

# Effects of mindfulness meditation on brain structure and function

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

1. Benno Bremer  
benno.bremert@tum.de
2. Kathrin Koch  
kathrin.koch@tum.de
3. Britta Hölzel  
britta.hoelzel@tum.de
4. María Mora Álvarez  
maria.mora@tum.de

## Contact information

### Type(s)

Scientific

### Contact name

Mr Benno Bremer

### ORCID ID

<https://orcid.org/0000-0002-3066-8998>

### Contact details

Ismaninger Str. 22  
Munich  
Germany  
81675  
+49 1719549738  
benno.bremer@tum.de

### Type(s)

Principal investigator

### Contact name

Prof Kathrin Koch

### ORCID ID

<https://orcid.org/0000-0003-4664-8016>

### Contact details

Ismaninger Str. 22  
Munich  
Germany  
81675

+49 8941407972  
kathrin.koch@tum.de

**Type(s)**  
Scientific

**Contact name**  
Ms María Mora Álvarez

**ORCID ID**  
<https://orcid.org/0000-0002-0578-2000>

**Contact details**  
Ismaninger Str. 22  
Munich  
Germany  
81675  
+49 8941407972  
maria.mora@tum.de

**Type(s)**  
Principal investigator

**Contact name**  
Dr Britta Hölzel

**Contact details**  
Ismaninger Str. 22  
Munich  
Germany  
81675  
+49 8941407972  
britta.hoelzel@tum.de

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
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  
Germany  
81675

## 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?
<a href="#">Results article</a>	Primary outcome results article	02/08/2022	03/08/2022	Yes	No
<a href="#">Results article</a>		19/12/2023	06/03/2024	Yes	No
<a href="#">Dataset</a>		23/09/2021	29/06/2022	No	No
<a href="#">Protocol file</a>			10/10/2022	No	No