STUDY PROTOCOL

FULL TITLE: Feasibility study of how best to engage obese men in narrative SMS (short message system) and incentive interventions for weight loss, to inform a future effectiveness and cost-effectiveness trial

SHORT TITLE Game of Stones: A research study that texts men to help them lose weight.

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Research Ethics Committee and Regulatory Approvals

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GLOSSARY

BCTs	**Behaviour Change Techniques**
Co-I	**Co-investigator**
DCE	**Discrete Choice Experiment**
FFIT	**Football Fans in Training research study**
HIC	**Health Informatics Centre, University of Dundee**
IP	**Intellectual Property**
Ipsos MORI	**A UK Market Research Company (https://www.ipsos-mori.com/)**
MHF	**Men's Health Forum**
NIHR	**National Institute of Health Research**
NICE	**National Institute for Health and Care Excellence**
PA	**Physical Activity**
PPI	**Public and Patient Involvement in research**
QOF	**Quality and Outcomes Framework for GP Practices**
QALYs	**Quality-adjusted Life Year**
RCT	**Randomised Controlled Trial**
Researchers	**Employees of the University of Stirling to conduct the research**
SMS	**Short Message Service (commonly known as text message)**
SPCRN	**Scottish Primary Care Research Network**
TCTU	**Tayside Clinical Trials Unit**
TSC	**Trial Steering Committee**

1a. LAY SUMMARY

In 2014, 24% of UK men were obese. However men rarely participate in weight loss programmes. This study looks at whether two interventions which show promise can help obese men lose weight and keep it off.

INTERVENTION 1: Sending (and receiving) text messages to a mobile phone. These will be written as though they come from other men who are also losing weight and include 'how to do it' diet and physical activity tips, combined with friendly humour and support.

INTERVENTION 2: The same texts plus promising men money (up to £400) at the start contingent on weight loss achievement. The money will vary over a year according to whether weight targets are met (5% of body weight lost at 3 months, 10% at 6 months and 10% at 12 months after the start of the study). This is called an endowment incentive and is based on research showing that modest payment helps people change their diet and physical activity. At the 3, 6 and 12 month weighing appointments, men will have the option of continuing with the original weight loss targets of 5%, 10% and 10% or setting lower targets of 5% of body weight at 6 months and 5% at 12 months. This is to maintain motivation and hope for men who do not meet the more ambitious weight loss targets.

WE WANT TO FIND OUT if the texts work better with incentives than alone. Both interventions are delivered from a computer and have potential to reach large numbers, including men who don't use health services. This work is done together with obese men and a charity for men to help us find the best ways to deliver the interventions to as many men as possible, including men in difficult life situations.

THE STUDY HAS TWO PARTS:

PHASE 1. Is in progress and is setting up the feasibility trial. Phase 1 has approval from the University of Stirling Research Ethics Committee.

PHASE 2. We will study whether it is acceptable and possible to randomise obese men (like tossing a coin) to three groups: texts only; texts and incentive; or to a 'control group' who wait a year and then get the texts for 3 months. We will assess the feasibility of recruiting 105 obese men from two regions of Scotland. Half of the men will get an invitation letter from their GP. The other half will be approached in the community, given information about the study and invited to take part. Men can take part if their trouser waist is 40 inches and more or their Body Mass Index is 30 or higher. We want to find out how long it takes to find 105 obese men who want to take part, how many come back to suitable venues at 3, 6 and 12 months to get weighed and answer questions about their quality of life, lifestyle and motivation. We will try to include men from all walks of life, so we will ask questions at the start like their age, address, who they live with, or if they have any illnesses like diabetes. At the end we will ask men about their experiences and men from the control group will receive texts for 3 months if they wish. Control group texts will be developed based on the feedback and qualitative interview data received from the men in the two intervention groups at 3 months. In order to improve the acceptability of the texts to more men, these texts will be a different style from the original narrative texts. Drop-outs from the control group at 12 months will be replaced through recruiting further men until we have a sample of at least 30 men receiving the alternative texts. We will interview approximately 18-30 men in more detail about their experiences of weight loss and of being in the study. We will follow up all men from the alternative text group for 3 months, seek their feedback on the texts and interview 10-16 men in more depth about their experience. A PhD student will find out if it is possible to follow up the men for another year, and ask them questions on whether it is acceptable and possible to link the study findings to their health records.

THE STUDY WILL TELL US if our approach is acceptable, possible to deliver and if it could help men to lose weight. If it is, then we will do a larger study.

1b SCIENTIFIC SUMMARY

IMPORTANCE: In 2014, 24% of UK men were obese and this prevalence is increasing. Systematic reviews suggest that far fewer men than women engage in formal weight loss programmes, but if they do they are less likely to drop out.

MAIN RESEARCH QUESTIONS:
1. Is a narrative SMS intervention with embedded behaviour change techniques (BCTs) and endowment incentives acceptable and feasible to deliver in a RCT?
2. How can intervention components and delivery processes be optimised to increase reach, engagement and follow up of obese men?
3. Are progression criteria met for a full RCT for one or both interventions?
4. What are the likely recruitment and attrition rates?
5. What would be the sample size for a full trial?

AIM: To co-produce with PPI, an acceptable and feasible RCT design with wide reach to test a narrative SMS intervention with embedded BCTs, with and without an endowment incentive, compared to waiting list. This will inform a future pragmatic, full-scale effectiveness and cost-effectiveness trial

DESIGN: A two phase feasibility study.

Phase 1 i) finalise the design of a narrative SMS intervention with embedded BCTs for men using qualitative research with representatives of the target population and PPI, and ii) develop an endowment incentive drawing on insights from behavioural economics, existing evidence and men's preferences for delivery based on survey/DCE evidence. Systematic review evidence, theory and learning from recent UK behaviour change trials were combined with an iterative mixed methods approach to refine the interventions through PPI and user testing.

Phase 2 is a 12 month feasibility RCT with 3 arms: SMS only; SMS and incentive; usual practice with waiting list for SMS intervention. Iterative mixed method data collection and analysis will help to refine the intervention parameters, design and processes in preparation for a potential full pragmatic effectiveness and cost-effectiveness

RCT SETTING: 2 communities in Scotland with disadvantaged areas; differing in employment, ethnic groups, urban and rural access

POPULATION: Obese adult men with BMI 30 or over and/or waist measurement 40 inches (102cm) or over. Recruitment through community venues (50%) and GP obesity registers (50%). Phase 1: a survey/DCE (n=1045 obese men); qualitative interviews/focus groups with 20-30 men, diverse PPI and a stakeholder workshop to finalise the intervention. Phase 2: 105 men randomised to three groups (n=35 each) and approximately 18-30 qualitative interviews

INTERVENTIONS: 1.Narrative SMS with embedded BCTs; 2.The same SMS plus endowment incentives

CONTROL: Waiting list for 12 months followed by an offer of alternative SMS intervention for 3 months based on feedback from intervention participants

ALL GROUPS: A pedometer for PA monitoring

PRIMARY OUTCOMES: Acceptability and feasibility of recruitment, retention, intervention components, time points for verifying weight with feasibility of assessor blinding, identifying core outcomes that are acceptable and matter for obese men

SECONDARY OUTCOMES: Differential recruitment, engagement with narrative SMS and incentive components and attrition by socio-economic status and setting. Quality of motivation (intrinsic and extrinsic), satisfaction with weight loss, qualitative experiences, risk of incentive gaming. Optimising retention, engagement, and follow-up using feedback received from men who have participated in the intervention arms of the feasibility trial. Meeting progression criteria, calculating the sample size and securing intervention funds for a full trial. Feasibility of follow up for a year after the intervention and data linkage to routinely collected health outcomes.

LIKELY FULL RCT PRIMARY OUTCOME: Weight loss at 1 year. SECONDARY: % weight loss, waist circumference, QALYs, costs

IMPACT: A novel theory based intervention ready for a full RCT, with broad reach and with central delivery at scale.

2. BACKGROUND

In the UK 24% of men are obese, with higher prevalence in those from deprived backgrounds[1]. Obesity conveys an increased risk of serious health conditions and is a major public health priority[2]. This proposal is in response to a commissioned call which NIHR has identified as a research priority topic. Our novel narrative SMS and endowment incentive feasibility study fits the research recommendations in recent NIHR reviews[3 4] and NICE recommendations to investigate i) "components, or combinations of components, that support weight loss or the prevention of weight regain", ii) "the effect of new technologies" and iii) "specific behaviour change techniques" (BCTs)[5]. This study is informed by two NIHR funded trials (three studies) of narrative SMS for alcohol problems (including in obese men) which are successfully recruiting hard to reach men and showing high engagement[6-8].

2.1. EXISTING RESEARCH

Despite a growing problem of overweight and obesity men are an underserved population in current evidence-based weight management programmes[4]. Most interventions are designed for mixed sex or female only populations despite evidence that many men desire different interventions to women[4]. Consequently limited evidence exists on the most effective strategies to recruit and retain men in weight management programmes. Innovative means of delivering male obesity interventions are needed, particularly for hard-to-reach groups[4]. Although some evidence of effective lifestyle interventions for obesity exists[5 9 10], little research to date has systematically consulted men on how to optimise engagement and make interventions user-friendly. Rigorous feasibility studies and piloting with service user input at all stages is recommended[4]. The cost-effectiveness of interventions for men is limited[4].

The maintenance of initial weight loss is generally poor[11]. Evidence suggests that ongoing and long-term support for weight loss maintenance is required[11 12], yet few weight management programmes are designed with maintenance in mind[4]. Evidence points to the need for male-specific highly engaging interventions that target weight maintenance. There are good theoretical reasons[13-17] and growing empirical evidence[6-8 18-22] to suggest that theory-based interventions delivered by SMS, and financial incentives may both engage men and result in weight loss maintenance. However, no trials have examined SMS in obese men with or without incentives.

2.2. RATIONALE FOR CURRENT STUDY

There is accumulating evidence that some weight management services need to be different for men (than for women) and that PPI is needed in their design[4]. Recent reports[23 24] recommend testing systematic, multiple interventions delivered at scale and experimentation where risk is low. Meaningful engagement of men reluctant to join existing services, particularly from disadvantaged backgrounds is important to address health inequalities[25].

Throughout this protocol, we use the term 'diet' however dieting terms are not popular with men[4] and in the interventions we will refer to changing and reducing food and drink (including alcohol) intake. Although lifestyle interventions with reducing diets and increasing PA are clinically effective[4 9], only 10-20% of participants are men and the type of diet does not affect long term weight loss[4]. The most effective interventions for men include specific behaviour change techniques (BCTs) to support translating diet and PA change targets into performance[4]. Examples of BCTs from effective interventions are action planning (e.g. specifying what to change, when and where), self-monitoring (e.g. keeping a food and step-count diary) and relapse prevention (e.g. planning how to respond to a lapse following initial change). If men can be engaged through an intervention that embeds evidence-based BCTs then there is potential for significant health gains. We will assess the feasibility of two novel and promising interventions for weight management in obese men to inform the design of a future full trial.

Impact: Given financial pressures within the NHS, acceptable and effective low cost obesity interventions will be highly sought after by NHS managers in the future. Innovative, efficient and scalable interventions, with broad reach and high engagement, are required to support obese men's weight management[4 26 27]. This is the first study to test a narrative SMS intervention, with and without financial incentives. The study will provide new evidence on whether financial incentives are needed to increase uptake, intervention engagement and adherence, and the impact on health inequalities. If found to be effective, centralised delivery of automated SMS with or without incentives, will facilitate implementation at scale. The interventions and the optimisation of forms of delivery have potential for generalisability to other populations or health behaviours.

Building on existing work and pilot studies

There is strong empirical support from NIHR studies for engagement of men with the narrative SMS for alcohol reduction[6-8]. Mark Grindle (Co-Investigator) has written the Characters, Story and Narrative SMS for this intervention based on his Digital Narrative Transformation Framework to Health Behaviour Change. The underlying principles and structures for the practical use of commercial narrative engagement strategies and the embedding of BCTs and key messages in digital health behaviour change interventions is informed by his 20 years working in Film, Television and Computer Games as a screenwriter, producer and developer. This practice based approach was formalised in his subsequent PhD research (based on that expertise) entitled 'The Power of Digital Storytelling to Influence Human Behaviour'[28]. Alison Avenell and Pat Hoddinott conducted systematic reviews of quantitative, qualitative and economic evidence for the management of obesity in men[4]. Alison Avenell conducted a review of incentives for weight loss[29] which Stephan Dombrowski is currently updating. Pat Hoddinott and Stephan Dombrowski conducted systematic reviews and a mixed method study investigating the mechanisms of action of incentives for behaviour change to inform a DCE which showed promise for combining incentives with SMS for smoking cessation in pregnancy[30].

3. RESEARCH AIM AND OBJECTIVES

Overall aim: To co-produce with PPI, an acceptable and feasible RCT design with broad reach to test a narrative theory-based SMS intervention with embedded BCTs, with and without an endowment incentive, compared to waiting list control, to inform a future full trial.

Phase 1. This phase has finalised the design of the narrative SMS intervention, the incentive intervention and the trial design through mixed methods research and PPI. This phase received ethics committee approval from The University of Stirling on 8th January 2016 and will be complete by 31st December 2016. The results of a survey conducted on our behalf by IPSOS Mori with 1045 obese men, PPI and qualitative data support the protocol described below. £400 is consistent with existing evidence on the amount required to change behaviour[19], is equivalent to 12 months of the weight loss drug Orlistat alone (excluding the costs of health service staff time and monitoring); is similar to the costs of attending

commercial weight loss groups for a year. PPI are supportive of the incentive intervention which can be seen as presenting an opportunity for "harder to reach" men to improve their health and wellbeing.

Phase 2. A feasibility trial to refine approach, recruitment, randomisation, intervention delivery, engagement, retention and follow-up processes.

Objectives:

1. To assess the acceptability and willingness of obese men to be randomised to i) SMS ii) SMS and endowment incentive or iii) waiting list for SMS
2. To assess the acceptability and feasibility of recruiting obese men from GP practice obesity registers and community venues (identified in Phase 1 of this study).
3. To determine the acceptability of intervention content, delivery and attendance levels for objective weight measures at baseline, 3, 6, and 12 months and any unintended consequences
4. To assess the likely impact on % weight loss at 12 months and health inequalities via assessment of differential uptake and potential effectiveness by socio-economic group

Progression criteria for a full trial

Progression criteria are based on systematic review evidence[4] and ongoing NIHR studies[6-8]. The findings of this study may or may not support a full trial, either two arm or three arm. The progression criteria are:

1. Acceptability of the intervention and the control group (by the majority of the target group); willingness to be randomised. Evidenced by quantitative and qualitative data on: satisfaction, recruitment, intervention engagement
2. Feasibility of recruiting 105 men in 4 months
3. 12 month outcomes on at least 72 % of men randomised per group, consistent with a recent UK weight management trial in men[10] and systematic reviews of male obesity literature[4]
4. Evidence of mean weight loss of at least 3% of baseline weight at 12 months in any intervention group; 3% is defined by NICE as clinically significant[5]
5. Independent SSC will decide whether the findings support a two or three arm trial or not
6. Commitment by e.g. government or NHS/local authorities to fund the incentive intervention, if it shows positive indicative effects, to ensure translation and sustainability

Main research questions:

1. Are adapted narrative SMS interventions with embedded BCTs, with or without endowment incentives, acceptable and feasible to deliver in a RCT?
2. How can intervention components and outcome measurement procedures be optimised to increase reach, engagement and follow-up of obese men?
3. Are alternative SMS based on mixed method data analysis more acceptable and likely to improve trial retention at 3 months than the existing text message intervention?
4. Are progression criteria met for a full RCT for one or both interventions?
5. What are the likely recruitment and attrition rates?
6. What would be the sample size for a full trial of weight loss outcomes at 12 months?
7. How do the two interventions (SMS with and without endowment incentives) compare for health equalities, reach, engagement and retention?
8. Is data-linkage to long-term health and resource outcomes feasible? (Phases 1 and 2)

Main research question for a future full trial: Is a narrative SMS intervention with embedded BCTs, with or without an endowment incentive, effective and cost-effective in supporting weight loss and weight loss maintenance at 12 months in obese men compared to a waiting list control?

4. RESEARCH DESIGN AND METHODS: PHASE 2 - FEASIBILITY RCT

4.1. SETTING AND STUDY POPULATION

Geographical settings: two socio-demographically diverse sites which cover urban, suburban, town and rural populations in Scotland

Inclusion criteria: Obese adult men aged 18 or over with and without known health conditions, who do or do not access GP services. Obesity is defined as a BMI equal to or over 30 and/or a trouser waist measurement equal to or above 40 inches (102cm)

Exclusion criteria: Insufficient English language for SMS intervention; no mobile phone access. Planning to move out of the area within 12 months. Current or recent participation in a research weight loss intervention study (in the last 3 months). Plans to engage in bariatric surgery in the next 12 months. For GP recruitment: severe medical, terminal or psychiatric illness (patient or close family member); impaired cognitive function that would limit understanding of study information and SMS messages.

Socioeconomic position and inequalities: Incentives can reduce health inequalities[21], and instil feelings of being valued for effort and achievement[30]. Healthy diets can cost more than unhealthy ones[31]. Very few men engage in weight management interventions[4], and there are concerns that offering services where men have to travel at set times can increase inequalities for access. We will select community venues and GP practices to access men from disadvantaged communities and ethnic minority groups. We aim to have broad reach to all socio-economic groups, and will use a sampling frame to monitor this. Iterative analysis will allow purposive recruitment of under-represented groups, e.g. unemployed. We propose to try different recruitment strategies described below to find out what works best, because there is little evidence available on how to recruit obese men to take part in interventions like ours. Mobile phones and SMS are almost universal across socio-economic groups and are available anytime, anywhere. PPI will ensure information is in plain clear language and the text messages have a reading age of below 12 (Gunning-Fog Index http://gunning-fog-index.com/fog.cgi). A descriptive statistical analysis plan will include impact on health inequalities.

4.2 RECRUITMENT

We will recruit 105 obese men (see section 10 for sample size justification) through GP obesity registers and community outreach[32] in two sites, and randomise 35 each to i) SMS ii) SMS and endowment incentive or iii) waiting list for SMS. The acceptability and feasibility of recruitment, randomisation, retention and outcome collection will be assessed (see 7.iv).

Our recruitment strategy is informed by principles of community recruitment strategies in order to access harder to reach populations in public health research[32]. These principles have been used by the Scottish Primary Care Research Network (SPCRN) who undertake recruitment to trials in Scotland. The proposed strategy described below has been successfully used in NIHR studies to recruit men and obese men for a narrative SMS intervention for alcohol reduction[6-8] which was delivered using the same University of Dundee software:

i) Recruitment through GP practice obesity registers (approximately 50% of sample). Obesity registers were part of the Quality and Outcomes Framework (QOF)[33] The Scottish Government withdrew QOF in Autumn 2015, after funding for this study was agreed. Recruitment will be undertaken by the SPCRN at the 2 sites. SCPRN advise that obesity registers and BMI recording will still enable identification of eligible men in GP practices. In 2013/14, obesity registers of adult patients showed a crude obesity prevalence of 8.1% of the entire GP registered population in Scotland. This underestimates the true prevalence estimated at 27.4% in Scotland in 2010[34]. GP Practices will receive an initial “Invitation to Participate”. SCPRN staff will work initially with four consenting GP practices, two at each site, to identify eligible men from practice data. Two hundred letters will be sent per practice. This is based on an estimated recruitment rate of 8-10%. The practices will identify men whose most recent documented BMI was 30 or higher. Clinical staff in the practice will screen the list of potentially eligible men and remove any men where they consider it would be unsuitable to

send the “Invitation to Participate” letter (see 4.1. exclusion criteria). Reasons for exclusion will be documented. This list will be transferred to The Health Informatics Centre at The University of Dundee. They will send out a Participant Study Summary leaflet, an invitation letter on GP practice headed paper and a pre-paid envelope with an-opt in/opt-out card using their Participant Tracker system. The opt in/out card will ask participants to indicate whether they are interested in receiving further information about the study or not. Those who indicate an interest will also be asked for their contact details. Two weeks after this letter, if the opt in/opt-out card is either not returned or is returned with the opt-in option selected, the researcher will telephone and discuss the study and potential participation in more detail (See iii below). This has been shown to be acceptable and feasible for trial recruitment to National Institute of Health Research funded studies in primary care in Scotland and is particularly important for recruiting harder to reach men (SCPRN feedback). Harder to reach men may have lower literacy levels and be more disorganised about opting into studies e.g. due to anxiety, low confidence, or social issues. Practice staff will be asked to remind eligible men about the study. Practices will be asked to put a poster up in the waiting room. Members of the research team will be available in the waiting room at set times to discuss the study with men and practices will be requested to provide a room for enrolling, interviewing and collecting data from men.

ii) Community outreach[32] (approximately 50% of sample). It is essential to access men who do not or seldom engage in health services. Alliance Scotland are assisting us through their Link Worker programme and will share their experiences of engaging hard to reach men in Glasgow (http://links.alliance-scotland.org.uk/). Community groups and PPI representatives are helping us to identify suitable community venues which men are familiar with. The researchers will have face to face discussions about the study on the high street, local authority venues like benefits centres, and public places like community centres, public libraries. PPI are advising us on acceptable ways to approach the topic. Community recruitment will proceed according to recognised methods and good practice for community recruitment.[32] The same Participant Study Summary leaflet used for the initial approach in GP practices will be given to men who express interest and provides postal, telephone, text, web and email contact information about how to join the study.

iii) Full study information leaflet and discussion with a researcher. If a man is interested in participating the researcher will offer the full study information leaflet and arrange to make contact (participant preference – telephone [mobile and landline], email, Skype) to further discuss what will be involved and answer any questions. A date, time and convenient venue for a meeting will be agreed. One reminder text, email or phone call (participant preference) will be made prior to the appointment. If the man does not attend the appointment two methods of contact (e.g. phone, text or email) will offer another opportunity to make an appointment and join the study. This is to allow men who may have run out of phone credit or forgotten a second chance and is important for men who are harder to reach. We will also aim to provide a web link to an audio recording of a researcher reading out the full study information for those with low literacy or poor vision (8.iii).

As we wish to minimise contamination between the different groups and minimise disappointment for those who do not get the incentives, care will be taken not to recruit individuals consecutively from the same networked venues e.g. workplaces, community groups.

iv) Enrolment. If men have expressed an interest in joining the study, they will be invited to attend an appointment at a convenient venue and time with a researcher. Collaboration with PPI and local stakeholders, together with findings from a survey of 1045 obese men has identified acceptable local community venues (e.g. GP surgeries, pharmacies, community centres, schools). GP surgeries were the most popular choice of venue for assessments.

Men will be able to attend with a relative or friend. At the enrolment appointment the researcher will ensure that the man has a copy of the full study information leaflet, will discuss this, answer any questions and gain written informed consent. Confidentiality of data will be explained and we will request that men do not discuss which group they are allocated to with

other men participating in the study or to talk about the study on social media. This is to reduce any contamination, which could interfere with the study outcomes in this individual RCT. Participants will be informed that they can choose whether to participate or not and they can withdraw from the study at any point if they wish, without any personal consequences.

iv) Baseline data collection: Researchers will document the number needed to approach for an attendance at baseline assessment (N= number approached/for one attendance at baseline assessment); and number needed to approach for a successful recruitment (N= number approached/for one randomised). To assess reach, we will document the number of men personally invited (GP recruits), approached in the community and indicating initial interest, attending enrolment appointment, consenting to randomisation, self-reported eligibility and verified eligibility (weight and waist circumference measured). Any reasons given for dropping out at any stage will be documented. The Health Informatics Centre (HIC) at the University of Dundee has participant tracker software (safe haven). Researchers will collect baseline data and assessments (Table 2) following the procedures described in 4.6. The researcher will request independent randomisation by Tayside Clinical Trials Unit (TCTU) using a secure remote web-based system (telephone backup). TCTU will stratify by the two recruitment methods: GP and community. After group allocation, all men will be given a pedometer and a unique ID which will allow them to access the study webpage appropriate for their allocated group.

v) Informing the participant of group allocation: The researcher will inform the participant which trial group they are allocated to after randomisation and ensure that they understand what will happen next. An additional specific information sheet will be provided for all three intervention groups, and discussed in detail with the participant. The participant will be given a login by TCTU and will have an opportunity to access the website with the researcher present, to ensure that there are no operational problems. If there is no internet access, the researcher will have screenshots of the website available. The researcher will answer any further questions.

vi) Future appointment preferences: The researcher will ask what the participants preferred venue, day and time for future appointments are. Target dates for future appointments will be provided. For all groups, the researcher will inform the participant that they will be in contact to arrange the appointment approximately one month in advance of these dates.

vii) Control group additions: Waiting list control group participants will be offered an alternative version of the SMS intervention. To account for possible dropout and lack of update, additional men will be recruited until 30 - 35 obese men are allocated to receive the alternative text messages. Additional men will be recruited using the same methods already approved which we have demonstrated to be acceptable and efficient. They will receive a revised information sheet to explain the text only intervention and follow-up assessments at 3 months and a revised consent form which includes consent to contact in future for longer term follow up.

Strategies for understanding and addressing recruitment if slower than expected:

- The number of GP practices sending invitation leaflets will be increased. Informed consent will be gained for audio-recorded qualitative interviews or ethnographic observations of a purposive sample of participants attending appointments with the researcher for initial enrolment, baseline data and randomisation. Interviews will be conducted to understand any issues that could be resolved to improve study recruitment and enrolment processes. The same strategy will be used if there are a high number of drop-outs in the early weeks of the trial. This strategy will be based on an ethnographic approach to understanding RCT recruitment and iteratively modifying processes to improve acceptability.
- Andrew Shanahan, Director of www.Manvfat.com has agreed to advertise the study to men living in the two recruitment regions. The ManVFat website has over 50,000 registered

users. This would require an ethics committee amendment request with a copy of the advert

- If the above strategies are unsuccessful, our PPI group will advise us on displaying posters (ethics amendment will be requested) in consenting community venues, distributing fliers to members of the public and the possibility of an advert in a local newspaper, through social media or on local radio will be considered. This will have the disadvantage that it will be difficult to estimate the number needed for initial approach in order to recruit each participant.

4.3. PLANNED INTERVENTIONS

Both interventions are outlined following TIDieR sub-headings and guidance[35].

INTERVENTION 1: NARRATIVE MULTI-COMPONENT SMS

WHY-Theory: Narrative SMS have been defined as interactive life stories based around a range of characters (varying in age and socio-demographics) which can simulate the processes that make group-based interventions successful: humour, banter, peer support, facts about diet and PA and evidence based BCTs[4 5 10]. The narrative form draws on real world learning from the film, television and games industry[28]. When theorised, the narrative enables engagement with characters who convey the message of the intervention, and facilitate the viewer's empathy. Through creating an empathic bond with the character, users pay more attention to and become engaged[36] and immersed[37 38] within the story. This appears to lead to optimal learning and conceptualisation of the target information.

The behavioural approach used draws on several psychological theories covering the three phases of behaviour change: i) motivation, ii) action and iii) maintenance. The specific theories to be used include Self-Determination Theory[17] (motivation), Health Action Process Approach[15] (motivation, action, maintenance), and Rothman's maintenance theory[13] (maintenance). These theories outline different complimentary aspects across the change process and will inform the study logic model.

WHY-Intervention Components: Options will include diet and physical activity components used in the effective FFIT weight management programme for men that achieved changes in behaviour and weight at 3 months and maintenance of both at 12 months[10]. These will be delivered through evidence and theory-based BCTs (web-links [written information also available on request] to e.g. NHS choices[39]), based on qualitative review evidence about men's preferences[4].

WHAT-Materials: i) Narrative SMS will be sent to participants throughout the year. All texts have been written clearly with the help of PPI to facilitate access by those with low literacy using the Gunning-Fog Index http://gunning-fog-index.com/fog.cgi. ii) participants will be provided with a webpage (written information if no internet access) offering a choice of evidence-based diet, PA approaches hints and tips. Each participant will be provided with a unique login ID after randomisation according to group allocation.

The front page of the study website will be accessible to all participants. It includes essential information about the trial and links to existing on-line resources e.g. The NHS choices website: http://www.nhs.uk/LiveWell/Loseweight/Pages/Loseweighthome.aspx; and ManvFat: https://manvfat.com/;

The SMS only group web page will have a brief biography and images of the fictional characters featured in the narrative SMS and information specific to this trial arm. There will be also be a link for self-monitoring weight, waist circumference and pedometer steps. Our PPI work to date suggests practical and affordable measurement aids such as notches on belts, a piece of string with felt pen mark, and/or a tape measure.

The SMS with incentives group web page will have access to the same information as the SMS only group. It will also have an additional page about the financial incentives and progress towards weight loss targets.

The SMS waiting list group (control) will only have access to this front page until they have provided outcome data at 12 months. They will receive alternative SMS for 3 months and, similar to the original intervention groups will receive weight loss targets for 3, 6 and 12 months, get access to the webpage information sources and the self-monitoring tools and a pedometer.

WHAT-Procedures: All participants will receive automatic SMS according to the algorithm and SMS library. Men will be encouraged to set ambitious weight loss targets to start with of: 5% of body weight lost at 3 months, 10% at 6 months and 10% at 12 months after the start of the study. These will be personalised and identical to those in the SMS with incentive group. At the 3, 6 and 12 month weighing appointments, men will have the choice of continuing with these weight loss targets of 5%, 10% and 10% or setting lower targets of 5% of body weight at 6 months and 5% at 12 months.

WHO PROVIDES, HOW AND WHERE: The SMS will be delivered by HIC using existing tried and tested automated technology linked to Tayside Clinical Trials Unit currently used in other RCTs[6-8]. Men will require a standard mobile phone (any type) to maximise reach.

WHEN and HOW MUCH: Survey data and PPI in Phase 1 suggest that a varying frequency of texts from multiple times a day to twice weekly is likely to be acceptable to many men who want to lose weight. Men will be able to take breaks from the text messages by informing the researchers. Reasons for taking the break (e.g. holidays) will be recorded.

Self-reporting will be facilitated via a study website (e.g. pedometer steps, waist circumference and current weight).

INTERVENTION 2: ENDOWMENT INCENTIVE ADJUNCT TO NARRATIVE SMS

WHY-Theory: Adding an endowment incentive for verified weight loss to the narrative SMS (above) is based on theory[14 16] and evidence[21 22 40-42]. The financial incentive is based on behavioural economics theory[14 16] and draws on insights that people ascribe more value to something because it belongs to them (endowment effect[14]) and are more motivated to avoid losses than they are to achieve similarly sized gains (loss aversion[14]).

WHY-Intervention Components: The specific incentive elements are informed by the Adams et al (2014)[43] framework.

WHAT- Materials: All participants will be 'endowed' with an incentive at the start of the trial. It will be placed into a hypothetical personal account which is theirs for a year (no withdrawals). For the endowment effect to work it is crucial that participants feel ownership of the incentive from the start. The Phase 1 study survey found that men preferred a hypothetical cheque at randomisation over a hypothetical bank statement or facsimile banknotes.

WHAT-Procedures: The endowment incentive specification for weight loss targets (Box1) is informed by our updated systematic review of incentives for weight loss; loss aversion theory; preferences of 1045 obese men in the Phase 1 survey/DCE, a stakeholder workshop and PPI. Our weight loss targets are more ambitious than the typical 3% mean weight loss in weight management programmes quoted in NICE[5], current systematic review evidence for obese men[4] and the 5% weight loss at 12 months in the FFIT trial[10]. The full sum of money can be secured or lost over the year depending on whether targets for weight lost since the start of the study are met: 5% of body weight lost at 3 months (£50 secured/lost), 10% at 6 months (£150 secured) and 10% at 12 months (£200 secured). At 6 and 12 months men lose some of the money for each % weight loss not attained between 5-10%. For weight loss below 5% since the start of the study, men lose all the money for that time point (see Table 1 below for details). Men will receive the money at 12 months based on the targets they met. Their weight at 12 months must be less than at baseline in order to receive any money, regardless of whether they have met interim weight loss targets. If men do not attend the 12 month assessment, they will not receive any money. The incentive will be triggered by researcher verified weight loss data at the baseline. 3, 6 and 12 month assessments (Blue Tooth Scales linked to the centralised database at University of Dundee with paper back-up copy). Feedback to men will be by text initially and will then be visible via the website.

Table 1. Incentive strategy contingent on meeting weight loss targets over 1 year

3 months: £50 – target 5%

	Money secured	Money lost
<5%	£0	£50
≥5%	£50	£0

6 months: £150 – target 10%

	Money secured	Money lost
<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%

	Money secured	Money lost
<5%	£0	£200
5%	£100	£100
6%	£120	£80
7%	£140	£65
8%	£160	£40
9%	£180	£20
≥10%	£200	£0

WHO PROVIDES: Incentives are provided as part of this research grant and are triggered by researcher weight goal verification. Feedback on weight achievement and incentive status will be through SMS and a study webpage.

HOW (Mode of Delivery): Men's preferences of direct bank transfer (self or charity donation) or secure postage of a cheque will be ascertained at the 12 month assessment. In our survey, 11% of the 1045 obese men would choose a charity donation.

WHERE: Weight goal verification will be in suitable venues with subsequent SMS notification.

WHEN and HOW MUCH: (See Box 2) At 12 months participants will receive money depending on weight loss achievements. PPI consultation recommended no interim payments. The logistics for paying men and the future sustainability of the programme support this.

PERSONALISING INCENTIVES Men will lose money if they do not reach weight loss targets. Men can choose the incentive purpose at each time point (money for oneself vs. for charity) and the weight loss target after the 3 months' assessment. The men in the SMS with incentives arm of the trial will have an additional web page explaining the incentive scheme and providing a visual chart to provide feedback on their incentive progress. All other elements will be the same as for the SMS only group, including a website chart (paper available if no web access) of the weight loss targets at 3, 6 and 12 months.

CONTROL GROUP

Waiting list for SMS intervention: At the 12 month outcome assessment men will be offered an alternative SMS intervention for 3 months, based on the feedback received from intervention men at 3 months and qualitative interview data. At baseline, men will receive information (web or print) about weight loss and a pedometer. There will be no interim measurements or contacts by the research team. Men are therefore free to choose whether to try to lose weight or to self-monitor during the 12 months. They will not have access to the self-monitoring page on the study website until after the 12 month outcome assessment. The NIHR commissioning brief 14/185 asks for non-provision/usual practice. The control arm is as close as possible to "doing nothing", whilst remaining ethical (information, free choice to lose weight and later assistance via SMS to reduce disappointment bias). Men will be asked about their weight and any efforts they have made to change between enrolment and the 12 month assessment, and those choosing to receive alternative text messages will be followed up in person after 3 months using the same procedures as employed during the 3 months follow up of intervention participants.

ALL GROUPS

Post randomisation, all men (intervention and control groups) will be provided with the standard NHS information on weight loss[39], other useful sources of information (web or print) and a pedometer with built in accelerometer as recommended[4,50] for PA self-report. All participants will receive £20 reimbursement of expenses for attending the 12 month assessment[48].

4.4. COMPLIANCE AND LOSS TO FOLLOW-UP

Both interventions are centrally delivered, so fidelity of delivery is not an issue. Engagement with the interventions, retention and reasons for drop-out are described in Sections 4.5 and 4.6.

4.5. OUTCOME MEASURES

Primary outcome: A decision whether to proceed to a full effectiveness and cost-effectiveness RCT for the SMS intervention, with or without an incentive, compared to a waiting list control. This will be based on the progression criteria set out in Section 3. Criteria include quantitative and qualitative outcomes for:

- Acceptability of the interventions and the control group (willingness to be randomised, intervention engagement, participant retention, qualitative views)
- Feasibility of recruiting 105 obese men across socioeconomic and cultural spectra, intervention delivery, outcome measures at each time point, the potential for assessor blinding
- Evidence of positive indicative weight loss effects at 12 months for at least one group
- Feasibility of gaining consent for longer term follow up and NHS data linkage

Secondary outcomes for this study:

Process data: differential recruitment, intervention engagement and retention by socio-economic status, recruitment strategy (GP practice or community venues) and geographical area (deprivation index). Impact on quality of motivation (intrinsic and extrinsic), satisfaction with weight loss. Qualitative experiences, including acceptability of the incentive, the impact on social networks and families, need for additional support, unintended consequences e.g. incentive gaming, sustainability. Usual practice while on the waiting list will be described, and compared with each intervention group.

Future full RCT- proposed primary outcome is: mean difference in weight loss (absolute and percentage) between groups at 12 months.

Future full RCT - proposed secondary outcomes (may change depending on the findings of this study)**:** waist circumference, QALYs, costs, cost-effectiveness. PhD studentship is investigating the feasibility of follow-up until 24 months and data linkage to routinely collected health outcomes, e.g. hospital admissions, obesity related diagnoses such as diabetes, cancers, heart disease, high blood pressure.

4.6. ASSESSMENT AND FOLLOW UP

Weight outcomes will be collected at baseline, 3, 6 and 12 months (standard time points in weight loss studies); these were acceptable in our survey of obese men and with our PPI group. Assessment at 3 months, will allow early identification (and rectification) of any problems with the trial design.

Assessments use validated tools where available and follow quality standards for measurement procedures. These are summarised in Table 1. More detail is provided in section 4.7

Table 1: Assessment schedule of essential and desirable variables according to male obesity programmes checklist from the Men's Health Forum (MHF)[44]

Essential variables	**0**	**3**	**6**	**12**
Socio-demographics, co-morbidities, disability, ethnicity	✓			
Anthropometry (height, weight, BMI, waist circumference)	✓	✓	✓	✓
Mixed methods process/acceptability data	✓	✓	✓	✓
Lifestyle behaviours and activities (diet, PA, smoking, alcohol)	✓		✓	✓
Health Economic Outcomes: EQ-5D, NHS health care use	✓		✓	✓
Theory-based mediators	✓	✓	✓	✓
Wellbeing	✓			✓

Mixed methods data collection: will assess the acceptability and feasibility of different venues, recruitment strategies, randomisation, retention and outcome collection. We will collect i) numerical data on attendance at appointments, ii) monitor intervention engagement through response rates to SMS, iii) researchers will informally ask men how they are getting on with being in the study and collect field notes of participant experiences when collecting outcome data at 3 months, 6 months and 12 months. A purposive sample of diverse and information rich men will be invited to volunteer for longer semi-structured qualitative interviews (6-10 from each trial group) at 12 month assessments or at a separate appointment (participant choice: face to face, telephone, Skype). The qualitative interview sampling frame and topic guide will be modified iteratively according to the emerging analysis. Perceptions on the original texts and the alternative texts will be explored by showing men a sample of the texts that they have not received. Think-aloud techniques will be used to understand preferences for style and content. The researchers will complete a reflexive diary of participant discussions, which will contribute to the mixed methods data collection and analysis.

We will examine issues of sustainability and future implementation into practice throughout this study. We will explore sustainable and efficient ways to verify weight measurements, should the SMS plus incentive intervention show most promise.

Follow up: A PhD student funded by University of Stirling will follow up men from month 12 to 24, after the interventions have finished. She will assess the acceptability and feasibility for a future full trial of gaining consent to access routinely collected NHS data via data linkage and to contact participants in the future. Interest in participating in the follow up study until 24 months is included in the initial consent form and will be confirmed verbally at the 12 month assessment. Assessments will occur remotely at 24 months after the start of the intervention for intervention and waiting list control participants and at 12 months after the start of the intervention for the extra participants reviving alternative SMS. Qualitative semi-structured interviews with men and their family members/significant others will ask about men's experiences with their weight after the intervention stops and whether it would be acceptable and feasible in a future trial to link the results of this study to men's future medical records (e.g. diabetes, heart disease, high blood pressure, hospital admissions, medication). The actual data linkage will not be done by the student unless additional resource can be found (ethics amendment would be requested). The student's work will inform data linkage decisions in a

future full trial. The student will ask about any unintended consequences arising from the study or need for additional support.

Outcome data collection: The assessment of weight and other outcome measures will be undertaken by researchers in suitable venues for participants (identified in Phase 1). This may be done at the participant's home if that is the only suitable venue for that participant. However, we are keen to encourage attendance at a community venue as this is a more sustainable model for the future. Men in the two intervention groups will receive an appointment and a SMS reminder at 3m, 6m and 12m (control group 12m only) to attend weight assessments. Non-attenders will receive two reminders to make contact with the researchers and given the opportunity to arrange another appointment. Reminders will use different methods e.g. SMS, email, phone, because mobile phone numbers change and harder to reach men may run out of phone credit. Researchers will use a portable stadiometer (height), measuring tape (waist circumference) and calibrated scales (weight) electronically linked by Bluetooth to a computer to transmit data directly to TCTU databases (manual systems as backup). Hard copies for all participant anthropometric measurements will also be noted to prevent any missing data caused by technology failure. The feasibility of offering both direct participant entered data onto a computer or paper version will be explored. Either the participant (with the researcher present for assistance) will enter the questionnaire data directly or the researcher will enter the data from completed paper versions of the questionnaire into the tablet (participant preference). All participants will be offered a £20 reimbursement to attend final 12 month outcome measures. Such reimbursements have been shown to increase follow-up rates[45].

The Delegation of Responsibilities Log will identify all trial personnel responsible for data collection, entry, handling and managing the database.

Towards the end of recruitment, we will attempt to assess the feasibility of blind outcome assessment. Researchers will remind men not to disclose which group they are in. One researcher who has not met the participant at enrolment will undertake either the 3, 6 or 12 months outcome assessments and will see if men reveal which group they are in. In a future trial, the feasibility of researchers being independent of the research team for blind outcome assessment and managed by SPCRN will be considered.

4.7. ASSESSMENT OF OUTCOME MEASURES FOR THE FEASIBILITY RCT

The following outcome assessments are based on existing research evidence, PPI and findings from Phase 1 of our study, with timing detailed in Table 1:

- *Anthropometry* (weight, waist circumference)
- *Acceptability*: Satisfaction with intervention overall, materials, and delivery[46].
- *Lifestyle behaviours*: including PA, Diet, Alcohol consumption and smoking
- *Wellbeing and Quality of Life*: Warwick Edinburgh Mental Wellbeing Scale[47], EQ-5D
- *Theory-based mediators of behaviour change* including motivational quality [intrinsic vs. extrinsic][48], and satisfaction with behaviour change and weight change[49]
- *Health Economic outcomes*: QALYs, NHS costs for future cost-effectiveness analysis

We will identify core outcomes that matter for obese men in a future full RCT and that are valid, acceptable and feasible through PPI consultation qualitative interviews.

Process evaluation measures which will be triangulated by qualitative data:

- Willingness to be randomised (assessed by reporting the numbers: approached; recruited, randomised, attending assessments, drop outs and reasons)
- Engagement with the interventions (including SMS components [i.e. number of SMS exchanged], incentive component [i.e. amounts awarded], number of self-report measurements e.g. weights, pedometer readings and hit rates for the study website information menus and visual feedback of progress towards targets
- Deviations from the intended intervention (technical factors relevant to sustainability)

4.8. ASSESSMENT OF UNEXPECTED CONSEQUENCES

Participants will be asked to report unexpected consequences from participating in the study, although systematic reviews of SMS or incentive interventions would suggest these are unlikely[18 20]..

Safeguarding for research participants is important. This is a very low risk study, however there is a possibility that men who are unsuccessful in their weight loss attempts may become upset and that this could impact on their emotional well-being. The researchers will be sensitive to this. In very rare circumstances, if the safety of the participant or of another person was thought to be at risk, the researcher would breach confidentiality. For example if a man told a researcher that he felt suicidal. Under these circumstances, the researcher would speak to the study leads or a senior member of staff in the host institution as soon as possible and in discussion with the participant the next steps would be agreed. The co-chief investigator, Prof Pat Hoddinott, is a GP and is therefore trained to manage such situations. Patient information leaflets (web and print) and SMS information which will provide local and national contacts where men can access additional support. The Health Informatics Centre in Dundee have experience of automatically screening incoming text messages in similar studies[6-8] for words like suicide, die, death. The study will use these tried and tested procedures. If a worrying SMS message is identified, the researchers will discuss this with a senior colleague and a plan would be agreed, which may or may not involve alerting appropriate services, following on a risk assessment.

Safeguarding the safety of researchers is also important. The researchers may work in pairs when recruiting or work alone, according to the neighbourhood and as advised by stakeholders with local knowledge. The Lone Worker Policy for staff working at the University of Stirling will be followed which includes informing a member of staff where and when research tasks are being carried out in the community, contact details and agreed report back times.

4.9. SAMPLE SIZE

Feasibility RCT: We aim 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[50]. We will conduct 18-30 face to face or telephone interviews (6-8 men from each trial group) recruited throughout the trial. This sample size is based on previous experience of conducting feasibility studies like this. A sampling frame will ensure diversity for socio-demographic and personal weight loss histories.

Mixed methods process evaluation: All men (n=105) who attend the 12 month assessment will be asked an open question for any suggestions for improving the study. Men who do not attend will be sent a final “thank you” letter informing them of how they can access the findings, and will be invited to provide feedback. Based on previous research experience of applying qualitative research in feasibility RCTs, 18-30 qualitative semi-structured interviews, with a diverse and information rich sample (6-10 from each trial group) are likely to be required to reach data saturation for key themes and for no new thematic issues to arise in interviews. However, some flexibility in the precise sample size is required, as it is impossible to predict important research questions that might arise in a complex intervention study like this. The PhD student will also conduct an additional 18-30 semi-structured interviews to investigate variation in engagement of men and to find out about their experiences after the intervention has finished.

4.10. THE ANALYSIS PLAN FOR THIS STUDY

Given the feasibility nature of the study, the data reported will mainly be descriptive. Summaries of quantitative outcome measures (all time points) will be tabulated by intervention group, including means and standard deviations for continuous variables e.g. weight loss (or medians and interquartile ranges if data are skewed), and proportions for any dichotomous or categorical data. The proportion of individuals contacted who were recruited and the proportion retained in the study at various time-points by group will be determined. Unadjusted mean differences and risk ratios will be calculated for 12 month outcomes to determine evidence of

potential effect of the interventions to test progression criteria, but no further estimates of effect size will be modelled. Completion rates will be reported so that the feasibility of each outcome measure can be assessed. A sample size calculation for a full trial will be performed, incorporating the standard deviation and response rates for the primary outcome. The proportions of participants who ask to stop the texts, withdraw from the study and attend the 3 month assessments will be compared for the original and alternative text messages.

Health Economics: The feasibility of measuring cost and outcomes for the cost-effectiveness analysis in the full trial will be explored. In a future full trial, cost-effectiveness of the interventions will be measured as a cost per Quality Adjusted Life Year (QALY) from an NHS perspective. The resources associated with the interventions will be abstracted from study forms. Other NHS resource use will be collected from participant questionnaires. Resource use estimates will be combined with unit costs obtained from standard sources or study specific estimates. QALYs will be derived from the responses to the EQ-5D. The incremental cost effectiveness ratio (ICER) will be estimated by dividing the difference in mean total costs between the intervention and control group by the difference in QALYs. Bootstrapping will be used to estimate variability in the ICER. A Value of Information analysis will be done to give an indication of the optimal sample size of a future trial.

Mixed method and qualitative data analysis: Anonymised transcripts of interviews, recruitment and attrition data, trial group, participant characteristics and outcomes will be entered into NVivo10 or similar software for analysis guided by a Framework approach[51]. The data collection, data analysis, reflection and refinement on the research questions, modification of the sampling strategy, topic guides and the coding frame will be an iterative process throughout the study. Notes from researchers' reflexive diaries kept during recruitment and assessment appointments and any free text responses from the on-line exit survey may also be entered onto NVivo and included in the analysis. Analysis will be driven by the key feasibility and acceptability research questions and objectives and any uncertainties emerging as the study progresses. Two researchers will independently develop a coding frame (agreed through team discussion) and identify key themes after reading a diverse sample of interviews. Thematic analysis will involve summarising mixed method data and constructing charts to compare and contrast data across the study groups and men with different characteristics. When reporting qualitative data findings, any quotations or data will be anonymised so that participants cannot be recognised.

4.11. THE ANALYSIS PLAN FOR THE MAIN TRIAL

If the feasibility study is successful, a full trial protocol will include a detailed statistical analysis plan (as per SPIRIT guidelines) which will specify the broad approach for main effects e.g. intention to treat analysis using generalised linear models. The analysis plan will also pre-specify subgroup and sensitivity analyses, outline a strategy for dealing with missing data (e.g. multiple imputation) and describe methods for mediation analysis (e.g. using structural equation modelling). Methods for analysing linked data will be determined once the results of the feasibility study are known.

5. ETHICAL ARRANGEMENTS

This is a low risk study, where participants could gain benefit to their own health through losing weight and gain financial benefit if they are randomised to the incentive group. The University of Stirling research ethics approval was granted on 8th January 2016 for Phase 1 of this study (June- December 2016) as no NHS sites or patients were involved. The approved protocol is available here: http://www.nets.nihr.ac.uk/projects/phr/1418509.

The main ethical issues are:

1. Ensuring that the incentives are benefiting the health of the individual and the wider public, in terms of the new knowledge that will be generated about how to engage men in weight loss activities, initiate and maintain weight loss. We aim to recruit men in difficult life situations, who do not have many opportunities and who often do not engage in health promoting activities. In

particular, ensuring that the information leaflet promotes the equipoise essential for a randomised controlled trial and minimises disappointment bias. For this reason the amounts of the incentives will not be disclosed in the information leaflet and will only be revealed after randomisation to the incentive arm. Our PPI and 3rd sector stakeholders will have helped us with this. Every effort will be made to ensure that the incentives are not unduly persuasive or coercive.

2. Safeguarding for research participants is important. This is a low risk study, however there is a possibility that men who are unsuccessful in their weight loss attempts may become upset and this could impact on their emotional well-being. The researchers will be sensitive to this. In very rare circumstances, if the safety of the participant or of another person was thought to be at risk, the researcher would breach confidentiality. For example if a man told a researcher that he felt suicidal. Under these circumstances, the researcher would speak to the study leads or a senior member of staff in the host institution as soon as possible and in discussion with the participant the next steps would be agreed. The co-chief investigator, Prof Pat Hoddinott, is a GP and is therefore trained to manage such situations. Patient information leaflets (web or print) and SMS information which will provide local and national contacts where men can access additional support can be provided. The Health Informatics Centre in Dundee have experience of automatically screening incoming text messages in similar studies for words like suicide, die, and death. The study will use these tried and tested procedures. If a worrying SMS message is identified, the researchers will discuss this with a senior colleague and a plan would be agreed, which may or may not involve alerting appropriate services, following on a risk assessment.

3. Safeguarding the safety of researchers is also important. The researchers may work in pairs when recruiting or work alone, according to the neighbourhood and as advised by stakeholders with local knowledge. The Lone Worker Policy for staff working at the University of Stirling will be followed which includes informing a member of staff where and when research tasks are being carried out in the community, contact details and agreed report back times.

4. Informed consent. We will adhere to the principles of the Declaration of Helsinki, the HRA guidance (http://www.hra.nhs.uk/). Research Governance procedures according to the University of Stirling will be adhered to: http://www.stir.ac.uk/research/integritygovernanceethics/ and NHS Site approvals will be in place before any NHS patients are recruited. The team have conducted research on financial incentives previously and are aware of the importance of avoiding perceived coercion, bribery and offering an ethical control arm which allows freedom of choice regarding weight loss. Men's Health Forum and our PPI group have chosen the study short name, helped us draft patient information leaflets, the text messages and the website design.

5. Data protection. Participant data, contact information and responses to text messages will all be managed and securely electronically in the Participant Tracker Software at the Health Informatics Centre, University of Dundee which is an approved safe haven. Data handling and storage will comply with the Data Protection Act 2003. . Researchers employed by the University of Stirling on this study will have will have secure passwords to access the Participant Tracker system at the University of Dundee. Researchers will have undertaken Good Clinical Practice training. Confidentiality will be assured for all data collected. Data from qualitative interviews will be anonymised by removing any information which could potentially identify the participant. Only professional transcribers who are approved by the University of Stirling and meet confidential data handling requirements will be used. Each participant will have a unique ID. The interview recordings, transcriptions and NVivo database will be stored securely in the University of Stirling BOX system, which is password protected and encrypted. The recorder will be wiped clean as soon as the recording has been successfully uploaded to the BOX system. Personal data and audio recordings will be destroyed as soon as it is certain that they are no longer required (i.e. at the end of the study/follow-up period)

6. RESEARCH GOVERNANCE

The study is sponsored by The University of Stirling and will be conducted in accordance with the research governance procedures at http://www.stir.ac.uk/research/integritygovernanceethics/. All researchers involved in recruitment and data collection will have attended NHS Health Scotland Good Clinical Practice training and will have current Research Passports. The University of Stirling has codes of practice for secure data management, researcher conduct and safety. Anonymised data will be stored for 10 years after study closure, in accordance with this guidance. Study closure is defined as the date on which the last participant has completed their follow-up assessment (anticipated 2019 when the PhD studentship ends).

6.1. STUDY MANAGEMENT

HODDINOTT (co-PI) and DOMBROWSKI (co-PI) will be responsible for the leadership and management of the project. They will jointly take overall responsibility for delivering the study complying with ethics and research governance procedures and the training/supervision of Stirling employed staff.

GRINDLE wrote the Characters, Story and Narrative SMS based on his Digital Narrative Transformation Framework. The underlying principles and structures for the practical application of commercial narrative engagement strategies in digital health behaviour change interventions is informed by his 20 years working in Film, Television and Computer Games as a screenwriter, producer and developer as well as his subsequent PhD research (based on that expertise) entitled 'The Power of Digital Storytelling to Influence Human Behaviour'. The Narrative SMS design team meet during monthly Script Conferences (led by Grindle) to contribute medical (PH), weight loss and maintenance (SD), weight management and nutrition (MM), health behaviour change (SD, CG) and men's health (MT). These meetings are attended by PPI representatives on a rolling basis to ensure that a range of views are represented.

VAN DER POL will lead on the assessment of the feasibility of collecting cost effectiveness data.

JONES will manage the SMS intervention technology, data collection and randomisation systems, and oversee monitoring and quality assurance. ELDERS will supervise the TCTU statistician undertaking the statistical analyses, who with PH, SD, CJ and collaborator HOGARTH (assistant director of TCTU) will form a data management team. The data management team will be responsible for quality assurance through regular monitoring of data collection, including recruitment, response rates, frequency, completeness and accuracy of data returns. The data management team will inform the Research Team and Project Management Group of any specific tasks required to address issues arising.

GRAY will facilitate PPI involvement with FFIT trial men's group and contribute expertise from the FFIT trial.

AVENELL will run existing literature searches for systematic reviews on men's obesity relevant to this study.

KEE and McKINLEY will contribute their expertise in incentive interventions and public health nutrition.

HARRIS will provide a social science perspective; assist with the qualitative and mixed methods research and the supervision of the research assistants.

Weekly Research Team meetings between SD, PH, MG, the RAs and PhD student will be supplemented with day-to-day support by email and telephone. Other grant holders and PPI will be invited to join by teleconference as appropriate.

The project management group (PMG) will consist of the named Co-Is and will meet every 2-4 months, with a face-to-face workshop to discuss the final analysis. The PMG will be responsible for ensuring milestones are met and for scientific quality and integrity.

6.2. STUDY STEERING COMMITTEE (SSC)

An independent SSC has been appointed, met on 30th September 2016 and discussed this protocol and the attached information materials and will meet on two further occasions to provide oversight. A SSC Charter has been agreed. Prof Ed Juszczak (NPEU Clinical Trials Unit Director, University of Oxford) has been appointed as the Independent Chair. Other independent members include: Prof Kate Jolly (Head of Department of Public Health, University of Birmingham); Ms Joyce Thompson (Dietetic Consultant in Public Health Nutrition and Tayside Nutrition MCN Lead Clinician); Mr Andrew Shanahan (PPI Representative, Director MAN v. FAT – the weight loss website for men); Mr Mark Kelvin (PPI representative, Programme Director, National Links Worker Programme, Health and Social Care Alliance Scotland). Ms Martine Stead (Deputy Director, Institute for Social Marketing, University of Stirling) will be the Sponsor's representative. PH and SD will be non-independent members, Mr Matthew McDonald will be the facilitator and other members of the research team may be invited as observers. SSC members are signing the remit and conditions as set out in the SSC Charter.

6.3 DATA MONITORING COMMITTEE (DMC)

A DMC is not considered necessary for this study. The SSC will undertake this role.

6.4 PUBLIC PATIENT INVOLVEMENT (PPI)

The MHF have contributed as PPI Co-Investigators to decisions and helped with writing study materials. They co-authored the NIHR systematic review on men's obesity with Alison Avenell and Pat Hoddinott[4]; produced a "How to make weight loss services work for men" guide[44] and a PA study in Ireland which inform this study. They have website expertise for engaging obese men in weight loss. Two focus groups with obese men participating in the successful FFIT Trial[10] informed the funding application for this study. Local stakeholders like the Scottish Community Health Council have helped us to identify obese men interested in helping us to design this study. 24 members of the community - all with direct and indirect experience of men's weight loss have informed this trial protocol. PPI representatives have attended monthly meetings to inform the narrative SMS. Eight PPI representatives of the target population have volunteered to pilot test the SMS messages ahead of the trial. Feedback on the SMS will be through a private Facebook page. PPI will ensure that the interventions, study processes and community venues are acceptable, feasible and optimise the recruitment, uptake, engagement and follow up of men, particularly from disadvantaged groups. Two independent PPI representatives are members of our SSC (see 6.2.) MHF will be involved in study reports and designing the dissemination strategy. MHF has strong links with Public Health in the devolved Governments, and with diverse communities of men, should wider PPI perspectives be desirable in future.

6.5. DISSEMINATION STRATEGY

We will produce a final report for NIHR as specified in our funding contract. In addition we will produce a Publication and Dissemination Strategy with PPI input which will be agreed by the Project Management Group and regularly updated to demonstrate progress. This will include publications in international peer reviewed journals and presentations in international scientific meetings. With the assistance of collaborators and PPI representatives we will disseminate findings to a health policy and general audience, mindful of whether a future definitive trial is indicated and the unintended consequences that media publicity could have on future research around sensitive topics like financial incentives. Summaries of publications and dissemination activities will be available on the study website for participants to access.

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