

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

<b>Submission date</b> 20/04/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/04/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 29/08/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input checked="" type="checkbox"/> 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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## Contact information

### Type(s)

Scientific

### Contact name

Dr Claire Garnett

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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

## **Study type(s)**

Prevention

## **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.

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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(s)**

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

### **Key secondary outcome(s)**

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  $\geq 8$ , 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

### **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  $\geq 8$ )
4. Have access to an iOS device (i.e. iPhone, iPod touch or iPad)
5. Want to drink less alcohol

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**University College London**

1-19 Torrington Place

London

United Kingdom

WC1E 7HB

**Sponsor information****Organisation**

University College London

**ROR**

<https://ror.org/02jx3x895>

**Funder(s)****Funder type**

Government

**Funder Name**

## Results and Publications

### 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](https://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](https://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?
<a href="#">Results article</a>		24/03/2024	29/08/2024	Yes	No
<a href="#">Protocol article</a>		01/02/2021	19/10/2022	Yes	No
<a href="#">Dataset</a>			29/08/2024	No	No
<a href="#">Other publications</a>		14/09/2023	15/09/2023	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes