	SMS only	SMS + I	SMS only
	N=36	N=33	N=36	N=33	N=36	N=33
Replies to texts, count	289	81	10	6	28	11
Replies to texts, mean (SD)	8.0 (24.2)	2.5 (7.9)	0.3 (0.7)	0.3 (1.0)	0.8 (3.3)	0.3 (1.0)
<b>Text replies, n (%)</b>						
0 replies	21 (58.3)	23 (69.7)	30 (83.3)	31 (93.9)	28 (77.8)	28 (84.8)
1-5 replies	9 (25.0)	7 (22.3)	6 (16.7)	2 (6.1)	7 (19.4)	5 (15.2)
6-10 replies	2 (5.6)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
11-15 replies	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
16-20 replies	1 (2.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>20 replies	3 (8.3)	1 (3.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)

Stopping texts, n (%)	1 (2.8)	2 (6.1)	3 (8.3)	3 (9.1)	1 (2.8)	1 (3.0)
Withdrawal due to texts (self-report)	2 (5.6)	2 (6.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Participants using website self-monitoring features, n (%)</b>						
Weight	8 (22.2)	5 (15.2)	6 (16.7)	3 (9.1)	4 (11.1)	3 (9.1)
Steps	10 (27.8)	6 (18.2)	7 (19.4)	2 (6.1)	3 (8.3)	2 (6.1)
Waistline	4 (11.1)	3 (9.1)	3 (8.3)	0 (0.0)	1 (2.8)	0 (0.0)
Belt notches	2 (5.6)	0 (0.0)	2 (5.6)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Number self-monitoring features used, n (%)</b>						
None	24 (66.7)	26 (78.8)	28 (77.8)	30 (90.1)	31 (86.1)	29 (87.9)
One	5 (13.9)	2 (6.1)	2 (5.6)	1 (3.1)	3 (8.3)	3 (9.1)
Two	3 (8.3)	3 (9.1)	3 (8.3)	2 (6.1)	1 (2.8)	1 (3.0)

Three	3 (8.3)	2 (6.1)	2 (5.6)	0 (0.0)	1 (2.8)	0 (0.0)
Four	1 (2.8)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)
<b>Number of entries on self-monitoring feature, count</b>						
Weight	69	115	45	23	42	46
Steps	419	296	350	102	397	74
Waistline	4	7	5	0	2	0
Belt notches	8	0	4	0	0	0

*Note.* M = mean, SD = Standard Deviation.

**Online supplement 3 Satisfaction and helpfulness ratings for overall programme and narrative texts at 12 months by deprivation status**

	SMS+I		SMS only		Total	
	SIMD 1, 2	SIMD 3+	SIMD 1, 2	SIMD 3+	SIMD 1, 2	SIMD 3+
	(n=14)	(n=7)	(n=16)	(n=10)	(n=30)	(n=17)
Satisfaction programme <sup>a</sup>	81.8, 21.7	79.9, 19.2	74.6, 23.5	81.0, 16.0	77.9, 22.6	80.5, 16.8
Helpfulness programme <sup>b</sup>	4.2, 1.1	3.9, 1.1	3.9, 1.1	4.2, 1.0	4.1, 1.1	4.1, 1.0
Helpfulness of narrative texts <sup>b</sup>	3.4, 1.3	3.4, 1.4	3.0, 1.5	3.8, 1.2	3.2, 1.4	3.6, 1.3

*Note.* All data mean (SD), <sup>a</sup> scored 0-100 (higher = more satisfied), <sup>b</sup> scored 1-5 (1 = low, 5 = high), SIMD = Scottish index of multiple deprivation 1 represents the most disadvantaged area; quintile SIMD 5 represents the least disadvantaged area SMS = Short message service, SMS+I = SMS plus incentive group.



## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3, 4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6, 7
	2b	Specific objectives or research questions for pilot trial	7
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8,9
	4c	How participants were identified and consented	8,9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10, 11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	7
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9

1	Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
2	Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
3		11b	If relevant, description of the similarity of interventions	n/a
4	Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	11-13
5	<b>Results</b>			
6	Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	40
7		13b	For each group, losses and exclusions after randomisation, together with reasons	40
8	Recruitment	14a	Dates defining the periods of recruitment and follow-up	15
9		14b	Why the pilot trial ended or was stopped	15
10	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	31-33
11	Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	31-45
12	Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-19
13	Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
14	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19
15		19a	If relevant, other important unintended consequences	n/a
16	<b>Discussion</b>			
17	Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	20
18	Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	22
19	Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22
20		22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	22
21	<b>Other information</b>			
22	Registration	23	Registration number for pilot trial and name of trial registry	4
23	Protocol	24	Where the pilot trial protocol can be accessed, if available	7
24	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24,25
25		26	Ethical approval or approval by research review committee, confirmed with reference number	7

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).

For peer review only



# BMJ Open

## Game of Stones: Feasibility randomised controlled trial of how to engage men with obesity in text message and incentive interventions for weight loss

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4 **Game of Stones: Feasibility randomised controlled trial of how to engage men with**  
5 **obesity in text message and incentive interventions for weight loss**  
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19 incentives  
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## ABSTRACT

### Objectives

To examine the acceptability and feasibility of narrative text messages with or without financial incentives to support weight loss for men.

### Design

Individually randomised three-arm feasibility trial with 12 months' follow-up.

### Setting

Two sites in Scotland with high levels of disadvantage according to Scottish Index for Multiple Deprivation (SIMD).

### Participants

Men with obesity (n=105) recruited through community outreach and general practitioner registers.

### Interventions

Participants randomised to a) narrative text messages plus financial incentive for 12 months (SMS+I), b) narrative text messages for 12 months (SMS only), or c) waiting list control.

### Outcomes

Acceptability and feasibility of recruitment, retention, intervention components and trial procedures assessed by analysing quantitative and qualitative data at three, six and 12 months.

### Results

105 men were recruited, 60% from more disadvantaged areas (SIMD quintiles 1 or 2). Retention at 12 months was 74%. Fewer SMS+I participants group (64%) completed 12-month assessments compared to SMS only (79%) and control (83%). Narrative texts were acceptable to many men, but some reported negative reactions. No evidence emerged that level of disadvantage was related to acceptability of narrative texts. Eleven SMS+I participants (31%) successfully met or partially met weight loss targets. The cost of the incentive per participant was £81.94 (95% CI £34.59-£129.30). Incentives were acceptable, but improving health was reported as the key motivator for weight loss. All groups lost

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3 weight (SMS+I -2.51kg (SD=4.94); SMS only -1.29kg (SD=5.03); control -0.86kg  
4 (SD=5.64) at 12 months).  
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### 7 **Conclusions**

8  
9 This three-arm weight management feasibility trial recruited and retained men from across  
10 the socioeconomic spectrum with the majority from areas of disadvantage, was broadly  
11 acceptable to most participants and feasible to deliver.  
12  
13

### 14 **Trial registration**

15  
16  
17 ClinicalTrials.gov Identifier: NCT03040518  
18

### 19 **Funding details**

20  
21 Funded by the National Institute for Health Research Public Health Research Programme  
22 (14/185).  
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## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This weight management study for men with obesity recruited men across the socio-economic spectrum, with a specific focus on more disadvantaged areas, to a randomised controlled feasibility study examining SMS with or without endowment incentives.
- Acceptability and feasibility were established using a multi-lens perspective drawing on quantitative, qualitative and trial procedure data.
- Effectiveness of intervention components will need to be established in a full multi-centre trial.

## BACKGROUND

Obesity is associated with an increased risk of serious health conditions such as type 2 diabetes, cardiovascular disease and some cancers.<sup>1</sup> In 2016, 26% of men in the UK were classified as obese, and men were less likely to be a healthy weight than women (31% of men compared with 35% of women).<sup>2,3</sup>

Despite the growing prevalence of obesity, men contribute a disproportionately low number of participants to evidence-based weight management programmes.<sup>4</sup> Most interventions are designed for mixed sex populations, but systematic review evidence suggests that, compared to women, men often benefit from different ways of providing interventions.<sup>4</sup>

### Text message interventions

The evidence for text message interventions supporting changes in lifestyle behaviours, including behaviour change for weight loss, is promising.<sup>5-7</sup> However, systematic reviews<sup>4-7</sup> report no text message delivered trials that target weight loss designed for men only. Text-based interventions can reach large numbers of people, including men from disadvantaged backgrounds,<sup>8</sup> and mobile technologies such as standard mobile phones allow delivery of evidence-based strategies anywhere and anytime.

Narrative approaches to promoting behaviour change have been suggested as a tool for communication-based interventions.<sup>9</sup> Narrative SMS can be broadly defined as interactive life stories, which are based around a group of characters with whom recipients can identify.<sup>10</sup> Text message based interventions using narratives have been used to engage hard to reach men in moderating their alcohol consumption, and were found to be acceptable.<sup>11-13</sup> Narrative approaches to weight management in men may be a promising tool to support behaviour and weight change.

### Financial incentive interventions

Systematic review evidence of financial incentives for behaviour change highlights the potential for incentives to change behaviours in low-income adults<sup>14</sup> and help reduce health inequalities.<sup>15</sup> However, little evidence exists that focuses on using financial incentives to support weight management in individuals from disadvantaged backgrounds<sup>16,17</sup>, particularly for men<sup>4</sup>. A discrete choice experiment found that paying people (£10-£30/week varying by age and weight) to take part in diet and physical activity (PA) interventions is likely to improve uptake, adherence and maintenance of behaviour change.<sup>18</sup> Moreover, the evidence



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3 for financial incentives for weight loss is growing.<sup>19-22</sup> In particular, deposit contracts, where  
4 participants deposit their own money and are reimbursed only if they achieve the target  
5 weight loss, are effective whilst the incentives are in place.<sup>4 23</sup> Deposit contracts draw on loss  
6 aversion where people are more motivated to avoid losses than they are to achieve similarly  
7 sized gains.<sup>24 25</sup> However, deposit contracts may not be equitable, as committing one's  
8 own money up front may not be possible, particularly for individuals with lower income.

11 Endowment incentive contracts may overcome limitations of deposit contracts. Endowment  
12 incentive contracts are financial incentives where a person is endowed with a (hypothetical)  
13 amount of money which they either 'secure' or 'lose' depending on achieving certain targets.  
14 A trial that framed financial incentives in this way found these incentives were effective for  
15 achieving PA goals in the short term.<sup>26</sup>

### 23 **Aim**

24 The aim of the Game of Stones feasibility trial was to examine the acceptability and  
25 feasibility of a men-only weight management intervention consisting of narrative text  
26 messages, with and without an endowment incentive, compared to waiting list control. The  
27 objectives were to:

- 28 1. Assess the acceptability and willingness to be randomised to: i) narrative text message  
29 and endowment incentives; ii) narrative text messages only; or iii) waiting list for text  
30 messages (control).
- 31 2. Assess the feasibility of recruiting from general practitioner (GP) practice obesity  
32 registers and community venues.
- 33 3. Determine the acceptability of intervention content, feasibility of delivery, fidelity and  
34 any unintended consequences.
- 35 4. Assess indicative effects on weight change and progression criteria for a full trial.

### 36 **METHODS**

37 CONSORT guidance for reporting randomised pilot and feasibility studies was followed<sup>27 28</sup>.

#### 38 **Trial design**

39 A three-arm individually randomised parallel-group controlled feasibility trial was conducted  
40 with an integrated qualitative and quantitative mixed methods approach<sup>29</sup>. Informed by MRC  
41 guidance on the evaluation of complex interventions, the study included an integrated mixed  
42 methods process evaluation<sup>30 31</sup>. Drawing on both qualitative and quantitative approaches  
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3 allowed the team to explore participants views (acceptability) of the intervention with  
4 participants as well as explore implementation processes such as recruitment, retention and  
5 barriers and facilitators to these.  
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9 Participants were randomised to receive narrative text messages and endowment incentives  
10 (SMS+I), narrative text messages only (SMS only), or a waiting list for text messages  
11 (Control). The protocol to the full study is available online:  
12

13 <https://www.journalslibrary.nihr.ac.uk/programmes/phr/1418509/#/>  
14

15  
16 Ethical approval for the study was obtained from the North of Scotland Research Ethics  
17 Service (Ref: 16/NS/0120).  
18

### 19 20 **Setting**

21  
22 Two Health Board areas in Scotland (Sites A and B) with high levels of disadvantage were  
23 the setting for this study (see participant recruitment section for additional details).  
24

### 25 26 **Eligibility criteria**

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28 Participants met the following eligibility criteria: men over 18 years old; BMI  $\geq 30$  kg/m<sup>2</sup>  
29 and/or a waist circumference of  $\geq 40$  inches (102 cm); owned a mobile phone capable of  
30 receiving text messages; could understand English language text messages; not already taking  
31 part in a weight loss study; not planning or waiting to have bariatric surgery; not planning to  
32 move within the next 12 months; considered by practice clinical staff as suitable for  
33 participation (GP practice recruitment only), for example, no severe medical, terminal or  
34 psychiatric illness (in patient or close family member) or no significantly impaired cognitive  
35 function.  
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### 38 39 **Sample size**

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41 This study aimed to randomise 105 men, 35 to each arm, in line with recent recommendations  
42 for pilot trials as sufficient to estimate key parameters for a full trial.<sup>32</sup> A sample size of 35  
43 per arm is sufficient to allow the population variance to be estimated (e.g. the SD in weight  
44 loss) with enough precision to deliver at least 80% power and 90% confidence in a full trial,  
45 with a standardised effect size between 0.2 and 0.5.<sup>32</sup>  
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### 48 49 **Participant recruitment**

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51 Participants were recruited via: 1) community outreach, and 2) GP practice obesity registers.  
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### *Community outreach*

Community recruitment strategies that report success for recruiting men in disadvantaged areas were used.<sup>11-13</sup> This included researchers working on stands with study information leaflets and table banners in supermarkets, fitness centres, hospital foyers, health centres, council workplaces and community centres across both sites. Eleven of the 13 recruitment venues were within more disadvantaged areas based on the Scottish Index of Multiple Deprivation (SIMD quintiles 1 and 2).<sup>33</sup> Men who showed interest were given study information and asked to leave their contact details with researchers.

In addition, some men were recruited through word of mouth. This included researcher discussions with family, friends, colleagues and local workers who passed on study information to eligible men they knew. Information leaflets were distributed across localities in shops, libraries, barbers and community centres. Interested men then contacted researchers to get more information.

### *GP practice obesity register letters*

Practices within more disadvantaged areas (SIMD quintiles 1 or 2) were invited to participate in the study. Of the 33 practices invited (n= 13 in Site A, n=20 in Site B), five practices participated (n=4 in Site A, n=1 in Site B).

Practice database searches identified potentially eligible men with a documented BMI of at least 30kg/m<sup>2</sup>. Lists were screened by clinical practice staff and details passed to the Health Informatics Centre at the University of Dundee who sent out GP-headed study invitation letters and information leaflets. Interested men contacted the research team or returned an 'opt-in' card.

### *Baseline Appointment*

Men interested in participating were invited to attend a face-to-face appointment. Detailed study information was discussed and written informed consent provided. Anthropometric measurements were conducted and eligibility assessed. Participants then completed a baseline questionnaire, and were randomised. Group-specific post-randomisation information was provided and discussed with the participant.

### *Randomisation*

At the baseline appointment, independent randomisation was performed by the researcher using the clinical trials unit's secure remote web-based system, stratifying by recruitment method (GP and community) and recruitment site (Site A and Site B).

### *Blinding*

The two recruitment researchers who also assessed outcomes and conducted qualitative interviews were mostly not blinded to group allocations. All other study team members were blinded. A demonstration of the feasibility for researcher outcome assessors to be blind to group allocation was conducted with eleven participants at the six month assessment. In this case, a researcher who had not previously met the participant arranged and undertook the assessment. These participants all complied with the request not to reveal their group allocation.

The trial statistician was fully blinded to intervention groups, and partially blinded for the control group due to the different response schedule (control participants were only assessed at baseline months and 12 months to reflect "usual life").

## **Intervention components**

### *Narrative text messages*

A narrative text message library consisting of 604 texts was written by a professional scriptwriter/researcher (MG) who designed the overall narrative with enough interlinked stories to engage participants over 12 months. Full details of the narrative texts development process are available elsewhere.<sup>10</sup> Narrative texts were sent to participants over the course of 12 months and were written from the point of view of a fictional character aiming to lose weight over 12 months. Narrative texts were written to appeal to men from disadvantaged backgrounds. All participants in the SMS+I and SMS only groups received automated texts according to a pre-determined schedule. Participants could reply to texts but did not receive a response. Texts were sent between 8:00AM and 10:00PM and ranged from 0-5 texts per day depending in the requirements of the narrative approach used. All participants were scheduled to receive the same number of text messages. Some texts were personalised including participants' names and men could select whether weight information should be presented in kilogrammes or stones and pounds. No further personalisation and tailoring

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3 options were offered. Texts were delivered by the Health Information Centre in Dundee using  
4 existing automated technology linked to a clinical trials unit database.  
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### 7 *Endowment incentive*

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9 The incentive strategy was informed by existing evidence and men's preferences elicited  
10 using a Discrete Choice Experiment completed by 1,045 men with obesity and reported  
11 elsewhere.<sup>10</sup> SMS+I participants were 'endowed' with a £400 incentive at baseline which was  
12 placed into a hypothetical personal account at the University of Stirling and given a mock-up  
13 personalised cheque. The full £400 could be secured by meeting weight loss targets at  
14 researcher assessments: 5% of body weight lost since baseline at three months (£50  
15 secured/lost), 10% lost since baseline at six months (£150 secured/lost) and 10% lost since  
16 baseline at 12 months (£200 secured/lost) (see online supplement 1). Weight loss was  
17 verified at all face-to-face appointments. At six and 12 months, men lost a proportion of the  
18 money for each % weight loss not attained between 5-10%. Weight at 12 months had to be  
19 less than at baseline to receive any money, regardless of whether interim weight loss targets  
20 had been met. Men received the money by direct bank transfer after the 12-month  
21 assessment. Feedback on meeting incentive targets was sent by automated text message and  
22 displayed on the personalised SMS+I webpage.  
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### 34 *Website*

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36 All trial participants were provided with a unique login ID for the Game of Stones website.  
37 The front page was accessible to all participants and included trial information and links to  
38 existing evidence-based online weight management resources. SMS +I and SMS only  
39 webpages had a brief biography and images of the fictional characters featured in narrative  
40 texts. Participants could enter their weight, pedometer steps, waist circumference and belt  
41 notches, which were displayed as basic visual progress charts. Only individual performance  
42 was displayed on the webpage, and no group averages were shown for social comparison.  
43 SMS+I webpages described the financial incentives and a visual progress chart of money  
44 secured/lost.  
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### 52 *Printed information*

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54 All participants received a weight loss fact sheet (British Dietetic Association, Weight Loss  
55 Food Fact Sheet) and a small card which could be carried in their wallet for noting website  
56 details and their appointment weight, weight loss targets and appointments.  
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### *Pedometer*

All participants received a study pedometer (3DFitBud, A420S, manufactured by 3DActive).

### **Comparator group**

At baseline, participants received access to the information section of the webpage, printed information (i.e. a weight loss fact sheet) and a pedometer. They attended a baseline and 12-month appointment only. Control group participants were offered texts for three months commencing after the 12 month data collection point.

### **Outcomes**

The outcomes for this study related to whether the design of Game of Stones was both acceptable and feasible to deliver as a full scale randomised controlled trial. An independent study steering committee advised whether the following pre-specified progression criteria in the study protocol were met sufficiently to proceed to a full trial.

1. Acceptability of the intervention and the control group (by the majority of the target group); willingness to be randomised.
2. Feasibility of recruiting 105 men in four months.
3. 12-month outcomes on at least 72% of men randomised per group, consistent with a recent UK weight management trial in men<sup>34</sup> and systematic reviews of male obesity literature<sup>4</sup>.
4. Evidence of mean weight loss of at least 3% of baseline weight at 12 months in any intervention group.
5. Commitment by, for example, government or NHS/local authorities to fund the incentive intervention to ensure translation and sustainability.

### **Outcome assessment**

Outcomes were assessed at baseline, three, six and 12 months for intervention participants (SMS+I and SMS only), and at baseline and 12 months for control participants. Individual appointments were at community centres, universities, NHS clinical research facilities, voluntary sector organisations, GP practice premises, or the participant's home if no suitable alternative venue could be found. At the 12 month appointment, all participants received a £20 voucher as reimbursement for their time. No travel expenses were provided.

The text message delivery system automatically the frequency of responses received to the texts. The website automatically recorded engagement with self-monitoring tools.

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3 Self-report questionnaires were completed during appointments and measured socio-  
4 demographics, co-morbidities, disability, ethnicity, and perceptions on intervention  
5 acceptability. Overall satisfaction with the intervention was assessed with the item: “*On a*  
6 *scale from 0 (not satisfied at all) to 100 (completely satisfied). How satisfied are you with the*  
7 *Game of Stones programme?*”. Acceptability of the intervention was assessed with the stem  
8 “*Overall the Game of Stones programme has been...*” followed by options ‘*understandable*’,  
9 ‘*useful*’, ‘*helpful*’, ‘*interesting*’ and ‘*relevant*’, with responses captured on a 5-point scale  
10 ranging from ‘*totally disagree*’ to ‘*totally agree*’. Helpfulness of the intervention was  
11 assessed with the item “*How helpful have you found the following in helping you lose*  
12 *weight?*” followed by options ‘*text messages*’, ‘*website*’, and ‘*pedometer*’, with responses  
13 captured on a 5-point scale ranging from ‘*totally unhelpful*’ to ‘*totally helpful*’. Measures of  
14 overall satisfaction, acceptability and helpfulness were adapted from Dombrowski et al.,  
15 (2012).<sup>35</sup>

16  
17 Anthropometry measures included height measured at baseline using a portable standing  
18 stadiometer (Seca 217, Birmingham, UK) to the nearest 0.1cm. Prior to weight  
19 measurements, participants removed shoes and bulky clothing and items from their pockets.  
20 Weight was recorded using portable calibrated electronic scales (Marsden M420, Rotherham,  
21 UK) to the nearest 0.01kg and waist circumference using a tape measure (Seca 203,  
22 Birmingham, UK) to the nearest 0.1cm.

23  
24 Information on possible adverse events was recorded at assessment visits via open questions  
25 and through automatic monitoring of text message replies including words like ‘suicide’,  
26 ‘die’, and ‘death’ indicative of potential adverse events, which were notified to the research  
27 team by email.

28  
29 Any negative participant reactions to their randomised group were recorded in researcher  
30 field notes. Willingness to be randomised was assessed by recording the number of  
31 participants refusing randomisation.

32  
33 Interviews took place during three and 12 month appointments and were conducted face-to-  
34 face and detailed methods are described elsewhere.<sup>10</sup> All audio recorded interviews were  
35 transcribed verbatim and anonymised. At three months, all SMS+I and SMS only men were  
36 invited to participate in either a brief feedback or an in-depth interview (participant choice).  
37 The three month topic guide focussed on the early acceptability of the intervention  
38 components in order to identify any refinements required over the remaining nine month  
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3 intervention. For the 12 month qualitative interviews, separate topic guides for the three trial  
4 groups were informed by the analysis of the three-month interviews, researcher field notes  
5 and to gain information power<sup>36</sup> to address the study objectives. Purposive sampling from the  
6 three trial groups was informed by the three month interview data and researcher field notes  
7 to provide diversity of perspectives. Researcher field notes taken at all assessments were  
8 referred to when interpreting interview data.  
9

10  
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13  
14 Qualitative interviews were conducted face-to-face with 50 of 58 men who attended the three  
15 month assessment (7-61 minutes, median=23 minutes). At 12 months, interviews were  
16 conducted with 14 participants from SMS+I (13-65 minutes, median=33 minutes), 13 from  
17 SMS only (10-59 minutes, median=28 minutes) and six from the control group (7-18  
18 minutes, median=11 minutes). Fourteen interviews at 12 months lasted <20 minutes, mostly  
19 for control participants who had received no contact from the research team between baseline  
20 and 12 months.  
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## 26 **Analysis**

### 27 *Quantitative analysis*

28  
29  
30 All continuous variables were summarised and tabulated using the following descriptive  
31 statistics: N (number of valid non-missing responses), mean, standard deviation (SD). Likert-  
32 scale variables were treated as continuous measures. The frequency and percentages (based  
33 on the non-missing sample size) of observed levels are reported for all categorical measures.  
34 The proportion of individuals contacted who were recruited and the proportions retained and  
35 withdrawn at each assessment by group was determined. Missing weight data are presented  
36 as baseline observation carried forward (BOCF) and last observation carried forward (LOCF)  
37 in addition to observed cases only.  
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### 45 *Qualitative and mixed method data analysis*

46  
47 Anonymised transcripts of interviews together with: attributes for recruitment channel;  
48 attendance at assessments, trial group and participant characteristics and weight loss  
49 outcomes were entered into NVivo12 software for analysis guided by the framework  
50 approach.<sup>37</sup> Reference to researcher field notes contributed to interview data interpretation.  
51 Iterative data collection and analysis were driven by the key feasibility and acceptability  
52 research questions and objectives. A coding frame was developed by three researchers  
53 independently reading a diverse sample of six interviews, followed by a team discussion to  
54 finalise the coding frame and identify key themes. Independent coding was conducted by four  
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3 researchers (EC, NG, MM and RS) and checked for consistency by FH. Two independent  
4 researchers (EC and NG) who were not involved in any other aspect of the study, assisted  
5 with coding and analysis to enhance rigour and reliability of data analysis. Emergent themes  
6 and interpretive analysis were discussed at weekly researcher meetings and at two Co-  
7 Investigator qualitative interpretation meetings.  
8  
9

10  
11  
12 At the final stage of mixed methods data interpretation, the quantitative attributes on NVivo  
13 were drawn on to triangulate the analysis and suggest further avenues for interrogation.  
14 Matrix coding queries in NVivo were generated to cross-reference attributes for trial group,  
15 participant SIMD and weight loss outcome at 12 months, with nodes coded for views of  
16 incentives and texts messages respectively. Credibility and reliability of qualitative analysis  
17 was enhanced by independent coding, use of memos to ensure transparency of interpretation,  
18 and interpretive charting conducted with input from the wider study team.  
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### 24 **Patient and Public Involvement**

25  
26  
27 A continuous and responsive approach to patient and public involvement (PPI) was adopted  
28 to prepare the grant application and throughout the study, as described by Gamble and  
29 colleagues.<sup>38</sup>  
30  
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32  
33 Continuous PPI was provided by a Co-Investigator partnership with the Charities Men's  
34 Health Forum GB and Men's Health Forum in Ireland. The partnership commenced in 2011  
35 with the ROMEO evidence syntheses of weight loss interventions for men with obesity.<sup>4</sup>  
36  
37

38  
39 During the study, Co-Investigators from each of the Men's Health Forum charities attended  
40 trial management meetings to contribute to decisions, intervention development, data  
41 analysis, interpretation of findings and reporting. They provided feedback on the grant  
42 application, protocol, text messages, information materials and engaged wider involvement of  
43 men from their organisation to assist with appropriate language.<sup>39</sup>  
44  
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46

47  
48 Continuous PPI at the study oversight level was provided by two independent lay members of  
49 the study steering committee which met on three occasions.  
50

51  
52 Responsive PPI occurred at the study funding application stage. Co-Investigator CG engaged  
53 men who provided PPI input in the FFIT Trial.<sup>34</sup> During the study, relevant members of the  
54 public were identified through several sources including: Men's Health Forum GB, Men's  
55 Health Forum in Ireland, Scottish Community Health Councils, Men's Sheds, University of  
56 Stirling PPI group, Alliance Scotland and other Co-Investigator contacts. Effort was made to  
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engage men from more disadvantaged communities. A total of 121 PPI contributors were involved in a range of study activities, including finding a study name, helping with wording of information material, and helping with designing the intervention content. For full details see the report to the funder.<sup>10</sup>

## RESULTS

### Recruitment and retention

Recruitment was completed in four months between March to June 2017 meeting the target number of 105 men randomised (Figure 1).

Overall, 177 men expressed an interest in the study. Baseline appointments were attended by 111 (63%), of which six (5%) were ineligible. All 105 men were willing to be randomised and consented to be randomised to the SMS+I (n=36), SMS only (n=33) and control (n=36) groups.

GP practice recruitment was undertaken in five GP practices (Site A n=4, Site B n=1) with 45 men recruited and randomised through GP practices. The additional 60 men were recruited through community outreach.

--- Figure 1 ---

The 12 month assessment was completed by 79/105 participants (75%). One of the 79 participants (control group) could not attend and provided self-reported information because he was out of the region due to work commitments, which means that 74% (78/105) of participants were retained for weight assessments at 12 months. Overall 12 month retention differed by group (SMS+I=23/36, 64%; SMS only=26/33, 79%; control=30/36, 83%). Fourteen participants (13%) were lost to follow-up, and 12 participants (11%) withdrew. Reasons for withdrawal were dislike of narrative texts (n=4), health (n=3), family (n=1), unknown (n=1), dissatisfaction with group allocation (n=1), appointment logistics (n=1) and multiple reasons (n=1).

### Baseline characteristics

Baseline characteristics are displayed in Table 1. On average, participants were 52.2 (SD=13.1) years old, had a BMI of 35.7 (SD=5.9) and a waist circumference of 116.8 cm (SD=11.8). BMI ranged from 27.5 kg/m<sup>2</sup> to 62.5kg/m<sup>2</sup>. Twelve participants (11%) had a baseline BMI less than 30 kg/m<sup>2</sup> due to the additional weight circumference entry criterion of  $\geq 40$  inches (102 cm).

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2  
3 The majority of men lived in disadvantaged areas defined as SIMD quintiles 1 or 2  
4 (n=62/104; 60%). Most participants were married (58%), reported at least one co-morbidity  
5 (63%), were of white ethnicity (91%), reported having children (76%), and were in full-time  
6 employment (48%).  
7  
8  
9

10 --- Table 1 ---  
11

### 12 **Intervention fidelity**

13  
14  
15 The intervention components were feasible to deliver with fidelity. The majority (95.4%) of  
16 the 38,214 text messages sent to the two intervention groups were delivered to the mobile  
17 phone, with 1,782 (4.6%) having no delivery status (i.e. lack of response from the mobile  
18 phone provider after 48 hrs and invalid phone numbers). No major technical errors occurred.  
19 All participants who secured financial incentives were paid by direct bank transfer, in line  
20 with their stated preference.  
21  
22  
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### 25 **Acceptability of intervention components**

#### 26 *Overall acceptability ratings and contamination*

27  
28 Table 2 displays intervention satisfaction indicators over the course of the study for  
29 participants attending assessments. Overall mean study satisfaction at 12 months was 81%,  
30 77% and 87% for the SMS+I, SMS only and control groups respectively. Satisfaction over  
31 time was comparable between both intervention groups. For scores on specific programme  
32 attributes see Table 2.  
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39  
40 Helpfulness ratings of the narrative texts, webpage and pedometer were highest for the  
41 pedometer and relatively stable throughout the measurement time points. At 12 months,  
42 helpfulness ratings (out of 5) for the pedometer were 3.9, 4.0, and 3.7 for the SMS+I, SMS  
43 only and control groups respectively. The narrative texts (SMS+I=3.4; SMS only=3.3) and  
44 the webpage (SMS+I=3.6; SMS only=3.4; control=3.5) were perceived as somewhat helpful  
45 on average at 12 months.  
46  
47  
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49

50 Minimal contamination between intervention groups was observed, with one participant at  
51 six and 12 months (SMS+I group) and another at 12 months (control group) reporting  
52 meeting other men in the study.  
53  
54

55 --- Table 2 ---  
56  
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### *Acceptability of narrative text messages*

Some men sent spontaneous replies to the narrative texts (0-3 months n=25/69, 36%; 3-6 months n=8/69, 12%, 6-12 months n=13/69, 19%; see online supplement 2). Most spontaneous replies were received between 0-3 months (n=370 replies) and decreased at 3-6 months (n=16 replies) and 6-12 months (n=39 replies).

Eleven participants (11/69, 16%) requested to no longer receive texts but asked to remain in the trial. Requests to stop narrative texts were similar in both groups (SMS+I=5/36, 14%; SMS only=6/33, 18%), and occurred throughout the study. Four participants (4/69, 6%) withdrew due to dislike of narrative texts between baseline and three months, two in each intervention group.

Qualitative interviews at three and 12 months demonstrated varied views on the narrative texts. Participants' views ranged from positive to indifferent to negative. Those who liked the narrative texts found the storyline entertaining, engaging and some participants felt a certain camaraderie for the main character:

*You get involved in the content and you start following the script, they're very funny and me being a [from city name] you can see the funny side and you can see the wit in that, .... and that's what keeps you reading them. (210010, SMS only, 12m)*

For other participants, the frequency of texts became a source of irritation, the storyline did not resonate with their own experience nor could they empathise with the fictional characters:

*I'm not a lover of chocolate, biscuits, cake, ice cream, I hardly ever touch them, hardly ever, so hearing about somebody eating pizza or sweets means nothing to me because I don't eat them anyway (120002, SMS+I, 12m)*

Some were uncertain of the role of the texts in helping to support weight loss. Others expressed an indifference towards the texts, and a decreasing interest in the story over time leading to infrequent engagement with text content. However, the regular reminder of being a participant in a weight loss programme through receiving texts was seen as important:

*I often wonder, do they relate to myself here. And the only commonality is both trying to lose weight. So in that respect it's just a reminder all the time, you should be reviewing your weight and watching what you're eating, so...from that it's a positive, yeah. (220017, SMS+I, 3m)*

1  
2  
3 A matrix coding query and analysis of the quotations generated from the NVivo qualitative  
4 and demographic data suggested no obvious relationships between the participant SIMD level  
5 and the qualitative accounts of acceptability of the narrative texts. This is in line with  
6 quantitative data showing similar acceptability ratings for overall programme satisfaction and  
7 helpfulness ratings of the narrative texts across SIMD levels (see online supplement 3). Some  
8 men would have liked more interactivity built into the texts, however, the text message  
9 system was set up for uni-directional messaging only.

#### 16 *Acceptability of endowment incentive*

17  
18 At three months, 31/36 SMS+I participants attended the appointment, with eight men losing  
19 5% or more of their baseline weight and securing £50. Attendance at six months was lower  
20 (n=23/36), with five participants achieving the weight loss target of >10% weight loss  
21 securing £150 each, and a further three participants losing between ≥5-10% of weight  
22 securing between £75-150. At 12 months, 23/36 participants attended the appointment, with  
23 three achieving >10% weight loss securing £200, and a further seven losing between ≥5-10%  
24 of weight securing between £100-200.

25  
26 Overall, £2,955 was paid in total to the 11 participants (11/36, 31%) successfully meeting or  
27 partially meeting weight loss targets. The full £400 was secured by three participants (3/36,  
28 8%). The cost of the incentive per participant was £81.94 (95% CI £34.59-£129.30). All  
29 participants who completed the study and secured money at three or six months received it at  
30 the end of the study. No participant lost previously secured money due to weight regain to  
31 baseline weight at 12 months. One participant secured money at an early appointment but  
32 withdrew from the study, did not attend at 12 months, and did not receive any money.

33  
34 No negative views were expressed about the incentives in qualitative interviews. Only one  
35 man reported being motivated by the financial incentive, and many expressed indifference.  
36 Participants reported the weight loss and health benefits as sufficiently rewarding.

37  
38  
39 *The money's not that much of an issue. I think the incentive for me is the health*  
40 *that, at the end of the day, your health improves. That's the most important*  
41 *incentive. The money, it's fine, it's there, but it's not the incentive (120022, SMS+I,*  
42 *3m)*

43  
44 Some interpreted the incentives as a final reward linked to their weight loss targets, whereas  
45 others fully understood the intended use of the loss aversion concept:

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2  
3 [W]e all know how much more distress it causes you to lose money than the  
4 pleasure of finding a fiver down the back of the couch, you know, so I think if you  
5 lose something it almost has a bigger impact on you than if you gain. (220040,  
6 SMS+I, 3m)  
7  
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### 10 *Acceptability of study webpages and pedometer*

11  
12 Some participants used the self-monitoring features on the webpage (see online supplement  
13 2) and reported valuing the ability to visually track their weight in interviews. However, most  
14 did not access the website. The majority (77%) did not own a pedometer at baseline, and  
15 pedometers were highly acceptable to participants.  
16  
17  
18  
19

### 20 **Acceptability of Control Group**

21  
22 Most control group participants (30/36, 83%) attended the 12 month appointment. Six  
23 qualitative interviews were conducted with men in the control group covering topics  
24 including acceptability of waiting 12 months for text messages, views about the study and  
25 improvement suggestions. Many reported being pleased to be involved in a research study.  
26 One participant had a strong negative reaction to being randomised to the control group and  
27 subsequently withdrew when invited to the 12 month assessment.  
28  
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### 33 **Weight outcomes**

34  
35 Table 3 displays weight change outcomes at three, six, and 12 months. The difference in  
36 mean percentage weight loss at 12 months for observed cases was -2.51% (95% CI -6.03 to  
37 1.01) for SMS+I v control and -0.51% (95% CI -3.91 to 2.89) for SMS only v control. The  
38 difference in absolute weight loss at 12 months was -2.87kg (95% CI -6.82 to 1.08) for  
39 SMS+I v control and -0.57kg (95% CI -4.40 to 3.25) for SMS only v control.  
40  
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44

45 ---Table 3 ---

46  
47 The SMS+I group displayed mean weight loss of over 3% at 12 months (-3.51%, SD=5.83).  
48 The SMS only and control groups remained below 3% weight loss on average (SMS only=-  
49 1.51%, 4.65; control=-1.00%, SD=5.31). The highest mean percentage weight loss at 12  
50 months for BOCF was -2.24% (SD=4.93) in the SMS+I group, followed by -1.19%  
51 (SD=4.16) and -0.80% (SD=4.77) in the SMS only and control groups respectively.  
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55

### 56 **Harms and unintended consequences**

57  
58 No harms or unintended consequences were reported.  
59  
60

## Progression to full trial

An independent study steering committee agreed that the Game of Stones study had demonstrated acceptability and feasibility agreeing that overall the pre-specified progression criteria were sufficiently met to support a full three-arm multi-site RCT.

## DISCUSSION

### Principal findings

This study successfully recruited 105 men from across the socioeconomic spectrum to a three-armed RCT and overall achieved 74% retention at 12 months' follow-up. Men living in more disadvantaged areas formed 60% of the sample. Narrative texts were broadly acceptable, but some participants disengaged or withdrew from the study due to dislike of texts. The endowment incentives were acceptable, and improving health was reported as a key motivator for weight loss. Positive indicative effects of weight loss were found in intervention and control groups.

### Strengths and weaknesses of the study

This study was underpinned by the ROMEIO systematic reviews and qualitative evidence synthesis of weight loss interventions for men with obesity<sup>40 41</sup>, with a continuing PPI partnership with the Men's Health Forum GB and Ireland charities. Mixed methods research combined quantitative and qualitative data which, together with patient, public and stakeholder involvement, provided a multi-lens perspective on this study.

Most assessments were not blind to group allocation. The difference in assessment schedules for intervention and control groups meant that study staff were only partially blind. A full trial should ensure full blinding of all outcome assessments. Researchers were unable to collect data via qualitative interviews, questionnaires and anthropometric measures with men who withdrew from the study or were lost to follow-up at the 12 month appointment. Those providing a withdrawal reason may have provided socially desirable responses. Text messages were personalised by including the participant's name and weight unit preference, but no tailoring or interactivity were possible due to technical limitations of the delivery system. This feasibility trial was not powered to detect effects on weight loss and, in line with recommendations<sup>27</sup>, no p-values are reported. Weight outcomes should be interpreted with caution.

### Relation to other studies

The Game of Stones study adds to the evidence base demonstrating the feasibility of recruiting men for research on sensitive subjects, such as obesity, through community outreach and GP practice lists.<sup>11-13</sup>

The average BMI and age of the study participants of around 35kg/m<sup>2</sup> and 50-55 years is similar to UK weight management trials recruiting in the community<sup>34</sup>, primary care<sup>42</sup>, or a combination of community and primary care.<sup>12</sup> Three international text message based weight management studies examining outcomes after 12 months recruited younger participants with lower BMI.<sup>43-45</sup> However, three mixed sex weight management studies with financial incentives (two including text message components) reported broadly similar participant demographics to this study.<sup>46-48</sup>

Retention levels of 74% were acceptable and are similar to systematic review evidence of men-only weight loss interventions which found an average retention of 78%, ranging from 44% to 100%.<sup>41</sup> International text message studies with mixed sex participants report similar retention rates at 12 months of 70.3%<sup>44</sup> and 73%<sup>43</sup>, with one study conducted in Latvia reporting 93% retention<sup>45</sup>. Two large UK studies recruiting mixed sex participants with obesity to weight management in primary care reported 75%<sup>42</sup> and 81%<sup>49</sup> retention at 12 months.

Two previous narrative text message intervention studies in men targeting alcohol reduction reported high acceptability levels and no negative reactions.<sup>12 13</sup> However, these studies were only 12 weeks in duration and overall contained fewer texts. The narrative texts in this study were broadly acceptable, although some negative reactions were reported. Study withdrawal due to texts and requests to stop texts suggest that the current narrative texts may not be universally acceptable to men. The text messages were designed by a professional scriptwriter/researcher with PPI input from the target population of men from disadvantaged backgrounds, but the narrative texts were similarly acceptable across the socio-economic spectrum. Intervention fidelity was high with the majority of sent texts successfully delivered and no adverse events were encountered, similar to previous text message-based intervention studies.<sup>11-13</sup>

The use of a financial incentive strategy for weight loss in men with obesity across the socioeconomic spectrum was feasible and acceptable. Two previous incentive studies used text messages to inform participants about their incentive achievement of weight loss targets,



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2  
3 and found it acceptable.<sup>46 47</sup> This extends the evidence base on the use of financial incentives  
4 as a complementary behaviour change strategy alongside other components.<sup>22 50</sup>  
5  
6

7 The financial incentive strategy was designed with future sustainability in mind and to be  
8 attractive to public sector funders. The text messages and incentive components are mostly  
9 automated, encourage self-management of weight and have a low administrative burden with  
10 one bank transfer pay out after 12 months, and verification of weight loss at three, six and 12  
11 months. Yancy et al. similarly provided incentives at three and six months for their six  
12 months' incentive intervention<sup>46</sup>. John et al. asked participants to be weighed monthly, for  
13 which they received \$20 per visit.<sup>47</sup> Few RCTs examine financial incentive strategies that are  
14 delivered for at least 12 months.<sup>50</sup> Two other studies providing financial incentives for 12  
15 months provided an intensive financial incentive schedule either weekly<sup>51</sup> or monthly<sup>52</sup>.  
16 Previous studies typically provided participants with weekly weight loss goals such as 11lb  
17 (0.45kg) per week, on which financial incentives were contingent.<sup>50</sup> Whilst these goals are  
18 similar to the weight loss targets in the current study, there were no intermittent or weekly  
19 targets. A balance needs to be struck between having more regular weight measurements and  
20 more immediate pay-outs, costs and future sustainability.  
21  
22

23 Patel et al. applied a similar framing which they called a loss incentive<sup>26</sup>. University  
24 employees were allocated a monthly hypothetical incentive of \$42 upfront and \$1.40 was  
25 taken away each time their daily goal of 7000 steps was not met. The current study adds to  
26 the evidence base demonstrating the acceptability and feasibility of loss framed interventions  
27 for weight loss and in settings outside workplaces.  
28  
29

### 30 31 32 **Conclusion**

33 This study tests a novel combination of narrative SMS with endowment incentives that have  
34 not previously been combined in this way to address weight loss and weight loss maintenance  
35 in men with obesity. This three-arm feasibility trial recruited men from across the  
36 socioeconomic spectrum with the majority coming from disadvantaged areas, had an  
37 acceptable retention rate, and was broadly acceptable to most participants, and feasible to  
38 deliver. Acceptability and feasibility progression criteria were met. A full trial is warranted to  
39 determine effectiveness and cost-effectiveness, with consideration of scalability.  
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The Study Steering Committee:

Associate Professor Ed Juszcak, Director, NPEU Clinical Trials Unit, Nuffield Department of Population Health, University of Oxford (Chair).

Professor Kate Jolly, Professor of Public Health & Primary Care, University of Birmingham.

Mr. Mark Kelvin, Programme Director (until 2018), Health and Social Care Alliance Scotland (the ALLIANCE).

1  
2  
3 Mr. Andrew Shanahan, Director MAN v FAT - the weight loss website for men  
4

5 Ms. Martine Stead, Deputy Director, Institute for Social Marketing, University of Stirling  
6

7 Miss Joyce Thompson Dietetic Consultant in Public Health Nutrition and Tayside Nutrition  
8  
9 MCN Lead Clinician, NHS Tayside.  
10

## 11 **AUTHOR CONTRIBUTIONS**

12  
13 SD co-led the study with PH as joint Chief-Investigator and co-led the design and overall  
14  
15 conduct of the study and led the writing of the manuscript, overseen by PH.  
16

17  
18 MM undertook the study set up, recruitment and data collection, co-ordinated various PPI  
19  
20 activities, contributed substantially to qualitative and quantitative data analysis and  
21  
22 interpretation. MvdP was a co-investigator, contributed to the design and the interpretation of  
23  
24 findings and led the DCE and health economic analysis. MG was a co-investigator,  
25  
26 contributed to the design and the interpretation of findings and led the development of the  
27  
28 narrative SMS component, the related PPI. AA was a co-investigator, contributed to the  
29  
30 design and the interpretation of findings. PC and MT linked to PPI networks, contributed to  
31  
32 the design, and interpretation of the findings. AE was a co-investigator, contributed to the  
33  
34 design and the interpretation of findings and oversaw the statistical analysis. NG and EC  
35  
36 contributed to the analysis and interpretation of the qualitative data. CG was a co-  
37  
38 investigator, facilitated PPI, contributed to the design, and interpretation of findings. FH was  
39  
40 a co-investigator, oversaw the qualitative data collection and analysis and contributed to the  
41  
42 interpretation of findings. AH undertook the statistical analysis at Tayside Clinical Trials  
43  
44 Unit. CJ was a co-investigator, contributed to the design and the interpretation of findings  
45  
46 and oversaw the automated SMS delivery system, recruitment tracking, the study website and  
47  
48 integration of data with databases at Tayside Clinical Trials Unit. FK and MMcK were co-  
49  
50 investigators and contributed to the design and the interpretation of findings. RS contributed  
51  
52 to recruitment, data collection and undertaking qualitative interviews and contributed to the  
53  
54 interpretation of findings.

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52  
53 This report presents independent research commissioned by the NIHR. The views and  
54  
55 opinions expressed by authors in this publication are those of the authors and do not  
56  
57 necessarily reflect those of the NHS, the NIHR, MRC, CCF, NETSCC, the Public Health  
58  
59 Research programme or the Department of Health. The views and opinions expressed by the  
60

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2  
3 interviewees in this publication are those of the interviewees and do not necessarily reflect  
4 those of the authors, those of the NHS, the NIHR, MRC, CCF, NETSCC, the Public Health  
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12  
13

#### 14 **COMPETING INTERESTS**

15  
16 Dr Grindle is Director of Eos Digital Health Ltd which holds all rights to DNA - The Digital  
17 Narrative Approach deployed to design and write the narrative text intervention.  
18  
19

20  
21 No other competing interests were declared.  
22

#### 23 **DATA AVAILABILITY**

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25 Access to data can be arranged through the Co-PIs of the study: Prof. Pat Hoddinott,  
26 (University of Stirling, p.m.hoddinott@stir.ac.uk) and Dr. Stephan Dombrowski (University  
27 of New Brunswick, stephan.dombrowski@unb.ca) to discuss data sharing, data requirements  
28 and conflicts of interest, in line with any EU and other regulations, including ethics  
29 approvals.  
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**Table 1 Participant baseline characteristics**

	<b>SMS + I</b>	<b>SMS only</b>	<b>Control</b>	<b>Total</b>
	<b>N=36</b>	<b>N=33</b>	<b>N=36</b>	<b>N=105</b>
Age (years), mean (SD)	50.9 (14.2) <sup>a</sup>	52.5 (15.1) <sup>b</sup>	53.1 (10.1)	52.2 (13.1) <sup>c</sup>
Waist circumference (cm), mean SD	115.8 (10.0)	114.9 (12.7)	119.5 (12.2)	116.8 (11.8)
Weight (kg), mean (SD)	108.6 (16.4)	107.8 (20.2)	110.7 (19.0)	109.1 (18.4)
Height (cm), mean (SD)	175.9 (6.6)	175.2 (6.7)	173.8 (5.9)	175.0 (6.4)
BMI (kg/m <sup>2</sup> ), mean (SD)	35.1 (5.3)	35.1 (5.9)	36.7 (6.5)	35.7 (5.9)
<b>BMI (kg/m<sup>2</sup>) categories, n (%)</b>				
<30	5 (13.9)	3 (9.1)	3 (8.3)	11 (10.5)
≥30->35	16 (44.4)	19 (57.6)	14 (38.9)	49 (46.7)
≥35->40	10 (27.8)	6 (18.2)	7 (19.4)	23 (21.8)
≥40->45	4 (11.1)	2 (6.1)	10 (27.8)	16 (15.2)
≥45->50	0 (0.0)	2 (6.1)	1 (2.8)	3 (2.9)
≥50	1 (2.8)	1 (3.0)	1 (2.8)	3 (2.9)
<b>SIMD deprivation category, n (%)</b>				
SIMD 1 (most disadvantaged)	11 (31.4) <sup>a</sup>	12 (36.4)	15 (41.7)	38 (36.5) <sup>d</sup>
SIMD 2	8 (22.9) <sup>a</sup>	9 (27.3)	7 (19.4)	24 (23.1) <sup>d</sup>
SIMD 3	6 (17.1) <sup>a</sup>	3 (9.1)	3 (8.3)	12 (11.5) <sup>d</sup>
SIMD 4	4 (11.4) <sup>a</sup>	4 (12.1)	6 (16.7)	14 (13.5) <sup>d</sup>
SIMD 5 (least disadvantaged)	6 (17.5) <sup>a</sup>	5 (15.2)	5 (13.9)	16 (15.4) <sup>d</sup>

**Marital status, n (%)**

Cohabiting	4 (11.1)	2 (6.3) <sup>e</sup>	5 (13.8)	11 (10.6) <sup>d</sup>
Divorced	2 (5.6)	0 (0.0) <sup>e</sup>	2 (5.6)	4 (3.9) <sup>d</sup>
Married	22 (61.1)	21 (65.6) <sup>e</sup>	17 (47.2)	60 (57.7) <sup>d</sup>
Separated	1 (2.8)	3 (9.4) <sup>e</sup>	2 (5.6)	6 (5.8) <sup>d</sup>
Single	7 (19.4)	5 (15.6) <sup>e</sup>	8 (22.2)	20 (19.2) <sup>d</sup>
Widowed	0 (0)	1 (3.1) <sup>e</sup>	1 (2.8)	2 (19.2) <sup>d</sup>
Prefer not to say	0 (0.0)	0 (0.0) <sup>e</sup>	1 (2.8)	1 (1.0) <sup>d</sup>

**Comorbidities, n (%)**

Arthritis	11 (30.6)	3 (9.1)	8 (22.2)	22 (21.0)
Cancer	0 (0.0)	0 (0.0)	1 (2.8)	1 (1.0)
Diabetes	4 (11.1)	5 (15.2)	6 (16.7)	15 (14.3)
Myocardial infarction	2 (5.6)	1 (3.0)	0 (0.0)	3 (2.9)
Hypertension	7 (19.4)	8 (24.2)	7 (19.4)	22 (21.0)
Stroke (including TIA)	1 (2.8)	1 (3.0)	0 (0.0)	2 (1.9)

**Ethnic group, n (%)**

Asian	2 (5.6)	1 (3.1) <sup>e</sup>	1 (2.8)	4 (3.8) <sup>d</sup>
Black	2 (5.6)	1 (3.1) <sup>e</sup>	1 (2.8)	4 (3.8) <sup>d</sup>
White	32 (88.8)	29 (90.7) <sup>e</sup>	34 (94.4)	95 (91.4) <sup>d</sup>
Prefer not to say	0 (0.0)	1 (3.1) <sup>e</sup>	0 (0.0)	1 (1.0) <sup>d</sup>

**Education**

Bachelor Degree (=SVQ5)	7 (19.4)	6 (19.5) <sup>b</sup>	11 (30.6)	24 (23.3) <sup>f</sup>
HNC/ HND (=SVQ4)	4 (11.1)	6 (19.5) <sup>b</sup>	2 (5.6)	12 (11.6) <sup>f</sup>
Higher Grade/ Advanced Higher/ A-Level or equivalent (=SVQ3)	3 (8.3)	5 (16.1) <sup>b</sup>	1 (2.8)	9 (8.7) <sup>f</sup>
Masters/ PhD or equivalent	1 (2.8)	1 (3.2) <sup>b</sup>	3 (8.3)	5 (4.8) <sup>f</sup>
No formal qualifications	7 (19.4)	3 (9.7) <sup>b</sup>	10 (27.8)	20 (19.4) <sup>f</sup>
Standard Grade/GCSE/ Intermediate 1 or 2	6 (16.7)	7 (22.6) <sup>b</sup>	4 (11.1)	17 (16.5) <sup>f</sup>
Still studying	2 (5.6)	1 (3.2) <sup>b</sup>	3 (8.3)	6 (5.8) <sup>f</sup>
Vocational qualifications (=SVQ1+2)	4 (11.1)	1 (3.2) <sup>b</sup>	0 (0.0)	5 (4.8) <sup>f</sup>
Other	0 (0.0)	1 (3.2) <sup>b</sup>	0 (0.0)	1 (1.0) <sup>f</sup>
Prefer not to say	2 (5.6)	0 (0.0) <sup>b</sup>	2 (5.6)	4 (3.9) <sup>f</sup>
<b>Working status, n (%)</b>				
Full time student	4 (11.1)	2 (6.3) <sup>e</sup>	1 (2.8)	7 (6.7) <sup>d</sup>
Employed - Full time (30+ hours per week)	16 (44.4)	16 (50.0) <sup>e</sup>	18 (50.0)	50 (48.1) <sup>d</sup>
Employed - Part time (8-29 hours per week)	3 (8.3)	3 (9.4) <sup>e</sup>	0 (0.0)	6 (5.8) <sup>d</sup>
Self-employed	3 (8.3)	3 (9.4) <sup>e</sup>	1 (2.8)	7 (6.7) <sup>d</sup>
Not in paid work	2 (5.6)	2 (6.2) <sup>e</sup>	12 (33.3)	16 (15.4) <sup>d</sup>
Retired	8 (22.2)	6 (18.7) <sup>e</sup>	4 (11.1)	18 (17.3) <sup>d</sup>
Household size, mean (SD)	2.6 (1.3)	2.6 (1.0)	2.4 (1.4)	2.5 (1.3)

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3 *Note:* <sup>a</sup> N=35, <sup>b</sup> N=31, <sup>c</sup> N=102, <sup>d</sup> N=104, <sup>e</sup> N=32, <sup>f</sup> N=103; BMI = Body Mass Index, CM =  
4 centimetres, GCSE = General Certificate of Secondary Education, kg = kilogram, N = overall  
5 participants, n = participants within specific category, SD = Standard Deviation, SIMD =  
6 Scottish index of multiple deprivation 1 represents the most disadvantaged area; quintile  
7 SIMD 5 represents the least disadvantaged area, SVQ = Scottish Vocational Qualification  
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For peer review only

**Table 2 Programme satisfaction, and contamination at three, six and 12 months**

	3 months		6 months		12 months		
	SMS + I (N=31)	SMS only (N=27)	SMS + I (N=23)	SMS only (N=21)	SMS + I (N=22)	SMS only (N=26)	Control (N=30)
Programme satisfaction (0-100), mean (SD)	80.3 (21.1)	75.0 (22.2)	76.2 (29.6)	79.0 (20.7)	80.9 (20.0)	77.0 (20.8)	87.3 (17.5) <sup>a</sup>
<b>Programme has been... (1 = low, 5 = high), mean (SD)</b>							
understandable	4.5 (0.9)	4.4 (0.8) <sup>b</sup>	4.4 (1.2) <sup>c</sup>	4.4 (1.2)	4.6 (1.1) <sup>d</sup>	4.6 (1.1) <sup>e</sup>	4.6 (0.9) <sup>a</sup>
useful	4.4 (0.9)	4.0 (1.0)	4.1 (1.3)	4.1 (1.1) <sup>d</sup>	4.1 (1.2)	4.0 (1.0)	4.3 (0.9)
helpful	4.3 (0.9) <sup>f</sup>	3.9 (1.0)	4.1 (1.3)	4.1 (1.1) <sup>d</sup>	4.1 (1.10)	4.0 (1.0)	4.3 (0.9)
interesting	4.3 (1.0)	4.2 (1.1)	4.2 (1.1)	4.4 (1.3) <sup>d</sup>	4.3 (0.8)	4.3 (1.2)	4.5 (1.0)
relevant	4.2 (1.1)	3.9 (1.2)	4.0 (1.3)	4.3 (1.1) <sup>d</sup>	4.1 (1.1)	4.2 (1.1)	4.5 (1.0)
<b>Helpfulness (1 = low, 5 = high), mean (SD)</b>							
Text messages	3.4 (1.5)	3.1 (1.3)	3.1 (1.3)	3.6 (1.3)	3.4 (1.3)	3.3 (1.4)	n/a

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Website	3.3 (1.2) <sup>g</sup>	3.3 (0.9) <sup>b</sup>	3.3 (1.2)	3.2 (0.8) <sup>d</sup>	3.6 (1.0)	3.4 (0.7) <sup>h</sup>	3.5 (1.1) <sup>b</sup>
Pedometer	4.1 (1.2) <sup>f</sup>	4.1 (0.9)	3.7 (1.4)	4.0 (1.0)	3.9 (1.2) <sup>i</sup>	4.0 (1.0) <sup>e</sup>	3.7, (1.4)
<b>Met other men in programme, n (%)</b>							
Yes	0 (0.0)	0 (0.0)	1 (4.3)	0 (0.0)	1 (4.5)	0 (0.0)	1 (3.3)

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*Note.* <sup>a</sup> N=29, <sup>b</sup> N=26, <sup>c</sup> N=22, <sup>d</sup> N=20, <sup>e</sup> N=25, <sup>f</sup> N=30, <sup>g</sup> N=28, <sup>h</sup> N=24, SD = Standard Deviation.

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**Table 3 Weight change at three, six, and 12 months**

	3 months		6 months		12 months		
	SMS + I	SMS only	SMS + I	SMS only	SMS + I	SMS only	Control
	N=36	N=33	N=36	N=33	N=36	N=33	N=36
<b>Weight change (kg), mean (SD)</b>							
Observed cases only	2.79 (3.50) <sup>a</sup>	-1.97 (3.97) <sup>b</sup>	-4.59 (5.62) <sup>c</sup>	-3.30 (4.92) <sup>d</sup>	-3.93 (5.74) <sup>c</sup>	-1.64 (5.64) <sup>b</sup>	-1.06 (6.29) <sup>e</sup>
BOCF	-2.40 (3.38)	-1.55 (3.60)	-2.93 (4.98)	-2.10 (4.21)	-2.51 (4.94)	-1.29 (5.03)	-0.86 (5.64)
LOCF	-2.40 (3.38)	-1.86 (3.88)	-3.38 (4.92)	-2.21 (4.39)	-2.98 (4.91)	-1.33 (5.04)	-0.86 (5.64)
<b>Weight change (%), mean (SD)</b>							
Observed cases only	-2.54 (3.47) <sup>a</sup>	-1.95 (3.72) <sup>b</sup>	-4.20 (5.54) <sup>c</sup>	-3.02 (4.22) <sup>d</sup>	-3.51 (5.83) <sup>c</sup>	-1.51 (4.65) <sup>b</sup>	-1.00 (5.31) <sup>e</sup>
BOCF	-2.18 (3.33)	-1.53 (3.39)	-2.69 (4.84)	-1.92 (3.65)	-2.24 (4.93)	-1.19 (4.16)	-0.80 (4.77)
LOCF	-2.18 (3.33)	-1.53 (3.39)	-3.11 (4.80)	-2.06 (3.85)	-2.68 (4.92)	-1.22 (4.16)	-0.80 (4.77)

**Weight change categories (observed cases only), n (%)**

weight gain	6 (19.4) <sup>a</sup>	8 (30.8) <sup>b</sup>	2 (8.7) <sup>c</sup>	6 (28.6) <sup>d</sup>	5 (21.7) <sup>c</sup>	10 (38.5) <sup>b</sup>	14 (48.3) <sup>e</sup>
0-<3% weight loss	13 (41.9) <sup>a</sup>	10 (38.5) <sup>b</sup>	10 (43.5) <sup>c</sup>	7 (33.3) <sup>d</sup>	5 (21.7) <sup>c</sup>	9 (34.6) <sup>b</sup>	7 (24.1) <sup>e</sup>
≥3-<5% weight loss	4 (12.9) <sup>a</sup>	4 (15.4) <sup>b</sup>	3 (13.0) <sup>c</sup>	2 (9.5) <sup>d</sup>	3 (13.0) <sup>c</sup>	4 (15.4) <sup>b</sup>	0 (0.0) <sup>e</sup>
≥5-<10% weight loss	8 (25.8) <sup>a</sup>	2 (7.7) <sup>b</sup>	3 (13.0) <sup>c</sup>	4 (19.1) <sup>d</sup>	7 (30.4) <sup>c</sup>	2 (7.7) <sup>b</sup>	6 (20.7) <sup>e</sup>
≥10% weight loss	0 (0.0) <sup>a</sup>	2 (7.7) <sup>b</sup>	5 (21.7) <sup>c</sup>	2 (9.5) <sup>d</sup>	3 (13.0) <sup>c</sup>	1 (3.9) <sup>b</sup>	2 (6.9)
<b>BMI change, mean (SD)</b>							
Observed cases only	-0.89 (1.1) <sup>a</sup>	-0.73 (1.32) <sup>b</sup>	-1.45 (1.79) <sup>c</sup>	-1.04 (1.49) <sup>d</sup>	-1.24 (1.89) <sup>c</sup>	-0.49 (1.68) <sup>b</sup>	-0.47 (2.13) <sup>e</sup>
BOCF	-0.75 (1.07)	-0.59 (1.22)	-0.92 (1.58)	-0.66 (1.28)	-0.78 (1.60)	-0.37 (1.50)	-0.37 (1.96)
LOCF	-0.75 (1.07)	-0.59 (1.22)	-0.93 (1.56)	-0.69 (1.34)	-0.93 (1.59)	-0.38 (1.50)	-0.37 (1.96)
<b>Waist circumference change (cm), mean (SD)</b>							
Observed cases only	-3.74 (4.62) <sup>a</sup>	-3.14 (4.3) <sup>b</sup>	-4.70 (6.29) <sup>c</sup>	-3.14 (4.34) <sup>d</sup>	-4.40 (6.08) <sup>c</sup>	-2.30 (4.37) <sup>b</sup>	-2.26 (4.97) <sup>e</sup>
BOCF	-3.22 (4.47)	-2.49 (3.9)	-3.00 (5.49)	-2.00 (3.76)	-2.81 (5.82)	-1.82 (3.98)	-1.82 (4.53)
LOCF	-3.22 (4.47)	-2.49 (3.9)	-3.71 (5.76)	-2.23 (4.03)	-3.51 (4.48)	-1.85 (3.97)	-1.82 (4.53)

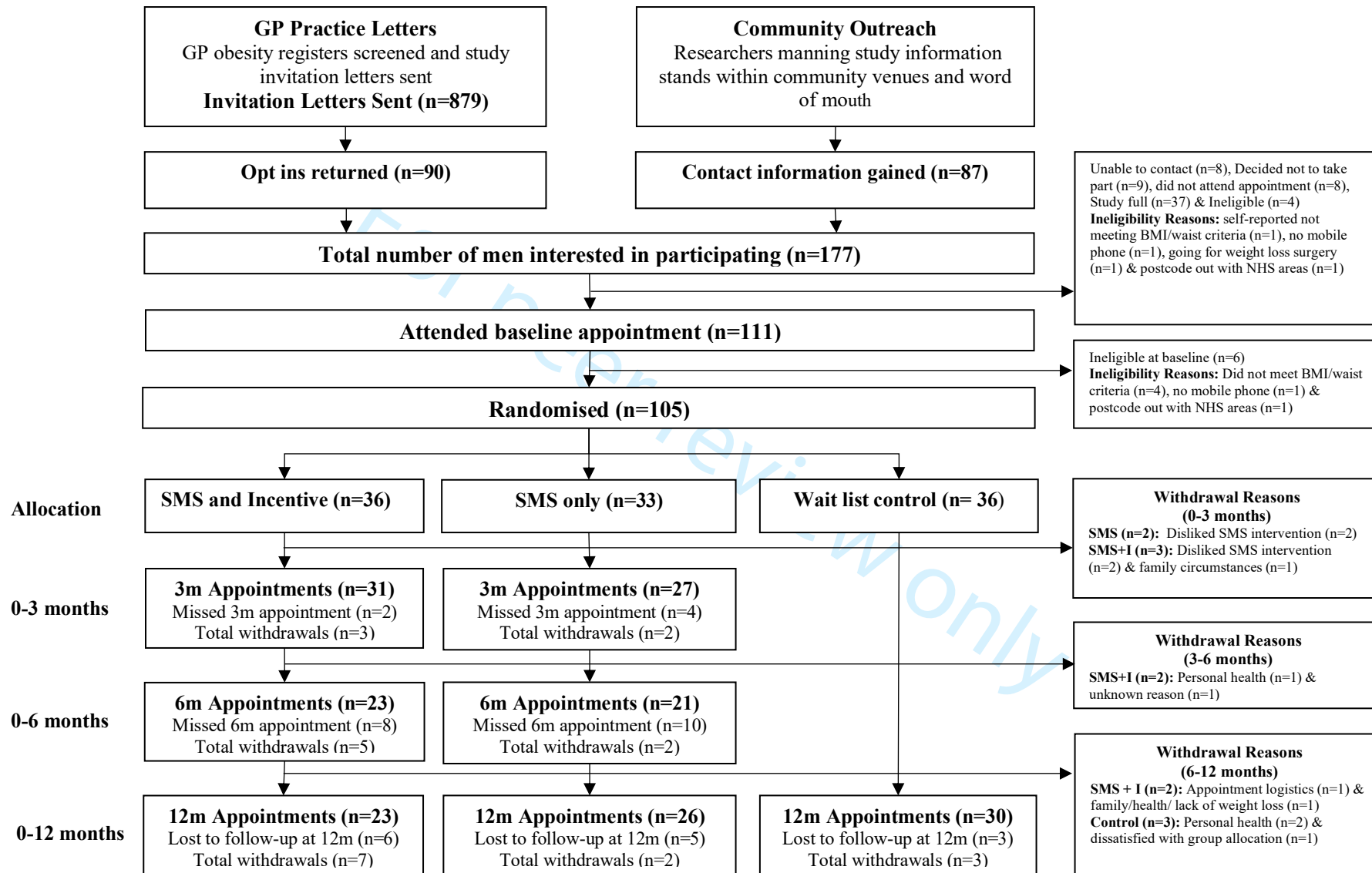
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3 *Note.* <sup>a</sup> N=31, <sup>b</sup> N=26, <sup>c</sup> N=23, <sup>d</sup> N=21, BOCF = baseline observation carried forward, cm = centimetres, LOCF = last observation carried  
4 forward, kg = kilogram, M = mean, SD = Standard Deviation.  
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Figure 1: Consort flow diagram

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**Online supplement 1: Incentive strategy contingent on meeting weight loss targets over 12 months**

	Money secured	Money lost
3 months: £50 – target 5% weight loss		
<5%	£0	£50
≥5%	£50	£0
6 months: £150 – target 10%		
<5%	£0	£150
5%	£75	£75
6%	£90	£60
7%	£105	£45
8%	£120	£30
9%	£135	£15
≥10%	£150	£0
12 months: £200 – target 10%		
<5%	£0	£200
5%	£100	£100
6%	£120	£80
7%	£140	£60
8%	£160	£40
9%	£180	£20
≥10%	£200	£0

**Online supplement 2 Intervention engagement over time for narrative texts and study webpage**

	0-3 months		3-6 months		6-12 months	
	SMS + I	SMS only	SMS + I	SMS only	SMS + I	SMS only
	N=36	N=33	N=36	N=33	N=36	N=33
Replies to texts, count	289	81	10	6	28	11
Replies to texts, mean (SD)	8.0 (24.2)	2.5 (7.9)	0.3 (0.7)	0.3 (1.0)	0.8 (3.3)	0.3 (1.0)
<b>Text replies, n (%)</b>						
0 replies	21 (58.3)	23 (69.7)	30 (83.3)	31 (93.9)	28 (77.8)	28 (84.8)
1-5 replies	9 (25.0)	7 (22.3)	6 (16.7)	2 (6.1)	7 (19.4)	5 (15.2)
6-10 replies	2 (5.6)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
11-15 replies	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
16-20 replies	1 (2.8)	1 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
>20 replies	3 (8.3)	1 (3.0)	0 (0.0)	0 (0.0)	1 (2.8)	0 (0.0)

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Stopping texts, n (%) 1 (2.8) 2 (6.1) 3 (8.3) 3 (9.1) 1 (2.8) 1 (3.0)

Withdrawal due to texts (self-report) 2 (5.6) 2 (6.1) 0 (0.0) 0 (0.0) 0 (0.0) 0 (0.0)

**Participants using website self-monitoring features, n (%)**

Weight 8 (22.2) 5 (15.2) 6 (16.7) 3 (9.1) 4 (11.1) 3 (9.1)

Steps 10 (27.8) 6 (18.2) 7 (19.4) 2 (6.1) 3 (8.3) 2 (6.1)

Waistline 4 (11.1) 3 (9.1) 3 (8.3) 0 (0.0) 1 (2.8) 0 (0.0)

Belt notches 2 (5.6) 0 (0.0) 2 (5.6) 0 (0.0) 0 (0.0) 0 (0.0)

**Number self-monitoring features used, n (%)**

None 24 (66.7) 26 (78.8) 28 (77.8) 30 (90.1) 31 (86.1) 29 (87.9)

One 5 (13.9) 2 (6.1) 2 (5.6) 1 (3.1) 3 (8.3) 3 (9.1)

Two 3 (8.3) 3 (9.1) 3 (8.3) 2 (6.1) 1 (2.8) 1 (3.0)



Three	3 (8.3)	2 (6.1)	2 (5.6)	0 (0.0)	1 (2.8)	0 (0.0)
Four	1 (2.8)	0 (0.0)	1 (2.8)	0 (0.0)	0 (0.0)	0 (0.0)

**Number of entries on self-monitoring feature, count**

Weight	69	115	45	23	42	46
Steps	419	296	350	102	397	74
Waistline	4	7	5	0	2	0
Belt notches	8	0	4	0	0	0

*Note.* M = mean, SD = Standard Deviation.

**Online supplement 3 Satisfaction and helpfulness ratings for overall programme and narrative texts at 12 months by deprivation status**

	SMS+I		SMS only		Total	
	SIMD 1, 2 (n=14)	SIMD 3+ (n=7)	SIMD 1, 2 (n=16)	SIMD 3+ (n=10)	SIMD 1, 2 (n=30)	SIMD 3+ (n=17)
Satisfaction programme <sup>a</sup>	81.8, 21.7	79.9, 19.2	74.6, 23.5	81.0, 16.0	77.9, 22.6	80.5, 16.8
Helpfulness programme <sup>b</sup>	4.2, 1.1	3.9, 1.1	3.9, 1.1	4.2, 1.0	4.1, 1.1	4.1, 1.0
Helpfulness of narrative texts <sup>b</sup>	3.4, 1.3	3.4, 1.4	3.0, 1.5	3.8, 1.2	3.2, 1.4	3.6, 1.3

*Note.* All data mean (SD), <sup>a</sup> scored 0-100 (higher = more satisfied), <sup>b</sup> scored 1-5 (1 = low, 5 = high), SIMD = Scottish index of multiple deprivation 1 represents the most disadvantaged area; quintile SIMD 5 represents the least disadvantaged area SMS = Short message service, SMS+I = SMS plus incentive group.



## CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	3, 4
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	6, 7
	2b	Specific objectives or research questions for pilot trial	7
<b>Methods</b>			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8,9
	4c	How participants were identified and consented	8,9
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10, 11
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	11-13
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	7
Sample size	7a	Rationale for numbers in the pilot trial	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	9
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	11-13
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	40
	13b	For each group, losses and exclusions after randomisation, together with reasons	40
Recruitment	14a	Dates defining the periods of recruitment and follow-up	15
	14b	Why the pilot trial ended or was stopped	15
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	31-33
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	31-45
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	15-19
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19
	19a	If relevant, other important unintended consequences	n/a
<b>Discussion</b>			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	20
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	22
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	22
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	22
<b>Other information</b>			
Registration	23	Registration number for pilot trial and name of trial registry	4
Protocol	24	Where the pilot trial protocol can be accessed, if available	7
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	24,25
	26	Ethical approval or approval by research review committee, confirmed with reference number	7

1 Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

2 \*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important  
3 clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological  
4 treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).  
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