

# Motivational Interviewing for promoting physical activity in patients with Rheumatoid Arthritis.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20297

### Source

NTR

### Health condition

Patients with Rheumatoid Arthritis (RA) according to the ACR criteria

## Sponsors and support

**Primary sponsor:** - Department of Rheumatology, Leiden University Medical Center  
- Clinical and Health Psychology, Leiden University

**Source(s) of monetary or material Support:** Vrienden van Sole Mio

## Intervention

## Outcome measures

### Primary outcome

1. Physical activity (SQUASH);
2. Amount of selfregulation (e.g. motivation) (TRSQ);

3. Selfregulationskills with regard to physical activity (HCCQ).

### **Secondary outcome**

1. Disease activity (RADAI);
2. Physical and mental status (RAND-36);
3. Anxiety, depression, somatic complaints and sleeping disorders (SCL-90);
4. Fatigue (CIS-20).

## **Study description**

### **Background summary**

In the past few years various initiatives with concern to promoting physical activity have been developed. In many studies it appeared that the participants had troubles persisting the physical activity program long term. Adding Motivational Interviewing (MI) and Self-regulation, aimed at a behavioral change, to a physical activity program could perhaps stimulate more physical activity (mainly long term).

The study concern a randomized controled trial among 120 patients with RA who are physically inactive (do not fulfill the Dutch Public Health Recommendation for physical activity; 5x weekly 30 minutes moderate/intensive physical activity) and who do not have any contra-indications for physical activity.

All RA patients with recieve information with regard to physical activity by a general physical therapist.

Half of these RA patients will further receive one MI session with a trained physical therapist and 2 self-regulation session with a trained clinical nurse specialist and two follow-up phone calls by the same clinical nurse specialist.

Main aim is to increase the physical activity level of RA patients and maintain this physical activity level long-term.

## Study objective

N/A

## Study design

1. Baseline (all outcome measures);
2. After 6 weeks (all outcome measures);
3. After 20 weeks (all outcome measures);
4. After 52 weeks (all outcome measures).

## Intervention

Motivational Interviewing and Self-regulation group (one session per week):

1. 1 groupsession with regard to physical activity (why it is important, health benefits and how to become physically active) to provided by a physical therapist to stimulate that patients become more physically active in daily live;
2. 1 individual session with a trained physical therapist (motivational interviewing) to increase the internal motivation of the patient;
3. 2 individual sessions with a trained clinical nurse specialist (self-regulation) to increase the patient's selfregulation skills;
4. 2 phonecalls by the trained clinical nurse specialist.

Control group:

1. 1 groupsession with regard to physical activity (why it is important, health benefits and how to become physically active)provided by a physical therapist (same as intervention group) to stimulate that patients become more physically active in daily live.

## Contacts

### Public

Postbus 9600  
E.J. Hurkmans  
Leiden 2300 RC

The Netherlands  
+31 (0)71 5263265  
**Scientific**  
Postbus 9600  
E.J. Hurkmans  
Leiden 2300 RC  
The Netherlands  
+31 (0)71 5263265

## Eligibility criteria

### Inclusion criteria

1. Patients are recruited in the Leiden University Medical Center, the rheumatology outpatient clinic;
2. Patients with RA who do not fulfill the Dutch public recommendations for physical activity (5 times weekly moderately physical active during 30 minutes).

### Exclusion criteria

Patients who are not capable to be physically active due to co-morbidity.

## 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): 01-02-2010  
Enrollment: 120  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 03-03-2010  
Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 32095  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

### In other registers

Register	ID
NTR-new	NL2123
NTR-old	NTR2240
CCMO	NL22049.058.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32095

## Study results

### Summary results

N/A