ISRCTN17404612 https://doi.org/10.1186/ISRCTN17404612

Targeting repetitive intrusive suicidal images and thoughts: towards a new suicide prevention strategy (Simagery)

Submission date
22/08/2022

Recruitment status
No longer recruiting

Registration date
26/08/2022

Overall study status
Completed

Last Edited
30/08/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
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 essential targets for suicide prevention. There is extensive research evidence from experimental and clinical studies that the vividness of negative as well as positive intrusive images may be reduced by Dual Task (e.g. eye movements) interventions taxing the working memory. The aim of this study is to find out whether eye movements during image retrieval also reduce the severity and frequency of suicidal imagery.

Who can participate?
Psychiatric outpatients aged 18 years and over with elevated levels of depression and suicidal ideation

What does the study involve?
Participants are randomly allocated to receive either treatment as usual (TAU) only or TAU with eye movement dual task (EMDT) add-on treatment. Treatment-as-Usual for depression within the participating mental health care institutions typically consists of (evidence-based) psychotherapy and/or antidepressant treatment. The EMDT add-on intervention involves taxing the working memory while retrieving suicidal intrusions and consists of two to six sessions, each about 1 hour, over the course of 6 weeks.

What are the possible benefits and risks of participating?
Burdens associated are six additional site visits, multiple questionnaires that have to be filled in, and potential psychological discomfort associated with participation (i.e. retrieving suicidal images may be emotionally confronting). A potential risk may be an increase in or worsening of suicidal images and their associated complaints. Potential benefits are a reduction in vividness and frequency of repetitive suicide-related images and thoughts, and reduced suicidality and depression. Moreover, there will be additional supervision of this at-risk group regarding their suicidal ideation, ensuring higher levels of safety.

Where is the study run from?
Vrije Universiteit Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?
October 2016 to December 2022

Who is funding the study?
ZonMw (Netherlands)

Who is the main contact?
Jael van Bentum, j.s.vanbentum@uu.nl

Contact information

Type(s)
Public

Contact name
Miss Jael van Bentum

ORCID ID
https://orcid.org/0000-0003-2758-095X

Contact details
Utrecht University
Heidelberglaan 8
Utrecht
Netherlands
3584 CS
+31 (0)30 2533550
j.s.vanbentum@uu.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NTR7563

Study information

Scientific Title
Reducing suicidal intrusions in depressed patients through an eye movement dual task in a multicenter parallel two-group randomized design

Acronym
Simagery

Study objectives
It is hypothesized 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/11/2017, The Medical Ethical Review Committee of the Amsterdam UMC, location VUmc (BS7, kamer H-443, Amsterdam, Postbus 7057 1007 MB , Netherlands; +31(0) 20 4445585; metc@vumc.nl), ref: 2017.237

Study design
Multicenter interventional single-blinded two-armed randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Suicidal intrusions in psychiatric outpatients with elevated levels of depression and suicidal ideation

Interventions
Patients are randomized on a 1:1 basis (stratified for mental health care institution) using a block randomization module in an electronic data capture system (Castor EDC):
1. Comparison group: treatment as usual (TAU) only
2. Intervention group: TAU with eye movement dual task (EMDT) add-on treatment

Treatment-as-Usual (TAU):
Treatment-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 TAU during the course of the study. After each assessment, the TAU mental health care provider will be updated on the patient (with the 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:
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 the 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.

Intervention Type
Behavioural

Primary outcome(s)
Frequency (Clinical Interview for Suicidal Intrusions; CISI) and severity (Suicidal Intrusions Attributes Scale; SINAS) of suicidal intrusions measured at baseline, 1-week post-treatment, 3, 6, 9 and 12 months follow up

Key secondary outcome(s))
1. Suicidal ideation measured using Suicidal Ideation Attributes Scale (SINAS) at baseline, 1-week post-treatment, 3, 6, 9 and 12 month follow-up
2. Depressive symptoms measured using Beck Depression Inventory-II (BDI-II) at baseline, 1-week post-treatment, 3, 6, 9 and 12 month follow-up
3. Quality of life measured using EQ-5D-5L at baseline, 1-week post-treatment, 3, 6, 9 and 12 month follow-up
4. Societal costs measured using Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P) at baseline, 3-month, and 12-month follow-up
5. Rumination measured using Ruminative Response Scale (RRS) at baseline, 1-week post-treatment, 3, 6, 9 and 12 month follow-up
6. Hopelessness measured using Beck Hopelessness Scale (BHS) at baseline, 1-week post-treatment, 3, 6, 9 and 12 month follow-up

Completion date
12/12/2022

Eligibility

Key inclusion criteria
1. Minimum age of 18 years
2. Score >20 on the Beck Depression Inventory
3. Have suicidal ideation: score >1 on the Suicidal Ideation Attributes Scale (SIDAS)
4. Currently receiving treatment (care-as-usual) at GGZ instelling
5. Adequate proficiency in the Dutch language
6. Have suicidal intrusions that are experienced as a burden

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
91

Key exclusion criteria
1. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) Psychotic disorder diagnosis
2. DSM-IV Depression with psychotic features diagnosis
3. DSM-IV Bipolar disorder diagnosis
4. High dropout risk (i.e. poor response rate when trying to get in contact with the 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

Date of first enrolment
27/11/2018

Date of final enrolment
13/09/2021

Locations

Countries of recruitment
Netherlands

Study participating centre
Altrecht
Nieuwe Houtenseweg 12
Utrecht
Netherlands
3524 SH

Study participating centre
Arkin - NPI
Amsterdam Oost
Domselaerstraat 126 & 128
1093 MB
Amsterdam Noord
Buikslotermeerplein 420
1025 WP
Amsterdam West
Overschiestraat 55

1062 HN
Amsterdam
Netherlands
1093MB

Study participating centre
GGZ Eindhoven
Dr. Poletlaan 40
Eindhoven
Netherlands
5626ND

Study participating centre
Dimence
Burgemeester Roelenweg 9
Zwolle
Netherlands
8021EV

Study participating centre
Vincent van Gogh Institute voor Geestelijke Gezondheid
Tegelseweg 210
Venlo
Netherlands
5912 BL

Study participating centre
Parnassia Groep
Klinisch centrum acute psychiatrie
Nectarinestraat 10
Den Haag
Netherlands
2552 LZ

Study participating centre
GGZ Oost-Brabant
Locatie Oss
Gezondheidslaan 65
Locatie Helmond
Wesselmanlaan 25/A, 5707 HA Helmond
Oss

Netherlands
5342 JW

Study participating centre
Pro Persona
Wagnerlaan 2
Arnhem
Netherlands
6815AG

Sponsor information

Organisation
VU Amsterdam

ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The data that support the findings of this study are available on request from the corresponding author (J.S. van Bentum; j.s.vanbentum@uu.nl). The data are not publicly available due to their containing information that could compromise the privacy of research participants. The individual participant data that underlie the results reported in the RCT's published article after deidentification can be obtained upon reasonable request by emailing a proposal to Prof. dr. Marit Sijbrandij (e.m.sijbrandij@vu.nl). To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years following article publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/07/2024	30/08/2024	Yes	No
Protocol article		09/05/2019	25/08/2022	Yes	No
Participant information sheet	Phase 2 version 6	05/03/2019	25/08/2022	No	Yes
Participant information sheet	Phase 3 version 5	05/03/2019	25/08/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes