The feasibility and potential efficacy of adding addiction-focused EMDR to regular addiction treatment ;A multiple baseline study in inpatients who use non-opioid drugs ;(June 2023)

Published: 02-11-2023
Last updated: 07-04-2024

Objective: to investigate areas of uncertainty about a possible future pilot RCT using AF-EMDR as an add-on intervention in inpatients who use non-opioid drugs and receive regular, inpatient addiction treatment, by determining: Feasibility....

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56192

Source
ToetsingOnline

Brief title
AF-EMDR MBS

Condition

- Other condition

Synonym
Non-opioid drugs addiction, non-opioid substance use disorder

Health condition

Verslaving

Research involving
Human

Sponsors and support

Primary sponsor: De Grift (verslavingszorg, Arnhem)
Source(s) of monetary or material Support: IrisZorg;daarnaast wordt subsidie aangevraagd bij diverse partijen waaronder de Vereniging EMDR Nederland (VEN).

Intervention

Keyword: Addiction, EMDR

Outcome measures

Primary outcome

Main study parameters/endpoints (feasibility)

Recruitment potential, measured by the proportion of patients at the clinic that are potentially eligible and are included versus those that are excluded.

Study adherence of participants from randomization until follow-up in terms of completion of ratings, assessments and interview.

Acceptability of AF-EMDR to participants in terms of compliance, measured by the total number of AF-EMDR sessions attended and the proportion of attended versus non attended (planned) sessions.

Adoption of the AF-EMDR protocol by the EMDR therapists in terms of adherence to the protocol, measured by an independent rater according to an a-priori established adherence rating protocol.

Experienced (by participants) acceptability and burden, facilitators and barriers and subjective effectiveness of the AF-EMDR intervention.

Secondary outcome

Secondary study parameters/endpoints (potential clinical efficacy)

Within and/or over AF-EMDR sessions change in:

Craving (Likert-type scale).

Level of Urge (LoU), Level of Positive Affect (LoPA) and Subjective Units of Distress (SUD) (Likert-type scales).

Baseline to follow-up assessment changes in:

Craving (MATE Q1: OCDS-5)

Craving-related self-control/self-efficacy (SCCQ).

Positive incentive value (SCCQ).

Substance use (past 30 days) (MATE section 1).

Changes in slope of the (combined) daily craving ratings from the baseline

versus the intervention phase.

Study description

Background summary

Rationale: It is well established that Substance Use Disorders (SUD) have severe health consequences. Despite behavioral and pharmacological treatment options, relapse rates remain high. In particular, for non-opioid drugs, such as amphetamines, cocaine, base-coke and cannabis, established, evidence-based pharmacological options to reduce craving, to substitute substance use or to enforce abstinence are lacking. Therefore, there is a need for effective interventions for patients who use non-opioid drugs to reach and maintain long-term abstinence.

A potential interesting intervention is addiction-focused Eye Movement Desensitization and Reprocessing (AF-EMDR) therapy. However, the limited research on AF-EMDR therapy and mixed findings thus far prohibit clinical use. Recently, on the basis of diverse findings thus far, an adjusted AF-EMDR therapy protocol has been developed.

Study objective

Objective: to investigate areas of uncertainty about a possible future pilot RCT using AF-EMDR as an add-on intervention in inpatients who use non-opioid drugs and receive regular, inpatient addiction treatment, by determining:

Feasibility.

Potential clinical efficacy.

Study design

Study design: a non-concurrent multiple baseline design is used in which participants are allocated at random to a baseline period of 7, 10, or 13 days after which they proceed to an intervention phase of two weeks in which they receive four 90 min. sessions of AF-EMDR and a follow-up interview after one month. During both the baseline and the AF-EMDR intervention phase, participants also receive Treatment As Usual (TAU: Community Reinforcement Approach (CRA)), aimed at SUD.

Intervention

Intervention: a total of four 90 min. sessions of AF-EMDR twice per week added

to TAU.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: on the basis of previous research, no risks are expected. The extra burden consists of filling in additional, self-report questionnaires at baseline- and follow-up (2 x * 15 min.), attending four x 90 min. AF-EMDR sessions, keeping a daily craving score during baseline and intervention phase (* 5 min.), and participate in a follow-up interview (* 30 min.). All participants receive an incentive (a voucher worth ¤15,-) after completing the baseline assessment and daily ratings and another voucher (worth ¤15,-) after concluding the follow-up assessment and interview, amounting to a total of two vouchers (total worth ¤30,-), as a compensation for the extra burden and possible travel-time involved in the follow-up interview.

Contacts

Public
De Grift (verslavingszorg, Arnhem)

Tarweweg 20
Nijmegen 6534AM
NL
Scientific
De Grift (verslavingszorg, Arnhem)

Tarweweg 20
Nijmegen 6534AM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, patients must meet the following criteria:

Diagnosis of a non-opioid drug use disorder according to the DSM-5 (American Psychiatric Association, 2013) criteria.

Age >= 18 years.

Good Dutch language proficiency (based on clinical judgement).

High craving past week (score >= 10 on the OCDS-5).

A planned inpatient stay of >= 4 weeks.

Written informed consent.

Exclusion criteria

Respondents who have received AF-EMDR therapy before, or will receive trauma-focused EMDR therapy during their inpatient stay are excluded as are patients during a tapering regime (they can be included following successful tapering however).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-09-2023
Enrollment:	9
Type:	Anticipated

Ethics review

Approved WMO Date:	02-11-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT05923697
CCMO	NL84818.091.23