Emotional learning and pain in fibromyalgia

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37875

Source
ToetsingOnline

Brief title
Directed forgetting and pain

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
fibromyalgia; muscle, joint or bone pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: emotional, fibromyalgia, memory, pain

Outcome measures

Primary outcome

The primary study parameter is the directed forgetting effect (less number of items recalled after the *forget* cue compared to those after the *remember* cue) for the neutral, positive, negative and pain-related words separately in patients with fibromyalgia compared to healthy controls.

Secondary outcome

Secondary parameters are associations between directed forgetting and: 1) CPM efficacy, and 2) numerical ratings of arousal, valence or personal-relevance of each word.

Study description

Background summary

Directed forgetting reflects the capacity to intentionally forget irrelevant material but at the same time to remember relevant material. Intentional forgetting has been shown to depend on active inhibition mediated by frontal cortical areas. Deficits in directed forgetting have been found in a number of psychiatric disorders associated with reduced frontally-mediated inhibitory function. Moreover, reduced inhibitory capacity may be particularly reflected in processing emotional negative material relevant to the disease. No studies have assessed performance on the directed forgetting task in patients with fibromyalgia before. It is to be expected that patients with fibromyalgia will have poor directed forgetting as well since frontal inhibitory functions seem to be deficient in this syndrome. Furthermore, it is hypothesized that patients with fibromyalgia will have a bias to remember negative rather than positive or neutral information, which will be most pronounced for pain-related material. This focus on negative information may interfere with daily activities.

Study objective

The main aim of this study is to investigate directed forgetting of emotional versus neutral words in patients with fibromyalgia compared to healthy controls. Secondary objectives are to examine potential associations between directed forgetting and 1) efficiency of pain control as examined by conditioned pain modulation (CPM), and 2) ratings of arousal, valence, and personal-relatedness of the words to determine which aspect mediates the directed forgetting effect most.

Study design

This is a monocenter observational case-control study. Participants will be screened for study participation and informed consent will be signed. The experiment involves 9 phases: 1) welcome and filling out baseline questionnaires, 2) pain testing, 3) filling out some questionnaires, 4) encoding phase of the directed forgetting task in which all participants are presented with 12 neutral, 12 positive, 12 negative, and 12 pain-related words and are given instructions to remember or forget each word after it is presented, 5) complete a Dutch reading test as a distraction test, 6) free recall of words, 7) a recognition test comprised of 96 words (48 old and 48 new words), 8) numerical ratings of the 48 experimental words, and 9) filling out remaining questionnaires.

Study burden and risks

Participants will complete one visit of approximately 1* hours at the Pain Clinic of the UMC Utrecht. Risks associated with study participation are minimal. The equipment used to induce pain is safe and commonly used in clinical practice. This study will test for the first time whether patients with fibromyalgia have a dysfunction in the ability to forget disturbing information and whether this is associated with endogenous pain modulation. There will be no direct benefit to participants. Participants will be able to terminate study participation at any time, for any reason.

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

Fibromyalgia patients will have a diagnosis of primary fibromyalgia according to the American College of Rheumatology classification criteria (Wolfe et al., 1990).
Control participants will be age-matched to fibromyalgia patients and will be healthy and pain-free as determined by a general health questionnaire.
All subjects will be adults 18 years or older
Speak Dutch fluently

Exclusion criteria

The inability to give informed consent
A serious neurological or psychiatric condition besides fibromyalgia
Current participation in another research protocol that could interfere or influence the outcome measures of the present study
Current use of sedative psychotropic drugs such as benzodiazepines, barbiturates, tricyclic antidepressants, anticonvulsants, sedatives and classical antihistaminics, except amitriptyline in low dosages (up to 50 mg/day).
When there is any serious injury to the body regions to be tested as reported by the research participant.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-12-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL40119.041.12