The efficacy of a multidisciplinary treatment program in patients with osteoarthritis of the hands.

No registrations found.

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

Summary

ID

NL-OMON26321

Source
Nationaal Trial Register

Brief title
NOAH

Health condition

Hand osteoarthritis (NLD: handartrose).

Sponsors and support

Primary sponsor: Rheumatology Centre, Sint Maartenskliniek, Postbus 9011, 6500 GM Nijmegen
tel. 024-365 9984
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

1. AUSCAN (Handfunction);

2. OARSI responders criteria.

Secondary outcome

1. Visual analogue scale for pain, stiffness and tiredness;

2. Tender joint count of hand and wrist joints rated according to Ritchie;

3. Joint mobility: hand and wrist joints, measured according to the EMP-ROM; a measure to assess joint mobility in rheumatoid arthritis (Vliet Vlieland et al, 1992);

4. Grip and pinch strength; assessed on a Jamar Dynamometer;

5. Dutch- AIMS: subscales for hand and finger function; impact of hand OA;

6. Arthritis self efficacy scale (Lorig et al, 1989);

7. Self perceived change (on 8 point Likert scale);

8. Canadian Occupational Performance measure: a measure of a client's self-perception of performance in the areas of self-care, productivity and leisure, validated in Dutch patients (Dedding et al, 2004);
-SF-36: a generic questionnaire to assess quality of life.

Study description

Background summary

In the recently published EULAR guidelines for management of hand osteoarthritis (OA) it is strongly recommended to treat all patients with hand OA with a combination of pharmacological and non-pharmacological interventions. However, research on the efficacy of non pharmacological interventions, such as education and exercises, is very limited and mainly based on low quality studies. Therefore, experts in this field underline the need for further research on the optimal form and combination of non-pharmacological interventions tailored to the needs of patient with hand OA. The aim of this study is to examine the efficacy of a multidisciplinary intervention in patients with hand OA, to examine the added value of a booster session and to explore the association of patient-related factors with changes in pain and function after multidisciplinary treatment.
The experimental intervention (multidisciplinary non-pharmacological treatment given by specialized nurse and occupational therapist) consists of an intake by an occupational therapist, followed by 4 group sessions (6-8 patients) of 2,5 hours. Elements are individual goal setting, exercises, education, and splints if considered necessary. The control intervention consists of a 30 minutes education session by a specialized nurse. Patients referred for multidisciplinary treatment of Rheumatology Centre of the Sint Maartenskliniek

(locations Nijmegen and Woerden) and the Department of Rheumatology of University Medical Centre Utrecht will be invited to participate in the study. Patients will be randomised twice on two different time points; first at baseline (randomly assignment to immediate start of multidisciplinary intervention or 30 minutes of education followed by waiting time of 3 months); and for the second time three months after multidisciplinary treatment (randomly assignment to booster session or not). Outcome measures (at 0, 3, 6, 9 ,12 and 15 months) include measures of pain, hand function, ADL functioning, self efficacy and quality of life. Prognostic variables to be collected are: demographic and disease related data; use of medication, radiological evidence of hand OA (Kelgrenn and Lawrence score of hand); comorbidity, utilization of health services in the past year, active /passive coping strategies, readiness to change; health locus of control, social support, and kinesiophobia.

Study objective

1. To examine the effect of a multidisciplinary treatment program in comparison to a short monodisciplinary intervention (education by a specialized nurse in a 30 minutes session) on pain, limitations in activities and well-being;

2. To examine the additional effect of a booster session 5 months after multidisciplinary treatment;

3. To identify subgroups of patients who particularly benefit from a multidisciplinary intervention in the short and long term.

Study design

Baseline and after 3,6,9, 12 and 15 months.

Intervention

Experimental:

The multidisciplinary treatment program consists of an intake by an occupational therapist, followed by 4 group sessions (6-8 patients) of 2,5 hours. During the intake an occupational therapists makes in a semi structured interview an inventory of individual problems by means of the Canadian Occupational Measurement Scales (COPM).

Elements of the treatment program are:

1. Setting individual treatment goals (after groups discussing and reflecting on goals mentioned during intake;

2. Education about OA and treatment options (medication, aids, splints, exercise);

3. Providing insight in the relation of daily activities versus pain, fatigue and limitations in activities by means of discussing diaries;

4. Discussion and reflection on strategies to cope with pain, fatigue and limitations in activities (balance between rest and physical activity, individual use of medication, use of compensatory strategies in daily activities, use of aids, use of splints);

5. Strategies to communicate with others;

6. Formulating measures and actions to achieve individual goals;

7. Exercises to improve strength and hand mobility;

8. Practice of the use of household activities;

9. Referral for a splint if considered necessary by the occupational therapist.

Control:

education and instruction about exercises (30 minutes session).

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Eligibility criteria

Inclusion criteria

1. Referred for multidisciplinary treatment in one of the participating centres;

2. OA of the hand according to the ACR classification criteria;

3. AUSCAN score > 1;

4. Limitation in activities due to hand OA is the most or second most important problem for the patient;

5. Willing to participate in a group treatment program.

Exclusion criteria

1. Other inflammatory diseases such as rheumatoid arthritis, arthritis psoriatica;

2. Carpal tunnel syndrome;

3. Joint arthroplasty in one or more of the joints of the hand/wrist;

4. Diagnosis of fibromyalgia.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008
Enrollment:	150

Type:	Anticipated

Ethics review

Positive opinion

Date:	21-12-2007
Application type:	First submission

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
NTR-new	NL1148
NTR-old	NTR1191
Other	Department of Rheumatology, Sint Maartenskliniek, Nijmegen : 201860
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A