The influence of stimulus parameters on the reported location of electrocutaneous stimuli

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

Summary

ID

NL-OMON35894

Source
ToetsingOnline

Brief title
Localization of electrocutaneous stimuli

Condition

- Other condition

Synonym
Na

Health condition

nvt

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: body schema, electrocutaneous stimulation, subjective localization, touch

Outcome measures

Primary outcome

Main parameters of the various experiment series are the following stimulus parameters: location, strength, frequency, duration and modality. In one experiment, gaze direction of the subject will be varied. The outcome measures are reported location, which will be analysed in respect to variance and mean per site as well as clustering behaviour.

Secondary outcome

The secundary outcome measures are obtained from the preparatory measurements which are performed before the actual localization procedure. These are the sensation threshold per electrode and the reported stimulus intensities and qualities.

Study description

Background summary

The body schema is the unconscious awareness of our body, which is fed by various sensory modalities. Various disorders have been hypothesized to be reflected in this awareness. When people report the location of a cutaneous stimulus they refer to their body schema, therefore studying the reported locations of stimuli on the skin may provide information about this schema. Although tactile localization has been studied repeatedly, many factors which may influence spatial perception of touch remain unidentified, which impedes

interpretation of the results. Localization data is known to have both systematic and stochastic errors when comparing it to the actual stimulus sites. The systematic component differs between subjects. It is at present unknown whether the systematic component is a trait of a subject or whether it changes when repeating the same measurement at another time. Also, the effect of stimulus strength and duration on the stochastic and systematic components is unkown. Another unknown is whether the spatial perception of touch and nociception are the same. Finally, the study of spatial perception would benefit from a critical evaluation about the statistical methods used for analyzing the data.

Study objective

In this study we address the influence of stimulus strength, modality and duration on reported locations of cutaneous stimuli. In addition, we assess the reproducibility of these reports and test whether we can improve the analysis of localizations by identifying clusters in this data. All stimuli will be applied using electric stimulation on the skin.

Study design

The study consists of 5 series of experiments which use electric stimuli of tactile afferents: 1. Reproducibility and clustering study consisting of a pilot phase (5 subjects, 2 experiments each) and final series (25 subjects, 2 experiments each). 2. Influence of stimulus strength on tactile localization (45 subjects). 3. Effect of stimulus frequency and duration on tactile localization with a pilot stage (5 subjects) and final stage (40 subjects). 4. The effect of gaze direction on clustering in tactile localization with a pilot stage (max 5 subjects) and final stage (15 subjects). Experiment series 5 also includes nociceptive electric stimuli and will compare the localization of tactile and nociceptive stimuli (15 subjects).

Study burden and risks

Each experiment will last approximately 1.5-2 hours depending on the experiment. The first hour consists of preparations; the remainder is taken up by the main experiment. In 4/5 experiments all stimuli feel as a dull tap. In the tactile/nociceptive comparison experiment half of the stimuli will feel as a light pinprick. There are no risks involved in participating in these experiments. The needle electrodes used in experiment series 5 can cause mild skin irritation which disappears within half an hour after removal of the electrodes. These electrodes are sterilizable.

Contacts

Public
Universiteit Twente

Postbus 217
7500 AE
NL
Scientific
Universiteit Twente

Postbus 217
7500 AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Aged 18-30 years
Right-handed

Exclusion criteria

Skin condition on the left lower arm
Excessive amount of hair on the lower arm

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2011
Enrollment:	155
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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: 29141
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35875.044.11
OMON	NL-OMON29141