# AN INVESTIGATION INTO THE SHORT TERM EFFECTIVENESS OF WHOLE BODY VIBRATION TRAINING IN ACUTE LOW BACK PAIN SUFFERERS.

By

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Dissertation submitted in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic at the Durban University of Technology.

I, Nicolaas Tjaart van der Merwe, do declare that this dissertation is representative of my own work in both conception and execution.

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### DEDICATION

I dedicate this research to my mother, Ria and father Nico. Your vision in seeing me achieve all that was set out for me has been the engine room behind my continued perseverance. Thank you for your ongoing support, deep love, compassion and kindness toward me every step of the way.

I commit this research to my Lord Jesus Christ, who gave me the ability to complete this work.

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# ABSTRACT

Core strengthening has become a major trend in the rehabilitation of patients suffering with acute low back pain.

Clinical trials have shown that core strengthening is beneficial for patients with low back pain. According to the literature, core strengthening consists of activating the trunk musculature in order to stabilize hypermobile symptomatic joints and thus, lessen mechanical stress to the spine.

Literature suggests that vibration/acceleration training may be a more effective and sufficient method of core stability exercises, with regards to core muscle endurance and activation in treatment of acute low back pain. This may have more advantages than using traditional core stability exercises in the treatment of acute low back pain.

However, vibration/acceleration training as core stability exercises has yet to be investigated. In order to choose the most appropriate treatment protocol for managing this condition, it is essential for research to be carried out to identify the most effective treatment, which would allow for better overall management of low back pain during the acute period.

Therefore, this study was designed to establish the effectiveness of vibration/acceleration training as a core stability exercise in the treatment of acute low back pain and to establish whether this protocol should be utilized routinely in the management of this condition.

#### **SUMMARY**

It has been noted in many recent research studies, that low back pain is a serious problem and there are many epidemiological and statistical studies documenting the high incidence and prevalence of low back pain which can cost thousands of rands in lost working hours and medical bills. (Manga., 1993; Stuge 2004)

Clinical trials, investigating the benefits of core stability muscle training programs for patients with acute low back pain, revealed encouraging results as they may decrease the hypermobility of symptomatic joints that is associated with a weakening of the stabilizing system of the spine. (Hides, Jull and Richardson, 2001; Stanford, 2002; Stuge, 2004)

In recent years the role of therapeutic exercise has shifted from improving strength, posture and mobility, to stabilizing hypermobile lumbar segments and to decreasing mechanical stress to the spine. Core strengthening has become a major trend in rehabilitation of low back pain and pelvic girdle pain. (Lee, 2004; Vleeming 2006; Ostgaard, Stuge and Sturesson . 2004)

Currently, the most appropriate treatment protocol used is spinal manipulation and/or manual therapy, with spinal manipulation as the treatments of choice for low back pain (Giles and Singer, 1997). However, due to multi systemic involvement of the muscular system, neural system and passive systems in lower back pain, the treatment needs to target all three of the subsystems of spinal stability to be most effective (Panjabi, 1992; Richardson, Snijders et all., 2002).

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With vibration/acceleration training, the neural, muscular and passive subsystems would be targeted, causing an increase in muscle strength; flexibility; range of motion; bone density; and blood circulation within the body - particularly the lumbar spine region, as this is the target region (Rittweger, Bellerand and Felsenberg. 2000). Thus, it is hypothesised that an increase in core muscle strength would be noticed with a decrease in pain, an increase in pain threshold and the ability to continue with normal physical activity and normal lifestyle.

Therefore, the aim of this study is to establish the effectiveness of vibration/acceleration training in acute low back pain sufferers with regards to core muscle endurance and activation in the treatment of acute low back pain.

This randomized, comparative clinical trial study consisted of thirty subjects divided into two groups of fifteen. The method was that of self-selection sampling with random allocation - which is the gold standard method of allocation for research of this sort - with the advantage of this method being that it is an effective way to find subjects (Mouton, 1996; Wilson, 2006)

Participants were randomised into two equal groups of fifteen, each using computer generated random number tables. This then divided the 30 participants into a control group and a treatment or whole body vibration exercise group.

Both groups exercised twice a week, for three weeks; as part of the treatment protocol.

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Statistical analysis was completed under the guidance of a biostatistician, from the College of Health Science, University of KwaZulu - Natal. The subjective data was obtained using the Numerical Pain Rating Scale (Appendix A) and the Quebec Back Pain and Disability Scale (Appendix K). The objective data was obtained using the Stabilizer Biofeedback Device. Data was entered and analysed in SPSS version 15(SPSS Inc. Chicago, III, USA). Baseline demographics and factors were compared between the two treatment groups in order to ensure completeness of randomization using students' t-tests in the case of quantitative data, and Pearson's chi square tests, as this is appropriate for categorical variables.

Repeated measures ANOVA were used to assess the presence of a treatment effect. A significant time\*group interaction effect (p<0.001) did signify a statistically significant treatment effect. Profile plots were used to interpret non-significant effects and trends as well as the direction of the treatment effects.

According to the statistical analysis, both groups showed improvements subjectively and objectively - with regards to acute low back pain, which is in keeping with the literature. In terms of the inter-group analysis, significance was measured at a p-value of p<0.001. A p-value of 0.131 was noted for time prone measures of core stability endurance; 0.173 for time supine; 0.163 for Quebec Back Pain and Disability Scale (QDS) measures and 0.395 for Numerical Pain Rating Scale (NRS) measures.

Inter-group findings; therefore, revealed that a slight difference existed in favour of the vibration/acceleration training group, but not sufficient enough to conclude that it is more effective than core muscle exercises alone.

It is recommended that more research be carried out to gain conclusive results indicating the least complicated and most beneficial treatment protocol.

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### **DEFINITION OF TERMS**

#### Acute vs. Chronic pain:

Acute pain is a type of pain that typically lasts less than 3 to 6 weeks, or pain that is directly related to soft tissue damage. Acute pain is of short duration but it gradually resolves as the injured tissues heal. Acute pain is distinct from chronic pain and is relatively more sharp and severe.

Chronic pain is defined as pain that lasts longer than 6 weeks. Acute pain becomes chronic pain when the period of pain exceeds 6 weeks and the healing process takes longer than the natural course of healing (Hansson, 2006).

#### **Chiropractic:**

Chiropractic is a discipline within the healing arts, especially concerned with the etiology, pathogenesis, diagnostics, therapeutics and prophylaxis of functional disturbances, pathomechanical states, pain syndromes and other neurophysiologic effects related to the statics and dynamics of the neuromusculoskeletal system - particularly those related to the spine and the pelvis (Schafer and Faye, 1990).

#### **Contra-indication:**

Any condition, especially any disease condition, that renders one particular line of treatment improper or undesirable (Gatterman, 1990).

#### Core stabilization:

The rehabilitation and retraining of the so-called core stabilizers of the lumbar spine (TA, multifidus and Obliquus internus abdominis muscles), to provide increased stability around the neutral zone (Boden, 2002).

#### Low back pain:

This is defined as pain resulting from the inherent susceptibility of the spine to static loads, due to muscle gravity forces and to kinetic deviation from the normal function in the lower back and pelvic girdle (Gatterman, 1990).

#### **Objective clinical findings:**

For the purpose of this study, this refers to the data obtained from the measurement of the core stability muscle endurance, using the Stabilizer Biofeedback Device.

#### Subjective clinical findings:

For the purpose of this study, these are defined as those clinical findings ascertained using the patient's perception of the pain, including the Numerical Pain Rating Scale and the Quebec Back Pain Disability Scale.

# Whole Body Vibration or Acceleration Training:

Whole Body Vibration (WBV) is a term used to describe human exposure to vibration through feet, buttock and/or back. The mechanical stimulation then generates acceleration forces to work on the body (Rittweger, Ehrig, and Just, 2002).

#### CHAPTER 1

#### **INTRODUCTION**

#### 1.1. The problem and its setting

Low back pain (LBP) is a major international problem and there are many epidemiological and statistical studies documenting the high incidence and prevalence of LBP (Manga *et al.*, 1993). Surveys suggest that the lifetime incidence of LBP ranges from 60-90% with a 5% annual incidence. For persons younger than 45 years, LBP represents the most common cause of disability, and it is the third most common cause of disability in persons aged older than 45 years (Hills, 2006). No consensus exists among physicians, physiotherapists, or chiropractors concerning the most appropriate treatment and management of LBP. While there is no mortality associated with LBP; morbidity, in terms of lost productivity, use of medical services and cost to society is staggering (Hills, 2006). Similarly, the lifetime incidence of LBP in Indian and Coloured communities in South Africa was found to be 78.2% and 76.6% respectively (Docrat, 1999). In the Black South African communities it was found to be 57.6% by Van der Meulen (1997).

It has been hypothesised that the increasing incidence of LBP is the result of a reduction in physical activity and therefore, the increasing rate of sedentary lifestyles has resulted in the once strong muscle system - that is responsible for maintaining peoples postures and movements - becoming progressively more inactive, which negatively impinges weakened lumbar core stability in many individuals (Back Care, 2000; Lee, 2004).

Therefore, the factors that affect lumbar stability have been an area of extensive research and particular attention has been paid to the core muscles, as they form a muscular corset to stabilize the body and spine. Comprehensive strengthening or facilitation of these muscles has been suggested as a way to prevent and rehabilitate various lumbar spine and musculoskeletal disorders (Akuthota *et al.*, 2004).

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Amongst the core stabilisation muscles, are the transverses abdominus (TA), multifidus and the internal obliquus abdominus muscles that are the main functional muscles acting as the strong stabilizers in the lumbar spine (Lee, 2004; Vleeming, 1998). These muscles lie deep within the trunk of the body, acting like a corset to reduce pressure on the spine (Davis et al., 2004). A study of the TA muscles found that LBP patients had reduced endurance and that its protective ability was decreased (Evans *et al.*, 2000). In addition, it was noted that there was wasting and inhibition of the multifidus muscle; reducing its ability to stabilize the spine (Hides et al, 1994; Newton, 2004; Lee, 2004; Vleeming, 2006).

Low back pain involves a muscular, as well as connective and neural system, as seen in paragraphs above. This therefore, makes it even more difficult to treat, due to multi systemic involvement (Lee, 2004; Vleeming, 1998; Panjabi, 1992).

According to Richardson et al. (1999), general exercise programs for the lower back has also proven to have limitations due to pain and goals that could not be reached because of extreme pain. Studies have also shown that with general exercise programs the emphasis is normally placed on the global musculature of the joint, which are the general movers of that joint (O'Sullivan, 2005).

Recently, vibration exercise has been developed into a new form of treatment, which activates muscles via reflex action on the motor system (Rittweger *et al.*, 2003).Vibration/acceleration training can be used to focus on these specific core muscles, thus taking the emphasis off the global musculature as suggested by O'Sullivan (2005).

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With vibration training, the patient is positioned on a vibrating plate that vibrates at a constant, set speed. The vibration causes reflex contraction as a result of the local stimulation to muscles or tendons. The change in muscle length is then picked up by the muscle spindle in the muscle, which then innervates the 'a' efferent fibres of the muscle through the 'la' afferent fibres. The vibration also contracts and shortens each separate muscle group continually, thus increasing the strength of the muscle (Den Haag, 2002; Delecluse *et al.*, 2003).

Research has shown that vibration training could be used to activate the multifidus, transversus abdominis and the obliquus internus abdomisis muscles, which are the principle stabilisers in the lumbar spine; as these studies have been shown to have a strengthening effect on them. The strengthening of these muscles will then give more stability to the patient's spinal joints and reduce their back pain, enabling them to carry out normal activities of daily living without physical limitations (Richardson *et al.*, 1999; O'Sullivan, 2005; Lee, 2004; Vleeming, 1998; Panjabi, 1992).

Therefore, the aim of this study was to test the short term effect of vibration/acceleration training and placebo vibration training as a control on acute low back pain sufferers.

#### 1.2. The objectives of the study

<u>Objective one</u>: The first objective was an intra-group analysis (vibration alone vs. placebo vibration) with respect to objective (Biofeedback device/Stabilizer) and subjective (NRS and QDS) findings.

<u>Objective two</u>: The second objective was an inter-group analysis (vibration alone vs. placebo vibration) with respect to subjective (NRS and QDS) and objective (Biofeedback device/Stabilizer) findings.

<u>Objective three</u>: The third objective was to integrate the data obtained from objectives one and two, to determine which would be a more effective treatment of acute low back pain.

 <u>Hypothesis</u>: It was hypothesized that vibration/acceleration training would be a better form of core stability exercises and would be effective in the management of acute low back pain, in terms of both subjective and objective clinical findings.

#### 1.3. The rationale

The magnitudes of the prevalence of acute LBP in western countries have highlighted the need for an effective treatment method to use as a preventative measure, before acute LBP becomes a chronic problem (Hills, 2006).

As low back pain involves muscular as well as connective and neural systems (Lee, 2004; Vleeming, 1998; Panjabi, 1992), it has been found that by using vibration/acceleration training it will be targeting the entire systems and not just one or two components of the subsystem (Richardson *et al.*,1999).

Vibration/acceleration training produces vibrations that are perceived as a mechanical stimulus by the body and causes a stretch reflex, which depends on frequency, resulting in rapid and intense muscle contraction. These vibrations have considerable benefits, such as improving muscle strength; flexibility; range of motion; bone density and stimulation of blood circulation. With these benefits, the lifetime incidence of low back pain may be decreased with the use of the power-plate in acute low back pain patients (Rittweger *et al.*, 2002; Den Haag, 2002; Delecluse *et al.*, 2003).

Core strengthening has become a major trend in rehabilitation. Core stability muscle training on the vibration /acceleration programs has yet to be investigated as a means to improve overall patient management for this condition, by means of rehabilitating the abdominal 'corset' and stabilizing symptomatic hyper mobile segments of the lumbar spine in low back pain sufferers.

Upon review of the related literature, it appears that no controlled studies have been compiled to compare the clinical efficiencies of vibration/acceleration training in terms of core stability exercises for acute low back pain.

Although a variety of treatment protocols (manipulation. manual therapy and physiotherapy) may be used for the treatment of acute low back pain, this study wishes to determine whether vibration/acceleration training, to promote core stability, should be routinely considered in the management for patients suffering or diagnosed with acute LBP.

In the remaining chapters, the researcher will review the literature on acute LBP (Chapter 2); describe in detail the methodology of this study (Chapter 3) and present the statistics (Chapter 4); the results (Chapter 5) and the subsequent conclusions (Chapter 5). Thereafter, recommendations will be made for suggested improvements on the management of acute LBP.

# CHAPTER 2

# LITERATURE REVIEW

#### 2.1. Introduction

This chapter reviews the current literature and clinical trials conducted on the subject of acute low back pain.

The management of acute low back pain and mechanical low back pain in general, are discussed with a particular focus on the relationship between core stabilization, whole body vibration or acceleration training and low back pain.

## 2.2. Epidemiology of low back pain

## 2.2.1. Incidence and prevalence of acute low back pain

Incidence is the rate at which healthy people in a given population develop a disease or symptom over a specified period of time. Lifetime incidence, therefore, reflects the number of people who develop a condition at some time in their lives. Prevalence is defined as a measure of the number of people in a certain population group, who have a symptom or disease at a specific time (Borenstein <u>et al.</u> 1995).

According to Burton and Cassidy (1992), low back pain has a lifetime prevalence of between 60% and 90% for any population. Cox (1990) supports this by stating that low back pain is only slightly less prevalent than the common cold amongst the population of the United States.

The lifetime incidence of low back pain in western society is 60-80% of the population (Koes, 1991) and is further supported by McGregor, stating that low back pain (LBP) is the largest single cause of disability; with some estimates suggesting that it affects 50% to 80% of the population (McGregor *et al.*, 1998).

Jayson (1992) reported that racial differences in the frequency of low back pain had not been adequately studied. South Africa's lifetime incidence of low back pain in Indian and Coloured communities was in keeping with Koes' (1991) findings, where it was found to be 78.2% and 76.6% respectively, and the prevalence was 45% and 32,6% respectively (Docrat, 1999).

#### 2.2.2. Gender and low back pain

According to Hills (2006), gender is a dominant factor in the development of LBP, as 50-90% of women develop LBP during pregnancy. Ergonomics and social situations of LBP patients, during pregnancy, have not shown any correlation with the development of LBP symptoms during pregnancy.

In the formal black South African settlement of Chesterville, the incidence and prevalence of LBP was found to be higher for women than men. The lifetime incidence for women was 61.7% as opposed to 51.8% for men, and the prevalence was 56.4% for women as opposed to 48.4% for men (van der Meulen, 1997). A significant association between gender and lifetime incidence was found. Gender was found to be significantly associated with low back pain prevalence and the female gender was more at risk of developing low back pain (van der Meulen, 1997).

This trend was also found in a study by Docrat (1999), in which the prevalence of low back pain in the Indian and Coloured communities in South Africa was found to be higher for women, as compared to men.

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## 2.3 Etiology of low back pain

According to Haldeman (2005), the etiology of acute LBP is multi factorial in nature. This includes primary anatomical, organic, metabolic and musculoskeletal (Fairbank <u>et al.</u> 1990; Gatterman and Panzer, 1990). Of particular interest to this study, is the relationship between metabolic (e.g. hormonal imbalance) and musculoskeletal (e.g. spinal instability) factors, which figure 1.1. demonstrates below.





# 2.3.1. Etiology of acute low back pain in the general population

Weiner and McCulloch (2000) report that musculoskeletal disorders are amongst the most common medical conditions reported, the primary site being the lower back of which 90% can be attributed to mechanical causes. It has been found that mechanical disorders of the low back are quite specific and local in nature, affecting certain anatomical regions (Giles and Singer, 1997; O'Sullivan, 2005; Hills, 2006). However, Frymoyer (1988) states that the most common diagnoses in cases of acute low back pain are unspecific, such as lumbosacral strain and sprain, and only 10% to 20% of patients can be given a precise diagnosis (Abenhaim et al., 2000; O'Sullivan, 2005).

There are commonly three diagnoses associated with LBP (Schaefer and Faye, 1989: O'Sullivan, 2005):

- 1. Lumbar facet syndrome
- 2. Sacroiliac syndrome
- 3. Lumbar radicular syndrome (discogenic or mechanical in origin)

These syndromes may be caused by:

- 1. sprain/strain
- 2. poor posture
- 3. disuse
- 4. overuse
- 5. developmental abnormalities
- 6. joint dysfunction (fixation/hypermobility)
- 7. degenerative changes
- 8. combination of any of the above
- (Schaefer and Faye; 1989; O'Sullivan, 2005).

According to Kirkaldy-Willis (1988), three further aspects must be considered when looking at the origins of low back pain. These include:

- 1. Emotional factors anxiety, depression, fear, tension.
- Changes in muscle impaired local circulation, sustained muscle contraction, vasoconstriction, structural muscle changes and abnormal contraction.
- Changes in the three joint complex strains, synovitis, facet joint syndrome, degeneration and disc degeneration (O'Sullivan, 2005; Waddell, 2004).

For the purpose of this study, only patients with lumbar facet and/or sacroiliac syndrome were included in the research to maintain homogeneity as suggested by Shaefer, Faye (1989) and Waddell (2004).

According to Waddell (2004), the precise cause of pain cannot always be determined. Therefore, approaches to diagnosis and treatment differ and confusion results. Devising a clear strategy for diagnosis of common LBP problems can lead to treatment that is more effective, reduced time off work and loss of income (Weiner and McCulloch, 2000). Giles and Singer (1997) state that it is more important to place low back pain into a diagnostic category than to determine its precise etiology.

Back pain is a symptom and not a diagnosis, as a precise pathoanatomic or pathophysiologic diagnosis is usually elusive. However, its cause, the resultant pain, is due to the chemical irritation of nociceptors(Pain receptors) (Wyke, 1985). There is neither a single cause nor an easy answer to the development of low back pain; rather the related literature points to the result of long term degeneration and tissue failure as the cause. This excludes all cases of severe trauma where the mechanism of low back pain is obvious (Lee, 2004; O'Sullivan, 2005; Vleeming, 2006; Waddell, 2004).

#### 2.3.2 Muscles of the Lumbar and Sacroiliac Joints

#### 2.3.2.1 Muscles of Lumbar Motion

The functions for most muscles in the back are to maintain posture and movements of the vertebral column (Dutton, 2004).

Those muscles that are involved in movement of the intervertebral joints include:

- Muscles that flex the back with the aid of gravity by bilateral action (Rectus abdominus and psoas major);
- Muscles that flex the back by bilateral action (Erector spinae, multifidus and semispinalis thoracis);

- Muscles that laterally bend the back by unilateral action (Iliocostalis thoracis, iliocostalis lumborum, longissimus thoracis, multifidus, external oblique, internal oblique and quadratus lumborum); and
- Muscles that rotate the back by unilateral action (Rotatores, multifidus, external oblique, acting simultaneously with the opposite internal oblique and semispinalis thoracis).

## 2.3.2.2 Muscles of Sacroiliac Motion

Some 35 muscles attach to either the sacrum or ilium. Any muscle that attaches to a bone has the potential to move that bone, within certain degrees of motion. However, the muscles of the sacroiliac joints function for the most part by applying stabilization to that joint (Dutton, 2004).

Joint motion within the sacroiliac joint is actually controlled for the most part by:

- a. Movement of the sacrum when the spinal cord changes position; and
- b. Movement of the sacrum when the lower extremities change position (Bernard and Cassidy, 1991; Lee, 2004; Vleeming, 1995).

There are three major muscle groups that are expected to create stability for effective load transfer during movement of the sacroiliac joint motion. These are:

- Muscle group one are the muscles that flex, extend, or rotate the vertebral column and move the sacrum (Erector spinae, rectus abdominus, multifidus and iliopsoas);
- Muscle group two are the muscles that flex, extend, abduct, adduct, supinate, and pronate the thigh, moving the ilium (Iliopsoas, hamstrings, sartorius, piriformis and gluteus maximus); and
- Muscle group three are the muscles that tilt the pelvis anteriorly or posteriorly moving the sacrum, and those tilting the pelvis laterally, moving the ilium (Gluteus maximus, sartorius, rectus abdominus and iliopsoas) (Mior *et al.*, 1999).

Knowledge of these muscles and their function, in relation to the associated lumbar and sacroiliac joints, is vital for an understanding of their role in neurological control of movement, as they are controlled by a number of muscle receptors. These include muscle spindle receptors, Golgi tendon organs, pressure receptors, and unmyelinated pain receptors (Wyke types I – IV, respectively).

These play important functions in:

- a. Reflex contraction, called the stretch reflex;
- b. Nociceptive and thermal detection; and
- c. Detection of rapid mechanical deformation (Leach, 1994).

Keeping in mind that back pain is a symptom and not a diagnosis, the resultant pain is due to the chemical irritation of these receptors (Wyke, 1985).

#### 2.3.2.3. Concept of Spinal stability

Core stability is a description of the muscular control required around the lumbar spine to maintain functional stability (Akuthota, 2004). Wisbey-Roth (1996: 501 – 508; 2000) defined core stability as the optimal alignment and control of the spine and pelvic girdle to ensure efficient load transfer of forces across the segment, resulting in greater precision and safety of dynamic activity (precise information used). Core stability results from highly coordinated muscle activation patterns involving many muscles, which provide support and control of the joints, and that the recruitment patterns must continually change, depending on the task (Jull, 1993; McGill, 2003).

Panjabi (1992) was the first to suggest a three pillar system of spinal stability, which included the active, passive and control subsystems, which was later updated by Lee, in 1998, and again by Lee and Vleeming (2004) to a four component model of integrated joint function, as illustrated below in Fig 1.2.



Lee D G/Lee L J 2004

According to the Lee (2004) model of integrated joint function, adequate approximation of the joint surfaces must be the result of all forces acting across the joint to secure stability. Therefore, the body's ability to effectively transfer load through joints is dynamic and requires integrated functioning of the neuromusculoskeletal system. The first component, form closure, comprises of intact bones, joints and ligaments. In a stable joint, with closely fitting articular surfaces, no extra forces are needed to maintain the stability of the system, given the actual load situation. To assess stiffness, the zones of motion available to every joint must be considered, including the neutral and the elastic zones. The neutral zone is a small range of movement near the joint's neutral position, where minimal resistance is given by the osteoligamentous structures. The elastic zone is the part of the motion from the end of the neutral zone, up to the physiological limit. The size of the neutral zone may increase with injury, articular degeneration and/or weakness of the stabilizing musculature (Panjabi, 1992; Lee, 1998; Snijders et al., 1993; Vleeming, 1995).

The second component, according to Lee (2004), is called force closure and relies on optimal function of the muscles, which includes the ability to contract tonically in a sustained manner. Force closure reduces the size of the neutral zone and thus, shear is controlled between the two joint surfaces. Several ligaments, muscles and fascial systems contribute to force closure of the pelvis. The inner unit consists of the muscles of the pelvic floor, TA, multifidus and the diaphragm - also known as the local stabilizers. The outer unit consists of several slings or systems of muscles (global stabilizers and mobilizers) that are anatomically connected and functionally related. When muscles contract, they produce a force that spreads further than the origin and insertion of the active muscle. This force is transmitted to the muscles, tendons, fascia, ligaments, capsules and bones that lie both in series and in parallel to the active muscle. In this manner, forces are produced distant from the origin of the initial muscle contraction (Lee, 1998; Snijders et al., 1993; Vleeming, 1995).

The third component, motor control, is the ability of the muscles to perform in a co-ordinated manner such that the generated forces are adequately compressed through the articular structures at an optimal point; in other words, the timing of specific muscle action and release is essential. Motor skill requires co-ordination of muscle action for stability to be maintained and loads to be transferred effortlessly. The last component is that of neural control (emotions and awareness), which ultimately drives the pattern of motor control. This requires constant accurate afferent input from the mechanoreceptors in the joint and surrounding soft tissues, appropriate interpretation of the afferent input and a suitable motor response (Lee, 1998, 2004; Snijders et al., 1993; Vleeming, 1995). The lumbar multifidus (LM) and TA muscles in particular, have been shown to have the greatest contribution to the control of the neutral zone (Panjabi, 1992 and Richardson, 1995). Wilke (1995), in a biomechanical study, demonstrated that the LM provided more than two thirds of the stiffness increase at the L4-L5 Lumbar segments. Results of a study by Hodges (2003), indicate that elevated intra-abdominal pressure and contraction of the diaphragm and TA, provide a contribution to the control of intervertebral stiffness or stabilization, particularly with regards to the drawing in of the abdominal wall.

#### • The spinal stabilizing system according to Panjabi:

Panjabi's theory of the spinal stabilizing system (1992) consists of three separate but closely linked systems that play a major role in stabilizing the lower back: the passive spinal column, the active spinal muscles, and the neural control system.





# <u>Components of the spinal stabilizing system:</u>

The three subsystems that play a role directly and/or indirectly in the stability of the spinal system are outlined by Panjabi (1992) as:

# • <u>The passive musculoskeletal subsystem:</u>

This includes vertebrae, facet joints, intervertebral discs, spinal ligaments and joint capsules, as well as the passive properties of the muscles.

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#### 2.3.3 The lumbar zygopophyseal joints:

#### 2.3.3.1 Anatomy

The zygopophyseal joint is formed by the junction between the superior and inferior facets of the articular processes, on one side of two adjacent vertebrae.

A synovial membrane lines the articular capsule, ligamentum flavum and synovial joint folds. They are diarthroidal synovial joints surrounded by a capsule posterolaterally and the ligamentum flavum anteromedially (Gatterman, 1995).

The articular processes are large, thick, and strong. The superior articular processes are concave and face posterior and medial, while the inferior articular processes are convex and face anterior and lateral. The lumbar facets lie primarily in the sagittal plane, but become more coronal at the lumbrosacral junction (Bergmann <u>et al.</u> 1993).

#### 2.3.3.2 Innervation

The zygopophyseal joint capsule receives a rich supply of sensory innervation. The sensory supply is derived from the medial branch of the posterior primary division (dorsal ramus), at the level of the joint, and each joint also receives a branch from the posterior primary division of the level above (Gardner, 2000).

Three types of sensory receptors occur in the facet joint capsule:

- <u>Type 1</u>: sensitive static and dynamic mechanoreceptors that fire constantly, due to continual joint motion.
- <u>Type 2</u>: less sensitive mechanoreceptors that fire only on joint motion.

Type 3: slow conducting mechanoreceptors (Gatterman, 1995:).

#### 2.3.3.4 Function

The lumbar facets normally carry 18 per cent of axial load and up to 33 per cent in extended postures. The facets with their articular capsules provide up to 45 per cent of the torsional strength of the lumbar spine (Bergmann <u>et al.</u> 1993).

The lumbar facet joints also guide and restrain movement between vertebrae and protect the discs from shear forces, excessive flexion and axial rotation (Giles, 1997).

### 2.3.4 The sacroiliac joints:

#### 2.3.4.1 Anatomy

The sacroiliac articulation is a true synovial joint, having a joint cavity containing synovial fluid and enclosed by a joint capsule. The articular surface is described as auricular, a letter C lying on its side. The articular surfaces have different contours, which develop into interlocking elevations and depressions (Giles, 1997).

The morphologic configuration of the sacroiliac joints is not static and is extremely variable from individual to individual (Bergmann <u>et al.</u> 1993). Microscopic examination of the joint surfaces reveals a fibrocartilage that covers the iliac side, while the sacral surface shows a thicker, hyaline cartilage (Gatterman, 1990).

A number of strong ligaments aid in stabilizing the pelvic mechanism:

- The posterior sacroiliac ligaments
- The sacrotuberous ligaments
- The anterior sacroiliac ligaments
- The sacrospinous ligaments
- Sacroiliac interosseous ligaments
- Iliolumbar ligaments (Bergmann <u>et al.</u> 1993).

There is scant mention in the literature of the structure of the capsule of the sacroiliac joint because the joint is so intimately surrounded by thick ligaments. Results from research state that the posterior capsule is rudimentary or absent and the anterior sacroiliac ligament is a thickening of the anterior capsule (Gardner <u>et al.</u> 2000).

#### 2.3.4.2 Innervation

The articular branches of these joints are derived from the superior gluteal nerves, the sacral plexus and the dorsal rami of the S1 and S2 nerves. The posterior aspect of the sacroiliac joint is innervated by both posterior rami of L5-S2 spinal nerves, while the anterior aspect is innervated by both posterior branches from the L3-S2 roots and superior gluteal nerve L5-S2 (Moore <u>et al.</u> 1999).

## 2.3.4.3 Function

The shape and the configuration of the posterior joints are important to their function. The articular surfaces have different contours, which develop into interlocking elevations and depressions. This bony configuration produces what has been termed, a keystone effect of the sacrum, effectively distributing axial compressive forces through the pelvic mechanism. Forces from the lower extremities divide, heading upward toward the spine and anteriorly toward the pubic symphysis, while downward forces of gravity on the spine split to both sides (Bergmann <u>et al.</u> 1993).

#### 2.3.5 Active and Passive Subsystems

#### 2.3.5.1. The active musculoskeletal subsystem:

This system includes the muscles and tendons surrounding the spinal column.

The muscles of the trunk can be divided into an outer global system and a deep local system. The global system consists of the large torque producing muscles that provide general spinal stability by countering external loads and produce large multiplanar movements of the spine. Examples include the quadratus lumborum and erector spinae (Stanford, 2002).
The local muscles of the spine attach directly to the vertebrae and are primarily responsible for segmental stability. The multifidus and transversus abdominus muscles are considered to be local muscles of the lumbar spine (Stanford, 2002).

The attachments, actions and innervations of the main core muscles are demonstrated in the following two figures:

Figure 5: The left transversus abdominis muscle and its attachments,

innervation and action



(The University of Auckland, Bioengineering Institute, <u>www.auckland.ac.nz</u>).

Figure 6: Multifidus muscle and its attachments, innervation and action



(The University of Auckland, Bioengineering Institute, www.auckland.ac.nz).

## The spinal stabilizing functions of transversus abdominus and multifidus are discussed below:

a. The lumbar multifidi (LM):

The LM have been found to be the largest contributors to intersegmental stability within the neutral zone<sup>1</sup>. The LM do not appear to change in length during active lumbar movements, which supports the theory that the LM are responsible for stabilizing intersegmentally,

<sup>&</sup>lt;sup>1</sup> The neutral zone is that part of the range of physiological motion, measured from the neutral position, within which the spinal motion is produced with a minimal internal resistance. The neutral zone appears to be a clinically important measure of spinal stability function.

rather than assisting the global muscles in producing trunk movement (McGill, 1991).

LM, when compared to other muscles in close proximity to L4-L5, contributed two-thirds of the increased stiffness imparted by the contraction of the muscles (Wilke <u>et al.</u> 1995).

## b. The transversus abdominus (TA):

This muscle functions differently from the other abdominal muscles. The TA contracts regardless of the direction of trunk movement. Also, with trunk perturbations, it is recruited prior to all other abdominal muscles (O'Sullivan <u>et al.</u> 1998).

TA is the only abdominal muscle active during phasic movements, highlighting its role as an active stabilizer of the spine, and it prepares the body for the disturbances produced by movement of the lower limbs (Richardson, 1995).

TA is the only abdominal muscle that has an aponeurotic attachment to the middle layer of the thoracolumbar fascia (TLF) (Bogduk, 1997). TA helps control intersegmental motion via production of lateral tension in the TLF, which raises intra-abdominal pressure (Evans and Oldrieve, 2000; Vleeming, 1995).

The contraction of the transversely orientated fibres of TA, independently of the other abdominal muscles, reduces the laxity of the sacroiliac joints to a larger extent than a bracing action using all of the lateral abdominal muscles (Richardson <u>et al.</u> 2002).

### 2.3.5.2 The neural control and feedback subsystem:

This includes the various force and motion transducers located in ligaments, tendons and muscles and the neutral control centre (brain).

## 2.3.5.3 Normal functioning of the spinal stabilizing system:

The spinal stabilizing system adjusts so that the neutral zone remains within certain physiological thresholds to avoid clinical instability. An increase in the neutral zone indicates clinical instability<sup>2</sup> (Panjabi, 1992; Lee, 2004). Thus, normal functioning of the subsystems of the spinal stabilizing system is important in providing spinal stability (Vleeming et al., 2006)

## 2.3.5.4 The passive (ligamentous) subsystem:

Components of this subsystem do not provide any significant stability to the spine in the vicinity of the neutral position. It is towards the ends of the ranges of motion that the ligaments develop reactive forces that resist spinal motion.

This subsystem is passive only in the sense that it, on its own, does not generate or produce spinal motions, but is dynamically active in monitoring transducer signals for measuring vertebral position and motions (Panjabi, 1992: Lee 2004; Richardson et al., 2002).

## 2.3.5.5 The active (musculotendenous) subsystem:

The muscles and tendons of the active subsystem are the means through which the spinal system generates forces and provides the required stability to the spine. The magnitude of the force generated in each muscle is measured by the force transducer's build into the tendons of the muscles. Therefore, this aspect of the tendons is part of the neural control subsystem (Panjabi, 1992:I; Lee 2004; Richardson et al., 2002 ).

<sup>&</sup>lt;sup>2</sup> Clinical instability is defined as a significant decrease in the capacity of the spinal stabilizing system, to maintain the intervertebral neutral zones within the physiological limits so that there is no neurological dysfunction, no major deformity and no incapacitating pain. An increase in the neutral zone size is an indicator of clinical instability. Dysfunction within any of the three subsystems can lead to an increase in size of the neutral zone. (Panjabi, 1992:II)

#### 2.3.5.6 The neural control subsystem:

This subsystem receives information from the various transducers, determines specific requirements for spinal stability and causes the active subsystem to achieve the stability goal. Individual muscle tension is measured and adjusted until the required stability is achieved. The requirements for the spinal stability and, therefore, the individual muscle tensions, are dependent on dynamic posture, that is, variation of lever arms and inertial loads of different masses and external loads (Panjabi, 1992:I; Lee 2004; Richardson et al., 2002).

### 2.3.6 Dysfunction in the three subsystems:

#### 2.3.6.1 Passive subsystem dysfunction:

Dysfunction may be caused by mechanical injury, such as overstretching of ligaments, development of tears and fissures in the annulus, development of micro-fractures in the end-plats and extrusion of disc material into the vertebral bodies (Panjabi, 1992:I; Lee 2004; Richardson et al., 2002).

### 2.3.6.2 Active subsystem dysfunction:

This subsystem may develop deterioration of its ability to receive and/or carry out the neural commands, to provide accurate feedback of muscle tension information to the neural control unit, or to produce co-ordinated and adequate muscle tensions; such deformation may result from disuse, degeneration, disease or injury (Lee 2004; Richardson et al., 2002). As the muscles and tendons of the active subsystem are the means through which the spinal stabilizing system generates forces and provides the required stability to the spine, the effect of the weakened abdominal muscles results in dysfunction within the active musculoskeletal subsystem, which results in spinal instability and LBP (Richardson et al., 2002).

#### 2.3.6.3 Neural subsystem dysfunction:

This system has the enormously complex task of monitoring and adjusting the forces in each of the muscles surrounding the spinal column. Errors in the firing patterns of muscles may cause dysfunction in this subsystem. Too small or too large muscle forces and/or too early or too late firing of muscles can affect this subsystem. In addition to damaging the active subsystem, muscle force errors might lead to overload of a passive structure (e.g. Disc) (Panjabi, 1992:I; Lee ,2004, Lee et al., 1998).

There is evidence to suggest that the presence of acute low back pain often results in a general loss of function and de-conditioning, as well as changes to the neural control system, affecting timing of patterns of co-contraction, balance, reflex and righting responses (O'Sullivan <u>et al.</u> 1997). Such disruptions to the neuro-muscular system leave the lumbar spine potentially vulnerable to instability, particularly within the neutral zone (Cholewicki & McGill, 1996). This is supported by the clinical trial performed by Uys (2006), which showed that the spinal manipulative correction of joint dysfunction, within the lumbar and sacroiliac regions of the spine, allowed for improved endurance time measures for the abdominal core stabilizing musculature in patients suffering with chronic mechanical low back pain.

#### In summary:

According to McGill (1993), only a modest amount of stability is required to stabilize a joint; if there is too little stiffness, the joint will buckle under load. Too much stiffness will cause massive loads and limit joint motion. Too much compression over a long period of time will wear out the joints and lead to osteoarthritis. Too little compression creates episodes of giving way and collapse (Lee, 2004). Interestingly, the literature shows that in most situations only a modest amount of stability is required to stabilize a joint (McGill, 2003). Cholewicki and McGill (1996) and Cholewicki (1997) have demonstrated that sufficient stability of the lumbar spine (neutral spine) is achieved with modest levels of co-activation of agonist and antagonist muscles that lie each side of

the joint. Motor control endurance is essential to achieving the stability target under all possible conditions of performance (McGill 2003).

The muscles of the local system are deep and, anatomically, are closely related to the individual vertebrae. They are capable of increasing spinal segmental stiffness. Muscles of the global system are primarily the larger torque-producing muscles and are more remote from the joint but important for controlling spinal orientation and balancing external loads. Both local and global muscle systems, and the normal synergistic function between the two systems, are required for spinal stabilization and support (Jull, 2000).

Akuthota (2004) proposes that the core musculature serves as the centre of the functional kinetic chain and a comprehensive strengthening or facilitation of these core muscles has been advocated as a way to prevent and rehabilitate various lumbar spine and musculoskeletal disorders, and as a way to enhance performance.

Literature supports the theory that the most acceptable means to stabilize a hypermobile lumbar spine that may be symptomatic, is to strengthen the abdominal core stability in order to decrease mechanical stress to the spine (Saal, 1988; Panjabi, 1992; Jull and Richardson, 1994).

According to Panjabi (1992), the resultant weakening of the abdominal muscles may have negative implications on spinal stability. This is because these muscles are responsible for maintaining the stability of the spine (Lee 2004; Richardson et al., 2002).

Panjabi (1992) stated that if there was an increased passive neutral zone – for example, due to degeneration or trauma – then the muscles would be potentially capable of decreasing the neutral zone and bringing it to within normal values, thus reducing the instability (Lee 2004; Lee et al. 1998; Richardson et al., 2002).

Therefore, the literature supports the suggestion that weakened abdominal musculature may be an important cause of acute LBP.

### 2.3.7. Lumbar facet and sacroiliac syndrome

#### 2.3.7.1 Lumbar facet syndrome:

• Symptoms:

Pain is often localised and unilateral, but may also be referred to the groin, greater trochanter, and posterior thigh as far as the knee (Kirkaldy-Willis <u>et al.</u> 1992). Activities that may increase the pain include; sleeping on the abdomen, sitting in an upright position, and lifting a load in front of the body at or above the waistline. When symptoms are acute, sneezing and coughing may accentuate the pain (Gatterman, 1995).

• Clinical signs:

Hyperextension movements of the back may increase the pain, whereas flexion reduces it (Gatterman, 1995).

Ranges of motion abnormalities include changes in active, passive, and accessory joint motion. It is thought that a decrease in motion is a common component of joint dysfunction. Range of motion abnormalities are identified through motion palpation and stress radiography (Bergmann <u>et al.</u> 1993).

### 2.3.7.2 Sacroiliac syndrome:

• Symptoms:

Pain accompanying the sacroiliac syndrome is typically unilateral, dull in character, and located over the buttocks. It may radiate posteriorly down the thigh or to the groin and anterior thigh. Occasionally, it may extend down the lateral or posterior calf to the ankle, foot and toes. Sensory changes are rare (Gatterman <u>et al.</u> 1990). Pain may be worse with weight bearing, moving from sitting to standing, and walking. It is also relieved by recumbency (Gardner <u>et al.</u> 2000).

## • Clinical signs:

Focal tenderness over the involved sacroiliac joint, which increases with joint challenge. This may be accompanied by a leg length indiscrepancy, guarded gait and myospasm of gluteal/low back musculature. Altered sacroiliac motion and joint play may be found along with palpatory and postural signs of misalignment (Gardner, 2000).

### In summary:

With the incidence and prevalence of LBP being so high, it could be reasonably postulated that both sacroiliac and/or lumbar facet dysfunction could be instrumental (Bernard and Kirkaldy-Willis, 1987; Toussaint et al., 1999).

## 2.4. Management of acute low back pain

## 2.4.1 The management of mechanical low back pain in the general population

A wide range of therapies, including rest, medications, physical modalities, and surgery, to name only a few, are available as treatment for LBP. The variety of possible therapies has resulted in confusion for the primary care physician concerning appropriate treatment for specific forms of LBP (Borenstein, 1995). This disparity leads to the meritable conclusion that more research is required to accurately identify solutions for the management of low back pain (Walker, 1997). Patients should be encouraged to limit bed rest. A major thrust of the guidelines is to encourage movement and a return to full function. The recommendations on bed rest, spinal manipulation, and exercise may all be seen as methods to motivate patients to regain normal motion of the lumbosacral spine. Recommendations for medications maximize the use of drugs with mild toxicities and little abuse potential. In general, investigation and invasive therapies are limited to those LBP patients who fail to improve over a 4 to 12-week period. Only a small minority of patients require surgical intervention (Borenstein, 1995; Richardson and Jull, 1995).

Research shows that the therapy of LBP patients can be frustrating for the busy primary care physician. A number of therapeutic options are possible for these patients, but none are clearly curative. Published guidelines are useful for treating most patients with LBP. They are not applicable to most patients with lumbosacral disease, including those with systemic causes of LBP (Borenstein, 1995; O'Sullivan et al., 1997).

### 2.5 Whole body vibration exercise or Acceleration training

## 2.5.1 The effects of Whole body vibration exercise or Acceleration training

Bosco (1999) found that regardless of your physical condition, utilization of Whole Body Vibration (WBV) or acceleration training, at the right frequency setting, will lead to subconscious stretch reflexes that in turn will tighten almost all the patient's muscles simultaneously. This is compared to just 45% of muscle fibres used by the general population during conventional training. Traditional power training increases muscle strength because people's bodies react to the extra resistance created by the weights or elastic, over and above normal gravity. But with WBV training, the body reacts to acceleration rather than extra mass: a force many times greater than standard training stimuli and one repeated 30 or 50 times a second. Due to this higher rate of muscle contraction, the body has to adapt even more to overcome this greater load, leading to training targets being achieved faster due to specific, dynamic, high intensity training (Bosco. et al.,1999).

WBV or acceleration training increases the production of regenerative and repair hormones (Kvorning et al., 2006), improves blood circulation in skin and muscles (Rittweger, J., et al.2002), strengthens bone tissue, improves lymph drainage and increases the basal metabolic rate. All this results in more strength, more speed, more stamina, rapid recovery of muscles and tissue, increased flexibility, mobility and co-ordination, collagen improvement, and fat reduction (Cardinale and Lim, 2003).

The "more is better" principle does not apply to vibration training. The added value of WBV or acceleration training, is improved training quality and effectiveness, so you can shorten your sessions and recover quickly afterwards (Kvorning et al., 2006; Rittweger, J., et al.2002; Cardinale and Lim, 2003).

Whole body vibration has been used in sports medicine, rehabilitation, general wellness and health and in specific athletic training. (Bosco, C., et al. 1999; de Ruiter et al., 2003).

## 2.5.2 Effects of Whole body vibration exercise or Acceleration training on skeletal muscle.

Vibration of a muscle stimulates the primary endings of the muscle spindle (la afferents), which excites a-motoneurons, causing contraction of the motor units and this results in a tonic contraction of the muscle - referred to as the tonic vibration reflex. Electromyogram data have revealed that the tonic vibration reflex has both a monosynaptic and a polysynaptic component (Cram and Kasman, 1998).

Further evidence demonstrating the complexity of the tonic vibration reflex can be observed in a decerebrate cat, as even in this condition, the tonic vibration reflex can be elicited. The response of the tonic vibration reflex is also dependent on the frequency of vibration, the level of precontraction of the muscle, and the position of the body (Martin, 1997).

During an exposure to vibration, the stretch reflex and the Hoffman-reflex (Hreflex) are inhibited, and this has been referred to as the vibration paradox induces the tonic vibration reflex but inhibits the stretch reflex and the Hreflex. This is due to presynaptic inhibition of the Ia afferents of the muscle spindle, which permits excitation of the pathways relating to vibration and inhibition of the pathways responding to stretch (Thompson and Belanger, 2002).

The depression of the H-reflex has been shown to be greater than the depression of the stretch reflex, although the exact mechanism for this difference has been difficult to identify. In the post vibratory period, the stretch reflex displays a marked potentiation in contrast with the H-reflex that displays a gradual recovery up to normal values over a period of about 100 seconds (Thompson and Belanger, 2002).

The depression of the H-reflex during exposure to vibration is greater, as the amplitude of the vibration increase at a constant frequency, but the depression remains unchanged if the amplitude is constant as the frequency of vibration increases (Thompson and Belanger, 2002).

Research also indicates that vibration compensates for the reduction in motor output in a fatigued state, when the exposure is preceded by a prolonged maximal voluntary contraction (i.e., 4 minutes) (Martin, 1997). It has been hypothesized that, in a fatigued state, vibration compensates for the decreased g-motoneuron drive by exciting the la afferents and this results in the reflexive excitation of the a-motoneurons and greater force output. The effects of vibration on skeletal muscle described above are well documented (Martin, 1997; Thompson and Belanger, 2002).

## 2.5.3. Effectiveness of Whole body vibration exercise or Acceleration training in the treatment of acute low back pain.

It is thought that chronic low back pain (CLBP) emerges from acute pain of muscle and connective tissues, which persists in approximately 30% of acute cases and becomes chronic (Thomas E et al., 1999). This generally occurs without specific damage or symptoms that could be shown through imaging or neurophysiological techniques. Besides somatic factors, psychological and social factors play an important role in chronification (McGorry <u>et al.</u>, 2000). Therefore, CLBP often is referred to as "unspecific."

The pathophysiologic emergence of LBP is as unclear as its diagnostic criteria. Besides pain sensation, findings generally encountered in patients with LBP are reduced lumbar flexibility, reduced flexion–relaxation observed in healthy subjects, and static balance (Alexander and LaPier, 1998; Kaigle et al., 1998). Hence, it is mostly accepted that muscular systems, as well as connective tissues and neural systems, are involved in the pathophysiology of LBP.

An often-repeated view is that different initial damages may lead to a muscular hypertonus, and hence to an inadequate circulation, which promotes muscular atrophy and pathophysiological loading patterns, which further establish pain and pain chronification (Marras et al., 1999: Webster et al., 2000).

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Although exercise therapy appears to be without benefit in the acute state, some types of exercise seem to be effective (van Tulder et al., 2000). Among these types are resistance training, stretching, or freely chosen exercise (Hartigan et al., 1995; Johannsen et al., 1995; Khalil et al., 1992). In particular, lumbar extension has turned out to be effective if performed correctly for acute low back pain (Rissanen et al., 1995).

Whole-body vibration (WBV) exercise is a type of exercise currently being tested in sports, geriatrics, and rehabilitation (Bosco et al., 1999; Fritton et al.1997). It elicits muscular activity *via* stretch reflexes. Recently, we have shown that metabolic power increases during whole-body vibration exercise (Rittweger <u>et al</u>. 2001), and that this WBV-related metabolic power is augmented by the application of additional loads to the shoulders (Rittweger et al. 2002), suggesting an enhanced activity of the trunk muscles.

In experimental acute lower back pain, stretch reflexes are unchanged, whereas EMG modulation during voluntary lumbar flexion–extension clearly is affected (Zedka et al., 1999). Hence, a hypothesis that WBV could elicit trunk muscle stretch reflexes, and thus be a means of activating and strengthening these muscles. It has been shown that vertical platform vibration of 3 to 10Hz evokes electrical activity of the erector spinae muscle, indicating an increased muscular torque caused by vibration (Seroussi et al. 1989). The researchers, however, discussed their results mainly with respect to the emergence and 'chronification' of lower back pain.

Personal experience, however, and case observations have shown that controlled WBV may indeed be beneficial for acute lower back pain. Therefore, the current study was designed to test the applicability of WBV for patients with acute LBP in a randomized therapy control study.

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#### 2.6. Core stabilization

## 2.6.1 Co-contraction between transversus abdominus and multifidus muscles

Poor postural control places excessive stress on the body tissues and can leave the spine vulnerable to injury (Kendall et al., 1993). One important aspect of posture, with reference to the lumbar spine, is the ability of the trunk muscles to protect the spinal tissues from excessive motion. To do this, the muscles surrounding the trunk must be able to co-contract isometrically in functional situations (Richardson et al., 1990).

The transverus abdominus and multifidus muscles are two core stabilizers that have been found to be related through a co-contraction pattern, which is considered to provide support and joint stabilization (Richardson and Jull, 1995).

## Figure 7: Co-contraction between transversus abdominus and multifidus muscles



(www.back-exercises.com. Retrieved on 10 December 2007)

### 2.6.2 Dysfunction of the co-contraction mechanism

The literature reports varying disruptions in the patterns of recruitment and cocontraction within and between different muscle synergies in low back pain populations (O'Sullivan et al., 1997b).

There is growing evidence that the deep abdominals and lumbar multifidus muscles are preferentially adversely affected in the presence of low back pain (Hides et al., 1996), chronic low back pain (Roy et al., 1989; Biedermann et al., 1991; Hodges & Richardson 1996), and lumbar instability (Sihvonen et al., 1991; Lindgren et al., 1993; O'Sullivan et al., 1997).

Evidence that the transversus abdominus and multifidi muscles are significantly affected during and after episodes of low back pain, indicates that rehabilitation should focus on retraining these muscles in particular. Further, the finding that the multifidi do not spontaneously recover is extremely relevant to clinical settings. It suggests that although patients may appear to be pain free, without stabilization exercise they may actually be vulnerable to future episodes of low back pain (Stanford, 2002).

There have also been reports that compensatory substitution of global system muscles occurs in the presence of local muscle system dysfunction. This appears to be the neural control system's attempt to maintain the stability demands of the spine in the presence of local muscle dysfunction (Richardson & Jull, 1995; Edgerton et al., 1996; O'Sullivan et al., 1997).

#### 2.6.3 Core stabilization exercises

Meticulous technique is imperative while performing these exercises. Each exercise is designed to develop isolated and co-contraction muscle patterns to stabilize the lumbar spine. Each patient should be monitored during the exercise program to define the optimal spine position. Care should be taken to ensure proper form while performing the relevant exercises (Saal, 1990).

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A high level of awareness is demanded of subjects in order that they isolate the co-contraction of the local muscle system without global muscle substitution. The aim is to train the specific isometric co-contraction of transversus abdominus with lumbar multifidus at low levels of maximal voluntary contraction, and with controlled respiration (O'Sullivan, 2000).

The transversus abdominus and multifidi consist primarily of slow-twitch, type-1 fibres that allow for low load, endurance contraction. Therefore, it follows that prolonged low-intensity isometric exercise would be most beneficial for re-educating and strengthening these muscles.

## 2.6.4 Benefits of core stabilization exercises utilizing whole body vibration`

Exercise beginning with isolated contraction of the transversus abdominus and multifidi followed by progressive stability training, has been shown to be effective in improving muscle endurance (Stanford, 2002). Several clinicians have reported using WBV or acceleration training in their spinal stabilization program to challenge balance and facilitate recruitment of spinal stabilizers once the patient has mastered the activity on the floor (Liggett, 1999).

The use of WBV or acceleration training has undergone exponential growth over the past years, with evidence showing benefits in improving joint range of motion, strength, spinal stabilization and proprioception. The incorporation of proprioception and kinesthetic sense exercises are necessary to stimulate joint receptors and for restoring normal muscular firing patterns necessary for functional activity. The premise of using an unstable base of support to stimulate joint proprioceptors, such as the WBV or acceleration training, has been effective on other joints as well (Liggett, 1999). A study by Liggett & Randolph (1999) compared abdominal strength gains from exercises performed on a mat, in comparison to those performed on a ball, and found that although both improved abdominal muscle strength, the ball exercises produced the largest strength gain.

Cosio-Lima et al. (2003) performed a study in which the effects of Swiss ball exercises and conventional floor exercises in women were compared. Results indicated that a short term core exercise program using the ball resulted in greater gains in torso balance and electromyographic neuronal activity in previously untrained women when compared to performing exercises on the floor.

Therefore, the use of dynamic core stability exercises, utilizing the WBV or acceleration training, may be a more effective means of progressing a core stabilization exercise program (Liggett & Randolph, 1999; Cosio-Lima, 2003; Stanford, 2002).

### 2.6.5 Effects of the core stabilization exercises

The purpose of the exercise is to isolate the correct muscle action in all exercise positions and develop holding ability. The importance of isolating the muscle action relates to motor control issues (Richardson & Jull, 1995). Exercise involving co-contraction of the deep abdominal and back muscles is in line with stabilization. Furthermore, a simultaneous isometric co-contraction of transversus abdominus and multifidis muscles, while maintaining the spine in a static neutral position, should help re-educate the stabilizing role of these muscles (Richardson & Jull, 1995).

Literature supports the theory that the most acceptable means to stabilize a hypermobile lumbar spine that may be symptomatic, is to strengthen the abdominal core stability to decrease mechanical stress to the spine (Saal, 1988; Panjabi, 1992; Jull and Richardson, 1994; Lee, 2004; Vleeming, 2006).

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Panjabi (1992) stated that if there was an increased passive neutral zone – for example, due to degeneration or trauma – then the muscles would be potentially capable of decreasing the neutral zone and bringing it to within normal values, thus reducing the instability. So, it can be suggested that reeducating the stabilizing role of the core musculature would have this described effect of reducing the neutral zone, and thus decreasing the instability within the lumbar spine.

Therefore, core stability exercises, as a means to stabilize hypermobile segments and regain mechanical control of the spine, may be particularly beneficial for acute low back pain sufferers (Cosio-Lima et al., 2003).

### 2.6.6 Effectiveness of the core stabilization program

- A single case study by Stanford (2002), to evaluate the effect of specific lumbar stabilizing exercises, revealed that the subject had increased lumbar range of motion, decreased pain measures, increased functional ability and also gave a high self report of improvement as compared to the initial consultation.
- b. A randomized clinical trial into the effectiveness of core stabilizing exercises involving the transversus abdominus and multifidus muscles showed that after one year, recurrence in the treatment group was 30% compared to 85% in the non-treatment group (p<0.001) and 35% in the treatment group compared to 75% in the non-treatment group after a 3year follow-up (Hides et al., 2001).

#### In summary:

Clinical trials investigating the benefits of core stability muscle training programs for patients with low back pain revealed positive results (Hides et al., 2001; Stanford, 2002; Stuge, 2004).

Core stabilization involves the transverus abdominus and multifidus muscles, which have been found to be related through a pattern of co-contraction, which is considered to provide support and joint stabilization (Richardson and Jull, 1995). Current evidence suggests that utilizing a dynamic stability approach to performing exercises may hold further advantages with respect to muscle activation (Liggett, 1999; Liggett & Randolph, 1999; Cosio-Lima et al., 2003).

Therefore, the literature supports the suggestion that core stabilization exercises may be effective in the treatment of acute low back pain.

### 2.7 Summary

The review of literature revealed that weakening of core stabilsing musculature (Panjabi, 1992; Richardson et al., 1999) and joint dysfunctions of the lumbar facet and sacroiliac joints (Manga et al., 1993; Bergmann et al., 1993), are important causes of low back pain.

Bailes (1998) showed that the correction of lumbar facet and sacroiliac joint syndromes, using manipulation, is effective in the treatment of low back pain.

Literature supports the theory that the most acceptable means to stabilize a hypermobile lumbar spine that may be symptomatic, is to strengthen the abdominal core stability to decrease mechanical stress to the spine (Saal, 1988; Panjabi 1992; Jull and Richardson, 1994).

Clinical trials, investigating the benefits of core stability muscle training programs for patients with low back pain, revealed positive results (Hides et al., 2001; Stanford, 2002; Stuge, 2004).

Due to ligaments laxity and the weakening of the entire abdominal 'corset' that occurs in the general population, core stability exercises as a means to stabilize hypermobile segments and regain mechanical control of the spine, may be particularly beneficial for these people (Cosio-Lima et al., 2003).

Literature suggests that optimal core muscle strength, control and endurance working synergistically with the rest of the neuromusculoskeletal system, is necessary for lumbar spine stability (Panjabi, 1992, Jull and Richardson, 2000, Arakoski, 2001, Lee, 2004, McGill, 2003, Akuthota, 2004; Vleeming, 2006).

The success, achieved through the effects of WBV or acceleration training, is suggestive that its use in dynamic core muscle stability training may be more beneficial than normal static exercises and lead to improved endurance of the lumbar pelvic stabilizers, leading to a decrease in mechanical stress on the low back.

The literature supports the outcome hypothesis that dynamic WBV or acceleration training is a better option for core stabilizing exercises in terms of objective and subjective clinical findings, as opposed to static core muscle stabilization exercises, in the treatment of acute low back pain.

Therefore, the aim of the study is to test this hypothesis based upon the literature, by determining whether dynamic WBV or acceleration training is a more effective form of core muscle stabilization in acute low back pain sufferers with regards to core muscle endurance and activation in the treatment of acute low back pain.

## Chapter 3

## Materials and Methods

## 3.1 Introduction

This chapter gives a detailed description of the methods employed in data collection from the subjects and the interventions utilized, as well as the methods of statistical analysis and the process of the evaluation of the data. The study was a quantitative, randomized, comparative clinical assessment of the effectiveness of core stabilization utilizing acceleration or vibration training in patients with acute LBP between the ages of 18 and 60. This involved two groups which received core stabilization exercises on the Power-plate for the treatment of acute LBP. Questionnaires were presented prior to each treatment in order to gather empirical data on the patients' perceived reaction to treatment and pain rating following the treatment.

## 3.2 Advertising

For the purpose of the study the means of advertising included posters and leaflets. Leaflets regarding the research were handed out at the Durban University of Technology campus, sport clubs and action sport arenas, in the greater Durban area - with the permission of the respective authorities - in order to attract potential participants (Appendix D).

## 3.3 Sampling

## 3.3.1 Size

The sample size required a total of 30 patients allocated to two groups (15 per group) in order to achieve statistical validity. All subjects volunteered as per prevailing ethical requirements, and 6 withdrew from the study after being unable to adhere to the follow up visit times as stipulated in the Information Letter provided at the start of the study.

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### 3.3.2 Allocation

Patients who met the requirements for the study, according to the inclusion and exclusion criteria, were assigned to a treatment group or control group using a computer generated randomized numbers table. For the purpose of the study, 30 patients were selected using selective sampling from the patients who satisfied the criteria.

## 3.3.3 Method

The method used for sampling was self-selection sampling with computer generated randomization numbers tables utilized for group placement.

A telephonic interview was conducted initially, and pertinent questions were asked to determine whether the patients were suitable candidates for the research sample. These questions included:

- Are you between 18 and 60 years of age?
- Where is your area of pain? Is it LBP?
- Do you have any associated radicular or leg pain?
- Do you have a history of trauma or surgery?
- How long has the pain been there? Has it been less than 2 weeks?
- Do you have any numbness, tingling, pins and needles, muscle weakness or other neurological signs?

These questions decreased the chance of unsuitable candidates being called upon for an initial consultation and referral was made at the telephonic screening stage where appropriate care was required.

Compliance with the following criteria was obtained at the first consultation from the patient history (appendix H), physical (appendix I), and regional lumbar and pelvic examinations (appendix B), in order to assess whether the subjects qualified for the study.

## 3.4 Inclusion criteria

Inclusion criteria included the following:

- Patients had to be between the ages of 18 and 60 to avoid necessity for parent/guardian consent (Giles, 1997).
- Patients must have lower back pain of less than 2 weeks in duration with no previous history of spinal surgery. (Rittweger *et al.,* 2003; Kirkaldy-Willis, 1992).
- The cut-point on the NRS was set at 4. Although the establishment of cut-points is still in its infancy, patients had to have an NRS rating of 4 or greater to be included in the study. This allows for greater group/sample homogeneity (Mouton, 1996). Grading pain intensity scaled into simple categories provides useful information for both clinicians and epidemiologists, and methods to classify pain severity for numerical rating scales have been recommended (Fejer et al., 2005). Fejer et al. (2005) determined that the boundary between a mild and a moderate level of pain is at 4 on a 0–10 numeric rating scale. Zelman et al. (2005) showed that cut-points of 4 and 7 optimally classified the sample for both worst pain and average pain, creating categories of mild, 0-3; moderate, 4-6; severe, 7 and higher.

As the cut-point for this study was 4, patients with mild pain levels were excluded from the study, which allows for real changes to be observed in the research setting.

## 3.5 Exclusion criteria

Exclusion criteria included the following:

- spinal tumors or metastases
- recent fractures of the axial skeleton

- inflammatory disease of the spine
- cauda equina syndrome
- progressive neurological defects
- heart failure
- recent abdominal surgery
- hip or knee endoprothesis or metal implants
- recent venous thrombosis
- arterial occlusive disease
- pregnancy
- epilepsy
- Patients who falsified their medical history
- Patients who undertook any specific abdominal or lower back exercise during the study, above and beyond normal exercise routines
- Patients who required further clinical testing for diagnosis would be excluded from the study
- Patients who have been introduced to power-plate before (not naïve to it).

- All patients that fail to comply with the Informed Consent Form (Rittweger *et al.* 2003)
- Subjects who failed to sign the Informed Consent Form were excluded by default, as this was taken to mean that they were either unable to understand the constraints of the study, or were unwilling to participate or have their information made part of the study findings
- Patients taking any form of medication for their pain had to comply with a 3-day washout period as proposed by Poul et al. (1993).
- Illiterate patients because they were unable to read the subject Information sheets from which feedback was required for subsequent improvement, as some of these tools had only been validated in the English language. There are currently studies underway which are addressing the need for questionnaires in different languages.

## 3.6 Intervention / Treatment Types

The first group, Group A, will receive 2 consultations weekly for 3 weeks.

During the first consultation the patient will be educated on how to contract the transverse abdominal muscle by using the four point kneeling position test.

Thereafter, an abdominal draw-in test with a biofeedback unit (Stabilizer Manual Chattanooga Group Inc., 4717 Adams Road, Hixson TN 37343, USA) will be used to test the patient's transverse abdominal muscle strength. This would be the first reading. The patient would then be introduced to the Power – plate and the feeling of training on the vibrating plate. The patient would be prepared for vibration training on the Power-plate starting at 30 seconds on a frequency of 30Hz per position and escalating 15 seconds per week, thereafter, ending on a frequency of 40Hz and 60 seconds training in the following positions with the plate on an amplitude of 1-3m (low): (Appendix J)

- A15 Abdominal Crunch
- A16 Lower Abdominals
- A17 Standing Abdominals

Frequency, amplitude and duration would be increased per week to increase the intensity of the workout on the core muscles as they get progressively stronger and used to the vibration training as explained above.

The second group, Group B (control) will receive **2 consultations weekly for 3 weeks.** 

During the first consultation the patient will be educated on how to contract the transverse abdominal muscle by using the four point kneeling position test.

Thereafter, an abdominal draw-in test with a biofeedback unit (Stabilizer Manual Chattanooga Group Inc., 4717 Adams Road, Hixson TN 37343, USA) will be used to test the patient's transverse abdominal muscle strength. This would be the first reading. The patient would then be introduced to the Power – plate and the feeling of training on the vibrating plate.

The patient would be prepared for detuned (control) vibration training on the Power-plate starting at 30 seconds per position with the time increasing by 15 seconds each week - up to 60 seconds per position in the final week- training in the following positions on the plate: (Appendix J)

- A16 Lower Abdominals
- A17 Standing Abdominals
- A18 Lateral Abdominals both sides

## 3.7 Intervention frequency

The patients underwent six consultations over a period of three weeks, with two consultations a week. They received core stability exercises at each visit.

## 3.8 Data Collection

## 3.8.1 Frequency

The groups completed a Quebec Back Pain and Disability Scale questionnaire and a Numerical Pain Rating Scale (Jenson *et al.*, 1986) prior to the initial consultation and at the third, fifth and the sixth visit. (i.e. Prior to the first visit of each week.)

## 3.8.2 Data Collection Instruments

## 3.8.2.1. Subjective data:

## Subjective data was collected using the following measuring instruments:

## 1. Numerical Pain Rating Scale (NRS):

Pain has been considered to be immeasurable by some, but a number of subjective and objective methods have been devised. Subjective methods appear to be more satisfactory than objective methods. Several methods of subjective measurement have been reviewed.

This method consists of an 11-point (0-10) scale with numbers being allocated in ascending order according to reported pain intensity and has the advantage that it is relatively easy for the patient to understand and use (Liggins, 1982). According to Jenson et al. (1986), the utility and validity of the 11-point numerical rating scale yielded similar results in terms of the number of subjects who respond correctly to them and their predictive validity when compared to five other methods of measurement of clinical pain intensity. Therefore, the 11-point numerical rating scale can be considered to be a reliable measure of clinical pain intensity.

#### 2. Quebec Low Back Pain Disability Questionnaire (QDS):

The Quebec Back Pain Disability Scale (QDS) (Kopec et al., 1995) is a 20item self-administered instrument, designed to assess the level of functional disability in individuals with low back pain. It adopts a generally accepted conceptual definition of disability as a restriction of ability to perform daily activities.

The scale contains 20 items and covers six empirically derived sub-domains of disability in back pain. All items contribute to the assessment of global disability and are relevant and acceptable to the patients. The items are scored 0 to 5 and the scale provides an overall disability score, ranging from 0 to 100, by simple summation of the scores for each item (Kopec et al., 1995).

The scale is brief and easy to self-administer. Comparisons with the Roland and Oswestry scales suggest that the QDS is more reliable and is more sensitive to change as the best available measures (Kopec et al. 1995).

#### 3.8.2.2. Objective data:

#### 1. Stabilizer Biofeedback Device:

Subjects had their core stability assessed using the Stabilizer Biofeedback Device. The presence of adequate core stability activation was assessed utilizing the abdominal draw-in test. The prone test for transversus abdominus and the supine position for training transverse abdominus were used to assess endurance of the transversus abdominus (Stabilizer manual Chatanooga Group Inc., 4717 Adams Road, Hixson TN 37343, USA).

This Stabilizer Biofeedback Device has been established as a satisfactory tool in the measuring and retraining of the transverse abdominus and multifidus muscles (Cairns, 2000).

#### 2. Core stability activation:

In accordance with Richardson <u>et al.</u> (1999), before formal testing begins participants are taught to contract transversus abdominus in four-point kneeling. This position provides a facilitated stretch to the deep abdominals resulting from the forward drift of the abdominal contents. This stretch leads to an inhibitory effect on the superficial muscles, particularly rectus abdominis (Richardson & Jull 1995). When this ability was recognized to be present, participants were then instructed to lie prone on a chiropractic table with their head turned to one side. The Stabilizer Biofeedback Device was placed below their abdomen, with the centre at the navel and the distal edge at the anterior superior iliac spine. It was then inflated to the baseline pressure of 40 mmHg.

Participants were then examined as to test whether they could initiate transversus abdominus activation in this prone position. A drop in pressure of 6-8 mmHg was seen with a correct contraction. This test was performed at the initial consultation. If the subject could not do this, the subject was retrained in the four point kneeling and prone positions to perform this activation satisfactorily, prior to taking the quantitative time-based readings. If the subject still could not manage a satisfactory activation, the subject was instructed to perform a contraction of transversus abdominus, as trained by the researcher, to the best of their ability and a time-based reading of this contraction was taken.

Quantitative time-based readings of transversus abdominus endurance were taken using the Stabilizer Pressure Biofeedback Unit.

#### The prone test for transversus abdominus and internal oblique:

A 3-chamber pressure cell was placed centrally below the abdomen, with the umbilicus in the centre of the inflatable sleeve, and inflated to a baseline of 40 mmHg. The subject was then instructed to draw the abdominal wall up and in without moving the spine or pelvis. The pressure reading should have decreased by 6-10 mmHg.

A variation of 2 mmHg was allowed for normal breathing pattern. A measurement was taken of the time at which the patient could no longer hold the contraction at the baseline level (40mmmHg – 6 to 10 mmHg).

#### The supine test for transversus abdominus:

A 3-chamber pressure cell was placed centrally below the lumbar spine with the bottom of the sleeve in line with the Posterior Superior Iliac spines (PSIS's), and inflated to a baseline of 40 mmHg. The patient was instructed to draw in the abdominal wall without moving the spine or pelvis. The pressure reading should have remained at 40 mmHg; i.e. no movement of the spine. A variation of 2 mmHg was allowed for normal breathing pattern. A measurement was taken of the time at which the patient could no longer hold the contraction at the baseline level (40 mmHg).

### 3.9 Description of statistics

Data was collected from the NRS and the QDS questionnaire and the Biofeedback unit/ Stabilizer. This was done 4 times; on visit 1, visit 3, visit 5 and visit 6.

## 3.10 Statistical Methodology

Data was collected from the NRS, QDS and the Biofeedback unit / Stabilizer.

Statistical analysis was completed under the guidance of a statistician from the University of KwaZulu-Natal Medical School. The subjective data was obtained using the Numerical Pain Rating Scale (Appendix A) and the Quebec Back Pain and Disability Scale (Appendix K). The objective data was obtained using the Stabilizer Biofeedback Device.

Data was entered and analysed in SPSS version 15 (SPSS Inc. Chicago, III, USA). Baseline demographics and factors were compared between the two treatment groups to ensure completeness of randomization using students' t-tests in the case of quantitative data - Pearson's chi square tests would be appropriate for categorical variables.

Repeated measures ANOVA was used to assess the presence of a treatment effect. A significant time\*group interaction effect (p<0.05) did signify a statistically significant treatment effect. Profile plots were used to interpret non-significant effects and trends, as well as the direction of the treatment effects.

### CHAPTER FOUR

#### **RESULTS**

### Statistical methodology

SPSS version 15.0 (SPSS Inc, Chicago, III, USA) was used to analyse the data. A p value <0.05 was considered as statistically significant. Baseline outcome measures and demographics were compared between the two treatment groups to ensure that they were equivalent prior to the intervention, using independent samples' t-tests and Pearson's chi square tests. For assessment of the effect of the intervention, repeated measures ANOVA testing were used. A significant time\*group effect indicated a statistically significant differential treatment effect. The direction and trend of the treatment effect was assessed using profile plots.

#### Results

### 4.1 Demographics:

Thirty participants were randomized to one of two treatment groups. 50% of the sample was male and 83.3% were White, while 6.7% were Black and 10% Indian. The ethnic distribution of the sample is shown in Table 4.1. Mean age was 31.4 years with a standard deviation of 11 years and a range from 19 to 59 years.

### Table 4.1: Ethnic distribution of sample

	Frequency	Percent
White	25	83.3
Black	2	6.7
Indian	3	10.0
Total	30	100.0

The majority (43.3%) of the sample were students. Business owners made up 13.3% of the sample, medical reps 10% and housewives 6.7%. This is shown in Table 2.

	Frequency	Percent
Chiropractic Students	3	10.0
Homeopathy students	5	16.6
Engineering students	3	10.0
Accounting students	<u>2</u>	<u>6.7</u>
Total Student	13	43.3
Business	4	13.3
owners		
Medical reps	3	10.0
Housewives	2	6.7
Engineer	1	3.3
Events Co-	1	3.3
ordinator		
Financial	1	3.3
advisor		
Graphic	1	3.3
designer		
lecturer	1	3.3
Payroll admin	1	3.3
Photographer/	1	3.3
Film		
Property	1	3.3
consultant		
Total	30	100.0

## Table 4.2: Occupations of sample

# Comparison of demographics and baseline outcomes between treatment groups:

Tables 4.3 and 4.4 show that there was no significant difference between the treatment groups in terms of ethnicity (p=0.260) or gender (p=0.715).

			Gro	oup	Total
			Vibration	Non-	
			group	vibration	
				group	
Ethnicity	White	Count	14	11	25
		%	56.0%	44.0%	100.0%
		within			
		race			
	Black	Count	0	2	2
		%	.0%	100.0%	100.0%
		within			
		race			
	Indian	Count	1	2	3
		%	33.3%	66.7%	100.0%
		within			
		race			
Total		Count	15	15	30
		%	50.0%	50.0%	100.0%
		within			
		race			

|--|

Pearson's chi square p = 0.260
			Group		Total
			Vibration group	Non- vibration group	
Gender	Male	Count	7	8	15
		% within Gender	46.7%	53.3%	100.0%
	Female	Count	8	7	15
		% within Gender	53.3%	46.7%	100.0%
Total		Count	15	15	30
		% within Gender	50.0%	50.0%	100.0%

## Table 4.4: Comparison of gender between treatment groups

Pearson's chi square p =0.715

Age was also not significantly different between the treatment groups (p=0.561) as the mean age was 30.2 years in the vibration group and 32.6 years in the non-vibration group (Table 4.5).

	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
age	Vibration group	15	30.20	10.115	2.612	0.561
	Non-vibration group	15	32.60	12.141	3.135	

There were no statistically significant differences between any of the outcome measures at baseline between the two treatment groups, as shown in Table 4.6.

	Group	N	Mean	Standard Deviation	Standard Error Mean	p value
Prone time(sec)	Vibration group	15	56.47	46.898	12.109	0.432
	Non- vibration group	15	73.47	49.429	12.763	
Prone (mmHg)	Vibration group	15	2.80	1.146	0.296	0.748
	Non- vibration group	15	2.93	1.100	0.284	
QDS	Vibration group	15	21.93	12.481	3.223	0.121
	Non- vibration group	15	30.47	16.483	4.256	
NRS	Vibration group	15	4.20	2.210	0.571	0.426
	Non- vibration group	15	3.60	1.844	0.476	

Table 4.6: Comparison of baseline (time) outcomes between treatment groups

# 4.2 Assessment of the treatment effect

# 4.2.1 Prone time (seconds)

There was a statistically significant overall time effect for "time prone" (p<0.001), meaning that both treatment groups changed significantly with regard to this effect over time prone. Figure 4.1 shows that the direction of this change was an increase in both groups. However, there was no difference between the two treatments over time, as they both increased at the same rate. This is shown by the time\*group effect which was not statistically significant (p=0.131) and in addition, the profile plot shows that the profiles of the two groups were more or less parallel over time.

## Table 4.7: Between and within subjects effects for time prone (seconds)

Effect	Statistic	p value
Time	Wilk's lambda=0.268	<0.001
Group	F=0.514	0.479
Time*group	Wilk's lambda=0.809	0.131



Figure 4.1: Profile plot of mean time prone (seconds) by treatment group over time

# 4.2.2 Prone (mmHg)

Table 4.8 shows that prone mmHg decreased significantly over time in both groups (p<0.001), but that there was no difference between the groups in terms of rate of change over time (p=0.697). This is shown in Figure 4.2, where both groups show a decrease at a similar rate over time, although the non-vibration group maintained a linear decrease over time while the vibration group showed an initial poor rate, followed by a faster decrease after the  $3^{rd}$  treatment.

Table 4.8. Between	and within sub	viects' effects for	<sup>,</sup> nrone (mmHa)
TUDIC 4.0. DOLWCOIL			

Effect	Statistic	p value
Time	Wilk's lambda=0.482	<0.001
Group	F=0.044	0.835
Time*group	Wilk's lambda=0.947	0.697



Figure 4.2: Profile plot of mean prone (mmHg) by treatment group over time

#### 4.2.3 Time supine (seconds)

Again, both groups showed significant increases in supine time (p<0.001) but the difference in rate of increase over the treatment period was not quite statistically significant (p=0.173). However, Figure 4.3 shows a trend towards a treatment effect of the vibration group since the profiles are no longer parallel, and crossing over of profiles appears after the 2<sup>nd</sup> visit. Thus, the rate of increase was marginally faster in the vibration group than in the nonvibration group. However, because of the very small sample size, there were not enough respondents to see if there would have been a statistically significant difference. A larger sample size would have been necessary to show this.

# Table 4.9: Between and within subjects' effects for time supine

# <u>(seconds)</u>

Effect	Statistic	p value	
Time	Wilk's lambda=0.193	<0.001	
Group	F=0.014	0.908	
Time*group	Wilk's lambda=0.828	0.173	





# 4.2.4 Supine (mmHg)

For this outcome, all three effects of time, group and time\*group were statistically significant (Table 4.10). However, in the presence of a significant time\*group effect the main effect of time and group cannot be interpreted. This is because when there is a significant interaction between time and groups (significant treatment effect) it means that the effect over time is dependent on the treatment group. Therefore, the treatment effect was significant (p=0.020) and Figure 4.4 shows that the vibration group showed a faster rate of increase than the non-vibration group over time, whilst the non-vibration group only increased moderately.

## Table 4.10: Between and within subjects' effects for supine (mmHg)

Effect	Statistic	p value
Time	Wilk's lambda=0.306	<0.001
Group	F=6.256	0.019
Time*group	Wilk's lambda=0.691	0.020





#### 4.3 QDS

The QDS score decreased significantly in both groups over time (p<0.001). However, there was no evidence of a treatment effect for vibration according to this outcome (p=0.163). In fact, Figure 4.5 suggests that the non-vibration group showed a steeper rate of decline over time than the vibration group, although this difference is not statistically significant.

Table '	11:	<b>Between</b>	and	within	subjects'	effects	for	QD:	S

Effect Statistic		p value
Time	Wilk's lambda=0.275	<0.001
Group	F=0.288	0.596
Time*group	Wilk's lambda=0.734	0.163





#### 4.4 NRS

Pain decreased significantly in both groups over time (p<0.001) but this decrease was at the same rate in both groups and there was no evidence of a treatment effect of vibration (p=0.395). Figure 4.6 show that the profiles of the two groups had almost the same slope over time.

	Table 4.12:	Between an	d within sul	bjects' eff	ects for NRS
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Effect	Statistic	p value
Time	Wilk's lambda=0.327	<0.001
Group	F=2.90	0.100
Time*group	Wilk's lambda=0.816	0.395





# Chapter 5

# **Discussion and Conclusions**

### 5.1. Introduction

Specifically, this chapter will concern itself with the study conclusions, methodological issues and recommendations for future studies.

Data collection took place immediately prior to each of six treatments involving vibration/acceleration training or core stability exercises.

#### 5.2. Discussion

#### 5.2.1. Demographics

Demographically 83.3% of the respondents were White while 6.7% were Black and 10% Indian. The male female ratio in the study was 1:1 with 15 females and 15 males that participated in the study. The 1:1 ratio is in close relation to that suggested by van der Meulen in 1997, of which the prevalence was 56.4% for women as opposed to 48.4% for men. The study showed that a significant association between gender and lifetime incidence was found. Gender was found to be significantly associated with low back pain prevalence, as the female gender is more at risk of developing low back pain (van der Meulen, 1997).

Tables 4.3 to 4.5 shows that there was no significant statistical difference between the two groups in terms of race, gender and age (p = 0.260; p = 0.715; p = 0.561). The mean age was 30.2 years in the vibration group and 32.6 years in the non-vibration group, as seen in Table 4.5.

Table 4.6 showed no statistically significant differences in base line measurements of both groups.

#### 5.2.2. Assessment of the treatment effect

#### 5.2.2.1 Prone:

The prone time had a statistically significant (p<0.001) change in both groups over time, in that it increased over the 6 weeks (Fig 4.1). The rate of increase in both groups is at the same gradient as seen in the two profile plots, which makes the time\*group effect statistically non-significant (p=0.131).

The prone mmHg readings showed a decrease over time, with the vibration group showing a poor initial decrease rate; however, this was followed by a faster decrease after 3 treatments, which is clearly seen on the profile plots (Fig 4.2).

#### 5.2.2.2 Supine

Supine time again showed an increase over time (p<0.001), but the difference in rate of increase was not statistically significant (p=0.173). Fig 4.3 does, however, show a trend towards a treatment effect of the vibration group as the profiles are no longer parallel as they cross over. This ,thus, shows that the rate of increase was faster in the vibration group for time supine compared to the non-vibration group.

The mmHg supine was statistically significant (p=0.020), as seen in table 4.10. Fig 4.4 confirms the difference in the response rate with a clear difference in the profile plots; with the vibration group showing a faster rate of increase than the non-vibration group in the supine position.

Jull and Richardson (1993) suggest that there is evidence emerging to show that the oblique abdominals and TA muscles may not always be optimally recruited or may fatigue in their normal stabilizing role even in normal, currently asymptomatic individuals. This is in keeping with the findings of this study with respect to initiation of core contraction and endurance, as shown in Figures 4.1 to 4.4. The mean values of the pressure readings taken during the abdominal drawin test (Table 4.2. and Fig 4.4.) were keeping with the findings of Richardson *et al.* (1999). They reported that successful performance of the abdominal draw-in test is indicated by a pressure reduction of 6-10 mmHg, which is in keeping with the mean pressure readings noted during this study of 7.93 – 10.13 mmHg. However, more recent studies by Robertson (2005), Martin (2006) and Ferguson (2007) have recorded mean pressure readings of 13.00 – 13.08mmHg, 10.96 – 13.15mmHg and 10.9mmHg respectively.

In terms of the abdominal draw-in test mentioned above, the vibration group and non-vibration group both had a statistically significant (p=0.020) pressure reduction (in mmHg). It has been suggested that a well-developed core allows for improved force output, increased neuromuscular efficiency and decreased incidence of overuse injuries (Hedrick, 2000).

Motor control endurance, according to McGill (2003), is essential to achieving the stability target under all possible conditions of performance. Further to this, Hodges (2003) indicated that elevated intra-abdominal pressure and contraction of the diaphragm and TA provided a mechanical contribution to the control of spinal intervertebral stiffness or stabilization - particularly with regards to the drawing-in of the abdominal wall. In the current study, there was a statistically significant difference (p < 0.001) in terms of core muscle endurance (time in seconds) for the abdominal draw-in test. This may suggest that aside from having greater endurance of the core, it may also have greater lumbar stabilization. This may be truer for the vibration group than the control or exercise group when looking at Fig 4.3 and 4.4.

#### 5.2.2.3. QDS

The QDS scores showed a decrease in both groups, but the non-vibration group showed a steeper decrease than the vibration group (Fig 4.5). However, this is not statistically significant.

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### 5.2.2.4. NRS

Fig 4.6 showed that pain decreased at the same rate in both groups. Therefore, this does not show a treatment effect of vibration/acceleration training.

### In Summary:

This study has not shown that vibration treatment is a statistically significantly better treatment for this condition according to most of the outcome measurements used in this study, except for the supine mmHg measurement, where the vibration group showed significant improvement over the non-vibration group. There was a suggestion of a trend towards a faster improvement in the vibration treatment group for time supine, but the other outcomes showed no difference, or even suggested that the non-vibration group may have improved faster (QDS and NRS). The placebo effect was very large in this study, making it difficult to assess the true effect of the vibration treatment. A larger study is necessary to provide further evidence for or against a treatment effect of vibration treatment.

## 5.3. Conclusions

The purpose of this study was to investigation the short term efficacy of vibration/acceleration training on the Power-plate in acute low back pain sufferers, with regards to core muscle strength and endurance.

The Objectives and Hypothesis as set out before the study were as follows:

<u>Objective one</u>: The first objective was an intra-group analysis (vibration alone vs. placebo vibration) with respect to objective (Biofeedback device/Stabilizer) and subjective (NRS and QDS) findings.

<u>Objective two</u>: The second objective was an inter-group analysis (vibration alone vs. placebo vibration) with respect to subjective (NRS and QDS) and objective (Biofeedback device/Stabilizer) findings.

<u>Objective three</u>: The third objective was to integrate the data obtained from objectives one and two, to determine which would be a more effective treatment of acute low back pain.

 <u>Hypothesis</u>: It was hypothesized that vibration/acceleration training would be a better form of core stability exercises and would be effective in the management of acute low back pain, in terms of both subjective and objective clinical findings.

Based on the results discussed above, the following can be stated with regard to the objectives and hypotheses:

The vibration/acceleration group (Group A) showed an improvement in both the objective (Biofeedback) and subjective (N.R.S & Quebec Back Pain and Disability Scale) clinical findings, which was in agreement with the hypothesis set out at the beginning of the study.

The control group (Group B) showed an improvement in both the objective (Biofeedback) and subjective (N.R.S & Quebec Back Pain and Disability Scale) clinical findings, which was also in agreement with the hypothesis set out at the beginning of the study.

However, when the relative effectiveness of vibration/ acceleration training was compared to core stability exercises, the vibration/acceleration group did not significantly outperform the core muscle exercise group in terms of pain decrease and core muscle endurance. There was no statistical significant evidence that vibration/acceleration training is a superior form of core muscle training, with the exception of the supine mmHg measurement where the vibration group showed significant improvement over the exercise group.

However, because of the very small sample size, there were not enough respondents to show that there would have been a significant statistical difference. A larger sample size would be necessary to illustrate this.

Therefore, this was only partially in keeping with the hypothesis set out at the beginning of the study, as it was hypothesised that vibration/acceleration training is a more effective form of core stabilization exercises in the management of acute low back pain.

#### 5.3. Recommendations

With the research conducted in this study the most reliable and best possible research protocol and statistical package was used. General trends that were observed in the study lead to the following suggested improvements of follow-up studies.

#### Suggested improvements:

The sample size of this study was limited to thirty subjects. For logistical reasons, this research was performed as a pilot study. Therefore, the relatively small population group of thirty that was used with the statistical package, yielded statistically significant results, but trends observed within the study may allow for the recommendation of larger study in the future.

Less financial constraints would allow the researcher to produce a more efficient and valuable study in terms of a larger sample size, and improve sample homogeneity and representation of the general population within the study. South African studies should be more demographically balanced in order to give a fair and true reflection of what treatments work within certain communities or ethnic groups. In South Africa, we have a unique opportunity to do research within these different racial and economic groups, yet our focus tends to be on the demographics of our patients. This could lead to age groups as well as race group specific studies, to determine the difference with age and race in smaller sub-groups of the South African community.

Due to the broadening patient base into all races and cultures in South Africa, it is recommended that the pain and disability questionnaires be multi-lingual. It is recommended that alternative ways of measuring levels of pain and disability be explored.

Due to the fact that the study is on the short term effect of Vibration or acceleration training, no long term follow-up evaluation was done, which would help to address the cost-effectiveness of the treatment protocol utilized. The true benefit of vibration /acceleration training as core stability exercises in terms of severity and recurrence of low back pain, may only have become apparent at a one-month or six-month interval. This would also allow for the investigation of the long term benefit of the treatment.

Measurement error may have occurred using the Stabilizer Biofeedback devise despite it being established as a satisfactory tool in the measuring and retraining of the transverse abdominus and multifidus muscles. Small but significant changes could be detected as more advanced technology is developed that is more accurate and sensitive.

Stricter inclusion and exclusion criteria with respect to age, race and extent of pain and disability is needed. This should apply especially to the matching of treatment groups in terms of all the demographic variables. For this study, it was noted that the non-vibration group had more Black respondents as opposed to the Vibration/acceleration group, which may have affected the results, although all the repeated measures of the ANOVA models were covariate. With stricter criteria trend on pain relief and healing rates might be more significantly observed in certain age groups compared to others. Due to physiological change within the body, it is thus suggested that the age groups be more specific and smaller in follow-up studies.

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# Appendix A: NRS

#### NRS Pain Rating Scale

#### Patient Name:

Date:

#### Pain Severity Scale:

Rate your usual level of pain today by checking one box on the following scale:

0	1	2	3	4	5	6	7	8	9	10	
					_		_		_		

Bolton and Wilkinson., 1998 : 1-7

### **Appendix B:**

### Lumbar Regional

#### **REGIONAL EXAMINATION - LUMBAR SPINE AND PELVIS**

Patient	t:						File#:	Da	ite:	١	\	
Intern	Resider	nt:					Clinici	an:				
STAN Posture– Body Tyj Skin Scars Discolou	<b>DING:</b> scoliosis, a pe ration	antalgia, k	yphosis			Minor's Muscle t Spinous Scober's Bony an	Sign one Percussio: Test (6ci d Soft Tis	n m) sue Contour	rs			
GAIT Normal v Toe walk Heel Wal Half squa R. Rot ROM:	valking ting lking at						L. Rot		Flex			
Forward Extension L/R Rota L/R Later	<b>d Flexion</b> n = $20-35^{\circ}$ ation = $3-13^{\circ}$ R.Lat ral Flexion F	$a = 40-60^{\circ}$ $8^{\circ}$ $a = 15-20^{\circ}$ lex	? (15 cm f	řrom floo	r)		L.Lat Flex					
Which • Loca • Supp SUPIN Observe a Palpate a Pulses - a - Abdomin	movt. re ation of pai ported Ada <u>NE:</u> abdomen ( bdomen\gr abdominal lower extra al reflexes	produce n ms: Relief Ag hair, skin, roin remity	es the pa f? (SI) ggravates? nails)	<b>in or is t</b> (disc, mu	<b>he wors</b> (	t <b>?</b>			Ext			
SLR		Degree	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	F	Foot	Braggar
<u></u>	L											

R

	L	R
Bowstring		
Sciatic notch		
Circumference (thigh and calf)		
Leg length: actual -		
apparent -		
Patrick FABERE: pos\neg – location of pain?		
Gaenslen's Test		
Gluteus max stretch		
Piriformis test (hypertonicity?)		
Thomas test: hip \ psoas? \ rectus femoris?		
Psoas Test		

Spinous Percussion Valsalva Lhermitte

		D	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	Foot	Braggard
TRIPOD		Degree									
Sl, +, ++	L										
	R										

Slump 7 test	L					
	R					

#### LATERAL RECUMBENT:

LATERAL RECOVIDENT.	L	R
Ober's		
Femoral n. stretch		
SI Compression		

#### **PRONE:**

PRONE:	L	R
Gluteal skyline		
Skin rolling		
Iliac crest compression		
Facet joint challenge		
SI tenderness		
SI compression		
Erichson's		

Pheasant's	

	Latent	Active	Radiation
MF tp's			
QL			
Paraspinal			
Glut Max			
Glut Med			
Glut Min			
Piriformis			
Hamstring			
TFL			
Iliopsoas			
Rectus Abdominis			
Ext/Int Oblique muscles			

#### **NON ORGANIC SIGNS:**

Pin point pain Burn's Bench test Hoover's test Repeat Pin point test Axial compressionTrunk rotation Flip Test Ankle dorsiflexion test

#### **NEUROLOGICAL EXAMINATION**

Fasciculations

Plantar	Plantar reflex								
level	Tender?	Dermat	omes	DTR					
		L	R		L	R			
T12				Patellar					
L1				Achilles					
L2									
L3				Proproception					
L4									
L5									
S1									
S2									
S3									

MYOTOMES					
Action	Muscles	Levels	L	R	
Lateral Flexion spine	Muscle QL	T12-L4			
Hip flexion	Psoas, Rectus femoris	L1,2,3,4			5+ Full strength
Hip extension	Hamstring, glutes	L4,5;S1.2			4+ Weakness
Hip internal rotat	Glutmed, min;TFL, adductors				3+ Weak against grav
Hip external rotat	Gluteus max, Piriformis				2+ Weak w∖o gravity
Hip abduction	TFL, Glut med and minimus				1+ Fascic w\o gross movt
Hip adduction	Adductors				0 No movement
Knee flexion	Hamstring,	L4,5:S1			
Knee extension	Quad	L2,3,4			W – wasting
Ankle plantarflex	Gastroc, soleus	S1,2			
Ankle dorsiflexion	Tibialis anterior	L4,5			
Inversion	Tibialis anterior	S1			
Eversion	Peroneus longus	L4			
Great toe extens	EHL	L5			

#### **BASIC THORACIC EXAM**

History Passive ROM Orthopedic

#### **BASIC HIP EXAM**

History **ROM:** Active Passive : Medial rotation : A) Supine (neutral) If reduced
b) hard \ soft end feel
c) Trochanteric bursa

### **Appendix C:**

### **SOAPE Note**

Patient Name:		File #:	Page:
Date: Visit: Attending Clinician:	Intern:	Signature:	
S: Numerical Pain Rating Scale (P Least 012345678910 w	Tatient ) Intern Rating	<i>A:</i>	
0:		<i>P</i> :	
<i>E:</i>			
Special attention to:		Next appointment:	
Date: Visit: Attending Clinician:	Intern:	Signature:	
S: Numerical Pain Rating Scale (1 Least 012345678910 v	Patient ) Intern Rating Norst	<i>A:</i>	
0:		Р:	
<i>E:</i>			
Special attention to:		Next appointment:	
Date: Visit: Attending Clinician:	Intern:	Signature	

#### DURBAN UNIVERSITY OF TECHNOLOGY

# Appendix D:

Advertisement

# DO YOU SUFFER FROM LOW BACK PAIN

### And between the ages of 18-60?

Research is currently being carried out at the Durban University of

Technology

### **Chiropractic Day Clinic**

# <u>FREE TREATMENT</u>

Is available to those who qualify to take part in this study.

For more information contact Tjaart on 2042205 / 2512



### **Appendix E:**

### Informed consent form

#### **INFORMED CONSENT FORM**

(To be completed by patient / subject )

#### Date:

**Title of research project:** An investigation into the short term effectiveness of whole body vibration training in low back pain sufferers.

Name of supervisor: Dr. Garrick Haswell [Mtech: Chiropractic]		
Tel: (031) 2010341		
Name of research student: Tjaart van der Merwe		
Tel: (031) 2042205 / 0833874215		
Please circle the appropriate answer	YES /N	0
1. Have you read the research information sheet?	Yes	No
2. Have you had an opportunity to ask questions regarding this study?	Yes	No
3. Have you received satisfactory answers to your questions?	Yes	No
4. Have you had an opportunity to discuss this study?	Yes	No
5. Have you received enough information about this study?	Yes	No
6. Do you understand the implications of your involvement in this study?	Yes	No
7. Do you understand that you are free to withdraw from this study?	Yes	No
• at any time		
• without having to give any a reason for withdrawing, a	ind	
• without affecting your future health care.		
8. Do you agree to voluntarily participate in this study	Yes	No
9. Who have you spoken to?		

#### Please ensure that the researcher completes each section with you if you have answered NO to any of the above. Please obtain the necessary information before signing

#### **Please Print in block letters:**

Patient /Subject Name:	Signature:
Parent/ Guardian:	Signature:
Witness Name:	Signature:

### **APPENDIX F:**

### LETTER OF INFORMATION



DATE:

Dear Participant, welcome to my research project.

Title of Research:

An investigation into the short term effectiveness of whole body vibration training in low back pain sufferers.

NAME OF RESEARCH STUDENT
Nicolaas Tjaart van der Merwe

Contact number (0833874215 / 2042205)

#### NAME OF RESEARCH SUPERVISOR

**Dr. Garrick Haswell** [MTech-Chiropractic] Contact number (031) 2010341

You have been selected to take part in a study investigating the short term efficiency of vibration training on the Power-plate in low back pain sufferers with regards to core muscle strength. Thirty people will be required to complete this study.

All participants, including you, will be randomly split into two equal groups. Each of the groups will receive a standard clinical treatment with core stability exercises on the Power-plate for the purposes of this study.

#### **Inclusion and Exclusion:**

If you are taking any medication, a 3-day washout period is required before taking part in the study. This is because medications may have an effect on the symptoms, and you may be excluded from the study. If you are undergoing any other form of treatment for your back pain you may be excluded from the study.

*Please try not to alter your normal lifestyle or daily activities in any way,* as this could interfere with the results of the study. Those taking part in the study must be between the ages of 18 and 60.

Any patients with spinal tumours or metastases, recent fractures of the axial skeleton, inflammatory disease of the spine, cauda equina syndrome, progressive neurological defects, heart failure, recent abdominal surgery, hip or knee endoprothesis or metal implants, recent venous thrombosis, arterial occlusive disease, pregnancy or epilepsy will be excluded from this study due to it being a contra-indication to vibration training. Any patient that has been introduced to the power-plate before will be excluded from this study.

Patients that are found to be dishonest in the history provided by them, that require further clinical testing for diagnosis, and all patients that fail to comply with the informed consent form will be excluded from the study.

#### **Research process:**

At the first consultation you will be screened for suitability as a participant using a case history, physical examination and lumbar spine regional examination. You will be asked to complete a measurement of your low back pain

Treatments:

All treatments will be performed under the supervision of a qualified chiropractor by the research student and will be free of charge.

Risks and discomfort:

The treatment is safe and is unlikely to cause any adverse side effects, other than transient tenderness and stiffness that is common post vibration training. Patients may experience post exercise soreness, however, this will be transient and the patients are not expected to have prolonged pain / soreness.

Remuneration and costs:

Treatment for the duration of the research process will be free of charge. Subjects taking part in the study will not be offered any other form of remuneration for taking part in the study. Upon completion of the research process, the normal cost of consultations will be charged for those patients wanting further treatment. All patient information is confidential and the results of the study will be made available in the Durban Institute of technology library in the form of a mini-dissertation.

Implications for withdrawal from the research: You are free to withdraw at any stage.

Benefits of the study:

Your full co-operation will assist the Chiropractic profession in expanding its knowledge of this condition and thus making future rehabilitation of patients suffering from chronic low back pain more successful.

Confidentiality and ethics:

All patient information will be kept confidential and will be stored in the Chiropractic Day Clinic for 5yrs, after which it will be shredded.

Please do not hesitate to ask questions on any aspect of this study. Should you wish, you may contact my research supervisor at the above details or alternatively you could contact the Faculty of Health Sciences Research and Ethics Committee as per Mr. Vikesh Singh (031) 2042701.

Thank you. Yours sincerely,

Nicolaas Tjaart vd Merwe (Research student) Dr Garrick Haswell (Supervisor)

### Appendix G :

### **Core stability assessment tests**

#### Core stability assessment tests: The Stabilizer Biofeedback Device

#### 1. <u>Testing for the presence of core stability activation:</u>

In accordance with Richardson <u>et al.</u> (1999), before formal testing begins participants were taught to recruit transversus abdominus in four-point kneeling. This position provided a facilitated stretch to the deep abdominals resulting from the forward drift of the abdominal contents. This stretch leads to an inhibitory effect on the superficial muscles, particularly rectus abdominis (Richardson & Jull 1995).

When this ability was recognized to be present, participants were then instructed to lie prone on a chiropractic table with their head turned to one side. The Stabilizer Biofeedback Device was placed under their abdomen, with the centre at the navel and the distal edge at the anterior superior iliac spine (ASIS). It was then inflated to the baseline pressure of 70 mmHg.

Participants were then examined as to whether they could initiate transversus abdominus activation in this prone position. A drop in pressure of 6-8 mmHg was seen with a correct contraction.

This test was performed at the initial consultation. It was noted yes/no, for statistical purposes, as to whether the subject could perform a correct activation of transversus abdominus.

If the subject could not do this, the subject was retrained in the four point kneeling and prone positions to perform this activation satisfactorily, prior to taking the quantitative time-based readings.

If the subject still could not manage a satisfactory activation, the subject was instructed to perform a contraction of transversus abdominus, as trained by the researcher, to the best of their ability and a time-based reading of this contraction was taken for the prone and supine positions.

#### 2. The prone test for transversus abdominus and internal oblique:

- A 3-chamber pressure cell was placed centrally under the abdomen, with the umbilicus in the centre of the inflatable sleeve, and inflated to a baseline of 70 mmHg.
- The subject was then instructed to draw the abdominal wall up and in, without moving the spine or pelvis.
- The pressure reading should have decreased by 6-10 mmHg.
- A variation of 2 mmHg was allowed for normal breathing pattern.
- A measurement was taken of the time at which the patient could no longer hold the contraction at the baseline level (70mmHg 6 to 10 mmHg).

#### 3. Supine position for testing transversus abdominus:

- A 3-chamber pressure cell was placed centrally under the lumbar spine with the bottom of the sleeve in line with the posterior superior iliac spines (PSIS), and inflated to a baseline of 40 mmHg.
- The patient was instructed to draw in the abdominal wall without moving the spine or pelvis.
- The pressure reading should have remained at 40 mmHg; i.e. no movement of the spine.
- A variation of 2 mmHg was allowed for normal breathing pattern.
- A measurement was taken of the time at which the patient could no longer hold the contraction at the baseline level (40 mmHg).

# <u>Appendix H:</u> <u>Case History</u>

DURBAN INSTITUTE OF TECHNOLOGY					
<u> </u>	<u>HIROPRACTIC I</u> CASE HIST	DAY CLINIC ORY			
Patient:			_ Date: _		
File # :			Age: -		
Sex :	Occupation:				
Intern :					
				Cionatura	
				Signature	
FOR CLINICIANS USE ONL	<u>.Y:</u>				
Initial visit		<b>C</b> :			
Chinician:		Signature :			
Case History:					
Examination: Previous:				Current	
Trevious.				Current.	
X-Ray Studies: Previous:				Current	
rievious.				Current.	
Clinical Path. lab:				Current	
Flevious.				Current.	
CASE STATUS:					
PTT: S	Signature:		Date:		
Reason for Conditional					
Signature:			Date:		

Conditions met in Visit No:	Signed into PTT:	Date:	
Case Summary signed off:		Date:	

#### Intern's Case History:

#### 1. Source of History:

#### 2. Chief Complaint : (patient's own words):

#### 3. Present Illness:

		Complaint 1	Complaint 2
<	Location		
<	Onset : Initial:		
	Recent:		
(1)	Cause:		
<	Duration		
<	Frequency		
<	Pain (Character)		
<	Progression		
<	Aggravating Factors		
<	Relieving Factors		
<	Associated S & S		
<	Previous Occurrences		
<	Past Treatment		
	Outcome:		

#### 4. Other Complaints:

- 5. Past Medical History:
- < General Health Status
- < Childhood Illnesses
- < Adult Illnesses

- < Psychiatric Illnesses
- < Accidents/Injuries
- < Surgery
- < Hospitalisations

#### 6. Current health status and life-style:

- < Allergies
- < Immunizations
- < Screening Tests incl. xrays
- < Environmental Hazards (Home, School, Work)
- < Exercise and Leisure
- < Sleep Patterns
- < Diet
- < Current Medication Analgesics/week:
- < Tobacco
- < Alcohol
- < Social Drugs

#### 7. Immediate Family Medical History:

- < Age
- < Health
- < Cause of Death
- < DM
- < Heart Disease
- < TB
- < Stroke
- < Kidney Disease
- < CA
- < Arthritis
- < Anaemia
- < Headaches

- < Thyroid Disease
- < Epilepsy
- < Mental Illness
- < Alcoholism
- < Drug Addiction
- < Other
- 8. Psychosocial history:
- < Home Situation and daily life
- < Important experiences
- < Religious Beliefs

#### 9. Review of Systems:

- □ General
- □ Skin
- □ Head
- □ Eyes
- □ Ears
- □ Nose/Sinuses
- □ Mouth/Throat
- □ Neck
- Breasts
- □ Respiratory
- □ Cardiac
- □ Gastro-intestinal
- □ Urinary
- □ Genital
- □ Vascular

- □ Musculoskeletal
- □ Neurologic
- □ Haematologic
- □ Endocrine
- D Psychiatric

### Appendix I:

# **Physical**

Durban Institute of Technology						
PHYSICAL EXAMINATION: SENIOR						
Patient Na Student :	ame :				File no : Signature :	Date :
VITALS:					<u>e</u>	
Pulse rate:					Respiratory rate:	
Blood pressure:	R	L			Medication if hypertens	ive:
Temperature	e:				Height:	
Weight:	Any recent change? Y	/ N		If Yes	: How much gain/loss	Over what period
GENERAL	L EXAMINAT	ION:				
General Imp	pression					
Skin						
Jaundice						
Pallor						
Clubbing						
Cyanosis (Central/Per	ripheral)					
Oedema						
Lymph nodes	Head and neck					
	Axillary					
	Epitrochlear					
	Inguinal					
Pulses						
Urinalysis						
SYSTEM SPECIFIC EXAMINATION:						
CARDIOVAS	CULAR EXAMI	NATION	1			
RESPIRATORY EXAMINATION						
ABDOMINAL EXAMINATION						
NEUROLOGICAL EXAMINATION						
COMMENTS						
Clinician				120	Signature :	

# **APPENDIX J:**

### **Exercise Positions**

#### **Positions 1-3:**



#### A 15 - Abdominal Crunch

Position/Straps: Place black pad on plate

Posture: Lift legs, slightly bent, move chest toward legs, tense abdominals, tilt pelvis Tension: Abdominals and lower torso Variations: Put feet on step at hip width

#### 2.



#### A 16 - Lower Abdominals

Position/Straps: Position fingers over the edge of the plate, lower arms flat on the plate Posture: Lift hips, back straight, pull feet towards plate Tension: Abdominals and lower torso Variations: Perform while kneeling



#### A 17 - Standing Abdominals

Position/Straps: Stand in the middle of the plate, hands at chest height Posture: Legs slightly bent, back straight, tense abdominals, push upper body down Tension: Abdominals and lower torso

Variations: Bend arms more, bend upper body deeper

#### (Power Plate Manual NG 2004)

# APPENDIX K:

### **Quebec Back Pain and Disability Scale**

#### THE QUEBEC BACK PAIN DISABILITY SCALE Name:

Age: \_\_\_\_\_ Date: \_\_\_\_\_Score: \_\_\_\_\_

This questionnaire is about the way your back pain is affecting your life. People with back problems may find it difficult to perform some of their daily activities. We would like to know if you find it difficult to perform any of the activities listed below, because of your back. For each activity there is a scale of 0 to 5 (0 = normal; 5 = severe). Please choose one response option for each activity (do not skip any activities) and check the corresponding box.

Today, do you find it difficult to perform the following activities because of your back?	0	1	2	3	4	5
1. Get out of bed.						
2. Sleep through the night (sleep at least 6 hours).						
3. Turn over in bed.						
4. Ride in a car (travel 1 hour in a car).						
5. Stand up for 20 – 30 minutes.						
6. Sit for 4 hours in a chair.						
7. Climb one flight of stairs.						
8. Walk a few blocks (300 – 400 m).						
9. Walk several miles.						
10. Reach up to high shelves.						
11. Throw a ball.						
12. Run two blocks (about 200 m).						
13. Take food out of the refrigerator.						
14. Make your bed.						
15. Put on socks (panty hose).						
16. Bend over a sink for 10 minutes.						
17. Move a chair.						
18. Pull or push heavy doors.						
19. Carry two bags of groceries.						
20. Lift and carry a heavy suitcase (or 40 pounds).						
SUB-TOTAL						
TOTAL SCORE						
amonts:						

#### Comments:

SCORE: \_\_\_\_\_ DATE: \_\_\_\_\_ Scored by:

From Kopec JA, Esdaile JM, Abrahamowicz M, Abenhaim L, Wood-Dauphinee S, Lamping DL. The Quebec Back Pain Disability Scale: Measurement properties. Spine 1995; 20:341 - 352.

### **Appendix L:**

### **Data collection sheet**

Date of initial visit:

Patient Name: Race: Occupation: Age:

#### File no:

#### Prone test for transversus abdominus and internal oblique:

Reading	Visit	Time	mmHg
1	1		
2	3		
3	5		
4	6		

#### Supine position for training transversus abdominus:

Reading	Visit	Time	mmHg
1	1		
2	3		
3	5		
4	6		

#### Quebec Disability Scale NRS Pain Rating Scale

Reading	Value	Reading	Value
1		1	
2		2	
3		3	
4		4	
5		5	
6		6	

Mean Average: ..... Mean Average: .....
# **Appendix M:**

# **Power-Plate Contract**



# 13 March 2007

# To Whom it may concern

## RE: The Power Plate and research at the DUT : Contract

It has been agreed that the following be contributed by the various stakeholders per student in terms of finance:

DUT Institutional contribution Power Plate contribution to the value of (machine and support costs) R 4700.00 R20 000.00

The DUT costs would support:Statistical analysisR1500.00Library charges (articles)R 600.00The supply of the instruments (if specific for the treatment outcomes)<br/>(As above Power Plate contribution)Costs incurred in planning and running a clinical trial (duplication of<br/>relevant paperwork)R 600.00AdvertisingR1500.00Telephone / fax costsR 500.00

Thus, the student would, therefore, have access to R 4700 (DUT Contribution), for use in the completion of the dissertation.

The student involved would be Mr N.T. van der Merwe.

Training:

Power-Plate will provide training to the researcher, as well as staff and assistants at the department.

#### <u>Equipment</u>

It was agreed that Power-Plate would supply the DUT with the Power-Plate Instrument; this would then be given **on loan for a period of 6 months**. This period will be re-evaluated according to the progress of the project. An asset number will be assigned by the DUT that would allow for coverage by insurance from the DUT.

#### The process

The research process as per the DUT research algorithm would be followed, such that the students receive maximal benefit in the learning process (appendix A and appendix B).

The students would be responsible for completing the research process and compiling a dissertation, further to this the students would complete a publishable paper, for publication in a mutually agreed journal.

#### <u>Time :</u>

The time required for the completion of the study (ies) will then be reliant on:

- Patient population required for the completion of the study
- The compilation of the written thesis.

Topics for research that were agreed to in the proposal stages included:

- An investigation into the short term effect of vibration training on chronic low back pain sufferers with regards to core muscle strength.
- An investigation into the effect of vibration training in combination with manipulation as a treatment option for low back pain.
- A follow-up study on the long term effect of vibration training on chronic low back pain sufferers with regards to core muscle strength.
- An investigation into the short term effectiveness of whole body vibration training in low back pain sufferers.

These topics would be refined through the research process and in consultation with the Power-Plate representative.

#### General arrangements:

- 1 DUT agrees to submit research forms outlining the research proposals and protocols of all projects to PPSA and PP International for their input, before commencement of the research.
- 2 DUT agrees to make their facilities available for Power-Plate SA to present training courses and workshops to the general public when needed. These arrangements will be made in advance with Mr N.T. van der Merwe.
- 3 DUT agrees to make the Power-Plate machine available to staff, students and patients of the Chiropractic school for training and treatment.
- 4 DUT agrees to provide monthly feedback on the use of and results achieved on the Power-Plate.
- 5 DUT agrees to make the results of the research conducted on Power-Plate available to PPSA as soon as they become available.

Communication would be affected by e-mail.

All signatories agree to this contract and are happy with its contents

DUT Finance

Me Karin Young Associate Director Head: Department of Chiropractic

Dr Charmaine Korporaal Senior Lecturer Department of Chiropractic

Power Plate representative

# <u>Appendix A:</u>

RESEARCH PROCEDURE - M. TECH						
	Idea submitted to Research	o the Corr	e Departmental Imittee			
-						
	ldea approved b Research	y the 1 Cor	Departmental nmittee			
Student develops the proposal (DIT 186) with the supervisor and or co- supervisor.						
The student submit	ts the DIT 186 for De	epart	mental Research C	ommittee review.		
DIT 186 passed subject to minor corrections and / or alterations being made by the student OR DIT 186 need resubmission to the Departmental Research Committee for second review						
$ \left  \right\rangle $						
The DIT 186 is ther and Biosafety Com	n submitted to the Fa mittee) for ethical a	acult .nd Ir	y Research Commi Istitutional budget	ttee (The Ethics clearance.		
DIT 186 passed subject to minor corrections and / or alterations being made by the student OR DIT 186 need resubmission to the Departmental Research Committee for second review						
The student is info the propo	ormed via relevant p sal, supervisor / co-s	oroto super	col and procedure visor and Institution	of the approval of onal funds		

Appendix **B** 

# FACULTY OF HEALTH

## G186 – RESEARCH PROPOSAL

## NOTE TO STUDENTS

Please complete in font ARIAL – 12 Number all pages

Please check that you have completed all the following before submission

- A Administrative section Sections A to E "Application for APPROVAL OF A RESEARCH PROPOSAL in terms of Rule G40 (1)"
- B Sections F, G and H of the Faculty of Health G186 (research proposal).

Thank you

Faculty of Health mnp/feb013/research

Application for APPROVAL OF A RESEARCH PROPOSAL in terms of Rule G40(1)

**NOTE:** Should you wish to use a floppy/hard disk which contains the G186, please consult your Research Co-ordinator. Please consult your Research Co-ordinator to ensure that you use the latest version of this form.

**SECTION A** - To be completed by student [If handwritten, please print]

Student Number: .....

Surname: ...... Title: .....

Full First Names: .....

Postal Address: .....

.....

Telephone No: ...... (Work) ..........(Home)

Date of Birth: ....

Name of Matriculation (or equivalent) qualification/s attained (attach certified copy/ies)

Post matriculation (or equivalent) qualification/s attained (attach certified copy/ies) Working experience (attach proof)

Qualification for which topic is to be registered (e.g. Master's Degree in Technology: Fine Art)

Title of MINIDISSERTATION (in respect of Master's Diploma/Degree in Technology) or THESIS (in respect of Doctor's Degree in Technology)

Estimated direct total costs of research to Durban Institute of Technology R .....

#### **ETHICS - Please see section E**

#### AS FAR AS I KNOW AND CAN ASCERTAIN:

- (a) no other similar dissertation/thesis exists; AND
- (b) all references detailed in the dissertation are complete in terms of all personal communications engaged in and published works consulted.

I HEREBY DECLARE THAT THE ABOVE FACTS ARE CORRECT. I ACKNOWLEDGE THAT:

- (1) I have the responsibility to determine that no similar research at a tertiary institution is being or has been conducted; AND
- (2) any approval of my research and any funding of it by Durban Institute of Technology is conditional upon (1).

I will adhere to the Institution's Research Ethics Policy as it relates to my research.

Signed:	
STUDENT	DATE

SECTION B – To be completed by Supervisor/Promoter

- I, (full names of Supervisor/Promoter)
- (a) acknowledge the responsibility to advise the student on how to conduct the necessary literature search in order to ascertain that no other similar research at a tertiary institution is being or has been conducted;
- (b) accept the appointment as Supervisor/Promoter and the concomitant responsibilities;
- (c) approve of the proposal;
- (d)\* approve of the Joint Supervisor(s) / Joint Promoter(s) proposed by the Head of Department;
- (e)\* recommend that the student's project be registered as secret.

Signed:	
SUPERVISOR/PROMOTER	DATE
*delete and sign alongside if not applicable	

**SECTION C** – To be completed by Head of Department and then forwarded to Faculty HQC/ BOFEX

Department: .....

Proposed: <u>Supervisor</u> (in respect of Master's Diploma/Degree in Technology) or <u>Promoter</u> (in respect of Doctor's Degree in Technology):

Title:
Name:
Qualifications:
Postal Address:
Telephone: (Work) (Home)

Proposed Joint Supervisor(s) / Joint Promoter(s):

1.	l itle:
	Name:
	Qualifications:
	Postal Address:
	Telephone: (Work) (Home)

I, (full names of HOD)

- (a) am satisfied that the student is in possession of the necessary academic entrance qualifications;
- (b) approve of the topic/field of investigation;
- (c) propose the Supervisor/Promoter detailed above;
- (d)\* propose the Joint Supervisor(s) / Joint Promoter(s) detailed above;
- (e)\* recommend that the student's project be registered as secret.

Signed:	
HEAD OF DEPARTMENT	DATE
*delete and sign alongside if not applicable	

**SECTION D** – To be completed by Dean of the relevant Faculty

The Faculty of: (Complete)

- (a) recommends the attached proposal;
- (b) proposes the Supervisor/Promoter detailed above;
- (c)\* proposes the Joint Supervisor(s) / Joint Promoter(s) detailed above;
- (d)\* recommends that the student's project be registered as secret.

Signed: .....
DEAN DATE
\*delete and sign alongside if not applicable

#### SECTION E APPLICATION FOR ETHICAL APPROVAL OF RESEARCH PROPOSAL

The proposed research is categorised as research:

	Yes	No
on humans and organizations		
on animals		
with environmental implications		

(Head of Department to tick the appropriate box)

It has been reviewed and complies with the Durban Institute of Technology Research Ethics Policy, the general Guidelines, and the relevant specific Guidelines for the Ethical Conduct of Research.

CATEGORY	
----------	--

Comment	s:	••••••
Signed:	Head of Department	Date
Signed: Dean/Fac	ulty Research Committee Chairman	Date
Signed:	Durban Institute of Technology Research Ethics and Biosafety Committee Chairman	b Date
Th	e completed Ethical Issues Checklist and all documents used	to inform potential research

The completed Ethical Issues Checklist and all documents used to inform potential research participants, including Participant Information Sheets, Consent Forms, research instruments, advertisements and letters, must be submitted for ethical approval.

## FACULTY OF HEALTH

#### **SECTION F**

1. Title

#### 2. Summary (approximately 250 words)

#### 3. Aim/Purpose of study

4. Rationale for the Study and Research Questions (give clear reasons why the Research is necessary and indicate potential value of the study in about 4-5 concise statements)

1. 2. 3.

4.

- Literature review (Include any controversies, gaps and / or shortcomings in general knowledge in the literature) maximum of 1000 words.
- 6. 6.1 Research Design (Research Methods) (You are advised to consider study type, data collection tools and statistical methods)

#### **6.2 Timeframe** (flowchart or critical path with dates)

#### 6.3 Confirmation of consultation of statistician

I hereby confirm that I have been consulted by .....(student's name) on the statistical aspects of this proposal.

Signed..... Statistician

Date:

**7. References** (pertaining to entire document. Should ideally not exceed 10 key references)

SECTION G: Ethics statement (Complete the attached ethics questionnaire) SECTION H: Budget (complete the accompanying sheet)

# SECTION H – BUDGET

SECTION 1 – To be completed by student REQUEST FOR FUNDING OF THE PROJECT (give details)

		COST	
1.	Consumables		
	(including questionnaires)		
2.	Outside Specialist Services		
	(e.g. testing services, chemical analyses)		
3.	Books/Documents		
4.	Library Charges		
	(including literature/data bank search, inter-library loans)		
5.	Small items of equipment		
6.	Major items of equipment		
7.	Miscellaneous (specify)		
	GRAND TOTAL		

**NB:** The following will **not** be supported

- (1) any fees;
- (2) costs of preparing dissertation/thesis including typing and printing; AND
- subsistence to discuss research progress or research ideas or to visit libraries
   ALL APPROVED funding is ADMINISTERED by the academic department concerned.

## ETHICAL ISSUES CHECKLIST FOR RESEARCH APPROVAL

To be completed by all people wishing to conduct research under the

auspices of Durban Institute of Technology.

- 1. Use the Durban Institute of Technology Research Ethics Policy and Guidelines to ensure that ethical issues have been identified and addressed in the most appropriate manner, before finalizing and submitting your research proposal.
- 2. Please indicate [by a X as appropriate] which of the following ethical issues could impact on your research.
- 3. Please type the motivations/further explanations where required in the cell headed COMMENTS.
- 4. The highlighted response cells indicate those responses that are of particular interest to the Research Ethics and Biosafety Committee
- 5. The checklist is divided into sections relevant to all research; research on animals; research on humans; research on human health issues and biotechnology.

NO.	QUESTION	<u>YES</u>	NO	N/A
	CONFIDENTIALITY			
1.	Does the data collection process involve access to (personal or otherwise) confidential personal data (including access to data for purposes other than this particular research project) without prior consent of subjects? If yes, motivate the necessity.			
	<u>COMMENTS</u>			
2.	Will the data be collected and disseminated in a manner that will ensure confidentiality of the data and the identity of the participants? Explain your answer.			
	<u>COMMENTS</u>			
3.	Will the materials obtained be stored and ultimately disposed of in a manner that will ensure confidentiality of the participants? If no, explain. If yes specify how long the confidential data will be retained after the study and how it will be disposed of.			
	<u>COMMENTS</u>			
4.	Will the research involve access to data banks that are subject to privacy legislation? If yes, specify and explain the necessity.			
	COMMENTS			
	BENEFITS			
5.	Is this research expected to benefit the participants or organisations directly or indirectly? Explain any such benefits.			
	COMMENTS			
6.	Does the researcher expect to obtain any direct or indirect financial or other benefits from conducting the research? If yes, explain.			
	COMMENTS			

# ALL RESEARCH

<u>NO.</u>	QUESTION	YES	NO	N/A
	SPONSORS, INTERESTS AND INDEMNITY			
7.	Will this research be undertaken on the behalf of or at the request of a pharmaceutical company, or other commercial entity or any other			
	COMMENTS		-	
8.	If yes to 7, will that entity undertake in writing to abide by Durban Institute of Technology Research Ethics Policy and Guidelines? If yes, do not explain further. If no, explain.			
	COMMENTS			
9.	If yes to 8, will that entity undertake in writing to indemnify the institution and the researchers? If yes, do not explain further. If no, explain.			
	COMMENTS			
10.	Does the researcher have indemnity cover relating to research activities? If yes, specify. If no, explain why not.			
	COMMENTS			
11.	Does the researcher have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? If yes, specify.			
	COMMENTS			
12.	Does permission need to be obtained in terms of the location of the study? If yes indicate how permission is to be obtained.			
	COMMENTS			
	DECEPTION/COVERT DATA COLLECTION			
13.	Is deception of any kind to be used? If so provide a motivation for acceptability.			
	COMMENTS			
14.	Does the study involve covert data collection? If yes, explain why this is necessary and what steps have been taken to address the ethical implications of this.			
	COMMENTS			

### **RESEARCH ON ANIMALS**

15.	Does the research involve the use of animals? If yes, describe the nature of this involvement.		
	COMMENTS		

<u>NO.</u>	QUESTION	YES	NO	N/A
16.	Is the research being conducted at an approved facility? If no, explain why. If yes, indicate which facility.			
	COMMENTS			

# **RESEARCH ON HUMANS**

	RECRUITMENT		
17.	Does recruitment involve direct personal approach from the researchers to the potential subjects? Explain the recruitment process		
	COMMENTS		
18.	Are participants linked to the researcher in a particular relationship, for example employees, students, family? If yes, specify how.		
	COMMENTS		
19.	If yes to 18, is there any pressure from researchers or others that might influence the potential subjects to enroll? Elaborate.		
	COMMENTS		
20.	Does recruitment involve the circulation/publication of an advertisement, circular, letter etc? If yes, specify and provide copy.		
	COMMENTS		
21.	Will subjects receive any financial or other benefits as a result of participation? If yes, explain the nature of the reward, and safeguards.		
	COMMENTS		
22.	Is the research targeting any particular ethnic or community group? If yes, motivate why it is necessary/acceptable. If you have not consulted a representative of this group, give a reason. In addition explain any consultative processes, identifying participants. Should consultation not take place, give a motivation.		
	COMMENTS		
	INFORMED CONSENT		
23.	Does the research fulfill the criteria for informed consent? [See guidelines]. If yes, no further answer is needed. If no, please specify how and why.		
	COMMENTS		

<u>NO.</u>	QUESTION	YES	NO	N/A
<u>24.</u>	Will the research involve the use of no-treatment or placebo control conditions? If yes, explain how subjects' interests will be protected.		]	
25.	Will a Subject Information Letter be provided and a written consent be obtained? If no, explain. If yes, attach copies to proposal. In the case of subjects who are not familiar with English (e.g. it is a second language), explain what arrangements will be made to ensure comprehension of the Subject Information Letter, Informed Consent Form and other questionnaires/documents.			
26.	COMMENTS           Will results of the study be made available to those interested? If no, explain why. If yes, explain how.           COMMENTS			
	DISKS TO PARTICIPANTS	-		
27.	Will participants be asked to perform any acts or make statements that might be expected to cause discomfort, compromise them, diminish self-esteem or cause them to experience embarrassment or regret? If yes, explain.			
	<u>COMMENTS</u>			
28.	Might any aspect of your study reasonably be expected to place the participant at risk of criminal or civil liability? If yes, explain.			
	COMMENTS			
29.	Might any aspect of your study reasonably be expected to place the participant at risk of damage to their financial standing or social standing or employability? If yes, explain.			
	COMMENTS			
30.	Does the research involve any questions, stimuli, tasks, investigations or procedures which may be experienced by participants as stressful, anxiety producing, noxious, aversive or unpleasant during or after the research procedures? If yes, explain.			
	<u>COMMENTS</u>			

#### RESEARCH ON HUMAN HEALTH ISSUES/ BIOTECHNOLOGY

31.	Does the protocol require any physically invasive, or potentially harmful procedures [e.g. drug administration, needle insertion, rectal probe, pharyngeal foreign body, electrical or electromagnetic stimulation, etc]? If yes, please outline below the procedures and what safety precautions will be used.		
	COMMENTS		

<u>NO.</u>	QUESTION	YES	NO	N/A
32.	Will any treatment be used with potentially unpleasant or harmful side effects? If yes, explain the nature of the side effects and how they will be minimized.			
	<u>COMMENTS</u>			
33.	Will any samples of body fluid or body tissues be required specifically for the research that would not be required in the case of ordinary treatment? If yes, explain and list such procedures and techniques.			
	COMMENTS			
34.	Are any drugs/devices to be administered? If yes, list any drugs/devices to be used and their approved status.			
	COMMENTS			
	GENETIC CONSIDERATIONS			
35.	Will participants be fingerprinted or DNA "fingerprinted"? If yes, motivate why necessary and state how such is to be managed and controlled.			
	<u>COMMENTS</u>			
36.	Does the project involve genetic research e.g. somatic cell gene therapy, DNA techniques etc? If yes, list the procedures involved			
	<u>COMMENTS</u>			

The undersigned declare that the above questions have been answered truthfully and accurately

STUDENT NAME: Nicolaas Tjaart van der Merwe SIGNATURE: DATE:

# SUPERVISOR NAME: Dr Garrick Haswell SIGNATURE:

DATE:

### CO-SUPERVISOR NAME: SIGNATURE:

DATE: