Nocebo effects on pressure pain

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23815

Source
NTR

Brief title
Nocebo effects on pressure pain

Health condition

The study is conducted in a sample of healthy volunteers.

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: Netherlands Organization for Scientific Research (NWO) - Vici grant

Intervention

Outcome measures

Primary outcome

The change in nocebo effect from after nocebo conditioning (part 1) to after counterconditioning, extinction, and continued nocebo conditioning (part 2) will be compared across groups. Nocebo effects will be calculated by taking the mean difference of pain ratings during experimental trials (placebo TENS device activation) versus pain ratings during control trials (placebo TENS device deactivation) in the test phase.

Secondary outcome

The comparison of the induction of nocebo effects after nocebo conditioning and sham conditioning. The mean difference between self-reported pain ratings during experimental and control trials of the testing phase (i.e., nocebo effects) will be calculated for nocebo conditioning and sham conditioning groups, and then compared.

Study description

Background summary

Nocebo effects are known to adversely affect the experience of various physical symptoms, such as pain and itch. Recent studies have shown that nocebo effects can be experimentally induced and reduced by associative learning mechanisms of classical conditioning and counterconditioning, respectively, especially when combined with verbal suggestions. Prior pain conditioning studies have used heat or electrical pain to test nocebo pain manipulations in the lab. Nocebo conditioning and counterconditioning has, however, not been investigated for more clinically relevant pain modalities, such as pressure pain. Additionally, prior research has always used deception for inducing nocebo effects and open-label conditioning and counterconditioning have not been studied before. The aim of the current study is to investigate whether nocebo effects on pressure pain can be induced via open-label conditioning and reduced via open-label counterconditioning, combined with open-label verbal suggestions about the activation of a placebo Transcutaneous Electrical Nerve Stimulation (TENS) device.

Study objective

The primary objective of the study is to investigate whether an induced nocebo effect can be effectively reduced by open-label counterconditioning, combined with open-label verbal suggestions, as compared to continued nocebo conditioning and extinction. To assess whether a nocebo effect is effectively reduced, the experimental (counterconditioning) and control (continued nocebo conditioning, extinction) groups will be compared on the change in the nocebo effect from before to after counterconditioning. The nocebo effect will be determined by calculating the mean difference between self-reported pain ratings during experimental trials and control trials from after nocebo conditioning to after counterconditioning. We expect participants in the counterconditioning and extinction groups to show a decreased nocebo effect, whereas we expect participants in the continued nocebo conditioning group to show no change or a slightly increased nocebo effect. Furthermore, we expect participants in the counterconditioning group to show a larger reduction of the nocebo effect than participants in the extinction group.
Secondary, we will investigate whether nocebo effects on pressure pain can be induced via open-label classical conditioning combined with open-label verbal suggestions in experimental (nocebo conditioning) as compared to a control (sham conditioning) group.

Study design

One lab session of approximately 2 hours. Aside from individual calibration of pressure pain intensities, participants will receive 4 non-painful pressure stimuli during practice session. In each group, learning phase consists of a total of 20 trials with either moderately painful pressure stimuli (nocebo conditioning, continued nocebo conditioning), slightly painful pressure stimuli (extinction), or non-painful pressure stimuli (counterconditioning) in the experimental trials and slightly painful pressure stimuli in the control trials. In the control group (sham conditioning), participants will receive moderately painful and slightly painful stimuli in a randomized order. The test phase for all groups consists of 6 trials with slightly painful pressure stimuli presented in both experimental and control trials. The induction and reduction of nocebo effects will be analyzed using the self-reported pain levels in the testing phase.

5-10 minute breaks will be taken across different experimental parts (calibration, induction of nocebo effects, reduction of nocebo effects).

Intervention

Open-label verbal suggestions about a placebo TENS device and open-label conditioning to induce and reduce nocebo effects on pressure pain, in the form of nocebo conditioning, continued nocebo conditioning, counterconditioning, and extinction.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy female volunteers between 18 and 35 years old, with a good understanding of

written and spoken Dutch.

Exclusion criteria

Severe somatic or psychiatric morbidity (e.g., heart/lung diseases, DSM-V psychiatric disorders), Raynaud’s disease, chronic pain complaints at present or in the past, current pain complaints, current use of medication, injuries on the non-dominant hand, refusal/inability to remove nail polish or artificial nails for the experiment, pregnancy, color-blindness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2018
Enrollment:	124
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
Coded research data cannot be made publicly available, as participants did not give their specific consent to sharing their coded data.

Ethics review

Positive opinion

Date:	17-09-2019
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	NL8033
Other	Psychology Research Ethics Committee, Leiden University : CEP18-1114/442

Study results