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

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
26/05/2025		[X] Protocol		
Registration date	Overall study status Ongoing  Condition category Mental and Behavioural Disorders	Statistical analysis plan		
23/06/2025		Results		
Last Edited		☐ Individual participant data		
13/06/2025		[X] 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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#### Contact information

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#### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### 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

#### 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			Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
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