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Alcohol-avoidance training for alcohol-dependent patients

Submission date 05/08/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/09/2020	**Overall study status** Completed	
Last Edited 28/01/2021	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Problem drinking that becomes severe is given the medical diagnosis of “alcohol use disorder” or AUD. AUD is a chronic relapsing brain disorder characterized by an impaired ability to stop or control alcohol use despite adverse social, occupational, or health consequences.
Alcohol-avoidance training using PC and joystick is a promising new add-on intervention for patients with AUD, helping them to avoid relapse. However, many patients also suffer from anxiety and mood disorders, and we don't know whether training also helps them.

Who can participate?
Alcohol-dependent in patients who are currently abstinent and receive treatment at a rehabilitation clinic

What does the study involve?
All patients receive 12 weeks of inpatient treatment as usual. On top of that, half of the patients complete 12 sessions of Alcohol-Avoidance Training. During training, patients use a joystick to push away pictures of alcoholic drinks and pull closer pictures of non-alcoholic drinks.

What are the possible benefits and risks of participating?
The possible benefit is a reduced risk of relapse. There are no risks.

Where is the study run from?
The study is run at the salus clinic Lindow, Germany.

When is the study starting and how long is it expected to run for?
January 2009 to December 2010

Who is funding the study?
The German Pension Fund (Deutsche Rentenversicherung Bund).

Who is the main contact?
Prof. Dr. Mike Rinck, m.rinck@psych.ru.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Affective comorbidity moderates the relapse-preventive effect of alcohol-related approach bias modification

Study objectives
Active Alcohol-Avoidance Training reduces relapse rates in comorbid and non-comorbid, currently abstinent alcohol-dependent patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved (original date unknown, confirmed on 01/09/2020) Deutsche Rentenversicherung Berlin-Brandenburg (Knobelsdorffstr. 92, 14059 Berlin, Germany; +49 3030021601; ulrich.eggens@drv-berlinbrandenburg.de), ref: n/a

Study design
Single-center interventional blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
During their 3-months stay at a rehabilitation clinic, currently abstinent alcohol-dependent patients are randomly assigned to an active training group vs. a control group.

Active training condition: In addition to treatment-as-usual, patients complete 12 sessions of alcohol-avoidance training. During each session, they use a joystick and a PC to push away 100 pictures of alcoholic drinks and pull closer 100 pictures of non-alcoholic drinks.
Control condition: Treatment-as-usual only.

Added 28/01/2021:
Randomization procedure:
For each patient, the randomization procedure involved a 40% chance to receive the active training condition and a 60% chance to receive the control condition. The researchers had to deviate from the usual 50:50 ratio because the clinic did not have sufficient resources (PCs, lab time, assistant time) to give the intensive 12-session training to 50% of the patients.

Blinding:
The participants were not blinded during the training, but researchers and interviewers were

blinded regarding the outcome. The researchers who worked with the training data did not know the clinical outcome, and the therapists who administered the 1-year follow-up interviews did not know whether the patient had participated in a study at all (let alone in which experimental condition). Moreover, training data and clinical data were combined only after both data sets had been finalized.

Intervention Type
Behavioural

Primary outcome measure
Relapse at 1-year follow-up measured by a standard questionnaire given on paper or via telephone

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Alcohol-dependent, currently abstinent
2. Aged ≥ 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
720

Total final enrolment
729

Key exclusion criteria
1. Non-native speaker of German
2. History of schizophrenia or psychotic disorders
3. Visual or hand-motoric handicaps

4. Strong withdrawal symptoms
5. Neuro-cognitive problems

Added 28/01/2021:
6. Participation in the study by Eberl et al. (2013) or any other earlier study

Date of first enrolment
28/09/2009

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Germany

Study participating centre
salus clinic Lindow
Strasse nach Guehlen 10
Lindow
Germany
16835

Sponsor information

Organisation
Radboud University Nijmegen

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Sponsor type
University/education

Website
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ROR
https://ror.org/016xsfp80

Funder(s)

Funder type
Government

Funder Name
German Pension Fund (Deutsche Rentenversicherung Bund)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request