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Texting to Reduce Alcohol Misuse (TRAM)

Submission date
01/08/2013

Recruitment status
No longer recruiting

Registration date
14/08/2013

Overall study status
Completed

Last Edited
25/06/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Alcohol-related problems represent a major public health challenge. People who are socially disadvantaged are at a substantially higher risk of developing alcohol-related diseases. The group who drink most alcohol and binge drink most frequently are young to middle aged disadvantaged men. There is a pressing need to change the culture of drinking among this group in order to prevent alcohol-related problems in later life. The main objective of this study 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.

Who can participate?
Men aged 25-44 years living in areas of high deprivation will be recruited. Men will be included in the study if they have had two or more episodes of heavy drinking (more than eight units in a single session) in the preceding month.

What does the study involve?
Men will be recruited to the study by two methods: by letter of invitation from their own GP; and through a community outreach approach where men will be recruited from a variety of venues and work-places within the community. Participants will be randomly allocated to one of two groups. Both groups will receive a series of text messages delivered by mobile phone over a period of three months. Messages sent to the intervention group are designed to help the men to realise that they are at risk from their drinking and motivate them to change their drinking behaviour. The messages will help to increase their self-confidence to refuse drinks, encourage them to make a commitment to drinking less and support them to continue a pattern of reduced binge drinking. The control group will receive text messages on general health promotion. Participants will be followed up at three months and twelve months after the intervention has been delivered. The men will be asked to complete questionnaires by telephone interview.

What are the possible benefits and risks of participating?
The potential benefits are that participants will reduce their frequency of binge drinking. Participants in the intervention group will receive specific information about reducing alcohol consumption and strategies to for relapse prevention, so that they may achieve sustained behaviour change.No potential risks have been identified. The intervention is based on Alcohol

Brief Interventions (ABI) to reduce alcohol consumption which have been extensively used in health care settings and have been shown to be effective in reducing consumption.

Where is the study run from?
The study is being run from the University of Dundee. Collaborators are also based at the Universities of Aberdeen, Glasgow Caledonian, Newcastle, St Andrews and Stirling in the UK and Melbourne, Australia. Participants will be recruited at four centres which cover major regions of Scotland, UK: Tayside, Glasgow, Forth Valley and Fife.

When is the study starting and how long is it expected to run for?
The study started in July 2013 and will run for three years and three months. Recruitment of participants will begin in March 2014 and will last for ten months.

Who is funding the study?
The study is funded by the NIHR Public Health Research Programme, UK.

Who is the main contact?
Professor Iain Crombie
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHR 11/3050/30; 1.0

Study information

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

Acronym
TRAM

Study objectives
A brief alcohol intervention delivered by mobile phone will reduce binge drinking among disadvantaged young to middle-aged men.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service (EoSRES) REC 1, 18/06/2013, ref: 13/ES0058

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Alcohol-related problems

Interventions
Current interventions as of 26/08/2014:
Participants are randomised to two groups. 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.

1. Intervention group: A series of interactive text messages will be delivered over a three month period. The intervention will be delivered in four stages:
Stage 1 will welcome participants, establish empathy and raise awareness about alcohol harms.
Stage 2 consists of a series of pre-intentional texts which will encourage intention to change.
Stage 3 is designed to transform intentions into action.
Stage 4 addresses relapse prevention to achieve sustained behaviour change.
2. The control group will also receive a series of interactive text messages for the twelve weeks of the intervention. The texts will be designed to be behaviourally neutral, by avoiding the behaviour change strategies employed in the active intervention. 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.

Previous interventions:
Participants are randomised to two groups. 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.
1. Intervention group: A series of interactive text messages and images will be delivered over a three month period. The intervention will be delivered in four stages:
Stage 1 will welcome participants, establish empathy and raise awareness about alcohol harms.
Stage 2 consists of a series of pre-intentional texts which will encourage intention to change.
Stage 3 is designed to transform intentions into action.
Stage 4 addresses relapse prevention to achieve sustained behaviour change.
2. The control group will receive one text message per week for the twelve weeks of the intervention. The texts will be designed to be behaviourally neutral, by avoiding the behaviour change strategies employed in the active intervention. 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.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of men consuming more than 8 units of alcohol on at least three occasions in the previous 30 days, one year after the intervention has been delivered

Secondary outcome measures
1. The proportion of men consuming more than 8 units of alcohol on at least three occasions in the previous 30 days, three months after the intervention has been delivered.
2. The proportion of men consuming more than 16 units in a single session in the previous 30 days, three months after the intervention has been delivered.
3. The proportion of men consuming more than 16 units in a single session in the previous 30 days, twelve months after the intervention has been delivered.
4. The proportion of men drinking hazardously [measured by the Fast Alcohol Screening Test

(FAST)], twelve months after the intervention has been delivered.
5. Total alcohol consumption (units in the previous 30 days), twelve months after the intervention has been delivered.

Overall study start date
01/07/2013

Completion date
30/09/2016

Eligibility

Key inclusion criteria
Men aged 25 - 44 years living in socially disadvantaged communities who have consumed more than eight units of alcohol in a single drinking session at least twice in the preceding four weeks.

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
798

Key exclusion criteria
1. Men who are currently attending an Alcohol Problem Service
2. Men who cannot communicate in English (verbally and by text message)
3. Men who will not be contactable by mobile phone for any part of the intervention period.

Date of first enrolment
01/03/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre

University of Dundee
Dundee
United Kingdom
DD2 4BF

Sponsor information

Organisation
University of Dundee and Tayside Health Board (UK)

Sponsor details
Tayside Medical Science Centre (TASC)
Ninewells Hospital & Medical School
Research & Development Office
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Sponsor type
University/education

Website
http://www.tasc-research.org.uk

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The full results will be published in Public Health Research. The anticipated publication date is January 2018. Further papers in high-impact peer reviewed journals are planned to be published in late 2017 and early 2018.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the NHS Research Ethics approval for the study was on the basis of only the research team and individuals from regulatory authorities having access to the raw data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/12/2014		Yes	No
Results article	results	01/10/2017		Yes	No
Basic results		22/09/2017	23/11/2017	No	No
Results article	results	01/06/2018		Yes	No