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A Loving Kindness Meditation program for patients with persistent depressive disorder

Submission date
14/12/2017

Recruitment status
No longer recruiting

Registration date
29/03/2018

Overall study status
Completed

Last Edited
28/10/2021

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
Depression is one of the most common mental disorders and one of the main causes of health impairment worldwide. One of the reasons for the severe impairment associated with depression is its potential chronic progression. Many people suffer from such a chronic form of depression: they feel continuously depressed over the course of several years or even decades. Additionally, people with chronic depression often suffer from exhaustion, insomnia and deficiency in concentration as well as feelings of hopelessness or worthlessness. Nevertheless, chronic depression is often neglected in healthcare practice and not adequately treated. This study examines whether people with chronic depression benefit from a group meditation program with a subsequent individual therapy phase. Those who suffer permanently from depression often feel an intense feeling of rejection towards themselves and other people, and at the same time feel rejected by others. This often leads to the impression of being isolated and separated from one's environment, which can maintain the depressive symptoms. Therefore, one of the main treatment goals is to develop and foster a positive attitude towards oneself and others. The Metta meditation originating from Buddhism promotes the connection to oneself and to others. Metta is a term that describes kindness, active interest in others, love, friendship, or sympathy. Such a kind of benevolent attitude can be practiced through meditation techniques. In order to use this approach for people with chronic depression, the working group of Prof. Stangier has developed a new treatment program: meditation techniques combined with modern behavioural therapy. This approach has already achieved promising results in small studies and is now to be subjected to a thorough examination. Through the combination of metta meditation and cognitive behavioural therapy, it is hoped that depression can be overcome and further relapses can be prevented.

Who can participate?
People aged between 18 and 70 who have constantly been suffering from depressive symptoms for at least two years, which are the main course of impairment. Furthermore, participants should be willing to practice meditation daily (about 30 minutes). For the period of therapy, there should be no further psychotherapy treatment.

What does the study involve?
Participants are randomly allocated to two groups: treatment and wait list group. Patients of

both groups receive a treatment: the experimental group directly and the wait list group starting four months later after the treatment of the experimental group has ended. In the treatment program typical mechanisms of depression such as rumination and the ‘inner critic’ are to be overcome. The treatment includes an 8-week group meditation program (10-12 participants) including mindfulness and metta meditation. The group meditation program is supplemented by an 8-week individual therapy phase. In individual therapy, the skills learned in the group are transferred to everyday life and interpersonal problems are addressed.

What are the possible benefits and risks of participating?
The effectiveness of the methods in this study is evidenced by the group meditation program in chronic depression. There are numerous studies on acute depression for the effectiveness of cognitive behavioural therapy. No increased risks are expected for participants compared to conventional therapy. Should the participants unexpectedly get worse, they can contact the study supervisors at any time in person, by email or telephone to arrange a conversation. Before the study begins, participants are advised of this possibility – the contact details are listed in the Patient information and the Declaration of Informed Consent. In an emergency, immediate contact with stationary psychiatric facilities in the Frankfurt area can be made. Since the intervention is carried out by an approved therapist, any worsening of the mental condition of the participants can be detected and met accordingly.

Where is the study run from?
Goethe University Frankfurt (Germany)

When is study starting and how long is it expected to run for?
October 2017 to September 2020

Who is the main contact?
Isabel Thinnes
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Study website
http://www.psychologie.uni-frankfurt.de/63425002/080_Meditationsstudie-bei-chronischer-Depression

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
STA 512/19-1 (sponsored by DFG-Deutsche Forschungsgemeinschaft)

Study information

Scientific Title
Metta-based group meditation and individual CBT in patients with chronic depression – a randomized controlled study

Acronym
MeCBT

Study objectives
1. Does the combination of group meditation and individual CBT lead to a significantly greater reduction in depression after completion of treatment compared to a wait-list control condition?
2. Can the therapy effects also be maintained for the 6-month follow-up?
3. Compared to control group: Are there any significant changes to patients' mindfulness, benevolence, rumination, emotion regulation, social Solidarity, social motivation, behavioral and cognitive avoidance
a) to an intermediate measurement after group meditation program?
b) after completion of the overall treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission of the Medicine Department, Goethe Universität Frankfurt am Main - approval pending

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic depression / Persistent Depressive Disorder (DSM-5)

Interventions
In our study, two approaches are to be combined in an approximately four-month treatment program: a metta-based group meditation program (MGM) focusing on the meditation of mindfulness and Metta/Loving Kindness (8 sessions, 120 min.); and an individualized program for CBT (8 sessions, 50 min.), which is linked to the objectives of MGM.

Patients allocated for trial are randomly distributed uniformly to two test conditions: treatment and wait list control group. The sample is stratified based on the characteristic 'existence of an early traumatic experience'. Patients of both groups receive a treatment: the experimental group directly and the wait list control group after the therapy of the experimental group has ended.

The mindfulness exercises are based on the manual of Segal, Williams and Teasdale (2013) and include body scan, seat meditation and breathing space exercise. The exercises for Metta meditation are based on the manual of Kearney et al. (2013); German adaptation: Stangier & Mendes, 2015) and aims to focus on the perception of positive attitudes and feelings towards oneself and other persons. They consist of formulas in which wishes are formulated in relation to the chosen person (e.g. "I wish you to feel satisfied and happy"). Starting from a benefactor in life (a person who has done something good), the desires are gradually extended to a friend, a neutral person, himself, a difficult person and finally to all human beings. Individual CBT is conducted to support transfer of meditation practice into everyday life. It is adapted to the patients' individual needs and includes various state of the art CBT interventions.

Intervention Type
Other

Primary outcome measure
Severity of depressive symptoms, assessed by the Quick Inventory of Depressive Symptomatology, Clinical Rating (QIDS-C) and the Beck depression inventory-II (BDI-II) at baseline (T0), 8 weeks after baseline (after end of group treatment; T1), at the end of the entire treatment at 16 weeks after baseline (T2), and at 42 weeks after baseline (i.e. 6 months after end of overall treatment; T3)

Secondary outcome measures
All outcomes measured at baseline (T0) and at the end of the entire treatment, 16 weeks after baseline (T2). Furthermore, mindfulness, benevolence, rumination, emotion regulation (here only assessed by the ASQ), and behavioral and cognitive avoidance will also be measured at 8 weeks after baseline (after end of group treatment; T1) and at 42 weeks after baseline (i.e. 6 months after end of overall treatment; T3). Social motivation will also be measured at T3.

1. Mindfulness, assessed using the Five Facet Mindfulness Questionnaire (FFMQ)
2. Benevolence, assessed using the Compassionate Love Scale (CLS)
3. Rumination, assessed using the Response Styles Questionnaire, German version (RSQ-D)
4. Emotion regulation, assessed using the Affective Style Questionnaire (ASQ) and the

Operationalized Skills Assessment Inventory
5. Social connectedness, assessed using the Inclusion of Other in the Self Scale (IOS)
6. Social motivation, assessed using the Social Adaptation Self-evaluation Scale (SASS)
7. Social pain, assessed using the Social Pain Questionnaire
8. Behavioral and cognitive avoidance, assessed using the Behavioral Activation for Depression Scale (BADS)

Overall study start date
01/10/2017

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Primary DSM-5 diagnosis of persistent depressive disorder (PDD) confirmed by the SCID depression section
2. On/off medication stable for at least 4 weeks before inclusion
3. Age between 18 and 70 years
4. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
To be assessed for eligibility: N=90, To be allocated to trial: N=48

Total final enrolment
48

Key exclusion criteria
1. Substance use disorders (current or within last 3 months)
2. Acute suicidality
3. Acute/past manic or psychotic symptoms
4. Borderline personality disorder
5. Organic mental disorder
6. Severe medical conditions
7. Concurrent psychotherapy

Date of first enrolment

19/12/2017

Date of final enrolment
30/04/2019

Locations

Countries of recruitment
Germany

Study participating centre
Clinical Psychology and Psychotherapy
Varrentrappstr. 40-42
Frankfurt
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60486

Sponsor information

Organisation
Goethe University.Frankfurt

Sponsor details
Theodor-W.-Adorno-Platz 1
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Sponsor type
University/education

Website
https://www.uni-frankfurt.de

ROR
https://ror.org/04cvxnb49

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Publication of study protocol in a high-impact peer reviewed journal in summer 2018 (currently in submission). The main results are intended to be published in a high-impact peer reviewed journal within 6 months after the trial end date (approximately 2020/2021).

Intention to publish date
31/03/2021

Individual participant data (IPD) sharing plan
Individual participant data (including data dictionaries) will be available. This includes individual participant data that underlie the results, reported in articles that are yet to be published, after deidentification (text, tables, figures, and appendices). Data will be available beginning 6 months and ending 36 months following article publication. Data will be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. It will be shared to achieve aims in the approved proposal. Proposals may be submitted up to 36 months following article publication. To gain access, data requestors will need to sign a data access agreement. After 36 months the data will be available in the University's data warehouse but without investigator support other than deposited metadata. For information regarding submitting proposals and accessing data please contact stangier@psych.uni-frankfurt.de.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/01/2020	08/01/2020	Yes	No
Results article		08/10/2021	28/10/2021	Yes	No