IMPROVE: Improving anxiety treatment by Modulating emotional memories PRiOr to in Vivo Exposure:
A randomized controlled trial.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON52802

Source
ToetsingOnline

Brief title
IMPROVE - Modulating emotional memories: a RCT

Condition

- Anxiety disorders and symptoms

Synonym
panic disorder (involuntary reoccurring panic attacks)

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: NWO VICI awarded to prof. dr. I.M. Engelhard

Intervention

Keyword: Anxiety disorders, CBT, EMDR, RCT

Outcome measures

Primary outcome

- Treatment tolerability and adherence: actual drop-out during treatment (i.e., EMDR/SC and CBT) and no show in CBT sessions, as well subjective measures: willingness to start exposure treatment, behavioral avoidance, and considered drop out (assessed after treatment).

- Reductions in symptoms: anxiety (symptoms/diagnosis), related psychological problems (e.g., depression), functional impairments, quality of life, need for additional treatment after the trial.

Secondary outcome

1. Predictors

- Study parameters for patients are: extinction learning, intrusive memories from past and future events, clinical profiles, treatment expectancy, therapeutic alliance, intolerance of uncertainty, anxiety sensitivity, and worry.

- Study parameters for therapists are: demographics, trait anxiety, intolerance of uncertainty, attitudes towards evidence based practice and treatment

manuals, treatment credibility, therapist prediction of clinical change and

working alliance.

2. Mechanisms

- Exposure process variables: threat expectancy and threat severity.

3. Cost-effectiveness

- Direct and indirect cost within the healthcare system, as well as health

related expenses for the patient and productivity losses.

Study description

Background summary

Cognitive behavioral therapy (CBT), with its key element exposure in vivo, is the most effective treatment for anxiety disorders but many patients do not benefit sufficiently from it, so there is an urgent need for improvement. Previous research has revealed that many patients with anxiety disorders report vivid and distressing mental images of threat related to the content of their anxiety disorder and these images possibly impede exposure therapy. These images are however not targeted in standard CBT for anxiety disorders. An effective treatment that focuses on mental images of threat and the desensitization of aversive memories is Eye movement Desensitization and Reprocessing (EMDR). Though a clinical EMDR protocol for anxiety has been developed and used in clinical practice for years, no research to date has tested whether modulation of fear-related memories combined with CBT enhances treatment effects in patients with anxiety disorders.

Study objective

The first goal of the current research is to investigate whether EMDR prior to CBT, compared to an active psychological control condition (*supportive counseling*), improves treatment tolerability, adherence, and effectiveness. The second goal is to unravel theory-driven variables as well as non-specific patient and therapist factors that predict treatment outcome and optimal treatment allocation. The third goal is to elucidate mechanisms of change of

this novel approach (EMDR+CBT) in the treatment of anxiety disorders. Lastly, cost-effectiveness of the new approach (EMDR+CBT) will be assessed.

Study design

A multicenter RCT with two groups (EMDR and SC) repeated measures design (T1-Baseline, T2-Between, T3-Post, follow-up1, followup2).

Intervention

Two standardized interventions will be used before CBT: EMDR and SC. We will use the standard Dutch EMDR 2020 protocol from the Dutch EMDR society. SC will serve as a credible intervention that controls for non-specific treatment effects and will be based on the protocol by Bryant, Harvey, Dang and Basten (1998). It focuses on a discussion of topics that are relevant to the patient and the therapist offers support but does not use CBT techniques. Patients will receive a 90 minute EMDR or SC case formulation session. Followed by 4x90 minute sessions of EMDR or SC once weekly before starting CBT. All patients will then receive 8x90 minute sessions of CBT once weekly. CBT will be based on the current treatment guidelines for panic disorder, which involves exposure therapy. All assessments will be provided online. Treatment sessions will be provided face to face or online depending on the preference of the patient and clinician.

Study burden and risks

Earlier studies showed symptom reductions in all treatments (SC, EMDR and CBT), therefore participants will potentially profit from either treatment condition. Worsening of symptoms or adverse events as a result of the interventions are not expected. A potential benefit for all participants is an well-controlled treatment with longer sessions compared to the treatment as usual protocol. Compared to treatment as usual (TAU), no additional risks are involved. As in TAU, a clinician will be present during treatment sessions. In the unlikely event of any negative consequence of treatment, the principal and main investigators will be informed directly. Time investment for treatment in the study is roughly equal to normal treatment procedures. Additional time investment includes completing an extinction learning task and questionnaires before, during and after treatment, two follow-up assessment. When additional care is needed, TAU will be provided. Time investment can be justified by the clinical and scientific relevance of the study. Benefits could consist of a more tolerable and effective treatment compared to TAU. Patients can withdraw at any time from the study without further consequences.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients of >18 years of age
- Sufficient mastery of the Dutch language to complete questionnaires
- Ability to understand questionnaires and written informed consent
- Meeting DSM-5 criteria for primary panic disorder (with or without agoraphobia) (assessed with MINI-S-DSM-5)
- Stable medication for at least six weeks and willingness by the patient and physician to keep the medication stable during the study period (until FU1). The use of sedating medication (e.g. benzodiazepines) is no contraindication, however participants are strongly advised not to use sedating medication prior to- or after treatment sessions and subsequent days. Use of sedating medication will be registered
- Willingness and ability not to be under the influence of alcohol or drugs twenty-four hours before and after each session, general use will be

discouraged as much as possible

Exclusion criteria

- Neurological disorder
- Acute or recent history of suicide attempts according to the M.I.N.I. section C
- Self-reported visual or auditory impairments that could hinder treatment
- Self-reported epilepsy, pregnancy, or heart disease (these are common exclusion criteria for using a fear conditioning task, see 8.3.3)
- Not willing or able to fill in (online) questionnaires.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-06-2021
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2020

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-02-2023
Application type:	Amendment
Review commission:	METC NedMec

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
ISRCTN	ISRCTN29668369
CCMO	NL73918.041.20