Habituation to pain in healthy subjects: An fMRI-EEG study using a multilevel approach

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

Summary

ID

NL-OMON49084

Source
ToetsingOnline

Brief title
Habituation to pain: An fMRI-EEG study

Condition

- Other condition

Synonym
nvt

Health condition

nvt

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: EEG, fMRI, Habituation, Pain

Outcome measures

Primary outcome

The main study parameter is Blood Oxygen Level Dependent (BOLD) activity,

measured using fMRI. BOLD activity of areas over time will be modeled.

Secondary outcome

- Brain activity measured with EEG

- Pain ratings during the habituation protocol. After each painful stimulus,

the subject will rate the pain on a VAS scale.

- Pain ratings during the intensity protocol. After each painful stimulus, the

subject will rate the pain on a VAS scale.

Study description

Background summary

Habituation to pain is a phenomenon that generally occurs after repeated painful stimulation. However, its neural mechanisms are still largely unknown. It is important to investigate the healthy process of habituation to pain before further studies can investigate chronic pain patients. Research has shown that individuals with chronic pain may have impaired habituation to pain, which may underlie the chronic pain condition. Therefore, this study will serve as a first step into investigating the neural mechanism of habituation to pain using functional magnetic resonance (fMRI) combined with electroencephalography (EEG).

Study objective

The current study investigates which brain areas are related to habituation of pain (using fMRI) and enables a direct coupling with concurrent EEG. We will test the hypothesis that activation of areas in the brain show changes over time as correlate of the psychophysical habituation process.

Study design

Single session experimental study with repetitive painful stimulation while measuring fMRI and EEG responses. Questionnaire measures will be obtained before and after the experiment.

Study burden and risks

From this experiment, brain regions will be identified which participate in the mechanism of habituation to pain. With these insights, habituation to pain in healthy participants can be compared with chronic pain patients in a later study. This will give insights into the mechanisms of habituation to pain and its disruption in chronic pain, and may serve as a starting point future real-time neurofeedback treatment of chronic pain complaints. There are no direct benefits for the subjects in participation in the experiment besides a monetary compensation or course credits.

Habituation and intensity protocol
Participants will receive up to 200 very brief (10 milliseconds) painful electrical intracutaneous stimuli during an fMRI-EEG protocol. A similar habituation and intensity protocol will be used as in earlier research in EEG which has been approved by this METC board (ABR 40284). In EEG research, subjects generally evaluated the burden of the experiment as low. The painful stimulation will be close to the pain threshold and will thus not cause extreme pain. The pain threshold will be determined before the scanning procedure. This will be in a controlled setting where subjects can stop the experiment at any time.

MRI-EEG
All MRI guidelines will be strictly followed ensuring a safe procedure. No long-term negative health effects of 3T MRI have been reported. Participants will be routinely screened for any MRI contraindications (e.g., pacemaker, metal implants). Participants can only take part if they agree that incidental findings will be evaluated by a qualified radiologists who will inform their general practitioner to invite them for follow-up tests if needed. Participants are asked to lie still while measuring BOLD fMRI and EEG. There will be short breaks between the scans to allow participants to relax, and the participant can communicate with the researcher between scans. During the scans the participant has the possibility to stop the experiment by pressing an alarm bell. The scanning process results in loud noises for which the participants receive hearing protection in the form of earplugs. We will use standard

procedures for fMRI-EEG, thus patient discomfort will not be higher than in other similar studies performed at Scannexus.

Questionnaires
Questionnaires related to anxiety, depression and pain are to be completed.

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

- Age 18-65

Exclusion criteria

- MRI contraindications (pacemaker, claustrophobia, vein clip, pregnancy, etc.)
- Chronic (> 3 months) or recurrent pain in the last three months or other chronic diseases that may intervene with chronic pain, such as diabetes
- Current use of psychotropic medication
- Reported psychiatric or neurological disorders
- Reported regular use of so-called recreational drugs (e.g., cannabis)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2021
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	09-12-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL74667.068.20