# THE EFFECTS OF THE PENDL TRAINING ON HIP FLEXIBILITY, BALANCE, BACK STRENGTH AND FUNCTIONAL SIT-TO-STAND POWER IN ADULTS WITH CHRONIC LOW BACK PAIN FOLLOWING AN 8-WEEK TRAINING PROGRAM WHEN COMPARED TO A CONTROL GROUP: AN EXPLORATORY STUDY

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Finally, I dedicate my life work to every oppressed and exploited person in this world who is experiencing systematic injustice, physical or mental agony and to everyone who is truthful to oneself for seeking knowledge and enlightenment to free the minds and souls from the captivity of one's inner-ignorance and own prejudice views.

### **ABSTRACT**

Core stability training is one of the most common rehabilitation strategies for improving lumbopelvic hip control and the dynamic stability of the lumbar spine in people with low back pain (LBP). A new device called a PENDL, that allows exercise while suspended, may be helpful in improving strength and flexibility in people with CLBP. **PURPOSE:** To evaluate a PENDL training program in adults with CLBP by quantifying changes in 1) hip flexion/extension flexibility, 2) functional sit-to-stand peak power, 3) isometric/ isotonic back strength and 4) balance. **METHODS:** Participants with CLBP pain intensity equal to or less than 40% in the Oswestry Low Back Pain Disability Questionnaire were randomized into experimental (n = 4) and control (n = 6) groups. Range of motion (ROM) of the hip was assessed using a sit and reach test and the Imire and Barbuto hip extension (ROM-HE) test. Balance was assessed using a BTrackS system and back strength (BS) using a dynamometer (BS-DYN). The core was assessed using a plank (BS-PLNK) and functional sit-to-stand peak power (FSSPP) measured with a Tendo unit. Experimental group participants completed 10 exercises on the PENDL three times per week for 8 weeks. **RESULTS:** There were significant increases improvements in BS-DYN (p = .018), BS-PLNK (p < .001), FSSPP (p = .04), and ROM-HF (p = .017). Changes in ROM-HE (p = .047) and balance (p = .77) were not significantly different. **CONCLUSION:** The PENDL may be a viable modality for improving hip flexibility, back strength and functional sit-to-stand power in people with CLBP.

# TABLE OF CONTENTS

|  | Page |
|--|------|
| LIST OF TABLES.  | vii  |
| LIST OF FIGURES.   | viii |
| LIST OF APPENDICES   | ix   |
| CHAPTER I: INTRODUCTION  | 1    |
| Significance of Studies  | 3    |
| Overall Purpose for the Two Studies.                                     | 3    |
| CHAPTER II: LITERATURE REVIEW  | 5    |
| Low Back Pain Classification.  | 5    |
| Factors Influencing CLBP; The Pathophysiology of Pain                    | 6    |
| Current Rehabilitation & Fitness Interventions for Back Pain Management. | 8    |
| Core stability Training.   | 9    |
| Kinesiology Taping   | 9    |
| Resistive Exercise   | 10   |
| Whole-Body Vibration   | 11   |
| Aquatic Exercise   | 11   |
| PENDL — The Device.  | 12   |
| Components and Description of the PENDL                                  | 13   |
| Legs   | 13   |
| Arms   | 13   |

| Harnesses   | 13        |
|---|-----------|
| Articulating shoulder harness                             | 14        |
| Articulating top-torso harness                            | 14        |
| Rig   | 14        |
| Vines   | 14        |
| Tether  | 14        |
| Overall Summary   | 16        |
| CHAPTER III: THE EFFECTS OF THE PENDL TRAINING ON HIP FLE | EXIBILITY |
| AND BALANCE IN ADULTS WITH CHRONIC LOW BACK PAI           | N AFTER   |
| AN 8-WEEK TRAINING PROGRAM WHEN COMPARED TO A             | CONTROL   |
| GROUP: AN EXPLORATORY STUDY                               | 17        |
| Introduction  | 17        |
| Methods   | 19        |
| Participants  | 19        |
| Instrumentation   | 20        |
| Flexibility Assessment of the Hip (Lumber Region)         | 20        |
| Balance Assessment  | 20        |
| Procedures  | 21        |
| Statistical Analysis                                      | 23        |
| Results   | 25        |
| Discussion  | 25        |

| Chapter III References. 28                                     |
|--|
| Appendices for Study I   |
| CHAPTER IV: THE EFFECTS OF THE PENDL TRAINING ON BACK STRENGTH |
| AND FUNCTIONAL SIT TO STAND PEAK POWER IN ADULTS WITH          |
| CHRONIC LOW BACK PAIN: AN EXPLORATORY                          |
| STUDY35  |
| Introduction   |
| Methods  |
| Participants   |
| Instrumentation  |
| Strength Assessment of the Back (Lumber Spine)                 |
| Functional Sit-to-Stand Back Power Assessment                  |
| Procedures   |
| Statistical Analysis   |
| Results43  |
| Discussion   |
| Chapter IV References  |
| Appendices for Study II  |
| CHAPTER V: OVERALL CONCLUSIONS                                 |
| DISSERTATION REFERENCES58                                      |

# LIST OF TABLES

| CHAPTER II | I                       |    |
|------------|-------------------------|----|
| Table 1    | Descriptive Statistics. | 24 |
| Chapter IV |                         |    |

Table 1

# LIST OF FIGURES

| CI    | T A | $\mathbf{D}^{T}$ | וידי | R ` | rt |
|-------|-----|------------------|------|-----|----|
| ( , F | 1 A | . 1              |      | ĸ   | П  |

Figure 1 Illustrating the PENDL components and its use in various maneuvers....15

# LIST OF APPENDICES

| CHAPTER III |                     |
|-------------|---------------------|
| Appendix A  | IRB Approval Letter |
| CHAPTER IV  |                     |
| Appendix A  | IRB Approval Letter |

### CHAPTER I

### INTRODUCTION

Low back pain (LBP) affects 9.4% of the population or 57.6 million people globally (Walker et al., 2018). As a result, LBP accounts for 25% of all missed work days in the United States (Walker et al., 2018). These productivity losses are estimated to have an annual financial impact of \$61.2 billion dollars (Walker et al., 2018). Chronic low back pain (CLBP) is defined as discomfort or pain between the costal margin region and lower gluteal folds, with or without symptoms in lower limbs lasting more than 3 months (Oliveira et al., 2019).

In order to improve general health as a start, the US Office of Disease Prevention and Health Promotion guidelines recommend 150 min/wk of moderate exercise or 75 min/wk of vigorous exercise (Walker et al., 2018). Lotzke et al. (2018) indicated that multiple factors contribute to a decreased level of physical activity in individuals with CLBP. The strongest predictors of decreased physical activity in his study were sex, age, low motivation, poor health status, pain and fear avoidance (catastrophizing, fear of movement and low self-efficacy are examples of fear-avoidance; Lotzke et al., 2018). According to Lotzke et al. (2018), fear-avoidance continues up to 2 years after lumbar spine surgery and is a significant predictor of pain and poor functional outcomes. It is important to identify the barriers that prevent patients with CLBP from participating in physical activity in order to change behavior and increase habits toward physical activity among CLBP patients (Schaller et al., 2017).

There have been numerous modalities used as strategies for rehabilitation and management of CLBP and many researchers have explored these modalities to understand their effect on mitigating CLBP. Even with these therapeutic treatment options for CLBP, CLBP continues and in many cases gets worse over time. There is no absolute cure for CLBP otherwise individuals would be utilizing the treatment and CLBP would be eradicated. Currently, one of the best treatment choices for patients with CLBP is physical exercise. Both short-term and long-term effects of exercise include reducing pain and disability while improving balance (Oliveira et al., 2019). A published CLBP management guideline for older adults recommends stretching, strengthening, balance, and endurance training to reduce pain intensity, functional decline, and care costs (Oliveira et al., 2019). Various types and intensities of therapeutic exercises can be included as an effective means of treatment in patients with CLBP. According to Walker (2018), in a meta-analysis on the effectiveness of workplace exercise programs, most of the studies documented improvement in absenteeism. This was in spite of the relatively low quality of most of these studies included in the analysis.

The first research evidence that supported the effect of training while suspended on the PENDL for CLBP treatment was in Alasmar and Stevens (2021) study which explored a new intervention option for mitigating CLBP using the PENDL. Their exploratory controlled study suggested that after an 8-week training while suspended on the PENDL, a significant decrease in CLBP between the control and experiment groups was observed. The PENDL has been developed allowing individuals with CLBP to

exercise while suspended in a harness apparatus. This device has been reported by a handful of pioneer users and enthusiasts that there were benefits for mitigating CLBP and improving health related quality of life and skill related fitness components without medication or surgical intervention.

## Significance of Studies

Since CLBP is a prevalent and significant disorder leading to pain and decreased productivity, investigating a potential modality that can be used either in conjunction with existing treatment modalities or independently would only provide an insight to exercise science and can ultimately add to the scientific research body of knowledge in the field of exercise science. This research study will evaluate the effect of this suspension device in adults with CLBP pain and the device's implication on hip flexibility, balance, back strength, and functional sit-to-stand power. Some of the benefits for evaluating this newly designed fitness machine in this trial would only enhance our understanding to its impact on improving fitness and health, reducing musculoskeletal CLBP while participating in a fun activity and ultimately improving overall health and wellbeing. Secondary benefit for this study could provide a large cross section of the public a new tool and an alternative choice to use in order to improve hip flexibly, balance, back strength and functional sit-to-stand back power.

## **Overall Purpose for the Two Studies**

The two studies in this dissertation will investigate an 8-week training intervention program using the PENDL with adults who are experiencing CLBP. The

purpose of the first study was to determine the effect of the 8-week PENDL training on the flexibility of the hip flexors and extensors and balance. It was hypothesized that training on the PENDL would yield improvement in each outcome measure. The purpose of the second study was to determine the effect of the 8-week training program using the PENDL on back strength (isometrically and isotonically) and functional sit-to-stand peak power. It was hypothesized that training on the PENDL would yield improvement in the outcome measures.

### CHAPTER II

### LITERATURE REVIEW

This literature review begins with a synopsis of CLBP classification, the factors influencing the pathophysiology as they relate to CLBP. A description of current pain management systems and an overview of pervious research studies explored the effectiveness of different interventions and modalities to mitigate CLBP. The literature review concludes with a description of and background information on the PENDL system and an overall summary.

## LBP Classification

Low back pain is classified as either mechanical or non-mechanical in nature. Back pain of a mechanical nature can be spondylolisthesis, disc herniation, scoliosis, facet joint syndrome, spinal stenosis and spondylolysis; while fracture, infection and tumor can attributed to non-mechanical causes for back pain (Anandkumar et al., 2018). Only 15% of LBP cases can be related to a specific diagnosis while 85% is nonspecific in origin (Anandkumar et al., 2018). When there is no specific case or pathology to LBP, it is classified as NSLBP and is considered chronic when the duration of pain exceeds 12 weeks. In clinical practice, individuals with chronic NSLBP form a heterogeneous group and the origin of back pain can be linked to various multidimensional factors (Anandkumar et al., 2018). The occurrence of NSLBP can be attributed to the following causes: physical (e.g. maladaptive movement strategies), psychological (e.g. depression and anxiety), neurophysiological (e.g. central sensitization), social (e.g. low job

satisfaction), cognitive (e.g. negative beliefs and unhelpful thoughts), lifestyle (e.g. sleep deprivation and disturbances and smoking), and genetic (e.g. family history of chronic pain; Anandkumar et al., 2018).

## Factors Influencing CLBP; The Pathophysiology of Pain

Pain can cause anxiety, distress, and, at times, traumatic experiences. However, pain also functions as an essential survival mechanism. Pain acts as a stimulus to modify behaviors detrimental to the integrity of body and may flag potential or actual tissue damage (Tagliaferri et al., 2019). The perception of pain varies from person to person which makes pain a subjective experience which is influenced by emotions, genes, and individual states of psychology, sensory, social, and cultural factors. At the peripheral level, noxious stimuli depolarize nociceptors, which can be thermal, mechanical, or chemical, and the information travels to the dorsal horn of the spinal cord through afferent fibers, where these signals can be modulated before reaching the supra-spinal centers (Tagliaferri et al., 2019). Following signal transmission to the brain, information from the periphery is analyzed and stored in multiple regions of the brain (e.g. emotional, sensory, memory, and awareness; Tagliaferri et al., 2019).

Depending on how the threat is contextualized, the stimuli can be sensed as pain of differing intensities. For example, the nociceptive information can be either inhibited or facilitated by the descending pathways. This is how pain is influenced by top-down, dynamic and contextual factors (e.g. anxiety, pain memories, mood, threat) which can dictate pain experience outcomes (Tagliaferri et al., 2019). As Tagliaferri (2019), noted,

In contrast to acute pain, where there is a clear protective role, the ongoing experience of pain, definitive of chronic pain conditions, has been suggested to reflect a mismatch between the information on the state of the tissues coming from the peripheral receptors (no acute tissue injury) and the central processing of this information (perceived pain reflecting threat to the tissues; p. 212).

Therefore, pain can shift from being an essential protection mechanism for survival to becoming overly protective from the augmented state of sensitivity which is unrelated to the pathology of tissue.

Chronic low back pain in some individuals can be characterized by a sustained state of enhanced sensitivity of the CNS pain system in the brain and the spinal cord. Both the central (brain and spinal cord) and the peripheral (nociceptive terminal) nervous systems can go through changes which increase their sensitivity. For example, increasing synaptic strength via long-term potentiation; thus, the proactive reactions and the processing efficacy of pain can be enhanced (Tagliaferri et al., 2019).

Pro-inflammatory cytokine release increases the hypersensitivity at the spinal cord; while glial cell and astrocyte activation, can increase synaptic efficiency of ascending nociceptive stimuli and reduce inhibitory tone as in the example of the wind-up mechanism (Tagliaferri et al., 2019). For this reason, temporal summation, which is brief repetitive thermal, electrical, or mechanical stimuli delivered 1 to 3 times per second for 5 to 10 seconds, could explain why the wind-up phenomenon increases. With this increase, the first to the last repetition of the temporal pain is also increased. As a

result, this process within the spinal cord can trigger dynamic changes in second-order neurons of the spine such as those located in the dorsal horn which provide an important role in the development and maintenance of the central sensitization in CLBP (Tagliaferri et al., 2019). It is also noted that central sensitization can provide the platform or the framework to better understand the transition of large-scale brain network activity in acute to CLBP. As Tagliaferri (2019) noted,

In acute or experimental pain conditions, the brain networks activated are those mostly involved in the processing of the sensory-discriminative nature of pain (eg, somatosensory cortex), whereas in chronic pain, the activity shifts to the brain networks related to emotional processing (eg, prefrontal cortex; p. 213).

Pain experience and expression are affected as a result of inter-play between psychological systems (e.g. emotion, cognition, learning) and physiological systems (e.g. motor, sensory, autonomic); which can explain the presence of behavioral consequences (i.e. cognitive and memory deficits) in individuals with CLBP. It is recognized that psychological factors can moderate pain intensity through neurobiological pathways in CLBP while these psychological factors can influence disability and the treatment response. (Tagliaferri et al., 2019). Therefore, during the assessment and treatment of CLBP, the multidimensionality of pain should be considered.

## Current Rehabilitation & Fitness Interventions for Back Pain Management

There have been numerous modalities used as strategies for rehabilitation and management of CLBP. The following is a list of research studies that were conducted in

pervious literatures to determine the effectiveness of each approach. These studies are grouped based on the methods used. This section of the literature review exemplifies the various interventions used in which there was no study found that investigated the effect of an intervention method such as the PENDL or similarly suspended devices in air on mitigating CLBP, increasing hip flexibility, back strength, functional sit-to-stand power and improving balance.

Core Stability Training. Core stability training is one of the most commonly used rehabilitation strategies for improving lumbopelvic hip control (LPHC) and the dynamic stability of the lumbar spine in people with CLBP. In a study conducted conducted by Fong et al., (2015) with a group of young, healthy individuals without CLBP, traditional core stability exercises on a stable surface were found to be less effective in inducing core muscle activity in plank, chest press, and 45-degree row when compared with exercises targeting core stability using instability devices such as the TRX or BOSU ball. The same study also found when using electromyography (EMG) to measure muscle activity, hip abduction during a plank induced the greatest abdominal muscle activity; while hamstring curl induced the greatest paraspinal muscle activity (Fong et al., 2015). **Kinesiology Taping.** Kinesiology taping (KT) is a relatively new technique and practice that has been used in the clinical/pain management of CLBP. The tape is elastic, porous, and has adhesive properties which allow the users to apply it easily to the low back region so it does not restrict mobility during exercise (Fong et al., 2015). Even though KT effects in clinical studies have been controversial, some beneficial effects have been

reported. Benefits such as: joint misalignment correction, neuromuscular performance enhancement, and muscular function normalization were observed (Fong et al., 2015). The same study suggested that KT is a good addition to strength training of the core muscles in people with long-term CLBP when core muscles were measured during TRX activity using EMG (Fong et al., 2015). In addition, a systematic review with a meta-analysis of randomized controlled trials investigated the effects of KT on pain and disability in individuals with CLBP and found that KT significantly improved disability when compared to the placebo taping (Li et al., 2015).

Resistive Exercise. Resistive exercise has been used an intervention to treat CLBP. The Pilates method has shown to be effective in reducing pain and improving function in individuals with CLBP. The principles that Pilates is based on are: power house, concentration, control, precision, flow of movement, and breathing (Oliveira et al., 2019). Pilates is prescribed by health professionals and practitioners as a treatment for patients with CLBP due to its application to flexibility, strength, and stability exercises of the deep muscles of the abdomen with emphasis on movement control (Oliveira et al., 2019). In addition, Oliveira et al., (2019) demonstrated that Pilates exercise is no more effective than other types of exercise (i.e. cycling or McKenzie method) in reducing pain and disability. The same study examined the effectiveness of the Pilates method compared to treadmill aerobic exercises in the treatment of older adults with CLBP when assessing randomized groups after 8-week and 6-month training (Oliveira et al., 2019).

While Baduanjin is a popular and widely practiced form of Eastern exercise, it is used as a resistive form of exercise for management of CLBP using one own's body weight (Li et al., 2019). Baduanjin is similar to Tai Chi. In one study, Baduanjin was found to be superior to routine drug treatment (ibuprofen) in alleviating pain and was reported that back pain was decreased on the Oswestry disability index score (Li et al., 2019). In addition, the effect of Tai Chi alone or as additional therapy was also explored by Qin et al., (2019) in those with LBP. The researchers in the same study drew a conclusion that Tai Chi also improved function disability and decrease pain for patients with LBP (Qin et al., 2019).

Whole-Body Vibration. Kim et al. (2018) explored the effect vertical versus horizontal vibration exercise in CLBP patients and found that horizontal vibration exercises are as effective as vertical vibration exercises in reducing CLBP, strengthening the lumbar muscle, and improving the balance and functional abilities in patients with CLBP. Wang et al., (2019) examined the effects of whole-body vibration exercise for non-specific CLBP on 84 participants who completed a 12-week training program and found when compared to a control group that the Oswestry disability index scores decreased significantly.

Aquatic Exercise. Aquatic exercise has been popular among individuals with LBP. Aquatic exercise, in people with or without CLBP activates the gluteal muscles, the trunk musculature, among other skeletal mussels (Psycharakis et al., 2019). Abadi et al., (2019) has investigated the effect of aquatic exercise program on CLBP in women who are

obese. The same study found that progressive aquatic exercise was a convenient and effective intervention program to reduce pain intensity, and improve personal care, sitting, standing, sleeping, and employment abilities in obese CLBP women (Abadi et al., 2019).

## **PENDL** — The Device

The "PENDL" system is a newly created and manufactured exercise apparatus. This device was patented in 2019. Add-on components to the PENDL will be patented as their design is completed and testing is finalized. This innovative concept stems from the idea of the swinging pendulum. It is a device that is suspended from a ceiling with harnesses attached to keep the body floating in air and protected from falling during the swing. The device allows various movement that mimic different type of maneuvers that are well translated to various sports such as rollerskating, skateboarding, skiing, martial arts, dancing, hang gliding, wingsuit flying and skydiving to name few. In addition, this device may offer other aspects of training to improve health related fitness components. Although speculative, it may enhance muscular strength, stability, balance, coordination, reaction time, increase range of motion, speed and power, and may contribute to improved cardiovascular fitness and thus, help overall health and wellness. This device has not been explored in the rehabilitation arena nor it has been examined in previous research studies before this time.

## **Components and Description of the PENDL**

require the user to have a hold with their hands.

The PENDL is a suspension exercise apparatus which can be used as a recreational suspension device, a suspension athletic training tool, and possibly a device used in rehabilitation. The PENDL is made up of 5 major components: the legs (which also hold the footpads), the arms, a safety harness, a rig to suspend from and attach components to, and 1 or more vines to use for control and self-propulsion.

Legs. The legs run the full length of the user's body, with the footpads attached the user can stand up while the legs support the user's weight and form while suspended from feet to shoulders. Legs are intended to "thread" the user's body by going around and in front of the feet, knees and legs up to the hip, at the hip the legs move behind the user and run up the shoulder blades. In the standard/orthodox method the foot is centered over the bottom of the leg at the arch on top of footpad, the legs go in front of the lower body from feet to knees and hips providing support from the front. From the hips the legs go behind the rider from hip to shoulders to give support and padding from the back.

Arms. The Arms are used to support the user by their hands and arms, assisting the user with vertical positioning, steering, balance, and many exercises and movements that

*Harnesses.* The harnesses are all top torso stability and safety harnesses made to keep the user from falling and hitting their heads or torso on the ground.

Rescue harness. The Rescue Harness is a standard padded loop harness that goes under the arms and behind the rider's back to keep them from falling forward or backwards (doubles as a seat)

Articulating shoulder harness. The Articulating Shoulder Harness secures the user by the shoulders and upper back by sliding the arms through arms loops much like a backpack is worn.

Articulating top-torso harness. The Articulating Top-Torso Harness secures the user by the shoulders and upper back as well as the mid torso (or waist – depending on size) by sliding the arms through arms loops much like a backpack is worn. This harness attaches to 2 shock absorbers connected to the rig.

**Rig.** The rig is made up of all components used to mount and suspend the PendL from any supporting structure like a beam, ceiling, or trees. In addition, a swivel is attached to the rig which is used to allow 360 degree spin along with carabiners that are used on all pendL components.

*Vines.* The vines are used for steering and self-propulsion and are suspended away from the pendL but within arm's reach.

**Tether.** The tether is used for training purposes and to assist with propulsion.

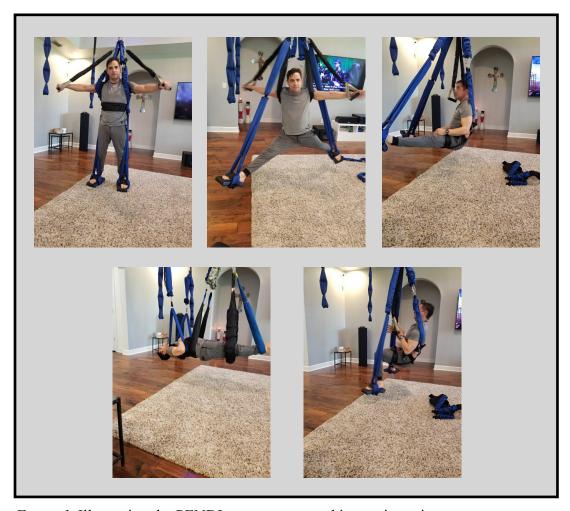


Figure 1. Illustrating the PENDL components and its use in various maneuvers

## **Overall Summary**

As noted previously, there have been numerous research studies exploring the various intervention modalities used as strategies to increase hip flexibility, back strength, functional sit-to-stand power and improve balance in adults who are experiencing CLBP. However, none of these studies have explored the effect of PENDL training on hip flexibility, balance, back strength, and functional sit-sit-to stand power in adults with CLBP. The uniqueness of the PENDL system is its "novelty" as a device being suspended in air and on unstable surface. This was the first research study to evaluate the effect of this device, in adults with CLBP and its implication on the four various measures of fitness components that were mentioned earlier. Therefore, the purpose of this research study was to evaluate the effect of this suspension device in adults with CLBP and the device's implication on hip flexibility, balance, back strength, and functional sit-to-stand power.

### **CHAPTER III**

THE EFFECTS OF THE PENDL TRAINING ON HIP FLEXIBILITY AND BALANCE
IN ADULTS WITH CHRONIC LOW BACK PAIN AFTER AN 8-WEEK TRAINING
PROGRAM WHEN COMPARED TO A CONTROL GROUP:

## AN EXPLORATORY STUDY

## Introduction

Low back pain (LBP) affects 9.4% of the population or 57.6 million people globally (Walker et al., 2018). As a result, low back pain accounts for 25% of all missed work days in the United States (Walker et al., 2018). These productivity losses are estimated to have an annual financial impact of \$61.2 billion dollars (Walker et al., 2018). Chronic low back pain (CLBP) is defined as discomfort or pain between the costal margin region and lower gluteal folds, with or without symptoms in lower limbs, lasting more than 3 months (Oliveira et al., 2019).

There are various modalities used for the rehabilitation and the management of CLBP. In addition to standard medical treatment, numerous alternative strategies have been investigated to determine their effect in mitigating CLBP: Kinesiology taping (Li et al., 2015), resistive exercise in Pilates (Oliveira et al., 2019), Baduanjin (Li et al., 2019), Tai Chi (Qin et al., 2019), whole-body vibration (Kim et al., 2018 & Wang et al., 2019), and aquatic exercise (Abadi et al., 2019 & Psycharakis et al., 2019). These modalities have various degrees of effectiveness based on the severity of the CLBP, the skill of the practitioner, and the consistency, frequency and duration of treatment (Chou, 2010).

Eighty-two percent of patients who are subjected to CLBP still experience pain a year after the starting treatment (Chou, 2010). This indicates the need to instigate new treatment modalities and revise current treatment interventions.

Currently, one of the most effective treatment choices for patients with CLBP is physical exercise (Oliveira et al., 2019). Both short-term and long-term effects of exercise include reducing pain and disability while improving balance and strength (Oliveira et al., 2019). Specifically, flexibility training is a commonly used and effective rehabilitation strategy for reducing pain and improving lumbo-pelvic hip control (LPHC) and the dynamic stability of the lumbar spine in people with CLBP (Fong et al., 2015).

The PENDL has been developed to allow people with CLBP to exercise while suspended in a harness apparatus to facilitate greater range of motion during exercises. Advantages of the PENDL system can be its easy access, enjoyment, and its effectiveness in reducing CLBP (Alasmar & Stevens, 2021). A randomized exploratory research study was conducted to evaluate an 8-week strength training program using this newly created suspension device (the PENDL) in adults who experienced CLBP and its implication on reducing CLBP (Alasmar & Stevens, 2021). The results of this pilot study demonstrated a statistically significant difference in reducing CLBP in an experiment group when compared to a control group (Alasmar & Stevens, 2021). In addition, participants in Alasmar and Stevens' study (2021) reported qualitative improvements in fitness, day to day activities, playtime with their kids, and leisure activities with family members.

Because reduction in hip flexibility and poor balance have been associated with CLBP.

perhaps these fitness components contributed to the decrease in CLBP observed in the study participants. Since no study has investigated the mechanisms which contributed to the reduction in CLBP when using the PENDL, it is speculated that the CLBP reduction in Alasmar and Stevens' exploratory study may be associated with increases in hip flexibility and improved balance.

The purpose of this randomized control exploratory research study is to evaluate an 8-week strength training program using the PENDL in adults with chronic low back pain and quantify changes in hip flexibility and balance. It is hypothesized that adults with CLBP who complete an 8-week training program using the PENDL will exhibit increased range of motion (ROM) in hip flexion and hip extension and demonstrate improvements in balance compared to those who did not train on the PENDL.

## Methods

**Participants**. Male and female adult participants (N = 12; body mass index = 27.2  $\pm$  4.2 kg/m²), 18 to 65 years-of-age ( $45 \pm 12$  years) with CLBP were alternately enrolled in one of two groups. Odd number participants (i.e., 1, 3, 5, 7...etc.) were assigned to the experiment group (n = 6;  $45 \pm 10$  years); while those whose numbers upon arrival were even (i.e., 2, 4, 6, 8...etc.) were assigned to the control group (n = 6;  $45 \pm 14$  years). Participants with chronic non-specific LBP who, on an average, have been experiencing CLBP for about 3 months or more and have reported pain intensity equal to or less than 40% in the Oswestry Low Back Pain Disability Questionnaire (OLBPQ; Fairbank & Pynsent, 2000) qualified for inclusion in this study.

### Instrumentation.

Flexibility Assessment of the Hip (Lumber Region). To measure hip flexion, the sit-and-reach test was conducted (Riebe et al., 2018). The test was preformed using an Acuflex I tester (sit-and-reach box). The participants sat with their back and head in contact with the wall, shoulder rounded as much as possible while placing one hand on top of the other and fully extending the arms forward as far as possible without letting the head and back come away from wall. The participant gradually bent at the hips to reach forward, pushing the sliding device/indictor as far as possible and holding the position for 2 seconds. Three trials were conducted, and the best measurement score in inches, to the nearest quarter inch, was recorded out of the 3 trials with 10 seconds rest in between each trial. Extension of the hip was also assessed measuring hip extension test. The test was performed in a pronated position. The participant kept the pelvis in contact with the floor and elevated their chest using their arms. The score was measured by the perpendicular distance from the suprasternal notch to the floor in centimeters using a tape measure. Three trials were conducted, and the best measurement score was recorded.

*Balance Assessment.* Balance was assessed using the BTrackS made by Balance Tracking Systems. This device measures static balance by assessing the amount of sway that is detected through built in sensors on the force plate in which, it detects the degree and direction of sway anterior-posterior and media-lateral (Schlicht et al., 2001). The lower the number, the less sway was detected. Participants stood in the force plate on

both feet with their hands placed on their hips and their eyes closed for 20 seconds. A familiarization trial was followed by 3 measurement trials.

**Procedures.** Participants were from a university and surrounding community in the southeastern United States. The recruitment method was word of mouth and interoffice/department email communication. Participants completed the Physical Assessment Readiness Questionnaire and were excluded from the study if physical activity was contraindicated. Other exclusion criteria included starting or discontinuing treatment related to back pain in the last two weeks or reporting CLBP that had not continued for more than 3 months. Treatment related to back pain included: a) medications related to back pain, b) physical therapy treatment or inpatient medical rehabilitation, and c) regular physical activity, defined as 30 minutes, three times or more per week. Participants who reported disc herniation, pregnancy, previous or scheduled surgeries of the spine within the last three months; severe cardiorespiratory diseases; cancer; dependent walking (using walking aid or assistance from another person), cognitive disorders, post-traumatic conditions (e.g., CLBP following an accident), and insufficient understanding of the English language were also excluded form participation (Fairbank & Pynsent, 2000). This study was approved by the University Institutional Review Board (see Appendix A) and participants provided written informed consent prior to testing and training.

On the first visit, participants in both groups completed the following assessments: 1) anthropometric measures and body mass index, 2) range of motion

(ROM) of the hip using a) sit and reach test for hip flexion (HF) and b) hip extension (HE) test, and 3) balance using the BTrackS system. The assessment of the outcomes was repeated by all participants after 8 weeks. Only participants in the experimental group performed the five functional movement exercises, during the first visit, as an educational session with the supervision of the principal investigator using the PENDL. This familiarization session provided participants an opportunity to choose if their comfort level with the PENDL allowed them to commit to or opt out of the study. In addition, this familiarization session shortened the participant's learning curve on the device once they began training.

Participants in the experiment group completed an 8-week training program on the PENDL. The program included meeting three times per week (30 hours total) for 40-45 minutes and a 5-7 minutes warm up and cool down. Participants in the experiment group were required to complete all 24 sessions in this study. Make-up for missed sessions was required.

The program included 10 exercises. The training exercises were selected based on having significant elements of LPHC function and were identified for reducing symptomology or risk of CLBP. The exercises were chosen to represent a balanced variation of functions required for normal daily activities (Gabel et al., 2018). The suspension squat and leg extension/flexion exercises, respectively, require functional movement while co-actively engaging the abdominal region, which occur or simulate daily occupational and sports activities (Gabel et al., 2018). The following exercises were

used in this study and included a variation of progression/regression dependent on the initial fitness level and improvement across the 8 weeks of training: 1) side leg split (hip abduction/adduction), 2) front leg splits (hip flexion/extension) and/or lunge form, 3) squat, 4) squat, abduction and adduction, 5) squat and twist, 6) squat, jump and spin and/or squat, jump and hold isometric contraction, 7) hip (flexion/extension — unilateral or bilateral while knees flexed or extended), 8) bridge and bridge with hip abduction/adduction, 9) pronated hip extension — unilateral or bilateral while knees flexed or extended, and 10) traction of the spine while suspended inversely.

## **Statistical Analysis**

Data analysis was conducted using SPSS Inc. Version 26. The mean and standard deviation were calculated for study outcomes (see Table 1). Baseline difference between the two groups on the outcome variables were assessed using analysis of covariance (ANCOVA) to control for pretest ROM-HF, ROM-HE and balance and to improve internal validity. The change scores were calculated comparing the experiment group to the control group on ROM-HF, ROM-HE, and balance after the 8-week training program using the PENDL. The statistical significance was determined at alpha level of p < 0.05 for all analyses.

Table 1

Descriptive Statistics

|                     | Experimental | Control      |
|---------------------|--------------|--------------|
| Variables           | M(SD)        | M(SD)        |
| Pretest ROM-HF      | 11.19(1.07)  | 10.62(4.48)  |
| Posttest ROM-HF     | 13.50(1.62)  | 10.42(4.33)  |
| Mean Change ROM-HF  | 20.67%*      | -1.96%       |
| Pretest ROM-HE      | 30.87(7.49)  | 32.67(4.32)  |
| Posttest ROM-HE     | 40.50(4.04)  | 36.17(3.29)  |
| Mean Change ROM-HE  | 31.17%*      | 10.71%       |
| Pretest Balance     | 31.00(12.41) | 24.33(8.36)  |
| Posttest Balance    | 31.75(8.54)  | 24.83(12.27) |
| Mean Change Balance | 2.42%        | 2.05%        |

*Note*. ROM-HF = range of motion in hip flexion (in inches); ROM-HE = range of motion in hip extension (in centimeter); balance (in BTrackS score); \* = p < 0.05

### Results

Two participants in the experiment group were excluded in the beginning of the study. One is due to illness and the second is not adhering to the illegibility criteria bringing down the number of participants in the experiment group to four. Since participants' safety was a priority in this study, there were no reported injury incidences or cancelation sessions due to soreness during this study. Following the 8-week training on the PENDL, there was a statistically significant increase in ROM-HF (F(1,7) = 9.57, p = .017,  $\eta^2_p = 0.58$ ) and ROM-HE (F(1,7) = 5.82, p = .047,  $\eta^2_p = 0.45$ ); while balance (F(1,7) = 0.09, p = .77,  $\eta^2_p = 0.01$ ) showed no significant improvements between the two groups when controlling for preset scores.

## **Discussion**

The purpose of this study was to examine an 8-week training program using the PENDL in adults with CLBP and to quantify changes in hip flexibility and in balance. It was hypothesized that adults with CLBP, who completed the 8-week training program, would demonstrate increases in ROM-HF and ROM-HE and exhibit improvements in balance compared to those who did not train on the PENDL. When covarying for the pretest scores, this study demonstrated a significant increase in ROM-HF and ROM-HE indicating a large and medium effect size respectively following the 8-week training on the PENDL. These results support the hypothesis that improvements in ROM-HF and ROM-HE were associated with the 8-week training on the PENDL in individuals with CLBP when prescribing exercises that target the LPHC region which may have

contributed to the increase in the hip ROM. When comparing these results to previously researched studies that used other treatment methods (e.g. Pilates and water-based aerobic training) than the PENDL system to improve hip ROM in adults with CLBP, the results were similar (Irandoust et al., (2017); Oliveira et al., 2019 & Schlicht et al., 2001). This could provide the seekers an alternative intervention choice for improving hip flexibility which can be safe and fun. In addition, while the results of this study had supported the effects of PENDL training on increased hip ROM significantly in people with CLBP, perhaps the decrease in CLBP observed in Alasmar and Stevens (2021) study when training on the PENDL may be associated with the change mechanisms observed in the increased hip ROM after the 8-week training. However, further investigation is suggested to explore if this association between the two variables can be supported.

On the other hand, this study has demonstrated no statistical significant improvement in balance following 24 sessions using the PENDL. The result of this study does not support the hypothesis that adults with CLBP, who completed the 8-week training program would exhibit improvements in balance compared to those who did not train on the PENDL. Theoretically, balance could be effected when being suspended on unstable surface such as the PENDL. It is a reasonable outcome to have an association between the stimulation of the vestibular system and its relation to balance (Bear et al., 2016). Since training on the PENDL may stimulate the vestibular system which may have an effect on balance, balance was measured in this study and no statistical significant improvement in balance was observed. Perhaps neuromuscular adaptation may take

longer than the 8-week training timeframe implemented in this study to show any significant difference in balance improvement. Further investigation in this area is recommended to understand the PENDL training effects on balance prescribing exercise protocol that may last longer that 8 weeks.

While this study was an initial investigation for the potential application of the PENDL on improving hip ROM and balance in those with CLBP, the sample size in this study was limited by the Coronavirus 2019 pandemic. Perhaps a larger sample size in a followup study would increase the generalizability of the sample to determine whether there would be an effect on balance if a more representative sample was used. In addition, extending these longitudinal studies to 16 or 18 weeks instead of the current 8 weeks conducted in this study may allow a fully integrated training adaptation and provide further understanding of the PENDL's effect on training adaptation.

In summation, the main objective of this study was to understand the PENDL training effects on ROM-HF, ROM-HE, and balance in people with CLBP. Second, the findings in the current study may provide a large cross section of the public, who find the current exercise tools and therapeutic modalities to be less attractive as treatment options, a new tool and an alternative choice to use in order to stay healthy. Finally, due to the nature of this apparatus and its design configuration, the effects of the PENDL training on the stimulation of the vestibular system and the proprioception of the participants in their efforts to control the oscillation and the spinning motion while being suspended off the ground are also worth exploring in future research studies.

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APPENDICES FOR STUDY I

## APPENDIX A

# IRB APPROVAL LETTER

## **IRB**

#### INSTITUTIONAL REVIEW BOARD

Office of Research Compliance, 010A Sam Ingram Building, 2269 Middle Tennessee Blvd Murfreesboro, TN 37129 FWA: 00005331/IRB Regn. 0003571



## IRBN001 - EXPEDITED PROTOCOL APPROVAL NOTICE

Tuesday, September 01, 2020

Protocol Title Changes in lumbar range of motion, muscular strength, and pain

following an 8-week training program using PendulFit in

individuals who experience low back pain

Protocol ID 20-2198

Principal Investigator Rawsam Samir Alasmar (Student)

Faculty Advisor Sandra Stevens

Co-Investigators NONE

Investigator Email(s) rsa2z@mtmail.mtsu.edu; sstevens@mtsu.edu

Department Health and Human Performance

Funding NONE

## Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU IRB through the **EXPEDITED** mechanism under 45 CFR 46.110 and 21 CFR 56.110 within the category (4) Collection of data through noninvasive procedures. A summary of the IRB action is tabulated below:

| IRB Action          | APPROVED for ONE YEAR   |                           |                          |
|---------------------|---|---------------------------|--------------------------|
| Date of Expiration  | 8/31/2021   | Date of Approval: 8/14/20 | Recent Amendment: 9/1/20 |
| Sample Size         | FORTY (40)  |                           |                          |
| Participant Pool    | Target Population:  |                           |                          |
|                     | Primary Classification: Adults (18 years or older)                                  |                           |                          |
|                     | Specific Classification: Individuals with chronic back pain                         |                           |                          |
| Type of Interaction | ☐ Virtual/Remote/Online interaction   |                           |                          |
|                     | In person or physical interaction – Mandatory COVID-19 Management                   |                           |                          |
| Exceptions          | In person data collection with COVID-19 Management Plan is permitted.               |                           |                          |
|                     | Contact information is allowed for recruitment and project coordination purposes    |                           |                          |
| Restrictions        | 1. Mandatory SIGNED Informed Consent.   |                           |                          |
|                     | 2. Identifiable data/artifacts, such as, audio/video data, photographs, handwriting |                           |                          |
|                     | samples, personal address, driving records, social security number, and etc.,       |                           |                          |
|                     | MUST NOT BE COLLECTED.  |                           |                          |
|                     | 3. Mandatory Final report (refer last page).  |                           |                          |
|                     | 4. CDC guidelines and MTSU safe practice must be followed                           |                           |                          |
| Approved Templates  | IRB Templates: Signature Informed Consent   |                           |                          |
|                     | Non-MTSU Templates: Verbal recruitment script                                       |                           |                          |
| Funding             | NONE  |                           |                          |
| Comments            | NONE  |                           |                          |

IRB Registration, 0003571

#### **Post-approval Requirements**

The PI and FA must read and abide by the post-approval conditions (Refer "Quick Links" in the bottom):

- Reporting Adverse Events: The PI must report research-related adversities suffered by the participants, deviations from the protocol, misconduct, and etc., within 48 hours from when they were discovered.
- Final Report: The FA is responsible for submitting a final report to close-out this protocol before 8/31/2021
  (Refer to the Continuing Review section below); REMINDERS WILLNOT BE SENT. Failure to close-out or request for a continuing review may result in penalties including cancellation of the data collected using this protocol and/or withholding student diploma.
- Protocol Amendments: An IRB approval must be obtained for all types of amendments, such as:
   addition/removal of subject population or investigating team; sample size increases; changes to the research
   sites (appropriate permission letter(s) may be needed); alternation to funding; and etc. The proposed
   amendments must be requested by the FA in an addendum request form. The proposed changes must be
   consistent with the approval category and they must comply with expedited review requirements
- COVID-19: Regardless whether this study poses a threat to the participants or not, refer to the COVID-19
   Management section for important information for the FA.

#### Continuing Review (The PI has requested early termination)

Although this protocol can be continued for up to THREE years, The PI has opted to end the study by 8/31/2021

The PI must close-out this protocol by submitting a final report before 8/31/2021 Failure to close-out may result in penalties that include cancellation of the data collected using this protocol and delays in graduation of the student PI.

## **Post-approval Protocol Amendments:**

The current MTSU IRB policies allow the investigators to implement minor and significant amendments that would fit within this approval category. Only TWO procedural amendments will be entertained per year (changes like addition/removal of research personnel are not restricted by this rule).

| Date       | Amendment(s)  | IRB Comments |
|------------|---|--------------|
| 09/01/2020 | 1. Procedural amendment: The following parameters/measurements are            | IRBA2021-179 |
|            | added: a) leg strength power assessment, b) balance assessment, and           |              |
|            | c) activity monitoring.   |              |
|            | 2. Informed consent script and the recruitment script are modified to reflect |              |
|            | these changes.  |              |

## Other Post-approval Actions:

The following actions are done subsequent to the approval of this protocol on request by the PI/FA or on recommendation by the IRB or by both.

| Date | IRB Action(s) | IRB Comments |
|------|---------------|--------------|
| NONE | NONE          | NONE         |

## COVID-19 Management:

The PI must follow social distancing guidelines and other practices to avoid viral exposure to the participants and other workers when physical contact with the subjects is made during the study.

- The study must be stopped if a participant or an investigator should test positive for COVID-19 within 14 days
  of the research interaction. This must be reported to the IRB as an "adverse event."
- The MTSU's "Return-to-work" questionnaire found in Pipeline must be filled by the investigators on the day
  of the research interaction prior to physical contact.
- . PPE must be worn if the participant would be within 6 feet from the each other or with an investigator.
- Physical surfaces that will come in contact with the participants must be sanitized between use
- FA's Responsibility: The FA is given the administrative authority to make emergency changes to protect
  the wellbeing of the participants and student researchers during the COVID-19 pandemic. However, the FA
  must notify the IRB after such changes have been made. The IRB will audit the changes at a later date and
  the FA will be instructed to carryout remedial measures if needed.

#### Data Management & Storage:

All research-related records (signed consent forms, investigator training and etc.) must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application.

 $IRBN001-Expedited\ Protocol\ Approval\ Notice\ (Stu)$ 

Institutional Review Board, MTSU

FWA: 00005331

IRB Registration. 0003571

The data must be stored for at least three (3) years after the study is closed. Additional Tennessee State data retention requirement may apply (refer "Quick Links" for MTSU policy 129 below). The data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects.

The MTSU IRB reserves the right to modify/update the approval criteria or change/cancel the terms listed in this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board Middle Tennessee State University

#### Quick Links:

- Post-approval Responsibilities: http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php
- Expedited Procedures: <a href="https://mtsu.edu/irb/ExpeditedProcedures.php">https://mtsu.edu/irb/ExpeditedProcedures.php</a>
- MTSU Policy 129: Records retention & Disposal: <a href="https://www.mtsu.edu/policies/general/129.php">https://www.mtsu.edu/policies/general/129.php</a>

## **CHAPTER IV**

THE EFFECTS OF THE PENDL TRAINING ON BACK STRENGTH AND FUNCTIONAL SIT TO STAND PEAK POWER IN ADULTS WITH CHRONIC LOW BACK PAIN: AN EXPLORATORY STUDY

## Introduction

Low back pain (LBP) affects 57.6 million people or 9.4% of the population globally (Walker et al., 2018). This is attributed to 25% of all missed days from work in the United States (Walker et al., 2018). The financial impact every year for these productivity losses due to LBP were estimated to be \$61.2 billion dollars (Walker et al., 2018). Chronic low back pain (CLBP) is characterized as pain or discomfort that originates between the lower gluteal folds and the costal margin region with or without symptoms in lower limbs and lasts for more than 3 months (Oliveira et al., 2019).

There have been numerous rehabilitation interventions used for the management of CLBP. Beside the standard medical treatment, various alternative strategies have been explored to understand their effect in mitigating CLBP. Some examples for alternative treatment to traditional medicine that were investigated by researchers are resistive exercise in Pilates (Oliveira et al., 2019), whole-body vibration (Kim et al., 2018 & Wang et al., 2019), Kinesiology taping (Li et al., 2015), aquatic exercise (Abadi et al., 2019 & Psycharakis et al., 2019), Tai Chi (Qin et al., 2019), and Baduanjin (Li et al., 2019). While the degrees of effectiveness for these treatment modalities varies based on the severity of CLBP, 82% of patients experiencing CLBP continue to experience pain 1 year

post treatment (Chou, 2010). This indicates the need to revise current treatment interventions while instigating new treatment modalities. Selection of the treatment modality is influenced by both the patients' preferred treatment method along with the practitioners' skillset (Alasmar & Stevens, 2021). Currently, physical exercise is considered to be one of the best treatment choices for patients who experience CLBP (Oliveira et al., 2019). Both long-term and short-term effects of exercise include reducing pain and disability while improving strength and balance (Oliveira et al., 2019). Furthermore, one of the most effective and commonly practiced rehabilitation techniques for mitigating CLBP and improving lumbo-pelvic hip control (LPHC) and the lumbar spine dynamic stability in people with CLBP is core stability training (Fong et al., 2015). A study performed in a group of young healthy individuals without CLBP found that exercises targeting core stability using instability devices such as the BOSU ball or TRX to be more effective in inducing core muscle activity in plank, chest press, and 45-degree row when compared with traditional core stability exercises on a stable surface (Fong et al., 2015).

Considering the need for training on safe, yet unstable surfaces, the PENDL may be an effective training choice. The PENDL has been developed to allow individuals who experience CLBP to exercise on an unstable surface safely while suspended in a harness apparatus. A randomized pilot study was aimed to explore an 8-week strength training program using the PENDL in adults with CLBP and the effects of its use on reducing CLBP (Alasmar & Stevens, 2021). The results of this exploratory study showed a

statistically significant reduction in CLBP in the experiment group when compared to a control group (Alasmar & Stevens, 2021). In addition, a qualitative change in fitness were reported by the participants in the same study. Following training, the participants reported perceived improvements in their fitness, activity of daily livings and during playtime with their kids and family members (Alasmar & Stevens, 2021). Although speculative, the decrease in CLBP for this study sample may be related to increases in back strength and power, two variables have been associated with CLBP (Kell & Asmundson, 2009). However, there has not been a study that has explored the effects of PENDL training on increases in back strength (BS) and functional sit-to-stand peak power (FSSPP). It is possible that reduction in CLBP in Alasmar and Stevens' study could be associated with increases in BS and FSSPP.

The purpose of this randomized control exploratory research study was to evaluate an 8-week strength training program using the PENDL in adults with CLBP and quantify changes in BS, and improved FSSPP. It was hypothesized that adults with CLBP who completed an 8-week training program using the PENDL system would demonstrate improvements in BS and exhibit increased FSSPP compared to those who did not train on the PENDL.

# Methods

**Participants**. Male and female adult participants (N = 12; body mass index = 27.2  $\pm$  4.2 kg/m<sup>2</sup>), 18 to 65 years-of-age (45  $\pm$  12 years) with CLBP were alternately enrolled in one of two groups. Odd number participants (i.e., 1, 3, 5, 7...etc.) were assigned to the

experiment group (n = 6;  $45 \pm 10$  years); while those whose numbers upon arrival were even (i.e., 2, 4, 6, 8...etc.) were assigned to the control group (n = 6;  $45 \pm 14$  years). Participants with chronic non-specific LBP who, on an average, have been experiencing CLBP for about 3 months or more and have reported pain intensity equal to or less than 40% in the Oswestry Low Back Pain Disability Questionnaire (OLBPQ; Fairbank & Pynsent, 2000) qualified for inclusion in this study.

## Instrumentation.

Strength Assessment of the Back (Lumber Spine). Strength of the back was measured using a dynamometer measuring the force generation isotonically. Participants stood on the dynamometer platform with knees locked during back extension to eliminate the use of knee extensor muscles during the test grasping the bar in alternated grip pulling the chain upward. The highest measurement out of 3 trials was then recorded with 30 seconds rest between each trial (Gibson et al., 2019). In addition, an isometric contraction was measured by performing a proper plank. A proper plank constituted straight alignment of all four anatomical cavities with co-active isometric contraction of all muscles while being sustained in seconds (one trial).

Functional Sit-to-Stand Back Power Assessment. Functional Sit-to-Stand back power (FSSBP) was measured using a Tendo-Unit where the participants affixed a belt around the waist with a string attached from the belt to the Tendo-Unit. Participants were asked to cross both arms around the shoulders then stand from a seated position as fast and as powerful as they could where the power was measured based on the velocity of

work and distance traveled at a given time through the string. The highest peak power out of the 5 trials with 30 seconds rest between each trial was recorded and compared. (Netz et al., 2004; Schlicht et al., 2001).

**Procedures.** Participants were from a university and surrounding community in the southeastern United States. The recruitment method was word of mouth and interoffice/department email communication. Participants completed the Physical Assessment Readiness Questionnaire and were excluded from the study if physical activity was contraindicated. Other exclusion criteria included starting or discontinuing treatment related to back pain in the last two weeks or reporting CLBP that had not continued for more than 3 months. Treatment related to back pain included: a) medications related to back pain, b) physical therapy treatment or inpatient medical rehabilitation, and c) regular physical activity, defined as 30 minutes, three times or more per week. Participants who reported disc herniation, pregnancy, previous or scheduled surgeries of the spine within the last three months; severe cardiorespiratory diseases; cancer; dependent walking (using walking aid or assistance from another person), cognitive disorders, post-traumatic conditions (e.g., LBP following an accident), and insufficient understanding of the English language were also excluded form participation (Fairbank & Pynsent, 2000). This study was approved by the University Institutional Review Board (see Appendix A) and participants provided written informed consent prior to testing and training.

On the first visit, the following assessments were conducted and data were collected for both groups: participant's 1) anthropometric measures and body mass index, 2) BS using a) dynamometer (DYN) and b) a proper plank (PLNK) held in seconds, and 3) FSSPP using the Tendo-Unit system measuring the highest peak power. The assessment of the outcomes was repeated by all participants in both groups after 8 weeks. Only the participants in the experimental group performed five functional movement exercises, during their first visit, as an educational session with the supervision of the principal investigator using the PENDL. This familiarization session provided participants an opportunity to choose if their comfort level with the PENDL allowed them to commit to or opt out of the study. In addition, this familiarization session shortened the participant's learning curve on the device once they began training.

Participants in the experiment group completed an 8-week training program on the PENDL. The program included meeting three times per week (30 hours total) for 40-45 minutes and a 5-7 minute warm up and cool down. Participants in the experiment group were required to complete all 24 sessions in this study. Make-up for missed sessions was required.

The program included 10 exercises. The training exercises were selected based on having significant elements of LPHC function and were identified for reducing symptomology or risk of CLBP. The exercises were chosen to represent a balanced variation of functions required for normal daily activities (Gabel et al., 2018). The suspension squat and leg extension/flexion exercises, respectively, require functional

movement while co-actively engaging the abdominal region, which occur or simulate daily occupational and sports activities (Gabel et al., 2018). The following exercises were used in this study and included a variation of progression/regression dependent on the initial fitness level and improvement across the 8 weeks of training: 1) side leg split (hip abduction/adduction), 2) front leg splits (hip flexion/extension) and/or lunge form, 3) squat, 4) squat, abduction and adduction, 5) squat and twist, 6) squat, jump and spin and/or squat, jump and hold isometric contraction, 7) hip (flexion/extension — unilateral or bilateral while knees flexed or extended), 8) bridge and bridge with hip abduction/adduction, 9) pronated hip extension — unilateral or bilateral while knees flexed or extended, and 10) traction of the spine while suspended inversely.

# **Statistical Analysis**

Data analysis was conducted using SPSS Inc. Version 26. The mean and standard deviation were calculated for study outcomes (see Table 1). Baseline difference between the two groups on the outcome variables were assessed using analysis of covariance (ANCOVA) to control for pretest BS-PLNK, BS-DYN, and FSSPP and to improve internal validity. The change scores were calculated comparing the experiment group to the control group on BS-PLNK, BS-DYN, and FSSPP after the 8-week training program using the PENDL. The statistical significance was determined at alpha level of p < .05 for all analyses.

Table 1

Descriptive Statistics

|                     | Experimental | Control   |
|---------------------|--------------|-----------|
| Variables           | M(SD)        | M(SD)     |
| Pretest BS-DYN      | 109(26)      | 109(47)   |
| Posttest BS-DYN     | 124(37)      | 99(47)    |
| Mean Change BS-DYN  | 14.22%*      | -9.31%    |
| Pretest BS-PLNK     | 76(38)       | 93(51)    |
| Posttest BS-PLNK    | 114(38)      | 76(53)    |
| Mean Change BS-PLNK | 50.17%*      | -18.07%   |
| Pretest FSSPP       | 1323(410)    | 1498(387) |
| Posttest FSSPP      | 1694(649)    | 1375(326) |
| Mean Change FSSPP   | 28%*         | -8.26%    |

*Note*. BS-DNY = back strength-dynamometer (in kilograms); BS-PLNK = back strength-plank (in seconds); FSSPP = functional sit-to-stand peak power (in watts); \* = p < 0.05

## Results

Two participants in the experiment group were excluded in the beginning of the study. One is due to illness and the second is not adhering to the illegibility criteria; which has resulted in 4 participants being in the experimental group. Since participants' safety was a priority in this study, there were no reported injury incidences or cancelation sessions due to soreness during this study.

A one way between-subjects ANCOVA was calculated to examine the effect of PENDL training on BS-DYN, BS-PLNK, and FSSPP covarying their pretest scores when comparing the two groups. Following the 8-week training on the PENDL, there were significant increases in the experimental group in force generation in BS-DYN (F(1,7) = 9.32, p = .018,  $\eta^2_p = 0.57$ ), seconds sustained in BS-PLNK (F(1,7) = 11.74, p = .01,  $\eta^2_p = 0.63$ ) and FSSPP (F(1,7) = 6.37, p = .04,  $\eta^2_p = 0.48$ ) when controlling for pretest scores.

## Discussion

The purpose of this exploratory study was to evaluate an 8-week training program using the PENDL in adults with CLBP and quantify changes in BS-DYN, BS-PLNK and FSSPP. It was hypothesized that participants who completed the training program would demonstrate improvements in BS-DYN and BS-PLNK and exhibit increases in FSSPP when compared to those who in the control group. The data supported the hypothesis of improvements in BS-DYN (isotonically), BS-PLNK (isometrically), and FSSPP. There were large effect sizes for back strength (isotonically and isometrically) and a medium effect size for FSSPP when covarying for the pretest scores. While the results of this

study had supported the effects of PENDL training on increased BS-DYN (isotonically), BS-PLNK (isometrically) and FSSPP significantly in people with CLBP, perhaps the decrease in CLBP observed in Alasmar and Stevens (2021) study when training on the PENDL may be associated with the change mechanisms observed in the increases in BS-DYN, BS-PLNK and FSSPP after the 8-week training. However, further investigation is suggested to explore if the associations among these variables can be supported.

When comparing these results to previous literatures that used other treatment methods (e.g. Pilates and intense strength training) to improve back strength and functional sit-to-stand peak power, the current results were similar (Oliveira et al., 2019; Paasuke et al., 2002, Schlicht et al., 2001). This can provide both clinicians and patients an alternative treatment choice for improving back strength and functional sit-to-stand power that can be safe and fun. In addition, due to the design configuration of this apparatus and how it operates, it is worth noting the possibility for investigate in future research studies the effects of the PENDL training on stimulating multiple sensory receptors (i.e. proprioception and the vestibular system) while attempting to control the oscillation and the spinning motion while being suspended off the ground.

While this study was an initial investigation for the potential application of the PENDL on improving back strength and functional sit-to-stand peak power in individuals with CLBP, the occurrence of the Coronavirus 2019 pandemic limited the sample size.

However, the sample size in this study suffice the need for understanding the effects of

training on the PENDL as the statical significant was different between the two groups with large effect size.

In summary, the main objective of this study was to expand the understanding for the effects of the PENDL training on back strength (isometrically and isotonically) and functional sit-to-stand peak power. Second, the findings in the current study may provide an alternative choice and a new intervention tool to use in mitigating CLBP.

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APPENDICES FOR STUDY II

## APPENDIX A

# IRB APPROVAL LETTER

## **IRB**

#### INSTITUTIONAL REVIEW BOARD

Office of Research Compliance, 010A Sam Ingram Building, 2269 Middle Tennessee Blvd Murfreesboro, TN 37129 FWA: 00005331/IRB Regn. 0003571



## IRBN001 - EXPEDITED PROTOCOL APPROVAL NOTICE

Tuesday, September 01, 2020

Protocol Title Changes in lumbar range of motion, muscular strength, and pain

following an 8-week training program using PendulFit in

individuals who experience low back pain

Protocol ID 20-2198

Principal Investigator Rawsam Samir Alasmar (Student)

Faculty Advisor Sandra Stevens

Co-Investigators NONE

Investigator Email(s) rsa2z@mtmail.mtsu.edu; sstevens@mtsu.edu

Department Health and Human Performance

Funding NONE

## Dear Investigator(s),

The above identified research proposal has been reviewed by the MTSU IRB through the **EXPEDITED** mechanism under 45 CFR 46.110 and 21 CFR 56.110 within the category (4) Collection of data through noninvasive procedures. A summary of the IRB action is tabulated below:

| IRB Action          | APPROVED for ONE YEAR   |                           |                          |
|---------------------|---|---------------------------|--------------------------|
| Date of Expiration  | 8/31/2021   | Date of Approval: 8/14/20 | Recent Amendment: 9/1/20 |
| Sample Size         | FORTY (40)  |                           |                          |
| Participant Pool    | Target Population:  |                           |                          |
|                     | Primary Classification: Adults (18 years or older)                                  |                           |                          |
|                     | Specific Classification: Individuals with chronic back pain                         |                           |                          |
| Type of Interaction | ☐ Virtual/Remote/Online interaction   |                           |                          |
|                     | ☑ In person or physical interaction – Mandatory COVID-19 Management                 |                           |                          |
| Exceptions          | In person data collection with COVID-19 Management Plan is permitted.               |                           |                          |
|                     | Contact information is allowed for recruitment and project coordination purposes    |                           |                          |
| Restrictions        | 1. Mandatory SIGNED Informed Consent.   |                           |                          |
|                     | 2. Identifiable data/artifacts, such as, audio/video data, photographs, handwriting |                           |                          |
|                     | samples, personal address, driving records, social security number, and etc.,       |                           |                          |
|                     | MUST NOT BE COLLECTED.  |                           |                          |
|                     | 3. Mandatory Final report (refer last page).  |                           |                          |
| Assessed Townslates | 4. CDC guidelines and MTSU safe practice must be followed                           |                           |                          |
| Approved Templates  | IRB Templates: Signature Informed Consent   |                           |                          |
| Funding             | Non-MTSU Templates: Verbal recruitment script                                       |                           |                          |
| Funding             | NONE  |                           |                          |
| Comments            | NONE  |                           |                          |

Institutional Review Board, MTSU

#### FWA: 00005331

IRB Registration, 0003571

#### Post-approval Requirements

The PI and FA must read and abide by the post-approval conditions (Refer "Quick Links" in the bottom):

- Reporting Adverse Events: The PI must report research-related adversities suffered by the participants, deviations from the protocol, misconduct, and etc., within 48 hours from when they were discovered.
- Final Report: The FA is responsible for submitting a final report to close-out this protocol before 8/31/2021
  (Refer to the Continuing Review section below); REMINDERS WILLNOT BE SENT. Failure to close-out or request for a continuing review may result in penalties including cancellation of the data collected using this protocol and/or withholding student diploma.
- Protocol Amendments: An IRB approval must be obtained for all types of amendments, such as:
   addition/removal of subject population or investigating team; sample size increases; changes to the research
   sites (appropriate permission letter(s) may be needed); alternation to funding; and etc. The proposed
   amendments must be requested by the FA in an addendum request form. The proposed changes must be
   consistent with the approval category and they must comply with expedited review requirements
- COVID-19: Regardless whether this study poses a threat to the participants or not, refer to the COVID-19
   Management section for important information for the FA.

#### Continuing Review (The PI has requested early termination)

Although this protocol can be continued for up to THREE years, The PI has opted to end the study by 8/31/2021

The PI must close-out this protocol by submitting a final report before 8/31/2021 Failure to close-out may result in penalties that include cancellation of the data collected using this protocol and delays in graduation of the student PI.

#### Post-approval Protocol Amendments:

The current MTSU IRB policies allow the investigators to implement minor and significant amendments that would fit within this approval category. Only TWO procedural amendments will be entertained per year (changes like addition/removal of research personnel are not restricted by this rule).

| Date       | Amendment(s)  | IRB Comments |
|------------|---|--------------|
| 09/01/2020 | 1. Procedural amendment: The following parameters/measurements are            | IRBA2021-179 |
|            | added: a) leg strength power assessment, b) balance assessment, and           |              |
|            | c) activity monitoring.   |              |
|            | 2. Informed consent script and the recruitment script are modified to reflect |              |
|            | these changes.  |              |

## Other Post-approval Actions:

The following actions are done subsequent to the approval of this protocol on request by the PI/FA or on recommendation by the IRB or by both.

| Date | IRB Action(s) | IRB Comments |
|------|---------------|--------------|
| NONE | NONE          | NONE         |

## **COVID-19 Management:**

The PI must follow social distancing guidelines and other practices to avoid viral exposure to the participants and other workers when physical contact with the subjects is made during the study.

- The study must be stopped if a participant or an investigator should test positive for COVID-19 within 14 days
  of the research interaction. This must be reported to the IRB as an "adverse event."
- The MTSU's "Return-to-work" questionnaire found in Pipeline must be filled by the investigators on the day
  of the research interaction prior to physical contact.
- PPE must be worn if the participant would be within 6 feet from the each other or with an investigator.
- Physical surfaces that will come in contact with the participants must be sanitized between use
- FA's Responsibility: The FA is given the administrative authority to make emergency changes to protect
  the wellbeing of the participants and student researchers during the COVID-19 pandemic. However, the FA
  must notify the IRB after such changes have been made. The IRB will audit the changes at a later date and
  the FA will be instructed to carryout remedial measures if needed.

# Data Management & Storage:

All research-related records (signed consent forms, investigator training and etc.) must be retained by the PI or the faculty advisor (if the PI is a student) at the secure location mentioned in the protocol application.

IRBN001 - Expedited Protocol Approval Notice (Stu)

Institutional Review Board, MTSU

FWA: 00005331

IRB Registration. 0003571

The data must be stored for at least three (3) years after the study is closed. Additional Tennessee State data retention requirement may apply (refer "Quick Links" for MTSU policy 129 below). The data may be destroyed in a manner that maintains confidentiality and anonymity of the research subjects.

The MTSU IRB reserves the right to modify/update the approval criteria or change/cancel the terms listed in this letter without prior notice. Be advised that IRB also reserves the right to inspect or audit your records if needed.

Sincerely,

Institutional Review Board Middle Tennessee State University

#### Quick Links:

- Post-approval Responsibilities: <a href="http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php">http://www.mtsu.edu/irb/FAQ/PostApprovalResponsibilities.php</a>
- Expedited Procedures: <a href="https://mtsu.edu/irb/ExpeditedProcedures.php">https://mtsu.edu/irb/ExpeditedProcedures.php</a>
- MTSU Policy 129: Records retention & Disposal: <a href="https://www.mtsu.edu/policies/general/129.php">https://www.mtsu.edu/policies/general/129.php</a>

## CHAPTER V

## **OVERALL CONCLUSIONS**

The purpose of this dissertation was to investigate the effects of PENDL training on four fitness component mechanisms observed in adults with CLBP. To address this purpose, two studies were implemented, the first exploring the effects of PENDL training on balance and hip flexibility, the other on the effects on back strength and functional sitto-stand power. The ultimate objective of the two studies was to evaluate the feasibility of a newly designed fitness machine, the PENDL system, on people with CLBP.

A study by Alasmar and Stevens (2021) demonstrated a statically significant difference in CLBP for an experimental group who trained on the PENDL 3 times per week for 8 weeks compared to a control group who did not train. While the previous investigation demonstrated a decrease in back pain, the mechanisms contributing to this improvement were not identified. This project built on this knowledge to expand our understanding of possible mechanisms responsible for the observed reduction in back pain. The two current studies were a follow up to Alasmar and Stevens (2019) study to better understand if there were changes in the 4 mechanisms mentioned earlier. The two studies demonstrated a significant increases in the range of motion of the hip (both flexion and extension), back strength (both isometrically and isotonically) and functional sit-to-stand peak power. While the mechanisms of hip flexion and back strength (both isometrically and isotonically) showed a large effect size, flexibility of the hip extension

and functional sit-to-stand peak power showed a medium effect size when controlling for pretest scores.

This can be an important knowledge to share among the scientific community and the fitness and rehabilitation industries. Since the results of this study provided strong statistical significant evidence with large effect size, this may support the idea of implementing this knowledge into applied practical use by designing and rolling out a standardized exercise programs that can be prescribed to assist those who need to attain their goals for increasing ROM of the hip and improving their back strength and functional sit-to-stand power. The LPHC region was the target area when the exercise programs were prescribed in the two studies with the goal of increasing ROM of the hip both in flexion and extension, back strength both isometric and isotonic, functional sit-to-stand power and balance.

However, when measuring balance, no statistically significant improvement was observed between the two groups. Theoretically, balance could be effected when being suspended on unstable surface such as the PENDL. It is a reasonable outcome to have an association between the stimulation of the vestibular system and its relation to balance (Bear et al., 2016). Since training on the PENDL may stimulate the vestibular system which may have an effect on balance, balance was measured in this study. Perhaps neuromuscular adaptation may take longer than the 8-week training timeframe implemented in this study to show any significant difference in balance improvement. Thus, further investigation in this area is recommended to understand the PENDL

training effects on balance prescribing exercise protocol that may last longer than 8 weeks. In addition to that, perhaps using statistical power (G\*Power) of a larger sample size can be beneficial to further our understanding of the statistical significant effect when training on the PENDL on balance.

Given the novelty of the apparatus used for training and the challenges presented by the Coronavirus 2019 pandemic, the sample size was limited. However, data collected in these trails were adequate to achieve our purposes since the statical significant effect for PENDL training on hip flexibility, back stretch, and FSSPP was different between the two groups. Future investigations should include a more robust follow-up study with a larger sample size using the same study exercise design to further our understanding of the effects of training on the PENDL on balance. Future studies may also be expanded to other special populations and assessments of health-and skill-related fitness outcomes.

In summation, data from the current dissertation provided evidence for safety and the feasibility of training individuals with CLBP on the PENDL. There were no untoward events, and all participants completed all training sessions. Secondly, in this sample of individuals with CLBP, training on the PENDL for 8 weeks, 3 times a week, resulted in improvements in ROM of the hip (both in flexion and extension), back strength (both isometric and isotonic), and functional sit-to-stand power. Lastly, due to the nature of this apparatus and its design configuration, it may trigger various receptors and stimulate multiple sensory systems while training on it. This could lead to additional investigation work that can be an extension to future research studies to be explored for therapeutic and

exercise uses within the rehabilitation and fitness industries. Examples for such studies could span investigating the PENDL effect on autism, vertigo, sports specific skill improvement, Spinal Cord Injury, Attention Deficit Hyperactivity Disorder, Post Traumatic Stress Disorder; just to name few. This can ultimately contribute to the scientific research body of knowledge in the fields of allied health, exercise science and physiology.

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