

Effects of mindfulness meditation on brain structure and function

Submission date 14/02/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/03/2024	Condition category Other	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Mindfulness describes the ability to consciously engage in a state of non-judgemental, present moment attendance. Mindfulness can be trained through the practice of mindfulness meditation. Research has demonstrated that mindfulness meditation has beneficial effects on health and cognition. However, the underlying neural mechanisms are not yet fully understood. This study aims to extend knowledge on these mechanisms. This can help to improve applications of mindfulness meditation in clinical and non-clinical settings.

Who can participate?

Healthy adults between 18 and 65 with little or no meditation experience

What does the study involve?

Participants are recruited from the general public via public advertisement and are assigned to either 31 days of mindfulness meditation training or an active control condition. In the mindfulness meditation, training an experienced mindfulness meditation instructor provides information on mindfulness meditation and guided meditation sessions. In the active control condition, information on various topics of general health is provided. Training sessions are in video or audio format. Both training programs can be accessed via an online platform and are delivered in training sessions of 15 minutes. Before and after the intervention, participants undergo (functional) magnetic resonance imaging (MRI). Participants also complete questionnaires on various aspects of psychological wellbeing.

What are the possible benefits and risks of participating?

Possible benefits of the experimental treatment include positive side-effects of meditation, such as reduction of stress levels and improvement of cognitive functions. Participants of the control condition may profit by gaining knowledge about health and health-related behaviour. The risks of participating are generally low and include intolerance of the MRI measure.

Where is the study run from?

The study is being run from the Technical University of Munich and takes place in the Klinikum Rechts der Isar, Munich (Germany)

When is the study starting and how long is it expected to run for?

June 2017 to October 2018

Who is funding the study?

Fundraising is conducted by one of the study's investigators (Britta Hölzel) and includes contributions from individual donators wanting to support mindfulness research

Who is the main contact?

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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
Effects of a 31-days web-based mindfulness training on brain structure, cognitive performance, brain activation and functional connectivity

Study objectives

Mindfulness meditation increases attentional performance, increases activation of attention-related areas of the brain and alters functional connectivity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/08/2017, Ethics committee of Technische Universität München (Ismaninger Straße 22, 81675 München, +49 89 4140-7737, ethikkommission@mri.tum.de); ref: 284/17 S

Study design

Monocentric interventional single-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Effects of mindfulness meditation on brain structure and function in healthy adults

Interventions

Participants are pseudo-randomly assigned to either a mindfulness meditation training or a strictly informative control intervention containing information on various topics of general health. Both training programs are web-based and delivered in portions of 15 minutes over the course of 31 days.

Intervention Type

Behavioural

Primary outcome(s)

1. Cognitive performance is measured using various parameters of attentional performance before and after the intervention.
2. Structural changes are measured using MRI before and after the intervention.
3. Brain activation and functional connectivity are measured using fMRI before and after the intervention.

Key secondary outcome(s)

1. Psychological wellbeing is measured using questionnaires on various parameters of psychological wellbeing before and after the intervention.

Completion date

28/10/2019

Eligibility

Key inclusion criteria

1. Age range 18-65 years
2. MRI suitability
3. Ability to provide consent
4. Written informed consent
5. Right-handedness

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

58

Key exclusion criteria

1. Presence of psychiatric or neurologic conditions
2. Meditation experience of more than three meditations within the past year or more than ten meditations within the entire life span
3. Use of psychotropic drugs
4. Pregnancy

Date of first enrolment

27/08/2018

Date of final enrolment

28/09/2019

Locations**Countries of recruitment**

Germany

Study participating centre

Klinikum Rechts der Isar, Technical University of Munich

Ismaninger Str. 22

Munich

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Sponsor information

Organisation

Technical University of Munich

ROR

<https://ror.org/02kkvpp62>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Data have been made publicly available via the Open Science Framework at <https://doi.org/10.17605/osf.io/rz3hs>

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Primary outcome results article	02/08/2022	03/08/2022	Yes	No
Results article		19/12/2023	06/03/2024	Yes	No
Dataset		23/09/2021	29/06/2022	No	No
Protocol file			10/10/2022	No	No