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Eye Movement Desensitization and Reprocessing (EMDR) in Alcohol Dependent Patients

This study is ongoing, but not recruiting participants.

Sponsor:
IrisZorg

Collaborators:
Fonds Psychische Gezondheid
Vereniging EMDR Nederland
EMDR Research Foundation

Information provided by (Responsible Party):
W. Markus, IrisZorg

ClinicalTrials.gov Identifier:
NCT01828866

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History of Changes

Purpose

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.

This proposal consists of two studies to test and determine the acceptability, feasibility and 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.

Condition	Intervention
Alcohol Dependence	Behavioral: EMDR Behavioral: Community Reinforcement Approach

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: From Feasibility to Efficacy: the Use of EMDR to Reduce Craving and Drinking Behaviour in Alcohol Dependent Outpatients - A Multiple Baseline Study and Randomized Controlled Trial (RCT)

Further study details as provided by IrisZorg:

Primary Outcome Measures:

- Changes in number of heavy drinking days in the previous 30 days [Time Frame: Changes in baseline number of heavy drinking days in the previous 30 days, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in patient-reported number of heavy drinking days (defined as days on which 5 or more standard drinks of alcohol were consumed during the previous 30 days, as assessed with the alcohol TimeLine FollowBack (TLFB) method).

Secondary Outcome Measures:

- Time to first alcohol consumption [Time Frame: Up to 6 months post-intervention] [Designated as safety issue: No]

  Time to first alcohol consumption as measured by the alcohol Timeline FollowBack method (TLFB)

- Changes in number of total drinks consumed in the previous 30 days [Time Frame: Changes in baseline number of total drinks consumed in the previous 30 days, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in number of drinks consumed in the previous 30 days as measured by the alcohol TLFB

- Changes in average drinks per occasion in the previous 30 days [Time Frame: Changes in baseline average drinks per occasion in the previous 30 days, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  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 [Time Frame: Changes in baseline severity of patient-reported problematic alcohol use, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in severity of patient-reported problematic alcohol use during the previous month as measured by the Alcohol Use Disorders Identification Test (AUDIT)

- Changes in biomarker levels [Time Frame: Change from baseline assessment, at post-intervention, and follow-up after 1 and 6 months] [Designated as safety issue: No]

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

- Changes in alcohol attentional bias [Time Frame: Changes in baseline alcohol attentional bias, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in alcohol attentional bias as measured by the Alcohol Stroop

- Changes in alcohol implicit associations [Time Frame: Changes in baseline alcohol implicit associations, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in alcohol implicit associations as measured by the valence Implicit Association Task (IAT)

- Changes in patient-reported craving [Time Frame: Changes in baseline patient-reported craving, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in patient-reported craving as measured by the Penn Alcohol Craving Scale (PACS)

- Changes in patient-reported desire thinking [Time Frame: Changes in baseline patient-reported desire thinking, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in patient-reported desire thinking as measured by the Desire Thinking Questionnaire (DTQ)

- Changes in patient-reported coping self-efficacy [Time Frame: Changes in baseline patient-reported coping self-efficacy, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in patient-reported coping self-efficacy as measured by the Self-Efficacy List for Drug users (SELD)

- Changes in patient-reported quality of life [Time Frame: Changes in baseline patint-reported quality of life, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in patient-reported quality of life as measured by the EuroQol-5D (EQ-5D) and the Community Reinforcement Approach Happiness scale (CRA-HS)

- Changes in patient-reported rumination [Time Frame: Changes in baseline patient-reported rumination, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  Changes in patient-reported rumination as measured by the Perseverative Thinking Questionnaire (PTQ)

- Changes in patient-reported positive and negative affect [Time Frame: Changes in baseline patient-reported positive and negative affect, at post-intervention, and 1 and 6 month follow-up] [Designated as safety issue: No]

  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)

- Drop out [Time Frame: Up to 6 months post-intervention] [Designated as safety issue: No]

  Drop-out of study

Other Outcome Measures:

- History of drinking and other substance use [Time Frame: Baseline] [Designated as safety issue: No]

  History of drinking and other substance use as measured by the Measurements in the Addictions for Triage and Evaluation (MATE)

- Patient-reported motivation to stay abstinent [Time Frame: Baseline] [Designated as safety issue: No]

  Patient-reported motivation to stay abstinent as measured by the Readiness to Change Questionnaire, Dutch version (RCQ-D)

- Psychiatric comorbidity [Time Frame: Baseline] [Designated as safety issue: No]

  Psychiatric comorbidity as measured by the Mini-International Neuropsychiatric Interview (MINI-plus)

- Use of anti-craving, abstinence enforcing or other psychoactive medication [Time Frame: At baseline, post-intervention and 1 and 6 month follow-up] [Designated as safety issue: No]

  Use of anti-craving, abstinence enforcing or other psychoactive medication as derived from patient and patient dossier during assessments

- Time-in-treatment: total time of TAU (at last assessment) [Time Frame: Up to 6 months follow up] [Designated as safety issue: No]

  Time-in-treatment defined by total time of TAU from start of regular treatment until 6 month follow up.

- Intensity of treatment: number of treatment sessions [Time Frame: Up until 6 months follow up] [Designated as safety issue: No]

  Intensity of treatment: number of treatment sessions received from start of regular treatment until 6 months follow up

- Contents of treatment received [Time Frame: Up until 6 month follow up] [Designated as safety issue: No]

  Treatment modules received that constitute TAU for a specific participant

Enrollment:	109
Study Start Date:	September 2013
Estimated Study Completion Date:	August 2016
Estimated Primary Completion Date:	August 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Community Reinforcement Approach Treatment as usual, provided in out-patient setting	Behavioral: Community Reinforcement Approach CRA is based on behavioural therapy principles: 1. Functional analysis 2. Communication skills 3. Problem-solving skills 4. Sobriety sampling 5. Social networking 6. Refusal of substances 7. Reinforcing activities 8. Relapse management 9. Medication monitoring Other Name: CRA
Experimental: Community Reinforcement Approach + EMDR Treatment as usual + additional sessions of EMDR	Behavioral: EMDR EMDR is a protocolized, evidence-based treatment for PTSD. Here we use it to target addiction memory representations that elicit craving and may influence drinking behavior. The EMDR study protocol is based on the standard EMDR protocol and other EMDR approaches used in addiction. Other Name: Eye Movement Desensitization and Reprocessing Behavioral: Community Reinforcement Approach CRA is based on behavioural therapy principles: 1. Functional analysis 2. Communication skills 3. Problem-solving skills 4. Sobriety sampling 5. Social networking 6. Refusal of substances 7. Reinforcing activities 8. Relapse management 9. Medication monitoring Other Name: CRA

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- A primary diagnosis of alcohol dependence or abuse (meeting the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV-TR criteria (American Psychiatric Association, 2000);
- Age of at least 18 years or older;
- Can speak and read Dutch language;
- Consent (written) to postponed information given.

Exclusion Criteria:

- Meeting the DSM-IV-TR (American Psychiatric Association, 2000) criteria for current (in the past 2 weeks) addiction and regular use (at least once per week in the last two weeks before baseline screening) of drugs other than alcohol or nicotine (relative exclusion: decision on case-by-case basis whether it leads to therapy-interference);
- Meeting the DSM-IV (American Psychiatric Association, 2000) criteria for current (in the last two weeks before baseline screening) regular alcohol use (at least > 21E (women) or > 28E (men) per week) (relative exclusion: decision on case-by-case basis) (relative exclusion: decision on case-by-case basis whether it leads to therapy-interference);
- Meeting the DSM-IV (American Psychiatric Association, 2000) criteria for current post-traumatic stress disorder (PTSD);
- Severe, current (since the start of regular treatment) psychiatric symptoms (especially manic, psychotic, suicidal and aggressive symptoms) that may endanger participants or others and jeopardize study adherence.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01828866

Locations

Netherlands

IrisZorg
Arnhem, Gelderland, Netherlands, 6800 AJ

Sponsors and Collaborators

IrisZorg

Fonds Psychische Gezondheid

Vereniging EMDR Nederland

EMDR Research Foundation

Investigators

Principal Investigator: Wiebren Markus, MSc IrisZorg, NISPA, BSI (Radboud University)

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Markus W, de Weert-van Oene GH, Becker ES, DeJong CA. A multi-site randomized study to compare the effects of Eye Movement Desensitization and Reprocessing (EMDR) added to TAU versus TAU to reduce craving and drinking behavior in alcohol dependent outpatients: study protocol. BMC Psychiatry. 2015 Mar 18;15:51. doi: 10.1186/s12888-015-0431-z.

Responsible Party:	W. Markus, MSc, IrisZorg
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Health Authority:	Netherlands: Medical Ethics Review Committee (METC)

Keywords provided by IrisZorg:
EMDR
Alcohol
Relapse
Craving

Additional relevant MeSH terms:

Alcoholism	Ethanol
Alcohol-Related Disorders	Anti-Infective Agents, Local
Substance-Related Disorders	Anti-Infective Agents

Chemically-Induced Disorders
Mental Disorders

Central Nervous System Depressants
Physiological Effects of Drugs

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