CHRONIC PAIN SELF-MANAGEMENT SUPPORT IN PRIMARY HEALTH CARE

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LAY ABSTRACT

Chronic pain is associated with suffering, disability, and health care costs. This thesis includes five papers aimed at better understanding reduced function and evaluating a new self-management program for people living with chronic pain. The results of this research suggests people with more medications, longer lasting pain, negative thoughts and emotions related to their pain, and sensitivity to pressure are more likely to have poor functional abilities. A new self-management approach, Chronic pain self-management support with pain science education and exercise (COMMENCE), is described and evaluated. The results suggest people with chronic pain participating in COMMENCE experience greater improvements in function than people on a wait-list for the program. It appears people living with more chronic health conditions are likely to have poorer function at the end of the program. The findings of this thesis may help to inform management of chronic pain in primary healthcare.

ABSTRACT

Chronic pain is one of the most frequent reasons for a primary health care visit and people with pain identify improved function as an important goal. Self-management support provides an opportunity to improve function for people with chronic pain, but existing evidence suggests negligible changes in function. This thesis includes five manuscripts with overarching objectives of improving the understanding of reductions in function related to pain and evaluating a new self-management program aimed at improving function for people with chronic pain.

The first manuscript is a cross-sectional evaluation of factors associated with reduced function in people with chronic pain referred for self-management support in primary health care. The findings suggest number of medications, depressive symptoms, cognitive factors associated with pain, mechanical hyperalgesia, and duration of symptoms explain 63% of the variance in function in people with chronic pain, multiple comorbidities, and barriers to accessing healthcare.

The second manuscript is a case-series describing the participation and outcomes of six participants in Chronic pain self-management support with pain science education and exercise (COMMENCE). This study contributes to the literature by detailing the COMMENCE intervention and describing the varied responses of six participants.

The third and fourth manuscripts are a protocol for a randomized controlled trial (RCT) and a completed RCT evaluating the effectiveness of COMMENCE in comparison to a wait-list control. The results suggest COMMENCE improves function for people with chronic pain (mean difference = -8.0 points on the Short Musculoskeletal

Function Assessment; 95% confidence interval: -14.7 to -1.3).

The fifth manuscript is a planned secondary analysis of the RCT described above. This study suggested people with a greater number of comorbidities are likely to have poorer function at the end of COMMENCE after controlling for age, gender, and baseline function. Together, these factors explained 63% of the variance in function.

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DECLARATION OF ACADEMIC ACHIEVEMENT

For all five manuscripts, Jordan Miller conceptualized the research questions, designed the studies (and the self-management program evaluated), led the data collection, analyzed the data (where applicable), and wrote the initial drafts of all manuscripts.

Chapter 2 - Dr. MacDermid helped to refine the objectives and methods, provided guidance for data collection and analysis, and edited the manuscripts. Dr. Richardson, Dr. Walton, and Ms. Gross reviewed the objectives and design, provided content expertise, and edited the manuscript.

Chapter 3 – Dr. MacDermid and Dr. Richardson helped to refine the research objectives and design. Dr. Richardson and Ms. Gross provided content expertise on self-management and rehabilitation for persistent pain. Dr. Walton, Dr. Richardson, Ms. Gross, and Dr. MacDermid all provided feedback on the manuscript.

Chapter 4 – Dr. MacDermid helped to refine the objectives and methods, and provided feedback on the protocol manuscript. Dr. Richardson and Dr. Walton reviewed the objectives and methods and provided feedback on the manuscript.

Chapter 5 - Dr. MacDermid performed the blinded analysis of between group comparisons using the data analysis plan developed by Mr. Miller. Dr. MacDermid, Dr. Walton, and Dr. Richardson reviewed the manuscript.

Chapter 6 – Dr. MacDermid, Dr. Walton, Dr. Richardson, and Ms. Gross all reviewed the objectives and methods and edited the manuscript.

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CHAPTER 3

CHAPTER 1. INTRODUCTION

The burden of pain-related disability in primary health care

Chronic pain is a prevalent condition effecting between 19% and 29% of people in Canada (Moulin, Clark, Speechley, & Morley-Forster, 2002; Schopflocher, Taenzer, & Jovey 2011). Many people with chronic pain experience reduced function and quality of life. In fact, chronic pain conditions are the leading cause of years lived with disability and disability-adjusted life years (Newton et al., 2015; Vos et al., 2012a). Improving function is important to those living with chronic pain (Casarett, 2001), but it is also important to reducing the socioeconomic burden associated with the increased health care expenditures and decreased work productivity associated with chronic pain (P. Langley et al., 2010a, 2010b; Murray et al., 2013).

People with chronic conditions are the most frequent visitors to primary health care providers (Glynn et al., 2011; van Oostrom et al., 2014). People with multiple chronic conditions are likely to report chronic pain, with a prevalence of 67% (Eckerblad et al., 2015). Facilitating improvements in function in people with chronic pain and multiple chronic conditions is uniquely challenging as chronic pain and other chronic conditions can all contribute to reduced functional abilities (Kadam & Croft, 2007; Vos et al., 2012a). Despite growing epidemiological research recognizing the prevalence of multimorbidity, clinical research that includes people with multiple chronic conditions in primary health care is limited (Fortin, Lapointe, Hudon, & Vanasse, 2005). Based on the prevalence of chronic pain and multimorbidity and the socioeconomic costs of the healthcare for this group, research focusing on this

population should be prioritized.

People with barriers to accessing healthcare are another population in which the burden of chronic pain is high. Increasing age, lower socioeconomic status, and people with mental health concerns are all more likely to experience chronic pain (McBeth & Jones, 2007). These groups often experience barriers to accessing healthcare (Browne et al., 2012) and are often under-represented in clinical trials (Bartlett et al., 2005). In order to be able to effectively generalize the results of research on improving function for people with chronic pain, the clinical research should be directed at the population of people in which the burden is greatest which means including individuals often excluded from health research.

Treatment of chronic pain in primary health care

Treatment of chronic pain in primary health care is a challenge. Clinical practice guidelines recommend a multimodal or multidisciplinary approach to treatment of chronic pain that includes exercise, medication, advice to stay active, and cognitive approaches (American Society of Anesthesiologists, 2010; Smith, Hardman, Stein, & Colvin, 2014). Multidisciplinary management of chronic pain is often difficult to access for persons with chronic pain due to geographical and economic barriers (Peng et al., 2007). A systematic review of "usual care" for people with low back pain in primary care settings suggests the average patient is prescribed medication, but not given physical activity or exercise recommendations (Somerville et al., 2008). Commonly prescribed opioid medications have actually been associated with no change or a small

reduction in function at 6-months follow-up (Ashworth, Green, Dunn, & Jordan, 2013), so perhaps it is not surprising that the outcomes of usual care for people with chronic low back do not include improvements in function (Somerville et al., 2008).

Current practice patterns do not match clinical practice guidelines in the treatment of chronic pain in primary health care (Somerville et al., 2008). While multidisciplinary chronic pain teams may be difficult to access in many parts of the world, multimodal approaches in primary health care settings may provide an opportunity to improve access to care more consistent with clinical practice guidelines. In order to facilitate use of multimodal approaches in primary health care, additional research is needed on multimodal approaches implemented in these settings. To be consistent with clinical practice guidelines(American Society of Anesthesiologists, 2010; Smith et al., 2014), these multimodal approaches should integrate physical activity, exercise and cognitive approaches to the treatment of chronic pain.

The potential for self-management support

Self-management support may be one means of delivering the multimodal care suggested in clinical practice guidelines. Self-management programs have been supported nationally and internationally as a means of helping people living with chronic conditions to manage their own health (Health Council of Canada, 2005; Who, 2002). Self-management has been defined by Barlow as an individual's "ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Efficacious self-management

encompasses ability to monitor one's condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life" (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). The goal of self-management programming is to provide supportive interventions to allow the participant to manage their own health more effectively.

There are a number of health conditions for which self-management support has positive outcomes. Self-management support can facilitate improvements of clinical measures of glucose control, self-efficacy, and quality of life in people living with diabetes (Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012), improved function and quality of life for people living post stroke (Lennon, McKenna, & Jones, 2013), and improved hypertension to reduce cardiovascular risk (Glynn, Murphy, Smith, Schroeder, & Fahey, 2010). For several chronic conditions, self-management support has been associated with reduced health care visits (Panagioti et al., 2014). These changes in behaviour and health outcomes with self-management programming may suggest investigating self-management for improving health outcomes in people with chronic pain may be beneficial.

Looking more specifically at the evidence on self-management support for conditions associated with chronic pain, such as arthritis, suggests self-management programs are unlikely to produce improvements in pain, function, or quality of life (Kroon et al., 2014). While self-management supports do not appear to improve function, exercise interventions have been shown to be effective at improving function for this population (Anwer, Alghadir, & Brismée, 2015; Tanaka, Ozawa, Kito, &

Moriyama, 2013, 2015).

Similar findings are available for low back pain. Self-management does not appear to provide clinically meaningful improvements in function for low back pain (Du et al., 2011), but exercise approaches result in clinically important changes in function (Searle, Spink, Ho, & Chuter, 2015). Also, pain neurophysiology education may be effective at improving function for people with low back pain (Louw, Diener, Butler, & Puentedura, 2011). Research aimed at incorporating exercise and pain neurophysiology education into self-management programs that improve self-efficacy and knowledge (Steinsbekk et al., 2012), and reduce health care utilization (Panagioti et al., 2014) was needed to determine whether improved function is possible with such an approach. This evidence led to the development of an intervention called Chronic pain self-management support with pain science education and exercise (COMMENCE), which incorporates pain science education and exercise into a self-management program. COMMENCE is detailed and evaluated throughout the chapters of this thesis.

Using social cognitive theory and self-efficacy theory to inform self-management

In addition to incorporating evidence on effective interventions to target improvements in function, behaviour change theories can help to contribute to the development of self-management programming. Albert Bandura's Social Cognitive Theory (Albert Bandura, 1986) and self-efficacy theory (Albert Bandura, 1977; Albert Bandura, 1997) are frequently used to inform self-management programs (Richardson et al., 2014). These two theories were used to inform COMMENCE and the research to

evaluate it. Social cognitive theory is founded on the concept of triadic reciprocal determinism. This model suggests reciprocal causation between behaviour, personal factors (including cognitive, emotional, and biological factors), and environmental influences. Each of the relationships in this triad were used to inform aspects of COMMENCE.

The reciprocal relationship between personal factors and behaviour is perhaps the relationship that was most influential in the design of COMMENCE. This reciprocal relationship suggested by Bandura (Albert Bandura, 1986) implies personal factors such as thoughts and emotions can influence behaviour and that the behaviour in turn influences the thoughts and emotions. An example of how this concept permeates the self-management program is the inclusion of pain neurophysiology education. Pain neurophysiology education can change the way people think about pain (G. L. Moseley & Butler, 2015). By conceptualizing pain differently, people may change their beliefs about their own abilities and limitations. Also, this change in understanding of pain may change the person's perception of the safety of certain activities such as exercise and whether participation in physical activity or exercise could influence pain. All of these changes in thoughts or beliefs are examples of personal factors that could influence the person's behaviour. This may be evident from research suggesting people with chronic low back pain can bend forward further after pain neurophysiology education and that the same education may contribute to improvements in self-reported functional abilities (G. L. Moseley, Nicholas, & Hodges, 2004). As people engage differently in activities and they are able to observe this change in their own behaviour, their thoughts about their

own abilities change as well. This could, for example, further increase their confidence in performing a specific activity.

One of the personal factors in the above description of pain neurophysiology has been described by Bandura as self-efficacy. Self-efficacy was defined by Bandura as, "people's judgments of their capabilities to organize and execute courses of action required to attain designated types of performances (p. 391)" (Albert Bandura, 1986). Many of the strategies included in COMMENCE, described in more detail in chapter 3, are designed to facilitate changes in self-efficacy. Another example from COMMENCE included to target self-efficacy is the inclusion of short-term goal setting and reflection on progress towards goals. By encouraging the participant to set short-term, realistic goals and reflecting on the achievement of those goals, the program puts the participant in the situation where they can observe a successful change in behaviour early in the program. An important component of this process is reflection and self-evaluation. If the participant observes a positive change in behaviour, their self-efficacy for that activity may change, which may have a positive influence on future attempts at changing behaviour. This process demonstrates how the reciprocal relationship between personal factors such as self-efficacy and behaviour can influence each other and how this idea influenced aspects of COMMENCE.

Understanding the influence of personal factors on behaviour was important to the outcomes collected in each manuscript of this thesis as well. A number of personal factors were collected throughout this research due to their potential influence on behaviour and functional outcomes. The first factor was a measure of self-efficacy. This

was collected with an understanding that people's beliefs about their abilities are likely to influence their behaviour (Perry & Francis, 2013). Also, cognitive factors associated with pain such as catastrophic thinking (M. J. Sullivan et al., 2001) and fear of movement or re-injury (G. Crombez, Vlaeyen, Heuts, & Lysens, 1999) were collected based on the concept that our thoughts and beliefs can influence our actions.

The second side of the triadic reciprocal causation model is the relationship between environmental factors and personal characteristics. This relationship also informed aspects of COMMENCE. COMMENCE involves participating in a group environment at a health centre with a health care provider. The addition of a social network including a group of people who are also living with chronic pain and a health care provider contributes a change in the environment of participants. Other examples of environmental changes may occur when the participant changes their weekly activities and participation in life-roles. These changes in environment may influence the expectations and beliefs of the participant. A key concept of Social Cognitive Theory introduced by Bandura is that of modelling (Albert Bandura, 1986). Participants in the self-management program are models for each other. The reason COMMENCE includes a group visit each week is so that participants can share similar experiences, successes, and challenges. When one participant finds a way to overcome a challenge, this may serve as an example for other members of the group to follow. Observing others in the group engage in behaviour change can lead to changes in a person's self-efficacy for making similar changes. An important aspect of this reciprocal relationship is that the person also evokes reactions from their social environment and as such, this relationship

is not unidirectional.

Finally the concept of a reciprocal causation between behaviour and environment also influenced planning for COMMENCE. The participant is changing their behaviour by attending COMMENCE. The behaviour of attending the self-management program and sharing their experiences influences their environment. For one, just by attending, they are adding a physiotherapist and several other participants in the group program to their social environment. The input the participant has in the group further influences that environment. Also, many of the participants will set goals and engage in new activities that will involve changes in their environment and that new environment will influence whether or not that new activity is continued or discontinued.

In summary, Social Cognitive Theory influenced the development of COMMENCE and the research included in this thesis. This is evident through the consideration of the participants' environment, personal factors, and behaviour and how these three factors interact. In particular, the recognition that participants' are self-regulatory individuals played an important role. Emphasis is placed on providing an environment in the self-management program that encourages increases in self-efficacy with the understanding that the participants' self-efficacy is likely to impact their behaviour (A Bandura, 1977). Ultimately, changes in behaviour such as participation in exercise has the potential to improve participants' functional abilities and health status (Van Middelkoop et al., 2011). The specific strategies included in COMMENCE that were influenced by Social Cognitive Theory and the rationale for those strategies are described in more detail in chapter 3.

Using the Neuromatrix Model to inform self-management for chronic pain

In addition to being influenced by behaviour change theory, the research included in this thesis is influenced by Ronald Melzack's Neuromatrix Model of pain (Melzack, 2001). The Neuromatrix Theory proposed by Melzack suggests pain is a multidisciplinary experience produced by a wide spread network of neurons throughout the brain, coined the "body-self neuromatrix". There are three domain inputs that can trigger a pain "neurosignature". These include a cognitive-evaluative domain, a sensory-discriminative domain, and a motivational-affective domain. Several of the predictors used in chapters 2 and 6 of this thesis can be conceptualized within these domains. For example, measures of cognitive factors associated with pain such as catastrophic thinking (Michael J L Sullivan, Stanish, Waite, Sullivan, & Tripp, 1998), fear of movement/re-injury (G. Crombez et al., 1999), and a sense of perceived injustice (Michael J L Sullivan, Scott, & Trost, 2012) have demonstrated relationships with pain and can be conceptualized in the cognitive-evaluative domain. Psychophysical measures including pressure pain threshold and sensitivity to cold tests measure the participant's response to sensory discriminative input. While we did not collect any biological measures necessary to measure the motivational-affective domain directly, measures including depression (Strobel, Hunt, Sullivan, Sun, & Sah, 2014) and post-traumatic stress symptoms (Steudte-Schmiedgen et al., 2015) may serve as proxy measures for limbic system and hypothalamic-pituitary-adrenal axis activity. The neuromatrix model helps to conceptualize how these factors may influence pain and disability through the three input

domains.

There are also three output domains in the neuromatrix model. The three domains are the pain perception domain, action programs, and stress-regulation programs. Throughout this thesis, function is considered the primary outcome and dependent variable. Function can be visualized as an output of the neuromatrix that may fit best in the action program domain. Secondary measures in the randomized controlled trial in chapter 3 can be conceptualized in the action programs domain (self-efficacy) and pain perception domain (pain intensity, cognitions related to pain).

The neuromatrix model has also helped to inform the COMMENCE intervention. In the design of COMMENCE, considering the Neuromatrix Model facilitated the conceptualization of pain as a multidimensional experience. The Nueromatrix model helps to organize the factors that can contribute to the pain experience in three input domains. These three domains provide a way to organize potential targets for interventions that could influence the amount of pain and disability. COMMENCE includes strategies that target cognitive-evaluative dimensions of pain including pain neurophysiology education which can reduce pain catastrophizing (G. L. Moseley et al., 2004), graded exposure which can reduce pain-related fear (Leeuw et al., 2008; J. W. S. Vlaeyen, De Jong, Onghena, Kerckhoffs-Hanssen, & Kole-Snijders, 2002), and goal setting which can improve self-efficacy (Levack et al., 2010). COMMENCE does not include strategies to change pain through sensory-discriminative inputs, but discusses how exercise can facilitate changes in the way the neuromatrix responds to physical stimuli (Ray & Carter, 2007). Thus exercise can change the way the "body-self

neuromatrix" responds to inputs from the sensory discriminative domain. Finally, COMMENCE includes strategies to help the person cope with stress such as breathing and relaxation strategies which have been shown to change autonomic functioning (Meeus et al., 2015). These strategies could be conceptualized as targeting pain and reduced function through changes in the motivational-affective domain of the neuromatrix inputs.

COMMENCE also includes strategies that could be conceptualized as targeting the action patterns of the participant. The act of engaging in additional important life-role activities, physical activity, or exercise could all be examples of changing action patterns. Also, people with chronic pain often experience changes in involuntary movement patterns or muscle activation patterns (Lamoth, Meijer, Daffertshofer, Wuisman, & Beek, 2006). These changes in movement patters could be targeted through movement and exercise. Finally, effective communication strategies and active coping strategies are encouraged throughout the program. These communication strategies can also be conceptualized as action patterns targeted by COMMENCE.

One of the limitations of the Neuromatrix model is an under-representation of social factors and how they can influence pain and pain-related disability. For example, socioeconomic factors have been shown to have a relationship with chronic pain and pain-related disability (Dorner et al., 2011). However, it is difficult to conceptualize the input domain through which these complex social factors would influence pain and pain-related disability. Using the Social Cognitive Theory alongside the Neuromatrix model encourages consideration of the reciprocal relationships between environmental

influences, personal factors and behaviour, which may not be emphasized by the Neuromatrix model alone.

Using the Neuromatrix model to conceptualize the complex, multidimensional nature of pain as well as the Social Cognitive Theory for the reciprocal relationships between environmental influences, personal factors, and behaviour was important to the development of COMMENCE and the research designed to evaluate this multimodal program.

Thesis objectives

The overarching aim of this thesis is to contribute knowledge needed to improve the treatment of pain-related disability in primary health care and ultimately improve the lives of people living with pain.

Achieving this aim requires consideration of a number of points raised throughout this introduction. First, the goals of the person living with pain must be considered. Most people with pain (80%) report reductions in pain as an important end-goal of pain trials (Casarett, 2001). On further questioning, many describe interference with participation in their usual activities as the reason for their goal of pain reduction. Also, improved function is stated as a an important end-point for clinical trials by 30% of people experiencing chronic pain (Casarett, 2001). Function was chosen as the primary outcome or dependent variable throughout all of the studies in this thesis due to its value to people living with pain in addition to the potential impact of improved function on the socioeconomic and health system burden of chronic pain (P. Langley et

al., 2010a; Murray et al., 2013).

Second, the population being studied should represent the population in which the burden of pain is highest. The prevalence of chronic pain is high in people with multiple comorbidities (Eckerblad et al., 2015) and this population often experiences reduced function (Jackson et al., 2015; Kadam & Croft, 2007). Also, people with chronic pain and multimorbidity are frequent users of healthcare resources (Glynn et al., 2011; van Oostrom et al., 2014) and are very likely to be the population best representative of the people seeking care for pain in primary health care setting. Pain is also prevalent in a population of people with additional health challenges or barriers to accessing health care such as poverty (Dorner et al., 2011; Kuo & Lai, 2013), mental health conditions (Lerman, Rudich, Brill, Shalev, & Shahar, 2015; Sterling, Jull, & Kenardy, 2006), or addictions concerns (Hjsted, Ekholm, Kurita, Juel, & Sjgren, 2013). In order to be able to generalize the results of these studies to these populations, this thesis work was carried out at Woodstock and Area Community Health Centre where the priority populations include people with multiple morbidities, mental health conditions, addictions concerns, poverty, no health insurance, and isolated seniors. This partnership with a primary health care setting allowed our research to include the population in which the burden of chronic pain is high. This will maximize the ability to generalize the results to similar primary health care settings.

Investigating function in a population of people with multiple chronic conditions and social challenges poses unique research challenges. Perhaps most importantly, there are a number of factors that could be contributing to reduced function in this population.

Chronic pain and multimorbidity are both associated with disability (Jackson et al., 2015; Kadam & Croft, 2007; Vos et al., 2012a), as are addictions and mental health conditions such as depression (Edwards et al., 2011; R. J. Turner, Lloyd, & Taylor, 2006). A better understanding of the factors associated with reduced function could help inform future treatments aimed at improving function in people with chronic pain and multiple chronic conditions.

Finally, in order to accomplish the aim of providing evidence to improve function for people with chronic pain, new interventions developed for evaluation must have strong theoretical foundations and incorporate existing evidence on strategies to improve function for people living with chronic pain. Incorporating evidence on treatments aimed at improving function for people with pain as well as pain and behaviour change theories has led to the development of the COMMENCE intervention evaluated in this thesis.

These considerations led to the following specific objectives for this thesis:

1) To investigate the factors associated with poorer function in a population of people with chronic pain referred for self-management support in a primary health care setting
2) To describe a new physical therapist-led chronic pain self-management program and individual responses to the intervention.
3) To evaluate the effectiveness of 6-weeks of Chronic pain self-management support with pain science education and exercise (COMMENCE) at improving function over 18-weeks in people with chronic pain in comparison

to a wait-list control.

4) To evaluate the effectiveness of COMMENCE at improving pain intensity, pain interference, self-efficacy, catastrophic thinking, fear of movement/re-injury, pain neurophysiology knowledge, how much participants are bothered by difficulty with functional activities, fatigue, depressive symptoms, and work status with COMMENCE in comparison to a wait-list control over 18-weeks.
5) To identify demographic, clinical, psychological, or psychophysical variables that are predictive of response to COMMENCE.

Outline of thesis manuscripts

The first manuscript (Chapter 2) is titled "Factors associated with disability in people with chronic pain referred for self-management support". As stated in the introduction, treatments aimed at improving function for people with chronic pain in primary health care rely on understanding the factors associated with reduced function in this population. Chapter 2 aims to improve our knowledge in this area by investigating factors association with poorer function in people with chronic pain and multiple comorbidities. This is the population of people most likely to seek care for pain-related disability in primary health care settings and a population in which the contributors to disability are complex.

The second manuscript (Chapter 3) is titled "Physical therapist led chronic pain self-management support with pain science education and exercise in primary health

care: A case series." The purpose of this multiple case studies design was to describe the newly developed self-management program: Chronic pain self-management support with pain science education and exercise (COMMENCE) and to describe the varied responses of several individuals who participated in the program. A multiple case studies design was chosen to describe the new intervention because it allowed for a more detailed description of the intervention in order to facilitate replication in practice. Also, a multiple case studies design allows for visualization of the varied trajectories of participants and potential explanations for these varied trajectories, which is often difficult in a randomized controlled trial.

The third manuscript (Chapter 4) is titled: "Chronic pain self-management support with pain science education and exercise (COMMENCE): Study protocol for a randomized controlled trial". The protocol was a plan for evaluating the effectiveness of the intervention described in Chapter 3. In addition to evaluating the effect of COMMENCE on function (primary outcome), the protocol planned to evaluate the effect of COMMENCE on the following secondary outcomes was evaluated: pain intensity, pain interference, self-efficacy, catastrophic thinking, fear of movement/re-injury, pain neurophysiology knowledge, how much participants are bothered by difficulty with functional activities, fatigue, depressive symptoms, and work status. The outcome of participants in COMMENCE were compared comparison to a wait-list control over an 18-week period. The results of these comparisons are presented in Chapter 5. This protocol also includes a planned secondary analysis to determine predictors of response. This study is included in Chapter 6. Also included in this protocol were plans for analysis

of data from both the treatment group and wait-list group after the wait-list group receives treatment to be completed in 2016. This will allow for an estimate of whether the effects are maintained over a longer term in the treatment group, provide a secondary estimate of treatment effect in the wait-list group, and determine whether a wait period influences the effect estimates for COMMENCE.

The fourth manuscript (Chapter 5) is a randomized controlled trial titled: "ChrOnic pain self-ManagementMent support with pain science EducatioN and exerCisE (COMMENCE): A randomized controlled trial". This manuscript corresponds to the effectiveness objectives outlined in the protocol in Chapter 4. This is the first randomized controlled trial to evaluate an intervention that incorporates pain neurophysiology education and exercise into a self-management program. The results could have an important impact on the treatment of pain in primary health care settings by providing evidence on the effectiveness of a new self-management intervention aimed at improving function for people with chronic pain.

The fifth and final manuscript (Chapter 6) is titled "Predictors of functional outcomes of chronic pain self-management support with pain science education and exercise." This study was a planned secondary analysis of the randomized controlled trial in Chapter 5. The secondary analysis evaluates baseline factors associated with function at the end of COMMENCE while controlling for age, gender, and baseline function. An understanding of the predictors of poor functional outcomes could help clinicians direct treatment to the most appropriate individuals. Also, by identifying individuals who are unlikely to respond to the intervention, future research could be directed at improving treatments for

those unlikely to benefit.

Together, the results of these five manuscripts provide knowledge needed to improve the care of people living with chronic pain. All five manuscripts contribute important knowledge to help improve functional outcomes of people with pain who seek care from primary health care providers. This knowledge includes a better understanding of the factors associated with reduced function in this population, a clearly outlined intervention aimed at improving function, evidence on theeffectiveness of the intervention, and knowledge about the factors associated with poorer function after participation in the intervention.

The reader may notice overlap between the manuscripts. All five manuscripts have distinct objectives and make unique contributions to the understanding of function and facilitating improvements in function in people with chronic pain who seek care from primary health care providers. Given the similar population, primary outcome or dependent variable, predictors or covariates, and intervention investigated, the introductions and descriptions of measures may overlap between manuscripts.

The final chapter (Chapter 7) is a discussion that will discuss how these manuscripts advance the science of improving function for people with chronic pain, the clinical and research implications of this work, and limitations of this body of work.

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CHAPTER 2: FACTORS ASSOCIATED WITH POORER FUNCTION IN PEOPLE WITH CHRONIC PAIN REFERRED FOR SELF-MANAGEMENT SUPPORT

TITLE

Factors associated with poorer function in people with chronic pain referred for self-management support

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Abstract

Background: People with chronic pain often experience multiple comorbidities and reduced function, but it is unclear what factors are contributing to poorer function in this population. The purpose of this study was to determine what factors are associated with poorer function in a population of people referred for chronic pain self-management support. **Methods:** This cross sectional study included 102 participants with chronic pain. Function was measured by the Short Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI). Potential predictors of poorer function included age, gender, duration of symptoms, number of comorbidities, pain intensity, fatigue, cognitive risk factors for persistent pain-related disability, depressive symptoms, post-traumatic stress symptoms, sensitivity to cold and mechanical hyperalgesia. Bivariate correlation analysis was performed for each variable. Variables were grouped by construct to form composite indices when determined appropriate. Individual variables or indices with a significant bivariate correlation with poorer function were entered into a multiple regression model. **Results:** Age, gender, and sensitivity to cold all demonstrated no significant association with SMFA-DI. Education (rho = -0.28), duration of pain (rho = 0.34), number of pain locations (rho = 0.25), number of medications (rho = 0.33), disease count (rho = 0.36), pain intensity (r =0.28), fatigue (rho=0.34), catastrophic thinking(r=0.52), fear of movement/re-injury(r=0.30), sense of perceived injustice(r=0.49), self-efficacy(r=-0.54), depressive symptoms(r=0.62), post-traumatic stress symptoms(r=0.42), and mechanical hyperalgesia (r=-0.37 to -0.28) all demonstrated a bivariate association reduced function. The final model included

depressive symptoms, number of medications, duration of symptoms and pressure pain threshold over the tibialis anterior (R-Squared = 0.63; F= 26.7, $p<0.01$). **Conclusions:** This study suggests depressive symptoms, number of medications, duration of symptoms, and mechanical hyperalgesia at a standardized location are associated with reduced function. Future research should aim at evaluating these factors longitudinally in a similar population of people with chronic pain and multiple comorbidities.

Background

Chronic diseases and mental health conditions are prevalent and people living with chronic conditions are frequent visitors to primary health care providers[1, 2]. Many of the people living with chronic diseases live with multiple chronic conditions such as diabetes, heart disease, depression, or hypertension. Chronic or recurrent pain is a common symptom experienced by people with multiple chronic conditions, having a reported prevalence of up to 67% of people with multimorbidity[3]. Chronic pain is one the of the most frequent reasons for seeking care from a health care provider[4, 5]. Both chronic pain[6, 7] and multimorbidity[8–10] are associated with reduced function. This complexity makes it difficult to understand what factors are associated with poorer function in a population of people with chronic pain and multiple comorbidities.

People with chronic pain frequently cite improvements in function as an important end-goal for health care[11]. The huge variance seen in people with chronic pain and multiple comorbidities make facilitating improvements in function challenging[12]. In particular, it may be challenging to target function due to a limited understanding of what factors contribute to reduced function in people with chronic pain and multiple comorbidities. Musculoskeletal, mental health, and cardiovascular conditions are all associated with reduced function and some are more closely associated with disability than others[13]. In addition, pain intensity[14], fatigue[15], catastrophic thinking[16, 17], fear of symptom exacerbation[18, 19], and low self-efficacy[20] may contribute to reduced function. A better understanding of the factors associated with reduced function in a population of people with complex chronic pain and multiple

comorbidities may help to inform treatment strategies aimed at improving function for these individuals.

One of the challenges in applying the existing literature on predictors of disability to primary health care practice is the populations being studied. Often the recruitment strategies or inclusion/exclusion criteria result in a population of people that does not represent the complexity seen in some primary health care settings. For example, much of the research takes place in tertiary care centers, include only single conditions such as low back pain or osteoarthritis, or exclude participants with comorbidities[21–23]. In many primary health care settings, people with chronic pain and multiple comorbidities are the most frequent users of healthcare[1, 2]. More research is needed to determine the factors associated with disability in this population.

Self-management programs have received support in the literature as a means of improving the ability of people with chronic pain to manage their own health[24–27]. Randomized controlled trials of self-management programs have shown these programs to be effective at improving knowledge and self-efficacy; but many self-management programs have not improved pain or function for people with chronic pain[26, 27]. Self-management programs may be able to target improvements in function more specifically if program developers understand the factors associated with reduced function in a population of people with complex chronic pain and multiple morbidities.

The objective of this cross-sectional study was to investigate the factors associated with poorer physical function and to identify those that explain significant

unique variance in functioning in a population of people with chronic pain referred for self-management support.

Materials and methods

Design

This study used a cross-sectional design to evaluate baseline data of the participants with chronic pain referred for self-management support.

Participants

102 participants with chronic were referred to a chronic pain self-management program from a member of the multidisciplinary team at Woodstock and Area Community Health Centre (WACHC) in Woodstock, Ontario, Canada. WACHC provides primary care, health promotion, and community development programs aimed at improving the health of priority populations. All participants met at least one of the criteria for the priority populations at WACHC: addiction concerns, mental health challenges, low income, lack of health insurance, and/or isolated seniors. The population referred had a high rate of comorbidities and social challenges.

Participants were included in the analyses if they were able to read, write, and speak English and experienced daily pain lasting for greater than 12 weeks. The pain could be consistent pain or pain with certain aggravating factors. Exclusion criteria were: cancer related pain, casted fracture or surgery within the last 26 weeks, evidence of upper motor neuron lesion, and medical "red flags" including unremitting night pain, palpable

tumor, sudden weight loss or weight gain, bowel or bladder incontinence, saddle anaesthesia, bilateral or multi-segmental loss of sensory or motor function, fever/chills, diplopia, dysphagia, dysarthria, drop attacks, or unexplained nystagmus.

Ethics Approval

All participants provided voluntary written informed consent with the treating physiotherapist and study investigator prior to the assessment. Ethics approval was provided by Hamilton Integrated Research Ethics Board.

Assessment methods

All measures were collected at WACHC at the initial assessment before participants started a program called, Chronic Pain Self-Management Support with Pain Science Education and Exercise. The demographic information and self-report measures were collected on printed forms and psychophysical tests were conducted with one of four trained research assistants.

Dependent variable

The dependent variable was function as measured by Short-Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)[28]. The SMFA-DI is a measure of function with higher scores representing poorer function. The SMFA-DI includes 34 questions. Twenty-five questions asked participants how much difficulty they were having with functional tasks on a scale of 1 (no at all difficult) to 5 (unable to do). Nine questions asked participants how often they were experiencing functional problems on a

scale of 1 (none of the time) to 5 (all of the time). The SMFA-DI score is out of 100 and calculated using the following formula: SMFA-DI = (sum of items 1 to 34 - 34) /136) * 100.

Independent variables

Demographic and clinical information: The following demographic and clinical characteristics were collected due to their potential association with poorer function: age, gender, education (<high school diploma, high school diploma, post-secondary degree or diploma), and duration of symptoms (months).

Self-report measures: The following self-report measures were collected as factors that may be associated with function. The construct measured by each of these measures, the range of the scale, and additional details on the measure are described in Table 1.

- Numeric Pain Rating Scale (NPRS)[29]
- Numeric Fatigue Rating Scale (NFRS)[30]
- Number of regions with pain
- Patient Health Questionnaire (PHQ-9)[31–33]
- Post-traumatic Stress Disorder Checklist (PTSD-C)[34, 35]
- Pain Catastrophizing Scale (PCS)[17, 36, 37]
- Tampa Scale of Kinesiophobia - 11 (TSK-11)[38]
- Injustice Experience Questionnaire (IEQ)[39]

- Pain Self Efficacy Questionnaire (PSEQ)[40–42]
- Disease count[43, 44]
- Number of medications[45]

Psychophysical measures: Two psychophysical measures were performed to test sensitivity to pressure and cold. These tests were performed at local (the point identified as "most tender") and standardized (the area of skin over the muscle belly of the upper fibres of trapezius and tibialis anterior) points.

*Pressure pain threshold***:** Pressure pain threshold (PPT) was measured using a handheld digital algometer calibrated using a known-weight technique (The Wagner FDX-25; Wagner Instruments, Greenwich, CT). The methods used have demonstrated high reliability [46, 47]. A trained research assistant pressed the algometer perpendicularly into the skin at an approximate rate of 50 kPa/s (5 N/s). The test was performed three times at each site and on each side of the body. The researcher read the following instructions prior to applying the pressure[48]: "I'm going to begin applying pressure to your skin. I want you to tell me the moment the sensation changes from comfortable pressure to slightly unpleasant pain." At the "most tender" point, the tender side was tested first, followed by the non-tender side. At the standardized locations, the right side was tested first, followed by the left.

*Cold hyperalgesia testing***:** A novel cold hyperalgesia was used to assess sensitivity to cold. The device used a Peltier Cooler, a pair of acrylic and copper cylinders. When the materials reached equilibrium (0º Celcius) and were applied to the skin, the heat transfer properties of each meant the acrylic 'felt' warmer than the copper. The two cylinders were applied to the skin to the three points on the body three times, bilaterally, in the same randomized order as the pressure pain threshold. The order of the two materials was also randomized using a block random number generator. The participant was asked to rate how cold the cylinder is on a 21 point scale (0 is unable to detect the temperature, 10 is cold but not painful, 11 is cold and slightly uncomfortable, and 20 is unbearable pain).

Data analyses

Analysis was conducted using Stata, version 13 (StataCorp, College Station, TX, USA). Descriptive statistics were presented for all variables. Spearman's rank correlation was calculated to estimate the correlation between each independent variable and SMFA-DI when data was categorical (gender, education) and for continuous data when assumptions for Pearson correlation were not met. Pearson r was calculated when all assumptions were met. Bivariate normality was assessed using the Doornik-Hansen test [49]. Scatterplots were visualized to assess for linearity and homoscedasticity.

Prior to performing a backwards elimination stepwise multiple regression analyses to determine the unique predictors of poorer function, independent variables were analyzed in the following groups based on the constructs being measured.

- Symptom measures: pain intensity (NPRS), number of regions with pain, fatigue (NFRS)
- Mental health measures: depressive symptoms (PHQ-9), post-traumatic stress symptoms (PCL)
- Cognitive risk factor measures: catastrophic thinking (PCS), fear of movement (TSK-11), sense of perceived injustice (IEQ), self-efficacy (PSEQ)
- Multiple morbidity measures: number of medications, disease count
- Psychophysical measures: PPT and sensitivity to cold over the tibialis anterior, upper fibres of trapezius, and most tender point.

The groups listed above were first analyzed independently to determine whether a single measure or composite index best predicted SMFA-DI scores. The aggregation of measures has been recommended as a way to reduce the risk of over-fitting a model when there are a large number of predictors and a relatively small sample size[50]. For each group listed above, all variables were entered into a multiple regression analysis. Unique contributors of SMFA-DI were retained, either individually or as a composite index, for the final regression analysis. When composite indices were created, measures were pooled with equal weighting. Pooled indices have demonstrated improved efficiency in clinical trials[51, 52] and could reduce the degrees of freedom for the multiple regression model. Equal weighting has been recommended when factors have equal perceived value based on theoretical grounds as well as when there is insufficient knowledge of causal relationships and a lack of consensus on alternative weighting options[53].

Next, a series of multiple regression analyses were performed using either the composite index or individual variable selected from each of the groups above. Age, gender, education (dummy coded), and duration of symptoms were entered into the model if they had a significant bivariate association with SMFA-DI. All variables were entered and removed individually if not contributing uniquely to the model as determined by a partial F with a statistical significance at the $p<0.05$ level. Standard checking of statistical assumptions (linearity, multivariate normality, no multicollinearity, no auto-correlation, homoscedasticity) were performed for all regression analyses.

The internal validity of the final derived model was assessed by performing a resampling validation using 400 bootstrap samples that repeatedly partitioned the data into training and test samples. Shrinkage was calculated by subtracting the mean R-squared from the test samples from the mean R-squared from the training samples and determining the percentage shrinkage from the original model. This was an important step to determine the stability of the model and the degree of over-fitting[54].

Results

The sample of 102 participants with chronic pain had a mean age of 52.8 years (Standard deviation, SD 12.6), a mean pain intensity of 7.4 on an 11-point NPRS (SD 1.8), pain at a median 7 out of 24 regions (IQR 3 to 13), and median of 3 chronic conditions (IQR 2 to 4). Descriptive statistics are provided for all variables in table 2. The number of each comorbidity are presented in table 3.

Bivariate correlation analysis

The results of the bivariate correlation analyses of each independent variable with poorer function (SMFA-DI) are presented in table 4. NFRS, number of regions with pain, number of medications, disease count, duration of pain, and all psychophysical tests did not meet the bivariate normality assumption for Pearson correlation using the Doornik-Hansen test [49]. These variables along with categorical variables (gender, education) were analyzed using Spearman's rank correlation. All other variables met the assumptions and were analyzed using a Pearson correlation. Age, gender, and all sensitivity to cold tests showed no correlation with SMFA-DI. All other variables showed a significant correlation with SMFA-DI. The most closely associated variables were depressive symptoms (r=0.62), self-efficacy (r=-0.53), and catastrophic thinking (r = 0.52).

Symptom measures

A multiple regression model including pain intensity (NPRS), number of regions with pain, and fatigue (NFRS) explained 15.9% of the variance in SMFA-DI ($F = 6.10$, $p<0.01$). All three variables uniquely contributed to the model, so a composite "symptom index" was created with all three components weighted equally. The formula used for this index was:

symptom index = (NPRS/10X100) + (NFRS/10X100) + (regions with pain/24X100)

A linear regression with symptom index as the only independent variable explained 15.7% of the variance in SMFA-DI ($F=6.1$, $p<0.01$). The symptom index was carried forward for the full multiple regression model.

Cognitive risk factor measures

A multiple regression model including catastrophic thinking (PCS), fear of movement (TSK-11), sense of perceived injustice (IEQ), and self-efficacy (PSEQ) explained 36.0% of the variance in SMFA-DI ($F=13.5$, $p<0.01$). Only PCS and PSEQ contributed uniquely to the model. When IEQ and TSK-11 were removed from the model, a model consisting of PCS and PSEQ explained 34.3% of the variance in SMFA-DI ($F=25.6$, $p<0.01$). A composite "cognitive factor index" was created weighting PCS and PSEQ equally:

Cognitive factor index = (PCS/52X100)-(PSEQ/60*100)

A linear regression model with the cognitive factor index as the only independent variable explained 34.1% of the variance in SMFA-DI ($F=51.2$, $p<0.01$).

Mental health measures

A multiple regression model including depressive symptoms (PHQ-9) and post-traumatic stress symptoms (PCL) explained 38.8% of the variance in SMFA-DI ($F=31.4$, $p<0.01$). Only PHQ-9 contributed uniquely to the model. When PCL was removed from the model, PHQ-9 explained 38.5% of the variance ($F=62.5$, $p<0.01$). Only the PHQ-9 was carried forward for the full multiple regression model.

Multiple morbidity measures

A multiple regression model including number of medications and disease count explained 16.4% of the variance in SMFA-DI ($F=8.74$, $p<0.01$). The number of medications was the only unique predictor within this model. When disease count was removed from the model, the number of medications explained 11.1% of the variance in SMFA-DI ($F=12.6$, $p<0.01$). Number of medications was carried forward to the full multiple regression model.

Psychophysical measures

Sensitivity to cold measures were not associated with function and therefore not entered into this multiple regression model. A multiple regression model including PPT over the tibialis anterior, upper fibres of trapezius, most tender point, and contralateral to the most tender point were entered into a regression model that explained 11.6% of the variance in SMFA-DI ($F=3.05$, $p=0.02$). Only PPT over the tibialis anterior contributed uniquely to the model. After all other variables were removed individually, a linear regression model with PPT over the tibialis anterior as the only independent variable explained 9.6% of the variance in SMFA-DI ($F=10.25$, $p<0.01$). PPT over the tibialis anterior was carried forward to the full multiple regression model.

Full multiple regression model:

Age and gender were not entered into the model as they did not demonstrate a bivariate association with SMFA-DI. Education (dummy coded) and duration of

symptoms were entered as potential predictors along with symptom index, cognitive factor index, PHQ-9, PPT over tibialis anterior, and number of medications. All variables were forced into the model and variables were removed individually if they did not contribute uniquely ($p<0.05$) to the model, a final model included: more depressive symptoms (PHQ-9), greater number of medications, greater cognitive factor index score (higher PCS and lower PSEQ), higher PPT over the tibialis anterior, and longer duration of symptoms. The model explained 63.1% of the variance in SMFA-DI ($F= 26.7$, $p<0.01$). See table 4 for regression results.

The final regression equation was:

SMFA-DI = 30.25 + 0.89(number of medications) + 0.82(PHQ-9) + 0.07(cognitive factor index) + 0.03(duration of symptoms) – 0.15(PPT over tibialis anterior)

Internal validation

The resampling validation using 400 bootstrap samples revealed a mean R-squared in the training samples of 0.66 and a mean R-squared in the test samples of 0.56. This represents a shrinkage of 14.7% from the model developed with the full sample.

Discussion

The results of this study suggest greater number of medications, greater depressive symptoms, longer duration of symptoms, cognitive factors associated with pain-related disability, and increased mechanical hyperalgesia at a standardized location are associated with poorer function in a population of people with chronic pain and multiple

morbidities. These factors explained approximately 63% of the variance in reduced function. Previous evidence is in agreement with the findings suggesting depressive symptoms[55–57], measures of comorbidity such as number of medications[13, 58], longer duration of symptoms[59], pain catastrophizing[16, 60], low self-efficacy[61, 62], and PPT[48] are associated with disability.

This study adds to the existing literature by investigating relationships between reduced function and a number of demographic, clinical, psychological, and psychophysical factors in a population of people with chronic pain and multiple comorbidities. The sample included in this study had a high prevalence of mental health concerns, addictions concerns, multiple morbidities, low income, and social isolation (see table 3). The burden of chronic pain is high in this population, but people multiple morbidities, mental health conditions, or social challenges are often excluded from pain research either directly by exclusion criteria or indirectly through recruitment strategies at health care facilities where there are known to be inequities in access to care[26, 27, 63].

There are a number of reasons to interpret these results with caution. First, the model demonstrates instability with internal validation (14.7% shrinkage). While there is no minimum standard for acceptable shrinkage with internal validation, external validation is needed to determine the generalizability of results. Interestingly, if the cognitive factor index is removed from this model, the R-squared is reduced to 0.60 with a shrinkage of 9.1% upon internal validation testing. If both pressure pain threshold and the cognitive factor index are removed from the model, the resulting model has an R-squared of 0.54 and a shrinkage of 7.9%. This may suggest that depressive symptoms,

number of medications and duration of symptoms are more stable and robust predictors of reduced function. While PPT and the cognitive factor index add explanatory power to the model, they may also contribute to the instability of the model. The implications of this are that if readers are looking for the most stable model from the factors in this study associated with reduced function, they should consider using a model including just depressive symptoms, number of medications, and duration of symptoms. If researchers are looking for candidate predictors for future research in a similar population, the cognitive factor index and mechanical sensitivity should be considered.

One of the most important limitations this study is its cross sectional design. Cross-sectional relationships need to be interpreted as association and not causal relationships. That is to say, depressive symptoms, number of medications, duration of symptoms, cognitive factors and mechanical hyperalgesia are associated with reduced function; however, we cannot infer from this study that these factors cause reduced function. Previous research has demonstrated that depressive symptoms, catastrophic thinking, low self-efficacy, and PPT can all be prognostic indicators for people with acute to chronic pain[48, 64–66]; however, prospective longitudinal research using structural equation modelling and path analysis is needed to determine causal relationships. By investigating factors associated with poorer function, this study provides specific candidate factors to be targeted in such research.

Another potential limitation of this research is the small sample size. This study involved analysis of the baseline data from a randomized controlled trial investigating the effects of a self-management program for people with chronic pain. Sample size

calculations were based on the randomized controlled trial and an a priori sample size calculation for candidate predictors of function was not performed for the purpose of this study. Recognizing sample size was small, the authors opted to create composite aggregate measures for groups of predictor variables based on theoretical grounds. After forming composite indices, 9 predictors were entered into the model. Power analysis suggested a required sample size of 114 for a model that could detect moderate effects (0.15) for each predictor with 9 potential predictors, a type 1 error rate of 0.05, a power of 0.80,, The sample size of 102, therefore, could result in a model that over-fits the data or a model that is underpowered to detect predictors with a small to moderate effect. Results should be replicated in a larger sample, but using a similar population to improve confidence in the results.

There were benefits and limitations to using the composite indices in this study. The benefit to using the composite measures was a reduction in degrees of freedom through reduction in the number of independent variables entered into the multiple regression model while maintaining representation of all of the constructs measured. As previously suggested, this can reduce the risk of over-fitting the regression model to the data (Babyak, 2004). The tradeoff of using a composite index is the loss of specific information about the measures included in the pooled index[52]. This means interpreting the relationship between the components of the composite index and function can be challenging as the amount of variation that can be attributed to each construct is not evident.

The results of this study have potentially important clinical and research implications. Improved functional outcomes are important to people living with pain[11]. In order to effectively target function with treatment, understanding the factors associated with reduced function is important. For example, recognizing that depressive symptoms are associated with poorer function in this population could help direct treatment and program development. Strategies aimed at improving depressive symptoms alongside function may not only facilitate improvements in depression, but may also provide an avenue for improving function. For example, exercise can direct positive effects on function[67], but may also improve depression[68] which provides a second potential avenue for improving function depending on the direction of the relationship between depression and function.

Similarly, understanding the prevalence of multiple comorbidities and the association between comorbidities and reduced function could influence program development. Self-management support aimed at improving function may benefit from integration of tailored self-management strategies for a variety of chronic conditions. Also, the association between duration of symptoms and reduced function may mean that people with chronic pain and multiple morbidities experience functional decline over time. This emphasizes the importance of finding effective treatments that reduce or eliminate functional decline to be implemented early after the onset of pain or disease.

Finally, the association between cognitive factors reduced function may help direct treatment and future research. Clinical practice and research targeting factors associated

with reduced function may lead to strategies to improve function as has been demonstrated with previous work[69, 70].

Conclusions

This study provides preliminary evidence that depressive symptoms, number of medications, duration of symptoms, cognitive factors associated with pain and disability, and mechanical hyperalgesia are associated with reduced function in a group of people with chronic pain and multiple morbidities in a primary health care setting. Future research should focus on evaluating these factors longitudinally and externally validating the model developed.

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Conflict of Interest Statement

The authors disclose that there are no conflicts of interest.

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Table 1: Self-reported measures

Construct	Measure	Items	Scale range	Instructions and scale details
Symptom measures				
Pain Intensity	Numeric Pain Rating Scale (NPRS)	1	0-10	Please rate the intensity of your pain on average over the past 2-weeks from 0 (no pain at all) to 10 (most intense pain imaginable)
Pain locations	Number of body regions with pain	1	0-24	Please check each of the following areas in which you are experiencing pain: head, neck, low back, mid/upper back, and left and right: shoulder, arm, elbow, wrist, hand, hip, leg, knee, ankle, foot.
Fatigue	Numeric Fatigue Rating Scale (NFRS)	1	0-10	Please rate your fatigue on average over the past 2-weeks from 0 (no fatigue at all) to 10 (worst imaginable fatigue)
Cognitive factor measures				
Catastrophic thinking	Pain Catastrophizing Scale (PCS)	13	0-52	Indicate the degree to which you experience each of these thoughts or feelings when experiencing pain on a scale of 0 (not at all) to 4 (all the time). The scale items capture the participants tendency ruminate about their pain, magnify their pain, or feel helpless in managing their pain.
Fear of movement/re-injury	11-item Tampa Scale of Kinesiophobia (TSK-11)	11	11-44	Rate your agreement with each of the following items on a 4-point Likert scale of 1 (strongly disagree) to 4 (strongly agree). The TSK-11 is a shortened (11-item) version of the 17-item Tampa Scale of Kinesiophobia identifying fear of movement/re-injury.
Sense of perceived injustice	Injustice Experience Questionnaire (IEQ)	12	0-48	Please indicate how frequently you experience the following thoughts or feelings when you think about your pain. Each item is rated on a scale from 0 (never) to 4 (all the time).
Self efficacy	Pain Self Efficacy Questionnaire (PSEQ)	10	0-60	Please rate how confident you are that you can do the following things at present, despite the pain. Each item is answered on a scale of 0 (not at all confident) to 6 (completely confident). The items cover household, self-care, social, recreational, and vocational activities as well as the ability to cope without medication.
Mental health measures				
Depressive symptoms	Patient Health Questionnaire - 9 (PHQ-9)	9	0-27	Over the past 2 weeks, how often have you been bothered by the following problems? Each item is rated on a scale of 0 (not at all) to 3 (nearly every day). The PHQ-9 is based on the DSM-IV criteria for depression.
Post-traumatic stress symptoms	Post-traumatic Stress Disorder Checklist –Civilian Version (PCL)	17	17-85	Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please indicate how much you have been bothered by that problem in the last month. Each item is rated on a scale of 1 (not at all) to 5 (extremely). The PCL is based on the DSM-IV criteria for PTSD.
Comorbidity measures				

Medications	Number of medications		0-	Please record all medications you are taking. This measure is a simple count of the number of medications a participant is taking and has been used as a proxy measure for number of comorbidities[29].
Comorbidities	Disease count	1	0-30	Unweighted disease count was used as a measure of the number of morbidities. The list of 30 items used for this disease count were originally suggested by Elixhauser[19]. They included: congestive heart failure, cardiac arrhythmias, valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hyptertension, paralysis, other neurological disorders, chronic obstructive pulmonary disease, diabetes, hypothyroidism, renal failure, liver disease, peptic ulcer disease, HIV or AIDS, lymphoma, metastatic cancer, solid tumor wihtout metastasis, arthritis, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, blood loss anemia, deficiency anemias, alcohol abuse, drug abuse, psychoses, depression.

Table 2: Descriptive statistics

	Mean (SD)	Median (IQR)	N(%)
Age	52.8(12.6)		
Gender			
Male			27 (26.5)
Female			75 (73.5)
Education			
Less than high school education			24 (23.5)
High school diploma			51 (50.0)
College or University diploma or degree			27 (26.5)
Duration of pain		120 (48-204)	
Number of regions with pain		7 (3-13)	
Number of medications		5 (3-8)	
Comorbidities (disease count)		3 (2-4)	
Function (SMFA-DI)	44.3 (14.5)		
Pain intensity (NPRS)	7.4 (1.8)		
Fatigue (NFRS)	6.9(7.1)		
Catastrophic thinking (PCS)	28.0(13.9)		
Fear of movement/re-injury(TSK)	28.6(9.7)		
Sense of perceived injustice (IEQ)	26.4(12.8)		
Self-efficacy (PSEQ)	29.7(13.9)		
Depressive symptoms (PHQ-9)	13.3(7.4)		
Post-traumatic stress symptoms (PCL)	44.3(17.4)		
Pressure pain threshold over tibialis anterior		33.6(22.7-47.3)	
Pressure pain threshold over upper fibres of trapezius		21.7(12.6-30.1)	
Pressure pain threshold over most tender point		18.7(11.3-26.6)	
Pressure pain threshold over contralateral side to most tender point		19.3(12.6-31.6)	
Cold sensitivity over tibialis anterior			
Material 1		4.8(2.7-7.7)	
Material 2		4.7(2.7-8.3)	
Cold sensitivity over upper fibres of trapezius			
Material 1		5.4(3.5-9.1)	
Material 2		5.4(3.2-10.0)	
Cold sensitivity over most tender point			
Material 1		5.7(3.3-10.3)	
Material 2		5.3(3-10.7)	
Cold sensitivity over contralateral side to most tender point		5.7(3.3-9.7)	
Material 1		4.8(3.3-9.3)	
Material 2			

Table 3: Frequency of comorbidities (n=96)

Comorbidity	Number of participants (%)
Congestive heart failure	5 (5.3)
Cardiac arrhythmias	7 (7.5)
Valvular disease	0 (0)
Pulmonary circulation disorder	2 (2.1)
Peripheral vascular disorders	6 (6.4)
Hypertension	37 (39.4)
Paralysis	2 (2.1)
Other neurological disorder	12 (12.8)
Chronic obstructive pulmonary disease or asthma	23 (24.5)
Diabetes	27 (28.7)
Hypothyroidism	11 (11.7)
Renal disease, insufficiency, or failure	5 (5.3)
Liver disease	3 (3.2)
Peptic ulcer disease	3 (3.2)
HIV or AIDS	1 (1.1)
Lymphoma	0 (0)
Metastatic cancer	4 (4.3)
Solid tumour without metastisis	4 (4.3)
Rheumatoid arthritis	7 (7.5)
Coagulopathy	1 (1.1)
obesity	15 (16.0)
Weight loss	0 (0)
Fluid and electrolyte disorders	0 (0)
Blood loss anemia	1 (1.1)
Deficiency anemias	13 (13.8)
Alcohol abuse	10 (10.6)
Drug abuse	10 (10.6)
Psychoses	8 (8.5)
Depression	58 (61.7)

Table 4: Correlation of independent variables with poorer function (SMFA-DI)

	Pearson correlation coefficient		**Spearman correlation coefficient**	
	Pearson r	**p-value**	**Spearman rho**	**p-value**
Age	-0.05	0.61		
Gender (male)			0.0215	0.8301
Education Less than high school education High school diploma College or University diploma or degree			-0.2852	<0.01
Duration of pain			0.34	<0.01
Areas of pain			0.25	<0.01
Number of medications			0.33	<0.01
Disease count			0.36	<0.01
Pain intensity (NPRS)	0.28	<0.01		
Fatigue (NFRS)			0.34	<0.01
Catastrophic thinking (PCS)	0.52	<0.01		
Fear of movement/re-injury(TSK)	0.30	<0.01		
Sense of perceived injustice (IEQ)	0.49	<0.01		
Self-efficacy (PSEQ)	-0.54	<0.01		
Depressive symptoms (PHQ-9)	0.62	<0.01		
Post-traumatic stress symptoms (PCL)	0.42	<0.01		
Pressure pain threshold over tibialis anterior			-0.37	<0.01
Pressure pain threshold over upper fibres of trapezius			-0.28	<0.01
Pressure pain threshold over most tender point			-0.34	<0.01
Pressure pain threshold over contralateral side to most tender point			-0.28	<0.01
Cold sensitivity over tibialis anterior Material 1 Material 2			 0.12 0.10	 0.24 0.35
Cold sensitivity over upper fibres of trapezius Material 1 Material 2			 0.02 0.04	 0.86 0.66
Cold sensitivity over most tender point Material 1 Material 2			 0.14 0.16	 0.15 0.11
Cold sensitivity over contralateral side to most tender point Material 1 Material 2			 0.08 0.12	 0.41 0.23

Table 5 – Regression results: predictors of poorer function (SMFA-DI)

Variable	Beta value	95% Confidence interval	t (p-value)	Partial R-squared	Semipartial R-squared
Number of medications	**0.89**	**0.38 to 1.39**	**3.51 (p<0.01)**	**0.15**	**0.07**
Depressive symptoms (PHQ-9)	**0.82**	**0.44 to 1.19**	**4.35 (p<0.01)**	**0.16**	**0.07**
Cognitive factor index	**0.07**	**0.01 to 0.12**	**2.29 (p=0.03)**	**0.08**	**0.03**
Pressure pain threshold over tibialis anterior	**-0.15**	**-0.25 to -0.05**	**-2.98 (p<0.01)**	**0.06**	**0.03**
Duration	**0.26**	**0.01 to 0.04**	**3.47 (p<0.01)**	**0.14**	**0.06**
Constant	**30.25**	**23.5 to 37.0**	**8.93 (p<0.01)**		

Model: F(5,78)=26.65, p<0.01; R-squared = 0.63, adjusted R-squared 0.61

CHAPTER 3: PHYSICAL THERAPIST LED CHRONIC PAIN SELF-MANAGEMENT SUPPORT WITH PAIN SCIENCE EDUCATION AND EXERCISE IN PRIMARY HEALTH CARE: A CASE SERIES

TITLE

Physical therapist led chronic pain self-management support with pain science education and exercise in primary health care: A case series

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Abstract

Previous evidence suggests self-management programs for people with chronic pain have improved knowledge and self-efficacy, but have often not improved function. The purpose of this case series was to describe a new self-management program aimed at improving function and to describe the response of participants to this intervention. Six participants who had been experiencing chronic pain for at least five years were included. All participants were enrolled in six weeks of ChrOnic pain self-ManageMent support with pain science EducatioN and exercise (COMMENCE). Participants completed an assessment at 0 weeks, 7 weeks (1-week follow-up), and 18 weeks (12-week follow-up). The primary outcome was function measured by the Short Musculoskeletal Function Assessment – Dysfunction Index. Secondary outcomes included how much patients are bothered by functional difficulties measured by the Short Musculoskeletal Function Assessment - Bother Index, pain intensity measured by a numeric pain rating scale, fatigue measured by a numeric fatigue rating scale, pain interference measured by the PROMIS Pain Interference short-form 8a, cognitive factors associated with pain measured by the Pain Catastrophizing Scale, 11-item Tampa Scale of Kinesiophobia, Injustice Experience Questionnaire, Revised Neurophysiology of Pain Questionnaire, self-efficacy measured by the Pain Self-Efficacy Questionnaire, depressive symptoms measured by the Patient Health Questionnaire – 9, and post-traumatic stress measured by the Post Traumatic Stress Disorder Checklist – Civilian Version. Participants were all satisfied with treatment received. Change in function ranged from 41.9% improvement to 11.5% decline. Two potential explanations for variances in response, attendance and

social context, are discussed. Several challenges were identified by participants as barriers to attendance that should be considered by physical therapists in primary health care settings.

Background

Primary health care often includes a diverse team of health-care providers and services working towards the ultimate goal of "better health for all."[1] The role of physical therapists in primary health care is gaining attention in recent years[2–6]; however, physical therapy in primary health care has a history dating back to the 1970s when physical therapists adopted primary care roles in the United States Army[7]. Since that time, numerous studies have provided evidence that physical therapists can provide quality, cost-effective primary care[3,8–11].

Chronic conditions are among the most common reasons for a visit to a primary health care provider and chronic pain and musculoskeletal conditions, specifically, are among the most significant contributors to years lived with disability[12]. The prevalence of these conditions is expected to rise with an aging population. Self-management support has received global attention as a potential response to the rise in chronic conditions in primary health care[13]. Evidence on the effectiveness of self-management programs for people experiencing chronic pain is limited. Most research investigating the effects of self-management on pain and disability has included people with either arthritis or low back pain. There is a dearth of literature including more diverse populations of people with chronic pain[14]. The available evidence suggests self-management support results in increases in knowledge and self-efficacy, but small or negligible effects on pain and function[14–16].

Physical therapist involvement in the development and delivery of self-management programming appears to be growing[17]. Given the important role physical

therapists can play in improving function[18], involving physical therapists in self-management programs provides an opportunity to improve functional outcomes. Three treatment approaches within the scope of physical therapy practice that contribute to improvements in function are: pain neurophysiology education[19–21], applying cognitive behavioural principles[22,23], and individualized, goal-oriented exercises[24–27]. Despite evidence of improved function with these approaches, they have not been consistently incorporated into self-management programs.

Case studies aim to "investigate contemporary phenomena within its real-life context."[28] They allow for an in depth description of new health care interventions while considering the context in which the interventions are delivered. Also, describing multiple case studies together allows for exploration of differences and similarities between cases[29]. The purpose and nature of the comparisons between cases is a fundamental element of multiple case studies and should be set when selecting cases and constructing the study design.

The purpose of this case series was to describe a new physical therapist-led chronic pain self-management program and individual responses to the intervention. The cases were selected to demonstrate a range of effects sizes (low versus high effect exemplars) and to highlight barriers and facilitators to participation to improve understanding variations in treatment adherence and fidelity of self-management programming. The intervention described and evaluated in this study was ChrOnic pain self-ManageMent support with pain science EducatioN and exerCisE (COMMENCE). The innovative aspects of COMMENCE were incorporating pain neurophysiology

education, cognitive-behavioural principles, and individualized, goal-oriented exercise within a self-management program that was delivered in a primary health care setting targeting a marginalized population of people with barriers to accessing healthcare.

Case descriptions

This case series included six participants recruited at Woodstock and Area Community Health Centre (WACHC) in Ontario, Canada. All participants were referred by a health care provider at WACHC. WACHC provides care to priority populations with barriers to accessing healthcare, including people with: addictions concerns, mental health challenges, low income, lack of health insurance, and isolated seniors. Importantly, this sample represents a population of people with chronic pain and multiple morbidities often excluded from treatment and research by barriers to accessing health care.

Included participants were adults who had been experiencing non-cancer related pain for at least 5 years. They did not meet any of the exclusion criteria: cancer related pain, medical "red flags" suggestive of a non-neuromusculoskeletal etiology of symptoms, casted fracture within the last 12 weeks, surgery within the last 26 weeks, and evidence of upper motor neuron lesion.

The six participants were selected based on their varied adherence and responses to the intervention. The participants selected can be visualized as three pairs: Participants 1 and 2 completed 9/12 visits and experienced minimal changes at 12-week follow-up. Participants 3 and 4 experienced barriers to accessing the self-management program and discontinued participation after two or fewer visits. Participants 5 and 6 completed at

least 10/12 visits and experienced several clinically meaningful improvements at 12-week follow-up.

All participants provided informed consent prior to participation. Ethics approval was obtained from Hamilton Integrated Research Ethics Board.

Examination

Participants completed assessments at baseline, 1-week after completion of the 6-week intervention, and 12-weeks after the end of the intervention. Demographic and clinical information was collected at baseline. Self-reported outcome measures were completed at all time-points. Additionally, participants underwent a thorough examination including screening for red-flags, neurological assessment, strength testing, range of motion assessment, and functional movement assessment.

Demographic and clinical information: The following information was collected at baseline: age, sex, length of time since symptom onset, diagnosis provided by a medical professional as reported by the patient, medication use, and comorbidities.

Self-report measures: The primary outcome was function as measured by the Short-Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)[30]. Secondary outcomes included: Short Musculoskeletal Function Assessment – Bother Index (SMFA-BI)[30], Numeric Pain Rating Scale (NPRS)[31], Numeric Fatigue Rating Scale (NFRS)[32], PROMIS Pain Interference Item Bank - 8 items[33], Pain Catastrophizing Scale (PCS)[34–36],

Tampa Scale of Kinesiophobia - 11 (TSK-11)[37], Injustice Experience Questionnaire (IEQ)[38], Neurophysiology of Pain Questionnaire (NPQ)[39], Pain Self Efficacy Questionnaire (PSEQ)[40–42], Patient Health Questionnaire – 9 (PHQ-9)[43–45], Post-traumatic Stress Disorder Checklist – civilian version (PTSD-C)[46,47], global perceived effect, patient satisfaction, and patient expectations for recovery. Expectations for recovery were assessed with two questions: i) Do you think your pain will improve? ii) Do you think your functional abilities will improve? Table 1 shows the construct measured by each outcome measure, the range of each scale, and the minimum change considered clinically important for each measure.

Adverse events or harms: The physical therapist asked participants at each individual visit about adverse events associated with the intervention.

Intervention

ChrOnic pain self-ManageMent with pain science EducatioN and exerCisE (COMMENCE) was a six week program that included two sessions per week with a physical therapist. The first session each week was in a group setting. This session included education on pain science, cognitive-behavioural approaches, and self-management strategies. The second session was an individualized, one-to-one session including support for implementing self-management strategies and development of an individualized, goal-oriented exercise program. Appendix 1 describes the weekly

objectives and Appendix 2 provides a rationale for each of the included treatment strategies.

***Group pain science and self-management education*:** Group sessions were interactive 1.5 hour sessions with 3-6 people once per week for 6 weeks. The participants received pain science education about the function of the nervous system, changes in multiple body systems when pain persists, neuroplasticity, the relationship between physical activity and pain, and the influences of stress, thoughts and emotions on pain. Self-management strategies focused on applying the information learned with the goal of increasing activity levels and participation in life role activities while controlling symptoms. Participants were given a workbook that they brought to each appointment to track participation and allow problem solving to overcome any potential barriers to implementation.

***Individualized self-management and exercise*:** The 30-45 minute individualized sessions varied between individuals and were delivered once per week for six weeks. The individual sessions allowed for discussion about personal implementation plans for self-management strategies learned in the group session. Also, the physical therapist worked with the patient to develop an individualized exercise program aimed at working towards patient-specific goals. The tailoring of exercises involved a series of questions that the physical therapist asked the participant. First, the physical therapist asked the participant to explore movements of the painful area of the body that did not increase pain. The

participant was encouraged to perform 6-8 repetitions of these movements, frequently throughout the day. Second, participants were asked to consider barriers and facilitators to the function and participation goals they set at the beginning of the program. The therapist and participant then work together to develop an exercise program to help the participant enhance facilitators and minimize physical and cognitive barriers to participation through graded physical activity and exercise. Finally, the dosage was individualized by asking the participant to determine an amount of the exercise or activity that does not result in an increase in pain 30-60 minutes after finishing the exercise.

Outcomes

Each of the six participants presented with long lasting pain in varied body locations. Table 2 presents the demographic characteristics of each participant at baseline.

In order to help visualize the varied outcomes, the six participants will be referenced as three pairs. The first pair (participant 1 and 2) will be referred to as the "high attendance, little change" pair. They both attended 9/12 scheduled sessions (75%). The second pair (participant 3 and 4) both experienced barriers to participating in the program and will be referred to as the "low attendance" pair. Participant 3 attended 2/12 sessions (17%) and participant 4 attended 1/12 sessions (8%). The third pair (participant 5 and 6) will be referred to as the "high attendance, positive change" group. Participant 5 attended 11/12 sessions (92%) and participant 6 attended 10/12 sessions (83%).

Missed sessions for participants 1, 2, 5, and 6 were due to illness (4), specialist medical appointments (2), forgotten appointments (1), and anxiety interfering with

leaving the house (2). Participant 3 experienced an exacerbation of depression and was admitted to hospital for suicidal ideations after two sessions. Participant 4 attended one session before a change in job that resulted in extended hours of work and the decision to discontinue participation.

The participants demonstrated variable changes in the primary outcome, function, throughout the follow-up period as measured by the SMFA-DI (see Figure 1). At the 1-week follow-up, one of the two "high attendance, little change" pair, one of the two "low attendance" pair and one of the two "high attendance, positive change" pair experienced meaningful improvements in function. The remaining 3 participants experienced no clinically meaningful change. At the 12-week follow-up, one of the two "high attendance, little change" pair experienced no change and the other had a small decline in function. Both participants in the "low attendance" pair experienced a decline in function, and both of the participants in the "high attendance, positive change" pair experienced an improvement in function.

The outcomes for each of the primary and secondary measures are presented in Table 3. At 12-week follow-up, Participant 1 experienced improvement in fatigue and fear of movement/re-injury, but increased pain. Participant 2 had improved scores on fatigue, depressive symptoms, and self-efficacy; however, she scored worse on measures of pain and function. Participant 3 reported improvement in fear of movement/re-injury and a long-term worsening of function. Participant 4's scores on fear of movement/re-injury and sense of perceived injustice improved, while function had worsened from

baseline. Participant 5 and 6 both demonstrated clinically meaningful changes in all outcomes except fear of movement/re-injury for participant 5.

Two participants (1 and 2) reported transient (<72 hours) increases with pain after exercise or increases in activity with at least one session. Otherwise, there were no adverse events or side-effects reported.

Discussion

People with chronic pain frequently suggest improved function is an important goal for treatment[48]. Also, reducing the financial burden of chronic pain requires improved ability to reduce disability[49–51]. Self-management support for chronic pain is an opportunity to facilitate improvements in function and participation for people living with chronic pain[52]. This case series described the response of six individuals to chronic pain self-management support with pain science education and exercise (COMMENCE). While the case series design does not allow comment on the effectiveness or efficacy of the intervention, it provides an opportunity to provide details on the COMMENCE intervention that is currently being evaluated in a randomized controlled trial (ClinicalTrials.gov, NCT02422459). It also provides an opportunity to discuss several observations from this case series: the opportunity for physical therapists to improve self-management programs by targeting function, the large variance in response to self-management programs, and the multiple complex barriers to attendance that many people with chronic pain experience.

There has been discussion by self-management facilitators and researchers regarding peer-led versus professional led self-management programs[53,54]. Qualitative evidence suggests that while participants in self-management programs view health care professionals as more knowledgeable, they do not necessarily view health care professional led programs as more valuable[54]. Also, it has been suggested that peer-led programs may help to build greater capacity for self-management support[53]. COMMENCE contains three treatment strategies that may not be delivered effectively by lay-persons: pain science education, cognitive behavioural principles, and individualized, goal-oriented exercises. A hypothesis which drove the development of COMMENCE was that physical therapists are better positioned to implement these self-management approaches given their expertise in facilitating functional improvements in people with disabilities. A recent scoping review[17] identified seven previous studies that involved a physical therapist in self-management support for chronic pain suggesting others may share this perceived value. Future research is likely to provide important evidence on differences between self-management support and functional interventions provided by health care providers versus lay-persons. A randomized controlled trial by Coleman and colleagues is currently underway comparing these two different delivery methods for self-management support[55].

One potential advantage of using a case series to describe new interventions is the ability to visualize and analyze individual patient trajectories. In this case series, a large variance in individual responses is evident. The means of these six participants might suggest a 10% improvement in function at 1-week follow-up and a 5% improvement in

function at 12-week follow-up. However, it is clear from the individual trajectories of each patient that two individuals experienced improved function throughout the study, while others experienced no change or a small decline. Changes in function ranged from a 9 point (7.5%) decline in function to a 51 point (43.6%) improvement at 1-week follow up. At 12-week follow-up, changes in function ranged from a 12 point (11.5%) decline in function to a 49 point (41.9%) improvement. Similar variances in response were demonstrated with other outcomes (see Table 3). Importantly, the variance may represent differences in response to the treatment or fluctuations in self-reported function over time in this population of people with complex pain. Future research with a control group may provide valuable information regarding whether this variance is related to the intervention itself or the population being studied.

One potential reason for the variance in response to the program is differences in treatment attendance. At 12-week follow-up, the two participants who attended less than 3/12 (25%) visits experienced a clinically meaningful decline in function. Of the two participants that attended 9/12 (75%) of visits, one experienced no change and the other a small decline in function. The two participants who attended at least 10/12 (83%) of visits both experienced clinically meaningful improvement. The variance in functional change could represent a dose-response relationship with COMMENCE. Alternatively, certain factors that make people more likely to attend could also make people more likely to experience improvements in function. A sensitivity analysis within a randomized controlled trial evaluating the effectiveness of COMMENCE that compares those that

complete the treatment program with those that do not complete treatment will investigate the relationship between attendance and outcomes with greater rigour.

Another potential explanation for the variance in response is differences in social contexts. The potential influence of social contexts can be seen by comparing the social contexts of the "high attendance, little change" pair (participant 1 and 2) with the "high attendance, positive change" pair (participant 5 and 6). Participant 1 and 2 both suggested their social contexts negatively influenced their self-management. Participant 1 reported challenges carrying out self-management skills and focusing on his own recovery because he was a committed caregiver for his partner. He suggested the stress of his caregiver responsibilities contributed to his pain and that it was difficult to focus on new self-management strategies given other responsibilities. His outcome measures suggest short-term improvement, but no change at 12-week follow-up. One possible explanation is that scheduled appointments allowed him to dedicate time to increases in physical activity and self-management, but it was difficult to prioritize these behaviors after the end of the program. It is worth noting the concordance of this finding with evidence suggesting a high prevalence of chronic pain in caregivers[56].

Participant 2 had a long history of chronic pain, anxiety, depression, and post-traumatic stress disorder. She reported that group settings and certain social situations exacerbate her anxiety and post-traumatic stress and she cancelled two visits for this reason and rescheduled two others. Similarly, she reported having a very small social network due to her social anxieties. This context could relate to her chronic pain and

pain-related disability as people with post-traumatic stress[57] and low levels of social support[58] are more likely to experience chronic pain and pain-related disability.

In contrast, participants 5 and 6 reported social supports contributed to their success with increasing functional abilities and participation in important life roles. Participant 5 lived with three brothers who were supportive of his increases in physical activity. Also, he reported taking on additional roles around his home throughout the program, which provided a sense of accomplishment. Similarly, participant 6 reported being surrounded by supportive family and friends, which contributed to her changes in function. She suggested her goals of being able to take her grandchildren to the park and coach one of her grandchildren in soccer positively influenced her participation and perseverance throughout the program. Also, she suggested that increasing her abilities allowed her to volunteer at her church, which was an important source of positive re-enforcement for the changes she was making.

The influences of social contexts and attendance on response to self-management programs are not mutually exclusive. This can be seen with the "low attendance" pair (participants 3 and 4). Participant 3 had high levels of chronic pain and depression. While her scores on depression were very high at the start of the study, she did not report any suicidal ideations. After just 2 visits she separated with her husband. At this point, her depression worsened and she had suicidal ideations with a plan to carry out those ideations. At this time, she was referred to emergency psychiatric care at a local hospital. Her worsening pain and disability at this time was very likely influenced by her depression[59,60]. Also, her hospitalization interfered with participation in COMMENCE,

which reduced the change that the program influenced her outcomes. Participant 4 worked modified hours and duties in a produce department in a grocery store at the initial assessment. After just 1 visit, he took a new job as a produce manager at a different store. This transition allowed him to return to full hours, so he did not feel comfortable devoting time to a 6-week treatment program during a transition to a new employer. His reduction in function throughout the treatment period could be due to the inability to participate or due to increased stress secondary to the responsibilities of his new job.

A key theme from this case series is that people with complex chronic pain experienced challenges with attendance. Missed appointments or discontinued treatment occurred due to mental health concerns, change in work status, illness, or conflicting health care appointments. Low attendance poses challenges for clinical practice as low adherence has been shown to predict poorer outcomes in self-management programming[61]. Challenges with attendance were anticipated. Multiple morbidities are common in people with chronic pain and people with multiple morbidities frequently report difficulty with self-management and access to health care[62,63]. This case series identified attendance and adherence as an important challenge for clinicians who work with people experiencing pain. Clinicians working with these populations need to be prepared to help participants problem solve to overcome barriers to attendance and to reschedule frequently to allow adequate treatment fidelity.

Low attendance also makes it challenging for researchers to achieve acceptable retention rates in chronic pain research. Chronic pain is an important burden in a marginalized population of people with multiple morbidities, poverty, mental health

concerns, or social isolation. Yet, this population is often under-represented in chronic pain research. This may be due to recruitment strategies involving health care facilities where there are often inequities in access[64]. Pain research in these marginalized populations is important to ensure generalizability of results; however, the low attendance in this case series helps identify a potential challenge in expanding pain research into these populations.

Conclusion

This case series demonstrated an example of how physical therapists can target function in primary health care by enhancing self-management programming with the addition of pain science education, cognitive behavioural principals, and individualized, goal-oriented exercise. The varied responses of participants and barriers to participation evident from these cases are important considerations for physical therapists working in primary health care settings and may indicate that certain subtypes of this population are more likely to respond to this type of self-management program.

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Table 1: Description of outcome measures and potential predictors of treatment response

Construct	Outcome Measure	Scale range	Minimal important difference
Function	**Short Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)**	**34-170**	**10 points***
How much participants are bothered by difficulty with functional activities	Short Musculoskeletal Function Assessment – Bother Index (SMFA-BI)	12-60	5.5 points*
Pain Intensity	Numeric Pain Rating Scale (NPRS)	0-10	2 points[65]
Fatigue	Numeric Fatigue Rating Scale (NFRS)	0-10	1.4 points[66]
Pain Interference	PROMIS Pain Interference Item Bank - 8 items	8-40	5 points*
Catastrophic thinking	Pain Catastrophizing Scale (PCS)	0-52	38% of scale[35]
Fear of symptom exacerbation	11-item Tampa Scale of Kinesiophobia (TSK-11)	11-44	5.6 points[67]
Sense of perceived injustice	Injustice Experience Questionnaire (IEQ)	0-48	7 points*
Pain neurophysiology knowledge	Neurophysiology of pain test (NPT)	0-13	1.1 points*
Self efficacy	Pain Self Efficacy Questionnaire (PSEQ)	0-60	11 points[68]
Depressive symptoms	Patient Health Questionnaire - 9 (PHQ-9)	0-27	5 points[44]
Post-traumatic stress symptoms	Post-traumatic Stress Disorder Checklist –Civilian Version (PCL)	17-85	8.5 points*

Legend: * In the absence of an established MCID or MDC, this case series considered half a standard deviation as a minimally important difference[69]. In these instances, clinical data from Woodstock and Area Community Health Centre was used to establish the standard deviation.

Table 2: Baseline demographic information

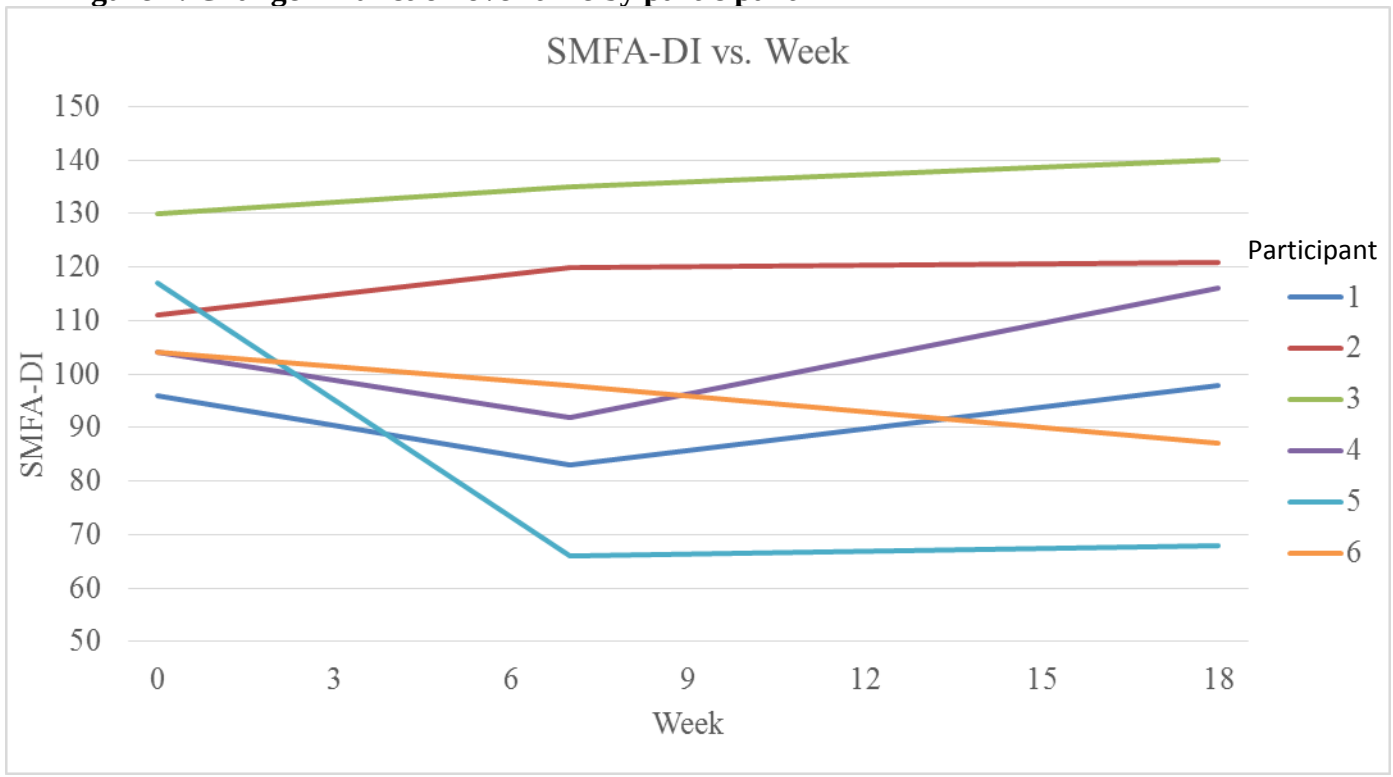
Pair	**High attendance, little change**		**Low attendance**		**High attendance, positive change**	
Participant	**1**	**2**	**3**	**4**	**5**	**6**
Age	48	36	47	51	49	45
Sex	Male	Female	Female	Male	Male	Female
Education	High school diploma	High school diploma	High school diploma	High school diploma	Less than high school diploma	Less than high school diploma
Duration of pain	5 years	12 years	20 years	5 years	31 years	28 years
Area of pain	Primary concern: left hip Secondary concerns: neck, right knee	Primary concern: widespread pain including - headaches, bilateral shoulders, wrists, lower back and legs	Primary concern: low back with referral into legs Secondary concern: upper back and neck	Primary concern: left shoulder, arm, wrist, and hand Secondary concern: headaches, right shoulder, arm, and hand	Primary concern: low back with referral into legs Secondary concerns: headaches, neck, bilateral shoulder, arm, hand, foot, and ankle	Primary concern: bilateral shoulders Secondary concerns, left elbow, wrist, and hand, lower back, bilateral hips and knees
Diagnosis reported by participant	Osteoarthritis	Fibromyalgia	Disc herniation	Fibromyalgia, Complex Regional Pain Syndrome	No diagnosis	Fibromyalgia, Osteoarthritis
Medications	Acetaminophen, Gabapentin, Oxycodone, Percocet,	Celexa, Gabapentin, Lorazapam, Methadone, Olanzapine	Bisoprolol, Carbamazepine, Celecoxib, Clonazepam, Domperidone, Gabapentin, Mirtazapine, Tolterodine, Venlafaxine	Bisoprolol, Crestor, Cymbalta, Diclofenac, Hydromorphone, Plavix, Rabeprazole,	None	Celebrex, Cymbalta, Duvoid, Hydrochlorothiazide, Propranolol, Quetiapine
Comorbidities	None	Anxiety, Depression, Post-traumatic Stress Disorder	Anxiety, Depression, Hypertension Urinary incontinence	Depression, Hypertension, Gastric reflux	None	Depression Diabetes Hypertension

Table 3: Summary of outcomes

Pair	**High attendance, little change**						**Low attendance**						**High attendance, positive change**					
Participant	**1**			**2**			**3**			**4**			**5**			**6**		
Assessment time-point (week)	**0**	**7**	**18**	**0**	**7**	**18**	**0**	**7**	**18**	**0**	**7**	**18**	**0**	**7**	**18**	**0**	**7**	**18**
SMFA-DI (34-136)	96	83*	98	111	120	121#	130	135	144#	104	92*	116#	117	66*	68*	104	98	87*
SMFA-BI (12-48)	34	28*	20*	48	38*	48	54	56	58	32	24*	31	33	8*	12*	27	22*	20*
NPRS (0-10)	8	9	10#	7	8	10#	9	10	9	7	7	8	9	2*	4*	8	5*	3*
NFRS (0-10)	7	5*	5*	9	7*	7*	9	10	8	8	7	7	8	3*	5*	9	7*	6*
PHQ-9 (0-27)	20	20	23	21	18	11*	26	24	23	13	10	13	20	2*	8*	22	13*	8*
PI (8-40)	40	32*	40	36	31*	32	36	38	35	32	19*	30	24	12*	17*	31	19*	12*
PCS (0-52)	43	7*	39	45	39	41	48	38	38	31	21	24	34	8*	17*	28	9*	4*
TSK-11 (11-44)	36	34	30*	31	30	30	29	26	22*	30	22*	24*	22	16*	20	31	24*	24*
IEQ (0-48)	31	25	27	45	47	44	28	41#	29	27	17*	19*	29	11*	14*	34	23*	11*
PCL-C (17-85)	58	34*	26*	78	64*	76	70	62	72	38	27*	32	45	32*	26*	62	35*	30*
PSEQ (0-60)	15	37*	24	6	11	17*	25	18	32	29	33	38	40	46	45	35	32	45
Pain expectations (yes/no/unsure)	u	u	u	u	u	u	n	u	u	y	y	y	u	y	y	y	y	y
Function expectations (yes/no/unsure)	u	u	u	u	u	u	y	y	y	y	y	y	u	u	u	y	y	y
GPE (-3 to +3)		0	0		1	1		-1	0		1	1		2	2		1	1
Satisfaction (-3 to +3)		1			1			2			2			3			3	

Legend: *=clinically meaningful improvement, #=clinically meaningful decline; abbreviations: SMFA = short musculoskeletal function assessment, DI = dysfunction index, BI = bother index, NPRS = numeric pain rating scale (average pain intensity over the past 2 weeks), NFRS = numeric fatigue rating scale (average fatigue over the past 2 weeks), PHQ-9 = 9-item Patient health questionnaire, PI= 8-item PROMIS pain interference scale, PCS = pain catastrophizing scale, TSK-11 = 11-item Tampa Scale of Kinesiophobia, IEQ = Injustice Experience Questionnaire, PCL-C = Post-traumatic stress disorder checklist – Civilian Version, PSEQ = Pain self-efficacy questionnaire, pain expectations = Do you think your pain will improve? y = yes; n = no; u = unsure, Function expectations = do you think your functional abilities will improve? y = yes; n = no; u = unsure, GPE = global perceived effect (-3= much worse, -2= moderately worse, -1 = slightly worse, 0 = no change, 1 = slightly better, 2 = much better, 3 = completely better, Satistfaction = patient reported satisfaction with health care (-3 = very dissatisfied, -2 = moderately dissatisfied, -1 = slightly dissatisfied, 0 = neutral, 1 = slightly satisfied, 2 = moderately satisfied, 3 = very satisfied)

Figure 1: Change in function over time by participant



Legend: SMFA-DI = Short musculoskeletal function assessment – Dysfunction Index; Assessment time points = 0 weeks (before intervention), 7 weeks (1-week after intervention), and 18 weeks (12 weeks after intervention).

Appendix 1: COMMENCE weekly objectives

Week	Self-management	Pain Education	Individualized exercise	Cognitive-behavioural principles
1 - Introduction to pain physiology, goal setting and exercise	• Introduction to progressive goal setting by actively setting short and long-term goals • Introduction to activity scheduling to plan and record activities each day	• Introduction to pain physiology • Discuss biological, psychological, social influences on pain • Breakdown the common misconception of a close relationship between tissue damage and pain through stories and metaphors demonstrating the complexity of pain • Describe neuroplasticity and potential for changes in abilities with gradual increases in activity	• Frequent (every 2 hours) movement that doesn't increase pain as a tool for pain-relief and reduced sensitivity to movement • Exercises that simulate functional tasks (1-2 times/day). Participants are encouraged to self-monitor intensity and volume with the instructions not to avoid pain at the time of exercise, but to avoid pain that lasts an hour afterwards	• Establish a strong therapeutic relationship in which the patient is on an 'equal level' with the health care provider • Encourage disclosure • Increase expectation of improvement in function through description of neuroplasticity and potential for change • Begin to develop a sense of control over activities through active goal setting and activity planning
2 - Movement and neuroplasticity	• Review activity log and use activity schedule to plan for upcoming week • Collaborate on a graded activity plan to work towards one of goals set in previous week	• Briefly review pain physiology from week 1 • Discuss influence of pain on movement and movement on pain • Describe how frequent movement can facilitate increases in activity participation • Review neuroplasticity and how we can use movement strategies to encourage changes in pain and functional abilities	• Reflection on exercises from first week, problem solving barriers to successful performance, recognizing successes • Use the reflection on week 1 to modify, maintain, or progress exercises covered during first week • Add 1-3 goal oriented exercises determined collaboratively • Develop plan for frequent aerobic activity	• Continue to build expectation of improvement in function by discussing the potential for movement to improve pain and function • Develop abilities and confidence necessary to create a plan to work towards goals • Empower the patient with exercises that can be performed without an increase in symptoms
3 – The complex relationships between stress and pain	• Review activity log and progress towards goals • problem solve barriers to goals set in the previous week	• Briefly review the influence of pain on movement and movement on pain • Discuss the relationship between stress and pain using stories,	• Reflect on exercises from week 2 • Use the reflection on week 2 to modify, maintain, or progress exercises	• Providing people with an explanation of the physiological link between stress and pain may help to validate their symptoms and help them feel understood

	• Establish activity and participation goals for third week • Introduce novel breathing and relaxation strategies • Develop a plan to utilize relaxation and other stress reducing activities • Discuss strategies for improved sleep	metaphors, and evidence to clearly depict the relationship • Describe the interaction of the nervous system, endocrine system, and immune systems in response to stress and pain • Discuss positive influences on stress response systems (regular exercise, relaxation, enjoyable activities, social supports)	• Encourage participant to consider which exercises are ready for progression • Review plan for frequent aerobic activity and modify plan if needed • Develop plan to implement physical activities that have been practiced with exercise into daily life	• Continue to develop a sense of control over symptoms and activity levels with increases in activity participation • Increasing number of 'tools' to utilize when experiencing increases in symptoms may increase confidence in trying new activities or resuming discontinued activities
4 – Thoughts, emotions and pain	• Review activity log and progress towards goals during third week • Problem solve any barriers to goals from third week • Establish activity and participation goals for fourth week • Review stress reduction strategies and assess successes and barriers • Provide thought monitoring tools • Introduce positive self-talk • Develop plan to implement new strategies	• Briefly review the relationships between activity, stress and pain • Discuss how both positive and negative thoughts can influence stress and pain using physiology, stories and metaphors • Discuss the relationship between emotions and pain • Discuss strategies to improve mood: increases in activity, reflecting on positive change, engaging with support networks, and enjoyable activities	• Reflect on exercises from week 3 • Use the reflection on week 3 to modify, maintain, or progress exercises • Encourage participant to consider how many total exercises is realistic for part of a long-term daily routine and add exercises if needed/able • Review plan for frequent aerobic activity and modify plan if needed	• Validate participant's negative thoughts and relationship with pain • Provide strategies to reduce impact of negative thoughts (thought monitoring and self-talk) • Encourage reflection on changes in activity level, recognize accomplishments and plan to overcome challenges • Describing thoughts as another modifiable contributing factor to the pain experience can be empowering
5 – Planning for and dealing with flare ups	• Review activity log and progress towards goals during fourth week • Problem solve any barriers to goals from fourth week • Establish activity and participation goals for fifth week • Review thought monitoring and self-talk strategies discussed last	• Briefly review the relationships between activity, thoughts, emotions and pain • Discuss potential physiological explanations for flare-ups • Discuss relationship between active coping and recovery from flare-ups	• Reflect on exercises from week 4 • Use the reflection on week 4 to modify, maintain, or progress exercises • Discuss potential progression ideas for each exercise and plotting course towards long-term exercise goals	• Encourage self-efficacy through development of plans for reducing the number of flare-ups and dealing for flare-ups when they occur • Recognizing ability to self-monitor and independently perform self-management strategies to encourage

	week and evaluate successes and barriers to implementation • Develop a personal plan for implementing strategies to minimize the number of flare-ups • Develop a personal plan for dealing with flare-ups with emphasis on thinking about "active coping strategies first"		• Review plan for frequent aerobic activity and modify plan if needed	confidence with self-management
6 – Review, progression, and self-monitoring	• Review activity log and progress towards goals during fifth week • Develop plan for future activity planning and logging • Review short-and long-term goals and create an updated plan to work towards these goals • Discuss self-monitoring through identifying strategies that worked well throughout the program and strategies that did not work well and developing a plan to utilize helpful strategies	• Review pain physiology and the relationships between movement, activity, stress, thoughts, emotions and pain • Review multifaceted approach covered over the last 6 weeks: changes in activity levels, exercises, stress and emotional regulation, thought monitoring, self-talk, planning for and dealing with flare-ups • Discuss the importance of adherence, monitoring progress, and overcoming barriers	• The exercise goal for the final week is not to add any new exercises, but to ensure confidence with the existing exercise program and to ensure participant is confident with ability to progress exercises over time as able	• The goal during the final session is to let the patient take the lead in planning for the future. It is important for the patient to feel like s/he has control and feels empowered to continue to implement strategies learned and practiced during the intervention • Establishing self-monitoring strategies and plans to deal with unanticipated flare-ups or barriers will aid in building the confidence in self-management and progression

Appendix 2: Rationale for interventions, strategies, and objectives included

Objective or Treatment strategy	Reason for inclusion
Self-management	
Progressive goal setting	Progressive goal setting is an important way to involve the client in their own care. It can improve motivation to adhere to recommendations[70] and is an important component of the chronic care model[71]. Progressive goal setting has been an important component of many self-management programs and can contribute to improvements in adherence and function [72–74].
Graded exposure	Fear of movement and re-injury is associated with increased disability and influences prognosis in people experiencing pain[75–77]. Exposure therapy is a behavioural strategy that involves exposing a person with a fear to a feared stimuli at a low intensity and in a context that is not associated with fear with the aim of reducing or extinguishing the fear. In the context of chronic pain, graded exposure is a strategy aimed at reducing fear of movement or activity by gradually exposing the person to the feared activity in a context which does not evoke a great deal of fear. This approach has been shown to reduce pain related fear and disability[78–80].
Graded activity	Gradual increases in activity are not only effective at reducing disability in people experiencing fear of movement and fear of activity. Graded activity and graded exercise approaches have demonstrated positive benefits for others who are experiencing chronic pain as well[26,27,80–82]. Gradual increases in activity are a key component of COMMENCE and attention is drawn in the education to the effects of activity on biological, psychological, and social factors associated with pain and related disability.
Activity scheduling and activity log	People with chronic pain often understand that increased activity and exercise participation are beneficial[83]. Many even have a goal to increase activity levels. Unfortunately, there is a gap between motivation to increase activity levels and participation in increased activity due to challenges implementing behaviour changes[84–86]. A strategy that is gaining support for aiding in behaviour change is targeting implementation intentions rather than motivation intentions. Several studies have demonstrated that implementation intention interventions help reduce the gap between a motivation to change activity levels and achieving the behaviour change[84–86]. Having a regular activity schedule may help the participant plan how they will implement the change in activity level. An activity log provides an opportunity for the participant to monitor success of the implementation plan.
Encourage use of social supports	People with chronic pain who have high levels of social support from others are more likely to experience improvements in pain and disability[58]. While the number of social supports available to an individual may be challenging to modify, the use of the social supports in place is something that could be encouraged in the intervention through activity scheduling. The group setting may provide an opportunity for new social supports.
Education and discussion about healthy sleep patterns and behaviours	Sleep deprivation is a common complaint in people experiencing chronic pain[87]. COMMENCE is a client focused intervention and although most of the treatment strategies included in this intervention aim at increasing activity participation, strategies are provided to address other common complaints that are important to the participants. Strategies included in this education session include education on sleep behaviours, controlling external stimuli, sleep restriction, reducing catastrophic thinking around reduced sleep, and using increases in activity during the day to improve sleep at night[88].
Relaxation strategies	Some relaxation strategies have been shown to reduce pain and improve stress responses[89]. Traditionally, relaxation approaches have been passive in nature. However, there is reason to question whether passive relaxation approaches will have any influence on increased function

	and participation, which is the focus of COMMENCE. Relaxation strategies, therefore, will be framed as tools to manage symptoms in order to be able to participate in gradual increases in activity.
Self-monitoring and problem solving	Adherence to treatment is integral to the success of treatment[61]. Self-monitoring is introduced from the first day of COMMENCE to encourage active involvement of the participant and ultimately a feeling of self-efficacy. This includes monitoring completion of the activity log and progress towards goals. This monitoring encourages the participant to celebrate successes and problem solve through barriers to progress. Strategies are provided towards the end of the program to monitor progress towards longer-term goals.
Pain science education	
Pain neurophysiology education	Pain neurophysiology education is included based on its demonstrated ability to reduce pain and improve function in people experiencing pain when applied alongside active rehabilitation. For example, in people with low back pain, intensive education that emphasizes cognitive-behavioural or neurophysiological aspects of pain have demonstrated improvements in pain, disability, health-care utilization, self-efficacy and negative pain cognitions[19,90].
Education and discussion about biological, psychological, and social influences on pain	A scientific lay explanation of biological, psychological, and social factors associated with pain may help the participant understand some of their symptoms, feel legitimized, and understand the rationale for some of the treatment approaches provided. Epidemiological studies have demonstrated that biological, psychological, and social factors are associated with chronic pain and disability and can predict which patients have a poor prognosis[91,92]. People with pain are open to discussion of psychological and social influences on pain when they are presented as contributing factors to pain rather than the cause of pain[83]. Education on the many factors that influence pain are important to helping the participant understand the biopsychosocial approach encouraged in this self-management program.
Education and discussion about the lack of a linear relationship between pain and tissue damage	Misconceptions about a close or even causal relationship between tissue damage and pain are common and can contribute to the persistence of pain and disability[93–95]. These misconceptions may lead to fear of movement and activity[93]. The fear avoidance model suggests that fear of movement and activity leads to withdrawal and avoidance of participating in usual activities, which can lead to the development and maintenance of depression and disability[96,97]. While there are limitations to this model[98], the importance of addressing fear as part of the treatment of chronic pain is evident and providing an accurate understanding of this relationship may contribute to changes in perception of movement and activity.
Education and discussion about neuroplasticity and adaptability of other systems	Higher expectations of recovery following an injury is predictive of better rehabilitation outcomes[99–101]. Teaching people with pain about neuroplasticity and adaptability of other systems may help to increase expectations of positive change through a better understanding of the means through which these changes can occur. Education regarding neuroplasticity has been a component of many of the effective pain neurophysiology education protocols[19].
Education and discussion about the relationship between stress and pain	Research continues to demonstrate close relationships between stress and pain[102,103]. For example, presence of post-traumatic stress disorder symptoms is a prognostic indicator of a poor recovery in people with neck pain after a whiplash injury[102–104]. Discussing the relationship between stress and pain may help the participant understand the relationship as well as 'how and why' some of the interventions included in this treatment program, such as stress reduction strategies, can influence pain and disability.
Education and discussion about the relationship	The concept that negative cognitions can contribute to the onset or maintenance of the pain experience or associated disability is well established[34,38,76]. Helping people understand these relationships is important to helping them reduce negative cognitions that may pose

between thoughts and pain	barriers to participation in usual activities. This discussion helps to introduce treatment strategies such as thought monitoring, self-talk and graded exposure.
Education and discussion about the relationship between emotions and pain	The International Association for the Study of Pain (IASP) defines pain as: "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[105]." Pain itself is an emotional experience, but there are close relationships between other emotions and pain. Depressive symptoms are commonly associated with chronic pain[106,107]. Anger and frustration may also be associated with more intense pain and greater disability[108,109]. Participants are encouraged to identify positive and negative emotions and understand how they can influence pain. Discussion focuses on how they can modify these potential contributing factors through gradual increases in activity and participation.
Use of stories and metaphors	The use of analogies and metaphors as a means of teaching complex science has been discussed for a long time[110]. Only recently has this method of communication been discussed in the area of teaching people about pain. One randomized trial suggests using stories and metaphors to teach people with pain about pain is an effective strategy to change pain related beliefs[111]. The education included in COMMENCE is complex and therefore it is important that the messages are delivered in an engaging and easy to understand way.
Exercise	
Movement and exercise that does not increase pain intensity	In healthy populations, people often experience an analgesic effect from participation in movement and activity, especially moderate-high intensity aerobic exercise[112,113]. It is hypothesized that this analgesic effect is associated with release of endogenous opioids, release of growth factors, and changes in top down inhibition of nociceptive input[114,115]. In people who have been experiencing pain for an extended period of time, this analgesic effect is often lost[116]. Despite this, exercises have been associated with improved outcomes in people experiencing chronic pain[24,26,27]. It is important that patients understand these physiological changes and how increasing activity is important even though the exercises may not provide a temporary analgesic effect as they would prior to the persistence of pain. A hypothesis of COMMENCE is that it is important that at least some of the exercises start at an intensity level that does not exacerbate symptoms, so that participants can experience exercise that does not increase pain. Exercises that cause increases in pain may cause the participant to avoid physical activity, especially in those who are already demonstrating avoidance behaviours. Emphasis, therefore, is placed on increases in activity at a rate and intensity that do not increase symptoms for an extended period after exercise.
Progressive functional exercises	Progressive exercises have shown consistent increases in function across multiple chronic pain conditions[24,26,27,81]. However, current evidence does not provide us with suggestions of the most effective type of exercise, beyond suggesting that it is important for the exercise to be region specific [25–27]. A hypothesis of COMMENCE is that exercises more specific to the functional goals of the participant will be more effective at improving functional abilities. This hypothesis has two underlying assumptions: specificity principles make goal-specific exercises more effective at changing function and goal-oriented exercises are more meaningful to participants which makes them more likely to be adhered to.
Aerobic exercise	Aerobic exercise can result in positive physiological changes to the nervous system, motor system, endocrine system, and immune system. Evidence in people with persistent pain suggests regular aerobic exercise can improve function and mood[117]. Also, it is included as a means of developing participant confidence in the ability to perform activities in gradually progressing dosages and for the other health benefits associated with regular aerobic exercise.
Cognitive behavioural principles	

Developing a strong relationship between health care provider and patient	A strong alliance between the health care provider and the patient is an important contributor to the success of rehabilitation interventions[118–120]. Specific focus is placed on developing a strong relationship between the health care provider and the participant in COMMENCE. This is accomplished with effective communication skills, which have been shown to improve patient satisfaction and adherence to behaviour change[118]. Also, health care providers are encouraged to explore their patients' beliefs, refer to the patients' beliefs in the education, and checking the understanding of the explanations provided. All of these strategies may help to develop a strong therapeutic relationship.
Encouraging disclosure	Encouraging emotional disclosure has been shown to be effective for heterogenous populations of people with pain[121,122]. This may be particularly important in people who are catastrophic thinkers. People who score high on measures of catastrophizing have a tendency to increase their communication of the pain experience and pain behaviours until they feel that their message is received[123]. Disclosure is considered important in allowing these participants to focus on increases in activity and progress towards their goals.
Developing self-efficacy	People with chronic pain who have a higher sense of self-efficacy tend to experience better functional outcomes[124,125]. Self-efficacy can be important to the performance and maintenance of behaviour change in people experiencing pain[126,127]. The main mechanism through which self-efficacy will be targeted is gradual increases in performance of goal-relevant activities. A number of additional strategies are used in an attempt to maximize self-efficacy: patient-led collaborative goal setting, using activity scheduling and activity logs in order to create a plan of action and self-monitor progress towards goals, reflection on changes in activity accomplished during the program, experience problem solving through barriers to increases in activity, and reflection on independent use of the strategies provided during the program.
Reflection on changes in activity levels throughout the program	Reflection on changes in activity and participation is encouraged throughout the program. People with misconceptions about pain such as catastrophic thinking and over-predicting pain with activity may be encouraged to change these misconceptions if they participate in increases in activity without exacerbating symptoms and recognize these successes. Also, reflection on changes in activity could influence self-efficacy and participation in life-role activities through re-evaluation of current abilities.
Thought monitoring	Cognitive behavioural approaches have been demonstrated to contribute to reducing negative cognitions such as catastrophic thinking[22]. People who experience reductions in catastrophic thinking are more likely to improve in response to treatment[128]. It has been suggested that in order to reduce catastrophic thinking, one should first help the person understand that negative thinking can have negative effects on emotions, behaviour, and function. The therapist can help the participant identify when he or she is experiencing negative thoughts that may impact behaviour and help the participant distance him/herself from those negative thoughts[129]. This is encouraged through thought monitoring.
Helpful Self-talk	Changing negative self-talk to positive self-talk and self-reassurance can be a helpful tool to provide positive reinforcement along-side increases in activity. An example of changing self-talk could include shifting from, "This hurts too much, I will never get it done" to "This is getting sore, but I know if I break up the task, I can get it done, and I will feel better having accomplished it." Another example of self-talk could include shifting from, "This is really painful, something very serious must be going on" to "This is painful, but I know it is safe to continue."

CHAPTER 4: CHRONIC PAIN SELF-MANAGEMENT SUPPORT WITH PAIN SCIENCE EDUCATION AND EXERCISE (COMMENCE): STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

TITLE

ChrOnic pain self-ManagementMent support with pain science EducatioN and exerCisE (COMMENCE): Study protocol for a randomized controlled trial

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Abstract

Background: Previous research suggests self-management programs for people with chronic pain improve knowledge and self-efficacy, but result in negligible effects on function. This study will investigate the effectiveness self-management support with pain science education and exercise on improving function for people with chronic pain in comparison to a wait-list control. A secondary objective is to determine which variables help to predict response to the intervention.

Methods/Design: This study will be an unblinded, randomized controlled trial with 110 participants comparing a 6-week program including self-management support, pain science education and exercise to a wait-list control. The primary outcome will be function measured by the Short Musculoskeletal Function Assessment – Dysfunction Index. Secondary outcomes will include pain intensity measured by a numeric pain rating scale, pain interference measured by the 8-item PROMIS pain interference item-bank, how much patients are bothered by functional problems measured by the Short Musculoskeletal Function Assessment - Bother Index, catastrophic thinking measured by the Pain Catastrophizing Scale, fear of movement/re-injury measured by the 11-item Tampa Scale of Kinesiophobia, sense of perceived injustice measured by the Injustice Experience Questionnaire, self-efficacy measured by the Pain Self-Efficacy Questionnaire, pain sensitivity measured by pressure pain threshold and cold sensitivity testing, fatigue measured by a numeric fatigue rating scale, pain neurophysiology knowledge measured by the Neurophysiology of Pain Questionnaire, health care utilization measured by number of visits to a health care provider, and work status.

Assessments will be completed at baseline, 7 - and 18-weeks. After the 18-week assessment, the groups will cross-over; however, we anticipate carry-over effects with the treatment, therefore, data from after the cross-over will be used to estimate within group changes and to determine predictors of response, not for direct between group comparisons. Mixed effects modelling will be used to determine between group differences for all primary and secondary outcomes. A series of multiple regression models will be used to determine predictors of treatment response.

Discussion: This study has the potential to inform future self-management programming through evaluation of a self-management program that aims to improve function as the primary outcome.

Trial registration: ClinicalTrials.gov NCT02422459, registered on 13 April, 2015

Background

Approximately 19 to 29% of Canadians, Americans and Europeans experience chronic pain [1–3] and pain-related disability is the largest contributor to years lived with disability[4]. Pain related-disability has an important impact on the quality of life, workplace productivity, and the health care system[5–7]. It is important, therefore, to investigate strategies to improve quality of life and reduce pain-related disability for people living with chronic pain.

Self-management refers to an individual's "ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life." [8] Self-management support aims to increase participants' skills and confidence in managing their health through the provision of education and supportive interventions.

Self-management programs commonly evaluated in the literature have included education on a number of self-management strategies and often an opportunity to practice these skills: problem solving, communication with health care providers, use of health care resources including medication, general stretching, strengthening, and aerobic exercise, goal setting, diaries, self-monitoring, relaxation, symptom management strategies and cognitive strategies to help cope with pain [9, 10]. Evidence on the effectiveness of self-management support for people experiencing chronic pain is limited. Most research investigating the impact of self-management support on pain and disability

include people with either arthritis or low back pain[9]. The evidence suggests self-management support improve knowledge and self-efficacy, but do not produce clinically important effects on pain or function[9–11]. It is not clear whether these results generalize to more diverse populations of people with chronic pain.

Two treatment approaches for people with chronic pain that have not been included in traditional self-management programs and demonstrate improvements in function are: pain neurophysiology education and individualized, goal-oriented exercises. Pain neurophysiology education has been defined as an educational intervention, "describing the neurobiology and neurophysiology of pain, and pain processing by the nervous system."[12] Pain neurophysiology education is effective for individuals with chronic low back pain[12–14], whiplash associated disorder[15], and chronic fatigue syndrome[16]. The influence of pain neurophysiology education on pain and function in other chronic pain conditions has yet to be investigated with a rigorous trial. Similarly, while most self-management programs encourage participation in exercise and physical activity; most have not included individualized exercise programs despite evidence of reduced disability for both musculoskeletal and neuropathic pain conditions with these approaches[17–21]. The intervention evaluated in this study will be self-management support that incorporates individualized exercises and pain neurophysiology education with a primary aim of improving function.

It is also not clear from previous research which persons are most likely to respond to chronic pain self-management support. Previous research has suggested a number of factors that may contribute to chronic pain and reduced functional

rehabilitation outcomes. For example, high initial pain levels[22–24], female sex[23], lower expectations of recovery[25], low pressure pain thresholds[26], cold hyperalgesia[27–29], catastrophic thinking[30–32], sense of perceived injustice[33], and fear of movement or re-injury[34–36] have all been associated with chronic pain, disability, or poor rehabilitation outcomes. Some of these variables have been suggested as prognostic indicators with more consistency than others. This study will investigate whether some of these prognostic indicators help predict response to chronic pain self-management support with pain education and individualized exercise.

Objectives

Primary objective

1. This study will test the hypothesis that participants with chronic pain experience greater improvement in function over 18-weeks with 6-weeks of ChrOnic pain self-ManageMent support with pain science EducatioN and exerCisE (COMMENCE) in comparison to a wait-list control.

Secondary objectives

2. This study will test the hypotheses that people with chronic pain experience greater improvement in pain intensity, pain interference, self-efficacy, catastrophic thinking, fear of movement/re-injury, pain neurophysiology knowledge, how much participants are bothered by difficulty with functional activities, fatigue, depressive symptoms, health care utilization and work status with COMMENCE in comparison to a wait-list control after 18-weeks.

3. This study will compare the change in outcomes demonstrated by the wait-list group during their treatment period (18-36 weeks) to the change demonstrated during the wait-list period (0-18 weeks).
4. This study will estimate whether the impact of the intervention is maintained over an intermediate term follow-up (18-36 weeks) in the treatment group.
5. This study will determine whether the estimate of the magnitude of the effect is influenced by an 18-week delay.
6. This study will identify demographic, psychological, or psychophysical variables that are predictive of treatment response.

Methods/Design

Study design

This study is a randomized trial with two parallel groups. Participants will be allocated in a 1:1 ratio to treatment and wait-list groups. After the 18-week assessment (after the 6-week treatment period and 12-week follow-up), the group initially receiving COMMENCE will receive no treatment and the group initially on the wait-list will receive COMMENCE for 6 weeks. Both will be assessed again at 25- and 36-weeks from baseline (1- and 12-weeks after the wait-list group finishes treatment) (See figure 1 for study flow). During the treatment, wait-list or follow-up periods, participants can continue with usual care with their family physician.

Between group comparisons (objectives 1 and 2) will be limited to the 0-18 week period prior to the wait-list group receiving treatment. However, 18-36 week period was

added for ethical reasons (ie. the wait-list group will receive the treatment) and to allow for four additional analyses to address objectives 3 to 6.

Blinding

Due to the nature of the treatment and comparison, participants and the treating physiotherapist will not be blinded to group allocation. The assessor who is completing the two objective measures will be blind to the treatment allocation at all assessment time points. The investigator performing the analysis will be blinded to the treatment allocation.

Participants and setting

For the purposes of this study, 110 participants with chronic pain will be recruited at Woodstock and Area Community Health Centre (WACHC) in Woodstock, Ontario, Canada. All participants will be referred to the program by a health care provider at WACHC. WACHC has an interdisciplinary team of health care providers that work collaboratively to provide primary care, health promotion, and community development programs to priority populations in Oxford County, Ontario, Canada. Since participants will be referred from WACHC, they will meet at least one of the criteria for WACHC's priority populations: addictions concerns, mental health challenges, low incomes, lack of health insurance, and isolated seniors. Therefore, this sample will include people often excluded from research and treatment by barriers to accessing healthcare.

Included participants will all have been experiencing non-cancer related chronic pain. Chronic pain will be defined as anyone who has been experiencing pain for greater than 12 weeks. The pain can fluctuate in intensity, but the patient must report experiencing pain on a daily basis over the 3 month period. The presentation can be that of musculoskeletal pain or neuropathic pain and can be associated with a traumatic (e.g. injury or surgery) or non-traumatic etiology (e.g. degenerative changes, unknown etiology). Exclusion criteria will include: cancer related pain, medical "red flags" suggestive of a non-neuromusculoskeletal etiology of symptoms, casted fracture or surgery within the last 26 weeks, and evidence of upper motor neuron lesion. "Red flags" could include: unremitting night pain, palpable tumor, sudden weight loss or weight gain, bowel or bladder incontinence, saddle anaesthesia, bilateral or multi-segmental loss of sensory or motor function, fever/chills, diplopia, dysphagia, dysarthria, drop attacks, nystagmus.

Sample Size

The sample size necessary for a randomized controlled trial with three repeated measures at 0, 7 and 18 weeks was calculated using online sample size software (GLIMMPSE 2.0) using methods detailed by Muller et al [37–39]. The calculation was performed using a significance level of 0.05, a power of 0.8, a minimum detectable mean difference between groups of 10 points on the Short Musculoskeletal Function Assessment Dysfunction Index (SMFA-DI)[40] at both 7 weeks and 18 weeks, and a standard deviation at each time-point of 23 points on the SMFA-DI based on baseline

data from a series of 20 people with chronic pain referred to physiotherapy at WACHC. The calculations were made assuming a correlation between baseline and 7-weeks of 0.84, a correlation between baseline and 12-weeks of 0.82, and a correlation between 7-weeks and 18-weeks of 0.84, based on the same clinical population. The needed sample size calculated was 88 participants. To account for a potential 20% drop-out rate, the investigators will recruit 110 participants (n=55 in each group).

Allocation

The allocation sequence will be generated by a study investigator (JMD) who is not involved in the enrolment of participants or assigning interventions. A computer-generated blocked random number schedule will be used to determine allocation sequence. The block size will be unknown to the other study investigators. Participants will only be assessed and randomized if agreeable to participating in the group that starts one week after the assessment. If participants are unavailable for the upcoming group, both the assessment and randomization will be deferred. The allocation sequence will be concealed through the use of sequentially numbered, opaque envelopes, which will be opened by the physiotherapist (JM) and communicated to the patient after the initial assessment is completed.

Enrolment

Patients will be screened and enrolled by the single treating physiotherapist (JM) after receiving a referral from a health care provider on the WACHC interdisciplinary team.

The health care providers at WACHC will be instructed to refer anyone with non-cancer related pain for at least 3 months. The physiotherapist will then screen to determine whether the participant meets the inclusion or exclusion criteria for participation in the trial.

Intervention/treatment

COMMENCE consists of two visits with a physiotherapist per week over six weeks. One of the two visits is in a group setting, where the emphasis is on pain science education and self-management strategies using cognitive behavioural principles to support behaviour change. The second visit is an individualized, one-to-one session focused on providing support to implement self-management strategies and develop an individualized, goal-oriented exercise program. Both the individual sessions and the group sessions will be carried out by a single physiotherapist (JM) for all participants.

Group pain neurophysiology and self-management education: The group sessions will include 2-6 people. The reason for a maximum of 6 people is pragmatic due to the maximum number of individual appointments the physiotherapist can accommodate in his schedule at the community health centre. The treatment group will proceed with as few as two people in case of low recruitment or high drop out rate. The group sessions will be interactive 1.5 hour sessions once per week over 6 weeks. The participant will be educated on science of pain[12, 41] including the function of the nervous system, other systems involved in the pain experience, changes in these systems when pain persists,

neuroplasticity, and self-management strategies to apply the information learned with the goal of increasing physical activity and participation in life role activities while controlling symptoms. The self-management strategies included in this study are informed by evidence as well as self-efficacy theory and social cognitive theory[42–45]. Self-management strategies will include: progressive goal setting[46–48], activity scheduling [49, 50], thought monitoring[51], relaxation[52], sleep education[53], reflection[51], self-monitoring[10], graded activity[53–55] and exercise[19, 20]. The self-management education has been designed with the priority populations in mind. Lower average income is one of the priority populations and this is associated with lower levels of education and literacy[56]. The material will be targeted towards those with less than high school education. Participants will be given a workbook that guides them through the self-management strategies including: goal setting, activity scheduling, using an activity and exercise log, thought monitoring, and graded activity planning. It will be reviewed between the physiotherapist and participant at each individual session to facilitate communication, encourage discussion regarding an individual implementation plan for each of the self-management strategies discussed in the group, and to provide an opportunity to review any material covered in the group session.

Individualized self-management and exercise: The individualized sessions will be pragmatic 30-45 minute sessions once per week. The content will be tailored to the individual and delivered by the same physiotherapist (JM) who delivers the group sessions. The individualized sessions will include developing an implementation plan for

the self-management strategies discussed in the group session. Participants will also collaborate with the physiotherapist on a graded activity plan to work towards functional goals and individual exercises to improve functional abilities to facilitate achieving functional goals. There will be three types of exercises encouraged: i) Frequent pain free movement, 4-6 times per day, 6-10 repetitions at a time. Participants collaborate with the physiotherapist to find simple movements that can be performed easily throughout their daily routines. The purpose of these exercises is to reduce sensitivity to movement and build confidence with movement that does not increase pain. ii) Exercises that simulate functional tasks needed to perform goals, 1-2 times per day at an intensity that allows them to perform 8-15 repetitions at a time. The purpose of these exercises is to increase functional abilities needed to resume participation in life-role activities and participation goals set by the participant. Education regarding progression will be provided frequently throughout the program. iii) Regular aerobic exercise. Participants will choose any aerobic activity they would like to participate in, set a baseline volume and intensity for that activity, and create a plan with the physiotherapist for progression over time. The volume and intensity will be determined using recommendations that participants do not need to avoid pain at the time of exercise, but should choose an intensity that does not result in pain 1-2 hours after exercise. All three types of exercise will be delivered with messaging consistent with the self-management education suggesting exercise is an effective way to manage pain and to prepare for increases in participation in physical activity and life-role activities.

Co-intervention: Participants will be free to continue with other treatments. Other treatments will be recorded through self-report at each assessment time-point and analyzed for between group differences.

Wait-list control

The wait-list control will be waiting to participate in COMMENCE after the 18-week assessment and participants will be free to continue with "usual care". This includes continued use of prescribed medications and recommendations from other health care providers. The wait-list comparison was chosen rather than a more robust comparator due to previous evidence suggesting no difference in function when comparing other self-management programs to no-treatment or usual-care control groups.

Withdrawing Participants from this Study

Participants may withdraw from the treatment at any time. Participants who choose to withdraw will be documented and data will be analyzed as a member of the group to which they were randomly assigned.

Ethical Clearance

All participants will provide voluntary written informed consent after a discussion about what study participation entails and the potential benefits and risks. Informed consent will be obtained by the treating physiotherapist (JM) prior to the initial assessment after receiving a referral from a health care provider for each potential participant. Ethics

approval has been obtained from Hamilton Integrated Research Ethics Board (HIREB #13-472).

Outcomes

Self-report measures: All self-report measures have been demonstrated to be reliable and valid in a population of people with persistent pain. The range of each scale as well as minimal change considered clinically meaningful for this study are described in Table 1.

The primary outcome will be function as measured by the Short-Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)[40].

Secondary outcomes will include:

- Short Musculoskeletal Function Assessment – Bother Index (SMFA-BI)[40]
- Numeric Pain Rating Scale (NPRS)[57]
- Numeric Fatigue Rating Scale (NFRS)[58]
- PROMIS Pain Interference Item Bank - 8 items[59]
- Patient Health Questionnaire (PHQ-9)[60–62]
- Pain Catastrophizing Scale (PCS)[30, 63, 64]
- Tampa Scale of Kinesiophobia - 11 (TSK-11)[65]
- Pain Self Efficacy Questionnaire (PSEQ)[66–68]
- Neurophysiology of Pain Questionnaire (NPQ)[69]
- number of health care visits

- work status.

Potential predictors of response will include baseline measures for each of the outcome measures listed above as well as:

- Post-traumatic Stress Disorder Checklist (PTSD-C)[70, 71]
- Injustice Experience Questionnaire (IEQ)[33]
- number of medications[72]
- disease count[72].

Demographic information: The following information will be collected at the initial assessment and analyzed as potential covariates and predictors of response: age, sex, work status prior to symptom onset, length of time since symptom onset in months, diagnosis provided by a medical professional as reported by the patient, medication use, previous treatment received, and expectations for recovery. Expectations for recovery will be assessed with two questions: i) Do you think your pain will improve? ii) Do you think your functional abilities will improve?

Psychophysical measures: Two psychophysical measures will be performed in order to estimate sensitivity of the nervous system both locally (at the point identified as "most tender") and at two standardized locations (the area of skin over the muscle belly of the upper fibres of trapezius and tibialis anterior).

*Pressure pain threshold***:** Pressure pain threshold will be measured using a handheld digital algometer (The Wagner FDX-25; Wagner Instruments, Greenwich, CT) as has been previously demonstrated to be reliable[26, 73]. The algometers will be calibrated using a known-weight technique prior to commencing the study. The algometer will be pressed perpendicularly into the skin at a rate of approximately 50 kPa/s (5 N/s). The tester will be trained to ensure ability to apply pressure consistently at this rate. Three measurements of pressure pain threshold will be recorded for each site and on each side of the body. The pressure pain threshold will be determined using the following standardized instructions, used in a previous study investigating pressure pain threshold[74]: "I'm going to begin applying pressure to your skin. I want you to tell me the moment the sensation changes from comfortable pressure to slightly unpleasant pain." For consistency the more tender side will be tested first followed by the less-tender side at the "most tender" location. At the standardized locations, the right side will be tested first, followed by the left.

*Cold hyperalgesia testing***:** Cold hyperalgesia will be tested using a novel test. This device consists of a Peltier Cooler used to cool 2 pairs of cylinders. The two pairs of cylinders are made of acrylic and copper. When the temperature of the cooler is 0 degrees, the cylinders of different materials will feel similar to different temperatures on the skin. The acrylic cylinder will feel like 18 degrees, and the copper will feel like 0 degrees. Each of the two cylinders will be placed in contact with the skin at the three locations in the same randomized order as was used for pressure pain threshold. The

order of the two materials will also be randomized with each of the two materials being placed on the skin three times on each side. The participant will be asked to rate how cold the cylinder is on a 21 point scale (0 is unable to detect the temperature, 10 is cold but not painful, 11 is cold and slightly uncomfortable, and 20 is unbearable pain).

Adverse events or harms: Participants will be asked by the physiotherapist at each visit about adverse events that the patient associates with treatment. Any adverse events requiring medical care beyond the scope of the treating physiotherapist will be referred immediately.

Treatment adherence: Treatment adherence will be assessed through a combination of attendance (categorized as <25%, 25-49%, 50-74%, ≥75% of visits) and adherence to self-management strategies. Adherence to recommended self-management strategies will be described as either completed or not-completed by the clinician when reviewing the participant workbook at the individual treatment session.

Timeline for assessments: Assessments will take place at baseline, 7-weeks (1-week follow-up), 18 weeks (12-week follow-up), 25 weeks (1-week follow-up after wait-list group treatment period) and 36 weeks (12-week follow-up after wait-list group treatment period). See figure 1 for flow diagram. Demographic information will be collected at the baseline assessment. Self-reported outcome measures will be collected at all assessment

time-points. The two objective tests will be collected at baseline, 18 weeks, and 36 weeks.

Participant retention

Participant retention will be encouraged by clearly asking only those willing to commit to all assessment and treatment time-points enroll in the study. Also, free parking is provided for all treatment and assessment visits, treatment is provided free-of-charge, and a small gift card ($20) is provided at each assessment time-point to thank participants and encourage patient follow-up.

Data collection and management

Self-report data will be collected directly on hard copies of the outcome measures listed and referenced above. The measures will be completed at WACHC with the treating physiotherapist and a research assistant present. Demographic data will be collected on pre-piloted study forms. Data will be transferred directly to a database by a trained research assistant or study investigator. Data quality will be assured through checking 10% of the data entered. The data will be collected and stored using only participant codes with no patient identifiers. Hard copies of forms will be stored in a locked cabinet within a locked office at WACHC. The electronic database will be password protected and stored on a password protected computer. Only study investigators or staff will have access to the data.

Data monitoring and auditing

This trial will not have a data monitoring committee and will not include auditing of study conduct outside of the study investigators. This decision was made because of an estimated low risk to participants. Participants with chronic pain will be medically stable and are not expected to be at a high risk of mortality. Also, self-management programs, exercise, and pain education have all been studied without no serious adverse events reported, so no harm to patients is expected with this intervention. There are no stop rules or preliminary analyses planned.

Analysis

Statistical analysis will be conducted using Stata software, version 13 (StataCorp, College Station, TX, USA). Baseline characteristics for both treatment and wait-list groups will be presented as means and standard deviations for normal data, and medians and interquartile range for non-normal data, and number of patients and percentages for categorical data. Between group comparisons will be made for baseline data using a Student's t-test for continuous data and Chi squared or Fisher's exact test for categorical variables to determine the results of the randomized allocation.

To address objectives #1 and 2, between group differences in change in primary (SMFA-DI) and secondary outcomes will be analyzed using linear mixed-effects modelling with repeated measures at 0, 7, and 18 weeks. A p value of less than 0.05 will be considered indicative of statistical significance for all comparisons. The minimum changes required for the change to be considered clinically meaningful for each scale are

listed in Table 1. An advantage of using linear mixed-effects modelling is the ability to utilize all available data points without multiple imputation when there are multiple missing data points [75]. Between group comparisons will be limited to data collected before the 18-week assessment time-point due to anticipated carry over effects due to the long-term changes in function associated with exercise approaches for people with chronic pain[19, 20]. Analysis will use intention to treat principles.

To address objective #3, a within group analysis in the wait-list group will be performed comparing the change in function during the treatment period (weeks 18-36) to the change in function during the wait-list period (weeks 0-18) using a mixed effects model. If there is no change during the wait-list period, this analysis allows for a secondary estimate of treatment effect similar to a diamond response design[76]. Goldsmith et al suggest that if the magnitude of the effect of the intervention is similar to that estimated through the comparison between groups during the 0-7 week period, then they may be pooled for a more precise estimate of treatment effect[76].

To address objective #4 and estimate whether treatment effects are maintained beyond the 18-week assessment, the functional score (SMFA-DI) at the end of treatment (7 weeks) will be compared with the functional score at the 25- and 36-week assessments using a linear mixed effects model.

To address objective #5, the influence of the 18-week delay on the treatment effect will be determined by comparing the magnitude of treatment effect from the waist list group (from objective #3) with the estimate of the magnitude of treatment effect from the treatment group (from objective #1).

In order to address objective #6, each of the patient demographics, outcome measure scores, and objective measures will be tested for univariate relationship with SMFA-DI change score at 18 weeks (difference between SMFA-DI at 18 weeks and SMFA-DI at baseline) using a Pearson r for continuous variables and Chi squared tests for categorical variables. Variables with a significance of <0.10 will be included in the multivariate analysis so that no potential predictive variables will be overlooked. Potential predictor variables will be entered into a series of multiple regression models to determine which combination of baseline variables best predict SMFA-DI after treatment controlling for baseline function.

Sensitivity analyses

There will be two planned sensitivity analyses. The first sensitivity analysis will compare participants who attend at least 75% (9/12) of treatment visits to the wait-list control group to gain an estimate of efficacy versus effectiveness. If there are any cases removed from analysis due to a high influence on the mixed effects model (cooks distance > 4/n)[77], a sensitivity analysis will also be performed to compare the results of the mixed effects model with and without highly influential points included.

Protocol modifications

Any changes to protocol will be communicated with all study investigators and the Hamilton Research Ethics Board in writing. If there are any changes, the trial registry

(clinicaltrials.gov) will be updated electronically. If the risks to participants change, all trial participants will be contacted directly by phone to communicate the change.

Discussion

There are a number of limitations in this protocol that may contribute to risk of bias. First, due to the nature of the intervention and comparison, the participants and the health care provider cannot be blinded. The primary outcome is a self-report measure completed by the participants (not blinded) and secondary outcomes are either self-report measures (not blinded) or psychophysical tests conducted by research assistants (blinded). The principle investigator (JM) is also the treating physiotherapist and will be present at the assessments. Additionally, the nature of the comparison could influence the risk of bias. Patients in the wait-list group will understand that they are not receiving the intervention under investigation and this could bias their self-report assessments at 7- and 18 weeks.

Having a single therapist and centre influences the generalizability of the results. While easily generalizable to the physiotherapist and setting in which the study was carried out, the ability generalize the results to other settings and other settings is limited due to the potential of a therapist effect. A limitation of the current study design is that results may be attributed to either the intervention or the therapist effect without the ability to distinguish between the two potential mechanisms.

Another important factor when considering the generalizability of results is the population being studied. The priority populations at WACHC include people with: addictions concerns, mental health challenges, low incomes, lack of health insurance, and

isolated seniors. This group experiences a number of barriers to accessing healthcare and therefore it is possible that attendance and adherence to the program will be low. Also, people with multiple morbidities have a lower functional status and experience greater functional decline with age [78]. This may limit the potential for functional gains in this population and may make it challenging to determine which factors are contributing to reduced function in this populationThese factors makes generalizability to a population experiencing similar barriers to accessing healthcare easier; however, generalizability to other populations without such barriers more challenging.

The population of people with barriers to accessing healthcare also poses a risk of higher attrition rates. For example, people with depression, substance abuse issues, and lower education are more likely to be lost due to failure to locate[79, 80]. The investigators have put in place measures to try to minimize the attrition rate including asking for multiple methods of contacting the participant and plans to make multiple attempts to contact the participant for follow-up appointments.

Another limitation of this study design is the short-term follow-up before the wait-list group receives treatment. Estimating whether changes in function are maintained in the longer term (up to 36 weeks) will rely on within group analysis of the treatment group. Given the lack of comparison, these results should be interpreted with caution. Changes at 25- and 36-week follow-up could be due to lasting treatment effects; however, period effects could also contribute to any long-term changes. Despite the limitations, the investigators considered it important to estimate the longer-term changes in function to inform future research on long-term efficacy.

Similarly, the comparison of the treatment period (weeks 18-36) with the wait-list period (weeks 0-18) in the wait-list group should be interpreted with caution given the lack of comparison group. Between group comparisons performed during week 0-18 will provide a better estimate of treatment effect; however, the secondary estimate of treatment effect can add precision to effect estimates and allows investigators to estimate the impact of an 18-week delay before starting the self-management program. It is important that within group changes are not be compared between groups as this has the potential to be misleading[81].

Treatment of the chronic pain is a challenge[82, 83]. Improving function is frequently reported as an important outcome by people living with chronic pain[84] and reducing pain-related disability is important for reducing the financial burden [5–7]. Self-management represents an important opportunity to improve pain related disability and ultimately the impact of chronic pain[85]. Unfortunately, existing evidence suggests chronic pain self-management support does not result in substantial changes in participant function[9, 10]. This study aims to evaluate a new approach to chronic pain self-management that targets function as the primary outcome. If this approach is demonstrates effectiveness, this could inform self-management programming to include greater focus on pain neurophysiology education and physiotherapist led, individualized, goal-oriented exercise. By determining which factors help to predict an intervention response, practitioners will have valuable information on the prognosis of participants entering the program. Future research may help to develop tailored approaches to self-

management for persons less likely to respond to this approach. Ultimately, this research could help to improve self-management for people with chronic pain.

The results of this trial will be published in peer reviewed journals and presented at international conferences in the fields of pain and rehabilitation.

Trial status:

Recruitment started in September, 2013. At the time of protocol submission, this study is recruiting patients.

Abbreviations:

ANOVA: Analysis of Variance

COMMENCE : Chronic Pain Self-Management Support with Pain Science Education and Exercise

IEQ: Injustice Experience Questionnaire

NFRS: Numeric Fatigue Rating Scele

NPQ: Revised Neurophysiology of Pain Questionnaire

NPRS: Numeric Pain Rating Scale

PCS: Pain Catastrophizing Scale

PHQ-9: 9-item Patient Health Questionnaire

PPT: Pressure Pain Threshold

PROMIS: Patient Reported Outcome Measurements Information System

PI: Pain Interference

PSEQ: Pain Self-Efficacy Questionnaire

PTSD-C: Post-Traumatic Stress Disorder Checklist – Civilian Version

SMFA: Short Musculoskeletal Function Assessment

DI: Dysfunction Index

BI: Bother Index

TSK: Tampa Scale of Kinesiophobia

WACHC: Woodstock and Area Community Health Centre

Dissemination

This study will be published in a leading journal and presented at international conferences in the field of pain and rehabilitation. A lay summary of results will be sent to study participants. Additionally, study results will be disseminated to clinicians through courses, presentations, and workshops to a community of practice of physiotherapists in primary health care and a network of physiotherapists interested in the treatment of pain.

Financial or competing interests:

None of the study investigators have any financial or non-financial competing interests to report.

Authors' contributions

JM is the principal investigator. He led the conception, study design, writing and editing of the protocol. JMD, DW, and JR all participated in the study methods and writing of the protocol.

JM carried out all statistical analyses to determine sample size. All authors read and approved the final manuscript.

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Figure 1 – Study flow diagram

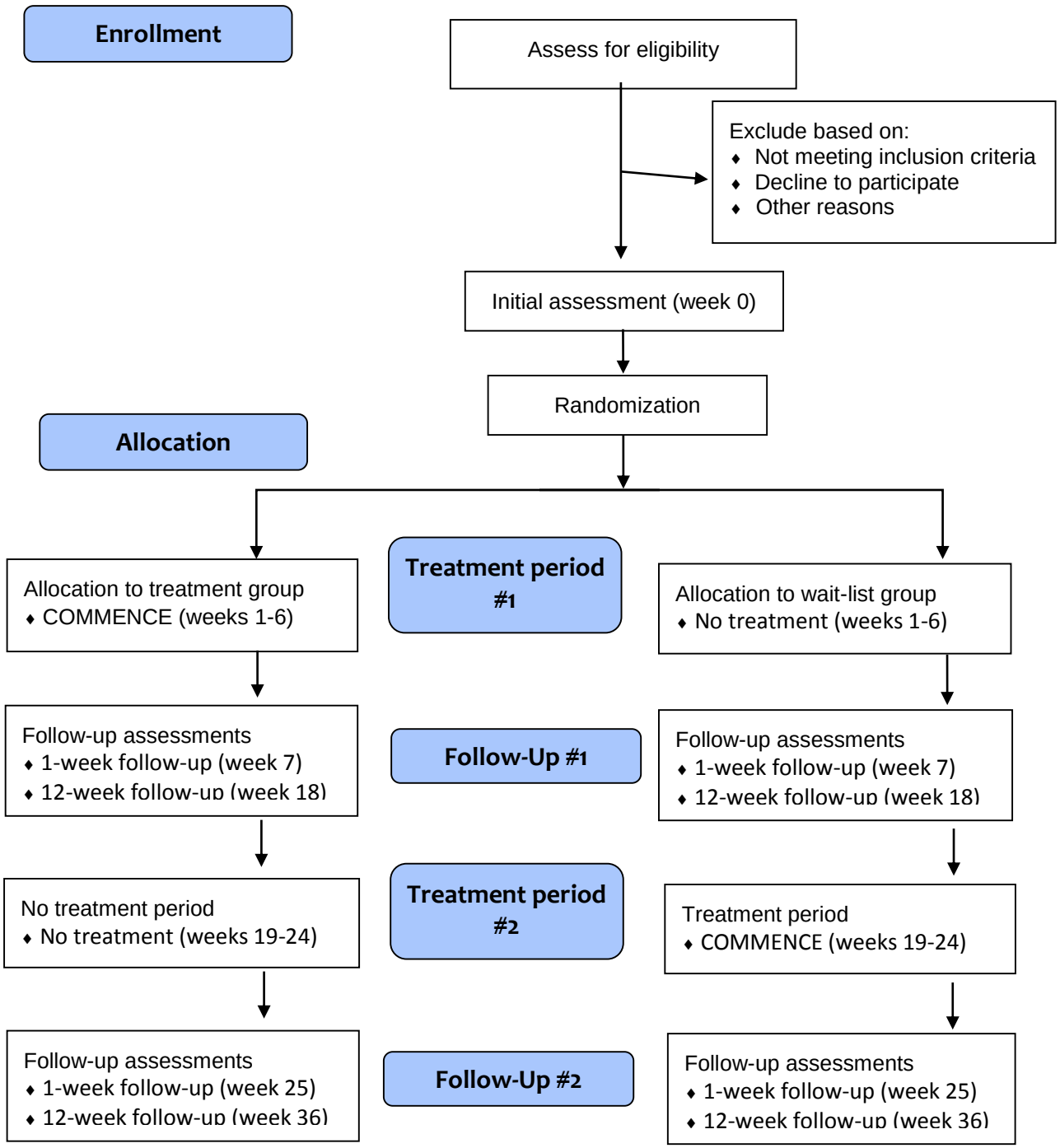

Table 1 - Outcome measures and potential predictors of response

Construct	**Outcome Measure**	**Scale range**	**Minimal important difference**
Function	**Short Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)**	**34-170**	**10 points***
How much participants are bothered by difficulty with functional activities	Short Musculoskeletal Function Assessment – Bother Index (SMFA-BI)	12-60	5.5 points*
Pain Intensity	Numeric Pain Rating Scale (NPRS)	0-10	2 points[1]
Fatigue	Numeric Fatigue Rating Scale (NFRS)	0-10	1.4 points[2]
Pain Interference	PROMIS Pain Interference Item Bank - 8 items	8-40	5 points*
Depressive symptoms	Patient Health Questionnaire - 9 (PHQ-9)	0-27	5 points[3]
Catastrophic thinking	Pain Catastrophizing Scale (PCS)	0-52	38% of scale[4]
Fear of symptom exacerbation	11-item Tampa Scale of Kinesiophobia (TSK-11)	11-44	5.6 points[5]
Pain neurophysiology knowledge	Neurophysiology of pain test (NPT)	0-13	1.1 points*
Self efficacy	Pain Self Efficacy Questionnaire (PSEQ)	0-60	11 points[6]
Work status	Working vs not-working Working full hours vs. modified hours Working full duties vs. previous duties		
Health care utilization	# of health care visits during 12-weeks prior to treatment vs. health care visits during 12-week follow-up period		
Post-traumatic stress symptoms	Post-traumatic Stress Disorder Checklist	17-85	
Sense of perceived injustice	Injustice Experience Questionnaire (IEQ)	0-48	
Medication use	Number of medications Medication by class		
Comorbidities	Disease count		
Cold sensitivity	A novel test of cold sensitivity		
Pressure sensitivity	Pressure Pain Threshold (PPT)		

Legend: This table depicts each construct being measured as either an outcome or potential predictor of response, the measure used to evaluate that construct, the range of the scale (if applicable), and the minimal important difference for scales that will be measured as outcomes.

*In the absence of an established MCID or MDC, change greater than half a standard deviation will be considered clinically meaningful[7]. In these instances, clinical data from Woodstock and Area Community Health Centre was used to establish the standard deviation.

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CHAPTER 5: CHRONIC PAIN SELF-MANAGEMENT SUPPORT WITH PAIN SCIENCE EDUCATION AND EXERCISE (COMMENCE): A RANDOMIZED CONTROLLED TRIAL

TITLE

ChrOnic pain self-ManagementMent support with pain science EducatioN and exerCisE (COMMENCE): A randomized controlled trial

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Abstract

Background: Previous research indicates chronic disease self-management improves knowledge and self-efficacy, but chronic pain self-management has demonstrated negligible effects on function. This unblinded randomized controlled trial investigated the effectiveness chronic pain self-management support with pain science education and exercise (COMMENCE) on improving function in comparison to a wait-list control at 1- and 3-month follow-up for people living with chronic pain.

Methods: This trial included 102 participants and compared a 6-week program of self-management support, pain science education and exercise to a wait-list control. The primary outcome was function measured by the Short Musculoskeletal Function Assessment – Dysfunction Index. Secondary outcomes included how much patients are bothered by functional problems, pain intensity, pain interference, catastrophic thinking, fear of movement or re-injury, self-efficacy, fatigue, pain neurophysiology knowledge, global rating of change, satisfaction, number of heath care visits, and work status. Assessments were completed at baseline, 1-week follow-up, and 12-week follow-up. Mixed effects modelling was used to determine between group differences for all primary and secondary outcomes.

Results: The results suggest clinically meaningful improvement in function with COMMENCE in comparison to the wait-list control (mean difference = -8.0 on the SMFA-DI; 95% confidence interval: -14.7 to -1.3). Also, participants in COMMENCE experienced greater improvements in how much they were bothered by functional difficulties, pain neurophysiology knowledge, and participants in COMMENCE reported

greater global improvement, greater satisfaction with their health care, and had fewer specialist appointments during the 12-week follow-up period. There was a statistically significant difference between groups in pain intensity and catastrophic thinking, but these differences may not be clinically meaningful. There were no significant differences between groups for fatigue, pain interference, depressive symptoms, number of primary health care visits, diagnostic imaging, and work status.

Conclusion: This study suggests COMMENCE is effective at improving function for people living with chronic pain.

Background

Chronic pain is experienced by approximately 1 in 5 people [32,38,55]. For many, chronic pain is disabling making pain one of the leading contributors to years lived with disability [56]. Chronic pain is also associated with a large societal burden due to increased healthcare utilization and reduced workplace productivity [20,36,37]. It is important to find effective treatment strategies aimed at improving function to help improve the quality of life of people experiencing chronic pain and to reduce the societal impacts of chronic pain.

Self-management support is one potential strategy to reduce pain related-disability. Self-management has been defined as a person's "ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition. Efficacious self-management encompasses ability to monitor one's condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life." [7] Self-management supports involve the provision of supportive interventions to help individuals manage their health conditions more effectively.

Research investigating the effectiveness of self-management programs for people with chronic diseases has demonstrated improved knowledge and self-efficacy [60], but research on chronic pain self-management for osteoarthritis has suggested negligible effects on physical function [16,34,60]. For people living with pain, this is problematic as people with chronic pain suggest improved function is an important health outcome [9]. In self-management programs previously evaluated in the literature, topics often

included: problem solving, communication with health care providers, use of health care resources including medication, general stretching, strengthening and aerobic exercise, goal setting, diaries, self-monitoring, relaxation, symptom management strategies and cognitive strategies to help cope with pain [16,34]. It is uncertain whether additional self-management supports may facilitate improvements in function. Pain neurophysiology education and individualized exercises have demonstrated small to moderate improvements in functional outcomes for people with chronic pain [27,41,52,53,62,72,83]; however, these interventions have not been consistently included in self-management programming.

One of the populations in which interventions to improve function are most needed are people with chronic pain and multiple morbidities. People living with multiple chronic conditions are the most frequent visitors to primary health care [25,63] and approximately 67% of people with multiple morbidities experience chronic pain [18]. Both chronic pain and multiple morbidities contribute to reduced function [22,31,38,68,81] making the development of interventions aimed at improving function in this population more challenging. To date, most of the research evaluating self-management programs for people with pain have included people with either low back pain or arthritis [16] making it difficult to use evidence to guide the development of self-management programming aimed at improving function for this population.

Another population of people that would benefit greatly from improved self-management programming are persons who experience barriers to accessing healthcare. People with lower socio-economic status, mental health concerns, addictions and social

isolation have barriers to accessing healthcare[8,35] and inequities have been demonstrated in those who seek care from chronic disease self-management programs [23]. Given recruitment strategies often involve recruitment of patients at health care facilities that demonstrate inequities, chronic pain research may also under-represent these populations with inequities in access to care.

The aim of the present study was to evaluate a self-management program that incorporates pain science education and individualized exercise in a population of people with chronic pain, multiple morbidities, and barriers to accessing healthcare.

Objectives

1. The primary objective of this study was to evaluate the effectiveness of 6-weeks of ChrOnic pain self-ManageMent support with pain science EducatioN and exerCisE (COMMENCE) at improving function over 18-weeks in people with chronic pain in comparison to a wait-list control.

2. The second objective of this study was to evaluate the effectiveness of COMMENCE at improving pain intensity, pain interference, self-efficacy, catastrophic thinking, fear of movement/re-injury, pain neurophysiology knowledge, how much participants are bothered by difficulty with functional activities, fatigue, depressive symptoms, global rating of change, health care satisfaction, health care utilization and work status with COMMENCE in comparison to a wait-list control over 18-weeks.

Methods

Study design

This study was a randomized trial with two parallel groups. Participants were allocated in a 1:1 ratio to treatment and wait-list groups. Assessments were completed at baseline, 1-week and 12-weeks following the 6-week self-management program.

After the 12-week follow-up, the group on the wait-list received COMMENCE for 6 weeks and both groups were followed up at 25- and 36-weeks from baseline (1- and 12-weeks after the wait-list group finishes treatment). The analysis of data after the first 12-week follow-up will be presented in a later publication (See figure 1 for study flow). The protocol for this study was registered (ClinicalTrials.gov, NCT02422459) and published previously (see Chapter 4). This includes prior publication of intervention and research methods. There were no deviations to the protocol published to report.

Blinding

The participants and physiotherapist were not blinded due to the nature of the intervention. Also, the primary and secondary outcomes were self-reported with the physiotherapist present at all time-points and therefore the outcome assessor was not blinded. A blinded investigator performed the analysis.

Participants and setting

This study included 102 participants with chronic pain recruited from Woodstock and Area Community Health Centre (WACHC) in Woodstock, Ontario, Canada. All

participants were referred by another health care provider at WACHC. WACHC has an interdisciplinary team of health care providers that work collaboratively to provide primary care, health promotion, and community development programs to priority populations in Oxford County, Ontario, Canada. Since participants were referred from WACHC, they all met at least one of the criteria for WACHC's priority populations: addictions concerns, mental health challenges, low income, lack of health insurance, and isolated seniors. Therefore, this population included people with at least one potential barrier to accessing healthcare.

This study included only participants who were experiencing chronic non-cancer related pain who could read, write, and speak English. Chronic pain was defined as anyone who has been experiencing pain for greater than 12 weeks. The pain could be constant or brought on by aggravating factors, consistent or fluctuating, but pain had to be present on a daily basis over a 3-month period. The presentation could have been that of musculoskeletal pain or neuropathic pain and could be associated with a traumatic (e.g. injury or surgery) or non-traumatic etiology (e.g. degenerative changes, unknown etiology). Exclusion criteria were: cancer related pain, medical "red flags" suggestive of a non-neuromusculoskeletal etiology of symptoms, casted fracture or surgery within the last 26 weeks, and evidence of upper motor neuron lesion. "Red flags" could include the following unexplained signs or symptoms: unremitting night pain, palpable tumor, sudden weight loss or weight gain, bowel or bladder incontinence, saddle anaesthesia, bilateral or multi-segmental loss of sensory or motor function, fever/chills, diplopia, dysphagia, dysarthria, drop attacks, nystagmus.

Allocation

The allocation sequence was generated by a study investigator not involved in the enrolment of participants or assigning interventions (JMD). A computer-generated blocked random number schedule was used to determine allocation sequence. The block size was unknown to the other study investigators. Participants were only assessed and randomized if agreeable to participating in the group that starts one week after the assessment. If participants were unavailable for the upcoming group, both the assessment and randomization were deferred. The allocation sequence was concealed through the use of sequentially numbered, opaque envelopes, which were stored in a locked cabinet that was only accessible to the physiotherapist who accessed and opened the envelope after the initial assessment and communicated the group allocation to the participant.

Enrolment

A single physiotherapist screened using the inclusion and exclusion criteria and enrolled participants after anyone with chronic non-cancer related pain were referred by a health care provider at WACHC.

Intervention/treatment

ChrOnic pain self-ManageMent support with pain science EducatioN and exerCisE (COMMENCE) consisted of two visits with a physiotherapist per week over six weeks (12 visits over 6 weeks; 6 in a group, 6 one-on-one). One of the two visits was in a

group setting, where the emphasis was on pain science education and self-management strategies using cognitive behavioural principles to support behaviour change. The second visit was an individualized, one-to-one session focused on providing support to implement self-management strategies and develop an individualized, goal-oriented exercise program. Both the individual sessions and the group sessions were carried out by a single physiotherapist for all participants.

***Group pain neurophysiology and self-management education*:** The group sessions included 3-6 people. The reason for a maximum of 6 people was pragmatic due to the maximum number of individual appointments the physiotherapist could accommodate in his schedule at the community health centre. The treatment groups proceeded with as few as three people in a group. The group sessions were interactive 1.5 hour sessions once per week over 6 weeks. The participants were educated on science of pain[41,51] including the function of the nervous system, other systems involved in the pain experience, changes in these systems when pain persists, neuroplasticity, and self-management strategies to apply the information learned with the goal of increasing physical activity and participation in life role activities while controlling symptoms. The self-management strategies included in this study were informed by evidence as well as self-efficacy theory and social cognitive theory[3–6]. Self-management strategies included: progressive goal setting[11,14,73], activity scheduling [39,44], thought monitoring[80], relaxation[48], sleep education[21], reflection[80], self-monitoring[34], graded activity[21,24,40] and individualized exercise[27,72]. More detail on the study

intervention can be found in a case series study that describes the intervention and rationale in more detail[49]. Participants were given a workbook to guide them through the self-management strategies including: goal setting, activity scheduling, using an activity and exercise log, thought monitoring, and graded activity planning. The therapist and participant reviewed the workbook together at each session as a way of facilitating communication, self-monitoring, and problem solving.

***Individualized self-management and exercise*:** The individualized sessions were pragmatic 30-45 minute sessions once per week. The content was tailored to the individual and delivered by the same physiotherapist who delivered the group sessions. The individualized sessions included developing an implementation plan for the self-management strategies discussed in the group session and a graded activity and individualized exercise plan to improve functional abilities and increase participation in life activities. There were three types of exercises encouraged: i) frequent pain free movement, 4-6 times per day, 6-10 repetitions at a time. Participants collaborated with the physiotherapist to find simple movements that could be performed easily throughout their daily routines. The purpose of these exercises was to reduce sensitivity to movement and build confidence with movement that does not increase pain. ii) Exercises that simulate functional tasks needed to perform goals, 1-2 times per day at an intensity that allowed them to perform 8-15 repetitions at a time. The purpose of these exercises was to increase functional abilities needed to resume participation in life-role activities and participation goals set by the participant. Education regarding progression was provided

frequently throughout the program. iii) Regular aerobic exercise. Participants chose an aerobic activity that was meaningful and realistic for them to perform, set a baseline volume and intensity for that activity, and created a plan with the physiotherapist for progression over time. The volume and intensity was determined using recommendations that participants did not need to avoid pain at the time of exercise, but should choose an intensity that didn't result in pain 1-2 hours after exercise. All three types of exercise described above were delivered with messaging consistent with the self-management education suggesting exercise is an effective way to manage pain and to prepare for increases in participation in physical activity and life-role activities.

Wait-list control

The wait-list control group delayed participation in COMMENCE after the 18-week assessment and participants were free to continue with "usual care". This included continued use of prescribed medications and recommendations from other health care providers. The wait-list comparison was chosen rather than a more robust attention control due to previous evidence suggesting no difference in function when comparing other self-management programs to no-treatment or usual-care control groups.

Co-intervention: Participants in both groups were free to continue with other treatments. Other treatments were recorded through self-report at each assessment time-point and analyzed for between group differences.

Ethical considerations

All participants provided voluntary written informed consent after a discussion about what study participation entailed and the potential benefits and risks. Informed consent was obtained by the treating physiotherapist (JM) prior to the initial assessment. Ethics approval has been obtained from Hamilton Integrated Research Ethics Board (HIREB #13-472).

Outcomes

Primary outcome measure

The dependent variable was function as measured by Short-Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)[77]. The SMFA-DI is a 34-item measure of function with higher scores representing poorer function. More details regarding the scale can be found in Table 1.

Secondary outcome measures

All self-report measures have been demonstrated to be reliable and valid in a population of people with persistent pain. Further details about each scale, the range of the scale, and the minimal change considered clinically meaningful for this study are described in Table 1.

- Short-Musculoskeletal Function Assessment – Bother Index (SMFA-BI)[77]
- Numeric Pain Rating Scale (NPRS)[30]
- Numeric Fatigue Rating Scale (NFRS)[50]

- PROMIS Pain Interference Item Bank – Short-form 8a (PI)[1]
- Pain Catastrophizing Scale (PCS)[71,74,75]
- Tampa Scale of Kinesiophobia - 11 (TSK-11)[79]
- Injustice Experience Questionnaire (IEQ)[76]
- Pain Self-Efficacy Questionnaire (PSEQ)[57,58,66]
- Revised Neurophysiology of Pain Questionnaire (NPQ)[10]
- Patient Health Questionnaire (PHQ-9)[33,42,45]
- Global rating of change
- Patient satisfaction
- number of health care visits (to a primary health care provider, emergency department, specialist, or diagnostic imaging)
- work status.

Potential covariates

The following variables were collected at the initial assessment as potential covariates.

- age
- gender
- duration of symptoms (months)
- work status prior to symptom onset
- whether or not the participant had received active rehabilitation in the past
- number of body regions with pain
- number of medications[29]

- disease count[19,29]
- expectations for improvement in pain
- expectations for improvement in recovery
- Injustice Experience Questionnaire (IEQ)[76]
- 9-item Patient Health Questionnaire (PHQ-9)[33,42,45]
- Post Traumatic Stress Disorder Checklist – Civilian Version (PCL)[13,69].

More details on number of regions with pain, comorbidity (number of medications and disease count), expectations for improvements in pain and function, IEQ, PHQ-9, and PCL are described in Table 1.

Adverse events or harms

Participants were asked by the physiotherapist at each visit about adverse events that the participant associates with treatment. All adverse events were documented and recorded.

Treatment adherence

Treatment adherence was assessed through attendance (categorized as <25%, 25-49%, 50-74%, ≥75% of visits) and completion of each self-management strategy. Adherence to each self-management strategy was recorded by the physiotherapist as completed or not completed based on whether or not the participant had recorded the strategy in the workbook. Each strategy was also recorded as completed if the participant reported completing the strategy, but found it too difficult to record it in his/her workbook.

Timeline for assessments

Assessments were completed at baseline, 1-week follow-up (7-weeks), and 12-week follow-up (18 weeks). See figure 1 for flow diagram. Demographic and clinical information was collected at the baseline assessment. Self-reported outcome measures were collected at all assessment time-points.

Participant retention

Participant retention was encouraged by clearly asking only persons willing to commit to all assessment and treatment time-points enroll in the study. Also, free parking was provided for all treatment and assessment visits, treatment was provided free-of-charge, and a small gift card ($20) was provided at each assessment time-point to thank participants and encourage patient follow-up. Investigators provided phone call reminders prior to assessments and multiple phone call attempts to reschedule follow-up appointments when necessary.

Data collection and management

Self-report data was collected directly on hard copies of the outcome measures listed and referenced above. The measures were completed at WACHC with the treating physiotherapist and a research assistant present. Demographic data was collected on study forms. Data quality was assessed through checking 10% of the data entered by an independent research assistant with an error rate of less than 0.1%.

Analysis

Stata software, version 13 (StataCorp, College Station, TX, USA) was used for analysis. Baseline characteristics for both treatment and wait-list groups were presented as means and standard deviations for normal data, and medians and interquartile range for non-normal data, and number of patients and percentages for categorical data. Between group comparisons were made for baseline data using a Student's t-test for continuous normal data and Chi squared test for variables that were categorical or not normally distributed to ensure adequate randomization procedures. Participants who did versus did not complete the final follow-up assessment were also compared using chi-square and t-tests to ensure participants lost to follow-up were missing at random.

Between group differences in the primary outcome (SMFA-DI) were analyzed using linear mixed-effects modelling with repeated measures at 0, 7, and 18 weeks using an independent covariance structure with treatment group and time as independent variables. Age and gender were force entered into the model as covariates, and number of medications and baseline PHQ-9 score were included as significant covariates. PCL was collinear with PHQ-9 (r=0.73) and therefore not included in the model. The other baseline measures were not significant covariates and thus were not included in the model.

Differences between groups in secondary outcomes were also evaluated using linear mixed effects modelling with age, gender, number of medications and baseline PHQ-9 as covariates. Between group differences were analyzed using contrasts at each time-point and p-values were corrected for multiple comparisons using the Bonferroni

method. Work status was compared between groups at each time-point using a mixed effects logistic regression. A p value of less than 0.05 was considered indicative of statistical significance for all comparisons. The minimum changes required for the change to be considered clinically meaningful for each scale are listed in Table 1.

Missing items from within a scale were entered as the mean item score from within the same scale. The planned analysis was to perform this up to a maximum of 50% of each scale as recommended for both the SMFA and PROMIS instruments, but the maximum number of items imputed was 4 on the SMFA-DI. An advantage of using linear mixed-effects modelling is the ability to utilize all available data points without multiple imputation when there are missing data at multiple time points [64]. Analysis for primary and secondary outcomes were performed using intention to treat principles.

Sensitivity analyses

There were two planned sensitivity analyses. The first sensitivity analysis compared participants who attended at least 75% (9/12) of treatment visits to the wait-list control group to gain an estimate of efficacy versus effectiveness. This sensitivity analysis was performed using a linear mixed effects models as with the intention to treat analysis and presented in the results.

The second sensitivity analysis was planned to compare the results of the mixed effects model with highly influential points removed to a mixed effects model with all points included (using an extension of Cooks distance[15,67] for generalized linear

mixed effects models to identify highly influential points). This second sensitivity analysis was not performed as no highly influential points were removed from the model.

Results

The final sample (n=102) consisted of 75 females and 27 males with a mean age of 53 years, median duration of pain of 10 years, living with a median 3 comorbidities, and taking a median 4 medications. A summary of baseline characteristics and covariate measures at baseline is presented in table 2. There were no statistically significant differences between groups in any variable. The comorbidities present in each group are described in table 3.

The rate of follow-up was similar between groups at 1-week follow-up with 47/52 (90%) of the wait-list group and 45/50 (90%) of the treatment group. The number of completed assessments at 12-week follow-up were not significantly different with 42/52 (81%) of the wait-list group and 37/50 (74%) of the treatment group completing the assessment. Participants who did versus did not complete the 12-week follow-up did not differ on any outcome or baseline characteristic.

The mean scores and standard deviations for continuous outcome measures at baseline, 1-week follow-up, and 12-week follow-up are presented in table 4. Work status is described at each time-point in table 5.

The results of the multivariate regression analyses are presented in table 6. At the final outcome measurement point, the results suggest a clinically meaningful improvement in function on the SMFA-DI (mean difference between groups (MD) = -

8.0; 95% confidence interval (CI): -14.7 to -1.3). Figure 2 depicts the change in function over time by group. Also, secondary measures in which a clinically meaningful changes were evident at 12-week follow-up included: how much participants were bothered by difficulty with function on the SMFA-BI (MD = -12.0; 95% CI: -20.8 to -3.2), knowledge of pain neurophysiology on the RNPQ (MD 2.8 points; 95% CI: 1.6 to 3.9), global rating of change on a 7-point scale (MD = 1.4 points; 95% CI: 0.8 to 2.1), and patient satisfaction with their health care on a 7-point scale (MD = 1.2; 95% CI: 0.7 to 1.8).

The results for three outcomes suggest statistically significant change, but the effect estimate does not reach the level of clinical importance at 12-week follow-up. These include pain intensity on an NPRS (MD = -1.0; 95% CI: -2.1 to -0.1), catastrophic thinking on the PCS (MD= -8.2; 95% CI: -14.5 to -2.0), and self-efficacy (MD =7.0; 95% CI: 0.8 to 13.2).

The results for five outcomes suggest no significant or clinically meaningful change at 12-week follow-up: fatigue (MD =-0.7; 95% CI -1.6 to 0.25) , pain interference (MD -1.6; 95% CI -4.7 to 1.4), depressive symptoms (MD -3.0; 95% CI -5.5 to -0.8), health care visits (MD -0.27; 95% CI -1.26 to 0.73), and work status (chi2 = 3.1, p = 0.21).

The results do not appear to be dependent on gender with no significant differences between effect estimates in females (MD = -7.9; 95% CI: -15.5 to -0.2) and males (MD = -0.1; 95% CI: -22.3 to 4.2). The results stratified by gender are depicted in Table 7.

Adherence and sensitivity analysis

Attendance in the treatment group was highly variable. 26 (52%) participants in the treatment group attended at least 9/12 sessions, 4 (8%) participants attended 6-8 sessions, 8 (16%) participants attended 3-5 sessions, and 12 (24%) attended less than 3 sessions. Adherence to each self-management strategy is reported in table 8.

The results of the sensitivity analysis revealed a slightly larger effect estimate for those that attended at least 9 out of 12 sessions in comparison to the wait-list group (MD = -11.9; 95% CI: -19.5 to -4.4). The results are presented in Table 9. The mean change scores increase with increased attendance as one would expect with an effective intervention. These results are presented in table 10.

Co-intervention

Both groups were free to continue with usual care throughout the treatment and follow-up period. Treatments outside of COMMENCE received by each group are recorded in Table 11.. There were no significant difference between the two groups in any of the treatments received.

Adverse events

Eight participants (16%) reported experiencing transient increases in pain (<72hours) after increases in physical activity or exercise. There were no other adverse events reported.

Discussion

This study determined that a COMMENCE intervention was effective in improving function in a group of people with chronic pain, multiple comorbid health issues and barriers to care. This is in contrast to previously evaluated self-management programs that demonstrated negligible changes in function[16,34] in people with low back pain or arthritis.

The between group differences in function may suggest the strategies included in COMMENCE that have not been included in previously evaluated in self-management programs targeted function more specifically in this study. In particular, pain neurophysiology education and individualized, goal-oriented exercises were incorporated based on previous evidence that these interventions can contribute to improved function[27,41,72]. Previous self-management programs have focused on general exercise advice, goal setting, problem solving, effective communication with health care providers, diaries, self-monitoring, relaxation, symptom management strategies and cognitive strategies to help cope with pain [16,34]. The exercises in previous self-management programs for arthritis and low back pain have included general strengthening, stretching, and aerobic exercises. Some trials report tailoring the exercises to participant abilities, but previous studies have not reported selecting exercises specific to the participants' goals. The exercises included in COMMENCE were individualized based on aggravating and relieving movement patterns as well as functional movement patterns needed to achieve activity and participation goals set by the participant. Also, the

exercises were introduced using pain neurophysiology to help participants understand the rationale for the exercises and the intensity at which the exercises should be performed. The introduction of the exercises using pain science may have helped participants understand when to progress exercises and why the exercises may facilitate improvements in function. It is possible that the changes in function were due to the individualized nature of the exercises included in COMMENCE or due to participants understanding of pain changing the way they engage in self-management strategies.

Another aspect of this program that may contribute to improvements in function is that COMMENCE is health professional led and condition specific. Previous evidence from Coleman and colleagues suggested a physiotherapist led, conditions specific self-management program for people with arthritis was effective at improving function[12]. The agreement of our results may suggest benefit to condition-specific self-management programming led by a physiotherapist. The challenge of condition specific self-management is evident by the number of comorbidities in our study population. People in the current study had a median of 4 comorbidities. In particular, mental health conditions were prevalent in the study sample and this study produced negligible effects on depression. Also, diabetes and hypertension were common comorbidities and the impact of the intervention on these factors was not measured. A future challenge for clinical practice and research may be incorporating a tailored approach to self-management for multiple conditions into COMMENCE to facilitate self-management of chronic conditions that occur frequently alongside chronic pain and related disability.

This study is in agreement with previous evidence that suggests little change in pain with self-management programming[16,34]. This study is also in agreement with previous evidence suggesting participants are satisfied with the care they receive in self-management programs[34]. While this study suggested statistically significant improvements in self-efficacy, the results (mean difference = 7 points) did not reach the MCID of 11 points on the PSEQ. This is also in agreement with previous research suggesting no change in self-efficacy in self-management support for osteoarthritis[34].

Several of the secondary outcomes were included to investigate potential mechanisms through which COMMENCE might influence function, although it was beyond the scope of this paper to perform an analysis to determine whether these factors were mediators of change in function. The secondary measures included due to a potential relationship with reduced function were: catastrophic thinking (PCS), fear of movement or re-injury (TSK-11), self-efficacy (PSEQ), depressive symptoms (PHQ-9), and pain neurophysiology knowledge (RNPQ). The results suggest a 28% improvement in PCS, which did not reach the a prior level of clinical importance of 38%[71]. This non-meaningful result should be interpreted with caution as the reported MCID for catastrophic thinking was determined using return to work as the standard for clinical importance[71]. While this study suggested COMMENCE did not result in clinically meaningful change as it relates to return to work, it is not certain that this change falls short of clinically meaningful as it relates to function. Further, MCID may not apply equally along the full range of the scale[82] and given the high initial values in this study sample, a smaller change may be clinically meaningful. COMMENCE did not improve

TSK-11, PSEQ, or PHQ-9 suggesting changes in fear, self-efficacy, and depressive symptoms are unlikely to be the underlying mechanisms that result in the change in function.

This final factor investigated as a potential mechanism contributing to changes in function was pain neurophysiology knowledge. Participants in this study demonstrated improved knowledge (21.5% of the RNPQ), but the changes seen are smaller than previous research suggests (32% of the RNPQ)[54]. This could be explained by a higher starting score on the RNPQ in the current study (38.5%) in comparison to previous research (29%)[54]. Alternatively, it could be due to the pain neurophysiology education being just one component in a multifactorial self-management program. With the amount of information delivered during COMMENCE, the retention of pain neurophysiology knowledge may have been reduced. Regardless of the lower magnitude of effect, change in pain knowledge could provide a variable for evaluation in future research evaluating potential mediators of functional change with interventions including pain neurophysiology education.

Since the intervention included exercise, some of the functional improvement may have related to increased physical capability. A limitation of the current study is the lack of physical performance measures, which may also represent an important variable that relates to self-reported function. Further, success in meeting exercise goals may have facilitated success in achieving functional goals despite the lack of changes in self-efficacy, depressive symptoms, or fear of movement or re-injury. Given the findings in

this study of small to moderate improvements in knowledge, psychological features and physical capability may have combined to enhance function.

There are a number of limitations in this study that should be considered when interpreting the results. First, due to the nature of the intervention and comparison, the participants and the health care provider were not blinded. The primary and secondary outcomes were self-report measure completed by the participants (not blinded). The treating physiotherapist was also present at the follow-up assessments. Also, the sample size was small and did not achieve the 110 participants calculated a priori. However, a power of greater than 0.9 was achieved for all primary and secondary outcomes using the standard deviation for each outcome found in the present study, a type 1 error rate of 0.05, and the a priori determined minimum clinically meaningful change. Finally, another potential limitation is the use of a wait-list control as a comparison group. Further research could include more robust comparators.

There are two limitations to the generalizability of the results of this study. The first is the participation of a single physiotherapist and involvement of a single site. The results, therefore, may not be generalizable to other populations and it is not possible to determine whether the results were attributed to the effects of the intervention or the therapist. The second is the population being studied. The priority populations at WACHC include people with: addictions concerns, mental health challenges, low incomes, lack of health insurance, and isolated seniors. These factors makes generalizability to populations without such barriers more challenging.

While the population may pose challenges in generalizing results to other populations, the population is a strength when applying the results to many primary health care settings where the population is often complex and experiencing multiple morbidities. This is important for a number of reasons. First, attendance is often low in this group making the provision of care challenging[46]. Lower adherence negatively impacts outcomes of self-management programs[59], so excluding participants with barriers to participation may result in greater estimates of effectiveness. Also, populations of people with barriers to accessing care have higher attrition rates with high rates of loss due to failure to locate[17,26]. This loss due to failure was experienced in the current study as well. The investigators in this study achieved a 76% follow-up rate using multiple methods of contacting the participant, providing multiple opportunities to reschedule assessments, and small cost reimbursements that were critical to retaining participants.

Treatment of chronic pain is a challenge[2,78]. Improving function is frequently reported as an important outcome by people living with chronic pain[9]. The results from the COMMENCE trial suggests the COMMENCE intervention provides anopportunity to improve function in primary health care settings in people with chronic pain and multiple comorbidities. There are a number of important additional research implications. The response to COMMENCE was positive, but variable[49]. A secondary analysis of trial data was planned from the outset to investigate factors that help to predict responders versus non-responders. The results of this secondary analysis may help clinicians direct treatment to the most appropriate participants and focus future research on identifying

more effective strategies for persons who are unlikely to respond to COMMENCE. Future research could also investigate factors predictive of adherence. Adherence was highly variable and greater participation was associated with better treatment response in this study. A better understanding of factors that may be barriers to participation is needed to help participants to overcome the barriers and improve outcomes for people who were unable to fully participate in this study.

Conclusion

This study provides evidence that self-management support with pain science education and exercise (COMMENCE) improves function over a 12-week follow-up period in comparison to a wait-list control. Future evidence should evaluate factors that contribute to adherence and response to COMMENCE.

Abbreviations:

COMMENCE : Chronic Pain Self-Management Support with Pain Science Education and Exercise

IEQ: Injustice Experience Questionnaire

NFRS: Numeric Fatigue Rating Scele

NPQ: Revised Neurophysiology of Pain Questionnaire

NPRS: Numeric Pain Rating Scale

PCS: Pain Catastrophizing Scale

PHQ-9: 9-item Patient Health Questionnaire

PPT: Pressure Pain Threshold

PROMIS: Patient Reported Outcome Measurements Information System

PI: Pain Interference

PSEQ: Pain Self-Efficacy Questionnaire

PTSD-C: Post-Traumatic Stress Disorder Checklist – Civilian Version

SMFA: Short Musculoskeletal Function Assessment

DI: Dysfunction Index

BI: Bother Index

TSK: Tampa Scale of Kinesiophobia

WACHC: Woodstock and Area Community Health Centre

Financial or competing interests

None of the study investigators have any financial or non-financial competing interests to report.

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Table 1: Description of outcome and covariate measures

Construct	Measure	Scale range	Minimum clinically meaningful change	Details
Primary outcome				
Function	Short-musculoskeletal Function Assessment (SMFA-DI)	0-100	7.3*	The SMFA-DI is a 34 item questionnaire with 25 items asking participants to rate how much difficulty they are having with functional tasks on a scale of 1 (no at all difficult) to 5 (unable to do) and 9 items on how often the person is experiencing functional problems answered on a scale of 1 (none of the time) to 5 (all of the time). The raw SMFA-DI score (34 to 170) is converted to a score out of 100 using the following formula: SMFA-DI = (sum of items 1 to 34 - 34) /136) * 100. Higher scores represent poorer function. 10 points on the raw scale was estimated as clinically meaningful in the study protocol using half of a standard deviations. Half a standard deviation is 7.3 on the final score out of 100
Secondary Outcomes				
How much a participant is bothered by difficulty with functional activities	Short-musculoskeletal Function Assessment (SMFA-BI)	0-24	10.5*	The SMFA-BI is a 12 item questionnaire asking participants to rate how much they are bothered by difficulty with functional activities on a scale of 1 (not at all bothered) to 5 (extremely bothered). The raw score (12 to 96) is converted to a score out of 100 using the following formula: SMFA-BI = (sum of items 35 to 46 - 12) /84) * 100. Higher scores represent greater bother by difficulty with functional activities. 10 points on the raw scale was estimated as clinically meaningful in the study protocol using half of a standard deviations. Half a standard deviation is 10.5 on the final score out of 100.
Pain Intensity	Numeric Pain Rating Scale (NPRS)	0-10	MCID = 2 points[70]	The NPRS used in this study asked participants to rate the intensity of their pain on average over the past 2-weeks from 0 (no pain) to 10 (worst imaginable pain)
Fatigue	Numeric Fatigue Rating Scale (NFRS)	0-10	MCID = 1.4 points[65]	The NFRS asked participants to rate their fatigue on average over the past 2-weeks from 0 (no fatigue) to 10 (worst imaginable fatigue)
Pain Interference	PROMIS Pain Interference Item Bank – Short-form 8a (PI)	0-100	5*	Pain interference is a measure of the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities. The PROMIS PI Short-form 8a asks the

				participant to rate 8 items on a scale of 1 (not at all) to 5 (very much) over the past 7 days. The PROMIS Assessment Center (https://www.assessmentcenter.net/) was used for scoring. The Assessment Center uses item-level calibrations for scoring and the final score is a t-score with 50 being the 50th percentile of a large sample of the United States population.
Work status				Work status was measured using three categories: working the same job as prior to the onset of pain, working a new job or a job with modified hours or duties due to pain, or not working
Global rating of change	Global Rating of Change (GROC)	-3 to +3	0.75*	Participants were asked to rate the overall change they have experienced since the initial assessment on a 7-point scale from -3 (much worse) to +3 (completely better).
Patient satisfaction	Patient satisfaction	-3 to +3	0.75*	Participants were asked to rate their satisfaction with the health care they received since the initial assessment on a 7-point scale from -3 (very dissatisfied) to +3 (very satisfied).
Catastrophic thinking	Pain Catastrophizing Scale (PCS)	0-52	MCID = 38%[71]	The PCS asks participants to rate the degree to which they experience 13 thoughts or feelings when they experience pain. Each item was rated on a scale of 0 (not at all) to 4 (all the time). The scale includes 13 items that capture the participants tendency ruminate about their pain, magnify their pain, or feel helpless in managing their pain.
Fear of movement, symptom exacerbation, or re-injury	11-item Tampa Scale of Kinesiophobia (TSK-11)	11-44	MDC = 5.6 points[28]	The TSK-11 asks participants to rate their agreement with 11 statements on a 4-point Likert scale of 1 (strongly disagree) to 4 (strongly agree). The TSK-11 is a shortened (11-item) version of the 17-item Tampa Scale of Kinesiophobia that aims to identify people with a fear of movement, symptom exacerbation, or re-injury.
Self efficacy	Pain Self Efficacy Questionnaire (PSEQ)	0-60	MCID = 9 to 11 points[47]	The PSEQ asks participants to rate how confident they are that you can do the following things at present, despite the pain. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident. The PSEQ includes 10 items that cover household, self-care, social, recreational, and vocational activities as well as the ability to cope without medication.
Pain knowledge	Revised Neurophysiology of Pain Questionnaire (NPQ)	0-13	1.1 points*	The revised neurophysiology of pain questionnaire is designed to measure understanding of pain neurophysiology. It uses thirteen questions that can be answered “True”, “False” or “Unsure”.

Depressive symptoms	Patient Health Questionnaire - 9 (PHQ-9)	0-27	5 points[43]	The PHQ-9 asks participants to rate each of nine DSM-IV criteria for depression as 0 (not at all) to 3 (nearly every day).
Health care utilization	Health care visits			The number of health care visits were calculated from the participants' electronic medical record over the 12-weeks prior to the assessment. This was completed at baseline and 12-week follow-up. The number of visits in the following categories were calculated: primary health care visits (with any registered health care provider at the community health centre including physician, nurse, nurse practitioner, social worker, dietician, and physiotherapist outside of the study), emergency department visits, specialist visits (including any specialist e.g. physiatrist, orthopaedic surgeon, neurologist, neurosurgeon), and diagnostic imaging visits (e.g. x-ray, MRI, ultrasound, CT scan). Whether or not the reason for the visit was related to their pain or abilities was not recorded.
Global rating of change	Global rating of change	-3 to +3		This global rating of change scale asks the participant to rate their overall change since the baseline assessment on a scale of -3 (much worse to +3 completely better).
Satisfaction with healthcare	Satisfaction with healthcare	-3 to +3		This patient satisfaction scale asks the participant to rate their satisfaction with their health care on a scale of -3 (very dissatisfied) to +3 (very satisfied).
Covariate measures				
Post-traumatic stress symptoms	Post-traumatic Stress Disorder Checklist –Civilian Version (PCL)	17-85		The PTSD-C is a 17-item scale based on the DSM-IV criteria for PTSD. Each item is rated on a scale of 1 (not at all) to 5 (extremely).
Sense of perceived injustice	Injustice Experience Questionnaire (IEQ)	0-48		The IEQ asks participants how frequently they experience 12 thoughts or feelings when they think about pain. Each item is rated on a scale from 0 (never) to 4 (all the time).
Medications	Number of medications	0-		This measure is a simple count of the number of medications a participant is taking. This measure has been used as a proxy measure for number of comorbidities[29].
Comorbidities	Disease count	0-30		Unweighted disease count was used as a measure of the number of morbidities. The list of 30 items used for this disease count were originally suggested by Elixhauser[19]. They included: congestive heart failure, cardiac arrhythmias, valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hyptertension, paralysis, other neurological disorders, chronic obstructive

				pulmonary disease, diabetes, hypothyroidism, renal failure, liver disease, peptic ulcer disease, HIV or AIDS, lymphoma, metastatic cancer, solid tumor wihtout metastasis, arthritis, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, blood loss anemia, deficiency anemias, alcohol abuse, drug abuse, psychoses, depression.
Number of regions with pain				The number of boy regions with pain were assessed by asking participants to check any of the following 24 body regions: head, neck, low back, mid/upper back, as well as left and right: shoulder, arm, elbow, wrist, hand, hip, leg, knee, ankle, foot.
Expectations for pain relief				Participant expectations for pain relief were assessed by asking participants: Do you think your pain will improve throughout this program?
Expectations for improved function				Participant expectations for improvements in function were assessed by asking participants: Do you think your functional abilities will improve throughout this program?

*****In the absence of an established MCID or MDC, this case series considered half a standard deviation as a minimally important difference[61]. In these instances, clinical data from Woodstock and Area Community Health Centre was used to establish the standard deviation.

Table 2: Baseline characteristics of participants

	Treatment group			Wait-list group		
	Mean (SD)	**Median (IQR)**	**N(%)**	**Mean (SD)**	**Median (IQR)**	**N(%)**
Age	53.4(13.5)			52.2(11.7)		
Gender						
Male			12(24)			15(29)
Female			38(76)			37(71)
Education						
Less than high school education			13(26)			11(21)
High school diploma			21(42)			30(58)
College or University diploma or degree			16(32)			11(21)
Duration of pain		120 (59-201)			120(37-228)	
Number of regions with pain		6(3-13)			7(4-14)	
Number of medications		5 (3-7)			4(1-8)	
Comorbidities (disease count)		3(2-5)			3(2-5)	
Depressive symptoms (PHQ-9)	13.1(6.4)			13.1(7.8)		
Post-traumatic stress symptoms (PCL)	43.9(17.1)			45.0(17.1)		
Sense of perceived injustice (IEQ)	26.4(12.8)			26.7(14.0)		
Pain expectations						
Yes			11(22)			14(27)
No			6(12)			1(2)
I don’t know			33(66)			37(71)
Function expectations						
Yes			17(34)			16(31)
No			4(8)			3(6)
I don’t know			29(58)			33(63)

Table 3: Frequency of comorbidities

	Treatment group (n=49)	**Wait-list group (n=43)**
Comorbidity	**Number of participants (%)**	**Number of participants (%)**
Congestive heart failure	3 (6.1)	2 (4.7)
Cardiac arrhythmias	5 (10.2)	2 (4.7)
Valvular disease	0 (0)	0 (0)
Pulmonary circulation disorder	1 (2.0)	1 (2.3)
Peripheral vascular disorders	3 (6.1)	3 (7.0)
Hypertension	23 (46.9)	14 (32.6)
Paralysis	1 (2.0)	1 (2.3)
Other neurological disorder	5 (10.2)	7 (16.3)
Chronic obstructive pulmonary disease or	11 (22.4)	12 (27.9)
Diabetes	14 (28.6)	13 (30.2)
Hypothyroidism	7 (14.3)	4 (9.3)
Renal disease, insufficiency, or failure	4 (8.2)	1 (2.3)
Liver disease	2 (4.1)	1 (2.3)
Peptic ulcer disease	2 (4.1)	1 (2.3)
HIV or AIDS	1 (2.0)	0 (0)
Lymphoma	0 (0)	0 (0)
Metastatic cancer (history)	1 (2.0)	3 (7.0)
Solid tumour without metastisis	2 (4.1)	2 (4.7)
Rheumatoid arthritis	3 (6.1)	4 (9.3)
Coagulopathy	0 (0)	1 (2.3)
obesity	6 (12.2)	9 (20.9)
Weight loss	0 (0)	0 (0)
Fluid and electrolyte disorders	0 (0)	0 (0)
Blood loss anemia	0 (0)	0 (0)
Deficiency anemias	4 (8.2)	9 (20.9)
Alcohol abuse	3 (6.1)	7 (16.3)
Drug abuse	6 (12.2)	4 (9.3)

Psychoses	4 (8.2)	4 (9.3)
Depression	32 (65.3)	26 (60.5)

Table 4: Outcome measures at baseline, 1-week follow-up, and 12-week follow-up

	Baseline				**1-week follow-up**				**12-week follow-up**			
		Treatment		**Wait-list**		**Treatment**		**Wait-list**		**Treatment**		**Wait-list**
	n	**Mean (SD)**	**N**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**n**	**Mean (SD)**
Function (SMFA-DI)	50	44.3(12.8)	52	44.4(16.2)	45	35.3(17.4)	48	44.1(18.1)	38	36.2(18.1)	42	43.2(20.3)
How much person is bothered by functional difficulties (SMFA-BI)	50	60.0(19.6)	52	58.8(22.7)	45	44.2(23.9)	48	54.1(23.7)	38	42.7(22.2)	42	53.9(25.9)
Pain intensity (NPRS)	50	7.2(1.8)	52	7.6(1.8)	45	5.7(1.9)	47	7.2(2.3)	38	5.6(2.1)	42	6.6(2.5)
Fatigue (NFRS)	50	6.9(1.7)	52	7.0(2.2)	45	5.7(2.1)	47	6.1(2.8)	37	5.6(2.2)	42	6.1(2.4)
Pain Interference (PI)	50	65.3(7.2)	52	65.2(7.1)	45	61.6(7.2)	48	63.2(8.5)	37	61.6(7.7)	41	62.8(9.1)
Catastrophic thinking (PCS)	49	28.0(13.9)	52	27.9(15.4)	45	19.2(14.0)	47	25.6(16.3)	36	18.3(15.3)	40	25.0(16.6)
Fear of movement/re-injury(TSK)	50	27.7(7.7)	52	28.4(7.7)	45	25.8(8.1)	47	28.6(7.5)	37	25.6(7.3)	40	26.3(8.9)
Self-efficacy (PSEQ)	50	31.4(14.2)	52	28.1(13.5)	45	35.5(13.2)	47	30.5(14.9)	37	36.0(13.4)	40	30.9(17.2)
Depressive symptoms (PHQ-9)	50	13.1(6.4)	52	13.1(7.8)	45	9.7(6.3)	48	12.5(7.5)	36	10.6(6.7)	41	13.2(8.2)
Revised neurophysiology of pain questionnaire (RNPQ)	50	5.0(2.2)	52	4.8(2.1)	45	7.0(2.4)	47	4.2(2.1)	37	6.8(2.1)	40	4.0(2.3)
Health care visits during prior 12 weeks												
Primary health care visits	45	3.8(4.1)	43	4.0(3.7)					45	2.8 (2.7)	43	3.2(3.3)
Emergency department visits	45	0.1(0.4)	43	0.4(0.8)					45	0.2(0.6)	43	0.2(0.6)
Specialist appointment visits	45	0.7(1.2)	43	0.4(0.8)					45	0.3(0.6)	43	0.5(0.9)
Diagnostic imaging visits	45	0.6(0.8)	43	0.8(1.0)					45	0.3(0.7)	43	0.5(0.9)
Global rating of change					45	0.7(1.3)	48	-0.6(1.5)	38	0.6(1.1)	41	-0.8(1.7)
Patient satisfaction					45	1.8(1.4)	48	0.6(1.5)				

Table 5: Work status at baseline, 1-week follow-up, and 12-week follow-up

	Baseline		**1-week follow-up**		**12-week follow-up**	
	Treatment	**Wait-list**	**Treatment**	**Wait-list**	**Treatment**	**Wait-list**
	N(%)	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**

Work status						
Not working	43(86)	48(92)	37(80)	44(90)	30(77)	39(91)
Working new or modified job	3(6)	0(0)	0(0)	0(0)	0(0)	0(0)
Working same job	4(8)	4(8)	9(20)	5(10)	9(23)	4(9)

Table 6: Results of mixed effects model with repeated measures at baseline, 1-week and 12-week follow-up

	Contrast	**95% CI**	**Bonferroni 95% CI**	**P**	**Bonferroni p**
Function (SMFA-DI)					
1-week follow-up	-8.9	-12.4 to -3.8	-15.3 to -2.4	<0.01	<0.01
12-week follow-up	-8.0	-11.7 to -2.7	-14.7 to -1.3	<0.01	0.01
How much person is bothered by functional difficulties (SMFA-BI)					
1-week follow-up	-8.7	-16.6 to -3.4	-17.1 to -0.3	0.01	0.04
12-week follow-up	-12.0	-20.2 to -6.3	-20.8 to -3.2	<0.01	<0.01
Pain intensity (NPRS)					
1-week follow-up	-1.4	-2.0 to -0.1	-2.4 to -0.5	<0.01	<0.01
12-week follow-up	-1.0	-1.6 to 0.4	-2.1 to -0.1	0.02	0.04
Fatigue (NFRS)					
1-week follow-up	-0.6	-1.4 to 0.3	-1.6 to 0.3	0.12	0.36
12-week follow-up	-0.7	-1.6 to 0.25	-1.8 to 0.3	0.08	0.24
Pain Interference (PI)					
1-week follow-up	-1.4	-4.4 to 1.3	-4.4 to 1.6	0.26	0.77
12-week follow-up	-1.6	-4.7 to 1.4	-4.8 to 1.7	0.25	0.75
Catastrophic thinking (PCS)					
1-week follow-up	-6.2	-10.3 to -2.2	-12.2 to -0.2	0.01	0.04
12-week follow-up	-8.2	-12.7 to -4.0	-14.5 to -2.0	<0.01	<0.01
Fear of movement/re-injury(TSK)					
1-week follow-up	-2.9	-5.0 to 0.05	-6.3 to 0.6	0.05	0.14
12-week follow-up	-1.1	-3.3 to 2.0	-4.7 to 2.6	0.49	1.00
Self-efficacy (PSEQ)					
1-week follow-up	5.2	-1.8 to 6.0	-0.7 to 11.2	0.04	0.11
12-week follow-up	7.0	-0.3 to 8.0	0.8 to 13.2	<0.01	0.02
Depressive symptoms (PHQ-9)					

1-week follow-up	-2.5	-4.9 to -0.5	-5.7 to 0.7	0.06	0.18
12-week follow-up	-3.0	-5.5 to-0.8	-6.4 to 0.4	0.03	0.10
Revised neurophysiology of pain questionnaire (RNPQ)					
1-week follow-up	2.8	1.7 to 3.6	1.7 to 3.9	<0.01	<0.01
12-week follow-up	2.8	1.6 to 3.6	1.6 to 3.9	<0.01	<0.01
Health care visits during prior 12 weeks at 12 week follow-up					
Primary health care visits	-0.27	-1.26 to 0.73	-	0.60	
Emergency department visits	0.02	-0.23 to 0.27		0.87	
Specialist appointment visits	-0.26	-0.56 to 0.05		0.09	
Diagnostic imaging visits	-0.18	-0.51 to 0.14		0.27	
Global rating of change					
1-week follow-up	1.4	0.9 To 2.0	0.8 to 2.0	<0.01	<0.01
12-week follow-up	1.4	0.7 to 2.1	0.8 to 2.1	<0.01	<0.01
Patient satisfaction with healthcare					
1-week follow-up	1.2	0.6 to 1.9		<0.01	

Legend: Mixed effects model included age, gender, number of medications, and PHQ-9 (Depressive symptoms) as covariates.

Table 7: Results of mixed-effects analysis stratified by gender

	coefficient	**95% CI**	**p**	**Contrast**	**Bonferroni 95% CI**	**P**	**Bonferroni p**
SMFAD females							
1-week follow-up	-9.7	-14.6 to -4.9	<0.01	-10.7	-18.1 to -3.4	<0.01	<0.01
12-week follow-up	-6.9	-12.1 to -1.7	<0.01	-7.9	-15.5 to -0.2	0.01	0.04
SMFAD males							
1-week follow-up	-3.9	-12.3 to 4.5	0.37	-5.0	-17.9 to 7.9	0.35	1.00
12-week follow-up	-8.0	-16.8 to 0.8	0.08	-9.1	-22.3 to 4.2	0.10	0.31

Legend: Mixed effects model included age, gender, number of medications, and PHQ-9 (depressive symptoms) as covariates

Table 8: Adherence to included self-management strategies at individual visits

	Number of visits including strategy	Number of attendees	Attendees completing strategy	% of attendees completing strategy
Goal setting	1	33	30	90.9
Frequent pain-free movements (completion = at least 3 times/day)	1	33	26	78.8
	2	33	28	84.8
	3	27	23	85.2
	4	26	22	84.6
	5	24	20	83.3
	6	24	22	91.7
Goal-specific exercises (completion = at least once/day)	1	33	27	81.8
	2	33	30	90.9
	3	27	22	81.5
	4	26	21	80.8
	5	24	20	83.3
	6	24	21	87.5
Activity schedule and log	2	33	24	72.7
	3	27	21	77.8
	4	26	16	61.5
	5	24	12	50.0
	6	24	12	50.0
Graded activity plan	2	33	28	84.8
	3	27	26	96.3
	4	26	24	92.3
	5	24	22	91.7
	6	24	20	83.3
Breathing (completion = at least once/day)	3	27	21	77.8
	4	26	15	57.7
	5	24	10	41.7
	6	24	11	45.8
Relaxation strategy (completion = at least once/day)	3	27	19	70.4
	4	26	15	57.7
	5	24	12	50.0
	6	24	9	37.5
Develop plan for improved sleep	3	27	17	63.0
Positive self-talk	4	26	18	69.2
	5	24	12	50
Thought monitoring	4	26	8	30.8
	5	24	6	25
Develop flare up plan	5	24	21	87.5
Reflection on progress towards goals	4	26	23	88.5
	6	24	24	100

Legend: Completion of self-management strategy was recorded by the treating physiotherapist if the participant recorded completing the strategy in their workbook. Participants were also judged to have completed the strategy if they self-reported completion, but reported they found using the workbook too consuming of time or attentional resources.

Table 9: Results of sensitivity analysis comparing people in treatment group who attended at least 75% of visits (n=25) to control group (n=52)

	Contrast	Bonferroni 95% CI	P	Bonferroni p
SMFAD attenders only				
1-week follow-up	-12.5	-19.9 to -5.0	<0.01	<0.01
12-week follow-up	-11.9	-19.5 to -4.4	<0.01	<0.01

Legend: Mixed effects model included age, gender, number of medications, and PHQ-9 (depressive symptoms) as covariates

Table 10: Effect estimates by attendance

	n	SMFA-DI change score (standard deviation)
Attended 0-2 visits (0-25%)	21	0.9(12.0)
Attended 3-5 visits (25-49%)	9	-0.8(13.0)
Attended 6-8 visits (50–74%)	9	-8.7(6.4)
Attended 9-12 visits (75-100%)	25	-11.5(13.7)

SMFA-DI change score = SMFA-DI at 12-week follow-up – SMFA-DI at baseline

Table 11: Co-interventions by group

	Treatment group	Wait-list group	Chi squared
Did you receive other treatment?			
Yes	13	11	0.04 (p=0.85)
No	28	26	
Providers			
Family physician	4	9	2.10 (p=0.15)
Physiatrist	0	4	0.94 (p=0.33)
Psychologist	3	1	1.28 (p=0.26)
Neurologist	0	2	1.92 (p=0.17)
Rheumatologist	1	0	1.11 (p=0.29)
Orthopaedic surgeon	1	3	1.00 (p=0.32)
Neurosurgeon	1	0	1.11 (p=0.29)
Physical therapist	1	3	0.92 (p=0.34)
Occupational therapist	0	2	1.92 (p=0.17)
Chiropractor	0	1	0.94 (p=0.33)
Acupuncturist	0	1	0.94 (p=0.33)
Other	5	5	0.01 (p=0.94)
Treatment			
Medication	5	6	0.04 (p=0.85)
Nerve block	0	1	0.94 (p=0.33)
Other injection	2	3	0.14 (p=0.71)
Exercise	2	4	0.50 (p=0.48)
Education	1	0	1.11 (p=0.29)
Ergonomic advice	1	1	0.00 (p=0.95)
Acupuncture	1	1	0.00 (p=0.95)
Psychologist care	0	0	0.00 (p>0.99)
Electrical modalities	0	1	0.94 (p=0.33)
Multidisciplinary treatment	0	0	0.00 (p>0.99)
Other	2	5	1.48 (p=0.22)

Figure 1: Study flow diagram

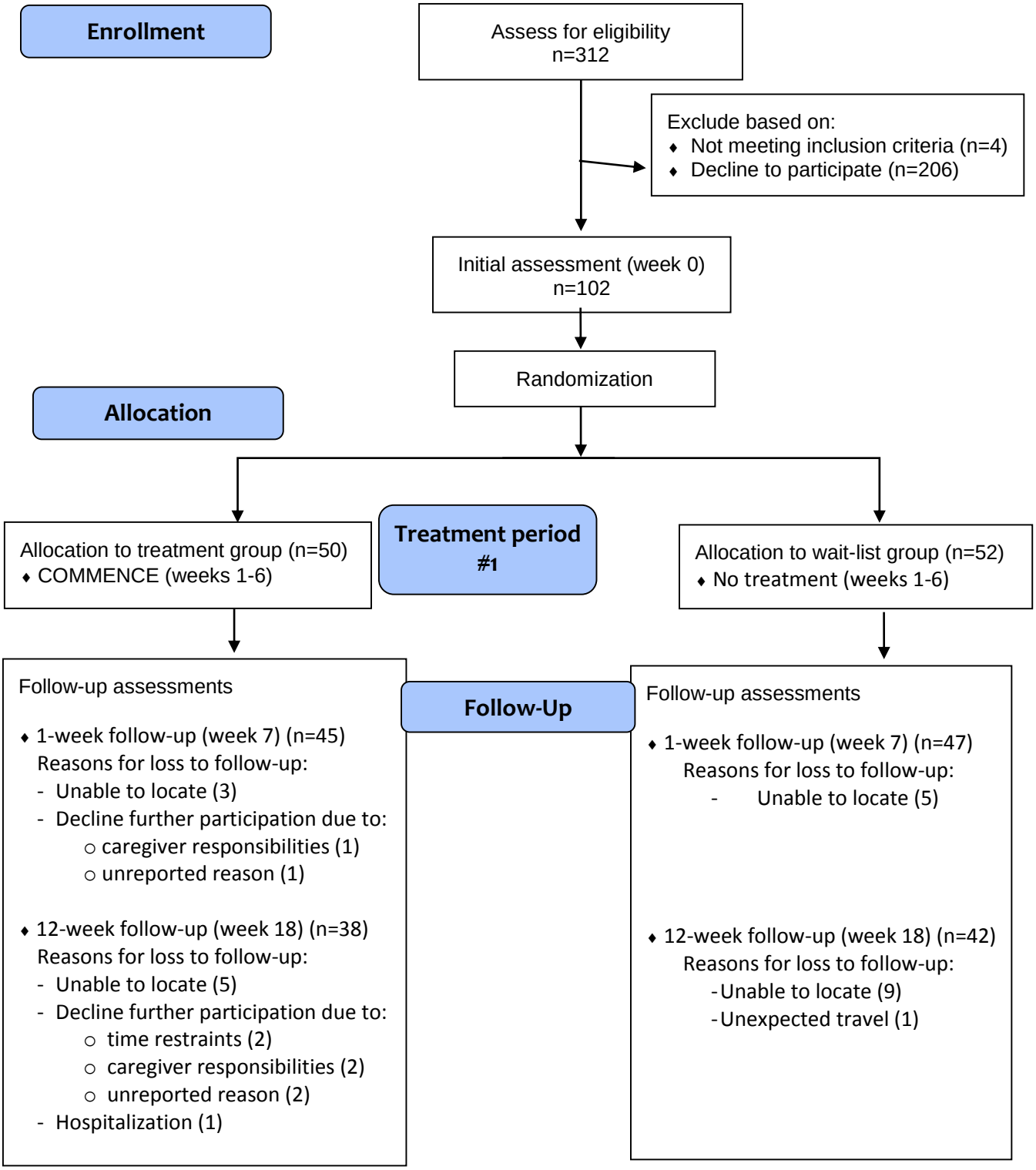
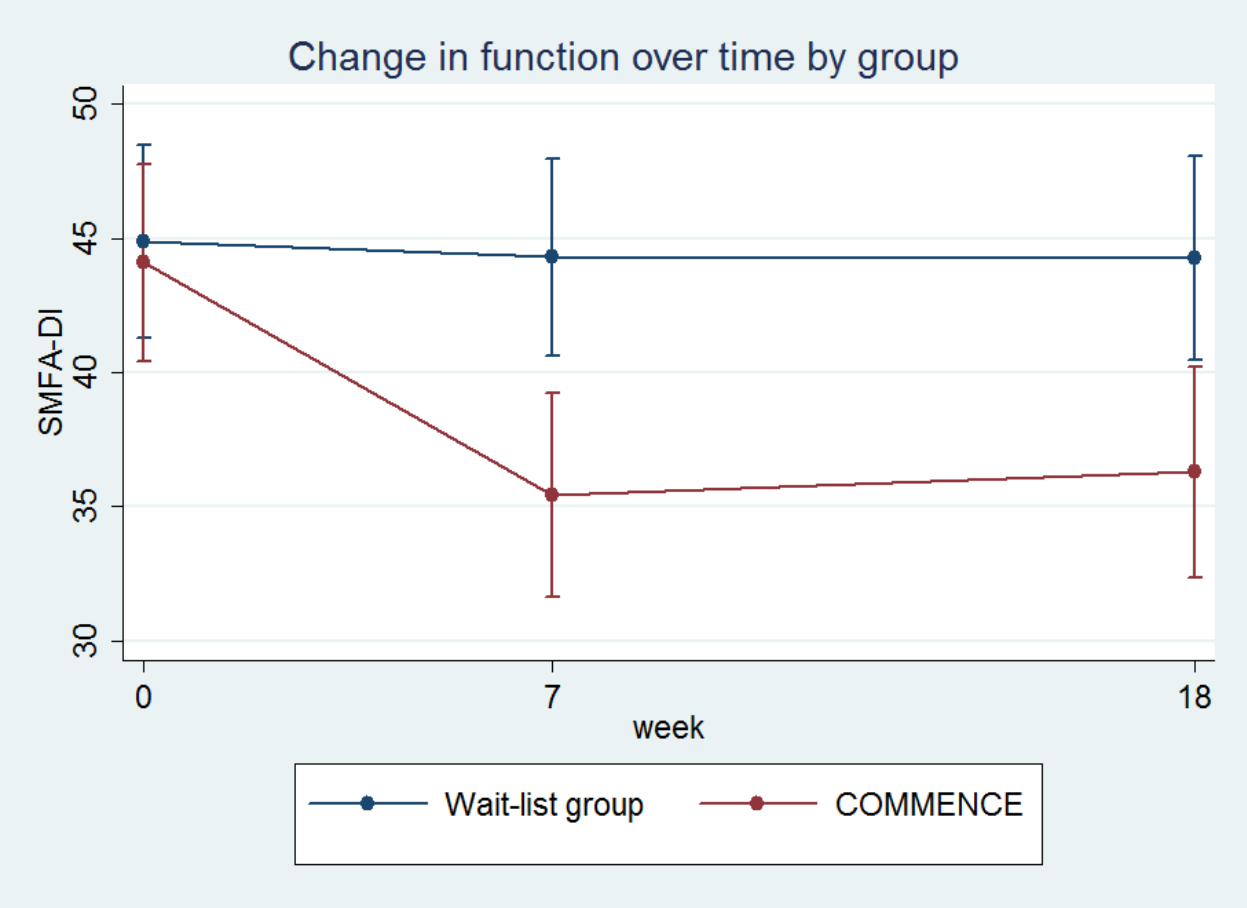


Figure 2 – Change in function over time by group



CHAPTER 6: PREDICTORS OF FUNCTION AFTER CHRONIC PAIN SELF-MANAGEMENT SUPPORT WITH PAIN SCIENCE EDUCATION AND EXERCISE

TITLE

Predictors of functional outcomes of chronic pain self-management support with pain science education and exercise

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Abstract

Background: Chronic pain self-management support with pain science education and exercise has been shown to have a positive effect on function for people with chronic pain in a primary health care setting; although effects are variable. The purpose of this study was to determine which combination of variables predict poorer function 1-week following the program. **Methods:** This study was a planned secondary analysis of a randomized controlled trial with 102 participants that compared chronic pain self-management support with pain science education and exercise (COMMENCE) to a wait-list control. Function was measured using the Short Musculoskeletal Function Assessment – Dysfunction Index. Potential predictors of poorer function included age, gender, duration of symptoms, number of comorbidities, expectations for recovery, pain intensity, fatigue, cognitive risk factors for persistent pain-related disability, depressive symptoms, post-traumatic stress symptoms, and mechanical hyperalgesia. The bivariate correlation for each independent variable with function at 1-week follow-up was estimated using Pearson or Spearman correlation coefficients. Variables with a significance of <0.10 were included into a multiple regression model to determine which combination of baseline variables best predicted function at 1-week follow-up, controlling for age, gender, and baseline function. **Results:** Only baseline disease count (Spearman rho = 0.28) and pain intensity (r = -0.20) had a bivariate association with reduction in function. The predictive model for function after the intervention consisted of age, gender, pre-treatment function and disease count. This model had an R-squared of 0.63 [$F(4,66)=29.03$, $p<0.01$)]. **Conclusions:** This study provides preliminary evidence

that greater comorbidity and poorer baseline function both contribute poorer function after participation in a chronic pain self-management program that includes pain science education and exercise.

Background

An estimated 19% to 29% of people in North America and Europe experience chronic pain [1–3]. Chronic pain is one of the largest contributors to disability[4] and it poses a large socioeconomic burden including health care costs and reduced workplace productivity[5–7]. Understanding how to reduce pain-related disability is important to improving the quality of life of people experiencing pain and reducing the burden health care systems.

Recent evidence from a randomized controlled trial suggests chronic pain self-management support with pain science education and exercise (COMMENCE) is effective at improving function for people with chronic pain[8], but the response to the program was highly variable. The variance was evident in a multiple case study design in which functional changes in the six presented cases varied from an 11.5% decline to a 41.9% improvement[9]. While a qualitative approach was able to discern that personal circumstances influenced participation in the program, quantitative methods are needed to discern what factors contribute to variations in outcome and to quantify the extent of their influence.

Evidence suggests a number of prognostic indicators that may be helpful in identifying people more or less likely to experience poorer function while receiving

healthcare. Factors previously associated with reduced functional rehabilitation outcomes include: high initial pain levels[10–12], duration of symptoms[13], number of comorbidities[14,15], female sex[11], lower expectations of recovery[16], low pressure pain thresholds[17], cold hyperalgesia[18–20], depression[21,22], post-traumatic stress disorder[19], catastrophic thinking[23–25], sense of perceived injustice[26], and fear of movement or re-injury[27–29]. In anticipation that factors described in the literature might predict responses to COMMENCE, a slate of potential predictors was included in the baseline assessments. However, most of the evidence about potential predictors of poorer function cited above, comes from studies on multidisciplinary rehabilitation or individualized therapy. Many of the factors identified above have not been evaluated as potential predictors of self-management outcomes. Further, the context for our intervention was a population who had complex medical and social issues that might affect prognostic processes.

A systematic review of prognostic indicators for self-management programs for people with chronic pain suggests fewer depressive symptoms and greater self-efficacy predict better functional outcomes[30]. The studies included in this systematic review evaluated predictors of response in people with low back pain and employees who were continuing to work, but reported pain[30]. It is not certain whether these results can be applied to persons with chronic pain and multiple comorbidities often seen in primary health care practices[31,32]. Since both chronic pain[5,33] and multimorbidity[15,34,35] are associated with reduced function, there is reason to investigate predictors of response in this population specifically.

A greater understanding of predictors of functional outcomes after COMMENCE could help in further development of the program. Identifying those persons most likely to respond to the program could help facilitate targeting the intervention to those most likely to benefit. Identifying those unlikely to respond to COMMENCE could reduce costs and help inform future research and program development aimed at improving health outcomes for those unlikely to respond to this type of intervention.

Given the need for empirical data to predict responses to COMMENCE, the objective of this study was to identify demographic, clinical, psychological, or psychophysical variables that were predictive of poorer function after chronic pain self-management support with pain science education and exercise (COMMENCE).

Methods

Design

This study was a planned secondary analysis of a randomized controlled trial comparing COMMENCE to a wait-list control. This was an embedded prospective cohort study using the treatment period of both the treatment group (baseline to 7-weeks) and wait-list group (18-25 weeks). See figure 1 for a study flow diagram.

The original plan for this analysis was published in the randomized controlled trial protocol[36]. There was one deviation from the original protocol. The planned end-point of this study was the 12-week follow-up, but given high attrition rates at the final assessment time-point the investigators decided to assess the early treatment response

(i.e. 1-week after the end of the program). The investigators felt confident that this was appropriate given the maintenance of outcomes over the 12-week follow-up period[8].

Participants

All participants (n=102) were experiencing chronic pain and were recruited at Woodstock and Area Community Health Centre (WACHC) in Woodstock, Ontario, Canada. Participants met the criteria for at least one of the priority populations serviced by WACHC: addictions concerns, mental health challenges, low incomes, lack of health insurance, and isolated seniors.

All Participants had experienced pain for at least 12-weeks. All participants were able to read, write, and speak English. Exclusion criteria included: cancer related pain, casted fracture or surgery within the last 26 weeks, evidence of upper motor neuron lesion, and medical "red flags" including unremitting night pain, palpable tumor, sudden weight loss or weight gain, bowel or bladder incontinence, saddle anaesthesia, bilateral or multi-segmental loss of sensory or motor function, fever/chills, diplopia, dysphagia, dysarthria, drop attacks, or unexplained nystagmus.

Intervention

The intervention in this study was ChrOnic pain self-ManageMent support with pain science EducatioN and exerCisE (COMMENCE). COMMENCE consisted of two visits with a physiotherapist per week over six weeks. One of the two visits was in a group setting, where the emphasis was on pain science education and self-management

strategies using cognitive behavioural principles to support behaviour change. The second visit was an individualized, one-to-one session focused on providing support to implement self-management strategies and develop an individualized, goal-oriented exercise program. Both the individual sessions and the group sessions were carried out by a single physiotherapist for all participants. A case series investigating the response of six individuals to RESPONSE provides a more detailed description of the intervention[37].

Ethical Approval

All participants provided informed consent with the treating physiotherapist and study investigator prior to the assessment. Ethics approval was provided by Hamilton Integrated Research Ethics Board.

Assessment methods

Assessments were conducted at baseline, 7-weeks, 18-weeks, 25-weeks, and 36-weeks. For the purposes of this prognostic study, predictor variables were collected at the pre-treatment assessment. For the treatment group, the pre-treatment assessment was at baseline. For the wait-list group, the pre-treatment assessment was at 18-weeks. For the treatment group, the dependent variable (function) was collected at the 7-week assessment and for the wait-list group, the dependent variable was collected at the 25-week assessment.

Dependent variable

The dependent variable was function as measured by Short-Musculoskeletal Function Assessment – Dysfunction Index (SMFA-DI)[38]. The SMFA-DI includes 25 questions asking participants to rate the difficulty they are having with specific functional tasks on a scale of 1 (not at all difficult) to 5 (unable to do) and 9 questions asking participants how often they experience functional problems on a scale of 1 (none of the time) to 5 (all of the time). The final SMFA-DI score (0-100) is calculated using the following formula: SMFA-DI = (sum of items 1 to 34 - 34) /136) * 100. Missing items were inputted as the mean of the answered items from the same scale as per the scoring instructions[39]. Higher scores on the SMFA-DI represent poorer function.

Independent variables

Demographic and clinical information: The following demographic and clinical characteristics were collected as potential predictors of reduced functional outcomes: age, gender, education (<high school diploma, high school diploma, post-secondary degree or diploma), and duration of symptoms (months).

Self-report measures: The following self-report measures were collected as potential predictors of function. The construct measured by each of these scales along with the instructions and range of the scale are described in Table 1.

- Numeric Pain Rating Scale (NPRS)[40]
- Numeric Fatigue Rating Scale (NFRS)[41]
- Number of regions with pain

- Patient Health Questionnaire (PHQ-9)[42–44]
- Post-traumatic Stress Disorder Checklist (PTSD-C)[45,46]
- Pain Catastrophizing Scale (PCS)[23,47,48]
- Tampa Scale of Kinesiophobia - 11 (TSK-11)[49]
- Injustice Experience Questionnaire (IEQ)[26]
- Pain Self Efficacy Questionnaire (PSEQ)[50–52]
- Disease count[53,54]
- Number of medications[55]
- Expectations for improvements in pain
- Expectations for improvement in function

Psychophysical measures: Two psychophysical measures were performed in order to estimate sensitivity of the nervous system both locally (at the point identified as "most tender") and at two standardized locations (the area of skin over the muscle belly of the upper fibres of trapezius and tibialis anterior).

*Pressure pain threshold***:** Pressure pain threshold was measured using a handheld digital algometer (The Wagner FDX-25; Wagner Instruments, Greenwich, CT) and methods previously shown to demonstrate high reliability[17,56]. The algometers were calibrated using a known-weight technique prior to commencing the study. The algometer was pressed perpendicularly into the skin at a rate of approximately 50 kPa/s (5 N/s) by trained research assistants. Three measurements of pressure pain threshold were recorded

at each site and on each side of the body. The following instructions were given prior to pressure application[57]: "I'm going to begin applying pressure to your skin. I want you to tell me the moment the sensation changes from comfortable pressure to slightly unpleasant pain." For consistency the more tender side was tested first followed by the less-tender side at the "most tender" location. At the standardized locations, the right side was tested first, followed by the left.

*Cold hyperalgesia testing***:** Cold hyperalgesia was tested using a novel test. This device consists of a Peltier Cooler used to cool 2 pairs of cylinders. The two pairs of cylinders were made of acrylic and copper. When the temperature of the cooler was 0 degrees, the cylinders of different materials felt similar to different temperatures on the skin. The acrylic cylinder felt like 18 degrees, and the copper felt like 0 degrees. Each of the two cylinders were placed in contact with the skin at the three locations in the same randomized order as was used for pressure pain threshold. The order of the two materials was also randomized with each of the two materials being placed on the skin three times on each side. The participant was asked to rate how cold the cylinder is on a 21 point scale (0 is unable to detect the temperature, 10 is cold but not painful, 11 is cold and slightly uncomfortable, and 20 is unbearable pain).

Data analyses

Analysis was conducted using Stata, version 13 (StataCorp, College Station, TX, USA). Descriptive statistics were presented for all variables. Prior to pooling the pre-

treatment data from the treatment group (baseline) and wait-list group (18-weeks), t-tests (continuous data) or chi-squared tests (categorical data) were performed to investigate differences between groups for all measures. Similarly, post-treatment data from the treatment group (7-weeks) was compared with post-treatment data from the wait-list group (25-weeks). Given no significant differences between groups, measures between groups were combined and will be from here forward referred to as pre-treatment measures and post-treatment measures.

Correlation analysis was performed to estimate the correlation between each pre-treatment measure and change in SMFA-DI (post-treatment – pre-treatment). Spearman's rank correlation was used for analysis when data was categorical (gender, education) and for continuous data when assumptions for Pearson correlation were not met. Pearson r was used for analysis when all assumptions were met. Bivariate normality was assessed using the Doornik-Hansen test[58]. Scatterplots were visualized to assess for linearity and homoscedasticity.

Independent variables with a bivariate correlation with change in function ($p<0.1$) were then entered into a multiple regression model to determine what factors predict post-treatment function. Age, gender, and pre-treatment SMFA-DI score were force entered as covariates. Variables not contributing to the model (F-statistic $p<0.05$) were removed. Standard checking of statistical assumptions for multiple regression was performed.

Resampling validation was used to assess the internal validity of the final model. A resampling validation using 400 bootstrap samples was performed, repeatedly

partitioning data into training and test samples. Shrinkage was calculated by subtracting the mean R-squared from the test samples from the mean R-squared from the training samples and determining the percentage shrinkage from the original model. This was an important step to determine the stability of the model and the degree of over-fitting[59].

The model was then applied to the wait-list period of the wait-list group to determine whether the regression model developed using the treatment-periods of both groups was more likely evaluating predictors of response or identifying prognostic factors for functional outcomes regardless of treatment participation. Shrinkage was calculated using the following formula: Shrinkage = [(R-squared from the model developed in treatment periods – R-squared from model applied to the wait-list period) / R-squared from the model developed in treatment periods]*100

Results

The final sample included 102 participants at the pre-treatment assessment and 79 participants at the post-treatment assessment (1-week follow-up). Participants had a mean age of 52.8 years(+/-12.6), a median duration of pain of 10 years (IQR 4 – 16.5) and had a median of 3 comorbidities (IQR 2-4). Descriptive statistics for all independent variables are provided for both groups independently and for the pooled pre-treatment data in table 2 and 3.

Bivariate correlation analysis

The results of the bivariate correlation coefficient for the correlation between each independent and change in SMFA-DI are presented in table 4. Only higher disease count (Spearman rho = 0.28, p=0.02) and higher pain intensity (r = 0.20, p=0.04). had a significant correlation with increase in SMFA-DI.

Final regression model

Age, gender, pre-treatment SMFA-DI, and disease count were entered into the multiple regression model. The final model explained 63% of the variance in post-treatment SMFA-DI [$F(4,66)=29.03$, $p<0.01$). The model suggested greater number of comorbidities was associated with higher post-treatment SMFA-DI (poorer function). See table 5 for results of the regression analysis.

The final regression equation was:

Post treatment SMFA-DI = 3.75+ 2.14(disease count) + 0.74(pre-treatment SMFA-DI) - 1.43 (gender; female=0, male=1) – 0.13 (age)

When this model was applied to the wait-list group during the wait-list period, the model explained 77% of the variance in post-treatment SMFA-DI with a shrinkage from the model developed from the treatment period of -22.2%. The partial R-squared of disease count decreased from 0.10 to 0.07 and became a non-significant predictor within the model. See table 6 for the results of the regression model applied to the wait period of the wait-list group.

Internal validation

The resampling validation suggested a mean R-squared in the training samples of 0.65, a mean R-squared in the test samples of 0.57, and a shrinkage of 12.7%%.

Discussion

The results of this study provide preliminary evidence that people with chronic pain who have a greater number of comorbidities are more likely to have poorer function at the end of a self-management program after controlling for baseline function.

Perhaps the most interesting finding from this research is that the findings from the COMMENCE study did not replicate findings from previous studies. Previous research in primary care has identified greater pain, catastrophic thinking, and wider spread symptoms as prognostic indicators for people seeking care for chronic low back pain[60]. Younger age, less pain, and shorter duration of symptoms were associated with better function at follow-up for people with chronic pain participating in multidisciplinary treatment[13]. In people with fibromyalgia attending multidisciplinary treatment, greater depressive symptoms were predictive of poorer functional outcomes[61]. Fear avoidance beliefs and a sense of perceived injustice have also been associated with poorer functional outcomes in people with chronic pain[26,62]. Positive expectations for recovery have been associated with improved functional outcomes as well[16,63]. None of these prognostic indicators were identified in the present study. The findings that fewer comorbidities was associated with greater function at future follow-up, was consistent with the present findings[13].

There were a number of factors previously shown to be associated with the transition from acute to chronic pain that were investigated in this study to determine whether they were prognostic indicators in a population of people with chronic pain. The factors included low pressure pain thresholds[17], cold hyperalgesia[18–20], and post-traumatic stress disorder[19]. These factors were not associated with functional outcomes in the present study. Gender was assessed both as a covariate in an aggregated analysis and in a disaggregated analysis. No difference was found between males and females, while previous evidence has suggested females are more likely to experience pain-related disability[11]. A personal observation made by the physiotherapist in this study was a high prevalence of caregiver activities amongst male participants. It is uncertain which gender constructs are influencing functional outcomes. Future research is needed to investigate whether gendered roles may contribute to differences in function in people with chronic pain.

The findings that only poorer baseline function and higher disease count predicted poorer function at the end of the self-management program suggest it may be very difficult to identify participants with poorer function at the end of treatment based on baseline data. The clinical implications are that participants cannot be triaged based on the baseline factors investigated in this study. Also, we were not able to identify which factors were associated with persons who were unlikely to respond to COMMENCE and hence were unable to recommend a target population for future research aimed at identifying different treatment options for persons unlikely to respond to COMMENCE.

There are several reasons to interpret this evidence with caution. First, the model was developed in a small sample as the sample size calculation was performed for the randomized controlled trial of which this was a secondary analysis. A power analysis suggests a sample of 86 was needed to identify additional factors with a moderate effect (0.15) with a type 1 error rate of 0.05 and a power of 0.8^{64}. This means the model in the current study with 78 people could miss predictors with small to moderate effects and the developed model may over-fit the data. The instability of the model may also decrease the confidence in the model developed. The shrinkage with internal validation was 17.3% and while there is no minimum standard for acceptable shrinkage, these results do suggest the model may be somewhat unstable. Future research investigating predictors of response should include larger prospective cohort studies.

Another potential limitation was not collecting potential confounders at baseline including several social factors. The priority populations at WACHC include people with low income, isolated seniors, people with mental health or addiction concerns, people lacking of health insurance. Of these, only addictions and mental health concerns were captured as potential predictors or confounders. Addictions concerns are collected only as part of disease count and mental health conditions were captured as part of the disease count as well as depression and post-traumatic stress screens. Sociodemographic data and social or environmental contextual factors were not collected and represent potential confounding factors not captured.

An important avenue for future research is identifying changes in the variables investigated in this study and their relationship to changes in function using analysis to

identify mediators of change in function. This would help to determine mechanisms through which COMMENCE may have an impact on outcomes. A second important area of research is identifying factors associated with adherence to COMMENCE in this population. In the present study, 50% of participants completed at least 9 out of 12 treatment sessions. Given previous evidence suggests increased adherence is associated with improved self-management outcomes[65], it is possible that multiple morbidities are associated with decreased adherence and that decreased adherence may explain some of the variance in functional outcomes.

Conclusions

This study provides preliminary evidence that baseline function and disease count help to predict function after participation in chronic pain self-management support with pain science education and exercise.

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Conflict of Interest Statement

The authors disclose that there are no conflicts of interest.

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Table 1: Description of self-reported independent variables

Construct	Measure	Scale range	Details
Dependent variable			
Function	Short-musculoskeletal Function Assessment (SMFA-DI)	0-100	The SMFA-DI is a 34 item questionnaire with 25 items asking participants to rate how much difficulty they are having with functional tasks on a scale of 1 (no at all difficult) to 5 (unable to do) and 9 items on how often the person is experiencing functional problems answered on a scale of 1 (none of the time) to 5 (all of the time). The raw SMFA-DI score (34 to 170) is converted to a score out of 100 using the following formula: SMFA-DI = (sum of items 1 to 34 - 34) /136) * 100. Higher scores represent poorer function. 10 points on the raw scale was estimated as clinically meaningful in the study protocol using half of a standard deviations. Half a standard deviation is 7.3 on the final score out of 100
Independent variable			
Pain Intensity	Numeric Pain Rating Scale (NPRS)	0-10	The NPRS used in this study asked participants to rate the intensity of their pain on average over the past 2-weeks from 0 (no pain) to 10 (worst imaginable pain)
Fatigue	Numeric Fatigue Rating Scale (NFRS)	0-10	The NFRS asked participants to rate their fatigue on average over the past 2-weeks from 0 (no fatigue) to 10 (worst imaginable fatigue)
Catastrophic thinking	Pain Catastrophizing Scale (PCS)	0-52	The PCS asks participants to rate the degree to which they experience 13 thoughts or feelings when they experience pain. Each item was rated on a scale of 0 (not at all) to 4 (all the time). The scale includes 13 items that capture the participants tendency ruminate about their pain, magnify their pain, or feel helpless in managing their pain.
Fear of movement, symptom exacerbation, or re-injury	11-item Tampa Scale of Kinesiophobia (TSK-11)	11-44	The TSK-11 asks participants to rate their agreement with 11 statements on a 4-point Likert scale of 1 (strongly disagree) to 4 (strongly agree). The TSK-11 is a shortened (11-item) version of the 17-item Tampa Scale of Kinesiophobia that aims to identify people with a fear of movement, symptom exacerbation, or re-injury.
Self efficacy	Pain Self Efficacy Questionnaire (PSEQ)	0-60	The PSEQ asks participants to rate how confident they are that you can do the following things at present, despite the pain. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident. The PSEQ includes 10 items that cover household, self-care, social, recreational, and vocational activities as well as the ability to cope without medication.
Pain knowledge	Revised Neurophysiology of Pain Questionnaire (NPQ)	0-13	The revised neurophysiology of pain questionnaire is designed to measure understanding of pain neurophysiology. It uses thirteen questions that can be answered “True”, “False” or “Unsure”.

Sense of perceived injustice	Injustice Experience Questionnaire (IEQ)	0-48	The IEQ asks participants how frequently they experience 12 thoughts or feelings when they think about pain. Each item is rated on a scale from 0 (never) to 4 (all the time).
Depressive symptoms	Patient Health Questionnaire - 9 (PHQ-9)	0-27	The PHQ-9 asks participants to rate each of nine DSM-IV criteria for depression as 0 (not at all) to 3 (nearly every day).
Post-traumatic stress symptoms	Post-traumatic Stress Disorder Checklist –Civilian Version (PCL)	17-85	The PTSD-C is a 17-item scale based on the DSM-IV criteria for PTSD. Each item is rated on a scale of 1 (not at all) to 5 (extremely).
Medications	Number of medications	0-	This measure is a simple count of the number of medications a participant is taking. This measure has been used as a proxy measure for number of comorbidities[66].
Comorbidities	Disease count	0-30	Unweighted disease count was used as a measure of the number of morbidities. The list of 30 items used for this disease count were originally suggested by Elixhauser[54]. They included: congestive heart failure, cardiac arrhythmias, valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hyptertension, paralysis, other neurological disorders, chronic obstructive pulmonary disease, diabetes, hypothyroidism, renal failure, liver disease, peptic ulcer disease, HIV or AIDS, lymphoma, metastatic cancer, solid tumor wihtout metastasis, arthritis, coagulopathy, obesity, weight loss, fluid and electrolyte disorders, blood loss anemia, deficiency anemias, alcohol abuse, drug abuse, psychoses, depression.
Number of regions with pain			The number of boy regions with pain were assessed by asking participants to check any of the following 24 body regions: head, neck, low back, mid/upper back, as well as left and right: shoulder, arm, elbow, wrist, hand, hip, leg, knee, ankle, foot.
Expectations for pain relief			Participant expectations for pain relief were assessed by asking participants: Do you think your pain will improve throughout this program?
Expectations for improved function			Participant expectations for improvements in function were assessed by asking participants: Do you think your functional abilities will improve throughout this program?

Table 2: Mean function at pre-treatment and post-treatment, and change-score

	Pooled		Treatment		Wait-list	
	N	Mean(SD)	N	Mean(SD)	N	Mean (SD)
Function (SMFA-DI)						
Pre	92	43.8(16.6)	50	44.3(12.8)	42	43.2(20.3)
Post	84	35.8(18.9)	45	35.3(17.4)	39	36.3(20.8)
Change score	82	-8.9(11.9)	45	-8.4(11.9)	37	-9.5(11.9)

Table 3: Pre-treatment characteristics and measures

	Pooled pre-treatment				**Treatment group pre-treatment**				**Wait-list group pre-treatment**			
	N	**Mean (SD)**	**Median (IQR)**	**N(%)**	**N**	**Mean(SD)**	**Median (IQR)**	**N(%)**	**n**	**Mean (SD)**	**Median (IQR)**	**N(%)**
Age	102	52.8(12.6)			50	53.4(13.5)			52	52.2(11.7)		
Gender												
Male				27(26)				12(24)				15(29)
Female				75(74)				38(76)				37(71)
Education												
< high school education				24(24)				13(26)				11(21)
High school diploma				51(50)				21(42)				30(58)
College or University				27(26)				16(32)				11(21)
Do you think your pain will improve during program?												
Yes				20(22)				11(22)				9(21)
No				16(17)				6(12)				10(24)
I don't know				56(61)				33(66)				23(55)
Do you think your function will improve during program?												
Yes				32(35)				17(34)				15(36)
No				11(12)				4(8)				7(17)
I don't know				49(53)				29(58)				20(48)
Duration of pain	88		120(48-198)		42		120 (59-201)		46		120(37-228)	

Number of regions with pain	101		7(3-13)		50		6(3-13)		51		7(4-14)	
Number of medications	102		4(2-7)		50		5 (3-7)		52		4(1-8)	
Comorbidities (disease count)	92		3(2-4)		47		3(2-5)		45		3(2-5)	
Pain intensity (NPRS)	92	7.0(2.2)			50	7.2(1.8)			42	6.6(2.5)		
Fatigue (NFRS)	92	6.6(2.1)			50	6.9(1.7)			42	6.1(2.4)		
Catastrophic thinking (PCS)	90	26.7(15.2)			49	28.0(13.9)			40	25.0(16.6)		
Fear of movement/re-injury(TSK)	90	27.1(8.2)			50	27.7(7.7)			40	26.3(8.9)		
Sense of perceived injustice (IEQ)	90	25.4(13.4)			50	26.4(12.8)			40	24.1(14.2)		
Self-efficacy (PSEQ)	90	31.2(15.5)			50	31.4(14.2)			40	30.9(17.2)		
Depressive symptoms (PHQ-9)	91	13.1(7.2)				13.1(6.4)			52	13.1(7.8)		
Post-traumatic stress symptoms (PCL)	91	43.7(17.0)			50	43.9(17.1)			41	43.4(17.1)		
Pressure pain threshold over tibialis anterior	100		33.6(22.7-47.3)		50		33.8(25.7 to 48.4)		50		31.1(21.2 to 44.2)	
Pressure pain threshold over upper fibres of trapezius	100		21.7(12.6-30.1)		50		22.7(15.1 to 31.7)		50		19.2(12.3 to 28.1)	
Pressure pain threshold over most tender point	100		18.7(11.3-26.6)		50		19.9 (12.1 to 28.2)		50		15.7(10.6 to 26.5)	
Pressure pain threshold over contralateral side to most tender point	99		19.3(12.6-31.6)		50		20.2(13.8 to 34.0)		49		19.3 (10.9 to 26.7)	
Cold sensitivity over tibialis anterior Material 1 Material 2	100		4.8(2.7-7.7) 4.7(2.7-8.3)		50		4.8(2.3 to 7.3) 5.0(2.3 to 8.0)		50		4.8(2.7 to 7.7) 4.7(2.7 to 9.7)	

Cold sensitivity over upper fibres of trapezius Material 1 Material 2	100		5.4(3.5-9.1) 5.4(3.2-10.0)		50		5.3(3.3 to 7.5) 5.3(3.7 to 8.8)		50		5.7(3.5 to 10.0) 5.7(3.0 to 10.8)	
Cold sensitivity over most tender point Material 1 Material 2	100		5.7(3.3-10.3) 5.3(3-10.7)		50		6.0(3.2 to 9.8) 4.8(3.0 to 4.8)		50		5.7(3.3 to 11.0) 5.7(3.0 to 11.3)	
Cold sensitivity over contralateral side to most tender point Material 1 Material 2	99		5.7(3.3-9.7) 4.8(3.3-9.3)		50		6.2(3.2 to 9.3) 4.5(3.0 to 9.0)		49		5.2(3.7 to 10.0) 5.0(3.3 to 11.0)	

Table 4: Correlation of independent variables at baseline with reduction in function (increase in SMFA-DI) from pre-treatment to post-treatment

	Pearson r	**p-value**	**Spearman rho**	**p-value**
Age	-0.09	0.42		
Gender (male)			-0.09	0.44
Education Less than high school education High school diploma College or University diploma or degree			.02	0.83
Do you think your pain will improve?			-0.09	0.44
Do you think your function will improve?			-0.06	0.63
Duration of pain			0.01	0.92
Areas of pain			0.01	0.91
Number of medications			0.12	0.30
Disease count			0.28	0.02
Function (SMFA-DI)	-0.20	0.06		
Pain intensity (NPRS)	-0.23	0.04		
Fatigue (NFRS)			-..08	0.59
Catastrophic thinking (PCS)	0.04	0.75		
Fear of movement/re-injury(TSK)	0.08	0.48		
Sense of perceived injustice (IEQ)	-0.02	0.89		
Self-efficacy (PSEQ)	0.00	0.97		
Depressive symptoms (PHQ-9)	0.04	0.72		
Post-traumatic stress symptoms (PCL)	0.08	0.48		
Pressure pain threshold over tibialis anterior			0.11	0.34
Pressure pain threshold over upper fibres of trapezius			0.10	0.41
Pressure pain threshold over most tender point			0.12	0.28
Pressure pain threshold over contralateral side to most tender point			0.09	0.46
Cold sensitivity over tibialis anterior Material 1 Material 2			 0.07 0.13	 0.56 0.26
Cold sensitivity over upper fibres of trapezius Material 1 Material 2			 0.13 0.18	 0.25 0.29

Cold sensitivity over most tender point				
Material 1			0.13	0.25
Material 2			0.14	0.24
Cold sensitivity over contralateral side to most tender point				
Material 1			0.06	0.63
Material 2			0.09	0.45

Table 5 – Regression model predictors of function at 1-week follow-up in the treatment group

Variable	Beta value	95% Confidence interval	t (p-value)	Partial R-squared	Semi-partial R-squared
Age	-0.13	-0.35 to 0.09	--1.14(p=0.26)	0.02	0.01
Gender	-1.43	-6.97 to 4.11	-0.52(p=0.61)	<0.01	<0.01
Pre-treatment function (SMFA-DI)	0.74	0.57 to 0.92	8.65(p<0.01)	0.52	0.40
Disease count	2.14	0.62 to 3.65	2.81(p<0.01)	0.10	0.04
Constant	3.75	-10.45 to 17.96	0.53(p=0.60)		

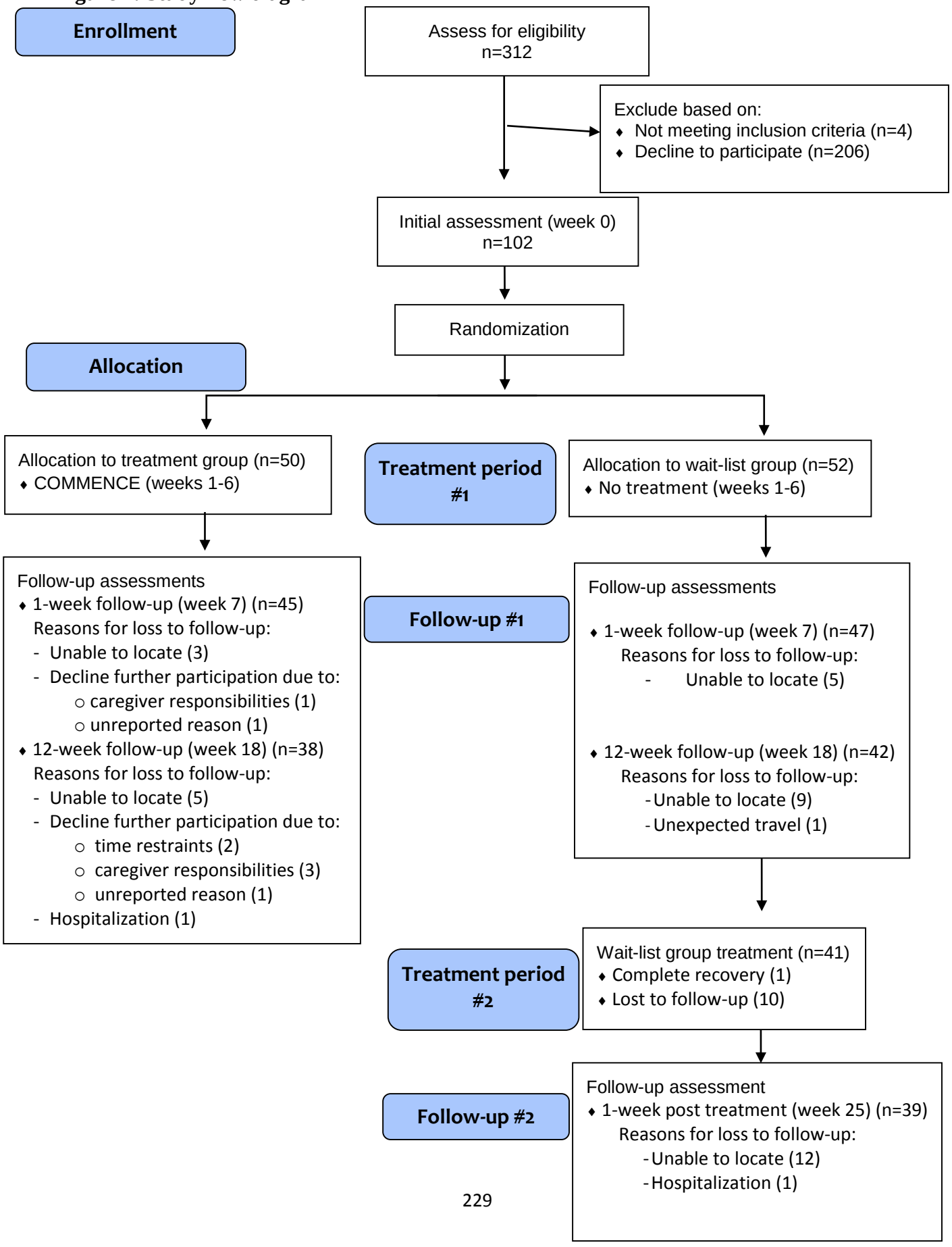
Model: F (4,66) = 29.03, p<0.01; R-squared = 0.63, adjusted R-Squared = 0.61; internal validation shrinkage = 12.7% shrinkage

Table 6 – Application of the regression model developed during the treatment period to the wait-list period of the wait-list group

Variable	Beta value	95% Confidence interval	t (p-value)	Partial R-squared	Semipartial R-squared
Age	-0.22	-0.47 to 0.31	-1.77 (p=0.08)	0.08	0.02
Gender	--1.74	-8.30 to 4.81	-0.54 (p=0.59)	0.01	<0.01
Baseline function (SMFA-DI)	0.89	0.71 to 1.08	9.70(p<0.01)	0.72	0.58
Disease count	1.34	-0.35 to 3.03	1.61(p=0.12)	0.07	0.02
Constant	12.20	-4.03 to 28.42	1.52(p=0.14)		

Model: F (4,37) = 31.11, p<0.01; R-squared = 0.77, adjusted R-squared = 0.75; shrinkage compared to model developed during treatment period = -22.2%%

Figure 1: Study flow diagram



CHAPTER 7: DISCUSSION

As many as 29% of people experience chronic pain (Kennedy, Roll, Schraudner, Murphy, & Mcpherson, 2014; P. C. Langley, 2011; Moulin, Clark, Speechley, & Morley-Forster, 2002) and many of those experiencing pain live with disability for years (Newton et al., 2015; Vos et al., 2012a). The burden of chronic pain and related disability on our health care system and society is substantial (P. Langley et al., 2010a, 2010b; Murray et al., 2013). The primary health care system, for example, is faced with a large number of visits related to chronic pain (Friessem, Willweber-Strumpf, & Zenz, 2009; Mannion, Brox, & Fairbank, 2013), but the outcomes of usual care for people seeking primary care suggest no improvement in pain or function for this population (Somerville et al., 2008). Further research was needed to find ways to improve function for people with pain needs to be a research priority.

This thesis included 5 manuscripts that aimed at providing knowledge needed to improve the treatment of pain-related disability in primary health care through self-management support. A brief summary of the findings of each article, the contributions this body of work made to the scientific literature, limitations of this research, and future directions are described throughout this chapter.

Summary of findings from each chapter

Chapter 2: Factors associated with poorer function in people with chronic pain referred for self-management support

The purpose of the first study (Chapter 2) was to determine what factors are

associated with poorer function in a population of people referred for chronic pain self-management support. The results of this cross-sectional study suggested depressive symptoms, number of medications, a cognitive factor index consisting of pain catastrophizing and self-efficacy measures, duration of symptoms and pressure pain threshold over the tibialis anterior uniquely contributed to a model that explained 63% of the variance in function. One of the important implications of this study is that function in people with chronic pain is multifactorial. This study provides clinicians and researchers knowledge of some of the factors that are associated with reduced function in a population of people with chronic pain and multiple morbidities.

Summary of Chapter 3: Physical therapist led self-management support with pain science education and exercise: A case series

The purpose of the second study (Chapter 3) was to describe a new intervention, chronic pain self-management support with pain science education and exercise (COMMENCE), and to describe the varied responses of six participants to this program. Often in clinical practice and research it is difficult to replicate the treatment carried out in randomized controlled trials due to issues with reporting (Dijkers, 2015). COMMENCE is the first intervention evaluated that incorporates pain neurophysiology education, individualized exercise and cognitive behavioural principles within a self-management program. Because COMMENCE is a multimodal intervention with many components, it would have been difficult to describe the intervention in enough detail for replication in a randomized controlled trial (Chapter 5). This case series allowed for a

more detailed depiction of the program along with rationale for each strategy included in the intervention to help inform clinicians and researchers who may utilize the intervention in future practice or research. The findings of this study indicate the responses to COMMENCE are varied. For example, changes in function ranged from 43% improvement to 12% decline in function. The varied response encourages future research to identify responders versus non-responders. Also, variance in attendance was noted between participants. This has important implications for clinicians and researchers as well. Adherence is important for self-management outcomes (Nicholas et al., 2012) and therefore varied attendance is likely to be associated with varied responses to the intervention. This is important for clinicians to understand, but it is also important for researchers because challenges in attendance are likely to be associated with higher attrition rates in research. Clinicians and researchers can benefit from a better understanding of the challenges faced by people with multiple morbidities and social determinants that can interfere with participation.

Chapter 4 summary: ChrOnic pain self-ManagementMent support with pain science EducatioN and exerCisE (COMMENCE): Study protocol for a randomized controlled trial

The third manuscript in this thesis (Chapter 4) was a study protocol for a randomized controlled trial evaluating COMMENCE, the intervention introduced in Chapter 3. The primary purpose of the study protocol was to provide a plant for evaluating the effectiveness of COMMENCE at improving function in comparison to a wait-list control. It is important to publish protocols prior to analyzing the data in a

randomized controlled trial to reduce the risk of publication bias and selective reporting of results (Eysenbach, 2004). This study protocol uses rigorous methods in laying out the plan for evaluating COMMENCE and discusses some of the limitations of the design. The protocol also describes four planned secondary analyses. The results of one of these secondary analyses (identifying variables that are predictive of treatment response) are presented in Chapter 6. The other 3 analyses will be published in 2016 when the final follow-up is completed 12-weeks following the last wait-list group going through treatment. The first of these is a within group comparison of the change during the treatment period to the change during the wait-list period for the wait-list group. This will provide a secondary estimate of treatment effect. The second is an estimate of whether the effects of the intervention are maintained over an additional 18 weeks (18-36 weeks) by continuing to follow the treatment group while the wait-list group undergoes treatment and follow-up. The third secondary analysis is a estimating the impact of an 18-week wait on the outcomes of the COMMENCE by comparing the changes experienced by the treatment group to the changes experienced by the wait-list group. All three of these planned analyses can have important implications. First, if the effect estimates of the within group comparison for the wait-list group are similar to those of the treatment group, the estimates can be pooled for a more precise estimate of treatment effect (Goldsmith, Gross, MacDermid, Santaguida, & Miller, 2011). This is valuable for clinicians and participants to form realistic expectations and for researchers to plan future work. Second, an estimate of whether the treatment effects are maintained over a longer follow-up period is important to understanding longer term outcomes for participants and

could help inform plans a decision on whether or not to add booster sessions depending on whether the results are maintained. Finally, the impact of an 18-week wait on outcomes is important for any primary health care settings where there is likely to be a wait for physiotherapy services.

Summary of Chapter 5: Chronic pain self-management support with pain science education and exercise (COMMENCE): A randomized controlled trial

The fourth study (Chapter 5) was a randomized controlled trial comparing the outcomes of a group of people participating in COMMENCE with a group of people on a wait-list to receive COMMENCE. The results suggest COMMENCE is effective at improving function in people with chronic pain. Also, COMMENCE improved several secondary outcomes including: how much participants were bothered by functional difficulties, pain neurophysiology knowledge, global rating of change, and satisfaction with health care. Three secondary measures in which there was a statistically significant, but not clinically meaningful change were: pain intensity, catastrophic thinking, and self-efficacy. Finally, four secondary outcomes showed no difference between groups: fatigue, pain interference, depressive symptoms, and work status. The effects of the program do not appear to differ by gender and people who attend more sessions experience more change in function. The results of this study have important implications for clinical practice and research. For clinical practice, COMMENCE provides an effective treatment option for improving function in people with chronic pain in primary health care settings. For research, the findings suggest the unique components of COMMENCE (pain neurophysiology education and individualized exercise) may be

important for improving function. Future research could help to determine the active treatment components of COMMENCE and the mechanism through which these approaches influence function.

Chapter 6 summary: Predictors of function after chronic pain self-management support with pain science education and exercise

The purpose of the fifth study (Chapter 6) was to determine which combination of variables predict function at the end of COMMENCE, controlling for baseline function, age, and gender. Only the number of chronic conditions (disease count) contributed uniquely to the model. The implications of these results are that it is very difficult to identify those who are likely to have higher or lower function at the end of treatment using factors beyond number of comorbidities and baseline function. Clinically, this suggests that we may not be able to target this program to specific risk factors for a poor function beyond the end of the program. The research implications are that there is more research needed to identify factors that determine responders and non-responders and outside of disease count and baseline function.

Overall findings

The findings of each of the studies in this thesis inform one other. First, the finding that depressive symptoms, number of medications, a cognitive factor index, and mechanical hyperalgesia are all associated with poorer function suggests reduced function in this population is multifactorial (Chapter 2). A possible implication of this finding is that interventions to target function in this population may need to be

multimodal and considerate of the multiple factors associated with reduced function in this population. COMMENCE meets the criteria of a multimodal program that targets function for people with multiple chronic conditions (Chapter 3). The pain neurophysiology education can help to reduce cognitive factors associated with pain-related disability (Moseley, Nicholas, & Hodges, 2004). Individualized exercise can help improve chronic pain (van Middelkoop et al., 2010), mechanical sensitivity (Naugle, Fillingim, & Riley, 2012) and other chronic conditions such as depressive symptoms, diabetes, and hypertension (Clark, 2015; Mura, Moro, Patten, & Carta, 2014; Sharman, La Gerche, & Coombes, 2015). However, the results of the randomized controlled trial (Chapter 5) suggests COMMENCE does not influence depressive symptoms and therefore future work could investigate the effects of adjunct treatment aimed at improving depressive symptoms. This could provide important health outcomes for this population since depression had a moderate correlation with poorer function and was the most prevalent comorbidity in this study.

The variance in response to COMMENCE evident from the case series in Chapter 3 suggested some people may be more likely to experience improvement than others. The cases included suggested comorbid health concerns and socioenvironmental factors may contribute to the variance in response. In response to the results, recommendations for future research investigating predictors of functional outcomes were made. This was evaluated in Chapter 6. The study investigating predictors of function after COMMENCE (Chapter 6) found only baseline function and number of comorbidities explained a significant amount of the variance. This was somewhat

surprising given the number of prognostic indicators included as potential predictors based on previous evidence. While there is a cross-sectional relationship between depressive symptoms, cognitive factors, number of medications, and mechanical sensitivity with poorer function (Chapter 2); the evidence from Chapter 6 suggests that of these factors only number of comorbidities (for which number of medications is a proxy measure) is predictive of functional outcomes of COMMENCE. Chapter 6 included a number of prognostic indicators that were anticipated to explain some of the variance in function following COMMENCE, but the cases in Chapter 3 may suggest that social and environmental factors may play an important role in attendance and functional outcomes. Future research predicting response of self-management programs should consider including measures of social factors that could form barriers to attendance or improvements in function.

The finding of the randomized controlled trial (chapter 5) that COMMENCE is effective at improving function for people with chronic pain is an important finding, but the case series (chapter 3) helps to demonstrate the heterogeneity in responses to the intervention. Together, these findings provide a clearer picture of the effects of COMMENCE on function. The finding in the randomized controlled trial that only people who attended at least 50% of scheduled visits experienced clinically meaningful improvement confirmed the findings of the case series in which two of the six participants experienced social and health related barriers to attendance and small decline in function at the 12-week follow-up.

Contribution of this thesis work to the scientific literature

The five manuscripts included in this thesis, together, make an important contribution to the understanding of reduced function in people with chronic pain in primary health care settings.

Perhaps the most substantial contribution of this thesis work is the finding that a self-management program incorporating pain neurophysiology education and exercise is effective at improving function for people with chronic pain who seek care from a primary health care provider. This is the first study to investigate this particular treatment combination and the results suggest COMMENCE has the potential to improve functional outcomes for people living with chronic pain. Given the substantial burden of pain-related disability on people living with pain (Newton et al., 2015; Vos et al., 2012a), the health care system, and workplace productivity (P. Langley et al., 2010a, 2010b; Murray et al., 2013), this finding could have an impact on both an individual and societal level. Research on the generalizability of the program and knowledge translation strategies to facilitate use of the program in practice are needed.

Current "usual care" in primary health care settings for chronic pain often involves the prescription of medications (often opioids) and no recommendation for physical activity or exercise (Somerville et al., 2008). It is understood that opioids do not improve function for people with chronic pain (Ashworth, Green, Dunn, & Jordan, 2013) and this concurs with the finding that people seeking care for chronic low back pain do not experience improvements in function over the following 6-months (Somerville et al., 2008). The finding that COMMENCE can improve function for people with chronic pain

suggests that if implemented in primary health care settings, it could improve functional outcomes for people with chronic pain in comparison to usual care.

One of the strengths of this research is the population that was included in the research. All of the studies in this thesis were carried out at Woodstock and Area Community Health Centre where the priority populations include people experiencing: mental health conditions, addiction concerns, poverty, social isolation, and lack of health insurance. Most of the sample had multiple comorbidities, which is important because people with multiple comorbidities are the greatest consumers of health care resources in primary health care and are very likely to seek care for chronic pain (Eckerblad et al., 2015; Glynn et al., 2011; van Oostrom et al., 2014). The importance of the sample is especially important for generalizability when the outcome of interest is function since both chronic pain and multiple morbidities contribute to reduced function (Fortin et al., 2006; Kadam & Croft, 2007; P. C. Langley, 2011; Rijken, van Kerkhof, Dekker, & Schellevis, 2005; Vos et al., 2012b). Carrying out the research in a sample that is representative of the population of people seeking care from primary health care providers may increase the confidence that the results can be generalized to primary health care settings.

The importance of the population is evident when considering the results of Chapter 2. Much of the existing literature on factors associated with poorer function is carried out in a sample of people with a specific pain condition, such as osteoarthritis (Sinikallio, Helminen, Valjakka, Väisänen-Rouvali, & Arokoski, 2014) or low back pain (Grotle, Foster, Dunn, & Croft, 2010). This makes the results difficult to generalize to the

population of people seeking care from primary health care providers who often have heterogeneous reports of pain and multiple comorbidities. The findings of chapter 2 suggest that depressive symptoms, number of medications, a cognitive factor index consisting of pain catastrophizing and self-efficacy measures, duration of symptoms and mechanical hyperalgesia are associated with reduced function, while symptoms are not. The finding that symptoms are not associated with function in this population has important implications. It suggests that treatment approaches that are effective at improving pain are not necessarily going to improve function. As stated previously, "usual care" often consists of medication, but not exercise (Somerville et al., 2008). Since many pain medications do not improve function for people with chronic pain (Ashworth et al., 2013), these findings suggest the need for more effective interventions for improving function.

Similarly, the population studied in this thesis is important to the implications of Chapter 5 (the randomized controlled trial). Research on the effectiveness of chronic pain self-management programs are often targeted at a specific population such as people with arthritis or low back pain (Du et al., 2011; Kroon et al., 2014). This is the first study to evaluate a self-management program for people with a heterogeneous population of people with chronic pain in which the majority of participants have multiple comorbidities. The sample allows greater confidence in applying the results of this trial to a similar heterogeneous population of people with pain and multiple comorbidities in a primary health care setting.

The results of Chapter 3 (the case series) complement the results of Chapter 5 (the

randomized controlled trial). Multiple case studies allow for the comparison of individual trajectories throughout the program. While the randomized controlled trial in Chapter 5 suggests this program is effective, it is evident from the case series in Chapter 3 that the responses to the program are not homogeneous. Some of the heterogeneity appeared to be due to health and social challenges. Recognizing some of the complex health and social challenges in the population being studies is important for both clinicians and researchers. Clinicians should be prepared to accept variable responses, to find strategies to help participants overcome barriers to participation, and to reschedule appointments frequently. Researchers should be prepared for results with high variance and high attrition rates when working with this population.

Chapter 6 (predictors of functional outcomes) also makes an important contribution to the scientific literature. Many of the factors investigated in this study as potential predictors of poorer function have been demonstrated consistently to be predictors of poorer function in previous research. For example, several of the cognitive factors investigated in this study have been shown to predict poorer function after other rehabilitation interventions. These include catastrophic thinking (Sullivan, Stanish, Waite, Sullivan, & Tripp, 1998), sense of perceived injustice (Sullivan, Scott, & Trost, 2012), fear of movement or re-injury (Swinkels-Meewisse et al., 2006), and lower self-efficacy (Thompson, Urmston, Oldham, & Woby, 2010). In the present study, none of these factors were associated with poorer function after participation in COMMENCE. This difference may be due to the population. Since number of chronic conditions (disease count) was associated with poorer function following participation, it is possible

that in a population of people with multiple comorbidities that cognitive factors often associated with pain-related disability make a smaller contribution to the model. Another possible explanation for these differences in results is the intervention itself. As described in Chapter 3 (the case series), COMMENCE included many cognitive behavioural principles aimed at improving self-efficacy and reducing negative cognitions associated with reduced function in people with chronic pain. Given the finding in Chapter 2 (factors associated with disability) suggested catastrophic thinking and lower self-efficacy were associated with reduced function at baseline, but the finding in Chapter 6 (predictors of function after COMMENCE) suggested catastrophic thinking and lower self-efficacy did not predict function after the intervention, it is possible that COMMENCE effectively targeted these cognitive factors, which could contribute to the finding that they did not predict function after the intervention.

Limitations and future research

One of the limitations in applying the results of this thesis is that COMMENCE was delivered by the principal investigator. When an intervention evaluated is carried out by a single health care provider, it is not possible to tease apart the effects of the intervention from therapist effects. This may be especially important when the person carrying out the treatment developed the intervention, so has a level of excitement for the intervention and expectations that the intervention has the components important to making the intervention successful. Ideally, future research should compare the effect estimates found in this trial with the effect estimates achieved when other health care providers are

trained to deliver the intervention.

Another important limitation is that the sample used for Chapters 2 and 6 was the sample from the randomized controlled trial. This is important because the sample size calculation was based upon the randomized controlled trial leaving the regression analysis for Chapter 6 underpowered and the need to create composite indices in Chapter 2. These are challenges inherent to performing planned secondary analyses when the sample size calculation is based on the original study. The models in Chapter 2 and 6 should undergo validation testing in an external sample to determine whether the models can be generalized to similar populations.

Another limitation of Chapter 2 is that results suggest association and not causal relationships. The factors identified in Chapter 2 provide important candidate factors for future prospective cohort studies that investigate causal relationships using structural equation modelling or path analysis. Investigating the directional relationships between variables could help to determine contributors to reduced function rather than just factors associated with function. This future step in research could have important implications for informing interventions aimed at improving function or for future modifications of COMMENCE.

Another potential limitation in interpreting the results of the research included in this study is the complexity of the intervention. While the rationale for each component of the intervention is included in the appendix in Chapter 3, it is not certain which specific components were the active treatments in improving function. This could provide an important avenue for future research that could lead to more efficient care through the

inclusion of only the effective components. An example of this type of research is investigating the effects of pain neurophysiology education. The inclusion of pain neurophysiology education and individualized exercise in COMMENCE was based on evidence suggesting these treatment approaches are effective at improving function for people with chronic pain (Gross et al., 2015; Louw, Diener, Butler, & Puentedura, 2011; Searle, Spink, Ho, & Chuter, 2015). It is not clear from the studies in this thesis whether the addition of these factors contributed to the improved function. A factorial design with factors including pain neurophysiology education, individualized exercise, cognitive behavioural principals, and self-management education could help to determine the active components.

Alternatively, research on the mechanism through which COMMENCE influences function could help to determine the active components of treatment. For example, a prospective cohort study evaluating whether change in pain neurophysiology knowledge is a mediator of functional outcomes for people participating in COMMENCE. Similarly, evaluating physical performance tests such as a walk test, strength and mobility tests could help to determine whether changes in physical performance mediate a change in self-reported function. Finally, evaluating pain catastrophizing and self-efficacy as mediators for change in function may help to determine whether some of the cognitive behavioural strategies were influencing function these potential cognitive mediators.

Another interesting and important avenue for future research is investigating factors associated with adherence versus non-adherence. As evident from the case-series, there are many social and health factors that can contribute to adherence or non-adherence.

Given the complexity of the social determinants of health in this population, a mixed methods approach to evaluate potential barriers and facilitators to attendance and adherence would be beneficial. Evidence on barriers to attendance could lead to strategies to help participants overcome these barriers and also to develop tailored strategies for less intensive interventions with fewer appointments targeted to those unlikely to be able to attend the 12 sessions included in COMMENCE.

Conclusion

This thesis contributes to the literature by suggesting depressive symptoms, number of medications, a cognitive factor index consisting of pain catastrophizing and self-efficacy measures, duration of symptoms and pressure pain threshold over the tibialis anterior are associated with poorer function in a group of people with chronic pain and multiple morbidities. Also, the thesis suggests that while responses are variable, chronic pain self-management support with pain science education and exercise (COMMENCE) is effective at improving function for people living with pain in a primary health care system.

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