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Evaluating the effects of body-based mindfulness interventions on psychological well-being and psychophysiological functioning in healthy adults

Submission date 09/11/2026	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 16/11/2026	**Overall study status** Ongoing	
Last Edited 16/11/2026	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

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Scientific

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Study information

Scientific Title
Effectiveness of a body-based mindfulness intervention on psychological and psychophysiological outcomes in healthy adults: an interventional study

Study objectives
1. To evaluate the effectiveness of structured Body-Based Mindfulness Interventions in promoting psychological well-being and emotional functioning in healthy adults
2. To investigate changes in psychological functioning through standardized self-report measures administered before and after participation in the intervention
3. To examine changes in psychophysiological functioning through objective physiological assessments
4. To explore the relationships between psychological and psychophysiological outcomes following participation in the intervention

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2022, Ethics Committee for Psychological Research of the European University of Rome (Comitato Etico per la ricerca psicologica dell'Università Europea di Roma (Via degli Aldobrandeschi, 190, Rome, 00163, Italy; +39 06 665431; ricerca@unier.it), ref: Prot. n. 13/2022

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Parallel

Purpose
Basic science, Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Promotion of psychological well-being and psychophysiological functioning in healthy adults.

Interventions
The intervention consists of a structured Body-Based Mindfulness Programme aimed at promoting an integrated awareness of bodily sensations, emotional experiences, and cognitive processes. It is based on an experiential approach to mindfulness that combines formal meditation practices with body-oriented activities designed to enhance interoceptive awareness, emotional processing, self-regulation, and mind-body integration.

The programme is delivered in group settings by trained instructors with meditation experience and appropriate psychological or psychotherapeutic training. It follows a structured thematic framework, with activities focusing on different aspects of embodied awareness and the relationships between bodily sensations, emotions, thoughts, and personal experiences.

The programme integrates several complementary experiential components:
1. Formal mindfulness practices: guided meditation exercises aimed at developing present-moment awareness, sustained attention, and non-judgmental observation of bodily sensations, thoughts, and emotional states.
2. Breathing and body-awareness exercises: practices involving mindful breathing, attention to respiratory patterns, recognition of muscular tension, and observation of internal bodily sensations, with particular emphasis on interoceptive awareness.
3. Body-based movement practices: structured and spontaneous movement activities, including stretching, rhythmic movements, shaking, and free dance, aimed at facilitating bodily awareness, physical expression, and the exploration of the relationship between movement and emotional experience.
4. Relaxation and receptive awareness: exercises involving stillness, mindful listening, and relaxation in different postures, encouraging participants to observe internal sensations, release bodily tension, and develop awareness of changes in their physical and emotional states.
5. Experiential and interpersonal activities: role-playing, group discussions, and opportunities for sharing personal experiences, aimed at facilitating emotional recognition, self-reflection, interpersonal awareness, and the integration of bodily and psychological experiences.

The programme may also incorporate specific psychosomatic meditation practices, including Evolution Meditation and Power Meditation. These practices integrate active and receptive phases and are designed to promote embodied awareness through the alternation of movement, bodily activation, stillness, and relaxation.

Evolution Meditation consists of five sequential phases:
1. Body Awakening and Release, involving attention to bodily sensations and gentle stretching
2. Active Shaking, involving rhythmic bodily movements accompanied by music
3 . Free Dance, encouraging spontaneous and expressive movement
4. Sitting and Listening, focusing on internal sensations and mindful listening
5. Deep Release and Final Awareness, involving relaxation in a supine position and sustained attention to bodily sensations

The practice combines movement, music, silence, and periods of receptive awareness to facilitate the recognition and exploration of bodily and emotional experiences.

Power Meditation follows a complementary experiential approach, integrating active and receptive phase's to encourage bodily awareness, emotional processing, and the development of a more integrated relationship between physical and psychological experiences.

The intervention is delivered to adult participants within a controlled study design, in which an intervention group is compared with a waiting-list control group.

Intervention Type
Behavioural

Primary outcome(s)
1. Psychological functioning and emotional well-being measured using the State-Trait Anxiety Inventory (STAI-Y), Center for Epidemiologic Studies Depression Scale (CES-D), Five Facet Mindfulness Questionnaire (FFMQ), Negative and Positive Mood States – Short Form (NPMS-SF), Emotion Regulation Questionnaire (ERQ), Body-Oriented Mindfulness Scale, Perceived Stress Scale (PSS), and the Symptom Checklist-90-Revised (SCL-90-R), at baseline (pre-intervention) and one week after completion of the intervention (approximately nine months after baseline)

2. Psychophysiological functioning and autonomic regulation, including heart rate variability (HRV), measured using a Holter device for electrocardiographic monitoring at continuous time points

3. Psychophysiological functioning and autonomic regulation, including cortisol awakening response (CAR), measured using salivary cortisol concentrations in samples collected at awakening (0 minutes) and at 30 and 45 minutes after awakening

Key secondary outcome(s)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Ability to understand the study information and participate in the intervention and study assessment procedures
3. Adequate proficiency in Italian to understand the study materials and complete the assessment procedures
4. Provision of written informed consent prior to enrolment

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit

99 Years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Presence of current mental disorders or clinically significant psychological conditions
2. Current or recent psychological or psychiatric treatment, including psychotherapy and/or psychopharmacological treatment
3. Medical or physical conditions that may significantly interfere with participation in the intervention or completion of the study assessments

Date of first enrolment
01/09/2022

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
Italy

Study participating centre
IUP Institute, Psychotherapy and Neuropsychosomatic School, Bagni di Lucca, Lucca, Italy.
Italy

Study participating centre
The Global Village NGO, Bagni di Lucca, Lucca, Italy.
Italy

Study participating centre
European University of Rome, Rome, Italy.
Italy

Sponsor information

Organisation

Institute of Humanistic Body-Oriented Psychotherapy (IUP – Istituto Umanistico Psicocorporeo)

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from the corresponding author (contact details will be provided in the relevant publications).

IPD sharing plan summary
Available on request