

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M.E.A.L. Kroese

Contact details
University Hospital Maastricht
BZe VII - Transmurale Zorg
P.O. Box 5800
Maastricht
Netherlands
6202 AZ
+31 (0)43 3874406
mkroes@adcc.azm.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

23/01/2004

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

Age group

Not Specified

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Not Specified

Target number of participants

214

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)

Sponsor details

P.O. Box 5800

Maastricht

Netherlands

6202 AZ

+31 (0)43 3876543

info@azm.nl

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Other

Funder Name

Care Funds (Zorgvernieuwingsgelden) (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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