ISRCTN12347878 https://doi.org/10.1186/ISRCTN12347878

New ways to cope with depression

Submission date
01/03/2022

Recruitment status
No longer recruiting

Registration date
28/03/2022

Overall study status
Completed

Last Edited
31/03/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
'Neue Wege aus der Depression', 'New ways to cope with depression' is a study in which two promising psychotherapeutic therapies are examined with regard to reducing symptoms of depression. Those therapeutic approaches are (1) bouldering psychotherapy (BPT), a therapy that integrates bouldering exercises into a psychotherapeutic group setting and (2) mental model therapy (MMT). MMT is based on cognitive behavioral therapy, but assumes that thinking errors, illusions, and misconceptions not only have an acute emotional effect, but also cause medium- and long-term failures. While, for example, through cognitive behavioral therapy, patients can learn how to handle their emotions in acute situations, MMT might help to see the world more objectively in general.
Our former studies proved the effectiveness of BPT in reducing depression. The effectiveness of MMT as a new therapy ought to be confirmed in this study. In addition, information on the impact factors of both therapies will be collected. Moreover, we want to take a closer look at different psychological and physiological factors, which might modulate the treatments' success. Therefore we look at different variables before and after the treatments. These are among others: anxiety, self-efficiency, hand strength, core stability and several biomarkers.

Who can participate?
Adult persons who suffer from acute depression and who are not participating in another psychotherapeutic group therapy are invited to apply for participation.

What does the study involve?
The participants are randomly assigned to one of the following groups:
1. Treatment group 1: ten sessions of bouldering psychotherapy group
2. Treatment group 2: ten sessions of mental model therapy group
3. Control group: treatment as usual

What are the possible benefits and risks of participating?
Benefits:
Patients participating in the BPT group will receive a therapeutic approach, which has proven effective in treating depression in former studies. There is reason to believe that mental model therapy, which is based on cognitive behavioral therapy can also improve mood by changing lifestyle habits, and thus represents a promising, effective therapeutic approach to depression.
Risks:

In previous studies, which contained more than 1000 hours of therapeutic bouldering there were no injuries that required medical treatment. Nevertheless, there is a risk of slight injuries, which does not exceed the risk of other physical activities. Study-specific risks do not exist for the MMT group nor the control group.
From each participant two samples of blood will be taken. This is a routine procedure, nevertheless the risks associated with venous blood collection, such as hypotension, dizziness, nausea, pain and bruising at the injection site, injury to nerves and infection of the injection site, cannot be 100% excluded.

Where is the study run from?
University Hospital Erlangen (Germany)

When is the study starting and how long is it expected to run for?
October 2021 to September 2024.

Who is funding the study?
Psychiatric University Hospital Erlangen (Germany) (Head of Department: Prof. Dr. J. Kornhuber)

Who is the main contact?
PD Dr. Katharina Luttenberger, katharina.luttenberger@uk-erlangen.de

Contact information

Type(s)
Principal investigator

Contact name
Dr Katharina Luttenberger

ORCID ID
https://orcid.org/0000-0002-9877-5423

Contact details
Schwabachanlage 6
Erlangen
Germany
91054
+49 91318534650
Katharina.luttenberger@uk-erlangen.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
21-332-B

Study information

Scientific Title
New ways to cope with depression – prospective investigation of the impact factors of bouldering psychotherapy (BPT) and WISE-Therapy (What's Important: Schedule and Engage) for adults suffering from acute depression compared to a control group.

Acronym
NW-Depression

Study objectives
1. Patients participating in the bouldering psychotherapy (IG-BPT) improve (regarding the severity of their depression measured by the MADRS) significantly more than patients participating in the control group.
2. Patients participating in WISE-Therapy (IG-WISE) improve (regarding the severity of their depression measured by the MADRS) significantly more than patients participating in the control group.

Explorative, impact factors of the intervention groups as well as effects of treatment preferences will be investigated. It is expected that IG-BPT will lead to a greater increase in blood osteocalcin levels than the control group and IG-WISE. It is also hypothesized that the increase in hand strength as well as the increase in trunk stability after the intervention will be greater in the IG-BPT group than in the other two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2021, Friedrich-Alexander-Universität Erlangen-Nürnberg (Krankenhausstraße 12, 91054 Erlangen, Germany; +49 9131 8522270; ethikkommission@fau.de), ref: 21-332-B

Study design
Randomized controlled assessor-blinded trial with three arms

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
Participants are randomised to one of three study arms by specific software.

Study arm 1: Intervention Group (bouldering psychotherapy)
Participants receive therapy in groups of ten led by two psychotherapists/boulder leaders. This programme combines methods of psychotherapy and action-oriented methods of boulder therapy. It consists of classical approaches such as mindfulness-based techniques, relaxation methods and cognitive-behavioural therapy as well as specific boulder exercises. Bouldering is

climbing without a rope on climbing walls at an altitude that permits the climber to jump off. Participants are asked to do this for two hours a week for ten weeks and are followed up after 12 months after the end of treatment.

Study arm 2: Intervention Group (WISE-Therapy)
Participants receive therapy in groups of ten that is led by two psychotherapists. The intervention is manualized. It is based on cognitive behavioural therapy and focuses on mental models. Participants are asked to do this for two hours a week for ten weeks and are followed up after 12 months after the end of treatment.

Study arm 3: control group:
There is no additional therapy for the participants of the control group. They get the established psychotherapeutic and psychiatric treatment of the University hospital in Erlangen.

Intervention Type
Behavioural

Primary outcome(s)
Depression is measured using the score of an observer-rating scale (Montgomery Asberg Rating Scale, MADRS) by computer-assisted video interviews at baseline, within two weeks after the intervention and 12 months after the intervention

Key secondary outcome(s))
1. Anxiety is measured using the Generalized Anxiety Disorder Scale-7 (GAD-7) at baseline, within two weeks after the intervention and 12 months after the intervention.
2. Self-efficacy is measured using the 'Skala zur Allgemeinen Selbstwirksamkeit' (SWE) at baseline, within two weeks after the intervention and 12 months after the intervention.
3. The Sense of Coherence is measured using the short version of the 'Sense of Coherence scale' (SOC) at baseline, within two weeks after the intervention and 12 months after the intervention.
4. The Locus of Control is measured using the 'Internal External Locus of Control' (IE-4) at baseline, within two weeks after the intervention and 12 months after the intervention.
5. The body-based mindfulness is measured using the 'State Mindfulness Scale for Physical Activity' (SMS-PA-12) at baseline, within two weeks after the intervention and 12 months after the intervention.
6. Mindfulness state is measured using the 'Multidimensional State Mindfulness Questionnaire' (MSMQ) at baseline, within two weeks after the intervention and 12 months after the intervention.
7. Physical activity is measured using the 'BSA-Questionnaire' (BSA-F) at baseline, within two weeks after the intervention and 12 months after the intervention.
8. Hand strength is measured using the 'Baseline Hydraulic Hand Dynamometer' at baseline and within two weeks after the intervention.
9. Core stability is measured using McGill's 'Torso muscular endurance test battery' at baseline and within two weeks after the intervention.
10. The blood concentration of osteocalcin is measured using ELISA at baseline and within two weeks after the intervention
11. Age, gender, height and weight (BMI), occupation, actual treatment (medication /psychotherapy), previous treatment, therapy preferences and experiences with meditation are detected by using open questions at baseline.
12. Changes concerning actual treatment (medication/psychotherapy) are detected by using open questions within two weeks after the intervention
13. Cognitive processing is measured by using the 'cognitive reflection test' (CRT-3) within two

weeks after the intervention.
14. To detect effective factors of the group therapies the experience of the therapeutic processes in the groups is measured by using the 'Fragebogen zum Erleben von therapeutischen Prozessen in der Gruppe' (FEPiG) and by using semi-structured interviews about effective factors and the acceptance of the form of therapy within two weeks after the intervention.
15. The usability of the APP is measured using the 'mHealth App Usability Questionnaire' (MAUQ) (Only participants of the bouldering psychotherapy)

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Depression, diagnosed by a diagnostic interview based on the DSM-V diagnostic criteria.
2. Informed consent to participate in the study (especially regarding the randomised allocation and data acquisition)
3. Possibility to come to the therapy locations and time capacities to participate in the interventions.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Total final enrolment
130

Key exclusion criteria
1. Age <18 years
2. Presence of current serious mental illnesses that make participation in group therapy difficult (such as psychosis, mania, current self-injury, acute substance dependence, current suicidal tendencies, etc.)
3. Physical contraindications (physical ailments or, pregnancy, BMI <17.5 or >40 kg/m²)
4. Current treatment that confounds with study outcomes (participation in psycho-therapeutic group therapy; initiation of psychiatric medication in the 8 weeks prior to the start of the intervention)

Date of first enrolment
29/03/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Erlangen (Universitätsklinikum Erlangen, Psychiatrische und Psychotherapeutische Klinik) - Bereich Medizinische Psychologie und Medizinische Soziologie
Schwabachanlage 6
Erlangen
Germany
91054

Sponsor information

Organisation
Universitätsklinikum Erlangen

ROR
https://ror.org/0030f2a11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsklinikum Erlangen

Alternative Name(s)
Erlangen University Hospital

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

Fully anonymised data will be available upon request or shared via Zenodo upon publication (Katharina Luttenberger: Katharina.luttenberger@uk-erlangen.de)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/12/2024	03/12/2024	Yes	No
Protocol article		22/09/2023	22/09/2023	Yes	No
Participant information sheet	in German		07/03/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes