QScale: A Visual Scale for Standardized Pain Sensitivity Measurements - An Explorative Study in Pain-free Subjects

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The primary objective is to explore the validity and reliability of the QScale during pain sensitivity measurements in pain-free subjects.

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

Summary

ID

NL-OMON46805

Source
ToetsingOnline

Brief title
QScale: A Visual Scale for Pain Sensitivity Measurements

Condition

- Other condition

Synonym
Chronic Pain

Health condition

Chronische pijn, centrale sensitisatie

Research involving
Human

Sponsors and support

Primary sponsor: Onderzoeksgroep Biomedical Signals and Systems (BSS), University of Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Pain, Cold Pressor Test, Electrocutaneous stimulation, Quantitative Sensory Testing

Outcome measures

Primary outcome

Pain sensitivity measurement [mA]

Secondary outcome

Participant characteristics:

- Age;

- Sex;

- BMI.

Study description

Background summary

An increased pain sensitivity plays a key role in the development and persistence of chronic pain. This pain sensitivity can be measured by performing electric Quantitative Sensory Testing (eQST); a technique widely used in clinical research, but not yet in clinical practice. The lack of structural application of pain sensitivity measurements clinical practice can be explained by, among other things, the variability in the measurement. This is mainly caused by (1) differences in the way researchers perform the pain sensitivity measurement and (2) differences in the way subjects interpret and perform the measurement related tasks. An eQST measurement can be conducted in various ways since it is not standardized when it comes to the instructions and equipment. Besides the fact that instructions can be given slightly different each time, the measurement outcome is also dependent on the participants* interpretation of the oral instruction. In a scientific study, this variability

can mainly be overcome by having one researcher conducting all measurements. In clinical practice however, there will be many different people performing the measurement, resulting in variability in the measurement that needs to be overcome.

At BSS, the QScale has been developed specifically for electrical skin stimulation on the basis of drawings of the perceived stimulation at different stimulus strengths. This has resulted in a scale in which participants can report both the quality as well as the intensity of the sensations by appointing one of the visualizations instead of an oral description (*annoying*, *painful*). This visual scale permits to link changes in sensation to the strength of the stimulus, without omitting a strong dependency on the oral instruction of the researcher or its interpretation by the subject. The next step in the development of the QScale is to explore the validity (cold pressor test) and reliability (one week test-retest) of the scale. Additionally, comparisons will be made between the oral instructions and the QScale (part A) and between two different electrodes while given visual instructions (part B).

Study objective

The primary objective is to explore the validity and reliability of the QScale during pain sensitivity measurements in pain-free subjects.

Study design

Mono-center, cross-sectional study.

Study burden and risks

Participants will be asked to come to the Human Physiology Lab of the BSS group at the University of Twente for two sessions, which will be scheduled one week apart from one another. The general outline of the study procedure of part A and part B is identical. Before the first pain sensitivity measurements are conducted, the participants will first be connected to the equipment and familiarized with the measurement. Shortly thereafter a cold pressor test is carried out, in which the participant has to immerse one hand into the water for a maximum of two minutes. As the cold pressor test is also a cardiovascular test, there are risks involved for participants with (un)known cardiovascular problems. The cold pressor test can be experienced as painful. Directly after this test another pain sensitivity measurement will be done. The exact same procedure will be repeated approximately one week after the first appointment. Participants are compensated for their participation and will obtain no direct personal benefit.

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

1) A signed, written informed consent;
2) Age between 18 and 40.

Exclusion criteria

1) Patient's refusal during the study;
2) Skin problems at the site of the eQST measurement;
3) Language problems;
4) Diabetes;
5) Implanted stimulation device;
6) Pregnancy;

7) Pain complaints at the time of the experiment;
8) A medical history of chronic pain;
9) Unable to undergo eQST measurement.
10) Visual impairment (visual aid is allowed)
11) Cardiac arrhythmias
12) Heart valve defects
13) Heart muscle diseases
14) Open wound on the hand that will be immersed

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL64831.044.18