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Evaluating the effectiveness of the smartphone app Drink Less for the reduction of alcohol consumption among hazardous and harmful adult drinkers in the UK

Submission date
20/04/2020

Recruitment status
No longer recruiting

Registration date
29/04/2020

Overall study status
Completed

Last Edited
29/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims

Hazardous and harmful alcohol consumption is a leading cause of avoidable deaths, ill-health, disability, and cancer in the UK. Health practitioners can help people to cut down by regularly asking about drinking and offering advice. Unfortunately, less than 1 in 10 hazardous and harmful drinkers in England receive this help due to barriers such as lack of time. Digital technology provides support that can overcome these barriers and has the added advantages of being widely accessible and available. Health inequalities are a particular concern with regards to alcohol consumption as the most deprived groups in society suffer the most alcohol-related harm. Digital interventions have the potential to reduce health inequalities and help disadvantaged groups when designed with input from these user groups. But there is little research comparing the effectiveness of different types of digital technologies. This study aims to evaluate the effectiveness and cost-effectiveness of digital support for helping hazardous and harmful drinkers to reduce their alcohol consumption.

Who can participate?

People are eligible to take part if they are aged 18 years or over, currently consume alcohol at a level where they would benefit from reducing their drinking, live in the UK, have access to an iOS device (i.e. iPhone, iPod touch or iPad), want to drink less alcohol, and are willing to complete three follow-up assessments after one, three and six months.

What does the study involve?

Participants will be randomly recommended one of two types of digital support for the reduction of alcohol consumption. The trial will be conducted online with adults (aged 18+) in the UK who consume hazardous or harmful levels of alcohol. Participants will be followed-up by email with a survey on their drinking behaviour using validated measures at 1, 3 and 6 months. The study findings will provide evidence on the effectiveness and cost-effectiveness of different types of digital support for alcohol reduction.

What are the possible benefits and risks of participating?
Possible benefits to participants include access to digital support to reduce their alcohol consumption, being healthier if they successfully reduce their drinking and helping to shape future research. They will also be compensated for their participation with gift vouchers up to £36 for completion of the three follow-up surveys at 1, 3 and 6 months. The researchers do not anticipate any problems related to participation in this study.

Where is the study run from?
The study is being run from University College London with other members of the research team at University of Bristol, University of Sheffield, University of Newcastle, Imperial College London, and Public Health England (UK)

When is the study starting and how long is it expected to run for?
July 2018 to November 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Claire Garnett
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Study website
https://www.ucl.ac.uk/epidemiology-health-care/research/behavioural-science-and-health/research/ucl-tobacco-alcohol-research-group-utarg/ides-trial

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44831

Study information

Scientific Title
Evaluating the effectiveness of an alcohol reduction smartphone app, Drink Less, compared with the NHS alcohol advice webpage, at reducing alcohol consumption among hazardous and harmful drinkers in the UK at 6-month follow up: a randomised controlled trial

Acronym
iDEAS

Study objectives
Current hypothesis as of 27/05/2022:
1. At a 6-month follow-up, participants (hazardous and harmful drinkers) randomised to receive the digital recommendation to use Drink Less, compared with the NHS alcohol advice webpage, will have:
1.1. Greater reduction in weekly alcohol consumption adjusting for baseline weekly consumption
1.2. Greater reduction in heavy episodic alcohol consumption
1.3 Reduction in full adapted AUDIT score
1.4. Fewer alcohol-related problems and injury, and use of healthcare services
1.5. Improved quality of life
2. At a 1- and 3-month follow-up, participants (hazardous and harmful drinkers) randomised to receive the digital recommendation to use Drink Less, compared with the NHS alcohol advice webpage, will have a greater reduction in weekly alcohol consumption adjusting for baseline weekly consumption
3. The change in alcohol-related outcomes will be moderated by the amount of user engagement with Drink Less

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Previous hypothesis:
1. At a 6-month follow-up, participants (hazardous and harmful drinkers) randomised to receive the digital recommendation to use Drink Less, compared with the NHS alcohol advice webpage, will have:
1.1. Greater reduction in weekly alcohol consumption from baseline
1.2. Greater reduction in heavy episodic alcohol consumption from baseline
1.3. Fewer alcohol-related problems and injury, and use of healthcare services
1.4. Improved quality of life
2. At a 6-month follow-up, there will be a smaller proportion of hazardous drinkers among the participants randomised to receive the digital recommendation to use Drink Less, compared

with the NHS alcohol advice webpage
3. The change in alcohol-related outcomes will be moderated by the amount of user engagement with Drink Less

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/03/2020, UCL Research Ethics Committee (Office of the Vice-Provost (Research), University College London, 2 Taviton Street, London, WC1H 0BT, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), REC ref: 16799/001

Study design
Two-arm parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hazardous and harmful alcohol consumption

Interventions
Current intervention as of 27/05/2022:
Participants who complete the baseline assessment will be randomised individually to intervention and control 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).

The intervention is the recommendation to use the Drink Less app. Drink Less is a stand-alone smartphone app-based intervention that is freely available via the Apple app store in the UK. Drink Less is for hazardous and harmful drinkers to help them reduce their alcohol consumption. Drink Less consists of seven 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. The app contains standard features such as information about the UK drinking guidelines.

On downloading the app, users are asked to complete the AUDIT, provide socio-demographic details and then receive the personalised Normative Feedback module. At this point, users reach the dashboard where there is an optional tutorial to take them through the app. Users can

access all of the app 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.

The control is the recommendation to view the alcohol advice NHS webpage 'Tips for cutting down'. The NHS webpage also has links to other webpages aimed at hazardous and harmful drinkers (e.g. 'Benefits of cutting down'). This is reflective of 'usual care' in this context of digital interventions, is the control that best serves the primary purpose of the trial, and is of direct policy relevance. Any changes to the NHS webpage during the trial will be documented.

Participants will be followed-up by email with a survey on their drinking behaviour using validated measures at 1, 3 and 6 months.

Previous intervention:
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The control is the recommendation to view the NHS webpage on alcohol advice. The NHS webpage also has links to other webpages aimed at hazardous and harmful drinkers (e.g. 'Tips on cutting down' and 'Benefits of cutting down'). This is reflective of 'usual care' in this context of digital interventions, is the control that best serves the primary purpose of the trial, and is of direct policy relevance. Any changes to the NHS webpage during the trial will be documented.

Participants will be followed-up by email with a survey on their drinking behaviour using validated measures at 1, 3 and 6 months.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 27/05/2022:
Self-reported weekly alcohol consumption estimated over the last month, in standard units, derived from the extended quantity-frequency questions of the Alcohol Use Disorders Identification Test (AUDIT) at baseline and 6 months follow-up adjusted for baseline

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Previous primary outcome measure:
Self-reported weekly alcohol consumption estimated over the last month, in standard units, derived from the extended quantity-frequency questions of the Alcohol Use Disorders Identification Test (AUDIT) at baseline and 6 months follow-up

Secondary outcome measures
Current secondary outcome measures as of 27/05/2022:
1. Self-reported weekly alcohol consumption estimated over the last month, derived from the extended quantity-frequency questions of the Alcohol Use Disorders Identification Test (AUDIT) at baseline and 1 and 3 months follow-up adjusted for baseline
2. Heavy episodic alcohol use (measured using AUDIT question 3) at 6-month follow-up
3. Full adapted AUDIT score at 6-month follow up
4. Alcohol-related problems or consequences and alcohol-related injury measured using the Alcohol Short Index of Problems at 6 months follow-up
5. Use of healthcare services measured using a shortened Service Use Questionnaire at 6 months follow-up
6. Health-related quality of life measured using the EQ-5D-5L at 6 months follow-up

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Previous secondary outcome measures:
1. Self-reported weekly alcohol consumption estimated over the last month, derived from the extended quantity-frequency questions of the Alcohol Use Disorders Identification Test (AUDIT) at baseline and 1 and 3 months follow-up
2. Proportion of hazardous drinkers measured using AUDIT score, where hazardous drinkers are those scoring >=8, at baseline and 6 months follow-up
3. Alcohol-related problems or consequences and alcohol-related injury measured using the Alcohol Short Index of Problems at 6 months follow-up
4. Use of healthcare services measured using a shortened Service Use Questionnaire at 6 months follow-up
5. Health-related quality of life measured using the EQ-5D-5L at 6 months follow-up

Overall study start date
01/07/2018

Completion date
24/11/2022

Eligibility

Key inclusion criteria

Participants will be included if they:
1. Are aged 18 years or over
2. Live in the UK
3. Are hazardous and harmful drinkers (AUDIT score>=8)
4. Have access to an iOS device (i.e. iPhone, iPod touch or iPad)
5. Want to drink less alcohol

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 5562; UK Sample Size: 5562

Total final enrolment
5602

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

Date of first enrolment
01/07/2020

Date of final enrolment
29/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 7HB

Sponsor information

Organisation
University College London

Sponsor details
Office of the Vice Provost (Research)
2 Taviton Street
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WC1H 0BT
+44 (0)20 7679 8582
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127651

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 07/11/2023:
The study protocol (and updates), including the statistical analysis plan, is available via the NIHR website.

Garnett C, Brown J, Oldham M, Loebenberg G, Michie S, Beard E, Pizzo E, Munafò M, Field M, Hickman M, Kaner E, Angus C, Greaves F, Burton R. 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 six-month follow-up: protocol for a randomised controlled trial. NIHR Public Health Research [127651]. https://fundingawards.nihr.ac.uk/award/NIHR127651

Results will be disseminated by open-access peer-reviewed journal articles, presentations at scientific conferences, press releases, a stakeholder, and blog posts. NIHR authorship guidelines will be followed

A stakeholder summit was hosted in central London in February 2023 to disseminate the trial findings to the public, research and policy stakeholders.

Trial findings were presented at the International Network on Brief Interventions for Alcohol and Other Drugs (INEBRIA) 2023 conference held in North Carolina and at the Society for the Study of Addiction (SSA) conference in Newcastle in 2023.

Previous publication and dissemination plan:
The study protocol, including the statistical analysis plan, is available via the NIHR website and any updates to the protocol will be available here too.

Garnett C, Brown J, Oldham M, Loebenberg G, Michie S, Beard E, Pizzo E, Munafò M, Field M, Hickman M, Kaner E, Angus C, Greaves F, Burton R. 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 six-month follow-up: protocol for a randomised controlled trial. NIHR Public Health Research [127651]. https://fundingawards.nihr.ac.uk/award/NIHR127651

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. A workshop will be hosted in central London on completion of the trial to engage with stakeholders.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
Current IPD sharing plan as of 07/11/2023:
The anonymous datasets analysed during the current study and code are 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.

Previous IPD sharing plan:
The anonymous datasets analysed during the current study will be made publicly available on Open Science Framework after the subsequent results publication. 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.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol article	01/02/2021	19/10/2022	Yes	No
Other publications	14/09/2023	15/09/2023	Yes	No
Dataset		29/08/2024	No	No
Results article	24/03/2024	29/08/2024	Yes	No