Online self-management in hand osteoarthritis

No registrations found.

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

Summary

ID

NL-OMON27109

Source
NTR

Health condition

hand osteoarthritis, rheumatism, online cognitive-behavioral therapy, online CBT, iCBT, self-management, chronic pain,
handartrose, online cognitieve gedragstherapie, online CGT, eCGT, ehealth, e-health, zelfmanagement, zelfmanagementinterventie, chronische pijn, reuma

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: Leiden University Medical Center, Leiden, the Netherlands; Programma Zorgvernieuwing

Intervention

Outcome measures

Primary outcome

The primary endpoint is the difference in change from baseline on VAS pain coping between

patients in the intervention and control condition after the intervention and at 6 weeks and 3 months follow-up.

Secondary outcome

Secondary endpoints are the differences between patients in the intervention and control condition on several other psychological and physical outcome measures, measured at baseline, after the intervention and at 6 weeks and 3 months follow-up.

Endpoints, measured with validated questionnaires:

 hand pain and well-being by visual analogue scales

 physical and mental HR-QoL by the RAND SF-36 and EQ-5D-5L

 pain and disability by AUSCAN subscales

 pain interference in daily functioning and pain severity by the Multidimensional Pain Inventory (MPI)

 illness cognitions by the Illness Cognition Questionnaire (ICQ)

 coping strategies by the Pain Coping Inventory (PCI)

 illness perception by the Illness Perception Questionnaire (IPQ)

Also, cost-effectiveness of the intervention will be measured, by assessing productivity loss and health care use of participants (using iPCQ and iMCQ).

Study description

Background summary

Hand osteoarthritis 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 OA. 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 care as usual is studied.

Study objective

Objectives: to study the effectiveness of the online self-management intervention in patients with hand OA and to explore the possibilities to implement the intervention in clinical practice after the study period.

Study design

Primary and secondary outcomes are measured at baseline, after 3 months, after 4,5 months (follow-up) and after 6 months (follow-up).

Intervention

An RCT will be performed, in which 35 participants will be randomized to either care as usual (hand OA care path, including consultation with the rheumatologist and a 1,5 hour consultation with a clinical nurse or occupational therapist) and 35 participants to care as usual plus the online self-management intervention. The intervention is based on cognitive-behavioral methods. It starts off with a face-to-face introduction consultation. 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 strengthen 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria (these are all to be checked by the doctor/research nurse at the consultation):

- Diagnosed with hand OA, following American College of Rheumatology (ARC) criteria (Altman et al., 1990)

- Referred to the hand OA care path

- Complaints from hand OA including pain, 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

A potential subject who meets any of the following criteria will be excluded from participation in this study (these are all to be checked by the doctor/research nurse at the consultation):

- Difficulties in (written) communication (e.g., due to analphabetism)

- Severe psychiatric comorbidities that interfere with the study protocol

- On-going psychological treatment elsewhere

- Patients with secondary OA due to diseases such as 1) inflammatory rheumatic diseases, as rheumatoid arthritis, psoriatic arthritis, etc, 2) bone diseases, as M.
Paget, osteochondritis, 3) metabolic diseases associated with joint disease, as hemochromatosis, acromegaly, 4) severe crystal arthropathies, as topheus polyarticular gout.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2016
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-01-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50628

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6127
NTR-old	NTR6266
CCMO	NL55536.058.15
OMON	NL-OMON50628

Study results