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Sports therapy for depression in the German health care system

Submission date	Recruitment status	[X] Prospectively registered
21/06/2018	No longer recruiting	[X] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
26/06/2018	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
13/09/2023	Mental and Behavioural Disorders	[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet (in German)

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

Secondary outcome measures
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

Overall study start date
01/04/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

480 patients aged 18-65 years suffering from depressive disorder (recruited from three community-based health care systems in Berlin, Germany). The study is powered for cluster-adjusted regression analysis as a non-inferiority trial (= .05; 1-β = .95) based on an effect size of f = .3. Conventional repeated measures analysis of variance design with two measurement occasions yields a total sample size of 147 patients. Adjusting for 24 patients in 20 randomly assigned clusters (psychotherapists), and an intra-cluster correlation ICC of .08, using the design effect provided by Donner yields a total sample of 429 patients. Accounting for dropout, 480 patients will be recruited, each 240 in intervention and control group.

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
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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
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Sponsor information

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Sponsor type
University/education

Website
https://www.uni-potsdam.de/soz-praev-med/index.html

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
The trialists plan to submit a method paper concerning rationale, design and analysis plan in October 2018. Publication of primary trial analysis and results. Presentation of process analyses and secondary outcome variables at conferences and publication in peer-reviewed journals.

Intention to publish date
01/03/2024

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

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Protocol article	protocol	14/04/2020	17/04/2020	Yes	No
Other publications	validation of the translated Work and Social Adjustment Scale (WSAS)	21/06/2021	24/06/2021	Yes	No