Induction and generalization of nocebo effects on itch

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Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22739

Bron
NTR

Verkorte titel
TBA

Aandoening

Healthy participants

Ondersteuning

Primaire sponsor: Leiden University, Leiden, the Netherlands
Overige ondersteuning: China Scholarship Council (CSC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Nocebo effects on cowhage-evoked itch. After receiving the verbal suggestion, the participants will receive two trials with 25 cowhage spicules each, once after application of

the ‘itch solution’ and once after application of the ‘control solution’. Our primary outcome is the comparison of the difference in average itch scores between the ‘itch solution’ and the ‘control solution’ trials.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study on healthy participants, we primarily aim to investigate whether nocebo effects on cowhage-evoked itch can be induced by verbal suggestion. In addition, we test whether nocebo effects can generalize from cowhage-evoked itch to mechanical itch and mechanical touch. The nocebo effects on cowhage-evoked itch will be induced by telling the participants that an ‘itch solution’ will increase the itch sensation evoked by cowhage spicules and a control solution will not affect this itch sensation. In this procedure, alloknesis areas surrounding the cowhage application sites will be measured for each trial. Subsequently, to test generalization, mechanical itch and mechanical touch stimuli will each be applied during six trials: three with the control solution and three with the conditioned solution. This study uses a within-subjects design. Itch ratings and alloknesis areas surrounding the cowhage application sites will be compared between trials in which the supposed ‘itch solution’ or the control solution is applied.

Doel van het onderzoek

1. The primary objective of this study is to investigate whether nocebo effects on cowhage-evoked itch can be induced by verbal suggestion. We hypothesize that the verbal suggestion that the solution applied is an ‘itch solution’ will induce higher itch evoked by cowhage spicules than the suggestion that it is a control solution.
2. The secondary objective of this study is to test whether nocebo effects generalize from cowhage-evoked itch to mechanically induced itch and to mechanically induced touch. We hypothesize that the verbal suggestion that the solution applied is an ‘itch solution’ will induce higher itch sensations evoked by mechanical stimulations than the suggestion that it is a control solution.
3. Exploratory objectives of this study are 1) to explore whether nocebo effects on cowhage-evoked itch also affect the alloknesis area surrounding the application site and urge to scratch evoked by cowhage. 2) to explore whether nocebo effects generalize to the urge to scratch evoked by the mechanical itch and mechanical touch stimuli. 3) to explore the role of individual characteristics (e.g., anxiety) in the induction and generalization of nocebo effects within itch stimuli and across sensory modalities (i.e., from itch to touch).

Onderzoeksopzet

All participants will fill out baseline questionnaires to assess demographic and psychological characteristics. After baseline mechanical itch and touch assessments, participants will receive cowhage spicules twice, once with the ‘itch solution’ and once with the ‘control

solution’. After each cowhage stimulus, alloknesis areas surrounding the cowhage sites will be assessed with a brush. Following this, they will receive three different mechanical itch stimuli and three different mechanical touch stimuli twice, once with the ‘itch solution’ and once with the ‘control solution’. The whole experiment will take around one and half an hour per participant in a single session.

Onderzoeksproduct en/of interventie

Participants will receive a verbal suggestion that an ‘itch solution’ will increase the itch sensation evoked by cowhage spicules and that a ‘control solution’ will not affect their itch sensation. In fact, both solutions are water and do not affect itch.

Contactpersonen

Publiek

Leiden University
Andrea Evers

+31 71 527 6891

Wetenschappelijk

Leiden University
Andrea Evers

+31 71 527 6891

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy participants between 18 and 35 years old;
2. Fluency and regular use of English

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Refusal to give written informed consent
2. Have received a diagnosis from a doctor of severe physical illness (e.g., multiple sclerosis, heart or lung disease, diabetes, hypothyroidism)
3. Have a psychiatric diagnosis (e.g., depression, autism, ADHD)
4. Are suffering or have suffered from itch lasting for ≥ 6 weeks (e.g., due to allergy or hay fever)
5. Experience itch ≥ 3 on a 0 (not itch at all) to 10 (worst itch imaginable) scale at the start of the testing session
6. Current use of medication
7. Use of drugs (e.g., cannabis, XTC) more than 3 times a month
8. Use of alcohol, any medication or any other form of drugs in the 24 hours prior to participating in the study.
9. Pregnancy or lactation
10. Insensitivity to cowhage, i.e., inability of cowhage spicules to evoke itch (participation will be stopped right after baseline stimuli)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	17-01-2020
Aantal proefpersonen:	44
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Coded individual participant data relevant to the publication will be shared in an online data repository after publication of the research findings. Privacy sensitive information will not be

shared to protect participants’ privacy.

Ethische beoordeling

Positief advies

Datum:	29-07-2020
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	NL8808
Ander register	Psychology Ethics Committee Leiden University : CEP19-1205/571

Resultaten