# Associative and Observational Learning of Nocebo Effects on Itch

No registrations found.

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

# **Summary**

### ID

NL-OMON27468

**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:** NWO Vici Grant Number: 45316004

### Intervention

### **Outcome measures**

#### **Primary outcome**

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.

#### Secondary outcome

Observational learning: Our first secondary outcome is the comparison of the difference in average itch ratings between the nocebo associated trial and the control trial of the test phase (the nocebo effect) between the observational learning and sham conditioning groups.

Scratching behavior: Video recording of the participant's lab session will be collected with the participant's consent, and used to analyze the frequency and duration of scratching behavior during the experiment.

Psychological factors: Questionnaire measures of empathy (Interpersonal Reactivity Index; Pulos, Elison, & Lennon, 2004), state anxiety (Spielburger State Anxiety Inventory; Marteau & Bekker, 1992), social desirability (Marlow-Crowne Social Desirability Scale; Crowne & Marlow, 1960), mindfulness (Five Factor Mindfulness Questionnaire; Tran, Gluck, & Nader, 2013), stress (Perceived Stress Scale; (Cohen, Kamarck, & Mermelstein, 1983), mood (Positive and Negative Affect Scale; Watson, Clark, & Tellegen, 1988) and sleep quality (Sleep Condition Indicator; Espie et al., 2014) will be used to investigate possible moderators of nocebo effects on itch as a secondary, exploratory analysis.

# **Study description**

#### **Background summary**

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).

#### Study objective

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

#### Study design

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.

#### Intervention

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 noceboassociated 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.

# Contacts

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# **Eligibility criteria**

### **Inclusion criteria**

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

### **Exclusion criteria**

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.

# 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):	14-03-2019
Enrollment:	66
Туре:	Actual

### **IPD** sharing statement

#### Plan to share IPD: Yes

#### **Plan description**

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.

# **Ethics review**

Positive opinion Date: Application type:

24-04-2019 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

RegisterIDNTR-newNL7696OtherPsychology Ethics Committee Leiden University : CEP19-0225/128

# **Study results**