Targeting repetitive intrusive suicidal images and thoughts: towards a new suicide prevention strategy.

Published: 14-11-2017
Last updated: 15-04-2024

To develop and test an innovative evidence-based therapeutic tool (EMDT add-on intervention) that reduces the frequency and intensity of intrusive suicidal images and thoughts, in order to prevent the transition from suicidal ideation to suicidal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Suicidal and self-injurious behaviours NEC
Study type	Interventional

Summary

ID

NL-OMON55749

Source
ToetsingOnline

Brief title
SIMAGERY

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
intrusions, Suicide

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw (Dossiernummer 537001003)

Intervention

Keyword: EMDT, Mental Imagery, Prevention, Suicide

Outcome measures

Primary outcome

The main study parameter is the level of compellingness, vividness, and frequency of suicidal intrusions (images and thoughts) as measured by the Intrusion interview (see attachment 1).

Secondary outcome

Additional parameters are:

- Depressive symptoms (BDI-II)

- Suicidal behaviour

- Suicidal Ideation

Furthermore, we will be looking at:

- Quality of Life

- Societal costs

- Rumination

- Hopelessness

- Executive functioning (as a potential process measure to unravel the underlying mechanism of the intervention)

Study description

Background summary

Suicide prevention interventions have been developed, however little remains known about which processes link suicidal plans to the act of suicide (O'Connor & Nock, 2014). Recent studies revealed that the majority of patients diagnosed with major depression or bipolar disorder report repetitive intrusive suicide-related images and thoughts (Crane et al., 2014; Hales, Deeprose, Goodwin, & Holmes, 2011; Holmes et al., 2005). These images may be both distressing and comforting to an individual (Crane et al., 2014). Furthermore, suicide-related images and thoughts are conceptually linked to the process of rumination (replaying one's problems and their causes over and over in one's head), and as such may play a pivotal causal role in the development of suicidality (Morrison & O'Connor, 2008). In fact, an important mechanism that increases suicidal intrusions is their attempt to avoid them. Especially the cognitive effort of stopping intrusions appears to have a counterproductive effect, as it inflates their frequency and intensity instead (Abramowitz, Tolin, & Street, 2001), rendering feelings off uncontrollability related to suicidal ideation and images. Our central assumption is that the frequency and intrusiveness of suicidal imagery determines the actual risk of suicide. Experimental and clinical studies show that vividness of both negative and positive intrusive images may be reduced by dual task interventions taxing the working memory such as eye movements (van den Hout et al., 2011). It is assumed that recalling an emotional image and performing eye movements require working memory resources. Since the eye movements reduce resources for recall, the image is rendered less intense, even upon recall (Engelhard, van den Hout, Janssen, & van der Beek, 2010). We hypothesize that eye movements during suicidal imagery retrieval, will reduce the intensity and frequency of such imagery, and may be crucial in preventing suicide amongst depressed patients.

Study objective

To develop and test an innovative evidence-based therapeutic tool (EMDT add-on intervention) that reduces the frequency and intensity of intrusive suicidal images and thoughts, in order to prevent the transition from suicidal ideation to suicidal behavior.

Research Questions:
1. What is the prevalence (presence, frequency) and nature (qualitative content and intensity) of intrusive suicidal mental images and thoughts in depressed patients with suicidal ideation?
2. Is the degree of suicidal ideation associated with the presence, frequency, qualitative content and intensity of intrusive suicidal mental images and thoughts?
3. Is EMDT effective as an additive intervention in reducing intrusive suicidal mental images and thoughts in depressed patients?
4. Is EMDT effective as an additive intervention in reducing suicidal ideation, depressive symptoms, and functional disability in depressed patients?
5. Is the reduction of intrusive suicidal imagery as a result of EMDT the underlying mechanism of change of a reduction in suicidal ideation, and/or

depressive symptoms?
6. Is the reduction of suicidal imagery as a result of EMDT the underlying mechanism of change of the transition from suicidal ideation and thoughts to suicidal behavior?

Study design

First, a Pilot study (Phase 1) is conducted to inform us about the feasibility, potential adverse events, and the usability of the intervention. This monocenter study will take place at GGZ InGeest Amsterdam where 6 patients are included. They are initially screened with the BDI-II and SIDAS. Eligible patients will be interviewed about their suicidal intrusions (using the Intrusion Interview). Next, participants receive (a maximum of) 6 EMDT sessions.

Once results of the pilot study are analyzed, the multicenter research will take place and is split up into two phases. Phase 2 (qualification phase) includes an observational study examining the compellingness, content, frequency, and intensity of vivid intrusive suicidal imagery and ideation in 350 patients. After providing oral and written informed consent, patients will perform a small Breathing Focus Task and will be interviewed by trained staff members of the mental health care institution they are currently being treated. In addition, they are asked to complete a set of (online) self-report instruments.

Phase 3 (intervention phase) will consist of an open, multicenter randomized controlled trial that will evaluate the effects of an EMDT add-on intervention in reducing the intensity and frequency of suicidal imagery and ideation in 90 suicidal patients. Participants from the qualification phase (phase 2) who are burdened by suicidal imagery are eligible and invited to participate in this next phase. They are initially screened with a diagnostic interview if necessary (MINI) and the BDI-II and SIDAS. After given written and oral informed consent, participants are asked to complete a set of (online) self-report measures (baseline assessments). Recruitment and interventions will take place at the mental health care institution where they are currently receiving treatment, including Altrecht, Dimence, Parnassia Groep, ProPersona, and GGZ Eindhoven.

Participants will be randomized on a 1:1 basis (stratified for mental health care institution) into the intervention group (Care-as-usual + EMDT add-on treatment [n=45]) or the control group (Care-as-usual treatment only [n=45]). Participants in the experimental group will receive six EMDT add-on sessions over a period of six weeks. Multiple assessments will be carried out at: pre-treatment (baseline), during treatment, post-EMDT (3 or 6 weeks after baseline), and at 3, 6, 9, and 12 months follow-up periods. Self-report assessments will be administered online, while the Intrusion Interview and a brief cognitive task will be administered face-to-face at the mental health

care institution by trained staff members of the institution.

Intervention

The EMDT Protocol has been developed in co-creation with patients and mental health professionals involved in mental health care for depressed patients with suicidal ideation (through focus groups). Seven (formerly) depressed patients with suicidal ideation have been approached to participate in a focus group interview. Another focus group of six mental health care professionals will be composed. In the focus group interviews, the needs and requirements for the newly developed EMDT intervention to target suicidal intrusions and the safety requirements of the new add-on module will be identified. This will be noted in a 'List of practice recommendations for evidence-based EMDT aimed at intrusive suicidal imagery'. This way, we will ensure that EMDT meets the needs of patients and their mental health care providers. Moreover, the pilot study (phase 1) includes a structured evaluation interview in which we receive feedback from the participants about their experiences with the treatment.

EMDT add-on treatment
The treatment will be an add-on module that addresses intrusive suicidal images and can be added to regular treatment. It will consist of six sessions each approximately 1 hour, in the course of three to six weeks, delivered at the participants* mental health care center. Trained and supervised intervention psychologists from each participating center will carry out the EMDT sessions.

Each session will consist of the following steps:
1. Selection of intrusive suicidal flash-forward target images with related ideation, informed by the baseline intrusion interview (Qualification phase).
2. Consecutive set of eye movements of 24 seconds by 10 second breaks (I. Engelhard et al., 2012; van Veen et al., 2015). Between the sets, subjective units of distress scale (SUDS, scale 0-10) are administered to assess level of distress during imagery.
3. If the image still produces stress, the dual task procedure will be repeated for the target.
4. This procedure is repeated for all target images until all SUDS are at approximately 0.
All EMDT sessions will be videotaped (after informed consent from the patient), and a random sample of 30% will be rated for treatment integrity.

Study burden and risks

Initially it is understood that many people exercise great caution with regard to inclusion of a high-risk vulnerable group, and want to avoid an increased risk of being suicidal. However, to date, extensive research shows that participating in research has not resulted in increased risks and that experimental treatments at reducing suicidality often also show this effect

(Huisman, 2017). Looking at the prevalence in a clinical suicidal population regarding suicide attempts, there is an increased possibility that at least one suicide attempt will occur throughout the study. Again, this is not due to any risks associated to the EMDT-add on intervention or participation in the study, but rather because of the high prevalence of suicide attempts in this particular clinical sample. If the patient is showing increased high suicidal risk, the therapist may motion toward the hospitalization of patients for their own safety. (More information can be found in the risk-classification form B2.4 and section 9.3).

A potential unforeseen risk that could occur is in accordance with the working mechanisms of EMDR in that the fear associated to the images could be diminished. This, in turn, might take away the inhibiting effect of fear with suicidality (thus making it less scary to perform a suicidal act). A second potential unforeseen risk is that a small portion of the patients may experience an increase or worsening of symptoms when actively recalling and engaging with the suicidal intrusions.

Physical discomfort: there is a possibility that the patient will feel worn out or tired after an EMDT session, as taxing working memory and retrieving vivid intrusions may be experienced as exhausting.
Psychological discomfort: retrieving vivid, emotional suicidal intrusions may cause an increase in feelings scared and stressed. (This is an important aspect of the treatment: during the EMDT session, the patient is asked to place themselves in the most emotional status of the intrusion)

Prior to treatment, the patient is invited to complete a screening. Multiple questionnaires will be administered online. the intrusion interview and the additional 6 EMDT sessions require the patient to visit their mental health institution.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*Participants in Phase 1 will not be included in Phase 2 and 3.
Participants of Phase 2 however, may be eligible to participate in Phase 3 as well., In order to be eligible to participate in the Pilot study (Phase 1), a subject must meet all of the following criteria:
a. Have a minimum age of 18 years
b. Score ><= 20 on the Beck Depression Inventory
c. Have suicidal ideation: score ><=1 on Suicidal Ideation Attributes Scale (SIDAS)
d. Currently receiving treatment (Care-as-usual) at GGZ InGeest Amsterdam
e. Adequate proficiency in the Dutch language
f. Have suicidal intrusions (as measured through the Intrusion Interview) that are experienced as a burden, In order to be eligible to participate in Phase 2, a subject must meet all of the following criteria:
a. Have a minimum age of 18 years
b. Have suicidal ideation: score ><=1 on Suicidal Ideation Attributes Scale (SIDAS)
c. Currently receiving treatment (Care-as-usual) at a mental health institution
d. Adequate proficiency in the Dutch language, In Phase 3, a subject must meet the following additional criteria:
e. Have suicidal intrusions (as measured through the Intrusion Interview) that are experienced as a burden.
f. Score ><=20 on the Beck Depression Inventory

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in phases 1 or 3 of this study:
a. DSM-IV Psychotic disorder diagnosis
b. DSM-IV Depression with psychotic features diagnosis
c. DSM-IV Bipolar disorder diagnosis
d. High dropout risk (i.e. poor response rate when trying to get in contact with potential participant), Exclusion criteria for phase 2 are slightly different:
a. Current DSM-IV Psychotic disorder diagnosis
b. High dropout risk (i.e. poor response rate when trying to get in contact with potential participant)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-11-2017
Enrollment:	356
Type:	Actual

Ethics review

Approved WMO

Date:	14-11-2017

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2021
Application type:	Amendment
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	NL60318.029.17