A randomised placebo controlled trial of the management of non-specific low back pain using the Nubax® vertebral distraction device.

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DEDICATION

For Chloe and Joshua - my children. The ones in my life who keep me grounded.
INTRODUCTION

Non-specific chronic low back pain (NSCLBP) has been widely documented as a major health problem in industrialised countries with extensive economic and personal costs. Numerous studies have been completed documenting the loss of quality of life due to this problem.

One of the methods used extensively in previous decades to treat NSCLBP is lumbar traction. A comprehensive study of the efficacy of a home based lumbar traction unit has not been fully investigated in the ongoing management of chronic low back pain (CLBP).

AIM

The aim of the study was to apply a fixed protocol of use for the Nubax®, a home lumbar traction unit, to subjects suffering from CLBP, and demonstrate the effect on their pain, stiffness and physical function (quality of life) compared to that of control subjects who underwent the same protocol of use and adjunct physiotherapy treatment (massage and exercises) but with a sham unit (providing no traction).

METHOD

Ethical approval was obtained to undertake a randomised controlled study of up to 55 subjects suffering from NSCLBP. Quality of life was assessed using two questionnaire assessments (a modified Western Ontario and McMaster Universities Osteoarthritis Index and the Roland Morris Disability Questionnaire) on all patients on three occasions, at baseline (pre-start), 3 weeks and 6 weeks (finish) during the study. Activity levels were measured using Actigraph activity monitors at the same intervals as the questionnaires.
Subjects were randomised into either the treatment to sham unit group (A), full treatment group (B), or the sham to treatment group (C) and were all assessed prior to commencing in the study. This included routine lumbar x-rays and a standard orthopaedic physiotherapy assessment. Subjects were reviewed once per week to assess range of lumbar motion, ensure compliance, review the three home exercises and provide a standard soft tissue lumbar massage for 10 minutes. Group A (treatment to placebo) changed from using the treatment Nubax® to the sham unit after 3 weeks, group B (full treatment) remained using the treatment Nubax® for the full 6 weeks, and group C (placebo to treatment) commenced with the sham unit and crossed over to the treatment Nubax® after 3 weeks.

RESULTS AND CONCLUSIONS

It was hypothesised that controlled use of the Nubax® over a 3 week period would enable individuals with daily CLBP to reduce their level of pain and stiffness and improve their functional ability. Controlled use of the sham unit was expected to produce poorer outcomes compared to the treatment Nubax® system.

The Roland Morris Disability Questionnaire (RDQ) and a modified version (to fit subjects with CLBP) of the Western Ontario McMaster’s Index (WOMAC) were used to determine the efficacy of the Nubax® in conjunction with basic physiotherapy treatment (three core stability exercises and lumbar soft tissue massage) on quality of life. The RDQ did not show statistical or clinically significant changes. There was a statistically significant improvement in the total score for the modified WOMAC questionnaires as well as for the physical function domain for those subjects utilising the treatment Nubax® compared to the sham unit, enabling a cautious acceptance of this hypothesis.
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CHAPTER ONE
THE PROBLEM

INTRODUCTION

Chronic low back pain (CLBP) has been widely documented as a major health problem in industrialised countries, proving to be an economic burden with direct and indirect costs reaching billions of dollars (Waddell, McIntosh, Hutchinson, Feder, & Lewis, 1999; Ostelo, Stomp-van den Berg, Vlaeyen, Wolters, & de Vet, 2003; Walker, Muller, & Grant, 2003). The personal and social costs to individuals who suffer from CLBP are difficult to measure. There have been studies, (Walker et al., 2003; Kovacs et al., 2004) documenting loss of function and quality of life and their repercussions for health policy planning and research.

Research into ways of diagnosing and managing acute back pain has provided evidence-based guidelines for safe and effective management, thereby potentially increasing full recovery or reducing recurrences (Bogduk, 2004). Managing CLBP using a variety of treatment modalities and other interventions has also been widely researched with inconsistent outcomes thus limiting evidence-based guidelines for effectively managing this condition (Werners, Pynsent, & Bulstrode, 1999; Malunga, & Nadler, 1999; Quittan, 2002; Bogduk, 2004).

There has been a significant amount of research (Beurskens, de Vet, Koke, Lindeman, Regtop, van der Heijden, & Knipschild, 1995b; Krause, Refshauge, Dessen, & Boland, 2000; Lee & Evans, 2001; Borman, Keskin, & Bodur, 2003; Harte, Baxter, & Gracey, 2003) on standard lumbar traction treatment including manual, motorised, auto-traction and gravitational traction devices, which have not utilised a standard protocol regarding the magnitude, duration or frequency of treatment.

Manual traction involves a therapist providing a traction force via the lower limbs putting the low back at varying degrees of flexion to cause distraction of the lumbar vertebrae. Motorised traction involves a machine with the traction force causing distraction of the
lumbar spine from the upper body using a pelvic and thoracic stabilising girdle. Auto-
traction involves a set external weight pulling from a pelvic brace or lower limb splinting
system to create lumbar distraction. Gravitational traction involves the upper or lower
half of the body being stabilised whilst gravity distracts the other half of the body away
from the stabilised section. Using this system, heavier people experience greater traction
forces.

The Nubax® is a personal home traction unit that the manufacturer claims will assist in
the management of CLBP. The Nubax® utilises a combination of auto-traction and
gravitational traction in that the user employs their body weight to gently pull the trunk
away from the fixed pelvic girdle. According to the manufacturer’s specifications
controlled traction is to be carried out twice daily for 3 minutes in the neutral lumbar
position. That is, the position of the lower back is neither in extension or flexion, and
there are no excessive forces compressing either the discs or the facet joints.

Chronic low back pain is a major problem worldwide, with patients often requiring
lengthy rehabilitation periods following an acute exacerbation or requiring ongoing
intervention from health professionals and pharmaceutical management in order to
manage their work and maintain their quality of life (Borman et al., 2003; Ostelo et al.,
2003; Walker et al., 2003).

Traction, as a form of self-management carried out independently on a regular basis for
individuals to maximise their speed of recovery and quality of life, requires further
research. The optimal traction load, duration and frequency for people of varying age,
size and underlying low back pathology requires further research to provide safe and
effective treatment guidelines.

The underlying pathology of CLBP that responds readily and consistently with traction as
a treatment modality also requires research. Chronic low back pain varies widely in its
pathological origins as well as in effective management on an individual basis. Research
on the effectiveness of traction as a form of treatment is needed, and studies regarding
optimum duration and frequency of its use are also required to provide some evidence-based guidelines for effectively managing this condition.

STATEMENT OF THE PROBLEM

There is no evidence-based research into the efficacy of the Nubax® in managing CLBP, nor data to confirm the specific pathological conditions for which it is indicated and effective. The aim of this research was to evaluate the efficacy of a daily traction regime using the Nubax® in combination with conservative physiotherapy treatment for managing CLBP. The effectiveness was studied over a period of time (3 to 6 weeks) by evaluating quality of life including subjective levels of pain, stiffness and physical function.

SIGNIFICANCE OF THE STUDY

Spinal traction has been out of vogue as a treatment modality for both acute and chronic low back pain for some time, however recently there has been re-interest in its potential as a way of managing CLBP (Harrison, Caailliet, Harrison, Janik, & Holland, 2002; Harte et al., 2003). Previous research has been equivocal with a lack of consistency and standardisation in research protocols (Beurskens et al., 1995b; Krause et al., 2000; Harte et al., 2003). The impetus for this research resulted from the increased interest in the use of personal traction devices as a treatment modality, and a need to evaluate the Nubax® manufacturer's efficacy claims.

The manufacturers of the Nubax® have promoted their product world-wide for use in the management of both acute and CLBP, however, no research has been completed on the protocol for its use or the efficacy of the unit for the management of CLBP. This study will determine whether the traction therapy afforded by this personal home traction device (combined with conservative physiotherapy treatment) is effective in managing CLBP and improving quality of life, by reducing pain and stiffness and increasing physical function.
Following the completion of this research it is anticipated there will be available, evidence-based data supporting a treatment protocol, and treatment outcomes focusing on quality of life and functional ability. Once an effective protocol for using the Nubax® has been established and the patient pathologies identified that may benefit, some clear evidence-based guidelines might then be available for individuals to manage their own low back pain for long periods with minimal intervention from health practitioners. Furthermore, long-term use of pain medication and anti-inflammatories may be reduced, and people may be able to maintain and improve their quality of life despite the existence of their underlying back conditions.

HYPOTHESIS

It is hypothesised that controlled use of the Nubax® personal traction device in combination with (conservative) physiotherapy treatment over a 3 week period will enable individuals with CLBP to reduce their level of pain and stiffness, while improving their quality of life and functional ability. Controlled use of the sham unit will produce poorer outcomes than the treatment Nubax® system.

LIMITATIONS

1/. The treating Physiotherapist was aware of which subjects were participating in the treatment or control group from the outset, thus potentially affecting the treatment provided. The investigator was responsible for the supervision of the exercise programs and low back massage. Potential experimenter bias has not been eliminated.

2/. Subjects with long-term pain spanning several years may not show improvements within the time period in which the study was conducted (3-6 weeks of treatment). A follow up review 6 months later could be completed to review whether those that continued using the Nubax® eventually improved or continued to improve, but this is beyond the scope of the study.

3/. Some subjects may show improvements with the conservative physiotherapy treatment alone. That is, the passage of time and the physiotherapy treatment may
provide subject improvements regardless of Nubax® use. Full recovery of the flare up may have occurred by the time the control/crossover group (C) participants underwent the treatment protocol.

4/. The subjects all had chronic pain far at least 3 months since the original onset. Those subjects with long term pain of extensive duration may developed have the mind-set that no treatment can assist them with recovery or pain management, inordinately affecting the outcome measures which were self-reported.

5/. The outcome measures were assessed using self-reporting instruments consisting of the Roland-Morris Disability Questionnaire, a Modified WOMAC questionnaire and completion of Nubax® home use diaries. This provided the inherent limitation that the subject responses are deemed truthful.

6/. All subjects wore activity monitors for three periods of 3 days duration over the 6 week study. This included one weekend day and two week days. It may be that their activity varied significantly from day to day. During the activity monitor phase, subjects’ activity levels may not be representative of their normal routine. The subjects may have modified their activity levels and intensity simply because they were aware the levels were being measured for the 3 day period they were wearing the monitors.
DEFINITION OF TERMS

Chronic Low Back Pain

Chronic low back pain (CLBP) has been defined in a number of ways by researchers. According to Bogduk, for example, CLBP is present in a patient if their back pain has persisted for longer than 3 months (Bogduk, 2004). Other researchers have suggested that CLBP is present in patients if their current pain has either existed for more than 6 weeks, or they have a history of recurrent disabling back pain causing an absence from work or significant modifications in activities of daily living (Harrison et al., 2002).

For inclusion into this study, CLBP was defined as back pain of at least 3 months duration from the initial onset (Bogduk, 2004). This pain must have been suffered daily, or with at least two recurrences over the course of a year significant enough to warrant lost time at work, or to reduce the individual’s ability to carry out normal activities of daily living. It was not determined whether subjects with significant recurrences had daily low grade CLBP enabling them to maintain work levels and activities of daily living between recurrences, or were completely pain free. The subjects must be currently suffering a significant exacerbation of their CLBP.

Lumbar Traction

Lumbar traction is vertebral axial decompression of the lumbar spine. This can be provided by a variety of equipment using manual, motorised or gravitational traction to cause distraction of the lumbar vertebral bodies, stretching of the ligaments and paravertebral muscles, widening of the intervertebral foramina and separation of the apophyseal joint facets.
Activities of Daily Living

These are the normal daily activity requirements an individual has to carry out such as getting dressed, regular housework (cooking and cleaning), showering and toileting and other light domestic activities (walking and going up/down steps).

METS

The energy cost of an activity can be measured in a unit called METS, which are multiples of one’s basal metabolic rate. The basal metabolic rate is the energy required for essential physiological functioning after 8 hours of sleep and 12 hours of fasting (i.e., the number of calories required to keep your body functioning while at rest). One MET is equal to energy expenditure while at rest, or 3.5 millilitres of oxygen used per minute, per kilogram of body weight.

Nubax®

This is a home traction unit, which is a fully portable, user-operated device for administering clinically correct traction to the back and spinal column. It is suitable for adults weighing 40 kg to 140 kg and is able to produce tension-forces from 200 N to 500 N dependent on body mass and setting. Tension forces of approximately 300 N were developed for vertical loads of 40 kg or more (Ackland, 2004).

The unit is designed to be used independently, enabling the individual to control their traction duration and frequency. It employs a patient’s own body weight to generate a controlled traction force on the spine whilst the user is in a horizontal, prone lying position. A pelvic belt supports the waist and the patient’s body weight gradually takes the upper body into the traction position via padded pillars under the axillae (see Figure 1). Figure 2 shows the fixation points of the Nubax®.
Figure 1. Patient set-up and operation of the Nubax®.

Ergonomically correct, square shoulder, friction-free traction... that you can fold up and take away.

Figure 2. Fixation and pivot points of the Nubax®.
CHAPTER TWO
LITERATURE REVIEW

INTRODUCTION TO LOW BACK PAIN

Low back pain (LBP) is regarded as one of the most common complaints amongst the general adult population from work-related and sports-related injuries, to general degeneration with age and arthritis (Malanga & Nadler, 1999; Quittan, 2002; Harte et al., 2003). Approximately 80% of the population suffers from back pain at some stage in their lives with the majority of these episodes resolving spontaneously within 2-4 weeks. However, 60-80% will suffer a recurrence within one year (Hides, Richardson, & Jull, 1996).

For a large number of people, LBP is an ongoing problem over a long period of time with significant ramifications both personally and professionally. For the purposes of this study, LBP is defined as a symptom relating to the lumbar spine and lumbo-sacral region; there is no provision for subsets of differential diagnoses (Walker et al., 2003). The low back region is defined as the region between the last ribs and the gluteal folds (Walker et al., 2003).

Research shows that CLBP is one of the most debilitating conditions as far as quality of life, functional ability and activity levels are concerned (Borman et al., 2003). It is also expensive to treat and often requires ongoing or long-term medication and/or treatment from various health professionals along with significant social supports (Waddell, 1999; Ostelo et al., 2003; Walker et al., 2003). There are large economic and social costs involved with managing LBP especially in the workforce where back injuries (both acute and chronic) lead to substantial amounts of lost time and other indirect costs.

Walker et al. (2003) reported on the economic burden of LBP in Australian adults. The direct cost in 2001 was estimated to be A$1.02 billion with indirect costs estimated at A$8.15 billion. These direct costs of LBP are predominantly diagnostic and treatment-
related (chiropractors, physiotherapists, massage therapists, general practitioners and acupuncturists) with indirect costs predominantly being the cost to industry with lost time in the workforce (Walker et al., 2003). The costs of LBP have been studied in other countries revealing the extent of LBP as a major health problem and economic burden prompting further research into managing and reducing these costs.

Given the enormity of LBP and its repercussions socially and to industry, a number of studies have led to improved diagnosis and treatment in the acute stages so as to prevent it becoming a chronic problem (Malanga & Nadler, 1999; Koes, Tulder, Ostelo et al., 2001; McGuirk, King, Govind et al., 2001; Quittan, 2002). There are evidence-based guidelines indicating how acute LBP should be managed. Bogduk (2004) suggested that if these guidelines are followed, over 70% of patients would recover and be pain free, with a recurrence rate of less than 25%.

Further studies have focused on improved management of CLBP (Wheeler, 1995; Werners et al., 1999; Quittan, 2002) facilitating improvements in functional ability, quality of life and return to work numbers. CLBP traditionally causes a loss of functional ability, quality of life and psychological distress (Bogduk, 2004) and there appears to be little consensus regarding a safe and effective treatment (Beurskens et al., 1995b; Beurskens, De Vet, & Wheeler, 1995a; Malunga & Nadler, 1999; Quittan, 2002; Borman et al., 2003; Harte et al., 2003).

PATHOLOGY / ETIOLOGY OF LBP

Disorders of the zygapophyseal joints, the intervertebral discs and the sacroiliac joint are the most common causes of LBP (McKenzie, 1994; Bogduk, 2004). These can often be seen as structural pathology utilising imaging procedures. McKenzie (1994) also identified three categories of non-specific low back pain: a) postural syndrome, b) dysfunction syndrome, and c) derangement syndrome. In these cases the cause could not be identified by radiological information. Increased axial loading on the spine, such as during lifting, bending forward and prolonged sitting, reduces intervertebral separation and increases intradiscal pressure thus
facilitating mechanical LBP. If prolonged, this can lead to disc degeneration, facet joint arthropathy, degenerative spondylosis, subligamentous and/or extruded herniation and segmental instability (Bogduk, 1994; Gose, Naguszewski & Naguszewski, 1998). Disc degeneration also occurs with ageing. Where there are naturally repeated pressures of axial loading on the lumbar spine, osteophytes develop along the vertebral body borders and facet arthropathy increases (Videman, Saina, Crites Battle, Koskinen, Gill, & Paanaman, 1995). Singular pathological changes or a combination of progressive changes can result in stenosis at the neuroforamen or central canal (Gose et al., 1998).

Magnetic resonance imaging (MRI) and computed tomographhy (CT) are used to locate the source of some CLBP, but they often reveal degenerative changes such as spondyloysis and spondilolisthesis which are as frequent in asymptomatic individuals as symptomatic (Bogduk, 2004). They are, therefore, not considered to be valid diagnoses of the cause of CLBP.

In Bogduk’s (2004) clinical update on the management of CLBP, he discussed the three main methods of treating CLBP as being monotherapies, multidisciplinary therapies and reductionism. He described reductionism (page 80), one method of managing CLBP, as “*the pursuit of a pathoanatomical diagnosis for chronic low back pain with the view to implementing a target specific treatment.*” According to Bogduk (2004), joint blocks and discography can identify 15-40% of zygapophyseal joint pain, 40% of sacroiliac joint pain and 40% of disc disruption as the cause of pain symptoms.

There are various techniques emerging for the treatment of sacroiliac joint pain involving the denervation of the joint, and radiofrequency neurotomies are already being used widely for zygapophyseal joint pain. Discography/discograms are being used to reveal the internal disc architecture such as radial fissures and annular tears (Bogduk, 2004). In these cases the external disc remains intact and unlike a disc herniation, is usually due to repeated loading and generally causes painful discs which can then be treated in isolation. Arthrodesis of the affected joint has been used in the past with minimally invasive techniques such as intradiscal electrothermal therapy (IDET) being trialled as an
alternative. This is where the internal derangement of the painful disc is coagulated percutaneously with flexible electrodes in the disc.

Further research is required on the pathological and anatomical diagnoses of LBP to enable the implementation of effective target-specific treatment.

LUMBAR TRACTION

Lumbar traction in various forms has been used in the past to manage both acute and chronic LBP. It has generally been used in conjunction with other treatment modalities by physiotherapists, with varying degrees of success (Beurskens et al., 1995a; Borman et al., 2003; Quittan, 2002; Harte et al., 2003; Ostelo et al., 2003; Bogduk, 2004).

Spinal traction or vertebral axial decompression as a treatment modality for LBP lost favour with a number of therapists over recent times (Ackland, 2004). This was possibly due to the limited outcome data, medical imaging or other biomedical information that may demonstrate the effectiveness of treatment. However, research into the therapeutic effects of the Vax-D table demonstrated significant reductions in intradiscal pressure providing beneficial effects in patients with nerve root compression or conditions associated with discogenic dysfunction (Ramos & Martin, 1994). Their study supports previous research using discography and epidurography, in that these help reduce intradiscal pressure, encouraging retraction of disc herniations and facilitating healing (Mathews, 1968; Gupta & Ramarad, 1978).

Various studies support the view that for traction to provide therapeutic benefit, it can be relatively low dose and axial unloading can occur in a short time frame. Twomey (1985) studied the effects of sustained traction on lumbar vertebral segments revealing the greatest amount of distraction of the vertebrae occurred immediately upon traction load being applied. Another study by Falkenberg et al. (2001) determined the optimal time for axial spinal unloading on the basis of muscle activity using the LTX 3000™ Lumbar Rehabilitation System was 10 minutes. There are, however, limited data to determine the
in vivo effects of different types of traction using various equipment, positions and treatment times.

Although low dose (placebo) traction has been shown to provide some pain relief (Beurskens et al., 1997; Krause et al., 2000), other research examining the efficacy of traction for LBP regarding comparisons between a treatment group (receiving large traction forces) and a control group (receiving low traction forces) have been inconclusive (Beurskens et al., 1995b; Borman et al., 2003; Harte et al., 2003). The vertebral decompression provided by the low or high dose traction forces could provide relief from radicular symptoms by reducing pressure on sensitised neural tissue.

Traditional motorised lumbar traction has been used extensively within the physiotherapy sector, employing a variety of treatment protocols regarding the magnitude of traction as well as the length and frequency of treatment. There has been a lack of consistency in the traction protocols used in previous research, therefore the results have been inconclusive due to a lack of standardisation in methodology (Beurskens et al., 1995b; Beuskens et al., 1997; Harte et al., 2003). The application of optimal treatment weights, length of treatment sessions, frequency of treatment, the use of continuous or intermittent traction and length of overall traction program are all areas that lack consensus within the research literature. Determination of optimal parameters can only be drawn from the recommendations of expert opinion, supplemented by limited evidence on the mechanical and physiological effects of traction (Harte et al., 2003).

The mechanical effects of traction are predominantly vertebral separation and widening of the interverbral foramen (Beurskens et al., 1995b; Lee & Evans, 2001), with traction causing a flexion movement, stretching the posterior soft tissues, and subjecting the motion segments to anterior shear. Therefore, traction should be avoided in patients with anterior translational instability conditions such as spondilolisthesis and spondylosis.

A recent study by Borman et al. (2003) dealt with some of the methodological problems of past research. For instance, the traction protocol was fixed for all subjects in the treatment group at 20 minutes per day, 5 days a week for 2 weeks, and all subjects carried
out the same exercises and local treatment. However, the study population was heterogenous (male and female, various ages with multiple causes of back pain) and there was no sham intervention used on the control subjects. Two areas requiring further methodological rigour identified from previous research have been the need for a sham intervention to be used, and subgroups of patients likely to benefit need to be specifically studied. Heterogenous groups of subjects include patients unlikely to respond to traction, thereby diluting the effects of the intervention. Studying homogenous groups of patients, with clearly defined LBP in terms of the nature and duration of the condition, would provide more conclusive information on patients likely to benefit from a particular intervention.

A systematic review of randomised controlled trials on the efficacy of traction for back pain carried out by Harte et al. (2003) revealed little improvement in the methodological rigour of recent studies, thereby ensuring evidence for the effectiveness of traction on LBP remains inconclusive. Documented research design flaws included inconsistent traction parameters (dose and frequency), comparisons of heterogeneous study populations, traction used in conjunction with one or more other treatment modalities and a lack of valid sham intervention (Krause et al., 2000; Harte et al., 2003). Recommendations for future research advised on increased methodological rigour, increasing the strength of the study and potentially providing conclusive evidence on the effectiveness, or not, of traction as a treatment tool in managing CLBP.

Many forms of lumbar traction require expensive, heavy pieces of equipment or require patients to suspend themselves upside down or invert themselves for a period of time making traction a difficult method of providing ongoing pain management. The Nubax® provides a controlled tensile force to the trunk whilst the patient kneels forward taking the trunk into a horizontal position. There is no requirement for inversion of the body, thus alleviating any hydrostatic effect on the blood that may occur using some other traction devices. The tension load is under direct control of the user at all times and can be released by taking some weight on the hands. A technical report by Ackland (2001) assessed the tension loads applied to the spine using the Nubax® and found a similar magnitude of traction to that in the Vax-D protocol (Gose et al., 1998). Ackland (2001)
surmised then that the beneficial effects attributed to the Vax-D by previous researchers might eventuate for patients utilising the Nubax®. This is yet to be tested in a randomised clinical trial.

OUTCOME MEASURES

With the need for evidence-based data to substantiate the increasing cost of health care, there have been numerous studies performed to determine the validity, reliability and responsiveness of various outcome measure scales (Bellamy, 2002; Magnussen, Strand & Lygren, 2004; Ostelo, de Vet, Knol & van Den Brandt, 2004). Outcome measures are used to provide information on the impact of an intervention, with patient-centred measures becoming increasingly popular (Beaton & Schemitsch, 2003). The benefit of any intervention in clinical practice requires the health status measurement tool to be reliable, valid and responsive to changes in pain, stiffness, physical function and quality of life as well as being brief, simple and easy to score (Bellamy, 2002).

An appropriate assessment tool should take into account the level of functional status (a patient's ability to perform their normal activities of daily living) as well as their well being (a patient’s overall assessment of their pain and stiffness/general health). A comparison between groups of patients having the same treatment preferably requires the groups to be similar in other respects such as age, chronicity of pain and pathology.

An outcome measure must also be sufficiently sensitive to measure small, but clinically relevant changes. Without this feature the study’s results can be inaccurate and misleading. Much of the early research (pre-1992) used objective clinical outcome measures such as range of motion, straight leg raise and muscle power, however, many of these have not been shown to be reliable or valid measures of treatment effectiveness (Kirkley & Griffin, 2003). With the development of evidence-based practice guidelines, it is now clear that treatment efficacy should be determined by changes in patient function or participation, and not changes in impairments. The emphasis is now towards the patient’s perception of change, measured through questionnaires relating to disability, quality of life and the patient's ability to cope.
Traditional (impairment based) objective measures of patient outcome are not good indicators of the functional (i.e., physical limitations) and psychological (i.e., quality of life) aspects of a patient’s health (Kirkley & Griffin, 2003; Pengel et al., 2004). Historically, research into the effects on health-related quality of life by any intervention has been descriptive (Aaronson, 1989). The methodology, development and selection of quality of life measures to be used in clinical trials, as well as their reliability and validity has been researched extensively (Aaronson, 1989; Deyo et al., 1994; Deyo et al., 1998; Sun et al., 1997; Bellamy, 2002; Roos & Toksvig-Larsen, 2003; Kovacs et al., 2004).

The Roland-Morris Disability Questionnaire (RDQ)

The RDQ is a generic, validated, health-related quality of life questionnaire that has been widely used as a tool for assessing the relative efficacies of a variety of treatment interventions. It comprises 24 questions, giving a total score out of 24 relating to perceived disability with activities of daily living (ADLs), from zero (no pain or difficulty with ADLs) to 24 (extreme pain and difficulty with all ADLs).

Numerous studies have reported the reliability and validity of the RDQ. The responsiveness of pain, disability and physical impairment measures among patients with LBP was compared by Pengel et al. (2004) over a 6 week period using the RDQ in different formats along with the patient-specific functional scale and physical impairment measures. The findings suggested that more emphasis should be placed on the change in pain and disability during a treatment period, rather than on change in physical impairments (Pengel et al., 2004).

Turner, Fulton-Kehoe, Franklin, Wickizer & Wu (2003) compared the RDQ and other generic health status measures in terms of validity, reliability, responsiveness to change, and floor and ceiling effects on worker’s compensation back injury claimants. They concluded that the RDQ was a valid measure of assessing physical disability among workers with back injuries. Another study carried out to determine the validity and internal consistency of the RDQ resulted in it being labelled as one of the most validated...

More data are needed, however, to determine the minimally important change in scores and the responsiveness of the RDQ and other instruments to change (Deyo et al., 1998). This sensitivity to change is the ability of a measure of functional status to detect a clinically important change over time (Chansirinukor, Maher & Latimer, 1996). Clinical relevance is established by the minimally important change of a health status questionnaire (de Vet, H.C., Terwee, C.B., Ostelo, R.W., Beckerman, H., Knol, D.L. & Bouter, L.M., 2006). Those subjects with change scores greater than this minimal important change are judged to have made a clinically significant improvement or deterioration.

A study by Wyrwich (2004) noted that the Minimal Clinically Important Difference (MCID) varied across a sample when stratified by the subject’s baseline scores. Here, RDQ change scores were anchored against global ratings (from patients and their clinicians) used to assess perceived change at the end of a treatment period. A global change rating of five points was used to define subjects who had a MCID, which corresponded with a RDQ score change threshold of five points.

The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index

The WOMAC is a validated, disease specific questionnaire. It consists of 24 questions divided into three domains: pain, stiffness, and difficulty with physical function. Individual questions were assigned a score between zero (no pain, stiffness or difficulty with physical functions) and four (extreme pain, stiffness or difficulty with physical functions). The results give a score out of 96, which are then normalised to produce a total score between zero (best outcome) and 100 (worst outcome). The original scoring system developed by Bellamy, Buchanan, Goldsmith, Campbell & Stitt (1988) was used in this study to assess the effect of the treatment intervention on a patient’s low back symptoms.
Sun, Sturmer, Gunther & Brenner (1997) conducted a review of the empirical evidence on the reliability and validity of 45 commonly used clinical scores. Their validity study focused on the correlation between various scores which were found to be high for overall numerical ratings. Comprehensive studies of WOMAC scores showed satisfactory responsiveness to different treatment effects. The WOMAC physical function scale was compared to other symptomatic outcome measures for detecting changes after symptomatic therapy in knee osteoarthritis and was found to be more sensitive than Lequesne's index which gives an outcome score of 0-100 (Gentelle-Bonnassies, Le Claire, Mezieres, Ayral, & Dougados, 2000).

The detection and proof of intervention effects can be determined by the use of an MCID score (Angst, Aeschelmann, & Stucki, 2001). The WOMAC has been recommended as the most sensitive, condition-specific outcome measure for osteoarthritis of the hip and knee, with the WOMAC total score and WOMAC domain of physical function being the most sensitive to change (Angst, Aeschelmann, & Stucki, 2001). This study determined that in rehabilitation intervention effects larger than 12 percent of the baseline score can be detected as MCID. A study by Tubach et al. (2004) concluded that the MCID is affected by the initial baseline scores of subjects but not by age, disease duration or gender. This study determined that the MCID for subjects with low baseline symptoms (scores) was 2.6 on the WOMAC function score (0-100) and up to 20.4 for those with high baseline symptoms (scores). Both studies agreed that patients dealing with more severe symptoms have to experience a greater change to be considered to have improved.

Bellamy (2002) reviewed the 20-year history of the development of the WOMAC and found the WOMAC version 3.0 focused on an investigator selected study joint. According to Roos and Toksvig-Larsen (2003), the WOMAC is the most commonly used outcome instrument in recent times for assessment of patient relevant treatment effects in osteoarthritis. Previous studies have used the WOMAC to assess functional outcomes in patients suffering from hip or knee osteoarthritis (Roos, Klassbo & Lohmander 1999; Gentelle-Bonnassies et al., 2000; Kirkley & Griffin, 2003).
People with LBP, like those with osteoarthritis, suffer from increases in pain and stiffness as well as a decrease in physical function. A modified version of the WOMAC, therefore, may provide an effective outcome measure for use in this study—using the total score as well as the breakdown of scores into these three domains. As it has not been used as an outcome measure in previous LBP studies, there are no sensitivity statistics available for use and no references available. The modified WOMAC was chosen for use as a second outcome measure in this study, due to its comprehensive health status questions covering the three applicable domains. Furthermore, it was intended to be used to correlate the quality of life outcomes from the RDQ, as well as the physical function levels recorded on the activity monitors. The MCID established in research relating to the WOMAC for hip and knee osteoarthritis was used cautiously on the modified WOMAC used here for LBP.

There are other questionnaires more commonly used as outcome measures for patients with CLBP such as the Maine-Seattle Back Questionnaire (for evaluating patients with lumbar sciatica or stenosis), the SF-36 (a non-specific generic outcome measure), the Functional Ratings Index (a valid, sensitive, self-report disability measure) and the Oswetry Disability Index (a commonly used measure of back specific function). A study by Pengel et al. (2004) on the responsiveness of pain, disability and physical impairments in patients with LBP concluded that routine measurement of physical impairments in clinical practice and research was not optimal. Their study suggested that more emphasis should be placed on change in pain and disability scores. In the absence of a suitable, LBP-specific tool to assess symptoms, function and ADLs in the population, the WOMAC (with amended wording in the questions to relate to LBP) might prove worthwhile in this research project.

**Activity Monitors**

Activity monitors are accelerometry-based devices for measuring physical activity to determine energy expenditure by indirect calorimetry. Changes in walking velocity produce significant changes in body kinematics and kinetics, which are detected by the
activity monitor. An objective measure of energy expenditure is then available to use in establishing the resultant effect of an intervention on levels of physical activity.

Several studies (Pate, 1993; Welk, Blair, Wood, Jones & Thompson 2000; Leenders, Nelson & Sherman, 2003; Puyau, Adolph, Vohra, Zakeri & Butte, 2004) have evaluated different activity monitors to determine their relative and absolute validity in providing an objective record of the frequency, intensity and duration of physical activity. These studies found that activity monitors could be effectively used to discriminate sedentary, light, moderate and vigorous levels of physical activity. Self-report methods to determine levels of physical activity, and changes in these levels during or post intervention, are limited in their objectivity (Melanson & Freedson, 1996). Thus valid, reliable, non-reactive and precise instruments are required to do this. There are many models of activity monitors used to provide an objective measure of physical activity with the internal real-time clock allowing for the discrimination of individual activity patterns (Melanson & Freedson, 1996).

Walking velocity and bodily movement are measured by activity monitors in one of three planes (Leenders et al., 2003). Changes in walking velocity produce significant changes in body movements, which are detected by the activity monitor. The relationship between bodily movement and energy expenditure or METs is determined by indirect calorimetry. This relationship was reviewed by Leenders et al. (2003) who studied the ability of various activity monitors to detect movement during treadmill walking. It was found that changes in walking velocity produced significant changes in bodily movement that was detected by each monitor. These bodily movements were differentiated better at slow speeds than energy expenditure estimates.

Powell and Rowlands (2004) reviewed inter-monitor variability of eight accelerometers during typical physical activities. They found that inter-monitor reliability was good with the coefficient of variation being <6% during locomotor activities and 8-25% during sit to stand. However, variability increased as the intensity of activity escalated. Welk, Schaben & Morrow (2004) completed a generalised study on the reliability of accelerometry-based activity monitors using multiple units over time. They concluded
that there were concerns over the reliability of some devices, and further research was required on calibration protocols to improve this for different research applications.

**SUMMARY**

Chronic low back pain, generally regarded as LBP persisting for over 3 months (Bogduk, 2004) is a widespread problem. Multiple evidence-based guidelines have been established worldwide for the effective management of acute LBP based on scant data. The management of CLBP has to date, no definitive, unambiguous, evidence-based guidelines for practitioners to follow.

Lumbar traction has been extensively used in the past as a management tool, both on its own and in combination with other modalities (Borman et al., 2002). However, the literature related to lumbar traction as an effective physiotherapy tool in the management of CLBP is conflicting and inconclusive. This has mainly been due to differences in the diagnostic categories of LBP, and lack of standardisation of the available traction techniques and methodology (Borman et al., 2002). The main mechanism by which traction relieves pain seems to be via separating the vertebrae, thereby removing pressure and contact forces from injured tissue, increasing peripheral circulation with a massage effect on soft tissues and reducing muscle spasm (Krause et al., 2000).

The Nubax® is a home-use lumbar traction device shown to provide a substantial force on the lumbar spine and surrounding musculature. The methodology for its use has a set protocol making it a readily assessable traction tool.

The Roland Morris Disability Questionnaire is a valid and condition-specific outcome measure for low back pain which was used predominantly to determine the efficacy of the Nubax® in increasing physical function and quality of life. Though originally developed for assessing patients with knee or hip osteoarthritis, a modified WOMAC tool was considered to provide a useful second outcome measure for this research.
CHAPTER THREE
METHODS AND PROCEDURES

OVERVIEW

Ethical approval (Appendix O) for the study was obtained from the University of Western Australia. The study itself was undertaken in two phases. The first phase was a qualitative component where the clinical use of the treatment device was examined from meetings with health care professionals working in the area of LBP management and testimonials from individuals with LBP. The second phase was that of a controlled, randomised clinical trial.

PILOT STUDY – PRE-COMMENCEMENT QUALITATIVE STUDY

Objectives

The objective of the initial qualitative element of the study was to ascertain the opinions of health professionals and people with LBP for the practical use of the Nubax® for individuals with LBP. Specifically, this was to assist in identifying if there were any perceived factors that may influence the clinical utility of this device. This included elements of the cohort best suited to the use of the system, any potential factors that may influence the prognosis of clients using the Nubax®, any reported concerns relating to patient safety or harm and finally, the possible clinical dose that may provide a meaningful change in symptoms.

Method

The researcher undertook a series of meetings with individuals from various professions associated with the product development, research (biomechanics and clinical trials), clinicians in the management of LBP and clients who had undertaken the use of the Nubax® system. From these meetings, the key features of a proposed questionnaire to identify specific aspects of use and clinical utility were ascertained. Further discussions
and verification revealed no additional information was needed to add to the specific objectives.

**Questionnaires**

Following the meetings, a series of questions were developed to survey a greater cohort of clinicians and patients who have used the Nubax® system. Written testimonials by customers who had purchased a Nubax® unit were also examined.

The questions are attached as Appendices C and D with the cover letters attached at Appendices E and F. The questionnaires were designed to identify detailed information on the type of patients (i.e., underlying pathology) who had or had not benefited from using the Nubax® unit. Specific inclusion and exclusion criteria were then determined with particular emphasis on pathologies and chronicity of pain. Factors such as increased rate of recovery following an acute injury, or acute exacerbation of chronic low back pain and the use of the Nubax® unit were reviewed, together with anecdotal evidence regarding pain management over time.

The series of questions were sent to 38 health care practitioners (physiotherapists and chiropractors). Questions and cover letters were also sent to 16 patients/customers who had used/purchased a Nubax® unit and had written a testimonial on their experience.

Follow-up discussions were held with health professionals who had used the product in the treatment of patients with LBP. The information sought in these discussions included the protocol(s) they have employed with their patients, as well as any recommendations they may have for future use of the Nubax® (i.e., time of day, length of traction time and frequency of use). The general consensus of the dose and the type of patients documented from the questionnaires were presented to the clinicians and they did not identify any potential for harm or negative issues.
Summary

The pilot study helped establish the typical Nubax® protocol used previously in managing chronic LBP. There were no clear indications as to the best diagnostic cohort for the intervention. Individuals noted changes within 2 weeks of using the system and testimonials suggested that continued use beyond this period was of value. As a result of this information, the design of the clinical phase of the study was developed to include a 3 week intervention block with a crossover design. One subgroup would receive two consecutive treatment blocks to determine if there was any extended dose effect.

PHASE TWO – INTERVENTION STUDY

Sample / Subject Recruitment

Fifty-three subjects with CLBP were recruited over a period of 10 months (staggered intake into the project), beginning in May 2004 and finishing in April 2005. The sample comprised individuals from the Perth metropolitan area who responded to an advertisement placed in the Stirling Times community newspaper and the Western Suburbs community newspaper (Appendix J) requesting volunteers for the study. A statistical power test based on previous research (Borman et al., 2003) established that for an effect size of 0.8 and an alpha level of 0.05, 43 subjects were required to complete the study. Of the 53 recruited subjects, there were 11 withdrawals at some time during the 6 week study phase. The recruitment sequence and withdrawals are illustrated in Table 1, Chapter 4.

Potential subjects responded to the advertisement by contacting a call centre at the Nubax® registered office. At initial phone contact, the potential subjects were assessed with the inclusion/exclusion criteria as standard questions to determine their suitability for the study. The treating therapist was provided with a list of potential subjects together with their contact details and their responses to the inclusion/exclusion criteria.
Each potential subject was contacted by telephone and given a brief synopsis of the research. Questions were answered as to what the study involved so they could decide whether they wished to participate. Subjects who expressed an interest and availability to participate were then scheduled to attend an information session. The potential subjects were contacted in order of response to the advertisement and were recruited in the same manner so as to minimise recruitment bias. They were not recruited based on any other factors such as the number and types of previous treatments or attitude towards the research design and recruiter.

**Familiarisation Session**

At the familiarisation session, potential subjects were provided with the ‘Subject Information Sheet’ (Appendix H), which detailed the commitments required within both the treatment and control groups. Subjects then completed an ‘Informed Consent’ form (Appendix I) and were provided with an activity monitor to wear for three consecutive days. They were also scheduled to attend their initial assessment in the following week.

Those potential subjects who did not have recent radiological investigations of their lumbar spine (within the previous two years) were given a referral (by the researcher) to have a plain X-ray performed of their lumbar spine prior to commencement of the study. X-ray images were to be brought to the initial assessment to ensure they did not meet any of the exclusion criteria of underlying pathology.

**Inclusion Criteria**

To be eligible for inclusion in this study, the participants had to meet the following criteria:

- The subject must suffer NSCLBP, and that the initial onset of LBP must be at least 3 months prior to commencement of the study.
• The subject must either suffer from daily pain or have an acute recurrence at least twice per year, significant enough to lose time from work or prevent them from carrying out their normal activities of daily living.
• The subject must be currently suffering an acute exacerbation of CLBP or suffer ongoing daily CLBP.
• The subject must be over 18 years of age and living in the Perth metropolitan area.
• The subject must be able to attend one physiotherapy session per week.

Exclusion Criteria

Those subjects who had any of the following criteria were excluded from participating in this study either at the initial interview stage or at the initial assessment:

• The subject must not have had low back surgery in the previous 6 months.
• The subject must not be pregnant, nor have been pregnant within the previous 12 months due to the presence of the hormone Relaxin, which promotes joint instability.
• The subject cannot receive alternative treatments to the lumbo-sacral region in conjunction with their involvement in this study (aside from medication).
• The subject will be excluded if plain X-rays of the lumbar spine reveal bilateral pars defects, vertebral fracture(s), osteoporosis, Grade 2+ spondylolisthesis (if unstable), spondylosis, or the presence of surgical hardware in the spine.
• The subject will be excluded if cauda equina syndrome is diagnosed.
• The subject will be excluded if there is knee pathology preventing them attaining and maintaining a kneeling position for 3 minutes.
• The subject will be excluded if they have a current Worker’s Compensation claim.
• The subject will be excluded if they have referred lower limb pain.
Baseline Testing / Instructions to Subjects

One hour was set aside for an information session prior to the commencement of each group of subjects. It was explained at this session that there were three groups of subjects, all of whom would be blinded to group allocation. At the initial assessment the following baseline measures were taken:

- The range of pain-free lumbar motion, measured as the distance from fingertips to knee joint for forward flexion and lateral flexion.
- A note was made regarding whether extension and rotation were pain free or not.
- Activity monitor readings were taken in regard to their pre-commencement level of physical activity over a 3 day period.
- Two questionnaires (RDQ and modified WOMAC) were administered to determine their current level of pain, stiffness and physical function.

These measures would be repeated after 3 weeks of participating in the study and again after 6 weeks (i.e., at the completion of the study).

Subjects were advised of the time commitment required, which included using the unit provided for 3 minutes after being up and moving around for 15 minutes each morning, and again for a further 3 minutes just prior to retiring to sleep for the evening. The home exercises needed to be performed once per day and would take around 5 minutes to complete. The home use diary was to be used to record subject compliance. Each subject had to confirm that they had used the allocated unit at the allocated times each day and if not, document why they had not done so (see Appendix G for Nubax® Home Use Diary).

All potential subjects were advised that they could withdraw from the study at any time during the 6 week program. They were all provided with an after hours number for contact with the investigator at any time with any problems or questions.
Subject Assessments and Measurement Schedule

At the information session all potential research subjects booked a 40-minute appointment for their initial assessment, return of their activity monitors and review of radiology reports. A full subjective/objective assessment was taken at this time (see Appendix M for the Physiotherapy Assessment Form) which covered past and current history of pain, stiffness and activity levels, aggravating/easing factors and an orthopaedic/neurological assessment reviewing lumbar range of motion, reflexes and sensation. Notes were made of any evident scoliosis as well as any leg length discrepancy (for possible future case studies). The initial assessment also included setting up the treatment/placebo unit for each subject, filling out the two questionnaires and teaching the three core stability home exercises which were to be performed once daily throughout the study.

Lumbar range of motion is a traditional objective measure of patient outcome, but was not the focus of this research. Recent research by Kirkley and Griffin (2003) has shown it was not a good indicator of the functional aspects of patient health. Physical impairments are good at determining clinical efficacy of interventions to direct clinical decision making, diagnosis and prognosis, however, the focus of this study was the assessment of a lumbar traction device on quality of life and functional outcomes. A cursory range of lumbar motion was recorded at baseline, week three and week six, however, more contemporary measures of the RDQ and a modified WOMAC test battery were used to measure the LBP outcomes.

Questionnaires and Activity Monitor Testing

The RDQ graded the level of disability with a score out of 24 (see Appendix A). A higher score indicated that the individual experienced more pain, stiffness and disability. The modified WOMAC gave a score out of 96 (see Appendix B), which was converted to a score out of 100. As for the RDQ, higher scores on the modified WOMAC represented a poorer outcome.
The modified WOMAC was further divided into a pain score out of 20, a stiffness score out of 8 and a physical disability score out of 68.

Activity monitors (Actigraph AM7164-2.2, MTI Health Services, Florida, USA) were used throughout this study. They gave a variety of readings, including the number of steps taken, calories used, the amount of time spent in light, moderate, hard and extremely hard physical activity, and METS (energy consumption) expended. The total number of METS per day and the total over the three monitoring days were recorded for the purposes of assessing each individual’s activity level at baseline, week three and at the completion of 6 weeks of involvement in the study. However, as 28 out of 53 subjects were non-compliant or inconsistent with their use of the activity monitors (52% non-compliance), eventually these data were not used as an outcome measure in this study.

Intervention Program

Following the initial assessment, each subject made 20 minute appointments for the following 6 weeks at the same time on the same day of each week. At each of these subsequent appointments a 10 minute soft tissue massage of the lumbar region was given, the three core stability home exercises (see Appendix L) were reviewed and questions were answered.

After completing 3 weeks of the study, group B (i.e., full treatment group) was re-assessed for their pain free lumbar range of motion. The two questionnaires were completed again, the activity monitors were worn for a further three consecutive days (the same days as initial baseline measures), the home exercises were reviewed, a standard lumbar massage given, and any questions answered. They were instructed to continue on as for the previous 3 weeks using the same unit.

Groups A (treatment crossing over to control) and C (control crossing over to treatment) also wore the activity monitors for a further 3 days, had the lumbar massage, review of home exercises, lumbar range of motion reassessed and completed the questionnaires.
They were also instructed to return the treatment/placebo unit they had been using and this was changed to the alternate unit for the final 3 weeks.

All subjects had a final review at the 6 weeks time point, at which time all the outcome measures were re-assessed and the treatment/placebo units returned. They were all given a testimonial form to complete advising of any problems they had with the study and any suggestions for future studies. The form also covered work hours to determine the possible effect of work on those who took part. Those who returned their testimonials had no change in work hours so these data have not been included in the results chapter.

**Apparatus**

The treatment unit is shown in Figure 1. The sham/placebo unit was identical to the treatment unit but had an extra bolt at the pivot point shown in Figure 2. The bolt prevented the upper body from moving forward into a position providing traction. The bolts were approximately 8 cm in length and when the subject let the upper body move forward the top of the bolt came into contact with the shoulder poles preventing any further forward movement of the upper body.

**METHOD OF RECORDING AND COLLECTING DATA**

**Questionnaires**

All subjects filled out their two baseline questionnaires prior to their initial assessment. These were placed into pre-paid envelopes and mailed to an independent, blinded research assistant at UWA for scoring and data entry. At the completion of the first 3 weeks of the study, all subjects then repeated the two questionnaires prior to their re-evaluation and treatment. Similarly, at the completion of the final week of the study all subjects returned for their final assessment, return of the treatment/placebo unit, the home use diary, their testimonial and to complete a final two questionnaires.
Activity Monitors

As this was an objective measure, the researcher did not need to be blinded to the results on an ongoing basis. Each subject was given a monitor at the information session once they had decided to participate and completed an informed consent. Their use was explained and questions answered. Subjects wore the activity monitor for three consecutive days. These days included two week days and one weekend day (i.e., Thursday, Friday and Saturday; or Sunday, Monday and Tuesday). The 3 days for each subject had to be the same at subsequent tests so as to maintain consistency with respect to their normal weekly routines.

After each group had returned their monitors the data were down-loaded at UWA, recording the daily total of METS and the 3 day total. The 3 day total was the reading used to review any changes in physical activity during and after the 6 week study. Unfortunately, the activity monitors were no longer used following the third intake of research subjects as the early data indicated no change in activity scores for individual subjects, both within subjects and between subjects. This was partly due to a large number of subjects being non-compliant or unreliable in their use of the monitors. Therefore the opportunity to examine the other outcome measures (RDQ and WOMAC) in the context of functional mobility and level of activity (Activity monitors and METS) was not possible.

Lumbar Range of Motion

Lumbar range of motion was assessed at the initial assessment, at the end of week three and the completion of week six. The information was recorded on the initial physiotherapy assessment form. These measurements documented any change in range of movement in the short term, but were not used to assess the efficacy of the treatment.
Subjective Assessment / Home-use Diary and Testimonials

Each subject was given a home-use diary at the initial assessment. This was easily completed by ticking the “am” and “pm” spaces at the end of each day to indicate they had complied with the protocol of treatment/placebo unit use. If a subject was unable to use the treatment/placebo unit at any particular time they marked that space with a cross and made a notation as to why it was missed on that day and time. These diaries were returned at the final assessment to indicate individual and overall compliance with the requirements of the study.

At the post week three assessment, each subject was given a testimonial (see Appendix N) to complete on attendance at the final assessment session. These were employed to detail their work hours and duties, and overall feelings about participating in the study. By this means, our intent was to marry the information from the testimonial regarding work hours with the objective activity monitor data for the three consecutive days. However, due to the unreliability of returned testimonials, (n=19), and considerable differences in information provided on an individual basis, these data have not been reported in the thesis. Subjects were required to note in the final assessment, whether they felt that using the Nubax® and participating in the study reduced their levels of pain and stiffness. Any comments on how the study was conducted and ideas for modifying the equipment and future research were also noted.

Treatment

Each subject attended the private practice once per week for a standard soft tissue massage to the lumbar region musculature (from the base of the 12th rib to the top of the buttocks) for 10 minutes. They had their home exercises reviewed at this time. The home exercises were basic core stability exercises in the neutral lumbar position. They involved maintaining a transversus abdominus muscle contraction during pain free range of lumbar rotation in supine, and with diaphragmatic breathing in crook lying supine and straight prone/prone on elbows.
At the completion of week three and again week six, the questionnaires were administered, lumbar range of motion re-assessed and a soft tissue massage given. Following the completion of the study, specific advice was given to each individual regarding ongoing independent exercises for their underlying pathology.

RESEARCH DESIGN

This study was a single blind, randomised controlled study with three arms utilising two 3 week treatment blocks, including a placebo treatment block with a sham unit, and a cross over component. This is illustrated in Figure 3.

Figure 3. Design of the treatment phase of the study.

Each subject was assigned to one of the treatment groups (A or B) or the control group (C) using block randomisation according to gender, age and body weight. Two treatment groups, comprising of 20 subjects (Group A), and 14 subjects (Group B), commenced their treatment with the treatment unit for 3 weeks, and a control group (Group C) consisting of 19 subjects commenced with a sham unit for the initial 3 weeks. At the crossover, treatment group A (n=15 after attrition) commenced a 3 week period using the sham unit, whereas treatment Group B (n=13 after attrition) continued with the treatment unit for a further 3 weeks. Control Group C (n=14 after attrition) commenced with the treatment unit for the final 3 weeks of the study.
Whilst each subject was blinded as to which Nubax® unit they were commencing with (treatment or sham/control), once they swapped at the end of week three (groups A and C), the subjects became aware they had an alternative unit as it felt “different”. Some subjects, predominantly from Group A, who had been using the treatment unit and then crossed over to the sham unit were even quite angry as they felt that an improvement had occurred and knew they were then changed to a unit that “did nothing”. Thus, the single blinding was only in effect until the change over after week 3.

STATISTICAL PROCEDURES

Baseline Descriptive Data

After randomisation, baseline comparisons between groups were tested using a series of unpaired t-tests for outcome measures and demographic details. Unpaired t-tests were performed on the following factors: age, height, weight, baseline RDQ scores and baseline modified WOMAC scores to determine if initial differences existed between the three subject groups for these factors. The mean and standard deviation (SD) were recorded for the continuous variables and statistically significant differences were attributed to probability level of less than 0.05.

Change Scores for Primary Outcome Measures

A. Initial Block (baseline to week three)

Change scores (see Appendix K) were used to document the treatment response in absolute values for all the primary outcome variables: RDQ and modified WOMAC (total score plus the three sub-domains of pain, stiffness and physical function). The sign of the respective change scores were altered to maintain consistency where a positive change score reflected a clinical improvement (i.e., decrease in pain or increase in physical function). These were plotted using the mean for each group and the 95% confidence intervals (CI). These data were displayed and statistically significant changes were determined when the confidence intervals did not include the no-change (zero) score.
B. Combined Two Blocks (baseline to week 6)
Change scores were also determined from baseline to 6 weeks for each group separately. This was to examine the effect of the blocked treatment changes for combinations of sham unit (3 weeks) and treatment unit (3 weeks) as allocated to the group. The procedure also enabled the examination of any dose effect via the interaction of the placebo and the treatment order. This research design was used since it was unclear if there existed a dosage effect, or an optimal combination of Nubax® and the sham unit protocol. Graphically, the impact of the cumulative blocks are shown using the change scores for week 3 and the total change scores for both blocks.

C. Group Differences
In the initial block of 3 weeks, two of the three groups received the Nubax® intervention and one group received the sham unit. The comparison of the two groups using a repeated measures ANCOVA was undertaken, using the initial baseline value as the covariate. This statistical method controlled for small variations in the baseline between groups and improved the statistical power of the group comparison (Altman & Vickers, 2001).

Levels of Significance
The alpha level for statistical significance was pre-set at 0.05 (power is not performed post hoc). Statistical significance was established at the 95% level of confidence and no corrections for multiple comparisons were made.

Intention to Treat Analysis
For each group, change scores were determined from baseline to week six in order to examine the effect of the blocked treatment changes for the combination of placebo and Nubax® treatment as allocated to each group. This was used to examine the dosage effect via the interaction of the placebo and treatment order. An intention to treat analysis was performed where missing data were substituted by the previous assessment value (Fergusson, Aaron, Guyatt & Hebert, 2002).
CHAPTER FOUR
RESULTS

SUBJECT CHARACTERISTICS

Eighty-four people responded to the advertisement placed in the local metropolitan papers asking for interested participants in this research project. All of their details were recorded by the Nubax® call centre along with their responses to the inclusion / exclusion criteria questions. Each was contacted from the Nubax® call centre list by the treating physiotherapist who provided further information and answered questions if necessary. The list was followed from the top and all potential subjects were advised of the project requirements and of the information session to follow.

On attendance and acceptance of participation in the study 53 subjects were recruited (see Table 1). All subjects gave their informed consent at the completion of the information session. Some subjects still required plain x-rays of their lumbar spine prior to commencing and the referral for this was provided by the treating physiotherapist at this information session. Subjects were randomly assigned to either a treatment to control crossover group (Group A), 6 week treatment group (Group B), or control to treatment crossover group (Group C). Randomisation involved stratification according to three factors: age, body mass and sex. The three groups for age were 18-30 years, 30-60 years, and over 60 years. The three groups for weight were under 55 kg, 55-80 kg, and over 80 kg. Each group of subjects recruited were then randomised in block form in an effort to get similar numbers of men and women in the various weight and age categories participating in groups A, B, and C.

Ten subjects missed a weekly massage and review due to travelling difficulties or time constraints; however, all subjects attended following weeks 3 and 6 for completion of their questionnaires, massage, review of exercises and re-assessment of lumbar range of movement. One subject withdrew from the study between week 3 and week 6.
Therefore, data were available for all subjects (n=42) who completed weeks 0-3 and (n=41) who completed weeks 0-6.

Table 1. The Number of Subjects who were Contacted, Recruited, Excluded, Withdrew, and Completed the Intervention to Week 3, and to Week 6.

<table>
<thead>
<tr>
<th>N</th>
<th>Total subjects contacted</th>
<th>Total subjects excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>83</td>
<td>Spondilolisthesis/bilateral pars defect present on X-Ray 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable to achieve kneeling position 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unavailable for duration of study/commencement date 17</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uninterested / unable to fulfil requirements of study 10</td>
<td></td>
</tr>
<tr>
<td>53</td>
<td>Total subjects initially recruited</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Withdrawals due to sickness, other commitments (prior week three) 11</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Withdrawal due to exacerbation of pain (post week three) 1</td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>Total subjects completing week three</td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>Total subjects completing week six</td>
<td></td>
</tr>
</tbody>
</table>

DEMOGRAPHICS

Twenty-six men and 27 women were recruited for this study. Group A consisted of 12 men and eight women, Group B was made up of seven men and seven women, and Group C had a total seven men and 12 women (Figure 4). The two crossover groups were intended to be equal with 15 subjects completing the full treatment for 6 weeks. However, following the initial assessment and randomisation, two potential subjects decided they were unable to participate due to time constraints, thus leaving a difference in the number of subjects commencing in each group.

A series of unpaired t-tests was then undertaken to test for initial differences between the groups on the variables, height, weight, age, and baseline scores of RDQ and modified WOMAC. The results of these analyses indicated no significant differences ($p > .05$) between the groups for age, weight, height, and baseline scores for the RDQ and
modified WOMAC (see Table 2). These findings suggest randomisation of subjects was successful.

Figure 4. Intervention type for the three groups of participants, and the variables measured at baseline, at 3 weeks, and at 6 weeks.
Table 2. Descriptive Statistics for the First Group and \( p \) values for T-test Baseline Comparisons.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group Comparison</th>
<th>Mean</th>
<th>SD</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>RDQ</td>
<td>A v B</td>
<td>9.0</td>
<td>4.4</td>
<td>.421</td>
</tr>
<tr>
<td></td>
<td>B v C</td>
<td>7.7</td>
<td>5.2</td>
<td>.209</td>
</tr>
<tr>
<td></td>
<td>C v A</td>
<td>10.2</td>
<td>5.6</td>
<td>.492</td>
</tr>
<tr>
<td>Mod. WOMAC</td>
<td>A v B</td>
<td>38.2</td>
<td>12.7</td>
<td>.891</td>
</tr>
<tr>
<td></td>
<td>B v C</td>
<td>39.1</td>
<td>22.4</td>
<td>.935</td>
</tr>
<tr>
<td></td>
<td>C v A</td>
<td>38.5</td>
<td>16.2</td>
<td>.952</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>A v B</td>
<td>172.8</td>
<td>10.2</td>
<td>.765</td>
</tr>
<tr>
<td></td>
<td>B v C</td>
<td>171.8</td>
<td>10.0</td>
<td>.903</td>
</tr>
<tr>
<td></td>
<td>C v A</td>
<td>171.3</td>
<td>13.4</td>
<td>.679</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>A v B</td>
<td>75.8</td>
<td>16.9</td>
<td>.771</td>
</tr>
<tr>
<td></td>
<td>B v C</td>
<td>77.5</td>
<td>14.9</td>
<td>.666</td>
</tr>
<tr>
<td></td>
<td>C v A</td>
<td>75.2</td>
<td>15.5</td>
<td>.895</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>A v B</td>
<td>47.5</td>
<td>13.1</td>
<td>.316</td>
</tr>
<tr>
<td></td>
<td>B v C</td>
<td>42.9</td>
<td>13.0</td>
<td>.064</td>
</tr>
<tr>
<td></td>
<td>C v A</td>
<td>51.2</td>
<td>11.9</td>
<td>.362</td>
</tr>
</tbody>
</table>

\( RDQ = \) Roland Morris Disability Questionnaire

\( Modified \ WOMAC = \) Modified questions of the Western Ontario and McMaster Universities Osteoarthritis Index to relate specifically to the low back.

MEDICAL HISTORY / PATHOLOGY

The underlying pathology of each subject was documented according to the radiology report provided with the investigations. Subjects who had plain x-rays, an MRI or CT of their lumbar region within the preceding 18 months brought them along to the initial assessment, and those without had a plain lumbar x-ray completed for the study. Table 3 shows the main diagnoses for the patient cohort with multiple classifications possible. If no specific pathology was identified with radiological investigation, subjects were classed as having non-specific CLBP. Due to the vast differences in severity and chronicity of the underlying pathology, and associated symptoms, as well as the
combinations of pathology, a specific responder group has not been quantitatively analysed. No subjects reported referred lower limb pain.

Table 3. Total Number of Diagnoses Reported for the CLBP Subjects ($N = 53$).

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Degenerative (facet joint)</td>
<td>9</td>
</tr>
<tr>
<td>Degenerative (disc)</td>
<td>9</td>
</tr>
<tr>
<td>Disc protrusion</td>
<td>4</td>
</tr>
<tr>
<td>Spondylolisthesis (Grade 1-2 Stable)</td>
<td>-</td>
</tr>
<tr>
<td>Scoliosis</td>
<td>2</td>
</tr>
<tr>
<td>Non-specific</td>
<td>3</td>
</tr>
</tbody>
</table>

INTERVENTION AND COMPLIANCE

Compliance to the exercise and traction protocols was good. Of the 41 subjects who completed the 6 week study, 31 attended every week at the scheduled time, one subject missed one weekly massage and review, and the final 10 subjects attended only for weeks 1, 3 and 6 due to the extensive travel involved. All participants reported that they had completed their home exercises on a daily basis, with six subjects missing several sessions with the sham unit. Four of these subjects were from treatment group A and stated that they knew as soon as they crossed over from the treatment unit to the sham unit that it wasn’t doing anything so there was little point using it daily. One was aware immediately he was using a sham unit in treatment group C so was non-compliant until he crossed over to the treatment system and one subject missed two sessions due to work commitments. Eleven others missed more due to withdrawal at the 3 week point. The majority of subjects (69%) were fully compliant with all protocols.
BASELINE CHARACTERISTICS AND RESULTS

The characteristics of age, height and weight were assessed at baseline to determine whether there were any significant differences in those parameters that are known to be important prognostic factors in the primary outcome variables. An analysis of these characteristics revealed that there were no differences observed between each of the treatment groups ($p > .05$) (Table 2).

**Roland-Morris Disability Questionnaire**

Results from the RDQ, a generic health status measure used in this study as an outcome for LBP, revealed that no differences were observed ($p > .05$) at baseline between groups A, B and C (see Table 2).

**Modified WOMAC**

Results from the modified WOMAC, a disease specific measure for patients with osteoarthritis of the hip or knee, but used here as an outcome measure for functional mobility and the perception of stiffness and pain during functional tasks, revealed that no differences were observed ($p > .05$) at baseline between groups A, B and C (see Table 2).

**Activity Monitor Readings**

Due to a large number of subjects (i.e., 19/53) being inconsistent or non-compliant with the use of their activity monitors, the METS data recorded from this study was not used or analysed as an outcome measure for LBP. Therefore, only the modified WOMAC remained for assessment of functional limitation, pain and stiffness related to the individual's level of activity.
BASELINE TO WEEK 3 CHANGES IN OUTCOME PARAMETERS

The following section details the outcome from the first block of treatment, where two group’s (treatment vs sham) change scores are compared. Group differences are reported using the mean and 95% Confidence Interval (CI) for the change scores over the assessment period. Statistical differences were determined using an analysis of covariance with the baseline score as the covariant. In circumstances where there was a significant interaction between the covariant and the group, an unpaired comparison was used to determine differences between the groups. One should note that the means and 95% CI in the following graphs are not corrected for any correlation of the covariate (baseline value).

**Roland-Morris Disability Questionnaire**

During the initial block of treatment (baseline to 3 weeks), the mean improvements of both the placebo and treatment groups were similar (Tables 4 and 5, Graph 1). The treatment group made statistically significant improvements in regard to disability as measured by the RDQ.

It should be noted that all 53 subjects who began the trial were included in this intention to treat analysis, in which missing data for 11 subjects were substituted using ‘the last value carried forward’ approach.

The ANCOVA was used, as the sample size was a limitation, resulting in low statistical power. A significant interaction between the covariate (baseline score) and the group ($p = .0268$) was found with the group difference being essentially explained by the significant covariate ($p<.0001$) and the corresponding interaction. With a significant baseline covariate, the analysis demonstrated that any improvement in RDQ scores was affected by the subject’s initial level of disability. The post-hoc Fischer’s comparison did not detect a statistical difference between the groups ($p = .9935$).
Table 4. Descriptive Statistics for the RDQ Change Scores at Week 3 for the Treatment and the Placebo Groups.

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>34</td>
<td>0.9</td>
<td>2.4</td>
<td>0.414</td>
</tr>
<tr>
<td>Placebo</td>
<td>19</td>
<td>0.9</td>
<td>3.0</td>
<td>0.686</td>
</tr>
</tbody>
</table>

Table 5. ANCOVA Summary for the RDQ Comparing Weeks 0 - 3.

<table>
<thead>
<tr>
<th></th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covariant (baseline)</td>
<td>1</td>
<td>829.5</td>
<td>142.2</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Group</td>
<td>1</td>
<td>28.0</td>
<td>4.803</td>
<td>.0332</td>
</tr>
<tr>
<td>Baseline x Group</td>
<td>1</td>
<td>30.4</td>
<td>5.216</td>
<td>.0268</td>
</tr>
</tbody>
</table>

Post hoc Fischer’s $p = .9935$ for group differences controlled for interaction.

The mean change scores for the RDQ for both the treatment and placebo groups were 0.9 points which did not reach MCID. Therefore, the results were not clinically significant for the RDQ for either group.

Graph 1. The mean and 95% confidence limits of the RDQ change scores for the sham and treatment intervention groups for the first block of treatment (weeks 0-3).
Modified WOMAC

Tables 6 and 7 and Graph 2 relate to the modified WOMAC total score. During the initial block of treatment, the treatment group made significant improvements (p<0.05) experiencing a mean change of 8.0 points (CI: 2.9-13.2), with the placebo group having a mean change of 4.0 points (CI: -1.1-9.1). Both groups recorded mean improvements, but the placebo group 95% CI included the zero (no change), so it did not reach statistical significance. The covariant effect of p < 0.0001 was statistically significant showing that patients with the poorest overall baseline conditions to start with experience greater improvements.

Table 6. Descriptive Statistics for the Modified WOMAC Total Score at Week 3 for both groups.

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>34</td>
<td>8.0</td>
<td>10.0</td>
<td>1.720</td>
</tr>
<tr>
<td>Placebo</td>
<td>19</td>
<td>4.0</td>
<td>10.6</td>
<td>2.422</td>
</tr>
</tbody>
</table>

Table 7. ANCOVA Summary for the Modified WOMAC Total Score Weeks 0 - 3.

<table>
<thead>
<tr>
<th></th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covariant (baseline)</td>
<td>1</td>
<td>6598.7</td>
<td>74.88</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Group</td>
<td>1</td>
<td>357.7</td>
<td>4.059</td>
<td>.0494</td>
</tr>
<tr>
<td>Baseline x Group</td>
<td>1</td>
<td>214.9</td>
<td>2.439</td>
<td>.1239</td>
</tr>
</tbody>
</table>
Graph 2. The mean and 95% confidence limits of the Modified WOMAC total change scores for the sham and treatment intervention groups for weeks 0-3.

The covariant effect for the modified WOMAC pain score was statistically significant (p<0.0001) revealing that patients with the poorest scores at baseline experience the greatest improvement. A comparison between groups for the respective change scores demonstrated no significant difference between the groups. Despite this, the treatment group demonstrated a significant, though small reduction in pain in the first 3 weeks of treatment (Graph 3). This was not evident in the placebo group. The placebo group experienced a mean change of 0.6 points (CI: -0.5-1.6), while the treatment group improved by 1.9 points (CI: 0.6-3.4), which is relatively small. Therefore, it can be stated that the traction had limited effect on pain.

Table 8. Descriptive Statistics for the Modified WOMAC Pain Score at Week 3 for both groups.

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>34</td>
<td>1.9</td>
<td>2.7</td>
<td>0.468</td>
</tr>
<tr>
<td>Placebo</td>
<td>19</td>
<td>0.6</td>
<td>2.1</td>
<td>0.489</td>
</tr>
</tbody>
</table>
Once again, the covariant effect for the modified WOMAC stiffness domain indicated that there was a greater improvement when the patient had a high stiffness score at baseline. The combined treatment group demonstrated a statistically significant improvement in stiffness, but this was small in magnitude (see Tables 10 and 11, Graph 4). The mean change score was 0.9 points (CI: 0.2-1.5) for the treatment group. In the placebo group, with a mean of 0.3 points (CI: -0.3-0.9), these changes did not reach statistical significance. No differences were shown between the groups following the ANCOVA analysis using baseline stiffness scores as the covariate (Fischer’s post hoc test \( p = .2913 \)). Therefore the traction intervention had limited effect on subject’s stiffness.
Table 10. Descriptive Statistics for the Modified WOMAC Stiffness Score at Week 3 for both groups.

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>34</td>
<td>0.9</td>
<td>1.5</td>
<td>0.253</td>
</tr>
<tr>
<td>Placebo</td>
<td>19</td>
<td>0.3</td>
<td>1.2</td>
<td>0.269</td>
</tr>
</tbody>
</table>

Table 11. ANCOVA Summary for the Modified WOMAC Stiffness Score Weeks 0 - 3.

<table>
<thead>
<tr>
<th></th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covariant</td>
<td>1</td>
<td>71.18</td>
<td>42.13</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Group</td>
<td>1</td>
<td>0.5</td>
<td>0.309</td>
<td>.5809</td>
</tr>
<tr>
<td>Baseline x Group</td>
<td>1</td>
<td>0.001</td>
<td>0.001</td>
<td>.9811</td>
</tr>
</tbody>
</table>

Graph 4. The mean and 95% confidence limits of the modified WOMAC stiffness change scores for the sham and treatment intervention groups for weeks 0-3.

As with the other sub-domains, the covariant effect for physical function was statistically significant, whereby patients with a poorer physical function score at baseline experienced the greatest improvement. The mean change for the modified WOMAC physical function score within the treatment group was statistically significant with a mean change of 5.2 points (CI: 1.4 - 9.2). The placebo group also had a small mean improvement of 1.4 points (CI: -1.4 - 4.2), but the 95% CI indicated the change was not significant (see Tables 12 and 13, Graph 5). Although the univariate main effect for
group was not significant \((p>0.05)\), Fisher’s post hoc test following the ANCOVA (using the baseline physical function scores as the covariate) found that the treatment group showed statistically significantly \((p = .0235)\) greater physical function change score compared to the placebo group.

Table 12. Descriptive Statistics for the Modified WOMAC Physical Function Score at Week 3 for both groups.

<table>
<thead>
<tr>
<th></th>
<th>Count</th>
<th>Mean</th>
<th>SD</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>34</td>
<td>5.2</td>
<td>7.4</td>
<td>1.259</td>
</tr>
<tr>
<td>Placebo</td>
<td>19</td>
<td>1.4</td>
<td>5.8</td>
<td>1.323</td>
</tr>
</tbody>
</table>

Table 13. ANCOVA Summary for the Modified WOMAC Physical Function Score Weeks 0 - 3.

<table>
<thead>
<tr>
<th></th>
<th>df</th>
<th>Mean Square</th>
<th>(F)</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covariant (baseline)</td>
<td>1</td>
<td>5100.5</td>
<td>119.13</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Group</td>
<td>1</td>
<td>54.7</td>
<td>1.277</td>
<td>.2640</td>
</tr>
<tr>
<td>Baseline x Group</td>
<td>1</td>
<td>2.9</td>
<td>0.068</td>
<td>.7954</td>
</tr>
</tbody>
</table>

Graph 5 The mean and 95% confidence limits of the Modified WOMAC Physical Function change scores for the sham and treatment intervention groups for the first block of treatment (weeks 0-3)
COMPARISON OF OVERALL GROUP RESPONSE FOR THE INITIAL 3 WEEKS AND OVERALL INTERVENTION (6 WEEKS).

This section of analysis observes the changes in each group separately by comparing the response of the initial block with that of the overall response (week 0-6). The purpose of this analysis was to examine any dose effects of treatment since one group received six continuous weeks of Nubax® use, whereas the other two groups experienced 3 weeks of placebo and Nubax® unit alternatively. It is important to note that the prior experience influenced the placebo effect. The graphics show the mean and 95% CI of the change scores of the overall intervention (at 6 weeks) with the superimposed means score at 3 weeks.

Group B received treatment for both sessions and demonstrated no advantage over the initial 3 weeks of treatment for group A or for the final outcome for group C (sham followed by treatment). The impact of the placebo sham is evident with small improvements in group C (sham followed by treatment) and an overall decline in status if the treatment is followed by the sham treatment (group A). Overall however, the magnitude of these change scores is small and does not meet thresholds for clinical significance.

Table 14. Data for Comparison of Groups Weeks 0-3 and 0-6 for RDQ.

<table>
<thead>
<tr>
<th>Weeks 0-3</th>
<th>Weeks 0-6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>Mean</td>
</tr>
<tr>
<td>-----------</td>
<td>------</td>
</tr>
<tr>
<td>RDQ 0-3A</td>
<td>1.5</td>
</tr>
<tr>
<td>RDQ 0-3B</td>
<td>0.1</td>
</tr>
<tr>
<td>RDQ 0-3C</td>
<td>0.9</td>
</tr>
</tbody>
</table>
Graph 6 The change scores for the RDQ for the three groups for the performance for the first block of treatment (week 0 to 3) and for the whole treatment (week 0 to 6 filled triangles).

For Group A (weeks 0-3) there was a statistically significant improvement \((p = .0289)\) in the RDQ with a mean score of 1.5 and no intersection of the 95% CI with the zero (no change) score (see Graph 6). Once this group swapped to the sham unit they actually had a decline in mean RDQ score to \(-0.8\) for 0-6 weeks \((p = .2710)\). Group B had a mean change score of 0.143 for weeks 0-3 \((p = .6987)\) and this increased further with a mean score of 1.214 for 0-6 weeks \((p = .2919)\), however, these changes were not significant. Group C commenced with the sham unit and also increased their mean RDQ score from 0.947 at 0-3 weeks \((p = .1842)\) to a mean score of 1.474 at 0-6 weeks \((p = .0640)\), but these changes were not significant.
Group A commenced with the Nubax® unit and at 0-3 weeks had a mean WOMAC Total change score of 7.9 ($p = .0043$). Following the crossover to the sham unit after 3 weeks, this group experienced a decline in mean score to 2.1 (0-6 weeks, $p = .4461$) (see Table 15, Graph 7). This group demonstrated the negative changes one might expect by the implementation of a sham protocol after a treatment. The full treatment group, Group B, had a mean change score of 8.2 at 0-3 weeks ($p = .0050$) and with further use of the Nubax® this improved marginally to a mean score of 9.5 (0-6 weeks, $p = .0185$). Receiving an additional session of treatment demonstrated limited additional treatment value.

Table 15. Data for Comparison of Groups Weeks 0-3 and 0-6 for Modified WOMAC Total Score.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>$p$</th>
<th>Group</th>
<th>Mean</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOMAC 0-3A</td>
<td>7.9</td>
<td>.0043</td>
<td>WOMAC 0-6A</td>
<td>2.1</td>
<td>.4461</td>
</tr>
<tr>
<td>WOMAC 0-3B</td>
<td>8.2</td>
<td>.0050</td>
<td>WOMAC 0-6B</td>
<td>9.5</td>
<td>.0185</td>
</tr>
<tr>
<td>WOMAC 0-3C</td>
<td>4.0</td>
<td>.1163</td>
<td>WOMAC 0-6C</td>
<td>10.5</td>
<td>.0108</td>
</tr>
</tbody>
</table>

Graph 7. The change scores for the modified WOMAC Total Score for the three groups for the performance for the first block of treatment (week 0 to 3) and for the whole treatment (week 0 to 6 filled triangles).
The group commencing with the sham unit, Group C, had a mean change score of 4.0 at 0-3 weeks \((p = .1163)\) and an increased mean change score of 10.5 by week 6 following the crossover to the treatment unit \((p = .0108)\). Again, this group demonstrated changes that might be expected by the implementation of a sham treatment before a treatment resulting in an improvement.

Group A had a mean modified WOMAC Pain change score of 2.0 at 0-3 weeks \((p = .0079)\) and at 0-6 weeks the mean score was 1.9 \((p= .0603)\) (see Table 16, Graph 8). No changes of an additional session of sham treatment were demonstrated. Group B had a mean change score of 1.9 at 0-3 weeks \((p =.0104)\) and at 0-6 weeks a mean score of 2.4 \((p = .0005)\). This group demonstrated limited additional value with an additional session of treatment with the Nubax® unit. Group C had a mean score of 0.6 at 0-3 weeks \((p = .2668)\) following using the sham unit, and a mean score at 0-6 weeks of 2.6 \((p = .0008)\) showing an improvement following the implementation of the treatment.

Table 16. Data for Comparison of Group Weeks 0-3 and 0-6 for Modified WOMAC Pain Score.

<table>
<thead>
<tr>
<th>Weeks0-3</th>
<th>Group</th>
<th>Mean</th>
<th>(p)</th>
<th>Weeks 0-6</th>
<th>Group</th>
<th>Mean</th>
<th>(p)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAIN 0-3A</td>
<td>2.0</td>
<td>.0079</td>
<td></td>
<td>PAIN 0-6A</td>
<td>1.9</td>
<td>.0603</td>
<td></td>
</tr>
<tr>
<td>PAIN 0-3B</td>
<td>1.9</td>
<td>.0104</td>
<td></td>
<td>PAIN 0-6B</td>
<td>2.4</td>
<td>.0005</td>
<td></td>
</tr>
<tr>
<td>PAIN 0-3C</td>
<td>0.6</td>
<td>.2668</td>
<td></td>
<td>PAIN 0-6C</td>
<td>2.6</td>
<td>.0008</td>
<td></td>
</tr>
</tbody>
</table>
Group A had a mean WOMAC Stiffness change score of 1.2 at 0-3 weeks \((p = .0050)\) whilst at 0-6 weeks the mean score was 0.357 \((p = 0.3807)\) (see Table 17, Graph 9), demonstrating a decline of the treatment effect with the introduction of the sham intervention. Group B had a mean score of 0.4 at 0-3 weeks \((p=.0882)\). However, at 0-6 weeks the mean score increased to 1.3 \((p=.0030)\) demonstrating possible treatment value with an additional 3 week session of treatment. Group C also had a low mean score at 0-3 weeks being 0.3 \((p=.2756)\). At 0-6 weeks the mean score increased to 0.9 \((p=.0628)\), and though not statistically significant, this might demonstrate some benefits of introducing the sham treatment prior to a treatment.

Clinical significance of these findings cannot be judged due to the inability to determine if such changes are clinically meaningful. However, cautiously using the MCID used in previous research, these results would not demonstrate clinical significance.
Table 17. Data Comparison of Groups Weeks 0-3 and 0-6 for Modified WOMAC Stiffness Score.

<table>
<thead>
<tr>
<th>Group</th>
<th>Weeks 0-3</th>
<th></th>
<th>Weeks 0-6</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td></td>
<td>Mean</td>
<td></td>
</tr>
<tr>
<td>STIFFNESS 0-3A</td>
<td>1.2</td>
<td></td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>STIFFNESS 0-3B</td>
<td>0.4</td>
<td></td>
<td>1.3</td>
<td></td>
</tr>
<tr>
<td>STIFFNESS 0-3C</td>
<td>0.3</td>
<td></td>
<td>0.9</td>
<td></td>
</tr>
</tbody>
</table>

Graph 9. The change scores for the modified WOMAC Stiffness Score for the three groups for the performance for the first block of treatment (week 0 to 3) and for the whole treatment (week 0 to 6 filled triangles).

Group A had a mean score of 4.7 at 0-3 weeks ($p = .0102$). By 6 weeks the mean score had decreased to -1.7 ($p = .5600$) showing a reduction in function after crossing over to the sham unit for the final 3 weeks (see Table 18, Graph 10). Group B had a mean score of 5.9 at 0-3 weeks ($p = .0111$). At 0-6 weeks Group B's mean score increased marginally to 7.0 with a ($p = .0928$), but so also had the variance. Group C had a mean
change score of 1.4 at 0-3 weeks ($p = .2982$). At 0-6 weeks the mean score increased to 4.7 but remained not significant ($p = .2005$). Group C demonstrated changes that would be expected by the implementation of a sham treatment before a treatment (resulting in an improvement trend). Group A demonstrated a decline in overall treatment utility when the treatment was followed by a sham. Clinical significance of these findings using the

Table 18. Data Comparison Groups Weeks 0-3 and 0-6 for Modified WOMAC Physical Function Score.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>$p$</th>
<th>Group</th>
<th>Mean</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYS FUNC 0-3A</td>
<td>4.7</td>
<td>.0102</td>
<td>PHYS FUNC 0-6A</td>
<td>-1.7</td>
<td>.5600</td>
</tr>
<tr>
<td>PHYS FUNC 0-3B</td>
<td>5.9</td>
<td>.0111</td>
<td>PHYS FUNC 0-6B</td>
<td>7.0</td>
<td>.0928</td>
</tr>
<tr>
<td>PHYS FUNC 0-3C</td>
<td>1.4</td>
<td>.2982</td>
<td>PHYS FUNC 0-6C</td>
<td>4.7</td>
<td>.2005</td>
</tr>
</tbody>
</table>

Graph 10. The change scores for the modified WOMAC Physical Function Score for the three groups for the performance for the first block of treatment (week 0 to 3) and for the whole treatment (week 0 to 6 filled triangles).
MCID of previous research cautiously here would demonstrate use of the treatment unit for 3 weeks does increase physical function which is further increased, although marginally with ongoing use for a further 3 weeks.

SUMMARY OF RESULTS

There were 53 subjects who participated in this study with two Groups (A and C) utilising the treatment Nubax® and the sham unit respectively for 3 weeks with a crossover, and one Group (B) using the treatment system for the full 6 weeks. The method of subject randomisation was successful as no differences were found between the demographics and self-administered questionnaires at baseline for all three groups.

The comparison of the two groups (treatment and placebo) for the first block (baseline to Week 3) and the second block (baseline to Week 6) was undertaken using the change scores with the initial baseline value as the covariate. This statistical method controls for small variations in the baseline between groups and improves the statistical power of the group comparison.

A statistically significant improvement was demonstrated when the CI (95%) does not include zero (no change). Clinically (despite the statistical differences), we observed a limited beneficial effect of the treatment unit over the placebo. At 6 weeks there was little additional improvement in the change scores for both Groups A and B. This is despite Group B receiving the treatment intervention for a further 3 weeks. This suggests that there is a dose-related effect where the individuals receive little additional benefit for the second term of the real treatment over that of the placebo. However, the second lot of treatment for the initial placebo group was associated with a large improvement. Interestingly this seems to have an amplified effect for this group compared to the original responses of Groups A and B. This is open to conjecture, however, as the significance (clinically) of the findings was marginal.
CHAPTER FIVE
DISCUSSION

INTRODUCTION

Results from this study address the effect of using a home traction device called a Nubax® unit on managing CLBP regarding levels of pain, stiffness and physical function.

A randomised clinical trial is considered the “gold standard” for clinical research (Portney & Watkins, 1993) as it is the most rigorous epidemiological approach. With respect to the present study, there was no difficulty in recruiting the sample, however the study requirements did impact on a few subjects, causing withdrawals due to time and travel constraints. An “intention to treat” analysis was conducted on the final data set providing interesting information on the use of the Nubax® and the protocol used.

The discussion chapter will address the issues of subject recruitment and randomisation, discuss aspects of the treatment intervention and the impact of the results in relation to the effect on patient pain, stiffness and physical function.

SUBJECT RECRUITMENT AND RANDOMISATION ISSUES

The target population was consistent with comparative studies based on the following subject selection criteria: subjects were over the age of 18, with CLBP, receiving traction as the main source of treatment and the comparison group receiving sham traction. Quality of life outcome questionnaires were used as primary outcome measures (Harte et al., 2002). Previous studies have used poor methodologies, making it difficult to make a valid judgment about the efficacy of lumbar traction. However, the current study addressed some of these issues by using a consistent relative level of traction for all subjects (dependent on their body weight), avoiding the requirement of overcoming body friction against a traction table by using a kneeling traction device, having a consistent
traction protocol for all subjects of 3 minutes twice per day, and having a sham (placebo) traction device for comparison with the treatment intervention.

Other methodological problems encountered by previous researchers were hopefully addressed in this study. These included: blinding the subject as to which treatment they were experiencing, obtaining good compliance with treatment protocols, the use of at least one relevant outcome measure, and the use of intention to treat analysis. Some problems in past research were unable to be addressed such as the heterogenous nature of the subjects regarding underlying pathology and the severity of their disability.

Krause et al. (2000) evaluated the effects and recommended application of lumbar traction for treatment of LBP. Problems identified in previous studies were: comparison of heterogenous populations, applications of several treatment modalities in conjunction with the traction, varying traction dosage and the lack of a sham intervention (Harte et al., 2003). The protocol used in this study was extremely strict in the timing of traction and dosage as well as the exercises and massage used in conjunction. Furthermore, there was a control group that utilised a sham traction. The present study integrated a true placebo (sham unit of the actual device), which few randomised controlled trials in this area have performed. This ensured that all patients had the same contact with the treatment provider, which benefited patients and minimised the traction specific response.

The quality and appropriateness of the use of traction as an intervention in managing CLBP requires attention. As no two patients are the same in their subjective or objective presentation, it is difficult to address the clinical appropriateness of research into CLBP management by physical therapy, including traction. Each treatment is tailored to the individual and tends to be complex with an array of health services provided in a package of care (Harte et al., 2002).
The Research Design

The design and subject recruitment of this study strived to overcome previous methodological difficulties by using the Nubax® home traction device as the main form of treatment along with basic core stability exercises and soft tissue massage in combination. Previous studies have not used this approach. It might have been beneficial to study the use of the Nubax® alone to determine whether it would be an effective and acceptable clinical treatment.

There was extensive groundwork done, examining the use of this device in the clinical setting. The fact that there was no consensus on the use of the system meant that the research design attempted to cover more bases than would be expected in a single modal intervention tested by a randomised controlled trial. Having the three groups of subjects was an attempt to look at the influence of treatment dose.

Conducting a single mode randomised clinical trial for the management of CLBP is a difficult process. Often the research based on specific interventions have had a foundation of anecdotal history and clinical practice. The first phase of this research thesis was to examine the clinical practice of the use of the Nubax® device. From this qualitative element of the thesis, it was clear that the use of the traction device reflected a wide scope of practice of clinicians across various professions. The findings of the qualitative elements of this thesis were interpreted predominantly in two areas (Diagnosis and Dose).

The qualitative assessment of the specific diagnosis for which clinicians might employ the Nubax® device, was highly variable. There was no specific indication of the use of the Nubax® system based on patho-anatomy nor presenting complaints. Without any valid form of classification or indication for the use of the device, a general "non-specific CLBP" population was targeted for this clinical investigation.

Furthermore, the findings of the first part of this research suggested that there was a large variation in the duration of use of the system (dose). Some practitioners reported good
responses within 2 weeks and also during prolonged use. Therefore, the second phase of
the research thesis involved a dose (3 weeks to 6 weeks) assessment. Few studies in
physiotherapy management have examined dose related questions. This is partly due to
the difficulties in controlling the responses of individuals and other logistical problems.
The use of 3 minutes seemed to be a conservative duration for the traction. However, this
was set as a method of precaution for potential harmful effects and yet, the actual optimal
time of traction at each specific use of the device remains unclear.

Previous studies have used mechanical traction, whereby the level of traction was
required to overcome the friction forces between the patient and the bed (Beurskens, de
Vet, Koke, van der Heijden, & Knipschild, 1995). However, this unit did not require any
patient/bed friction forces to be overcome. The study by Ackland (2004) determined the
traction forces provided by the Nubax® units were normalised for each individual subject
because the traction load was based on their own body weight. Nevertheless, the form of
traction used in this study is new, so dosage recommendations and a treatment plan had
little direction other than that provided by the initial pilot study. The optimal length of
traction time and frequency of treatment were reviewed in the pre clinical trial work
influencing the protocol used in this study.

The ANCOVA analysis was used in this study and the changes, when viewed
systematically, are very small. The difference between the level of placebo traction and
treatment traction intervention was limited so any changes seen are associated with the
actual load on the spine. As for the clinical impact demonstrated by this research design,
there was probably less value than might have been shown under a different research
design.

**Compliance**

Compliance with the testing protocols and follow up visits was good and there was
genuine willingness of patients to participate in the study.
Randomisation

Data analysed at baseline revealed that no differences were observed between the three groups for each of the primary outcome measures, nor for any of the variables known to be significant prognostic factors in the primary outcome variables. Therefore, it was concluded that the randomisation procedure was successful and further analysis need not account for any initial differences in the treatment groups. However, to give greater statistical power in the subsequent analysis, change scores were used to document the treatment response in absolute values for all the primary outcome variables: RDQ and modified WOMAC scores (total score and three domains: pain, stiffness and physical function). The subjects could have been blocked better according to the degree of their condition, which would have made the analysis of each block of subjects easier to review the effectiveness of the traction.

The use of MCID is important for evidence-based cost effective medicine as its use detects and proves the relevance of intervention effects (Angst, Aeschlimann & Stucki, 2001). Changes in scores exceeding the MCID are clinically relevant by definition (de Vet et al., 2006). Subjects with severe symptoms generally require a higher level of change to constitute an improvement compared to those with mild symptoms (Tubach et al., 2004). The MCID varies across tertiles of the baseline score, but does not vary across age, disease duration tertiles, or gender. Due to this variation it might have been more appropriate to block randomise subjects into low, moderate and severe symptoms to enable clearer analysis of the MCID for each group.

Pathologies

All subjects recruited into the study underwent plain lumbar x-rays identifying their underlying pathology, unless they had recent radiological investigations that could be used. One subject had a high-grade spondilolisthesis and did not participate, however the remaining subjects exhibited a range of underlying pathology within the study requirements.
Chronicity

The duration or chronicity of each subject’s LBP was recorded at the initial assessment. To participate in this study and fulfill the criteria of having CLBP, each subject had to have suffered from LBP for at least 3 months. Furthermore, this pain was to be significant enough to prevent them working or carrying out their normal ADLs. Documented chronicity of pain ranged from 3 months to 30 years, ranging from low grade daily pain with intermittent exacerbations two to three times per year, to high level daily pain with certain activities.

The varied chronicity of LBP was a problem identified in this study as a heterogenous population was used, meaning the time from onset of symptoms to the time of inclusion in this study was wide and variable. This, however, does not cause any variation in MCID (Tubach et al. 2004). The degree of disability was also markedly varied, potentially skewing the results as the MCID varies with differing degrees of disability from low to severe. Those with more severe disability required a higher change in scores to notice an improvement. Those subjects with higher pain, disability and physical function scores were obviously more debilitated and had the potential to benefit from the traction more than those with low grade disability.

To achieve a homogenous group for future research patients must be clearly defined in terms of pathology, symptoms and chronicity of their LBP. It was difficult to develop responder or target populations in this study due to the sample size and mixed diagnosis of causative pathology. Blinding of the care provider was also difficult to achieve in this study.

THE EFFECT OF THE INTERVENTION WEEKS 0-3

Measures of Disability, Subjective Levels of Function and Data Logging of Activity

The domains of handicap and functional limitations were evaluated using three assessment tools. The first was a reliable and validated assessment specifically targeted for lower back pain, the RDQ (Pengel et al. 2004), while the second was a reliable and
validated disease-specific functional assessment scale for the hip and knee, the WOMAC (Sun et al. 1997) which was slightly modified in the wording to suit these patients. This scale (modified WOMAC) had three sub-domains of functional limitation related to activity/mobility, pain limiting activity and finally, the perception of stiffness during activity. The third assessment tool was an objective measure of activity via an Actigraph activity monitor (Pate, 1993), which was intended to be used to match the levels of disability between the RDQ and the WOMAC scale. These monitors measured activity and levels of mobility, which were intended to be cross validated with the RDQ levels of disability and a scale that reflected a mix of both activity and disability (modified WOMAC). However, this cross validation was not possible due to a low level of subject compliance with the use of the activity monitors. As a result the use of the WOMAC with this population is novel, and the ability to consider the validity in terms of a scale to assess levels of activity and mobility is an area for future research.

RDQ

According to Wyrwich (2004), the MCID for the RDQ is a change score of 5 points, but the ideal threshold for the MCID differs across a sample when stratified by participants' initial scores. Therefore, the effect of the treatment was dependent on the subjects' baseline score. Tubach et al. (2004) also found this effect in their investigation of LBP using the RDQ, where the MCID varied between 3 and 13 points depending on the baseline range of scores.

Patients with a high level of functional disability at baseline must change more points on the RDQ than those with less functional disability at baseline, for there to be considered a clinically significant change. The group of subjects in the present study did not have high baseline scores, thereby revealing that it was not a high disability group. The change required to show a clinically significant improvement would therefore, be lower than 5 points but certainly higher than the mean value for the RDQ change scores for both the placebo and treatment groups (0.9 points).
Comparison of the treatment group and the placebo group revealed a statistically significant improvement \((p < .05)\) in the treatment group, but this change was not clinically relevant. The RDQ has been used extensively in previous research to determine the efficacy of specific treatments for subjects with LBP. However, the results from this randomised controlled trial did not support the hypothesis.

**Modified WOMAC**

Improvement in the domains of pain, stiffness and physical function incorporated in the WOMAC (Bellamy, 1988) is indicated by a lower score. The mean scores for the total modified WOMAC and each domain were analysed to compare the three groups over time. For each group, change scores were determined from baseline to week 3. Previous research employing the WOMAC has used this self-administered disease specific questionnaire to assess treatments on osteoarthritis of the hip or knee. There is no benchmark indicating the smallest detectable MCID following intervention on CLBP using the modified WOMAC instrument.

A modified version of the WOMAC was used in this study as it appeared to provide a comprehensive assessment of a patient’s pain, stiffness and ability to function in normal ADLs, which can be related to LBP or any weight bearing part of the body. The MCID used in previous studies by Angst, Aeschlimann and Stucki (2001) and Tubach et al. (2004) were cautiously applied in this analysis.

Given that the MCID can be attained and detected in rehabilitation intervention with effects larger than 12% of baseline score (6% of maximum score) (Angst, Aeschlimann & Stucki, 2001), the treatment group and sham groups showed global clinically significant improvements. Tubach et al. (2004) estimated MCID to range from 2.6 points (low disability) to 20.4 points (high disability). Those subjects in the present study who presented with worse pain, stiffness and physical function obviously had more scope to improve, which was shown in the magnitude of their change scores. Therefore, the traction had a significant overall effect statistically and clinically for these subjects.
The modified WOMAC baseline scores were positioned in the middle of the range indicating an average / moderate disability. The magnitude of the actual changes were relatively small, even though the modified WOMAC total change scores and physical function change scores were shown to be clinically significant when cautiously applying the MCID data previously reported in the literature. This is due to the fact that most of the patients did not have high degrees of disability to start with, along with the duration of the first block of intervention being only 3 weeks, and the actual sham unit only changed the traction load with all other treatment parameters remaining the same. Using an intention to treat analysis also tends to give a conservatism to the results (Fergusson et al., 2002).

Further analysis was performed with Groups A and B pooled to form the treatment group \( (n = 34) \), with Group C \( (n = 19) \) forming the placebo group. At the end of week 3 both groups had made improvements indicated by their WOMAC total change scores, but only the treatment group achieved statistically and clinically significant results. The same pattern was demonstrated with the domain of physical function with a significant group difference shown after week 3 \( (p < .05) \).

These results cannot be related directly to data from other studies that have used the WOMAC for arthritis hip and knee assessments. However, when applying the MCID cautiously, the modified WOMAC total score and that for the domain of physical function showed a sufficiently large improvement in mean change scores to be considered clinically significant. According to Angst et al. (2001), the WOMAC stiffness domain is the least responsive scale, with the pain and functional disability being the most sensitive to change. This was certainly shown to be the case in this study.
THE EFFECT OF THE INTERVENTION WEEKS 0-6.

RDQ

All three groups were also compared using the RDQ from weeks 0-6 to try to establish a dose or maintenance effect. These data were shown in Table 14 and Graph 6. The filled triangles indicated the mean change scores at week 6 with the arrows indicating an increase or decrease following the second block of 3 weeks.

Group A, who commenced with the treatment unit for 3 weeks then crossed over to the sham unit for the final 3 weeks had a decline in mean change scores indicating a return to their original level of disability. This was potentially a psychological influence and would be expected when subjects cross over from a treatment to placebo, especially when differences in traction force between the units were revealed.

Group B, who had the full 6 weeks using the treatment unit, experienced very low changes in mean scores at 3 weeks and marginally higher mean change scores at 6 weeks. This potentially shows a dose effect that with continued use over a longer period of time further improvements continued to be made, but the changes were not statistically or clinically significant.

Group C commenced with the sham unit for 3 weeks and crossed over to the treatment unit for the following 3 weeks. The increase in mean change scores at week 6 was small but still marginally greater than the mean change score for group B. This potentially shows that using a lower dose of traction first and then increasing the level may provide a better outcome than using the full traction dose for the entire 6 weeks.

Reviewing previously established MCID, the results of the RDQ change scores were too low to be clinically meaningful.
Modified WOMAC

The mean scores for the total modified WOMAC and each domain were analysed to compare the three groups over time. For each group, change scores were not only determined from baseline to 3 weeks but also baseline to 6 weeks (see Table 15, Graph 7).

As shown in the graph, only when the groups received Nubax® treatment did they achieve statistically significant results. However, with moderate mean change scores (MCID>8) for Group C following the 3 weeks, use of the treatment unit this can be seen to be clinically meaningful for both groups B and C, who used the treatment unit in the final 3 weeks.

This potentially indicates a maintenance effect for the treatment group and a dose effect for group C when crossing over to the treatment unit. Group C had the greatest mean change score of 10.5 points after week 6, from 4.0 points at weeks 0-3, which was not only the greatest improvement but the highest change in mean scores from weeks 0-3 to post week 6. The dose effect that occurred in the first 3 weeks for Group A was reduced after the cross-over to the sham unit. This may indicate that ongoing use of the Nubax® is required to maintain the initial improvement as well as continue to improve further, as demonstrated with Group B.

The change scores for the modified WOMAC domain of pain (see Table 16, Graph 8) and stiffness (see Table 17, Graph 9) were not at the MCID level and were, therefore, not clinically significant.

Reviewing the data comparing the groups for the modified WOMAC domain of physical function (see Table 18, Graph 10), shows the dose effect at weeks 0-3 between groups as well as an increased dose effect for group C and maintenance/dose effect for group B. It also shows a large increase in variance after 6 weeks between the groups. This might be explained by the varying levels of disability to start with as well as potential
psychological factors. The results of the modified WOMAC total score and domain score of physical function support the use of the Nubax® in managing CLBP.

THE EFFECTIVENESS OF THE NUBAX® IN ADDITION TO STANDARD PHYSIOTHERAPY TREATMENT

During the first block of treatment, both the RDQ and the modified WOMAC data in the domains of pain and stiffness did not support the use of the treatment unit in reducing pain and stiffness, however, the modified WOMAC data in the domain of physical function did support the use of the Nubax®.

The data suggests that, ideally, the Nubax® should be used for a minimum of 3 weeks, at which point, there have been improvements in quality of life as indicated marginally by the RDQ and more so by the modified WOMAC.

The results of this study suggest that auto traction in conjunction with standard physiotherapy treatment may be effective in managing and reducing the effects of CLBP. A review of randomised controlled trials by Harte et al. (2003) noted that studies on auto traction are difficult due to fatigue or intolerance in maintaining a prolonged position by the patient or therapist. Therefore, motorised traction studies can be more successfully standardised for repeatability. However, the protocol for use of the Nubax® in this study was a short, manageable period of time enabling repeatability.

Studies by Borman et al. (2002), Beurskens et al. (1995) and Beuskens et al. (1997) concluded that lumbar traction was not effective in managing LBP. These studies all reviewed standard motorised lumbar traction of varying magnitude and a combination of other treatment modalities such as heat, ultrasound and exercise programs. A study performed by Sherry, Kitchener & Smart (2001) reviewed the VAX-D, a form of lumbar traction or vertebral axial decompression, and concluded that there was a statistically significant improvement in patients with CLBP following treatment.
It is difficult to compare this study to those previously performed due to the new and different form of traction being researched here. As far as patient perception was concerned, the results of this study suggest that use of the Nubax® for sufferers of CLBP will improve their quality of life and physical function, but have little effect on their levels of pain and stiffness, if used for a minimum of 3 weeks. Used on an ongoing basis these improvements may continue.

Whilst the WOMAC has not been used in previous treatment efficacy studies for LBP, it proved to be sensitive to changes in quality of life and the specific domain of physical function within this study. The total questionnaire scores as well as the individual physical function domain score in the final results also supported the hypothesis.
CONCLUSIONS

The results of the research revealed that using the Nubax® treatment unit with basic physiotherapy treatment for a 3 week period, produced a statistically significant improvement in modified WOMAC total score and modified WOMAC physical function compared with using the sham unit. Crossing over after the initial 3 weeks from the treatment unit to the sham unit produced a deteriorating trend for subjects in Group A in pain, stiffness and physical function after the final 3 week treatment block.

However, patients in Group C, who commenced with the sham unit for the initial 3 weeks experienced no statistical or clinical change. This group of subjects then demonstrated, both statistically and clinically significant improvement in modified WOMAC total score and pain score following the crossover to the treatment unit for the final 3 weeks.

Those subjects in Group B who utilised the treatment unit for the full 6 week period demonstrated continued improvement on all outcome measures during the second block of treatment, but most especially in regard to stiffness. As for the other outcome measures, most change occurred within the first 3 week block of treatment.

Thus, the hypothesis that utilising the Nubax® unit in conjunction with physiotherapy treatment increases physical function ability and reduces pain and stiffness compared to utilising the sham unit is accepted with caution. Further research is required for this acceptance to be strong as the results from using the RDQ here were marginal and therefore, inconclusive.

Future research designs may incorporate single sex samples with similar pathology, chronicity and severity of pain, providing a more homogenous subject group. This would potentially increase the strength of the results on the efficacy of the Nubax® as a
treatment modality and provide more information on patient groups for whom it is most suited.

RESEARCH DESIGN AND RECOMMENDATIONS FOR FUTURE RESEARCH

This project was conducted as a single blind randomised controlled study on the efficacy of the Nubax®, a home lumbar traction unit. The research structure consisted of two blocks of treatment for three subject groups with a crossover design. It was anticipated that the control groups using the sham unit would have no improvement in physical function and quality of life variables, while those utilising the treatment unit would experience improvements, which increased, or were maintained, with continuing use. This was shown to be the case, however, it was surprising to see the return to previous or lower than baseline function following cessation of use, or crossover to the sham unit in group A from weeks 3 to 6.

For future research it would be interesting to analyse ongoing use of the Nubax® over a prolonged period of time such as 6 months. Such a design would help determine whether subjects were prevented from having acute recurrences, were able to maintain their improved quality of life over a long period, or continued to improve with ongoing use of the unit.

Another important future research focus could be the actual traction load associated with the dose. There is a suggestion that the initial sham (no load) followed by the 3 weeks of actual traction resulted in similar changes to the 6 weeks of continuous treatment. This suggests a load by dose interaction. This warrants some further research investigating the dose which may be manipulated by increasing the duration of use of the device at each specific treatment session (i.e. 3 minutes to 6 minutes or more) and the duration and frequency of use over time.

This study also included physiotherapy treatment of basic core stability exercises as well as lumbar soft tissue massage. Future research to enable the Nubax® to be assessed on its efficacy as a stand-alone treatment for CLBP would also be useful. This would be
difficult to present to allied health professionals and other medical practitioners because it would reduce their involvement and intervention. There would be a safety concern with this, regarding harm minimisation and the Nubax® use with appropriate pathologies.

More research into the efficacy of the Nubax® for acute LBP as well as for specific pathologies such as scoliosis would also provide an increased knowledge of the benefits of traction in managing pain and stiffness reduction and an increase in physical function within this subject group. Psychological effects of CLBP were not assessed within this study, but would be beneficial to future research as utilising the Nubax® in conjunction with other treatment modalities may enable individuals to self-manage for longer durations. This would result in decreased financial commitments for sufferers of CLBP and could also empower them to take control of their own management.

Finally, if the use of the device increases across various professions and clinicians document the clinical profile of each patient prior to the use of the device, then long term anonymous auditing of the clinical utility (benefit and harm) may provide insight to the pragmatic utility of such a device.

RECOMMENDATIONS FOR THE MANAGEMENT OF PATIENTS WITH CHRONIC LOW BACK PAIN

Following this study, it is clear that patients suffering from CLBP can expect a some improvement in pain, stiffness and physical function following 3 weeks of utilising the Nubax® unit along with basic physiotherapy treatment. A qualified health professional is required to set up and educate patients on the use of this home traction device and monitor its use from the perspective of minimising harm. The protocol of 3 minutes of traction twice a day has been shown to be effective in improving quality of life over a 3 week period, with ongoing improvements following continued use for a further 3 weeks. Varying the amount of traction the unit provides, so that patients commence with a reduced level of traction and build up to their maximum individual dose, could potentially provide a greater improvement than a protocol that encourages full traction from the outset.
Used in conjunction with basic physiotherapy treatment, the Nubax® unit may be a useful treatment tool in reducing and managing the debilitating symptoms of CLBP and factors influencing the magnitude of the response from any one individual, like many forms of therapy, are yet to be elucidated.
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APPENDICES
APPENDIX A

The Roland-Morris Low Back Pain and Disability Questionnaire

Patient Name: ___________________________ File#: ___________________________

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

☐ I stay at home most of the time because of my back.
☐ I change position frequently to try to get my back comfortable.
☐ I walk more slowly than usual because of my back.
☐ Because of my back, I am not doing any jobs that I usually do around the house.
☐ Because of my back, I use a handrail to get upstairs.
☐ Because of my back, I lie down to rest more often.
☐ Because of my back, I have to hold onto something to get out of an easy chair.
☐ Because of my back, I try to get other people to do things for me.
☐ I get dressed more slowly than usual because of my back.
☐ I only stand up for short periods of time because of my back.
☐ Because of my back, I try not to bend or kneel down.
☐ I find it difficult to get out of a chair because of my back.
☐ My back is painful almost all of the time.
☐ I find it difficult to turn over in bed because of my back.
☐ My appetite is not very good because of my back.
☐ I have trouble putting on my sock (or stockings) because of the pain in my back.
☐ I can only walk short distances because of my back pain.
☐ I sleep less well because of my back.
☐ Because of my back pain, I get dressed with the help of someone else.
☐ I sit down for most of the day because of my back.
☐ I avoid heavy jobs around the house because of my back.
☐ Because of back pain, I am more irritable and bad tempered with people than usual.
☐ Because of my back, I go upstairs more slowly than usual.
☐ I stay in bed most of the time because of my back.
APPENDIX B

**Modified WOMAC Osteoarthritis Index**

The following questions concern the amount of pain you are currently experiencing in your low back. For each situation, please enter the amount of pain you have experienced in the past 48 hours.

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Walking on a flat surface.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>2.</td>
<td>Going up or down stairs.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>3.</td>
<td>At night while in bed.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>4.</td>
<td>Sitting or lying.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>5.</td>
<td>Standing or upright.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

The following questions concern the amount of joint stiffness (not pain) you have experienced in the past 48 hours in your low back. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints. How severe is your stiffness?

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>6.</td>
<td>After first awakening in the morning?</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>7.</td>
<td>After sitting, lying or resting later in the day?</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the past 48 hours because of your low back. What degree of difficulty do you have with...

<p>| | | | | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>8.</td>
<td>Descending stairs.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>9.</td>
<td>Ascending stairs.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>10.</td>
<td>Rising from sitting.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>11.</td>
<td>Standing.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>12.</td>
<td>Bending to floor.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>13.</td>
<td>Walking on flat surfaces</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>14.</td>
<td>Getting in/ out of car</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

**What degree of difficulty do you have...**

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>15.</td>
<td>Going shopping.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>16.</td>
<td>Putting on socks/ stockings.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>17.</td>
<td>Rising from bed.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>18.</td>
<td>Taking off socks/ stockings.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>19.</td>
<td>Lying in bed.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>20.</td>
<td>Getting in/out of bath or shower.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>21.</td>
<td>Sitting.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>22.</td>
<td>Getting on/off toilet.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>23.</td>
<td>Heavy domestic duties.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>24.</td>
<td>Light domestic duties.</td>
<td>None</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
## APPENDIX C

### Patient Questionnaire

**What is your underlying pathology? Do you have radiological evidence for this?**


**How long have you suffered from back pain?**


**How often do you have recurrences of your back pain?**


**What treatment have you had in the past, how often, and how long did it take for you to recover from previous episodes?**


**Can you describe the pain you had in terms of frequency, intensity, and some of the activities you were unable to do due to your pain?**


**How long have you been using the Nubax®?**


What is the current protocol you are using, as in the frequency of use, time of day, and how long is you in the traction position for?

What time of day does using the Nubax® work best/worst for you?

Since you have been using the Nubax®, how has the frequency and intensity of your pain been affected?

Since you have been using the Nubax®, how has your quality of life been affected, and what are you able to do now that you could or could not do prior to using the Nubax®?

Would you recommend the Nubax® to other people with similar pain?

What other treatment have you had in conjunction with using the Nubax®?

Thank you so much for your time and I hope the Nubax® has assisted you in your recovery and continues to be a useful treatment tool for your ongoing pain management.

Kirrily Pearce (Physiotherapist)
APPENDIX D

Practitioner Questionnaire

How many of your patients have been educated in the use of and used the NUBAX?

_________________________________________________________________________

_________________________________________________________________________

What treatment protocol was used with the patients educated in the use of the NUBAX?

_________________________________________________________________________

_________________________________________________________________________

Which patients responded well to using the NUBAX? I.e.: underlying pathology

_________________________________________________________________________

_________________________________________________________________________

Do you have radiological evidence of the underlying pathology for the patients you have educated in and who have used the NUBAX? If so, what type of evidence i.e.: CT, MRI, and XR.

_________________________________________________________________________

_________________________________________________________________________

Which patients did not respond well whilst using or after using the NUBAX?

_________________________________________________________________________

_________________________________________________________________________

What was the level of compliance and did you utilise any particular method to measure this?

_________________________________________________________________________

_________________________________________________________________________
Were there any adverse events or exacerbation of symptoms whilst the NUBAX was being used as part of your treatment?

________________________________________________________________________________________________________________________________________

What other treatment modalities or exercises were utilised in conjunction with the NUBAX unit and at what stage was the Nubax introduced?

________________________________________________________________________________________________________________________________________

Please describe the characteristics of your patients pain and what indicators did you use to determine whether they would benefit from using the NUBAX?

________________________________________________________________________________________________________________________________________

Do you have any patients currently using the NUBAX?

________________________________________________________________________________________________________________________________________

If so, am I able to discuss the use of the NUBAX with them and any subjective feedback they may have on the quality of their pain, frequency of pain and overall effect on their quality of life or are you happy to forward or for me to forward a questionnaire on the use of the NUBAX to them individually?

Thankyou very much for your time and I look forward to working with you on developing the NUBAX as a useful treatment tool in the future.
Dear NUBAX user,

My name is Kirrily Pearce and I am currently completing my Master of Science Degree, which involves a study on the efficacy of the home traction unit – the NUBAX. You have previously written a testimonial on your experience in using this unit and how it assisted in your own pain management.

I have enclosed a questionnaire asking more in detail questions about your individual situation regarding pain, pathology and the effectiveness of the NUBAX for you. It would be much appreciated if you could complete this to assist in my studies and return the questionnaire to me in the self addressed stamped envelope provided.

Thankyou very much for taking the time to complete the questionnaire and if there is anything not covered you would like to discuss with me personally I would love to hear from you.

Kind regards

KIRRILY PEARCE
(Physiotherapist)
APPENDIX F

Letter To Participant

School of Human Movement and Exercise Science
The University of Western Australia
35 Stirling Highway, Crawley WA 6009
Phone +61 8 6488 2668
+61 8 6488 2361
Fax +61 8 6488 1039
Email tackland@cyllene.uwa.edu.au

10th April 2004

Dear NUBAX user,

My name is Kirrily Pearce and I am currently completing my Master of Science Degree, which involves a study on the efficacy of the home traction unit – the NUBAX. You have previously written a testimonial on your experience in using this unit with your patients and how it assisted in their recovery and pain management.

I have enclosed a questionnaire asking more in detail questions about your individual situation regarding pain, pathology and the effectiveness of the NUBAX for you. It would be much appreciated if you could complete this to assist in my studies and return the questionnaire to me in the self addressed stamped envelope provided.

Thankyou very much for taking the time to complete the questionnaire and if there is anything not covered you would like to discuss with me personally I would love to hear from you.

Kind regards

KIRRILY PEARCE
(Physiotherapist)
## APPENDIX G

### Nubax® Home Program Plan

<table>
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<tr>
<th>WEEK 1</th>
<th>WEEK 2</th>
<th>WEEK 3</th>
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<tbody>
<tr>
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</tr>
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</table>

<table>
<thead>
<tr>
<th>WEEK 4</th>
<th>WEEK 5</th>
<th>WEEK 6</th>
</tr>
</thead>
<tbody>
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<td>Day 6-am:</td>
<td>pm:</td>
<td>Day 6-am:</td>
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<tr>
<td>Day 7-am:</td>
<td>pm:</td>
<td>Day 7-am:</td>
</tr>
</tbody>
</table>

**Program Completed**
APPENDIX II

Treatment Efficacy Of The Nubax -Subject Information Sheet

Introduction
You have volunteered to participate in a groundbreaking study of the treatment efficacy of the NUBAX (a personal home traction unit) on chronic low back pain at the University of Western Australia. In this project we have analysed the amount of low back traction over a period of time in the NUBAX to gain the maximum benefit of distraction of the lumbar vertebrae. This is the protocol you will use as a subject in this study. As this is the first time this kind of study has been performed utilising the NUBAX we wish to have as many subjects with chronic low back pain participating to gain the most reliable data possible. Your willingness to participate is much appreciated.

Background: Why this Project is Important
Low back pain is regarded as one of the most common complaints amongst the general adult population from work related and sports-related injuries, to general degeneration with age and arthritis. Research shows that chronic low back pain is one of the most debilitating as far as reduced quality of life; functional ability and activity levels are concerned. It is also expensive to treat and often requires ongoing or long-term medication and treatment from various health professionals.

The NUBAX is a personal assistant home traction unit that is anticipated to assist in the self-management of chronic low back pain. There has been a significant amount of research on standard lumbar traction treatment performed for longer sessions at infrequent intervals. This study utilises a self-traction unit that is controlled over short periods of time (twice daily) in a neutral lumbar position. The NUBAX has been promoted around the world, however, no research has been completed on a protocol for its use and the types of pathologies it is effective for.

Project Aims
This project proposes a study of the treatment efficacy of the NUBAX on chronic low back pain. The aims of the project are:

1. To identify a protocol for use of the NUBAX i.e.: the length of time and frequency of use to attain and maintain good pain relief/management and improve quality of life.

2. To determine which underlying pathologies benefit the most from utilising the NUBAX in a self-management program in conjunction with core stability exercises.

Sample
In order to gain as much objective data concerning the effectiveness of the NUBAX with a variety of underlying low back pathology, it will be necessary to access a large number of patients from the Perth metropolitan area. We propose to test up to 50 subjects, who will be allocated randomly to a control or a treatment group for the initial three weeks of the study. Following this period half the treatment group will continue utilising the NUBAX for a further three weeks and the other half will crossover to the control group with the control group crossing over to a treatment group. All subjects must be over the age of 18 years.

Procedures
At the initial interview with the Physiotherapist, potential subjects will be determined, and provided with the information required to decide whether or not to participate in the study. Upon receipt of your informed consent, you will be allocated to either the control group, or the treatment group. Patients in both groups will receive standard Physiotherapy treatment consisting of low back massage and three home exercises, as well as be educated in the use of the NUBAX unit for the home-based portion of treatment.

The NUBAX treatment protocol requires you to use the machine for two 3-minute sessions per day. These will be once in the morning (approximately 15 minutes after getting out of bed), and again last thing before going to bed at night. Following the 6-week program all patients may continue with standard
Physiotherapy treatment with or without the NUBAX (upon consultation with your Physiotherapist). Any further treatment will be undertaken at your own expense.

All participants will have a review at the completion of each week to completion at six weeks. Each review will take approximately 30 minutes with your treating Physiotherapist and the costs will be borne by the research project. Patients who are assigned to the control group will have reviews at weeks 1,2 and 3, and then progress to the treatment group protocol from weeks 3-6, whereupon a final review will take place. Patients who are assigned to the treatment group will also have reviews at weeks 1,2 and 3 with half being allocated to a control group for the final three weeks and half continuing on as a treatment group. All subjects will continue to be reviewed weekly for the final three weeks, with the final review at the completion of week 6.

The following outcome measures will be recorded:

- Home use treatment compliance (you will be required to keep a daily NUBAX home use diary which will be provided to you).
- Standard test batteries to monitor incidence of pain, and improvements in physical function (these questionnaires will be conducted by your Physiotherapist prior to commencement, following week 3 and at the completion of week 6).
- Physical activity (you will be required to wear an activity monitor for three consecutive days (one weekend day and two week days) prior to participating in the study, after week 3 and at the completion of week 6).

**Your rights**

Your participation in this research is completely voluntary, and you may withdraw your consent at any time without prejudice. You need give no reason, nor justification for such a decision, and should this be your decision, any records pertaining to your involvement to date will be destroyed unless otherwise agreed by you.

Furthermore, your participation does not prejudice any right to compensation, which you may have under statute or common law. When you are fully satisfied with the scope of your involvement in this research, and have had any questions answered satisfactorily by the project investigators, please read and sign the attached consent form.

**Project Investigators**
Kirrily Pearce, Human Movement and Exercise Science,
A/Prof Tim Ackland, Human Movement and Exercise Science,
A/Prof Garry Allison, Human Movement and Exercise Science,
APPENDIX I

Treatment Efficacy Of The Nubax - Informed Consent

I ____________________________ (the participant), have read the information provided and any questions I have asked have been answered to my satisfaction. I agree to participate in this activity, realising I may withdraw at any time without reason and without prejudice.

I understand that all information provided is treated as strictly confidential and will not be released by the investigator unless required to by law. I have been advised as to what data is being collected, what the purpose is, and what will be performed with the data upon completion of the research.

I agree that research data gathered for the study may be published provided my name or other identifying information is not used.

__________________________ (Participant)  ____________ (Date)

__________________________ (Research coordinator)  ____________ (Date)

The Human Research Ethics Committee at the University of Western Australia requires that all participants are informed that, if they have any complaint regarding the manner, in which a research project is conducted, it may be given to the researcher or, alternatively to the Secretary, Human research Ethics Committee, Registrar’s Office, University of Western Australia, 35 Stirling Highway, Crawley, WA 6009 (telephone number 6488-3703). All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.
APPENDIX J
Advertisement

Chronic Back Pain FREE Treatment!

If you would like to participate in a University of Western Australia research study on chronic low back pain and meet the following criteria, please contact me on XXXXXX for further details. Treatments commence June 2004.

- Non-specific chronic low back pain – initial onset >3 months ago.
- Recurrences at least twice per year for long term sufferers that lead to time lost from work or significantly affects your ability to complete normal activities of daily living.
- Currently experiencing an exacerbation of your chronic low back pain or suffering ongoing daily chronic low back pain.
- No recent back surgery (last six months)
- No lumbar instability.
- Over 18 years of age.
- No referred lower limb pain
- Has not been pregnant in the last 12 months.
- No current Worker’s Compensation Claim.
- Currently having no other treatment other than medication.
- Can attend Physiotherapy in Kallaroo once/week for six weeks.
APPENDIX K

Excel Spreadsheet of Subject Data
APPENDIX L

Nubax Home Exercise Program

1. **Transversus Abdominus (deep abdominals) strengthening**
   Lie on your back with your knees comfortably bent. Concentrate on breathing at your own comfortable pace (diaphragmatic breathing) and maintain the breathing throughout all the exercises. Place your hands just inside your hipbones feeling your stomach below the belly button. Gently draw your belly button towards your spine (20% effort) and maintain this position as you breathe for 10 seconds. Repeat x 10.

   ![Transversus Abdominus Strengthening](image)

2. **Knee Rolls**
   In the same position as above. Hold your knees gently together and roll your knees from side to side within your pain limits. As you roll your knees to one side gently breathe out and as you bring your knees back to the middle gently breathe in. Try to maintain your belly button drawn in gently and your diaphragmatic breathing throughout. Repeat each side x 10

   ![Knee Rolls](image)

3. **Back extension exercises**
   Lying on your stomach resting your upper body on your elbows. Have your elbows directly underneath your shoulders gently drawing your shoulder blades down. In this position maintain your diaphragmatic breathing and practice gently drawing your belly button towards your spine without moving your back or upper body. Hold for 5 to 10 seconds and then gently release. Repeat x 10 then relax on your stomach for 1 minute before getting up and moving around again.

   ![Back Extension Exercises](image)

APPENDIX M
**Assessment Form**

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- Ease
- ADL/Sport/Hobbies
- Medication
- Cough
- Investigations

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APPENDIX N

Testimonial

Please provide a written testimonial documenting your involvement in the NUBAX study covering your views on the following:
- length of the study
- requirements of the study
- use of the control unit if applicable
- use of the treatment NUBAX
- participation in the home exercises
- any modifications you feel may benefit future participants
- how your quality of life and pain management was affected during the time period of the study
- please document your work hours/days and the busiest days/times each week for comparison with the activity monitor data
APPENDIX O

Ethical Approval