An online self-management intervention for patients with fibromyalgia -- a randomised controlled trial

Published: 30-11-2016
Last updated: 15-05-2024

To study the effectiveness of the online self-management intervention in patients with fibromyalgia.

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

Summary

ID

NL-OMON55570

Source
ToetsingOnline

Brief title
Online self-management in fibromyalgia

Condition

- Other condition

Synonym
fibromyalgia (FM), fibromyalgia syndrome (FMS)

Health condition

fibromyalgie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Subsidie vanuit Innovatiefonds Zorgverzekeraars

Intervention

Keyword: cognitive-behavioral therapy, fibromyalgia, online intervention, self-management

Outcome measures

Primary outcome

The primary outcome will be pain coping, measured with a VAS score.

Secondary outcome

As secondary outcomes, a number of other psychological and physical outcome measures will be assessed (e.g., HR-QoL, well-being, pain impact on daily life, pain cognitions), as well as quality of the therapeutic relationship and cost-effectiveness of the intervention.

Study description

Background summary

Fibromyalgia has a high clinical burden, as reflected by considerable pain, decreased strength and mobility, physical disability, and an often decreased health-related quality of life (HR-QoL). Self-management factors related to physical and psychosocial adjustment, such as patients* perceptions about their disease and coping, play an important role in HR-QoL and functional ability in patients with chronic diseases, such as fibromyalgia. Improving capacities of patients in managing a chronic condition is increasingly recognized as important in the treatment of (somatic) conditions and becomes more common in clinical practice and research. In this study, the effect of an online self-management intervention focusing on coping skills related to chronic pain in comparison to a waitlist control condition is studied.

Study objective

To study the effectiveness of the online self-management intervention in patients with fibromyalgia.

Study design

An RCT will be performed, in which 35 participants will be randomized to the online self-management intervention and 35 participants to a waitlist control group. Baseline, post-intervention, 6-week, and three-month follow-up questionnaires will be used to measure primary and secondary outcomes.

Intervention

The intervention is based on cognitive-behavioral methods. It starts off with a face-to-face introduction consultation in which personal goals for the intervention are set. Subsequently, the tailored self-management intervention will be offered via an online program. The intervention consists of six modules containing pain education, practical assignments, relaxation training, and registrations. The first and last modules are an introductory and closure module; in between are four modules aimed at learning how to cope with the consequences of a chronic condition in daily life. The modules focus on (1) activity, (2) mood, (3) thoughts, and (4) the social environment. At least once a week, participants receive feedback on the assignments and motivational support from a psychologist, by means of text messages in a secured mail box in the online program. After finishing the online program, patients will be approached by their treating psychologist for two booster sessions via telephone. In these booster sessions it will be evaluated how the patient further attained his/her pre-set goals for the intervention. Strategies to strenghten the achieved results will be discussed. The booster sessions will take place 1 month and 2,5 months after finishing the online program.

Study burden and risks

In the waitlist control condition, patients will receive the intervention after the intervention ends in the intervention group (after 6 months). In the intervention group patients will be offered an internet-based self-management intervention, which potentially improves their pain coping and other psychological and physical outcomes. No risk is involved with participation in this study. The only burden for participants is investment of time.

Contacts

Public
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL
Scientific
Universiteit Leiden

Wassenaarseweg 52
Leiden 2333 AK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosed with fibromyalgia, as previously confirmed by their treating GP or a medical specialist
- Pain complaints with a minimal duration of 3 months
- Minimum age of 18 years
- Fluent in Dutch language
- Able to give informed consent
- Own a computer with internet access

Exclusion criteria

- Difficulties in (written) communication (e.g., due to analphabetism)
- Severe physical and psychiatric comorbidities that interfere with the study protocol, such as psychosis, addiction, suicidal ideation
- On-going psychological treatment elsewhere
- Participation in other clinical trials
- Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2017
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-01-2019
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	22-01-2021
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: 28775
Source: NTR
Title:

In other registers

Register	ID
Other	6267
CCMO	NL58130.058.16
OMON	NL-OMON28775

Study results

Date completed:	08-11-2021
Actual enrolment:	70