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Health psychological approaches as treatments for depression: steps towards enjoyment in life

Submission date
26/05/2025

Recruitment status
No longer recruiting

Registration date
23/06/2025

Overall study status
Completed

Last Edited
13/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression is characterized by feeling hopeless and worthless. Affected persons perceive a barrier to feeling happiness and well-being, called anhedonia. Psychological aspects like rejection of oneself and others and physical aspects, like loss of energy and exhaustion, are intertwined.
The aim of this study is to test the efficacy of a meditation-based group therapy compared to an active control group, i.e. nondirective supportive therapy, for treating anhedonia in depressive patients.

Who can participate?
Patients aged between 18 and 65 years with depressive disorder and increased anhedonia, on /off medication stable for at least 4 weeks before inclusion

What does the study involve?
Both programs comprise 10 sessions of group therapy with an extensive initial and final diagnostic examination as well as an individual appointment before the group sessions begin. Group sessions can take place either online or in person. The decision for one of the settings has to be made in advance and cannot be changed once the programs begin.
Online questionnaires for self-assessment are sent to participants at T1 (baseline), T2 (after half of the group sessions), T3 (after treatment), T4 (follow-up, 6 months after treatment).

What are the possible benefits and risks of participating?
Possible benefits: extensive diagnostic examination and feedback, improvement of depressive symptoms, contribution to research about the treatment of anhedonia and depression
Possible risks: no change in depressive symptoms or deterioration of mental health

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

When is the study starting and how long is it expected to run for?
December 2021 to June 2026

Who is funding the study?
This study is funded by the LOEWE Top Professorship for Stefan G. Hofmann of the Hessian Ministry of Science and Arts (Germany)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Metta-based cognitive behavioral therapy (MeCBT) as a transdiagnostic treatment for Anhedonia in patients with depression

Acronym
STYLE

Study objectives
1. We expect a significant decline of anhedonia symptoms and a significantly larger effect for Metta-based cognitive behavioral therapy (MeCBT) compared to nondirective supportive psychotherapy (nsPT).
2. We expect significant superiority by MeCBT at T1 and T2 in all these secondary variables. (Secondary outcome measures include self-rated social and physical anhedonia, quality of life, symptoms of depression, emotional and cognitive-behavioral avoidance, social functioning, prosocial interactions and benevolence.)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/05/2022, Local ethics committee of the Department of Psychology and Sports Sciences at Goethe University Frankfurt (Theodor-W.-Adorno-Platz 6, Frankfurt am Main, 60323, Germany; +49 (0)69 798 35253; klein@psych.uni-frankfurt.de), ref: 2022-06a-c

Primary study design
Interventional

Study design
Single-centre randomized controlled observer blind trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anhedonia, depression

Interventions
Experimental intervention: MeCBT consisting of 10 sessions group treatment focusing on metta meditation and behavioral activation.

Control intervention: nsPT consisting of group treatment of the same timeframe as the experimental intervention and including psychoeducation and supportive interventions.

Both treatment arms receive treatment-as-usual (TAU) by their physician. Antidepressive medication will be controlled for its impact on outcome.

Duration of intervention per patient: 10 weeks, 6-month follow-up.

If eligibility for the study is confirmed, and informed consent to randomization is given, patients will be randomized. To allocate study participants to treatment conditions, a randomization list is created using the statistical software R. The group allocations are printed out and placed in sealed envelopes. For each newly included participant, a research assistant draws an envelope and reads off the group allocation.

Intervention Type
Behavioural

Primary outcome(s)
Anhedonia (clinician rating) assessed with the Clinical Assessment of Negative Symptoms (CAINS) at baseline (T1) and after treatment (T3)

Key secondary outcome(s)
1. Self-rated hedonic capacity for social and interpersonal pleasure measured using the Anticipatory and Consummatory Interpersonal Pleasure Scale (ACIPS) at T1 (baseline), T2 (after half of the group sessions), T3 (after treatment), T4 (follow-up, 6 months after treatment)
2. Symptoms of depression measured using Beck's Depression Inventory-II (BDI-II) and Quick Inventory of Depressive Symptomatology (QIDS) at T1, T2, T3, T4,
3. Emotional and cognitive-behavioral avoidance, measured using the Behavioral Activation for Depression Scale (BADS) at T1, T2, T3, T4
4. Social functioning, measured using the Social Adaptation Self-evaluation Scale (SASS) at T1, T2, T3, T4
5. Benevolence, measured using Fragebogen zu Wohlwollen (FWW) at T1, T2, T3, T4
6. Mindfulness, measured using the Facet Mindfulness Questionnaire (FFMQ) at T1, T2, T3, T4
7. Cognitive and behavioral coping with depressive symptoms, measured using the Response Style Questionnaire – Deutsch (RSQ-D) at T1, T2, T3, T4
8. Positive and negative affect, measured using the Positive and Negative Affect Schedule (PANAS) at T1, T2, T3, T4
9. Acceptance of online group sessions, measured using Fragebogen zur Erfassung der Akzeptanz der Videotherapie (FAV) at T3
10. Behavioral Inhibition System and Behavioral Approach System, measured using Behavioral Activation and Behavioral Inhibition Scales (BIS/BAS) at T1

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Snaith-Hamilton Pleasure Scale (SHAPS-D) score >2
2. Depressive disorder
3. Aged 18-65 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Increased suicidality
2. Substance abuse or dependency
3. Diagnosis of borderline personality disorder
4. Untreated PTSD
5. Psychotic disorder
6. Bipolar disorder
7. Severe physical illness
8. Insufficient German language skills
9. Concurrent psychotherapeutic treatment

Date of first enrolment
22/03/2024

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
Germany

Study participating centre

Goethe-Universität Frankfurt
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Sponsor information

Organisation
Philipps University of Marburg

ROR
https://ror.org/01rdrb571

Funder(s)

Funder type
Government

Funder Name
Hessisches Ministerium für Wissenschaft und Kunst

Alternative Name(s)
Hessen State Ministry of Higher Education, Research and the Arts, Hessian Ministry for Science and the Arts, Hessian Ministry of Higher Education, Research and the Arts, Hessian Ministry for Science and Art

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

Individual participant data that underlie the reported results will be shared on request after deidentification.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			13/06/2025	No	No
Study website			13/06/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes