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STUDY PROTOCOL

Title page

Full title

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 six-month follow-up: protocol for a randomised controlled trial

Sponsor

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Protocol version 1.2

Version control table

Version number	Date	Details
1.0	9 March 2020	No substantial changes to submitted research plan

1.1	5th May 2020	Edited following comments from the trial steering committee to include; additional information about technical support for trial participants, clarification that the 2 unit reduction used in the sample size calculation was weekly, an additional sensitivity analysis using an instrumental variable model and additional measures and analyses to assess for the effects of COVID-19. Exclusion criteria have also been updated to reflect the decision not to exclude participants based on previous treatment for alcohol. Updated declaration of conflict of interest statements for GL and MO. ISRCTN number updated.
1.2	25th February 2022	The protocol has been updated to reflect changes to the study procedure and planned analysis. The changes to the study procedure are outlined below; Protocol updated to reflect changes to the follow-up procedure at 1- and 3-months. Due to practical constraints, participants receive four email follow-ups as opposed to the originally stated procedure of three emails, two phone calls, one postal survey and one postcard. From 15/01/2022, participants also receive one text message reminder at the same time as the second email. The procedure for the 6-month follow-up remains unchanged apart from the addition of two text messages (from 15/01/2022). We have also updated this section to reflect the fact that participant responses up until two weeks after the initial period of acceptance (30 days after the survey was due) will be accepted. This is to maximise data retention and to account for time taken to receive participant responses by post at 6-month follow-up.

The protocol has also been updated to reflect a change in the comparator condition. As an advert for the study appears on the alcohol advice support page which we had originally planned to have as the comparator condition, participants in the comparator condition are directed towards the NHS page 'tips on cutting down'.

We are now providing additional reimbursement to those participating in the interview evaluating the acceptability of both interventions to compensate for their time and to enable timely collection of this data.

The changes to the planned analysis are described below;

In response to comments from the Data Monitoring Committee and the Trial Steering Committee, we have changed the primary outcome measure from change in weekly alcohol consumption to weekly alcohol consumption at 6-month follow-up adjusted for baseline, to increase the power of the primary analysis. The original planned primary analysis using change scores will still be reported as a sensitivity analysis.

We report an error on the response options for questions 1 and 2 of the AUDIT. Due to the error on question 2, we do not have the extended range of response options for AUDIT-C question 2 collected up until the 15/1/2021 (see Appendix 1). Extended scores from participants who responded to baseline and follow up surveys before this date will be imputed. The error affects the outcome calculation as we cannot use the calculator originally planned to estimate change in usual alcohol consumption from the extended AUDIT-C for our primary outcome measure. We have adapted this

		calculator to match the response options as measured. The error also means that we cannot exactly determine the standard AUDIT score as required for 'proportion of hazardous drinkers', one of the original secondary outcome measures. As such, this has been updated throughout to comparing differences between groups in full adapted AUDIT score. Finally, the protocol has also been updated to reflect changes which will affect the 'per-protocol' sensitivity analysis. Originally, we had planned to examine adherence with the protocol by tracking which participants followed the recommendation link. However, this was not possible using the Qualtrics platform. Instead, we ask at 1- and 6-month follow-up whether participants looked at or used the recommended intervention. Those reporting that they did use the recommendation at either time point in the intervention condition (Drink Less app) and comparator condition (NHS webpage) will be included in the per-protocol analysis. Upon advice from the DMC, an additional sensitivity analysis which will exclude withdrawn respondents and first entries from duplicate respondents has also been added.
1.3	13th June 2022	In response to comments from the Data Monitoring Committee and the Trial Steering Committee, we have also changed the secondary outcome measure from change in weekly alcohol consumption to weekly alcohol consumption at 1 and 3-month follow-up adjusted for baseline, to increase the power of the secondary analysis. Also updated to specify the inclusion of a second text message at 1 and 3 months to boost retention.
1.4	11th November 2022	Additional secondary analyses added to examine difference in treatment effectiveness depending on baseline drinking levels in terms of primary

outcome (alcohol consumption at 6 months) and two secondary outcomes (alcohol consumption at 1 and 3 months).

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List of abbreviations

ANOVA	Analysis of Variance
ANCOVA	Analysis of Covariance
AUDIT	Alcohol Use Disorders Identification Test
COM-B	Capability, Opportunity, Motivation – Behaviour (a model of behaviour)
EQ5D	EuroQol five-dimension scale
MTSS	Motivation to Stop Scale
OS	Operating System (iOS is the operating system used by Apple)
QALYs	Quality-Adjusted Life Years
RCT	Randomised Controlled Trial

Study summary

Study Title	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 six-month follow-up: protocol for a randomised controlled trial.
Study Duration	36 months (1st March 2020 to 28th February 2023).
Study Design	Two-arm, parallel group, randomised controlled trial.
Study Participants	Adults who are hazardous and harmful drinkers, live in the UK, have access to an iOS device and want to drink less alcohol.
Planned Sample Size	5,562 participants randomised 1:1 to receive intervention (2,781) or comparator (2,781).
Intervention	The *Drink Less* smartphone app (developed at UCL).
Comparator	The NHS alcohol advice webpage.
Follow Up Assessments	1, 3 and 6 months after baseline assessment.
Primary Outcome	Weekly alcohol consumption at 6-month follow-up adjusted for baseline consumption, in standard units, derived from the quantity-frequency questions of the AUDIT.
Secondary Outcomes	- Weekly alcohol consumption at 1- and 3-month follow-ups adjusted for baseline consumption - Heavy episodic alcohol use (AUDIT question 3) - Full adapted AUDIT score - Alcohol-related problems or consequences and alcohol-related injury (Alcohol Short Index of Problems) - Use of healthcare services - Health-related quality of life (EQ5D)
Process Outcomes	- Urges to drink - Motivation to drink less - Self-regulatory capacity

	- Self-monitoring capacity - Engagement with intervention - Acceptability of intervention and comparator

Introduction

Hazardous and harmful alcohol consumption is a major public health concern and contributes to health inequalities with the most deprived groups suffering the most harm from alcohol [1]. Fewer than 7% of hazardous and harmful drinkers receive face-to-face interventions in primary care to support alcohol reduction [2] with key barriers to the delivery of these interventions by practitioners being lack of time and low confidence about discussing alcohol with patients [3,4]. Digital interventions, such as websites and smartphone apps, may be effective for reducing alcohol consumption [5], and may overcome barriers to delivery of face-to-face interventions as they potentially have a broad reach and relatively low implementation costs (once developed), so can be delivered at scale [6]. As digital technologies become more integrated into everyday life and widely used, digital interventions can have a large positive impact on public health and wellbeing at a population level. Smartphone apps are a promising mode of intervention delivery because smartphones have become increasingly affordable to end users and prevalent among the UK population [7]. However, most digital alcohol interventions that have been evaluated are web-based and there is little evidence on the effectiveness of apps. The few trials of apps have been based in other countries and usually with younger adults [8–11]. Therefore, there is an urgent need for a robust evaluation of an evidence- and theory-informed alcohol reduction app, which, if effective, could be widely recommended to drinkers in the UK. The *Drink Less* app was designed to help people reduce their alcohol consumption, and has been developed and refined using a systematic and iterative process [12,13]. The app is ready for a definitive evaluation to establish whether recommending it to people is more effective than usual digital care for the reduction of alcohol consumption.

What is already known

Digital interventions – primarily web-based – may reduce alcohol consumption, with an average reduction of 23g of alcohol (2.9 UK units) per week compared with participants in the control group [5]. In this Cochrane review of 42 RCTs, only one of the digital interventions used a smartphone app, and this RCT was conducted in Sweden amongst university students [8]. Updates of this review found a further three studies that used smartphone apps: one in Sweden amongst university students [9], one for the general population in Canada [10] and another for young adults in Australia [11]. Therefore, despite the availability of hundreds of alcohol-related apps, none have been evaluated in a RCT among the general population of adults in the UK. The majority have also been developed without reference to scientific evidence or theory [14]. The lack of evidence highlights the necessity of a robust and pragmatic evaluation of an evidence- and theory-informed alcohol reduction app, which, if effective, could be widely recommended.

The Drink Less smartphone app

Drink Less is one of the most popular alcohol reduction apps on the UK Apple app store and aims to help hazardous and harmful drinkers reduce their alcohol consumption. *Drink Less* is capable of reaching a large proportion of the UK population at a low incremental cost. The development and evaluation of *Drink Less* was guided by the Medical Research Council's guidance on complex interventions [15] and the Multiphase Optimisation Strategy [16]. The development of the *Drink Less* app was informed by the COM-B model of behaviour [17] and multiple sources of evidence [14,18,19]; and is reported in full elsewhere [12]. A factorial screening trial was conducted to identify the most effective modules (distinct behaviour change interventions) within the app, which established that four of the five modules appeared to have an effect on reducing alcohol consumption after four weeks if combined with one of the other modules [13]. Data also suggested that users of *Drink Less* found it to be engaging [13], which is important to reduce participant attrition.

The strategy for optimising the effectiveness and usability of the app was based on: i) findings from the previous factorial trial, ii) a content analysis of user feedback, and iii) an updated evidence review and meta-analysis of behaviour change techniques in digital alcohol interventions. The optimisation process is reported in full elsewhere [*in preparation*]. Both the initial development and optimisation of *Drink Less* have involved input from users across the social spectrum on the functionality, design, and language used in the app [20]. The same approach was used for a smoking cessation digital intervention that was found to be effective for increasing smoking cessation rates across the social spectrum [21].

The next step in the Multiphase Optimisation Strategy is to conduct a RCT to evaluate the long-term effectiveness and cost-effectiveness of the digital recommendation of the optimised *Drink Less* app, compared with alcohol advice from the NHS alcohol advice webpage (usual digital care, available to anyone seeking alcohol support), in reducing alcohol consumption among hazardous and harmful drinkers. This research will be the first RCT of an alcohol reduction app for the general population in the UK and will evaluate whether it is worth investing resources into promoting and disseminating the app on a larger scale.

Research questions

1. At a 6-month follow-up, does the digital recommendation to use *Drink Less* compared with the NHS alcohol advice webpage to hazardous and harmful 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 webpage 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 webpage, if rolled out on a national level through active promotion to the public, over a 20-year period?

Methods

Design

A two-arm, parallel group, RCT with a 1:1 allocation comparing the intervention (*Drink Less*) with usual digital care (the NHS alcohol advice webpage), with an embedded mixed-methods process evaluation.

Setting

The study will take place online with participants who live in the UK.

Participants

Inclusion criteria

Participants will be included if they: are aged 18 years or over, live in the UK, are hazardous and harmful drinkers (Alcohol Use Disorders Identification Test (AUDIT) score>=8), have access to an iOS device (i.e. iPhone, iPod touch or iPad), and want to drink less alcohol.

Exclusion criteria

Participants will be excluded if they are unwilling to complete follow-up assessments or are unable to read English (for pragmatic reasons).

Recruitment

Recruitment is due to run from July 2020 to March 2022 via a multi-pronged strategy including: an advertisement on the NHS website; a mail-out to a database of UK-based users of the Smoke Free app and press releases and local advertising through health care providers and/or national and local government colleagues. The advertisements will be co-developed with public representatives.

Sample size

A sample size of 5562 participants (2781 in the comparator group and 2781 in the intervention group) is required to detect a mean difference reduction of 2 UK units (16g

of alcohol) in last week alcohol consumption at 90% power with an alpha of 0.05 and a two-tailed test. This was calculated using G*Power software [22]. The estimated effect size is in line with the Cochrane review on digital alcohol interventions [5] and is roughly equivalent to that found in face-to-face brief interventions [23].

A sub-sample of 26 participants (13 from each group [24]), who consented to a short interview about their experience of the trial, will be selected after the 6-month follow-up, as part of the mixed-methods process evaluation. Participants will be purposively sampled to achieve good diversity in terms of socio-demographic characteristics, and with high and low engagement. Data will be analysed and data collection will continue in an iterative process (adding 10 participants at a time) until thematic 'meaning' saturation is reached (see Analysis).

Intervention

Drink Less is a stand-alone app-based intervention that is freely available via the Apple app store in the UK [25]. *Drink Less* was developed for hazardous and harmful drinkers to help them reduce their alcohol consumption. *Drink Less* consists of evidence-based modules to help users change their drinking behaviour: Goal Setting; Self-monitoring & Feedback; Action Planning; Normative Feedback, Cognitive Bias Re-training, Behavioural Substitution and Information about Antecedents, which map to behaviour change techniques (see Figure 1). The development and content of the original *Drink Less* version is reported in full elsewhere [12] and the optimised version is reported online (https://osf.io/mc8yz/). The app contains standard features such as the UK Chief Medical Officers' low-risk drinking guidelines (14 units a week) [26].

On downloading the app, users are shown the privacy policy and then are asked if they are taking part in the iDEAS trial, and if they are, to enter their email address. Users are then asked to complete the AUDIT, provide socio-demographic details and then receive the Normative Feedback module. Users are then guided through setting a goal and shown how to use the key features of the app. Users can access all of the modules from the dashboard and the menu bar. The dashboard (the landing page of the app) has suggestions for the user to complete each day, as well as features of and links to the modules. Users can choose to have daily reminders to complete their drinks and mood diary for the previous day. The app provides a 'toolbox' of features for users to choose from and access as and when they want. The app is not tailored to the user except for personalised feedback in two modules: Normative Feedback and Self-monitoring & Feedback. Any modifications to the app during the trial (e.g., bug fixes) will be documented and reported.

Drink Less is expected to reduce the alcohol consumption of its users based on (i) its robust theoretical basis (the COM-B model of behaviour [17]), (ii) its evidence base, and (iii) user feedback that indicates users believe that it helps them to reduce their drinking and has a positive effect on their health and well-being. It is also expected to reduce urges to drink, increase motivation to drink less, and increase self-regulatory

capacity to drink less (see Figure 1 for the logic model). *Drink Less* is also highly rated by users (average 4.4-star rating in the Apple (UK) App Store as of 25/2//22 with over 60,000 unique users since its launch).

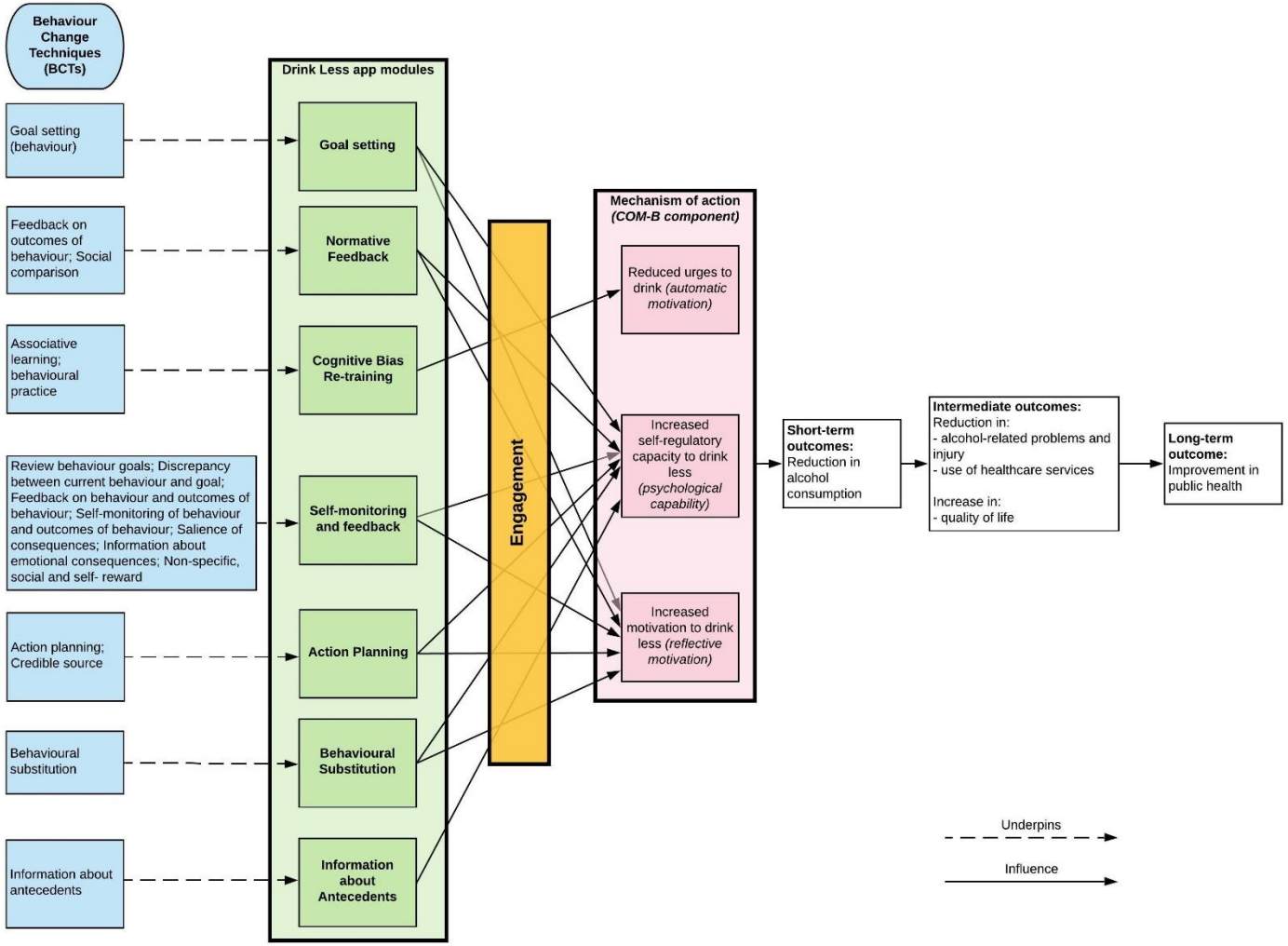

Figure 1: Logic model for the process of change of the Drink Less app (developed by the internal research team)

Comparator

The comparator group will receive the recommendation to view the NHS alcohol advice webpage 'tips on cutting down' [27]. This can be considered reflective of 'usual digital care' in this context as it is the digital support currently available to treatment-seeking individuals from the NHS. Therefore, this comparator best serves the primary purpose of the trial [28] which is to investigate whether it is worth promoting *Drink Less* over the 'usual digital care', and is of direct policy relevance. Furthermore, it is important to have a comparator that is relevant to the same target population as the intervention, and both *Drink Less* and the NHS webpage are aimed at adults in the general population. Any changes to the comparator during the trial will be documented.

Procedure

Figure 2 illustrates the study design and flow of participants and

Table 1 summarises the schedule of enrolment and follow-up assessment for trial participants.

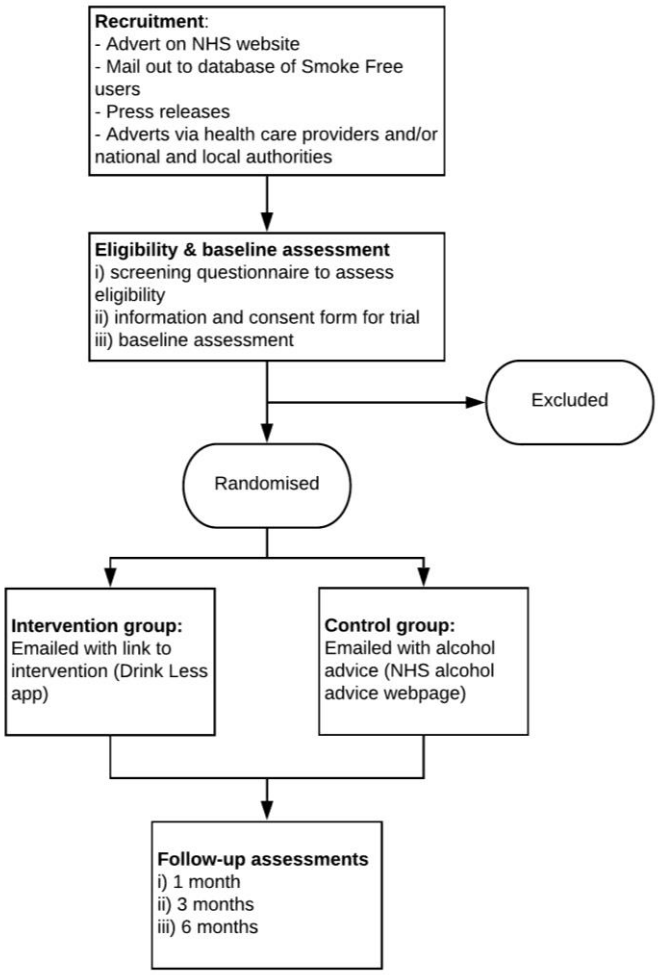

Figure 2: Flowchart of procedure

Table 1: Schedule of enrolment and follow-up assessments

Assessment	Time-point			
	Baseline	1 month	3 months	6 months
Informed consent	x			
Eligibility screening	x			
Randomisation	x			
Intervention/ comparator initiation	x			
Sociodemographic characteristics[a]	x			
Weekly alcohol consumption	x	x	x	x
Full adapted AUDIT score	x			x
Alcohol-related problems or consequences and alcohol-related injury				x
Use of healthcare services				x
Health-related quality of life				x
Psychological measures	x			x
Engagement	♦	———	———	♦
Acceptability				x
Adverse events		x	x	x
Debriefing				x

[a] *Sociodemographic characteristics include: age, sex, ethnicity, education, occupation, income*

Eligibility Assessment

Participants will self-enrol into the study and potential participants will be asked to respond to a web-based screening questionnaire to assess the inclusion and exclusion criteria.

Consenting

If people meet the eligibility criteria they will be shown the information sheet [*link here*] and informed that they will be re-contacted on three occasions (at 1, 3 and 6 months). Participants will then be asked to provide consent online to participate in the study.

Baseline Assessment

Participants will complete a web-based assessment of socio-demographic measures and the AUDIT (see Measures), and their contact details (email address, telephone number and postal address) for follow-up assessments.

Randomisation

Participants who complete the baseline assessment will be randomised individually to intervention and comparator groups using block randomisation (block size of 50) and a random allocation sequence generated by an online automated algorithm (at a ratio of 1:1). Participants will be blinded to study arm. There will be no involvement of the

researchers in the randomisation process and there will be complete allocation concealment.

Intervention and Comparator Delivery

Participants will be emailed within 24 hours of the baseline assessment and randomisation with the recommendation to either use *Drink Less* (the intervention) or the NHS alcohol advice webpage (comparator). Participants allocated to the intervention condition will be provided with instructions on how to download the *Drink Less* app along with the contact details of the project team who will provide ongoing technical support. These emails will be co-developed with public representatives.

Follow-Up Assessments

Follow-up assessments will be conducted 1, 3 and 6 months after baseline. The 6-month follow-up assessment will assess the primary and secondary outcome measures, and psychological measures; the follow-up assessments at 1 and 3 months will assess the primary outcome measure only. We will attempt to recontact participants for 30 days from their first invitation to complete the survey. To maximise data retention and to allow for time taken for answers to be posted at 6 month-follow up, data provided up to two weeks after this final contact will also be accepted.

For the 1- and 3-month follow-ups, participants will be sent up to four automated emails with a link to a web-based survey for the follow-up assessments from days 0, 5, 9 and 11. From 15/01/2022, participants also receive a text message reminder at the same time as the second email (day 5) and fourth email (day 11). At six months, as well as three emails (days 0, 5 and 9) and (from 15/01/2022) two text messages (days 5 and 9), participants who do not complete the web-based follow-up assessment will be sequentially offered opportunities to do so via phone (called twice from days 10-17), mailed survey (from day 18) and mailed postcard (from day 30). Participants will be compensated with gift vouchers of up to £36 for completing the three surveys: £6 for the survey at 1 and 3 months; £12 at 6 months with an additional £12 if the 6-month survey is completed within 24 hours.

At the 6-month follow-up, participants will indicate whether they are happy to be called for a short interview about their experience of the trial. Acceptability will then be measured after the 6-month follow-up via telephone interviews; there is an additional reimbursement of a £20 Amazon voucher for this interview.

Participants will be asked whether they experienced any unexpected consequences, adverse events or other harms from participating in the study (in an open-ended question at the 1-, 3- and 6-month follow-up), and whether they have used any other forms of support for alcohol reduction (at the 6-month follow-up).

Debriefing

On completion of the trial, after the final follow-up at 6 months, all participants will be given a list of further support including both the *Drink Less* app and the NHS website.

Measures

Sociodemographic measures

Sociodemographic measures will be assessed at baseline: age (in years, continuous), sex (% female), ethnicity (% white), education (% post-16 educational qualifications), occupation (to derive social grade AB, C1, C2, D, E dichotomised into: ABC1 (managerial, professional and intermediate occupations) vs C2DE (skilled, semi-skilled, unskilled manual and lowest-grade worked or unemployed)), and annual household income (% >£26,000 [29]).

COVID-19 measures

The recent COVID-19 pandemic is affecting many aspects of people's lives in the UK. A lockdown is currently in place, limiting many people's ability to leave their homes, apart from essential journeys. Early evidence suggests that COVID-19 may affect alcohol consumption, some lighter drinkers are drinking less than usual and some heavier drinkers are drinking more. In order to assess for the effects of the pandemic in the analysis, participants will respond to a brief COVID-19 survey at each time point. Users will be asked "Do you currently feel like COVID-19 is affecting your alcohol consumption and how you feel about drinking alcohol?" If participants respond 'no' they will continue with the rest of the survey. Participants responding "yes" will be asked to answer five follow up questions assessing the extent to which the pandemic is affecting their concerns about their alcohol consumption, their motivation to cut down and their patterns of consumption. Change in concerns about drinking will be measured by the question "Is COVID-19 and its associated effects (e.g. financial, social or health) currently affecting how worried you feel about your alcohol consumption?" followed by three response options 'more worried', 'no change' and 'less worried'. Change in motivation to reduce alcohol consumption will be measured by the question "Is COVID-19 and its associated effects currently affecting your motivation to reduce your alcohol consumption?" with three response options 'more motivated', 'no change' and 'less motivated'. Three questions measure changes in drinking patterns. Change in the frequency of drinking is measured by the question "Is COVID-19 and its associated effects affecting how frequently you consume alcohol?" with three response options 'consume alcohol more frequently', 'no change' and 'consume alcohol less frequently'. Change in the volume of alcohol consumed is measured by the question "Is COVID-19 and its associated effects currently affecting how many units of alcohol you generally consume when you do drink?" with three response options 'generally drink more units', 'no change' and 'generally drink less units'. Finally, change in the frequency of binge drinking is measured by the question "Is COVID-19 and its associated effects currently affecting how often you consume 6 or more units of alcohol on a single occasion?" with three response options 'more likely to consume 6 or more units on a single occasion', 'no change', and 'less likely to consume 6 or more units on a single occasion'. The date of

national responses to COVID-19 (e.g. lockdown) will also be monitored and recorded by the research team.

Primary outcome measure

The primary outcome measure is self-reported weekly alcohol consumption at 6-month follow-up estimated over the last 6 months, in UK standard units adjusted for baseline weekly consumption. Weekly alcohol consumption will be derived from the quantity-frequency questions of the AUDIT [30], adjusting for heavy episodic use (question 3 of the AUDIT) and therefore allocating an individual to a category of consumption that is closest to their actual consumption. An error was made on questions 1 and 2 of the AUDIT questionnaire, see Appendix 1 for details on non-standard response options for questions 1 and 2 as measured in this study and Appendix 2 for further detail on how weekly units will be derived from the AUDIT-C as measured in this trial. The quantity-frequency questions of AUDIT exhibit similar sensitivity and specificity to the full AUDIT [31] and have demonstrated excellent reliability and responsiveness to short-term change [32]. This method of deriving alcohol consumption has been used in other trials [33–36] and has high levels of agreement in levels of self-reported consumption when compared with other retrospective daily diary measures [37,38]. This measure minimises response burden on participants due to its brevity, which is a critical issue in digital trials that have minimal contact with participants and can suffer from high levels of attrition[39]. Extended responses were not collected until the 15/1/2021 for participants selecting '10 or more units' to question 2 of the AUDIT due to researcher error[1]. This equates to 656 participants (12% of the total expected) at baseline, 186 (3%) at 1-month, 79 (1%) at 3-month and 1 (<.1%) at 6-month follow-up. Extended response options will be imputed for these participants using multiple imputation. We will follow the procedure already detailed for multiple imputation in the sensitivity analysis section. This will involve 5 imputed datasets combined using Rubin's rules, with baseline characteristics used to predict the missing data. We will assess the bias of our imputation method by comparing the estimates obtained after imputation with the 'true' parameter value for a set of participants who do not have missing data.

Secondary outcome measures

- Self-reported weekly alcohol consumption estimated over the last month at 1- and 3-month follow-up adjusted for baseline consumption
- Heavy episodic alcohol use (measured using AUDIT question 3) at 6-month follow-up;
- Full adapted AUDIT score at 6-month follow-up;
- Alcohol-related problems or consequences and alcohol-related injury (measured using the Alcohol Short Index of Problems [40]) at 6-month follow-up;

[1] Data missing due to researcher error, therefore this data is missing at random and unrelated to participant characteristics.

- Use of healthcare services (measured using the Service Use Questionnaire [41,42]) at 6-month follow-up;
- Health-related quality of life (measured using the EQ-5D-5L) at 6-month follow-up;

The self-report AUDIT questionnaire has 10-items that measure alcohol consumption, harms and dependence. The AUDIT is a reliable and standardised alcohol-related outcome measure that is commonly used in alcohol trials [5,23], has high test-retest reliability when completed online [43], and allows the derivation of a core outcome set for consistency across trials, and to minimise research waste and selective reporting [44]. Please see Appendix 1 for how the full adapted AUDIT score will be calculated.

Process measures

The mixed-methods process evaluation involves assessing psychological measures, engagement and acceptability.

Psychological measures will be assessed as potential mechanisms of action at baseline and 6-month follow-up using four theoretical measures: urges to drink; motivation to drink less; self-regulatory and self-monitoring capacity (see Figure 1 for the Logic Model). Strength of urges to drink will be measured by the question "How strongly have you felt the urge to drink alcohol in the past 24 hours?" with six options from 'Not at all' to 'Extremely strong'. The strength of urges to drink measure has been chosen as it can be done through a single item question and has fair long-term test re-test reliability [45]. The motivation to drink less will be measured with the single-item Motivation to Stop Scale (MTSS). The MTSS and the urges to drink measure are both used in the Alcohol Toolkit Study allowing for national comparisons and have been successfully used in an observational study that estimates patterns of alcohol consumption and reduction in a sample in England [46]. Self-regulatory capacity will be measured by "How difficult do you find it to control your drinking?" using a 5-point scale from 'Not at all' to 'Extremely'. Self-monitoring capacity will be measured by "How often, if at all, do you keep track of how many units of alcohol you personally drink each week?" ranging from 'Never' to 'Always'.

Engagement with *Drink Less* will be assessed in terms of app download, and frequency, amount, duration, and depth of engagement [47] – all automatically recorded within the app, among participants in the intervention group. This will provide objective data on how participants interact with the app. App download will be assessed by whether the participant downloaded and opened *Drink Less* (a binary yes/no measure). Frequency of engagement will be assessed by number of sessions, where a new session is defined as a new screen view after 30 minutes of inactivity [48]. Amount of engagement will be assessed by time on app, in minutes. Duration of engagement will be assessed by number of days used. Depth of engagement will be assessed by the percentage of available screens viewed. Participants will also be asked about their use of the app in the semi-structured interviews to complement and enhance the patterns identified from

the objective engagement data. For example: "Can you tell me about your experience of using the app?", and "In what situations did you use it and why?" Adherence to either the intervention or comparator will be measured as to whether the link in the email to download *Drink Less* or view the NHS webpage, respectively, was clicked on via a mailing system.

The acceptability of the intervention will be assessed in a number of short semi-structured interviews among a sub-sample of participants in both the intervention and comparator group after the 6 month follow-up. The interview will focus on perceptions of the intervention in terms of the acceptability of the app – the extent to which participants consider the app to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention [49]. The interview topic guide will be based on the Theoretical Framework of Acceptability [49].

Economic measures

Unit costs for the economic evaluation will be taken from standard sources (e.g., PSSRU, NHS tariffs).

Data management and monitoring

Baseline and follow-up assessment data will be collected online and held securely in Data Safe Haven. All personal data will be pseudonymised. Engagement data will be collected automatically from the app and downloaded via python/pandas script into Data Safe Haven from a secure https protocol and 'Nodechef' (an online platform for hosting mobile apps). The audio recording of the semi-structured interviews on acceptability will be pseudonymised and transferred directly from the recording device to Data Safe Haven. Any participant who opts out of the study will have their data deleted.

An independent data monitoring committee will have access to the unblended comparative data and will monitor these data. The committee will make recommendations on whether there are any ethical or safety reasons to terminate the trial that the chair will report to the trial steering committee.

Analysis

The data will be analysed using R Studio [50]. The data analyst will be blinded to participants' group and the analysis plan will be finalised and uploaded onto Open Science Framework prior to the start of data analysis when the trial will be analysed in accordance with the pre-specified plan.

Descriptive statistics of participants' sociodemographic characteristics and AUDIT score will be reported for who the study recruited and who then accessed the intervention. The difference between the intervention and comparator groups on baseline characteristics will be assessed using one-way ANOVAs for continuous variables (age, AUDIT score) and 2-sided chi-squared tests (or Fisher's exact test for rare events) for

categorical variables (sex, ethnicity, education, occupation, income, COVID-19 survey measures).

ANOVAs are generally considered robust against small deviations from the normality assumption with only a small effect on the Type I error rate [51]. However, if there is evidence of significant deviation we will attempt to resolve this with transformations (e.g., logarithmic or square root transformations) or choose the nonparametric Kruskal-Wallis H Test which does not require the assumption of normality.

Analysis of primary and secondary outcomes

The primary analysis will use a conservative intention-to-treat approach to missing data with the assumption of no change for participants who do not respond to follow-up (i.e., analysis of outcome data from all randomised participants). The effect of group allocation on the primary outcome, weekly alcohol consumption[1], will be examined with a one-way ANCOVA, adjusting for baseline consumption[52–54].

Sensitivity analyses will be conducted for the primary outcome at 6 months: 1) Change between baseline and 6-month follow-up in weekly alcohol consumption estimated over the last 6 months, in standard units, derived from the quantity-frequency questions of the AUDIT.[2]; 2) responders-only (i.e. those who completed the 6-month follow-up survey); 3) using multiple imputation for non-responders on baseline characteristics (with five imputed data sets [55] combined using Rubin's rules [56]) and assuming a normal distribution with a mean of 0 and SD reflecting the variation in change among responders; 4) per-protocol approach whereby only participants who reported using the intervention or comparator at 1- or 6-month follow-up are included in the analyses, and whereby participants whose treatment was contaminated are excluded; 5) an instrument variable analysis accounting for non-use in the intervention group and contamination in the comparator by operationalising the difference in app usage between the two conditions, and 6) last observation carried forward, 7) Counterfactual analysis excluding withdrawn and first case from duplicate respondents.

Secondary analyses will assess: 1) the secondary outcomes at 1, 3 and 6 months using ANOVA and chi-squared analyses as appropriate (with self-reported weekly alcohol consumption at 1 and 3 months adjusted for baseline consumption), 2) the change over time in self-reported weekly alcohol consumption across 1-, 3- (secondary outcomes) and 6-month (primary outcome) follow-up data and 3) interactions between group allocation and baseline drinking (modelled using natural cubic splines to allow for non-linearity) on the primary outcome (alcohol consumption at 6 months) and on two secondary outcomes (self-reported alcohol consumption at 1 and 3 months).

[2] We pre-registered the primary analysis outcome variable as change in weekly consumption. Afterwards, in consultation with the Data Monitoring Committee and Trial Steering Committee, we became aware of the strengths of the follow-up score and baseline adjustment approach[53,67]. In order to be transparent we will also report change in weekly consumption.

Confidence intervals, effect sizes (partial eta squared for ANOVA analyses, odds ratios for chi-squared and regression analyses), and exact p values will be reported. Bayes Factors will be calculated using a half normal distribution to specify the predicted effect (of a 2 UK unit reduction per week) with a peak at 0 (no effect) and the standard deviation equal to the expected effect size with Robustness Regions reported to specify the range of expected effect sizes that support the same conclusion [57].

Finally, interactions will be assessed between group allocation with age, sex, ethnicity, education, occupation, income and COVID-19 measures (survey and national responses) for primary and secondary outcomes. Where significant interactions are found the findings will be stratified, drawing on the PROGRESS-Plus framework to explicitly consider health equity between the intervention and comparator group [58].

Process evaluation

The process evaluation will involve quantitative analysis of the psychological and engagement measures and qualitative analysis of interview transcripts relating to the acceptability of the intervention.

The extent of user engagement with *Drink Less* will be evaluated through descriptive statistics of the engagement measures. Detailed modelling of variations between participants will be conducted to explore variation in engagement and psychological measures by sociodemographic characteristics, baseline AUDIT scores and COVID-19 measures (survey and national responses). A mediation analysis will be conducted to determine if any effect of group allocation on the primary outcome is mediated by changes in the psychological measures. The psychological measures will also be integrated into the modelling of effectiveness outcomes for *Drink Less* to identify links between the outcomes, participant engagement and psychological measures.

Anonymised interview transcripts on the intervention's acceptability will be analysed using a combined framework and thematic analysis approach. This involves initially coding participant responses according to the TFA construct they are judged to represent best, then grouping similar responses within each construct inductively to generate content themes representing how that construct contributes to reported acceptability. Twenty-six participants will be interviewed initially (13 from each group [24]), then data will be analysed and data collection will continue in an iterative process (adding 10 participants at a time) until thematic 'meaning' saturation is reached. Meaning saturation is defined as the point at which the issues are fully understood and no further dimensions, nuances, or insights are found [59].

Health economic evaluation

The economic evaluation will take a two-stage approach to analyse the cost-utility of *Drink Less* from the NHS perspective. The first stage will be an analysis of the cost-effectiveness of the app in the trial population over the duration of the trial itself (including follow-up). Costs will include the cost of the interventions in both arms and

the cost of NHS resource use (i.e., cost of changes in service use and treatments). The cost-effectiveness analysis will take into account the total development cost of *Drink Less* but keep it separate from the incremental evaluation as there are no anticipated additional costs per user using the app. Effects will be measured in terms of i) reduction in alcohol consumption and ii) health-related quality of life, measured in Quality-Adjusted Life Years (QALYs). The cost-utility will be measured in terms of Incremental Cost-Effectiveness Ratio, the ratio between the difference in costs and difference in effects between the intervention and comparator groups.

As there can be a delay of several years between reductions in alcohol consumption and improvements in health [60], the full impacts of interventions designed to reduce alcohol consumption on health and healthcare costs may not be seen until well beyond the time horizon of an RCT. The second stage of the economic evaluation will address this limitation by using the established and widely-used Sheffield Alcohol Policy Model [61,62] to assess the longer-term cost-effectiveness of the intervention, if rolled out on a national level through active promotion to the public, over a 20-year time horizon.

Both short- and long-term evaluations will assess the impact on health inequalities using a Distribution Cost-Effectiveness Analysis framework [63,64]. Costs and QALY outcomes will be estimated separately by socioeconomic group, defined by social grade (AB, C1, C2, D or E). These group-specific results will be combined with estimates of health pre-intervention and the opportunity cost of additional healthcare spending to place the intervention on the 'health equity impact plane'. Published estimates of inequality aversion, quantifying the extent to which society is willing to trade off changes in cost-effectiveness for changes in health inequalities, will be used to identify the optimal strategy after accounting for the inequality impacts of each approach.

Ethical approval

Ethical approval has been obtained from UCL Research Ethics Committee [16799/001].

Dissemination policy

Results will be disseminated by open-access peer-reviewed journal articles, presentations at scientific conferences, press releases, a stakeholder workshop, and blog posts. NIHR authorship guidelines will be followed. Study materials, anonymised data and code will be made available on Open Science Framework (on the project page: osf.io/q8mua), and the source code for the app will be released under the GNU General Public License (v3) on Github.

Study Organisational Structure

The study involves a collaboration between University College London, University of Bristol, University of Newcastle, University of Sheffield and Imperial College London.

Patient and public involvement (PPI)

Patient and public involvement (PPI) has informed the research plans and will continue throughout this project. We have had input from a PPI network within UCL Hospital and the Alcohol Discussion Group based in Stirling (organised by the UK Centre of Tobacco and Alcohol Studies) on the lay summary and research proposal, and amended it accordingly. Members of the public will continue to be actively involved throughout this research process at various stages including: developing research tools (such as recruitment adverts, information and consent forms, and follow-up emails); analysing and interpreting findings; dissemination of findings; and implementation. We will also work with public representatives to develop dissemination plans to help ensure our findings are widely disseminated including to groups and forums that the research team may not be aware of.

We have two public representatives on the trial steering committee who will provide input on the research project based on their direct experience.

Finance

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Declaration of competing interests

CG, EP, MM, MF, MO, GL and SM have no conflicts of interest in undertaking this research. JB and EB have received unrestricted funding related to smoking cessation research. JB sits on the scientific advisory board for the SmokeFree app. MH has received unrestricted speaker fees in the last 5 years from MSD, Gillead, Abbvie unrelated to this project. EK led two Cochrane Collaboration reviews in the field of screening and brief alcohol interventions including digital interventions and is currently leading an NIHR School of Public Health Research project which involves a network meta-analysis bringing together both bodies of evidence. She has no other conflicts of interest to declare. MF received funding from Alcohol Change UK in 2019 to conduct a rapid evidence review of digital interventions for the reduction of alcohol-related harm. FG is employed by both PHE and Imperial; he has no other conflicts of interest. RB is a visiting researcher at King's College London and the University of Southampton, and has done consultancy for WHO Europe; she has no other conflicts of interest. CA has received funding for commissioned research from Systembolaget, the Swedish government-owned alcohol retail monopoly, and Alko, its Finnish equivalent; he has no other conflicts of interest.

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Appendices

Appendix 1: Overview of original AUDIT-C questions, extended AUDIT-C questions and those used in the iDEAS trial and how they will be scored.

AUDIT q1: How often do you have a drink containing alcohol?

Original AUDIT-C q1	Extended AUDIT-C q1	AUDIT-C q1 used in iDEAS trial	Scoring for full adapted AUDIT score
Never	Never	Never	0
Monthly or less	Monthly or less	Less than monthly	1
		Monthly	1
2-4 times per month	2-4 times per month	Weekly	2
2-3 times per week	2-3 times per week	2-3 times a week	3
4+ times per week	4-5 times per week	4-6 times a week	4
	6+ times per week	Daily	4

AUDIT q2: How many units of alcohol do you drink on a typical day when you are drinking?

Original AUDIT-C q2	Extended AUDIT-C q2	AUDIT-C q2 used in iDEAS trial up until 15/1/21	AUDIT-C q2 used in iDEAS trial from 15/1/21 onwards	Scoring for full adapted AUDIT score
0-2	0-2	1	1	0
		2	2	0
3-4	3-4	3	3	1
		4	4	1
5-6	5-6	5-6	5-6	2
7-9	7-9	7-9	7-9	3
10+	10-12	10+	10-12	4
	13-15		13-15	4
	16+		16+	4

AUDIT questions 3-10 are as standard.

Appendix 2: Weekly unit derivation from AUDIT-C with non-standard response options as measured in this trial.

Frequency (AUDIT-C q1)		**Quantity (AUDIT-C q2)**		**Heavy Episodic Drinking (AUDIT-C q3)**[d]	
Response option	Score	Response option	Score	Response option	Score
Never	0[a]	1 units	1	Never	0
Less than monthly	0.0729[b]	2 units	2	Less than monthly	0.8019
Monthly	0.25	3 units	3	Monthly	2.75
Weekly	1	4 units	4	Weekly	11
2-3 times a week	2.5	5-6 units	5.5	Daily or almost daily	33
4-6 times a week	5	7-9 units	8		
Daily	7	10-12 units[e]	11[c]		
		13-15 units	14		
		16+	21		

[a] if AUDIT-C q1 = Never (0), then weekly alcohol consumption =0 regardless of other responses

[b] midpoint between yearly (after which participants should respond never) and once every two months - so average of (((1/12)/4)+(0.5/4))/2 = 0.0729

[c] Extended response options (10+) will be imputed for participants responding to baseline survey and follow ups before 15/01/2021 due to an error.

[d] AUDIT-C q3: "How often you have six or more drinks on one occasion?" where a drink = 1 unit. Because it's "six or more" we add 5 to be consistent with treatment of "or more" in the quantity question and use the frequencies as above (except for daily or almost daily, which is calculated as the average difference between daily and weekly)
Never = 0
Less than monthly = 0.0729 x (6+5) = 0.8019
Monthly = 0.25 x (6+5) = 2.75
Weekly = 1 x (6+5) = 11
Daily or almost daily = (7+3.5)/2 x (6+5) = 57.75