

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21959

Bron

NTR

Verkorte titel

N/A

Aandoening

Fibromyalgia.

Ondersteuning

Primaire sponsor: azM

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Social participation;

2. Medical consumption;

3. Quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	23-01-2004
Aantal proefpersonen:	214
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	18-10-2005
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	NL367
NTR-old	NTR406
Ander register	: N/A
ISRCTN	ISRCTN32542621

Resultaten

Samenvatting resultaten

N/A