

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
27/01/2006	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
27/01/2006	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
24/07/2013	Musculoskeletal Diseases	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fibromyalgia

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Social participation
2. Medical consumption
3. Quality of life

Key secondary outcome(s))

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

Completion date

01/05/2006

Eligibility

Key inclusion criteria

1. Recently diagnosed fibromyalgia
2. Age 18-65
3. Be able to read and write Dutch
4. Be able physically 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Upper age limit

65 years

Sex

Not Specified

Key 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

Date of first enrolment

23/01/2004

Date of final enrolment

01/05/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
University Hospital Maastricht
Maastricht
Netherlands
6202 AZ

Sponsor information

Organisation

Academic Hospital Maastricht (AZM) (Netherlands)

ROR

<https://ror.org/02d9ce178>

Funder(s)

Funder type

Other

Funder Name

Care Funds (Zorgvernieuwingsgelden) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2013		Yes	No