Enhancing the perception of pain using virtual reality: a pilot study

Published: 13-01-2021
Last updated: 15-05-2024

To assess the effect of Virtual Reality mediated visual and auditory lowering of electrical pain detection and tolerance thresholds

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

Summary

ID

NL-OMON50817

Source
ToetsingOnline

Brief title
VR-PainCart pilot

Condition

- Other condition

Synonym
Pain

Health condition

Pijn

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Contact Research Organisation

Intervention

Keyword: Pain perception, Pain tests, Paincart, Virtual Reality

Outcome measures

Primary outcome

* Electrical Stair: PDT (mA), PTT (mA), Area Under the VAS pain Curve (AUC) (mA*mm), and post-test VAS (mm).

* Electrical Stair (including virtual reality simulation without enhancement): PDT (mA), PTT (mA), Area Under the VAS pain Curve (AUC) (mA*mm), and post-test VAS (mm).

* Electrical Stair (including virtual reality simulation with enhancement): PDT (mA), PTT (mA), Area Under the VAS pain Curve (AUC) (mA*mm), and post-test VAS (mm).

Secondary outcome

Questionnaires on personal characteristics, stress, anxiety and the relationship with electrial pain detection and tolerance thresholds.

Study description

Background summary

The VR simulation is added to a nociceptive pain measurement, the electrical stair test from the PainCart®. This test has been proven sensitive in clinical trials in detecting the pharmacodynamic effects of multiple analgesics. The measurements are performed in a quiet room, each subject is assigned to a separate room to minimize any distraction. The electrical stair test uses two electrodes on the tibial bone to assess cutaneous electrical pain. Single electrical stimuli are provided with a duration of 0.2 ms, increasing from 0 mA to a maximum of 50 mA in steps of 0.5 mA. The maximum duration of the test is 120 seconds.

In this study a VR simulation is introduced aimed at enhancing the pain perception. Two VR environments (VR-neutral and VR+) are developed, both simulating a room with a PainCart setup. The environments include an avatar of the subject, the chair, and equipment of the electrical stair pain test, including electrodes on the leg and a VAS slider. The VR-neutral simulation has no additional aspects; it shows a similar setup as the test without VR. During the VR+ simulation, a wound appears simultaneously with the intensity of the pain test. The visual enhancement is supported with accompanying sounds of electrical sparks. The simulation of the wounds starts and stops simultaneously with the stimulation, both controlled by the subject. After 40 seconds of simulation the intensity of the audio-visual stimulation no longer increases. The VAS slider is visible in the simulation and used to record the Pain Detection Threshold (PDT) and Pain Tolerance Threshold (PTT).

Study objective

To assess the effect of Virtual Reality mediated visual and auditory lowering of electrical pain detection and tolerance thresholds

Study design

A maximum of 24 subjects will experience in set order all three setups: PainCart without VR (*normal*), VR-neutral and VR+.

Study burden and risks

not applicable

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 male subjects aged 18-40 years, inclusive; healthy is defined as no clinically relevant abnormalities identified.
* Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

* History of symptoms or any significant including (but not limited to) neurological or psychiatric disorder., if assessed by the Principal Investigator as possibly interfering with the study objectives.
* High pain tolerance (80% or higher value for the pain tolerance of the electrical stair test)
* Presence of Virtual Reality Sickness (simulator sickness).
* Smoker of more than 5 cigarettes per day prior to screening or who use tobacco products equivalent to more than 5 cigarettes per day.
* Consume, on average, > 8 units/day of (methyl)-xanthines (e.g. coffee, tea, cola, chocolate) or not able to refrain from use during each stay at the CHDR clinic.
* Have a urine drug screen detecting illicit drug of abuse (morphine, benzodiazepines, cocaine, amphetamine, THC, methamphetamines, MDMA) or a positive alcohol breath test;

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):	15-03-2021
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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: 28178
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL75934.056.20
OMON	NL-OMON28178