The role of nocebo effects in identifying patients at risk for pain progression in fibromyalgia

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This research project examines whether: -susceptibility to nocebo effects predicts future pain progression in patients with chronic widespread pain, i.e. fibromyalgia (part 1), - nocebo-related learning processes differ between patients and healthy…

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

Summary

ID

NL-OMON55629

Source
ToetsingOnline

Brief title
Nocebo effects in fibromyalgia pain progression

Condition

- Other condition

Synonym
chronic widespread pain, Fibromyalgia

Health condition

Fibromyalgie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO Vici Grant

Intervention

Keyword: Conditioning, Fibromyalgia, Nocebo effects, Prospective predictive study

Outcome measures

Primary outcome

In part 1, individual susceptibility to nocebo conditioning (pain levels in conditioned trials versus control trials) will be studied as predictor of the main follow-up parameter, i.e., changes in self-reported clinical pain from baseline to follow-up. In part 2, susceptibility to nocebo conditioning will be examined and compared between patients and healthy controls. In part 3, within-group stability in susceptibility to nocebo conditioning will be examined across 1 month.

Secondary outcome

Secondary study parameter of part 1 include individual differences in susceptibility to extinction learning as secondary predictor of pain progression. We will also explore the relation of these predictors, i.e. nocebo conditioning and extinction, to secondary follow-up parameters of fibromyalgia progression and daily symptom fluctuations. In part 2, extinction learning will be examined and compared between patients and healthy controls, and in part 3 within-group stability in extinction learning, and between-group comparisons of stability in nocebo-related learning processes (conditioning and extinction) will be examined across 1 month.

Study description

Background summary

Somatic symptoms often become chronic or progress due to sensitization processes. Nocebo effects, i.e. adverse treatment outcomes not attributable to active treatment components, could play a role in symptom progression.

Study objective

This research project examines whether: -susceptibility to nocebo effects predicts future pain progression in patients with chronic widespread pain, i.e. fibromyalgia (part 1), - nocebo-related learning processes differ between patients and healthy controls (part 2), and - nocebo-related learning processes are stable over time (part 3).

Study design

The current proposal consists of three interrelated studies with overlapping procedures. Part 1 is a prospective predictive study, in which individual susceptibility to nocebo conditioning with pressure pain stimuli in the laboratory is examined as predictor of pain progression in patients with fibromyalgia. Pain progression will be assessed after one year by questionnaires and experience sampling method (ESM; 21 days). For part 2, the nocebo-related learning processes (conditioning and extinction) of a subgroup of patients will be examined and compared to that of matched healthy controls at baseline. For part 3, in the same subgroups as for part 2, the stability of nocebo-related learning processes between baseline and 1-month follow-up measures will be examined.

Intervention

not applicable

Study burden and risks

Multiple studies on patients with fibromyalgia have used pressure pain stimuli and no risks are associated with applying pressure to the thumbnail. Administering pressure to the thumbnail can lead to possible discomfort (e.g., slight numbness, discoloration), however, this is temporary and dissapears on its own. Pressure intensities will be calibrated to individual pain sensitivity levels. Since we will use a nocebo conditioning procedure, patients will experience possible increases of pain in the laboratory session; however, with the combination of extinction procedure and a recovery period, including e.g., a relaxation task, following immediately, this pain increase will be

short-lived. In total,103 patients and 34 healthy controls, matched to a subgroup of 34 patients, will complete one laboratory session of approximately 2,5 hours and 2 hours, respectively. The same subgroup of 34 patients and 34 matched healthy controls will participate in a second laboratory session of 2 hours, one month after the first. All participants will fill out online questionnaires and only patients will fill out ESM diary measures at baseline and one-year follow-up with only the burden of time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

18-65 years old female
Good understanding of written and spoken Dutch
Additionally for Patients:

Diagnosis of fibromyalgia (provided by a rheumatologist)

Exclusion criteria

For patients:
Physical conditions other than fibromyalgia explaining pain symptoms
Psychiatric conditions not related to fibromyalgia symptoms (e.g., schizophrenia)
Use of painkillers different than usual dose of treatment on the day of experimentation*
For healthy controls:
Chronic pain complaints (>=3 months) in the past or present or a diagnosis of fibromyalgia
Severe physical or psychiatric co-morbidities that may interfere with the study protocol (e.g., DSM-V diagnosis)
Current pain (>=3/10 on the Numeric Rating Scale) on the day of experimentation*
Use of painkillers within 24 hours before the day of experimentation*
Common criteria for both groups:
Pregnancy or lactation
Color blindness
Injuries/open wounds on the non-dominant hand or arm*
Carrying a pacemaker/implanted pumps
Having implanted metals on the non-dominant hand or arm
Refusal to remove artificial nails, nail polish, or any other substance covering the thumbnail*
Unsuccessful pressure calibration, i.e., not being able to stably distinguish relevant pressure intensities
*Exclusion criteria marked with a * pertain to the day of testing. In case one or more of these criteria are met at the day of testing, the appointment will be rescheduled if possible.

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):	10-01-2020
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Pressure Pain Device
Registration:	No

Ethics review

Approved WMO

Date:	13-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	05-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	24-12-2020

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-12-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL67541.058.18