PATIENT-CENTERED OUTCOMES FOR CHRONIC SPINE PAIN: MULTIDIMENSIONAL SUCCESS CRITERIA AND TREATMENT MATCHING

By

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Our study aimed to (1) define patient-centered success criteria for chronic pain treatment across multiple relevant domains (pain, fatigue, emotional distress, and interference with daily activities) using our newly developed Patient-Centered Outcomes Questionnaires (PCOQs); (2) derive and validate subgroups of chronic pain patients; and (3) examine the potential for treatment matching using our patient subgroups. We recruited 70 patients with chronic spine pain from five University of Florida or affiliated pain clinics. Participants completed pre-treatment and post-treatment measures, including our PCOQ and Follow-up PCOQ. Post-treatment assessment occurred two months after treatment initiation.

Pre-treatment success criteria derived using a direct scaling approach were more stringent than criteria developed using other approaches. At the onset of treatment, our patients considered a 58% reduction in pain to represent treatment success. Success criteria for pain developed using other approaches (e.g., expert opinion) have ranged

from 30 to 50%. Pre-treatment success criteria for fatigue, distress, and interference were 61%, 64%, and 66%, respectively. Results showed that patients adjusted their success criteria over time in the direction of becoming less stringent, and they used their less stringent post-treatment criteria to make global judgments of treatment success. Consequently, future research might investigate the evolution of patients' success criteria over the course of different treatments.

Success criteria for pain derived using a scale comparison approach were a raw change of 17.5 points (0 to 100 numerical rating scale) and percent change of 25%. Other criteria were 7.5 points (11%) for fatigue, 5.0 points (13%) for distress, and 9.5 points (12%) for interference. Future research should validate these success criteria, particularly for the less studied domains of fatigue, distress, and interference. Once validated, they can be used to calculate effect size estimates, permitting comparisons across studies and ultimately helping to evaluate the efficacy of various treatments. Clinicians can also use these criteria to help them assess the care of individual patients.

Finally, our results suggest that pain patients are heterogeneous. Even among patients whose pathology is specific to the spine, two distinct subgroups emerged. Future research might explore whether these and other patient subgroups have different criteria for treatment success.

CHAPTER 1
INTRODUCTION

Chronic pain is a major health problem in America. Estimates indicate that up to 18% of the population suffers from persistent pain at any given time (Turk, 2002). Beyond the number of people affected, chronic pain places a substantial economic burden on the United States health care system. Health care expenditures for chronic pain exceed $20 billion annually (Turk, 2002). This figure does not include the cost of treatment at pain rehabilitation programs, which is in the range of $1.4 billion per year (Turk, 2002). Notably, health care expenditures represent only a fraction of the costs associated with chronic pain. Disability compensation, lost productive time, and lost tax revenue also factor into estimates (Turk, 2002). A recent survey found that among working adults with common pain conditions, including back pain and arthritis, lost productivity due to decreased performance costs approximately $61.2 billion per year (Stewart, Ricci, Chee, Morganstein, & Lipton, 2003). Considering all sources of expenditures, chronic pain is projected to cost the United States economy roughly $100 billion each year (Department of Health and Human Services, National Institutes of Health, 1998).

Aim 1: Developing Patient-Centered Success Criteria

Numerous studies have examined the effectiveness of various treatments for chronic pain (Turk & Melzack, 2001). These studies used standard statistical methods that result in conclusions about statistical significance, or the reliability of treatment changes. Statistical significance, while necessary, is not sufficient to show treatment effectiveness. The statistical significance of a finding largely depends on sample size. A

trial involving a large number of patients can detect differences between treatment and control groups or between the same patients pre- and post-treatment that are statistically reliable, but trivial from a clinical perspective. Conversely, a trial involving a small sample may not achieve statistical significance, but may indicate important differences.

Regardless of the specific problem, comparisons of central tendency do not elucidate the proportion of patients who benefit from the treatment, or the extent of improvement in these patients. Statistically significant group differences could reflect major improvement in a few patients, or minor improvement in many patients. They also could reflect improvement in some patients, but no change (or even deterioration) in other patients (Farrar, Portenoy, Berlin, Kinman, & Strom, 2000). Therefore, clinicians might have difficulty interpreting and applying the results of central tendency analyses to the care of individual patients (Farrar et al., 2000). Consequently, studies of chronic pain should also consider whether treatment is clinically significant. A more useful statistic for clinicians is the percentage of patients who attain a clinically important improvement (Farrar et al., 2000).

In deciding what constitutes a clinically significant outcome for pain treatments, researchers might consider looking to the patient rather than to health care providers, caregivers, or third-party payers. Pain and its sequelae are intrinsically subjective and influenced greatly by a person's mood, previous pain experience, expectations, and coping resources. Although patient self-report instruments and pain scales are widely used in clinical settings, different health care providers and researchers could still reach different conclusions about treatment success if they apply different interpretive criteria to these instruments. Furthermore, chronic pain patients and their therapists may have

different views of treatment success (Daniel, Long, Murphy, Kores, & Hutcherson, 1983). Given the subjective nature of the pain experience and potential discrepancy between patients' and health care providers' conclusions about treatment success, decisions about what constitutes treatment success ought to consider the patient perspective.

The patient-centered model of health care delivery, which holds that patients' views should be recognized, appreciated, and incorporated into treatment decisions and outcome evaluation, has been adopted as a goal of clinical medicine (Lane & Davidoff, 1996), as it promotes greater satisfaction with health care, increased compliance with medical regimens, and maintenance of patient-provider relationships (Fischer, Stewart, Bloch, Lorig, Laurent, & Holman, 1999). Consequently, a growing body of literature addresses patient views of treatment outcome. Investigations have been conducted across medical conditions, such as epilepsy (Gilliam, Kuzniecky, Meador, Martin, Sawrie, Viikinsalo, Morawetz, & Faught, 1999), multiple sclerosis (Schwartz, Cole, & Gelber, 1995), and post-traumatic stress (Zatzick, Kang, Hinton, Kelly, Hilty, Franz, Le, & Kravitz, 2001).

To date, there have been few patient-centered investigations of treatment outcome for chronic pain. Furthermore, most investigations focused exclusively on pain reduction, although patients enter pain rehabilitation with multiple presenting problems in addition to pain (e.g., mood disturbance, fatigue, disability) and identify diverse treatment goals. Casarett, Karlawish, Sankar, Hirschman, and Asch (2001) found that 32% of patients in their study identified improved sleep as an important clinical endpoint. Improved activities of daily living and improved mood were identified as important treatment goals

by 30 and 8% of patients, respectively. More recently, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMPACCT) convened with the purpose of identifying core outcome domains for clinical trials of chronic pain treatment (Turk, Dworkin, Allen, Bellamy, Brandenburg, Carr, Cleeland, Dionne, Farrar, Galer, Hewitt, Jadad, Katz, Kramer, Manning, McCormick, McDermott, McGrath, Quessy, Rappaport, Robinson, Royal, Simon, Stauffer, Stein, Tollett, & Witter, 2003). Included in the core outcome domains were emotional functioning and physical functioning. Therefore, any comprehensive examination of patient-centered outcomes must address a host of treatment endpoints.

After identifying relevant endpoints, researchers must establish how much change in a given domain constitutes success. In other words, they must determine the degree of symptom improvement considered important, referred to in the literature as the minimal clinically important difference (MCID). Previous attempts to establish MCIDs used diverse approaches, most of which are not based on patient perceptions. Many approaches are flawed in additional ways, further limiting their utility. The simplest approach was based on the principle of face validity. Moore, McQuay, and Gavaghan (1996) chose 50% pain relief as the MCID because of its clinical intuitiveness. Yet, the significance of this criterion to chronic pain patients has not been determined.

The approach taken by Slater, Doctor, Pruitt, and Atkinson (1997) involved comparing patients' symptoms to those of healthy individuals. Slater and colleagues defined the MCID in depressive symptoms as change such that the patient's score on the Beck Depression Inventory, a self-report measure of depression, following treatment was closer to the mean of healthy individuals than to the mean of chronic pain patients.

Again, the significance of this criterion to the patients it is applied to has not been ascertained.

Some investigators relied on expert opinion in establishing MCIDs. For example, Goldsmith, Boers, Bombardier, and Tugwell (1993) conducted eight focus groups with practicing clinicians, epidemiologists, biostatisticians, and physicians working either in various industries (e.g., pharmaceutical) or for regulatory agencies to determine clinically important outcomes for rheumatoid arthritis. The experts independently rated whether profiles containing information about six variables— swollen joint count (range = 0 to 66), painful joint count (range = 0 to 68), pain intensity (range = 0 to 10 cm), disability (range = 0 to 10 cm), patient global assessment (range = 0 to 10 cm), and physician global assessment (range = 0 to 10 cm)—represented important improvement. When 6 to 8 of the focus groups achieved 70% positive agreement, the profile was considered to reflect important improvement. Measures of central tendency then were calculated on profiles representing important improvement to derive an MCID for each of the six variables. The MCID values were 2 (17%) for swollen joints, 3 (27%) for painful joints, 2.2 (36%) for pain, 3.6 (49%) for disability, 2.2 (35%) for patient global assessment, and 2.3 (39%) for physician global assessment. While this approach is more sophisticated than other approaches, it still does not capture the patient's view.

A common method of deriving MCIDs involves comparing two scales. This approach has two major variations (Redelmeier, Guyatt, & Goldstein, 1996). In the first approach, patients are asked to rate a given domain (e.g., current pain intensity on a 100 mm VAS) and then indicate whether they are doing better or worse in that domain than before. This approach identifies the threshold at which the average patient begins

judging himself as improved. Farrar, Young, LaMoreaux, Werth, and Poole (2001) used this approach with patients with neuropathic and non-neuropathic chronic pain conditions. Their goal was to determine the MCID in pain intensity associated with a "much improved" global impression of change. Using an 11-point numerical rating scale (NRS), they found that a raw change of 2 (30%) represented clinically important improvement. Salaffi, Stancati, Silvestri, Ciapetti, and Grassi (2004), using the same approach, found that a raw change of 2 (33%) on a 10 cm NRS corresponds to a "much better" global impression of change among patients with chronic musculoskeletal pain. In a study of patients with osteoarthritis (OA) of the lower extremities, MCIDs associated with a "slightly better" change of health in general related to the OA joint ranged from .80 to 1.01 points (17 to 22%) on a continuous 0 to 10 NRS (Angst, Aeschlimann, Michel, & Stucki, 2002).

The second approach uses interpersonal judgments (Redelmeier et al., 1996). After rating themselves on various domains, patients are asked to converse with another patient with the same condition and then rate themselves on the same domains relative to their conversational partner. The MCID typically is defined as the difference in mean scores between conversations in which partners rate themselves as "about the same" and those in which they rate themselves as "somewhat better." Wells, Tugwell, Kraag, Baker, Groh, and Redelmeier (1993) used this approach to determine the following MCIDs for rheumatoid arthritis patients: .22 units (7%) for physical ability as assessed by the Stanford Health Assessment Questionnaire (HAQ; range = 0 to 3), .62 cm (6%) for pain as measured on a 10 cm VAS, and 9% for overall condition as assessed on a 5-point

scale. In another study of arthritis patients, Redelmeier and Lorig (1993) derived a slightly smaller MCID of .17 units for the HAQ.

Although both approaches to scale comparison are patient-centered, important limitations exist. First, much variability exists in researchers' a priori definitions of the clinically important difference—Wells et al. (1993) chose "somewhat better" whereas Farrar et al. (2001) chose "much improved"—making comparisons across studies difficult, and raising questions about the ability of any one definition to truly capture the notion of minimal improvement. Most important, these investigator-determined a priori definitions may not reflect the degree of symptom improvement that is important to patients.

A final method of determining MCIDs is specific to the domain of pain. Farrar et al. (2000) derived an MCID in analgesia by comparing the change in pain intensity for adequately treated episodes of cancer-related breakthrough pain (i.e., episodes not necessitating rescue medication as an adjunct to oral transmucosal fentanyl citrate) to the change in pain intensity for inadequately treated episodes. They selected as the MCID the change in pain intensity that most accurately distinguished satisfactorily and unsatisfactorily treated episodes in addition to having relatively equal sensitivity and specificity. Analyses yielded an MCID of 2 on an 11-point NRS, which corresponds to 33% change. Farrar and colleagues (2003) then replicated these MCIDs with a second data set. According to Farrar (2000), the "use of rescue" outcome "may offer a more objective and specific measure of the patient's perspective on what represents clinically important analgesia" and "allows the patient to integrate his or her perception of the amount of relief and any potential side effects experienced (p. 292)." However, this

approach is most appropriate for trials of fast-acting medications for the treatment of breakthrough or acute pain, and may not be generalizable to chronic pain (Farrar, 2000).

Given the limitations associated with previous attempts to establish MCIDs for chronic pain, additional approaches are needed that take into account major areas of concern to patients. Therefore, our first aim was to define MCIDs from the spine pain patient's perspective across four domains of concern (pain, fatigue, emotional distress, and interference with daily activities) using newly developed Patient-Centered Outcomes Questionnaires (PCOQs). Preliminary research using the PCOQ found that chronic pain patients might require larger reductions in their pain than has previously been reported in the literature, for them to consider treatment successful (Robinson, Brown, George, Edwards, Atchison, Hirsh, Waxenberg, Wittmer, & Fillingim, in press). In fact, MCIDs derived using a direct scaling approach were 3.4 points (on an 11-point NRS) or 56% for pain, 3.35 points (57%) for fatigue, 3.64 points (65%) for distress, and 4.3 points (68%) for interference (Robinson et al., in press).

Our study expands on previous work using the PCOQ by adding a post-treatment measure: the Follow-up PCOQ. Our goal was to derive success criteria for each of the domains by ascertaining the change in scores from pre-treatment to post-treatment that most accurately distinguishes successful treatment from unsuccessful treatment as determined by patient global judgment. Once identified, these MCIDs can be used to calculate effect size estimates, such as the number needed to treat (Cook & Sackett, 1995), permitting comparisons across studies and ultimately helping to establish the efficacy of various treatments (Farrar et al., 2001; Redelmeier et al., 1996).

Aims 2 and 3: Identifying Patient Subgroups and Examining Treatment Matching

The etiological mechanisms of many nonmalignant chronic pain conditions, including spine pain, remain poorly understood. Thus, diagnosis is based predominantly on current and past signs and symptoms, rather than on specific pathological findings. Turk and Okifuji (2001) said that because the specificity of these diagnostic criteria has not been established, patients with diverse characteristics may erroneously be given the same diagnosis and treatment. In other words, "a heterogeneous group of patients may be treated as if they are homogeneous" (Turk & Okifuji, 2001, p. 400). This may partly explain why treatment-outcome studies consistently find that only a subset of patients with a particular diagnosis benefits from the prescribed treatment.

To offset the pain patient homogeneity assumption, researchers attempted to identify subgroups of chronic pain patients. For example, Dworkin and LeResche (1992) derived subgroups using physical signs and symptoms. Other investigators (e.g., Jamison, Rock, & Parris, 1988) used traditional measures of personality and psychopathology, such as the Minnesota Multiphasic Personality Inventory or Symptom Checklist-90, to empirically derive pain patient subgroups. Still others (Keefe, Bradley, & Crisson, 1990) created subgroups based on pain behaviors. Although these approaches yielded several classification systems, the question remains as to whether these systems are clinically useful. According to Turk and Okifuji (2001), one way to substantiate the clinical utility of a classification system involves demonstrating the differential effectiveness of therapies matched to the defining characteristics of the subgroups. The few studies that addressed this issue (Guck, Meilman, Skultety, & Poloni, 1988; McGill, Lawlis, Selby, Mooney, & McCoy, 1983; Moore, Armentrout, Parker, & Kivlahan, 1986) failed to

demonstrate the differential effectiveness of treatments customized to subgroup characteristics.

Of note, Turk and colleagues had some success with their classification system, which is based on the West Haven-Yale Multidimensional Pain Inventory (WHYMPI). Three subgroups of chronic pain patients emerged from cluster analysis of WHYMPI responses: Dysfunctional, Interpersonally Distressed, and Adaptive Copers. The Dysfunctional subgroup reports high pain severity, life interference, and psychological distress, as well as low activity level (Turk & Rudy, 1988). Interpersonally Distressed patients perceive their significant others as unsupportive of their pain problems. Finally, the Adaptive Coper subgroup reports relatively low levels of pain and interference, and relatively high levels of social support and activity.

Preliminary studies examining the differential responsiveness of the WHYMPI subgroups to different treatment programs provide support for the clinical utility of the classification system. Rudy, Turk, Kubinski, and Zaki (1995) evaluated the differential responses of the three WHYMPI subgroups of temporomandibular disorder (TMD) patients to a treatment involving interocclusal appliance, biofeedback-assisted relaxation, and stress management. Results showed that significantly more Dysfunctional patients than Interpersonally Distressed or Adaptive Coper patients achieved clinically significant improvements with respect to pain intensity, depression, and perceived impact of TMD on their lives. Furthermore, a greater number of Interpersonally Distressed patients than Adaptive Coper patients showed clinically significant improvements in these domains. In general, results showed that the treatment was effective, but only for certain subgroups of TMD patients.

Turk and associates (Turk, Rudy, Kubinski, Zaki, & Greco, 1996; Turk, Zaki, & Rudy, 1993) then developed a treatment plan that targets the needs of TMD patients in the Dysfunctional subgroup. They evaluated the efficacy of this treatment program (interocclusal appliance, biofeedback-assisted relaxation, and cognitive therapy for depression) against a more conservative treatment program (interocclusal appliance, biofeedback-assisted relaxation, and supportive counseling). The Dysfunctional patients who received cognitive therapy as part of their treatment showed significantly more improvement, especially in the domains of pain and depression, than did the Dysfunctional patients who received supportive counseling as part of their treatment. Therefore, by incorporating a treatment component tailored to Dysfunctional patients, Turk and colleagues were able to augment treatment outcome.

In a study of patients with fibromyalgia syndrome, Turk, Okifuji, Starz, and Sinclair (1998) predicted that the WHYMPI subgroups would show different outcomes to standard rehabilitative treatment involving medical, physical, occupational, and psychological elements. Findings support their hypothesis, with patients in the Dysfunctional subgroup showing improvements in nearly all domains and patients in the Interpersonally Distressed subgroup showing no improvement, presumably because the treatment did not address their particular clinical needs, which reside primarily in the interpersonal domain. Patients in the Adaptive Coper subgroup showed only minor improvements compared to patients in the Dysfunctional subgroup, although they had less room for improvement given their better pre-treatment functioning. Again, these results highlight the importance of matching treatment to the clinical needs of the group.

These studies provide preliminary support for the utility of the treatment-matching approach. However, further research is needed before the treatment-matching approach can reasonably be applied to clinical practice. It is hoped that streamlining treatment based on patient characteristics rather than adopting the "one size fits all" approach to treatment ultimately will improve outcomes and decrease costs (Turk & Okifuji, 2001).

A second aim of our study was to empirically derive subgroups of chronic pain patients using the PCOQ. More specifically, we classified chronic spine pain patients into subgroups based on their ratings of the perceived importance of improvement in pain, fatigue, emotional distress, and interference with daily activities. On the basis of preliminary data from four University of Florida or affiliated pain clinics (Robinson et al., in press), we expected three subgroups to emerge. We predicted that one subgroup ("pain-focused" subgroup) would show a greater relative interest in pain relief. We expected a second subgroup ("multifocused-high" subgroup) to report that improvement in all four domains is extremely important. We expected the final subgroup ("multifocused-moderate" subgroup) to provide moderate importance ratings across domains. In addition to replicating previous findings, our study aimed to establish the validity of the patient subgroups by examining pre-treatment differences among the subgroups on demographic and psychosocial variables. We hypothesized that the two multifocused subgroups would have significantly greater duration of pain than participants in the "pain-focused" subgroup. We also expected that the "multifocused-high" subgroup would have the highest scores on self-report measures of pain, distress, and disability. We predicted the "pain-focused" subgroup to have the lowest scores on measures of pain, distress, and disability.

Our final aim was to examine the potential for treatment matching using the patient subgroups derived from the PCOQ. We predicted that patients who received treatment that was matched to their clinical needs would show superior treatment outcomes, when compared to patients who received treatment that was not matched to their clinical needs. Therefore, we expected patients in the "pain-focused" subgroup to show better outcomes after treatment that focused exclusively on their pain (i.e., palliative pain management), and we expected patients in the multifocused subgroups to show better outcomes after treatment that addressed not only their pain, but also their fatigue, emotional distress, and interference with daily activities (i.e., multidisciplinary pain management).

CHAPTER 2
METHODS

Participants

Participants were 70 patients (27 male, 43 female) with a primary complaint of chronic spine pain of at least 3 months duration. Participants were recruited from five University of Florida or affiliated pain clinics, and they provided informed consent in accordance with Institutional Review Board requirements. The mean age of participants was 50.9 (SD = 12.5) years. Most participants (88.6%) were Caucasian and 11.4% were African-American. Participants reported a mean of 13.0 (SD = 2.2) years of formal education. Of participants, 66% percent were married. Participants reported a mean duration of pain of 91.1 (SD = 95.7) months, with pain duration ranging from 4 to 468 months.

Participants underwent one of two types of treatment as part of their routine clinical care: palliative pain management (interventional anesthesia/oral analgesic only) or multidisciplinary pain management (behavioral/rehabilitation intervention component included). The two treatment approaches are described in greater detail below.

Design

The design of the study was longitudinal, with pre-treatment and post-treatment assessments. Post-treatment assessment occurred approximately 2 months after initiation of treatment. Post-treatment data were collected on 55 of the 70 participants (21 males, 34 females). Nine participants were lost to follow-up for the following reasons: phone number disconnected (3), no longer residing at stated phone number (1), on extended

vacation (1), could not reach at home despite multiple attempts (4). Four participants withdrew by choice at follow-up, and two participants were withdrawn by the research team at follow-up because they never received the intended treatment.

Procedure

Before starting treatment, eligible participants were approached by a co-investigator or other research staff, given a brief description of the study, and then asked if they would consider participating in the study. Interested participants were asked to read and sign the informed consent form. After agreeing to participate in the study, participants completed the Demographics Questionnaire and the following paper-and-pencil measures: McGill Pain Questionnaire, Beck Depression Inventory, Pain Anxiety Symptoms Scale, Roland Disability Questionnaire, Pain Disability Index, and Patient-Centered Outcomes Questionnaire. Participants also rated the intensity and unpleasantness of their pain on visual analog scales (VASs). Two months post-treatment, research staff contacted participants by telephone to complete two measures, the Follow-up PCOQ and Pain Service Satisfaction Test.

Treatments

Because of ethical considerations, treatment was not randomly assigned. All participants were recruited from existing treatment programs, making our study highly ecologically valid. Withdrawal before completion of the study did not affect the participant's treatment.

Palliative Pain Management

Participants receiving palliative pain management underwent one or more of the following four treatments: injection, radiofrequency denervation, non-narcotic analgesic medication, and opioid medication. Injections consist of epidural administration of

steroid or anti-inflammatory medication, sometimes in combination with local anesthetic. The injection is delivered under fluoroscopic guidance into the epidural space at the spinal level determined by clinical exam to be the area relevant to the clinical pain distribution. Injections serve to decrease pain by reducing nerve root irritation.

Radiofrequency denervation is a commonly performed interventional treatment for axial low back pain (Dreyfuss, Halbrook, Pauza, Josi, McLarty, & Bogduk, 2000; North, Han, Zahurak, & Kidd, 1994). The procedure is done by positioning a percutaneous electrode next to the medial branches of the posterior nerve rami for a particular facet joint, and then using a generator to induce heat through the electrode. This causes a lesion of the nerve's ability to send messages to the posterior column of the spinal cord. Radiofrequency denervation is completed under fluoroscopic guidance, and it may be done unilaterally or bilaterally and at a single spinal level or at multiple spinal levels. The number of levels to be lesioned is determined by prior diagnostic lidocaine injection of the medial branches.

Patients typically receive chronic opioid medication if, and when, there are no other interventions, including non-narcotic analgesic medication (e.g., Ultram), that might manage their pain more effectively. Use of long- and short-acting opioids in a pattern to better manage pain is discussed with the patient, as are potential side effects and adverse outcomes. After this discussion, the initial dosing pattern of medication is started. Opioid medications typically prescribed include OxyContin, MS Contin, Methadone, and the Duragesic Patch. In most cases, a second prescription for breakthrough medication also is given. If the patient responds favorably with no intolerable side effects at the initial dose, he or she is maintained on the medication, and the dose is adjusted to achieve as much

pain reduction as possible without intolerable side effects. Should the patient have intolerable side effects from the initial dose, he or she is switched to another opioid medication.

Multidisciplinary Pain Management

Participants receiving multidisciplinary pain management participated in a pain management group and/or underwent a standard rehabilitation program. Participants sometimes received pharmacological therapy as an adjunct to this behavioral/ rehabilitation approach. The pain management group is a psychoeducational group comprising cognitive-behavioral pain coping skills training, an empirically supported treatment for chronic pain conditions (Keefe, 1996). This 10-session, structured, outpatient group emphasizes instruction, rehearsal, and practice during session and at home. Sessions are held once per week for 90 minutes. Patients initially are taught to conceptualize their pain in terms of the gate control theory of pain (Melzack & Wall, 1965). Then, they are instructed in diaphragmatic breathing, which involves breathing deeply from the diaphragm in a controlled manner. During the next session, patients are taught progressive muscle relaxation, a series of exercises involving tensing and relaxing various muscle groups, and given an opportunity to rehearse the technique in session. The third session is devoted to discussing activity-rest cycling, a method for controlling pain and increasing activity level that consists of planned periods of activity, interspersed with planned regular rest periods. During the fourth session, patients are introduced to cognitive restructuring, which involves systematically identifying and changing negative automatic thoughts to more encouraging, realistic thoughts. They spend the next three sessions participating in cognitive restructuring exercises using examples generated by both group leaders and group members. The eighth session focuses on problem-solving,

and the final sessions focus on evaluating progress and maintaining treatment gains. Other topics covered during group include pleasant activity scheduling, mini-relaxation, and attention diversion techniques (e.g., pleasant imagery, focal point use).

The standard rehabilitation program consists of 18 sessions (3 per week), with each session lasting approximately 90 minutes. Each session involves strength, range of motion, flexibility, and aerobic training. Passive treatments (e.g., hot packs, ice packs, electrical stimulation) are not employed during session, but patients are instructed in the proper use of these modalities at home. Patients are prescribed a custom therapeutic exercise program that addresses strength, range of motion, and flexibility deficits detected during their evaluation. In addition, they undergo aerobic exercise, which has been shown in a controlled trial to be an effective treatment for disability reduction in chronic low back pain patients (Mannion, Muntener, Taimela, & Dvorak, 2001). Exercise prescription is done in a "graded" manner (Lindstrom, Ohlund, Eek, Wallin, Peterson, Fordyce, & Nachemson, 1992). Graded exercise prescription differs from traditional exercise prescription because it focuses on improvement in activity tolerance, not on pain abatement. During the final session, patients are issued a home exercise program for continuation of unsupervised therapeutic exercise.

Measures

Demographics

The Demographics Questionnaire obtains information about a person's age, sex, race, marital status, education, medical diagnosis, pain duration, and previous treatment for the pain condition.

Pain

Participants completed visual analog scale (VAS) measures of pain intensity and pain unpleasantness. For pain intensity, the scale ranges from 0 to 100, where 0 represents "no pain sensation" and 100 represents "most intense pain sensation imaginable." For pain unpleasantness, the scale ranges from 0 (not at all unpleasant) to 100 (most unpleasant imaginable). The VAS provides ratio level pain measurement and has been validated in multiple studies (Price, McGrath, Rafii, & Buckingham, 1983).

The McGill Pain Questionnaire (MPQ; Melzack & Katz, 2001) consists of 102 words in 20 subclasses. For each of the subclasses, patients are asked to choose the word that best describes their pain at the present moment. Each word in each subclass has a rank value, and rank values are summed to derive scores for the sensory, affective, and evaluative dimensions of pain, as well as a total score. The MPQ is a reliable, valid, and consistent measurement tool (Melzack & Katz, 2001).

Mood/Distress

The Beck Depression Inventory (BDI; Beck, Steer, & Garbin, 1988), a widely used self-report measure of depression, assesses the extent to which an individual exhibits each of 21 behaviors, thoughts, or affective features commonly associated with depression. The BDI yields a total score (range = 0 to 63), as well as two subscale scores measuring cognitive and somatic symptoms of depression. Geisser, Roth, and Robinson (1997) showed that the BDI is a valid instrument for use with chronic pain patients.

The Pain Anxiety Symptoms Scale (PASS) is a 40-item self-report questionnaire that measures four dimensions of pain-related anxiety, namely cognitive anxiety, escape/avoidance, fearful appraisal, and physiological anxiety (McCracken, Zayfert, & Gross, 1992). Participants respond to each item by selecting a frequency rating from

0 (never) to 5 (always). Five items are reverse scored. Frequency ratings are added to derive a total score and four subscale scores. Total scores can range from 40 to 200. The PASS is valid measure, as evidenced by significant correlations with other measures of anxiety (McCracken et al., 1992). Alpha coefficients ranging from .81 to .94 indicate the PASS and its subscales have good internal consistency (McCracken et al., 1992).

Disability

The Pain Disability Index (PDI) measures the degree to which chronic pain interferes with the following life areas: family/home responsibilities, recreation, social activity, occupation, sexual behavior, self care, and life-support activity (Pollard, 1984). Amount of disability experienced in each of the seven domains is rated on an 11-point scale ranging from 0 (no disability) to 10 (total disability). The ratings are summed to derive a total score (range = 0 to 70). The PDI has acceptable psychometric properties, with an internal consistency coefficient of .86 (Tait, Pollard, Margolis, Duckro, & Krause, 1987).

The Roland Disability Questionnaire (RDQ) is a 24-item checklist designed to measure functional impairment due to spine pain (Roland & Morris, 1983). The number of items endorsed is summed to arrive at a total score ranging from 0 (no disability) to 24 (severe disability). The RDQ has adequate psychometric properties, with test-retest reliability values ranging from .72 to .91 (Jensen, Strom, Turner, & Romano, 1992; Roland & Morris, 1983).

Patient-Centered Outcomes

The Patient-Centered Outcomes Questionnaire (PCOQ; Appendix A) consists of five sections. In the first section, patients indicate their usual levels (during the past week) of pain, fatigue, emotional distress, and interference with daily activities on

101-point NRSs (0 = none, 100 = worst imaginable). In the second section, patients indicate their desired levels of pain, fatigue, emotional distress, and interference with daily activities using the same 101-point NRSs. The third section requires patients to indicate where their pain, fatigue, emotional distress, and interference with daily activities would have to be on 101-point NRSs (0 = none, 100 = worst imaginable) for them to consider treatment successful. In the fourth section, patients indicate the levels of pain, fatigue, emotional distress, and interference with daily activities they expect after treatment on the same 101-point NRSs. Finally, participants are asked to rate on 101-point NRSs (0 = not at all important, 100 = most important) how important it is for them to see improvement in each of the four domains.

Pilot data on 21 subjects indicates the PCOQ has acceptable test-retest reliability over a 48-hour period, with reliability values ranging from .84 to .90 ($\underline{p}$s < .001) for usual levels. Reliability values for importance ratings ranged from to .62 to .82 ($\underline{p}$s < .01) for the domains of pain, emotional distress, and interference with daily activities. The correlation for fatigue did not reach statistical significance ($r = .33$, $\underline{p} = .14$). Reliability values for success criteria are rather low in this sample despite achieving statistical significance across all domains ($r = .43$ to .58, $\underline{p}$s < .05) but emotional distress ($r = .287$, $\underline{p} = .21$). Data from our study indicate the PCOQ has good concurrent validity with standardized measures of pain, mood/distress, and disability. For example, the correlation between usual level of pain from the PCOQ and the pain intensity VAS was .52 ($\underline{p} < .001$). Usual emotional distress was highly related to total scores on the BDI ($r = .65$, $\underline{p} < .001$) and PASS ($r = .72$, $\underline{p} < .001$) and usual interference was significantly associated with PDI ($r = .75$, $\underline{p} < .001$) and RDQ ($r = .69$, $\underline{p} < .001$) total scores.

The Follow-up PCOQ (Appendix B) includes six sections. The first section has patients estimate their pre-treatment levels of pain, fatigue, emotional distress, and interference with daily activities on the same 101-point NRS used in the PCOQ (0 = none, 100 = worst imaginable). The next section requires patients to indicate the levels of pain, fatigue, emotional distress, and interference with daily activities associated with treatment success on the same 101-point NRSs. In the third section, patients rate on 101-point NRSs (0 = not at all important, 100 = most important) how important it is for them to see improvement in each of the four domains. In the next section, patients rate on 101-point NRSs (0 = none, 100 = worst imaginable) their usual levels of pain, fatigue, emotional distress, and interference with daily activities after treatment. In the fifth section, patients specify whether they improved, stayed the same, or worsened across each domain since the start of treatment and then, if applicable, rate on 101-point NRSs (0 = none, 100 = complete) the amount of improvement or worsening they experienced in each of the domains. Patients also indicate whether they improved, stayed the same, or worsened overall. In the last section, patients decide whether they would consider their treatment successful. For each of the domains, patients choose yes or no. Patients also evaluate the overall success of their treatment by choosing yes or no.

Treatment Satisfaction

The 20-item Pain Service Satisfaction Test (PSST) assesses patient satisfaction with pain treatment (McCracken, Klock, Mingay, Asbury, & Sinclair, 1997). The PSST has high internal consistency, and is positively correlated with treatment-related changes in pain, depression, and anxiety (McCracken & Turk, 2002).

Analytical Strategy

Aim 1: Developing Patient-Centered Success Criteria

Analyses used usual ratings from the PCOQ, and usual ratings and success judgments from the Follow-up PCOQ. First, we calculated change scores for each of the four domains (pain, fatigue, emotional distress, interference with daily activities) by subtracting Follow-up PCOQ usual ratings (i.e., post-treatment usual ratings) from PCOQ usual ratings (i.e., pre-treatment usual ratings). Then, to characterize the association between change scores and patient judgment of treatment success, we derived receiver-operating characteristic (ROC) curves for each of the four domains using logistic regression analyses. For each analysis, judgment of success (yes, no) served as the dependent variable and either the raw change or percent change score served as the independent variable.

For these analyses, area under the ROC curve was interpreted as the probability of distinguishing participants who were successfully treated on the domain from participants who were not successfully treated on the domain. The area under the ROC curve can range from .5 (no accuracy) to 1.0 (perfect accuracy). We then computed optimal cut-offs (i.e., MCIDs) for each domain from these ROC curves. We expected optimal cut-offs to have a high hit rate coupled with a good balance of sensitivity and specificity.

Aim 2: Identifying Patient Subgroups

We conducted a hierarchical agglomerative cluster analysis (Ward's method, squared Euclidian distance) on PCOQ importance ratings to derive the patient subgroups. Once we identified the subgroups, we conducted a series of analyses to examine potential subgroup differences on demographic and psychosocial variables. First, we performed one-way analyses of variance (ANOVAs) to examine possible subgroup differences in

age, education, and pain duration. Then, we performed a discriminant function analysis using PCOQ usual ratings of pain, fatigue, emotional distress, and interference with daily activities to discriminate spine pain patients classified into each of the subgroups. We performed a second discriminant function analysis using standardized measures of pain (MPQ), distress (BDI, PASS), and disability (PDI, RDQ) to discriminate spine pain patients classified into each of the subgroups. Lastly, we calculated effect sizes (Cohen's d; Cohen, 1988) on PCOQ and standardized measures of pain, fatigue, distress, and disability to examine the magnitude of subgroup differences in standard deviation units. More specifically, we calculated effect sizes by dividing mean subgroup differences by pooled standard deviation for each measure ($\underline{M}_1 - \underline{M}_2/SD_P$). We interpreted the effect sizes using Cohen's (1988) criteria of .20, .50, and .80 for small, medium, and large effects, respectively.

Aim 3: Examining Treatment Matching

Analyses used PSST scores, PCOQ usual ratings, Follow-up PCOQ usual ratings, and MCIDs derived in Aim 1. First, we performed a 2 (subgroup) X 2 (treatment) ANOVA on post-treatment PSST scores to examine the effects of subgroup membership and type of treatment on pain treatment satisfaction. Next, we performed 2 (subgroup) X 2 (treatment) X 2 (time) mixed-model ANOVAs on usual ratings of pain, fatigue, emotional distress, and interference with daily activities to investigate the effects of subgroup membership and type of treatment on these ratings across time. Subgroup and treatment served as between-subjects factors and time was the within-subjects factor. Finally, we conducted chi-square analyses for each of the domains to examine the relationship between type of treatment and treatment success as determined by MCID attainment using MCIDs established in Aim 1.

CHAPTER 3
RESULTS

Descriptive Statistics

Participants reported moderate usual levels of pain, fatigue, emotional distress, and interference with daily activities before treatment ($\underline{M}$ = 51.1 to $\underline{M}$ = 65.4) (Table 3-1). Furthermore, participants considered a 26.9/100 pain level or a mean reduction in pain of 38.5 points (58%) to represent treatment success. A 23.2/100 fatigue level or a mean reduction in fatigue of 36.9 points (61%), an 18.3/100 distress level or a mean reduction in distress of 32.8 points (64%), and a 21.6/100 interference level or a mean reduction in interference of 43.1 points (66%) also represented successful treatment. As a group, participants viewed improvements in all domains (pain, fatigue, emotional distress, and interference with daily activities) as very important ($\underline{M}$ = 83.4 to $\underline{M}$ = 89.1).

Table 3-1. Descriptive Statistics from the PCOQ (N = 70)

Level	Domain	Mean*	SD	Observed Range
Usual	Pain	65.4	21.6	20-97
	Fatigue	60.1	24.4	0-100
	Distress	51.1	30.0	0-100
	Interference	64.7	27.4	0-100
Success	Pain	26.9	18.3	0-75
	Fatigue	23.2	18.4	0-70
	Distress	18.3	19.3	0-80
	Interference	21.6	18.5	0-80
Importance	Pain	89.1	20.3	10-100
	Fatigue	83.4	24.4	0-100
	Distress	84.0	26.2	0-100
	Interference	87.0	23.7	0-100

* Numerical Rating Scale = 0 to 100

Participants reported moderate usual levels of pain, fatigue, distress, and interference post-treatment (M = 47.5 to M = 56.4) (Table 3-2). After treatment, they considered a 33.9/100 pain level, 30.2/100 fatigue level, 26.1/100 distress level, and 28.1/100 interference level to represent treatment success. Again, participants viewed improvements in all domains as quite important (M = 78.8 to M = 88.9).

Table 3-2. Descriptive Statistics from the Follow-up PCOQ (N = 55)

Level	Domain	Mean*	SD	Observed Range
Usual	Pain	56.4	27.4	0-100
	Fatigue	53.5	27.9	0-100
	Distress	47.5	30.9	0-100
	Interference	53.5	30.6	0-100
Success	Pain	33.9	17.6	0-75
	Fatigue	30.2	17.9	0-70
	Distress	26.1	17.9	0-70
	Interference	28.1	16.6	0-75
Importance	Pain	88.9	21.2	0-100
	Fatigue	78.8	28.1	0-100
	Distress	83.0	25.1	0-100
	Interference	82.8	26.9	0-100

* Numerical Rating Scale = 0 to100

Four paired-samples t-tests were conducted to evaluate whether participants' PCOQ (i.e., pre-treatment) success criterion and Follow-up PCOQ (i.e., post-treatment) success criterion significantly differed for each domain. The results showed that participants' Follow-up PCOQ (i.e., post-treatment) success criterion for pain was significantly higher than their PCOQ (i.e., pre-treatment) success criterion for pain [t(52) = 2.125, p = .038], suggesting that participants had higher target values for pain treatment success (i.e., less stringent success criteria for pain) after treatment. Similarly, patients had higher target values (i.e., less stringent success criteria) for successful treatment of fatigue and distress after treatment, t(52) = 2.14, p = .037 and t(52) = 2.16, p = .035, respectively. Results for interference approached statistical significance [t(52) = 1.77,

$\underline{p}$ = .083] but did not reach the $\underline{p} \leq .05$ standard. These findings indicate that participants adjusted or re-defined their success criteria during the course of treatment in the direction of becoming less strict.

A series of chi-square analyses were conducted to determine if participants who met their post-treatment success criterion for a particular PCOQ domain were more likely to judge themselves as successfully treated on that domain (yes/no success judgments) than participants who did not meet their post-treatment success criterion for the domain. The results showed that success criteria and success judgments were significantly related for the domain of pain, Pearson χ^2 (1, $\underline{N}$ = 52) = 22.768, $\underline{p} < .001$. Compared to patients who did not meet their post-treatment success criterion for pain, patients who met their post-treatment success criterion for pain were 3.7 times (100% v 27%) more likely to judge their pain as having been successfully treated (Table 3-3).

Similar results were found for the domains of fatigue [Pearson χ^2 (1, $\underline{N}$ = 51) = 11.574, $\underline{p}$ = .001], distress [Pearson χ^2 (1, $\underline{N}$ = 51) = 27.019, $\underline{p} < .001$], and interference [Pearson χ^2 (1, $\underline{N}$ = 51) = 19.538, $\underline{p} < .001$]. Thus, patients who met their post-treatment success criteria for fatigue, distress, and interference were 2.6 (86% v 32%), 5.3 (94% v 18%), and 3.7 (89% v 24%) times more likely, respectively, than patients who did not meet their post-treatment success criteria for these domains to judge treatment of these domains a success (Table 3-4, Table 3-5, and Table 3-6). These findings suggest participants used their success criteria to assist them in making global judgments of treatment success.

Table 3-3. Pain: Observed Frequencies

		Success Judgment	
		No	Yes
Achieved Post-treatment Success Criterion?	No	n = 27 73%	n = 10 27%
	Yes	n = 0 0%	n = 15 100%

Table 3-4. Fatigue: Observed Frequencies

		Success Judgment	
		No	Yes
Achieved Post-treatment Success Criterion?	No	n = 25 68%	n = 12 32%
	Yes	n = 2 14%	n = 12 86%

Table 3-5. Distress: Observed Frequencies

		Success Judgment	
		No	Yes
Achieved Post-treatment Success Criterion?	No	n = 28 82%	n = 6 18%
	Yes	n = 1 6%	n = 16 94%

Table 3-6. Interference: Observed Frequencies

		Success Judgment	
		No	Yes
Achieved Post-treatment Success Criterion?	No	n = 25 76%	n = 8 24%
	Yes	n = 2 11%	n = 16 89%

Aim 1: Developing Patient-Centered Success Criteria

Optimal cut-off points (i.e., MCIDs) for pain generated from the ROC curves are a raw change of 17.5 points and a percent change of 25% (Table 3-7). That is, MCIDs for pain were a reduction in pain greater than or equal to 17.5 points (on a 0 to 100 NRS) or a 25% or greater reduction in pain. Optimal cut-off points for the other domains were 7.5 points or 11% for fatigue, 5.0 points or 13% for emotional distress, and 9.5 points or 12% for interference with daily activities (Table 3-7). Hit rates for these cut-offs ranged from

73 to 85%. In other words, these cut-offs accurately classified 73 to 85% of patients as either successfully or unsuccessfully treated.

Table 3-7. Success Criteria and Associated Classification Accuracy Statistics

Domain	Variable (Cut-off*)	ROC (*SE*)	HR	SENS	SPEC	PPV	NPV
Pain	Raw Change (≥17.5)	.86 (.05)***	.85	.72	.96	.95	.79
	Percent Change (≥25%)	.85 (.06)***	.85	.72	.96	.95	.79
Fatigue	Raw Change (≥7.5)	.80 (.07)***	.73	.70	.75	.70	.75
	Percent Change (≥11%)	.78 (.07)***	.73	.71	.75	.71	.75
Distress	Raw Change (≥5)	.76 (.07)***	.77	.82	.73	.69	.85
	Percent Change (≥13%)	.82 (.07)***	.82	.81	.83	.77	.86
Interference	Raw Change (≥9.5)	.76 (.07)***	.73	.67	.79	.73	.73
	Percent Change (≥12%)	.77 (.08)***	.75	.70	.79	.73	.76

Classification accuracy statistics are based on identification of patients who were successfully treated on the domain relative to patients who were not successfully treated on the domain. ROC = area under the receiver-operating characteristic curve; HR = hit rate; SENS = sensitivity, SPEC = specificity; PPV = positive predictive value; NPV = negative predictive value; * Numerical Rating Scale = 0 to 100; *** $p \leq .001$.

Aim 2: Identifying Patient Subgroups

Contrary to the hypothesized three-cluster solution, the hierarchical agglomerative cluster analysis (Ward's method, squared Euclidian distance) on PCOQ importance ratings revealed a two-cluster solution (Figure 3-1, Table 3-8). Cluster 1 comprised 7 participants who had low to moderate importance ratings across the domains of pain, fatigue, distress, and interference, whereas Cluster 2 comprised 63 participants who had high importance ratings across domains. The obtained cluster solution limited statistical power in subsequent inferential analyses.

A series of one-way ANOVAs did not reveal any differences between the clusters on the demographic variables of age [$F(1, 68) = 2.270$, $p = .136$], education [$F(1, 68) = .310$, $p = .579$], and pain duration [$F(1, 66) = 1.689$, $p = .198$]. A discriminant function analysis was conducted to determine whether four variables—usual pain, usual fatigue, usual distress, and usual interference from the PCOQ—could predict cluster membership.

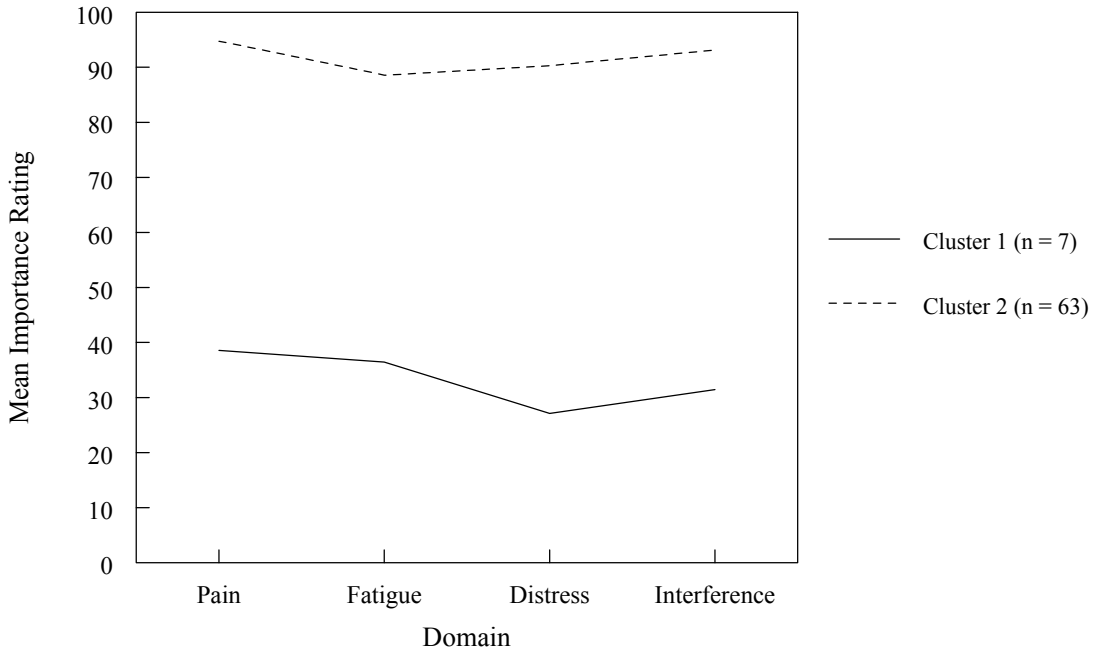

Figure 3-1. Cluster Solution for PCOQ Importance Ratings.

Table 3-8. Scores on PCOQ and Standardized Measures (Mean ± SD) by Cluster

Measure	Cluster 1 (n = 7)	Cluster 2 (n = 63)
PCOQ Usual Pain	53.6 ± 21.0	66.7 ± 21.4
PCOQ Usual Fatigue	55.7 ± 30.5	60.6 ± 23.9
PCOQ Usual Distress	31.4 ± 32.8	53.3 ± 29.1
PCOQ Usual Interference	42.1 ± 36.0	67.2 ± 25.5
MPQ Total	29.6 ± 17.8	32.0 ± 15.3
BDI Total	13.7 ± 11.8	19.3 ± 11.5
PASS Total	78.6 ± 36.0	86.1 ± 37.6
PDI Total	33.2 ± 20.0	41.7 ± 15.0
RDQ Total	11.0 ± 8.1	14.6 ± 5.6

PCOQ = Patient-Centered Outcomes Questionnaire; MPQ = McGill Pain Questionnaire; BDI = Beck Depression Inventory; PASS = Pain Anxiety Symptoms Scale; PDI = Pain Disability Index; RDQ = Roland Disability Questionnaire

The overall Wilks' lamda did not quite reach statistical significance, $\Lambda = .884$, χ^2 (4, $\underline{N} = 70$) = 8.102, $\underline{p} = .088$, indicating that the predictors did not differentiate the two clusters.

A second discriminant function analysis using five predictors—MPQ, BDI, PASS, PDI, and RDQ total scores—also did not predict cluster membership, $\Lambda = .945$, χ^2 (5, $\underline{N} = 68$) = 3.577, $\underline{p} = .612$. However, examination of effect sizes (Table 3-9), revealed moderate to large effect sizes (range = .48 to .94) for PCOQ usual pain, PCOQ usual distress, PCOQ usual interference, BDI Total, PDI Total, and RDQ Total. Participants in Cluster 1 had lower scores than participants in Cluster 2 across these measures (Table 3-8), suggesting that participants in Cluster 1 had significantly less pain, depression/distress, and disability/interference than participants in Cluster 2. Taken together, these findings partially support hypotheses regarding subgroup differences.

Table 3-9. Effect Sizes of Cluster Differences (Cohen's *d*)

Measure	Cohen's *d*
PCOQ Usual Pain	.61
PCOQ Usual Fatigue	.19
PCOQ Usual Distress	.74
PCOQ Usual Interference	.94
MPQ Total	.15
BDI Total	.48
PASS Total	.19
PDI Total	.55
RDQ Total	.61

Aim 3: Examining Treatment Matching

Hypotheses regarding treatment matching could not be explored because the previous finding of a "pain-focused" versus multifocused subgroups was not replicated. However, several analyses were done involving the two clusters obtained from the present sample to examine potential treatment effects. A 2 (subgroup: Cluster 1,

Cluster 2) X 2 (treatment: palliative, multidisciplinary) ANOVA on post-treatment PSST scores revealed only a main effect of subgroup, $\underline{F}(1, 48) = 6.652$, $\underline{p} = .013$, $eta^2 = .12$, indicating that participants in Cluster 1 were significantly more satisfied with their treatment ($\underline{M} = 57.4$) than participants in Cluster 2 ($\underline{M} = 44.1$) regardless of the type of treatment received.

A series of 2 (subgroup: Cluster 1, Cluster 2) X 2 (treatment: palliative, multidisciplinary) X 2 (time: pre-treatment, post-treatment) mixed-model ANOVAs were performed on usual ratings of pain, fatigue, distress, and interference to investigate the effects of subgroup membership and type of treatment on these ratings across time. Subgroup and treatment served as between-subjects factors and time was the within-subjects factor. The mixed-model ANOVA on usual ratings of pain did not reveal any statistically significant main or interaction effects. Likewise, mixed-model ANOVAs on usual ratings of fatigue and distress did not reveal any statistically significant main or interaction effects. The mixed-model ANOVA on usual ratings of interference revealed significant main effects of subgroup [$\underline{F}(1, 51) = 6.367$, $\underline{p} = .015$, $eta^2 = 0.11$] and treatment [$\underline{F}(1, 51) = 7.112$, $\underline{p} = .010$, $eta^2 = 0.12$], and a significant subgroup by treatment interaction effect [[$\underline{F}(1, 51) = 6.459$, $\underline{p} = .014$, $eta^2 = 0.11$]. The interaction (Figure 3-2) may be misleading, however, due to the fact that only two participants in Cluster 1 received multidisciplinary treatment. Closer examination of the main effect of subgroup revealed that participants in Cluster 1 had a lower mean usual level of interference ($\underline{M} = 32.8$) than participants in Cluster 2 ($\underline{M} = 59.6$). Additionally, participants receiving multidisciplinary treatment had a lower mean usual level of interference ($\underline{M} = 32.0$) than participants receiving palliative treatment ($\underline{M} = 60.4$).

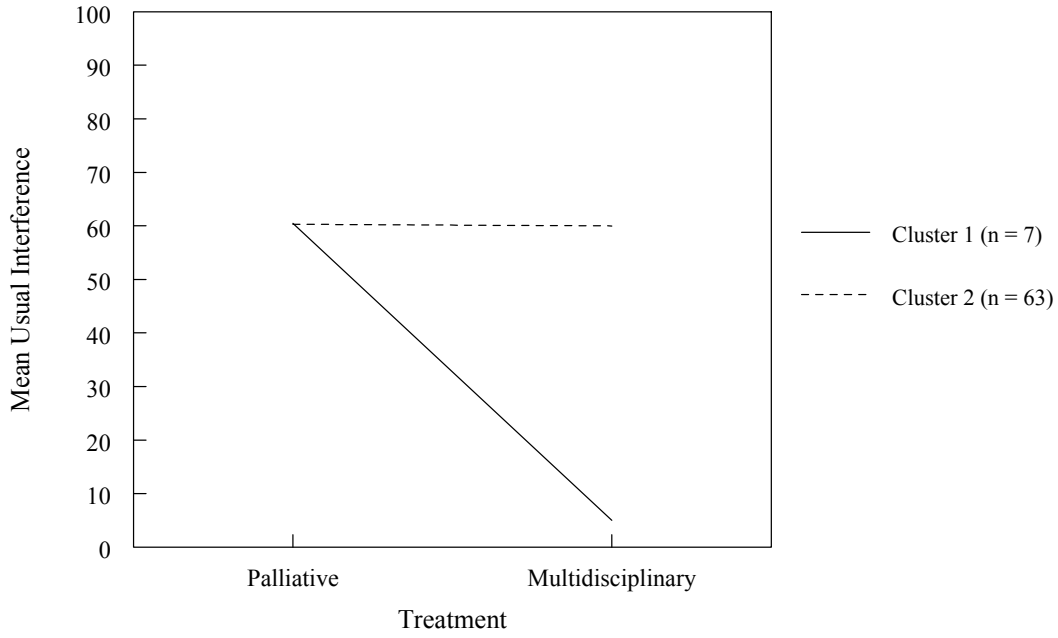

Figure 3-2. Subgroup by Treatment Interaction for Usual Interference.

Finally, a series of chi-square analyses were conducted to examine the relationship between type of treatment (palliative v multidisciplinary) and treatment success as determined by MCID attainment (yes, no) for each of the domains using MCIDs established in Aim 1. For the domain of pain, results showed that type of treatment was unrelated to MCID attainment, Pearson χ^2 (1, $\underline{N}$ = 54) = .616, $\underline{p}$ = .433. In other words, participants who received palliative pain management and participants who received multidisciplinary pain management were equally likely to attain the MCID for pain. Nonsignificant results also were obtained for the domains of fatigue [Pearson χ^2 (1, $\underline{N}$ = 53) = .190, $\underline{p}$ = .663], distress [Pearson χ^2 (1, $\underline{N}$ = 54) = 2.030, $\underline{p}$ = .154], and

interference [Pearson χ^2 (1, $\underline{N}$ = 54) = .533, $\underline{p}$ = .465], suggesting that type of treatment was unrelated to treatment success in this sample.

CHAPTER 4
DISCUSSION

Our study aimed to establish patient-determined MCIDs for treatment of chronic pain. Consistent with previous research using the PCOQ (Robinson et al., in press), we found that spine pain patients require large reductions in pain for treatment to be deemed successful. At the onset of treatment, patients in our study considered a 26.9/100 pain level or a mean reduction in pain of 38.5 points (58%) to represent treatment success. This patient-defined success criterion derived using a direct scaling approach is more stringent than criteria developed using other methods, including expert opinion (e.g., Goldsmith et al., 1993; Moore et al., 1996) and scale comparisons (e.g., Farrar et al., 2001; Angst et al., 2002).

Our study expands on previous research by deriving MCIDs for other domains relevant to pain treatment. Our findings suggest spine pain patients also require large reductions in fatigue (23.2/100 or 61%), emotional distress (18.3/100 or 64%), and interference with daily activities (21.6/100 or 66%) for treatment to be considered successful. These pre-treatment MCIDs are highly consistent with those established in our prior study (Robinson et al., in press), suggesting they are reliable and valid. Our findings also confirm that successful treatment of chronic pain is not defined exclusively in terms of pain reduction, but involves a host of endpoints.

If patients adhere to these success criteria throughout treatment, then clinical trials that apply expert-generated MCIDs or use only standard statistical methods might overestimate the efficacy of their treatments. Therefore, it is important to know whether

chronic pain patients adjust their criteria for treatment success over time. Results of our study suggest patients do indeed modify their success criteria from pre-treatment to post-treatment in the direction of becoming less stringent, as target values for successful treatment of pain, fatigue, and emotional distress were significantly higher two months after treatment initiation (33.9, 30.2, and 26.1, respectively). Based on our findings, it appears that patients used these post-treatment cut-offs to make decisions about treatment success. In our study, patients who met their post-treatment success criterion for a particular domain were significantly more likely than patients who did not meet their post-treatment success criterion for the domain to judge treatment of the domain a success. These results further support the utility of patient-defined success criteria.

It should be noted that 48-hour test-retest reliability values for PCOQ success criteria were somewhat low in another sample of 21 chronic pain patients. One possible explanation for this finding is that patients' success criteria are influenced by their current levels of pain, fatigue, emotional distress, and interference with daily activities, such that as their current levels naturally fluctuate from day to day so do their success criteria. Fluctuations in success criteria might be larger than corresponding fluctuations in usual levels. Patients also might be less familiar with and experienced at rating success criteria than they are at rating usual levels, thereby introducing more error variance into ratings of success. These explanations are admittedly speculative and somewhat beyond the scope of our study. Despite the questionable test-retest reliability of PCOQ success criteria, mean success criteria for the four PCOQ domains were highly consistent across our two samples of chronic pain patients. As discussed, success criteria derived in this study were almost identical to success criteria derived in our original study (Robinson et

al., in press) aside from the change from a 0 to 10 NRS to a 0 to 100 NRS. Furthermore, in our study, pre-treatment and post-treatment success criteria still were reliably different even with additional error variance incorporated into the analyses.

The aforementioned patient-centered success criteria were derived using a direct scaling approach. Another more commonly used approach to developing MCIDs involves comparing two scales, typically the change on a given domain (e.g., change in pain on a 0 to 10 NRS) and a global rating of improvement (e.g., "much improved"). This methodology has promise, but use of different anchors (e.g., "much improved" versus "somewhat better") has led to differing results (e.g., Farrar et al., 2001; Wells et al., 1993). In fact, Salaffi and colleagues (2004) calculated MCIDs in pain associated with both a "slightly better" and "much better" global impression of change among their sample of chronic musculoskeletal pain patients, and obtained different raw and percent changes for the two anchors. Furthermore, investigator-determined anchors might not reflect the degree of improvement necessary for patients to consider treatment successful. Therefore, our study sought to (1) characterize the association between NRS change scores and treatment success as determined by patient global judgment and (2) select as MCIDs the change scores that best distinguished between successfully and unsuccessfully treated patients. This procedure was done not only for the domain of pain, but also for the domains of fatigue, emotional distress, and interference with daily activities.

Using the scale comparison approach, we derived the following MCIDs: 17.5 points (on a 0 to 100 NRS) or 25% for pain, 7.5 points (11%) for fatigue, 5.0 points (13%) for emotional distress, and 9.5 points (12%) for interference with daily activities.

These MCIDs accurately classified 73 to 85% of patients as successfully or unsuccessfully treated. MCIDs for pain were most accurate in classifying patients. Interestingly, our MCIDs for pain are fairly consistent with those derived by Farrar et al. (2001) using a 0 to 10 NRS and a "much improved" global impression of change (2 points or 30%).

Future research should focus on validating these patient-determined MCIDs, particularly for the less studied domains of fatigue, emotional distress, and interference with daily activities. Once validated, they can be used to calculate effect size estimates, such as the number needed to treat (Cook & Sackett, 1995), permitting comparisons across studies and ultimately helping to evaluate the efficacy of various treatments for chronic pain (Farrar et al., 2001; Redelmeier et al., 1996). Additionally, MCIDs can be useful in assessing the care of individual patients. Future research should also explore whether success criteria are absolute or related to pre-treatment levels. A recent study by Salaffi and colleagues (2004) suggests MCIDs may not be standardized along the whole NRS. They found that patients with a higher level of pain before treatment required greater reductions in pain to obtain clinically important improvements than did patients with relatively low pain levels before treatment. Consequently, in applying our MCIDs to individual patients or other pain populations, one should note that our sample had moderate to moderately high mean levels (on a 0 to 100 NRS) of pain ($\underline{M}$ = 65.4), fatigue ($\underline{M}$ = 60.1), emotional distress ($\underline{M}$ = 51.1), and interference with daily activities ($\underline{M}$ = 64.7) at the onset of treatment. Finally, future research should investigate the evolution of success criteria throughout the course of different treatments. Our results suggest patients change their success criteria while undergoing treatment. However, it

remains unclear whether patients are more or less likely to adjust their success criteria with different treatments. For example, patients receiving cognitive behavioral therapy (CBT) might be expected to change their success criteria considerably, given that the goals of CBT are to examine potential maladaptive beliefs (e.g., unrealistic expectations regarding treatment) and re-define treatment outcomes.

A second aim of our study was to empirically derive and validate patient subgroups using patient ratings of the perceived importance of improvement in the four PCOQ domains. Contrary to our hypothesized three-cluster solution, only two clusters emerged. One subgroup (Cluster 2) rated improvement in all domains as extremely important, whereas the other, smaller subgroup (Cluster 1) reported relatively low importance ratings across domains. Further examination of the cluster analysis revealed that the hypothesized "multifocused-moderate" subgroup merged with the "multifocused-high" subgroup to form Cluster 2. Patients in Cluster 2 had higher pre-treatment usual levels of pain than patients in Cluster 1. They also were more distressed and disabled at the start of treatment. Interestingly, the clusters did not differ on chronicity of pain, suggesting that pain duration does not influence subgroup membership. Based on these data, one could speculate that patients in Cluster 1 might be less likely than patients in Cluster 2 to require multidisciplinary treatment to obtain clinically important treatment outcomes. Future research might examine this hypothesis.

Our findings provide support for the notion that chronic pain patients are heterogeneous. Even among patients whose pathology is specific to the spine, distinct subgroups emerged. Of note, we did not replicate our previous finding of a truly "pain-focused" subgroup (Robinson et al., in press). The possibility exists that a subset of

patients with chronic pain in other body regions might believe that treatments addressing nociception are most pertinent to them. Future investigations using larger and more diverse samples of chronic pain patients are needed to examine this hypothesis. Another explanation for our inconsistent findings might lie with the variables on which the subgroups were derived. Importance ratings might not be the best criteria on which to base subgroup membership. Other variables, such as usual ratings or success criteria, might produce more stable and meaningful patient subgroups. Therefore, future investigations should consider using other PCOQ variables to develop patient subgroups.

Our final aim was to examine the potential for treatment matching using the patient subgroups derived from the PCOQ. Because a "pain-focused" subgroup did not emerge, we could not fully explore hypotheses regarding treatment matching. Nonetheless, we did analyses to examine treatment effects across the two subgroups derived in Aim 2. Although patients in Cluster 1 were more satisfied with treatment than patients in Cluster 2, they did not achieve greater reductions in their pain, fatigue, emotional distress, and interference with daily activities from pre-treatment to post-treatment. This pattern of findings occurred irrespective of the type of treatment received (palliative pain management or multidisciplinary pain management). Additional analyses showed, at least in our sample, that type of treatment is unrelated to MCID attainment. That is, patients receiving palliative pain management and patients receiving multidisciplinary pain management were equally likely to obtain MCIDs for pain, fatigue, emotional distress, and interference with daily activities. This finding is somewhat surprising given overwhelming evidence for the superiority of multidisciplinary treatment approaches

(Flor, Fydrich, & Turk, 1992). Nonetheless, it further underscores the need to determine what treatments are effective for which subgroups of chronic pain patients.

Potential limitations of our study deserve mention. First, our reduced sample size likely prevented a separate "multifocused-moderate" patient subgroup from emerging in the cluster analysis. Notably, we conducted our original cluster analysis (Robinson et al., in press) on 110 patients, whereas we performed this cluster analysis on 70 patients. Likewise, we could not conduct certain follow-up chi-square analyses, particularly those examining possible subgroup by treatment interactions, because of small cell sizes. A second limitation of our study pertains to the non-uniformity of the two treatment approaches. Ideally, patients receiving palliative pain management would have been given the same treatment (or at least the same class of treatment, pharmacological or interventional) and patients undergoing multidisciplinary pain management would have received identical treatment components. Another potential limitation of our study involves the use of dichotomous judgments of success as the standard against which MCIDs were developed. The possibility exists, for instance, that patients' global judgments of treatment success for the domain of pain were influenced by factors unrelated to pain intensity, such as satisfaction with care. Similarly, patients' global judgments of treatment success for the other PCOQ domains (fatigue, distress, and interference) might have been unduly influenced by their global judgments for pain. Nevertheless, enabling patients to incorporate into their global judgments of treatment success all factors perceived as germane to the decision produces success criteria that are ecologically valid. A final concern relates to the generalizability of these findings to other chronic pain populations. Patients with chronic spine pain might view treatment success

differently than patients with other types of chronic pain. Therefore, our MCIDs might not be applicable to other painful conditions. However, we are encouraged that our MCIDs for pain are similar to those developed with other pain populations (e.g,. Farrar et al., 2001).

These limitations notwithstanding, our study is the first to develop MCIDs from the patient perspective across multiple domains relevant to treatment of chronic pain. Once validated, these MCIDs can easily be used by both clinicians and researchers to evaluate the effectiveness of various treatment approaches for chronic pain. Our study also further debunks the pain patient homogeneity assumption (Turk & Okifuji, 2001) by identifying at least two distinct subgroups of spine pain patients that differ on important variables, such as pain intensity, distress, and disability. It remains to be seen whether additional subgroups will emerge from larger and more diverse samples of chronic pain patients. Finally, as we were unable to adequately examine the treatment-matching hypothesis (Turk & Okifuji, 2001), future research should explore the potential benefits of tailoring treatment to the behavioral and psychosocial characteristics of these and other subgroups of patients with chronic pain.

APPENDIX A
PATIENT-CENTERED OUTCOMES QUESTIONNAIRE (PCOQ)

MANY PEOPLE EXPERIENCE PAIN, FATIGUE (I.E., FEELING TIRED), EMOTIONAL DISTRESS (E.G., WORRIES, FEELING SAD), AND INTERFERENCE WITH DAILY ACTIVITIES (E.G., NOT BEING ABLE TO WORK OR DO HOUSEHOLD CHORES) AS A RESULT OF THEIR MEDICAL CONDITION. WE WOULD LIKE TO UNDERSTAND HOW YOU HAVE BEEN IMPACTED IN EACH OF THESE AREAS. WE WOULD ALSO LIKE TO LEARN MORE ABOUT WHAT YOU WANT YOUR TREATMENT TO DO FOR YOU.

FIRST, WE WOULD LIKE TO KNOW YOUR **USUAL** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE.

On a scale of ***0 (none)*** **to** ***100 (worst imaginable),*** please indicate your usual level (during the past week) of …

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

NOW, WE WOULD LIKE TO LEARN ABOUT YOUR **DESIRED** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE. IN OTHER WORDS, WE WOULD LIKE TO UNDERSTAND WHAT YOUR IDEAL TREATMENT OUTCOME WOULD BE.

On a scale of ***0 (none)*** **to** ***100 (worst imaginable)***, please indicate your desired level of …

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

PATIENTS UNDERSTANDABLY WANT THEIR TREATMENT TO RESULT IN DESIRED OR IDEAL OUTCOMES LIKE YOU INDICATED ABOVE. UNFORTUNATELY, AVAILABLE TREATMENTS DO NOT ALWAYS PRODUCE DESIRED OUTCOMES. THUS, IT IS IMPORTANT FOR US TO UNDERSTAND WHAT TREATMENT OUTCOMES YOU WOULD CONSIDER **SUCCESSFUL**.

On a scale of ***0 (none)*** **to** ***100 (worst imaginable)***, please indicate the level each of these areas would have to be at for you to consider treatment successful.

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

NOW, WE WOULD LIKE TO KNOW WHAT YOU **EXPECT** YOUR TREATMENT TO DO FOR YOU.

On a scale of ***0 (none)*** **to** ***100 (worst imaginable)***, please indicate the levels you <u>expect</u> following treatment.

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

FINALLY, WE WOULD LIKE TO UNDERSTAND HOW **IMPORTANT** IT IS FOR YOU TO SEE IMPROVEMENT IN YOUR PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE FOLLOWING TREATMENT.

On a scale of ***0 (<u>not at all important</u>)*** **to** ***100 (<u>most important</u>)***, please indicate how important it is for you to see improvement in your…

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

APPENDIX B
FOLLOW-UP PCOQ

FIRST, WE WOULD LIKE TO KNOW YOUR **PRE-TREATMENT** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE.

On a scale of ***0 (none)*** **to** ***100 (worst imaginable)***, please estimate your pre-treatment level of …

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

BASED ON YOUR PRE-TREATMENT LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE, PLEASE INDICATE WHAT TREATMENT OUTCOMES YOU WOULD CONSIDER **SUCCESSFUL**.

On a scale of ***0 (none)*** **to** ***100 (worst imaginable)***, please indicate the level each of these areas would have to be at for you to consider treatment successful.

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

NEXT, WE WOULD LIKE TO UNDERSTAND HOW **IMPORTANT** IT IS FOR YOU TO SEE IMPROVEMENT IN YOUR PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE.

On a scale of ***0 (not at all important)*** **to** ***100 (most important)***, please indicate how important it is for you to see improvement in your…

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

FINALLY, WE WOULD LIKE TO KNOW YOUR **USUAL** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE **FOLLOWING TREATMENT**. IN OTHER WORDS, WHAT ARE YOUR CURRENT LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE?

On a scale of ***0 (none)*** **to** ***100 (worst imaginable)***, please indicate your usual level (during the past week) of …

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

ACCORDING TO OUR RECORDS, YOUR **PRE-TREATMENT** LEVELS OF PAIN, FATIGUE, EMOTIONAL DISTRESS, AND INTERFERENCE [ON A SCALE FROM 0 (NONE) TO 100 (WORST IMAGINABLE)] WERE AS FOLLOWS:

- pain _____
- fatigue (or tiredness) _____
- emotional distress _____
- interference with daily activities _____

NOW WE WOULD LIKE TO KNOW IF YOU HAVE **IMPROVED, STAYED THE SAME, OR WORSENED** SINCE THE START OF TREATMENT.

1. Has your <u>pain</u> improved, stayed the same, or worsened?

   Please choose one:
   _____ Improved (Please complete Part A below.)
   _____ Stayed the same (Please move on to #2.)
   _____ Worsened (Please complete Part B below.)

   Part A: On a scale of ***0 (no improvement)*** **to** ***100 (complete improvement)***, please indicate how much your pain has improved _____ (Please move on to #2.)

   Part B: On a scale of ***0 (no worsening)*** **to** ***100 (complete worsening)***, please indicate how much your pain has worsened _____ (Please move on to #2.)

2. Has your <u>fatigue (or tiredness)</u> improved, stayed the same, or worsened?

   Please choose one:
   _____ Improved (Please complete Part A below.)
   _____ Stayed the same (Please move on to #3.)
   _____ Worsened (Please complete Part B below.)

   Part A: On a scale of ***0 (no improvement)*** **to** ***100 (complete improvement)***, please indicate how much your fatigue has improved _____ (Please move on to #3.)

   Part B: On a scale of ***0 (no worsening)*** **to** ***100 (complete worsening)***, please indicate how much your fatigue has worsened _____ (Please move on to #3.)

3. Has your emotional distress improved, stayed the same, or worsened?

   Please choose one:
   _____ Improved (Please complete Part A below.)
   _____ Stayed the same (Please move on to #4.)
   _____ Worsened (Please complete Part B below.)

   Part A: On a scale of ***0 (no improvement)*** **to** ***100 (complete improvement)***, please indicate how much your emotional distress has improved _____ (Please move on to #4.)

   Part B: On a scale of ***0 (no worsening)*** **to** ***100 (complete worsening)***, please indicate how much your emotional distress has worsened _____ (Please move on to #4.)

4. Has your interference improved, stayed the same, or worsened?

   Please choose one:
   _____ Improved (Please complete Part A below.)
   _____ Stayed the same (Please move on to #5.)
   _____ Worsened (Please complete Part B below.)

   Part A: On a scale of ***0 (no improvement)*** **to** ***100 (complete improvement)***, please indicate how much your interference has improved _____ (Please move on to #5.)

   Part B: On a scale of ***0 (no worsening)*** **to** ***100 (complete worsening)***, please indicate how much your interference has worsened _____ (Please move on to #5.)

5. Overall, have you improved, stayed the same, or worsened?

   Please choose one:
   _____ Improved (Please complete Part A below.)
   _____ Stayed the same (Please move on to the next page.)
   _____ Worsened (Please complete Part B below.)

   Part A: On a scale of ***0 (no improvement)*** **to** ***100 (complete improvement)***, please indicate how much you have improved _____ (Please move on to the next page.)

   Part B: On a scale of ***0 (no worsening)*** **to** ***100 (complete worsening)***, please indicate how much you have worsened _____ (Please move on to the next page.)

FINALLY, WE WOULD LIKE TO LEARN WHETHER YOU WOULD CONSIDER YOUR TREATMENT **SUCCESSFUL**.

- Was treatment of your pain successful?

  Please choose one:

  _____ Yes
  _____ No

- Was treatment of your fatigue (or tiredness) successful?

  Please choose one:

  _____ Yes
  _____ No

- Was treatment of your emotional distress successful?

  Please choose one:

  _____ Yes
  _____ No

- Was treatment of your interference with daily activities successful?

  Please choose one:

  _____ Yes
  _____ No

- Overall, was your treatment successful?

  Please choose one:

  _____ Yes
  _____ No

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BIOGRAPHICAL SKETCH

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