Chronic pain treatment:

from psychological predictors to

implementation

Han Samwel

2008

Mijn proefschrift gaat over pijn, chronische pijn. Over mensen die aan pijn lijden die niet overgaat. Over het moeten leven met pijn die chronisch is, vaak zonder nog traceerbare oorzaak;
Pijn begonnen als de druppel die valt in het water waarbij de druppel zelf opgaat in het water maar steeds grotere kringen veroorzaakt, lang voorbij het vallen.
Chronische pijn als de uitdijende gevolgen van een lang verdwenen druppel.

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Voor Singha

...en als eerbetoon aan
mijn jongste broer Peter,
een eenvoudig en prachtig mens,
die onlangs plotseling overleed...

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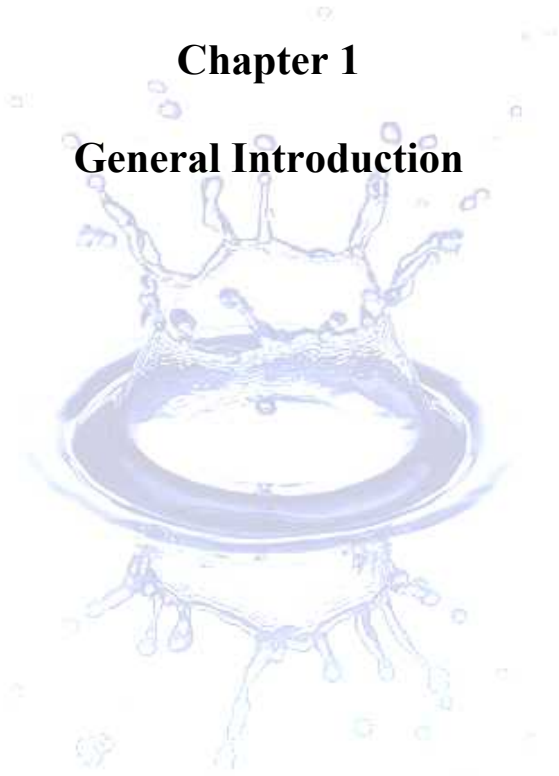
General Introduction



Chronic pain and its burden

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" [1]. The definition clearly refers to the concept of pain as a subjective experience with an interaction of various factors, including sensory, cognitive and behavioural processes. There is no consensus however when pain is to be defined as chronic, though. Most commonly, researchers place the threshold at three months[2] as it has been shown that patients who still experience persisting pain after more than twelve weeks are significantly more at risk of chronification. Moreover, within this initial period, the longer the pain lasts, the more emotions and cognitions, (newly learned) pain behaviour and pain consequences will make recovery more complex[3]. In this thesis chronic pain is conceptualised as pain of a benign origin that has persisted for more than 3 months and hence excludes pain sensations that occur as a direct consequence of an underlying pathophysiological process.

With prevalence in Western countries of 2 to 46%, chronic pain constitutes a major societal problem[4,5]. A recent European survey[5] reported a prevalence rate for pain lasting in excess of 6 months of 19% of the adult population, of whom 66% indicated to be suffering moderate (Numeric Rating Scale: 5-7) and 34% severe pain (Numeric Rating Scale: 7-10) with 46% of the patients reporting constant and 54% intermittent pain. Yet, only 2% of these patients were being seen by a pain specialist. Elliot et al.[6] found only 17% of all chronic pain patients to have no need for health-care services in order to be able to cope with their pain. In the Netherlands, the prevalence of chronic (>3 months) musculoskeletal pain was estimated up to 44.4% of the population[7] with 26% being reserved for chronic low back pain only[8].

Chronic pain has severe consequences for society and leads to high economic costs chiefly due to functional disability, absenteeism and job loss[6,8,9,10]. In the Netherlands, the costs associated with low back pain alone are estimated at 4 billion euros[8] with only 7% of the expenditure being related to medical interventions; the bulk (93%) concerns indirect costs owing to absenteeism and disability benefits.

Chronic pain strongly affects a patient's daily functioning and may lead to functional disability[6,8,9]. Functional disability is defined as limitations in daily activities and in the fulfilment of regular roles in daily life[11] e.g. work absenteeism and severe limitations self-care[6,9]. The condition may also affect mood[12]. The prevalence of depression in chronic pain patients depends on the definition of depression and ranges from 30 to 54%[13] and is thus even higher than in other chronic disease populations[2,12]. Depression and chronic pain are often observed as co-existing conditions but their interaction is not yet fully understood. Although depression was frequently studied preceding pain, in recent years there is a growing consensus that depression should be viewed as a consequence of persistent and inescapable pain and that patients with more severe pain are at risk

of developing more severe depression[14].
While biomedical factors have frequently been shown to have a limited influence on pain levels, functional disability and depression[15], there is relatively strong evidence that psychological factors do affect these outcomes in chronic pain patients and are at least as important for the patient's functioning as the pain itself [16]. Hence, in explaining the level of pain intensity, functional disability and depression in chronic pain and in addition to biomedical factors, a great deal of attention has been paid to the patients' psychological makeup[17,18,19,20,21].

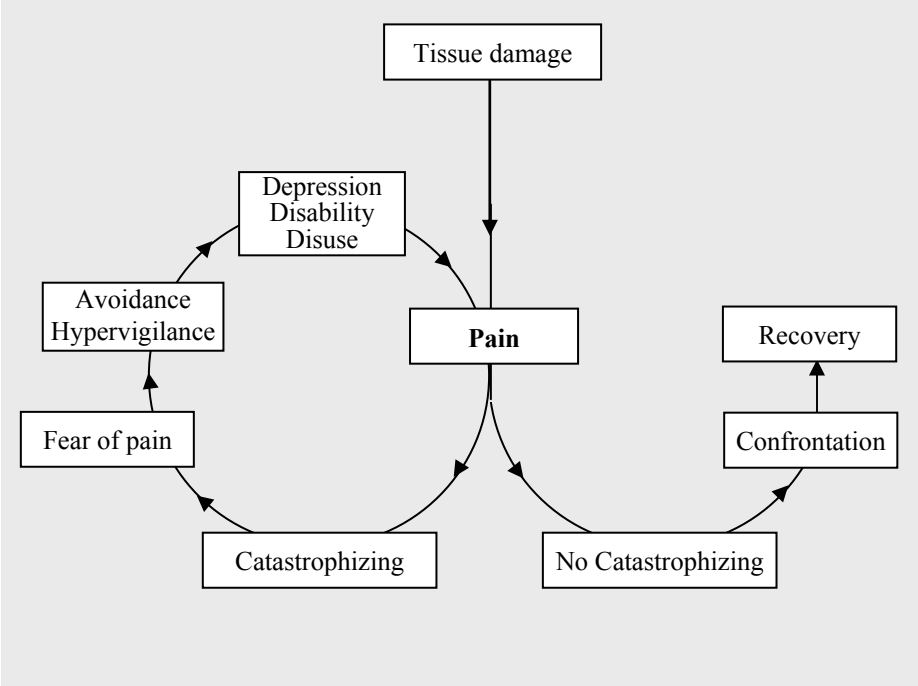


Figure 1: Fear-Avoidance Model (Vlaeyen et.al [37])

Psychological determinants of chronic pain

In recent decades, the fear-avoidance model (see Figure 1) has been studied for the prediction of the level of pain intensity, functional disability and depression and their course in chronic pain patients[22,23,24,25,26,27,28,29,30]. A central construct in this model is fear of pain. In the model fear of pain is thought to enhance avoidance behaviour with the fear of pain being based on the theory of kinesiophobia[22,24]. The construct refers to specific anxiety-related cognitions about the consequences of pain-related behaviour. In the learning history of pain, fear of pain functions as an anxiety response, directed towards the immediate consequences of active behaviour with regard to pain intensity. In the course of the pain problem, patients

may be caught in a vicious circle of fear, catastrophizing, avoidance behaviour and functional disability. In the fear-avoidance model, pain-avoidance behaviour is hypothesized as a mediator between fear of pain and negative pain outcomes[26,27,28,29,30].

The fear-avoidance model considers catastrophizing as an aggravating factor that amplifies the fear of pain and the subsequent avoidant behaviour. Catastrophizing is based on models of anxiety disorders and in this context refers to anticipated negative consequences of chronic pain in the future and the perceived lack of ability to cope with these consequences. Catastrophizing is defined as the tendency to magnify or exaggerate the threat value or seriousness of the pain sensation[31]. Although catastrophizing can be seen as adaptive in the short term, i.e. as an active, future-oriented, problem-focused attempt to escape from pain, it becomes maladaptive when the pain problem cannot be solved and becomes chronic. Recent research suggests that catastrophizing interacts with the social context and that the level of catastrophizing may fluctuate proportionate to the degree of satisfaction with the spouse's responses[32]. Its negative impact on the musculoskeletal and cardiovascular system may increase functional disability and undesirable physical consequences and result in limited functioning. There are numerous studies available that emphasize the major role catastrophizing plays in chronic pain[20]. Catastrophizing proved to be an important predictor of pain intensity[20,31], functional disability[31,33,34] as well as depression[32,35,36].

Besides catastrophizing, fear of pain has recently been studied as a cognitive predictor of pain outcomes. Fear-of-pain beliefs are proposed as maladaptive responses to the pain experience and are defined as patient-specific fears that physical activities will result in reinjury and consequent pain[30,37]. Several studies have shown fear of pain to predict pain intensity[39] and functional disability[27,38,40,41] in chronic pain samples, even when biomedical variables are controlled for. Several studies on low back pain provide support for the importance of fear of pain. In their experimental studies using various physical tasks Vlaeyen et al.[37,38] and Crombez et al.[27] found that fear of pain had a relatively substantial impact on the patients' performance levels. In their study with back-pain patients in primary care Klenerman and colleagues[42] found fear of pain in combination with other variables to predict functional disability one year after the onset of the pain complaints. In a study with a pain-free sample[18], the participants with heightened levels of fear of pain ran twice the risk of developing lower back pain in the following twelve months than their counterparts with lower-level or absent

Avoidance behaviour has gained broad support as an important behavioural predictor of both pain intensity and functional disability within the fear-avoidance model. The phenomenon is defined as a behavioural means of pain coping aimed at avoiding any exacerbation of pain and patterns include avoidance of movement, activity, social interactions and leisure pursuits. Avoidance behaviour (i.e. resting and retreating) is considered a maladaptive response to pain. Apart from avoiding

physical as well as social activities that are expected to aggravate their pain and suffering, patients are prevented from correcting their negative expectations of the consequences of activities through their avoidant behaviour and instead strengthen their maladaptive cognitions of catastrophizing and fear of pain. Several studies support the role of avoidance behaviour in regenerating, perpetuating or magnifying pain complaints, functional disability and depression in chronic pain patients. For example, in a cross-sectional study of 76 war veterans with chronic pain, Snow-Turek et al.[43] found that avoidance behaviour was closely related to depression. Brown et al.[44] demonstrated that in a prospective study evaluating patients suffering from rheumatoid arthritis passive cognitive and behavioural pain-coping strategies contributed to the level of depression after 6 months. Avoidance behaviour has also been shown to solely predict the pain intensity, functional disability and severity of depression in different chronic-pain populations cross-sectionally and over time[45,46,47]. Evers et al.[34,48] found that the level of avoidance of activity in recently diagnosed rheumatoid arthritis patients predicted their levels of functional disability after one and after three years.

The constructs of the fear-avoidance model, the mechanisms of fear of pain, catastrophizing and avoidance behaviour, are almost exclusively focused on the immediate, anticipated consequences of pain and the model's relevance for chronic pain is still under discussion. Firstly, the model originally focused on patients with musculoskeletal pain, especially low back pain, and the literature on the model's role in cohorts with other pain sites is more limited. Secondly, the fear-of-pain model has a value in explaining the transition of acute to chronic pain but there are indications that other factors may also have a contribution in the chronic phase of the pain problem[49]. As suggested by Pincus et al.[50], the question could be raised whether a more generalized attitude of helplessness, which is related to depression, might be more applicable in populations with long-term, heterogeneous pain, i.e. an acquired helplessness resulting from a longstanding history of unsuccessful pain coping. Based on the learned helplessness model of depression[51], helplessness implies a focus on generalized, long-term consequences of chronic pain in daily life. It refers to an adopted, attributional style with which people interpret negative events (e.g. chronic pain) and its consequences as uncontrollable, unpredictable and unchangeable and hence generalize the consequences to their daily functioning[51,52]. Helplessness is characterized by negative outcome expectancies and general, stable negative attributions ascribed to the condition. In pain patients, it may sustain or amplify avoidance behaviour and hence give rise to or perpetuate chronic pain, functional disability and depression.. In chronic pain patients helplessness may be an important consequence of their learning history. Anxiety and depression models hypothesize that situations from which one cannot escape, such as chronic pain, are perceived as a threat and will hence induce specific negative cognitions about pain and its negative consequences[53]. In the short term, these cognitions will mainly evoke anxiety responses (e.g. fear of pain); in the long

term, however, they may lead to a generalized cognition of helplessness and ultimately to a more passive behavioural coping and a subsequent maintenance or aggravation of the pain, functional disability and depression[54].

Numerous studies have demonstrated the great significance of helplessness as a risk factor for chronic pain: several cross-sectional studies, for example, demonstrated that it considerably accounted for the level of pain, functional disability and depression in various chronic pain samples[55,56,57,58,59]. Prospective studies on patients with rheumatoid arthritis also supplied support for a central role of helplessness, indicating a predictive value for the level of pain, functional disability and depression over time[52,60,61].

In addition to the mentioned negative cognitive and behavioural pain-coping factors, acceptance has recently been studied as a positive cognitive coping strategy in the face of chronic pain[52,62]. Acceptance is defined as stopping to fight against the pain, acknowledging that one has pain, and being able to make an effort to live a satisfying life despite the pain[52,62]. It has been shown to be predictive of better functioning in the longer term[52,62], and various authors have advocated the assessment of this positive, health-promoting variable in outcome studies[19,52,62]. Vowles et al.[63] further showed that increase in acceptance after CBT treatment predicted less pain and functional disability. Within the fear-avoidance model, as opposed to catastrophizing inducing fear of pain and avoidance of pain-provoking activities, acceptance is seen as a precondition to confront the pain, which will subsequently help improve functioning over time.

Taken together, there are strong indications that passive coping strategies of catastrophizing, fear of pain and avoidance behaviour, derived from the fear-avoidance model, helplessness (derived from the helplessness model), as well as acceptance as a possible health-promoting strategy affect pain intensity, functional disability and depression in various populations suffering from chronic pain. Consequently, in this thesis the fear-avoidance model was extended by the learned helplessness model and acceptance as a health-promoting cognitive behavioural factor as the conceptual basis for our studies of chronic pain patients.

Chronic pain treatment

There is increasing evidence that chronic pain patients tend to benefit from multidisciplinary treatment schemes, especially programmes combining cognitive-behavioural (CBT) and physiotherapy modules[14,64,65,66]. In their comprehensive review, Flor et al.[64] showed that multidisciplinary pain treatment was superior to monodisciplinary interventions on various outcome measures among which pain intensity, functional disability, depression and medication consumption although effects are commonly modest[19]. Moreover, treatment effects tend to remain stable over time[64,67,68]. Yet, the literature on the efficacy of multidisciplinary treatment still does not allow firm conclusions to be drawn as Flor et al.[64] could not isolate specific combinations of treatment modalities with superior treatment results,

rendering it difficult to compare the effectivity of the different pain treatment studies. However, most of the multidisciplinary interventions studied effects of specific pain sites (low back pain[64], musculoskeletal pain[69] or headache[70]) or specific groups of pain patients (e.g. geriatric patients[71]) facilitating interpretations of the treatments' comparative effectivity. To further generalize treatment effects in this thesis, we studied the effectivity of various pain treatments in heterogeneous groups of chronic pain patients using a multidisciplinary treatment allocation approach.

Large differences in treatment outcomes between individual pain patients impede a sound evaluation of the efficacy of the treatment under study. It is therefore imperative that patients that may benefit most of multidisciplinary treatment schemes are adequately identified[14]. Studies into the psychological predictors of treatment outcome may reveal patient characteristics that are essential for a proper selection of patients for specific treatment modalities, thus allowing an optimisation of overall treatment effects. Yet, empirical studies that have examined the relative predictive values of fear-avoidance factors, helplessness or acceptance in relation to the effects of multidisciplinary pain treatment approaches are scarce. The few studies that were directed at identifying cognitive-behavioural predictors at the start of treatment either yielded nonsignificant or inconsistent results[14,72,73], and those charting changes during multidisciplinary treatment found decreases in catastrophizing or helplessness to be related to decreases in pain intensity, functional disability, depression and medication consumption[74,75,76,77].

Aims, structure and outline of the thesis

The literature on chronic pain, as summarized above, indicates that fear-avoidance factors (catastrophizing, fear of pain and avoidance behaviour), helplessness and acceptance may have a predictive value in explaining pain outcomes and effectivity of chronic pain treatment. Consequently, the two main objectives of this thesis were to study cognitive-behavioural predictors of chronic pain during natural course and to identify predictors of the effects of multidisciplinary chronic pain treatments within the conceptual context of the fear-avoidance and learned helplessness models. Especially the cognitive-behavioural predictors of multidisciplinary pain treatment (including medical, paramedical and cognitive-behavioural modules) as delivered in the Pain Centre of the Radboud University Nijmegen were the subjects of study. In addition, we wished to learn more about referral practices for chronic pain patients in the primary-care setting in the Netherlands and also charted the satisfaction of the referring GPs with the treatments our pain clinic provided for their patients.

In *Part 1*, we look for predictive factors in a heterogeneous group of chronic pain patients and in Part 2 for potential predictors of the effects of medical and paramedical chronic pain treatments and those of the effects of a multidisciplinary allocation of pain treatment. We based our selection of potential predictors on the

fear-avoidance and helplessness models as these were in our view best suited to provide a valid explanation for pain outcomes after chronic pain treatment. Part 3 of the thesis charts the way local general practitioners (GPs) that referred patients to the Nijmegen Pain Centre judged the care the centre provided. In addition, the dissemination and implementation of a cognitive-behavioural treatment of chronic pain by primary-care psychologists is described. Finally, a summary and discussion of the various chapters is given.

Part 1 concerns the potential psychological predictors of chronic pain treatment outcomes. In *Chapter 2*, we investigate in a cross-sectional study the relative contribution of two fear-avoidance factors, viz. fear of pain and avoidance behaviour, and helplessness, to the level of pain intensity, functional disability and depression in a group of 169 chronic pain patients referred for treatment to the multidisciplinary Pain Centre of the Radboud University Medical Centre, the Netherlands. The main research question was whether helplessness contributed to the prediction of subjective pain levels, functional disability and depression beyond the two fear-avoidance factors. *Chapter 3* reports a longitudinal study into the relative contribution of the fear-avoidance factors, i.e. fear of pain, avoidance behaviour and catastrophizing, and helplessness to fluctuations in the functional disability after three months of a group of chronic pain patients waiting for pain treatment in the multidisciplinary pain centre. The central question in this study was whether helplessness would predict the patients' functional disability beyond the three fear-avoidance factors.

Part 2 describes the outcomes and the psychological predictors of medical, paramedical and cognitive-behavioural pain treatment approaches on the pain intensity, functional disability and depression in chronic pain patients treated at the Nijmegen pain centre. In *Chapter 4*, we explored the effects of an invasive medical procedure, i.e. radio frequency lesioning of the cervical spinal ganglion (RF-DRG), with the aim to establish whether pre-treatment cognitive coping factors of helplessness and catastrophizing, and physical and social dysfunctioning were predictive of change in the patients' post-treatment pain intensity. In *Chapter 5*, we studied the outcome predictors of Transcutaneous Electrical Nerve Stimulation (TENS) in a prospective, randomised, placebo-controlled trial in which we compared high-frequency TENS with sham TENS. We studied the question whether the cognitive factors of catastrophizing, helplessness and avoidance behaviour could predict change in the patients' pain intensity after a 14-day TENS treatment. In *Chapter 6*, we studied the effects of a multidisciplinary pain treatment allocation protocol in an heterogeneous intervention group of 110 chronic pain patients three months after the start of treatment, on their pain intensity, functional disability, depression and medication use. We compared these short-term effects with the outcomes of a 110-waitinglist control group. We, in addition, examined the predictive value of the fear-avoidance factors fear of pain, catastrophizing and avoidance behaviour, as well as helplessness and acceptance for the significant

outcomes.
In *Chapter 7*, we evaluated the longer-term, i.e. 12-month effects of a multidisciplinary allocation of pain treatment on the pain intensity, functional disability, depression and medication use in a heterogeneous group of 86 chronic pain patients. We also looked whether the 3-month changes in the patients' fear-avoidance factors (catastrophizing, fear of pain and avoidance behaviour), helplessness and acceptance predicted the significant 12-months' changes.
Part 3 evaluates Dutch referral practices for patients presenting with chronic pain and describes the implementation of a cognitive-behavioural pain treatment programme delivered by primary-care psychologists as based on the expertise of the Nijmegen Pain Centre of the psychological factors involved in the course of chronic pain. In *Chapter 8*, we examined the expectations of GPs of their referrals to the multidisplinary pain centre and analysed what aspects of the pain care contributed to the evaluation of the GPs of the care, the multidisciplinary pain centre provided for their chronic pain patients. In *Chapter 9*, we describe our endeavours to implement the current knowledge of the multidisciplinary pain centre of the psychological aspects involved in chronic pain, pain treatment and cooperation between psychologists and GPs in primary and secondary care settings. Psychologists practising in the catchment area of the pain centre who were interested in psychological pain treatment were trained in diagnosing chronic pain and delivering a cognitive-behavioural treatment protocol.
Lastly, the main results of the different studies are summarised in *Chapter 10*, the final chapter of the thesis, where also the theoretical and clinical implications are discussed.

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PART 1

Psychological factors in chronic pain

Chapter 2

The role of helplessness, fear of pain and passive pain-coping in chronic pain patients.

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Abstract

Objective: The goal of this study was to examine the relative contribution of helplessness, fear of pain and passive pain-coping to pain level, disability and depression in chronic pain patients attending a Multidisciplinary Pain Centre.

Methods: One hundred and sixty-nine chronic pain patients who had entered treatment at the Multidisciplinary Pain Centre completed various questionnaires and a pain diary.

Results: Helplessness, fear of pain and passive pain-coping strategies were all related to the pain level, disability and depression. When comparing the contribution of the predictors in multiple regression analyses, helplessness was the only significant predictor for pain level. Helplessness and the passive behavioural pain-coping strategies of resting significantly predicted functional disability. The passive cognitive pain-coping strategy of worrying/catastrophizing significantly predicted depression.

Conclusion: These findings indicate a role for helplessness and passive pain-coping in chronic pain patients and suggest that both may be relevant in the treatment of pain level, functional disability and/or depression.

Introduction

Chronic pain can have multiple consequences for patients in daily life, such as limiting their daily functioning and causing heightened levels of depression[1,2,3,4]. While biomedical factors have frequently been shown to have a limited influence on pain level, functional disability and depression[2], there is relatively strong evidence that psychological factors can affect these outcomes over time in chronic pain patients.

In recent decades, the Fear-avoidance model has been studied as an explanation for the level of disability and depression and their course in chronic pain patients[5,6,7,8,9,10,11,12,13]. A central concept in this model is pain-avoidance behaviour[5,7,8,9,11,12]. Avoidance behaviour includes avoidance of movement, activity, social interactions and leisure pursuits. Avoidance behaviour (such as passive behavioural coping strategies of resting and retreating) is considered a maladaptive response to pain. Patients avoid physical as well as social activities that are expected to cause an increase in pain and suffering. Moreover, avoidance behaviour may prevent patients from correcting their negative expectations of the consequences of activities and strengthen the passive cognitive coping strategy of worrying. Worrying is based on models of anxiety disorders and refers to a tendency to prioritise the processing of threatening material, interpret ambiguous stimuli in a threatening way[14]. Although worrying/catastrophizing can be supposed to be adaptive in the short-term, since it can be characterized as an active future oriented problem-focused attempt to escape from pain, it becomes maladaptive when the pain problem cannot be solved and becomes chronic. In the specific situation of chronic pain as an uncontrollable and inescapable situation, the construct of worrying is similar to catastrophizing as it refers to ruminating about chronic pain and the consequences of chronic pain in the future[15,16]. In time, avoidance behaviour and worrying/catastrophizing are assumed to lead to a considerable reduction in the level of physical and psychological functioning. Their negative impact on the musculoskeletal and cardiovascular system may increase functional disability and undesirable physical consequences and result in limited functioning.

Several studies support the role of avoidance behaviour and worrying/ catastrophizing for pain, functional disability and depression in chronic pain patients. For example, in a cross-sectional study on 76 veterans with chronic pain, Snow-Turek et al.[17] found that passive pain-coping, including avoidance behaviour and worrying/catastrophizing, were closely related to depression. In a prospective study, Brown et al.[18] demonstrated that passive pain-coping contributed to the level of depression after 6 months in rheumatoid arthritis patients. Avoidance behaviour and worrying/catastrophizing have also been shown to solely predict the pain level, functional disability and distress in different chronic pain populations cross-sectionally and over time[19,20,21]. Finally, Evers et al.[22,23] found that the level of functional disability after one and three years in recently diagnosed rheumatoid

arthritis patients could be predicted by the use of the passive coping strategies of both avoidance of activity and worrying/catastrophizing. Taken together, there is considerable evidence that passive cognitive and behavioural pain-coping negatively affect pain level, functional disability and depression in various pain patients. In the Fear-avoidance model, fear of pain beliefs are hypothesized as a maladaptive response to the pain experience[13], which leads to avoidance behaviour. Fear of pain is based on the theory of kinesiophobia[6] and can be defined as patients' specific fear that physical activities will result in reinjury and consequent pain[24]. So the construct refers to specific anxiety-related cognitions about the consequences of pain-related behaviour. In the learning history of pain the fear of pain by patients functions as an anxiety response, directed towards the immediate consequences of active behaviour with regard to pain intensity. In the course of the pain problem, patients may be caught in a vicious circle of fear, worrying/catastrophizing, avoidance behaviour and functional disability[13]. Several studies on low back pain provide support for the importance of fear of pain. Vlaeyen et al.[24] and Crombez et al.[25] found that fear of pain had a relatively substantial impact on the level of performing physical tasks in experimental studies.

In a study with back pain patients in primary care[26], fear of pain in combination with other variables was found to predict functional disability one year after the onset of pain. In another study[27] with a pain-free sample, subjects with heightened levels of fear of pain ran twice the risk of developing low back-pain in the following twelve months.

Constructs of fear of pain and worrying/catastrophizing focus relatively closely on the immediate, anticipated consequences of pain. The question could be raised whether a more generalized attitude of helplessness might be more applicable in populations with long term pain, due to an enduring learning history of unsuccessfully coping with pain. Based on the theory of learned helplessness model of depression[28], helplessness implies a focus on generalised, long-term consequences of chronic pain in daily life. Helplessness refers to an attributional style, explaining negative events such as chronic pain and its consequences as uncontrollable, unpredictable and unchangeable and generalizing these consequences to daily functioning[22,28]. Helplessness is characterized by negative outcome expectancies and general, stable negative attributions ascribed to the condition. In pain patients, it may further contribute to avoidance behaviour and hence may result in chronic pain, functional disability and depression. A considerable number of studies have demonstrated the major role of helplessness as a risk factor for pain, functional disability and depression in chronic pain patients. For example, several cross-sectional studies demonstrated that helplessness accounted considerably for the level of pain, functional disability and depression in various chronic pain samples[29,30,31]. Prospective studies on patients with rheumatoid arthritis supply further support the central role of helplessness,

indicating a predictive value for the level of pain, functional disability and depression over time[32,33,34].

The extent to which helplessness is useful in explaining pain, functional disability and depression beyond fear of pain and passive coping in chronic pain is a question that may be raised. Helplessness may be an important consequence of the learning history in chronic pain patients, particularly in patients with longstanding pain. Anxiety and depression models hypothesize that situations from which one cannot escape, such as chronic pain, are perceived as a threat and will induce specific negative cognitions on pain and their negative consequences[35]. These cognitions will in the short term induce anxiety reactions but may result in a generalized cognition of helplessness and ultimately lead to more depression, functional disability and pain[36]. To our knowledge, there is no available study that has examined the relative contribution of helplessness, fear of pain and passive pain-coping for the prediction of the pain level, functional disability and depression in chronic pain patients. The goal of the present cross-sectional study was to clarify the relative contribution of helplessness, fear of pain and passive pain-coping to the level of pain, functional disability and depression in chronic pain patients entering for treatment at a multidisciplinary pain centre.

Patients and Methods

Patients

Study participants were recruited from patients who were accepted for treatment at the Multidisciplinary Pain Treatment Centre of the Radboud University Medical Centre in Nijmegen, the Netherlands. In order to qualify for inclusion in the study, patients had to be at least 18 years old and their pain problem had to be present for more than 3 months. The sample consisted of patients with unexplained pain for whom no biomedical cause could be identified. Exclusion criteria were cancer-pain or other biomedical causes, serious psychiatric disorders that could interfere with treatment and/or the inability to read or write Dutch. All patients who were accepted for treatment and meeting the criteria from November 1999 to January 2001 were asked to participate. From the total sample of 192 patients, 169 patients (88%) agreed to participate in the study.

The average age of the participants was 47.1 years (SD 13.9, range 18-86). Most of the patients were women (63.9%) and married or living with a partner (79.1%). Twelve percent had completed a primary education, and 71% had finished secondary education (7 and 12 years mean duration of formal education, respectively). Patients reported pain at the following pain locations: back: 60 (35.5%), legs: 45 (26.6%), neck and shoulders: 39 (23.1%), arms: 15 (8.9%), head and face: 9 (5.3%), belly: 7 (4.1%), breast: 7 (4.1%), pelvis: 5 (3.0%). In total 18 patients (10.7%) reported pain at 2 sites. Mean pain duration was 59.9 months (SD 70.1) with a range of 3-420 months.

Study design

After acceptance for treatment at the Multidisciplinary Pain Treatment Centre, patients were sent a booklet of questionnaires and a pain diary. Patients were asked to complete the questionnaires and diary for 7 days and send them back to the hospital.

Measures

Pain Intensity

Study participants were asked to rate their pain on a 10-centimeter Visual Analogue Scale for 7 days at 3 points in time each day. The Pain VAS scale ranged from no pain at all to the worst pain ever experienced. Twenty-one pain ratings were recorded for every patient and the average pain level was calculated on the basis of these ratings. Multiple VAS ratings have been shown to be more reliable and valid for measuring average pain intensity than a single rating[37]. Cronbach's Alpha in our study was 0.96.

Functional disability

Functional disability was measured with the Dutch version of the Pain Disability Index (PDI)[38,39,40]. The PDI was developed as a brief, self-report indicator of pain-related disability[38]. It was constructed as a 7-item questionnaire, which is scored on a scale of 0 (no disability) to 10 (total disability). The items ask for the level of limitations in the total range of role functioning: family/home responsibilities, recreation, social activities, occupation, sexual behaviour, self-care and life-supporting activities. Reliability and validity were judged as satisfactory[39,40]. The average level of the items scored was used to calculate the disability index. Cronbach's Alpha in our study was 0.86.

Depression

Depression was measured with the depression scale of the Dutch version of the Symptom Checklist-90 (SCL-90)[41,42], measuring 16 symptoms of depression, which are rated on a 5-point scale (1: not at all to 5: very much). Representative items are: "feeling worthless" and "feeling desperate about the future". The reliability and validity were judged as satisfactory[41,42]. Cronbach's Alpha in our study was 0.92.

Fear of pain

Fear of pain was measured with the Dutch version of the Tampa Scale of Kinesiophobia (TSK)[24,43], measuring fear of increasing pain and injury by physical activity. The questionnaire consists of 17 items, which are scored on a 4-point scale (1: highly disagree to 4: totally agree). Representative items are: "For someone in my condition, it is advisable not to be physically active", "My pain means there is physical damage". The level of pain-related fear is calculated on the basis of the total score. The TSK proves to be a valid instrument for measuring pain-related fear[24,43,44]. Cronbach's Alpha in our study was 0.85.

Passive pain-coping

Passive pain-coping was measured with the Pain Coping Inventory (PCI)[22,45,46], which measures 3 passive cognitive and behavioural coping strategies when dealing with pain. Both reliability and validity are judged as satisfactory [22,45,46]. The PCI is rated on a 4-point Likert scale (1: rarely or never to 4: very frequently). Cognitive passive coping was assessed on the basis of worrying/catastrophizing (9 items). Representative items are: "I start worrying when in pain" and "I think that the pain will worsen." For worrying/catastrophizing, Cronbach's Alpha in our study was 0.76. Behavioural passive coping was assessed with two scales, retreating and resting (7 and 5 items, respectively). Representative items for retreating are: "When I am outdoors, I try to return home as soon as possible" and "I retreat to a restful environment.". For retreating, Cronbach's Alpha in our study was 0.74. Representative items for resting are: "I quit my activities" and "I rest by sitting or lying down.". For resting, Cronbach's Alpha in our study was 0.81.

Helplessness

Helplessness was measured with the Helplessness scale of the Illness Cognition Questionnaire (ICQ), measuring different cognitions about the way patients think about and give meaning to their chronic illness[34]. In order to make a comparison possible with other pain-related predictors of passive pain-coping and fear of pain, the term "illness" in the ICQ was replaced by "pain". The Helplessness-items of the ICQ are: 1: my pain frequently makes me feel helpless. 2: my pain limits me in everything that is important to me. 3: my pain controls my life. 4: because of my pain, I miss the things I like to do most. 5: my pain prevents me from doing what I would really like to do. 6: my pain makes me feel useless at times. The items are rated on a 4-point scale (1: not at all to 4: completely). The reliability and validity of the ICQ were found to be highly satisfactory[34]. Cronbach's Alpha in our study was 0.84.

Statistical analysis.

Pearson correlation coefficients were calculated to explore the interrelations between helplessness, fear of pain and passive pain-coping strategies and the outcome measures of pain, functional disability and depression. Sequential regression analyses were then performed with pain level, functional disability and depression as dependent variables.

The following independent variables were entered in the sequential regression analysis: helplessness, fear of pain and passive pain-coping were entered in consecutive steps after controlling for demographic variables, physical and psychological functioning (functional disability and depression for pain, pain and depression for functional disability, pain and functional disability for depression). The entry order of helplessness, fear of pain and passive pain-coping strategies was also changed to study the single contribution of the predictors after controlling for baseline levels of pain, functional disability and depression.

Results

In Table 1 the means and standard deviations of all variables for all subgroups (back pain, leg pain, neck/shoulder pain other pain locations and more than one pain location) are presented. Since there were no significant differences between any of these subgroups on any of the measures, analyses were done for the whole sample. When studying relationships between predictors (see Table 2), the constructs of helplessness, fear of pain and passive pain-coping strategies were found to be moderately associated (between .24 and .50). In relation to the outcome measures (see also Table 2), helplessness, fear of pain and passive pain-coping strategies of worrying/catastrophizing, retreating and resting were significantly positively correlated with pain level (between r=.17 and .38), functional disability (between r=.34 and .62) and depression (between r=.17 and .56).

Table 1: Means and standard deviations for the total sample and the subgroups of back pain, neck/shoulder pain, leg pain, other pain locations and more than one pain location of all measures.

	Total Sample n=169		**Back Pain** n=48		**Leg Pain** n=41		**Neck/ Shoulder Pain** n=26		**Other Pain locations** n=36		**More than one Pain location** n=18	
	M	sd	M	sd	M	sd	M	sd	M	sd	M	sd
Pain	54.3	19.9	56.6	16.2	56.9	18.7	57.0	20.4	51.0	15.6	51.6	17.1
Disability	4.2	1.9	4.8	1.8	4.3	2.0	5.4	1.9	4.3	1.5	4.7	1.8
Depression	24.4	6.9	27.4	11.7	24.6	14.7	32.6	7.5	27.0	8.9	26.1	7.9
Helplessness	14.6	4.7	15.6	4.2	14.1	4.0	16.2	5.1	14.5	3.7	16.3	3.7
Fear of pain	39.3	7.7	38.7	9.0	39.3	9.9	39.7	7.8	38.0	8.0	36,6	7.7
Pass. pain-coping												
- worrying/ catastrophizing	2.0	0.5	2.2	0.5	2.0	0.5	2.2	0.5	2.2	0.5	2.1	0.5
- retreating	1.5	0.5	1.5	0.4	1.5	0.5	1.8	0.5	1.6	0.5	1.5	0.4
- resting	2.5	0.6	2.6	0.6	2.5	0.8	2.7	0.6	2.6	0.7	2.6	0.6

All outcome variables were significantly correlated, except pain and depression. Finally, demographic variables and pain duration were overall not significantly related to the outcome measures. Only male sex (r=-.17, p<.05), age (r=-.15, p<.05) and education level (r=-.16, p<.05) were marginally negatively related to depression.

The relative contributions of fear of pain, helplessness and passive coping to the pain level, disability and depression were subsequently analysed with sequential regression analyses.

Table 2: Correlates of pain, disability, depression, helplessness, fear of pain and passive pain-coping.

	Pain	Disability	Depression	Helplessness	Fear of pain	Worrying	Retreating
Disability	.36**						
Depression	.11	.40**					
Helplessness	.38**	.62**	.40**				
Fear of pain	.24**	.37**	.24**	.50**			
Pass. pain-coping							
- worrying/ catastrophizing	.17*	.34**	.56**	.45**	.43**		
- retreating	.20*	.41**	.43**	.38**	.36**	.49**	
- resting	.21*	.47**	.17*	.48**	.37**	.24**	.26**

** p < .05, **p < .01*

First, the contributions of demographic variables (gender, age, education) and pain duration were analysed by entering them as independent variables. Results indicated that these variables did not explain any significant variance. Consequently, demographic variables and pain duration were no longer entered in the regression analysis. The regression analyses for the different outcome measures of pain, functional disability and depression were conducted with helplessness, fear of pain and passive pain-coping as independent variables, after controlling for baseline levels of pain, functional disability and depression in all analyses (see Table 3).

Pain level. After controlling for the level of functional disability and depression, helplessness at step 3 added 6% of the variance (F-change=9.88, p<.01). Fear of pain and passive coping strategies did not significantly add further variance. The results did not change when entering fear of pain or passive pain-coping at step 3, fear of pain and passive pain-coping still did not significantly contribute any variance. Beta coefficients for the whole model demonstrated that only helplessness significantly contributed to pain level (t=2.63, p<.01).
Disability. After controlling for pain level and depression at step 1 and 2, helplessness at step 3 explained an additional 8% of the variance (F-change=44.47, p<.001). Fear of pain did not significantly explain additional variance for disability at step 4. The results did not change when entering fear of pain at step 3. Passive pain-coping explained another 6% at step 5 (F-change=4.92, p<.01). When entering passive pain-coping at step 3, it significantly predicted 8% of the variance (F-change=18.14, p<.001). However, helplessness still explained 6% at step 4 (F-change=14.22, p<.001). Beta coefficients for the whole model showed that helplessness (t=3.77, p<.001) and the passive pain-coping strategy of resting (t=3.77, p<.001) significantly predicted functional disability.

Table 3: Hierarchical regression analyses of pain, disability and depression

Order of entry	**R2 Change**	**Beta**	**Order of entry**	**R2 Change**	**Beta**	**Order of entry**	**R2 Change**	**Beta**
Dep. variable: Pain level			**Dep. variable: Disability**			**Dep. variable: Depression**		
1. Disability	.12***	.18	1. Pain level	.12***	.14	1. Pain level	.01	-.07
2. Depression	.00	.16	2. Depression	.10***	.24**	2. Disability	.10***	.18*
3. Helplessness	.06**	.27**	3. Helplessness	.08***	.22**	3. Helplessness	.06**	.07
4. Fear of pain	.00	.00	4. Fear of pain	.00	.04	4. Fear of pain	.01	-.01
5. Pass. pain-coping	.00		5. Pass. pain-coping	.06**		5. Pass. pain-coping	.28***	
- worrying/ catastrophizing		-.03	- worrying		.04	- worrying		.55***
- retreating		.05	- retreating		.04	- retreating		.11
- resting		-.00	- resting		.27***	- resting		-.11
Total R^2	.18			.36			.46	

** p < .05, **p < .01, ***p< .001*

Depression. After controlling for pain and functional disability at step 1 and 2, helplessness at step 3 explained an additional 6% of the variance in depression (F-change=9.72, p<.01). Fear of pain did not significantly explain additional variance for depression at step 4. In addition, when fear of pain was entered at step 3 no significant result was obtained. Passive pain-coping in step 5 explained an additional 28% of the variance (F-change=25.14, p<.001). When helplessness was entered at step 4, and passive pain-coping at step 3, passive pain-coping explained 33% of the variance (F-change=30.06, p<.001). However, helplessness still significantly explained 3% of the variance (F-change=4.45, p<.01). Beta coefficients for the whole model indicated that only the cognitive coping strategy of worrying/catastrophizing significantly explained depression (t=7.29, p<.001).

Discussion

The purpose of the study was to examine the role of helplessness, fear of pain and passive pain-coping in pain level, functional disability and depression in chronic pain patients.

Firstly, the study showed that in a heterogeneous chronic pain population helplessness and passive pain-coping strategies have a greater contributing value than fear of pain. Secondly, it showed that pain level, functional disability and depression are explained by different predictors. Pain level is best predicted by helplessness, functional disability is best predicted by helplessness and the passive behavioural coping strategy of resting, and depression is best predicted by the passive cognitive coping strategy of worrying/catastrophizing.

Helplessness appeared to be the strongest contributor to functional disability and pain level, independent of fear of pain and passive pain-coping. The central role of helplessness is in line with findings from other studies[29,30,31,32,33,34]. Independent of helplessness, the passive behavioural pain coping strategy of resting additionally explained functional disability. This corresponds with findings from previous studies showing a relationship between passive pain coping and functional disability[22,47,48,49], underscoring the hypothesis that avoidance behaviour is an important predictor for functional disability. Finally, the passive cognitive pain coping strategy of worrying/catastrophizing largely explained levels of depression, in addition to helplessness. This matches findings from other studies[50] that worrying/catastrophizing has additional value in explaining depression beyond other predictors. This finding is also consistent with the great amount of studies, which emphasize the close relation between worrying/catastrophizing and depression in chronic pain patients[2,19,21,51,52,53]. Together, these findings indicate that helplessness is an important factor for explaining pain level and functional disability. Passive behavioural coping is an additional factor for explaining functional disability, while the passive cognitive coping of worrying/

catastrophizing is important for explaining depression. Fear of pain had no value for explaining any of the outcome variables in addition to helplessness and passive pain coping. This finding seems to be inconsistent with other studies, which indicate that fear of pain contributes to the prediction of functional disability. A possible explanation for this finding could be that the construct of fear of pain might only apply to musculoskeletal pain[9,11]. In order to test this hypothesis, post hoc analysis was performed to analyse the TSK scores for different subgroups (back pain, neck/shoulder pain, leg pain and other pain locations). For the purpose of this analysis, patients with more than one pain location were excluded. An independent samples T-test revealed no significant differences between the different subgroups in the level of TSK, indicating that fear of pain is similar common in pain patients with different pain locations. Since fear of pain is supposed to be particularly relevant in back pain, post hoc analyses of the regression analyses were additionally performed with back pain patients only (n=60). Results showed that the beta coefficients of fear of pain for pain level, functional disability and depression were also nonsignificant in this sub sample. Instead, the same contributors were found as in the main sample, i.e. helplessness had a unique and significant predictive value for pain level and functional disability. In addition, resting contributed most to the level of functional disability and worrying/catastrophizing had the greatest value for explaining depression. Overall, these results suggest that the main contributing factors to pain level, functional disability and depression in chronic pain patients are their view of the uncontrollability and negative outcome expectation of their condition (helplessness) together with passive pain coping (avoidance of activity and worrying/catastrophizing), and not their fear of increasing pain and injury by physical activities (fear of pain). However, prospective and experimental studies are needed to further clarify the role of helplessness, fear of pain and passive pain-coping, as well as the role of other possible relevant fears (e.g. fear of functional disability or fear of disease progression) in various populations of patients with chronic pain.

A number of limitations of our study should be acknowledged. This is a cross-sectional study and therefore conclusions about causal relationships cannot be drawn. Secondly, the sample of pain patients is heterogeneous. Patients with heterogeneous pain sites may have different limitations in daily life, treatments and relevant fears. In addition, all patients were included in a specialized University Pain Clinic. In the Netherlands, chronic pain patients first start treatment in the pain ward of a general hospital. Patients may only be referred to a University Pain Centre when their pain problem has not been solved to a satisfying extent. Accordingly, the sample of pain patients in our study might only be representative for patients with complex pain problems who seek treatment in a specialized pain centre. Finally, the study is based on self-report measures. This means that all variables were subjectively measured by questionnaires and this may have

implications for the internal validity of the study as there may be an overlap in the constructs, measured in the study.

When the relationships found in our study will be supported by future prospective and experimental research, specific recommendations for treatment modules may be drawn. Our findings suggest that helplessness and passive pain-coping are important factors in patients with chronic pain, and it may be relevant to examine the presence of helplessness and passive pain-coping in chronic pain patients in the diagnostic phase of pain treatment and to integrate the treatment of these process variables in outcome-specific treatment modules[50,54,55].

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Chapter 3

The role of fear-avoidance and helplessness in explaining functional disability in chronic pain: a prospective study.

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Abstract

Objective: Based on Fear-avoidance and Helplessness models, the relative contribution of fear-avoidance factors (fear of pain, avoidance behaviour and worrying) and helplessness was examined to fluctuations in functional disability in chronic pain patients.

Methods: One hundred and eighty-one chronic pain patients completed various questionnaires and a pain diary after acceptance for treatment at an Interdisciplinary Pain Centre and three months later.

Results: Fear of pain, avoidance behaviour and helplessness at baseline all predicted functional disability after three months. When comparing these predictors in stepwise regression analyses, helplessness contributed to the prediction of change in functional disability beyond fear of pain. Of all predictors, avoidance behaviour most strongly predicted change in functional disability.

Conclusion: Findings support a role for factors of both the fear-avoidance and the helplessness model, and suggest a central role for avoidance behaviour in functional disability in chronic pain patients, waiting for treatment.

Introduction

Chronic pain is a major problem in the community with prevalence between 2-46% in Western countries, leading to high economic costs mainly as a consequence of functional disability[1,2,3]. In addition to biomedical factors, a great deal of attention has been given to psychological factors in explaining the level of functional disability in chronic pain[4,5,6]. Functional disability is defined as limitations in daily activities and in the fulfilment of regular roles in daily life[7].

In the last decades, the Fear-avoidance model was supposed to play a central role in explaining functional disability for subacute and chronic pain[8,9]. The Fear-avoidance model is theoretically based on anxiety cognitions, particularly fear of pain, which affect catastrophizing about the painful consequences of activities and enhance avoidance behaviour. In the acute phase of the pain problem, catastrophizing about the consequences of pain may enhance specific anxiety related cognitions (fear of pain) that movements/activities will lead to reinjury and pain and may subsequently induce avoidance behaviour which in turn will lead towards functional disability and depression. Fear of pain refers specifically to the fear that activity will lead to an increase in pain[9], based on the theory of kinesiophobia[10,11]. So, the construct refers to specific anxiety-related cognitions about the consequences of pain-related behaviour. In the learning history of pain, fear of pain functions as an anxiety response, directed towards the immediate consequences with regard to pain intensity. Fear of pain in turn is supposed to initiate catastrophizing and avoidance behaviour[9]. Fear of pain and avoidance behaviour are reinforced by the experience that it is a way to limit the pain but in the chronic phase they lead to increased functional disability[9,10,12,13,14]. Many studies have shown the empirical validity of the fear-avoidance model. For example, fear of pain has been shown to play an important role in the development of back pain and lower levels of physical functioning[15,16] and to predict future functional disability and work status in both subacute and chronic pain patients[17,18,19,20]. Moreover, the role of avoidance behaviour[21,22] and worrying/catastrophizing[22.23] in the development and maintenance of chronic pain and functional disability was widely supported.

However, in the chronic phase of the pain problem, the ongoing experience of unsuccessful coping may also induce depressogenic cognitions of helplessness in accordance with the learned helplessness theory[24,25,26] and act as an additional negative cognition as activities are not expected to enhance better overall functioning and in time may lead to further increase in functional disability and depression[27]. Helplessness is defined as an attributional style, explaining negative events such as chronic pain and its consequences as uncontrollable, unpredictable and unchangeable and generalizing these consequences to daily functioning[26,28], possibly enhancing avoidance behaviour and functional disability in time. In contrast to both fear of pain and worrying/catastrophizing, helplessness is directed towards coping with the present situation in stead of possible future events and is

focused on general functioning. So in time, helplessness may gain significance over fear of pain as controlling pain seems not possible and consequences of the chronic pain condition in daily functioning appear inescapable. This means that, next to fear-avoidance factors, the learned helplessness model of depression may have an additional important role in explaining fluctuations in chronic pain functional disability[28,29]. Both cross-sectional and prospective studies support the role of helplessness in predicting functional disability in chronic pain[28,30,31,32]. However, there is only limited knowledge about the relative role of fear-avoidance factors and helplessness in chronic pain functional disability and whether they both may affect the maintenance of functional disability. In this study, predictors of both models are integrated in order to examine their relative and independent contribution to the fluctuations of functional disability in time. To our knowledge, this is the first prospective study, examining the role of the fear-avoidance model and the helplessness model in chronic pain functional disability in one study.
The goal of the present prospective study was to clarify the role of the fear-avoidance model (i.e. fear of pain, avoidance behaviour and worrying/ catastrophizing) and the helplessness model in explaining the short-term fluctuations in functional disability in chronic pain patients waiting for treatment at a multidisciplinary pain centre. It was hypothesized, that helplessness would contribute to the prediction of fluctuations in functional disability beyond fear-avoidance factors.

Patients and Methods

Patients

Study participants were recruited from patients who were accepted for treatment at the Interdisciplinary Pain Treatment Centre of the Radboud University Nijmegen Medical Centre, the Netherlands. In order to qualify for inclusion in the study, patients had to be at least 18 years old and their pain problem had to be present for more than 3 months. Exclusion criteria were cancer-pain or other biomedical causes such as rheumatoid arthritis, serious psychiatric disorders that could interfere with treatment and/or the inability to read or write Dutch. In total 181 patients meeting these criteria participated in the study.
The average age of the participants was 48.7 years (sd=12.9, range=18-79). Most of the patients were women (64.1%). The majority of the patients (76.9%) were married or living with a partner. Of all patients, 13.8% had completed a primary education and 75.5% had finished secondary education (7 and 12 years mean duration of formal education, respectively). The primary pain sites were: back: 58 (32.0%), legs: 56 (30.9%), neck and shoulders: 36 (19.9%), arms: 24 (13.3%), pelvis: 12 (6.6%), whole body: 11 (6.1%), head and face: 9 (5.0%), belly: 9 (5.0%) and breast: 8 (4.4%). In total 27 patients reported 2 sites, 6 patients reported 3 sites and 1 patient reported 4 sites. Mean pain duration was 64.1 months (sd=71.2) with

a range of 3-420 months.

Study design

After acceptance for treatment at the multidisciplinary pain centre, patients were sent a booklet of questionnaires and a pain diary. Patients were asked to complete the questionnaires, to keep the pain diary for 7 days and send them back to the hospital. After 3 months, 2 weeks before entering the pain centre for treatment, patients were again sent a booklet of questionnaires and a pain diary. They were asked to complete the questionnaires, to keep the pain diary for 7 days and take the booklets with them when entering for treatment.

Measures

Pain Intensity

Since multiple VAS ratings have been shown to be more reliable and valid for measuring average pain intensity than a single rating[33], study participants were asked to rate their pain on a 10-centimeter Visual Analogue Scale for 7 days at 3 points in time each day. The Pain VAS scale ranged from no pain at all to the worst pain ever experienced. Twenty-one pain ratings were recorded for every patient and the mean pain level was calculated on the basis of these ratings. Cronbach's alpha for pain intensity in our study was 0.96.

Functional disability

Functional disability was measured with the Dutch version of the Pain Disability Index[7,34,35]. The PDI was developed as a brief, self-report indicator of pain-related disability[34]. It was constructed as a 7-item questionnaire, which is scored on a scale of 0 (no disability) to 10 (total disability). The items reflect the total range of role functioning: family/home responsibilities, recreation, social activities, occupation, sexual behaviour, self-care and life-supporting activities. The average level of the items scored was used to calculate the disability index. Cronbach's alpha for functional disability in our study was 0.86.

Fear of pain

Fear of pain was measured with the Dutch version of the Tampa Scale of Kinesiophobia[11,36,37], measuring fear of increasing pain and injury by physical activity. The questionnaire consists of 17 items, scored on a 4-point scale (1: highly disagree to 4: totally agree). Representative items are: "For someone in my condition, it is advisable not to be physically active" and "My pain means there is physical damage". The total score reflects the level of pain-related fear. Cronbach's alpha in our study was 0.80.

Avoidance behaviour

Avoidance behaviour was measured with the composite score of the Retreating and Resting scale (respectively 7 and 5 items, respectively) of the Pain Coping Inventory (PCI)[22,38,39]. The PCI measures cognitive and behavioural attempts to cope with pain on a 4-point Likert scale (1: rarely or never to 4: very frequently).

Representative items of avoidance behaviour are: “When in pain, I retreat to a restful environment”, ”When in pain, I quit my activities” and “When in pain, I rest by sitting or lying down.”. Cronbach’s alpha for avoidance behaviour in our study was 0.77.

Worrying/catastrophizing

The construct of worrying is similar to catastrophizing and refers to anticipated negative consequences of pain and the lack of ability to cope with these consequences in the future. Worrying/catastrophizing was assessed by the Worrying (9 items) scale of the Pain Coping Inventory (PCI)[38,39]. Representative items are: “I start worrying when in pain” and “I think that the pain will worsen.” Cronbach’s alpha for Worrying in our study was 0.75.

Helplessness

Helplessness was measured with the Helplessness scale of the Illness Cognition Questionnaire (ICQ). The ICQ assesses cognitions about the way patients think about and give meaning to their chronic illness[28]. In order to enable comparison with the other pain-related predictors, the term “illness” in the ICQ was replaced by “pain”. Representative items of the Helplessness scale are: “my pain frequently makes me feel helpless”, “my pain limits me in everything that is important to me” and “my pain controls my life”. The items are rated on a 4-point scale (1: not at all to 4: completely). Cronbach’s alpha for helplessness in our study was 0.87.

Statistical analysis

Because of skewed distributions of scores at pain duration, square root transformations were applied. In order to explore the relationship between the study variables at first assessment and the change in functional disability, Pearson correlation coefficients were calculated between the predictors at first assessment and the change scores of functional disability. Residual gain scores for functional disability were used as change scores and were calculated by regressing the outcome variable at the second assessment on the baseline score of the variable[40]. Sequential regression analyses were then performed with functional disability at second assessment as dependent variable to study the contribution of the predictors at baseline, after controlling for functional disability and pain at first assessment at step 1 and 2. At first, all predictors that were significantly related to change in functional disability were entered separately in step 3 to determine whether they significantly predicted change in functional disability, after controlling for functional disability and pain intensity at first assessment. Secondly, all predictors were entered in different steps to study their relative contribution, when simultaneously controlling for the other predictors.

Results

Changes in functional disability

During the study period, mean functional disability decreased significantly: T0=5.00 (sd=2.0) and T1=4.77 (sd=2.0) (t=2.12, p<.05). However, there were considerable individual variations in the course of functional disability: 75 patients (41.0%) showed a decrease in functioning in the study period (of whom 40 (22%) more than 0.5 sd and 15 (8%) more than 1 sd) whereas 105 patients (58%) showed an increase in functioning (of whom 64 (35%) more than 0.5 sd and 29 (16%) more than 1 sd).

Table 1: Correlates of study variables at first assessment

	Functional disability	Pain Intensity	Helpless-ness	Fear of pain	Avoidance behaviour
Pain intensity	.42***				
Helplessness	.57***	.27***			
Fear of pain	.42***	.24**	.50***		
Avoidance behaviour	.53***	.20*	.48***	.45***	
Worrying	.33***	.11	.44***	.43***	.45***

** p <.05, ** p <.01, *** p <.001*

Correlates of functional disability at first assessment

As presented in Table 2, functional disability at first assessment was moderately correlated with more pain intensity (r=.42, p<.001). No significant relations were found for any of the demographic variables (gender, age and education) and pain duration (data not shown).

Functional disability was moderately to strongly correlated with all predictors (between r=.33 and r=.57, p<.001), indicating that more fear of pain, avoidance behaviour, worrying/catastrophizing and helplessness were related to higher levels of functional disability at study entry.

Correlates of change in functional disability.

When studying relationships of functional disability over time, demographic variables and pain duration were not significantly associated with change in functional disability (data not shown). However, pain intensity at first assessment was significantly correlated with an increase in functional disability (r=.30, p<.001). In addition, with the exception of worrying/catastrophizing (r=.07, n.s.), all predictors at first assessment proved to be correlated with change in functional disability, i.e., higher levels of helplessness, fear of pain and avoidance behaviour were significantly related to an increase in functional disability after 3 months (see first column of Table 2).

Table 2: Sequential regression analyses of functional disability at second assessment

	Functional disability T2		
	r^a	**Adj. Δ R^2**	**β**
1. Functional disability T1	.75***	.57***	.50***
2. Pain intensity T1	.30***	.05***	.23***
3. Fear of pain	.17*	.01*	.03
4. Helplessness	.19**	.01*	.11
5. Avoidance behaviour	.19**	.01*	.15**
Total adj. ΔR^2		.65	

** p <.05, ** p <.01, *** p<.001*

[a] *correlations with residual gain scores of functional disability (except for functional disability T1)*

Predictors of change in functional disability

Hierarchical regression analyses were performed with all predictors that were significantly related to change in functional disability: i.e. fear of pain, avoidance behaviour and helplessness, after controlling for functional disability at step 1 (explaining 57% of the variance, F-change=234.13, p<.001) and for pain intensity at step 2 (explaining another 5%, F-change=21.02, p<.001). When entering the predictors separately at step 3, fear of pain (F-change=5.05, p<.05), avoidance behaviour (F-change=12.70, p<.001) and helplessness (F-change=9.27, p<.01), all significantly predicted change in functional disability.

In order to study the relative effects of the predictors that were significantly related to change in functional disability (fear of pain, avoidance behaviour and helplessness), they were entered in different steps in the analyses. When entering fear of pain at step 3, helplessness at step 4 and avoidance behaviour at step 5, all predictors added 1% to the total variance on a p<.05 basis (F-change=5.05, 5.79 and 6.91 respectively), indicating that helplessness and avoidance behaviour independently contributed to the course of functional disability above fear of pain (see Table 3). When entering helplessness at step 3, avoidance behaviour still had a significant contribution when entering at step 4 (F-change=8.15, p<.01). Fear of pain had no additional contribution at step 4, showing that fear of pain had made no independent contribution to the course of functional disability beyond helplessness. Finally, when entering avoidance behaviour at step 3, neither fear of pain nor helplessness significantly contributed to the variance at step 4, suggesting that helplessness and fear of pain had no independent contribution beyond avoidance behaviour. Beta coefficients of the whole model demonstrated that only avoidance behaviour contributed significantly to the change in functional disability (t=2.63, p<.01), independent of entry order.

Discussion

Based on the fear-avoidance and helplessness model, the purpose of the present prospective study was to examine the relative contribution of fear-avoidance factors (fear of pain, avoidance behaviour and worrying/catastrophizing) and helplessness to the prediction of the short-term fluctuations in functional disability in a heterogeneous sample of chronic pain patients, waiting for multidisciplinary pain treatment. Our study showed that, after controlling for initial pain level and functional disability, the fluctuations in functional disability were predicted by more fear of pain, avoidance behaviour and helplessness. Specifically, helplessness contributed to the prediction of change in functional disability beyond fear of pain. In addition, avoidance behaviour most strongly predicted functional disability when compared with fear of pain and helplessness.

In line with previous studies, fear of pain predicted change in functional disability, emphasizing the role of fear of pain in functional disability in subacute and chronic pain[41,42]. However, fear of pain had no unique contribution to the course of functional disability above the level of helplessness and avoidance behaviour. Findings are similar to a previous cross-sectional study, in which helplessness and avoidance behaviour both explained the level of functional disability while fear of pain did not have a significant additional contribution[43]. Fear of pain includes cognitions that pain may be avoided by ending or preventing from pain-provoking activities, which presupposes a level of controllability. However, in a pain population with a long-term chronification of pain, the specific fear of pain may eventually have been generalized into a broader cognition of not being able to control and stop the pain experience, resulting in helplessness cognitions and avoidance behaviour which are more directly linked to functional disability.

Helplessness had a predictive value for change in functional disability. This finding is congruent with previous studies showing the relevance of helplessness for the course of functional disability in time[28,31]. Beyond these studies, this prospective study extends previous findings in showing that helplessness may have an independent contribution to change in functional disability beyond fear of pain. Findings confirm the relevance of depressogenic cognitions in long-term pain when pain cannot be prevented or avoided. The construct of helplessness implies cognitions of uncontrollability to change the problem of pain that may initiate avoidance behaviour, aimed at preventing pain instead of changing the experience of pain or trying to actively cope with the consequences of pain in daily life.

Relative to the other predictors, avoidance behaviour was the most important predictor of the fluctuations in functional disability. The predictive value of avoidance behaviour for functional disability is consistent with the great number of studies on functional disability[9,22,44]. This study also indicates that, relative to helplessness and fear of pain, the behavioural component of the fear-avoidance model may be a key component as it is directly linked to functional disability. Further analyses confirmed that the relation between helplessness and functional

disability was explained by avoidance behaviour. The findings are in line with a prospective study of Smith and Wallston[30], who in a path-analysis found that avoidance behaviour mediated the relations between helplessness and disability, indicating that the fear-avoidance model and the helplessness model may be linked in their relation to functional disability (also see Sullivan et al[29]) in such a way that both fear of pain and helplessness induce avoidance behaviour, resulting in functional disability. This means that our study presents preliminary indications that both the fear-avoidance model and the learned helplessness model may contribute to explaining functional disability in chronic pain.

In contrast with other studies, underscoring the relationship between worrying/catastrophizing and functional disability in different chronic pain populations[22,45,46,47,48], worrying/catastrophizing had no predictive value for the prediction of change in functional disability. The construct of worrying/ catastrophizing as an anxiety-related coping strategy may be directed towards a future with pain, which should be avoided[29]. When the pain problem does not end, the fear of a painful future proved to be unavoidable and it may be suggested that worrying/catastrophizing may generalize into a more depressive cognition of uncontrollability, such as helplessness cognitions.

Patients in our study were waiting for treatment in the pain centre. It cannot be excluded that this condition may have affected the present findings. The perspective of a possible pain reduction by means of an effective treatment may have influenced cognitive and behavioural coping and subsequent fluctuations in functional disability. It may be speculated that expectation of pain relief may especially be relevant for fear of pain and helplessness cognitions. Fear of pain is directly linked with the fear that activities will induce pain increase. A perspective of less pain may reduce the fear that more activities will lead to more future pain. This perspective may also directly affect cognitions of helplessness as the expectation of a possible pain decrease might renew cognitions of control and decrease cognitions of pain as an uncontrollable condition in daily functioning. Since functional disability on average slightly decreased, we cannot exclude this possibility. However, there were considerable individual variations in the course of functional disability in the study sample, indicating that there was no general decrease in functional disability as a result of treatment expectations. In addition, findings are in line with other studies showing that fear of pain and helplessness prospectively predict changes in functional disability in chronic pain[15,22,32].

Some limitations of our study have to be considered. Firstly, three months between the first and the second assessment is a rather short time period to assess the fluctuations in functional disability for patients with average pain duration of more than five years. Future studies have to replicate the findings for longer time intervals, following Evers et al[49] who found in a study on rheumatoid arthritis patients that avoidance behaviour at times of diagnosis predicted functional disability after one and three years. Secondly, although significant contributions to

the variance of functional disability were found, the total amount of explained variance was modest. This means that the conclusions should be interpreted with caution. Thirdly, we studied the fear-avoidance model and the learned helplessness model separately though it may be hypothesized that the predictors of both models might interact and enhance each other. However, more repeated measurements over a longer period are required to additionally examine possible reciprocal and reinforcing effects of fear of pain and helplessness. Future studies should focus on the integration of the fear-avoidance model and the learned helplessness model in order to examine functional disability in time. Fourthly, all patients were included in a specialized university pain clinic. Patients are usually referred to a university pain centre when their pain problem has not been solved to a satisfying extent. Accordingly, the sample of pain patients in our study might only be representative for patients with complex pain problems who seek treatment in a specialized pain centre.

Despite these limitations, our study suggests that in future studies it may be useful to integrate the fear-avoidance and learned helplessness model in chronic pain by showing that both fear-avoidance factors and helplessness predict functional disability in time. In addition to fear of pain and helplessness, attention may be particularly directed towards avoidance behaviour as a possible link between the fear-avoidance and learned helplessness model for functional disability in chronic pain. Future prospective studies should examine if and in which way the two models may interact in explaining functional disability in chronic pain patients.

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PART 2

Psychological predictors of chronic pain treatment effectivity

Chapter 4

Psychological predictors of the effectiveness of radiofrequency lesioning of the cervical spinal dorsal ganglion (RF-DRG)

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Abstract

In this study 54 patients suffering from chronic cervicobrachialgia (mean pain duration 7 years) were treated with radiofrequency lesioning of the cervical spinal dorsal root ganglion (RF-DRG).

The aim of the study was to investigate whether psychological variables would be predictive for the changes in pain intensity after medical treatment.

The following psychological aspects were measured: pain cognitions: helplessness and catastrophizing, physical and psychosocial dysfunctioning and overall distress.

The level of catastrophizing before treatment appeared to predict 10% of the changes in pain intensity after treatment.

Changes in pain intensity after RF-DRG were positively correlated with changes in psychosocial dysfunctioning and negative self-efficacy.

Introduction

Recently three studies demonstrated the effectiveness of a radiofrequency lesion of the cervical dorsal root ganglion (RF-DRG)[1,2,3]. Short term success rates were observed between 50[1] to 88%[2] in patients suffering from cervicobrachialgia in terms of pain reduction. For instance, Kleef et al[2] reported a mean decrease of 3.1 on VAS scores, Slappendel et al[1] found a mean 1.7 VAS decrease.

Noteworthy is that Slappendel et al[1] found no differences between the two study-conditions (67 and 40 degrees C). This finding raises questions with respect to the working mechanisms in pain reduction after treatment.

Another way to justify the RF-DRG treatment besides pain VAS-scores is the improvement in psychosocial functioning after treatment. There is a substantial evidence for a relatively high level of psychosocial dysfunctioning in chronic pain patients. Pain is associated with elevated levels of depression, inactivity, negative thinking and overall distress[4,5,6]. There are also indications that cognitive coping strategies, especially perceived lack of helplessness and catastrophizing, are positively correlated with pain intensity[7] and even predict psychosocial functioning in time[8,9,10]. These are important findings because they show the impact of at least some psychological factors on pain intensity.

The aim of the present study, as part of the study of Slappendel et al[1], was to answer the following questions:

Do pain cognitions, physical and psychosocial functioning and/or psychological distress predict the change in pain intensity after treatment with RF-DRG?

Are changes in psychological variables correlated with changes in pain intensity after treatment with RF-DRG?

Patients and methods

Treatment of patients with cervicobrachialgia

All patients with cervicobrachialgia were examined by an anaesthesiologist during the first visit to the pain clinic and were also seen by a neurologist as well as an orthopaedic surgeon. A neurosurgeon or rheumatologist was also consulted if indicated. Cat-scans were obtained in all patients. In addition psychological assessment was completed by the clinical psychologist.

After the intake procedure a therapeutic protocol was established, which consists of conventional measures e.g. analgesics, trigger-point injections with local anaesthetics, physical therapy, transcutaneous nerve stimulation, psychological intervention and social support. Only when causal therapy was not possible (orthopaedic or neurosurgical surgery) and conventional therapy was not effective the patient was advised to undergo RF-DRG.

Study design

When the patient complained of unilateral monosegmental cervical pain diagnostic

blockades were performed to identify the putative pain provoking cervical spinal root. These blocks included the levels C3 to C7. After a clearly identified cervical spinal root by a prognostic blockade patients were asked to participate in the study and to provide a written informed consent. Inclusion and exclusion criteria are summarized in Table 1.

Inclusion criteria
- Patients suffering from unilateral pain in neck, shoulder or arm of chronic benign pain origin - Age: between 20 and 60 years - A duration of pain for at least six months - Conventional therapeutically approach not effective - No indication for surgical therapy as validated by X-ray and CAT-scan of the cervical spinal column - Positive diagnostic blockade for monosegmental pain
Exclusion criteria
- Evidence of deafferentation pain (hyperpathia, hypoesthesia, dysesthesia) in the upper extremity involved - Previous surgery of the cervical spinal column - Hypersensitivity to radiopaque dye solutions and / or local anaesthetics - Clotting disorders, major mental disease

Table 1: Inclusion- and exclusion criteria for treatment with Rf-DRG.

Measures

Physical and psychosocial functioning was studied by The Sickness Impact Profile (SIP). The Sickness Impact Profile was designed to assess the effects of health care on different aspects of daily functioning. It consists of 136 items, divided in 12 different scales: sleeping/resting, emotional behaviour, physical care, housekeeping, mobility, social interactions, walking, intellectual functioning, communication, work, recreation and eating. It is possible to distinguish 2 major scales from these scales: physical functioning and psychosocial functioning. The items are scored on a yes/no basis. In this study the Dutch version was used. The reliability and validity of the SIP are judged as sufficient[11,12,13].

Psychological distress was assessed by the Hopkins Symptom Check List (HSCL), which is used in order to evaluate therapeutic treatments[14]. The items are scored on a 5-points scale. For the purpose of this study only the overall distress scale was used, which consists of all 57 items. The instrument was validated for the Dutch population by Luteijn et al[15] and both reliability and validity are judged as sufficient.

The pain cognitions were studied by the Pain Cognition List (PCL-E). This Dutch instrument was designed to judge the cognitions of chronic pain patients concerning their pain. It consists of 81 items that are scored on a 1-5 basis and clustered in 5 major scales. For the purpose of the present study use was made of the scales: helplessness (negative self-efficacy: 17 items) and catastrophizing (17 items). The reliability and validity are judged as sufficient[16].
Pain intensity was measured by the Visual Analogue Scale, which is a pain scale between zero and ten, whereas zero indicates no pain and ten indicates maximum pain.

The present battery of instruments was composed in order to have a broad view on important aspects of dimensions of psychological dysfunctioning and pain cognitions, which are associated with chronic pain.
The questionnaires were administered before RF-DRG was performed and three months after treatment.

Medical treatment: RF-DRG of the cervical spinal root ganglion
RF-DRG was being executed using fluoroscopy with a C-arm. The C-arm was positioned parallel to the axis of the intervertebral foramen. Under direct vision an electrode was introduced parallel to the beam of the X-rays into the selected cervical foramen (tunnel vision). Under direct vision an electrode (54 mm insulated 23 Gauge needle with 4 mm bare tip, Radionics®) was introduced into the selected cervical foramen, by preference the dorsal caudal part of the foramen, were the ganglion is located[17]. The stylet was replaced by a thermocouple electrode, of which the correct position was verified by electrical 50 Hz stimulation. A twinkling sensation in the corresponding dermatome had to be obtained between voltages of 0.3 and 0.7 Volt. After obtaining correct sensory physiological placement, a motor response was provoked under 2 Hz stimulation. This should not occur below a voltage of at least two times the threshold value obtained during the sensory 50 Hz stimulation parameter. The anatomical placement of the electrode was controlled by fluoroscopy in anterior posterior view finding the electrode in line with the facetal joints. After these conditions were met the electrode was withdrawn and 2 ml lidocaine 2% was injected through the needle. Subsequently after five minutes the electrode was reinserted in the cannula and a 90 second RF-DRG was applied[18]. Because of the finding that the groups in the two study-conditions did not differ in pain reduction was found after treatment and that the demographic variables were similar the two groups of participating patients were taken together for the purpose of this study.

Patients
In total 314 patients with cervicobrachialgia visited the pain clinic in the participating hospitals in the period of January 1993 to June 1995. Inclusion and

exclusion criteria are formulated in Table l. Only patients between 20 and 60 years old were admitted to the study. The duration of the pain was at least six months.
After diagnostic blockades of the cervical spinal ganglion sixty-three patients, with a clearly identified spinal root, were included in the study. Nine patients were excluded because of insufficient data. The data of fifty-four patients could be analysed. The participating patients were dominantly female (67%). The mean age was 44.8 years (sd=12.6).

Statistics
Differences between pre-treatment and post-treatment scores were calculated with Wilcoxon's Signed Rank Test (see Table 2).
In order to study correlations between the pre-treatment psychological variables and the pre-treatment and post-treatment VAS the Spearman Correlation coefficient was calculated (see Table 3). In order to explore the predictive value of psychological variables on change in VAS scores after 3 months, a stepwise multiple linear regression analysis was conducted with the changes in VAS-scores as dependent variable and the following independent variables: age, gender, base line VAS-score, psychological distress (HSCL, 1 scale); psychological and physical dysfunctioning (SIP, 2 scales) and pain cognitions: helplessness and catastrophizing (PCL, 2 scales).
In order to investigate whether changes in psychological variables were related to the changes in pain scores Spearman Correlation coefficients were calculated (see Table 4).

Results

In Table 2 the means and standard deviations of pain intensity and psychological variables: pain cognitions (helplessness and catastrophizing, psychological and physical dysfunctioning and psychological distress) are shown before and after RF-lesioning treatment. VAS-scores after three months showed a significant reduction (1.7, $p<0.001$). In contrast with the pain reduction none of the psychological variables demonstrated any significant changes after treatment.
Table 3 shows Spearman's correlation coefficients between all psychological variables before treatment and VAS before RF-DRG treatment and difference scores in terms of percentage between pre-treatment and post-treatment VAS. Before treatment physical dysfunction and psychological distress were considerably associated with pain intensity (.42 and .35).
A relatively low level of change in pain intensity was significantly associated with a relatively high level of pre-treatment catastrophizing (-.35, $p<0.01$).
In Table 4 correlations between change-scores are presented. Helplessness (.33, $p<0.05$) and psychosocial dysfunction (.32, $p<0.05$) showed significant correlations with the pain reduction. In contrast with expectations physical dysfunctioning and distress did not relate positively with changes in pain scores.

Stepwise regression analyses indicated that the only significant predictors of post-treatment pain intensity are the initial VAS-scores and catastrophizing. The total r2 (=multiple correlation coefficient) is 0.20. Both VAS and catastrophizing before treatment are responsible for 10% of the variance. None of the other psychological variables show any predictive power.

Table 2: Mean, standard deviation and difference for all psychological variables before and 3 months after RF-DRG treatment (Wilcoxon's Signed Rank Test)

	T0		T3		
variable	M	sd	M	sd	Dif mean
VAS	6.4	1.6	4.7	2.9	-1.7 *
Helplessness	44.8	13.0	43.9	15.6	-0.9
Catastrophizing	45.5	13.9	45.8	15.4	0.3
Physical dysfunctioning	8.2	9.0	7.3	9.8	0.5
Psychosocial dysfunctioning	11.5	9.1	11.9	12.0	-0.3
Total distress	40.5	13.0	39.8	11.9	-0.7

* *p<.001*

Table 3: Spearman's correlation coefficients between all psychological variables before treatment and (1) VAS before RF-DRG treatment and (2) procentual difference scores in VAS

	VAS	**rel dif VAS**
Helplessness	.26	-.12
Catastrophizing	.16	-.35 **
Physical dysfunctioning	.41**	-.15
Psychosocial dysfunctioning	.28*	-.24
Total distress	.35 **	-.24

* *p<.05;* ** *p<.01*

Table 4: Spearman's correlation coefficients between the difference in psychological variables before and after RF-DRG treatment and the procentual difference scores in VAS

	rel dif VAS
Helplessness	.33 *
Dif catastrophizing	.17
Dif physical dysfunctioning	.00
Dif psychosocial dysfunctioning	.32*
Dif total distress	.22

* *p<.05*

Discussion

In this study one psychological variable, catastrophizing, was able to predict the outcome after RF-DRG treatment. Catastrophizing is defined as a cognitive process characterized by a lack of confidence and control and an expectation of negative outcome. In a recent study Sullivan et al[19] suggest that the construct of catastrophizing may be viewed as a conceptually integrated construct that comprises three related components: rumination, magnification and helplessness. In their study they found that especially rumination was most strongly associated with functional disability. Rumination is considered a maladaptive coping strategy that intensifies the experience of pain[20,21].

The value of catastrophizing as a predictive variable for pain variance is not generally accepted. Some authors consider catastrophizing as the cognitive component of depression and/or overall psychological distress and not as a different construct[4,5,8]. However, our results clearly indicate that catastrophizing and not psychological distress is able to predict changes in pain scores after medical treatment. Although patients were treated with RF-DRG this psychological variable accounted for 10% of the change in pain scores. Our findings may lead to the hypothesis that a psychological treatment, which decreases the level of catastrophizing, may increase the effect of medical treatment. For treatment planning it may be a useful strategy to identify pain patients with a high level of catastrophizing. This selection of patients might profit from an additional psychological treatment, before and/or accompanying the medical treatment which is applied. Future studies should target the increase of positive effects on pain experience as a result of a multidisciplinary treatment, including psychological and medical treatment, compared with monodisciplinary treatment or no treatment at all.

In our study the cognitive coping pre-treatment scores show that no high correlation (>.30) could be established between any of the pain cognitions and pain intensity. This finding means that the conclusion of Jensen et al[4] in a review on coping with chronic pain and several authors on correlational studies of chronic pain[8,22,23] that catastrophizing is correlated highly with pain intensity could not be confirmed.

When examining the changes after RF-DRG treatment, however, the results show that only helplessness and psychosocial dysfunctioning correlate significantly with the changes in VAS. These may be surprising results because they show that pain reduction does not correspond with better physical functioning. More specifically physical dysfunctioning was associated with pain intensity before medical treatment but did not improve when pain was reduced as a result of treatment. Also distress showed no correlation in change scores. Although distress is correlated with VAS before medical treatment, pain reduction was not accompanied by an improvement in distress-scores. It may be hypothesized that changes in physical dysfunctioning and distress may be ruled by more complex mechanisms than only

by pain level and may demand other multidisciplinary treatment strategies.

Conclusion

What are the clinical implications of these findings? Aspects of psychosocial functioning may be considerable consequences of the pain as suggested by Linton[6]. When these are not focused within a treatment program they will persist in spite of changes in pain scores. This means that treatment of cervicobrachialgia should not only focus on medical treatment but should be combined with psychological treatment in a multidisciplinary pain program for those patients with a higher level of dysfunctioning or catastrophizing coping strategies. This corresponds with the findings of Flor et al[24] in a meta-analytic review, who showed that multidisciplinary pain treatments are superior to unimodal treatments and no treatment in pain clinics. The overall conclusion may be twofold. Conclusion one: there is a considerable correlation between physical, psychological dysfunctioning and pain intensity before treatment with RF-DRG. However, conclusion two, because successful RF-DRG treatment (in terms of decrease in VAS-scores) is not accompanied by a better total functioning (in terms of less physical and psychosocial dysfunctioning and overall distress) the findings in our study support the recent developments in which pain clinics focus in their treatment programs on both pain reduction and better overall functioning[24]. In a review, article Turk et al[26] mentioned no less than 9 possible treatment goals that were used in chronic pain treatment, covering all major aspects of physical and psychosocial functioning.
In addition, it may be important to specify pre-treatment diagnostic instruments in order to identify pain patients with cervicobrachialgia who have catastrophizing coping strategies so that this group may profit from an additional psychological pain treatment in addition to a treatment with RF-DRG.

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Chapter 5

Predicting outcome of TENS in chronic pain: a prospective, randomized, placebo controlled trial

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Abstract

Transcutaneous electrical nerve stimulation (TENS) is an easy to use non-invasive analgesic intervention applied for diverse pain states. However, effects in man are still inconclusive, especially for chronic pain. Therefore, to explore the factors predicting result of TENS treatment in chronic pain we conducted a prospective, randomized, placebo-controlled trial (n=163), comparing high frequency TENS (n=81) with sham TENS (n=82). Patients' satisfaction (willingness to continue treatment; yes or no) and pain intensity (VAS) were used as outcome measures. The origin of pain and cognitive coping strategies were evaluated as possible predictors for result of TENS treatment.

Results: Fifty-eight percent of the patients in the TENS group and 42,7% of the sham-TENS group were satisfied with treatment result (chi square=3.8, p=0.05). No differences were found for pain intensity. Patients diagnosed with osteoarthritis and related disorders (especially of the vertebral column) or peripheral neuropathic pain were less satisfied with high frequency TENS [OR=0.12 (95% CI 0.04-0.43) and 0.06 (95% CI 0.006-0.67) respectively]. Injury of bone and soft tissue (especially postsurgical pain disorder) provided the best results. Treatment modality or interactions with treatment modality did not predict intensity of pain as a result of treatment. We conclude, that predicting the effect of high frequency TENS in chronic pain depends on the choice of outcome measure. Predicting patients' satisfaction with treatment result is related to the origin of pain. Predicting pain intensity reflects mechanisms of pain behaviour and perceived control of pain, independent of treatment modality. Pain catastrophizing did not predict TENS treatment outcome.

Introduction

Transcutaneous electrical nerve stimulation (TENS) is an easy to use non-invasive analgesic intervention, applied for diverse pain states and introduced in the early 1970s. However, its effects are still inconclusive for chronic pain[1], although a systematic review indicates benefit for pain in osteoarthritis of the knee[2].

A number of causes are considered responsible for inducing or maintaining chronic pain, e.g. inflammation and nerve or spinal cord injury[3]. There are however significant differences in the underlying peripheral mechanisms of nociceptive and neuropathic pain. Damage of deep (muscle, joint and viscera) tissue is typically associated with peripheral inflammation, while injury of nerves often leads to neural degeneration, neuroma formation and generation of spontaneous neural inputs[4]. However, both are significantly influenced by changes in the central nervous system (i.e. central sensitization/disinhibition). Interestingly, long-lasting or intense nociceptive barrage from the periphery has been reported to give rise to persistent and self-sustaining central hyperexcitability long after all possible tissue healing has occurred[4]. In osteoarthritis however, evidence is found that central hyperexcitability is maintained by nociceptive barrage[5], probably by peripheral sensitisation, as a result of neurogenic inflammation[6]. There is growing evidence that the pain in osteoarthritis is at least partly due to inflammation[7].

In animal models, effects of high and low frequency TENS have been extensively studied in inflammation and to a lesser extent in nerve ligation, for review see Sluka and Walsh[8]. High-frequency TENS reverses primary and secondary hyperalgesia induced by carrageenan inflammation[9,10,11,12,13,14], but does not diminish mechanical allodynia following chronic constriction injury of the rat sciatic nerve[15]. However whether these results are true for high frequency TENS in chronic pain in human research, still needs to be explored. In predicting effect of TENS[16] found that patients with intractable, stabbing, pulsating, electrifying, paroxysmal and un-modulated pain - suggesting neuropathic pain[17] - have less chance to achieve successful treatment outcome.

Besides mechanisms of peripheral and central hyperexcitability, psychological factors also influence chronic pain processing and treatment outcome. Cognitive coping strategies appeared to be correlated with pain intensity[18] and especially helplessness[19] and catastrophizing[20,21] are found to predict outcome of treatment in chronic pain. However, effects of cognitive copings strategies on results of TENS treatment are unknown[16] found that, marked depression, highly stressful conflict situations and ongoing litigation diminished success rate of TENS treatment.

Therefore, the purpose of this study is to explore the effects of the origin of pain and cognitive coping strategies and mood on predicting short-term results of high-frequency TENS in the treatment of chronic pain. We expect pain in osteoarthritis and related disorders, but not peripheral neuropathic pain to be a positive predictor for results of high frequency TENS.

Methods

Design

To predict outcome of TENS treatment, we performed a prospective, randomized and controlled trial comparing TENS and sham TENS. A concealed block-wise randomisation procedure was used, and patients, therapists and research assistants were blinded for treatment allocation.

Randomisation procedure and concealment of allocation

The researcher assigned consecutive numbers to eligible patients, when they agreed to participate in this study. The research assistant, only delivering the TENS or sham TENS devices to the patients, used these numbers to determine treatment assignment, as provided by the randomisation list. This list of sequential numbers, which-block wise refer to treatment allocation, was generated with help of a computer by the department of Epidemiology & Biostatistics. To further guarantee concealment, patients were asked to leave their treatment device with the receptionist before visiting the researcher for evaluating treatment after the treatment period.

Subjects

Patients with chronic pain participating in this study were referred to the Pain Centre of the Radboud University Medical Centre Nijmegen by their General Practioner or by a medical specialist. Results of medical investigations were retrieved from the specialists before the patient was invited for the first visit to the Pain centre. Both anaesthesiologists and physiotherapists of the Pain Centre screened patients for TENS treatment.

Patients were eligible for this study if they met the inclusion criteria. Inclusion criteria were: 1. patients with chronic non-cancer pain referred to the Pain Centre; 2. duration of pain > 6 months; 3. age above 18 years. Exclusion criteria were: 1. previous TENS treatment (because this could affect sham TENS credibility[22]); 2. pain in face or head (because visible electrode placement might affect compliance, and hair could impair optimal electrode placement); 3. several different pain sites (because of the limited area TENS electrodes can serve); 4. history of a cerebral vascular accident (because possible spinothalamocortical pathway damage could affect the outcome of TENS – and possibly sham TENS treatment, too); 5. no assistance at home – e.g. relatives or friends - to help replace or connect the electrodes, thus jeopardizing optimal TENS use; 6. involvement in ongoing litigation because of their pain[16]; and 7. psychological intervention proposed by the Pain Centre psychologists (this would interact with TENS treatment outcome in an unpredictable way, and withholding it would be unethical). Eligible patients were included in this study after signing informed consent. The Central Committee on Research Involving Human Subjects approved this study.

Apparatus

For TENS and sham TENS treatment, identical devices (ELPHA II 1000, Danmeter A/S, Denmark) were used, which were specially prepared for this study. For high frequency TENS, stimulation pulse frequency was set to 80 Hz and pulse width to 50ms. Disposable 5 cm x 6.4 cm self-adhering electrodes were used with an active area of 6.5 cm2. Sham TENS devices showed a maximum of 10 or 20 mA on the display (current intensity below the level of perception of the patient; assessed during the visit by the physiotherapist), but no current was actually delivered to the electrodes.

General procedure

Patients eligible for the TENS treatment received written information in which they were asked to participate in the study. In the letter, it was explained that TENS seems to be effective at high and low intensities, and that treatment would be by one of these two options. There would also be a chance of receiving a sham TENS device in which the settings of pulses were neither effective nor harmful.

After inclusion, baseline measures were carried out and one week later patients visited the physiotherapist for TENS application and for instruction on both TENS treatment modalities. Electrodes were applied over the superficial cutaneous nerves in the painful segment(s)[23]. Once acquainted with the method of treatment, the patient left the physiotherapist and visited the research assistant whose only task was to deliver the high frequency or sham TENS device to the patient, as determined by the randomisation list. “With the assignment to apply TENS treatment continuously during the day, and the written instruction how to use the device and not to change pain medication, the patient left the outpatient clinic. Ten days later, the patient returned for evaluation of the treatment effect. More details of the methods are described elsewhere[24].

Outcome measures

Two outcome measures were used to predict result of TENS treatment.

The primary outcome measure was the proportion of patients satisfied with the initial treatment result and willing to continue treatment (yes or no). This outcome measure can be regarded as an index of patient’s assessment of the benefits (efficacy) of the treatment versus its side effects (e.g. problems in handling the device), providing a patient-based evaluation of treatment[25].

The secondary outcome measure was pain intensity. Pain intensity was measured using a 10-centimeter VAS, ranging from no pain at all to the most intense pain imaginable[26]. Patients were instructed to rate their pain from that particular moment on the same time every day, for a period of 14 consecutive days, starting one week before treatment. For this purpose a pain diary was used.

Predictors

Based on medical causes of pain, patients were classified in three pain diagnoses groups: Osteoarthritis and related disorders (ORD), assuming peripheral sensitisation by neurogenic inflammation[6,7]; Peripheral neuropathic pain (PNP) as a result of lesions of the peripheral nervous system; and finally, the remainder of patients was classified as Injury of bone and soft tissue and visceral pain disorders (IBST) - assuming self-sustaining central hyperexcitability[4], as there were no signs of inflammation or peripheral nerve lesions, for visceral pain disorders it is suggested that central sensitisation may contribute to the pain hypersensitivity[27]. ORD was specified as pain related to osteoarthritis, osteoporosis, bursitis and tendonitis - both osteoarthritis and bursitis and tendonitis share mechanisms of peripheral sensitisation; the number of nerve fibers immunoreactive to substance P are increased around the vessels of the tissue related to the site of pain[28,29], which also applies for the number of vessels in that area[29,30]. The diagnosis of PNP was established when symptoms for neuropathic pain (e.g. allodynia, hyperalgesia, hyperpathia, dysesthesia, paroxysms) were accompanied by a pain related neurological dysfunction, caused by nerve or root injury or compression and because of diabetic neuropathy.

According to Lampl et al.[16] factors describing severity of pain adversely affect the outcome of TENS treatment. We therefore added the following pain characteristics as possible predictors: intensity of pain, duration of pain, variation in pain, and disability because of pain.

For pain intensity, the average pain level (VAS) of the base-line week was calculated. The standard deviation (sd) was used as a measure of variation of pain.

Disability because of pain was measured with the Dutch version of the Pain Disability Index (PDI)[31,32,33], which is scored on a scale of 0 (no disability) to 10 (total disability). The items ask for the level of limitations in the total range of role functioning: family/home responsibilities, recreation, social activities, occupation, sexual behaviour, self-care and life-supporting activities. Reliability and validity were judged as satisfactory[33,34]. The sum of levels of the items scored was used to calculate the disability index.

For psychological factors we selected cognitive coping strategies and perceived control over pain and finally depression as possible predictors for result of TENS treatment.

Pain coping was measured with the Pain Coping Inventory (PCI)[35,36], which measures 3 passive cognitive and behavioural coping strategies when dealing with pain. The PCI is rated on a 4-point Likert scale (1: rarely or never to 4: very frequently). Cognitive passive coping is assessed by means of worrying/ catastrophizing (9 items). Behavioural passive coping is assessed with two scales, retreating and resting (7 and 5 items, respectively). A priori, based on face validity we expected questions 10-13 of retreating (avoid upsetting events, seeking restful environment, avoid annoying sound and avoid light; when in pain) - referring to

coping with arousal due to pain- would reflect a separate factor within retreating. We therefore performed a principal component analysis with retreating, which revealed two factors, with only question 14 (Take care of food/drink) loading on a different factor. Accordingly we added the modified construct of retreating containing questions 10-13 and 32-33 (separate myself and return home soon; when in pain) as a possible separate predictor. Arousal due to pain might reflect ongoing or recurrent nociceptive pain caused by peripheral nociceptive stimulation presumably acting in addition to peripheral and central (dorsal horn) sensitisation; a condition in which TENS is found to be effective, for review see Sluka and Walsh[8].

Pain cognition was measured with the Pain Cognition List (PCL)[37]. This instrument represents a measure for the verbal-cognitive response system of chronic pain and consists of fifty items, each of which is assigned to one of five factors (pain impact, catastrophizing, outcome efficacy, acquiescence and reliance on health care). Items are scored on a 5-point scale (1: highly disagree to 5: totally agree). In our study the scales for catastrophizing and helplessness (negative self-efficacy) were used to predict outcome.

Helplessness (perceived control) over pain was measured by answering the following question: “Can you decrease the severity of your pain by performing activities; distracting from pain; relaxation exercises; reducing activities or resting; or none of these possibilities?” Patients were assigned to one of three groups. Group number one comprised of patients perceiving no control; group number two consisted of patients only perceiving control by decreasing activities or resting and group number three were patients perceiving control by activities, distraction or relaxation exercises.

Depression was measured with the Dutch version of the Beck Depression Inventory (BDI)[38]. Validity was judged as satisfactory[39].

Statistical methods

All analyses were done on the intention-to-treat population, defined as all randomized patients that started with treatment (also called modified intention-to-treat population). Level of significance used was 0.05. Apart from the primary parameters, all analyses were exploratory in nature. The primary outcome parameter was the proportion of patients satisfied with treatment result and willing to continue (sham) TENS treatment (yes or no). The difference between the two treatment groups was tested with the chi square test. The second outcome parameter was the difference in the time course of the VAS-score during the first treatment week and the mean of the VAS-score in the baseline week. These were analysed using a mixed repeated measures model.

To investigate the possible predictive role of given parameters on the result outcome (patients’ satisfaction), the following procedure was used. Using as criterion the highest likelihood score statistic within a logistic model, the best

Table 1: Baseline prognostic variables; pain and psychological characteristics

	TENS (n = 81)	**Sham-TENS** (n = 82)	**TOTAL** (n = 163)
Pain diagnoses[1]**, n (%)**			
Peripheral neuropathic pain	16 (20)	25 (30)	41 (25)
Osteoarthritis and related disorders	31 (38)	26 (32)	57 (35)
Injury of bone and soft tissue and visceral pain	34 (42)	31 (38)	65 (40)
Intensity of pain, Mean ± SE mm			
Average pain in baseline week (VAS)[2]	62.2 ± 2.1	61.5 ± 2.0	61.9 ± 1.4
Variation of pain, Mean ± SE mm			
SD of pain intensity in baseline week	11.4 ± 0.8	11.1 ± 0.7	11.2 ± 0.6
Perceived control of pain, n (%)			
By decreasing activities or resting	43 (53)	42 (51)	85 (52)
By performing activities or distraction	16 (20)	20 (24)	36 (22)
None	22 (27)	20 (24)	42 (26)
Pain disability (PDI)[3]			
Sum score, Mean ± SE mm	28.0 ± 1.8	28.8 ± 2.0	28.4 ± 1.34
PCI[4]**,** Mean ± SE mm			
Resting (5-20)	12.8 ± 0.4 (n=77)	12.4 ± 0.4 (n=77)	12.6 ± 0.3 (n=154)
Retreating (7-28)	11.2 ± 0.5 (n=77)	11.9 ± 0.5 (n=77)	11.6 ± 0.3 (n=154)
Worrying (9-36)	17.6 ± 0.7 (n=77)	17.3 ± 0.6 (n=77)	17.4 ± 0.5 (n=154)
PCL[5]**,** Mean ± SE mm			
Helplessness (17-85)	43.4 ± 1.2 (n=78)	44.5 ± 1.4 (n=77)	43.9 ± 0.9 (n=155)
Catastrophizing (17-85)	43.6 ± 1.7 (n=78)	44.2 ± 1.7 (n=77)	43.9 ± 1.2 (n=155)
BDI[6]**,** Mean ± SE mm			
Depression-score (0-63)	10.2 ± 0.8 (n=77)	10.5 ± 0.8 (n=77)	10.3 ± 0.6 (n=154)

[1]See table 2 for more details; [2]Visual analogue scale (0-100); [3]Pain Disability Index (0-70); [4]Pain Coping Inventory; [5]Pain Cognition List; [6]Beck Depression Inventory

subset of 1, 2, 3, … parameters at a time was determined. For each of these best subsets, Akaike's Information Criterion (AIC) was computed, a measure of the goodness of fit, corrected for the number of predictors. As final predictor set, that subset was chosen for which AIC was smallest (starting with the best subset with 1 predictor), before increasing again.
To investigate the possible predictive role of given parameters on the VAS score on day 14 the following procedure was used. Using as criterion the highest R2 within a multiple linear regression model, the best subset of 1, 2, 3, … parameters at a time was determined. As final predictor set, that subset was chosen for which R2, compared with the subset with one predictor less, still increased with at least 0.01 (starting with the best subset with 1 predictor).

Results

Subjects

Two hundred and three patients were included in this study. One hundred and sixty-five patients signed informed consent and 38 patients refused. Two of the included patients withdrew before the actual treatment took place; they were both assigned to the TENS group. Pain diagnoses, pain characteristics and psychological assessment revealed no differences between TENS and sham TENS groups (see Table 1), neither did demographic data or other pain characteristics, as reported previously[24]. The results of the classification of pain diagnoses groups are shown in Table 2. Because some booklets were not returned or lost, data of the PCL from three patients, and data of the PCI and BDI from four patients in the TENS group and five patients of the sham TENS group (PCL, PCI and BDI) were missing.

Outcome

The proportions of patients satisfied with treatment result, differed significantly for high frequency TENS compared to sham TENS (58,0% and 42,7% respectively, chi square=3.8, p=0.05). However, no significant differences in pain intensity were found for patients treated with TENS or sham TENS (p=0.53).

Predicting patients satisfaction with treatment result (willingness to continue treatment)

Descriptive data of the predictors are presented in table 3, arranged by type of pain diagnoses and including success rate (patients satisfied with treatment result) of TENS and sham TENS.
As can be seen by the odds ratios in Table 4, both for the ORD-group as for the PNP-group, the chance that patients were satisfied and willing to continue treatment was less for high frequency TENS. However, for patients with higher sum scores of the modified retreating scale of the PCI the chance for continuing

Table 2: Type of pain diagnoses and rate of patients satisfied with treatment result for TENS and sham TENS

Peripheral neuropathic pain (n=41)	**Treatment (n)**	**Rate of patients satisfied with treatment result**
Nerve injury	TENS (0) Sham (2)	- 0
Dorsal root injury	TENS (0) Sham (1)	- 0
Nerve compression	TENS (5) Sham (8)	3/5 5/8
Dorsal root compression	TENS (10) Sham (14)	6/10 7/14
Diabetic neuropathy	TENS (1) Sham (0)	1/1 -
Osteoarthritis and related disorders (n=57)		
Osteoarthritis (vertebral column)	TENS (21) Sham (21)	6/21 7/21
Osteoporosis of the spine	TENS (3) Sham (1)	2/3 0
Osteoarthritis (hip, knee, ankle)	TENS (2) Sham (2)	2/2 1/2
Bursitis and tendonitis	TENS (5) Sham (2)	2/5 0
Injury of bone and soft tissue and visceral pain (n=65)		
Soft tissue lesions	TENS (5) Sham (5)	4/5 2/5
Bone fractures	TENS (7) Sham (2)	4/7 1/2
Whiplash injury	TENS (4) Sham (4)	3/4 3/4
Postsurgical pain *	TENS (13) Sham (12)	10/13 4/12
Visceral pain	TENS (5) Sham (8)	4/5 5/8

** Indicates significant difference between TENS and sham TENS; p=.047, Fisher's exact test.*

Table 3: Proportions of patients satisfied with treatment result for TENS and sham TENS[1] a and mean scores (SD) of predictors arranged by type of pain diagnoses

	Peripheral neuropathic pain (n=41)		**Osteoarthritis and related disorders** (n=57)		**Injury of bone and soft tissue and visceral pain** (n=65)	
	TENS	Sham	TENS	Sham	TENS	Sham
Satisfied patients, % (rate)	62.5 (10/16)	48.0 (12/25)	38.7 (12/31)	30.8 (8/26)	73.5 (25/34)	48.4 (15/31)*
PCI[2], retreating[3](6-24)	10.4 (4.5)	9.1 (2.9)	10.0 (3.2)	11.9 (4.8)	8.9 (3.7)	9.4 (2.9)
Duration of pain (years)	6.7 (5.2)	6.7 (6.0)	5.6 (7.8)	9.1 (11.7)	6.4 (6.6)	4.4 (3.7)
Variation of pain intensity[4]	9.7 (6.3)	11.3 (6.6)	11.9 (7.7)	10.7 (6.9)	11.7 (8.0)	11.1 (6.4)

*[1]not corrected for the effects of retreating , duration of pain or variation of pain intensity. [2]Pain Coping Inventory. [3]modified retreating subscale (see text). [4]SD of VAS scores in baseline week. * Indicates significant difference (X^2=4.33, p= .037) between TENS and sham TENS.*

scale of the PCI the chance for continuing treatment was greater for high frequency TENS. As regards patients of the PNP-group, longer duration of pain increased the (diminished) chance for willingness to continue high frequency TENS. Independent of treatment modality, greater variation of pain intensity during the base-line week resulted in a greater chance in continuing treatment.

Table 4: Logistic regression report predicting willingness to continue treatment

Variable	ORs (95% CI)	*p*-value
Treatment*ORD[1]	0.12 (0.04-0.43)	0.001
Treatment*PCI[2] retreating[3]	1.18 (1.07-1.31)	0.001
Treatment*PNP[4]	0.06 (0.006-0.67)	0.022
Treatment*duration*PNP[4]	1.40 (0.94-2.08)	0.099
Variation of pain intensity[5]	1.05 (1.0-1.10)	0.066

Treatment: TENS=1, sham TENS=0. Percentage concordant: 69.5%. [1]Osteoarthritis and related disorders; [2]Pain Coping Inventory; [3]modified retreating subscale (see text); [4]Peripheral neuropathic pain; [5]sd of VAS scores in baseline week. ORs: odds ratios; 95% CI: 95% confidence intervals.

Predicting pain (VAS)

Results of predicting pain intensity are shown in Table 5. Treatment modality or interactions with treatment modality did not predict intensity of pain as a result of treatment. Pain intensity (adjusted for baseline values) was predicted by resting (PCI subscale) scores (negative), and pain disability (PDI) scores (positive). Perceiving reduction of pain by decreasing activities and resting, or with performing activities, relaxation exercises and distraction from pain, were positive predictors of pain intensity.

Table 5: Multiple linear regression report predicting VAS score on day 14 (after one week of treatment)

Variable	Regression Coefficient	Standard Error	t-value	Probability Level
Mean baseline pain intensity, VAS[1]	0.80	0.09	8.62	<0.001
PCI, resting [2]	-2.24	0.56	-3.99	<0.001
PDI[3], total sum score	0.50	0.15	3.22	<0.002
Perceiving pain reduction by resting	11.31	3.83	2.95	<0.004
Perceiving pain reduction by activities	10.31	4.67	2.21	0.028

Model: $F(5.146)=26.19$. $p< .001$. $R^2=0.47$. [1]Visual analogue scale; [2]subscale "resting" of Pain Coping Inventory; [3]Pain Disability Index.

Discussion

The results of our study show that predicting the effect of high frequency TENS depends on the choice of outcome measure. The chance that patients were satisfied with high frequency TENS treatment was reduced, both for pain related to osteoarthritis and related disorders as for peripheral neuropathic pain, whereas for patients, who retreat more because of arousal when in pain (modified retreating scale of the PCI), the chance was increased. Only for chronic pain because of bone or soft tissue injury the proportion of patients satisfied with treatment result was significantly higher for high frequency TENS compared to sham TENS (Table 3).
However, contrary to patient's satisfaction with treatment result, pain intensity as result of treatment was not explained by treatment modality. Furthermore, pain catastrophizing and depressive mood did not predict treatment outcome.
As hypothesized - based on results of animal research[15] - we found that peripheral neuropathic pain was a negative predictor for results of high frequency TENS. A possible explanation is that high frequency TENS as applied in the present study, decreases nociceptive input in the dorsal horn by means of selectively stimulating large diameter afferent neuron fibers[40], resulting in activating inhibitory interneurons in lamina II. This A-fiber mediated inhibition is diminished in rats with sectioned nerves[41], probably by apoptosis of inhibitory interneurons as a result of peripheral nerve injury[42]. Only for this group we found that with increasing duration of the existing pain, the chance of patients to be satisfied with treatment result augmented; whether this results from adaptive changes in the nervous system in the course of time, or that these patients are satisfied with less gain, needs further investigation.
We expected pain in osteoarthritis and related disorders to be a positive predictor for high frequency TENS treatment, but instead, it appeared a negative predictor. In a review Osiri et al.[2] conclude that high frequency TENS is shown to be effective in pain control over sham TENS in the treatment of osteoarthritis of the knee. However in our study, - as can be deduced by the data from table 2 – a proportion of 73% of the patients in this group suffered from severe osteoarthritis of the vertebral column, with only 6/21 (29%) and 7/21 (33%) of the patients satisfied with high frequency TENS and sham TENS treatment respectively. Accordingly, in a comparable group of patients with chronic low back pain, Moore and Shurman[43] found poor results from high frequency TENS treatment as well. A possible explanation is that inflammation near to the dorsal root and even a minor lesion of articular structures of the vertebral column is found to induce changes in neurotrophic factors in the dorsal root neurons[44,45,46]. These neuropathic changes might impair the working mechanisms of high frequency TENS, however this needs verification.
Patients who retreat because of arousal when in pain, benefit from TENS treatment (modified retreating scale, PCI). As mentioned before, we assume higher scores reflect higher levels of nociceptive pain; in which TENS is found to be effective,

for review see Sluka and Walsh[8]. However, this modified scale needs further validation.

Independent of treatment modality, baseline variation in pain intensity influences patients' satisfaction in treatment result, with increased pain variation resulting in greater chance of success of treatment. This is in accordance with the results of Lampl et al[16], who found that TENS in un-modulated pain is less effective. We assume that higher rates in fluctuation of pain intensity reflect a greater availability of inhibitory controls. Furthermore, participating in a study will heighten the sensitivity and vigilance of the patients, thereby increasing the detection of beneficial improvements[47], especially when pain intensity fluctuates, improvements are more likely to be noticed by the patients and attributed to treatment effect.

Only for chronic pain because of injury of bone and soft tissue (including a minor group of visceral pain disorders), the proportion of patients satisfied with treatment result was significantly higher for high frequency TENS compared to sham TENS (Table 3). This cannot easily be explained by the influence of the other predictors of patients' satisfaction, as can be seen by the data in Table 3.

Predicting pain (VAS)

For predicting pain intensity (VAS), as a result of high frequency TENS or sham TENS application, treatment modality does not show any interference. So, in the present study intensity of pain seems not to be influenced differently by either TENS or sham TENS treatment. After treatment, patients who were more disabled because of pain and those perceiving control of pain (by resting, performing activities and distraction from pain) have higher pain intensity scores than less disabled patients and those not perceiving control. Presumably, those patients already experiencing control of their pain seem to tolerate more pain during either TENS or Sham TENS treatment or benefit less from either treatment modality. Furthermore, patients who seek more rest because of their pain manifest less pain, as a result of either Sham TENS or TENS treatment.

Predictors found in other studies

Other factors predicting less effect of TENS treatment, described in the study of Lampl et al[16], were marked depression, and pain qualities as stabbing, pulsating, paroxysmal and electrifying pain. Marked depression, as predictor was not found in the present study, which could be due to the low depression score, explained by the exclusion of patients indicated for psychological treatment. Whereas for the various pain qualities, this agrees with our findings as these symptoms are more common in patients with neuropathic pain than those with non-neuropathic pain[48].

In a previous study in our centre, catastrophizing proved to be a factor explaining pain reduction by radiofrequency lesioning of the cervical spinal dorsal ganglion[20]. Catastrophizing did not explain pain or patients' satisfaction with treatment result in the present study, although the study was performed with the same measure

(PCL) and only slightly different scores in both studies [mean and sd: 45.5 (13.9) and 43.9 (14.9)]. A possible explanation could be that both TENS and sham TENS, stimulated a perception of pain control because patients handled their (sham) TENS devices themselves, thus diminishing the feeling of helplessness about pain, which is a major characteristic of catastrophizing[49].

Predicting pain versus predicting patients' satisfaction

Most striking is the fact that predictors for pain intensity differ from those who predict patients' satisfaction with treatment result, both in nature as in interaction with treatment modality. Although closely related, these two outcome measures differ because patients' satisfaction comprises the considerations of the relevancy of the experienced improvements for the patient (e.g. for the pain that was most annoying, threatening, disturbing or disabling), whereas the VAS score reflects a measure of pain intensity perceived at a fixed time of the day. As described before[24] the satisfied patients exhibited on average a 28.5% pain reduction, which signifies a clinical important relief of pain[50]. Patients' satisfaction might therefore, predict clinical important relief of pain.

Strong and weak points of the study

High frequency TENS was applied in a standardized way and a main outcome measure was patients' satisfaction with result of treatment, which would have warranted the relevance for daily practice. Furthermore compliance (registered operation time of the device) was not different for the TENS or sham TENS group, and there was only a weak correlation between the actual and perceived treatment application (i.e. TENS or sham TENS), as reported previously[24].

The main purpose of this study was to explore the effects of the origin of pain on the result of high frequency TENS in chronic pain. However the classification of the origin of pain may have flaws. Especially, the difference between the PNP group and the injury group (IBST) may be arguable, as a large proportion of the patients in the latter group developed chronic pain after surgery (see Table 2), and it is assumed that neuropathic pain is the most common type of post surgical pain[51]. Although there were no signs of sensory loss, we cannot fully exclude the existence of neuropathic pain in this group, as there is no gold standard for defining neuropathic pain[52]. However it would mean that the effect of high frequency TENS on PNP is not definite, because contrary to the PNP group, in the postsurgical pain group high frequency TENS performed significantly better than sham TENS (see, Table 3 and 2, respectively). Interestingly, TENS is found to reduce postoperative analgesic consumption[53]. However, there is a need for the development of a mechanism-based classification of pain, as proclaimed by Woolf et al[54] and Woolf and Decosterd[55].

We conclude, that predicting the effect of high frequency TENS in chronic pain depends on the choice of outcome measure. Predicting patients' satisfaction with treatment result is related to the origin of pain: both, peripheral neuropathic pain

and osteoarthritis, especially of the vertebral column negatively predict treatment outcome; whereas injury of bone and soft tissue (especially postsurgical pain disorder) is a positive predictor. Predicting changes in pain intensity following treatment reflects mechanisms of pain behaviour and perceived control of pain, independent of treatment modality. Pain catastrophizing did not predict TENS treatment outcome.

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Chapter 6

Multidisciplinary allocation of chronic pain treatment: effects and cognitive-behavioural predictors of outcome

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Abstract

Objectives: multidisciplinary treatment approaches have been found to be effective for chronic pain patients although there are large individual differences in outcomes. To increase overall treatment effects, tools are needed to identify patients most likely to benefit of tailored multidisciplinary modules oriented treatment.

Design: the present study evaluates the effects of a multidisciplinary pain treatment allocation protocol in chronic pain patients and seeks to identify cognitive-behavioural predictors of outcome. Pain intensity, functional disability, depression and use of medication in an intervention group of 110 chronic pain patients were compared to the outcomes of a 110 control group.

Results: paired pre- and post-treatment t-tests indicated that all primary outcomes had significantly decreased in the intervention group. ANCOVA revealed a main group effect for pain intensity levels and functional disability after treatment. Both had significantly reduced in the intervention group in comparison with the control group. Multiple regression analyses of the predictors showed higher levels of acceptance to significantly predict larger reductions in pain intensity in the treatment but not in the control condition.

Conclusion: the findings indicate that an outpatient multidisciplinary allocation of chronic pain treatment was effective with regard to pain intensity and functional disability. Especially those patients who were able to accept their condition may profit more from pain reduction.

Introduction

There is increasing evidence that chronic pain patients tend to benefit from multidisciplinary pain treatment schemes, especially programmes combining cognitive-behavioural (CBT) and physiotherapy modules[1,2,3,4]. Flor et al.[1] showed that multidisciplinary pain treatment was superior to monodisciplinary interventions on various outcome measures such as pain intensity, mood, functional disability and medication consumption, with the effects remaining relatively stable over time. However, the effects reported are generally modest, frequently attributed to the large individual differences in treatment outcomes. Consequently, it is essential that patients that may benefit most of multidisciplinary treatment schemes are identified[2].

Researchers have generally focused on the detection of relevant cognitive-behavioural factors to predict treatment efficacy. Based on the fear-avoidance model, pain-related anxiety, particularly fear of pain and worrying/catastrophizing, have been assumed to enhance avoidance behaviour, resulting in increased pain, functional disability and depression in the long term[5,6]. Recently, helplessness, i.e. the notion that chronic pain and its consequences are uncontrollable and unchangeable and the generalization of the consequences to daily functioning[7], has additionally been shown to play a significant role in explaining the course of functional disability in chronic pain within the framework of the fear-avoidance model[8,9]. As acceptance has been shown to be predictive of better functioning in the longer term[8,10], various authors have also advocated the assessment of this positive, health-promoting variable in outcome studies[4,8]. Acceptance is defined as acknowledging that one has pain and being able to make an effort to live a satisfying life despite the pain[8,11].

For correct referrals, it is crucial to know whether chronic pain patients that worry/catastrophize about their pain and its consequences and/or feel helpless about their ability to change their situation and have accordingly developed avoidant pain behaviours, would indeed profit most of treatment modules aimed at changing pain cognitions and behaviour, as has been suggested. Perhaps patients that are unable to accept the pain and its consequences may profit from pain treatment programmes that are specifically aimed at their learning to shift their focus from pain reduction to coping with the pain as an unavoidable condition and to strive toward improving their daily functioning despite the pain[11]. Yet, empirical studies that have examined the relative predictive values of mentioned variables in relation to multidisciplinary pain treatment approaches are scarce. The few studies that were directed at identifying cognitive-behavioural predictors at the start of treatment either yielded nonsignificant or inconsistent results[12,13,14,15]. Studies charting changes during multidisciplinary treatment found decreases in fear of pain, worrying/catastrophizing or helplessness to predict decreases in pain intensity, functional disability, depression and/or medication consumption[16,17,18,19,20,21]. Increase in acceptance cognitions appeared to predict

better outcomes after treatment[10].

To bridge this gap in our knowledge, with the present study we sought to examine and compare the effects of a multidisciplinary allocation protocol on the self-reported variables of pain intensity, functional disability, depression and use of medication in a cohort of chronic pain patients relative to a waiting-list control group and to identify cognitive-behavioural predictors (i.e. fear-avoidance factors, helplessness and acceptance) of treatment outcome in order to get more insight into the clinical impact of this strategy of chronic pain treatment. In this study, the consequences of the multidisciplinary pain treatment allocation protocol was the focus of study in stead of the effects of different treatment modules. We hypothesized that the treatment allocation protocol would be effective on all primary outcomes relative to the control condition. As previous studies indicated that patients with higher levels of worrying, avoidance behaviour, fear of pain and helplessness would suffer more from pain, functional disability and depression all predictive of inferior long-term outcomes[6,22], we hypothesized that this type of patients would profit more from a multidisciplinary treatment allocation protocol as reducing cognitive-behavioural factors was the specific focus of one of the treatment modules. In addition, we assumed that higher levels of pre-treatment acceptance would induce more favourable outcomes as acceptance might allow a more positive perception of changes in pain levels. However, based on recent studies showing that a lower level of acceptance predicts more pain and functional disability[23,24], we further assumed that patients low on acceptance would also benefit more from a multidisciplinary treatment allocation protocol as one of the goals of one of the treatment modules specifically aimed at raising the participants' acceptance levels.

This implies that superior outcomes would be predicted by these cognitive-behavioural variables, i.e. that patients with higher levels of worrying/ catastrophizing, avoidance behaviour, fear of pain or helplessness and lower levels of acceptance would show a more favourable outcome.

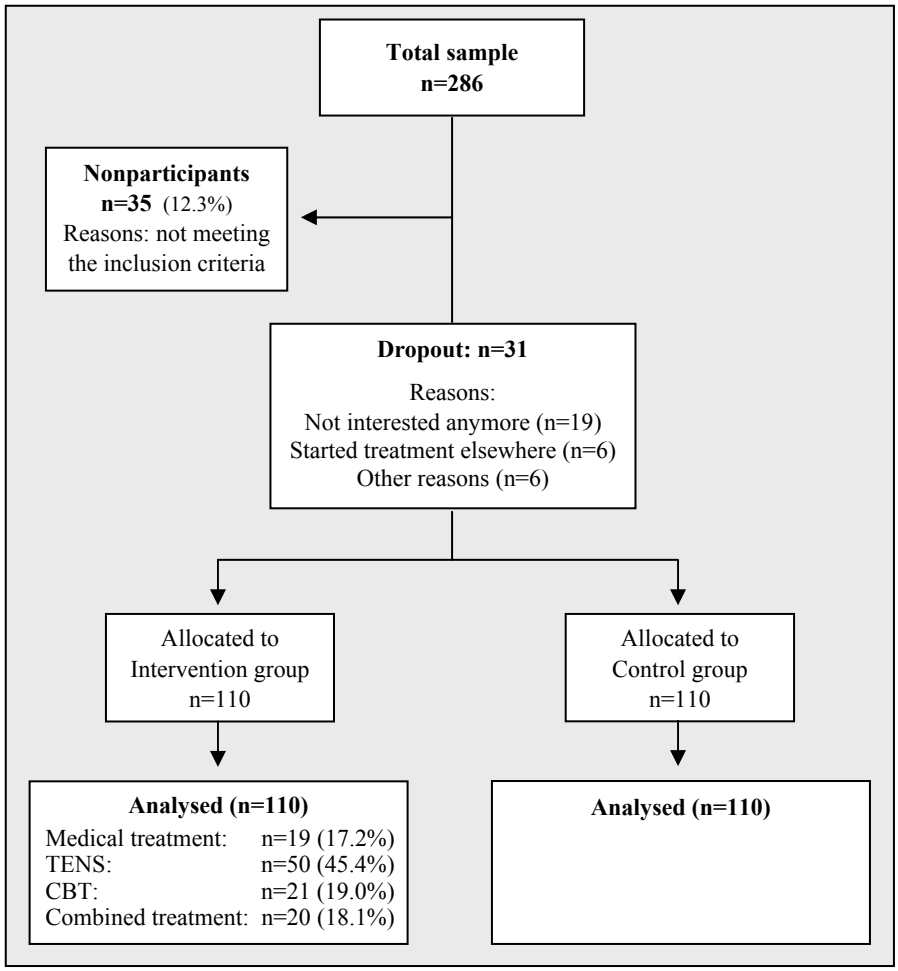
Materials and methods

Patients and procedure

Participants were recruited from chronic pain patients who had been referred for treatment to the interdisciplinary outpatient pain centre of the Radboud University Nijmegen Medical Centre, the Netherlands. To qualify for inclusion in the present study patients had to be at least 18 years old and have suffered from specified pain complaints for more than 3 months. Exclusion criteria were pathophysiological causes such as pain due to cancer, serious psychiatric disorders that could interfere with treatment, and the inability to read or write Dutch. Also patients that were scheduled for one or more treatment modalities outside the treatment centre (exercise therapy and/or individual psychological treatment) or patients that were

not allocated to any treatment, were excluded from the study. The original sample comprised 286 patients. Based on the exclusion criteria a total of 35 patients were excluded. As to the demographic variables of age, marital status, education and pain duration, there were no statistically significant differences between the study

Figure 1: Flowchart of the study participants



group and the nonparticipant group although there were significantly more women in the latter group (76.8% vs. 58.8%: $z=-2.57$, $p<.05$). Of the sample of 251 patients that met the inclusion criteria and initially agreed to participate, we eventually failed to obtain sufficient data for 31 patients (23%), which were subsequently excluded from the analyses (see Figure 1). Subsequent dropout analyses revealed that there were no statistically significant differences between

the final sample (n=220) and these dropouts. We thus tested a total of 220 patients in our study of whom we obtained all required data. Based on time of referral, the first 110 patients were allocated to the intervention group and the last 110 to the control group.
The remaining 220 patients all completed the same set of validated questionnaires (see Measures) and 7-day pain and medication diaries prior to entering the centre's standard three-month waiting-list period (T0) and again at the end of this period, i.e. one week prior to the study's screening procedure (T1) and a third time 3 months into their respective treatments (T2). The first 110 patients that were allocated to one or more of the treatment modalities were included in the treatment condition and the next 110 patients in the control condition (See Figure 1). The total inclusion period was 9 months. Prior to their participation to the study, which was approved by the hospital's medical ethics committee, all patients gave their informed consent.

Table 1: Demographic variables and pain duration for the two patient groups at study entry

	Treatment group (n=110)	**Control group** (n=110)
Sex: number of women (%)	64.0 (58.2)	68.0 (61.8)
Mean age (in years)	48.1 (sd= 14.3)	48.1 (sd=12.4)
Married (%)	78.2	76.2
Educational level		
primary	12.6	12.8
secondary	83.5	85.4
tertiary	3.9	2.8
Mean Pain duration (in months)	62.8 (sd=75.1)	63.5 (sd=77.6)

The demographic variables of both the control and the intervention group are presented in Table 1. There were no significant group differences in sex, marital status or educational level: in both groups the majority of patients were women and most participants were married and had completed secondary education. The primary pain sites for the treatment and the control groups were: legs: 34 (30.9%) vs. 27 (24.5%); back: 33 (30.0%) vs. 38 (34.5%); neck and shoulders: 27 (24.5%) vs. 19 (17.3%); arms: 16 (14.5%) vs. 12 (10.9%); pelvis: 8 (7.2%) vs. 7 (5.5%); head and face: 5 (4.5%) vs. 8 (6.4%); belly: 3 (2.7%) vs. 7 (5.5%); whole body: 3 (2.7%) vs. 10 (8.8%); breast 2 (1.8%) vs. 8 (6.4%). Fourteen (12.7%) and 16 (14.5%) patients, respectively, reported pain at more than one site. However, there were no patients who met the criteria for fibromyalgia. Mean pain duration was 62.8 months (sd=75.2, median 32.0) versus 63.5 (sd=77.6, median 36.0) with a

range of 6-420 months in both groups. There were no significant group differences on any of the pain locations and pain duration.

Pain treatment modalities

After the regular three-month waiting-list period an anaesthesiologist, a physiotherapist and a psychologist screened the questionnaires of all 220 patients. Allocation to one or more of the treatment modules was based on meeting the inclusion criteria of the different treatment modules as a result of screening the questionnaires, regarding demographic variables, painrelated variables, coping and pain outcomes and a standardised one-hour interview by the anaesthesiologist, physiotherapist and the psychologist.

The standardised interview consisted of a standardised examination of anamnestic pain related data by the anaesthesiologist, physical activity and functional limitations by the physiotherapist and data concerning the etiology of the pain episode, cognitive, behavioural and social consequences of pain by the psychologist. There were no dropouts in the intervention group after treatment allocation and start of treatment.

Medical treatment. Medical treatment was aimed at pain reduction by attuning and minimizing pain medication on a time-contingent basis. The inclusion criteria for this treatment modality were high medication use without strict medical indication, medication use on a pain-contingent basis, presence of adverse drug effects or use of conflicting or resembling pain medication. The mean number of face-to-face contacts was two.

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive intervention to alleviate pain. An experienced physiotherapist applies a small portable battery-powered stimulator, connected by electric wiring to self-adhesive electrodes, to the patient's skin. After proper instruction and adjustment of pulse variables and electrode placement, patients are able to manage the TENS treatment by themselves during their daily activities. They can monitor their pain level and adjust the pulses to alleviate the pain, which hence may reduce their cognitions of helplessness and avoidance behaviour. Eligible were patients suffering from pain due to peripheral nerve-root lesions, excluded were patients reporting pain in the face or head or on several pain sites. The mean number of face-to-face contacts was five.

Cognitive-behavioural group therapy (CBT) consisted of ten 90-minute sessions and was targeted at reducing the patients' functional disability and depression by reducing negative cognitions and avoidance behaviour using the following treatment components: stress-management and problem-solving techniques, cognitive therapy and relaxation exercises. In addition, patients worked on individual goals. In the first session, every patient formulated a specific CBT goal based on their personal underlying problems (e.g. work-related conflicts or marital problems). In the subsequent sessions, patients trained and implemented their

personalized problem-solving techniques. Groups consisted of minimally 5 and maximally 12 patients and were led by two psychologists both fully trained in CBT. Inclusion criteria for group CBT were untreatable pain (defined as pain that cannot be reduced by either medication and/or TENS) and severe limitations in physical or psychological functioning. Exclusion criteria were incapacity to function in a group or indications of a psychiatric disorder. The average number of attended CBT sessions was nine out of ten.

Figure 1 provides an overview of the number of patients per treatment modality, showing that 19 patients (17.2%) received medical treatment, 50 patients (45.4%) received TENS treatment and 21 patients (19.0%) had CBT. Twenty patients (18.1%) that met the criteria for more than one treatment modality received a combination of medical treatment and TENS. Patients who already had received TENS treatment and were considered to have an optimal medication scheme, only received CBT with the goal of better functioning and reduction of depression We did not offer a combination of medical treatment or TENS with group CBT because it was expected that, due to their pain-reduction objectives, both the medical treatment and TENS would undermine CBT treatment compliance as this intervention is specifically directed at training effective, long-term pain-coping strategies.

Measures

Pain Intensity

Since multiple Visual Analogue Scale (VAS) ratings have been shown to be more reliable and valid to establish average pain intensity than a single rating[25], our participants were asked to rate their pain on a 10-centimeter VAS for 7 days at 3 points during each day. The Pain VAS scale ranged from “no pain at all” to “the worst pain ever experienced”. The patient’s average pain level was calculated based on these 21 pain ratings. Cronbach’s Alpha for pain intensity in our study was 0.93.

Functional disability

Functional disability was measured with the Dutch version of the Pain Disability Index (PDI)[26,27]. The 7-item questionnaire was developed as a brief, self-report indicator of pain-related disability[25] and is scored on a scale from 0 (no disability) to 10 (total disability). The items reflect the total range of role functioning: family/home responsibilities, recreation, social activities, occupation, sexual behaviour, self-care and life-supporting activities. To obtain the mean disability level, the items scores were averaged. Cronbach’s Alpha for functional disability in our study was 0.80.

Depression

Depression was assessed using the depression scale of the Dutch version of the Symptom Checklist-90[28] measuring 16 symptoms of depression, which are rated

on a 5-point scale ("not at all" to "very much"). The Depression scale of the SCL-90 has been amply validated for the Dutch population in various patient groups including chronic pain patients[1]. It also proved to be sensitive to change, does not contain somatic items that could interfere with other somatic complaints in chronic pain patients and is widely used to assess therapy outcomes in chronic pain[17]. Cronbach's Alpha for depression in our study was 0.89.

Use of medication

Consistent with the ATC/DDD guidelines[29] medication intake was measured by comparing the defined, average amount of drugs needed to obtain the desired effect on pain in the general population (Defined Daily Doses: DDD) and the actual use of drugs (Used Daily Doses: UDD). The actual use of medication is calculated by dividing the USD of a drug by the DDD of the same drug. When patients used more than one drug to alleviate their pain, the relative outcomes of the different drugs (UDD/DDD) were summed to obtain the total level of medication use[29,30].

Avoidance behaviour

Avoidant behaviour was reflected by the composite score of the 13-item passive pain-coping scales Retreating and Resting of the Pain Coping Inventory (PCI)[31,32]. The PCI measures cognitive and behavioural attempts to cope with pain on a 4-point Likert scale ("rarely or never" to "very frequently"). Representative items are: "When in pain and I am outdoors, I try to return home as soon as possible" and "When in pain, I rest by sitting or lying down.". Cronbach's Alpha for avoidance behaviour in our study was 0.84.

Worrying/catastrophizing

Worrying/catastrophizing was assessed by the 9-item Worrying scale of the Pain Coping Inventory (PCI)[31,32]. Representative items are: "I start worrying when in pain" and "I think that the pain will worsen." Cronbach's Alpha for worrying in our study was 0.82.

Fear of pain

Pain-related fear was gauged with the recently adjusted version of the Tampa Scale of Kinesiophobia (TSK)[33,34], reflecting level of fear of movement due to possible subsequent pain/reinjury. The scale's 13 items are scored on a 4-point scale ("highly disagree" to "totally agree"). Representative items are: "My pain means there is physical damage" and "My pain tells me to stop exercising so I do not injure myself". Cronbach's alpha for fear of pain in our study was 0.78.

Helplessness

Patients completed the 6-item Helplessness scale of the Illness Cognition Questionnaire (ICQ). The ICQ was developed to measure illness cognitions in situations of an uncontrollable chronic condition like chronic pain[8]. To facilitate comparison with the other pain-related predictors, the term "illness" in the ICQ was replaced by "pain". The ICQ proved to be reliable and valid in assessing illness cognitions (e.g. helplessness and acceptance) in patients with chronic pain[8] as well as in patients with other chronic diseases such as multiple sclerosis and

chronic skin diseases[8,35]. In addition, scales of the ICQ have earlier been shown to be sensitive to change in studies evaluating CBT in chronic pain[36]. The Helplessness scale measures cognitions that focus on the negative consequences of pain and to what extent the patient generalizes them to daily-life functioning on a 4-point scale ("not at all" to "completely"). Representative items were: "My pain controls my life" and "My pain limits me in everything that is important to me". Cronbach's Alpha for helplessness in our study was 0.86.

Acceptance

Patients rated the 6 Acceptance items of the ICQ on a 4-point scale ("not at all" to "completely") to gauge their cognitions with respect to acknowledgment of their chronic pain condition and their notions on their ability to manage the negative consequences of the pain. The items of acceptance in the ICQ are as follows: "I have learned to accept the limitations imposed by my pain", "I have learned to live with my pain", "I can accept may pain well", "I can cope effectively with my pain", "I can handle the problems related to my pain" and "I think I can handle the problems related to my pain, even if the pain gets worse". These items reflect the cognition of being able to cope with the pain and the consequences of the pain, irrespective of the outcomes of the coping process. Cronbach's Alpha for acceptance in our study was 0.89.

Statistical analysis

In our analyses we compared the pre- and posttreatment (T1 and T2) scores on the questionnaires and seven-day pain-and-medication diaries of the patients in the intervention group with the T0 (start of waiting-list period) and T1 (pre-screening) ratings of the patients in the control condition.

Because of skewed distributions of the pain-duration scores, square-root transformations were applied. Differences between the intervention and the control group at study entry were tested with Student's t-tests for continuous variables and Chi-square analyses for categorical variables. ANCOVA was used to measure the main group effect of the various pain treatments on the primary outcome measures (pain intensity, functional disability, depression and medication use) and the secondary outcomes (avoidance behaviour, worrying, fear of pain, helplessness and acceptance) with group as the fixed factor and baseline score as covariate. For significant main group effects for the outcome variables, paired t-tests between the first and second assessment were conducted separately to gain a better understanding of the nature of the interaction. Effect sizes were obtained by calculating the difference between the means of the two assessments divided by their pooled standard deviations (sd)[37]. To help detect potential predictors of the primary outcome variables in the treatment condition we adopted Baron and Kenny's strategy for mediating effects[38,39] and calculated correlations between all demographic variables, pain duration and all predictors at baseline and the change scores of the primary outcome variables. In accordance with the stepwise method,

when correlations were significant, the relevant predictors were included as covariates in the regression analyses. Residual gain scores were used to establish changes in outcome variables, which were calculated by regressing the outcome variable at the post-treatment assessment on the baseline score of the outcome measure[39]. To determine the predictive value of the predictor for the treatment condition, the centred interaction term of Group x Predictor was entered into the regression analysis as the final, fourth step after controlling for the outcome variable at T1 at step 1, the group condition (treatment vs. control condition) at step 2 and the predictor at step 3.

Table 2: Means (M) and standard deviations (sd) of the primary and secondary outcome variables at first and second assessment for the treatment condition (TC: T1 and T2) and control condition (CC: T0 and T1); n=110 for both conditions; main group effect of all outcomes between treatment condition and control condition (F)

		First assessment		Second assessment		
Primary Outcome variables		M	sd	M	sd	F
Pain intensity	TC	52.44	18.18	45.35	19.41	7.909 (p=.005)
	CC	55.45	17.55	52.70	17.56	
Functional disability	TC	4.93	1.69	4.32	1.68	6.526 (p=.011)
	CC	5.01	1.88	4.78	1.99	
Depression	TC	28.45	10.82	26.40	10.80	0.158 (p=.691)
	CC	27.05	10.11	25.90	10.49	
Medication use	TC	0.63	0.82	0.53	0.67	1.371 (p=.243)
	CC	0.76	0.94	0.64	0.94	
Secondary Outcome variables						
Avoidance behaviour	TC	2.11	0.47	2.02	0.46	0.129 (p=.721)
	CC	2.14	0.49	2.03	0.53	
Worrying	TC	20.15	5.52	18.02	5.18	1.045 (p=.308)
	CC	19.22	4.79	17.96	4.84	
Fear of pain	TC	28.27	8.81	26.15	7.83	0.158 (p=.801)
	CC	27.16	7.58	25.25	7.66	
Helplessness	TC	14.72	4.42	13.84	4.44	0.548 (p=.460)
	CC	15.14	3.70	14.27	4.11	
Acceptance	TC	12.83	3.75	14.31	4.11	9.145 (p=.003)
	CC	13.08	4.06	13.57	4.07	

Table 3: Cross-sectional correlations in the treatment condition between the study variables at first and second assessment (T1 and T2)

Study variables		Pain intensity	Functional disability	Depression	Medication	Avoid. behaviour	Worrying	Fear of pain	Helplessness
Funct. disability	T1	.42***							
	T2	.50***							
Depression	T1	.23**	.39***						
	T2	.28***	.34***						
Pain medication	T1	.22**	.16*	.11					
	T2	.18**	.29***	.20**					
Avoid. behaviour	T1	.21**	.51***	.40***	.12				
	T2	.22*	.58***	.36***	.17**				
Worrying	T1	.15*	.33***	.60***	.15*	.39***			
	T2	.21**	.44***	.60***	.23***	.46***			
Fear of pain	T1	.21**	.40***	.24***	.19**	.29***	.44***		
	T2	.11	.35***	.27***	.15*	.40***	.43***		
Helplessness	T1	.33***	.58***	.50***	.09	.50***	.48***	.49***	
	T2	.41***	.64***	.44***	.24***	.57***	.63***	.50***	
Acceptance	T1	-.12	-.16*	-.23***	-.10	-.21**	-.40***	-.18**	-.29***
	T2	-.26***	-.26***	-.40***	-.19**	-.23***	-.51***	-.19**	-.48***

** p < .05, ** p < .01, *** p < .001*

Results

Pre-treatment patient characteristics

Table 1 lists the means of the demographic variables and pain duration and Table 2 the means and sd of the primary and secondary outcome variables at first assessment for the two study groups. Group comparisons did not yield any significant differences on any of the variables.

At first assessment, all variables are moderately correlated (range r=.18-.50), indicating that all variables were related with each other but represented different constructs. As expected, correlations were about the same at both assessments.

Primary outcomes

Table 2 depicts the means and sd of the primary outcome variables at both assessments for both groups. ANCOVA revealed a significant main group effect for pain intensity ($F(1, 215)=7.909$, $p=.005$) and functional disability ($F(1, 214)= 6.526$, $p=.011$). Paired t-tests showed that pain intensity had decreased significantly in the treatment condition ($t=4.17$, $df=106$: $p<.001$) but not in the control condition, which also applied to functional disability ($t=6.20$, $df=106$: $p<.001$). ANCOVA group effects were not significant for depression nor for use of medication ($F(1, 217)=0.158$, $p=0.691$ and $F(1, 218)=1.371$, $p=.243$, respectively).

Secondary outcomes

The ANCOVAs yielded a significant main group effect for acceptance ($F(1, 214)= 9.145$, $p=.003$). Paired t-tests showed that acceptance had increased significantly in the treatment condition ($t=-5.56$, $df=106$: $p<.001$) but not in the control condition. ANCOVA group effects were not significant for worrying ($F(1, 217)=1.045$, $p=.308$) nor for avoidance behaviour ($F(1, 217)=0.129$, $p=.721$), fear of pain ($F(1, 210)=0.158$, $p=.801$) or helplessness ($F(1, 216)=0.548$, $p=.460$).

Effect sizes

For the intervention group the effect sizes for the primary outcome measures of pain intensity and functional disability and for the secondary outcome measure of acceptance were close to medium (0.37, 0.36 and 0.38, respectively) [37]. In contrast, the effect sizes for the control condition revealed almost no changes (0.15, 0.06 and 0.12, respectively).

Cognitive-behavioural predictors of treatment outcomes

To facilitate the identification of predictors of the primary outcome variables, we computed correlations between all demographic variables, pain duration and all predictors at baseline (avoidance behaviour, worrying/catastrophizing, fear of pain, helplessness and acceptance) and the change scores of the outcome variables in the treatment condition. For pain intensity, no significant correlations were found apart

from a correlation with acceptance, which proved statistically significantly related to a decrease in pain intensity in the treatment (r=.20, p=.038) but not in the control condition (r=.05, p=.551). To examine the effect of group on the predictive value of acceptance, the centred interaction term of Group x Acceptance was entered into the regression analysis as the fourth step after controlling for the outcome variable at step 1, group (treatment vs. control condition) at step 2 and acceptance at step 3.

Table 4: Regression analysis of change in pain intensity after multidisciplinary pain treatment

Order of entry	**R.Sq. Change**	**Beta**
Dep. Variable: Pain T2		
1. Pain T1	.34***	.57***
2. Group	.02***	.10
3. ZCL Acceptance	.00	-.08
4. Group x acc	.01*	-.12*
Total R^2	.37	

** p < .05, ** p < .01, *** p < .001*

Table 4 shows that, after having controlled for baseline pain level (explaining 34%: F-change=111.55, df=214, p=.000), condition (treatment vs. control, explaining another 2%, df=213, p<.007) and acceptance (not explaining any significant additional variance), the regression analyses with pain intensity at T2 as the dependent variable revealed that the interaction of acceptance and condition at step 4 significantly predicted another 1% of the pain intensity at T2 (F-change=4.29, df=212, p<.024). Beta coefficients of the full model demonstrated that the interaction of acceptance and condition contributed significantly to the patients' post-treatment level of pain (p<.05), indicating that after therapy those patients that had reported higher degrees of pre-treatment acceptance also had larger pain reductions than the patients reporting lesser degrees of pre-treatment acceptance (see Figure 2). With regard to functional disability, depression and use of medication, avoidance behaviour proved associated with changes in depression and helplessness significantly correlated with change in medication intake. However, regression analyses failed to yield significant predictors. For illustration purposes, we split the sample into two groups (acceptance ≥ 13 and acceptance < 13) to show that patients with a higher pre-treatment level of acceptance profited more from treatment with respect to pain reduction.

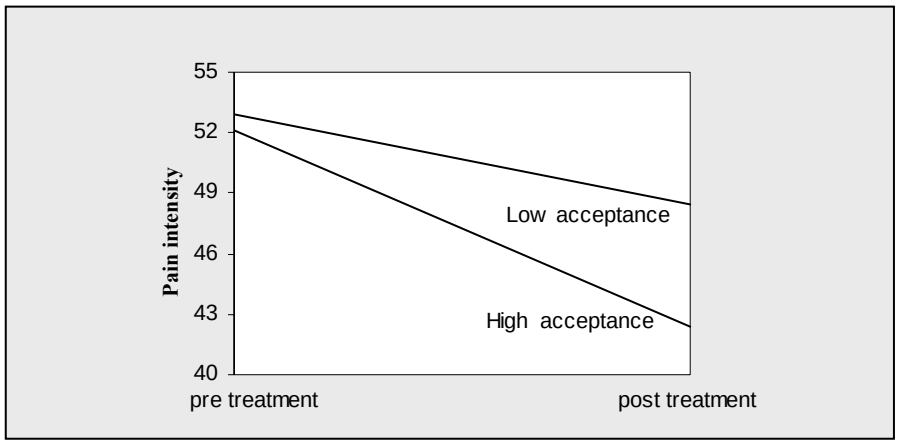


Figure 2: Change in pain intensity for patients with high/low acceptance (median split) in the treatment group between pre-treatment and post-treatment.

Discussion

With the current study we sought to determine the effects of a multidisciplinary outpatient allocation protocol of chronic pain treatment on the physical and psychological outcomes of chronic pain patients and to trace process variables that could have a predictive value for treatment efficacy. Our findings showed that the participating patients tended to benefit from our pain allocation approach with regard to pain intensity and functional disability. As regards cognitive-behavioural treatment predictors, we established that patients reporting higher pre-treatment levels of acceptance benefited more from treatment in terms of pain reduction than patients indicating lower levels of acceptance.

In line with other studies on multidisciplinary treatment approaches[1,2,3,4], the treatment effects for pain and functional disability were significant although generally not more than small. In contrast, depression did not diminish beyond natural course. This lack of effect may be due to negative mood not being the main focus of the treatment modalities delivered, which is especially the case in pharmacological and TENS programmes. As only a relatively small percentage of our patients received treatment specifically aimed at reducing their depressive symptoms, it would be worthwhile if future studies were to also evaluate such targeted treatment modules. We also did not find any significant reductions in medication consumption beyond the natural course, which is congruent with Becker et al.'s findings[40]. Before being referred to our pain centre many of the patients had already had their medication schedule revised in a regional pain centre. Moreover, our centre's pharmacological intervention was not exclusively aimed at reducing the patients' drug intake. It also targeted elimination of the uncontrolled, pain-contingent use of medication through which in many cases

stabilisation was obtained but no overall reduction. Clearly, an adequate delineation of treatment effects on medication intake merits a different operationalisation. The overall moderate effects may also be attributed to large individual differences in outcomes, underscoring the need for reliable predictors of treatment effects[36,41].

Of all possible cognitive-behavioural predictors of treatment outcome, only acceptance predicted pain reduction. Contrary to our expectations, the patients with higher pre-treatment levels of acceptance proved to show more reduction in pain. Several earlier studies had indeed supported the importance of acceptance in chronic pain. Cross-sectional and prospective studies evaluating various chronic pain populations showed that acceptance was consistently associated with lower pain intensity, superior daily functioning and fewer depressive symptoms[8,11,23,42,43] . In their recent correlational study of chronic pain patients, McCracken and Eccleston[44] reported that acceptance accounted for more variance in functional disability and depression than any of the other cognitive-behavioural factors. Pain treatment studies have reported similar findings. Geiser[45], for instance, found that increases in acceptance during multidisciplinary pain treatment predicted a decrease in post-treatment functional disability. Vowles et al.[46] showed that in chronic back-pain patients an acceptance-based pain treatment reduced impairment more than a control-based intervention did. Although in our study, higher acceptance only modestly predicted pain reduction, the results are a first indication of acceptance as a predictor of treatment outcome and as an instrument to optimise patient selection and subsequent treatment outcomes. Cognitions of acceptance may thus reflect that a patient's focus is more directed towards (augmenting) adaptive coping behaviour, which positively affects treatment outcome, supporting previous findings correlating acceptance with less attention to pain[43] and active coping behaviour[8]. These and the current findings underscore the contribution of acceptance as an adaptive coping strategy, thus extending our understanding of the mechanisms of improvement in multidisciplinary chronic-pain treatment approaches. The lack of significant predictive power of the other cognitive-behavioural factors is generally in line with earlier chronic-pain-treatment studies[4,14] that also yielded inconsistent results. Evidently, the interaction between the various cognitive-behavioural factors and pain treatment might be more complex, requiring more in-depth studies into potential reciprocal effects of cognitive-behavioural predictors for short-term treatment effects.

Several aspects warrant a cautious interpretation of the results reported. Firstly, it cannot be excluded that there was some selection bias due to non-randomized treatment allocation. However, patients were allocated to the intervention or control condition on a consecutive basis so the investigators had no influence on the allocation of individual patients, one of the preconditions for randomisation. In addition, the two groups did not differ with respect to demographic or pain-related data. In future studies, propensity score matching[47] may be applied if the patient

characteristics in the intervention and control groups do differ due to non-randomized allocation. Secondly, the patients in the control condition were evaluated after a waiting-list period of three months. A randomized controlled trial or an active control condition (e.g. a support group) would have allowed elimination of a possible bias in treatment effects. Thirdly, as the allocation to the intervention or the control group was based on time of entry, a time bias (e.g. seasonal effects) cannot be excluded. Fourthly, all our participants were acknowledged chronic-pain sufferers referred for treatment to our specialized, academic pain centre and had, on average, experienced pain in excess of five years. Most of the participants indicated to have received previous medical treatment comprising one or more comparative treatment modules in recent years. Hence, we cannot exclude a selection bias. In addition, the anticipation of imminent pain treatment may have raised treatment expectations in the control group, which may have positively affected their pain cognitions and subsequent course of pain behaviour. Moreover, our search for outcome predictors was based on the short-term effects of various, patient-tailored chronic-pain treatment modules and the reported results cannot be generalised to long-term outcomes. A follow-up study might provide more insight into the stability of treatment effects[48]. At this moment we know of only one study on the natural course in chronic-pain patients, showing that acceptance predicted a decrease of pain and depression after one year[8]. Finally, it can be argued that in daily life the multidimensional problems of chronic pain, functional disability, depression and use of medication are interrelated such that it hampers most attempts at outpatient interventions aimed at changing one or more of these modalities as the patient's contacts are limited and treatment conditions can only marginally be controlled. This is confirmed by the findings of Williams et al.[49] and Härkäpää et al.[50] showing that a multidisciplinary inpatient pain treatment was superior to an outpatient programme in terms of pain reduction and improvement of functional ability. Possibly, the treatment intensity in time and frequency of inpatient interventions might be more important for treatment success than the content of specific (multidisciplinary) treatment schemes.

Despite these limitations, our study has provided further evidence that patients suffering from chronic heterogeneous pain tend to profit from pain treatment schemes in that the tailored interventions reduce their pain levels and functional disability. We also found preliminary support that patients who are accepting their condition are most likely to benefit from treatment in terms of pain reduction.

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Chapter 7

Multidisciplinary Allocation of Pain Treatment: Long-Term Outcome and Correlates of Cognitive-Behavioural Processes

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Abstract

Objective: To investigate the long-term effects of multidisciplinary allocation of pain treatment on pain intensity, functional disability, depression, and medication use in outpatients with chronic pain, and to identify cognitive-behavioural predictors [worrying/catastrophizing, avoidance behaviour, fear of pain, helplessness, and acceptance] of the primary outcome measures.

Methods: Eighty-six outpatients with chronic pain who were treated at a multidisciplinary pain centre completed various questionnaires and a pain diary one week before treatment started, and three and 12 months later.

Results: Functional disability and depression improved significantly 12 months after the start of treatment in comparison with before treatment. The decrease in scores for the cognitive-behavioural variables worrying/catastrophizing, fear of pain, helplessness, and avoidance behaviour at three months was associated with the decrease in functional disability and depression at 12 months.

Conclusion: Patients with chronic pain may benefit in the long term from multidisciplinary allocation to pain treatment with respect to functional disability and depression. Changes of cognitive-behavioural processes seem to contribute to achieving long-term effects of multidisciplinary allocation of pain treatment. There is a need for high quality clinical trials in this field in order to clarify the specific contribution of cognitive-behavioural process variables.

Introduction

There is considerable evidence that multidisciplinary treatment of chronic pain, involving medical, physical, and cognitive-behavioural components is effective in improving pain intensity, functional disability, and depression in various chronic pain populations[1,2,3,4]. However, in most studies there were large inter-individual differences, with a considerable proportion of patients reporting no effects or even deterioration in functioning[5,6], which may indicate that self-management skills have not improved sufficiently during treatment.

Consequently, studying predictors of long-tem treatment effects may give relevant information about the factors that influence effects of treatment. The fear-avoidance model of chronic pain[7,8,9] provides a theoretical basis for studying cognitive-behavioural factors in chronic pain. Within this model, fear of pain functions as an anxiety response, directed towards the immediate consequences with regard to pain intensity. Fear of pain in turn is supposed to initiate worrying/catastrophizing about the consequences of pain and hence increases avoidance behaviour, leading in the long term to increased pain, functional disability, and depression[9]. Within the fear-avoidance model, avoidance behaviour is reinforced by the experience that it is a way to control pain by limiting the pain experience. However, in the chronic phase of the pain problem, the ongoing experience of unsuccessful coping may induce depressogenic cognitions of helplessness in accordance with the Learned Helplessness Theory[10,11]. Helplessness acts as an additional negative cognition as activities are not expected to enhance better overall functioning, and may in time induce avoidance behaviour and lead to a further increase in functional disability, depression[12,13], and medication intake as a passive coping strategy. Consequently, both models separately may provide a valid contribution to explaining the course of functioning in patients suffering from a relative longer period of pain and may provide instruments for multidisciplinary pain treatment. There is also preliminary evidence that acceptance[12,14] may be an important factor in people suffering from long-term functional disability and pain[13,15]. Accepting the experience of pain and its consequences may induce a more active, confrontational way of coping and subsequently lead to better functioning[16,17]. Previous studies have shown that changes in cognitive-behavioural predictors during the treatment period affect outcomes immediately after treatment and after a follow-up period. In particular, a decrease in worrying/ catastrophizing[18,19], helplessness[19,20], and an increased acceptance[19,21,22] have been shown to be predictive of a favourable treatment outcome. However, long-term effects of multidisciplinary pain treatment and cognitive-behavioural correlates of treatment success, including fear-avoidance predictors (worrying/catastrophizing, fear of pain, and avoidance behaviour), helplessness, and acceptance have not yet been studied.

It has been repeatedly suggested that tailoring medical, physical, and psychological pain treatment modalities to specified patient characteristics is a promising way to

optimise treatment effects, particularly in the long term[4,23,24]. An earlier study showed that such a multidisciplinary pain treatment strategy of tailoring medical, physical, and psychological pain treatment components to specified patient criteria has a short-term effect on pain intensity and functional disability[15]. In the present study we investigated the long-term effects of this outpatient, multidisciplinary allocation of pain treatment on pain intensity, functional disability, depression, and use of pain medication, and studied cognitive-behavioural correlates of outcome. We hypothesized that the pain treatment would be effective after 12 months on primary outcome measures (pain intensity, functional disability, depression, and use of pain medication) and that these long-term effects would be predicted by change in cognitive-behavioural factors (worrying/catastrophizing, avoidance behaviour, fear of pain, or helplessness) and less acceptance at three months after start of treatment as patients would learn to actively cope with their pain.

Patients and procedure

Patients

Study participants were patients who had been accepted for treatment at the interdisciplinary pain treatment centre of the Radboud University Nijmegen Medical Centre in the Netherlands. To qualify for inclusion in the study, patients had to be at least 18-years-old and have had pain for more than three months. Exclusion criteria were cancer pain, biomedical disorders that could interfere with treatment (e.g., rheumatoid arthritis, serious psychiatric disorders), and/or the inability to read or write Dutch. In addition, patients who were treated elsewhere, i.e. received exercise therapy and/or individual cognitive-behavioural treatment, and patients who did not receive any treatment were excluded from the study. After inclusion, all patients completed questionnaires and a pain diary before treatment and after three and 12 months. Demographic variables of the study group are presented in Table 1.

Multidisciplinary Allocation of Pain Treatment

Patients who had been accepted for treatment by the multidisciplinary team were assessed by an anaesthesiologist, a physiotherapist, and a clinical psychologist, and completed questionnaires on medical and psychological functioning. Treatment consisted of a multidisciplinary pain diagnosis, based on agreement between the three disciplines and subsequent allocation to one or more of the following treatment modules on basis of meeting specified criteria:

Medical Treatment

The aim of medical treatment was to reduce pain by adjusting and minimizing pain medication on a time-contingent basis. Criteria for medical treatment were medication without pain effect, medication use on a pain-contingent basis, presence of negative side effects, and/or use of conflicting or similar pain

medication.

Transcutaneous Electrical Nerve Stimulation

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive intervention that alleviates pain[25]. The TENS stimulator is a small portable battery-powered stimulator, connected by electric wiring to self-adhesive electrodes, applied to the skin. Patients can carry the stimulator while they perform their daily activities. After instruction and adjustment of pulse variables and electrode placement by an experienced physiotherapist, patients are able to manage TENS treatment by themselves. The aim of TENS treatment was to reduce pain. Criteria for TENS treatment was pain because of peripheral nerve root lesions.

Group Cognitive-Behavioural Therapy

Cognitive-behavioural therapy (CBT) consisted of 10 sessions of 1.5 hours with the following treatment components: stress management techniques, problem solving, cognitive therapy, and relaxation. In addition, patients worked on individual goals. In the first session, each patient formulated a specific CBT goal, based on specific underlying problems such as work-related conflicts or marital problems. In the following sessions, patients learned problem-solving techniques and practiced these to solve their problems. The group consisted of five to 12 patients and was led by two psychologists. The aim of group CBT was to decrease functional disability and depression. Criteria for group CBT were medically untreatable pain and low levels of physical, psychological, and social functioning[26]. Patients who met the criteria for more than one treatment modality received a combination of treatments. Duration of all treatment modules was maximum of three months. We did not offer a combination of medical treatment or TENS with group CBT because it was expected that, due to their pain-reduction objectives, both the medical treatment and TENS would undermine CBT treatment compliance as this latter intervention is specifically directed at coping with pain. Patients who already had received TENS treatment and were considered to have an optimal medication scheme, only received CBT with the goal of better functioning, and reduction of depression.

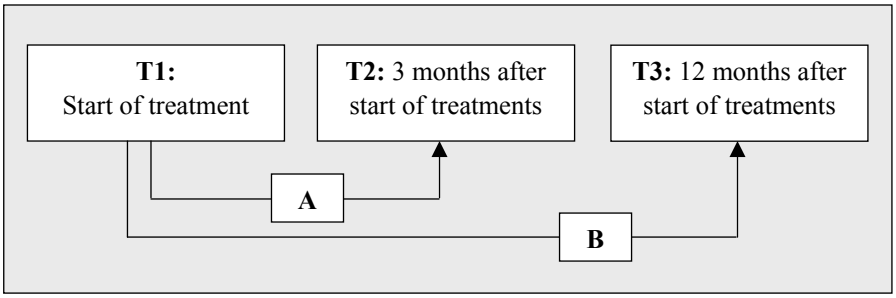

Figure 1. Study Design: study period of predictors (A) and study period of primary outcomes (B)

Measures

Patients completed validated questionnaires and a seven-day pain-and-medication diary one week before treatment started and three and 12 months later (Figure 1).

Pain Intensity

Since multiple visual analogue scale (VAS) ratings have been shown to be more reliable and valid for measuring average pain intensity than a single rating[27], study participants were asked to rate their pain on a 10-centimeter VAS for seven days at three time points each day. The pain VAS scale ranged from no pain at all to the worst pain ever experienced. The average of the 21 pain ratings for each patient was calculated. Cronbach's alpha for pain intensity in our study was 0.91.

Functional Disability

Functional disability was measured with the Dutch version of the Pain Disability Index (PDI)[28,29]. The Pain Disability Index was developed as a brief self-report indicator of pain-related disability[27]. It was constructed as a seven-item questionnaire scored on a scale from 0 (no disability) to 10 (total disability). The items reflect a range of role functioning: family/home responsibilities, recreation, social activities, occupation, sexual behaviour, and self-care and life-supporting activities. The average level of the items scored was used to calculate the disability index. Cronbach's alpha for functional disability in our study was 0.82.

Depression

Depression was measured with the depression scale of the Dutch version of the Symptom Checklist-90[30] measuring 16 symptoms of depression, rated on a five-point scale from 1 (not at all) to 5 (very much). Cronbach's alpha for depression in our study was 0.87.

Use of Medication

Use of medication was measured according to the Anatomical Therapeutical Chemical Classification/Defined Daily Dose (DDD) guidelines[31] by comparing the defined, average amount of drugs needed to obtain the desired effect on pain in the general population (DDD), and the actual use of drugs (used daily dose (UDD)). The actual use of medication was calculated by dividing the UDD of a drug by the DDD of the same drug. When patients used more than one drug for pain, the relative amounts of the different drugs (UDD/DDD) were summed to give a total level of medication use[31,32,33].

Avoidance Behaviour

Avoidance behaviour was measured with the composite score of the passive pain coping scales of Retreating and Resting [13 items] of the Pain Coping Inventory (PCI)[34,35]. The PCI measures cognitive and behavioural attempts to cope with pain on a four-point Likert scale from 1 (rarely or never) to 4 (very frequently). Representative items are, 'When in pain and I am outdoors, I try to return home as soon as possible', 'When in pain, I rest by sitting or lying down, 'When in pain, I quit my activities'. Cronbach's alpha for avoidance behaviour in our study was

0.83.

Worrying/catastrophizing

Worrying/catastrophizing was assessed with the Worrying (nine items) scale of the PCI[34,35]. Representative items are "I start worrying when in pain" and "I think that the pain will worsen." Cronbach's alpha for worrying/catastrophizing in our study was 0.81.

Fear of Pain

Fear of pain was measured with the recently adjusted version of the Tampa Scale of Kinesiophobia (TSK)[36,37], which measures fear of movement due to possible subsequent pain/reinjury. The TSK consists of 13 items, scored on a four-point scale, from 1 (highly disagree) to 4 (totally agree). Representative items are "My pain means there is physical damage" and "My pain tells me to stop exercising so I do not injure myself." Cronbach's alpha for fear of pain in our study was 0.79.

Helplessness

Helplessness was measured with the Helplessness scale of the Illness Cognition Questionnaire (ICQ). The ICQ assesses how patients think about and give meaning to their chronic illness[12]. Helplessness is assessed with six items and measures cognitions that focus on the negative consequences of pain and generalize them to daily functioning. In order to enable comparison with the other pain-related predictors, the term "illness" in the ICQ was replaced by "pain." Representative items of the Helplessness scale of the ICQ are: "My pain frequently makes me feel helpless", "My pain limits me in everything that is important to me", and "My pain controls my life." The items are rated on a four-point scale from 1 (not at all) to 4 (completely). Cronbach's alpha for helplessness in our study was 0.86.

Acceptance

Acceptance was measured with the Acceptance Scale of the ICQ[12]. The six-item scale measures acceptance in terms of cognitions that focus on the person acknowledging that he/she suffers from chronic pain and perceiving that he/she has the ability to manage the negative consequences of the pain. To enable comparison with the other pain-related predictors, the term "illness" in the ICQ was replaced by "pain." Representative items of the Acceptance scale of the ICQ are: "I have learned to accept the limitations imposed by my pain", "I have learned to live with my pain", and "I can handle the problems related to my pain." Cronbach's alpha for Acceptance in our study was 0.87.

Statistical Analysis

Because of skewed distributions of scores at pain duration, square root transformations were applied. Differences in demographic variables, pain duration, and outcome variables between the completers (patients who completed pain treatment and provided follow-up data) and non-completers (patients who completed pain treatment but did not provide follow-up data) before treatment were tested with chi-square analyses for categorical variables and student's t-test

for continuous variables, with $p<.05$ indicating a statistically significant difference. Univariate variance analyses were conducted to test differences between completers and non-completers for short-term treatment effects (at three months) on primary and secondary outcomes. The long-term effects of treatment (at 12 months) on the primary outcomes (pain intensity, functional disability, depression, and use of medication) were tested by two-tailed paired t-tests. Cognitive-behavioural factors (worrying/catastrophizing, avoidance behaviour, fear of pain, helplessness, and acceptance) were regarded as secondary outcome variables. Effect sizes were calculated in accordance with the formula of Dunlap et al.[38]. The number of patients with clinically significant changes was calculated by summing the number of patients with a positive change exceeding half a standard deviation[39]. To investigate cognitive-behavioural predictors, correlations were calculated between the long-term change in the scores of the significant primary outcome variables (between before and 12 months after start of treatment) and the short-term change in scores of cognitive-behavioural predictors (between before and three months after start of treatment). Residual gain scores were used to calculate changes in outcome and predictor variables and were calculated by regressing the variable at the three-month (predictor) or at the 12-month assessment (outcome) on the baseline score of the measure[40]. In the case of significant correlations between primary outcomes and the cognitive-behavioural predictors, these predictors were entered separately in univariate regression analyses with the outcome variable at the 12-month follow-up as dependent variable, after controlling for the outcome variable at baseline (before treatment). Subsequently, the predictors were entered in consecutive steps in multivariate regression analyses in order to study their relative contribution. To control for possible confounding effects of demographic variables (gender, marital status, age, education level) and pain duration at baseline, correlations were calculated between these variables and the change in the scores of the primary outcome variables at the 12-month follow-up. In the case of significant correlations, these variables were entered at step 2 before the predictors in the regression analyses.

Results

In total 110 patients meeting the inclusion criteria were consecutively included in the study. Most of the patients were women (61.6%), married (67.1%), and had a secondary education level (83.5%).

The primary sites of pain were the legs (29 patients, 33.7%), back (28 patients, 32.5%), neck and shoulders (24 patients, 27.9%), arms (14 patients, 16.2%), pelvis (three patients, 3.4%), head and face (three patients, 3.4%), belly (three patients, 3.4%), whole body (one patient, 1.1%), and breast (one patient; 1.1%). In total 12 patients (13.9%) reported pain at two sites and four patients (4.6%) reported pain at three sites. Mean pain duration was 68.1 months (median=42, sd=79.4, range 7-

420 months).
Of all patients, 24 patients (22%) did not complete the follow-up (moved house, n=3; not interested or no time available, n=21); they are referred to as "non-completers." Thus, of the 110 patients included in the study, the data of 86 (78%) were analysed.

Table 1: Means of demographic variables and pain duration of the study group at study entry

Measure	n=86
Gender: % women	61.6
Mean age (sd)	48.9 (14.1)
Married	67.1
Educational level	
primary	14.1
secondary	83.5
tertiary	2.4
Mean pain duration in months (sd)	68.1 (79.4)

In total 16 (18%) patients received medical treatment, 38 (44%) patients received TENS treatment, 14 (16%) patients received group CBT, and 18 (21%) patients received a combination of medical treatment and TENS.

Comparison of Completers and Non-Completers
Comparison of the final study sample (n=86) and non-completers (n=24) revealed no significant differences in demographic variables (gender, age, education, marital status), pain duration, or any of the primary (pain intensity, functional disability, depression, and medication use) and secondary outcome variables (worrying/ catastrophizing, avoidance behaviour, fear of pain, helplessness, and acceptance) at baseline between the groups. Additionally, no significant differences in short-term treatment effects were found for pain intensity, functional disability, depression, or use of medication between completers and non-completers.

Long term effects
Outcome variables (means and standard deviations) are presented in Table 2. Analysis of changes in the treatment group from before treatment to 12 months after treatment showed that functional disability and depression decreased significantly ($t=3.80$, $p<.001$ and $t=2.47$, $p<.05$, respectively), and that level of pain decreased, but not significantly ($t=1.92$, $p=.058$).

Table 2: Results of primary outcome variables and secondary outcome variables (n=86); (T1 = before start of treatment; T2 = 3 months after start of treatment; T3 = 12 months after start of treatment, sd=standard deviation)

	T1		T2		T3	
	Mean	sd	Mean	sd	Mean	sd
Primary outcomes						
- pain intensity	53.96	17.7	45.32	19.4	49.55	22.0
- disability	4.86	1.7	4.19	1.6	4.26	1.8
- depression	28.05	10.6	26.29	10.7	26.06	10.3
- medication use	0.71	0.95	0.51	0.70	0.59	0.97
Secondary outcomes						
- worrying/catastrophizing	19.91	5.7	17.73	4.7	17.84	5.3
- avoidance behaviour	2.09	0.48	1.99	0.48	1.99	0.50
- fear of pain	27.87	9.11	26.04	7.84	27.10	7.70
- helplessness	14.29	4.4	13.35	4.4	13.14	3.8
- acceptance	12.93	3.9	14.73	4.3	14.72	4.2

Table 3: Correlations between short-term changes in cognitive-behavioural predictors and long-term changes in disability and depression; (T1-T2 = before and 3 months after start of treatment, T1-T3 = before and 12 months after start of treatment)

Prediction of long-term change	**Decrease in functional disability** (T1-T3)	**Decrease in depression** (T1-T3)
Decrease in avoidance behaviour (T1-T2)	0.15	0.27**
Decrease in worrying/catastrophizing (T1-T2)	0.31**	0.32**
Decrease in fear of pain (T1-T2)	0.24*	0.27*
Decrease in helplessness (T1-T2)	0.21*	0.25*
Increase in acceptance (T1-T2)	-0.08	0.05

** p< .05, ** p< .01*

Medication use did not decrease significantly (t=1.29, p=.20). Effect sizes were moderate for functional disability (0.34) and small for pain intensity (0.19), depression (0.19), and use of medication (0.11). The number of patients with clinically significant improvement was moderate for pain intensity (n=28; 32%) and small for functional disability (n=17; 20%), depression (n=7; 8%) and medication use (n=10; 9%). Of the secondary outcomes, worrying/catastrophizing (t=4.46, p<.001), avoidance behaviour (t=2.09, p<.05), fear of pain (t=2.20, p<.05),

and helplessness (t=3.17, p<.01) significantly decreased, and acceptance (t=-4.82, p<.001) increased significantly (see Table 3). Effect sizes were small for worrying/catastrophizing (0.37), avoidance behaviour (0.20), fear of pain (0.21), helplessness (0.28), and acceptance (0.44). The number of patients with clinically significant improvement was moderate for acceptance (n=26; 30%), helplessness (n=19; 22%), and worrying (n=18; 21%), and small for fear of pain (n=7; eight percent).

Prediction analyses of long-term changes were performed for the significant primary outcomes of functional disability and depression. No significant correlations were found between demographic variables and pain duration at baseline and long-term change scores for functional disability and depression. Subsequently, correlations were calculated between short-term change scores of the predictors (before and three months after treatment) and long-term change scores of functional disability (before and 12 months after treatment) (see Table 3).

A decrease in worrying/catastrophizing (r=0.31, p<.01), fear of pain (r=0.24, p<.05), and helplessness (r=0.21, p<.05) up to three months after treatment was significantly correlated with the long-term decrease in functional disability.
Hierarchical regression analyses were performed with functional disability at 12 months as dependent variable, after controlling for baseline functional disability at step 1 of the regression analysis (see Table 4). Univariate analyses revealed that short-term decrease in worrying/catastrophizing at step 2 explained five percent (F-change=9.21, p<.01) and short-term decrease in fear of pain at step 2 explained three percent (F-change=5.02, p<.05). Short-term decrease in helplessness tended toward significance (F-change=3.92, p=.051). Beta coefficients of the whole model revealed that, in addition to the baseline level of functional disability, only decreased worrying/catastrophizing had a tendency toward significance (t=1.98, p=.05). Multivariate analyses revealed no additional explained variance at step 3 for any of the predictors. When analysing predictors of the reduction in depression (see Table 4), we found that a short-term (at three months) decrease in worrying (r=0.32, p<.01), avoidance behaviour (r=0.27, p<.01), fear of pain (r=0.27, p<.01), and helplessness (r=0.25, p<.05) was significantly correlated with the long-term (at 12 months) decrease in depression. After controlling for depression at baseline (explaining 74% of the variance, F-change=102.91, p<.001), we found in univariate regression analyses with depression at 12 months as dependent variable that a decrease in worrying (F-change=9.51, p<.01), avoidance behaviour (F-change=6.89, p<.01), fear of pain (F-change=6.16, p<.05), and helplessness (F-change=5.42, p<.05) all significantly predicted the decrease in depression at 12 months, when entering the predictors separately at step 2. Multivariate analyses revealed no additional explained variance at step 3 for any of the predictors.

Table 4: Univariate regression analysis of functional disability and depression at T3 as dependent variables and the predictors entered separately at step 2 after controlling for the dependent variable at T1 at step 1
(T1 = before start of treatment, T2 = 3 months after start of treatment, T3 = 12 months after start of treatment)

Order of Entry	**F Change**	**R2 Change**	**Beta**	**Order of Entry**	**F Change**	**R2 Change**	**Beta**
Dependent Variable Functional Disability T3				**Dependent Variable Dep. T3**			
1. Functional Disability T1	71.20***	0.46***	0.70***	1. Depression T1	102.91***	0.55***	0.74***
2. Worr/cat T1-T2	9.21**	0.05**	0.23**	2. Worr/cat T1-T2	9.51**	0.04**	0.21**
1. Functional Disability T1	68.16***	0.47***	0.68***	1. Depression T1	102.94***	0.55***	0.74***
2. Fear of pain T1-T2	5.02*	0.03*	0.14	2. Avoidance behaviour T1-T2	6.89*	0.03*	0.17*
1. Functional Disability T1	70.93***	0.46***	0.68***	1. Depression T1	91.60***	0.54***	0.74***
2. Helplessness T1-T2	3.92	0.02	0.15	2. Fear of pain T1-T2	6.16*	0.03*	0.18*
				1. Depression T1	99.39***	0.55***	0.74***
				2. Helplessness T1-T2	5.42*	0.03*	0.17*

** p< .05, ** p< .01, *** p< .001*

Discussion

The purpose of the present study was to examine the long-term effects of a tailored outpatient allocation of pain treatment strategy and to identify cognitive-behavioural factors that may reflect treatment processes and predict long-term changes. We identified a small but significant long-term decrease in functional disability and depression, suggesting that patients with chronic pain patients have sustained benefit from a multidisciplinary allocation of pain treatment strategy with regard to functional disability and depression. We found that the long-term decrease in functional disability and depression was associated with the short-term decrease in the cognitive-behavioural factors worrying/catastrophizing, avoidance behaviour, fear of pain, and helplessness. This suggests that these factors have a role in the treatment process and that the long-term effects of treatment might partly be ascribed to changes in these factors.

The sustained but limited long-term decrease in functional disability and depression is consistent with the findings of other studies of multidisciplinary pain treatment strategies[1,41,42]. In another study involving the same patient sample (Samwel et al., this thesis), we found that functional disability and depression also significantly decreased immediately after treatment in comparison to a waiting list control group, as was the level of pain; however, unlike the effects of treatment on functional disability and depression, the effect of treatment on pain was not sustained during the 12-month follow-up. Use of medication did not decrease beyond that expected, possibly because the main aim of treatment was to reduce the consequences of pain and the uncontrolled, pain-contingent use of medication rather than to reduce medication use, per se. In fact, medication use may increase to achieve adequate pain control, which implies that a decrease in medication use is not a goal in itself.

In view of the limited long-term effects, it is important to study process variables moderating treatment effects. The long-term decrease in functional disability and depression was associated with the short-term decrease in worrying/ catastrophizing, fear of pain, avoidance behaviour, and helplessness. These findings suggest that treatment focused on changing these aspects would bring about a beneficial change in functional disability and depression. This finding also indicates that treatment for chronic pain that aims to improve functioning and which includes cognitive-behavioural components to increase self-management skills after treatment may help patients to sustain the improvements attained during treatment. This is in line with the fear-avoidance model, which hypothesizes that a decrease in fear-avoidance factors will in the long-term lead to a less pain preventing way of coping with pain and in stead and consequently less functional disability and depression. Our findings also suggest that within this model, less avoidance behaviour does not automatically lead to more fear of pain and consequently re-increase of avoidance behaviour. In addition, the learned helplessness model, hypothesizing that reducing helplessness cognitions may re-

induce a more active coping behaviour and subsequent better functioning and mood. It may be concluded that applying treatment components reducing levels of worrying, fear of pain, avoidance behaviour, and helplessness may improve the effects of a tailored multidisciplinary pain treatment strategy. In addition, our study supports the hypothesis that both the fear-avoidance model and the learned helplessness model may contribute to a theoretical basis for understanding treatment processes in multidisciplinary treatment.

Our study had a number of limitations. Firstly, we did not include a control group and the allocation to treatment was not randomized. Thus, we cannot exclude that the improvement was due to spontaneous remission rather than the treatment. However, the long-term effects on functional disability were consistent with effects reported earlier[20,43,44]. Secondly, it is possible that only those patients who considered treatment to have been beneficial were willing to provide follow-up data, which may lead to overestimation of the treatment results[45,46]. Thirdly, the small to moderate effect sizes may be due to the limitations of an outpatient-based treatment setting. It could be argued that inpatient treatment settings have more instruments for treating patients with chronic pain of unknown origin[47,48]. This could mean that hypotheses concerning treatment effects should be adjusted for the setting (inpatient versus outpatient) and should be studied with respect to cost-effectiveness (for example, what are the overall costs for a mean decrease in pain intensity of one point on VAS scale for one pain patient?). Fourth, clinically significant improvement was calculated by means of minimally detectable changes[39]. It may be argued that the criteria as suggested by Norman et al.[39] does not necessarily imply clinically meaningful changes. Future studies have to address this issue in more detail by examining, for example, various methods to assess clinically significant change in different health care programs. Finally, our follow-up period was 12 months, but that of other studies varied from three months to four years[49], which makes it difficult to compare results. Hazard et al.[50] showed that different variables predict outcome depending of the length of the follow-up period. It may be worthwhile to standardize follow-up periods in future long-term studies on treatment effects in order to improve comparison of study data.

Despite these limitations, our study provides further support that patients with chronic pain can attain long-lasting benefit, in terms of functional disability and depression, from an outpatient multidisciplinary treatment. Our findings suggest that the fear-avoidance and the learned helpless model may function as a solid conceptualisation of treatment processes in multidisciplinary pain treatment strategies, suggesting that cognitive-behavioural treatment processes may contribute to achieving long-term treatment effects. However, there is a need for high quality clinical trials in this field in order to clarify the specific contribution of cognitive-behavioural process variables to long-term treatment effects.

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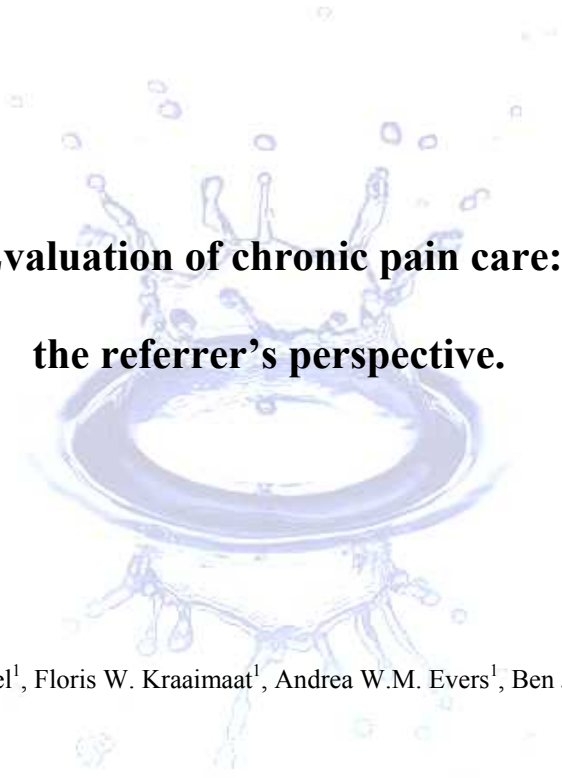
PART 3

Referral issues and implementation of current knowledge on psychological treatment of chronic pain.

Chapter 8



Evaluation of chronic pain care:

the referrer's perspective.

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Abstract

Background: Chronic pain patients are often referred to specialised pain facilities only in an advanced stage of the pain condition. The referrers' evaluation of the care of their patients in a pain centre may affect their willingness to continue to refer their patients to specific chronic pain treatment facilities. It may also yield important information of how to improve the quality of such a facility. Yet, there are no studies available that examined the factors, associated with general practioners' evaluation of the care of patients by a specialised pain centre.

Methods: As part of a larger study on treatment effectivity[1], we carried out a survey among general practioners (GPs) of one hundred and ten subsequent patients who were treated in the multidisciplinary pain centre of the Radboud University. Referring GPs of eighty-three chronic pain patients (75%) who had been accepted for treatment at the multidisciplinary pain centre completed a questionnaire three months after start of treatment. The questions dealt with the expectations of the referral, the evaluation of different aspects of the pain care and the overall evaluation.

Results: GPs had varied expectations of the referral: establishing the cause of pain (n=12: 14.3%), the installment of medical (n=28: 33.3%), paramedical (n=23: 27.4%) or psychological (n=25: 29.8%) treatment. Thirteen patients were referred without a specific treatment goal (15.5%). GPs were satisfied with the overall care for their patients (mean score of 7.8 on a 0-10 scale, sd=0.9). Patients being diagnosed by the disciplines asked for was evaluated most positively while prior information about the waiting time before treatment was evaluated least. Correlation analyses indicated that meeting the expectations of the referral correlated most with the overall referral evaluation.

Conclusion: GPs varied greatly in their expectations when referring their patient to a pain centre and regarded meeting their expectations of the referral as a key item for evaluating the care. Prior information, especially with regard to waiting time was least evaluated. In order to optimise referrer policies, a pain centre should communicate more actively with the GPs with regard to referral expectations and pretreatment waiting time.

Introduction

Chronic pain patients are referred to specialised pain centres particularly in an advanced stage of the pain condition. Only 2 percent of these patients are currently treated by a pain-specialist[2]. From a patient perspective, sixty percent of the patients experienced their pain as not adequately treated. Only 17 percent of chronic pain patients had no need of health care services in order to be able to cope with their pain[3] although numerous studies indicate that multidisciplinary chronic pain treatment can be effective[,4,5,6,7]. Consequently, it is important to investigate the reasons for referral for treatment to a specialised pain facility in order to provide the adequate care for patients, suffering from chronic pain. In the Netherlands, most chronic pain patients are referred to pain centres by general practioners (GPs). Therefore GPs can be considered as gate controllers who determine the accessibility to second echelon facilities and as such have a decisive role in controlling medical consumption. The way the GP perceives the quality of a possible treatment facility of their patient is mainly based on the experience with earlier referrals and therefore may affect the communication with a patient on referral questions and the willingness to refer. Therefore, it is crucial to know how GPs evaluate the quality of the pain treatment for their patients as this may affect the willingness to refer other chronic pain patients in the future. The evaluation of referring general practioners can be considered as an important criterion in the evaluation of a pain centre. However, this issue is still an unexplored territory as until recently it was not regarded as a possible outcome in chronic pain studies[8]. Consequently, the literature is scarse about satisfaction of referrers of chronic pain patients with the care of specific pain facilities. We found only one study on satisfaction of general practioners of chronic pain care[9]. This study revealed that, although 96% of the GP responders considered pain centres as beneficial, only 14% of their chronic pain patients were referred to these facilities. However, this study examined evaluation regarding chronic pain treatment in the second echelon in general and not specified to the care of chronic patients in specific multidisciplinary pain centres.

Our study aims specifically at getting insight into the expectations of GPs when referring chronic pain patients to a multidisciplinary pain centre. GPs are more inclined to refer their patients when they evaluate the outcomes of past referrals as positive. Therefore it is crucial to know on what basis GPs evaluate referrals. In a previous study among more than 40 general practioners as part of recurrent educational meetings, open interviews of general practioners pointed that the following: priori information, multidisciplinary screening and adequate reports are considered important. In line with these findings, the study questions were formulated as follows: firstly, what did GPs expect from the pain centre at referral and secondly, which of the above mentioned aspects of pain treatment (priori information about the pain centre, diagnostic procedures, adequate reports and

meeting the goals of the referral) were associated with the level of overall satisfaction..

Procedure

As part of a larger study on treatment effectivity[1], we carried out a survey among GPs of 110 subsequent chronic pain patients who were treated in the Pain Centre of the Radboud University Medical Centre, Nijmegen, The Netherlands. A questionnaire was mailed to the GP of the patient they had referred, three months after the start of treatment. In total 69 GPs of total 83 patients completed the questionnaires (75.4%). This implies that some GPs were asked to participate in the study more than once according to their referrals.

Minimal age of patients to be included was 18 years. Exclusion criteria were pain due to pathophysiological causes such as cancer, serious psychiatric disorders, and the inability to read or write Dutch. The average age of the 83 participating patients was 48.1 years (sd=12.8, range 18-79). Most of the patients were women (63.8%). The primary sites of pain were the lower extremities (28 patients; 33.7%), back (27 patients; 32.5%), neck and shoulders (23 patients; 27.7%), upper extremities (14 patients; 16.8%), pelvis (3 patients; 3.6%), head and face (3 patients; 3.6%), abdominal pain (3 patients; 3.6%), whole body (1 patient; 1.2%), breast (1 patient; 1.2%). In total 12 patients (14.4%) reported pain at two sites and 4 patients (4.8%) reported pain at three sites. Mean pain duration was 68.1 months (median=42, sd=79.4) with a range of 7-420 months.

After the regular three-month waiting-list period an anaesthesiologist, a physiotherapist and a psychologist screened all patients and allocated them to one or more of the treatment modules (medical treatment, transcutaneous electrical nerve stimulation TENS, cognitive-behavioral group therapy).

Medical treatment. In this study, medical treatment consisted of optimising pain medication. Medical treatment was aimed at pain reduction by attuning and minimizing pain medication on a time-contingent basis. The inclusion criteria for this treatment modality were improper drug, medication use on a pain-contingent basis, presence of adverse effects or use of conflicting or resembling pain medication.

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive intervention to alleviate pain. An experienced physiotherapist applies a small portable battery-powered stimulator, connected by electric wiring to self-adhesive electrodes, to the patient's skin. After proper instruction and adjustment of pulse variables and electrode placement, patients are able to manage the TENS treatment by themselves during their daily activities. They can monitor their pain level and adjust the pulses to alleviate the pain, which hence may reduce their cognitions of helplessness and avoidance behaviour. Eligible were patients suffering from pain

Evaluation of pain care

We want to know your opinion about the care of your patient by the Pain Center. Your patient: ---------- was seen in the Pain Center of the Radboud University on ----------

1 What did you expect of the pain center?

Please, cross one or more of the answer alternatives.

- ☐ for an advice on the possibilities of pain treatment
- ☐ for finding the cause of the pain
- ☐ for a specific treatment namely.:
  - ☐ medical
  - ☐ paramedical (e.g. physiotherapy)
  - ☐ psychological
  - ☐ otherwise, namely:
- ☐ for a psychological diagnosis
- ☐ to finish the medical shopping
- ☐ did not know any alternates
- ☐ otherwise, namely: ----------

If you did not refer your patient yourself, did you support the referral: yes / no

2 How do you evaluate the care of your patient by the Pain Center?

	Do not agree at all				Totally agree
a) I had sufficient information about the Possibilities of the Pain Center before referring	1	2	3	4	5
b) The reports on the diagnosis and treatment of my patient were adequate	1	2	3	4	5
c) The diagnosis and treatment of my patient met the goals of my referral	1	2	3	4	5
d) My patiënt was examined by the disciplines I asked for	1	2	3	4	5

Can you give a mark, between 0 and 10, for the total care of your patient? ----------

Do you have any concluding remarks?

Figure 1: GP Evaluation questionnaire

due to peripheral nerve-root lesions, excluded were patients reporting pain in the face or head or on several pain sites.

Cognitive-behavioural group therapy (CBT). CBT consisted of ten 90-minute sessions and was targeted at reducing the patients' functional disability and depression by reducing negative cognitions and avoidance behaviour using the following treatment components: stress-management and problem-solving techniques, cognitive therapy and relaxation exercises. In addition, patients worked on individual goals. In the first session, every patient formulated a specific CBT goal based on their personal underlying problems (e.g. work-related conflicts or marital problems). In the subsequent sessions, patients trained and implemented their personalized problem-solving techniques. Groups consisted of minimally 5 and maximally 12 patients and were led by two psychologists both fully trained in CBT. Inclusion criteria for group CBT were untreatable pain and severe limitations in physical or psychological functioning. Exclusion criteria were incapacity to function in a group or indications of a psychiatric disorder.

Measures

GP Evaluation questionnaire

The GPs were asked to complete a short questionnaire, based on an earlier survey examining GP priorities when referring their patient to a pain centre (see Figure 1). Questions concerned the benefits for the GP to be obtained by the referral. Expectations consisted of clarification of the cause of pain including psychological aspects, advices on medical, paramedical and psychological treatment, or the advice to the patient to stop "medical shopping". Items rated on a yes/no basis. Satisfaction with the following were rated on a scale of 1 (don't agree at all) – 5 (totally agree): I had sufficient information about the possibilities of the Pain Centre before referring; the reports on the diagnosis and treatment of the patient were adequate; the diagnosis and treatment of my patient met the expectations of my referral; my patient was examined by the right disciplines. Finally, overall satisfaction was rated by a mark between 0 (totally insufficient) –10 (excellent).

Statistical analysis

For the overall satisfaction, the mean and standard deviation were calculated. In order to examine the association of different aspects of care with an index of overall satisfaction, Pearsons correlations were computed.

Results

Evaluation of care

Overall evaluation of the care of their patients was 7.58, sd=0.92 (10-points scale). GPs of 7 patients rated the overall care under 6.00 (see Table 1). Major reason for

low rating was lack of information on the length of the waiting period of the patients prior to entering the pain centre.
The patient being seen by the disciplines asked for had the highest scores (mean=4.01, sd=0.85: scale 1-5: see Table 1). Also the reports about the diagnosis and treatment were rated with high scores (mean=3.98, sd=0.82: scale 1-5). Most GPs found that the referral of their patient had met the expectations they had in mind (mean=3.88, sd=0.85: scale 1-5). The information they had prior to the referral was rated somewhat lower (mean=3.76, sd=1.08: scale 1-5).

Table 1: Evaluation of the care of their patients by the pain centre; n=83. Overall evaluation (between 0: absolutely insufficient, to 10: excellent) and evaluation of different aspects of care (between 1: don't agree at all, to 5: agree totally)

Subject	Mean (range)	sd
Overall evaluation	7.58 (0-10)	0.92
Evaluation of specific aspects of care		
sufficient priori information of the Pain Center	3.76 (1-5)	1.08
adequate diagnosis and treatment report	3.98 (1-5)	0.82
care met the goals of referral	3.88 (1-5)	0.85
patient was diagnosed by the right disciplines	4.01 (1-5)	0.85

Table 2: Expectations of general practioners of referral to the pain centre (n=83)

Expectations of referral	Number (%)
Advice on pain treatment	55 (65.5)
Finding the cause of pain	12 (14.3)
Specific pain treatment:	
medical	28 (33.3)
paramedical	23 (27.4)
psychological	25 (29.8)
Psychological diagnosis	3 (3.6)
Finishing medical shopping	10 (11.9)
I don't know any more	13 (15.5)

Expectations of referral

With regard to pain diagnosis, GPs of in total 55 patients (65.5%) asked for an advice on pain treatment (see Table 2) and GPs of 12 patients (14.3%) wanted the

pain cause to be found. With respect to pain treatment, GPs of 23 patients (27.4%) specifically wanted a paramedical treatment and GPs of 25 patients (29.8%) wanted a psychological treatment. Although many GPs stated specific diagnosis or treatment goals, GPs of 13 patients (15.5%) admitted that their referral was motivated by not knowing any alternative for their patient and that the referral was the last hope for pain relief. GPs of 10 patients (11.9%) stated that their referral should be used to end further medical shopping behaviour.

Correlations of treatment expectations with overall evaluation

The way, the care of the pain centre met the expectations of the referrer correlated most with the overall evaluation (r=.63; p<.001, see Table 3). The general information prior to the referral correlated least with overall evaluation (r=.27; p<.001).

Table 3: Correlation coefficients between evaluation of different aspects of care

Aspects of care:	Total evaluation
Sufficient priori information of the Pain Centre	.27***
Adequate diagnosis and treatment report	.58***
Care met the expectations of referral	.63***
Patient was diagnosed by the right disciplines	.55***

*** *p<.001*

Discussion

The goal of this study was to examine the way, GPs of chronic pain patients referred to the multidisciplinary pain centre evaluated the performance of the pain centre. Although GPs in general evaluated the care provided by the pain centre positively, they were less satisfied with the information, prior to their patient entering the pain centre. Specifically, most GPs not satisfied with this aspect indicated that they were not informed about the duration of the waiting period before assessment and treatment, inducing uncertainty, for both GP and patient. Long waiting lists are notorious in the treatment of chronic pain. Most chronic pain patients have a long history of waiting for diagnosis and treatment in different pain care facilities. Adequate information on this issue therefore is judged to be important by GPs as well as patients.

The positive evaluation by the GPs of the care by the pain centre was closely related with the outcome that the pain centre complied with the expectations of the referral. However, there was a great variety in goals as mentioned by GPs, including medical diagnosis elucidating the cause of pain and treatment,

paramedical or psychological treatment or an advice to the patient to stop "medical shopping". A fair number of 13 patients (15.5%) were referred without a special goal, only as a 'jump into the dark or a cry for help". In future studies it may be important to examine the question, whether the GP discusses non-medical goals or the lack of a clear strategy in pain treatment. This attitude may promote the openness of the communication the GP and the patient. This issue is also important, as the pain centre has to take into account the expectations of both the patient and the referrer.

What might be the clinical implications of the present study? Firstly, in order to optimise the number of referrals by GPs, it is important to improve the service in reaction to the study findings, particularly to optimise the pre pain care communication. When patients are referred, the GP should receive more information about the approximate waiting period and the possibility of easy contact with the pain centre for further information and the possibility of a first advice for pain management. Secondly, more attention should be paid to address in detail the formulated expectations of referral by GPs in the post treatment reports by a pain centre. Thirdly, monitoring GP satisfaction should be a standardised regular procedure in order to assess the way, GPs evaluate pain care.

There are some important limitations of the study to be mentioned. Firstly, we did not study the expectations of the individual patient. It may be crucial to get insight into the way referrers' and patients' expectations may differ. Secondly, we did not study the GP characteristics and the quality of the relation of the GP with the patient. Therefore we may have missed important other factors that may have affected the evaluation beyond the quality of the care of the pain centre. Thirdly, we need to compare responding and non-responding GPs. It cannot be excluded that the GPs who did not complete the questionnaire evaluated the care of the pain centre less positively than the responders. Finally, in our study, only patients who had a pain treatment within the Pain Centre were included in the study. It cannot be excluded that the decision of refraining from treatment may also affect referrer evaluation. In future studies, also patients who did not have a pain treatment as a consequence of the diagnosis procedure should be included.

In conclusion, this is a first attempt to get insight into the way, referring GPs evaluate the care of their chronic pain patients by a multidisciplinary pain centre. Although there are some important limitations, the study demonstrates that it is important that a pain centre gains insight into the expectations of the GPs. Referral questions after the patient has finished the diagnosis and/or treatment procedure should be answered in detail. Future studies should focus on the quality of the communication between the GP and pain centre with respect to the concordant expectations of the care of a pain centre and the way, adequate information of the GP by a pain centre may affect referral policies.

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Chapter 9

Psychological treatment of pain:

Implementation in primary care.

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Abstract

Background: In the Netherlands, psychological pain treatment is mainly provided by second echelon pain treatment facilities. Negative consequences of this situation are a long waiting period before start of psychological pain treatment and referrals of pain patients to pain centres only in a chronic stage of the pain who should have had psychological treatment in an earlier stage in order to prevent chronification of the pain problem. In order to solve these issues, the Pain centre of the Nijmegen University Medical Centre St Radboud started a project, aiming at implementing cognitive-behavioural treatment (CBT) in the first echelon health care by creating a network of first echelon psychologists, specialised in providing CBT to (chronic) pain patients.

Methods: The implementation project was executed in four subsequent steps: 1) a symposium was organised in order to interest first echelon psychologists in becoming involved and providing information about a training course; 2) a training course was organised. In total 39 psychologists attended and completed the course; 3) the psychologists who had completed the course joined a regional network "cognitive-behavioural treatment of chronic pain" with periodical intervision sessions, and 4) efforts were made to boost hospital and primary care referrals to the psychologists of the network.

Results: In 2006 the regional network consisted of 28 skilled primary care psychologists. The number of referrals were 49 from the multidisciplinary pain centre and 53 from GPs. The average waiting list for CBT for chronic pain patients was 3 weeks (at the start of the project in 1997, the waiting period was 14 weeks).

Conclusion: The implementation project was successful in creating a network of skilled psychologists, boosting first echelon referrals and reducing the waiting period before the start of treatment.

Introduction

Patients suffering acute pain will initially visit their general practioner (GP) for alleviation of their complaints (primary intervention). Frequently, the pain has a manifest nociceptive origin such as tissue damage. If treatment does not ameliorate or eliminate the pain, the complaints become subacute and associated with additional adverse effects like prolonged sick leave. Psychological factors, most notably cognitions and behaviours, start playing an increasingly prominent role in the patient's perception of the pain symptoms and their consequences. In such cases, patients may be referred to a primary-care psychologist to prevent the complaints from becoming chronic (secondary prevention[1]). If the pain persists for more than 12 weeks, the likelihood that it will abate diminishes with time and the risk of chronicity increases by the same token[2,3]. At this stage psychological factors that perpetuate the complaints tend to dominate, the (direct) link between the pain and any tissue or nerve damage has lost any tangible relevance and the interaction between psychological and medical factors has gained in complexity[4]. Here, the intervention of a clinical psychologist affiliated with a hospital pain clinic is warranted, with the treatment objective being to modify the patient's perpetuating factors and to minimise the implications of any chronic complaints (tertiary prevention). In cases where a brief cognitive-behavioural intervention suffices, this may be provided by the primary-care psychologist.

The pain centre of the Nijmegen University Medical Centre St Radboud operates from the perspective of multidisciplinary collaboration[1] entailing that all disciplines, i.e. anaesthesiologists, physiotherapists and psychologists, are involved in the diagnostic process and jointly decide on the treatment goals and which disciplines are to deliver the care indicated.

Psychologists affiliated with a multidisciplinary pain treatment team see numerous patients with chronic pain, affording them ample opportunity to gain in-depth knowledge of the characteristics typical of this population[5]. The clinical psychologist at the centre is annually involved in the diagnoses of at least 200 patients. The number of patients with subacute or chronic pain that receive psychological treatment in a primary-care context, on the other hand, is much smaller. Here, psychologists see an estimated 1 to 2 patients a year, which prevents them from acquiring sufficient expertise.

Psychological interventions for patients with subacute or potentially chronic pain should, however, preferably be delivered in a primary-care setting, as such a timely cognitive-behavioural treatment (CBT) of existing perpetuating factors may well prevent chronicity. There are additional motives for having primary-care professionals provide such interventions. First, the pain-centre psychologist will only deliver the indicated treatment and subsequently cease contact with the patient, whereas his primary-care colleague will keep in touch with his patient in view of relapse prevention as his job description includes both treatment and

secondary prevention. This has the advantage that patients who are finding it increasingly difficult to cope with their pain will be seen by their own therapist without delay, also because of the limited physical distance between the patient's home and the consulting room. Moreover, primary-care therapists tend to have no or short waiting lists and aim to schedule the first visit within three workdays of the referral. Treatment for pain patients at risk of an imminent relapse is hence prompt, allowing them to quickly resume optimal pain-coping strategies. If treatment is unavailable or insufficiently prompt, this will heighten the risk of the patient relapsing and reverting to his somatic tendencies (i.e. defining the pain exclusively as a medical problem and seeking a medical solution). Secondly, communication lines between GPs and primary-care psychologists are short, especially if they both work at the same health centre, which enables the therapist to help the GP with any questions pertaining to their mutual patient.

In a survey among 67 primary-care psychologists conducted within the framework of a further training course, 63% indicated to have difficulties in their contacts with (chronic) pain patients resulting from a lack of specialised knowledge and skills[4]. This shows that for these therapists in-depth insight and proficiency are crucial to ensure an adequate treatment of this patient group. The absence of such expertise may inhibit hospital psychologists, GPs and company doctors from referring pain patients indicated for secondary prevention, i.e. psychological treatment, to a primary-care psychologist, causing cumulative problems:

- Pain teams refer few or no patients to primary-care services;
- GPs do not refer patients to primary-care psychologists;
- GPs refer patients to the hospital with a psychological query the primary-care therapist should be able to address, and
- Primary-care psychologists are prevented from acquiring the necessary expertise due to the lack of referrals.

The above illustrates that to guarantee a qualitatively sound and timely psychological treatment of patients with subacute pain in a primary-care context ample knowledge and experience as well as an adequate supply of eligible patients are required. Our first research question therefore was: Can we encourage a sufficient number of primary-care psychologists to acquire the expertise necessary to adequately treat patients diagnosed with subacute or chronic pain within the service area of the academic hospital? The second question we wished to answer was: Can we establish a regional referral policy for pain patients that will enable the primary-care psychologists to acquire the necessary expertise?

In this article we give an account of our project aimed at the phased implementation of the cognitive-behavioural treatment of pain in a primary-care context. The main objectives were 1) to create a regional network of knowledgeable and skilled primary-care psychologists to diagnose and treat

patients with subacute and chronic pain and 2) to realise a sufficient volume of pain patients referred for treatment to the network members.
The project comprised the following four stages:

1. Organising a symposium to introduce primary-care psychologists to the cognitive-behavioural treatment of patients with pain complaints and cataloguing the practical problems associated with such psychological interventions and encouraging interested therapists to attend a training course in the diagnosis and treatment of patients with subacute or chronic pain symptoms.
2. Designing a training course to help interested psychologists to acquire the necessary competency.
3. Creating and supporting a regional treatment network by scheduling regular network meetings and promoting the network members to all GPs in the district.
4. Boosting the number of referrals of pain patients to the network.

Next, the various stages of the project will be described in more detail.

The implementation roadmap

Stage 1: The symposium

With the symposium we aimed to explore how primary-care psychologists perceived their dealings with chronic pain patients, to interest them in becoming involved in the treatment of this patient group and to inform them about the possibility to attend a training course designed to provide them with the necessary knowledge and skills. We posed the following three questions: (1) Have you ever treated chronic pain patients?; (2) If so, which problems did you encounter with these patients in particular?; And (3) Would you be interested in attending an applied training course specifically aimed at this patient group?
All primary-care psychologists within the service area of the Nijmegen university hospital received an invitation and 67 therapists responded and subsequently attended the conference. They indicated to have limited experience in the treatment of chronic pain patients and most had encountered difficulties, most notably with the patients' reluctance to accept a psychological frame of reference for the treatment of their pain complaints. They also indicated that the patients' somatic fixation and the absence of a somatic substrate tended to complicate the treatment[4]. Nearly all expressed an interest in treating patients with subacute or chronic pain as well as a need for additional training to raise their proficiency in this domain.

Following the symposium various regional providers of ambulatory mental health services (GGZ Gelderland) were contacted to obtain information about and support for the proposed, dedicated training course. It was agreed that they would each appoint one of their psychologists as a liaison to assist our pain centre in the selection and design of the course components. Our team subsequently convened

several times with three of these liaisons to further delineate the needs and wishes of colleagues working in the field and to incorporate these in the course. The final course content was submitted to all local mental health centres for approval.

Table 1: "The psychologist as a pain specialist" course syllabus

Session	Topic	Contents
1	Reference framework	Cognitive-behavioural model of pain
2	Diagnosis	- Medical aspects of chronic benign pain - Diagnostics: Respondent and operant approaches
3	Patient-therapist interaction	Defining patient-therapist relationship, resistance to treatment
4	Treatment	- Cognitive-behavioural approach - Respondent and operant approaches
5	Back pain	Diagnosis and treatment of lower back pain
6	Headache	Diagnosis and treatment of headache and neck pain
7	Fibromyalgia	Diagnosis and treatment of fibromyalgia and other diffuse pain syndromes
	Societal aspects	Legislation and policies regarding health care

Stage 2: The training course[6]

Information about the resultant dedicated training course entitled "The psychologist as a pain specialist" was sent to all psychologists practising in the hospital's service area. The clinical psychologist of the Nijmegen Pain Centre subsequently delivered the course in 1998, 1999 and 2005.

Requisites for course subscription and attendance were a minimum of two years of practical experience in (mental) health-care service delivery and an adequate knowledge of the theoretical framework of CBT. These criteria were founded on evidence in the literature showing that, worldwide, CBT for chronic pain was the most effective of treatment approaches[7,8]. We, moreover, wished to attain homogeneity in the theoretical background of the course participants, which we deemed essential for all potential referring parties (predominantly GPs) as this would leave them in no doubt about the background, treatment principles and approach of the newly trained psychologists.

The course aimed to provide the participants with
- Knowledge of the medical and social aspects of subacute and chronic pain,
- The insights and skills required for a proper diagnosis and delivery of CBT for chronic pain patients and
- Information regarding collaboration with other professionals involved in the pain treatment (GPs, medical officers, physiotherapists and medical consultants).

Central to the course was the treatment protocol developed by the pain centre that has since been expanded and published in book form[9]. The course comprised seven three-hour sessions (see Table 1) and was attended by a total of 39 primary-care psychologists all working in the pain centre's service area.

Stage 3: The regional pain treatment network

After having completed the training course, all 39 psychologists joined the regional network named "Cognitive-behavioural treatment of chronic pain". By becoming a member, all therapists confirmed they had completed the course and pledged they would attend the network's half-yearly intervision meetings (see below). Their names were listed in the information booklet the UMC St Radboud Pain Centre issues for the benefit of GPs in its service area. The network members were also posted on the knowledge centre's website, which in 2006 was regularly visited by health professionals seeking relevant referral options.

As stated, all network members were invited to attend the network's biannual supervision/intervision meetings whose objective it was to:

1. Update the members on the latest developments in and approaches to pain and pain treatments;
2. Discuss any issues relating to hospital referrals, e.g. whether all patients the hospital referred for treatment actually ended up with the psychologist and whether the patient information the hospital provided was sufficiently detailed;
3. Exchange therapeutic experiences;
4. Discuss cases put forward by the members;
5. Organise oral presentations by the members about themes pertaining to pain and its treatment.

In addition, the clinical psychologist who had delivered the training courses and was now supervising the network meetings was always available by phone and email to offer advice on the diagnosis or treatment of individual patients.

Stage 4: Boosting referrals

Boosting referrals: Hospital referrals

Once the multidisciplinary pain team had decided CBT was warranted, the question who should deliver the treatment became the focus of discussion. The decision whether a pain patient was eligible for referral to a primary-care psychologist was founded on the following criteria:

- All options for medical treatment have been exhausted or no further indications exist for additional medical diagnoses or interventions.
- Implications for daily functioning (e.g. pain intensity, functional limitations, mood, medical consumption) are mild to severe;
- Psychological factors negatively affecting daily functioning have been established;
- Individual brief CBT is deemed opportune;
- There are no factors, such as acute psychosocial stressors, that could interfere with brief CBT.

If these criteria were fulfilled, the patient was referred to the network psychologist whose practice was closest to the patient's home.

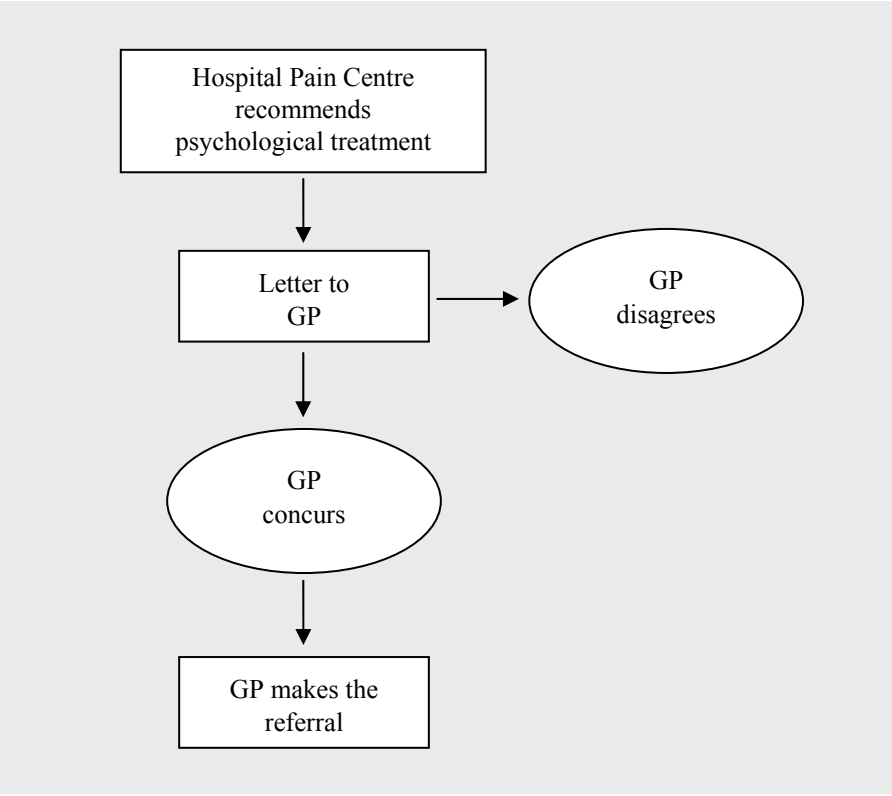

Figure 1: Procedure for referrals for CBT.

The procedure for hospital referrals was as follows (see Figure 1): when the hospital's pain centre had decided to refer a patient to a primary-care psychologist, the decision was passed on to the GP in the form of a letter recommending brief CBT, stating the relevant details of the proposed network psychologist.

Acting on the advice, the GP would then refer the patient to the recommended psychologist. If he did not concur with the recommendation, the final decision remained with him. If need be, the pain centre's clinical psychologist elaborated the team's recommendation but he would not oppose the course of action proposed by the GP, thus abiding by the GP's coordinating role[10]. With this approach we sought to remove some of the barriers that might prevent GPs from endorsing the recommended treatment.

Boosting referrals: Primary-care referrals

The primary-care psychologist is trained in delivering brief, tailored interventions, which implies that his focus is on the amelioration or eradication of a patient's psychological symptoms. The treatments he offers are hence primarily directed at resolving Axis-I psychopathology as described in the DSM-IV classification system (APA)[11], which also defines pain disorder (see text box below).

Pain Disorder (as defined in DSM IV; APA, 1994)

1. The primary presentation is pain in one or more anatomical sites, which is sufficiently severe to merit medical treatment.
2. The pain causes significant suffering or limitations in social or occupational functioning or functioning in other essential domains.
3. Psychological factors are assumed to play a key role in the onset, the nature and severity, and the exacerbation or perpetuation of the pain.
4. The pain is not intentionally instigated or simulated.
5. The pain has not been previously attributed to a mood disorder, anxiety disorder or psychotic disorder and does not fulfil the criteria for dyspareunia.

Text box 1: Definition of pain disorder according to the DSM-IV classification manual.

The DSM-IV definition indicates that subacute or chronic pain is not to be (re)defined as a psychiatric disorder but should rather be treated as a disorder in its own right.

Boosting the number of primary-care referrals necessitated an unequivocal referral procedure for both the GP and the primary-care therapist, which procedure will be described in more detailed next.

Although the primary-care psychologist always voluntarily subjects himself to peer supervision and sometimes works in a group practice or multidisciplinary treatment centre, he often is the sole attending health professional, despite his association with the referring GP. In our treatment context it was vital that he kept in close, proactive contact with the GP, with the roles of the two professionals being organised as follows: as the pain patient's treatment coordinator, the GP takes the

decisions with respect to any potential interventions, with the task of the primary-care psychologist being limited to the delivery of the psychological intervention as consented by the GP. Following the GP's referral, the psychologist makes a diagnosis and, if indicated, formulates a treatment plan, after which he again consults with the GP prior to initiating the proposed treatment, allowing the GP to remain actively involved in the decision-making process vis-à-vis his patient's treatment. If the psychologist were to commence the treatment solely based on his own diagnosis without consulting the GP, the latter may feel excluded or disregarded, possibly creating a reluctance to refer any of his future pain patients. After having reached his diagnosis, it is therefore crucial for the psychologist to seek concurrence with the referring GP to ensure that the proposed CBT is always mutually agreed to and to underpin the coordinating role of the GP, thus strengthening the consistency of a patient's treatment. This approach, moreover, ensures that in his communications with his patient the GP will adopt the motivations of the psychologist and thus not confuse or burden the patient with his lack of knowledge or irritation. In primary-care practices the collaboration among the affiliated physicians has not only been formalised, it is also implemented through frequent team meetings and mutual familiarity with the procedures applied by the individual members. The GP hence remains in control of his patient's treatment, reducing the risk of interfering or conflicting primary and secondary care delivery and any resulting iatrogenic complications such as excessive and continued medical consumption and undertreatment of perpetuating factors.
For GPs this referral protocol is a prerequisite allowing them to keep fulfilling their gatekeeper role. In all further training courses for GPs on pain treatment approaches it was always emphasised that coordination of a patient's treatment(s) would remain with them and thus also the definitive decision about the direction the treatment would take. Accordingly, the protocol sets the same rules for all the professionals involved in a pain patient's extramural care. Yet, many GPs are unfamiliar with what the primary-care psychologist can offer in the context of pain management, preventing many patients meriting treatment from being properly referred. This is why in their consultation with the GP the psychologists should proactively offer the following information:

- The treatment is based on a cognitive-behavioural framework and is thus directed at the patient's current cognitions and behaviours.
- The treatment does not try to identify a psychological cause for the pain but targets the underlying psychological factors that intensify or perpetuate the pain.
- The treatment is patient-specific and brief (on average 10 to 15 sessions) and does not entail modifying personality traits, however desirable.
- The therapist is prepared to consult with the GP on a regular basis and will initiate such contacts.

During the network meetings it is continuously monitored if and to what extent the

therapist and GP actively cooperate and how the psychologist can best inform the GP about treatment approaches for their pain patients. If necessary, this can be practised by means of role-playing. Repeatedly elucidating the referral procedure and the parties' respective roles will reduce the risk of frictions and any resulting decline in the number of referrals.

The referral network: first results

Up until 1998 the Pain Centre's clinical psychologist treated all pain patients indicated for CBT. Already after the first training course in 1999, 58 patients could be referred to the new network's primary-care psychologists, reducing the time between referral and the first treatment session with 11 weeks (from 14 weeks in 1997 to 3 weeks in 2005; see Table 2). Our 2006 survey among the network members revealed that in 2005 for the first time more patients had been referred to the network's therapists by their GPs than by the pain centre (53 and 49, respectively). By comparison, in 1998 none of the therapists had had a single patient referred to them with subacute or chronic pain as the grounds for referral.

The reduced waiting times demonstrated the success of the extramural collaboration as did the increment in primary-care referrals, illustrating that more GPs had became aware of the network psychologists. In 2006 the network comprised 28 active members (see Table 2); 11 had meanwhile withdrawn, among other reasons due to relocations outside the district or practice discontinuations.

Table 2: Outcome of the implementation project "Psychological treatment of pain in primary care"

	1996	**1997**	**1998**	**1999**	**2005**	**2006**
Number of trained psychologists			12	13	14	Regional network members: 28
Number and origin of referrals	0	0	Pain centre: 22 GPs: 0	Pain centre: 58		Pain centre: 49 GPs: 53
Time on waiting list (weeks to first session)	12	14	7	3	3	3

Bottlenecks

In the course of expanding the collaboration in the treatment of pain patients in the Netherlands, two major bottlenecks emerged.

Firstly, not all patients that our pain team referred to a network psychologist for CBT adhered to the advice. A recent survey among 159 chronic pain patients from the Nijmegen Pain Centre (unpublished data) showed that only 13 of the 47 patients (28%) referred for treatment to a primary-care psychologist complied with the recommendation, whereas 26 of the 32 patients (81%) that had been advised to attend a psychological group intervention delivered by the pain centre's own clinical psychologist indeed did so. The patients indicated that they interpreted a referral for treatment outside the hospital as the end of their medical intervention scheme, something they did not wish to accept. The limited compliance rate could hence be partly attributed to the implications of the current referral process, which, in a relatively short space of time, forces patients to abandon their medical orientation and replace it by an exclusively psychological point of reference, which shift is likely to require more time or supplementary motivational intervention[12].

A second explanation was that not all GPs concurred with the recommendation for CBT. Some entertained a different view of their patients' pain problems, and in our policy it is this view that is acknowledged. The rejection was in some cases also due to a lack of information about the treatment options the primary-care therapist has at his disposal. To resolve this latter problem the Pain Centre organised special training sessions for GPs and joint sessions for GPs and network psychologists to inform the local GPs more extensively about the potential of collaboration with the network psychologists in the context of the treatment of chronic pain. These sessions run parallel to the training course the new network psychologists attend. The medium-range objective of the courses therefore also was to overcome any differences in opinions the GPs and primary-care psychologists might have regarding psychotherapeutic treatment options.

Secondly, in most cases the health insurers in the Netherlands do not fully reimburse the costs for psychological treatment in primary-care settings. Each insurer has its own policy as regards coverage: some provide no coverage while others cover ten to twenty therapy sessions or allocate a set annual amount. This means that for some patients the costs associated with treatments delivered by a primary-care therapist are prohibitive. Sometimes practical solutions can be found. Sessions may, for instance, be more widely spread over time, more use can be made of home assignments, or the therapist and client can communicate via telephone or the Internet. However, these methods are all likely to negatively affect treatment efficacy. As this problem with health insurance coverage is not limited to chronic pain patients but holds for all patients seeking first-line psychotherapeutic care, it is evident that discussion of the issue needs to take place at the national level.

Discussion

This report describes a project conducted by the Pain Centre of the Nijmegen University Medical Centre St Radboud to interest and train primary-care psychologists in the treatment of subacute or chronic pain patients with the aim to set up a regional treatment network and initiate an adequate supply of patients. The results after 8-years are positive. In 2005 the network included 28 active members to whom over 100 patients were referred for treatment, 53 of whom had been directly referred by their GPs. The project also uncovered several practical bottlenecks. Thus, not all patients that had been referred actually applied for treatment owing to a lack of internal motivation or because their GPs disagreed with the referral. Furthermore, the limited insurance coverage for first-line psychotherapeutic interventions proved to be prohibitive for some patients to seek treatment with a primary-care professional.

Various steps need to be taken to remove these obstacles. The pain centre's referring psychologist needs to allocate more time to convince the pain patients deemed eligible for first-line CBT by offering them a brief intervention to interrupt their somatic orientation and motivate them for a psychological approach to their problem. This should become an integral part of the hospital's formal referral policy. In addition, the referral protocol should stipulate that in cases where the GP opposes the recommended referral, the clinical psychologist is duly informed of this decision to allow him to discuss with the GP the reasons for his opposition and to jointly decide on any alternative steps. Finally, the umbrella organisations representing the patients and health-care providers will have to discuss the issue of insurance coverage with representatives of the nation's health-care insurance companies.

Overall, and despite the mentioned hurdles, the delivery of psychological treatment for pain patients by a network of specially trained primary-care therapists practising in the service area of our hospital's pain clinic was successful. This functional, regional network should be seen as a first step towards a national implementation. In view of the growing interest in the primary-care treatment of subacute pain and the prevention of chronicity and sick leave[13] it is opportune for other regional service areas to set up similar networks. The medium-range objective is to expand the number of networks such that they can be said to form a national grid allowing all pain patients to receive treatment in the vicinity of their home by a competent psychologist who works closely together with their GP or the local hospital. To this end, all academic pain centres in those service areas that at present have no operational network will be contacted and invited to join the phased implementation programme presented in this article. It is not until this last objective is achieved that we will have succeeded in our long-term ambition to create a qualitatively sound nationwide care delivery system of psychological interventions for patients suffering from subacute or chronic pain in the Netherlands.

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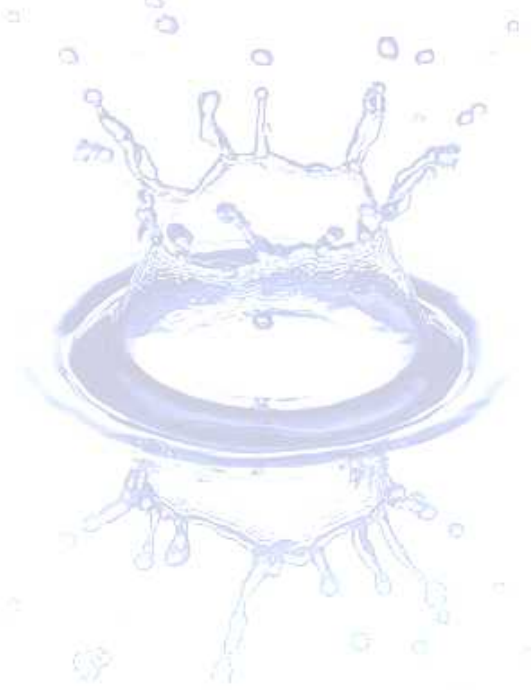
Chapter 10

Summary and discussion



Summary

In this thesis we explored psychological predictors of the course of chronic pain and predictors of treatment outcome in chronic pain patients referred for treatment to the multidisciplinary pain centre of the Radboud University Medical Centre, the Netherlands. We specifically focused on the cognitive-behavioural factors hypothesized to affect pain intensity and daily functioning within the context of the fear-avoidance model and helplessness models, and to identify predictors of the effects of medical, paramedical and cognitive-behavioural chronic pain treatment strategies. In addition, referrer satisfaction and implementation aspects were described. The first part of the thesis reported on the role of cognitive-behavioural factors in chronic pain patients referred to a multidisciplinary pain centre. Part 2 discussed the predictive value of selected cognitive-behavioural factors for the short-term outcomes of RF-DRG (radiofrequency lesioning of the cervical spinal dorsal root ganglion), TENS (transcutaneous electrical nerve stimulation) and the short- and long-term effects of a multidisciplinary pain treatment allocation approach. The choice of predictors was based on the fear-avoidance and helplessness models and the recent literature on the role of acceptance in chronic pain. In Part 3, referrers' evaluation and the implementation of the current knowledge of psychological factors implicated in chronic pain and the consequences for psychological pain treatment in primary care were described.

Part 1: Psychological predictors of pain intensity, functional disability and depression in chronic pain

In *Chapter 2*, the contribution of helplessness, fear of pain and passive pain-coping strategies of catastrophizing and avoidance behaviour was studied in 169 chronic pain patients. All factors proved related to the patients' pain levels, functional disability and depressive symptoms although for pain level helplessness was the only significant predictor. Helplessness and the passive coping strategy of resting significantly predicted functional disability and the catastrophizing coping strategy significantly predicted depression. These findings show that helplessness and passive pain-coping patterns of catastrophizing and avoidance behaviour indeed play a role in the perpetuation of symptoms in chronic pain patients and that both aspects should be addressed in their treatment(s) if pain levels, functional disability and/or depressive symptoms are to be significantly reduced. Moreover, helplessness proved to be an important predictor beyond fear of pain, suggesting that, as a generalized cognition of not being capable of coping with the consequences of the pain problem, helplessness may seriously impede chronic pain patients' functioning beyond specific pain-related fears.

The study presented in *Chapter 3* explored the predictive values of helplessness, fear of pain, catastrophizing and avoidance behaviour for the course of functional disability after three months, and also in this study helplessness contributed to the

prediction of change in functional disability beyond fear of pain. Of all predictors, avoidance behaviour most strongly predicted change in functional disability. These findings thus supported the relevance of helplessness as an important factor in chronic pain patients and hence the relevance of depressogenic cognitions in long-term pain when pain cannot be prevented or avoided. The construct of helplessness implies cognitions of uncontrollability and inability to change the pain problem that may initiate avoidance behaviour aimed at preventing pain instead of cognitive and behavioural efforts directed at changing the experience of pain or attempts to actively cope with the consequences of the pain in daily life. In populations with longstanding chronic pain complaints, fear of pain may eventually generalize into a broader cognition of not being able to control and stop the pain experience, resulting in helplessness cognitions and passive coping strategies that are more directly linked to functional disability[1]. In contrast, the construct of fear of pain may have a focused effect in patients with musculoskeletal pain[2,3] as in these patients physical activities and elevated pain levels may be more closely linked and therefore may induce a conditioning mechanism of the perception that activity will intensify the pain. Also, fear of pain may be more relevant in the transition from subacute to chronic pain as in this stage patients are more focused on trying to cope with their pain[4]. The construct of helplessness may be more closely linked with the experience of chronic pain sufferers that experiencing chronic pain without the perspective of improvement or control causes a more general physical, emotional and social dysfunctioning[5]. Instead, in chronic pain, fear of pain may be crucial for a limited number of pain patients that hold on to specific pain-related cognitions and a sense of controllability, i.e. that a decrease in pain should lead to less fear and an increase in activities. In many chronic pain patients, however, activities will induce some short-term increase in pain thereby strengthening their fear-of-pain cognitions but beyond these, in the long term amplifying cognitions of helplessness as attempts of active coping eventually fail.

Part 2: Psychological predictors of the effects of chronic pain treatments

The aim of the study presented in *Chapter 4* was to investigate whether psychological variables (including the pain cognitions helplessness and catastrophizing) would be predictive of the changes in pain intensity after treatment with radiofrequency lesioning of the cervical spinal dorsal root ganglion (RF-DRG) and whether successful pain reduction would lead to a corresponding improvement in overall functioning. Patients suffering from chronic cervicobrachialgia with a mean pain duration of seven years were treated and the posttreatment results showed that their pretreatment levels of catastrophizing predicted changes in pain intensity following RF-DRG. This means that the more pain-related catastrophizing cognitions the patients entertained, the less their subjective pain levels changed after treatment. Thus, consistent with the fear-avoidance model, our finding emphasized the importance of catastrophizing as a

pain cognition that negatively affects pain treatment outcomes. As far as we know, ours is the first study to show that catastrophizing impedes outcomes of medical treatments for chronic pain. Possibly, in patients who catastrophize, rumination negatively affects the experience of pain and thus decreases the possibilities of perceiving changes in pain intensity[6,7]. In addition, successful RF-DRG treatment, as reflected by a decrease in the patients' VAS scores, was not accompanied by an improvement in total functioning in terms of reduced physical and psychosocial dysfunctioning and depression. This supports the hypothesis that chronic pain negatively affects the patients' overall daily functioning and that stand-alone medical treatment may affect their perceived pain levels but not necessarily induces augmentations of other aspects of their daily functioning. Flor et al.[8] supported this assumption in their comprehensive review of the outcomes of mono- and multidisciplinary pain treatments by showing that multidisciplinary schemes were superior to monodisciplinary interventions. Theirs and our findings once more indicate that in chronic pain patients medical treatment alone does not necessarily affect other aspects of the patients' functioning than their level of perceived pain. In addition, it disproves the notion that reducing their pain levels will subsequently automatically improve other dimensions of their daily functioning, a notion often used as a rationale for a monodisciplinary, medically oriented treatment approach. In recent years, it has repeatedly been stated that in their treatment programmes pain centres should focus on both pain reduction and improving overall functioning[9,10]. Based on the presented evidence, when overall better functioning is the goal of chronic pain treatment, a multidisciplinary approach might be preferred.

In *Chapter 5*, predictive factors of the effects of transcutaneous electrical nerve stimulation (TENS) in the treatment of chronic pain were studied in a prospective, randomised, placebo-controlled trial comprising chronic pain patients, comparing high frequency TENS with sham TENS and using the patients' satisfaction (willingness to continue treatment) and pain intensity as outcome measures. Cognitive-behavioural coping strategies were evaluated as possible predictors for TENS effects. In the TENS group 58% of the patients were satisfied with the treatment results, and for the sham-TENS group this was 42%. No significant differences were found for pain intensity. Avoidance behaviour (retreating when in pain) was the only cognitive-behavioural predictor of posttreatment patient satisfaction, which implies that patients that tended to retreat more in response to an increment in their pain were more satisfied with the results of TENS. In addition, more helplessness (low perceived control) appeared to predict a decrease in pain intensity. Accordingly, patients that use more passive coping strategies of avoidance behaviour and experience more feelings of helplessness seem to benefit more from this type of treatment. From the perspective of the fear-avoidance model this would also imply that TENS might stimulate passive pain-coping strategies that may thus prevent a patient from adopting a more active coping style.

If corroborated, consistent with our conclusions on mono- versus multidisciplinary treatment schemes described in the previous chapter, this again raises the question whether it should be recommended to combine TENS with a cognitive-behavioural treatment module aimed at helping the patients challenge their helplessness cognitions by replacing them by more active strategies.

Chapter 6 dealt with the short-term effects of a multidisciplinary pain treatment allocation protocol for chronic pain patients and cognitive-behavioural predictors of treatment outcome. The study compared pain intensity, functional disability, depression and use of medication in an intervention group of chronic pain patients to the outcomes of a control group. In accordance with the fear-avoidance model and the helplessness model, we again took catastrophizing, fear of pain, avoidance behaviour and helplessness as potential predictors of outcome, but, based on recent publications, we also studied acceptance of pain as an additional possible predictor. Following treatment, all primary outcome measures had, although modest in proportion, significantly decreased in the intervention group: pain intensity as well as functional disability had significantly been reduced relative to the levels indicated by the controls. The moderate effects in our study are in line with other studies on multidisciplinary chronic pain treatments[11] and may reflect a problem inherent to the complexity of chronic pain and the limited possibilities of outpatient treatment strategies. Various earlier studies had already shown that inpatient treatment programmes yielded better results than outpatient interventions[12,13]. The studies might suggest that the sensory, cognitive-behavioural, emotional and social aspects of the pain problem interact in such a complex way that outpatient treatments with limited contacts do not suffice Future studies might directly compare out- and inpatient modalities and relate the treatment effects to the treatment's cost-effectiveness to gain a better insight into the different dimensions of treatment efficacy in chronic pain.

With regard to the predictive role of the cognitive-behavioural factors, only higher pretreatment levels of acceptance proved to predict larger reductions in pain intensity in the treatment condition (but not in the control condition), underlining the significance of acceptance as a health-promoting factor in chronic pain. Acceptance is regarded as a health-promoting cognition[14,15] as it is directed at living a satisfying life in spite of the perceived pain[14]. Cognitions of acceptance may reflect that a patient's focus is more on (augmenting) adaptive coping patterns, which positively affects treatment outcome, supporting previous findings correlating acceptance with less attention to pain[16] and active coping behaviour[15]. Furthermore, patients who are more accepting of their pain may cope better as they tend to perceive small changes in pain intensity better and are more inclined to interpret these changes more positively than patients with less accepting coping strategies. Acceptance may thus affect especially the affective and evaluative dimensions of pain perception[17,18]. The current findings extend our understanding of the mechanisms of improvement in multidisciplinary chronic pain treatment

approaches as this is the first time that acceptance has been identified as a positive predictor of treatment outcome in this population. They also support the role of acceptance in chronic pain patients as contrasting a fearful and avoiding way of coping and acceptance may in the fear-avoidance model serve as a prerequisite for a more confronting coping strategy. The various results on the role of acceptance seem to imply that pain patients who have adopted a more accepting coping strategy may profit more from treatments directed at reducing pain, than patients who exhibit a more avoiding cognitive-behavioural pattern. The present results further suggest that pain treatment might benefit by including a treatment module specifically directed at increasing the level of acceptance.

In the study described in *Chapter 7* we looked at the long-term effects after 12 months of a tailored multidisciplinary pain treatment allocation strategy on pain intensity, functional disability, depression, and medication use in patients with chronic pain. In addition we studied the level of short-term (3 months) changes in the cognitive-behavioural predictors (catastrophizing, avoidance behaviour, fear of pain, helplessness, and acceptance) being associated with long-term outcomes. Functional disability and depression had both improved significantly due to treatment, which is in line with the effects Flor et al.[8] reported. The decrease in the scores of catastrophizing, fear of pain, helplessness, and avoidance behaviour after three months was associated with the decrease in functional disability and depression at twelve months. Again, although both functional disability and depression had improved significantly, the effects were limited. The modest short-term reduction in subjective pain intensity had not been maintained. This is also in line with a recent study McCracken et al.[19] conducted on the effects of an acceptance-based treatment. Congruent with our short-term study, the overall effects were also moderate, which implies that achieving a long-term reduction of pain and a better overall functioning in patients with longstanding pain is more complex and challenging to achieve as cognitive behavioural patterns may have become fully integrated with the patients' everyday functioning[1].

Part 3: Referrer evaluation and implementation

Chapter 8 discussed the results of a survey we held among the general practitioners (GPs) of chronic pain patients that were treated at the multidisciplinary pain centre. As it is the GPs that decide whether or not to refer their patients for treatment of their chronic pain complaints, it is of major importance that the pain centre keeps informed of how they evaluate the care and services multidisciplinary pain treatment facilities provide because this may affect their willingness to refer their patients in future. However, the pain centre had no accurate information about the way, GPs judged the referrals. The survey asked the GPs in a standardized self-report measure to indicate their expectations of the referral, to judge various aspects of the care provided as well as give an overall impression. As to the overall care their patients had received, the GPs evaluated positively but they had varied

expectations of the referral, not only with respect to medical diagnoses and treatments but also in relation to paramedical or psychological treatment schemes. Meeting the referral expectations they had set themselves was the most important criteria for them. The GPs evaluated the pre-treatment information less positively, especially information about the waiting period and about the possibility of making contact with the pain specialist. Our survey emphasizes the importance of pain centres to communicate actively with the GPs in order to meet the specific referral expectations and to monitor GP retrospective referral evaluation.

In *Chapter 9*, the process was described through which we implemented the current knowledge about the psychological factors implicated in chronic pain in a treatment scheme designed to be delivered in a primary care setting. After a symposium on the cognitive-behavioural treatment of chronic pain and after gathering information about treatment issues from the attending professionals, 39 primary-care psychologists working in the pain centre's catchment area attended a training course covering dedicated diagnostic techniques and a cognitive-behavioural treatment programme for chronic pain patients. Moreover, using a model of collaboration, special attention was paid to the communication with physiotherapists and GPs concerning treatment issues. The psychologists subsequently joined a regional network of first-line pain psychologists and attended a refresher course every six months. The short-term goal of the project was to transfer the current knowledge of psychological pain treatment to the field of primary-care psychologists and to expand the existing options for health-care professionals in primary and secondary care to refer pain patients to specialised psychologists. In 2005, a survey among the then active network psychologists revealed that referrals from GPs had meanwhile exceeded those of the pain centre. Currently, the project is expanded to other locations so that in the longer term increasingly more specialised primary-care psychologists will be involved in the treatment of patients diagnosed with subacute and chronic pain. Patients with subacute pain may then be referred to a network psychologist as part of a standard multidisciplinary diagnostic procedure and will only be referred to a specialized multidisciplinary pain centre when the initial treatment has failed. In this way, the expertise of both professionals is optimally and also more cost-effectively exploited for the benefit of the patient.

Extension of the fear-avoidance model

The studies presented in this thesis all supported the relevance of the constructs of catastrophizing, fear of pain and avoidance behaviour within the fear-avoidance model. Both in our natural-course and in the effect studies cognitive-behavioural factors of fear-avoidance, helplessness and acceptance proved to predict patient outcomes. The studies in Part 1 also revealed that, when both fear-avoidance factors and helplessness were entered into a correlational and longitudinal

prediction model of chronic pain, helplessness predicted pain outcomes beyond fear-of-pain cognitions. This is in line with earlier studies on the role of helplessness in chronic pain[15,20,21,22]. Our current findings thus suggest that in chronic pain populations helplessness may be a valid factor in explaining pain outcomes such as pain intensity, functional disability and depression over time. It may further be speculated that fear of pain and helplessness have a complementary role in the mechanism of pain and its perception over time in different phases (from subacute to chronic) and populations (musculoskeletal and others). Future studies on the fear-avoidance model[3] might focus on examining the transition from acute, subacute and chronic pain, study short and long term consequences of chronic pain and include pain populations of various pain locations.

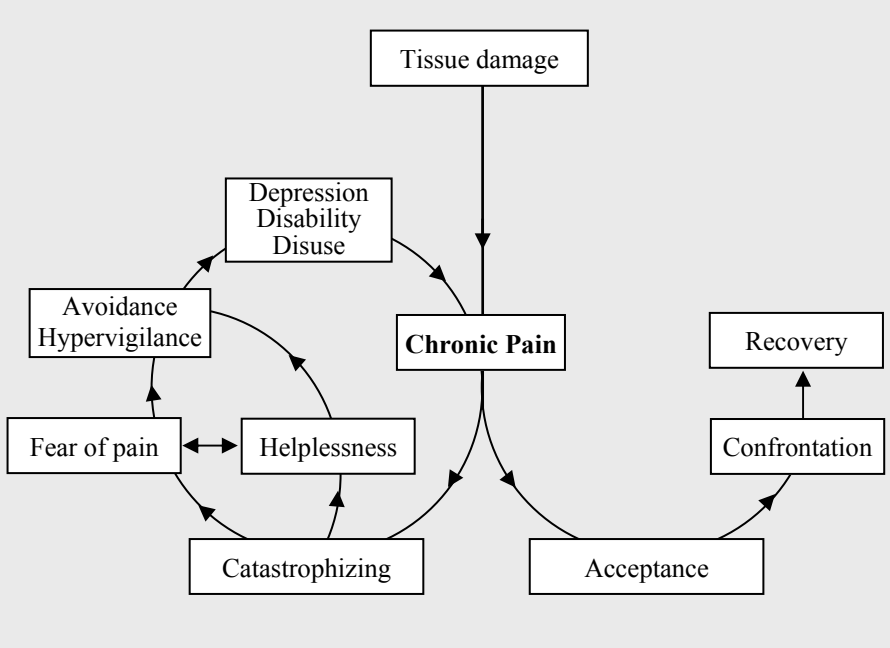


Figure 1: Proposed extension of Vlaeyen et al's Fear-Avoidance Model (1995)

Besides helplessness having been substantiated as an additional factor in the fear-avoidance model, the study presented in Chapter 6 emphasized the role of acceptance in chronic pain. This cognitive strategy might support patients acknowledge that they suffer pain, which realization enables them to make an effort to live a satisfying life despite their complaints[14,15], especially when the pain appears uncontrollable[23]. Although the exact content of the construct of acceptance is still under discussion[24], our findings add to the already large body of recent research comprising correlational studies[25], longitudinal studies[15,19] and outcome studies[15,26] that supported acceptance as a health-promoting factor. Together, the

evidence suggests that patients with longstanding pain experiences, when pain has become chronic, some will develop cognitions associated with catastrophizing and helplessness and adopt subsequent passive cognitive and behavioural coping patterns. However, others might develop an acceptance-based set of helpful cognitions that facilitate more active behavioural coping strategies, leading to a better overall functioning. In conclusion, based on recent and our current findings in chronic pain patients, the fear-avoidance model might be extended to include helplessness and acceptance cognitions in these patient populations (see Figure 1).

Clinical implications

The studies reported in this thesis unequivocally supported earlier findings that cognitive-behavioural factors are relevant mediators in the development and maintenance of chronic pain. Cognitive as well as behavioural coping strategies proved to have considerable impact on the patients' perceived pain levels and overall functioning over time. The effect studies described in this thesis also indicated the relevance of these factors by showing that both cognitive and behavioural coping strategies are predictive of the outcome of medical, paramedical and multidisciplinary treatment allocation strategies. The presented results underscore the necessity of a multidisciplinary approach in the treatment of chronic pain. More specifically, cognitive-behavioural screening should be part of a standard diagnostic procedure to be performed in each individual chronic pain patient with chronic complaints that has been referred to a specialized pain centre. Dependent on the results, the patient should be offered a tailored, cognitive-behavioural treatment programme, next to a possibly indicated medical or paramedical treatment. This implies that pain clinics should adhere to the biopsychosocial model of pain by operating on a multidisciplinary rather than a monodisciplinary basis as the monodisciplinary model is based on the assumption that pain reduction as a result of a medical or paramedical treatment will lead to improvement in daily functioning. Earlier publications as well as our study of the effects of RF-DRG have shown that a pain reduction resulting from successful stand-alone medical or paramedical interventions will not automatically induce improvement in the patient's daily functioning. The studies in this thesis on pain treatment effectivity revealed that even with a multidisciplinary allocation protocol for pain treatment only moderate improvements in daily functioning were achieved. This implies that when treatment is aimed at both a reduction of pain and an augmentation of the patient's overall daily functioning, the treatment should be intensive and directly target these goals by tailoring treatment to patient characteristics. Based on the findings presented in this thesis indicating that in chronic pain helplessness and acceptance play affect pain intensity and functioning next to fear of pain factors, pretreatment screening could be improved by involving a close delineation of a patient's pain cognitive behavioural patterns (fear of pain,

catastrophizing, avoidance behaviour, helplessness and acceptance).
With regard to pain treatment strategies, our studies indicate that chronic pain treatment may benefit from including treatment modules based on altering cognitive behavioural factors (fear of pain, catastrophizing, avoidance behaviour, helplessness and acceptance. In cases where helplessness cognitions prevail, treatment could benefit from adding a cognitive training module aimed at inducing cognitions of internal control and more positive expectational schemes[27] in accordance with the principles of Beck's cognitive therapy[28]. If, on the other hand, cognitions related to the fear of pain concept are prominent, the programme should include exposure in vivo[29]. A cognitive module might replace negative cognitions that exacerbate the pain problem by a more accepting attitude that acknowledges rather than fights the enduring complaints, to enhance the patient's ability to ignore the pain and redirect his focus to other stimuli than the pain sensation[30,31]. McCracken et al.[32] defined pain perception as the practice of broad, present-focused, and behavioural neutral awareness. In the case of avoidance behaviour, an operant treatment module should be offered that helps the patient adopt active and confronting pain-coping behaviours[33,34]. Finally, patients scoring low on acceptance should receive an acceptance-based intervention to stop them fighting the pain and helps them to fit their pain sensations into their daily lives, enhancing their overall functioning[19].

The modest effects of the multidisciplinary pain treatments obtained in the studies in the second part of this thesis point to a specific problem pain centres in the Netherlands are faced with. Along the lines of the biopsychosocial model of pain and the widely accepted definition of pain of the IASP (the International Association for the Study of Pain), chronic pain should be regarded as a total of pain suffering. This implies that treating chronic pain means diminishing the pain itself as well as the associated symptoms and consequences of the pain (functional disability and depressive mood). Pain treatment should therefore also always be aimed at improving functioning in daily life. This implies that, when a reduction of pain is not attainable, improving overall functioning is still a legitimate goal. In sum, within the context of our findings, pain centres should not solely focus on conquering pain or alleviating its intensity by means of (para-) medically oriented interventions but should put the emphasis on cognitive-behavioural coping strategies. However, this does not coincide with the expectations of the patients that are referred to specialized pain facilities. McCracken et al.[35] showed that patient satisfaction is associated with the perceived reduction in pain intensity.
As was shown in Chapter 8, the reasons and expectations of the GPs that referred their pain patients to the Pain Centre included a broad spectrum of reasons, including desire to call a halt to their patients' endless, futile search for pain relief and subsequent medical consumption. This again raises the question about the function of pain centres within the spectrum of pain treatment facilities that treat

any pain complaint from acute pain to chronic, medically unsolvable pain. At present they define themselves as facilities that aim at relieving pain and at addressing the associated symptoms of pain suffering as well as at ending the vicious cycle of seeking medical pain relief[36]. For a sound and transparent chronic pain care, treatment goals of pain centres have to be clearly defined to offer both the referrers and patients a clear insight into the possible treatment options.

Conclusions and recommendations

In line with the summary and discussion, the main conclusions of this thesis for the care of patients with chronic pain referred to a Multidisciplinary Pain Centre can be formulated as follows:

- Cognitive-behavioural factors affect pain outcomes of pain intensity, functional disability and depression.
- Cognitive-behavioural factors affect the effects of monodisciplinary (medical and paramedical) and multidisciplinary chronic pain treatment strategies.
- Helplessness and acceptance have a role in predicting pain outcomes and predicting treatment effects in addition to the fear-avoidance factors of catastrophizing, fear of pain and avoidance behaviour.
- Referrers' evaluation predominantly depends on expectations for referral being met/fulfilled.

In line with the conclusions of the thesis, the following recommendations can be formulated:

- For patients with chronic pain referred to a Multidisciplinary Pain Centre, the fear-avoidance model might be extended by including helplessness and acceptance cognitions.
- Pre-treatment screening of chronic pain patients referred to a Multidisciplinary Pain Centre should include cognitive-behaviour factors of fear-of-pain, catastrophizing, avoidance behaviour, helplessness and acceptance.
- Chronic pain treatment for patients referred to a Multidisciplinary Pain Centre may benefit by including helplessness and acceptance oriented treatment modules.
- A multidisciplinary chronic pain treatment facility has to provide a transparant and pro-active communication with the referrers in order to meet the referral expectations.

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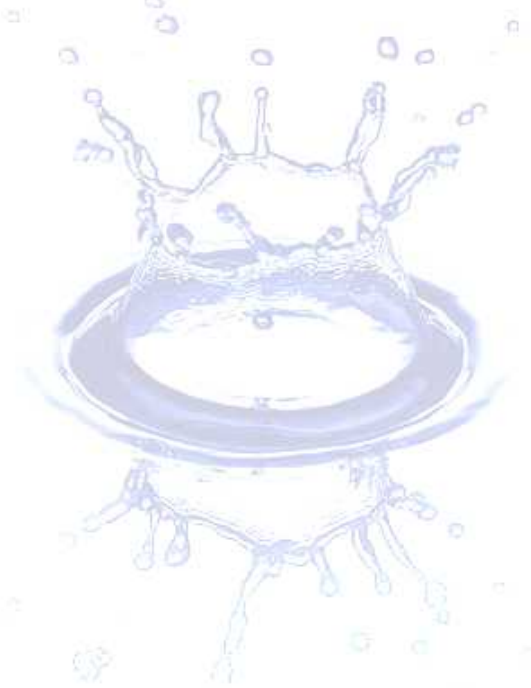
Chapter 11

Samenvatting en Discussie



Inleiding

In dit proefschrift hebben we psychologische voorspellers van het beloop van chronische pijn en van de behandeleffecten onderzocht bij patiënten die voor pijnbehandeling werden verwezen naar het Multidisciplinaire Pijncentrum van het UMC St Radboud in Nijmegen. We hebben ons daarbij vooral gericht op cognitieve en gedragsfactoren waarvan werd verondersteld dat zij invloed hebben op zowel het pijnniveau als op het dagelijkse functioneren. Daarnaast werd onderzoek gedaan naar mogelijke voorspellers van de effecten van medische, paramedische en cognitief-gedragsmatige vormen van chronische pijnbehandeling. Deze factoren werden onderzocht binnen de context van het Fear-avoidance model en het Learned Helplessness model. Aansluitend werden de evaluaties van verwijzers over de zorg voor hun patiënten door het pijncentrum en het project van implementatie van psychologische pijnbehandeling binnen de eerstelijnszorg beschreven.

In het eerste deel van het proefschrift werd de rol van cognitieve en gedragsfactoren beschreven bij patiënten die gemiddeld meer dan zes jaar last hadden van pijnklachten.

In het tweede deel werd de voorspellende waarde beschreven van enkele cognitieve en gedragsfactoren voor de korte termijn effecten van RF-DRG (radio frequente laesie van de cervicale spinale dorsale ganglion), van TENS (transcutane electrische zenuw stimulatie) en de korte en lange termijn effecten van een multidisciplinaire pijnbehandeling strategie waarbij patiënten op grond van het diagnostisch onderzoek werden toegewezen aan één of meerdere behandelmodules. De keuze van de verschillende voorspellers was gebaseerd op het Fear-avoidance model, het Learned Helplessness model en de meest recente literatuur over de rol van acceptatie bij chronische pijn.

In deel 3 werd de wijze waarop huisartsen in hun rol als verwijzer van chronische pijnpatiënten dachten over de zorg voor hun patiënten onderzocht. Tot slot werd het proces van implementatie binnen de eerstelijnszorg beschreven van de huidige kennis over psychologische aspecten bij chronische pijn en de consequenties daarvan voor de psychologische pijnbehandeling.

Deel 1: psychologische voorspellers van pijnintensiteit, functionele beperkingen en depressie bij chronische pijn

In *hoofdstuk 2* werd de bijdrage bestudeerd van hulpeloosheid, angst voor pijn en passieve pijncoping strategieën aan het niveau van pijnintensiteit en functioneren bij 169 chronische pijnpatiënten. Alle genoemde factoren bleken gerelateerd te zijn aan het pijnniveau, de functionele beperkingen en depressieve symptomen. Hulpeloosheid bleek echter de enige significante voorspeller. Hulpeloosheid en de passieve copingstrategie rusten voorspelden functionele beperkingen en catastroferen voorspelde depressie. Deze bevindingen tonen aan dat hulpeloosheid en passieve copingstrategieën een rol spelen bij het voortduren van symptomen bij

chronische pijnpatiënten en dat zowel hulpeloosheid als passieve copingstrategieën deel zouden moeten uitmaken van behandelingen die ten doel hebben om pijn, functionele beperkingen en depressie te verminderen. Daarnaast bleek hulpeloosheid een belangrijker voorspeller te zijn dan angst voor pijn, wat een aanwijzing kan zijn dat een gegeneraliseerde cognitie van hulpeloosheid, nl. het idee dat men niet in staat is om adequaat om kunnen gaan met de consequenties van de pijnklacht, een grotere invloed heeft op het functioneren van een chronisch pijnpatiënt dan een meer specifieke angst voor pijn.
In het onderzoek, dat in *hoofdstuk 3* werd gepresenteerd, werd de voorspellende waarde onderzocht van hulpeloosheid, angst voor pijn, catastroferen en vermijdingsgedrag (rusten en terugtrekken) voor het beloop van de functionele beperkingen na drie maanden. Ook in deze studie bleek hulpeloosheid een belangrijkere voorspeller te zijn dan angst voor pijn. Van alle predictoren bleek vermijdingsgedrag de verandering van de functionele beperkingen het beste te voorspellen. Deze eerste bevindingen ondersteunen de relevantie van hulpeloosheid als een belangrijke factor bij chronische pijnpatiënten en als een depressogene cognitie bij langdurige pijn die niet voorkomen of vermeden kan worden. Het construct van hulpeloosheid behelst cognities van oncontroleerbaarheid en onvermogen om het pijnprobleem te veranderen. Deze cognitie werkt daarmee vermijdingsgedrag in de hand welke gericht is op het voorkomen van pijntoename in plaats van cognitieve of gedragsmatige pogingen om de ervaring van de pijn zelf te veranderen of pogingen om actief met de consequenties van de pijn in het dagelijkse leven om te gaan.
Het is mogelijk dat bij patiënten met langdurige pijn de specifieke angst voor de pijn kan generaliseren naar een bredere cognitie waarbij men denkt, niet in staat te zijn om de pijnervaring te controleren of te stoppen. Dit kan uitmonden in cognities van hulpeloosheid en een meer passieve, vermijdende wijze van omgaan met de pijn en kan daardoor leiden tot meer functionele beperkingen. Het construct van de angst voor de pijn kan een meer specifiek effect hebben voor patiënten met pijn aan het bewegingsapparaat. Dit heeft wellicht ermee te maken dat bij deze patiënten fysieke activiteiten en een verhoogd pijnniveau sterker met elkaar verbonden zijn en een mechanisme van operante conditionering induceert van de waarneming dat activiteiten leiden tot meer pijn en daarom vermeden dienen te worden. Daarnaast kan angst voor pijn relevanter zijn voor de overgang van subacute naar chronische pijn daar in dit stadium patiënten meer gericht zijn op het zoeken naar manieren om om te kunnen gaan met de pijn. Een recente review van de literatuur kon deze hypothese echter niet bevestigen. Mogelijk is het construct van hulpeloosheid directer verbonden met de ervaring van patiënten met chronische pijn dat het ervaren van pijn zonder een perspectief van herstel of een vorm van controle over de pijn kan leiden tot een algemener fysiek, emotioneel en sociaal lijden. Angst voor pijn daarentegen zou van meer belang kunnen zijn voor een beperkt aantal pijnpatiënten dat blijft vasthouden aan specifieke

pijngerelateerde cognities en een mate van controleerbaarheid van de pijn, bijvoorbeeld dat een pijnvermindering zou leiden tot minder angst en daardoor tot meer activiteiten. Echter, bij veel chronische pijnpatiënten zal een toename van activiteiten op korte termijn leiden tot meer pijn. De hogere pijnintensiteit induceert angstcognities die in de loop van de pijnepisode kunnen leiden tot meer cognities van hulpeloosheid wanneer pogingen om tot meer activiteiten te komen uiteindelijk blijken te falen.

Deel 2: Psychologische voorspellers van de effecten van chronische pijnbehandelingen

Het doel van de studie, gepresenteerd in *hoofdstuk 4*, was het onderzoeken van de vraag of psychologische variabelen (pijncognities: hulpeloosheid en catastroferen, fysiek en psychosociaal dysfunctioneren) voorspellend zijn voor veranderingen in pijnintensiteit na behandeling met radiofrequente laesie van cervicale spinale dorsale root ganglion (RF-DRG) en de vraag in hoeverre een gerealiseerde pijnreductie leidt tot een overeenkomstige verbetering in het dagelijkse functioneren. Vierenvijftig patiënten met chronische cervicobrachialgie en een gemiddelde pijnduur van zeven jaar werden behandeld en de resultaten na behandeling lieten zien dat het niveau van catastroferen vóór behandeling voorspellend was voor veranderingen van de pijnintensiteit na RF-DRG. Dat betekent dat hoe meer catastroferende cognities patiënten onderhielden, hoe minder de pijn als gevolg van de behandeling veranderde. Dit resultaat bevestigt, in overeenstemming met het fear-avoidance model, dat pijngerelateerd catastroferen een belangrijke cognitie is die de effecten van pijbehandeling negatief beïnvloedt. Voor zover wij kunnen nagaan, is dit de eerste studie die aantoont dat catastroferen de uitkomsten van een medische pijnbehandeling bij chronische pijnpatiënten negatief beïnvloedt. Mogelijk betekent dit dat bij patiënten die catastroferen, overdreven negatieve aandacht voor de pijn de pijnervaring versterkt en het daarmee moeilijker maakt om (positieve) veranderingen in het pijnniveau na behandeling te kunnen waarnemen. Daarnaast ging een succesvolle RF-DRG behandeling, zoals weerspiegeld in een lagere VAS-score na behandeling, niet samen met een verbetering van het dagelijkse functioneren (het samengaan van fysiek en psychosociaal functioneren en depressie). Deze bevinding bevestigt de hypothese dat chronische pijn het dagelijkse functioneren negatief beïnvloedt en dat een uitsluitend medische behandeling mogelijk het ervaren pijnniveau vermindert maar dat dit niet noodzakelijkerwijs betekent dat ook het dagelijkse functioneren mee verandert. Flor et al bevestigden deze hypothese in hun uitgebreide review over de uitkomsten van monodisciplinaire en multidisciplinaire pijnbehandelingen door aan te tonen dat multidisciplinaire behandelingen effectiever waren dan mono-disciplinaire behandelingen. Deze en andere bevindingen vormen een aanwijzing dat bij chronische pijnpatiënten a) uitsluitend een medische behandeling niet per definitie ook invloed heeft op andere aspecten van het dagelijkse functioneren dan het

ervaren pijnniveau en b) de hypothese dat het verlagen van het pijnniveau automatisch leidt tot verbetering van andere aspecten van het dagelijkse functioneren niet ondersteund wordt. Deze hypothese wordt vaak gebruikt als rationale voor een monodisciplinaire, medisch gerichte behandelstrategie. Het onderstreept nog eens de vraag wat de primaire doelstellingen van chronische pijnbehandelingen dienen te zijn. De laatste jaren is herhaaldelijk aangegeven dat pijncentra zich met hun behandelstrategieën dienen te richten op zowel pijnreductie alsook op het verbeteren van het dagelijkse functioneren. Op grond van de gepresenteerde bevindingen ondersteunen we het uitgangspunt dat, wanneer ook het verbeteren van het dagelijkse functioneren een centrale doelstelling van behandeling is, een multidisciplinaire benadering gewenst is.

In *hoofdstuk 5* werden de voorspellende factoren bestudeerd van de effecten van transcutane elektrische zenuwstimulatie (TENS) in een prospectieve gerandomiseerde placebo gecontroleerde studie. In deze studie werden 163 chronische pijnpatiënten onderzocht waarbij hoge frequentie TENS vergeleken werd met sham TENS en de tevredenheid van patiënten (de bereidheid om de behandeling voort te zetten) en pijnreductie werden beschouwd als primaire uitkomstmaten. De pijnintensiteit vóór de behandeling en cognitief-gedragsmatige coping factoren werden onderzocht als mogelijke voorspellers voor de effecten van TENS. In de TENS groep waren 58 procent van de patiënten tevreden met de behandelresultaten en voor de sham TENS was dit 42 procent. Er werden geen significante verschillen gevonden met betrekking tot pijnreductie. De behandel-modaliteit (TENS of sham TENS) of interacties met de behandelmodaliteit bleken geen voorspellers te zijn voor de pijnintensiteit na behandeling. Terugtrekken bleek de enige cognitief-gedragsmatige voorspeller van de tevredenheid van patiënten na de behandeling wat inhoudt dat patiënten die geneigd zijn om zich terug te trekken in reactie op een verhoging van de pijnintensiteit, meer tevreden waren met de resultaten van TENS behandeling. Tot onze verrassing, en in tegenstelling tot de bevindingen met betrekking tot patiëntentevredenheid, bleek hulpeloosheid (lage ervaren controle) pijnreductie te voorspellen. Dit betekent dat patiënten die geneigd zijn om passief om te gaan met de pijn en meer hulpeloosheid cognities hanteren meer lijken te profiteren van deze behandeling. Vanuit het perspectief van het fear-avoidance model zou dit ook inhouden dat het toepassen van TENS behandeling het toepassen van passieve copingstrategieën stimuleert en daarmee voorkomt dat de patiënt op langere termijn een meer actieve copingstijl ontwikkelt. Dit roept de vraag op of, in overeenstemming met onze conclusies over mono- versus multidisciplinaire behandelingstrategieën welke in het vorige hoofdstuk beschreven werden, het combineren van TENS met een cognitief-gedragsmatige behandelingsmodule een zinvolle optie is waarbij patiënten met cognities van hulpeloosheid of die geneigd zijn om zich terug te trekken bij pijnvermeerdering uitgedaagd worden om meer actieve copingstrategieën te ontwikkelen.

Hoofdstuk 6 handelde over de korte termijn effecten van een multidisciplinair toewijzingsprotocol ten behoeve van verschillende pijnbehandelingsmodules en werden de voorspellers van de behandeluitkomsten gepresenteerd. In deze studie werden pijnintensiteit, functionele beperkingen, depressie en het gebruik van pijnmedicatie in een interventiegroep van 110 chronisch pijnpatiënten vergeleken met de uitkomsten van een wachtlijst controlegroep van ook 110 patiënten. In overeenstemming met het fear-avoidance model en het helplessness model werden catastroferen, angst voor pijn, vermijdingsgedrag en hulpeloosheid onderzocht als mogelijke voorspellers van de behandeluitkomsten en, gebaseerd op de meest recente onderzoeksliteratuur, werd acceptatie van pijn toegevoegd als een mogelijke voorspeller. Hoewel beperkt bleken alle uitkomstmaten na behandeling significant verminderd te zijn in de interventiegroep. Zowel pijnintensiteit als functionele beperkingen waren bovendien significant verminderd in vergelijking met de controlegroep. De relatief beperkte resultaten in onze studie zijn in overeenstemming met andere studies over multidisciplinaire chronische pijnbehandelingen hetgeen een illustratie is van een probleem dat inherent is aan de complexiteit van chronische pijn en de beperkte mogelijkheden van poliklinische pijnbehandelstrategieën. Een aantal eerdere studies hadden al aangetoond dat klinische behandelprogramma's betere behandelresultaten lieten zien dan poliklinische behandelingsvormen. Deze studies lijken aan te geven dat de sensorische, cognitief-gedragsmatige, emotionele en sociale aspecten van pijn op een dermate complexe wijze interacteren dat poliklinische behandelvormen met beperkte contactmomenten met behandelaars niet voldoende zijn en op deze wijze niet meer dan beperkte behandelresultaten zullen bereiken. Daarmee rijst de vraag op naar de kosteneffectiviteit. Poliklinische pijnbehandelvormen met een beperkt aantal contactmomenten zijn natuurlijk veel goedkoper dan klinische behandelvormen. Maar, wanneer betere behandelresultaten worden verlangd, zouden meer financiële bronnen dienen te worden aangewend om deze behandelingen mogelijk te maken. Omdat dit echter een meer politiek dan gezondheidszorgtechnisch onderwerp is, dient deze discussie op een ander niveau gevoerd te worden hetgeen buiten het domein van dit proefschrift valt. Het zou desalniettemin raadzaam kunnen zijn om studies naar behandeleffecten in de toekomst te relateren aan kosteneffectiviteit daar een dergelijke benadering ertoe kan bijdragen dat er een nauwkeuriger inzicht komt in de werkelijke behandel-effectiviteit van chronische pijn.

Met betrekking tot de voorspellende waarde van de cognitief-gedragsmatige factoren bleek dat slechts acceptatie van pijn een grotere pijnreductie voorspelde in de interventiegroep (maar niet in de controlegroep). Deze bevinding onderstreept daarmee het belang van acceptatie als een krachtige, adaptieve coping strategie bij chronische pijn. Er werden geen voorspellers gevonden voor een reductie van de functionele beperkingen. Acceptatie wordt beschouwd als een gezondheidbevorderende cognitie welke zich richt op het ontwikkelen van een bevredigend leven ondanks de ervaren pijn. Acceptatie cognities lijken te wijzen op een

gerichtheid van patiënten op het ontwikkelen van adaptieve coping-strategieën, welke een positief effect hebben op behandeluitkomsten en daarmee eerdere studies bevestigen die verbanden traceerden tussen acceptatie en minder aandacht voor de pijn en een actief coping gedrag. Daarnaast zouden patiënten die meer accepterende cognities hanteren, meer in staat zijn om kleine ver-anderingen in het pijnniveau te traceren en zijn zij meer geneigd om deze veranderingen positiever te evalueren dan patiënten met minder accepterende cognities. Op deze wijze kan acceptatie vooral invloed hebben op de affectieve en evaluatieve dimensie van de pijnwaarneming. De bevindingen zoals hiervoor beschreven kunnen daarmee het begrip vergroten van de verklarende mechanismen van pijnvermindering als gevolg van multidisciplinaire chronische pijnbe-handelingen daar het de eerste keer is dat acceptatie beschreven werd als een positieve voorspeller van de behandeluitkomsten van chronische pijn. De studies bevestigen acceptatie ook als contrasterend een met angstige en vermijdende wijze van coping. Daarmee zou acceptatie binnen het fear-avoidance model gedefinieerd kunnen worden als een voorwaarde voor een meer confronterende wijze van pijncoping. De verschillende bevindingen over de rol van acceptatie lijken erop te duiden dat pijnpatiënten die een meer accepterende wijze van pijncoping hebben ontwikkeld meer baat kunnen hebben bij behandelingen waarbij het persoonlijke contact beperkt is, zoals het geval is bij poliklinische behandelvormen, dan patiënten die een meer vermijdende copingstijl hebben ontwikkeld of een meer depressieve grondstemming hebben. Deze laatste groep zou meer kunnen profiteren van een meer intensieve behandeling welke klinisch gegeven wordt.

In de studie, beschreven in *hoofdstuk 7*, keken we naar de lange termijn effecten van een multidisciplinair toewijzingsprotocol van verschillende pijnbehandelings-modules. Ook in deze studie werden pijnintensiteit, functionele beperkingen, depressie en het gebruik van pijnmedicatie onderzocht als primaire uitkomstmaten. Daarnaast werd gekeken in hoeverre de korte termijn (3 maanden) veranderingen in de cognitief-gedragsmatige voorspellers (catastroferen, vermijdingsgedrag, angst voor pijn, hulpeloosheid en acceptatie) geassocieerd waren met de lange termijn effecten. Functionele beperkingen en depressie verbeterden beide significant als gevolg van de behandeling, hetgeen overeenkomt met de effecten die door Flor et al[8] werden gepresenteerd. De vermindering van het niveau van catastroferen, angst voor pijn, hulpeloosheid en vermijdingsgedrag na 3 maanden waren geassocieerd met de vermindering van functionele beperkingen en depressie na 12 maanden.

Hoewel functionele beperkingen en depressie significant verbeterden waren de resultaten ook in deze studie beperkt. De korte termijn reductie van de pijnintensiteit bleek op lange termijn niet stabiel. Deze bevinding kan erop duiden dat een hoger niveau van accepteren vóór behandeling niet voldoende is om korte termijn effecten vast te houden. Zoals in de vorige studie werd gevonden is acceptatie een belangrijke positieve copingfactor. Het toevoegen van een

behandelmodule, gericht op het verhogen van het niveau van acceptatie zou wellicht de lange termijn effectiviteit kunnen vergroten. Dit is ook in overeenstemming met een recente studie van McCracken et al over de resultaten van een behandeling, gericht op het vergroten van niveau van acceptatie. Ook in deze studie waren de resultaten echter niet meer dan gemiddeld, wat ook weer lijkt te wijzen op de grote complexiteit van chronische pijn waarbij het copinggedrag steeds meer geïntegreerd is in het dagelijkse functioneren en het daarom ook veel moeilijker is om dit gedrag te veranderen[1].

Deel 3: Evaluatie van verwijzers en implementatie

In *hoofdstuk 8* werden de resultaten beschreven van een onderzoek dat gehouden werd onder huisartsen van 83 chronisch pijnpatiënten die werden behandeld in het multidisciplinaire pijncentrum UMC St Radboud Nijmegen. Daar het vooral de huisartsen zijn die beslissen over het al of niet verwijzen van hun patiënten ten behoeve van behandeling van hun pijnklachten, is het uiteraard belangrijk dat het pijncentrum op de hoogte is en blijft van de wijze waarop de huisartsen de zorg van een multidisciplinair pijncentrum evalueren. Deze evaluatie kan invloed hebben op mogelijke toekomstige verwijzingen. Het pijncentrum UMC St Radboud had echter geen actuele informatie over de wijze waarop de huisartsen de zorg voor hun patiënten waardeerden. In het onderzoek werd de huisartsen gevraagd naar hun verwachting over de zorg voor hun patiënt, naar verschillende aspecten van de gegeven zorg en een algemene conclusie.

De huisartsen bleken de zorg voor hun patiënten positief te waarderen. Zij hadden echter zeer uiteenlopende verwachtingen over de verwijzing. Deze hadden niet alleen met betrekking het stellen van een medische diagnose of behandeling, maar ook op paramedische en psychologische zorg. Het voldoen aan die verwachting bleek in het onderzoek het belangrijkste criterium voor hun uiteindelijke evaluatie van de zorg. De huisartsen waardeerden de informatie voorafgaand aan de behandeling het meest negatief, vooral als het ging om informatie over de wachttijden en de mogelijkheid om contact te maken met de pijnspecialist. De resultaten van het onderzoek benadrukken het belang voor pijncentra om pro-actief te communiceren met de huisartsen om op deze wijze tegemoet te kunnen komen aan hun verwachtingen en om achteraf de evaluaties van de huisartsen te registreren.

In *hoofdstuk 9* werd het proces beschreven van de implementatie van de kennis over de psychologische factoren bij chronische pijn en een daaruit voortvloeiende kortdurende psychologische behandeling, toegespitst op uitvoering binnen de eerstelijnszorg. Allereerst werd een symposium georganiseerd over cognitief-gedragsmatige behandeling van chronische pijn en werd informatie ingewonnen bij eerstelijnspsychologen over hun kennis en behoeften aan bijscholing. Daarna kregen 39 eerstelijnspsychologen binnen het verzorgingsgebied van het UMC St Radboud een training over het uitvoeren van diagnostische technieken en het geven

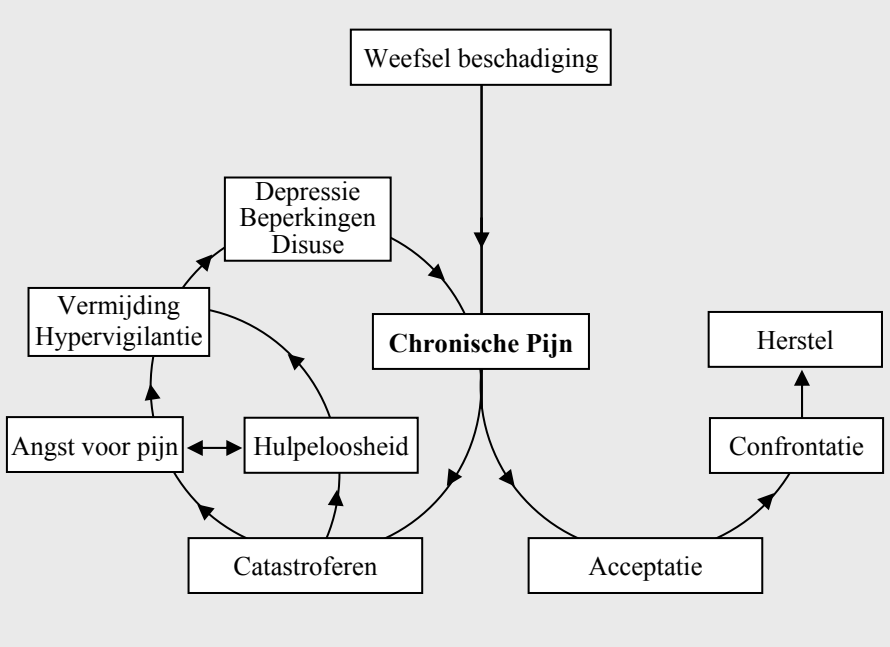
van een kortdurende cognitief-gedragsmatige behandeling aan chronische pijnpatiënten. Ook werd, vanuit een samenwerkingsmodel beschreven in het boek "De psycholoog als pijnbehandelaar" (2002), veel aandacht besteed aan de communicatie met fysiotherapeuten en huisartsen over behandelingsaspecten. De psychologen die de training hadden afgerond, werden opgenomen in een regionaal netwerk van eerstelijnspsychologen en woonden elk half jaar een inter- en supervisiebijeenkomst bij. Het korte termijn doel van het project was het overbrengen van de actuele wetenschappelijke en klinische kennis over de mogelijkheden van een psychologische behandeling naar het werkveld van eerstelijnspsychologen en het vergroten van de bestaande mogelijkheden voor tweede- en eerstelijns professionals (medisch specialisten, huisartsen en fysiotherapeuten) om chronische pijnpatiënten te verwijzen naar gespecialiseerde psychologen. Onze lange termijn doelstelling echter was ook om vooral huisartsen te stimuleren om pijnpatiënten eerder, in het subacute stadium van het pijnprobleem, te verwijzen naar een eerstelijnspsycholoog daar juist in deze periode het omgaan met de pijn minder geïntegreerd is binnen het dagelijkse functioneren en daardoor meer veranderbaar lijkt. Een onderzoek uit 2005 liet zien dat bij de eerstelijnspsychologen die op dat moment actief waren binnen het netwerk, het aantal verwijzingen door huisartsen hoger was dan het aantal verwijzingen vanuit het pijncentrum. In 2007 bestond het netwerk uit 29 eerstelijnspsychologen. Deze resultaten zijn veelbelovend en het is de bedoeling dat het project wordt uitgebreid naar andere regio's van Nederland zodat in de naaste toekomst steeds meer gespecialiseerde eerstelijnspsychologen betrokken zullen zijn bij de diagnostiek en behandeling van subacute en chronische pijnpatiënten. Patiënten met subacute pijn zullen dan verwezen kunnen worden als deel van een multidisciplinaire diagnostische procedure en zullen alleen dan verwezen worden naar een gespecialiseerd multidisciplinair pijncentrum wanneer de behandeling binnen de eerstelijnszorg niet effectief bleek. Op deze wijze wordt de expertise van zowel de eerstelijns- als tweedelijns professionals optimaal en kosteneffectief benut ten behoeve van de zorg voor pijnpatiënten

Uitbreiding van het Fear-avoidance model

De studies die in dit proefschrift werden beschreven ondersteunden het belang van de constructen catastroferen, angst voor pijn en vermijdingsgedrag binnen het fear-avoidance model. Zowel binnen de beloopstudies als de effectstudies bleken fear-avoidance cognities en gedrag een voorspellende waarde te hebben voor de uitkomsten. De studies in het eerste deel van dit proefschrift lieten echter ook zien dat, wanneer naast fear-avoidance factoren ook hulpeloosheid werd geïntroduceerd binnen een correlationeel en longitudinaal predictiemodel, hulpeloosheid een grotere voorspellende waarde had voor de uitkomsten dan fear-avoidance cognities. Deze bevindingen zijn in overeenstemming met eerdere studies over de

rol van hulpeloosheid bij chronische pijn. Onze resultaten suggereren dat bij patiënten met chronische pijn, hulpeloosheid een belangrijke factor kan zijn bij het verklaren van negatieve aspecten van het functioneren zoals pijnintensiteit, functionele beperkingen en depressie in de tijd. Ook zijn er aanwijzingen dat angst voor pijn en hulpeloosheid een complementaire rol kunnen hebben bij de mechanismen van pijn en functioneren in de tijd. Binnen het fear-avoidance model zou angst voor pijn de meest belangrijke cognitie kunnen zijn voor een beperkt aantal patiënten met pijn in het bewegingsapparaat terwijl hulpeloosheid een veel nadrukkelijker rol kan hebben bij vergeefse pogingen van patiënten om de pijn te beïnvloeden bij patiënten met andere pijnlocaties dan die van het bewegingsapparaat. Deze hypothese houdt in, dat toekomstige studies rond het eerste fear-avoidance model[3] zich dienen te richten op de korte en lange termijn consequenties van chronische pijn en patiënten dienen te includeren met verschillende pijnlocaties.

Naast hulpeloosheid als een belangrijke bijkomende factor binnen het fear-avoidance model, werd in *hoofdstuk 6* de rol van acceptatie van chronische pijn beschreven. Deze positieve copingstrategie helpt patiënten te erkennen dat zij chronisch pijn hebben, en door zich dit te realiseren kunnen zij zich richten op pogingen om ondanks de pijn een voor hen waardevol leven te leiden, vooral wanneer de pijn oncontroleerbaar blijkt. Hoewel de exacte betekenis van het construct van acceptatie nog onderwerp is van discussie, ondersteunen onze resultaten de bevindingen van een uitdijend aantal correlationele studies, longitudinale studies en effectstudies die acceptatie als een veelbelovende positieve, gezondheidbevorderende copingfactor definiëren. Deze studies suggereren dat patiënten met langdurige pijn, wanneer de pijn chronisch is geworden en niet gecontroleerd kan worden door eerder toegepaste copingstrategieën, zich op een kruispunt bevinden van potentiële cognitieve copingstrategieën. Aan de ene kant kunnen patiënten negatieve cognities ontwikkelen zoals catastroferen en hulpeloosheid met daaraan gekoppelde passieve gedragsmatige coping patronen. Aan de andere kant echter kunnen patiënten een meer acceptatie georiënteerde manier van omgaan met de pijn ontwikkelen wat een meer actief copinggedrag faciliteert hetgeen op langere termijn kan leiden tot een beter dagelijks functioneren. Samenvattend, gebaseerd op de recente literatuur en onze onderzoeksbevindingen, kunnen we concluderen dat het fear-avoidance model uitgebreid kan worden door hulpeloosheid en acceptatie toe te voegen (zie figuur 1).



Figuur 1: Voorstel voor uitbreiding van het Fear-Avoidance Model (Vlaeyen et al, 1995)

Klinische implicaties

De studies die in dit proefschrift werden beschreven, bevestigden alle de eerdere bevindingen nl. dat cognitief-gedragsmatige factoren belangrijke mediatoren zijn in het ontwikkelen en onderhouden van chronische pijn. Zowel cognitieve als gedragsmatige copingstrategieën bleken een aanzienlijke invloed te hebben op de door de patiënten ervaren pijn en dagelijkse functioneren in de tijd. De effectstudies in dit proefschrift wezen ook op het belang van deze psychologische factoren door aan te tonen dat zowel cognitieve als gedragsmatige coping-strategieën voorspellers waren van de uitkomsten van een toewijzingsprotocol van medische, paramedische, psychologische en multidisciplinaire behandeling. De beschreven effecten onderstrepen daarmee de noodzaak van een multidisciplinaire benadering bij de behandeling van chronische pijn. Daarbij zou een psychologisch screeningsonderzoek deel moeten uitmaken van een gestandaardiseerde diagnostische procedure bij elke patiënt met chronische pijn die verwezen wordt naar een gespecialiseerd pijncentrum. Afhankelijk van de resultaten van dit onderzoek, zou de patiënt een toegespitste cognitief-gedragsmatige behandeling aangeboden dienen te krijgen naast of voorafgaan aan een mogelijk geïndiceerde medische of paramedische behandeling. Dit houdt in dat pijncentra zich dienen te

conformeren aan een biopsychosociaal model van pijn en een multidisciplinair diagnose en behandelingsbeleid te formuleren. Monodisciplinariteit is in strijd met het biopsychosociaal model van pijn daar het uitgaat van de veronderstelling dat pijnreductie als gevolg van een medische of paramedische behandeling per definitie zou leiden tot een verbetering van het dagelijkse functioneren. Onze studie over de effecten van RF-DRG (beschreven in hoofdstuk 4) en eerdere publicaties hebben laten zien dat een pijnreductie als gevolg van een effectieve monodisciplinaire, medische of paramedische interventie, niet automatisch leidt tot een verbetering van het functioneren van een patiënt. De effectstudies in dit proefschrift lieten zien dat zelfs met een multidisciplinair toewijzingsprotocol voor pijnbehandeling slechts beperkte resultaten werden bereikt. Dit betekent dat, wanneer behandeling gericht is op zowel pijnreductie als het verbeteren van het dagelijkse functioneren, deze behandeling intensief dient te zijn en meer gericht dient te zijn op deze doelstellingen door deze te koppelen aan specifieke patiëntkenmerken.

De studies welke in dit proefschrift werden gepresenteerd laten zien dat bij chronische pijn hulpeloosheid en acceptatie invloed hebben op de pijnintensiteit en het dagelijkse functioneren naast angst voor pijn. Op basis hiervan zou het diagnostisch onderzoek vóór behandeling kwalitatief verbeterd kunnen worden door de cognities van de patiënt (angst voor pijn, catastroferen, hulpeloosheid en acceptatie) en het pijngedrag (pijnvermijding of accepterend gedragspatroon) nauwkeurig in kaart te brengen. Wanneer deze factoren zijn onderzocht, kan de pijnbehandeling zelf verbeterd worden door die copingmechanismen te veranderen die voor de individuele patiënt belangrijk blijken te zijn.

Met betrekking tot de pijnbehandelstrategieën laten onze studies zien dat chronische pijnbehandeling aan kwaliteit zou kunnen winnen door modules te integreren die gebaseerd zijn op het veranderen van pijncognities (angst voor pijn, catastroferen, hulpeloosheid en acceptatie) en/of het veranderen van specifiek pijngedrag (vermijdende of accepterende gedragspatronen).

Voor patiënten die hulpeloosheid cognities hanteren zou de behandeling een trainingsmodule moeten includeren, gericht op het induceren van cognities van interne controle en meer positieve verwachtingen in overeenstemming met de principes van de cognitieve therapie van Beck en een gedragsmodule, gebaseerd op de principes van graded activity. Wanneer angst voor pijn cognities meer op de voorgrond staan, zou de behandeling een module dienen te bevatten met exposure in vivo. In het geval van de aanwezigheid van catastroferende cognities zou een cognitieve module kunnen worden geïncludeerd, gericht op het vervangen van negatieve cognities die het pijnprobleem versterken door accepterende cognities die meer uitgaan van het erkennen van het pijnprobleem in plaats van het blijven vechten tegen de voortdurende pijnklachten. Daarnaast zou een gedragsmodule zinvol kunnen zijn die het vermogen van de patiënt versterkt om de pijn te negeren en de aandachtsfocus te verleggen naar concurrerende stimuli in plaats van de

pijnstimulus. In aansluiting daarop zou de acceptance and commitment therapy (ACT) toegepast kunnen worden. Deze therapievorm stimuleert de patiënt om met de aandacht bij de pijnsensatie te blijven, echter zonder de gebruikelijke daaraan gekoppelde negatieve gedachten. McCracken et al definieerde de pijnwaarneming in dit verband als een neutraal, actief bewustzijn van de pijnsensatie zonder een vorm van cognitieve of gedragsmatige vermijding. Wanneer er sprake is van vermijdingsgedrag, zou een operante behandelings-module aangeboden kunnen worden dat de patiënt helpt om een meer actief en pijngericht gedragspatroon te ontwikkelen. Tot slot zou aan patiënten die zeer laag scoren op het hanteren van accepterende cognities een acceptatie gerichte interventie aangeboden kunnen worden die tot doel heeft om te stoppen met het bevechten of ontkennen van de pijn en consequenties en ertoe kan bijdragen dat de pijn wordt geïntegreerd in het dagelijkse leven, waardoor op de langere termijn het dagelijkse functioneren kwalitatief kan verbeteren.

De beperkte effecten van de multidisciplinaire behandeling welke naar voren kwamen in de studies in het tweede deel van dit proefschrift wijzen op een specifiek probleem waarmee pijncentra in Nederland mee te maken hebben. In overeenstemming met het biopsychosociaal pijnmodel en de wijd geaccepteerde definitie van pijn volgens de IASP (International Association for the Study of Pain) dient pijn beschouwd te worden als een totaal van pijnlijden. Dit houdt in dat de behandeling van chronische pijn zowel het verminderen van de pijnintensiteit inhoudt als de daarmee gepaard gaande symptomen en gevolgen van de pijn (zoals functionele beperkingen en depressie). Pijnbehandeling dient daarom altijd te streven naar functioneel herstel en het verbeteren van de grondstemming. Dit houdt dus ook in dat, wanneer pijnreductie niet haalbaar blijkt, het verbeteren van het dagelijkse functioneren een legitieme doelstelling blijft. Samenvattend betekent dit dat pijncentra, in overeenstemming met onze bevindingen, zich niet uitsluitend dienen te richten op het verminderen van de pijnintensiteit door het uitvoeren van (para-) medische behandelingen maar zich meer dienen te richten op het ontwikkelen van cognitieve gedragsmatige interventies. Dit komt echter niet overeen met de verwachtingen van patiënten die verwezen worden naar gespecialiseerde pijncentra. McCracken et al toonden aan dat de patiënten-tevredenheid vooral samenhangt met de mate van ervaren pijnreductie.
Zoals in hoofdstuk 8 werd aangetoond, waren de grond en de verwachtingen van huisartsen die patiënten naar het pijncentrum verwezen meer geassocieerd met het verlangen om de eindeloze en vaak vergeefse zoektocht van hun patiënt naar pijnreductie en de daarmee gepaard gaande medische consumptie te stoppen. Dit roept des te meer de vraag op naar de status van de pijncentra en de manier waarop zij zichzelf definiëren in het spectrum van instellingen die pijn behandelen vanaf acute pijn tot chronische, medisch onbehandelbare pijn. Tot op heden definiëren zij zichzelf als instellingen die ernaar streven om pijn te verzachten en om daaraan

gekoppelde symptomen van pijnlijden alsook het beëindigen van de vicieuze cirkel van het eindeloos zoeken naar het beëindigen van het pijnprobleem. Tot dusverre zijn in Nederland de definities van behandeldoelstellingen, de inhoud van behandelmodules en de profielen van de pijncentra niet consistent, wat veel ruis veroorzaakt in de perceptie van zowel de verwijzende huisartsen als de betrokken patiënten. Er is behoefte aan een systeem van duidelijke en transparante chronische pijnbehandeling en het is daarom belangrijk dat de pijncentra zowel aan de verwijzende huisartsen als aan de patiënten een eenduidig inzicht geven in hun doelstellingen, die kunnen variëren van pijnvermindering tot het aanleren van betere pijncoping strategieën. Deze houding van openheid en transparantie zal onrealistische verwachtingen bij alle betrokken partijen kunnen voorkomen.

Conclusies en aanbevelingen

In overeenstemming met de samenvatting en discussie, kunnen de belangrijkste conclusies als volgt worden geformuleerd:

- Cognitief-gedragsmatige factoren hebben invloed op pijnintensiteit, functionele beperkingen en depressie.
- Cognitief-gedragsmatige factoren hebben invloed op de effecten van medische, paramedische en multidisciplinaire chronische pijnbehandelingsstrategieën.
- Hulpeloosheid en acceptatie spelen een rol in het voorspellen van pijnuitkomsten en in het voorspellen van behandeleffecten naast de fear-avoidance factoren (catastroferen, angst voor pijn en vermijdingsgedrag).
- De waardering van verwijzers is vooral gebaseerd op de mate waarin tegemoet wordt gekomen aan de eigen verwachtingen van de verwijzing.

In overeenstemming met de hierboven geformuleerde conclusies, kunnen de volgende aanbevelingen worden geformuleerd:

- Bij chronische pijn kan het concept van het fear-avoidance model worden uitgebreid door de cognities hulpeloosheid en acceptatie in het model te integreren.
- Bij het diagnostisch onderzoek, voorafgaand aan de pijnbehandeling, is het zinvol om pijncognities (angst voor pijn, catastroferen, hulpeloosheid en acceptatie) en vermijdingsgedrag te onderzoeken.
- Behandeling van chronische pijn kan kwalitatief verbeteren door het integreren van behandelmodules, gericht op het veranderen van hulpeloosheid en acceptatie.
- Een instelling voor het behandelen van chronische pijn dient transparant en pro-actief te communiceren om meer tegemoet te kunnen komen aan de verwachtingen van de verwijzers.

List of Publications

Han Samwel, Ton Staps: Op zoek naar een nieuw perspectief: angst, kankerpatiënten en verpleegkundigen. *Tijdschrift voor Ziekenverzorging 1991;25(14); 14: 490-495.*

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Dankwoord

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Het Pijnkenniscentrum heeft het mij mogelijk gemaakt, om via het geven van scholingen in contact te komen met andere disciplines die zich bezighouden met pijn: anesthesiologen, huis-, bedrijfs- en verzekeringsartsen, fysiotherapeuten, verpleegkundigen. Dit heeft mij veel inzicht gegeven in het verschillend perspectief van deze disciplines ten opzichte van pijn- en pijnbehandeling en de wijze waarop het werk van de psycholoog daarin waargenomen werd. Dit heeft mijn liefde voor juist het onderzoek naar multidisciplinaire aspecten van pijn en pijnbehandeling flink aangewakkerd. In die zin is het voltooien van het proefschrift voor mij ook een kroon op het werk bij, en zeker ook van, het helaas mogelijk binnenkort voorbije Pijnkenniscentrum.

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Mijn zoon
Mijn wereldgozer

Singha

Curriculum Vitae

Curriculum Vitae

Han Samwel is geboren op 18 augustus 1954 in Poeldijk, het Westland. Na de lagere school deed hij een uitermate vergeefse poging op de HBS en verhuisde na een angstig jaar opgelucht naar de MULO die hij vervolgens in 3 jaar afrondde. In de twee jaar die daarop volgden, voltooide hij de HAVO. Als zoon van een kleine ondernemer koos hij vervolgens onder lichte doch effectieve ouderlijke druk voor de HEAO waar hij de bedrijfseconomische richting in 4 jaar afrondde. Een stage bij een groot accountantskantoor maakte voor hem echter duidelijk dat een carrière binnen de bedrijfseconomie onontkoombaar zou leiden tot een vroegtijdige en fatale verschraling van zijn bestaan.

Kortom, hij moest opnieuw beginnen.

Na een bezinningsperiode tijdens de militaire dienst als telefonist, een functie die extreem veel tijd liet voor reflectie, besloot hij naar de Sociale Academie te gaan omdat hij “met mensen wilde werken”. Na een jaar waarin hij kennismaakte met de revolte van studenten tegen het afbrokkelende gezag van de verbolgen docenten wat tijdens de lesuren hartstochtelijk werd uitgevochten (het was immers het turbulente jaar 1977), verliet hij wat mismoedigd, maar vele legendarische ervaringen rijker, de Academie. Hij wilde desondanks een nieuwe poging wagen en ging als leerling Z-verpleegkundige werken in het Westerhonk, een instelling voor mentaal zwaar gehandicapte mensen. Hier beleefde hij een van de gelukkigste jaren van zijn werkzame leven omdat hij mensen verzorgde die ook vaak lichamelijk zwaar gehandicapt waren en niet verbaal konden communiceren, zodat hij contact moest leren maken via een nog niet door hem ontgonnen taal: aandacht, gebaren en verzorgen.
Na een jaar ging hij als leerling B-verpleegkundige werken bij de stichting Bloemendaal, een instelling voor psychiatrische patiënten waar hij in 1983 zijn diploma behaalde. Direct daarna startte hij zijn studie Psychologie, tot 1986 in Leiden, omdat hij “dieper met mensen wilde werken”. Na de verpletterende ontmoeting met Elisa, zijn latere vrouw, op een zwalkend schip in zwaar tij verbrandde hij terstond alle (andere) schepen achter zich en volgde haar met verlicht gemoed naar Nijmegen waar hij manmoedig de plots opdoemende Bourgondische verleidingen weerstond en in voortvarend tempo in 1989 zijn diploma Psychologie, klinische richting behaalde. Hij ging met zijn diploma, de eerste jaren nog onder vergeefs protest onbezoldigd, werken bij het pijncentrum van het UMC St Radboud dat in die periode langzaam gestalte kreeg. Hij heeft mede de psychologische diagnostiek en behandeling vormgegeven en zich ingezet voor een actieve samenwerking tussen de verschillende disciplines. Dit heeft in 2002 geleid tot de publicatie van het boek:”De psycholoog als pijnbehandelaar”. Van 1993 tot 1998 volgde hij de specialisatie tot klinisch psycholoog-

psychotherapeut. Daarna, op zoek naar alweer een uitdaging, nam hij het initiatief tot een onderzoek naar de effecten van de behandeling door het pijncentrum, iets wat tot dan nog niet uitgevoerd was. Dit onderzoek leidde, gedrenkt in het zweet van de zoektocht naar de onderzoeker in de clinicus, tot dit proefschrift.
Naast zijn werk in het UMC St Radboud is hij vanaf 1990 tot heden ook werkzaam in het Canisius Wilhelmina Ziekenhuis bij de afdeling Klinische Psychologie waar hij vooral actief is op de afdelingen Longziekten en cardiologie.
Han Samwel is sinds 1990 gehuwd met Elisa Bol en zij hebben een zoon, Singha, die in 1994 werd geboren.