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EFFECTIVENESS OF AN INTERDISCIPLINARY CHRONIC ARTHRITIS PAIN GROUP  
INTERVENTION IN AN OUTPATIENT HEALTHCARE SETTING

by

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M.S. University of Central Florida, 2015

A dissertation submitted in partial fulfillment of the requirements  
for the degree of Doctor of Philosophy  
in the Department of Psychology  
in the College of Sciences  
at the University of Central Florida  
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Major Professor: Jeffrey Cassisi

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## **ABSTRACT**

Rheumatoid arthritis (RA) is a chronic autoimmune disease that often results in inflammation, pain, fatigue, functional impairment, and psychosocial difficulties. The current study examines the effectiveness, feasibility, and sustainability of an interdisciplinary chronic pain intervention for patients with RA. Wearable fitness trackers were incorporated into the intervention and objectively measured participant physical activity. A total of 44 participants received the intervention and completed outcome measures.

Results supported improvements across multiple domains at the end of treatment and at 4-week follow-up compared to treatment baseline. Mixed multilevel repeated measures modeling revealed significant overall improvements in many primary (i.e., self-efficacy for managing chronic disease, pain intensity, pain interference, depression, and health-related quality of life), secondary (i.e., physical functioning, overall quality of life, and chronic pain acceptance), and in an objective measure of physical activity (i.e., average steps per day).

Effect sizes were generally small to medium and were similar to or better than those reported in meta-analyses. Patients with comorbid fibromyalgia syndrome recorded significantly worse scores across measures, but showed steady improvement throughout the intervention. Mixed-method analysis suggested that patients were interested in and satisfied with the intervention. Implications for optimization and long-term sustainability are discussed.

This study was supported by funding awarded by the University of Central Florida College of Medicine and the Foundation for Rehabilitation Psychology Dissertation Award.

This dissertation is in dedication to my parents who have instilled in me values of hard work, perseverance, and commitment to academic endeavors. Without these values, I would not have been as driven to overcome adversity to get to where I am today. I am forever grateful to have had such a positive influence from such wonderful, loving parents and seek to do right by the values they have nurtured in me.

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## INTRODUCTION AND LITERATURE REVIEW

Arthritis, the leading cause of disability among Americans, has significant impacts on both physical and mental health (Centers for Disease Control and Prevention, 2014). Rheumatoid arthritis (RA) is a chronic, inflammatory autoimmune disease and is one of the more common forms of arthritis, affecting approximately 1.3 million adults in the U.S., primarily women (Schiller, Lucas, Ward, & Peregoy, 2012). During the course of the disease, immune cells attack the synovial membranes in the body (i.e., the flexible capsules surrounding joints), causing inflammation, pain, stiffness, and damage to cartilage and bone (Aletaja, et al., 2010). Over time, the joints can become irreversibly deformed, causing permanent losses in range of motion, dexterity, and strength. RA primarily impacts the smaller joints (i.e., in the hands and feet), which results in functional impairment in many activities of daily living such as gripping items, turning doorknobs, buttoning, writing, typing, and walking distances (Aletaja, et al., 2010; Bombardier, et al., 2012).

In addition to the impact on physical function and wellbeing, individuals with RA also experience a multitude of psychosocial difficulties. Pain, fatigue, and medications often contribute to weight gain, sleep difficulties, depression, low motivation, and associated distress (Irwin, et al., 2012; Matcham, Rayner, Steer, & Hotopf, 2013). Any combination of these factors impact engagement in social activities and/or family dynamics (e.g., perceived failure to fulfill parental duties; Benka, et al., 2014; Matcham, et al.). Other common concerns among individuals with RA are feeling misunderstood and invalidated by others (e.g., “it’s *just* arthritis”) and having difficulty accepting changes in functioning (e.g., “I’ve always taken care of myself *and* everyone else”; Peter, et al., 2014). As the presentation and needs of patients with RA are varied, patients are at risk for fragmentation of health care (i.e., patients may see multiple separate

providers for a single, complex issue). Integrated healthcare approaches are useful in addressing the multifaceted problems faced by patients with RA (Coleman, Austin, Brach, & Wagner, 2009; Cunningham, & Kashikar-Zuck, 2013).

### Patterns of Pain in Rheumatoid Arthritis

Nociception refers to the processing of neural information, alerting one to potential tissue damage in the body, leading to the sensation of pain. Pain, on the other hand, is perhaps best viewed as a biopsychosocial phenomenon where a physical sensation triggers neurological, cognitive, emotional, and behavioral responses (Gatchel et al., 2007). Pain is a subjective experience and patients rarely distinguish the physical sensation from these various responses, thus making it difficult to reliably measure or define pain (Turk & Melzack, 2011). Pain is traditionally classified as either acute, with sudden onset in response to a harmful stimulus, or chronic, persistent pain lasting at least three months (Lee, Nassikas, & Clauw, 2011). Acute pain can be adaptive, as it provides an important signal to tend to potential damage in the body (e.g., one may rest a sprained ankle, allowing it to heal). In chronic pain, however, pain signals can encourage maladaptive responses (e.g., one may rest in the presence of persistent pain, leading to muscle atrophy and deconditioning; Gatchel et al., 2007).

According to the biopsychosocial model of chronic pain, individual experience is influenced by a variety of biological and psychosocial factors (Gatchel et al., 2007). For example, genetic factors can influence susceptibility, neural pathways can become potentiated and signal pain without the presence of a stimulus, and hormonal fluctuations can impact perceptions. Additionally, pain is typically experienced as unpleasant which triggers an affective response as well as negative cognitive patterns, such as catastrophic thinking and lack of perceived control (Kerns, Sellinger, & Goodin, 2011).

Patterns of pain in patients with RA vary depending on a number of factors including disease-related, behavioral, and psychological factors. Most patients experience persistent intermittent joint pain, swelling, and stiffness as a normal part of the disease (Aletaja, et al., 2010; Smolen, et al., 2010). This can be transient or longer lasting (e.g., minutes vs. months) depending on the severity of the disease, presence of inflammation, and a patient's responsiveness to their medication regimen. Additionally, level and type of daily activity impact pain (Metsios, et al., 2008; Stenström & Minor, 2003). More sedentary lifestyles tend to correspond with greater joint stiffness, making movement painful; muscle deconditioning, making exercise more difficult and painful; and obesity, which places further strain on joints. On the other hand, overactivity can trigger inflammation which increases pain and often necessitates a recovery period with limited activity. Inactivity or inconsistent activity over time tends to result in chronic physical dysfunction, increasing the likelihood of pain and related complications (Nielson, Jensen, Karsdorp, & Vlaeyen, 2013). Finally, psychological factors impact pain experience, both directly and indirectly. The experience of pain itself can negatively impact a person's mood, anxiety, motivation, and sleep. However, low mood, anxiety, stress, low motivation, and poor sleep can also potentiate and worsen the experience of pain (Gatchel, et al., 2007).

Patients with RA also commonly experience "flares," acute episodes of joint inflammation and pain. Flares occur when there are bursts of disease activity which can attack one or more joints for a period ranging from a few hours to a week or more (Bingham, et al., 2009). The pain and functional limitation associated with flares tends to be more severe and disruptive than that experienced on an ongoing basis. Flares are also often accompanied by fatigue, flu-like symptoms, and patient distress (Hewlett, et al., 2012).

Even when inflammation and disease activity is well controlled, patients with RA often continue to struggle with chronic pain (Wolfe, et al., 2014). Research suggests that chronic pain from RA may correspond with neurological changes (e.g., central sensitization) that increase the likelihood of developing other types of difficulties, such as fibromyalgia syndrome ([FMS]; Lee, Nassikas, & Clauw, 2011; Wolfe, Häuser, Hassett, Katz, & Walitt, 2011). About 15-20% of patients with RA have comorbid diagnoses of FMS as compared to 2-8% prevalence estimates in the general population (Dolan, Tung, & Raizada, 2016). A comorbid diagnosis of FMS is considered if a patient is experiencing chronic widespread pain (i.e., other than small joint pain), somatic symptoms (e.g., fatigue, sleep disturbances), and cognitive symptoms (e.g., difficulty concentrating, feeling “in a fog”), that all exceed what could be explained by RA or other medical conditions (Wolfe, et al., 2010). Factors such as severe disease activity, psychosocial distress, and obesity increase the likelihood that patients with RA will develop FMS (Wolfe, et al., 2011).

### Treatment of Rheumatoid Arthritis

There is no cure for RA. Successful treatment of RA includes slowing the progression of the disease, managing pain and other symptoms, and maximizing quality of life (Smolen, et al., 2010). As RA is a heterogeneous disease, treatments vary widely depending on the severity of the disease and related functional impairment. The presence of comorbid conditions, such as FMS, further complicates effective intervention. The role of the rheumatologist is crucial in managing RA. Best practice guidelines for the medical treatment of RA are outlined by the American College of Rheumatology (ACR; Singh, et al., 2012; Smolen, et al., 2010).

## Rheumatological Care

Medication is the first line of treatment for patients with RA. Fortunately, the availability and effectiveness of medications for RA has greatly improved over the last decade (Aletaja, et al., 2010; Singh, et al., 2012). The most common forms of treatment are disease-modifying antirheumatic drugs (DMARDs), usually taken in pill form; biologic agents, commonly a self-administered injection; and combination therapy, using both a DMARD and a biologic agent to treat RA. These medications help to control the disease by targeting different molecules in the body that slow its progression (Singh, et al., 2012). Medications are elected for a particular patient by a rheumatologist depending on symptom and disease severity, patient reports of pain, comorbid conditions, and lifestyle factors (Smolen, et al., 2010; Singh et al.). Serological status, meaning the presence (seropositive) or absence (seronegative) of certain biomarkers in the blood, may also impact medication regimen and therapeutic response (Pratt & Isaacs, 2014). Physicians routinely perform exams, monitor blood inflammatory markers (e.g., C-Reactive Protein and Erythrocyte Sedimentation Rate), and review imaging tests of affected joints in order to monitor the progression of the disease and the effectiveness of the medication regimen (Smolen, et al.).

Patients diagnosed with comorbid FMS can pose challenges to physicians in adjusting disease-modifying medications and in attempting to bring the disease into remission (Durán, Combe, Niu, Rincheval, Gaujoux-Viala, & Felson, 2015). Increased complaints of pain, fatigue, sleep disruption, depression, distress, and physical dysfunction among patients with comorbid FMS can become confounded with the disease process and result in limited improvements on RA disease activity measures (Joharatnam, McWilliams, Wilson, Wheeler, Pande, & Walsh, 2015; Wolfe, et al., 2014). Multiple entities have suggested a multimodal approach to the treatment of both RA and FMS (Borenstein, et al., 2010; Kidd, Langford, & Wodehouse, 2007). For example,



a patient may receive additional medications or other treatment to manage both the chronic and acute pain associated with the disease. Further medications or outside referrals to address pain, fatigue, difficulties with sleep, symptoms of depression, or anxiety may be considered, especially in patients with comorbid diagnoses of FMS. Exercise therapy may also be prescribed as an adjunctive therapy both in treating pain and preventing future comorbidities and complications (Combe, 2007).

### Physical Fitness and Activity

Individuals with RA are at an elevated risk of developing cardiovascular and other chronic diseases, highlighting the importance that patients maintain a healthy lifestyle (i.e., eating well and exercising consistently; Peters, et al., 2010). Patients with RA often struggle to maintain physical fitness as easily as healthy individuals (Eurenius & Stenström, 2005). Evidence from randomized controlled trials (RCTs) and systematic reviews supports the safety and benefits of exercise therapy, ranging from low to high intensity, for patients with RA (de Jong, et al., 2003; Metsios, et al., 2008; Stenström & Minor, 2003). Common types of exercise training include resistance, aerobic, and aquatic training. The goals of exercise are generally to improve range of motion, build strength, and improve cardiovascular health (Metsios, et al.). In order to avoid under or overactivity, progressive adjustment of goals is recommended (Stenström & Minor, 2003).

Exercise therapy also results in improvement in symptoms associated with FMS, such as fatigue, physical functioning, and wellbeing, suggesting that it may be a particularly useful adjunctive therapy for patients with comorbid RA and FMS (Busch, Barber, Overend, Peloso, & Schachter, 2007; Hegarty, Conner, Stebbings, & Treharne, 2015). Education as well as cognitive-behavioral strategies have been shown to improve adherence to exercise programs in

patients with RA (Hoffman, Peters, Geidl, Hentschke, & Pfeifer, 2013; Metsios, et al.).

Education may correct inaccurate perceptions of chronic pain as signs of harm to the body, while cognitive-behavioral strategies may counteract low motivation commonly felt by patients with RA (Kerns, Sellinger, & Goodin, 2011; Metsios, et al.).

### Mental and Behavioral Health Care

Though mental health concerns (e.g., depression, anxiety, stress) are highly prevalent among patients with RA, patients are seldom provided with the opportunity to discuss these concerns in the context of their medical care (Dures, et al., 2014). Chronic depression leads to worse physical function and higher mortality among patients with RA, even when controlling for disease-related factors, and also increases the likelihood of the development of FMS (Matcham, Rayner, Steer, & Hotopf, 2013; Morris, Yelin, Panopalis, Julian, & Katz, 2011; Wolfe, Häuser, Hassett, Katz, & Walitt, 2011). Emotional support has been shown to weaken the link between functional disability and depression over time, particularly among patients with a greater degree of disability (Benka, et al., 2014). This suggests that addressing mental health concerns may also benefit physical health and lowered quality of life associated with RA (Haroon, Aggarwal, Lawrence, Agarwal, & Misra, 2007).

Cognitive-behavioral therapies are considered the “gold standard” psychological intervention for chronic pain (Ehde, Dillworth, & Turner, 2014; Turner, Holtzman, & Mancl, 2007). Much empirical support exists for cognitive-behavioral intervention with patients with RA; effect sizes of treatment outcomes are typically small to moderate, with larger effects for improved coping and self-efficacy and smaller effects for depression, disability, and joint inflammation (Csaszar, Bagdi, Stoll, & Szoke, 2014; Dixon, Keefe, Ceipis, Perri, & Abernethy, 2007; Ehde, Dillworth, & Turner; Kerns, Sellinger, & Goodin, 2011; Knittle, Maes, & De Gucht,

2010). Acceptance and commitment therapy (ACT), a third-wave cognitive-behavioral therapy, is increasingly more broadly implemented and has been found to have chronic pain treatment effects similar to those found for other forms of CBT (Veehof, Oksam, Schreurs, & Bohlmeijer, 2011; Zautra, et al., 2008). Two major theoretical mechanisms of ACT, pain acceptance and value-based action, mediate large and sustained improvements in depression and anxiety; moderate decreases in pain-related disability and number of medical visits; and small decreases in reported pain (Vowles, McCracken, & Eccleston, 2007; Vowles, McCracken, & O'Brien, 2011). Interventions that incorporate other common evidence-based techniques such as psychoeducation, relaxation training, active problem-solving, and coping skills building have also been shown to be effective in addressing the varied concerns in patients with RA (Csaszar, Bagdi, Stoll, & Szoke, 2014; Englbrecht, et al., 2012; Kerns, Sellinger, & Goodin, 2011).

Mental and behavioral health interventions are becoming more prominent in medical settings. One study demonstrated that an ACT group intervention for chronic pain was feasible in a primary care setting and was well-perceived by patients (McCracken, Sato, Wainwright, House, and Taylor, 2014). Another study found that cognitive-behavioral therapy tailored for patients with newly diagnosed RA in addition to their regular medical care resulted in improved outcomes compared to patients receiving standard medical care (Evers, Kraaimaat, van Riel, & de Jong, 2002). Research suggests that patients with RA with recurrent depressive episodes, who express greater distress, with shorter disease duration, and/or who are at higher risk for chronic impairment receive greatest benefit of these types of interventions (Knittle, Maes, & De Gucht, 2010; van Koulil, et al., 2007; Zautra, et al., 2008).

### Opportunities for Improved Rheumatologic Care

Rheumatologists are tasked with managing many parts of a complex disease, along with the sequelae, in what may be only a twenty minute visit every three months (Smolen, et al., 2010). Given the time constraints of these visits, some patient concerns may go unaddressed or even unnoticed. As a result, patients are left with a variety of unmet healthcare needs (Kjeken, Dagfinrud, Mowinckel, Uhlig, Kvien, & Finset, 2006). This is especially true for patients with more complex clinical presentations, such as those with uncontrolled disease, serologically unclear presentations, and those with comorbid FMS. Even patients that successfully follow through with referrals or seek external aide are still at risk for receiving fragmented care, meaning the care they receive for individual symptoms or symptom clusters may be less effective than treating the “whole person” in a multi- or interdisciplinary fashion. Integrated interventions for chronic pain, which often combine medication management, physiotherapy, education, and psychosocial components, are a promising solution to the problem of fragmented care (Peek, 2013).

There exist a multitude of ways in which health services may be integrated (Peek, 2013). In the context of pain management, this has traditionally taken the form of multi- or interdisciplinary care (Gatchel, McGeary, McGeary, and Lippe, 2014). *Multidisciplinary* care consists of multiple treatment components from multiple providers (which may or may not be co-located). Systematic reviews and meta-analyses of multidisciplinary treatments for chronic pain provide ample support for their efficacy and long-term cost-effectiveness over treatment as usual (Kamper, et al., 2015; Scascighini, Toma, Dober-Spielmann, & Sprott, 2008). One potential limitation of this type of care is that there is often little communication between these providers and each provider may have separate treatment goals (Gatchel, et al., 2014).

*Interdisciplinary* care also consists of multiple treatment components delivered by multiple providers; however, this type of care is characterized by co-location of services, frequent communication and coordination of goals among the treatment team, and active patient involvement (Gatchel, et al., 2014). Essentially, an interdisciplinary intervention involves a unified treatment team to comprehensively address patient needs. Research suggests that this level and type of integration is cost-effective and may have synergistic effects that exceed the short- and long-term clinical outcomes seen in co-located multidisciplinary care (Gatchel, et al., 2014; Gatchel & Okifuji, 2006; Turk & Swanson, 2007).

The majority of interdisciplinary chronic pain interventions are brief, intensive, and occur in tertiary care settings (Gatchel, et al., 2014). Many patients with RA may experience chronic pain and never enter care in these specialized settings, leaving many of these individuals without the benefits received through interdisciplinary pain management (Gatchel, et al., 2014). Further, relatively brief interventions in tertiary settings may not meet all of the needs of individuals with chronic, evolving health conditions, such as RA (Gatchel, et al., 2014). More research is needed to highlight the ways in which interdisciplinary care can be effectively incorporated into primary and secondary outpatient healthcare settings (Gatchel, McGeary, McGeary, and Lippe, 2014; Li, et al., 2008). With regards to RA management, this may include improved communication between the rheumatologist and pain management center or incorporating behavioral health services into the outpatient practice setting, among other solutions (Esselens, Westhovens, & Verschueren, 2009; Li, et al., 2008). One recent pilot study examined the effectiveness of a group medical visit with promising results (Shojania & Ratzlaff, 2010). Multiple patients with RA attended a shared medical appointment with a rheumatologist along with other providers, allowing for the patients' varied needs to be met in a single visit.

Finally, as we progress further into the digital age, technology is becoming increasingly integrated into healthcare delivery. Telehealth is a promising future direction in many areas of healthcare, including facilitating patient follow-up between office visits and improving coordination of care across multiple providers in chronic pain management (Ehde, Dillworth, & Turner, 2014). Mobile and online applications and games are rapidly emerging and may serve to help keep patients motivated and engaged in their healthcare outside the context of their regular medical visits (Howie, Hirsch, Locklear, & Abernethy, 2014). The integration of technology into medical care provides increased opportunities for capturing real-time patient data, offering an improved alternative to retrospective self-report. The collection of more accurate information assists both data-driven treatment planning and clinical research efforts.

#### Current Study

The current study seeks to add to the literature by examining the effectiveness, feasibility, and sustainability of an interdisciplinary group intervention for chronic arthritis pain in the context of an outpatient rheumatology clinic. The intervention was designed to help patients diagnosed with RA who experience chronic pain to develop the knowledge and skills necessary to successfully manage their symptoms and to live a meaningful life. Wearable fitness trackers were incorporated into the intervention with the goals of objectively measuring physical activity and improving motivation through the continuous feedback and in-session review of physical activity. A pragmatic, quasi-experimental research design was utilized to address study aims.

#### Aim 1: Effectiveness

Multiple primary and secondary outcomes were chosen to evaluate the effectiveness of the current intervention across key pain-related domains, consistent with recommended guidelines (Dworkin, et al., 2008). Specifically, primary outcome measures were chosen to

reflect the interdisciplinary treatment goal (i.e., self-efficacy for managing chronic disease) and four core pain-related domains (i.e., pain intensity, pain interference, depressive symptoms, and health-related quality of life; Dworkin, et al., 2008). Primary outcomes will be the principle determinants of intervention effectiveness (Turk, et al., 2008). A number of secondary measures were chosen to provide supplemental information about other outcomes that are relevant, but not integral, to effectiveness (i.e., physical functioning, perceived wellbeing, sleep quality, and other quality of life domains). Additionally, chronic pain acceptance was selected as an additional secondary outcome in order to capture therapeutic change consistent with the ACT foundation of the current intervention. Chronic pain acceptance has been shown to mediate improvements in pain and related outcomes in ACT efficacy trials (Vowles & McCracken, 2008). Finally, objective physical activity was measured by wearable fitness trackers and included in outcomes. Improved physical activity has been shown to be a major mechanism of change in pain-related outcomes (Stenström & Minor, 2003).

Repeated measure analyses were used to assess changes in key outcome variables across study time points (i.e., intake, treatment baseline, midpoint, end of treatment, 4-week follow-up). Main effects of Time were predicted consistent with change over time in participant measures. In order to further assess these changes, changes both pre- and post-treatment were examined. First, the hypothesis (1) of significant differences in study measures between intake and treatment baseline was first tested. Given the lack of comparison group, it would be difficult to conclude that any subsequent differences were a likely effect of the intervention should this hypothesis receive support. Should this hypothesis not receive support, there would be no evidence of significant pre-treatment changes in outcomes and subsequent analyses would examine changes from treatment baseline. Specifically, given the latter possibility, it was hypothesized: 2)

Significant improvements would be seen between treatment baseline and the end of treatment in (a) primary outcomes, (b) secondary outcomes, and (c) objective activity measures. 3a)

Responses to study measures would remain significantly improved at follow-up compared to treatment baseline. Further, given that outcomes are surrounding self-management of pain and disease, it is feasible that outcomes may continue to improve as patients continue to implement skills beyond the intervention. 3b) Thus, significant improvements in outcome measures were predicted between the end of treatment and 4-week follow-up time points.

Moderators of intervention outcomes were also examined. Given the added complexity of patients with comorbid FMS, 4) participants with comorbid diagnoses were hypothesized to significantly differ across measures compared to participants without comorbid FMS (i.e., significant main effect of FMS). Further, interdisciplinary care is strongly recommended for successful management of FMS due to the variable needs of these patients and related risk of fragmented care (Arnold, Gebke & Choy, 2016). Thus, 5) it was predicted that there would be a significant FMSxTime interaction indicating that participants with comorbid FMS showed greater improvement in outcome measures with this integrated intervention than participants without comorbid FMS.

The role of serostatus as a treatment moderator is understudied and thus was explored in the current study. Existing research illuminates the differences in medication responsiveness and prognosis between patients with seropositive and seronegative RA; however little attention has been paid to responsiveness to other forms of intervention (Pratt & Isaacs, 2014). Given that seropositive patients have more severe disease on average, they may receive greater benefit from the present intervention in terms of managing pain and functional disability. On the other hand, seronegative patients typically experience ambiguity with their health condition prior to



diagnosis and may benefit from increased confidence in their ability to manage their disease. Therefore, 6) the main effect of serostatus and its interaction effect with time were explored.

Given the pragmatic nature of the study, the clinical significance of outcomes was also evaluated. Effect sizes of treatment outcomes were calculated and are compared to those found in the available literature in order to provide information about the present intervention's relative effectiveness (Dixon, Keefe, Ceipis, Perri, & Abernethy, 2007; Ehde, Dillworth, & Turner, 2014; Knittle, Maes, & De Gucht, 2010; Veehof, Oskam, Schreurs, & Bohlmeijer, 2011). In addition, responder analysis evaluated individual changes over time in key outcomes in light of predetermined clinically important differences (Dworkin, et al., 2008).

#### Aim 2: Feasibility and Sustainability

Despite evidence of the efficacy of interdisciplinary interventions, many barriers impede the translation of research into practice (DeBar, et al., 2012). Thus, data related to the feasibility and sustainability of these types of interventions is increasingly important. In order to assess the present intervention's feasibility, patient, provider, and facility factors were examined and discussed. In particular, it was predicted that: 1) patients would demonstrate interest in receiving the current intervention (as indicated by participant recruitment information); 2) participants enrolled in the study would remain engaged throughout the intervention (as evidenced by attendance, dropout rates, and facilitator evaluations of participation); and 3) participants would be satisfied with the intervention (as measured by a combined quantitative and qualitative questionnaire). Finally, the sustainability of this type of intervention is discussed in the context of the current structure of the healthcare system and emerging areas of research.

## **RESEARCH DESIGN AND METHODOLOGY**

### **Participants and Recruitment**

Participants were recruited from the patient population at a rheumatology clinic located within an outpatient academic medical center providing both primary and specialty healthcare. New or returning patients with RA were referred by their rheumatologist and then contacted by a behavioral health specialist to assess for study inclusion. In order to be included in the study, patients were required to be 18 years or older, have a diagnosis of RA, and report experiencing chronic pain. Diagnoses of RA were assigned by board-certified rheumatologists in accordance with ACR classification criteria (Aletaha, et al., 2010). Patients were not eligible for the study if they were pregnant or if they had major health concerns or suicidality that would not be adequately addressed in the group intervention context. Individual intervention and/or community referrals were available to patients who did not meet study criteria or who chose not to participate in the study.

Patients that met study criteria were then scheduled for an individual intake interview during which they were given study information, provided informed consent, were interviewed about their experience with RA and pain, and completed study questionnaires. After completing the intake session, participants were enrolled into the next available group wave, received the intervention, and then attended a follow-up session four weeks post intervention to complete the study. Of the 130 patients that were referred to the study, 52 were enrolled in the study and 46 participated in at least one group session. See results for more detailed recruitment information. All study-related activity took place in the outpatient healthcare clinic and was approved by the University Institutional Review Board and clinic administration.

### Intervention Background and Development

The Living Well with Chronic Pain group was developed to address the unmet needs of patients in an outpatient rheumatology clinic. An informal needs assessment conducted by rheumatology and behavioral health identified patients with RA as a large patient population with multiple unmet needs. Specifically, given the time constraints of medical visits, patients are not always able to receive thorough medical education, to learn and receive guidance about (safe) physical activity, and/or to address their social and behavioral health needs. These three areas of need formed the main components of the present group. A review of the literature served to further explicate RA patient needs, important therapeutic processes for patients with RA, and evidence-based practices for treating RA and chronic pain. As a result, an integrated treatment approach was developed, guided by the biopsychosocial model, to address the various medical, physical, and behavioral health needs of patients with RA who experience chronic pain.

The main goal of the medical education component was to remove lack of knowledge as a barrier to successful management of RA. Medical education is viewed as a critical factor in the self-management of chronic disease (Riemsma, Kirwan, Taal, & Rasker, 2003). Further, additional patient access to physicians may increase patient engagement in their health care and provide a forum for learning that is not as available in the context of their typical health visits.

Given the prominence of maladaptive patterns of activity (i.e., over or underactivity) among patients with RA, the primary goal of the physical activity component was to provide information about how to develop adaptive patterns of physical activity in the service of maintaining and improving physical function. Fear of physical activity is common in patients who experience pain (Leeuw, Goossens, Linton, Crombez, Boersma, & Vlaeyen, 2007). Additionally, some physical activity may be contraindicated in the presence of certain pain (e.g.,

pain during acute flares) but not in other cases (e.g., general chronic pain). Therefore, patients were provided education and information about safe physical activity with RA and related pain and introduced to a broadly-applicable exercise program.

The mental and behavioral health component was designed to serve several purposes. Psychoeducation about a variety of topics as well as skills building were included in order to increase knowledge and awareness of self-management strategies. Specifically, sessions included information about basic cognitive-behavioral principles, successful goal setting, sleep hygiene, coping with stress and mood changes, and communication skills. In addition, behavioral health techniques were incorporated to expand upon topics covered in the medical and physical activity components. For example, activity pacing was introduced in conjunction with material covered by the physical therapist and different techniques were used to build motivation to engage in health behaviors (e.g., exercise programs). Finally, key ACT processes of pain acceptance and commitment to valued action were incorporated throughout the intervention to address maladaptive patterns of cognition and behavior surrounding living with chronic pain and disease.

Though each component contained its own goals and patients have heterogeneous clinical presentations, each session and each member of the interdisciplinary team shared the united goal of increasing patient efficacy for the self-management of their chronic condition. Each component was designed to build upon one another such that the intertwined nature of RA and its physical and psychological sequelae was highlighted and addressed. Each member of the treatment team was familiarized with the content provided in all components of the intervention and was able to relate information across domains. Finally, the inclusion of other patients with RA introduced elements of peer support, provided real-life examples of patients struggling and thriving with RA, and facilitated validation of feelings common across patients. Group format

was chosen for the additional benefit of cost-effectiveness relative to individual-level intervention.

### Intervention

The Living Well with Chronic Pain group consisted of 8 weekly sessions, each lasting 90 minutes, held at the outpatient specialty clinic. The unified goal of the intervention was to increase patient self-efficacy in managing RA and pain. In order to achieve this, the therapeutic processes of pain acceptance and value-based activation, consistent with ACT, provided the framework through which the various treatment components were delivered (Veehof, et al., 2011). Patients learned how: to disengage from living life to avoid pain and illness (experiential avoidance); to accept that RA is a chronic disease and that chronic pain, acute flares, and changes in functioning are part of the disease (acceptance); and to make behavior changes that lead to a healthier, more valuable life despite the presence of pain and RA (valued living).

Each session was led by one or more members of the treatment team (i.e., two rheumatologists, physical therapists, and behavioral health specialists). Members of the treatment team held regular informal meetings and discussions about group progress and goals. A typical session consisted of (1) a review of physical activity measured by electronic fitness bands as well as behavioral goals set by patients the prior week, (2) an introduction of the topic of the week during which patients received related education and worksheets, (3) time to elicit and process patient experiences, and (4) setting behavioral goals for the following week. In the event that a patient missed a session, they were offered the opportunity to attend a brief (usually 30 minute) make-up session. An outline of each session, corresponding objectives, and session leaders is included in Table 1. See Appendix A for treatment guide. Patients also attended a four-week

Table 1

*Session Outline and Objectives*

<b>Week</b>	<b>Topic</b>	<b>Facilitators</b>	<b>Objectives</b>
1	Group Introduction and Medical Education	Behavioral Health Specialists Rheumatologist	<ol style="list-style-type: none"> <li>1. Orient patients to group and develop an accepting/ open environment.</li> <li>2. Provide patients with accurate information about RA and its course/treatment as well as an opportunity to clarify misconceptions.</li> <li>3. Introduce core cognitive-behavioral elements.</li> <li>4. Engage patients in the treatment process.</li> </ol>
2	Safe Physical Activity with RA	Physical Therapist Behavioral Health Specialists	<ol style="list-style-type: none"> <li>1. Strengthen patient understanding of core cognitive-behavioral principles using their personal examples.</li> <li>2. Educate patients about safe physical activity with arthritis and introduce a broadly-applicable exercise program.</li> <li>3. Introduce principles of activity pacing.</li> </ol>
3	Values and Goal Setting	Behavioral Health Specialists	<ol style="list-style-type: none"> <li>1. Describe how acceptance can be an effective option for those living with chronic pain.</li> <li>2. Facilitate patient exploration and clarification of values.</li> <li>3. Develop successful goal-setting skills.</li> </ol>
4	Improving Sleep	Behavioral Health Specialists	<ol style="list-style-type: none"> <li>1. Strengthen understanding of values and aid in clarification.</li> <li>2. Provide education about sleep hygiene and behavioral sleep strategies.</li> <li>3. Facilitate identification of target behaviors and goal development.</li> </ol>
5	Stress and Mood	Behavioral Health Specialists	<ol style="list-style-type: none"> <li>1. Review and develop coping skills that facilitate psychological flexibility in the presence of anxiety and mood symptoms.</li> <li>2. Reframe mood/emotions and anxious thoughts/sensations as barriers to valued living.</li> </ol>
6	Overcoming Barriers	Behavioral Health Specialists Rheumatologist Physical Therapist	<ol style="list-style-type: none"> <li>1. Provide a “panel of experts” to facilitate successful problem-solving in the face of barriers to committed action.</li> <li>2. Facilitate the development of successful problem-solving skills and willingness to encounter barriers.</li> </ol>
7	Relationships and Communication	Behavioral Health Specialists	<ol style="list-style-type: none"> <li>1. Continue the development of successful goal-setting and problem-solving skills.</li> <li>2. Explore impact of chronic illness on relationships.</li> <li>3. Review strategies that successfully communicate needs.</li> </ol>
8	Lifelong Change	Behavioral Health Specialists	<ol style="list-style-type: none"> <li>1. Briefly review major themes of treatment.</li> <li>2. Provide closure at the conclusion of group treatment.</li> </ol>

follow-up session in order to review continued progress, problem-solve new difficulties in meeting goals, and to complete follow-up questionnaires.

### Measures

#### Intake Interview and Review of Medical Records

Participants were assessed by a behavioral health specialist using a semi-structured interview designed for the study. Interviews lasted for approximately 30 minutes. Information obtained included demographic information, medical history, recent pain experience, current psychosocial functioning, and goals for the group intervention.

A review of patient medical records provided supplementary information about medical history and clinical presentation. Data obtained for study purposes included: medical diagnoses, medication lists, body mass index, and serological status. Participants were considered to have FMS if it was either indicated in their chart or they reported receiving that diagnosis from an external physician. Participants were considered to be seropositive/negative if they were labeled as such in their medical chart. In the absence of this label, participants were considered seropositive if elevated Rheumatoid Factor or Anti-Citrullinated Protein Antibodies were detected in laboratory samples and were considered seronegative if these antibodies were failed to be detected.

#### Primary and Secondary Outcomes

Multidimensional Health Assessment Questionnaire (MDHAQ): The MDHAQ is a brief self-report measure of disease activity over the past week recommended as a standard for use in clinical rheumatology practice with patients with RA by ACR (Anderson et al., 2012). The Rapid-3 (R3) score can be calculated from the MDHAQ is often recorded at each medical visit to track fluctuations in reported symptoms over time. Scores ranging from  $\leq 3$ , 3.1-6, 6.1-12, and

≥12 indicate remission, low, moderate, and high severity of symptoms, respectively (Pincus, Yazici, & Bergman, 2007). The R3 score is the sum of its three domain scores: functional impairment (R3: Function), pain intensity (R3: Pain), and global wellbeing (R3: Wellbeing).

The R3: Function score (0-10 scale) is calculated based on participant reports of difficulties in activities of daily living (e.g., get in and out of bed, turn regular faucets on and off, walk outdoors on flat ground). The R3: Pain and R3: Wellbeing scores are based on single items measuring pain intensity (No pain [0] to Pain as bad as it could be [10]) and participant ratings of global wellbeing (Very well [0] to Very poorly [10]). Higher scores on all MDHAQ subscales are indicative of greater disease activity. The R3: Pain subscale was used in analyses as the primary indicator for pain intensity. IMMPACT guidelines suggest that, using a 0-10 scale, changes of 1 and 2 points indicate slightly and much improved levels of pain, respectively (Dworkin, et al., 2008).

Pain Interference: Participants rated their average amount of pain interference over the past week using a scale of 0 (Does not interfere) to 10 (Completely interferes).

Beck Depression Inventory-II (BDI): The BDI is a 21-item self-report inventory designed to assess for the severity of common symptoms of depression over the past two weeks (Beck, Steer, & Brown, 1996). Participants rate the severity of each symptom based on statements that correspond to a score ranging from 0 to 3; the total score is the sum of all item responses with higher scores indicating greater severity of symptoms. Empirically-derived clinical cutoff scores aid in the interpretation of scores (i.e., 0-13, 14-19, 20-28, and 29+ indicate minimal, mild, moderate, and severe depressive symptoms, respectively). IMMPACT guidelines suggest that a change of 5 or more points on the BDI signifies a clinically important change in depressive symptoms (Dworkin, et al., 2008).



World Health Organization Quality of Life (QOL): The QOL is a 26-item inventory published by the World Health Organization that examines quality of life overall and in various domains: physical health, psychological health, social relationships, and quality of environment (WHOQoL Group, 1998). The following independent scales are produced with standard scores ranging from 0-100: QOL: Overall, QOL: Health, QOL: Psychological, QOL: Social, QOL: Environment.

Self-Efficacy in Managing Chronic Disease Scale (SEMCD): The SEMCD is a 6-item scale that assesses a patient's confidence in their ability to successfully manage their chronic condition as well as the associated pain, fatigue, emotional distress, and other related concerns (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001). For each item, participants rate their confidence on a scale of 0-10; total scores range from 0-60 with higher scores indicating greater self-efficacy.

Generalized Anxiety Disorder-7 (GAD): The GAD is a 7-item questionnaire commonly used in medical settings designed to screen for general anxiety problems (Spitzer, Kroenke, Williams, & Lowe, 2007). Scores of 5, 10, and 15 indicate mild, moderate, and severe levels of anxiety, respectively.

Sleep Quality: Participants rated their average quality of sleep over the past week with a single item on a scale of 0 (Not at all rested) to 10 (Completely rested).

Chronic Pain Acceptance Questionnaire (CPAQ): The CPAQ is a 20-item scale measuring an individual's overall acceptance of pain, consistent with the principles of ACT (McCracken, Vowles, Eccleston, 2004). The measure yields a total score as well as pain willingness (e.g., "Keeping my pain level under control takes first priority whenever I'm doing something." [reverse scored]) and activity engagement (e.g., "I lead a full life even though I have chronic pain.") subscale scores. Participants rate how often each statement applies to them

on a scale of 0 (Never true) to 6 (Always true). Higher total, pain willingness, and activity engagement scores indicate greater pain acceptance, recognition that avoidance and control strategies are often maladaptive, and involvement in activities despite pain, respectively. CPAQ scores have been found to correspond to pain-related disability and distress (Vowles & McCracken, 2008).

### Objective Activity Measures

Participants were provided with a wearable activity tracker (i.e., Fitbit Flex) for use in the study. The Fitbit Flex is a commercially-available activity tracking device that uses tri-axial accelerometry to estimate wearer physical activity. The Fitbit Flex has been found to have good test-retest reliability and to be a reasonably valid estimator of step count (Diaz, et al., 2015; Kooiman, et al., 2015). For the current study, number of daily steps and active minutes were downloaded at the end of the study from participants' consumer dashboard via fitbit.com. Weekly averages were calculated for both activity channels. Active minutes took into account minutes labeled lightly, fairly, and very active.

Participants were provided the activity trackers during the first session with instructions to create a user account through the consumer website and to begin wearing the device on their non-dominant wrist. Participants were encouraged to use the first week as an opportunity to monitor their typical activity and establish a "baseline" level of activity. During the second session, participants reflected on their experiences with the device. Between the second and third session, participants joined a closed group through the consumer website that enabled group members and facilitators to review one another's step activity. The group activity board was reviewed at the beginning of the third and each subsequent session.

## Feasibility Measures

Patient Experience: At 4-week follow-up, participants completed a patient experience survey created for current study purposes (see Appendix B). The survey consisted of 13 items that participants rated on a scale of 1 (Completely Disagree) to 5 (Completely Agree). Sample items include: “I feel that I am better able to manage pain as a result of this group” and “I would recommend other patients join this group.” Participants are also asked to rate their overall satisfaction with the group on a scale of 0 (Completely Dissatisfied) to 10 (Completely Satisfied). In addition, participants were provided the opportunity to provide written responses to the following questions: “What aspects of the group did you find most helpful?” “What aspects of the group did you find least helpful?” and “What specific changes would you recommend be made to this group?”

Patient Participation: Patient participation was rated independently at the end of each session by each of the behavioral health specialists using a rating form developed for the study (see Appendix A). Participation quantity was rated on a scale of 1 (Minimal) to 5 (Frequent). Participation quality was assessed with three items rated on the following scales: 1 (Critical of others) to 5 (Supportive of others); 1 (Withdrawn/Defensive) to 5 (Open/Willing); and 1 (Inappropriate/ Oversharing) to 5 (Appropriate sharing). Participants received a score of 0 in the event of an absence. Interrater reliability was assessed using a two-way mixed, consistency, average-measures intra-class correlation and found to be excellent ( $ICC = .88$ ).

## Analysis

Changes in all outcome variables across the five time points (intake, treatment baseline, midpoint, end of treatment, and 4-week follow-up) were assessed using Mixed Multilevel Repeated Measures Modeling. This type of modeling was chosen over other analytic approaches

(e.g., repeated measures ANOVA) as it more accurately captures the nested nature of the data (i.e., observations nested within individuals) and is very tolerant of missing data (Littell, Stroup, Milliken, Wolfinger, & Schabenberger, 2006). Models were specified using SAS procedure PROC MIXED with maximum likelihood estimation. An autoregressive covariance structure with random effects covariance component was imposed on the data. This combined covariance structure accounts for both the repeated measurements within subjects and the random effects between subjects (Littell, Pendergast, & Natarajan, 2000). The Kenward-Roger correction was specified for the estimation of  $F$ -statistics, standard errors, and degrees of freedom. This correction is recommended in repeated measures modeling, reduces Type I error rates, and adjusts for small sample bias (Bell, Ene, Smiley, & Schoeneberger, 2013; Guerin, & Stroup, 2000).

A model building process described by Bell and colleagues (2013) was used to assess change in each outcome. In this method, an unconditional model is first specified followed by models of increasing complexity (i.e., by adding level-1, then level-2 effects). AIC and BIC values were examined to assess model fit and identify the most parsimonious model. Subsequently, results from the best fitting model were used to examine study hypotheses. Results include tests of fixed and random effects and provide parameter estimates at each time point. Tests of effects are reported in Table 3. Follow up comparisons were made between groups (RA vs. RA+FMS, seropositive vs. seronegative) and between time points (intake vs. treatment baseline, treatment baseline vs. end of treatment and follow-up) consistent with study hypotheses (see Table 4).

Physical activity (i.e., average steps and active minutes per day) was analyzed the same as above, with the following difference. Given the differing frequency and scale of time points

(i.e., weekly from session 1 through follow-up) a RANDOM, rather than REPEATED, statement was specified to more accurately capture participant growth in activity. The same estimation methods were used and parameters reported as the repeated measures analyses. Similarly, follow-up analyses allowed for the pairwise comparisons of activity between groups and time points, consistent with *a priori* hypotheses.

IMMPACT guidelines were followed regarding the selection and analysis of multiple outcomes (Dworkin, et al., 2008; Turk, et al., 2008). In order to address inflated Type I error probability, Bonferroni-adjusted significance levels were used to assess for significant effects on the five primary outcome measures ( $p < .01$ ; Turk, et al., 2008). Given the relatively small sample size and associated limitations to statistical power in addition to the aim of effectiveness (rather than efficacy), unadjusted significance levels ( $p < .05$ ) were chosen to assess remaining outcomes in order to provide the most clinically useful information. Statistical outcomes are interpreted in tandem with effect sizes and responder analysis to assess overall study effectiveness.

Although the chosen analytic approach is not statistically impacted by missing data, it may affect interpretation of results. Percentages of missing primary and secondary outcome data points were calculated across all participants who attended at least one session ( $n = 46$ ) at each time point in order to explore the impact of attrition. At intake there was 8.7% missing data, treatment baseline: 5.9%, midpoint: 9.2%, end of treatment: 18.7%, and 24.7% missing data at follow up. Thus, it is important to interpret results with caution.

## RESULTS

### Sample Description and Intake Assessment

Between February 2015 and June 2016, a total of 46 participants attended the initial session of the Living Well with Chronic Pain group intervention, 44 (95.7%) of which were considered treatment completers (i.e., attended a minimum of 4 sessions) and were included in subsequent analyses. Most participants were female (84.1%), married or living with a partner (77.3%), and identified as Caucasian (63.6%). Remaining participants identified as Hispanic/Latino (18.2%), African-American/Black (11.4%), and Middle Eastern (4.5%). Many participants (45.4%) received a 4-year degree or more, 29.6% attended some college or received a 2-year degree, 22.7% completed high school, and 1 participant (2.3%) did not complete high school. At the time of intake, 43.2% were working full-time, 18.2% were working part-time, 18.2% were retired or not working, and 20.5% were on disability.

Participants ranged in age from 26-80 and were diagnosed with RA for an average of 9.04 ( $SD = 8.46$ ) years. In terms of medication, participants were prescribed and taking DMARDs (47.7%), biologic agents (15.9%), combination therapy (29.5%), or antimalarials only (4.5%). One participant was not taking any medication for RA. Independent samples *t*-tests revealed significant differences at intake between participants with comorbid FMS (31.8%) and those without (69.2%). No significant differences were found at intake between participants who were seropositive (69.2%) and seronegative (31.8%). A summary of participant data at intake assessment are presented in Table 2.

Table 2

*Intake Assessment*

<b>Measure (Scale)</b>	<b>RA (<i>n</i> = 30) <i>M</i> (<i>SD</i>)</b>	<b>RA+FMS (<i>n</i> = 14) <i>M</i> (<i>SD</i>)</b>
Age (Years)	54.52 (14.61)	51.71 (13.09)
Diagnosed with RA (Years)	7.55 (6.27)	12.24 (11.54)
Rapid 3 (0-30) **	11.70 (5.70)	17.77 (3.43)
Pain over past week (0-10) **	5.38 (2.55)	7.25 (1.20)
Pain Interference (0-10)	3.72 (3.22)	5.46 (2.70)
Self-Report Exercise (times per week)	2.75 (2.17)	1.86 (2.67)
BMI (kg/m <sup>2</sup> ) *	29.94 (7.03)	35.35 (8.26)
Self-Efficacy for Managing Chronic Disease (0-60) *	43.70 (12.14)	33.31 (11.69)
Chronic Pain Acceptance (0-120) *	69.22 (10.53)	58.71 (16.79)
Depression (BDI; 0-63) **	8.30 (6.55)	17.00 (10.44)
Anxiety (GAD; 0-21)	4.00 (4.41)	6.07 (4.32)
Quality of Life- Overall (0-100) *	63.75 (24.42)	47.32 (19.10)
Physical Health (0-100) ***	61.07 (20.41)	39.80 (15.72)
Psychological (0-100) **	72.22 (14.53)	54.17 (20.99)
Social Relations (0-100) *	75.00 (18.05)	59.52 (21.15)
Environment (0-100) *	78.64 (11.77)	67.19 (17.71)

*Note.* Significant group differences were determined using independent samples *t*-tests. Differences at the  $p < .05$ ,  $p < .01$ , and  $p < .001$  level are marked with \*, \*\*, and \*\*\* respectively. Reported *p* values do not assume equal variances. Rapid 3 scores take into account ratings of pain, physical functioning, and overall wellbeing.

The most commonly reported pain medications used by participants were NSAIDs ( $n = 29$ ), followed by acetaminophen ( $n = 12$ ), tramadol ( $n = 11$ ), opioids ( $n = 7$ ), anticonvulsants/anti-epileptics ( $n = 7$ ), serotonin-norepinephrine reuptake inhibitors ( $n = 7$ ), and muscle relaxants ( $n = 5$ ). Chi-square tests indicated that participants with comorbid FMS were more likely to report taking tramadol ( $p = .04$ ) and serotonin-norepinephrine reuptake inhibitors ( $p < .0005$ ) than participants without FMS.

### Aim 1: Effectiveness

Changes in outcome variables across five time points (intake, treatment baseline, midpoint, end of treatment, and 4-week follow-up) were assessed using Mixed Multilevel Repeated Measures Modeling. Results include tests of fixed and random effects and provide parameter estimates at each time point. Tests of effects are reported in Table 3. Follow up comparisons were made between groups (RA vs. RA+FMS, seropositive vs. seronegative) and between time points (intake vs. treatment baseline, treatment baseline vs. end of treatment and follow-up) consistent with study hypotheses (see Table 4). Bonferroni-adjusted significance levels were used to assess for significant effects on the five primary outcome measures ( $p < .01$ ), while unadjusted significance levels ( $p < .05$ ) were chosen to assess remaining outcomes.

#### Assessment of Pre-treatment Changes

Intake sessions took place anywhere from 10 weeks before to the same day of treatment baseline ( $M = 3.02$  weeks;  $SD = 2.16$ ). There were no significant changes in any study measures from the intake assessment time point to the treatment baseline time point (all  $ps < .30$ ; see Table 4). Thus, there is no evidence of differences in study measures prior to the intervention (hypothesis 1). Subsequent analyses were performed consistent with remaining study hypotheses.



Table 3

*Main and Interaction Effects of Repeated Measures Outcome Models*

	Variable	Time	FMS	FMSxTime	Serostatus
<b>Primary Outcomes</b>					
	Self-Efficacy (SEMCD)	$F(4,100) = 7.72^{***}$	$F(1,42.7) = 9.14^{**}$	$F(4,100) = 0.63$	$F(1,43.2) = 0.08$
	R3: Pain	$F(4,108) = 3.39^*$	$F(1,42.7) = 4.01, p = .051$	$F(4,108) = 0.52$	$F(1,42.3) = 0.15$
	Pain Interference	$F(4,116) = 5.78^{***}$	$F(1,43) = 6.11^*$	$F(4,116) = 1.79$	$F(1,43.1) = 0.64$
	Depression (BDI)	$F(4,116) = 8.14^{***}$	$F(1,43.1) = 13.00^{***}$	$F(4,116) = 1.11$	$F(1,43.2) = 0.02$
	QOL: Physical Health	$F(4,107) = 5.02^{***}$	$F(1,42.7) = 12.37^{***}$	$F(4,107) = 0.43$	$F(1,42.9) = 0.03$
<b>Secondary Outcomes</b>					
	R3: Physical Function	$F(4,109) = 6.67^{***}$	$F(1,43.1) = 8.11^{**}$	$F(4,109) = 0.25$	$F(1,43) = 0.11$
	R3: Global Wellbeing	$F(4,109) = 3.07^*$	$F(1,43.2) = 5.32^*$	$F(4,109) = 0.01$	$F(1,43.2) = 0.46$
	Sleep Quality	$F(4,112) = 0.66$	$F(1,44.4) = 4.31^*$	$F(4,112) = 3.23^*$	$F(1,44.3) = 0.00$
	QOL: Psychological	$F(4,108) = 5.73^{***}$	$F(1,43) = 12.98^{***}$	$F(4,108) = 0.24$	$F(1,43.1) = 0.64$
	QOL: Environment	$F(4,111) = 3.98^{**}$	$F(1,42.5) = 6.44^*$	$F(4,111) = 0.31$	$F(1,42.7) = 1.28$
	QOL: Social Relations	$F(4,117) = 4.39^{**}$	$F(1,42.9) = 8.32^{**}$	$F(4,117) = 0.43$	$F(1,43.1) = 1.55$
	QOL: Overall	$F(4,77.3) = 5.23^{***}$	$F(1,42.6) = 9.24^{**}$	$F(4,77.3) = 1.08$	$F(1,42.8) = 0.15$
	Chronic Pain Acceptance	$F(4,110) = 11.70^{***}$	$F(1,43.7) = 7.98^{**}$	$F(4,110) = 0.66$	$F(1,43.9) = 0.95$
<b>Objective Activity Measures</b>					
	Steps/day	$F(10,327) = 3.03^{**}$	$F(1,37.3) = 8.11^{**}$	$F(10,327) = 0.65$	$F(1,37.1) = 4.32^*$
	Active Minutes/day	$F(10,289) = 1.29$	$F(1,66.7) = 0.54$	$F(10,289) = 1.34$	$F(1,66.3) = 4.13^*$

Note. *F*-tests of time, FMS comorbidity, FMSxTime interaction, and serostatus on each outcome are reported. Differences at the  $p < .05$ ,  $p < .01$ , and  $p < .001$  level are marked with \*, \*\*, and \*\*\* respectively.

Table 4

*Adjusted Means and Standard Errors of Outcomes across Study Time Points*

Variable	Sample	Intake <i>M (SE)</i>	Treatment Baseline <i>M (SE)</i>	Midpoint <i>M (SE)</i>	End of Treatment <i>M (SE)</i>	4-Week Follow-Up <i>M (SE)</i>
<b>Primary Outcome Measures</b>						
Self-Efficacy (SEMCD; 0-60)	RA ( <i>n</i> = 30)	43.49 (2.03) <sup>+</sup>	42.57 (2.05) <sup>+</sup>	46.35 (2.05) <sup>+</sup>	46.46 (2.10) <sup>+, a</sup>	47.18 (2.13) <sup>+, a</sup>
	RA+FMS ( <i>n</i> = 14)	33.52 (2.99) <sup>+</sup>	31.33 (2.95) <sup>+</sup>	35.28 (3.03) <sup>+</sup>	36.84 (3.09) <sup>+, a</sup>	39.64 (3.03) <sup>+, a</sup>
	Total ( <i>n</i> = 44)	40.43 (1.80)	39.24 (1.80)	42.94 (1.81)	43.51 (1.84) <sup>a</sup>	44.89 (1.85) <sup>a</sup>
R3: Pain Intensity (0-10)	RA ( <i>n</i> = 30)	5.20 (0.50)	4.77 (0.47) <sup>+</sup>	4.51 (0.47)	3.84 (0.49) <sup>+, a</sup>	3.88 (0.50) <sup>a</sup>
	RA+FMS ( <i>n</i> = 14)	6.19 (0.79)	6.58 (0.68) <sup>+</sup>	5.53 (0.70)	5.66 (0.70) <sup>+</sup>	5.26 (0.70) <sup>a</sup>
	Total ( <i>n</i> = 44)	5.43 (0.43)	5.25 (0.40)	4.74 (0.41)	4.35 (0.42) <sup>a</sup>	4.26 (0.43) <sup>a</sup>
Pain Interference (0-10)	RA ( <i>n</i> = 30)	3.82 (0.55)	3.17 (0.55) <sup>+</sup>	3.03 (0.55)	2.60 (0.56)	2.51 (0.58)
	RA+FMS ( <i>n</i> = 14)	5.59 (0.77)	6.44 (0.75) <sup>+</sup>	4.37 (0.78)	4.03 (0.78) <sup>a</sup>	4.12 (0.78) <sup>a</sup>
	Total ( <i>n</i> = 44)	4.27 (0.46)	4.11 (0.45)	3.35 (0.46)	2.95 (0.47) <sup>a</sup>	2.91 (0.48) <sup>a</sup>
Depression (BDI) (0-63)	RA ( <i>n</i> = 30)	8.40 (1.47) <sup>+</sup>	7.99 (1.47) <sup>+</sup>	6.89 (1.47) <sup>+</sup>	6.57 (1.49) <sup>+</sup>	5.90 (1.50) <sup>+, a</sup>
	RA+FMS ( <i>n</i> = 14)	17.03 (2.13) <sup>+</sup>	17.89 (2.13) <sup>+</sup>	6.57 (2.15) <sup>+</sup>	15.36 (2.15) <sup>+, a</sup>	13.39 (2.15) <sup>+, a</sup>
	Total ( <i>n</i> = 44)	11.07 (1.34)	11.09 (1.34)	9.99 (1.34)	9.47 (1.35) <sup>a</sup>	8.39 (1.36) <sup>a</sup>
QOL: Physical Health (0-100)	RA ( <i>n</i> = 30)	60.38 (3.19) <sup>+</sup>	60.63 (3.20) <sup>+</sup>	63.05 (3.21) <sup>+</sup>	63.81 (3.28) <sup>+</sup>	67.16 (3.34) <sup>+, a</sup>
	RA+FMS ( <i>n</i> = 14)	39.71 (4.61) <sup>+</sup>	42.77 (4.61) <sup>+</sup>	45.59 (4.73) <sup>+</sup>	48.28 (4.72) <sup>+</sup>	49.17 (4.73) <sup>+</sup>
	Total ( <i>n</i> = 44)	54.30 (2.90)	55.52 (2.91)	57.93 (2.93)	59.16 (2.97)	61.38 (2.99) <sup>a</sup>
<b>Secondary Outcome Measures</b>						
R3: Physical Function (0-10)	RA ( <i>n</i> = 30)	2.06 (0.32) <sup>+</sup>	2.00 (0.31) <sup>+</sup>	1.60 (0.31) <sup>+</sup>	1.28 (0.32) <sup>+, a</sup>	1.6 (0.32) <sup>+, a</sup>
	RA+FMS ( <i>n</i> = 14)	3.55 (0.48) <sup>+</sup>	3.44 (0.45) <sup>+</sup>	2.95 (0.46) <sup>+</sup>	2.93 (0.46) <sup>+, a</sup>	3.15 (0.46) <sup>+</sup>
	Total ( <i>n</i> = 44)	2.48 (0.28)	2.42 (0.28)	2.00 (0.28)	1.78 (0.28) <sup>a</sup>	2.06 (0.28) <sup>a</sup>
R3: Global Wellbeing (0-10)	RA ( <i>n</i> = 30)	3.82 (0.46) <sup>+</sup>	3.51 (0.44) <sup>+</sup>	4.05 (0.44)	3.71 (0.46)	2.92 (0.47) <sup>b</sup>
	RA+FMS ( <i>n</i> = 14)	5.80 (0.73) <sup>+</sup>	5.33 (0.64) <sup>+</sup>	5.22 (0.66)	5.11 (0.66)	4.37 (0.66)
	Total ( <i>n</i> = 44)	4.29 (0.40)	4.01 (0.38)	4.36 (0.38)	4.09 (0.39)	3.32 (0.40) <sup>a, b</sup>

Variable	Sample	Intake	Treatment Baseline	Midpoint	End of Treatment	4-Week Follow-Up
Sleep Quality (0-10)	RA (n = 30)	6.70 (0.38)	6.40 (0.37)	6.45 (0.36)	6.58 (0.37)	7.35 (0.39) <sup>+, a, b</sup>
	RA+FMS (n = 14)	5.63 (0.59)	5.64 (0.50)	5.68 (0.52)	6.27 (0.52)	4.93 (0.53) <sup>+, b</sup>
	Total (n = 44)	6.40 (0.32)	6.16 (0.30)	6.19 (0.30)	6.47 (0.31)	6.55 (0.32)
QOL: Overall (0-100)	RA (n = 30)	63.03 (3.82) <sup>+</sup>	65.81 (3.84) <sup>+</sup>	69.26 (3.86)	74.00 (3.95) <sup>+, a</sup>	73.10 (4.04) <sup>+, a</sup>
	RA+FMS (n = 14)	47.07 (5.53) <sup>+</sup>	44.39 (5.53) <sup>+</sup>	56.89 (5.70)	53.62 (5.68) <sup>+, a</sup>	52.78 (5.69) <sup>+, a</sup>
	Total (n = 44)	58.52 (3.35)	59.48 (3.36)	65.10 (3.39)	67.38 (3.44) <sup>a</sup>	67.34 (3.49) <sup>a</sup>
QOL: Psychological (0-100)	RA (n = 30)	72.59 (3.15) <sup>+</sup>	73.46 (3.16) <sup>+</sup>	75.59 (3.16) <sup>+</sup>	77.63 (3.21) <sup>+, a</sup>	78.21 (3.25) <sup>+, a</sup>
	RA+FMS (n = 14)	53.70 (4.55) <sup>+</sup>	53.40 (4.55) <sup>+</sup>	57.63 (4.63) <sup>+</sup>	57.77 (4.62) <sup>+</sup>	60.82 (4.63) <sup>+, a</sup>
	Total (n = 44)	66.48 (2.84)	67.04 (2.84)	69.70 (2.84)	70.80 (2.88)	72.64 (2.90)
QOL: Social Relations (0-100)	RA (n = 30)	75.99 (3.81) <sup>+</sup>	75.31 (3.82) <sup>+</sup>	74.52 (3.85) <sup>+</sup>	76.93 (3.91) <sup>+</sup>	78.57 (3.96)
	RA+FMS (n = 14)	59.13 (5.51) <sup>+</sup>	54.97 (5.51) <sup>+</sup>	57.71 (5.63) <sup>+</sup>	63.03 (5.63) <sup>+, a</sup>	67.91 (5.63) <sup>a</sup>
	Total (n = 44)	70.08 (3.30)	68.25 (3.31)	68.47 (3.34)	71.53 (3.38)	74.70 (3.40) <sup>a</sup>
QOL: Environment (0-100)	RA (n = 30)	78.98 (2.67) <sup>+</sup>	78.47 (2.68) <sup>+</sup>	81.07 (2.69) <sup>+</sup>	81.19 (2.73) <sup>+</sup>	83.15 (2.76) <sup>+, a</sup>
	RA+FMS (n = 14)	66.56 (3.86) <sup>+</sup>	65.67 (2.68) <sup>+</sup>	66.20 (3.93) <sup>+</sup>	69.30 (3.93) <sup>+</sup>	71.88 (3.94) <sup>+, a</sup>
	Total (n = 44)	74.93 (2.34)	74.66 (2.34)	76.22 (2.36)	76.97 (2.38)	79.69 (2.40) <sup>a</sup>
Pain Acceptance (CPAQ; 0-120)	RA (n = 30)	68.95 (2.57) <sup>+</sup>	69.43 (2.55) <sup>+</sup>	72.79 (2.61) <sup>+</sup>	73.22 (2.64)	78.27 (2.71) <sup>+, a, b</sup>
	RA+FMS (n = 14)	58.45 (3.47) <sup>+</sup>	56.17 (3.47) <sup>+</sup>	61.39 (3.58) <sup>+</sup>	65.55 (3.64) <sup>a</sup>	68.03 (3.57) <sup>+, a</sup>
	Total (n = 44)	66.27 (2.16)	65.81 (2.15)	69.81 (2.20)	71.42 (2.23) <sup>a</sup>	75.63 (2.26) <sup>a, b</sup>

Note. Higher R3: Physical Function and R3: Global Wellbeing subscale scores represent greater problems or difficulties in these areas. Adjusted means were calculated during repeated measures analysis in SAS and are reported for the total sample (n = 44), patients with RA only (n = 30), and patients with RA and comorbid FMS. Select pairwise comparisons were made consistent with *a priori* hypotheses (i.e., group and time point comparisons). Significant differences between participants with and without FMS at a given time point are marked with a <sup>+</sup>. Values marked with <sup>a</sup> and <sup>b</sup> represent significant differences ( $p < .05$ ) from treatment baseline and end of treatment scores, respectively; only hypothesized pairwise comparisons are reported.

## Treatment Outcomes

### Primary and Secondary Outcome Measures

In terms of primary outcomes, there was a significant effect of Time on SEMCD ( $p < .0001$ ), Pain Interference ( $p = .0003$ ), BDI ( $p < .0001$ ), and QOL: Physical Health ( $p = .001$ ). The effect of Time on R3: Pain did not meet criteria for statistical significance in the present analysis,  $p = .012$ . In line with hypothesis 2a, improvements in SEMCD, R3: Pain, Pain Interference, and BDI were seen at the end of treatment compared to treatment baseline. The difference between QOL: Physical Health scores at treatment baseline compared to the end of treatment was not significant; however, in support of hypothesis 3a, improvements in all five measures were seen at follow-up compared to treatment baseline. No significant differences were seen in any primary outcome measure between the end of treatment and follow-up (hypothesis 3b).

Of the secondary outcomes, there were significant effects of Time on R3: Physical Function ( $p < .0001$ ), R3: Global Wellbeing ( $p = .019$ ), and QOL: Overall ( $p = .0009$ ), Psychological ( $p = .0003$ ), Environment ( $p = .002$ ), and Social Relations ( $p = .005$ ) subscale scores (see Table 3). The effect of Time on Sleep Quality was not significant,  $p = .62$ . Significant improvements were seen in R3: Physical Function and QOL: Overall at the end of treatment compared to treatment baseline providing partial support for hypothesis 2b (see Table 4). In support of hypothesis 3a improvements were seen in R3: Physical Function, R3: Global Wellbeing, QOL: Overall, QOL: Environment, and QOL: Social Relations compared to treatment baseline. In partial support of hypothesis 3b, R3: Global Wellbeing was significantly improved at follow-up compared to the end of treatment. No other significant differences were seen between the end of treatment and follow-up.

Consistent with study hypotheses, there was a significant effect of Time on CPAQ scores,  $p < .0001$ . Specifically, scores at the end of treatment (hypothesis 2c) and at 4-week follow-up (hypothesis 3a) were significantly greater (indicating more acceptance) than at treatment baseline ( $p = .001$  and  $p < .0001$ , respectively). In support of hypothesis 3b, CPAQ scores were significantly greater at follow-up compared to the end of treatment,  $p = .02$ . For descriptive purposes, changes in the two CPAQ subscales (i.e., activity engagement and pain willingness) among patients with and without comorbid FMS are depicted in Figure 1.

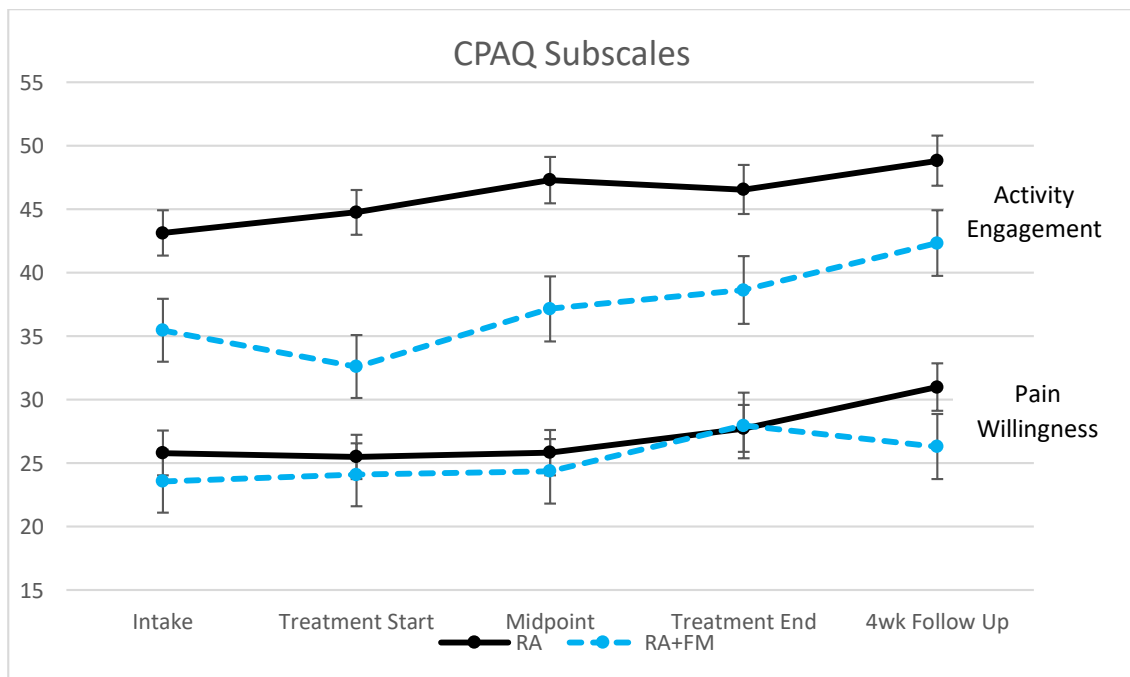


Figure 1. Changes in CPAQ subscales over treatment time points.

### Objective Activity Measures

Physical activity data were successfully obtained from 38 participants and included in subsequent analyses. There was a significant effect of Time on Steps,  $p = .001$ . Specifically, there were significant increases from treatment baseline ( $M = 5,223$ ,  $SE = 472$ ) compared to end of treatment ( $M = 6,387$ ,  $SE = 456$ ,  $p = .0007$ ) and follow-up ( $M = 6,031$ ,  $SE = 470$ ,  $p = .025$ ). No significant differences were found between the end of treatment and follow-up. See Figure 2

for a more detailed pattern of change. There was no significant effect of Time on active minutes per day ( $p = .23$ ; see Table 3).

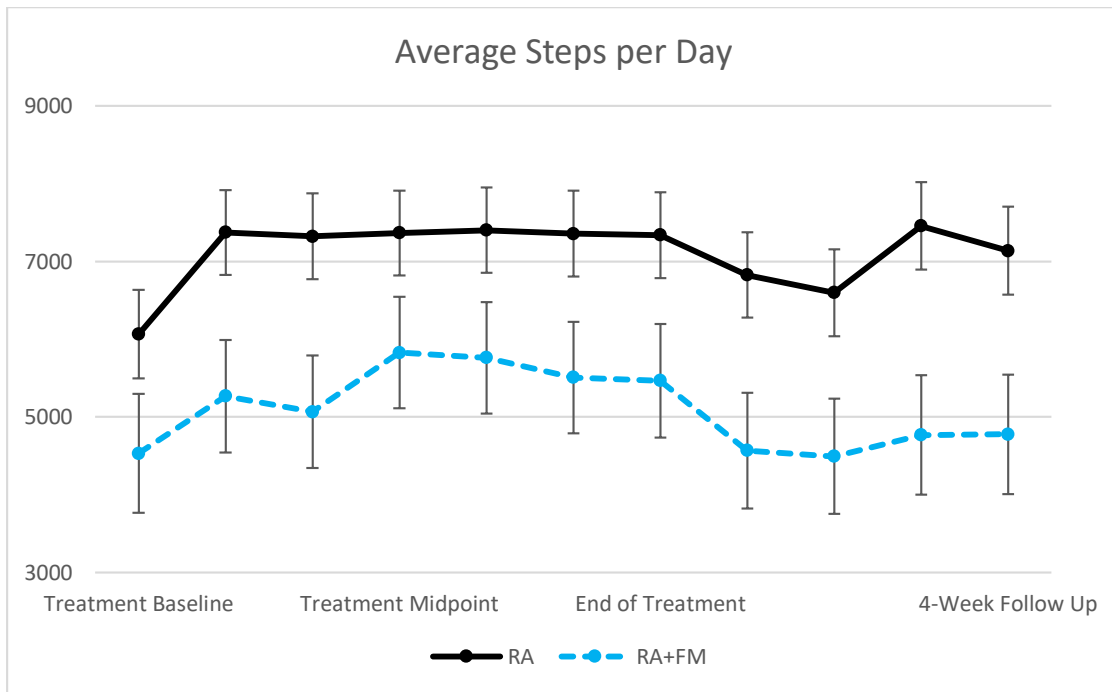


Figure 2. Average steps per day between patients with and without comorbid FMS.

### Treatment Moderators

Consistent with hypothesis 4, there was a significant effect of FMS on many *primary outcomes* (SEMCD,  $p = .004$ ; Pain Interference,  $p = .017$ ; BDI,  $p = .0008$ ; QOL: Physical Health,  $p = .001$ ), all *secondary outcomes* (R3: Physical Function,  $p = .007$ ; R3: Global Wellbeing,  $p = .026$ ; Sleep Quality,  $p = .04$ ; QOL: Overall,  $p = .004$ ; QOL: Psychological,  $p = .0008$ ; QOL: Environment,  $p = .006$ ; QOL: Social Relations,  $p = .01$ ; and CPAQ,  $p = .007$ ), and one *objective activity measure* (Steps per day,  $p = .007$ ). However, the effects of FMS on R3: Pain ( $p = .051$ ) and Active Minutes ( $p = .46$ ) were not significant (see Table 3). Hypothesis 5 was not supported as there were no significant FMSxTime interactions with the exception of Sleep Quality ( $p = .015$ ). Overall, this indicated that the patterns of change in outcome variables did not significantly differ between patients with and without comorbid FMS. Pairwise

comparisons revealed that both groups demonstrated significant improvements in many outcome measures at the end of treatment and 4-week follow-up compared to treatment baseline. See

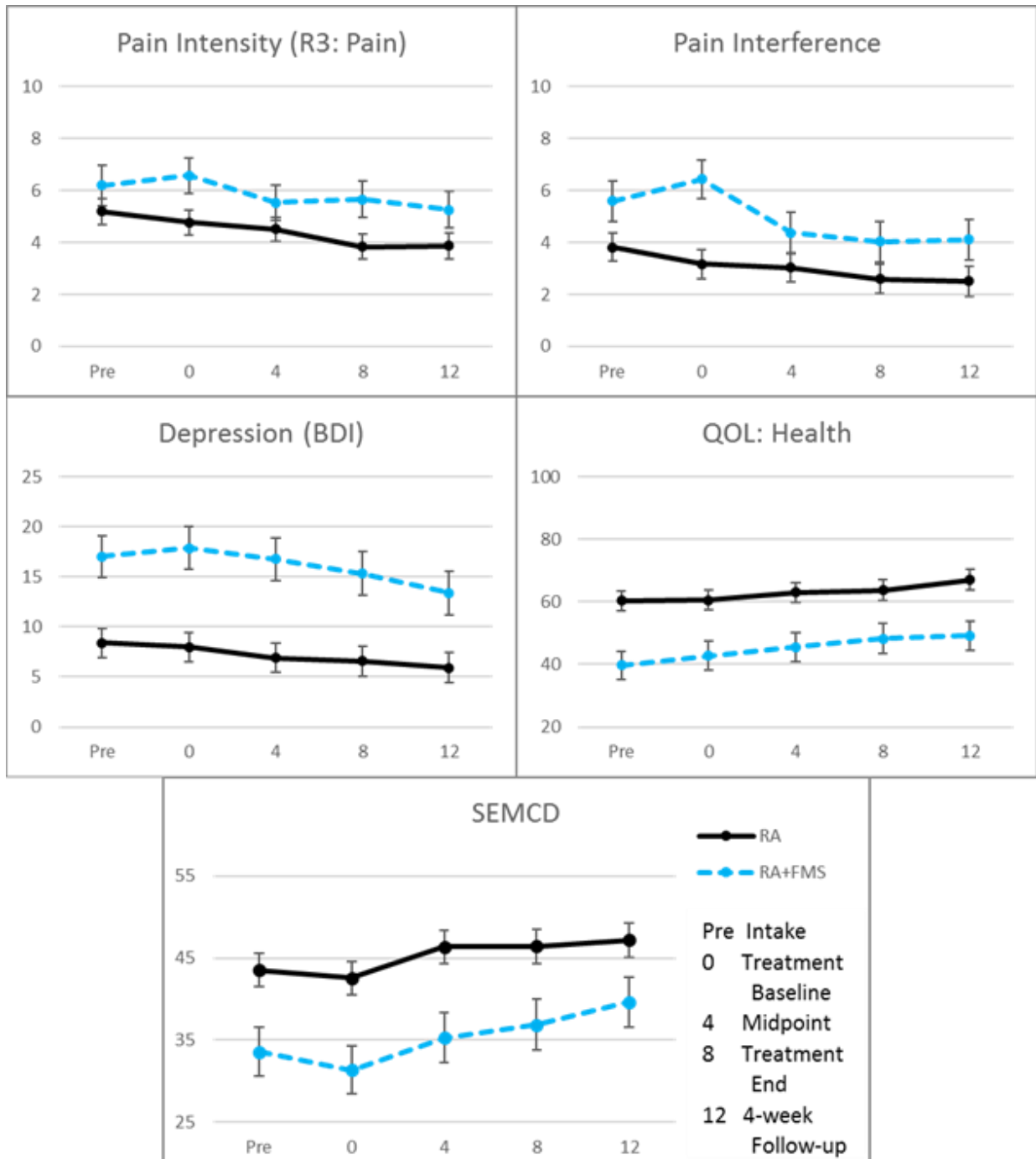


Figure 3. Summary of effects of FMS comorbidity on primary treatment outcomes.

Table 4 for adjusted means and standard errors along with significant hypothesized group and time point differences. Effects of primary outcome variables for each subgroup are presented in Figure 3.

There were no significant effects of Serostatus on any of the outcome variables (all  $p$ s > .05), with the exception of Steps per day ( $p = .045$ ) and Active Minutes per day ( $p = .046$ ; see Table 3). Follow up analysis indicated that seropositive and seronegative participants did not significantly differ on any study measures at treatment baseline, end of treatment, or at follow-up.

#### Clinical Significance of Change

Effect sizes of each outcome for the total sample and the subsamples with and without FMS are displayed in Table 5. Hedge's  $g$  is reported as it reduces bias due to small and unequal sample sizes. Overall, small to medium effects were seen in most outcome variables. Some larger effect sizes were seen among patients with comorbid FMS, particularly in terms of SEMCD, pain interference, CPAQ, and QOL: Social. In contrast, small to medium effects for average steps per day were seen in participants without comorbid FMS while minimal to no effects were seen in participants with FMS.



Table 5

*Effect Sizes of Changes in Outcome Variables*

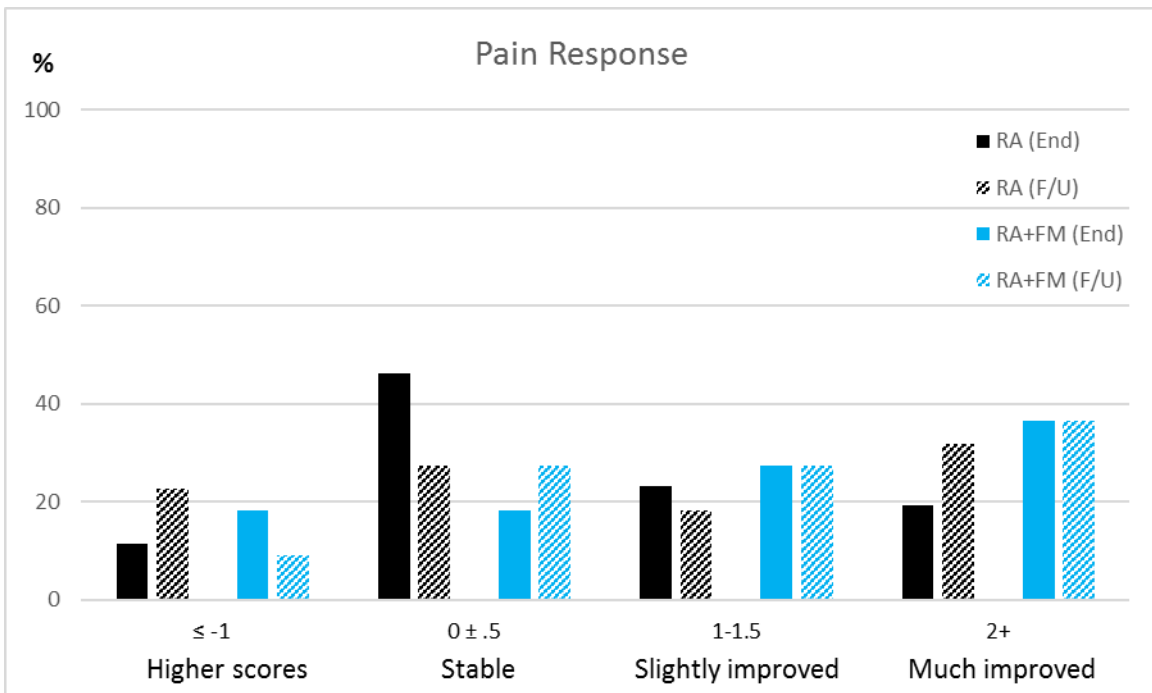
Study Measure	Effect Size (Hedge's <i>g</i> )		
	Total sample End, F/U	RA End, F/U	RA+FM End, F/U
<b>Primary Outcomes</b>			
Self-Efficacy	.57, .58	.51, .67	.81, .63
R3: Pain	.41, .41	.41, .43	.50, .51
Pain Interference	.41, .65	.25, .48	.89, 1.20
Depression (BDI)	.22, .38	.24, .49	.29, .46
QOL: Health	.21, .27	.24, .49	.68, .39
<b>Secondary Outcomes</b>			
R3: Functioning	.47, .22	.51, .37	.49, .06
R3: Wellbeing	.05, .36	.01, .39	.26, .46
QOL: Overall	.46, .45	.44, .61	.64, .41
QOL: Psychological	.33, .42	.34, .70	.40, .31
QOL: Social	.27, .45	.13, .45	.58, .58
QOL: Environmental	.21, .47	.14, .56	.35, .47
Chronic Pain Acceptance	.48, .83	.30, .75	.96, 1.11
<b>Objective Activity Measures</b>			
Avg Steps/day	.35, .32	.42, .51	.23, -.18
Avg Active Minutes/day	.06, .00	-.04, .07	.15, -.09

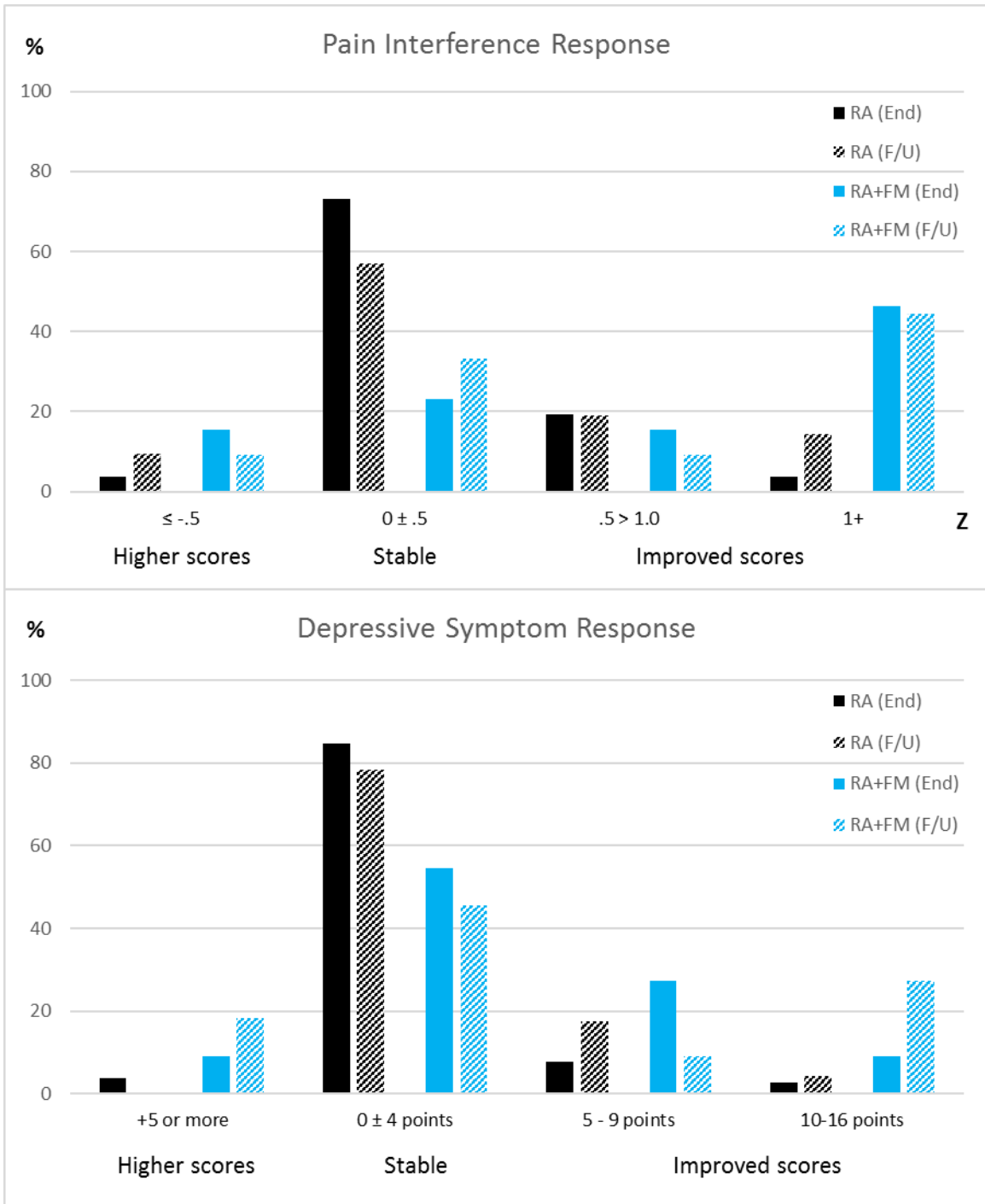
*Note.* Effect sizes calculated represent change from treatment baseline to the end of treatment and at 4-week follow-up.

Treatment response rates were calculated for the primary outcome measures using IMMPACT-recommended guidelines for determining minimal clinically important differences (Dworkin, et al., 2008). Accordingly, an improvement of 1 and 2 points in self-reported pain was considered to be minimal and much improvement, respectively; improvements of 5 or more points on the BDI were considered clinically important; and one-half standard deviation improvements were considered to be important changes in the remaining outcome measures (i.e., pain interference, SEMCD, QOL: Health). Given the significant differences in many outcomes between patients with and without comorbid FMS, response rates are reported for each subgroup.

In general, modest percentages of patients demonstrated at least minimal clinically important differences in each treatment outcome. See Figure 4 for a summary of response rates.

Response rates for changes in physical activity (i.e., average steps per day) were also calculated given the varying activity-related goals of participants. At the end of treatment compared to treatment baseline, 50% (n = 12) of participants recorded improvements in average daily steps by at least 1,000 steps, 8 of which were improvements of over 2,000; 33% (n = 8) recorded no changes greater than 1,000 steps; and 16.7% (n = 4) recorded decreases of 1,000 or more steps. In contrast, at 4-week follow-up compared to treatment baseline, 36.4% (n = 8) recorded improvements in average daily steps by at least 1,000 steps, 4 of which were improvements of over 2,000; 50% (n = 11) recorded no changes greater than 1,000 steps; and 13.6% (n = 3) recorded decreases of 1,000 or more steps.





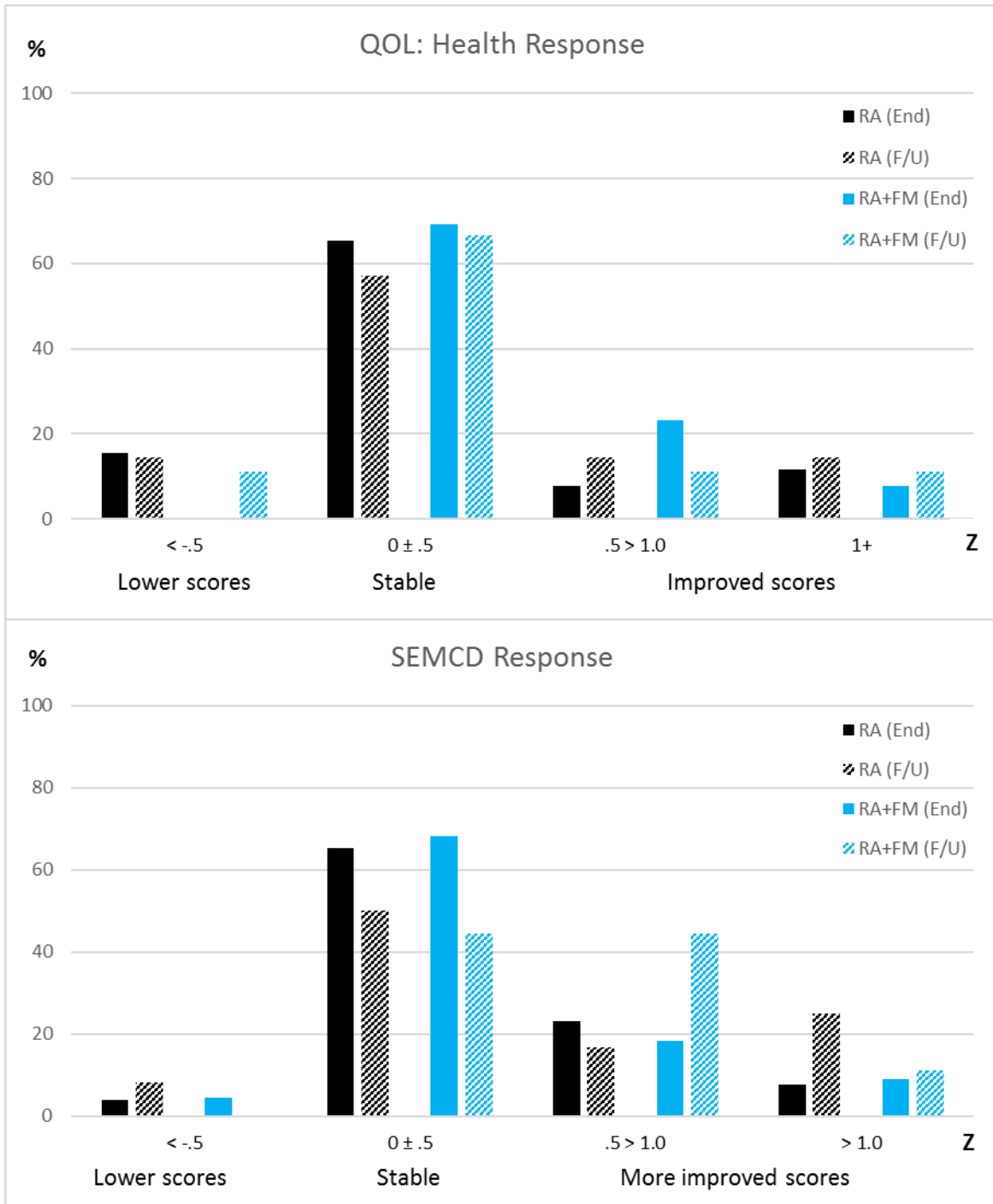


Figure 4. Outcome response rates among participants with and without comorbid FMS

Aim 2: Feasibility

Qualitative and quantitative data were examined in order to address this study aim. Data points are derived from patient recruitment efforts, participant self-reports during intake interview, participant qualitative and quantitative responses to a questionnaire, and group

facilitator ratings of participation in order to provide descriptive information related to patient interest, engagement, and satisfaction.

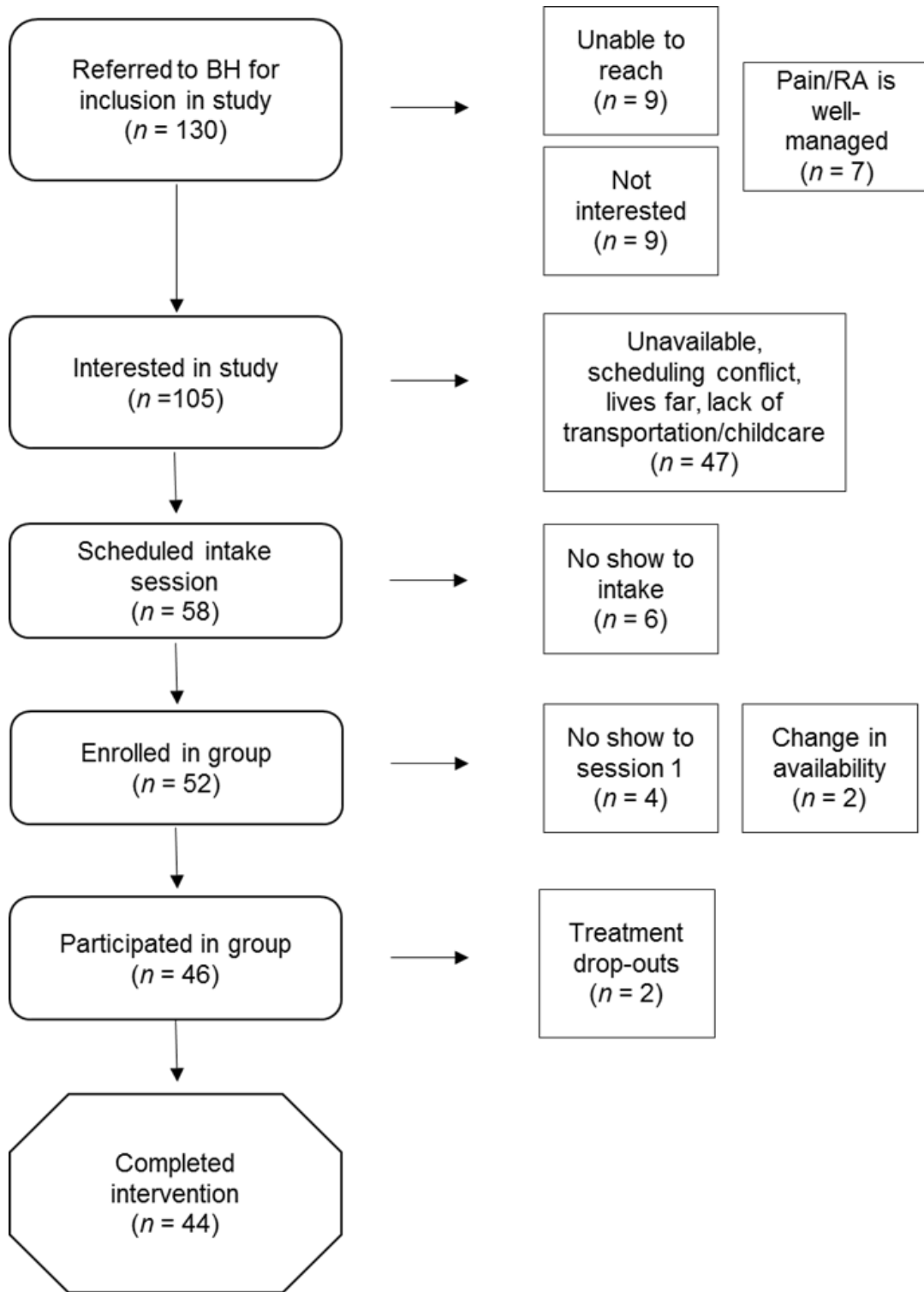


Figure 5. Flow of participants.

## Patient Interest

A total of 130 patients were referred for participation in the study over a 14-month span, 105 (80.8%) of which expressed initial interest. Among those interested, 58 (55.2%) scheduled a study intake session, 52 of which were enrolled into the study. See Figure 5 for a more detailed recruitment analysis.

Table 6

### *Participant-Reported Intervention Goals*

<b>Goal</b>	<b>n (%)</b>
Gain knowledge	16 (30.8%)
Short and long-term management of symptoms	14 (26.9%)
Learn from others	14 (26.9%)
Improve coping skills	13 (25.0%)
Peer support	9 (17.3%)
Improve/increase activity	9 (17.3%)
Learn specific info from physical therapist	8 (15.4%)
Improve wellbeing/quality of life	8 (15.4%)
Manage stress and/or emotional health	7 (13.5%)
Improve pain management	6 (11.5%)

*Note.* Participant-reported intervention goals at intake ( $n = 52$ ).

During the intake interview, participants were asked to name their intervention goals, which were summarized and transcribed by the interviewer. Two researchers independently derived thematic concepts based on recorded responses and then collaborated to identify a list of themes to characterize participant goals. See Table 6 for identified themes of participant goals along with the frequency in which each theme was listed by participants. About half (44%) of participants reported previous experience with a mental health provider (e.g., grief counseling, family therapy, individual psychotherapy).

## Patient Engagement

Of the 52 participants originally enrolled in the study, 46 (88.5%) attended at least one session and 44 (84.6%) were considered treatment completers (i.e., attended at least four of the eight sessions). The modal number of sessions attended among those who attended at least one session was 7 ( $M = 6.65$ ;  $SD = 1.46$ ). Attrition rates were low as only two participants (4.3%) were considered treatment drop outs. Overall, 26.9% attended all 8 sessions, 32.7% attended 7, 13.5% attended 6, 9.6% attended 5, and 1.9% attended 4, 3, and 1 sessions.

Independent ratings from two group facilitators ( $ICC = .88$ ) provided information about participation (using 0-5 scales). Among participants who attended at least one session ( $n = 46$ ), participation frequency ( $M = 3.30$ ;  $SD = 0.97$ ), supportiveness ( $M = 3.53$ ;  $SD = 0.91$ ), openness ( $M = 3.63$ ;  $SD = 0.95$ ), and appropriateness ( $M = 3.59$ ;  $SD = 0.92$ ) were all rated in the average to slightly above average ranges. Given that scores of zero were included in averages, reported scores might not fully reflect the quality and quantity of participation when group members were present.

## Patient Satisfaction

Overall, 38 participants rated their overall satisfaction with the intervention as 9.51/10 ( $SD = 1.10$ ). Additional participant ratings on the patient experience questionnaire are presented in Figure 6.

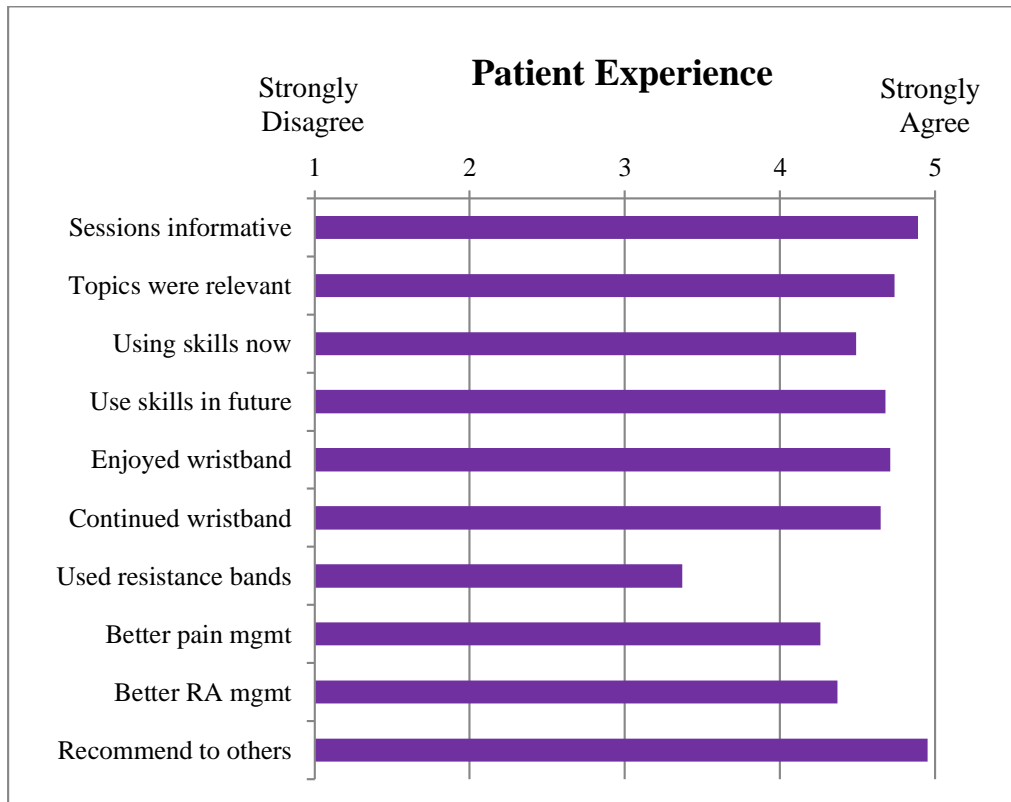


Figure 6. Participant ratings of patient experience at follow-up.



## DISCUSSION

The purpose of this study was to implement and evaluate an 8-week interdisciplinary chronic pain intervention for patients with rheumatoid arthritis (RA) in an outpatient academic healthcare setting. The interdisciplinary team, consisting of rheumatology, physical therapy, and behavioral health, collaborated toward the overarching goal of increasing patient efficacy for the self-management of their chronic condition. Each intervention component (i.e., medical education, physical activity, mental/behavioral health) contained additional, interrelated goals. A total of 44 participants received the intervention and completed outcome measures. Primary outcomes to determine intervention effectiveness included self-efficacy for managing chronic disease, pain intensity, pain interference, depression, and health-related quality of life. Secondary outcomes included physical functioning, wellbeing, other quality of life domains, and sleep quality. Evidence-based mechanisms of change assessed were chronic pain acceptance and physical activity, objectively measured by wearable fitness trackers. Change in outcomes were examined both pre-treatment (i.e., from intake to treatment baseline) and post-treatment (i.e., from treatment baseline through the end of treatment and 4-week follow-up). A mixed-method analysis of intervention feasibility and sustainability follow.

### Aim 1: Effectiveness

Overall, many study hypotheses surrounding the effectiveness of the intervention were supported. Multilevel repeated measures modeling revealed significant main effects of Time for the majority of primary outcomes (i.e., self-efficacy for managing chronic disease, pain interference, depression, health-related QOL), secondary outcomes (i.e., physical function, overall wellbeing, remaining QOL domains, and chronic pain acceptance), and objective activity measures (i.e., average steps per day). In examining pre-treatment changes, hypothesis 1 was not

supported as there was no evidence of significant differences between study intake and treatment baseline (mean duration = 3.02 weeks;  $SD = 2.16$ ). This implies that any subsequent changes are less likely random or due to inconsistent responding. Follow up analyses supported hypothesized changes in primary outcomes (hypotheses 2a and 3a); significant improvements in self-efficacy, pain intensity, pain interference, and depression were seen at the end of treatment and at 4-week follow-up compared to treatment baseline. Mean health-related QOL gradually increased throughout the intervention period; the difference between follow-up scores and treatment baseline were statistically significant. In addition, hypotheses (2b and 3a) surrounding changes in secondary measures received partial support. While scores generally trended toward improvement over the intervention period, only physical functioning and overall QOL were significantly improved at the end of treatment. In addition to those measures, social and environmental QOL were significantly improved at follow-up. Minimal support was seen for hypothesis 3b, as only perceived wellbeing improved significantly from the end of treatment to follow-up.

Overall, effect sizes for primary and secondary outcomes were in the small to moderate range. Effect sizes for pain ( $g = .41$ ) and self-efficacy ( $g = .57$ ) observed in the current study were larger than those reported in meta-analyses of psychological interventions for arthritis pain ( $g$  for both = .18; Dixon, Keefe, Scipio, Perri, & Abernethy, 2007; Knittle, Maes, & de Gucht, 2010). Observed effects for depression ( $g = .22$ ) were consistent with those found in meta-analyses ( $g = .21-.23$ ). Taken together, it appears that the present intervention resulted in small to medium improvements across several domains that were largely maintained at follow-up. The current intervention produced some larger effect sizes than those found in previous psychological

interventions. This is consistent with synergistic effects seen in interdisciplinary interventions (Gatchel, et al., 2014).

A significant main effect of FMS was seen, in support of hypothesis 4. Consistent with the documented challenges of patients with RA and comorbid FMS, these participants produced significantly worse scores on nearly all study outcome measures at intake compared to participants without comorbid FMS. Hypothesis 5 was not supported as there was no significant FMSxTime interaction. Subsequent analysis revealed that both groups showed statistically significant improvement in primary and secondary outcomes, but that the FMS group consistently remained significantly worse on measures compared to participants without this comorbidity. Refer to Table 4 for specific values and Figure 3 for highlighted examples.

An examination of measures of clinical significance provides slightly different information about differences between these two subgroups. While small to medium effects were seen in most outcome variables, some larger effect sizes, suggesting greater improvement, were seen among patients with comorbid FMS, particularly in terms of self-efficacy, pain interference, and QOL (social and health-related). It may be the case that limitations in (sub)sample size reduced the power to detect these differences in multilevel modeling. Further, differences were observed in response rates of primary outcome variables (see Figure 5). Greater proportions of clinically-relevant improvement were seen post-treatment in pain interference (73.5%), self-efficacy (55.5%), and depression (36.4%) in the FMS subsample compared to those without comorbid FMS (23.0%, 19.2%, 10.4%, respectively). Given the well-documented difficulty in treating patients with RA and comorbid FMS, these intervention effects are encouraging.

Consistent with the overarching therapeutic orientation of the intervention (i.e., ACT), significant improvements were seen in chronic pain acceptance. Visual examination of CPAQ

subscales (see Figure 1) suggests that the largest change occurred in activity engagement (i.e., leading a value-driven lifestyle despite the presence of pain), rather than pain willingness (i.e., acceptance that pain is present and cannot always be controlled). This is consistent with the intervention's emphasis on goal-setting and behavior change. Though cognitive patterns about pain (e.g., *I can't be active when I am in pain*) were also addressed in the course of the intervention, opportunities to target and process these patterns were more limited. It appears that participants with and without comorbid FMS demonstrated similar improvements in chronic pain acceptance, with greater overall between-group differences in the activity engagement subscale. CPAQ scores continued to significantly improve from the end of treatment to follow-up (hypothesis 3b). Previous literature has demonstrated similar patterns and shown that greater chronic pain acceptance correlates with lower pain, reduced depression, improved physical disability, fewer medical visits, and improved work status (Vowles & McCracken, 2008).

Another main therapeutic target of the intervention was the development of adaptive patterns of physical activity, including increased and more consistent activity. The physical activity outcomes chosen for the current study were average steps and active minutes per day, as measured by wearable fitness trackers (i.e., the Fitbit Flex). As participants were provided the trackers during session 1, no pre-treatment activity data was recorded. However, participants were instructed to begin wearing the tracker and encouraged not to change their daily routine so as to establish a baseline level of activity that would facilitate future goal setting. Participants did not receive additional feedback (e.g., examination of individual activity during group sessions) until later sessions. Thus, week 1 averages were used as the basis for comparison for changes in activity. There were significant differences in average steps per day across participants at the end of treatment and follow-up compared to week 1 (hypotheses 2c and 3a).

In examining patterns displayed in Figure 2, it appears that an increase in steps was seen at week 2 and sustained through the end of treatment, with a decline in steps after treatment ended. At the end of treatment compared to treatment baseline, half of the participants recorded improvements in average daily steps by at least 1,000 steps, compared to about a third at follow-up. Participants with comorbid FMS recorded significantly fewer steps on average compared to those without FMS, but showed a similar pattern of change throughout the intervention period. Effect sizes of changes in steps were small to medium among patients with RA ( $g = .42$ ), consistent with meta-analytic findings for improved physical activity in arthritis pain interventions ( $g = .45$ ; Knittle, Maes, & de Gucht, 2010). Effect sizes were minimal in patients with comorbid FMS ( $g = .23$ ).

No significant differences were seen in active minutes per day. However, it is important to note that active minutes were recorded automatically based on step-related activity. Participants had the option to manually enter non step-related activities (e.g., biking) as active minutes; however, it was observed that participants did not do this consistently. In addition, step-related activity was not a specific intervention target, but rather served as a global indicator of activity. Several patterns of improvement observed by group facilitators would not have been captured by examining global increases in steps. Anecdotally, some participants focused on more appropriate activity pacing (i.e., consistent activity rather than a pattern of bursts followed by extended recovery periods) while others set goals to engage in yoga, swimming, biking, stretching, functional/grip exercises, or going to physical therapy.

Finally, evidence for significant differences between participants with seropositive and seronegative RA was very limited (exploratory hypothesis 6). Average steps per day was the only outcome in which there was a statistically significant effect of Serostatus,  $p = .045$ . Given

the lack of specific hypothesis of difference in physical activity and the scarcity of statistical findings amid multiple analyses, the significant effects of Serostatus on Steps and Active Minutes per day are not interpreted. There is new evidence to suggest that seronegativity is correlated with FMS; however, this was not seen in the present study (results not reported; Doss, Mo, Carroll, Crofford, & Denny, 2016). Research examining Serostatus and common comorbidities (e.g., FMS) is needed to further differentiate these groups as distinct clinical phenotypes. A cross-sectional comparison of patients across stages of diagnosis would perhaps be an illuminating first step.

In summary, consistent with the multifaceted nature of intervention, small to medium improvements were seen across multiple domains. These effects were similar to or larger than those found in meta-analyses of psychological interventions for arthritic pain (Dixon, Keefe, Scipio, Perri, & Abernethy, 2007; Knittle, Maes, & de Gucht, 2010). Unsurprisingly, patients with comorbid FMS scored consistently worse on measures compared to those with RA alone. Although there was no significant FMSxTime interaction to suggest differences in rates of change between subgroups, an examination of effect sizes and responder analyses suggest that the FMS group may have made more clinically-relevant improvements in self-efficacy, pain interference, and depression. This has important implications for treating this complex patient population. On the other hand, effect sizes indicated that the subgroup of patients with RA demonstrated small to medium improvements in step-related activity while patients with RA and comorbid FMS showed minimal and unsustained improvement. Although step counts do not take into consideration other types of exercise (e.g., biking, yoga), other studies have spoken to the difficulty increasing and sustaining consistent physical activity among patients with FMS (Dolan, Tung & Raizada, 2016). Given the substantial associated improvements in pain, fatigue,

sleep, and mood management associated with exercise, it is important to continue adapting interdisciplinary interventions to target these behaviors.

### Aim 2: Feasibility and Sustainability

The Triple Aim of improved (1) patient experience, (2) population health, and (3) per capita cost is widely cited as a guiding force for the optimization of healthcare in the current U.S. climate (Berwick, Nolan, & Whittington, 2008). More recently, an additional aim of (4) provider satisfaction has been added (i.e., forming the Quadruple Aim) in light of the high prevalence and negative consequences associated with provider burnout (Bodenheimer & Sinsky, 2014). Thus, in order for an intervention to be successfully translated into current practice, pragmatic studies must highlight values related to these domains. Both qualitative and quantitative data from the current study were examined in an effort to speak to factors related to the feasibility of the intervention and to identify areas for future optimization to increase its sustainability.

Substantial interest in the present interdisciplinary intervention was established during study recruitment (see Figure 5). Of the 130 patients approached for the study across 14 months, 80.8% expressed initial interest, 49.5% of which proceeded to enroll in the study. Patients who were not interested in the study (19.2%) were either unable to be reached, stated that their pain and/or RA were well-controlled at the moment, or did not provide a specific reason why they were not interested. Patients who were interested, but did not enroll in the study (40.8%) stated that they were unavailable or had a scheduling conflict, lived too far away to attend regular sessions, could not arrange transportation or childcare, or did not attend the scheduled intake session. Overall, it appeared that patients responded positively to the idea of an interdisciplinary intervention to address chronic pain associated with RA. Sessions were held in the evenings so as to increase accessibility to patients who were working; however, timing remained a barrier for

some patients. Patients who were enrolled in the study cited specific personal goals for participating the intervention, including: improving their knowledge and ability to manage their pain and other RA symptoms, increasing physical activity and/or learning specifically from the physical therapist, better managing stress and/or emotional health, improving general coping skills, improving wellbeing and/or quality of life, and providing/receiving peer support and learning from other patients. See Table 6 for frequency of goal endorsement. Patient goals largely aligned with intervention targets.

Participants remained actively engaged throughout the course of the intervention as evidenced by high attendance (mean sessions attended = 6.65,  $SD = 1.46$ ) and low attrition. Only two participants who attended the first session (4.3%) attended fewer than half of the eight sessions and were considered treatment drop outs. One of these participants attended only the first session and the other attended three of the first four sessions. It is unclear why these participants did not return to the intervention as they were subsequently unable to be reached. Two group facilitators rated individual participation at each session. In general, moderate to frequent participation was observed. Group members were typically supportive, open, and appropriate in their interactions with facilitators and one another. All group participants willingly, with occasional prompting, set behavioral goals and reported their goal attainment at each session.

Participants rated overall high satisfaction with the intervention ( $M = 9.51/10$ ;  $SD = 1.10$ ). See Figure 6 for responses to additional patient experience questionnaire items. Participants had the opportunity to provide qualitative comments about their experiences and satisfaction with the intervention. Participants commonly identified learning from various professionals and peer support to be the most helpful aspects of the intervention. One participant



wrote, “All aspects of the program were helpful. Changing my attitude regarding my pain and knowing that I could make positive choices improved my level of pain. Wearing the [activity tracker] made me aware of the exercise that I was doing and encouraged me to do more. I will continue tracking my steps.” When queried about least helpful aspects, participants commonly left that item blank or indicated that there were none. A few comments were noted about the timing of the sessions (e.g., time of day, day of week). Finally, when queried about potential changes to the intervention, participants commonly suggested that additional follow-up sessions be included in the intervention. A few other individual suggestions were noted regarding including more content about specific topics, such as nutrition, spirituality, and physical therapy.

Interdisciplinary team members all voiced satisfaction with being able to collaborate with other disciplines. Although maintaining communication and flexibility can be challenging in practice, the benefits are rewarding. One study rheumatologist observed about standard practice, “Although pain is the main symptom that my patients have, most of them also have difficulty with sleep, anxiety, and depression. It is frustrating to not be able to give them the help they need for other facets of their condition that affect their pain and sense of wellbeing.” One study physical therapist noted that, “good communication among practitioners and the patients helped to overcome many of the hurdles I typically see with this patient population. I do think we were able to achieve better outcomes as a result.” One behavioral health provider perceived the synergistic effects of team-based care and described valuing, “when we see patients really begin to understand how their behavior, physical health, social and emotional functioning interact. There is an amazing sense of empowerment that seems to follow and patients take an active role in their own disease management and wellbeing.”

Overall, patients were interested in, engaged in, and satisfied with the present intervention. The intervention was designed to meet the needs of a specific population: patients with RA who experience chronic pain. Recruitment and patient interest data support the demand for this type of intervention. The interdisciplinary team and the multi-faceted goals of the intervention appeared to work well to meet the needs of the participants, as evidenced by high satisfaction ratings and qualitative comments. Providers had positive reactions to collaborating on an interdisciplinary team.

The sustainability of an intervention is largely determined by the proportions of the resulting costs and benefits. Chronic pain is associated with high per person healthcare costs as well as significant lost work productivity at rates higher than those from heart disease, cancer, and diabetes (Gaskin & Richard, 2012). RA and FMS have been shown to each be associated with high economic burden with almost double the costs for patients with RA and comorbid FMS (Silverman, Dukes, Johnston, Brandenburg, Sadosky, & Huse, 2009). Interdisciplinary chronic pain interventions have been shown to result in greater cost-effectiveness compared to standard medical intervention by increasing patient self-management, decreasing healthcare utilization, and improving functional disability (DeBar, et al., 2012; Gatchel, McGeary, McGeary, & Lippe, 2014). In addition, emotional support has been shown to be prospectively beneficial to patients with RA by impacting the relationship between depression and functional disability (Benka, et al., 2014). The current study found significant improvements in several variables that have been shown to be associated with long-term cost offsets, such as self-efficacy for management of chronic disease, pain interference, physical function, and depression (DeBar, et al., 2012; Gatchel, McGeary, McGeary, & Lippe, 2014). Further, these outcomes were found

to be equally or more improved among patients with RA and comorbid FMS, a group with heightened economic burden.

Relative costs at the clinic-level should also be taken into consideration. Provider time, facility and resource usage, and administrative support may have strong impacts on local sustainability of interventions. For each intervention wave, a rheumatologist and physical therapist each provided 3 hours of clinical service on a voluntary basis for study purposes. Two behavioral health providers contributed a combined 30+ clinical service hours per intervention wave. This included group facilitation as well as individual intake sessions, but does not take into account time spent in administrative tasks (e.g., scheduling) and coordinating with the interdisciplinary team. This study was financially supported by an internal grant and a dissertation award. Limitations in the current health insurance payment structure (i.e., fee-for-service) would likely impede continuation of this intervention. Other payment structures, such as capitated or blended payment models, may be better suited to sustain this type of interdisciplinary care; however, it is uncertain as to whether and when these payment models will become more widespread in the U.S. (Ginsburg, 2013).

Certainly the provision of wearable fitness trackers to each patient is not likely a financially-sustainable intervention option. In addition, a recent study suggests that wearable activity trackers might not necessarily lead to long-term changes (Jakicic, et al., 2016). However, emerging research highlights the use of mobile apps and just-in-time adaptive frameworks to efficiently, inexpensively, and effectively target health behavior changes (King, et al., 2013; Nahum-Shani, Hekler, & Spruijt-Metz, 2015). Many individuals have smart phones and many mobile apps are inexpensive or freely-available. Preliminary studies have shown promising impacts to health behaviors (King, et al., 2013). This may address some of the challenges seen in

the present study in terms of maintaining gains in physical activity. In addition, this may satisfy the desire for continued follow up expressed by some participants. Continued research is needed in order to study how to effectively integrate technology into medical settings (Midboe, et al., 2011).

Overall, the sustainability of an intervention is highly dependent on the context in which it is delivered. In addition to factors already mentioned, multiple opportunities exist to optimize the current intervention and increase its reach to patients. Future studies might consider examining the optimal intervention dose and identifying the most effective components of this multifaceted intervention. While the interdisciplinary design is likely a primary benefit in and of itself, it is worthwhile to identify and optimize those components that lead to the greatest amount of clinical change. In addition, though patients with RA compose a sizable population, it is worth considering how to generalize this intervention to be applicable to other patients with chronic pain. Increasing the reach of the intervention may enhance its value to additional providers and other stakeholders in the outpatient clinic.

### Limitations

Given the pragmatic nature of the study, several limitations merit acknowledgment. In particular, the lack of comparison group and random assignment make it difficult to draw conclusions about treatment outcomes with certainty. While there was no evidence of change in study measures prior to the intervention, it is unclear whether subsequent changes resulted from the intervention, one of its components, or from other forms of healthcare received by patients. Nonetheless, changes consistently occurred after the onset of the intervention and in line with study hypotheses. Limitations to data include the lack of pre-treatment activity measurement prior to intervention. The first week of activity was used as a basis for comparison, though it is

noted that this may not reflect a true baseline measure of activity. It is possible that wearing the activity monitor may have had immediate impact on participant behavior as they had access to feedback through the commercial website and mobile application. Similarly, subsequent changes in activity may have resulted from self-monitoring effects. That being said, it is unlikely that this alone would explain the increase in activity given the sudden decline after the intervention ended.

The generalizability of the effectiveness of this intervention may be limited as it was designed to translate an evidence-based intervention to a specific practice setting. It is unclear how results would vary with this particular intervention were it to be led by different facilitators or in different practice settings. In addition, the long-term effects of the intervention are yet unknown as follow-up measures were limited to 4-weeks post-intervention. Additional follow-up and information about subsequent healthcare utilization are particularly important in examining the cost-effectiveness of the present intervention.

Finally, there were statistical limitations due to small sample size and multiple analyses. It is unclear whether the current sample is representative of the heterogeneous RA population. Not only is the sample size modest, but some patients were not included in the present study including those never referred, unable to be contacted, or not interested in or available for the study. This is not to mention patients who are not served in the present outpatient clinic, including those who are uninsured or who are not under the care of a rheumatologist. In addition, relatively small sample size may have limited statistical power to detect some effects. On the other hand, multiple analyses with a less conservative approach to error correction may have led to erroneous conclusions. That said, robust statistical modeling was used in assessing hypotheses related to effectiveness and was supplemented by examination of effect sizes and responder

analyses. An inclusive examination of the results supports the findings as discussed, despite these limitations.

### Conclusions

In summary, data from the current study are highlighted to reflect the core principles of the Quadruple Aim: (1) patients were highly satisfied with the interdisciplinary intervention; (2) improvements across multiple domains were seen with the present intervention; (3) improvements were seen in measures that correlate with longer-term health benefits that may offset some of the initial costs of interdisciplinary care; (4) providers were satisfied with working on an interdisciplinary team to address a complex, heterogeneous disease. Interdisciplinary interventions are particularly implicated for patients with complex and varied presentations, such as those with RA and/or FMS. It is important to continue gathering data surrounding the implementation of evidence-based collaborative care to further advocate for changes in policy and healthcare payment structure that will support the long-term sustainability of these interventions.

## **APPENDIX A: LIVING WELL WITH CHRONIC PAIN GROUP TREATMENT GUIDE**

# Living Well with Chronic Pain:

## Group Treatment Guide

Written and Compiled by Natasha DePesa

Last Updated: 06/2015





## Therapist Notes

### **Purpose of Treatment Guide:**

The purpose of this guide is to facilitate the development and maintenance of the Living Well with Chronic Pain group treatment program at UCF Health. The semi-structured pain assessment, treatment outline, patient handouts, and therapist resources should serve as a useful guide for those new to arthritis and chronic pain management.

### **Patient Population:**

This treatment guide was developed for use with patients with rheumatoid arthritis (RA) who experience chronic pain. Please review the resources included in this guide for detailed information about the assessment, classification, and treatment/management of these conditions. This treatment guide can easily be adapted for use with other patient populations who experience chronic pain.

### **About the Group:**

The Living Well with Chronic Pain group treatment is designed to take a comprehensive approach to chronic arthritis pain management. The group treatment consists of 8 weekly 90-minute sessions. Patients are referred to the Living Well with Chronic Pain group by their medical provider at UCF Health. Group members participate in individual assessments prior to enrolling into a group. Therapists may use the semi-structured interview included in this guide to aid their assessment. Patients are referred to individual therapy or other treatment, depending on patient presentation, should severe disease activity, medical comorbidities, psychopathology, or opioid overuse be detected. Once enrolled in the group, patients are expected to attend each session.

### **Treatment Team:**

The treatment team consists of a rheumatologist, a physical therapist, and two behavioral healthcare providers. The behavioral healthcare providers will co-facilitate each session and be responsible for assessment, organization, and information management and will serve as the point of contact for both patients and providers. The behavioral healthcare providers should be experienced in Acceptance and Commitment Therapy. The rheumatologist (currently, either Dr. Shazia Béq, M.D. or Dr. Neha Bhanusali, M.D.) is responsible for conducting the medical education portion of the treatment (session 1) and serves as an important resource for patient referrals, medical questions, etc. The physical therapist (currently Dr. Nick Inosencio, PT, DPT from CORA Rehabilitation) is responsible for the physical therapy education portion of the treatment (session 3) and also serves as a resource for related questions. Both the rheumatologist and the physical therapist also attend session 6 (Overcoming Barriers) in order to serve on the “panel of experts” and are invited to join any other sessions they choose.

**Session Overview:**

Week 1: Group Introduction and Medical Education

Week 2: Safe Physical Activity with Rheumatoid Arthritis

Week 3: Values and Goal Setting

Week 4: Improving Sleep

Week 5: Mood and Anxiety

Week 6: Overcoming Barriers

Week 7: Relationships and Communication

Week 8: Lifelong Change

**Overall Goals of Treatment:**

- to create an accepting and supportive environment in which patients may discuss concerns related to their chronic conditions and wellbeing
- to provide patients with information regarding their medical condition, pain, and the medical management of their disease
- to educate patients about safe physical activity with arthritis and to introduce a broadly-applicable exercise program that patients can engage in during treatment
- to describe the interactions of pain, mood, sleep, and behavior
- to identify adaptive vs. maladaptive responses to pain
- to build motivation to engage in patient-valued and medically-recommended activities
- to develop problem-solving and coping skills that help patients set realistic goals and overcome barriers
- to maintain and advance the integrated healthcare initiative of UCF Health and the UCF Department of Psychology

**Individual Pre-group Assessment:**

Review chronic pain assessment guidelines (see resources) before conducting any assessments. You may use the included semi-structured interview (included) to facilitate your assessment. The main goal of the individual assessment session is to determine the patient's suitability for group treatment. However, it is also important to get to know each patient and their needs individually in order to best meet the needs of the group.

**Weekly Assessment and Monitoring:**

The Weekly Check-In measure as well as a weekly activity and pain monitoring form (both included) are useful for collecting clinically useful information as well as for tracking change.

**Other Useful Free Measures (listed only):**

- RAPID-3 (brief measure of disease activity used in medical settings)
- Brief Pain Inventory (free for clinical use with permission)
- World Health Organization Quality of Life BREF
- PHQ-9 (or other depression measure)
- GAD-7 (or other anxiety measure)
- Chronic Pain Acceptance Questionnaire

## CHRONIC PAIN GROUP INTAKE INTERVIEW

Name: \_\_\_\_\_

Interviewer: \_\_\_\_\_

DOB: \_\_\_\_\_

Date: \_\_\_\_\_

Age: \_\_\_\_\_

Referred by: \_\_\_\_\_

Race/Ethnicity:

Male

Female

### Current Diagnoses & Symptoms:

### Current Medications (Adherence):

### Pain:

Onset/duration:

Location(s):

Quality (dull, aching, cramping, burning, tingling, throbbing, etc.):

Intensity (0-10):

Worst:

Best:

Average:

Now:

Triggers:

Management Strategies (how much did/do they work?):

Impairment in ADLs?

**Current Lifestyle:**

Living arrangement

Work/daily schedule

Diet

Physical activity

Sleep

Alcohol/tobacco/drug use

Major stressors

**Social History:**

Early development and childhood

Highest level of education

Employment

Spiritual/ religious beliefs

Legal history



**Mental Status / Behavioral Obs:**

Are results of ax believed to be an accurate reflection of current functioning?

**Appearance:**

Dressed appropriately      Inapprop      Well-groomed      Unkept      Casually dressed  
Older/younger than stated age

**Behavior:**

Cooperative/uncooperative      Good/ poor eye contact  
Animated      Apathetic      Guarded      Irritable      Defensive      Suspicious      Hostile

**Pain Behaviors:**

**Motor:**

Normal      Hypokinetic      Hyperactive      Agitated/tense      Tics      Pain behaviors

**Level of Consciousness:**

Alert      Impaired      Grossly normal      Somnolent

**Attitude:**

Cooperative      Defiant      Hostile      Reluctant      Irritable      Suspicious      Hypervigilant

**Speech:**

Rate: normal      rapid      slow      Volume: normal      low      high  
Pressured      Mute      Paucity      Articulate

**Mood:**

**Affect:**

Full range      Appropriate      Stable      Blunted      Flat      Constricted      Labile      Congruent/  
incongruent with mood and topic      Tearful  
Sad      Angry      Euythmic      Anxious (during testing)

**Thought Process:**

Goal directed / Coherent      Circumstantial /Tangential      Perseveration      Thought-blocking  
Flight of ideas      Loose associations      Disorganized      Linear      Logical

**Thought Content:**

Appropriate      Preoccupation      Obsessions      Grandiose      Delusions

**Memory:**

Grossly intact      Impaired recall      Impaired recent      Impaired remote

**Judgment:**

Normal / No impairment      Mildly impaired      Significantly impaired      Age appropriate

**Insight:**

No impairment / true insight      Mildly impaired / intellectual insight      Significantly impaired  
Minimizes illness      Denial of illness      Blames outside factors      Age appropriate

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Weekly Check-In

1. Pain [0 (None) – 10 (Worst Imaginable)]:

Highest: \_\_\_\_\_

Lowest: \_\_\_\_\_

Average: \_\_\_\_\_

Right now: \_\_\_\_\_

How much has pain interfered with your general activity this week [0 (not at all) – 10 (completely)]?

\_\_\_\_\_

2. Sleep:

Average hours/night: \_\_\_\_\_

Average quality [0 (not at all rested) – 10 (completely rested)]: \_\_\_\_\_

Difficulties (check those that apply):

Falling asleep

Staying asleep

Waking up several times

3. Exercise (15+ minutes):

Number of times: \_\_\_\_\_

What type? \_\_\_\_\_

4. How many different social/leisure activities did you participate in this week? \_\_\_\_\_

5. Over the past week, how often were you bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Little interest or pleasure in doing things	0	1	2	3
4. Feeling down, depressed or hopeless	0	1	2	3



Activity and Pain Monitoring

0 (no pain at all) to 10 (worst pain possible)

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Morning							
	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____
Afternoon							
	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____
Evening							
	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____	Avg Pain: ____

**Weekly Goals:** \_\_\_\_\_

## **Living Well with Chronic Pain**

### **Session 1: Group Introduction and Medical Education**

#### Objectives:

1. Orient patients to the group and develop an accepting and open environment.
2. Provide patients with accurate information about rheumatoid arthritis and its course/treatment as well as an opportunity to clarify misconceptions.
3. Introduce core elements of cognitive-behavioral therapy.
4. Engage patients in the treatment process.

#### Agenda:

1. Orientation to group
  - a. Give overview of goals of treatment, the roles of the treatment team, group rules
2. Group member introductions
  - a. Ask for their name, to describe their course of RA, something positive about themselves, and what they expect to gain from the group
3. Medical education/Q&A
  - a. Led by rheumatologist
4. Pain psychoeducation: complement medical education
  - a. What is pain? What purpose does it serve?
  - b. What causes pain for patients with RA? How is it treated?
  - c. What makes pain worse/better?
5. How does pain interact with thoughts, feelings, and behavior? (overview only, future sessions will elaborate on specific domains)
  - a. Activity: Cross-Sectional Formulation Worksheet- have patients come up with examples, both pain-related and non pain-related
6. Introduce activity and pain monitoring
  - a. Explain importance of monitoring
7. Homework:
  - a. Complete CSF Worksheet using a real-life example
  - b. Complete monitoring sheet

## **Living Well with Chronic Pain**

### **Session 2: Safe Physical Activity with Rheumatoid Arthritis**

#### Objectives:

1. Strengthen understanding of values and aid in clarification, where needed.
2. Educate patients about safe physical activity with arthritis and introduce a broadly-applicable exercise program that patients can engage in during treatment.
3. Continue developing successful, value-based goal-setting skills.

#### Agenda:

1. Weekly Check-In
2. Review monitoring homework
  - a. Reinforce successful completion
  - b. Did you notice anything from monitoring?
3. Introduce activity pacing and role of exercise in pain management (this may be done after PT presentation, depending on PT preference/availability)
  - a. Review Pacing Worksheet
4. Physical therapy presentation/ Q&A
  - a. Led by PT
5. Activity: Identify 3 potential exercises that would be safe and effective.
  - a. Explore personal value of physical activity
6. Homework:
  - a. Practice at least one exercise during the week.
  - b. Complete monitoring sheet

## **Living Well with Chronic Pain**

### **Session 3: Values and Goal Setting**

#### Objectives:

1. Strengthen patient understanding of core cognitive-behavioral principles using their personal examples.
2. Describe how acceptance can be an effective option for those living with chronic pain.
3. Facilitate patient exploration and clarification of values.
4. Develop successful goal-setting skills.

#### Agenda:

1. Weekly Check-In: patients complete form, review as helpful
2. Review monitoring homework
  - a. Reinforce successful completion
  - b. Did you notice anything from monitoring?
3. Review goals- problem-solve any difficulties
4. Discuss chronic pain: course and management
  - a. Creative hopelessness: elicit management strategies from patients
    - i. Take note of how many are change-based as well as how effective these strategies are (short-term and long-term).
    - ii. Introduce (or elaborate on) acceptance as another strategy.
  - b. Compare and contrast acceptance vs. change agenda
    - i. Both can be useful. Choose mindfully.
    - ii. Review Vicious/Coping Circle worksheet: moving away from pain vs. moving towards values.
5. Introduce values
  - a. Differentiate values vs. goals
  - b. Activity: Values Clarification Worksheet- pick 2 or 3 of your most important areas and explore values
6. Successful goal setting
  - a. Specific, Measurable, Attainable, Rewarding (value-based), Time-limited (SMART)
  - b. Activity: Activity Selection Worksheet- brainstorm a few SMART goals that are in the service of your identified values
  - c. Select one goal for homework
7. Homework:
  - a. Meet identified goal
  - b. Complete Values Clarification and Activity Selection Worksheets
  - c. Complete monitoring sheet

## **Living Well with Chronic Pain**

### **Session 4: Improving Sleep**

#### Objectives:

1. Differentiate medical and behavioral indicators of sleep disruption.
2. Facilitate identification of target behaviors and goal development.

#### Agenda:

1. Weekly Check-In
2. Review monitoring homework and activity goals
  - a. Problem solve difficulties meeting goals
3. Describe the interaction of pain and sleep
  - a. Introduce related sources of sleep interference (e.g., nocturia, medication side effects, sleep apnea)
  - b. Elicit group examples of sleep difficulties
  - c. Activity: assess sleep habits
    - i. Describe your typical bedtime routine.
4. Discuss good sleep hygiene (refer to worksheets)
  - a. Activity: identify 3 potential habits that might interfere with sleep and an alternative for each
5. Homework:
  - a. Commit to one habit change over the next week.
  - b. Commit to one additional value-based goal.
  - c. Complete monitoring sheet

## **Living Well with Chronic Pain**

### **Session 5: Mood and Anxiety**

#### Objectives:

1. Review and develop coping skills that facilitate psychological flexibility in the presence of anxiety and mood symptoms.
2. Frame mood/emotions and anxious thoughts/sensations as barriers to values rather than fused states.

#### Agenda:

1. Weekly Check-In
2. Review monitoring homework and activity goals
  - a. Problem solve difficulties meeting goals
3. Introduce the interactions of mood, anxiety, activity, and pain
  - a. Review mood in the context of vicious cycles
  - b. Describe function and physiology of anxiety, anxiety-avoidance cycle, and function of worry
4. Describe methods to effectively cope with mood variations and anxiety (Note: Remember, this is an overview of coping skills, not therapy for depression and anxiety. Mention that everyone experiences anxiety and depression from time to time. However, when symptoms become problematic, they may benefit from therapy or other interventions.)
  - a. What is happening? What are your thoughts, feelings, body sensations, and behavior? (refer to CSF Worksheet)
    - i. Mindfulness: just notice
  - b. Thoughts
    - i. Unhelpful Thinking Styles Worksheet
    - ii. Choosing how to relate to your thoughts
  - c. Feelings/Emotions
    - i. Acknowledge and validate your feelings
    - ii. Emotion regulation strategies
  - d. Body Sensations
    - i. Progressive Muscle Relaxation
    - ii. Breathing Exercise
      1. Activity: practice breathing and mindfulness
  - e. Behavior
    - i. Valued actions
    - ii. Small pleasant events
5. Homework:
  - a. Commit to two value-based goals (1 health, 1 wellness).
  - b. Complete monitoring sheet

## **Living Well with Chronic Pain**

### **Session 6: Overcoming Barriers**

#### Objectives:

1. Provide a “panel of experts” to facilitate successful problem-solving in the face of barriers to committed action.
2. Facilitate the development of successful problem-solving skills and willingness to encounter barriers.

#### Agenda:

1. Weekly Check-In
2. Review monitoring homework and activity goals
  - a. Problem solve difficulties meeting goals
3. Continue review of coping methods presented the week prior (if time ran out)
  - a. Elicit areas of difficulty for group members
4. Identify, discuss, and problem solve barriers to goals
  - a. Rheumatologist, PT, and therapists will represent their area of expertise
  - b. Group members will provide suggestions and support
5. Anticipating barriers (review Goal Setting Sheet)
6. Homework:
  - a. Complete Goal Setting Sheet
  - b. Complete monitoring sheet

## Living Well with Chronic Pain

### Session 7: Relationships and Communication

#### Objectives:

1. Continue the development of successful goal-setting and problem-solving skills.
2. Explore impact of chronic illness on relationships.
3. Review strategies that successfully communicate needs.

#### Agenda:

1. Weekly Check-In
2. Review Goal Setting Sheet
  - a. Problem-solve difficulties meeting goals
3. Describe the impact of chronic pain/illness on families and relationships
  - a. Elicit examples from group members
  - b. Explore thoughts and feelings
    - i. Burden on family, guilt, invalidation, “silent illness”
  - c. Not accepting that pain and illness has an impact, does not mean that pain and illness does not have an impact
    - i. Some roles may need to be redefined/renegotiated
    - ii. This is very difficult without communication
4. Discuss ways to successfully communicate about pain and illness, both in the context of romantic relationships, families, and friends as well as with medical providers
  - a. “suffering in silence” leaves everyone dissatisfied
    - i. It affects thoughts, feelings, and behavior, which impacts relationships
    - ii. Medical providers cannot successfully help what they don’t know about
    - iii. Oversharing can have negative consequences as well
  - b. Assertiveness can facilitate successful communication
    - i. Place your needs as important while acknowledging the needs of others
    - ii. “I statements”- take ownership of your feelings, no one can argue
    - iii. Learn when and how to ask for help and to say ‘no’
5. Homework:
  - a. Complete Goal Setting Sheet
  - b. Complete monitoring sheet



## Living Well with Chronic Pain

### Session 8: Lifelong Change

#### Objectives:

1. Briefly review major themes of treatment.
2. Provide closure at the conclusion of group treatment.

#### Agenda:

1. Weekly Check-In
2. Review Goal Setting Sheet
  - a. Problem-solve difficulties meeting goals
3. What were your take home messages?
4. Revisit major themes of therapy in the context of continuing and maintaining gains
  - a. You cannot always control your thoughts or feelings; you can control your behavior/how you respond to them.
  - b. Values and goal setting- get unstuck and move forward- live your values
    - i. Start here when you get off track
  - c. Acceptance vs. change
    - i. If you can change a situation to improve it, ACT!
    - ii. If you cannot change a situation, accept that and see what valued actions you can take.
    - iii. Either way, move forward.
  - d. Willingness to confront barriers
    - i. Problem-solving- examine your options
    - ii. Examine potential costs and benefits
    - iii. Using your support system
5. Reflect on therapy experience
  - a. Where do you go from here?

## Information Resources for Therapists

### **Chronic Pain Resources:**

American Chronic Pain Association (ACPA): <http://theacpa.org/>

ACPA Resource Guide to Chronic Pain Medication and Treatment:  
[http://theacpa.org/uploads/documents/ACPA\\_Resource\\_Guide\\_2014\\_FINAL%20\(2\).pdf](http://theacpa.org/uploads/documents/ACPA_Resource_Guide_2014_FINAL%20(2).pdf)

ACT for Chronic Pain Resources:  
[http://www.div12.org/PsychologicalTreatments/treatments/chronicpain\\_act.html](http://www.div12.org/PsychologicalTreatments/treatments/chronicpain_act.html)

Okifuji, A. & Turk, D. C. (2014) Assessment of Patients with Chronic Pain with or Without Comorbid Mental Health Problems in S. Marchand et al. (Eds.), *Mental Health and Pain* (pp. 227-259). Springer: Verlag, France

ICSI Guidelines for Assessment and Management of Chronic Pain: Hooten WM, Timming R, Belgrade M, Gaul J, Goertz M, Haake B, Myers C, Noonan MP, Owens J, Saeger L, Schweim K, Shteyman G, Walker N. Institute for Clinical Systems Improvement. Assessment and Management of Chronic Pain. Updated November 2013.

### **Rheumatoid Arthritis Resources:**

American College of Rheumatology (ACR): <http://www.rheumatology.org/>

2010 Rheumatoid Arthritis Classification Criteria: An American College of Rheumatology/ European League Against Rheumatism Collaborative Initiative. *ARTHRITIS & RHEUMATISM*, 62(9), 2569-2581.

Saag, K. G., Teng, G. G., Patkar, N. M., Anuntiyo, J., Finney, C., Curtis, J. R., ... & Furst, D. E. (2008). American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Care & Research*, 59(6), 762-784.

Singh, J. A., Furst, D. E., Bharat, A., Curtis, J. R., Kavanaugh, A. F., Kremer, J. M., ... & Saag, K. G. (2012). 2012 Update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis care & research*, 64(5), 625-639.

Patient Info: [http://www.rheumatology.org/Practice/Clinical/Patients/Information\\_for\\_Patients/](http://www.rheumatology.org/Practice/Clinical/Patients/Information_for_Patients/)

NIH General Info: [http://www.niams.nih.gov/Health\\_Info/Rheumatic\\_Disease/default.asp](http://www.niams.nih.gov/Health_Info/Rheumatic_Disease/default.asp)

Arthritis Foundation: <http://www.arthritis.org/>

Arthritis Society: <http://www.arthritis.ca/pain>

## **APPENDIX B: FACILITATOR RATINGS OF PARTICIPATION**

## Facilitator Ratings of Participation

ID: \_\_\_\_\_ Rater: \_\_\_\_\_ Session # \_\_\_\_ Date: \_\_\_\_\_

Goal 1: \_\_\_\_\_

Goal 2: \_\_\_\_\_

Fully met

Fully met

Partially met

Partially met

Not met

Not met

Barriers: \_\_\_\_\_

Barriers: \_\_\_\_\_

New Goals:

1) \_\_\_\_\_

2) \_\_\_\_\_

Participation Quantity:

0 Absent	1 Minimal	2 --	3 Average	4 --	5 Frequent
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Participation Quality:

1 Critical of Others	2 --	3 Neutral	4 --	5 Supportive of Others
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1 Withdrawn/ Defensive	2 --	3 Neutral	4 --	5 Open/ Willing
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1 Inappropriate/ Oversharing	2 --	3 Neutral	4 --	5 Appropriate sharing
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Behavioral Observations:

## **APPENDIX C: PATIENT EXPERIENCE QUESTIONNAIRE**

## Patient Experience Questionnaire

	Strongly Disagree		No Opinion		Strongly Agree
The group sessions were informative.	1	2	3	4	5
The group sessions were relevant to me.	1	2	3	4	5
I have been using the skills learned in this group.	1	2	3	4	5
I will likely use the skills learned in this group in the future.	1	2	3	4	5
The group facilitators were knowledgeable.	1	2	3	4	5
The group facilitators were respectful to all group members.	1	2	3	4	5
The group facilitators created a comfortable group environment.	1	2	3	4	5
I enjoyed wearing/using the Fitbit.	1	2	3	4	5
I continued using the Fitbit after the group sessions ended.	1	2	3	4	5
I have used the resistance bands and/or yoga strap provided in session 2.	1	2	3	4	5
I feel that I am better able to manage pain as a result of this group.	1	2	3	4	5
I feel that I am better able to manage rheumatoid arthritis as a result of this group.	1	2	3	4	5
I would recommend other patients join this group.	1	2	3	4	5

How would you rate your overall satisfaction of this group? \_\_\_\_\_  
 (0= Not at all satisfied, 10= Completely satisfied)

What aspects of the group did you find most helpful and why?

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What aspects of the group did you find least helpful and why?

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What specific changes would you recommend be made to this group?

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**APPENDIX D: IRB APPROVAL OF HUMAN RESEARCH**





University of Central Florida Institutional Review Board  
Office of Research & Commercialization  
12201 Research Parkway, Suite 501  
Orlando, Florida 32826-3246  
Telephone: 407-823-2901 or 407-882-2276  
[www.research.ucf.edu/compliance/irb.html](http://www.research.ucf.edu/compliance/irb.html)

## Approval of Human Research

From: UCF Institutional Review Board #1  
FWA00000351, IRB00001138

To: Shazia Ashraf Beg and Co-PIs: Jeffrey E. Cassisi, Natasha S. De Pesa, Neha G. Bhanusali

Date: June 16, 2016

Dear Researcher:

On 06/16/2016, the IRB approved the following minor modification to human participant research until 01/18/2017 inclusive:

Type of Review: IRB Addendum and Modification Request Form  
Expedited Review

Modification Type: Change of location of files from UCF Health to a locked cabinet in a limited access room in the Psychology Department.

Project Title: Multifaceted Group Intervention for Chronic Arthritic Pain: Feasibility in a Primary Care Setting

Investigator: Shazia Ashraf Beg

IRB Number: SBE-14-10668

Funding Agency: UCF College of Medicine(UCF COM)

Grant Title:

Research ID: N/A

The scientific merit of the research was considered during the IRB review. The Continuing Review Application must be submitted 30 days prior to the expiration date for studies that were previously expedited, and 60 days prior to the expiration date for research that was previously reviewed at a convened meeting. Do not make changes to the study (i.e., protocol, methodology, consent form, personnel, site, etc.) before obtaining IRB approval. A Modification Form **cannot** be used to extend the approval period of a study. All forms may be completed and submitted online at <https://iris.research.ucf.edu>.

If continuing review approval is not granted before the expiration date of 01/18/2017, approval of this research expires on that date. When you have completed your research, please submit a Study Closure request in IRIS so that IRB records will be accurate.


Use of the approved, stamped consent document(s) is required. The new form supersedes all previous versions, which are now invalid for further use. Only approved investigators (or other approved key study personnel) may solicit consent for research participation. Participants or their representatives must receive a signed and dated copy of the consent form(s).

All data, including signed consent forms if applicable, must be retained and secured per protocol for a minimum of five years (six if HIPAA applies) past the completion of this research. Any links to the identification of participants should be maintained and secured per protocol. Additional requirements may be imposed by your funding agency, your department, or other entities. Access to data is limited to authorized individuals listed as key study personnel.

In the conduct of this research, you are responsible to follow the requirements of the [Investigator Manual](#).

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On behalf of Sophia Dziegielewski, Ph.D., L.C.S.W., UCF IRB Chair, this letter is signed by:

A handwritten signature in black ink that reads "Joanne Muratori". The signature is written in a cursive style with a large initial "J".

Signature applied by Joanne Muratori on 06/16/2016 12:21:27 PM EDT

IRB Manager

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