The effects of emotions on symptoms in fibromyalgia and the modulating role of physiology and emotion regulation. An experimental study.

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

Summary

ID

NL-OMON29834

Source
ToetsingOnline

Brief title
Effects of emotions on symptoms in fibromyalgia

Condition

- Musculoskeletal and connective tissue disorders NEC

Synonym
chronic pain syndrome, fibromyalgia

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht

Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: emotion regulation, emotions, fibromyalgia, symptoms

Outcome measures

Primary outcome

The primary outcome measures are change in pain and fatigue and change in sensory threshold, pain threshold, and pain tolerance.

Secondary outcome

Secondary outcome measures are emotions (manipulation check of emotion induction), the (para)sympathetic measures 'pre-ejection period', 'total peripheral resistance' and 'respiratory sinus arrythmia', and emotion regulation styles (suppression, alexithymia, anger-in, anger-out, expression, and reappraisal).

Study description

Background summary

Fibromyalgia is a prevalent condition that is accompanied by chronic widespread pain and secondary symptoms such as fatigue. The condition is medically unexplained and there is still much indistinctness regarding the maintaining and intensifying factors of the symptoms of fibromyalgia. Emotions may be one such factor. Outer-directed emotions such as anger may especially intensify pain, while inner-directed emotions such as sadness may decrease pain and increase fatigue. The impact of emotions on symptoms may depend on physiological activation . Anger is accompanied by an increase in noradrenaline, which leads to an increase in pain in fibromyalgia. It is unclear whether emotions lead to a similar physiological activation in patients with fibromyalgia and controls. Individual differences in how people handle their emotions in daily life (emotion regulation) may also influence the association between emotions and symptoms. Like emotion are emotion regulation styles related to physiological activity and symptom report. Suppression of

emotions, alexithymia, and anger-in and anger-out may strengthen the association between emotions and symptoms, while the relation may be less strong or absent in people who generally express or reappraise their emotions.

Study objective

The study aims to examine whether the emotions anger and sadness influence pain and fatigue in female patients with fibromyalgia and a control group from the general population and whether physiological reactivity and individual differences in emotion regulation impact on these associations.
The study aims to answer the following research questions:
a) Does induced anger lead to heightened pain report and a reduced pain threshold and pain tolerance in female patients with fibromyalgia and to reduced pain report and a heightened pain threshold and pain tolerance in female controls?
b) Does induced sadness lead to larger increases in fatigue in female patients with fibromyalgia than in female controls?
c) Do induced anger and sadness lead to increased sympathetic and parasympathetic activity and does this physiological activiation differ between patients and controls?
d) Can change in symptom report be predicted from sympathetic and parasympathetic reactivity?
e) Do individual differences in emotion regulation influence the association between emotions and symptoms?

Study design

The study has a quasi-experimenal crossover design and takes 2 hours per participant. Traveling expenses are paid. The experiment consists of a baseline period and three counterbalanced conditions (recall of a neutral, angry, and sad situation). During all conditions, noninvasive continuous physiological assessments are performed of heart rate, blood pressure, and impedance, emotions and symptoms are reported, and pain threshold and pain tolerance will be determined by means of a pain measure (increasing electrical current).

Intervention

Research participants will be asked to recall a neutral, angry, and sad event from their recent past and repeated pain measurements will be conducted to determine sensory threshold, pain threshold, and pain tolerance.

Study burden and risks

The study is considered to bring no risks for the participants. Negative emotions will be induced, but this concerns self-selected situations from the participant. The determination of pain threshold and pain tolerance has been

applied in different studies in chronic pain patients without problems.
Furthermore, participants can stop their participation at any moment during the experiment and they will be debriefed after the experiment.

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

Patient group: female gender, primary or secondary fibromyalgia diagnosis by rheumatologist according to ACR-classification criteria (Wolfe et al., 1990), indicated at questionnaire study to be interested in information about another study.
Control group: female gender, matched on age, educational level, and region; indicated at questionnaire study to be interested in information about another study

Exclusion criteria

Patient group: male gender, no official diagnosis by rheumatologist according to ACR-classification criteria, indicated at questionnaire study not being interested in information on another study.
Control group: male gender, indicated at questionnaire study not being interested in information on another study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2006
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO

Date:	24-10-2006
Application type:	First submission
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	NL12779.041.06