Effectiveness and cost-effectiveness of Pain Rehabilitation Programs (PRP) for patients with chronic musculoskeletal pain: less is better?

Published: 18-08-2011
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To analyse the effect of shortening duration of PRP on effectiveness and cost effectiveness of PRP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON36237

Source
ToetsingOnline

Brief title
Effectiveness of PRP: less is better?

Condition

- Muscle disorders

Synonym
chronic pain, non-malignant pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ontwikkelcentrum pijnrevalidatie

Intervention

Keyword: Chronic musculoskeletal pain, Cost-effectiveness, Effectiveness, Pain Rehabilitation Programs, Therapy dose

Outcome measures

Primary outcome

Pain related disability, measured with the Pain Disability Index, will be the

main outcome.

Secondary outcome

For cost-effectiveness direct and indirect costs will be calculated.

Study description

Background summary

Pain Rehabilitation Programs (PRP*s) are proven to be effective for patients with chronic musculoskeletal pain (CMP). But there is no available evidence about the relationship of dose on the effect of PRP. We hypothesized that shortening PRP will not be less than 4 points inferior on the Pain Disability Index (PDI) to care as usual.

Study objective

To analyse the effect of shortening duration of PRP on effectiveness and cost effectiveness of PRP.

Study design

The study is a single blind, 2 armed, randomized controlled clinical trial, with a group sequential non inferiority design.

Intervention

The control intervention will be care as usual. The experimental intervention will not differ in content of PRP. The experimental group will receive PRP in 4 weeks less than care as usual.

Study burden and risks

There are no risks associated with participation on the study. Two extra questionnaires has to be filled in compared to usual care. The number of visits for PRP will be the same as usual care for the control group and 4 weeks less for the experimental group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients 1. are referred to the 12,16 or 20 weeks Pain Rehabiltiaton Program (PRP) at the UMCG, 2. have chronic musculoskeletal pain (CMP), 3. experience disability caused by CMP, 4. attend no other kinds of treatment, 5. are 18 years or older, 6. are willing to participate in

the study, 7. WPN 3 and 4. Defined as:the social and psychosocial factors are complex and relevant regarding maintaining pain related disability.

Exclusion criteria

Patients 1. are included for 8 weeks of PRP 2. are not willing to participate in the study, 3. are unable to understand the Dutch language, 4. have relevant comorbidities.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2011
Enrollment:	276
Type:	Actual

Ethics review

Approved WMO

Date:	18-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL30094.042.11