[Simagery] Targeting repetitive intrusive suicidal images and thoughts: towards a new suicide prevention strategy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27900

Source
Nationaal Trial Register

Brief title
SIMAGERY

Health condition

Suicidal, intrusions, mental problems, depression,

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Feasibility (measured by i.e. treatment adherence and data collection using online questionnaires)

Secondary outcome

Suicidal ideation (BSSI, SIDAS), depressive symptoms (BDI-II), suicidal intrusions (SINAS), Psychological distress (BSI)

Study description

Background summary

Suicide is a major public health problem, and it remains unclear which processes link suicidal plans to the act of suicide. Growing evidence shows that the majority of suicidal patients diagnosed with major depression or bipolar disorder report repetitive suicide-related images and thoughts. In addition, experimental and clinical studies show that vividness of negative as well as positive intrusive images may be reduced by Dual Task (e.g. eye movements) interventions taxing the working memory. We propose that the eye movements during image retrieval will also reduce intensity and frequency of suicidal imagery.

The current registration is for the pilot trial, a preliminary study set up to evaluate feasibility, potential adverse events, and implementation of the (EMDT) intervention, to inform a full-scale, definitive randomized controlled trial.

Study participants are 6 depressed adults (18 years and older) with suicidal ideation. Participants will receive (max.) 6 sessions of EMDT as an add-on treatment to their care-as-usual.

The main study parameter will be the feasibility (i.e. treatment adherence, data collection) of setting up a multi-center randomized controlled trial evaluating the add-on Eye Movement Dual Task (EMDT) treatment.

Study objective

The pilot study has the following objectives associated to the preparations of a full-scale randomized controlled trial:

1. To evaluate the feasibility, acceptability, and implementation of the add-on Eye Movement Dual Task (EMDT) treatment

2. To test for potential adverse events and use this knowledge to create a safety protocol

Study design

Baseline (Intrusion Interview)

During treatment (max. 6 weeks)

Post-treatment

Intervention

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 max. six sessions each of approximately 1 hour, in the course of three to six weeks, delivered at the participants' mental health care center.

Eligible suicidal intrusion

The flash-forward/suicidal intrusion eligible to be treated by the EMDT treatment must score high on burdensomeness as measured by the Intrusion Interview. If the suicidal intrusion is interpreted as positive, i.e. if it's used as a coping strategy, it is no longer eligible. In other words, the image may not present a desired situation that is attractive to the patient.

Each session will consist of the following steps:

1. Selection of intrusive suicidal flash-forward target images with related ideation (as informed by the baseline intrusion interview).

2. Consecutive set of eye movements of approximately 24 seconds by 10 second breaks. 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.

The patients are receiving care-as-usual treatments during the course of the pilot study. Care-as-Usual for depression within the participating mental health care institution typically

consists of (evidence-based) psychotherapy and/or antidepressant treatment.

Contacts

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Eligibility criteria

Inclusion criteria

a. Have a minimum age of 18 years

b. Score >20 on the Beck Depression Inventory

c. Have suicidal ideation: score >20 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

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2017
Enrollment:	6
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-05-2018
Application type:	First submission

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
NTR-new	NL6946
NTR-old	NTR7202
Other	: METC protocol no. NL60318.028.17 (Phase 1)

Study results

Summary results

Bentum, J., Sijbrandij, M., Huibers, M., Huisman, A., Arntz, A., Holmes, E., & Kerkhof, A. (2017). Treatment of Intrusive Suicidal Imagery Using Eye Movements. International Journal of Environmental Research and Public Health, 14(7), 714. MDPI AG. Retrieved from http://dx.doi.org/10.3390/ijerph14070714