Counterconditioning as treatment for pain

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27907

Source
Nationaal Trial Register

Brief title
TBA

Health condition

The study is conducted in a sample of patients with fibromyalgia

Sponsors and support

Primary sponsor: Leiden University
Source(s) of monetary or material Support: Netherlands Organization for Scientific Research (NWO) - Vici grant

Intervention

Outcome measures

Primary outcome

The feasibility of the intervention (e.g., satisfaction of participants, drop-out rate). Descriptive statistics (means, standard deviations, etc.) of relevant variables will be calculated.

Secondary outcome

The comparison of the nocebo effects on pressure pain after counterconditioning and sham counterconditioning. The effect size and confidence interval of the difference in pain from pre- to post-treatment and at 3- and 6-months follow-up will be calculated for the intervention group and the control group, and then compared.

Study description

Background summary

Treatment opportunities for persistent physical symptoms, such as chronic pain, are currently limited. It is suggested that nocebo effects (i.e. adverse outcomes not attributable to an active treatment, putatively mediated by negative expectations) can negatively influence symptom progression. With procedures of counterconditioning, combined with verbal suggestions, previously learned associations (causing negative expectations) between different stimuli can be reversed. Therefore, counterconditioning could provide an innovative method for reducing physical symptoms. In the current study, the feasibility of using counterconditioning methods as a novel treatment method for reducing pain symptoms will be examined in a clinical population of fibromyalgia patients.

Study objective

The primary objective of the current pilot study is to investigate the feasibility of a 6-week counterconditioning treatment method aimed to reduce pain in patients with fibromyalgia. This will be assessed by looking at the drop-out rate; by measuring participant's satisfaction with the intervention; by examining what, according to the participants, is causing the possible increase and reduction of experimentally evoked pressure pain in the test phase of (counter)conditioning (e.g., the TENS device, the placebo or nocebo effect); by examining the amount of experimentally-evoked pressure pain reported during the test phase of counterconditioning, whether this reduces over time, as well as the speed of this reduction.

Additionally, we will explore whether an induced nocebo effect in the intervention group can be successfully reduced (or even reversed) by comparing the change in the conditioned nocebo effect from the test phase of conditioning (session 1) to the counterconditioned nocebo effect from the test phase of counterconditioning (session 6 + 3- and 6-month follow-up) in the intervention group and the control group. We will also explore whether these effects generalize to clinical pain symptoms. Last, we will explore whether there is a relationship between individual characteristics, such as pain catastrophizing and participants' expectations about the intervention, and the changes due to counterconditioning.

Study design

9 lab sessions (intake session, 6-week intervention, 3-and 6-month follow-up). Each lab

session lasts approximately 45 minutes, with the exception of the intake session and the first session, which last 30 minutes and two hours, respectively. The homework exercises will take approximately 10 minutes per day.

Intervention

Counterconditioning methods will be used for desensitization of pain symptoms in the intervention group. Participants in the intervention group will participate in a conditioning procedure once during session 1, in order to ensure that a specific association with the primary symptom of pain is established that can be counterconditioned.

During conditioning and counterconditioning, the learning phase consists of 20 pressure stimuli, which are either moderately painful (nocebo conditioning) or non-painful (counterconditioning) during the experimental trials and slightly painful during control trials. In the control group, all stimuli will be given in a randomized order. The test phase for all groups consists of 6 trials with slightly painful pressure stimuli presented in both experimental and control trials.
ln sessions 2-6, only the (sham) counterconditioning procedure will be repeated, meaning only non-painful and slightly painful stimuli will be used.

Participants in both groups are asked to rate their levels of pain after every pressure stimulus on an NRS, which will later be used to calculate the individual reduction of the nocebo effect.

Participants will be given homework exercises to strengthen the intervention and promote generalization of symptom desensitization to everyday life.

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Eligibility criteria

Inclusion criteria

Female volunteers (≥ 18 years), with a diagnosis of fibromyalgia (FM) provided by a general practitioner or medical specialist, with current pain complaints as a result of FM, and with a good understanding of written and spoken Dutch.

Exclusion criteria

Physical conditions other than FM explaining pain symptoms, severe psychiatric comorbidities that are not related to the fibromyalgia symptoms (e.g., schizophrenia), pregnancy or lactation, refusal to remove artificial nails, nail polish, or any other substance covering the thumbnails, having metal-containing implants in the non-dominant arm (including non-removable piercings), carrying a pacemaker or implanted pumps, injuries/open wounds on the non-dominant arm.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2019
Enrollment:	36
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Coded research data will be made publicly available in an online data repository after

publication of the research findings.

Ethics review

Positive opinion
Date: 28-11-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55456
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8189
CCMO	NL66812.058.18
OMON	NL-OMON55456

Study results