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Reducing alcohol-related harm in disadvantaged men: development and feasibility assessment of a brief intervention delivered by mobile phone

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1. Project title

Reducing alcohol-related harm in disadvantaged men: development and feasibility assessment of a brief intervention delivered by mobile phone.

2. Background

2.1 Existing research

Alcohol-related morbidity and mortality represent a major public health challenge. The cost of alcohol to society has been estimated at more than £55 billion per year in England[1] and more than £2 billion per year in Scotland[2]. These costs occur through lost productivity, increased health care and other public sector costs and through social disruption. Alcohol-related harms are not evenly distributed in the population. People who are socially disadvantaged are at a substantially higher risk of developing alcohol related diseases[3,4]. Levels of binge drinking are highest among young and disadvantaged men[5]. There is a pressing need to change the culture of drinking among this group in order to prevent alcohol-related problems in later life.

2.2 Risks and benefits

The proposed intervention involves a novel method of delivery of a brief intervention to reduce hazardous drinking. Brief interventions to reduce harmful drinking have been widely used in health care settings and no reports of risk have been made[6]. The potential benefits to the participants are the health and social benefits which accrue from adopting more moderate drinking habits. Society will benefit from reduced social disruption resulting from drunkenness, reduced healthcare costs and from reduced sickness absence from the health effects of excess consumption.

2.3 Rationale

The group who drink most alcohol and binge drink most frequently are young to middle aged disadvantaged men[5]. Men aged 25 – 44 years are seldom in contact with health services and few are in full-time education. They will therefore not be reached by current initiatives to tackle excessive drinking. Targeting this group would lead to reductions in heavy drinking before chronic health harms develop. This group may be receptive to brief interventions: 27% of young men reported feeling the need to cut down on their drinking[5].
Brief interventions based on psychological theories have been developed to tackle alcohol-related problems. There is extensive evidence that brief interventions are effective[6-9]. Thus there is a need to develop alternative methods of delivering brief interventions to disadvantaged men aged 25 – 44 years. Given the extent of the current problem, the delivery methods need to be able to contact large numbers of individuals at low cost.
Text messaging has been used to modify adverse health behaviours[10,11] and to increase healthcare uptake[12,13]. This approach is well suited to young to middle-aged men because their ownership of mobile phones is high. This

method has been successfully used as a smoking cessation tool in New Zealand[11] and the intervention is being implemented nationally in a government funded programme[14]. Text messaging is also one component of the NHS stop smoking programme in England[15].
The text messages can be supported and reinforced by visual images. There is evidence that psychological theory can be embedded in visual media (e.g. posters, pictures in leaflets, films or animations) and alongside verbal and/or textual explanation, can improve patient understanding and self-care behaviours[16]. The use of images can enhance the coherence of the message (i.e. more clearly demonstrate how cause and effect are linked) by making the symptoms and their consequences appear less abstract and more concrete. Increasing coherence[17] and concreteness[18] in relation to illness and risk perceptions have been shown to influence attitudes[19,20] and intentions and increase the likelihood of behaviour change. Visual media is acceptable to patients and, due to its less abstract and more concrete nature, may be more memorable than verbal or text based messages[21,22]. Images may therefore be an effective and acceptable adjunct to text messaging to increasing coherence and concreteness about alcohol related harm and the benefits of moderate drinking.
The important question is whether text messaging could be helpful in tackling harmful drinking. Alcohol presents different challenges to the stop smoking campaign. Alcohol consumption is widely viewed as acceptable and in moderate amounts may be good for health. Further changing adverse health behaviours among disadvantaged groups is challenging because the uptake of health promotion interventions is much lower than in more advantaged groups[23]. Thus we need to determine whether a brief interventions delivered by mobile phone will help moderate heavy drinking among young to middle aged disadvantaged men.

3. Research objectives

The objective of the planned research is to develop and test the feasibility of a novel intervention to reduce the frequency of heavy drinking among young to middle-aged disadvantaged men. The intervention has been developed from brief interventions which have been successful when delivered by face-to-face interviews, but will use mobile phone technology to deliver a series of text and images. If the development and pilot evaluation are successful, the intervention will be tested in a full-scale randomised controlled trial in a further study for which new funding will be sought.

Research questions of the full-scale trial of the novel intervention
Can a brief intervention delivered by mobile phone:
1. Reduce the frequency of heavy drinking by disadvantaged men
2. Increase awareness of the harms of excessive drinking
3. Increase intentions to avoid becoming drunk
4. Increase self-efficacy for refusing drinks

The need for the feasibility study

The intervention to be used in the proposed trial has several components and thus is a complex intervention. The MRC framework for complex interventions recommends that the feasibility of all aspects of the trial be piloted and that the causal mechanism by which the intervention will work should be tested in advance of a formal trial[24]. The methods of recruitment to the trial and the retention of participants within it need to be piloted. The disadvantaged are recognised to be a difficult group to recruit so the proposed recruitment strategy needs to be tested. The potential for the intervention to influence beliefs and attitudes also needs to be assessed. Previous research has evaluated interventions delivered by face-to-face interview, often conducted by a health professional within a health care setting. The acceptability of the use of mobile phones to deliver the intervention and the potential of the intervention to influence drinking behaviour need to be assessed. We therefore propose to conduct a preliminary study to develop the recruitment strategies, to finalise the design of the intervention, to assess retention in the study and to investigate the likelihood of the intervention being effective.

Aims of the feasibility study

To investigate the feasibility and likelihood of success of a complex intervention to reduce the frequency of heavy drinking among young to middle aged disadvantaged men.

Research questions of the feasibility study

1. What are the best ways to recruit and retain disadvantaged men in a study aimed at reducing the frequency of heavy drinking?
2. What is the type of content and timing of the delivery of a series of text messages and images that is most likely to engage young to middle aged men?
3. Is the intervention likely to be an acceptable way to influence the frequency of heavy drinking?

4. Research design

Overview

The study will be conducted in three phases. Phase 1 will comprise six focus groups to develop the recruitment strategy, to optimise the design of the text messages and images and to determine the most acceptable sequence for their delivery. Phase 2 will involve the recruitment of 60 participants who will be randomised to receive either the alcohol intervention or a general health promotion intervention. The interventions will be delivered to mobile phones using a programmed computer system. Participants will be followed-up for 3 months to assess recruitment and retention, willingness to respond to text messages and to complete the final assessment of drinking behaviour. Phase 3 will involve in-depth interviews with 20 participants to assess the acceptability of the intervention, the impact it had on their willingness to moderate their drinking and factors which might limit their ability to drink less.

For clarity of presentation Phase 1 will be described here because it is short and does not fit readily with the types of information elicited in Sections 5–10.

Phase 1 Focus groups

Focus group participants will be purposively recruited from several venues in areas of high deprivation: Sunday amateur football clubs, public houses and betting shops. Five of the six focus groups will be held with men aged 25-44 years. Potential participants will be men who have consumed eight or more units of alcohol during a single session on at least two occasions during the previous four weeks. The sixth focus group will be with women. A women only focus group is included because this will give a different perspective on men's reasons for drinking, refusal skills, awareness of harms and likelihood of responding to the intervention. Women who participate will be partners of men who meet the entry criteria.

The Focus groups will review the methods to be employed in Phase 2. Specifically it will investigate:

- strategies to recruit and retain disadvantaged men in a study on drinking
- the appropriateness of the theoretical approach underpinning the intervention
- the acceptability of the components of the intervention
- the acceptability of the recruitment process (credibility of source, invitation letter, initial screening phone call).

The discussion on the design of text messages will explore:

- the types of questions that are acceptable; the language used to describe drinking and its consequences; beliefs and attitudes about the benefits and potential harms of alcohol; and attitudes to receiving messages on drinking (credibility, perceived relevance, likelihood of influencing drinking behaviour)
- the design of the images that will induce interest and stimulate a review of drinking habits
- total number of texts to be sent, frequency of sending texts, maximum length of texts

All interviews and focus group discussions will be digitally recorded and fully transcribed. Transcripts will be analysed using framework analysis[25]. Analysis will be facilitated by the use of text management software (NVivo) and carried out by a research fellow with formal training in qualitative research and practical experience of analysis. Two researchers will be involved in the analysis to ensure reliability of interpretation and coding.

4. Research design continued - Phases 2 and 3

The trial of feasibility and likely impact of the intervention will be assessed by carrying out all of the stages of a pragmatic randomised controlled trial.

Randomisation
The randomisation will be carried out by the Glasgow Clinical Trials Unit under the leadership of Professor J Norrie. After identifying and obtaining consent from an eligible participant the Research Assistant will contact the randomisation system at the Robertson Centre for Biostatistics, Glasgow Clinical Trials Unit. This randomisation system will be an Interactive Voice Response telephone system or accessed over the web. The randomisation system will then, after successfully randomising the participant, remotely contact the Dundee SMS text messaging server and the sequence of calls appropriate for that participant's randomised allocation will be set up.

Intervention delivery
The interventions will be delivered by an automated computer system, which will be programmed to send out text messages and images to mobile phones in a predetermined sequence. The computer system will be devised and operated by the staff at the School of Computing at Dundee University under the direction of Professor I Ricketts.
The exchange of text messages with the clients will be via a secure server based within the School of Computing at the University of Dundee. Messages delivered to the client will appear to originate from the project's mobile phone but the message content and client address will be assembled on the secure server and routed via the JISC funded JANET network to a UK based Mobile Network Service Provider and thereby to the clients. All replies from the clients will follow the reverse path. The Mobile Service Provider offers support for a variety of connections including email, web browser and individually tailored www solutions. In this feasibility study the team will provide the simplest solution compatible with providing an effective communication between the client and the project team. The secure server and associated software tools will be provided at no cost to the project.

Blinding
The researcher who collects both baseline and outcome data will not be involved in the randomization process or the delivery of the active and control interventions. Thus the researcher will be blinded to treatment group.

Stopping rule/Discontinuation criteria
The intervention is only delivered over a three month period. Extensive previous research on brief interventions to tackle harmful drinking have found no evidence of harm. The issue of discontinuation is not applicable to this study. However we will monitor any emerging safety issues such as reported increases in drinking or depression, which might be caused by the drinkers being confronted by these health messages about alcohol.

5. Study population:

Study group
Men aged 25-44 years living in areas of high deprivation will be recruited. Deprivation is measured using the Scottish Index of Multiple Deprivation[26],

which is similar to the English Index of Multiple Deprivation. Men will be recruited from the 25% of electoral wards with the highest deprivation scores. Individual level socio-economic position will be measured on all men recruited to the study. It will be measured using education, nature of housing and occupation (NS-SEC) following the recommendations of Galobardes et al[27,28].

Inclusion/ exclusion criteria
Men will be included in the study if they have had two or more episodes of heavy drinking (≥8 units in a single session) in the preceding month. Exclusion criteria are: men who are currently attending care at an Alcohol Problem Service; and men who will not be contactable by mobile phone for any part of the intervention period.

Recruitment strategy
Two recruitment strategies will be tested.

Strategy 1: Potential participants will be identified from GP practice lists which contain data on age, gender and postcode. Postcode will be used to derive the Index of Multiple Deprivation (SIMD) score[29]. Potential participants will receive a letter from their GP inviting them to take part. The telephone numbers of those willing to take part will be obtained using the techniques employed in a previous study by this group[30]. In that study telephone numbers were obtained for 99 % of disadvantaged mothers of young children. Telephone numbers were obtained from a combination of GP records, extensive web searches of publicly available databases and further contacts with GP staff. Of those contacted by phone 77% were recruited to the study. Systematic reviews show that repeated attempts at contact and monetary incentives increase recruitment to research studies[31,32]. Up to four attempts at contact by phone will be made. Men who agree to take part will be offered an initial £10 gift voucher to offset any charges incurred by receiving and responding to text messages. They will also be sent a £5 gift voucher for each week of the study that they respond to text messages, and a £10 voucher for completing the outcome assessment.

Strategy 2: Respondent-driven sampling is a recently developed technique for surveying hard to reach groups, particularly those who engage in stigmatized or illegal behaviours[33,34]. It was designed to overcome the limitations of other techniques such as snowball sampling and key informant sampling. The technique assumes that the target population are distributed through a number of socially networked groups and is thus suitable for a group behaviour such as drinking. It has been extensively and successfully used with injecting drug users and groups at high risk of HIV infection[35]. The sampling strategy begins with the identification of a small number of “seed” individuals obtained from different locations. In this study seeds will be recruited from several venues in areas of high deprivation: Sunday amateur football clubs, public houses and betting shops. The seed individuals identify suitable subjects from their social networks and recruit them to the study. To

prevent over recruitment by individuals with large social networks each seed individual can only recruit a maximum of five individuals.
A key element of the technique is the use of incentives to each seed person for taking part in the study and for each of the individuals they recruit. Thus the seed individuals will receive a £5 gift voucher for each person they recruit, All participants recruited by this method will also receive the sequence of gift vouchers as described for Recruitment Strategy 1 (for joining and responding actively to the text messages).

Initial screening and Baseline assessment
Potential participants will be screened by a phone call from a researcher to establish current drinking levels. Those who report binge drinking (≥8 units in a single session) at least twice in the previous four weeks will be recruited. They will also complete a short structured questionnaire that will include the validated CAGE questionnaire for alcohol dependence[36].

6. Planned intervention

Experimental intervention
A brief intervention to reduce harmful drinking will be delivered by text messages to a mobile phone. A series of interactive text messages and images will be designed using messaging theory[37-39], social cognition models[40] and systematic reviews of interventions to tackle alcohol problems[6,8,9]. The intervention has four components:
i Positive alcohol expectancies: the perceived benefits of heavy drinking
The literature suggests the perceived benefits of alcohol for young people are mood enhancement and enjoyment, stress relief and escapism, easier socialising and social success, and conformity with peers[41]. Many of these are not compatible with being very drunk. This presents the opportunity to explore the inconsistency between an individual's drinking habits and the intended aims of drinking. Thus text messages will discuss the mismatch between being drunk and having fun.

ii Subjective norms: misperceptions about peers' levels of alcohol consumption
Beliefs about how much peers drink have been found to be powerful predictors of drinking behaviour[42]. Many people overestimate what their peers drink and drink more in consequence. Systematic reviews have shown that personalised normative feedback is effective in reducing alcohol consumption and alcohol related problems[43,44]. Thus text messages will state that many people overestimate what their peers drink and will reinforce this with data on current consumption by men of their age.

iii Perceptions of harms
Younger people who binge drink tend to view themselves as party drinkers or occasional drinkers and may be unaware of the long term harms of their drinking[45]. A belief that drinking will have few negative consequences is associated increased levels of consumption[46]. Young people tend to think that

they will not come to harm, unless they have previously suffered harm[41]. The text messages will briefly present the true risks of alcohol.

iv Refusal self-efficacy

Low levels of drinking refusal self-efficacy have been shown to predict the acquisition and maintenance of binge drinking[45]. Thus texts will present techniques for refusing drinks and for leaving drinking situations early.

Message development

The design of the text messages will be based on current communication theory. This identifies the series of steps in the casual chain from message receipt to behaviour change. To be effective a message must be: attended to, comprehended, processed, accepted and acted on[38]. Communication theory identifies four features of a message which affect the likelihood of behaviour change: the source (ie credibility) of the message, its style and content, the nature of the recipient and the context (the circumstances in which the message is received). Each of these features affects the impact of the message on behaviour change[14,47]. The nature of the message comprises many facets including its length, content (number of arguments), language and style (such as use of images). Other design features are the personal relevance of the message[47], whether the arguments are gain-framed (emphasising the benefits of moderate drinking) or loss-framed[37] and items included to maintain interest (such as interesting and unexpected statements). The design of the message content will be assessed by the user group (disadvantaged men aged 25-44) at the focus group stage.

Image development

The images will be developed by a collaborative team involving a sociologist, a psychologist, a computer scientist and design specialists from the Dundee 3D Visualisation Group. Team members (led by Dr Williams) have successfully created images linking obesity and risk of arteriosclerosis. The design process will embed psychological theory of behaviour change in the development of images. The images will increase participants' awareness of their susceptibility to alcohol related harm and increase their confidence and skill in moderating alcohol consumption. The design follows a four stage sequential process in which professionals work with the user group (disadvantaged men aged 25-44) to review:

- The theoretical basis: the creation of conceptual content
- The structure: creating a visual narrative
- The "look": visual rendering of narrative and concepts
- The interpretation and impact.

Delivery of the intervention

A series of 28 interactive text messages and images will be sent over a four week period. The frequency and timing of the messages will be determined following the focus group discussions. Each of the four components of the intervention will be addressed in several messages. Some of these messages

will also ask a question which, when answered, will generate an appropriate automated response. A few messages of general interest, designed to promote retention in the trial, will also be sent.

Comparator intervention
The comparator group will receive the same number of text messages and images. These will cover the general health promotion messages from current government public health policy[48]. These include diet, physical activity, smoking and mental wellbeing. The text messages and images will be designed to maintain interest in study to ensure that the control group complete the outcome assessment.

7. Outcome measures

Outcomes will be measured by telephone interview at three months after the baseline assessment. The primary outcome measure will be the change in frequency of heavy drinking (consumption of ≥8 units in a single session). This measure of consumption has been used for many years in national surveys of alcohol consumption[5,49]. Self-reported alcohol consumption is the primary outcome measure used in almost all randomised trials testing interventions to reduce alcohol consumption[6]. Secondary outcomes will assess the extent to which the intervention has influenced perceptions of harms, benefits of moderated drinking, intentions for future drinking. The feasibility study will develop and test a short structured questionnaire which can be used in a telephone interview to measure these factors. The questionnaire will be completed at baseline and at outcome assessment to enable changes on these measures to be assessed.

Phase 3 Post trial evaluation
A more detailed assessment of the impact of the intervention will be made in a sub-sample of 20 randomly selected participants (10 intervention and 10 control). Face to face interviews will elicit their views on all aspects of Phase 2. It will explore their reasons for participating in the study and the stages of the recruitment process. It will also examine the ways that the delivery of the intervention could be improved, the aspects of the intervention that caused them to review their drinking patterns and consider moderating their drinking. It will also explore the factors which might limit their ability to drink less with the aim of identifying ways in which the intervention could be improved. The interviews will be recorded and transcribed. The transcripts will be analysed thematically to identify additional improvements that could be made to the recruitment process and the intervention.

8. Assessment and follow-up

8.1 For Phase 2 a short structured questionnaire will be administered by telephone at baseline and at three months. For Phase 3 an in-depth interview will be carried out within two weeks of completion of the Phase 2 interview.

8.2 Assessment of harms

This study involves a novel method of delivery of a widely used brief intervention to reduce harmful drinking. The method of delivery has been used for other types of health behaviour and no harms have been identified. However we will monitor any emerging safety issues such as reported increases in drinking or depression, which might be caused by the drinkers being confronted by these health messages about alcohol. In addition participants who report problems related to their drinking, either at the baseline assessment or follow-up will be advised to contact their GP.

9. Proposed sample size

The Phase 2 feasibility assessment will involve randomising 60 men to intervention or control. This will be sufficient to test the feasibility of all aspects of the study and to assess the components of the intervention package. Two recruitment strategies will be tested to obtain the 60 participants: recruitment from three multi-partner general practices; and a respondent-driven sampling. The Phase 3 post trial evaluation will involve a random sample of 20 men (10 intervention, 10 control).

10. Statistical 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. 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.

11. Ethical arrangements

The study will comply with the ESRC Research Ethics Framework[50].
Permission to conduct the study will be sought from the Tayside Committee on Medial Research Ethics. As this study involves a widely used brief intervention it raises few ethical issues. It is possible that the telephone interview will identify individuals with serious alcohol related problems. These men will be asked to seek help from their own GPs. In addition, the researcher will ask permission to contact the GP about their alcohol problem, to increase the chance that they will receive the help they need.
Study participants will be informed that they can withdraw from the study at any time. If participants withdraw during the intervention period they will not receive further text messages.
The study does not use any existing database.

12. Research governance

The University of Dundee will act as sponsor for the project. The governance of both the feasibility study and the subsequent full trial will be overseen by the Glasgow Clinical Trials Unit (GCTU), a fully registered NIHR CRN trials unit. As such, GCTU designs, conducts, analyses, reports and archives all its clinical studies to exacting regulatory, legal, ethical and scientific requirements, including Good Clinical Practice. As this is a study which is designed to develop and test the feasibility of a novel method of delivering a widely used brief intervention it is not necessary to have a Steering Committee and a DMEC at this stage. For the full trial which will follow this study, both a Steering Committee and a DMEC will be established.

13. Project timetable and milestones

Ethical permission will be sought and obtained before the start date of the project. Research staff will also be appointed before the study begins. The start date will be the 1st March 2010.

1st March 2010 – 11th April 2010: prepare for focus groups

- Develop a schedule to be used for the focus groups
- Identify and recruit organisations which have members suitable for the focus group
- Establish acceptable recruitment procedures
- Develop computer software to administer the sending of the text messages

12th April 2010 – 31st August 2010: conduct focus groups, design intervention

- Recruit potential participants
- Conduct the first three focus groups
- Transcribe focus group discussions and begin analysis so that new topics or themes for discussion can be identified
- Begin to develop the intervention and control packages in conjunction with the text message design team and the image design team

1st September 2010 – 30th November 2010: conduct and analyse focus groups, design intervention

- Conduct the remaining three focus groups
- Continue framework analysis of the focus group data
- Further develop the messages and images and assess their acceptability in focus groups
- Design baseline and follow up questionnaires

1st December 2010 – 15th January 2011: finalise design and pilot recruitment methods

- Work with psychologist, sociologist, the image design group and the Department of Computing to finalise the text messages and images to be used in the intervention

- Develop and pilot the screening interview and methods for gaining informed consent
- Pilot the intervention

17th January 2011 – 13th February 2011: Test the feasibility of the two recruitment strategies

- Recruitment Strategy 1
  - Recruit three GP practices who will provide participants for the feasibility study
  - Assist practices in identifying patients suitable for recruitment and in the preparation of letters of invitation
  - Search for mobile phone numbers of potential participants
- Recruitment Strategy 2
  - Test procedures for identifying seed individuals
  - Determine whether social networks are sufficiently large

14th February 2011 – 30th April 2011: Screen and recruit participants

- Screen up to 180 potential participants to identify those eligible for randomisation
- Recruit and randomise 60 subjects (6 per week)
- Conduct baseline assessment

21st February 2011 – 31st August 2011: deliver intervention and follow up interviews

- Deliver intervention over the 28 day period following randomisation
- Conduct outcome assessment at 3 months
- Recruit post-trial sub sample and conduct in depth interviews

1st September 2010 – 30th November 2011: analysis and report writing

- Complete analysis
- Complete final report for funding body
- Prepare papers for publication

14. Expertise

All co-applicants contributed to the study design and to the writing of the protocol. Professor Crombie is an epidemiologist. He conceived the project and will supervise its conduct, help develop the intervention and participate in the analysis. Professor Norrie is a statistician and an experienced trialist. He will be responsible for randomisation of participants and governance arrangements for the trial. Professor Ricketts is a computer scientist. He will be responsible for the delivery of the text messages and images and for monitoring participant responses to these messages. Dr Williams is a medical sociologist. He will guide the conduct and analysis of the focus group data and will help to develop the intervention, particularly the design of the images. Professor Humphris is a health psychologist. He identified the relevant psychological models, and will help develop the intervention and participate in

the analysis. Dr Rice is a consultant psychiatrist and head of the Tayside Alcohol Services. He has extensive experience in tackling alcohol-related problems, particularly in helping clients to reduce alcohol consumption. Dr Irvine is an experienced researcher. She will supervise the research assistant on a day to day basis and will assist with: conducting the focus groups; analysis of focus group data, developing the intervention, recruitment procedures; and analysis of the data. Dr Slane is a general practitioner. He advised on recruitment strategies for hard to reach groups and the use of brief interventions for alcohol. All co-applicants will contribute to the writing of the final report.

15. Members of the Public

Involving members of the public in the design of the intervention and in the delivery of the intervention is an essential part of this project. We will recruit two members of the user group community prior to the start of the study. They will initially be involved in the design of recruitment processes and the information leaflets and letters of invitation. This will ensure that the language used is appropriate and acceptable. The men will also have a role in planning the schedules to be used to guide focus group sessions. On completion of Phase 1, the men will join the design teams to ensure that the interventions are acceptable and the outcomes are relevant and measurable. The men will be invited to attend all project meetings, and will be strongly encouraged to attend the early study design meetings. The user group representatives will be identified through local community groups (e.g. football leagues, public houses and betting shops). Community group leaders will be approached and asked to nominate individuals who may be willing to take part in the study.

16. Justification of the costs

An experienced full time research assistant (grade 7 spine point 31) is required for 21 months to conduct the focus groups, analyse focus group data, help develop the intervention, recruit all trial participants, conduct baseline and follow-up interviews and analyse the outcome assessments.

Costs for conducting four focus groups and the 20 in-depth interviews include room hire at local community centres, travel expenses for the research assistant and participants, and gift vouchers to thank them for taking part in the study. Secretarial support (grade 2, spine point 2) for the transcription of focus group discussions will be required for two months at 50% whole time equivalent. A qualitative researcher (grade 8 spine point 40) will also be required for eight months at 25% whole time equivalent to assist with the analysis of the focus group data.

Image development by the Dundee 3D Visualisation Group at Dundee University will involve a design consultant (grade 8 spine point 40) who will be required for four months at 50% whole time equivalent.

Two user group representatives will be involved throughout the project. They will be invited to participate in project meeting and sessions to design the text messages and images used for the intervention. They will be reimbursed at £20 per session for their time plus £10 for travelling expenses.

Governance of the project and administration of the randomisation of participants will be overseen by the Glasgow Clinical Trials Unit. Randomisation will cost £1,500 and long term data archiving will cost a further £1,200.

A computer programmer (grade 7, spine point 32) will be required for two months to develop the computer system to administer the sending and receiving of text messages. A dedicated mobile telephone number will be required for the duration of the study (£35.50/month for 21 months). Sending a daily multimedia message (MMS) to each of 60 clients and receiving their test message (SMS) replies for the period of the evaluation will cost £1,700.

Participants in the feasibility trial need to be reimbursed for the use of their mobile phones, as the study cannot be administered cost free to participants. There is also strong evidence that financial incentives promote recruitment and retention to research studies. Participants will be given a £10 gift voucher for agreeing to take part in the study, and will subsequently be given £5 per week if they respond by text message to the intervention. Finally they will be given a £10 voucher for completing the follow up interview. Thus, the 60 participants randomised will each receive £40 for completing the study.

Part of this study is to test respondent-driven sampling, where participants nominate others suitable for recruitment to the study. A fee of £5 is paid for every participant recruited. This method of recruitment has been shown to be successful in hard to reach groups.

A computer and printer will be required for the administration of the study, the development of text messages for the intervention, and the analysis of data. Landline calls to recruit participants, obtain consent and conduct baseline and follow up interviews will also be required. A modest sum will be required for stationery and printing costs for letters of invitation, information leaflets, data transcripts and reports. Although most of the scientific papers required will be available online it is estimated that ten will be obtained through interlibrary loan. Provision has been made for one person to attend one international public health conference. Finally, £1,700 will be required for advertising and recruitment costs.

References

1 Lister G, Fordham R, Mugford M, Olukoga A, Wilson E, McVey D. Evaluating social marketing for health: The need for consensus. The societal cost of potentially preventable illness. 2nd National Social Marketing Conference; 2007; Oxford.
2 The Scottish Government. *Costs of Alcohol Use and Misuse in Scotland*. (web only publication): The Scottish Government, 2008. http://www.scotland.gov.uk/Publications/2008/05/06091510/11
3 Mackenbach JP, Stirbu I, Roskam A-JR, Schaap MM, Menvielle G, Leinsalu M, et al. Socioeconomic Inequalities in Health in 22 European Countries. The New England Journal of Medicine 2008;358(23):2468-2481.
4 Audit Scotland. *Overview of Scotland's health and NHS performance in 2006/07*. Edinburgh, 2007. http://www.audit-scotland.gov.uk/docs/health/2007/nr_071214_nhs_overview.pdf
5 Bromley C, Sproston K, Sheldon N. *The Scottish Health Survey - 2003*. Edinburgh: Scottish Executive, 2005. http://www.scotland.gov.uk/Publications/2005/11/25145024/50251
6 Kaner EF, Beyer F, Dickinson HO, Pienaar E, Campbell F, Schlesinger C, et al. Effectiveness of brief alcohol interventions in primary care populations. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD004148. DOI: 10.1002/14651858.CD004148.pub3.
7 Raistrick D, Heather N, Godfrey C. *Review of the effectiveness of treatment for alcohol problems*. London: The National Treatment Agency for Substance Misuse, 2006. http://www.nta.nhs.uk/publications/documents/nta_review_of_the_effectiveness_of_treatment_for_alcohol_problems_fullreport_2006_alcohol2.pdf
8 Bertholet N, Daeppen JB, Wietlisbach V, Fleming M, Burnand B. Reduction of alcohol consumption by brief alcohol intervention in primary care: systematic review and meta-analysis. Arch Intern Med 2005;165(9):986-95.
9 Moyer A, Finney J, Swearingen C, Vergun P. Brief interventions for alcohol problems: a meta-analytic review of controlled investigations in treatment-seeking and non-treatment-seeking populations. Addiction 2002;97(3):279-292.
10 Vidrine DJ, Arduino RC, Lazev AB, Gritz ER. A randomized trial of a proactive cellular telephone intervention for smokers living with HIV/AIDS. AIDS 2006 20(2):253-60.
11 Rodgers A, Corbett T, Bramley D, Riddell T, Wills M, Lin RB, et al. Do u smoke after txt? Results of a randomised trial of smoking cessation using mobile phone text messaging. Tob Control 2005 14(4):255-61.
12 Geraghty M, Glynn F, Amin M, Kinsella J. Patient mobile telephone 'text' reminder: a novel way to reduce non-attendance at the ENT out-patient clinic. J Laryngol Otol 2008 122(3):296-8.
13 Franklin VL, Greene A, Waller A, Greene SA, Pagliari C. Patients' engagement with "Sweet Talk" - a text messaging support system for young people with diabetes. J Med Internet Res 2008 10(2):e20.
14 Whittaker R, Maddison R, McRobbie H, Bullen C, Denny S, Dorey E, et al. A multimedia mobile phone-based youth smoking cessation intervention:

findings from content development and piloting studies. J Med Internet Res 2008 10(5):e49.
15 NHS Choices. Smokefree. <http://smokefree.nhs.uk/what-suits-me/support-at-home/>
16 Krouse HJ. Video modelling to educate patients. Journal of Advanced Nursing 2001;33(6):748-757.
17 Hall S, Weinman J, Marteau TM. The motivating impact of informing women smokers of a link between smoking and cervical cancer: the role of coherence. Health Psychology 2004;23(4):419-424.
18 Shahab L, Hall S, Marteau T. Showing smokers with vascular disease images of their arteries to motivate cessation: a pilot study. British Journal of Health Psychology 2007;12(2):275-283.
19 Babin LA, Burns AC. Effects of print ad pictures and copy containing instructions to imagine on mental imagery that mediates attitudes. Journal of Advertising 1997;26(3):33-44.
20 Burns AC, Biswas A, Babin LA. The operation of visual imagery as a mediator of advertising effects. Journal of Advertising 1993;22(2):71-85.
21 Paivio A, Walsh M, Bons T. Concreteness effects on memory: when and why? Journal of Experimental Psychology: Learning, Memory and Cognition 1994;20(5):1196-1204.
22 Gardner MP, Houston MJ. The effects of verbal and visual components of retail communications. Journal of Retailing 1986;62:64-78.
23 Goddard M, Smith P. Equity of access to health care services: theory and evidence from the UK. Soc Sci Med 2001 53(9):1149-62.
24 Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. *Developing and evaluating complex interventions: new guidance*. Medical Research Council, 2008. www.mrc.ac.uk/complexinterventionsguidance
25 Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, editors. *Analysing qualitative data*. London: Routledge, 1994.
26 Social Disadvantage Research Centre. *Scottish Indices of Deprivation*. University of Oxford, 2003.
27 Galobardes B, Shaw M, Lawlor DA, Lynch JW, Davey Smith G. Indicators of socioeconomic position (part 1). J Epidemiol Community Health 2006 60(1):7-12.
28 Galobardes B, Shaw M, Lawlor DA, Lynch JW, Davey Smith G. Indicators of socioeconomic position (part 2). J Epidemiol Community Health 2006 60(2):95-101.
29 Office of the Chief Statistician. *Scottish Index of Multiple Deprivation 2004 Technical Report* Scottish Executive, 2004. http://www.scotland.gov.uk/Resource/Doc/26350/0025281.pdf
30 Crombie IK, Kiezebrink K, Irvine L, Wrieden WL, Swanson V, Power K, et al. What maternal factors influence the diet of 2-year-old children living in deprived areas? A cross-sectional survey. Public Health Nutrition 2008;doi:10.1017/S1368980008003819.
31 Edwards PJ, Roberts IG, Clarke MJ, DiGuiseppi C, Wentz R, Kwan I, Cooper R, Felix L, Pratap S. Methods to increase response rates to postal

questionnaires. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: MR000008. DOI: 10.1002/14651858.MR000008.pub3.
32 Smith W, Chey T, Jalaludin B, Salkeld G, Capon T. Increasing response rates in telephone surveys: a randomized trial. J Public Health Med 1995;17(1):33-8.
33 Abdul-Quader AS, Heckathorn DD, Sabin K, Saidel T. Implementation and analysis of respondent driven sampling: lessons learned from the field. J Urban Health 2006 83(6 Suppl):i1-5.
34 Heckathorn DD. Respondent-driven sampling: a new approach to the study of hidden populations. Social Problems 1997;44(2):174-199.
35 Johnston LG, Malekinejad M, Kendall C, Iuppa IM, Rutherford GW. Implementation Challenges to Using Respondent-Driven Sampling Methodology for HIV Biological and Behavioral Surveillance: Field Experiences in International Settings. AIDS Behav 2008;12:S131-S141.
36 Ewing JA. Detecting alcoholism. The CAGE questionnaire. JAMA 1984;252:1905-1907.
37 Rothman AJ, Bartels RD, Wlaschin JS, P. The strategic use of gain- and loss-framed messages to promote healthy behavior: how theory can inform practice. Journal of Communication 2006;56:S202-S220.
38 Fishbein M, Cappella JN. The Role of Theory in Developing Effective Health Communications. Journal of Communication 2006;56(S1): S1-S17.
39 Viswanath K, Emmons KM. Message Effects and Social Determinants of Health: Its Application to Cancer Disparities. Journal of Communication 2006;56(S1):238-S264.
40 Conner M, Norman P, editors. *Predicting Health Behaviour*. 2 ed: Open University Press, 2005.
41 Engineer R, Phillips A, Thompson J, Nicholls J. *Home Office Research Study 262. Drunk and disorderly: a qualitative study of binge drinking among 18- to 24-year-olds*. London: Home Office Research, Development and Statistics Directorate, 2003.
http://www.homeoffice.gov.uk/rds/pdfs2/hors262.pdf
42 Wild TC. Personal drinking and sociocultural drinking norms: a representative population study. J Stud Alcohol 2002 63(4):469-75.
43 Carey KB, Scott-Sheldon LA, Carey MP, DeMartini KS. Individual-level interventions to reduce college student drinking: a meta-analytic review. Addict Behav 2007 32(11):2469-94.
44 Larimer ME, Cronce JM. Identification, prevention, and treatment revisited: individual-focused college drinking Addict Behav 2007 32(11):2439-68.
45 Oei TP, Morawska A. A cognitive model of binge drinking: the influence of alcohol expectancies and drinking refusal self-efficacy. Addict Behav 2004 29(1):159-79.
46 Dijkstra A, Sweeney L, Gebhardt W. Social cognitive determinants of drinking in young adults: Beyond the alcohol expectancies paradigm. Addict Behav 2001;26(5):621-773
47 Briñol P, Petty RE. Fundamental Processes Leading to Attitude Change: Implications for Cancer Prevention Communications. Journal of Communication 2006;56(S1):S81-S104.

48 Department of Health. *Choosing Health: Making healthy choices easier*. London: UK Parliament, 2004. http://www.dh.gov.uk/assetRoot/04/12/07/92/04120792.pdf
49 The Information Centre. *Health Survey for England*. London, 2008. http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles-related-surveys/health-survey-for-england
50 Economic and Social Research Council (ESRC). *Research Ethics Framework (REF)*. 2005. http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf

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