Generalization of placebo and nocebo effects across pain modalities and from pain to itch.

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1.The primary objective of this study is to test whether placebo and nocebo effects generalize within pain stimulus modalities, i.e. from heat pain to pressure pain. 2.The secondary objective of this study is to test whether placebo and nocebo...

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

Samenvatting

ID

NL-OMON28928

Bron
Nationaal Trial Register

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

Generalization of placebo and nocebo effects to pressure pain. Following the heat pain conditioning and test, participants will receive 6 medium pressure pain stimuli; 3 stimuli with ENS ‘ON’ and 3 with ENS ‘OFF’. After each stimulus, participants will be asked to rate their pain intensity by using a 0-10 numerical rating scale. Our primary outcome is the comparison of the difference in average pressure pain between ENS ‘ON’ and ‘OFF’ in placebo and nocebo groups, respectively. Additionally, maximum pressure pain ratings between ENS ‘ON’ and ‘OFF’ in these groups will also be compared.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study on healthy participants, we are investigating whether placebo and nocebo effects on pain can generalize to another type of pain and to itch. Placebo and nocebo effects will be induced by combining verbal suggestion (by telling the participant that the sensation will decrease/increase) with conditioning with heat pain (by actual changes in the stimulus intensity of induced heat pain). To test generalization, pressure pain stimuli will be applied during six trials; three with a control cue and three with a conditioned cue. Moreover, cowhage-evoked itch will be applied twice, once with a control cue and once with a conditioned cue. This study uses a within-subjects design, pain/itch ratings with the conditioned cue will be compared with the control cue in the placebo and nocebo group, respectively.

Doel van het onderzoek

1.The primary objective of this study is to test whether placebo and nocebo effects generalize within pain stimulus modalities, i.e. from heat pain to pressure pain.
2.The secondary objective of this study is to test whether placebo and nocebo effects generalize across somatosensory modalities, i.e., from heat pain to cowhage-evoked itch.
3.The exploratory objective of this study is to explore the role of individual characteristics variables (i.e., anxiety and depression; stress; attention to pain and itch; optimism and pessimism; pain catastrophizing; itch catastrophizing) in the generalization of placebo and nocebo effects within pain stimulus modalities and from pain to itch.

Onderzoeksopzet

The whole experiment will take around 2 hours and 30 minutes per participant in a single session.

Onderzoeksproduct en/of interventie

Participants will learn the links between the changes of heat pain intensity with an Electrical Nerve Stimulation (ENS) device ‘ON/OFF’. This ENS device serves as a sham device and does not work in the main test. In the placebo group, participants will be told that ENS ‘ON’

means a decrease of heat pain (a conditioned cue) and ENS ‘OFF’ means no change of heat pain (a control cue). In fact, participants will receive low heat pain with ENS ‘ON’ and medium heat pain with ENS ‘OFF’ during the learning phase. In the nocebo group, participants will be told that ENS ‘ON’ means an increase of heat pain (a conditioned cue) and ENS ‘OFF’ means no change of heat pain (a control cue). In fact, participants will receive high heat pain with ENS ‘ON’ and medium heat pain with ENS ‘OFF’ during the learning phase.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy participants between 18 and 35 years old;
2. Fluent in the English language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1.Refusal to give written informed consent
2.Severe morbidity (e.g., multiple sclerosis, heart or lung disease, chronic itch or pain complaints)
3.DSM-IV psychiatric disorders (e.g., depression, autism)
4.Regular use of recreational drugs

5.Current use of medication
6.Pregnancy or lactation

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	08-04-2019
Aantal proefpersonen:	82
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. Privacy sensitive information 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:	08-10-2019
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	NL8072
Ander register	Psychology Ethics Committee Leiden University : CEP18-1218/491

Resultaten

Samenvatting resultaten
Not yet