EVALUATING THE EFFICACY OF GRADED *IN VIVO* EXPOSURE FOR THE TREATMENT OF FEAR IN PATIENTS WITH CHRONIC BACK PAIN: A RANDOMIZED CONTROLLED CLINICAL TRIAL

A Dissertation

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Marc Woods, candidate for the degree of Doctor of Philosophy, has presented a thesis titled, ***Evaluating The Efficacy of Graded In Vivo Exposure For The Treatment of Fear In Patients With Chronic Back Pain: A Randomized Controlled Clinical Trial,*** in an oral examination held on March 16, 2006. The following committee members have found the thesis acceptable in form and content, and that the candidate demonstrated satisfactory knowledge of the subject material.

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ABSTRACT

Psychological treatments for chronic pain, particularly those based upon cognitive behavioural (CB) principles, have generally been shown to be efficacious. Recently, a treatment has been developed based upon the fear-avoidance model of chronic pain, which suggests chronic pain can be relieved by exposing the individual to movements and tasks that have been avoided due to fear of (re)injury. This graded *in vivo* exposure treatment has been found to be beneficial in case studies. The present investigation was the first randomized controlled clinical trial to compare graded *in vivo* exposure to other treatment/control conditions. Forty-four chronic low back pain patients were randomly assigned to either graded *in vivo* exposure, graded activity, or a wait list control condition. Patients in the graded *in vivo* exposure treatment condition demonstrated (a) significantly greater improvements on measures of fear avoidance beliefs, perceived disability, and pain self-efficacy when compared to those in the graded activity group; and (b) significantly greater improvements on measures of fear-avoidance beliefs, fear of pain/movement, and pain catastrophizing when compared to those in the wait-list control condition. All of these differences were significant at $p > .01$. Additionally, only patients in the graded *in vivo* exposure condition demonstrated significant pre- to post-treatment improvements on each dependent variable, and all of these improvements were maintained at one month follow-up. Implications of these findings for the treatment of individuals with chronic pain are discussed in relation to the fear-avoidance model of pain.

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1.1 Overview

Chronic pain is a far-reaching and debilitating ailment. It has been shown to occur amongst 30% of the population of developed countries (Bonica, 1987) and is associated with many health conditions (e.g., musculoskeletal injury, headache, organic pathology). Individuals with chronic pain are more likely to suffer from co-morbid psychiatric disorders (e.g., depression, sleep disturbance, substance abuse, post-traumatic stress disorder; Norton, Asmundson, Norton, & Craig, 1999) and to experience a significant degree of personal suffering (Craig, 1994). Chronic low back pain is one of the most common reasons for seeking health care (Carey et al., 1995; Hart, Deyo, & Cherkin, 1995), and its prevalence rates are estimated to be about 3% amongst the general population (Nachemson, 1992). Chronic back pain also incurs significant costs to employers and health care systems. It has been reported in the US that 60 million days of sick leave and benefits are given each year for individuals with chronic low back pain alone (Waddell, 1992). Resulting productivity losses are estimated at $28 billion per year (Rizzo, Abbot, & Berger, 1998), and associated medical costs at $25 billion per year (Frymoyer & Cats-Baril, 1991). The significant impact of chronic low back pain on health care costs and quality of life suggest the importance of understanding what it is, how it develops, and methods of effectively treating it.

This dissertation reviews models of chronic pain that have contributed to current conceptualizations of the problem. In particular, a fear-avoidance model of chronic pain (Asmundson, Norton, & Vlaeyen, 2004) has received significant attention and support in

the past two decades. A treatment based upon this model, which suggests that chronic pain can be relieved by exposing the individual to movements and tasks that have been avoided due to fear of (re)injury, has been developed. This graded *in vivo* exposure treatment has been found to be efficacious in case studies (e.g., Boersma, et al., 2004; Vlaeyen, de Jong, Geilen, Heuts, & van Breukelen, 2001). To date, however, there has been no randomized controlled assessment of the efficacy of graded *in vivo* exposure for the treatment of chronic low back pain. The present investigation was designed to compare graded *in vivo* exposure to graded activity and a wait list control condition amongst 44 randomly assigned chronic low back pain patients. It was hypothesized that individuals treated using graded exposure would demonstrate significantly greater reductions in fear, avoidance, anxiety, and perceived pain and disability compared to the other treatment groups. Implications of these findings for the treatment of individuals with chronic pain are discussed in relation to the fear-avoidance model of pain.

1.2 Models of Chronic Pain

Models of pain and chronic pain have evolved through several centuries of practical and empirical work. Below, the central tenets of traditional biomedical, psychodynamic, and biopsychosocial models are outlined. The purpose is not to comprehensively review these, but to demonstrate their role and influence on the current state of the art.

1.2.1 Biomedical models

Traditional biomedical models of pain suggest that pain is a sensory or neurological experience, and that functional impairment due to chronic pain is relative to pain severity (Turk & Flor, 1999). Thus, as with any sense, pain is deemed to begin with

the action of a physical stimulus on specialized receptors. These receptors then transmit their signals to the brain's "pain centers" (Leventhal & Everhart, 1979). An underlying assumption of the biomedical model is that pain and disease are caused by external factors that interfere with an otherwise normal system.

There are several criticisms of this model. Most notably, there has been little relationship found between nature and severity of pathology and the extent of disability (Linton & Buer, 1995; Rose, Klenerman, Atchison, & Slade, 1992). The majority of patients who suffer from back pain evidence no structural lesions and, in contrast, some individuals who are symptom-free have been found to have diagnostic abnormalities (Jensen, Turner, & Romano, 1994). The biomedical model also fails to give consideration to the role of personal or psychological factors in the experience of pain and the development and perpetuation of chronic pain.

1.2.2 Psychodynamic models of chronic pain

The first models of pain to emphasize the role of psychological factors were based on psychodynamic theory (Merskey & Spear, 1967). Several psychodynamic models were postulated, though Freud's model focussing on emotional pain (Breuer & Freud, 1893-1895/1957) and Engel's (1959) concepts of psychogenic pain and the pain-prone personality have received the most attention. However, no psychodynamic model has received significant empirical support (for reviews, see Gamsa, 1994, and Roth, 2000). They have, therefore, been largely discarded. Nonetheless, the focus on psychological factors in the experience of pain, wrought by psychodynamic theorists, led to the development of other psychological models, many of which attempted to integrate both physiological and psychological mechanism of pain. In particular, Melzack and Wall

(1965) and Melzack and Casey (1968) are acknowledged as having produced the first integrated model – gate control theory.

1.2.3 Gate control theory

Though a full description of the gate control theory is beyond the scope of this thesis, in brief, Melzack and Wall (1965) and Melzack and Casey (1968) suggested that "gates" in the central nervous system control the transfer and intensity of nociceptive information to the brain. The operation of these gates was believed to be controlled by sensory, cognitive, and affective inputs that were processed in parallel and could reciprocally influence one another. Melzack (1999) amended the gate control theory and suggested that the brain has a body-self neuromatrix. This neuromatrix processes information from parallel input pathways (e.g., cognitive-evaluative, affective-motivational, somatosensory) in order to produce an output pattern that induces pain. Both gate control theory and the neuromatrix model emphasize the dual importance of physiological and psychological factors in the experience of pain, and present an explanation to account for how individuals with the same injury could vary in their perception of pain. This emphasis has lead to the continued expansion of integrated models.

1.2.4 Biopsychosocial approaches

As the name suggests, biopsychosocial approaches posit that biological, psychological, and social factors interact to determine the experience of pain. The focus is on illness behaviour, defined as an individual's perceptual, evaluational, and action-oriented responses to physical symptoms (Mechanic, 1962). These responses are perceived to operate dynamically with one another, their relative role in the exacerbation

and maintenance of the pain condition changing in relation to the evolution of the condition and according to individual differences. Biopsychosocial models of pain based on cognitive-behavioural principles have received considerable substantiation over the past 20 years. One model in particular – the fear-avoidance model of pain – has received significant attention in the recent literature (Asmundson, Norton, & Norton, 1999; Lethem, Slade, Troup, & Bentley, 1983; Linton, 2000; Vlaeyen & Linton, 2000). First, however, the operant and biobehavioral models, which laid the foundation for the development of the fear-avoidance model, will be reviewed.

The operant model, developed by Fordyce and colleagues (Fordyce, 1976; Fordyce, Shelton, & Dundore, 1982) focuses on the role of positive and negative reinforcement in the development of chronic pain. This model suggests that, after an acute injury, those activities that reduce suffering (e.g., avoidance of activity) are negatively reinforced. The individual may also receive positive reinforcement (e.g., increased attention) for occupying the sick role (i.e., being in poor health). This combination of positive and negative reinforcement for behaviours associated with maintaining the sick role may lead to their persistence and maladaptive presentation.

The biobehavioural model (Turk, Meichenbaum, & Genest, 1983) was the first model to comprehensively incorporate both cognitive and behavioural components. Turk et al. suggested that some individuals have a predisposition to be sensitive to pain and to react with fear to nociceptive information. This sensitivity interacts with stress to alter physiological (e.g., autonomic and central nervous system) responsivity. The manner in which the individual attends (e.g., via hypervigilance or catastrophization) and responds (e.g., through avoidance behaviours) to the resulting nociceptive information determines

the manifestation and persistence of the symptoms. The role of cognitions and avoidance behaviours, as postulated by this model and the operant model, has received significant attention and mixed empirical support (for a review, see Asmundson & Wright, 2004), and has influenced the development of the fear-avoidance model of chronic pain.

1.3 Fear-Avoidance Models of Chronic Pain

Fear-avoidance models of chronic pain have been the subject of significant attention in the past two decades. This section will describe, in some detail, the development of this model, from its original conception by Lethem et al. (1983), to more dynamic and contemporary versions (e.g., Vlaeyen & Linton, 2000). Also, empirical support for the fear-avoidance model, and the formulation of treatments based on it, will be described.

1.3.1 *The original fear-avoidance model*

The fear-avoidance model of pain was originally postulated by Lethem et al. (1983) in order to explain how and why some individuals with acute low-back pain develop exaggerated pain perception. They identified four courses that pain can follow after its onset:

1. Natural remission, which occurs when both the organic cause of the pain resolves and there is a corresponding decrease in its sensory and emotional components.
2. Progressive organic pain, which occurs when the organic basis of the pain worsens, accompanied by a worsening of both the sensory and emotional components.
3. Static organic pain, in which both the organic and sensory components plateau, but the emotional component continues to worsen.

4. Organic resolving pain, which occurs when the organic basis resolves, accompanied by a reduction in the sensory component, yet the emotional component continues to increase.

The former two courses of pain are synchronous in that the emotional and sensory components correspond. The latter two courses, in which the sensory and emotional components are desynchronous, represent the original conceptualization of the fear-avoidance model. These courses were deemed to be cases in which exaggerated pain perception (defined as pain experience and behaviour that is out of proportion to any nociceptive stimulation or identifiable organic pathology) and fear of pain would occur.

Lethem et al.'s (1983) fear-avoidance model suggests that some individuals develop fear of pain in response to the experience of acute pain. This fear of pain may then elicit one of two types of coping responses: confrontation or avoidance. People who confront are believed to perceive pain as being temporary and to be motivated to return to their normal activities. This style of coping is hypothesized to be adaptive, and to lead to a reduction in fear. In contrast, avoidance coping is thought to be motivated by a desire to avoid pain experiences and painful activities, and is related to a reduction in physical and social activity. This form of coping is deemed to be maladaptive as it leads to maintenance and exacerbation of the fear. This fear, in turn, is related to the development of exaggerated pain perception. Lethem et al. hypothesized that whether an individual confronts or avoids pain is determined by their psychosocial context. This context is composed of four factors, including stressful life events, personal pain history, coping strategies, and personality characteristics. The role of cognitions in the development of

chronic pain became the primary focus of attention in subsequent reformulations of the fear-avoidance model.

1.3.2 Contemporary fear-avoidance models

Subsequent models of fear-avoidance have focused more explicitly on the role of cognitions in avoidance behaviours. Vlaeyen and Linton (2000) outlined a cognitive-behavioural model of fear-avoidance based on Lethem et al's (1983) original fear-avoidance model, Philips' (1987) position on the importance of cognitions in avoidance behaviour, and their own earlier work (Vlaeyen, Kole-Snijders, Boeren, & van Eek, 1995). In this model, Vlaeyen and Linton place significantly more emphasis than Lethem et al. on cognitions and their role in the development of chronic pain and disability. In particular, Vlaeyen and Linton predict several ways by which chronic pain and disability can ensue from fear related to pain (see Figure 1).

Following an injury, if the experience is perceived in a non-threatening manner (e.g., it will not result in long-term disability) then it may be confronted and dealt with adaptively, thereby leading to recovery. This pathway is similar to that suggested by Lethem et al. (1983). However, if negative cognitions such as catastrophic thinking follow an injury, they may serve as an antecedent to fear of pain. The development of fear of pain is likely to be characterized by avoidance behaviours. These avoidance behaviours result in a decrease in daily activities and, therefore, an increased level of functional disability. Avoidance behaviours are likely to persist as they tend to occur in response to the expectation of the occurrence of pain, and not necessarily the actual occurrence of pain. Since the individual is not provided with opportunities to have

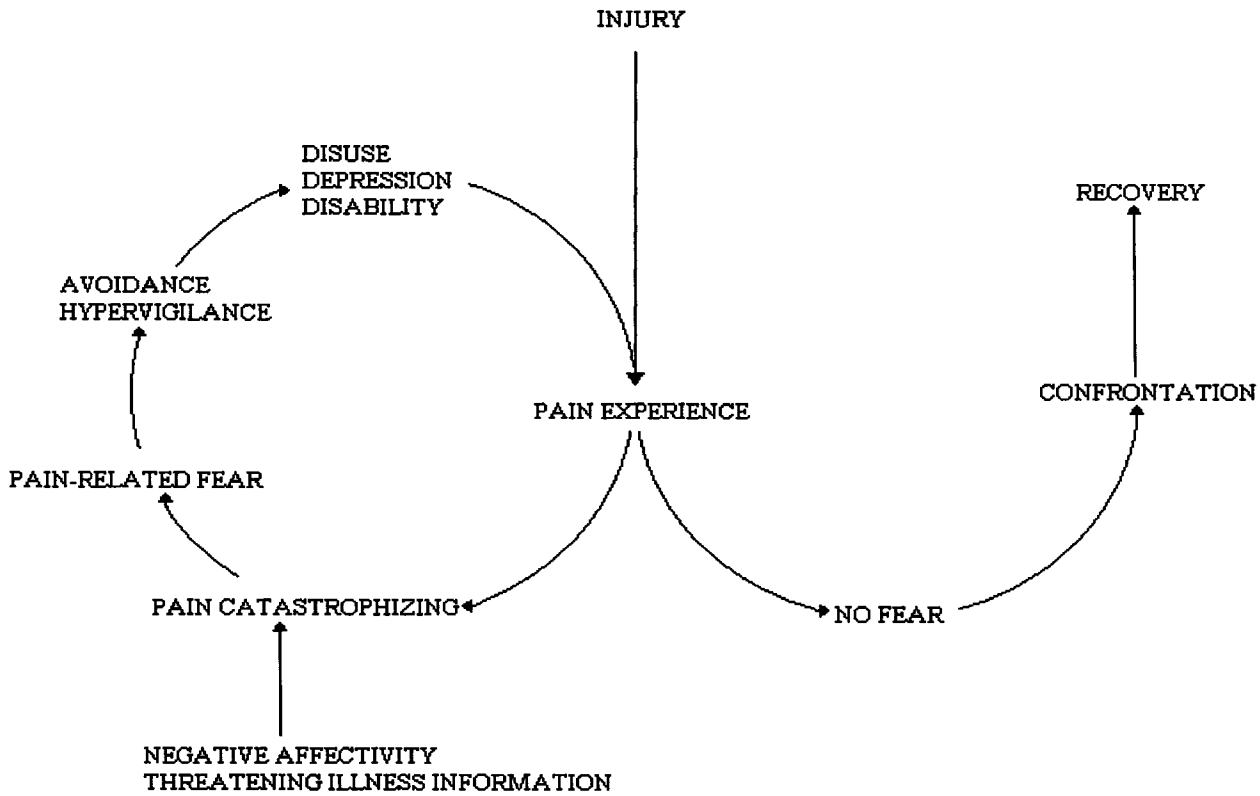

Figure 1. Fear-avoidance model, adapted from Vlaeyen and Linton (2000).

Note. From "Fear-avoidance and its consequences in chronic musculoskeletal pain: A state of the art," by Vlaeyen & Linton (2000), *Pain, 85*, 317-332. Copyright 2000 by International Association for the Study of Pain. Reprinted with permission.

disconfirmatory experiences (i.e., experiences with feared objects or situations where pain does not occur), he/she is unlikely to correct these distorted thoughts and beliefs about the impact of activities on their experience of pain. Due to a decrease in activities, there may be long-term detriments to the musculoskeletal and cardiovascular systems (known as deconditioning) which may, in turn, cause the pain problem to worsen and impair functional ability. Psychological disturbances (e.g., depression) may also result in a decreased ability to cope with pain. Additionally, Vlaeyen and Linton's (2000) revised fear-avoidance model posits that any fear and anxiety, including that related to pain, may increase the individual's sensitivity to pain-related information and decrease ability to adaptively cope.

Vlaeyen and Linton (2000) also suggest that fear of pain is associated with increased psychophysiological reactivity to the feared situation. In particular, activation of the autonomic nervous system in response to fear is believed to play a role in the development of chronic pain. Though the precise mechanism by which this occurs is not yet understood, the hypothesized role of the autonomic nervous system has led to some revision of Vlaeyen and Linton's model (see Figure 2; Norton & Asmundson, 2003). Norton and Asmundson (2003) have suggested that the physiological component of fear may interact with the behavioural and cognitive components in a positive symptom feedback loop that negatively effects one's coping ability, tendency to catastrophize and appraise pain, and mood. Specifically, this amended model predicts that physiological symptoms (i.e., the effects of autonomic dysregulation) aggravate injured tissue and directly cause an increase in pain, thereby reinforcing pain-related fears and increasing avoidance behaviours. Alternatively, rather than directly producing pain, physiological

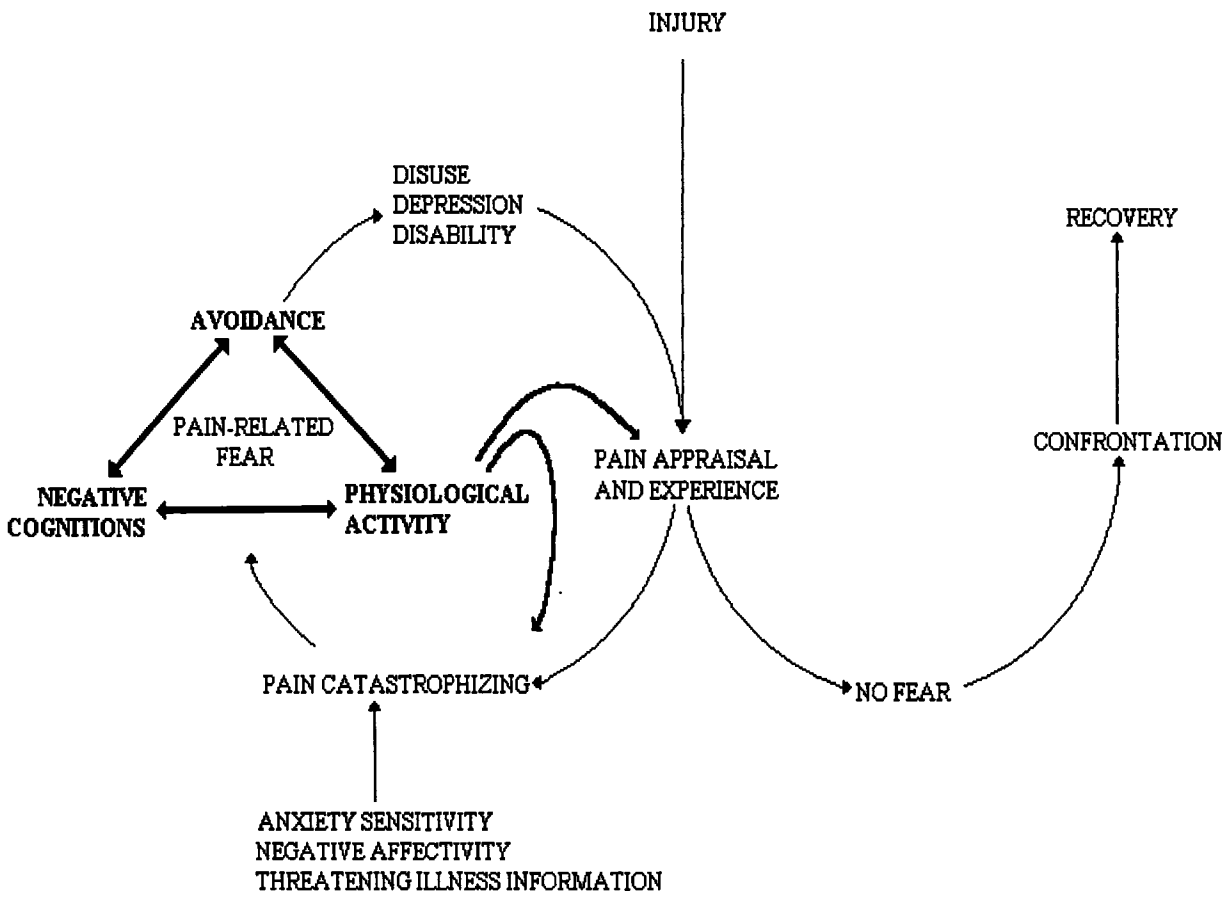

Figure 2. The role of physiological activity in the revised fear-avoidance model, adapted from Norton and Asmundson (2003).

Note. From "Amending the fear-avoidance model of chronic pain: What is the role of physiological arousal?" by Norton and Asmundson (2003), *Behavior Therapy, 34*, 17-30. Copyright 2003 by Association for Advancement of Behavior Therapy. Reprinted with permission.

arousal may be more likely to generate bodily sensations (i.e., muscular tension) that are misinterpreted as signs of the presence of injury, thereby leading to an increase in avoidance behaviour. These mechanisms may strengthen the fear related to pain, leading to the development of chronic pain by triggering the experience of pain or reinforcing negative beliefs about the nature and meaning of pain.

1.3.3 The fear-anxiety-avoidance model

The fear-avoidance model proposed by Vlaeyen and Linton (2000) has also been amended by Asmundson, Norton, et al. (2004) to further clarify the distinction between fear and anxiety and behaviours aroused by these states. Asmundson et al. state that fear is a present-focussed emotion, usually directed towards some concrete stimulus or event, and designed to protect the individual from immediate threat. In contrast, anxiety is a future-oriented cognitive-affective state and is focussed on vague or uncertain anticipated threats. Both fear and anxiety have physiological, cognitive, and behavioural components (Lang, 1968). Though the physiological component – arousal of the autonomic nervous system in order to aid the fight or flight response – is largely similar in both fear and anxiety (though typically somewhat stronger in fear), the cognitive component in anxiety is purported to be more significant than in fear. In fear, the cognitive component, usually characterized by thoughts of danger and threat, acts to focus attention on the threat and to motivate action. Action takes the form of defensive behaviour (i.e., fight or flight). However, with respect to anxiety, the cognitive component serves mainly to focus attention on discerning the presence of a threat. In concordance with this endeavour, interpretive biases and threat-related schemata based on past experiences and threat beliefs are activated so as to inform any action that is taken. In anxiety, this action

involves preventative behaviour (e.g., avoidance), which may protect the individual from future threat, rather than defensive behaviour, as seen in relation to fear responses.

Asmundson, Norton, et al. (2004) further posit that both the fear-escape and anxiety-avoidance systems may mutually trigger and reinforce one another. The increased vigilance toward threat evidenced in an anxious individual may enhance the likelihood of a threat being perceived, thereby activating the fear-escape system. In turn, fear may cause an individual to recognize a recurring threat and increase one's anxiety when faced with stimuli associated with a threat. This formulation of fear and anxiety requires some alteration to the fear-avoidance model as postulated by Vlaeyen and Linton (2000). That is, since anxiety and not fear motivates avoidance behaviour, anxiety must act as a mediating variable between fear and avoidance (see Figure 3). Thus, the fear-avoidance model has been more aptly named the fear-anxiety-avoidance model (Asmundson, Norton, et al., 2004).

1.3.4 Summary

Though the factors that affect the development of fear and avoidance have expanded from Lethem's original model to more comprehensively include cognitive, emotional, and physiological mechanisms, throughout its evolution the central tenet has remained the same. Fear or anxiety related to pain produces avoidance behaviours and eventually leads to chronic pain. This central tenet, and the underlying processes theorized by contemporary fear-avoidance models, has received significant support to date.

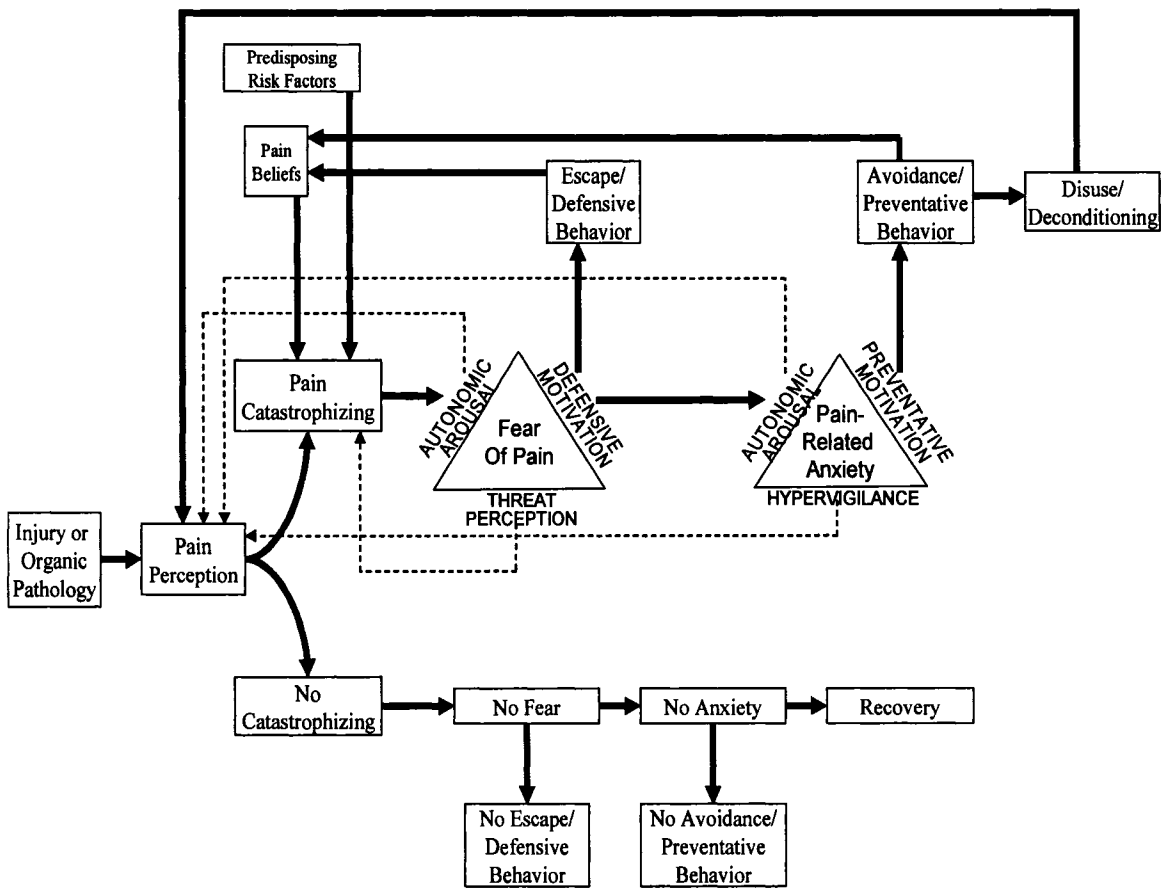

Figure 3. The fear-anxiety-avoidance model, adapted from Asmundson, Norton & Vlaeyen (2003).

Note. From "Fear-avoidance models of chronic pain: An Overview," by Asmundson, Norton, and Vlaeyen (2004). In G.J.G. Asmundson, J.W.S. Vlaeyen, and G. Crombez (Eds.), *Understanding and treating fear of pain.* Copyright 2004 by Oxford University Press. Reprinted with permission.

1.4 Empirical Support for the Fear-Avoidance Model

There has been mounting attention and support for contemporary fear-avoidance models, as originally described by Lethem et al. (1983) and expanded by Vlaeyen et al. (1995), Vlaeyen and Linton (2000), and Asmundson, Vlaeyen, and Crombez (2004). This support and attention is evidenced by numerous journal articles and a recent book publication focusing on varying aspects of the fear-avoidance model of chronic pain (e.g., Asmundson, Vlaeyen, et al., 2004; Boersma & Linton, 2005; Vlaeyen, Kole-Snijders, Rotteveel, Ruesink, & Heuts, 1995; Vlaeyen & Linton, 2000; Woby, Watson, Roach, & Urmston, 2004a). Support for the model has extended not only to the basic postulates of the theory, but also to practical applications, such as treatments (e.g., Vlaeyen, de Jong, Sieben, & Crombez, 2002). The intent of this section is to summarize key empirical research supporting the different aspects of the fear-avoidance model, thereby providing an overview of the strengths of the model, and its limitations.

1.4.1 Fear and behavioural avoidance

The validity of the original fear-avoidance model, and its utility in discriminating between individuals with chronic pain and those without, has been illustrated in a study conducted by Rose et al. (1992). Using the Fear Avoidance Model Questionnaire (FAMQ), which was designed to assess the factors postulated by Lethem et al. (1983) that determine whether one confronts or avoids in response to pain, Rose et al. compared Post-Herpetic neuralgia patients, Reflex Sympathetic Dystrophy patients, and chronic low back pain patients with three different groups of individuals recovered from acute pain (either shingles, fractures, or low back pain). A discriminant function analysis revealed that the FAMQ was effective in discriminating between individuals with chronic

pain and those without. Regardless of the type of pathology, 82% of the participants could be correctly identified based on the degree of measured fear-avoidance, thereby demonstrating a relationship between fear-avoidance and chronic pain. This finding has been supported in subsequent research by McCracken, Zayfert, and Gross (1992). McCracken et al., using a 40-item scale (the Pain Anxiety Symptoms Scale [PASS]) designed to measure cognitive, behavioural, physiological, and fearful appraisal aspects of the fear of pain construct, found that fear of pain made significant independent contributions (proportion of variance accounted for ranged from 5.2% to 17%) to the prediction of disability in 104 chronic pain patients. Similarly, Woby et al. (2004a) found that amongst 83 patients with chronic back pain, both catastrophising and fear-avoidance beliefs related to work and physical activity (as measured by the Fear-Avoidance Beliefs Questionnaires [FABQ]; Waddell, Newton, Henderson, Somerville, & Main, 1993) were independently related to level of disability (as measured by the Roland and Morris Disability Questionnaire [RDQ]; Roland and Morris, 1983). However, only fear-avoidance beliefs related to physical activity were predictive of disability in this sample. Woby, Watson, Roach, & Urmston (2004b) also assessed whether changes in fear-avoidance beliefs, catastrophising, and appraisals of control over pain were predictive of pain intensity and disability in a group of 54 chronic back pain participants enrolled in a cognitive behavioural treatment (consisting of educational, exercise, and goal-setting components). They found that reductions in fear-avoidance beliefs and increases in perceptions of control over pain were significantly related to a decrease in disability, but not pain intensity. These findings strongly support the relationship between fear-avoidance beliefs and disability.

Further support for the fear-avoidance model – particularly that fear leads to avoidance behaviours – comes from Crombez, Vervaet, Baeyens, Lysens, and Eelen's (1996) investigation of whether pain expectancies affect pain experienced during a performance task (a straight leg raise) in participants with chronic low back pain. Although there was no medical support that the exercise would cause any damage to the back, participants were likely to believe that the performance task would cause pain. Though this belief did not result in increased reporting of pain, this study provided evidence that participants were less likely to expend maximal effort on the task, particularly on the first trials when the task was unfamiliar. These results suggest that individuals who have a fear of pain tend to avoid performing tasks to their maximum ability if they believe the task will cause pain. Subsequently, Crombez, Vervaet, Lysens, Baeyens, and Eelen (1998) found that individuals with chronic pain who avoid activities that they perceive as back straining demonstrated both an attentional focus on back sensations and a high fear of pain and (re)injury. Avoidance was not found to be related to pain intensity. These findings are in keeping with the predictions of contemporary fear-avoidance models (Asmundson , Norton, et al., 2004; Vlaeyen & Linton, 2000) and provide the basis for the hypothesis that avoidance behaviours can lead to chronic pain. In particular, the avoidance of feared movements may be the underlying mechanism responsible for higher levels of disability in individuals with fear of pain.

Crook and Moldofsky (1994), in their assessment of the return to work patterns of individuals who suffered from an acute injury to their lower back, found that participants who did not return to work within 3 months of the onset of the pain had a 50% likelihood of being off work at 15 months. Thus, avoidant behaviour seemed to lead to long-term

disability, while confrontative coping strategies tended to be more adaptive. Similarly, Hursey and Jacks (1992), using a series of questionnaires that assessed fear of pain, psychological and physical well-being, and coping, examined the impact of fear of pain on 76 headache sufferers. They observed that, though fear of pain was not related to headache characteristics such as severity, frequency, or duration, it was positively correlated with increased disruption of pleasurable activities. These findings are consistent with the notion that fear of pain may result in avoidance of activities, thereby increasing functional disability and the development of chronic pain. This notion has been further supported in research conducted by Asmundson, Norton, and Allerdings (1997).

Asmundson et al. (1997) used the Multidimensional Pain Inventory (MPI) to classify 200 chronic back pain patients as either dysfunctional (higher than average pain severity, affective distress and perceptions of the degree to which pain interferes with their life; lower levels of activity and pain self-efficacy), adaptive (low pain severity, interference and affective distress; high pain self-efficacy and activity levels), or as being interpersonally distressed (low perceptions of social support). They found that patients classified as being dysfunctional evidenced more pain-related fear and avoidance than individuals classified as adaptive copers or those classified as being interpersonally distressed. McCracken, Spertus, Janeck, Sinclair, and Wetzel (1999) subsequently replicated these results using 190 chronic pain patients divided into dysfunctional, adaptive, or interpersonally distressed copers.

In sum, these findings suggest that avoidance behaviour is related to fear of pain, leads to a decrease in the performance of daily activities, including work, hobbies, and

social activities, and is likely, therefore, to substantially contribute to long-term disability. Further research has implied that the link between fear, avoidance behaviour, and disability is mediated by cognition.

1.4.2 Fear- avoidance and cognitions

Though medical indices such as pain severity have not typically been associated with chronic pain disability, fear-avoidance cognitions have (Waddell et al., 1993). In particular, individuals with chronic pain may have an attentional bias towards pain related phenomena. Though a recent review (Pincus & Morley, 2001) has concluded that there is inconsistent evidence to support this contention, Severeijns, Vlaeyen, van der Hout, and Weber (2001) have found that individuals suffering from chronic pain who catastrophized reported greater pain intensity and psychological distress, and felt more disabled compared to individuals who did not catastrophize. It has, therefore, been hypothesized that individuals who catastrophize (defined as an exaggerated and negative orientation toward pain; Buer & Linton, 2002) may tend to focus on negative aspects of an experience and to interpret bodily signals as being cues for pain. In turn, this attentional focus may lead to greater sensitivity to, and negative interpretation of, interoceptive information associated with movement. Thus, individuals with chronic pain who also have a fear of pain might demonstrate an attentional bias towards pain stimuli.

Preliminary support for this idea comes from research on pain-free individuals (Keogh, Ellery, Hunt & Hannent, 2001) using a dot-probe task. The dot-probe task measures attentional allocation by comparison of detection latencies for dot-probes that follow the presentation of a cue word. Keogh et al. found that participants with a high fear of pain, compared to those determined to have a low fear of pain, evidenced greater

attentional bias toward pain-related information. However, these findings were not supported in more recent studies using chronic pain populations. Roelofs, Peters, and Vlaeyen (2003) did not find that chronic low back pain patients who were high in fear of pain had selective attention to words related to injury or movement using a modified Stroop task. Similarly, Asmundson, Carleton, and Ekong (2005) failed to demonstrate that chronic headache patients, when compared to healthy controls, had selective attention to words related to pain or injury on a dot-probe task. Though Pincus and Morley (2001) account for some of the inconsistencies in the literature as being due to methodological differences (e.g., between dot-probe and Stroop tasks), they nevertheless concluded that research does not reliably support a general attentional bias in individuals with chronic pain, even those who have a fear of pain. This supposition is supported by recent research by Asmundson, Wright, and Hadjistavropoulos (2005), who administered both a dot-probe and a Stroop test to patients with chronic pain and healthy controls, and concluded that there was no difference in the way they attend to threatening linguistic stimuli. However, other methods have provided more consistent evidence supporting the impact of anxiety on attentional focus in chronic pain patients.

According to Eysenck's (1997) cognitive theory of anxiety, and Eccleston and Crombez's (1999) application of this theory to pain, bodily sensations may be perceived as being threat-related and will, therefore, increase anxiety. Initial support for this conception was presented by Dougher, Goldstein, and Leight (1987) in their assessment of the relationship between different sources of anxiety and pain. Within a group of 80 healthy undergraduate students, the induction of general anxiety was not enough to increase a participant's sensitivity to pain. Only participants in whom pain-specific

anxiety was induced evidenced an increase in pain responsivity. Similarly, McCracken, Gross, Aikens, and Carnkike (1996) found that measures of general anxiety are not as highly correlated to disability as measures of specific pain-related fears.

Asmundson and Norton (1995), Asmundson and Taylor (1996), and Norton and Asmundson (2004) have also observed that higher levels of anxiety sensitivity (a personality trait believed to increase one's reactivity to potentially anxiety provoking stimuli) are associated with increased levels of fear of pain and avoidance behaviour in patients with chronic musculoskeletal and headache pain. Further confirmation for this finding comes from Asmundson, Kuperos, and Norton (1997). They compared 19 chronic pain patients with 22 healthy control participants on a computerized dot-probe task designed to evaluate attentional focus towards pain-related thematic cues. Only chronic pain patients who were high in anxiety sensitivity had difficulty changing their focus of attention from pain-related stimuli. In contrast, chronic pain patients with low anxiety sensitivity levels demonstrated no such difficulty. Thus, the operation of the information processing system in patients with chronic pain may be dependent on a trait predisposition to fear pain – chronic pain patients with higher levels of fear (as suggested by higher anxiety sensitivity) have an increased attentional focus on pain and pain stimuli. This sensitivity may result in pain stimuli having an increased negative impact on the individual's affect and behaviours.

The above research supports the contention that pain-related cognitions may act as a moderator of an individual's attentional focus and behavioural responses to pain stimuli. Vlaeyen et al. (1995) suggested that it is the specific fear and anxiety related to the belief that movement can cause (re)injury that will enhance avoidance behaviour.

This fear of movement has been termed kinesiophobia (Kori, Miller, & Todd, 1990) and its role in avoidance and chronic pain has been illustrated in a variety of investigations. For example, Vlaeyen et al. (1995), in an assessment of 103 chronic low back pain patients, found that kinesiophobia was related to increased catastrophising. In a second study, Vlaeyen et al. showed that individuals with greater kinesiophobia evidenced more avoidance of a specific motor task (i.e., lifting a weighted bag). Crombez et al. (1998) also demonstrated that chronic pain patients who avoided activities had a high fear of (re)injury and tended to focus on back sensations.

In sum, these findings provide significant support for the contention that fear of pain, and more specifically, kinesiophobia, may play a mediating role between avoidance behaviour and increased disability. Unfortunately, many of the above described studies do not allow for the inference of causal relationships. Though pain-related fear may result in increased avoidance and disability, it is also possible that disability and avoidance cause fear. Several prospective studies, however, support the former contention.

Klenerman et al. (1995) assessed psychological variables, including indicators of fear-avoidance, in 300 acute low back pain patients. At one year follow-up, fear of pain variables were predictive of whether an individual developed chronic pain. However, this study has been criticised due to the lack of standardized measures used to assess the fear-avoidance variables (Vlaeyen & Linton, 2000). In another prospective investigation, Linton, Buer, Vlaeyen, and Hellsing (2000) administered the FABQ at baseline and one year follow-up with 415 members of the general population. It was found that fear-avoidance beliefs do exist among individuals without a pain problem and that people who had a higher than median score on the FABQ were twice as likely to have a pain episode

in the year following baseline measurement. The former finding, though not the latter, was replicated in a subsequent prospective study (Buer & Linton, 2002). Buer and Linton found that catastrophising showed a dose-response relationship with the report of experienced pain (i.e., as one increased, so did the other), and that fear-avoidance had a negative relationship to activities of daily living, so that as fear increased, activities decreased. These findings received partial support by Woby et al. (2004b), who found that, while fear-avoidance beliefs did predict level of disability, they were not related to pain intensity in a sample of chronic low back pain patients receiving cognitive behavioural therapy. More recently, Boersma and Linton (2005) conducted a prospective investigation in which they classified 363 acute back pain patients as Fear-Avoidant, Distressed Fear-Avoidant, Low Risk, or Low Risk-Depressed Mood and compared the patients in each grouping on outcome measures one year later. Amongst the Fear-Avoidant patients 35% developed long-term sick leave, and 62% amongst the Distressed Fear-Avoidant patients. These findings suggest the importance of fear-avoidance and distress in the development of disability, and their potential importance in the development of early interventions.

1.4.3 Fear-avoidance and physiology

Although the cognitive and behavioural components of the fear-avoidance model have received detailed investigation, the role of physiology has been largely overlooked (Vlaeyen & Linton, 2000). Norton and Asmundson (2003), as described earlier, have recently suggested several mechanisms by which physiological arousal can influence the development of chronic pain, though further research is required to validate their formulations. It has also been suggested that long-term avoidance of activities and

behaviours results in a disuse syndrome that negatively impacts the musculoskeletal system (Kottke, 1996). This negative impact can take the form of either physical deconditioning (i.e., muscular atrophy, loss of ligamentous flexibility, decalcification and weakening of skeletal structures, and weakening of associated tissues), or impaired muscle co-ordination and guarded movements (Vlaeyen & Linton, 2000). However, a recent review of the literature on disuse and deconditioning (Verbunt et al., 2003) indicated little support for the disuse syndrome, though there has been some evidence that muscular coordination becomes impaired in individuals with lower back pain.

1.4.4 Fear-Avoidance and self-efficacy

Self-efficacy, as defined by Bandura (1986, 1991) consists of one's beliefs in their capability to mobilize motivation, cognitive resources, and actions to meet situational demands. Self-efficacy expectancies are believed to affect 1) one's likelihood of choosing and performing a particular task, 2) expenditure of effort, 3) persistence in adverse circumstances, and 4) level of success experienced. Despite the important implications of these concepts to the development of avoidance behaviour, little research has specifically assessed the role of self-efficacy in the fear-avoidance model. Self-efficacy has, however, been found to be related to chronic pain patients' physical functioning, adjustment to chronic pain, and use of coping strategies (see Nicholas, in press, for a complete review). For example, in an assessment of the impact of patient self-efficacy (regarding ability to perform activities of daily living) on outcome in a 3-week rehabilitation program for individuals with low back pain, Altmaier, Russell, Kao, Lehmann, and Weinstein (1993) found that increased self-efficacy beliefs did not affect physical functioning immediately following treatment, but on 6-month follow-up self-

efficacy beliefs were shown to be predictive of improved function and decreased reports of pain. Similarly, Rudy, Lieber, Boston, Gourley, and Baysal (2003), in a functional comparison of individuals with disability who either had chronic pain or not, found that individuals with chronic pain performed at a much lower level than those without chronic pain. Task self-efficacy was one of the strongest predictors of differences in performance between the two groups. Individuals with chronic pain who had lower ratings of task self-efficacy tended to perform at a lower level compared to individuals with higher ratings of self-efficacy. Similarly, amongst a primary care population with sub-acute or chronic pain, Denison, Asenlof, and Lindberg (2004) found that task self-efficacy accounted for a greater proportion of variance in disability scores than catastrophising or kinesiophobia. Council, Ahern, Follick, and Kline (1988) have also reported that self-efficacy ratings by a group of chronic low back pain patients for expected ability to perform specified activities correlated with the actual performance of those activities, and Lackner and Carosella (1999) noted that pain self-efficacy was predictive of lifting capacity. These findings suggest the importance of assessing self-efficacy in any treatment or rehabilitation program for chronic pain patients.

1.4.5 Summary

Significant research has demonstrated the interactive role of avoidance behaviours, catastrophic cognitions, physiological mechanisms, and fear and anxiety in producing chronic pain. It is also likely that self-efficacy has a role in the development of avoidance and/or coping behaviours, and may impact rehabilitation. These findings strongly suggest that pain-related fear and avoidance are important components of chronic pain. As such, cognitive-behavioural treatment (CBT) approaches that

incorporate this conceptualization would seem highly applicable to the treatment of chronic pain, at least where fear and anxiety are significant.

1.5 Treatment of Chronic Pain

It has been suggested that approximately 30% of patients with chronic back pain are dysfunctional and may be considered high in fear (Asmundson et al., 1997). The development of chronic pain treatment approaches that focus on fear is increasingly pertinent: A recent review of physical treatments of chronic pain concluded that, though such treatments are potentially therapeutic, there are few high quality studies supporting their effectiveness (Wright & Sluka, 2001). In contrast, a recent meta-analysis (Morley, Eccleston, & Williams, 1999) of randomized controlled trials of CBT for the treatment of chronic pain concluded that CBT, compared to other treatments and wait-list controls, produced significantly greater improvements in pain experience, pain behaviour, activity levels, and cognitive coping and appraisal (positive coping measures). Additionally, in comparison to only wait-list controls, Morley et al. found CBT produced significantly greater changes in mood and affect, social role functioning, and coping and appraisal (negative coping measures). Thus, CBT appears to be an effective treatment for chronic pain. Unfortunately, the specific CBT approach of applying graded *in vivo* exposure to feared situations in order to reduce avoidance behaviour has only just begun to be developed and tested, and little systematic research has yet been conducted (see Vlaeyen & Linton, 2000). Below, the graded *in vivo* approach is explained and studies pertinent to pain-related fear and avoidance are reviewed.

1.5.1 Development and preliminary support

Philips (1987) was one of the first to argue for the application of graded exposure in order to produce changes in pain cognitions and avoidance behaviour. She stated that chronic pain and chronic fear (i.e., phobias) have many features in common. That is, both are aversive experiences that result in avoidance behaviours. As such, both may be treated in a similar manner – through graded exposure. Graded exposure is a cognitive-behavioural technique based on Wolpe's (1961) work on systematic desensitization, and originally developed for the treatment of phobias (e.g., fear of spiders, fear of flying, fear of enclosed spaces). Graded exposure involves repeatedly and systematically approaching, instead of avoiding, the thing that is feared until the fear associated with that thing is diminished. This is accomplished according to a graded hierarchy, so that exposure occurs first to those things that are less feared before attempting the next most difficult task. Exposure thereby enables the individual to learn that the feared thing is not, in fact, dangerous. This form of treatment has been found to be highly effective in providing relief from phobias (Barlow, 2002; Wilson, 1984).

Individuals with chronic pain who catastrophize and avoid activities are unlikely to have many opportunities to experience corrective feedback, thereby allowing the catastrophic beliefs about pain and injury to persist. Graded exposure may allow for the opportunity to obtain disconfirmations between the expected pain, experienced pain, and other consequences of the activity. There has also been some support for the effectiveness of exposure in reducing fear and avoidance in chronic pain patients.

Crombez et al. (1996) have demonstrated that individuals with chronic low back pain will correct their pain expectancies after exposure to a potentially back stressing

exercise. Participants were 29 chronic low back pain patients who were asked to flex and extend their knee three times with maximal force using a Cybex machine. Baseline, expected, and experienced pain were measured for each trial. They found that pain patients over-predicted pain, but these pain expectancies did not increase the degree of experienced pain. Furthermore, pain expectancies were corrected after the first trial, though no reduction in experienced pain was noted. Though an exaggeration of pain expectancy reoccurred when the task was initially performed with the other leg, these expectancies were again corrected after repetition of the exercise. These findings have been replicated with two other physical activities – straight leg raises and bending forward (Goubert, Franken, Crombez, Vansteenwegen, & Lysens, 2002). In this latter investigation, although pain expectancies decreased between repetitions of the same movement, learning did not generalize to a different movement, suggesting that exposure does not produce a fundamental change in the belief that "movements, in general, cause excessive pain or harm". Rather, learning is fairly specific to the experience.

Based upon these findings, and the literature on the utility of exposure in treating fear and phobias (e.g., see Barlow, 2002), Vlaeyen and colleagues (Vlaeyen et al, 2001; Vlaeyen, de Jong, Ongehena, Kerckhoffs-Hanssen, & Kole-Snjijders, 2002) developed a graded *in vivo* exposure treatment protocol. Graded *in vivo* exposure consists of the activation of fear, and the challenging, and subsequent disconfirmation of, catastrophic expectations. This treatment begins with a cognitive-behavioural assessment, followed by an education component, and then *in vivo* exposure with behavioural experiments. The aim of graded *in vivo* exposure, as with most cognitive-behavioural treatments of chronic pain, is not to "cure" the pain, but to improve the quality of life by decreasing the fear

and anxiety associated with the pain and by increasing the level of functioning (i.e., increasing activities, returning to work) of the individual.

1.5.2 Assessment

The primary purpose of the cognitive-behavioural assessment is to determine the specific nature of the patient's pain-related fear. In order to accomplish this, several questionnaires (e.g., Tampa Scale for Kinesiophobia [TSK], FABQ, PASS, Hospital Anxiety and Depression Scale [HADS], McGill Pain Questionnaire [MPQ], Pain Disability Index [PDI]) assessing pain-related fear and disability, and a semi-structured interview (see Appendix A), are administered. The interview focuses on cognitive, behavioural, and psychophysiological aspects of the patient's symptoms, as well as antecedents and maintenance factors of the pain problem. Additionally, the consequences, both direct and indirect, of the pain-related fear are assessed in the interview.

During the assessment process, specific and explicit treatment goals are established and a graded fear hierarchy developed. In order to assist in the development of the fear hierarchy, Vlaeyen et al. (2001) have used the Photograph Series of Daily Activities (PHODA; Kugler, Wijn, Geilen, de Jong, & Vlaeyen, 1999). The PHODA consists of 98 photographs depicting various activities and movements of daily life. The patient is required to place each photograph on a "fear thermometer", thereby creating a hierarchy of feared movements. Additionally, when a patient has difficulty estimating the harmfulness or fear related to a movement or activity (typically because they have avoided it extensively), behavioural tests may be attempted. During the performance of the behavioural test (or avoided activity), performance indices such as time, distance, and

repetitions are recorded in order to provide a more objective measure of avoidance behaviour. For example, a particular patient may avoid sitting at a computer desk for any length of time for fear of worsening their back injury. The patient would be asked to sit at a desk until pain, weakness, fatigue, or any other reason causes them to stop. During this behavioural test the individual's self-reported anxiety before and fear during the task can be measured, as well as the length of time they are able to stay in the chair, and their reason for moving. Such tests also allow anticipatory anxiety to be measured separately from fear experienced during performance of the task, and give a more objective account of avoidance behaviour (Vlaeyen, de Jong, Sieben, et al., 2002).

1.5.3 Educational component

The education component involves helping the patient to reformulate the way they view their pain so they no longer perceive it as a serious disease or a condition that requires careful protection. Rather, the view that pain is a common condition that can be self-managed is promoted. This change in perspective is accomplished, in part, through a careful explanation of the fear-avoidance model, demonstrating how the person's symptoms, behaviours, and beliefs create a vicious cycle that perpetuates the pain problem (see Figure 3). That is, the experience of pain may lead to catastrophic thoughts about that pain (e.g., "if I do this I'm going to get injured again"), thereby producing fear and anxiety related to the activity and regarding pain itself. This fear and anxiety, in turn, will increase the likelihood that one will escape situations perceived to be pain-arousing and/or to avoid the activity all together. Over the long term, this escape and avoidance behaviour results in a significant reduction of functional activities (e.g., going to work, exercising, household chores), correspondingly producing physiological dysfunction that,

in combination with the decrease in activity, results in disability. Increases in level of disability will, in turn, increase the amount of pain experienced, and the cycle perpetuates. Based on this formulation, customized to fit the context of the patient's fears, the ultimate goal of the education component is to improve the willingness of patients to participate in heretofore avoided activities.

1.5.4 In vivo exposure

Following the education component, patients are exposed to low anxiety activities identified in the graded hierarchy of fear-eliciting situations. Exposure occurs *in vivo* (i.e., in real life), and is not imaginal in nature. General principles of exposure are followed. These include obtaining participant agreement to repetitively perform each previously avoided activity until disconfirmation that the activity is harmful has occurred, and their anxiety begins to decrease significantly. Decreases in anxiety are monitored through self-report (e.g., by having the participant predict the likelihood of harm or to rate how distressing performance of the task is across repetitions, on a scale of 1-10, where 10 is the most distress imaginable). Each activity or movement is first modelled by a therapist in order to demonstrate the correct ergonomic method of performing the activity and to clearly illustrate that the activity or movement is not fear-provoking to the therapist. In order to promote independence, however, the presence of the therapist is withdrawn as therapy progresses. Behavioural experiments, which involve the empirical testing of patient-produced hypotheses, are conducted as appropriate throughout exposure sessions. Following a patient prediction that a certain activity will produce pain, an appropriate behavioural experiment is carried out and the consequences evaluated.

1.5.5 Clinical outcome studies

The first clinical outcome study on the effects of graded *in vivo* exposure in chronic pain patients was conducted by Vlaeyen et al. (2001). Four individuals with low back pain who reported significant kinesiophobia were randomly assigned to receive graded *in vivo* exposure followed by graded activity, or the same treatments in the opposite order. Pain-related fears and cognitions were assessed on a daily basis, and pain catastrophising, control, disability, and pain-related fear were measured (see Table 1 for list of questionnaires) before and after the treatment. Using a time-series analysis on the daily measures, the authors found that pain-related cognitions and fears reduced only with the graded exposure, and not the graded activity, regardless of what order the treatments were received. Furthermore, according to analysis of pre- and post-treatment measures, decreases in disability and catastrophising corresponded to decreases in pain-related fear and decreased avoidance. The finding that graded *in vivo* exposure reduces fear and disability in patients with chronic pain has been subsequently replicated in a number of case studies (see Table 1; Boersma et al., 2004; de Jong et al., 2005; Linton, Overmeer, Janson, Vlaeyen, & de Jong, 2002; Vlaeyen, de Jong, Onghena, et al., 2002). In sum, these findings suggest that graded *in vivo* exposure may provide more significant improvements in patients with chronic pain than traditional treatments (e.g., graded activity). To date, however, investigations have consisted only of case studies. Research using a larger sample size, a randomized-controlled methodology, and comparison against active (i.e., graded activity) and static (i.e., waitlist) controls, is required to better evaluate the effects of graded *in vivo* exposure (Linton et al., 2002).

Table 1

Comparison of in vivo exposure treatment case studies

Study	# of Patients	Measures	Treatment Length	Outcome
Vlaeyen et al. (2001)	4	TSK PCS PASS VAS PCL RDQ	3 weeks	Decreases in pain-related fear (TSK), catastrophising (PCL), and disability (RDQ)
Vlaeyen et al. (2002)	2	TSK PCS PASS VAS PHODA RDQ PVAQ	5 weeks	Decreases in pain-related fear (TSK) and catastrophising (PCS), and pain intensity (VAS)
Linton et al. (2002)	2	TSK PHODA Behavioural Performance	4.5 weeks (8 sessions)	Decreases in pain-related fear (TSK & PHODA), and avoidance (Behavioural Performance)
Boersna et al. (2004)	6	TSK PHODA Self-ratings of function and pain	2-3 sessions/week for a total of 6-10 sessions	Decreases in pain-related fear (TSK & PHODA); improved self-rated functioning
de Jong et al. (2005)	6	TSK PCS PASS PVAQ RDQ PHODA Activity Monitor	6 weeks	Decreases in pain-related fear & catastrophising (TSK & PCS); increased activity (measured via monitor); maintenance of improvements at 6-month follow-up

Note. TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophising Scale; PASS = Pain Anxiety Symptom Scale; VAS = Visual analog scales; PCL = Pain Cognition Checklist; RDQ = Roland Disability Questionnaire; PHODA = Photograph series of Daily Activities; PVAQ = Pain Vigilance and Awareness Questionnaire

1.6 Purpose and Hypotheses

The purpose of the present investigation was to further evaluate the effectiveness of graded *in vivo* exposure in the treatment of chronic back pain. This cognitive-behavioural form of treatment was compared to an alternate commonly-used behavioural approach based solely on graded increments to activity, and to wait-list controls. In contrast to prior, similar investigations, the present research will use a larger sample and randomized control methodology. Also, four weeks following the conclusion of treatment, a follow-up assessment will be conducted in order to assess maintenance of expected treatment gains.

Based on the results of earlier investigations (e.g., Linton et al., 2002; Vlaeyen et al., 2001; Vlaeyen, de Jong, Ongehena, et al., 2002), it is hypothesized that:

1. Patients receiving graded *in vivo* exposure, but not graded activity or wait-list controls, will evidence improvements in kinesiophobia, fear-avoidance beliefs, pain-related behaviours, pain catastrophising, pain self-efficacy, symptoms of chronic back pain, and disability due to pain.
2. In the graded *in vivo* exposure group, all expected improvements will be maintained four weeks following the conclusion of treatment.
3. It is also hypothesized, in keeping with the findings of Vlaeyen et al. (1995) and Asmundson et al. (1997), that patients treated with graded *in vivo* exposure who have the greatest distress (i.e., fearful pain beliefs, as assessed by the TSK) prior to treatment will demonstrate the greatest overall improvement (as assessed by the dependent measures) at post-treatment and follow-up in each of the areas indicated in the first hypothesis.

Chapter 2: Method

2.1 Participants

Recruitment of participants was accomplished using newspaper and e-mail advertisements, and posters describing the purpose of the study. Posters were hung in physicians' and physiotherapists' offices and within the Wascana Rehabilitation Center, Regina, Saskatchewan. Only patients with back pain were sought to participate, as prior case research assessing the effectiveness of graded *in vivo* exposure has been conducted primarily with this population. Controlled trials of this group are required before expanding efforts to include individuals with other pain conditions. Additional eligibility criteria included that all patients be between 18 and 65 years of age, that they score 38 or higher on the TSK (this cut-off score was adapted from Vlaeyen et al., 2001), that they not have any pending medical investigations or surgery for their back pain, and that they were not receiving other psychotherapy or physical therapy (e.g., through insurance agencies) for their condition. All patients were randomly assigned by the primary experimenter or a research assistant, via the rolling of a six-sided dice, to one of three conditions (a dice roll of 1 and 4 = graded *in vivo* exposure, 2 and 5 = graded activity, 3 and 6 = wait-list control).

Participants were recruited from April, 2004 until March, 2005. The recruitment goal for this study was to obtain 60 patients (20 per treatment group) with low back pain. A group size of 20 is consistent with other randomized controlled trial research comparing CBT to behaviour therapy for chronic pain. Indeed, in a recent meta-analysis of such studies, Morley et al. (1999) reported the average group to comprise of 23 patients.

A total of 151 potential participants responded to recruitment advertisements. Of these individuals, 88 met eligibility criteria and were invited to participate in the study. Of these 88 participants, all initially agreed to participate and 44 completed the study. Though the proposed group size was not obtained, the number of participant completers is significantly larger than prior research samples assessing graded *in vivo* exposure therapy, which has exclusively consisted of case studies (Boersna et al., 2004; Linton et al., 2002; Vlaeyen et al., 2001; Vlaeyen, de Jong, Ongehena, et al., 2002).

The number of treatment completers versus drop-outs were as follows: graded *in vivo* exposure, 15 vs. 21; graded activity, 13 vs. 12; wait-list control, 16 vs. 6. There were five individuals who volunteered and were eligible, but were not assigned to a treatment group when they elected to drop-out. The majority of other individuals (23 out of 33) who dropped out of one of the treatment conditions did so prior to the assessment (n = 16) or following the assessment but prior to the first treatment session (n = 7). The proportion of drop-outs was not significantly greater in the graded *in vivo* exposure treatment compared to the graded activity (58.3% vs. 48.0%; $\chi 2$ (1, N = 61) = .63, p > .42, $\eta 2$ > .01) but was greater in graded *in vivo* exposure compared to the wait-list control condition (58.3% vs. 27.3%; $\chi 2$ (1, N = 58) = 5.29, p = .02, $\eta 2$ > .09). The proportion of drop-outs was not significantly greater in the graded activity condition than the wait-list control (48% vs. 27.3%; $\chi 2$ (1, N = 47) = 2.12, p >.14, $\eta 2$ > .04).

Table 2 depicts the demographic information of the participants assigned to each treatment condition and for drop-outs. Independent samples t-tests (for age) and chi-square analyses (for sex, education level, and employment status) comparing demographics between treatments showed no differences in age, sex, education level, or

Table 2

Demographic and clinical characteristics by treatment group

Characteristics	GivE (n = 15)	GA (n = 13)	WLC (n = 16)	Total (n = 44)	Drop-outs (n = 44)
Age					
Mean	46.13	47.23	46.12	46.45	43.78
(SD)	(11.9)	(12.0)	(12.5)	(11.9)	(9.88)
Sex					
Male	7	4	4	15	18
Female	8	9	12	29	23
Employment status					
Employed	11	9	14	34	30
Unemployed	4	4	2	10	11
Education Level					
< = Grade 12	2	5	5	12	18
> Grade 12	13	8	11	32	22

Note. GivE = Graded *in vivo* Exposure, GA = Graded Activity; WLC = Wait-List Control

Table 3

Independent samples t-test and chi-square p-values from comparisons of demographic variables between treatment groups

Characteristics	GivE vs. GA	GivE vs. WLC	GA vs. WLC	Completers vs. Drop-Outs
Age	.811	.998	.811	.265
Sex (male:female)	.399	.215	.734	.354
Employment status (employed:unemployed)	.907	.389	.352	.661
Education Level (pre:post-high school)	.133	.241	.690	.090

Note. Independent samples t-test values are given for "Age". All other values are from chi-square analyses. GivE = Graded *in vivo* Exposure; GA = Graded Activity; WLC = Wait-List Controls

employment status in participants (see Table 3), though the proportion of males to females in the graded *in vivo* exposure condition was significantly different than the proportion in the wait-list control condition ($\chi 2$ (1, N = 27) = 4.03, p = .045, $\eta 2 > .14$). Independent samples t-tests (for age) and chi-square analyses (for sex, education level, and employment status) were also used to compare demographics between completers and drop-outs (see Table 3). There were no significant differences found.

2.2 Measures

Questionnaires were chosen to assess fear of movement, fear-avoidance beliefs, pain-related anxiety, cognitions and behaviours, general anxiety, depression, severity and symptoms of pain, perceived level of disability, self-efficacy, and therapeutic alliance. The full-scale score for each questionnaire was used as the outcome variable except where otherwise indicated. Each of these questionnaires, with the exception of the Pain Disability Index, the Hospital Anxiety and Depression Scale, and the Working Alliance Inventory are publicly available for use. In addition, demographic information (e.g., age, sex, employment, length of time since injury, existence of insurance claims, treatment history, frequency and type of other treatments received during period of participation in research) was collected. The questionnaires described below fall into four domains – primary outcome measures, secondary outcome measures, measures of therapeutic integrity, and subsidiary outcome measures. Primary outcome measures were identified as those relating to fear, anxiety and avoidance behaviour (i.e., measures that are most directly related to the fear-avoidance model). Secondary outcome measures were identified as those relating to ratings of pain, disability and non-pain related anxiety and depression. Measures of therapeutic integrity consisted of questionnaires that assessed

some aspect of the therapist or therapy. These questionnaires were not given to participants in the wait-list control condition. Subsidiary outcome measures were those that were not administered at each time point and were only given to participants in the graded *in vivo* exposure treatment condition.

2.2.1 Primary outcome measures

1. The Tampa Scale for Kinesiophobia (TSK; Miller, Kori, & Todd, 1991; Appendix B) is a 17-item questionnaire used to assess kinesiophobia. All items are answered using a 4-point Likert scale with response alternatives ranging from *strongly disagree* to *strongly agree*. The TSK has two subscales – the Pathological Somatic Focus subscale, which assesses the cognitive and emotional aspects of fear of pain, and the Activity Avoidance subscale, which focuses on behavioural aspects. The Dutch version of the TSK has received the majority of psychometric scrutiny and has been found to be both reliable (total score $\alpha = .77$) and valid (significant correlations with concurrent scales that assessed aspects of fear of pain ranged from .23 - .54). Its subscales were noted to have relatively low inter-correlations (.02 to -.31), and a four-factor solution (Harm, Fear of (re)injury, Importance of exercise, and Avoidance of activity) was preferable to the two original subscales (Vlaeyen et al., 1995). Crombez, Vlaeyen, Heuts, and Lysens (1999) have also found that the TSK total score is correlated negatively to performance on a back flexion and extension task, and correlated positively to self-reported disability. Due to the higher consistency of the TSK total score, and the inter-correlations between factors, use of the total scale score is preferred to the subscale scores.

2. The Fear Avoidance Belief Questionnaire (FABQ; Waddell et al., 1993; Appendix C) is a 16-item measure with two subscales that focus specifically on beliefs about how work and physical activity affect low back pain. Using a normative sample of 210 patients, Waddell et al. demonstrated good internal consistency for the FABQ amongst both chronic and acute pain patients (α = .88 and .77, respectively). Crombez et al. (1999), however, subsequently found that although the Work subscale had an acceptable internal consistency (α = .84 and .92 in two samples), the Physical subscale was inadequate (α = .52 and .57). Test-retest reliability of the FABQ has been found to be favourable at 0.74, with all items except two showing a concordance of greater than 0.61. Waddell et al. also indicated that Work subscale scores were strongly correlated with self-reported disability and work loss, and that both subscales were somewhat related to reported pain intensity. More recent investigations have also demonstrated that the subscales are differentially related to physical and work-related activities (for a review, see McNeil & Vowles, 2004).

3. The Pain Anxiety Symptoms Scale (PASS; McCracken et al., 1992; Appendix D) contains 40 items, divided evenly into four subscales, that are responded to using a Likert scale from 0 (*never*) to 5 (*always*). The subscales – Cognitive Anxiety, Fearful Appraisal, Escape/Avoidance, and Physiological Anxiety – were designed, respectively, to assess negative and anxious cognitions associated with pain, fearful thinking about pain, avoidance of painful activities, and physiological symptoms of anxiety associated with pain. McCracken et al. (1992) have reported the internal consistency of the PASS as good, with a total scale α of .94 and subscale coefficients ranging from .81-.89. Test-retest after 14 days has yielded reliability correlations of $\geq$ 0.93 among the subscales,

with the exception of the escape/avoidance subscale, which had an $r > 0.77$ across administrations (McCracken, Zayfert, and Gross, 1993). A short-form of the PASS – the PASS-20 – has recently been developed (McCracken & Dhingra, 2002). The PASS-20 has four subscales, similar to the original measure, each consisting of 5 items for a total of 20. Coons, Hadjistavropoulos, and Asmundson (2004) have shown that the PASS-20 measures the same subscales as the PASS. The PASS-20 was normed using a group of 282 chronic pain patients. McCracken and Dhingra showed the internal consistency of the subscales of the PASS-20 to be adequate (mean $\alpha = 0.81$), and each subscale to be strongly correlated with the corresponding subscale of the full form (mean $r = .95$). The PASS-20 was used in the present investigation.

4. The Pain Catastrophising Scale (PCS; Sullivan, Bishop, & Pivik, 1995; Appendix E), as suggested by its name, was designed to assess pain-related catastrophising. It has three factors (Rumination, Magnification, and Helplessness) comprising a total of 13 items. Each item consists of a thought or feeling related to the experience of pain and is responded to on a 5-point scale (0 = *not at all*, 4 = *all the time*) relating the degree to which the individual experiences that thought or feeling in a painful situation. Administration of the PCS to 425 undergraduate students demonstrated that a three-factor solution accounted for 69% of the variance (Sullivan et al., 1995). This three factor structure was subsequently supported by Van Damme, Crombez, Bijtebier, Goubert, and Van Houdenhove (2002) using the Dutch version of the PCS amongst 550 pain-free students, 162 chronic back pain patients, and 100 fibromyalgia patients. Sullivan et al. (1995) also demonstrated the internal consistency of the PCS amongst undergraduate students. The three subscales were found to be adequate (Rumination $\alpha =$

.87, Magnification α = .60, Helplessness α = .79) and the internal consistency for the entire scale was found to be good (α = .87). Subsequently, Osman et al. (2000) demonstrated that amongst a sample of 60 pain outpatients, the total scale α was .92, and the α's for the Rumination, Magnification, and Helplessness scales were .85, .75, and .86 respectively. The validity (concurrent and criterion-related) of the PCS was demonstrated in several studies. Sullivan et al. (1995), in a comparison of catastrophisers and noncatastrophisers on both a cold pressor task and an aversive electrodiagnostic medical procedure, found that individuals classified as catastrophisers based on their PCS score reported significantly greater emotional distress, negative pain-related thoughts, and pain intensity than non-catastrophisers. Osman et al. (2000) also found that the total PCS score was useful in differentiating between pain outpatients and a pain-free community sample.

2.2.2 Secondary outcome measures

1. The Hospital Anxiety and Depression Scale (HADS; Snaith & Zigmond, 2000; Appendix F) was designed to assess general psychological changes. It has two subscales – Anxiety (HADS-A) and Depression (HADS-D) – each containing seven items. In order to avert overlap with somatic disorders (e.g., chronic pain), no items pertaining to physical symptoms are used in the scale. A recent review of 747 articles that used the HADS (Bjelland, Dahl, Haug, & Neekelmann, 2002) has confirmed its two-factor structure and concluded that it is useful for assessing the presence and symptom severity of anxiety and depression in the general population, as well as somatic, psychiatric, and primary care patients. Bjelland et al. also reported the internal consistency of the HADS to be good across studies (HADS-A α = .68 - .93, mean of .83; HADS-D α = .67-.90,

mean of .82). The HADS has also been found to have adequate concurrent validity with other measures of depression and anxiety (r = .49 - .83).

2. The McGill Pain Questionnaire - Short Form (SF-MPQ; Melzack, 1987; Appendix G) is a commonly used tool for the measurement of pain experience. Though the original MPQ (Melzack, 1975) was composed of three factors and required up to 20 minutes to fill out, the SF-MPQ can be completed relatively quickly and consists of 15 of the most commonly used adjectives that describe sensory and affective aspects of pain (Wright, Asmundson, & McCreary, 2001). The SF-MPQ also has a present pain index (PPI) and a visual analogue scale (VAS) to help assess pain intensity. The SF-MPQ has been found to correlate highly with the original MPQ (Melzack & Katz, 2001) and a recent factor analysis (Wright et al., 2001) using data from 188 chronic back pain patients has demonstrated that a two-factor solution (sensory and affective) provides the best fit, with each factor exhibiting an internal consistency of 0.77.

3. The Pain Disability Index (PDI; Pollard, 1984; Appendix H) consists of seven questions, each rated on a 10-point Likert scale (1 = *no disability*, 10 = *total disability*), that assess the degree to which patients perceive their pain to interfere with daily functioning. Tait, Chibnall, and Krause (1990), using a sample of 444 patients with chronic pain, demonstrated that the PDI consists of a single factor that accounts for 56% of the variance in the data. The internal consistency for this factor was good (α = .86) and test re-test reliability was significant, though somewhat low (r = .44). The PDI was also found to have concurrent validity – individuals who are rated as having high disability scored differently on other measures of functional impairment compared to individuals

rated as low disability. Furthermore, patients with high versus low scores were found to exhibit significantly different pain behaviours.

4. The Pain Self-Efficacy Questionnaire (PSEQ; Nicholas, 1989; Appendix I) is a 10-item measure designed to assess the self-efficacy of chronic pain patients to perform tasks that are commonly reported to be problematic amongst this population. Patients are requested to respond on a 7-point Likert scale (0 = *not at all confident,* 6 = *completely* confident; this scale was reversed in the present study in order to make scoring consistent with all other measures) indicating how confident they are that they can perform each of the ten tasks at present despite their pain. Amongst a sample of 103 chronic low back pain patients, the PSEQ was found to have good internal consistency ($\alpha = .92$), adequate test-retest reliability at 3 and 6 months ($r = .73$), and to possess a one-factor structure accounting for 58.6% of the total variance (Nicholas, in press). Furthermore, the PSEQ was found to have significant negative correlations ($r > .40, p < .001$) with measures of disability, illness and pain beliefs, and significant positive correlations ($r > .40, p < .001$) with measures of function, activity and coping. These results support the concurrent and construct validity, respectively, of the PSEQ.

2.2.3 Measures of therapeutic alliance

1. The Working Alliance Inventory – Client Form (WAI; Horvath & Greenberg, 1989; Appendix L) is a 36 item self-report scale designed to assess the therapeutic relationship. The WAI includes three scales, including the Bond scale, which measures the therapeutic bond (e.g., attachment, mutual liking, trust), the Tasks scale, which measures agreement on joint tasks (e.g., techniques and strategies of treatment), and the Goals scale, which measures agreement about treatment goals (e.g., areas targeted for

change). Patients are requested to respond to each item on a 7-point Likert scale (1 =*does not correspond at all,* 7 = *corresponds exactly*). The reliability estimate for the client form of the WAI has been reported at Cronbach's $\alpha = 0.98$, and test–retest reliability was $r = 0.83$ across a 2-week period (Tracey & Kokotovic, 1989). For the purpose of this study, the WAI was only administered to the two active treatment groups, and only after the 4th and 8th sessions.

2. Treatment credibility was assessed by two questions, each rated on a 10-point Likert scale (0 = *not at all,* 10 = *completely*): 1) How logical did this type of treatment seem to you?; 2) How confident would you be in recommending this treatment to a friend who had chronic back pain? These questions were administered once upon completion of treatment.

2.2.4 Subsidiary outcome measures

The Photograph Series of Daily Activities (PHODA; Kugler, et al., 1999) is an assessment tool used to help develop graded fear hierarchies. The PHODA consists of 98 photographs depicting various activities and movements of daily life. The patient is required to place each photograph on a *fear thermometer*, thereby creating a hierarchy of feared movements. This device was developed for, and has been used successfully in prior research on graded *in vivo* exposure for the treatment of chronic pain (Vlaeyen et al., 2001; Vlaeyen, de Jong, Ongena, et al., 2002).

2.3 Procedure

Prior to initiation of this research, ethical approval was obtained from the Research Ethics Board of the University of Regina and from the Regina Qu'Appelle Health Region Research Ethics Board. Upon successful recruitment, patients were

randomly assigned to the graded *in vivo* exposure, graded activity, or wait-list control group (with the proviso that each group comprised up to 20 patients maximum). Duration of therapy (eight 45 minute sessions conducted on a twice-weekly basis over a period of four weeks) and time spent with a therapist was equivalent in both treatment groups. Participants in the two treatment groups were administered questionnaires by the therapist for that treatment group prior to the start of treatment, after the 4th session of treatment, upon completion of treatment, and 4 weeks following. Participants in the wait-list control group were similarly administered the questionnaires prior to the commencement of their participation, and at the 2nd, 4th and 8th week following.

Graded activity, based upon principles of operant conditioning, involves the shaping of healthy behaviours through positive reinforcement of predefined activity quotas (Vlaeyen, de Jong, Sieben, et al., 2002). All exercises and activities carried out in the graded activity condition were derived from existing physiotherapy treatments for low back pain, and each participant's graded activity program was individualized based upon his/her observed work demands and functional capacity. All activities were conducted under the supervision of a Registered Physiotherapist. Participants engaged in activities until the point at which pain prevented them from continuing or they were able to perform the specific physical activity without significant discomfort (e.g., if a participant was able to complete 10 sit-ups without discomfort, they would then attempt 15 sit-ups; once able to complete 15 sit-ups, they would attempt 20 sit-ups). The number and scheduling of treatment sessions was identical for both the graded activity and graded *in vivo* exposure conditions (i.e., 8 sessions, twice per week, for four weeks).

The therapy manual (Appendix K) for graded *in vivo* exposure was based on Vlaeyen, de Jong, Sieben, et al. (2002). In brief, graded *in vivo* exposure involved educating the patient about the cognitive-behavioural perspective on fear-avoidance and its consequences, followed by the application of graded exposure techniques. Session one consisted of an assessment interview (as described above), educating the patient about the fear-avoidance model of chronic pain, and formulation of the patient's problems within this context, including an assessment of feared activities and establishment of an individualized hierarchy of fear-eliciting movements using PHODA. Due to the thorough nature of the educational component and assessment procedures, the first session often required more than an hour. Sessions two through five focussed almost entirely on exposure to the activities identified in the fear hierarchy. Behavioural tests were performed in order to challenge patient expectations (e.g., "I am going to be severely re-injured if I attempt this activity"). Prior to each exposure, the patient's current and expected level of pain, and their level of anxiety related to the activity, were rated on a 0-10 point scale, where 0 = no pain/fear and 10 = most pain/anxiety possible. Subsequent to the performance of each exposure task, the level of pain and fear actually experienced during the task were evaluated using the same 0-10 point scale. This information was used to exhibit and track improvements across repeated exposures and tasks. The final session was used to review the treatment process and give the patient direction on relapse prevention.

2.3.1 Therapists

Graded *in vivo* exposure was conducted by the researcher or a graduate student in the Clinical Psychology program at the University of Regina who was trained in

provision of the treatment. Training of the graduate student consisted of a review of the treatment manual, watching video tapes of individual sessions, role-playing therapy with the researcher, and live supervision, provided by the researcher, for the assessment session and the first treatment session. Both the researcher and graduate student were supervised by a Registered Doctoral Psychologist in the Regina Qu'Appelle Health Region.

Treatment for the graded activity group was conducted by a Registered Physiotherapist from the University of Regina. Throughout both treatments, care was taken to follow the suggestions of Hadjistavropoulos and Kowalyk (2004) to ensure a strong therapeutic relationship. A positive relationship between therapist and patient has been associated with positive treatment outcomes (Orlinski, Grawe, & Parks, 1994) and is especially necessary with cognitive behaviour therapies in order to assist the patient to appraise thoughts and alter behaviours (Safran & Segal, 1990). To facilitate the development of the therapeutic relationship in patients with fear of pain, Hadjistavropoulos and Kowalyk (2004) have made several suggestions. These include actively monitoring the quality of the relationship and the therapist's reactions towards the client in order to properly cultivate the relationship and deal with problems as they occur; being empathic, or actively communicating an understanding of the patient's perspective; working collaboratively with the patient to set treatment goals; promoting the patient's self-efficacy (e.g., by providing the opportunity for successes at relevant tasks), particularly regarding their ability to perform feared activities; and assignment of homework tasks (e.g., further repetitions of the exposure activities).

2.4 Design and Analyses

A mixed factor (treatment group x time) design was used to compare the relevant variables between treatment groups, and to assess outcome and changes over time within each group. This design was chosen for several reasons. Primarily, the mixed factorial design is ideal for assessing treatment effects over time (Keppel, Saufley, & Tokunaga, 1992). Mixed factor designs also provide a relatively sensitive and powerful test when groups are limited in size (Keppel et al., 1992), as is the case in the present research. Furthermore, as each treatment mode was 4 weeks in duration, it would not have been feasible (due to time constraints and a desire to reduce drop-out rates) to expose all participants to both treatments. Thus, a two independent treatment groups design was most appropriate. The wait-list control group offers a baseline group with which to compare the treatment groups.

Data from the questionnaires were entered into SPSS and the first hypothesis was tested initially with omnibus analyses on each primary and secondary dependent variable (DV) using 3 (treatment: graded *in vivo* exposure vs. graded activity vs. wait-list control) x 4 (time: pre-treatment, mid-treatment, post-treatment, and follow-up) mixed factorial ANOVAs. Subsequently, in order to determine the differential impact of treatment from pre- to post-treatment on each DV, 3 (treatment: graded *in vivo* exposure vs. graded activity vs. wait-list control) x 2 (time: pre- and post-treatment) analyses were performed. Additional 2 x 2 mixed factor analyses on specific treatment conditions (graded *in* vivo exposure, graded activity, and/or control) and times (pre- to post-treatment or pre-treatment to follow-up) were also conducted using a mixed factorial ANOVA design in order to determine specifically how treatment conditions differentially impacted the DVs

across time. The figures depicting the outcomes of the omnibus analyses were used to determine when it was appropriate to conduct a 2 x 2 comparison (e.g., though graded *in vivo* exposure was compared to both of the other treatment conditions on all DVs, graded activity was only compared to the control group when graded activity also showed a trend for greater change than the graded *in vivo* exposure and/or when graded *in vivo* exposure was found to have a significantly stronger effect than the graded activity or control conditions).

The second hypothesis was assessed using paired t-tests to determine change from pre- to mid-treatment, mid- to post-treatment, and post-treatment to follow-up. Paired t-tests were also used to assess the degree of change within each treatment from pre- to post-treatment and follow-up. Paired t-tests have been found to be suitable for comparison of change across time (Keppel et al., 1992).

The third hypothesis, requiring comparisons between high and low distress participants who received graded *in* vivo exposure, was also tested using repeated measures analyses. However, due to the limited size of the sample (n = 15), it was not feasible to conduct an omnibus 2 (high and low distress) x 4 (time) analysis. Rather, 2 (high and low distress participants) x 2 (time: pre-treatment to post-treatment) mixed repeated measures factorial analyses were used to compare each DV.

Chapter 3: Results

The alpha level for the 3 (treatment) x 4 (time) and 3 (treatment) x 2 (time) and mixed factorial tests was set at .05. The alpha level for all other tests (i.e., specific repeated measures, paired t-tests) was set at .01. This more stringent alpha level was chosen to reduce the likelihood of Type I errors associated with the large number of comparisons being conducted. Results of evaluation of assumptions of normality and homogeneity of variance-covariance matrixes were satisfactory. The assumption of sphericity for all 3 (treatment) x 4 (time) and 3 (treatment) x 2 (time) repeated measures analyses was met or was corrected for using the Greenhouse-Geisser correction provided by SPSS. No outliers at three standard deviations or more from the mean were identified at any time point. This liberal limit of three standard deviations for outliers was chosen due to the small sample size and the importance of maintaining as many data points as possible to provide adequate statistical analyses. Effect sizes are reported for each analysis.

3.1 Preliminary Analyses/Subsidiary Measures

Means and standard deviations for each dependent variable (DV), at each time of measurement, and for each treatment condition are reported in Table 4. Means and standard deviations for subscales of selected DVs (i.e., PASS, HADS) are reported in Table 5, and in Table 6 for high and low distress participants in the graded *in vivo* exposure treatment condition. Reliability analyses on pre-treatment measures show that, with the exception of the TSK ($\alpha = .57$), all measures had acceptable internal consistency (FABQ $\alpha = .86$; PASS $\alpha = .92$; PCS $\alpha = .94$; HADS $\alpha = .68$; SF- MPQ $\alpha = .86$; PDI $\alpha =$

Table 4

Means and Standard Deviations for Primary and Secondary Outcome Measures

Measure	Pre		Mid		Post		Follow-Up	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
TSK								
GivE	41.20	1.90	38.40	3.67	32.67	4.75	33.93	5.90
GA	43.85	3.79	39.50	6.78	40.00	5.21	39.64	5.41
Control	41.94	3.11	39.62	4.13	39.07	5.84	37.67	5.96
FABQ								
GivE	30.40	14.40	28.33	11.67	18.67	10.42	22.20	15.53
GA	38.62	18.69	40.31	18.41	36.38	20.78	40.82	19.29
Control	36.38	15.57	33.00	16.60	36.71	5.84	30.54	18.71
PASS								
GivE	33.27	13.45	33.70	10.44	24.93	10.55	26.73	13.70
GA	37.62	16.50	43.85	12.84	38.31	17.66	39.36	15.88
Control	42.69	20.37	45.31	21.21	40.50	18.59	39.77	21.09
PCS								
GivE	17.93	8.81	17.73	10.27	11.93	5.35	9.87	8.52
GA	20.31	11.21	20.38	13.38	18.31	11.45	18.18	12.58
Control	21.69	10.42	21.81	9.74	23.33	11.56	20.92	11.72
HADS								
GivE	10.60	4.36	11.53	5.40	8.53	5.13	7.67	6.87
GA	14.54	5.33	14.23	6.06	14.62	6.63	13.91	6.49
Control	11.81	4.48	12.13	6.39	13.40	7.47	12.77	7.88
SF-MPQ								
GivE	16.80	6.80	14.07	17.44	10.67	6.53	10.27	8.50
GA	18.77	9.03	14.62	8.46	15.08	8.36	14.45	9.16
Control	17.75	8.49	16.38	8.48	17.47	7.90	17.15	9.45
PDI								
GivE	20.40	11.53	14.20	7.78	11.20	10.32	12.20	11.50
GA	23.31	15.06	21.00	17.23	18.85	16.28	23.73	18.91
Control	24.00	13.26	19.67	10.61	19.33	11.94	18.77	12.56
PSEQ								
GivE	15.73	9.63	14.47	11.22	9.06	8.74	11.80	10.73
GA	15.08	9.77	17.23	12.47	17.62	14.54	17.00	14.79
Control	17.13	8.95	16.80	12.40	17.20	12.82	14.50	9.11
WAI								
GivE	--	--	212.6	32.24	235.67	21.17	--	--
GA	--	--	220.50	12.47	217.92	25.07	--	--

Note. Pre = Pre-treatment; Mid = Mid-Treatment; Post = Post-treatment; GivE = Graded *in vivo* exposure; GA = Graded activity; Control = Wait-list control; TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; HADS = Hospital Anxiety and Depression Scale; SF-MPQ = McGill Pain Questionnaire – Short Form; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire; WAI = Working Alliance Inventory

Table 5

Means and Standard Deviations for PASS and HADS Subscales

Measure	Pre		Mid		Post		Follow-Up	
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
PASS CA								
GivE	10.73	5.18	10.73	3.88	7.93	3.63	8.60	4.42
GA	13.31	4.99	14.69	3.84	13.23	5.53	13.27	5.90
Control	14.75	5.71	13.63	6.33	11.31	4.91	12.93	5.16
PASS EA								
GivE	10.47	4.47	11.60	4.01	8.93	3.99	8.40	3.91
GA	16.38	20.53	12.46	4.96	11.00	5.86	10.64	5.02
Control	11.56	5.51	12.25	6.07	10.54	4.18	10.29	4.05
PASS F								
GivE	7.20	5.07	7.27	4.07	5.87	3.29	5.67	4.70
GA	7.31	4.94	9.15	6.23	6.92	5.69	8.64	5.32
Control	9.63	7.58	10.56	6.96	7.92	4.17	10.20	7.50
PASS PA								
GivE	5.47	4.16	5.67	4.81	2.73	2.84	3.73	4.79
GA	6.31	4.32	8.62	5.01	6.77	5.49	8.09	5.36
Control	5.63	5.97	7.25	6.81	5.92	5.82	7.20	6.47
HADS A								
GivE	6.53	2.23	7.00	3.05	5.27	2.40	4.53	3.38
GA	8.92	2.63	8.46	3.04	8.77	3.61	8.18	4.09
Control	7.25	3.00	7.31	4.29	7.40	4.24	7.92	4.31
HADS D								
GivE	4.20	2.96	4.53	3.07	3.27	3.34	3.13	4.05
GA	5.69	3.75	5.77	4.11	5.85	5.90	5.82	3.87
Control	4.56	2.16	4.81	2.81	6.00	4.02	4.85	4.14

Note. Pre = Pre-treatment; Mid = Mid-Treatment; Post = Post-treatment; GivE = Graded *in vivo* exposure; GA = Graded activity; Control = Wait-list control; PASS = Pain Anxiety Symptom Scale; HADS = Hospital Anxiety and Depression Scale; PASS CA = Cognitive Anxiety; PASS EA = Escape/Avoidance; PASS F = Fearful Appraisal; PASS PA = Physiological Anxiety; HADS A = Anxiety; HADS D = Depression

Table 6

Means and Standard Deviations for High and Low Distress Participants in the Graded in vivo Exposure Treatment Condition

Measure	Pre		Post	
	M	*SD*	*M*	*SD*
TSK				
High Distress	43.00	.58	32.71	4.11
Low Distress	39.63	.92	32.63	5.53
FABQ				
High Distress	33.42	16.01	21.85	9.56
Low Distress	27.75	13.36	15.88	10.93
PASS				
High Distress	30.42	10.59	24.14	4.29
Low Distress	35.75	15.82	26.63	14.33
PCS				
High Distress	19.28	8.19	14.42	4.72
Low Distress	16.75	9.71	9.75	5.15
HADS				
High Distress	12.14	5.39	10.00	6.48
Low Distress	9.25	2.92	7.25	3.58
SF-MPQ				
High Distress	18.85	7.26	12.57	8.30
Low Distress	15.00	6.28	9.00	4.41
PDI				
High Distress	25.71	10.76	15.14	13.38
Low Distress	15.75	10.66	7.75	5.52
PSEQ				
High Distress	17.57	8.141	10.85	10.38
Low Distress	14.13	11.06	7.50	7.39

Note. TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; HADS = Hospital Anxiety and Depression Scale; SF-MPQ = McGill Pain Questionnaire – Short Form; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire

.87; PSEQ α = .89). The internal consistency of the TSK was likely low because all participants were required to have a score higher than 38 on the TSK, and this resulted in a restriction of scores on this measure. Correlations between measures were assessed without data substitution at pre-treatment and are provided in Table 7. The correlation matrix illustrates that many of the questionnaires were related to one another, which is to be expected given the focus of many of the questionnaires on different aspects of fear, anxiety and/or pain.

Treatments differed on participant-rated credibility ($t = 2.364$, $df = 24$, $p = .027$, $\eta 2 > .435$), with the graded *in vivo* exposure treatment being seen as more credible than the graded activity treatment. Treatments did not differ in ratings of therapeutic alliance at either of the time points at which the WAI was administered (1st administration: $t = -.072$, $df = 25$, $p = .489$, $\eta 2 > .014$; 2nd administration: $t = 1.995$, $df = 25$, $p = .057$, $\eta 2 > .371$). However, therapist ratings for the graded *in vivo* exposure treatment did show an improvement across time compared to the therapist ratings for the graded activity treatment ($F(1, 26) = 9.103$, $p = .006$, $\eta 2 = .267$). Within the graded *in vivo* exposure treatment, there were no differences in therapeutic alliance ratings between the two therapists at either the first administration of the WAI ($t = .355$, $df = 13$, $p = .729$) or the second administration ($t = 1.447$, $df = 13$, $p = .172$).

Due to methodological errors (e.g., failure of participant to return the questionnaire package), several participants who completed treatment were missing data. Table 8 shows the number of participants who completed each treatment who were missing an entire data set from at least one time period. In order to reduce the number of cases that would be excluded from the analysis, data for the participants who were

Table 7

Correlations between measures at pre-treatment

		TSK	FABQ	PASS	PCS	HADS	SF-MPQ	PDI	PSEQ
TSK	Correlation								
	Significance	.							
FABQ	Correlation	.243							
	Significance	.126	.						
PASS	Correlation	.412	.458						
	Significance	.007	.003	.					
PCS	Correlation	.414	.432	.735					
	Significance	.007	.005	.001	.				
HADS	Correlation	.376	.471	.340	.544				
	Significance	.015	.002	.030	.001	.			
SF-MPQ	Correlation	.331	.467	.473	.621	.643			
	Significance	.035	.002	.002	.001	.001	.		
PDI	Correlation	.336	.654	.378	.301	.591	.562		
	Significance	.031	.001	.015	.056	.001	.001	.	
PSEQ	Correlation	.197	.582	.337	.350	.428	.339	.714	
	Significance	.216	.001	.031	.025	.005	.030	.001	.

Note. TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; HADS = Hospital Anxiety and Depression Scale; SF-MPQ = McGill Pain Questionnaire – Short Form; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire; N = 41.

Table 8

Number of participants per group missing a set of data at one time point

	Pre-treatment	Mid-Treatment	Post-Treatment	Follow-Up
GivE (n = 15)	2	0	0	2
GA (n = 13)	1	0	0	2
WLC (n = 16)	0	0	1	3

Note. GivE = Graded *in vivo* Exposure; GA = Graded Activity; WLC = Wait-List Controls

missing pre-treatment data (n = 3) were estimated using mean substitution based upon the entire pre-treatment data set. Using the entire sample to estimate missing data at subsequent time points was not viable because treatment-based changes were expected. It was also not feasible to estimate missing data at post-treatment and follow-up based only on the remaining data in each treatment condition because of the relatively small number of cases per condition. Thus, only missing data at pre-treatment was estimated using mean substitution. In order to determine whether the mean substitution values were reliable and valid indices, regression equations were also run to estimate the missing data. Table 9 shows the mean substitution value, the regression equation values for each of the participants with missing pre-treatment data, and the mean of the regression equation values for each DV. The values obtained from both methods were consistent, thereby supporting their concordant validity, though the mean substitution value was consistently more conservative that the mean regression equation value. Though only analyses with mean substitution data are reported here, all analyses testing the first hypothesis were also conducted without mean substitution. Omnibus ANOVA analyses without mean substitution data were not found to have probability values that deviated substantially from probability values in the analyses with mean substitution.

3.2 Hypothesis 1: Primary Outcome Measures

3.2.1 Omnibus testing

Primary outcome measures were identified as those relating to fear, anxiety and avoidance behaviour (i.e., TSK, FABQ, PASS, PCS). The results from mixed factorial analyses assessing change in each DV across all three treatments and all four times (pre-, mid-, and post-treatment, and follow-up) are depicted in Table 10. These analyses

Table 9

Mean substitution and regression equation values

Measure	Mean Substitution Value	Regression Equation Values			
		P11	P12	P28	Mean
FABQ	34.853	35.91	30.65	41.17	35.91
PASS	37.975	39.90	30.43	49.37	39.90
PCS	20.000	21.14	15.57	26.70	21.14
HADS	12.219	12.72	10.27	15.16	12.72
SF-MPQ	17.707	18.43	14.90	21.96	18.43
PDI	22.536	23.72	17.84	29.59	23.72
PSEQ	16.048	16.53	14.09	18.97	16.53

Note. FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; HADS = Hospital Anxiety and Depression Scale; McGill = McGill Pain Questionnaire; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire; P11 = Participant # 11; P12 = Participant # 12; P28 = Participant # 28

Table 10

Mixed factorial 3 (treatment) x 4 (time) ANOVAs for primary dependent variables

Measure	**Time**			**Treatment**			**Time x Treatment**		
	F	*p*	η2	*F*	*p*	η2	*F*	*p*	η2
TSK	18.802	.001	.363	2.739	.079	.142	4.393	.001	.210
FABQ	1.056	.371	.030	2.676	.083	.136	2.493	.027	.128
PASS	2.666	.052	.073	2.216	.125	.115	1.471	.207	.080
PCS	3.096	.030	.081	2.167	.130	.110	2.976	.010	.145

revealed a statistically significant main effect for time on the TSK (p = .001), and the PCS (p = .030), and a trend towards statistical significance on the PASS (p = .052). There was also a statistically significant time x treatment group interaction on the TSK (p = .001), FABQ (p = .027), and the PCS (p = .010). No treatment main effects were found to be significant on any primary outcome measure. Figures 4 - 7 depict the results of the 3 x 4 analyses. These figures show that individuals in the graded *in vivo* exposure treatment condition appeared to experience greater improvements on the DVs compared to the other conditions over the course of treatment and at follow-up.

Follow-up analyses were conducted to more specifically establish whether treatment effects differed between specific time points. Consistent with the outcome of the omnibus 3 (treatment) x (4 time) analysis, 3 (treatment) x 2 (time: pre- to post-treatment) mixed factorial ANOVAs on each primary outcome DV (see Table 11) revealed statistically significant main effects for time on the TSK (p = .001) and the PCS (p = .023), and a near statistically significant trend on the FABQ (p = .065). There was a statistically significant main effect for treatment found on the TSK (p = .002), and a trend towards a statistically significant main effect for treatment on the FABQ (p = .069) and PASS (p = .069). A statistically significant time x treatment group interaction was also found for the TSK (p = .007) and FABQ (p = .033). These results, and Figures 4 – 7, provide evidence that there was a change from pre- to post-treatment on most primary outcome measures, and that the extent of this change appeared to differ based on treatment.

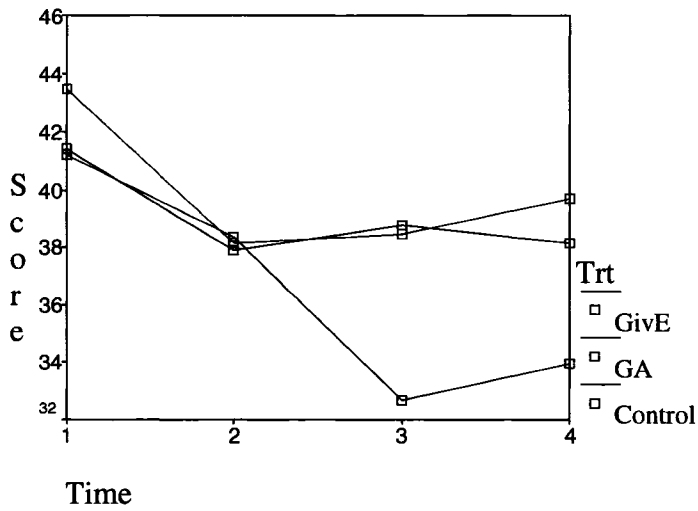

Figure 4. Mean TSK scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

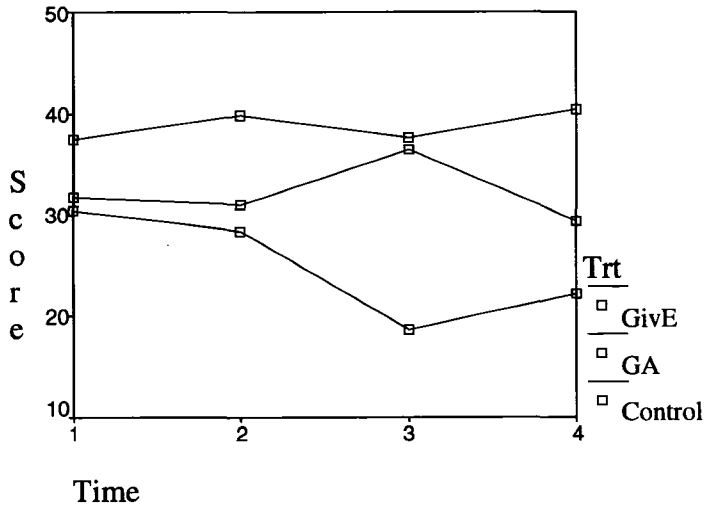

Figure 5. Mean FABQ scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

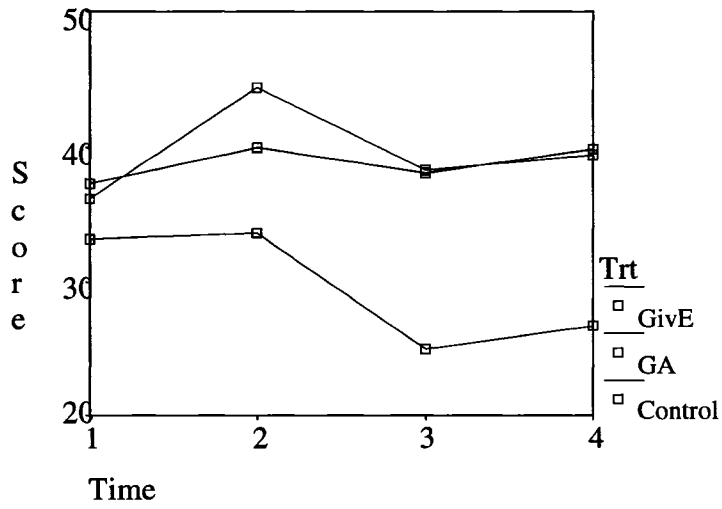

Figure 6. Mean PASS scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

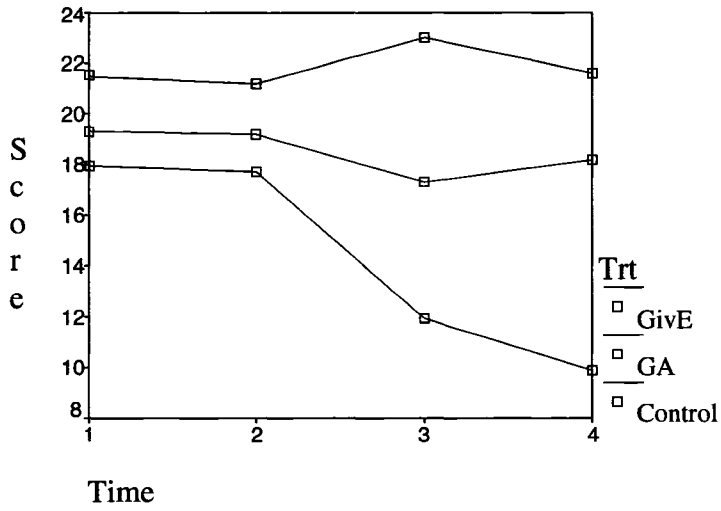

Figure 7. Mean PCS scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

Table 11

Mixed factorial 3 (treatment) x 2 (time: pre- and post-treatment) ANOVAs for primary dependent variables

Measure	**Time**			**Treatment**			**Time x Treatment**		
	F	*p*	η2	*F*	*p*	η2	*F*	*p*	η2
TSK	46.354	.001	.537	7.555	.002	.274	5.559	.007	.218
FABQ	3.607	.065	.085	2.873	.069	.128	3.744	.033	.161
PASS	2.322	.136	.056	2.861	.069	.128	1.608	.213	.076
PCS	5.549	.023	.122	2.450	.099	.109	2.454	.099	.109

3.2.2 Two by two comparisons

Two (treatment: graded *in* vivo exposure and graded activity or wait-list control) by two (time: pre-treatment and post-treatment) repeated measures comparisons were conducted to determine specifically how treatment conditions influenced the DVs across time. As graded *in* vivo exposure tended to produce the most change (as depicted in Figures 4-7), graded activity was only compared to the control group when graded *in vivo* exposure was found to have a stronger effect than one of the other two treatment conditions, or when graded activity also showed a trend for greater change than the graded *in vivo* exposure or control conditions. Data from the mid-treatment time point were not considered in these analyses because pre-treatment to post-treatment change was of primary interest, and because Figures 4 - 7 indicate that relatively little improvement occurred between pre-treatment and mid-treatment.

Tables 12a and 12b show the results of the 2 x 2 analyses (Note: Treatment main effects are not reported in tables depicting the results of 2 x 2 analyses [i.e., Tables 12a, 12b, 15a, 15b] as the treatment main effects are not of interest and do not provide relevant information [Huck and MacLean, 1975]. Only statistically significant interaction effects are reported in text). From pre- to post-treatment, individuals in the graded *in vivo* exposure treatment evidenced greater improvements than did individuals in the wait-list control group on the TSK (p = .003) and the FABQ (p = .018). From pre-treatment to follow-up, graded *in vivo* exposure produced greater change than the control group on the PCS (p = .018), and greater change than the graded activity group on the FABQ (p = .008). The degree of change produced by graded *in vivo* exposure from pre- to post-treatment or follow-up, compared to graded activity, approached statistical significance

Table 12a

Repeated measure comparisons from pre- to post-treatment for primary dependent variables

Measure	Treatments	Time			Time x Treatment		
		F	*p*	η2	*F*	*p*	η2
TSK	GivE vs GA	40.367	.001**	.608	5.787	.024*	.182
	GivE vs WLC	45.664	.001**	.620	10.891	.003**	.280
FABQ	GivE vs GA	12.641	.001**	.327	5.854	.023*	.184
	GivE vs WLC	3.326	.079	.110	6.297	.018*	.189
PASS	GivE vs GA	3.059	.092	.105	4.268	.049*	.141
	GivE vs WLC	3.837	.061	.124	1.390	.249	.049
PCS	GivE vs GA	9.609	.005**	.270	2.402	.133	.085
	GivE vs WLC	4.379	.046*	.135	4.189	.050*	.130
	GA vs WLC	.519	.478	.020	.454	.506	.017

Note. GivE = Graded *in vivo* exposure; GA = Graded activity; WLC = Wait-list control; TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; * significant at $p < .05$; ** = significant at $p < .01$

Table 12b

Repeated measure comparisons from pre-treatment to follow-up for primary dependent variables

Measure	Treatments	Time			Time x Treatment		
		F	*p*	η2	*F*	*p*	η2
TSK	GivE vs GA	29.363	.001**	.880	2.650	.117	.099
	GivE vs WLC	27.609	.001**	.525	2.993	.096	.107
FABQ	GivE vs GA	1.103	.304	.044	8.295	.008*	.257
	GivE vs WLC	6.344	.018*	.196	1.047	.316	.039
	GA vs WLC	.007	.933	.000	3.009	.097	.120
PASS	GivE vs GA	.328	.572	.013	2.755	.110	.103
	GivE vs WLC	.836	.369	.031	2.184	.152	.077
PCS	GivE vs GA	6.225	.020*	.206	3.612	.069	.139
	GivE vs WLC	5.680	.025*	.179	6.369	.018*	.197

Note. GivE = Graded *in vivo* exposure; GA = Graded activity; WLC = Wait-list control; TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; * significant at $p < .05$; ** = significant at $p < .01$

for several of the DVs (e.g., TSK: $p = .024$, FABQ: $p = .023$, PASS: $p = .049$, PCS: $p = .069$), but failed to meet it at the a priori $p = .01$ standard. Similarly, individuals in the graded *in vivo* exposure, compared to those in the wait-list control condition, demonstrated a trend for improvements on the PCS ($p = .050$). Graded activity did not produce greater change on any of the DVs compared to the wait-list control condition.

3.2.3 Subscale comparisons

Several of the questionnaires in the primary analyses have subscales. However, the PASS contains subscales (cognitive appraisal, escape/avoidance, fearful appraisal, and physiological anxiety) that are of particular relevance to the fear-avoidance model of chronic pain. Though PASS scores did not differ across time between the three treatment conditions, a secondary analysis focussing on the four PASS subscales was conducted in order to determine if the constructs measured by the specific subscales were differentially affected by treatment condition across time. A 3 (treatment) x 4 (time) repeated measures ANOVA utilizing the four PASS subscales as the DVS indicated that there was no main effects for time ($F(12, 262) = 1.688, p = .069, \eta 2 = .064$) or treatment ($F(8, 62) = 1.181, p = .325, \eta 2 = .132$), and no time-by treatment interaction ($F(24, 347) = 1.104, p = .336, \eta 2 = .062$). Similarly, a 3 (treatment) x 2 (time: pre-treatment to post-treatment) repeated measures analysis revealed that there was no main effect for time ($F(4, 34) = 2.591, p = .054, \eta 2 = .234$) or treatment ($F(8, 68) = 1.373, p = .224, \eta 2 = .139$) or the time by treatment interaction ($F(8, 68) = 1.338, p = .240, \eta 2 = .136$).

Specific 2 (treatment) x 2 (time: pre-treatment to post-treatment) repeated measures analyses showed that the physiological anxiety subscale decreased significantly in the graded *in vivo* exposure condition compared to the graded activity condition ($F(1,$

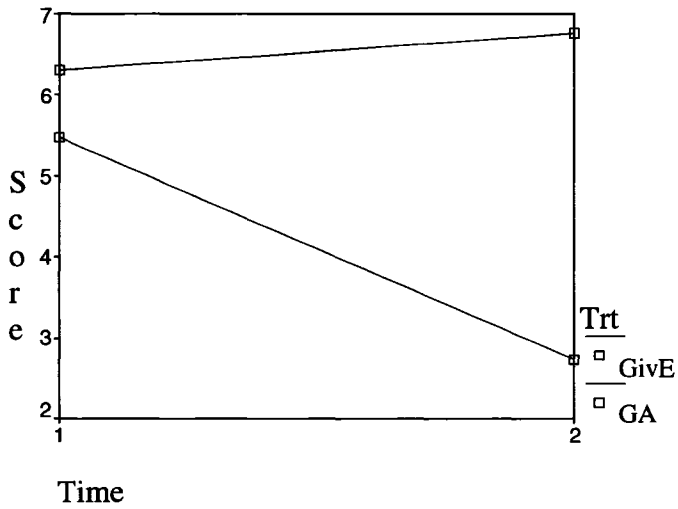

Figure 8. Mean PASS Physiological Anxiety scores by treatment condition at pre-treatment (Time 1) and post-treatment (Time 2). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity). Original in Colour.

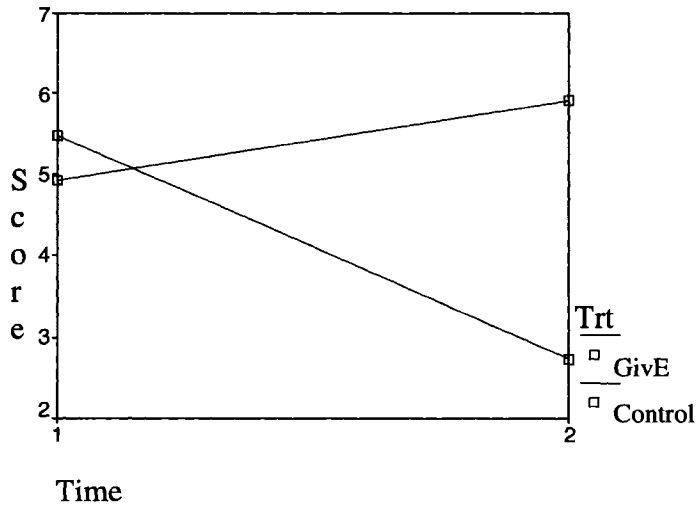

Figure 9. Mean PASS Physiological Anxiety scores by treatment condition at pre-treatment (Time 1) and post-treatment (Time 2). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; Control = Wait-List Control). Original in Colour.

36) = 7.050, p = .013, $\eta 2$ = .213; see Figure 8), and approached statistical significance compared to the control group ($F(1, 48) = 6.024$, p = .021, $\eta 2$ = .188; see Figure 9). None of the other PASS subscales differed between treatment conditions.

3.3 Hypothesis 1: Secondary Outcome Measures

3.3.1 Omnibus testing

Secondary outcome measures were identified as those relating to ratings of non-pain related anxiety and depression, pain, disability and pain self-efficacy (i.e., HADS, SF-MPQ, PDI, PSEQ). The results from omnibus mixed factorial 3 (treatment) x 4 (time: pre-, mid-, and post-treatment, and follow-up) ANOVAs assessing change in each DV are depicted in Table 13 and Figures 10 - 13. These analyses revealed a main effect for time on the SF-MPQ (p = .005) and PDI (p = .004), and a treatment x time interaction on the HADS (p = .036). There was also a trend towards a statistically significant interaction on the PSEQ (p = .069). There were no main effects for treatment on any DV. Similarly, 3 (treatment) x 2 (time: pre- to post-treatment) analyses (see Table 14) revealed that there was a main effect for time on the SF-MPQ (p = .002) and PDI (p = .001), a main effect for treatment on the HADS (p = .047), and a near-statistically significant trend for an interaction effect between time and treatment on the PSEQ (p = .058). These results, and Figures 10 – 13, provide evidence that there was a change from pre- to post-treatment on most primary outcome measures, and that the extent of this change appeared to differ based on treatment.

3.3.2 Two by two comparisons

Two (treatment: graded *in* vivo exposure and graded activity or wait-list control) by two (time: pre-treatment and post-treatment) repeated measures comparisons were conducted

Table 13

Mixed factorial 3 (treatment) x 4 (time) ANOVAs for secondary outcome measures

Measure	Time			Treatment			Time x Treatment		
	F	*p*	η2	*F*	*p*	η2	*F*	*p*	η2
HADS	1.106	.343	.031	2.353	.110	.119	2.349	.036	.118
SF-MPQ	5.170	.005	.129	1.724	.193	.090	1.050	.392	.057
PDI	5.557	.004	.137	1.857	.117	.096	1.308	.283	.070
PSEQ	.883	.453	.025	.457	.637	.026	2.027	.069	.107

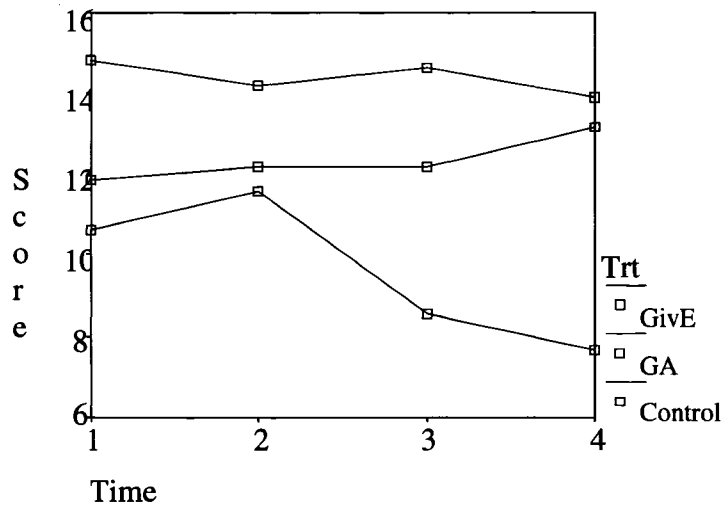

Figure 10. Mean HADS scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

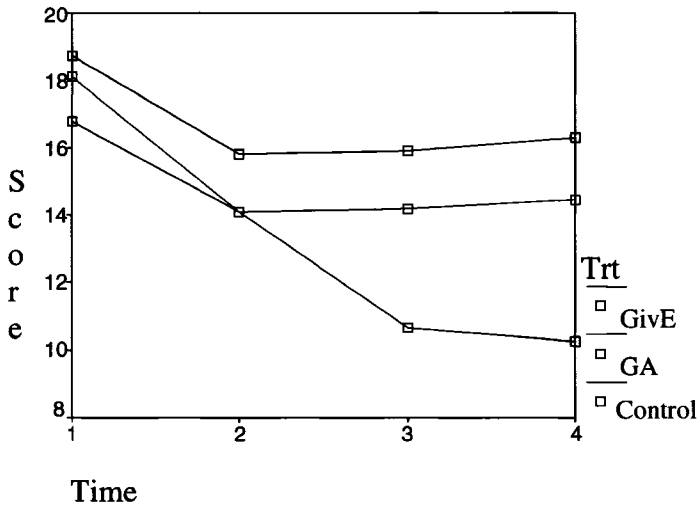

Figure 11. Mean SF-MPQ scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

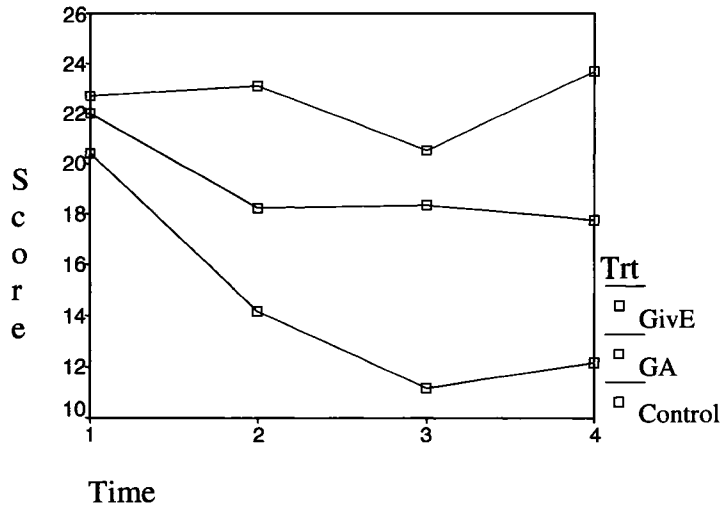

Figure 12. Mean PDI scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

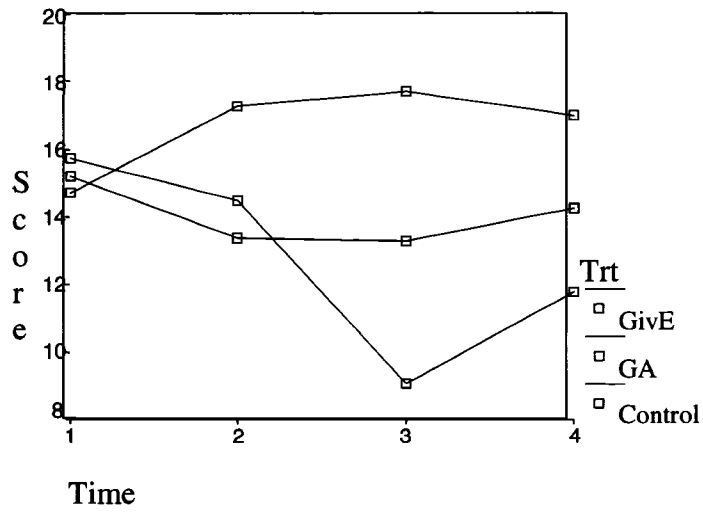

Figure 13. Mean PSEQ scores by treatment condition at pre-treatment (Time 1), mid-treatment (Time 2), post-treatment (Time 3) and follow-up (Time 4). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity; Control = Wait-List Control). Original in Colour.

Table 14

Mixed factorial 3 (treatment) x 2 (time: pre-treatment and post-treatment) ANOVAs for secondary outcome measures

Measure	**Time**			**Treatment**			**Time x Treatment**		
	F	*p*	η2	*F*	*p*	η2	*F*	*p*	η2
HADS	.112	.739	.003	3.299	.047	.142	2.427	.101	.108
SF-MPQ	11.025	.002	.216	1.460	.244	.068	2.033	.144	.092
PDI	25.279	.001	.387	.940	.399	.045	1.853	.170	.085
PSEQ	.795	.378	.019	1.055	.358	.050	3.055	.058	.133

to determine specifically how treatment conditions impacted the DVs across time. As graded *in* vivo exposure tended to produce greater change (as depicted in Figures 10 – 13), graded activity was only compared to the control group when graded *in vivo* exposure was found to have a stronger effect than one of the other two treatment conditions, and/or when graded activity also showed a trend for greater change than the graded *in vivo* exposure or control conditions. Data from mid-treatment were not considered in these analyses because pre-treatment to post-treatment change was of primary interest, and because Figures 10 – 13 indicate that relatively little improvement occurred between pre-treatment and mid-treatment.

Table 15a and 15b show the results of the 2 x 2 analyses. Graded *in vivo* exposure produced greater improvements than graded activity on the PSEQ (p = .009) from pre- to post-treatment, and on the PDI (p = .005) from pre-treatment to follow-up. No other interaction effects were found, though there was a non-statistically significant trend for graded *in* vivo exposure to produce more improvement than graded activity on the HADS (p = .051), and more improvement than the control condition on the HADS (p = .044), SF-MPQ (p = .089), PDI (p = .081), and MPQ (p = .080). Graded activity did not produce greater change on any of the DVs compared to the wait-list control condition.

3.3.3 Subscale comparisons

Though several of the questionnaires in the secondary analyses have subscales, the HADS contains the only measure of depression within the study, as well as a measure of non-specific anxiety. The omnibus analysis also evidenced a trend for graded *in vivo* exposure to reduce HADS scores compared to the graded activity and wait-list control

Table 15a

Repeated measure comparisons from pre- to post-treatment for secondary dependent variables

Measure	Treatments	Time			Time x Treatment		
		F	*p*	η2	*F*	*p*	η2
HADS	GivE vs GA	3.623	.068	.122	4.205	.051*	.139
	GivE vs WLC	.180	.675	.006	3.864	.059	.121
SF-MPQ	GivE vs GA	16.239	.001**	.384	1.002	.326	.037
	GivE vs WLC	5.722	.024*	.170	3.098	.089	.100
PDI	GivE vs GA	26.084	.001**	.501	3.138	.088	.108
	GivE vs WLC	25.409	.001**	.476	3.286	.081	.105
PSEQ	GivE vs GA	1.593	.218	.058	7.923	.009**	.234
	GivE vs WLC	3.444	.074	.110	3.309	.080	.106
	GA vs WLC	.298	.590	.011	.331	.570	.013

Note. GivE = Graded *in vivo* exposure; GA = Graded activity; WLC = Wait-list control; HADS = Hospital Anxiety and Depression Scale; SF-MPQ = McGill Pain Questionnaire – Short Form; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire; ** = significant at $p < .05$; * = significant at $p < .01$

Table 15b

Repeated measure comparisons from pre-treatment to follow-up for secondary dependent variables

Measure	Treatments	Time			Time x Treatment		
		F	*p*	η2	*F*	*p*	η2
HADS	GivE vs GA	5.021	.035*	.173	1.394	.249	.055
	GivE vs WLC	.751	.394	.028	4.49	.044*	.147
SF-MPQ	GivE vs GA	9.880	.004**	.292	.802	.379	.032
	GivE vs WLC	4.366	.047*	.144	2.036	.165	.073
PDI	GivE vs GA	5.712	.025*	.192	9.325	.005**	.280
	GivE vs WLC	8.542	.001**	.247	1.171	.289	.043
	GA vs WLC	.329	.572	.015	.976	.334	.042
PSEQ	GivE vs GA	.251	.621	.010	3.502	.074	.127
	GivE vs WLC	4.378	.047*	.149	2.208	.150	.081

Note. GivE = Graded *in vivo* exposure; GA = Graded activity; WLC = Wait-list control; HADS = Hospital Anxiety and Depression Scale; McGill = McGill Pain Questionnaire; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire; ** = significant at $p < .05$; * = significant at $p < .01$

condition, and it was of interest to determine whether this trend was better accounted for by changes in scores on the HADS depression or anxiety subscales. The HADS subscales were, therefore, subjected to a 3 (treatment) x 4 (time: pre-, mid-, post-treatment, and follow-up) omnibus repeated measures analysis to determine whether mood and anxiety were affected differentially across treatments. This analysis did not indicate any effect for time ($F(6, 208) = .772, p = .593, \eta 2 = .022$), treatment ($F(4, 68) = 1.320, p = .271, \eta 2 = .072$), or the interaction between the two ($F(12, 208) = 1.350, p = .193, \eta 2 = .072$), suggesting that the different treatments did not differentially effect HADS subscale scores over time. Consistent with the omnibus test, a 3 (treatment) x 2 (time: pre- to post-treatment) analysis revealed no main effect for time ($F(2, 39) = 1.250, p = .298, \eta 2 = .060$), treatment ($F(4, 78) = 1.895, p = .120, \eta 2 = .089$), or the interaction between the two ($F(4, 78) = 1.479, p = .217, \eta 2 = .070$). However, subsequent 2 (treatment) x 2 (time: pre- and post-treatment) analyses revealed a trend for a time by treatment effect between the graded *in vivo* exposure and both the graded activity ($F(1, 16) = 4.205, p = .051, \eta 2 = .139$; Figure 14) and control conditions ($F(1, 19) = 4.943, p = .034, \eta 2 = .150$; Figure 15) for the depression subscale.

3.4 Hypothesis 2: Stability of Improvements

Paired t-tests were conducted to assess change from post-treatment to follow-up in the graded *in vivo* exposure treatment. Table 16 shows that no changes ($p < .01$) in any of the DVs occurred between post-treatment and follow-up, with the exception of the PSEQ, on which scores tended to worsen ($p = .01$). Overall, these findings suggest that improvements in scores on the dependent measures for participants in the graded *in* vivo exposure treatment were maintained in the four weeks following the end of treatment.

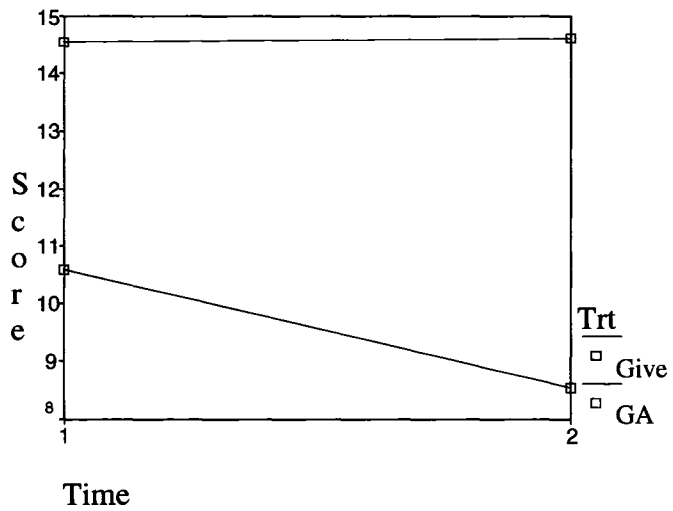

Figure 14. Mean HADS depression subscale scores by treatment condition at pre-treatment (Time 1) and post-treatment (Time 2). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; GA = Graded Activity). Original in Colour.

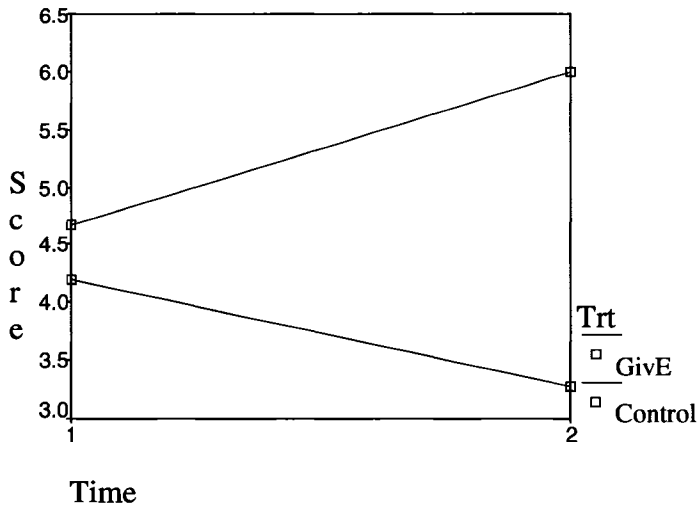

Figure 15. Mean HADS depression subscale scores by treatment condition at pre-treatment (Time 1) and post-treatment (Time 2). (Trt = Treatment Condition; GivE = Graded *in vivo* Exposure; Control = Wait-List Control). Original in Colour.

Table 16

Paired t-test for each DV in the graded in vivo exposure condition

Measure	Times	*t*	*df*	*p*	η2
TSK	1 vs 2	2.811	14	.014	.433
	2 vs 3	6.355	14	.001	.560
	3 vs 4	-1.252	14	.231	-.118
FABQ	1 vs 2	.789	14	.443	.079
	2 vs 3	5.187	14	.001	.100
	3 vs 4	-1.337	14	.203	-.132
PASS	1 vs 2	-.170	14	.867	-.016
	2 vs 3	4.148	14	.001	.384
	3 vs 4	-.760	14	.460	-.073
PCS	1 vs 2	.133	14	.896	.010
	2 vs 3	3.162	14	.007	.334
	3 vs 4	1.185	14	.256	.144
HADS	1 vs 2	-1.262	14	.228	-.095
	2 vs 3	4.305	14	.001	.273
	3 vs 4	1.341	14	.201	.071
SF-MPQ	1 vs 2	1.225	14	.241	.188
	2 vs 3	2.856	14	.013	.236
	3 vs 4	.269	14	.792	.020
PDI	1 vs 2	2.949	14	.011	.301
	2 vs 3	1.805	14	.093	.162
	3 vs 4	-.820	14	.426	-.046
PSEQ	1 vs 2	.818	14	.427	.060
	2 vs 3	3.529	14	.003	.259
	3 vs 4	-2.867	14	.012	-.138

Note. GivE= Graded *in vivo* exposure; Time 1 = Pre-Treatment; Time 2 = Mid-treatment; Time 3 = End of treatment; Time 4 = Follow-up; TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; HADS = Hospital Anxiety and Depression Scale; SF-MPQ = McGill Pain Questionnaire; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire

3.5 Hypothesis 3: High vs. Low Distress

It was hypothesized that patients treated with graded *in vivo* exposure who have the greatest distress (i.e., fearful pain beliefs, as assessed by the TSK) prior to treatment would demonstrate the greatest overall improvement (as assessed by the dependent measures) at post-treatment and follow-up. A median split procedure, using the pre-treatment scores of the TSK, was used to divide participants in the graded *in vivo* exposure group into high distress and low distress groups. Given the limited number of participants (n = 15) in the graded *in vivo* treatment, a repeated measures with multiple DVs was not performed. Rather, a series of 2 (high and low distress participants) x 2 (time: pre-treatment to post-treatment) mixed repeated measures factorial analyses were used to assess each DV. Prior analyses indicated that each of the DVs showed significant improvement within the graded *in* vivo exposure condition; therefore, the time main effects are not reported here. Table 17 shows that there was no time by distress interaction for any of the DVs, suggesting that the high distress participants did not show greater improvements on any of the measures than did the low distress participants.

3.6 Process and Significance of Change

3.6.1 Treatment specific change

The repeated measures factorial analyses consistently indicated a main effect for time for many of the DVs amongst both the primary and secondary outcome measures. Therefore, paired-samples t-tests were conducted on each DV for each treatment group to compare change from pre- to post-treatment and pre-treatment to follow-up in order to identify which treatment conditions produced improvements on each DV. Tables 18a and 18b illustrate the relevant data. Participants in the graded *in vivo* exposure treatment

Table 17

Pre-treatment to post-treatment repeated measure comparisons of high and low distress participants in the graded in vivo exposure condition

Measure	**Time x Distress**			
	F	*df*	*p*	η2
TSK	1.810	1	.201	.122
FABQ	.004	1	.951	.001
PASS	.461	1	.509	.034
PCS	.308	1	.588	.023
HADS	.010	1	.921	.001
SF-MPQ	.004	1	.948	.001
PDI	.923	1	.354	.066
PSEQ	.001	1	.978	.001

Note. TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; HADS = Hospital Anxiety and Depression Scale; McGill = McGill Pain Questionnaire; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire

Table 18a

Paired t-test for each primary outcome measure and the PHODA at various time points.

Measure	Comparisons		t-test			
	Treatment	Times	*t*	*df*	*p*	η2
TSK	GivE	1 vs 3	6.810	14	.001	.763
		1 vs 4	5.220	14	.001	.638
	GA	1 vs 3	2.540	12	.025	.389
		1 vs 4	2.641	10	.026	.380
	C	1 vs 3	2.564	14	.023	.297
		1 vs 4	2.375	11	.037	.363
FABQ	GivE	1 vs 3	4.999	14	.001	.423
		1 vs 4	2.585	14	.020	.264
	GA	1 vs 3	.689	12	.504	.056
		1 vs 4	-1.724	10	.115	-.101
	C	1 vs 3	-.370	13	.717	-.049
		1 vs 4	1.028	12	.324	.102
PASS	GivE	1 vs 3	3.014	14	.009	.326
		1 vs 4	1.623	14	.127	.233
	GA	1 vs 3	-.201	12	.844	-.020
		1 vs 4	-.784	10	.451	-.095
	C	1 vs 3	.447	13	.662	.056
		1 vs 4	-.430	12	.675	-.038
PCS	GivE	1 vs 3	3.196	14	.006	.381
		1 vs 4	3.114	14	.008	.422
	GA	1 vs 3	1.157	12	.270	.088
		1 vs 4	.451	10	.661	.047
	C	1 vs 3	.030	14	.976	.003
		1 vs 4	-.123	12	.904	-.011
PHODA	GivE	1 vs 3	7.285	14	.001	.605

Note. GivE= Graded *in vivo* exposure; GA = Graded activity; C = Wait-list control; Time 1 = Pre-Treatment; Time 3 = End of treatment; Time 4 = Follow-up; TSK = Tampa Scale for Kinesiophobia; FABQ = Fear avoidance Behaviour Questionnaire; PASS = Pain Anxiety Symptom Scale; PCS = Pain Catastrophising Scale; PHODA = Photograph series of Daily Activities

Table 18b

Paired t-test for each secondary outcome measure and the WAI at various time points.

Measure	**Comparisons**		**t-test**			
	Treatments	Times	*t*	*df*	*p*	η2
HADS	GivE	1 vs 3	3.042	14	.009	.212
		1 vs 4	2.705	14	.017	.247
	GA	1 vs 3	-.096	12	.925	-.006
		1 vs 4	.673	10	.516	-.068
	C	1 vs 3	-.838	14	.416	-.107
		1 vs 4	-.723	12	.484	-.097
SF-MPQ	GivE	1 vs 3	2.944	14	.011	.418
		1 vs 4	2.680	14	.018	.391
	GA	1 vs 3	3.593	12	.004	.208
		1 vs 4	2.049	10	.068	.197
	C	1 vs 3	.446	14	.663	.057
		1 vs 4	.434	12	.672	.070
PDI	GivE	1 vs 3	6.909	14	.001	.387
		1 vs 4	4.549	14	.001	.335
	GA	1 vs 3	1.834	12	.092	.141
		1 vs 4	-.396	10	.700	-.028
	C	1 vs 3	1.859	14	.084	.167
		1 vs 4	.970	12	.351	.141
PSEQ	GivE	1 vs 3	4.358	14	.001	.341
		1 vs 4	2.493	14	.026	.189
	GA	1 vs 3	-.834	12	.421	.102
		1 vs 4	-.702	10	.499	-.088
	C	1 vs 3	.020	14	.984	.003
		1 vs 4	.456	11	.658	.038
WAI	GivE	2 vs 3	-3.559	14	.003	-.389
	GA	2 vs 3	.523	11	.611	.052

Note. GivE= Graded *in vivo* exposure; GA = Graded activity; C = Wait-list control; Time 1 = Pre-Treatment; Time 3 = End of treatment; Time 4 = Follow-up; HADS = Hospital Anxiety and Depression Scale; SF-MPQ = McGill Pain Questionnaire; PDI = Pain Disability Index; PSEQ = Pain Self-Efficacy Questionnaire; WAI = Working Alliance Inventory

group, but not the graded activity or wait-list control groups, demonstrated statistically significant improvements on every measure from pre- to post-treatment and pre-treatment to follow-up, and almost every measure from pre-treatment to follow-up. Only on the FABQ (p = .020), PASS (p = .127) and PSEQ (p = .026) did graded i*n vivo* exposure not produce statistically significant change at $p < .01$. In contrast to the graded *in vivo* exposure group, statistically significant improvements for the graded activity group were demonstrated only on the SF-MPQ (p = .004) from pre- to post-treatment, and there were no improvements evidenced on any of the DVs for the wait-list control group (though both of these conditions demonstrated a trend towards significance on the TSK). The change demonstrated by the graded *in vivo* exposure participants was not always statistically significantly greater than the change demonstrated by participants in the other two groups, as illustrated in the previous mixed factorial repeated measures.

Additional paired t-tests were conducted on the measures for which change was demonstrated (as evidenced in Table 18a and 18b) in order to determine whether change in scores occurred more prominently from pre- to mid-treatment or from mid- to post-treatment. The results of the paired t-tests are shown in Table 16, and indicate that the majority of improvement in the graded *in vivo* exposure condition appeared to occur between mid- and post-treatment. In contrast to the general pattern for the graded *in* vivo exposure condition, the graded activity condition scores on the SF-MPQ improved statistically significantly between pre- and mid-treatment (t = 2.720, df = 12, p = .019), and then to plateau from mid-treatment to post-treatment (t = -.358, df =12, p = .727).

3.6.2 Clinically significant change

Clinically significant change has been defined by Jacobson and Truax (1991) as "the extent to which therapy moves someone outside the range of the dysfunctional population or within the range of the functional population" (p. 12). Jacobson and Truax also indicated that one possible way of identifying clinically significant change is to determine whether the post-treatment score falls outside two standard deviations of the mean of the population of interest. In the present investigation, Jacobson and Truax's definition was utilized with TSK scores from pre-treatment to post-treatment. The TSK was chosen to assess clinically significant change because it was a primary outcome measure, it has strong psychometric properties (as described previously), and because TSK scores were a central determinant of eligibility for participation. Figure 16 indicates the proportion of participants in each treatment condition who demonstrated clinically significant change according to the definition provided by Jacobson and Truax. Chi-square analyses showed a greater proportion of participants demonstrated clinically significant change in the graded *in vivo* exposure treatment compared to either the graded activity ($\chi 2$ (1, $N = 28$) = 12.25, $p = .001$, $\eta 2 > .44$), or wait-list control conditions ($\chi 2$ (1, $N = 30$) = 13.89, $p = .001$, $\eta 2 > .46$). No difference was found between the graded activity and wait-list control conditions ($\chi 2$ (1, $N = 28$) = .01, $p > .916$, $\eta 2 > .001$).

A less conservative measure of clinical significance – defined as a decrease in score on the TSK by more than 2 SD – was also utilized to assess the significance of change from pre- to post-treatment. Figure 17 indicates the proportion of participants in each treatment condition who demonstrated clinically significant change according to this definition. Chi-square analyses show that there was a greater proportion of participants

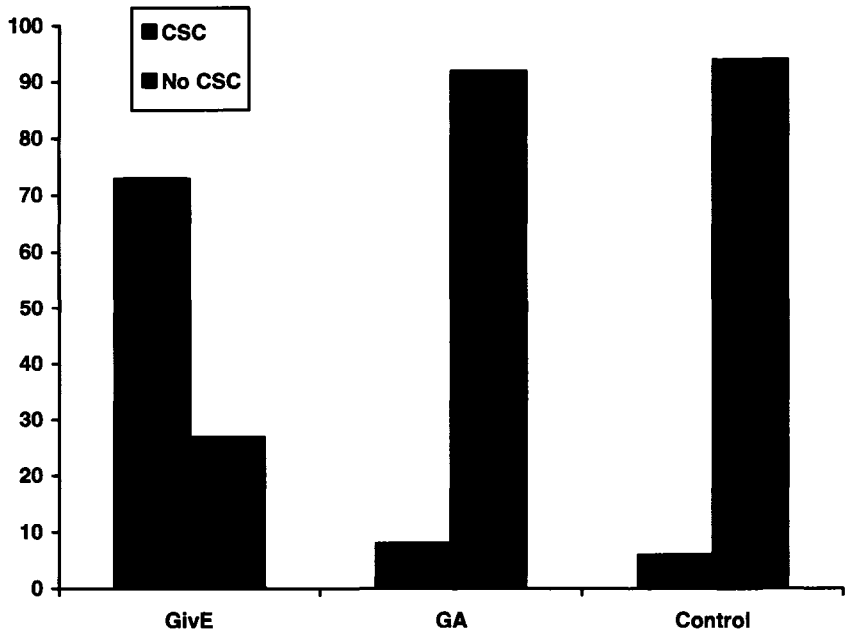

Figure 16. Proportion of participants in each treatment condition who demonstrated clinically significant change, according to Jacobson and Truax's (1992) definition, on the TSK. (GivE = Graded *in vivo* Exposure; Control = Wait-List Control; CSC = Clinically Significant Change). Original in Colour.

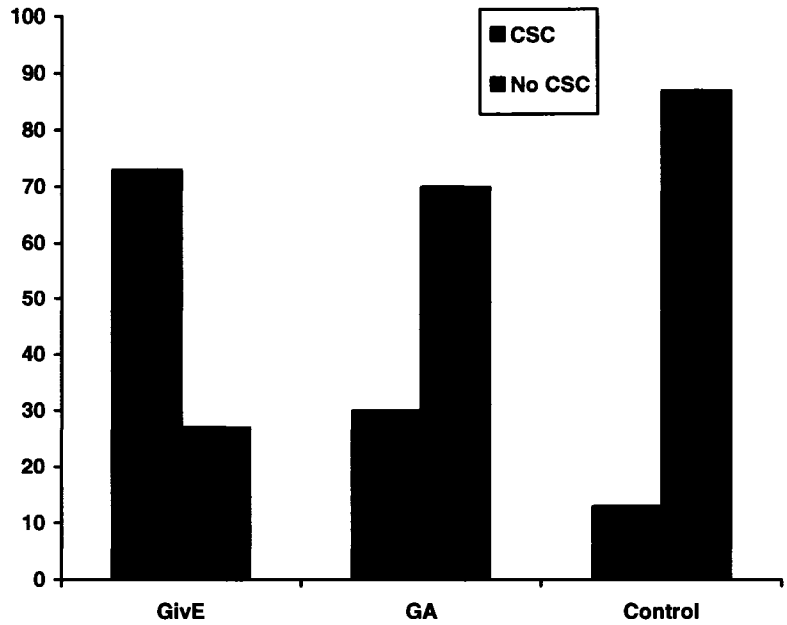

Figure 17. Proportion of participants in each treatment condition who demonstrated a 2 SD decrease in score on the TSK. (GivE = Graded *in vivo* Exposure; Control = Wait-List Control; CSC = Clinically Significant Change). Original in Colour.

who demonstrated clinically significant change in the graded *in vivo* exposure treatment compared to either the graded activity ($\chi 2$ (1, $N = 27$) = 4.3, $p = .038$, $\eta 2 > .16$) or wait-list control conditions ($\chi 2$ (1, $N = 30$) = 10.9, $p = .001$, $\eta 2 > .36$). No difference was found between the graded activity and wait-list control conditions ($\chi 2$ (1, $N = 27$) = 1.5, $p > .214$, $\eta 2 > .05$).

The proportion of individuals who no longer met criteria for being categorized as having fear of pain was also of interest as an indicator of the clinical significance of change produced by each treatment modality. This method of assessing clinically significant change has been utilized in prior research (e.g., Openshaw, Waller, & Sperlinger, 2004). Figures 18 and 19 show the proportion of participants in each treatment group with a TSK score below 38 (the cut-off for entry into the study) at post-treatment and follow-up, respectively. As would be expected from the analysis of clinically significant change, a statistically significantly greater proportion of participants in the graded *in vivo* exposure compared to participants in the graded activity condition fell below the cut-off score at post-treatment ($\chi 2$ (1, $N = 28$) = 9.6, $ps < .002$, $\eta 2 > .34$), but not follow-up ($ps > .14$). Graded *in vivo* exposure was also found to be superior in this regard to the control condition at both post-treatment ($\chi 2$ (1, $N = 30$) = 7.7, $ps < .005$, $\eta 2 > .25$) and follow-up ($\chi 2$ (1, $N = 12$) = 4.3, $ps < .038$, $\eta 2 > .16$). No significant differences were evidenced between the graded activity and control conditions at either post-treatment or follow-up.

Individuals in the graded *in vivo* exposure treatment also demonstrated statistically significant reductions from pre-treatment to post-treatment ($t = 7.29$, $df = 14$,

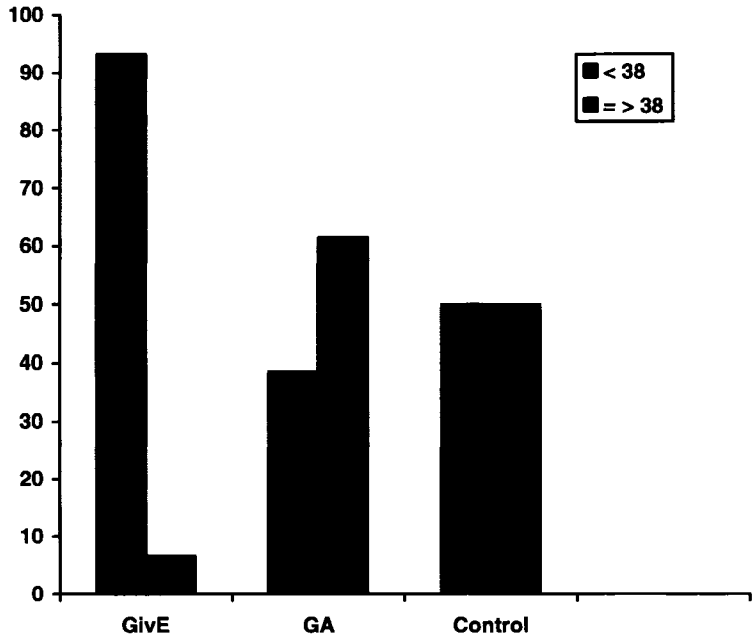

Figure 18. Proportion of participants in each treatment condition who had TSK scores below 38 at post-treatment. (GivE = Graded *in vivo* Exposure; Control = Wait-List Control; CSC = Clinically Significant Change). Original in Colour.

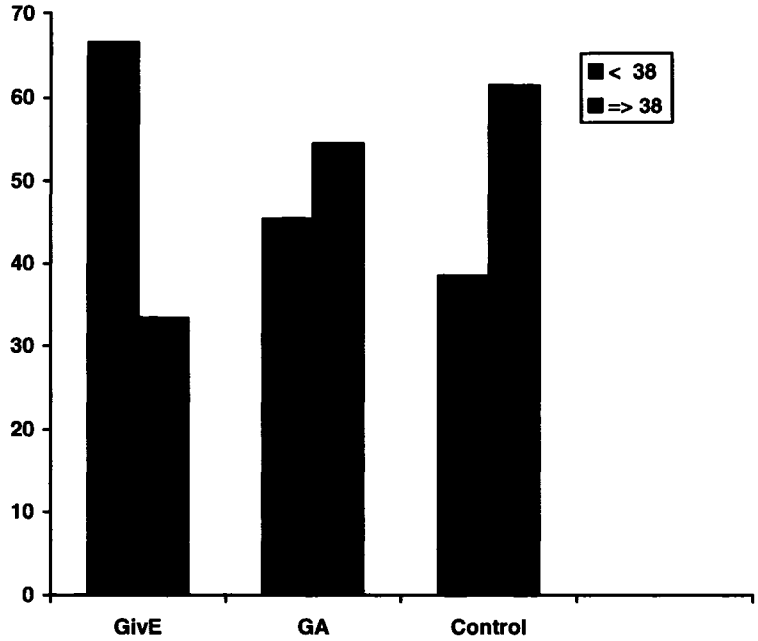

Figure 19. Proportion of participants in each treatment condition who had TSK scores below 38 at follow-up. (GivE = Graded *in vivo* Exposure; Control = Wait-List Control; CSC = Clinically Significant Change). Original in Colour.

$p < .001$) in scores on the PHODA, which provided a measure of the degree to which patients feared and avoided particular activities. Decreases in PHODA scores suggest increases in functioning. Participants who received graded *in vivo* exposure demonstrated an average decrease of 65% in PHODA scores.

Chapter 4: Discussion

The aim of the present study was to examine the effectiveness of graded *in vivo* exposure treatment, in comparison to graded activity and a wait-list control condition, as a means of reducing fear of pain/movement and other negative emotions experienced by patients with chronic pain. Forty-four patients with chronic low back pain and high fear of pain were randomly assigned to one of the three treatment conditions and were assessed at pre-, mid-, and post-treatment, and one-month following the end of treatment. Generally, the results provide support for the hypotheses. The first hypothesis – that patients receiving graded *in vivo* exposure, but not patients in the graded activity or wait-list control conditions, would evidence improvements in kinesiophobia, fear-avoidance beliefs, pain-related behaviours, pain catastrophising, symptoms of chronic back pain, and disability due to pain – was partially supported. The second hypothesis – that improvements amongst individuals in the graded *in vivo* exposure condition would be maintained at one-month follow-up – was supported. The third hypothesis – that individuals in the graded *in vivo* exposure treatment who had higher distress (as measured by the TSK) would evidence greater improvements – was not supported. The analyses also addressed several other relevant issues, including an examination of the clinical significance and process of change for patients in the graded *in vivo* exposure treatment. The major findings, and how they inform the most recent version of the fear-avoidance model (Asmundson, Norton, et al., 2004) and current treatment protocols are discussed below.

4.1 Assessment of the Hypotheses

4.1.1 Preliminary Analyses

No statistically significant difference between treatments was found for ratings of the therapeutic relationship, suggesting that the quality of the therapeutic relationship is unlikely to have differentially influenced outcome across treatments. However, ratings of the therapeutic relationship did improve statistically significantly from mid-treatment to post-treatment with the graded *in vivo* exposure therapists, but not with the graded activity therapist. The latter finding is not unexpected as graduate students in clinical psychology, including those who delivered the graded in vivo exposure protocol in this study, have specific and in-depth training focusing on the development of therapeutic relationships, and therefore would be expected to demonstrate improved relationships with their clients over the course of therapy.

In contrast to the results of the comparison of the therapeutic relationship across treatments, treatment credibility ratings did differ across treatments: Graded *in vivo* exposure was rated as being a statistically significantly more credible treatment than graded activity. In one respect, this result is surprising given that one would expect members of the general population to be more likely to perceive a physically based treatment for chronic pain to have more credibility than a psychological based treatment. In fact, this conjecture seems to have credence given the high number of drop-outs from the graded *in vivo* exposure treatment. However, it is possible that, to some extent, the sample of participants that completed graded *in vivo* exposure was self-selected – many of the individuals who dropped out gave indications that they perceived graded *in vivo* exposure to be an inappropriate form of treatment for their condition, or stated that they

had hoped they would be assigned to the graded activity treatment. In this case, it is not unexpected that graded *in vivo* exposure received higher ratings of credibility as it is likely that only patients who had some belief in its credibility remained in treatment (of course, the same argument could be made for graded activity – though the drop-out rates were not as high for this group). Nor is it surprising that graded *in vivo* exposure received higher credibility ratings given that it seems to be a more effective treatment than graded activity. Unfortunately, because credibility ratings were not obtained until post-treatment, we are unable to deduce whether the differences in credibility ratings may have affected treatment outcome or whether perceived credibility may have been impacted by treatment progress.

4.1.2 Graded in vivo exposure vs. other treatment conditions

As noted above, the results of the present study provide mixed support for the first hypothesis. Compared to graded activity, individuals receiving graded *in vivo* exposure showed statistically significantly greater improvement on three of the eight dependent variables (DVs), including fear-avoidance beliefs [FABQ], pain disability [PDI], and pain self-efficacy [PSEQ]). There was also a trend for graded *in vivo* exposure to show greater improvement on measures of fear of pain/movement (TSK), pain anxiety (PASS), pain catastrophising (PCS), and anxiety and depression (HADS) compared to graded activity. Differential improvements were not observed between graded *in vivo* exposure and graded activity on the SF-MPQ. Compared to the wait-list control condition, individuals in graded *in vivo* exposure also exhibited statistically significantly greater improvement on three of the eight DVs, including fear of pain/movement [TSK], fear-avoidance beliefs [FABQ], and pain catastrophising [PCS]). There was also a trend for graded *in vivo*

exposure to elicit greater improvement than wait-list on measures of pain self-efficacy (PSEQ), disability (PDI) anxiety and depression (HADS), and perceived pain (SF-MPQ). Differential improvements were not observed between graded *in vivo* exposure and wait-list control on the PASS. Graded activity and wait-list control did not exhibit differential effects on any of the variables. These findings collectively indicate that graded *in vivo* exposure is a more effective treatment for chronic back pain than either graded activity or no intervention.

The FABQ was the only variable found to evidence statistically significant improvement amongst participants in the graded *in vivo* exposure condition relative to both graded activity and wait-list controls. Thus, a decrease in fear-avoidance beliefs seems to be unique to graded *in vivo* exposure. This finding is consistent with previous research showing that only fear-avoidance beliefs, and not catastrophising, are predictive of disability in chronic back pain patients (Woby et al., 2004a), and suggests that patients become more comfortable with an activity by readjusting their beliefs about the outcome of performing the activity. The finding is consistent with the purpose of the treatment – to help reduce avoidance by exposing patients to activities that they find anxiety-arousing, thereby giving them the opportunity to change their catastrophic beliefs about pain or injury that reinforce their fear.

Fear of pain/movement and pain catastrophising were reduced statistically significantly more in the graded *in vivo* exposure condition compared to the wait-list control, but not the graded activity (though there was a trend for improvement when compared to graded activity). Though this is not as hypothesized, it is plausible that since the wait-list control group was not exposed to any form of additional physical activity,

these individuals did not have the opportunity to disconfirm their negative beliefs (Vlaeyen and Linton, 2000). In contrast, those receiving graded activity were conducting various movements and may have circuitously discovered disconfirming evidence for their catastrophic expectations. In other words, while this was neither the focus nor emphasis of graded activity, there was likely some incidental learning that resulted in a reduction of fear of movement/pain and catastrophic thinking. Consistent with this conjecture, prior research has shown that graded activity provides improvements in fear of pain, anxiety, and depression (Friedberg, 2002).

Pain disability and pain self-efficacy were improved statistically significantly more in graded *in vivo* exposure compared to graded activity, but not wait-list control. This was somewhat surprising given that graded activity is an established treatment for chronic back pain (Lindstrom et al., 1992) designed to reduce disability via increasing exercises that improve musculoskeletal strength, mobility, and functioning. Additionally, exercises such as those performed through graded activity have been found to have many health benefits, including improved self-efficacy for physical activity (Robbins, Pis, Pender, & Kazanis, 2004). Thus, improvements in disability and pain self-efficacy in graded *in vivo* exposure would be expected to be greater when compared to the wait-list control than when compared to graded activity.

One reason why the effects of the graded *in vivo* exposure treatment were not consistently greater than the other conditions may be because of the implicit education about the fear-avoidance model provided across all treatments. Each questionnaire was clearly labelled, and many of the questions on the various measures had obvious face validity. Thus, participants in all three conditions had the opportunity to understand that

the focus of the questionnaires and, therefore, the focus of the research, was on how treatment affected fear, avoidance, negative/catastrophic thoughts, pain self-efficacy, and perceptions of pain and disability. In fact, when individuals in the wait-list control condition were contacted following completion of data collection in order to offer them treatment, several indicated that they no longer required treatment because the process of completing the questionnaires had made them realize that they had been too worried about the impact of activity and this worry had perpetuated their inactivity. These individuals reported increased activity levels and improved functioning and coping with pain, and no longer desired additional treatment. This unanticipated benefit may have confounded, to a small degree, the outcome of this study. That is, the shift in attitude reported by some of the individuals on the wait-list may have altered their questionnaire scores over the course of the study, thereby decreasing the likelihood that statistically significant differences would be detected between the graded *in vivo* exposure treatment and the wait-list conditions. Though there were no reports of this effect with individuals who participated in graded activity (graded activity participants were not contacted subsequent to their treatment), it is possible that some of them were similarly influenced. In fact, de Jong et al. (2005) have noted that provision of education was sufficient to reduce pain-related fear and catastrophising, though not sufficient to produce an improvement in participation in daily activities. The present findings further suggest that even if unintentional psychoeducation was operating in one or both control conditions, the additional component of *in vivo* exposure was necessary to effect a change in several key domains.

Another potential reason that the effects of the graded *in vivo* exposure treatment were not consistently greater than the other conditions may be due to the relatively small sample size, which may have had a negative effect on the power to detect true differences (Tabachnick & Fidell, 1996). This possibility seems likely given the tendency of individuals receiving graded *in vivo* exposure to demonstrate trends towards statistically significant improvements on several outcome measures when compared to individuals in the other conditions.

The extent to which participants in graded *in vivo* exposure completed exposure activities between sessions might also have influenced outcome. The effectiveness of most cognitive behavioural therapies, graded *in vivo* exposure included, relies in part on participants' compliance with prescribed homework tasks (Hawton, Salkovskis, Kirk, & Clark, 1996). As described in the treatment manual (Appendix K), homework assignments of graded *in vivo* exposure tasks were collaboratively agreed upon throughout the course of therapy. The participants' experiences with these assignments were then reviewed as a part of the following therapy session. While all those receiving graded *in vivo* exposure indicated general compliance with homework during review, no systematic data were collected regarding the frequency or effectiveness with which they practiced exposure tasks. It is, therefore, possible that individuals in this study varied in their compliance with homework tasks, and those who completed more homework tasks might have experienced greater benefits from the graded *in vivo* exposure (or graded activity) than those who had poorer compliance. Turk and Okifuji (2002) have indicated that differences in compliance with prescribed behaviours may impact the apparent effectiveness of treatment. Thus, future research comparing the effectiveness of different

treatments would benefit from systematically assessing compliance to prescribed activities between therapy sessions in order to determine if this compliance level is affecting treatment outcome.

4.1.3 Maintenance of change

The discussion above illustrates that graded *in vivo* exposure was the only condition that produced either statistically significant improvement, or a trend towards it, on each of the outcome measures. The second hypothesis was concerned with whether improvements wrought by the graded *in vivo* exposure condition would be maintained four weeks following the conclusion of treatment. This hypothesis was supported. Improvements at post-treatment were maintained at four-week follow-up for all outcome measures except pain self-efficacy, which was found to statistically significantly decrease (though from pre-treatment to follow-up there was a trend for overall improvement). Gheldof, de Jong, Vinck, and Houben (2004) have stated that extensive rehearsal and exposure is required in order for behavioural and attitudinal change to be lasting. The ability of individuals who were provided graded *in vivo* exposure to maintain treatment gains for one-month following just eight treatment sessions (the first of which was an assessment and the last a review), offers provisional evidence that Gheldof et al.'s supposition is not necessarily true.

The maintenance of treatment gains may be due to several components of the graded *in vivo* exposure treatment. In particular, the education component provides patient-specific information that illustrates how patient behaviours (avoidance), cognitions (catastrophic thoughts), and emotions (fear, anxiety) reinforce their disability, and stresses that chronic pain is a manageable condition. This principle is reinforced by

the therapist throughout the course of treatment and may help patients to develop positive attitudes (which may lead to approach behaviour; Wilson, Lindsey, and Schooler, 2000) towards physical activity in general, and graded *in vivo* exposure tasks in particular. Patients are then provided the tools (i.e., graded exposure tasks) with which they can improve their functioning, and are given successful experiences in doing so. This improvement in functioning, resumption of enjoyable activities, and increased comfort with and independence when performing tasks, is naturally reinforcing. In fact, many of the patients who participated in treatment recounted feeling very pleased with their newly rediscovered ability to perform a variety of activities. Some patients also described feeling a surge of pride and confidence in their physical ability following the successful completion and reduction in anxiety of a particularly dreaded task. Thus, patients are not only reinforced by the therapist for their progress, but also experience increased self-efficacy due to their active and effective participation in treatment. The combination of these factors may serve to further improve the patient's attitude towards physical activities and enhance the likelihood that treatment gains will be maintained.

4.1.4 High vs low distress

The results of the present investigation do not support the hypothesis that individuals in the graded *in vivo* exposure treatment who had high distress would experience the greatest improvement. In retrospect, this was an ill-conceived prediction given the limited sample size, the eligibility criteria requiring a high level of distress (as measured by a cut-off score of 38 or greater on the TSK), and the narrow range of pre-treatment TSK scores (39-44). Eight individuals with "low" distress were compared to the remaining seven with "high" distress in the graded *in vivo* exposure treatment, though

all of these individuals had been initially selected for having high fear of pain scores. It is, therefore, unsurprising that no differences were found. In order to adequately assess this hypothesis, a larger sample would be necessary. It would also be helpful to assess a sample that had a wider range of scores on the measure being used to provide a classification of "high" or "low" distress.

4.1.5 Summary of outcomes

Graded *in vivo* exposure is more effective than graded activity and wait-list control conditions in treating chronic back pain patients with high fear of pain/re-injury. This is apparent on a variety of outcome measures. Furthermore, participants who completed graded *in* vivo exposure maintained improvements one-month following completion of treatment. While high distress patients were not found to experience greater improvements than lower distress patients in the graded in vivo exposure condition, methodological constraints (selecting high and low fear groups from patients pre-screened to be high in fear of pain/kinesiophoba) may have reduced the chances of rejecting the null hypothesis. Though additional research is still warranted to provide less equivocal support for graded *in vivo* exposure, the present investigation helps to establish an improved understanding of the process of change that occurs within graded *in vivo* exposure therapy and supports the clinical significance of the treatment.

4.2 Graded In Vivo Exposure: Process and Significance of Change

Previous case studies (e.g., Vlayen et al., 2001, 2002) have indicated that graded *in vivo* exposure improves functioning and reduces anxiety, fear, catastrophising and perceptions of pain and disability more so than graded activity. As described above, the outcome measures from pre- to post-treatment and post-treatment to follow-up evidenced

statistically significant change in those receiving graded in vivo exposure versus those in the other conditions. Further evidence for the efficacy of graded *in vivo* exposure for treating chronic back pain comes from an examination of clinically significant change (defined by Jacobson and Truax (1992) as whether the post-treatment score falls outside two standard deviations of the mean of the population of interest). Of the 15 participants who were assigned to and completed the graded *in vivo* exposure treatment, 14 finished with TSK scores less than 38 – the score necessary for initial inclusion in the trial – and 11 had TSK scores that were more than two standard deviations below the pre-treatment population mean. Thus, not only did 93% of the graded *in vivo* exposure participants no longer meet criteria for being a chronic pain patient with significant fear of movement/pain, 73% evidenced clinically significant decreases in fear of movement/pain. These improvements were greater than those demonstrated by individuals in either the graded activity or wait-list control conditions, suggesting that graded *in vivo* exposure is a more effective treatment for reducing fear of movement/pain.

The clinical significance of the extent of change was not reported by prior cases studies; however, they did report other aspects of change that have clinical relevance. Vlaeyen et al. (2001) found that, amongst their sample of four patients with chronic back pain, exposure produced reductions in catastrophising and fear of movement within three treatment sessions. Similarly, de Jong et al. (2005) showed that provision of education based on the fear-avoidance model of chronic pain produced reductions in fear and catastrophising after just one session. Within the present sample there was a statistically significant decrease in perceived disability and fear of pain/movement, but no other variable, by mid-treatment (4 treatment sessions). Rather, scores on the majority of

outcome measures were found to improve between mid-treatment and post-treatment. Nevertheless, it is noteworthy that across several treatment studies, fear of pain reduces rapidly. This finding suggests that a reduction in fear of pain/movement precedes reductions in avoidance, catastrophising, and perception of pain, and improvements in functioning and self-efficacy. Thus, fear of pain may be the gate key that determines additional progress in treatment. In contrast, Vlaeyen et al. (1995) found that catastrophising is predictive of fear of pain. These differing postulates could be further tested by performing a session by session analysis of treatment progress, focusing on both the course of progress for each individual, and comparisons between individuals who make significant improvements and those who do not. Such research may help to illuminate the relative importance of fear of pain/movement in treatment of chronic pain.

The results of the present study also suggest that perceived disability might decrease in concordance with the fear. The reduction of perceived disability after just two weeks of treatment is striking considering the extent of time that individuals with chronic pain have suffered from their condition – an average of 15.7 years for the present sample – and their typical resistance to other methods of treatment that they receive (e.g., physiotherapy, massage therapy). Similarly, given the time-limited nature of the treatment, maintenance of decreases in perceived disability for a month following the end of treatment is important.

4.2.1 Summary

In general, and consistent with prior case study research, graded *in vivo* exposure seems to produce clinically significant improvements in treatment completers. In addition to the therapeutic relevance of the present research, the results inform the theoretical

model upon which graded *in vivo* exposure was developed: the fear-avoidance model of chronic pain (Lethem et al., 1983; Asmundson et al., 2003).

4.3 Theoretical Relevance: The Fear-Avoidance Model

The results of the present investigation provide strong support for the utility of the fear-avoidance model of chronic pain. In particular, many of the factors that were found to be improved in the graded *in vivo* exposure treatment compared to the other conditions are components within the fear-avoidance model that explain the development, maintenance and treatment of chronic pain. Each of these factors, and their relationship to the fear-avoidance model of chronic pain, will be discussed.

4.3.1 Cognitions and functioning

The fear-avoidance model (Vlaeyen & Linton, 2000) suggests that negative cognitions, such as catastrophic thinking, may result in anxiety/fear of pain which, in turn, is likely to be characterized by avoidance behaviours and increased disability. Eccleston and Crombez's (1999) application of Eysenck's (1997) cognitive theory of anxiety to pain suggests a mechanism through which negative cognitions may occur – the misinterpretation of bodily sensations as being threat-related produces hypervigilance (an increased attentional focus and sensitivity to the threatening stimuli), thereby increasing pain experience, anxiety, and the likelihood of avoidance. These contentions have been supported by a number of authors (Dougher et al., 1987; McCracken, et al., 1996; Van Damme, Crombez, Eccleston, & Roelofs, 2004). It was demonstrated in the present study that individuals who completed graded *in vivo* exposure experienced a statistically significant decrease in pain-related catastrophic thoughts, fear-avoidance beliefs, and pain-related anxiety. Decreases in catastrophising that result from graded *in vivo*

exposure may work to reduce anxiety and avoidance via a reduction in the perceived threat of the activity. This idea is certainly consistent with the use of graded *in vivo* exposure in the treatment of phobias and obsessive-compulsive disorder (Butler, 1996) – exposure provides the opportunity for the patient to learn that the situation/activity is not dangerous. More specifically, in patients with chronic pain, graded *in vivo* exposure exposes the patient to threatening (and therefore anxiety arousing) activities that they have previously avoided so that they are able to disconfirm their negative beliefs about the activities and replace them with more accurate and adaptive cognitions about the potential effects of performing a given activity. These more "accurate and adaptive" beliefs may simply be the result of an improved ability to predict pain, thereby resulting in a decrease in hypervigilance and threat evaluation which, in turn, results in a decrease in anxiety and avoidance and a concordant increase in functioning. These postulates are consistent with the predictions of the fear-avoidance model and with previous research. For example, Jensen et al. (1992) found that decreased beliefs in pain as harmful and disabling, increased beliefs in control over pain, and decreased catastrophising resulted in improvements in disability, depression, and health care use.

In addition to the above-described relationship between cognitive distortions and the other variables in the fear-avoidance model (via hypervigilance and threat evaluation), catastrophising might also act as a mediator for perceived pain. Perceived pain was, in fact, found to decrease within the graded *in vivo* exposure condition in the present study, though this effect was not statistically significantly greater than that obtained by the graded activity or wait-list conditions. Conversely, Severeijns et al. (2001) have shown that individuals suffering from chronic pain who catastrophized

reported greater pain intensity and psychological distress than individuals who did not catastrophize. Buer and Linton (2002) also found that catastrophzing is related to perception of pain, and Woby et al. (2004b) have found that negative beliefs about pain predicted level of disability. These findings are supported by the present study as improvements in avoidance, pain perception and self-efficacy (between mid-treatment and post-treatment) coincided with decreases in catastrophising.

In a recent review, Keogh and Asmundson (2004) have summarized the relationship between catastrophising and fear of pain, providing evidence that it is strong and consistent. Unfortunately, a short-coming of the literature they reviewed, and of the present research, is that neither enables a causal relationship to be determined. The analysis of the process of change amongst patients in the graded *in vivo* exposure condition in the present investigation provides preliminary evidence that a decrease in fear of pain/movement heralds additional improvements.

4.3.2 Fear and avoidance

There has been strong evidence establishing the relationship between fear, avoidance, and disability, both in clinical and non-clinical samples (see Asmundson, Vlaeyen, et al., 2004 for a comprehensive review). The analysis of treatment effects over time in the present study indicated that decreases in fear of movement due to pain, and ratings of perceived disability, preceded the improvements in the other variables. The former finding is consistent with several prior studies that have suggested that fear of pain leads to anxiety and avoidance behaviour which, in turn, leads to physical disability and decreases in psychological well-being. Vlaeyen et al. (1995) suggested that it is the specific fear and anxiety related to the belief that movement can cause (re)injury (i.e.,

kinesiophobia) that will enhance avoidance behaviour. Vlaeyen et al. (1995) found that fear of movement was related to increased catastrophising in low back pain patients and that individuals with greater kinesiophobia evidenced more avoidance of a specific motor task (i.e., lifting a weighted bag). Crombez et al. (1998) also demonstrated that chronic pain patients who avoided activities had a high fear of (re)injury and tended to focus on back sensations. Thus, a link between fear, cognitions (via the attentional focus) and avoidance is depicted. Further research has indicated that fear of pain is predictive of development of chronic back pain (Klenerman et al., 1995). Thus, fear of pain/movement seems to have a central and predictive role in both the development of chronic pain, and recovery from this condition. This tenet is supported by the findings of the present research as fear of pain/movement was one of the first variables to evidence improvement. However, the decrease in perceived disability by mid-treatment may not fit this model if this decrease did not occur following the change in fear of pain/movement.

4.3.3 Perceived disability and fear-avoidance

According to the fear-avoidance model (Asmundson, Vlaeyen, et al., 2004), disability is the result of anxiety and avoidance; therefore, improvements in perceived disability should not occur until anxiety and avoidance behaviour have been reduced. This may not, however, have been the case in the present research (though the exact time point at which changes in perceived disability occurred is not determinable by the present investigation). It is possible that the significant reduction in fear of pain, and the initial successes that the participants enjoyed with the exposure tasks, were sufficient to provoke a lessened belief in their disability. However, it is also possible that decreases in perceived disability occurred at the same time, or even prior to, the decrease in fear of

pain/movement. If the latter supposition is accurate, it may be discordant with what would be predicted from the fear-avoidance model (though it should be noted that it was merely a decrease in perceived disability, and not a decrease in an objective measure of disability, that showed improvement). Nonetheless, it is striking that individuals with chronic pain would show significant reductions in the extent to which they perceive themselves as disabled after a mere four sessions of therapy over a two-week period. Additional studies will need to further examine the interaction and predictive value of the various elements of the fear-avoidance model, paying particular attention to whether change in perceived disability precedes other improvements (i.e., in anxiety or avoidance behaviour), or is a product of them.

4.3.4 Pain self-efficacy and the fear-avoidance model

Jourden, Bandura, and Banfield (1991) suggested that self-efficacy effect's one's likelihood of choosing and performing a particular task, expenditure of effort, persistence in adverse circumstances, and level of success experienced. However, the role of self-efficacy in the fear-avoidance model has received relatively little attention in prior research, though self-efficacy has been found to be related to chronic pain patients' physical functioning, adjustment to chronic pain, and use of coping strategies (see Nicholas, in press) and Denison et al. (2004) have demonstrated that task self-efficacy accounts for more variance in disability scores than either fear of pain/movement or catastrophising.

Pain self-efficacy improved during the course of graded *in vivo* exposure in the present study, and this improvement was statistically significantly greater compared to the graded activity condition. This improvement in pain self-efficacy was likely because

graded *in vivo* exposure enabled patients to experience successful performance accomplishments which, in turn, provided a sense of mastery. Turk and Okifuji (2002) have suggested that techniques that enhance sense of mastery will be effective in enhancing behavioural change (i.e., reduced avoidance and increased physical activity). With respect to chronic pain and fear-avoidance, Turk and Okifuji have suggested that exposure to feared activities without the occurrence of the expected negative consequences may both reduce the fear and improve pain self-efficacy, thereby reducing avoidance and improving functioning. These hypotheses certainly seem to be supported by the results of this study and are in line with prior research by Council et al. (1988) who noted that self-efficacy ratings by a group of chronic low back pain patients for expected ability to perform specified activities correlated with the actual performance of those activities.

Given the present results and those of prior research suggesting the importance of self-efficacy in chronic pain, explicit consideration should be given to including a self-efficacy component into the fear-avoidance model. The most recent version of the fear-avoidance model (Asmundson, Norton, et al., 2004) does not clearly identify the dynamic interaction between personal factors, such as self-efficacy, fear/anxiety caused by pain, and the extent of escape/avoidance. It is likely that pain self-efficacy would fall into the "predisposing risk factor" segment of the model (see Figure 3) and that pain self-efficacy is one component of a positive feedback loop that also includes kinesiophobia, avoidance, and disability, each component reciprocally influencing one another. Thus, as any of these components improves, there may be a positive influence on the other components (resulting in improved pain self-efficacy and functioning, and decreased anxiety and

avoidance). However, additional research with this seemingly important risk factor is warranted and may clarify its specific role.

4.3.5 Summary

The importance of cognitions and fear-avoidance in the fear-avoidance model, and as contributors to the development, maintenance and treatment of chronic pain, are well-established. The present research provides some evidence to confirm what has been previously supported and to further suggest the importance of reduction in pain-related fear as a key process in treatment outcome. In contrast, the role of pain self-efficacy in the fear-avoidance model has received relatively little attention. The results of the present investigation suggest that it may be an important variable to consider. These findings, and those discussed in previous sections, have practical implications for the treatment of chronic pain.

4.4 Clinical Relevance

Blanchard (1979) indicated that the clinical application of a treatment can be evaluated along several dimensions, including the proportion of the treated patient sample that demonstrates significant therapeutic improvement, the clinical meaningfulness of the changes obtained, and the degree of transfer of change from the clinical setting to other relevant environments. Within the current investigation, it was found that almost the entire sample (93%) who completed graded *in vivo* exposure had significant decreases on a measure of fear of movement, and that a majority (73%) had decreases of greater than two standard deviations on the same measure. There was also a consistent effect for patients in the graded *in vivo* exposure to evidence decreases in fear, avoidance, pain, and disability throughout the course of treatment. Additionally, as a requirement of treatment,

patients completed exposure tasks in other environments (i.e., at home) and reported their successes. The outcome of this study provides support for the contention that focusing on patients' fear of movement/pain is a viable method for improving quality of life and reducing disability amongst individuals with chronic back pain and a high fear of pain/movement. Thus, for a substantial proportion of back pain patients who have no identifiable organic cause for their problem, and who suffer from a fear of their pain and/or (re)injury, graded *in vivo* exposure may offer a theoretically and empirically supported treatment alternative that effectively alleviates their affliction.

Graded *in vivo* exposure appears not only effective, but also efficient. Gheldof et al. (2004) suggested that it takes extensive rehearsal and exposure to produce lasting behavioural and attitudinal change. The present results provide some evidence to the contrary as participants made significant improvements in just eight sessions, and maintained these improvements for one-month following the end of treatment. Given the chronicity of the pain problem, and the typical cost of providing treatments that are often long-term in nature, graded *in vivo* exposure offers an alternative that is both time and cost-efficient. Additionally, the focus of graded *in vivo* exposure is to improve functioning, and it appears to be effective in doing so – this may enable a substantial reduction in medical and productivity costs resulting from use of sick leave and health care benefits.

The present study also has implications for practice in primary care. In a recent review, Balderson, Lin, and Von Korff (2004) noted that physicians are often painfully unaware of the psychosocial issues that are relevant to chronic pain conditions. Physicians are an important population to target for provision of information about fear-

avoidance and chronic pain for several reasons. In particular, fear-avoidance has been estimated to be a critical factor in approximately 30% of the chronic pain population (Asmundson et al., 1997). However, almost 60% of the population who responded to recruitment advertisements for this study met criteria for having a high fear of pain, and this number is likely an underestimate given that some of the potential participants would not have been diagnosed with a chronic pain condition. Thus, fear of pain may be more prevalent in chronic pain populations, and in individuals with chronic back pain in particular, than was previously estimated. This finding is arresting given recent research by Linton, Vlayen, and Ostelo, (2002), who found that a considerable proportion of physicians hold beliefs that may encourage fear-avoidance. It will, therefore, be important to educate primary health care workers about the impact of fear-avoidance, and how it can be assessed (e.g., by screening acute pain patients for fear-avoidance beliefs using a measure such as the TSK that would enable a quick and easily interpreted evaluation of fear-avoidance). Following a brief assessment of fear-avoidance, physicians could provide pain patients with information reinforcing the importance of continuing/returning to activities of daily living (i.e., work, recreation) and education regarding the difference between hurt and harm. When appropriate, physicians can also refer patients with high fear-avoidance to a psychologist for appropriate treatment.

Another issues of clinical relevance highlighted in the present investigation is that of patient drop-out. There was a very high percentage of drop-outs in both the graded *in vivo* exposure and the graded activity conditions (58% and 48% respectively). Blanchard et al. (2003) described a "high" drop-out rate as being 20% amongst randomly assigned participants. Clearly, the drop-out rate in this study is substantially greater. However, it

should be noted that most of the drop-outs that occurred in the graded *in vivo* exposure group transpired at the assessment stage, prior to the start of treatment.

Though individuals who dropped out following at least one treatment session were sent a questionnaire to determine their reasons for doing so, only one participant returned this questionnaire. While no firm conclusions can be drawn, several potential reasons for the high drop-out rate are hypothesized. Many participants initially indicated they had thought treatment would consist of a physical therapy and/or evidenced some scepticism over the potential efficacy of the graded *in vivo* exposure treatment. This lack of interest and confidence in a psychologically-oriented therapy for a problem they perceived as being physiological may have led to increased drop-out rates, further exacerbated because they were randomly assigned and unable to choose their treatment of preference. Also, because many of the participants dropped out prior to beginning treatment, they did not experience the benefits of therapy (e.g., increased functioning, decreased anxiety). The experience of these benefits may have increased the likelihood of following through with treatment. In fact, several participant completers verbally reported that they were pleased with their newfound functioning, despite initial beliefs that therapy would not be very effective.

Barlow (1988) indicated that in order for a therapy to be considered effective, it needs to include methods for improving adherence and reducing drop-out. Of course, one of the central difficulties that chronic pain patients with high fear and avoidance have is in consistently participating in a range of activities, and treatment could certainly be construed as an activity that would require significant physical effort. Thus, the high drop-out rates might be specific to a high fear-avoidance chronic pain population. Despite

the potential reasons for the high drop-out rate, it is clear the work is needed to reduce the drop-out rate. It would be beneficial for future studies to assess drop-out rates and participants' reasons for dropping out, in order to determine if the high drop-out rate experienced in this study is idiosyncratic, or a potential challenge to this form of illness or treatment. Turk and Rudy (1991) support the latter contention as they have indicated that noncompliance with treatment regimens is quite prevalent across diverse treatment modalities and pain syndromes. One method for potentially addressing this reticence to participate in treatment is through motivational interviewing, a technique that has recently received attention as an effective means for improving treatment adherence in patients with chronic pain (e.g., Jensen, 2002). These techniques could be incorporated into future graded *in vivo* exposure treatment protocols.

The results of the present investigation also provide a platform from which further research can be conducted to investigate the effectiveness of graded exposure in treating other chronic pain conditions. Given its effectiveness for the treatment of chronic low back pain, it would be appropriate to determine whether graded *in vivo* exposure can also be utilized to treat fear and avoidance for other musculoskeletal conditions. Additionally, further research on the utility of graded *in vivo* exposure with a chronic pain population may be able to resolve some of the limitations in the present study.

4.5 Limitations

Though conducting randomized controlled clinical trials to assess the efficacy of graded *in vivo* exposure in patients with chronic pain is an advancement over prior case study research in this area, there were several limitation to the present research. Most significant were the difficulties procuring the intended 20 participants per treatment

condition and having to settle for a relatively small sample size (n = 44) that was somewhat unevenly distributed across treatments. The difficulty in procuring the expected number of participants was the result of several factors. Most saliently, there was a very high percentage of drop-outs in both the graded *in vivo* exposure and the graded activity conditions (as discussed above). Another difficulty in obtaining the desired sample size was the limited population that was available. Recruitment for this study occurred over a 12-month period in a small western Canadian city, and entailed multiple forms of advertisement (e.g., posters, newspaper advertisements, e-mails) conducted at multiple time points. With successive recruitment attempts there was a notable decrease in the number of volunteers, suggesting that the number of potential candidates was dwindling. Relatedly, the admission criterion for this research was stringent (only 58% of volunteers with low back pain were eligible). Though a cut-off score of 38 on the TSK is consistent with some prior research (i.e., Vlaeyen et al., 2001), Boersma et al. (2004) used a TSK cut-off score of 35 in conjunction with other criteria. Using a less stringent cut-off score would have allowed a substantial number of additional volunteers to participate in this research.

There were several additional limitations beyond the sample size issues. First, is the lack of a long-term follow-up. Though a longer follow-up is clearly warranted, only a one-month post-treatment follow-up was able to be conducted due to the time constraints of conducting doctoral research. However, a 12-month follow-up, which will enable us to evaluate the long-term efficacy of the treatments, is presently underway. Second, only self-report measures (though only ones that were proven to have strong psychometric characteristics) were included in the design, and no objective measures (e.g., of

disability) were used. Gheldof et al. (2004) have reviewed the short-comings of self-report measures, including the likelihood of distortions due to demand characteristics, attributional bias, and contextual cues. Unfortunately, there are few practical and well-standardized indirect and non-reactive measures of the psychological variables of interest in this study, and there were financial and organizational constraints to utilizing measures that were available (e.g., functional capacity evaluations).

It is possible that therapist effects may have impacted treatment outcome, as there were three different therapists who provided treatment to participants (one physiotherapist and two psychology graduate students). Independent observer ratings of each therapist in both the graded *in vivo* exposure condition and the graded activity condition would have enabled a more thorough assessment of whether therapist variables impacted treatment outcome. Unfortunately, practical and financial constraints did not allow for this measure to be taken. Additionally, ratings of therapeutic alliance did not differ within or between treatments, suggesting that the therapeutic relationship did not differentially affect treatment outcome.

There were also several difficulties specific to the process of conducting the present study. In particular, the principle investigator began his pre-doctoral internship in the midst of data collection, necessitating the training of an additional therapist and staff for data management. This was accomplished with only minor delays to data collection, and, as previously noted, ratings of the therapeutic alliance did not differ between therapists for the graded *in vivo* exposure condition. Finally, during the principle investigator's departure, the physiotherapy clinic in which the graded activity treatment was being provided was moved, and the clinic altered their computer system. These

changes resulted in significant administrative difficulties, including some loss of data, and delays in start of treatment for several participants.

4.6 Conclusions and Future Directions

Kuch, Cox, and Evans (1996) state that, for individuals with chronic pain, restoration of an acceptable level of functioning is the "ultimate" goal. Barlow (1988) stated that, in order to be effective, exposure must have a convincing rationale, involve confrontation of the feared situation, continue until fear and avoidance are significantly reduced, and produce improvement that generalizes to other relevant situations and is maintained. Evidence from the present investigation suggests that, as defined by Barlow, graded *in vivo* exposure is an effective treatment for patients with chronic low back pain. Moreover, graded *in vivo* exposure allows Kuch et al.'s "ultimate" goal to be achieved. Specifically, participants in the graded *in vivo* exposure treatment demonstrated marked improvements – both statistical and clinical – when compared to another treatment or a wait-list control condition on measures of functioning, fear of pain/movement, pain-related anxiety, general anxiety and depression, fear, avoidance behaviour, perceptions of pain and disability, and pain self-efficacy. Further randomized controlled clinical trials need to be conducted with larger numbers in order to better establish the effectiveness of graded *in vivo* exposure for the treatment of chronic back pain, particularly in helping patients to function more adaptively. Additionally, at present, the majority of the literature has focused on treatment of chronic back pain. In order for graded *in vivo* exposure to be a utilitarian treatment, it needs to be applied to a variety of conditions. Thus, it would be helpful to begin conducting case studies and randomized controlled

trials assessing this treatment in patients with a diversity of chronic pain conditions (e.g., fibromyalgia, upper back pain, lower/upper extremity pain conditions).

The demonstrated effectiveness of graded *in vivo* exposure also provides support for the fear-avoidance model of chronic pain. Specifically, the findings support the fear avoidance model's contention that confronting feared activities and allowing clients to develop more accurate appraisals and cognitions related to the performance of these activities, will reduce anxiety and avoidance, thereby increasing functioning. Self-efficacy, a previously unexplored variable in the fear-avoidance model, may offer a significant contribution to the model. In particular, it is likely that the reduction in anxiety and improvement in functioning that occurs through graded *in vivo* exposure increases pain self-efficacy to perform activities, thereby increasing the likelihood that the individual will continue to perform previously avoided activities, and further confront feared activities. Thus, an increase in pain self-efficacy may influence the maintenance of improvements derived from graded *in vivo* exposure. Further research will need to be conducted to identify and establish the contribution of pain self-efficacy to the fear-avoidance model, and the role of pain self-efficacy in the improvement and maintenance of functioning in people with chronic pain conditions.

Our understanding of the fear-avoidance model might also be further enhanced by additional treatment research which provides a real-world (as opposed to a laboratory setting) application of the theoretical constructs. For example, it will be important to explore the use of graded in vivo exposure in multidisciplinary treatment settings. Such settings are common in the treatment of chronic pain, thus necessitating that graded *in vivo* exposure be adapted for this treatment setting if it is to be utilized effectively and in

a more wide-spread fashion. Additionally, applying it in a multi-disciplinary setting may assist with acceptance of therapy (e.g., if both a physiotherapist and psychologist were involved with its delivery) and reduce drop-outs. Only in the real-world are the principles and relationships hypothesized by the model tested clinically and potential idiosyncrasies exposed (e.g., improvements in disability prior to improvements in catastrophising). These idiosyncrasies provide further areas of exploration and enable us to eventually obtain an improved knowledge of the model, how it can be evolved, and how it can be applied.

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Appendix A

Semi-Structured Interview

Background Information/Antecedents

1) What does your pain feel like?
2) When did the pain start?
3) What were the circumstances of pain onset?
4) If there was a sudden pain onset, what did you do, think, and feel at that moment?
5) What has your doctor and/or other medical specialists told you about your condition?
6) What tests have been preformed to identify the cause of your problem? What have these tests found?

Maintaining Factors

7) What do you think is causing your pain?
8) What are you not doing because of the pain problem?/ If you no longer had the problem, what differences would it make to your life (be specific)?
9) What factors make it easier or harder to perform and activity/stop avoiding?
10) What do you think will happen in the near future if the pain remains untreated?
11) What do you do to cope with your pain problem?

Other Issues

12) What other life stresses are you experiencing? (e.g., job loss, marital difficulty, loss of social contacts)
13) How will improvement of your pain condition affect these other problems?

Appendix B

The Tampa Scale for Kinesiophobia

Please answer every question by circling the number that best describes your situation.

1. I'm afraid that I might injure myself if I exercise.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

2. If I were to try to overcome it, my pain would increase.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

3. My body is telling me I have something dangerously wrong.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

4. My pain would probably be relieved if I were to exercise.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

5. People aren't taking my medical condition seriously enough.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

6. My accident has put my body at risk for the rest of my life.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

7. Pain always means that I have injured my body.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

8. Just because something aggravates my pain does not mean it is dangerous.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

9. I am afraid that I might injure myself accidentally.
   1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.
    1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body.
    1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

12. Although my condition is painful, I would be better off if I were physically active.
    1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

13. Pain lets me know when to stop exercising so that I don't injure myself.
    1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

14. It's really not safe for a person with a condition like mine to be physically active.
1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

15. I can't do all things normal people do because it's too easy for me to get injured.
1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

16. Even though something is causing me a lot of pain, I don't think it's actually dangerous.
1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

17. No one should have to exercise when he/she is in pain.
1 = strongly disagree 2 = disagree 3 = agree 4 = strongly agree

Appendix C

The Fear-Avoidance Beliefs Questionnaire

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking, or driving affect or would affect *your* back pain.

	Completely disagree			Unsure			Completely agree
1. My pain was cause by physical activity.....	0	1	2	3	4	5	6
2. Physical activity makes my pain worse.....	0	1	2	3	4	5	6
3. Physical activity might harm my back.....	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse.....	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse.....	0	1	2	3	4	5	6

The following statements are about how your normal work might affect or would affect your back pain.

	Completely disagree			Unsure			Completely agree
6. My pain was cause by my work or by an accident at work.....	0	1	2	3	4	5	6
7. My work aggravated my pain.....	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain.....	0	1	2	3	4	5	6
9. My work is too heavy for me.....	0	1	2	3	4	5	6
10. My work makes or would make my pain worse.....	0	1	2	3	4	5	6
11. My work might harm my back.....	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain.....	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain.....	0	1	2	3	4	5	6
14. I cannot do my normal work until my pain is treated.....	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal work within 3 months.....	0	1	2	3	4	5	6
16. I do not think I will ever be able to go back to that work.....	0	1	2	3	4	5	6

Appendix D

The Pain Anxiety Symptoms Scale

Please use the following scale to rate how often you engage in each of the following thoughts or activities. Circle the number beside the statement to indicate you rating.

		Never					Always
1.	I can't think straight when in pain	0	1	2	3	4	5
2.	During painful episodes it is difficult for me to think of anything besides the pain	0	1	2	3	4	5
3.	When I hurt I think about pain constantly	0	1	2	3	4	5
4.	I find it hard to concentrate when I hurt	0	1	2	3	4	5
5.	I worry when I am in pain	0	1	2	3	4	5
6.	I go immediately to bed when I feel severe pain	0	1	2	3	4	5
7.	I will stop any activity as soon as I sense pain coming on	0	1	2	3	4	5
8.	As soon as pain comes on I take medication to reduce it	0	1	2	3	4	5
9.	I avoid important activities when I hurt	0	1	2	3	4	5
10.	I try to avoid activities that cause pain	0	1	2	3	4	5
11.	I think that if my pain gets too severe it will never decrease	0	1	2	3	4	5
12.	When I feel pain I am afraid that something terrible will happen	0	1	2	3	4	5
13.	When I feel pain I think I might be seriously ill	0	1	2	3	4	5
14.	Pain sensations are terrifying	0	1	2	3	4	5
15.	When pain comes on strong I think that I might become paralyzed or more disabled	0	1	2	3	4	5
16.	I begin trembling when engaged in an activity that increases pain	0	1	2	3	4	5
17.	Pain seems to cause my heart to pound or race	0	1	2	3	4	5
18.	When I sense pain I feel dizzy or faint	0	1	2	3	4	5
19.	Pain makes me nauseous	0	1	2	3	4	5
20.	I find it difficult to calm my body down after periods of pain	0	1	2	3	4	5

Appendix E

The Pain Catastrophising Scale

Client No.: _____ Age: _____ Sex: M(__) F(__) Date: _____

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery. We are interested in the types of thoughts and feelings that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the following scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

0 – not at all **1** – to a slight degree **2** – to a moderate degree **3** – to a great degree **4** – all the time

When I'm in pain ...

1. ☐ I worry all the time about whether the pain will end.
2. ☐ I feel I can't go on.
3. ☐ It's terrible and I think it's never going to get any better.
4. ☐ It's awful and I feel that it overwhelms me.
5. ☐ I feel I can't stand it anymore.
6. ☐ I become afraid that the pain will get worse.

7 ☐ I keep thinking of other painful events.

8 ☐ I anxiously want the pain to go away.

9 ☐ I can't seem to keep it out of my mind.

10 ☐ I keep thinking about how much it hurts.

11 ☐ I keep thinking about how badly I want the pain to stop.

12 ☐ There's nothing I can do to reduce the intensity of the pain.

13 ☐ I wonder whether something serious may happen.

...Total

Appendix F

The Hospital Anxiety and Depression Scale

This questionnaire is designed to help you doctor to know how you feel. Read each item and place a firm tick in opposite the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies: your immediate reaction to each item will probably be more accurate that a long thought out response.

Tick only one box for each item

1. I feel tense or wound up:	**2. I feel as if I am slowed down:**
3 Most of the time	3 Nearly all the time
2 A lot of the time	2 Very often
1 Time to time	1 Sometimes
0 Not at all	0 Not at all
3. I still enjoy the things I used to enjoy:	**4. I get a sort of frightened feeling like butterflies in the stomach:**
3 Definitely as much	3 Most of the time
2 Not quite so much	2 A lot of the time
1 Only a little	1 Time to time
0 Hardly at all	0 Not at all
5. I get a sort of frightened as if something awful is about to happen:	**6. I have lost interest in my appearance:**
3 Very definitely and quite badly	3 Definitely
2 Yes, but not too badly	2 I don't take so much care as I should
1 A little, but it doesn't worry me	1 I may not take quite as much care
0 Not at all	0 I take just as much care as ever
7. I can laugh and see the funny side of things:	**8. I feel restless as if I have to be on the move:**
3 As much as I always could	3 Very much indeed
2 Not quite as much now	2 Quite a lot
1 Definitely not so much now	1 Not very much
0 Not at all	0 not at all
9. Worrying thoughts go through my mind:	**10. I look forward with enjoyment to things:**
3 A great deal of the time	0 As much as ever I did
2 A lot of the time	1 Rather less than I used to
1 From time to time but not too often	2 Definitely less than I used to
0 Only occasionally	3 Hardly at all
11. I feel cheerful:	**12. I get sudden feelings of panic:**
3 Not at all	3 Very often indeed
2 Not often	2 Quite often
1 Sometimes	1 Not very often
0 Most of the time	0 Not at all

13. I can sit at ease and feel relaxed:	**14. I can enjoy a good book or radio or TV programme:**
0 Definitely	0 Often
1 Usually	1 Sometimes
2 Not often	2 Not often
3 Not at all	3 Very seldom

Appendix G

The McGill Pain Questionnaire – Short Form

Part 1: Describe your pain by checking the appropriate spaces:

	NONE	MILD	MODERATE	SEVERE
THROBBING	0)_____	1)_____	2)_____	3)_____
SHOOTING	0)_____	1)_____	2)_____	3)_____
STABBING	0)_____	1)_____	2)_____	3)_____
SHARP	0)_____	1)_____	2)_____	3)_____
CRAMPING	0)_____	1)_____	2)_____	3)_____
GNAWING	0)_____	1)_____	2)_____	3)_____
HOT/BURNING	0)_____	1)_____	2)_____	3)_____
ACHING	0)_____	1)_____	2)_____	3)_____
HEAVY	0)_____	1)_____	2)_____	3)_____
TENDER	0)_____	1)_____	2)_____	3)_____
SPLITTING	0)_____	1)_____	2)_____	3)_____
TIRING – EXHAUSTING	0)_____	1)_____	2)_____	3)_____
SICKENING	0)_____	1)_____	2)_____	3)_____
FEARFUL	0)_____	1)_____	2)_____	3)_____
PUNISHING – CRUEL	0)_____	1)_____	2)_____	3)_____

Part 2: Place an "X" on the line to indicate your current level of pain.

No Pain_____**Worst Possible Pain**

Part 3: Which word best describes the pain you are presently feeling?

0 NO PAIN _____
1 MILD PAIN _____
2 DISCOMFORTING _____
3 DISTRESSING _____
4 HORRIBLE _____
5 EXCRUCIATING _____

Appendix H

The Pain Disability Index

The rating scales below are designed to measure the degree to which several aspects of your life are presently disrupted by chronic pain. In other words, we would like to know how much your pain is preventing you from doing what you would normally do, or from doing it as well as you normally would. Respond to each category by indicating the *overall* impact of pain in your life, not just when the pain is at its worst.

For each of the seven categories of life activity listed, please circle the number on the scale which describes the level of disability you typically experience. A score of 0 means no disability at all, and a score of 10 signifies that all of the activities in which you would normally be involved have been totally disrupted or prevented by your pain.

1. *Family/Home Responsibilities.* This category refers to activities related to the home or family. It includes chores and duties performed around the house (e.g., yard work) and errands or favors for other family members (e.g., driving the children to school).

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

2. *Recreation.* This category includes hobbies, sports, and other similar leisure time activities.

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

3. *Social Activity.* This category refers to activities which involve participation with friends and acquaintances other than family members. It includes parties, theatre, concerts, dining out, and other social functions.

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

4. *Occupation.* This category refers to activities that are a part of or directly related to one's job. This includes nonpaying jobs as well, such as that of a housewife, or volunteer worker.

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

5. *Sexual Behavior*. This category refers to the frequency and quality of one's sex life.

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

6. *Self Care*. This category includes activities which involve personal maintenance and independent daily living (e.g., taking a shower, driving, getting dressed, etc).

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

7. *Life-Support Activity*. This category refers to basic life- disability supporting behaviors such as eating, sleeping, and, breathing.

0	1	2	3	4	5	6	7	8	9	10
no disability										total disability

Appendix I

Pain Self-Efficacy Questionnaire

M.K.Nicholas, 1988

Please rate how **confident** you are that you can do the following things at present, **despite the pain**. To indicate your answer circle **one** of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:

0 1 2 3 4 5 6

Not at all Confident — **Completely confident**

Remember, this questionnaire is **not** asking whether of not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain.**

---

1. I can enjoy things, despite the pain.

0 1 2 3 4 5 6

Not at all Confident — **Completely confident**

2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.

0 1 2 3 4 5 6

Not at all Confident — **Completely confident**

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

0 1 2 3 4 5 6

Not at all Confident — **Completely confident**

4. I can cope with my pain in most situations.

0 1 2 3 4 5 6

Not at all Confident — **Completely confident**

5. I can do some form of work, despite the pain. ("work" includes housework, paid and unpaid work).

0 1 2 3 4 5 6

Not at all Confident **Completely confident**

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite pain.

0 1 2 3 4 5 6

Not at all Confident **Completely confident**

7. I can cope with my pain without medication.

0 1 2 3 4 5 6

Not at all Confident **Completely confident**

8. I can still accomplish most of my goals in life, despite the pain.

0 1 2 3 4 5 6

Not at all Confident **Completely confident**

9. I can live a normal lifestyle, despite the pain.

0 1 2 3 4 5 6

Not at all Confident **Completely confident**

10. I can gradually become more active, despite the pain.

0 1 2 3 4 5 6

Not at all Confident **Completely confident**

Appendix J

Activity Specific Measure of Fear and Pain

For each activity performed, please rate how much you fear the activity before and after you perform the activity. Also, please rate your current level of pain, the amount of pain you expect to experience while performing the activity, and the amount of pain you actually experienced when performing the activity. All rating should be made using a **0 – 100 point scale** where 0 = none, and 100 = the highest possible.

Current Level of Pain:_____

Name of Activity	**Trial #**	**Fear Before**	**Actual Fear**	**Expected Pain**	**Actual Pain**
	1				
	2				
	3				
	4				
	5				
	6				
	7				
	8				
	9				

Appendix K

Daily Measure of Fear and Pain

Instructions: Once each evening, please respond to each question on a scale from 1-10, where 1 = none and 10 = worst imaginable.

1. How much pain did you experience in your back, on average, this day? _____

2. What was your average level of anxiety today? _____

3. How much fear did you experience, on average, while performing activities today? _____

Appendix L

Working Alliance Inventory

WORKING ALLIANCE INVENTORY-CLIENT FORM

Below is a list of statements about your relationship with your therapist. Consider each item carefully and circle the number that corresponds with your level of agreement for each of the following items.

Does not Correspond At all			Corresponds Moderately			Corresponds Exactly
1	2	3	4	5	6	7

1. I feel uncomfortable with my therapist.
   1 2 3 4 5 6 7

2. My therapist and I agree about the things I will need to do in therapy to help improve my situation.
   1 2 3 4 5 6 7

3. I am worried about the outcome of these sessions.
   1 2 3 4 5 6 7

4. What I am doing in therapy gives me new ways of looking at my problems.
   1 2 3 4 5 6 7

5. My therapist and I understand each other.
   1 2 3 4 5 6 7

6. My therapist perceives accurately what my goals are.
   1 2 3 4 5 6 7

7. I find what I am doing in therapy confusing.
   1 2 3 4 5 6 7

8. I believe my therapist likes me.
   1 2 3 4 5 6 7

9. I wish my therapist and I could clarify the purpose of our sessions.
   1 2 3 4 5 6 7

10. I disagree with my therapist about what I ought to get out of therapy.
1 2 3 4 5 6 7

11. I believe the time my therapist and I are spending together is not spent efficiently.
1 2 3 4 5 6 7

12. My therapist does not understand what I am trying to accomplish in therapy.
1 2 3 4 5 6 7

13. I am clear on what my responsibilities are in therapy.
1 2 3 4 5 6 7

14. The goals of these sessions are important to me.
1 2 3 4 5 6 7

15. I find what my therapist and I are doing in sessions is unrelated to my concerns.
1 2 3 4 5 6 7

16. I feel the things I do in therapy will help me to accomplish the changes I want.
1 2 3 4 5 6 7

17. I believe my therapist is genuinely concerned for my welfare.
1 2 3 4 5 6 7

18. I am clear as to what my therapist wants me to do in these sessions.
1 2 3 4 5 6 7

19. My therapist and I respect each another.
1 2 3 4 5 6 7

20. I feel that my therapist is not totally honest about his/her feelings towards me.
1 2 3 4 5 6 7

21. I am confident in my therapist's ability to help me.
1 2 3 4 5 6 7

22. My therapist and I are working towards mutually agreed upon goals.
1 2 3 4 5 6 7

23. I feel that my therapist appreciates me.
1 2 3 4 5 6 7

24. We agree on what is important for me to work on.
1 2 3 4 5 6 7

25. As a result of these sessions, I am clearer as to how I might be able to change.
1 2 3 4 5 6 7

26. My therapist and I trust one another.
1 2 3 4 5 6 7

27. My therapist and I have different ideas on what my problems are.
1 2 3 4 5 6 7

28. My relationship with my therapist is very important to me.
1 2 3 4 5 6 7

29. I have the feeling that if I say or do the wrong things my therapist will stop working with me.
1 2 3 4 5 6 7

30. My therapist and I collaborate on setting goals for my therapy.
1 2 3 4 5 6 7

31. I am frustrated by the things I am doing in therapy.
1 2 3 4 5 6 7

32. We have established a good understanding of the kinds of changes that would be good for me.
1 2 3 4 5 6 7

33. The things that my therapist are asking me to do don't make sense.
1 2 3 4 5 6 7

34. I don't know what to expect as a result of therapy.
1 2 3 4 5 6 7

35. I believe the way we are working with my problem is correct.
1 2 3 4 5 6 7

36. I feel my therapist cares about me even when I do things that he/she does no approve of.
1 2 3 4 5 6 7

Appendix M

Ethical Approval Forms

UNIVERSITY OF REGINA

OFFICE OF RESEARCH SERVICES

Regina, Saskatchewan
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DATE: March 12, 2004

TO: Mr. M. Woods
#606, 3144 Edinburgh Drive
Regina, SK S4V 1A9

FROM: J. Roy
A. Chair, Research Ethics Board

Re: Evaluating the Efficacy of Graded *In Vivo* Exposure for the Treatment of Fear in Patients with Chronic Back Pain: A Randomized Controlled Clinical Trial. (42S0304).

Please be advised that the University of Regina Research Ethics Board has reviewed your proposal and found it to be:

✓ 1. ACCEPTABLE AS SUBMITTED. Only applicants with this designation have ethical approval to proceed with their research as described in their applications. The *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* requires the researcher to send the Chair of the REB annual reports and notice of project conclusion for research lasting more than one year (Section 1F). **ETHICAL CLEARANCE MUST BE RENEWED BY SUBMITTING A BRIEF STATUS REPORT EVERY TWELVE MONTHS.** Clearance will be revoked unless a satisfactory status report is received.

_____ 2. ACCEPTABLE SUBJECT TO CHANGES AND PRECAUTIONS (SEE ATTACHED). Changes must be submitted to the REB and subsequently approved prior to beginning research. Please address the concerns raised by the reviewer(s) by means of a supplementary memo to the Chair of the REB. Do not submit a new application. Please provide the supplementary memorandum**, or contact the REB concerning the progress of the project, before **June 12, 2004,** in order to keep your file active. Once changes are deemed acceptable, approval will be granted.

_____ 3. UNACCEPTABLE AS SUBMITTED. Please contact the Chair of the REB for advice on how the project proposal might be revised.

Dr. Joan Roy

c. G. Asmundson, supervisor

JR/sm/ethics2.dot

** supplementary memorandum should be forwarded to the Chair of the Research Ethics Board at the Office of Research Services (AH 505) or by e-mail to research.ethics@uregina.ca

Appendix N

Therapy Manual

Graded *In vivo* Exposure:

A Brief Therapy Manual

by

Marc Woods

Graded *in vivo* Exposure: A Brief Therapy Manual

1.0 Overview

Graded *in vivo* exposure for chronic pain is a treatment designed to help individuals with chronic musculoskeletal pain and a fear of pain or movement to improve their level of functioning. This is accomplished through the reductions in their fear of pain and related avoidance behaviours. This brief treatment manual is largely based on the outline provided by Vlaeyen, de Jong, Sieben, and Crombez (2002) for treatment of individuals with fear of pain, and the chapter by Butler (1996) describing cognitive-behavioural therapy for people with phobias.

Graded *in vivo* exposure was originally developed and outlined by Vlaeyen, de Jong, Geilen, Heuts, and van Breukelen (2001), and Vlaeyen, de Jong, Ongehena, Kerckhoffs-Hanssen, and Kole-Snjijders (2002). In brief, this form of therapy consists of the activation of fear, and the challenging, and subsequent disconfirmation of, catastrophic expectations about movement. Treatment commences with a cognitive-behavioural assessment, followed by an education component, *in vivo* exposure tasks with behavioural experiments, and, finally, a review session. The aim of graded *in vivo* exposure, as with most cognitive-behavioural treatments of chronic pain, is not to "cure" the pain, but to improve the quality of life by decreasing the fear and anxiety associated with the pain and by increasing the level of functioning (i.e., increasing activities, returning to work) of the individual.

Throughout therapy, care is taken to follow the suggestions of Hadjistavropoulos and Kowalyk (2004) to ensure a strong therapeutic relationship. A positive relationship between therapist and patient has been associated with positive treatment outcomes

(Orlinski, Grawe, & Parks, 1994) and is especially necessary with cognitive behaviour therapies in order to assist the patient to appraise thoughts and alter behaviours (Safran & Segal, 1990). To facilitate the development of the therapeutic relationship in patients with fear of pain, Hadjistavropoulos and Kowalyk have made several suggestions. These include actively monitoring the quality of the relationship and the therapist's reactions towards the patient in order to properly cultivate the relationship and deal with problems as they occur; being empathic, or actively communicating an understanding of the patient's perspective; collaboratively working with the patient to set treatment goals; promoting the patient's self-efficacy, particularly regarding their ability to perform feared activities; and assignment of homework tasks (e.g., further repetitions of the exposure activities). All patients should also be explicitly informed that they are free to stop treatment at any time.

2.0 First Session: Assessment

The primary purpose of the cognitive-behavioural assessment is to determine the specific nature of the patient's pain-related fear. This assessment can be completed in one 60-90 minute session that consists of the administration of several questionnaires and a semi-structured interview, educating the patient about the fear-avoidance model of chronic pain, and formulation of the patient's problems within this context, including an assessment of feared activities and establishment of an individualized hierarchy of fear-eliciting movements.

2.1 Confidentiality

Prior to the administration of the questionnaires and interview, issues and limitations of confidentiality, as relevant to your work place, should be reviewed. This is

particularly important with chronic pain patients as they are often involved with insurance claims and may not want information from therapy to be released to their insurance company.

2.2 Questionnaires and interview

Questionnaires may be used to assess different aspects of pain-related fear and disability. Though there are a variety of different measures that may be used, the following questionnaires have strong psychometric properties: the Tampa Scale for Kinesiophobia, Fear Avoidance Beliefs Questionnaire, Pain Anxiety Symptom Scale, Pain Catastrophising Scale, McGill Pain Questionnaire, and the Pain Disability Index. Following administration of the assessment battery, a semi-structured interview is conducted. The interview, outlined in Appendix A, focuses on cognitive (e.g., negative thoughts), behavioural (e.g., avoidance of activities), and psychophysiological (e.g., diagnoses, experience of pain) aspects of the patient's symptoms, as well as antecedents and maintenance factors of the pain problem. This information helps to determine the extent to which pain-related fear contributes to the chronic pain condition. It is particularly important to focus on the maintaining factors of the pain and the pain related fear. Maintaining factors are most often negative thoughts about the danger of the behaviour, avoidance of the behaviour, and hypervigilance towards threatening signals. Thus, core negative thoughts should be elicited at this stage of therapy. Additionally, the consequences, both direct (e.g., avoidance of activities) and indirect (e.g., loss of social contacts), of the pain-related fear are assessed in the interview. Finally, the interview should also be used to identify whether more complicated problems (e.g., insurance

claims, relationship difficulties, or psychiatric disturbances) might arise during therapy. If so, the usage of graded *in vivo* exposure may need to be re-considered.

2.3 Educational component

The education component involves helping the patient to reformulate the way they view their pain so that they no longer perceive it as a serious disease or a condition that requires careful protection. Rather, the view that pain is a common condition that can be self-managed is promoted. This change in perspective is accomplished, in part, through a careful explanation of the fear-avoidance model, demonstrating how the patient's specific symptoms, behaviours, and beliefs can create a vicious cycle that perpetuates the pain problem (pain → catastrophic thoughts → fear → avoidance → disability → pain; see also Figure 1). For example, while attempting to move a heavy plank, a construction worker might experience a serious strain to his back. The experience of pain may lead him to develop fear-provoking catastrophic thoughts about that pain and activity (e.g., "If I try to lift anything heavy again, I will get injured"; "Any feelings of discomfort in my back mean I am going to experience another serious injury"). In turn, these catastrophic thoughts produce anxiety related to the activity (as identified through the establishment of a fear hierarchy) and regarding pain itself. This anxiety will then increase the likelihood that he will either escape situations perceived to be pain-arousing, or avoid the activity entirely (e.g., he would stop trying to lift or move any objects he thought to be heavy, and/or cease performing physical activities such as weight lifting that would cause muscle tension in his back). Over the long term, this avoidance and escape behaviour may result in a significant reduction of functional activities (e.g., cessation of significant housework; loss of job),

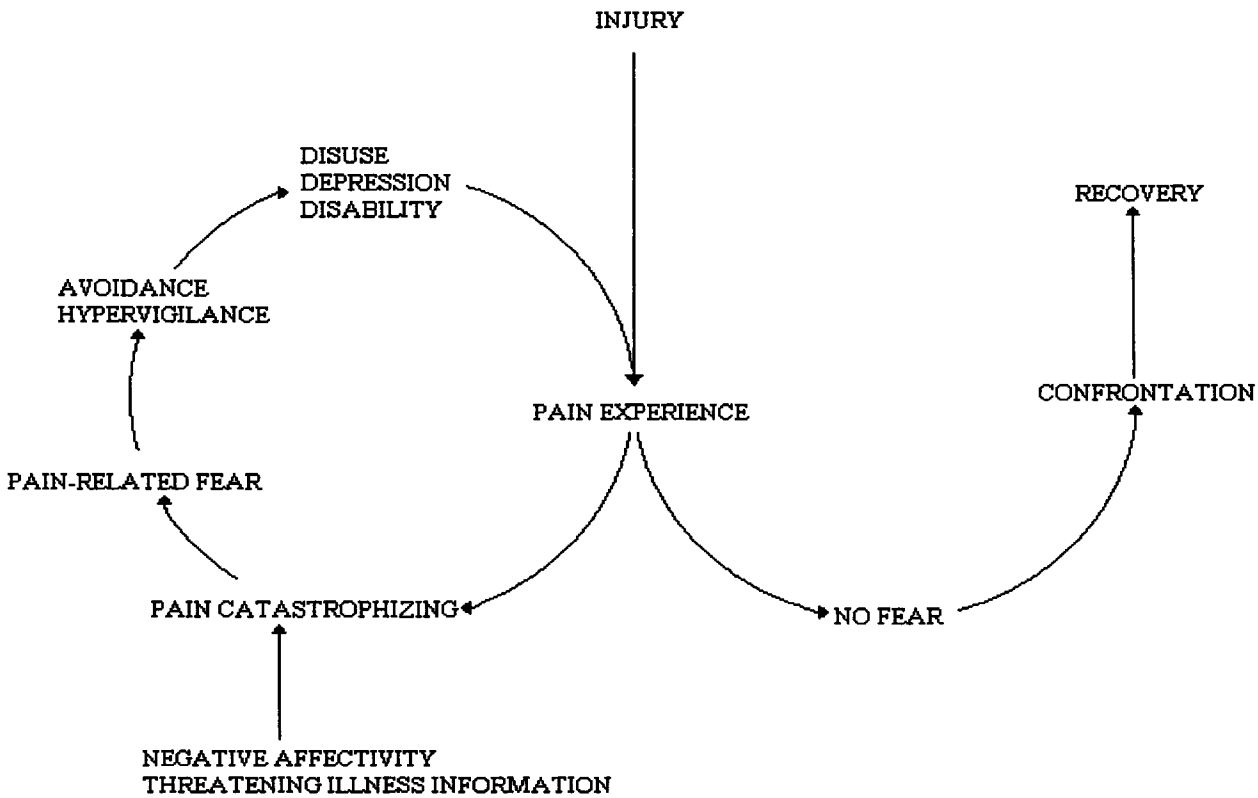

Figure 1. Fear-avoidance model, adapted from Vlaeyen and Linton (2000).

Note. From "Fear-avoidance and its consequences in chronic musculoskeletal pain: A state of the art," by Vlaeyen & Linton (2000), Pain, 85, 317-332. Copyright 2000 by International Association for the Study of Pain. Reprinted with permission.

correspondingly producing physiological dysfunction that, in combination with the decrease in activity, results in further disability. An increase in level of disability, in turn, amplifies the amount of pain experienced, and the cycle begins again.

When explaining the model to the patient, Figure 1 can be used as a visual aid. It might also be helpful to avoid using terminology (e.g., catastrophizing) that could be interpreted as suggesting there is no basis for the patient's beliefs about their pain. Thus, "catastrophic thoughts" might be replaced with "negative" or "anxious" thoughts. If the patient has difficulty understanding the relationship between negative thoughts, feelings, and behaviours, you may further simplify the explanation by using Albert Ellis's (1962) ABC model of internal self-talk. According to Ellis, A = an event, B = interpretation of an event, and C = the behavioural and emotional consequence. The consequence is the result of our interpretation of the event, and not of the event itself. For example, if a person hurts their back (A), they might think that they will never be able to return to work (B), therefore they will feel frustrated and give up easily when trying to improve their physical functioning (C).

Based on the above-described formulation, customized to fit the specific context of the patient's fears, the ultimate goal of the education component is to improve the willingness of patients to participate in heretofore avoided activities. This message will follow naturally through use of the fear-avoidance model to describe the patient's problem, and it may be worthwhile to ask the patient how to break the vicious cycle described in the fear-avoidance model. This will give the patient a chance to actively think about what to do, thereby promoting the self-help rationale.

2.4 Goal setting

The general goal of therapy – to improve functioning, not to reduce pain – is consistent with the educational component and should be explicitly stated and agreed upon. Following this, other specific treatment goals should be established using positive language. For example, a typical goal might be to go for a walk three times a week, go grocery shopping on your own, or to go out with some friends to a movie. When the goal is to return to work, it might be worthwhile to have the patient consult with an occupational therapist or career counsellor. There are several advantages to establishing treatment goals. One is that they will help to focus the patient towards the possibility of change and improving daily functioning, and away from pain and physical symptoms. Also, in formulating their own goals, patients become active participants in therapy. Finally, goal setting will help in structuring the treatment and developing a graded fear hierarchy. For example, if a patient wishes to resume household activities, then such activities should be included in the graded hierarchy.

2.5 Establishing a fear hierarchy

During the assessment process a graded fear hierarchy is established. A graded fear hierarchy is a comprehensive list of activities that the patient fears, ordered from least amount of fear to greatest amount of fear (see Table 1). The hierarchy should reflect the full range of activities feared by the patient, beginning with things that provoke only mild fear (e.g., picking up a light object from the floor), and ending with things that are beyond the patient's current abilities (e.g., skiing). In order to assist in the development of the fear hierarchy, Vlaeyen et al. (2001) have used the Photograph Series of Daily

Table 1

Sample of a Fear Hierarchy

	Rating Scale 0-100
1. Walking more than 100 meters	5
2. Picking up light objects	10
3. Standing for more than 10 minutes	10
4. Swimming	20
5. Picking up moderately heavy objects (e.g., chair)	30
6. Light Jogging	50
7. Vacuuming	55
8. Going grocery shopping by myself	70
9. Picking up heavy objects (e.g., 50 lbs or more)	90
10. Cleaning the entire house	100

Activities (PHODA; Kugler, Wijn, Geilen, de Jong, & Vlaeyen, 1999). The PHODA consists of 98 photographs depicting various activities and movements of daily life. The patient is required to place each photograph on a "fear thermometer", thereby creating a hierarchy of feared movements. Additionally, when a patient has difficulty estimating the harmfulness or fear related to a movement or activity (typically because they have avoided it extensively), behavioural tests may be attempted. During the performance of the behavioural test or avoided activity, performance indices such as time, distance, and repetitions are recorded in order to provide a more objective measure of avoidance behaviour. For example, a particular patient may avoid sitting at a computer desk for any length of time for fear of worsening their back injury. The patient would be asked to sit at a desk until pain, weakness, fatigue, or any other reason causes them to stop. During this behavioural test the individual's anxiety before and fear during the task can be measured (e.g., on a scale from 0-100%), as well as the length of time they are able to stay in the chair, and their reason for moving. Such tests allow anticipatory anxiety to be measured separately from fear experienced during performance of the task, and give a more objective account of avoidance behaviour (Vlaeyen, de Jong, Sieben, & Crombez, 2002).

2.6 Engagement in treatment

Some patients may be resistant to the idea that their chronic pain condition has a psychological component. The educational portion of the assessment should help to address this problem. However, if a patient continues to be resistant to a psychological perspective or treatment, it might be helpful to ask the patient how long they have been trying to deal with their problem through physical treatments, and how effective these treatments have been. Many patients have had multiple forms of physical therapy,

including physiotherapy, acupuncture, massage therapy, medications, and even surgery, yet their pain condition continues to result in a significant level of impairment. The therapist can then propose that it may be worthwhile to try an alternative treatment, particularly since this form of treatment will only require four weeks of the patient's time – a substantially lesser amount than the patient has already invested in physical treatments. If, after four weeks of complying with this treatment, the patient does not experience significant improvement, then the patient can reasonably return to solely physical methods of dealing with their pain. Thus, the patient is not asked to give up their view of their pain condition, they are merely testing an alternative perspective (for a more detailed description, see Salkovskis, 1996).

3.0 Sessions 2 – 8: Graded in vivo exposure

Following the assessment session, treatment sessions are scheduled for 45 minutes two times per week for 4 weeks. In the first treatment session, patients are exposed to low anxiety activities identified in the graded hierarchy of fear-eliciting situations. The first activity selected should provoke only mild anxiety, and be easy enough for the patient to attempt. Exposure occurs *in vivo* (i.e., in real life), and is not imaginal in nature. Initially, each activity or movement is modelled by the therapist to demonstrate the correct ergonomic way of performing the activity and that the activity or movement is not fear-provoking to the therapist. In order to promote independence, however, the presence of the therapist is quickly reduced as therapy progresses.

General principles of exposure are followed throughout treatment. These include obtaining patient agreement to repetitively perform each previously avoided activity until the belief that that the activity is harmful is disconfirmed, and the patient's anxiety

decreases significantly. Once this has occurred, a more difficult item on the fear hierarchy is attempted. Decreases in anxiety are monitored through self-report (e.g., by having the patient predict the likelihood of harm and rating how distressing performance of the task is across repetitions, on a scale of 0-100, where 100 is the most distress imaginable; see Appendix B). Patients should also be encouraged to perform homework tasks such as exposure to activities in a variety of contexts (e.g., walk around the house, down the block, in a shopping mall, up a hill) so that learning will generalize.
When improvements are obtained (e.g., there is a lessening of fear/anxiety for particular task, level of functioning is increased), it is important for the therapist to discuss the reasons for change (e.g., by asking, "What does your ability to perform this activity/movement tell you?") with the patient in order to highlight important implications of the patient's experience (e.g., that practice helps them to reduce their anxiety/fear and increase their functional ability) and support for the treatment rationale. By understanding both the rationale, and practicing exposure tasks, the patient has the opportunity to learn that they can reduce their fears, improve their functioning, and that they are responsible for this improvement. This learning should always be discussed and made explicit.

Throughout exposure therapy, behavioural experiments (as described above) may be carried out. Behavioural experiments involve the empirical testing of patient-produced hypotheses. Following a patient prediction that a certain activity will produce pain, an appropriate behavioural experiment is carried out and the consequences evaluated. For example, if a patient predicted that walking briskly down a corridor would cause intolerable pain, that prediction would be tested by having the patient attempt the activity.

Prior to the attempt, the therapist might first demonstrate the proper method of performing the activity. The patient would also be asked to rate how much pain they expect to experience (using a scale from 0-100), and how much anxiety (0-100) they have about performing the activity. The experienced pain and anxiety ratings during the test are then recorded and compared to the predictions, and differences discussed.

In addition to *in vivo* exposure that occurs within therapy sessions, the patient is required to perform homework tasks involving the repetition of activities/movements until little or no anxiety is aroused. The rationale is that frequent and regular repetitions are required to generate and maintain improvement. As with many tasks (e.g., riding a car, typing on a computer) the more practice that is conducted, the better the individual becomes. Patients should be encouraged to use a self-monitoring form (see Appendix B) to keep track of changes in their levels of anxiety/fear and pain across exposures.

Should a patient fail to complete homework, it will be necessary to explore the reasons (e.g., practical difficulties, irrational fears) for the failure. There are several common causes for poor completion of homework tasks. For example, the patient may not adequately comprehend the treatment model. If the model is not understood, it may be unlikely that the patient will accept that the treatment could be helpful, and therefore the patient may be less willing to attempt homework tasks. Therefore, it would be important for the therapist to review the treatment model and rational so that they are understood by the patient. Also, in order to improve the patient's willingness to comply with treatment, it might be helpful to collaboratively look for evidence that exposure has been, or is likely to be, beneficial. Some patients might also perceive the tasks to be unreasonable or artificial (e.g., repetitively carrying a basket of laundry from room to

room). If so, it should be explained that the activities are like exercises prescribed by a physiotherapist after an injury: Their purpose is to improve functioning, and once this has been accomplished, the artificial task no longer needs to be performed.

3.0 Final Session and Maintenance of Change

The last session, which lasts from 15-30 minutes, is dedicated to a final and brief review of the model (focussing on the negative cycle and how to break it), the principles of *in vivo* exposure therapy (the need for practice of exposure tasks to reduce fear/anxiety and improve functioning), and the patient's progress thus far (functional improvement, as shown by specific examples from the patient's fear hierarchy; review of goal achievement). It is important to stress the self-help nature of the therapy - the patient, and the work they put in, brought about any improvement. The patient can, therefore, maintain their progress and continue to benefit by practicing the same principles that have aided them throughout therapy.

Expectations and plans for the future should also be discussed, particularly regarding the likelihood of fluctuations in anxiety, pain, and functioning. Such setbacks can be disconcerting if the patient is not forewarned and a plan put in place to deal with them. Any plan should be phrased in the patient's words, and reiterate that relapses can be dealt with using the same methods of exposure as have been successful thus far. The patient should also be reminded to keep in mind the general principle of maintaining or improving their level of functioning, not simply relieving their pain. Specific examples of the effectiveness of exposure in reducing fear and anxiety, and increasing level of functioning, might be warranted in this endeavour.

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Appendix A

Interview Topics

Background Information/Antecedents

14) What does your pain feel like?

15) When did the pain start?

16) What were the circumstances of pain onset?

17) If there was a sudden pain onset, what did you do, think, and feel at that moment?

18) What has your doctor and/or other medical specialists told you about your condition?

19) What tests have been performed to identify the cause of your problem? What have these tests found?

Maintaining Factors

20) What do you think is causing your pain?

21) a) What are you not doing because of the pain problem?/ If you no longer had the problem, what differences would it make to your life (be specific)?

b) What do you think would happen [to your back/pain/injury] if you did perform [specify activity]?

22) What factors make it easier or harder to perform an activity/stop avoiding?

23) What do you think will happen in the near future if the pain remains untreated?

24) What do you do to cope with your pain problem?

Other Issues

25) What other life stresses are you experiencing? (e.g., job loss, marital difficulty, loss of social contacts)

26) How will improvement of your pain condition affect these other problems?

Activity Specific Measure of Fear and Pain

For each activity performed, please rate how much you fear the activity before and after you perform the activity. Also, please rate your current level of pain, the amount of pain you expect to experience while performing the activity, and the amount of pain you actually experienced when performing the activity. All rating should be made using a **0 – 100 point scale** where 0 = none, and 100 = the highest possible.

Current Level of Pain:_____

Name of Activity	**Trial #**	**Fear Before**	**Actual Fear**	**Expected Pain**	**Actual Pain**
	1				
	2				
	3				
	4				
	5				
	6				
	7				
	8				
	9				

Daily Measure of Fear and Pain

Instructions: Once each evening, please respond to each question on a scale from 0-100, where 0 = none and 100 = worst imaginable.

Date: _____

1. How much pain did you experience in your back, on average, this day? _____

2. What was your average level of anxiety today? _____

3. How much fear did you experience, on average, while performing activities today? _____

Date: _____

1. How much pain did you experience in your back, on average, this day? _____

2. What was your average level of anxiety today? _____

3. How much fear did you experience, on average, while performing activities today? _____

Date: _____

1. How much pain did you experience in your back, on average, this day? _____

2. What was your average level of anxiety today? _____

3. How much fear did you experience, on average, while performing activities today? _____

Date: _____

1. How much pain did you experience in your back, on average, this day? _____

2. What was your average level of anxiety today? _____

3. How much fear did you experience, on average, while performing activities today? _____