Physical and Psychological Effects of Combined Motor Control and Isolated Lumbar Extension Exercise Versus General Exercise for Chronic Low Back Pain: A Randomized Controlled Trial

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complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abstract For Masters

Physical and psychological effects of combined motor control and isolated lumbar extension exercise versus general exercise for chronic low back pain: a randomized controlled trial

Alexa Roussac

Exercise is the most common treatment approach for patients with chronic low back pain (LBP) and its psychological factors should also be considered given their known negative influence on recovery. Motor control and general strengthening exercises are two commonly used exercise therapies for chronic LBP, yet few studies have examined both the physical and psychological effects of these exercise interventions on chronic LBP. The purpose of this randomized controlled trial (RCT) was to compare the effectiveness of combined motor control and isolated lumbar extension exercises (MC+ILEX) versus general strengthening exercise (GE) on pain, disability, and psychological factors in patients with chronic LBP.

A total of 50 participants with LBP were randomly assigned to each group (n=25 per group). Both groups received 2 supervised exercise sessions for 12-weeks. Outcomes measures were obtained at baseline, 6-week and 12-week and included pain intensity (NPRS), disability (ODI), depression and anxiety (HADS), pain catastrophizing (PCS), Kinesiophobia (TSK) and insomnia (ISI). Repeated measures ANOVA was used to assess the main effects of group, time, and group*time.

There were no significant differences between groups for any outcome at any time point. Participants in both groups had significant improvements in NPRS, ODI, and TSK (all $p<0.01$) scores from baseline to 12-week. Participants in the MC+ILEX group also had significant improvements for PCS ($p=0.04$).

Our findings indicate that MC+ILEX and GE have similar positive effects in patients with chronic LBP. Both exercise interventions were effective to improve pain, disability, and psychological factors.

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Introduction

Low back pain (LBP) is the leading cause of disability worldwide (Hartvigsen et al., 2018). In 2015, 540 million people reported living with the burden of chronic LBP (Vos et al., 2016). Due to the disruptive nature of chronic LBP, there have been many different solutions offered for the management of this condition. its symptoms. Given the highly addictive nature of opioids and their abuse potential, the CDC recommends that health care providers find alternatives to opioids and other pharmaceuticals for pain management (Dowell et al., 2016). Exercise is a highly researched and successful method of reducing pain symptoms as well as increasing function (Jackson et al., 2011; Vincent et al., 2014; Kell & Asmundson, 2009). In addition to being highly accessible, affordable, and enjoyable to many, exercise is an excellent substitute for the prescription of opioids as it is safer and completely avoids the possibility of physical dependence.

Although the physical aspect of LBP is a prominent focus of LBP research, there are other elements of the pain to consider. The evolution of LBP from an acute to chronic has been found to be rooted in psychological factors (Pincus et al., 2002). Those afflicted are not only burdened with fear of movement but may also believe are also convinced that they are not going to get better(Leeuw, Goossens, et al., 2007). In exercise studies, pain catastrophizing has been found to mediate a reduction of pain, disability and depressive symptoms (Vincent et al., 2014; Smeets et al., 2006). The fear avoidance model offers a possible explanation as to why a certain treatment will work for some individuals and not for others (Leeuw, Houben, et al., 2007). Evidence of the importance of the consideration of the fear avoidance model can be seen in studies that fail to take pain related fear into consideration during their intervention. For instance, Kell et. al performed two very similar studies with almost identical exercise interventions 2 years apart and had substantially different results (Kell et al., 2011; Kell & Asmundson, 2009). Despite the similarities between the interventions, one had much better results than the other and neither considered pain related fear when evaluating the participants. The variability between the results may be partly explained by the lack of consideration for pain related given its negative effect on recovery.

One of the challenges of evaluating previous studies on exercise for LBP is that some studies do not consider psychological factors. Given the impact that pain related fear, catastrophizing and Kinesiophobia have on a treatment's effectiveness, it is important to look at how these factors may mediate the recovery of the participants. Currently, there is a lot of research that examines the effectiveness of exercise on LBP and disability but studies that have explored the mediating role of pain related fear and catastrophizing on the reduction of LBP symptoms remain scarce. Moreover, while most studies using an exercise intervention observe an improvement in pain and function, very few describe in detail what kind of intervention was performed (Jackson et al., 2011; Kell & Asmundson, 2009). Whether pain education combined with exercise is more effective to reduce chronic LBP symptoms than therapeutic exercise alone also warrants further attention (Hajihasani et al., 2019; Jones et al., 2020).

The current study focuses on the secondary outcomes of a two-arm randomized controlled trial including two different exercise interventions for subjects with chronic LBP. The primary analysis of the larger study will examine the change in muscle morphology and function as a result of the experimental interventions and the secondary measures will examine the effectiveness of the training on pain related fear, pain, disability, depression and anxiety and sleep. The present study will focus on the secondary measures of the larger trial and will investigate 1) the effectiveness of a general exercise strengthening program and combined motor control and isolated lumbar exercise program on pain catastrophizing, Kinesiophobia, anxiety, depression, sleep quality, pain and disability as compared to the muscle control group and 2) the associations between baseline pain catastrophizing with pain and disability following the exercise intervention.

Literature Review

Low Back Pain

LBP is a widespread and debilitating condition that will affect 65-85% of the American population over their lifetime (Berry et al., 2019). It is also among the top 10 causes of disability worldwide (Vos et al., 2020). Not only does LBP have drastic effects on personal health but it can also hinder one's ability to work. In North America alone, LBP is one of the leading causes of absenteeism in the workplace (Mostagi et al., 2015), resulting in less income and job stability. Because of the daily struggles of chronic pain, LBP has been a leading source of high direct and indirect costs to the medical system as well as paid leave due to physical inability to work (Hüppe et al., 2019). In about 85% of the cases, no specific cause can be identified as the source of LBP. As such, it is suggested that clinicians consider the multidimensional nature of LBP including the physical, psychological and social impacts on an individual basis (Tagliaferri et al., 2020).

Exercise therapy for LBP

Exercise therapy is the most common form of conservative treatment for chronic LBP. However, there remains limited evidence that one particular type of exercise is more effective than others (Owen et al., 2020; Niederer & Mueller, 2020). A recent network metanalysis (2021) including 249 RCTs provided moderate evidence that exercise therapy is more effective than no treatment or usual care for treating LBP and that Pilates and McKenzie therapy are more effective on pain and functional outcomes than any other type of exercise (Hayden et al., 2021). This is the first report of an exercise being found to be clearly superior and so prompts the need to further testing (Gordon & Bloxham, 2016; Owen et al., 2020). Pilates is comprised of a lot of controlled movements and core activation and so similar exercise interventions may yield the same positive results. In fact, a Cochrane review specifically omitted Pilates when comparing the effectiveness of motor control exercises versus other types of exercise for LBP because of the possible overlap in principles between the two interventions (Saragiotto et al., 2016). A major limitation of the findings of Hayden et. al's metanalysis is that the interventions that appear to be the most beneficial are also quite costly and so accessibility to these types of exercises would be limited to those who could afford the extra expense involved (Hayden et al., 2021). Despite Pilates and McKenzie therapy being the current best options, other forms of exercise are also beneficial, such as resistance exercise. In accordance with the recommendations of Hayden et. al, functional outcomes must be in line with patients' goals and be financially feasible indicating that the best option of exercise is ultimately a personal decision based on the needs of the individual (Hayden et al., 2021).

Resistance Exercise and Low Back Pain:

Physiologically, resistance exercise reduces pain by reducing the phosphorylation of NMDA receptors in nerve cells as well as increasing serotonin levels (Lima et al., 2017). A recent network metanalysis comparing different kinds of exercise and their effectiveness for LBP found that resistance and stabilization/motor control exercises were most likely to improve physical function and mental health (e.g. Anxiety and depression) versus other types of exercise (Owen et al., 2020). When compared to aerobic exercise and an inactive control, resistance exercise has been shown to yield significantly better improvements in pain levels, disability and overall quality of life (Kell & Asmundson, 2009). This highlights the importance of musculoskeletal fitness and its effectiveness on pain, disability and quality of life and neural adaptions responsible for muscle strengthening. Pain reduction by way of resistance exercise is a valuable tool for people of all ages given its accessibility and many benefits in different areas of health (Vincent et al., 2014). In fact, when compared to inactive controls, resistance training has been found to be equally beneficial in both middle aged and older aged recreational hockey players (Jackson et al., 2011). In a randomized control trial, both age groups experienced significant reductions in pain and disability as well as a significant improvement in quality of life scores with no differences in effectiveness between groups indicating that regardless of age, resistance training has an overall positive effect (Jackson et al., 2011). Another systematic review further compared the effectiveness of various exercise programs on LBP symptoms and proposes that a general exercise program could be beneficial given that LBP is not a homogenous condition and therefore, focusing on one area of fitness limits the reach of the intervention(Gordon & Bloxham, 2016). The muscle group(s) targeted during strength training intervention is also or interest. A recent systematic review also concluded that patients with LBP have reduced gluteus medius muscle strength as well a more trigger points when compared to those without LBP (Sadler et al., 2019). Given their importance in posture and hip flexion, exercise interventions focusing on the activation of the gluteus medius and hip musculature warrant further attention in subjects with chronic LBP.

Motor Control, Isolated Lumbar Exercise and Low Back Pain

Motor control exercises (MCE) are designed to train optimal control and coordination of deep and superficial trunk muscles and include the initial activation of muscle in isolation with a subsequent integration into more complex tasks in order to move from a planned contraction to an automatic contraction (Saragiotto et al., 2016). Studies have indicated that people with LBP struggle to control deep and superficial trunk muscles and so motor control exercises were developed to aid in the retraining of said muscles in order to reduce LBP symptoms (Hodges & Richardson, 1997, 1998). MCE have been found to have significant positive outcomes when performed by individuals living with LBP by means of the reduction of pain, disability and increasing impression of change and quality of life (Macedo et al., 2012). A Cochran review evaluating the effectiveness of MCE on LBP symptoms determined that there was low to high quality evidence that MCE was not clinically more beneficially than any other type of exercise and that there was moderate to high evidence that MCE was not more clinically beneficial than any type manual therapy (Saragiotto et al., 2016). A recent meta-analysis examined the effectiveness of MCE as compared to other types of exercise and found that MCE was no more effective than other types of exercise in the short term in terms of the reduction of pain symptoms and disability however, no difference was found in long term (Zhang et al., 2021). These differences in results could be due to the lack of homogeneity in the definition of MCE used by researchers leading to the inclusion of studies that don't necessarily follow the true principles of MC exercises (Ganesh et al., 2021)

Isolated lumbar exercises aim to improve paraspinal muscle morphology and function (Berry et al., 2019). A preliminary study assessing the effectiveness of a high intensity resistance exercise program that targeted paraspinal muscles demonstrated that this exercise not only improve pain, disability, anxiety and strength but also that there was correlation between disability and strength with reduced fatty infiltration and increased hypertrophy of paraspinal muscles (Berry et al., 2019).

Both types of exercise directly target the muscle groups involved in LBP and so combining the two focuses the intervention on the strengthening and improved muscle quality of the area implicated in LBP.

The Fear Avoidance Model

Pain related fear occurs when an individual associates a certain pain stimulus as a main threat (Leeuw, Goossens, et al., 2007). The pain experience leads to catastrophizing where the individual focuses on the most negative outcomes possible of the pain stimuli (Ellis, 1962). Pain related fear and catastrophizing play a vital role in the management of LBP, as both factors are related to personal perception of pain stimulus, which can add an obstacle recovery. Pain related fear may be a propagating factor of LBP for individuals who exhibit avoidance behaviour (Leeuw, Goossens, et al., 2007) as such individuals are less likely to seek out active treatments, such as exercise, and are more likely to avoid movements that they deem to be potentially pain-inducing.

The Fear Avoidance Model (FAM) was developed to explain chronic musculoskeletal pain in people who had physically healed from their previous injuries but were still experiencing symptoms (Vlaeyen & Linton, 2000). The FAM describes two opposing responses when faced with pain: one being that of low fear leading to recovery and the other, a cyclical pattern of fear and avoidance (Vlaeyen & Linton, 2000). As the injured individual continues to avoid the perceived threat of pain, the pain and disability also increases. Negative thoughts about pain are believed to be the initiator of pain-related fear behaviour. As fear sets in, the individual avoids daily activities which results in functional disability. As the avoidance behaviours persist, there is less of a chance to reverse the avoidant behaviours because the behaviour has transformed into an anticipation of pain as opposed to being in response to pain. The lack of activity has negative physiological consequences and can therefore exacerbate the existing pain problem.

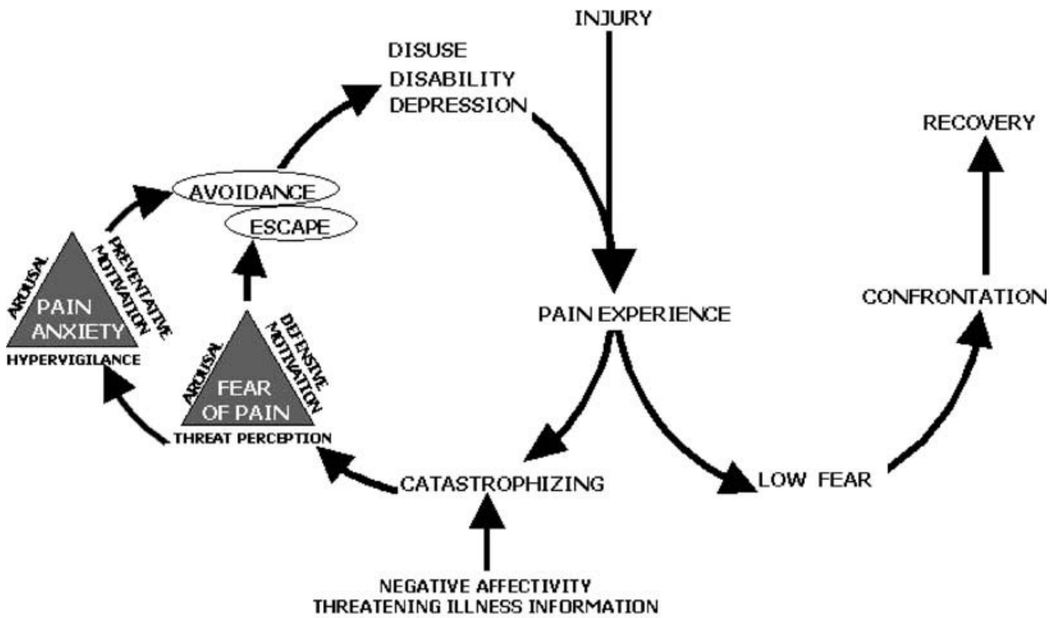


Figure 1 The fear-avoidance model of chronic pain. Based on the fear-avoidance model of Vlaeyen and Linton (2000). and the fear-anxiety-avoidance model of Asmundson et al. (2004).

People who are prone to fearful behaviour were more likely to be hypervigilant of pain and have a more difficult time shifting their focus away from the possibility of pain making it less likely for them to perform tasks of daily living. The individuals will then be more reactive when faced with situations that could be perceived as painful (Vlaeyen & Linton, 2000).

Neuromatrix Model of Pain

Another major theory in pain neuroscience is the neuromatrix model of pain introduced by Dr. Ronald Melzack. The mode emphasizes chronic pain as being rooted in a multidimensional experience and not just the feeling of pain stimulus. According to the neuromatrix model, chronic pain is the result of perception, homeostasis, and behavior because of a given injury, pathology, or chronic stress (Melzack, 2005). Chronic pain is the result of the genetically determined body-self neuromatrix being altered by sensory input and thus creating a neural pattern that determines how each individual experiences pain. The neuromatrix model of pain can be used to explain LBP as a chronic condition by linking the symptoms to possible influx of constant subtle causes (Melzack, 2005). Previous experiences that lead the individual to LBP symptoms in the past result in anticipation that would in turn activate the neuromatrix and cause the body to anticipate a much larger pain response compared to the actual pain stimulus (Melzack, 2005).

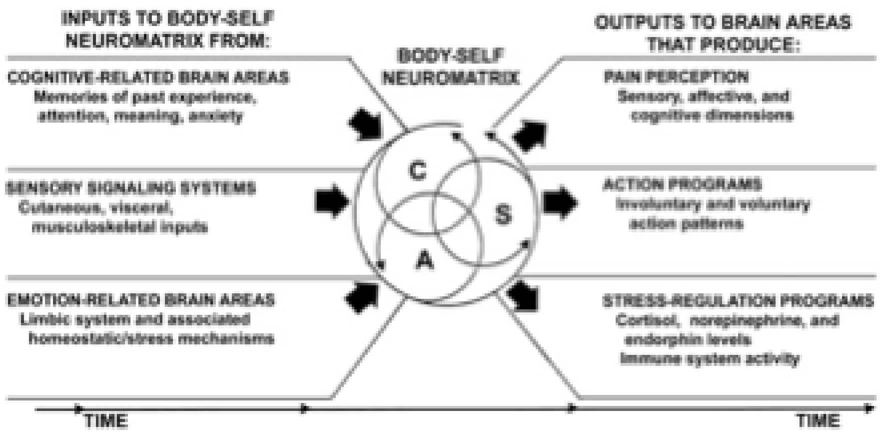


Figure 2 Factors that contribute to the patterns of activity generated by the body-self neuromatrix, Melzack (2001)

Pain Catastrophizing

Pain catastrophizing is defined as having excessive negative thoughts concerning painful stimuli which can create a stress reaction and feelings of distress when faced with pain (Sullivan et al., 1995). The Pain Catastrophizing Scale (PCS) is a validated questionnaire that is most commonly used to assess and help quantify an individual's pain experience (Sullivan et al., 1995; Hapidou et al., 2012) and identify catastrophic thoughts or feelings in relation to painful experiences (Marshall et al., 2017). The PCS is a 13-item questionnaire, with each item being rated from zero to four (e.g. 0= not at all, 4= all the time) (Marshall et al., 2017). The total score ranges from 0-52 where higher scores are indicative of more catastrophic thoughts and feelings (Marshall et al., 2017).

Pain catastrophizing is often studied as a mediator of exercise on symptom recovery. A mediator is a possible causal mechanism used to explain the relationship between two variables (Marshall et al., 2017). Pain catastrophizing has been found to significantly mediate the relationship between pain and disability in individuals that reported engaging in physical activity on a weekly basis (Marshall et al., 2017). A recent cross sectional study examined the mediating effect of multiple psychological factors closely related to LBP on pain and disability and found that fear, catastrophizing and depression were all significant positive mediators of pain and disability in those living with LBP (Marshall et al., 2017).

A study comparing the effectiveness of a total body resistance program combined with lumbar extension exercises versus lumbar extension exercises alone and an inactive control in obese adults with chronic LBP found that the combined resistance/isolated lumbar extension exercise program was successful in significantly reducing pain catastrophizing symptoms as compared to the 2 other groups over the 4 month span of the intervention. (Vincent et al., 2014). PCS scores for the combined group decreased from 11.5 (12.6) at baseline to 4.1 (5.9) for a change of 7.4 (Vincent et al., 2014). A clinically significant change in PCS scores has been determined to be 6.71(Suzuki et al., 2020) and so the combination of resistance exercise with isolated lumbar extension exercises has both statistically and clinically significant positive effects on pain catastrophizing in obese adults with chronic LBP.

Individuals living with LBP have been found to have higher pain sensitivity as compared to pain-free controls. Meints et al reported that those who experience higher levels of deep tissue hyperalgesia also had higher levels of catastrophizing, indicating the possibility of catastrophizing mediating pain levels in patients living with LBP (Meints et al., 2019).

Kinesiophobia

Kinesiophobia is a fear of movement or reinjury because of possible pain (Vincent et al., 2014). As with pain related fear and catastrophizing, kinesiophobia allows the individual to rationalize or explain justify the avoidance of movement that could be beneficial in reducing their pain symptoms.

Kinesiophobia is most assessed using the of the Tampa Scale of Kinesiophobia (TSK). This validated questionnaire is used to evaluate an individual's level of fear of re-injury due to movement or activity. The original version (TSK-17) included 17-item. Over the years, however, shorter versions have been developed and validated including TSK -13 (Calley et al., 2010), from which 4 original item were removed. This shortened version of the TSK did not affect the internal consistency of the scale (Swinkels-Meewisse et al., 2003). In an effort to further reduce the time devoted to completing the survey, Woby et al. developed the TSK-11. A shorter version of the questionnaire that is better for brevity and reduces respondent burden (Larsson et al., 2014). This condensed version of the TSK removed six of the original questions: 4, 8,9 ,12, 14, 16. The shortened version was to have evidence for reliability, validity and responsiveness (Woby et al., 2005). The TSK-11 questionnaire is an 11-item, 4-point Likert scale (e.g. 1=strongly agree and 4=strongly disagree), with scores ranging between 11 and 44, with higher scores representing a higher level of Kinesiophobia (Larsson et al., 2016). The average score for individuals living with chronic pain was found to be 22.8 out of the total possible 44 as determined by Larsson et al. who performed a cross-sectional study and examined the development of Kinesiophobia in older adults over a 12-month period by administering the TSK-11 to 2000 participants. The same participants were re-sent the questionnaire after 12 months and of the 1141 follow up replies, the average Kinesiophobia level did not change over time and was found to be 22.8 (Larsson et al., 2016). There was also a high positive correlation between Kinesiophobia, pain and perceived poor health (Larsson et al., 2016).

Psychosocial Factors and LBP:

The physical and psychological aspects of LBP have been established to be heavily related and thus should be considered when devising a treatment plan for any patient (Martinez-Calderon et al., 2020). To account for the strong association between psychological factors and LBP, some studies have included cognitive behavioural therapy (CBT) or used CBT principles in their interventions. Interestingly, there is no clear consensus as to whether the addition of CBT to an exercise program is more beneficial than an exercise program alone. One systematic review that examined 61 RCTs found that both a multidisciplinary approach and exercise alone were equally beneficial in reducing Kinesiophobia (Martinez-Calderon et al., 2020). The same conflicting results were found when examining studies that compared pain education combined with exercise versus exercise alone and their effectiveness on pain related fear. Two of the three studies considered Kinesiophobia in their secondary measures and had completely different results: one had a significant decrease in Kinesiophobia and the other did not (Jones et al., 2020). Both studies had very small sample sizes and different exercise interventions that could account for the differences in their results (Jones et al., 2020).

A population-based cohort study examined whether pain catastrophizing and Kinesiophobia were predictors of LBP. The study was performed by sending out a questionnaire on musculoskeletal pain and then sending another questionnaire 6 months later (Picavet, 2002). The questionnaires used included both the PCS and a modified TSK questionnaire. Interestingly, the results suggested that those without pain at the beginning of the study were more likely to experience LBP symptoms by the end of the study if they exhibited high initial pain catastrophizing or Kinesiophobia scores (Picavet, 2002).

Another study examined the effectiveness of combined trunk stabilization techniques with a general exercise intervention compared to a general exercise intervention alone (control) on pain, disability and various psychological determinants including pain catastrophizing (Koumantakis et al., 2005). Both the intervention and the control groups had significant within group decreases in Kinesiophobia as well as pain and disability. There was, however, no significant difference in disability nor pain between the intervention and general exercise groups. Interestingly, regardless of exercise intervention, there was an improvement in LBP symptoms (Koumantakis et al., 2005). Encouraging those living with chronic pain to seek the benefits of activity appear to be helpful thus should be accounted for when designing a treatment plan.

Given the multidisciplinary nature of low back pain and the number of different factors that contribute to the experience of pain and disability, treatment plans should address physical, psychological social and health related elements of quality of life to ensure that the patient has the best chance at recovery (Tagliaferri et al., 2020).

Depression and Anxiety

Living with chronic pain has many negative mental effects. Those living in constant state of LBP are 3-4 times more likely to experience clinical depression than the rest of the population (Teychenne et al., 2019). The Hospital Anxiety and Depression scale (HADS) is a self-reported questionnaire that consists of 14 items: 7 for anxiety and 7 for depression, each item scored from 0 to 3 (Marshall et al., 2017). A maximum of 21 is possible for each sub scale and the higher the score, the higher the level of depression and anxiety (Marshall et al., 2017). This scale is both reliable and valid and has good internal consistency (Bjelland et al., 2002). The normal range for each scale is between 0 and 7, 8 to 10 indicate the possibility of anxiety of depression and scores of 10 and up are indications of disorder (Turk et al., 2015).

A study performed by Chun-Hao et al. used the HADS to verify the reliability and validity of the Depression and Somatic symptoms scale in when used to evaluate individuals living with LBP (Liu et al., 2019). Individuals living with both LBP and a major depressive disorder scored 11.2 (4.1) for the depression scale and 13.0 (3.1) for the anxiety scale and those without a major depressive disorder scored 5.3 (3.7) for the depression scale and 6.7 (4.1) for the anxiety scale (Liu et al., 2019). The HADS is a useful tool given that it is able to discriminate between individuals diagnosed with clinical depression and anxiety and those who are not despite the fact that they all live with chronic pain.

Physical activity has been successful in reducing depression levels (Smeets et al., 2006). When compared to CBT alone, CBT and physical activity combined and an inactive control with LBP, an active physical treatment significantly decreased depression symptoms (Smeets et al., 2006). Of note, only 7.6% of participants would have met the requirements for clinical depression at baseline and thus raising the question of the clinical significance of the reduction (Smeets et al., 2006). Furthermore, a systematic review by Hjihasani et al. examined whether the addition of CBT to an exercise program further decreased depressive symptoms. Of the 10 studies examined, none reported any significant additional reduction in depressive symptoms due to the introduction of CBT (Hajihasani et al., 2019).

Depression can also be considered a mediating factor of LBP in that higher pain and disability scores can be explained by depression (among other factors) (Marshall et al., 2017). Marshall et al found that there was a significant positive relationship between the mediating effect of fear-avoidance and depression on pain and disability in patients living with LBP. The mediating effect of depression and fear-avoidance on pain and disability implies that the study of the effect of exercise on LBP needs to consider psychological factors to properly evaluate its effectiveness.

Sleep

Sleep disturbance is a factor to consider when assessing LBP as good sleep is an important part of quality of life. The Insomnia Severity Index is used to assess levels of insomnia experienced on a 7-item scale. Each item is scored from 0-4 for with a total possible score of 28 indicating severe insomnia (Bastien, 2001). A clinically meaningful change in ISI scores is a reduction of 6 points out of the possible 28 (Yang et al., 2009). Bahouq et al examined the sleep quality in patients living with LBP using the ISI and found that back pain intensity predicted insomnia with 78% of the participants suffering with insomnia (Bahouq et al., 2013). Given how widely sleep disturbance affects individuals living with LBP, the association between insomnia and LBP merits further investigation.

Rationale

LBP is a widespread and persistent condition that does not discriminate. Exercise is a highly researched and promising option for the management of pain symptoms however the most successful types of exercise are often not the most cost effective and are therefore less accessible to the general population (Hayden et al., 2021). In addition to the management of physical symptoms, there are also psychological factors to consider. Pain catastrophizing, Kinesiophobia, depression and anxiety and sleep disturbances are all psychological factors that play a vital role in the treatment of LBP given their substantial negative influence on recovery. Few studies examined the effectiveness of a general exercise strengthening program on these psychological factors.

While the importance of considering psychological factors in the treatment of chronic LBP is now recognized, recent systematic reviews concluded that the inclusion of a psychological component to an intervention does not always result in better treatment outcomes (e.g. greater reduction pain, disability, depression post-treatment)(Hajihasani et al., 2019). There is also moderate strength of evidence suggesting that both multidisciplinary interventions and exercise alone can reduce Kinesiophobia in patients with chronic LBP (Martinez-Calderon et al., 2020). Indeed, the multidimensional and complex nature of chronic LBP suggests that many factors influence pain and disability. As such, it is recommended that clinicians consider a broad range of physical, psychological, social and health-related measures in the management of patients with chronic LBP (Tagliaferri et al., 2020). How psychological factors such as pain catastrophizing and Kinesiophobia may influence improvement in different treatment approaches and outcomes (e.g. pain and disability) warrants further attention. Clearly, additional high-quality studies are needed to clarify the relationship between psychological factors and treatment outcomes in patients with chronic LBP.

Objectives

1) The objective of this study was to examine the effectiveness of a general strengthening exercise program and a muscle control and isolated lumbar exercise program on pain, pain catastrophizing, Kinesiophobia, anxiety, depression, quality of life, disability and sleep quality in patients with chronic LBP as compared to the MC+ILEX group.

2) Examine the association between baseline pain catastrophizing scores with pain and disability levels following the exercise intervention.

Hypothesis

We hypothesized that over the span of the 12-week intervention, there will be a significant decrease in pain, catastrophizing, Kinesiophobia, depression, anxiety, sleep disorders and disability in both groups (e.g. MC+ILEX and GE). We also hypothesized that given the significant influence of pain catastrophizing and its effectiveness on recovery that there would be a correlation between baseline pain catastrophizing scores and pain and disability scores across all time points.

Methods

Study Design

This parallel randomized control trial was conducted at the PERFORM Centre, Concordia University, and registration trial # NTCT04257253. The proposed project was approved by the Research Ethical Committee of the Institution and the Central Ethics Research Committee of the Quebec Minister of Health and Social Services (# CCER-19-20-09).

The intervention occurred over 12 weeks with 2 supervised visits per week at the PERFORM Centre, Concordia University. All outcome measures were be obtained at baseline, 6 weeks, 12-week and 24-week post-treatment.

Participants and Recruitment:

A total of 50 participants with non-specific chronic LBP were randomly assigned to each group. Participants were randomly assigned to treatment groups (1:1) using consecutively numbered sealed opaque envelopes. A computer-generated randomization sequence with permuted blocks was created by an individual not involved in the study. The participants were initially intended to be recruited from the Montreal General Hospital (MGH) Orthopedic Clinic and PERFORM athletic therapy clinic run by Concordia university however recruitment using outside sources was interrupted with due to COVID-19 public health measures. Therefore, participants were recruited through advertisement in the Concordia and NDG/Montreal West communities. Participants expressing interest in the study were contacted by the study coordinator to confirm interest and enroll them in the study. Inclusion and exclusion criteria for participants is outlined in Table 1. The current study represents the secondary measures of a primary study examining the effects of the MC+ILEX and GE exercise programs on paraspinal muscle morphology and function and so the effect size was calculated based on the primary measures. The only blinding possible during the study was of the assessor, blinding of the participants and the trainers was not possible.

Table 1 Inclusion and exclusion criteria for participants.

Inclusion Criteria

- **Chronic, non-specific low back pain (LBP) for a minimum of 3 months (with or without leg pain),**
- **Between the ages of 18 and 65 years old**
- **Speak either French or English**
- **Are currently seeking care for LBP**
- **Score either "moderate" or "severe" on the modified Oswestry Low Back Pain Questionnaire (>20)**
- **Do not engage in any sport or fitness training specifically for the lower back muscles either currently or 3 months before the start of the trial**

Exclusion Criteria

- **Any evidence of nerve root compression or reflex motor sign deficits.**
- **Previous spinal surgery or vertebral fractures.**
- **Major lumbar spine structural abnormalities.**
- **Health conditions that prevent the safe participation in physical exercise as determined by the Physical Activity Readiness Questionnaire.**

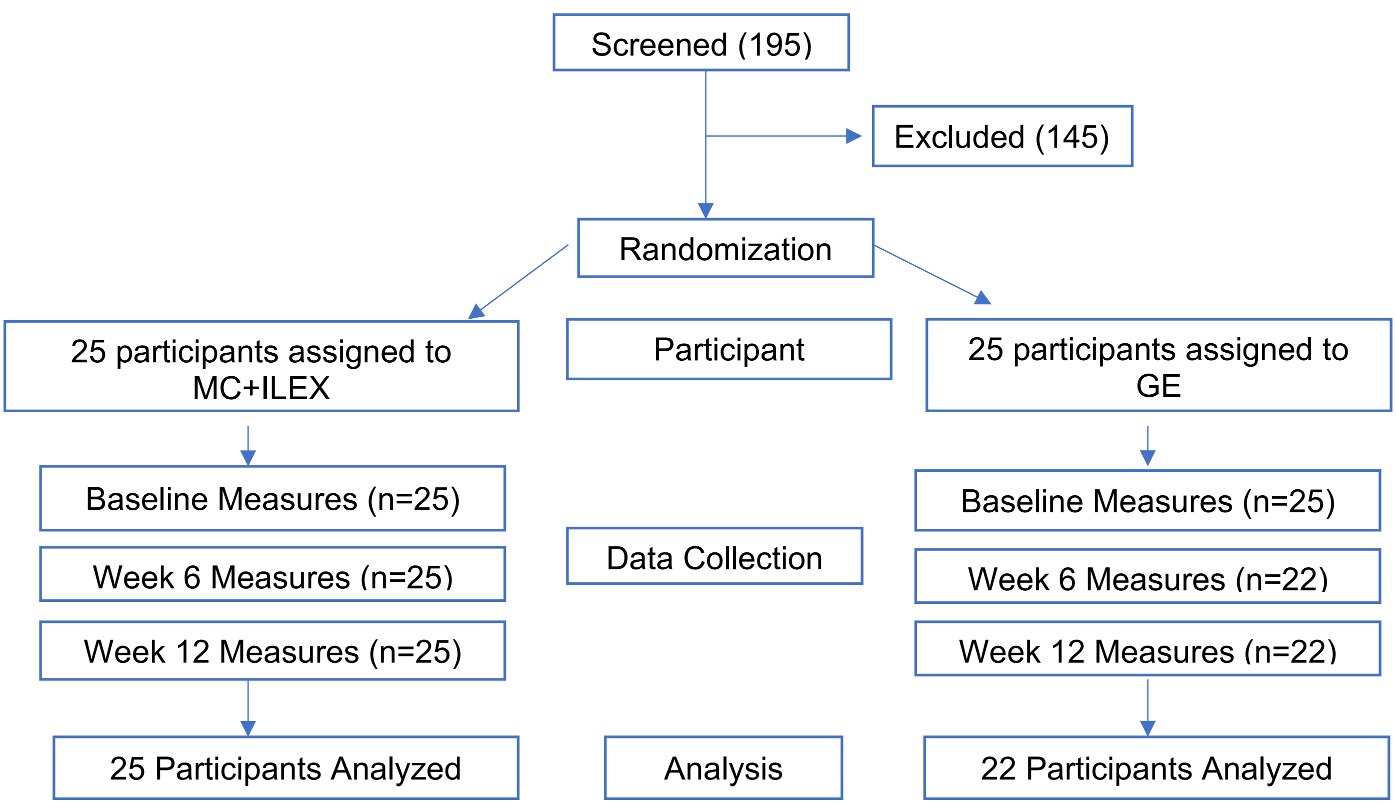


Figure 3 Consort Flow Diagram

Planned interventions

General exercise:

The general exercise group (GE) engaged in a supervised GE program that was administered individually twice a week on the Concordia University PERFORM center conditioning floor. The overall structure of the workout was a 10-minute warmup, 40-minute workout and 10 minutes of stretching. The aerobic warm-up consisted of either an incline walk on the treadmill of the intensity of the participant's choosing or stationary bike. The workout was a lower-body targeted resistance training regimen followed by trunk-leg stretches. The stretches were lower body focused and will consist of Cat Cow, Pigeon, deep lunge, piriformis stretch although others were added depending on how the participant was feeling that day. Each stretch was held for 10 seconds each for 3 times on each side in accordance with ACSM guidelines.

The program was divided into a 2-day split with different muscle group focuses for each day (Table 4). The difficulty of the intervention was progressively increased over the course of the 12-week intervention based on a study procedure developed by Iversen et al. (2017). The weekly progression is outlined in Table 3 and the weights were increased by 5% as soon as participants were able to complete 2 more reps than the amount assigned for that period. Should an exercise be too difficult or not feasible for the participant, an alternate exercise was provided that target the same muscle groups as the original exercise. For example, two participants were unable to complete squats, one due to an injury and the other due to fear and so the horizontal leg press machine was substituted as it targets similar muscle groups and allowed for a workout of similar intensity to the rest of the group. The program was administered by a master's student in the Health, Kinesiology and Applied Physiology (HKAP) department who has a bachelor's degree in exercise science who also encouraged the participants through explanation of the reasoning behind the movements as well as motivated them throughout the workout.

As most patients with LBP have low physical capacities and sedentary lifestyles, due to the nature of their pain, the overall goal of this intervention was to return participants to the normal activities of daily living (e.g., rising, bending, lifting, walking) by enhancing lower-body strength and flexibility. Such general exercise program can reduce pain and improve function (e.g. moderate level of evidence)(Gordon & Bloxham, 2016) but are not intended, nor expected to have an impact on paraspinal muscle morphology (Shahtahmassebi et al., 2014).

Table 2 Difficulty progression over the 12-week GE control

Week	**1-2**	**3-5**	**6-8**	**9-12**
Repetitions:	15-20	12-15	10-12	8-10

Table 3 Two-day split exercise program performed by the GE group.

Day 1: Glutes and Hamstrings	**Day 2: Quads, glutes and abs**
Hip extension (multi-hip machine)	Goblet squat (dumbbells)
Prone Leg curl machine	Step up: progressively made more difficult with added weight holding dumbbells and adding height to the step.
Lat pull down machine	Leg extension machine
Seated row machine	Peck deck machine
Hip abduction machine	Lying side leg raises: lying on exercise mats Eventually progress to standing single leg lifts with the cable machine
Hip adduction machine	Abdominal crunch: progressively more difficult (hold at the top of movement and eventually adding light dumbbells)

Home Program:

In addition to the prescribed intervention to be completed twice a week in a gym setting, the participants were assigned a home program outlined in table 4. The participants were provided with resistance bands with which to do their home program and were be instructed to perform the program 2-3 times per week in addition to the in-person training. Each exercise was performed for 10 reps for three sets each accompanied by a warmup and stretches of their choosing.

Table 4 General Exercise Home Program exercises.

Home Program
Box squats: more difficult by adding weight and bands around the knees
Banded kickbacks: progress with heavier band
Banded sidestep: progress with heavier band
Band pull-aparts: progress with heavier band
Clamshells: progress with heavier band

MC+ILEX

The MC+ILEX group had 2 supervised individual 1-hour sessions for the 12 weeks of data collection in the multifunctional rooms at Concordia University's PERFORM Center. This intervention was comprised of 2 parts to be performed in parallel: muscle control (MC) comprised of exercises directed at re-establishing proper coordination, control and co-contraction of deep lumbar muscles that support the spine at rest and during movement and isolated lumbar extensor strength exercise (ILEX) using the MedX machine.

Motor Control (MC):

The MC intervention was divided into 2 phases: the cognitive phase (phase 1) and associative and autonomous (Phase 2):

Phase 1: Cognitive Phase

Phase 1 is starts with an evaluation of muscle activation and breathing patterns. The intervention is then tailored to each participants' individual deficiencies found during the initial assessment. The objective of this phase of the intervention was to increase the co-contraction and coordination of deep trunk muscles and minimize the activity of the surrounding muscles. This was done with the use of cues outlined in table 5. Deep trunk muscle activation began in various positions depending on level and progressively increased in difficulty as the participant improved activation ability. Difficulty was increased once the participant was able to complete 10 reps while holding for 10 seconds requiring minimal coaching and was able to breathe normally throughout.

Breathing assessment was done in a supine seated position and was evaluated for asymmetry, expansibility and for accessory muscle recruitment (Sternocleidomastoid and scalene). Both phases of the intervention emphasized the importance of diaphragmatic breathing.

Table 5 MC+ILEX group, example of position and cues for multifidus and transverse abdominis activation.

Multifidus Activation	
Positions	Prone or on hands and knees (some people are better in 1 to start) Fingers on either side of spinous process; evaluation of different spinal levels from T1/T2 to T5/S1
Cues	Try to swell muscle up into my fingers Think about tilting pelvis without actually doing it Imagine tensing a cable from your pelvis up through your spine
Ideal Response	Symmetrical contraction No global muscle activation Normal breathing Able to hold 10 x 10s
Transverse Abdominis Activation	
Positions	Start supine or crook-lying Find neutral pelvis Place fingers slightly medial and inferior to ASIS
Cues	Try to pull your belly button down to the table Try to move your fingers together (medially)
Ideal Response	Gradual increase in tension; 10–15% effort Symmetrical contraction No global muscle activation Normal breathing Able to hold 10 x 10s

Phase 2: associative and autonomous

Progression to phase 2 relied on the participant being able to activate deep trunk muscles with minimal help from accessory muscles all while maintaining proper diaphragmatic breathing and involved additional loads to the muscles progressing from static positions to dynamic positions. The aim was to progress toward functional movements all while maintaining proper deep trunk muscle activation. The difficulty of the exercises was adjusted with by placing the participant in more challenging positions: supine to sitting, by increasing the load by adding limb movement and by introducing the need for dynamic stability by placing the participant on an unstable surface such as a ball. The purpose of this phase was to progress the participants toward automatic activation of deep trunk muscles in coordination with superficial muscles.

Isolated Lumbar Extensor Strength (ILEX)

The second part of the intervention was the ILEX training performed on the MedX machine (Figure 4). ILEX training began with establishing the participants' one repetition maximum (1RM) force at 24° incline. The participants began at 55% of the previously established 1RM and had to complete 2 sets of 15-20 repetitions at that weight. Weights were increased by 5% once the participants were able to complete the 15-20 reps at the initial weight and was increased in the same manner for subsequent progressions.

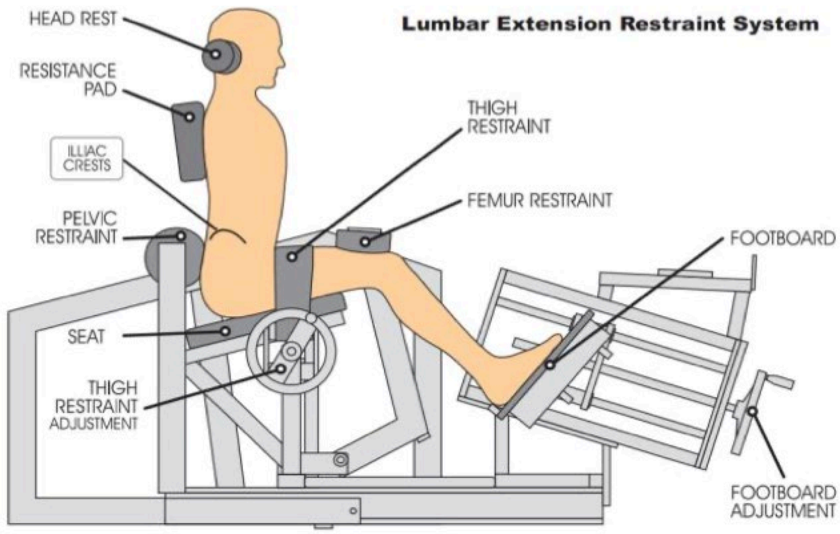


Figure 4 Schematic illustration of the MedX Lumbar medical machine.(Conway, 2016)

Home Program

As with the GE group, the MC+ILEX group was assigned a home program to perform at least twice a week. The program was divided into 3 phases and progression from one phase to the next was up to then discretion of the participant once the previous phase was deemed to be too easy. The MC+ILEX participants were provided with the same set of 3 resistance bands as the GE group to be used to increase the difficulty of the movements prescribed.

Table 6 MC home progra

Phase	• Exercise
Phase 1	• Supine TA contractions → work up to 10 seconds • Prone multifidus contractions with contralateral leg lift; work up to 10 seconds • Progress to contraction without leg lift • Sitting contractions up to 10 seconds • Standing contractions up to 10 seconds
Phase 2	• Transverse Abdominus • Supine contraction, knees bent, with alternating sides leg lifts 2x10; work up to holding each for 10 seconds • Start one leg in each contraction, reset contraction during rest • Progress to one lift each side in same contraction

	• Supine contraction followed by glute bridge, 2x10; work up to holding 10 seconds • Progress to lifting one leg during glute bridge • Progress to single leg glute bridge • Seated Contraction on exercise ball 2x10 up to 10 seconds • Progressions: closing eyes, adding leg lift • Standing Contractions 2x10 working up to 10 seconds • Progressions: Closing eyes, single leg balance • Multifidus • Contraction on hands and knees, 2x10 working up to 10 seconds • Add alternating arm lift • Add alternating leg lift • Add contralateral arm and leg at same time
Phase 3	• Squat with contractions 2x10 • Standing anti-rotation against resistance band 2x10-30 seconds each side • Standing trunk rotations against resistance band 2x10 each side • Alternating Lunges with contraction 2x10 • Add rotation

Outcomes

The following outcome measures and self-reported questionnaire were obtained at baseline, 6-week and 12-week mark.

Table 7 Outcome measures and their corresponding questionnaires.

Measure	Questionnaire
Disability/function status	Oswestry Low Back Pain Disability Index
Health status	SF-12 Item Health Survey
Level of physical activity	The International Physical Activity Questionnaire
Pain	Numerical pain rating scale (visual analogue scale)
Pain related fear including catastrophizing	The Pain Catastrophizing Scale
Kinesiophobia	Tampa Scale of Kinesiophobia
Depression and anxiety	The Hospital Anxiety and Depression Scale
Sleep Quality	Insomnia Severity Index

Oswestry Low Back Pain Disability Index (ODI)

The Oswestry Disability Index (ODI) is the most common questionnaire used to asses disability stemming from LBP (Lee et al., 2017). The ODI is a 10-item self-reported survey and is scored based on points. Each item has 6 options scored from 0-5. The scores from each item are then added up to represent a percentage of disability. The higher the percentage, the higher the disability with the minimum score being 0 and the maximum score being 100 (Fritz & Irrgang, 2001; Chapman et al., 2011). The ODI has been found to be reliable and has been validated in 14 different languages (Chapman et al., 2011). In normal populations, the weighted mean ODI score has been found to be 10.19 whereas for individuals with low back pain, the weighted mean was found to be 43.3 (Fairbank & Pynsent, 2000). Interestingly, the minimal important change (MIC) for the ODI is dependent on intervention. It has been suggested that the MIC as a result of surgical intervention should be around 15 and for all other intervention, an MIC of 10 (Ostelo et al., 2008). The MIC of concerning LBP for the ODI was hard to pinpoint because LBP- related disfunction is quite subjective (Ostelo et al., 2008).

SF-12 Item Health Survey

The Medical Outcomes Study Short Form 12 Health Survey (SF-12) is a 12-item self-reported health related quality of life survey that is used to monitor patients that are suffering with chronic illness (Huo et al., 2018). The SF-12 is subset of the original 36-item survey (Ware, 1996). The questionnaire was shorted as 36 items was deemed a hinderance to its usefulness (Lam et al., 2013). The SF-12 successfully represents all 8 health scales that compose the SF-36: role physical (2-items), physical functioning (2 items), role emotional (2 items), mental health (2 items), general health (1 item), vitality (1-item), bodily pain (1 item) and social functioning (1 item) and has been found to be both a reliable and valid alternative to the longer survey (Ware, 1996). These scales represent the physical component scales and mental component scales (MCS) of the survey (Gandhi, 2001). Each item is rated on a scale of 0-100 and an average of all 12 items is taken at the end. Scores below 50 are considered to be in better health and those above 50 are considered to be in worse health. The SF-12 has been extensively tested and shown to be both reliable and valid (Huo et al., 2018).

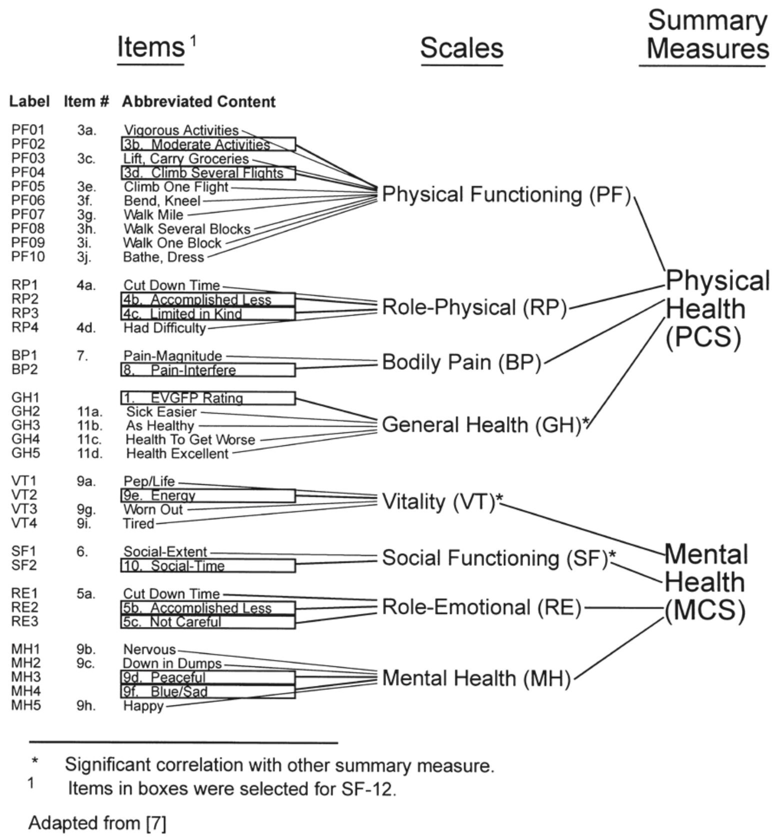


Figure 5 SF-12 Items (Gandek et al., 1998.)

The International Physical Activity Questionnaire (IPAQ)

The IPAQ is a self-reported recording of the physical activity performed by an individual over the past 7 days and was designed to be used by individuals between the ages of 15-65 (Craig et al., 2003). The reliability and validity of the IPAQ was tested at 14 centers in 12 countries and was found to be reliable and valid (Craig et al., 2003). The IPAQ score is calculated based on metabolic expenditure collected through a series of 7 questions. A MET expenditure under 600 MET-min/week is considered physically inactive, 600-3000 MET-min/week is considered mid-range and 3000 MET-min/week is considered to be a high activity level (Altuğ et al., 2016).

A study that examined the likelihood of LBP in medical professionals in North Poland found that those who had a sedentary lifestyle were more likely to experience low back pain as opposed to those who fell within the moderately active category. Those who were in the highest physical activity category were also very likely to develop LBP symptoms due to the stress their bodies endure (Citko et al., 2018). The IPAQ has been deemed both reliable and valid (Tran et al., 2013)

Visual Numerical pain rating scale (NPR):

The visual numerical pain rating scale (NPRS) is widely used to assess pain intensity in patients with LBP. It is an 11-point rating scale scored from 0-10 with zero being the lowest and 10 being the highest (Hawker et al., 2011). It has a very good respondent burden given that it takes less than a minute to answer and is easy to understand (Hawker et al., 2011). This pain-rating scale have shown good validity and reliability for assessing pain intensity (Alghadir et al., 2018) in addition to being used friendly for the respondent, it is also easy to note clinically significant change. Improvement of 2 units (30%) or more on the 0 to 10 scale is considered clinically significant (Farrar et al., 2001).

The Pain Catastrophizing Scale (PCS)

The PCS is a 13-item questionnaire that assesses the participant's level of catastrophizing. Each item is rated from 0-4 for a possible total of 52. The higher the score, the higher the level of catastrophizing. The PCS is both reliable and valid (Sullivan et al., 1995)

Tampa Scale of Kinesiophobia (TSK)

The TSK measures pain-related fear in an individual through a 11-item scale (Tkachuk & Harris, 2012). He scores range between 17 and 68 with increasing scores showing increased levels of Kinesiophobia. The TSK is highly reliability and valid (Tkachuk & Harris, 2012)

The Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item questionnaire used to assess a patient's level of depression and anxiety. Each item is rated from 0-3 with either depression or anxiety having scores between 0 and 21 with 21 being the highest level possible. The HADS is both reliable and valid (Villoria & Lara, 2018)

Insomnia Severity Index (ISI)

The ISI measures an individual's self-perception of insomnia (Bastien, 2001). It is a 7-item scale with each item rated between 0-4 for a total possible score of 28 indicating sever insomnia. It is both reliable and valid (Bastien, 2001).

Statistical Analysis

Independent t-tests and chi-square tests were used to examine difference in demographic characteristics between groups for continuous and categorical variables, respectively. Repeated measures ANOVA were used to examine the difference in outcome between groups overtime (e.g., baseline, 6-week, 12-week) and assess possible time*group interactions. The normality and sphericity assumptions were verified and tenable. Pearson Correlations were used to examine the relationship between baseline psychological factors and LBP outcomes (e.g. pain and disability) post-intervention given the smaller sample size where a small correlation was 0.1, moderate 0.3 and a strong correlation was >0.5 (Cohen, 1988). Significance level for all statistical analyses was set at p<0.05.

Results

Participants and adherence:

Twenty-two participants of the initial 25 participants assigned to the GE group completed the 12-week study (Figure 3). Two participants were excluded for non-compliance and 1 had to drop out due to conflicting time commitments. The MC+ILEX group had all 25 participants complete the intervention giving a total of 47 participants completing the study. This resulted in 94% participant retention rate overall. There was no statistical difference in any of the baseline demographic characteristics between groups (Table 7). The study was completed over a period of 12 months beginning in October 2020 and finishing in October 2021.

Attendance for the study was high with the MC+ILEX group reporting a mean attendance of 22.12(SD=1.64) out of a possible 24 sessions and the GE group attending a mean of 22.36 (SD=1.29). Overall attendance was 22.23 (SD=1.48) sessions giving an overall attendance rate of 92.62%. The results of a self-reported data monitoring questionnaire at the end of the study indicated that most of the participants attempted the assigned home programs with only 15% reporting having never tried the programs. The main adverse event was muscle soreness, which was reported by all participants. No other adverse event was reported. The main co-intervention was massage along with 2 participants seeking chiropractic intervention during the study as well as a couple continuing physiotherapy treatments for existing injuries on other parts of the body, other than the lumbar spine.

Table 8 Demographic data for participants in the MC+ILEX and GE groups and overall population

Characteristic	Muscle Control (MC) n=25	General Exercise n=22	Total Group n=47	P value Between groups
Demographic				
Male, n (%)	5 (20.0)	9 (40.9)	14 (29.8)	0.12
Female, n (%)	20 (80.0)	13 (59.1)	33 (70.2)	
BMI, X (SD)	26.09 (5.01)	26.56 (5.55)	26.31 (5.22)	0.76
Age (years), X (SD)	45.16 (10.66)	39.23 (11.26)	42.38 (11.23)	0.07
Marital Status n (%)				
single	6 (24.0)	8 (36.4)	14 (29.8)	

common law	5 (20.0)	7 (31.8)	12 (25.5)	0.41
married	11 (44.0)	5 (22.7)	16 (34)	
divorced	3 (12.0)	2 (9.1)	5 (10.6)	
Education, n (%)				
High School Diploma	3 (12.0)	0	3 (6.4)	0.30
CEGEP or eqv.	3 (12.0)	4 (18.2)	7 (14.9)	
Bachelors	9 (36.0)	11 (50.0)	20 (42.6)	
post grad	10 (40.0)	7 (31.8)	17 (36.2)	
Employment n (%)				
employed	9 (36.0)	13 (59.1)	22 (46.8)	0.25
not employed	2 (8.0)	0	2 (4.3)	
not working	0	1 (4.5)	1 (2.1)	
self-employed	9 (36.0)	4 (18.2)	13 (27.7)	
homemaker	2 (8.0)	0	2 (4.3)	
student	2 (8.0)	2 (9.1)	4 (8.5)	
retiree	1 (4.0)	2 (9.1)	3 (6.4)	
Physical Activity level n (%)				
sedentary	9 (36.0)	7 (31.8)	16 (34)	0.38
minimal	7 (28.0)	9 (40.9)	16 (34)	
moderate	9 (36.0)	4 (18.2)	13 (27.7)	
heavy PA	0	1 (4.5)	1 (2.1)	
Smoking				
yes	1 (4.0)	0	1 (2.1)	0.61
yes; smokeless	1 (4.0)	1 (4.5)	2 (4.3)	
no; quit >3mo	1 (4.0)	0	1 (2.1)	
no	22 (88.0)	21 (95.5)	43 (91.5)	
Alcohol				
no	9 (36.0)	10 (45.5)	19 (40.4)	0.29
1x/week	9 (36.0)	7 (31.8)	16 (34.0)	
2-3x/week	7 (28.0)	3 (13.6)	10 (21.3)	
almost daily	0	2 (9.1)	2 (4.3)	
Low Back Pain Timeline				
Months X (SD)	73.52 (82.81)	108.14 (114.26)	89.24 (98.88)	0.24
First episode	7 (28.0)	3 (13.6)	10 (21.3)	0.23
Medication				
yes	6 (24.0)	2 (9.1)	8 (17)	0.18
Meds Length				
<3 months	2 (8.0)	0	2 (4.3)	0.42
3mo-1yr	1 (4.0)	1 (4.5)	2. (4.3)	
>1yr	3 (12.0)	1 (4.5)	4 (8.5)	
Over the Counter				
never	6 (24.0)	5 (22.7)	11 (23.4)	0.54
sometimes	19 (76.0)	15 (68.2)	34 (72.3)	
daily	0	1 (4.5)	1 (2.1)	
NSAID				

never	19 (76.0)	18 (81.8)	37 (78.7)	0.41
sometimes	6 (24.0)	3 (13.6)	9 (19.1)	
Muscle relaxant				
never	15 (60.0)	17 (77.3)	32 (68.1)	0.12
sometimes	10 (40.0)	4 (18.2)	14 (29.8)	
Narcotic				
never	23 (92.0)	21 (95.5)	44 (93.6)	0.19
sometimes	2 (8.0)	0	2 (4.3)	
Antidepressant				
never	21 (84.0)	18 (81.8)	39 (83.0)	0.16
sometimes	0	2 (9.1)	2 (4.3)	
daily	4 (16.0)	1 (4.5)	5 (10.6)	
Neuroleptic				
never	24 (96.0)	20 (90.9)	44 (93.6)	0.36
sometimes	1 (4.0)	0	1 (2.1)	
daily	0	1 (4.5)	1 (2.1)	
LBP Location				
right	5 (20.0)	2 (9.1)	7 (14.9)	0.21
left	2 (8.0)	6 (27.3)	8 (17.0)	
bilateral	12 (48.0)	7 (31.8)	19 (40.4)	
central	6 (24.0)	7 (31.8)	13 (27.7)	
Leg pain				
no	10 (40.0)	8 (36.4)	18 (38.3)	0.80
yes	15 (60.0)	14 (63.6)	29 (61.7)	
Leg Pain location				
none	10 (40.0)	7 (31.8)	18 (38.3)	0.37
Right, above knee	4 (16.0)	0	4 (8.5)	
Left, above knee	3 (12.0)	4 (18.2)	7 (14.9)	
Both, above knee	5 (20.0)	4 (18.2)	9 (19.1)	
Right, below knee	0	1 (4.5)	1 (2.1)	
Left, below knee	1 (4.0)	3 (13.6)	4 (8.5)	
Both, below knee	2 (8.0)	2 (9.1)	4 (8.5)	

Psychological Measures:

The results of the within-subjects repeated measures ANOVA used to assess psychological measured revealed no significant difference between groups for any questionnaire at any timepoint nor was the interaction between groups and timepoints was significant for any of the questionnaires examined (Table 8). There were, however, multiple significant changes within groups for many of the parameters examined (Table 8). Pain improved significantly from baseline to 6-week (GE:$p<0.001$, MC+ILEX:$p<0.001$) and baseline to week 12 (GE:$p<0.001$, MC+ILEX: $p<0.001$) for both groups. Disability improved significantly in both groups from baseline to 6-week (GE: $p=0.03$, MC+ILEX: $p=0.05$), baseline to week 12 (GE: $p<0.001$, MC+ILEX: $p<0.001$) and from week 6 to week 12 (GE: $p=0.009$, MC+ILEX: $p=0.003$). The SF-12 only had significant results for the physical component (SF-12 PCS), GE for baseline to 6-week (p=0.02) and MC+ILEX for baseline to 12-week (p=0.004). Sphericity was violated for the ODI, PCS and TSK so Greenhouse-Geisser was used to account for sphericity for those 3 measures.

The MC+ILEX group had a significant improvement in PCS scores from baseline to 6-week (p=0.038) and baseline to 12-week (p=0.006). Both groups had significant improvement in TSK scores from baseline to 6-week (GE: p=0.045, MC+ILEX: p=0.021) and baseline to 12-week (GE: p=0.003, MC+ILEX: p<0.001) with the MC+ILEX group also having significant improvement from 6-week to 12-week (p=0.016).

Table 9 Comparison of means from ANOVAs

Outcome	GE (n=22)	MC+ILEX (n=25)	Adjusted between group difference (95%CI)	P value	F value	P value for overall group x time interaction
Pain						
Baseline	5.20 (1.49)	5.23 (1.79)	-0.033 (-1.13 to 1.06)	0.95		
6-week	3.73 (1.31)[a]	3.58 (1.81)[a]	0.15 (-.92 to 1.22)	0.78	1.10 (df =2)	0.34
12-week	3.56 (1.83)[b]	2.80 (1.84)[b]	0.76 (-0.44 to 1.96)	0.21		
ODI						
Baseline	27.52(10.04)	29.54 (10.04)	-2.02 (-8.07 to 4.03)	0.51		
6-week	22.00(9.96)[a]	23.08 (11.7)[a]	-1.08(-7.67 to 5.50)	0.74	0.11 (df =1)	0.85
12-week	18.19 (7.72)[b,c]	19.08 (10.89)[b,c]	-0.89 (-6.64 to 4.86)	0.76		
SF-12 PCS						
Baseline	40.75(9.56)	38.78(7.74)	1.97 (-3.24 to 7.17)	0.45		
6-week	46.16 (7.49)[a]	42.26 (7.51)	3.91 (-0.62 to 8.43)	0.09	1.14 (df =2)	0.33
12-week	45.44 (6.93)	45.20 (7.78)[b]	0.24 (-4.22 to 4.7)	0.91		
SF-12 MCS						
Baseline	45.67(12.27)	48.83 (8.41)	-3.15 (-9.41 to 3.15)	0.32		
6-week	46.43 (10.12)	47.03 (9.26)	-0.60 (-6.43 to 5.23)	0.84	1.02 (df =2)	0.37
12-week	49.85 (11.45)	49.34 (12.84)	0.51 (-6.85 to 7.87)	0.89		
PCS						
Baseline	17.05 (11.60)	18.71 (12.80)	-1.66 (-9.05 to 5.72)	0.65		
6-week	12.67 (11.89)	13.04 (8.09)[a]	-0.38 (-6.43 to 5.68)	0.90	0.27 (df =2)	0.77
12-week	10.90 (8.89)	10.33 (9.54)[b]	0.57 (-4.99 to 6.14)	0.84		
TSK						
Baseline	26.80(6.42)	27.12 (7.51)	-0.33 (-4.63 to 3.98)	0.88		
6-week	23.70 (5.04)[a]	23.96 (7.52)[a]	-0.26 (-4.24 to 3.72)	0.90	0.05 (df =2)	0.96
12-week	21.95 (5.02)[b]	21.83 (7.21)[b,c]	0.12 (-3.74 to 3.97)	0.95		
Anxiety						
Baseline	8.80 (4.69)	9.04 (3.91)	-0.24 (-2.86 to 2.38)	0.85		
6-week	8.70 (4.89)	7.79 (4.15)	0.91 (-1.84 to 3.66)	0.51	0.82 (df =1)	0.44
12-week	7.20 (4.74)	7.17 (5.28)	0.03 (-3.05 to 3.12)	0.98		
Depression						
Baseline	5.40 (3.47)	5.83 (3.17)	-0.43 (-2.456 to 1.59)	0.67		
6-week	4.75 (4.33)	6.42 (3.90)	-1.67 (-4.18 to 0.84)	0.19	1.72 (df =2)	0.19
12-week	4.35 (3.57)	4.75 (4.19)	-0.40 (-2.80 to 2.00)	0.74		
ISI						

Baseline	12.0 (5.60)	11.63 (6.81)	0.375 (-3.535 to 4.285)	0.85	0.32 (df =2)	0.72
6-week	10.84 (5.31)	9.25 (6.80)	1.59 (-2.249 to 5.433)	0.41		
12-week	10.32 (6.62)	9.33 (6.20)	0.982 (-2.980 to 4.944)	0.62		

[a] = significant difference within group between baseline to 6-weeks
[b] = significant difference within group between baseline to 12-weeks
[c] = significant difference within group between 6-weeks to 12-weeks

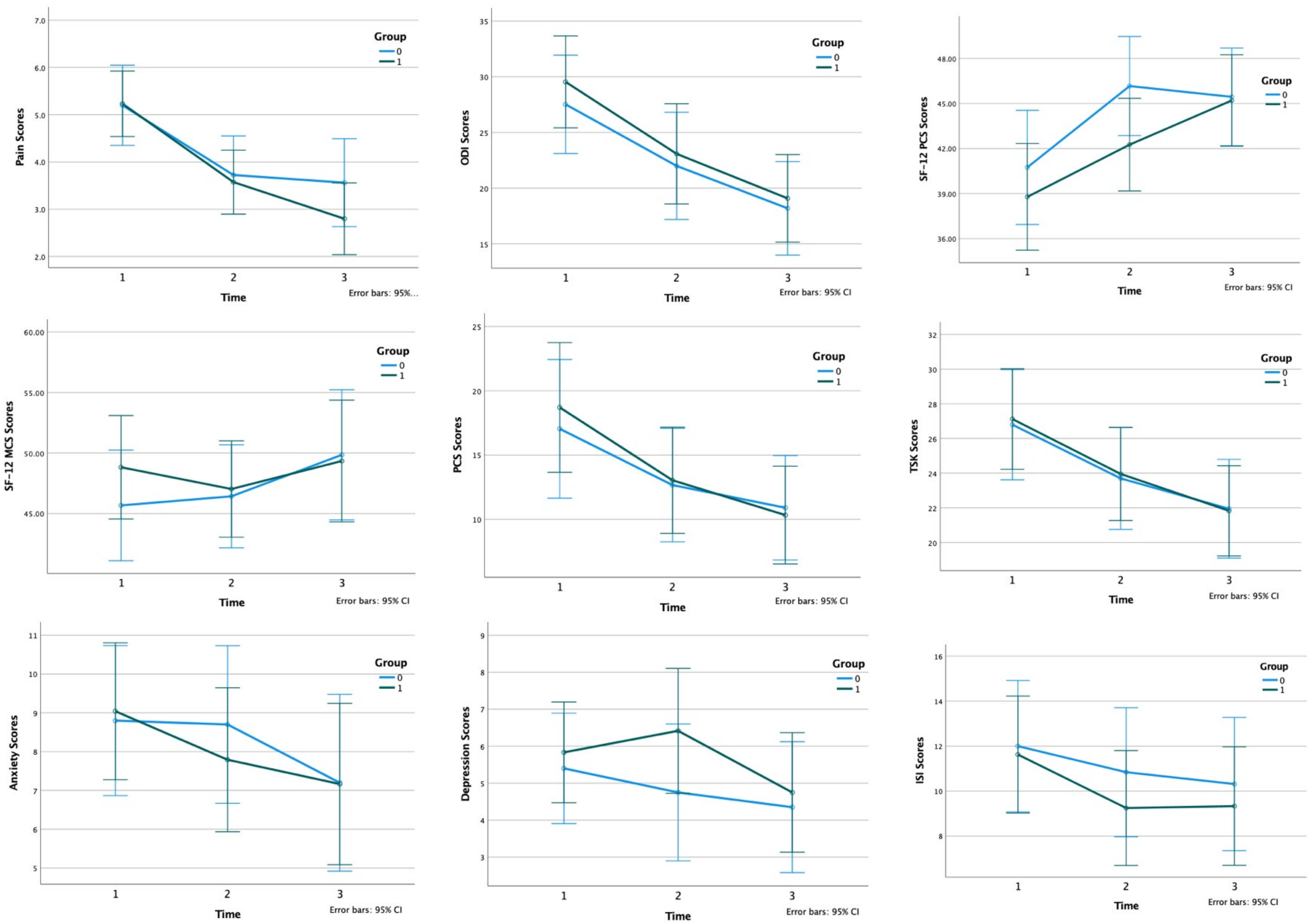


Figure 6 Comparison of means from ANOVAs

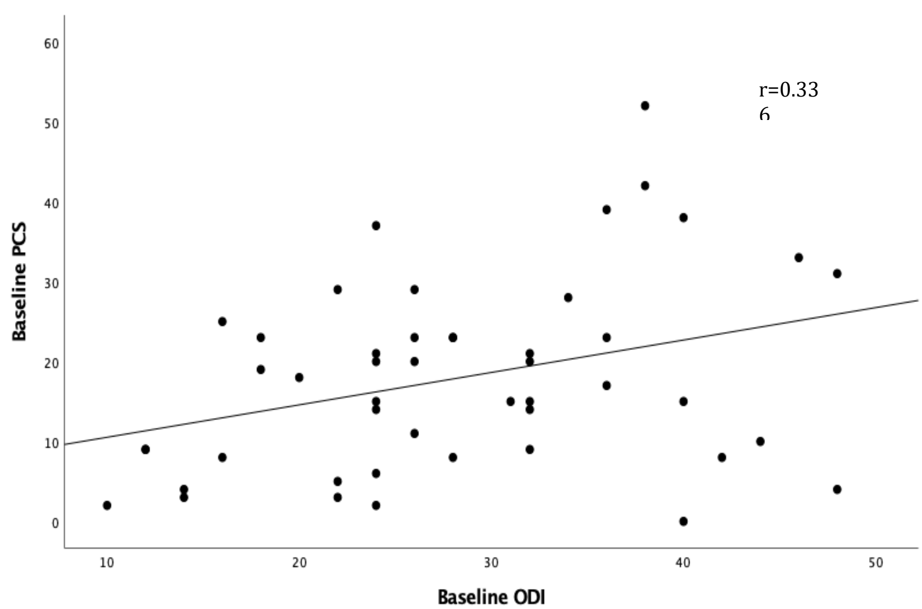
Catastrophizing, Pain and Disability

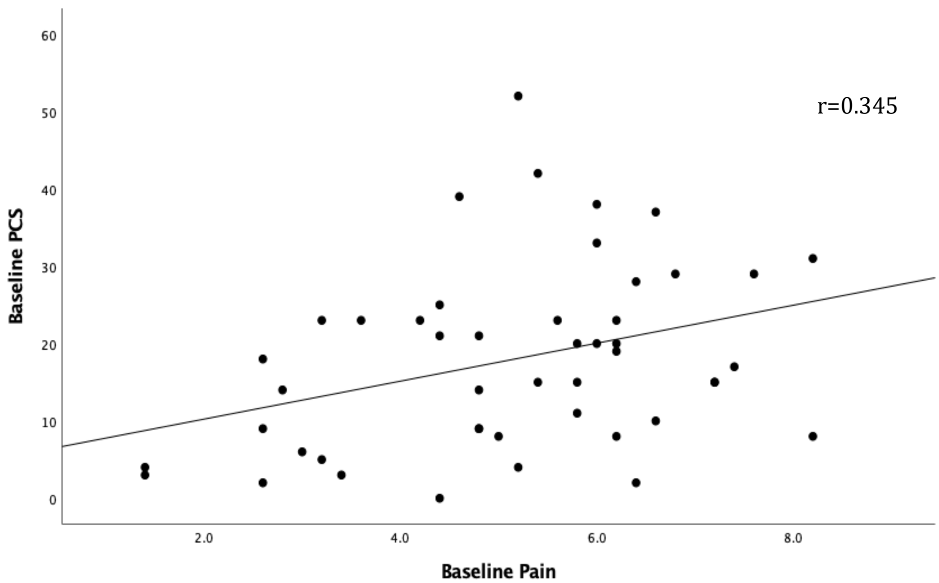
The correlation between baseline PCS scores and pain and ODI scores was examined across 4 different timepoints for each measurement: baseline, 6-week, 12-week and change from baseline and 12-week (Table 9). There was a moderate significant correlation between baseline PCS and ODI scores (r=0.336, p=0.021) and pain scores (r=0.345, p=0.017) as well as 6-week pain scores (r=0.378, p=0.014).

Table 10 Summary of Pearson Correlation data

	Baseline PCS scores			
	Pearson Correlation	**p-value**	**Confidence Intervals** Lower	Upper
ODI n=47				
Baseline	0.336*	0.02	0.019	0.597
6-week	0.25	0.09	-0.022	0.533
12-week	0.175	0.25	-0.122	0.467
Δ (baseline to 12 week)	-0.195	0.20	-0.515	0.136
NPR n=47				
Baseline	0.345*	0.01	0.085	0.556
6-week	0.378*	0.01	0.121	0.591
12-week	0.262	0.08	-0.001	0.531
Δ (baseline to 12 week)	-0.72	0.64	-0.360	0.230

*=Significant correlation based on significance level p=0.05





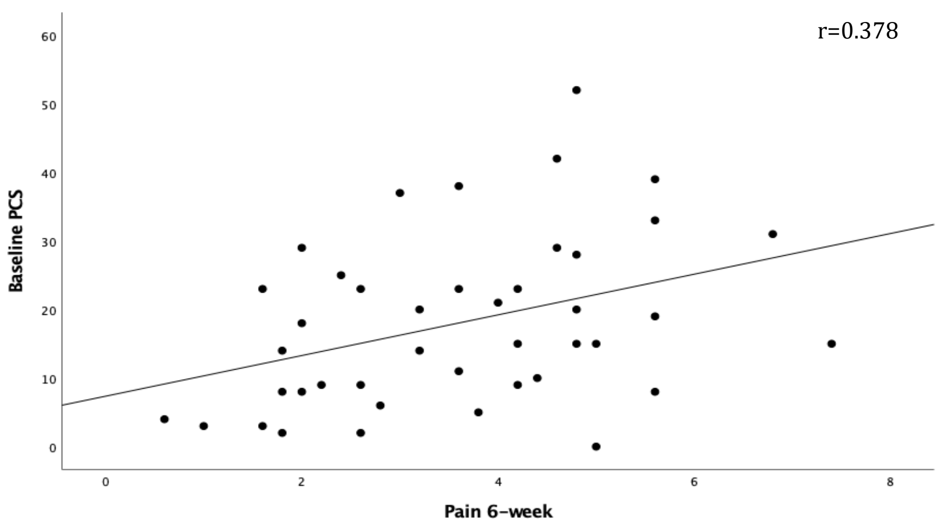


Figure 7 Correlation between baseline PCS scores and pain and disability

Discussion

The primary aim of this study was to compare the effectiveness of a 12-week GE program versus a 12-week MC+ILEX program on pain, disability, anxiety, depression, quality of life, insomnia, catastrophizing and Kinesiophobia. There was no significant difference between groups at any timepoint indicating that both interventions were equally successful in reducing LBP symptoms. The results of previous studies comparing different exercise interventions for the management of chronic LBP symptoms have limited support of one exercise program being better than the other. In a recent network metanalysis, Hayden et. al (2021) provided moderate support for Pilates and McKenzie therapy having a larger treatment effectiveness on pain and disability when compared to other types of exercise including motor control and general exercise. Another recent metanalysis comparing motor control exercises versus both hands-on (manual therapy) and hands-off (including general exercise and Pilates) interventions found low-moderate support in favor of MC exercises (Zhang et al., 2021). Of interest, a previous Cochrane review on the effectiveness of MC on LBP found low quality, not clinically important in support of MC over other exercises in the short term however, high quality support that MC was not clinically superior to other types of exercise in the long term(Saragiotto et al., 2016). All the aforementioned studies compared MC exercises to various other types of exercise yet obtained very different results. These conflicting results bring to light that there may be other factors to consider when comparing MC exercises to other therapies and that the differences may be attributed to the heterogeneity in the definition and design of the MC exercises used in studies (Ganesh et al., 2021). Our MC intervention was also combined with ILEX yet still had no significant difference from the GE program in terms of the improvement of LBP symptoms. A recent metanalysis of RCTs compared region-specific exercises versus general exercise programs for the management of spinal and peripheral musculoskeletal disorders and found no clinically significant difference between the two types of intervention for LBP related pain, disability and quality of life (Ouellet et al., 2021). This further supports the results of the present study and implies that although there are some studies that have reported that some types of exercise may be superior for the management of LBP symptoms, it remains an area that requires more exploration.

Our findings, however, revealed significant improvements in pain, disability and psychological factors within groups over time. Indeed, both pain and disability significantly improved for both groups across all time points: baseline to 6-week, 6-week to 12-week and baseline to 12-week. These results are in line with our hypothesis as well as with the results of previous studies. A systematic review comparing various types of exercise for LBP examined the effectiveness of all the types of exercise and concluded that both general exercise and MC were effective to reduce pain and disability (Owen et al., 2020). In the present study, only the MC+ILEX group had a significant improvement in PCS scores, with significant improvements from baseline to 6-week and baseline to 12-week. It was expected that both groups would have significant improvements in this outcome given that the PCS scores between groups at the various timepoints appear to follow relatively similar trends however, the GE had no significant changes in PCS scores at any timepoint. Vincent et al (2014) had a significant reduction in PCS scores over the course of their total body resistance exercise intervention however their baseline scores and post-intervention scores were lower as compared to our sample: 11.5 (12.6) at baseline to 4.1 (5.9) for a change of 7.4 (Vincent et al., 2014). The GE group had a maximum change in PCS score of 6.15, which is below the previously established clinically significant change of 6.71 (Suzuki et al., 2020). However, both the GE and MC+ILEX groups experienced significant improvements in Kinesiophobia scores over the 12 weeks. Specifically, both groups had significant improvement in TSK scores from baseline to 6-week and baseline to 12-week with the MC+ILEX group also having significant improvement from 6-week to 12-week. This finding is also in accordance with our hypothesis as well as with previous studies that have reported the positive effectiveness of exercise on Kinesiophobia levels

(Cruz-Díaz et al., 2018; Monticone et al., 2014). Martinez-Calderon et al (2019) performed a systematic review of 61 studied to examine the relationship between fear and conservative interventions and found that exercise alone was effective in reducing Kinesiophobia in people with LBP (Martinez-Calderon et al., 2020). Our observations support that engaging in physical activity is successful in reducing fear of movement in people with LBP and by doing so, allows them to experience the other psychological and physical benefits associated with exercise. Furthermore, our findings corroborate with previous studies (Iversen et al., 2018; Cruz-Díaz et al., 2018; Monticone et al., 2014) suggesting that improvement in the mental aspects of LBP is possible without any psychological intervention.

However, contrary to our hypothesis, there were no significant differences in quality-of-life mental scores (e.g., SF-12), anxiety, depression, or insomnia over the course of the intervention. This was not expected as higher levels of somatization, depression and anxiety have been found in people with LBP as opposed to their healthy counterparts (Fazel et al., 2021). This could be explained by the current participant pool having very low mean baseline depression, anxiety, and insomnia scores and so there was minimal room for significant improvements.

The secondary aim of this study was to examine the association between baseline pain catastrophizing scores with pain and disability levels following the exercise intervention. There were moderate correlations between baseline PCS scores and both pain and ODI at baseline as well as with 6-week pain scores. This does not support our hypothesis that there would be a significant correlation between baseline PCS and both pain and ODI across all time points. The moderate correlation between baseline pain catastrophizing scores and baseline pain and disability scores is reflective of the results of previous studies. A systematic review examining the relationship between disability and pain catastrophizing reported a moderate association between chronic LBP-related disability and pain catastrophizing (Alamam et al., 2021). Pain catastrophizing has also been found to be associated with clinical pain in patients with chronic LBP (Meints et al., 2019). Pain catastrophizing was also found to mediate pain and disability in people living with LBP (Marshall et al., 2017). In this study we examined the association between baseline catastrophizing scores and the change in pain and disability over the course of a exercise intervention. While we found a moderate association between baseline pain catastrophizing with baseline ODI and baseline and 6-week pain scores (e.g., higher pain catastrophizing scores were associated with both higher pain and disability scores) there was no association between baseline PCS scores and the change in ODI and pain over the 12-week intervention.

Given the results of the current study, future studies should compare different exercise interventions to further distinguish which types of exercise are most successful in improving LBP symptoms and related psychological factors. A strength of the present study is the detailed description of the exercise interventions. To properly evaluate the efficacy of an exercise intervention, each intervention and exercise program must be clearly outlined and reproducible to allow possible replication. Future studies should also provide a clear definition of MC exercises to avoid overlaps with other similar exercises. The mental components of chronic pain should also be examined by producing high quality studies to clarify the relationship between psychological factors and treatment outcomes. Investigating the mediating effect of pain catastrophizing and Kinesiophobia on improvement during different treatments for LBP also warrant further attention.

A strength of this study is the number of psychological parameters examined. Previous exercise studies focus primarily on pain and disability scores, including only a few psychological outcomes, however, the current study not only examined pain and disability but 6 psychological measures: quality of life, pain catastrophizing, Kinesiophobia, anxiety, depression, and insomnia. This allowed for a more in-depth examination of the effectiveness of exercise on the psychological effects of exercise without directly administering a psychological intervention. This study also had excellent participant adherence. There was a low dropout rate giving 94% participant retention combined with a 92.62% participant adherence to the program. Only 15% of the participant pool self-reported not completing the home program. This speaks to the enjoyment factor of the study given that a very high percentage completed the 12 weeks of the study and had great attendance. Another strength was the homogeneity of the trainings administered. Each treatment group was assigned one supervisor to administer the treatment and so this assured that the participants in each group all received the same training style and methods in their respective groups. Although this could also be viewed as a limitation given possibility of participant bias, the present study relied on the participants completing all 12-weeks of the intervention and so establishing a good rapport was important for the sake of participant retention.

A major limitation of this study was the sample size and the participant pool; sample size calculation was based on the primary outcome of this RCT (e.g., multifidus muscle size). Participant recruitment was extremely limited given the added obstacles associated with the COVID-19 pandemic such as center hours and capacity restrictions. Instead of recruiting from multiple different sources of LBP patients as initially planned, selection was limited to those who applied either through word of mouth or those who were close to the Concordia University community. Had the sample size been bigger, the mediating effects of pain catastrophizing on the various other psychological factors could have been examined. Another limitation was the lack blinding possible. Participants were aware of what group they were in given the nature of their respective interventions and the specificity of the trainings administered as well as the prolonged interaction the researchers had with the participants did not allow for blinding for any of the parties involved.

Conclusion

The results of this study provide preliminary evidence to suggest that MC combined with ILEX have similar benefits to a general exercise intervention in terms of improvement of psychological factors, pain, and related disability in chronic LBP. Baseline pain catastrophizing scores were also positive correlated with pain and disability. Our findings suggest that the scope of exercise goes well beyond physical improvements and has positive results when used for the management of chronic LBP symptoms. The results of this study are in line with most recent consensus (Hayden et al., 2021) that although there may be some exercise programs that are more beneficial in the reduction of chronic LBP symptoms, an important factor is finding a program you enjoy and able to perform consistently to gain the physical and mental benefits of exercise.

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