ISRCTN01005959 https://doi.org/10.1186/ISRCTN01005959

TOP (Training op Onbewuste Processen) training: Retraining automatic cognitive processes in alcohol addict outpatients

Submission date
26/09/2013

Recruitment status
No longer recruiting

Registration date
24/10/2013

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Although many drug users are aware of the harmful effects of drug abuse and seek help to abstain from using drugs, the risk for lapse and relapse remains extremely high. This destructive behavior has lead us to study the reasons and mechanisms underlying drug-seeking conduct, even when explicit motivations to quit it are present. The main point is that rational and conscious mental processes do not solely guide the behavior, which appears to be also affected by other mechanisms that go beyond individual intentionality. Hence, what are these mechanisms for this contrasting behavior? Why people should continue in engaging in harmful and dysfunctional behaviors? A recent study stated the existence of two parallel and interacting processing systems guiding human behavior: a fast, impulsive and unconscious system and a slow, relatively controlled, reflective, or conscious, system. According to this perspective, addiction problems can result from an imbalance between impulsive reactions towards the drug-use (e.g., approach tendencies and attentional bias) and a weak reflective and voluntary control. This imbalance then makes the individual more at risk of being triggered by drug-cues and automatically prompted to fall into the addictive behavior loop. In light of this dual-process model of addiction, new interventions aimed at the treatment and modification of the impulsive processes, or 'cognitive biases', involved in addiction, have been developed, namely the Cognitive Bias Modification (CBM) techniques. The aim of this study is to investigate the effectiveness of two computerized CBM trainings among adult alcohol addict outpatients: the alcohol attentional bias and approach bias re-trainings. The main goal is to test the main and added effects of the two CBMs on the remission progress from the alcohol dependence immediately after the treatment and after 3 months, with changes in the number of lapse or relapse episodes, treatment status and therapeutic outcome as the primary outcome measures.

Who can participate?
Adult alcohol addict outpatients.

What does the study involve?
Participants will be randomly allocated to one of four experimental groups, which combine the real and control (placebo/dummy) versions of the attentional and approach bias CBM retrainings:

1. Attentional bias retraining + approach bias retraining
2. Attentional bias retraining + approach bias placebo
3. Attentional bias placebo + approach bias retraining
4. Attentional bias placebo + approach bias placebo
Participants will participate in a total of 15 sessions: two baseline measurement sessions, 11 training sessions, a post-intervention measurement session and a follow-up measurement session after 3 months. Each training session will start with a brief motivational interview with a trained experimenter, focusing on the support and promotion of participants' motivation and self-efficacy in taking part in the trial and perform the CBM sessions. After the interview, participants complete the two CBM tasks. The post-treatment and follow-up measurement sessions will evaluate any change in the participants' clinical and therapeutic status (number of lapses/relapses, actual treatment, clinical variables evaluation), as well as the effects of the CBM training on modifying the alcohol-related impulsive processes (i.e., cognitive biases) and mediating the clinical outcomes.

What are the possible benefits and risks of participating?
Participants will be less likely to lapse or relapse and will gain a greater control over their reactions towards alcohol. There are no concrete risks of participating.

Where is the study run from?
Public Health service for addiction disorders (SerD - Servizio per le Dipendenze) at the Public Hospital of San Donà di Piave (ULSS10), (VE) Italy.

When is the study starting and how long is expected to run for?
The study started in July 2013 and will run until March 2015.

Who is funding the study?
University of Padova, Department of Philosophy, Sociology, Education and Applied Psychology (FISPPA), Italy.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Combined Cognitive Bias Modification (CBM) training within a brief motivational interview framework in alcohol addict outpatients: for whom is the combination most effective?

Study objectives
It is expected that, for each of the two CBM trainings, participants in the intervention condition will show a lower percentage of lapse or relapse and a positive modification of their treatment status than participants in the control condition. Generalization of each specific CBM paradigm to other biases is explored, as well as the additive effect of the combination of the two CBM trainings. It is expected that each CBM paradigm will decrease or reverse the specific targeted bias and that these changes can possibly mediate the effects on the clinical outcome. It is also expected that participants with strong automatic biases and/or low inhibitory control will benefit more from CBM than participants with weaker biases and/or stronger executive functions. The effect of several independent clinical variables on the primary and secondary clinical outcomes will be further explored, in particular the type of parallel treatments participants are undergoing (medication intake and/or other psycho-therapeutic interventions).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Psychology Departments of the University of Padova; 08/02/2013; ref: Pr. 1242

Study design
Single-centre randomised double-blind trial, 2x2 factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Alcohol addiction

Interventions
A 2x2 factorial design with the following four arms:
1. Attentional bias retraining+approach bias retraining
2. Attentional bias retraining+approach bias placebo
3. Attentional bias placebo+approach bias retraining
4. Attentional bias placebo+approach bias placebo

Participants are allocated randomly to one of the four conditions, stratified by gender and medication intake (alcohol agonist and antagonist medications, psychoactive medications, other medication).

Research Flow for all four treatment arms:
1. Recruitment
2. Baseline assessment: Two sessions in one week. After the first session the participant is randomly allocated to one of four conditions.
3. Training: 12 sessions in 5-6 weeks (5 days interval between sessions)
4. Post-test: post-test assessment on the 11th training session (participants are unaware of the upcoming assessment session to avoid any confounding variable on the performance)
5. Follow-up: after 3 months.

Each CBM training session consists of a first part of brief motivational interview (about 15 minutes) and two tasks (about 15 minutes each): the attentional bias retraining and the approach bias retraining. The two tasks were designed to be as similar as possible (similar pictures and number of trials), to enable comparisons of the training effects.
1. Brief Motivational Interview:
At the beginning of each session, participants will undergo a brief motivational interview with the investigator (15 minutes), focusing on the training experience and related feelings and thoughts. The interview reviews the previous training session performance and related perceptions, and introduces the incoming session objectives (decreasing error rates and/or increasing response speed) to renew and strengthen participants' motivation. The interview is conduced according to a brief semi-structured interview protocol based on the Motivational Interviewing approach (MI - Miller & Rollnick, 1991/2002), which adheres to the theoretical principles of Prochaska et al.s Transtheoretical Model of Behavior Change (Prochaska, DiClemente, & Norcross, 1992; Prochaska , Norcross, & DiClemente, 1994). As a general guideline, the brief MI should start with the open discussion about the previous session, recover the main objectives and motives related to the participation in the clinical trial, carefully listen to the participants perceptions of the tasks and normalize their experience, stimulate, when needed, and generally support the feelings of self-efficacy and self-confidence in actively performing the tasks, reinforce the commitment and the efforts in each session, keep the

participants attention to the concrete advantages and motives that are guiding their therapeutic progress. According to the TTM perspective, the change processes involved in the brief MI protocol here devised deal with the behavioral processes, namely the self-efficacy and management reinforcement, the stimuli control, and the support relationship, leaving the in-depth engagement of the experiential processes to the individual clinical setting.

2.1. Attentional bias retraining:
The alcohol-triggered attentional bias is assessed and re-trained via the Visual Probe Task (VPT). The VPT is a computerized reaction time task in which participants are asked to respond to probes located in two different positions on the computer screen. Each trial starts with a fixation cross in the middle of the screen (between 500-1000 ms, uniformly distributed), followed by the simultaneous presentation of an alcohol and a soft drink picture (500 ms) next to each other. Immediately after the stimuli presentation, a small arrow pointing upwards or downwards replaces one of the two pictures (measuring faster detection of alcohol-related stimuli) or is positioned on top of one of the two pictures (measuring the difficulty in the attentional disengagement from alcohol-related stimuli) (500 ms). Participants are asked to respond to the arrow direction as fast as possible by pressing the corresponding keys of the keyboard. Attentional bias for alcohol, as measured by faster responses when the arrow are located at the alcohol stimuli place, where the attention was already focused, than when are positioned at the location of the soda pictures, has been related to alcohol use/abuse and craving. In the assessment block, the arrow replaces alcohol (alcohol trials) and soft drinks pictures (soda trials) equally often. Attentional bias is computed by subtracting RTs on alcohol trials from those on soda trials in the two arrow presentation conditions. In the CBM block, participants in the experimental condition are trained to direct their attention away from alcoholic beverages towards soda drinks, by exposing them only to soda trials, whereas participants in the placebo condition perform the task as in the assessment version (50/50 proportion alcohol and soda trials).

2.2. Approach bias retraining:
The alcohol-triggered approach bias is assessed and re-trained via the modified Approach Avoidance Task (AAT). Participants are asked to react to the stimuli format (3 degrees left- or right-tilted) and ignore the stimuli contents (alcohol and soft drinks pictures), using the corresponding keys on the keyboard. According to the stimuli format, participants have then to push away or pull closer the stimuli (e.g., left-tilted=push, right-tilted=pull). Participants responses come along with a zooming effect, which increases picture size in the pulling closer response and decreases it in the pushing away response. Alcohol addicts and heavy drinkers have been found to present an approach bias towards alcohol, i.e. they give faster responses to alcohol/pull trials than alcohol/push trials.
In the assessment block, alcohol and soft drinks pictures are presented equally often in the push and pull format. Approach bias for alcohol is computed by comparing RTs for push, pull, alcohol and soda trials [(alcohol/push - alcohol/pull)-(soda/push-soda/pull)]. In the CBM block, participants in the experimental condition are trained to avoid alcohol, by exposing them only to alcohol/push and soda/pull trials, whereas participants in the placebo condition perform the task as in the assessment version (equal proportion of alcohol and soft drinks presented in both formats).

Joint/secondary sponsor details:
Public health service for addiction disorders
San Donà di Piave (Italy) (ULSS10 - SerD)

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in the participants' treatment status, as assessed by the presence of any lapse or relapse during the 3 months after the intervention and the treatment status (medication intake, other form of therapeutic interventions), and clinical outcome, as defined by the clinical evaluation of the participants' therapeutic progress (successful or not). It is expected that, for each of the two CBM paradigms, participants in the real intervention condition will show a lower percentage of lapse or relapse and positive modification of their treatment status than participants in the control condition.

Secondary outcome measures
The change in the automatic alcohol cognitive biases is assessed at the pre- and post-intervention measurement sessions, using both the trained measures of attentional bias and approach bias, as well as different tasks to test the generalization effects: the Color Stroop Task (as a measure of inhibitory executive control ability) and the Brief Implicit Association Test (as a measure of approach associations with alcohol).
The approach and attentional bias are eventually assessed during the follow-up measurement session using the same stimuli of the post-intervention session, to check for the duration of the training effects.

Secondary outcome measures (assessed at each measurement point) also include:
1. Other substances abuse (CORE questionnaire)
2. Motivation to treatment (Motivation to Treatment questionnaire)
3. Alcohol-related problems (AUDIT)
4. Craving (Obsessive Compulsive Drinking Scale)
5. Anxiety (State Trait Anxiety Inventory - Y questionnaire)
6. Depression symptoms (Beck Depression Inventory-II)

Overall study start date
01/07/2013

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Aged over 18 years, both female and male
2. Primary diagnosis of alcohol addiction disorder (DSM-IV-TR diagnostic criteria)
3. Alcohol abstinence for at least two months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
At least 120

Key exclusion criteria
1. Neuro-cognitive problems or visual or hand-motoric handicaps
2. Severe neurological disorders (e.g., Korsakoff syndrome)
3. Comorbity with psychotic disorders
4. Low fluency in Italian language

Date of first enrolment
15/06/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Italy

Study participating centre
University of Padova
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Sponsor information

Organisation
University of Padua

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Sponsor type
University/education

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ROR
https://ror.org/00240q980

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Padova

Alternative Name(s)
University of Padova, University of Padua, UNIPD

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/02/2015		Yes	No