

Is alcohol-avoidance training effective and feasible in regular treatment?

Submission date 18/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/02/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

An alcohol use disorder (AUD) is drinking that causes distress and harm. Alcohol-Avoidance Training (AAT) using a PC and joystick is a promising new treatment for patients with AUD, helping them to avoid relapse. However, it is not known whether AAT also works in practice in different types of clinics. The aim of this study is to find out whether AAT reduces relapse rates in currently abstinent alcohol-dependent patients in 10 German rehabilitation clinics.

Who can participate?

Alcohol-dependent inpatients who are currently abstinent and receive treatment at one of 10 German rehabilitation clinics.

What does the study involve?

Patients are randomly allocated to the active training group or the control group. In addition to usual treatment, all patients in the active training group receive six sessions of AAT. During AAT, patients use a joystick to push away pictures of alcoholic drinks and pull closer pictures of non-alcoholic drinks. Patients in the control group receive only treatment-as-usual.

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 Salus Clinic Lindow (Germany)

When is the study starting and how long is it expected to run for?

July 2010 to January 2015

Who is funding the study?

The German Pension Fund (Deutsche Rentenversicherung Bund) (Germany)

Who is the main contact?

Prof. Dr Mike Rinck
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Contact information

Type(s)

Scientific

Contact name

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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

Effectiveness and feasibility of alcohol-avoidance training: a phase 4 multi-center randomized controlled trial

Acronym

AATMC

Study objectives

Active Alcohol-Avoidance Training reduces relapse rates in currently abstinent alcohol-dependent patients in 10 German rehabilitation clinics.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/02/2011, Ethics Board: Ethikkommission der Fakultät Human- und Sozialwissenschaften der Universität Chemnitz (Ethics Committee of the Dept. of Human and Social Sciences, Chemnitz University, Technical University Chemnitz, 09107 Chemnitz, Germany;

+49 (0)371-53134535;
ethik@hsw.tu-chemnitz.de), ref: 02022011

Study design

Multicenter interventional non-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Prevention of relapse in currently abstinent patients with Alcohol Use Disorder

Interventions

During their 3-months stay at one of the 10 participating rehabilitation clinics, currently abstinent alcohol-dependent patients are randomly assigned by coin toss to an active training group or a control group.

Active training condition: In addition to treatment-as-usual, patients complete six 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.

Total duration of follow-up: 12 months

Intervention Type

Behavioural

Primary outcome measure

Relapse measured using a standard questionnaire given on paper or via telephone at 3-months, 6-months, and 12-months follow-up

Secondary outcome measures

1. Evaluation of the training by patients, measured using a questionnaire at the end of the training
2. Return rate recorded at each follow-up point per clinic

Overall study start date

01/07/2010

Completion date

01/01/2015

Eligibility

Key inclusion criteria

Alcohol dependence, currently abstinent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1400 (140 per clinic)

Total final enrolment

1586

Key exclusion criteria

1. Non-native speaker of German
2. History of schizophrenia or psychotic disorders
3. Visual or hand-motor handicaps
4. Strong withdrawal symptoms
5. Severe neurological disorders

Date of first enrolment

01/09/2012

Date of final enrolment

01/10/2013

Locations

Countries of recruitment

Germany

Study participating centre

AHG Klinik Toennisstein

Hochstraße 25

Bad Neuenahr-Ahrweiler

Germany

53474

Study participating centre
AHG Klinik Wilhelmsheim
Wilhelmsheim 11
Oppenweiler
Germany
71570

Study participating centre
Bernhard-Salzmann-Klinik
Buxelstraße 50
Guetersloh
Germany
33334

Study participating centre
Fachklinik Fredeburg
Zu den Drei Buchen 1
Schmallenberg
Germany
57392

Study participating centre
Fachkrankenhaus Hansenbarg
Franz-Barca-Weg 36
Hanstedt
Germany
21271

Study participating centre
Fontaneklinik Motzen
Fontanestraße 5
Mittenwalde OT Motzen
Germany
15749

Study participating centre
Paracelsus Wiehengebirgsklinik
Kokenrottstraße 71
Bad Essen

Germany
49152

Study participating centre
Salus Klinik Friedrichsdorf
Landgrafenplatz 1
Friedrichsdorf
Germany
61381

Study participating centre
salus klinik Huerth
Willy-Brandt-Platz 1
Huerth
Germany
50354

Sponsor information

Organisation
Radboud University Nijmegen

Sponsor details
Behavioural Science Institute
PO Box 9104
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Sponsor type
University/education

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

ROR
<https://ror.org/016xsfp80>

Funder(s)

Funder type

Other

Funder Name

German Pension Fund (Deutsche Rentenversicherung Bund)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. No additional documents are available.

Intention to publish date

01/01/2022

Individual participant data (IPD) sharing plan

Anonymized participant-level data will be available upon request from Mike Rinck (m.rinck@psych.ru.nl).

IPD sharing plan summary

Available on request