The effect of internet-based working memory training on automatic preferences for alcohol use in a clinical sample.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35211

Source
ToetsingOnline

Brief title
Working memory training and alcohol.

Condition

- Other condition

Synonym
Addiction of alcohol, alcohol dependence

Health condition

Verslaving (alcohol)

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Alcohol, Automatic preferences, Training, Working memory

Outcome measures

Primary outcome

We are interested in the difference in performance of our participants on the

three timepoints (pretest, posttest and follow-up)

- Working memory performance (visuospatial working memory taak, backward digit

span, letter span taak)

- Automatic preferences for alcohol (Implicit Association Test)

See section 7.1.1 of the research protocol for an elaborated

desciption/information.

Secondary outcome

- Alcohol use and relapse (Time Line Follow Back Questionnaire)

- Working memory (equal, but not trained task)

- Executive functioning (Stroop task, Concept Shifting Test, Letter Digit

Coding Test)

- Control (Mastery questionnaire)

- Approach/avoidance of alcohol (Approach and Avoidance of Alcohol

Questionnaire)

- Craving (Visual analogue scale)

- Motivation to change drinking behavior questionnaire

- Self-efficacy questionnaire

- Intelligence (Groninger Intelligence Test)

- Memory (verbal learning test)

- Psychological wellbeing (Symptom Check List 90)

- Completement of the working memory training

- Number of excluded subejcts/ drop outs

See section 7.1.2 en 7.1.3 of the research protocol for an elaborated

desciption/information.

Study description

Background summary

Alcohol abuse causes disruptions in the human cognitive domain. For instance planning, attention, inhibition of inappropriate actions and working memory are affected by long-term alcohol abuse. It has been shown that an impairment of the aforementioned executive functions may result in maladaptive behaviour. For instance, drinking behaviour can get out of control, due to the fact that automatic impulses may not be suppressed appropriately. Working memory forms/is the basis for learning, planning, organizing, staying focused, control of impulses and reasoning.

Study objective

The primary aim of this study is to investigate the effect of a computer-based WMT on executive functioning (and especially WM performance) in a clinical sample of alcohol dependent subjects. Secondly, we will examine if an improvement in WM is related to improved control over drinking behaviour (e.g. the amount of consumed alcohol beverages and alcohol cravings). Thirdly, we are

interested whether this improvement in cognitive functioning is additional to the effect of the regular treatment, especially in the long run.

Hypotheses:
1.WM performance will be improved in the experimental group (training condition) after WMT in comparison with the two control groups (control condition).
2.Alcohol cravings and automatic preferences (impulses) for alcohol will be reduced in the experimental group after WMT in comparison with the two control groups. This reduction is linked to the improvement in WM performance.
3.Chronic heavy drinkers, participants with relatively strong automatic preferences for alcohol, will profit the most from this WMT in comparison with participants who have lower automatic preferences for alcohol. Their WM performance will improve and there will be less alcohol cravings, less automatic preferences (impulses) for alcohol and a lower relapse rate.
4.The (possible) improvement in cognitive functioning after WMT will be additional to the effect of the regular treatment.

Study design

We will use a double-blind randomized trial. The study will have a 3x4 split-plot design (with time-point as within subject factor and group (working memory training versus active control condition/passive control condition) as between subjects factor). Before and after training, we will measure working memory performance and drinking behaviour. After 3 months, a follow-up measurement will take place. A neuropsychological assessment (measurement of intelligence and cognitive functioning) will be surveyed by the researchers at pre-test.

Intervention

WMT is an intervention that is used to strengthen executive functions (Klingberg, 2010). It is found that WMT is highly relevant for reducing clinical symptoms and to improve WM capacity and other cognitive abilities in a variety of clinical samples (Beck et al., 2010; Borella et al., 2010; Klingberg et al., 2005; Houben, Wiers & Jansen, 2011).

The WMT used in the present study is based on the exact same tasks used in the study of Houben, Wiers and Jansen (2011) and the results of this study were promising. The participants in this study showed an improvement in WM performance after WMT. Their WMT was based on the ideas, tasks and studies of Klingberg and associates (e.g. 2002). The daily exercises are designed to train both the visuo-spatial and verbal WM. All participants (in both the training and control conditions) will be tested during the WMT on three kind of WM tests: the visuospatial WM span task, the backwards digit span task, and the letter span task (based on Klingberg et al., 2002). All three tasks consist of

30 trials.

•Visuospatial WM task: during this task, a certain number of squares in a 4x4 grid changed in colour on the computer screen. Participants have to reproduce this sequence by clicking on the squares that have changed colour in the correct order using the computer mouse.

•Backward digit span: during this task, a sequence of numbers will be presented on the computer screen. Participants have to reproduce this sequence in reversed order, using either the computer mouse or the number keys on the keyboard.

•Letter span task: during this task, a sequence of letters will be presented on the computer screen in a circle. One of the positions in this circle is the be indicated and participants have to reproduce the corresponding letter using the keyboard.

In the training condition (participants in the experimental group (group 3)), the difficulty level of all three WM tasks will be automatically adjusted on a trial-by-trial basis. Initially, each task involved sequences of three items. The length of the sequences will increase and decrease according to participants* performance. When participants correctly reproduce the sequences on two consecutive trials, one item will be added to the sequence on the next trial. When participants are not able to correctly reproduce the sequences on two consecutive trials, the sequence in the next trial will contain one item fewer. In the control condition (participants in group 2), the difficulty level of the WM tasks will not be adjusted, remaining at the initial, easy level throughout each task (i.e., three items in each sequence).

Study burden and risks

The risk of participating in this study are considered minimal. The working memory training and questionnaires are non-invasive and scarecely stressful. When taken into consideration that the participants have to be mental competent to give informed consent and the the risks of participating in this study are minimal, we feel that the burden of approximately 40 minutes for 25 consecutive days are justified, in order to gain more insight in the relationship between working memory and automatic preferences for alcohol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Alcohol dependence: diagnosed according to criteria DSM IV (American Psychiatric Association, 2000);Participants will be screened with the Alcohol Use Disorder Identification Test (AUDIT; Saunders et al.1993), and are only allowed to participate when they score 8 or higher on the AUDIT (i.e., the cut-off score for hazardous drinking; Saunders et al. 1993). ;Age over 18 years;A minimum of 4 years of formal schooling and no history of mental retardation;Native Dutch speaker;Mental competency to give informed consent. Mental competency as defined by the Dutch law (WGBO: Wet of Geneeskundige Behandel Overeenkomst) is determined by the medical specialist (e.g. psychiatrist) based on the patient*s health record, observations and conversation with the regular therapist. If necessary, the psychiatrist will have a short conversation with the patient. The concerning psychiatrists are: Dr. Michael Wellner, Dr. Robert Hilse, Dr. Claudia Decker and Dr. An Joos. They are all employees of Addiction Care of the Mondriaan Zorggroep.;Participants must have access (preferable at their own home) to a computer with an internet connection.

Exclusion criteria

AUDIT score lower than 8 (the cut-off score for hazardous drinking; Saunders et al.

1993);History of acquired brain injury (e.g. cerebral contusion, cerebrovascular accident);Participants who show signs of poor compliance (e.g. not completing a session in time and session loss) and/or poor response on the questionnaires will be excluded from the experiment by the researchers. ;Polydrug users are excluded from the study when their primary drug (core addiction) is different than alcohol. Possible polydrug use will be registered.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2012
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO

Date:	30-01-2012
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26354
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Identificatienummer is aangevraagd op www.trialregister.nl; wordt verwacht binnen 4 weken.
CCMO	NL38350.068.11
OMON	NL-OMON26354