

Enhancing a brief online intervention to reduce alcohol consumption

Submission date 06/02/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Excessive alcohol consumption is associated with a range of negative health (e.g. liver disease, high blood pressure) and social outcomes (e.g., physical assaults, crime). In England, 23% of men and 16% of women drink at a level that puts them at an increased or higher risk of harm (2013 figures). There is therefore an important need to design interventions that can help people reduce how much alcohol they consume. Brief interventions (programs) that give people feedback on their alcohol consumption, health risk information and advice to cut down have been found to be effective in primary care. There is great potential to expand the reach of these interventions through the use of digital (online) technologies; however, current approaches have fallen short of this promise. This study will test the effects of two potential enhancements to a brief online alcohol intervention. First, online interventions can be free-roaming such that users can view material in any order or tunnelled such that users view the material in a predetermined order. Second, alcohol interventions typically suggest strategies for reducing consumption. However, research has shown that such strategies are more effective when they are linked to specific high-risk situations through the use of if-then plans (e.g. If I am out with heavy drinking friends, then I will not have a drink until I've eaten). The aim of this study is to test whether the type of planning task (choosing strategies or making if-then plans to cut down) influences the effectiveness of the intervention.

Who can participate?

All members of staff at University of Sheffield who are part of a list of research volunteers.

What does the study involve?

Participants who consent to take part are asked to complete an online questionnaire which asks them to report on their typical alcohol consumption. They are then randomly allocated to receive one of four versions of the DBIU online program and asked to view the information presented in the website. The first version involves viewing information pages in a set order which includes strategies to cut down alcohol consumption. The second version involves viewing information pages in a set order which includes plans to cut down alcohol consumption. The third version involves being able to access all of the pages relevant to them and their risk level in any order with strategies to cut down. The fourth version involves being able to access all of the pages relevant to them and their risk level in any order with plans to cut down. In all groups, the

strategies to cut down involve being presented with a list of ten strategies for cutting down taken from the Australian "Drink-Less" programme. Participants are instructed to select up to three strategies to cut down by dragging them into boxes (or to write their own strategies in the boxes). The plans to cut down involve being presented with a list of ten high-risk situations for heavy episodic drinking as well as the ten strategies for cutting down used in the strategies conditions. Participants are then instructed to form up to three if-then plans by dragging situations and strategies into boxes to form if-then plans (or to write their own if-then plans in the boxes). All participants are asked to complete further online questionnaires after one and six months to assess their alcohol consumption.

What are the possible benefits and risks of participating?

Reducing alcohol consumption can decrease the risk of both short-term alcohol-related problems and long-term negative health outcomes. It is hoped that the intervention will help people to reduce their levels of alcohol consumption. There are no major risks or discomfort are anticipated.

Where is the study conducted?

The study is run from the University of Sheffield and takes place online (UK)

When is study starting and how long is it expected to run for?

January 2017 to December 2017

Who is funding the study?

Alcohol Research UK (UK)

Who is the main contact?

Professor Paul Norman

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Contact information

Type(s)

Public

Contact name

Prof Paul Norman

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Sponsor's research project number: 149152

Study information

Scientific Title

Assessing the effects of website structure (free-roam versus tunnelled) and planning activities (choosing strategies versus forming if-then plans) on alcohol consumption in a brief online intervention

Study objectives

1. The tunnelled version of the intervention will lead to increased engagement (pages visited, time spent on website) and greater reductions in alcohol consumption than the free-roam version
2. Asking participants to form specific if-then plans will lead to greater reductions in alcohol consumption than asking them to choose general strategies
3. There will be an interaction between the structure of the intervention and the type of plan participants are asked to make, such that the effect of making if-then plans will be augmented in the tunnelled structure

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Sheffield, Department of Psychology Research Ethics Committee, 01/02/2017, ref: 012635

Study design

2 x 2 factorial randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Alcohol consumption

Interventions

Participants will complete a baseline online questionnaire to assess their typical alcohol consumption. The randomisation function in Qualtrics will then be used to randomly allocate participants to one of four versions of the “Don’tBottleItUp” (DBIU) website to provide a 2 (structure: tunnelled vs. free-roam) × 2 (planning: strategies vs. if-then plans) between-participants factorial design. The four versions that will be compared are therefore: tunnelled version with strategies to cut down, (tunnelled version with plans to cut down, free-roam version with strategies to cut down, and free-roam version with plans to cut down.

All participants, when they enter the DBIU website, will be asked to complete the AUDIT measure that will categorise them into low, increasing, higher and high/possible dependent risk categories. All participants will receive feedback on their AUDIT score (i.e. their risk category) and will be provided with information on the government’s recommendations for weekly alcohol consumption.

Tunnelled versions:

Participants who receive tunnelled versions of the DBIU website will be asked to view the following pages in a set order – i.e. information on what units mean, information on the risks of drinking (tailored to their risk category), and comparisons with national drinking levels. The next page for lower risk drinkers will comprise advice that they do not need to cut down and that they should continue to drink within recommended limits. The next page for increasing risk drinkers will include advice on strategies or plans to cut down (see below for further details). The next page for higher risk/possibly dependent drinkers will provide information on alcohol dependence and advice to consult a health professional. The final page will comprise advice on strategies or plans to cut down (see below for further details). The next page for high risk /possibly dependent drinkers will provide information on alcohol dependence and advice to consult a health professional. This will be followed by a page providing information on alcohol support services that also includes a short advice video about high risk drinking.

Free-roam versions:

Participants who receive the free-roam versions of the DBIU website, will be able to access all the pages relevant to their risk category (as described above) in any order by clicking on links to each page.

Choosing strategies to cut down:

Participants categorised as increasing and higher risk drinkers who are randomly allocated to the strategies conditions will be presented with a list of ten strategies for cutting down taken from the Australian “Drink-Less” programme (Gomel et al., 1994). Participants will be instructed to select up to three strategies to cut down by dragging them into boxes (or to write their own strategies in the boxes).

Making plans to cut down:

Participants categorised as increasing and higher risk drinkers who are randomly allocated to the planning conditions will be presented with a list of ten high-risk situations for heavy episodic drinking taken from Maddock et al. (2000) as well as the ten strategies for cutting down used in the strategies conditions. Participants will be instructed to form up to three if-then plans by

dragging situations and strategies into boxes to form if-then plans (or to write their own if-then plans in the boxes).

Intervention Type

Behavioural

Primary outcome measure

Engagement with the intervention:

1. Number of pages visited on the intervention website is measured by reviewing web-usage data (i.e. from a backend database that logs each user's activity on the DBIU website) after completion of the intervention
2. Total time spent on the intervention website is measured by reviewing web-usage data (i.e. from a backend database that logs each user's activity on the DBIU website) after completion of the intervention

Alcohol consumption:

Number of units of alcohol consumed in a typical week is measured using a retrospective seven-day alcohol diary at 6 months.

Secondary outcome measures

Engagement with the intervention:

1. Number of strategies/if-then plans made (by increasing risk and higher risk drinkers) is measured by reviewing web-usage data (i.e. from a backend database that logs each user's activity on the DBIU website) after completion of the intervention
2. Viewing an advice video (by high risk/possible dependent drinkers) versus not is measured by reviewing web-usage data (i.e. from a backend database that logs each user's activity on the DBIU website) after completion of the intervention

Alcohol consumption:

1. Number of units of alcohol consumed in a typical week is measured using a retrospective seven-day alcohol diary at 1 month
2. Number of days drinking in a typical week is measured using a retrospective seven-day alcohol diary at 1 and 6 months
3. Mean units of alcohol consumed on a drinking day is measured using a retrospective seven-day alcohol diary at 1 and 6 months
4. Peak daily consumption is measured using a retrospective seven-day alcohol diary at 1 and 6 months
5. Frequency of binge drinking is measured using a retrospective seven-day alcohol diary at 1 and 6 months
6. Hazardous drinking is measured by the AUDIT questionnaire at 6 months

Overall study start date

01/01/2017

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Members of staff at the University of Sheffield
2. Aged 18 years and over

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

At least 632 participants at baseline and 506 at six-month follow-up (as determined by an a priori power analysis)

Total final enrolment

286

Key exclusion criteria

No exclusion criteria.

Date of first enrolment

28/02/2017

Date of final enrolment

31/05/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Sheffield

Western Bank

Sheffield

United Kingdom

S10 2GW

Sponsor information

Organisation

University of Sheffield

Sponsor details

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Sponsor type

University/education

Website

<http://www.shef.ac.uk/ris/index>

ROR

<https://ror.org/05krs5044>

Funder(s)**Funder type**

Charity

Funder Name

Alcohol Research UK

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

It is planned that the results of the trial will be disseminated in the following ways:

1. A brief "Alcohol Insight" report for the ARUK website (2018)
2. Presentation at the Alcohol Research UK Annual Conference (2018)
3. Submission of a paper to a peer-reviewed journal (2018)

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Paul Norman (p.norman@sheffield.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/11/2019	07/09/2020	Yes	No