1. Project title

Reducing binge drinking among disadvantaged men through an intervention delivered by mobile phone: a multi-centre randomised controlled trial

Trial acronym: TRAM (Texting to Reduce Alcohol Misuse)

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 £3.5 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. Levels of binge drinking, heavy drinking in a single session, are highest among young and disadvantaged men[3]. People who are socially disadvantaged are at a substantially higher risk of developing alcohol-related diseases[4,5].

Brief interventions, based on psychological theories of behaviour change, have been developed to tackle alcohol-related problems. There is extensive evidence that they are effective[6-9]. However these interventions were developed for and are usually delivered in health care settings. The group who binge drink most frequently, young to middle aged disadvantaged men[3], are seldom in contact with health services. They will therefore not be reached by current initiatives to tackle excessive drinking. A further challenge is that the uptake of public health interventions among socially disadvantaged men is low[10]. There is a need for an intervention which effectively reduces binge drinking in this harder to reach population.

2.2 Risks and benefits

This study tests a brief intervention tailored to disadvantaged men and delivered by mobile phone. Brief interventions to reduce hazardous drinking have been widely used in health care settings and no reports of risk have been made[8]. 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 crime and social disruption resulting from drunkenness, reduced healthcare costs and from reduced sickness absence from the health effects of excess consumption.

2.3 Rationale

Text messaging provides a method for delivering brief alcohol interventions which can reach large numbers of individuals at low cost. Text messaging has been used successfully to modify other adverse health behaviours[11, 12] and to increase healthcare uptake[13, 14]. This approach is particularly well suited to young to middle-aged men because their ownership of mobile phones is high. Recent systematic reviews have shown that text messages can successfully change behaviour[15-17]. However no studies have tackled binge drinking and none have been targeted at disadvantaged men.

We recently completed an NIHR funded feasibility study (09/3001/09) which demonstrated that all stages of a trial of a brief intervention delivered by mobile phone could be completed successfully[18]. It identified a high frequency of hazardous drinking among disadvantaged men creating a pressing need for effective interventions to tackle their binge drinking. The success of the feasibility study led to the recommendation that a full trial to assess the

effectiveness and cost effectiveness of the intervention should be conducted. This protocol describes the full trial.

3. Research objectives

The **main objective** is to determine whether a brief intervention delivered by mobile phone is an effective and cost-effective method of reducing the frequency of binge drinking by disadvantaged men. The impact of the intervention on other measures of drinking, such as total consumption, will also be assessed. The study will explore which components of the behaviour change strategy influence drinking behaviour. These components will be measured using the process measures which were developed in the feasibility study.

Research questions

1) Can a brief intervention delivered by mobile phone reduce the frequency of binge drinking among disadvantaged men?
2) Is the intervention cost-effective?
3) Which components of the behaviour change strategy (intentions to avoid becoming drunk, self-efficacy for refusing drinks, goal setting and action planning for reducing binge drinking frequency) are associated with changes in drinking behaviour?

4. Research design

Overview

The study will be a four centre parallel group randomised controlled trial. The four centres cover major regions of Scotland: Tayside, Glasgow, Forth Valley and Fife.

Results of the feasibility study

The use of evidence-based recruitment strategies resulted in the target sample size being exceeded. Baseline and follow-up interviews were completed by phone. Most of the men were hazardous drinkers making them a high priority for intervention. Behaviour change constructs were successfully rendered in mobile phone texts and images. Overall 95% of text messages were delivered to the participants' phones. Process measures were developed for the study, using text questions to elicit real time responses to the intervention. These showed that the intervention achieved high levels of engagement with key components of the behaviour change strategy. Retention within the study was 96%, with outcomes being measured on all the retained men. The feasibility study also identified ways in which the study design could be improved, primarily modifications to the recruitment strategy and the intervention. The improvements have been incorporated in the design of this full trial.

Randomisation

The randomisation will be carried out using the secure remote web-based system provided by the Tayside Clinical Trials Unit. Randomisation will be stratified by participating centre and the recruitment method and restricted using block sizes of randomly varying lengths.

Intervention delivery

The intervention will be delivered as text messages using SMS (Short Message Service). Messages will be sent by an automated computer system which will be programmed to send out text messages to mobile phones in a predetermined sequence. The system which proved successful in the feasibility study will be used, although it will need to be modified to cope with the change from feasibility study to full trial.

The exchange of text messages with the participants will be via a secure server based within the Health Informatics Centre at the University of Dundee. Messages delivered to the participants will appear to originate from the project's mobile phone but the message content and participant's 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 participants 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 the feasibility study textlocal (http://www.textlocal.com/) provided the simplest solution compatible with providing an effective communication between the participants and the project team.

Blinding

The randomisation and the delivery of the active and control interventions are by a remote secure system. The researchers who collect the baseline and outcome data will have no access to this system and will be blind to treatment group. The baseline interview will be conducted before randomisation. The 3 month outcome assessments will be conducted by two of the blinded researchers. At the 12 month assessment the researchers will swop participants to ensure that each researcher only conducts one follow-up interview with each participant.

Stopping rule/Discontinuation criteria

Extensive previous research on brief interventions to tackle harmful drinking has found no evidence of harm. This was confirmed in the feasibility 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. There are no plans to stop the trial early due to overwhelming evidence of benefit, nor to terminate the study on the grounds of futility. As such we do not feel there is the need to form an independent Data Monitoring Committee for this study.

5. Study population:

Study group

Men aged 25-44 years living in areas of high deprivation will be recruited. Recruitment will be in four centres which cover major regions of Scotland: Tayside, Glasgow, Forth Valley and Fife. Deprivation is measured using the Scottish Index of Multiple Deprivation[19], which is similar to the English Index of Multiple Deprivation. Men will be recruited if they live in areas classified as being in the most disadvantaged quintile.

Inclusion/ exclusion criteria

Men will be included in the study if they have had two or more episodes of binge 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

To ensure good coverage of disadvantaged men two recruitment strategies will be used in this trial.

Strategy 1: Recruitment through primary care, supported through the Scottish Primary Care Research Network, proved to be a very successful method in the feasibility study. Potential participants will be identified from 20 GP practice lists (5 in each of the 4 centres). These lists contain data on age, gender and postcode. Postcode will be used to derive the Index of

Multiple Deprivation (SIMD) score[20]. Potential participants will receive a letter from their GP inviting them to take part. Those who do not opt out will be contacted by telephone. Up to six attempts at contact by phone will be made.

Strategy 2: An outreach strategy, Time-Space Sampling, will be employed[21, 22]. The feasibility study showed that a community outreach recruitment strategy identified men at particularly high risk of alcohol-related harm. These men are a high priority for intervention. However the feasibility study also showed that the method used, respondent-driven sampling, could potentially lead to contamination of the control group. It involves chain referral recruitment in which individuals can nominate friends for participation. The feasibility study showed that participants shared text messages with friends, which would lead to the intervention and control groups sharing messages. Time Space Sampling avoids this problem. It does not include the technique (chain referral) which could lead to contamination. Time-Space Sampling recruits from venues which the target group are known to frequent and involves sampling at selected times of day and days of week. The approach requires initial fieldwork to identify appropriate venues and suitable times for recruitment. At each of the 4 centres 20 venues will be identified. These will include charities that support long term unemployed, Criminal Justice, FE colleges, healthy living initiatives, budget supermarkets, housing associations, post offices, pawn brokers, betting shops and pubs. The intention is to recruit approximately 5 men from each venue. This will be achieved by revisiting each venue at five different times to prevent friendship groups from being included in the study.

Systematic reviews show that repeated attempts at contact and monetary incentives increase recruitment to research studies[23, 24]. 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 once a fortnight for the duration of the intervention. A £10 voucher will be sent for completing the outcome assessment.

Initial screening

Potential participants will be screened by 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.

Baseline assessment

The frequency of binge drinking will be measured using questions taken from the US Behavioural Risk Factor Surveillance System[25]. These questions also enable total consumption of alcohol to be measured. The Fast Alcohol Screening Test (FAST)[26] will be used to determine the frequency of hazardous drinking; it is short and suitable for telephone use. Individual level socio-demographic status will be measured using marital status, employment status, education and nature of housing. No other questions on alcohol will be asked at the baseline interview to prevent such questions influencing drinking behaviour in the control group. This possibility was raised by the feasibility study and is supported by recent systematic reviews[27, 28] which confirm that baseline questions can lead participants to re-evaluate drinking behaviour.

6. Socioeconomic position and inequalities

The main objective of this study is to reduce the frequency of binge drinking among disadvantaged men. The intervention has been tailored for this group and will be delivered only to them. If effective it will reduce short and long term alcohol-related problems, thus

reducing inequalities in health. The recruitment methods and the intervention design and delivery methods will also be useful for research addressing other adverse health behaviours which lead to inequalities in health.

7. Planned intervention

The feasibility study intervention

The brief intervention used in the feasibility study was a series of Short Message Service (SMS) and Multimedia Messaging Service (MMS) messages delivered by mobile phone over a 4 week period. The content of the intervention text messages was derived from seven types of literature: alcohol brief interventions[6-9]; text message interventions[15-17]; two psychological models (Theory of Planned Behaviour[29, 30] and the Transtheoretical Model[31]), Motivational Interviewing[32], Communication Theory[33] and reviews of specific behaviour change techniques[34].

The messages were constructed to take advantage of the conventional pattern of heavy weekend drinking. They tapped into three windows of opportunity: before weekend drinking, after a heavy drinking episode and midweek sobriety. Messages were tailored to the target group by embedding them in the language and the drinking culture of disadvantaged young men. The messages used popular texting terms and abbreviations. A variety of techniques were employed to increase message effectiveness: use of gain-framed texts; pairing of messages; and inclusion of questions to promote interactivity. Extensive process measures showed high levels of engagement with key components of the behaviour change strategy.

The strengthened intervention

Analysis of the feasibility study identified areas for improvement of the intervention. Additional text messages will be created to address action and coping planning and relapse prevention. These additional strategies are taken from the Health Action Process Approach[35] which seeks commitment to action and also promotes maintenance of a reduced frequency of binge drinking. The aim is to address the so called intention-behaviour gap which has been identified as a weakness of many intervention designs based on the Theory of Planned Behaviour. The interactive text messages of the augmented intervention will be sent over a 12 week period. The behaviour change strategy follows four stages with several texts addressing each stage.

Stage 1. Introductory texts: welcome to the study, establish empathy, raise awareness

The early texts will foster interest in the study and, following the principles of Motivational Interviewing[32], will[3232] empathise with the difficulty of changing drinking behaviour. Humour will be used frequently. Texts will explain the definition of binge drinking and increase the salience of the short term harms of binge drinking. Other texts will build on this by initiating engagement with the short-term personal and social benefits of reduced drinking.

Stage 2. Pre-intentional texts: create intention to change

Following Motivational Interviewing[32] the texts will explore the discrepancy between an individual's drinking habits (becoming drunk) and the intended aims of drinking (having fun and socialising). Texts will seek to modify alcohol expectancies[36] by promoting engagement with the benefits of moderated drinking and will increase awareness of significant others' views of reduced drinking. They will also address self-efficacy for refusing drinks and avoiding heavy drinking situations.

Stage 3. Intentional: transform intention into action
Texts will encourage commitment to goal setting and the formation of specific action plans. They will also encourage identification of barriers to change and the development of coping strategies[35]. This will be aided by presenting common risk situations and possible coping strategies, an approach which has been found to be effective in reducing binge drinking[37].

Stage 4. Actional: sustaining behaviour change
In this phase texts will increase self-efficacy for maintenance of reduced drinking and support habit formation of less frequent binge drinking. Participants will be encouraged to develop strategies for relapse prevention[35]. The texts will also address recovery self-efficacy. Texts will also prompt rehearsal of responses to risky situations and increase men's confidence and skills in maintaining behaviour change and recovering from any setbacks in the longer term. The purpose of these texts is to sustain behaviour change by reinforcing self-efficacy for maintenance of long term behaviour change and augmenting recovery self-efficacy.

Comparator intervention
The comparator group will receive one text message per week for the twelve weeks of the intervention. This would mean the comparator group would receive a similar amount of attention to the groups in conventional alcohol brief interventions[8]. The texts will be designed to be behaviourally neutral, by avoiding the behaviour change strategies employed in the active intervention. Several text messages from the control group of the feasibility study will be used. The messages will consist of jokes and interesting or unusual facts about health unrelated to alcohol. They will be designed to maintain interest in the study to ensure that the control group complete the outcome assessments.

8. Outcome measures
The primary outcome will be assessed at 12 months from the end of the intervention. It is the proportion of men consuming >8 units on at least 3 occasions in the previous 30 days. This outcome is particularly suitable for disadvantaged men: the feasibility study showed that most of the participants had regular episodes of binge drinking with periods of complete abstinence in between. This makes reduction in the frequency of binge drinking a key target for reducing alcohol-related harm. This measure of consumption is used by national surveys of alcohol consumption[38]. The questions on alcohol consumption were taken from the US Behavioural Risk Factor Surveillance System[25].

Five secondary outcomes will be measured. To assess the immediate impact of the intervention one secondary outcome will assess binge drinking at 3 months from the end of the intervention. This will enable us. The frequency of heavy binge drinking (>16 units in a session) will be recorded at 3 and 12 months from the end of the intervention. This level of drinking was found to be common among disadvantaged men in the feasibility study. The Fast Alcohol Screening Test (FAST)[26] will be used to determine the frequency of hazardous drinking; it is short and suitable for telephone use. Total consumption of alcohol will be measured to ensure comparability with other brief intervention trials.

Process assessment during intervention delivery
The successful methods of process assessment developed for the feasibility study will be used. Fidelity of delivery of the text messages will be monitored electronically. Engagement with the study will be measured by the frequency of responses to questions included in the text messages. Content analysis of the responses given will identify the nature of engagement with components of the behaviour change intervention. The feasibility study showed high

levels of engagement with subjective norms, control beliefs, perceived behavioural control and behavioural intentions. Additional text questions will be added to monitor identification of barriers to change, the development of coping strategies, self-efficacy for maintenance of reduced drinking and the development of strategies for relapse prevention.

9. Assessment and follow-up

9.1 Outcomes will be measured by telephone interview at three and twelve months after the delivery of the intervention. Interviewers will be blind to intervention status. The feasibility study demonstrated that a structured questionnaire administered by telephone interview could be used to measure these outcomes.

Several strategies will be employed to maximise completion of the outcome assessments. The final text messages to intervention and control groups will build on the engagement of participants in the study and ask them to keep in touch. Participants will be sent a letter prior to each follow-up assessment to remind them about the follow-up assessment and the gift voucher they will be given for completing the assessment. (Participants' current addresses are recorded at the start of the study and used to send the participants their gift vouchers.) The letter will ask participants to update us by text message if they have changed their mobile phone number. Participants will also be asked to provide a second telephone number which could be used if we are unable to contact them by mobile phone or by letter. This may be their landline number or the telephone number of a relative or close friend. In addition, participants will be asked to provide their email address, if available. Participants will be informed that these options (alternative phone number and email address) will only be used if they cannot be reached on the mobile telephone number provided. The study has a unique mobile phone number which is used throughout the project. All text responses from participants will be recorded and reviewed.

9.2 Assessment of harms

This study involves a novel method of delivery of a widely used brief intervention to reduce harmful drinking. This feasibility study identified no evidence of harm. Further no harms have been reported in text message intervention studies used for other types of health behaviour. 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 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.

10. Proposed sample size

The primary endpoint is the proportion of men binge drinking (consuming >8 units in one session) on at least 3 occasions in the previous 30 days. The sample size calculation focuses on a reduction in the frequency of binge drinking. The feasibility study found that frequent binge drinking was very common in the target group. This type of drinking is likely to be the major cause of harm in disadvantaged men.

The sample size calculation is based on the difference in the proportion of frequent binge drinking between intervention and control groups at the 12 month follow up assessment. It uses the finding from the baseline interviews from the feasibility study, that 57% of men consumed >8 units on at least 3 occasions in the previous 30 days. The proposed effect size is that the intervention will reduce the frequency of binge drinking from 57% to 46%, a net reduction of 11%. A recent systematic review of conventional brief interventions[8] found an

11% difference in frequency of binge drinking between intervention and control. To detect a reduction in the frequency of binge drinking in this way from 57% to 46% (at the 5% significance level with a power of 80%) would require a sample size of 319 per group or 638 in total. The required sample size was then increased by 20% to allow for losses to follow-up, making the total sample size 798. We expect that the loss to follow-up will be less than this, as the loss in our three month feasibility study was only 4%. However, as most alcohol brief intervention trials have a loss to follow-up of over 20%[8], it is prudent to make suitable allowance.

11.1 Statistical analysis

The analysis will be by intention to treat. The primary outcome is dichotomous and effect sizes will be presented as proportions of intervention and control groups who have reduced their frequency of binge drinking. Odds ratios and 95% confidence intervals will be calculated. The secondary outcomes will be assessed in a similar way. Further analyses will use logistic regression to explore which of the cognitive antecedents of behaviour change predicts change in the primary outcome. These will include the process measures plus intention to reduce consumption (measured by the Readiness Ruler[39] and self-efficacy for reducing consumption (using items from the Drinking Refusal Self-efficacy Questionnaire[40]). Goal setting and action planning will use the scales developed by Renner, Schwarzer et al[41]. The analysis will also explore whether the recruitment method (through primary care or time space sampling) influences treatment effect.

11.2. Economic Evaluation

The economic evaluation will take a societal perspective and will model the potential cost-effectiveness of the intervention assuming a UK-wide implementation. Resources relating to both recruitment strategies will be collected in addition to the resources required to implement the intervention. These will then be used to predict the costs relating to national rollout where resources will be costed according to their opportunity cost. Health status will be measured by the EQ-5D[42], a validated quality of life questionnaire designed to be simple to administer. Assaults, disorderly behaviour, contacts with police/criminal justice, plus accident and emergency and other health care usage will be measured by the widely used short Service Use Questionnaire (courtesy of S Parrot at the Department of Health Sciences, University of York). The longer term impact on Quality Adjusted Life Years (QALYs) and other harms will be modelled using quantified relationships between consumption (mean weekly consumption and peak daily consumption) and alcohol attributable harms[43]. The cost-effectiveness will then be presented as the cost per person reducing their binge drinking and as the cost per QALY saved. Subgroup differences in cost-effectiveness will be explored for the two recruitment strategies. A sensitivity analysis will be conducted to assess the robustness of the conclusions reached to changes in the key assumptions.

12. Ethical arrangements

The study will comply with the ESRC Research Ethics Framework[44]. Permission to conduct the study will be sought from the NHS Research Scotland Permissions Co-ordinating Centre (NRS Permissions CC) with the East of Scotland Research Ethics Service as the lead centre. As this study involves a widely used brief intervention it raises few ethical issues.

13. Research governance

The University of Dundee will act as sponsor for the project. The governance of the trial will be overseen by the Tayside Clinical Trials Unit (TCTU), a fully registered NIHR CRN trials unit. As such, TCTU designs, conducts, analyses, reports and archives all its clinical studies to exacting regulatory, legal, ethical and scientific requirements, including Good Clinical Practice.

A Steering Committee will be established. It will comprise a chairman, an alcohol expert, the chief investigator, a statistician, the trial manager and a lay person. The chairman, alcohol expert, statistician and lay person will be wholly independent of the study. The role of the Steering Committee is to monitor all aspects of the conduct and progress of the trial, to ensure that the protocol is adhered to and to take appropriate action to safeguard participants and the quality of the trial.

14. Project timetable and milestones

The Trial Manager will be appointed before the study begins, but will begin employment on the start date of the study, the 1st July 2013. As this is a multi-centre trial the process of applying for ethical permission will be begun before the study starts.

Months 1-2

- Trial manager induction.
- Obtain for ethical permission
- Establish the steering committee and register the trial

Months 3-8

- Modify the intervention, create new texts and images
- Update the computer programme for intervention delivery
- Revise baseline and follow up questionnaires
- Prepare for the economic evaluation
- Conduct fieldwork for recruitment
- Train research staff

Months 9-18

- Screen disadvantaged men to recruit 798 in total, (399 through primary care, 399 by time space sampling
- Conduct baseline interviews
- Randomise
- Deliver the intervention

Months 15–24

- Conduct three month post-intervention delivery follow-up interviews.

Months 24-33

- Conduct twelve month post-intervention follow-up interviews, approximately 116 per month

Months 34–39

- Analysis, report preparation and dissemination
- Prepare papers for publication.

15. Members of the Public

Two members of the public, recruited from socially disadvantaged areas, will be members of the Trial Management Group and will contribute to all aspects of the study including the participant information leaflet, the intervention texts and other research materials. Four other members of the public will be involved in recruiting participants through the community outreach strategy Time-Space sampling. Public involvement will be strengthened by holding a series of four workshops with community groups, one in each of the recruitment centres. These will be organised through Healthy Living Initiatives, Alcohol Focus Scotland and the local NHS Drug and Alcohol Team. They will involve travel costs for delegates and two members of the research team. A light lunch will be offered to improve attendance. Two members of the research team will meet with stakeholders at the national level to engage in discussions about the potential impact of this study: policy makers and representatives from Alcohol Focus Scotland, an alcohol charity.

These activities will be supported by the University of Dundee's public engagement office Revealing Research. This is dedicated to supporting researchers to engage the public with their research and supports researchers to communicate their research to public audiences including families, schools, adults and policymakers. The office resides within the External Relations directorate, as does the University's Press Office, which is very experienced in gaining international media coverage of research funding and outcomes. Finally all participants will be sent lay summaries of the main findings of the study.

16. References

1. Evaluating social marketing for health: The need for consensus. The societal cost of potentially preventable illness. 2nd National Social Marketing Conference; 2007; Oxford.
2. York Health Economics Consortium, University of York. The Societal Cost of Alcohol Misuse in Scotland for 2007. Edinburgh: Scottish Government, 2010.
3. Bromley C, Sproston K, Sheldon N. The Scottish Health Survey - 2003. Edinburgh: Scottish Executive, 2005.
4. Mackenbach JP, Stirbu I, Roskam A-JR, Schaap MM, Menvielle G, Leinsalu M, et al. Socioeconomic Inequalities in Health in 22 European Countries. *N Engl J Med* 2008;358(23):2468-81.
5. Audit Scotland. Overview of Scotland's health and NHS performance in 2006/07. Edinburgh, 2007.
6. Raistrick D, Heather N, Godfrey C. Review of the effectiveness of treatment for alcohol problems. London: The National Treatment Agency for Substance Misuse, 2006.
7. 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.
8. Kaner EF, Dickinson HO, Beyer F, Campbell F, Schlesinger C, Heather N, 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*.
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):279-92.
10. Blaxter M. Evidence for the effect on inequalities in health of interventions designed to change behaviour: Department of Social Medicine, University of Bristol, 2007.

11. 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.
12. 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.
13. 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.
14. 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.
15. Cole-Lewis H, Kershaw T. Text Messaging as a Tool for Behavior Change in Disease Prevention and Management. *Epidemiol Rev* 2010;32(1):56-69.
16. Fjeldsoe BS, Marshall AL, Miller YD. Behavior Change Interventions Delivered by Mobile Telephone Short-Message Service. *Am J Prev Med* 2009;36(2):165-73.
17. Whittaker R, Borland R, Bullen C, Lin RB, McRobbie H, Rodgers A. Mobile phone-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2009:Issue 4. Art. No.: CD006611. DOI: 10.1002/14651858.CD006611.pub2.
18. Crombie IK, Falconer DW, Irvine L, Williams B, Ricketts IW, Humphris G, et al. Reducing alcohol-related harm in disadvantaged men: development and feasibility assessment of a brief intervention delivered by mobile phone *NIHR Journals Library Report* 2012;In press.
19. Social Disadvantage Research Centre. Scottish Indices of Deprivation: University of Oxford, 2003.
20. Office of the Chief Statistician. Scottish Index of Multiple Deprivation 2004 Technical Report Scottish Executive, 2004.
21. Semaan S. Time-space sampling and respondent-driven sampling with hard-to-reach populations. *Methodological Innovations Online* 2010;5(2):60-75.
22. Agadjanian V, Zotova N. Sampling and surveying hard-to-reach populations for demographic research: A study of female labor migrants in Moscow, Russia. *Demographic Research* 2012;26:131-50.
23. 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.
24. 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.
25. Stahre M, Naimi T, Brewer R, Holt J. Measuring average alcohol consumption: the impact of including binge drinks in quantity-frequency calculations. *Addiction* 2006 101(12):1711-8.
26. Health Development Agency and University of Wales College of Medicine. Manual for the Fast Alcohol Screening Test (FAST). London: Health Development Agency, 2002.
27. McCambridge J, Kypri K. Can Simply Answering Research Questions Change Behaviour? Systematic Review and Meta Analyses of Brief Alcohol Intervention Trials. *Plos One* 2011;6(10).
28. Bernstein JA, Bernstein E, Heeren TC. Mechanisms of change in control group drinking in clinical trials of brief alcohol intervention: Implications for bias toward the null. *Drug and Alcohol Review* 2010;29(5):498-507.

29. Conner M, Sparks P. Theory of Planned Behaviour and Health Behaviour. In: Conner M, Norman P, editors. *Predicting Health Behaviour*. 2nd ed: Open University Press, 2005.
30. Darker CD, French DP, Eves FF, Sniehotta FF. An intervention to promote walking amongst the general population based on an 'extended' theory of planned behaviour: A waiting list randomised controlled trial. *Psychology & Health* 2010;25(1):71-88.
31. Prochaska JO, Diclemente CC. Trans-theoretical therapy - toward a more integrative model of change. *Psychotherapy-Theory Research and Practice* 1982;19(3):276-88.
32. Rollnick S, Miller WR. What is Motivational Interviewing? *Behavioural and Cognitive Psychotherapy* 1995;23:325-34.
33. Fishbein M, Cappella JN. The Role of Theory in Developing Effective Health Communications. *Journal of Communication* 2006;56(S1): S1-S17.
34. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change techniques. *Applied Psychology* 2008;57(4):660-80.
35. Schwarzer R. Modeling health behaviour change: How to predict and modify the adoption and maintenance of health behaviours. *Applied Psychology: An International Review* 2008;57:1-29.
36. 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.
37. Arden MA, Armitage CJ. A Volitional Help Sheet to Reduce Binge Drinking in Students: A Randomized Exploratory Trial. *Alcohol and Alcoholism* 2012;47(2):156-59.
38. The Information Centre. Health Survey for England. London, 2008.
39. Heather N, Smailes D, Cassidy P. Development of a Readiness Ruler for use with alcohol brief interventions. *Drug and Alcohol Dependence* 2008;98(3):235-40.
40. Oei TP, Young RS. Drinking refusal self-efficacy questionnaire. In: Allen JP, Wilson VB, editors. *Assessing alcohol problems. A guide for clinicians and researchers*. 2 ed. Bethesda: National Institute on Alcohol Abuse and Alcoholism, 2003.
41. Renner B, Schwarzer R, Kwon S, Spivak Y, Panzer M. Risk and Health Behaviors. Documentation of the Scales of the Research Project: "Risk Appraisal Consequences in Korea" (RACK). Second Edition. Berlin: International University Bremen & Freie Universität Berlin, 2007.
42. Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Annals of Medicine* 2001;33(5):337-43.
43. Purshouse R, Brennan A, Latimer N, Meng Y, Rafia R, Jackson R, et al. Modelling to assess the effectiveness and cost-effectiveness of public health related strategies and interventions to reduce alcohol attributable harm in England using the Sheffield Alcohol Policy Model version 2.0. Report to the NICE Public Health Programme Development Group: The University of Sheffield, 2009.
44. Economic and Social Research Council (ESRC). Research Ethics Framework (REF), 2005.