From feasibility to efficacy: the use of Eye Movement Desensitization and Reprocessing (EMDR) to reduce craving and drinking behaviour in alcohol dependent outpatients - A multiple baseline study and RCT

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

Summary

ID

NL-OMON41570

Source
ToetsingOnline

Brief title
EMDR in alcohol dependent patients

Condition

- Other condition

Synonym
Alcohol dependence / Alcoholism

Health condition

alcohol afhankelijkheid

Research involving
Human

Sponsors and support

Primary sponsor: IrisZorg
Source(s) of monetary or material Support: IrisZorg;Fonds Psychische Gezondheid;Vereniging EMDR Nederland (VEN) en EMDR research foundation

Intervention

Keyword: Addiction, Alcohol, Craving, EMDR

Outcome measures

Primary outcome

Multiple baseline study:

• Changes in number of total drinks consumed since last assessment as measured

by a patient-kept daily diary;

RCT:

• Changes in heavy drinking days (defined as consuming >=5 alcohol drinks on a

given day) in the past 30 days as measured by the alcohol

Timeline Followback (TLFB; Sobell & Sobell, 1992);

Secondary outcome

Multiple baseline study:

• Changes in patient-reported craving as measured by the Penn Alcohol Craving

Scale (PACS; Flannery, Volpicelli, & Pettinati, 1999);

• Changes in patient-reported positive and negative affect as measured by the

(translated) International Positive And Negative Affect Scale

short-form version (I-PANAS-SF; Thompson, 2007);

• Changes in severity of patient-reported problematic alcohol use during the previous month as measured by the Alcohol Use Disorders I Identification Test (AUDIT; Saunders, Aasland, Babor, de la Fuente, & Grant, 1993; Dutch translation: Schippers & Broekman, 2010);

• Changes in patient-reported desire thinking as measured by the Desire Thinking Questionnaire (DTQ; Caselli & Spada, 2011; Dutch version);

• Changes in patient-reported coping self-efficacy as measured by the Self-Efficacy List for Drug users (SELD; De Weert-Van Oene, Breteler, Schippers, & Schrijvers, 2000);

• Changes in patient-reported quality of life as measured by the EuroQol-5D (EQ-5D; The EuroQol group, 1996) and the Community Reinforcement Approach Happiness scale (CRA-HS; Meyers & Smith, 1995);

• Changes in patient-reported rumination as measured by the Perseverative Thinking Questionnaire (PTQ; Ehring, Zetsche, Weidacker, Wahl, Schönfeld, & Ehlers, 2011);

• Changes in alcohol attentional bias as measured by the Alcohol Stroop (Stroop, 1935; Williams, Mathews, & MacLeod; 1996);

• Changes in alcohol implicit associations as measured by the Drinking Identity IAT (Lindgren, Neighbors, Teachman, Wiers, Westgate, & Greenwald, 2012).

RCT:

• Time to first alcohol consumption (post-intervention) as measured by the alcohol TLFB;

• Changes in number of total drinks consumed in the past 30 days as measured by the alcohol TLFB;

• Changes in average drinks per occasion in the past 30 days as measured by the alcohol TLFB;

• Changes in severity of patient-reported problematic alcohol use during the previous month as measured by the AUDIT;

• Changes in biomarker levels as measured by laboratory tests of serum γ-glutamyltransferase (GGT) and carbohydrate-deficient transferrin (CDT);

• Changes in alcohol attentional bias as measured by the Alcohol Stroop;

• Changes in alcohol implicit associations as measured by the Drinking Identity IAT;

• Changes in patient-reported craving as measured by the PACS;

• Changes in patient-reported desire thinking as measured by the DTQ;

• Changes in patient-reported coping self-efficacy as measured by the SELD;

• Changes in patient-reported quality of life as measured by the EQ-5D and the CRA-HS;

• Changes in patient-reported rumination as measured by the PTQ;

• Changes in patient-reported positive and negative affect as measured by the (translated) I-PANAS-SF;

• Differential drop-out in EMDR + TAU and TAU only group.

Study description

Background summary

One interesting approach to the treatment of addiction is the use of Eye Movement Desensitization and Reprocessing (EMDR) (Shapiro, 1989). Although research on the feasibility and efficacy of EMDR on addiction is limited and often lacks methodological rigor, the results are promising and suggest that further research on this subject is warranted.

Study objective

This proposal consists of two studies to test and determine the acceptability, feasibility and preliminary efficacy of EMDR as an intervention to reduce craving and alcohol use in alcohol dependent outpatients as well as to gain further understanding in underlying working mechanisms

Study design

The first study has the form of a (non-concurrent) multiple baseline study across subjects (3 alcohol-dependent out-patients) with a follow up period of 1 month.

The second study has the form of a pilot randomized controlled trail (RCT) with out-patient alcohol-dependent patients (n=100) with 2 (parallel) groups and repeated measures amounting to a 2 x 4 between participants design with group (EMDR + treatment as usual (TAU) vs. TAU) and time of assessment (pre- x post-intervention x 1 month x 6 months follow up) as factors. The allocation ratio is 1 : 1 for the 2 groups. Both participants and research assistants (who carry out assessments) will be blinded to group assignment while therapists will be blinded to outcome of assessments. The principal investigator will be blinded to group assignment until data analysis is finished.

Intervention

Participants of the multiple baseline study and those assigned to the experimental group of the RCT receive EMDR (aimed at drinking behaviour and craving) + TAU. EMDR is a protocolized treatment for posttraumatic stress disorder (PTSD) (Shapiro, 2007). Hase, Schallmayer and Sack (2008) demonstrated its potential in relapse prevention of alcohol-dependent patients. EMDR is provided by trained EMDR therapists.

TAU is Community Reinforcement Approach (CRA) treatment, consisting of several interventions, based on behavioural therapy principles (Meyers & Smith, 1995).

Study burden and risks

Participants complete questionnaires and computer tasks and give blood samples at specified intervals. Benefits for participants of the multiple baseline study and experimental group of the RCT are that they receive additional treatment which may help to resist urges and prevent the reinitiation or escalation of drinking behaviour. All participants receive an incentive (a voucher worth ¤ 25) after each follow-up assessment to reduce loss-to-follow-up. Participants who receive EMDR are instructed to recall memories which, at first, elicit craving for alcohol. This may cause some inconvenience during sessions but clinical experience thus far suggests that this is well tolerated.

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

Age: 18 years or older
Primary diagnosis of alcohol dependence

Exclusion criteria

Severe, current (since intake) psychiatric symptoms (e.g. suicidality, mania, psychosis, agression)
Current, co-morbid PTSD
Recent (last 2 weeks before baseline screening) regular (once or more/week) cannabis or harddrug use
Recent (last 2 weeks before baseline screening) regular alcohol use (> 21E (women) or > 28E (men)/week)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2013
Enrollment:	122
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-07-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01828866
CCMO	NL43892.044.13

Study results

Date completed:	01-09-2016
Actual enrolment:	114