

# The effectiveness of an internet physical activity/self-management program in patients with osteoarthritis who did not recently receive a treatment.

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Participants of the internet physical activity / self-management program will increase their level of physical activity and physical function compared to the control group.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON27365

### Bron

Nationaal Trial Register

### Verkorte titel

Artroseinbeweging.nl

### Aandoening

osteoarthritis  
artrose  
physical activity  
fysieke activiteit

### Ondersteuning

**Primaire sponsor:** NIVEL

**Overige ondersteuning:** anonymous financier

### Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

1. The amount of physical activity (SQUASH);<br>
2. Physical function (HOOS/KOOS);<br>
3. Self perceived change.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

Rationale:

Osteoarthritis (OA) is a common joint disorder, threatening mobility and an active lifestyle. Among patients with OA of hip or knee a large group is not regularly using health care; in this study we call this group 'outside-care patients' and define them as those patients who did not have a treatment for their OA (next to their medication and/or consult of their GP) in the last year. Since many of these patients believe nothing can be done for their complaints, these patients do not know how to manage their OA. Therefore, there is an urgent need for an intervention which is specifically developed for outside-care patients.

Objective:

To investigate the effectiveness of an internet physical activity / self-management program (artroseinbeweging.nl).

Study design:

A randomized, wait-list controlled clinical trial.

Study population:

'Outside-care patients' which are defined as those patients who did not have a treatment for their OA (next to their medication and/or consult of their GP) in the last year.

## Intervention:

The internet program artroseinbeweging.nl consists of two elements, physical activity and self-management. Each element will be explained next. The total duration of the program is 8 weeks. Each week, the participant is asked to log in to the program, to receive his/her next week assignment. As a reminder, emails will be sent to the participants at the beginning of each week. The physical activity program consists of an individually-tailored training program for the participants. Each week the participant receives new physical activity assignments which need to be performed at 3 days during the next week. Each week the level of the physical activity assignment increases stepwise until a short-term goal has been reached (after 8 weeks). Next to this, information on self-management topics is given to the patients. The following topics will be discussed: pain during performance of physical activity, becoming a self-manager, use of medication, coping with negative feelings, coping with sleeping problems, arthritis caregivers, healthy eating habits, healthy body weight and coping with social environment. Each time, the participants log into the computer program a new topic appears at the homepage.

## Main study parameters/endpoints:

Primary outcome measures are the amount of physical activity (SQUASH), physical function (HOOS/KOOS) and self perceived change.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Since the study has low demands on the participants, and selection criteria are used to exclude participants with a contra indication for physical activity, the risks for participation are very low. Since all activities (assessment and the program artroseinbeweging.nl) are spread through internet, the burden of the study is also minimal.

## **Doel van het onderzoek**

Participants of the internet physical activity / self-management program will increase their level of physical activity and physical function compared to the control group.

## **Onderzoeksopzet**

Assessments will be performed at baseline and after 3 and 9 months through internet questionnaires.

## **Onderzoeksproduct en/of interventie**

The internet program 'artroseinbeweging.nl' is developed on basis of literature on self-management programs, physical activity interventions and internet interventions. Also, experts on these fields have been interviewed and our own experiences with the principles of behavioural graded activity (a method to increase the level of physical activity step-by-step) are used. Finally, focus groups have been organised with patients about the developed program and the program is tested by a small group (n=20) of patients to fine-tune the program.

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#### Part 1: Physical activity:

The physical activity program consists of several elements. In the first week, patients are informed about the benefits of physical activity in combination with osteoarthritis. Furthermore, patients are asked to choose an activity which they want to improve (e.g. walking, cycling, gardening and swimming). Next, they are asked to indicate their current level of the chosen activity and to formulate a short-term goal which they want to reach in 8 weeks (e.g. walking for 30 minutes). Based on this information, an individually-tailored training program is made for the participants. Each week the participant receives new physical activity assignments which need to be performed at 3 days during the next week. Each week the level of the physical activity assignment increases stepwise until the short-term goal has been reached (after 8 weeks).

#### Part 2: Self-management:

Each week, information on a self-management topic is given to the patients. This information is based on the self management program for patients with arthritis of Lorig et al. (2006). The following topics will be discussed: pain during performance of physical activity, becoming a self-manager, use of medication, coping with negative feelings, coping with sleeping problems, arthritis caregivers, healthy eating habits, healthy body weight and coping with social environment. Each time, the participants log into the computer program a new topic appears at the homepage. For most topics, participants are asked to consider whether they need/want to change something concerning the topic (for example: eat more fruit and vegetable, lose 10 kg body weight, etc). In case participants want to change something, they are assisted in formulating goals and an action plan.

At the website 'artroseinbeweging.nl' extra options are given. Patients can find information on osteoarthritis, information on the website 'artroseinbeweging.nl', information on the study in which they are participating, information on exercises which they can perform and a forum to contact other participants.

Control intervention:

The waiting list group will be offered to follow the internet program 9 months after the start of the study.

## Contactpersonen

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## Deelname eisen

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

1. Patient did not receive a treatment from medical caregivers, such as medical specialist and physiotherapist, for their OA in the last years. Exceptions are consults with GP and medical treatment;
2. Age between 50 and 70 years;

3. Patient has self-reported osteoarthritis of hip or knee.

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

1. Other pathology explaining their complaints;
2. Contra-indication for physical activity;
3. No accessibility of internet;
4. Inability to understand the Dutch language.

Patients will be asked about their comorbidities in relation to performing physical activity by using the PAR-Q (The Physical Activity Readiness Questionnaire) (Cardinal et al, 1996). In case they have a potential contraindication for physical activity (e.g. cardiovascular disorder, diabetes), they are advised to consult their GP about their participation of the internet program.

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Actieve controle groep

### **Deelname**

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

## Ethische beoordeling

Positief advies

Datum: 26-08-2010

Soort: Eerste indiening

## 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	NL2376
NTR-old	NTR2483
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

### Samenvatting resultaten

N/A