Counterconditioning as treatment for chronic pain symptoms: a pilot study

Published: 11-10-2019
Last updated: 15-05-2024

The primary objective is to investigate the feasibility of using counterconditioning as a novel treatment method aimed to reduce pain in female fibromyalgia patients.

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

Summary

ID

NL-OMON55456

Source
ToetsingOnline

Brief title
Counterconditioning as treatment for pain

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

Intervention

Keyword: Counterconditioning, Fibromyalgia, Nocebo effects, Pilot Study

Outcome measures

Primary outcome

The main study parameter will be the feasibility of the counterconditioning intervention. This will be done by looking at the drop-out rate, by measuring participant*s satisfaction with the intervention; by examing 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 exploring 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.

Secondary outcome

Not applicable.

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 intervention for reducing pain

symptoms will be examined in a clinical population of fibromyalgia patients.

Study objective

The primary objective is to investigate the feasibility of using counterconditioning as a novel treatment method aimed to reduce pain in female fibromyalgia patients.

Study design

A randomized, controlled, between-within-subjects study design will be used. Participants will be randomly assigned to one of two conditions: 1) a 6-week counterconditioning intervention, or 2) a 6-week control condition using sham conditioning (attention control). Feasability of the intervention (e.g., satistfaction of participants, drop-out rate) will be investigated. Additionally, experimentally-evoked pressure pain and clinical outcome measures will be explored during weekly lab sessions for 6 weeks and again at a 3- and 6-month follow up.

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, in order to ensure that a specific association with the primary symptom of pain can be counterconditioned. Participants will be given homework exercises to strengthen the intervention and promote generalization of symptom desensitization to everyday life.

Study burden and risks

Multiple studies have used pressure pain in fibromyalgia patients and no risks are associated with using pressure pain devices. Since we will be using a conditioning procedure in the first session, pain might show a temporary increase, but because counterconditioning procedures will follow immediately, this increase will be very short-lived. This study might show indications that this intervention could be effective in this difficult-to-treat patient group.

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

Diagnosis of fibromyalgia (provided by GP or medical specialist)
Current pain symptoms because of fibromyalgia
>= 18 years old female
Good understanding of written and spoken Dutch

Exclusion criteria

Physical conditions other than fibromyalgia explaining pain symptoms;
Psychiatric conditions 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 thumbnail;
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
Not being able to clearly distinguish between three different pressure pain

intensities during testing

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2020
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	11-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-05-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-12-2021
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

ID: 27907
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66812.058.18
OMON	NL-OMON27907

Study results

Date completed:	17-10-2022
Actual enrolment:	17