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Developing and testing the feasibility of an intervention to reduce alcohol consumption in obese men

Submission date
26/08/2014

Recruitment status
No longer recruiting

Registration date
28/08/2014

Overall study status
Completed

Last Edited
18/04/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity (being very overweight) and the harm caused by drinking too much alcohol are major public health problems. People who are obese and also drink too much alcohol are at a very high risk of developing a number of health problems, particularly liver disease. Many obese men want to lose weight, but are reluctant to try the conventional ways to do so. This study will develop a treatment (or intervention) designed especially for men that aims to reduce the amount of alcohol they drink through the motivation of weight loss. It will offer help and support in order to change the behaviour of those taking part. A key feature of the intervention will be an emphasis on the benefits of losing weight. It is designed to reach large numbers of men at risk of obesity and alcohol-related problems and targets those who might not be identified through the health care system. The aim of this study is to find out whether a full study to test whether the intervention works is feasible. If so, the intervention will subsequently be tested in a full study.

Who can participate?
Men aged 35-64 years who regularly drink over 21 units of alcohol per week and are obese (BMI>30)

What does the study involve?
Men are recruited to the study by two methods: by letter of invitation from their own GP and through a community outreach approach where men are recruited from a variety of venues and work-places within the community. Participants are randomly allocated to either a intervention or control group. Those in the intervention group have a 20-30 minute face to face session with a trained coordinator which focuses on how they may lose weight though cutting down on their alcohol intake. It looks at, among other things, strategies for coping in situations which may encourage heavy drinking, and a personal plan to reduce how much alcohol they drink. Motivational text messages are then sent to each participant over the next two months. Those in the control group are given a conventional 10-20 minute face to face session on alcohol abuse. Participants in both groups are followed up five months later to assess their progress.

What are the possible benefits and risks of participating?
The potential benefits are that participants will be encouraged to reduce the amount of alcohol they drink.

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, Newcastle and Stirling in the UK.

When is the study starting and how long is it expected to run for?
May 2014 to January 2016

Who is funding the study?
NIHR Health Technology Assessment (HTA) (UK)

Who is the main contact?
Prof. 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

HTA 12/139/12; 1.1

Study information

Scientific Title
Modifying Alcohol Consumption to Reduce Obesity (MACRO): developing and feasibility testing of a complex community-based intervention for men

Acronym
MACRO

Study objectives
A tailored alcohol intervention will reduce alcohol consumption among obese men through the motivation of weight loss.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/1213912/#/
Protocol can be found at: https://njl-admin.nihr.ac.uk/document/download/2007198

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service (EoSRES) REC 2, 28/05/2014, ref: 14/ES/0050

Study design
Feasibility study with a randomised controlled component

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Obese men who regularly drink alcohol

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.

Intervention group:
The intervention will be delivered in two stages: an initial face to face session and a series of text messages. The face to face session will focus on weight loss through reduced alcohol consumption. It will include: feedback on the persons alcohol use and weight and will use motivational enhancement to clarify how reducing alcohol consumption can assist with weight loss and can reduce the harmful synergistic effects of obesity and heavy alcohol consumption. It will encourage the analysis of high risk situations for drinking; assist with planning coping strategies; and introduce the development of a personal plan to reduce consumption. This session will be delivered by trained lay coordinators and will last approximately 20 - 30 minutes. Sessions will be audio recorded and will be scrutinised by an independent researcher to assess fidelity of delivery of the intervention. After the face to face session a series of messages and images will be delivered by mobile phone over two months. These messages will reinforce the content of the face to face intervention and extend the behaviour change strategy.

Control group:
The comparator group will receive a conventional brief alcohol intervention which will be delivered in one face to face session by a trained lay person. The session will last approximately 10 - 20 minutes.

Participants are followed up at five months post-recruitment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Recruitment (measured at baseline) and retention (measured at follow up, five months post-recruitment)
2. Acceptability of the intervention, measured using a bespoke questionnaire at follow up
3. Engagement with components of the behaviour change strategy, assessed by monitoring responses to the text message intervention during the two-month intervention period
These measures test whether the feasibility study was successfully conducted. Each will be based on data collected at several timepoints throughout the study, as they are concerned with study conduct.

Secondary outcome measures
1. The impact of the study on the perceived benefits of moderated drinking, measured using a bespoke questionnaire at follow up, five months post-recruitment
2. Intention to reduce alcohol consumption, measured using a bespoke questionnaire at follow up, five months post-recruitment
3. Self-efficacy in ability to reduce drinking and lose weight, measured using the Drinking Refusal Self-efficacy Skills questionnaire at follow up, five months post-recruitment

The two primary outcome measures for a full RCT of the intervention will also be measured, although there will be insufficient numbers of participants in the feasibility study to detect treatment effects:

1. Reported weekly alcohol consumption, measured using the Alcohol Timeline Follow Back (TLFB) at baseline and at follow up, five months post-recruitment
2. Weight loss, measured using Seca 813 medical scales at baseline and at follow up, five months post-recruitment

Overall study start date
01/05/2014

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1. Men aged 35-64 years
2. Regularly consume >21 units of alcohol per week
3. Obese (BMI>30)

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
60

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

Date of first enrolment
16/03/2015

Date of final enrolment
22/06/2015

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
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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
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study will be published in Health Technology Assessment Volume 21 in March 2017. Further papers in high-impact peer reviewed journals are planned to be published in October/November 2017.

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Iain Crombie (i.k.crombie@dundee.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/01/2017	26/01/2017	No	No
Results article	results	01/04/2017		Yes	No
HRA research summary			28/06/2023	No	No