

Trial Description

Title

Affective startle modulation during therapy in patients with depression

Trial Acronym

ASD

URL of the trial

[---]*

Brief Summary in Lay Language

The startle reflex is a defensive reaction triggered by sudden, intense stimuli (e.g. loud noise). This reaction can be measured by physiological methods, such as the measurement of the eye-blink reflex. The startle reflex response is modulated by one's ongoing emotional state. Negative stimuli (e.g. visualization of unpleasant pictures) usually potentiate the startle eye blink response, while positive stimuli typically inhibit this response. In this way, it is possible to physiologically study emotional processing through the measurement of the startle reflex. Previous studies have shown that processing of emotional content is disrupted in some psychiatric disorders. The aim of this study is to investigate how affective responses change during the different phases of Cognitive Behavioral Therapy treatment in patients with Depression. 80 participants are planned: 40 patients with Depression undergoing Cognitive-behavioral therapy, and 40 healthy participants with no diagnosed psychological disorder. Affective processing will be assessed through modulation of the startle response at three different time points: before start of therapy, after the 12th therapy session and after the 24th session. For this purpose, participants are shown pictures with different emotional contents (pleasant, neutral and unpleasant), with simultaneous presentation of a loud noise (startle stimuli). The startle reaction (eye blinking) is measured through electromyography (EMG). Furthermore, electrodermal responses (EDA) are acquired as an additional measure of emotional reaction to the pictures. The control group is acquired following a similar time plan. It is expected that emotional responses of patients with depression will differ from the control group at the beginning of the therapy, but that these differences are reduced throughout the therapy.

Brief Summary in Scientific Language

Affective startle modulation is a valid paradigm to measure emotion processing in humans. As many studies show, affective modulation of the startle reflex is altered in humans with psychiatric disorders. However, studies examining to what extent altered emotion processing can be influenced by psychotherapy are scarce. This study aims investigate the effect of psychotherapy on affective modulation in patients with Depression. Furthermore, it intends to assess the relation between affective startle modulation throughout therapy with changes in clinical symptoms and therapeutic success.



Organizational Data

- DRKS-ID: **DRKS00012537**
- Date of Registration in DRKS: **2017/07/19**
- 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.: **17-10 , Ethikkommission der Fakultät für Empirische Humanwissenschaften und Wirtschaftswissenschaft der Universität des Saarlandes**

Secondary IDs

Health condition or Problem studied

- Free text: **Major Depressive Disorder**
- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

- Arm 1: **Patients with the primary diagnosis of Depressive disorder, starting a Cognitive Behavioural Therapy. Assessment of the startle reflex during visualization of pictures with different emotional content through electromyography (EMG) and electrodermal responses (EDA) before beginning of therapy, as well as after the 12th and 24th therapy sessions. Additional acquisition of interviews and questionnaires related to depression and subjective ratings of the shown pictures.**
- Arm 2: **Control group (healthy participants): all tests like in Arm 1 following a similar time interval.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
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Blinding: [---]*

Who is blinded: [---]*

Control: **Other**

- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Startle responses during visualization of pictures with different affective content measured through Electromyography (EMG). Emotional reaction to the presented material measured through electrodermal responses (EDA).

Three different acquisition points: 1) before beginning of therapy (during or directly after the probatory sessions), 2) after the 12th therapy session, 3) after the 24th therapy session. Acquisition of the control group runs in a parallel design (same time between acquisition points).

Secondary Outcome

Interview and questionnaires focusing on depression (SKID, BDI-II, BSI, DAS) and subjective ratings of the pictures (Visual analogue scale) at the above named 3 acquisition points

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Universität des Saarlandes, Klinische Psychologie und Psychotherapie, Saarbrücken**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/10/02**

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- 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: **no maximum age**

Additional Inclusion Criteria

Patients with the primary diagnosis of Depressive disorder undergoing Cognitive-behavioural therapy;
Control group: matched healthy participants

Exclusion criteria

- **no long-term medication (exceptions: oral contraception or occasionally a painkilling tablet up to one week before the start of the study; patient group: prescribed psychiatric medication)**
- **no drug or substance abuse**
- **no noise sensitivity and/or hearing impairment like tinnitus**

Addresses

■ Primary Sponsor

Universität des Saarlandes Klinische Psychologie und Psychotherapie
Ms. Dr Tanja Michael
Campus, Geb. A1.3
66123 Saarbrücken
Germany

Telephone: **++49 +681 302 71000**

Fax: **++49 +681 302 4437**

E-mail: **t.michael at mx.uni-saarland.de**

URL: **<http://www.uni-saarland.de/lehrstuhl/michael/startseite.html>**

■ Contact for Scientific Queries

Universität des Saarlandes Klinische Psychologie und Psychotherapie
Ms. Dr. Diana Ferreira de Sá

Contact for Scientific Queries

Universität des Saarlandes Klinische Psychologie und Psychotherapie

Ms. Dr. Diana Ferreira de Sá

Campus, A1.3

D-66123 Saarbrücken

Germany

Telephone: **++49 +681 302 71209**

Fax: **++49 +681 302 4437**

E-mail: **diana.ferreira at uni-saarland.de**

URL: **<http://www.uni-saarland.de/lehrstuhl/michael/startseite.html>**

■ **Contact for Public Queries**

Universität des Saarlandes Klinische Psychologie und Psychotherapie

Ms. Dr. Diana Ferreira de Sá

Campus, A1.3

D-66123 Saarbrücken

Germany

Telephone: **++49 +681 302 71209**

Fax: **++49 +681 302 4437**

E-mail: **diana.ferreira at uni-saarland.de**

URL: **<http://www.uni-saarland.de/lehrstuhl/michael/startseite.html>**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

**Anschubfinanzierung des Forschungsausschusses und des Präsidiums der
Universität des Saarlandes**

66123 Saarbrücken

Germany

Telephone: **[---]***

Fax: **[---]***

E-mail: **[---]***

URL: **[---]***

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

Universität des Saarlandes

Klinische Psychologie und Psychotherapie

66123 Saarbrücken

Germany

Telephone: **[---]***

Fax: **[---]***



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Universität des Saarlandes
Klinische Psychologie und Psychotherapie
66123 Saarbrücken
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

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.