Attentional interference by itch and pain

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46015

Source
ToetsingOnline

Brief title
Attentional interference by itch and pain

Condition

- Other condition

Synonym
Itch, pruritus; Pain

Health condition

aandoeningen die gepaard gaan met (chronische) jeuk en pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO Veni subsidie

Intervention

Keyword: Attentional processes, Itch, Pain, Pruritus

Outcome measures

Primary outcome

Behaviourally, attentional interference, reflected by reaction times and accuracy for visual targets during the SAT, will be compared between itch and pain stimulation and vibrotactile stimulation. Neurophysiologically, attentional interference, reflected by EEG alpha desynchronization, will be compared between itch and pain stimulation compared to vibrotactile stimulation.

Secondary outcome

Secondary outcomes of the study, on a behavioural level, are interaction effects between stimulus type (itch, pain, vibrotactile control) and congruency (congruent: attention directed ipsilaterally to the stimulation & incongruent: attention directed contralaterally to the stimulation), which will be explored over the time course of the somatosensory stimuli during the SAT. On a neurophysiological level, EEG alpha desynchronization over the time course of the somatosensory stimulation, irrespective of the SAT, will be investigated. Exploratory, EEG alpha desynchronization over the time course within the blocks during the SAT will also be investigated.

Other study parameters are the results of both computerized behavioural attention tasks, i.e. the dot-probe task for itch measuring attentional processing of itch pictures and the Flanker task measuring attentional

interference in general. In addition, the relationship between the individual characteristics potentially related to attentional itch and pain processing and the outcomes of the behavioural attention tasks will be explored.

Study description

Background summary

Of the general population, approximately 14% suffer from chronic itch and approximately 20% suffer from chronic pain, which both can severely affect patients* quality of life. For pain, it has been shown that attentional processes can be dysregulated, mainly difficulty disengaging from pain, as shown by studies using behavioural attention tasks. This can result in attentional interference in daily activities. Additionally, neurophysiological studies also indicate that the alpha-desynchronization patterns, a neurophysiological measure of attentional processing, as measured by for example electroencephalography (EEG), are altered in patients with chronic pain. For itch, attentional processes have barely been investigated. Our recently developed somatosensory attention task (SAT) with somatosensory itch and pain inductions allows to quantify the extent to which itch and pain interfere with task execution, and thereby gives insight into the attentional processes associated with itch and pain (e.g., attentional disengagement). However, this task needs to be optimized further as in previous versions of the SAT the targeted intensity of itch and pain was not reached in a considerable proportion of participants and extensive randomization of targets limited the potential to analyse attentional processing over the time course of a stimulus. Moreover, neurophysiological correlates of attentional processing have not been investigated so far with respect to itch and only sparsely for pain. Such information about attentional interference by itch and pain in healthy participants is necessary before these processes are to be investigated more thoroughly in patients with chronic itch or pain.

Study objective

The primary objectives are to investigate attentional interference by somatosensory itch and pain stimuli in healthy subjects, both on a behavioural (SAT) level and a neurophysiological level (EEG alpha-desynchronization).

Secondary objectives include investigating whether itch or pain attract attention to its spatial location and it will be explored whether this attention allocation varies over the time course of a stimulus. Moreover, neurophysiologically the pattern of alpha-oscillations during the time course

of the itch and pain stimuli, irrespective of the SAT, will be investigated. The pattern of alpha-oscillations will also be explored during the SAT if the EEG-signal allows to do so (e.g., the signal is not contaminated by artefacts due to the visual target stimuli within the SAT).

Other objectives include investigating attentional processing of itch pictures, using a previously developed dot-probe task, and one*s general ability to disengage attention (irrespective of itch and pain) using the Flanker task. Additionally, associations between the outcomes of the behavioural and neurophysiological attention tasks and individual characteristics related to attention will be explored.

Study design

This is an experimental study including healthy subjects in a within-subjects design. The study consists of two parts. First, participants fill out self-report questionnaires at home (ca. 15 mins). Second, participants visit the laboratory where the behavioural attention tasks will be administered (ca. 3 h). The experiment includes breaks.

General procedure: Potential participants receive written information about the study. They are informed about the study procedures and they are informed that the study investigates perception of itch and pain. They are not explicitly informed about the goal of investigating attentional mechanisms, as this knowledge could influence study results. Prior to visiting the lab, potential participants will fill out several screening questionnaires via an online system (Qualtrics). Subsequently, eligible participants will make an appointment for participation. The testing session will take place at the Faculty of Social and Behavioural Sciences, Leiden University and will take approximately 3 hours. After an explanation of the procedures and a brief check of the in- and exclusion criteria, participants will be asked to sign the informed consent form. First, a short general attentional interference task will be employed; the flanker task. Afterwards, EEG electrodes will be applied to the head of the participant, and EEG will be measured during rest, followed by recordings during three different types of somatosensory stimuli: electrical itch and pain stimuli and vibrotactile (pulsation) stimuli. Subsequently, participants will conduct the SAT in which the three types of somatosensory stimuli are applied. Thereafter, the electrodes for the somatosensory stimuli will be removed. Lastly, participants will perform a short computerized behavioural attention task: the dot-probe task for itch. After finishing the measurements, electrodes for EEG will be removed.

Study burden and risks

No risks are known for the administration of the questionnaires, computer tasks, pulsating tactors (as control condition) and EEG measures. Also for the

electrical stimulation, the safety of participants is guaranteed throughout the entire experiment, as an apparatus qualified for clinical research will be used, which continuously confines the amount of electrical transmission given to the participant. The electrical stimulation does induce itch or pain for short duration and can cause temporary redness of the skin. No direct benefits are expected to be experienced by the participants.

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 volunteer* 18-30 years old* fluent in Dutch language

Exclusion criteria

Severe or long-term physical or psychiatric morbidity (e.g., multiple sclerosis, diabetes mellitus, heart or lung disease, rheumatoid arthritis, vasculitis, major depressive disorder, atopic dermatitis, migraine), use of pacemaker, chronic itch or pain complaints, current use of medication (e.g., antihistaminics, analgesics), pregnancy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	24-10-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-10-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL58255.058.16