Induction and generalization of nocebo effects on itch

No registrations found.

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

Summary

ID

NL-OMON22739

Source
NTR

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

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.

Secondary outcome

Generalization of nocebo effects to mechanical itch and to mechanical touch. Following the cowhage test phase, the participants will receive mechanical itch stimuli and mechanical touch stimuli by using six different von Frey filaments twice, once after application of the 'itch solution' and once after application of the 'control solution'. Our outcomes are the comparison of the difference in average itch scores between the 'itch solution' and the 'control solution' for the mechanical itch and the mechanical touch stimuli separately. Additionally, peak itch, peak and average urge to scratch scores, as well as the awareness of a sensation will be compared between the 'itch solution' and the 'control solution' trials for both cowhage and mechanical itch and mechanical touch stimuli.
Nocebo effects on the alloknesis area surrounding the cowhage sites. The average alloknesis areas surrounding the cowhage application sites will be assessed using a brush and will be compared between the 'itch solution' and the 'control solution' trials to test possible nocebo effects on alloknesis area as an exploratory analysis.
Psychological factors. The individual characteristics (i.e., state anxiety, depression, anxiety, stress, itch-related attention, itch-related magnification, rumination, helplessness) will be used to test possible moderators of the induction and generalization of nocebo effects within and across sensory modalities (i.e., itch and touch) as an exploratory analysis.

Study description

Background summary

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.

Study objective

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).

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	17-01-2020
Enrollment:	44
Type:	Unknown

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	29-07-2020
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	NL8808
Other	Psychology Ethics Committee Leiden University : CEP19-1205/571

Study results