Alcohol-avoidance training for alcoholdependent patients

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

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

Sponsor details

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Sponsor type University/education

Website http://www.ru.nl/english/

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