The Nijmegen randomised, singleblind, controlled trial on the effect of a multidisciplinary self-management programme in people with OsteoArthritis of the Hands

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Aim of this study is to investigate the short and long term effectiveness of a multidisciplinary self-management program (by an occupational therapist and a specialized nurse) on limitations in activities and pain.

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON32309

Source
ToetsingOnline

Brief title
NOAH

Condition

- Joint disorders

Synonym
arthritis, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Landelijk Katholiek Reumacentrum

Intervention

Keyword: hand osteoarthritis, Non-pharmacological intervention, randomised clinical trial, Self-management

Outcome measures

Primary outcome

The difference in percentage patients that is clinical responder in pain

(Visual Analogue Scale (VAS)), physical functioning (The Australian Canadian

(AUSCAN) questionnaire for Hand OA) and self perceived effect (patient global

assessment (PGA)) according to the OMERACT OARSI responders criteria.

Secondary outcome

Handfunction

- Dutch AIMS2 subscale hand and fingers

Quality of Life / impact of hand OA

- The Canadian Occupational Performance Measure (COPM)). A *patient oriented*

measurement designed to identify the

perceived main problems of patients

- Impact of handproblems: Subscale of the Dutch-AIMS2:

- SF-36 questionnaire

Pain

- Pain Coping Inventory (PCI);

- Tender joint count (hand joints).

Overig

- Self-efficacy: Arthritis self-efficacy scale and Dutch General Self-efficacy

scale;

- Gripstrength in Nm: pinch and gripstrength.

Study description

Background summary

In the recently published EULAR guidelines for management of hand OA it is strongly recommended to treat al patients with hand OA with a combination of pharmacological and non-pharmacological interventions. However, research on the effectiveness of non pharmacological interventions is very limited. In the EULAR recommendations is recommended to treat patients with a non-pharmacological intervention existing of education and hand exercises. However, this recommendation is based on one low quality study with limited patients.

Study objective

Aim of this study is to investigate the short and long term effectiveness of a multidisciplinary self-management program (by an occupational therapist and a specialized nurse) on limitations in activities and pain.

Study design

A single blind randomized controlled trial. The experimental intervention is a multidisciplinary treatment program for hand OA. The control group starts with a three months waiting time followed by the same multidisciplinary treatment program. After the intervention patients will be randomized into a group who receive an additional booster session or not. The assessor is blinded towards the results of the randomization procedure.

Intervention

Multidisciplinary self-management treatment (occupational therapist and a specialized nurse) existing of four group sessions, 2.5 hours each. The content of the treatment program includes information about OA and treatment

options; principles of joint protection; education about active coping strategies; range of motion and strengthening exercises; and, if considered necessary, advice about orthoses in patients with OA of CMC I. Depending on the results of the randomization procedure patients follow an additional booster session. In the additional booster session the successes and failures of patients to implement strategies to cope with pain and limitations in their daily life will be discussed. Furthermore, the major topics addressed in the first four sessions will be repeated.

Study burden and risks

The burden for patients in this study will be low. The outcome measures are widely accepted questionnaires. The blood test (taken at study entry) will be obtained by a trained employee. One standard X-ray (both hands) will be obtained before the start of the study.

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

- Hand OA according to the ACR classification tree for symptomatic Hand OA: Hand pain, aching, or stiffness during most days and 3 or 4 of the following features:
Hard tissue enlargement of 2 or more of 10 selected joints*
Hard tissue enlargement of 2 or more DIP joints
Fewer than 3 swollen MCP joints
Deformity of at least 1 of 10 selected joints*
* The 10 selected joints are the second and third distal interphalangeal (DIP), the second and third proximal interphalangeal, and the first carpometacarpal joints of both hands.
- Score at AUSCAN > 1 ;
- Pain in hand(s) is main problem;
- Refered by a rheuamtologist (secundary care);

Exclusion criteria

- Other rheumatic diseases like rheumatoid artritis, fibromyalgia, gout, psoriatic arthritis;
- Compression syndrome of n. medianus;
- Psychiatric problems;
- Prothesis of one or more joints of the hand/wrist;
- Red flags
- Persons who are not willing to participate in a group intervention
- insufficient ability to read and communicate in Dutch to fullfill questionnaires

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL20186.091.07