PREPARE- pre-pain rehabilitation treatment, in chronic non-specific musculoskeletal pain patients.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29174

Source
Nationaal Trial Register

Brief title
PREPARE (Pre-pain rehabilitation)

Health condition

Motivational interviewing, Chronic non-specific pain, Rehabilitation

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

Participation measured by the USER-P.

Secondary outcome

1. Adherence;

2. Drop-out;

3. Physical functioning (PDI);

4. Quality of life (SF-36);

5. Client-centeredness (CCCQ);

6. Credibility of the treatment (CEQ);

7. Self-efficacy (DGSE);

8. Self-reported main complaints (PSC).

Study description

Background summary

Rationale:

Non-adherence and drop-out are major problems in pain rehabilitation. Motivational interviewing (MI)-based interventions have shown promising effects in reducing non-adherence and drop-out in chronic pain patients. As a consequence this may result in better motivation and patient outcome as well.

Therefore, an MI-based nurse-led pre-pain rehabilitation (MIP intervention) addressing motivation, expectations and beliefs is developed to prepare indicated patients for treatment. MIP is compared with usual care (UC).

Objective:

To study the (cost-)effectiveness of MIP (MI-based pre-treatment), compared to UC (usual care) condition as a nurse-led add-on to pain rehabilitation in terms of participation and treatment drop-out in patients with chronic pain.

Study design:

A two-armed RCT including two interventions: A Motivational interviewing (MI)-based

intervention (= MIP intervention) and a usual care (=UC) control intervention containing health information only, are provided by nurses as pre-treatment before the start of the pain rehabilitation treatment. Follow-up will be 6 months.

Study population:

184 (n=92 per arm) patients with chronic non-specific musculoskeletal pain visiting the rehabilitation department in the hospital for an intake interview.

Intervention:

2 sessions of the MIP intervention condition and UC condition are provided before the start of the pain rehabilitation treatment. MIP consists of MI-based sessions to prepare and motivate the patient for pain rehabilitation treatment and its bio psychosocial approach. UC consists of education about the aetiology and the rehabilitation approach of chronic pain.

Main study parameters/endpoints:

Primary outcome is the level of participation at the last follow-up measure 6 months after finishing rehabilitation treatment. Secondary outcomes are treatment drop-out and adherence, motivation, pain intensity, credibility of the treatment, self-efficacy, and self-reported main complaints. Costs will be calculated measuring the costs of the MIP-/ UC-condition, productivity losses and health care utilization as well quality of life to account for effect cq. utility. For the process evaluation, parameters such as exposure to the conditions, experiences, client-centeredness, facilitators, barriers and satisfaction are explored during the pre-treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients who are participating in the study need to complete questionnaires with regard to effect evaluation, cost-effectiveness evaluation, and process evaluation at 5 moments (T0, T1, T2, T3, and T4). To reduce the burden for patients the research-related assessments at T0 and T3 will be integrated in the clinical assessment battery of usual care. To complete the questionnaire T0 and T2, T3, T4, 45 minutes are required. T1 takes 20 minutes.

Study objective

The (cost-)effectiveness of PREPARE (Pre-pain rehabilitation) treatment, a Motivational

interviewing (MI)-based nurse-led intervention on motivation and adherence for, and participation after pain rehabilitation treatment in chronic non-specific musculoskeletal pain syndrome patients: a randomized controlled trial (RCT).

Study design

1. Baseline (T0);

2. After two intervention sessions (T1);

3. After the assessment (T2);

4. After the pain rehabilitation treatment (T3);

5. 6 months after T2 (T4).

Intervention

2 appointments each lasting 45 min up to 1h with a trained nurse take place at the department of rehabilitation medicine:

1. In the MIP intervention condition, the sessions are based on Motivational interviewing (MI);

2. In the UC control condition, health information and health education around chronic pain and pain rehabilitation is provided.

Both interventions are provided by separately trained nurses each providing the two conditions. The nurses are experienced in the field of rehabilitation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Non-specific chronic musculoskeletal pain syndrome;

2. Pain duration >3 months;

3. Over 18 years of age, max. 65 years;

4. Eligible and (as yet) indicated for outpatient pain rehabilitation treatment, main indication criteria: Chronic pain;

5. Adequate literacy to complete assessment measures.

Exclusion criteria

1. Pregnancy;

2. Surgery planned in the foreseeable future;

3. Patient involved in litigation procedures;

4. Psychopathology which makes the indication for the pain rehabilitation treatment impossible.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2011
Enrollment:	184
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-09-2011
Application type:	First submission

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
NTR-new	NL2918
NTR-old	NTR3065
CCMO	NL38087.068.11 / 11-2-073;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A