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A web-based intervention to reduce alcohol consumption in problem drinkers

Submission date
04/06/2014

Recruitment status
No longer recruiting

Registration date
13/06/2014

Overall study status
Completed

Last Edited
11/12/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Many heavy drinkers want to reduce their drinking but most do not seek treatment, which puts them at risk of health problems and alcohol dependence. Barriers to standard treatments include availability and cost. The inability to stop inappropriate behaviour (disinhibition) plays a causal role in heavy drinking. Recent research suggests that computerised training tasks that improve inhibition lead to reductions in alcohol consumption, at least in the short-term. Internet interventions (E-health) can overcome traditional barriers to treatment. The aim of this study is to assess the effectiveness of different forms of inhibition training delivered via the Internet, for the reduction of alcohol consumption in problem drinkers.

Who can participate?
Heavy drinkers aged between 25-65 who are motivated to cut down their alcohol consumption

What does the study involve?
Participants attend the test site for initial screening before completing a brief online alcohol intervention (www.downyourdrink.org.uk). They are asked to monitor their alcohol consumption for 1 week, and when they return to the laboratory 1 week later they complete initial measures of inhibition and an alcohol association task before being randomly allocated to one of four groups. Three of the groups undergo different types of inhibition training and one group undergoes sham training. They are sent a link every other day (on average) for 28 days which takes them to a secure website hosting the training assessments and self-report measures of alcohol consumption. At the end of the 28-day training period, they return to the test site and complete the measures of inhibition and the alcohol association task again. Finally, their alcohol consumption is monitored via email at 2, 4 and 6 weeks after the end of the training period.

What are the possible benefits and risks of participating?
Participants may find the training too time-consuming, in which case they will be advised to withdraw from the study. Regular monitoring of their own alcohol consumption may prompt some participants to be concerned that they have a serious alcohol problem, in which case they are advised to withdraw from the study and contact their doctor.

Where is the study run from?
Study visits take place in laboratories at the University of Liverpool (UK). The Internet intervention can be completed anywhere at the participant's convenience (e.g., home, work).

When is the study starting and how long is it expected to run for?
April 2014 to December 2015

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Matt Field
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IPHS-1314-LB-238

Study information

Scientific Title
A comparison of three types of web-based inhibition training for the reduction of alcohol consumption in problem drinkers

Study objectives
Participants randomised to the active inhibition training groups will show reductions in alcohol consumption over four weeks of training and six weeks of follow-ups, compared to those who receive a control intervention. The trialists do not make any a-priori hypotheses about differential effectiveness of the different forms of inhibition training, although they will compare them against each other. They are recruiting more participants than they require on the assumption that some participants will reduce their drinking before randomisation, and these participants may need to be excluded from primary analyses. They also predict psychological changes as a result of inhibition training: Cue-specific inhibition training will lead to improvements in cue-specific inhibition; General inhibition training will lead to improvements in general inhibition; and Alcohol No-Go training will lead to changes in automatic affective alcohol associations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Liverpool Research Ethics Committee, 07/02/2014, ref. IPHS-1314-LB-238

Study design
Phase II single-site randomised double-blind controlled intervention

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Alcohol use disorders

Interventions
All participants will complete a brief online alcohol intervention (www.downyourdrink.org.uk) before one-week of self-monitoring of alcohol consumption, before randomisation to one of the following groups. All participants will complete their training sessions on the Internet every other day, on average, for 28 days (maximum of 14 training sessions in total):
1. Cue-specific inhibition training. Participants will rapidly categorize alcohol and neutral pictures by pressing keys on their keyboard. On 50% of alcohol trials (25% of all trials) they will be required to inhibit this response whenever they see the stop signal (two red lines superimposed over the alcohol image). The stop signal initially occurs at 250 ms after stimulus presentation. Performance is tracked and with every successful training session (participant successfully inhibits on > 50% of inhibition trials) the subsequent training session becomes more difficult: the stop signal appears 10 ms later, which makes inhibition more difficult. There will be 200 trials (100 alcohol images and 100 neutral images), with 50 inhibition trials, in each training session.
2. General inhibition training. Participants will rapidly categorize arbitrary stimuli (the letters 'X' and 'O') by pressing keys on their keyboard. On 50% of trials they will be required to inhibit this response whenever they see the stop signal (two red lines superimposed over the letter). The stop signal initially occurs at 250 ms after stimulus presentation. Performance is tracked and with every successful training session (participant successfully inhibits on >50% of inhibition trials) the subsequent training session becomes more difficult: the stop signal appears 10 ms later, which makes inhibition more difficult. There will be 200 trials (100 letter X and 100 letter O), with 50 inhibition trials, in each training session.
3. Alcohol No-Go training. On each trial, an alcohol or neutral picture will be presented with the letter 'P' or 'R' superimposed in the corner of the picture. The letter P is the 'Go' cue that signifies that participants should rapidly respond by pressing the space bar. The letter R is the No-Go cue that signifies that participants should inhibit their response on that trial. The Go cue will always occur on neutral picture trials and the No-Go cue will always appear on alcohol picture trials, thus participants will always inhibit in response to alcohol pictures. There will be 200 trials (100 alcohol No-Go trials and 100 neutral Go trials) in each training session.
4. Control (sham training). Participants will rapidly categorize alcohol and neutral stimuli by pressing keys on their keyboard. There will be no inhibition trials. There will be 200 trials (100 alcohol images and 100 neutral images) in training session.

Added 07/02/2017:
A random number generator was used for randomization; follow-up period was 6 weeks after intervention ceased.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Alcohol consumption, specifically the total number of units consumed and the number of heavy drinking days (defined as >60 g of alcohol for men and >40 g alcohol for women), measured

using a two-week retrospective alcohol diary (the Timeline Follow-Back) at baseline, after the first two weeks of intervention and after the second two weeks of intervention

Secondary outcome measures
The number of abstinent days, measured using a two-week retrospective alcohol diary (the Timeline Follow-Back) at baseline, after the first two weeks of intervention and after the second two weeks of intervention

Overall study start date
01/04/2014

Completion date
12/12/2015

Eligibility

Key inclusion criteria
1. Aged 25-65
2. Heavy drinker (14+ UK units per week if female, 21+ units per week if male)
3. Have computer and internet access

Note: 1 UK unit = 8 g of alcohol

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
268

Key exclusion criteria
1. History of alcohol or substance use disorder
2. Attention deficit hyperactivity disorder (ADHD)
3. Previous or current treatment for alcohol or substance use disorder or an impulse control disorder

Date of first enrolment
07/04/2014

Date of final enrolment
12/12/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of Liverpool
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (ref: MR/K001558)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be submitted to a peer-reviewed journal in spring 2017.

Intention to publish date
01/05/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Matt Field (m.field@liv.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/08/2014		Yes	No
Results article	results	01/12/2018		Yes	No