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

No registrations found.

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

Summary

ID

NL-OMON28928

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Healthy participants

Sponsors and support

Primary sponsor: Leiden University, Leiden, the Netherlands
Source(s) of monetary or material Support: China Scholarship Council (CSC)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Generalization of placebo and nocebo effects to cowhage-evoked itch. Following the heat pain conditioning, participants will receive cowhage twice, once with ENS ‘ON’ and once with ENS ‘OFF’. As soon as participants feel itch for the first time, they will be asked to rate their itch intensity by using a 0-10 numerical rating scale every 10 seconds for 3 minutes. Our primary outcome is the comparison of the difference in average itch ratings between ENS ‘ON’ and ‘OFF’ in placebo and nocebo groups. Additionally, maximum itch ratings between ENS ‘ON’ and ‘OFF’ in these groups will also be compared.
Psychological factors: the individual characteristics (e.g.,, anxiety) will be used to investigate possible moderators of placebo and nocebo effects within and across modalities.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	08-04-2019
Enrollment:	82
Type:	Unknown

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	08-10-2019
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	NL8072
Other	Psychology Ethics Committee Leiden University : CEP18-1218/491

Study results

Summary results
Not yet