

# Sports therapy for depression in the German health care system

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Both physical exercise and psychotherapy have been shown to have moderate to large effects for the treatment of depressive disorders. However, little is known about the effectiveness of sports therapy for depression in “real world” settings, e.g., implemented in a community healthcare setting. The aim of this study is to test the effectiveness of sports therapy as compared to short-term treatment-as-usual (TAU) psychotherapy in a sample of outpatients with depressive disorders including adjustment disorder in a community-based health care system in Germany.

### Who can participate?

Patients aged 18 to 65 with depressive disorder or adjustment disorder

### What does the study involve?

Participants are randomly allocated to 28 psychotherapists who are randomly allocated to the TAU psychotherapy or sports therapy condition. Control group psychotherapists provide short-term TAU psychotherapy only. Intervention psychotherapists provide a diagnostic assessment and offer monthly follow-up phone calls and psychological crisis interventions while patients undergo sports therapy over 4 months in groups of 4 to 12 people supervised by trained exercise professionals twice a week, yielding a total of 32 sessions of 60 min each. Sports therapy includes endurance exercise complemented by strength training, coordination and flexibility exercise. During sports therapy and TAU psychotherapy, mood, motivation, physical activity, emotion regulation, and cognition are assessed. Depression severity is measured at the start of the study and at the end of the sports therapy and at 2-, 6-, and 12-months follow-up.

### What are the possible benefits and risks of participating?

All possible participants receive an immediate appointment with a psychotherapist to figure out an individual optimal treatment strategy. If sports therapy is indicated, they can start immediately, or if another therapy is indicated or they are not eligible for the study they will receive psychotherapy care as usual. Sports therapy is free of charge for the participants (as is TAU psychotherapy). There is a small risk for sports injuries during the sports therapy comparable to the risks of leisure sports activities.

Where is the study run from?  
Universität Potsdam (Germany)

When is the study starting and how long is it expected to run for?  
April 2018 to March 2022

Who is funding the study?  
Innovationsausschuss des Gemeinsamen Bundesausschusses (G-BA) [Innovation Fund of the Joint Federal Committee] (Germany)

Who is the main contact?  
Prof. Michael Rapp  
mrapp@uni-potsdam.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
01NVF17050

## Study information

**Scientific Title**  
Sports therapy for depression in the German health care system: the STEP.De effectiveness trial

**Acronym**  
STEP.De

**Study objectives**

Compared to TAU psychotherapy, patients undergoing sports therapy will exhibit similar treatment effects in a community-based health care system over a period of 4 months.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics Committee of University of Potsdam, 18/06/2018, No 17/2018

### **Study design**

Two-arm cluster-randomized non-inferiority effectiveness trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Depressive disorder (ICD-10: F32.0, F32.1, F33.0, F33.1, F34.1) or adjustment disorder (F43.2, F48.0, F43.8, F43.9, F41.2)

### **Interventions**

Current intervention as of 11/08/2022:

Patients will be recruited via local community-based insurance carriers providing specialized treatment plans for psychotherapy in depression. Participants will be randomly assigned to 28 psychotherapists who are randomized to the TAU psychotherapy or sports therapy condition (cluster randomization at the psychotherapist level). Control group psychotherapists will provide TAU psychotherapy only. Intervention psychotherapists will provide a diagnostic assessment and offer monthly follow-up phone calls and psychological crisis interventions while patients undergo sports therapy over 4 months in groups of 4 to 12 people supervised by trained exercise professionals twice a week, yielding a total of 32 sessions of 60 min each. Sports therapy will include endurance exercise complemented by strength training, coordination and flexibility exercise. During sports therapy and TAU psychotherapy, electronic momentary assessment will be used for process analyses of mood, motivation, physical activity, emotion regulation, and cognition.

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Previous intervention:

Patients will be recruited via local community-based insurance carriers providing specialized treatment plans for psychotherapy in depression. Participants will be randomly assigned to 20 psychotherapists who are randomized to the TAU psychotherapy or sports therapy condition (cluster randomization at the psychotherapist level). Control group psychotherapists will provide TAU psychotherapy only. Intervention psychotherapists will provide a diagnostic assessment and offer monthly follow-up phone calls and psychological crisis interventions while patients undergo sports therapy over 4 months in groups of 4 to 12 people supervised by trained exercise professionals twice a week, yielding a total of 32 sessions of 60 min each. Sports therapy will include endurance exercise complemented by strength training, coordination and

flexibility exercise. During sports therapy and TAU psychotherapy, electronic momentary assessment will be used for process analyses of mood, motivation, physical activity, emotion regulation, and cognition.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Depression severity measured with the Beck Depression Inventory (BDI-II) at baseline and immediately after the sports intervention

## **Key secondary outcome(s)**

All ratings will be performed by raters partially blinded for the interventional character of the study at baseline, after two and four months, and two, six, and twelve months after the sports intervention:

1. Hamilton Rating Scale for Depression (HAM-D)
2. Work ability (WHO Disability Assessment Schedule 2.0, WHODAS 2.0; Work and Social Adjustment Scale, WSAS)
3. Physical activity (IPAQ)
4. Psychopathological symptoms (modified VDS90-R)
5. Self-efficacy (GSE-6)
6. Psychological need frustration and satisfaction (BPNSFS)
7. Quality of life (SF-12, EQ-5D)
8. Health care climate (HCCQ)
9. Sports motivation (BRQ-12)
10. Mindfulness (Mindful Attention Awareness Scale [MAAS])
11. Telemetric physical activity recordings
12. Depression severity as assessed by the BDI at all timepoints will be used for secondary analyses to explore sustainability of treatment effects
13. Health insurance data will be used for health economic analysis using a difference-in-difference approach

## **Completion date**

31/03/2022

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 11/08/2022:

1. Male and female patients aged between 18 and 65 years
2. Suffering from any of the following disorders as evinced by chart documentation and validated in confirmatory structured interviews (Structural Clinical Interview I for DSM - IV (SCID - I); Axis 1: psychological disorders, depression section):
  - 2.1. Mild or moderate depressive episode (F 32.0, F 32.1)
  - 2.2. Recurrent depressive disorder, current episode mild or moderate (F 33.0, F 33.1)
  - 2.3. Dysthymia (F34.1)
  - 2.4. Adjustment disorder (F43.2)
  - 2.5. Neurasthenia F48.0
  - 2.6. Other reactions to severe stress F43.8
  - 2.7. Reaction to severe stress, unspecified F43.9
  - 2.8. Mixed anxiety and depressive disorder F41.2

3. Ability to engage in regular physical exercise according to the adjusted Physical Readiness Questionnaire (Par-Q)

4. Basic skills in handling personal computer and/ or tablet as well as internet access

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Previous inclusion criteria:

Both male and female patients aged between 18 and 65 years suffering from any of the following disorders as evinced by chart documentation and validated in confirmatory structured interviews (Structural Clinical Interview I for DSM - IV (SCID - I); Axis 1: psychological disorders, depression section):

1. Mild or moderate depressive episode (F 32.0, F 32.1)

2. Recurrent depressive disorder, current episode mild or moderate (F 33.0, F 33.1)

3. Dysthymia (F34.1)

4. Adjustment disorder (F43.2)

Ability to engage in regular physical exercise according to the adjusted Physical Readiness Questionnaire (Par-Q). Basic skills in handling personal computer and/ or tablet as well as internet access.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

393

**Key exclusion criteria**

1. Ongoing outpatient psychotherapy

2. Physical disability

3. Legal guardianship

4. Active substance dependence or severe use disorder

5. Other serious mental or neurological illness

6. Presence of long-term medication with benzodiazepines or opiates (several weeks)

7. High-dose (> .7 DDD) pharmacotherapy with tricyclics or neuroleptics

**Date of first enrolment**

17/08/2018

**Date of final enrolment**

14/04/2021

# Locations

## Countries of recruitment

Germany

## Study participating centre

**Social and Preventive Medicine, Department of Sports and Health Sciences**

Universität Potsdam

Am Neuen Palais 10

Potsdam

Germany

D- 14469

## Study participating centre

**Clinical Psychology and Psychotherapy, Neurobiological mechanisms of therapeutic interventions**

Freie Universität Berlin

Habelschwerdter Allee 45

Berlin

Germany

D-14195

## Study participating centre

**BKK-VBU – Service Area Management**

Lindenstraße 67

Berlin

Germany

D-10969

## Study participating centre

**Sport- und Gesundheitspark Berlin e.V.; Sports and Health Park / Centre for Sports Medicine (SGP)**

Fritz-Lesch-Str. 29

Berlin

Germany

D-13053

## Study participating centre

**CONVEMA – Service Management GmbH**

Karl-Marx-Allee 90A

Berlin

Germany  
D-10243

**Study participating centre**

**BAHN BKK**  
Franklinstraße 54  
Frankfurt am Main  
Germany  
D-60486

**Study participating centre**

**BMW BKK**  
Mengkofenerstraße 6  
Dingolfing  
Germany  
D-84130

## Sponsor information

**Organisation**

Social and Preventive Medicine, Universität Potsdam

## Funder(s)

**Funder type**

Government

**Funder Name**

Innovationsausschuss des Gemeinsamen Bundesausschusses (G-BA) [Innovation Fund of the Joint Federal Committee]

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Michael Rapp (mrapp@uni-potsdam.de).

**IPD sharing plan summary**

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	14/04/2020	17/04/2020	Yes	No
<a href="#">Other publications</a>	validation of the translated Work and Social Adjustment Scale (WSAS)	21/06/2021	24/06/2021	Yes	No
<a href="#">Other publications</a>	validation of the BPNSFS in the clinical context by examining the role of th2. develop a short version of the German BPNSFS	31/01/2023	31/07/2025	Yes	No