Assessing the effects of positive expectations through open label suggestions on itch

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The study objective is to assess whether positive expectations, induced by verbal suggestions in an open-label design (i.e. knowing about the suggestions), can reduce 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-OMON53166

Source
ToetsingOnline

Brief title
Open label suggestions and itch

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 mean 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, effects on positive and negative affect and generalized expectations will be explored. The possible influence of psychological parameters on outcomes will be explored as well.

Study description

Background summary

The current evidence suggests that it might be possible to influence itch through inducing positive expectations by verbal suggestions. 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. However, no study to date has investigated whether suggestions can induce positive outcome expectations and reduce itch, with participants knowing that expectations can reduce itch.

Study objective

The study objective is to assess whether positive expectations, induced by verbal suggestions in an open-label design (i.e. knowing about the suggestions), can reduce itch during a short-term validated histamine test.

Study design

A randomized, controlled, between-subjects study design will be applied. Participants will be randomly assigned to 1) the verbal suggestions condition (open-label positive verbal suggestions) or 2) the control condition (no positive verbal suggestions). Participants will be invited for a single session, during which they will be exposed to transdermal histamine iontophoresis. Self-reported itch will be assessed during and following histamine iontophoresis. Prior to the session, participants are asked to fill in online questionnaires.

Intervention

Positive expectations will be induced by means of verbal suggestions in the verbal suggestion condition.

Study burden and risks

Participants need to invest a total of approximately 1,5 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 12,50 euros for participation in this study.

Contacts

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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 study protocol; current chronic itch or pain complaints; current use of analgesics, anti-inflammatory drugs, antihistamines, antibiotics; pregnancy

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2015
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2015
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

No registrations found.

In other registers

Register	ID
CCMO	NL54570.058.15