Painrehabilitation: More is Better?

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

Samenvatting

ID

NL-OMON20757

Bron
Nationaal Trial Register

Aandoening

Patients with chronic musculoskeletal pain referred to a Pain Rehabilitation Program are potential participants for the study.

Ondersteuning

Primaire sponsor: Center for Rehabilitation,
University Medical Center Groningen (UMCG)
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Self reported disability will be the main outcome and will be measured with the Pain Disability Index (scale range 0-70).

Toelichting onderzoek

Achtergrond van het onderzoek

Pain Rehabilitation Programs (PRP's) are proven effective for patients with chronic musculoskeletal pain (CMP). Evidence about the relationship of dose on the effect of PRP however, is unavailable. We hypothesized that shortening PRP will not be less than 4 points inferior to care as usual.
The objective of the study is to analyse the effect of shortening duration of PRP on effectiveness and cost effectiveness of PRP.

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

All patients with CMP referred to PRP of the UMCG (The Netherlands) are potential participants for the study.

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.

Pain related disability, measured with the Pain Disability Index (PDI), will be the main outcome. The non-inferiority margin is predefined as 4 points difference on PDI to tolerate as non-inferior. For cost-effectiveness direct and indirect costs will be calculated.

Doel van het onderzoek

Pain Rehabilitation Programs (PRP's) are proven effective for patients with chronic musculoskeletal pain (CMP). Evidence about the relationship of dose on the effect of PRP however, is unavailable. We hypothesized that shortening PRP will not be less than 4 points inferior to care as usual.
The objective of the study is to analyse the effect of shortening duration of PRP on effectiveness and cost effectiveness of PRP.

Onderzoeksopzet

All outcomes will be measured before start, at the end of PRP and at 3 months and 12 months follow up.

Onderzoeksproduct en/of interventie

The content of the control and experimental intervention is the same. The only difference is the dose of the program. The control group of patients will be treated by care as usual, which means they will receive 12, 16 or 20 week PRP as indicated. The experimental group of patients will receive their treatment in less weeks and contact hours. Patients, who are indicated for 20 weeks, will receive 16 weeks PRP. Patients, who are indicated for 16 weeks

PRP, will receive 12 weeks PRP. Patients, who are indicated for 12 weeks PRP, will receive 8 weeks PRP.

Prolongation of PRP can occur based on agreement between the patient and the PRP team about the reasons for prolongation. These reasons do not differ from usual care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are eligible for the study when:

1. They participate in the 12, 16 and 20 weeks Pain Rehabilitation Program (PRP) at the University Medical Centre Groningen (UMCG);

2. They have CMP for more than three months without a specific pathological cause;

3. They experience disabilities caused by CMP;

4. WPN 3 and 4. Defined as: social and psychological factors are complex and are relevant

regarding maintaining pain related disability;

5. They attend no other kinds of treatment (except for pain medication);

6. They are 18 years or older;

7. They are willing to participate in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. They are referred to the 8 weeks PRP;

2. They are unable to understand the Dutch language;

3. They have relevant co morbidities such as heart failure, rheumatoid arthritis, psychiatric disorders.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	276
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-04-2012
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	NL3233
NTR-old	NTR3385
Ander register	METc : 2011.118
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A