# 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).

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The primary objective of this current project is to study the (cost-) effectiveness of Motivational interviewing in non-specific musculoskeletal chronic pain patients who are indicated for pain rehabilitation treatment. It is hypothesized that an MI...

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|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36212

**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 level of

participation of the participants at baseline (T0), T2, T3, and 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).

Primary process measure of the first research question is treatment drop-out. Drop-out will be registered in the patient registry in the institution by as whether the patient was finally indicated for rehabilitation (or was dropped-out by the professionals), and has finished the pain rehabilitation as proposed or dropped out prematurely.

2nd research question (mediation)

Adherence to the pre-treatment intervention and to the rehabilitation treatment (which is also assessed for research question 1) could mediate the relationship between treatment and outcome.

3rd research question (cost-effectiveness and cost-utility)

To evaluate the economic effects of MIP and ACC, relevant cost categories of resource use and volumes of these categories must be measured. Finally, volumes have to be multiplied by the belonging costs.

Costs can be divided in direct and indirect costs and sub classified in health care costs and non-health care costs(Hakkaart- van Roijen, Tan et al. Geactualiseerde versie 2010). Four cost categories are resulting from this.

Direct costs inside the health sector are costs which result directly from a certain intervention or treatment. They include in this study costs of the pain rehabilitation treatment and the economic consequences of the intervention

condition in terms of changes in health care utilisation. Indirect costs inside the health sector are medical costs in gained life years due to a special care or treatment and do not apply here. Direct costs outside the health sector include costs of (un)paid help, out-of pocket expenses, and travel costs of attending the pain rehabilitation treatment. Indirect costs outside the health sector include production losses (absenteeism) due to the chronic pain problem(Hakkaart- van Roijen, Tan et al. Geactualiseerde versie 2010)

Indirect (non-)health care costs such as medical consumption is assessed by a cost diary in which the participants record medical consumption related to their chronic pain(Goossens, Rutten-van Molken et al. 2000) and costs of informal care and domestic help. Therefore, the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (Tic-p) (Hakkaart-van Roijen, van Straten et al. 2002) is used. This self-reporting questionnaire consists of 15 items and assesses health care use a recall period of 3 months.

Productivity losses are assessed by the Short Form Health and Labor Questionnaire (SF-HLQ)(Hakkaart-van Roijen and Bouwmans 2007). The SF-HLQ measures the extent of production losses of paid and unpaid work in four modules: absence from work, reduced productivity at paid work, unpaid labor production and impediments to paid and unpaid labor. It consists of 11 items and is added to the TIC-P.

Costs will be calculated by multiplying quantity (volume) by cost price and calculating the sum total of the various types of costs(Drummond and McGuire 2001). To analyse differences in costs, costs per patient-year were calculated. This means that the observed costs of the participants will be extrapolated to

a 1-year period. The updated Dutch manual for cost analysis in health care research will be used containing guidelines for standardized cost prices(Hakkaart- van Roijen, Tan et al. Geactualiseerde versie 2010). Where no standard cost prices are available, real costs or tariffs will be used to estimate costs. Cost prices will be presented in Euros and the baseline year is 2012, or otherwise discounted. The discounting rate of costs is 4%, these of effects 1.5%(Oostenbrink, Koopmanschap et al. 2002; O'Brien, Staud et al. 2010; Hakkaart- van Roijen, Tan et al. Geactualiseerde versie 2010).

To weight costs against effects of the MIP-/ ACC intervention, participation as well as quality of life is used as effect measure. Participation is the primary outcome measure and described above, quality of life is measured by the Short-Form 36 (SF-36) General Health Survey. This is a general self-report measure of health status and includes eight health concepts which can be used to measure physical and mental functioning(Ware and Kosinski 2001). This questionnaire has been extensively tested for validity in various countries, disease groups, and settings(Aaronson, Muller et al. 1998).

For the cost-utility analysis (CUA), costs per year are weighted by utility. Therefore, costs as mentioned above are used. To measure utility, the quality of life measure is also used.

4th research question (process evaluation)

Feasibility of the planned intervention in terms of pre-treatment integrity and fidelity (dose of treatment) is assessed by questionnaires which the participating nurses have to fill after every pre-treatment session. The

certain steps taken during the intervention, the content of the discussion during the sessions, and the clients* active participation have to be documented in this semi-structured questionnaire. The structure will be based on the work of Steckler and Linnan (Steckler and Linnan 2002) and adapted to the specific situation of our study.

Also given the explicit emphasis in MI as a spirit rather than a technique(Rollnick, Butler et al. 2010), the check of treatment integrity and treatment fidelity is necessary. Therefore, the MI Treatment Integrity Code (MITI version 3.1)(Moyers, Martin et al. 2010) will be used. It has shown to be a cost-effective and reliable tool (!!! INVALID CITATION !!!) which is also a validated instrument to check MI-fidelity(Forsberg, Berman et al. 2008; Moyers, Martin et al. 2010) . Although the MITI is developed with the intention to be used in non-research settings(Moyers, Martin et al. 2010), Moyers et al. (2005) state that it also can be used in trials examining MI. Feedback during the training and during intervision sessions will be also given based on the MITI. Research has also shown that proficiency rating by skilled coders predicted treatment outcome (Miller and Mount 2001; Moyers, Martin et al. 2003; Madson and Campbell 2006). To be able to do so, all pre-treatment sessions are audio taped, and a random sample will be scored by the above mentioned MITI instrument.

5th research question (process evaluation)

Satisfaction in participants, and satisfaction and experiences with the intervention in nurses and rehabilitation consultants will be explored. Also

the perceived client-centeredness is assessed.

In participants, the satisfaction with the pre-pain rehabilitation treatment and the pain rehabilitation treatment will be assessed separately by means of a structured questionnaire. At the end of the pre-treatment (either MIP or ACC) and at the end of the rehabilitation treatment it will be assessed. Both questionnaires are rated on a 4-point Likert scale ranging from totally disagree (0) up to totally agree (4).

In the case of drop-out from the treatment, the participant is still asked for ratings on satisfaction with the (pre-)treatment and about reasons for drop-out from treatment. The information will be used to evaluate satisfaction with pain rehabilitation and of reasons for drop-out from treatment for the process evaluation. It has to be said that we are interested in reasons for dropping out from the treatment not about reasons for dropping out from the study. In the latter case, we do not ask the participant to give any reason for this.

The stage of change is assessed by the Multidimensional Pain Readiness to Change Questionnaire 2 (short version). It measures the chronic pain participants* readiness to change. The questionnaire is based upon the transtheoretical model of behavior change of Prochaska and DiClemente. The MPRCQ2-26 consists of 26 items and is scores on a 7-point Likert scale (Nielson, Jensen et al. 2003; Nielson, Jensen et al. 2008; Nielson, Armstrong et al. 2009). Psychometric properties are evaluated and appeared to be satisfactory (Nielson, Armstrong et al. 2009).

Client-centredness is evaluated by the Client Centred Care Questionnaire (CCCQ). The questionnaire was originally developed for the use in clients

receiving homecare(de Witte, Schoot et al. 2006). By making some minor revisions, it can also be used in the rehabilitation setting(Schoot, Friesen et al. 2010). It has shown good psychometric qualities(de Witte, Schoot et al. 2006).

In the participating nurses, experiences will be explored during the supervision meetings. The nurses are also asked to fill in a semi-structured questionnaire about their satisfaction and experiences with the intervention and related barriers and improvements at the end of the intervention.

**Secondary outcome**

Secondary outcomes of the first research question are motivation, adherence to the (pre)treatment, level of functioning, pain intensity, quality of life (SF-36), credibility of the treatment, self-efficacy, and self-reported main complaints.

Motivation is assessed by the Treatment Motivation Questionnaire (TMQ). The TMQ assesses intrinsic and extrinsic information about entering and remaining treatment(Ryan, Plant et al. 1995). It consists of 26 items representing the factors internal and external motivation, interpersonal help seeking and confidence in treatment. Items are slightly adapted to the rehabilitation context.

Adherence to the pre-treatment intervention (MIP and ACC) is computed by dividing the number of the intervention sessions that an individual participant has indeed visited and two offered pre-treatment sessions. Adherence to the rehabilitation treatment is computed by dividing the number of planned treatment sessions (which amount is tailored to the patients* needs) that an

individual participant has indeed visited by the number of indicated pain rehabilitation treatment sessions. Level of functioning will be measured by the Pain Disability Index (PDI) (Pollard 1984) which has shown good psychometric properties(Chibnall and Tait 1994). It will be used to assess the participants* self-reported level of functioning and disability resulting from chronic pain.
The PDI rates on an 11-point Likert scale ranging from 0 (no disability) to 10 (total disability) the degree of pain interference with functioning. Seven areas such as family/ home responsibilities and occupational activity are assessed. A total score is derived by summing up the item responses, thus the score range is 0 up to 70. Higher scores indicate more disability (Pollard 1984). A one-factor structure was confirmed and normative data are available(Chibnall and Tait 1994).
Pain intensity is assessed by a 10-cm Visual Analogue Scale (VAS). The VAS is a common and valid tool for measuring pain intensity (Revill, Robinson et al. 1976; Carlsson 1983).
Quality of life is also used for the cost-effectiveness analysis (CEA) and the cost-utility analysis (CUA) of research question 3. It is described there.
Credibility and expectancy is measured by the Credibility and Expectancy Questionnaire (CEQ)(Devilly and Borkovec 2000). The CEQ demonstrated good psychometric properties(Devilly and Borkovec 2000).
General self-efficacy is assessed by the Dutch General Self-efficacy questionnaire(Schwarzer and Jerusalem 1995).
In order to evaluate the change of the participants* self-reported main complaints, those are assessed by the questionnaire Patient Specific Complaints

(PSC)(Köke 2007) (Beurskens, de Vet et al. 1999). The participants select from a list 3 to 5 most important physical health complaints related to chronic pain(Beurskens, de Vet et al. 1999). It is sufficiently tested for patients with chronic musculoskeletal pain(Beurskens, de Vet et al. 1996).

Secondary outcome 2nd research question

Acceptance, flexible goal-adjustment, pain catastrophizing, pain-related fear (kinesiophobia), and depression are additionally taken into account as possible mediators of the relationship between (pre)treatment and outcome.

Acceptance is assessed by the 10-item Acceptance and Action Questionnaire-II (AAQ-II)(Bond and Hayes in preparation). The Dutch version has shown a high internal consistency and a good validity(Jacobs, Kleen et al. 2008). Answers have to be given on a 7-point Likert scale ranging from *never be true* up to *always true*.

Flexible goal-adjustment (FGA), an component of psychological flexibility is measured with the Tenacious Goal Pursuit and Flexible Goal Adjustment Scale Brandstädter and Renner Questionnaire(Brandtstadter and Renner 1990). The scale describes the tendency to adjust personal goals and standard to situational limitations. It consists of 15 items with belonging five possible answers ranging from *totally agree* up to *not agree at all*. Therefore, total scores range from 0 to 60. The scale*s internal consistency is satisfactory ( *= 0.80)(Brandtstadter and Renner 1990).

Pain-catastrophizing is assessed by the Pain Catastrophizing Scale-Dutch version (PCS-DV). 13 statements (items) have to be scored on a 5-point Likert

scale ranging from 0 (*not at all*) to 4 (*always*). An example of a statement is: *I anxiously want the pain to go away.* The total score is calculated by summing up the scores of the three subscales. The PCS has shown good psychometric characteristics (Osman, Barrios et al. 2000; Van Damme, Crombez et al. 2002), this is also valid for the Dutch version (DV).

Pain-related fear is measured by the Tampa Scale of Kinesiophobia (TSK). The TSK is developed to measure fear of movement/(re)injury during movement. It consists of 17 statements which have to be rated on a 4-point Likert scale ranging from *strongly disagree* to *strongly agree*. The TSK has predictive validity and is sufficient reliable (* =.77). The scale*s psychometric properties are good(Swinkels-Meewisse, Swinkels et al. 2003).

Depression is assessed by the Becks Depression Inventory (BDI)(Beck, Steer et al. 1988; Beck and R.A. 1993). The BDI is a well-known in pain research and a reliable, valid and widely used instrument(Beck, Steer et al. 1988).

# 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.

In the latest decennia, more evidence came available supporting the positive effect of behavioural therapy in chronic pain. The main assumption underlying the approach of behavioural therapy is that pain and resulting disability are not only influenced by biomedical factors, but also by psychological and social factors. In treatment, to this is referred as biopsychosocial approach(Gatchel,

Peng et al. 2007). Therefore, 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..
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 of the patient. Unfortunately, in the current rehabilitation care, non-adherence and drop-out are major problems. Adherence has been defined by the WHO as *the extent to which a person's behaviour * taking medication, following a diet, and/or executing lifestyle changes- corresponds with agreed recommendations from a health-care provider(Sabate 2003).

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).
It is known that adherence is influenced by multiple factors such as the health care provider- patient relationship, the patient*s self-efficacy to be able to make changes (Bandura 1997), and patients* satisfaction with improvement (Hirsh, Atchison et al. 2005).
Predictors for drop-out in low back pain rehabilitation are high level of pain severity (Carosella, Lackner et al. 1994; Lansinger, Nordholm et al. 1994), patients* beliefs and expectations about the success of a given treatment(Sloots, Dekker et al. 2010; !!! INVALID CITATION !!!), being less active in sports(Bendix, Bendix et al. 1998), having a high number of sick leave days before the start of the treatment (Carosella, Lackner et al. 1994; Lansinger, Nordholm et al. 1994; Bendix, Bendix et al. 1998), and a lower age(Carosella, Lackner et al. 1994) are all predictors for drop out.
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 (Curran, Williams et al. 2009).
In order to improve adherence and motivation to prevent drop-out, motivational interviewing (MI) has been proposed. MI was originally developed for problem drinkers(Miller 1983) and in the beginning applied in the addiction field only (e.g. (Skutle and Berg 1987; Heather, Rollnick et al. 1996). Miller and Rollnick, the founders of MI, defined it as *directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence*(Miller and Rollnick 1991). The overall goal is to increase the clients* intrinsic motivation to change and enhance behavioural change(Mesters 2009). A review on working mechanisms in MI found evidence for three constructs: Firstly, change talk and clients* experience of discrepancy

was related to better outcomes. Secondly, therapist MI-inconsistent behaviour was related to worse outcomes. Thirdly, the use of a decisional balance exercise showed also a strong association to better outcomes (Apodaca and Longabaugh 2009).

Nowadays, MI has also been applied in some studies with chronic pain conditions. 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). In 2010, a Cochrane review in interventions to improve adherence in chronic musculoskeletal pain indicated that those who got an exercise programme containing an additional motivation programme were more likely to attend the exercise classes(Jordan, Holden et al. 2010).
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.
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).

In this project MI is introduced as an add- on intervention before a rehabilitation programme for patients with chronic musculoskeletal pain. The project has 3 major goals.
First, we want to know whether MI, when used as add-on to a rehabilitation programme will lead to better adherence to treatment and less drop-out and as a consequence to better patient outcome. The (cost-) effectiveness of MI will be compared to an attention control.
Second, since MI is fairly new in chronic pain rehabilitation, the goal is to get insight into the working elements of MI in this setting. Depression, pain catastrophizing, pain related fear, treatment expectancy and credibility, acceptance, flexibility, motivation and treatment integrity are seen as possible mediators for MI. Partly because these were found previously for exposure and cognitive behavioural treatment for chronic pain (pain catastrophizing, pain related fear, flexibility, expectancy and credibility(Goossens, Vlaeyen et al. 2005; Smeets, Vlaeyen et al. 2006; Leeuw, Houben et al. 2007; Smeets, Beelen et al. 2008), and partly because these are identified as the basis elements of MI (motivation, change talk, etc.) (Apodaca and Longabaugh 2009).
Third goal is to assess the fidelity of the MI, since the impact of MI largely depends on performance of the MI intervention (Glasziou, Chalmers et al. 2010).

Thereby, also satisfaction of both clients and practitioners, client centeredness are important factors to take into account(Emmons and Rollnick 2001).

## Study objective

The primary objective of this current project is to study the (cost-) effectiveness of Motivational interviewing in non-specific musculoskeletal chronic pain patients who are indicated for pain rehabilitation treatment. It is hypothesized that an MI-based intervention facilitates the patients* preparedness regarding rehabilitation treatment following the biopsychosocial approach in terms of expectations and motivation.
As we are as well interested in the improvement of adherence and a decrease of drop-out in pain rehabilitation and in participation and functioning after rehabilitation, our study consists of two phases which each have different main purposes. During phase one, the pre-treatment phase till the standard screening, we are especially interested in the amount of drop-out caused by the patient and by means of the subsequent multiprofessional screening, and the level of the patient*s motivation. In the second phase, the follow-up, we are especially interested to evaluate participation and functioning.

The main research questions are:
1. What is the effectiveness of MIP(MI-based pre-treatment), compared to ACC (attention control condition) as an add-on to pain rehabilitation in terms of participation and treatment drop-out in patients with chronic non-specific musculoskeletal pain?
3. What are the mediating mechanisms of MIP versus ACC as an add-on to pain rehabilitation in patients with chronic non-specific musculoskeletal pain?
2. What is the cost-effectiveness of a MI-based pre-treatment (MIP), compared to control ACC (attention control condition) as an add-on to pain rehabilitation from a societal perspective?
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 unique features of the ACC and MIP conditions, below first the usual practice in the pain rehabilitation will be explained.

Usual practice in pain rehabilitation
In the usual practice in pain rehabilitation, patients will be selected for rehabilitation treatment by the consultant in rehabilitation medicine. In patients with insufficient knowledge about chronic pain, the consultant in rehabilitation medicine provides additionally more information about 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).
In order to judge a patient*s readiness for behavioural rehabilitation at the intake interview, the consultant in rehabilitation medicine will evaluate whether (1) medical and/or (2) motivational aspects are present and whether these will interfere with treatment progress (step 1). Additionally, a questionnaire about pain status, pain-related fear and other topics is taken at the intake moment.
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.
Between step 1 and 2 patients will be placed at a waiting list for on average 12 weeks.
At step 2, a standard multiprofessional screening for pain rehabilitation will take place. At these screening, different professionals such as occupational therapists, physiotherapists and psychologists evaluate the situation of the patient. Additionally, questionnaires such as about the severity of the pain, psychiatric co morbidity and pain-related fear are taken. The screening will result in an indication for pain rehabilitation or a reference outside the pain rehabilitation. At step 3 finally the rehabilitation can start. Directly after the treatment and after three months follow-up, other questionnaires are taken by the patient for evaluative reasons.

The situation during the PREPARE study
In the PREPARE study, the situation as illustrated in figure 1 will be hold.
The unique feature of the PREPARE study is that it adds on a pre-treatment before the ultimate decision for rehabilitation during the standard multiprofessional screening between step 1 and 2.
Instead of the consultant in rehabilitation medicine who gives education, this is delegatded to a trained nurse. Figure 2 illustrates the situation during the PREPARE study.

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 a medium to high level of motivation will be asked for a written consent to receive further information about the PREPARE study.
In the case of written consent, the study team will provide the patient with 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 ACC. For a detailed description of both interventions see section *treatment of subjects*.
During the waiting-list period, patients will receive the ACC or MIP intervention in order to prepare them for rehabilitation treatment.

Assessment periods
For the (cost-)effectiveness evaluation, measurements will be carried out at baseline (T0), after the MIP/ ACC (T1), after the multiprofessional screening (T2), after finishing pain rehabilitation treatment (T3) and six months after finishing rehabilitation (T4) (research question 1-3). To take into account drop-out from and adherence to the (pre-) rehabilitation treatment, process measures such as start date of the treatment and no show are also taken by the means of the administrative patient registry. Cost measurements will be carried out at three moments; T0, T2 and T4.
At T0 and T3, other questionnaires are added to the existing standard set of questionnaires which have to be undertaken by the patient.

The current study is divided in two parts, phase 1 and phase 2. Phase 1 consists of the two pre-treatment sessions (either MIP or ACC) and the standard multiprofessional screening.
As we are focusing on a suitable preparation for patients who are probably ambivalent regarding the bio psychosocial approach of behavioural pain rehabilitation treatment, the number of patients who are finally indicated for rehabilitation by the screening is of great interest (phase 1). Also loss to follow up during pre-treatment, and non-adherence to as well our pre-treatment intervention as the treatment, are for us of interest. Also, as an indirect effect, in the patient*s level of motivation we are interested.
Loss to follow up during treatment, non-adherence to as well our study as the treatment, and drop-out during the rehabilitation treatment are *additionally to our primary outcome measure participation - important process measures (phase 2).

**Intervention**

Common features of the MIP (intervention condition) and ACC (control condition) are that the participant is invited for two appointments with a nurse at the rehabilitation department. The duration of the two sessions in both conditions is approximately 45 minutes up to 1 hour.

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. This means that the nurse is instructed to respond in a proper way upon the actual stage of motivation of the patient which is measured by a checklist before the first session and also will become obvious during the session.
The nurse is directive within this process, but the patients* autonomy is strengthened and his or her right to decide is respected.
During the 1st appointment, a trustful relationship between patient 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 the ACC control condition
In the control condition patients 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 the consultant. 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). The ultimate goal of the attention control condition (ACC) is to provide the participant with information.
The content of the two sessions is as follows:
The 1st session starts with a general health education about topics related to chronic pain and treatment which are also part of the *Mastering pain*-book.
The 2nd session is guided by the same book about chronic pain and pain rehabilitation. Also information is provided regarding core elements of pain rehabilitation such as the bio psychosocial approach inherent rehabilitation treatment and the importance to exercise. Contrary to the MIP condition, no feedback is given related to the stage of change of the participant.

**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). Some questionnaires are currently already part of usual care, whereas others are integrated for this study only. To complete the questionnaire T0 and T2, T3, T4, 45 minutes are

required. T1 takes 20 minutes.

## 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

Non-specific chronic musculoskeletal pain syndrome.
Pain duration >3 months [16].
Age between 18 and 65 years.
Eligible and (as yet) indicated for outpatient pain rehabilitation treatment, main indication criteria: chronic pain.
Medium to high level of motivation for pain rehabilitation from the consultant*s perspective.
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.
Patient involved in litigation procedures.
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: | Will not start |
| Enrollment: | 194 |
| Type: | Anticipated |

## Ethics review

Not approved

| | |
|---|---|
| Date: | 03-08-2011 |
| Application type: | First submission |
| 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 | NL36029.068.11 |
| Other | TC= 2841 |