Mindfulness effects on pain beyond placebo effects

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22609

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

Average pain unpleasantness during the post-intervention cold pressor test (CPT, maximally 3-minute immersion, with ratings every 30 seconds on a numerical rating scale ranging from 0 no pain – 10 most unpleasant pain imaginable). In the analyses, this will be controlled for average pain unpleasantness during the baseline CPT.

Secondary outcome

Average pain intensity during the post-intervention CPT, controlled for average pain intensity during the baseline CPT.
Additional exploratory outcomes are detailed in the analysis plan (DOI: 10.17605/OSF.IO/H98WT, https://osf.io/h98wt/).

Study description

Background summary

Understanding how mindfulness really works is a requirement for its optimal application to reduce pain 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 pain 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 pain 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 pain. We investigate how decentering (a core 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, pain unpleasantness will be assessed during a cold pressor test.

In our primary analysis, we will examine if the mindful decentering and positive treatment expectations manipulations additively or interactively affect pain unpleasantness. 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.
Secondary, we will examine the additive or interactive effects of the decentering and expectation manipulations on pain intensity during the cold pressor test.
Additional exploratory hypotheses are detailed in the analysis plan (DOI: 10.17605/OSF.IO/H98WT, https://osf.io/h98wt/).

Study design

Participants take part in one experimental session. The primary outcome is assessed during a single post-intervention cold pressor test of maximally 3 minutes during which pain unpleasantness and intensity are assessed every 30 seconds.

Intervention

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 pain relief. Participants in the sham treatment expectations group will be told that the training is a widely used sham training known to not affect pain.

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. Participants in both groups are asked to adopt the instructed perspective in the subsequent cold pressor test.

Contacts

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Eligibility criteria

Inclusion criteria

1) 18-35 years
2) Fluent in Dutch

Exclusion criteria

1) Severe physical or psychological morbidity that could adversely affect study participation (e.g., heart and lung diseases, or DSM psychiatric disorders),
2) Chronic pain complaints (≥ 6 months) at present or in the past,
3) Current pain (>1 on 0-10 numerical rating scale),
4) Raynaud's disease,
5) Extensive injuries of the hand or lower arm,
6) Current use of (analgesic) medication (e.g., analgesic in last 24 hours), and
7) Current pregnancy or breastfeeding,
8) Consumption of alcohol (>1 glass) or drug in last 24 hours.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-09-2020
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:	03-09-2020
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	NL8877
Other	Leiden University Psychology Research Ethics Committee : 2020-02-28-K.J. Peerdeman-V1-2233

Study results