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Synopsis

Evaluating the effectiveness of the Drink Less smartphone app for reducing alcohol consumption compared with usual digital care: a comprehensive synopsis from a 6-month follow-up RCT

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Abstract

Background: Digital interventions can be effective for reducing alcohol consumption. However, most digital interventions that have been evaluated are websites and there is little evidence on the effectiveness of smartphone apps, especially in a United Kingdom context. We developed an evidence- and theory-informed app, Drink Less, to help increasing-and-higher-risk drinkers (Alcohol Use Disorders Identification Test score ≥ 8) reduce their alcohol consumption.

Objective: To evaluate the effectiveness of Drink Less for reducing alcohol consumption compared with usual digital care in the United Kingdom.

Design: Two-arm, double-blind, parallel-group, randomised controlled trial with 1 : 1 group allocation and an embedded process evaluation, with 6-month follow-up.

Setting: Remotely conducted among participants living in the United Kingdom, recruited from July 2020 to March 2022.

Participants: Five thousand six hundred and two increasing-and-higher-risk drinkers aged 18+ who had access to an iPhone operating system device and wanted to drink less alcohol.

Interventions: Participants were recommended to use the intervention (Drink Less) or recommended the comparator (National Health Service alcohol advice web page).

Drink Less is an app-based intervention to help increasing-and-higher-risk drinkers reduce their alcohol consumption. It consists of evidence-based modules (e.g. goal setting, self-monitoring) and was systematically and transparently developed and refined.

This synopsis should be referenced as follows:
Garnett C, Oldham M, Loebenberg G, Dinu L, Beard E, Angus C, *et al.* Evaluating the effectiveness of the Drink Less smartphone app for reducing alcohol consumption compared with usual digital care: a comprehensive synopsis from a 6-month follow-up RCT. *Public Health Res* 2025;**13**(5). https://doi.org/10.3310/LNNB8060

The National Health Service alcohol advice web page was considered usual digital care and provides tips on cutting down.

Main outcome measures: The primary outcome was self-reported weekly alcohol consumption at 6-month follow-up (derived from the extended Alcohol Use Disorders Identification Test – Consumption), adjusted for baseline alcohol consumption.

Results: The retention rate at 6-month follow-up was 80%. The data were not missing completely at random with differences detected in educational qualifications, occupation and income, indicating that multiple imputation was the most appropriate analytic approach. This found that Drink Less resulted in a 2.00 United Kingdom unit greater weekly reduction (95% confidence interval −3.76 to −0.24) at 6-month follow-up compared with the National Health Service alcohol advice web page. Compared with the National Health Service alcohol advice web page, Drink Less cost an additional £1.28 per user, when including the sunk costs (already incurred and cannot be recovered), but saved £0.04 per user when considering only the annual maintenance costs. Drink Less costs only an extra £0.64 per additional weekly unit of alcohol reduction, and may be cost saving if sufficient people use the app to cover the sunk costs. There was no statistically significant difference in quality-adjusted life-years between the two groups.

Limitations: This trial relied on retrospective self-reported alcohol consumption. Results from the pre-registered sensitivity analysis of multiple imputation were inconsistent with those from the pre-registered primary analysis (a conservative approach to missing data where non-responders were assumed to be drinking at baseline levels), which found a non-significant weekly reduction of 0.98 units (95% confidence interval −2.67 to 0.70) in the intervention compared with comparator group. Multiple imputation was recommended by the independent Data Monitoring Committee based on the pattern of missing data.

Conclusions: Drink Less appears effective for reducing alcohol consumption among increasing-and-higher-risk drinkers compared with the National Health Service alcohol advice web page in the United Kingdom, and may be cost saving if widely used in the population.

Future work: Drink Less is in a strong position to be promoted widely and provide inexpensive support to increasing-and-higher-risk drinkers in the United Kingdom. Future work should investigate different promotion strategies and ways of implementing the app within healthcare settings and adapting it for other countries.

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A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/LNNB8060.

Introduction

Rationale for research and background

Increasing and higher-risk drinking [scoring 8 or more on the Alcohol Use Disorders Identification Test (AUDIT)] is a major public health concern and contributes to health inequalities[1] with the most disadvantaged groups suffering the most alcohol-related harm.[2] Face-to-face brief interventions are effective in reducing alcohol reduction but are received by < 1 in 10 increasing and higher-risk drinkers in England.[3] The low rate of delivery is in part due to key barriers to intervention delivery, such as lack of time and low confidence about discussing alcohol with patients.[4,5] Digital interventions, such as smartphone apps, may also be effective for reducing alcohol consumption,[6] and overcome barriers to delivery of face-to-face interventions while having a broad reach and relatively low implementation costs.[7]

Apps are a promising way of delivering interventions because smartphones have become increasingly affordable to end users and are used by a large proportion of the UK population.[8] The tendency for smartphones to be carried much of the time and used repeatedly means that apps are with the user almost all of the time, which offers the potential to engage users in real time and in their everyday situations. However, most of the digital alcohol interventions that have been evaluated are web-based and there is little evidence on the effectiveness of apps.[6] Despite there being hundreds of alcohol-related apps available on app stores, the majority were developed without reference to scientific evidence or theory,[9] and none had been evaluated in a randomised controlled trial (RCT) among the general population of adults in the UK. This lack of evidence highlights the necessity for an evaluation of an evidence- and theory-informed alcohol reduction app, which, if effective, could be widely recommended and used by increasing and higher-risk drinkers in the UK.

The Drink Less app is one of the most popular alcohol reduction apps on the UK Apple app store. Drink Less aims to help increasing and higher-risk drinkers reduce their alcohol consumption. It is a stand-alone app that is freely available and capable of reaching a large proportion of the UK population at a low incremental cost. Its development was guided by the Medical Research Council's guidance on complex interventions[10] and the Multiphase Optimisation

Strategy.[11] The original development was informed by the capability, opportunity, motivation – behaviour model of behaviour[12] and multiple sources of evidence;[9,13,14] and is reported in full elsewhere.[15] The app was then refined to improve the effectiveness and usability of the app based on findings from a factorial trial with short-term outcomes,[16] a content analysis of user feedback and a meta-analysis of behaviour change techniques in digital alcohol interventions.[17]

The next step in the Multiphase Optimisation Strategy was to conduct a RCT to evaluate the long-term effectiveness and cost-effectiveness of the digital recommendation of the refined Drink Less app, compared with the NHS alcohol advice web page (usual digital care), in reducing alcohol consumption among increasing and higher-risk drinkers. This research was the first RCT of an alcohol reduction app for the general population in the UK and was designed to inform whether it is worth investing resources into promoting and disseminating the app on a larger scale.

Objectives

The objective of the iPhone operating system (iOS) Drink Less, evaluating the Effectiveness of an Alcohol Smartphone app (iDEAS) trial was to evaluate the effectiveness and cost-effectiveness of recommending use of the Drink Less app, compared with recommending the use of usual digital care in a RCT.

This trial addressed the following research questions:

1. At a 6-month follow-up, does the digital recommendation to use *Drink Less* compared with the NHS alcohol advice web page to increasing and higher-risk drinkers:
    a. Reduce weekly alcohol consumption (in UK standard units)?
    b. Reduce heavy episodic alcohol consumption?
    c. Reduce full adapted AUDIT score?
    d. Reduce alcohol-related problems and injury, and use of healthcare services?
    e. Improve health-related quality of life?
2. What is the extent of user engagement with *Drink Less* and does user engagement moderate these outcomes?
3. Through what psychological measures does engagement with *Drink Less* change drinking behaviour?
4. What are participants' views on the acceptability of the intervention?
5. What is the cost–utility and potential impact on health inequalities of *Drink Less* compared with the NHS alcohol advice web page in terms of reduction in alcohol consumption and health-related quality of life using a short time horizon?
6. What is the longer-term cost-effectiveness and potential impact on health inequalities of Drink Less compared with the NHS alcohol advice web page, if rolled out on a national level through active promotion to the public, over a 20-year period?

Methods for data collection and analysis

Full details of the proposed trial and analysis plan are published as a protocol (RA1).[18]

The trial was a two-arm, double-blind RCT comparing the effectiveness of the Drink Less app (intervention) with the NHS alcohol advice web page (usual digital care or comparator group). Increasing and higher-risk drinkers (scoring 8 or more on the AUDIT)[19] in the UK were recruited online between July 2020 and March 2022 and were followed up after 1, 3 and 6 months with substantial financial incentives (up to £36) for completing all three follow-up assessments. A score of 8 on the AUDIT can be achieved in a number of different ways. As an example, someone reporting no signs of current harms or dependence could receive a score of 8 if they reported drinking two to three times per week, consuming 5–6 UK units on a typical drinking day, and also weekly consumption of 6 or more UK units.

Receiving the financial incentives was based on completing the follow-up assessments and was not contingent on downloading or using either of the intervention or comparator. Participants were recruited via a multipronged strategy including: advertisement on the NHS website; social media, radio advertising, and local advertising through healthcare providers.

The pre-registered primary outcome was self-reported weekly alcohol consumption at 6 months (derived from the extended AUDIT – Consumption) adjusting for baseline consumption. Secondary outcomes included heavy episodic alcohol use, alcohol-related problems and alcohol-related injury, use of healthcare services and health-related quality of life.

There was an embedded process evaluation involving both: (1) quantitative analysis of measures of psychological characteristics and engagement with the intervention, and (2) qualitative framework and thematic analysis of interview transcripts among a subsample of participants (n = 26) relating to the acceptability of the intervention.

The health economic evaluation took a two-stage approach to analyse the cost–utility of Drink Less from the NHS perspective. The first stage was an analysis of the cost-effectiveness of the app in the trial population over the duration of the trial itself (including follow-up). Costs included intervention costs in both groups and the cost of NHS resource use. Effects were measured in terms of (1) reduction in alcohol consumption and (2) health-related quality of life. The second stage used the established and widely used Sheffield Alcohol Policy Model (SAPM)[20,21] to assess the longer-term cost-effectiveness of the intervention, if rolled out on a national level over a 20-year time horizon through two different scenarios: (1) mass media campaign actively promoting the intervention to the public, and (2) embedding the intervention into general practitioner (GP) practices (i.e. app prescribing).

Results summary

The research articles being synthesised in the synopsis are detailed in *Table 1* and the research pathway is shown in *Figure 1*.

Methodology paper of recruitment and retention strategies (RA2)

This study used a number of different recruitment and retention strategies in a large remotely conducted RCT, which results in some unique challenges around recruitment and retention.

This study aimed to:

1. Compare different remote recruitment methods in terms of participant costs, rates of retention, data quality and sociodemographic diversity.
2. Compare the proportion of returned responses using different strategies for follow-up at 1-, 3- and 6-month follow-up, and compare the time and costs associated with these follow-ups.
3. Describe broader methodological issues relating to recruitment, retention and data quality, and evaluate how successful different strategies were in terms of mitigating those issues.

The most common recruitment methods were social media adverts (44%), the NHS website (35%), radio or newspaper adverts (13%) with the other recruitment methods accounting for 8% of the total sample. The cost per recruiting participants from different methods varied from £0 to £11.01 per participant, and costs were greater when recruiting men, ethnic minority groups and those from more disadvantaged backgrounds. Targeted recruitment approaches with social media and radio adverts were helpful in recruiting men but less helpful with regard to ethnic minority groups and people from more disadvantaged backgrounds. All of the recruitment methods under-represented people from more disadvantaged backgrounds with the NHS website, word of mouth and Google adverts, all recruiting only about one-third of participants from a more disadvantaged background. Although both Google adverts and word of mouth were poor in terms of the overall proportion of participants recruited (3% each), they did recruit a better proportion of participants from a more disadvantaged background, suggesting that larger investment in these methods could be a good strategy for future trial advertising.

The retention rate at 6-month follow-up was 80% and of those who responded, 92% responded after receiving one of up to three e-mail reminders with substantial financial incentives for responding promptly, an additional 2% responded after receiving up to two phone calls, an additional 3% responded after receiving a postal survey and an additional 2% responded after receiving a postcard (with only the primary outcome measure included). The e-mail reminders required much less human resource than the phone calls, postal surveys and postcards.

Remotely conducted trials can benefit from having a range of different recruitment methods and costing appropriately for targeted approaches to advertising. E-mail reminders with substantial financial incentives can achieve excellent retention rates. Retention rates can be increased further by using the sequential options of phone calls, postal surveys and postcard, though these sequential options are comparatively resource-intensive. It is also important to continue monitoring, identifying and reacting to new methodological challenges throughout the trial period. This is to improve both the individual study at the time and future research by sharing this experiential learning.

Data management of bots and manual participant deception (RA3)

The main trial used remote methods for recruitment which meant we could recruit large numbers of participants relatively conveniently and cheaply compared with in-person methods. Remote methods also have the advantage of avoiding issues surrounding allocation concealment or bias due to lack of blinding. However, as this was done remotely, the participant screening was based on self-report with little verification. There was up to £36 available in financial compensation for completing three follow-up surveys over 6 months so participants may have engaged in deception to earn money.

In this report, we discussed the issues surrounding participant deception associated with trials conducted

TABLE 1 Research papers being synthesised

Research article	Component title	Summary of component	Details of publication
1	Protocol and study plan	This protocol outlined the background for the trial, the methods and the analysis plan.	Garnett C, Oldham M, Angus C, Beard E, Burton R, Field M, *et al*. Evaluating the effectiveness of the smartphone app, drink Less, compared with the NHS alcohol advice webpage, for the reduction of alcohol consumption among hazardous and harmful adult drinkers in the UK at 6-month follow-up: protocol for a randomised controlled trial. *Addiction* 2020;116:412–25. https://doi.org/10.1111/add.15287
2	Methodology paper of recruitment and retention strategies	We presented methodological insights from the trial in terms of recruitment and retention strategies. We highlighted how different sources of remote recruitment compare in terms of cost-effectiveness, retention rates, data quality and demographic diversity. We also outlined the cost-effectiveness of different follow-up methods and outlined broader challenges and recommendations around data quality.	Oldham M, Dinu L, Loebenberg G, Field M, Hickman M, Michie S, *et al*. Methodological insights on recruitment and retention from a remote randomised controlled trial examining the effectiveness of an alcohol reduction app: a descriptive analysis. *JMIR Form Res* 2023;8:e51839. https://doi.org/10.2196/51839
3	Data management with regard to participant deception	The aim of this paper was to use this RCT as a case study of a remotely conducted trial to highlight and discuss (1) the issues with participant deception affecting remote research trials with financial compensation, and (2) the importance of rigorous data management to detect and address these issues. We outlined the nature of the issue along with strategies to combat these issues and ensure data quality. Based on our experiences, we made recommendations for other researchers for limiting bots and manual participant deception.	Loebenberg G, Oldham M, Brown J, Dinu L, Michie S, Field M, *et al*. Bot or not? Detecting and managing participant deception when conducting digital research remotely: case study of a randomized controlled trial. *J Med Internet Res* 2023;25:e46523. https://doi.org/10.2196/46523
4	Main trial findings	The aim of this paper was to report the main trial findings as outlined in the protocol (component 1). We report all primary and secondary analyses as well as all planned sensitivity analyses. This paper establishes the effectiveness of the Drink Less app at reducing alcohol consumption among increasing and higher-risk adult drinkers among the general population in the UK. This study informs the decision on whether it is worth investing resources in large-scale implementation.	Oldham M, Beard E, Loebenberg G, Dinu L, Angus C, Burton R, *et al*. Effectiveness of a smartphone app (drink less) versus usual digital care for reducing alcohol consumption among increasing-and-higher-risk adult drinkers in the UK: a two-arm, parallel-group, double-blind, randomised controlled trial. *EClinicalMedicine* 2024;70:102534. https://doi.org/10.1016/j.eclinm.2024.102534
5	Process evaluation – acceptability	This paper reported the findings from the qualitative interviews comparing the acceptability of the two interventions: Drink Less app and NHS website, as part of the embedded mixed-methods process evaluation in the RCT of the Drink Less app. These qualitative interviews were semi-structured and conducted with a subsample of participants. We examined the retrospective acceptability of Drink Less, relative to the NHS website, to increasing and higher-risk drinkers in the UK after their participation in the RCT. These findings on the intervention's acceptability are used in the interpretation of the quantitative trial findings.	Oldham M, Dina LM, Loebenberg G, Perski O, Brown J, Angus C, *et al*. Evaluating the acceptability of the drink less app and the National Health Service Alcohol Advice web page: qualitative interview process evaluation. *J Med Internet Res* 2024;26:e42319. https://doi.org/10.2196/42319

continued

This synopsis should be referenced as follows: Garnett C, Oldham M, Loebenberg G, Dinu L, Beard E, Angus C, *et al*. Evaluating the effectiveness of the Drink Less smartphone app for reducing alcohol consumption compared with usual digital care: a comprehensive synopsis from a 6-month follow-up RCT. *Public Health Res* 2025;**13**(5). https://doi.org/10.3310/LNNB8060

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TABLE 1 Research papers being synthesised (*continued*)

Research article	Component title	Summary of component	Details of publication
6	Process evaluation – engagement and mechanisms of action	This paper focused on the mechanisms of action, i.e. the psychological constructs and engagement with the intervention as part of the embedded mixed-methods process evaluation in the RCT of the Drink Less app. This paper assisted with the interpretation of the main findings and explored why the intervention was effective and how to make it even more effective, informing potential improvements to be made to the app.	Garnett C, Dinu LM, Oldham M, Perski O, Loebenberg G, Beard E, *et al*. Do engagement and behavioural mechanisms underpin the effectiveness of the drink less app? *NPJ Digit Med* 2024;7:174. https://doi.org/10.1038/s41746-024-01169-7
7	Health economic evaluation – short- and long-term modelling	This paper reported a health economic evaluation examining the cost-effectiveness of the Drink Less app and the long- and short-term implications for health. We analysed cost-effectiveness using a short-term time horizon (the within-trial period and follow-up). The effectiveness of the intervention was measured in terms of changes in alcohol consumption. The cost–utility of the intervention was calculated as the mean cost difference between the intervention and comparator group, divided by the difference in effects to give the ICER. We used the established and widely used SAPM to estimate longer-term cost-effectiveness of the intervention, if rolled out on a national level, over a 20-year horizon without affecting the timeliness or feasibility of the trial.	Angus C, Oldham M, Burton R, Dina LM, Field M, Hickman M, *et al*. Modeling the potential health, health economic, and health inequality impact of a large-scale rollout of the drink less app in England. *Value in Health* 2025;28:215–23. https://doi.org/10.1016/j.jval.2024.11.007

ICER, incremental cost-effectiveness ratio.

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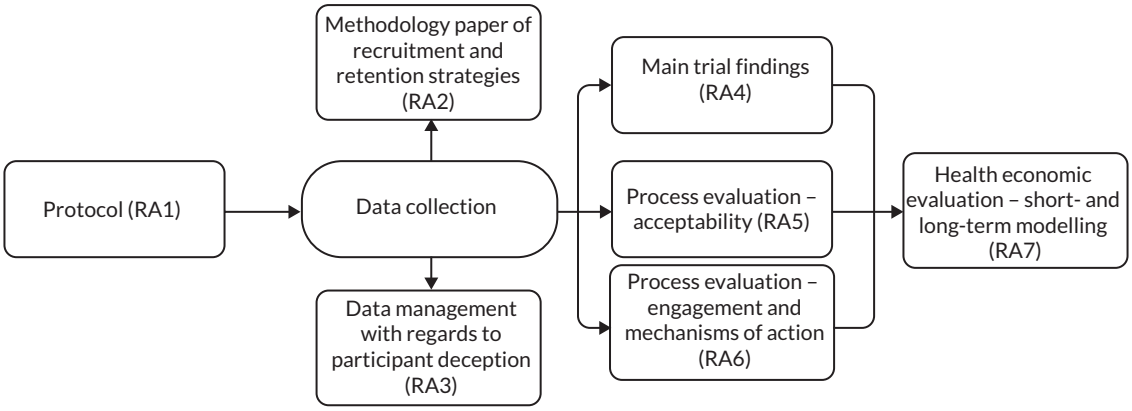

FIGURE 1 Research pathway.

remotely with financial compensation, and the importance of rigorous data management to mitigate these issues.

Recruitment began in July 2020, and address checking (e.g. verifying postcodes matched the first line of their address) and telephone verification (e.g. checking the number provided was not false or that the participant was known at that number) during data screening detected two types of participant deception:

1. Bots – automated responses typically generated in clusters.
2. Manual – participants providing false information.

About three-quarters of the participants enrolled in the first 2 months of recruitment were identified as bots (*n* = 863/1142). In response to this, we added a Completely Automated Public Turing test to tell Computers and Humans Apart (CAPTCHA) and no more bots were subsequently detected.

Manual deception occurred throughout the trial; 5% of all participants (*n* = 298/5956, excluding bots) who enrolled in the study were identified as engaging in manual deception. This percentage fluctuated during recruitment, peaking in November 2020 (*n* = 110) and then decreasing to a negligible level towards the end of recruitment in February 2022. This decrease occurred after adding further screening questions, removing the prominence and amount of financial compensation from adverts on social media, and the requirement to provide a mobile phone number to verify their identity.

Having rigorous plans in place for data management is necessary to detect participant deception occurring in trials conducted remotely. These issues can be mitigated by having a CAPTCHA in a screening survey, using attention checks, a requirement to provide a mobile number for identity checks, and not prominently advertising the financial compensation available on adverts on social media.

Main trial findings (RA4)

The primary outcome measure was assessed at the 6-month follow-up survey. There was a retention rate of 80% (*n* = 4458/5602) and no significant difference was detected between groups (79% in the intervention group and 80% in the comparator group).

Significant differences in terms of educational qualifications, occupation and income were detected between those who were and who were not successfully followed up. There were higher proportions of those from more disadvantaged backgrounds (i.e. lower income, lower social grade and pre-16 educational qualifications) among those who were not successfully followed up compared with those who were successfully followed up. This indicated that the data were not missing completely at random and, given this pattern of missing data, multiple imputation for the missing 20% of primary outcome data was the most appropriate approach.[22]

The pre-registered primary analysis used a conservative intention-to-treat approach which assumed that the 20% of non-responders were drinking at baseline levels of alcohol consumption. This analysis found a weak reduction of 0.98 units [95% confidence interval (CI) −2.67 to 0.70] in weekly alcohol consumption among the intervention group (Drink Less) compared with the comparator group (NHS alcohol advice web page). However, these data were insensitive to detect the hypothesised effect.

When the missing primary outcome data were modelled using multiple imputation, which was a pre-registered sensitivity analysis and recommended as most appropriate by the data monitoring committee and previous research,[22]

there was a significant 2.00-unit (16 g of ethanol) reduction in weekly alcohol consumption among the intervention group (Drink Less, mean = 33.04 units) compared with the comparator group (NHS alcohol advice web page, mean = 35.04 units) at 6-month follow-up (adjusted mean difference −2.00, 95% CI −3.76 to −0.24). Drink Less was also equally effective for increasing and higher-risk drinkers across all levels of baseline alcohol consumption. All the planned analyses – including the multiple imputation analyses – were conducted together by the trial statistician and subsequently presented to the independent data monitoring committee, who recommended greater focus be given to the multiple imputation analysis after reviewing the pattern of missingness.

Using multiple imputation for the secondary outcomes, a reduction in weekly alcohol consumption of approximately 2 units was found between groups at both the 1-month (adjusted mean difference −1.95, 95% CI −3.85 to −0.06) and 3-month (adjusted mean difference −1.78, 95% CI −3.58 to −0.01) follow-up surveys, although no other differences on the other secondary outcomes (i.e. alcohol-related problems and injury, use of healthcare services, health-related quality of life) were detected.

The trial demonstrated that the Drink Less app might be effective in helping increasing and higher-risk drinkers to reduce their weekly alcohol consumption compared with usual digital care. This pattern of an additional 2-unit reduction in weekly alcohol consumption among the Drink Less group compared with usual digital care was seen at all time points (1, 3 and 6 months). The 2-unit reduction was what the trial was powered to detect and it is important given the dose–response relationship between how much an individual drinks and their likelihood of experiencing harm.[23] This effect size is also comparable to that obtained from other digital alcohol interventions.[6]

Process evaluation of intervention acceptability (RA5)

A subsample of purposively sampled 26 increasing and higher-risk drinkers took part in semistructured interviews on the acceptability of (1) the smartphone app, Drink Less (intervention), and (2) the NHS alcohol advice web page (usual digital care and comparator). The interview questions were mapped on to the seven facets of acceptability according to the Theoretical Framework of Acceptability;[24] affective attitudes, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy. A measure of perceived personal relevance was also included. Framework and thematic analysis of data was undertaken.

The Drink Less app was perceived as being ethical, easy, user-friendly and effective for the period the app was used. Participants reported particularly liking the tracking and feedback sections of the app, which they reported as particularly personally relevant and resulted in a positive affect when achieving their goals. They reported no opportunity costs.

They discussed that the app functioned as a 'supermarket' or toolbox whereby they could choose and use the components of the app that worked best for them. Participants reported different strategies and goals and most thought that the app was effective in reducing their alcohol consumption, particularly in the shorter term. This toolbox function extended to a depth of use: participants also reported that use was influenced by the level of support they felt they needed that day, which could include spending more time on the app making plans and behavioural substitutions when their cravings were higher. Participants reported being confident in using the app, and that it was intuitive and accessible. However, some thought that there was a learning curve at the start of using the app and some participants reported specific difficulties in using the app such as logging cocktails (which are not included as default options in the drinking diary) or customising weekly goals (e.g. number of alcohol-free days, units). Some participants reported negative affect when logging heavier drinking days or failing to achieve their goals, which led to disengagement in the longer term. Another factor reported as leading to disengagement was boredom. Some participants reported that although the app was not burdensome to use, it became something of a chore.

Participants reported that the NHS alcohol advice web page was very quick, easy and intuitive to use and accessible to anyone with internet access. Participants reported that the web page could be a useful tool for other people, but they judged that they already knew the information it contained and said that the information was less personally relevant to them, and the web page was described as being basic and generic. Some found that the web page had provided the starting point for them in reducing their alcohol consumption by signposting them to other tools or resources, whereas others thought it had not had an impact on their alcohol consumption. There were concerns raised by participants about contacting a healthcare professional as some thought this would be ineffective and were not confident that the services would be available. Participants suggested that the web page could benefit from having more personalised features, such as signposting for different levels of consumption.

Process evaluation of engagement with intervention and mechanisms of action (RA6)

We used data from the RCT and focused on participants' psychological characteristics and engagement with the intervention as part of the embedded mixed-methods process evaluation. The psychological measures assessed as potential mechanisms of action were urges to drink, motivation to drink less, self-regulatory behaviours and self-monitoring behaviours, measured at baseline and at the 6-month follow-up. Engagement was measured using subjective (self-reported adherence to the recommended digital tool at 1- and 6-month follow-ups) and objective [number of app downloads, mean number of sessions (frequency), time spent in the app in minutes (amount), number of available screens viewed (depth), number of days the app was used (duration)] measures.

Self-reported adherence (subjective engagement; using multiple imputation for missing data) among the intervention group to the Drink Less app at either 1- or 6-month follow-up was 78.0% (95% CI 77.6 to 78.4), which was significantly higher than self-reported adherence to the NHS alcohol advice web page among the comparator group (71.5%, 95% CI 71.0 to 71.9; $t = 19.46$; $p = 0.028$).

Among participants in the intervention group, 1858 participants (66.6%, 95% CI 64.9 to 68.4%) followed the recommendation to download the Drink Less app and enter their e-mail address.

Evaluating the objective engagement with Drink Less, we found that among all participants in the intervention group (including those who did and did not download Drink Less), there was a mean 34 sessions in the app [standard deviation (SD) = 65.06] and a median of 5 [interquartile range (IQR) = 0–32]. Moreover, they spent a mean of 54 minutes (SD = 115.25) in the app, and a median of 10 (IQR = 0–54), for a mean number of 25 days (SD = 44.44), and a median of 4 (IQR = 0–26). Finally, participants in the intervention group viewed, on average, 17.4 unique screens (SD = 14.94), and a median of 18 (IQR = 0–30).

We investigated the psychological measures and self-reported adherence as potential mechanisms of action (using a complete-case analysis). We found that there was a mediation effect of self-reported adherence from treatment status (i.e. intervention vs. comparator group) on alcohol reduction at 6-month follow-up [average causal mediation effects (ACME) −0.559 (95% CI −0.85 to −0.30); $p < 0.001$], although no significant direct effect of treatment status on alcohol reduction was detected when not considering self-reported adherence as a mediator (average direct effects −1.155, 95% CI −2.93 to 0.59; $p = 0.202$). This indicates that the effect of Drink Less on alcohol reduction is mediated through self-reported adherence to the digital tool and that the effect is not detected if participants do not self-report adherence to the tool.

Similarly, self-monitoring behaviour was also found to mediate the effect of the intervention on alcohol reduction: ACME −0.880 (95% CI −1.244 to −0.55); $p < 0.001$. No significant mediating effects of the other psychological measures investigated (urge to drink, self-regulatory behaviour) on alcohol reduction were detected. No significant interaction was detected between motivation to drink less and intervention on alcohol reduction ($F_{1,5011.39} = 0.285$, $p = 0.594$), indicating that there was insufficient evidence to support a moderating effect of motivation to drink less at baseline on alcohol reduction in increasing and higher-risk drinkers at 6-month follow-up.

We only had objective engagement data for the intervention, Drink Less, and not for the comparator, the NHS alcohol advice web page. Therefore, we could not use intervention group as the treatment status in the mediation analysis of engagement measures. So when investigating engagement with the Drink Less app among participants in the intervention group, we used self-reported adherence as the treatment status and we found no causally mediating effects of number of sessions (ACME 0.062, 95% CI −1.26 to 1.47; $p = 0.962$), time on app (ACME 0.480, 95% CI −0.84 to 1.79; $p = 0.520$), number of days used (ACME −0.101, 95% CI −1.36 to 1.23; $p = 0.880$), or unique screens viewed (ACME 0.491, 95% CI −0.88 to 1.86; $p = 0.450$) on alcohol reduction at 6-month follow-up were detected. However, there were significant direct effects of the treatment status (self-reported adherence) on alcohol reduction among participants in the intervention group. This indicates that among participants in the intervention group, there was a direct effect of self-reported adherence on alcohol reduction at 6-month follow-up and there was no mediation effect detected from the measures of engagement.

Taken together, these findings show that most participants (67%) randomised to the Drink Less app engaged with the app within 6 months of the recommendation to do so. The effect of the recommendation to use the Drink Less app on alcohol reduction at 6-month follow-up is mediated by (self-reported) adherence.

In terms of potential mechanisms of actions by which the Drink Less app reduces alcohol consumption, self-monitoring behaviour was shown to mediate the effect

of the intervention on alcohol reduction at 6-month follow-up. This suggests that the app may work through increasing users' self-monitoring behaviour (i.e. how often they kept track of how many units of alcohol they drank each week). Consistent with this finding, the interface of the app is focused on the self-monitoring and feedback module, and is the module that users engage with the most.

Health economic evaluation (RA7)

We undertook a cost-effectiveness analysis to compare both the costs and outcomes associated with the Drink Less versus NHS alcohol advice web page. This analysis was preferred to a cost–benefit analysis because, in general, it is very difficult and not appropriate to measure the benefits of a healthcare intervention in monetary terms. Indeed, the outcome measure used here was the reduction in alcohol consumption and the quality-adjusted life-years (QALYs), which combine length of life and quality of life, and is consistent with the National Institute for Health and Care Excellence (NICE) recommendations.[25] Cost-effectiveness was expressed as incremental cost per unit of alcohol reduction. The base-case analysis took a UK NHS and Personal Social Services perspective.[25] Source use data were included from the trial and UK unit costs were applied.[26] Costs were calculated in 2023 Great British pounds and inflated where appropriate.[27] The time horizon was 6 months, reflecting the main outcomes' follow-up in the trial, and was the longest time period over which data were collected for all participants. Given the time horizon, discounting was not applied to costs or outcomes.

The effect of group allocation on the primary outcome, weekly alcohol consumption, was examined above. Generic health-related quality of life was measured using EuroQol-5 Dimensions, five-level version (EQ-5D-5L).[28,29] Each EQ-5D-5L health state was converted into a single summary index (utility value) applying a formula that attaches weights to each of the levels in each dimension based on valuations by general population samples.[30] Unfortunately, the EQ-5D-5L was administered to participants only at 6-month follow-up and not at baseline; therefore, we had to use a utility value at baseline that was not patient level based, but using available evidence.[31] We constructed a utility profile for every participant assuming a straight-line relation between their utility values at each measurement point (with the estimated utility value at baseline for both groups based on available evidence and the patient-level value at 6-month follow-up). If the person died, the utility was recorded as zero at the time of death. QALYs for every participant from baseline to 6 months were calculated as the area under the utility profile.

The Drink Less application cost includes £114,585 of sunk costs (investment) and £3331 of annual maintenance costs. The NHS web page cost includes £1172 of sunk costs and £14,335 of annual web page maintenance. The NHS web page development cost was based on an NHS quote (the page building and design was already set up) of 19 hours work salary of a senior content designer. The annual costs included total maintenance costs estimated from publicly available documents.[32,33] This was initially calculated as £141,133 per page (assuming equal costs per page), but, based on feedback from the NHS and given the simplicity of the comparator page, we assumed running costs of 10% of the entire costs to maintain one web page and the annual cost to review the content of the web page. Taking into account the total number of unique users who completed the AUDIT in 1 year, 86,182 (as of June 2023), the unit cost of the Drink Less was £0.04 per user excluding the sunk costs, or £1.37 including the sunk costs. Taking into account the total number of unique users who used the web page in 1 year, the unit cost of the NHS web page is £0.08 per user excluding the sunk costs, or £0.09 including the sunk costs.

Patients using the NHS website recorded on average more accident and emergency admissions, GP consultations and social worker visits, but fewer hospital admissions. Using multiple imputation of missing values, there is a mean difference of 0.22 (95% CI −0.13 to 0.56) units of NHS services for the Drink Less app, but the result is not statistically significant.

As mentioned above, the result of the multiple imputation shows that the Drink Less app is effective in reducing weekly alcohol intake of 2 units.

The analysis of the EQ-5D-5L questionnaires shows that the utility at 6 months is very similar in both groups: 0.7925 (SD = 0.242) and 0.793 (SD = 0.197) in the comparator and intervention group, respectively. Using a baseline utility of 0.8414 (SD = 0.1887) in both groups, the QALYs at 6 months are 0.4084 in the comparator group and 0.4086 in the intervention group, with a difference of 0.00025 QALYs for those in the Drink Less group. Using the multiple imputation, the results in the two groups are still similar and not statistically significant: the utility is 0.79142 and 0.79151 in the comparator and intervention group with a mean difference of 0.00087 (CI −0.1123 to 0.0110) favouring those in the Drink Less group. Using multiple imputation there was no difference in QALYs between intervention and comparator groups (QALYs at 6 months using multiple imputation are 0.408205 and 0.408228 in the comparator and intervention groups respectively, with a difference of 0.0000225). The sensitivity analysis

shows that there is no difference when controlling for age and gender.

The cost-effectiveness of the intervention is measured in terms of ICER, the ratio between the difference in costs of the Drink Less and NHS app and the difference in effects. The ICER represents the extra cost (or saving) of Drink Less to achieve a reduction of 1 unit of weekly alcohol consumption. The ICER was not calculated using the QALYs because the results are not statistically significant. We report the results including the sunk costs and only considering the annual costs of the two interventions. We also report the ICER using the cost of the interventions and the NHS service use costs, but the results are not statistically significant. The results show that the Drink Less intervention is cheaper compared to the NHS website, when considering only the annual costs, but it costs £1.28 extra per patient when including sunk costs. Overall, the patients in the intervention group consume less NHS resources compared with the comparator group. The Drink Less app is effective in reducing the weekly unit of alcohol consumption by 2 units. The difference in QALYs is not statistically significant.

The ICER shows that the Drink Less intervention is effective, it costs £0.64 per extra unit of alcohol reduction and it can be cost saving when the amount of patients covered allows to spread the sunk costs of the application.

We undertook a long-term, model-based cost-effectiveness analysis to appraise the potential costs and health benefits of a wider roll-out of the Drink Less app under two alternative roll-out scenarios: (1) a mass media campaign designed to increase uptake of the app among increasing and higher-risk drinkers and (2) embedding of the app in discussions that GPs have with their patients about alcohol. This analysis was performed using the SAPM version 4.1. SAPM is a hybrid behavioural–epidemiological simulation model which has previously been used to appraise the potential impact of a wide range of alcohol policies, including assessing the cost-effectiveness of a range of Screening and Brief Intervention programmes.[20,21,34] SAPM estimates changes in alcohol consumption arising from an intervention, in this case, the roll-out of the Drink Less app, and estimates the subsequent changes in hospital admissions, NHS costs and mortality arising from these changes in drinking.

The mass media scenario was estimated to cost £889,549.96 for a one-off campaign, based on the budget of the Office for Health Improvement and Disparities' Stoptober smoking cessation campaign in 2019. Data from the Alcohol Toolkit Study (ATS) for England found that 26.9% of increasing and higher-risk drinkers were motivated to reduce their drinking and evidence from the iDEAS trial found that 67% of those motivated to cut down subsequently downloaded Drink Less. We, therefore, modelled the mass media campaign as leading to 18% (26.9% × 67%) of increasing and higher-risk drinkers to download Drink Less and also explored more and less optimistic assumptions in sensitivity analyses.

For the GP embedding scenario, we used data from the ATS in 2019 that showed that 5.5% of increasing and higher-risk drinkers aged under 35 and 12.9% of those aged 35 or more had spoken to their GP or a healthcare professional about their drinking in the past year. We modelled GPs using these conversations to refer patients to the Drink Less app, assuming a 67% uptake rate in line with the iDEAS trial, with more or less optimistic assumptions explored in sensitivity analyses. The cost of GPs' time was estimated at £184/hour[35] and assuming the conversation lasted 5 minutes. We modelled a 5-year roll-out of this embedding, assuming no additional benefit for repeat contacts.

For both scenarios, we modelled a 2-unit per week reduction in mean alcohol consumption among increasing and higher-risk drinkers who downloaded the app in line with the iDEAS trial results. In line with evidence that the effects of a brief intervention can persist for at least 4 years[36] and that recipients will continue to have access to the app for the long term, we assumed this effect would continue for the full 20-year time horizon of the model. We explored a more pessimistic assumption that effects decay linearly to nothing over 7 years in a sensitivity analysis. The baseline year for our analysis was 2019, to avoid modelling the as-yet-unknown effects of the COVID-19 pandemic on alcohol mortality and healthcare risks. Baseline alcohol consumption data are taken from the Health Survey for England 2018 and 2019 pooled. Baseline mortality data are taken from Office for National Statistics figures for 2012–6 and baseline hospital admissions data is derived from Hospital Episode Statistics for 2012–3 to 2016–7. Health state utilities stratified by age and sex for each of the 45 alcohol-related health conditions included in SAPM[37] are taken from previously published figures.[34] All costs are presented in 2019 costs and costs and health benefits are discounted at 3.5%.[38] Both scenarios are compared to a 'do-nothing' scenario where there is no uptake of the Drink Less app among increasing and higher-risk drinkers.

Our primary outcomes were mean alcohol consumption per week, cumulative changes in alcohol-attributable hospital admissions, deaths and QALYs over 20 years and cost-effectiveness. We also examined the inequality

impacts of each scenario by stratifying these outcomes by quintiles of the Index of Multiple Deprivation (IMD) and undertaking a distributional cost-effectiveness analysis (DCEA)[39] using assumptions in line with previous DCEAs using SAPM.[40]

We found that the mass media roll-out led to 1.6 million increasing and higher-risk drinkers downloading the Drink Less app, leading to a reduction in population mean consumption of 0.07 units/week (−0.7%), 94,111 fewer hospital admissions, 2184 fewer alcohol-attributable deaths and 19,239 QALYs gained with a net discounted cost to the NHS of −£298.8M (i.e. a cost saving). The GP embedding scenario led to 3.1 million app downloads, reducing population alcohol consumption by 0.13 units per week (−1.4%). This was associated with 188,452 fewer hospital admissions, 4599 fewer alcohol-attributable deaths and 38,897 QALYs gained at a net discounted cost to the NHS of −£519.7M. Thus, both scenarios are cost saving and health-improving relative to no Drink Less roll-out, but the cost and health benefits are approximately twice as large under the GP embedding scenario. Even under the most pessimistic scenario where the effect of the app on alcohol consumption waned over time, both scenarios remained cost saving (−£72.8M and −£71.9M, respectively) and health-improving (6186 and 11,450 QALYs gained). However, the cost profile of the two scenarios over time differs, with the lower initial cost of the mass media campaign meaning that this approach is estimated to reduce NHS costs from the outset, whereas the GP embedding scenario is estimated to cost £16M net in the first year, breaking even by the fourth year after implementation.

In terms of the inequality impacts of each scenario, under both roll-out approaches, there are more app downloads among increasing and higher-risk drinkers in less deprived IMD groups compared to more deprived groups, leading to correspondingly larger reductions in mean alcohol consumption: −0.07 units/week in the least deprived quintile and −0.05 units/week in the most deprived in the mass media scenario and −0.15 and −0.10, respectively, in the GP embedding scenario. Despite this, the QALY gains in the mass media scenario are shared broadly evenly across IMD quintiles because more deprived groups experience substantially higher rates of alcohol harms. The gains accrue disproportionately more in the two most deprived quintiles under the GP embedding scenario. Further, both scenarios are estimated to save NHS costs, and because existing NHS spending is higher in more deprived groups, the money saved by the Drink Less roll-out is likely to be disproportionately spent on improving the health of more deprived groups. Overall, the DCEA analysis implies both scenarios will reduce overall inequality, while also improving population health. The positive inequality impact is over four times greater in the GP embedding scenario than in the mass media scenario.

These results show that a wider roll-out of the Drink Less app is estimated to be cost saving, health improving and inequality reducing, under both modelled scenarios and that these conclusions are robust to more pessimistic assumptions.

Discussion and interpretation

Principal findings

Drink Less appears effective in helping digitally literate and motivated increasing and higher-risk drinkers reduce their weekly alcohol consumption. Although there was not a significant difference between groups in the primary analysis, this analysis was not sensitive to detect the hypothesised effect and given the pattern of missing data, multiple imputation was the most appropriate way to handle the missing data.[22] A pre-registered sensitivity analyses using multiple imputation showed the Drink Less app intervention group reduced their weekly alcohol consumption at 6-month follow-up by an additional 2 units compared with the comparator group. This decrease was consistent at all time points among those in the Drink Less group, with a 2-unit decrease in weekly alcohol consumption at 1- and 3-month follow-up compared with the NHS alcohol advice web page. We did not detect any benefit of the Drink Less app on the prevalence of heavy episodic drinking or full AUDIT score, or any impact on any of the broader secondary outcomes related to alcohol-related problems, use of healthcare services or health-related quality of life. Drink Less appeared equally effective for increasing and higher-risk drinkers across all levels of baseline alcohol consumption.

Furthermore, the Drink Less app was perceived as being an acceptable intervention among the participants interviewed after participation in the trial. Drink Less was perceived as being fair to all users, user-friendly and effective for the period the app was used. Participants reported particularly liking the tracking and feedback sections of the app which they reported increased the personal relevance of the intervention. Being able to use the app to meet goals and seeing their progress visually represented in the app resulted in positive affect. The app was not perceived as being burdensome, with no opportunity cost of using the app. Participants reported

that the mode of delivery meant that the intervention could be readily incorporated into their day-to-day life. Factors such as negative affect when not meeting goals and boredom led to disengagement in the longer term for some participants.

In terms of methodological findings, we found that retention rates for trials conducted remotely can be as high as 70% with multiple e-mail reminders along with substantial financial incentives but can be increased further, by around 10%, by using phone calls, postal surveys and postcards. This trial also highlighted the importance of continued monitoring, identifying and reacting to new methodological challenges. Participant deception can be a major issue in conducting research remotely, and it is necessary to have rigorous plans for data management. These can include: having a CAPTCHA in a screening survey, using attention checks, a requirement to provide a mobile number for identity checks, and not prominently advertising the financial compensation on social media adverts.

In terms of the process evaluation, we found that participant engagement with Drink Less was significantly higher than with the NHS alcohol advice web page. Self-reported adherence to the recommended digital tool (at either 1- or 6-month follow-up) mediated the effect of the intervention on alcohol reduction. In terms of potential mechanisms of actions by which the Drink Less app reduces alcohol consumption, self-monitoring behaviour was shown to mediate the effect of the intervention on alcohol reduction at 6-month follow-up. This suggests that the app may work through increasing users self-monitoring behaviour (i.e. how often they kept track of how many units of alcohol they drank each week).

Compared with the NHS alcohol advice web page, the Drink Less app cost an additional £1.28 per user, when including the sunk costs of the initial investment, but it saved £0.04 per user when considering only the annual maintenance costs. The Drink Less app was also more effective in reducing alcohol consumption, with 2 units fewer per week consumed than those in the comparator group after 6 months. Drink Less costs only an extra £0.64 per additional weekly unit of alcohol reduction. It was cost saving when using only the annual costs or when used by a large number of users. There was no statistically significant difference between QALYs in the groups. Drink Less is inexpensive, and it should be scalable and reach a large proportion of the UK population at a low incremental cost for the NHS, and may be cheaper than the existing web page if sufficient people use the app to cover sunk development costs.

Long-term modelling using the SAPM found that a mass media campaign to increase uptake of the Drink Less app would reduce population alcohol consumption by 0.7%, avert 2184 alcohol-attributable deaths and lead to 19,239 additional QALYs over 20 years, at a net cost saving to the NHS of £298.8M. Embedding the Drink Less app in General Practice would have a larger impact, reducing alcohol consumption by 0.13%, averting 4599 alcohol-attributable deaths and gaining 38,897 QALYs at a net cost saving of £519.7M. Both scenarios are also estimated to reduce health inequalities, with the GP embedding approach having the greatest effect. These findings suggest that a large-scale roll-out of the app is likely to be health-improving, cost-saving and inequality-reducing.

Contribution to existing knowledge

Brief alcohol interventions delivered face-to-face are effective at reducing alcohol consumption among increasing and higher-risk drinkers but only 6.5% of increasing and higher-risk drinkers receive them,[3] in part due to lack of time and confidence among healthcare practitioners.

Digital interventions have the potential to reach large numbers of increasing and higher-risk drinkers at relatively low costs and overcome barriers to delivery of brief alcohol interventions face to face.

Previous research has shown that digital interventions can reduce alcohol consumption, with participants who received a digital intervention drinking approximately 2.9 UK units less per week than participants who received the comparator, across 42 studies.[6] However, this systematic review predominantly included websites, and only 1 of the 42 digital interventions reviewed used a smartphone app ('Partyplanner') and this RCT was conducted in Sweden among university students.[41] In preparing for this research and as the field of research on digital interventions is expanding rapidly, we updated the review from March 2017 to April 2019 and found three additional studies involving smartphone apps for: university students in Sweden,[42] the general population in Canada[43] and for young adults (aged 16–25) in Australia.[44]

Despite the availability of hundreds of alcohol-related apps, this is the first RCT evaluating the effectiveness of an alcohol reduction app among the general population in the UK. Compared with usual digital care, the Drink Less app was effective in reducing alcohol consumption. Individuals recommended to use the Drink Less app drank 2 units fewer on a weekly basis than those in the comparator group after 6 months and the app was perceived to be an acceptable intervention. As such, Drink Less offers an effective, scalable population-level intervention that could

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Garnett C, Oldham M, Loebenberg G, Dinu L, Beard E, Angus C, *et al.* Evaluating the effectiveness of the Drink Less smartphone app for reducing alcohol consumption compared with usual digital care: a comprehensive synopsis from a 6-month follow-up RCT. *Public Health Res* 2025;**13**(5). https://doi.org/10.3310/LNNB8060

reach a large proportion of the UK population at a low incremental cost. This is particularly important given that following the COVID-19 pandemic the UK has announced a new strategic focus on digital public health with key services pivoting largely to remote delivery.

Equality, diversity and inclusion

We took a number of actions to ensure our research was inclusive, including consulting with patient and public involvement (PPI) representatives on the language and terminology used in research materials, and following relevant guidance such as the UK government guidance on writing about ethnicity.[45]

The trial enrolled 5602 increasing and higher-risk drinkers who were aged 18 and over and lived in the UK. Sociodemographic tracking during the trial revealed that female, white and higher socioeconomic status respondents were being over-recruited, and strategies targeted at a more diverse sample in terms of gender, socioeconomic status and ethnicity were introduced. This included targeting social media advertisements on Facebook (Facebook, Inc., Menlo Park, CA, USA) at men, and radio adverts on Talk Radio, Asian Sounds (in English and Urdu) and Punjabi Radio (in English and Punjabi).

In the final sample, 57% were female, 42% were male, 0.5% reported having an 'other' gender identity and 0.1% preferred not to say. The majority of the sample were white (95%), 2% were people from a mixed ethnic group, 2% were Asian, 1% were black, 0.2% were Chinese, 0.4% reported an 'other' ethnicity, 0.3% 'preferred not to say' and < 0.1% reported an unknown ethnicity. The majority of the sample self-reported that they earned an above-average income (75%) and were of a more advantaged social grade (58%).

The pre-registered analysis plan specified that we would assess interactions between group allocation and age, gender, ethnicity, education, occupation and income for the intervention effectiveness. Where significant interactions were found, the findings were stratified by the variable of interest to explore subgroup effects. A significant interaction was detected between gender and group assignment and the stratified analysis showed that women in the intervention group had a significantly lower alcohol consumption than women in the comparator group (mean difference −2.46, 95% CI −4.58 to −0.33), although no significant difference was detected among men (mean difference 1.08, 95% CI −1.66 to 3.82) or those reporting 'other' gender (mean difference 8.82, 95% CI −13.33 to 30.98). No significant interactions were detected for age, ethnicity, education, occupation or income.

In data from the ATS among respondents meeting the inclusion criteria for the trial (aged 18 or over, an increasing and higher-risk drinker, and any motivation to cut down on their drinking), 37% of respondents were women, 94% identified their ethnic group as white, and 69% were from a more advantaged social grade (ABC1).[46] This suggests that the sample recruited for the trial was broadly representative of the relevant wider population in terms of ethnicity and social grade, with the trial over-representing women among its participants.

We had a wide and inclusive approach to recruitment, though took a predominantly digital approach. Part of this was always planned given the remote nature in which the trial was conducted, although the protocol did specify that there would be local advertising through healthcare providers which was delayed until towards the end of the recruitment period because of the impact of the COVID-19 pandemic.

The sample characteristics are also likely to be different as the trial was focused on online support tools for helping people reduce their alcohol intake and this was made clear when participants were signing up for the trial. The latest report on adults' media use from Ofcom in 2021 found that 6% of households in the UK have no internet access[47] and, as of 2022, 93% of adults in the UK own a smartphone.[48] While this indicates that smartphone ownership is increasingly prevalent among the UK population, it is critical to acknowledge that it is not universal and that not everyone who owns a smartphone will use it for health-related purposes. It is important to consider the issue of digital exclusion with regard to digital interventions[49] as not everyone can afford devices or data (digital poverty) or have the knowledge or confidence to use them (digital literacy). More vulnerable populations, such as older adults, those out of work or financially vulnerable, and those living with a physical or mental condition that affects their use of digital technology, are more likely to experience digital exclusion. The impact of digital exclusion must be considered with any roll-out of Drink Less at a population scale, and digital interventions should be just one part of a comprehensive alcohol policy, and not solely relied upon.

Furthermore, for this trial, participants had to have access to an iOS device (i.e. iPhone, iPod touch or iPad) because the Drink Less app, while free to use, is currently only available on iOS devices in the UK. This was because iOS apps tend to have fewer compatibility and debugging issues, and greater use and retention of apps. Android have a different user base (iPhone owners tend to be wealthier,[50] younger and more likely to be female).[51] We mitigated this potential issue by conducting extensive

user testing among individuals from disadvantaged social groups throughout the development and refinement process to try and ensure the app is acceptable to all users.[17,52]

We acknowledge that the best-case scenario would have been Drink Less as a native app on both iOS and Android devices; however, this was not possible within the funding available. Other options to create a non-native Android version (e.g. iOS emulators – unofficial software that replicates the behaviour of an iPhone and allows some iOS apps to run on an Android device) were likely to have had compatibility issues that would have negatively impacted engagement and consequently led to a biased estimate of effectiveness depending on the platform used. This trial has provided a proof of concept and strong rationale for developing a native Android version of Drink Less. This would maximise the potential impact of Drink Less on public health by reaching a larger proportion of smartphone users.

Strengths and limitations

The strengths of this study include recruitment of a large and diverse sample and the use of a RCT, which reduced bias. The trial was conducted remotely, with participants signed up online and automated e-mail follow-up invitations complemented with some sequential offline follow-up options (e.g. telephone calls and a postal survey). The remote nature of the trial is a strength as increased automation of recruitment and follow-up procedures reduced resource demand and financial cost. Remote trials also better reflect engagement with digital interventions in the real world, and not needing to travel to baseline or follow-up appointments can increase external validity.

There are however limitations to this trial. Although at the time of pre-registration we acted in accordance with our best knowledge in terms of the pre-registered primary analysis, we have since become aware that assuming no-change-from-baseline has been shown to be associated with higher levels of bias than multiple imputation. Future trials should consider pre-registering primary analyses using multiple imputation approaches, particularly when data are not missing completely at random. The focus is on self-reported consumption over a retrospective 6-month period which can be problematic as heavy drinkers can underestimate their alcohol consumption, although there is no reason to expect that this underestimation would be different across groups. Furthermore, researcher error impacted on the precision of measurements in this study. An error was made on the response options for questions 1 and 2 of the AUDIT. Rather than the response option '2–4 times per month', we instead provided the response option 'weekly'. As such it might be that more individuals in our study drinking twice a week selected 'monthly', as opposed to 'weekly' than would have selected 'monthly' relative to '2–4 times a month'. This could have resulted in some drinkers reporting a lower AUDIT score than had the correct response options been used, although this would have applied equally to both groups. On question 2 of the AUDIT (asking participants about the quantity of their alcohol consumption), the extended options, which enable more precision when calculating weekly consumption for heavier drinkers, were not measured until January 2021. However, these data were collected for most participants (88%) and imputed where it was missed and therefore had limited impact on the findings of this trial. Furthermore, the trial was conducted during the start of the COVID-19 pandemic; while no statistically significant group differences in the COVID-19 measure were detected, this may have implications for the external validity of the trial.

In terms of the process evaluation, we were unable to assess whether objective measures of engagement mediated the effect of the intervention on alcohol reduction as we were unable to measure objective engagement in the comparator group for the NHS alcohol advice web page. As a result, we tested whether engagement mediated the effect of self-reported adherence on alcohol reduction, though it may have been that any individual mediation effect due to engagement was swamped by the direct effect of the self-reported adherence on alcohol reduction.

In terms of the health economic evaluation, the cost of the NHS alcohol advice web page was estimated to the best of our knowledge using publicly available sources, but we had to make an assumption in estimating the annual maintenance costs. The NHS resource use data were collected retrospectively, and this might have caused some recollection problems on resources used; however, there is no reason to believe this problem would differ between study groups.

The EQ-5D-5L questionnaires were not collected at baseline and so we had to use available evidence on initial utility to estimate the QALYs. There is no way to know if the patients in our study presented a different utility value and what was the initial difference in utility between the two groups.

There are two further limitations related to the generalisability of these findings. Due to very small numbers in some ethnic minorities, ethnicity was treated as white versus ethnic minorities throughout the trial papers. Grouping all ethnic minorities together in this

way does not allow for examination of differences in a culturally heterogeneous group. Furthermore, the Drink Less app is currently only available to those with an iOS device and as such iOS device ownership was an inclusion criterion for the trial. There are some demographic differences in iPhone ownership, compared with Android devices: iPhone owners are younger and more likely to be female[51] and wealthier,[50] which could further reduce the generalisability of these findings.

Take-home messages

There are four key take-home messages from this research:

1. Drink Less is the first alcohol reduction app for increasing and higher-risk drinkers in the UK with evidence for its effectiveness.

Drink Less has had a rigorous approach to its development and refinement which has been reported systematically and transparently. The findings from this trial show that Drink Less is the first evidence-based app to help a general population of increasing and higher-risk drinkers in the UK reduce their alcohol consumption.

2. The findings from this trial indicate that it is worth investing resources in promoting Drink Less and its large-scale implementation.

Drink Less appears to be more cost-effective in reducing alcohol consumption in increasing and higher-risk drinkers. Compared with the NHS alcohol advice web page, Drink Less costs an additional £1.28 per user, when including the sunk costs of the initial investment, but it saved £0.04 per user when considering only the annual maintenance costs. Drink Less was also more effective in reducing alcohol consumption. The intervention cost only an extra £0.64 per additional weekly unit of alcohol reduction. Longer-term modelling suggests that a large-scale roll-out of the Drink Less app is likely to reduce alcohol-attributable harm and improve population health, while reducing NHS costs and health inequalities.

3. Drink Less was considered user friendly, personally relevant and easy to use by participants.

Among those participating in interviews, the Drink less app was considered to be an acceptable intervention. The embedded mixed-methods process evaluation provided different insights and context for how Drink Less was used, and how and why it worked. This provided an in-depth understanding of whether the acceptability of the intervention influences participants' engagement. The Drink Less app appeared to work through the mechanisms of action of self-reported adherence to the app and increased self-monitoring behaviour.

4. The importance of open science.

Transparent and systematic reporting is important for the replication of interventions and can provide a helpful template for other researchers to use. The principles of making materials, data, results, source code and publications freely available is important for efficient scientific progress and to avoid unnecessary waste and reduce development costs for other researchers. This trial also provided specific guidance for other researchers on recruitment and retention strategies for digital trials, and how to mitigate issues around participant deception.

Reflections

This trial was conducted during the COVID-19 pandemic, which impacted both on drinking patterns in the UK and on available recruitment methods. The COVID-19 pandemic has had a sustained impact on drinking behaviour in the UK with the prevalence of increasing and higher-risk drinking at an increased level since the first lockdown,[53] with larger increases among those from more disadvantaged social grades.[54] This may have had an impact on recruitment with a larger proportion of the UK population eligible to take part in the trial and potentially increased motivation to take part in a study related to their drinking.

Furthermore, the COVID-19 pandemic meant that we were unable to recruit from one of our originally planned methods, GP surgeries, for much of the recruitment period. The methodology paper of recruitment and retention strategies (RA2) found that the small sample recruited from GP surgeries was more balanced, and perhaps would have resulted in a more balanced sample overall were we able to recruit using this method for the whole recruitment period.

Challenges faced

This project started in March 2020 and coincided with the first national COVID-19 lockdown in the UK. As a result of this, some of the project's 13 researchers were working at reduced capacity due to illness, isolation or carer's leave, and in extremely difficult circumstances. Despite this, the project continued to meet all its milestones.

Engagement with partners and stakeholders

This project has had strong engagement with partners and stakeholders throughout the planning and conducting of the trial. We have collaborated with a wide range of partners and stakeholders in the dissemination of the trial

findings. We hosted a stakeholder summit to disseminate the key findings from the trial and had a panel discussion on the implications of the findings with a public member of the independent Trial Steering Committee (TSC), a TV and radio presenter with well-documented interests in alcohol (Adrian Chiles), as well as representatives from policy (Senior Alcohol Advisor at the Office for Health Improvement and Disparities) and practice (Director of Science, Evidence and Analytics at NICE, and an Acting Consultant in Public Health in the NHS).

Patient and public involvement

Aim

The aim of PPI in all aspects of the trial was to ensure that the voices of increasing and higher-risk drinkers and members of the public were included throughout the research process so that the trial was acceptable to potential participants and findings are of maximum relevance to the target population.

Methods

We worked with PPI representatives from developing the original grant proposal through to dissemination of the findings. This involvement included: contributing to design, membership of the independent TSC; developing research tools and materials; interpreting the data generated by the research; and dissemination of findings.

The public involvement was conducted through focus groups, e-mail correspondence and/or telephone calls. We worked with the following PPI groups: the Alcohol Discussion Group (in Stirling, online), the University College London Tobacco and Alcohol Research PPI group and the Sheffield Addiction Recovery Research Panel. We held four online TSC meetings over the course of the project and two members of the TSC were PPI representatives. They provided input on the research project based on their direct experience.

Alongside this, we had public involvement in developing research tools and materials such as recruitment adverts, information and consent forms, and follow-up e-mails to ensure that any written information was in user-friendly and plain language, and to maximise recruitment and retention rates.

Public representatives were also involved in the analysis and interpretation of the trial findings, to check the validity of our conclusions from the public perspective and helped us to highlight findings that were more relevant to the public. One of the TSC public representatives spoke at the Stakeholder Summit (where the main findings from the trial were disseminated) as part of a panel led by experts in research, policy, practice and with lived experience focusing on the implications of the trial for wider research and next steps.

Study results

The PPI representatives on the TSC helped us to find ways of widening participation in the trial and provided insight into why participants join trials. They had a lot of useful input on the trial protocol and planned recruitment procedures.

Patient and public involvement groups were incredibly useful in highlighting use of jargon or technical words that we removed/altered, and in helping create adverts that would appeal to the general public and engage people in our research. We subsequently contacted all of the groups who had assisted us with PPI since the research idea was conceived and provided them with feedback on how their input had shaped and changed our project.

Regarding interviews, PPI members contributed to the structure and wording of interview questions in order to improve acceptability of the interviews. We also incorporated participants' views in the qualitative analysis of the interviews by having participant input at the coding and interpretation stage. This ensured that the researcher's codes and themes reflected the content of the interviews and helped identify additional themes.

Our PPI representatives on the TSC also contributed to a discussion on the interpretation of the results. The PPI representative on the panel for the stakeholder summit provided thoughtful responses to the findings of the trial and what they meant for people living with alcohol problems. We also had PPI contributions to and feedback on the plain language summary for this report.

Discussion and conclusions

The PPI has only had a positive influence on the trial and has been essential throughout. The PPI has resulted in more appropriate and relevant research tools (including information and consent forms, recruitment advertising, and follow-up survey e-mails) in addition to the approaches we used to the follow-up of participants at our primary end point. We also had public involvement in terms of the importance of assessing engagement with the app, suggestions as to where to direct advertising, and what groups might be interested in participating in the project.

Our PPI representatives on the TSC will continue to contribute to dissemination efforts by helping to prepare lay summaries for conference presentations. They will

also contribute to wider dissemination, by reviewing draft scripts for public-facing videos that will summarise the main trial findings.

Reflections and critical perspective

The active public involvement in this trial has been vital across all stages of this research project. We believe there were a number of factors relating to the success of public involvement in this trial including: involving people throughout the research cycle, building on existing relationships, sufficient resources to support effective involvement, enthusiasm and commitment of all involved, and providing feedback to representatives.

The COVID-19 pandemic meant that the majority of PPI input in this project was done online. This had benefits and downsides. The benefits were that we were able to engage with a number of groups across England and Scotland, which potentially broadened the points of view captured. However, online discussion made it harder to build rapport and it is possible that in-person meetings might have enabled the researcher to draw out views from individuals who were quieter and less willing to share. It is also possible that online meetings may have put up a barrier for some PPI participants, including those who are less digitally literate or from less advantaged backgrounds who may not have had access to tech or the internet.

Impact and learning

This project has resulted in the first rigorous evaluation of a theory-informed alcohol reduction app for increasing and higher-risk drinkers in the UK with evidence for its effectiveness at reducing alcohol consumption. The Drink Less app continues to be freely available on the Apple App Store providing a scalable population-level intervention with the potential to reach a large proportion of the UK population.

In terms of equity, Drink Less was equally effective for increasing and higher-risk drinkers across all levels of baseline alcohol consumption. We explicitly considered the health equity implications of the intervention by assessing interactions between the group allocation and age, sex, ethnicity, education, social grade and income on the primary outcome. Only one significant interaction was detected: there was an interaction between sex and group assignment with women in the intervention group having a significantly lower alcohol consumption than women in the comparator group (mean difference −2.46, 95% CI −4.58 to −0.33), and no significant difference detected between men in the intervention group and in the comparator group (mean difference 1.08, 95% CI −1.66 to 3.82).

Compared with the NHS alcohol advice web page, Drink Less cost an additional £1.28 per user, when including the sunk costs of the initial investment, but it saved £0.04 per user when considering only the annual maintenance costs. The Drink Less app was also more effective in reducing alcohol consumption, with 2 units fewer per week consumed than those in the comparator group after 6 months, and was therefore cost-effective (it cost only an extra £0.64 per additional weekly unit of alcohol reduction). It was cost saving when using only the annual costs, meaning that increasing the number of users of the tool could be cost saving compared with the NHS website. The application could be used as a support tool for the NHS to reduce alcohol consumption.

This trial has provided key lessons for future research, particularly based on the methodology paper of recruitment and retention strategies (RA2) and data management with regard to bots and manual participant deception (RA3). Given the convenience of conducting trials remotely, particularly in the context of the COVID-19 pandemic, the methodological lessons learnt during this trial can help inform future research and ensure adequate resource provision. The findings from the process evaluation indicate that it is adherence to Drink Less, that is following the recommendation, not simply the recommendation itself, that has the effect on alcohol reduction, which has important implications for how apps are advertised (RA6).

We have presented this work and these findings at a number of national and international conferences, as well as submitted research articles. These talks have been well received and a symposium given at the International Network on Brief Interventions for Alcohol and Other Drugs annual conference contributed to the creation of a Special Interest Group on Intervention Research Methods. We will also be working with video animators to create public and policy videos (each tailored to the different stakeholder groups and accessible to different audiences) to share the key findings from the trial.

As part of this trial, we worked with the not-for-profit social enterprise, Evidence to Impact, to produce a comprehensive market appraisal and business model for the Drink Less app's financial sustainability and to maximise its future impact by being prepared for scaling up its implementation. This model of sustainability is important to account for maintenance of the app (in line with iOS software updates, bugs and advances in

technology) along with any more major updates as and when they may be required.

The starting premise for the business plan is that we want Drink Less available as widely as possible, and on a not-for-profit or 'cost recovery' basis only. Evidence to Impact looked at what the best business and funding model for Drink Less might be, with particular reference to the prescribing pathways, and where it would best fit in relation to published funding models put in place by various Clinical Commissioning Groups.

Given the finding from RA2 that participants recruited from GP surgeries were more representative of the general population, a model including prescribing pathways may be of particular importance when considering how to minimise health inequities.

There were three main recommendations from this report for the sustainability of the app:

1. download fees of £1.99 per use
2. core funding from charities and/or organisations on a 'collective' basis
3. ongoing research funding.

They recommended that the lead researchers set up a 'task and finish' group to consider and implement recommendations from the report, and then consider identifying the best partners to manage Drink Less on an ongoing basis. The 'task and finish' group work is ongoing, and the research team are having ongoing conversations with interested parties.

There are two pieces of related and future work arising from this project, both the chief investigator, Dr Claire Garnett, and the lead researcher, Dr Melissa Oldham, will be starting research fellowships in the coming months. Dr Claire Garnett will be starting a National Institute for Health and Care Research Advanced Fellowship on 1 September 2023 titled 'Alcohol harm reduction in at-risk drinkers in the UK: a mixed-methods approach to increase the number and success of reduction attempts made'. The overarching aims of this fellowship are to increase:

1. the proportion of increasing and higher-risk drinkers making alcohol reduction attempts
2. the success of these attempts.

Part of this work will involve refining the Drink Less app to give users tailored alcohol reduction suggestions based on their desired goal and drinking patterns, and evaluating it in a within-app randomised trial.

Dr Melissa Oldham will start a Griffith Edwards Society for the Study of Addiction Fellowship in January 2024. The aims of the fellowship will be to:

1. increase risk perceptions among increasing and higher-risk drinkers
2. increase reduction attempts among increasing and higher-risk drinkers.

This project has also highlighted two key lessons learnt for future alcohol trials in terms of the most appropriate analytic approaches. First, that the primary outcome should be the outcome measure at follow-up adjusted for baseline, and not a change score[55] given the purpose of a parallel-group RCT is to compare the parallel groups, not to compare a participant with themselves at baseline. Computing change scores also requires a number of assumptions to hold, for example, that the variable is not used as an inclusion/exclusion criterion for the study (otherwise regression to the mean will be strong); this assumption is frequently not met. Second, assuming that missing follow-up data imply no change leads to biased results of intervention effects; therefore, data should be assessed for the mechanism by which they are missing to determine the most appropriate analytic approach to missing data.[22]

Implications for decision-makers

This study adds to the body of literature on the effectiveness of digital interventions, and apps in particular, for reducing alcohol consumption among increasing and higher-risk drinkers in the UK. The results show that, compared to usual digital care, the Drink Less app can help increasing and higher-risk drinkers to reduce their alcohol consumption by 2 units of alcohol per week.

Drink Less offers an effective, cost-effective and acceptable intervention at a reasonable cost for individuals that is scalable and could reach a large proportion of the UK population at a low incremental cost. This is of particular importance given the restructuring of public health infrastructure following the COVID-19 pandemic and that the UK has announced a new strategic focus on digital public health with key services pivoting largely to remote delivery.

Drink Less is the only evidence-based alcohol reduction app in the UK and the next key step is to create an Android version of the app. This is important given the issue around digital exclusion and that while smartphone ownership is increasingly prevalent in the UK population,

it is not universal and some people, such as those who are older, out of work, or living with a health condition are less likely to own and use digital technology. Drink Less is currently only available on iOS devices, and while Android and Apple share the market fairly equally, Android has a different user base (less wealthy, older and more likely to be male).[51] This trial has now provided a proof of concept for the effectiveness of the Drink Less app and a strong rationale for developing a native Android version so that Drink Less can be used by a larger proportion of the UK population. Further to this, over the years since the app was released in 2016, we have received a number of user requests from people for an Android version.

We acknowledge that while having an Android version of the app is an important step in mitigating the issue of health inequities and digital exclusion, it is not sufficient and digital interventions should be just one part of any alcohol-related support and/or policy and not the only available support. Digital interventions can have a role as stand-alone interventions, as demonstrated in this trial, though could also have an important role as an integrated part of healthcare systems to complement face-to-face interventions. Ideally, digital interventions would remain free at the point of use, although this aspiration requires broader consideration given the need for sustained funding to maintain digital interventions. For example, in Germany, the DiGA initiative allows doctors to prescribe apps to the citizens covered by public health and these costs are reimbursed through health insurance.

The NHS alcohol advice web page was the comparator in this trial given it is currently usual digital care in the UK. Participants reported that the NHS alcohol advice web page was very quick, easy and intuitive to use and accessible to anyone with internet access. However, it was judged by participants as containing information that was less personally relevant to them, and some said that it provided the starting point for them by signposting them to other tools or resources. Given the evidence for the effectiveness of Drink Less, it could be that the NHS alcohol advice web page signposts people to Drink Less and recommends that they download and use it.

Research recommendations

We identified the following research recommendations for priority areas future research:

1. Detailed modelling of how the app works

Future research should conduct more detailed modelling of engagement with Drink Less in terms of what components participants are using (i.e. what) as well as the extent of engagement (i.e. how) and the sequence in which participants use the app to see whether there are any patterns of usage that are associated with better outcomes. This could be important for providing users with suggested ways in which to use the app, and to help inform other interventions for alcohol and other drugs about the most important components of the app. Observational research into the long-term effects of the app would also be of interest.

2. Wider implementation in the UK

Given the evidence on the effectiveness of the Drink Less app, it is important to understand the best way for widespread implementation (e.g. a mass media campaign, GP recommendations) and the longer-term effects of these scenarios.

3. Implementation in other countries

Drink Less was developed for increasing and higher-risk drinkers in the UK and, as such, has the UK drinking guidelines, details on UK units and uses data from the UK for comparing users to the general population of drinkers. There has been interest from users in making it available in other countries and this could be an important area of future research.

4. Evidence synthesis of digital intervention trials and recruitment methods

Future research should investigate the effect of different recruitment methods (e.g. offline through GP surgeries vs. online through social media advertising) on the sociodemographic characteristics of the participants recruited given the important implications for digital exclusion.

Conclusions

In digitally literate and motivated increasing and higher-risk drinkers in the UK, the Drink Less app is effective at reducing weekly alcohol consumption by an additional 2 units compared with usual digital care. Drink Less was perceived as being acceptable, user-friendly, personally relevant and effective among participants without being thought of as burdensome. Engagement with Drink Less was high and self-reported adherence to the intervention and increased self-monitoring behaviour mediated the effect of the intervention on alcohol reduction. The intervention costs only an extra £0.64 per additional weekly unit of alcohol reduction. It can be cost saving if

used in a large cohort and long-term modelling suggests a wider roll-out would be health-improving and cost-saving as well as inequality-reducing. This provides evidence to support investment into promoting the Drink Less app to increasing and higher-risk drinkers in the UK.

Additional information

CRediT contribution statement

Claire Garnett (https://orcid.org/0000-0002-6589-299X): Conceptualisation (equal), Data curation (equal), Formal analysis (equal), Funding acquisition (equal), Investigation (supporting), Methodology (equal), Supervision (equal), Validation (equal), Writing – original draft (equal), Writing – editing and reviewing (equal).

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Data-sharing statement

We shall make data available to the scientific community with as few restrictions as feasible, while retaining exclusive use until the publication of major outputs. Anonymised data have been deposited online at https://osf.io/2j9df/. All data requests should be submitted to the corresponding author for consideration.

Ethics statement

Ethics approval was obtained from University College London Research Ethics Committee (16799/001) on 24 March 2020.

Information governance statement

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/LNNB8060.

Primary conflicts of interest: Colin Angus, Marcus Munafo, Gemma Loebenberg, Larisa Dinu, Matt Field, Emma Beard and Susan Michie declare no conflicts of interest. Melissa Oldham's salary is partially funded by Medical Research Council (MR/W026430/1). Jamie Brown has received unrestricted research funding to study smoking cessation from Pfizer and J&J, who manufacture smoking cessation medications and sits in an unrenumerated role on the scientific advisory board for the SmokeFree app. Claire Garnett and Melissa Oldham have done paid consultancy work for the behaviour change and lifestyle organisation, 'One Year No Beer', providing fact checking for blog posts. Felix Greaves is employed by DHSC and previously by NICE and Public Health England PHE. Felix Greaves was a member of PHR – Research Funding Board, PHR Prioritisation Group, PHR Programme Advisory Board. Robin Burton was employed by the Office for Health Improvement and Disparities. Matt Hickman is co-director of NIHR Health Protection Research Unit in Behavioural Science and Evaluation and a trustee for the Society for the Study of Addiction. Matt Hickman was a member of PHR – Research Funding Board. Elena Pizzo was a member of HTA Clinical Evaluation and Trials Committee until November 2023. Eileen Kaner is a NIHR Senior Investigator and Director of the NIHR funded Applied Research Collaboration Northeast and North Cumbria and outside the submitted work has previously co-authored papers that analysed raw market research consumer-based data provided to Newcastle University under a direct contract with Kantar Worldpanel at no cost to Newcastle University. Kantar Worldpanel received reimbursement from AB InBev to cover the costs of the data, Kantar Wordpanel having similar commercial relationships with other customers who pay to have data collected on food and non-food items available for sale in supermarkets and other retail outlets covered by the WorldPanel.

Department of Health and Social Care disclaimer

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN64052601.

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Award publications

This synopsis provided an overview of the research award Evaluating the effectiveness of the alcohol reduction smartphone app, Drink Less, compared with the NHS alcohol advice webpage, for the reduction of alcohol consumption among hazardous and harmful drinkers in the UK at 6-month follow-up: a randomised controlled trial. Other articles published as part of this thread are:

Garnett C, Oldham M, Angus C, Beard E, Burton R, Field M, *et al*. Evaluating the effectiveness of the smartphone app, Drink Less, compared with the NHS alcohol advice webpage, for the reduction of alcohol consumption among hazardous and harmful adult drinkers in the UK at 6-month follow-up: protocol for a randomised con. *Addiction* 2020;**116**:412–25. https://doi.org/10.1111/add.15287

Loebenberg G, Oldham M, Brown J, Dinu L, Michie S, Field M, *et al*. Bot or not? Detecting and managing participant deception when conducting digital research remotely: case study of a randomized controlled trial. *J Med Internet Res* 2023;**25**:e46523. https://doi.org/10.2196/46523

Oldham M, Dinu L, Loebenberg G, Field M, Hickman M, Michie S, *et al*. Methodological insights on recruitment and retention from a remote randomised controlled trial examining the effectiveness of an alcohol reduction app: a descriptive analysis. *JMIR Form Res* 2023;**8**:e51839. https://doi.org/10.2196/51839

Oldham M, Beard E, Loebenberg G, Dinu L, Angus C, Burton R, *et al*. Effectiveness of a smartphone app (drink less) versus usual digital care for reducing alcohol consumption among increasing-and-higher-risk adult drinkers in the UK: a two-arm, parallel-group, double-blind, randomised controlled trial.

EClinicalMedicine 2024;**70**:102534. https://doi.org/10.1016/j.eclinm.2024.102534

Oldham M, Dina LM, Loebenberg G, Perski O, Brown J, Angus C, *et al*. Evaluating the acceptability of the drink less app and the national health service alcohol advice web page: qualitative interview process evaluation. *J Med Internet Res* 2024;**26**:e42319. https://doi.org/10.2196/42319

Garnett C, Dinu LM, Oldham M, Perski O, Loebenberg G, Beard E, *et al*. Do engagement and behavioural mechanisms underpin the effectiveness of the drink Less app? *NPJ Digit Med* 2024;**7**:174. https://doi.org/10.1038/s41746-024-01169-7

Angus C, Oldham M, Burton R, Dina LM, Field M, Hickman M, *et al*. Modeling the potential health, health economic, and health inequality impact of a large-scale rollout of the drink less app in England. *Value Health* 2025;**28**:215–23. https://doi.org/10.1016/j.jval.2024.11.007

For more information about this research please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR127651).

Additional outputs

Conference presentations

Oldham M, Garnett C, Abroms L, Gelberg L. *Evaluating Digital Interventions for Alcohol and Other Drugs Symposium*. International Network on Brief Interventions for Alcohol and Other Drugs Conference, North Carolina, 2023.

Oldham M, Loebenberg G, Dinu L. *Methodological Considerations with Digital Alcohol Interventions Symposium*. International Network on Brief Interventions for Alcohol and Other Drugs Conference, Edinburgh, 2022.

Garnett C. *The Development, Refinement and Evaluation of the Alcohol Reduction App, Drink Less*. Society for the Study of Addiction Conference, Bristol, 2022.

Oldham M, Loebenberg G. *Methodological Insights on Recruitment and Data Quality from a Remote Randomised Control Trial Examining the Effectiveness of an Alcohol Reduction App*. Oxford Mixer, Oxford, 2022.

Seminars and wider dissemination

Garnett C. *Exploring the Real World Evidence Value Chain: Case Study with the Drink Less App*. International Research Visit to the University of Toronto, Toronto, 2023.

Garnett C. *Drink Less and the* iDEAS *Trial*. iDEAS Stakeholder Summit, London, 2023.

Oldham M. *Evaluating the Effectiveness of the Drink Less App in Reducing Consumption amongst Increasing and Higher Risk Drinkers*. iDEAS Stakeholder Summit, London, 2023.

Loebenberg G. *Acceptability of the Drink Less App*. iDEAS Stakeholder Summit, London, 2023.

Dinu L. *Engagement with the Drink Less App*. iDEAS Stakeholder Summit, London, 2023.

Garnett C. *Open Source App Code: Challenges and Consequences*. Open Digital Health, Online, 2022.

Garnett C. *The Development, Refinement and Evaluation of the Alcohol Reduction App, Drink Less*. Office for Health Innovation and Disparities, Online, 2022.

Media

Interviews

Garnett C. Media Interview on BBC Radio 5Live to discuss the NIHR-funded iDEAS trial and explain how people could find out more about the trial and how to take part. The intended purpose of this activity was to recruit participants for the iDEAS trial, which was achieved, 2021.

Oldham M. Media Interview on BBC Radio 5Live to discuss alcohol cultures and explain how people could find out more about the trial and how to take part. The intended purpose of this activity was to recruit participants for the iDEAS trial, which was achieved, 2022.

Podcasts

Oldham M. Guest on podcast focusing on alcohol research (The Alcohol 'Problem' podcast) – Spoke about the trial and wider research in order to increase awareness of the trial and boost recruitment, 2021.

Newspaper coverage

IPaper News Coverage. July 2020. https://inews.co.uk/news/health/digital-apps-websites-advice-drinking-university-college-london-565033.

About this synopsis

The contractual start date for this research was in March 2020. This article began editorial review in September 2023 and was accepted for publication in February 2025. The authors have

been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Public Health Research editors and publisher have tried to ensure the accuracy of the authors' article 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 article.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

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List of abbreviations

ACME	average causal mediation effects
ATS	Alcohol Toolkit Study
AUDIT	Alcohol Use Disorders Identification Test
CAPTCHA	Completely Automated Public Turing test to tell Computers and Humans Apart
DCEA	distributional cost-effectiveness analysis
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
ICER	incremental cost-effectiveness ratio
iDEAS	iOS Drink Less, evaluating the Effectiveness of an Alcohol Smartphone app
IMD	Index of Multiple Deprivation
iOS	iPhone operating system
NICE	National Institute for Health and Care Excellence
PPI	patient and public involvement
QALY	quality-adjusted life-years
RCT	randomised controlled trial
SAPM	Sheffield Alcohol Policy Model
TSC	Trial Steering Committee

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