

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

Submission date 26/05/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/06/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

1. Dr. Elisabeth Arens, e.aren@psych.uni-frankfurt.de
2. Prof. Dr. Ulrich Stangier, stangier@psych.uni-frankfurt.de

Study website

<https://www.psychologie.uni-frankfurt.de/138395189/STYLE>

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

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

Study design

Single-centre randomized controlled observer blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual, University/medical school/dental school

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/12/2021

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

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 type

University/education

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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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/06/2027

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