Effects of Aquatic Therapy versus Standard Care on Non-Specific Chronic Low Back Pain and Feasibility of mHealth Application Play the Pain: A Pilot Randomized-Controlled Trial

Nicolas Vaillancourt

A Thesis
In
The Department of
Health, Kinesiology and Applied Physiology

Presented in Partial Fulfillment of the Requirements for the Degree of
Master of Science (Health and Exercise Science)

at Concordia University
Montreal, Quebec, Canada

May 2024

© Nicolas Vaillancourt, 2024

CONCORDIA UNIVERSITY

SCHOOL OF GRADUATE STUDIES

This is to certify that the thesis,

By: Nicolas Vaillancourt

Entitled: Effects of Aquatic Therapy versus Standard Care on Non-Specific Chronic Low Back Pain and Feasibility of mHealth Application Play the Pain: A Pilot Randomized-Controlled Trial

and submitted in partial fulfillment of the requirements for the degree of

Master of Science (Health and Exercise Science)

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

Signed by the final Examining Committee:

_____Chair
Dr. Peter Darlington

_____Examiner
Dr. Richard DeMont

_____Examiner
Dr. Geoffrey Dover

_____Examiner
Dr. Najmeh Khalili-Mahani

_____Thesis Supervisor
Dr. Maryse Fortin

Approved by _____
Dr. Maryse Fortin, Graduate Program Director

June 06. 2024 _____
Dr. Pascale Sicotte, Dean of Faculty

Masters Abstract

Effects of Aquatic Therapy versus Standard Care on Non-Specific Chronic Low Back Pain and Feasibility of mHealth Application Play the Pain: A Pilot Randomized-Controlled Trial

Nicolas Vaillancourt

Introduction: The effects of aquatic exercise on psychological function associated with chronic LBP remains poorly understood and adherence to exercise-based interventions in CLBP is low. A promising solution to improve adherence is through the integration of mobile health application *Play the Pain*, which allows for continuous self-tracking of pain.

Objectives: The primary objective of my thesis was to compare the effects of aquatic therapy to standard care on CLBP in terms of pain, disability, and psychological factors. The secondary objective was to determine the feasibility of using *Play the Pain* in a CLBP clinical intervention in terms of adherence and satisfaction.

Methods: 34 participants with CLBP were randomized to the aquatic therapy (AT) group or the standard care (SC) group (AT, n=18; SC, n=16), while 12 participants tested *Play the Pain*. Outcome measures were pain (NPRS), disability (ODI), quality of life (SF-12), depression and anxiety (HADS), pain catastrophizing (PCS), kinesiophobia (TSK-11), insomnia (ISI) and adherence and satisfaction with the app.

Results: Both groups significantly improved pain, disability, pain catastrophizing and quality of life with no differences between groups. Twelve participants used *Play the Pain* and 6 completed the exit survey. The adherence to the app was at 41.6% and the user satisfaction was low.

Conclusions: Our results provide preliminary evidence on the efficacy of aquatic therapy to improve pain, disability and psychological outcomes associated with CLBP. We encountered many technical difficulties during the study that prevented our ability to adequately determine the feasibility of *Play the Pain*.

Acknowledgements

I would like to thank my supervisor, Dr. Maryse Fortin, for her constant guidance and mentorship throughout my Masters thesis. I am grateful for your trust in me, and for allowing me to oversee see a project of this magnitude. I would also like to thank my colleague and friend Chanelle Montpetit, who administered the study with me every step of the way. Chanelle, your help was vital to the completion of my Masters Thesis. I would like to thank Brent Rosenstein and Victor Kerin. Thank you, Brent, for assisting Chanelle and I through this project and making sure everything went smoothly every step of the way. Victor, I am grateful for your help in the mHealth project, your contribution was invaluable. To all INSPIRE lab members, thank you for all the feedback in the different presentations I gave regarding my topic and the continued support during my Masters. Lastly, I would like to thank Dr. Dover, Dr. DeMont and Dr. Khalili-Mahani for lending me their time by agreeing to be part of my thesis committee.

Contributions of Authors

Manuscript 1

Study Conception and Design: Nicolas Vaillancourt, Brent Rosenstein, Chanelle Montpetit & Maryse Fortin
Data Collection: Nicolas Vaillancourt & Chanelle Montpetit
Analysis and Interpretation of Results: Nicolas Vaillancourt & Maryse Fortin
Manuscript Preparation: Nicolas Vaillancourt & Maryse Fortin

Manuscript 2

Study Conception and Design: Nicolas Vaillancourt, Chanelle Montpetit, Najmeh Khalili-Mahani & Maryse Fortin
Data Collection: Nicolas Vaillancourt & Chanelle Montpetit
Analysis and Interpretation of Results: Nicolas Vaillancourt, Victor Kerin & Maryse Fortin
Manuscript Preparation: Nicolas Vaillancourt, Victor Kerin & Maryse Fortin

All authors reviewed the final manuscript and approved the contents.

Table of Contents

List of Figures

List of Tables

Chapter 1: Review of Literature

1. Low Back Pain Prevalence

Low back pain (LBP) is the leading cause of disability worldwide[1]. In 2020, an estimated 619 million people where affected by LBP and by 2050, the estimated number of cases will rise to 843 million globally[2]. Lifetime prevalence of LBP in the general population of developed countries ranges from 75% to 84%[3]. LBP prevalence is elevated across all ages, even in children and adolescents. An estimated 7% to 72% of 10 to 19 years old have suffered from LBP at some point in their life[4]. Once individuals reach 18 years of age, the prevalence of LBP becomes closer to that of adults[4]. The prevalence of LBP increases with age[5] and varies between sexes. Global prevalence of LBP is greater in females than males and most prevalent in the age range of 40 to 80 years old[6].

2. Low Back Pain Economic Burden

The economic burden of LBP can be due to direct or indirect costs. The direct costs associated with the economic burden of LBP are healthcare costs, while the indirect costs are due to lost worker productivity. Indirect costs represent approximately 85.5% of the economic burden of LBP, while direct costs represent about 14.5% of the cost[7]**.** LBP is a major cause of both healthcare costs and lost worker productivity[7]. A 2002 study showed that in Canada, medical costs associated with LBP range from 6 to 12 billion CAD per year and is still rising[8]. A 2001 study in Australia found the economic burden of LBP to be an estimated 9 Billion AUD with 8 billion AUD being attributed to indirect costs and 1 Billion AUD attributed to direct healthcare costs[9]. There are a lot of variations between studies in measures of economic burden associated with LBP, especially from indirect costs. A 2023 systematic review analyzing the regions of North America, Europe and the West Pacific estimated yearly direct costs associated with LBP to range from 2.3 Billion EUR to 2.6 Billion EUR, while the indirect costs ranged from 0.24 Billion EUR to 8.15 Billion EUR[10]. Since increased age is associated with a higher prevalence of LBP, the evermore aging populations is cause for concern[11]. Projections show there will be an increased number of people with LBP in the future, with a more rapid increase in low-income and middle income countries[12]. LBP pain is the most common reason for adults to retire early from the workforce[11]. Individuals who retire early from the workforce have 87% less wealth accumulation than those who remain in full-time employment[13].

3. Low Back Pain Definition

Following a consensus approach toward the standardization of back pain definitions, researchers have been using the following LBP definition: "*low back pain is defined as pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain"*[14]. LBP is subdivided into three categories: acute, subacute, and chronic.

Acute is LBP lasting 0 to 6 weeks, subacute is LBP lasting 6 to 12 weeks and chronic is LBP lasting over 12 weeks[15]. This thesis focused on LBP lasting over 12 weeks.

3.1.1. Pain Classifications

According to the International Association for the Study of Pain[16], pain can be classified as nociceptive, neuropathic and nociplastic. Nociceptive pain occurs from actual or threatened damage to non-neural tissue via the activation of nociceptors. Neuropathic pain occurs due to a lesion of the somatosensory nervous system. Nociplastic pain happens due to altered nociception without any clear evidence of actual or threatened tissue damage which would normally cause the activation of nociceptors. Biological factors that can exacerbate chronic pain perception include tissue health, central sensitization, cortical reorganization, and genetic predisposition.

4. Specific and Non-Specific Low Back Pain

LBP can be further subdivided into specific and non-specific LBP[12]. Specific LBP is caused by a known specific pathophysiological mechanism[17]. The mechanism of specific LBP can be spinal or non-spinal in origin. Non-spinal causes of specific LBP include: disease of the pelvic organs, vascular disorders or systemic disorders and malignancy[12,17]. Disease of the pelvic organs like prostatitis or endometriosis and vascular disorders like an aortic aneurysm can cause LBP[17]. Specific LBP from malignancies are uncommon, but they are most common in people with metastatic cancer[12]. Spinal causes of specific LBP include: vertebral fracture, axial spondyloarthritis, spinal infections, spinal stenosis and cauda equina syndrome[12,17]. Spondyloarthritis is a chronic inflammatory disease that mainly affects younger individuals of ages 20 to 40 years old[12]. Spinal infections include spondylodiscitis, vertebral osteomyelitis, epidural abscess and facet joint infection[12]. Spinal infections are rare and associated with a high rate of mortality. Cauda equina syndrome is an extremely rare condition where the nerve roots of the lumbar spine are compressed and occurs as a complication of an intervertebral disc herniation[12]. In some cases, when there is nerve root involvement, herniated discs can be a specific cause of LBP[17]. However, different types of herniated discs are also prevalent in asymptomatic individuals and are therefore not always a specific cause of LBP[18]. Degenerative disc disease is common in aging populations and often present in asymptomatic individuals, therefore we cannot attribute degenerative disc disease as a specific cause of LBP[18]. Non-specific LBP occurs without a clear nociceptive cause and accounts for 80 to 90% of all cases of LBP[19]. Non-specific LBP occurs due to a combination of biological, psychological and social factors[20,21]. This thesis focused on non-specific LBP.

5. Pain Models

5.1. The Gate Control Theory of Pain

The gate control theory of pain was conceived by Ronald Melzack and Patrick Wall in 1965[22]. The theory illustrates the role of the spinal cord in pain modulation and has since been refined. The theory explains that the spinal cord acts a gate between peripheral nerve conduction and the transmission of nociceptive information to the brain[23]. Nociceptive information is synapsed from primary afferent neurons to the spinal cord. There are three types of primary

afferent neurons which carry information from the peripheral nervous system to the spinal cord: A-Beta fibers, A-delta fibers, and C fibers. A-Beta fibers have a large diameter, which allows for rapid transmission of non-noxious stimuli to the spinal cord. A-delta and C-fibers have small diameters and conduct noxious stimuli to the spinal cord at slow rate of transmission. Nociceptive signals from A-delta and C-fibers are transmitted to the brain and interpreted as pain. The "gate" portion of the theory comes from the metaphorical opening and closing of the transmission point between the spinal cord and the brain. Interestingly, by stimulating A-beta fibers, the "gate" can be closed, which inhibits A-delta and C-fibers and results in a decrease in pain. The original minds behind the theory highlighted that the gate control theory must account for a number of factors. Two of those factors are particularly important: 1) pain can persist after tissue healing and 2) pain is a multi-dimensional experience that can be affected by emotional and cognitive factors. These factors can be accounted for by the neuromatrix model of pain and the biopsychosocial model of pain, which did not yet exist at that time.

5.2. The Neuromatrix Model of Pain Theory

The neuromatrix model of pain was conceived in the 1990s by Rondald Melzack and is a continuation of his work on the gate control theory of pain. The neuromatrix model of pain proposes pain is a multi-dimensional experience produced by a complex neural network called the body-self neuromatrix[24,25]. According to the author, the body self-neuromatrix is comprised of three neuromodules: sensory, affective, and cognitive neuromodules. Each neuromodule is a functional unit within the body-self neuromatrix responsible for generating a unique aspect of the pain experience. The sensory neuromodule refers to the part of the body and the nervous system responsible for relaying sensory information to the brain. The affective neuromodule is related to the emotional aspects of pain such as anxiety, depression, and fear. The cognitive neuromodule attaches meaning to the experience and is related to memories of past experiences and attention. During a painful experience, the body-self neuromatrix interprets and synthesizes information and generates a complex bodily response. The outputs of the body-self neuromatrix can be separated into three sections: pain perception, action programs and stress-regulation programs. Pain perception is the perceived painful response while action programs can be interpreted as the commands the brain sends to the body in response to the painful experience. Action patterns can be voluntary or involuntary adaptive changes that occur in the body, such as behavioral changes. Stress-regulation programs are the body's response to pain and the body's reaction to a disturbance in homeostasis. The disruption of homeostasis produces a hormonal response aimed at returning to homeostasis. The stress-regulation programs control the release of the stress hormones cortisol and norepinephrine, which are part of the body's fight or flight response. The fight or flight response is an important survival mechanism designed to induce stress and prepare the body for action. However, prolonged production of cortisol may damage soft-tissue and produce a state of chronic pain[25].

5.3. The Biopsychosocial Model of Pain

The biopsychosocial model was first proposed by George Engel in 1977 and was progressively introduced to research in pain management during the 1980s[20]. The biopsychosocial model of pain challenged the paradigm of pain management by claiming painful

experiences are not only a result of biomedical causes[26]. During the last few decades, the biopsychosocial model has been refined and has helped with the understanding and treatment of chronic pain. There is some overlap between the driving concepts of the neuromatrix model of pain theory and the biopsychosocial model of pain. However, the biopsychosocial model of pain is the most widely accepted perspective to the understanding and treatment of chronic pain[20]. The biopsychosocial model focuses on both injury and pain. Injury is defined as an objective biological event involving the disruption of specific body structures or organ systems caused by either anatomical, pathological or physiological changes[20]. The model explains that pain is not always a direct result of injury, and pain should instead be viewed as a complex modulated response that occurs from an interaction of biological, psychological and social factors[20]. Therefore, the severity of pain is not directly proportional to the severity of the injury. The interpretation of nociceptive signals, or pain, is a subjective experience that is unique to each person[20]. There are many components included in the biopsychosocial model of pain that can influence a person's painful experience. These factors are a combination of biological, psychological, and social factors.

5.4. Biological Factors of Pain

5.4.1. Tissue Health

Damage to soft tissue structures is a common biological source of pain. Soft tissue structures like skin, muscles and joints contain specialized peripheral sensory neurons called nociceptors. Normally, nociception and the perception of pain is evoked only under conditions of mechanical pressure and temperatures extreme enough to potentially injure tissues[27]. High threshold physical and noxious chemical stimuli are detected by nociceptors. Therefore, if damage to a tissue is substantial enough, nociceptors will be stimulated and send nociceptive information to the brain via the central nervous system. This nociceptive information is delivered to the brain as noxious stimuli to the brain, which the brain then interprets as pain. Noxious stimuli interpretation, or pain, varies greatly depending on the person. Soft-tissue structures associated with joints of the low back that can become damaged include the sacroiliac joint, the intervertebral discs, nerve roots, the lumbar intervertebral joints and facet joints, and vertebral ligaments such as the intervertebral ligaments and the iliolumbar ligaments. Soft-tissue structures associated with musculature of the low back that can become damaged include the multifidus, the erector spinae, the quadratus lumborum, the psoas major and minor, and the gluteus muscles. Following injury and damage to the tissues, the body will create an inflammatory cascade to elicit a healing response. The inflammatory cascade produces chemical mediators like histamines and bradykinin which causes chemical nociception[27]. The inflammatory response can be acute or chronic depending on the nature of the injury. Chronic injuries can be associated with chronic inflammation and produce chemical nociception for an extended period of time[27].

5.4.2. Central Sensitization

Chronic pain can cause overstimulation of the nervous system by constantly sending afferent nociceptive signals to the brain. The overstimulation causes the nervous system to go into a state of hyper reactivity to stimuli, a state otherwise known as windup[20]. When the nervous system is in a state of windup, the threshold of a normal painful response becomes lowered

which causes pain to persist even after the tissues have healed. Central sensitization is characterized by allodynia and hyperalgesia.

5.4.2.1. Allodynia and Hyperalgeasia

Allodynia is a type of neuropathic pain that causes an extreme sensitivity to stimuli that are normally non-painful, like touch. Hyperalgesia is a heightened painful response to a stimulus that is normally painful[16]. There is no consensus in the literature on the presence of central sensitization in CLBP[28]. Some studies have reported hyperalgesia CLBP patients[29–32], some studies found higher pain thresholds in patients with CLBP[33], while others found no differences in pain thresholds between CLBP patients and healthy controls[34–36]. A specific subgroup of CLBP patients who also have fibromyalgia have been found to have central sensitization[37].

5.4.3. Cortical Reorganization

Cortical reorganization occurs when the brain undergoes structural and functional changes in response to prolonged stimulus. and can occur in patients with CLBP[38]. Abnormal functional connectivity between the medial prefrontal cortex and brain regions within the default mode network were observed in patients with CLBP[39]. These cortical reorganizations are correlated with pain duration, pain severity and pain interference[39]. Brain activity associated with acute LBP is limited to regions of the brain involved in acute pain[40]. However, brain activity related to CLBP is confined to the emotional circuits of the brain[40]. This finding suggests with chronification of LBP, the brain can undergo a significant shift in neural mapping and activity. Several studies have also found that maladaptation to chronic pain can cause dysfunction in the emotional and cognitive regions of the brain[41–43]. The dysfunction in emotional and cognitive regions of the brains could be linked to the psychosocial factors of CLBP.

5.4.4. Genetic Predisposition to CLBP

There can be genetic predispositions to developing CLBP. Twin studies found the heritability of back pain to be in the range of 32% to 68%[44–46]. A genome wide association study of 509 000 individuals from Freidin et al.[47] found specific genes associated with the development of CLBP. The genes associated with predisposition to CLBP can be classified as biomedical and biopsychosocial, with the principal predisposition being from biopsychosocial genes. The biomedical genes associated with CLBP are linked to altered functioning of the central nervous system, poor skeletal muscle function and increased likelihood of developing degenerative disc disease[47]. The biopsychosocial type genes are linked to poor psychological functioning with an increased likelihood of having anxiety and depressive disorders[48]. The genetic predisposition to CLBP through genes associated with anxiety and depression further supports the psychosocial aspect of the biopsychosocial model of pain.

5.5. Psychological Factors of CLBP

Psychological factors like depression, anxiety, pain related fears, fear-avoidance beliefs and self-efficacy are important predictors and exacerbators of CLBP[20,21,49]. In general, psychological factors can be classified as emotional or cognitive. Emotion is the more immediate reaction to nociception and cognition attaches meaning to the emotional experience of pain[20].

Cognition can therefore amplify the experience of pain causing additional distress. Depression is a mood disorder that negatively affects how a person feels. Common symptoms of depression include persistent feelings of sadness, hopelessness, irritability, frustration, guilt, loss of interest in hobbies, decreased energy and unexplained aches and pains. Symptoms must last two weeks to have a diagnosis of depression with depression severity ranging from mild to severe[50]. The prevalence of depression disorder in individuals with CLBP is high. A study of 1,172 individuals with CLBP found that 25% had moderate to severe depression[51]. Depression co-existing with chronic pain has been the subject of a "chicken and the egg" debate. *Does chronic pain cause depression or does depression lead to chronic pain?* The literature suggests that both are true. There is evidence supporting pre-existing depression as a risk factor to chronic pain development[52]. In contrast, a review found depression to more often be developed as a result of chronic pain[53]. Depression is an exacerbator of pain severity in individuals with CLBP. Individuals with CLBP and depression report significantly higher pain levels and significantly lower health-related quality of life[54]. Anxiety is a psychological and physiological state characterized by cognitive, somatic, emotional, and behavioral components producing fear and worry[46]. Generalized anxiety disorder occurs when feelings of anxiety occur for several months or years[55]. Generalized anxiety disorder is the most diagnosed anxiety disorder in the CLBP population[56]. A study looking at 1,172 individuals with CLBP found a prevalence of generalized anxiety disorder of 23.9%[56], similar to the prevalence of depression in CLBP. Anxiety is associated with a lower threshold to nociceptive stimuli, meaning individuals with generalized anxiety disorder feel more pain for the same stimulus compared to healthy controls[57]. Anxiety also contributes to exacerbation of chronic pain by being a mediator for pain catastrophizing and fear avoidance beliefs[58].

5.5.1. Pain Catastrophizing and the Fear-Avoidance Model

Pain catastrophizing and fear avoidance beliefs are the most important predictors and exacerbators of CLBP. Pain catastrophizing is type of pain related fear, defined as an exaggerated negative orientation toward actual or anticipated painful experiences[20]. Catastrophizing is associated with increased pain intensity and duration, as well as psychological and physical dysfunction across clinical and nonclinical population[20]. The fear-avoidance model began as a theoretical framework explaining how catastrophic thinking may lead to chronic pain and disability[59]. The fear-avoidance model is separated into affective (fear) and behavioral (avoidance) components. Individuals with pain catastrophizing believe pain equates with harm to the body, which often evolves into pain-related fears. Pain-related fears lead to avoidance behaviors and hypervigilance to avoid painful sensations. Avoidance behaviors and hypervigilance lead to disuse, degeneration of tissues, depression and disability which further exacerbates pain and creates a cycle of chronic pain.

5.5.2. Pain Catastrophizing and Kinesiophobia

Avoidance behaviors can be specific to physical movement and physical activity. Kinesiophobia is defined as "*a condition in which a patient has an excessive, irrational, and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or re-injury*"[60] . A study of 11,214 individuals with chronic pain found a 39% prevalence of high pain catastrophizing, with a large portion of patients having CLBP[61]. Fear-

avoidance beliefs have been shown to be important predictors of developing or sustaining CLBP and are associated with long term disability. High pain catastrophizing and fear-avoidance beliefs at baseline have been established as a predictor of pain and disability at 12 months in CLBP[49]. High fear-avoidance beliefs related to work are predictors of pain, disability and of still being on sick leave at 12 months[62]. Similar outcomes have been seen in individuals with high levels of kinesiophobia[63].

5.5.3. Self-Efficacy

Self-efficacy is an important component in the self-management of CLBP. Self-efficacy is defined as "*one's belief in their capacity to organize and execute the courses of action required to produce given attainments*"[64]. Self-efficacy therefore refers to an individual's belief in their capacity to complete a task, rather than a measure of their actual capacity to complete said task. In the context of pain, pain self-efficacy is best described as one's confidence in their ability to function properly despite being in pain[65]. Recent studies suggest improved self-efficacy contributes significantly more to the improvement of long term pain and disability in CLBP compared to catastrophizing and fear of movement[66,67], however more evidence is needed to support these claims. Self-efficacy has also shown to have a protective effect on long term pain development[68]. The protective effect of self-efficacy could be particularly effective in individuals with high pain-related fears. When self-efficacy is high, elevated pain-related fears might be mitigated, which may not lead to less pain and disability[69].

5.6. Social Factors

The last components of the biopsychosocial model of pain are the social factors. The prevalence of CLBP is influenced by an array of social factors like socioeconomic status, employment status, social isolation, cultural factors, previous treatment experiences and interpersonal relationships[20]. There is overwhelming evidence showing an increased prevalence of CLBP in populations of low socioeconomic status compared to high socioeconomic status[70]. Individuals with a lower education status, in a situation of unemployment or of ethnic backgrounds have a higher prevalence of CLBP[70]. Increased social support is associated with less disability in CLBP and social isolation predicts disability related to CLBP[70].

6. Treatment Guidelines for Chronic Low Back Pain

Early in the 20th century, healthcare practitioners often recommended bedrest for both acute LBP and CLBP. Bedrest has been shown to increase pain, disability and workdays missed compared to simply continuing regular activities[71]. Bedrest only further exacerbates pain-related fears and creates disuse and degeneration, leading to more pain and long term disability as predicted by the fear-avoidance model[72]. Treatment guidelines for CLBP have moved toward a much more active, patient-oriented approach with considerations of the biopsychosocial nature of CLBP[17,73]. The following clinical treatment guidelines for CLBP are from the American College of Physicians, the UK National Institute for Health and Care Excellence and the Danish national guidelines[74–76]. First-line treatment guidelines are: 1) advice to remain active, 2)

education on chronic pain management, 3) exercise therapy and 4) cognitive behavioral therapy[77]. Second-line or adjunctive treatment recommendations are spinal manipulations, massage, acupuncture, mindfulness-based stress reduction, interdisciplinary rehabilitation, and non-steroid anti-inflammatory drugs. Recommending individuals with CLBP to remain active and educating them on the nature and management of chronic pain are simple yet very important effective treatments for CLBP. Advice to remain active and education is easy to implement and can be beneficial for persons of lower socioeconomic status with poor access to healthcare. Second-line treatment guidelines should be selected according to the needs of the patient and used as an adjunct to provide the best all-around care. Spinal manipulations and massage therapy are good complements to exercise therapy as they can help increase range of motion of the spine and decrease muscle tension associated with CLBP. However, spinal manipulations and massage therapy require more expertise. Mindfulness based-stress reduction is a type of psychological intervention that can be mastered and implemented by physical therapists during their interventions, which can have beneficial effects for patients with pain-related anxiety[17]. Pharmaceutical interventions like non-steroid anti-inflammatory drugs significantly decrease pain and disability compared to placebo[78]. There is no evidence supporting the effectiveness of acetaminophen as a treatment of CLBP. Multidisciplinary biopsychosocial rehabilitation aims at improving physical dysfunction as well as addressing psychosocial issues related to CLBP. Multidisciplinary biopsychosocial interventions are more effective than any stand-alone intervention[79]. They incorporate exercise and physical therapy; psychological counseling and they target work and social related behavioral issues.

7. Treatment Recommendations for Psychosocial Factors Associated with CLBP

Behavioral therapy is the most effective treatment for high levels of catastrophizing and pain-related fears associated with CLBP[80]. The main types of behavioral therapy for CLBP are operant therapy and cognitive behavioral therapy. Operant therapy is a psychological technique used to increase or decrease the frequency of wanted or unwanted behaviors by introducing positive reinforcement to wanted behavior and consequences to unwanted behavior. Cognitive behavioral therapy is a structured short-term practical form of psychotherapy[81]. Cognitive behavioral therapy challenges patients to identify and change negative thoughts and beliefs causing their dysfunction[82]. Specific and effective cognitive behavioral techniques in treating LBP include cognitive therapy, graded increases in activity, activity scheduling and relaxation training[82]. The prevalence of poor psychosocial functioning is elevated in CLBP[51,56,61] and poor psychosocial functioning has adverse effects on CLBP[20,21,49,49,62,63,68,69]. Cognitive behavioral therapy improves patient outcomes by targeting poor psychosocial functioning like depression, anxiety, pain catastrophizing and pain-related fears. There is no significant difference between operant and cognitive behavioral therapy in short and intermediate-term pain relief for CLBP[80]. Supervised exercise therapy is an effective treatment of fear-avoidance beliefs and kinesiophobia in individuals with CLBP compared to no-treatment control groups[83]. However, exercise is not more effective than cognitive behavioral therapy in reducing fear-avoidance beliefs[83]. These findings suggest that exercise can be a viable treatment to decrease fear avoidance beliefs in individuals with CLBP. However, individuals with high levels of fear-avoidance beliefs might require behavioral therapy. Although cognitive behavioral therapy is effective to decrease pain-related fears in individuals with CLBP, poor access remains a significant barrier to widespread use[77].

7.1. Exercise Therapy

There is overwhelming evidence supporting exercise therapy as the most-effective treatment of CLBP[77]. A recent systematic conducted by Hayden et al. review pooled the results of randomized controlled trials to determine the efficacy of exercise on pain intensity[84]. The review analyzed 26 studies comparing the effects of exercise therapy to usual care or no treatment and found a 16.4% greater decrease in pain for the exercise therapy groups[84]. The review also analyzed 47 studies comparing the effects of exercise to other conservative interventions and found an 8.6% greater decrease in pain for the exercise therapy groups[84]. The systematic review also pooled the results of randomized controlled trials to determine the efficacy of exercise therapy on function. They analyzed 30 studies comparing exercise therapy to usual care or no intervention and found a 7.4% greater improvement in function in the exercise therapy groups. The review also looked at 44 studies comparing exercise therapy to other conservative interventions and found a 4% greater improvement in function for the exercise therapy groups. The scale and depth of this review has shown exercise therapy to be the most effective conservative intervention to improve pain and function associated with CLBP. However, some types of exercises are more effective than others in the treatment of CLBP. Exercises targeting dynamic lumbar stabilization, motor control, postural strengthening and functional restoration are considered more effective to decrease pain and improve function[85,86]. Aerobic exercise and resistance training are the most effective exercise modes to improve mental health and psychological factors in individuals with CLBP[86]. Multimodal exercise therapy interventions are therefore needed to target both physical and psychological outcomes associated with CLBP.

7.2. Therapeutic Aquatic Exercise (Aquatic Therapy)

7.2.1. Physical Properties of Water and Physiological Benefits

Water immersion during aquatic therapy produces beneficial biological and physiological effects in the human body. These biological changes occur due to the physical properties of water. Essential physical properties of water are density, hydrostatic pressure, buoyancy, viscosity and thermodynamics[87].

7.2.1.1. Buoyancy

Since the human body has a density lower than water, water exerts an upward force on the body allowing for buoyancy. Buoyancy counteracts the forces of gravity acting on the body and consequently reduces the compressive forces on the intervertebral joints of the spine. Increased immersion progressively offloads the compressive forces acting on the joints. Immersion up to the pelvis offloads body weight by approximately 40%, immersion to the umbilicus offloads body weight by approximately 50% and immersion to the chest offloads body weight by approximately 60%[87]. Neck deep immersion only creates approximately 15lbs of compressive forces on the joints of the spine[87]. Shallow water functional exercises allow users to mimic land-based exercises with significant reduction of joint compression forces.

7.2.1.2. Hydrostatic Pressure

Water exerts a hydrostatic pressure of 22.4 mm Hg/ft on the body. The effects of hydrostatic pressure act immediately upon immersion and increase venous and lymphatic return, reducing edema to the injured area[87]. Aquatic exercise also has beneficial effects on the cardiorespiratory system. The pulmonary demands increase while exercising in water due to the pressure exerted against the chest. Respiratory muscles must work harder to counteract the hydrostatic pressure[88]. Neck deep submersion increases total work of breathing at rest increases by 60%[89]. Aquatic aerobic exercise can therefore yield similar gains in cardiovascular fitness at lower intensities compared to land-based exercise[90].

7.2.1.3. Viscosity

Water's physical property of viscosity refers to the internal friction specific to a fluid during motion. This means a limb moving relative to the water will be subjected to a drag force. The drag force is proportional to the velocity, allowing for safe and controlled progression of exercises in rehabilitation[91].

7.2.1.4. Thermodynamics

The last physical property of water that provides physiological benefits occurs through thermodynamics. Water is a very efficient conductor of heat, transferring heat from the water to the body 25 times faster than air[87]. Therapeutic pools maintain temperatures of 33.5 to 35.5 degrees Celsius to allow for prolonged exposure and providing therapeutic effects without users getting cold[87]. The spine is therefore very well protected during water immersion and allows for effective rehabilitation for individuals with high levels of pain and disability associated with CLBP[92–94]. Physiological mechanisms of aquatic therapy include reflex regulation of smooth muscle in blood vessels and increased cardiac output[95]. As cardiac output increases, most of the blood flow is redistributed to muscles. Muscle blood flow increases by 225% during aquatic exercise compared to land-based exercise[96]. Increased blood flow to muscles promotes healing of damaged tissues and helps remove waste metabolites associated with damaged tissue cells[97]. Increased cardiac output contributes to aquatic aerobic exercise being able to yield similar gains in cardiovascular fitness at lower intensities compared to land-based exercise[90].

7.2.2. Muscle Activation

Aquatic exercise has been shown to produce similar levels of muscle activation to the erector spinae, multifidus, gluteus maximus/medius, rectus abdominis and the internal/external obliques when comparing aquatic exercises with their land-based equivalent[98]. Aquatic exercise can therefore yield similar muscle fiber recruitment to land-based exercise.

8. Therapeutic Aquatic Exercise Compared to No Intervention

A randomized controlled trial by McIlveen & Robertson[99] conducting a group aquatic therapy intervention (N=45) found significantly greater improvements in function compared to a waiting list (N=50). The aquatic therapy intervention lasted 4 weeks, with two 50- minute sessions per week and consisted of 50 minutes of pre-determined exercise related to spine health. The aquatic exercises focused on dynamic trunk stabilization, flexibility, and functional

exercises. The aquatic exercise group saw a 27% improvement on the Oswestry Disability Index (ODI) and the control group saw only an 8% improvement. A randomized controlled trial by Han. Et al.[100] looked at the effect of aquatic exercise (N=10) compared to no intervention (N=9) in elderly individuals with CLBP. The aquatic exercise intervention lasted 10 weeks at a frequency of 5 sessions per week. The intervention was well rounded and focused on strengthening the trunk and low back muscles. The aquatic exercise group saw a significant improvement in pain with a decrease of 52.1% on the visual analog scale (VAS) and a significant improvement in strength measured by peak torque of lumbar flexion and extension. Peak torque in flexion improved by 48.31% and peak torque in extension improved by 152.85%. Similar results were found in a controlled clinical trial by Baena-Beato et al.[101] comparing the effects of aquatic exercise (N=24) to a waiting list (N=25). The aquatic exercise intervention lasted 8 weeks with 5 sessions per week. The aquatic exercise intervention was given in groups of 8 and supervised by both a physical therapist and a trained exercise specialist. Despite the high volume of sessions, the adherence was high with all participants completing at least 90% of the sessions (36/40). Each session included 10 minutes of warm-up, 15–20 minutes of resistance exercise, 20–25 minutes of aerobic exercise, and 10 minutes of cool-down stretching exercises. The aquatic exercise group had a significant improvement in pain with a change of –3.83 (± 0.35 mm) on the Visual Analog Scale (VAS) and a significant improvement in disability with a reduction of 12.7 ± 1.3 points on the ODI. A study by Abadi et al.[92] looked at the effects of an aquatic exercise intervention (N=20) compared to an unspecified control intervention (N=19). The aquatic exercise intervention lasted 12 weeks with two 60-minute sessions per week. The focus of the aquatic exercises was general strengthening, aerobic conditioning, and general stretching. There was no focus on dynamic lumbar stabilization and core strengthening. Nevertheless, the aquatic exercise group saw a significant improvement in pain and function compared to the control group. There is sufficient evidence supporting aquatic exercise being effective to reduce pain, disability and improve functional outcomes in CLBP. Aquatic therapy is more effective than no intervention to reduce pain, disability and improve functional outcomes in CLBP. However, to recommend aquatic exercise as a treatment option we must make a comparison to other treatment recommendations for CLBP.

9. Therapeutic Aquatic Exercise Compared to Physical Therapy Modalities

A single-blind randomized clinical trial by Peng et al.[102] looked at the effects of therapeutic aquatic exercise (N=56) on CLBP compared to physical therapy electrical modalities (N=57). The aquatic exercise intervention lasted 12 weeks with three 60-minute sessions per week. The aquatic exercise sessions included a warm-up, a main strengthening session with a focus on dynamic lumbar stabilization and a cool down with some stretching and relaxation exercise. The control group received electrical modalities with the same frequency of treatment. The aquatic exercise group had a baseline Numerical Pain Rating Scale (NPRS) score of 3.96 (±1.14) and 3-month /6-month / 12-month post-intervention NPRS scores of 1.64 (±1.15) / 2.07 (±1.09) / 2.27 (±1.39). The control group had a baseline NPRS score of 4.02 (±1.37) and 3-month /6-month / 12-month post-intervention NPRS scores of 2.47 (±1.31) / 3.30 (±1.80) / 3.72 (±1.87). The aquatic exercise group had significantly greater improvements in pain compared to the physical therapy modalities group at all time points. The questionnaire used to measure function was the Roland-Morris Disability Questionnaire (RMDQ) with a score range of 0-24 where higher scores indicate higher disability. The aquatic exercise group had a baseline RMDQ score of 8.82

(±5.82) and 3-month / 6-month / 12-month post-intervention RMDQ scores of 3.23 (±2.90) / 3.55 (±4.19) / 3.52 (±4.43). The control group had a baseline RMDQ score of 8.37 (±5.41) and 3-month / 6-month / 12-month post-intervention RMDQ scores of 4.63 (3±.98)/ 5.61 (±5.49) / 6.67 (±6.47). The aquatic exercise group had a significantly greater reduction in disability across all time points compared to the physical therapy modalities group. These findings suggest a supervised therapeutic exercise intervention can have long-term benefits in decreasing pain and disability in CLBP. An important part of this study is their inclusion of fear-avoidance beliefs and kinesiophobia questionnaires in their secondary outcome measures. The aquatic exercise group had a significant decrease in fear-avoidance beliefs at all time points compared to control and a significant decrease in kinesiophobia at 12-month compared to control. The questionnaire used to measure fear-avoidance beliefs is the Fear-Avoidance Beliefs Questionnaire (FABQ) with a subscale specific to physical activity (FABQ-PA). The FABQ-PA has a score range of 0-24 with a higher score indicating higher fear-avoidance beliefs related to physical activity. The aquatic exercise group had a baseline FABQ-PA of 12.29 (±4.34) and 3-month / 6-month / 12-month post-intervention FABQ-PA scores of 9.05 (±4.89) / 8.86 (±4.72) / 7.71 (±4.79). The control group had a baseline FABQ-PA of 12.29 (±4.34) and 3-month / 6-month / 12-month post-intervention FABQ-PA scores of 11.25 (±4.70)/ 10.40 (±5.09) / 10.82 (±5.86). The questionnaire used to measure kinesiophobia was the Tampa-Scale of Kinesiophobia (TSK-17) with a score range of 17-68 where a higher score indicates increased kinesiophobia. Generally, scores above 37 are considered high and predictive of poor health outcomes[103]. The aquatic exercise group had a baseline TSK score of 44.82 (±5.70) and a 12-month (9 months post-intervention) TSK-17 score of 37.84 (±8.26). The control group had a baseline TSK-11 score of 42.30 (±4.99) and a 12-month TSK-17 score of 41.12 (±5.88). Although the post-interventions TSK scores remained high and over the cutoff score of 37, the aquatic exercise intervention showed significant improvements in kinesiophobia compared to the physical therapy modalities group. The improvements in fear avoidance beliefs and kinesiophobia could explain why the aquatic exercise group maintained significant improvements in pain and disability long after the intervention was completed. The improvement in psychological factors may have contributed to breaking the cycle of chronic pain explained by the fear-avoidance model. Self-efficacy could have been an important factor in these improvements, however self-efficacy was not included in the outcome measures. The main limitation of this study is their failure to include an adequate control group. To highlight the benefits of aquatic exercise on pain, disability, and psychological factors, there needs to be a control group with the standard of care and/or land-based exercise. The authors also did not include pain catastrophizing in their outcome measures, which is an important component of the biopsychosocial model of pain and the fear-avoidance model.

10. Therapeutic Aquatic Exercise Compared to Land-Based Exercise

Comparing aquatic exercise to land-based exercise is important to understand if one type of exercise therapy is more effective. Sjogren et al.[104] was among the first to compare the efficacy of aquatic exercise versus land-based exercise on chronic low back pain. The aquatic exercise intervention (N=30) was 6 weeks of two 50-minute sessions per week focused on lumbar spine range of motion, general strengthening, and endurance training. The land-based intervention (N=30) followed the same structure, which included similar exercises adapted to land. Both interventions were supervised and given in groups. The aquatic exercise group had a baseline VAS pain score of 4.97 (± 2.88) and a post-intervention VAS pain score of 4.18 (± 3.15). The

land-based exercise group had a baseline VAS pain score of 4.77 (± 2.47) and a post-intervention VAS pain score of 4.23 (±2.74). Both groups had a statistically significant decrease in pain with no difference across groups. However, the improvement in pain scores for both groups does not meet the minimal clinically important difference. The aquatic exercise group had a baseline modified Oswestry Disability Index (ODI) score of 42.18 (± 17.02) and a post-intervention ODI score of 34.14 (± 17.05). The land-based exercise group had a baseline ODI score of 36.00 (± 15.65) and a post-intervention ODI score of 32.39 (± 16.34). The improvements in function were statistically significant for both groups with no difference across groups. The underwhelming results of this study could be attributed to the design of the interventions. As more was learned about effective exercise therapy modes to treat CLBP, the efficacy of both aquatic exercise and land-based exercise interventions got better. The importance of dynamic lumbar stabilization was not yet well understood at the time of this study. A randomized controlled trial by Yozbatiran et al.[105] compared the effects of an aquatic exercise intervention (N=15) and a land-based exercise intervention (N=15) on CLBP. Both interventions lasted 4-weeks with three 60-minute exercise sessions per week. The aquatic exercise program consisted of general aerobic and strengthening exercises. The land-based program was identical but adapted to land-based versions of the exercise. The aquatic exercise group had a baseline VAS pain score of 5.46 (± 2.19) and a post-intervention VAS pain score of 1.93 (±1.70). The land-based exercise group had a baseline VAS pain score of 5.06 (± 2.28) and a post-intervention VAS pain score of 2.53 (±1.55). Both groups saw a statistically and clinically significant decrease in pain with no significant differences across groups. The aquatic exercise group had a baseline ODI of 40.00 (± 20.14) and a post-intervention ODI of 20.66 (±13.49). The land-based exercise group had a baseline ODI of 38.40 (± 14.32) and a post-intervention ODI of 21.06 (±12.73). Both groups had a statistically significant decrease in disability with no difference across groups. Both groups also had significant improvements in objective strength and flexibility tests with no significant differences across groups. A randomized controlled trial by Dundar et al.[93] compared the effects of an aquatic exercise intervention (N = 32) compared to an unsupervised land-based exercise intervention (N = 33). The aquatic exercise intervention lasted 4 weeks with five weekly 60-minute sessions given in groups of 8. The program focused on general fitness and included aerobic training, functional resistance training which included dynamic lumbar stabilization, and stretching. The land-based exercise group received a musculoskeletal assessment from a physical therapist and were given a land-based exercise program to complete at home without supervision. The land-based exercise program was demonstrated only once by the physical therapist and had a similar structure to the aquatic exercise program. The aquatic exercise group had a baseline VAS pain score of 4.72 (± 2.05) and a post-intervention VAS pain score of 1.46 (±1.21). The land-based exercise group had a baseline VAS pain score of 4.82 (± 2.40) and a post-intervention VAS pain score of 1.71 (±1.52). Both groups had a statistically and clinically significant decrease in pain scores with no significant difference across groups. The aquatic exercise group had a baseline ODI score of 38.5 (± 9.1) and a post-intervention ODI score of 18.42 (± 8.2). The land-based exercise group had a baseline ODI score of 37.9 (± 9.3) and a post-intervention ODI score of 27.65 (± 8.9). Both groups had a significant decrease in disability, however the aquatic exercise group had a statistically significantly greater improvement than the land-based group. These results suggest aquatic therapy may be more effective to reduce disability (improve function) than land-based exercise. However, the land-based exercise group was unsupervised and home-based, which is an important limitation of this study.

11. Limitations in Previous Aquatic Therapy Studies

To date, there have been two common limitations in aquatic exercise studies treating CLBP. The first limitation is no studies have compared the effectiveness of aquatic exercise to the current standard of care. The first-line treatment recommendations have evolved and changed since most of these studies were published. The current standard of care was highlighted in the first- and second-line guidelines and generally consists of advice to remain active, education on pain management, functional restoration exercises and dynamic lumbar stabilization exercise / core exercises accompanied by spinal mobilizations, massage therapy and more. The second limitation is to date there has been only one study examining the effects of aquatic exercise on some of the psychological factors associated with CLBP. Considering the nature of CLBP, determining the impact aquatic exercise has on pain catastrophizing, kinesiophobia, depression, and anxiety is important to understand the long-term benefits that aquatic exercise can have in the treatment of CLBP. Apart from Peng. et al.[102], no studies have included psychological factors in their outcome measures. The main limitation of the study from Peng et al.[102] is their lack of an adequate control group. To highlight the benefits of aquatic exercise on psychological factors there needs to be a control group with land-based exercise component. They also did not include pain catastrophizing in their outcome measures, which is an important component of the biopsychosocial model of pain and the fear-avoidance model. Therefore, more research is needed to fully understand all the effects of aquatic exercise on CLBP and compare it to the clinical standard of care to highlight the benefits of aquatic exercise.

12. Barriers to the Treatment of Chronic Low Back Pain

The main barrier to the treatment of CLBP is the adherence to treatment, mainly unsupervised exercise therapy. Although exercise is effective conservative treatment for CLBP available, low adherence to prescribed interventions make the management of CLBP difficult. A systematic review examined the main barriers to treatment adherence in exercise-based musculoskeletal rehabilitation. The review determined the main barriers are low baseline levels of physical activity, low self-efficacy, depression, anxiety, helplessness, greater perceived number of barriers to exercise and increased pain levels during exercise[106]. Considering the high prevalence of fear-avoidance beliefs, low-self efficacy, anxiety and depression in individuals with CLBP[51,51,61], the barriers to treatment adherence pose a serious challenge and require new solutions. Another randomized controlled trial found that low levels of education, low levels of physical activity and high baseline levels of fear-avoidance beliefs related to work and physical activity at baseline were related to low exercise adherence[107]. Interventions need to be comprehensive and target improvements in fear-avoidance beliefs, depression, anxiety, and self-efficacy. Although effective in improving mental health, poor access to cognitive behavioral therapy remains a barrier to widespread use[82]. Aquatic exercise is a promising form of exercise therapy which could yield positive impacts on the physical and mental health of individuals with CLBP when integrated in a comprehensive treatment plan[102]. Patients report pain significantly less often during aquatic exercise than land-based exercise[98], which may increase adherence.

13. Mobile Health Devices

Mobile health (mHealth) devices have demonstrated great potential in increasing the adherence and efficacy of treatment interventions in the management of chronic diseases. Mobile health is an umbrella term for the use of technological tools in health care, such as mobile phones and other wireless devices. Mobile health devices include smartwatches, medical devices and mHealth applications (app). Recent efforts to manage chronic diseases and increase treatment adherence have been achieved through the integration of mHealth devices. A systematic review of 107 mHealth interventions aimed at improving treatment adherence looked at the feasibility and effectiveness of mHealth devices[108]. Fifty of the 107 studies had a randomized controlled trial study design. The studies included in the review were looking at the effect on treatment adherence and effectiveness in chronic diseases such as diabetes, cardiovascular disease, and chronic lung disease. In general, studies found mHealth devices to be usable, feasible and appreciated among users. The systematic review determined 56% of randomized controlled trials using mHealth devices demonstrated significant effects on treatment adherence, with treatment adherence defined as medication adherence, engagement in healthy behaviors, frequency of symptom monitoring, and gains in knowledge and perceived self-efficacy. Among the reviewed studies, 40% had a significant improvement in clinical outcomes, with clinical outcomes varying depending on the disease in question. For instance, clinical outcomes for diabetes included frequency of hypoglycemic events and changes in insulin dosage, while clinical outcomes for cardiovascular disease included changes in blood pressure and lipid profile.

13.1. mHealth Devices and Applications for Chronic Pain

The positive effect of mHealth devices on chronic disease treatment is relatively novel[108], therefore there is limited data on chronic pain and CLBP populations. Mobile health applications like *Manage My Pain* have been developed for persons with persistent pain to keep a detailed journal of their symptoms and painful episodes and present comprehensive reports to their healthcare professionals. These reports allow for healthcare professionals to get detailed and specific information regarding the condition of their patients, which should allow for a better understanding of their condition. *Manage My Pain has* been tested in persons with persistent pain and deemed to be feasible and appreciated by users in pain clinics[109]. Individuals who used *Manage My Pain* rated lower anxiety at short-term follow-up and a greater reduction in pain catastrophizing at long-term follow-up compared to control[109].

Some mHealth applications have been developed to be a one stop shop in the management of chronic pain. Mobile health application *Snapcare* was developed for the self-management of CLBP. The smartphone application is centered around giving personalized exercise plans based on the health data and pain levels of users at baseline and after each activity session. The personalized exercise goals are progressed based on the comfort level of the patient, measured via patient reported outcome measures and exercise data collection. A single-blind RCT was conducted to determine the efficacy of pain-relieving medication combined with *Snapcare* versus a group who was given pain relieving medication and the recommendation of meeting physical activity guidelines[110]. The *Snapcare* group showed a greater reduction in pain,

disability, and increased compliance with prescribed exercises. Significant limitations exist with this trial due to an inadequate control group that does not meet the standard of care and with the trial being funded by the creators of *Snapcare*. Despite these limitations, the trial shows some potential in using mHealth applications in the management of CLBP.

13.2. Play the Pain

Play the Pain is a novel mHealth application designed to help individuals with the management of chronic pain[111,112]. *Play the pain* data is connected to administrative accounts overseen by healthcare professionals to optimize communication and quality of care. The interface of the app is separated into four parts: talk, share, play and track. The talk function is designed to allow users to discuss with an automated message system about topics related to their management of their condition. The design of the talk function is not to provide educational material or directives on chronic pain management, but to let users openly express themselves about topics they are passionate about. The share function is a form of social media where users can share their experience with chronic pain with other users through blog posts on the *Play the Pain* servers. The share function is designed to create to give users a sense of belonging, and to validate users in their experience with pain, which can give them tools on how to better manage their condition. The play function of the app allows users to connect and launch other mobile applications from the *Play the Pain* application. Recommended categories of applications to connect includes games, brain training, drawing, mediation, exercise, music, dieting and more. The purpose of the play function is to allow users to explore different ways they can self-manage their chronic pain. The track portion of the application allows users to continuously keep track of different outcome measures relevant to chronic pain. The track function of *Play the Pain* is similar to the construct of *Manage my Pain*. However, *Play the Pain* cannot generate summary reports for healthcare practitioners. Users can track their pain, their activities, their sleep, their medication use and their emotions. The pain tracking function allows users to describe the location of the pain with an interactive model of the human body. After determining the location of the pain, users are prompted to scale the intensity with a movable cursor from slight pain to extreme pain. The emotion tracking feature is an interactive web of emotions with a wide range of feelings including anxious, afraid, worried, happy, calm, etc. Each emotion can be clicked on and given an intensity ranging from “a little” to “a lot”. The sleep tracking function tracks the duration of sleep with a dichotomous scale. The two options are “more than 7 hours’’ and “less than 7 hours’’. After choosing an option, users are asked to describe the quality with a 5-point Likert scale. The options are: “Great”, “Good”, “OK”, “Not good” and “Very bad”. Each option is accompanied by a smiley face visually representing the choice. The medication tracking feature asks if the medication taken is prescribed or not, with an empty box for a description of the type of medication and the dosage. The activity tracking feature has 24 options to choose from and allows users to describe the activities they have done in the past 48 hours. These options include physical activity such as resistance training, dancing, walking, yoga, swimming, jogging, and cycling. Other activities included are treatment alternatives often used for chronic pain, such as physiotherapy, cognitive behavioral therapy, meditation, acupuncture, and recreational drug use. The last category of the activity tracking feature is focused on hobbies including gaming, reading, painting, and watching television. In addition, there is an “Other” section for activities that were not included in the list. The philosophy of *Play the Pain* is to let the user share what is on their mind, and to give the clinician a better understanding of their

condition and how patients cope with pain. The feasibility of *Play the Pain* in a healthcare setting with a chronic pain population has never been studied. Therefore, the effect of *Play the Pain* on feasibility of use remains unknown. Consequently, the effect of *Play the Pain* on treatment adherence and effectiveness on CLBP is still unknown.

14. Thesis Rationale

CLBP is a significant public health issue that affects an alarming number of people, young and older individuals alike, causing a significant burden on the global economy[1,4,8]. CLBP is associated with a decreased quality of life and poor psychological functioning[17,51,56]. Poor psychological functioning exacerbates painful symptoms, decreases treatment adherence and increases the likelihood of pain chronicity[62,63,68]. Therefore, we must find conservative treatment options that also address psychological outcomes to effectively treat CLBP. Exercise therapy is the most effective form of conservative treatment for CLBP[17], making exercise therapy a first-line treatment recommendation[77]. Therapeutic aquatic exercise has been shown to be an effective form of exercise therapy to decrease pain and disability associated with CLBP. However, the effect of aquatic therapy on psychological outcomes associated with CLBP remains poorly understood and unstudied. Mobile health devices have been used for the management of chronic diseases and have shown promising effects on treatment adherence. However, the effect of mHealth devices on treatment adherence in CLBP has never been tested. *Play the Pain* is a promising novel mHealth application that could improve adherence in exercise-based interventions for CLBP. However, Play the Pain has never been tested in a real world setting with individuals who have CLBP. Additionally, having access to the user data and backend of the *Play the Pain* gave the app a unique advantage over its competitors, as that allowed us to conduct a study while assessing the user experience, outcomes related to usage of the app and capture the psychological variates that can impact pain management. This app also differs from other commercial apps in that it has data portal for therapist to monitor and communicate with the user.

Therefore, the objective of my thesis was to 1) determine the effect of therapeutic aquatic exercise on pain, disability and psychological outcomes as compared to standard care in participants with CLBP and 2) explore the feasibility and user experience of implementing mHealth application *Play the Pain* in a clinical setting.

Chapter 2: Project 1 - Effects of Aquatic Therapy versus Standard Care on Non-Specific Chronic Low Back Pain: A Randomized Controlled Trial

15. Introduction

Low back pain (LBP) is the most prevalent musculoskeletal condition in the world and the leading cause of disability worldwide[12]. The economic burden of LBP is extremely high. In Canada, medical costs associated to LBP range from 6 to 12 billion dollars per year and is rising[8]. LBP is subdivided in three categories: acute, subacute, and chronic. Acute is LBP lasting 0 to 6 weeks, subacute is LBP lasting 6 to 12 weeks and chronic is LBP lasting over 12 weeks. LBP can be further subdivided into specific versus non-specific pain. Specific LBP is caused by a known lesion site whereas non-specific LBP occurs without a clear nociceptive cause[12] and non-specific LBP accounts for 90% of all low back pain[19].

The biopsychosocial model of pain helps understand the complex nature of non-specific chronic low back pain (CLBP). The biopsychosocial model explains that pain is a complex interaction of biological, psychological, and social factors[20]. The biological aspect is the discharge of nociceptive stimuli from an actual or potential lesion site. Pain is the interpretation of the nociceptive stimuli by the brain. Pain is therefore a subjective experience that varies depending on the individual's psychological state and social background[20]. CLBP is associated with negative psychological states like depression and increased anxiety[56,56]. These high levels of depression and anxiety can cause exacerbation of pain[20]. Pain-related fear is an important psychological factor to consider when treating CLBP. Increased levels of pain-related fears can create a cycle of chronic pain[59]. When confronted to a painful experience, individuals with high levels of pain-related fear will catastrophize. Pain catastrophizing is an exaggerated negative orientation towards actual or anticipated pain[20] and can lead to a fear of movement (kinesiophobia) from the potential of getting re-injured and experiencing more pain. Increased fear of movement creates a pattern of movement avoidance behavior and creates more disability, disuse and causes more painful experiences, which exacerbates the cycle of chronic pain[59]. High levels of pain-related fears and fear-avoidance beliefs, like pain catastrophizing and kinesiophobia, are important predictors to the development of CLBP and disability[49]. Individuals with high levels of pain-related fears and fear-avoidance beliefs at baseline have increased levels of long-term pain and disability[49,62]. Since CLBP is associated with high levels of pain catastrophizing and kinesiophobia, interventions must address them to treat and prevent long term pain and disability[17].

Current first-line treatment guidelines for individuals with CLBP include education on pain management, recommendations to remain active, cognitive behavioral therapy, and exercise therapy[77]. Cognitive behavioral therapy is effective to decrease pain-related fears in individuals with CLBP, however poor access to cognitive behavioral therapy is a significant barrier to widespread use[77]. Exercise therapy has shown to decrease pain and disability in individuals with CLBP[17,73,113]. Therapeutic aquatic exercise is an effective form of exercise therapy to decrease pain and disability associated with CLBP[92,93,101,102,114,115]. Aquatic therapy is widely used in the management of musculoskeletal injuries at all stages of healing, for acute and chronic injuries[87]. Immersion in chest deep water reduces the compressive forces on the spine by 60% and significantly reduces load on the intervertebral joints[87]. Reduced load on the intervertebral joints

of the spine allows individuals with CLBP to move with more confidence and feel less pain during aquatic exercise compared to land-based exercise. Patients with CLBP report pain significantly less often during aquatic exercise versus land-based exercise[98]. The viscosity of water allows for an easily adapted resistance when performing strengthening exercises during aquatic therapy[87]. The effectiveness of therapeutic aquatic exercise to decrease pain and disability in individuals with CLBP and the added physiological benefits of therapeutic aquatic exercise should have a beneficial effect on psychological factors associated with CLBP. However, few studies have investigated the effect of therapeutic aquatic exercise on psychological factors associated with CLBP. The literature therefore offers a very limited understanding of the potential benefits aquatic exercise may have on psychological factors associated with CLBP.

The primary aim of this pilot study was to compare the effects of an aquatic exercise intervention to a standard care intervention on pain intensity, disability, and psychological factors in individuals with CLBP. We hypothesized that both groups would see an improvement in pain, disability, and psychological factors with a greater improvement in the aquatic therapy group for all outcomes.

16. Methods

Study Design: This study was a pilot randomized controlled trial where the experimental group received aquatic therapy and the control group received standard care. Participants were recruited through the School of Health website, poster advertising and media advertising. All research activities took place at the School of Health at Concordia University. Both interventions were given one-on-one under the supervision of a Certified Athletic Therapist. The aquatic therapy was given in the Swimex700 therapeutic pool of the School of Health Athletic Therapy clinic, and the control group received treatment in the School of Health Athletic Therapy Clinic and conditioning floor.

Participants: Individuals were eligible to participate in the study if they met the following inclusion criteria:

- Chronic non-specific LBP (>3 months), defined as pain in the region between the lower ribs and gluteal folds, with or without leg pain.
- Currently seeking care for LBP.
- Aged between 18 to 65 years old.
- English or French speakers
- Have a score of "moderate" or "severe" disability on the modified Oswestry Low Back Pain Questionnaire
- Do not currently engage in sports or fitness training specifically for the lower back muscles (3 months prior the beginning of the trial).

Exclusion criteria

Participants were be excluded if they met one of the following criteria:

- Evidence of nerve root compression or reflex motor signs deficits (e.g., weakness, reflex changes, or sensory loss with same spinal nerve),
- Previous spinal surgery or vertebral fractures,
- Other major lumbar spine structural abnormalities (e.g., spondylolysis, spondylolisthesis, or lumbar scoliosis >10°)
- Comorbid health conditions that would prevent active participation in exercise programs (e.g., screened with Physical Activity Readiness Questionnaire)

Randomization: A computer software generated a list pairing each participant number with a corresponding group. The group allocations were enclosed within opaque envelopes labeled with numbers.

Blinding: Participants and therapists were not blinded to group allocation, as it is generally not possible in exercise intervention trials.

Outcome measures: The primary outcome measures were pain, disability, pain catastrophizing, kinesiophobia, quality of life, depression, and anxiety. The Numerical Pain Rating Scale (NPRS) was used to measure pain, and the modified Oswestry Low Back Pain Disability Index (ODI) was used to measure disability. The Pain Catastrophizing Scale (PCS) was used to measure pain catastrophizing, and the short-form Tampa Scale of Kinesiophobia (TSK-11) was used to measure kinesiophobia. Depression and anxiety were measured with the Hospital Anxiety and Depression Scale (HADS), and quality of life was measured with the SF-12 questionnaire. All questionnaires demonstrated good validity and reliability and are the gold standard measurements in CLBP research for their respective outcome measures.

Therapeutic Aquatic Exercise Intervention: The participants in the aquatic therapy group received a standardized aquatic exercise program. Each session lasted 60 minutes, beginning with a 10-minute warm-up, followed by 40 minutes of strengthening, and finishing with a 10-minute cool-down. The warm-up consisted of aerobic activity such as walking and marching, dynamic stretching, and muscle activation of upper and lower body muscles. The 40-minute strengthening focused on a circuit format of dynamic lumbar stabilization exercises, hip stabilization exercises, aerobic conditioning, and general strengthening exercises, with little amounts of rest between the exercises. The 10-minute cool-down consisted of a brief relaxation period (walking, standing), static stretching, and mobility training. Each exercise had a modification to decrease difficulty and a progression to increase difficulty. The difficulty of each training session was monitored via the 10-point Borg Rating of Perceived Exertion scale and a verbal pain rating scale (0-10). The target rating of perceived exertion varied depending on the condition of each participant and where they were in their rehabilitation process. The supervising Athletic Therapist monitored pain levels of participants and demonstrated sound clinical judgment to avoid unnecessary exacerbation of symptoms.

Standard Care Intervention: Participants in the control group received standard care treatment in the School of Health Athletic Therapy clinic and the School of Health conditioning floor. The standard care intervention was not standardized but rather personalized to the needs of each participant. The objective of the standard care intervention was to replicate care that would otherwise be seen in a real-world clinical setting using the best conservative treatment methods recommended. Each intervention began with a 60 minute assessment including collection of

relevant background information, medical history, lifestyle and physical activity habits, a functional assessment, and a physical and neurological exam. The clinician gave their clinical impression and developed a treatment plan based on the findings in their assessment. The hands-on portion of the treatment plan included spinal manipulations and mobilizations, muscle energy techniques, massage, myofascial releases, soft tissue releases, proprioceptive neuromuscular facilitation (PNF) stretching, and heat application. The early phases of the rehabilitation plan mostly focused on manual therapy with basic strengthening exercises to improve spine health which were demonstrated and given as a home exercise program. As the intervention progressed, a greater portion of the treatment sessions focused on exercise therapy. Towards the end of the intervention, the entire treatment session was entirely exercise-based, unless the clinician felt the inclusion of manual therapy was still relevant to the participant.

Procedures: A baseline assessment was undergone by all participants, which included completing the questionnaires. Participants were then randomly allocated to either the aquatic therapy group or the standard care group (1:1). Participants were randomized to one of the groups using sealed opaque envelopes with the order determined by the random computer-generated sequence. Both groups were provided with bi-weekly, 60-minute supervised sessions, for 10 weeks. Both interventions were given one-on-one with the participant and supervised by one of the two Certified Athletic Therapists leading the project. Once their intervention was completed, participants filled out post-intervention questionnaires.

Statistical Analysis: Primary outcome measures were analyzed with descriptive statistics to verify normality of data. Baseline demographic means from each group were compared to ensure the samples were homogenous. Continuous variables were compared using an independent samples t-test and categorical variables were compared using a chi-square test. Changes in pain, disability, and psychological outcomes for between-group and within-group differences from pre- to post-intervention were assessed using repeated measures analysis of variance (ANOVA), while adjusting for age, sex, BMI, and LBP duration. The statistical analysis follows commonly used methods for randomized controlled trials and have been used in similar high quality studies[102]. All statistical tests were performed using the latest version of SPSS (version 29.0).

17. Results

One hundred eighty-one potential participants were screened for eligibility and 39 were included and randomized to the aquatic exercise group or the standard care group (Figure 1). The main reasons for exclusion were age, ODI scores below the minimum threshold or pre-existing spinal abnormalities. An additional 3 participants were excluded following incidental findings on their baseline MRI, which was done in the context of a larger study. In total, 36 participants were recruited and randomly allocated to each group (n=19 aquatic therapy, n=17 standard care). One participant from each group dropped out due to the time commitment of the study. The mean attendance rate was high, with a mean attendance rate of 17.61 ± 2.17 sessions for the aquatic exercise group while the mean attendance rate for the standard care group was 17.56 ± 1.47 sessions, out of 20 possible sessions. The baseline demographic characteristics were similar between groups (Table 1) for age, sex, BMI, level of physical activity (IPAQ) and education level. However, there were significant differences across groups for LBP duration ($p=0.007$), which were accounted for in the statistical analysis.

Figure 1: Consort Flow Diagram

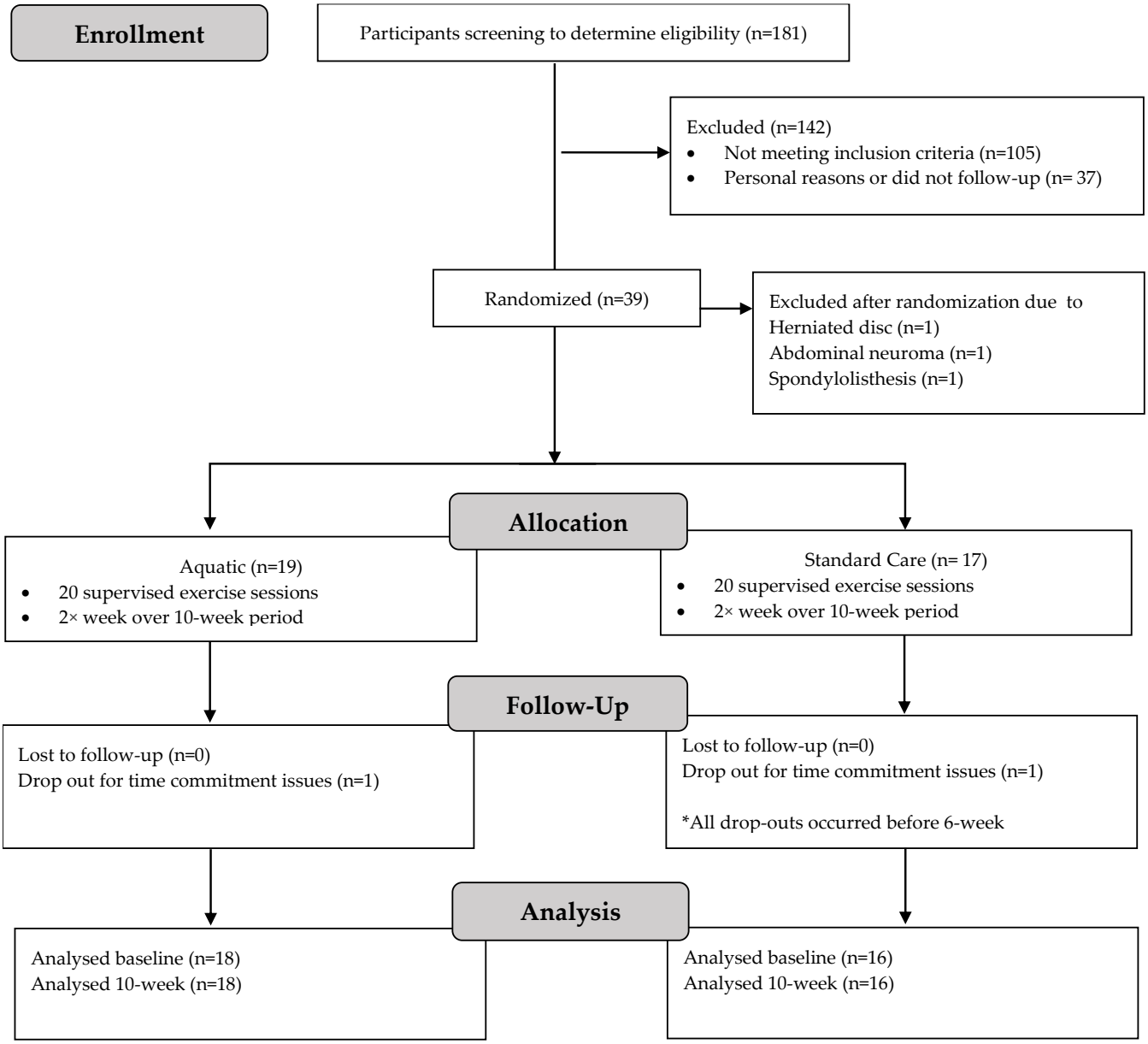


Figure 1. Consort Flow Diagram

Table 1: Demographics and baseline characteristics (mean ± standard deviation, or n and %)

Group		**Aquatic Exercise (n=18)**	**Standard Care Group (n=16)**	**p-value**
Age		36.44 ± 10.4	37.38 ± 9.6	0.79
BMI		26.39 ± 3.75	24.58 ± 3.64	0.16
IPAQ (MET)		2506 ± 2183.84	3206.2 ± 2102.3	0.36
Sex (n)	Male	9 (50%)	6 (38%)	0.46
	Female	9 (50%)	10 (62%)	
Education (n)	College or less	3 (17%)	7 (44%)	0.21
	Undergraduate	6 (33%)	3 (19%)	
	Graduate	9 (50%)	6 (37%)	
LBP Duration (n)	3-5 months	1 (6%)	0 (0%)	0.007
	6-11 months	0 (0%)	4 (25%)	
	1-5 years	11 (61%)	2 (13%)	
	5+ years	6 (37%)	10 (62%)	

A main effect of group was observed in the quality of life scores between groups (SF-12 total, $p=0.039$) (Table 2). There were no significant main effects of group*time interactions observed across all outcomes, but the group*time interaction for the disability scores neared significance (ODI, $p=0.054$). The aquatic therapy group had a significant decrease in pain intensity (NPRS, $p<0.001$), disability (ODI, $p<0.001$) and a significant improvement in quality of life (SF-12 mental, $p=0.001$; SF-12 total, $p<0.001$). The aquatic therapy group also a significant decrease in pain catastrophizing, kinesiophobia, anxiety and depression, and insomnia (PCS, $p<0.001$; TSK-11, $p=0.002$; HADS, $p<0.001$). Similar to the aquatic therapy group, the standard care group saw a significant decrease in pain (NPRS, $p<0.001$), disability (ODI, $p<0.001$) and quality of life (SF-12 mental, $p=0.002$; SF-12, total $p<0.001$). Pain catastrophizing and anxiety/depression also significantly decreased in the standard care group (PCS, $p<0.001$; HADS, $p=0.007$), but there was no significant change in kinesiophobia (TSK-11, $p=0.085$) or insomnia (ISI, $p=0.077$).

Outcome		Aquatic Exercise (n=18)	Standard Care Group (n=16)	Adjusted between group mean difference, 95% CI	P value	Main effect of group	Main effect of group*time interaction
Pain (NPRS)	Baseline	5.14 ± 0.41	5.84 ± 0.44	N/A			
	Post-Intervention	2.20 ± 0.42	2.65 ± 0.45	-0.45 (-1.74 to 0.83)	p=0.47	p=0.26	p = 0.74
Adjusted pre-post difference, mean 95% CI		-2.95 (-3.95 to -1.95)	-3.19 (-4.25 to -2.12)			F=1.36	F=0.11
Main effect of time		p<0.001	p<0.001				
Disability (ODI)	Baseline	31.34 ± 1.95	24.46 ± 2.07	N/A			
	Post-Intervention	13.30 ± 2.07	11.92 ± 2.20	1.38 (-7.69 to 4.92)	p=0.66	p= 0.132	p = 0.054
Adjusted pre-post mean difference		-18.04 (-21.80 to -14.28)	-12.54 (-16.54 to -8.54)			F=2.41	F=4.04
Main effect of time:		p<0.001	p<0.001				
QoL (SF-12 Mental)	Baseline	35.82 ± 1.41	39.26 ± 1.50	N/A			
	Post-Intervention	44.08 ± 2.08	47.64 ± 2.21	-3.56 (-9.90 to 2.78)	p=0.26	p= 0.09	p = 0.97
Adjusted pre-post mean difference		8.26 (3.49 to 13.04)	8.38 (3.30 to 13.46)			F=3.08	F=0.001
Main effect of time:		p=0.001	p=0.002				
QoL (SF-12 Physical)	Baseline	41.74 ± 2.62	45.35 ± 2.80	N/A			
	Post-Intervention	46.48 ± 2.24	49.42 ± 2.38	-2.94 (-9.77 to 3.88)	p=0.38	p= 0.28	p=0.87
Adjusted pre-post mean difference		4.73 (-0.94 to 10.41)	4.07 (-1.96 to 10.1)			F=1.20	F=0.026
Main effect of time:		p=0.098	p=0.18				
QoL (SF-12 Total)	Baseline	77.56 ± 2.54	84.61 ± 2.70	N/A			
	Post-Intervention	90.56 ± 2.39	97.06 ± 2.54	-6.50 (-13.79 to 7.83)	p=0.078	p= 0.039	p=0.89
Adjusted pre-post mean difference		13.00 (7.72 ± 18.28)	12.45 (6.84 to 18.06)			F=4.69	F=0.02
Main effect of time:		p<0.001	p<0.001				
Catastrophizing (PCS)	Baseline	19.8 ± 2.50	17.79 ± 2.57	N/A			
	Post-Intervention	10.58 ± 2.80	9.44 ± 2.89	1.14 (-7.34 to 9.62)	p=0.79	p= 0.68	p=0.68
Adjusted pre-post mean difference		-9.21 (-12.09 to -6.32)	-8.34 (-11.32 to -5.37)			F=0.17	F=0.17
Main effect of time:		p<0.001	p<0.001				
Kinesiophobia (TSK-11)	Baseline	24.95 ± 1.09	23.12 ± 1.16	N/A			
	Post-Intervention	20.11 ± 1.49	20.38 ± 1.58	-0.26 (-4.81 to 4.28)	p=0.91	p= 0.63	p = 0.34
Adjusted pre-post mean difference		-4.84 (-7.81 to -1.86)	-2.75 (-5.91 to 0.41)			F=0.23	F=0.93
Main effect of time:		p=0.002	p=0.085				
Anxiety & Depression (HADS)	Baseline	14.32 ± 1.45	11.89 ± 1.54	N/A			
	Post-Intervention	10.35 ± 1.56	9.23 ± 1.66	1.12 (-3.63 to 5.87)	p=0.63	p= 0.42	p=0.32
Adjusted pre-post mean difference		-3.97 (-5.74 to -2.20)	-2.66 (-4.55 to -0.78)			F=0.68	F=1.03
Main effect of time:		p<0.001	p=0.007				
Insomnia (ISI)	Baseline	12.53 ± 1.26	11.44 ± 1.30	N/A			
	Post-Intervention	7.46 ± 1.48	8.76 ± 1.53	-1.29 (-5.75 to 3.17)	p=0.56	p= 0.95	p=0.26
Adjusted pre-post mean difference		-5.06 (-7.97 to -2.16)	-2.69 (-5.68 to 0.31)			F=0.004	F=1.32
Main effect of time:		p=0.001	p=0.077				

Table 2: Adjusted Mean Results with Standard Error for Pain, Disability and Psychological Outcomes

Figure 2: Graph representing adjusted mean change in NPRS from baseline to post-intervention with standard error.

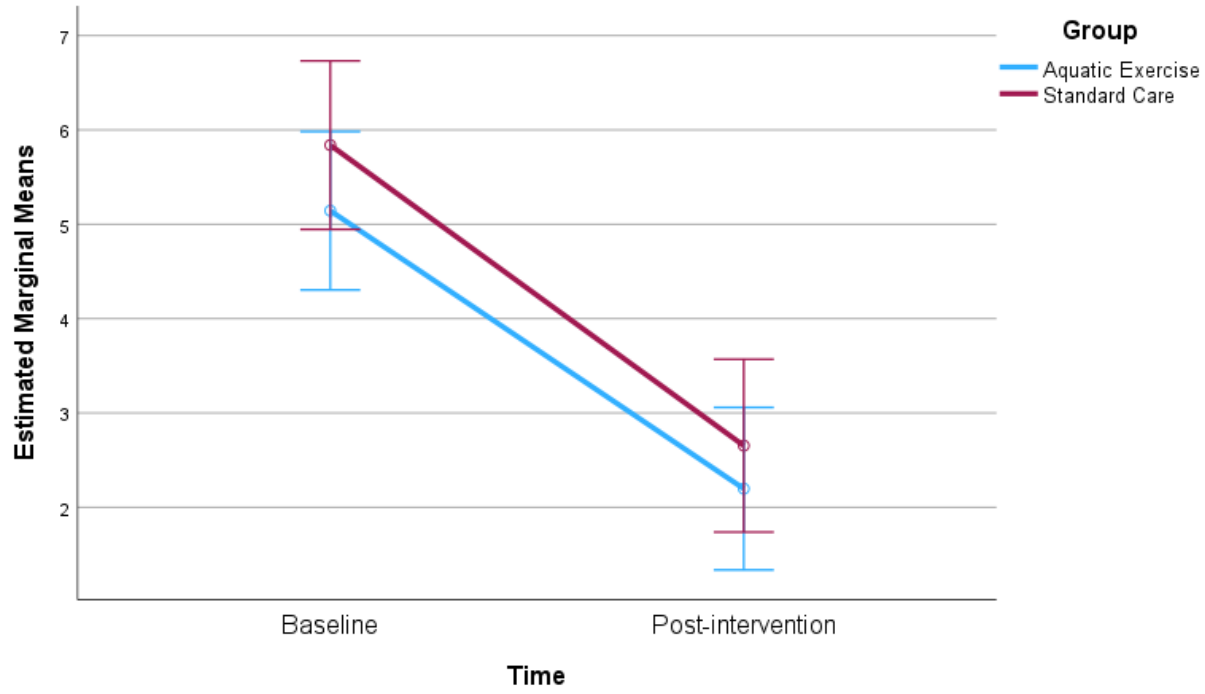


Figure 3: Graph representing adjusted mean change in ODI from baseline to post-intervention with standard error.

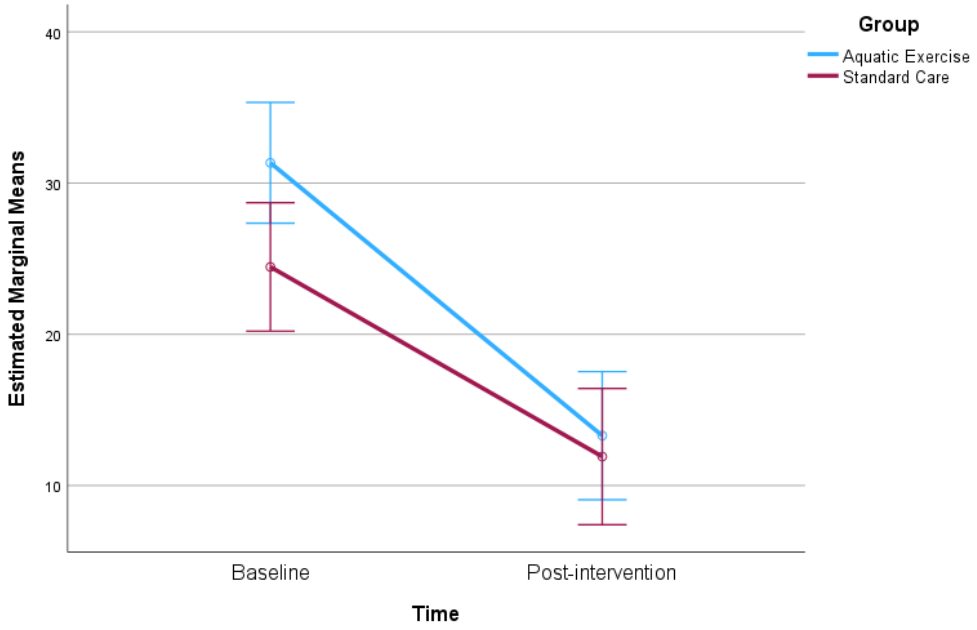


Figure 4: Graph representing adjusted mean change in SF-12 total score from baseline to post-intervention with standard error.

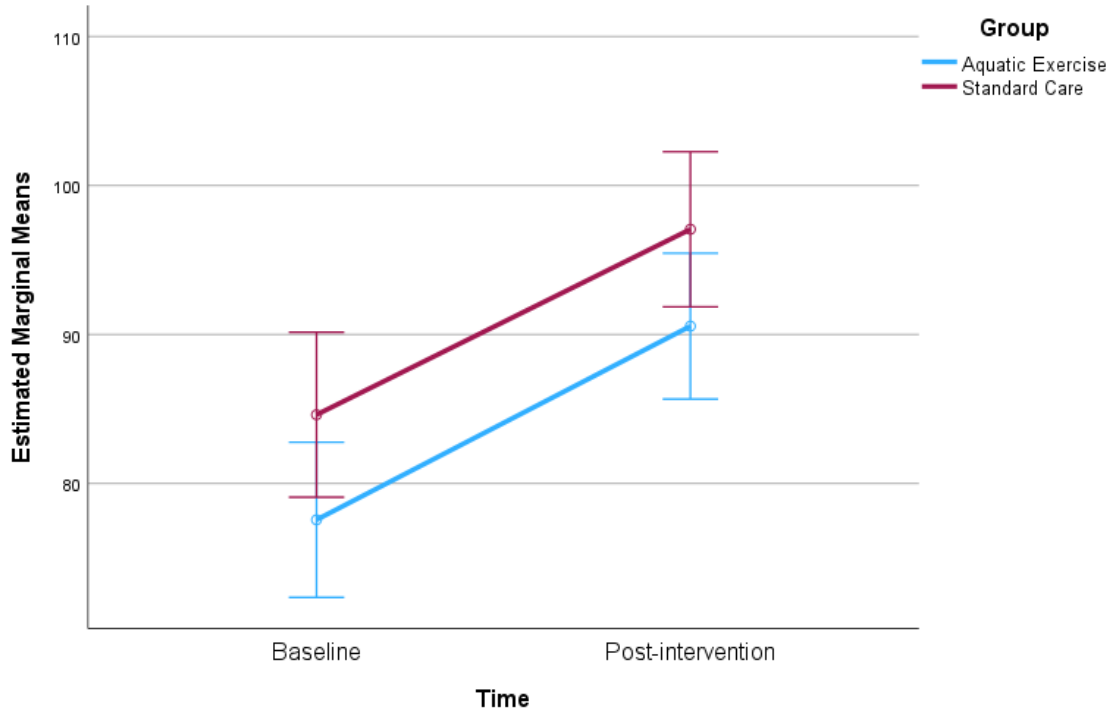


Figure 5: Graph representing adjusted mean change in PCS score from baseline to post-intervention with standard error.

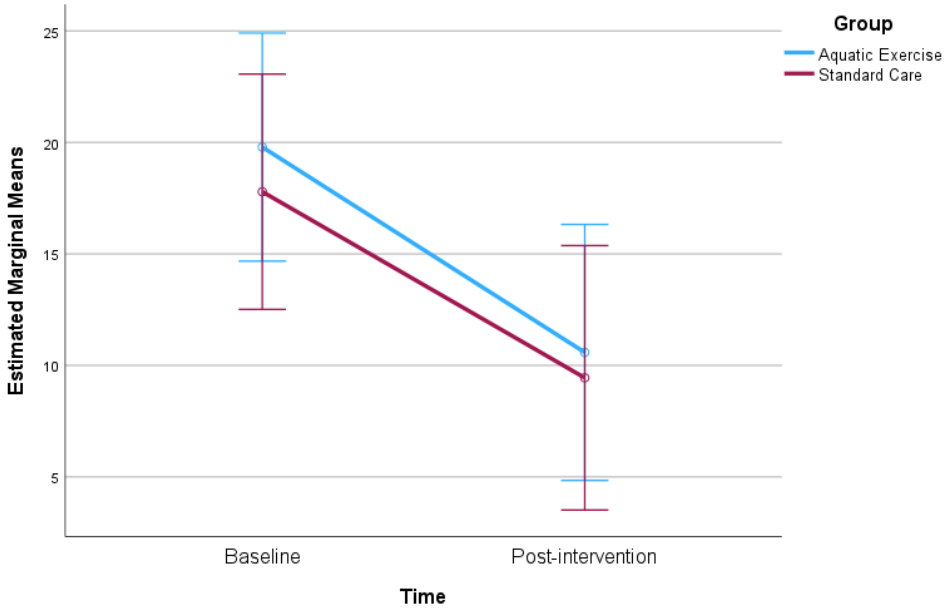


Figure 6: Graph representing adjusted mean change in TSK-11 score from baseline to post-intervention with standard error.

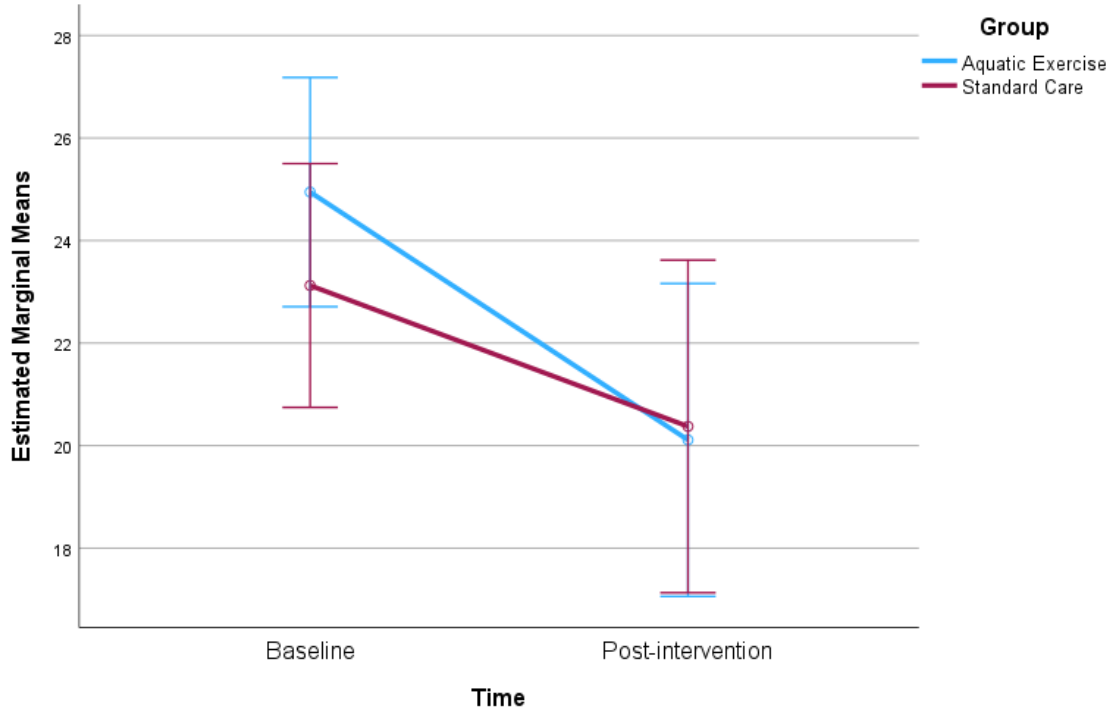
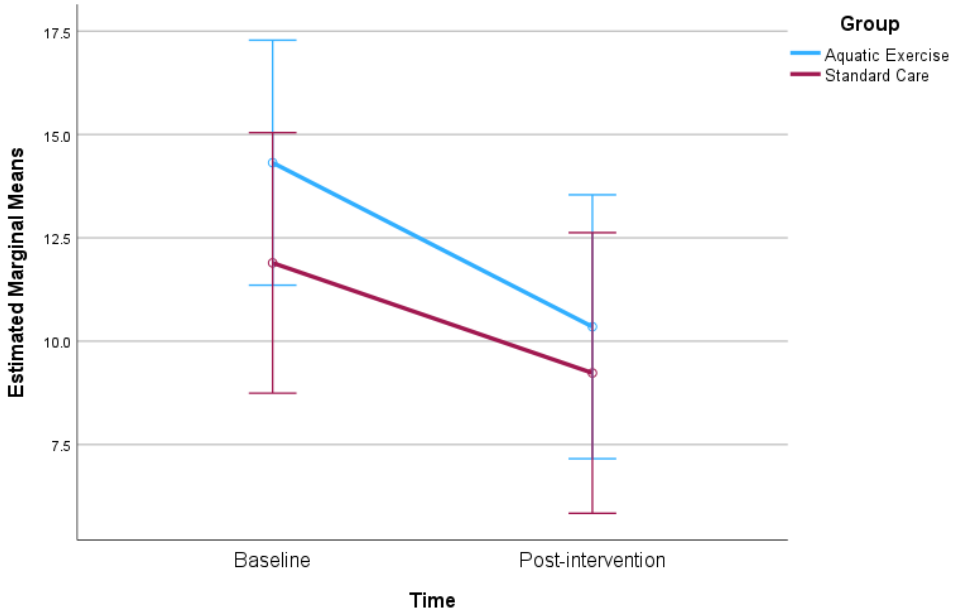


Figure 7: Graph representing adjusted mean change in HADS score from baseline to post-intervention with standard error.



18. Discussion

The primary aim of the study was to determine the effects of aquatic therapy versus standard care on the psychological factors associated with CLBP. To date, very few studies have explored the benefits aquatic therapy may have on psychological factors associated with CLBP despite the potential of aquatic therapy. Overall, both the standard care and aquatic therapy interventions were effective to improve pain, disability, depression and anxiety, and pain catastrophizing with no significant differences between the interventions. However, only the aquatic exercise group significantly improved kinesiophobia and insomnia. There were also slight differences between groups for the change in disability over time, with an ODI group*time interaction that neared significance (p=0.054), suggesting slightly greater change in the aquatic therapy group.

In the context of CLBP, analyzing the clinically significant change for each outcome is important. The aquatic therapy intervention was as effective as standard care to decrease pain in individuals with CLBP. A 2-point change on the NPRS represents minimal clinically important difference (MCID) that exceeds the bounds of measurement error[116]. The aquatic therapy group had a decrease of 2.95 points on the NPRS and the standard care group had a decrease of 3.19 points on the NPRS. Therefore, both the aquatic therapy group and the standard care group had a clinically meaningful change in pain. These improvements are consistent with previous studies who used a similar design of bi-weekly 60 minutes aquatic exercise sessions[101,102]. There was a significant improvement in disability for both groups on the ODI. The aquatic therapy group had an 18.04 point decrease on their ODI disability score while the standard care group had a 12.54 point decrease. Although there is no consensus on the MCID for the ODI, prior research has identified the MCID of the ODI to be from 5.2 points to 16.3 points[117]. Both groups met the criteria for MCID and both groups had a post-intervention mean ODI score of "low disability". Although not significant, the aquatic exercise group saw a greater reduction in their ODI score compared to the standard care group. These results suggest aquatic exercise may yield slightly better improvements in self-reported function than standard care. The exercises included in the aquatic therapy intervention focused on aerobic exercise, functional resistance training, and dynamic lumbar stabilization. In their systematic review, Owen et al.[86] reported dynamic lumbar stabilization exercises and resistance training to be the most effective exercise modes to improve function in CLBP. There are key differences when applying these exercise modes on land versus in the water. These differences could be accounted for due to physical properties of water and the associated physiological effects of aquatic therapy. During water immersion, buoyancy counteracts the forces of gravity acting on the body and consequently reduces up to 60% of compressive forces on the intervertebral joints of the spine[87]. Shallow water functional exercises allow users to mimic land-based exercises through greater range of motion that might otherwise be painful on land. Despite the effects of buoyancy, aquatic exercise has shown to produce similar levels of muscle activation of the erector spinae, multifidus, gluteus maximus/medius, rectus abdominis and external/internal obliques to land-based exercises[98]. Aquatic exercise can therefore yield similar results to land-based exercise to improve strength. Additionally, the viscosity of water allows for safe and controlled progression of resistance exercises[91]. Limbs moving relative to the water will be subjected to a drag force proportional to the velocity of movement. Being able to move through full range of motion and progressing through exercises while being in less pain likely allowed the aquatic therapy group to see greater improvements in function.

The improvements in quality of life had similar trends for both groups. Both groups had a significant improvement in the SF-12 mental composite score and the SF-12 total score with no significant change in the SF-12 physical composite score. These results suggest although the overall quality of life improved, most of the improvements were due to improvements in mental health. Prior research has set the MCID for the SF-12 mental composite score in CLBP at 3.77 points[118]. Both groups met the MCID for the SF-12 mental composite score and the improvement in mental health is reflected in the anxiety and depression (HADS) outcomes. Anxiety and depression (HADS) significantly decreased for both groups. HADS scores ranging from 8-10 are considered mild, 11-14 moderate and 15-21 are considered severe anxiety and depression[119,120]. Our aquatic therapy group had a baseline HADS score of 14.32, placing them on the higher end of the moderate anxiety and depression category. At post-intervention, the aquatic therapy group had a score of 10.35, placing them on the lower end of the mild category, which can be interpreted as a clinically significant improvement. The benefits of exercise therapy on mental health are well documented and reflected in the results of our study. Meta-analyses have determined exercise to have a moderate to large antidepressant effect in individuals with depressive disorder[121]. Aerobic exercise is the most effective exercise modality to reduce depression and anxiety in CLBP[86]. The aquatic exercise protocol in our study was designed to increase cardiovascular demands by incorporating dynamic exercises with low rest time between exercises to maintain an elevated heart rate. Additionally, water exerts a hydrostatic pressure on the body and increases the total work of breathing at rest by 60% during neck deep immersion[89]. Aquatic aerobic exercise can yield similar gains in cardiovascular fitness at lower intensities compared to land-based exercise[90]. A potential mechanism for improvement in depression and anxiety is through endogenous opioid (B-endorphin) release and modulation. B-endorphins are responsible for modulating stress responses and produce a feeling of well-being[122]. Studies have reported a decreased B-endorphin secretory capacity[123] in CLBP and diminished B-endorphins levels in circulation[124]. Aerobic exercise of sufficient intensity acutely increase B-endorphin levels[125,126]. Increased B-endorphin levels have been associated with decreased symptoms of depression, improved coping with stress[122], and decreased CLBP intensity[127]. Therefore, improving the regulation of B-endorphins through aquatic aerobic exercise likely contributed to improving symptoms of depression and anxiety in CLBP. The standard care group also saw a significant decrease in depression and anxiety, though the mean change was slightly lower than the aquatic therapy group. The standard care group also underwent exercise-therapy, with a greater focus on functional and resistance training. Resistance training of sufficient intensity improves cardiovascular fitness and can also improve B-endorphin modulation[125,128].

Both interventions had beneficial effects on pain catastrophizing. According to the pain catastrophizing user manual, a score of 20 on the PCS is considered moderate risk for the development of pain chronicity, while a score of 30 is considered high risk and clinically relevant pain catastrophizing[129]. The aquatic therapy group had a mean baseline PCS score of 19.8 ± 2.50, putting them close to the threshold for moderate risk of chronicity. At post-intervention, the aquatic therapy group had a mean PCS score of 10.58 ± 2.80, placing them well below the threshold for risk of chronicity. In CLBP, a change of 8 to 11 points on the PCS is considered clinically significant[130], meaning the aquatic therapy group met the threshold for MCID. The standard care group had similar baseline and post-intervention levels of catastrophizing and met the threshold for MCID post-intervention. Interestingly, there were less changes in kinesiophobia (TSK-11) than the other psychological outcomes. To our knowledge, there are no established cutoff scores for the TSK-11 in CLBP. Despite the change in the TSK-11 for the aquatic exercise

group being statistically significant, we cannot determine with certainty if the change meets the criteria for MCID. The primary focus of both interventions was to provide a reduction in pain and disability. Since both interventions were effective to improve pain and disability, this progress can enable individuals to reclaim activities they once avoided due to pain or fear of pain. Consequently, they may adopt a more proactive and resilient perspective towards their condition, partly through the enhancement of self-efficacy via exercise[131]. Self-efficacy is an important component in the self-management of CLBP. Self-efficacy is defined as "*one's belief in their capacity to organize and execute the courses of action required to produce given attainments*"[64]. Poor self-efficacy leads to anxiety, depression, pain catastrophizing, and a poor outlook on one's condition[77]. Self-efficacy therefore refers to an individual's belief in their capacity to complete a task, rather than a measure of their actual capacity to complete said task. In the context of pain, pain self-efficacy is best described as one's confidence in their ability to function properly despite being in pain[65]. For instance, as they progress, they may enjoy longer walks without exacerbating their pain or do household chores that were previously too difficult. Attending social gatherings that were once avoided due to isolation associated with pain might become possible again. These milestones are partially reflected in the ODI, including components like self-reported increased walking capacity, pain-free completion of chores, attending of social gathering, and pain free personal care. Our results suggest exercise, land-based and aquatic, may provide an effective way through which individuals with CLBP feel like they are actively taking control of their condition, and provides them with meaningful feelings of improvement. By changing individuals' perspectives on their condition, their way of thinking may have been steered toward a more constructive outlook. In essence, the cumulative effect of pain alleviation, functional improvements and greater self-efficacy empowers individuals to engage in meaningful activities once again, giving them a sense of accomplishment leading to an improvement in depression, anxiety, overall quality of life and pain catastrophizing.

The multifactored nature of CLBP requires a good understanding of the individual factors that may be contributing to each person's condition. A strength of this study was the one-on-one nature of each session with a Certified Athletic Therapist knowledgeable in pain management and spine rehabilitation. Individual sessions allow for more targeted care and better support for each person's specific needs. Common complaints from individuals with CLBP include unfulfilling interactions with healthcare professionals, partly from a perceived lack of support[132]. Providing individuals with CLBP with support and dedicated time for their care allows them to feel like their well-being is a priority. Regular dedicated one-on-one sessions with the patient allows the therapist to guide the patient during their rehabilitation process and reduce fears and barriers associated with pain and exercise when they come up. Common beliefs in individuals with CLBP is attributing CLBP solely to structural and anatomical factors[132]. Identifying the cause of their pain and having a clinical diagnosis is important for patients with CLBP[133]. Without a diagnosis, individuals with CLBP feel uncertain about the right course of action and develop avoidance behavior for fear of exacerbating their condition. When individuals with CLBP are unable to identify the cause of their pain, they often self-diagnose a structural cause for their pain[132]. However, the number of diagnoses given to an individual is directly associated with pain perception. Therefore, the more diagnoses are given to a person, the greater their behavior change and increase in fear-avoidance beliefs will be[133]. These statements may seem to be contradictory, but they simply show the complexity of treating CLBP. Therefore, the wording and terminology used around this population is extremely important. When the cause of pain cannot be identified, patients with CLBP must not be dismissed as this will show a lack of

support, which has been shown to worsen their condition[132]. Consequently, when presenting a diagnosis that is potentially contributing to their pain, presenting the information in a manner devoid of dramatization is crucial, as the diagnosis might not necessarily be the root cause of their pain[77]. For instance, one study reports individuals with CLBP perceiving their back to be "out of place" following chiropractor visits[132]. Despite no evidence on the presence of vertebral subluxations as a specific cause of CLBP, this type of dogma is commonly used in traditional clinics as part of the assessment process and should be avoided. The concerns of patients with CLBP regarding their condition can be alleviated through proper education on pain management and spine rehabilitation provided by a knowledgeable therapist well-versed on the recommended guidelines for managing of CLBP[77].

Limitations

This was a pilot study with a relatively small sample size, therefore larger studies are needed to confirm the generalisability of these results. Due to limited resources, the assessors responsible for overseeing the post-intervention testing were also responsible for administering the interventions and were therefore not blinded. The mean baseline physical activity levels were higher than expected, as both groups were over, or nearly over, the threshold of high physical activity of 3000 METs per week. These physical activity levels are high considering most of our sample did not engage in regular physical activity. The IPAQ is based on self-reported measures of physical activity and tends to overestimate the amount of time spent doing moderate and vigorous physical activity[134]. There were some differences in between the groups which may have affected the results. The aquatic therapy group did not receive a physical examination as part of their treatment, which could have affected therapeutic alliance between the participant and the therapist. Subsequently, the aquatic therapy group also had no physical contact with the therapist, which could have an impact on their perceived support in regard to their condition.

19. Conclusion

Both the aquatic exercise group and the standard care group had significant improvements in pain, disability, quality of life, depression, anxiety and pain catastrophizing. Most gains in patient-reported outcomes proved to be of clinical importance. Only the aquatic exercise group had a significant decrease in kinesiophobia, although the change could not be established as clinically significant due to lack of data on cutoff scores. Our findings also suggest aquatic therapy may have added benefits to improve LBP-related disability. These findings also solidify the current standard of care and provide preliminary evidence on the efficacy of aquatic therapy on psychological outcomes in CLBP. Further studies should investigate the effects of different types of exercise modalities on psychological outcomes associated with CLBP to better understand the underlying mechanisms involved.

Chapter 3: Project 2 – Feasibility and User Experience of Mobile Health Application *Play the Pain* in a 10-week Clinical Intervention for Persons with Chronic Low Back Pain

20. Introduction

Low back pain (LBP) is the leading cause of disability worldwide[1]. In 2020, and estimated 619 million people where affected by LBP and by 2050 the estimated number of cases will rise to 843 million globally[2]. The rising prevalence of LBP poses a significant burden on the health of affected individuals and the global economy. In 2023, the estimated yearly direct costs associated with LBP from the regions of America, Europe and the West Pacific range from 2.3-2.6 billion €, while the indirect costs ranged from 0.24-8.15 Billion €[10]. While many cases of LBP generally resolve, some studies estimate up to 25% of cases become chronic LBP (CLBP)[135]. CLBP is a common cause of early retirement and significantly decreases the quality of life of those affected[11]. The etiology of CLBP is complex, which makes pinpointing the cause of pain difficult. CLBP is associated with increased disability, anxiety, depression and pain-related fears[77].

Exercise therapy is one of the most effective forms of conservative treatment for CLBP. There is overwhelming evidence showing exercise therapy decreases pain and disability associated with CLBP[17,73,113]. However, adherence to exercise-based treatments in CLBP is very low. CLBP is a complex and multifactored condition that cannot be fully encompassed by the standard biomedical model of pain management. CLBP occurs due to a complex interaction of biological, psychological, and social factors. There are therefore many internal and external factors that can affect treatment adherence. Common internal causes of non-adherence to exercise interventions in people with CLBP include pain with movement, low motivation, depression, anxiety, fear avoidance beliefs and low self-efficacy[106,107,136]. Common external causes of non-adherence include difficulty integrating exercise in their daily life, difficulty bridging between supervised and unsupervised exercise sessions, lack of follow-up from healthcare providers and difficulty contacting healthcare providers[136,137]. Effective solutions to increase treatment adherence include supervision of exercise sessions[136], however increasing supervised exercise sessions does not address the decrease in adherence that occurs during the transition to unsupervised exercise.

The success of exercise therapy is highly dependent on patient-adherence[85]. New solutions are therefore needed to increase patient engagement in exercise-based interventions. Recent efforts to improve patient outcomes in the management of chronic conditions has been through the integration of mobile health (mHealth) technology and devices. The increased prevalence of smartphones and internet usage presents promising opportunities for improving delivery of care in a wide range of healthcare interventions. Mobile health solutions present unique advantages thanks to their convenience and increased accessibility. Mobile health devices have been successfully integrated in the management of chronic diseases. A systematic review of 50 randomized controlled trials using mHealth devices in the treatment of chronic disease determined 56% of studies demonstrated significant effects on treatment adherence, with treatment adherence defined as medication adherence, engagement in healthy behaviors, frequency of symptom monitoring, and gains in knowledge and perceived self-efficacy[108]. Among the reviewed mHealth studies, 40% had a significant improvement on clinical outcomes.

The integration of mHealth devices for better management of CLBP in terms of improved adherence and outcomes holds promise. For instance, a mHealth app designed to allow for self-tracking of CLBP symptoms was deemed feasible and improved anxiety at short-term follow-up, and demonstrated a greater reduction in pain catastrophizing at long-term follow-up compared to control[109]. Similarly, a mHealth application who provided a 12-week home exercise program for individuals with CLBP showed greater improvements in pain and disability to control[110].

Play the Pain is a novel mHealth app designed to cater to the different needs for populations with chronic pain. The application was designed to prompt individuals to stay active and allows for continuous self-tracking of emotional and environmental factors that influence pain coping strategies[111,112]. The app was designed to give users autonomy in their use of the app and provide healthcare professionals with a better understanding of their patients' pain coping strategies. *Play the Pain* allows for self-tracking of pain, emotions, activities, sleep, and medication use. Improved tracking features allow patients to feel better connected to their healthcare provider and could improve their perceived support. *Play the Pain* allows users to be actively involved in their rehabilitation and could improve self-efficacy in individuals with CLBP and could potentially have a beneficial impact on adherence to exercise interventions. However, no studies have assessed the feasibility of using *Play the Pain* in a clinical setting.

The aim of this study was to assess the feasibility and user experience of using mHealth application *Play the Pain* in a clinical intervention in terms of adherence and satisfaction with the app. We hypothesized that it would be feasible to implement *Play the Pain* in a clinical setting and that patients with CLBP would meet the adherence threshold and be satisfied with the app.

21. Methods

Study Design: As we recognized the need for ecological monitoring with the purpose of keeping users engaged and motivated to track their activities and symptoms, we tested the feasibility and user experience of play the pain with the intention of capturing the psychosocial variates that can impact pain management. Thus, this feasibility study focused on the user experience and self-tracking functions and was conducted in parallel to a pilot randomized controlled trial that investigated the effects of an aquatic therapy intervention compared to standard care on CLBP. The study lasted 10 weeks, and participants in both groups tested the mobile health application. Participants were recruited through posters and media advertising and all research activities took place at the School of Health at Concordia University. The interventions were individual and supervised by a Certified Athletic Therapist.

Participants: Participants for the feasibility trial were recruited from the pool of participants for the CLBP randomized controlled trial. The participant inclusion criteria were based on the aquatic therapy pilot randomized controlled trial:

- Have a mobile phone compatible with *Play the Pain.*
- Chronic non-specific LBP (>3 months), defined as pain in the region between the lower ribs and gluteal folds, with or without leg pain.
- Currently seeking care for LBP.
- Aged between 18 to 65 years old.
- English or French speakers

- Have a score of "moderate" or "severe" disability on the modified Oswestry Low Back Pain Questionnaire
- Do not currently engage in sports or fitness training specifically for the lower back muscles (3 months prior the beginning of the trial).

Exclusion criteria

Participants were excluded if they met one of the following criteria:

- Evidence of nerve root compression or reflex motor signs deficits (e.g., weakness, reflex changes, or sensory loss with same spinal nerve),
- Previous spinal surgery or vertebral fractures,
- Other major lumbar spine structural abnormalities (e.g., spondylolysis, spondylolisthesis, or lumbar scoliosis >10°)
- Comorbid health conditions that would prevent active participation in exercise programs (e.g. screened with Physical Activity Readiness Questionnaire)

Therapeutic Aquatic Exercise Intervention: The participants in the aquatic therapy group received a standardized program. Each session lasted 60 minutes, beginning with a 10-minute warm-up, followed by 40 minutes of strengthening, and finished with a 10-minute cool-down. Participants in the aquatic therapy group performed trunk/hip stabilization exercises, aerobic conditioning, and general strengthening exercises in the treatment pool. The supervising Athletic Therapist monitored pain levels of participants and demonstrated sound clinical judgment to avoid unnecessary exacerbation of symptoms.

Standard Care Intervention: Participants in the control group received the standard care treatment in the School of Health Athletic Therapy clinic and conditioning floor. The standard care intervention was not standardized but rather personalized to the needs of each participant. The objective of the standard care intervention was to replicate care that would otherwise be seen in a real-world clinical setting. Participants in the control group received a musculoskeletal assessment and a personalized rehabilitation plan consisting of a combination of land-based exercise, manual therapy techniques and heat application.

Play the Pain: Participants in both groups used the mHealth application *Play the Pain*. To avoid an inadvertent co-intervention in the trial, the "play'' function of the app was not for this feasibility study. The function of interest for this study was the "track'' function. Participants were able to track their pain, their activities, their sleep, their medication use and their emotions. After determining the location of the pain, users were prompted to scale the intensity with a movable cursor from slight pain to extreme pain. Emotional tracking features an interactive web with a wide range of feelings. The sleep tracking function tracks the duration and quality of sleep. The activity tracking feature has 24 options to choose from and includes physical activity, leisurely activities and health promoting activities in the last 48 hours. Participants in the study were asked to use the app daily, however they were not given specific guidelines on what should be tracked each day. The philosophy of *Play the Pain* is to let the user share what is on their mind, and to give the clinician a better understanding of their condition and how patients cope with pain[111,112].

Outcome measures: The outcome measures were related to the feasibility and satisfaction of *Play the Pain*. Adherence to *Play the Pain* and satisfaction were collected through administrative data and an end-of-study survey.

Adherence: Adherence was measured by tracking weekly usage of the app. The weekly usage threshold was set at a two logging inputs per week. This means for a week to be considered "satisfactory", participants needed at least two separate days in the week with at least one logged input. There are no clearly established guidelines for determining threshold for adherence, however previous mHealth studies have set the threshold for adherence at 70%[138]. Therefore, the total weekly threshold for adherence was set at 70% for each participant with a minimum of two inputs per week. This means for the adherence of a participant to be above the threshold, they need at least 7 out of 10 weeks with at least 2 inputs per week.

Satisfaction: Satisfaction with the app was measured through an online exit-survey. Survey questions were answered via Likert scale and included questions about barriers and facilitators. The survey included multiple-choice questions designed to measure satisfaction with various features of the application and overall impression. Each multiple-choice question utilized a 5-point Likert scale, including a neutral option. Additionally, the survey incorporated open-ended questions to allow participants to express any additional feelings, comments, or suggestions regarding their experience with the app.

Procedures: Participants came in for a baseline assessment and were randomly allocated to the aquatic therapy group or the standard care group (1:1). Participants were introduced to the application when they came to the School of Health for their first visit and were provided with clear instructions on how to install and use the app. Each participant's account was linked to an administrative account managed by the research team, allowing us to track each participant and their use of the application. At the end of the intervention, the participants were asked to complete the questionnaire regarding their satisfaction with the use of the application. Participants from both the standard care group and the aquatic therapy group used the application and no specific guidelines were given on how to use the app, only a recommendation to try and integrate the app daily.

Statistical Analysis*:* Descriptive statistics were used to summarize the feasibility outcomes.

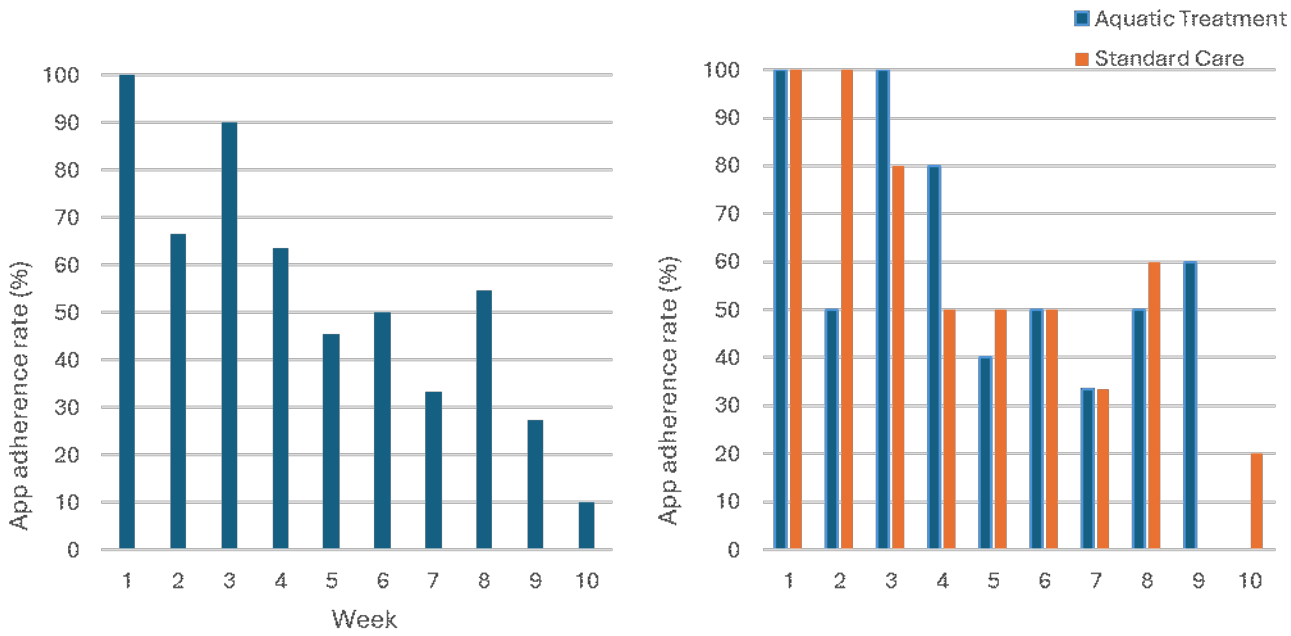
22. Results

22.1. Adherence

Twelve participants from the CLBP study participated in the feasibility study. Due to technical and logistical challenges, the application was unavailable to the participants on multiple occasions during the interventions. On average, the app was available for 8.16 total weeks out of 10 possible weeks for the participants. Every participant experienced at least one week where the application was unavailable to them. Therefore, the total amount of total weeks eligible for each participant was adjusted in consequence. Only 5 out of 12 participants met the minimum threshold for adherence (e.g., 2 inputs/week), for a total of 41.6% adherence. When considering the cumulative app usage over all available weeks for all participants, the instances of successful adherence, with at least two inputs per week, amounted to 50.2%. As seen in figure 8, the adherence rate steadily decreased over the course of the intervention. The usage rates and

trends of decreasing adherence were similar for both the aquatic therapy and the standard care group.

Figure 8: Average adherence rate of "Play the Pain" app over 10-week period (n=12)



22.2. Satisfaction

Only 6 out of the 12 participants (50%) completed the online exit-survey. Half the participants found the activities tracking and emotions tracking useful to their rehabilitation, while 50% did not find the sleep tracking features useful and over 25% did not find the medication tracking feature useful (Figure 9). Almost 75% agreed the app was frustrating to use and only 25% agreed the app was easy to figure out. Close to 75% of users found the prompts, error messages and use of terms and concepts clear and easy to use. Twenty five percent of the users reported appreciating the look and feel of the app while the responses were evenly distributed with regards to the information of on the screen being organized and easy to use. Fifty percent of participants found the pain and emotion tracking features easy to use, while the other tracking features were not used by close to 75% of participants (Figure 10). Overall satisfaction with the app was evenly distributed, with approximately one third being satisfied, one third neutral and the other third very dissatisfied or dissatisfied, . Interestingly, only about 25% of users said they would continue using the app after the intervention despite almost 75% of users recommending *Play the Pain* for individuals with CLBP.

Figure 9: Attitudes towards using "Play the Pain" application (n=6)

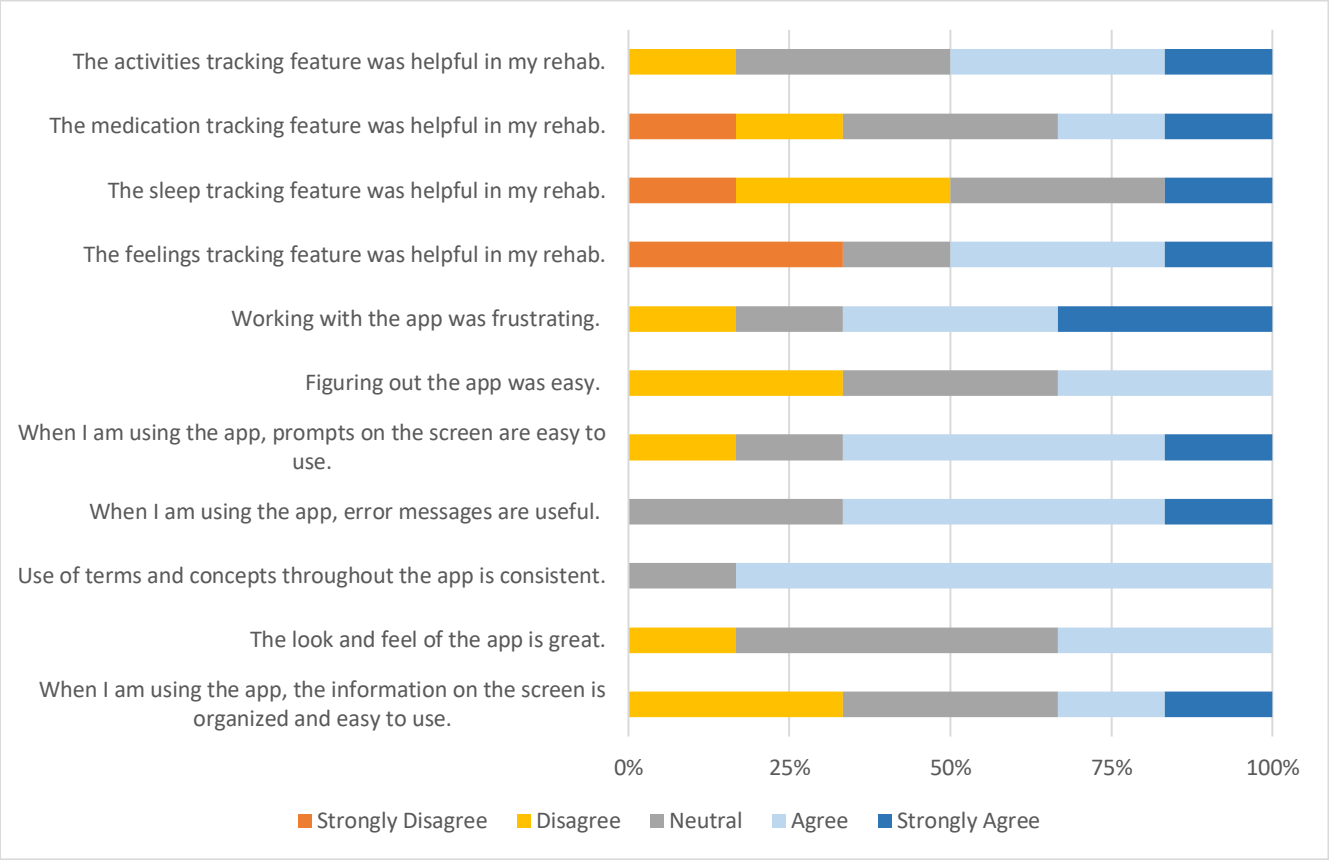
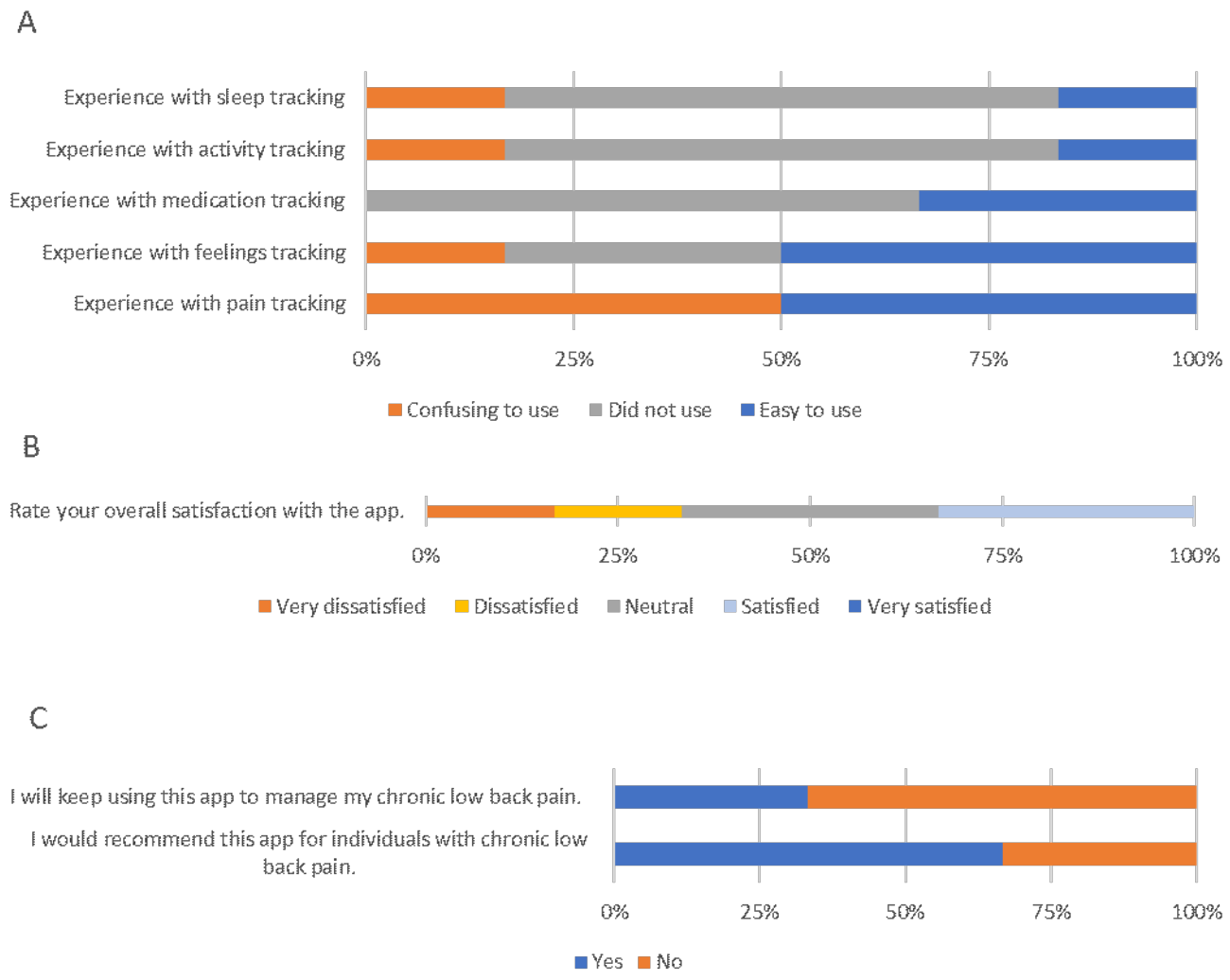


Figure 10: Overall experience using the "Play the Pain" application (n=6)



23. Discussion

This study aimed to assess the feasibility of integrating *Play the Pain* into a clinical intervention for CLBP, with the outcomes focusing on adherence to and user satisfaction with the app. Although the adherence and user satisfaction results obtained were insufficient to support feasibility of *Play the Pain*. While some participants demonstrated satisfactory adherence with the app, most had low usage which resulted in overall unsatisfactory adherence rates. The final weekly adherence rate was 41.6%, which is below the 70% threshold for adherence that was set. Shedding light on some of the challenges that occurred during the study will help give clarity to the adherence results. Only 12 participants out of 34 potential participants were able to participate in the feasibility study. The main reason for the small sample size is due to software incompatibility issues. The version of *Play the Pain* used during the study was only compatible with IOS operating system from Apple devices and old generation Android devices. Most participants had phones with recent generations of android operating systems like

in Samsung and google devices and were unable to download the app. Over the course of the intervention, there were multiple occasions of server maintenance issues lasting at least one week each time, which caused the app to become inaccessible to all participants during that timeframe. Lack of financial support caused to pay for server maintenance did not allow for proper tracking of outcomes related to the app. The lack of access to the application significantly limited our ability to determine adherence to the application. Every participant had at least a minimum of one week where the application was unavailable to them, while some could not participate because ultimately the servers were down permanently. Previous studies using mHealth applications reported login difficulties to be a significant barrier to use, as difficulty accessing mHealth apps negatively affects motivation in the self-management of CLBP[139]. Since participants in the study had limited access to the app, not only does measuring adherence become more difficult, but the motivation of participants to use the app naturally decreases, which leads to lower adherence rates. Additionally, features like pain tracking encountered "bugs" during the study which limited the access to this functionality. While these software issues were successfully resolved, they hindered access to the applications functionality and undeniably contributed to reducing the overall adherence. Therefore, due to technical problems encountered during the study ranging from server maintenance issues, device incompatibility issues and technical bugs, feasibility could not truly be assessed during the context of the current study.

The results from the online exit-survey demonstrated low satisfaction with the app in terms of usability and relevance. Low overall satisfaction from the survey does not provide supporting evidence in terms of the feasibility of implementing *Play the Pain* in clinical settings. Previous mHealth observational studies have highlighted user retention to be one the main challenges[140]. Usability and satisfaction with the interface are important attributes that determine user retention, which impact the effectiveness of a mHealth application. For instance, key factors associated with better usability is having a simple and user-friendly interface featuring clear graphics[140]. As seen in Figure 9, almost 75% of participants reported being frustrated with the app, while only 25% were able to easily figure out how to use the app. Increased frustration with the app and difficulty figuring out how to operate the app suggests poor usability, which in turn leads to an unwillingness to keep using the app. Unwillingness to pursue using the app is highlighted in Figure 10, as only approximately 25% of respondents said they would continue using the app after the study. As seen in Figure 9, most users failed to see the relevance of sleep, medication and activity tracking features to their rehabilitation, which led to very few participants using these features, per Figure 10. These findings indicate limitations in the app's ability to effectively address CLBP through complete lifestyle monitoring. Overall, the participants' suggestions in the survey offered helpful insights into areas for improving and optimizing the app. To increase user adherence and satisfaction, the user interface and different functionalities of the app could be improved. One participant stated the app would need a "*thorough evaluation on the user experience and user interface design*". Most participants enjoyed the idea of having a pain tracking feature, however they had suggestions to improve the user experience. For instance, improving the ability to locate the region of interest would help, as one person said the pain locator was "*difficult to use*" and "*too many clicks were required to add a pain log*". Some did not enjoy the sliding scale to measure pain, with one person saying, "*the pain sliding pain scale is difficult to manipulate*", while another mentioned the experience could be improved by "*adding a number scale*". Only a small portion of participants used the activity, medication, and

sleep tracking features. Therefore, not everyone felt these features to be relevant to their rehabilitation, and one person mention they would like the option to "*hide/show some of the tracking features*" to only display the features they were using. Activity tracking is an important feature, especially for healthcare professionals in the context of exercise interventions. One participant said they would use the activity tracking feature more if they "*could retroactively add activities without being limited to the past 48 hours only*". For the sleep tracking function, some users felt limited by the answer choices: *"The sleep section gives more than 7 hours or less than 6 as options. What if I slept 6 or 7 hours?".* One of the reasons for integrating Play the Pain in clinical interventions is to improve the connection between the patient and the healthcare provider. Improved communication between the patient and the healthcare provider allows the patient to feel supported and understood by their healthcare provider. A challenge for the healthcare provider is to keep track of all the daily inputs from their patients simultaneously. One participant mentioned the providers did not seem to always have all the information at hand from their recent tracking inputs during their follow-up sessions and proposed *"adding a feature that allows the healthcare provider to generate a summary report to help the healthcare provider keep track of all their patients".* Addressing these issues will be important to allow for future pilot testing of the app in a clinical setting. Additionally, addressing the user's perception of ease with the interface will be important to increase patient engagement and satisfaction.

Limitations

Only 12 out of 34 potential participants were able to participate in the feasibility study. The main reason for the small sample size was due to software incompatibility issues and server maintenance issues. The version of *Play the Pain* used in the study was incompatible with recent android devices. Additionally, only 6 out of 12 participants completed the end of study survey to measure satisfaction, which limited our ability to adequately measure satisfaction with the app. Over the course of the intervention, there were financial limitations that caused the app servers to go down, which caused the app to become inaccessible to all participants during that timeframe. The servers remained down before we could finish collecting data, which caused us to lose more participants and reduced our sample size. Additionally, the pain tracking feature encountered "bugs" during the study, which limited the access to this functionality and affected adherence and satisfaction outcomes.

24. Conclusion

The objective of this study was to determine the feasibility and user experience of novel mHealth app P*lay the Pain.* With the app still being under development and having faced many technical difficulties during the study which directly impacted the adherence, the "true" feasibility and satisfaction of the app could not properly be assessed. Nonetheless, from these challenges and the data collected we learned that such apps are appreciated and seem necessary, but significant efforts and investment are necessary to create such research platforms. Through the exit-survey, users provided valuable suggestions to improve the user interface and overall usability of the app, which would help increase adherence and satisfaction in future studies. Being faced with technical challenges that may limit the usability of the app is to be anticipated in their early stages of design. Therein lies the importance of testing the design and functionality of the app in a real world setting to better understand its strengths and weaknesses.

Chapter 3: Future Directions and General Discussion

The results from project 1 provided us with valuable preliminary findings on the efficacy of both aquatic therapy and Athletic Therapy in the treatment of CLBP. The key findings from the study highlight the importance of exercise therapy in the treatment of CLBP, as well as the importance of therapeutic alliance when addressing a complex multi-factored condition such as CLBP. The aquatic therapy standardized protocol proved to be as effective as standard care in the short-term treatment of CLBP. The standardized nature of the intervention allows for an easier transfer of knowledge. Future directions will include providing clinics with therapeutic pools with our protocol and our findings. In order to make the aquatic therapy intervention more accessible, we will try to adapt it to a community setting so that individuals with CLBP can participate in group classes at their local pool.

For project 2, the study did not go as planned as the application was still under development, we faced important technical and financial limitations. Therefore, the feasibility and user experience could not be fully assessed. However, despite these challenges, participants shared important suggestions regarding their user experience and interface experience that should be considered and incorporated the next generations of the application to improve user satisfaction. These suggestions can be summarized to *i)* improving the clarity and choice options for the tracking features *ii)* making the overall design more user friendly and *iii)* improving the feel and haptics of the app. *Play the Pain* holds tremendous potential to have a significant impact on the quality of care due to its widespread accessibility and affordability. The next generation of *Play the Pain* should address the suggestions from real world users with CLBP to allow for improvement and optimization of the app. Once these technical aspects have been addressed, future studies should focus on *Play the Pain* alone, without any other interventional component to fully capture and monitor all psychosocial variates that can impact pain management. This will allow for higher quality study where the true impact and self-tracking functions of the app can be truly assessed, to provide a better understanding of the barriers and facilitators to mHealth application usage in CLBP.

Bibliography

1. Vos T, Lim SS, Abbafati C, et al. Global burden of 369 diseases and injuries in 204 countries and territories, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet*. 2020;396(10258):1204-1222. doi:10.1016/S0140-6736(20)30925-9

2. Ferreira ML, De Luca K, Haile LM, et al. Global, regional, and national burden of low back pain, 1990–2020, its attributable risk factors, and projections to 2050: a systematic analysis of the Global Burden of Disease Study 2021. *The Lancet Rheumatology*. 2023;5(6):e316-e329. doi:10.1016/S2665-9913(23)00098-X

3. Thiese MS, Hegmann KT, Wood EM, et al. Prevalence of low back pain by anatomic location and intensity in an occupational population. *BMC Musculoskelet Disord*. 2014;15(1):283. doi:10.1186/1471-2474-15-283

4. Jeffries LJ, Milanese SF, Grimmer-Somers KA. Epidemiology of Adolescent Spinal Pain: A Systematic Overview of the Research Literature. *Spine*. 2007;32(23):2630-2637. doi:10.1097/BRS.0b013e318158d70b

5. Dionne CE, Dunn KM, Croft PR. Does back pain prevalence really decrease with increasing age? A systematic review. *Age and Ageing*. 2006;35(3):229-234. doi:10.1093/ageing/afj055

6. Hoy D, Bain C, Williams G, et al. A systematic review of the global prevalence of low back pain. *Arthritis & Rheumatism*. 2012;64(6):2028-2037. doi:10.1002/art.34347

7. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *The Spine Journal*. 2008;8(1):8-20. doi:10.1016/j.spinee.2007.10.005

8. Church J, Saunders D, Wanke M, Pong R, Spooner C, Dorgan M. Citizen Participation in Health Decision-Making: Past Experience and Future Prospects. *Journal of Public Health Policy*. 2002;23(1):12. doi:10.2307/3343116

9. Walker BF, Muller R, Grant WD. Low Back Pain in Australian Adults: The Economic Burden. *Asia Pac J Public Health*. 2003;15(2):79-87. doi:10.1177/101053950301500202

10. Fatoye F, Gebrye T, Ryan CG, Useh U, Mbada C. Global and regional estimates of clinical and economic burden of low back pain in high-income countries: a systematic review and meta-analysis. *Front Public Health*. 2023;11:1098100. doi:10.3389/fpubh.2023.1098100

11. Cieza A, Causey K, Kamenov K, Hanson SW, Chatterji S, Vos T. Global estimates of the need for rehabilitation based on the Global Burden of Disease study 2019: a systematic analysis for the Global Burden of Disease Study 2019. *The Lancet*. 2020;396(10267):2006-2017. doi:10.1016/S0140-6736(20)32340-0

12. Hartvigsen J, Hancock MJ, Kongsted A, et al. What low back pain is and why we need to pay attention. *The Lancet*. 2018;391(10137):2356-2367. doi:10.1016/S0140-6736(18)30480-X

13. Schofield D, Kelly S, Shrestha R, Callander E, Passey M, Percival R. The impact of back problems on retirement wealth. *Pain*. 2012;153(1):203-210. doi:10.1016/j.pain.2011.10.018

14. Dionne CE, Dunn KM, Croft PR, et al. A Consensus Approach Toward the Standardization of Back Pain Definitions for Use in Prevalence Studies: *Spine*. 2008;33(1):95-103. doi:10.1097/BRS.0b013e31815e7f94

15. Furlan AD, Malmivaara A, Chou R, et al. 2015 Updated Method Guideline for Systematic Reviews in the Cochrane Back and Neck Group: *Spine*. 2015;40(21):1660-1673. doi:10.1097/BRS.0000000000001061

16. Terminology | International Association for the Study of Pain. International Association for the Study of Pain (IASP). Accessed May 31, 2023. https://www.iasp-pain.org/resources/terminology/

17. Chiarotto A, Koes BW. Nonspecific Low Back Pain. Solomon CG, ed. *N Engl J Med*. 2022;386(18):1732-1740. doi:10.1056/NEJMcp2032396

18. Brinjikji W, Luetmer PH, Comstock B, et al. Systematic Literature Review of Imaging Features of Spinal Degeneration in Asymptomatic Populations. *AJNR Am J Neuroradiol*. 2015;36(4):811-816. doi:10.3174/ajnr.A4173

19. Koes BW, van Tulder MW, Thomas S. Diagnosis and treatment of low back pain. Published online 2022:6.

20. Gatchel RJ, Peng YB, Peters ML, Fuchs PN, Turk DC. The biopsychosocial approach to chronic pain: Scientific advances and future directions. *Psychological Bulletin*. 2007;133(4):581-624. doi:10.1037/0033-2909.133.4.581

21. Koenig AL, Kupper AE, Skidmore JR, Murphy KM. Biopsychosocial functioning and pain self-efficacy in chronic low back pain patients. *J Rehabil Res Dev*. 2014;51(8):1277-1286. doi:10.1682/JRRD.2014.02.0047

22. Wall PD. A gate control system modulates sensory input from the skin before it evokes pain perception and response. *Science*. 1965;150:971-979.

23. Travis Campbell, Jillian Johnson, Kristin Zrnicke. *Encyclopedia of Behavioral Medicine*. [2nd ed.]. Springer; 2020. doi:10.1007/978-3-030-39903-0

24. Melzack R. Pain and the Neuromatrix in the Brain. *Journal of Dental Education*. 2001;65(12):1378-1382. doi:10.1002/j.0022-0337.2001.65.12.tb03497.x

25. Melzack R. Evolution of the Neuromatrix Theory of Pain. The Prithvi Raj Lecture: Presented at the Third World Congress of World Institute of Pain, Barcelona 2004. *Pain Practice*. 2005;5(2):85-94. doi:10.1111/j.1533-2500.2005.05203.x

26. George Engel. The Need for a New Medical Model: A Challenge for Biomedicine. *Science*. 1977;4286(New Series):129-136.

27. Dubin AE, Patapoutian A. Nociceptors: the sensors of the pain pathway. *J Clin Invest*. 2010;120(11):3760-3772. doi:10.1172/JCI42843

28. Roussel NA, Nijs J, Meeus M, Mylius V, Fayt C, Oostendorp R. Central Sensitization and Altered Central Pain Processing in Chronic Low Back Pain: Fact or Myth? *The Clinical Journal of Pain*. 2013;29(7):625-638. doi:10.1097/AJP.0b013e31826f9a71

29. Giesecke T, Gracely RH, Grant MAB, et al. Evidence of augmented central pain processing in idiopathic chronic low back pain. *Arthritis & Rheumatism*. 2004;50(2):613-623. doi:10.1002/art.20063

30. Clauw DJ, Williams D, Lauerman W, et al. Pain Sensitivity as a Correlate of Clinical Status in Individuals With Chronic Low Back Pain: *Spine*. 1999;24(19):2035. doi:10.1097/00007632-199910010-00013

31. Giesbrecht RJS, Battié MC. A Comparison of Pressure Pain Detection Thresholds in People With Chronic Low Back Pain and Volunteers Without Pain. *Physical Therapy*. 2005;85(10):1085-1092. doi:10.1093/ptj/85.10.1085

32. Laursen BS, Bajaj P, Olesen AS, Delmar C, Arendt-Nielsen L. Health related quality of life and quantitative pain measurement in females with chronic non-malignant pain. *European Journal of Pain*. 2005;9(3):267-267. doi:10.1016/j.ejpain.2004.07.003

33. Peters ML, Schmidt AJM. Differences in pain perception and sensory discrimination between chronic low back pain patients and healthy controls. *Journal of Psychosomatic Research*. 1992;36(1):47-53. doi:10.1016/0022-3999(92)90113-G

34. Peters ML, Schmidt AJM, Van den Hout MA. Chronic low back pain and the reaction to repeated acute pain stimulation. *Pain*. 1989;39(1):69-76. doi:10.1016/0304-3959(89)90176-0

35. Diers M, Koeppe C, Diesch E, et al. Central Processing of Acute Muscle Pain in Chronic Low Back Pain Patients: An EEG Mapping Study. *Journal of Clinical Neurophysiology*. 2007;24(1):76-83. doi:10.1097/01.wnp.0000241093.00844.0e

36. Meeus M, Roussel N, Truijen S. Reduced pressure pain thresholds in response to exercise in chronic fatigue syndrome but not in chronic low back pain: An experimental study. *J Rehabil Med*. 2010;42(9):884-890. doi:10.2340/16501977-0595

37. Aoyagi K, He J, Nicol AL, et al. A Subgroup of Chronic Low Back Pain Patients With Central Sensitization. *The Clinical Journal of Pain*. 2019;35(11):869-879. doi:10.1097/AJP.0000000000000755

38. Zhang L, Zhou L, Ren Q, et al. Evaluating Cortical Alterations in Patients With Chronic Back Pain Using Neuroimaging Techniques: Recent Advances and Perspectives. *Front Psychol*. 2019;10:2527. doi:10.3389/fpsyg.2019.02527

39. Tu Y, Jung M, Gollub RL, et al. Abnormal medial prefrontal cortex functional connectivity and its association with clinical symptoms in chronic low back pain. *Pain*. 2019;160(6):1308-1318. doi:10.1097/j.pain.0000000000001507

40. Hashmi JA, Baliki MN, Huang L, et al. Shape shifting pain: chronification of back pain shifts brain representation from nociceptive to emotional circuits. *Brain*. 2013;136(9):2751-2768. doi:10.1093/brain/awt211

41. Seminowicz DA, Wideman TH, Naso L, et al. Effective Treatment of Chronic Low Back Pain in Humans Reverses Abnormal Brain Anatomy and Function. *J Neurosci*. 2011;31(20):7540-7550. doi:10.1523/JNEUROSCI.5280-10.2011

42. Berger SE, Baria AT, Baliki MN, et al. Risky monetary behavior in chronic back pain is associated with altered modular connectivity of the nucleus accumbens. *BMC Res Notes*. 2014;7(1):739. doi:10.1186/1756-0500-7-739

43. Mao CP, Zhang QL, Bao FX, Liao X, Yang XL, Zhang M. Decreased activation of cingulo-frontal-parietal cognitive/attention network during an attention-demanding task in patients with chronic low back pain. *Neuroradiology*. 2014;56(10):903-912. doi:10.1007/s00234-014-1391-6

44. Junqueira DRG, Ferreira ML, Refshauge K, et al. Heritability and lifestyle factors in chronic low back pain: Results of the Australian Twin Low Back Pain Study (The AUTBACK study): Genetic and lifestyle influences in chronic low back pain. *EJP*. 2014;18(10):1410-1418. doi:10.1002/ejp.506

45. Nyman T, Mulder M, Iliadou A, Svartengren M, Wiktorin C. High Heritability for Concurrent Low Back and Neck-Shoulder Pain: A Study of Twins. *Spine*. 2011;36(22):E1469-E1476. doi:10.1097/BRS.0b013e3181e2c878

46. MacGregor AJ, Andrew T, Sambrook PN, Spector TD. Structural, psychological, and genetic influences on low back and neck pain: A study of adult female twins: Genetic Contribution to Low Back and Neck Pain. *Arthritis & Rheumatism*. 2004;51(2):160-167. doi:10.1002/art.20236

47. Freidin MB, Tsepilov YA, Palmer M, et al. Insight into the genetic architecture of back pain and its risk factors from a study of 509,000 individuals. *Pain*. 2019;160(6):1361-1373. doi:10.1097/j.pain.0000000000001514

48. George SZ, Dover GC, Wallace MR, et al. Biopsychosocial Influence on Exercise-induced Delayed Onset Muscle Soreness at the Shoulder: Pain Catastrophizing and Catechol-O-Methyltransferase (COMT) Diplotype Predict Pain Ratings. *The Clinical Journal of Pain*. 2008;24(9):793-801. doi:10.1097/AJP.0b013e31817bcb65

49. Demmelmaier I, Åsenlöf P, Lindberg P, Denison E. Biopsychosocial Predictors of Pain, Disability, Health Care Consumption, and Sick Leave in First-Episode and Long-Term Back Pain: A Longitudinal Study in the General Population. *IntJ Behav Med*. 2010;17(2):79-89. doi:10.1007/s12529-009-9055-3

50. Depression. National Institute of Mental Health (NIMH). Accessed May 31, 2023. https://www.nimh.nih.gov/health/topics/depression

51. Hu Y, Yang Z, Li Y, et al. Prevalence and Associated Factors of Depressive Symptoms Among Patients With Chronic Low Back Pain: A Cross-Sectional Study. *Front Psychiatry*. 2022;12:820782. doi:10.3389/fpsyt.2021.820782

52. Von Korff M, Resche LL, Dworkin SF. First onset of common pain symptoms: a prospective study of depression as a risk factor. *Pain*. 1993;55(2):251-258. doi:10.1016/0304-3959(93)90154-H

53. D A Fishbain, R Cutler, H L Rosomoff, S Rosomoff. Chronic pain-associated depression: antecedent or consequence of chronic pain? A review. *Clin J Pain*. 1997;13(2):116-137. doi:10.1097/00002508-199706000-00006

54. Tsuji T, Matsudaira K, Sato H, Vietri J. The impact of depression among chronic low back pain patients in Japan. *BMC Musculoskelet Disord*. 2016;17(1):447. doi:10.1186/s12891-016-1304-4

55. Anxiety Disorders. National Institute of Mental Health (NIMH). Accessed May 31, 2023. https://www.nimh.nih.gov/health/topics/anxiety-disorders

56. Hu Y, Yang Z, Li Y, Xu Y, Zhou X, Guo N. Anxiety Symptoms and Associated Factors Among Chronic Low Back Pain Patients in China: A Cross-Sectional Study. *Front Public Health*. 2022;10:878865. doi:10.3389/fpubh.2022.878865

57. Thompson T, Keogh E, French CC, Davis R. Anxiety sensitivity and pain: Generalisability across noxious stimuli. *Pain*. 2008;134(1):187-196. doi:10.1016/j.pain.2007.04.018

58. Woo AK. Depression and Anxiety in Pain. *Reviews in Pain*. 2010;4(1):8-12. doi:10.1177/204946371000400103

59. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain*. 2000;85(3):317-332. doi:10.1016/S0304-3959(99)00242-0

60. SH Kori, RP Miller, DD Todd. Kinisophobia: a new view of chronic pain behavior. *Pain Management*. 1990;(3):35-43.

61. Brouwer B, Waardenburg S, Jacobs C, et al. Biopsychosocial baseline values of 15 000 patients suffering from chronic pain: Dutch DataPain study. *Reg Anesth Pain Med*. 2020;45(10):774-782. doi:10.1136/rapm-2020-101476

62. Trinderup JS, Fisker A, Juhl CB, Petersen T. Fear avoidance beliefs as a predictor for long-term sick leave, disability and pain in patients with chronic low back pain. *BMC Musculoskelet Disord*. 2018;19(1):431. doi:10.1186/s12891-018-2351-9

63. Picavet HSJ. Pain Catastrophizing and Kinesiophobia: Predictors of Chronic Low Back Pain. *American Journal of Epidemiology*. 2002;156(11):1028-1034. doi:10.1093/aje/kwf136

64. A Bandura. Self-efficacy: The exercise of control. *W H Freeman/Times Books/ Henry Holt & Co*. Published online 1997.

65. Nicholas MK. The pain self-efficacy questionnaire: Taking pain into account. *European Journal of Pain*. 2007;11(2):153-163. doi:10.1016/j.ejpain.2005.12.008

66. van Hooff ML, Vriezekolk JE, Kroeze RJ, O'Dowd JK, van Limbeek J, Spruit M. Targeting self-efficacy more important than dysfunctional behavioral cognitions in patients with longstanding chronic low back pain; a longitudinal study. *BMC Musculoskelet Disord*. 2021;22(1):824. doi:10.1186/s12891-021-04637-3

67. Paris-Alemany A. How Does Self-Efficacy Influence Pain Perception, Postural Stability and Range of Motion in Individuals with Chronic Low Back Pain? *Pain Physician*.

68. Puschmann AK, Drießlein D, Beck H, et al. Stress and Self-Efficacy as Long-Term Predictors for Chronic Low Back Pain: A Prospective Longitudinal Study. *JPR*. 2020;Volume 13:613-621. doi:10.2147/JPR.S223893

69. Woby SR, Urmston M, Watson PJ. Self-efficacy mediates the relation between pain-related fear and outcome in chronic low back pain patients. *European Journal of Pain*. 2007;11(7):711-718. doi:10.1016/j.ejpain.2006.10.009

70. Karran EL, Grant AR, Moseley GL. Low back pain and the social determinants of health: a systematic review and narrative synthesis. *Pain*. 2020;161(11):2476-2493. doi:10.1097/j.pain.0000000000001944

71. Antti M, Unto H, Timo A, et al. The Treatment of Acute Low Back Pain — Bed Rest, Exercises, or Ordinary Activity? *The New England Journal of Medicine*. 1995;332(6).

72. Hilde G, Hagen K, Jamtvedt G, Winnem M. Advice to stay active as a single treatment for low-back pain and sciatica. In: The Cochrane Collaboration, ed. *Cochrane Database of Systematic Reviews*. John Wiley & Sons, Ltd; 2002:CD003632. doi:10.1002/14651858.CD003632

73. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. *The Lancet*. 2017;389(10070):736-747. doi:10.1016/S0140-6736(16)30970-9

74. Stochkendahl MJ, Kjaer P, Hartvigsen J, et al. National Clinical Guidelines for non-surgical treatment of patients with recent onset low back pain or lumbar radiculopathy. *Eur Spine J*. 2018;27(1):60-75. doi:10.1007/s00586-017-5099-2

75. Qaseem A, Wilt TJ, McLean RM, Forciea MA, for the Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. 2017;166(7):514. doi:10.7326/M16-2367

76. Overview | Low back pain and sciatica in over 16s: assessment and management | Guidance | NICE. Published November 30, 2016. Accessed May 31, 2023. https://www.nice.org.uk/guidance/ng59

77. Foster NE, Anema JR, Cherkin D, et al. Prevention and treatment of low back pain: evidence, challenges, and promising directions. *The Lancet*. 2018;391(10137):2368-2383. doi:10.1016/S0140-6736(18)30489-6

78. Enthoven WT, Roelofs PD, Deyo RA, van Tulder MW, Koes BW. Non-steroidal anti-inflammatory drugs for chronic low back pain. Cochrane Back and Neck Group, ed. *Cochrane Database of Systematic Reviews*. 2016;2016(8). doi:10.1002/14651858.CD012087

79. Sj K, At A. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain. Published online 2014.

80. Henschke N, Ostelo RW, van Tulder MW, et al. Behavioural treatment for chronic low-back pain. Cochrane Back and Neck Group, ed. *Cochrane Database of Systematic Reviews*. Published online July 7, 2010. doi:10.1002/14651858.CD002014.pub3

81. What is Cognitive Behavioral Therapy? https://www.apa.org. Accessed May 31, 2023. https://www.apa.org/ptsd-guideline/patients-and-families/cognitive-behavioral

82. Ehde DM, Dillworth TM, Turner JA. Cognitive-behavioral therapy for individuals with chronic pain: Efficacy, innovations, and directions for research. *American Psychologist*. 2014;69(2):153-166. doi:10.1037/a0035747

83. Hanel J, Owen PJ, Held S, et al. Effects of Exercise Training on Fear-Avoidance in Pain and Pain-Free Populations: Systematic Review and Meta-analysis. *Sports Med*. 2020;50(12):2193-2207. doi:10.1007/s40279-020-01345-1

84. Hayden JA, Ellis J, Ogilvie R, Malmivaara A, van Tulder MW. Exercise therapy for chronic low back pain. Cochrane Back and Neck Group, ed. *Cochrane Database of Systematic Reviews*. 2021;2021(10). doi:10.1002/14651858.CD009790.pub2

85. Hayden JA, Ellis J, Ogilvie R, et al. Some types of exercise are more effective than others in people with chronic low back pain: a network meta-analysis. *Journal of Physiotherapy*. 2021;67(4):252-262. doi:10.1016/j.jphys.2021.09.004

86. Owen PJ, Miller CT, Mundell NL, et al. Which specific modes of exercise training are most effective for treating low back pain? Network meta-analysis. *Br J Sports Med*. 2020;54(21):1279-1287. doi:10.1136/bjsports-2019-100886

87. Becker BE. Aquatic Therapy: Scientific Foundations and Clinical Rehabilitation Applications. *PM&R*. 2009;1(9):859-872. doi:10.1016/j.pmrj.2009.05.017

88. Hong SK, Cerretelli P, Cruz JC, Rahn H. Mechanics of respiration during submersion in water. *Journal of Applied Physiology*. 1969;27(4):535-538. doi:10.1152/jappl.1969.27.4.535

89. M Arborelius Jr, U I Ballidin, B Lilja, C E Lundgren. Hemodynamic changes in man during immersion with the head above water. *Aerosp Med*. 1972;46(6):592-598.

90. Denning WM, Bressel E, Dolny D, Bressel M, Seeley MK. A Review of Biophysical Differences between Aquatic and Land-Based Exercise. *IJARE*. 2012;6(1). doi:10.25035/ijare.06.01.07

91. Po T. Determination of hydrodynamic drag forces and drag coe• cients on human leg/foot model during knee exercise. *Clinical Biomechanics*. Published online 2000.

92. Abadi FH, Sankaravel M, Zainuddin FF, Elumalai G, Razli AI. The effect of aquatic exercise program on low-back pain disability in obese women. *J Exerc Rehabil*. 2019;15(6):855-860. doi:10.12965/jer.1938688.344

93. Dundar U, Solak O, Yigit I, Evcik D, Kavuncu V. Clinical Effectiveness of Aquatic Exercise to Treat Chronic Low Back Pain: A Randomized Controlled Trial. *Spine*. 2009;34(14):1436-1440. doi:10.1097/BRS.0b013e3181a79618

94. Olson DA, Kolber MJ, Patel C, Pabian P, Hanney WJ. Aquatic Exercise for Treatment of Low-Back Pain: A Systematic Review of Randomized Controlled Trials. *American Journal of Lifestyle Medicine*. 2013;7(2):154-160. doi:10.1177/1559827612457323

95. Epstein M. Renal effects of head-out water immersion in humans: a 15-year update. *Physiological Reviews*. 1992;72(3):563-621. doi:10.1152/physrev.1992.72.3.563

96. U I Balldin, C E Lundgren, J Lundvall, S Mellander. Changes in the elimination of 133 xenon from the anterior tibial muscle in man induced by immersion in water and by shifts in body position. *Aerosp Med*. 1971;42(5):489-493.

97. John E. Hall, Arthur C. Guyton. *Textbook of Medical Physiology*. 13th Edition. Elsevier; 2016.

98. Psycharakis SG, Coleman SGS, Linton L, Kaliarntas K, Valentin S. Muscle Activity During Aquatic and Land Exercises in People With and Without Low Back Pain. *Physical Therapy*. 2019;99(3):297-310. doi:10.1093/ptj/pzy150

99. Mcllveen B, Robertson VJ. A Randomised Controlled Studv of the Outcome of Hydrotherapy for Sbbjects with Low Back or Back and Leg Pain. 1998;(1).

100. Han G, Cho M, Nam G, et al. The Effects on Muscle Strength and Visual Analog Scale Pain of Aquatic Therapy for individuals with Low Back Pain. *J Phys Ther Sci*. 2011;23(1):57-60. doi:10.1589/jpts.23.57

101. Baena-Beato PÁ, Artero EG, Arroyo-Morales M, Robles-Fuentes A, Gatto-Cardia MC, Delgado-Fernández M. Aquatic therapy improves pain, disability, quality of life, body composition and fitness in sedentary adults with chronic low back pain. A controlled clinical trial. *Clin Rehabil*. 2014;28(4):350-360. doi:10.1177/0269215513504943

102. Peng MS, Wang R, Wang YZ, et al. Efficacy of Therapeutic Aquatic Exercise vs Physical Therapy Modalities for Patients With Chronic Low Back Pain: A Randomized Clinical Trial. *JAMA Netw Open*. 2022;5(1):e2142069. doi:10.1001/jamanetworkopen.2021.42069

103. Roelofs J, Van Breukelen G, Sluiter J, et al. Norming of the Tampa Scale for Kinesiophobia across pain diagnoses and various countries. *Pain*. 2011;152(5):1090-1095. doi:10.1016/j.pain.2011.01.028

104. Sjogren T, Long N, Story I, Smith J. Group hydrotherapy versus group land-based treatment for chronic low back pain. *Physiother Res Int*. 1997;2(4):212-222. doi:10.1002/pri.107

105. N Yozbatiran, Y Yildirim, B Parlak. Effects of fitness and aquafitness exercises on physical fitness in patients with chronic low back pain. *Pain Clin*. 2004;(16):35-42.

106. Jack K, McLean SM, Moffett JK, Gardiner E. Barriers to treatment adherence in physiotherapy outpatient clinics: A systematic review. *Manual Therapy*. 2010;15(3):220-228. doi:10.1016/j.math.2009.12.004

107. Taulaniemi A, Kankaanpää M, Rinne M, Tokola K, Parkkari J, Suni JH. Fear-avoidance beliefs are associated with exercise adherence: secondary analysis of a randomised controlled trial (RCT) among female healthcare workers with recurrent low back pain. *BMC Sports Sci Med Rehabil*. 2020;12(1):28. doi:10.1186/s13102-020-00177-w

108. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth Chronic Disease Management on Treatment Adherence and Patient Outcomes: A Systematic Review. *J Med Internet Res*. 2015;17(2):e52. doi:10.2196/jmir.3951

109. Bhatia A, Kara J, Janmohamed T, et al. User Engagement and Clinical Impact of the Manage My Pain App in Patients With Chronic Pain: A Real-World, Multi-site Trial. *JMIR Mhealth Uhealth*. 2021;9(3):e26528. doi:10.2196/26528

110. Chhabra HS, Sharma S, Verma S. Smartphone app in self-management of chronic low back pain: a randomized controlled trial. *Eur Spine J*. 2018;27(11):2862-2874. doi:10.1007/s00586-018-5788-5

111. Khalili-Mahani N, Holowka E, Woods S, et al. Play the Pain: A Digital Strategy for Play-Oriented Research and Action. *Front Psychiatry*. 2021;12:746477. doi:10.3389/fpsyt.2021.746477

112. Khalili-Mahani N, Woods S, Holowka EM, Pahayahay A, Roy M. Toward a digital citizen lab for capturing data about alternative ways of self-managing chronic pain: An attitudinal user study. *Front Rehabilit Sci*. 2022;3:942822. doi:10.3389/fresc.2022.942822

113. Buchbinder R, van Tulder M, Öberg B, et al. Low back pain: a call for action. *The Lancet*. 2018;391(10137):2384-2388. doi:10.1016/S0140-6736(18)30488-4

114. Baena-Beato PA, Arroyo-Morales M, Delgado-Fernêndez M, Gatto-Cardia MC, Artero EG. Effects of Different Frequencies (2–3 Days/Week) of Aquatic Therapy Program in Adults with Chronic Low Back Pain. A Non-Randomized Comparison Trial. *Pain Med*. 2013;14(1):145-158. doi:10.1111/pme.12002

115. Cuesta-Vargas AI, Adams N, Salazar JA, Belles A, Hazañas S, Arroyo-Morales M. Deep water running and general practice in primary care for non-specific low back pain versus general practice alone: randomized controlled trial. *Clin Rheumatol*. 2012;31(7):1073-1078. doi:10.1007/s10067-012-1977-5

116. Childs JD, Piva SR, Fritz JM. Responsiveness of the Numeric Pain Rating Scale in Patients with Low Back Pain: *Spine*. 2005;30(11):1331-1334. doi:10.1097/01.brs.0000164099.92112.29

117. Hägg O, Fritzell P, Nordwall A. The clinical importance of changes in outcome scores after treatment for chronic low back pain. *Eur Spine J*. 2003;12(1):12-20. doi:10.1007/s00586-002-0464-0

118. Díaz-Arribas MJ, Fernández-Serrano M, Royuela A, et al. Minimal Clinically Important Difference in Quality of Life for Patients With Low Back Pain. *Spine*. 2017;42(24):1908-1916. doi:10.1097/BRS.0000000000002298

119. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale An updated literature review. *Journal of Psychosomatic Research*. Published online 2002.

120. Stern AF. The Hospital Anxiety and Depression Scale. *Occupational Medicine*. 2014;64(5):393-394. doi:10.1093/occmed/kqu024

121. Josefsson T, Lindwall M, Archer T. Physical exercise intervention in depressive disorders: Meta-analysis and systematic review. *Scandinavian Med Sci Sports*. 2014;24(2):259-272. doi:10.1111/sms.12050

122. Pilozzi A, Carro C, Huang X. Roles of β-Endorphin in Stress, Behavior, Neuroinflammation, and Brain Energy Metabolism. *IJMS*. 2020;22(1):338. doi:10.3390/ijms22010338

123. Li Y, Liu J, Liu Z zhi, Duan D peng. Inflammation in low back pain may be detected from the peripheral blood: suggestions for biomarker. *Bioscience Reports*. 2016;36(4):e00361. doi:10.1042/BSR20160187

124. Bruehl S, McCubbin JA, Harden RN. Theoretical review: altered pain regulatory systems in chronic pain. *Neuroscience & Biobehavioral Reviews*. 1999;23(6):877-890. doi:10.1016/S0149-7634(99)00039-1

125. De Meirleir K, Naaktgeboren N, Van Steirteghem A, Gorus F, Olbrecht J, Block P. Beta-endorphin and ACTH levels in peripheral blood during and after aerobic and anaerobic exercise. *Europ J Appl Physiol*. 1986;55(1):5-8. doi:10.1007/BF00422884

126. Goldfarb A, Hatfield B, Potts J, Armstrong D. Beta-Endorphin Time Course Response to Intensity of Exercise: Effect of Training Status. *Int J Sports Med*. 1991;12(03):264-268. doi:10.1055/s-2007-1024678

127. Choi HY, Lee CH. Can Beta-Endorphin Be Used as a Biomarker for Chronic Low Back Pain? A Meta-analysis of Randomized Controlled Trials. *Pain Medicine*. 2019;20(1):28-36. doi:10.1093/pm/pny186

128. Ozaki H, Loenneke JP, Thiebaud RS, Abe T. Resistance training induced increase in VO2max in young and older subjects. *Eur Rev Aging Phys Act*. 2013;10(2):107-116. doi:10.1007/s11556-013-0120-1

129. Sullivan MJ. The Pain catastrophizing scale: User manual. Published online 2009.

130. Monticone M, Portoghese I, Rocca B, Giordano A, Campagna M, Franchignoni F. Responsiveness and minimal important change of the Pain Catastrophizing Scale in people with chronic low back pain undergoing multidisciplinary rehabilitation. *Eur J Phys Rehabil Med*. 2022;58(1). doi:10.23736/S1973-9087.21.06729-0

131. Craft LL, Perna FM. The Benefits of Exercise for the Clinically Depressed. *Prim Care Companion CNS Disord*. 2004;6(3). doi:10.4088/PCC.v06n0301

132. Singh G, Newton C, O'Sullivan K, Soundy A, Heneghan NR. Exploring the lived experience and chronic low back pain beliefs of English-speaking Punjabi and white British people: a qualitative study within the NHS. *BMJ Open*. 2018;8(2):e020108. doi:10.1136/bmjopen-2017-020108

133. Bonfim IDS, Corrêa LA, Nogueira LAC, Meziat-Filho N, Reis FJJ, De Almeida RS. 'Your spine is so worn out' – the influence of clinical diagnosis on beliefs in patients with non-specific chronic low back pain – a qualitative study'. *Brazilian Journal of Physical Therapy*. 2021;25(6):811-818. doi:10.1016/j.bjpt.2021.07.001

134. Lee PH, Macfarlane DJ, Lam T, Stewart SM. Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review. *Int J Behav Nutr Phys Act*. 2011;8(1):115. doi:10.1186/1479-5868-8-115

135. Meucci RD, Fassa AG, Faria NMX. Prevalence of chronic low back pain: systematic review. *Rev Saúde Pública*. 2015;49(0). doi:10.1590/S0034-8910.2015049005874

136. Boutevillain L, Dupeyron A, Rouch C, Richard E, Coudeyre E. Facilitators and barriers to physical activity in people with chronic low back pain: A qualitative study. Jepson R, ed. *PLoS ONE*. 2017;12(7):e0179826. doi:10.1371/journal.pone.0179826

137. Palazzo C, Klinger E, Dorner V, et al. Barriers to home-based exercise program adherence with chronic low back pain: Patient expectations regarding new technologies. *Annals of Physical and Rehabilitation Medicine*. 2016;59(2):107-113. doi:10.1016/j.rehab.2016.01.009

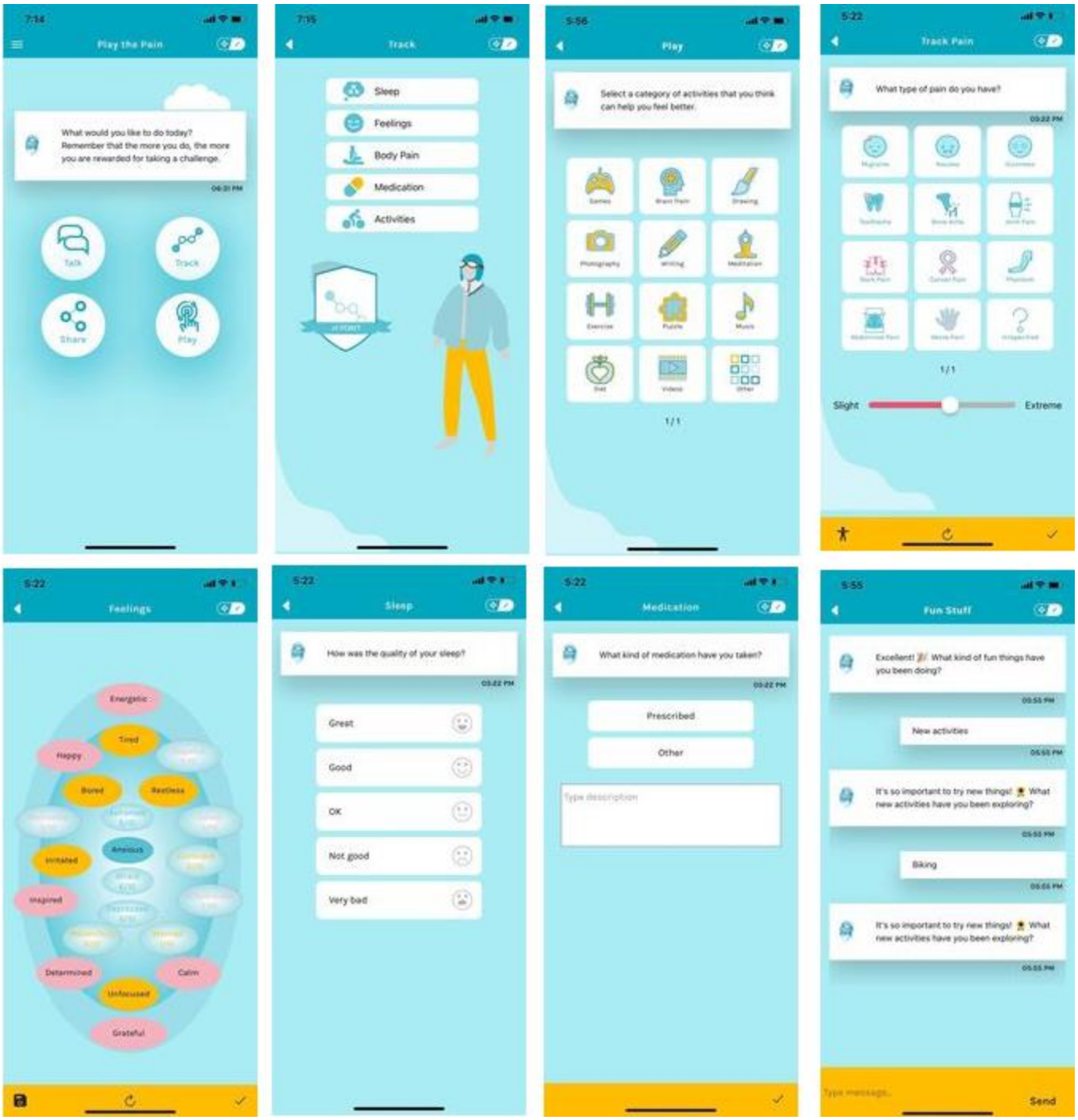
138. Patoz MC, Hidalgo-Mazzei D, Pereira B, et al. Patients' adherence to smartphone apps in the management of bipolar disorder: a systematic review. *Int J Bipolar Disord*. 2021;9(1):19. doi:10.1186/s40345-021-00224-6

139. Svendsen MJ, Wood KW, Kyle J, et al. Barriers and facilitators to patient uptake and utilisation of digital interventions for the self-management of low back pain: a systematic review of qualitative studies. *BMJ Open*. 2020;10(12):e038800. doi:10.1136/bmjopen-2020-038800

140. Deniz-Garcia A, Fabelo H, Rodriguez-Almeida AJ, et al. Quality, Usability, and Effectiveness of mHealth Apps and the Role of Artificial Intelligence: Current Scenario and Challenges. *J Med Internet Res*. 2023;25:e44030. doi:10.2196/44030

Appendix:

24.1. Play the Pain User Interface



24.2. Aquatic Therapy Protocol

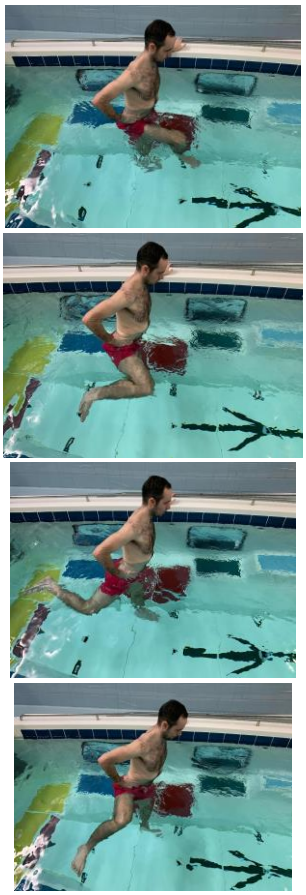
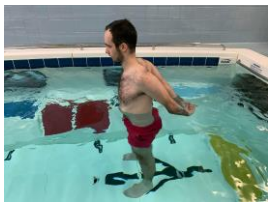
	Aquatic Exercises	Volume	
Warm-Up (10 minutes)	**Water walking:** forwards, backwards, sideways - left and right. Progressively increase walking speed.	3 minutes (30s / direction)	
	Small hops: feet shoulder width apart, squat, then jump and bring feet close together and squat back down	1 min (30 sec/ direction)	 
	Leg kicks: kick front, kick out by side, kick back	1 min (30s / leg)	  

	Marching: raise knees, heel to buttocks - as tolerated	2 minute (1 min each)	
	Horizontal kicking: on stomach, while holding onto edge of pool, kick legs and try to maintain body horizontal. Use floating device under the waist to modify difficulty.	1 minute (30s each)	
	Upper body oscillations: Moving both arms in an oscillatory fashion from in front of you to out by your side.	1 minute	 
	Bow and Arrow: rotate the torso by bringing your arms close to your body as if you're shooting a bow and arrow. Alternate sides.	1 minute	 
Training Session (40 minutes)	**Multi-directional Lunges:** forward, backward, sideways lunges back and forth.	2 sets x 10 repetitions / direction	

	Squats: Place both arms by your side. Bend down in a squat position and then return to starting position. Can control speed of exercise done to make it harder.	2 sets x 1 – 2 minutes	
	Step-Ups: Using an underwater step, place one foot on the step with hands on your waist and transfer weight to step up.	2 sets x 8 - 12 repetitions / side	 
	Single leg squat: Stand on one leg with both arms by your side. Perform the single leg squat until the knee moves in front of the toes. Remove hand support to increase difficulty.	2 sets x 8 – 12 repetitions / side	 
	Standing Hip Abduction: Stand on one leg, while either maintaining your balance or holding on to the side of the pool. Bring the leg that you aren't standing on outwards as far as possible as long as the movement comes your hip. Use an elastic band above the ankles to make the exercise harder.	2 sets x 10 repetitions / side	
	Standing Hip Extension: Stand on one leg, while either maintaining your balance or holding on to the side of the pool. Bring the leg that you aren't standing on behind you as far as possible as long as the movement is	2 sets x 10 repetitions / side	

	only coming from your hip. Use an elastic band above the ankles to make the exercise harder.		
	Concentric chest press + row: Lunge or squat down to chest-deep water and hold dumbbell floats vertically between hands with arms fully outstretched in front just below the water surface. Pull dumbbell floats close to the chest (bringing arms backwards towards body) and then push forwards to starting position, while staying put.	2 sets x 1 - 3 minutes	 
	Underwater punches: Lunge down to have your arms just below the water surface, with one arm fully outstretched in front and the other close to body. Holding Aqualogix dumbbells, perform alternate punching with each arm.	2 sets x 1 – 3 minutes repetitions	
	Concentric Shoulder Flexion + Shoulder Extension: Place one arm by side and the other outstretched in front just below water surface with palms facing direction of movement. Alternately bring one arm upwards just below the water surface while bringing the other arm to the side. Use hand paddles to increase resistance and change the front leg between sets.	2 sets x 10 - 20 repetitions	 
	Knee Raises: Hold the aquatic dumbbell in each hand with arms by sides while in a seated position. Raise one knee until thigh is parallel to the surface of the water. Alternate legs.	2 x 10 - 20 repetitions	

	Horizontal Woodchopper: Have your hands with your arms fully outstretched in front just below water surface. Rotate your torso gradually as far to one side as possible and then back to the midline. Alternately do the same with other side.	2 sets x 10 - 20 repetitions / side	 
	Diagonal Woodchopper: Have your hands with your arms fully outstretched in front just below water surface. Rotate your torso gradually as far to one side as possible while bringing the hands down diagonally and then back to the midline. Alternately do the same with other side.	2 sets x 10 – 20 repetitions / side	 
	Water Ab Rollout: Start in upright posture with arms outstretched in front of you and your hands resting on the surface holding dumbbell floats. Slowly move the dumbbell floats forwards while keeping your body in a neutral posture tilting on the tips of the toes, and then return to starting position. You should feel the movement working your abdominal muscles.	2 sets x 10 - 15 repetitions	
Cool-Down (10 minutes)	**Free water-activity:** walking, standing, swimming	1 minute	

	Stretching / Mobility exercises: Hip CARs (controlled articular rotations)	2 - 5 x each leg	
	Stretching/Mobility exercises: Standing quad stretch	2 x 30s per muscle group	
	Stretching/Mobility exercises: Standing hamstring stretch (extend leg + lean in)	2 x 30s per muscle group	
	Stretching/Mobility exercises: Anterior chain stretch: grab arms behind back + open up chest	2 x 30s per muscle group	

	Stretching/Mobility exercises: Seated figure 4 stretch	2 x 30s per muscle group	
	Stretching/Mobility exercises: Standing open book (hold onto side of pool, lift leg + rotate away)	2 x 30s per muscle group	
	Relaxation: Lay on your back with a noodle supporting you under your waist and occiput and take deep breaths.	1 – 5 minutes	

** Exercises will progress over the weeks by adding resistance to certain exercises (water current, ankle weights, hand paddles, dumbbell floats, kickboards, resistance bands, discs), as well as increasing in the number of repetitions.*