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Feasibility and Acceptability of Graded In-Vivo Exposure Therapy for Fibromyalgia Patients

A dissertation submitted in partial satisfaction of the requirements for the degree Doctor of Philosophy

in

Clinical Psychology

by

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The Dissertation of Maya Sarah D'Eon is approved, and it is acceptable in quality and form for publication on microfilm or electronically:

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ABSTRACT OF THE DISSERTATION

Feasibility and Acceptability of Graded In-Vivo Exposure Therapy for Fibromyalgia Patients

by

Maya Sarah D'Eon

Doctor of Philosophy in Clinical Psychology

San Diego State University, 2016
University of California, San Diego, 2016

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Rationale. Fibromyalgia syndrome (FMS) is a chronic pain condition that affects between 1 and 11% of the general population worldwide. Aerobic and strength exercises improve FMS symptoms and reduce physical weakness; however, adherence to exercise programs is low. About 40% of people with FMS have high pain-related fear of movement. The fear-avoidance model proposes that catastrophizing, pain-related fear, and behavioral avoidance lead to the development and maintenance of disability and

depression. Graded in-vivo exposure therapy targets these negative components to reduce fear avoidance, and has demonstrated efficacy in improving outcomes in the chronic low back pain population, but has not been examined within the FMS population.

Design. A two-armed pilot trial was conducted to examine the feasibility and acceptability of study procedures and an exposure intervention for FMS patients with moderate to high pain-related fear of movement. The intervention was delivered individually to participants over 13 sessions and was compared to a self-management education condition. Recruitment took place over a 1-year period, and 29 participants were randomly assigned to an intervention condition. Four participants completed the exposure intervention, and eight completed the education condition. Four assessments were conducted to examine changes in process measures, outcome variables, and program satisfaction. The data of primary interest for this dissertation were focused on adherence, attrition, recruitment, eligibility criteria, randomization, assessment measures, treatment trends, and concurrent pharmacological treatment.

Results. As per the CONSORT-modified checklist for reporting feasibility research, threshold criteria were used to determine the feasibility and acceptability of the study components. The results indicated that the feasibility and acceptability criteria were met for eligibility criteria, randomization procedures, and assessment measures. The criteria were not met for recruitment procedures, adherence, and attrition, which suggests the need for modifications in these areas. Examination of treatment trends suggests that the exposure intervention produced improvements in variables of interest. In addition, there was limited evidence of concurrent pharmacological treatment for anxiety symptoms.

Conclusions. Effective interventions are needed to increase physical activity within the FMS population. Based on these findings, a randomized controlled trial to examine treatment efficacy was recommended, after modifications have been made to the study procedures and the intervention protocol.

Introduction

Fibromyalgia Syndrome (FMS)

Fibromyalgia syndrome (FMS) is a chronic, painful condition that is estimated to affect between 1 and 11% of the general population (Giacomelli, Sernissi, Rossi, Bombardieri, & Bazzichi, 2014; McBeth & Mulvey, 2012; Wolfe et al., 1990), with the prevalence increasing with age (McBeth & Mulvey, 2012; Wolfe, Brahler, Hinz, & Hauser, 2013a). It is estimated that about 5 million people have been diagnosed with FMS in the United States (Lawrence et al., 2008). FMS is also one of the most commonly seen conditions by rheumatologists (Goldenberg, 1987; McBeth & Mulvey, 2012; Richards & Scott, 2002). Women are seven times more likely to develop FMS than men (Lawrence et al., 2008); however, recent changes to diagnostic criteria involving the removal of tender point examination are expected to reduce the female-to-male ratio to 2:1 (Nisell & Kosek, 2011). This is because the increased prevalence among women might be explained by their lower pain threshold and greater pain sensitivity than men (Garcia, Godoy-Izquierdo, Godoy, Perez, M & Lopez-Chicheri, 2007; Nisell & Kosek, 2011; Soetano, Chung, & Wong, 2006).

FMS is comprised of a constellation of symptoms, with the central symptom of widespread musculoskeletal pain (Wolfe et al., 1990). Specifically, individuals with FMS report experiencing allodynia (pain perceived in the absence of noxious stimuli) and hyperalgesia (exaggerated pain response in the presence of noxious stimuli). In addition, most individuals with FMS report experiencing chronic fatigue (Bennett, 2009; Hawkins, 2013; Wolfe et al., 1990; Wolfe et al., 2010) and various forms of sleep disturbance, including poor overall sleep, frequent awakenings, difficulty falling asleep, morning

stiffness, and exhaustion after awakening (Bennett, 2009; Hawkins, 2013; Moldofsky, 2009). Electroencephalograph studies have revealed that FMS is associated with alpha-delta intrusion, which results in reduced restorative sleep (delta wave sleep), leading to increased fatigue and pain (Moldofsky, Scarisbrick, England, & Smythe, 1975; Moldofsky, 2009). In fact, sleep studies have shown that FMS symptoms can be induced in healthy individuals through sleep deprivation (Moldofsky et al., 1975; Moldofsky & Scarsibrick, 1976; Yunus, 2007). Other common FMS symptoms include cognitive dysfunction and bowel dysfunction (Okifuji & Hare, 2013; Theadom, Cropley, & Humphrey, 2007; Wolfe et al., 1990). The cognitive dysfunction found within FMS has been coined "fibro-fog" and largely consists of short-term memory loss and concentration difficulties (Bennett, 2009; Hawkins, 2013; Wolfe et al., 1990). In addition to the physical symptoms of FMS, members of this patient population are more likely to experience almost all forms of mental illness than members of the general population (Fietta, Fietta, & Manganelli, 2007; Wolfe et al., 2013a), with notable presence of depression, anxiety, and difficulties in coping with stressors (Hawkins, 2013). In fact, nearly half of FMS patients present with depression and anxiety (Hawkins, 2013; Yunus, 2007). It has been suggested that a bi-directional relationship exists between FMS and psychological factors (Hawkins, 2013).

The etiology of FMS is unknown and underlying pathophysiology has not been established (McBeth & Mulvey, 2012), but a number of risk factors have been shown to be associated with the development of FMS (Nisell & Kosek, 2011). The risk factors include psychological distress (e.g., Robinson et al., 2004), trauma (Ablin, Buskila, & Clauw, 2009; Jones, King, Mist, Bennett, & Horak, 2011; Walen, Cronan, & Bigatti,

2001), genetic predisposition (Arnold et al., 2004; Giacomelli et al., 2014; Hawkins, 2013; Holliday et al., 2010; Xiao, Russell, & Liu, 2012), chronic localized pain (Okifuji & Hare, 2013), and dysfunctional pain processing (Staud, 2004; Staud, Nagel, Robinson, & Price, 2009). The findings in the literature are inconsistent regarding the presence of FMS biomarkers and there are no agreed-upon biomarkers for effective and reliable use in clinical practice (Giacomelli et al., 2014). Given the experienced symptoms and high degree of illness uncertainty, the impact of FMS on a person's life is substantial. Individuals with FMS are likely to experience functional deficits and work-related disability, as well as lower quality of life relative to other chronic conditions, such as rheumatoid arthritis and Sjogren's disease (Burckhardt, Clark, & Bennett, 1993; Henriksson & Liedberg, 2000; Kaplan, Schmidt, & Cronan, 2000; Nisell & Kosek, 2011; Strombeck, Ekdahl, Manthorpe, Wikstrom, & Jacobsson, 2000).

History of FMS Diagnosis and Classification

The present-day understanding of FMS has developed from years of theorizing and research. Clinical presentation of FMS symptom clusters has been recorded as early as the mid-ninth century (Okifuji & Hare, 2013; Simons, 1975). At the time, it was considered a rheumatic condition and described as widespread tenderness (Simons, 1975). In the late 1900s, this symptom cluster was referred to as 'fibros*itis* syndrome' because it was believed to be caused by inflammation of connective tissues (Gowers, 1904; Stockman, 1904). This explanation held until the 1970s, when burgeoning research demonstrated that muscle and connective tissue abnormalities and inflammation were unlikely to be the underlying causes of the syndrome (Bennett, 1981; Simms et al., 1994; Wolfe et al., 1990; Yunus, Masi, Calabro, Miller, & Feigenbaum, 1981). Throughout the

1970s and 1980s, research was conducted to better understand the clinical presentation of symptoms and inform diagnostic criteria (Okifuji & Hare, 2013), and in 1979, Smythe introduced the conceptualization of FMS as a pain amplification disorder. This shift in belief led Fibrositis to be renamed Fibromyalgia Syndrome during the 1980s (Wolfe et al., 1990).

In 1990, Wolfe and colleagues developed the original American College of Rheumatology (ACR) diagnostic criteria for FMS following a large multicenter study comparing 293 FMS patients with 265 controls who had localized, regional, or rheumatic pain. Their criteria were shown to have high sensitivity (88.4%) and specificity (81.8%). These original criteria included the presence of widespread pain lasting at least three months and the presence of pain in 11 of 18 pre-determined tender point areas (Wolfe et al., 1990). According to the ACR 1990 criteria, widespread pain referred to pain in each quadrant of the body: axial pain, left- and right-side pain, and upper and lower body pain (Wolfe et al., 1990). This set of criteria was introduced in order to stimulate systematic research into the nature of FMS (Wolfe, Walitt, & Hauser, 2013b).

Since establishment of the 1990 ACR criteria, research into FMS has dramatically increased. A Pubmed keyword search ("fibrositis OR fibromyalgia") was conducted on March 1, 2014 and revealed that 545 journal articles were published on FMS prior to 1990 as compared to 4,619 that were published since that time. Despite established diagnostic criteria, tender point examinations were rarely performed by physicians and when performed, were often done incorrectly (Bennett, 2009; Fitzcharles & Boulos, 2003; Hawkins, 2013; Wolfe et al., 2010). In addition, research since 1990 has demonstrated the noteworthy presence of fatigue, cognitive symptoms, and additional

somatic symptoms within this population that were not captured in the ACR criteria (Mease, 2007; Wolfe et al., 2010). To address growing appreciation of the complexity of symptom presentation, new diagnostic criteria were developed based on the results of a multicenter study comparing 433 patients with FMS diagnosis with 396 non-inflammatory pain controls (Wolfe et al., 2010). In the ACR 2010 criteria, musculoskeletal pain attributed to 50% of the diagnostic criteria score, as opposed to 100% of the score in the 1990 criteria, with the other 50% being attributed to self-reported fatigue, sleep, and cognitive symptoms, and the level of symptom severity (Wolfe et al., 2010; Wolfe et al., 2013b). These new criteria removed the need for a physical tender point examination and were designed to facilitate systematic and consistent clinical diagnosis in primary and secondary care facilities (Okifuji & Hare, 2013; Wolfe et al., 2010).

In 2011, these criteria were further modified to facilitate physician classification of symptoms (See Table 1 for 1990, 2010, and 2010 modified ACR criteria). This modified version included additional items capturing the presence of headaches, pain or cramping in lower abdomen, and depressive symptoms to account for empirical findings of their presence in a large majority of FMS patients (Wolfe et al., 2011). More research is needed to assess acceptance, reliability, and validity of the modified ACR 2010 criteria (Wolfe et al., 2011).

Table 1. Representation of the ACR criteria for FMS diagnosis and classification

1990 ACR Criteria	2010 ACR Criteria	2010 Modified ACR Criteria
Two criteria must be met: 1. Widespread pain lasting at least 3 months 2. Tender point examination with pain in at least 11 of 18 sites for four quadrants of the body	Three criteria must be met: 1. Widespread Pain Index (WPI) ≥ 7 and the Symptom Severity Score (SS) ≥ 5, or the WPI is 3–6 and the SS ≥ 9 2. FMS symptoms present at a similar level for at least 3 months 3. Another disorder does not explain the pain	Three criteria must be met: 1. WPI ≥ 7 and the SS ≥ 5, or the WPI is 3–6 and the SS ≥ 9 a. SS scale now includes rating severity of headaches, pain or cramps in lower abdomen, and depression within 6 months 2. FMS symptoms present at a similar level for at least 3 months 3. Another disorder does not explain the pain

Current Understanding of FMS Mechanisms

There is still a significant gap in knowledge regarding the nature of FMS (Wolfe et al., 2013a). Research over the last few decades has yielded new proposed underlying mechanisms to explain the clinical presentation of FMS. There is mounting evidence that suggests that FMS is caused by abnormalities in the central nervous system (CNS) and the presence of central sensitization (Dadabhoy & Clauw, 2006; Okifuji & Hare, 2013; Wolfe et al., 2013b). Central sensitization is experienced as an amplified pain response in the presence of noxious stimulation and pain response in the absence of noxious stimulation (Li, Simone, & Larson, 1999; Meeus & Njis, 2007; Staud & Smitherman, 2002). In fact, early prediction that FMS is related to central nervous system abnormalities came from findings of reported allodynia and hyperalgesia (Kosek, Ekholm, & Hansson, 1995; Kosek, Ekholm, & Hansson, 1996a) and dysregulation of pain inhibition mechanisms (Kosek, Ekholm, & Hansson, 1996b; Lautenbacher & Rollman, 1997; Nisell & Kosek, 2011). Studies of the FMS population have suggested that symptoms might be caused by self-perpetuating neurosensitization processes that are

driven by CNS-activated response patterns (Mease et al., 2007). Repeated exposure to noxious stimuli may initiate heightened nervous system responses (Eriksen & Ursin, 2004; Meeus & Nijs, 2007). Specifically, repeated exposure to noxious stimulation leads to heightened and prolonged activation of dorsal horn neurons, which produces central sensitization (Meeus & Nijs 2007; Staud & Smitherman, 2002).

There is a growing body of research that supports this theory of FMS being attributed to central sensitization. Research has shown that compared to healthy controls, individuals with FMS demonstrate increased windup sensitivity (i.e., exaggerated pain response in presence of repeated noxious stimuli; Okifuji & Hare, 2013; Staud, 2004). More recently, imaging studies have revealed that individuals with FMS display heightened transmission and nociceptive input processing (Gracely, Petzke, Wolf, & Clauw 2002; Jensen et al., 2009), as well as diminished activity in pain inhibition mechanisms (Jensen et al., 2009; Nisell & Kosek, 2011). Nociception refers to the physiological response to current or past tissue damage (Meeus & Nijs, 2007; Winkelstein, 2004). According to this perspective, FMS has been described as a phenotype within a larger spectrum of similar central sensitivity disorders that exist (Hawkins, 2013).

Unlike early beliefs, examination of the role of local muscle tissue has yielded mixed findings, with most studies suggesting its limited direct contribution to FMS (Okifuji & Hare, 2013). However, it is possible that changes (e.g., damage) to peripheral tissue may contribute to local pain sensitivity, which is proposed to lead to central sensitization (Okifuji & Hare, 2013; Staud, 2011). Research has shown that having chronic localized pain increases the risk of developing FMS (Forseth, Forre, & Gran,

1999; Mease, 2005; Nisell & Kosek, 2011). For instance, prior to fully developing FMS, over 75% of people experienced prolonged localized pain (Henriksson, Carlberg, Kjallman, Lundberg, & Henriksson, 2004; Nisell & Kosek, 2011). Among those with FMS, 20% had whiplash pain (Buskila, Neumann, Vaisberg, Alkalay, & Wolfe, 1997), 25% had chronic low back pain (Lapossy, Maleitzke, Hrycaj, Mennet, & Müller, 1995), and upwards of 30% had inflammatory rheumatic disorders (e.g., rheumatoid arthritis, lupus, Sjogren's disease; Gladman et al., 1997; Bonafede, Downey, & Bennett, 1995; Middleton, McFarlin, & Lipsky, 1994; Neumann & Buskila, 2003; Nisell & Kosek, 2011; Romano, 1992a; Romano, 1992b; Staud, 2006; Wolfe, Cathey, & Kleinheksel, 1984). Research is still being directed towards further understanding the etiology and mechanisms that drive the FMS symptom presentation.

FMS Treatments

Existing treatments have been largely ineffective in alleviating the full constellation of FMS symptoms (Okifuji & Hare, 2013; van Koulil et al., 2007). This might be related to the reality that FMS is a heterogeneous population in terms of symptom presentation and treatment response (Okifuji & Hare, 2013; Wilson et al., 2009), which highlights the importance of taking a patient-centered and a customized approach to treatment (Ablin et al., 2013; Nisell & Kosek, 2011; van Koulil et al., 2010). Despite the growing appreciation of FMS as a heterogeneous population, treatments are not commonly tailored to the individual's unique presentation or built from a theoretical foundation (Pincus, Smeets, Simmonds, & Sullivan, 2010), which might explain high attrition rates and low effect sizes found in many intervention studies (van Koulil et al., 2007). Currently accepted FMS treatments include pharmacotherapy, behavioral

interventions (e.g., exercise), and psychological treatments (e.g., cognitive behavior therapy; McBeth & Mulvey, 2012). Although psychological and pharmacological treatments have been evaluated for FMS, few have shown substantial positive long-term effects. In addition, randomized control trials (RCTs) in FMS research have generally demonstrated small to moderate effect sizes (Rossy et al., 1999; van Koulil et al., 2007).

There is growing evidence suggesting that the combination of education, exercise, and psychological therapy may be effective in leading to lasting improvements in pain and other FMS symptoms (Martin et al., 2012; Nisell & Kosek, 2011; Okifuji & Hare, 2013; van Koulil et al., 2007; Van Wilgen, Bloten, & Oeseburg, 2007). Combined aerobic exercise and cognitive behavior therapy (CBT) for chronic pain have some of the strongest empirical support for improving health status and physical functioning (Ablin et al., 2013), with post-treatment changes in pain, disability, and mood (Keel, Bodoky, Gerhard, & Müller, 1998; Lemstra & Olszynski, 2005; Nisell & Kosek, 2011; van Koulil et al., 2007). Across international treatment guidelines, CBT, aerobic exercise, and combined treatment (i.e., exercise and psychological intervention) are strongly recommended (Ablin et al., 2013; Arnold, Clauw, Dunegan, & Turk, 2012; Fitzcharles et al., 2013a). Further recommendations have been made for multimodal treatment that combines the delivery of education, medications, exercise, and CBT (Hawkins, 2013; Okifuji & Hare, 2013). Empirical support for the greater effectiveness of multimodal treatment over monotherapy is mounting (Okifuji & Hare, 2013).

Pharmacotherapy. There are three pharmacologic treatment options that are approved by the Federal Drug Administration (FDA): an anti-epileptic medication called pregabalin (Lyrica), and two SNRI antidepressants called milnacipram (Savella) and

duloxetine (Cymbalta; McBeth & Mulvey, 2012; Nisell & Kosek, 2011). A number of randomized placebo-controlled studies have examined these medications and demonstrated their short-term effectiveness in producing pain reduction and sleep improvement, with the need for further research examining the long-term effectiveness of these and other non-FDA approved medications that are frequently taken, because of the long-term use of these medications (Nisell & Kosek, 2011). Ultimately, pharmacologic treatments generally yield limited benefit when administered as a monotherapy (Ablin et al., 2013), which may not come as a surprise given the number of symptoms and presence of comorbidities found in this patient population (Hawkins, 2013). Other concerns regarding pharmacologic treatment include the increased likelihood of side effects that often mimic FMS symptoms and that can pose considerable health dangers when administered at higher doses (Ablin et al., 2013; Hawkins, 2013). It has also been argued that medications do not target mechanisms that might maintain long-term consequences, like disability, distress, and physical deconditioning (van Koulil et al., 2007).

Self-management education. Education is considered an important part of FMS treatment (Hawkins, 2013). Self-management education is a commonly recommended treatment for FMS, with a focus on delivering information about the condition and ways to manage symptoms (Hawkins, 2013; Lorig & Fries, 2006). The Arthritis Self-Management Program (ASMP) is the most commonplace education-based program that was developed for individuals with arthritis and has been used with individuals with osteoarthritis, rheumatoid arthritis, and fibromyalgia (Lorig, Gonzalez, Laurent, Morgan, & Laris, 2008). The ASMP covers education regarding symptom management, medication management, effective communication, health decision making, healthy

eating, exercise and physical activity, sleep, and health-related problem solving. The ASMP has been evaluated in different modes of delivery, including in-person group settings and online (Lorig et al., 1998; Lorig, Ritter, Laurent, & Plant, 2008). Findings suggest that education is effective in increasing pain coping and self-efficacy (Ablin et al., 2013; van Koulil et al., 2007; Wagner et al., 2001); however, there is evidence that education alone may not impact pain and disability (van Koulil et al., 2007). There have been mixed findings regarding its benefits for individuals with FMS (Lorig et al., 2008; Oliver, Cronan, Walen, & Tomita, 2001; van Koulil et al., 2007); however, it is a recommended treatment and frequently delivered to individuals with FMS (Hawkins, 2013; Lorig & Fries, 2006).

Cognitive behavior therapy. Cognitive behavior therapy (CBT) is one of the most commonly delivered non-pharmacologic FMS treatments (van Koulil et al., 2007). The specific CBT techniques that have been used vary across studies and include cognitive restructuring (e.g., Bennett & Nelson, 2006; Edinger, Wohlgemuth, Krystal, & Rice, 2005; Turk, Okifuji, Sinclair, & Starz, 1998), psychoeducation (e.g., Bennett & Nelson, 2006; Creamer, Singh, Hochberg, & Berman, 2000; Nielson, Walker, & McCain, 1992; Redondo et al., 2004; Rodero, Garcia, Casanueva, & Sobradiel, 2008), activity pacing (e.g., Nielson et al., 1992; Nisell & Kosek, 2011; Redondo et al., 2004), problem solving (Rodero et al., 2008; Thieme, Flor, & Turk, 2006), and relaxation strategies (Bennett & Nelson, 2006; Nielson et al., 1992; Redondo et al., 2004; Thieme et al., 2006; Vlaeyen, de Jong, Geilen, Heuts, & van Breukelen, 2002; Wigers, 1996). CBT is a widely used and accepted treatment for FMS; however, there are mixed findings regarding the effectiveness of CBT treatment of FMS with some showing strong and

long-lasting benefits and others showing limited and short-lived effects (Bennett & Nelson, 2006; Glombiewski et al., 2010; Goldenberg, Burckhardt, & Crofford, 2004; Rossy et al., 1999; Sim & Adams, 2002; Thieme & Gracely, 2009; van Koulil et al., 2007). In addition, clinical trials examining the effectiveness of this treatment modality are typically small, have methodological weaknesses, and have limited impact on the primary symptoms of FMS (Okifuji & Hare, 2013). Mixed or modest effects related to CBT might be attributed to the heterogeneity of the population being treated as though they are homogeneous (van Koulil et al., 2010).

Exercise and physical activity. Physical activity refers to the engagement in movement across a variety of settings and contexts (Busch et al., 2011). Exercise may be defined as a structured form of physical activity in which repetitive movements are engaged in with the explicit goal of improving fitness (Busch et al., 2011). A significant portion of the FMS population is considered physically inactive and experience associated physical deconditioning (Busch et al., 2011; Nijs et al., 2013; Okifuji & Hare, 2013; Wolfe et al., 1990). Compared to healthy individuals, people with FMS have weaker muscle strength, less endurance, and lower aerobic fitness (Kosek et al., 1996b; Bennett, 1989; Jacobsen, Wildschiodtz, & Danneskiold-Samsoe, 1991; Nisell & Kosek, 2011; Rooks, Silverman, & Kantrowitz, 2002). Among those with FMS who maintain a level of physical activity, performance often falls in suboptimal levels or in greater than submaximal levels of physical activity, which increases the risk of experiencing significant increases in pain and fatigue, as well as musculoskeletal injury (Busch et al., 2011; Nisell & Kosek, 2011; Ramsay et al., 2000). Essentially, too little physical activity

leads to physical deconditioning and too much activity worsens FMS symptoms (Busch et al., 2011; Jones et al., 2009).

Physical activity and exercise interventions are designed to improve physical functioning, FMS symptoms, health, and well being (Busch et al., 2011). Frequent engagement in aerobic and strength exercise has been shown to improve FMS symptoms (e.g., pain intensity, sleep, functioning) and reduce physical deconditioning in high-quality studies and meta-analytic reviews (Busch et al., 2011; Hawkins, 2013; Jones, Adams, Winters-Stone, & Burckhardt, 2006; Mease, 2005; Okifuji & Hare, 2013; Steiner, Bigatti, & Ang, 2013). Effect sizes within these studies have generally been large (Busch et al., 2011). Research suggests that benefits received from exercise are dependent on the type and level of intensity, with particular benefits found in moderately intense aerobic exercise that includes stretching and strengthening (Jones et al., 2006; Kelley, Kelley, & Jones, 2011; Okifuji & Hare, 2013). Even at low intensity, physical activity and formal exercise have been shown to improve pain and tenderness symptoms among individuals with FMS (e.g., walking, swimming, jogging; Busch, Schachter, Peloso, & Bombardier, 2003; Busch, Barber, Overend, Peloso, & Schachter, 2007; Mannerkorpi & Iversen, 2003; Meiworm, Jakob, Walker, Peter, & Keul, 2000; Nisell & Kosek, 2011); however, moderate intensity is needed to receive long-lasting clinical benefits of exercise (Busch et al., 2011; Okifuji & Hare, 2013).

Research supports the assertion that individuals with FMS are capable of engaging in moderately intense physical activity (e.g., Kaleth, Saha, Jensen, Slaven, & Ang, 2013); however, adherence is often low because of the concern about exercise-related pain and fatigue (Busch et al., 2011; Lambin, Thibault, Simmonds, Lariviere, &

Sullivan, 2011; Richards & Scott, 2002). Upwards of 40% of individuals with FMS have high fear of movement and pain (Nijs et al., 2013; van Koulil et al., 2008; Vlaeyen et al., 1995). It is commonly perceived that stiffness and pain experienced after exercise is an indication that exercise exacerbates FMS (Richards & Scott, 2002); however, these experiences might actually be attributed to the effects of physical deconditioning, overactivity, or normal sensations experienced after exercise. Behavioral avoidance is the most common behavioral response to pain and worries about pain (Hasenbring & Verbunt, 2010), which might explain the low levels of exercise and physical activity in this population.

To address the high attrition rates, empirically-supported guidelines for exercise recommend starting with low levels of intensity and gradually increasing and introducing additional types of exercise over time, especially those valued by the individual (Busch et al., 2011; Hawkins, 2013; Jones et al., 2008; Okifuji & Hare, 2013). Exercise intensity should be increased slowly over time to prevent injury and pain flare-ups, which are likely to drive avoidance behaviors (Hawkins, 2013; Sprott, 2003). If increased intensity and duration is not tolerated, it is recommended that the individual strive to increase exercise frequency (Busch et al., 2011; Hawkins, 2013; Jones et al., 2008; Okifuji & Hare, 2013). In order to assist patients in getting physically ready for engagement in formal exercise, research has shown that increasing lifestyle activity and movement in daily life produces improvements in pain and symptoms (Fontaine, Conn, & Clauw, 2010; Fontaine, Conn, & Claw, 2011). This might be a step in the direction of getting individuals to engage in frequent moderately intense exercise that has the potential for long-term symptom improvement (Busch et al., 2011).

The Original Fear-Avoidance Model

Pain perception is a multifaceted experience, comprised of sensory and emotional responses (Crombez, Eccleston, Van Damme, Vlaeyen, & Karoly, 2012; Lethem, Slade, Troup, & Bentley, 1983; van Koulil et al., 2007). Vlaeyen, Kole-Snijders, Boeren, and van Eek (1995) and Vlaeyen and Linton (2000) proposed the fear avoidance (FA) model based on the work of Lethem et al. (1983), Philips (1987), and Waddell, Newton, Henderson, Somerville, and Main (1993). This cognitive-behavioral model proposes that the manner in which one interprets and responds to pain leads to two different pathways towards chronic pain and disability or towards recovery. The FA model provides a theoretical explanation of why some individuals develop chronic, exaggerated pain beyond what would be expected based on physiological abnormalities alone (Crombez et al., 2012; Philips, 1987). The original FA model proposes that although acute pain is a product of sensory and physiological processes, chronic pain and disability are largely the result of interrelationships between cognitive, affective, and behavioral responses to pain (Lethem et al., 1983; Wideman et al., 2013). This model was first applied to individuals who experienced acute back pain to explain why some individuals recover to full functioning and experience reduced pain, while others further develop chronic pain and pain-related disability (Lethem et al., 1983; Slade, Troup, Lethem, & Bentley, 1983; Vlaeyen et al., 1995; Vlaeyen & Linton, 2000).

As presented in Figure 1, the original FA model suggests that the cycle originates from a pain episode that sets off a series of cognitive, affective, and behavioral responses that have the potential to exaggerate pain response and lead to disability. Specifically, in the dysfunctional pathway, pain leads to pain catastrophizing, which is followed by pain-

related fear and associated hypervigilance, and behavioral avoidance. Over time, fear avoidance is proposed to lead to physical deconditioning, depression, and pain-related disability. The FA model suggests that some individuals are less likely to develop chronic pain and disability, and instead experience recovery from either pain symptoms or the impact of pain on their functioning. In this alternative pathway, the individual does not experience heightened fear in response to a pain episode, which increases the likelihood of approach-oriented behaviors rather than avoidance (Asmundson, Norton, & Vlaeyen, 2004; Vlaeyen et al., 1995; Vlaeyen & Linton, 2000). Activity engagement increases the likelihood that the individual will engage in behaviors that will support recovery (e.g., physical therapy). According to the FA model, re-defining the experience of pain as non-threatening and reducing pain-related fear is a viable target for increasing approach-oriented behaviors and, thereby, functioning (Crombez et al., 2012; Pincus et al., 2010).

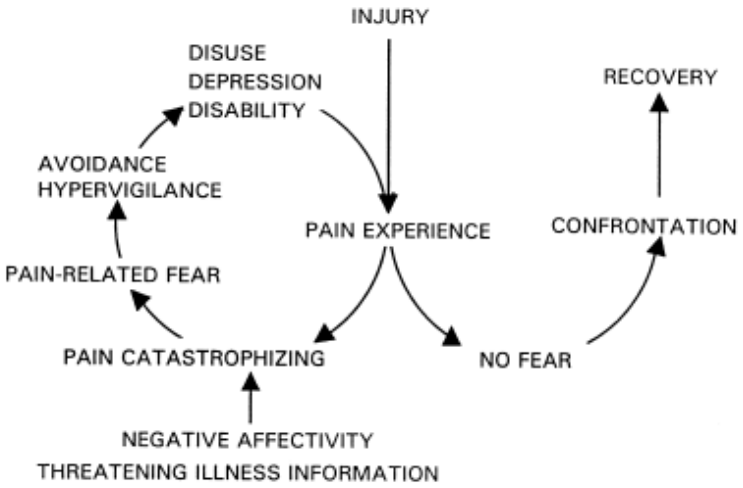


Figure 1. Original fear avoidance model

Retrieved from, Vlaeyen, J. W. S., & Linton, S. J. (2000). Fear-avoidance and its consequences in chronic musculoskeletal pain: A state of the art. *Pain, 85,* 317-332.

The fear-avoidance pathway. With the initiation of a pain experience, an individual perceives pain as a threat and engages in catastrophic thinking regarding the

meaning and consequences of the pain. The term catastrophizing was first introduced by Ellis (1962) to describe the anxious process of ruminating about extreme negative consequences of a threatening stimulus (Leeuw et al., 2007). Pain catastrophizing can be described as the cognitive interpretation of pain as being highly threatening (Crombez, Eccleston, Baeyens, & Eelen, 1998; Leeuw et al., 2007; Rosenstiel & Keefe, 1983). When one experiences pain, the physiological changes and autonomic arousal that results may be misinterpreted as a signal of injury or damage that perpetuates avoidance behaviors (Norton & Asmundson, 2003; van Koulil et al., 2007). Individuals with chronic pain are reinforced in their catastrophic interpretations of pain by societal messages that their pain is a threat. For instance, diagnostic labels themselves may indirectly send the message to individuals that their pain is the result of significant pathology, which likely increases the perceived threat of pain (Leeuw et al., 2007). There is also the commonly held belief that pain is an indication of injury and damage that *inevitably* leads to disability and the belief that pain can only be treated with medications (Crombez et al., 2012). According to the FA model, when pain is perceived as an indication of injury or sign of pathology that is outside of one's realm of control, pain-related fear increases (Crombez et al., 2012; Vlaeyen & Linton, 2000; Vlaeyen & Linton, 2012). Pain-related fear is proposed to promote escape behaviors. In fact, behavioral avoidance is the most commonly employed behavioral response to pain (Hasenbring & Verbunt, 2010).

Classical conditioning is theorized to be one driver of non-adherence to exercise and avoidance of physical activity (See Figure 2; Thieme & Turk, 2012). According to this perspective, pain is an unconditioned stimulus that triggers an unconditioned physiological response. That is, the fear response is an autonomic nervous system

reaction consisting of changes in skin conductance, muscle reactivity, and heart rate (Leeuw et al., 2007; Vlaeyen & Linton, 2000). These physiological changes prepare an individual to escape from the perceived threat; therefore, pain-related fear is expressed through escape and avoidance behaviors (Vlaeyen & Linton, 2000). Over time, individuals start to associate neutral cues with the unconditioned stimulus, developing fear and avoidance in response to these cues, even in the absence of pain (Vlaeyen & Linton, 2012). Interoceptive fear conditioning results from the pairing of pain and an internal stimulus, such as movement (i.e., proprioceptive fear conditioning; Vlaeyen & Linton, 2012), in which individuals develop heightened fear and behavioral avoidance (conditioned response) in response to movement and activity engagement alone (conditioned stimulus; Thieme & Turk, 2012). Later anticipation of pain related to a physical activity might trigger avoidance of that activity, as well as other activities over time (i.e., stimulus generalization), as a means of avoiding perceived injury or pain flare up (Thieme & Turk, 2012). According to the FA model, individuals may further develop kinesiophobia over time because of this process (i.e., fear/phobia of [re]injury and/or movement; Crombez et al., 2012; Kori, Miller, & Todd, 1990), which perpetuates the avoidance response. Operant conditioning likely also plays a role in the development and maintenance of avoidance behaviors. Avoidance in response to pain or thoughts about pain might serve to negatively reinforce this behavior over time because one believes that he/she has successfully avoided harm (Thieme & Turk, 2012).

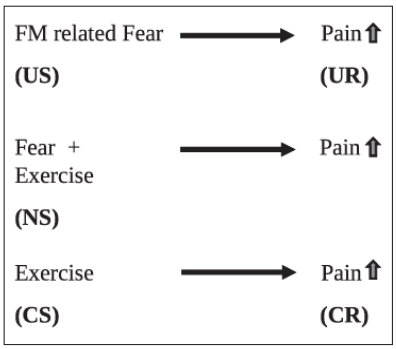


Figure 2. Proposed classical conditioning of increased pain response related to exercise

Retrieved from, Thieme, K., & Turk, D. C. (2012). Cognitive-behavioral and operant-behavioral therapy for people with fibromyalgia. *Reumatismo, 64*(4), 275-285.

According to the FA model, pain-related fear also impacts cognitive functioning by increasing hypervigilance for cues of pain-related threats and making individuals less able to shift attention to non-pain-related information, which negatively impacts their ability to cope in other areas of life (Leeuw et al., 2007; Vlaeyen & Linton, 2000). Over time, individuals are more likely to become hypervigilant to pain-related information and attend less and less to other information in their environment (Crombez et al., 2012). Additionally, escape from a perceived threat associated with activities/movement reduces fear in the moment, and paradoxically increases fear over time because it does not allow an individual to disconfirm his/her fear-based beliefs (Crombez et al., 2012; Leeuw et al., 2007; Vlaeyen & Linton, 2000).

Pain-related fear, hypervigilance for pain cues, and resulting avoidance in the face of *acute pain* serve a protective function for the body because it allows time for tissue damage or injury to heal. However, these responses are dysfunctional in the context of chronic pain because it paradoxically leads to physical deconditioning, increased pain, depression, and disability (Arntz, Dreessen, & de Jong, 1994; Arntz & Claassens, 2004; Crombez et al., 2012; Leeuw et al., 2007; Vlaeyen & Linton, 2012). Chronic fear and

avoidance are proposed to lead to disability through the development of *disuse syndrome*, in which inactivity weakens the musculoskeletal and cardiovascular systems (Bortz, 1984; Kottke, 1966; Leeuw et al., 2007; Vlaeyen & Linton, 2000; Wideman et al., 2013) and/or leads to dysfunctional muscle coordination (Leeuw et al., 2007; van Koulil et al., 2007;Vlaeyen & Linton, 2000). Essentially, through inactivity, an individual experiences physical deconditioning that, in turn, increases the likelihood that he/she will develop persistent physical problems (Pincus et al., 2010) and disability (i.e., inability to perform daily activities; Crombez et al., 2012; Verbunt, Smeets, & Wittink, 2010). Inactivity also negatively impacts one's psychological functioning, because the less one is exposed to and engages in valued activities, the less likely he/she is to have positive affective experiences and the more likely he/she is to experience isolation and distress (Crombez et al., 2012). In addition, isolation reduces one's exposure to positive social reinforcers, which further negatively impacts mood (Crombez et al., 2012; van Koulil et al., 2007; Vlaeyen & Linton, 2000). In turn, depression and physical disuse are known to decrease one's pain tolerance (McQuade, Turner, & Buchner, 1988; Romano & Turner, 1985; Vlaeyen & Linton, 2000), perpetuating the *vicious cycle* that defines the FA model.

The Expanded Fear-Avoidance Model

Since the introduction of the FA model twenty years ago, it has become the dominant framework used to explain the development and maintenance of pain-related disability among individuals with musculoskeletal pain (Wideman et al., 2013). Although the model was originally developed to explain why some individuals with acute pain develop chronic symptoms and disability, it has since been proposed as the mechanism driving persistence of chronic pain and development of pain-related disability (Leeuw et

al., 2007). While the core elements of the model have remained unchanged, the FA model has expanded over time to account for the impact of learning, motivation, and self-regulation (Wideman et al., 2013). For instance, Asmundson and colleagues (2004) updated the FA model to account for the individual roles of fear (present-moment emotion) and anxiety (future-oriented emotion) in promoting behavioral responses to pain. As shown in Figure 3, the expanded FA model accounts for parallel pathways from fear and anxiety to escape and avoidance, which both lead to disuse, disability, and depression (Asmundson et al., 2004; Leeuw et al., 2007). Unlike fear, which is a present-oriented affective state triggered by the perceived presence of a threat, anxiety is a future-oriented emotion. Whereas fear drives escape from a threat, anxiety leads to avoidance/preventative behaviors and hypervigilance (Leeuw et al., 2007). Specifically, the anxiety pathway was added to the FA model to account for generalized avoidance of activities (Asmundson et al., 2004; Leeuw et al., 2007). Anxiety functions to detect potential threats early on and leads to hypervigilance for pain cues (Vlaeyen & Linton, 2000). This is proposed to lead to generalized avoidance of activities based on the prediction of pain that would be experienced and its consequences. Hypervigilance and avoidance serve to reduce anxiety in the present moment and, similar to fear, serve to maintain it over time (Leeuw et al., 2007).

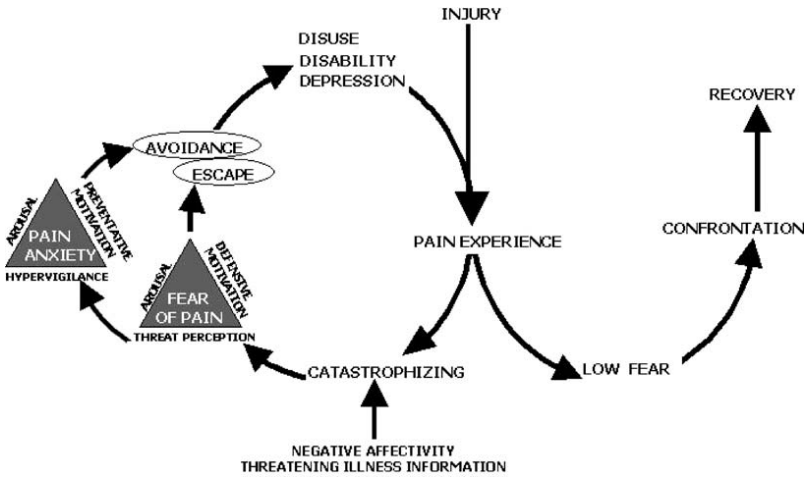


Figure 3. Expanded fear avoidance model

Retrieved from, Leeuw, M., Goossens, M. E. J. B., Linton, S. J., Crombez, G., Boersma, K., & Vlaeyen, J. W. S. (2007). The fear-avoidance model of musculoskeletal pain: Current state of scientific evidence. *Journal of Behavioral Medicine, 30*, 77-94.

Empirical Support for the Fear Avoidance Model

Support for the FA model has largely been demonstrated in cross-sectional and longitudinal studies of the chronic low back pain population (Pincus et al., 2010; Wideman et al., 2013). Several studies have demonstrated the validity of this model (Crombez et al., 2012; Keefe, Rumble, Scipio, Giordano, & Perri, 2004; Leeuw et al., 2007; Pincus, Burton, Vogel, & Field, 2002; Pincus et al., 2010; Turk, 2005) In one of the most direct examinations of the model, Cook, Brawer, and Vowles (2006) used structural equation modeling to examine each component of the FA model and found that catastrophizing was related to pain-related fear, depression, and disability, and that pain-related fear was related to depression and disability, which were, in turn, related to pain severity. This was not a prospective study, so causal inferences could not be made. Additional cross-sectional evidence and laboratory-controlled findings support the proposal that catastrophic thinking may precede the development of pain-related fear (Hasenbring & Verbunt, 2010; Leeuw et al., 2007; Vlaeyen & Linton, 2000) and that

fear-related cognitions and avoidance predict the development of disability (Hasenbring & Verbunt, 2010; Truchon, Côté, Fillion, Arsenault, & Dionne, 2008).

Few prospective studies have been conducted to test the FA model, and the findings have been inconsistent. Two such studies found that catastrophic thoughts did not occur prior to the development of pain-related fear, and that changes in fear did not precede changes in depression (Bergbom, Boersma, & Linton, 2012). However, Klenerman and colleagues (1995) conducted a prospective study and found that pain-related fear preceded and predicted disability. In addition, findings regarding the causal relationship between avoidance and physical deconditioning among individuals with chronic low back pain have been mixed (Leeuw et al., 2007; Wideman et al., 2013). Despite these mixed findings regarding the specific directional pathways within the FA model, it has been well accepted by patients, who report that it is easy to understand and reflects their perceived experience. It has also guided the development of treatment interventions (Crombez, Beirens, Van Damme, Eccleston, & Fontaine, 2009; Crombez et al., 2012; Eccleston, Crombez, Aldrich, & Stannard, 1997). In support of a mediating pathway, CBT treatment studies with chronic pain patients have indicated that reductions in catastrophizing and reported helplessness reduce the likelihood of disability and depression (e.g., Burns, Kubilus, Bruehl, Harden, & Lofland, 2003; Smeets, Vlaeyen, Kester, & Knottnerus, 2006; Spinhoven et al., 2004). The FA model has yet to be examined directly within the FMS population.

Evidence for the FA Model in FMS

The FA model suggests that the presence of catastrophizing leads to fear, anxiety, and behavioral avoidance, creating a *vicious cycle*. This cycle is proposed to lead to

increased pain resulting from physical deconditioning, as well as to increased risk of disability and depression. Although the FA model as a whole has not been directly studied within the FMS population, mounting evidence suggests that cognitive, affective, and behavioral responses to pain play an important role in the development and maintenance of chronic musculoskeletal pain, related disability, and mood disturbance (Hasenbring & Verbunt, 2010). A number of studies have individually examined components of the FA model and their relationships to one another and to patient outcomes within the FMS population.

A growing body of research with FMS patients demonstrates that people with FMS engage in **catastrophic thinking,** which in turn decreases their health and wellbeing. Patients with FMS display greater pain-focused vigilance and more notable engagement in catastrophizing than those with chronic low back pain (Crombez, Eccleston, Van den Broeck, Goubert, & Van Houdenhove, 2004). Within the FMS population, catastrophizing is associated with heightened emotional distress, increased pain perception, and functional impairments (Buckelew et al., 1996; Hassett, Cone, Patella, & Sigal, 2000; Martin et al., 1996; Meeus & Nijs, 2007; Turk, Robinson, & Burwinkle, 2004; van Koulil et al., 2007). Turk (2004) suggested that maladaptive thinking plays an increasingly greater role in the maintenance and exacerbation of the FMS pain experience, whereas physical pathology, conversely, plays a reduced role over the course of the illness. Moreover, findings suggest that individuals with FMS who engage in catastrophic thinking report greater pain intensity than their non-catastrophizing counterparts (Hassett et al., 2000; Geisser et al., 2003; Meeus & Nijs, 2007). Gracely and Ambrose (2011) found that pain catastrophizing in FMS patients,

independent of depressiveness, was related to heightened neural activation patterns throughout regions involved in pain anticipation, pain attention, pain affectivity, and motor control. In addition, Severeijns, Vlaeyen, van den Hout, and Weber (2001) found that pain catastrophizing accounted for a significant proportion of variance in pain intensity, disability, and psychological distress. These findings suggest the presence and importance of catastrophizing in this patient population.

Researchers have also demonstrated the presence and impact of **pain-related fear** among individuals with FMS. As previously discussed, approximately 40% of individuals with FMS have high fear of pain and movement (Nijs et al., 2013; Turk et al., 2004; van Koulil et al., 2008). In FMS, pain-related fear and kinesiophobia have both been found to be associated with heightened pain intensity (Turk et al., 2004) and lower pain threshold (de Gier, Peters, & Vlaeyen, 2003; Turk et al., 2004), as well as with disability and depression (Turk et al., 2004; van Koulil et al., 2007). For instance, De Gier et al. (2003) examined pain-related fear in individuals with FMS, and they found that higher fear was associated with greater vigilance, catastrophizing, disability, emotional distress, and pain than in those with low fear. They also found that individuals with heightened pain-related fear demonstrated lower tolerance for physical activity, heightened tender point pain, and lower cognitive processing speed. In a study conducted by Turk et al. (2004), participants with higher pain-related fear also reported greater levels of disability and higher pain severity than did those with lower fear (Turk et al., 2004). Individuals classified as having high pain-related and activity-related fear were also more likely to have a diagnosis of depressive disorder than those with low fear (79.8% vs. 29.2%; Turk et al., 2004).

Worries about pain and pain-related fear are also associated with **behavioral avoidance of physical activity** among individuals with FMS (Lambin et al., 2011; Nijs et al., 2013; Turk et al., 2004). Together, catastrophizing and fear of pain are shown to lead to various forms of behavioral avoidance, including decreased activities of daily living (ADLs), increased use of analgesics, and non-adherence to exercise-based treatment regimens, which have been associated with increased disability, depression, and suicidal ideation among chronic pain populations, including FMS patients (Burckhardt, Clark, O'Reilly, & Bennett, 1997; Edwards, Bingham III, Bathon, & Haythornthwaite, 2006; Gracely et al., 2004; Hassett et al., 2000; Martin et al., 1996; Sanchez et al., 2011; Sullivan et al., 1995; Vlaeyen & Linton, 2000). These and similar findings have also led to the suggestion that attachment to worries about activity engagement and associated fear of pain might explain heightened levels of depression (Hassett et al., 2000) and disability in this patient population (Martin et al., 1996; Nijs et al., 2013; Turk et al., 2004).

Treatment of Fear-Avoidance: Graded In-Vivo Exposure Therapy

The FA model proposes that fear-avoidance should serve as a target for intervention to move individuals toward functional recovery and to prevent the development or maintenance of pain-related disability (Wideman et al., 2013). Interventions that are designed to improve chronic pain outcomes without targeting fear avoidance have demonstrated limited success (Eccleston, Williams, & Morley, 2009; Pincus et al., 2010) and have largely lacked theoretical foundation (Pincus et al., 2010). Many of the currently accepted psychological and non-pharmacological FMS treatments do not address the fear-avoidance mechanisms that might directly drive the presentation

of symptoms within a significantly large FMS subgroup (van Koulil et al., 2007). Alternatively, cognitive-behavioral interventions in other pain populations that have targeted fear-avoidance beliefs have led to decreased pain catastrophizing, pain-related fear, and disability (de Jong et al., 2005b; de Jong, Vlaeyen, de Gelder, & Patijn, 2011; den Hollander et al., 2010; Leeuw et al., 2007).

Preliminary research with chronic low back pain patients suggests that graded in-vivo exposure therapy targeting fear avoidance may be more effective than graded activity engagement in increasing approach-oriented behaviors and improving health outcomes (Leeuw et al., 2008; Vlaeyen et al., 2002). Graded in-vivo exposure therapy is based on the same principles of classical conditioning that are proposed to drive the FA model. Through repeated exposure to avoided activities, this approach is proposed to weaken the association between the conditioned stimulus (e.g., movement/activity) and the conditioned response (i.e., avoidance and escape behaviors). Research has shown that during extinction of a conditioned response (e.g., avoidance), the original association between the conditioned and unconditioned stimulus (i.e., pain and movement) remains present, and new inhibitory learning occurs as a new 'conditioned stimulus-no unconditioned stimulus' association is formed (Bouton, 2002; Craske et al., 2008; Leeuw et al., 2007; Vlaeyen & Linton, 2012). That is, the individual still holds the 'pain-movement' association; however, exposure to movement without increased pain leads to the formation of a 'movement-no pain' association, which can result in new conditioned response patterns.

Graded in-vivo exposure therapy for treatment of pain-related fear avoidance is comprised of the following activities: delivery of education regarding the FA model and

chronic pain, development of hierarchy of fear-inducing movements/activities, systematic and graded exposure to these activities through behavioral experiments, and evaluation and assessment of catastrophic interpretations before and after activity engagement (Leeuw et al., 2007; Vlaeyen et al., 2001; Vlaeyen et al., 2002). Exposure to avoided activities provides the opportunity to challenge and disconfirm catastrophic mispredictions regarding chronic pain and one's ability to cope, which leads to reduced fear and increased approach-oriented behaviors (Crombez et al., 2012; Leeuw et al., 2007; Leeuw et al., 2008; Vlaeyen et al., 2004). Adding cognitive techniques, such as alternative thought generation in behavioral experiments, may be important for challenging catastrophic misinterpretations in order to see benefits from treatment (Leeuw et al., 2007).

A few studies have examined graded in-vivo exposure as a treatment for fear avoidance, and although they have suffered from methodological limitations, they have consistently been shown to improve health outcomes (Pincus et al., 2010). To date, this treatment has been largely studied among individuals with chronic low back pain and complex regional pain syndrome. A number of single-subject experiments with chronic low back pain patients have shown that graded in-vivo exposure led to improvements in fear, catastrophizing, activity engagement, and functioning (Boersma et al., 2004; de Jong et al., 2005a; de Jong et al., 2005b; Linton, Overmeer, Janson, Vlaeyen, & de Jong, 2002; Vlaeyen et al., 2002; Vlaeyen & Linton, 2012; Woods & Asmundson, 2008). Among those with complex regional pain syndrome, exposure therapy led to reduced pain-related fear and increased engagement in activities (de Jong et al., 2005a; Leeuw et al., 2007).

Randomized Controlled Trials (RCTs) have been conducted in chronic low back pain patients and have yielded moderate effect sizes (Vlaeyen & Linton, 2012). For instance, Woods and Asmundson (2008) compared the impact of graded in-vivo exposure, graded activity, and a wait-list condition for individuals with low back pain and found that participants who received exposure therapy showed greater improvements in pain-related fear, fear-avoidance beliefs, pain-related anxiety, and pain self-efficacy than participants in the other conditions (Pincus et al., 2010). Leeuw et al. (2008) examined exposure in-vivo therapy among individuals with low back pain as well, and found that it led to reduced pain catastrophizing and perceived harmfulness of activities and found that it was as effective as graded activity therapy in leading to improvements in disability, functioning, pain severity, and level of daily activity at 6 months followup. Combined, the growing empirical evidence in chronic pain populations (low back, complex regional pain syndrome) supports the efficacy and possible generalizability of this treatment, warranting further investigation (Leeuw et al., 2007).

It has been suggested that graded in-vivo exposure therapy has the potential for being one of the most effective cognitive-behavioral treatments for reducing fear avoidance among individuals with chronic pain, including those with FMS (Davey, 1997; Nij et al., 2013; Turk et al., 2004; Vlaeyen & Linton, 2012), and has yet to be directly tested within the FMS population. However, there is preliminary evidence suggesting that treatments targeting avoidance behaviors may be effective in this patient population. Van Koulil and colleagues (2010) delivered a comprehensive group-based CBT + exercise intervention that was comprised of 16 twice-weekly, 4-hour sessions with 1.5 hours of homework daily. Participants were classified as pain avoiders and pain

persisters based on a semi-structured interview (i.e., clinical judgment) and a self-report measure of pain avoidance behavior. In both groups, the treatment goals were to lessen daily cognitive, emotional, and social consequences of pain and associated symptoms. Among those classified as pain avoiders, the CBT portion of their treatment focused on increasing daily activity engagement, as well as reducing avoidance behaviors, pain-related cognitions, and pain-related fear. In addition, this intervention incorporated members of the participant's social network to reduce the occurrence of problematic social contingencies. In sessions, the participants learned to set goals related to activity engagement and gradually increase level of activity with exposure to activities that produced fear. Exercise training focused on increasing levels of physical ability and flexibility, starting each session with relaxation training, aerobics (e.g., gymnastics), and aquatherapy or anaerobic exercise (e.g., strength, functional walking).

Results from this intervention showed clinically relevant improvements in pain, fatigue, disability, anxiety, and mood that were maintained at 6-month followup. They also reported low attrition rate (13.3%). This study demonstrated the efficacy of a comprehensive treatment that incorporated the element of graded exposure to avoided physical activity; however, no studies to date have examined the unique impact of this treatment modality among individuals with FMS. Prior to examining the efficacy of graded in-vivo exposure therapy within this population, it is necessary to determine the feasibility and acceptability of this intervention to most effectively inform RCT development.

Feasibility of Graded In-Vivo Exposure Therapy in FMS

A pilot trial was developed with the purpose of guiding the development and implementation of a graded in-vivo exposure therapy intervention for a future large-scale RCT. The purpose of this dissertation is to examine the feasibility and acceptability of a 13-week graded in-vivo exposure therapy intervention with a sample of individuals with FMS who have moderate to high fear of movement and/or pain. Evidence that graded in-vivo exposure therapy will be an effective treatment for FMS is largely speculative and derived from findings of a multimodal treatment study that incorporated exposure techniques (i.e., van Koulil et al., 2010) and empirical evidence supporting the existence of relationships among FA model components within the FMS population. No study has directly examined graded in-vivo exposure on its own within this patient population. It is necessary to first determine feasibility and acceptability of an intervention protocol, study design, and procedures because this allows for direct examination of issues to be resolved prior to conducting a main study assessing treatment efficacy. Feasibility refers to the ability to execute the intervention and study procedures (i.e., delivery) and acceptability refers to the appropriateness of the intervention and study design (i.e., uptake) from the participant's perspective (Feeley et al., 2009; Santacroce, Maccarelli, & Grey, 2004). Without assessment of feasibility and acceptability prior to conducting a large-scale RCT, non-significant findings that might be related to problems with the protocol or procedures might be misinterpreted as being caused by intervention ineffectiveness (Feeley et al., 2009). As recommended by Thabane et al. (2010), the CONSORT-modified checklist for reporting feasibility research that is displayed in Table 2 was followed as a guideline for structuring this dissertation and will be further followed in structuring the dissertation.

This structure has been implemented in a growing number of published feasibility studies (e.g., Carroll et al., 2013; Cooper et al., 2011; Wilson et al., 2012).

Table 2. CONSORT-modified checklist for reporting feasibility research

Paper Section	Item	Descriptor
Title and *Abstract*	1	- Does the title or abstract indicate that the study is a 'pilot'?
Introduction		
Background	2	- Scientific background for the main study and explanation of rationale for assessing feasibility through piloting
Methods		
Participants and setting	3	- Eligibility criteria for participants in the pilot study (these should be the same as in the main study – if different, state the differences) - The settings and locations where the data were collected
Interventions	4	- Provide precise details of the interventions intended for each group and how and when they were actually administered (if applicable) – state clearly if any aspects of the intervention are assessed for feasibility
Objectives	5	- Specific scientific objectives and hypotheses for the main study - Specific feasibility objectives
Outcomes	6	- Clearly define the primary and secondary outcome measures for the main study - Clearly define the feasibility outcomes and how they were operationalized – these should include key elements such as recruitment rates, consent rates, variance estimates, etc.
Sample Size	7	- Describe how sample size was determined - In general for a pilot of a phase III trial, there is no need for a formal sample size calculation. However, confidence interval approach may be used to calculate and justify the sample size based on key feasibility objective(s).
Feasibility Criteria	8	- Clearly describe the criteria for assessing success of feasibility – these should be based on the feasibility objectives
Statistical Methods	9	- Describe the statistical methods for the analysis of primary and secondary feasibility outcomes
Ethical Aspects	10	- State whether the study received ethics approval - State how informed consent was handled – given the feasibility nature of the study
Results		
Participant Flow	11	- Flow of participants through each stage (a flow chart is strongly recommended) - Describe protocol deviations from pilot study as planned, together with reasons - State the number of exclusions at each stage and reasons for exclusions

Table 2. CONSORT-modified checklist for reporting feasibility research, continued

Paper Section	Item	Descriptor
Results		
Recruitment	12	- Report the dates defining the periods of recruitment and follow-up
Baseline Data	13	- Report the baseline demographic and clinical characteristics of the participants
Outcomes and Estimation	14	- For each primary and secondary outcome, report the point estimates of effect and its precision (e.g., 95% confidence interval [CI]) – if applicable
Discussion		
Interpretation	15	- Interpretation of results should focus on feasibility, taking into account: · The stated criteria for success of feasibility; · Study hypotheses, sources of potential bias or imprecision – given the feasibility nature of the study
Generalizability	16	- Generalizability (external validity) of the feasibility. State clearly what modifications in the design of the main study (if any) would be necessary to make it feasible
Overall Evidence of Feasibility	17	- General interpretation of the results in the context of current evidence of feasibility - Focus should be on feasibility

Method

Participants

This graded in-vivo exposure therapy intervention was delivered to adults with FMS who had moderate to high pain-related fear and anxiety associated with physical activity engagement. In order to capture this proposed subgroup of the FMS population, eligibility criteria were developed based on literature review and past RCTs with FMS patients that were conducted within the research laboratory (e.g., Cronan, Groessl, & Kaplan, 1997; Cronan et al., 1998). A total of 29 individuals met eligibility criteria and were randomly assigned to one of the two intervention conditions. The average age of participants was 51 years (SD = 12.12), 86.7% of the sample were women, and 70% self-identified as Non-Hispanic White. Detailed baseline demographic information is provided in Table 3 and is stratified by the assigned intervention condition. Of note, on average, participants in the exposure condition were a decade older than those in the education condition. A one-way ANOVA revealed that this age difference is statistically significant, $F(1,27) = 5.07$, $p = 033$. Several 2x2 Fisher's Exact Tests were run for gender, ethnicity (white vs. non-white), income (60k and below vs. above), education (Less than college vs. college), marital status (in relationship vs. not), and employment status (working vs. not). These analyses suggest that participants in the two intervention conditions did not differ significantly on these demographic variables.

Table 3. Summary of baseline demographic profile of participants in each intervention condition

Demographics	Exposure N = 18	Education N = 11
Age in Years		
M	54.56	44.64
SD	9.71	14.05
Range	37	34
Gender		
Women	83.3%	100%
Men	16.7%	--
Ethnicity		
Non-Hispanic White	66.7%	72.7%
African American	16.7%	9.1%
Latin/Hispanic/Mexican American	16.7%	18.2%
Marital Status		
Single	22.2%	27.3%
Married	44.4%	27.3%
Separated/Divorced	33.3%	45.5%
Annual Household Income		
Below $30,000	44.4%	18.2%
$30,001- $60,000	16.7%	54.5%
$60,001-$120,000	27.8%	27.3%
Above $120,000	11.1%	--
Employment Status		
Full-Time	11.1%	36.4%
Part-Time	16.7%	--
Unemployed	33.3%	18.2%
Retired	22.2%	--
Disabled	16.7%	36.4%
Student	--	9.1%
Education Attained		
High School	66.7%	45.5%
Professional Certification	11.1%	18.2%
Bachelor Degree	11.1%	27.3%
Masters Degree	11.1%	--
Doctorate	--	9.1%
Time Since Diagnosis in Years		
M	8.44	7.36
SD	8.15	8.20
Range	25	23

Eligibility criteria. At the outset of the study, individuals were required to meet a set of inclusion criteria in order to be eligible for participation. Individuals were excluded if they failed to meet any of the criteria listed below or were unable to complete the initial

assessment. They were also excluded if they reported having another pain condition in addition to FMS.

Inclusion Criteria:

- Physician's diagnosis of FMS that was confirmed by a trained research assistant with a Manual Tender Point Survey (MTPS)
- If taking medications, individuals must have been taking stable doses for at least 4 weeks
- Score of 55 or above on the PASS-20 (i.e., measure of pain-related anxiety)
- Score of 40 or above on the TSK (i.e., measure of movement-related fear)
- Read and speak English
- Be at least 18 years of age

After 4 months of recruitment efforts (i.e., July, 2013), modifications were made to the eligibility criteria to address two issues that emerged. First, over half of all individuals who called the study coordinator and were screened for initial eligibility met the cut-off criteria on the PASS-20 or the TSK, but not on both. The emerging concern was that the pilot trial's entry criteria may be too stringent, which was corroborated by a review of past fear-avoidance treatment studies that only used one of these measures to determine eligibility (Leeuw et al., 2008; Vlaeyen et al., 2002). As such, inclusion criteria were adjusted to require individuals to score above the cut-off on only one of these survey measures. Second, the vast majority of people who expressed interest in participating in the study also reported having at least one other pain-related condition. After discussion with the study's medical consultant, Dr. Bill McCarberg, criteria were revisited and it was determined that comorbid pain conditions would be acceptable if the condition did not interfere with engagement in physical activity and movement. Cases were discussed with Dr. McCarberg on an individual basis when there was uncertainty regarding eligibility.

Final Inclusion Criteria:

- Score of 55 or above on the PASS-20 ***or*** Score of 40 or above on the TSK
- Read and speak English
- Be at least 18 years of age
- Physician's diagnosis of FMS that was confirmed by a research assistant with a MTPS
- If taking medications for FMS, individuals must have been taking stable doses for at least 4 weeks

Final Exclusion Criteria:

- Presence of another widespread pain condition
- Presence of a comorbid pain condition that interferes with physical activity

Based on these new exclusion criteria, four individuals were deemed ineligible based on the presence of the following pain-related conditions: degenerative discs (N = 2) and complex regional pain syndrome (N = 2). In total, 30 participants were recruited and met all eligibility criteria. Figure 4 presents a CONSORT Flow diagram with the flow of participants through each stage of the study: eligibility assessment, random allocation, intervention participation, and followup. In addition, Table 4 provides detailed information regarding recruitment.

It should also be noted that at the outset of the study, a protocol was put in place that required that active participants with any changes to medications place their participation on hold for four weeks. This was designed to reduce the risk that reported changes in symptoms were caused by medication alterations and not the intervention. This practice was changed because medication changes were commonplace among participants (e.g., termination, altered dose, new medication), and research staff experienced difficulties in re-engaging participants in the intervention after the four-week

absence. Therefore, the protocol was modified to allow participants to continue to engage in the intervention without a break and to monitor and record changes to medications.

Table 4. Participant recruitment and screening

	Number of Individuals
Total number who inquired about the study (via any means)	155
- Number who were not eligible based on test scores	8
- Number who were not eligible based on other factors	11
Total number who not interested in the study	99
- Number who were not interested and gave reason	22
- Number who were not interested and gave no reason (i.e., no communication)	77
Total number who passed phone screening and *scheduled* in-person initial assessment	37
- Number who attended and met *all* eligibility criteria	30
- Number who did not show up for in-person initial assessment	7

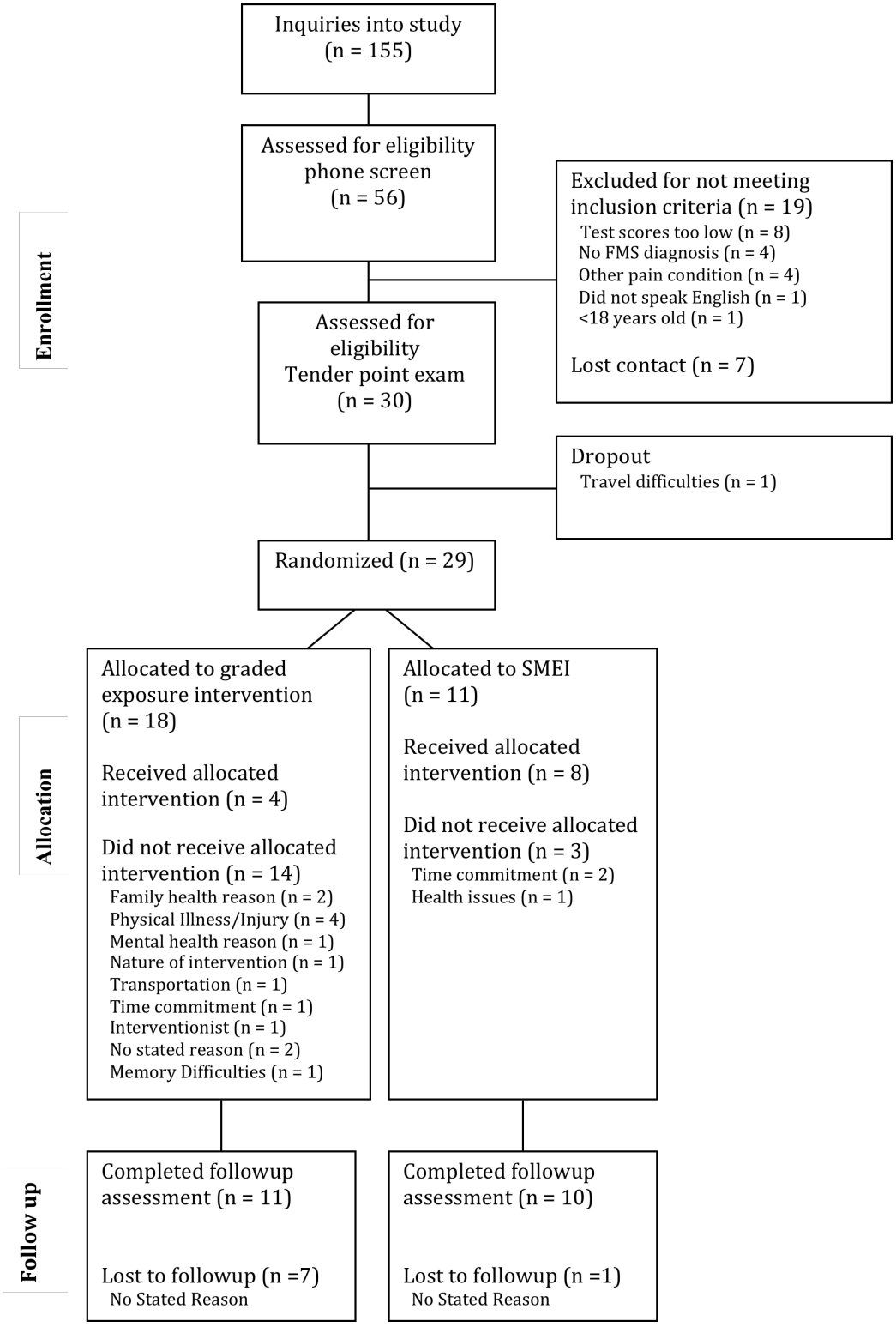


Figure 4. CONSORT diagram of participant flow through the pilot trial

Setting

This two-armed randomized pilot trial was conducted in a San Diego State University (SDSU) research laboratory that was equipped with a physical examination room, intervention rooms, a conference room for research meetings, and research offices for data storage and management. Intervention sessions and each of the four assessment sessions (i.e., baseline, 6 week, post-treatment, and 12-week followup) were held at this location. If a participant was unable to attend an assessment session because of transportation or physical limitations, arrangements were made to conduct the assessment in the participant's home (n = 1) or over the telephone (n = 1).

Procedure

Recruitment. Recruitment efforts started in early March 2013 and continued until February 2014. In order to recruit members of the San Diego community who would meet eligibility criteria, a variety of recruitment strategies were put into place. A study website was designed and published, providing visitors with contact information (telephone number, email link), a description of the study, the eligibility criteria, the time and travel commitment required, and instructions for obtaining further information about the study. 'Google AdWords' was used to support visibility of the website within San Diego County. Specifically, when someone within the specified local region performed web searches for pertinent keywords (Fibromyalgia, research study, San Diego, pain, FM, Fibromyalgia therapy, FMS, pain anxiety), Google AdWords presented a link to the website at the top of the Google search list. In addition, online advertisements were posted on research network websites (i.e., Clinical Connections and Clinical Trials), and on a community message board (i.e., Craig's List). Efforts were made to reach out to

FMS support groups and online 'Meetup' groups in San Diego by sending electronic messages to group leaders and to members. In addition, a total of 402 flyers were mailed to primary care physicians and pain specialist physicians providing them with information regarding the study, contact information for the study, and request for patient referrals. Flyers were also manually delivered to various local community centers. Additionally, two one-time print ads were placed in local newspapers (i.e., Union Tribune, Navy Dispatch).

A total of 155 individuals made inquiries after receiving information about the study from these sources (Website = 90, 'Clinical Connections' = 27, newspaper = 8, word of mouth = 7, physician flyers = 14, support groups = 5, 'Craig's List' = 3, unknown = 1). Of those 155 individuals, 99 did not complete the eligibility screening. Specifically, 22 of those individuals directly indicated that they were not interested in participation for the following reasons: distance (n = 8), transportation difficulties (n = 4), the nature of the exposure intervention (n= 3), disinterest in both interventions (n = 1), lack of medication in study (n = 1), time commitment (n = 2), scheduling conflicts (n = 2), and physical limitations (n = 1). The remaining 77 who called or emailed to inquire about the study were unable to be reached to perform eligibility screening despite numerous attempts.

Screening. When an interested person made contact, the study coordinator arranged to speak with him/her on the phone to conduct the initial eligibility screening. On this call, the study coordinator provided the person with information regarding the nature of the study, the screening procedure that would be performed over the phone, the eligibility requirements, the possible secondary in-person screening, and the study

participation requirements. She explicitly informed the caller that he/she had the right to withdraw from participation at any time. If the person agreed to be screened, he/she was then assessed for initial eligibility. First, the coordinator asked whether the caller was at least 18 years old and whether he/she had received a physician's diagnosis of FMS. If those criteria were met, the coordinator administered the Pain Anxiety Symptom Scale-20 (PASS-20) and the Tampa Scale for Kinesiophobia (TSK). If the participant scored above the cut-off on the PASS-20 or the TSK, the coordinator informed the participant that he/she met the initial eligibility criteria for the study. A total of eight callers were determined to be ineligible for participation based on their test scores. Another 11 participants were determined to be ineligible for other reasons (no FMS diagnosis = 4, presence of exclusionary pain condition = 5, did not speak English = 1, younger than 18 =1).

For those who passed the preliminary phone screening (n = 37), an in-person appointment was scheduled. Of those who were scheduled, seven did not show up for their scheduled appointments or return calls to reschedule; therefore, these individuals were not further assessed for eligibility. Upon arrival at the research laboratory, a research assistant met with the individual to provide further information regarding the nature of the study and the two interventions being examined, reviewed the consent form, answered all questions, and requested that the participant sign a consent form. A copy of the signed form was also provided to the potential participant, along with the Participant's Bill of Rights. Then, the research assistant performed the Manual Tender Point Survey (MTPS). Research assistants received extensive training in performing this diagnostic examination procedure by a physician who specializes in diagnosis and

treatment of FMS (Dr. Bill McCarberg). The MTPS is a 5-to-10-minute assessment based on the 1990 ACR criteria for FMS classification. In this procedure, 21 sites on the body (18 survey sites and 3 control sites) were examined for pain by applying digital pressure on each site for four seconds. The force increased by one kilogram each second, until four kilograms of pressure was applied to each site. Participants were asked to state whether or not they experienced pain at each site and how intense their pain was on a scale from 0 (no pain) to 10 (worst pain ever experienced). From those estimates, a fibromyalgia intensity score and control intensity score were calculated. Participants were also asked to point to parts of the body where they experienced pain, the duration of their pain, and had their height and weight measured.

If the person met the 1990 ACR criteria via MTPS, the research assistant informed the participant that he/she was considered eligible for study participation. Those who agreed to participate in the study completed the first baseline assessment measures at that time, and then were randomly assigned to an intervention condition. Those who qualified for participation in the study were also asked to consent to audio recording the intervention sessions for supervisory purposes. Participants were told verbally and in written form that they could refuse to be audiotaped without penalty. A total of 30 participants met all eligibility criteria and 29[1] were randomly assigned to an intervention condition.

Randomization. Participants were randomly assigned to either the graded in-vivo exposure therapy intervention or to a self-management education intervention (SMEI).

[1] One participant met all eligibility criteria and completed the baseline assessment measures, and opted to drop out of the study prior to randomization, citing a high likelihood of travel difficulties if he were to participate.

The study coordinator kept a concealed box with folded papers with the name of an intervention on each (i.e., ‘movement’, ‘education’). The box was held above the participant’s head and the participant reached in to select his/her assignment. At the outset of the study, equal numbers of papers representing each intervention were placed into the box and were replaced when participants dropped out of the study. As shown in Figure 4, a total of 18 participants were assigned to the graded in-vivo exposure intervention and 11 were assigned to the SMEI condition. The use of a sampling with replacement technique explains the unequal number of participants assigned to each intervention condition.

Sample Size

It has been argued that the sample size for a pilot study should be based on the specific feasibility and acceptability objectives of the pilot trial and not focused on the examination of the estimated effect of the intervention on clinical outcomes (Arnold et al., 2009; Feeley et al., 2009). When first designing this study, a sample size goal of 24 was set, because 12 participants per group was a convention for feasibility research (Julious, 2005). As the study was underway, it became apparent that there were significant recruitment and retention challenges. It has been suggested that innovative early-stage research often suffers from diminishing returns as the sample size increases, and that cost efficiency should be incorporated into the determination of recruitment goals. That is, the relative costs of increasing the sample size outweigh the value of the data collected from additional participants. As such, alternative sample size calculation conventions have been proposed, such as the calculation of n_{root}. Using this calculation, the ideal sample size was determined to be the one that minimizes the ratio of the overall

projected costs to the square root of a proposed sample size (Bacchetti, Deeks, & McCune, 2011). Calculation of n_{root} was used to determine a final sample size goal for the pilot trial. The n_{root} calculation took into account cost estimates for sample sizes of 14, 16, and 18 because the sample size at the time of calculation was 14 and consideration was being given to additional recruitment efforts. The results suggested that a sample size of 14 was the most defensible number in terms of cost efficiency: the scientific value produced per dollar spent. This sample size effectively minimized the ratio of the total cost to the square root of the sample size. It was determined that increasing the sample size beyond this would yield diminishing returns in value. Based on this sample size calculation and the resource expenditure (time, person-month effort) required to recruit and retain participants in this feasibility study, recruitment was terminated after this sample size was recruited. Below are the raw data used for this analysis.

For N = 14

Full Payment for participants to date	$ 1,475.00
Recruitment costs to date	$ 4,888.00
Supplies used in the study	$ 747.00
Total	$ 7,110.00

For N = 16

Total at N = 14	$ 7,110.00
Additional recruitment costs[1]	$ 508.00
Payment to additional successful participants	$ 200.00
Estimated payment to participants that will drop out[2]	$ 50.00
Total	$ 7,868.00

1. Future recruitment costs have the following breakdown: mailing flyers ($241.00), Clinical Connection Account ($79/month), Webs.com account ($10/month) for a three-month period
2. This estimate is based on the finding that 17 payments have been made to those who have dropped out of the study relative to 14 that are active or have completed, which is roughly a ratio of 1.2. 1.2 x 2 new participants needed = 2.4 possible dropouts in order to recruit more participants to reach 16.

For N = 18

Total at N = 16	$ 7,868.00
Additional recruitment costs[1]	$ 178.00
Payment to additional successful participants (N = 2)	$ 200.00
Estimated payment to participants that will drop out	$ 50.00
Total	$ 8,296.00

1. Additional recruitment costs include two additional months of payments for clinical connections and webs.com account (i.e., 5 more months of recruitment than for N = 14)

Two additional points should be made regarding sample size for this pilot trial. First, the sample size of 14 refers to the number of participants who were expected to successfully complete the intervention and the follow-up assessment. However, only 12 participants completed the interventions. After terminating recruitment efforts, it was discovered that an additional three participants were misidentified as eligible because of an error in the screening process that had occurred. Two of these participants were intervention completers who had to be retroactively removed from the final sample data.

The overall sample size for the present study is larger when attrition rates are considered. Although only 12 participants completed the intervention portion of this study (i.e., exposure N = 4; education N = 8), an additional seven participants who dropped out of the exposure intervention and two who withdrew from the education intervention returned to complete the follow-up assessment. This increases the overall sample size for the final assessment to 21 participants.

Ethical Approval and Confidentiality

This pilot trial received ethical approval from the institutional review board (IRB) at San Diego State University (SDSU). Approval for this dissertation was received from the IRBs at SDSU and the University of California, San Diego (UCSD). In order to

ensure that confidentiality and privacy were maintained, identification numbers were assigned to each participant, and his/her information was de-identified throughout the study. All data were kept separate from participant contact information in locked file cabinets with access limited only to research personnel working on the protocol. Electronic data were de-identified and stored on password-protected computers with access limited to those who were directly involved in the research. All research personnel received extensive training in the Protection of Human Participants, which has been adapted in accordance with HIPAA regulations.

Interventions

Graded in-vivo exposure intervention. The protocol used for this intervention was translated and modified from a Dutch graded in-vivo exposure protocol employed by Vlaeyen et al. (2001; 2002) with chronic low back pain participants with pain-related fear. In one of their studies, it was unclear how long their protocol was delivered to participants (i.e., Vlaeyen et al., 2001). In their 2002 study, the intervention was delivered as a part of a larger rehabilitation program in which participants learned about graded activity, pacing, relaxation, and ergonomics. The graded in-vivo exposure intervention was delivered within a four-week period either before or after receipt of a graded activity intervention. The time frame for delivering graded in-vivo exposure, the frequency of sessions, and the length of each session as a treatment for fear-avoidance has varied across studies (e.g., Boersma et al., 2004; Leeuw et al., 2008; Linton et al., 2002; Macedo, Smeets, Maher, Latimer, & McAuley, 2010). Within this pilot trial, the graded exposure intervention was delivered individually to participants in 13 weekly sessions: an initial 90-minute introduction and education session followed by 12 weekly, 60-minute

sessions. This time frame and session length was selected to translate to a duration and frequency that could be readily adopted in a mental health treatment setting and would allow sufficient time for engagement in multiple activities and movements.

During the initial 90-minute session, participants were provided with education regarding chronic pain, fibromyalgia pain, the fear-avoidance model, and graded in-vivo exposure therapy. It should be noted that the FMS-specific educational content was developed by members of the research team (Maya D'Eon [M.D.] Terry Cronan [T.C.], Mark Jacobson [M.J.]) and replaced content about chronic low back pain from the original protocol used by Vlaeyen and colleagues (2001, 2002). Following the delivery of education, motivational interviewing techniques were used to enhance motivation and readiness for continued participation in the program. Specifically, time was dedicated to discussing the benefits and costs of engaging in the program (therefore, increased physical activity) and not engaging in the program (i.e., not changing one's level of physical activity). The participant's level of readiness was scored on a 10-point scale, and he/she was encouraged to evaluate why the score was not higher or lower. The use of these strategies was designed to assist the participant in evaluating his/her current level of readiness for engagement and to assist them in planning ahead for some barriers that might arise during the intervention.

The latter half of the session was dedicated to constructing a hierarchy of physical activities or movements using the subjective units of distress scale (SUDS). Consistent with the original Dutch protocol, the SUDS were rated from 1 (activities generating no pain-related distress) to 10 (activities generating the most pain-related distress imaginable). Activities were generated collaboratively in the session with the participant,

with the requirements that they had to be movement-based activities, be amenable to performance in and out of sessions, and were avoided to some degree in the participant's daily life because of pain-related anxiety and associated worries. It was also requested that the activities were those that the participant had a strong familiarity with so that he/she could describe it in detail, vividly imagine performing the activity in session, and re-create that activity. Participants were encouraged to select activities that held value to them and that they would be motivated to work towards increased engagement in. Consequently, only activities with relevance to the participants were selected.

The second session was designed to provide participants with additional education regarding the structure of the program and associated rationale. First, behavioral experiments (i.e., in vivo exposures) were explained in a step-by-step fashion. Second, activity pacing was instructed as an alternative to engaging with activities with a task completion orientation, which often leads to overactivity and associated pain and fatigue. Incorporating activity pacing within the graded exposures was a new addition to this pilot trial protocol. This was added based on the large body of literature supporting the need for a graduated approach to activity engagement within this population and the potential for heightened symptom experience in the context of overactivity. Given the high potential for physical deconditioning in this population and possibility of overactivity interfering with the goals of the intervention, pacing was deemed a necessary addition. Research has also shown that pacing is an effective pain regulation technique to prevent possible pain-related disability in FMS (Karsdorp & Vlaeyen, 2009; Nisell & Kosek, 2011). In addition to including pacing, instruction in goal setting was added to this pilot trial and introduced in this session. Participants were taught ways to effectively set goals

by ensuring that they were **s**pecific, **m**easureable, **a**ttainable, **r**ealistic, and **t**imely (SMART). Participants were informed that SMART goal setting would be incorporated into the development of each behavioral experiment and that pacing would be incorporating into the performance of each behavioral experiment. If time allotted, the first activity for a behavioral experiment was selected.

Throughout sessions 3 to 12, the intervention was designed so that participants worked with the interventionist to develop and participate in in-session behavioral experiments, completed at-home behavioral experiments of those same activities, and evaluated the experiences in session. The majority of participants required three sessions to complete the sequence of events (i.e., plan, participate, and process behavioral experiments). Following this process, the participant either continued to engage in additional behavioral experiments with the same activity (if distress was still high), a modified version of the activity (e.g., increase in task difficulty, intensity, frequency), or selected a new activity higher on the hierarchy. The final thirteenth session was dedicated to a review of the educational content, review of the individual's progress through the program, and relapse prevention (see Table 5 for description of session activities and Appendix A for copy of the intervention manual).

Table 5. Description of each session in the graded in-vivo exposure therapy intervention

Session	Session Focus	Specific Activities
1	- Introduction and education	- Education about: chronic pain, fibromyalgia pain, fear-avoidance model, the intervention program - Motivational interviewing - Construction of pain-related anxiety hierarchy
2	- Education and plan first behavioral experiment	- Education about: behavioral experiments (step-by-step instruction), pacing, SMART goal setting - (If time) plan first behavioral experiment
3	- Develop detailed plan for behavioral experiment (and perform, if time)	- Select activity - Make a concrete plan using SMART goal setting structure and incorporating pacing - Identify catastrophic thoughts and rate believability - Rate pain-related anxiety/worry - Generate alternative thoughts and rate believability - (If time) perform the activity and process the experience
4	- Perform behavioral experiment and process	- Revisit the catastrophic thoughts and associated believability ratings and update - Revisit alternative thoughts and associated believability ratings and update - Rate pain-related fear - Perform behavioral experiment: ▪ Interventionist performs the activity ▪ The participant performs the activity and provides fear ratings throughout until 50% decrease in fear or increase in pain prevents further activity ▪ Evaluate the experience: re-rate believability of catastrophic thoughts and alternative thoughts, examine the post-activity fear rating and discuss the participant's impressions of the behavioral experiment - Use SMART goal setting to plan at-home behavioral experiments using same activity
5	- Process at-home behavioral experiment(s) - Plan the next behavioral experiment	- Review the behavioral experiment(s) performed at home using the same structure outlined in session 4 - Discuss 'lessons learned' across behavioral experiments - Re-rate pain-related anxiety on the hierarchy
6- 12	- Develop, perform, and process behavioral experiments	- Repeat same structure as sessions 3 to 5
13	- Review of progress and relapse prevention	- Review of educational content - Review of lessons learned throughout intervention - Instruct about setbacks vs. relapse - Develop a relapse prevention plan

Control condition: Self-management education intervention (SMEI). Cronan and colleagues (e.g., Cronan et al., 1997; Cronan et al., 1998; Oliver et al., 2001) developed the self-management education intervention (SMEI) based on the Arthritis

Self-Management Program (ASMP) developed at Stanford University for individuals with various forms of Arthritis and FMS (Fries, 1986; Lorig & Fries, 1990). The SMEI was adapted for use in the FMS population by incorporating education that directly targeted the FMS experience (Oliver et al., 2001). For the present pilot trial, the original SMEI content remained intact within the intervention, and additional educational content was added to provide updated research and to ensure that each session would mirror the other intervention in terms of session length and treatment time frame. Unlike the graded in-vivo exposure intervention, the SMEI was not tailored to the individual. The sessions were delivered in a uniform manner to all recipients of this intervention.

The SMEI was administered individually to participants in 13 weekly sessions, with the first session being designed to last 90 minutes and the remaining 12 sessions being designed to last 60 minutes. This duration was selected to match duration and frequency of attention received in the graded in-vivo exposure intervention. Each session covered a separate educational topic. Specifically, the following self-management education topics were covered, in order: Intake and introduction, overview of FMS, pain, treatment strategies, fatigue, sleep, exercise, stress and relaxation techniques, dealing with emotions, communication skills, social support and communication, nutrition, and living well with FMS. The final session was added to this intervention in order to extend the number of topics to 13 weeks. This content provided a summary of information learned throughout the program and education regarding up-to-date research on factors that contribute to living well with FMS (see Appendix B for intervention manual).

Interventionist Training and Supervision

The interventionist in the graded in-vivo exposure therapy intervention (M.D.) was a doctoral student in clinical psychology who had received clinical training and supervision in this therapeutic technique from licensed clinical psychologists. The interventionist worked alongside senior researchers (T.C., M.J) to adapt and modify the original intervention materials for the study and received supervision in the development of the intervention manual. To facilitate training, session content was reviewed and style of delivery was discussed with the senior researchers prior to the initial delivery of sessions. The interventionist received weekly supervision from a licensed clinical psychologist (M.J.). The intervention sessions with participants were audio-recorded for the purposes of supervision and ensuring that the protocol was followed consistently across participants and sessions. Any challenges to protocol delivery were first discussed during weekly supervision and if they were unable to be resolved in a protocol-consistent manner, they were further discussed with the research team to determine whether modifications to the protocol were needed.

There were three interventionists who delivered the SMEI. One of these interventionists was a post-bachelor research assistant, another was an undergraduate research assistant with extensive experience in the health care field, and the last was a master's student in the SDSU psychology department. It should be noted that studies and community programs typically have lay volunteers deliver self-management education for chronic pain (Lorig, 1992; Lorig et al., 1998). Each interventionist was trained by a senior researcher (T.C.) to understand and deliver the content in a reliable and consistent manner. Interventionists audio-recorded their sessions, which were reviewed by the

senior researcher and discussed with each interventionist at regular intervals. Interventionists were encouraged to listen to each other's sessions and to develop deliberate practice plans to ensure that each interventionist worked towards similar styles of delivery.

Assessments

Participants completed assessments at four time points: prior to random allocation, after the 6-week intervention session, after the final 13-week intervention session, and 12 weeks following completion of the intervention. The first assessment was completed immediately prior to random assignment and consisted of completing a battery of questionnaires and verbally providing medical history information. The 6-week and 13-week assessments were completed immediately following the associated intervention session. Participants completed the same battery of questionnaires as they did during the baseline assessment, in addition to verbally indicating if any changes were made to their medications. In addition, the 13-week assessment included a program evaluation survey. The 12-week follow-up assessment included the recurring battery of questionnaires and additional assessment tools that were added over the course of the pilot trial (i.e., MoCA, SAPAS, POAM-P). Each of the measures and their delivery schedules are outlined in the Measures section. It should be noted that participants who opted to drop out of the interventions were contacted by a senior researcher (T.C.) and were invited to participate in a final assessment that included the 12-week follow-up assessment measures, in addition to a program evaluation survey. Participants were paid $25 USD for each assessment session attended. Assessment data collection is currently ongoing.

Measures

Tampa scale for kinesiophobia (TSK). The Tampa Scale for Kinesiophobia (TSK) is a 17-item self-report measure assessing perceived harmfulness of daily activities and movement-related fear (Roelofs, Goubert, Peters, Vlaeyen, & Crombez, 2004). The TSK is comprised of two subscales assessing activity avoidance and beliefs regarding fear of (re)injury. There are also items assessing beliefs about exercise. Participants indicate their level of agreement with each statement on a 4-point Likert scale ranging from 1 (Strongly Disagree) to 4 (Strongly Agree). The TSK has good reliability (a = .77; Vlaeyen & Linton, 2000), good internal consistency (alphas have ranged from .68 to .80) and established criterion validity and construct validity (Crombez, Vlaeyen, Heuts, & Lysens, 1999; Roelofs, et al., 2004; Vlaeyen & Crombez, 1999). No cut-off scores have been established and validated with the FMS population to differentiate between high and low kinesiophobia; however, the TSK has been used in research with the FMS population to assess fear of movement (e.g., Lambin et al., 2011; Turk et al., 2004; van Koulil et al., 2010). One study of 391 Dutch individuals with FMS revealed a mean TSK score of 28.2 (SD = 7.1; Roelofs et al., 2004). In a second study (i.e., Roelofs et al., 2004), a sample of N = 398 randomly-selected Dutch individuals with FMS had a mean TSK score of 34.2 (SD = 8.2). Similarly, Turk et al. (2004) found that their entire sample of 233 female FMS participants had a mean score of 35.3 (SD = 6.5). The present pilot study selected a cut off of 40 to select individuals who may be considered more fearful of movement than the average person with FMS. This cut-off score has been used in selecting chronic low back pain participants for graded in-vivo exposure studies and was proposed to represent moderate to high fear of movement (i.e., Vlaeyen et al., 2001; Vlaeyen et al., 2002). In

addition to the use of the TSK as a screening measure, participants completed this questionnaire at all assessment times.

Pain anxiety symptom scale-20 (PASS-20). The Pain Anxiety Symptom Scale-20 (PASS-20) was used to measure pain-related anxiety. The PASS-20 is a short form of the PASS (McCracken & Dhingra, 2002). This is a 20-item, self-administered questionnaire that has four subscales: cognitive, escape/avoidance, fear, and physiological anxiety. Participants indicate how often they engage in certain thoughts or activities related to pain using a 6-point Likert-type scale ranging from 0 (Never) to 5 (Always), with higher scores indicating greater pain-related anxiety. High internal consistency has been demonstrated (alphas .75 to .91), as well as good reliability, and good predictive and construct validity (McCracken & Dhingra, 2002). In a randomly selected sample of 398 people from the FMS population, Roelofs et al. (2004) reported a mean score of 37.1 (SD = 19.2), which is similar, though, lower than those with chronic low back pain (M = 46.4, SD = 21.5). No cut-offs exist for differentiating between high and low pain-related anxiety in the FMS population. The cut-off score of 55 was selected as a criterion for eligibility in the present pilot trial in the interest of limiting the selected sample to a subgroup of the FMS population that had notable pain-related anxiety. This score was found within the upper range of the scores in Roelofs et al.'s (2004) sample. Aside from being employed as a screening tool in this pilot trial, the PASS-20 was also administered at all assessment times.

Revised fibromyalgia impact questionnaire (FIQ-R). The Revised Fibromyalgia Impact Questionnaire (FIQ-R) is a 21-item self-report measure with three subscales (function, overall impact, symptoms) designed to assess the disease-specific

impact of FMS (Bennett et al., 2009). This questionnaire is valid and has good psychometric properties (Bennett et al., 2009). Across a number of intervention studies, the FIQ-R has been used to measure changes in FMS impact on symptoms and functioning over time (Jones et al., 2011). The FIQ-R has strong internal reliability (alpha = .95) and has good convergent and discriminative validity (Bennett et al., 2009). The FIQ-R was administered to participants in this pilot trial at all assessment times.

Pain catastrophizing scale (PCS). The Pain Catastrophizing Scale (PCS) is a 13-item self-report measure using a 5-point Likert-type scale (0 = Not at all to 4 = All the time) to assess catastrophizing about pain (Sullivan, Bishop, & Pivik, 1995). Specifically, participants are asked to think about past pain episodes and to report the degree to which they had specific thoughts and feelings during that time. The PCS has three subscales: rumination, magnification, and helplessness. Higher scores reflect greater levels of catastrophizing within each of these categories, with scores greater than 24 reflecting notable levels of catastrophizing (Morris et al., 2011). Strong evidence of criterion, concurrent, and discriminant validity has been gathered within pain populations (Osman et al., 2000). It also has good-to-excellent internal consistency (total alpha = .87, rumination = .87, magnification = .66, helplessness = .78; Sullivan et al., 1995). For the present pilot trial, the PCS was administered to participants at all assessment times.

Patient health questionnaire-9 (PHQ-9). The Patient Health Questionnaire-9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) is a 9-item short-form version of the Patient Health Questionnaire (Kroenke et al., 2001), which is designed to measure depressive symptoms and functional impairment. Participants report how often they engage in certain thoughts or activities using a 4-point Likert-type scale ranging from 0

(Not at all) to 3 (Nearly every day). Higher scores indicate greater levels of depression, and this measure is sensitive to change over time. This brief measure has been established as a valid tool for assessing severity of depressive symptoms (Kroenke et al., 2001). Internal reliability of the PHQ-9 is excellent (alpha in primary care study = .89, alpha in OB-Gyn study = .86; Kroenke et al., 2001). Test-retest reliability has also been shown to be excellent (Kroenke et al., 2001). Within this pilot trial, the PHQ-9 was administered at all assessment times.

Brief survey of pain attitudes (SOPA-B). Brief Survey of Pain Attitudes (SOPA-B) is a short form of the Survey of Pain Attitudes (SOPA; Tait & Chibnall, 1997). The SOPA-B is a 30-item self-report measure designed to assess adaptive and maladaptive pain-related attitudes and beliefs. Similar to the full-scale SOPA, the subscales assess beliefs about: pain control, others' responses to one's pain, medication as pain treatment, medication as cure for pain, pain-related disability, the relationship between pain and emotions, and pain-related harm. Participants indicate the extent to which they believe statements regarding pain to be true using a 5-point Likert scale ranging from 0 (Very Untrue) to 4 (Very True). With some items being reverse-scored, higher scores are related to greater maladaptive beliefs within each category. The internal consistencies of the subscales were adequate to excellent (alphas = .56 [Medication] to .83; Tait & Chibnall, 1997), and test-retest reliability and construct validity have been demonstrated (Jensen, Turner, & Romano, 2000). The SOPA-B was administered at all assessment times.

Arthritis self-efficacy scale (ASES). The Arthritis Self-efficacy Scale (ASES) is a 20-item questionnaire assessing self-efficacy beliefs regarding function, symptoms, and

pain (Lorig, Chastain, Ung, Shoor, & Holman, 1989). Participants report their perceived level of certainty in their ability to manage pain (pain subscale), perform self-management activities (function subscale), and manage other symptoms (symptoms subscale) on a scale from 10 (Very Uncertain) to 100 (Very Certain). The subscales are internally consistent (alphas = .75 to .90) and construct and concurrent validity have been demonstrated in the arthritis population (Lorig et al., 1989). Test-retest correlations ranged from 0.71 to 0.85 (Lorig et al., 1989). Although the ASES was originally developed for the arthritis population, it has been translated for use in the FMS population by changing the word "arthritis" to "fibromyalgia" or "condition" (Bailey, Starr, Alderson, & Moreland, 1999; Buckelew et al., 1994; Buckelew, Murray, Hewett, Johnson, & Huyser, 1995; Gowans et al., 2001). The ASES was administered at all assessment times within the present pilot trial.

Fear avoidance beliefs questionnaire (FABQ). The Fear Avoidance Beliefs Questionnaire (FABQ) is a 16-item survey that assesses beliefs about the impact of work and physical activity on pain (Waddell et al., 1993). This pilot study had participants complete the physical activity subscale, which is comprised of 4 statements regarding the perceived impact of physical activities on pain (e.g., "physical activity makes my pain worse"). Each statement is rated on a 6-point Likert scale ranging from 0 (Completely Disagree) to 6 (Completely Agree). Overall, the FABQ has demonstrated high internal consistency (alphas = .88 and .77). The physical activity subscale has acceptable test-retest reliability (ICC = .72 to .90; Chaory et al., 2004; Pfingsten, Kröner‐Herwig, Leibing, Kronshage, & Hildebrandt, 2000) and is considered a valid measure

(Williamson, 2006). In the present pilot study, the FABQ was administered to participants at each assessment time.

Demographic and medical history questionnaire. A demographic and medical history questionnaire was developed for this pilot trial and was administered at the baseline assessment visit in order to determine age, socioeconomic status, educational level, marital status, gender, and medical history. A research assistant verbally asked participants all the questions on this measure in a structured interview. The items used in this assessment survey have been used in previous studies within this research laboratory (Cronan et al., 1998; Oliver et al., 2001). At all other assessment times, an abbreviated measure was developed to record any changes to medications that were made since the previous assessment.

Program evaluation measure. The program evaluation measure used in the present study was developed and used in a previous RCT with FMS patients (Cronan et al., 1998; Oliver et al., 2001). The measure includes 19 questions rated on Likert scales designed to assess evaluations of various aspects of the intervention, its utility, and its delivery (See Appendix C for the measure). For instance, the item "Would you recommend this program to a friend?" is rated on a 5-point Likert-type scale from 1(No) to 5 (Yes). In addition, the following four open-ended questions were included: "What did you like most about the program?"; "What did you like least about the program?"; "What could you recommend to improve this program?"; and, "Do you have any other comments that you would like to make about this program? If so, please state here." This measure was provided to participants immediately following the 13-week intervention session alongside the other assessment measures. For participants who dropped out of the

study and agreed to attend a follow-up assessment, a modified version of the program evaluation measure was incorporated into their assessment. Specifically, the following item was added: “What was the reason that you left this program?”

Montreal cognitive assessment (MoCA). The MoCA is an assessment tool for measuring global cognitive functioning and detecting mild cognitive impairment (Nasreddine et al., 2005). An examiner asks the participant to perform a series of cognitive tasks that measure performance in areas of attention, concentration, visuospatial skills, executive functioning, memory, language, abstraction, calculation, and orientation. It has been suggested that scores ranging from 25.2 to 29.6 are indicative of healthy cognitive functioning, 19 to 25.2 are reflective of mild cognitive impairment, and 11.4 to 21.0 are found among individuals with Alzheimer’s disease (Nasreddine et al., 2005). The MoCA has been shown to be highly sensitive to detecting mild cognitive impairment and Alzheimer’s disease (90% and 100%, respectively) and has excellent specificity (87%; Nasreddine et al., 2005). This assessment tool has excellent test-retest reliability (.92) and good internal consistency on the standardized items (alpha = .83; Nasreddine et al., 2005). The MoCA has been employed in a study of 13 women with FMS, which reported a mean score of 23.6 (SD = 3), which was statistically significantly lower than the mean score found in healthy controls (M = 26.45, SD = 2.88; Borg et al., 2014). In the present pilot trial, the MoCA was conducted at the final 12-week follow-up assessment and to participants who dropped out and returned for a final assessment. This was added to the assessment measures in response to observed cognitive difficulties (e.g., attention and memory) among participants in the graded in-vivo exposure intervention.

Standardized assessment of personality – Abbreviated scale (SAPAS). The Standardized Assessment of Personality- Abbreviated Scale (SAPAS) is an 8-item brief interview assessment of personality disorder. This screen requires participants to identify the relevance of 8 self-descriptions using yes/no responses (e.g., "In general, are you a perfectionist?"). In the psychometric evaluation of this measure, a score of 3 or higher accurately identified 90% of participants who had a DSM-IV Axis II disorder (Moran, Leese, Lee, Walters, Thornicroft, & Mann, 2003). The SAPAS has demonstrated high sensitivity (.94) and specificity (.85; Moran et al., 2003), as well as concurrent validity (Hesse & Moran, 2010). This measure was added to the 12-week follow-up assessment after research staff observed treatment interfering behaviors that were hypothesized to be driven by the presence of personality disorders. Two participants self reported having diagnosed Borderline Personality Disorder.

Patterns of activity measure- Pain (POAM-P). The Patterns of Activity Measure-Pain (POAM-P) is a 30-item self-report questionnaire designed to assess pain-related responses on three subscales: avoidance, overdoing, and pacing (Cane, Nielson, McCarthy, & Mazmanian, 2013). Participants rate their level of engagement in various pain-related activities on a Likert-type scale, ranging from 0 (Not at All) to 4 (All the Time). The scales have demonstrated excellent internal consistency (avoidant = .86, overdoing = .90, pacing = .94), and construct validity has been established through high correlations with related measures (Cane et al., 2013). This measure was incorporated late in the intervention after research staff observed a number of participants demonstrating overactivity rather than avoidance patterns. As such, this questionnaire was added to the 12-week follow-up assessment time.

Objectives and Outcomes

The graded in-vivo exposure therapy intervention was designed to target catastrophizing, pain-related fear and anxiety, and avoidance behaviors, which are theorized to drive the development and maintenance of physical deconditioning, pain-related disability, and depression. The objective of a future large-scale RCT would be to measure change in both the process variables (i.e., catastrophizing, pain-related fear and anxiety, avoidance/approach behaviors) and outcome variables (e.g., health-related quality of life, depression). Prior to conducting an RCT, the pilot trial was conducted with the purpose of establishing feasibility (delivery) and acceptability (uptake) of the 1) *intervention* and 2) *study design and procedures*. Based on the recommendations of Thabane et al. (2010), feasibility and acceptability objectives and outcomes were developed and are presented in Table 6.

Table 6. Feasibility and acceptability objectives, outcomes, measures, and statistical methods

Feasibility and Acceptability Objectives	Feasibility and Acceptability Outcomes[a]	Measures	Statistical Methods[b]
Intervention:			
Adherence	1. Frequency and percentage of participants that completed each number of sessions 2. Mean and median number of weeks to complete all sessions 3. Frequency and mean number of session absences 4. Percentage of assigned at-home behavioral experiments that were completed	Log records of all participant attendance, absence, and reasons Homework adherence form completed by participants prior to session	Frequency, percentage, mean, median, standard deviation, range
Withdrawals/ Drop outs	1. Number and percentage of participant withdrawals at each time point 2. Reasons for discontinuation	Log records of active and inactive participants (dates of entry, session participation, withdrawal and stated reasons) Program Evaluation Measure: Open-ended question: what was the reason that you left this program?	Frequency, percentage, qualitative description of reasons and labeling into thematic categories
Participant Satisfaction	1. Percentage of participants that rated satisfaction as "mostly" to "completely" 2. Percentage of participants that rated "likely" and "yes" for recommending program to a friend	Program Evaluation Measure: 5-point Likert scale questions: How satisfied with this program are you overall? Would you recommend this program to a friend?	Frequency, percentage, mean, median, range, standard deviation
Expected Treatment Impact	1. Participant profiles on measures at each time point	TSK, PASS-20, PHQ-9, FIQ-R, PCS, SOPA-B, ASES, FABQ, MoCA, SAPAS, POAM-P	Absolute scores, mean, standard deviation, mean change, median, range

a. The listed outcomes are not all-inclusive; additional estimates will be calculated and are listed within the 'statistical methods' column.
b. Confidence intervals (CIs) will be calculated for each estimate

Table 6. Feasibility and acceptability objectives, outcomes, measures, and statistical methods, continued

Feasibility and Acceptability Objectives	Feasibility and Acceptability Outcomes[a]	Measures	Statistical Methods[b]
Design and Procedures:			
Recruitment	1. Number of participants recruited within 3-month time periods 2. Number and proportion/percentage of participants recruited through each method	Log records of recruitment efforts, outcomes, and participation patterns	Frequency, percentage
Eligibility Criteria	1. Number of individuals who completed each stage of screening process 2. Number and percentage of eligible individuals who decided to participate in the study 3. Number and percentage of individuals who were ineligible for various reasons 4. Number and percentage of participants meeting cut-off on TSK or PASS-20 or both	Log records of screening results for all individuals TSK, PASS-20, Manual Tender Point Survey scores	Frequency, percentage
Randomization	1. Number and percentage of participants that agreed to be randomized	Log records of number of individuals agreeing to randomization	Frequency, percentage
Assessment Measures	1. Questionnaire completion rate 2. Item response rates on each questionnaire at each assessment time point	TSK, PASS-20, PHQ-9, FIQ-R, PCS, SOPA-B, ASES, FABQ, MoCA, SAPAS, POAM-P	Frequency, percentage, qualitative description of aberrant response patterns
Co-Intervention	1. Number of medications and medication types taken for FMS symptoms at pre- and post-intervention 2. Number, type, and dosage of medication for pain	Demographic and medical history questionnaire, medication updates recorded during assessments	Frequency, mean, SD, range, qualitative description of medication name and dosage

a. The listed outcomes are not all-inclusive; additional estimates will be calculated and are listed within the 'statistical methods' column.
b. Confidence intervals (CIs) will be calculated for each estimate

Feasibility and acceptability of *study design and procedures*. The following five aspects of study design and procedure that were examined for feasibility and/or acceptability are: 1) recruitment, 2) eligibility criteria, 3) randomization procedures, 4) assessment measures, and 5) co-intervention. Each of these components is integral to the delivery and uptake of an intervention. Problems arising from any of these factors can negatively impact the success of a large-scale RCT and have the potential to mislead researchers to report that an intervention is ineffective. As such, it is crucial that pilot research critically examine each of these elements to ensure that issues are resolved prior to translation into a full-scale RCT. It should be noted that co-intervention refers to the receipt of outside treatment for symptoms that are being directly targeted by the intervention being studied. Within the present pilot trial, pharmacotherapy was documented, as were changes to a participant's dose or medications throughout the study. This is an important factor to examine because changes to medications targeting anxiety symptoms might lead to improvements or decrements that can be misattributed to the intervention. Therefore, it is a study objective to examine frequency and type of concomitant medication use within this sample.

Feasibility and acceptability of the *intervention*. The objectives for this pilot trial were to establish the level of feasibility and acceptability of the intervention through examination of adherence and withdrawals, participant satisfaction, and potential treatment impact trends. Table 6 provides operational definitions for the feasibility and acceptability outcomes that were examined and the associated methods of measurement. For the graded in-vivo exposure intervention to be considered feasible and acceptable for further RCT testing in its current form, it was necessary to ensure that it could be

delivered as designed (feasibility) and that participants would respond positively through their engagement and their direct self report (acceptability). In addition, although sample size limits the ability to examine between-group and within-group differences statistically and to make generalizations regarding treatment outcomes, a pilot trial provides an opportunity to examine trends that may be suggestive of the presence or absence of treatment effects within this sample. However, interpretation of treatment impact is limited at this stage of research.

For all feasibility and acceptability outcomes related to the intervention and study design and procedures, data from both treatment groups (graded in-vivo exposure, SMEI) was examined and are presented.

Feasibility and Acceptability Criteria

A number of the feasibility and acceptability outcomes presented in Table 6 were selected in order to systematically and comprehensively explore the collected data, and others have been explicitly selected to set the threshold criteria for determining the viability of translating this pilot trial into an RCT (see Table 7). A review of the literature has revealed that there are no formal guidelines to follow for selecting feasibility and acceptability criteria and that studies vary greatly in their selected thresholds. The criteria for this pilot trial that are outlined in Table 7 were established in consultation with a senior researcher (T.C.) who would serve as principal investigator (PI) on an RCT based on the data from the pilot trial. In addition, review of the literature has guided the development of some of the specific threshold criteria. For instance, an 80% questionnaire completion rate has been used in a prior feasibility study (Carroll et al., 2013). In addition, the proposed 60% intervention completion rate was derived from

review of an RCT conducted by Linton et al. (2008) in which participants with spinal pain who had fear of work-related activities engaged in a 13-week graded in-vivo exposure intervention. In that study, 62% of participants who were randomized completed the intervention compared to 84% who remained in the waitlist control over that same time frame. Given that individuals with FMS have additional unique barriers to treatment adherence, such as higher prevalence of mental illness comorbidities and additional physical symptoms (fatigue, cognitive dysfunction), the proposed criterion for this feasibility study are lower than the rates found in Linton et al.'s (2008) study.

Table 7. Feasibility and acceptability criteria for dissertation

Feasibility and Acceptability Criteria for Success
Design and Procedures
N = 30 participants recruited within a three-month period
90% of eligible participants agree to randomization and participation
80% questionnaire completion rate
90% questionnaire item completion rate
Intervention
60% of randomized participants complete intervention
70% complete 4 + sessions (i.e., complete 1+ behavioral experiments)
50% complete intervention within 17 weeks
70% of assigned at-home behavioral experiments completed
80% of participants rate satisfaction as "mostly" to "completely"
80% of participants rating likely to yes for recommending program to a friend

Thabane et al. (2010) suggest that feasibility research generally leads to one of the following proposed outcomes: *Stop* (main study/RCT is not feasible, criteria are not met), *Continue, but modify protocol* (feasible with modifications to intervention and/or study design and procedures), *Continue without modifications, but monitor closely* (feasible as is with close monitoring of specific study components), and *Continue without*

modifications (feasible as is). The criteria set for the present study were examined with the purpose of proposing specific directions for future empirical investigation into a graded in-vivo exposure intervention for the FMS population.

Results

Statistical Methods

The analytic methods for this study were largely descriptive and designed to evaluate the feasibility and acceptability of the study design and procedures, as well as the graded in-vivo exposure therapy intervention. It has been argued that pilot trials should solely examine feasibility outcomes rather than treat the study as a smaller-scale RCT, because the small sample size and modifications typically made throughout the trial limit the ability to statistically examine treatment effects and to calculate sample size without introducing bias (Arain, Campbell, Cooper, & Lancaster, 2010; Thabane et al., 2010). SPSS V.20 was used to analyze the data collected from this pilot trial. Table 6 outlines feasibility and acceptability outcomes that were assessed, measures that were used for data collection, and descriptive statistics that were used.

Feasibility and Acceptability of Study Design and Procedures

Design and Procedures: Recruitment. To establish the feasibility of recruitment efforts, it was determined that the strategies employed in the pilot trial would need to result in the recruitment of 30 participants within a three-month period (Criterion 1). In addition, the number and proportion of participants recruited via each recruitment method was examined to determine the feasibility of strategies for use in a larger-scale randomized controlled trial (RCT).

Criterion 1: Thirty participants recruited within a three-month period. **This criterion was not met**, because it took 10 months, and cost over $7,000.00, to recruit a total of 30 participants. Table 8 displays the frequency of inquiries and the number of recruited participants from various sources within three-month intervals. The percentage

of inquiries and the number of participants recruited from each source are presented in Figures 5 and 6. In addition, Table 9 provides the overall costs associated with each recruitment method, as well as the cost per recruited participant from each method. Based on an examination of these data, the website generated the greatest number of inquiries when combined with Google AdWords; however, the conversion rate was relatively low (9%) and this was the most expensive recruitment strategy to employ. Conversely, posting an advertisement on *Clinical Connections,* a study-participant matching website, yielded a higher conversion rate (26%) and the number of participants recruited was similar to the study website. Although the study website and Clinical Connections yielded the most recruited participants from a single source, it should be noted these strategies were employed for a longer period of time than the other recruitment methods.

Utilizing the newspaper ads yielded a higher conversion rate than other strategies (50%); however, the overall number of inquiries was low and the cost for each ad was relatively high. Similarly, recruitment from support groups also led to a high conversion rate (60%) from a small number of inquiries (n = 5) and there were no associated costs. In examining the various recruitment strategies, none emerged as feasible strategies on their own for a large RCT based on the cost, number of inquiries, and recruitment conversion rate.

There were a variety of cited reasons for the failure to convert inquiries into recruited participants, including: the distance required to attend the intervention (n = 10), transportation difficulties (n = 3), the movement and physical activity required in the exposure intervention (n = 6), the time commitment (n = 3), being found ineligible for

participation based on screening measures (n = 8), being found ineligible based on other criteria (n = 11), scheduled for assessment and did not attend (n = 7).

Table 8. Frequency of inquiries and recruited participants over three-month intervals

March 6 – May 31, 2013		
Source	**# Inquired**	**# Recruited**
Website	56	6
Newspaper	6	3
Clinical Connections	9	2
Craig's List	3	0
FMS Support Group	N/A	N/A
Physician Flyers	N/A	N/A
Word of Mouth	0	0
Total	**74**	**11**
June 1 – Aug 31, 2013		
Source	**# Inquired**	**# Recruited**
Website	32	2
Newspaper	2	1
Clinical Connections	9	2
Craig's List	0	0
FMS Support Group	N/A	N/A
Physician Flyers	7	1
Word of Mouth	3	2
Total	**53**	**8**
Sept 1 – Nov 30, 2013		
Source	**# Inquired**	**# Recruited**
Website	2	0
Newspaper	N/A	N/A
Clinical Connections	6	2
Craig's List	N/A	N/A
FMS Support Group	5	3
Physician Flyers	4	2
Word of Mouth	4	2
Total	**22**[a]	**9**
Dec 1 – Feb 28, 2014		
Source	**# Inquired**	**# Recruited**
Website	0	0
Newspaper	N/A	N/A
Clinical Connections	3	1
Craig's List	N/A	N/A
FMS Support Group	N/A	N/A
Physician Flyers	3	1
Word of Mouth	0	0
Total	**6**	**2**

a. The reason this total is 22 is because one additional individual made a telephone inquiry about the study by leaving a voicemail and was unable to be reached to ascertain the source of inquiry.

Table 9. Summary of recruitment outcomes associated with each method

Recruitment Method	Dates Implemented	Overall Cost	# Inquiries	# Recruited (%)	Acquisition Cost
Flyers to Physicians	6/12/13, 11/12/13	$241.31	14	4 (28.57)	$60.33
Newspaper	3/16/13, 6/19/13, 6/30/13, 7/2/13	$1,266.00	8	4 (50)	$316.50
Craig's List Posting	3/12/13, 3/27/13, 4/10/13	$0	3	0 (0)	$0
Clinical Connections	6/13 – 1/14	$553.00	27	7 (25.93)	$79.00
Website with Google Adwords	3/6/13 – 8/31/13	$2,482.91	88	8 (9.09)	$310.36
Word of Mouth	--	--	7	4 (57.14)	--
Unknown	--	--	1	0	--
Website alone	9/13 – 1/6/14	$49.75	2	0 (0)	$24.88
Support Groups	9/4/13 – 10/14/13	$0	5	3 (60)	$0

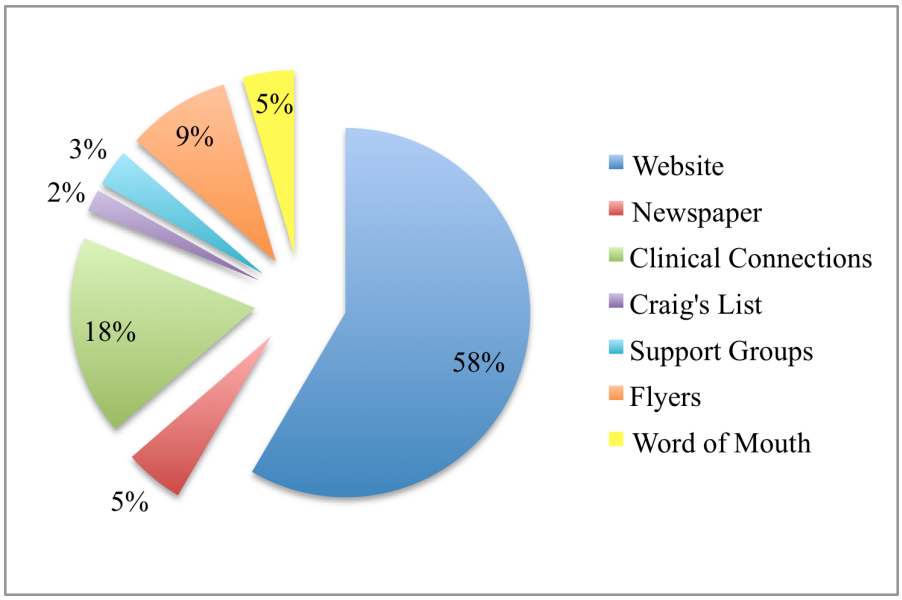


Figure 5. Pie chart displaying the percentage of inquiries acquired from each source

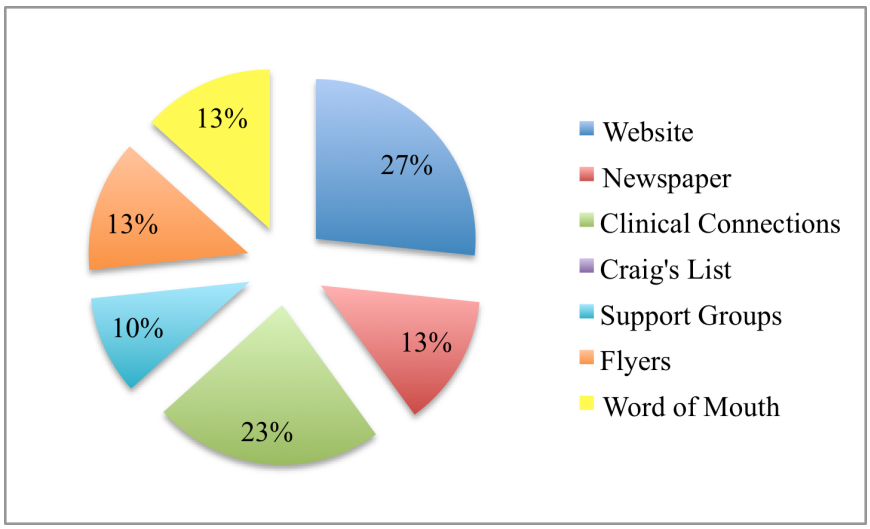


Figure 6. Pie chart displaying the percentage of participants successfully recruited from each source

Design and procedures: Eligibility criteria. The eligibility screening procedures and criteria were explored descriptively. The CONSORT flow diagram (Figure 4) and Table 10 display the number of individuals who completed each stage of the screening process and those who were excluded for a variety of reasons.

A total of 99 individuals who called the study coordinator chose not to participate in the eligibility screening procedures. Of those, approximately 78% (n = 77) did not complete eligibility screening and did not provide a reason for their lack of interest in participating in the study. Another 10% (n = 10) reported travel distance, 6% (n = 6) reported that they did not want to participate in the movement-based intervention, 3% (n = 3) reported transportation difficulties, and the remaining 3% (N = 3) reported time commitment as the reason for not participating in the screening procedures.

Of the 56 participants who were screened for eligibility, 19 (33.93%) were found to be ineligible for participation. Of those who were found to be ineligible during the phone screening, 8 did not meet the cut-off criteria on the TSK and/or the PASS-20. The

remaining 11 individuals were ineligible for the following reasons: no formal FMS diagnosis (n = 4), presence of additional pain conditions (Degenerative discs, n = 2; Complex regional pain syndrome, n = 2), unable to fluently speak English (n =1), were younger than 18 years of age (n = 1), and had recently started medications (n = 1). It should be noted that the individual who started new medications was re-contacted to re-assess his/her eligibility following a four-week period; however, the individual could not to be reached.

A total of 37 participants (66% of those assessed) passed the initial phone screening. Tables 11 to 14 provide descriptive summaries of their TSK and PASS-20 scores. Entry into the study required that participants received a score of 40 or greater on the TSK and/or a score of 55 or greater on the PASS-20. Within the study, 79.3% of the entire sample scored at or above the cut-off criteria on both the TSK and PASS-20. In the exposure condition, most of the participants scored at or above the cut-off for both measures than on any one measure alone (Table 13). There was a small number of participants (N = 4) who were found to be eligible for participation based solely on their TSK score, and no one entered into this intervention condition based on their score on the PASS-20 alone. In the education condition, a small subset of participants was found to be eligible based on only the TSK (n =1) or the PASS-20 (n = 1) score, with the remaining being eligible based on both measures.

Table 10. Participant recruitment and retention

Recruitment and Baseline Assessment	**Number of Individuals**	
Total # who inquired about the study (via any means)	155[a]	
# that were not eligible based on test scores	**8**	
# that were not eligible based on other factors	**11**	
Total # not interested in the study	**99**	
- # that were not interested and gave reason	22	
- # that were not interested and gave no reason (i.e., no communication)	77	
Total # that completed phone screening and were scheduled for TP exam and assessment	**37**	
- # who attended and met *all* eligibility criteria	30	
- # who did not show up for TP* and baseline assessment	7	
After Baseline Assessment Period	**Movement**	**Education**
# eligible who *attended* 0 sessions and dropped	1	1
# eligible who *attended* session 1 and dropped	3	0
# eligible who *attended* session 2 and dropped	6	1
# eligible who *attended* session 3 and dropped	1	1
# eligible who *attended* session 4 and dropped	1	0
# eligible who *attended* session 5 and dropped	0	0
# eligible who *attended* session 6 and dropped	1	0
# eligible who *attended* session 7 and dropped	0	0
# eligible who *attended* session 8 and dropped	0	0
# eligible who *attended* session 9 and dropped	0	0
# eligible who *attended* session 10 and dropped	0	0
# eligible who *attended* session 11 and dropped	0	0
# eligible who *attended* session 12 and dropped	1	0
# eligible who *attended* session 13 and dropped	0	0
# successfully completed entire study (all sessions + 25 week)	4	8

***** TP refers to Tender Point exam.

Note. An additional 1 person completed TP exam and baseline assessment, but dropped out prior to random assignment

a. Total number of inquiries were calculated as follows:
   # from website: 90
   # from Clinical Connections: 27
   # from Newspaper: 8
   # from Word of Mouth: 7
   # from Flyers at Drs office: 14
   # from FMS support group (meet-up): 5
   # from Craigslist: 3
   # from unknown (person left voicemail and unable to reach to ask): 1
   Total # of inquiries: 155

Table 11. Summary of TSK and PASS-20 scores during eligibility screening

Statistics	TSK (Cut-off 40)			PASS-20 (Cuff-off 55)		
	Exposure	Education	Entire Sample	Exposure	Education	Entire Sample
Mean (SD)	47.39 (5.30)	48 (5.90)	47.53 (5.37)	64.94 (10.58)	64.73 (13.67)	65.10 (11.48)
Median	47.50	47	47	62	62	62.50
Min-Max	40-58	37-59	37-59	49-80	36-87	36-87
% Surpassed Cut-off (#)	100% (18)	90.91% (10)	96.67% (29)	77.78% (14)	90.91% (10)	83.34% (25)
Total N	18	11	30	18	11	30

Table 12. Summary of TSK scores during eligibility screening for intervention completers and dropouts

Statistics	Exposure Completers	Exposure Dropouts	Education Completers	Education Dropouts
Mean (SD)	51 (7.26)	46.36 (4.41)	46.63 (5.07)	51.67 (7.51)
Median	52.50	47	47	52
Min-Max	41-58	40-52	37-53	44-59
% Surpassed Cut-off (#)	100% (4)	100% (14)	87.5% (7)	100% (3)
Total N	4	14	8	3

Table 13. Summary of PASS-20 scores during eligibility screening for intervention completers and dropouts

Statistics	Exposure Completers	Exposure Dropouts	Education Completers	Education Dropouts
Mean (SD)	64.25 (11.15)	65.14 (10.83)	63.63 (13.38)	67.67 (17.01)
Median	61.50	62.50	64	61
Min-Max	54-80	49-79	36-77	55-87
% Surpassed Cut-off (#)	75% (3)	78.57% (11)	87.5% (7)	100% (3)
Total N	4	14	8	3

Table 14. Percentage of participants who met entry criterion on the TSK, PASS-20, or both

Measures	Exposure Completers n=4	Exposure Dropouts n = 14	Education Completers n = 8	Education Dropouts n = 3
TSK	25%	21.43%	12.50%	0
PASS-20	0	0	12.50%	0
Both	75%	78.57%	75%	100%

After meeting initial phone screening eligibility criteria, seven people (12.50%) lost contact with study personnel and did not complete the second-stage screening (i.e., manual tender point survey). The remaining 30 individuals completed the manual tender point survey and were found to be eligible for participation. One individual withdrew his participation from the study following the tender point examination, citing travel difficulties, and was not randomized to an intervention condition. Ultimately, 29 participants were randomized into either the exposure condition (n = 18) or the education condition (n = 11).

Design and procedures: Randomization. To establish the feasibility and acceptability of randomization procedures, 90% of eligible participants had to agree to participate in the randomization procedures.

Criterion 1: 90% of eligible participants agreed to participate in the randomization procedure. **This criterion was met** because 96.67% (n = 29; 95% CI: 90.25 to 103.09%) of the eligible participants agreed to participate in the randomization procedures. It should be noted that the participant who did not participate in the randomization procedures declined further participation in the study because of stated concerns related to the distance he lived from the study site and not because of the randomization procedures. In addition, two participants (6.9%) dropped out of the study after randomization procedures but before the first intervention session. Dropping out prior to intervention participation may also be indicative of issues related to acceptability of the randomization procedures or of the outcome of intervention assignment.

Design and procedures: Assessment Measures. The level of feasibility and acceptability of the survey measures used in this pilot trial were determined by examining

questionnaire and item response rates for abnormal response patterns (i.e., missing responses, double item responding, write-in responses) within each questionnaire at each assessment time point. The following two criteria were set: 1) 80% questionnaire completion rate, and 2) 90% item completion rate.

Criterion 1: 80% questionnaire completion rate. One hundred percent of participants completed the full questionnaire packages that were provided to them at each time point. **As such, this criterion was met.**

Criterion 2: 90% questionnaire item completion rate. Each questionnaire was examined for the percentage of items completed by participants. In addition, completed questionnaires were examined for instances of missing responses, double item responding, and write-in responses (i.e., writing in a response that is not one of the provided options). All participants completed the following surveys in their entirety at all assessment time points: TSK, FIQ-R, PCS, ASES, FABQ, and the SAPAS.

For the remaining questionnaires, Tables 15 and 16 provide more detailed information regarding the response rates at each assessment time point and the response patterns. It should be noted that one participant (participant 25) left items blank on multiple questionnaires and contributed to a large portion of the missing items. On the **PASS-20**, each participant completed at least 95% of all items (i.e., 19/20 or greater) and all items were completed correctly (i.e., only one item circled). Only three items were missing, and there was no overlap in the item that was not completed by the three participants (see Table 16). On the **SOPA**, participants completed at least 93.33% of all items (i.e., 28/30 or greater). There was no overlap in the item that was not completed by the two participants who missed an item. There was one participant who responded to an

item with multiple responses circled. On the **PHQ-9**, participants completed at least 90% of all items (i.e., 9/10 or greater). Of those who completed nine of the ten items, all missed the final item on the measure that was presented at the bottom of the page and was answered in a different format than the previous nine items. This consistent finding suggests that there might be questionnaire design issues that reduce the likelihood of full questionnaire completion. On the **POAM-P,** participants completed at least 96.7% of items (i.e., 29/30 or greater). There were no items that were consistently left blank.

On the **mid-intervention program evaluation**, participants completed a minimum of 89.5% of the rating-scale items (i.e., 17/19 or greater). The three participants who left items blank reported that item 10c was not applicable to them by either including 'n/a' or '?' in the margin next to the item. This item asked participants to evaluate "role playing" within the program. Each of those participants was assigned to the education intervention, which does not incorporate role-play into the sessions. Two of the three participants also indicated that 10b was not applicable. This item asked participants to evaluate "exercises." Again, the two participants were assigned to the education intervention. Although there were sessions that incorporated interactive discussions and other sessions that incorporated at-home assignments, this was not a regular component of the education intervention. It should be noted that one of the participants who rated 10b to be not applicable also left this response blank at the **post-intervention assessment** (94.7% questionnaire completion rate; 18/19 items or greater).

On the **program evaluation** completed by dropout participants, various item options were left blank. Overall, participants completed at least 84.2% (16/19 or greater) of the items. As shown in Table 16, two participants left 10c and 10e blank, one left 10b

blank, and one left 10d blank. Question 10 asked participants to rate the following on a scale from 0 (not helpful) to 5 (very helpful): b) exercises, c) role-play, d) interactions, and e) facilitator communications. Each of these participants completed either two to three sessions prior to withdrawing from the interventions.

Table 15. Questionnaire item response rates at each assessment

Survey	Baseline %				Mid-Intervention %				Post-Intervention %				Follow up %			
	N	Min-Max	M	Mdn	N	Min-Max	M	Mdn	N	Min-Max	M	Mdn	N	Min-Max	M	Mdn
TSK	30	100-100	100	100	14	100-100	100	100	12	100-100	100	100	21	100-100	100	100
PASS-20	30	100-100	100	100	14	95-100	99.3	100	12	100-100	100	100	21	95-100	99.5	100
FIQ-R	30	100-100	100	100	14	100-100	100	100	12	100-100	100	100	21	100-100	100	100
PCS	30	100-100	100	100	14	100-100	100	100	12	100-100	100	100	21	100-100	100	100
ASES	30	100-100	100	100	14	100-100	100	100	12	100-100	100	100	21	100-100	100	100
SOPA	30	93.3-100	99.7	100	14	100-100	100	100	12	100-100	100	100	21	100-100	100	100
PHQ-9	30	90-100	99.3	100	14	90-100	97.9	100	12	90-100	98.3	100	21	90-100	99	100
FABQ	23[a]	100-100	100	100	14	100-100	100	100	12	100-100	100	100	21	100-100	100	100
Program Eval	--	--	--	--	14	89.5-100	98.1	100	12	94.7-100	99.6	100	9[b]	84.2-100	96.5	100
POAMP	--	--	--	--	--	--	--	--	--	--	--	--	20[c]	96.7-100	99.5	100
SAPAS	--	--	--	--	--	--	--	--	--	--	--	--	20[c]	100-100	100	100

Note. Min-Max refers to the smallest and largest percentage of items completed; M refers to Mean percentage; Mdn refers to the median percentage.

a. This survey was added later in the study, and was not administered to a subset of early-entry participants.

b. This survey was designed to be completed by intervention dropout participants.

Table 16. Description of abnormal response patterns on questionnaires

Participant ID	# missing responses (item number)	# items with multiple responses (item number)	# items with in-between responses (item number)
PASS-20			
14	1 (15)	0	0
16	1 (7)	0	0
25	1 (9)	0	0
SOPA			
09	2 (6, 14)	0	0
21	1 (4)	0	0
29	0	1 (27)	0
PHQ-9			
06	1 (10)	0	0
25	1 (10)	0	0
27	1 (10)	0	0
33	1 (10)	0	0
42	1 (10)	0	0
6-week Program Evaluation			
06	2 (10b, 10c)	0	0
25	2 (10b, 10c)	0	0
30	1 (10c)	0	0
Post Program Evaluation			
25	1 (10b)	0	0
Dropout Evaluation			
09	1 (10b)	0	0
13	2 (10c, 10e)	0	0
16		1 (5)	0
32	3 (10c, 10d, 10e)	0	0
POAM-P			
14	1 (6)	0	0
35	1 (25)	0	0
42	1 (13)	0	0

Design and procedures: Co-intervention. In order to explore the presence of co-interventions targeting anxiety and FMS symptoms (i.e., pain, fatigue/sleep disturbance, mood disturbance), pharmacotherapy information was collected for participants. At the outset of the study, participants in the exposure condition (n = 18) were prescribed an average of 5.33 medications for various mood and FMS symptoms (median = 5, SD = 3.46, range =12). Over the course of the intervention, medications changes were common. Of the participants who completed the final medication assessment, 71.4% of those who withdrew and 75% of those who completed the intervention had changed

either their prescribed medications or dosage over the course of the study. At the final assessment, participants who completed the exposure intervention (n = 4) were taking an average of 5.75 medications (median = 5.50, SD = 3.30, range = 8), and those who withdrew (n = 6) were taking an average of 6.50 medications (median = 7, SD = 4.14, range = 12). The participants who withdrew from the exposure intervention were prescribed more medications than those who completed the intervention.

At baseline, participants in the education condition (n = 11) were prescribed an average of 3.18 medications (median = 3, SD = 2.04, range = 6). Of the participants who completed the final medication assessment, 50% had changes made to their medication regimen (e.g., discontinuation, new medication, change of dosage) over the course of the study. At the final assessment period, education intervention completers (n = 8) were taking an average of 3.13 medication (median = 3, SD = 1.81, range = 5) and dropout participants (n = 2) were taking an average of 3.50 medications (median = 3.50, SD = 3.54, range = 5). On average, there were fewer medications being prescribed to participants in the education condition than in the exposure condition. However, an independent samples t-test indicated that this difference from the outset of the study was not statistically significant, $t(27) = 1.86$, $p = .07$. Tables 17 to 20 provide descriptive summaries of the prescription patterns for each intervention condition.

As shown in Tables 17 and 18, at baseline, the majority of participants in both intervention conditions were not actively receiving pharmacological treatment for anxiety symptoms, which was directly targeted in the exposure intervention. There were no notable reported changes to the prescription of anxiety medications over the course of the study. Close to half of the participants in each intervention condition reported being

prescribed medications for depressive symptoms, with the largest proportion of participants receiving serotonin-norepinephrine reuptake inhibitors (SNRIs), followed by selective serotonin reuptake inhibitors (SSRIs). With regards to pain management, approximately 27% of participants in each intervention condition reported that they were not actively receiving pharmacological treatment. In the exposure condition, the majority of participants were taking between two and three medications for pain management, with the highest number of medications being six. Conversely, in the education condition, the majority of participants were prescribed between one and two medications, with the highest number of pain medications being three.

As derived from Table 19, of the 72.2% of participants in the exposure intervention who were prescribed at least one pain medication, only 13.5% were prescribed medications that were FDA-approved for FMS treatment. Narcotic analgesic medications were the most commonly prescribed (35.14%). In the education condition, none of the participants were prescribed FDA-approved pain medications. Similar to the exposure condition, narcotic analgesics were the most commonly prescribed medications (33.33%).

Nearly half of the participants in the exposure condition reported being prescribed medications targeting sleep symptoms at the start of the study. It should be noted that one third of participants reported that they were prescribed benzodiazepines, which is in contrast to 9% of participants in the education condition. Fatigue was not directly addressed in the context of the exposure intervention; however, it should be noted that participants frequently cited this symptom as a reason for behavioral avoidance over the course of the intervention.

Table 17. Descriptive summary of active medications at baseline for each intervention condition

Medication Type/Class	Exposure Condition Baseline- % (#) participants N= 18	Education Condition Baseline- % (#) participants N = 11
Anxiety		
SSRI	5.56 (1)	0
TCA	0	0
Benzodiazepine	5.56 (1)	9.09 (1)
MAOI	0	0
Other	5.56 (1)	0
None	83.33 (15)	90.91 (10)
Mood/Depression		
SSRI	16.67 (3)	18.19 (2)
SNRI	33.33 (6)	27.27 (3)
TCA	0	9.09 (1)
Other	11.11 (2)	9.09 (1)
None	55.56 (10)	45.45 (5)
Sleep		
Benzodiazepine	33.33 (6)	9.09 (1)
Opiates	0	0
Non-Benzo Hypnotics	11.11 (2)	18.19 (2)
Other	11.11 (2)	9.09 (1)
None	55.56 (10)	63.64 (7)

Table 18. Summary of number of active medications at baseline for each intervention condition

Medications	Amount	Exposure %(N)	Education %(N)
Baseline		N =18	N=11
Total Medications	0	11.11% (2)	0
	1-2	16.67% (3)	45.45% (5)
	3-4	11.11% (2)	36.36% (4)
	5-6	22.22% (4)	9.09% (1)
	7-9	27.28% (5)	9.09% (1)
	10+	11.11% (2)	0
Anxiety	0	83.33% (15)	90.91% (10)
	1	16.67% (3)	9.09% (1)
Depression/Mood	0	72.22% (13)	81.82% (9)
	1	22.22% (4)	9.09% (1)
	2	5.56% (1)	9.09% (1)
Pain	0	27.78% (5)	27.27% (3)
	1	11.11% (2)	36.36% (4)
	2	16.67% (3)	27.27% (3)
	3	33.33% (6)	9.09% (1)
	4	0	0
	5	5.56% (1)	0
	6	5.56% (1)	0
Sleep	0	55.56% (10)	63.64% (7)
	1	33.33% (6)	36.36% (4)
	2	11.11% (2)	0

Table 19. Summary of active pain medications and dosage at baseline stratified by intervention condition

	Exposure Condition		Education Condition	
Pain Medications	**Number of Participants**	**Dosage**	**Number of Participants**	**Dosage**
Narcotic Analgesics				
Vicodin	3	10mg – 500mg	0	
Morphine	2	30mg – 60mg	0	
Percocet	1	Unknown	0	
Hydromorphone	1	Unknown	0	
Tramadol	3	50mg – 100mg	1	50mg
Methadone	1	10mg	0	
Oxycodone	1	30mg	2	15mg – 325mg
Fentanyl	1	150mcg	1	50mcg
Antidepressants				
Fluoxetine	1	20mg	0	
Amytriptyline	0		1	10mg
Duloxetine (Cymbalta)	3	30mg – 60mg	0	
Muscle Relaxants				
Carisoprodol (Soma)	1	350 mg	1	350mg
Cyclobenzaprine	2	10mg – 15mg	1	12.5mg
Methocarbamol (Robaxin)	4	500mg – 750mg	0	
Nonsteroidal Anti-Inflammatory Drug (NSAID)				
Celecoxib	0		1	200mg
Naproxen	1	500 mg	0	
Benzodiazepine				
Diazepam (Valium)	1	7mg	0	
Alprazolam (Xanax)	2	.05mg – 1mg	0	
Anticonvulsant				
Gabapentin	3	300mg – 600 mg	2	300mg – 600mg
Topiramate	1	50 mg	0	
Pregabalin	2	75mg – 150mg	0	
Atypical Antipsychotic				
Quetiapine (Seroquel)	1	10mg	0	
Serotonin Receptor Agonists (Migraine)				
Rizartriptan	1	10mg	0	
Sumatriptan	0		1	50mg
Zolmitriptan	1	5mg	0	
Other				
Propranalol (Beta Blocker)	0	0	1	10mg
None	5 (27.78%)		3 (27.27%)	

Table 20. Summary of number of active medications at post-intervention stratified by intervention condition

Medication Type/Class	Exposure Condition		Education Condition	
	Post- % (N) Completers Total N= 4	Post- % (N) Dropouts Total N = 6	Post- % (N) participants Total N = 8	Post- % (N) participants Total N = 2
Total Number of Medications				
0	0	16.67% (1)	12.50% (1)	0
1-2	25% (1)	0	25% (2)	50% (1)
3-4	0	16.67% (1)	37.50% (3)	0
5-6	50% (2)	0	25% (2)	50% (1)
7-9	0	50% (3)	0	0
10+	25% (1)	16.67% (1)	0	0
Anxiety				
0	50% (2)	100% (6)	87.50% (7)	50% (1)
1	50% (2)	0	12.50% (1)	50% (1)
Mood/Depression				
0	50% (2)	50% (3)	50% (4)	50% (1)
1	25% (1)	16.67% (1)	37.50% (3)	50% (1)
2	25% (1)	33.33% (2)	12.50% (1)	0
Pain				
0	0	16.67% (1)	50% (4)	0
1	25% (1)	0	12.50% (1)	50% (1)
2	0	50% (3)	12.50% (1)	0
3	50% (2)	16.67% (1)	25% (2)	50% (1)
4	35% (1)	0	0	0
5	0	16.67% (1)	0	0
Sleep				
0	50% (2)	50% (3)	62.5% (5)	100% (2)
1	25% (1)	33.33% (2)	25% (2)	0
2	25% (1)	16.67% (1)	12.50% (1)	0

Feasibility and Acceptability of the Interventions

The exposure and education interventions were examined for their feasibility and acceptability through comparing the extent to which the established protocol was successfully implemented and through exploration of the treatment trends.

Intervention: Adherence and attrition. Attendance and attrition data were examined to determine whether the following feasibility criteria were met: 1) 60% of randomized participants completed the intervention; 2) 70% completed four or more sessions [i.e., complete 1+ behavioral experiments]; 3) 50% completed the intervention

within 17 weeks; and 4) 70% of assigned at-home behavioral experiments were completed.

Criterion 1: 60% of randomized participants completed the intervention. When examining the overall sample, 29 participants were randomly assigned to participate in an intervention, and 41.39% (n = 12) of these individuals completed the intervention portion of the study. Of the 18 participants assigned to the exposure intervention condition, four participants (22.22%) completed the full intervention protocol. It should be noted that 55.56% (n = 10) of participants in the exposure intervention withdrew from the intervention prior to engaging in an in-session behavioral experiment. None of the participants reported that engagement in exposures was the reason for their withdrawal; instead, the most commonly cited reasons were health and wellbeing issues. Specifically, participants' own illness, illness of family members, and mental health concerns were reported. Table 21 provides the reasons participants gave for withdrawing from both intervention conditions. **For the exposure intervention condition, the first criterion was not met and suggests significant challenges in retaining participants**.

Of the four exposure intervention completers, two completed the intervention in the standard 13 sessions, one participant completed the intervention in nine sessions, and one participant completed the intervention in 14 sessions. The participant who completed the intervention in nine sessions (participant 18) reported significant decreases in overall fear avoidance and after attempts to engage the participant in additional activity selection for exposures, the decision was made to deliver the final session content at that time. For another participant (participant 33), an additional session was added to the intervention in order to provide assistance with more accurately rating his subjective units of distress

(SUDS). Over the course of the intervention, the participant only provided extreme SUDS ratings (10 or 1). Dr. Jacobson and the interventionist (M.D.) developed a worksheet to assist the participant in developing more accurate representations of his SUDS (See Appendix D). These findings suggest that the intervention was not consistently delivered as originally designed.

A total of 11 participants were randomly assigned to participate in the education intervention, and 72.73% (n = 8) of these individuals completed the full intervention in the planned 13 sessions. It should be noted that there were three participants who had two sessions delivered within the same appointment in order to ensure that they were able to complete the intervention prior to an interventionist leaving the study or the participant leaving the city. One of these participants received one double-session appointment, another received two, and the third participant received three. There were also three participants who withdrew from the intervention, and these individuals dropped out within the first three sessions. The two participants in the education condition who reported a reason for withdrawal stated that the time commitment was the reason. **The criterion for feasibility of attrition was met for the education intervention condition**.

Table 21. Frequency of stated reasons for withdrawal across each of the intervention conditions

Reasons for withdrawal	Exposure %(N)	Education %(N)
Transportation/Distance	7.1 (1)	0
Family Reasons	14.3 (2)	0
Health and Wellbeing	42.9 (6)	0
Intervention or Interventionist	14.3 (2)	0
Time Commitment	0	66.7 (2)
Loss of Interest	7.1 (1)	0
Unreported	14.3 (2)	33.3 (1)
Total N	14	3

Criterion 2: 70% completed 4 + sessions. This criterion was established to ensure that participants in the study were likely to engage in at least one in-vivo exposure. In the exposure condition, only 39.1% (N = 7) of the participants completed a minimum of four sessions and participated in at least one in-session exposure. **These findings show that criterion two was not successfully met**. Table 22 outlines the percentage and number of sessions completed for each of the intervention conditions.

Table 22. Percentage and number of intervention sessions completed in each intervention condition

Completed Sessions	Exposure %(N)	Education %(N)
0	5.6 (1)	9.1 (1)
1	16.7 (3)	0
2	33.3 (6)	9.1 (1)
3	5.6 (1)	9.1 (1)
4	5.6 (1)	0
5	0	0
6	5.6 (1)	0
7	0	0
8	0	0
9	5.6[a] (1*)	0
10	0	0
11	5.6 (1*)	0
12	0	0
13	11.1 (2*)	72.7 (8*)
14	5.6 (1)	0
Total N	18	11
M[b] (SD)	4.94 (4.89)	9.91 (5.34)
Median	2	13

Note. Asterisks denote participants who completed the full intervention.
a. This participant completed the intervention in nine sessions and was not considered a dropout.
b. M refers to the mean number of sessions completed within each intervention condition.

Criterion 3: 50% of participants completed the intervention within 17 weeks. Both interventions were designed to be delivered in 13 weekly sessions. In order to maximize the treatment effects, it was expected that participants would complete all sessions within a 17-week period. This criterion was designed to account for illness,

holidays, and other common treatment barriers. In the exposure intervention condition, it took session completers an average of 18.75 weeks (median = 19, SD = 2.87) to complete the intervention. Only one of the four participants completed the intervention in less than 17 weeks and that participant completed the intervention in nine sessions. The remaining three participants (75%) completed the intervention within 19 to 22 weeks. In the education intervention, it took participants an average of 16.88 weeks (Median = 17.50, SD = 2.85) to complete the intervention. In both conditions, the time delays in completing the intervention were related to holidays, participant illness, and worsened fibromyalgia symptoms. Tables 23 and 24 displays the number of sessions, number of weeks to complete the intervention, and number of participant absences for each intervention condition. **This criterion was met for the education condition, but not for the exposure condition.**

Table 23. Weeks to complete all sessions within the exposure condition

Participant ID	Total # Sessions	Total # Weeks	Total # Absences
18	9	15	6
24	13	19	6
33	14	22	8
34	13	19	6
M (SD)	12.25 (2.22)	18.75 (2.87)	6.5 (1)

Table 24. Weeks to complete all sessions within the education condition

Participant ID	Total # Sessions	Total # Weeks	Total # Absences
01	13	17	4
04	13	14	3
06	13	12	2
25	13	21	8
28	13	19	6
30	13	18	7
38	13	18	5
42	13	16	3
M (SD)	13 (0)	16.88 (2.85)	4.75 (2.12)

Criterion 4: 70% of assigned at-home behavioral experiments were completed.

Of participants who received the exposure intervention, the percentage of homework completed ranged from 0%[2] to 100%, with participants completing an average of 70.34% (SD = 38.20) of the at-home exposures. It should be noted that the average percentage of assigned homework completed by those who attended four or more sessions was 82.06% (SD = 24.43). As can be seen in Table 25, participants varied in the number of at-home exposures that were assigned to them and the number that were completed in this individualized intervention. Reported reasons for non-completion were: cold/flu-like symptoms, lack of energy, low motivation, and no anticipatory anxiety experienced prior to planned exposure. **Based on the average participant's homework completion, it is reasonable to assert that criterion 4 was met**.

[2] This represents one participant who withdrew from the intervention immediately following the session in which the homework was assigned.

Table 25. At-home exposures assigned to and completed by participants

Participant ID	# Sessions Completed	# Assigned	# Completed	% Completed
02	1	N/A	N/A	N/A
07	0	N/A	N/A	N/A
09	2	N/A	N/A	N/A
11	2	N/A	N/A	N/A
13	2	N/A	N/A	N/A
14	4	1	1	100%
17	2	N/A	N/A	N/A
18	9[a]	3	2	66.67%
19	12	5	2	40%
21	3	1	0	0%
24	13	7	6	85.71%
27	2	N/A	N/A	N/A
31	6	0	0	N/A
33	14[b]	6	6	100%
34	13	5	5	100%
35	1	N/A	N/A	N/A
36	1	N/A	N/A	N/A
39	2	N/A	N/A	N/A

N/A = no behavioral experiments were performed in the first two sessions as per protocol

a. Participant completed intervention in 9 sessions

b. Participant completed intervention with the inclusion of an additional session.

Intervention: Session Durations. The exposure intervention was designed to be delivered in 12 weekly, 60-minute sessions following an initial 90-minute session. Trained undergraduate research assistants listened to the audio recordings of sessions and recorded the overall length of the each session, as well as the amount of time the active intervention was delivered within each session. Each audio recording was reviewed by two of the three research assistants. There was high inter-rater reliability for the recorded length of each session as evidenced by high intraclass correlations (Raters 1 and 2 ICC = .992 [95% CI: .986, .996], Raters 1 and 3 ICC = .995 [95% CI: .992, .997], Raters 2 and 3 ICC = 1 [95% CI: 1, 1]). There was also high inter-rater reliability for the reported duration of time spent delivering the intervention material within the sessions (Raters 1 and 2 ICC = .997 [95% CI: .995, .998], Raters 1 and 3 ICC = .989 [95% CI: .981, 994], Raters 2 and 3 ICC = .991 [95% CI: .985, .995]). Any discrepancies in time between

raters were resolved by either re-listening to the audio recording together to agree on a final estimated start and finish time (i.e., when the individually-recorded difference was greater than 5 seconds) or by deferring to the more conservative estimate (i.e., when the difference was less than 5 seconds).

An examination of session length for each condition revealed that the average length of the initial exposure intervention session was 1 hour and 30 minutes (SD = 11 min, range = 38 min), and the average amount of time delivering the active intervention within that session was 1 hour and 27 minutes (SD = 12 min, range = 39 min). In the education condition, the average length of the first session was 47 minutes (SD = 12 min, range = 29 min) and the average time spent delivering the intervention material was 45 minutes (SD = 10 min, range = 29 min). These data suggest that there was a notable discrepancy between the planned length of time for the initial session and the actual length of the session in the education condition. This also translates to a 43-minute mean difference between the two intervention conditions.

The remaining sessions were each designed to be delivered in 60 minutes. In the exposure condition, the sessions lasted an average of 59 minutes (SD = 10 min, range = 53 min); the active intervention within the sessions lasted for an average of 57 minutes (SD = 10 min, range = 52 min). In the education condition, the sessions lasted an average of 46 minutes (SD = 12 min, range = 1hr 11 min); the active intervention within the sessions lasted for an average of 44 minutes (SD = 12 min, range = 1hr 11 min). Table 26 breaks down the mean length of each session and Table 27 provides the average length of sessions delivered by each of the three education interventionists. In the education condition, the majority of the sessions were delivered in a shorter duration than designed;

whereas the exposure condition was largely delivered within the expected time frame. This highlights a discrepancy between the amount of attention and time spent with participants within the two intervention conditions. As can be seen in Table 27, there was a discrepancy in intervention delivery time among the education interventionists, with interventionists 2 and 3 showing larger differences in the amount of time spent engaging with participants.

Table 26. Length of each session and time spent delivering the active intervention in each session

Session	Exposure Condition		Education Condition	
	Session Duration M(SD)	Intervention Duration M(SD)	Session Duration M(SD)	Intervention Duration M(SD)
1[a]	1hr 30m (11m)	1hr 27m (12m)	47m (12m)	45m (10m)
2	1hr 2m (6m)	1hr (6m)	45m (21m)	44m (22m)
3	1hr 6m (13m)	1hr 5m (13m)	51m (9m)	49m (9m)
4	58m (7m)	57m (8m)	49m (9m)	45m (11m)
5	57m (7m)	56m (7m)	45m (4m)	44m (4m)
6	52m (12m)	50m (10m)	41m (7m)	39m (8m)
7	55m (8m)	54m (8m)	51m (7m)	49m (7m)
8	1hr 5m (4m)	1hr 4m (4m)	50m (12m)	45m (12m)
9	1hr 3m (8m)	1hr 2m (8m)	39m (10m)	38m (10m)
10	51m (15m)	49m (14m)	37m (12m)	36m (12m)
11	58m (3m)	56m (5m)	45m (14m)	43m (11m)
12	53m (16m)	50m (14m)	52m (17m)	51m (16m)
13	58m (6m)	56m (5m)	44m (10m)	42m (11m)

Note. Length of time is recorded in hours (hr) and minutes (m)
a. This session was designed to be 90-minutes in length. All other sessions were designed to be 60 minutes in length.

Table 27. Length of each session and time spent delivering the active intervention in each session across education interventionists

Interventionist	Duration of First Session M(SD)	Intervention Duration of First Session M(SD)	Duration of Remaining Sessions M (SD)	Intervention Duration of Remaining Sessions M(SD)
1	40m *	39m *	52m (7m)	48m(9m)
2	1hr3m *	1hr3m *	1h01m (14m)	59m(14m)
3	45m (11m)	43m(7m)	40m (7m)	39m(7m)

* Only one audio recording for the initial session was located for an intake session with these interventionists.

Intervention: participant satisfaction. Participant satisfaction was examined to determine whether the following feasibility criteria were met: 1) 80% of participants rating satisfaction as "mostly" to "completely;" and 2) 80% of participants rating "likely" to "yes" for recommending the program to a friend.

Criterion 1: 80% of participants rate satisfaction as "mostly" to "completely." Participants completed program evaluations 6 weeks into their engagement in the intervention and again at their post-intervention assessment. Participants who withdrew from the intervention were invited back to complete a program evaluation on a separate occasion. When examining the sample as a whole at the 6-week assessment, 28.6% (n = 4) rated that they were "mostly satisfied" with the program and 71.4% (n = 10) rated that they were "completely satisfied." Following the final intervention session, 41.7% (n = 5) of the participants who completed the intervention rated that they were "mostly satisfied" and 50% (n = 6) reported being "completely satisfied" with the program. This finding suggests that 100% of the sample that completed the interventions were "mostly" or "completely" satisfied with the overall program. Of those who dropped out of the study but completed a post-withdrawal evaluation, 55.6% (n = 5) reported being "mostly satisfied" and the remaining 44.4% (n = 4) responded with "no opinion." Table 28 provides the mode satisfaction ratings across intervention conditions and within the entire sample, and Table 29 provides the mean ratings with associated confidence intervals.

Table 28. Descriptive statistics for the program satisfaction ratings

	Exposure Condition Mode (N)	Education Condition Mode (N)	Entire Sample Mode (N)
Mid-intervention Eval	5 (6)	5 (8)	5 (14)
Post-intervention Eval	4, 5[a] (4)	5 (8)	5 (12)
Drop-out Eval	3 (7)	4 (2)	4 (9)

Note: rating scale is 1 (not at all satisfied), 2 (somewhat unsatisfied), 3 (no opinion), 4 (mostly satisfied), 5 (completely satisfied)

a. This was a bi-modal distribution

Table 29. Mean ratings of participant satisfaction with associated standard deviation (SD) and confidence intervals (CI)

	Mid-Intervention Evaluation				Final Assessment				Drop-out Assessment			
	M (SD)	**95% CI**	**90% CI**	**80% CI**	**M (SD)**	**95% CI**	**90% CI**	**80% CI**	**M (SD)**	**95% CI**	**90% CI**	**80% CI**
Exposure	4.83 (0.41)	4.40, 5.26	4.50, 5.17	4.59, 5.08	4.50 (0.58)	3.58, 5.42	3.82, 5.18	4.03, 4.97	3.43 (0.54)	2.93, 3.92	3.04, 3.82	3.14, 3.72
Education	4.63 (0.52)	4.19, 5.06	4.28, 4.97	4.37, 4.88	4.38 (0.74)	3.75, 5	3.88, 4.87	4, 4.75	4 (0)	--[a]	--	--
Overall	4.71 (0.47)	4.44, 4.98	4.49, 4.94	4.55, 4.88	4.42 (0.67)	3.99, 4.84	4.07, 4.76	4.15, 4.68	3.56 (0.53)	3.15, 3.96	3.23, 3.88	3.31, 3.80

a. No CIs were calculated; all participants (n = 2) provided a rating of 4.

When examining the responses from participants in the exposure condition at the 6-week evaluation, 16.7% (n = 1) reported being "mostly satisfied" with the program and 83.3% (n = 5) reported being "completely satisfied." At the final assessment, 50% (n = 2) rated being "mostly satisfied" with the program and 50% rated being "completely satisfied" with the program. Of the four participants who completed both the 6-week and post-intervention evaluations, two reported that they were "completely satisfied" at both time points and two changed their ratings from "completely satisfied" at the mid-intervention point to "mostly satisfied" at the final assessment. Of those who withdrew from the intervention and who completed the final evaluation, 42.9% (n = 3) reported having been "mostly satisfied" with the intervention, with the remaining 57.1% (n = 4) responding with "no opinion." Table 30 provides more detailed information regarding program evaluations from the participants who provided the "no opinion" response.

Combining the final evaluations of all exposure participants (completers and dropouts), a total of 36.36% (n = 4) reported "no opinion" on their level of satisfaction, and 63.64% (n = 7) reported being either "mostly satisfied" (45.45%, n = 5) or "completely satisfied' (18.18%, n = 2). Data across assessment times suggest that participants were satisfied with the exposure intervention, even though it could be perceived as aversive because it directly targets avoidance behaviors and anxiety. **Based on the combined ratings of participants in the exposure condition (completers and dropouts), the 80% criterion was not met; however, if only the study completers were considered, the criterion was met.**

Table 30. Comments of dropouts on the program evaluation in the exposure condition who reported, "no opinion" for their level of satisfaction with the program

Participant ID	# Sessions Completed	Reported Withdrawal Reason	Aspects Liked About Intervention	Aspects Disliked About Intervention
13	2	Family health	The purpose of the intervention	None reported
14	4	Family health	The interventionist	None reported
31	6	Own health	None reported	Pace was slow
35	1	Intervention not good fit for her needs	"N/A"	Could not select Education condition

When examining responses within the education condition at the 6-week evaluation, 37.5% (n = 3) of participants rated that they were "mostly satisfied" and 62.5% (n = 5) rated that they were "completely satisfied" with the intervention. After the final education session, 37.5% (n = 3) participants rated that they were "mostly satisfied" and 50% (n = 4) rated that they were "completely satisfied" with the intervention, and the remaining 12.5% (n = 1) responded with "no opinion." Of the eight participants who completed both the mid-intervention evaluation and the post-intervention evaluation, three participants maintained their rating of "completely satisfied," two maintained their ratings of "mostly satisfied," one participant changed from "mostly" to "completely satisfied," and two changed from "completely" to "mostly satisfied." Of those who withdrew their participation from the intervention and completed an evaluation, 100% (n = 2) reported that they were "mostly satisfied" with the intervention. Combining the evaluations of all education participants' final ratings of their satisfaction of the intervention (completers and dropouts), 10% (n = 1) reported "no opinion" and 90% (n = 9) reported being either "mostly satisfied" (50%, n = 5) or "completely satisfied' (40%, n = 4). **Based on these findings, there is strong indication that participants were satisfied with the education intervention and the criterion was met.**

Criterion 2: 80% of participants rated "likely" to "yes" for recommending the program to a friend. When examining the sample as a whole at the 6-week assessment, 100% stated that "yes" they would recommend the program or that they would be "likely" to recommend the program to a friend. Specifically, 14.3% (n = 2) reported that they would "likely" recommend the program to a friend and 85.7% (n = 12) reported that they would definitely recommend this program to a friend. At the end of the intervention, 91.3% (n = 11) of the entire sample reported they would definitely or likely recommend the program to a friend. Specifically, 83.3% (n = 10) reported they would recommend the program to a friend, 8.3% (n = 1) stated they would be "likely" to recommend, and the remaining 8.3% (n = 1) indicated that "maybe" they would recommend. In addition, 66.7% of participants who withdrew from the interventions reported that they would recommend (55.6%, n = 5) or would be likely (3.3%, n = 1) to recommend the program to a friend. The remaining 33.3% reported that "maybe" (6.7%, n = 2) they would recommend the program or that they would "not likely" recommend the program to a friend (3.3%, n = 1). Table 31 provides the mode ratings across intervention conditions and the entire sample, and Table 32 provides the mean ratings with associated confidence intervals.

Table 31. Descriptive statistics for the reported likelihood of recommending the intervention to a friend

	Entire Sample Mode (N)	Exposure Condition Mode (N)	Education Condition Mode (N)
Mid-intervention Eval	5 (14)	5 (6)	5 (8)
Post-intervention Eval	5 (12)	5 (4)	5 (8)
Drop-out Eval	5 (9)	5 (7)	3, 5[a] (2)

Note: rating scale is 1 (No), 2 (Not Likely), 3 (Maybe), 4 (Likely), 5 (Yes)
a. This was a bimodal distribution

Table 32. Mean ratings of the likelihood of recommending the intervention to a friend with associated standard deviation (SD) and confidence intervals (CI)

	Mid-Intervention Evaluation				Final Assessment				Drop-out Assessment			
	M (SD)	95% CI	90% CI	80% CI	M (SD)	95% CI	90% CI	80% CI	M (SD)	95% CI	90% CI	80% CI
Exposure	4.83 (0.41)	4.40, 5.26	4.50, 5.17	4.59, 5.08	5 (0)	--[a]	--	--	4.14 (1.22)	3.02, 5.27	3.25, 5.04	3.48, 4.80
Education	4.88 (0.35)	4.58, 5.17	4.64, 5.11	4.70, 5.05	4.63 (0.74)	4, 5.25	4.13, 5.12	4.25, 5	4 (1.41)	-8.71, 16.71	-2.31, 10.31	0.92, 7.08
Overall	4.86 (0.36)	4.65, 5.07	4.69, 5.03	4.73, 4.99	4.75 (0.62)	4.36, 5.14	4.43, 5.07	4.51, 4.99	4.11 (1.17)	3.21, 5.01	3.39, 4.83	3.57, 4.65

a. No CIs were generated. All participants (N = 4) provided a rating of 5.

At the mid-intervention assessment, all participants in the exposure intervention reported that either they would be likely (16.7%, n = 1) to recommend or would definitely (83.3%, n = 5) recommend the intervention to a friend. At the end of the intervention, all participants reported that they would recommend the program to a friend (n = 4). It should be noted that the fifth participant who could not be located after the mid-intervention time point was the individual who reported being "likely" to recommend the program at the mid-intervention evaluation. Of the participants who withdrew from the intervention, 71.4% reported that they would recommend the program to a friend (57.1%, n = 4) or would be "likely" to recommend (14.3%, n = 1). Of the remaining participants, one (14.3%) reported that he/she would be unlikely to recommend and one reported that he/she would "maybe" recommend the program. Combining the final evaluations of all exposure participants, 81.83% responded that they would recommend the program to a friend (72.73%, n = 8) or would be likely to recommend the study to a friend (9.1%, n = 1). **These findings indicate that the criterion was met for the exposure condition.**

All of the participants in the education condition at the mid-intervention evaluation responded that they would recommend the program to a friend (87.5%, n = 7) or that they would be "likely" to recommend (12.5%, n = 1). At the end of the intervention, 87.5% of participants reported they would recommend the program to a friend (75%, n = 6) or would be likely to recommend (12.5%, n = 1). The remaining 12.5% responded with "maybe." Of the two participants who dropped out of the education intervention, one indicated that "maybe" he/she would recommend the program to a friend and the other indicated that "yes" he/she would recommend.

Combining the final evaluations of all education participants' ratings showed that 80% indicated that they would be likely (10%, n = 1) or would definitely (70%, n = 7) recommend the program to a friend. The remaining 2 participants responded "maybe." **These findings indicated that the criterion was met for the education condition.**

Intervention: Trends in intervention impact. Although examination of treatment efficacy was not the focus of this dissertation and cannot sufficiently be explored given the small sample size, changes in the process and outcome variables for each intervention condition were examined. Tables 33 to 35 display the mean scores for each measure at each assessment time for each intervention condition, as well as the mean change scores and associated 95, 90, and 80% confidence intervals. These data demonstrate that treatment trends appear to move in the expected directions within the exposure intervention. These trends were generally more pronounced in the education condition.

In exploring the treatment trends within the exposure condition, little emerges at the 95% confidence interval level. This is not surprising, given that the sample size of study completers was only four participants. When examining mean changes over time at the 80% confidence level, it appears that overall changes seem most pronounced between the baseline and mid-intervention period. Pain-related catastrophizing, pain-related anxiety, self-efficacy associated with pain and symptoms, depressive symptoms, and FMS-related health status all improved over that period of time. Given that the exposure intervention was designed to directly target catastrophizing, fear, and anxiety, these treatment trends are promising.

The improvement in self-efficacy with pain was found at all confidence interval levels, and the mean change was notably larger in this condition than in the education condition (i.e., mean change = 25, SD = 20.07 vs. mean change = 9.25, SD = 13.48). At the 80% confidence interval, improvements in pain-related catastrophizing and pain-related anxiety were found from the baseline assessment all subsequent assessments. Kinesiophobia also demonstrated trends towards reduction over time; however, this change was only significant between the baseline and post-intervention assessment at the 80% confidence interval level. The small sample size in this condition limits the interpretation of these patterns; however, the changes in all variables over time are in the expected direction. Although improvements were found, post-intervention scores for kinesiophobia indicate that, on average, participants reported experiencing moderate levels of kinesiophobia (M = 41.25, SD = 6.80). The group's average score for kinesiophobia did not decrease below the cut-off used to screen participants for eligibility in the study. However, reductions in pain-related anxiety were notable and the mean score (M = 53, SD = 19) fell below the cut-off used for study entry and remained at this level at the follow-up assessment (M = 50.75, SD = 20.35). The pattern towards notable symptom improvement was also demonstrated for pain-related catastrophizing at the 80% CI level. Among dropout participants in the exposure condition, improvements were found for kinesiophobia (90% CI) and pain-related anxiety (95% CI).

In the education condition, notable changes were seen at the 95% CI and were more apparent when examining the 90 and 80% CIs. At the 95% CI, symptoms of kinesiophobia and pain-related anxiety showed trends towards improvement from baseline to each of the subsequent assessment times for all participants except for

dropouts. The strength of fear-avoidance beliefs related to physical activity also showed notable reductions from baseline to the mid-intervention assessment. At the 90% CIs, participants also showed notable improvements in pain-related catastrophizing from baseline to all other assessments and in fear avoidance beliefs from baseline to the mid-intervention and to followup. There were also notable improvements in self-efficacy associated with functioning from baseline to the post-intervention and the follow-up assessments at the 95% CI, and from baseline to all assessment points at the 80% CI. In addition, self-efficacy for pain improved from baseline to all other time points (80% CI only) and self-efficacy for non-pain symptoms showed improvements from baseline to mid-intervention and post intervention assessments (90% CI).

Among the outcome variables of interest, FMS-related health status improved from baseline to follow-up at the 95% CI and from baseline to all subsequent time points at the other CIs. Improvements were also seen in depression from baseline to all other assessments at the 90% CI. These data show a pattern of improvement among the mechanisms within the fear-avoidance model and the outcome variables tested. Participants who dropped out of the education intervention did not show marked improvements in any of the symptoms assessed.

Participants' absolute scores on each measure at each time point were plotted in Figures 7a to 7i. There is more variability of scores among participants within the exposure condition than in the education condition. There are also a greater number of participants plotted for the education condition, which make the pattern of the changes emerge more clearly. It should be noted that one exposure participant's (participant 33) scores reflected extreme ratings; the participant also provided extreme ratings in the

intervention sessions (i.e., anxiety ratings of 1 or 10 exclusively). As mentioned previously, a worksheet was developed for this participant to use in the final three sessions specifically to assist him in better differentiating between levels of intensity of his affective experience (Appendix D). Given the timing of this micro-intervention, any changes to his style of self reporting would likely only have been seen at the third assessment (post-intervention) time point or later.

Table 33. Descriptive statistics for each measure at each assessment time point

Measure	Assessment	Exposure Condition				Education Condition				Overall Sample			
		N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max
TSK	Baseline	18	47.39 (5.30)	47.50	40-58	11	48 (5.90)	47	37-59	30[a]	47.53 (5.37)	47	37-59
	6 week	6	46 (11.37)	40	37-65	8	37.38 (5.60)	38.50	26-45	14	41.07 (9.29)	39.50	26-65
	13 week	4	41.25 (5.80)	40.50	35-49	8	35.63 (6.78)	38	24-42	12	37.50 (6.79)	39.50	24-49
	Follow up[a]	4	44.24 (6.40)	42.50	39-53	8	36.25 (6.74)	36	28-44	12	38.92 (7.45)	39.50	28-35
	Dropout[b]	7	40.57 (5.06)	42	32-47	2	51 (8.49)	51	45-57	9	42.89 (7.03)	42	32-57
PASS-20	Baseline	18	64.94 (10.58)	62	49-80	11	64.73 (13.67)	62	36-87	30	65.10 (11.48)	62.50	37-87
	6 week	6	50.67 (17.72)	46	36-85	8	44.38 (13.44)	46	22-63	14	47.07 (15.11)	46	22-85
	13 week	4	53 (19)	51.5	35-74	8	43.25 (10.26)	45	26-58	12	46.50 (13.73)	45	26-74
	Follow up	4	50.75 (20.35)	46.50	32-78	8	44.75 (15.32)	46.50	20-65	12	46.75 (16.47)	46.50	20-78
	Dropout	7	45.57 (14.63)	47	19-61	2	65 (14.14)	65	55-75	9	49.89 (16.10)	54	19-75
FIQR	Baseline	18	68.23 (14.32)	68.33	43.5-92.8	11	67.58 (10.84)	66.50	55.33-94.83	30	67.74 (12.76)	66.50	43.5-94.83
	6 week	6	56.33 (17.96)	51.58	35.67-89	8	56.35 (12.95)	55.67	37.17-81.83	14	56.35 (14.64)	53.83	35.67-89
	13 week	4	56.96 (25.15)	55.17	28.17-89.33	8	49.5 (15.70)	44.83	31-81	12	51.99 (18.51)	49.50	28.17-89.33
	Follow up	4	53.83 (19.67)	51.50	32.83-79.50	8	53.58 (17.21)	50.58	34-89	12	53.67 (17.15)	50.75	32.83-89
	Dropout	7	67.33 (14.59)	68	47.17-94	2	66.08 (3.18)	66.08	63.83-68.33	9	67.06 (12.70)	68	47.17-94
PCS	Baseline	18	29.72 (7.53)	30	19-42	11	27.91 (8.95)	27	10-43	30	29.57 (8.37)	30	10-45
	6 week	6	23.17 (13.18)	17	12-46	8	22 (7.78)	21.5	14-36	14	22.50 (9.99)	19.50	12-46
	13 week	4	23 (16.87)	20	6-46	8	18 (4.84)	18.5	9-24	12	19.67 (9.93)	18.5	6-46
	Follow up	4	19 (19.11)	12	5-47	8	20 (9.32)	23	5-29	12	19.67 (12.46)	18	5-47
	Dropout	7	26.86 (10.12)	28	8-37	2	38.50 (10.61)	38.50	31-46	9	29.44 (10.83)	31	8-46
PHQ-9	Baseline	18	13.22 (5.64)	14	2-22	11	15.27 (4.54)	13	11-23	30	14 (5.17)	14	2-23
	6 week	6	10.67 (7.20)	9	2-23	8	12.38 (3.96)	13	8-18	14	11.64 (5.40)	11.50	2-23
	13 week	4	10.50 (9.33)	10.50	0-21	8	11.50 (4.21)	10	7-19	12	11.17 (5.94)	10	0-21
	Follow up	4	11.50 (9.15)	12	0-22	8	11.50 (5.01)	11.50	5-18	12	11.50 (6.23)	11.50	0-22
	Dropout	7	11.71 (7.54)	11	2-25	2	13 (4.24)	13	10-16	9	12 (6.73)	11	2-25

Note: there was one individual who completed baseline assessments and was not assigned to a condition because he/she dropped out prior to random assignment.
a. Follow-up refers to the 25-week assessment time point for study completers
b. Dropout refers to the 25-week assessment time point for dropout participants

Table 33. Descriptive statistics for each measure at each assessment time point, continued

Measure	Assessment	Exposure Condition				Education Condition				Overall Sample			
		N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max
ASES Pain	Baseline	18	41.56 (14.46)	43	12-68	11	43.09 (12.50)	38	30-66	30	42.53 (13.48)	42	12-68
	6 week	6	67.67 (19.16)	71	36-88	8	52 (15.68)	52	28-78	14	58.71 (18.39)	56	28-88
	13 week	4	50 (22.69)	47	30-76	8	57.75 (23.84)	59	24-90	12	55.17 (22.73)	59	24-90
	Follow up	4	44 (19.66)	47	20-62	8	58.50 (23.83)	57	20-92	12	53.67 (22.75)	55	20-92
	Dropout	7	44.86 (16.85)	40	26-70	2	44 (2.83)	44	42-46	9	44.67 (12.63)	42	26-70
ASES Function	Baseline	18	58.95 (22.29)	60	22-100	11	66.16 (22.99)	64.44	18.89-96.67	30	61.56 (22.05)	62.78	18.89-100
	6 week	6	67.96 (25.26)	72.22	20-88.89	8	70.83 (22.50)	74.44	40-97.78	14	69.60 (22.81)	72.22	20-97.78
	13 week	4	66.11 (26.98)	73.33	27.78-90	8	75.42 (21.88)	85	30-94.44	12	72.31 (22.90)	80	27.78-94.44
	Follow up	4	76.67 (18.39)	77.22	54.44-97.78	8	75.42 (25.14)	80	24.44-100	12	75.83 (22.24)	80	24.44-100
	Dropout	7	50.79 (17.81)	47.78	25.56-81.11	2	67.22 (29.07)	67.22	46.67-87.78	9	54.44 (19.90)	47.78	25.56-87.78
ASES Other Symptoms	Baseline	18	42.59 (14.58)	39.17	21.67-71.67	11	45 (19.85)	45	16.67-80	30	43.5 (16.18)	41.67	16.67-80
	6 week	6	58.06 (28.74)	74.17	10-78.33	8	54.58 (19.47)	52.5	25-80	14	56.07 (22.91)	61.67	10-80
	13 week	4	50 (35.72)	47.5	13.33-91.67	8	57.71 (20.12)	60.83	30-86.67	12	55.14 (24.90)	60.83	13.33-91.67
	Follow up	4	43.75 (34)	42.5	10-80	8	51.88 (21.83)	56.67	25-80	12	49.17 (25.19)	56.67	10-80
	Dropout	7	43.81 (16.99)	41.67	25-73.33	2	35 (9.43)	35	28.33-41.67	9	41.85 (15.58)	41.67	25-73.33

Note: there was one individual who completed baseline assessments and was not assigned to a condition because he/she dropped out prior to random assignment.
a. Follow-up refers to the 25-week assessment time point for study completers
b. Dropout refers to the 25-week assessment time point for dropout participants

Table 33. Descriptive statistics for each measure at each assessment time point, continued

Measure	Assessment	Exposure Condition				Education Condition				Overall Sample			
		N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max
FABQ	Baseline	14	15.57 (4.38)	16	9-22	8	13.38 (4.47)	13.5	8-19	23	15 (4.47)	16	8-22
	6 week	6	12.83 (7.05)	10	7-24	8	10.25 (3.92)	10.50	5-18	14	11.36 (5.4)	10.50	5-24
	13 week	4	9.75 (2.63)	10.5	6-12	8	11.75 (3.20)	11	8-16	12	11.08 (3.06)	11	6-16
	Follow up	4	11.50 (1.92)	11	10-14	8	9.50 (4.63)	9	4-16	12	10.17 (3.95)	10.50	4-16
	Dropout	7	11.71 (3.82)	13	4-15	2	17 (1.41)	17	16-18	9	12.89 (4.08)	13	4-18
Additional Measures at Final Assessment													
MOCA	Completers	3	24.67 (3.22)	26	21-27	6	27.83 (2.93)	29	22-30	9	26.78 (3.23)	28	21-30
	Dropout	7	22.14 (5.27)	23	13-28	2	28.50 (0.71)	28.50	28-89	9	23.56 (5.36)	26	13-29
	All	10	22.9 (4.73)	24.5	13-28	8	28 (2.51)	29	22-30	18	25.17 (4.61)	26.50	13-30
Blind MOCA	Completers	1	8	8	8	1	19	19	19	2	13.50 (7.78)	13.50	8-19
	Dropout	0	N/A	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	All	1	8	8	8	1	19	19	19	2	13.50 (7.78)	13.50	8-19
SAPAS	Completers	4	2.75 (1.5)	3	1-4	7	3.71 (1.80)	4	1-6	11	3.36 (1.69)	4	1-6
	Dropout	7	3.14 (1.46)	4	1-5	2	3.50 (0.71)	3.50	3-4	9	3.22 (1.30)	4	1-5
	All	11	3 (1.41)	4	1-5	9	3.67 (1.58)	4	1-6	20	3.30 (1.49)	4	1-6

Note: there was one individual who completed baseline assessments and was not assigned to a condition because he/she dropped out prior to random assignment.
a. Follow-up refers to the 25-week assessment time point for study completers
b. Drop out refers to the 25-week assessment time point for dropout participants

Table 33. Descriptive statistics for each measure at each assessment time point, continued

Measure	Assessment	Exposure Condition				Education Condition				Overall Sample			
		N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max	N	M (SD)	Mdn	Min - Max
Additional Measures at Final Assessment													
POAM-P Avoidance	Completers	4	19.75 (3.86)	21.50	14-22	7	26.14 (10.51)	27	14-39	11	23.82 (9.01)	22	14-39
	Dropout	7	17.57 (7.83)	16	3-26	2	27 (2.83)	27	25-29	9	19.67 (8.02)	20	3-29
	All	11	18.36 (6.52)	20	3-26	9	26.33 (9.17)	27	14-39	20	21.95 (8.62)	21.50	3-39
POAM-P Overdoing	Completers	4	22.50 (8.51)	25.50	10-29	7	25.29 (7.20)	28	10-31	11	24.27 (7.40)	26	10-31
	Dropout	7	25.71 (9.83)	29	10-35	2	26.50 (10.61)	26.50	19-34	9	25.89 (9.31)	29	10-35
	All	11	24.55 (9.07)	26	10-35	9	25.56 (7.30)	28	10-34	20	25 (8.12)	27	10-35
POAM-P Pacing	Completers	4	24.50 (14.20)	23.50	11-40	7	21.71 (10.13)	23	6-34	11	22.73 (11.14)	23	6-40
	Dropout	7	18.57 (5.74)	19	11-27	2	28 (5.66)	28	24-32	9	20.67 (6.78)	20	11-32
	All	11	20.73 (9.45)	19	11-40	9	23.11 (9.41)	24	6-34	20	21.80 (9.26)	21.50	6-40

Note: there was one individual who completed baseline assessments and was not assigned to a condition because he/she dropped out prior to random assignment.

a. Follow-up refers to the 25-week assessment time point for study completers

b. Dropout refers to the 25-week assessment time point for dropout participants

Table 34. Mean change scores and associated 95% confidence intervals (CI) for each measure from baseline to subsequent assessments

Measures	Assessment Periods	Exposure Condition			Education Condition			Overall Sample		
		N	M Change (SD)	95% CI[a]	N	M Change (SD)	95% CI	N	M Change (SD)	95% CI
TSK	Baseline to 6-week	6	-4.50 (11.22)	-16.28, 7.28	8	-9.25 (3.41)	-12.10, -6.40	14	-7.21 (7.79)	-11.71, -2.72
	Baseline to Post-intervention	4	-9.75 (8.66)	-23.52, 4.02	8	-11 (7.60)	-17.35, -4.65	12	-10.58 (7.86)	-15.40, -5.76
	Baseline to Follow up for completers	4	-6.75 (10.28)	-23.10, 9.60	8	-10.38 (6.57)	-15.87, -4.88	12	-9.17 (7.71)	-14.06, -4.27
	Baseline to follow up for dropouts	7	-5.43 (6.08)	-11.05, 0.19	2	-0.50 (2.12)	-19.56, 18.56	9	-4.33 (5.74)	-8.74, 0.08
PASS-20	Baseline to 6-week	6	-8.67 (9.65)	-18.79, 1.46	8	-19.25 (13.67)	-30.68, -7.82	14	-14.71 (12.88)	-22.15, -7.28
	Baseline to Post-intervention	4	-11.25 (10.53)	-28.01, 5.51	8	-20.38 (15.42)	-33.26, -7.49	12	-17.33 (14.20)	-26.36, -8.31
	Baseline to Follow up for completers	4	-13.50 (11.03)	-31.05, 4.05	8	-18.88 (18.74)	-34.54, -3.21	12	-17.08 (16.24)	-27.40, -6.77
	Baseline to follow up for dropouts	7	-20.57 (17.39)	-36.65, -4.49	2	-6 (8.49)	-82.24, 70.24	9	-17.33 (16.64)	-30.13, -4.54
FIQ-R	Baseline to 6-week	6	-8.36 (9.44)	-18.27, 1.55	8	-9.88 (9.35)	-17.69, 2.27	14	-9.23 (9.05)	-14.45, -4.00
	Baseline to Post-intervention	4	-4.29 (9.87)	-20, 11.42	8	-16.73 (9.02)	-24.27, 2.87	12	-12.58 (10.76)	-19.42, -5.75
	Baseline to Follow up for completers	4	-7.42 (9.31)	-22.24, 7.41	8	-12.65 (11)	-21.84, -3.45	12	-10.90 (10.36)	-17.49, -4.32
	Baseline to follow up for dropouts	7	-2.48 (16.24)	-17.50, 12.54	2	-7 (9.90)	-95.94, 81.94	9	-3.48 (14.63)	-14.73, 7.76

Note: negative values indicate a decrease in mean score from the first time point to second.

Table 34. Mean change scores and associated 95% confidence intervals (CI) for each measure from baseline to subsequent assessments, continued

Measures	Assessment Periods	Exposure Condition			Education Condition			Overall Sample		
		N	M Change (SD)	95% CI[a]	N	M Change (SD)	95% CI	N	M Change (SD)	95% CI
PCS	Baseline to 6-week	6	-4.17 (5.42)	-9.85, 1.52	8	-6.63 (6.41)	-11.99, -1.26	14	-5.57 (5.92)	-8.99, -2.15
	Baseline to Post-intervention	4	-7 (8.25)	-20.12, 6.12	8	-10.63 (8.12)	-17.42, -3.83	12	-9.42 (7.98)	-14.49, -4.34
	Baseline to Follow up for completers	4	-11 (10.68)	-27.99, 5.99	8	-8.63 (8.90)	-16.06, -1.19	12	-9.42 (9.10)	-15.20, -3.63
	Baseline to follow up for dropouts	7	-3.43 (11.04)	-13.64, 6.78	2	4.50 (2.12)	-14.56, 23.56	9	-1.67 (10.21)	-9.52, 6.18
PHQ-9	Baseline to 6-week	6	-2.17 (3.54)	-5.89, 1.55	8	-3.38 (4.31)	-6.98, 0.23	14	-2.86 (3.90)	-5.11, -0.61
	Baseline to Post-intervention	4	-1.75 (4.35)	-8.67, 5.17	8	-4.25 (6.25)	-9.48, 0.98	12	-3.42 (5.62)	-6.98, 0.15
	Baseline to Follow up for completers	4	-0.75 (2.99)	-5.50, 4.00	8	-4.25 (5.87)	-9.16, 0.66	12	-3.08 (5.23)	-6.41, 0.24
	Baseline to follow up for dropouts	7	-1.57 (6.29)	-7.39, 4.25	2	1 (2.83)	-24.41, 26.41	9	-1 (5.66)	-5.35, 3.35
ASES-Pain	Baseline to 6-week	6	25 (20.07)	3.94, 46.06	8	9.25 (13.48)	-2.02, 20.52	14	16 (17.84)	5.70, 26.30
	Baseline to Post-intervention	4	13.50 (24.89)	-26.11, 53.11	8	15 (24.17)	-5.20, 35.20	12	14.50 (23.26)	-0.28, 29.28
	Baseline to Follow up for completers	4	7.50 (19.76)	-23.94, 38.94	8	15.75 (28.11)	-7.75, 39.25	12	13 (25.02)	-2.89, 28.89
	Baseline to follow up for dropouts	7	0 (24.03)	-22.22, 22.22	2	-1 (15.56)	-140.77, 138.77	9	-0.22 (21.53)	-16.77, 16.33

Note: negative values indicate a decrease in mean score from the first time point to second.

Table 34. Mean change scores and associated 95% confidence intervals (CI) for each measure from baseline to subsequent assessments, continued

Measures	Assessment Periods	Exposure Condition			Education Condition			Overall Sample		
		N	M Change (SD)	95% CI[a]	N	M Change (SD)	95% CI	N	M Change (SD)	95% CI
ASES-Function	Baseline to 6-week	6	-0.19 (13.80)	-14.66, 14.29	8	7.78 (12)	-2.25, 17.81	14	4.37 (12.94)	-3.11, 11.84
	Baseline to Post-intervention	4	-4.44 (14.08)	-26.85, 17.97	8	12.36 (10.73)	3.39, 21.33	12	6.76 (13.99)	-2.13, 15.65
	Baseline to Follow up for completers	4	6.11 (18.98)	-24.08, 36.31	8	12.36 (11.63)	2.64, 22.08	12	10.28 (13.92)	1.43, 19.12
	Baseline to follow up for dropouts	7	0.79 (9.99)	-8.45, 10.04	2	-13.89 (11.79)	-119.77, 91.99	9	-2.47 (11.58)	-11.37, 6.44
ASES-Symptoms	Baseline to 6-week	6	13.89 (16.62)	-3.56, 31.33	8	11.88 (16.10)	-1.58, 25.33	14	12.74 (15.71)	3.67, 21.81
	Baseline to Post-intervention	4	10 (20.05)	-21.90, 41.90	8	15 (20.20)	-1.89, 31.89	12	13.33 (19.37)	1.03, 25.64
	Baseline to Follow up for completers	4	3.75 (18.38)	-25.49, 32.99	8	9.17 (18.34)	-6.17, 24.50	12	7.36 (17.70)	-3.89, 18.61
	Baseline to follow up for dropouts	7	-5.71 (17.97)	-22.34, 10.91	2	-1.67 (4.71)	-44.02, 40.69	9	-4.81 (15.76)	-16.93, 7.30
FABQ	Baseline to 6-week	5	-3.80 (10.62)	-16.98, 9.38	6	-4.33 (2.94)	-7.42, -1.24	11	-4.09 (7.03)	-8.82, 0.64
	Baseline to Post-intervention	3	-5.67 (7.09)	-23.29, 11.96	6	-1.17 (2.23)	-3.51, 1.17	9	-2.67 (4.56)	-6.17, 0.83
	Baseline to Follow up for completers	3	-4.67 (8.08)	-24.75, 15.41	6	-3.33 (3.78)	-7.30, 0.63	9	-3.78 (5.07)	-7.67, 0.12
	Baseline to follow up for dropouts	6	-0.50 (5.86)	-6.65, 5.65	1	1	N/A	7	-0.29 (5.38)	-5.26, 4.69

Note: negative values indicate a decrease in mean score from the first time point to second.

Table 35. Mean change scores and associated 90 and 80% confidence intervals (CI) for each measure from baseline to subsequent assessments

Measures	Assessment Periods	Exposure Condition			Education Condition			Overall Sample		
		M Change (SD)	90% CI	80% CI	M Change (SD)	90% CI	80% CI	M Change (SD)	90% CI	80% CI
TSK	Baseline to 6-week	-4.50 (11.22)	-13.73, 4.73	-11.26, 2.26	-9.25 (3.41)	-11.53, - 6.96	-10.96, -7.54	-7.21 (7.79)	-10.90, -3.53	-10.02, -4.40
	Baseline to Post-intervention	-9.75 (8.66)	-19.93, 0.43	-16.84, - 2.66	-11 (7.60)	-16.09, - 5.91	-14.80, -7.20	-10.58 (7.59)	-14.52, -3.53	-13.57, -7.60
	Baseline to Follow up for completers	-6.75 (10.28)	-18.84, 5.34	-15.16, 1.66	-10.38 (6.57)	-14.77, - 5.98	-13.66, -7.09	-9.17 (7.71)	-13.16, -5.17	-12.20, -6.13
	Baseline to follow up for dropouts	-5.43 (6.08)	-9.89, -0.96	-8.74, -2.12	-0.50 (2.12)	-9.97, 8.97	-5.12, 4.12	-4.33 (5.74)	-7.89, -0.77	-7.01, -1.66
PASS-20	Baseline to 6-week	-8.67 (9.65)	-16.60, -0.73	-14.48, -2.85	-19.25 (13.67)	-28.40, - 10.10	-26.09, -12.41	-14.71 (12.88)	-20.81, -8.62	-19.36, -10.07
	Baseline to Post-intervention	-11.25 (10.53)	-23.64, 1.14	-19.87, -2.63	-20.38 (15.42)	-30.70, - 10.05	-28.09, -12.66	-17.33 (14.20)	-24.70, -9.97	-22.92, -11.74
	Baseline to Follow up for completers	-13.50 (11.03)	-26.48, -0.52	-22.53, -4.47	-18.88 (18.74)	-31.43, -6.32	-28.25, -9.50	-17.08 (16.24)	-25.50, -8.66	-23.48, -10.69
	Baseline to follow up for dropouts	-20.57 (17.39)	-33.34, -7.80	-30.03, -11.11	-6 (8.49)	-43.88, 31.88	-24.47, 12.47	-17.33 (16.64)	-27.65, -7.02	-25.08, -9.58
FIQ-R	Baseline to 6-week	-8.36 (9.44)	-16.13, -0.59	-14.05, -2.67	-9.88 (9.35)	-16.14, -3.61	-14.55, -5.20	-9.23 (9.05)	-13.51, -4.94	-12.49, -5.96
	Baseline to Post-intervention	-4.29 (9.87)	-15.91, 7.32	-12.38, 3.79	-16.73 (9.02)	-22.77, -10.69	-21.24, -12.22	-12.58 (10.76)	-18.16, -7.00	-16.82, -8.35
	Baseline to Follow up for completers	-7.42 (9.31)	-18.38, 3.54	-15.04, 0.21	-12.65 (11)	-20.02, -5.28	-18.15, -7.14	-10.90 (10.36)	-16.27, -5.53	-14.98, -6.83
	Baseline to follow up for dropouts	-2.48 (16.24)	-14.40, 9.45	-11.31, 6.36	-7 (9.90)	-51.20, 37.20	-28.54, 14.54	-3.48 (14.63)	-12.55, 5.59	-10.29, 3.33
PCS	Baseline to 6-week	-4.17 (5.42)	-8.62, 0.29	-7.43, -0.90	-6.63 (6.41)	-10.92, -2.33	-9.83, -3.42	-5.57 (5.92)	-8.37, -2.77	-7.71, -3.44
	Baseline to Post-intervention	-7 (8.25)	-16.70, 2.70	-13.75, -0.25	-10.63 (8.12)	-16.07, -5.18	-14.69, -6.56	-9.42 (7.98)	-13.56, -5.28	-12.56, -6.27
	Baseline to Follow up for completers	-11 (10.68)	-23.56, 1.56	-19.74, -2.26	-8.63 (8.90)	-14.58, -2.67	-13.07, -4.18	-9.42 (9.10)	-9.42, -14.13	-13, -5.84
	Baseline to follow up for dropouts	-3.43 (11.04)	-11.54, 4.68	-9.44, 2.58	4.50 (2.12)	-4.97, 13.97	-0.12, 9.12	-1.67 (10.21)	-8, 4.66	-6.42, 3.09

Table 35. Mean change scores and associated 90 and 80% confidence intervals (CI) for each measure from baseline to subsequent assessments, continued

Measures	Assessment Periods	Exposure Condition			Education Condition			Overall Sample		
		M Change (SD)	90% CI	80% CI	M Change (SD)	90% CI	80% CI	M Change (SD)	90% CI	80% CI
PHQ-9	Baseline to 6-week	-2.17 (3.54)	-5.08, 0.75	-4.30, -0.31	-3.38 (4.31)	-6.26, -0.49	-5.53, -1.22	-2.86 (3.90)	-4.70, -1.01	-4.26, -1.45
	Baseline to Post-intervention	-1.75 (4.35)	-6.87, 3.37	-5.31, 1.81	-4.25 (6.25)	-8.44, -0.06	-7.38, -1.12	-3.42 (5.62)	-6.33, -0.51	-5.63, -1.21
	Baseline to Follow up for completers	-0.75 (2.99)	-4.26, 2.76	-3.20, 1.70	-4.25 (5.87)	-8.18, -0.32	-7.19, -1.31	-3.08 (5.23)	-5.79, -0.37	-5.14, -1.02
	Baseline to follow up for dropouts	-1.57 (6.29)	-6.19, 3.05	-5, 1.85	1 (2.83)	-11.63, 13.63	-5.16, 7.16	-1 (5.66)	-4.51, 2.51	-3.63, 1.63
ASES-Pain	Baseline to 6-week	25 (20.07)	8.49, 41.51	12.91, 37.09	9.25 (13.48)	0.22, 18.28	2.51, 15.99	16 (17.84)	7.56, 24.44	9.56, 22.44
	Baseline to Post-intervention	13.50 (24.89)	-15.79, 42.79	-6.88, 33.88	15 (24.17)	-1.19, 31.19	2.91, 27.09	14.50 (23.26)	2.44, 26.56	5.34, 23.65
	Baseline to Follow up for completers	7.50 (19.76)	-15.75, 30.75	-8.68, 23.68	15.75 (28.11)	-3.08, 34.58	1.69, 29.81	13 (25.02)	0.03, 25.97	3.15, 22.85
	Baseline to follow up for dropouts	0 (24.03)	-17.65, 17.65	-13.08, 13.08	-1 (15.56)	-70.45, 68.45	-34.85, 32.85	-0.22 (21.53)	-13.57, 13.12	-10.25, 9.80
ASES-Function	Baseline to 6-week	-0.19 (13.80)	-11.53, 11.16	-8.50, 8.13	7.78 (12)	-0.26, 15.81	1.78, 13.78	4.37 (12.94)	-1.76, 10.49	-0.30, 9.03
	Baseline to Post-intervention	-4.44 (14.08)	-21.02, 12.13	-15.98, 7.09	12.36 (10.73)	5.17, 19.55	6.99, 17.73	6.76 (13.99)	-0.50, 14.01	1.25, 12.27
	Baseline to Follow up for completers	6.11 (18.98)	-16.22, 28.44	-9.43, 21.65	12.36 (11.63)	4.57, 20.15	6.54, 18.18	10.28 (13.92)	3.06, 17.49	4.80, 15.76
	Baseline to follow up for dropouts	0.79 (9.99)	-6.55, 8.13	-4.64, 6.23	-13.89 (11.79)	-66.50, 38.73	-39.54, 11.76	-2.47 (11.58)	-9.65, 4.71	-7.86, 2.92

Table 35. Mean change scores and associated 90 and 80% confidence intervals (CI) for each measure from baseline to subsequent assessments, continued

Measures	Assessment Periods	Exposure Condition			Education Condition			Overall Sample		
		M Change (SD)	90% CI	80% CI	M Change (SD)	90% CI	80% CI	M Change (SD)	90% CI	80% CI
ASES-Symptoms	Baseline to 6-week	13.89 (16.62)	0.21, 27.56	3.87, 23.90	11.88 (16.10)	1.09, 22.66	3.82, 19.93	12.74 (15.71)	5.30, 20.17	7.07, 18.41
	Baseline to Post-intervention	10 (20.05)	-13.59, 33.59	-6.42, 26.42	15 (20.20)	1.47, 28.53	4.90, 25.10	13.33 (19.37)	3.29, 23.38	5.71, 20.96
	Baseline to Follow up for completers	3.75 (18.38)	-17.87, 25.37	-11.30, 18.80	9.17 (18.34)	-3.12, 21.45	-0.01, 18.34	7.36 (17.70)	-1.82, 16.54	0.39, 14.33
	Baseline to follow up for dropouts	-5.71 (17.97)	-18.91, 7.49	-15.49, 4.07	-1.67 (4.71)	-22.71, 19.38	-11.93, 8.59	-4.81 (15.76)	-14.58, 4.95	-12.15, 2.52
FABQ	Baseline to 6-week	-3.80 (10.62)	-13.92, 6.32	-11.08, 3.48	-4.33 (2.94)	-6.76, -1.91	-6.11, -2.56	-4.09 (7.03)	-7.94, -0.25	-7, -1.18
	Baseline to Post-intervention	-5.67 (7.09)	-17.63, 6.29	-13.39, 2.06	-1.17 (2.23)	-3, 0.67	-2.51, 0.18	-2.67 (4.56)	-5.49, 0.16	-4.79, -0.55
	Baseline to Follow up for completers	-4.67 (8.08)	-18.29, 8.96	-13.47, 4.13	-3.33 (3.78)	-6.44, -0.23	-5.61, -1.06	-3.78 (5.07)	-6.92, -0.64	-6.14, -1.42
	Baseline to follow up for dropouts	-0.50 (5.86)	-5.32, 4.32	-4.03, 3.03	1	N/A	N/A	-0.29 (5.38)	-4.23, 3.66	-3.21, 2.64

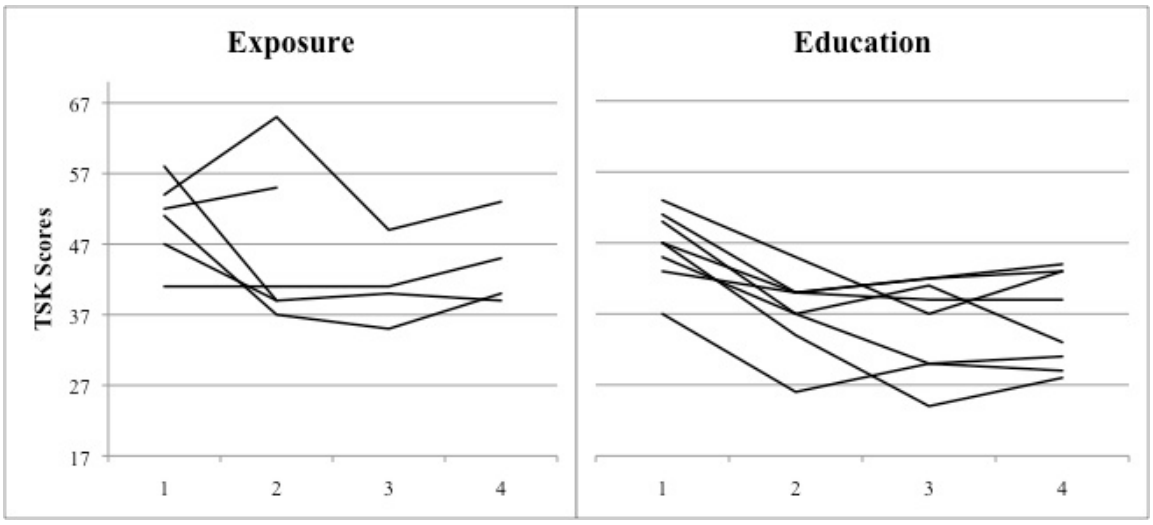


Figure 7a. Absolute scores on the TSK, a measure of kinesiophobia, with higher scores indicating greater symptom severity, at each of the four assessment time points (x-axis)

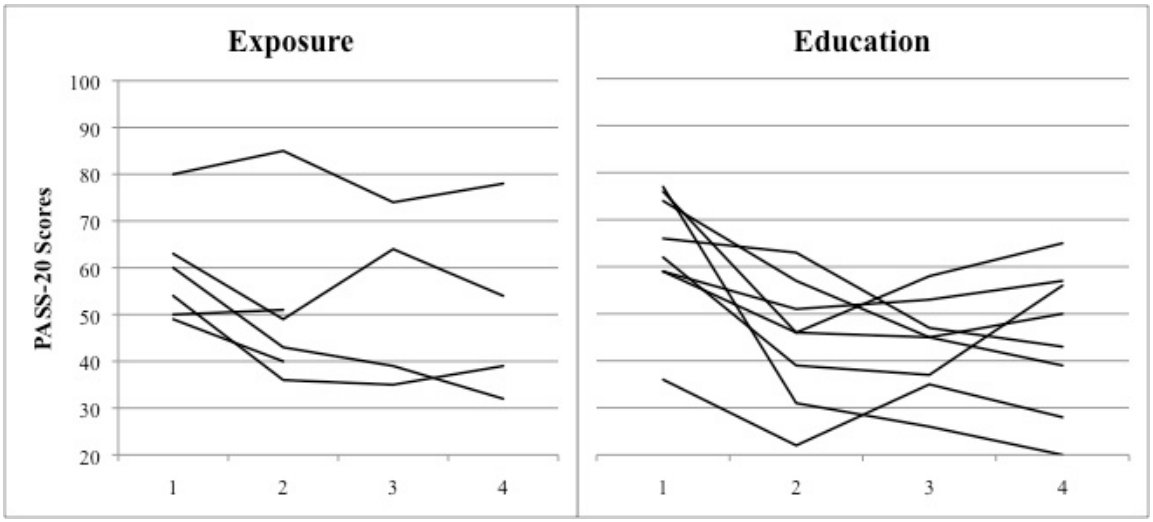


Figure 7b. Absolute scores on the PASS-20, a measure of pain-related anxiety, with higher scores indicating greater symptom severity, at each of the four assessment time points (x-axis)

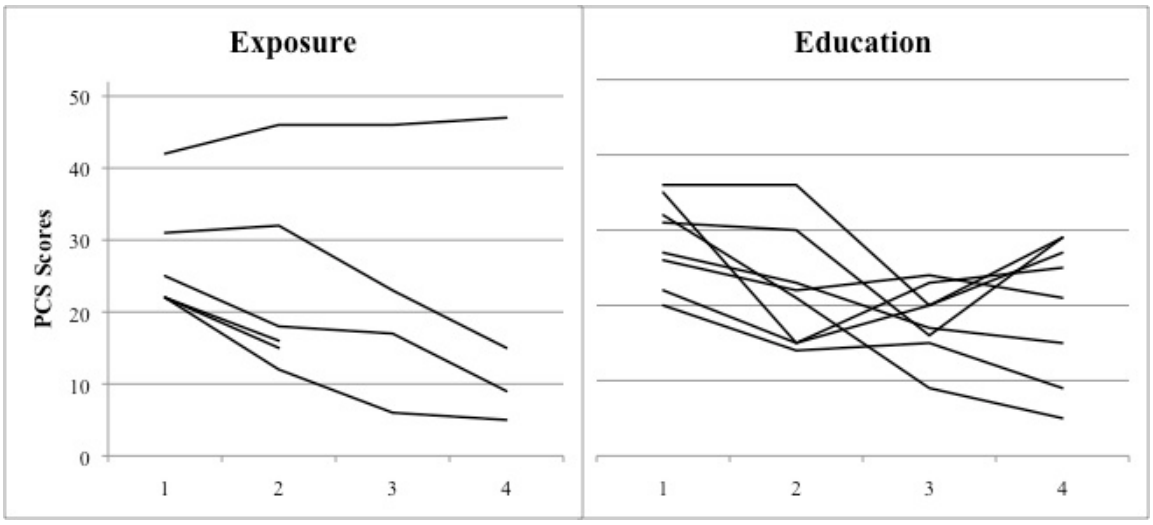


Figure 7c. Absolute scores on the PCS, a measure of pain-related catastrophizing, with higher scores indicating greater symptom severity, at each of the four assessment time points (x-axis)

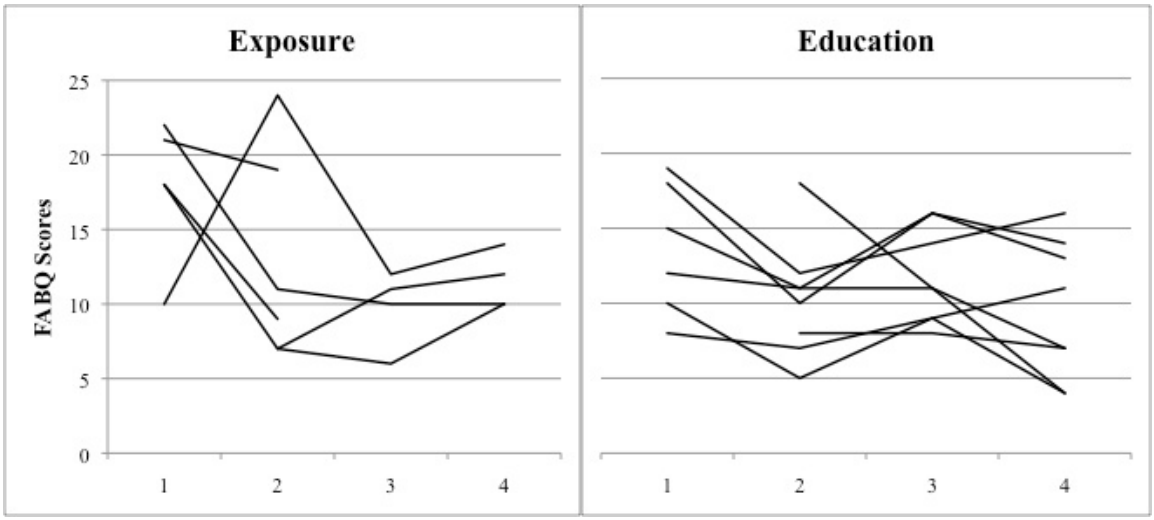


Figure 7d. Absolute scores on the FABQ, a measure of fear-avoidance beliefs, with higher scores indicating a greater number of beliefs held, at each of the four assessment time points (x axis)

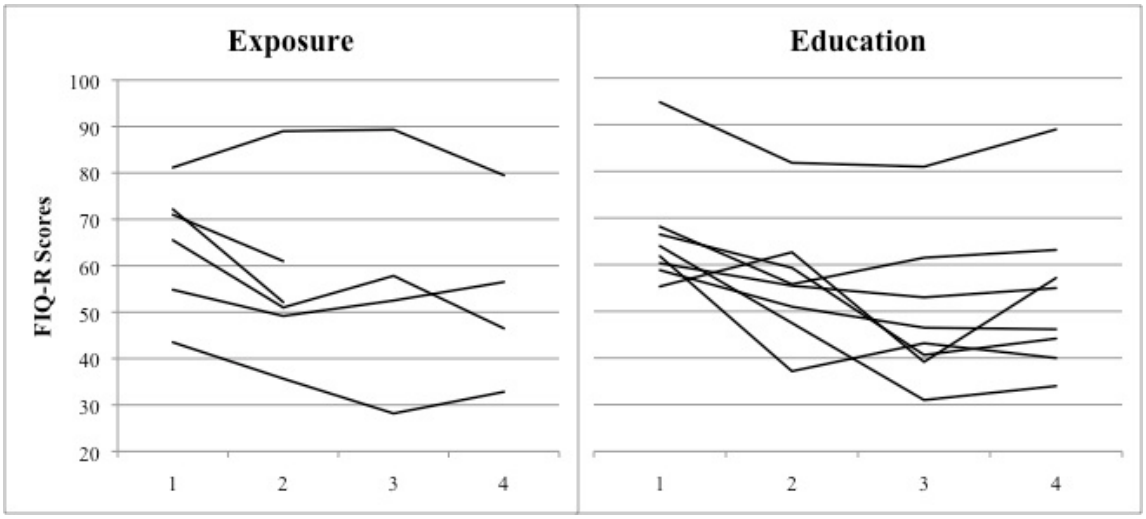


Figure 7e. Absolute scores on the FIQ-R, a measure of fibromyalgia-related health status, with higher scores indicating more severely impacted health status (i.e., worse health status), at each of the four assessment time points (x-axis)

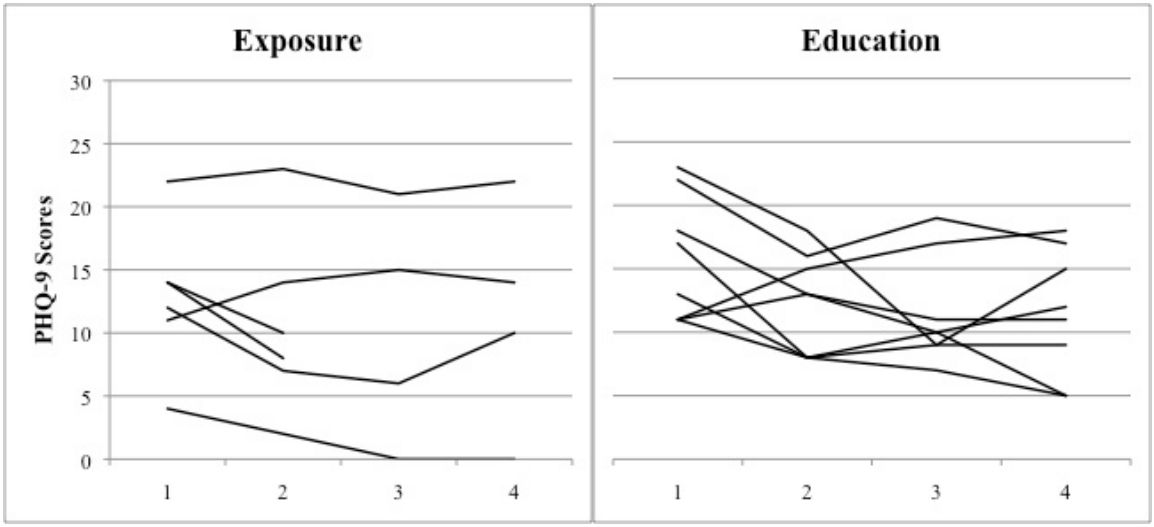


Figure 7f. Absolute scores on the PHQ-9, a measure of depressive symptoms, with higher scores indicating greater number and severity of symptoms, at each of the four assessment time points (x-axis)

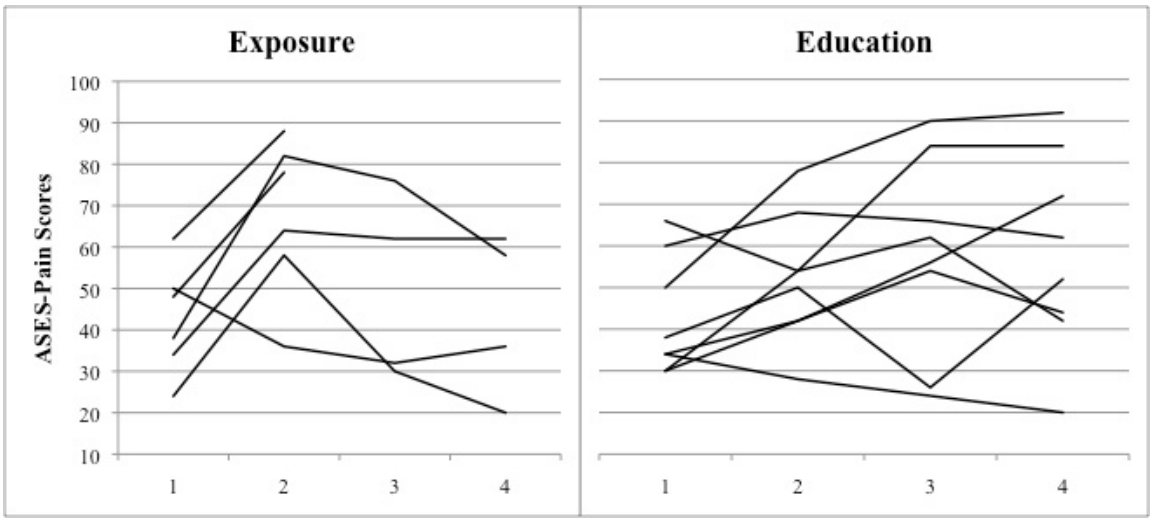


Figure 7g. Absolute scores on the ASES-Pain, a subscale measuring perceived self-efficacy of pain symptoms, with higher scores indicating greater efficacy, at each of the four assessment time points (x-axis)

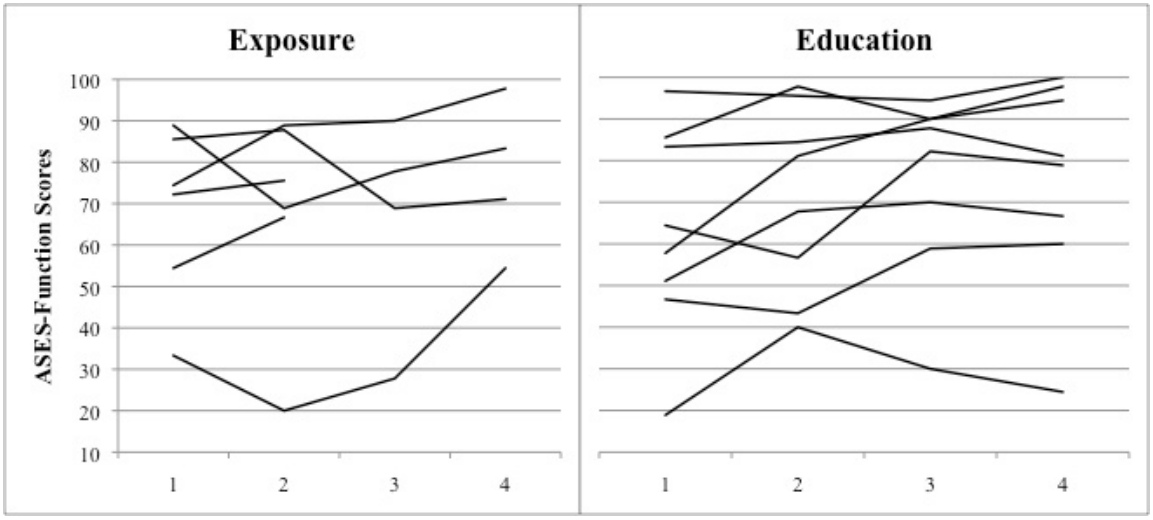


Figure 7h. Absolute scores on the ASES-Function, a subscale measuring perceived self-efficacy of physical functioning, with higher scores indicating greater self efficacy, at each of the four assessment time points (x axis)

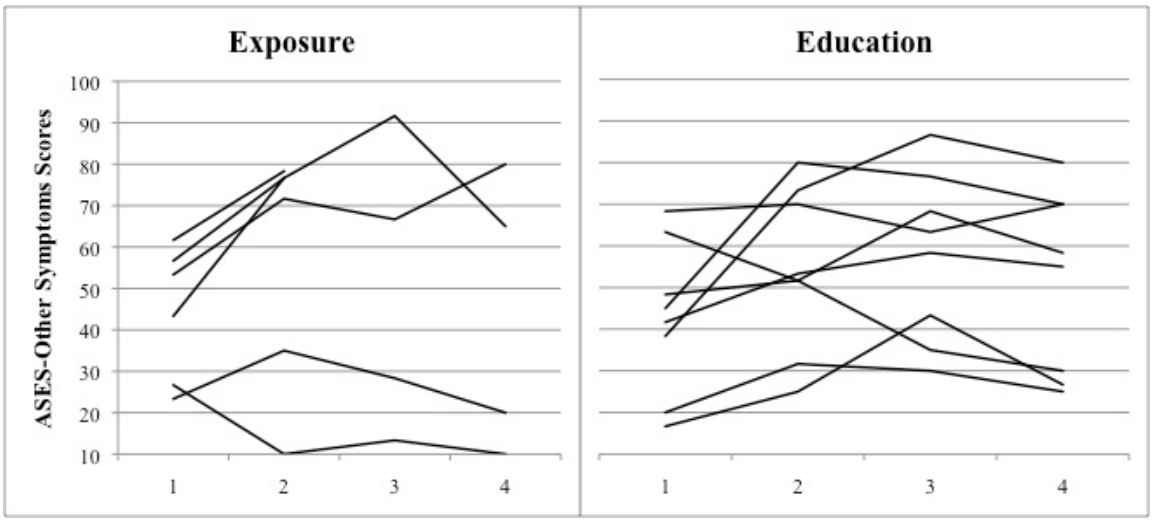


Figure 7i. Absolute scores on the ASES-Symptoms, a subscale measuring perceived self-efficacy of fibromyalgia symptoms, with higher scores indicating greater efficacy, at each of the four assessment time points (x axis)

Additional assessment findings. Additional measures of cognitive functioning, personality disorders, and pain-related behavioral response patterns were added to the study and examined because it was hypothesized that these may pose as barriers to effective participation in the exposure intervention.

Cognitive Functioning. A cognitive screening measure (MoCA) was incorporated into the post-intervention assessment battery in order to explore whether cognitive functioning might be a barrier to participation in the exposure intervention. The intervention incorporated cognitive restructuring of catastrophic thoughts, which requires meta-cognitive and attentional skills. In the exposure condition, the average score of dropout participants was 22.14 (median = 23, SD = 5.27), which is considered to be within the range of scores indicative of mild cognitive impairment (i.e., 19 to 25.2). The range of scores found in this group (13 to 28), however, span across scores that would be expected among individuals with dementia to those in the cognitively healthy range. The group's median score was consistent with scores found in past FMS studies (Borg et al.,

2014). Of study completers, the average score was 24.67 (median 26, SD = 3.22), which borders between mild impairment and healthy cognitive functioning, and is generally higher than the average score within the FMS population. There was one participant (participant 33) who scored an 8 on the Blind MoCA[3] (who was not factored into the mean score). This participant demonstrated a consistent pattern of extreme scoring throughout the assessments and intervention. Given his reported college-level education and his level of cognitive functioning within the sessions, his score seems to under-represent his abilities and might better reflect his personality and communication style. In the education intervention, both study completers (M = 27.83, SD = 2.93) and dropouts (M = 28.50, SD = 0.71) had mean scores that were higher than those in the exposure condition. Their scores were also considered to be in the cognitively healthy range. A one-way ANOVA, excluding participants 01 and 33 who completed the blind MoCA, suggests that the participants in the education condition had significantly higher scores on the MoCA than those in the exposure condition, $F(1, 16) = 7.55$, $p = .01$.

Personality disorders. The SAPAS was incorporated in the post-intervention assessment battery because of the presence of treatment-interfering behaviors that were hypothesized as being related to personality style. On average, among intervention completers and dropouts, average scores (exposure = 3, education = 3.67) indicated the potential presence of personality disorders within the sample. A score of three on this measure identifies the presence of a DSM-IV personality disorder among 90% of individuals (Moran et al., 2003). A total of 65% of the overall sample received a score of

[3] This participant completed the Blind MoCA over the phone because he was unable to attend the assessment session in person.

three or higher on this measure (54.5% of the exposure sample; 77.8% of the education sample). In fact, two of the dropout participants in the exposure condition self reported having a diagnosis of borderline personality disorder.

Pain-related behavioral response patterns. Over the course of the study, it was identified that there were some participants who seemed to frequently respond to their pain-related anxiety with over engagement in activity rather avoidance. As such, scores on the POAM-P were examined to determine whether the participants accurately fit into a model of fear-avoidance. This measure also identified engagement in pacing as a response to pain. Unfortunately, this measure was only administered at the post-intervention assessment period, which makes it impossible to assess whether changes in behavioral responses to pain occurred over the course of the intervention. If the intervention is effective and directly targets the mechanisms within the FA model, then one should expect to see the frequency of avoidance behaviors decrease and pacing behaviors to increase.

Based on a descriptive examination of mean scores, dropout participants in the exposure condition appeared to be more likely to engage in 'overdoing' than intervention completers (M = 25.71 and M = 22.50, respectively). As a group, exposure dropouts appeared to have profiles that consisted of a greater frequency of overdoing than pacing or avoidance (Table 36). The mean score for pacing was higher among exposure intervention completers than dropouts (M = 24.50 and M = 18.57, respectively). In fact, their mean score for pacing was higher than the mean score found in the education condition, as well as in a chronic pain sample from a previous study (Cane et al., 2013). However, these data were not statistically examined because the sample sizes were small

and standard deviations were relatively large. Exposure completers, on average, had a profile that represented greater engagement in pacing or overdoing than avoidance. This might be related to pacing skills learned in this intervention; however, direct examination of this is needed in an efficacy study. Within-group differences are visible in Figure 8.

In the education condition, scores for avoidance appeared to be relatively higher than those in a previous chronic pain study (Cane et al., 2013) and also those who engaged in the exposure intervention in this study. As a group, they demonstrated similar scores for each of the pain-response patterns (i.e., overdoing, pacing, avoiding). Within-group differences are visible in Figure 9.

Table 36. Profile of scores on the POAM-P subscales (avoidance, overdoing, pacing) at the final assessment for each intervention condition and a chronic pain sample from Cane et al., 2013

	Avoidance M (SD)	**Overdoing M (SD)**	**Pacing M (SD)**
Chronic Pain Sample	**23.9 (7.2)**	**22.3 (8.3)**	**21.4 (7.2)**
Exposure Completers	19.8 (3.9)	23.3 (9)	24.5 (14.2)
Exposure Dropouts	17.6 (7.8)	25.7 (9.8)	18.6 (5.7)
Education Completers	26.1 (10.5)	25.3 (7.2)	21.7 (10.1)
Education Dropouts	27 (2.8)	26.5 (10.6)	28 (5.7)

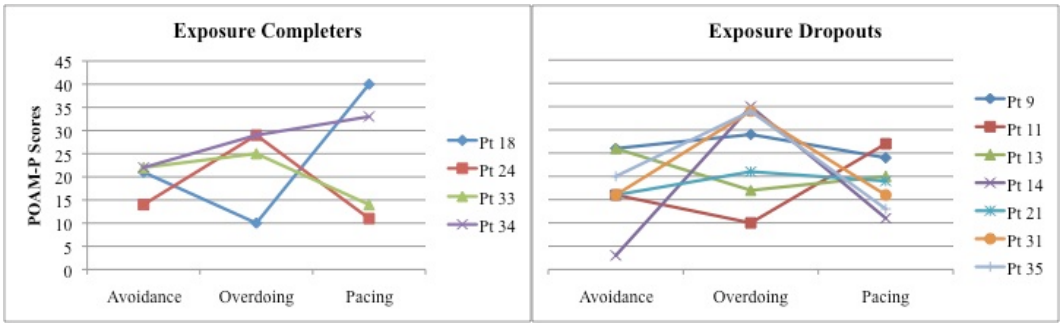


Figure 8. Participant POAM-P profiles for exposure intervention completers and dropouts

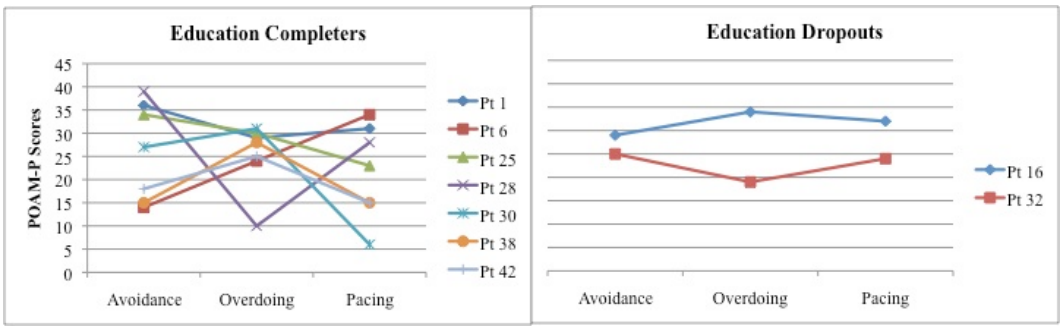


Figure 9. Participant POAM-P profiles for education intervention completers and dropouts

Feasibility and acceptability criteria outcomes. Table 37 provides a summary of each of the criterion tested and whether or not it was satisfied. In summary, study design and procedures were largely found to be feasible and acceptable with the exception of recruitment procedures. Feasibility and acceptability criteria related to intervention delivery were not all met. Specifically, criteria that were associated with participant satisfaction and engagement in assigned homework were successfully met; however, significant challenges remain with regards to participant retention and the ability to deliver the intervention protocol in its original form.

Table 37. Summary of findings regarding the feasibility and acceptability criteria

Feasibility and Acceptability Criteria	Criterion Satisfied (Y/N/Ym[1])
Design and Procedures	
N = 30 participants recruited within a three-month period	N
90% of eligible participants agree to randomization and participation	Y
80% questionnaire completion rate	Y
90% questionnaire item completion rate	Ym
Intervention	
60% of randomized participants complete intervention	N
70% complete 4 + sessions (i.e., complete 1+ behavioral experiments)	N
50% complete intervention within 17 weeks	N
70% of assigned at-home behavioral experiments completed	Y
80% of participants rate satisfaction as “mostly” to “completely”	Y
80% of participants rating likely to yes for recommending program to a friend	Y

1. *Ym* indicates that the criterion could reasonably be met if minor modifications are made.

Discussion

The purpose of this dissertation was to determine the degree to which the associated pilot trial design, procedures, and interventions were feasible and acceptable for translation into a large-scale randomized controlled trial (RCT) that would test treatment efficacy. Based on the findings, it is recommended that additional pilot testing be conducted and that an RCT be conducted only after modifications are made to aspects of the study design, procedures, and intervention protocols and are deemed to be feasible. The degree of feasibility and acceptability of the study design and procedures, and of the intervention protocols, were examined and recommendations are discussed below.

Feasibility and Acceptability of Study Design and Procedures

To determine the feasibility and acceptability of the study design and procedures, the following study elements were examined: recruitment procedures, eligibility criteria, random assignment procedures, and the assessment battery.

Recruitment Procedures: Significant Changes Needed. Within this pilot trial, recruitment proved to be a significant challenge, and each of the community-based recruitment strategies was limited in its ability to recruit participants. Because it took almost 10 months to recruit a baseline sample of 30 participants, and cost over $7,000, none of the strategies used for this study are recommended for use as a primary recruitment method in a larger RCT.

It is recommended that a partnership be formed with a health care system that could serve as a primary referral source. Partnership with a health maintenance organization (HMO) is a commonly used, no-to-low cost method for recruiting participants, and has been successfully employed by Oliver et al. (2001) to recruit 600

participants with FMS for a large RCT. It is reasonable to expect that this recruitment strategy could be effective. A potential limitation with recruiting participants only through a partnership with a health care system, like an HMO, is that the findings might not generalize to people who are either uninsured or who are not members of HMOs. However, within the general population, a large number of Americans belong to an HMO; therefore, if this was the sole recruitment source, the findings would generalize to a large number of patients.

Eligibility Criteria: Minor Changes Needed. In general, the final eligibility criteria for the present trial did not limit the ability to recruit participants with FMS who had moderate to high fear-avoidance. However, two changes were made to the eligibility criteria over the course of the trial to increase the ability to recruit participants. The first change was to require participants to meet cut-off scores on *either* the Tampa Scale for Kinesiophobia (TSK) or the Pain-Anxiety Symptoms Scale-20 (PASS-20), rather than on both. After this change was made, scores on these measures were examined, and most participants met the cut-off scores on both the TSK and PASS-20. There was no evidence to suggest that being eligible based on the TSK, PASS-20, or both measures differentially impacted attrition or adherence within the interventions; however, the small sample size limits the ability to draw firm conclusions. It is recommended that no changes be made to the use of the TSK and PASS-20 as screening measures. In the larger RCT, the relationships between scores on these measures and treatment trends should be examined to determine whether meeting cut-off criteria on one or both of these measures differentially impacts adherence and treatment outcomes.

A second mid-study change to the eligibility criteria was removing the requirement that participants suspend their participation in the interventions when changes were made to their medication regimens. This proved to be impossible to manage because of the high numbers of multiple medications and changes to them. The medication changes observed in this sample are commonly found among patients with FMS in the general population (e.g., Rivera, Vallejo, Esteve-Vives, & Grupo, 2012). For the RCT, it is recommended that medication changes not serve as an eligibility criterion, but instead be monitored so that the effects of medications on treatment outcomes can be determined.

Another potential study concern was the effects that taking a large number of medications might have on participant engagement within the interventions. Participants in the exposure condition were taking an average of 5.33 FMS medications, and participants in the education condition were taking an average of 3.18. This is relatively consistent with a previous study of 232 FMS patients, who were reported to be taking an average of 3.1 (SD = 1.6) medications for FMS symptoms (Rivera et al., 2012). However, within the current pilot trial, some participants were taking as many as 12 medications; this raised concerns regarding the potential for overmedication among participants and the barriers that this could present to a movement-based treatment. Of particular concern were participants who were taking multiple narcotic medications for pain management. Chronic opioid use within the FMS population is associated with a variety of effects, including cognitive impairment, sedation, dizziness, hyperalgesia, and impaired psychomotor functioning (Carville et al., 2008; Hawkins, 2013; Mease, 2005; Painter & Crofford, 2013). These symptoms may pose significant challenges to

participation in both the cognitive and behavioral components of the intervention. A prospective study showed that FMS patients treated with opioids reported worse symptoms and poorer functioning than non-users (Fitzcharles, Faregh, Ste-Marie, & Shir, 2013b).

Many treatment guidelines recommend against the prescription of narcotic analgesics for the treatment of FMS symptoms because of the paucity of empirical evidence for their effectiveness (Ablin et al., 2013; Traynor, Thiessen, & Traynor, 2011). Despite these recommendations, research suggests that 30% of FMS patients in North America take opioid medications (Fitzcharles et al., 2013b). In the present pilot trial, this estimate was higher, with 41% of participants taking one or more opioid medications. Based on these findings, there was concern that participants who might be overmedicated, especially those taking multiple narcotic medications, would not benefit from the intervention.

A partnership with an HMO as a primary means of recruitment might reduce the likelihood of overmedication among potential participants because many of these health care systems coordinate pharmacological care and maintain consolidated electronic medical records for patients. The use of electronic medical records has improved medication management and increased patient safety (Wang et al., 2003). In response to the concern with narcotic analgesics, it is recommended that participants who are taking narcotic medications, or who appear to be overmedicated, be required to receive written approval from their primary physician to participate in the interventions. Medications should also be monitored throughout the intervention to examine whether taking different amounts and forms of medications produces different treatment outcomes.

Other potential treatment barriers. Over the course of this pilot trial, concerns emerged regarding potential treatment barriers related to cognitive functioning, personality disorders, and behavioral responses to pain. Within the exposure intervention, notable cognitive difficulties were observed among participants who received scores on the Montreal Cognitive Assessment (MoCA) that were suggestive of cognitive impairment. Scores below 21 have been found among patients with diagnosed Alzheimer's (Nasreddine et al., 2005). In the present study, scores that fell into this range were only found among participants who dropped out of the exposure intervention[4]. One participant who struggled to understand and participate effectively with the cognitive components of the intervention was participant 21. Her struggles were one of the reasons that cognitive screening was incorporated into the pilot trial, and she received a score of 13/30 on the MoCA.

Cognitive dysfunction, in the form of concentration difficulties and short-term memory loss, is commonly experienced among patients with FMS and has been coined "Fibro-fog" (Wolfe et al., 1990; Bennett, 2009; Hawkins, 2013). Given the common experience of cognitive dysfunction within the FMS population, it should be expected that attention, concentration, and memory difficulties might arise among participants. Participants who reported having difficulties with the cognitive portions of the intervention and those who dropped out of the exposure intervention were also more likely to have scores that fell below average MoCA scores found in the FMS population (i.e., M = 23.6, SD = 3; Borg et al., 2014). For instance, of the participants who dropped

[4] This is with the exception of participant 33, who had a MoCA score of 8, which is not considered an accurate reflection of his cognitive functioning based on his observed cognitive functioning, as well as his educational background and employment history.

out and who completed the MoCA, 75% scored below that average of 23.6 (M = 22.14). Given the concern regarding the impact of cognitive impairment and evidence found in this trial, it is recommended that future participants be screened for their cognitive status using the MoCA, and that those who score more than one standard deviation below the norm in the FMS population should be excluded. This would mean that participants with scores of 20.6 or below would be considered ineligible for participation.

There was also concern among members of the research staff that some participants may have had personality styles that interfered with treatment; therefore, the Standardized Assessment of Personality-Abbreviated Scale (SAPAS) was included as a measure to assess for the presence of personality disorders. Scores suggested that more than half of the sample (65%) would meet criteria for at least one personality disorder. A review of past cognitive and behavioral intervention studies indicated that it is not common practice to screen for and exclude participants based on the presence of personality disorders. In addition, a literature review suggests that no therapeutic intervention studies with FMS patients have conducted a psychiatric interview within their screening procedures (Bernardy, Fuber, Kollner, & Hauser, 2010).

Personality disorders are relatively common within the FMS population. Rose et al. (2009) examined the prevalence of psychiatric conditions among outpatients with FMS. They used the Structured Clinical Interview for DSM-IV (SCID II) and found that 46.7% of participants met diagnostic criteria for one or more personality disorders, including obsessive-compulsive personality disorder (30%), borderline personality disorder (16.7%), and depressive personality disorder (16.7%). Using the same methods, Uguz et al. (2010) found similar results, with a greater prevalence of personality

disorders among FMS patients than among control participants. That is, DSM-IV Axis II disorders were found among 31.1% of FMS participants and only 13.3% of controls (obsessive compulsive personality disorder - 23.3% vs. 3.6%; avoidant personality disorder - 10.7% vs. 2.4%). Given the high incidence of personality disorders within the pilot trial sample, and the high prevalence within this patient population, it is recommended that individuals with personality disorders not be excluded from participation in the study. Excluding FMS participants with personality disorders would limit the generalizability of findings. Instead, personality disorder screening could be included in the study to examine how treatment trends differ as a function of personality profiles.

A third concern that emerged over the course of this pilot trial was that several participants in the exposure intervention condition reported that they engaged in overactivity, instead of avoidance of physical activity, in response to pain-related anxiety. These participants also reported difficulties with identifying activities that they avoided. They reported that they typically ignored the pain while engaging in activities until it became so severe that they were unable to engage in future activities for a prolonged period. These participants did not appear to fit the profile of someone who is fear-avoidant, despite meeting criteria for pain-related anxiety and/or kinesiophobia.

This pattern of findings has been investigated in past studies. Clinical and experimental studies have shown that high fear of movement, pain, or injury does not necessarily lead to increased avoidance (Hasenbring & Verbunt, 2010). In an intervention study, Van Koulil et al. (2010) classified participants as pain avoiders and pain persisters, based on a semi-structured interview (i.e., clinical judgment) and a self-report measure of

pain behavior (i.e., Goldenberg et al., 2004; van Koulil et al., 2008). Instead of avoiding pain, pain persisters minimize or avoid thinking of pain and continue to engage in activities even in the presence of severe pain (Hasenbring & Verbunt, 2010; Rosenstiel & Keefe, 1983; Van Koulil et al., 2010).

After classification of participants into these categories, Van Koulil et al. (2010) delivered interventions tailored for the two behavioral patterns. Treatment for pain avoiders focused on increasing engagement in daily activities and reducing behavioral avoidance, whereas treatment for pain persisters focused on activity pacing and reducing overactivity. Both of these interventions incorporated cognitive restructuring of either avoidance-related thoughts or pain-persistence thoughts. The results showed that tailoring treatment to these unique profiles led to clinically relevant changes in pain, fatigue, disability, anxiety, and mood, which were maintained at a 6-month follow-up assessment.

An avoidance-endurance model (AEM) of pain has been proposed to account for the presence of fear-avoidance and fear-persistence behaviors as separate mediators of later development and maintenance of disability and chronic symptoms (Hasenbring & Verbunt, 2010). In this model, a subgroup of pain persisters was hypothesized to first experience heightened anxiety in the presence of pain, and then engage in thought suppression and task persistence (i.e., a distress endurance response pattern). Individuals who fit this profile were thought to be at greater risk of over-engaging in activities and of experiencing increased pain, fatigue, and musculoskeletal injuries, which can lead to heightened peripheral and central sensitization (Busch et al., 2011; Hasenbring & Verbunt, 2010). Hasenbring and Verbunt (2010) suggested that individuals who fit the

profile of a pain persister, even in the presence of anxiety, would not benefit from an exposure-based treatment approach and would be more likely to benefit from other cognitive-behavioral strategies, such as reducing engagement in thought suppression.

Consideration should be given to incorporating the Patterns of Activity Measure-Pain (POAM-P) as an eligibility screening measure to identify individuals who are overactive in response to fear of pain. Cane et al. (2013) used this measure to assess pain responses in a chronic pain sample, and defined the 'Overdoing' profile based on a mean subscale score of 22.3 (SD = 8.3). It should be noted that many participants in this pilot trial had scores that were close to this mean; however, their profiles on the other subscales suggested that they also engaged in avoidance and/or pacing behaviors. Although individuals might engage in various behavioral coping strategies, the exposure intervention is unlikely to benefit individuals whose primary coping strategy is pain persistence. To identify these individuals, one could define a cut-off score that is greater than one standard deviation above the mean score for pain persisters reported by Cane et al. (2013). In addition, the individual's avoidance subscale scores should be examined to determine whether or not he or she also engages in notable levels of avoidance. Participants who have 'overdoing' subscale scores that are 1 SD above the mean (i.e., 30.6 or greater) *and* 'avoidance' subscale scores that are below the mean found by Cane and colleagues (M = 23.9) could be considered ineligible for participation. This may allow for the identification of participants whose primary behavioral response to pain is 'overdoing' or pain persistence, without screening out participants who might also actively engage in avoidance behaviors. Individuals with such a profile are not best

described by the fear-avoidance model and are unlikely to benefit from an exposure-based intervention.

Co-Intervention: No Changes Needed, Continue to Monitor. Within the present pilot trial, there was a high prevalence of medication use to reduce FMS symptoms and to improve mood; however, very few participants were being treated medically for anxiety, which was the primary symptom targeted in the exposure intervention. This finding is promising for the larger-scale RCT, because co-intervention concerns are minimal; it appears that anxiety might be an undertreated symptom within this subgroup of the FMS population and may be amenable to cognitive-behavioral intervention.

Randomization Procedures: No Changes Needed. The randomization procedures were acceptable to participants, given that the vast majority of eligible individuals agreed to participate in the random assignment process and attended at least one intervention session. A blinded, sampling-with-replacement technique was employed because it was anticipated that the two intervention conditions would have differential attrition rates. Sampling with replacement allowed for a greater number of participants to be assigned to the exposure condition, where attrition was a particular challenge. The random assignment method failed to distribute demographic characteristics, including age and cognitive functioning, equally between the two interventions; however, this may be expected with a small sample size. In an RCT, a larger sample should effectively distribute demographic characteristics between groups.

Assessment Measures

Assessment battery: Minor changes needed. The assessment battery appeared to be acceptable to participants, because all measures were completed. The only recommended change is to include the POAM-P (measure of behavioral pain responses), MoCA (measure of cognitive functioning), and SAPAS (personality disorder screener) within the baseline assessment battery and to continue to include the POAM-P in all assessment time points to determine whether behavioral responses to pain change as a result of the interventions.

Individual questionnaires: Minor changes needed. Five questionnaires in the assessment battery were not completed in their entirety (i.e., PHQ-9, SOPA, PASS-20, POAM-P, Program Evaluation). An examination of irregular responses (i.e., missing responses, double-answer responses, write-in responses) highlighted some issues that should be addressed in a future trial, which are described below. In addition, it is recommended that research assistants be trained to scan each questionnaire to identify any irregular and/or missing responses and to ask participants about these items before the end of the assessment session.

On the PHQ-9, a measure of depression, participants frequently left the final item blank. This item was presented in a different format and separated from the previous nine items. Thus, it is recommended that the final item be moved closer to the previous items to make it more visible to participants. There were also missing items on the SOPA, PASS-20, and POAM-P; however, there was no clear pattern of omission. This suggests that there was no particular item that was unacceptable to most participants. This might also indicate that that the questionnaire formatting might contribute to items being

unintentionally missed. It is recommended that spaces between numbered items be enlarged to ensure that participants do not miss items. On the POAM-P, an additional recommendation is to include instructions at the top of the page to ensure that participants understand what is expected of them. The instructions recommended by Cane et al. (2013) include, *People who have pain use different ways to do their daily activities. Think about how you usually do your daily activities*. The following sentence might clarify the instructions further: *Indicate the extent to which each statement below applies to you, using a 5-point scale ranging from 0 (not at all) to 4 (always).*

On the program evaluation, items 10 a-e appeared to be unacceptable to participants, who frequently left the items blank or wrote 'N/A' in the margins. This item asks participants to rate the degree of helpfulness of various aspects of the interventions. This suggests that some items were not relevant to one or both interventions. It is recommended that two versions of the program evaluation be made, with customized versions of items 10a-e that are relevant to each intervention. For the exposure intervention, the following items are recommended for inclusion: Workbook, In-Session Behavioral Experiments (exposures), At-Home Behavioral Experiments, and Communication with Facilitator. If the education intervention is used as a comparison group in the future, the following items are recommended: Workbook, In-Session Educational Material, Homework, and Communication with Facilitator. For both versions of this measure, it is also recommended that N/A answer options be added so that participants who dropped out of the intervention prior to engaging in the various intervention components would be able to respond appropriately.

Feasibility and Acceptability of the Intervention

The results showed that the exposure and education interventions each had problems and significant changes are needed in both conditions. For the exposure intervention, there were significant concerns regarding attrition, the length of the intervention, and the duration of sessions. Within the education intervention, there were concerns regarding the length of sessions. In addition, there was concern that the education intervention led to improvements in the mechanisms within the fear-avoidance model (fear, avoidance, catastrophizing). This suggests that the education intervention might actively target fear-avoidance and, therefore, does not appear to be an appropriate comparison condition.

Exposure Intervention

Attrition and adherence: Moderate changes needed. A significant number of participants in the exposure intervention condition dropped out. This is a common problem in graded in-vivo exposure intervention trials (Arch & Craske, 2009). Among patients with chronic pain, attrition rates in exposure interventions range from 29% to 58% (e.g., Leeuw et al., 2008; Linton et al., 2008; Woods & Asmundson, 2008). Interventions that require participants to engage in physical activity also report high dropout rates, with post-exercise pain and stiffness aggravation being commonly cited as reasons (Richards & Scott, 2002).

The exposure intervention attrition rate was high (78%). Most of the dropouts occurred immediately after the first two intervention sessions, but before the participants engaged in exposures. Two proposed modifiable reasons for these early, pre-exposure withdrawals include: 1) lack of participant identification with aspects of the intervention,

and 2) heightened anticipatory anxiety with associated decline in motivation to continue to participate.

During the first intervention session, some participants reported that they did not understand that the intervention would focus on their pain-related anxiety. Thus, there may have been a subset of participants who dropped out after the first sessions because they were not interested in or prepared to participate in an anxiety-based treatment. In addition, several dropouts stated that they did not believe that the intervention was appropriate for them because they did not avoid activities, but instead tended to be overactive. It was the presence of these individuals that led to the inclusion of the POAM-P to assess the presence of pain persistence. Overall, there was concern that additional steps need to be taken to ensure that participants are fully informed about the nature of the interventions and the reasons for their eligibility.

To address the potential concern that participants lacked adequate information regarding the intervention prior to random assignment, it is recommended that changes be made to the intervention description. In the pilot trial, potential participants were told that one of the interventions to which they might be assigned was a movement-based intervention that was designed to improve physical functioning by gradually increasing engagement in avoided activities with a trained interventionist. It is now recommended that the intervention be described as a therapeutic treatment focused on reducing fears and worries related to movement and pain, which involves testing worries and concerns, and performing avoided activities in a safe and monitored environment. In addition, they should be told that the intervention is designed for those who avoid some activities because of their worries and pain-related fear of movement. After the baseline measures

are taken during the phone screening, individuals should be informed of their scores on the TSK, PASS-20, and POAM-P. The research assistants should also tell the participant how to interpret their scores and why the scores might qualify them for participation in the study. The potential participants should be asked to provide verbal indication of their understanding of the nature of the intervention and the reason for their eligibility. This would provide an opportunity for individuals to decline to participate in the remainder of the eligibility screening process, thereby reducing the number of dropouts early in the intervention.

Alternatively, some participants may have dropped out of the exposure intervention because of heightened anticipatory anxiety prior to the first exposure. It often took three or four sessions to engage the participant in the first exposure, and many of the dropouts occurred after the session in which an activity was chosen and an exposure was planned. Although the cited reasons for withdrawal in the exposure condition alluded to illness and mental health as the driving forces, the large proportion of participants withdrawing immediately before the first exposure session suggests that the nature of the intervention and associated anticipatory anxiety might be one reason for their withdrawal from the intervention. Early in the therapeutic process, people have not yet experienced the benefits of exposures, and thus are faced only with heightened anticipatory anxiety (Arch & Craske, 2009). Behavioral avoidance is the most common behavioral response to anxiety and worries about pain (Hasenbring & Verbunt, 2010). It is important that efforts be made to maintain participant motivation to continue in the intervention long enough to engage in the exposures, which are designed to treat anxiety.

One potential way to support participants in maintaining motivation in the early sessions leading up to the exposures is to have them select valued activities for the exposures. Engaging in values-oriented actions has been shown to increase engagement in avoided activities and to contribute to reductions in pain-related anxiety among chronic pain patients (Vowles & McCracken, 2008). Incorporating values into the selection of activities might have the effect of connecting the participants with meaningful reasons for continued participation. The identification of valued activities was only informally introduced in the pilot trial, and it is recommended that this be a core component of the intervention protocol. That is, activities should either be ones that the participant values or activities that will allow him/her to gain skills and abilities to participate in valued activities in the future. The activity selection process could start with identifying value domains that are important to participants (e.g., relationships, health, spirituality, personal growth), and then generating ideas for physical activities that fall within the categories. This might help participants to see the activities as having greater significance or purpose in their lives.

Another recommendation is to incorporate motivational interviewing (MI) techniques in multiple sessions to directly address participant motivation. The MI techniques are designed to make participants aware of their level of readiness for change, often referred to as their *stage of change* (e.g., pre-contemplation, contemplation, preparation, action, maintenance). MI is commonly used in working with patients who are contemplating or preparing for change, but are not yet actively engaged in behavioral change (DiClemente & Velasquez, 2002). Incorporating MI can provide therapeutic structure for building awareness of one's stage of change, for considering the benefits and

costs of change, and for building commitment around change (DiClemente & Velasquez, 2002). For instance, it might be beneficial to incorporate the 'readiness ruler' at the outset and/or end of each session as an assessment of the participants' current level of motivation and stage of readiness to change. This would involve having participants rate their level of 'readiness' to engage in the therapeutic process, with discussion regarding their score (i.e., why it is not higher or lower). Any significant change in their weekly score, indicating a reduction in motivation to continue, might warrant a review of their decisional balance (i.e., benefits and costs of current behavioral avoidance vs. change) and discussion regarding the participant's decision on how to proceed. Overall, these strategies might reduce early attrition. However, attrition is likely to remain high in the RCT based on the findings of this pilot trial and the high attrition rates found across exposure-based interventions and physical activity interventions. As such, high attrition should be factored into determining the sample size needed.

Of those who participated in the intervention for multiple sessions and completed at least one in-vivo exposure, the majority completed the exposure activities assigned to them both inside and outside of the sessions, suggesting that the exposures were acceptable to many participants. Participants who completed an exposure expressed comprehension of the instructions and demonstrated motivation to complete many of the assigned exposure activities. It appears that no changes are needed to the instructions or design of the in-session and at-home exposures.

Intervention length and session duration: Significant changes needed. The exposure intervention was designed to be delivered within 13 weekly sessions, with the first session lasting 90 minutes and the remaining sessions lasting 60 minutes. There were

two significant challenges related to delivering this intervention as planned. First, the 60-minute time frame allotted for the weekly sessions proved to be too short to deliver the intervention content effectively. It was not enough time to plan, perform, and cognitively process an in-session exposure. This duration did not adequately account for the additional time needed to incorporate an activity-pacing plan into the exposures.

Although activity pacing is not a typical component of exposure-based therapies for anxiety disorders, it was deemed necessary for people with FMS. It was incorporated into the exposure intervention to help reduce the likelihood that participants would be overactive and experience heightened pain while performing the exposures. Activity pacing reduces the likelihood of pain flare-ups among FMS patients (Karsdorp & Vlaeyen, 2009; Nisell & Kosek, 2011) that predict avoidance behaviors (Hawkins, 2013; Sprott, 2003). A positive result of incorporating activity pacing within the exposures was that all participants reported that they did not experience any significant increase in pain during the in-session and at-home exposures. However, the inclusion of this additional treatment component meant that some exposures could not be performed within a session, that some exposures were interrupted before the participant was able to experience reductions in anxiety, and/or that there was often not enough time to process the exposure immediately after it was performed. This interruption disrupted the therapeutic process and made it nearly impossible to deliver the components of in-vivo exposure therapy in their empirically supported forms. It is suggested that activity pacing continue to be incorporated into the intervention protocol; however, pilot testing is recommended to determine the amount of time needed to deliver all aspects of the in-vivo

exposure (planning, performing, processing) effectively within the context of a session. It appears that 90 to 120 minutes are needed to deliver all treatment components.

The second challenge that was encountered was in delivering the exposure intervention within 13 sessions and within a reasonable time frame (i.e., within 17 weeks). Among treatment completers, the total number of sessions ranged from 9 to 14, and took between 15 and 22 weeks to complete. Given the variability in participants' anxiety levels, it is not surprising that participants differed in their treatment needs. However, this variability may necessitate changes in the current protocol. Changes to the number of sessions are advisable. With the suggested increase in session length from 60 minutes to 90 or 120 minutes, it is expected that most participants would need fewer sessions. The 13 sessions in the protocol were designed to be delivered within 13.5 hours. If sessions are increased to 90 minutes, it is possible that 12 hours of therapy could be delivered in eight sessions. If sessions were increased to two hours, six to eight sessions might be sufficient. When examining the treatment trends within this intervention condition, the most notable changes appeared after the first six sessions, which adds further support to this proposed modification.

Given the variability in treatment need and in the number of sessions delivered to participants, booster sessions should be considered to promote maintenance of learned skills and to support those who need more assistance in incorporating skills into their daily life. Booster sessions are often incorporated and recommended within cognitive behavior therapies (Whisman, 1990). Past exposure-based intervention studies have incorporated up to three booster sessions, based on patient need, which often took place

between one and six months after the intervention's completion date (e.g., Clark et al., 2003; Clark et al., 2006; Vincelli, Choi, Molinari, Wiederhold, & Riva, 2000).

In summary, it is recommended that the individual sessions be extended to either 90- or 120-minutes, and that the overall number of sessions be reduced to between six and eight, as indicated by additional pilot testing. Booster sessions are recommended, with the exact number tailored to participant need and interest.

Treatment trends. In the exposure condition, treatment trends suggest that participants experienced improvements in the various mechanisms of the fear-avoidance model that were proposed to increase the risk of disability and depression. That is, levels of kinesiophobia, pain-related anxiety, pain-related catastrophizing, and intensity of fear-avoidance beliefs decreased from baseline to later assessment times, with confidence intervals suggesting that notable improvements in pain-related anxiety, FMS-related self efficacy, and health status occurred during the first 6 weeks.

Participants were screened for levels of kinesiophobia and pain-related anxiety to determine their eligibility for participation. In a larger trial examining treatment efficacy, one goal might be to determine whether participants' scores on associated measures fall below study eligibility criteria by the end of the intervention (i.e., TSK score < 40, PASS-20 score < 55). This would suggest that the participants would no longer be eligible for study entry and that their current symptoms indicate that further treatment is not clinically indicated. With regards to changes in kinesiophobia, the mean score on the TSK suggested that the average participant was still experiencing moderate levels of movement-related fear and would still meet the eligibility criterion for entry in the intervention. However, the mean changes in scores represent a decrease over time, which

suggests some symptom improvement. Although the TSK assesses movement-related fear and is the most commonly used measure of kinesiophobia, it lacks sensitivity and does not assess fear related to any one specific movement or activity (Pincus et al., 2010). This means that one can score high on the TSK while experiencing reductions in fear related to specific activities and movements. While the TSK can provide insight into the degree to which one experiences generalized movement-related fear, it is recommended that additional questions be included in a larger trial to assess levels of movement-related fear associated with the specific activities targeted within the intervention. This can provide rich information regarding the extent of the intervention's reach.

Pain-related anxiety, as measured by the PASS-20, also showed trends toward decreasing over time, with the group's average level falling below the eligibility cut-off score by the end of the intervention and at the follow-up assessment. These trends were also found among the exposure intervention dropouts, and many of these participants withdrew after the first two sessions. This trend was not observed among dropouts in the education intervention. These trends may suggest that the treatment components delivered in the initial two sessions of the exposure intervention—including education about the FA model, activity pacing, and motivational interviewing— may have effectively targeted pain-related anxiety. Researchers have shown that education about fear and avoidance alone produces reductions in pain-related fear and catastrophizing, and that this impact is strengthened following later exposures among patients with chronic low back pain (Leeuw et al., 2007). In addition, motivational interviewing increases adherence to exercise programs and achievement of fitness goals (Busch et al., 2008), which may alternatively be avoided because of associated anxiety. In the present

exposure intervention, it is possible that education about fear-avoidance, activity pacing, and the inclusion of motivational interviewing targeted pain-related anxiety. If this intervention is found to be efficacious in a future RCT, a future step would be to dismantle the treatment components to identify which aspects are active in producing changes in the targeted process and outcome variables.

Through targeting the mechanisms within the fear-avoidance model, it was predicted that improvements should, in turn, be found for health status and mood. On average, participants in this intervention condition showed improvements in FMS health status, with scores on the FIQR changing toward less impact of FMS on health status. Depressive symptoms remained relatively stable over the course of the intervention. The mean score was in the moderately depressed range over the course of the intervention. This finding makes sense, given that average levels of kinesiophobia and pain-related anxiety were also still in the moderate range. It is possible that changes in depression might occur only after lasting improvements are seen in the mechanisms of the FA model. Overall, the direction of these trends provides justification for a larger trial to be conducted to examine treatment efficacy. However, treatment trends should be re-examined after changes to the intervention protocol have been pilot tested to determine whether the trends are consistent.

There were also trends indicating improved self-efficacy (of managing FMS symptoms and pain), which is not formally a component of the FA model. Although not incorporated into the FA model, self-efficacy has been negatively correlated with disability, pain catastrophizing, and kinesiophobia (Denison, Asenlof, & Lindberg, 2004)

and is an important predictor of successful engagement in exercise among individuals with FMS (Jones et al., 2009).

Overall, the findings provide sufficient evidence of positive trends to warrant investigation of treatment efficacy. However, there is a need for additional measures to assess participation in movement and physical activity. The FA model is designed to explain the development and maintenance of disability. In turn, graded in-vivo exposure therapy, which targets the mechanisms of the FA model, should improve physical functioning by increasing engagement in physical activity and reducing the effects of physical deconditioning. To assess this, consideration should be given to including measures of physical activity. There are many validated assessment tools that could be used to examine activity engagement and physical functioning, including self-report measures, wearable sensor devices (e.g., pedometer, actigraph), and observational methods. It is also recommended that a long-term, follow-up assessment be incorporated into the study design to capture changes in activity engagement and to increase the likelihood of observing associated changes in functional status that may follow.

Education Intervention: Significant Changes Needed. The education intervention was used in this pilot trial as a comparison treatment. The Arthritis Foundation currently offers this intervention to FMS patients. It was hypothesized that this intervention might lead to improvements in outcome variables (e.g., health status and mood) without directly targeting the mechanisms within the FA model (i.e., pain-related catastrophizing, fear and anxiety, escape and avoidance behaviors). However, the results suggest that the self-management education intervention was associated with changes in kinesiophobia, catastrophizing, and pain-related anxiety.

The education intervention sessions focused on FMS management, including 1) techniques for dealing with pain, fatigue, frustration, and isolation; 2) appropriate exercises to increase or maintain strength, flexibility, and endurance; 3) use of medications; 4) effective communications with health care professionals, family, and friends; 5) sleep; 6) healthy diets; 7) problem solving; and 8) informed decision making. Although no research has been conducted to show that the self-management education directly targets the mechanisms in the FA model, researchers have found that self-management education programs are effective in increasing pain-related coping skills and self-efficacy among patients with chronic illness (Lorig et al., 2001; Wagner et al., 2001). It is possible that participant fear and anxiety decreased through learning about various coping skills and building self-efficacy for managing FMS symptoms. As previously noted, self-efficacy has been shown to be negatively correlated with pain catastrophizing and kinesiophobia (Denison, Asenlof, & Lindberg, 2004). Through education focused on FMS, this information may have also indirectly challenged catastrophic thoughts by correcting misinformation or myths through the delivery of 'expert' information.

The treatment trends in the education condition appeared to be more notable than those in the exposure condition. This might be partially attributed to the baseline differences in participant functioning between the two intervention conditions. Participants in the education intervention were generally younger, had higher cognitive functioning, and were taking fewer medications than those in the exposure intervention. These differences suggest better health and overall functioning, which might contribute to improved performance in an intervention and a greater likelihood of staying in an

intervention. Overall, these findings suggest that the education intervention targeted the same symptoms as those in the exposure intervention.

It should be noted that although the education intervention was associated with improvements in self-reported movement-related fear, pain-related anxiety, and catastrophizing, there is limited information regarding its impact on engagement in avoided physical activities. To impact disability, these changes in fear and anxiety need to translate into engagement in physical activity. Although this intervention may produce decreases in fear and anxiety, it does not include a behavioral component to address the relationship between fear and avoidance, which is a necessary step toward improving functional outcomes.

Another issue with the education intervention was that the sessions were consistently shorter than planned and were also shorter than the exposure sessions. Combined with the concerns regarding the treatment content, these issues call into question the applicability of the education intervention as a suitable comparison condition for a future treatment efficacy study. These issues together suggest the need for a different comparison intervention for use in an RCT.

If the goal of an RCT is to compare the exposure intervention to another treatment that does not target catastrophizing, pain-related anxiety, and avoidance behaviors, then an attention control condition might be best suited as a comparison intervention. A comparison intervention should offer the same amount of attention as the exposure intervention, without the active treatment ingredients that are hypothesized to affect the process variables being tested. One potential option is the Stanford Nutrition Action Program (SNAP), an evidence-based nutrition intervention that teaches participants

methods of choosing and preparing foods to improve health (Howard-Pitney, Winkleby, Albright, Bruce, & Fortmann, 1997). This program was designed in a group format to be delivered within six weekly, 60-minute sessions. The PI for this pilot trial (T.C.) developed an 8-week, 90-minute version of the protocol by including an introductory session and a final review session. The benefit of this form of education intervention is that the focus is not on coping with FMS symptoms or other topics covered within the exposure intervention. There is no indication that this intervention will lead to changes in fear-avoidance variables. If the SNAP intervention were used, additional adjustments would need to be made to ensure that the protocol is feasible for delivery within one-to-one sessions. For instance, the current protocol incorporates small- and large-group interactions, which would need to be modified. To control for time and attention, it is recommended that the protocol for this nutrition intervention be designed to mirror the exposure intervention in terms of duration and number of sessions. This will require additional pilot testing to ensure that SNAP can be delivered in a manner similar to the exposure intervention and to confirm that the treatment trends show little evidence of changes in pain-related catastrophizing, pain-related anxiety, and avoidance.

Another issue to address is the between-interventionist differences in the length of sessions delivered. Additional steps need to be taken to ensure that interventionists receive the same training and that treatment fidelity is monitored. Prior to starting a new trial, it is recommended that interventionists be trained together and practice delivering the content to one another. Feedback should be given regarding inconsistencies that are observed by supervisors. Following the start of the intervention, supervisors should review all audiotaped sessions and should rate each for consistency with the protocol.

Feedback should be provided to interventionists on a regular basis. Weekly meetings with all interventionists could provide a venue for open discussion regarding challenges faced and recommendations for improvements. Overall, the treatment trends, and the challenges in delivering the education intervention as designed, suggest that this might not be an appropriate comparison treatment, and efforts should be made to pilot test a new intervention to serve as an attention control condition.

Summary of Recommendations

The results of this dissertation suggest that a large-scale RCT should be conducted to assess the treatment efficacy of an exposure-based intervention only after several modifications have been made. The most critical recommendation for study design is that a partnership with a health care organization be created so that an adequate number of participants can be recruited. With regard to the intervention protocols, significant changes to the design and delivery have been recommended for both conditions. Each of the recommended changes is outlined in table 38.

Table 38. Recommendations for modifications to the study design, procedures, and interventions

Recommendations
Study Design and Procedures
Recruitment:
· Form a partnership with a Health Maintenance Organization as a primary recruitment strategy
Eligibility Criteria:
· For individuals who appear to be overmedicated, require written permission from physician for participation
· Add cognitive screening to exclude those with scores of 20.6 or below on the MoCA
· Screen for individuals with an 'overdoing' score that is 30.6 or greater
Assessment Measures and Procedures:
· Add POAM-P, MoCA, and SAPAS to the first assessment battery
· Incorporate POAM-P into screening procedures and include in all assessments
· Apply recommended edits to the PHQ-9, SOPA, PASS-20, POAM-P, and Program Evaluation
· Assess level of kinesiophobia with additional questions about activities engaged in during exposures
· Add assessment for physical activity and functional status
· Add a long-term, follow-up assessment
Interventions
· Incorporate standardized and systematic procedures for interventionist training
· Include ongoing assessment of treatment fidelity
Exposure Intervention:
· Provide more explicit information about the exposure intervention in the recruitment materials and during the screening process
· Incorporate motivational interviewing techniques in multiple sessions, as clinically indicated
· Incorporate the selection of *valued* activities to use in exposures
· Pilot test longer sessions (90-min to 120-min)
· Pilot test smaller number of sessions
· Add between 1-3 booster sessions
Education Intervention:
· Replace this with an attention control condition (e.g., SNAP)
· Pilot test a new comparison intervention

Implications

After 30 years, researchers have provided greater insight and theories about the nature of FMS and how to approach treatment; however, more research is needed to design effective treatments and clearly define standards of care. Empirical support is growing for the perspective that FMS patients represent a heterogeneous population in terms of symptom presentation and treatment response (Okifuji & Hare, 2013; Wilson et al., 2009; Wolfe et al., 2013a). Despite this, FMS patients are typically treated as a homogeneous population, using a few commonly delivered treatments. This may account,

at least partially, for the high attrition rates and relatively modest effect sizes found across studies (van Koulil et al., 2010). Treatment should be tailored to subgroups of FMS patients and should target the mechanisms theorized to drive the development and maintenance of their symptoms.

A subgroup of FMS patients who experience significant treatment barriers is comprised of those who experience heightened pain sensitivity, catastrophizing, and mood disturbance, and who lack effective coping skills (Giesecke et al., 2003; Hawkins, 2013). Individuals in this subgroup are more likely to display poor treatment response and experience worse health outcomes than other subgroups of FMS patients (Giesecke et al., 2003). With upwards of 40% of the FMS population demonstrating pain-related fear and associated avoidance of physical activity, treatments are needed to address these barriers to engagement in effective treatment of FMS symptoms, such as moderately intense exercise. Graded in-vivo exposure therapy has been demonstrated as effective in increasing engagement in physical activity and reducing development and maintenance of pain-related disability and depression among other pain populations with heightened pain-related fear and avoidance (e.g., chronic low back pain, complex regional pain syndrome). It has been suggested that graded exposure may be one of the most effective cognitive-behavioral interventions for reducing fear avoidance and improving health outcomes in FMS patients (Nijs et al., 2013); however, no studies to date have systematically studied the efficacy of graded in-vivo exposure therapy in the FMS population.

This pilot trial was the first step toward establishing evidence for the effects of graded in-vivo exposure therapy on fear avoidance and health outcomes in FMS. Given

the significant challenges associated with designing a treatment intervention, it is necessary to formally test the feasibility and acceptability of study design, procedures, and intervention protocols prior to performing a study examining treatment efficacy. Systematic examination of feasibility and acceptability is critical for increasing the likelihood of success and reducing the likelihood of misattributed failure of a large-scale RCT. Without pilot testing an intervention prior to an RCT, null findings caused by feasibility or acceptability issues might be misattributed to treatment ineffectiveness. A pilot trial represents an opportunity to identify and address potential barriers to intervention success that ultimately improve the rigor and merit of a large-scale RCT. RCTs are used as the best evidence for treatment efficacy and effectiveness; therefore, findings hold significant implications for the future of a treatment. Further, it is important and valuable to report and publish pilot study results to inform the research community and advance knowledge in the field.

The last 30 years of research have clearly demonstrated the need for new and innovative approaches to FMS treatment and the need to shift focus from treating FMS patients as a homogeneous group to understanding and treating subgroups of FMS patients. The future of FMS treatment research will be defined by the studies designed today. To influence its direction, it is crucial that studies like this dissertation are conducted and that steps are taken to examine theoretically-based treatments designed for patient subgroups.

Appendix A: Graded In-Vivo Exposure Therapy Intervention Manual

GRADED MOVEMENT PROGRAM

Health Outcomes Laboratory

San Diego State University

Table of Contents

Introduction to the Program

Graded Movement Program is a research-based program that is built on the notion that worry about pain and limiting engagement in activities serve to maintain and worsen pain and the related symptoms. This program is centered on the following points:

1) Your pain is real and it is longstanding.
2) There are no treatments that will eliminate your pain completely.
3) Even though pain is a physical experience, there are a number of other factors that impact the experience (social, emotional, etc.).
4) Chronic pain is not a reason for inactivity.

This program is aimed at improving functioning by gradually increasing your activity and demonstrating to you that you can perform the activities you used to do in spite of your chronic pain.

We are working towards living more fully.

Treatment consists of 12, 60-minute weekly sessions. Each session will begin with a review of at-home assigned activities from the previous week, followed by the introduction of new activities. During each session, we will work on activities that you have avoided because of worry or concern about pain or movement; you will be asked to start engaging in the avoided activity in a safe environment.

Intake Session:

Chronic Pain in Fibromyalgia and Graded Movement Program

Acute and chronic pain

There is a clear difference between acute and chronic pain, both in their origins and in how the pain should best be treated. Both types of pain are explained below.

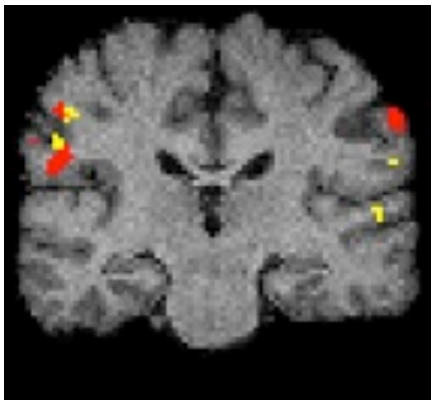
Definition of Acute Pain: A short-lived, unpleasant experience that involves both sensory and emotional components. With acute pain, there is often a clear connection between an injury and pain, and the pain only lasts for a limited period of time (less than 3 months). Acute pain serves a protective function- it tells your body to stop. Rest is appropriate for treating acute pain caused by events like overstressing of a muscle or being burned, because it increases the chances of recovery from the injury and, therefore, the pain.

Definition of chronic pain: Pain is classified as chronic when it lasts longer than expected (at least 3 to 6 months). This is pain that is not completely eliminated with pain control methods and treatments (Rest is not the best remedy). Chronic pain may exist in the absence of injury. Also, the extent of disability from chronic pain can't be completely determined from the degree of pain. People may function differently with the same amount of pain. Even when no cause of pain can be determined, pain may strongly influence one's life. Pain sufferers may need help from others. Feelings of helplessness, uncertainty, and desperation may result.

Physiology of fibromyalgia pain

Although there is still a lot that is unknown about the origins of fibromyalgia pain, there is growing research that supports that this is a physical experience. Research has shown that individuals with fibromyalgia have lower pain

thresholds and process pain more intensely than individuals without fibromyalgia. It is almost like there is an amplifier inside of you that intensifies pain.



This x-ray picture is from a study where light pressure was applied to people with and without fibromyalgia. For fibromyalgia participants, light pressure led to intense pain, as can be seen by the red areas of brain activation in pain centers of the brain. Participants without fibromyalgia showed less activation when the same amount of pressure was applied, as can be seen by the yellow areas. Participants without fibromyalgia only showed the same level of brain activation as those with fibromyalgia when much greater pressure was applied.

Although fibromyalgia pain is a physical experience, studies show that physical, thought-related, emotional, and social factors affect pain severity.

Factors that can increase pain:

1. Physical factors:
    a. "Readiness" of nervous system to receive pain signals
    b. Over-activity
    c. Lack of movement/decreased activity
2. Thought-related factors:
    a. Hyper-focusing on pain
    b. Boredom
    c. Worries about pain
3. Emotional factors:
    a. Stress
    b. Depression
    c. Anxiety
4. Social factors:
    a. Isolation
    b. Negative reactions of others

Lack of movement/reduced activities

Many people see rest as their best hopes for controlling chronic pain or preventing injury. However, that is a misconception. As we explained above, there is a clear difference between acute and chronic pain.

For acute pain, it is wise to rest the body, so it can recover from injury.
For chronic pain, there is no immediate injury or damage to the body. If you do nothing, rest, and do not move, it will lead to worse pain. Although inactivity offers protection in the short term for acute pain, it has the opposite effect in the long term for chronic pain and tends to increase the pain ("**Rest Rusts**"). A decrease in physical activity and active functioning because of the pain usually leads to separation from other people, isolation, reduction in hobbies, and depressed mood. Because of this cycle, chronic pain plays an important role in life; it becomes the center of attention because there is less and less to distract from the pain. Studies show that depression, worry, and excessive attention to pain can actually increase the pain experience!

Worries about the pain

It appears that the worries people have about pain can play an important role in how they deal with it and how they react to it. For instance, if someone interprets his or her pain to be a sign that something is wrong, the response is likely to be one of limiting activities that he/she believes might bring on the pain. If a person thinks that the pain is caused by something innocent and that movement is good for the pain, he or she will remain active.

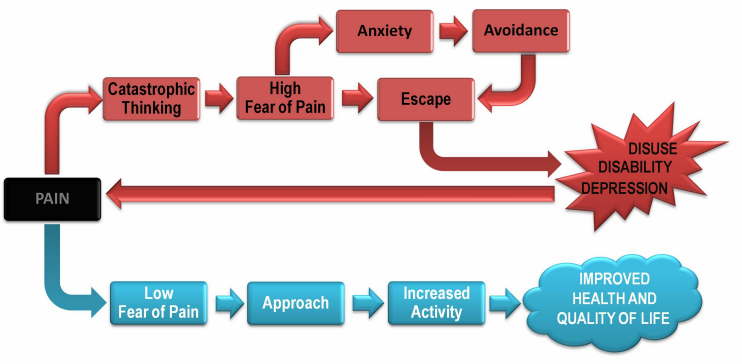
People with pain often expect to experience a strong increase in pain as a result of a wrong movement or expect that the activity will damage the body. Pain is interpreted as a cue that something bad is happening. These thoughts lead to

worry or anxiety about doing particular movements. Because of this anxiety or worry about increased pain, particular movements and activities are avoided. People are not always aware of these views, but expectations of increased pain can play an important role in reducing activity. It is important that you do not stop activity.

Vicious cycle

Thoughts about pain and the resulting worries about it can lead to a negative spiral that maintains the pain experience. Thoughts and worries about the consequences of specific movements can mean that an individual engages in less and less activity. Avoiding or decreasing movement can lead to a worsening of the pain. The body becomes used to inactivity, which makes it more difficult and painful to engage in the activity in the future (Remember: **Rest Rusts**). Therefore, people with pain often experience loss of hobbies, greater dependence, and depressed mood. In addition, the worry about increasing pain leads to directing more attention towards the pain. These consequences guarantee that people are more worried about activity, which makes them more sensitive to pain.

This is the **vicious cycle**. The consequences of the worry about pain and movement maintain the cycle (reduced activity, worse condition, depressed mood, excessive concern about pain).



Let's look more closely at these two paths. Following the red path, someone experiencing pain may begin to have negative thoughts that grow and grow (e.g., "I will never get better"; "How can I live like this?!"). This type of thinking leads to increased pain-related fear and safety-seeking behaviors, like avoiding movements or escaping from painful situations. Though avoidance and escape can be good for someone experiencing acute pain (e.g., pulling your hand off of a hot burner on the stove), it actually worsens the experience of pain when it is chronic. Continuing to avoid activities or movements leads to greater disability, changes in the way the brain perceives pain, weakness in muscles and other body parts that benefit from being used, and often leads to depression. All of these things make it more likely that the pain and fear of pain will persist.

The blue path starts with a different approach to the same pain experience. Someone following this path would not think of pain as a barrier to doing the things he or she wants and can physically do. This means experiencing a level of *adaptive* fear, while choosing to engage in activities, which ultimately leads to greater overall functioning and prevents decreased physical and emotional well being.

Fibromyalgia and Movement

A great deal of research shows that exercise and frequent movement leads to reduced pain intensity, improved physical fitness, and greater quality of life and well-being in people with fibromyalgia.

Engaging in more movement when you are experiencing pain seems counter-intuitive and might bring up concerns about safety and fears of worsening pain. This often leads to less activity and the "vicious cycle". For this reason, we are going to target safely increasing activities and also reducing fears of pain and movement.

The program

Unfortunately, there is no medical treatment that can completely eliminate fibromyalgia pain. You may have already tried a number of treatments in the past with little-to-no effect. Studies show that many of the available treatments for fibromyalgia syndrome produce small effects. The available treatments may reduce pain and increase functioning, but they are short lasting. The medical community suggests that movement is generally good for chronic pain, even though it can feel like it is not good for it. Movement can help; in this program, you will work towards increasing your activity level, which increases your functioning and is likely to produce good results.

Chronic pain is NOT a reason for inactivity

When chronic pain is a part of your life, it can become hard to know what activities are safe to do *with* pain. We are taught to assess safety of an activity based on acute pain, but this is no longer an accurate method when you live with chronic pain. In other words, chronic pain does not signal injury or harm. If you allow pain to serve as an indicator of whether or not to engage in an activity, you are likely to be limiting yourself. In order to live your life fully, it means *living* with the pain.

Functioning in the context of chronic pain

This program is directed toward getting people to do everyday activities that are avoided because of fear of pain even though they may include pain.

There are factors that play a central role in maintaining and worsening pain, including worry over pain and reduced activity and movements. The goal of the therapy is to lessen the worry and gradually increase movement and activities that are associated with the fear of pain. This is called “graded exposure in vivo.”

Even though gradually increasing activity might come with a temporary change in pain level, it actually has a favorable long-term effect on chronic pain and functioning over time. The model (Figure 1) shows that people who are quick to stop activities and movements are likely to suffer the vicious circle of bad effects.

Behavioral Experiments

Because worrying over the possible consequences of the activity plays an important role in the pain experience, this will be discussed within the sessions. During exposure to activities, you will test your expectations and worries to see how accurate they are. This is a kind of *behavioral experiment*. The result may be that your worries lessen and that avoiding activity is unnecessary because the activity is harmless, even if it comes with pain. You may conclude that pain is not a reason for inactivity. Hopefully, you will realize that you can do more than you think.

The program is responsible and *safe*. Your increased engagement in activities will be gradual. It is possible that the pain will increase during the treatment because certain muscle groups might not have been used for a while. This increased pain or muscle soreness will disappear after a while and is harmless. Through gradually increasing activity and finding that pain is no reason to decrease your activities, the goals will slowly be reached and functioning should improve.

We wish you great success with the program! If you still have questions about the meaning of the information above, don’t hesitate to ask your programist.

Motivating Treatment

Increasing your movement and engaging in more activity when living with chronic pain is not an easy task and is likely to occur with mixed feelings. It is important to become fully aware of your views about making behavior changes and views about staying the same. This can provide you and your programist with helpful information about your starting point.

Fill in the table below with the advantages and disadvantages connected with your current state (decreasing activity because of your pain or worry) and with the possibility of carrying out all daily activities despite the pain. In other words: what are the advantages and disadvantages for reducing activity? And what advantages and disadvantages do you see for engaging in more activity?

	Benefits/Pros	Costs/Cons
Increasing activity		
Not changing level of activity		

Set up your activity list!

Together with your programist, you are going to discuss a variety of daily activities, and prepare a list of activities that you perform more or less because of worries related to fibromyalgia pain. You probably value some of these activities more than others and there may be additional activities that you avoid that are not on the list. Make sure to share these with your programist to see whether they can be incorporated into the sessions.

You can use the space below to list the activities that have been selected to be included in the program and their corresponding worry scores in order from most (10) to least (1) worrisome:

ACTIVITY/MOVEMENT	SCORE
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Session 1

Explanation of behavioral experiments

The goal of this program is to teach you how to resume or increase your daily activities that have been reduced or avoided because of fear of pain. Your worries or anxiety about the possible consequences of movement play an important role in how you choose to live your life. Your anxiety and worry should decrease as you gradually resume activities and movements safely.

Worry occurs whenever you *think* about movements or activities. Many people avoid or limit their activities or only perform adapted versions of activities because of the fear they have about the consequences for health and safety.

During the program, together with the programist, you will gradually start performing the activities that you may have avoided to some degree. Following this, you and your programist are going to process this experience to test the accuracy and helpfulness of automatic beliefs and worries about the consequences of your movements. In other words, is it really true that you *should not* engage in certain activities? Perhaps you can do more than you thought, despite your fibromyalgia pain.
This will occur gradually. You will start with activities that do not cause you a great deal of worry. Together with the programist, you will choose an activity from those you listed that cause you mild-to-moderate worry for pain.

Together with your programist, you will choose an activity from your life (page 11) and perform a *behavioral experiment*. A behavioral experiment is a test of whether your thoughts/worries about performing an activity are correct. For

carrying out a behavioral experiment, you will follow the steps that are outlined below:

1. Selecting an activity: Choose an activity from your list that you are mildly-to-moderately worried about doing because of fibromyalgia pain (worry score of 4 or 5 out of 10).
2. Make a concrete plan: Make a clear plan with the programist for exactly how the experiment will be carried out. Describe the activity as specifically as possible. For example, how frequently must the activity be repeated? How intensely must it performed? How long must it be done? Where and when will it be done? etc.

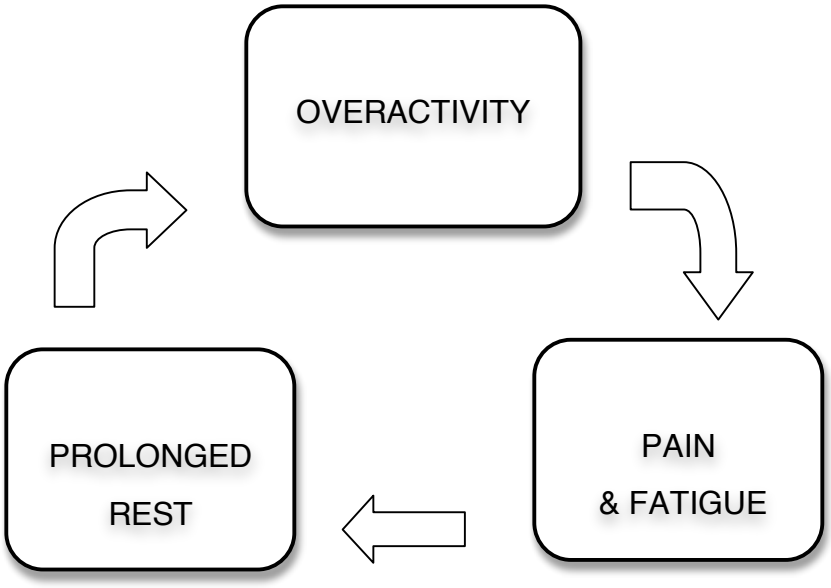
3. Catastrophic thoughts: What do you expect will happen if you carry out this activity? What are you worried about? We call these *catastrophic thoughts*.
    a. Believability of the catastrophic thoughts: On a scale from 1 to 10, rate how much you believe each catastrophic thought before you engage in the activity.
    b. How much worry do you have **before** carrying out the activity: On a scale from 1 to 10, rate your fear of engaging in the activity because of pain.
4. Alternative thoughts: What else could happen if you perform the activity? Try to come up with alternative thoughts, where the movements would have a neutral or positive outcome. We call these *alternative thoughts*.
    a. Believability of the alternative thoughts: On a scale from 1 to 10, rate how much you believe these alternative thoughts.
5. The programist does the activity.
6. You do the activity. While you do the activity, check in during the activity about half way through to see how you are feeling.
    a. Continue engaging in this activity until your worry rating decreased by at least 50%
7. Evaluate how the exercise went:
    a. Believability of the catastrophic thoughts after the experiment: evaluate how strongly you believe in these thoughts after the experiment.
    b. Change in the believability of the catastrophic thoughts after the experiment: calculate the difference from before to after.
    c. Believability of the alternative thoughts after the experiment: evaluate how strongly you believe in these thoughts after the experiment.

   d. Change in the believability of the alternative thoughts after the experiment: calculate the difference from before to after.
   e. How much worry do you have **after** carrying out the activity: On a scale from 1 to 10, rate your fear of engaging in the activity because of pain.
   f. How much worry do you have if you were to carry out the activity **in the future**: On a scale from 1 to 10, rate your fear of engaging in the activity because of pain.
   g. Personal evaluation of the behavioral experiment: how did the experiment go?
8. Evaluate how the overall behavioral experiment went and how the next experiment should be planned:
   a. Set up the same activity and action plan or similar one on the homework sheet to practice behavioral experiments throughout the week.
   b. Choose a new activity from the list. You can choose an activity that gives you similar or more anxiety/worry than the previous one. The next session's behavioral experiment will be carried out with this new activity.

Activity Pacing

When we engage in activities, we usually go into them with the mindset that we will continue the specific activity until it is complete. Some activities can take a long time (e.g., cleaning out the garage, yard work), and on some days, when pain is less severe, you might take on more and work for as long as it takes to complete what you started. This might leave you in a state of exhaustion and increased pain. To recover, you might find that you need to rest for a long period and might not be able to get back to any activity until after a prolonged period. This example shows how *over*activity can exacerbate pain and fatigue, leading to prolonged rest and reduced activity over time.

Pain & Fatigue Cycle

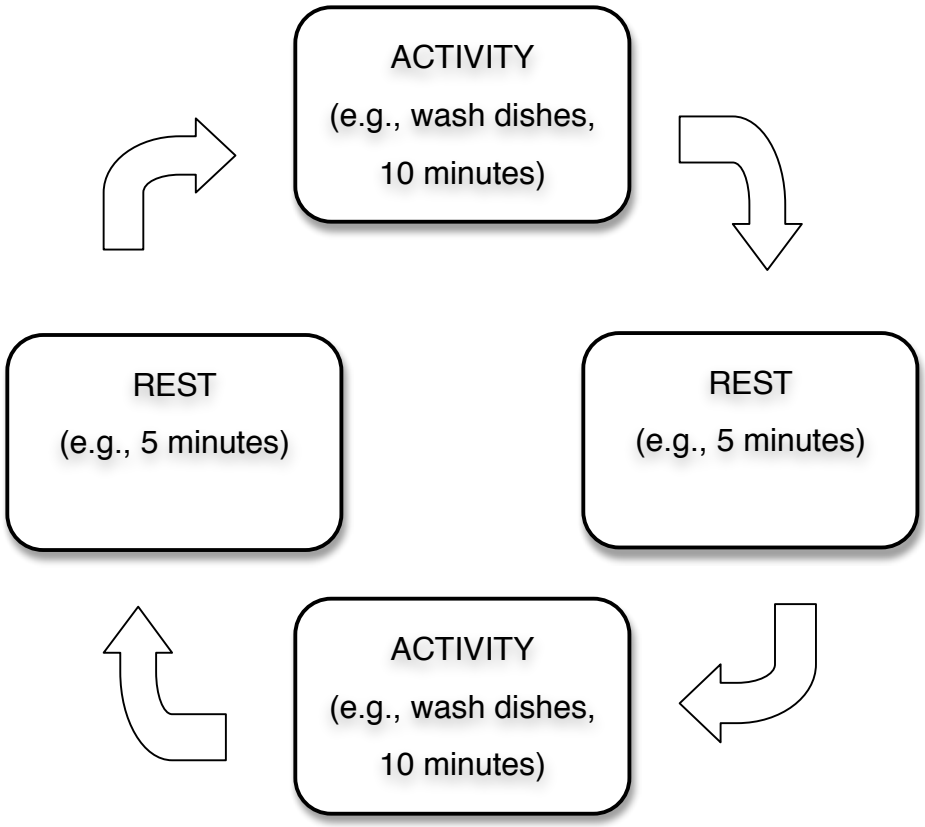


It is understandable how and why people get caught in this Pain & Fatigue cycle. We might get stuck because we need to take care of tasks or we value being active. The unfortunate effect of this cycle is that it leads to *less* productivity, *less* activity, and all together *more* frustration.

How can we break the cycle?
PACING activities is a way to break this cycle. To successfully pace activities, you need to gain a solid understanding of the activity you will partake in, how it affects your pain, and how long you can effectively participate in the activity without impacting your pain.

For example, someone may take on the task of washing dishes until all the dishes are done (e.g., about 30 minutes) and find that after 15 minutes of dish washing, his/her pain increases from 4 to 6 on scale of 1-10, and further increases from 6 to 8 after the activity is complete (30 minutes). In this example, pacing would mean washing dishes for 10 minutes, stopping *before* pain increases, and then resting for 5 minutes. After the rest period, he/she would return to the activity for another 10 minutes, followed by 5 minutes of rest, and so on.

Activity & Rest Schedule



With pacing, your focus is not on task completion, but on ***time*** when planning out your activity. Research has shown that this can lead to fewer daily spikes in pain, which is one way to help break the Pain & Fatigue cycle. Figuring out the best Activity/Rest schedule takes time and requires some trial and error.

Try a cycle for 3 days, and if there are no negative effects, you can try to increase activity time and/or decrease rest time. Here's an important note, if you experience a spike or increase in pain, cut your activity time in half for that day, but **continue to pace through the increased pain.** Then, gradually increase your activity time back to the original time over a few days (e.g., if you started with 10 minutes of activity and 5 minutes of rest, slowly return to this schedule over the course of a few days).

Adapted from 2013 *Cognitive-Behavioral Workshop for Managing Chronic Pain* by University of California, San Diego and San Diego VA Healthcare System.

When designing at-home behavioral experiments, make your concrete plans SMART:

Specific: the more specific your plan, the greater chance you have of accomplishing it. To get specific, answer the six "**W**" questions:

- **W**ho is involved?
- **W**hat steps will I need to take?
- **W**here will this take place?
- **W**hen will I do this and for how long?
- **W**hich items/requirements will I need?
- **W**hy am I doing this activity?

EXAMPLE: A general goal would be, "Get in shape." But a specific goal would say, "Join a health club and workout 3 days a week."

Measureable: define criteria to help you measure your progress and stay on track. To determine whether your plan is measurable, ask questions like:

- How much? How many?
- How will I know when it is accomplished?

Attainable: make sure that your plan is set up in advance in a way that is feasible. It should be something that provides you with a little challenge but not one that is too hard to do. Ask yourself:

- Have I generated a plan that I have the skills and knowledge to carry out?

EXAMPLE: Climbing a mountain trail might be attainable for someone who has practiced before and has the equipment, but might not be attainable for someone who has not received lessons or guidance.

Realistic: make sure that you have generated a plan that is realistic in the context of your week and your life. Your plan should be something that you are *willing* and *able* to do.

Timely: Your plan should take place within a time frame. Ask yourself:

- When will I start the activity?
- When will I finish the activity?

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 2

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 3

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 4

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 5

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 6

Revisit Activities

Take some time in this session to review how you are doing with the activities that you have worked on.

You can use the space below to list any activities that you would like to include in treatment and their corresponding worry scores in order from most (10) to least (0) worrisome:

_____ _____

_____ _____

_____ _____

_____ _____

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_____ _____

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 7

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 8

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 9

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

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_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 10

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 11

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Session 12

Review of Progress and Relapse Prevention

During the treatment you have worked hard, together with the programist, to resume/increase your daily activities. Hopefully, you found that you were able to do more than you thought. You probably noticed that your fears/worries about the consequences of performing specific activities decreased. However, it is possible that, at some point in the future after completion of the therapy, you notice that you are losing some ground. For example, it is possible that you will notice a change in your pain or activity level and have new concern about the pain and its consequences.

Think back to the past several weeks: What have you gained from this experience that you want to take away with you?

_____

_____

_____

_____

_____

Setback ≠ Relapse. It is important to note that minor setbacks can and likely will occur from time to time, but that this concern should not lead you to stop engagement in activities and become inactive.

At the beginning and during the program, you discussed the fact that chronic pain is not generally indicative of new damage or injury to the body. If chronic pain leads you to rest and become inactive, pain only becomes worse and it becomes more difficult to move. Being protective may help in the short run, but in the long run, it has negative effects and increases the pain experience (Remember, "**Rest**

Rusts"). So, it is important to do what you can in order to prevent yourself from getting into the **vicious cycle** again.

What concerns do you have about your ability to maintain your progress in the future?

_____

_____

_____

_____

_____

In the future, if you find that you are avoiding activity out of fear of pain, walk through the following steps:

1. Ask yourself: Have you been in a similar situation before?

2. Ask yourself: What happened then?

3. Review your workbook and ask yourself: How did I approach this problem during the program?

4. Imagine yourself doing a behavioral experiment. Before the activity, think of its execution according to the behavioral experiment form.

5. Carry out a behavioral experiment. Think about a catastrophic and an alternative thought, and assign each a number for believability. Carry out the activity and again evaluate the believability of each thought. Record the results on the behavioral experiment form.

In detail, describe an activity that you avoid or decrease because of fear about pain that you associate with it. What sort of thoughts do you have about the activity and what consequences do these thoughts have for your behavior? What can you do about these thoughts?

_____

_____

_____

_____

_____

_____

_____

What advice have you discussed with your programist?

_____

_____

_____

_____

_____

_____

Congratulations on completing the program!

Keep up the good work and best wishes to you.

At-Home Worksheets

Behavioral Experiment Form

1. Select the activity.

_____

2. Make concrete plan.

_____

_____

_____

3. Catastrophic thoughts.

_____

_____

_____

How believable do you find the catastrophic thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

How much worry do you have **before** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

4. Alternative thoughts.

_____

_____

_____

How believable do you find the alternative thoughts?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

5. The programist carries out the activity.

6. You carry out the activity as planned.

How much you are worried **while** carrying out the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

7. Evaluate how the exercise went:

a. Believability of the catastrophic thoughts after the experiment:

How believable do you find the catastrophic thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

b. Change in the catastrophic thoughts. _____points.

c. How believable do you find the alternative thoughts after the experiment?

1	2	3	4	5	6	7	8	9	10
totally not believable									very believable

d. Change in the believability of the alternative thoughts. _____points.

e. How much you are worried **after completing** the activity?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

f. How much worry do you think you would experience if you had to engage in the activity **again**?

1	2	3	4	5	6	7	8	9	10
unconcerned									very concerned

g. How did performing the activity actually go?

_____

_____

_____

_____

8. Set up the next experiment for next session:

_____

_____

_____

Appendix B: Education Intervention Participant Manual

Fight FMS

Terry Cronan, Ph.D.

San Diego State University

Objectives of the Study

- **Self-management education program** adapted from Arthritis SMP
- Shown to be effective with arthritis populations
- **Purpose:** Produce functional improvements among fibromyalgia patients

Structure of Classes

- **Weekly** class structure
- **13 sessions** total (this one and 12 more)
- We will increase your **knowledge** about fibromyalgia
- 1 session a week

*+ Important note regarding **medication changes***

1

Content of Classes

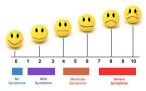
1. Overview of FMS
2. Pain
3. Treatment Strategies
4. Fatigue
5. Sleep
6. Exercise
7. Stress and Relaxation Techniques
8. Dealing with Emotions
9. Communication Skills
10. Social Support and Communication
11. Nutrition
12. Living Well with Fibromyalgia
13. On the Fibromyalgia Frontier

Week 1: FMS Overview

- **What is FMS?**
  - Prevalence
  - Diagnosis
  - Common Symptoms

- Why is FMS a rheumatic disease?
- What **causes** FMS?
- How is FMS **treated**?

Week 2: Pain



- What is the **purpose** of pain?
- What is considered **normal** pain?
- How can pain be **managed**?

Week 3: Treatment

- There are many possible treatment strategies for fibromyalgia
- Relaxation techniques
- Distraction
- Medication
- Other physical treatments

Week 4: Fatigue

- Fatigue **journals**
- What is fatigue?
- What **causes** fatigue?
- How do you **manage** your fatigue?

Week 5: Sleep

- Normal sleep/wake cycle
- Fibromyalgia and sleep
- Factors that can disturb sleep
- Ways to improve sleep

Week 6: Exercise

- What is exercise?
- Benefits to exercise
- How exercise decreases pain
- How to start an exercise program
- Types of exercise programs
- Sticking to an exercise program

Week 7: Stress & Relaxation

- What is stressful for you?
- What is stress?
- Healthy vs. unhealthy stress
- Stress and fibromyalgia
- How to begin managing your stress
- Relaxation techniques

Week 8: Dealing with Emotions

- How does it make you feel to have fibromyalgia?
- Possible losses caused by fibromyalgia
- Grief responses
- Dealing with loss
- Depression
- Dealing with emotions
- What is self-talk?
- Activity: Changing negative self-talk to positive self-talk

Week 9: Communication Skills

- Listening
- Gather information
- Use "I" messages
- Asking for help and refusing help

Week 10: Social Support

- Communicating with your **friends and family**
- Communicating with your **health care team**

Week 11: Nutrition

- Introduction to nutrition
  - Benefits
  - Essential nutrients
- Dietary awareness
  - Recommendations
  - Fat in the diet
  - Diet composition

Week 12: Living Well with Fibromyalgia

- Nourish your body
- Nourish your mind
- Nourish your spirit
- Feeling good about yourself
- Uplifting activities
- Balancing time and energy

Week 13: On the Fibromyalgia Frontier

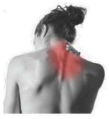
- Newest Advances in FMS:
  - Classification
  - Assessment tools
  - Diagnostics
  - Treatment
  - Treatment & Use of Technology

Fight FMS

Week 1 – FMS Overview

What is Fibromyalgia?

- Generalized muscular pain and fatigue
- ***Fibromyalgia*** means "pain in muscles, ligaments, and tendons"
- ***Fibrositis*** was the old term used—means inflammation (but there is none!)
- **Fibromyalgia involves *pain*, not *inflammation* of fibrous tissues**



Prevalence:

- Approximately **5 million** people in the US
- 3.3% of adults have fibromyalgia
- 4.9% of women, 1.6% of men
- Prevalence increases until 55-64 years of age in women, 45-54 in men
- Prevalence in older populations is higher (7.9% in women, 2.5% in men)

Diagnosing

- Laboratory tests, including blood tests and X-rays, reveal nothing
- Must **rule out** other diseases with similar symptoms to make a diagnosis
- FMS can **exist with other conditions**, which can complicate diagnosis

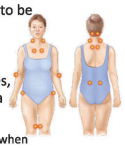
Diagnosing

- The following tests must be within **normal ranges for a primary diagnosis** of fibromyalgia:

1. Complete blood count
2. Antinuclear antibody
3. Erythrocyte sedimentation rate
4. Rheumatoid factor
5. Muscle enzymes
6. Thyroid function

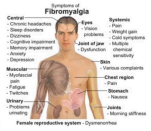
Diagnosing

- (1990) According to the American College of Rheumatology, a person must have both of the following symptoms to be diagnosed with fibromyalgia:
- History of widespread pain;
- Pain in 11 of 18 tender point sites, which are unique to fibromyalgia diagnosis
  - All persons experience discomfort when tender point pressed, FMS patients experience pain.



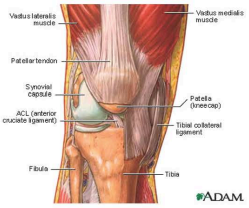
Common Symptoms

- Muscle pain
- Fatigue
- Sleep disturbance
- Chronic headaches
- Irritable Bowel Syndrome
- TMJ (Temporomandibular Joint Disorder)
- Nervous system symptoms
- Other signs and symptoms



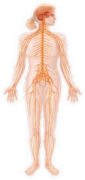
Why is FMS a Rheumatic Disease?

- Joints are places in the body where two bones meet
- Joints have supportive structures like muscles, tendons, and ligaments to help move the bones correctly
- All rheumatic diseases affect joints or connective tissues
- FMS affects supportive tissues around the joints



Why is FMS a Rheumatic Disease?

- Recent research indicates FMS might be a disorder of the **nervous system**
- Nervous system **processes pain**
- Research suggests that individuals who are affected by FMS receive more **amplified pain signals** in their brain than non-FMS individuals



Causes of Fibromyalgia

- No known cause—many theories
- Injury, illness, physical or emotional trauma theory
- **Muscle-contraction** theory
- **Hormone deficiency** theory
- **Abnormality of deep sleep** theory
- **Decreased brain serotonin** theory
- **Central augmentation of pain** theory

FMS Treatment

- There is no cure, but treatment is available for symptoms!
- **Rest, relaxation, education, exercise, stress reduction, medications, and self-help strategies**
- We will address all of these treatments!

Pain Diary

- Monitor pain levels 3x daily
- 0 = feeling great; 10 = feeling awful
- Ability to identify patterns

End of Session

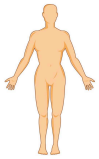
- Questions/Comments?
- Homework: Keep track of **pain levels** every day with a new pain diary sheet (and ***bring to next meeting!***)
- We look forward to seeing you next week!

Fight FMS

Week 2 – Pain

Pain Diary

- **Where** do you experience the most pain?
- **When** do you experience the most pain?
- Are there any **patterns**?
- FMS pain is widespread



Pain

- All persons with fibromyalgia experience two types of pain:
  1. *Tender point pain*
  2. *Widespread muscle pain*
- Pain is on both sides of body, both upper and lower body
- The pain is *manageable*

Purpose of Pain

- Pain is your body's natural alarm system
- Pain occurs where injury takes place
- Pain will tell you something (i.e., move your hand away from a HOT stove)
- Long-lasting (chronic) pain is harder to relieve, and not necessarily meant to be endured.
- Can be managed

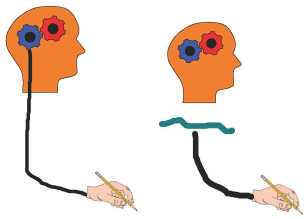
Purpose of Pain

Pain may be inevitable, but misery is optional!

How to Manage Pain

- Gate theory helps manage pain
- Pain signals travel up to the brain, through a "pain gate"
- Gate can be opened or closed
- Open gate = can feel pain
- Closed gate = no experience of pain
- Morphine closes the pain gate
- Endorphins close the pain gate too

The Pain Gate



The Pain Gate

OPENS Pain Gate:

- Stress
- Excessive physical activity
- Dwelling on pain
- Fatigue
- Anxiety
- Depression

CLOSES Pain Gate:

- Positive attitude
- Appropriate exercise
- Relaxation
- Medication
- Massage
- Distraction
- Humor
- Heat or cold treatments
- And more!

End of Session

- Questions/Comments?
- Next week: **Fatigue**
- We look forward to seeing you next week!

Fight MS

Week 3 – Treatment Strategies

Treatment Strategies

- Everyone's pain is **different**
- Every person requires a **unique** pain management **plan**
- Depression is reduced by **taking control** of one's pain and one's life
- The first method of pain control involves **controlling your mode of thinking**

Relaxation Techniques

- **Relaxation** can be accomplished with a variety of methods
- **Deep breathing** is an effective method for achieving relaxation!

Attention Diversion

- Also known as **distraction**!
- Focus on something else
- **Get involved** in a new interest, a game, reading, seeing a movie, volunteering, etc.

Example: Mother driving with children and gets in auto accident w/ broken arm

Imagery

- Conjure up a **mental scene** that is incompatible with the pain
- Imagine an **extremely pleasant** scene (e.g., a beautiful valley or beach or mountain)
- Listen to the birds and the leaves and the breeze
- You will be unable to attend to your pain

Maintain a "Wellness Lifestyle"

- Think helpful thoughts
- Keep a sense of humor
- Eat a balanced diet
- Exercise every day
- Enjoy activities with others
- Follow your treatment plan!

Heat and Cold Treatments

- **Heat and cold treatments can reduce pain and stiffness**!
- Cold packs **numb** the pain
- Heat packs **relax** your muscles
- You can use both **dry heat** and **moist heat** methods!

Heat Treatments

- Soak in a warm bath, shower, or Jacuzzi
- Place a heating pad on the painful area
- Use an electric blanket or mattress pad
- Use flannel sheets
- Use a hot water bottle wrapped in a towel
- Warm your clothes in the dryer!
- Use hot packs and cover with a towel

Cold Treatments

- Place a cold pack or ice bag on the painful area to numb the pain
- Make your own cold pack out of a bag of frozen vegetables, but make sure to use a towel to wrap the cold pack!

After Heat/Cold Treatments:

- Check the area for swelling or discoloration
- Carefully dry the area
- Gently move the painful areas to reduce stiffness
- Allow your skin to return to normal temperature before using another treatment

DO

- Use heat or cold packs for only 15-20 minutes at a time, and allow your skin to return to normal temperature before applying another pack
- Always wrap a cold/heat pack in a towel
- Follow the advice of your physician
- Check your skin before and after using heat or cold

DON'T

- Use a cold pack if you have Raynaud's phenomenon or poor circulation
- Use a heat/cold pack if you have cuts or sores
- Use a heat/cold pack that is too hot or too cold
- Use creams, rubs, or lotions while applying a heat/cold pack
- Use an electric device unless it is in good repair
- Make your bath or shower too hot
- Lie on or fall asleep on a heating pad

Other Treatment Options

- Some treatment options require **assistance**:
  1. Physical therapy/physical activity
  2. Massage
  3. Hypnosis
  4. Medications

Physical Therapy/Activity

- PT involves a **variety of approaches** to help patients who suffer from acute and chronic pain
- PT teaches **body mechanics** and proper **posture** to prevent further injuries
- **Exercise** also helps manage pain
- Exercise **strengthens** muscles and allows for more **mobility**

Massage

- **Deep muscle massage** allows pain control and relaxation
- Massage can relieve **muscle spasms and increase blood flow**
- Ask your doctor to recommend a professional!
- Can also massage your own muscles
- Apply **more** pressure stroking **towards** the heart and **less** stroking **away**!

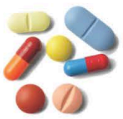
Hypnosis

- Hypnosis is an **altered state of consciousness** that can help reduce pain
- You must be **willing** to be hypnotized
- The mechanism is unclear—may **block pain** or may interfere with the **reporting** of pain

Medications

- Many types of medicines help control fibromyalgia pain:

Acetaminophen,
NSAIDs,
TCAs,
SSRIS,
corticosteroids,
opiates,
neuroleptics,
and other medications



Acetaminophen

- Pain relievers used for **minor, short-term pain**
- **Tylenol** is an example of Acetaminophen

NSAIDs

- Stands for *nonsteroidal anti-inflammatory drugs*
- Group of drugs used to **treat arthritis**
- In general, they **do not** do much for fibromyalgia
- May provide **pain relief** or **lessen stiffness**
- Aspirin, Ibuprofen, Indomethacin, Naproxen, Feldene

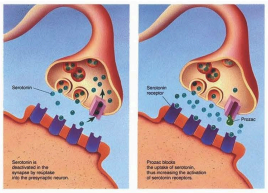
Tricyclic Antidepressants

- Also known as TCAs
- Help relieve chronic pain in people who are not depressed
- Block pain messages in the brain

- May help break out of chronic symptom cycle
- Can aid sleep and muscle relaxation
- Amitriptyline, Doxepin, Cyclobenzaprine

SSRIs and SNRIs

- Selective serotonin and serotonin-norepinephrine reuptake inhibitors
- Some researchers have found **low levels of serotonin** in people with fibromyalgia
- Fluoxetine, Sertraline, Paroxetine, Duloxetine



Corticosteroids

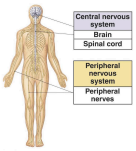
- Have a powerful **anti-inflammatory** effect
- Most people with fibromyalgia **do not** suffer from inflammation
- Have not been found to be effective for Fibromyalgia

Opiates

- Narcotics **imitate the body's own endorphins**
- **Addictive**
- However, **significantly reduce pain**
- Vicodin, Talwin, Tramadol, Tylenol with codeine, Percocet, Morphine, Demerol

Neuroleptics

- Affect levels of **GABA** in the brain
- These drugs treat epilepsy, seizures, anxiety, and pain
- Pregabalin, Gabapentin



Other Medications

- There are other **centrally acting** medications that may be useful to treat FMS
- Affect the **binding of chemicals** in the brain—can help reduce pain
- NMDA receptor antagonists

Side Effects

- Each medication comes with unique side effects
- See your physician or pharmacist for side effects of these medications
- Contact your physician about the following symptoms:

  Fever, skin rash, nausea or vomiting, ringing in the ears, dizziness, or headache

End of Session

- Questions/Comments?
- Homework:
  How is Your Energy? Worksheet
- We look forward to seeing you next week!

Week 4 – Fatigue

How is Your Energy?

- Are there certain **times of day** that are better or worse than others?
- How can we focus on **improving your energy** throughout the day?
- We can reduce fatigue

What is Fatigue?

- Fatigue is the feeling of **extreme tiredness or exhaustion**, often involving muscle weakness
- A frequent and troubling challenge for persons with fibromyalgia
- **Symptoms** may vary; these are common:

  General tiredness, increased pain, a loss of control, a loss of concentration, irritability

What Causes Fatigue?

- Disease/syndrome
- Pain
- Rest/sleep
- Being less active
- Overdoing
- Nutrition
- Medications
- Stress, depression, and other emotions
- Trying to hide your illness
- Boredom
- Surroundings

Managing Your Fatigue

- There are many **causes** of fatigue, and thus **many methods** exist to manage it
- People become fatigued when they don't have enough **resources to meet the demands** they are facing

Managing Your Fatigue

Self-management with problem solving using the four W's:

- What is the problem?
- When does my problem arise?
- Where am I when the problem arises?
- Why am I experiencing this problem?

Use the fatigue chart

Managing Your Fatigue

Self-management strategies:

- Prioritizing—make a "to do" list
- Planning—fits in with prioritizing
- Pacing—balance heavy and light tasks
- Make your work easier!

Making Work Easier

- Combine chores and errands
- Sit when you work
- Organize your work area
- Use labor-saving devices
- Use assistive devices
- Transport items on a cart
- Substitute lightweight items for heavy ones
- Buy smart items!

Managing Fatigue

- Get enough sleep
- Exercise
- Maintain good posture
- Ask for help when needed!
- Have fun!

End of Session

- Questions/Comments?
- Next session: Sleep
- We look forward to seeing you next week!

Fight FMS

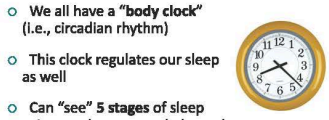
Week 5 – Sleep

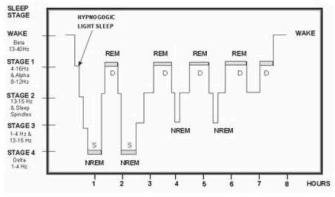
Sleep Disturbances

- **Most** persons with fibromyalgia suffer from **sleep disturbances**
- It is helpful to understand the body's **natural sleep/wake cycle** to apply it to sleep management

A Normal Sleep/Wake Cycle

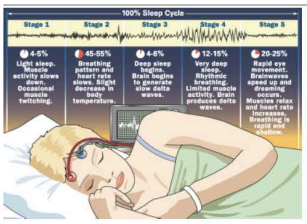
- We all have a **"body clock"** (i.e., circadian rhythm)
- This clock regulates our sleep as well
- Can "see" **5 stages** of sleep using an electroencephalograph
- Awake, Stages 1-5, and REM sleep





- It takes ~90 minutes for one full cycle of sleep
- We go through 4-6 cycles of sleep a night

A Normal Sleep/Wake Cycle



REM Sleep

- **REM** = Rapid Eye Movement
- The stage of sleep in which **dreams** occur
- Persons woken up in this stage of sleep report being in the **middle of a dream**
- EEG waves during this stage are called REM waves—**similar to awake** beta waves
- This suggests our **minds are active** while we dream although our **muscles are relaxed**

Fibromyalgia and Sleep

- Sleep problems are **common** for people with fibromyalgia
- Many **wake up** during the night or wake up and feel **unrested** (i.e., nonrestorative sleep)
- Stage 4 sleep (deepest sleep) is being **interrupted** by bursts of brain activity

Fibromyalgia and Sleep

- There is evidence that poor sleep is a factor in the **development** of fibromyalgia
- When volunteers **prevented** from reaching deep sleep, they developed symptoms similar to fibromyalgia's
- After normal sleep, symptoms disappeared

Fibromyalgia and Sleep

- **Direct cause** of fibromyalgia sleep problems is **not known**
- **Serotonin** may be an important factor
- Medicines that boost serotonin levels have been **helpful** in **restoring normal sleep** for persons with fibromyalgia

Factors that Disturb Sleep

- Sleeping pills
- Drugs and foods
- Eating
- Smoking
- Drinking alcohol
- Environment
- Stress
- Physical problems

Ways to Improve Sleep

- **Tricyclic antidepressants and/or SSRIs** are often prescribed to preserve restorative sleep
- **Improvement varies** from person to person
- May experience **side effects**

Q: What are other possible ways to improve sleep?

Ways to Improve Sleep

- Maintain a regular schedule
- Exercise
- Use relaxation techniques
- Eat a light snack before bed
- Make your bedroom quiet and comfortable
- Use your bedroom only for sleeping
- Take a warm bath before bed
- Listen to music
- Read
- Use ear plugs
- Write down worries before bed—address them tomorrow




End of Session

- Questions/Comments?
- Next session: Exercise
- We look forward to seeing you next week!

Fight MS

Week 6 – Exercise

Exercise

- One of the most **effective** treatments for fibromyalgia
- Defined as any movement of the muscular skeletal system with the intention of **increasing fitness**

- *Aerobic* exercise is beneficial for people with fibromyalgia
- Aerobic exercise involves elevating the heart rate **30-50 bpm** above your resting rate

Exercise

- American College of Sports Medicine recommends **20 minutes** of aerobic exercise **3x a week**
- Persons with fibromyalgia should consider this to be a **long-term goal** to work up to

Benefits of Exercise

- Improves cardiovascular health and endurance
- Decreases risk of diseases including:
  diabetes,
  osteoporosis,
  cancer,
  and heart disease

McCain et al., 1988

- Study done in **Canada** to research the effect of **aerobic exercise** on people with fibromyalgia
- **50%** of participants who completed 20-week aerobic exercise program showed "**marked improvement**" in pain
- **10%** of control participants experienced any improvement in pain

Benefits of Exercise

- Decreases pain
- Releases endorphins
- Decreases fatigue
- Improves mood
- Improves sleep
- Decreases depression and anxiety
- Increases muscle strength
- Improves bone density

What Increases Pain?

- Pain is perpetuated by **sedentary behaviors**
- People in pain often move less due to **guarding**, which leads to stiffness, increased muscle tension, and even more pain
- Inactivity leads to **deconditioning**—decreased stamina, strength, and flexibility

Exercise Program

- Exercise must be *regular* as benefits gained with exercise are temporary
- Dress comfortably and in layers
- Wear walking or running shoes with good arch and ankle support

Selecting an Exercise

- Exercises that include smooth movements tend to be the least painful
- Swimming/water exercises, walking on a level surface, walking on a treadmill, spinning, or other smooth exercise

Selecting Intensity

- Rate how you feel on a scale from 1 to 10:
  - 1 is similar to resting
  - Gentle exercise is 2-3
  - Aerobic exercise is 4-6
  - 10 is running up a flight of stairs

- If you can not talk while exercising, you may be exercising too vigorously
- If you develop pain, dizziness, or nausea, stop and contact your doctor immediately

Exercise Program

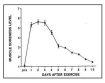
- It is easy to over do it. Be **patient** and **persistent**.
- Begin with only a **few minutes** of exercise a day.
- Set aside time during your day to exercise—don't count a walk to work as your 5-minute walk. Set aside another time.

Exercise Program

- Warm up your muscles before beginning higher intensity exercise or stretching
- Warm your muscles with slow walking and gradually increase the speed
- Cool down after finishing exercise, gradually decreasing intensity
- Cool-down should take 2-5 minutes

What to Expect

- Muscle soreness is common for up to three days after beginning of exercise



- Pain from fibromyalgia may be worsened at first, but then will get better. Do not over-extend yourself!
- Do not expect miracles—improvement will be slow

Exercise Program

- Set aside a **regular exercise time**
- Make exercise part of your **daily habits**
- Set realistic, doable **goals** each week
- **Proceed slowly** to avoid pain and frustration
- Be **patient and persistent**

End of Session

- Questions/Comments?
- Next session: Stress & Relaxation
- We look forward to seeing you next week!

Fight FMS

Week 7 – Stress & Relaxation Techniques

What is Stressful for you?

- *What are possible stressors in your life?*
- *Are all of these stressors fibromyalgia related?*
- *Are any good/fun things stressful?*

What is Stress?

- Stress is the body's reaction to something that is perceived as anxiety-producing
- When something overloads our psychological resources, we become stressed
- Stress is a normal reaction, not necessarily bad

Three Stressful Situations

1. **Harm/Loss:** This is when something has actually happened, e.g., injury or death
2. **Threat:** This is when there is a threat of something happening
3. **Challenge:** This is when there is potential for something good to happen yet you must heighten your psychological resources to meet the challenge

Body's Reaction to Stress

- Stress increases alertness and concentration
- Fight-or-flight response
- The mind and body produce adrenaline and other chemicals
- We also have an emotional response
- Can be calm and collected; can be scared and angry

Body's Reaction to Stress

- Muscles are tense
- Heart rate, blood pressure, and breathing rate all rise
- "Nervous stomach"
- Nausea or diarrhea
- May turn pale and feel cold/clammy
- Eyes dilate
- You are alert and ready to make a split-second decision

Healthy vs. Unmanaged Stress

- Healthy stress is temporary. If we "get stuck" in a stressful state, then our stress becomes unhealthy
- Healthy stress is always followed by relaxation
- Unmanaged stress lasts for longer periods of time, and limits your resources to meet your next challenge

Symptoms of Unmanaged Stress

- Headaches
- Irritable Bowel Syndrome
- Muscle tension
- Fatigue
- Irritability
- Worry, fear, depression
- Decreased performance
- Difficulty in making decisions
- Increased use of alcohol or drugs
- Changes in appetite
- Sleeping problems
- Disease flares
- Poorer immune function

Psychosomatic Symptoms

Stress and Fibromyalgia

- Persons with fibromyalgia report more daily hassles than matched arthritis or healthy groups, suggesting that people with fibromyalgia experience more stress on a daily basis
- Stress causes pain, fatigue, tension, and depression—which in turn cause stress! This is known as the stress/pain cycle

Managing Stress

- Identify your stressors:
  - What is causing my stress?
  - When is my stress occurring?
  - Where am I stressed?
  - Why is this stressful for me?

To identify something that causes stress in your life, answer the four Ws. Then apply the three As: alter, avoid, and adapt.

Managing Stress

- Is this situation really harmful?
- Are there other ways of looking at this situation?
- What is at stake?
- What am I saying to myself right now?
- What am I afraid will occur?
- How do I know that this will happen?
- What evidence do I have for this conclusion?
- What evidence contradicts this conclusion?
- What coping resources are available?
- Have I had failures in the past—or did I do ok?

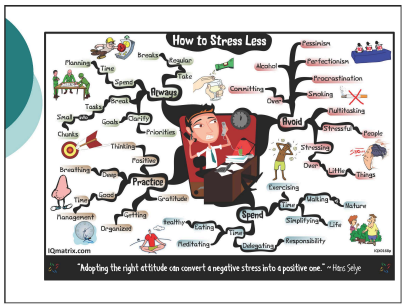
Relaxation Techniques

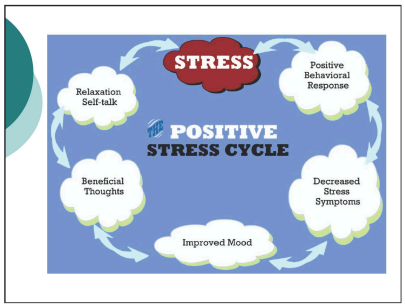
- Relaxation means relaxing your body *as well as* your mind!
- Techniques include deep breathing, progressive relaxation, and meditation

Let's try a relaxation technique right now…

End of Session

- Questions/Comments?
- Next session: Dealing with Emotions
- We look forward to seeing you next week!


How to Stress Less
Always
Avoid
Spend
Practice
"Adopting the right attitude can convert a negative stress into a positive one." ~Hans Selye

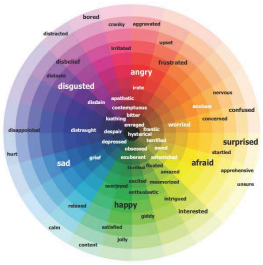

STRESS
Positive Behavioral Response
Relaxation Self-talk
THE POSITIVE STRESS CYCLE
Beneficial Thoughts
Decreased Stress Symptoms
Improved Mood


Fight FMS
Week 8 – Dealing with Emotions

Feelings about Fibromyalgia

- People have **mixed feelings** about a fibromyalgia diagnosis
- Need **validation** for symptoms
- May be **overwhelmed**
- May be experiencing a new **role as "the patient"**
- With a lot of emphasis on ***physical*** health, may neglect ***emotional*** health

Q: How does it make you feel to have fibromyalgia?



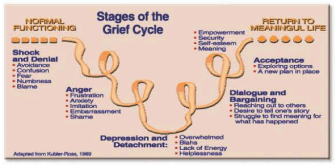
Feelings about Fibromyalgia

- You may be **unaware** that you are grieving because we associate grieving with death
- People feel grief about losses when diagnosed with an illness
- It is **healthy** to grieve losses

Impact of Losses Caused by Fibromyalgia

Loss of:	Results:
Mobility:	Dependence on others Giving up hobbies
Energy:	Giving up activities Isolation
Independence:	Low self-esteem Loss of privacy
Relationships:	Changes in family role Changes in sexual expression
Dreams and future plans:	Difficult to plan ahead Low self-esteem

Feelings about Fibromyalgia



- 5 stages of grief: shock, anger, depression, bargaining, and acceptance

Feelings about Fibromyalgia

- All of these responses are **natural**
- Stages may **skip** or go **out of order**
- **Other stages** may include:
  guilt,
  sadness,
  fear,
  and loneliness

Dealing with Loss

- There are effective strategies for dealing with the losses associated with illness:
  - **Communication**
  - **Respect for one another**
  - **Humor**
  - **Face your loss**
  - **Find support**
  - **Seek professional help**
  - **Search for meaning**

Depression

- Having **chronic pain can lead to depression**
- Depression can be long-lasting and **interfere** with your ability to take pleasure in life
- **Common factors for depression:** continuous stress, grieving over losses, side effects of medications, pain and fatigue, and chemical imbalance

Symptoms of Depression

- A persistent sad or anxious mood
- Loss of interest in ordinary activities
- Decreased energy, fatigue
- Trouble sleeping
- Increased or decreased appetite
- Difficulty concentrating
- Feeling helpless
- Feeling like a failure
- Frequent arguments
- Excessive crying
- Chronic aches and pains
- Thoughts of death or suicide

Remember:

If you or someone you know has suicidal thoughts, seek professional help immediately!

Dealing with Emotions

- Keep in contact with others
- Exercise
- Laugh
- Communicate with others
- Be active
- Reward yourself
- Plan a special event
- Have realistic expectations
- Practice healthy self-talk
- Seek professional help

What is Self-Talk?

- Self talk is our **internal dialogue,** our thoughts
- Self-talk can be **positive** or **negative**
- **Positive** self-talk = **supportive and kind**
- **Negative** self-talk= **critical and destructive**

- Negative self-talk involves words and phrases like *can't; won't; impossible; always; never; should; ought to; must; yes, but; if only*
- Self-talk affects our emotions
- **Identifying and changing** negative self-talk is an important tool to increase mood

Negative Self-Talk

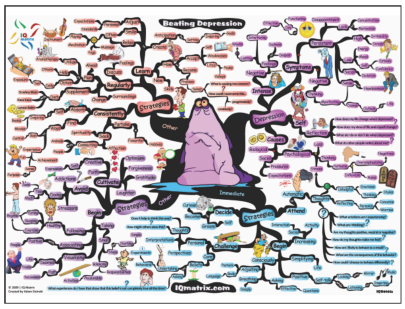
I would like to exercise, but I can't. I know that if I did exercise my fibromyalgia would flare up. I am too old to exercise.

My life will never be the same now that I have fibromyalgia. I will never be able to do the things that I like to do.

My friends never call me. People don't like being around me anymore.

End of Session

- Questions/Comments?
- Next session: Communication Skills
- We look forward to seeing you next week!



Fight FMS

Week 9 – Communication Skills

Listening

- Listening is the most important aspect of good communication
- Must practice *active listening*
- Make sure to:
  - **Look interested**
  - **Sound interested**
  - **Acknowledge what others are saying**
  - **Acknowledge the speaker's emotional state**

Gathering Information

- To communicate successfully, you must gather all pertinent information
- Make sure to:
  - **Ask for more information**
  - **Ask people what they mean**
  - **Be specific**

Owning Your Feelings

- Express your feelings with "I" statements; this keeps us from blaming others for our own emotional states and helps prevent arguments:
- "I like you"
- "I am not feeling well today"

Activity

Help turn these messages into "I" statements:

- You are not helping!
- You're going to make us late.
- Can't you stay out of my way?

Owning Your Feelings

- **Listen to yourself and others**
- **Keep trying**
- **Do not use your feelings to manipulate others**
- **Express your feelings**

Asking for Help

- Asking for help can be difficult because it involves admitting that we are unable to help ourselves
- We may also be afraid to impose on others
- More people help when asked specifically
- Make sure to:
  - **Come to the point**
  - **Be specific**

Refusing Help

- Refusing help can be difficult
- We do not want to discourage future help
- We do not want to sound ungracious
- Make sure to:
  - **Use an "I" message**
  - **Show appreciation**
  - **Leave the door open**

Activity

Think of a situation where you were offered help, but did not need it. How could you have gently refused the help?

End of Session

- Questions/Comments?
- Next session: Social Support & Communication
- We look forward to seeing you next week!

Week 10 – Social Support & Communication

Social Support

- Significant others, family members, friends, co-workers, and your health care team can be sources of social support
- Your social support network can influence how you experience fibromyalgia
- Lack of support is related to depression, helplessness, anxiety, greater pain, and greater use of medications

Communicating with Friends and Family Members

- Communication is important in dealing with fibromyalgia
- Must practice two-way communication
- Communication is important in building a strong social support network
- Satisfaction with one's social support network is related to pain behaviors
- Social support improves one's self-efficacy

Activity

Identify a close friend or family member and problems with communication in that relationship.

Understand that there are limitations of your friend or family member and possible gaps in communication.

- What do you dislike about the relationship with your friend or family member?
- What makes a good friend or family member?
- What can you do to be a good friend or family member?

Communicating with Your Health Care Team

- Communication with your health care team is important in dealing with fibromyalgia
- Must practice effective two-way communication with your doctor
- A trusting relationship takes time and effort from both parties

Activity

Identify problems with doctor/patient communication.

Understand that there are limitations of your physician, health care providers, and the health care system.

1. What do you dislike about your physician?
2. What makes a good physician?
3. What can you do to be the good patient?

Do Your PART!

P – **Prepare a list of questions, concerns, and symptoms**

A – **Ask questions!**

R – **Repeat what you have heard**

T – **Take action to reduce barriers to treatments**

End of Session

- Questions/Comments?
- Next session: Nutrition
- We look forward to seeing you next week!

Fight MS

Week 11 – Nutrition

Benefits of Good Nutrition

- Helps you look and feel better
- Reduces fatigue
- Helps you achieve and maintain a healthy weight
- Keeps you regular
- Decreases your risk for some cancers
- Improves your lipid profile
- Decreases risk for heart disease
- Maintains good bone health

A Healthful Diet

- "Is there something that I can eat that will help my fibromyalgia?"
- The answer is not simple
- No scientific evidence for a special diet for fibromyalgia
- However, everyone can benefit from consuming a healthful diet
- If you are eating well, you are helping your body deal with FMS

What Is a Healthful Diet?

- Eat a wide variety of different foods
- Eating vegetables, grains, fruits, fish, poultry, and other meats increases your chances of getting the right nutrients
- No one food contains everything
- If you eat the same foods every day, you may lack some nutrients

Essential Nutrients

- Water
- Carbohydrates
- Protein
- Fat
- Minerals
- Vitamins

Water

- Drink 6 to 8 oz. glasses of water a day
- Water to our body is like oil to a car
- You may experience a diuretic effect

Carbohydrates

- Supply our body with fuel
- Include starches, sugars, and fiber
- Should be 50-60% of your total caloric intake
  - Examples: breads, cereals, whole grains, rice, pasta, and potatoes

Remember: Fiber is undigestable and keeps you regular

Protein

- Essential for growth and for the maintenance and repair of tissues, muscles, and organs
- Found in meats, beans, dairy, eggs, nuts, vegetables, and grains
- Should be 10-20% of your daily caloric intake

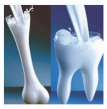
Fat

- Builds the membranes of cell walls
- Protects vital organs of the body
- Prevents heat loss
- Is a concentrated source of calories
- Should be 30% of daily caloric intake

- Better to consume monounsaturated fats, such as olive oil, peanut oil, and canola oil

Minerals

- Minerals are essential to proper muscle and nerve function
- Aid growth and transmission of nerve impulses
- Play a significant role in growth, repair, and maintenance of bone
- Best to supplement diet with calcium



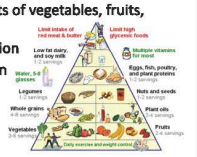
Vitamins

- Help regulate various processes that go on inside the body
- Convert the food we eat into energy that we use
- Do not supply energy
- Found in a variety of foods

- Supplements can help, but eating a varied diet is the best option

Tips

- Eat a variety of foods
- Maintain a healthy weight
- Choose a diet low in fat and cholesterol
- Choose a diet with lots of vegetables, fruits, and grains
- Use sugar in moderation
- Use salt in moderation
- Drink alcohol in moderation



Dietary Fat Awareness

- Fat does not directly affect fibromyalgia
- Eating too many calories leads to excess body fat
- Excess body fat leads to fatigue and pain
- High fat diets play a role in many diseases
- Fat releases more energy in the body than carbohydrates or proteins

Easy Formula for Fats

1. Read the food label
2. Multiply the number of fat grams in a food by 30
3. Compare that number to the total calories: It should be less than total calories

- This keeps your caloric intake under 30% fat

Consumer Tips

- Read food labels
- Become an expert at being aware of what you are eating
- Count calories and fat, and learn about what foods contain
- Be in control of your diet and health
- Many diets can help with symptoms related to FMS

End of Session

- Questions/Comments?
- Next session: Living Well
- We look forward to seeing you next week!

Fight FMS

Week 12 – Living Well with Fibromyalgia

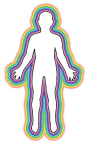
Miryam Ehrlich Williamson

Living Well

- Things will get better
- Must commit to a wellness lifestyle
- A wellness lifestyle is a commitment to nourishing your body, mind, and spirit
- This session is an overview of the key aspects of the wellness lifestyle

Nourish Your Body

- Exercise
- Use relaxation techniques
- Eat a balanced diet
- Follow energy-saving tips
- Limit/avoid alcohol, smoking, and recreational drugs



Nourish Your Mind

- Practice:
  - Optimism
  - Acceptance of changes/challenges as positive opportunity for growth
  - Healthy self-talk
  - Humor

Nourish Your Spirit

- Cultivate social support
- Maintain a positive self-concept and sense of purpose
- Find a sense of control
- Help others
- Choose uplifting activities

Feeling Good about Yourself

- Be nice to yourself
- Use healthy self-talk
- Do a reality check
- Learn to smile and laugh at yourself
- Recognize your unique qualities

Uplifting Activities

- Think about the things you enjoy doing
- List things that bring you pleasure/ happiness
- Build these things into your daily routine
- Schedule at least one thing a day

Balanced Time and Energy

- An essential part of living well is balancing your lifestyle
- The time target worksheet will help you analyze whether you are living a balanced life
- It may take time to learn to live a balanced life, but the time will come

End of Session

- Questions/Comments?
- Next Session:
  New Fibromyalgia Findings

Week 13 – New Findings Related to Fibromyalgia

What Now?

- Research continues to be performed to learn about fibromyalgia every day
- There are other treatment options being explored
- There are exciting new findings about the nature of the disease
- There are new technological treatments
- You will learn about all of these

New Prevalence Findings

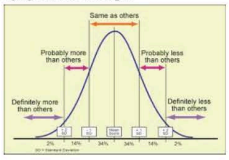
- Recent studies indicate fibromyalgia is equally common amongst men and women—despite the difference in diagnosis.

New Prevalence Findings

- 2,445 individuals were assessed using self report measures, and **FMS was distributed equally** among the sexes.
- Reported symptoms indicated a **range of symptomatic distress** among FMS individuals, rather than a categorical difference.
- Indicates that FMS should be classified as a **dimensional illness**, rather than a categorical one.

Dimensional Illness

- Can be best understood with a bell curve
- Persons with bad symptoms on the left, with less worse symptoms on the right



Possible Tests for FMS

- **Diagnosing FMS** is a known difficult obstacle to overcome
- No known test today can screen for FMS
- New studies suggest that there may be a way to screen for FMS with just a **blood test in the future**!

New Treatment Options

- A "**multifaceted**" approach to the treatment of fibromyalgia leads to the **most** functional improvements
- There are a wide variety of effective treatments, and many of them should be used **in conjunction** with each other.

Best Treatments

- Cardiovascular (aerobic) Exercise
- Cognitive Behavioral Therapy
- Patient Education
- Multidisciplinary Therapy
- Strength Training (anaerobic exercise)
- Hypnotherapy
- Balneotherapy (water or spa treatment)
- Acupuncture
- Chiropractic, manual, and massage therapy
- Electrotherapy
- Ultrasound
- Tender Point Injections
- Flexibility Exercise

Treatment Options

- **All** of the previous treatments have been shown to be **beneficial for some**
- Treatments at the **bottom** of the list, however, have **little evidence** of a significant amount of improvement of symptoms
- Best treatment is a **mix of the treatments** from the top of the previous list

Technology and Treatment

- There is a growing body of research looking into treatment options that use modern technologies
- Many of these treatments combine known efficacious treatments with convenient or interesting technologies

Technology and Treatment

- Dr. Lorig of Stanford University developed a self-management program for both arthritis and fibromyalgia that was interactive, community based, and completely online.
- Persons who used the online self-management program benefitted from the program more than others who received usual care.

Technology and Treatment

- Dr. Botella performed a study in Spain using Virtual Reality equipment.
- Patients underwent effective FMS therapies (such as CBT or education) while virtual reality equipment simulated outdoor environments
- The simulations helped regulate mood
- All patients responded favorably to the virtual reality treatment

Age and FMS

- There is evidence that life with FMS improves over time
- Dr. Cronan of SDSU performed an experiment with 600 patients with FMS
- As a person ages, their perception of their symptoms associated with FMS improves

Age and FMS

- Older persons tend to use the same coping strategies as younger persons.
- Why do older people with FMS have an easier time with the disease?

Age and FMS

- **Older individuals** tend to perceive their health status in a more **positive light** than do their younger counterparts
- Younger persons consider FMS to be more of an impediment to their lifestyle than older persons
- Older persons are **less emotionally affected** by their FMS, and thus tend to be happier overall

Age and FMS

- Your ability to cope with FMS will improve with time
- Your symptoms will seem like less of a big deal with every passing day
- With the coping strategies you have learned, you can learn to enjoy your life every day, and turn FMS into a small aspect of your life

Session Conclusion

- There is still much to be learned about the condition of FMS, and the best ways to treat it.
- New discoveries are made every year!
- Thank you for participating and helping us continue to learn more about this forefront of research!

End of Session

- Questions/Comments?

Appendix C: Original Program Evaluation Survey

Date _____ ID#_____

Evaluation

The following questionnaire is designed to assist in the evaluation of this program. Please circle one answer for each of the following items based upon your feelings and perceptions about the program. Your comments will be helpful in the planning of future programs.

1. How many sessions did you attend?

1 2 3 4 5 6 7 8 9 10 11 12 13

2. The purpose and goals of the program were:

Never explained (unclear)	Given little explanation (not very clear)	Somewhat explained (somewhat clear)	Explained fairly well (clear)	Fully explained (very clear)
1	2	3	4	5

3. The length of time for each session was:

Too short	Somewhat too short	Satisfactory	Somewhat too long	Too long
1	2	3	4	5

4. The number of sessions was:

Too Few	Somewhat too few	Satisfactory	Somewhat too many	Too Many
1	2	3	4	5

5. The pace of each session was:

Too Slow	Somewhat too slow	Just Right	Somewhat too fast	Too fast
1	2	3	4	5

6. The discussion and materials presented in this program were:

Not at all useful	Somewhat unuseful	Neither useful nor unuseful	Somewhat useful	Relevant and useful for me
1	2	3	4	5

7. The opportunity to participate and contribute in the program was:

Very poor	Somewhat poor	Neither poor nor good	Good	Excellent
1	2	3	4	5

8. Applying what you learned in this program to your daily life can be:

Very Unhelpful	Somewhat unhelpful	Neither helpful nor unhelpful	Somewhat helpful	Very helpful
1	2	3	4	5

9. Do you think that you could make use of the techniques used/taught in this program in the future?

Not at all	With some difficulty	Maybe	Somewhat easily	Very Easily
1	2	3	4	5

10. On a scale of 0 through 5, please evaluate the following:

	Not helpful	Very Unuseful	Somewhat Unuseful	Neither useful nor unuseful	Somewhat helpful	Very helpful
a. Handouts	0	1	2	3	4	5
b. Exercises	0	1	2	3	4	5
c. Role playing	0	1	2	3	4	5
d. Interactions	0	1	2	3	4	5
e. Facilitator Communications	0	1	2	3	4	5

11. Was the program:

a. Organized in presenting material?	No, disorganized 1	Somewhat disorganized 2	No opinion 3	Somewhat organized 4	Very organized 5
b. Clear in conveying information?	No, unclear 1	Somewhat unclear 2	No opinion 3	Somewhat Clear 4	Very clear 5
c. Interesting?	No, uninteresting 1	Somewhat uninteresting 2	No opinion 3	Somewhat interesting 4	Very interesting 5

12. Would you recommend this program to a friend?

No	Not Likely	Maybe	Likely	Yes
1	2	3	4	5

13. How would you rate this program overall?

Poor	Somewhat poor	Average	Good	Excellent
1	2	3	4	5

14. How satisfied are you with this program overall?

Not at all satisfied	Somewhat unsatisfied	No opinion	Mostly satisfied	Completely satisfied
1	2	3	4	5

15. Please include any comments that may help in the future planning of this program.

a. What did you like most about the program?_____

_____

_____

b. What did you like least about this program?_____

_____

_____

c. What could you recommend to improve this program?_____

_____

_____

d. Do you have any other comments you would like to make about this program? If so, please state them here. _____

_____

_____

Thank you!

Appendix D: Subjective Units of Distress Worksheet

My pain-related anxiety scale

This is going to serve as your yardstick for examining current levels of pain-related fear or anxiety. Please give an example of a type of experience that will bring about each level of anxiety for levels 1, 3, 5, 7, 9, and 10.

For example, "level 1 fear/anxiety of pain would be… stubbing my toe *because* …I do not think the pain experience will be intense or last long". For another example, "level 3 fear/anxiety of pain would be…walking to the store *because*… I expect some pain that I will be able to tolerate and that will not last for more than a brief period (30-60 minutes, maybe)."

Level 1 fear/anxiety of pain would be_____
because_____.
(no to low pain-related anxiety)

Level 2

Level 3 fear/anxiety of pain would be _____
because_____.

Level 4

Level 5 fear/anxiety of pain would be _____
because_____.
(moderate pain-related anxiety; you likely do not avoid activities completely that bring up this level of anxiety)

Level 6

Level 7 fear/anxiety of pain would be _____
because_____.

Level 8

Level 9 fear/anxiety of pain would be _____
because_____.

Level 10 fear/anxiety of pain would be _____
because_____.
(highest level of pain-related anxiety you could possibly experience; you likely completely avoid activities that bring up this level of anxiety)

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