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Texting to Reduce Alcohol Misuse (TRAM): main findings from a randomized controlled trial of a text message intervention to reduce binge drinking among disadvantaged men

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ABSTRACT

Aims To test the effectiveness of a theoretically based text-message intervention to reduce binge drinking among socially disadvantaged men. **Design** A multi-centre parallel group, pragmatic, individually randomized controlled trial. **Setting** Community-based study conducted in four regions of Scotland. **Participants** A total of 825 men aged 25–44 years recruited from socially disadvantaged areas who had two or more episodes of binge drinking (> 8 UK units on a single occasion) in the preceding 28 days: 411 men were randomized to the intervention and 414 to the control. **Intervention and comparator** A series of 112 interactive text messages was delivered by mobile phone during a 12-week period. The intervention was structured around the Health Action Process Approach, a comprehensive model which allows integration of a range of evidence-based behaviour change techniques. The control group received 89 texts on general health, with no mention of alcohol or use of behaviour change techniques. **Measurements** The primary outcome measure was the proportion of men consuming > 8 units on three or more occasions (in the previous 28 days) at 12 months post-intervention. **Findings** The proportion of men consuming > 8 units on three or more occasions (in the previous 28 days) was 41.5% in the intervention group and 47.8% in the control group. Formal analysis showed that there was no evidence that the intervention was effective [odds ratio (OR) = 0.79, 95% confidence interval (CI) = 0.57–1.08; absolute reduction 5.7%, 95% CI = −13.3 to 1.9]. The Bayes factor for this outcome was 1.3, confirming that the results were inconclusive. The retention was high and similar in intervention (84.9%) and control (86.5%) groups. Most men in the intervention group engaged with the text messages: almost all (92%) replied to text messages and 67% replied more than 10 times. **Conclusions** A theoretically based text-messaging intervention aimed at reducing binge drinking in disadvantaged men was not found to reduce prevalence of binge drinking at 12-month follow-up.

Keywords Binge drinking, community based, deprivation, men, narrative, text message intervention.

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INTRODUCTION

The risk of alcohol-related harm is highest among disadvantaged groups [1,2], making alcohol a major contributor to inequalities in health [1,3]. This may be explained partially by patterns of drinking; socially disadvantaged individuals may not drink more on average, but they are more likely to binge drink [4–6]. The group who binge

drink most frequently in the United Kingdom comprises young to middle-aged disadvantaged men [4,5]. There is a need for interventions which access and engage meaningfully with this hard-to-reach population.

Brief interventions have been developed to tackle alcohol-related problems. Systematic reviews have shown that they are effective [7,8], although some recent primary studies have not found them to be effective [9]. Further, most trials have been conducted in health-care settings, often with individuals who are seeking help, and none has been targeted at disadvantaged groups.

Text-message interventions have been found to be effective for health behaviours such as smoking cessation, but high-quality studies with adequate power are needed in other areas [10]. A recent systematic review reported that text-message interventions to reduce alcohol consumption is promising but preliminary, and again recommends further research [11]. The use of text messaging may increase the salience of an intervention [12], and almost all text messages are read within minutes of delivery [13]. It requires little effort from participants and can be accessed by them at any time or place. An additional benefit of text messaging is the potential for reaching large numbers of people, as mobile phone ownership is high [14].

Tackling excessive drinking by socially disadvantaged men is likely to be challenging, as the uptake of public health interventions among disadvantaged groups is low [15]. Behaviour change interventions are less effective with disadvantaged and low-income groups [16,17], and individual-level health promotion initiatives could widen inequalities in health [18–20]. Interventions should therefore be tailored to disadvantaged groups [21,22]. This study tested the effectiveness of a tailored, theoretically and empirically based alcohol intervention delivered by text message, to reduce binge drinking in disadvantaged men.

METHODS

Trial design

This four-centre parallel-group, pragmatic, individually randomized controlled trial was conducted in four regions of Scotland: Tayside, Glasgow, Forth Valley and Fife. The full trial protocol is available on the NIHR website (http://www.nets.nihr.ac.uk/projects/phr/11305030) and has been published elsewhere [23].

Participants

Participants were men aged 25–44 years who were recruited from areas of high deprivation, based on the Scottish Index of Multiple Deprivation (SIMD) [24]. This is an area-based index which allocates scores based on six domains: current income, employment status, housing tenure, health, educational attainment and access to communication. Men were eligible to take part if they had had two or more episodes of binge drinking ($>$ 8 UK units in a single occasion, corresponding to $>$ 64 g of alcohol) in the preceding 28 days. Exclusion criteria were: men currently attending an Alcohol Problem Service; and men not contactable by mobile phone during the intervention period.

Participants were recruited through primary care registers and by time–space sampling (TSS) [25], a community outreach method. Men were recruited from March to December 2014. Half the participants were recruited from the practice lists of 20 general practices. Staff from the Scottish Primary Care Research Network (SPCRN) identified potential participants, based on age and postcode, and their general practitioners (GPs) invited them to take part in the study. An opt-out strategy was used; researchers contacted individuals who did not opt out of the study by telephone approximately 2 weeks after the GP letter was sent. The remaining 50% of participants were recruited by TSS [25]. This involved sampling at different times of day from a variety of venues in disadvantaged areas, including: town centres, workplaces, community groups, football grounds, supermarkets, housing associations and main shopping streets. The researchers who recruited participants obtained verbal consent during a telephone interview and subsequent electronic consent by text message.

Randomization

Randomization used the secure remote web-based system provided by the Tayside Clinical Trials Unit. Randomization was stratified by participating centre and the recruitment method and restricted using block sizes of randomly varying lengths. The allocation ratio was 1 : 1, intervention to control. The researchers who conducted baseline and follow-up interviews were unaware of treatment group. Concealment of treatment groups was preserved until the analyses of the primary and secondary outcomes had been completed.

Intervention and control

All participants received a series of interactive text messages during a period of 12 weeks. The intervention group was sent 112 messages with up to four messages sent on a single day. These were developed systematically from formative research, public involvement and behaviour change theory. The basis of the behaviour change strategy was the Health Action Process Approach (HAPA) [26]. This model emphasizes the importance of motivational and volitional phases of the change process, and incorporates behavioural intentions, planning, action and

maintenance of the new behaviour. The HAPA model enabled the integration and logical sequencing of elements from a taxonomy of behaviour change techniques [27], components from a systematic review of the drinking intervention literature [7] and the six elements of the FRAMES acronym (Feedback, Responsibility, Advice, Menu Options, Empathy and Self-Efficacy) [28].

The text messages were tailored to the target group by casting them in the language and the drinking culture of disadvantaged young men. 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. To promote interactivity, 21 text messages asked a question designed to assess participants' engagement with key components of the behaviour change strategy. The texts were embedded in a narrative which follows the journey of a man as he moves from regular binge drinking to become a more moderate drinker. The character encounters difficulties and relapse in this journey, enabling him to model key behaviour change techniques (e.g. goal-setting, action planning and relapse recovery). A full description of the intervention is available elsewhere [29]. Only two men requested that their text messages be stopped. The control group received an attentional control comprising 89 text messages on general health. These messages did not mention alcohol and were not based on behaviour change theories.

Outcomes

Alcohol consumption was measured using the validated time-line follow-back (TLFB) [30] methodology, with modification for telephone use [31]. Because recent studies have emphasized the importance of measuring the strength and volume of drinks [32,33], the approach was adapted to obtain detailed information on the alcohol consumed on every drinking occasion during the previous 28 days. Participants were asked to provide details on the brand name, strength and volume of all drinks consumed during the previous 28 days, as well as the number of alcohol-free days. Thus, the number of UK units of alcohol consumed on every drinking occasion could be calculated.

The follow-up interviews were carried out by telephone interview at 3 and 12 months post-intervention, which was 6 and 15 months after recruitment to the study. The primary outcome was classed as a success if the individual had had fewer than three occasions of binge drinking (consuming > 8 UK units, corresponding to > 64 g of alcohol) during the previous 28 days. It was assessed at 12 months post-intervention. Five secondary outcomes were measured. Those on alcohol consumption were: the proportion of men binge drinking (> 8 units) on at least three occasions at 3 months post-intervention; the proportion of men with at least three occasions of heavy binge drinking (> 16 units) at 3 months and also at 12 months post-intervention, and total consumption of alcohol in the previous 28 days at 12 months post-intervention. The final secondary outcome was the proportion of hazardous or harmful drinkers at 12 months post-intervention, measured by the Alcohol Use Disorders Identification Test (AUDIT) [34]. All baseline and outcome data (at 3 and 12 months post-intervention) were collected by telephone interviews with research assistants blinded to treatment arm. At baseline, the only data collected were alcohol consumption, socio-demographic variables and a question on episodes of memory loss following drinking sessions.

Statistical analysis

The target sample size for the trial was 798 participants. Our prior feasibility study showed that 57% of disadvantaged men consumed > 8 units of alcohol on at least three occasions during the previous 28 days [35]. A systematic review reported that face-to-face alcohol brief interventions resulted in an 11% difference in binge drinking frequency [7]. This study was powered to detect a net difference of 11%, from 57 to 46%, in the proportion of men who consumed > 8 units of alcohol on at least three occasions during the previous 28 days at 12 months post-intervention (approximately 15 months post-randomization), with 80% power and 5% significance level. The estimate included an allowance for loss to follow-up of 20%.

Analysis was by intention-to-treat. The treatment effect for the primary outcome (the proportion consuming > 8 units on at least three occasions during the previous 28 days at 12 months post-intervention) was estimated using logistic regression. Three models were fitted: an unadjusted model (randomized group only); a model adjusted for baseline drinking (had participant consumed > 8 units on at least three occasions during the 28 days prior to the beginning of the study); and a full model adjusted for baseline drinking and other baseline covariates [method of recruitment (GP registers/TSS), recruitment centre, age group, living with a partner (yes/no), employed (yes/no), further education (yes/no), deprivation score (1–10) and one question from the Fast Alcohol Screening Test (FAST) [36]]. The fully adjusted model was the pre-specified primary analysis. There was no evidence for heterogeneity of treatment effect throughout sites ($P = 0.209$). The treatment effect on the primary outcome was the odds ratio (OR) (intervention: control) from the fully adjusted model, with its 95% confidence interval (CI).

The binary secondary outcomes (> 8 units on three or more occasions at 3 months post-intervention, > 16 units on three or more occasions at 3 months

and 12 months, > 16 units on three or more occasions and AUDIT score > 7 at 12 months post-intervention) were analysed as above, except that the adjustment for baseline drinking used the baseline analogue of each secondary outcome. The AUDIT questionnaire was not administered at baseline, so the adjusted models for the proportion with an AUDIT score > 7 at 12 months controlled for whether the participant had consumed > 8 units on at least three occasions during the 28 days prior to the beginning of the study.

For total alcohol consumption, a secondary outcome at 12 months post-intervention, a generalized linear model assuming a gamma distribution and log-link function [37] were used due to the skewness of the data. Again, three models were fitted as described above to this secondary outcome. The treatment effect was the mean difference in consumption between intervention and control.

Multiple imputation methods were used to assess the sensitivity of primary outcome results to missing data. Generalized linear models were used for multiple imputation, assuming that data were missing at random [38]. Multiple imputation included the explanatory variables used in the fully adjusted model above plus the primary and secondary outcome variables at baseline and at the 3- and 12-month follow-ups, as well as additional information collected at the 12-month follow-up interviews. This included demographic data at the 12-month follow-up, several questions on participant experiences in the study and items from the Service Use Questionnaire (courtesy of S. Parrott, University of York), the EQ-5D-5L [39] and the Office of National Statistics (ONS) Personal Well-being questionnaire [40].

The main analyses were carried out by a statistician (S.M.H.) who was independent of the trial team. The analysis followed the pre-specified Statistical Analysis Plan (available from the authors). The analysis was conducted using the Stata statistical software package (version 14.0; SPSS Inc., Austin, TX, USA), IBM SPSS Statistics version 22 (IBM Corp., Armonk, NY, USA, 2013) and SAS version 9.4 (SAS Institute Inc., Cary, NC, USA, 2013). The planned analysis yielded a non-significant result for the primary outcome. Thus, a Bayes factor [41] was calculated using the online calculator provided by Dienes [42]. A normal distribution was assumed for the difference in probabilities, with a prior effect size of 11% [standard error (SE) = 4.08%] for the reduction in the frequency of binge drinking. This was the value reported in the systematic review of brief alcohol interventions [7], and was the estimate that was used in the sample size calculation for the present study [23]. The calculation used the observed effect size obtained in the present study from the fully adjusted model, together with its SE.

RESULTS

Between March and December 2014, 3603 men were screened for eligibility to take part in the trial (Fig. 1). A total of 1485 men could not be contacted by telephone, 704 did not meet the inclusion criteria and another 589 men declined to take part. Thus, 825 men were randomized to the intervention (411 men) or control (414 men) arms of the trial.

The mean age of the participants was 34.6 years, 54.4% lived with a partner and 64% were in employment (Table 1). More than 60% of the participants had completed their education at high school (minimum leaving age of 16 years) and 77% lived in the most disadvantaged quintile according to the SIMD. The two treatment groups were similar on all demographic characteristics.

The two treatment arms were also similar on all the measures of baseline alcohol consumption (Table 2). More than 84% of the men reported having three or more occasions of binge drinking (> 8 units) in the previous 28 days (primary outcome measure) and almost half had three or more episodes of drinking > 16 units on a single occasion. Mean consumption was 134.0 (SD = 132.8) UK units of alcohol in the previous 28 days, well above the UK recommended healthy drinking levels. The mean number of alcohol-free days was high at 19.9 (SD = 5.9), such that almost all (92.5%) the alcohol was consumed during binge drinking occasions.

The first follow-up took place 3 months after the end of the intervention. A total of 737 of the 825 men randomized (89.3%) were interviewed (Fig. 1). Retention rates were almost identical for the two treatment arms: 89.1% (366 of 411) for the intervention group and 89.6% (371 of 414) for the control group.

At the final follow-up, 12 months post-intervention, 707 were followed-up (Fig. 1). Some men (n = 50) who were followed-up at 3 months were not contactable at 12 months, and other men (n = 20) who were not interviewed at 3 months were followed-up successfully at 12 months. Complete data were obtained for all men contacted at 12 months, except for three men on whom only data on alcohol consumption were collected. The retention rate at 12 months was 85.6%, only slightly less than at first follow-up. The retention rates were similar in the two treatment arms at 12 months post-intervention; 84.9% (intervention) and 86.5% (control).

Outcomes

At the first follow-up, there was a marked and similar fall in the two treatment arms of the proportion of men with three or more occasions of binge drinking (Table 3): from approximately 85% at baseline, the intervention group fell

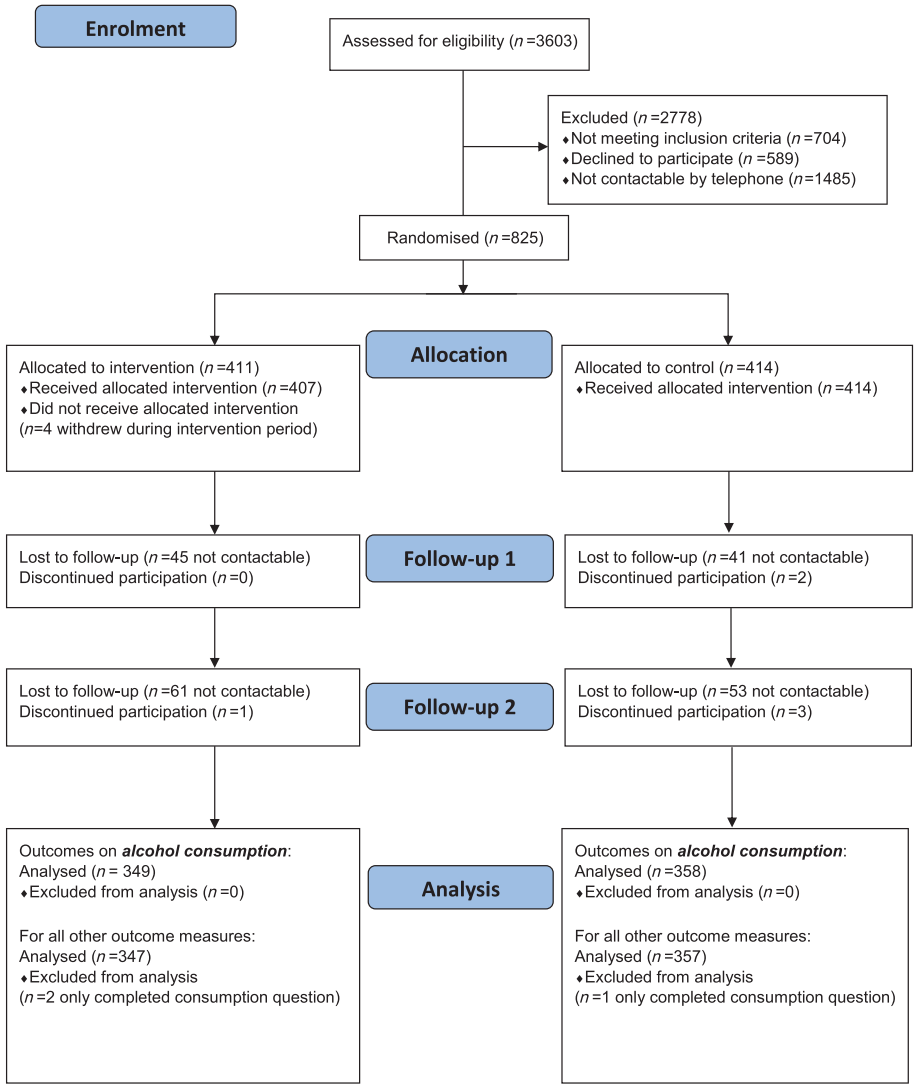

Figure 1 Participant flow though the study [Colour figure can be viewed at wileyonlinelibrary.com]

by 37.4% and the control group by 40.5%. The proportion of men with three or more occasions of heavy binge drinking (> 16 units) followed a similar pattern, with large falls in both groups (from approximately 47% at baseline to 21% on average at 3 months). The large falls in alcohol consumption seen at the 3-month post-intervention follow-up were largely sustained at the final follow-up (Table 3).

Three models were fitted to estimate the effect size of the intervention: no adjustment, adjustment for baseline binge drinking only and full adjustment for baseline covariates (Table 4). All produced similar estimates of treatment effect. The primary outcome measure showed no evidence for an effect of treatment. For the fully adjusted model, which was the one pre-specified in the Statistical Analysis Plan, the estimate was 0.79 (95% CI = 0.57–1.08, P = 0.14). This corresponds to a net absolute reduction of 5.7% in the proportion of men who binge drink on three or more occasions (95% CI = −13.3 to 1.9%). The confidence intervals indicate considerable uncertainty in the estimated treatment effect. Multiple imputation was conducted to take account of men lost to follow-up. The estimated treatment effect was very similar to that for the fully adjusted model, giving an OR of 0.77 (95% CI = 0.55–1.09, P = 0.143). None of the secondary outcome measures showed statistically significant effects, whether unadjusted, adjusted for baseline binge drinking only or fully adjusted. The five secondary outcomes showed inconsistent differences between intervention and control groups, with only one favouring the intervention.

As the analysis of the main outcome measure was not statistically significant, the Bayes factor was calculated. With an informative prior of 11% (SE = 4.08) for the reduction in the frequency of binge drinking (the value used in the original sample size calculation) the Bayes factor was 1.3. This was well above the threshold of 0.33 required to establish a null effect,

Table 1 Baseline demographic characteristics by treatment group.

Factor	*Intervention group n = 411 n (%)*	*Control group n = 414 n (%)*	*Total n = 825 (%)*
Age (years)			
25–34	221 (53.8)	215 (51.9)	436 (52.8)
35–44	190 (46.2)	199 (48.1)	389 (47.2)
Marital status[a]			
Married/lives with a partner	224 (54.6)	224 (54.1)	448 (54.4)
Single	186 (45.4)	190 (45.9)	376 (45.6)
Employment status			
Employed	276 (67.2)	252 (60.9)	528 (64.0)
Unemployed	135 (32.8)	162 (39.1)	297 (36.0)
Highest educational attainment			
High school	250 (60.8)	260 (62.8)	510 (61.8)
Vocational qualification/further training	132 (32.1)	112 (27.1)	244 (29.6)
University degree	29 (7.1)	42 (10.1)	71 (8.6)
Scottish Index of Multiple Deprivation decile			
1–2 (most deprived)	314 (76.4)	322 (77.8)	636 (77.1)
≥ 3	97 (23.6)	92 (22.2)	189 (22.9)

[a]Marital status not recorded for one man.

Table 2 Recent drinking history: comparison of intervention and control groups.

Drinking pattern	*Intervention group n = 411*	*Control group n = 414*	*Total n = 825*
Number (%) of men with three or more occasions of binge drinking (≥ 8 units) in previous 28 days	342 (83.2)	354 (85.5)	696 (84.4)
Number (%) of men with three or more occasions of heavy binge drinking[a] (> 16 units) in previous 28 days	191 (46.5)	201 (48.6)	392 (47.5)
Mean consumption in past 28 days (units, SD)	133.0 (132.7)	134.9 (133.0)	134.0 (132.8)
Proportion of total units that are consumed during binge occasions (> 8 units) (%)	92.4	92.6	92.5
Mean number of alcohol-free days (SD)	19.90 (5.9)	19.86 (5.8)	19.88 (5.9)

[a]Heavy binge drinking (> 16 units) is a subset of binge drinking (> 8 units). SD = standard deviation.

but also well below the threshold of 3.0 for moderate evidence in favour of the experimental hypothesis [41]. To explore this further the calculation was repeated with prior reductions between 10 and 6%, providing Bayes factors which increased progressively from 1.51 to 2.02. This shows that even with smaller values for the informative prior, the Bayes factor does not reach the threshold of 3.0 for moderate evidence in favour of the experimental hypothesis [41].

Acceptability of the study was high. Most men in the intervention group engaged with the text messages: almost all (92%) replied to text messages and 67% replied more than 10 times. At 12 months post-intervention almost all the men reported that they enjoyed taking part in the study (99.4%) and would recommend the study to others (96.4%). Most men (80.8%) discussed their participation in the study with other people.

DISCUSSION

This study, which evaluated a text-message intervention, is one of the largest trials of an alcohol brief intervention. It was conducted in Scotland with men recruited from socially disadvantaged areas, a group which is recognized to be hard to reach [43,44]. The participants demonstrated a pattern of binge drinking which places them at high risk of alcohol-related harm. The intervention did not have a statistically significant effect on the primary outcome (having three or more episodes of drinking more than 8 units in a single occasion in the preceding about 28 days). The Bayes factor confirmed that the results were inconclusive.

The estimated effect size corresponds to a net reduction of 5.7% in the proportion of men who binge drink on three or more occasions (95% CI = –13.3 to 1.9%). This is approximately half the 11% reduction in the frequency of

Table 3 Comparison of baseline and first follow-up alcohol consumption by treatment arm.

		Intervention group[c]	*Control group*[d]
Alcohol consumption in the previous 28 days			
% men with three or more occasions of binge drinking (> 8 units)	Baseline	83.2	85.5
Secondary outcome	3-month follow-up	44.8	44.7
Primary outcome	12-month follow-up	41.5	47.8
% men with three or more occasions of heavy binge drinking (> 16 units)[a]	Baseline	46.5	48.6
Secondary outcome	3-month follow-up	22.1	20.2
Secondary outcome	12-month follow-up	17.5	18.7
Mean consumption in past 28 days (units, SD)	Baseline	133.0 (132.7)	134.9 (133.0)
	3-month follow-up	77.6 (113.3)	78.7 (115.7)
Secondary outcome	12-month follow-up	77.2 (120.4)	79.4 (120.0)
% men AUDIT-positive			
Secondary outcome	12-month follow-up	72.6[b]	68.3 *n* = 357[b]

[a]Heavy binge drinking (> 16 units) is a subset of binge drinking (> 8 units); [b]three men did not give Alcohol Use Disorders Identification Test (AUDIT) data at 12-month follow-up, one in the intervention group and one from the control group; [c]baseline *n* = 411, 3-month follow-up *n* = 366, 12-month follow-up *n* = 349; [d]baseline *n* = 414, 3-month follow-up *n* = 371, 12-month follow-up *n* = 358. SD = standard deviation.

binge drinking reported in a systematic review [7]. The smaller effect observed in the present study could be due to chance or to a smaller actual effect size due to the difficulty of changing health behaviours in disadvantaged men: interventions commonly have much smaller effects in this demographic group [16]. The other possibility is that there was simply no effect. Research participation effects, in this case the collection of baseline data on alcohol consumption, could have biased the effect size to the null [45,46]. The small effect is unlikely to be due to poor fidelity of delivery, as we have shown elsewhere [47] that virtually all the text messages were received by the participants. Further, the participants' responses to these texts indicated high levels of engagement with key components of the behaviour change strategy.

The inconclusive finding is consistent with a recent systematic review of mobile phone interventions for alcohol misuse, which concluded that the evidence to date was promising yet preliminary [11]. An editorial by West [48] has argued for the use of the Bayes factor in addiction

Table 4 Effect sizes[a] for the primary and secondary outcomes.

	Unadjusted	*Adjusted for baseline drinking*	*Fully adjusted*	*P-value**
Primary outcome				
% > 8 units on three or more occasions at 12 months (*n* = 347, 358)[b]	0.78 (0.58 to 1.05)	0.79 (0.59 to 1.07)	0.79 (0.57 to 1.08)	0.140
Secondary outcomes				
% > 8 units three or more occasions at 3 months (*n* = 364, 371)[b]	1.00 (0.75 to 1.34)	1.04 (0.77 to 1.40)	1.05 (0.77 to 1.44)	0.751
% > 16 units on three or more occasions at 3 months (*n* = 364, 371)[b]	1.12 (0.79 to 1.60)	1.17 (0.81 to 1.70)	1.22 (0.83 to 1.81)	0.314
% > 16 units on three or more occasions at 12 months (*n* = 347, 358)[b]	0.92 (0.63 to 1.35)	0.93 (0.62 to 1.38)	0.97 (0.64 to 1.46)	0.871
% AUDIT-positive[c] (*n* = 345, 357)[b]	1.23 (0.89 to 1.70)	1.28 (0.92 to 1.78)	1.34 (0.95 to 1.89)	0.095
Total alcohol consumption at 12 months (*n* = 347, 358)[b]	−2.18 (−19.49 to 15.13)	4.66 (−10.10 to 19.42)	4.46 (−11.1 to 20.03)	0.573

[a]All effect sizes are expressed as odds ratios except for mean consumption, which is given as the mean difference in consumption between treatment groups. 95% confidence intervals are in parenthesis; [b]numbers for intervention and control group, respectively, for the fully adjusted model, by intention-to-treat; [c]as the Alcohol Use Disorders Identification Test (AUDIT) questionnaire was not administered at baseline, the % > 8 units on three or more occasions at baseline was used as the adjustment for baseline consumption. **P*-values are for the fully adjusted model.

science to help clarify whether or not non-significant results provide robust evidence for a null effect. This approach has helped to clarify the interpretation of three large trials of face-to-face alcohol brief interventions that failed to show significant benefits [9]. A recent re-analysis of these trials using Bayes factors concluded that there was moderate evidence for 'a lack of effect of brief intervention compared with simple clinical feedback and an alcohol information leaflet' [42].

The present study found that large falls had occurred in alcohol consumption in both the intervention and control groups at the interim follow-up 3 months after the intervention was delivered. These falls were sustained at the final follow-up. Large falls in consumption are seen commonly in control groups in trials of alcohol brief interventions [45,49]. The effect seen in the present study is at the upper end of the magnitude of falls identified in reviews of control group effects, and is thus unusually but not exceptionally large [45,49]. One explanation for this phenomenon is regression to the mean [50,51]. It occurs when individuals are selected for a study because they have a high value on a measure (such as alcohol consumption). As some individuals may have had an unusually high consumption at the baseline, it is likely they will have consumed less at follow-up. At the same time, people who had unusually low consumption at baseline would be excluded. Thus, the average consumption in those recruited will appear to fall. An empirical demonstration of this in a cohort study showed that the size of the fall in AUDIT score increased progressively as the threshold for entry was increased [52].

The strengths of this study were the large sample size and the high retention rate. A possible weakness of the study design was the use of an active or attentional control, comprising text messages of trivia on a variety of health topics. This was intended to increase retention in the study, but could also have influenced drinking behaviour by prompting the men to think about their health and their drinking. There is clearly a tension between minimizing the effect of the control package and maximizing retention. The issue is whether it is better to prevent differential loss to follow-up or to reduce research participation effects. The bias resulting from loss to follow-up would threaten the validity of the trial, making it the more serious concern.

CONCLUSIONS

This study provided no evidence that a text-message intervention reduced the frequency of binge drinking in disadvantaged men. It is possible that interventions with disadvantaged groups may have smaller effect sizes, making them harder to detect. This adds a further dimension to the alcohol paradox; disadvantaged individuals may suffer most from alcohol, but they may also find it most difficult to change their drinking behaviour. Further studies with larger sample sizes could improve the precision with which the effect size is estimated. In addition, more intensive text-message interventions delivered over a longer period may be required to increase the effectiveness of the intervention to reduce binge drinking in disadvantaged men. The success of the recruitment and retention strategies used in this trial suggests that such studies would be possible.

Trial registration

ISRCTN Registry: ISRCTN07695192. http://www.isrctn.com/ISRCTN07695192?q=crombie&filters=&sort=&offset=2&totalResults=3&page=1&pageSize=10&searchType=basic-search

Ethical approval

The study was approved by the East of Scotland Research Ethics Service (EoSRES) REC1, (REC reference 13/ES/0058). All participants gave informed consent.

Declaration of interests

None.

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