The feasibility and potential efficacy of adding Tobacco Treatment using EMDR (ToTEM) to a regular smoking cessation program;A pilot randomized controlled trail in inpatient daily smokers with a substance use disorder

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Objective: to investigate areas of uncertainty about a possible future definitive RCT using AF-EMDR as an add-on intervention to a Smoking Cessation Program (SCP), by determining:• Feasibility/process outcomes (e.g. recruitment, adherence, treatment...

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

Summary

ID

NL-OMON53586

Source
ToetsingOnline

Brief title
ToTEM

Condition

- Other condition

Synonym
smoking addiction, Tobacco use disorder

Health condition

Verslaving (stoornis in het gebruik van tabak)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: addiction, cigarettes, EMDR, smoking

Outcome measures

Primary outcome

Main study parameters/endpoints

o The retention of participants from randomization until the last follow-up.

o The acceptability of AF-EMDR to participants in terms of compliance, measured by the total number of sessions attended and the proportion of attended versus non attended (planned) sessions; a higher proportion of attended sessions reflects better compliance.

o The acceptability of AF-EMDR to therapists in terms of adherence to the protocol, measured by the score of an independent rater on an a-priori established adherence rating protocol; a higher score reflects better adherence.

Secondary outcome

Secondary study parameters/endpoints

o Recruitment potential, measured by the proportion of patients at the clinic that are potentially eligible and provide informed consent versus:

* Those that are eligible but do not provide informed consent.

* Those that are not eligible.

o The feasibility of the outcome measures in terms of completion of questionnaires (% per questionnaire and total).

o The acceptability of the outcome measures in terms of Likert-type ratings by participants, therapists and research assistants.

o Amount of missing data, measured by total number of missing values and the proportion of completed versus missing data.

Tertiary study parameters

o Demographics, as inventoried by a structured interview and patient files.

o Smoking (cessation history), inventoried by a structured interview and patient files.

o Current DSM-5 diagnoses, inventoried by a structured interview and patient files.

o Motivation to quit smoking, measured by a Likert-type scale from 0 to 10; a higher score reflects a higher motivation.

o Smoking cessation self-efficacy, measured by a Likert-type scale from 0 to 10; a higher score reflects a higher self-efficacy.

o Severity of nicotine dependence, measured by the Fagerström Test of Nicotine Dependence, providing a score from 0 to 10; a higher score reflects a more severe dependence.

o Time to relapse (from the end of the AF-EMDR intervention, if abstinence is achieved), measured in number of days from the end of the AF-EMDR intervention

until first cigarette smoked. The higher the number of days, the longer the time to relapse.

Changes from baseline (T0) to T1-T2-T3 in:

o Smoking behavior, measured by mean number of cigarettes smoked per day over the past 7 days; a higher score means a worse outcome.

o Tobacco craving, as measured by the total score on the Questionnaire of Smoking Urges - Brief version; a higher score means a worse outcome.

o Craving related self-control/self-efficacy. As measured by a subscale of the Self-control cognitions Questionnaire; a higher score means a worse outcome.

o Positive incentive value. As measured by a subscale of the Self-control cognitions Questionnaire; a higher score means a worse outcome.

Within AF-EMDR session changes in:

o Mean Level of Urge, measured by a Likert-type scale from 0 to 10; a higher score means a worse outcome.

o Mean Level of Positive Affect, measured by a Likert-type scale from 0 to 10; a higher score means a worse outcome.

Study description

Background summary

Rationale: It is well established that tobacco use has severe health consequences. The prevalence of Tobacco Use Disorder (TUD) is among the highest in populations with Substance Use Disorders (SUD). Despite behavioral and pharmacological treatment options, relapse rates remain high. Therefore, there

is a need for additional smoking cessation treatment options that aid 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 protocol has been developed.

Study objective

Objective: to investigate areas of uncertainty about a possible future definitive RCT using AF-EMDR as an add-on intervention to a Smoking Cessation Program (SCP), by determining:
• Feasibility/process outcomes (e.g. recruitment, adherence, treatment fidelity).
• Preliminary clinical efficacy in order to estimate the effect size for a future power analysis.

Study design

Study design: a pilot study with a two-armed randomized controlled design is used in which AF-EMDR + Treatment As Usual (TAU) (Community Reinforcement Approach (CRA) aimed at SUD + a SCP) is contrasted with TAU-only with an intervention phase of three weeks pre- and post intervention assessments and a follow-up after one and three months.

Intervention

Intervention: a total of six 45-90 min. sessions of AF-EMDR twice per week added to a SCP embedded in TAU.

Study burden and risks

Benefits and risks assessment, group relatedness
Potential benefits for participants who receive AF-EMDR are that they receive treatment which may help to resist urges and reduce smoking behaviour. Additionally, there is some benefit for all participants in that they will receive an incentive after each follow up assessment. On the basis of clinical research and experience with EMDR and AF-EMDR, no destabilization is to be expected in this population. However, participants who receive AF-EMDR are instructed to recall memories which elicit craving for smoking. 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)

Inclusion criteria

- Diagnosis of Tobacco Use Disorder according to the DSM-5 (American Psychiatric Association, 2013) criteria.
- Age >= 18 years.
- Good Dutch language proficiency (based on clinical judgement).
- Smoking, on average, >= 10 cigarettes per day pre-admission.
- A score of at least 5 on a scale from 0 to 10, for motivation and self-efficacy
- A planned inpatient stay of >= 4 weeks.
- Written informed consent.

Exclusion criteria

- Serious therapy interfering behavior or symptoms that also interfere with TAU, based on clinical judgement (e. g. psychiatric or medical crisis that requires immediate intervention).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2023
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	30-01-2023
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	NCT05594810
CCMO	NL79955.091.22

Study results

Date completed: 12-06-2023

Actual enrolment: 1

Summary results
Trial is onging in other countries