

# Mindfulness effects on stress beyond placebo effects

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26389

### Source

Nationaal Trial Register

### Brief title

TBA

### Health condition

The study is conducted in a sample of healthy volunteers.

## Sponsors and support

**Primary sponsor:** Leiden University, Leiden, the Netherlands

**Source(s) of monetary or material Support:** Mind & Life Europe

## Intervention

## Outcome measures

### Primary outcome

Stress assessed post-intervention using the short state version of the State-Trait Anxiety Inventory. In the analyses, this will be controlled for baseline stress assessed with the same scale.

### Secondary outcome

Additional exploratory outcomes are detailed in the analysis plan (OSF url <https://osf.io/mpzjk> and doi: 10.17605/OSF.IO/MPZJK)

## Study description

### Background summary

Understanding how mindfulness really works is a requirement for its optimal application to reduce stress and suffering. It has been suggested that mindfulness' effects might be attributed to placebo effects. Yet, it has been difficult to disentangle how the different elements of a mindfulness-based intervention contribute to stress relief in regular RCTs. To this end, we propose a rigorous examination of a putative core element of mindfulness (i.e. decentering, the insight that experiences are impermanent) and of placebo effects (i.e. positive treatment expectancies). These elements will be manipulated in a balanced placebo design. This allows for better understanding the potential additive or interactive effects of the elements of mindfulness-based interventions on stress relief. This research provides a better understanding of how mindfulness might work, and will thus inform on future research methods and on methods for optimizing mindfulness effects.

### Study objective

With this study we aim to disentangle mindfulness and placebo effects on stress. We investigate how decentering (a core active component of mindfulness) and positive treatment expectations (a core component of placebo effects) interactively contribute to pain relief. We do so using a balanced-placebo design, i.e., a 2 x 2 factorial between-participants design, in which participants receive either a mindful decentering or sham decentering treatment which is introduced as being either an effective or a sham treatment. At baseline and post-intervention stress will be assessed.

In our primary analysis, we will examine if the mindful decentering and positive treatment expectations manipulations additively or interactively affect stress. The latter would suggest, depending on the direction of the interaction, that the combination of mindful decentering and positive treatment expectations is either more - or less - effective than the summed effect.

Additional exploratory hypotheses are detailed in the analysis plan (OSF url <https://osf.io/mpzjk> and doi: 10.17605/OSF.IO/MPZJK)

### Study design

Participants take part in one session of an online experiment. The primary outcome is assessed once post-intervention.

### Intervention

To prevent floor effects, we will bring current stress to mind prior to the intervention by letting all participants read a short recent newspaper article regarding the corona crisis, asking them to briefly write about what worries them, and asking them to rate how worried they are about their health, financial, and social situation.

#### Expectation induction

Participants in the effective treatment expectations groups will be told that the training they will receive is a widely used training known to be very effective for stress relief. Participants in the sham treatment expectations group will be told that the training is a widely used sham training known to not affect stress.

#### Decentering induction

In the mindful decentering group, participants will listen to a short audiotape, with at its basis the insight that any thought or sensation arises and then dissipates again. Thus, that any such experience can be observed as a transient event. On the surface, the sham decentering instruction seems similar to the mindful decentering induction, but it is different in terms of content. Participants will listen to a short audiotape. A similar structure, wording, and calmness is given to this induction. Importantly, however, this induction does not include the key insight that experiences are impermanent events that can be observed as they arise and dissipate.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1) Fluent in Dutch

## Exclusion criteria

None

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-09-2020
Enrollment:	132
Type:	Anticipated

### IPD sharing statement

**Plan to share IPD:** Yes

#### Plan description

Coded research data will be made publicly available in an online data repository

## Ethics review

Positive opinion	
Date:	21-09-2020
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL8917
Other	CEP : 2020-07-14-K.J. Peerdeman-V2-2510

## Study results

### Summary results

N/A