

Internet-based cognitive bias modification for binge drinking prevention ('binge drinking' chez les jeunes: etude pilote de la prévention de l'alcoolisme par un réentraînement attentionnel en ligne)

Submission date 27/05/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/05/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Binge drinking is a term used to describe the consumption of lots of alcoholic drinks in a short period of time (hours to days) with the sole purpose of becoming drunk (intoxicated). Binge drinking is well known to have many negative effects on a person's physical and mental health, particularly in young people whose brains are still developing. There is some evidence to suggest that people who regularly binge drink are more sensitive to environmental stimuli related to alcohol, such as advertising. This is called attentional bias. An attentional bias towards alcohol may make a person who binge drinks more likely to engage in that behaviour. It may also make it harder for them to not drink, even if that is what they feel they would prefer, because it affects their will power. The aim of this study is to test an online attentional bias modification programme. The study will assess whether people who engage in binge drinking behaviour show reduced attentional bias towards alcohol-related stimuli following completion of the programme.

Who can participate?

Adults aged 18-29 who exhibit binge drinking behaviour and have a good command of French.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) take part in 8 online sessions of the attentional bias modification programme. Those in group 2 (control group) take part in 8 online sessions of a modified version of the attentional bias modification programme; it is not considered to have any therapeutic effect for the participant. All participants take part in the programme sessions over a four week period. Each session takes approximately 20 minutes to complete. Participants are asked to complete questionnaires at the start of the study, at the end of the 8 programme sessions, and again 1 month later.

What are the possible benefits and risks of participating?

There are foreseeable risks related to the use of the Attentional Bias Modification procedure. Meanwhile, we expect two potential benefits to the participants, a possible reduction in alcohol consumption after the completion of eight sessions of the intervention task and a monetary remuneration at the end of the study.

Where is the study run from?

University of Geneva (Switzerland)

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

July 2013 to March 2016

Who is funding the study?

Information Technology Commission of the University of Geneva (Switzerland)

Who is the main contact?

Dr G Ceschi

Ekaterina.Plys@unige.ch

Study website

<http://icbm.unige.ch/>

Contact information

Type(s)

Scientific

Contact name

Dr Grazia Ceschi

ORCID ID

<http://orcid.org/0000-0002-2065-6870>

Contact details

40, boulevard du Pont-d'Arve

Geneva

Switzerland

1211

+41 22 379 8064

Ekaterina.Plys@unige.ch

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Internet-based cognitive bias modification for binge drinking prevention: protocol for a randomised controlled trial

Acronym

iCBM-A Binge Drinking

Study objectives

1. Binge drinkers trained to attend to alcohol-unrelated stimuli will decrease their attentional bias towards alcohol and their alcohol consumption. We expect this effect to last for at least one month.
2. The attentional bias modification will mediate changes in alcohol consumption. Additionally, we will explore the effects of the Cognitive Bias Modification of Attention procedure on participants' subjective craving for alcohol. We expect that the reduction of attentional bias will be accompanied by a decrease in craving.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the University of Geneva, 19/07/2013.

Study design

Randomised controlled single-centre interventional study

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Alcohol consumption (binge drinking behaviour)

Interventions

1. Intervention group: eight sessions of an internet-based attentional bias modification programme. During the intervention, 95% of the probes will appear at the spatial location previously occupied by the alcohol-unrelated picture (contingency ratio of 95:05). The intervention takes place over four weeks, and each session lasts about 20 minutes.
2. Control group: eight sessions of the internet-based control task. For the control sessions, probes will replace alcohol-related pictures as often as alcohol-unrelated pictures (contingency of 50:50). The sessions take place over four weeks, and each session lasts about 20 minutes.

Intervention Type

Behavioural

Primary outcome measure

Baseline and post-intervention:

1. Self-reported assessment of alcohol consumption during last two weeks (Time-Line-Follow-Back)
2. Attentional bias towards alcohol (Dot Probe Detection Task)

One month follow-up:

1. Self-reported assessment of alcohol consumption during last two weeks (Time-Line-Follow-Back)

Secondary outcome measures

1. Self-reported assessment of binge drinking behaviour. Participants will be asked to evaluate their average alcohol consumption during last six months using the following questions:

- 1.1. How many times per week do you consume alcoholic drinks?
- 1.2. On a typical day when you are drinking, how many alcoholic drinks do you have?
2. Self-reported drug consumption (Alcohol, Smoking and Substance Involvement Screening Test)

Baseline:

1. Self-reported craving for alcohol (Alcohol Craving Experience Questionnaire)
2. Self-reported readiness to change alcohol use (The Stages of Change Readiness and Treatment Eagerness Scale)
3. Self-reported depressive symptoms (Beck depression inventory)
4. Self-reported anxiety (Spielberger State-trait anxiety inventory)
5. Social desirability (Crowne-Marlowe Social Desirability Scale)
6. Demographic data

Post-intervention and one month follow-up:

1. Self-reported craving for alcohol (Alcohol Craving Experience Questionnaire)

Overall study start date

15/07/2013

Completion date

30/05/2016

Eligibility

Key inclusion criteria

1. Aged 18-29
2. Presents with binge drinking behaviour: consumption of over five (for men) or four (for women) standard alcoholic drinks in a row at least once per fortnight during the previous 6 months

3. Attentional bias towards alcohol
4. Internet access
5. Good command of French

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

29 Years

Sex

Both

Target number of participants

80

Key exclusion criteria

1. Scores more than 3 on the Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) for all addictive substances except alcohol and nicotine
2. No psychotropic medication change or dosage change within the past three months from study start
3. Introduction of, or change in, psychotherapeutic treatments within 3 months preceding study start

Date of first enrolment

20/08/2015

Date of final enrolment

15/03/2016

Locations**Countries of recruitment**

Switzerland

Study participating centre**University of Geneva**

Abnormal Emotion and Trauma Laboratory

40, boulevard du Pont-d'Arve

Geneva

Switzerland

1211

Sponsor information

Organisation

University of Geneva

Sponsor details

Abnormal Emotion and Trauma Laboratory
40, boulevard du Pont-d'Arve
Geneva
Switzerland
1211

Sponsor type

University/education

Website

<http://www.unige.ch/fapse/psychoclinique/upcet-1/>

Organisation

Geneva University Hospitals

Sponsor details

Service d'addictologie
70C, Grand pré
Geneva
Switzerland
1206

Sponsor type

Hospital/treatment centre

Organisation

University Hospital of Geneva

Sponsor details

Sponsor type

Not defined

Website

<http://www.hug-ge.ch/>

ROR

Funder(s)

Funder type

University/education

Funder Name

Information Technology Commission of the University of Geneva (Switzerland)

Funder Name

Social Affaire and Health Department of the State of Geneva Grant: N 180490

Results and Publications

Publication and dissemination plan

The protocol of our randomized controlled trial is expected to be published in a peer-reviewed journal *Frontiers in Psychiatry* in November 2015. The results about efficacy of our internet-based cognitive bias modification platform are planned to be submitted to international peer-reviewed journals after the end of the experiment (expected for December 2016).

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration