CHAPTER ONE
INTRODUCTION

1.1 INTRODUCTION

Low back pain (LBP) is a highly prevalent problem and one of the main causes of disability in the society. Despite its high prevalence, source of pain is not established in majority of cases (Macedo et al., 2009; Freeman et al., 2010). Low back pain is the most common complaint seen by physical therapists and it is always the symptoms most often associated with the use of physiotherapy modalities (Coste et al., 1991). It has been estimated that 80% - 90% of people will suffer from LBP at sometime in their lifetime (Bakhtiary et al., 2005). The aetiology of low back pain is diverse; many causes have been related to weakness or injury of the soft tissues in the lumbar area (O’Sullivan, 2000). The low back is susceptible to injury because it supports most of the body weight (Odebiyi et al., 2007). People with LBP and associated disability usually improve rapidly within weeks, nonetheless pain and disability are usually ongoing and recurrences are common (Pengel et al., 2003).

It has been reported that despite the large number of pathological conditions that can give rise to LBP, 85% of these are without pathoanatomical/radiological abnormalities (Dankaerts et al., 2006). It is the non-specific LBP population which often develops into a chronic fluctuating problem with intermittent flares (Burton et al., 2004). Skeletal muscles play an important role in the pathology of low back disorders. It is known clinically that excessive motion beyond the normal physiological limits, sometimes referred to as spinal instability, may result in chronic low back pain (Hodge and Richardson, 1996).
Available evidence suggests that spinal muscles provide stability and muscle recruitment patterns significantly affect loading on the intervertebral joints (Van Dien et al., 2003). The stability of the spine is determined by the osseoligamentous armour that encapsulates the spine (Panjabi, 1992). The complex loading patterns associated with activities of daily living, act on these structures and if unprotected, can expose spinal vulnerability, predisposing to musculoskeletal injuries, such as LBP (Renkawitz et al., 2006).

The growing awareness of CLBP as a major clinical problem has promoted increased interest and research into this continuing epidemic (Cairns et al., 2000). Epidemiological research has focused primarily on the local stability system, which acts as a ‘corset like’ structure to tighten the waist, when the spine is in a loaded position (Hides et al., 2001). The correct alignment required to stabilize and accommodate movements depends on adequate strength and endurance on abdominal musculature (Hodges and Richardson, 1997). It is the activation of the dynamic spinal support system that is exposed and which provides the basis for the concept of stabilization training (Hides et al., 2001).

Hodges et al. (2003) reported on the anatomical, biomechanical and neurophysiological characteristics of Transversus abdominis (TrA) and Lumbar multifidus (LM), which are important components of the local stability system. Electromyographic (EMG) studies revealed that the LM along with TrA are the only muscles active during all trunk movement (Cresswell et al., 1994). Transversus abdominis is active in a non-directional-specific feed forward manner in preparation for the perturbation of the spine from arm movements.
The Electromyography (EMG) analysis shows that the onset of activity of the muscles of the abdominal wall in response to upper and lower limb movements indicated that the timing of onset of TrA was delayed in patients with CLBP, compared with individuals who have never experienced back pain (Hodges and Richardson, 1995).

Ultrasound imaging of LM muscle is of increasing interest to physiotherapists, both for clinical and research purposes. Ultrasound imaging has provided accurate assessment of muscle wasting in various muscles, clinically the application is two folds: as an objective assessment tool for detecting abnormalities, and monitoring changes during recovery (Hides et al., 1996), and for visual feedback during reeducation of muscle contraction (Hides et al., 1997). Measurement of muscle size using ultrasound has provided accurate assessment of muscle wasting in various muscles (Stokes et al., 1997). In a recent study Ultrasound measurement of LM muscle has been reported to be a potentially valuable, fast and easy way to evaluate muscle size at different levels of lumbar vertebrae in clinical settings (Larrie-Baghal, 2012).

The technique was also useful in demonstrating that LM size does not recover when pain subsides unless it undergoes specific exercises (Hides et al., 1996). Biomechanical models suggest that all muscles with intervertebral attachments are better suited for intersegmental stability provision (LM, TrA), as opposed to the larger trunk muscles (erector spinae, rectus abdominis), which are dedicated to movement generation (Bergmark, 1989). Inadequate activation of the local stabilizing trunk muscles may lead to instability of the lumbar spine (Panjabi, 1992). This evidence indicated that a programme for the TrA and LM is required for specific lumbar segmental stabilization training for muscle dysfunction in individuals with a history of lower back problems (Jull et al., 1995). In a study by Kasai (2006) it was concluded that stabilization
exercise has significant long term effect on CLBP in the reduction of pain and improvement in functional ability with low recurrence rate.

Basically stabilization exercise is aimed at protecting and supporting the spinal segment from re-injury by reestablishing and enhancing muscle control to compensate for any loss of muscle action caused by injury or degenerative changes (Richardson et al., 1999). A study by Gatti et al. (2011) also reported that stabilization exercise was found to be more effective in reducing disability in patients with CLBP. However the number of studies related to the use of stabilization exercise in the treatment of NCLBP and ultrasound scanning in the assessment of cross-sectional area and muscle thickness of lumbar multifidus is currently not in existence in Nigeria; hence this study was thus designed to determine the effects of stabilization exercise on pain, cross-sectional area and muscle thickness of lumbar multifidus in patient with CLBP.

1.2 STATEMENT OF PROBLEM

Low back pain (LBP) is one of the most common and costly medical problems in the society (O’Sullivan, 2000). Nearly 80-90% of people suffer LBP during their lifetime (Bakhtiary et al., 2005; Kasai, 2006), and about 10% of patients with prolonged symptoms that is pain severity and functional disability (3 months or more) are responsible for 80% of the total cost (Kasai, 2006). Considering the serious economic and social implication of chronic low back pain (CLBP), appropriate management is highly required. Different treatment modalities have been used, but with temporary relief of symptoms and lack of improvement of the atrophy of LM muscle which improves the stability of the lumbar spine. Symptoms are relieved with the use of physiotherapy modalities such as Transcutaneous Electrical Nerve Stimulator (TENS), massage and manipulative therapy. Temporary effects of these modalities have
increased the attention being paid to preferential retraining of the local stabilizing muscles of the spine (Danneels et al., 2001; Hides et al., 2001). Ultrasound imaging can be used to provide assessment of the location of LM muscle atrophy and serial measurement could be used to assess the effects of muscle rehabilitation in patients with LBP (Hides et al., 1995). This study was thus designed to determine the effects of stabilization exercise on chronic pain, disability and fear avoidance belief in non-specific chronic low back pain patients and whether stabilization exercise would assist in the improvement of status of local muscle system and atrophy of lumbar multifidus (LM) muscle in patients with non-specific chronic low back pain in Nigeria.

1.3 AIM OF THE STUDY
The overall aim of this study was to determine the effects of stabilization exercise on chronic pain, Cross-Sectional Area (CSA) and muscle thickness of Lumbar Multifidus (LM) muscle in patients with Chronic Low Back Pain (CLBP).

1.4 SPECIFIC OBJECTIVES
The specific objectives of this study were to determine the effects of Stabilization exercise on

2. The CSA of LM muscle in patients with NCLBP.
3. Muscle thickness of LM muscle in patients with NCLBP.
1.5 SIGNIFICANCE OF THE STUDY

The result of this thesis may provide physiotherapists an alternative way apart from electrotherapeutic modalities and general exercises in managing patients with NCLBP. The result of this thesis might create awareness on the importance of assessing CSA and thickness of LM as a measure of treatment improvement or progression in patients with NCLBP. The result of this thesis may add to the database research studies in the management of NCLBP and in the correlation between CSA and muscle thickness of lumbar multifidus in patients with NCLBP.

1.6 SCOPE OF THE STUDY

This study is a randomized control study which was conducted at the Lagos University Teaching Hospital, Idi-Araba, Lagos, Nigeria, and National Orthopaedic Hospital Igbobi, Lagos, Nigeria. The patients recruited for this study were male and female individuals with non-specific chronic low back pain between 25 and 65 years of age.

1.7 DEFINITION OF TERMS

**Stabilization Exercise:** It is a specific therapeutic exercise program aimed at reversing the loss in the motor control of the local muscle system and to restore the normal synergy between the local and the global muscle system.

**Low back pain:** Pain and discomfort localized below the costal margin and above the inferior gluteal folds with or without leg pain. This can be divided into three categories-diagnostic triage, viz spinal pathology, nerve root pain/ radicular pain and non specific low back pain.

**Non-specific chronic low back pain:** Low back pain that is not attributable to a recognizable specific pathology (e.g. infection, tumour, osteoporosis, fracture,
structural deformity, inflammatory disorder e.g. ankylosing spondylitis, radicular syndrome or cauda equina syndrome).

**Muscle Thickness:** Muscle contraction is seen on the ultrasound image as an increase in the thickness of the muscle as it shortens along its length.

**Spondylolisthesis:** is a condition of the spine whereby one of the vertebra slips forward or backward compared to the next vertebra.

**Osteoporosis:** Osteoporosis is a condition characterized by a decrease in the density of bone, decreasing its strength and resulting in fragile bones.

**Lumbar lordosis:** it is an exaggerated lumbar curve in the spine and anterior-wall convexity in the vertebral column.

**Isometric contraction:** An isometric muscle contraction, or static exercise, is one in which the muscle contracts but there is no movement at a joint. In this type of muscle contraction, there is no change in length of the muscle, and no movement at the joints but muscle fibers contract. The benefit of isometric exercises are that they can be used for rehabilitation as well as general strengthening without placing stress on the joints.

1.8 **LIST OF ABBREVIATIONS**

- **BMI** - Body mass index
- **CSA** - Cross-sectional area
- **DSM** - Deep spinal muscle
- **FD** - Functional disability
<table>
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<tr>
<th>Acronym</th>
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<tr>
<td>FABP</td>
<td>Fear Avoidance belief for physical activity</td>
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<td>FABW</td>
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<td>LBP</td>
<td>Low back pain</td>
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<td>LM</td>
<td>Lumbar multifidus</td>
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<td>NCLBP</td>
<td>Non-specific chronic low back pain</td>
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<td>CLBP</td>
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<td>PSIS</td>
<td>Posterior superior iliac spine</td>
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<td>TrA</td>
<td>Transversus abdominis muscle</td>
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<td>TENS</td>
<td>Transcutaneous electrical nerve stimulator</td>
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<td>EMG</td>
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CHAPTER TWO

LITERATURE REVIEW

2.1 SPINAL PATHOLOGY:

The human spine devoid of its musculature is inherently unstable (Norris, 1995). Biomechanical research has demonstrated that lumbar motion segments display bi-phasic stiffness properties across the physiological range of motion (Jemmet et al., 2004). Such findings have led to the development of a more comprehensive model of spinal function in which the central nervous system, skeletal muscle and the osseoligamentous structures are considered to be inter-reliant mechanism of spinal stabilization system (Panjabi, 2003). Due to the inability of the osseoligamentous spine to tolerate loads associated with normal activity, spinal muscles are now required to maintain adequate spinal stability, in which coordinated muscular activity is mandatory to prevent excessive loading leading to injury. Lumbar segmental instability is considered to represent a significant subgroup within the chronic low back pain population. This condition has a unique clinical presentation that displays its symptoms and movement dysfunction within the neural zone of the motion segment.

The loosening of the motion segment secondary to injury and associated dysfunction of the local muscle system renders it biomechanically vulnerable in the neural zone (O'Sullivan, 2000).

The clinical diagnosis of this chronic low back pain condition is based on the report of pain and observation of movement dysfunction within the neural zone and the associated finding of excessive intervertebral motion at symptomatic level. Four different clinical patterns are described based on the directional nature of the injury and
the manifestation of the patient’s symptoms and motor dysfunction. A specific stabilizing exercise intervention based on motor learning model is proposed and evidence for the efficacy of the approach provided (O’ Sullivan, 2000).

The evolution of spinal stability model has prompted much research focusing particularly on the functional set of deep muscles (Transversus abdominis and lumbar multifidus) with segmental pattern of attachment in the lumbar region conducive to the maintenance of intersegmental stiffness. They have been hypothesized, to be architecturally capable of developing the intersegmental stiffness required for spinal stability (Hodges et al., 2003; Jemmet et al., 2004).

The lack of large studies which comprehensively detailed the function of these important muscles in context of lumbar instability represents a gap in the literature.

2.2 BACK PAIN

Back pain, also known as dorsalgia, is pain felt in the back that usually originate from the muscles, nerves, bones, joints or other structures in the spine. The pain can often be divided into neck pain, upper back pain, lower back pain and tail bone pain. It may have a sudden onset or can be a chronic pain, it can be constant or intermittent, stay in one place or radiate to other areas. It may be a dull ache or a sharp or piercing or burning sensation. The pain may be felt in the neck or radiate into the arm and hand in the upper back or in the low back and might radiate into the leg or foot and may include symptoms other than pain such as weakness numbness or tingling.

Back pain is one of the humanity most recent complaints (Patel and Ogle, 2007). In the US, acute low back pain, also called lumbago, is fifth most common reason for physician visits. About nine out of ten adults experience back pain at some point in
there life time and five out of ten working adults have back pain every year (Patel and Ogle, 2007).

Back pain does not usually require immediate medical intervention. The vast majority of episode of back pain are self-limiting and non-progressive. Most back pain syndromes are due to inflammation especially in the acute phase which typically last for two weeks to three months. A few observational studies suggest that two conditions to which back pain is often attributed, lumbar disc herniation and degenerative disc diseases may not be more prevalent among those in pain than among the general population, and the mechanism by which these conditions might cause pain are not known (Borenstein et al., 2001; Kleinstuck, 2006).

Other studies suggest that for as many as 85% of cases, no physiological causes can be shown (van den Bosch et al., 2004). A few studies suggest that psychosocial factors such as on-the -job stress and dysfunctional family relationships may correlate more closely with back pain than structural abnormalities revealed in X-ray and other medical imaging scan (Carragee et al., 2005; Dionne, 2005).

There are several potential sources and causes of back pain (Bogduk, 2005). However the diagnosis of specific tissue of the spine as a cause of pain presents problems. This is because symptoms arising from different spinal tissues can feel very similar and is difficult to differentiate without the use of invasive diagnostic intervention procedures such as local anesthetic blocks.

One potential source of back pain is skeletal muscles of the back(Bogduk, 2005). Another potential source of low back pain is the synovial joints of the spine for example Zygapophysial joints. This has been identified as the primary source of pain in approximately one-third of people with chronic low back pain and in most people with
neck pain following whiplash (Bogduk, 2005). There are several common potential causes of back pain these include spinal disc herniation and degenerative disc disease or isthmic spondylolisthesis, Osteoarthritis and spinal stenosis, Trauma, Cancer, Infection, Fractures and Inflammatory diseases (Jensen et al., 1995).

It is frequently reported that back pain symptoms, pathology, radiological findings are poorly correlated, pain is not attributable to specific pathology or neurological encroachment in about 85% of people (Deyo, 1988). Clinicians should therefore be aware of the incidence and characteristic of specific back pain. About 4% of people seen with low back pain in primary care have compression fracture and about 1% has a neoplasm (Deyo et al., 1992). An observational study in more than 7000 women > 65 years reported that 5% developed at least one vertebral fracture in 4 years (Kado et al., 2003).

2.2.1 LOW BACK PAIN (LBP)

Low back pain is defined as pain and discomfort localized below the coastal and above the inferior gluteal fold with or without referred leg pain. Chronic low back is defined as low back pain persisting for at least 12 weeks unless specified otherwise (Airaksinen et al., 2004). This means physiotherapist deals with cases that may be characterized as sub acute back pain, cases that have lasted for very long periods of time and cases of recurrent pain in which the current episode has lasted for approximately 12 weeks (Airaksinen et al., 2004).

A simple and practical classification, which has gained international acceptance is to divide low back pain into three categories-the so called diagnostic triage, specific spinal pathology, nerve root/radicular pain, non specific low back pain (Airaksinen et al., 2004).
LBP fluctuate over time with frequent recurrence and exacerbation (Van tulder et al., 2003. Two systematic reviews reported on the prognosis, long term course or epidemiology of low back pain (Hestbaek et al., 2003, Pengel et al., 2003). The first review reported that after a first episode of low back pain the proportion of patient who still experienced pain after 12 month was on the average of 62%. The percentage of sick patient listed after 6 months was 16% and the percentage who experienced relapse of pain was 60% while the percentage who had relapse of work absence was 33% (Hestbaek et al., 2003). The second review concluded that rapid improvement in pain (58%), disability (58%) and return to work (82% of those initially off work) occurred in the first month after an initial episode of LBP. Further improvement was apparent until about three months. Thereafter pain, disability, and return to work remain almost constant. 73% of patient had at least one occurrence within 12 months (Pengel et al., 2003).

Current biomechanical understanding about the pathogenesis of LBP is still incomplete. Billions of pounds are spent annually on the treatment of LBP and lower back injuries (Waddell 1996), affecting up to 80% of people at some point during there lifetime (Katz, 2002; Ehylich, 2003; Wolfe and Pfleger, 2003). Intense research efforts have been made to understand the complex and unique structures of the spine (Wimmers et al., 2003; Dankaert et al., 2006). The evidence suggest that spinal muscles provide stability (van Dien et al., 2003) and muscle recruitment pattern significantly affect loading on the intervertebral joints (Marras et al., 2001). Therefore imbalanced muscle activation can theoretically load the spine incorrectly and induce LBP and musculoskeletal injury (Renkawitz et al., 2006). One of the highest research priorities
should be to determine the best strategies for treating individuals with history of LBP (Abenhaim et al., 2000).

2.2.2 TREATMENT OF LOW BACK PAIN

There are many treatment options for LBP. The review by Assendelft et al. (2007) compared spinal manipulation, manual therapy, exercise, back school and analgesics and concluded that the optimal treatment remain largely enigmatic. The review which compared sub group of LBP subjects highlighted the uneven quantity and methodological quality of randomized control trial. A criticism of the review was that for the exercise intervention trials were formulated into broad clusters with insufficient detailing of the exact treatment that was applied for this intervention.

The generalization of “exercise therapy” as a single form of treatment detracts greatly from the interpretation of the result. Exercise therapy is a multifaceted modality that requires specific prescription in which randomized control trial need to be narrowed in definition (Hayden et al., 2007). However a review of the literature reveals that a shift can be observed in the choice of intervention to a more active approach (Koes et al., 2001; Rasmussen-Barr et al., 2003; Koumantakis et al., 2005; Gronendick et al., 2007) being one of the key determinant for improvement for many sufferers (vanTulder, 2002). A study by Pengel et al., (2003) concluded that people with acute low back pain and associated disability usually improve rapidly within weeks, nonetheless pain and disability are typically ongoing and recurrences are common. Systematic reviews have concluded that exercise is a safe effective therapy when compared to usual care (vanTulder et al., 2000; Liddle et al., 2004; Rainville et al., 2004). Incoherence among three reviewers (Hildes, 1998; Abenhaim, 2000; Tugwell, 2001) contemporary
recommendations should focus research not on general exercise therapy, but instead on trials that investigate specific exercise intervention strategies (Hayden et al., 2007).

2.2.3 TYPES OF LOW BACK PAIN

Low back pain can be divided into three large classifications which are axial, referred and radicular pain. The most common is known as axial or mechanical back pain. This pain can run from a very sharp to a dull ache. It may occur all the time or it may come and go. It also varies in intensity from very mild to extremely severe, and the pain is always restricted to the low back area (Darrow, 2010). This type of mechanical pain is completely nonspecific with regard to the injured structures. Generally the pain gets worse with certain activity or positions. It is usually relieved by rest or changing position. This condition responds well to conservative care (Darrow, 2010). More often the injury involves more than just a misalignment of vertebrae or of the pelvis, nerves, muscles, tendons, ligament and skin can all have an influence on the degree of discomfort. A study has shown that people diagnosed with NCLBP might be categorised as having mechanical or inflammatory low back pain. In a study of expert opinion, a number of signs were identified as potentially indicating LBP of mechanical origin (Walker and Williamson, 2008).

These were intermittent pain during the day, pain that develops later in the day, pain on standing for a while, pain with lifting, pain with bending forward a little, pain on trunk flexion or extension, pain on doing a sit up, pain when driving long distances, pain getting out of a chair and pain on repetitive bending, running, and coughing or sneezing (Riskman et al., 2011).

In referred pain, patient complain of having an achy, dull type of pain that seem to move around. The discomfort comes and goes and varies in intensity. This aching pain starts in
the low back region and commonly spread into the groin, buttocks and upper thigh. (Darrow, 2010).

The last type of low back pain is known as radicular pain. In this case the pain is described as deep and usually constant. It follows the nerve down the leg and is often accompanied by numbness or tingling and muscle weakness. The most common type of this type of problem is the sciatic pain that radiates along the sciatic nerve, down the back of the thigh and calf into the foot. This type of pain is caused by injury to a spinal nerve. Some of the possible causes of this are a disc protrusion or bulge, arthritic changes or a narrowing of the opening through which the nerve exists (Darrow, 2010).

2.2.4 AETIOPATHOGENESIS OF LOW BACK PAIN

Common to all patient presentations is the reported vulnerability and observed lack of movement control and related symptoms within the neural zone. This is associated with inability to initiate co-contraction of the local muscles system within the neural zone. It appears that these patients develop compensatory movement strategies which stabilize the motion segment out of the neural zone and towards an end range position (Hides et al., 1996).

There is evidence that low back pain results from atrophy of muscles acting across the joints in the lower back (Hides et al., 1996). Several abnormal characteristics have been identified in the LM muscle in LBP subject. Structural abnormalities include histological changes where fatty infiltrate replace LM muscle tissue (Zhao et al., 2000; Yoshiara et al., 2003). It has been demonstrated that the LM inhibition and wasting does not reverse itself as the person recovers from acute spinal episode (Richardson, 1999). Part of the muscle may convert to fat (figure 1).
The amount of fat that is found in the LM strongly correlated with recurrent back pain episode in adult (Kjaer, 2007). Even in patients who do abdominal and spinal extension (strengthening) exercises the LM do not regain normal cross sectional thickness (Richardson, 1999). Clinical signs of muscle atrophy are a decrease in the cross sectional area (CSA) of the muscle and decreased muscle strength and endurance. Reduced muscle support will increase the load on the joints and lead to abnormal movement patterns. Muscle atrophy can occur secondary to muscle pathology viz denervation, disuse (Lieber, 1992). A reduction in the CSA of LM has been demonstrated in both acute and chronic low back pain pathology (Stokes et al., 1992; Hides et al., 1996; Kader et al., 2000).
Figure 1: Amounts of fat in the LM Muscles as seen in axial TI. Weight magnetic resonance imaging scans. These were rated as grade 0 if normal condition; grade 1 for slight fat infiltration (10-50%) and grade 2 for severe fat infiltration (>50%) (Kjaer, 2007)
2.2.5 SPECIFIC CAUSES OF LBP

It is frequently reported that low back pain symptoms pathology and radiological findings are poorly correlated. Pain is not attributable to spinal pathology or neurological encroachment in about 85% of people (Deyo, 1988). Clinician should be aware of incidence and characteristics of specific back pain. It is estimated that about 4% of people seen with low back pain have compression fractures and about 1% have neoplasm (Deyo et al., 1992).

A study that was conducted among 7000 women >65 years reported that 5% of the women develop at least one vertebral fracture in 4 years (Kado et al., 2003). The spondyloarthropaties and spinal deformities commonly involve the whole spine and it has been reported that spondyloarthropaties occur at a rate of 0.8-1.9% of the general population (Saraux et al., 1999).

The prevalence of scoliotic deformities that appear as a rib prominence upon forward bending is reported to be 1 and 4% (Dickson et al., 1980). Spinal infections are rare and chronic spinal infections are particularly rare. Spondylolisthesis and spondylosis are often classified as nonspecific low back pain because a considerable proportion of patient with such anatomic abnormalities are asymptomatic (Soler and Calderon, 2000).

In one large epidemiological study, a one-year incidence of lumbar radiculopathy is higher than 83/100000 (Airaksinen et al., 2004). Although there is general consensus on the importance and basic principles of different diagnosis, no scientific studies have actually been carried out to evaluate the effectiveness of diagnostic triage system recommended in most guidelines. All guidelines propose some form of diagnostic triage in which patient are classified as having, possible a) specific spinal pathology e.g. tumour, infection, inflammatory disorder, fracture, cauda-equina syndrome, non-
mechanical pain, thoracic pain, history of cancer, structural change, diffuse neurological deficit. b) Nerve root pain and non specific low back pain. (Airaksinen et al., 2004). Secondary LBP occurring in 2% of patient is associated with underlying pathology (Kuritzky et al., 2002). The most common neurological impairment associated with back pain is herniated disc and 95% of disc herniations occur at the lowest two lumbar intervertebral levels (Lively, 2002).

2.2.6 FUNCTIONS OF THE BACK MUSCLES

Each of the lumbar muscles is capable of several possible actions. No action is unique to any muscle and no muscle has a single action. Instead the back muscles provide a pool of possible actions that may be recruited to suit the needs of the vertebral column. Therefore the function of the back muscles needs to be considered in terms of the observed movement of the vertebral column (Bogduk, 2005).

In this regard, three types of movement can be addressed: minor active movement of the vertebral column, postural movement and major movement in forward bending and lifting. Because of the downward direction of their action, as the back muscles contract they exert a longitudinal compression on the lumbar vertebral column and this compression raises the pressure in the lumbar intervertebral discs. Any activity that involves the back muscles therefore is associated with increase in nuclear pressure. As measured in L3-L4 intervertebral disc, the nuclear pressure correlates with the degree of myoelectric activity in the back muscles (Bogduk, 2005).

As muscle activity increases disc pressure rises (Bogduk, 1997). Disc pressure and myoelectric activity of the back muscles have been used extensively to quantify the stress applied to the lumbar spine in various postures and by various activities. From
the standing position forward bending causes the greatest increase in disc pressure. Lifting a weight in this position raises disc pressure even further and the pressure is greatly increased if a load is lifted with lumbar spine both flexed and rotated.

Throughout this major manoeuvre, back muscle activity increase in proportion to the disc pressure (Bogduk, 1997). In the upright position the lumbar back muscles play a minor or no active role in executing movement for gravity provide the necessary force. During extension the back muscles contribute to the initial tilt drawing the line of gravity backwards but are unnecessary for further extension. Muscle activity is recruited when the movement is forced or restricted (Bogduk, 1997).

2.3 LUMBAR MULTIFIDUS (LM) MUSCLE

Lumbar multifidus (LM) consists of a number of fleshy and tendinous fasiculi which fill up the groove on either side of the spinous processes of the vertebrae, from the sacrum to the axis (figure 2). They are capable of producing extension, lateral flexion and rotation. However when the LM are studied as individual muscle they seem to act more as stabilizers rather than prime movers of the vertebral column. Electromyographic studies confirmed this result in which it was found that multifidi play a role in controlling intersegmental motion (Solomonow et al., 1998; Moseley et al., 2002). Macintosh and Bogduk (1986) studied the biomechanical function of the LM and found out that the principal action is posterior segmental rotation of the lumbar vertebrae. The role of LM is not to produce the actual rotation but to oppose the flexion effect of the abdominal muscles as they produce rotation (Bogduk, 1997).

The LM also present differences between the lumbar and the thoracic region. The lumbar part of the multifidi is more superficial, thick and contains more vertical fibres
Moreover LM were the only muscles present on theack of the lumbosacral transition meaning that they should produce enough tension to ensure posterior stabilization in this region. In the lumbar region separate bands emanating from 1 of lumbar spinous processes form the muscle (Macintosh and Bogduk 1991).

The band spread caudolaterally from the midline. In the anteroposterior view in general the fasiculi are oriented obliquely, caudally, and laterally. Five short fasicules are deepest and arise from the caudal and dorsal surface of each laminae (L1 and L5) and insert into the mammillary process of the vertebral 2 levels caudally the fasiciculi of L5 into the sacrum just above the first sacral foramen (figure 3).

The other fasicules which are larger are arranged radially from each of the 5 spinous processes and they are arranged into five overlapping groups. They are organized segmentally in a way that each lumbar vertebrae is anchored below to the mammillary processes, iliac crest and sacrum (figure 4&5) (Bogduk, 1997). According to the fibre type of LM muscle there seems to be more type1 fibre compared to type11 fibres, but with quite large variation (Bierdemann et al., 1991; Bajek et al., 2000; Zhao et al., 2000) found that in female, muscle fibers were running more obliquely relative to the spine compared with those of the male.

In the sacrum and lumbar spine the most distal fibers are progressively covered by the more proximal ones (Bojadsen et al., 2000). LM muscle has both movement and stabilizing roles working bilaterally with other lumbar muscles, produces extension of the lumbar spine (Bogduk, 1992). If the LM is short on a regional basis there will be exaggerated lumbar lordosis or lost lordosis with forward bending (Neumann, 2002). It acts as a stabilizer in rotation, counter balancing the flexion force produced
simultaneously with the oblique abdominal muscles (Bogduk, 1997). The LM muscle is segmentally innervated by medial branches of the dorsal ramus of the adjacent spinal nerves (Jean, 2005). The main purpose of the LM is to provide segmental stability to the spine (Richardson, 1999).
Figure 2: Lumbar multifidus muscle (Richardson, 1999)
Figure 3: Attachment of LM Muscle to the Sacrum (Richardson et al., 1999).
Figure 4: The Attachment of the deep layers of LM Muscle (Bogduk, 1997)
Figure 5: The Attachment of Superficial layers of LM Muscle (Bogduk, 1997).
2.3.1 CLINICAL ANATOMY AND ASSESSMENT OF LUMBAR MULTIFIDUS MUSCLE IN PATIENT WITH LOW BACK PAIN:

The lumbar multifidus (LM) are small but very important muscle of the back which lie on each side of the lumbar vertebrae, while the erector spinae and other long muscles move the spine as a whole, the LM provide segmental stability by orienting adjacent vertebrae to each other (Macintosh 1986; Richardson, 1999).

When one palpates a lumbar multifidus (LM) muscle, the fibre closest to the surface travel 3, 4 and 5 lumbar vertebral segment, while the deeper segment travel over the next vertebra to insert into the mammillary process of the segment two vertebrae in close proximity to the facet joint between it and the vertebra below the originating vertebra. The fascicles of the LM from each vertebrae overlap the fibers of the LM from the vertebrae above, as a consequence they fill the entire region of the back from the spinous processes to about anatomy thumb breath laterally (Alexander, 2013).

If the LM are short on a regional basis the client will have an exaggerated lumbar lordosis that is lost when they bend forward (Neumann, 2002). This helps to set the stage for the lumbar vertebrae to be more approximated or held together at the back than they should be LM shortness also occurs at the level of a single facet joint. Because the LM attach adjacent to the margin of the upward facing facet and originate above, tension or shortness in that particular segment tends to inhibit movement and or lock the movement at that facet joint (Alexander, 2013).

People with excessive lumbar lordosis often have short LM muscle. A client can flex forward at the hips to determine whether the lumbar spinal segment are stucked in a lordotic extended posture or if they can flex with respect to each other. Patients that maintain a lumbar lordosis as they flex forward have short and inextensible LM muscle.
When there is more local inability to flex it is more likely caused by only a single LM or isolated short or high tone LM. Patients who flex excessively in there lumbar spine have weak eccentrically overloaded LM muscle. This set the stage for chronic post exercise muscle soreness in the LM and as well as other spinal extensor muscle and recurrent spinal disc pathology (Magee, 2005).

LM dysfunction is often interwoven with facet joint dysfunction. Hypertonic short LM are often found in the location of facet joint hypomobility. The LM may adapt to the hypomobility by becoming short or they may encourage facet joint hypomobility by keeping the facet joint compressed and preventing its ability to function properly. The tone of LM in close proximity to spinal disc pathologies tends to be inhibited (Richardson, 1999). The resultant weakness in the LM often starts the recurrent disc problems (low back pain). Palpating each side of the client spine as they lie in prone position assesses muscular development and tone which can also be done in sitting and standing position (Hides, 2000). There should be a degree of muscular fullness on each side of the spinous processes, sometimes you feel that a particular segment or segments have excessive LM tone, these LM often have an excessive stabilizing role.

Sometimes you may find LM atrophy when you compare the fullness of LM along both sides of the spine you may feel a relative softness at one or more spot. This is an area where the LM has been inhibited and do not participate in intersegmental stability, which makes the region vulnerable to excessive flexion/rotation (Richardson, 1999; Hides, 2000). When to find a segment that is underdeveloped in this way, apply a little more testing pressure to it and compare it to adjacent section of the spine. It will often feel vulnerable and weak to the palpating fingers. Patients often report that it feels weak to them and may create part of the feeling of vulnerability they feel when their back is
bothering them. You can check on the function of the LM in these inhibited regions by asking the client to actively contract the muscles, which often confirms the inactivity of the segment to contribute to spinal stiffness. This active test is done in prone position, by instructing the client to gently swell muscles under my fingers (thumbs), hold the contraction while breathing normally (Richardson, 1999). There should be no spinal or pelvic movement while the client does this, it is often easiest to ask the client to do this in a region where they have LM fullness and when they can do this against the feedback of the fingers or thumb gradually move to the region where there seems to be inhibition. You will generally notice that the client ability to recruit the LM deteriorates as they get closer and closer to the area where the muscles have less cross-sectional area.

2.3.2 TRANSVERSUS ABDOMINIS

Transversus abdominis (TrA) muscle also known as transversalis muscle and transverse abdominal muscle is a muscle layer of the anterior and lateral abdominal wall which is just deep to the internal oblique muscle (Jemmett et al., 2004). It is thought to be the major muscle of the functional core of the human body. It arises as fleshy fibres from the lateral third of the inguinal ligament, from the anterior three-fourth of the inner lip of the iliac crest, from the inner surface of the cartilage of the lower six ribs interdigitating with the diaphragm and from the lumbodorsal fascia (figure 6). The muscle ends in front in a broad aponeurosis, the lower fibre of which curve downwards and medial ward and inserts together with those of internal oblique muscle into the crest of the pubis and pectineal line forming the inguinal aponeurosis falx. Throughout the rest of its extent the aponeurosis passes horizontally to the midline and is inserted into the linea alba. Its upper three-fourth lies behind the rectus muscle and blends with
the posterior lamella of the aponeurosis of the internal oblique, its lies in front of the rectus abdominis. However a recent in vitro study by Jemmet et al., (2004), limited to the examination of single specimen found evidence that TrA attaches only via the anterior layer of the thoracolumbar fascia. The findings could be simple variation in the normal anatomy. Transversus abdominis is innervated by lower intercostals nerve (Thoraco abdominal nerve root T7-T11) as well as the illiohypogastric nerve and the illioinguinal nerve. It acts in moving and stabilizing the trunk and flexing the vertebral column. (Hodges and Richardson, 1997).
Figure 6: Transversus abdominis muscle antero-posterior view (Hodges, 1997).
2.3.3 FUNCTION OF LUMBAR MULTIFIDUS (LM) AND TRANSVERSUS ABDOMINIS (TrA) MUSCLE

Transversus abdominis and LM are important component of local stability system, in which a number of studies have reported on the anatomical, biomechanical or neurophysiological characteristics of these muscles in the context of spinal stability (Anderson et al., 1996; Hodges 1999; Penning 2000; Hodges et al., 2003). These muscles co-contract simultaneously, functionally the proposed co-contraction of the LM and TrA muscle is unlikely to be obligatory, although there is evidence that TrA is continuously active with amplitude modification during gait (Saunders, 2004), and in static posture (Cresswell et al., 1992), whilst LM is active during phasic burst. However there is research to suggest similarities between TrA and LM. For example both muscles are active in non-directional specific feed forward manner in preparation for the perturbation of the spine from arm movement. Although contraction may not be simultaneous the mechanical effects may occur more or less simultaneously, because the electromechanical delay of TrA takes longer than LM due to the long elastic anterior fascia. Earlier activity of TrA may compensate for the delay (Macdonald et al., 2006). Several EMG studies have previously reported that muscle recruitment patterns in patients with low back pain differ from healthy subjects (Richardson et al., 1992; Hodges et al., 1996; Lariviere et al., 2000; O’Sullivan et al., 2000; Marras et al., 2001; Hodge and Hides, 2004). The dysfunction of TrA has been demonstrated as motor control deficit (Hodges and Richardson 1997). Changes in activation pattern and cross sectional area of the segmental portion of the LM has also been suggested (Hides, 2004). Several studies have demonstrated morphological changes in LM in LBP which shows a degree of type 1 muscle fibre atrophy (Hultmann et al., 1993; Rantanen et al., 1993; Sihvonen, 1993; Matila et al., 1999; Parkkola et al., 1999). Consequently the
muscle is weaker (Cassisi et al., 1993) and exhibits excessive fatigue (Klein et al., 1991; Roy et al., 1995; Chok et al., 1999).

It is also worth noting that TrA and LM are often difficult to activate and may weaken in sedentary individuals and those with LBP (Herringhton and Davies, 2005). Therefore evidence exists that this muscle may not be optimally recruited or may fatigue in its stabilizing role even in normal asymptomatic individuals (Parnianpou et al., 1988). Therefore asymptomatic individuals with dysfunctional TrA and LM muscle may be a risk group for developing LBP symptoms, because of their failure to fully activate their dynamic spinal support system.
2.4 **LUMBOPELVIC STABILITY CONTROL SYSTEM**

Spinal stability is defined in terms of region of laxity around the neural position of the spinal segment called the neural zone. This neural zone is shown to be increased with intersegmental injury or intervertebral disc degeneration and decreased with simulated muscle force across a motion segment (Panjabi, 1992). The size of the neural zone is considered to be an important measure in spinal stability.

It is influenced by passive, active and neural control system (Panjabi, 1992). The passive subsystem consists of vertebrae, intervertebral disc, zygoapophyseal joint and ligament. The active subsystem consists of the muscles and tendons surrounding and acting on the spinal cord. The neural subsystem comprises of the nerve and central nervous system which direct and control the active system in providing direct stability (figure 7). In the light of this Panjabi (1992) defined spinal instability as a significant decrease in the capacity of the stabilizing systems of the spine to maintain intervertebral neural zone within physiological limits so there is no major deformity or neurological deficit.
Figure 7: The diagram of the sub-systems (Panjabi, 1992)
2.5 DYNAMIC STABILIZATION OF THE LUMBAR SPINE:

Bergmark (1989) hypothesized the presence of two muscle systems that act for the maintenance of spinal stability which are the global and the local muscle system.

THE GLOBAL MUSCLE SYSTEM: which consists of large torque producing muscles that act on the trunk and spine without directly attaching to it. These muscles include, rectus abdominis, external oblique, internal oblique, and the thoracic part of lumbar iliocostalis which provide general trunk stabilization but they are capable of having an indirect segmental influence on the spine (figure 8).

There are several limitations of global muscles to spinal stability, first as the global muscles have no attachment to the vertebrae (Bergmark, 1989) they can only influence intervertebral motion as a result of compressive forces from co-activation of antagonist muscle. The global muscle generate torque at the trunk, this torque must be overcome by the antagonist activation in order to keep the spine upright and this co-activation result in compression load on the spine.

Excessive compression, which increase intra discal pressure and loading through posterior element of the spine has long been considered a risk factor for spinal degeneration and pain. Excessive global muscle co-contraction during light functional task may even be indicative of inappropriate trunk muscle control in patients with back pain. The second limitation for the global system is that the muscles of this system can only provide a nonspecific contribution to spinal control, that is global muscles cannot augment control selectively to a specific segment.

Third, global muscles have a limited ability to control shear forces. This has been argued biomechanically and from in vivo studies, for example when shear forces are
imposed on the spine there was no change in the activity of the global muscles, therefore deeper local muscles must control this element (Bergmark, 1989).

Fourthly antagonist global muscles co-activation results in a restriction of the spinal motion or rigidity of the spine (Craig, 2005). It is known that in healthy subjects the central nervous system uses movement rather than the simple stiffening of the spine to overcome challenges to stability and reduces energy expenditure in many tasks. A strategy of trunk stiffening requiring less complex neural control would compromise optimal spinal function.

Finally trunk muscles are involved in function other than spinal control and movement. As the superficial abdominal muscles depress the rib cage they are involved in forced expiration, increased activity of this muscle in people with pain may lead to compromised respiratory function, and thus reliance on global muscles for control may be problematic from a systematic point of view (Craig, 2005).
Figure 8: The global muscles (Hodge, 1997)
LOCAL MUSCLE SYSTEM:

Muscles that are directly attached to the lumbar vertebra and are responsible for providing segmental stability and directly controlling the lumbar segments are regarded as local muscles.

These muscles include the LM and TrA. Growing evidence is emerging that the local system of muscles function differently to global system of muscles and the relationship between the two groups alter depending on the loading conditions placed on the spine (O’Sullivan et al., 1997). It was reported that the lumbar spine is more vulnerable to instability in its neural zone and under this condition lumbar stability is maintained in vivo by increasing the activity (stiffness) of the lumbar segmental muscles (local muscle system) (Cholewick and McGill, 1996).

The coordinated muscle recruitment between large trunk muscles (global muscle system) and small intrinsic muscles (the local muscles) during functional activities ensures that mechanical stability is maintained. While the global muscle system provides the bulk of stiffness for the spinal column. The activity of the local muscle is considered necessary to maintain the segmental stability of the spine. In situations where the passive stiffness of a motion segment is reduced, the vulnerability of the spine towards instability is increased (Cholewicke and McGill, 1996). It is proposed that co contraction of local system of muscles such as TrA and LM, results in stabilizing effect on the motion segments of the lumbar spine particularly within the neural zone providing a stable base on which the global muscles can safely act (Wilke et al., 1995).

Local muscles allow controlled spinal motion and have the ability to control individual segment rather than providing a general compressive force across the spine (Craig, 2005).
The segmental stabilizing role of LM with separate segmental innervations acts to maintain the lumbar lordosis and ensure control of individual vertebral segments particularly within the neural zone (Panjabi et al., 1989). Lumbar multifidus can control intervertebral motion by generation of intervertebral compression and control of shear forces. The deep abdominal muscles are primarily active in providing rotational and lateral stability to the spine via the thoracolumbar fascia while maintaining level of intraabdominal pressure (McGill, 1991). The intraabdominal pressure mechanism primarily controlled by diaphragm, transversus abdominis and pelvic diaphragm produces a stiffening effect on the lumbar spine (Hodge et al., 1997).

In a recent study by Hides et al., (1996) it was concluded that retraining of deep muscle co-contraction could reverse the inhibition of LM muscle demonstrated by patients with first episode of acute low back pain. In addition there is increasing evidence that LM and TrA are preferentially affected in the presence of low back pain and lumbar instability (Hide et al., 1996) their contribution to spinal control is likely to involve modulation of intraabdominal pressure and tensioning of thoracolumbar fascia. Specific sub maximal training of these stability muscles of the lumbar spine decreases pain and functional disability in those suffering from mechanical LBP (Richardson and Jull, 1995).

2.6 DysFUNCTION OF THE NEUROMUSCULAR SYSTEM IN THE PRESENCE OF LOW BACK PAIN

The literature reports varying disruptions in the pattern of recruitments particularly within the neural zone and co-contraction of within and between different muscle synergies in the low back pain population (O’Sullivan et al., 1997). There is growing evidence that deep abdominal and lumbar multifidus muscles are preferentially adversely affected in the
presence of acute LBP (Hide et al., 1996), chronic LBP and lumbar instability (O’ Sullivan et al., 1997). There have been reports that compensatory substitution of global muscle system occurs in the presence of local system dysfunction. This appears to be neural control system’s attempt to maintain the stability demand of the spine in the presence of local muscle dysfunction (Richardson and Jull 1995; O’Sullivan et al., 1997).

There is also evidence to suggest that the presence of chronic low back pain often results in a general loss of function and deconditioning as well as changes to the neural control system, affecting timing of pattern co-contraction balance reflex and righting responses (O’Sullivan et al., 1997). Such disruptions to the neuromuscular system leave the lumbar spine potentially vulnerable to instability particularly within the neural zone (Cholewicke and McGill 1996). Dysfunction of the local stabilizer muscle occurs as a result of alteration of the normal motor recruitment, leading to decreased segmental control (Richardson et al., 1999). Dysfunction of the global stabilizer muscles occur from increased functional muscle length or decreased low-threshold recruitment (Gossman et al., 1982).

2.6.1 DIRECTIONAL PATTERNS OF LUMBAR SEGMENTAL INSTABILITY

The directional nature of instability based upon the mechanism of the injury resultant site of tissue damage and clinical presentation is well understood in the knee and shoulder, but poorly understood in the lumbar spine. Karen, (2003) reported on the basis of experimental and radiological data that the location of the dominant lesion in the motion segment determines the pattern of instability manifested. As the motion within the lumbar spine is three dimensional and involves coupled movement, tissue damage is likely to result in movement dysfunction in more than one direction of movement.

Common to all the patients presentation is the reported vulnerability and observed lack of movement control and related symptoms within the neural zone. This is associated with the
inability to initiate co-contraction of the local muscle system within the neural zone. It appears that these patients develop compensatory movement strategies which stabilize the motion segment out of the neural zone and towards an end range position. Extension activity reveals segmental hinging at the affected segment with a loss of segmental lordosis above this level and associated postural sway (Karen, 2003).

2.7 STABILIZATION TRAINING

Biomechanical models suggest that all muscles with intersegmental stability provision (multifidus and transversus abdominis as opposed to the larger trunk muscles (erector spinae and rectus abdominis) are dedicated to movement generation (Bergmark, 1989). Inadequate activation of the local stabilizing trunk muscles may lead to instability of the lumbar spine (Panjabi, 1992).

The evidence presented indicates that a program for the TrA and multifidus is required for specific lumbar stabilization training, which is reasoned as a knowledge of muscle dysfunction found in individuals with history of lower back problem (Jull et al., 1995).

Recruitment of the abdominal muscle during exercise to restore motor control has not been clearly defined. The basic concept of an isolated action of these is taught by asking the individual to gently draw in the abdominal wall especially in the lower abdominal area (Richardson and Jull, 1995). There are only a few methods of achieving a co-contraction of the local muscles instead of the global.

In the study by Norris (1995) abdominal hollowing was reported to be achieved in two different ways, by dynamic abdominal bracing and abdominal hollowing which have been shown to give muscle activity suitable for lumbar stabilization (Norris, 2001). It was the latter that most subject found easier to learn. Importantly a recent study by Urquhart et al.,
(2005) which standardized the instruction for voluntary exercise provide further EMG evidence to validate that the recruitment of TrA, with minimal activity of other abdominal muscles may be best achieved during the inward movement of the lower abdominal wall (Richardson et al., 1992).

Active person without a history of LBP have little difficulty in performing this task (Richardson and Jull, 1995). However it has been reported that it is not easily achieved by patients with LBP (O’Sullivan, 2000; Norris et al., 2001). It should also be that stability muscles have been described as better suited to endurance and better recruited at low resistance level (Urquhart et al., 2005).

Evidence support the use of four points kneeling or prone lying as the best position to perform the abdominal drawing in manoeuvre (ADIM) for training (Richardson and Jull 1995). It has been shown that a facilitatory stretch of the deep abdominal muscles resulting from the forward drift of abdominal content (Beith et al., 2001; Norris et al., 2001) is aided in this position and that EMG activity reveals an inhibitory activity of global muscle, rectus abdominis (Richardson and Jull, 1995; O’Sullivan, 1998; Beith et al., 2001). Abdominal muscle contraction is considered an essential component for maintaining lumbar and pelvic activity during the movement. Previous studies have reported that drawing the lower abdominal wall up towards the spine facilitate TrA and lumbar stability (Hodges 1999; Herrington and Davies 2005). Abdominal muscle contraction increases intraabdominal pressure preventing a spine shift anteriorly and anterior pelvic tilt (Cresswell et al., 1992).

Once the individual is able to reactivate and maintain the co-contraction pattern, the individual can hold the position while load is added via the weight of the lower limbs into a loaded position (Liebenson, 1998). In which the progression can be taken through several
stages (Norris, 2001; Koumantakis, 2005) which is based on the motor learning model (Saunders, 2004). Recently widely publicized studies supporting the specific stabilization exercises from the laboratory based research (Hodges and Mosely, 2003), and small scale randomized control studies with pre-defined sub-groups of LBP patient have provided positive evidence they are effective exercises (O’Sullivan et al., 1997; Hides et al., 2001).

The study by Sung (2003) looked at the effect of stabilization exercise program on the endurance of the LM muscle. This result suggested that exercise training emphasized the role that LM muscle plays in stabilizing the spine during functional movement. Suggesting that spinal stabilization exercises affect back muscles function by mechanism other than improved endurance of the stability musculature. Although the pattern of result from a longitudinal study suggest positive treatment effect. The cross sectional survey (Bryne et al., 2006) that investigated the current use of range of exercise therapy approach for LBP by out patients’ physiotherapists found specific stabilization exercises to be the most popular.

2.7.1 BENEFIT OF STABILIZATION EXERCISES WHEN COMPARED WITH GENERAL EXERCISES.

The study by (Akbari et al., 2008) hypothesised that stabilization exercise is effective in increasing transversus abdominis (TrA) and lumbar multifidus (LM) thickness and also decreases pain and activity limitation in patients with chronic low back pain without any sign of lumbar instability. The improvement ratio of LM and TrA thickness in stabilization exercise group is greater than improvement ratio in general exercise group. Some evidence support the role of stabilization exercises in LBP with respect to symptom recurrence but the two relevant randomized control trial have been conducted in specific subgroup of patient with LBP (Hide et al., 1996; O’sullivan et al., 1997). The first study compared
stabilization exercises against standardized medical care in acute episode unilateral low back pain (Hides et al., 1996). A 3 year follow up showed a link between improvement in LM cross-sectional area (CSA) and reduced LBP recurrence in group that received stabilization exercise (Hides et al., 2001).

The second study that compared stabilization exercises against general exercises in patients with lumbar spondylosis or spondylolisthesis indicated large short term and long term improvement in favour of stabilization exercises on pain and disability. However in this two trials specific effect of stabilization was not compared to general back and abdominal exercises (O’Sullivan et al., 1997). It could also be that an increase in serotonin levels produced with the use of stabilization exercise may have a role to play in the positive outcome of stabilization exercise in the management of patients with chronic low back pain (Shokunbi et al., 2007). It was also deduced from another study that stabilization exercises for patients with recurrent low back pain still at work seem more effective in improving disability (Rasmusen et al., 2009).

A study by May and Johnson (2008) also supported the view that there is a role for stabilization exercises in the treatment of patients with chronic low back pain. Ferreira et al., (2009) also deduced that participants with chronic low back pain receiving stabilization had greater improvement in recruitment of TrA than participants receiving general exercise or spinal manipulative therapy. Also the effect of stabilization exercises on pain reduction was greater in participants who had a poor ability to recruit TrA at baseline which suggest that treatment may be more effective in those with a poor ability to recruit TrA muscle. Macedo et al., (2009) also concluded that stabilization exercises is superior to minimal intervention and confers benefit when added to another therapy for pain at all time and disability at long term follow up.
2.7.2 STABILIZATION EXERCISE TREATMENT RATIONALE

People with back pain have changes in strategy for the control of trunk muscle in that activity of deep muscle is delayed, less tonic and these muscles are atrophied (Hides et al., 1994 Hodges and Richardson 1996). Although all muscles contribute to control of movement and stability of the spine, the deep muscle have a critical role for control of intervertebral motion (Hodge et al., 2003) but with potential advantage of allowing dynamic control of the spine. Evidence that people with back pain tend to adopt a strategy for increased stiffness and stability at the expense of the spinal function (van Dien et al., 2003) and non-resolution of changes in the muscle system is linked to recurrence of low back pain (Hides et al., 2001).

The evidence above underpins the primary aim of trunk stabilization exercises which is to reestablish normal control of the deep spinal muscles reducing the activity of more superficial muscles that tend to stiffen the spine and have increased activity in low back pain and then maintain normal control during progressive more demanding physical and functional task (Richardson, 1999).

The key features of stabilization exercise treatment approach is training of deep trunk muscles in isolation before progressing to demanding tasks that train coordination of the deep and superficial trunk muscles (Richardson, 1999). The premise of stabilization exercise approach is that simple functional exercises alone do not re-establish coordination of trunk muscles (Hodges and Richardson 1996).

Furthermore recent data confirmed that coordination of abdominal muscles can be restored with training of specific activation of trunk muscles but not a simple activation during a sit up tasks (Tsao and Hodges 2005). Also asymptomatic people with normal activity levels
who are unable to perform a task that is thought to reflect voluntary activation of the deep
trunk muscles are 6 times more likely to develop back pain than asymptomatic people who
are able to perform the same task (Moseley, 2004). Basically stabilization is aimed at
protecting and supporting the spinal segment from re injury by reestablishing and
enhancing muscle control to compensate for any loss of stiffness caused by injury or
degenerative changes (Richardson et al., 1999).

2.8 ULTRASOUND IMAGING IN REHABILITATION

Ultrasound imaging (USI) is currently used extensively in medicine. It provides safe and
cost effective and readily accessible method of examination of various organs and tissues
(Hides et al., 1995). Further more real time ultrasound has the potential to be of reasonable
benefit to rehabilitation and it serves the accuracy of clinician palpatory and observational
skills in detecting subtle contraction in muscles that is deep and difficult to directly access.

USI can also be used to diagnose a myriad of musculoskeletal problems with enhance
resolution. The structures most commonly imaged with ultrasound include tendon, muscles, nerves, joints and some osseous pathology (Lento & Primack, 2007). Possible
application in physiotherapy and research relate to measurement of muscle size and
observation and monitoring of muscle contraction while it actually occurs, which may be
useful for muscle rehabilitation especially in deep muscles which are often difficult to
assess (Hides et al., 1995).

Now there is an emerging role for its use both in physiotherapy practice and research. The
advantages of ultrasound imaging for use in practice and research in evaluation of
musculoskeletal system are its wide accessibility in hospitals and radiology practices, low
examination cost and avoidance of exposure to ionizing radiation (Chhem et al., 1994). It
can also help in the examination of large areas with extended field of view, however the clinician can interact with the patient who can then direct examination towards the symptomatic area, in this case the clinician can focus the examination to the most symptomatic area.

Ultrasound also has the advantage of being a dynamic study in which the affected part is imaged in real time, observing for pathological movement in tendon, bursa, muscles or joints, and the patient simultaneously provide feedback and vital information to the examiner during the dynamic examination that may reveal, tendon subluxation, joint subluxation, and ligament incompetence (Lento & Primack, 2007). Since diagnostic ultrasound imaging is real time the patient and even the referring physician can receive results immediately and then can outline a treatment strategy within the same visit.

Ultrasound imaging offer advantages when utilized for interventional procedures, various soft tissues can be directly entered, aspirated or drained. It has being estimated that attempted intra-articular knee injection may miss the target in about 29% of cases but with ultrasound guidance the suprapatellar bursa which communicate with the knee joint, cannot only be examined for an effusion or synovial proliferation but can be entered under direct visualization (Jackson et al., 2002). Blind subacromial bursa injection as well are known to have an inaccuracy rate of 24-31% depending on the approach, however with ultrasound guidance, this bursa appears as a visible thin hypoechoic line overlying the rotator cuff tendons and can be easily injected from a lateral approach, in this way ultrasound offers a more accurate and potentially more therapeutic interventional strategy to the musculoskeletal clinician (Henkus et al., 2006).

One limitation that ultrasound imaging has is its dependence on body habitus, ultrasound wave penetrance into tissues is inversely proportional to the wave. Recent advances have
improved high frequency linear array transducers and a lower frequency curvilinear transducer (3-5MHZ) which may be needed to provide adequate penetration for deeper structures (Rosenthal et al., 2001). Additional technical factors that affect ultrasound include artifact that can mimic real pathology, ultrasound involves the reliance of placing the transducer and hence the beam at $90^0$ angle to the structure being imaged (Lento & Primack, 2007). Any deviance from this will result in reflection of the beam away from the transducer causing a reduction in echogenicity (brightness) of the tissue being examined. This artifact is referred to as anisotropy and can be eliminated by maintaining the beam perpendicular to the involved tissue. Good technique also involves maintaining adequate skin contact, confirming the presence of pathology orthogonal planes and using the appropriate transducer size for the specific situation.

It has being estimated that 30% sport injuries affects muscles, the portability, ease of use and superior spatial resolution makes ultrasound imaging an excellent imaging modalities for detecting and classifying all this injuries. Additionally ultrasound can also identify non traumatic or primary muscle pathologies such as myositis (Lento & Primack, 2007). Occasionally patient are unable to completely localize the area involved especially when it involves a large muscle group, however extended field of view technology has made capturing area of muscle tissue feasible. Once the targeted muscle can be effectively activated ultrasound also allows the length of contraction time to be measured. It has been proven using direct method of imaging modalities, that the maximal voluntary contraction which can be generated by a muscle is closely related to it cross sectional area (CSA) (Young et al., 1984).

In the presence of pain strength testing may not be reliable or appropriate due to factors such as pain inhibition, motivation and fear of provocation of pain, in this situation size
measurement are important for measuring muscle atrophy (Stokes and cooper, 1993) and can be indirectly used to reflect the effect of reflex inhibition and if part of the muscle is selectively inhibited ultrasound imaging can be used to provide assessment of the location of muscle atrophy and serial measurement could be used to assess the effects of muscle rehabilitation (Hides et al., 1995).

The importance of increasing the entrance of paraspinal muscles in patients with low back pain has been recognized (Moffroid et al., 1993). The LM has been shown to fatigue faster in patients with low back pain than in asymptomatic control patient (Biedermann et al., 1991). Measurement of muscle size using ultrasound has provided an accurate assessment of muscle wasting in various muscles and a study was carried out in which normal reference ranges for the objective assessment of LM muscle was done (Stokes et al., 2005). Also a study by (Kiesel et al., 2007) hypothesized that measurement of muscle thickness changes using real time ultrasound is valid and potentially useful method to measure activation of lumbar multifidus muscle in an asymptomatic patient. Ultrasound imaging is a procedure used by physical therapist to evaluate muscle and related soft tissue morphology during exercise and physical tasks. Ultrasound imaging is used to assist in the application of therapeutic interventions aimed at improving neuromuscular function. This includes providing feedback to the patient and physical therapist to improve clinical outcome. USI is used in basic applied and clinical rehabilitative research to inform clinical practice (Kiesel et al., 2007).

Another study by Hides et al. (1999) and Han et al. (1999) also supported the fact that USI may be clinically useful for measuring LM muscle wasting. A study by Rankin et al. (2006) also provided robust reference data for the abdominal muscles in normal male and female in order to enable comparison with clinical group abnormalities and establish
sensitivity for evaluating effectiveness of intervention and a study by Andreason et al. (2006) confirmed that real time ultrasound can be used to measure TrA muscle activation.

It is known that muscle thickness changes when the muscle is activated (Hodges et al., 2003). The amount of thickness change that occurs with muscle activation can be quantified with use of ultrasound imaging by comparing resting muscle thickness values to those obtained during muscle activation. Measurement of muscle thickness change has been performed in gastrocnemius muscle (Maganaris et al., 1998), on the transversus abdominis muscle (McMeeken et al., 2004) and other trunk and peripheral muscle (Hodges et al., 2003). An alternative to imaging lumbar multifidus in transverse section (figure 9) is to adopt a parasagittal (longitudinal) orientation of the transducer (figure10). In this plane the zygapophyseal joint the overlying multifidus muscle bulk at 2 to 3 vertebral level could be visualized. Apart from being able to visualize more than one vertebral level at a time this orientation allows measurement of thickness of muscles and muscle contraction can be observed more easily than in the transverse plane. The parasagittal view has already been successfully used to provide feedback of multifidus muscle recruitment during two randomized control trials. Hide et al. (2001) showed that subjects with first episode low back pain had difficulty recruiting the multifidus muscle and first described the use of ultrasound imaging in parasagittal view as a form of visual feedback.
Figure 9: Transverse scan at the level of fourth lumbar vertebra (L4) showing the spinous process (triangle) in the center of the image and the echogenic lamina (arrows) appears as bright white horizontal landmarks, homogenous hypoechoic multifidus muscle (star).
Figure 10: Ultrasound image of the right multifidus muscle in Parasagittal section (longitudinal) view of the lumbar multifidus muscle spine. LM represents the lumbar multifidus muscle. Thickness measurement of multifidus muscle was conducted from the tip of the zygapophyseal (F) joint to the inferior edge of the superior border of the muscle. Measurement of L4-L5 is shown.
2.9 PRESSURE BIOFEEDBACK UNIT

A pressure biofeedback unit is an inflatable inelastic bag connected to a pressure gauge and an inflation device (figure 11) it has been proven to be useful clinical tool for assessment and to enhance training in selective muscle contraction in lumbar stabilization (Jull et al., 1993). In addition a pressure biofeedback unit can monitor the movement of the abdominal wall indirectly by recording changes in pressure (Cairns et al., 2000).

There are indications that segmental stabilization exercise is effective in the treatment of low back pain. The evaluation of successful training performance in patients requires a reliable outcome measure. The PRONE test gives the activity of TrA muscle performed in prone position using a pressure biofeedback unit. It has been used as an aid in training and to assist the subject’s ability to perform segmental stabilization exercise correctly (Katharina et al., 2009). Cynn et al. (2006) also support the use of pressure biofeedback as an outcome measure for lumbar stabilization exercise. A study by Rowland and Sparkes (2009) also concluded that pressure biofeedback unit is a reliable tool when utilized with population that can perform the abdominal drawing–in test.
Figure 11: Pressure Biofeedback Unit
2.10 TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION

Transcutaneous electrical nerve stimulation (TENS) means electrical nerve stimulation performed through the skin. The procedure of the electrical stimulation can be effected through either of two methods, invasive and non-invasive methods. By invasive method, the electrical stimulation is effected through implanted electrodes. The electrodes are here inserted through the skin. By non-invasive method on the other hand, the electrical stimulation is effect ed by surface electrodes applied on the skin overlying the nerve or nerves to be stimulated (Owoeye, 2001).

In general practice, transcutaneous electrical nerve stimulation (TENS) is more commonly applied by the non-invasive method, i.e. through the surface skin electrodes. The basic clinical indication for the application of TENS is pain. Although TENS is more commonly used in the management of rehabilitation of patients having chronic and intractable pains, this electrical stimulation can equally relieve acute pains (A variety of TENS machines are today available commercially. While there are those which can be operated by cells or batteries, there are also those models that can be operated by the mains (Owoeye, 2001).

Those that are operated by cells and batteries are however, more common as these can be operated by the patients under the supervision of a physiotherapist or a physician. The various models of TENS machines produce various wave forms: Some square or rectangular wave form while others may be in spikes. Either of these may be monophasic or biphasic wave form. The most important thing is to get very familiar with whichever model one has access to by studying the machine itself and its accompanying manual properly. In some of the models the desired waveform may be selected while the pulse width, the amplitude, and the frequency (pulse rate) can be
either adjusted or selected according to the need of the individual patient. No two patients of similar pathological condition may be found to be identical.

Specifically, the beneficial current, that is, in terms of the wave width, amplitude and frequency for each individual patient must be identified by the therapist. It is use of electric current produced by a device to stimulate the nerves for therapeutic purposes. TENS by definition covers the complete range of transcutaneously applied currents used for nerve excitation. The unit is usually connected to the skin using to or more electrodes. A typical battery-operated TENS is able to modulate pulse width, frequency and intensity. Generally TENS is applied at high frequency >50Hz with an intensity below motor contraction (sensory intensity) or low frequency with an intensity that produces motor contraction (Robinson and Lynn-Synder, 2007).

TENS is a non-invasive, safe nerve stimulation intended to reduce pain, both acute and chronic. While controversy exists as to its effectiveness in the treatment of chronic pain, a number of systematic reviews or meta-analyses have confirmed its effectiveness for chronic musculoskeletal pain (Johnson and Martins 2006). Recent clinical studies and meta-analysis suggest that having an adequate intensity of stimulation is necessary to achieve pain relief with TENS (Bordal et al., 2003; Rakel and Frantz, 2003).

2.11 MASSAGE THERAPY

Massage therapy has been defined as soft-tissue manipulation by trained therapists for therapeutic purposes (Field, 1998). Massage therapy has a long history, being first described in China during the second century B. C. and soon thereafter in India and Egypt (Field, 1998). More recently, massage therapy has been administered using mechanical devices in addition to hands-on treatment by therapists. Massage can be applied to single or multiple body parts or to the entire body. There are different types
of massage therapy including Swedish massage, Shiatsu, Rolfing, reflexology and craniosacral therapy. Most of the published trials on massage therapy have utilized Swedish or Swedish-type massage. Swedish muscle massage has a long history and is associated with various effects that are potentially beneficial in the symptomatic treatment of LBP, it relaxes the mind as well as the musculature and increases the pain threshold, possibly through endorphin release (Ernest and fialka, 1994).

It can also enhance local blood flow which could increase the clearance of local pain mediators. But in this context physiological effects should be clearly differentiated from clinical effectiveness or efficacy. On the European continent, massage has been a routine form of therapy for acute and chronic LBP for many decades. A recent survey from Vienna shows that no less than 87% of back pain patients received massage as one form of treatment (Wiesinger et al., 1997). The evidence for or against its efficacy has so far not been summarized systematically (Ernst, 1994).

A systematic review of controlled clinical trials on the subject is a useful start to an evolution of this approach. Despite the growing popularity of massage, there is inconsistent empirical support for its effectiveness in chronic pain. Typically, massage is viewed as an adjunctive therapy to help prepare the patient for exercise or other interventions, and is rarely administered as the main treatment (Furlan et al., 2002). Cochrane review concluded that massage therapy may be beneficial for patients with subacute and chronic non-specific LBP, particularly when combined with exercises and education. They also noted that the results of one high quality study showed that the benefits of massage last as long as 1 year following the end of active treatment. The benefit obtained from massage exceeded that achieved from relaxation, education or acupuncture.
However, the beneficial effects may be less than that provided by spinal manipulation or TENS. The Cochrane Review noted that there is insufficient evidence regarding the effects of massage on acute back pain and on specific forms of massage for chronic LBP (Cherkin et al., 2001). LBP is associated with a complex dysfunction of the paraspinal musculature (Cooper et al., 1993). It is conceivable therefore that massaging these muscles could help normalize muscular function. There is some evidence to show that massage lowers muscular tone and reduces muscular fatigability. Researchers claim that it can minimize pain and disability and there is speed return to normal function (Furlan et al., 2002).

The amount of benefit for massage was more than that achieved for joint mobilization, relaxation, self care education or acupuncture. It was concluded that in a Cochrane review 2002 that massage therapy might be beneficial for patients with chronic non specific low back pain especially when combined with exercises and education (Furlan et al., 2002). A study by Hernandez-reif et al. (2001) also concluded that massage therapy is effective in reducing pain, stress hormones and symptoms associated with chronic low back pain.
2.12 SPINAL ANATOMY

THE SPINE (VERTEBRAL COLUMN):

This is also called the vertebrae column. It starts at the skull and extends into the pelvis. The column contains 33 bones and they are made up of five regions named as cervical, thoracic, lumbar, sacral and coccygeal vertebrae which are stacked on top of each other. In man the cervical vertebrae are seven in number; the thoracic, twelve; the lumbar, five; the sacral, five; and the coccygeal, four; making a total of thirty-three. In all vertebrate animals the central axis of the body consists of a vertebral column. In order to provide a considerable range of movement of the trunk, the column consists, not of a single elongated bone, but of a number of independent, irregular bones, termed the vertebrae, which are firmly connected to another but are capable of a limited amount of movement on one another (Standring, 2004). The provision of a central axis is not the only function which the column has to sub serve. It is built up so as to surround the spinal cord, to which it affords necessary protection. The human vertebral column must also support the weight of the trunk and transmit it to the lower limbs. The vertebrae are grouped under the names cervical, thoracic, lumbar, sacral and coccygeal or caudal, according to the region in which they lie, but all conform to a plan not only in man but also in all other vertebrate animals. (Standring, 2004)

A typical vertebrae is made up of two principal parts, an anterior or ventral, termed the body, and a posterior or dorsal, termed the vertebral arch; these enclose a foramen, which is named the vertebral foramen (Standring, 2004). The opposed surfaces of the bodies of adjoining vertebrae are firmly connected to each other by discs of fibrocartilage, termed intervertebral discs. In the articulated column the bodies and the intervertebral discs form a continuous pillar, which constitutes the central axis of the
body and, in man supports and transmits the weight of the head and trunk. The vertebral foramina, placed one above another, constitute a canal in which the spinal cord is lodge and protected. Between contiguous vertebral, two intervertebral foramina, one on each side open into the canal and serve for the transmission of the spinal nerve and vessels.

The body of the vertebra is more or less cylindrical, but is subject to a wide range of variation in size and shape in different animals and different regions of the same animal. It upper and lower surfaces are flattened and, except for a smooth peripheral margin formed from the annular epiphysial disc are roughened to give attachment to the intervertebral disc. In front the body is convex from side to side and gently concave from above downwards, behind, it is flattened or slightly concave from side to side, and flat from above downward. On its anterior surface there are a few small apertures for the passage of veins, on its posterior surface there is large irregular aperture for the exit of basivertebral veins and a number of small foramina for nutrient arteries (Standring, 2004).

The vertebral arch as a pair of pedicles and a pair of laminae; it supports seven processes, one spinous, four articular and two transverse processes. The pedicles are a pair of short, thick processes which project backwards from the body at the junctions of its lateral and posterior surfaces. The concavities above and below the pedicles are named the vertebral notches; and when the vertebra are articulated with one another, the notches of contiguous vertebrae form the intervertebral foramina. (Standring, 2004). The laminae are broad plates directed backwards and medially from the pedicles. They fuse in the spinous process posteriorly, and so complete the posterior boundary of the vertebral foramen. The spinous process is directed backwards and downwards from the
junction of the laminae, and serves for the attachment of muscles and ligaments. They are subjected to great variations in size, shape and direction; they provide column and, to a lesser degree for movement of rotation. (Standring, 2004).

The articular process, two superior and two inferior, spring from the junctions of the pedicles and laminae. The superior process project upwards and their articular surfaces face more or less backwards. The inferior project downwards and their articular surfaces face more or less forwards. The processes meet the corresponding processes of the adjoining vertebrae and while permitting a certain degree of movement, definitely control and restrict its range. The transverse process project laterally from the junction of the pedicles and laminae; they serve as the attachment of muscles and ligaments and are the levers by means of which the rotator and lateral movements of the vertebrae can be effected (Standring, 2004).

CERVICAL VERTEBRA

The cervical vertebrae, seven in number, are the smallest of the movable vertebrae and can be identified easily owing to the peculiarity of their transverse processes, each of which is perforated by a foramen. The first, second and seventh cervical vertebrae present special distinguish features, but the remaining four conform to a common type (Standring, 2004).

The body of the cervical vertebrae is small and is broader from side to side than from before backwards. The vertebrae foramen is large in proportion to the size of the body and it is triangular in outline (figure12). These two features are accounted for, by the direction of the pedicles, which project laterally as well as backwards. The superior and inferior vertebral notches are almost equal, for the pedicle is attached to the body nearly midway between its upper and lower borders. The laminae are relatively long and
narrow, and are thinner above than below. The spine is short and its terminal and its terminal tubercle are often unequal in size. The superior and inferior articular processes form an articular pillar, which projects laterally at the junction of the pedicle and lamina. (Standring, 2004).

**ATLAS AND AXIS:**

The cervical spine is divided into two parts upper C1 and C2 and lower C3- C7. C1 is termed the atlas while C2 is the axis. The atlas is the first cervical vertebra abbreviated C1, its supports the skull and looks different from other vertebrae. The atlas consists of two bulky lateral masses, connected to each other in front by a short anterior arch, and behind by a long, curved, posterior arch, it therefore forms a ring of bone. The axis is the second cervical vertebra it looks like a dull tooth like process, the dens (Odontoid process) and stick upward into the ring of the atlas. The process bears on its anterior surface a small oval facet for articulation with the facet on the posterior surface of the anterior arch of the atlas and posteriorly it is grooved slightly by the transverse ligament of the atlas which helps to retain it in position. Atlas and axis allows the head to turn from side to side. (Bridwell, 2007).
FIGURE 12: The cervical vertebrae (Standring, 2004).
THORACIC VERTEBRAE

The thoracic vertebrae, twelve in number show a gradual increase in size from T1 through T12. All are distinguish by the presence of facets on the sides of the bodies and all but the last two by facet on the transverse process. The former articulate with the heads of the ribs and the latter with the tubercle of the ribs. The body of a typical thoracic vertebra resembles in shape a conventional heart from a playing-card, and its anteroposterior and transverse measurements are nearly equal. They are characterized by small pedicle long spinous process, and relatively large intervertebral foramen which results in less incidence of nerve compression (figure 13). The rib cage is joined to the thoracic vertebra. At T11 and T12 the ribs do not attach and are so called floating ribs. The thoracic range of motion is limited due to the many rib/vertebrae connections and the long spinous processes (Bridwell, 2007).
Figure 13: The thoracic vertebrae (Bridwell, 2007)
LUMBAR VERTEBRA

The lumbar vertebrae, five in number, can be distinguished from the other vertebrae by their great size and by the absence of costal facets on the sides of the bodies and they graduate in size from L1 through L5. This vertebra bears much of the body weight and related biomechanical stress. The pedicles are longer and wider than those in the thoracic spine (figure 14). The body is large, wider from side to side than from before backwards and a little deeper in front than behind the vertebral foramen are triangular in shape, larger in the thoracic region but smaller than in the cervical region.

The pedicles are short. The spinous processes are horizontal and more squared in shape and is thickened along its posterior and inferior borders. The superior articular process bear gently concave articular facets which face medially and backwards. The posterior border of each process is marked by a rough elevation, termed the mamillary process. The inferior articular processes bear slightly convex articular facets which face laterally and forwards. The transverse processes are thin and elongated except those of the fifth lumbar vertebrae which are strong and substantial. The intervertebral foramen is relatively large but nerve compression is more common than in the thoracic spine (Standring, 2004; Bridwell, 2007).
Figure 14: The lumbar vertebra (Standring, 2004)
SACRAL SPINE

The sacrum is located behind the pelvis, five bones (abbreviated S1 through S5) fused into a triangular shape forms the sacrum (figure 15). This fits into the two hip bones connecting the spine to the pelvis. Its narrow blunted apex is at the inferior end of the bone and articulates with the coccyx. At the opposite end the wide base articulates with the fifth lumbar vertebra, with which it forms the sacrovertebral angle. The bone is placed very obliquely and is curved longitudinally so that its dorsal surface is convex and its pelvic surface is concave.

This ventral concavity serves to increase the capacity of the true pelvis. Immediately below the sacrum are five additional bones fused together to form the coccyx (Bridwell and Rodt, 2008). The base is formed by the upper surface of the first sacral vertebra and presents all the features of a typical vertebra in a slightly modified form. Its anterior projecting edge is named the sacral promontory. The vertebral foramen is triangular and its shape is explained by the fact that the pedicles are short, widely separated, and are directed backwards and laterally. The laminae are very oblique and incline downwards, medially and backwards. Where they meet spinous process is represented by spinous tubercle. The superior articular process project upwards and bear concave articular facets which face medially and backwards to articulate with the inferior articular processes of the fifth lumbar vertebra (Standring, 2004).
Figure 15: The sacral bone (Standring, 2004)
COCCYX

The coccyx is a small bone, triangular in shape, which consists usually of four rudimentary vertebrae, fused together, but the number may be increased to five or reduced to three. The bone is directed downwards and ventrally from the apex of the apex sacrum, so that its pelvis surface upwards and forwards and its dorsal surface downwards and backwards. The base of the coccyx, formed by the upper surface of the body of the first coccygeal vertebra, presents an oval, articular facet for articulation with the apex of the sacrum. Dorsilateral to the facet, two processes, named the coccygeal cornua project upwards to articulate with the sacral cornua. A rudimentary transverse process projects laterally and slightly upwards from each side of the body of the first coccygeal vertebrae and may ascend to articulate or fuse with the inferior lateral angle of the sacrum; in that event five pairs of foramina are found in the sacrum. The second, third and fourth coccygeal vertebrae diminish successively in size and are usually fused with one another (Standring, 2004).

INTERVERTEBRAL DISCS

The intervertebral discs make up one-fourth of the spinal column’s length. There are no disc between the atlas (C1) and axis (C2) and Coccyx. The intervertebral discs are fibrocartilaginous serving as the spine shock absorbing system which protect the vertebrae brain and nerves). The intervertebral discs are composed of annulus fibrosus and nucleus pulposus (figure 16). The annulus fibrosus is a strong radial tire-like structure made up of lamellae; concentric sheets of collagen fibers connected to the vertebral end-plates. The sheets are orientated at various angles and the annulus fibrosus encloses the nucleus pulposus. The nucleus pulposus contains a hydrated gel like matter that resists compression (Bridwell and Rodt, 2008).
Figure 16: The axial overhead view of the intervertebral disc (Bridwell and Rodt, 2008).
FACET JOINTS

The joints in the spine are commonly called the facet joint. Other names for these joints are Zygapophyseal or apophyseal joints. Each vertebra as two forms of facet joints. One pair faces upward (superior articular facet) and one downward (inferior articular facet). There is one joint on each side (right and left). Facet joints are hinge-like and link vertebrae together. They are located at the back of the spine (posterior) (Bridwell and Malanga, 2008). Facet joints are synovial joints this means each joint is surrounded by capsule of connective tissue and provide a fluid to nourish and lubricate the joint. These joints allow flexion and extension and twisting motion. Certain types of movement are restricted. The spine is made more stable due to interlocking nature to adjacent vertebrae (Bridwell and Malanga, 2008).
2.13 LIGAMENTS OF THE SPINAL COLUMN:

Ligaments are fibrous band or sheet of connective tissue linking two or more bones, cartilage or structures together. Three of the more important ligaments in the spine are the ligamentum flavum, anterior longitudinal ligament and the posterior longitudinal ligament. The ligamentum flavum forms a cover over the dura matter: a layer of tissue that protects the spinal cord. This ligament connects under the facet joints to create a small curtain over the posterior opening between the vertebrae (Bridwell and Rodt, 2008).

The anterior longitudinal ligament attaches to the front (anterior) of each vertebra. This ligament runs up and down the spine (vertical or longitudinal). The posterior longitudinal ligament runs up and down behind (posterior) the spine and inside the spinal canal (Bridwell and Rodt, 2008). There are four ligaments connecting the occiput and the atlas together these are, Anterior Occipitoatlantal ligament, Posterior Occipitoatlantal ligament and Lateral Occipitoatlantal Ligament (figure 17).

The occipito ligament complex also connect the occiput with the axis, these are occipitoaxial ligament, alar ligament and apical ligament. There is also an atlantoaxial complex extending from atlas to axis, these are anterior atlantoaxial ligament, posterior antlantoaxial ligament and lateral ligament. There is also cruciate complex which help to stabilize the atlantoaxial complex these are, transverse ligament, superior longitudinal fascicles and inferior longitudinal fascicles (Bridwell and Rodt, 2008).
FIGURE 17: The Anterior and Posterior Longitudinal Ligament (Bridwell and Rodt, 2008)
NERVE STRUCTURE OF THE SPINE:

CENTRAL NERVOUS SYSTEM (CNS)

The Central Nervous System (CNS) is composed of the brain constituting the medulla oblongata, the pons, the cerebellum, the mid brain, the cerebrum and the spinal cord. The spinal cord which originates immediately below the brain stem extends from the level of the upper border of the atlas vertebra to that of the lower border of the first lumbar vertebra (L1) or upper border of the second but it lower end may sometimes be found as high as the lower border of the third lumbar vertebra. Spinal cord is the elongated nearly cylindrical part of the central nervous system which occupies the upper two-thirds of the vertebral canal. Its average length in male is 45cm; its weight is about 30gms. (Standring, 2004).

Beyond L1 the spinal cord becomes the Cauda Equina. The spinal cord provides connection between brain and peripheral nerve. In the centre of the spinal column is a vertical hole called the spinal canal, it contains the spinal cord. The bones that create the spinal canal serves as armor to help protect the spinal cord from injury, small nerve root branch off from the spinal cord through spaces on between each vertebrae and extends out into the entire body. The nerves are the body neural message system (Standring, 2004).
PERIPHERAL NERVOUS SYSTEM (PNS)

The CNS extends to the peripheral nervous system, a system of nerves that branch beyond the spinal cord, brain and brain stem. The PNS carries information to and from the CNS. The PNS includes the Somatic Nervous System (SNS) and the Autonomic Nervous System (ANS). The Somatic Nervous System includes the nerves serving the musculoskeletal and the skin. It is voluntary and reacts to outside stimuli affecting the body. The Autonomic Nervous System is involuntary automatically seeking to maintain homeostasis or normal function (Bridwell and Maiman, 2008).

The ANS is further divided into the Sympathetic Nervous System and the Parasympathetic Nervous System. The Sympathetic Nervous System is an involuntary system which is often associated with flight or fight response. The Parasympathetic Nervous System is responsible for promoting internal harmony such as regular heartbeat during normal activity (Bridwell and Maiman, 2008).

Just below the last thoracic (T12) and the first lumbar (L1) vertebra the spinal cord ends at the Conus Medularis. From this point the spinal nerve resembles a horse tail known as Cauda Equina extending to the coccyx (Bridwell and Maiman, 2008). The nerve root pass out the spinal canal through the intervertebral foramen, where they feed the body either anteriorly (motor) or posteriorly (sensory). The anterior divisions supply the front of the spine including the limbs. The posterior divisions are distributed to the muscles behind the spine.

2.15 MUSCLES OF THE SPINE:

Muscles are named according to their shape, location, or a combination of the them. They are further categorized according to function such as flexion, extension or
rotation. Skeletal muscle is striated in appearance. It is innervated under voluntary
control and has the fastest contraction rate of all muscles (Bridwell, 2007). These are
summarized below:

CERVICAL MUSCLES:

Name: Sternocleidomastoid.
Nerve: C2, C3.

Origin and Insertion: Manubrium, clavicle & mastoid process.
Functions: Extends & rotates head, flexes vertebral column

Name: Scalene
Nerve: Lower cervical

Origin and Insertion: Anterior tubercle of transverse process of 3, 4, 5 & 6 inserted
into the inner border of the first rib.
Functions: Flexes & rotates neck

Name: Spinalis Cervicis
Nerve: Middle/lower cervical

Origin and Insertion: Lower part of ligamentum nuchae, C7, T1, T2 inserted into
spine of axis.
Functions: Extends & rotates head

Name: Splenius Cervicis
Nerve: Middle/lower cervical

Origin and Insertion: Same as semispinalis capitis.
Function: Extends & rotates head
Name: Spinalis Capitus

Nerve: Middle/lower cervical

Origin and Insertion: Ligamentum nuchae and spine of C7-T6 vertebrae & posterior tubercle of the transverse process of C1-C3 vertebrae.

Functions: Extends vertebral column flexes head

Name: Semispinalis Cervicis

Nerve: Middle/lower cervical

Origin and Insertion: Upper T5, T6 inserted into the cervical spine from axis to C5.

Functions: Extends & rotates vertebral column

Name: Semispinalis Capitus

Nerve: C1 – C5

Origin and Insertion: Tip of transverse process of upper T6, T7, C7, articular process of C4, C5, C6 inserted into the medial part of the superior and inferior nuchal lines of the occipital bone.

Functions: Rotates head & pulls backward

Name: Iliocostalis Cervicis

Nerve: Middle/lower cervical

Origin and Insertion: arises from the angle of 3, 4, 5 & 6 ribs and inserted into the posterior tubercles of the transverse processes of the C4, C5, C6 vertebrae

Functions: Extends cervical vertebrae
**Name:** Longissimus Cervicis  
**Nerve:** Middle/lower cervical  
**Origin and Insertion:** Arises from transverse process of the T4, T5, inserted into posterior tubercles of the transverse processes of the C2-C6.  
**Functions:** Rotates head & pulls backward

**Name:** Longissimus Capitus  
**Nerve:** Middle/lower cervical  
**Origin and Insertion:** Arises from the T4 or T5 and articular process of C3, C4 inserted into the posterior margin of the mastoid process.  
**Functions:** Extends & rotates head

**Name:** Rectus Capitus Posterior Major  
**Nerve:** Dorsal ramus of C1  
**Origin and Insertion:** From spine of axis is inserted into the lateral part of the inferior nuchal line of the occipital bone, and into the bone immediately below the line.  
**Functions:** Extends head

**Name:** Rectus Capitus Posterior Minor  
**Nerve:** Dorsal ramus of C1  
**Origin and Insertion:** Arises from narrow pointed tendon from the tubercle on the posterior arch of the atlas, inserts into the medial part of the inferior nuchal line of the occipital bone and foramen magnum  
**Functions:** Rotates atlas
Name: Obliquus Capitus Inferior

Nerve: Dorsal ramus of C1

Origin and Insertion: lateral surface of the spine and adject part of the upper part of the lamina of the axis.

Functions: Extends & bends head laterally

Name: Obliquus Capitus Superior

Nerve: Dorsal ramus of C1

Origin and Insertion: upper part of transverse process of atlas inserted into the occipital bone.

Functions: Extends & bends head laterally.

THORACIC MUSCLES

Name: Longissimus Thoracis

Nerve: Dorsal primary divisions of spinal nerves

Origin & Insertion: Transverse process at inferior vertebral level & Transverse process at superior vertebral level and mastoid process.

Function: Extension, lateral flexion of vertebral column, rib rotation

Name: Iliocostalis Thoracis

Nerve: Dorsal primary divisions of spinal nerves

Origin & Insertion: Iliac crest, sacrum and angle of the ribs

Function: Extension, lateral flexion of vertebral column, rib rotation
Name: Spinalis Thoracis

Nerve: Dorsal primary divisions of spinal nerves

Origin & Insertion: Spinous process at inferior vertebral level and spinous process at superior vertebral level at the base of the skull.

Function: Extends vertebral column

Name: Semispinalis Thoracis

Nerve: Dorsal primary divisions of spinal nerves.

Origin & Insertion: Transverse process of C7-C12 and Carpitis back of the skull between nuchal line and cervicis; cervicis & thoracis: spine 4-6 vertebral above origin

Function: Extends & rotates vertebral column

Name: Rotatores Thoracis

Nerve: Dorsal primary divisions of spinal nerves

Origin & Insertion: Transverse process and lamina of vertebral above vertebral

Function: Extends & rotates vertebral column

LUMBAR MUSCLES

Name: Psoas Major

Nerve: L2, L3, sometimes L1 or L4

Origin & Insertion: Arises from transverse process of all lumbar vertebrae and inserted into lesser trochanter of the femur.

Function: Flexes thigh at hip joint & vertebral column

Name: Intertransversarii Lateralis

Nerve: Ventral primary division of spinal nerves
**Origin & Insertion:** Connect the accessory process of one vertebrae with the transverse process of the next.

**Function:** Lateral flexion of vertebral column

**Name:** Quadratus Lumborum

**Nerve:** T12, L1.

**Origin & Insertion:** Arises from iliolumbar ligament and iliac crest inserted into last rib and transverse process of upper 4 lumbar vertebrae

**Function:** Lateral flexion of vertebral column

**Name:** Interspinales

**Nerve:** Dorsal primary divisions of spinal nerves

**Origin & Insertion:** Arises between the axis and C3, C7, T1, T2, T3, T11 and T12 also between the five lumbar vertebrae.

**Function:** Extends vertebral column

**Name:** Intertransversarii Mediales

**Nerve:** A dorsal primary division of spinal nerves

**Origin & Insertion:** Connect the accessory process of one vertebrae with the mamillary process of the next.

**Function:** Medial flexion of vertebral column

**Name:** Multifidus

**Nerve:** Dorsal primary divisions of spinal nerves

**Origin & Insertion:** Posterior surface of the sacrum, posterior tubercle of the lumbar transverse process and the transverse process of the vertebral above & full length of the spinous process of the second or third spinous process.
**Function:** Extends & rotates vertebral column

**Name:** Longissimus Lumborum

**Nerve:** Dorsal primary divisions of spinal nerves

**Origin & Insertion:** Arises from the transverse process of the vertebral above

**Function:** Extends & rotates vertebral column

**Name:** Iliocostalis Lumborum

**Nerve:** Dorsal primary divisions of spinal nerves

**Origin & Insertion:** Inserted into the inferior border of lower 6th or 7th ribs.

**Function:** Extension, lateral flexion of vertebral column, rib rotation

**MUSCLE-FASCIA**

Fascia is a thickened connective tissue that envelops a muscle or a group of muscles. Superficial fascia is found directly under the skin. Epimysium is the fascia closest to the muscle. Perimysium divides the muscle into facicles – muscle fibers. Endomysium is another type of connective tissue that covers each muscle fiber (Bridwell, 2009). The thoracolumbar fascia covers the deep muscles of the back of the trunk. Above, it passes in front of the Serratus posterior superior and is continuous with the superficial lamina of the cervical fascia on the back of the neck.

In the thoracic region the thoracolumbar fascia is a thin fibrous lamina covering the extensor muscles of the vertebral column and separating them from the muscles connecting the vertebral column to the upper extremity. It is attached, medially, to the spines of the thoracic vertebrae; laterally, to the angles of the ribs (Standring, 2004).
In the lumbar region the thoracolumbar fascia is in three layers. The posterior layer is attached to the spines of the lumbar and sacral vertebrae and to the supraspinous ligament; the middle layer is attached medially, to the tips of the transverse processes of the lumbar vertebrae and to the intertransverse ligaments, below, to the iliac crest and above, to the lower border of the twelfth rib and to the lumbocostal ligament (Standring, 2004).
CHAPTER THREE
MATERIALS AND METHODS

3.1 MATERIALS

3.1.1 SUBJECTS SELECTION

A total of 122 patients (44 males, 78 females) with non-specific chronic low back pain (NCLBP) were recruited from Orthopaedic Clinic of Lagos University Teaching Hospital (LUTH), Idi- Araba, Lagos and National Orthopaedic Hospital Igbobi, Lagos. They were patients diagnosed with NCLBP. Clinical examination and assessment were done before inclusion of patients into the study.

INCLUSION CRITERIA

1. Only patients with a history of non-specific chronic low back pain (NCLBP) with or without pain radiating to one or both lower limbs.

2. Patients whose clinical assessment indicated that he or she is suitable for stabilization exercise programme (inability to sustain activated lumbar multifidus and transversus abdominis muscle for >10 seconds).

EXCLUSION CRITERIA

1. Patients confirmed to be pregnant from the date of their last menstrual period and blood Pregnancy test.

2. Patients with medical or surgical conditions which might hinder exercise performance. e.g. fractures, neurologic or mental disease.

3. Patients with specific LBP e.g., patients with LBP as a result of cancer or tuberculosis of the spine.

4. Patients with Spondylolisthesis, were confirmed through their radiographs.
5. Patients with previous back surgeries were confirmed through their past medical history.

6. Patients with Osteoporosis were confirmed through their radiographs.

3.2 ETHICAL CONSIDERATION

Ethical approval was obtained from the Health Research and Ethics Committee of Lagos University Teaching Hospital (Appendix v) and informed written consent was obtained from each patient prior to inclusion into the study (Appendix 1). Confidentiality of all information obtained from the patients was assured by safely and securely storing the questionnaires.

3.3 INSTRUMENTATION


2. Transcutaneous electrical nerve stimulator (TENS) DX 6605E.(Canada).

3. Combined weighing scale and height meter (Sheradon, England).

4. Pressure Biofeedback Unit (United State of America).

5. Outcome measures (Questionnaire).
   a. Oswestry Disability Questionnaire (OSDQ).
   b. Fear avoidance belief Questionnaire (FABQ).
   c. Modified Visual Analogue Scale (VAS).

DESCRIPTION OF INSTRUMENTS

1. **Ultrasound Scanning Machine (United State of America)**: A commercially available ultrasound machine (Mindray DP 2200) equipped with 3.5MHZ convex array transducer was used. Measurement of cross sectional area (CSA) and thickness of the lumbar multifidus muscle for all the patients were assessed with this instrument.
Ultrasound has been documented to be effective in the measurement of muscle CSA and thickness which as provided an accurate assessment of muscle wasting and contraction in lumbar multifidus muscle (Wallwork, 2009).

2. **Transcutaneous Electrical nerve Stimulator (TENS) Canada:** It is a portable EV-603M SD timer TENS with a pulse rate of 2 - 150 Hz and pulse width of 30 - 260ms. It is a double channel output, which consist of 4 self adhesive electrodes (40 x 40cm) made up of rubber impregnated with carbon controlled by intensity numbered 1 to 5. The unit was powered by 9 volt Duracell battery and frequency fixed at 100Hz. The electrodes were used to cause transmission of impulses to the area to be treated. TENS machine was applied for 10 minutes and it has been known to produce significant pain relief (Akinbo et al., 2004).

3. **Height Meter (Sheradon, England):** This is made of steel and calibrated in inches and centimeters (stadiometer). This measures to the nearest centimeter and was used to get the exact height of the patients. Patients were instructed to stand barefooted, head straight with back against a graduated stadiometer. The horizontal projection of the stadiometer was brought in contact with the head of the patients and with light pressure on the patient’s head the height was read off and recorded to the nearest 0.1 centimetre (ISAK, 2001).

4. **Weighing Scale (Sheradon, England):** A floor type weighing scale with weight measuring standard made by Ceca calibrated in kilogram (kg) from 0-120kg with model number ZT-120 was used to measure the body weight of the participants. The patients were instructed to stand erect and barefooted on the weighing scale, their eyes looking straight ahead and with hands held by the side. The body weight were then read off and recorded to the nearest 1 kilogramme (ISAK, 2001).
5. **Pressure Biofeedback Unit:** Activation of transversus abdominis muscle is regarded by many as an integral part of back pain management which can be actualized by the use of pressure biofeedback unit. This was validated and known to be efficacious in the monitoring of movement of abdominal wall. It is an inflatable inelastic bag connected to a pressure gauge. This has been proven to be a useful clinical tool for the assessment of transversus abdominis muscle to enhance training in lumbar muscle stabilization (Jull et al., 1993).

6. **Oswestry Disability Questionnaire (ODQ):** This is a questionnaire designed to give information on how the back or leg is affecting ability to perform every day tasks and it was used to assess the disability level of the patients (Appendix II). The subscale consists of 10 sections. Section 1-5 measures pain intensity, personal care, lifting, walking, and sitting. Sections 6-10 measures standing, sleeping, sex life, social life, and travelling respectively. For each section the maximum score is 5 and the minimum score is 0 respectively. The overall minimum and maximum scores were 0 and 100% respectively (Fairbank and Pynsent, 2000).

7. **Fear Avoidance Belief Questionnaire (FABQ):** This is a questionnaire that was developed by Waddell (1993) to investigate fear-avoidance beliefs among LBP patients in the clinical setting (Appendix III). It helps predict people that have high pain avoidance behavior. It consists of 2 subscales, which are reflected in the division of the outcome form into 2 separate sections.

The first subscale (item 1-5) is the physical activity subscale (FABQP) and the second subscale item (6-16) is the work subscale (FABQW). Each subscale is graded separately by summing the response respective scale items (0-6 for each item); for scoring
purposes, only 4 of the physical activity scale items are scored (24 possible points) while only 7 of the work items are scored (42 possible points). FABQP and FABQW are high if the scores are ≥ 15 and ≥ 34 respectively. It has been proven to be a useful clinical tool that demonstrates specific fear-avoidance beliefs about work which are strongly related to work loss due to low back pain (Waddell et al., 1993).

8. **Modified Visual Analogue Scale (VAS):** This was used to measure pain intensity pre- and post-treatment intervention (Appendix IV). The patients were shown the scale and asked to rate their present pain by making a circle around the number (0-10) that best describe the level (that is, intensity) of their perceived pain. The numerical value was taken and recorded as the patient’s pain rating. “0” signifies no pain and “10” signifies the worst pain experienced. The version of VAS employed in this study was a vertical line with numbers 0-10 on the left side and word descriptors on the right side (Waterfield and Sim, 1996).

All outcome measure parameters were assessed pre-intervention (baseline), end of 4th week (mid-intervention) and end of 8th week (post-intervention).

3.4 **RESEARCH DESIGN**

A single blinded randomized controlled trial.

3.5 **SAMPLE SIZE DETERMINATION**

The sample size was determined by using a formula as follows:

Sample formula: \[ N = \frac{4(\text{SD})^2 (Z_{\text{crit}} + Z_{\text{pwr}})^2}{D^2} \]
Where:

\[ N \quad = \quad \text{The total sample size (the sum of the sizes of the comparing groups)} \]

\[ SD \quad = \quad \text{Estimated measurement variability} \]

\[ Z_{\text{crit}} \quad = \quad \text{Desired significant criterion.} \]

\[ Z_{\text{pwr}} \quad = \quad \text{Desired statistical power} \]

\[ D \quad = \quad \text{Minimum expected difference in the means (John, 2003)} \]

The sample size was calculated thus:

\[
\frac{4(0.09)^2(1.96+0.842)^2}{(0.05)^2} \]

\[ N = 4(0.0081)(2.80)^2 \]

\[ N = \frac{4 \times 0.0081 \times 7.84}{0.0025} = 101.6 \]

The sample size was approximated to 102 subjects.

### 3.6 SAMPLING TECHNIQUE

One hundred and thirty-five (135) consecutively referred individuals with nonspecific chronic low back pain were screened; seven (7) patients were found ineligible for the study after screening and were therefore excluded. The eligible patients were randomly assigned to groups via a computer-generated random number sequence. However only 122 patients completed the study. Reasons for withdrawal by patients who did not complete the study were given (Figure 18).
**Group 1:** Stabilization exercises only: Patients in this group underwent stabilization exercise only.

**Group 2:** Stabilization exercises & TENS: Patients in this group underwent stabilization exercise and TENS therapy.

**Group 3:** Stabilization exercises & TENS + Massage: Patients in this group underwent stabilization exercise, TENS therapy and massage therapy.

**Group 4:** Patients in this group received only drug therapy e.g. Ibuprofen, Diclofenac, Aspirin, Paracetamol, Tramadol (control group).
Patients screened  
(n = 135)

Excluded (n= 7)

Eligible patients  
(n = 128)

R

Group 1 (Treatment)  
n = 32

Withdrawal from trial  
(n= 1) (Illness)

Completed trial  

n = 31

Group 2 (Treatment)  
n = 32

Withdrawal from trial  
(n= 1) (Transportation problems)

Completed trial  

n = 31

Group 3 (Treatment)  
n = 32

Withdrawal from trial  
(n= 2)  
(Illness, n=1)  
(Lack of effect, n =1)

Completed trial  

n = 30

Group 4 (Control)  
n = 32

Withdrawal from trial  
(n=2)  
(Transportation problem)

Completed trial  

n = 30

**Figure 18:** Recruitment and allocation of patients R: Randomization; Group 1: Stabilization exercise; Group 2: Stabilization exercise with TENS; Group 3: Stabilization exercise combined with TENS and Massage; Group 4: patients that received only drugs (control group).
3.7 PROCEDURE FOR DATA COLLECTION

3.7.1 PRE-INTERVENTION ASSESSMENT

The assessment involved evaluation of the motor control strategy during a specific trunk muscle task-drawing-in maneuver of the lower abdomen while maintaining an isometric contraction of the medial back muscles.

a. Assessment of Lumbar Multifidus muscle:

In supine position with a towel underneath the back, the patient was assisted by researcher to move into anterior pelvic tilt and the lumbar multifidus contraction was palpated. The towel was removed and patients were assisted into posterior pelvic tilt. This enabled patient to achieve neutral lordosis (or position). In prone position, posterior superior iliac spine (PSIS) was located and patients were instructed to slowly draw-in the lower abdomen. A light contraction felt during this procedure indicate that patient can activate the lumbar multifidus (LM) muscle. During the activation of LM muscle, patient was expected to maintain isometric hold and normal breathing with controlled lateral costal diaphragmatic breathing. Patient was expected to avoid breath holding, thoracic flexion and upper abdominal bracing that restricts the breathing. Patient was now instructed to be in supine position again and pressure biofeedback unit was placed underneath the patient’s back at the low back region of the lumbar vertebra and inflated to 40mmHg. The patient then performed drawing-in maneuver of the abdomen. The researcher ensured that the level of the gauge was between 30-40 mmHg for proper activation to be achieved (Figure 19).
Figure 19: Procedure for inflating the pressure biofeedback unit under the patient’s lower back region.
Information on age, gender, height, weight, occupation, marital status, clinical history of low back pain, numbers of low back pain episodes during 12 months prior to the study were obtained from patients through interview and from their hospital files. All the patients were instructed to complete all the outcome measures for pain intensity, functional disability and fear avoidance belief. These formed the baseline data of the patients.

b. **Measurement of Cross-Sectional Area (CSA) of Lumbar Multifidus Muscle**

The patients were required to lie prone on a plinth with the head in the mid line position; with a small roll placed under the forehead and two rolls under the shoulders. This position is expected to provide for comfort and ensure neutral positioning of the spine. The patients were expected to lie such that their feet were over the edge of the plinth with the arms by the sides. The lower lumbar spine was made flat by placing pillow under the hips to eliminate lumbar lordosis. The 4th lumbar spinous process was palpated using the level of the iliac crest as a guide and mark was made on the skin. Warmed gel was applied to the skin and a 3.5 array transducer was held at 90° to the surface (Figure 20). The array was then placed transversely over the L4 spinous process and moved directly lateral to the image of the multifidus muscles. The transducer was directly over the echogenic vertebral lamina; this was seen at the inferior border of the muscle and provided a consistent landmark. When a satisfactory image was obtained, it was stored on the screen, and an electronic on-screen calliper was used to trace around the muscle border given an immediate readout of the muscle CSA (Figure 21) (Hides et al., 1992).
Figure 20: Ultrasound scanning of Lumbar multifidus muscle cross-sectional area.
Figure 21: Bilateral transverse ultrasound image at the L4 vertebral level, with CSA area tracings.
c. **Measurement of multifidus Muscle thickness**

The patients were positioned in prone lying with pillow under the abdomen to minimize the lumbar lordosis. The lumbar vertebral levels were palpated and the location of the spinous process on the skin marked with a pen. The multifidus muscle was imaged in parasagittal (longitudinal) section allowing visualization of the zygapophyseal joints, multifidus muscle bulk and thoracolumbar fascia by instructing the participants to isometrically contract the lumbar multifidus muscle and retain the contraction. The thickness of the multifidus was measured at the levels of L4-L5 zygapophyseal joint using on-screen caliper (figure 22). Linear measurements were conducted from the tip of target zygapophyseal joint to the inside edge of the superior border of the multifidus muscle (figure 23) (Wallwork *et al.*, 2007).
Figure 22: Ultrasound scanning of the lumbar multifidus muscle thickness
Figure 23: Ultrasound image of the LM thickness in parasagittal section at rest (A) and on contraction (B) using a split screen.
3.7.2 INTERVENTION

There were four groups, three study groups (group 1, 2 and 3) and one control (group 4).

**Group 1:** Patients were treated with stabilization exercise, for 30 minutes duration with a frequency of two treatment sessions per week with a day interval for 8 consecutive weeks adopting the protocol of Hides *et al.* (2001).

**Group 2:** Patients were treated with stabilization exercise for 30 minutes with TENS therapy for 10 minutes, with frequency of two treatment sessions per week with a day interval for 8 consecutive weeks.

**Group 3:** Patients were treated with stabilization exercise for 30 minutes with TENS therapy for 10 minutes and massage therapy for 5 minutes, two treatment sessions per week with a day interval for 8 consecutive weeks.

**Group 4:** Patients were administered drugs for 8 consecutive weeks.

a) **STABILIZATION EXERCISE PROTOCOL**

*Component of stabilization exercise are as listed below:*

a. Abdominal bracing
b. Bracing with heel slides
c. Bracing with leg lift
d. Bracing with bridging
e. Bracing with bridging with leg lift
f. Bracing in standing
g. Quadruped arms lifts with bracing
h. Quadruped leg lifts with bracing
i. Quadruped alternate arm and leg lift with bracing
Patients were made to go through the treatment protocol of stabilization exercise before the commencement of the study. This is to train patients on the procedure pre-intervention, following the protocol of Hick et al. (2005) and Donald and Robert, (2006). Patient then proceeded to exercise proper as shown in Figure 24.

**Abdominal bracing** - 30 repetitions with 8-seconds: Patients were instructed in supine lying position to perform drawing-in maneuver of the abdomen and hold it for 8 seconds, 30 times for 2 minutes.

**Bracing with Heel Slides** - 20 repetitions per leg with 4-seconds: Patients were instructed in supine lying position to perform drawing-in maneuver of the abdomen and hold it with sliding of the heel per leg for 4 seconds, 20 times for 4 minutes.

**Bracing with Leg Lift** -20 repetitions per leg with 4-seconds: Patients were instructed in supine lying position to perform drawing-in maneuver of the abdomen and hold it with raising up the leg for 4 seconds, 20 times for 4 minutes.

**Bracing with Bridging** - 30 repetitions with 8-seconds, then progress to one leg: Patients were instructed in supine lying position to perform drawing-in maneuver of the abdomen and gently lift up the buttock and hold it for 8 seconds, 30 times for 2 minutes.

**Bracing with Bridging and Leg Lift** - 30 repetitions with 8-seconds, Patients were instructed in supine lying position to perform drawing-in maneuver of the abdomen and gently lift up the buttock and hold it with raising up the leg for 8 seconds, 30 times for 4 minutes.
**Bracing in Standing** - 30 repetitions with 8-seconds: Patients were instructed to perform drawing - in maneuver of the abdomen in standing for 8 seconds, 30 times for 2 minutes.

**Quadruped Arms Lifts with Bracing** (Flex one upper extremity) - 30 repetitions with 8 seconds on each side: Patients were instructed in prone kneeling position to perform drawing-in maneuver of the abdomen, flex one upper extremity and hold it for 8 seconds, 30 times on each side for 4 minutes.

**Quadruped Leg Lifts with Bracing** (Extending one lower extremity and lifting it off the exercise mat) - 30 repetitions with 8 seconds on each side: Patients were instructed in prone kneeling to perform the drawing-in maneuver of the abdomen, extend one lower extremity and lift it off exercise mat and hold it for 8 seconds, 30 times on each side for 4 minutes.

**Quadruped Alternate Arm and Leg lift with Bracing** (flex one upper extremity and extend contralateral lower extremity) - 30 repetition with 8seconds on each side: Patients were instructed in prone kneeling to perform the drawing-in maneuver of the abdomen, flex one upper extremity and extend contralateral lower extremity and hold it for 8 seconds, 30 times for 4 minutes. (Hick et al., 2005; Donald and Robert, 2006).
**Figure 24:** Some stabilization exercise procedures used in the study (Bakhtiary *et al.*, 2005)
(b) **TENS THERAPY PROTOCOL**

The area to be treated were properly exposed and the TENS electrodes were placed adequately by placing the active electrode securely at the paravertebral region at the area of greatest pain intensity at the lumbar region. A brief history of the origin and duration of the pain and any associated problems was conducted. Assessment and examination of the back for each fresh referral was conducted to establish the painful areas. Palpation and localization of the painful area was through mild pressure via the thumb on the painful area of the lumbar spine (Akinbo *et al.*, 2004).

(c) **MASSAGE**

Soft tissue massage of the lumbosacral area was given using the following techniques:

- Effleurage
- Kneading.
- Friction for 5 minutes (Cherkin *et al.*, 2009).

### 3.7.3 POST INTERVENTION ASSESSMENT

The patients in the four groups were re-assessed with the outcome measures vis-à-vis Visual analogue scale (VAS), Oswestry disability questionnaire (ODQ), fear avoidance belief questionnaire (FABQ), and ultrasound scanning after 4 weeks and 8 weeks respectively.
3.8 DATA ANALYSIS

Summary of the socio demographic data was done using descriptive statistics of mean and standard deviation. Kruskal Wallis test was used to analyse each outcome measure and analysis of variance (ANOVA) was used to analyse the cross-sectional area (CSA) and thickness pre and post treatment intervention across the groups. A least significant difference post hoc analysis was carried out to determine the exclusively significant group in the outcome measure parameters, CSA and muscle thickness of lumbar multifidus. Wilcoxon test was used to compare baseline and 8th week values of the outcome measure parameters, while paired t-test was used to compare the CSA and thickness of the lumbar multifidus muscle within the groups. Level of significance was set at p<0.05.
CHAPTER FOUR

RESULTS

4.1: DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS

The mean age of participants in Groups 1, 2, 3 and 4 were 45.84 ± 9.95 years, 47.03±12.07 years, 44.57±11.82 years and 50.83±13.03 respectively. The four groups did not differ significantly in age and height (Table 1).

4.2: OUTCOME MEASURE PARAMETERS AT BASELINE, End Of 4TH WEEK AND 8TH WEEK POST-INTERVENTION

At baseline (pre-treatment) Kruskal Wallis test showed no significant difference for pain intensity, functional disability (FD) and fear avoidance belief for physical and work activity (FABP and FABW) across the four groups (Table 2).

There was significant difference at 4th week for pain intensity, functional disability and FABP when across group comparison was done. While at 8 week post-treatment intervention there was significant difference in all the parameters measured across the groups for pain intensity, FD, FABP and FABW (Table 3). Least significant difference (LSD) post hoc analysis shows that the significance lies between group 1 & 4, groups 2 & 4 and groups 3&4 post intervention assessment (Figure 25).
Table 1: Demographic Characteristics of the Participants

<table>
<thead>
<tr>
<th></th>
<th>All participants</th>
<th>GRP1</th>
<th>GRP2</th>
<th>GRP3</th>
<th>GRP4</th>
<th>F</th>
<th>p-value</th>
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</thead>
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<td><strong>X±SD</strong></td>
<td><strong>X±SD</strong></td>
<td><strong>X±SD</strong></td>
<td><strong>X±SD</strong></td>
<td><strong>X±SD</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>N=122</strong></td>
<td><strong>n=31</strong></td>
<td><strong>n=31</strong></td>
<td><strong>n=30</strong></td>
<td><strong>n=30</strong></td>
<td><strong>n=30</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>47.06±11.84</td>
<td>45.84±9.95</td>
<td>47.03±12.07</td>
<td>44.57±11.82</td>
<td>50.83±13.03</td>
<td>1.59</td>
<td>0.19</td>
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<tr>
<td>Height (m)</td>
<td>1.72 ± 0.10</td>
<td>1.71±0.89</td>
<td>1.71±0.98</td>
<td>1.71±0.10</td>
<td>1.75± 0.11</td>
<td>1.41</td>
<td>0.24</td>
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<tr>
<td>Weight (kg)</td>
<td>74.85±11.14</td>
<td>78.10±11.70</td>
<td>74.23±14.16</td>
<td>75.83±9.31</td>
<td>75.27±7.91</td>
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<td>0.54</td>
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<td>BMI (Kg/m^2)</td>
<td>25.45± 3.97</td>
<td>26.57±3.76</td>
<td>25.50±3.42</td>
<td>26.31± 4.47</td>
<td>24.81± 3.88</td>
<td>1.28</td>
<td>0.28</td>
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</table>

**KEY:**

X± SD = Mean ±Standard Deviation

BMI = Body Mass Index

GRP1 - Group 1 = Stabilization exercise only

GRP 2 - Group 2 = Stabilization exercise with TENS

GRP 3 - Group 3 = Stabilization exercise with TENS and massage.

GRP4 - Group 4 = Control

N = Total subject population

n = Subjects in each group
Table 2: Outcome Measure parameters at Baseline, end of 4th Week and 8th Week

<table>
<thead>
<tr>
<th>OUTCOME MEASURE</th>
<th>GRP1 MEAN RANK</th>
<th>GRP2 MEAN RANK</th>
<th>GRP3 MEAN RANK</th>
<th>GRP4 MEAN RANK</th>
<th>H-Value</th>
<th>p-value</th>
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<tr>
<td>FD</td>
<td>59.97</td>
<td>70.08</td>
<td>64.05</td>
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<tr>
<td>Pain</td>
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<td>61.58</td>
<td>68.45</td>
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<tr>
<td>FABP</td>
<td>61.77</td>
<td>59.77</td>
<td>60.72</td>
<td>63.78</td>
<td>0.22</td>
<td>0.98</td>
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<td>FABW</td>
<td>61.60</td>
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<td>69.83</td>
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<tr>
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<tr>
<td>Pain</td>
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<td>103.72</td>
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<td>FABP</td>
<td>52.95</td>
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<tr>
<td>FD</td>
<td>47.48</td>
<td>49.94</td>
<td>46.43</td>
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</tr>
<tr>
<td>Pain</td>
<td>49.19</td>
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<td>48.55</td>
<td>91.82</td>
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</table>

* Significant difference p< 0.05

Key:

X ±SD = Mean ± Standard deviation

GRP 1 = Group 1 = Stabilization exercise only

GRP 2 = Group 2 = Stabilization exercise with TENS

GRP 3 = Group 3 = Stabilization exercise with TENS and massage.

GRP 4 = Group 4 = Control

Rx = Treatment

H = Kruskal Wallis test

FD = Functional disability

FABP = Fear avoidance Belief for physical activity

FABW = Fear avoidance belief for work activity
FIGURE 25: Schematic representation of post hoc analysis of Outcome Measure parameters at end of 8th Week in the four groups.

KEY:

☆ Significant difference p < 0.05

1- Group 1 – Stabilization exercise only
2- Group 2 – Stabilization exercise with TENS only
3 - Group 3 – Stabilization exercise with TENS and Massage
4- Group 4 – Control, FABP - Fear Avoidance Belief for Physical activity,

FABW = Fear Avoidance Belief Work activity.
FD = Functional disability
4.3: OUTCOME MEASURE PARAMETERS AT PRE-TREATMENT (BASELINE) AND POST-TREATMENT (END OF 8\textsuperscript{TH} WEEK).

Table 3 shows the comparison of the mean score of all the outcome measures parameters at (pre-treatment) baseline and end of 8\textsuperscript{th} week (post-treatment) intervention among the groups.

Wilcoxon - test showed that there was significant difference between pre- and post-treatment intervention assessment for all the outcome measures parameters assessed within each of the groups except group 4 (control) (Table 3).
Table 3: Outcome measure parameters at pre- treatment (baseline) and post- treatment (End of 8th Week).

<table>
<thead>
<tr>
<th>OUTCOME MEASURE</th>
<th>PRE - Rx (BASELINE) X±SD</th>
<th>POST - Rx (End of 8th wk) X±SD</th>
<th>z- Value</th>
<th>p – value</th>
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<td>GRP 1</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>16.58±5.99</td>
<td>15.90± 6.78</td>
<td>4.79</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19.42± 14.48</td>
<td>3.19±4.8 1</td>
<td>6.60</td>
</tr>
<tr>
<td>GRP 2</td>
<td>FD</td>
<td>36.00±14.34</td>
<td>8.29±7.67</td>
<td>4.86</td>
</tr>
<tr>
<td></td>
<td>n=31</td>
<td>6.55 ± 1.46</td>
<td>1.48± 1.09</td>
<td>4.89</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15.90±6.78</td>
<td>4.39±4.39</td>
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<tr>
<td></td>
<td></td>
<td>18.81±10.35</td>
<td>2.42±3.47</td>
<td>4.79</td>
</tr>
<tr>
<td>GRP 3</td>
<td>FD</td>
<td>34.73±15.03</td>
<td>7.20± 5.79</td>
<td>4.79</td>
</tr>
<tr>
<td></td>
<td>n=30</td>
<td>6.53 ± 1.77</td>
<td>1.20± 0.99</td>
<td>4.83</td>
</tr>
<tr>
<td></td>
<td></td>
<td>16.63±5.44</td>
<td>3.47±3.93</td>
<td>4.79</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20.13±13.39</td>
<td>3.35±4.59</td>
<td>4.37</td>
</tr>
<tr>
<td>GRP 4</td>
<td>FD</td>
<td>29.20±10.43</td>
<td>7.20± 5.79</td>
<td>4.79</td>
</tr>
<tr>
<td></td>
<td>n=30</td>
<td>7.00± 1.66</td>
<td>8.53± 9.10</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td></td>
<td>16.50± 6.99</td>
<td>16.31±4.86</td>
<td>0.59</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15.13±12.32</td>
<td>14.99±10.12</td>
<td>0.02</td>
</tr>
</tbody>
</table>

* Significant difference at p< 0.05

KEY:
- GRP 1 = Group 1 = Stabilization exercise only,
- GRP 2 = Group 2 = Stabilization exercise with TENS,
- GRP 3 = Group 3 = Stabilization exercise with TENS and Massage.
- GRP 4 = Group 4 = Control
- FABP = Fear Avoidance Belief for Physical activity,
- FABW = Fear Avoidance Belief Work activity.
- FD = Functional disability
- Rx = Treatment
- z = Wilcoxon test
4.4: COMPARISON OF THE PRE-TREATMENT (BASELINE) AND POST- TREATMENT (END 8TH WEEK) ASSESSMENT OF LUMBAR MULTIFIDUS CSA (CM$^2$) ACROSS AND AMONG THE GROUPS.

Analysis of variance (ANOVA) showed that there was no significant difference in the pre-intervention assessment and there was significant difference in the post intervention assessment of cross-sectional area (CSA) at L4 and L5 across the four groups (Table 4).

Paired t-tests showed a significant difference in the CSA between pre-and post-intervention within groups 1, 2 and 3 while there was no significant difference in group 4 (control) at L4 and L5 vertebrae level (Table 4). Least significant difference (LSD) post hoc analysis shows that the significance lies between group 1& 4, groups 2 &4 and groups 3&4 post intervention assessment (Figure 26 and 27).

4.5: COMPARISON OF PRE-TREATMENT (BASELINE) AND POST- TREATMENT (END of 8TH WEEK) ASSESSMENT OF LUMBAR MULTIFIDUS MUSCLE THICKNESS ACROSS AND AMONG THE FOUR GROUPS

Analysis of variance (ANOVA) shows that there was significant difference in the lumbar multifidus muscle thickness at L4 - L5 vertebrae level post-intervention assessment across the four groups (Table 5).

Paired t-tests showed that there was a significant difference between pre- and post intervention assessment of lumbar multifidus muscle thickness in groups 1, 2 & 3 while there was no significant difference in group 4 (control) (Table 5). Least significant difference (LSD) post hoc analysis shows that the significance lies between group 1& 3, groups 1 &4 and groups 2&4 post intervention assessment (Figure 28)
Table 4: Comparison of the pre- treatment (baseline) and post- treatment (End 8th week) assessment of lumbar multifidus CSA (cm²) across and among the groups.

<table>
<thead>
<tr>
<th>CSA</th>
<th>GRP1 X ± SD</th>
<th>GRP2 X ± SD</th>
<th>GRP3 X±SD</th>
<th>GRP4 X±SD</th>
<th>F</th>
<th>p – value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRE- Rx</td>
<td>7.79± 2.69</td>
<td>8.84± 1.58</td>
<td>8.18± 2.39</td>
<td>8.21±0.91</td>
<td>1.42</td>
<td>0.24</td>
</tr>
<tr>
<td>POST- Rx</td>
<td>11.85± 1.99</td>
<td>11.76± 1.93</td>
<td>11.84±2.46</td>
<td>8.22±0.91</td>
<td>26.72</td>
<td>0.01*</td>
</tr>
<tr>
<td>T</td>
<td>9.46</td>
<td>9.24</td>
<td>10.12</td>
<td>0.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p – value</td>
<td>0.001*</td>
<td>0.001*</td>
<td>0.001*</td>
<td>0.97</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRE- Rx</td>
<td>7.73± 3.00</td>
<td>9.19± 1.63</td>
<td>8.43± 2.29</td>
<td>7.99±0.94</td>
<td>2.96</td>
<td>2.84</td>
</tr>
<tr>
<td>POST- Rx</td>
<td>12.10± 2.19</td>
<td>11.80± 1.69</td>
<td>11.90±2.09</td>
<td>7.94±0.66</td>
<td>36.29</td>
<td>0.01*</td>
</tr>
<tr>
<td>T</td>
<td>8.67</td>
<td>11.97</td>
<td>8.83</td>
<td>0.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p – value</td>
<td>0.001*</td>
<td>0.001*</td>
<td>0.001*</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant difference at P < 0.05

KEY:

X± SD - Mean ± Standard deviation
GRP1 - Group 1 – Stabilization exercise only
GRP2 - Group2 – Stabilization exercise with TENS only
GRP 3 - Group 3 – Stabilization exercise with TENS and Massage
GRP 4 - Group4 - Control
CSA - Cross-sectional area
L4 - 4th Lumbar vertebra level
L5 - 5th Lumbar vertebra level
PRE - Rx – Baseline treatment,
POST - Rx – End of 8th week treatment
t - Paired test
Table 5: Comparison between the pre- treatment (baseline) and post-treatment (End 8\textsuperscript{th} week) assessment of lumbar multifidus Thickness (cm) across and among the groups at the level of L4-L5 vertebral level.

<table>
<thead>
<tr>
<th>THICKNESS</th>
<th>GRP1 X ± SD</th>
<th>GRP2 X ± SD</th>
<th>GRP3 X ± SD</th>
<th>GRP4 X±SD</th>
<th>F</th>
<th>p – value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4-L5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRE-RX</td>
<td>2.69 ± 0.74</td>
<td>2.81 ± 0.51</td>
<td>2.66 ± 0.57</td>
<td>2.93±0.57</td>
<td>0.51</td>
<td>0.60</td>
</tr>
<tr>
<td>POST-RX</td>
<td>3.19 ± 0.69</td>
<td>3.28 ± 0.47</td>
<td>3.01 ± 0.51</td>
<td>2.97±0.54</td>
<td>5.57</td>
<td>0.18</td>
</tr>
<tr>
<td>t</td>
<td>2.63</td>
<td>2.92</td>
<td>2.52</td>
<td>0.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>p- value</td>
<td>0.01*</td>
<td>0.01*</td>
<td>0.01*</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Significant difference at P < 0.05

KEY:

X± SD - Mean ± Standard deviation

GRP1 - Group 1 – Stabilization exercise only

GRP2 - Group 2 – Stabilization exercise with TENS only

GRP 3 - Group 3 – Stabilization exercise with TENS and Massage

L4 - 4\textsuperscript{th} Lumbar vertebra level

L5 - 5\textsuperscript{th} Lumbar vertebra level

PRE - Rx – Baseline treatment,

POST - Rx – End of 8th week treatment
**Figure 26:** Schematic representation of Posthoc analysis of the pre-treatment (baseline) and post-treatment (End 8th week) assessment of lumbar multifidus CSA (cm$^2$) at L4.

**KEY:**

☆ Significant difference $p< 0.05$

1. Group 1 – Stabilization exercise only
2. Group 2 – Stabilization exercise with TENS only
3. Group 3 – Stabilization exercise with TENS and Massage
4. Group 4 - Control, L4- 4th lumbar vertebra,

PRE - Rx – Baseline treatment,

POST - Rx – End of 8th week treatment
Figure 27: Schematic representation of post hoc analysis of the pre-treatment (baseline) and post-treatment (End 8th week) assessment of lumbar multifidus CSA (cm²) at L5.

KEY:

☆ Significant difference p< 0.05

1. Group 1 – Stabilization exercise only
2. Group 2 – Stabilization exercise with TENS only
3. Group 3 – Stabilization exercise with TENS and Massage
4. Group 4 – Control, L5- 5th lumbar vertebra,

PRE-Rx – Baseline treatment,

POST – Rx – End of 8th week treatment
Figure 28: Schematic representation of post hoc analysis of the pre-treatment (baseline) and post-treatment (End 8th week) assessment of lumbar multifidus muscle thickness (cm) at L4-L5.

KEY:

☆ Significant difference p< 0.05

1. Group 1 – Stabilization exercise only
2. Group 2 – Stabilization exercise with TENS only
3. Group 3 – Stabilization exercise with TENS and Massage
4. Group 4 - Control
   L4-  -  4th Lumbar vertebra level
   L5  -  5th Lumbar vertebra level
   PRE - Rx - Baseline treatment,
   POST - Rx – End of 8th week treatment
CHAPTER FIVE

DISCUSSION, CONCLUSION AND RECOMMENDATION

5.1 Discussion

The result of the present study has demonstrated that the use of stabilization exercise in the treatment of patients with non-specific chronic low back pain, reduce pain intensity, functional disability, fear avoidance belief and improves lumbar multifidus CSA as well as muscle thickness.

Participants in the four groups were similar in age and physical characteristics, and there were no significant difference in the physical characteristic in the four groups, this suggests that all the groups were comparable. This results conforms to the study of Hides et al. (2008) who in their study on the effect of stabilization training on multifidus muscle cross-sectional area among young elite cricketers with low back pain reported that there was no significant different in the age and physical characteristics of the groups that were studied.

There was a marked improvements in clinical outcomes (pain intensity, functional disability, fear avoidance belief) in three of the study groups that is, stabilization exercise only (Group1), stabilization exercise with TENS (Group 2) and stabilization exercise combined with TENS and massage (Group 3). This finding shows that most physiotherapy modalities commonly used for CLBP are efficacious particularly when used in combination (Furlan et al., 2008).

The findings that there was significant difference in groups 1, 2 and 3 buttress the use of combination therapy in the management of patients with CLBP. However this study shows that stabilization exercise alone is effective in the management of patients with CLBP. This was supported by the findings of Kofotolis et al. (2008), who in their study on the effect of rhythmic stabilization exercises and transcutaneous electrical nerve stimulation (TENS) and
their combination in treating women with chronic low back pain, concluded that stabilization exercise group displayed statistically significant improvement compared to the other groups. Other studies (Ferriera et al., 2006; Hides et al., 2008; Macedo et al., 2009; Kumar et al., 2009) compared stabilization exercise with general exercise and discovered that there was statistically significant improvement in the stabilization exercise group compared to the other groups.

The improvement in the parameters measured, that is, pain, fear and functional ability level could be as a result of the reestablishment of the normal control of the deep spinal muscles (DSM), which reduced the activity of more superficial muscles (rectus abdominis, external oblique, internal oblique) which when recruited stiffens the spine and increase activity in the low back muscles. This will result into decrease in pain, fear and disability level. More so that co-contraction of the local muscles (DSM) such as TrA and LM has been reported to be effective in the stabilization of the motion segments of the lumbar spine particularly within the neural zone, thus providing a stable base on which the global muscles (superficial muscles) can safely act (Wilke et al., 1995). However, Koumantakis et al. (2005) compared stabilization exercise with general exercise and reported that stabilization exercise do not provide additional benefit to patients with subacute and chronic low back pain. One possible reason for the difference in the result of Koumantakis et al. (2005) and the present study may be due to the fact that they did not take into consideration chronic low back pain patients with clinical signs of spinal instability.

The findings that there was an improvement in functional ability of patients in the groups that performs stabilization exercise alone and stabilization exercise combined with TENS and massage post intervention was corroborated by previous studies (Van Dieen et al., 2003; Ferriera et al., 2007; Rasmusen et al., 2009; Shokunbi et al., 2010; Gatti et al., 2011). These
studies reported that stabilization exercise is effective in enhancing functional ability in patients with NCLBP. This must have led to the improvement of the stability of the spine as stabilization exercise has a critical role for the control of intervertebral motion, but with potential advantage of allowing dynamic control of the spine (Richardson et al., 1999).

The present study revealed that the stabilization exercise only, stabilization exercise combined with TENS and stabilization exercise combined with TENS and massage had a significant effect in the improvement of FAB of patients in groups 1, 2 and 3. This assertion was supported by the result of the study of Fritz et al. (2001) which reported that fear avoidance belief of work activity were significant predictor of four weeks disability and work status, even after controlling initial level of pain and disability. The study by Waddell et al. (1993) confirms the importance of fear avoidance belief (FAB) assessment and demonstrated that specific fear avoidance belief of work activity are strongly related to work loss due to low back pain. This assertion was corroborated by the present study in all the groups.

The results also showed that all the participants in this study presented with atrophy of LM muscle pre-intervention, implying that individuals with NCLBP have associated atrophy of lumbar multifidus muscle. This may be due to the disuse atrophy resulting from inactivity of the back muscles. This finding supports previous studies (Hauggaard and Persson. 2007, Standaert et al., 2008, Hides et al., 2008, Wallwork et al., 2009) who reported that atrophy of the lumbar multifidus muscle has been attributed to low back pain and instability.

All subjects who reported pain reduction and improvement of functional disability (i.e. groups 1, 2, 3) in this study also had a corresponding improvement in CSA of the LM muscles post-treatment because enhanced stability of the lumbar spine segment is the mechanism for pain relief. This establishes association between CSA and pain with functional disability. This
finding agrees with the finding of Hides et al. (2008) who in their study on the effect of stabilization training on multifidus muscle cross-sectional area among young elite cricketers with low back pain reported that, increase in CSA of lumbar multifidus muscle automatically lead to pain reduction and improvement of functional ability in patients with low back pain.

This study also revealed that LM muscle thickness measured in the pre-intervention assessment increased significantly at 8th week post-intervention assessment across three of the groups except group 4 i.e. the control group at L4-5 vertebral level. This finding implies that increased contracted LM muscle was associated with greater improvement in CLBP patients with pain and functional disability. This is in agreement with the finding of previous studies; it agrees with the findings of Van et al. (2006); Kiesel et al. (2007) and Akbari et al. (2008) who reported that stabilization exercise decreased pain and increased LM muscle thickness in patients with chronic low back pain.

It has been reported that muscle thickness changes when the muscle is activated (Hodges et al., 2003). Muscle contraction is seen on the ultrasound image as an increase in thickness of the muscle as it shortens along its length. The amount of thickness change that occurs with muscle activation has been quantified using ultrasound imaging; by comparing resting muscle thickness values to those obtained during muscle activation. The present study showed that there was an improvement in the LM muscle thickness in three of the groups (1, 2, 3) after intervention. This increase in contracted LM muscle thickness was predictive of improved functional ability and hence promotes clinical improvement in patients with NCLBP.

The mean value (3.19) of LM muscle thickness of patients with NCLBP at L4-5 vertebral level post-intervention in this study corresponds with the mean value (3.20) in the study by Wallwork et al., (2007) who assessed thickness of LM muscle of healthy participants without a
history of low back pain. This implies that increased contracted LM muscle was associated with greater improvement in CLBP patients with related pain and functional disability. This is consistent with theories and evidence supporting the importance of the LM muscle to normal back function (Hides et al., 2001; Macdonald et al., 2006; Hides et al., 2008).

It has been reported that patients with LBP are less able to contract the LM muscle (Kiesel et al., 2008). Results from the present study suggest that changes in the contracted muscle thickness may be relevant clinically, since it has been shown that muscle contraction of LM seen on ultrasound image represents an increase in thickness of the LM muscle. However, it is very likely that the change in LM muscle thickness was due to greater activity of the muscle.
## 5.2 Summary of findings

<table>
<thead>
<tr>
<th>Specific Objectives</th>
<th>Summary of findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Determine the effect of stabilization exercise on pain severity and functional disability in patients with NCLBP.</td>
<td>Stabilization exercise only, decreased pain severity, enhanced functional ability and fear avoidance belief of patients with NCLBP.</td>
</tr>
<tr>
<td>2. Determine the effect of stabilization exercise on the changes in cross sectional area (CSA) of lumbar multifidus muscle in patients with NCLBP.</td>
<td>Stabilization exercise increased the CSA of LM muscle, this can be used as an index for the assessment of improvement level of patients with NCLBP.</td>
</tr>
<tr>
<td>3. Determine the effect of stabilization exercise on muscle thickness changes of lumbar multifidus muscle in patients with NCLBP.</td>
<td>Stabilization exercise increased LM muscle thickness, improved performance of isometric LM muscle contraction, functional ability and decreased the severity of pain in patients with NCLBP.</td>
</tr>
</tbody>
</table>

## 5.3 Conclusions

Stabilization exercise when used only, and also when combined with TENS and massage were all effective in relieving symptoms of pain, enhancing functional ability and fear avoidance belief in the patients with non-specific chronic low back pain (NCLBP). This study established that stabilization exercise only can be used successfully in the treatment of pain, functional disability and fear avoidance belief of patients with NCLBP.
Increase in CSA and thickness of LM muscle were results of hypertrophy secondary to exercise training. Treatment efficacy shows decrease in the complaints of the patients. It can be inferred that measurement of CSA and thickness of lumbar multifidus muscle can be used as an index for the assessment of improvement level of patients with non-specific chronic low back pain after treatment intervention. Also measurement of the thickness of LM muscle is clinically important and can be used as an index in the assessment of performance of isometric lumbar multifidus muscle contraction in patients with non-specific chronic low back pain.

5.4 **Recommendations**

Based on the findings of this study, the following recommendations were made:

1. Physiotherapist can use stabilization exercise in the management of NCLBP, since this study showed that stabilization exercise only is effective in the treatment of pain, disability and fear avoidance belief of patient with non-specific chronic low back pain.

2. Health workers involved in the management of LBP should include evaluation of CSA and thickness of lumbar multifidus muscle as an important aspect of their assessment of patients with NCLBP.

5.5 **Contributions to knowledge**

1. This study established that stabilization exercise only is effective in the reduction of pain intensity, functional disability and fear avoidance belief in patients with NCLBP.

2. This study established that stabilization exercise only increases thickness of LM muscle and improves performance of isometric LM muscle contraction. Therefore
measurement of LM can be used as an index for assessing improvement level of patients with NCLBP.

3. This study established that stabilization exercise increases the CSA of LM muscle and this can be used as an index for the assessment of improvement level of patients with NCLBP.
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APPENDIX I

INFORMED CONSENT

TITLE OF STUDY: The effect of stabilization exercise on pain cross-sectional area and muscle thickness of lumbar multifidus muscle in patients with chronic low back pain.

INVESTIGATOR(S): AKODU Ashiyat K (Mrs)

CONTACT PHONE NUMBER: 08034269053

Purpose of the study
You are invited to participate in a research study. The purpose of this study is to shed more light on the benefit of stabilization exercise on patients with Non-specific chronic low back pain.

Participants
You can participate in the study if you are a patient with nonspecific chronic low back pain with or without pain radiating to one or both lower limbs. If you are between the ages of 25-65 years with no medical or surgical conditions which might hinder exercise performance.

Procedures:
If you volunteer to participate in this study, you will be asked to do some exercise to your back.

Benefits of Participation
There may/may not be direct benefit to you as a participant in this study. However we hope to learn more on how stabilization exercise help to relief pain and disability level of people with chronic low back pain.

Risks of participation
Your safety is guaranteed during participation in this study as it carries minimal risk. However, you may become tired after undergoing the exercise. Your back muscle will also be scanned with a portable ultrasound machine. All these procedures and feeling are normal, not life threatening and should not cause harm or negative after effect to your health.
**Cost / Compensation**

There will not be financial cost to you to participate in this study. The study will take 30 – 45 minutes per session, two times in a week between 10a.m to 2p.m from Monday to Friday. It will last for duration of 8 weeks.

**Contact Information**

If you have any questions or concerns about the study, you may contact the above named investigator on the stated phone number. For questions regarding the rights of research subject any complaints or comments regarding the manner in which the study is being conducted, you may contact department of Physiotherapy, College of Medicine of the University of Lagos, Idi-Araba, Lagos.

**Voluntary participation**

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with the hospital. You are encouraged to ask questions about this study at the beginning or any time during the research study.

**Confidentiality**

All information gathered in this study will be kept completely confidential. No reference will be made in written or oral materials that could link you to this study. All records will be stored in a locked facility at University of Lagos and the teaching hospitals from which you are recruited.

**Participant Consent.**

I have read the above information and agree to participate in this study. I am at least 25 years of age. A copy of this form has been given to me.

-----------------------------------  --------------------------
Signature of participant             Date

-----------------------------------
Participant Name
# APPENDIX II

## MODIFIED OSWESTRY LOW BACK PAIN DISABILITY QUESTIONNAIRES

### Section 1: To be completed by patient.

<table>
<thead>
<tr>
<th>Name: ___________________________</th>
<th>Age: _______</th>
<th>Date: __________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occupation: _____________________</td>
<td>Number of days of back pain_________ (this episode)</td>
<td></td>
</tr>
</tbody>
</table>

### Section 2: To be completed by patient.

This questionnaire has been designed to give your therapist information as to how your back pain has affected your ability to manage in everyday life. Please answer every question by placing a mark on the line that best describes your condition today. We realize you may feel that two of the statements may describe your condition, but please mark only the line which most closely describes your current condition.

**Pain Intensity**

- __________ The pain is mild and comes and goes.
- __________ The pain is moderate and comes and goes.
- __________ The pain is moderate and does not vary much.
- __________ The pain is severe and comes and goes.
- __________ The pain is severe and does not vary much.

**Personal Care (Washing, Dressing, etc.)**

- __________ I do not have to change the way I wash and dress myself to avoid pain.
- __________ I do not normally change the way I wash or dress myself even though it causes some pain.
- __________ Washing and dressing increase my pain, but I can do it without changing my way of doing it.
- __________ Washing and dressing increase my pain, and I find it necessary to change the way I do it.
- __________ Because of my pain I am partially unable to wash and dress without help.
- __________ Because of my pain I am completely unable to wash or dress without help.

**Lifting**

- __________ I can lift heavy weights without increased pain.
- __________ I can lift heavy weights but it causes increased pain.
- __________ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned (i.e. on a table, etc).
- __________ Pain prevents me from lifting heavy weights off the floor, but I can manage light to medium weights if they are conveniently positioned.
- __________ I can lift only very light weights.
- __________ I cannot lift or carry anything at all.

**Walking**

- __________ I have no pain when walking.
- __________ I have pain when walking, but I can still walk my required normal distances.
- __________ Pain prevents me from walking long distances.
- __________ Pain prevents me from walking intermediate distances.
Section 2 (cont’d): To be completed by patient

Standing

__________ I can stand as long as I want without increased pain.

__________ I can stand as long as I want but my pain increases with time.

__________ Pain prevents me from standing for more than 1 hour.

__________ Pain prevents me from standing for more than ½ hour.

__________ Pain prevents me from standing for more than 10 minutes.

__________ I avoid standing because it increases my pain right away.

Sleeping

__________ I get no pain when I am in bed.

__________ I get pain in the bed, but it does not prevent me from sleeping well.

__________ Because of my pain, my sleep is only ¾ of my normal amount.

__________ Because of my pain, my sleep is only ½ of my normal amount.

__________ Because of my pain, my sleep is only ¼ of my normal amount.

__________ Pain prevents me from sleeping at all.

Social Life

__________ My social life is normal and does not increase my pain.

__________ My social life is normal but it increases my level of pain.

__________ Pain prevents me from participating in more energetic activities i.e. sports, dancing, etc.

__________ Pain prevents me from going out very often.
Pain has restricted my social life to my home.
I have hardly any social life because of my pain.

**Traveling**

- I get no increased pain when travelling.
- I get some pain while travelling, but none of my usual forms of travel make it any worse.
- I get increased pain while travelling, but it does not cause me to seek alternative forms of travel.
- I get increased pain while travelling which causes me to seek alternative forms of travel.
- My pain restricts all forms of travel except that which is done while I am lying down.
- My pain restricts all forms of travel.

**Employment/Homemaking**

- My normal job/homemaking activities do not cause pain
- My normal job/homemaking duties increase my pain, but I can still perform all that is required of me.
- I can perform most of my job/homemaking duties, but pain prevents me from performing more.
- Physically stressful activities. (i.e. Lifting, vacuuming, etc.).
- Pain prevents me from doing anything but light duties.
- Pain prevents me from doing even light duties.
- Pain prevents me from performing any job or homemaking chores.

---

**Section 3: To be completed by physical therapist/provide**

**SCORE:**

<table>
<thead>
<tr>
<th>Initial</th>
<th>Subsequent</th>
<th>Subsequent</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date: ____________ Date: ____________ Date: ____________

Number of treatment sessions: ____________________________

Diagnosis /ICD -9 Code: ____________________________

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# APPENDIX III

## FEAR AVOIDANCE BELIEF QUESTIONNAIRE

Name: ________________________________  Date __________________

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 saying how much physical activities such as bending, lifting, walking or driving affect or would affect your back pain:

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Completely Discharge</th>
<th>Unsure</th>
<th>Completely Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>My pain was caused by physical activity</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Physical activity makes my pain worse</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>I should not do physical activities which (might) make my pain worse</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>I should not do physical activities which (might) make my pain worse</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>I cannot do physical activities which (might) make my pain worse</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The following statements are about how your normal work affects or would affect your back pain:

<table>
<thead>
<tr>
<th>Number</th>
<th>Statement</th>
<th>Completely Discharge</th>
<th>Unsure</th>
<th>Completely Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>My pain was caused by my work or by an accident at work</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>My work aggravated my pain</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>I have a claim for compensation for my pain</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>My work is too heavy for me</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>My work makes or would make my pain worse</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>My work might harm my back</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>I should not do my normal work with my present pain</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I cannot do my work with my present pain</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I cannot do my normal work until my pain is treated</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>I do not think that I will be back to my normal work within 3 months</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>I do not think that will ever be able to go back to that work</td>
<td>0 1 2 3 4 5 6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# APPENDIX IV

MODIFIED VISUAL ANALOGUE SCALE

<table>
<thead>
<tr>
<th>Numerical Index</th>
<th>Pain Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No pain</td>
</tr>
<tr>
<td>1</td>
<td>Slight</td>
</tr>
<tr>
<td>3</td>
<td>Very mild</td>
</tr>
<tr>
<td>4</td>
<td>Mild</td>
</tr>
<tr>
<td>5</td>
<td>Very moderate</td>
</tr>
<tr>
<td>6</td>
<td>Moderate</td>
</tr>
<tr>
<td>7</td>
<td>Severe pain</td>
</tr>
<tr>
<td>8</td>
<td>Very severe</td>
</tr>
<tr>
<td>9</td>
<td>Horrible pain</td>
</tr>
<tr>
<td>10</td>
<td>Worst / Extreme pain</td>
</tr>
</tbody>
</table>
APPENDIX V

LAGOS UNIVERSITY TEACHING HOSPITAL
PRIVATE MAIL BAG 12003, LAGOS, NIGERIA

Chairman:
DR. OMOTAYO DAIBO, MBBS (Radbam).

Registrar of Administration:
AYO OLAGUNYI O.J. (Lagos), MPA (Lagos),
MINIM, ABAN, ANIPR

Chief Medical Director:
PROF. AKIN OSIBOGUN
MBBS (Lagos), PIPH (Columbia) FMCPH, FWACP

Chairman, Medical Advisor Committee:
DR. M. O. OGINLEYE, BDS, FWACS.

Health Research and Ethics Committee

REG. NO. HREC 19/12/2008a

15th August, 2011

NOTICE OF EXPEDITED REVIEW AND APPROVAL

PROJECT TITLE: “THE EFFECT OF STABILISATION EXERCISE AND TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION ON CHRONIC LOW BACK PAIN AND LUMBAR MULTIFIDUS MUSCLE”.

HEALTH RESEARCH COMMITTEE ASSIGNED NO.: ADM/DCST/HRREC/146

NAME OF PRINCIPAL INVESTIGATOR: AKODU ASHYAT KEHINDE

ADDRESS OF PRINCIPAL INVESTIGATOR: DEPT. OF PHYSIOTHERAPY, CMUL.

DATE OF RECEIPT OF VALID APPLICATION: 01-03-11

DATE OF MEETING WHEN FINAL DETERMINATION OF RESEARCH WAS MADE: 03-08-11

This is to inform you that the research described in the submitted protocol, the consent forms, and all other related materials where relevant have been reviewed and given full approval by the Lagos University Teaching Hospital Health Research Ethics Committee (LUTH-HREC).

This approval dates from 03-08-2011 to 03-08-2012. If there is delay in starting the research, please inform the HREC so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of this dates. All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study. In multiyear research, endeavor to submit your annual report to the HREC early in order to obtain renewal of your approval and avoid disruption of your research.

The National code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the code. The HREC reserves the right to conduct compliance visits to your research site without previous notification.

DR. N. U. OKUBADEJO
CHAIRMAN, LUTH HEALTH RESEARCH AND ETHICS COMMITTEE