Associative and Observational Learning of Nocebo Effects on Itch

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1. Primary: A nocebo effect on cowhage-evoked itch will be induced through a conditioning with verbal suggestion paradigm, as measured by a larger difference in perceived itch during nocebo-associated and control test phase trials for the active...

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

Samenvatting

ID

NL-OMON27468

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Healthy participants

Ondersteuning

Primaire sponsor: Leiden University, Leiden, the Netherlands
Overige ondersteuning: NWO Vici Grant Number: 45316004

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Nocebo effect on itch: Following one of the three previously described interventions, participants in all groups will complete an identical test phase of two cowhage

administrations, one following administration of the nocebo cream and one without. Both test phase trials will use the same low cowhage dose as used in the control trials of the learning phase. The order of these two trials will be randomized so that half of participants in each group receive the nocebo cream on their first trial, and half on the second trial. The same administration and itch rating procedures as described in the learning phase administrations will be used in the test phase. During each trial participants are asked to rate their itch on a 0-100 scale every 15 seconds for 3 minutes, starting 15 seconds after the first report of feeling itch following administration of the cowhage.

The nocebo effect is then measured as the difference in average itch ratings between the nocebo associated trial and the control trial of the test phase. Our primary outcome is the comparison of this difference (the nocebo effect) between the active conditioning and sham conditioning groups, and between the observational learning and sham conditioning groups.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study on healthy adult female volunteers we are investigating the efficacy of conditioning and observational learning for inducing nocebo effects on cowhage-evoked itch. Using a mixed model design, nocebo effects will be induced and measured within two active conditions (conditioning and observational learning), and compared to a third, control group of sham conditioning. Cowhage is a tropical plant that creates a brief itching sensation when rubbed into the skin, and is believed to act on the peripheral nociceptive pathways involved in pruritic symptoms in chronic dermatological conditions (e.g. Atopic Dermatitus).

Doel van het onderzoek

1. Primary: A nocebo effect on cowhage-evoked itch will be induced through a conditioning with verbal suggestion paradigm, as measured by a larger difference in perceived itch during nocebo-associated and control test phase trials for the active conditioning group compared to the sham conditioning group.
2. Secondary: A nocebo effect on cowhage-evoked itch will be induced through observational learning of a conditioning paradigm, as measured by a larger difference in perceived itch during nocebo-associated and control test phase trials for the observational learning group compared to the sham conditioning group.
3. Exploratory 1: A nocebo effect on itch will generalize to increased frequency and duration of scratching responses when induced with a classical conditioning and verbal suggestion paradigm, compared to the frequency and duration of scratching responses in the sham conditioning group
4. Exploratory 2: A nocebo effect on itch will generalize to increased frequency and duration of scratching responses when induced with an observational learning paradigm, compared to the frequency and duration of scratching responses in the sham conditioning group
5. Exploratory 3: The following psychological constructs will be measured with self-report

surveys to test exploratory hypotheses that these variables may act as moderators for the magnitude of nocebo effects on itch induced with conditioning or observational learning:
• Empathy
• Anxiety
• Social desirability
• Mindfulness
• Stress
• Mood
• Sleep quality

Onderzoeksopzet

Participants complete an online survey from home, lasting approximately 20 minutes, prior to an approximately 90 minute appointment in the lab where the experimental procedure is conducted and the primary outcome is assessed.

Onderzoeksproduct en/of interventie

Conditioning: Participants will undergo a conditioning paradigm acquisition phase consisting of four cowhage administrations. A verbal suggestion is made, informing participants that one of two creams applied prior to the cowhage will intensify the itch that they feel from the cowhage, For each trial, the researcher will act as though they are applying a small unit of one of the creams to one of the 2x2cm squares. The control trials are paired with a lower dose of cowhage, and the nocebo associated trials are paired with a larger dose of cowhage so that more itch is experienced during the nocebo-associated learning trials.

The order of the learning phase trials is fixed, consisting of 1) a control trial, 2) a nocebo-associated trial, 3) a control trial, and 4) a nocebo-associated trial.

Observational learning: Participants in the observational learning group will watch a video which depicts the conditioning acquisition phase procedure described above with a model participant. The model participant gives an average rating of 30 (on a 0-100 scale) for the control trials and an average rating of 60 for the nocebo-associated trials.

Sham conditioning: Participants in the sham conditioning group complete the same conditioning procedure described above, however each trial uses only the low dose of cowhage, so that no difference in itch between the two creams is perceived.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Female
Age 17-35
Good understanding of written and spoken English

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Have current or a history of chronic / recurring dermatological conditions.
Have current physical or mental illness.
Currently take medication for the management of pain or itch symptoms.
Have injuries on the hands, wrists, or arms at the time of participation.
Are pregnant or breastfeeding.
Are colorblind.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-03-2019
Aantal proefpersonen:	66
Type:	Werkelijke startdatum

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 .Privacy sensitive information, including the video recordings of scratching behavior will not be shared to protect participant privacy. Data will be shared through the use of an online, open access repository (e.g., DANS easy) of datasets which anyone can access via the internet, allowing for any analyses which interested parties may wish to perform.

Ethische beoordeling

Positief advies

Datum:	24-04-2019
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	NL7696
Ander register	Psychology Ethics Committee Leiden University : CEP19-0225/128

Resultaten