Can nocebo effects on itch be modified by a positive expectation induction?

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40445

Source
ToetsingOnline

Brief title
Can nocebo effects on itch be modified?

Condition

- Epidermal and dermal conditions

Synonym
Itch, pruritus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO VIDI project

Intervention

Keyword: Expectancy learning, Itch, Nocebo, Placebo

Outcome measures

Primary outcome

The main study endpoint is the difference in the levels of itch (VAS scores) evoked by the electrical stimuli associated with the conditioned cues versus the neutral cues in the testing phase of part II of the experiment. It is investigated whether nocebo effects (negative expectation effects) can be modified by a positive expectation induction by conditioning and verbal suggestion (low-itch expectation induction) (group 1), resulting in lower itch VAS scores than a repeated negative expectation induction (high-itch expectation induction) (group 2), or a neutral procedure (neutral expectation induction) (group 3).

Secondary outcome

The secondary study endpoints of the present experiment are: a) the itch related expectancy effects on scratching behavior; b) the itch related expectancy effects regarding itch evoked by histamine iontophoresis; c) the role of individual characteristics (e.g., optimism) on (the modifiability) of expectancy effects; and d) the role of 5-HTTLPR genotype and other genetic variants on (the modifiability) of expectancy effects.

Study description

Background summary

For highly prevalent conditions associated with chronic itch, treatment effects are usually modest and vary strongly across patients. Expectancy mechanisms may contribute to this variability. The influence of expectations have often been studied in a placebo- or nocebo design, in which expectations are, for example, induced by verbal suggestions or a conditioning procedure. Placebo and nocebo effects can be defined as favorable and unfavorable treatment responses, unrelated to the treatment mechanism, which are induced by expectations of improvement and worsening, respectively. Placebo and nocebo effects have been investigated primarily in studies that focus on pain. Recent research of our research group showed in a validated design that expectancy mechanisms of verbal suggestion and conditioning can also induce placebo and nocebo effects on itch. However, it is not yet known whether nocebo effects can also actively be modified, e.g., by inducing a positive expectation induction, resulting in less itch. This is a scientifically and clinically highly relevant research question for the development of treatment modules to change inadequate negative expectations of patients suffering from chronic itch complaints.

Study objective

The main objective of the study is to determine whether induced nocebo effects (negative expectancy effects) for itch can be modified by a positive expectation induction. Secondary objectives are to explore: a) the effects of expectation inductions on scratching behavior, b) the generalization of expectancy effects to other types of itch stimuli, c) the role of individual characteristics on expectancy effects, and d) the role of genetic predispositions on expectancy effects.

Study design

In healthy subjects, expectations with regard to electrically evoked itch will be induced by a conditioning with verbal suggestion procedure, in correspondence to a previous experiment conducted by the research group. For every stimulus, participants are asked to report the level of itch on a Visual Analogue Scale (VAS), and the scratching behavior of the participants will be recorded during the experiment. In part I, in all participants high-itch expectations will be induced (nocebo induction). More specifically, in the learning phase, short-lasting itch stimuli of medium and high intensity are repeatedly associated with certain colored cues displayed on a computer screen (e.g., two colored cues of which one cue is associated with itch stimuli of medium intensity (neutral cue), and the other with itch stimuli of high intensity (conditioned cue)). In line with the conditioning procedure, verbal suggestions for high itch will be given regarding itch stimuli associated with the conditioned cue. Subsequently, in the testing phase, expectancy effects for itch with regard to the colored cues will be tested by applying both the conditioned and neutral cues with itch stimuli of medium intensity. In part II, participants will be randomly assigned to one of three groups: the experimental

group, in which low-itch expectations will be induced (group 1) (similar to the procedure described above with the exception that the conditioned cues are now associated with low itch intensity stimuli), a control group in which once more high-itch expectations will be induced similar to part I (group 2), or a control group with a neutral itch induction procedure (neutral expectation induction) (group 3). In part III, generalization of the induced expectancy effects will be tested with respect to another itch stimulus, i.e., histamine iontophoresis.

Study burden and risks

Participants will complete a series of validated questionnaires at home to assess relevant individual characteristics, for approximately half an hour. Participants will then visit the department of Clinical, Health & Neuropsychology at the Leiden University once for approximately 4,5 hours. Sensations of itch will be induced using frequently applied and by the research group validated stimuli of short duration which are not burdensome. DNA is collected by asking participants to spit in a special tube. No risks are involved with participation in this study, only an investment of time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy human volunteers, 18 - 35 year old, fluent in Dutch language

Exclusion criteria

Severe morbidity (e.g., multiple sclerosis, diabetes mellitus, heart or lung diseases), psychiatric disorders (e.g., depression), use of pacemaker, color-blindness, diagnose of histamine hypersensitivity, and chronic itch or pain complaints.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2014
Enrollment:	99
Type:	Actual

Ethics review

Approved WMO Date:	26-02-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-05-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	28-05-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL47084.058.14