

More or Less Pain with Muse

Published: 18-08-2016

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To test the benefit of favorite music opposite to non favorite music on pain thresholds and pain modulation in healthy volunteers.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42852

Source

ToetsingOnline

Brief title

LLS-Pain

Condition

- Other condition

Synonym

Pain and painmodulation

Health condition

geen aandoeningen: gezonde vrijwilligers, pijn en pijnverwerking

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Music, Pain, QST

Outcome measures

Primary outcome

Main study parameters/endpoints: Pressure tolerance will be measured via algometry (Wagner force, USA) on five places on the dorsal side of the non dominant forearm and expressed in Newton (N). Electrical pain tolerance thresholds are assessed on two places on the dorsal side of the nondominant forearm and expressed in milliAmpere (mA). Duration in the icewaterbucket (IWB) with the dominant hand will be recorded in seconds (s) with a maximum of three minutes (180s). After the IWB test the pressure tolerance or the electrical pain tolerance thresholds will be recorded again. Conditioned pain modulation (CPM) will be calculated by use of the formula $((\text{pressure post-pressure pre})/\text{pressure pre}) \times 100$ expressing the precentage of painmodulation.

Secondary outcome

Secondary endpoints are the sensitivity for pain (assessed with the Pain Sensitivity Questionnaire (PSQ), amount and quality of sleep (Pittsburg Sleep Quality Index) and the Quality of Life (assessed with the EQ-5D).In addition, the subject will be asked after the completion of the investigation how burdensome they found the measurements.

Study description

Background summary

Pain is defined as *an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage*. The prevalence of pain in the Netherlands is around 18% (e.g. 3 million people). There is evidence that music can be of use to reduce pain during the postoperative period. In healthy volunteers it is shown that music reduces the pain response. However, it is not studied if favorite music has more benefit in tolerating pain than non-favorite music .

Study objective

To test the benefit of favorite music opposite to non favorite music on pain thresholds and pain modulation in healthy volunteers.

Study design

Consecutive, observational study with a cross-over design.

Study burden and risks

After signing inform consent and the check of the in- and exclusion criteria the volunteers have to fill in the three questionnaires. This will take about 15 minutes. After filing in the questionnaires the pain measurements will be performed which will take at max 20 minutes. The whole measurement series will take approximately 30 minutes.

In our experience, there is (almost) no risk to participate in this study.

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

18 years or older and they have knowledge of the Dutch language.

Exclusion criteria

the use of painkillers in the last 12 hours,
use of anti-depressants,
pain in arm neck or shoulder (one or both sides),
heart problems,
neurological disorders,
psychiatric disorders,
wounds on hands or forearm,
M. Raynaud, pregnancy,
alcohol percentage of > 220 UGL.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Will not start
Enrollment: 420
Type: Anticipated

Ethics review

Not approved
Date: 18-08-2016
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL58775.091.16