Text message intervention to reduce frequency of binge drinking among disadvantaged men: the TRAM RCT

Iain K Crombie,[1]* Linda Irvine,[1] Brian Williams,[2] Falko F Sniehotta,[3] Dennis J Petrie,[4] Claire Jones,[5] John Norrie,[6] Josie MM Evans,[7] Carol Emslie,[8] Peter M Rice,[9] Peter W Slane,[10] Gerry Humphris,[11] Ian W Ricketts,[12] Ambrose J Melson,[13] Peter T Donnan,[1] Andrew McKenzie,[1] Li Huang[14] and Marcus Achison[1]

[1]Division of Population Health Sciences, School of Medicine, University of Dundee, Dundee, UK
[2]School of Health and Social Care, Edinburgh Napier University, Edinburgh, UK
[3]Institute of Health and Society, Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, UK
[4]Centre for Health Economics, Monash Business School, Monash University, Melbourne, VIC, Australia
[5]Health Informatics Centre, University of Dundee, Dundee, UK
[6]Edinburgh Clinical Trials Unit, University of Edinburgh, Edinburgh, UK
[7]Faculty of Health Sciences and Sport, University of Stirling, Stirling, UK
[8]School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK
[9]Division of Neuroscience, School of Medicine, University of Dundee, Dundee, UK
[10]Erskine Practice, Arthurstone Medical Centre, Dundee, UK
[11]School of Medicine, Medical and Biological Sciences, University of St Andrews, St Andrews, UK
[12]School of Computing, University of Dundee, Dundee, UK
[13]Institute of Health and Wellbeing, University of Glasgow, Glasgow, UK
[14]Centre for Health Policy, School of Population and Global Health, University of Melbourne, Melbourne, VIC, Australia

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

Declared competing interests of authors: John Norrie reports that he was a member of the National Institute for Health Research (NIHR)/Health Technology Assessment (HTA) Commissioning Board 2010–16, is a member of the NIHR Journals Editorial Board (2015–present) and is deputy chairperson of the NIHR/HTA General Board (2016–present). Carol Emslie reports grants and non-financial support from the Scottish Health Action on Alcohol Problems, grants from the NIHR HTA programme and non-financial support from the British Sociological Association Alcohol Study Group outside the submitted work. She is also a member of the Alcohol Research UK Grants Advisory Panel (unpaid position). Peter T Donnan reports grants from Novo Nordisk Ltd, GlaxoSmithKline plc and AstraZeneca plc outside the submitted work. He is also is a member of the New Drugs Committee of the Scottish Medicines Consortium.

Published June 2018
DOI: 10.3310/phr06060

Scientific summary

The TRAM RCT

Public Health Research 2018; Vol. 6: No. 6
DOI: 10.3310/phr06060

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

Scientific summary

Background

Alcohol-related morbidity and mortality is a major public health challenge. Socially disadvantaged men are more likely to binge drink frequently and to experience high levels of alcohol-related harm. Recruiting disadvantaged groups to research studies is known to be challenging and interventions are often much less effective in these individuals. This study tested the effectiveness and cost-effectiveness of a tailored, theoretically and empirically based intervention, delivered by text message, to reduce binge drinking in disadvantaged men.

Methods

Study design

The study was a four-centre, parallel-group, pragmatic, individually randomised controlled trial. The randomisation was carried out using the secure remote web-based system provided by Tayside Clinical Trials Unit. Randomisation was stratified by participating centre and the recruitment method, and restricted using block sizes of randomly varying lengths. The concealment of treatment groups was preserved until the analyses of the primary and secondary outcomes had been completed.

Participants

Men aged 25–44 years were recruited from areas of high deprivation. Recruitment was conducted in four centres that cover major regions of Scotland: Tayside, Glasgow, Forth Valley and Fife. Deprivation was measured using the Scottish Index of Multiple Deprivation. Men were recruited from areas classified as being in the most disadvantaged quintile. To ensure good coverage of disadvantaged men, two recruitment strategies were employed, each to recruit half of the target sample size. One used primary care registers and the other used a community outreach method, time–space sampling (TSS).

Inclusion/exclusion criteria

Men were included in the study if they had ≥ 2 episodes of binge drinking (> 8 units of alcohol in a single session) in the preceding 28 days. Exclusion criteria were men who were currently attending care at an alcohol problem service and men who would not be contactable by mobile phone for any part of the intervention period.

Sample size

The study was powered to detect a net reduction of 11%, from 57% to 46%, in the proportion of men who had consumed > 8 units of alcohol on ≥ 3 occasions in the previous 28 days, with a power of 80% at a significance level of 5%. This revealed that a total sample of 638 men would be required. The estimate was increased to allow for losses to follow-up, making the final recruitment target 798 men.

Intervention

The text message intervention was delivered in a series of 112 interactive text messages delivered by mobile phone over a 12-week period. The intervention drew on literature from alcohol brief interventions, communication theory, behaviour change theories and a taxonomy of behaviour change techniques. The text messages were organised around a narrative that was used to engage participants and illustrate key steps in the behaviour change process. It followed the progress of a heavy drinker as he attempted, with relapse and recovery, to successfully reduce his binge drinking. The narrative structure enabled information and advice to be given in a non-patronising way and allowed the main character to model the behaviour

© Queen's Printer and Controller of HMSO 2018. This work was produced by Crombie *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. 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.

change processes involved in reducing alcohol consumption. The control group received an attentional control comprising 89 text messages on general health.

Outcome measures

Outcomes were assessed blind to treatment status. The primary outcome was assessed at 12 months post intervention. It was the proportion of men binge drinking (consuming > 8 units of alcohol) on ≥ 3 occasions in the previous 28 days. Five secondary outcomes were measured. They were (1) the proportion of men binge drinking (> 8 units of alcohol) on ≥ 3 occasions at 3 months post intervention; (2) the proportion of men with ≥ 3 occasions of heavy binge drinking (> 16 units of alcohol) at 3 months; (3) the proportion of men with ≥ 3 occasions of heavy binge drinking (> 16 units of alcohol) at 12 months post intervention; (4) the total consumption of alcohol in the previous 28 days at 12 months; and (5) the proportion of hazardous or harmful drinkers at 12 months post intervention, as measured by the Alcohol Use Disorders Identification Test (AUDIT). The analysis also explored whether or not the recruitment method (through primary care or TSS) influenced treatment effect.

Statistical analysis

The main analyses were carried out by an independent statistician who followed the prespecified statistical analysis plan. Logistic regression was used to investigate the effect of the intervention on the primary outcome, the proportion of men consuming > 8 units of alcohol on ≥ 3 occasions in the previous 28 days at 12 months post intervention. Odds ratios (ORs) were adjusted for baseline drinking and baseline covariates, including method of recruitment, centre and demographic factors. Equivalent models were fitted for the secondary outcomes.

Economic evaluation

The economic evaluation considered the short-term cost-effectiveness, adopting the perspective of the government [the costs of running the programme plus the 12-month follow-up cost of health-care, social and justice services compared with two measures of outcome: the reduction in binge drinking at the 12-month follow-up; and short-term quality-adjusted life-years (QALYs)]. The longer-term perspective modelled the impact on government costs (health care and social care) as well as wider societal impacts on crime and workplace harms. It also considered the predicted impact on QALYs up to 30 years post intervention. Both costs and outcomes were discounted at 3.5%. Data were collected on the resources required for recruitment and the intervention implementation. The incremental cost, incremental effectiveness and incremental cost-effectiveness ratios were estimated for an England and Scotland rollout when compared with a 'do-nothing' or standard practice scenario. The heterogeneity of the cost effectiveness by recruitment methods was also estimated.

Results

Study population

The target sample size of 798 participants was exceeded, with a total of 825 men recruited. The two recruitment methods achieved their targets and recruitment was successful across the four centres. The men recruited were spread across the age range; just over half lived with a partner and over one-third were unemployed. At baseline, most participants (84%) had ≥ 3 binge-drinking episodes (> 8 units of alcohol in a session), and many (47.5%) had ≥ 3 heavy binge-drinking episodes (> 16 units of alcohol in a session), in the previous 28 days. Almost all of the alcohol the men drank (93%) was consumed in binge-drinking sessions. The two treatment groups were similar on all demographic characteristics and measures of alcohol consumption.

There were marked differences in drinking patterns and demographic characteristics between men recruited by general practice registers and men recruited by TSS. For example, mean consumption was 56% higher in the men recruited by TSS than in those recruited from general practice registers; and significantly more of the men recruited by TSS were single and unemployed.

Engagement with the intervention

A total of 46,032 text messages were sent to the intervention group. Of these, 95.5% were successfully delivered. Most men engaged enthusiastically with the intervention, with 92% sending a response to at least one text message and 67% sending more than 10 responses. The nature of these responses indicated that many men reacted as intended to key steps in the behaviour change sequence. For example, 56% of the men specified the benefits that they would gain from reducing their alcohol consumption and 24% identified the benefits that they were enjoying from having cut down.

Retention

Two follow-up assessments were carried out: at 3 months and at 12 months post intervention. Retention at the 3-month follow-up was high (89.3%) and was almost identical in the intervention (89.1%) and control (89.6%) groups. At the 12-month follow-up, the retention rate had reduced slightly but remained high at 85.6%, and it was similar in the intervention (84.9%) and control (86.5%) groups. Baseline alcohol consumption was similar in those lost to follow-up from the intervention and control groups: for those men not followed up at 12 months post intervention, the proportion consuming > 8 units of alcohol on ≥ 3 occasions at baseline was 88.7% in the intervention group and 87.5% in the control group.

Outcome assessment

Primary outcome

The intervention had an estimated modest, statistically non-significant effect on the primary outcome at the 12-month follow-up [OR 0.79, 95% confidence interval (CI) 0.57 to 1.08]. This corresponds to a net reduction of 5.7% in the proportion of men who binge drink on ≥ 3 occasions (95% CI –13.3% to 1.9%). Multiple imputation, to take account of missing data, produced similar estimates of treatment effect (OR 0.77, 95% CI 0.55 to 1.09). There was a marked but statistically non-significant difference in the estimated effect by recruitment method. The proportion of men who binge drink on ≥ 3 occasions was reduced by 8.6% for those recruited from general practice registers but by only 2.1% for those recruited by TSS.

Secondary outcomes

The five secondary outcomes showed small, non-significant and inconsistent differences between the intervention and control groups. Two secondary outcome measures were assessed at 3 months. The proportion of men consuming > 8 units of alcohol on ≥ 3 occasions showed a small adverse effect (OR 1.05, 95% CI 0.77 to 1.44), as did the proportion of men with ≥ 3 occasions of heavy binge drinking (> 16 units of alcohol) (OR 1.22, 95% CI 0.83 to 1.81).

A further three secondary outcome measures were assessed at 12 months. The OR for the proportion of men with ≥ 3 occasions of heavy binge drinking (> 16 units of alcohol), was very close to unity (0.97, 95% CI 0.64 to 1.46). The proportion of men who were AUDIT positive (hazardous or harmful drinking) had a raised OR (1.34, 95% CI 0.95 to 1.89) and the total alcohol consumption over 28 days was higher in the intervention group (mean units 4.46, 95% CI –11.1 to 20.03 units).

Change in alcohol consumption over time in the control group

Between baseline and the final follow-up the proportion of men with ≥ 3 occasions of binge drinking (> 8 units of alcohol) in the control group fell by 37.4%. For the proportion of men with ≥ 3 occasions of heavy binge drinking (> 16 units of alcohol) the fall was 28.2%. Similarly, total alcohol consumption over 28 days in the control group fell by 53 units, or 40% of the baseline level. The falls in consumption in the control group were similar to those in the intervention group. For example, the fall from baseline in the proportion of men with ≥ 3 occasions of binge drinking (> 8 units of alcohol) was 40.7% in the intervention group and 37.4% in the control group. There was little net change in alcohol consumption between the 3-month and the 12-month follow-up in the control or intervention groups. An exploratory modelling exercise showed that regression to the mean could explain part of the fall in consumption.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Crombie *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. 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.

Economic analysis

The estimated cost per man to recruit and implement the intervention was modest, at £97 per participant (95% CI £83 to £110). Over 80% of this was incurred during the recruitment stage; the intervention itself was estimated to cost < £20 per participant. However, both the short- and the long-term cost per QALY analysis suggested that the brief intervention was dominated by a 'do-nothing' option, with the intervention's impacts on patterns of alcohol consumption, QALYs and downstream costs inconsistent and uncertain. It was estimated that the intervention would increase the short-term costs per person to government for the 12-month follow-up by £262 (95% CI –£237 to £761). The average cost per one fewer person regularly binge drinking at 12 months post intervention was estimated to be £4576. The brief intervention was estimated to result in a short-term QALY reduction of –0.0063 (95% CI –0.0373 to 0.0248) per participant, outweighing the small predicted longer-term discounted QALY gains of 0.0029 per participant. Subgroup analysis showed that recruitment from general practice registers was less expensive than recruitment by TSS. This, combined with the apparent greater effectiveness in reducing the frequency of binge drinking, makes the general practice register approach appear more attractive. However, there is large uncertainty about these estimates. For the general practice-only recruitment method, the average cost per one fewer person regularly binge drinking at 12 months post intervention was estimated to be £3311, but the estimated longer-term cost-effectiveness of the intervention in terms of cost per QALY was still dominated.

Limitations of the study

The study used an active control that, combined with the recruitment procedures and baseline assessments, could have biased the treatment effect towards the null. The measurement of alcohol consumption relied on self-reported drinking.

Discussion

Binge drinking was the dominant pattern of alcohol consumption, with almost all alcohol being taken in heavy drinking sessions. Interventions focused on reducing total consumption would have been inappropriate for the men recruited to this study.

The intervention was estimated to have a modest, statistically non-significant effect on the primary outcome at the 12-month follow-up, which corresponded to a net reduction of 5.7% in the proportion of men who binge drink on ≥ 3 occasions. The treatment effect was much larger in men recruited from general practice registers than in those recruited by the TSS method. The men recruited by TSS had higher alcohol consumption and were more likely to be single and unemployed. The intervention had small, inconsistent non-significant effects on the secondary outcomes at the 3- and 12-month follow-up points. Biases such as loss to follow-up and observer bias are unlikely to have affected the observed results. The lack of a statistically significant effect may reflect the difficulty of changing adverse health behaviours in disadvantaged individuals.

Large and consistent falls were found in all measures of alcohol consumption in the control group. The falls were similar to those in the intervention group. Regression to the mean can explain part of this fall, although other mechanisms may also be involved.

The cost per QALY analysis suggested that the brief intervention was dominated by a 'do-nothing' option. Although the cost per man to recruit and implement the intervention was modest, the intervention's impacts on patterns of alcohol consumption, QALYs and downstream costs were inconsistent and uncertain.

Conclusions

The trial has demonstrated that it is possible to recruit and retain large numbers of disadvantaged men in a research study. The text messages delivered a complex theoretically and empirically based intervention, which fostered enthusiastic engagement with the key components of the behaviour change sequence. The intervention produced a modest, statistically non-significant effect on the primary outcome. A future trial could reduce the uncertainty around the treatment effect of the intervention. The methods developed for this study provide a platform for the design and testing of interventions to reduce inequalities in health. A key feature of the method used is the ability to monitor engagement with key steps in the behaviour change strategy.

Recommendations for further research

A future trial could:

- reduce the uncertainty around the treatment effect size of the intervention
- test whether or not the intervention is less effective in men recruited by the TSS method, and explore possible explanations for this
- test whether or not a more direct and frank approach, stressing the harm of their frequent binge drinking, would be acceptable to disadvantaged men
- identify the mechanism(s) responsible for the fall in alcohol consumption in the control group
- assess the impact of the use of an attentional control (general health text messages) by including a second, minimal contact control (no text messages)
- explore whether or not the use of biomarkers is feasible in a large study of disadvantaged men
- investigate the impact of an extended intervention (i.e. at least 12 months) for reducing alcohol consumption in disadvantaged men
- use the methods of recruitment, retention and text message delivery to test the effectiveness of interventions designed to tackle other adverse health behaviours in disadvantaged groups.

Trial registration

This trial is registered as ISRCTN07695192.

Funding

Funding for this study was provided by the Public Health Research programme of the National Institute for Health Research.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Crombie *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. 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.

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

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@nihr.ac.uk

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

Criteria for inclusion in the *Public Health Research* journal

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

Reviews in *Public Health Research* 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.

PHR programme

The Public Health Research (PHR) programme, part of the National Institute for Health Research (NIHR), evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health. The scope of the programme is multi-disciplinary and broad, covering a range of interventions that improve public health. The Public Health Research programme also complements the NIHR Health Technology Assessment programme which has a growing portfolio evaluating NHS public health interventions.

For more information about the PHR programme please visit the website: http://www.nets.nihr.ac.uk/programmes/phr

This report

The research reported in this issue of the journal was funded by the PHR programme as project number 11/3050/30. The contractual start date was in September 2016. The final report began editorial review in October 2016 and was accepted for publication in July 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report 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 PHR programme or the Department of Health and Social Care. 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 PHR programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Crombie *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. 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).

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 and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

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

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

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Director of the NIHR Dissemination Centre, University of Southampton, 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 Wellbeing Research, 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 Great Ormond Street 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 editors: www.journalslibrary.nihr.ac.uk/about/editors

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