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Title

Reducing alcohol consumption in obese men: development and feasibility testing of a complex community-based intervention

Summary of research

Obesity and alcohol-related harm are major public health problems, but obese individuals who drink excessively are at a greatly increased risk, particularly from liver disease. Many obese men want to lose weight, but are reluctant to engage in conventional weight loss approaches. This project develops and evaluates the feasibility of a gender-specific intervention to reduce alcohol consumption through the motivation of weight loss. It offers extended support to achieve sustained behaviour change. The intervention is designed to reach large numbers of men at risk of obesity and alcohol-related problems including those who might not be identified through the health care system. This community based study will test the acceptability and feasibility of all stages of a randomised controlled trial. If successful, the effectiveness of the intervention will be tested in a subsequent study.

This 21 month study will be conducted in two phases. Phase 1 will develop the recruitment strategy and the novel alcohol intervention. It will comprise six focus groups with obese men aged 35-64 years, and in-depth interviews with six key stakeholders who could facilitate the recruitment of participants. Focus group participants will be identified from a range of potential venues (e.g. workplaces, community centres, public houses, football grounds, golf clubs and hospital foyers). Key stakeholders will be recruited from different institutions (e.g. a community centre, a hospital, a large supermarket, a GP practice, a training centre for unemployed people, and sports centres).

Phase 2 will recruit 60 men aged 35-64 years. Two complementary recruitment strategies will be used. One will identify obese men from primary care records. The other will adopt a community outreach approach, time-space sampling, which was designed to identify hard to reach groups. Men will be randomised to receive either the novel extended intervention or a comparator (a conventional alcohol brief intervention). A key feature of the study is that trained lay people will be involved in intervention delivery. The training programme used will be developed from the Department of Health manual[1] taking into account recent recommendations for training lay people. Each lay trainer will only deliver one type of intervention (novel intervention or comparator).

The men in Phase 2 will be randomised to a novel extended intervention group or a comparator group. Randomisation will be stratified by recruitment strategy. The novel extended intervention will use successful approaches to changing health behaviours informed by recent systematic reviews[2] and taxonomies of behaviour change techniques[3] [4], including one specific to alcohol brief interventions[5]. The theoretical model underpinning the intervention is the Health Action Process Approach (HAPA)[6] which describes the adoption, initiation and maintenance of a new behaviour as a process that involves a motivational and a volitional phase. The intervention will also draw on techniques developed for our successful NIHR feasibility study of a text message delivered intervention to reduce alcohol-related harm in disadvantaged men[7]. Thus, the intervention will be designed to increase the men's awareness of their susceptibility to health problems caused by obesity and alcohol; increase

their motivation to lose weight by reducing alcohol consumption; gain commitment to changing drinking patterns; encourage them to set goals and action plans to do so; increase refusal skills; and implement strategies to prevent relapse.

To maximise its effect the novel extended intervention will be delivered in three stages. An initial face to face session will focus on weight loss through reduced alcohol consumption. This session, delivered by a trained lay person, will last approximately 20 minutes. The face to face session will be augmented by a volitional help sheet, a tool designed to enable participants to avoid heavy alcohol consumption through forward planning. The final part of the intervention will comprise a series of messages and images delivered by mobile phone over two months. These messages will reinforce the content of the face to face intervention and extend the behaviour change strategy.

The comparator group will receive a conventional brief alcohol intervention[8] which will be delivered in one face to face session by a trained lay person. The session will last approximately 5-10 minutes.

Primary outcomes for assessing the success of the feasibility study are: recruitment and retention of participants; acceptability of the intervention; and engagement with components of the behaviour change strategy. The feasibility study will also measure secondary outcomes: the impact of the study on the perceived benefits of moderated drinking; intention to reduce alcohol consumption; and self-efficacy in ability to reduce drinking and lose weight. The two primary outcome measures for a full RCT of the intervention (reported weekly alcohol consumption and weight loss) will also be measured, although the study will not be powered to detect treatment effects. Two validated economic appraisal questionnaires (EQ-5D and CSRI) will also be included to inform the design of a definitive economic appraisal.

A major output from the study will be a manual for a community-based intervention. This will provide guidance on recruitment and retention of participants and design and delivery of the intervention. It will describe methods for the recruitment and training of lay people to deliver the intervention and provide step by step guidance for the lay trainers on delivering the intervention. It will outline all data collection methods including the process measures to monitor engagement with components of the behaviour change strategy.

Background and rationale

Obesity among men is a major public health problem. Data from 2011 revealed that 24% of men in England[9] and 28% of men in Scotland[10] were obese. Based on current trends, the UK Government's Foresight Programme predicts that obesity among men could reach 36% by 2015 and 60% by 2050[11].

Heavy alcohol consumption is associated with an increased risk of obesity[12 13]. Heavy drinking is often associated with overeating[14], thus increasing the prevalence of overweight and obesity. Obesity and heavy alcohol consumption have independent adverse effects on the liver. However, it is a large supra-additive risk of liver disease in people who are obese and are heavy drinkers that gives great cause for concern[15].

Evidence explaining why this research is needed now

There is a clear need for an intervention which could reduce both alcohol consumption and obesity in men. The benefits would be weight loss, reduced alcohol-related harm and a reduction in morbidity from the synergistic effect of obesity and high alcohol consumption[15]. However several problems need to be overcome to achieve this. Many obese men want to lose weight, but are reluctant to try conventional weight loss approaches which are generally targeted at women[16]. Maintenance of weight loss usually requires extended care interventions[17]. Attrition is high in weight loss studies[18 19]. Given the scale of the problem a low cost strategy to reach large numbers men at high risk is required. Thus a new approach is needed which addresses these challenges.

Aims and objectives

The main aim of this feasibility study is to develop a recruitment strategy and a gender-specific intervention tailored to reduce alcohol consumption among obese men. If successful, the intervention will subsequently be tested in a full scale randomised controlled trial.

Achieving this aim poses a number of challenges which the feasibility study will explore in order to provide practical solutions. The challenges arise from the nature of the study group and the design and delivery of the intervention. Identifying obese men who drink harmfully will be difficult. Recruiting and retaining these men in the study will require a sensitive careful approach. Equally, the intervention will need to be designed to appeal to the men and engage them in the behaviour change strategy. Part of the intervention will be delivered by lay trainers whose training and support are crucial to the effective delivery of the intervention. Finally, sensitive process measures are required to determine the fidelity of delivery and the extent to which there is engagement with the intervention.

Objectives for the feasibility study:

1. To determine the best ways to recruit and retain obese men in a study aimed at reducing heavy drinking.
2. To design an intervention that is an acceptable way to achieve a sustained reduction in alcohol consumption.
3. To identify the content and timing of the delivery that is most likely to engage obese men in an intervention to reduce alcohol consumption.
4. To develop high quality training to enable the lay trainers to deliver their component of the intervention.
5. To devise process measures to detect engagement with the steps on the causal model for behaviour change.
6. To compile a manual of methods for participant recruitment, training of lay staff and design and delivery of the intervention.

The main research question for the subsequent full scale study is: Can an extended alcohol intervention reduce alcohol consumption among obese men through the motivation of weight loss?

Research plan

This community based study is designed to develop and test the feasibility of a novel intervention to reduce alcohol consumption among obese men. The study will be conducted in two phases.

Phase 1

Phase 1 will involve: devising a recruitment strategy; designing the intervention; preparing the baseline questionnaire; constructing the framework for a manual for recruitment and delivery of the intervention; and recruiting and training lay people to deliver the intervention. Six focus groups will be convened with obese men who drink in excess of the national guidelines recruited from a variety of venues (e.g. workplaces, community centres, public houses, football grounds, golf clubs and hospital foyers). The focus groups will explore the drinking patterns of the men and their attitudes to obesity and motivation to lose weight and reduce alcohol consumption. They will discuss challenges and barriers to recruiting and retaining men in the study and explore potential recruitment strategies. Finally they will assess the acceptability of components of the intervention.

Six in-depth interviews will be conducted with key stakeholders and gatekeepers to community groups (e.g. managers from a community centre, a hospital, a large supermarket, a GP practice, a training centre for unemployed people, and sports centres) to investigate the best ways to recruit participants and deliver the intervention. The interviews will cover: identifying opportunities for meeting with potential participants (e.g. during the working day or during community group meetings); discussing possible venues for delivering the intervention (e.g. hospital, GP practice, community centre, golf club); and exploring with stakeholders opportunities for engaging the men in a study to reduce alcohol consumption.

Focus group discussions and in-depth interviews will be digitally recorded and fully transcribed. Analysis will be facilitated by the use of text management software (NVivo). Transcripts will be analysed thematically, using framework analysis[20] to allow systematic comparisons to be made. Two researchers will be involved in the analysis to ensure reliability of interpretation and coding.

Phase 2

Phase 2 will test all of the steps in the conduct of the full randomised controlled trial. It is fully described in the next sections, but briefly it will involve the recruitment of 60 men (aged 35-64 years) who will be randomised to receive either an alcohol intervention tailored for obese men or a conventional alcohol brief intervention. A key feature of the study is that the intervention and control packages will be organised in such a way that they can be delivered by a trained lay person. Using lay people to deliver the intervention makes roll-out in the long term a low cost method for delivering the intervention to large numbers of people. Recent guidance on training health trainers[1] and the competencies required to deliver behaviour change interventions[21] will be used to develop a manual for their training. The manual, a major output from the feasibility study, will also provide guidance on the recruitment of the target group and delivery of the intervention to be used in a definitive trial.

Health technology being assessed

The gender-specific, interactive intervention is designed to reach large numbers of men at risk of obesity and alcohol related problems. It specifically targets men who would not necessarily be

identified through attendance at health care facilities. The intervention offers extended support to encourage a sustained reduction in alcohol consumption through the motivation of weight loss. As well as the health benefits of weight loss, the more immediate benefits such as body image and increased sexual potency, will be highlighted. The intervention will use successful approaches to changing health behaviours informed by recent systematic reviews[2] and taxonomies of behaviour change techniques[3 4], including one specific to alcohol brief interventions[5]. The intervention will also draw on experience from our NIHR feasibility study[7] on ways to embed theory and behaviour change techniques into intervention design and delivery.

The theoretical basis of the intervention is the Health Action Process Approach (HAPA)[6], a comprehensive model which allows integration of a range of evidence based behaviour techniques. As with existing theories the Health Action Process Approach addresses pre-intentional motivational processes that lead to behavioural intentions. However this model suggests the adoption, initiation, and maintenance of new health behaviour occurs as a process that involves a motivational phase and a volitional phase. The volitional phase includes planning, action, and maintenance. Perceived self-efficacy has a crucial role in achieving success in all of the stages. This approach addresses the intention-behaviour gap, identified as a weakness in some behaviour change theories. It emphasises the post-intentional volition that leads to behaviour change. Volition relates closely to a range of effective behaviour change techniques, making the HAPA particularly suitable as an intervention model.

The causal model for behaviour change is: generate interest in the study within the community; increase awareness of consumption levels which are defined as harmful; identify motivational beliefs; increase awareness of susceptibility to alcohol related harm for men who are already obese; increase motivation to lose weight by reducing alcohol consumption; alter alcohol expectancies; gain commitment to change; develop goals, action plans and coping plans; increase refusal skills; implement strategies to prevent relapse; reduce total alcohol consumption which would in turn lead to weight loss. The three parts of the intervention are:

Part 1

A face to face session will focus on weight loss and its role in the prevention of alcohol-related harm. This session, delivered by a trained lay person, will last approximately 20 minutes. It will: include feedback on the person's alcohol use and weight; use motivational enhancement to clarify how reducing alcohol consumption can assist with weight loss and can reduce the harmful synergistic effects of obesity and heavy alcohol consumption; encourage the analysis of high-risk situations for drinking; assist with planning coping strategies; and introduce the development of a personal plan to reduce consumption. Sessions will be audio recorded and will be scrutinised by an independent researcher to assess fidelity of delivery of the intervention.

Four part time lay people will be trained to deliver the face to face component of the intervention and control packages. They will be paid for their training time and for the delivery of the intervention. Lay trainers will be identified through employment services, e-mail networks, a marketing campaign and a community outreach strategy. The Dundee Employment & Aftercare Project (DEAP) provides a free service publicising casual, part-time and fulltime jobs. Dundee and Abertay Universities run Jobshops, which provide a free recruitment service for students and graduates. Adverts offering

part-time employment will be placed in the weekly information messages sent by e-mail through existing university and NHS networks. Posters will be placed in venues such as community centres, sports centres and libraries. The training will be developed using the Department of Health trainers' manual[1] and guidance on the competencies required to deliver behaviour change interventions[21] which will clarify the role of the lay trainer. Training will be delivered through small group sessions with an emphasis on practising the skills delivered[22 23]. The two lay people delivering the intervention package will be trained separately from those delivering the control package. This will prevent contamination of the control group[24].

Retention of the lay trainers will be addressed by measures aimed to increase job satisfaction. Role clarity will be assured through a comprehensive job description supported by a university contract. Training manuals will be user-friendly and provide step by step guidance on all tasks to be performed. Training will involve informal teaching, delivered by an external consultant and supported by extensive role play. This will increase the lay trainers confidence in their ability to perform their role. Lay trainers will then conduct pilot intervention sessions with volunteers from the target group[25]. These will be reviewed in a supportive manner by the Research Fellow to resolve difficulties encountered. During the study lay trainers will meet frequently with members of the research team to exchange experiences, to discuss problems encountered and lessons learned. Lay trainers who experience particular difficulty will be offered individual support sessions. The intervention interviews will be audio recorded and will be scrutinised by an independent researcher to assess fidelity of delivery of this part of the intervention package.

Part 2

The face to face session will be augmented by giving participants a volitional help sheet[26], a tool which is designed to enable participants to avoid heavy alcohol consumption through forward planning. The volitional help sheet consists of a table containing lists of critical situations when heavy drinking is likely (temptations), and appropriate responses which could lead to the avoidance of heavy drinking.

Part 3

The final part of the intervention will comprise a series of Short Message Service (SMS) and Multimedia Messaging Service (MMS) messages delivered by mobile phone over a two month period. The benefits of weight loss will be promoted to encourage reduced alcohol consumption. Based on the Health Action Process Approach[6 27-29] and using techniques shown to be effective with obese adults[30], the men will be guided through the process of changing behaviour in order to reduce alcohol consumption and lose weight. A series of interactive text messages with images will be designed using the successful approach developed for our NIHR funded feasibility study[7]. In particular it will employ many of the devices used successfully to promote engagement with the intervention such as tailoring messages to the target group, use of humour, informal text style, questions to promote interactivity and sensitive timing of messages.

The text messages will reinforce the content of the face to face intervention and extend the behaviour change strategy. They will encourage participants to set realistic goals to reduce consumption; implement a plan of action; monitor drinking behaviour; identify barriers; and construct strategies to deal with barriers. Texts will increase self-efficacy for maintenance of reduced drinking

and participants will be encouraged to develop strategies for relapse prevention[6]. This interactive intervention delivered over an extended period will encourage sustained behaviour change. Participants will be encouraged to monitor weight loss on two occasions and report this by text message[30]. This may give men an incentive to lose weight and will also give an indication of engagement with the intervention.

Comparator (control group)

A brief alcohol intervention will be delivered in one face to face session by a trained lay person. The session, based on methods used in the SIPS Alcohol Screening and Brief Intervention Research Programme,[8] will last approximately 5 - 10 minutes. The SIPS Simple Structured Advice Intervention Tool[31] will be used to guide the session. The participant's risk of alcohol-related harm will be identified from reported levels of consumption. Participants will then be encouraged to think about the benefits of cutting down and in making plans to achieve this.

Design and theoretical/conceptual framework

This feasibility study will develop and test a novel, community-based group intervention in accordance with the MRC framework for complex interventions[32]. The study has been designed to provide essential information for the design and execution of a full randomised controlled trial.

Target population

Study participants will be obese men whose alcohol consumption is in excess of the government's recommended guidelines (maximum 21 units per week).

Inclusion/exclusion criteria

Inclusion criteria are men who: are aged 35-64 years; who regularly consume >21 units of alcohol per week; and are obese (BMI>30).

Exclusion criteria are men who: are already attending Alcohol Problem Services; are using weight management classes/services; will not be contactable by mobile phone during the study period.

Setting/context

This study is based in the community. Participants will be obese, but otherwise healthy community-dwelling men. Half of the participants will be identified by GP practices from patient registers and half will be recruited through community groups, workplaces and venues where the target population are likely to attend. The intervention will be delivered in the community by trained lay people. The majority of the participant contacts will be in community centres close to where the men live. NHS personnel will have no involvement in the delivery of the intervention.

Sampling

A review of the literature on recruitment of hard to reach men identified strategies to increase recruitment. The techniques adopted in this study are personalised approaches, multiple attempts at contact at different times of the day and financial incentives[33-36]. Men taking part in Phase 1 will receive a £10 gift voucher for taking part in focus groups and will also be given travel expenses. Phase 2 participants will be given gift vouchers of £10 on completion of the baseline and follow up interviews and will receive a £5 gift voucher fortnightly for the duration of the intervention period. Travel expenses will also be reimbursed.

In Phase 1 obese men for the focus groups will be purposively sampled from a variety of venues (e.g. workplaces, community centres, public houses, football grounds, golf clubs and hospital foyers). The Research Fellow will identify appropriate venues and suitable times for recruiting participants. This will cover areas with differing levels of social disadvantage. Employers, managers of community centres and proprietors of public houses and clubs, will be approached to grant permission for the researchers to approach potential participants to discuss the study. These gatekeepers will also be invited to distribute participant information leaflets to generate interest in the study. Key stakeholders (e.g. factory manager, hospital director, community centre manager, GP; voluntary sector representative), who would be involved in rolling out the intervention will also be interviewed in Phase 1. They will be purposively sampled from their workplaces.

The recruitment for Phase 2 will build on the findings from the Phase 1 focus groups. These will cover the opportunities for recruitment as well as potential barriers to recruitment and strategies to overcome these. Phase 2 will use two recruitment methods to ensure good coverage of obese men who drink heavily:

Recruitment strategy 1 (GP practices): Practices will be asked to identify men aged 35-64 years who are obese. Potential participants will receive a letter from their GP inviting them to take part in the study. Those who do not refuse to take part will be screened for eligibility (regularly drink more than 21 units of alcohol per week). Approximately 300 men will be nominated in order to identify and recruit 30 that fit the entry criteria. This will also allow estimation of recruitment rates for a full trial. Three criteria are proposed for judging the success of the recruitment strategy: that 10% of men aged 35-64 are registered as being obese; that 25% of obese men drink >21 units of alcohol per week; and that the proportion of eligible men (on obesity and drinking) who are recruited to the study is 50%.

Recruitment strategy 2 (Time-Space sampling): A community outreach strategy, time-space sampling[37] will be used to recruit half of the study population. This is to address the concern that GP records do not include all obese men[9]. Time-space sampling recruits participants from a number of venues and involves sampling at different times of day and days of week. This approach requires initial fieldwork to identify appropriate venues and suitable times for recruitment. Men fitting the inclusion criteria will be recruited from a list of venues to include: workplaces; community groups; hospital foyers; public houses; football grounds; and golf clubs. This list will be augmented by findings from the focus groups and from the interviews with key stakeholders. There are two targets against which the success the recruitment strategy can be assessed. The first is to identify at least 15 venues

at which men could be recruited. The second is to recruit no more than two men per visit (to avoid contamination) and to recruit at least one person per three visits to the venues.

Randomisation

Sixty men will be recruited and randomised to receive the intervention or control package. Randomisation will be carried out using the secure remote web-based system provided by the Tayside Clinical Trials Unit. Randomisation will be stratified by the recruitment method and restricted using block sizes of randomly varying lengths. The Research Fellow will not have access to the file giving details on randomisation and will be blind to intervention status. He/she will inform participants that they will be contacted by another researcher and offered an appointment for a face to face meeting.

Baseline data collection

Participants will be contacted by telephone to arrange an appointment. Suitable venues will be established e.g. community centre or at home. At this meeting, eligibility for participating in the study will be confirmed by accurately measuring height and weight to calculate BMI. Height will be measured using a portable Seca stadiometer with men in stockinged feet. Weight will be measured by Seca medical scales. Participants will be asked to remove shoes, heavy outer garments (jackets or coats) and loose change and keys. They will be asked to stand, facing forwards, in the centre of the scales with heels against the back edge of the scales. The measurement will be repeated if the participant moves during weighing. Participants will self-complete the baseline questionnaire (alcohol consumption, patterns of drinking, HAPA measures including intention and motivation to reduce consumption[6]). Socio-demographic data including education, employment, Scottish Index of Multiple Deprivation (SIMD)[38], and marital status will be collected at baseline.

The alcohol time line follow back (TLFB) questionnaire[39], which will be administered at baseline and follow up, will be used to measure alcohol consumption accurately over the previous 30 days. This will be used as the first primary outcome measure, weekly alcohol consumption. The Fast Alcohol Screening Test (FAST)[40] will be measured at baseline and follow up.

Follow up assessment

Participants will be invited to attend for a follow up visit, three months after the intervention is complete. The Research Fellow, who will be blind to study group allocation, will complete the follow up questionnaire by interview at a suitable venue.

Primary outcomes for assessing the success of the feasibility study are: retention of participants; acceptability of the intervention; and engagement with components of the behaviour change strategy. The feasibility study will also measure secondary outcomes: the impact of the study on the perceived benefits of moderated drinking; intention to reduce alcohol consumption; and self-efficacy in ability to reduce drinking and lose weight. Primary outcomes for the full trial, alcohol consumption and weight loss will also be measured. In preparation for anticipated economic appraisal alongside a

full RCT of the intervention following the feasibility study, the EQ-5D™, a standardised tool for measuring health outcome, and the Client Service Receipt Inventory (CSRI) will be administered at follow up. Although the feasibility study will not be powered to detect treatment effects, the inclusion of these measures will be employed for the design of a definitive economic appraisal.

Sample size

As this feasibility study will not estimate effectiveness, a formal sample size calculation is not required. For Phase 1, six focus groups will be sufficient to elicit the views of men and guide the development of the intervention. Six in-depth interviews will provide insight from a range of stakeholders on opportunities for recruiting and delivering the intervention in the community. For Phase 2, sixty individuals will be sufficient to test the feasibility of all aspects of the study.

Process evaluation

Several methods of process evaluation will be used to inform whether the intervention was delivered in the way it was intended; whether the approach is likely to be successful; and to identify ways in which the intervention could be improved[32]. A checklist of items to be addressed in the face to face brief intervention (for the intervention and control packages) will be compiled as part of the users' manual. The interviews will be audio recorded and will be scrutinised by an independent researcher to assess fidelity of delivery of this part of the intervention package.

The study will also use process measures successfully developed for text message interventions[41]. Fidelity of delivery of the text messages will be assessed by the data captured by the computer system used to deliver the text messages. Some of the text messages will ask questions. Responses to these messages will be analysed to assess engagement with the study and with the psychological constructs of the behavioural change strategy. This approach will also be used to monitor retention of participants in the study. Finally, the responses will be used to identify ways to improve the intervention by identifying parts of the intervention that were unpopular or misunderstood. The follow up interview will also be used to assess the acceptability and impact of the intervention, by asking detailed questions about all parts of the study.

Changes in quantitative process measures (e.g., HAPA measures) will be analysed in both groups. While the study is not powered for a formal mediation based process analysis, this approach allows descriptive analyses about the levels of self-efficacy, intention and planning of both groups after the intervention and may indicate areas in need of further optimisation.

Data analysis

As this is a feasibility study, formal hypothesis testing is not appropriate. Instead the analysis will assess the participants' experience of all aspects of the study. It will determine the appropriateness of the recruitment strategy and the design and delivery of the intervention.

In Phase 1, focus group discussions and in-depth interviews will be digitally recorded and fully transcribed. Analysis will be facilitated by the use of text management software (NVivo). Transcripts

will be analysed thematically, using framework analysis[20] to allow systematic comparisons to be made. Two researchers will be involved in the analysis to ensure reliability of interpretation and coding.

For Phase 2, descriptive statistics will be used to explore recruitment and retention rates. The analysis will also determine whether the outcome measures can be readily measured and whether they will enable the significance of changes in the outcome measures in the full trial to be analysed using paired t-tests, McNemar's test and the Wilcoxon test. The two primary outcome measures for a full RCT of the intervention would be: reported weekly alcohol consumption and weight loss. The feasibility study will measure both but will not be powered to detect treatment effects.

Dissemination and projected outputs

This feasibility study focuses on the development of methodology. Dissemination will therefore focus on those who would use the methodology to recruit individuals from the community or to develop new interventions to engage people in a behaviour change strategy over a sustained period. Three papers on: attitudes, beliefs and intentions of obese men on reducing alcohol consumption; the use of time-space sampling to recruit hard to reach groups; and the development of the intervention will be submitted to methodology journals. The work will also be submitted for presentation at public health conferences.

The recently formed Scottish School of Public Health Research (SSPHR) (http://ssphr.ac.uk/) will be used as a forum for the dissemination of findings. It was created to establish greater alignment between the needs of policy makers and practitioners and the activities of public health researchers. It involves civil servants, NHS staff, voluntary organisations, local government and researchers. Alcohol, one of SSPHR's main themes, is led by Professor Crombie. The SSPHR also publishes online research briefings which provide short accessible summaries of academic research.

Findings from the full trial will be disseminated to the many community groups who will be involved in recruiting participants and facilitating the delivery of the intervention. These include local authorities, alcohol charities, weight loss charities, charities that support long term unemployed, the criminal justice service and voluntary groups. Findings on recruitment and retention of participants may be useful for groups planning local initiatives. Maintenance of links with key stakeholders within the community is essential preparation for a subsequent full randomised controlled trial.

This study uses lay people to deliver the intervention. This offers a unique opportunity to raise the profile of the research within communities. We will put in place a training programme for the lay people who will deliver the intervention. This will provide local people with valuable skills, providing them with new opportunities for employment, but also giving them the skills to act as advocates for safe drinking within the community.

If the intervention is shown to be effective, the findings will be disseminated to all partner organisations, together with proposals for mechanisms for national roll out of the intervention. Meetings will be proposed to explore how the intervention can be incorporated into their current public health strategies on alcohol and obesity.

Plan of investigation and timetable

The timing of the study has been organised so that the delivery of the intervention and follow up of the men is not affected by heavy drinking and feasting over the Christmas festive period.

Phase 1

May – December 2014

Month (task completed or milestone reached by the end of the month)

1	Recruit community group leaders and stakeholders
2	Develop schedules to be used for the focus groups and in-depth interviews
3	Recruit focus group participants through workplaces; community groups; hospital foyers; public houses; football grounds; and golf clubs
5	Conduct focus groups and in-depth interviews
7	Transcribe focus group discussions and interviews and conduct analysis
7	Design the intervention, including approximately 50 SMS and MMS messages
7	Develop the computer programme to deliver the SMS and MMS messages
8	Construct framework for the manual to recruit participants and deliver the intervention
8	Recruit participants to pilot the intervention

January – February 2015

9	Design baseline questionnaire
9	Recruit three GP practices and identify venues for time/space sampling
9	Assist practices in identifying patients suitable for recruitment and in the preparation of letters of invitation
10	Train part-time lay people to deliver the intervention and control packages
10	Pilot the questionnaire and intervention and control packages
10	Set up meetings/appointments with groups and individuals to facilitate time/space sampling

Phase 2

March – July 2015

12	Screen potential participants to identify those eligible for randomisation
13	Recruit and randomise 60 subjects
13	Conduct baseline assessment
15	Deliver the intervention
15	Develop and pilot questionnaire for follow up interviews

August – September 2015

17	Conduct 3 month follow up telephone interviews with study participants
18	Collate and code questionnaires for data processing
20	Develop manual for recruitment, staff training and delivery of the intervention

October – January 2016

20	Analyse data
21	Write final reports and papers
21	Modify intervention according to findings from feasibility study in preparation for the full study
21	Finalise the manual for recruitment and delivery of the intervention

Project management

The Principal Investigator will maintain oversight of the whole project. This feasibility study will be carried out in one centre only, so progress will be monitored weekly. An experienced Research Fellow will be employed to undertake the study and take on part of the role of project manager. The Research Fellow will be supported in this by the PI.

A Steering Committee will be established prior to the start of the study. This will comprise all co-applicants and two lay members. The group will meet once before the study begins, then approximately every four months. An Executive Group comprising the principal investigator, project manager and Research Fellows will meet monthly to monitor week by week progress. In addition, the Executive Group will meet with co-applicants to develop parts of the project as required e.g. with the psychologists, medical sociologist and graphic designer to develop the text messages; with the computer scientists and a CTU representative to plan the development of the software for randomising participants and for delivering the intervention. Two user group representatives will be invited to attend all of the project development meetings.

Approval by ethics committees

Following the formal notification of a decision to fund the study in August 2013 we would prepare the submission for ethical approval. As soon as the contract is awarded we would submit an application to the local research ethics committee. We anticipate that the ethics application would be submitted by December 2013. The study is scheduled to begin in May 2014 so that the delivery of the intervention and follow up of the men is not affected by heavy drinking and feasting over the Christmas festive period. This start date will ensure that there is adequate time to obtain permissions required after the award is made.

Patient and public involvement

The design of the recruitment strategy and the intervention will be heavily influenced through public involvement. The consumer group will be involved at all stages of the study. Two user group representatives, to be recruited at the beginning of the study, will be invited to attend all project group meetings. They will advise on possible recruitment strategies and on the feasibility and acceptability of the components of the intervention, particularly on design issues e.g. using humour, images, relevant text language, and questions to ask to encourage engagement.

Representatives from local community groups e.g. managers of community centres, leaders of group activities will also be interviewed to establish where to contact groups and how best to approach them. The components of the intervention will be tested in focus groups comprised of men from the target group.

The intervention is designed to be delivered by trained lay members of the target group. An expert in alcohol research and government alcohol policy will advise on the design of the intervention making sure that it aligns with current UK policy on alcohol. One of the co-applicants, whose work involves

multi-agency partnership working to reduce inequalities in health, would promote the use of findings from this study to deliver and disseminate new interventions in local authorities.

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