

Trial Description

Title

Neurobiological correlates and mechanisms of the augmentation of psychotherapy with endurance exercise in mild to moderate depression

Trial Acronym

SPeED

URL of the trial

<https://www.researchgate.net/project/SPeED-Study-Exercise-therapy-and-psychotherapy-an-evaluation-study-with-patients-suffering-from-major-depressive-disorder-MDD>

Brief Summary in Lay Language

Exercise therapy and psychotherapy - an evaluation study with patients suffering from major depressive disorder (MDD) (SPeED-Study): Both psychotherapy (cognitive behavioral therapy) and exercise therapy (endurance training) have been found to be an effective treatment for MDD. We investigate the combination of exercise therapy and psychotherapy. Two groups participate in a twelve week endurance training (supervised training in small groups, twice weekly, 60 minutes). The intensity of the endurance training differs between the two groups. Subsequently, these two groups and a third waiting control group receive a cognitive behavioral therapy for twelve weeks. Diagnostic measures at several times include questionnaires (e.g. for depressive symptoms), sports-medical performance diagnostics, blood sampling, and magnetic resonance imaging of the brain. This study will contribute to a better understanding of the underlying mechanisms of the antidepressant effect of exercise therapy and psychotherapy in MDD.

Brief Summary in Scientific Language

Cognitive behavioral therapy (CBT) was found to be an effective treatment for major depressive disorder (MDD) and CBT-related changes of dysfunctional neural activations were shown in recent studies. Despite these effects, remission rates after CBT are not sufficiently high in MDD and the integration of effective augmentation strategies is needed. In recent meta-analyses, exercise therapy (especially endurance training) was reported to be an effective intervention in MDD. However, underlying neural mechanisms of the antidepressant effect of endurance training have been rarely investigated to date, and a better knowledge of these mechanisms especially in combination with CBT is lacking. The main aim of this study is to investigate underlying physiological, neurobiological, and psychological mechanisms of the augmentation of CBT with endurance training. By applying a longitudinal randomized controlled study design, we investigate if a preceding endurance training intervention will increase the success-rate of a subsequent CBT and if this augmentation effect will be associated with specific neurobiological changes. At four measure points (t1: baseline, t2: after exercise therapy respectively waiting period, t3: after psychotherapy, t4: follow up) primary and secondary outcomes were assessed. A



low intensity endurance training group will be included to disentangle physiological from unspecific effects (e.g. general effects of an additional group activity or the attention of an exercise instructor). Specific aims of this study are the association of exercise-induced changes in cortisol and neurotrophine-levels with changes in neural activations during working memory, monetary incentive delay, and emotion-regulation tasks, as well as the prediction of CBT treatment response with these parameters. Results of this study may provide important implications for the development of effective treatment strategies in MDD, concerning the augmentation of CBT by endurance exercise.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008869**
- Date of Registration in DRKS: **2015/07/28**
- 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.: **EA1/113/15 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32.0 - Mild depressive episode**
- ICD10: **F32.1 - Moderate depressive episode**
- ICD10: **F33.0 - Recurrent depressive disorder, current episode mild**
- ICD10: **F33.1 - Recurrent depressive disorder, current episode moderate**

Interventions/Observational Groups

- Arm 1: **High-intensity Endurance training (twice weekly over 12 weeks ca. 60 minutes of moderate to high intensity), subsequently: cognitive behavioral therapy (twice weekly over 12 weeks, 50 minutes)**
- Arm 2: **Low-intensity Endurance training (twice weekly over 12 weeks, ca. 60 minutes of low intensity), subsequently: cognitive behavioral therapy (twice weekly over 12 weeks, 50 minutes)**
- Arm 3: **No exercise intervention (control group, 12 weeks), subsequently: cognitive behavioral therapy (twice weekly over 12 weeks, 50 minutes)**
- Arm 4: **Healthy control group (no intervention, measures like t1 at one measure point (except HCCQ))**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject, investigator/therapist, assessor, data analyst**
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Factorial**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Severity of depressive symptoms measured via self rating (Beck Depression Inventory, BDI) and external rating (Hamilton Rating Scale for Depression, HAM-D) from baseline to follow-up (t1: baseline, t2: after exercise therapy respectively waiting period, t3: after psychotherapy, t4: follow up) .

Secondary Outcome

Brain-derived neurotrophic factor (BDNF) levels are measured taking serum samples (t1-t2 before and after exercise electrocardiogram (ECG) and t3). In functional magnetic resonance tomography (fMRT) blood-oxygen-level-dependent (BOLD) signal is measured during working memory-, reward learning- and emotion regulation tasks (t1-t3).

Self-efficacy measured via self rating (general self-efficacy scale, GSE)(t1-t4), Emotion-Regulation measured via self rating (emotion-regulation questionnaire, ERQ)(t1-t4), current physical activity measured via self rating (international physical activity questionnaire short form, IPAQ-SF)(t1-t4).

Cognitive abilities such as working memory and inhibition are measured via neuropsychological tests (digit span, digit symbol, stroop-task, verbal learning and memory test, VLMT)(t1-t4).

Psychological distress measured via self rating (brief symptom inventory, BSI)(t1-t4), dysfunctional attitudes measured via self report (dysfunctional attitude scale, DAS)(t1-t4), pain intensity measured via self-rating (visual analogue scale)(t1-t4), disability related to pain measured via self rating (pain disability index, PDI)(t1-

t4), basic psychological needs of relatedness, competence and autonomy measured via self rating (basic psychological need satisfaction and frustration scale, BPNSFS)(t1-t4), the atmosphere of health care in exercise training (t1-t2) and psychotherapy (t2-t3) is measured via self rating (health care climate questionnaire, HCCQ); physical fitness is measured during exercise ECG to calculate the maximum uptake of oxygen (VO₂max.) (t1-t2) and blood-samples are taken to identify lactate (t1-t2). Cortisol level will be measured via saliva samples (24h)(t1-t3).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité Berlin, Zentrum für Psychotherapie der Humboldt Universität zu Berlin, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/28**
- Target Sample Size: **105**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

The study is conducted with 18- to 65- years old, as physical healthy diagnosed ambulant psychotherapy patients with the main diagnosis of a mild to moderate depressive episode diagnosed according to ICD-10 (F32.0, F32.1), which can also occur in the context of a recurrent depressive disorder (F33.0, F33.1). The presence of a major depressive episode is assured by creating structured clinical interview I for DSM - IV (SCID I) ; Axis I: mental disorders, depression section. The healthy control group (18-65 years old). Subjects of the healthy control group are 18-65 years old and have no major depressive disorder.

Exclusion criteria

Following exclusion criteria are applied: current severe depressive episode with and without psychotic symptoms (F32.2, F32.3, F33.2 or F33.3), current borderline or dissocial personality disorder, acute suicide risk, current or lifetime schizophrenia spectrum disorder, delusional disorders (F2x.x), bipolar affective disorder (F31.x), current dependence (alcohol, heroin, amphetamine, cocaine), minimum period of rest 12 month, current severe neurological diseases and illnesses of central nervous system, severe chronic obstructive pulmonary disease (COPD), coronary heart disease, cardiac insufficiency, anaemia, body mass index > 35 or < 18, language problems, non-correctable hearing and visual impairments, MRI unsuitability, current use of benzodiazepines or beta blockers within the last 7 days, tricyclic antidepressants with a dose of > 50mg per day, neuroleptics with a dose of > 30% of the maximum daily dose, regular endurance training (more than two times per week for 45min).

Addresses

■ Primary Sponsor

**Department Sport- und Gesundheitswissenschaften, Sozial- und
Präventivmedizin, Universität Potsdam
Mr. Prof. Dr. Dr. Michael Rapp
Am Neuen Palais 10
14469 Potsdam
Germany**

Telephone: **03319771050**

Fax: **03319774078**

E-mail: **mrapp at uni-potsdam.de**

URL: **<http://www.uni-potsdam.de/soz-praev-med/index.html>**

■ Contact for Scientific Queries

**Freie Universität Berlin, Klinische Psychologie und Psychotherapie
Erziehungswissenschaften und Psychologie
Mr. Prof. Dr. Stephan Heinzel
Habelschwerdter Allee 45
14195 Berlin
Germany**

Telephone: **030 838 61564**

Fax: **030 838-461564**

E-mail: **stephan.heinzel at fu-berlin.de**

URL: **http://www.ewi-psy.fu-berlin.de/einrichtungen/arbeitsbereiche/klinische_psychotherapie/index.html**

■ Contact for Public Queries

**Universität Potsdam, Department Sport- und Gesundheitswissenschaften,
Sozial- und Präventivmedizin
Mr. Dr. Andreas Heißel
Am Neuen Palais 10
14469 Potsdam**



Contact for Public Queries

**Universität Potsdam, Department Sport- und Gesundheitswissenschaften,
Sozial- und Präventivmedizin
Mr. Dr. Andreas Heißel
Am Neuen Palais 10
14469 Potsdam
Germany**

Telephone: **015903150475**

Fax: **03319774078**

E-mail: **psyspeed at hu-berlin.de**

URL: **http://www.uni-potsdam.de/fileadmin/projects/soz-praev-med/assets/Forschung/Flyer_SPeED.pdf**

■ **Contact for Scientific Queries**

**Universität Potsdam, Department Sport- und Gesundheitswissenschaften,
Sozial- und Präventivmedizin
Mr. Dr. Andreas Heißel
Am Neuen Palais 10
14469 Potsdam
Germany**

Telephone: **03319771050**

Fax: **03319774078**

E-mail: **andreas.heissel at uni-potsdam.de**

URL: **<http://www.uni-potsdam.de/soz-praev-med/index.html>**

■ **Collaborator, Other Address**

**ZPHU - Zentrum für Psychotherapie am Institut für Psychologie der Humboldt-
Universität zu Berlin
Mr. Prof. Dr. Thomas Fydrich**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Collaborator, Other Address**

**Klinik für Psychiatrie und Psychotherapie, Campus Charité Mitte, Charité -
Universitätsmedizin Berlin
Mr. Prof. Dr. Andreas Ströhle**

Telephone: [---]*

Fax: [---]*

Collaborator, Other Address

**Klinik für Psychiatrie und Psychotherapie, Campus Charité Mitte, Charité -
Universitätsmedizin Berlin
Mr. Prof. Dr. Andreas Ströhle**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Collaborator, Other Address**

**Sport-Gesundheitspark Berlin e.V./ Zentrum für Sportmedizin
Mr. Dr. Andreas Heißel
Fritz-Lesch-Str. 29
Berlin
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.sport-gesundheitspark.de**

Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

**Emanuela Dalla Vecchia Stiftung Depressionsforschung
Mr.
Katharinenstrasse 12
10711 Berlin
Germany**

Telephone: **030890470**

Fax: **03089047100**

E-mail: **info at stidefo.de**

URL: **www.stidefo.de**

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

**Deutsche Forschungsgemeinschaft
Kennedyallee 40
53175 Bonn
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*



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**Deutsche Forschungsgemeinschaft
Kennedyallee 40
53175 Bonn
Germany**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/12/31**

Trial Publications, Results and other documents

- Paper **Neurobiological mechanisms of exercise and psychotherapy in depression: The SPeED study-Rationale, design, and methodological issues**

* 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.