

# Non-pharmacological treatment in generalized osteoarthritis.

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We hypothesize that a multidisciplinary group-based, self-management intervention is more effective on functioning in daily living and more cost-efficient than the active control group in patients with generalized osteoarthritis (GOA).

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON26708

### Bron

NTR

### Verkorte titel

MEGA-study: the Maartenskliniek Evaluation of Generalized osteoArthritis study

### Aandoening

Generalized osteoarthritis, Polyarticular arthritis, Randomized clinical trial, Multi-disciplinary therapy, Telephone

### Ondersteuning

**Primaire sponsor:** Sint Maartenskliniek

Department of reumatology

**Overige ondersteuning:** fund = initiator = sponsor

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Daily functioning: Health Assessment Questionnaire (HAQ);<br>

Minimal Important Change: 0.26;<br>

Time points: first year after treatment.<br><br>

1. Specific functioning: Patient specific complaints questionnaire (PSK);<br>

2. Quality of life: RAND-36;<br>

3. Fatigue: Checklist Individual Strength (CIS).<br><br>

Time points for all abovementioned variables are: 6 weeks, 6 months, 1 year after baseline.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

Rationale: An abundance of research literature illustrates that non-pharmacological treatment (NPT) is a useful treatment option in the management of hip or knee osteoarthritis (OA). To our knowledge however, only one study investigated the effect of NPT in the management of generalized osteoarthritis (GOA). This lack of research is a severe hiatus in current OA evidence. GOA-patients represent a substantial group of patients; it is estimated that 27% of patients with hip or knee OA also have GOA. Furthermore, the clinical picture of GOA is more complex than OA in a singular joint. Considering the latter, a comprehensive treatment programme focussing on the consequences of GOA on several aspects of health-related quality of life is warranted in this group of patients. In the literature several modes of delivery are proposed in the management of chronic diseases like arthritis.

### **Doel van het onderzoek**

We hypothesize that a multidisciplinary group-based, self-management intervention is more effective on functioning in daily living and more cost-efficient than the active control group in patients with generalized osteoarthritis (GOA).

### **Onderzoeksopzet**

Time points are: 6 weeks, 3, 6,9 and 12 months, 1 year after baseline and the average over 1 year after baseline.

### **Onderzoeksproduct en/of interventie**

Experimental intervention:

The intervention lasts 6 weeks (max 8 persons per group), consists of 7 meetings, and aims improve the patients health related quality of life by optimising the current lifestyle (i.e. physical activity and diet) and by enhancing the self-efficacy to control the disease (i.e. activity pacing, pain management and daily functioning). To enhance the patients' self-efficacy we use the 5As model of behaviour change counselling, which is an evidence-based approach appropriate for a broad range of different behaviours and health conditions. The

5As are as follows: Assessing patient level of behaviour, beliefs and motivation; Advising the patient based upon personal health risks; Agreeing with the patient on a realistic set of goals; Assisting to anticipate barriers and develop a specific action plan; and Arranging follow-up support. An example, a participant wears a pedometer to elicit his/her physical activity level (A1). Together with the health care provider, the patient discusses the outcome (A2) and set a goal to increase the level of physical activity (A3). Both the health care provider and the patient must believe the goal is good (A3) and feasible (A4). Consequently, patient and therapist closely monitor the personal goals (A5). Adjacent to the self-management programme, patients are also enrolled in an exercise programme aimed to 1. improve the quality of movement and 2. implement the learned exercises in the home situation.

#### Active Control:

Patients enrolled in the telephone counselling group, attend two group sessions and are further monitored through telephone contact and self-monitoring. As per with the experimental intervention, the active control intervention aims to optimise the patients' current lifestyle (i.e. physical activity and diet) and to enhance the patients' self-efficacy to control the disease (i.e. activity pacing, pain management and daily functioning). Again, all patients set a personal goals. Progress on these personal goals will be monitored by the health care provider through planned telephone contact. Patients are asked to self-monitor their own health-status, by filling out activity and eating diaries and wearing pedometers.

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Men and women are eligible to enter the trial if they are:

1. 18 years or older;
2. Diagnosed with GOA;
3. Properly motivated for changing lifestyle;
4. Willing to participate in a group;
5. Able to comply on the planned time schedule of both treatment conditions.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are excluded when they:

1. Are awaiting surgery;
2. Already participated, unsuccessfully, in a self-management program;
3. Are suspected of high levels of distress;
4. Are illiterate;
5. Are not capable of communicating in Dutch;
6. Can't come to the hospital.

## Onderzoeksopzet

### Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

## Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	160
Type:	Verwachte startdatum

## Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL2020
NTR-old	NTR2137
CCMO	NL29524.091.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Resultaten

## Samenvatting resultaten

N/A