

[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-OMON27251

Source

Nationaal Trial Register

Brief title

SIMAGERY

Health condition

suicidal, mental problems, depressive symptoms,

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Frequency of suicidal intrusions: Clinical Interview for Suicidal Intrusions [CISI], Suicidal Intrusions Attributes Scale [SINAS]

Secondary outcome

Suicidal ideation (SIDAS), depressive symptoms (BDI-II), quality of life (EQ-5D-5L), Societal costs (TiC-P), rumination (RRS), hopelessness (BHS)

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. According to cognitive psychology research, suicide-related images predict suicidality, and repetitive suicide-related images or flash-forwards are therefore an essential target for suicide prevention. There is extensive research evidence from experimental and clinical studies 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 and may be crucial in preventing the transition from suicidal imagery to actual suicidal behaviour.

The primary objective of SIMAGERY is to assess the prevalence of intrusive suicidal imagery and thoughts, and to evaluate the effectiveness of an Eye Movement Dual Task (EMDT) add-on treatment targeting suicidal imagery in depressed patients.

Study participants include depressed adults (18 years and older) with suicidal ideation (>1 SIDAS) and suicidal intrusions. Participants in the intervention group will receive a maximum of six EMDT-sessions and care-as-usual (CAU). Participants in the comparison group will only receive CAU.

The main study parameter is the frequency and intrusiveness of suicidal imagery. Furthermore, the vividness, emotionality, and quality of the suicidal intrusions are evaluated (Intrusion Interview); Secondary parameters include: suicidal behavior and suicidal ideation (SIDAS, BSSI), severity of depression (BDI-II), Brief Symptom Inventory (BSI), rumination (RRS) and hopelessness (BHS).

Study objective

We hypothesize that a dual task (eye movements) during suicidal imagery retrieval will reduce the frequency of such imagery.

Study design

Baseline

During treatment (max. 6 weeks)

Post-treatment

3 month follow up

6 month follow up

9 month follow up

12 month follow up

Intervention

There are two arms in this study:

1. comparison group: care as usual (CAU) only
2. intervention group: CAU with EMDT add-on treatment

Care as usual (CAU)

Care-as-Usual for depression within the participating mental health care institutions typically consists of (evidence-based) psychotherapy and/or antidepressant treatment. We will ensure that all patients will receive and continue CAU during the course of the study. After each assessment, the CAU mental health care provider will be updated on the patient (with consent of the patient).

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, 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:

3 - [Simagery] Targeting repetitive intrusive suicidal images and thoughts: towards ... 27-05-2025

1. Selection of intrusive suicidal flash-forward target images with related ideation.
2. Consecutive set of eye movements of 30 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, or the EMDT session is coming to an end.

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 >1 on Suicidal Ideation Attributes Scale (SIDAS)

- d. Currently receiving treatment (Care-as-usual) at GGZ instelling
- e. Adequate proficiency in the Dutch language
- f. Have suicidal intrusions 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)

In case their current therapist judges the overall complexity of trauma present, he or she can advise not to include despite the participant meeting the inclusion criteria.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-09-2018
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date: 17-10-2018

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	NL7355
NTR-old	NTR7563
Other	: METC protocol no. NL60318.028.17 (Phase 3)

Study results

Summary results

Holmes, E. A., Crane, C., Fennell, M. J., & Williams, J. M. (2007). Imagery about suicide in depression—"Flash-forwards"? Journal of Behavior Therapy and Experimental Psychiatry, 38(4), 423-434. doi:10.1016/j.jbtep.2007.10.004

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>