Online self-management in fibromyalgia

No registrations found.

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

Summary

ID

NL-OMON28775

Source
NTR

Health condition

fibromyalgia, fibromyalgie, online cognitive-behavioral therapy, online CBT, online cognitieve gedragstherapie, online CGT, selfmanagement, zelfmanagement, chronic pain, chronische pijn

Sponsors and support

Primary sponsor: Leiden University
Faculty of Social and Behavioural Sciences
Institute of Psychology
Health, Medical and Neuropsychology unit
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

The primary effect will be determined by comparing the VAS pain coping scores after the intervention between the waitlist control group and intervention group, corrected for baseline VAS pain coping scores.

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

Primary and secondary endpoints will be measured at baseline, after 3 months, 4,5 months and 6 months.

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.

Contacts

Public
LUMC
PO Box 9555
A.W.M. Evers
Leiden 2300 RB
The Netherlands
+31 (0)71 527 3627
Scientific
LUMC
PO Box 9555
A.W.M. Evers
Leiden 2300 RB
The Netherlands
+31 (0)71 527 3627

Eligibility criteria

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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-07-2017
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55570
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6128
NTR-old	NTR6267
CCMO	NL58130.058.16
OMON	NL-OMON55570

Study results