Trial Description

Title

The role of cognitive and emotional risk factors in decision-making

Trial Acronym

Suicide Risk

URL of the trial

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Brief Summary in Lay Language

**Several investigations emphasize an association between suicidal behavior (suicide ideas, realized or interrupted suicide attempts), as one of the major risk factors for completed suicides, and impaired decision-making under risk.
The current study aims to investigate mechanisms underlying such disturbed decision-making and their associations with other potentially mediating factors (e.g. traumatic childhood experiences, impaired cognitive control mechanisms or attention bias caused by emotional interference). A better understanding of such interactions could provide a valuable contribution to new approaches in suicide prevention.
In the study we will compare 20 previously suicidal, depressed patients with 20 depressed patients without suicidality and 20 healthy controls with regard to their decision-making abilities under risk.
All participants will be characterized regarding current and previous suicidality, depression, impulsivity, perfectionism, hopelessness, cognitive control mechanisms and traumatic childhood experiences. The main experiment includes three paradigms: Dynamically Optimized Sequential Experimentation, a validated decision-making task; Emotional Stroop-Task; and the Stop-Signal-Response-Task.
We expect a significantly poorer outcome in the patient group with previous suicidal behavioral concerning the parameters loss aversion and risk aversion, reaction times and accuracy under emotional conflicts, and reaction inhibition requests. Further correlational analyses will provide insights about potential interrelations.**

Brief Summary in Scientific Language

**Past suicidal behaviour (suicide ideas, realized or interrupted suicide attempts) is one of the major risk factors for completed suicides. Several investigations emphasize an association between suicidal behaviour and impaired decision-making under risk. At the same time, the knowledge about the mechanisms underlying such disturbed decision-making and other poten-tially mediating factors (e.g. traumatic childhood experiences, impaired cognitive control mech-anisms or attention bias caused by emotional interference) is exceedingly rare. A better under-standing of such interactions could provide a valuable contribution to new approaches in sui-cide prevention.
The current study aims to test previously suicidal, depressed patients (N=20) compared to de-pressed patients without suicidality (N=20) and healthy controls**

(N=20) with regard to their decision-making abilities under risk. Moreover, underlying influence factors including cognitive control mechanisms and traumatic childhood experiences will be tested as mediating variables. Further, all participants will be characterized regarding current and previous suicidality, depression, impulsivity, perfectionism and hopelessness. The main experiment includes three paradigms: Dynamically Optimized Sequential Experimentation (DOSE), a validated decision-making task; Emotional Stroop-Task (EST); and the Stop-Signal-Response-Task (SSRT). We expect a significantly poorer outcome in the patient group with previous suicidal behavioral concerning the parameters loss aversion and risk aversion (DOSE), reaction times and accu-racy under emotional conflicts (EST), and reaction inhibition requests (SSRT). Path-model analyses will provide insights about potential interrelations.
This pilot study will provide the basis for applying for funding of a further neuroimaging project.

Organizational Data

- DRKS-ID: **DRKS00015610**
- Date of Registration in DRKS: **2018/09/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EK 115/18 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F31.3 - Bipolar affective disorder, current episode mild or moderate depression**
- ICD10: **F31.4 - Bipolar affective disorder, current episode severe depression without psychotic symptoms**
- ICD10: **F43.2 - Adjustment disorders**

Interventions/Observational Groups

- Arm 1: **Depressed patients with previous suicidal behavior (suicide ideas, realized or interrupted suicide attempts) within the last six months.**

  Participants of all three groups will be examined in a single session according

the same procedure.
The main experiment includes three paradigms: Dynamically Optimized Sequential Experimentation (DOSE, a validated decision-making task with the main parameters loss aversion and risk aversion; Emotional Stroop-Task (EST; main parameters: reaction times and accuracy under emotional conflicts); and the Stop-Signal-Response-Task (SSRT; main parameters: impulsivity and reaction inhibition).

Additionally, the electrodermal activity (EDA) will be measured in a non-invasive procedure, in order to assess the emotional activity.

Hereafter, the participants will be asked to complete the following questionnaires:
• For diagnostic purposes: the structured clinical interview for DSM-IV (SCID) and the verbal intelligence test (IQ-WST).
• For assessment of depressive Symptoms: Becks Depressions Inventory-II (BDI-II) and Montgomery–Åsberg Depression Rating Scale (MADRS).
• For assessment of suicidality: Columbia Suicide Severity Rating Scale (C-SSRS), German Capability for Suicide Questionnaire (GCSQ) and german version of the Interpersonal Needs Questionnaire (INQ).
• For assessment of childhood adversity: Childhood Trauma Questionnaire (CTQ)
• For assessment of further cognitive high-risk states: Beck Hoplessness Scale, Temperament and Character Inventory (TCI), Trial-Making Test (TMT-A und TMT-B).
• For assessment of impulsivity: Barratt Impulsiveness Scale (BIS-11).

One blood sample will be taken to measure BDNF and sex hormones

- Arm 2: **Depressed patients without previous suicidal behavior (suicide ideas, realized or interrupted suicide attempts) in the lifetime.**

  Participants of all three groups will be examined in a single session according the same procedure as described above for group 1.
- Arm 3: **Healthy volunteers without a history of mental diseases or suicidality.**

  Participants of all three groups will be examined in a single session according the same procedure as described above for group 1.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Epidemiological study**

Allocation: **Other**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Other**

Purpose: **Other**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The current study aims to test previously suicidal, depressed patients compared to depressed patients without suicidality and healthy controls with regard to following primary outcome parameters:
Decision-making task (DOSE): loss aversion und risk aversion
Emotional stroop task (EST): Interference effect
Stop-Signal-Response-Task (SSRT): Inhibition effect
Childhood Trauma Questionnaire (CTQ): summarized score and subscores for physical, mental and sexual traumatic experience

Secondary Outcome

The secondary outcome parameters will be assessed using the following questionnaires and examinations:
-Becks Depressions Inventory-II (BDI-II; Self rating) und Hamilton Depression Scale (HAMD) (external rating)
-Suicide Severity Rating Scale (C-SSRS), German Capability for Suicide Questionnaire (GCSQ), Interpersonal Needs Questionnaire (INQ) (assessment of suicidality)
-Beck Hopelessness Scale (assessment of hopelessness)
-Temperament and Character Inventory (TCI) (assessment of personality attributes)
- Trail Making Task – TMT(A) und TMT(B) (cognitive flexibility)
- Barratt Impulsiveness Scale (BIS-11) (Impulsiveness)
-Cognitive Fusion Questionnaire (CFQ-D) und Metacognitions Questionnaire (MCQ) (ability of cognitive fusion)
-Laboratory parameters: Testosterone, Estrogen, Progesterone, Brain-derived neurotrophic factor (BDNF), Cortisol.
- Elektrodermal Activity (EDA)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Psychiatrie, Psychotherapie und Psychosomatik, Aachen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/09/20**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **60 Years**

Additional Inclusion Criteria

General inclusion criteria:
- Subject is 18 to 60 years of age on the day of signing informed consent.
- Subject agrees to participate by providing written informed consent
- Subject is able to obtain full insight into the objectives of the clinical trial and is fully contractually capable as assessed by an independent psychiatrist.
- For patients: voluntary treatment in the Department for Psychiatry, Psychotherapy and Psychosomatics.
Special inclusion criteria:
Group 1
- Suicidal behavior (suicide ideas, realized or interrupted suicide attempts) within the last 6 months
- Subject meets ICD-10 criteria for single depressive episode (F32.x), bipolar depression (F31.x), recurrent depression (F33.x) or adjustment disorder with depressive reaction (F43.2).
- Absence of acute suicidality and stabile psychopathological state.
- Persistence of depressive symptoms (BDI ≥ 14).
Group 2
- Lifetime absence of suicidal behavior (suicide ideas, realized or interrupted suicide attempts)
- Subject meets ICD-10 criteria for single depressive episode (F32.x), bipolar depression (F31.x), recurrent depression (F33.x) or adjustment disorder with depressive reaction (F43.2).
- Absence of acute suicidality and stabile psychopathological state.
- Persistence of depressive symptoms (BDI ≥ 14).
Group 3
- Healthy volunteers without a history of mental diseases or suicidality

Exclusion criteria

- Any comorbidity including following diagnostic categories: Organic, including symptomatic, mental disorders (F00-F09), Schizophrenia, schizotypal and delusional disorders (F20-F29), Mental retardation (F70-F79), Disorders of psychological development (F80-89).
- Subject has an unstable, severe medical disorder.
- Subject is hospitalized or treated coercively by order of the responsible local authorities.
- Subject (in the investigator's and - if necessary - an independent psychiatrist’s judgment) poses a serious suicidal or homicidal risk at the screening visit
- Subject has a clinically significant abnormality in the neurological assessments at screen or base
- subject is in a dependent position toward the investigators.

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*