Open- and closed-label suggestions and itch

No registrations found.

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

Summary

ID

NL-OMON27413

Source
Nationaal Trial Register

Brief title
Open- and closed-label suggestions and itch

Health condition

Itch, expectations;
Jeuk, verwachtingen

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: European Research Council Consolidator Grant

Intervention

Outcome measures

Primary outcome

The primary study outcome is the difference in self-reported itch rating during a short-term validated histamine test (histamine iontophoresis) between the combined open- and closed-label negative verbal suggestion group and the combined open- and closed-label positive

verbal suggestion group.

Secondary outcome

To investigate whether open-label verbal suggestions and closed-label verbal suggestions alone are able to induce outcome expectations and influence self-reported itch, separate analyses will be conducted for each type of verbal suggestions. The effects of suggestions (both combined and for open-label and closed-label separately) on outcome expectations will be assessed.

In addition, the effects of suggestions (both combined and for open- and closed-label conditions separately) on secondary outcomes, for example skin condition, and wellbeing, will be explored. Furthermore, the possible influence of psychological parameters on the expectation induction and study outcomes will be explored.

Study description

Background summary

In the present study, the effects of negative and positive outcome expectations, induced by verbal suggestions regarding a sham transdermal patch under both open-label and closed-label conditions, on self-reported itch are investigated. In a randomized controlled trial, participants will first be screened for the in- and exclusion criteria by filling out an online questionnaire, and, following inclusion, will be invited for a single laboratory session. Participants will be allocated to one of four study groups: 1) an open-label negative verbal suggestions group; 2) a closed-label negative verbal suggestions group; 3) an open-label positive verbal suggestions group; or 4) a closed-label positive verbal suggestions group. All participants will be told that the patch, which the study investigates, contains caffeine, which has a positive effect on cognitive abilities such as attention and processing speed of the brain. In addition, they will be told that the patch, as a side effect, has either a negative or positive effect (depending on group allocation) on the sensitivity of their skin to physical sensations such as itch. It is expected that negative outcome expectations following negative verbal suggestions will result in higher self-reported itch, and that positive outcome expectations following positive verbal suggestions will result in lower self-reported itch (both combined and for open-label and closed-label separately). Secondary outcome measures include, for example, skin condition and wellbeing.

Study objective

The primary objective of the study is to investigate whether negative and positive outcome expectations, induced by verbal suggestions regarding a sham transdermal patch, can influence self-reported itch during a short-term validated histamine test under both open-

label and closed-label conditions. It is expected that negative outcome expectations following negative verbal suggestions will result in higher self-reported itch, and that positive outcome expectations following positive verbal suggestions will result in lower self-reported itch. To investigate whether open-label verbal suggestions and closed-label verbal suggestions alone are able to induce outcome expectations and influence self-reported itch, separate analyses will be conducted for each type of verbal suggestions. The effects of suggestions (both combined and for open-label and closed-label separately) on outcome expectations will be assessed as well.

As a secondary objective, the effects of suggestions (both combined and for open- and closed-label conditions separately) on other factors, for example skin condition, and wellbeing, will be explored. In addition, the influence of psychological parameters on expectation induction and study outcomes will be explored.

Study design

The study consists of an online screening questionnaire, followed by a single laboratory session.

Intervention

Participants are randomly assigned to one of four groups: 1) the open-label negative verbal suggestions group, 2) the closed-label negative verbal suggestions group, 3) the open-label positive verbal suggestions group, or 4) the closed-label positive verbal suggestions group.

All participants will be told, as a cover story, that the study aims to investigate the effects of a transdermal patch on cognitive abilities. They will be told that the patch contains caffeine, which has a positive effect on cognitive abilities, such as attention and processing speed of the brain. Next, they will be told that the patch, as a side effect, has either a negative or positive effect (depending on group allocation) on the sensitivity of their skin to physical sensations such as itch.

Negative outcome expectations will be induced by verbal suggestions regarding the sham caffeine patch in the open- and closed-label negative verbal suggestions groups. Positive outcome expectations will be induced by verbal suggestions in the open- and closed-label positive verbal suggestions groups.

Participants will be told that they will experience either more or less itch (the nature of the instructions varies depending on group allocation) during a short-term validated histamine test, compared to a previously conducted baseline histamine test, as a result of the

transdermal patch.

When verbal suggestions are given under open-label conditions, participants will receive additional information regarding the effects of expectations and verbal suggestions on itch. For example, they will be told about either the nocebo or placebo effect, depending on group allocation, and that verbal suggestions can influence experienced itch. When verbal suggestions are given under closed-label conditions, participants will not receive this additional information.

Contacts

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Eligibility criteria

Inclusion criteria

Between 18 and 35 years old; good understanding of both written and spoken Dutch

Exclusion criteria

Refusal to give written informed consent; severe somatic or psychological morbidity (e.g., heart and lung diseases or DSM-V psychiatric disorders) that would adversely affect participant’s safety or that might interfere with the study protocol; current chronic itch or pain complaints; current use of analgesics, anti-inflammatory drugs, antihistamines, or antibiotics; recent vaccinations; pregnancy; colour blindness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-04-2018
Enrollment:	112
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46396
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6985
NTR-old	NTR7174
CCMO	NL64502.058.17
OMON	NL-OMON46396

Study results

Summary results
n/a