

# Fibromyalgia on the move...! Randomised study on the effect and cost-effectiveness of a multidisciplinary part-time daycare intervention.

No registrations found.

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

## Summary

### ID

NL-OMON21959

### Source

NTR

### Brief title

N/A

### Health condition

Fibromyalgia.

## Sponsors and support

**Primary sponsor:** azM

**Source(s) of monetary or material Support:** N/A

## Intervention

## Outcome measures

### Primary outcome

1. Social participation;

2. Medical consumption;
3. Quality of life.

### **Secondary outcome**

1. Pain;
2. Anxiety;
3. Self-efficacy;
4. Catastrophizing;
5. Fatigue;
6. Disability.

## **Study description**

### **Background summary**

Patients with fibromyalgia, a chronic benign pain syndrome, are referred frequently. An important cause is the fact that a well defined treatment to manage symptoms and pain is lacking. A number of studies have been performed on the effectiveness of a diversity of interventions, but only preliminary support of moderate strength exists for aerobic exercise. Since chronic pain tends to develop into a combination of physical, psychological and social disabilities, the physical rehabilitation for musculoskeletal disorders is getting more and more combined with psychological, behavioural and educational interventions. Several multidisciplinary programs for fibromyalgia are available, mainly in rehabilitation centres. However, only a few studies had been performed on the effectiveness of these treatment and the methodological quality of the studies is low. In addition to this, patients are eligible for such programs not until after trying the whole range of possible treatments in vain. If patients are able to follow the multidisciplinary program in an early stage of their disease, fixation can possibly be prevented. Because of this, a (larger) social drop-out will be averted in term, and medical consumption will decrease and quality of life will increase.

The overall research questions are:

1. What is the effectiveness of the multidisciplinary part-time day-care intervention in recently diagnosed fibromyalgia patients compared with best care (aerobic exercise) and usual care?

2.What is the cost-effectiveness of the multidisciplinary part-time day-care intervention in recently diagnosed fibromyalgia patients?

For this study, we have used a design in which a random sample is drawn out a 'natural course cohort' to create the intervention group. Through this, an unwanted negative influence of the control group has been prevented.

### **Study objective**

Fixation of complaints in fibromyalgia patients can be prevented by offering a multidisciplinary intervention in an early stage of the disorder. Because of this, a (larger) social drop-out will be averted in term, and medical consumption will decrease and quality of life will increase.

### **Study design**

N/A

### **Intervention**

1. 12-week multidisciplinary part-time day-care intervention;
2. 12-week aerobics exercise;
3. Usual care.

## **Contacts**

### **Public**

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### **Scientific**

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# Eligibility criteria

## Inclusion criteria

1. Recently diagnosed fibromyalgia;
2. Age 18-65;
3. Be able to read en write Dutch;
4. Physical be able to spend 12 hours a week on therapy;
5. Be able to be present at least 85% of the treatment time;
6. Motivated into all parts of the treatment program.

## Exclusion criteria

1. Involved in any litigation concerning disability income;
2. Serious psychopathology through which a patient is unsuitable to take part in the group treatment;
3. Serious depression (measured by SCL-90);
4. Specific medical diseases for which medical treatment is necessary immediately or through which patients can not take part in the physical therapeutic treatment;
5. Addiction problems;
6. Pregnancy;
7. Complicated home situation/Fibromyalgia is not most important problem;
8. Use of supportive equipment for ambulation.

# Study design

## Design

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2004
Enrollment:	214
Type:	Actual

## Ethics review

Positive opinion	
Date:	18-10-2005
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	NL367

**Register**

NTR-old

Other

ISRCTN

**ID**

NTR406

: N/A

ISRCTN32542621

## Study results

**Summary results**

N/A