Neural correlates of suicidal behaviour: a longitudinal study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON48668

Source
ToetsingOnline

Brief title
Neural correlates of suicide

Condition

- Psychiatric disorders NEC

Synonym
self-harm, suicide, suicide attempt

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw 537001005

Intervention

Keyword: emotion regulation, fMRI, suicide

Outcome measures

Primary outcome

The main study parameter is brain activation/connectivity measured with functional magnetic resonance imaging (fMRI) during different types of emotional processing tasks and resting state. For the second objective, the main study endpoint will be the association between brain activation at first measurement and suicidal ideation/attempts at follow-up. For the third objective, the main endpoint will be change in brain activation at follow-up (second MRI scan) as compared to the first measurement.

Secondary outcome

n.a.

Study description

Background summary

Suicide is an urgent societal problem, with alarming numbers that steadily increase in the Netherlands. However, the exact social, psychological and brain mechanisms underlying the risk of suicidal behavior remain largely unknown. It has been proposed that suicidal ideation may result from altered social-emotional processing, e.g. difficulties in cognitive control of emotion, in the face of adversity. This would lead to a *psychological pain* that can fuel hopelessness. Another important ingredient of hopelessness is a lack of flexibility to envision positive future scenarios. Feeling trapped in this desperate situation, suicide can be seen as the only solution. To come to the suicidal act some facilitating factors come into play, which we hypothesize to include reduced ability to take the perspective of others (which may reduce empathy in weighing the emotional consequences for close others). However, the exact nature of this process has not yet been elucidated. In this study, we will for the first time, examine several key cognitive-emotional processes in

relation to suicidal behavior using brain imaging: emotion regulation, envisioning future positive events and inferring on emotions of others. In addition, neural markers may identify those patients at high risk of future suicidality (suicide attempts and/or ideation) and can contribute to the development of more personalized treatment options by shedding light on the processes involved. Moreover, it is not yet known whether and to which extent such (neural) mechanisms "normalize" with time and treatment (i.e. are more similar to healthy comparison subjects). Most of the time participants receive a treatment with elements of cognitive behavior therapy (CBT) to reduce suicidal thoughts and behavior.

Study objective

The objectives of this study are threefold. First, we aim to understand the underlying neural mechanisms of suicidality. Therefore, we will investigate brain activation during resting state and three psychological processes that have been suggested to be of relevance to suicidality, but have not been studied yet using brain imaging: emotion regulation, positive imagery of future change and inferring on emotions of others. Second, to identify who is at risk for relapse of suicidal behavior despite adequate application of standard treatment protocol, we will investigate whether brain activation could serve as a marker for future suicidality, including both suicidal ideations and attempts. Third, to understand and target the underlying mechanisms, it is essential to know which mechanisms can be altered and are influenced by the current state of suicidality.

Study design

The current study has an experimental design. We will employ a longitudinal fMRI study in which we will follow a group of recent suicide attempters, for one year and patients with comparable psychopathology for six months. The tasks during fMRI scanning intend to measure emotion regulation, affective forecasting and inferring emotions of others. Furthermore, several interviews and questionnaires will be administered.

Study burden and risks

First, participants are asked to fill in questionnaires and interviews are held. For the patients with suicidal behavior, this will be divided over two days, for the control groups only one appointment will be scheduled. Second, participants will undergo (f)MRI scanning, during which participants have to perform tasks related to emotion regulation, envisioning positive future events and inferring on emotions of others, in addition a resting state scan and an anatomy scan will be made. This (f)MRI session will take approximately 75 minutes. After one year, for the patients with suicidal behavior, this whole session will be repeated. In between, participants will receive treatment in

accordance with current guidelines. All participants will be asked to fill in the suicidal ideation questionnaire after one, three and six months. This will take approximately 10 minutes. This will be done via mail.
Concerning the fMRI scanner, participants will be exposed to a field strength of 3 Tesla and to the noise of the scanner. Thus far, there is no evidence to suggest that exposing humans to a magnetic field of this strength has a negative influence on health. With regard to the noise, earplugs will be provided.
The suicide-attempted patients are a vulnerable group of people. Therefore, we will pro-actively offer a safety network for the suicide-attempted patients. This could benefit the patient that he/she will be actively be kept an eye on for the period of a year. This might help in prevention of a new attempt. We will do this by asking the participants to name a few people as their safety network, which we can contact in case we have suspicions about the well-being of the person or assess presence of suicidal ideation based on the follow-up measurements. This network will include the main psychiatric caregiver and family doctor.
The study is not intended to benefit the participants directly. However, the data collected during this study will enhance understanding of the neural basis of suicidal behavior. Participants receive a compensation of ¤30 for each MRI session(patients with suicidial behavior will receive ¤60 after completion of the baseline and follow-up measurement) for their participations.

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

All participants (N=94)
- 18 - 60 years of age
- Written informed consent
Suicide attempt patients (N=46)
- Had a recent suicide attempt as judged by a psychiatrist (not more than six months ago at moment of signing the informed consent)
Patient and Healthy controls (N=48)
- Matched to suicide attempt patients on age, sex, education, and handedness
- Never attempted suicide
Patient controls (N=24)
- Matched to suicide attempt patients on psychopathology
Healhty Controles (N=24)
- No current suicidal ideation defined by a BSS=0

Exclusion criteria

All participants:
- Presence of a neurological disorder
- A suicide attempt in light of auto-euthanasia in presence of a terminal somatic illness or
primarily caused by a psychotic delusion or hallucination
- Visual or hearing problems that cannot be corrected
- Insufficient knowledge of the Dutch language
- Not able to undergo 3 Tesla MRI scanning, these criteria include: (suspected) pregnancy, claustrophobia, MR incompatible implants or objects in the body (such as ear prostheses or other metal implants, operating clips or metal particles in the eye), tattoos containing pigments that form a safety risk, the refusal to be informed (by notifying the participants physician) of structural abnormalities that could be detected during the experiment. , For Healthy controls

- A past or current psychiatric disorder

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-10-2017
Enrollment:	94
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	16-09-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-01-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL61333.042.17