

Mindfulness effects on stress beyond placebo effects

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26389

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

The study is conducted in a sample of healthy volunteers.

Ondersteuning

Primaire sponsor: Leiden University, Leiden, the Netherlands

Overige ondersteuning: Mind & Life Europe

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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)

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Fluent in Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	22-09-2020
Aantal proefpersonen:	132
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

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

Ethische beoordeling

Positief advies	
Datum:	21-09-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A