Pre-pain rehabilitation (PREPARE) treatment in chronic pain: a randomized controlled trial (RCT)

Published: 28-11-2011
Last updated: 30-04-2024

1. What is the effectiveness of MIP (MI-based pre-treatment) compared to UC (usual care) on the level of participation and treatment drop-out in patients with chronic non-specific musculoskeletal pain following pain rehabilitation?2. What is the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37696

Source
ToetsingOnline

Brief title
Pre-pain rehabilitation (PREPARE) treatment in chronic pain: a RCT

Condition

- Other condition
- Musculoskeletal and connective tissue disorders NEC

Synonym
Chronic non-specific musculoskeletal pain

Health condition

Chronische aspecifieke musculoskeletale pijn

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic non-specific pain, Motivation, Motivational interviewing, Rehabilitation

Outcome measures

Primary outcome

1st research question (effect evaluation)

The primary outcome of the effect-evaluation will be the mean difference in change in level of participation of the participants at T4.

Participation will be measured by the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P) (van der Zee, Post et al. 2008; van der Zee, Priesterbach et al. 2010). The USER-P covers three aspects of participation by three separate scales namely Frequency, Restriction, and Satisfaction. It consists of 32 items and it was tested for reproducibility (van der Zee, Priesterbach et al. 2010). Each of the three sum scores is converted to a scale ranging from 0-100 scale, where higher scores reflect more social participation (each higher frequency, less restrictions, higher satisfaction). The psychometric qualities are studied at this moment (Van der Zee, Kap et al. 2011; Van der Zee and Post 2011).

2nd research question (cost-effectiveness and cost-utility

To evaluate the economic effects of MIP and UC, relevant cost categories of resource use and volumes of these categories must be measured. Finally, volumes

have to be multiplied by the belonging costs.

According to the principles of economic evaluations for interventions of chronic musculoskeletal pain by Goossens et al., (1999), the following cost categories will be included. 1) Direct health care costs inside which include the costs of the pain rehabilitation treatment and the pain-related health care utilisation during the follow-up period; 2) Direct costs outside the health sector which include costs of (un)paid help, out-of pocket expenses, and travel costs of attending the pain rehabilitation treatment; and 3) Indirect costs outside the health sector, which include production losses (absenteeism) due to the chronic pain problem (Hakkaart- van Roijen, Tan et al. Geactualiseerde versie 2010).

To analyse differences in costs, costs per patient-year will be calculated. This means that the observed costs of the participants will be extrapolated to a 1-year period.

For the cost-effectiveness analysis (CEA), costs will be weighted against the primary outcome measure participation.

For the cost-utility analysis (CUA), costs per year will be weighted against utilities based on the SF-36. The SF-36 is a reliable and valid instrument to measure health related quality of life (van der Zee and Sanderman 1993). The derived utilities at the four measurement points (baseline, post treatment, 6 and 12 months) will be finally used to compute the Quality Adjusted Life Years (QALY) score.

Secondary outcome

Secondary study parameters focused on the goal of activity-based

cognitive-behavioral pain rehabilitation are level of functioning, pain intensity, pain-catastrophizing, pain-related fear, patient-related complaints, depression, credibility and expectancy, acceptance, and flexible goal-adjustment.

Secondary study parameters focused on the immediate goal of the pre-treatment are adherence to the pre-treatment, drop-out, motivation, and self-efficacy.

Study parameters focused on the process of the intervention are feasibility in terms of a) integrity and b) fidelity of the intervention, and satisfaction with the pre-pain rehabilitation treatment and the pain rehabilitation treatment in patients, nurses and consultants in rehabilitation medicine.

Study description

Background summary

Chronic non-specific musculoskeletal pain is a major health burden. It occurs in approximately 10% of the general population (Gran 2003) and causes disability (Badley, Webster et al. 1995), medical expenses (Meerding, Bonneux et al. 1998) and a high amount of work absenteeism (Koes, van Tulder et al. 2006). Nowadays, medication, exercise, and behavioural therapy are mostly used in management of non-specific musculoskeletal pain.
The ultimate goal of behavioural therapy is to alter maladaptive thoughts, feelings, and behaviours in order to influence disability by increasing the level of functioning. The primary aim of rehabilitation treatment, based on cognitive behavioural therapy, is thus to learn to cope with pain and not curing pain with the intention to increase a patients level of participation in society and his/her quality of life.
As participation is the ultimate goal and key rehabilitation outcome in the long term, this is also the primary outcome measure of the proposed study. This is in accordance with the ICF (International Classification of Functioning, Disability and Health).

In order to obtain this, rehabilitation will focus on teaching the patient to influence his/ her health state positively and getting insight in the relation between complaints and the circumstances in which they occur (Köke 2005). However, in order to be effective, behavioural treatment needs cooperation of both the patient and the practitioner, and the adherence and motivation of the patient. Previous research showed that adherence and non-drop-out to treatment is related to a better outcome in physical and emotional functioning and pain severity
Unfortunately, in the current rehabilitation care, non-adherence and drop-out are major problems. Adherence rates are low in patients with chronic conditions (Sabate 2003) and subsequently drop-out in pain rehabilitation programmes is high. Drop out ranges from 9-42% (Peters, Large et al. 1992; Rainville, Ahern et al. 1993; Bendix, Bendix et al. 1998).
In order to improve adherence and motivation to prevent drop-out, motivational interviewing (MI) has been proposed.
Nowadays, MI has also been applied with promising results in twee RCT-studies within chronic pain conditions. MI as treatment approach is fairly new in the field of chronic pain,
At this moment, no evidence is available in patients with chronic non-specific musculoskeletal pain in the rehabilitation setting. Those patients are characterized by a high level of disability and complex problems, mostly of psychosocial origin.
Habib et al. (2005) found significantly increases in participation after a 2-session Motivational interviewing (MI)-based feedback interview compared with an attention placebo interview in chronic pain patients (Habib, Morrissey et al. 2005). Another recent study found an MI-adapted intervention added to physiotherapy in the treatment of chronic low back pain effectively enhancing motivation and exercise compliance compared to physiotherapy alone (Vong, Cheing et al. 2011).
As meta-analyses ranging from applications ranging for addiction-related problems to parenting skills showed that using MI as a pretreatment*wherein MI was designed to prepare clients for further treatment such as cognitive-behavioral therapy (CBT) or an inpatient program*yielded the best outcomes (Burke, Arkowitz et al. 2003; Hettema, Steele et al. 2005; Lundahl and Burke 2009).

Study objective

1. What is the effectiveness of MIP (MI-based pre-treatment) compared to UC (usual care) on the level of participation and treatment drop-out in patients with chronic non-specific musculoskeletal pain following pain rehabilitation?
2. What is the cost-effectiveness and cost-utility of a MI-based pre-treatment (MIP), compared to UC (usual care) from a societal perspective?
3. What are the mediating mechanisms of MIP versus UC in patients with chronic non-specific musculoskeletal pain?
4. What is the feasibility of the MIP intervention in terms of MI-fidelity (process evaluation)?

5. What are experiences of nurses, rehabilitation consultants and patients in terms of satisfaction with and barriers of the MIP intervention (process evaluation)?

Study design

The PREPARE study is a single-blind randomized controlled trial with a total follow-up of six months. The study will take place in two departments of rehabilitation medicine; one academic hospital (Maastricht University Medical Centre, MUMC+) and one hospital for regional care (Atrium hospital Heerlen). To understand the features of the UC condition, below first the usual practice in pain rehabilitation will be explained.

Usual practice in pain rehabilitation
In the usual practice in pain rehabilitation, patients are selected for rehabilitation treatment by the consultant in rehabilitation medicine during an intake interview. The judgement of a patient*s readiness for behavioural rehabilitation at the intake interview will be based on expert opinion by the consultant in rehabilitation medicine.
The intake consists of two parts. 1) Screening whether the patient is a potential candidate for rehabilitation treatment by the evaluation of both medical and motivational factors, and in the case of indication for rehabilitation treatment. The medical aspects evaluated are the origin and severity of the pain problem and the seriousness of interfering co-morbidity. In case to the consultant*s opinion, a medical or motivational reason is present that seems contra productive during treatment, the consultant will renounce rehabilitation treatment. A patient with a medium to high level of motivation will be indicated for pain rehabilitation.
In the case of an indication for rehabilitation treatment, 2) Providing education on the aetiology, treatment and prognosis of chronic non-specific musculoskeletal pain based on the book *Mastering pain* (in Dutch: *De pijn de baas*)(Winter 2008) and providing information about the goal of pain rehabilitation. The education is provided by nurses specialized in the field of rehabilitation.

As there exists a waiting list lasting on average 12 weeks between the indication for treatment by the consultant in rehabilitation medicine and the ultimate start of the treatment, all patients receive the two pain education sessions provided by nurses during this time.
At the start of the rehabilitation treatment, the first phase of treatment will take place: the assessment. This phase is aiming for a clear picture about functional limitations, and the origin of the pain, resulting in a treatment plan including treatment goals.
This phase starts with a clinical assessment battery. Patients are asked to fill in a set of questionnaires.
In addition, the patient will be interviewed by different professionals such as occupational therapists, physiotherapists and/ or psychologists to objectify a

patient*s current situation on the level of impairment, activities and participation. In addition, interfering personal and environmental factors (see ICF mentioned before) will be identified.
Finally, the last part of the assessment phase is the preparation of a treatment plan with concrete treatment goals to work on during treatment.
Post treatment and three months follow up; the clinical assessment battery is repeated aiming at treatment evaluation.

The situation during the PREPARE study
In the PREPARE study, the situation continues unchanged. The unique feature of the PREPARE study is that a Motivational Interviewing-based intervention is compared with the usual care pain education before the ultimate start of the rehabilitation treatment during the time on the waiting list.
To standardize and facilitate the motivation criterion, a 10-point Visual Analogue Scale (VAS) will be used to mark the patients* motivation for pain rehabilitation. Patients with an indication for treatment and a medium to high level of motivation will be asked to sign an interest form to receive further information about the PREPARE study.
After informed consent of the participant and the baseline measurement, the participant is randomized to receive either MIP or UC.
Participants will receive the MIP or UC condition during the period they will be on a waiting list for treatment. In this way, the actual date for the start of treatment will be unchanged.

Intervention

All patients will be invited to come to the rehabilitation department for two sessions with a nurse at the rehabilitation department.
Total contact time in both conditions is identical. The content of the conditions is different.

Unique features of the MIP intervention condition
The four general principles of MI are incorporated into all sessions in the MIP- condition. These four general principles of MI are:
1. expressing empathy by the use of reflective listening,
2. developing discrepancy between client goals and current problem behaviour,
3. rolling with resistance by avoiding argumentation by assuming that the client is responsible for the decision to change,
4. and supporting self-efficacy and optimism for change(Emmons and Rollnick 2001).
The content of each of the appointments is individually tailored to the patients* readiness to change.
During the 1st appointment, a trustful relationship between participant and nurse is built, the actual (life) situation, burden and impairments of the chronic pain in daily life, motivation, self-efficacy, and readiness to change for behaviour change is assessed and enhanced, the session is summarized and closed.

The 2nd appointment is a brief Motivational feedback session. The process of the 1st appointment will be discussed with the participant by giving feedback adapted to the state of readiness- to- change. Therein, motivation and self-efficacy for behaviour change is enhanced. In addition, topics related to chronic pain and treatment, such as education about the influence of exercise and a back ground in the bio psychosocial approach be part of the MIP intervention. Then, the session is summarized and closed.

Unique features of usual care
In the usual care condition, participants will receive pain education according to the information in the book *De pijn de baas* (Winter 2008) (Mastering pain). In current care, education based on information provided in *de pijn de baas* is already part of the treatment and is provided by a nurse. The ultimate goal is to provide the participant with information. Contrary to the MIP condition, no feedback is given related to the stage of change of the participant. However, literature shows that patients with chronic pain benefit are less likely to benefit from education compared with pain patients in an acute (or short-term) state (Engers, Jellema et al. 2008).

Nurses
Both the usual care condition (UC) and the MIP (intervention condition) are administered by registered nurses working in the field of rehabilitation. Nurses will guide participants in only one condition, and will thus be trained to provide only one of the two study conditions. Before the start of the study, the nurses are extensively trained by different certified trainers in skills necessary for the intervention condition cq. the control condition.
All the nurses involved in the MIP intervention condition have already been trained in MI. The nurses selected for delivering the MI condition, are experienced MI coaches. For this project, their knowledge and experience in MI in the specific context of chronic pain rehabilitation will be updated. The training will be tailored to their specific needs and will be provided in an evidence-based manner to the nurses (Miller, Yahne et al. 2004; Miller and Moyers 2007; Lane, Hood et al. 2008; Söderlund, Nilsen et al. 2008; Madson, Loignon et al. 2009). Training will also include intervision during the project. Therefore, the emphasis of the subsequent training will be on additionally regular intervision, supervision, training-on-the job and direct feedback on MIP sessions.
Nurses of the usual care condition will receive a refresher training in general communication skills and health information. These nurses are selected based on no prior knowledge about counselling and MI in particular. The training in the UC condition was provided by a person experienced in the training communication skills of health professionals. This is another trainer than in the MIP intervention condition.

In both conditions the nurses will receive a detailed manual that gives specific instructions for each session.

Study burden and risks

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). 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.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age between 18 and 65 years.

Eligible and indicated for outpatient pain rehabilitation treatment as it turns out from the main indication criteria: Non-specific chronic (pain duration >3 months) musculoskeletal pain syndrome. And sufficient motivation for pain rehabilitation from the consultant).
The chronic pain syndrome is not attributable to a recognisable, known specific pathology (e.g. infection, tumour, osteoporosis, fracture, structural deformity, inflammatory disorder (e.g. ankylosing spondylitis), radicular syndrome or cauda equina syndrome).
Adequate literacy to complete assessment measures.

Exclusion criteria

Pregnancy. Surgery planned in the foreseeable future. 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:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2012
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	28-11-2011

Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	02-04-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	18-12-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-01-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL38037.068.11