

Modifying Alcohol Consumption to Reduce Obesity (MACRO): development and feasibility trial of a complex community-based intervention for men

Iain K Crombie,^{1*} Kathryn B Cunningham,¹
Linda Irvine,¹ Brian Williams,^{2,3} Falko F Sniehotta,⁴
John Norrie,^{5,6} Ambrose Melson,^{1,7} Claire Jones,⁸
Andrew Briggs,⁷ Peter M Rice,⁹ Marcus Achison,¹
Andrew McKenzie,¹ Elena Dimova^{1,10} and
Peter W Slane¹¹

¹Division of Population Health Sciences, School of Medicine, University of Dundee, Dundee, UK

²Nursing, Midwifery and Allied Health Professions Research Unit, University of Stirling, Stirling, UK

³School of Health and Social Care, Edinburgh Napier University, Edinburgh, UK

⁴Institute of Health and Society, Medical Faculty, Newcastle University, Newcastle upon Tyne, UK

⁵Centre for Healthcare Randomised Trials (CHaRT), University of Aberdeen, Aberdeen, UK

⁶Edinburgh Clinical Trials Unit (ECTU), University of Edinburgh, Edinburgh, UK

⁷Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK

⁸Health Informatics Centre, School of Medicine, University of Dundee, Dundee, UK

⁹Division of Neuroscience, School of Medicine, University of Dundee, Dundee, UK

¹⁰Faculty of Health Sciences and Sport, University of Stirling, Stirling, UK

¹¹Erskine Practice, Arthurstone Medical Centre, Dundee, UK

*Corresponding author i.k.crombie@dundee.ac.uk

Declared competing interests of authors: John Norrie is a member of the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Commissioning Board and the NIHR HTA and the Efficacy and Mechanism Evaluation Editorial Board. Linda Irvine was the Trial Manager on the NIHR Public Health Research funded study 11/3050/30 [Texting to Reduce Alcohol Misuse (TRAM): a multi-centre randomised controlled trial of a text message intervention to reduce binge drinking among disadvantaged men] while the current study was being conducted.

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published April 2017

DOI: 10.3310/hta21190

Scientific summary

Modifying Alcohol Consumption to Reduce Obesity (MACRO)

Health Technology Assessment 2017; Vol. 21: No. 19

DOI: 10.3310/hta21190

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Heavy alcohol consumption by men who are obese greatly increases their risk of developing liver disease. Men who are obese and drink > 14 units of alcohol per week have a 19-fold increased risk of dying from liver disease.

Objectives

This study was commissioned by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme to develop an intervention to reduce alcohol consumption in obese men. It also assessed the feasibility of a trial investigating the effectiveness of the intervention. Six objectives were set, covering recruitment, intervention design and delivery, and the development of process measures to assess the fidelity of intervention delivery.

Methods

The study was conducted in the community. The participants were men aged 35–64 years who had a body mass index (BMI) of > 30 kg/m² and drank > 21 units of alcohol per week. Six focus groups were conducted with men from the target group to explore their attitudes and beliefs about drinking and weight. To help develop the recruitment strategy, six interviews were conducted with key stakeholders who were managers of organisations in the local community.

For the feasibility study, participants were recruited by two methods: (1) from general practitioner (GP) patient registers and (2) by community outreach. The intervention was delivered by a face-to-face session followed by a series of text messages. Laypeople (study co-ordinators) were trained to deliver the face-to-face session. The control group received a conventional alcohol brief intervention delivered in a face-to-face session.

Baseline height, weight and alcohol consumption were measured at the face-to-face session. A questionnaire was administered at the end of this session to assess acceptability of the study methods. Additionally, the face-to-face sessions were audio-recorded to monitor adherence to and competence at delivering the intervention. Performance was assessed against a checklist of key tasks.

Five months after baseline, men were invited to attend the follow-up face-to-face session, at which weight and alcohol consumption were measured. Questionnaires were also administered to assess hazardous drinking, drinking refusal skills, recall of the intervention and acceptability of the study methods.

Results

The results section is structured into the series of substudies that were conducted to develop and evaluate the methods that would be needed to conduct a randomised controlled trial (RCT).

Focus groups

Men talked openly about their drinking and were surprised to discover how much they drank. They could easily identify benefits of reduced drinking. The main barrier to reducing alcohol consumption was the potential impact on their social lives.

The men were concerned about their weight because of the embarrassment of a protruding stomach. They also reported that their weight limited their ability to carry out everyday tasks. When the topic was raised, men acknowledged the connection between alcohol consumption and being overweight. If asked, they could also identify ways in which drinking leads to the increased consumption of foodstuffs, that is, snacking and additional late-night meals. The men were unaware of the calorie content of alcoholic drinks and most had never counted units in alcoholic drinks.

Stakeholder interviews

The stakeholders considered alcohol consumption and weight to be major public health issues and believed that an intervention to tackle these issues would be a valuable contribution to society. They felt that many of their staff and clients would be eligible and willing to take part in the intervention. Furthermore, they thought that the aims of the research dovetailed with their organisation's philosophy and aims. The stakeholders were keen to help recruitment, although their role would be limited to passing on information about the study.

Design of the intervention

The intervention was systematically developed using formative research, public involvement and behaviour change theory. The intervention was organised in two phases: a face-to-face session delivered by trained laypeople (study co-ordinators) followed by a series of text messages. The face-to-face session was intended to increase motivation to drink less. It used the findings from the focus groups to structure discussions about the benefits of reducing drinking and the ways in which alcohol contributes to weight gain, through both the calories in alcohol and the effect that alcohol has on increasing food consumption. The text messages reinforced these discussions to provide a platform for the setting of goals to reduce alcohol consumption and the creation of specific action plans (when, where and how) to drink less. Coping strategies, relapse prevention and maintenance of the new behaviours were introduced and reinforced.

Comparator (control group)

The comparator was a brief alcohol intervention delivered in one face-to-face session by trained laypeople (study co-ordinators). It was based on the Brief Intervention used in the Screening and Intervention Programme for Sensible drinking (SIPS) alcohol screening and brief intervention research programme. It used the SIPS Simple Structured Advice intervention tool to give advice on the risks of alcohol-related harm and the benefits of cutting down. The participants were encouraged to make plans to reduce their drinking.

Recruitment and training of laypeople

A targeted strategy was developed to recruit laypeople to deliver the face-to-face component of the intervention. It identified a large number of applicants (45) in 3 weeks. An extended process of training and selection, with initial over-recruitment, identified six competent and enthusiastic trained laypeople (study co-ordinators). Repeated opportunities for role play with supportive feedback were essential to the training.

Recruitment of participants

Two recruitment strategies were used and each exceeded its target of 30 men. In total, 69 men were recruited. Recruitment through GP registers identified a large pool of potential participants (men with a BMI of $> 30 \text{ kg/m}^2$), enabling recruitment to proceed smoothly. The main reason for non-recruitment, accounting for 45% of all men nominated, was that they reported drinking < 21 units per week.

Recruitment by community outreach was challenging, with very few men recruited from each venue visited. This resulted in a higher workload than for recruitment through GP registers. Of the men

approached in community outreach, many (53%) did not drink enough to meet the entry criterion. The city centre was the most productive location for recruiting men by community outreach. Recruitment from large organisations was largely unsuccessful and leaving participant information sheets at potential venues for recruitment was ineffective.

Baseline findings

Of the 69 men recruited, 62 attended the face-to-face session at which baseline measurements were made. The sessions were held at a variety of community venues, of which the participant's home was the most popular. The screening methods for alcohol consumption and BMI identified men meeting the entry criteria. The participants covered a wide range of ages and socioeconomic statuses.

Almost all of the men (92%) were drinking hazardously (Fast Alcohol Screening Test positive). The average alcohol consumption of the men recruited was 47.2 units per week; this was more than twice that of the entry criterion (> 21 units per week). The men in the control group drank much more than the men in the intervention group (mean difference 8.8 units per week). Nearly all of the men (98%) engaged in binge drinking, and most (78%) did so at least weekly. The mean BMI at baseline was 35.7 kg/m², which was well above the threshold of 30 kg/m². Almost all of the men (95%) exceeded the threshold for a 19-fold increase in the risk of dying from liver disease (BMI of > 30 kg/m² and > 14 units of alcohol per week). As the mean alcohol consumption was 47.2 units per week, the participants' risk of dying from liver disease could be increased by more than 19-fold.

Evaluation of the delivery of the face-to-face session

The audio-recordings of the sessions showed that adherence to all tasks was very high for all study co-ordinators. In the intervention group, only one task was missed on a single occasion. Competence was also good on most tasks, although improvements could be made in encouraging discussion of current drinking and providing summaries at the end of the sessions. The control group study co-ordinators, who had a different set of tasks, also performed well; however, occasionally more discussion of the harms of heavy drinking was needed. Individual feedback was given to all study co-ordinators after every face-to-face session.

The participant questionnaire identified extremely high levels of approval of study components: organisation of the session (100%), acceptability of the venue (100%) and ability of the study co-ordinator to hold the participants' interest (100%). The written comments from participants showed that the sessions were run in a relaxed, friendly atmosphere, and that the information provided was perceived as useful by both intervention and control group participants.

Fidelity of delivery of the text messages

Ninety-five text messages were sent to men in the intervention group ($n = 31$). The computer system that sent the text messages also recorded whether or not the messages were delivered to the participants' phones. Nearly all of the text messages (98%) were received, and none of the participants missed consecutive messages. At key steps in the behaviour change sequence, text messages invited the men to respond to specific questions. The aim was to identify how men interpreted and reacted to the behaviour change techniques. The men responded to an average of 7.3 of the 14 questions asked, with almost all of the men (94%) responding to at least one question. The nature of their responses showed that men had understood the text messages and had put thought into their replies. For example, in response to a question on how drinking influences what you eat, men gave examples of making high-calorie food choices such as kebabs and pizza. The question on the main benefit of changing their current drinking pattern elicited responses about losing weight, being more active and improving health. Overall, the men responded as intended to the text messages, displaying a high level of engagement with the intervention.

Follow-up

A very high follow-up rate was achieved (98%). The two outcome measures that would be used in a full RCT, alcohol consumption and weight, were successfully measured.

The average weekly alcohol consumption remained high in both groups (mean 34.6 units) and most men continued to binge drink at least weekly. Despite their high consumption, most men (74%) believed that they were at low risk of harm from alcohol, possibly because they seldom suffered acute harms (e.g. hangovers) and made few visits to a GP or hospital.

Compared with baseline, both intervention and control groups reduced their alcohol consumption. The reduction was greater in the control group. Interpretation of this is difficult because the control group consumed much more alcohol at baseline than the intervention group. The average weight of the men was unchanged in both groups.

More men in the intervention group than in the control group (22 vs. 16) had thought about reducing their drinking or had made a plan to cut down. The intervention group participants were also more likely to think that they had successfully cut down (16 vs. 10) and to have made a plan to deal with difficult drinking situations (11 vs. 4). Among those who tried to cut down, the main reason was long-term health benefits. Other factors, such as money, short-term personal benefits and family concerns, were seldom mentioned.

The acceptability of the study at follow-up remained high. In the intervention group, 90% of men found the information they were given useful, 80% would recommend the study to others and 77% felt that they benefited from taking part. The figures for acceptability in the control group were similar.

Preparation for the economic assessment

The EuroQol-5 Dimensions™ identified men who experienced adverse outcomes that may be associated with obesity, that is, problems with mobility (30%) and pain or discomfort (49%). The Short Service Use Questionnaire detected very low levels of use of services (health, social and criminal justice).

Conclusions

This feasibility study developed a novel intervention and evaluated all the stages of a RCT that would test the effectiveness of the intervention. It also showed how the involvement of the public in all stages of the study can improve the design and conduct of research. The stakeholder interviews identified considerable potential for national roll-out of the intervention through organisations and businesses in the local community. The participant recruitment strategy, the design and delivery of the intervention and the interpretation of the findings were aided by user group representatives, focus group members, trained laypeople and key stakeholders. Enthusiastic laypeople were recruited and successfully trained to deliver the face-to-face sessions.

Both recruitment strategies were successful and the recruitment target was exceeded. However, recruitment from GP registers was much less onerous than that from community outreach. Most men drank very heavily and were obese. Almost all of the men (95%) were at a 19-fold increased risk of dying from liver disease (BMI of > 30 kg/m² and > 14 units of alcohol per week). The recruitment methods of this study can identify men who are in urgent need of intervention.

A very high follow-up rate was achieved and the main outcomes for a RCT were measured. The novel intervention used weight loss as a motivator to drink less. A variety of levers for behaviour change were identified and incorporated into the intervention. Methods for process evaluation were developed: the audio-recording of face-to-face sessions; a questionnaire to participants at baseline and follow-up; and an analysis of responses to text messages. These methods showed high fidelity of delivery of both intervention and control packages.

The men in the intervention group engaged enthusiastically with the intervention, particularly with the argument that drinking less was a useful way of losing weight. The responses to text messages demonstrated that the men were able to use the behavioural and cognitive skills demonstrated in the text messages, for example goal-setting and action planning.

In summary, a novel intervention tailored to the target group was developed. The main stages of a trial were completed successfully: recruitment, randomisation, intervention delivery, follow-up and measurement of study outcomes. The acceptability of the study methods was high. A RCT could be conducted to test the effectiveness and cost-effectiveness of the intervention. The recruitment methods of this study identified men who are at very high risk of liver disease. There is an urgent need for an intervention to reduce this risk in such men.

Recommendations for research

The study has shown that the definitive trial is feasible.

Trial registration

This trial is registered as ISRCTN55309164.

Funding

Funding for this study was provided by the HTA programme of the NIHR.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nhr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nhr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nhr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: <http://www.nets.nihr.ac.uk/programmes/hta>

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/139/12. The contractual start date was in May 2014. The draft report began editorial review in February 2016 and was accepted for publication in November 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

© Queen's Printer and Controller of HMSO 2017. This work was produced by Crombie *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Health Technology Assessment Editor-in-Chief

Professor Hywel Williams Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Health Sciences Research, Health and Wellbeing Research Group, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk