Effects of open- and closed label nocebo and placebo verbal suggestions on itch

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The study objective is to assess whether negative and positive outcome expectations, induced by verbal suggestions under both open-label and closed-label conditions, can influence self-reported itch during a short-term validated histamine test.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43008

Source
ToetsingOnline

Brief title
Open label nocebo and placebo

Condition

- Other condition

Synonym
Not applicable

Health condition

Het onderzoek wordt bij gezonde proefpersonen uitgevoerd. Uitkomsten uit deze lijn van onderzoek bieden nieuwe handvatten voor verklaringsmodellen en therapeutische interventies voor aandoeningen waarbij jeuk een symptoom is.

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Expectations, Itch, Verbal suggestions

Outcome measures

Primary outcome

The primary study parameter is self-reported itch during histamine iontophoresis.

Secondary outcome

Secondary study outcomes include wheal size, flare response, skin temperature, and self-reported skin condition following histamine iontophoresis, as well as scratching behaviour. In addition, the possible influence of psychological parameters on outcomes will be explored.

Study description

Background summary

There is evidence suggesting that negative and positive outcome expectancies can influence subjective symptoms such as itch. Previous studies show that negative and positive expectancies can be induced by verbal suggestions and application of an inert substance (e.g. a cream), and that these in turn might influence itch sensations. Additionally, although most studies on placebo and nocebo effects have only informed participants after the study that they received an inert substance (closed-label placebo/nocebo), there is a growing body of literature that suggests that placebo effects can occur even when it is known that a given substance is inert (i.e. open-label placebo). However, no study to date has investigated open-label nocebo effects, nor has investigated the efficacy of negative and positive verbal suggestions under both open-label and closed-label conditions in itch.

Study objective

The study objective is to assess whether negative and positive outcome expectations, induced by verbal suggestions under both open-label and closed-label conditions, can influence self-reported itch during a short-term validated histamine test.

Study design

A randomized, controlled, within-between-subjects study design will be applied. Participants will be randomly assigned to 1) the closed-label negative verbal suggestions group, 2) the open-label negative verbal suggestions group, 3) the closed-label positive verbal suggestions group or 4) the open-label positive verbal suggestions group. Participants will be invited for a baseline session, during which they will be exposed to histamine iontophoresis. One week following the baseline session, participants will be invited to the experimental session, during which they will receive verbal suggestions and be re-exposed to histamine iontophoresis. Self-reported itch will be assessed prior to, during and following histamine iontophoresis. Assessments of self-reported skin condition, physical parameters (e.g. wheal size, flare response) and behavioural parameters (i.e. scratching behaviour) will be done as well. During the baseline session, participants are asked to fill in additional demographic- and personality questionnaires.

Intervention

Positive outcome expectations will be induced by verbal suggestions in the open- and closed-label positive verbal suggestions groups. Negative outcome expectations will be induced in the open- and closed-label negative verbal suggestions groups. When suggestions are given under open-label conditions, participants will receive additional information regarding the effects of expectations and verbal suggestions on itch.

Study burden and risks

Participants need to invest a total of maximally 2 hours in the study. Given the relatively healthy study population, no adverse side effects are expected. The symptoms of transdermal histamine iontophoresis (local swelling, itch, and flare) will disappear within several minutes to a maximum of 2 hours. All other measurements are considered minimally invasive. Participants will receive a reimbursement of 15,00 euros for participation in this study.

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

Between 18 and 35 years old; good understanding of 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-IV 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, antibiotics or recent vaccinations; pregnancy

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2016
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO

Date:	21-09-2016
Application type:	First submission
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

ID: 24596
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58792.058.16
OMON	NL-OMON24596
OMON	NL-OMON25317