Retraining automatic cogntieve processes in problematic alcohol use.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29018

Source
NTR

Brief title
TOP

Health condition

Problematic alcohol use (Problematisch alcoholgebruik)

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: Dutch National Science Foundation, N.W.O. (VICI grant 453-08-001).

Intervention

Outcome measures

Primary outcome

The main outcome measure is change in the number of drinks consumed in the past 14 days, as assessed at baseline and three months after the intervention, using the TLFB method. It is expected that, for each of the CBM paradigms, participants in the intervention conditions will show a greater decrease in weekly alcohol use than participants in the control conditions.

Secondary outcome

The change in automatic cognitive biases will be assessed at the pre and post-intervention measurement as a manipulation check, using both the trained measures of attentional bias, approach bias and alcohol/go bias, as well as ‘untrained’ tasks to test generalization effects: the emotional Stroop task (as a measure of attentional bias) and the Brief Implicit Association Task to measure approach associations and positive (valence) associations with alcohol.

Secondary outcome measures include the number of drinks consumed in the past 14 days, the percentage of participants drinking within the limits for sensible drinking (set by the British Medical Association: a maximum of 21 standard units of alcohol per week for men, and 14 units a week for women) and binge drinking, all measured with the TLFB at the pre and post-measurements, and the 3, 6 and 12 month follow-ups.

Other secondary outcome measures (assessed at each measurement point) are: Alcohol-related problems (AUDIT), Craving (Desires for Alcohol Questionnaire), and Self-efficacy Brief Situational Confidence Questionnaire).

Quality of life (EQ-5D) and the economic costs stemming from health care uptake and productivity losses associated with problematic alcohol use (Trimbos/iMTA Questionnaire for Costs associated with Psychiatric illness, TiC-P) will be assessed at baseline and at the 3, 6, and 12 month follow-up.

Study description

Background summary

The aim of the current study is to investigate the effectiveness of three online CBM paradigms among problem drinkers aged 18-64 years: attentional bias retraining, alcohol/no-go training (targeting memory bias), and approach bias retraining. The main goal of the study is to test the effects of CBM on alcohol use at 3 months after the intervention, with changes in the number of alcoholic drinks consumed in the past two weeks as the primary outcome measure.

Study objective

It is expected that, for each of the three CBM paradigms, participants in the intervention conditions will show a greater decrease in weekly alcohol use than participants in the control

conditions. Generalization of each specific CBM paradigm to other biases will be explored, as will the effects of exposure to the various combinations of CBM paradigms. It is expected that each CBM paradigm will decrease or reverse the specific bias it trains and that these changes will mediate the effects on alcohol use. Furthermore, it is expected that participants with strong automatic biases and/or low working memory capacity and inhibitory control will benefit more from CBM than participants with weaker biases and/or stronger executive functions.

Study design

Baseline assessment, post-intervention assessment (about 6 weeks after baseline), follow-ups (3,6 and 12 months after the post-intervention assessment).

Intervention

Each of the twelve CBM sessions consists of three tasks (of about 15 minutes each): attentional bias retraining, alcohol/no-go training, and approach bias retraining. The three CBM paradigms were designed to be as similar as possible, to enable clear comparisons of the training effects.

1. Attentional bias retraining:

Attentional bias is assessed and trained using the visual probe task. In this task, a picture of an alcoholic and a picture of a non-alcohol beverage are presented next to each other on the screen for 500 ms. When the pictures disappear, a small arrow pointing up or down appears at the location of one of the pictures. Participants are instructed to respond to the direction of the arrow, by pressing the corresponding arrow key on the keyboard. Attentional bias for alcohol (i.e. faster detection of the direction of the probe when it appears at the location of the alcohol picture, where attention was already focused, than when it appears at the location of the soda picture) has been related to alcohol use and craving.
In the assessment block, the arrow replaces the picture of the alcoholic beverage (alcohol trials) and the picture of the non-alcoholic beverage (non-alcohol trials) equally often. Attentional bias for alcohol is computed by subtracting RTs on alcohol trials from those on non-alcohol trials. In the CBM block, participants in the experimental condition will be trained to direct their attention away from alcoholic beverages towards non-alcoholic beverages, by exposing them only to non-alcohol trials, while participants in the placebo condition receive 50% alcohol and 50% non-alcohol trials (as in the assessment block).

2. Alcohol/no-go training:

Alcohol related memory bias (positive associations with alcohol) is measured and trained using the alcohol/no-go task. In this task, a picture of an alcoholic or non-alcoholic beverage

is presented for 1500 ms, together with a go (i.e. the letter ‘p’) or no-go cue (‘f’) which is displayed randomly in one of four corners of the picture. Participants are instructed to respond to the presented letter, i.e. by pressing the spacebar as quickly as possible when they see the letter ‘p’, and do nothing (wait until picture disappears) when they see the letter ‘f’. The contingency between the letter and the response (p = press and f = inhibit, versus f = press and p = inhibit) is counterbalanced across participants. Previous studies on alcohol/no-go training have not investigated whether heavy drinkers show an ‘alcohol/go bias’, i.e. faster reaction times for alcohol/go trials compared to soda/go trials. In the current study, an assessment block is included (similar to the assessment block in the attentional and approach bias retraining) in order to explore whether problem drinkers demonstrate an ‘alcohol/go bias’ at baseline, and whether this bias is influenced by alcohol/no-go training.

In the assessment block, the pictures of alcoholic and non-alcoholic beverages are presented equally often with a go and with a non-go cue. Alcohol/go bias is computed by subtracting RT’s on alcohol/go trials from those on non-alcohol/go trials. In addition, the number of errors (incorrect go responses) can be compared between alcohol and non-alcohol no-go trials. In the CBM block, participants in the experimental condition will be trained to inhibit their response to alcohol, by exposing them only to alcohol/no-go trials and non-alcohol/go trials, while for participants in the placebo condition there is no contingency between the content of the picture and the required response (as in the assessment block).

3. Approach bias retraining:

Approach bias is trained with the modified Approach-Avoidance Task (AAT). In this paradigm, a picture of an alcoholic or non-alcoholic beverage is presented, which is tilted 3 degrees to the left or right. Participants are instructed to respond to format of the picture, e.g. by pushing all pictures tilted to the right away from them, and pulling all pictures tilted to the left towards them. The contingency between the format of the picture and the response (left = push and right = pull, versus left = pull and right = push) is counterbalanced across participants. Picture size gradually increases when the pull-key is pressed, while it decreases when the push-key is pressed. Heavy drinkers have been found to show an approach bias for alcohol, i.e. faster response to alcohol/pull trials than to alcohol/push trials.

In the assessment block, the pictures of alcoholic and non-alcoholic beverages are presented equally often in push and in pull format. Approach bias for alcohol is computed by comparing RTs for push, pull, alcohol and non-alcohol trials ((alcohol/push - alcohol/pull) - (non-alcohol/push - non-alcohol/pull)). In the CBM block, participants in the experimental condition will be trained to avoid alcohol, by exposing them only to alcohol/push and non-alcohol/pull trials, while for participants in the placebo condition there is no contingency between the content of the picture and the required response (as in the assessment block).

Contacts

Public
ADAPT lab, Developmental psychology
University of Amsterdam
Weesperplein 4 (room 6.22)
Denise Deursen, van
Amsterdam 1018 XA
The Netherlands
+31 (0)20 5256212
Scientific
ADAPT lab, Developmental psychology
University of Amsterdam
Weesperplein 4 (room 6.22)
Denise Deursen, van
Amsterdam 1018 XA
The Netherlands
+31 (0)20 5256212

Eligibility criteria

Inclusion criteria

Participants are included if they:

1. Are 18-65 years old;

2. Have an AUDIT score of 8 or above;

3. Drank ≥15 (women) or ≥21 (men) alcoholic drinks per week on average in the past 14 days;

4. Have (almost) daily internet access;

5. Do not currently receive professional help for alcohol use problems.

Exclusion criteria

Participants who currently receive professional help for alcohol use problems are excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2012
Enrollment:	351
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3712
NTR-old	NTR3875
Other	Ethics committee of the psychology department. of the University of Amsterdam / N.W.O. : 2010-OP-1117 / VICI grant 453-08-001;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A