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# Evaluating the effectiveness of a smartphone app to reduce alcohol consumption in hazardous and/or harmful drinkers

**Submission date**
10/02/2016

**Recruitment status**
No longer recruiting

**Registration date**
13/02/2016

**Overall study status**
Completed

**Last Edited**
17/12/2018

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Drinking too much alcohol (excessive alcohol consumption) is responsible for around 3.3 million deaths worldwide each year and costs the UK economy approximately £21 billion per year. Tackling excessive alcohol consumption is a public health priority and there is a need for interventions (programmes) to help people reduce the amount of alcohol they are drinking. This study is intended to test whether a smartphone app with five different sets of features can help people reduce the amount of alcohol they drink.

Who can participate?
Participants must be aged 18 and over, live in the UK, be classified as hazardous and/or harmful drinkers, want to make a serious attempt to reduce their drinking and provide an email address for them to be contacted through.

What does the study involve?
The app being tested, the Drink Less app, allows all users to set goals. The five different sets of features are: self-monitoring and feedback, action planning, normative feedback (comparison of a person's behaviour compared with what society expects); cognitive bias re-training (changing behaviour),and identity change. They exist in two forms – a 'full' version and a 'minimal' version. The full version contains all the elements that the researchers think will work and the minimal version contains a small number of features. The performance of the app is assessed by comparing the number of people who reduce how much they drink in each group. On downloading the smartphone app, Drink Less, participants are randomised to one of the 32 different experimental conditions (every combination of the 'full' and 'minimal' versions of the five modules. All participants are sent a questionnaire to answer one month after they have downloaded the app. This questionnaire asks about the participants drinking habits and how they find using the app.

What are the possible benefits and risks of participating?
This smartphone app should help people reduce their drinking. There are no predicted risks of taking part in the study.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
March 2016 to July 2016

Who is funding the study?
1. National Institute for Health Research School of Public Health Research
2. UK Centre for Tobacco and Alcohol Studies
3. Society for the Study of Addiction

Who is the main contact?
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# Additional identifiers

# Study information

### Scientific Title
Evaluating the effectiveness of five intervention modules within a smartphone app to reduce excessive alcohol consumption: protocol for a randomised control trial

### Study objectives
Participants randomly assigned to receive access to an intervention module (self-monitoring & feedback; action planning; normative feedback; cognitive bias re-training; identity change) within the smartphone app will reduce their consumption of alcohol more than those who do not receive access.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
UCL Ethics Committee under the ‘optimisation and implementation of interventions to change health-related behaviours’ project, 31/10/2014, ref: CEHP/2013/508

### Primary study design
Interventional

## Study design
Between-subject factorial randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Harmful or hazardous alcohol consumption

## Interventions
A smartphone app with five experimental intervention modules and one intervention module (setting and recording goals) provided to all users.
1. Self-monitoring & feedback
1.1. High
Ability to record drinks, graph showing units consumed, calories consumed, amount spent on alcohol. Monitor mood, productivity, clarity and sleep quality, graph illustrating how they differ on mornings after heavy drinking compared to mornings after light/no drinking. Feedback on progress towards goals: cumulatively as the week progresses, on the past week and on all previous weeks.
1.2. Low
Ability to record drinks, single graph showing units consumed. No other self-monitoring facilitated or feedback provided.
2. Action planning
2.1. High
Create implementation intentions, review implementation intentions already created, gain understanding of why to set implementation intentions.
2.2. Low
Gain understanding of why to set implementation intentions only.
3. Normative feedback
3.1. High
Questions assessing how users think they compare with others. Infographics illustrating how user's drinking actually compares with other adults and others of same gender and age.
3.2. Low
Text on risks of drinking too much (from Public Health England website).
4. Cognitive bias re-training
4.1. High
Cognitive bias modification game with users "avoiding" all alcohol related pictures and "approaching" soft drink pictures. Text included on why and how this sort of game is believed to work.
4.2. Low
Game without contingency rule that all alcohol related pictures are association with "avoid", in this version, 50% of alcohol related pictures are associated with "avoid" and 50% associated with "approach". Same for soft drink pictures.
5. Identity change
5.1. High
Memos – record messages about drinking or when drunk too much to watch in the future.
"I am" – identifying and considering those values that are important to you, and whether you do not live up to those values when you have drunk too much.
Flipsides of drinking – providing examples of the negative sides of positive alcohol expectancies.

5.2. Low
Text on how identity is an important factor in how we behave and advise to think about the undesired consequences of drinking too much.

On downloading the smartphone app, participants will have to provide informed consent, socio-demographic data, indicate their reason for using the app, provide their e-mail address (for the one-month follow-up questionnaire) and complete the full AUDIT questionnaire. After this they are provided with their AUDIT score and informed of their 'AUDIT risk zone'. At this point, all participants who meet the inclusion criteria will be randomised to one of 32 unique experimental conditions in a block randomisation method. From this point onwards, the app differs for the different experimental conditions. One month after downloading the app users will be emailed a follow-up questionnaire. If this is not completed, email reminders will be sent at periodic intervals (two days and one week). The follow-up questionnaire consists of the AUDIT and questions regarding satisfaction ratings for the app.

### Intervention Type
Behavioural

### Primary outcome(s)
Change in past week consumption of alcohol, calculated from the AUDIT ( Alcohol Use Disorders Identification Test) questions 1, 2, and 3, measured at baseline (on point of app download) and at one month follow-up.

An intention-to-treat approach will be used such that those who are lost to follow-up will be retained in the primary analysis and assumed to be drinking at baseline levels.

### Key secondary outcome(s)
1. Change in AUDIT score, assessed via measuring the difference between baseline and follow-up score on AUDIT
2. App usage data; measured by the number of screens viewed by each participant, the number of times they accessed the app and the mean time using the app
3. Usability ratings for the app:
3.1. How helpful did you find Drink Less?
3.2. How easy did you find Drink Less to use?
3.3. How satisfied are you with Drink Less?
3.4. How likely are you to recommend Drink Less to a friend?
All usability ratings will be on a 5-point scale (1: Not at all, 2: Slightly, 3: Somewhat, 4: Very, 5: Extremely).

### Completion date
28/08/2016

## Eligibility

### Key inclusion criteria
1. Aged 18 or over
2. Live in the UK
3. Have an AUDIT score between 8 and above (added 17/03/2016)
4. Confirmed they are making a serious attempt to reduce their drinking
5. Provided an email address

Initial inclusion criteria information:
3. Have an AUDIT score between 8 and 19 (inclusive)

**Participant type(s)**
Other

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 Years

**Sex**
All

**Key exclusion criteria**
Does not meet inclusion criteria

**Date of first enrolment**
18/05/2016

**Date of final enrolment**
10/07/2016

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**University College London**
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# Sponsor information

**Organisation**
University College London (UK)

**ROR**
https://ror.org/02jx3x895

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research School for Public Health Research

**Funder Name**
UK Centre for Tobacco and Alcohol Studies

**Funder Name**
Society for the Study of Addiction

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from Claire Garnett (c.garnett.12@ucl.ac.uk). Type of data: categorical and numerical data, anonymised data on the socio-demographic and drinking characteristics of participants and data on all outcome measures. Data will become available once the evaluation paper has been published in a peer-reviewed journal. There is no planned end date on which data will become unavailable. Data will be open access on Open Science Framework for anyone to access. Researchers can use the data for any types of analyses, and any mechanism. Consent was obtained from participants prior to the study. Each participant was assigned a unique number that was used to label all information. All data from the study was treated as strictly confidential and handled in accordance with the Data Protection Act 1998.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 12/03/2018 | | Yes | No |
| Results article | secondary analysis rresults | 14/12/2018 | | Yes | No |
| Protocol article | protocol | 08/07/2016 | | Yes | No |

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|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |