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Effects of mindfulness meditation on brain structure and function

Submission date
14/02/2022

Recruitment status
No longer recruiting

Registration date
15/02/2022

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 committe 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
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 measure
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.

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

Overall study start date
01/06/2017

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

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
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Sponsor information

Organisation
Technical University of Munich

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Sponsor type
University/education

Website
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ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2022

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?
Dataset		23/09/2021	29/06/2022	No	No
Results article	Primary outcome results article	02/08/2022	03/08/2022	Yes	No
Protocol file			10/10/2022	No	No
Results article		19/12/2023	06/03/2024	Yes	No