The effect of Eye Movement Desensitization and Reprocessing (EMDR) on Illness Anxiety Disorder (IAD): two multiple baseline n-of-1 trials across seven participants each.

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Primary Objective study 1: The primary objective of study 1 is to explore the effectiveness of EMDR treatment targeting images of historic traumatic events in reducing the daily rated illness anxiety symptoms of patients with IAD.Primary Objective...

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

Summary

ID

NL-OMON51800

Source
ToetsingOnline

Brief title
EMDR4IAD

Condition

- Anxiety disorders and symptoms

Synonym
hypochondria, illness anxiety disorder

Research involving
Human

Sponsors and support

Primary sponsor: PEP Groep (Praktijk Eerstelijns Psychologie)
Source(s) of monetary or material Support: NZA Subsidies opleidingsplekken GZ-psycholoog tot Klinisch Psycholoog en er zal subsidie worden aangevraagd bij de Vereniging van EMDR Nederland

Intervention

Keyword: EMDR, IAD, multiple baseline, N-of-1 trial

Outcome measures

Primary outcome

The daily Idiopathic illness anxiety scale (IIAS).

Secondary outcome

SCID-5-S, SCL-90 en BDI-II-NL, WI, IAS and PCL-5

Study description

Background summary

Mental imagery is a transdiagnostic feature that has been increasingly recognized as playing an important role in relation to autobiographical memory and psychopathology. After trauma, involuntary (intrusive) mental images and memories can make it difficult to recall positive memories, thus creating an automatic bias toward more negative information. Compared to verbal processing, the imagery-based route of processing emotional stimuli causes a stronger, but a negative affective response. Although empirical evidence is still scarce, these specific mechanisms also seem to be at work in patients with an illness anxiety disorder (IAD). The prospective and vivid intrusive images found in IAD cause patients great distress. These intrusive images increase somatic awareness which, as an emotion regulatory response, leads to typical IAD avoidance and reassurance-seeking behaviours. This suggests that the intrusive images found in IAD may be a promising novel target in treatment methods. With the aim to improve current treatments for IAD, the present study explores the effectiveness of Eye Movement Desensitization and Reprocessing (EMDR) in patients with IAD. EMDR treatment for IAD first targets the memories of past (traumatic) events before targeting future intrusive images of expected catastrophes. Although in general EMDR treatment starts by treating traumatic experiences related to the illness, it has been proposed (Bellecci-St. Romain,

2013; Engelhard et al., 2011) that it is not necessary to target the past events at all because the future catastrophe image has in it all the anxiety-provoking elements of the past event. The hypotheses tested in this multiple baseline design across two times seven participants, are 1) is EMDR treatment focusing on images of traumatic past events effective in reducing IAD symptoms 2) is EMDR treatment focusing on images of future catastrophes effective in reducing IAD symptoms and 3) comparing these interventions; is targeting only the images of future catastrophes with EMDR treatment just as effective as targeting images of historic events.

Study objective

Primary Objective study 1: The primary objective of study 1 is to explore the effectiveness of EMDR treatment targeting images of historic traumatic events in reducing the daily rated illness anxiety symptoms of patients with IAD.

Primary Objective study 2: The primary objective of study 2 is to explore the effectiveness of EMDR treatment targeting images of future catastrophes in reducing the daily rated illness anxiety symptoms for patients with IAD.

Secondary Objective: The secondary objective of the combined studies is to explore the differences in effectiveness and efficiency of EMDR treatment targeting images of historic traumatic events versus targeting images of future catastrophes, in reducing the daily rated illness anxiety symptoms for patients with IAD.

Study design

SCED Design: multiple baseline across seven participants.

The present study consists of two studies each of which consists of 7 N-of-1 studies. N-of1 studies or single case experimental design (SCED) studies are suitable for conducting scientifically relevant research in a clinical setting. With this design, the effectiveness of the applied intervention in one person can be scientifically investigated. This is made possible by collecting data daily and throughout the study and using all these data points to test the research question within the subject (*within subject*). Of the SCEDs the multiple baseline design (MBD) is recommended because of its high internal and external validity (Kratochwill et al., 2010; Shadish & Sullivan, 2011). Due to the large number of measurements within a person in the different phases (baseline, treatment, post-test, and follow-up phase) and by randomizing the length of the baseline, internal validity is guaranteed. Preferentially is a concurrent design in which all participants start at the same time with their baseline. This minimizes the influence and therefore threats to intern validity of any concurring events, for example, news reports on the COVID-19 pandemic. To preclude patients from waiting several months we decided to use a partly

concurrent design by letting 2 (or 3) patients start at the same time, making it a partly concurrent MBD. The changes within a person are assessed visually (by eye) as well as statistically tested using all data points. In this way, it can be determined within the individual whether the intervention offered actually makes a difference.

The design of the present study meets the criteria for a partly concurrent MBD study, based on which scientifically substantiated statements can be made about the effect the treatment has on this individual. By repeating this set-up in 7 participants, i.e., performing 7 N-of-1 studies, a meta-analysis can be performed on these 7 studies and a statement can be made about the 7 N-of-1 studies together. The outcomes (effect sizes) of this statistical analysis allow comparison with randomized and controlled trials and existing meta-analyses.

We repeat the above design with two variants of the intervention (EMDR). One focuses on images related to past events (MBD1). The other on images of future catastrophes (MBD2). The study, therefore, concerns 2 x 7 N-of-1 studies. In which we can compare the results of the meta-analyses on each of the 7 N-of-1 studies and thus answer our third research question.

The 7 participants in either MBD1 or MBD2 will be randomly assigned to Baseline length and starting day; 2 participants to Baseline length 1 (10, 11, 12, 13, or 14 observations), 2 participants to Baseline length 2 (15, 16, 17, 18, or 19 observations), and 2 participants to Baseline lengths 3 (20, 21, 22, 23, or 24 observations) and 1 last participant to either baseline length 1, 2 or 3. For each of the time series, the start of the intervention will be randomly chosen.

MBD1 - targeting images of historic traumatic events
Time series 1:
Baseline 1: at least 10 observations, Treatment 1: 49 observations, Baseline 2: 10 observations, Follow up: 10 observations
Time series 2:
Baseline 1: at least 15 observations, Treatment 1:49 observations, Baseline 2: 10 observations, Follow up: 10 observations
Time series 3:
Baseline 1: at least 20 observations, Treatment 1: 49 observations, Baseline 2: 10 observations, Follow up: 10 observations

MDB2 - targeting images of future catastrophes
Time series1:
Baseline 1: at least 10 observations, Treatment 2: 49 observations, Baseline 2: 10 observations, Follow up: 10 observations
Time series 2:
Baseline 1: at least 15 observations, Treatment 2: 49 observations, Baseline 2: 10 observations, Follow up: 10 observations
Time series 3:

Baseline 1: at least 20 observations, Treatment 2: 49 observations, Baseline 2: 10 observations, Follow up: 10 observations

Within the limitations of our practice, the replicated multiple baseline n-of-1 trial seems most fit to provide opportunities to enhance care that is both patient-centred and evidence-based. The results of our study can therefore be meaningful to our participants' well-being and at the same time contribute and give direction to further research on this subject, including those with other designs.

Intervention

EMDR (Eye Movement and Desensitization Disorder)

Study burden and risks

The EMDR-treatment has no known adverse effects or risks. The burden associated with participation in this study lies in daily answering the questions of the IIAS (1 or 2 minutes a day)

Contacts

Public
PEP Groep (Praktijk Eerstelijns Psychologie)

Vuurtorenplein 10
Noordwijk 2202 PB
NL
Scientific
PEP Groep (Praktijk Eerstelijns Psychologie)

Vuurtorenplein 10
Noordwijk 2202 PB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>18 years
DSM-5 diagnosis of an Illness Anxiety Disorder

Exclusion criteria

Participants will be excluded from participating in this study if they are currently under treatment for their IAD or receive any psychological or pharmaceutical treatment for another disorder or problem. Exceptions will be made for patients who are currently treated with selective serotonin reuptake inhibitors (SSRI*s) and on a stable dose for the last 3 months. Additionally, participants will be excluded if they can*t read and comprehend Dutch language, and if they are unable to give informed consent because of mental incapacity.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2023
Enrollment:	14

Type:	Actual

Ethics review

Approved WMO Date:	10-02-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL81315.018.22