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Study KuS (Klettern und Stimmung - Climbing and Mood) combined boulder and psychotherapy against depression

Submission date
12/06/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People with depression often feel down or sad for a weeks or months, requiring treatment and support. Depression is usually treated with a combination of medication and therapy. With the relationship between mood and exercise, researchers are exploring alternative treatments. A new therapy method called “Klettern und Stimmung- Climbing and mood (KUS)” uses action-oriented elements from the field of climbing to increase the mood of patients suffering from depression. Former studies have shown that bouldertherapy, a therapy approach that combines psychotherapeutic interventions (therapy that treats mental disorders using methods like talking, mindfulness and relaxation) in a bouldering group setting, has proven effective in the treatment of depression. However it is unsure if it is just as effective as more established methods. The aim of this study is to find out if this combination of bouldertherapy can be as effective as the well-established methods of therapy by comparing the outcomes of participants with depression.

Who can participate?
Adults aged 18 and older who have depression.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive a combination of bouldering and therapy. Bouldering consists of climbing without ropes and the therapy consists of relaxation methods, mindfulness and cognitive based therapy (talking therapy). Those in the second group receive the cognitive behavioural therapy. Those in the last group receive instructions for an exercise programme that addresses the same muscles used in bouldering. They are reminded to exercise with letters and emails and have an option to participate in the bouldering group after they finish their programme. All participants are asked to complete their programmes for two hours a week for ten weeks. Participants are followed up three, six and 12 months after the treatment to measure their depression, anxiety, self-esteem and body image.

What are the possible benefits and risks of participating?
Participants may benefit from the therapy, as it has been proven effective in treating depression in former studies. There is a risk of slight injuries in the boulder groups; however this does not exceed the risk of other physical activities.

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 2016 to October 2020

Who is funding the study?
Oh-Do-Kwan foundation (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
360_16B

Study information

Scientific Title
Study KuS (Klettern und Stimmung - Climbing and Mood)- Prospective investigation of the effectiveness of a combined boulder- and psychotherapy in comparison of an active control group and a cognitive behavioral group therapy for patients suffering of depression in an outpatient setting

Acronym
Studie KuS

Study objectives
1. Patients participating at the combined boulder- and psychotherapy improve (regarding the severity of their Depression measured by the MADRS) significantly more than patients participating at the active control group
2. Patients participating at the combined boulder- and psychotherapy improve (regarding the severity of their Depression measured by the MADRS) about as much as patients participating at cognitive-behavioral psychotherapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Friedrich-Alexander-Universität Erlangen-Nürnberg, 02.02.2017, ref: 360_16B

Study design
Interventional three armed multicenter blinded randomised study

Primary study design
Interventional

Study type(s)
Treatment

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

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

Study arm 1: Intervention Group (Combined boulder and psychotherpay)
Participants receive therapy in groups of ten that is lead 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-behavioral therapy as well as specific boulder exercises. Bouldering is climbing without rope on climbing walls at an altitude which permits the climber to jump off. Participants are asked to do this for two hours a week for ten weeks and are followed up for 12 months (at three, six and 12 months after the end of treatment).

Study arm 2: Intervention Group cognitive-behavioral therapy:
Participants receive therapy in groups of ten that is lead by two psychotherapists. The intervention is manualized and follows the treatment plan of a classical cognitive-behavioral therapy and integrates mindfulness-based techniques and relaxation methods. Participants are asked to do this for two hours a week for ten weeks and followed up for 12 months (at three, six and 12 months after the end of treatment.

Study arm 3: Active control Group:
This consists of a physical training programme which addresses the same muscles as bouldering

or climbing. The participants receive instructions for the programme per training manual and DVD as well as information about the link between exercising and mood. They are regularly reminded to exercise with letters and emails. Participants are asked to do this for two hours a week for ten weeks and followed up for 12 months (at three, six and 12 months after the end of treatment. After ten weeks, participants are offered to participating in the boulder group.

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 telephone interviews (CATI) at baseline, ten weeks, three, six and 12 months

Key secondary outcome(s))
1. Attitude towards the own body/body image is measured using scale "Vitale Körperdynamik" of the Fragebogen zum Körperbild (FKB-20) at baseline, ten weeks, three, six and 12 months
2. Anxiety is measured using Generalizied Anxiety Disorder Scale-7 (GAD-7) at baseline, ten weeks, three, six and 12 months
3. Social Phobia is measured using scale interpersonal sesitivity of the Symptom-Checklist (SCL-90-R) at baseline, ten weeks, three, six and 12 months
4. Avoidance Behavior is measured using the Items of the scale Mobility Inventory (MI) of the "Fragebogen zu körperbezogenen Ängsten, Kognitionen und Vermeidung (AKV)" at baseline, ten weeks, three, six and 12 months
5. Self-esteem is measured using the Rosenberg self-esteem scale (RSE) at baseline, ten weeks, three, six and 12 months
6. Self-efficacy is measured using the Skala zur Allgemeinen Selbstwirksamkeit (SWE) at baseline, ten weeks, three, six and 12 months
7. Coping is measured using the Coping-scale of the "Fragebogen zur Erfassung von Ressourcen und Selbstmanagementfähigkeiten (FERUS) at baseline, ten weeks, three, six and 12 months

Completion date
01/10/2020

Eligibility

Key inclusion criteria
Current Inclusion Criteria as of 13/03/2018:
1. Depression, measured by the score of the PHQ-9 (Cut-off ≥ 8)
2. Informed Consent to participate in the study (especially regarding randomised allocation and data acquisition)
3. Possibility to come to the therapy locations

Previous Inclusion Criteria:
1. Depression, measured by the score of the PHQ-9 (Cut-off ≥ 10)
2. Informed Consent to participate in the study (especially regarding randomised allocation and data acquisition)
3. Possibility to come to the therapy locations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
133

Key exclusion criteria
Current exclusion criteria as of 13/03/2018:
1. Acute suicidality
2. Severe psychiatric disorder (psychosis, mania, substance-abuse)
3. Physical contraindication (physical disorders or pregnancy)
4. BMI <17,5 or >40
5. Age < 18 years
6. Actual participation in group psychotherapy
8. Start of psychiatric medication within the last 8 weeks
9. Planned in-Patient stay during therapy

Previous exclusion criteria:
1. Acute suicidality
2. Severe psychiatric disorder (psychosis, mania, substance-abuse)
3. Physical contraindication (physical disorders or pregnancy)
4. BMI <18,5 or >35
5. Age < 18 years
6. Actual participation in group psychotherapy
8. Start of psychiatric medication within the last 8 weeks
9. Planned in-Patient stay during therapy

Date of first enrolment
27/03/2017

Date of final enrolment
01/04/2018

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
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Sponsor information

Organisation
OH-DO-KWAN Stiftung Ludmilla Pankofer und Carl Wiedmeier

ROR
https://ror.org/03we5jj07

Funder(s)

Funder type
Charity

Funder Name
OH-DO-KWAN Stiftung Ludmilla Pankofer und Carl Wiedmeier

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository Friedrich-Alexander-Universität Erlangen server and is available upon personal request.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/03/2020	07/10/2020	Yes	No
Results article		26/08/2021	10/09/2021	Yes	No
Results article		26/10/2021	05/09/2023	Yes	No
Protocol article	protocol	17/05/2019	11/03/2020	Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes