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Bouldering-psychotherapy against depression and stress

Submission date
16/01/2025

Recruitment status
Recruiting

Registration date
19/02/2025

Overall study status
Ongoing

Last Edited
27/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Psychological and psychotherapeutic care for children and adolescents in Germany is insufficient. A shortage of psychotherapeutic specialists for adolescents working for the legal health insurance leads to long waiting times for therapeutic care, long ways to a small number of psychotherapeutic offers impede the utilization and furthermore a lack of awareness of type, content, accessibility or financing options further hamper access to professional treatment. The COVID-19 pandemic has contributed to an increase in psychological distress and mental illness among adolescents and thus enlarged the existing shortage of therapeutic offers for adolescents. Thus, the Federal Chamber of Psychotherapists demands an expansion of services like group therapy, as these interventions are efficient, serve a larger number of individuals, and reduce stigma due to peer support. However, validated programs for depressive adolescents are rare.
This study examines the efficacy of a bouldering-psychotherapy (BPT) adopted for adolescents (BPT-J) in reducing depressive symptoms. BPT combines physical activation in the context of bouldering exercises with psychotherapeutic elements of cognitive behavioral therapy in a group setting. While the effectiveness of BPT has already been proven in adults, the effect (both curative and preventive) of BPT-J in adolescents has not been studied yet, so this is the primary outcome of this study. In addition, other psychological factors that could influence the success of treatment are being considered. These include quality of life, self-efficacy, suicidality and other comorbid psychological symptoms. A long-term goal of the BPT-J is also the implementation of the BPT-J in standard care, e.g. through cooperation with health insurance companies. Health economic evaluations are also to be carried out for this purpose.

Who can participate?
Adolescents aged 13 to 18 years with clinical or sub-clinical depressive symptoms who are able to travel to therapy locations (Erlangen, Nuremberg, Bamberg or Regensburg), have the timely availability of one afternoon per week for approximately 120 min and have access to digital devices for video or phone interviews.

What does the study involve?
Participants are randomly assigned to one of two groups:
1. Intervention Group (IG): Ten sessions of bouldering psychotherapy (BPT-J).

2. Waitlist Control Group (CG): Participants in the CG will be offered a BPT-J group after two measurement points. Aside from a waiting period of about 3 months, the CG will be equivalent to the IG.
Each group will complete self-rated and observer-rated questionnaires at four points over 1 year (baseline, after 3, 6 and 15 months) and take part in two interviews at the beginning of the study (before and after the intervention of IG).

What are the possible benefits and risks of participating?
Participants in the BPT-J group will receive a therapeutic offer with proven effectiveness in its adult version for treating depression. BPT-J is a low-threshold group therapy suitable for both curative purposes and secondary prevention. To maintain benefits and promote physical activity, an optional aftercare group is offered from the end of the intervention until the follow-up assessment. This group aligns with BPT-J content and focuses on participants' topics and requests.
Previous studies involving over 1,000 hours of therapeutic bouldering reported no injuries requiring medical treatment. However, there is a risk of minor injuries, similar to other physical activities.

Where is the study run from?
Centre for Health Services Research in Medicine & Department of Child and Adolescent Mental Health, Department of Psychiatry and Psychotherapy, Uniklinikum Erlangen (Germany)

When is the study starting and how long is it expected to run for?
October 2024 to September 2028

Who is funding the study?
Bavarian State Ministry of Health, Care and Prevention (Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention) (Germany)

Who is the main contact?
Prof. Dr. Carolin Donath, carolin.donath@uk-erlangen.de

Study website
http://www.boulderdichstark.de

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
G56c-G8096-2022/751-38

Study information

Scientific Title
BooSt: a randomized-controlled trial evaluating the efficacy of bouldering-psychotherapy against depression and stress in adolescents

Acronym
BooSt

Study objectives
1. Patients in the BPT-J group (intervention group; IG) demonstrate significantly greater improvement ($p<0.05$) in depressive symptom severity compared to patients in the control group (CG).
2. The difference between the intervention group (IG) and the control group (CG) is clinically significant, with an effect size of Cohen's $d \geq 0.35$ or $\eta^2 \geq 0.035$.
3. The proportion of patients showing clinically relevant improvement is higher in the BPT-J group (IG) than in the control group (CG). A number needed to treat (NNT) of ≤5 is considered adequate.

The impact on secondary outcomes (e.g. quality of life, self-efficacy, suicidality, comorbid psychological symptoms) will be explored. Additionally, predictors of treatment response will be investigated and identified, along with an assessment of health economic implications.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 15/01/2025, Friedrich-Alexander-Universität Erlangen-Nürnberg Ethics Committee (Krankenhausstraße 12, Erlangen, 91054, Germany; +49 (0)9131 85-22270; ethikkommission@fau.de), ref: 24-484-B

Study design
Prospective multi-center interventional assessor-blinded randomized-controlled trial with two arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention, Treatment

Participant information sheet
Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Depression and pre-clinical depression in adolescents

Interventions
Participants are randomised to one of two study arms by specific software. Age, gender and severity of depressive symptoms will be used as stratification variables. Randomization will be conducted blockwise per study cycle.

Study arm 1: Intervention Group BPT-J (Bouldering-Psychotherapy for adolescents)
Bouldering is climbing without a rope on climbing walls at an altitude that permits the climber to jump off. The bouldering intervention is a combination of bouldering and psychotherapy, consisting of 10 consecutive group sessions. Each session lasts two hours and takes place weekly in the late afternoon at a bouldering gym. Each group comprises approximately eight participants, who are guided by a team of two climbing therapists. The psychotherapeutic techniques of BPT-J emerge from Cognitive Behavioural Therapy (CBT) and are manualized and structured. The content focus of each session is on a specific psychological topic deemed relevant to the development and maintenance of depression like for example dealing with boundaries, self-efficacy, and self-esteem. All 10 sessions consist of three main components: an introduction (approximately 20 minutes), an action phase (approximately 75 minutes), and a closing segment (approximately 25 minutes). Every session includes mindfulness-based techniques, relaxation methods and elements of cognitive-behavioural therapy as well as specific boulder exercises.

Study arm 2: Waitlist Control Group (CG)
During the intervention phase, the control group (CG) will not receive any study-specific additional therapy but will have access to standard psychotherapeutic and psychiatric treatment options. Participants assigned to the CG will be offered the exact same treatment rationale as

the IG (a 10-week BPT-J group participation) after the conclusion of the measurement points t0 (baseline, pre-intervention) and t1 (after 3 months, post-intervention of IG). Besides the waiting interval of approximately 3 months, the CG will be equivalent to the intervention group.

Optional aftercare group
To sustain therapeutic gains and encourage ongoing physical activity, an open aftercare group will be offered from the end of the intervention until the follow-up assessment. Participation in this group is voluntary and will be documented and factored into the follow-up evaluation. The aftercare group will be thematically aligned with the content of the BPT-J program, with a specific focus on the interests and needs of the participants. The provision of this group offer was a prerequisite of the funder and also responds to the frequent requests from former participants for a structured program to support long-term maintenance.

Intervention Type
Behavioural

Primary outcome measure
The dimensional severity of depression, measured through both self-report and observer-report assessments. The Observer and Self-Assessment Scales for Depression (FBB-DES and SBB-DES) from the DISYPS-III will be used for evaluations by both parents and adolescents at t0 (pre-intervention), t1 (post-intervention IG), t2 (post-intervention CG) and t3 (follow-up 12 months after t1).

Secondary outcome measures
1. Categorical depression diagnosis will be measured with ILF-INTERNAL from DISYPS-III at t0 and t1
2. Health-related quality of life in adolescents will be assessed using the KIDSCREEN-10 through both self-report and observer-report (parents) at t0, t1, t2, and t3
3. Adolescent self-efficacy will be measured using the General Self-Efficacy Scale (SWE) by Jerusalem and Schwarzer through self-report at t0, t1, t2, and t3
4. Suicidal behaviour and thoughts will be assessed using the DISYPS interview and DISYPS self- (DISYPS-SBB) and observer-report questionnaire (DISYPS-FBB) through self-report at t0, t1, t2, and t3
5. Other psychological issues and comorbid symptoms will be assessed through observer-report by parents using the Strength and Difficulties Questionnaire (SQD-Deu) at t0, t1, t2, and t3
6. The cost-effectiveness analysis from a health economic perspective is performed using EQ-5D-Y in the adolescents' self-report and the resource utilization of the FIM-K, which is completed by the parents in the observer-report at t0, t1, t2, and t3

Overall study start date
01/10/2024

Completion date
30/09/2028

Eligibility

Key inclusion criteria
1. Acute depressive symptoms at least in the subclinical range, operationalized by a Patient Health Questionnaire score of ≥6 (PHQ-9)
2. Aged 13–18 years

3. Informed consent to participate in the study (particularly regarding randomization and data collection) from both participants and their legal guardians
4. Ability to travel to the therapy locations (climbing gym) to attend the interventions once a week
5. Timely availability of one afternoon per week (120 min) (except for official school breaks)
6. Access to digital devices for video or telephone interviews

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
220, with at least 110 patients in each group. With an expected dropout rate of 20%, approximately 275 individuals need to be enrolled in the study. Based on our experience, around 20% of those who apply to participate do not meet the inclusion criteria. Therefore, approximately 340 individuals need to be screened. As each group contains 8 patients, 4 cycles in each of the 4 locations (Erlangen, Nuremberg, Bamberg and Regensburg) are planned.

Key exclusion criteria
1. Adults (age over 18 years) or children (under 13 years) at the time of t0
2. Body Mass Index (BMI) at an age percentile below 10 or above 97, or a BMI of ≥35 kg/m2
3. Initiation of psychopharmacological medication or a change in active agent of psychopharmacological medication within 6 weeks (or less) prior to the study (initiation of psychopharmacological medication more than 6 weeks prior to the study or dose adjustment of an existing psychopharmacological medication does not constitute an exclusion criterion)
4. Planned inpatient stay (beyond short-term crisis intervention) during the intervention period
5. Physical contraindications to bouldering as determined by a physician (e.g. pregnancy)
6. Doctoral diagnosed psychotic disorders or mania (lifetime prevalence)
7. Substance dependency by medical diagnosis (lifetime prevalence)
8. Non-suicidal self-injurious behavior involving serious injuries that required medical treatment within the past six months
9. Acute suicidality without the ability to conform to a stepped help contract

Date of first enrolment
06/05/2025

Date of final enrolment
15/12/2026

Locations

Countries of recruitment
Germany

Study participating centre
Uniklinikum Erlangen
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Sponsor information

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Government

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Funder type
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Funder Name
Bavarian State Ministry of Health, Care and Prevention (Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2029

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available because we assure in the participant information sheet that data will not be passed to any third party.

IPD sharing plan summary
Not expected to be made available