The effect of differing clinical settings on chiropractic patients suffering from Mechanical Low Back Pain.

By

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I, Grant Walter Richardson, do declare that this dissertation is representative of my own work in both conception and execution.

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DEDICATION

I dedicate this work to all those people who helped me and encouraged me on this journey.

My parents who without their sacrifice, support and encouragement I would have not completed my studies.

To my friends who have helped and inspired me during those times where there did not seem to be a light at the end of the tunnel.
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ABSTRACT

Each healing encounter, and every treatment, has specific and non-specific treatment effects. Non – specific effects, or placebo effects, are the benefits felt by the patients because of the nature of the healing encounter. Although difficult to quantify and control, a number of authors recognize that the non-specific component of management has an additive effect on the overall clinical outcome. It has been reported that due to the physical interaction and social nature of chiropractic, there is a strong non-specific component in the management process, but to what extent it facilitates in the healing encounter is unknown. It has also been shown that spinal manipulation has a clinical effect which exceeds that of placebo; therefore it is possible for its effect to be muted or amplified, depending on the presence or absence of non-specific effects. For the above reasons this study was conducted in an attempt to map the size of the non-specific effect in the healing encounter by manipulating the practice setting in which the patients were treated.

This was achieved using a prospective, randomised, comparative clinical experiment consisting of 60 individuals with Low Back Pain (LBP), selected by convenience sampling. Individuals were then divided into 2 groups of 30. The first group's treatment consisted of the standard diversified method of manipulation in a Clinical Research Setting, and the second group received the same treatment except the treatment took place in a Normal Practice Setting.

Both groups received a maximum of 4 treatments over a two-week period, or until pain free with full range of motion. Subjective data was collected on the 1st, 2nd, 3rd and 4th consultations in the form of a Numerical Pain rating Scale, Oswestry Back Disability Index, and Orthopaedic Pain Rating Scale.

Data was imported into and analysed with SPSS version 11.5 (SPSS Inc, Chicago, Ill, USA). Baseline comparisons between the randomised groups were done with chi-square or Fisher's exact tests in the case of categorical or binary variables, and student's independent t-tests in the case of quantitative variables. Repeated measures ANOVA were used to assess the within subjects effect of time in the intra-group analysis and time by group interaction effect (treatment effect) for quantitative outcomes over 4 time points for the inter-group analysis. Pearson's correlation analysis was done on the changes in the outcomes over time within the groups. A p value of <0.05 was considered as statistically significant.

While both treatment settings were effective at reducing self reported pain according to the Numerical Pain Rating Scale (NRS), Orthopedic Pain Rating Scale (OPRS) and Oswestry Back Disability Index (OBDI) in patients with mechanical low back pain, the normal practice setting was the most effective since the rate of improvement was significantly greater for all outcomes tested.

It has been well established in this and many other research studies that chiropractic treatment has a significant effect on reducing mechanical low back pain. What was significantly shown in this study was that the setting in which the patients were treated affects the outcome of the treatment. Patients treated in a normal practice setting showed significant improvement over those treated in a clinical research setting.

The difference between the two settings is called the non-specific component. The non-specific component was reduced as much as possible in the clinical research setting group and increased in the normal practice setting group and the difference noted between these two settings was labelled the non-specific effect. By the end of the 4th treatment the normal practice setting group showed a 100% improvement as opposed to the clinical research setting group, which showed an 80% improvement with 20% of the patients' still requiring further treatment. In both groups the same treatments were given and the only difference was the setting in which the patient had been treated. Thus the difference in the rate of improvement between the two groups can be attributed to the non-specific effect.

The non-specific effect can affect the rate of patient improvement by up to 20 % when comparing a clinical research setting to a normal practice setting. This is a significant finding which can help the profession grow, develop and improve.

CONTENTS

TABLE OF CONTENTS

LIST OF APPENDICES

LIST OF FIGURES

LIST OF TABLES

GLOSSARY

ANOVA:

Analysis of variants between groups is used to test hypothesis about differences between two or more means.

Chi square Goodness:

This test is used to test if a sample of data comes from a population with a specific distribution.

Partial Correlation:

Partial correlation is the correlation of two variables while controlling for a third or more other variables.

Pearson's Correlation Analysis:

The linear relationship / correlation between two variables that reflect the degree to which the variables are related (-1 < 0 > 1) (SPSS (version 9) software suite).

Univariate ANOVA:

Univariate ANOVA patricians the variances into that caused by differences within groups and that caused by differences between groups, and then compares the ratio.

Wilk's Lambda:

Wilk's Lambda is a Statistic that examined intra-person variation in time and time by group interaction. The following is quoted from the help section in SPSS (version 9): "Lambda ranges between 0 and 1, with values close to 0 indicating the group means are different and values close to 1 indicating the group means are not different (equal to 1 indicates all means are the same)."

CHAPTER ONE:

INTRODUCTION

1.1 THE PROBLEM AND ITS SETTING

In every healing encounter, and every treatment, there are specific and non-specific treatment effects. Specific effects are due to the therapeutic action(s) of the modality (ies) applied. Non – specific effects, or placebo effects, are the benefits felt by the patients because of the nature of the healing encounter (Jamison 1998 b).

It has been reported that due to the physical interaction and social nature of chiropractic, there is a strong non-specific component in the management process, but to what extent it facilitates in the healing encounter is unknown (Jamison 1998 a).

Although difficult to quantify and control, a number of authors, recognise that the non-specific component of management has an additive effect on the overall clinical outcome (Jamison 1998 b, Triano 2001, Posner and Glew 2002). Therefore this non-specific effect is being recognised as a clinical intervention that does not act directly through known body mechanisms but may work through the mind (DeDeyn and Hooge 1996). For example, psychoemotional factors are known to influence the presentation and clinical outcome of patients with low back pain (Vernon 1991).

It has also been shown that spinal manipulation has a clinical effect, which exceeds that of placebo (Triano 2001). It is possible for its effect to be muted or amplified, depending on the presence or absence of non-specific effects.

Due to the above, an argument was made to conduct a study attempting to map the size of the non-specific effect of the healing encounter by manipulating some of the social factors prevalent, as previous studies have mapped behavioural aspects, this study concentrated on the practice setting.

1.2 AIM/ PURPOSE OF THE STUDY

1.2.1 To evaluate the differences between a clinical research setting and a normal practice setting by means of a participant observation study in order to be able to reproduce these settings for the purpose of the study.

Hypothesis one: there are no significant differences between the normal practice setting found in the field and that of the clinical research setting found in the Durban University of Technology Chiropractic Day Clinic (D.U.T.C.D.C.) as seen in the participant observation study.

1.2.2 To evaluate the non-specific effect of chiropractic treatment by comparing a normal practice setting versus a regimental clinical trial setting during the management of mechanical low back pain through objective clinical outcomes.

Hypothesis two: There is no relationship between each treatment in a specific group and the subjective clinical findings

1.2.3 To establish the characteristics of a private practice environment and a clinical trial practice environment by means of participant observation of both practice settings.

Hypothesis three: There is no relationship between each group and the subjective clinical findings.

1.2.4. To measure the relative effect of a controlled clinical setting versus an un-controlled setting for the management of mechanical low back pain through subjective clinical measures.

Hypothesis four: There is no relationship between the non-specific effect and the subjective clinical finding of each group.

1.2.5. To attempt to map the size of the non-specific effect from subjective data collected from each setting.

1.3 RATIONALE FOR THE STUDY AND RESEARCH QUESTIONS

1.3.1 Manual therapy has an element of placebo due to the nature of the intervention.

1.3.2 Placebo is also termed a non-specific treatment effect. Factors (Jamison 1998 b), which generate non-specific effects in chiropractic practice, are (Chapman- Smith 1995):

- For chiropractors to appear confident and enthusiastic.
- For chiropractors to create a healing setting and ritual.
- To emphasise manual contact and low technology in diagnosis and treatment.
- Through information and advice to give patients confidence, expectation of success and a new sense of control over their problems.

1.3.3 The assumption under which researchers have practiced traditionally is that non-specific effects (placebo) are limited in a controlled research setting. Therefore management protocols tested in a normal practice, rather than a clinical research setting have historically been viewed with an element of suspicion due to the presence of extraneous variables (As seen in Appendix I) capable of inflating the apparent effectiveness of these interventions.

1.3.4 Therefore in determining the overall clinical effect that manual therapy (SMT) has, it would seem appropriate to establish the size of the non-specific effect if they are present.

1.4 ASSUMPTIONS

1.4.1 The researcher was assumed to be a constant in terms of personality; however, some behavioural characteristics will be altered to create a more informal environment in the clinical setting and a more formal environment in the 'research setting'.

1.4.2 There are indications that the non-specific effect was enhanced as the practitioner gains confidence and experience, therefore the total effect is expected to be smaller due to the relative inexperience of the practitioner (Jamison 1997).

1.5 BENEFITS

1.5.1 To be able to quantify the non-specific component in chiropractic treatment

1.5.2 To know how the non-specific component affects chiropractic treatment.

1.5.3 To give us a better approach to patient care in the future.

1.5.4 To know how you as a practitioner can affect your patients outcome due to the approach you took.

1.5.5 To build a bigger body of knowledge about the non-specific aspect of chiropractic treatment.

1.6 LIMITATIONS OF THE STUDY

1.6.1 This study was conducted in an educational environment and although every attempt was made to simulate the characteristics of a private setting, this was not fully possible, due to medico-legal constraints.

1.7 CONCLUSION

The forthcoming chapters deal with the literature related to mechanical lower back pain as well as the non- specific effect in chiropractic treatment. It also deals with the study design, how the participants we selected and the clinical procedure that was followed. The interventions, data collection, and statistical analysis are also dealt with, concluding with the recommendations and conclusion of the study.

CHAPTER TWO:

REVIEW OF RELATED LITERATURE

2.0 INTRODUCTION

This chapter is concerned with the available literature on participant observation, the non-specific effect in chiropractic treatment, as well as the classification, diagnosis and treatment of Low Back Pain.

2.1 THE NON-SPECIFIC EFFECT IN CHIROPRACTIC TREATMENT

The term Non-specific effect and Placebo effects are two terms, which can be used interchangeably (Jamison 1998 b). The clinical improvement of patients may be attributed to any combination of regression to the mean, a placebo or a specific therapeutic effect. Of these the placebo is being more and more recognised as a clinical intervention that does not work through known bodily mechanisms but instead works through the mind (De Deyn and Hooge 1996). The thinking these days is that the placebo's role is changing from that of a control which adjusted for confounding variables to one of a useful non-specific treatment effects (White, Tursky and Schwartz 1985). Current definitions of placebo include two fundamental characteristics, namely: (a) being present in all therapeutic encounters and (b) having a non-specific effect.

In general practice the placebo effect is the power of the doctor alone to make the patient feel better, irrespective of medications. It is one of the most important factors in the consultation, yet generally it is neglected, unrecognised, and untaught (Thomas 1994). In every healing encounter, and with every treatment, there are specific and non-specific treatment effects. An example of this would be in back and leg pain; disc surgery removes part of the herniated disc relieving nerve root pressure, an analgesic drug modifies pain perception, and a chiropractic spinal adjustment restores range of joint motion and decreases nerve entrapment and irritation. These are specific treatment effects (Chapman- Smith 1995).

Non-specific effects, or placebo effects, are the benefits felt by the patient because of the nature of the healing encounter - the drama of surgery, the magic potency of pills, the reassurance of the laying on of hands, the definitive 'pop' of the chiropractic adjustment and the presence of a confident health professional (Chapman- Smith 1995).

Specific and non-specific treatment effects are often interactive (synergistic or antagonistic), with one enhancing or minimizing the other (Chapman- Smith 1995).

It is the interactions between the physician and the patient that can be extremely influential in patient outcomes and, in some (perhaps many) cases, patient and provider expectations and interactions may be more important than specific treatments (Vernon 1991). There is increasing scientific evidence confirming that expectations are as important as non-specific triggers influencing clinical outcomes. Research (Jamison 2004) has shown that verbally induced expectations of pain relief can reduce the amount of analgesia requested, alter the anatomical area in which relief is experienced and modify various psychological and

physiological parameters. As expectations are determined more by perception than reality, placebo-induced analgesia has the potential to contribute to the outcome of every chiropractic clinical encounter. Therefore the contribution of the placebo response to chiropractic care should ideally be maximized in every clinical encounter and acknowledged in chiropractic education (Jamison 2004).

Thus the placebo / non-specific effect has been reformulated as non-specific therapeutic intervention. The placebo, instead of being used as a control, is reconstructed as a valid, albeit non-specific treatment. Within this new paradigm, placebo is recognised as a “medicine” which does not act directly through known bodily mechanisms but which may work through the mind (DeDeyn and Hooge 1996). Non-specific chiropractic intervention may be undertaken at the physical, chemical and psychoemotional level (Coulehan 1991). As a result a number of psychological triggers have been identified which affect the non-specific component in treatment? It has also been noted that due to the nature of chiropractic practice being very physical and social there is the use of psychological wellness triggers, which enhance non-specific therapy outcomes but to what extent it facilitates in the healing encounter is unknown (Jamison 1997 and Jamison 1998 a).

The aforementioned wellness triggers can be placed in 4 distinct categories (Jamison 1998 a), which are further elaborated on in Table A, (pg 10):

1. A healing setting
2. A healing ritual
3. A positive outcome expectation
4. A positive efficacy expectation

NON–SPECIFIC THERAPY: A Checklist of Psychological Triggers	
Aim: To enhance non – specific therapy outcomes **Objective:** To employ psychological triggers in chiropractic clinical practice	
WELLNESS TRIGGER	**IMPLEMENTATION STRATEGY**
1. A healing setting	A comfortable waiting room A welcoming receptionist An approachable, caring practitioner
2. A healing ritual	A comprehensive analysis of the presenting problem, including: ▪ Validation of the problem ▪ An understandable explanation for the problem ▪ An acceptable explanation of how a chiropractor can help
3. A positive outcome expectation (emotional coping)	Change the outlook for the illness by: ▪ A strong practitioner conviction that chiropractic intervention is effective for the presenting problem ▪ The patients experiencing a somatic change following chiropractic examination and/or adjustment ▪ Accurate prediction of outcome (nature and time-frame) e.g. early muscle soreness, reduced pain, improved mobility
4. A positive efficacy expectation (task – orientated coping)	An enhanced sense of coping attributable to patients: ▪ Participating in establishing clinical reality ▪ Actively selecting chiropractic care as a strategy for addressing the problem ▪ Implementing self- care measures, e.g.: stretches, exercise, and or postural corrections which prevent or delay recurrences and enhance healing ▪ Self- monitoring functional changes and seeking professional intervention early

Table A (Jamison 1998 a). This model was used as a framework in the participant observation study in order to define the two types of settings.

Wellness triggers 1 & 2 in particular may incorporate everything from the set up of your waiting room right through to the way you assess your patient, diagnose and explain the condition to your patient.

The information patients are given regarding their conditions, content and form is reported by them as being a strong point in the chiropractic encounter. Patients are typically given an explanation in a context they can understand which meets patient expectations. Explanations are often supplemented by visual aids such as models, charts and radiographs which assist understanding and serve as conditioning stimuli which can promote placebo response. (Depending upon the patient's previous experiences other objects such as white coats; stethoscopes and x-ray machines may have a positive or negative effect on placebo response) (Chapman-Smith 1995).

Chiropractic practice also involves "the laying on of hands," both in examination and treatment, and this is generally regarded as having stronger non-specific effects than medication, machines or surgery. In addition the actual adjustment or manipulation typically produces a 'pop' or audible release. To most patients this provides obvious and tangible evidence of value. Something that was previously 'out' is now 'in'. (The noise is, however a sign of the collapse of a nitrogen gas bubble released from the synovial joint during gapping) (Chapman-Smith 1995).

Factors that may negatively influence the non-specific effect are: the Hawthorne effect and the White collar effect.

- Hawthorne effect is an experimental effect in the direction expected but not for the reason expected; i.e. a significant positive effect that turns out to have no causal basis

in the theoretical motivation for the intervention, but is apparently due to the effect on the participants of knowing themselves to be studied in connection with the outcomes measured (Mayo 1933).

- The White Coat Effect may be described in the following analogy: The variability of blood pressure (BP) during a doctor's measurement is referred to as the "white coat" effect. It has been observed in both normotensive and in hypertensive patients (Le Pailleur, et al. 2001).

It has been noted through participant observation that these wellness triggers differ vastly between a clinical research setting and a normal practice setting in the field (see Appendix J). Therefore it seems possible that the non-specific effect may vary from the pragmatic setting to the controlled research setting as encounted during the conducting of controlled clinical trials (Jamison 1998 a).

Therefore to generate non-specific effects and enhance the specific effects of treatment in chiropractic practice, it is important for chiropractors to appear confident and enthusiastic, to emphasise manual contact and low technology in diagnosis and treatment, and through information and advice and otherwise to give patients confidence, expectation of success and a new sense of control over their problems.

Therefore if these non-specific effects are to be captured in a chiropractic trial it would imply that it is ultimately wrong to test a given series of manipulations in a prescribed manner in a setting unlike practice - without office ambience, without patient education, prescription of

exercises and monitoring of these exercises and advice on follow-up visits, and forbidding variation in technique and site of treatment as dictated by the physical diagnosis.

In a British study demonstrating the importance of confidence, 34 200 patients reporting to a general medical practice with a variety of complaints (cough, sore throat, back pain, fatigue, headache etc.), were divided into two groups. One received what was termed a 'positive consultation.' This consisted of giving the patients a firm diagnosis and reassurance that they would recover in a few days. The other group received a 'non-positive consultation.' No firm diagnosis or reassurance was given. Patients in each group were then either given a 'treatment', which was actually a placebo pill, or no treatment. Thus, there were a total of four different groups (Chapman- Smith 1995).

The researchers discovered that it made very little difference whether or not a 'treatment' was administered. Two weeks after the initial consultation 50% of those not treated showed improvement compared to 53% of those who were treated. However the kind of consultation they received made a big difference - 64% of those receiving a positive consultation reported improvement compared to 39% of those who received a non-positive consultation. This study therefore suggests that the personal attributes of the clinician have a bigger impact on placebo effects than the therapy provided. The attitude of the doctor was more important than the presence or absence of a pill. For a chiropractor, attitude is more important than the intervention of manual treatment (Chapman- Smith 1995).

The British Medical Research Council trial of chiropractic was designed to be pragmatic in this way, combining specific and non-specific effects. The maximum number of treatments was

fixed but beyond that treating practitioners managed patients as they would normally in their own clinics. In this trial patients with acute and chronic mechanical low back pain were found to achieve much better results under chiropractic care than medical and physiotherapy care in hospital out- patient clinics (Chapman-Smith 1995).

The elements of chiropractic practice that encourage these non-specific benefits and which should be used by a chiropractor to enhance his treatment are:

- Confidence and Commitment
- Information and Advice
- The Laying on of Hands

These elements were identified on the basis of practice observation and evaluation, and patient studies (Chapman-Smith 1995).

From the foregoing mentioned, perhaps the most influential and remarkable aspect of most chiropractic encounters is the practitioner's commitment to chiropractic philosophy or theory. This is an important source of non-specific effects for several reasons - the chiropractor is more comfortable and confident, there is a real cause (subluxation) amenable to a tangible treatment (adjustment), there is a plan of treatment rather than "let’s wait and see", and these factors give the patient confidence and expectation of success - especially if the problem was previously dealt with ineffectively by another practitioner.

As Shapiro et al. (1954) explains, commitment to a treatment approach also tends to make a clinician more tolerant of the patient’s idiosyncrasies. The patient is accepted without criticism or

rejection. As an additional bonus, the commitment directed towards the patient is often interpreted as interest in them.

Chiropractors must also, "learn to harness and drive the powerful tool of the placebo response." If a chiropractor, or anyone else providing a form of manual therapy, "is knowledgeable about the procedures employed, is confident, and above all comes in close contact with the patient, success of almost any treatment occurs in 30-50% of patients." (Chapman-Smith 1995).

Discourse on manipulation usually raises the question of placebo effect. A frequent observation is that chiropractic patients are more satisfied by their treatment experience than when they are attended by other providers. A number of elements are thought to contribute to this popular contentment, including physician-patient interaction. Manipulation treatment often requires several encounters involving physical contact and direct physician attention over a focused time interval.

These results suggest that physician attention, in any form, appears to benefit patients with back pain. The data also show that, at least for thrusting techniques of manipulation, there is a treatment-specific advantage beyond the non-specific effects. Attributing patient response and satisfaction from health care encounters with manipulation to placebo alone is unjustifiable based on the clinical data (Triano 2001). The placebo effect is thus a part of the response in every doctor-patient encounter. So what? The question is: "Does the clinical affect exceed that of placebo?" In the case of spinal manipulation, that answer is "Yes." (Triano 2001)

Thus it stands to reason that the non-specific therapy should be an inherent component of every clinical encounter. While further research into the use of specific adjustments and manual techniques remains important for the future development of chiropractic clinical practice, failure to recognise, maintain and enhance the particular elements of non-specific intervention in chiropractic care may ultimately impoverish the profession (Jamison 1998 a). To ensure that chiropractic remains the leader in this area of health care, knowledge and understanding of wellness triggers and the non-specific effect need to be researched and put into practice as they form a vital part of chiropractic care.

This argument is based on the fact that a number of authors agree that the non-specific component of management has an additive effect on the overall clinical outcome (Jamison 1998 b, Triano 2001, Posner and Glew 2002). Both specific and non-specific treatments are interactive (synergistic or antagonistic), with one enhancing or minimising the other. This means that research should not always separate and exclude placebo effects. Treatment effects should be assessed more pragmatically, comparing one treatment to another in their own optimum settings of non-specific factors (Kleijnen and deCraen 1994). For example in a chiropractic trial this means that it is ultimately wrong to test a given series of manipulations in a prescribed manner in a setting unlike that of a private practice. That is, without office ambience, without patient education, prescription of exercises and monitoring of these exercises and advice on follow-up visits, and forbidding variation in technique and site of treatment as dictated by physical diagnosis (Chapman- Smith 1995).

2.2 LOW BACK PAIN

2.2.1 Definition

Low back pain is pain, muscle tension, or stiffness localised below the costal margin and above the inferior gluteal folds, with or without leg pain (sciatica), and is defined as acute when it persists for less than 12 weeks (Van Tulder et al. 1997). Non-specific low back pain is low back pain not attributed to a recognizable pathology (such as infection, tumour, osteoporosis, rheumatoid arthritis, fracture, or inflammation) (Van Tulder et al. 1997).

2.2.2 Prevalence of Low Back Pain

In the United States, approximately 90 % of adults experience back- pain at some time in life, and 50 % of persons in the working population have back pain every year. As many as 90 percent of patients with acute back pain return to work within three months, but many experience symptom recurrence and functional limitations (Patel and Ogle 2000).

2.2.3 Classification of Low Back Pain

In primary care practice, the specific anatomic cause of back pain is often impossible to define, and only a small percentage of patients have an identifiable underlying cause. Fewer than 2 % of patients have disc herniation. Even fewer have a life-threatening disease. Most patients with acute low back pain improve with conservative management and do not require immediate diagnostic studies (Patel and Ogle 2000).

A comprehensive history and physical examination can identify the small percentage of patients with serious conditions that require immediate further evaluation. Kirkaldy-Willis and Burton (1992: 105) utilise a three-phase classification of LBP, within which three degenerative processes are described, namely: dysfunction, instability and stabilization.

The three phases of classification are then broken up into specific lesions, namely:

- Dysfunctional Phase: Posterior Facet Syndrome, Sacroiliac Syndrome, Maignes Syndrome, Myofascial Pain Syndrome and Disc Herniation.
- Instability Phase: Facet and disc degeneration, lateral stenosis, central stenosis, disc herniation.
- Stabilization Phase: Lateral stenosis, central stenosis, multilevel stenosis, disc herniation.

This classification allows for a more structured understanding of the mechanical and pathophysiological process of each clinical lesion (Kirkaldy-Willis and Burton 1992: 121).

2.2.3 Presentation of Low Back Pain

The presentation of the Dysfunctional Phase (Posterior facet syndrome, Sacroiliac Syndrome) Low Back -Pain lesions are as follows:

2.2.4.1 <u>The typical symptoms of Posterior Facet Syndrome present as follows:</u>

Pain is often localized and unilateral. Pain maybe referred to the groin, greater trochanter, and to the posterior thigh as far as the knee (Kirkaldy-Willis and Burton 1992: 106).

2.2.4.2 The associated clinical signs are:

Tenderness to pressure on one side, at one level, and hypertonic muscles at the sight of the lesion (Kirkaldy-Willis and Burton 1992: 106). Hyperextension movements of the back increase the pain, whereas flexion reduces it. Activities that may increase the pain include sleeping on the abdomen, sitting in an upright position, lifting a load in front of the body at or above the waistline. When symptoms are acute, sneezing and coughing may accentuate the pain (Gatterman 1995: 162).

2.2.4.3 The typical symptoms of Sacroiliac Syndrome include:

Pain over the posterior aspect of the sacroiliac joint that varies in its degree of severity; referred pain in the groin, over the greater trochanter, down the back of the thigh to the knee, and occasionally down the lateral or posterior calf to the ankle, foot, and toes (Kirkaldy-Willis and Burton 1992: 124).

2.2.4.4 The associated clinical signs include:

Tenderness over the posterior superior iliac spine in the region of the sacroiliac joint. Movement of the joint is restricted. The diagnosis of the Sacroiliac Syndrome is confirmed by positive Faber Patrick test, Gaenslen's test and Extension test or Yeoman’s test (Kirkaldy-Willis and Burton 1992: 124). According to Aprill (1992), sacroiliac joint dysfunction appears to be an overlooked condition, which is not even considered a possibility by many clinicians involved in the diagnosis and treatment of patients with mechanical LBP. A survey by Aprill (1992) revealed that 25 % - 30 % of non-specific back

pain patients have symptomatic sacroiliac dysfunction in conjunction with other defined lesions (symptomatic annular fissure and symptomatic zygopophyseal joint dysfunction).

According to Giles et al. (1997), the effect of joint dysfunction on associated soft tissue structure, with possible venous stasis, nerve ischaemia, and soft tissue entrapment has been postulated as a potential mechanism for causing back pain of mechanical origin.

2.2.5 Diagnosis of Low Back Pain

The diagnosis of Low Back Pain (LBP) is very subjective as the doctor relies on the patient's responses to specific diagnostic tests given. The diagnosis relies on the positive results to a collection of Orthopaedic tests combined with characteristic history of low back pain which is free of "red flags".

The two lesions that we were concerned with in this study are Posterior facet Syndrome and Sacroiliac Syndrome. These two lesions are diagnosed through certain orthopaedic tests combined with a history of LBP.

2.2.5.1 <u>The specific tests for Lumbar Facet Syndrome (LFS) include:</u> Kemp's Test (Corrigan and Maitland 1998: 35), facet joint challenge, hyperextension in prone position (Gatterman 1990: 84 and 162), and a palpable muscle spasm with focal tenderness over the facet joints (Helbig and Casey 1988: 61- 64).

2.2.5.2 The specific tests for Sacroiliac Syndrome (SIS) include: Posterior shear or "Thigh thrust test" (Laslett and Williams 1994: 1244), Patrick Faber test (Broadhurst and Bond 1998: 342), Gaenslen's test (Magee 1992: 319) and Yeoman's test (Magee 1992: 320)

2.2.6 Treatment Of Low Back Pain

Patients with acute or chronic back pain frequently seek chiropractic intervention as opposed to traditional medical treatment (physiotherapy, drug therapy, surgery). The Agency for Healthcare Research and Quality (AHRQ), previously the Agency for Health Care Policy and Research (AHCPR), and the Clinical Standards Advisory Group acknowledge the potential value of a short course of spinal manipulation in patients with acute low back pain (Patel and Ogle 2000).

Manual therapy has shown to be one of the most successful treatment protocols for mechanical LBP (Assendelft et al. 1992). In A study by Ingeborg (2003) the manual therapy group showed a faster improvement than the physiotherapy group and the general practitioner care group up to 26 weeks, but differences were negligible by follow up at 52 weeks. The total costs of manual therapy (€447; £273; $402) were around one third of the costs of physiotherapy (€1297) and general practitioner care (€1379).

In 1994 the Agency for Health Care Policy and Research published Clinical Practice Guideline 14-Acute Low Back Problems in Adults (Bigos et al. 1992). The guideline defined acute low-back pain, evaluated various treatments, and made recommendations concerning the efficacy of those treatments. According to the Guideline, spinal manipulation is one of the safest and

effective treatments for most cases of acute low-back pain. In addition it has also been stated that spinal manipulation offers both pain relief and functional improvement" (Micozzi 1998:65).

Shekelle et al. (1991) stated that doctors of medicine and doctors of chiropractic from RAND, UCLA Schools of Medicine and Public Health, and other research organizations, conducted a literature review of 25 controlled trials and a meta-analysis of nine studies addressing chiropractic treatment of low-back pain. The literature review was published in the Annals of Internal Medicine and concluded, "Spinal manipulation hastens recovery from acute uncomplicated low-back pain".

Similarly in a critical review of related literature Di Fabio (1992) found 11 well–designed studies demonstrating the efficacy of manipulation in treating LBP. These studies showed particularly good symptomatic short-term relief of pain, and improvements in pain, flexibility, disability and ability status in the patient.

Clinical outcome studies consistently reported that manual therapy (SMT) is associated with higher patient satisfaction than other physical therapy methods. This suggests that manual therapy may have advantageous non-specific effects (Placebo effects) not shared by other types of physical therapy (Posner and Glew 2002).

2.3 RESEARCH METHODS FOR INTERVENTION STUDIES IN CHIROPRACTIC RESEARCH

Chiropractic research to date has focused on the testing of its specific treatments in order to prove its credibility. To do this researchers have focused on particular types of research studies. E.g. (Table B)

Types of Studies (From Rosner 1997) (Table B)	
Anecdotes	Recollection of case responses, lacking the details of a case report.
Case Report	Report on a single case.
Case Series	Report on a group of cases.
Single-Subject Time Series	Following the response of one case over time.
Cross-Sectional Study	Study of all subjects done at one point in time.
Retrospective (Case Control Study)	Study done after treatment (on many cases).
Cohort Study	Defined treatment to one group; no control
Randomized Clinical Trial	Defined treatment to one group, placebo or sham to a second (control); subjects randomly assigned to treatment or placebo.

These types of studies / publications follow the medical model, the gold standard being the randomized clinical trial (RCT). This is the classic design that involves two or more groups. One of which being a control group, thus making it experimental. RCT's also incorporate some kind of random assignment of patients to the groups. Randomization does two things; it first eliminates the bias on the part of the study coordinator, and secondly a random assortment is

more likely to place matching patients into different groups. Another issue in RCT's is the choice of "control" or sham care. The principle reason for the control group is to show that the particular drug or adjustment was the cause of any changes seen in the treatment group (Rosner 1997).

Unfortunately RCT's are almost always carried out in research institution settings which are nothing like a normal practice setting and the patients tend to be of a special class, complaining of only the condition being investigated. Again this is nothing like a normal practice setting (Rosner 1997). Chiropractic is also a very "hands on" type of practice and that alone according to the literature previously discussed, can have affects on patient outcome (Vernon 1991).

Thus in order to fully understand and study chiropractic, the practice as a whole needs

- To be researched separate from the techniques,
- Have the patient doctor interactions researched and
- To have the environment in which it occurs researched.

Hence Jamison's (1998 a) model (Table A pg 10) was used as a means to focus this type of investigation.

2.4 PARTICIPANT OBSERVATION

In this study two types of practice settings are being compared, and how they affect the outcome of our patients. The clinical research setting has been developed for the purpose of creating an environment in which clinical trials can be conducted. This type of setting is

designed to eliminate all types of bias and non-specific effects, testing only the treatment being given and not the environment and the interactions involved.

On the converse, a normal practice setting is uncharted territory and varies in each practice; nevertheless basic elements form a common / fundamental structure in each private practice.

Due to the need to standardize both settings, a research method needed to be employed in order to capture and define those two settings. According to Denzin the best known method to capture a setting and its interactions is through participant observation (Denzin 1989).

Participant Observation is the most popular and widely used research methods to do this. Denzin (1989) defines participant observation as a research "strategy that simultaneously combines document analysis, interviewing of respondents and informants, direct participation and observation, and introspection" (Denzin 1989: 158). When engaged in participant observation, the researcher collects information in and about a specific social location - an organization, office group, neighbourhood, school, club, etc. Some scholars use the term "ethnography" to describe the product or results of what Denzin (1989) and others label participant observation. In other words, the scholar’s access and data collection is termed participant observation, while the outcome is often called ethnography. Van Maanen (1988:1) defines ethnography as a "written representation of a culture (or selected aspects of a culture)".

2.6 CONCLUSION

The literature review reveals that the non-specific aspect of chiropractic treatment is a vital component needed to increase our treatment success; however the size or contribution is unknown. The literature suggested that it would be vital to better understand and quantify this component of treatment. With regards to Chiropractic treatment one of the most common conditions treated is low back pain and this is treated extremely successfully with chiropractic care.

Chiropractic care normally consists of manual therapy made up of soft tissue adjustment and chiropractic adjustments. The question that the literature was moving towards was: “Could this type of treatment be improved by adding to or improving on its components, namely the non-specific component?”

In the literature the non-specific component is also made up of many components one of which being the setting in which patients are treated in. The literature shows that patients treated in a positive setting respond better to treatment than those in a negative setting. It has been noted in an observation study that a normal practice setting is vastly different to that of a clinical research setting and may have an effect on the treatment outcome.

Therefore a study was needed to highlight the differences between the two practice settings, to measure the relative effect and map the size of the non-specific effect of chiropractic treatment in low back pain.

CHAPTER THREE:

MATERIAL AND METHODS

3.1 INTRODUCTION

This chapter deals with the participant observation, measurements and observations, study design, deception tactics, sampling of patients, procedure and statistical analysis.

3.2 PARTICIPANT OBSERVATION STUDY

Before the study could be done a participant observation study needed to be completed. The aim of the participant observation was to identify the differences between the clinical research setting, present in the D.U.T.C.D.C., and the normal practice setting present out in the field.

3.2.1. Procedure

The participant observation study was conducted in three different practices over a 3-day period. A total of 16 patient's treatments were seen of which 6 were initial appointments and the rest were follow-up appointments. Notes were compiled on the set up of the private practices as well as the way in which the practitioner interacted and examined and treated the patients (Appendix O).

3.2.2. Outcome

It was found that the two settings were vastly different in all respects. These findings can be found in Appendix I.

3.3 MEASUREMENTS AND OBSERVATIONS

3.3.1 The Data

The data consisted of both primary and secondary data.

3.3.2 The Primary Data

The primary data consisted of the following:

- Numerical Pain Rating Scale (Appendix B)
- Oswestry Back Pain and Disability Index (Appendix C)
- Orthopedic Pain Rating Scale (Appendix A)

Outcome measure	Independent variable
Numerical Pain Rating Scale-101	Global Subjective Pain Rating by Patients
Oswestry Back Disability Index	Global Subjective Disability Rating by Patients
Orthopedic Pain Rating Scale	Global Subjective Pain Rating by Practitioner

(Table C)

3.3.3 The Secondary Data

The secondary data was obtained from various sources: journal articles, textbooks, periodicals and medical search engines on the Internet (Pubmed, Mantis, Medscape and Medline).

3.4 STUDY DESIGN

The study was a prospective, randomised, comparative clinical experiment, involving two treatment groups. The first group (Group 1) received manual manipulation of the affected low back region using the diversified technique of manipulation in a simulated research orientated clinical environment at the D.U.T.C.D.C. The second group (Group 2) received manual manipulation of the affected low back region using diversified technique of manipulation in a simulated private practice type environment at the D.U.T.C.D.C. This approach was used because in general: for testing possible factors of influence with respect to their effect on target parameters, there is no alternative to the experimental study, and an indispensable part of it is the technique is randomization (Dannehl, 1997).

3.5 DECEPTION TACTICS

Two deceptions took take place in order to maintain the integrity of this study. This was vital in order to create the different treatment context. In no way did these deceptions harm or directly affect the patients. Both groups were given identical treatments as it was only the

setting in which they were treated which was different through the use of the deception tactics. Specifically:

3.5.1. Group 1 patients were supplied with an information letter stating that different adjustive techniques were being investigated (Appendix K).

3.5.2. Group 2 was naive to the fact that they were on a research study until the end of the 4th visit where they were approached to allow their data to be used in the study. On accepting this, the patients were included into the study and were advised that they could apply for a full refund. The reason for this is that research patients are ethically not meant to pay for there treatments, but due to the nature of the setting they were being treated in, it was vital that they did. The refund also acted as an incentive to get the patients to sign onto the study. This did not bias the outcomes as there were no patient withdrawals from the study in this group.

Those participants included into the study received a letter of information (Appendix B) and an informed consent form (Appendix J) which they signed. In line with the requirements as outlined in the Faculty of Health Sciences Research and Ethics Committee approval and Helsinki Declaration of 1975.

3.6 THE PARTICIPANTS

The 40 patients for this study were selected from those presenting with mechanical low back pain in the Kwa-Zulu Natal province.

3.6.1 Advertisement for participant recruitment

The public was informed of the study by advertising in local newspapers, advertisements placed at the D.U.T.C.D.C., local campuses, gyms, sports clubs and postal drops. The advert (Appendix D) asked for participants from the ages of 18 and 45 years of age suffering from low back pain. The examiner was able to exclude subjects that did not fit the inclusion criteria by interviewing all the prospective group 1 participants telephonically (Appendix P). Group 2 participants were to present as any normal non-research patient to the D.U.T.C.D.C., during the history taking the inclusion and exclusion questions were used. If the patient fitted the inclusion criteria they were asked to join the study following their fourth treatment. If they did not fit the criteria they were simply treated as a normal patient and not asked to join the study.

3.6.2 Sampling and group allocation of Participants

Consecutive convenience sampling took place by self- selection process due to the patients responding to the advert (Appendix D) or presenting to the D.U.T.C.D.C.

The first 20 patients were placed in Group 1 (research orientated clinical environment) and the following 20 patients were placed in Group 2 (private practice environment). This was done as the same room was never used throughout a patient's course of treatments, increasing the lack of a practice simulated setting. For that reason the clinical research group was completed first as the setting had to reflect that of the D.U.T.C.D.C. research setting. There was also only one researcher

involved and to maintain this continuity the clinical research group setting was completed before starting the normal practice group setting. Another reason for separating the two groups was that the adverts (Appendix D) that had the researchers name on could be removed and thus further enhances the normal practice group setting (Group 2 patients).

3.7 CLINICAL PROCEDURE

On responding to the advert (Appendix D) or presenting to the clinic the potential participants were asked questions about their conditions (Group 1 telephonically, Group 2 in the history taking), which indicated whether or not they fitted the following inclusion and exclusion criteria:

3.7.1 Inclusion criteria for participants

3.7.1.1. Only patients between the ages of 18 and 45 years of age were included in this study to keep the LBP being researched within the dysfunctional phase (Kirkaldy-Willis and Burton 1992: 105).

3.7.1.2. Only patients with acute (less than six weeks) LBP (Koes et al. 1996) were included. This includes patients with acute exacerbations of chronic LBP.

3.7.1.3. Any mechanical conditions associated with but secondary to the LBP (Lumbar Facet Syndrome or Sacroiliac Syndrome) were assessed and

noted in the lower back regional examination, but no treatment for these conditions was administered (e.g. active myofascial involvement.)

3.7.1.4. Patients already taking anti-inflammatory or analgesic medication (ibuprofen, paracetamol, etc.) were included in the study following a 3-day washout period (Seth, 1999). The Group 2 patients were asked to stop taking anti- inflammatory drugs as it would not give a true reflection of whether or not the chiropractic treatment was working. Their subsequent appointments were made 3 days later so a washout period could be attained.

3.7.2 Exclusion criteria for participants

3.7.2.1 Subjects presenting that were contra-indicated to manipulation as stated by Kirkaldy-Willis and Burton (1992: 291) i.e. destructive lesions of spine, ribs and pelvis, healing fracture or dislocation, gross instability, cauda equina syndrome, large abdominal aneurysm or visceral referred pain were excluded from the study. These were excluded on the grounds of clinical a history and examination, and no further investigations were performed (e.g. radiographs or scans).

3.7.2.2 Previous lumbar surgery and pregnant females (due to hormone-induced ligament laxity and possible resultant instability of sacroiliac joint occurring during pregnancy) (Vleeming et al. 1990: 131) were excluded from the study.

3.7.2.3 Patients receiving workers compensation or disability insurance for low back pain were excluded.

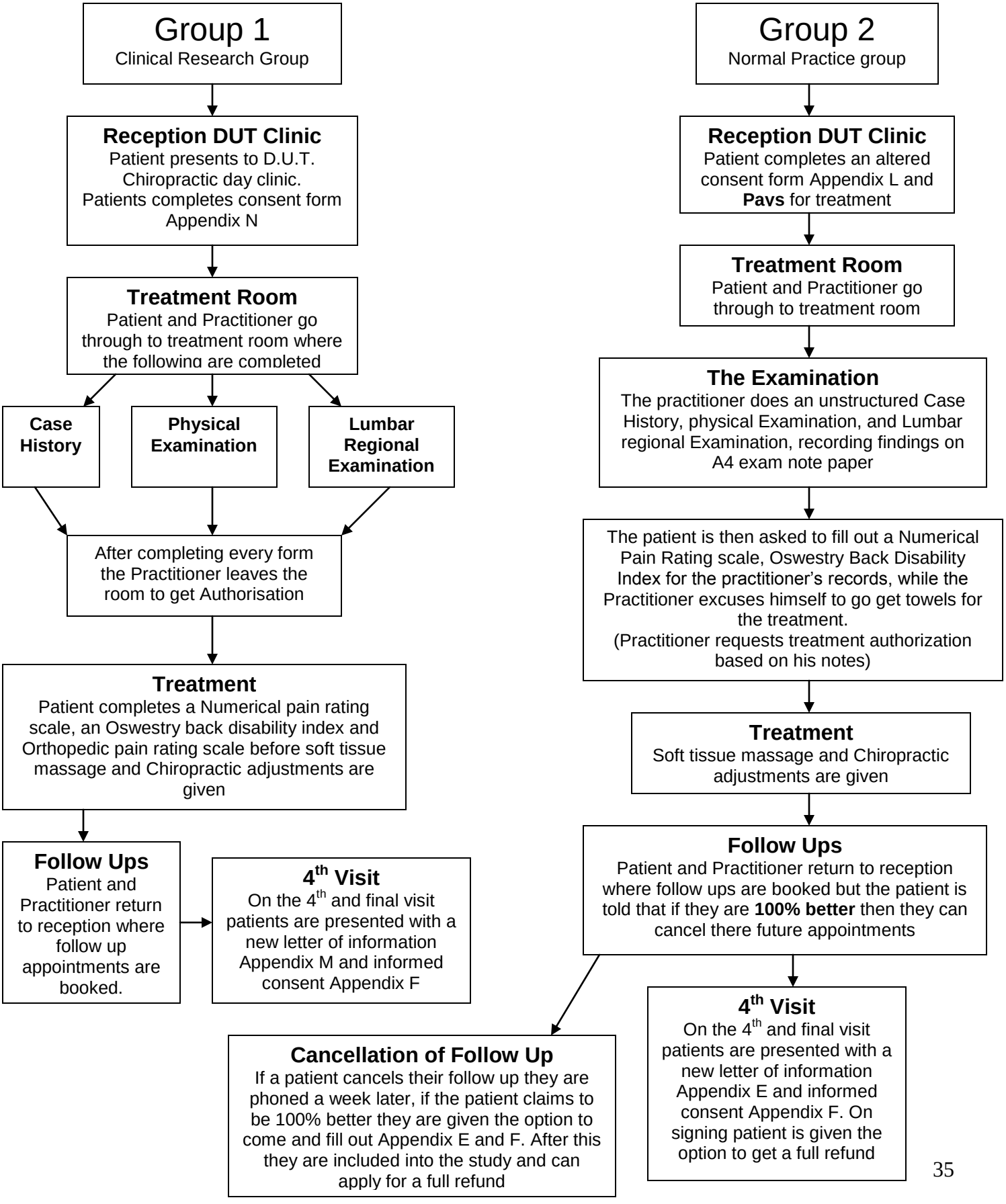
3.7.2.4 Patients presenting with bilateral LBP, leg pain, and or some type or neurological sign and symptoms were excluded. This suggested that the patients have some other underlying condition (Patel and Ogle 2000).

3.7.2.5 Patients were required not to change their lifestyle or activity levels during the research period to avoid biasing the results. By altering there lifestyle the patient could aggravate the condition or enhance the treatment thus giving a false result.

3.7.2.6 Patients that received any other form of treatment for LBP during the research period were excluded as it would bias the results.

Those participants that met the inclusion and exclusion criteria were placed into the two groups.

Clinical Experimental Procedure (Table D)



3.7.3 Group 1 procedure

These participants on presenting to the clinic were given a consent form (Appendix N) and were not required to pay for their consultation. The participant then went through to the researchers treatment room where the case history (Appendix G), physical examination (Appendix H), and lumbar regional examination (Appendix I) were completed. In between each of the aforementioned examinations the researcher left the treatment room to acquire authorization for each document from the clinician on duty. This is a medico-legal requirement the researcher needs to acquire in order to treat the patient legally (Durban University of Technology Clinic Manual 2007). The participant was then given Numerical pain rating scale (Appendix B) and Oswestry back disability index (Appendix C) to complete while the researcher completed the Orthopedic pain rating scale (Appendix A) which was used to determine the presence of Lumbar facet syndrome (LFS) and/or Sacroiliac syndrome (SIS).

The specific tests for LFS included: Kemp's Test (Corrigan and Maitland, 1990: 35), facet joint challenge, hyperextension in prone position (Gatterman, 1990: 84 and 162), and a palpable muscle spasm with focal tenderness over the facet joints (Helbig and Casey 1988: 61-64). The specific tests for SIS included: Posterior shear or "Thigh thrust test" (Laslett and Williams, 1994: 1244), Patrick Faber test (Broadhurst and Bond, 1998: 342), Gaenslen's test (Magee, 1992: 319) and Yeoman's test (Magee, 1992: 320). Only patients obtaining an Orthopedic rating of

6 out of 10 or higher were included in the study thus ensuring at least two orthopedic tests were positive for a diagnosis to be made.

Following that the participant was treated with soft tissue massage over the lumbar spine (not exceeding 5 minutes), and adjustment of related fixations. This was only done after the researcher had received authorization from the clinician to treat. A follow up appointment was then booked. This entire consultation took between 1 ½ hours and 2 hours.

The follow up appointments took approximately 45 minutes and again appendices A, B, and C were completed.

The Group 1 patients were required to complete four visits in a two-week period, and on the final visit they were presented with a new letter of information (Appendix M) and then a 2nd informed consent informed consent form (Appendix F). This was done to show the patient the true intention of the study and to gain their authorization to be included in the study.

3.7.4 Group 2 procedure

Group 2 patients were treated in a normal practice environment as defined by the observations done prior to commencement of the study (Appendix J). Group 2 participants presented as a normal patient to the reception of the D.U.T.C.D.C. where they paid upfront for their consultation. Here they were asked to fill out an

altered (Different from Appendix N) consent form (Appendix L). Following that they were greeted by the researcher and taken to the researcher's treatment room. Here the researcher performed a brief case history, relevant physical and lumbar regional exams recording his findings on an A4 note pad. The researcher also completed the orthopedic pain rating scale (Appendix A) and got the participant to complete the numerical pain rating scale (Appendix B) and Oswestry back disability index (Appendix C), claiming it was to monitor the participants progress. The researcher then excused himself to go get towels for the treatment. This is when the researcher got authorization for the treatment. On returning to the treatment room the patient was treated with soft tissue massage (for no longer than 5 minutes) over the lumbar spine and then the relevant fixations were adjusted.

Next the researcher and participant booked a follow-up appointment, but the participant had the choice, "if he/she was feeling 100% better" to cancel the follow up. If the participant cancelled the follow-up they were then telephoned a week later and asked the status of their condition. If the participant claimed to be 100% better then they were asked to participate in the study. If they were not 100 % better they were encouraged to complete the course of treatments and then offered to come onto the study. The participant was then given a letter of information (Appendix E) and a letter of informed consent (Appendix F). Once the participant signed the form, they were accepted onto the study and informed that they could apply for a full refund for all costs incurred under the guise of having been treated as an "outpatient" in the research study.

Group 2 participants were again required to attend a maximum of four visits in a two week period however they were given the choice as to whether or not they required those follow-up's. On claiming to be 100% better the participants results for the follow up visits were taken as 100% pain free and 0% disability.

3.8 STANDARDIZATION OF CLINICAL SETTING

From the aforementioned participant observation study a comparison was made between a normal practice setting and the clinical research setting already in place at D.U.T.C.D.C. From this comparison key points were noted and used to create and standardize each setting so they could be reproduced for the purpose of this study.

The differences which were noted were used to create the two settings are shown in the table (E) below. This table shows a direct comparison between the two settings that were set up for this study.

Clinical Research Setting	**Private Practice Setting**
Patients go through a randomization process on arriving at the clinic reception	Patients arrive at reception fill, out a patient information form, pay and wait for their researcher
Patients do not pay for treatments	Patients pay for their treatments
The researcher wears a clinic jacket like the rest of the researchers with a student name badge	Researcher is dressed smart casual with no clinic jacket or name badge
Treatment room is never constant	The same treatment room is used each time
Treatment room has very few personal effects in it (it is clinical)	Treatment room has researcher's personal effects in it e.g. Pictures of family members, posters on the walls, text books, other patient files, diagnostic equipment etc.
There are no certificates or qualifications on the walls	The researcher's qualifications can clearly be seen in his treatment room
Examination is very regimental and structured	Examination is very relaxed and immediately focused to the patient's problem
Clinician has to authorize each component of the examination	No authorization is needed at any time throughout the examination
The examination is time consuming (1 ½ - 2 hrs for initial)	Examination is tailored to the patient as is therefore less time consuming (45 - 60 min for initial)
Interaction between researcher and patient are limited due to the structure and rigidity of the examination	There is far more interaction between researcher and patient due to the customised examination
No diagnosis is given until the researcher has gained authorization from the clinician	Diagnosis is given as soon as researcher is comfortable to do so
Patients are expected and instructed to return for all the follow-ups as they are participating in a research study	Patients are given a choice as to whether they need another follow-up appointment depending on how well they feel.

(Table E)

3.9 INTERVENTION

Group 1 received a maximum of three treatments over a two-week period with a follow-up consultation one week later (Kirkaldy-Willis 1988: 249) (thus a total of 4 visits). These took place in either a normal practice environment or a research orientated clinical environment. If the LBP resolved completely before the three treatments were completed, the manual manipulation was discontinued but the patient was continually monitored throughout the remaining consultations.

Group 1 received soft tissue massage over the lumbar spine (which did not exceed 5 minutes duration) this was followed by manual manipulation using the diversified technique (Schafer and Faye 1990: 241- 269). This was a side-posture adjustment, using either a thenar or hypothenar contact and was applied to the affected lumbar or sacroiliac joint. This treatment took place in the research orientated clinical environment that already existed at the Durban University of Technology Chiropractic Day Clinic. The only advice given to participants in this group was restricted to, range of motion exercises and flexion, extension exercises and the patients were only demonstrated these and advised to start them after the 4^{th} visit.

Group 2 received soft tissue massage (for no longer than 5 minutes) over the lumbar spine and manual manipulation using the diversified technique of the affected lumbar or sacroiliac area, following the same technique as mentioned above. This treatment took place in a normal practice environment. Here a normal practice type environment was set-up by following the guidelines and findings from the participant observations done in a

normal private practice environment (Appendix J). The patients in this group were deceived by not letting them know that they were in a research study, as discussed in section 3.5 (Deception Tactics).

3.10 SUBJECTIVE MEASUREMENTS

The measures were obtained before the first, second and third treatments and at a follow-up consultation within one week following the third treatment. The data was collected through the use of the Oswestry Back Pain and Disability Index (Appendix C) and the Numerical Pain Rating Scale (Appendix B).

The subjective data was obtained through the use of the Revised Oswestry Back Pain and Disability Index (Appendix C), which was an effective way to record percentage disability as perceived by the patients suffering from low back pain (Hsieh et al. 1992: 25; Haas et al. 1995: 79). In a study by Davidson and Keating (2002) it was concluded that measurements obtained with the Oswestry Disability Questionnaire were the most reliable and had sufficient width scale to reliably detect improvement or worsening in most subjects.

The Numerical Pain Rating Scale-101 (Appendix B) (Jenson et al. 1986: 117) was also used, as it is a well-known and easy scale for the assessment of pain. It has been shown to be a reliable, valid and clinically sensitive measure of subjective pain (Shailaja and Anuradha 2003). The numerical pain rating scale has been shown to have adequate responsiveness for the use in both clinical and research settings (Childs et al, 2005).

By measuring the intra- group improvement, and the inter- group improvement, relationships can be identified between the groups and the practice settings being tested. Through the literature review we know that the non- specific effect is affected by the clinical setting. Therefore through statistical analysis of these relationships the non- specific effect will be quantified and defined.

3.11 OBJECTIVE MEASUREMENTS

The objective data was obtained through the use of the Orthopedic Pain Rating Scale (Appendix A), which was an effective way to diagnose the type of back pain as well as its severity (Riggien, 2004).

3.12 STATISTICAL ANALYSIS

Statistical Analysis was conducted using the SPSS (version 9) software suite. This Statistical software program was manufactured by SPSS Inc, 444N. Michigan Avenue, Chicago, Illinois, USA. Various Descriptive and Inferential Statistical techniques were used. The Descriptive procedures used were various tables and graphs and a few summary statistics including but not limited to means, proportions and percentages. Inferential Statistics did include various Hypothesis testing techniques. Due to the size of our samples, namely 20 in each group, we used parametric Statistical Tests such as ANOVA and multiple paired T-Tests and Independent T-Tests. All our tests set our type 1 error at 5%, or were mentioned differently

α = 0.05. If our p value as reported to be less than 0.05 we would declare a significant result and our Null Hypothesis would be rejected.

3.12.1 Objective 1 (Intra Tests within each Group)

For each subjective reading we compared the raw values across all 4 readings, testing for any significant differences in population means using the ANOVA test. If this test proved to be significant then this was followed up by multiple pair wise T-Tests, testing for any significant differences for all pairs of population means. The former test, tested if any mean differences did in fact occur whereas the later test was to tell us where they occur.

3.12.2 Objective 2 (Inter Tests between both Groups)

In this case the differences for each subsequent reading within each group were calculated. These common differences were then tested across both groups for any significant differences in population means using the independent T-Test. This was to highlight the differences or similarities in rates of change of perception of pain severity across both scenarios.

CHAPTER FOUR:

Statistical Methodology

4.1 INTRODUCTION

In this chapter I will present the results of the participant observation study as well as the analysis of the raw data collected in the study in the NRS, Oswestry back disability index and orthopedic pain rating scale.

Statistical Analysis was conducted using the SPSS (version 9) software suite. This Statistical software program was manufactured by SPSS Inc, 444N. Michigan Avenue, Chicago, Illinois, USA. Various Descriptive and Inferential Statistical techniques were used. The Descriptive procedures used were various tables and graphs and a few summary statistics including but not limited to means, proportions and percentages. Inferential Statistics did include various hypothesis-testing techniques. Due to the size of our samples, namely 20 in each group, we used parametric Statistical Tests such as ANOVA and multiple paired T-Tests and Independent T-Tests. All our tests set our type 1 error at 5%, or were mentioned differently $\alpha = 0.05$. If our p value as reported to be less than 0.05 we would declare a significant result and our Null Hypothesis would be rejected.

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In this case the differences for each subsequent reading within each group were calculated. These common differences were then tested across both groups for any significant differences in population means using the independent T-Test. This was to highlight the differences or similarities in rates of change of perception of pain severity across both scenarios.

4.2 RESULTS

4.2.1 Participant observation results

The framework used in the participant observation study was adopted from Jamison's (1998 a) "NON – SPECIFIC THERAPY: A Checklist of Psychological Triggers". All observations were recorded with this

framework in mind as seen in Appendix O. From my notes (Appendix O) a comparison between the clinical research setting and a normal practice setting was done and a framework created for the purpose of reproducing those settings in this study (Appendix J).

Through my observations of three independent chiropractic clinics, in the immediate Kwa-Zulu Natal Durban area, the researcher found that private practice is vastly different to that of the clinical/research environment in which patients are treated at the Durban University of Technology Chiropractic Day Clinic.

I the researcher observed three (Appendix O) different practitioners of which had varying degrees of private practice experience, from one year to as much as six years; all of whom were at different locations and treated a variety of patients, of different conditions and ages.

It was noted that the average treatment time was thirty minutes and that this was ample time to perform a relaxed yet successful and thorough assessment and treatment of a patient's condition.

The environmental setting from the reception to the treatment room induced a sense of relaxation and well-being. In all three practices the rooms were painted sunshine yellow and the décor was bright and

colourful adding to the favorable and calming atmosphere. To create a professional atmosphere, certificates, anatomical posters and often a bookshelf filled with medical texts were present. The practitioner often dressed in a smart casual attire to promote a relaxed yet professional environment.

The assessment was normally completed within 5- 15 minutes depending on whether it was an initial versus follow-up consultation. A brief history was taken and relevant questions about potential “red flags” were asked. The relevant regional was then done with only the most specific orthopedic tests were performed (those indicated by the history or “red flags”).

The treatment always involved a combination of therapies. E.g. Patient with sciatic type pain pattern had cold therapy over lower back, while T.E.N.S. was placed over the pain referral pattern, whilst dry needling was being performed on trigger points in the gluteals and piriformis. This would take 5 -10 minutes then the patient was adjusted and stretched and given home stretches or exercises to do. Multiple areas were also treated in the same visit e.g. Thoracic was treated with T.E.N.S. while the practitioner attended to the lower back complaint, and then all areas were adjusted afterwards. The treatment is very social with conversation occurring

throughout the assessment and treatment between patient and practitioner.

The patient-doctor interactions are also very different to those that occur in the research environment at the D.U.T.C.D.C. In private practice it seems less regimental and more relaxed. Patients in the clinical research setting may be more reluctant and less trusting as they know they are in a research setting and part of an experiment as opposed those patients who visit a normal practice setting where they know they are not part of an experiment (Hawthorne effect).

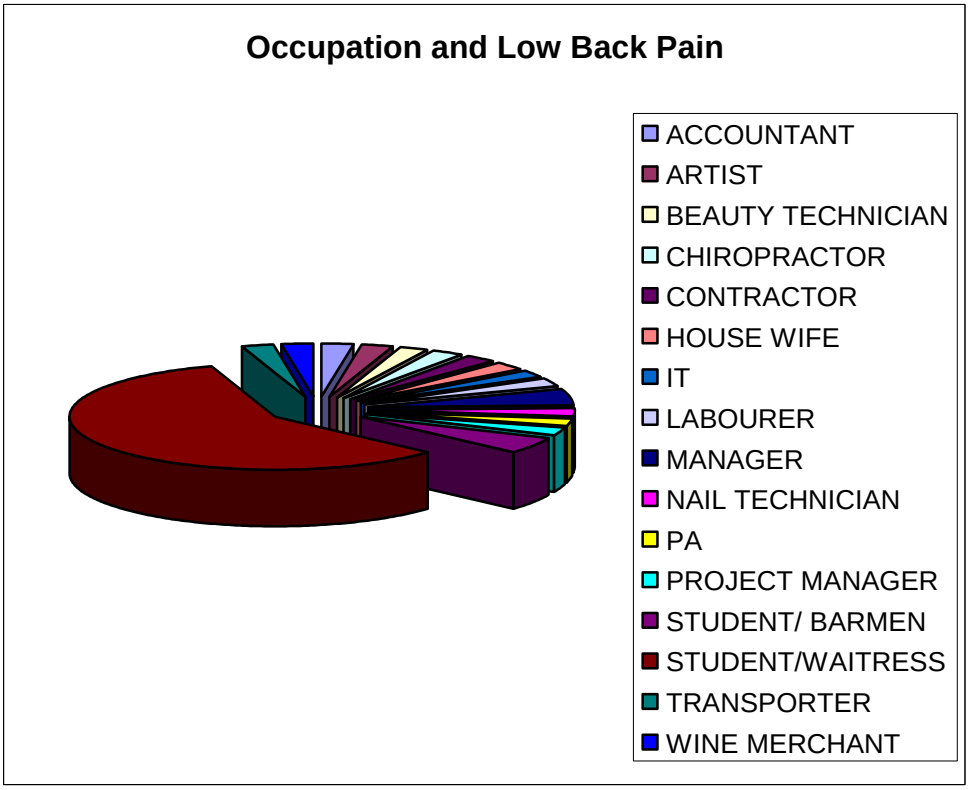
4.2.2 Demographics

An unequal number of participants between the two groups resulted due to the high drop out rate experienced during the study.

Resultantly forty-one participants were randomized into two groups, the clinical research setting group (n=20) and the normal practice setting group (n=21). Mean age of participants was 23.56 years (SD 5.9 years) and ages ranged from 18 to 45 years. There were 27 females (65.9%) and 14 (34.1%) males in the whole sample. In total 75.6% (n=31) suffered from Facet syndrome while 24.4% (n=10) had SI syndrome. More than half the sample (58.5%) were student waitresses by occupation, shown in Table 4.1.

Table 4.1: Frequency and percent of occupations in sample (n=41)

	Frequency	Percent
ACCOUNTANT	1	2.4
ARTIST	1	2.4
BEAUTY TECHNICIAN	1	2.4
CHIROPRACTOR	1	2.4
CONTRACTOR	1	2.4
HOUSE WIFE	1	2.4
IT	1	2.4
LABOURER	1	2.4
MANAGER	2	4.9
NAIL TECHNICIAN	1	2.4
PA	1	2.4
PROJECT MANAGER	1	2.4
STUDENT/ BARMEN	2	4.9
STUDENT/WAITRESS	24	58.5
TRANSPORTER	1	2.4
WINE MERCHANT	1	2.4
Total	41	100.0



4.2.2.1 Baseline comparisons

There was no difference between mean ages of the two groups in the population (p=0.725), and Table 4.2 shows very similar mean ages in the sample.

Table 4.2: T-test comparison of mean age between the groups

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	p value
AGE	clinical research setting group	20	23.90	7.152	1.599	0.725
	normal practice setting group	21	23.24	4.582	1.000	

There was no significant difference in proportions of each gender by treatment group (p=0.520). Table 3 shows that the clinical research setting group had 60% females while the normal practice setting group had a slightly higher percentage of 71.4%. However, this slight difference was not statistically significant.

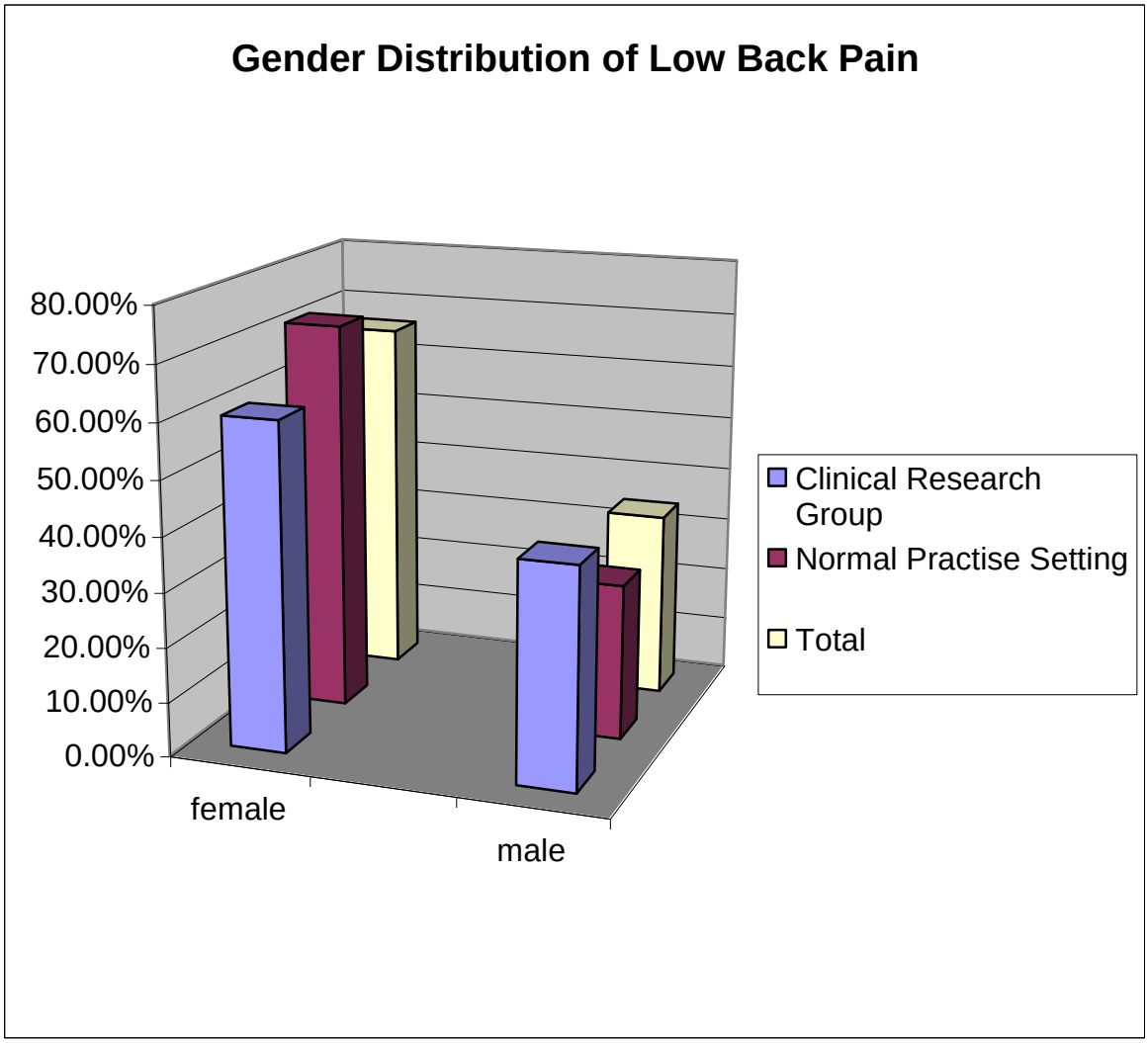


Table 4.3: Cross- tabulation of gender by treatment group (n=41)

			GROUP		Total
			clinical research setting group	normal practice setting group	
SEX	Female	Count	12	15	27
		% within GROUP	60.0%	71.4%	65.9%
	Male	Count	8	6	14
		% within GROUP	40.0%	28.6%	34.1%
Total		Count	20	21	41
		% within GROUP	100.0%	100.0%	100.0%

Fisher's exact p value =0.520

Table 4.4 shows that there was a very similar percentage of Facet syndromes in both treatment groups (75% in the clinical research setting group and 76.2% in the normal practice setting group). The p value was 1.000, meaning that any differences between the groups were negligible in the population.

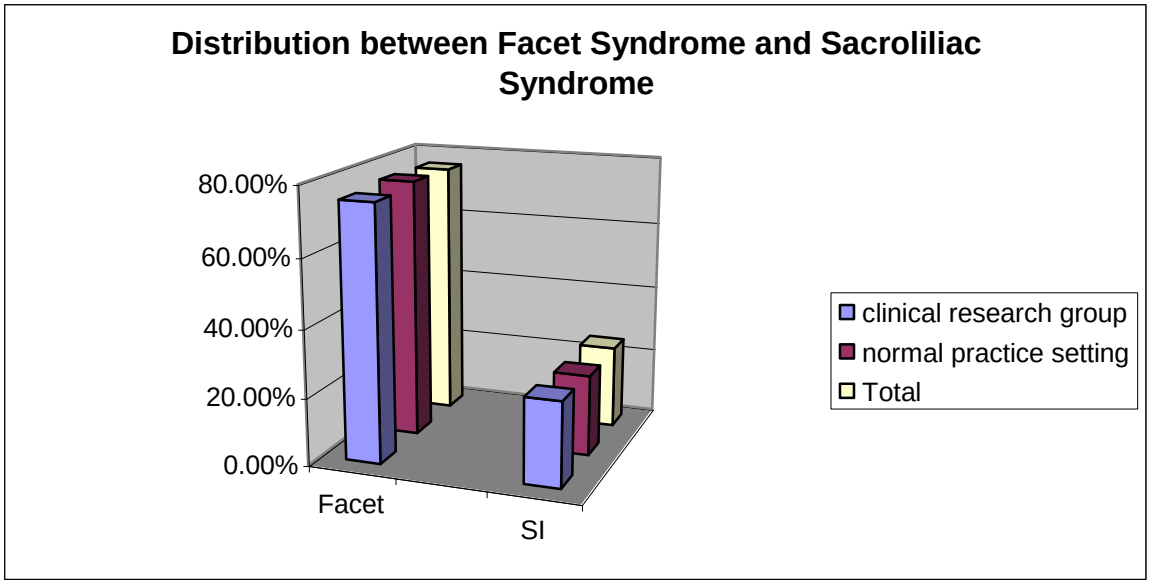


Table 4.4: Cross- tabulation of condition by treatment group (n=41)

			GROUP		Total
			clinical research setting group	normal practice setting group	
CONDITION	FACET	Count	15	16	31
		% within GROUP	75.0%	76.2%	75.6%
	SI	Count	5	5	10
		% within GROUP	25.0%	23.8%	24.4%
Total		Count	20	21	41
		% within GROUP	100.0%	100.0%	100.0%

Fisher's exact p value =1.000

Baseline outcome measures were compared between the groups to establish if randomization had been complete. There was a significant difference in mean NRS between the two groups at baseline (p=0.044). Table 4.5 shows that the clinical research setting group had a slightly higher mean NRS score at baseline than the normal practice setting group. None of the other measures were significantly different between the groups at baseline. This was reinforced by Mann-Whitney p values, which are very similar to the t-tests and give the same conclusions. The p values from Mann Whitney tests were:

NRS p=0.047

OPRST p=0.509

OBDI p=0.632

Table 4.5: T-test comparison of mean baseline outcomes between the groups

	GROUP	N	Mean	Std. Deviation	Std. Error Mean	p value
NRS (average of worst and least pain)	clinical research setting group	20	38.45	11.794	2.637	0.044*
	normal practice setting group	21	31.19	10.566	2.306	
Orthopedic pain rating scale (percentage)	clinical research setting group	20	72.25	6.382	1.427	0.572
	normal practice setting group	21	73.33	5.774	1.260	
Owsestry back disability index (percentage)	clinical research setting group	20	12.44681	11.264334	2.518782	0.246
	normal practice setting group	21	9.42249	3.335165	.727793	

- statistically significant at 0.05 level.

4.2.3 Intra-group analysis

4.2.3.1 Clinical research setting group

Within the clinical research group there was a highly significant decrease over the four time points for all outcome measures. Table 4.6 shows this.

Table 4.6: Within-subjects effect (time effect) for clinical research group (n=20)

Outcome (dependant variable)	Wilk's lambda for time effect	p value
Numerical Pain Rating Scale (NRS)	0.109	<0.001
Orthopedic Pain Rating Scale (OPRS)	0.168	<0.001
Oswestry Back Disability Index (OBDI)	0.458	0.003

4.2.3.2 Normal practice setting group

In the normal practice setting group there was also highly significant decreases over time for all outcome measures, with very low (highly significant) Wilk's lambda values (Table 4.7).

The statistics in Table 4.7 come from the multivariate repeated measures ANOVA. The f statistic is the between groups ANOVA f statistic which is a ratio of the variances between groups to within groups. The Wilk's Lambda is a statistic that examined intra-person variation in time and time by group interaction.

The following is quoted from the help section in SPSS (version 9): "Lambda ranges between 0 and 1, with values close to 0 indicating the group means are different and values close to 1 indicating the group means are not different (equal to 1 indicates all means are the same)." We assess the p value from Wilk's Lambda to see if the effect is significant or not.

Table 4.7: Within-subjects effect (time effect) for normal practice setting group (n=21)

Outcome (dependant variable)	Wilk's lambda for time effect	p value
NRS	0.098	<0.001
OPRS	0.006	<0.001
OBDI	0.098	<0.001

4.2.4 Treatment effect (intergroup analysis)

4.2.4.1 NRS

Table 4.8 shows that all three null hypotheses were rejected at the 0.01 level of significance. However, in the presence of a significant interaction effect (time by group), the main effects of time and group cannot be interpreted. Thus there was a significant treatment effect ($p<0.001$). Figure 4.1 shows that the profiles of the two groups were not parallel over time and that the normal practice setting group decreased in mean NRS faster and to a greater extent than the clinical research setting group. This is

adjusted for baseline differences which existed between the two groups. Thus the normal practice setting seems to provide the better environment in the case of NRS.

Table 4.8: Within and between subjects effects for NRS (n=41)

Effect	statistic	p value
Time	Wilk's lambda= 0.107	<0.001
Time*group	Wilk's lambda=0.512	<0.001
Group	F=38.48	<0.001

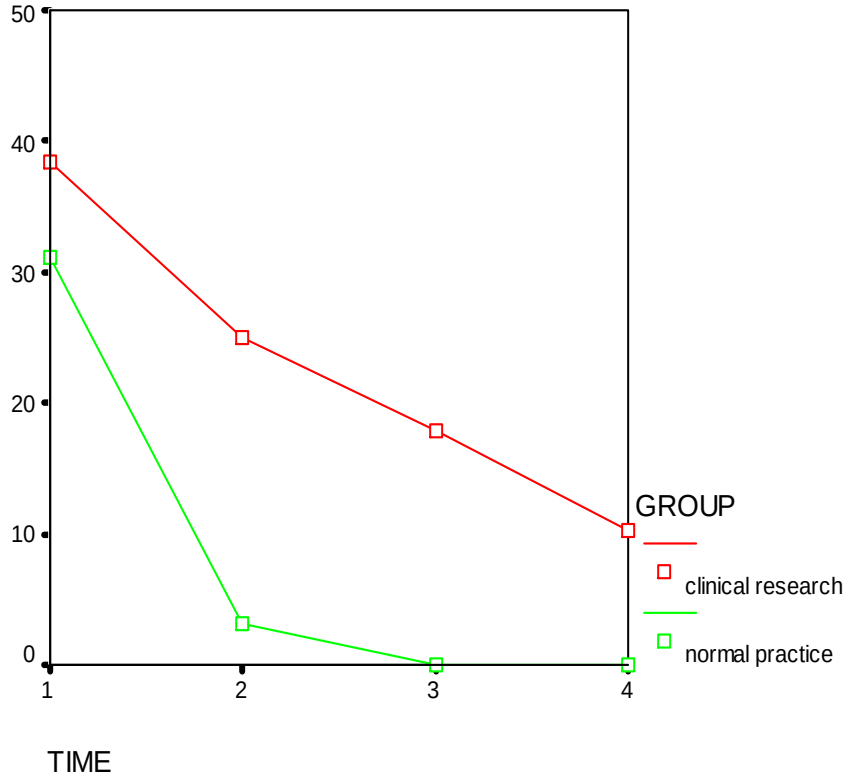


Figure 4.1: Profile plot of mean NRS over time by group (n=41)

4.2.4.2 Orthopedic pain rating scale (percentage)

With this outcome the null hypotheses were also rejected and highly significant effects were found. The time by group interaction was highly significant ($p<0.001$), meaning that there was a highly significant treatment effect. Examining Figure 4.2 reveals that once again it was the normal practice setting group that showed fastest rate of improvement, although both groups did improve over time. As with NRS, the fastest decrease in scores was found between the first two time points. The clinical research setting group only started to decrease after the second treatment.

Table 4.9: Within and between subjects effects for OPRS (n=41)

Effect	**statistic**	**p value**
Time	Wilk's lambda=0.055	<0.001
Time*group	Wilk's lambda=0.199	<0.001
Group	F=83.33	<0.001

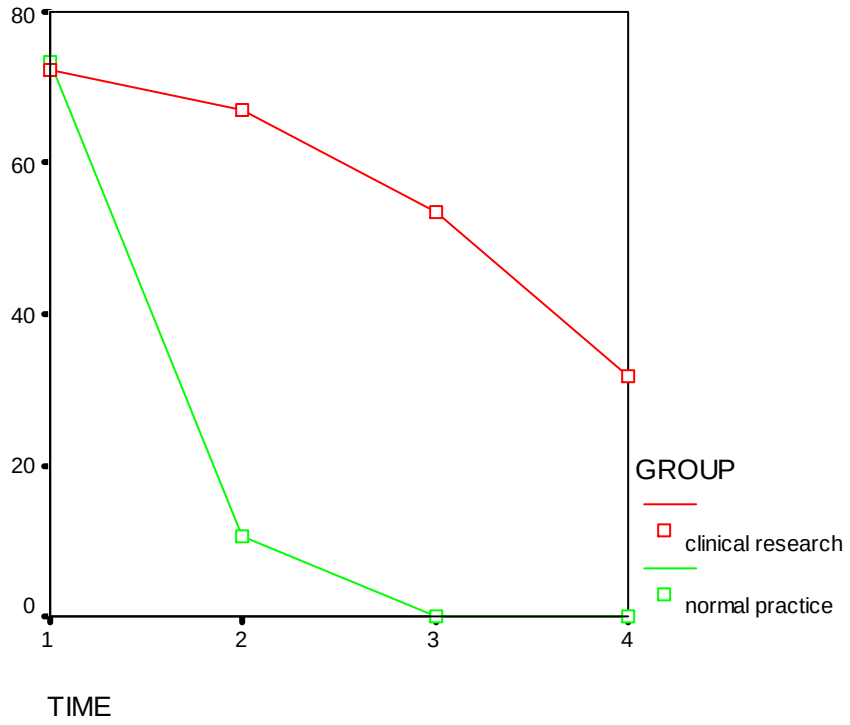


Figure 4.2: Profile plot of mean Orthopedic Pain Rating Scale over time by group (n=41)

4.2.4.3 Oswestry back disability index (percentage)

Both groups showed a mean decrease over time for OBDI, but the normal practice setting group decreased at a faster rate than the clinical research setting group ($p<0.001$).

Table 4.10: Within and between subjects effects for OBDI (n=41)

Effect	statistic	p value
Time	Wilk's lambda=0.350	<0.001
Time*group	Wilk's lambda=0.592	<0.001
Group	F=11.08	0.002

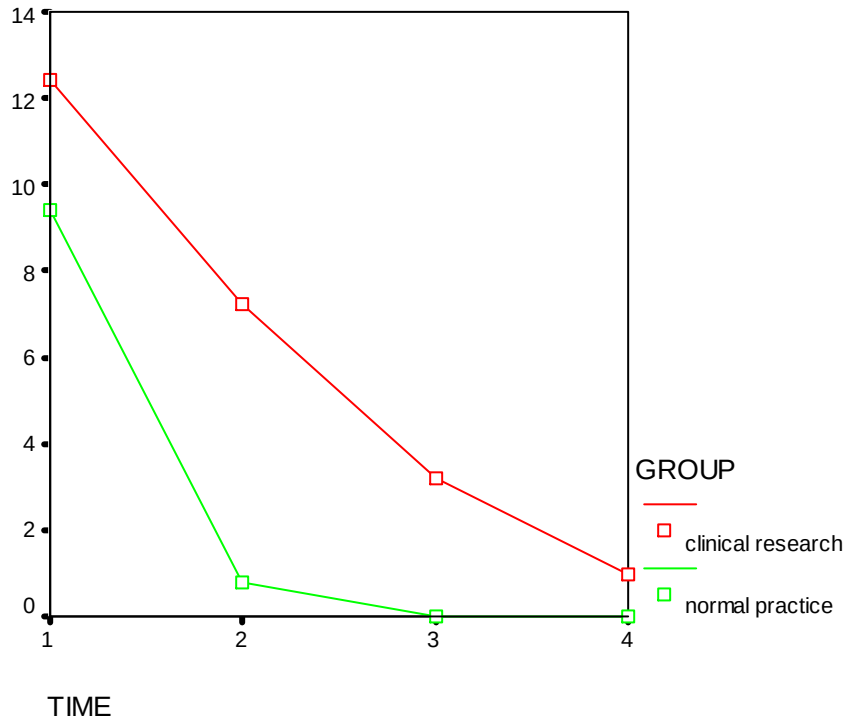


Figure 4.3: Profile plot of mean Oswestry back disability index score over time by group (n=41)

4.2.5 Intra-group correlations between outcome measurements

4.2.5.1 Clinical research setting group

There was a moderate positive correlation between change in NRS and change in OBDI in the clinical research setting group (r=0.675), thus as the NRS score decreased so did the OBDI score. The correlation between change in NRS and change in OPRS was weak, albeit significant (r=0.524). OPRS and OBDI were not correlated.

Table 4.11: Correlation matrix for changes in outcomes in the clinical research group (n=20)

		Change in NRS	Change in OPRS	Change in OBDI
Change in NRS	Pearson Correlation	1	.524(*)	.675(**)
	Sig. (2-tailed)	.	.018	.001
	N	20	20	20
Change in OPRS	Pearson Correlation	.524(*)	1	.077
	Sig. (2-tailed)	.018	.	.745
	N	20	20	20
Change in OBDI	Pearson Correlation	.675(**)	.077	1
	Sig. (2-tailed)	.001	.745	.
	N	20	20	20

* Correlation is significant at the 0.05 level (2-tailed).

** Correlation is significant at the 0.01 level (2-tailed).

4.2.5.2 Normal practice setting

Table 4.12 shows that there were no correlations between changes in outcomes in the normal practice setting group. This is because there was very little variability in the changes in this group, they all showed really large changes over the 4 time points.

Table 4.12: Correlation matrix for changes in outcomes in the normal practice setting group (n=21)

		Change in NRS	Change in OPRS	Change in OBDI
Change in NRS	Pearson Correlation	1	-.304	.141
	Sig. (2-tailed)	.	.180	.541
	N	21	21	21
Change in OPRS	Pearson Correlation	-.304	1	-.055
	Sig. (2-tailed)	.180	.	.812
	N	21	21	21
Change in OBDI	Pearson Correlation	.141	-.055	1
	Sig. (2-tailed)	.541	.812	.
	N	21	21	21

A negative correlation is very weak and insignificant. Insignificant correlation means that there was a lack relationship ref. Table (4.13, 4.14, 4.15). This can be interpreted as changes over time in the outcomes were

not related to each other. This could be because almost everyone in the normal practice setting group showed great improvement in all outcomes, leading to very little variability in changes over time. Hence no correlation was found.

Table 4.13: Scatter plot of changes in NRS versus OBDI

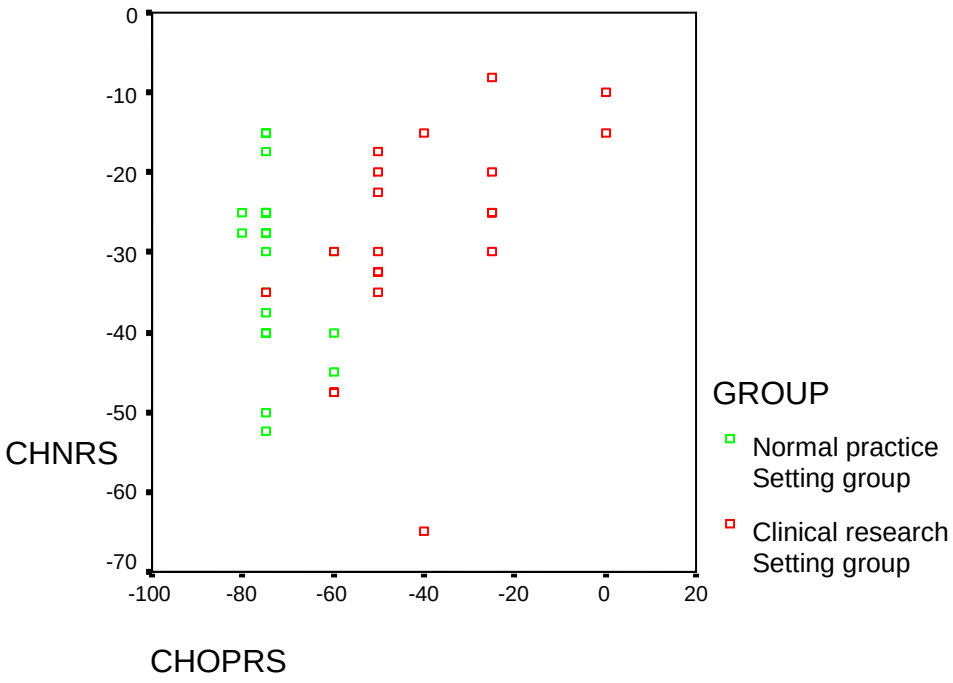


Table 4.14: Scatter plot of changes in NRS versus OBDI

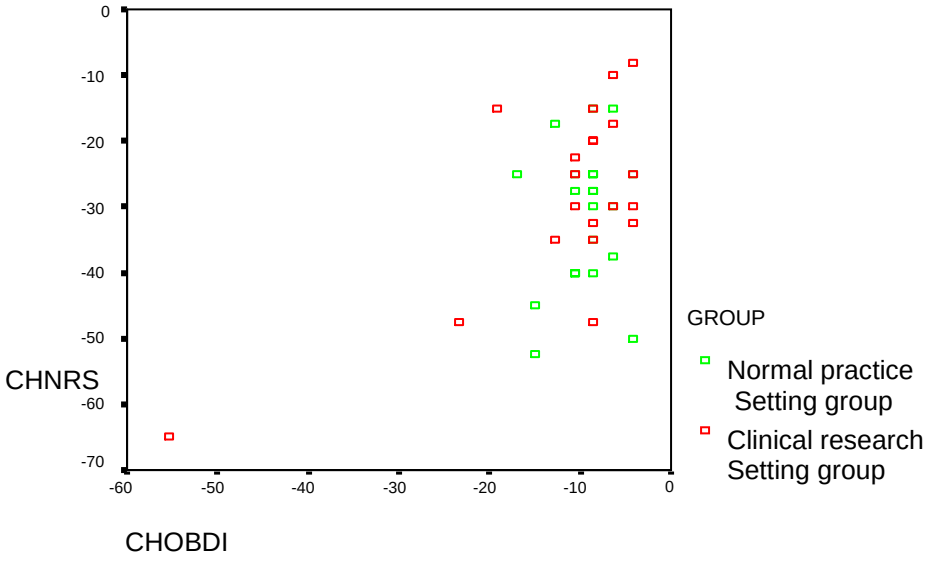
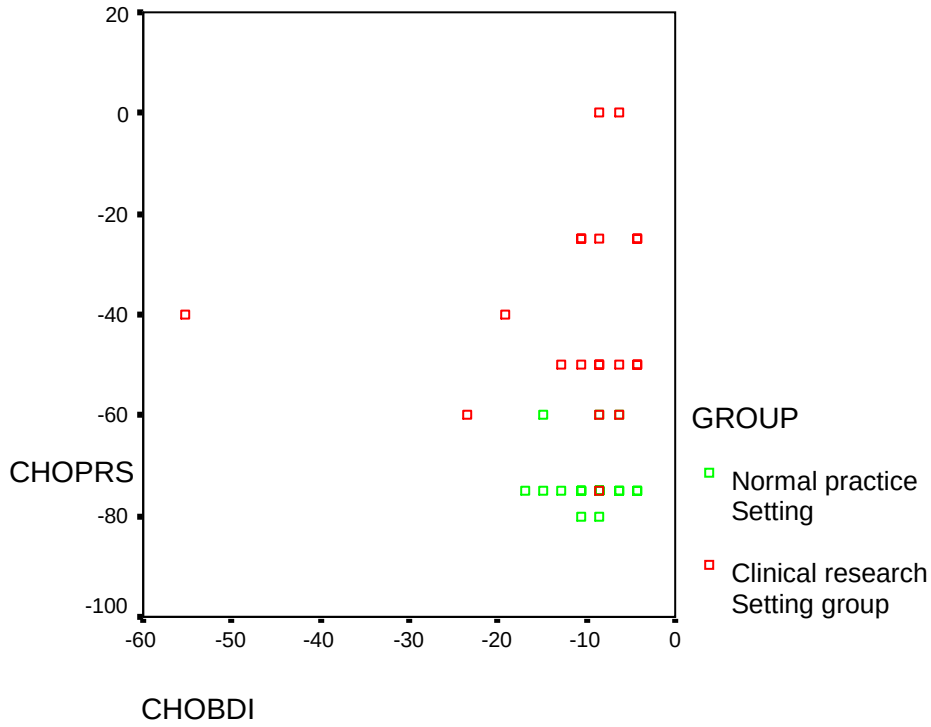


Table 4.15: Scatter plot of changes in NRS versus OBDI



4.3 SUMMARY AND CONCLUSION

While both treatment settings were effective at reducing self reported pain according to the NRS, Orthopedic pain rating scale and Oswestry back disability index in patients with mechanical low back pain, the normal practice setting was the most effective since the rate of improvement was significantly greater for all outcomes tested.

Hypothesis one: There was no relationship between each treatment in a specific group and the subjective clinical findings. **Rejected.**

Hypothesis two: There was no relationship between each group and the subjective clinical findings. **Rejected.**

Hypothesis three: There was no relationship between the non-specific effect and the subjective clinical finding of each group. **Rejected.**

Hypothesis four: There was no relationship between the non-specific effect and the subjective clinical finding of each group. **Rejected.**

CHAPTER FIVE:

DISCUSSIONS, CONCLUSION AND RECOMMENDATIONS OF THE RESULTS

5.0 INTRODUCTION

In this chapter we will discuss the results of the study and relate them to the literature so that a conclusion can be drawn.

5.1 COMMENTS ON DATA ANALYSIS

5.1.1 Demographics

There were a large percentage of waitresses in the study which indicated that waitresses are more prone to developing low back pain however this did not give a true representation of the population as the sample size was so small. It was not ideal that there was not an even distribution of age throughout the study as it is not a true reflection of the population also due to small sample size. The difference in gender distribution could have been related to the high drop out rate in-group 1, as well as accounting for the difference in the Numerical Pain Rating Scale-101 (NRS) under the assumption that females are more vocal at expressing their pain (Shailaja and Anuradha 2003). This could in turn be correlated to the fact that more females are waitresses.

With regards to the cross-tabulation of condition by treatment group, it was reported in both groups that the majority of the patients presented with lumbar facet syndrome (+- 75%) as opposed to sacroiliac syndrome (+-25%). In the T-test comparison of mean baseline outcomes between the groups, the p values were significant in the Oswestry back disability index and the Orthopedic pain rating scale. However the NRS –101-pain scale only showed a marginally significant difference.

5.1.2 Intra-group analysis

In the, Within-subjects effect (time effect) for clinical research setting group there was a highly significant decrease over the four time points. However in the, Within-subjects effect (time effect) for normal practice setting group, there was also a highly significant decrease with a very low (highly significant) Wilks lambda value.

5.1.3 Treatment effect (intergroup analysis)

It was noted in the Numerical Pain Rating scale, Oswestry back disability index and the Orthopaedic pain rating scale that both groups improved significantly over the time period. It was also noted that the rate at which the normal practice setting group improved was significantly faster than that of the clinical research setting group.

5.1.4 Intra-group correlations between outcome measurements

In the clinical research setting group there was a moderate positive correlation between the change in the Numerical Pain Rating Scale and the Oswestry back disability index. The correlation between the Numerical Pain Rating Scale and the Orthopaedic Pain Rating Scale was weak but still significant. In the normal practice setting there were no correlations between changes in outcomes as there was very little variability in the changes in the group. They did however show large changes over the four time points.

5.1.5 Treatment outcomes

In table 4.5 there is a t-test p-value of .044, which is confirmed by the non-parametric Mann-Whitney test. This means that there can be little doubt that this value is significant; because abnormal distribution of the mean values has no influence (normal distribution is assumed in the t-test).

Both groups improved significantly no matter the setting as indicated by tables 4.6 and 4.7, but the big difference is that the normal practice setting group did so more quickly (section from table 4.8 to 4.10). The significant rate of change in the normal practise setting group could be due to the patient being more receptive to the treatment as they are paying for it as well as having more confidence in the practitioner as discussed previously by Jamison (1998 a). Another important factor could be the time taken to address the patients condition, in the normal practice setting the patients problem was addressed immediately and treatment soon followed however in the clinical research setting group it took a significant

longer period of time before the problem was addressed and treated due to the regimental procedure the student intern had to follow (Jamison 1998 a). Another factor may have been that the clinical research group knew that they were in a research study and knew that they had to attend appointments and therefore subconsciously acted accordingly (Hawthorne effect: Mayo 1933). All these factors are part of the non-specific effect, thus it is the non-specific effect that is affecting the different groups.

The correlation matrix is useful in that it shows that the outcome measures correlate, however when the rate of change is too quick (4.12), it cannot be used. However, this shows that the outcome tools varied in a predictable fashion, indicating that they are appropriate for use in this context.

5.2 INTERGRATION WITH OTHER LITERATURE

It has been noted previously in this study that placebo and non-specific effects are one in the same. Very few studies have been done which try to identify, map and define non-specific effects. The medical profession has however done several studies on trying to understand and map the placebo, which was originally thought of as an ideal control (Jamison 1998 b). The thinking today is that the placebo or non-specific effect is present in every clinical encounter. Hróbjartsson (1996) suggested that the notions of control group and placebo treatment group should be replaced by the notions of "placebo effect maximising group" and "placebo minimizing group" as it cannot be removed from the clinical encounter.

Other studies have shown that used wisely, placebos might have a legitimate place in therapeutics. However wider recognition, of the practice and debate about its implications are imperative (Nitzan and Lichtenberg 2004). Vernon (1996) stated that in appropriate patients, doctors might consider giving a placebo when active treatment is both costly and likely to confer only marginal or transient benefit.

From the results we can see how patients respond in different settings. A similar study was done in Britain where patients were placed into groups that received a positive or negative consultation with the positive group healing faster than the negative group even though they received the same treatment (Chapman-Smith 1995). In this study we saw how the change in the setting in turn increased or decreased the non-specific triggers, which in turn had a significant effect in the patients' outcome.

5.3 CONCLUSIONS

It has been well established in this and many other research studies that chiropractic treatment has a significant effect on reducing mechanical low back pain. What was significantly shown in this study was that the setting in which the patients were treated in affects the outcome of the treatment. Patients treated in a normal practice setting showed significant improvement over those treated in a clinical research setting.

The difference between the two settings is called the non-specific component. The non-specific component was reduced as much as possible in the clinical research group and increased in

the normal practice setting and the difference noted between these two settings was labelled the non-specific effect. By the end of the 4th treatment the normal practice group showed a 100% improvement as opposed to the clinical research group, which showed an 80% improvement with 20% of the patients still requiring further treatments. In both groups the same treatments were given and the only difference being was the setting in which the patient had been treated. Thus the difference in the rate of improvement between the two groups can be attributed to the non-specific effect.

Thus it can be concluded that the non-specific effect can affect patient improvement by up to 20% depending on the type of environment they are treated in. This is a significant finding which can help the profession grow, develop and improve.

5.4 RECOMMENDATIONS

5.2.1 Methodological recommendations

- The normal practice setting needed to take place in a true practise setting out in the field as opposed to being set up in the Durban University of Technology Chiropractic Day Clinic. This could not be done due to medico-legal restrictions.
- More than one practitioner should have participated in this study to increase the validity of the study.
- A larger sample size should also have been used, but this was not possible due to patient availability. There was also a large drop out rate as patients were unreliable and did not attend follow-up appointments.
- A same room should have been used throughout the study. This could not be done due to the over crowding of the clinic and lack of treatment rooms.

- There is a need to define more clearly the components that make up the non-specific effect, as only general ones are available, as more research on the subject needs to be done.

5.2.2 Further research directions based on this study

- The normal practice setting should be done in a well-established chiropractic practice and not the D.U.T.C.D.C. as it is a clinical research type environment used for teaching.
- Further studies should be performed on the other components of the non-specific effect.
- Sample sizes in future studies should be increased to increase the validity of the results.
- More than one practitioner should participate in future studies so as to prevent any type of bias developing.
- Further observation studies should be done on the clinical research and normal practice settings to validate the findings found in this study.

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Appendix A

Orthopaedic Pain Rating Scale

Patients name: _____ Date: _____

File number: _____

	Initial	Second	Third	Fourth
Kemp's (2)				
Facet jt Chall (2)				
Prone hperext (2)				
Muscle spasm (2)				
Total (out of 8)				
Percentage				

	Initial	Second	Third	Fourth
Post shear (2)				
Patrick Faber (2)				
Gaenslen's (2)				
Yeoman's (2)				
PSIS Tender (2)				
Total (out of 10)				
Percentage				

(Riggien, 2004)

Appendix B

Numerical Rating Scale – 101 Questionnaire

Date: **File no:** **Visit no:**

Patient name:

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **WHEN IT IS AT ITS WORST.** A zero (0) would mean “no pain at all”, and one hundred (100) would mean “pain as bad as it could be”.

Please write only one number.

_____

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **WHEN IT IS AT ITS LEAST.** A zero (0) would mean “no pain at all”, and one hundred (100) would mean “pain as bad as it could be”.

Please write only one number.

_____

(Childs et al. 2005)

Appendix C

Oswestry Back Disability Index

(Davidson and Keating, 2002)

Patient name: _____ **File no.:** _____ **Date:** _____

This questionnaire has been designed to give the doctor information as to how your back pain has affected your ability to manage everyday life. Please answer every section and mark in each section only **ONE BOX.** We realize you may consider that two of the statements in any one section could relate to you, but please just mark the box which most closely describes your problem.

Section 1 – Pain intensity

- ❑ I have no pain at the moment.
- ❑ The pain is very mild at the moment.
- ❑ The pain is moderate at the moment.
- ❑ Pain is severe at the moment.
- ❑ Pain is the worst imaginable at the moment.

Section 2 – personal care (washing, dressing…)

- ❑ I can look after myself normally without causing extra pain.
- ❑ I can look after myself normally but it causes extra pain.
- ❑ It is painful to look after myself and I am slow and careful.
- ❑ I need some help but manage most of my personal care.
- ❑ I do not get dressed, I wash with difficulty and stay in bed.

Section 3 – Lifting

- ❑ I can lift heavy weights without extra pain.
- ❑ I can lift heavy weights but it gives extra pain.
- ❑ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example on a table.
- ❑ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ❑ I can lift only very light weight.
- ❑ I cannot lift or carry anything at all.

Section 4 – Walking

- ❑ Pain does not prevent me from walking any distance.
- ❑ Pain prevents me walking more than 1 mile (2.2 Km).
- ❑ Pain prevents me from walking more than ½ mile (1.1 Km).
- ❑ Pain prevents me from walking more than ¼ mile (0.5 Km).
- ❑ I can only walk using a stick or crutches.
- ❑ I am in bed most of the time and have to crawl to the toilet.

Section 5 – Sitting

- ❑ I can sit in any chair as long as I like.
- ❑ I can only sit in my favourite chair as long as I like.
- ❑ Pain prevents me sitting for more than 1 hour.
- ❑ Pain prevents me from sitting for more than ½ hour.
- ❑ Pain prevents me from sitting for more than 10 minutes.
- ❑ Pain prevents me from sitting at all.

Section 6 – Standing

- ❑ I can stand as long as I want without extra pain.
- ❑ I can stand as long as I want, but it gives extra pain.
- ❑ Pain prevents me from standing for more than 1 hour.
- ❑ Pain prevents me from standing for more than ½ hour.
- ❑ Pain prevents me from standing for more than 10 minutes.
- ❑ Pain prevents me from standing at all.

Section 7 – Sex life

- ❑ My sex life is normal and causes no extra pain.
- ❑ My sex life is normal but causes extra pain.
- ❑ My sex life is nearly normal but it is very painful.
- ❑ My sex life is severely restricted.
- ❑ My sex life is absent because of pain.
- ❑ Pain prevents any sex life at all.

Section 8 – Social life

- ❑ My social life is normal and gives no extra pain.
- ❑ My social life is normal but increases the degree of pain.
- ❑ Pain has no significant effect on my social life apart from limiting my more energetic interests, for example dancing.
- ❑ Pain has restricted my social life and I do not go out as often.
- ❑ I have no social life because of pain.

Section 9 – Sleeping

- ❑ I have no trouble sleeping.
- ❑ I can sleep well only by using pills.
- ❑ Even when I take pills I have less than 6 hours sleep.
- ❑ Even when I take pills I have less than 4 hours sleep.
- ❑ Even when I take pills I have less than 2 hours sleep.
- ❑ Pain prevents me from sleeping.

Section 10 – Travelling

- ❑ I can travel anywhere without extra pain.
- ❑ I can travel anywhere but it gives extra pain.
- ❑ Pain is bad but I manage trips over 2 hours.
- ❑ Pain restricts me to trips less than 1 hour.
- ❑ Pain restricts me to trips under 30 minutes.
- ❑ Pain prevents me from travelling, except to the doctor and or hospital.

Appendix D

Are you between the ages of

18 and 45

and suffer from

Low Back Pain ?

Research is being done at the

Durban Institute of Technology

Chiropractic Day Clinic.

This treatment is free provided you fit the specified criteria.

If you are interested telephone

Grant Richardson at **2042205/2512**
for more information.

Appendix E

DURBAN INSTITUTE of TECHNOLOGY

Letter of Information on Completion of study

Dear Patient

The main goal of this study was to compare the effect that a clinical research orientated practice environment would have on a patient being treated for mechanical low back pain versus a patient being treated in a normal practice environment like those found in the field.

Due to the nature of this study certain measures needed to be put in place in order for the integrity of the main goal of the study to remain intact. In order for the researcher to create the correct context for this study you were not placed under the impression that you were participating in a clinical trial. Instead the researcher placed you in an environment that gave the impression that you were being treated in a normal practice environment and that you were not part of any type of research study.

The investigations and treatments you received were the standard investigations and treatments given by the chiropractic profession for mechanical low back pain. You would have received 3 treatments and one follow-up treatment, over a two-week period. Your initial treatment would have taken approximately an hour, and thereafter half an hour each. All treatments were performed under the supervision of a qualified chiropractor without your knowledge in order to maintain the integrity of the main goal. If the treatment schedule was not maintained the researcher would have contacted you telephonically to ascertain the reason.

By consenting to become part of this research study on your final visit, all data that has been collected can be used in the study. You are also entitled to a full refund for those visits where data was collected, as research patients are not required to pay for treatments. If you decline to participate in the study your file will be destroyed and no data collected will be used.

If you would like to see more detailed notes on both groups please feel free to request them from me.

Yours sincerely

Grant Richardson: B Tech: Chiro. - Researcher (Tel: 2042205)
Dr. C. Myburgh: M Tech: Chiro. – Supervisor (Tel: 0829015790)

Appendix F

LETTER OF CONSENT ON COMPLETION OF STUDY

Date:_____

Title of research project: **The effect of differing clinical settings on chiropractic patients suffering from Mechanical Low Back Pain.**

Name of Supervisor: Dr. C. Myburgh: M Tech: Chiro.(Tel: 0829015790)

Name of Research Student: Grant Richardson: B Tech: Chiro.(Tel: 2042205)

Tick appropriate box

Group A will be treated in a clinical research environment. ☐

Group B will be treated in a normal practice environment. ☐

Please circle the appropriate answer

1. Have you read the research information sheet? **Yes No**
2. Have you had time to answer questions regarding this study? **Yes No**
3. Have you received satisfactory answers to your questions? **Yes No**
4. Have you had an opportunity to discuss this study? **Yes No**
5. Have you received enough information about this study? **Yes No**
6. Who have you spoken to? **Yes No**
7. Do you understand the implications of your involvement in this study? **Yes No**
8. Do you understand that you are free to withdraw from this study? **Yes No**
   a) at any time
   b) without having to give any reason for withdrawing, and
   c) without affecting your future healthcare.
9. Do you agree to voluntarily participate in this study? **Yes No**

If you have answered no to any of the above, please obtain the information before signing.

Please print in block letters

Patients name:_____ Sign:_____

Research Student name:_____ Sign:_____

Appendix G

DURBAN INSTITUTE OF TECHNOLOGY
CHIROPRACTIC DAY CLINIC
CASE HISTORY

Patient: _____ Date: _____

File # : _____ Age: _____

Sex : _____ Occupation: _____

Intern : _____ Signature _____

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature :

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. lab:
Previous: Current:

CASE STATUS:

PTT:	Signature:	Date:

CONDITIONAL:
Reason for Conditional:

Signature: Date:

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

Intern's Case History:

1. Source of History:

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

3. Present Illness:

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

4. Other Complaints:

5. Past Medical History:

- General Health Status
- Childhood Illnesses
- Adult Illnesses
- Psychiatric Illnesses
- Accidents/Injuries
- Surgery
- Hospitalizations

6. Current health status and life-style:

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

7. Immediate Family Medical History:

- Age
- Health
- Cause of Death
- DM
- Heart Disease
- TB
- Stroke
- Kidney Disease
- CA
- Arthritis
- Anaemia
- Headaches
- Thyroid Disease
- Epilepsy
- Mental Illness
- Alcoholism
- Drug Addiction
- Other

8. Psychosocial history:

- Home Situation and daily life
- Important experiences
- Religious Beliefs

9. Review of Systems:

- General
- Skin
- Head
- Eyes
- Ears
- Nose/Sinuses
- Mouth/Throat
- Neck
- Breasts
- Respiratory
- Cardiac
- Gastro-intestinal
- Urinary
- Genital
- Vascular
- Musculoskeletal
- Neurologic
- Haematologic
- Endocrine
- Psychiatric

Appendix H

DURBAN INSTITUTE OF TECHNOLOGY 22/10/2002

PHYSICAL EXAMINATION
SENIOR & RESEARCH

Patient:_____ **File#:**_____ **Date:**_____
_Student: **Signature:**

VITALS

Pulse rate			Respiratory rate	
Blood pressure	R	L	Medication if hypertensive:	
Temperature			Height	
Weight:	Any recent change Y/N	If Yes : how much gain/loss		Over what period

GENERAL EXAMINATION

General Impression	
Skin	
Jaundice	
Pallor	
Clubbing	
Cyanosis (Central/Peripheral)	
Oedema	
Lymph nodes - Head and neck	
- Axillary	
- Epitrochlear	
- Inguinal	
Pulses	
Urinalysis	

SYSTEM SPECIFIC EXAMINATION

CARDIOVASCULAR EXAMINATION

RESPIRATORY EXAMINATION

ABDOMINAL EXAMINATION

COMMENTS

NEUROLOGICAL EXAMINATION: See regionals

Clinician: **Signature:**

Appendix I

TECHNIKON NATAL CHIROPRACTIC DAY CLINIC
REGIONAL EXAMINATION - *LUMBAR SPINE AND PELVIS.*

PATIENT: _____

FILE #: _____ DATE: _____

INTERN/RESIDENT: _____

SUPERVISING CLINICIAN: _____

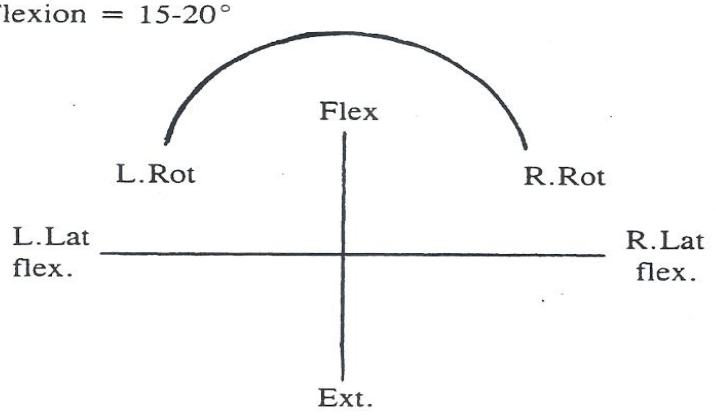
STANDING:

Posture
Minor's Sign
Skin
Scars
Discoloration
Muscle Tone
Bony & Soft Tissue Contours

Spinous Percussion
Schober's Test (6cm)
Treadmill
Body Type
Attitude

RANGE OF MOTION

Forward Flexion = 40-60°(15cm from floor)
Extension = 20-35°
L/R Rotation = 3-18°
L/R Lateral Flexion = 15-20°



SUPINE:

Skin
Hair
Nails
Palpate Abdomen/groin
Pulses (abdomen)

Observe abdomen
Fasciculations
Abdominal Reflexes

Pulses (extremities)
SLR
Bowstring
Plantar Reflex
Circumference (thigh, calf)
Leg Length:
- actual
- apparent

Sciatic Notch
Patrick FABERE
Gaenslen's Test
Gluteus Maximus Stretch
Hip Medial rotation
Psoas Test
Thomas' Test:
- hip joint
- Rectus Femoris

LATERAL RECUMBENT

S-I Compression
Ober's Test
Femoral Nerve stretch
Myotomes:
- QL
- Gluteus Medius

NON ORGANIC SIGNS

Pin Point Pain
Axial Compression
Trunk Rotation
Burn's Bench Test
Flip Test
Hoover's Test
Ankle Dorsiflexion Test.

GAIT

Rhythm
On toes (standing)
On Heels (standing)
Half squat on one leg

PRONE

Gluteal skyline
Skin rolling
Iliac crest compression
Facet joint challenge
S-I tenderness
Erichson's Test
Pheasant's Test
Myotome:
- Glut. Max

Active MF Trigger Pts:
- QL
- Glut. Med
- Glut. Min
- Glut. Max
- Piriformis
- Hamstrings
- TFL

NEUROLOGICAL EXAMINATION

DERMATOMES			MYOTOMES			REFLEXES		
	L	R		L	R		L	R
T12			Hip Flex			Pat.		
L1			Hip int rot			Achil		
L2			Hip ext rot			H/S		
L3			Hip abd					
L4			Hip add					
L5			Knee flex					
S1			Knee ext					
S2			Dorsiflex					
S3			Plantarflex					
			Eversion					
			Ext.hal.long					

Tripod
Kemp's Test

MOTION PALPATION and JOINT PLAY:

LEFT: Upper Thoracics:
Lumbar Spine:
Sacroiliac Joint:

RIGHT: Upper Thoracics:
Lumbar Spine:
Sacroiliac Joint:

Basic Exam: Hip
Case History:

ROM: Active:
Passive:
RIM:
Orthopaedic/Neuro/
Vascular:

Observ/Palpation:

Basic Exam: Thoracic Spine
Case History:

ROM: Motion Palp:
Active:
Passive:
Orthpaedic/Neuro/
Vascular:

Observ/Palpation:

Appendix J

Group 1: Clinical research orientated setting

1. The patients arrive at reception where they undergo a staged randomisation process with the receptionists.
2. The researcher who is dressed in clinic jacket and name badge to reinforce that the researcher is a student intern then greets them.
3. They then move to the clinic room where the research will seat the patient and go and get a clinician to do the initial history.
4. The researcher will then complete the history relative physical and regional examinations on clinic issued documents.
5. The researcher will excuse himself and go and get the relevant signatures. Making sure he tells the patient that this is what he is going to do.
6. On returning the patient is treated with manual therapy.
7. The patient and researcher return to reception where the follow up appointments are made on the intern register.
8. Follow-ups will take the same procedure except for the clinician coming in to do the history. On follow up a soap note will be completed in the clinic room and then the researcher will make a point of going to get it signed off before the follow up treatment can commence.

The interaction between the patient and researcher will be kept to a minimum by the researcher following the regime of the clinical format found in the clinic documentation. No diagnosis or even differential diagnosis will be given to the patient until after the soap note has been signed by the clinician. The clinic room will be sparse and clinical i.e.: no documentation or posters on the walls no standing models or props no magazines. Explanations will be kept as brief as possible and any type of documentation such as pain scales will be filled out by the patient under the understanding that it is for the proposed research

Group 2: Private practice setting

1. Patient will be greeted by the receptionist but will not undergo the staged randomisation process.
2. The researcher who will be dressed in smart casual attire will then greet the patient. No name badge or clinic jacket. The researchers diagnostic kit must already be in his clinic room in the desk.
3. Patient and researcher will go to the clinic room which will be made more welcoming by having posters, magazines etc on the walls as well as some of the researches personnel effects e.g. photos, text books, etc.
4. The researcher will then commence with a history relevant physical and regional examinations. All data will be initially captured on documentation similar to those used by practitioners out in the field or on an exam pad. The examination will be more flexible and less regimental. A differential diagnosis may be given after the examination is completed and all questions asked by the patients may be answered to the best of the researchers ability.

5. The researcher will then excuse himself from the room to get towels where he will then go get his notes temporally signed by the clinician on duty.
6. On returning with the towels the researcher will perform the same treatment on the patient like that in Group 1.
7. The researcher will then escort his patient to reception to book follow up appointments.
8. After the patient has left the researcher will then transfer his notes onto clinic issued documentation and present it to a clinician to get it signed off
9. On follow up visits the patients will be asked to fill in the pain scales so that the researcher has a visual account of the patients progress
10. Again the researcher will excuse him self to go get towels at the same time getting the soap note signed off.

In this group the examination will be more flexible and relaxed and less regimental as opposed to group 1 which is very regimental. The interaction between the researcher and patient is not restricted at all at any stage the researcher is able to give explanations and opinions as opposed to the group 1 where this will only be able to occur after the clinician has signed off.

Appendix K

Letter of Information (Research setting)

Dear Patient

Welcome to this research study on mechanical low back pain. I am comparing the effect of the lateral recumbent lumbar roll versus the lateral recumbent spinous pull in the chiropractic treatment of mechanical low back pain. All patients will be treated with chiropractic manipulation and soft tissue massage. Both are widely recognized treatments for acute (less than six weeks) mechanical low back pain. Manipulation and soft tissue massage are commonly used by chiropractors and are safe and relatively risk free procedures. The side effects for spinal manipulation and soft tissue massage can be slight post- manipulation soreness and stiffness, slight skin irritation and or bruising.

All treatment is free of charge and on a voluntary basis. There is no monetary compensation for being on this research. It will be conducted at the Durban Institute of Technology Chiropractic Day Clinic. Be assured that all information will be regarded as strictly confidential and you have the right to reject the use of anything, which you do not feel comfortable with. The study will consist of two groups of 30, equally and randomly divided. To participate in this study the following criteria will be required:

1. You must be between the age's 18- 45 years of age.
2. You must have recently (last six weeks) experienced low back pain.
3. If any contraindications to manipulation or soft tissue massage are suspected on examination, you may not be included in this study.
4. You may not take any NSAID, anti-spasmodic or analgesic drug therapy. (Neither allopathic nor homeopathic) for three days before, during the treatment period.
5. No other manual therapy may be undertaken during the research period.
6. You may not be pregnant or breast-feeding during the research.
7. You are required to not change your lifestyle or level of activity during the research to avoid bias results.

The benefits of being on this study include: personal high-quality care for your low back pain, treatment for the recommended period of time for your condition, all free of charge. The freedom to continue or stop the treatment, as you feel necessary and, the opportunity to contribute to furthering tertiary education and valuable research for chiropractic treatment of low back pain.

You will receive 3 treatments and one follow-up treatment, over a two-week period. Your initial treatment will take approximately two hours, and thereafter half an hour each. All treatments will be performed under the supervision of a qualified chiropractor. You will remain in the study as long as you commit to the appointment schedule and there will be no adverse consequences if you decide to stop participating in the research. If for any reason the research thinks it is in your best interests to terminate your participation in the research, he has the authority to do so. If there are any unusual findings by the researcher you will be informed of these. At this point I also remind you that there are no right or wrong answers and I appeal to you to be as accurate and honest as possible in your responses to all questions.

Yours sincerely

Grant Richardson: B Tech: Chiro. - Researcher (Tel: 2042205)
Dr. C. Myburgh: M Tech: Chiro. – Supervisor (Tel: 0829015790)

Appendix L
(Patients in Normal Practice Setting)

CONFIDENTIAL PATIENT INFORMATION

Date: ……..

Male/Female: ……..

Surname: ……. Title: …….

First names: ……. Initials: …….

Birth date: ……. I.D. number: ……

Occupation: …….. Marital status: …….

Medical aid: …….. M/A number: ……...

Med doctor: …….. Last visit: …….

Chiropractor: …… Last visit: …….

Postal address: Residential address: ……
…….
…….
…….
…….

Tel – work: ……... Tel – home: …….

Cell no. …….

Employer: …….....

Employers address:
……
……
……
……
…….....

Chiropractor: ……

FINANCIAL INFORMATION

The current fee schedule of the Chiropractic Day Clinic is:

Initial visit: **R60.00**
Subsequent visits: **R50.00**

X-rays and other services: Varies with procedures

Most **Medical Aid** schemes pay for Chiropractic Services. Please check with your scheme for the extent of such coverage. Statements for submission to you Medical Aid will be forwarded to you at the **end of the month.**

The terms of payment at this clinic are **strictly cash**, to be paid for **in advance** of any services rendered.

Please note: No Medico/Legal Reports will be generated here.

I accept full financial responsibility for consultations and/or services

Date: ……. **Signature: ……..**

TO BE COMPLETED IN THE CASE OF PATIENTS UNDER THE AGE OF 18

I, …….. , Parent/Guardian of: ……...
Who is a minor, have been fully informed of the treatment protocols to be implemented and hereby consent to the commencement of this treatment plan at the this Chiropractic Day Clinic.

Name of Guardian: ……

Signature of Guardian: …….

Relationship of Guardian to Minor: ……..

Appendix M

Letter of Information on Completion of study

Clinical Research Group Setting

Dear Patient

The main goal of this study was to compare the effect that a clinical research orientated practice environment would have on a patient being treated for mechanical low back pain versus a patient being treated in a normal practice environment like those found in the field.

Due to the nature of this study certain measures needed to be put in place in order for the integrity of the main goal of the study to remain intact. In order for the researcher to create the correct context for this study you were placed under the impression that you were participating in a clinical trial, where different adjusting techniques were being tested, when in fact it was the environment that was being studied.

The investigations and treatments you received were the standard investigations and treatments given by the chiropractic profession for mechanical low back pain. You would have received 3 treatments and one follow-up treatment, over a two-week period. Your initial treatment would have taken approximately 2 hours, and thereafter half an hour each. All treatments were performed under the supervision of a qualified chiropractor. If the treatment schedule was not maintained the researcher would have contacted you telephonically to ascertain the reason and encouraged you to complete the required number of visits.

By consenting to become part of this research study on your final visit, all data that has been collected can be used in the study.

If you would like to see more detailed notes on both groups, please feel free to request them from me.

Yours sincerely

Grant Richardson: B Tech: Chiro. - Researcher (Tel: 2042205)
Dr. C. Myburgh: M Tech: Chiro. – Supervisor (Tel: 0829015790)

Appendix N
(Patients in Clinical Research Setting)

CONFIDENTIAL PATIENT INFORMATION

Date: …….

Male/Female: ……..

Surname: ……. Title: …….

First names: ……. Initials: …….

Birth date: ……. I.D. number: …….

Occupation: …….. Marital status: …….

Medical aid: …….. M/A number: ……...

Med doctor: …….. Last visit: …….

Chiropractor: …… Last visit: …….

Postal address:
…….
…….
…….
…….

Residential address: …….

Tel – work: ……... Tel – home: …….

Cell no. …….

Employer: …….....

Employers address:
……
……
……
……

Chiropractor: ……..

FINANCIAL INFORMATION

The current fee schedule of the Chiropractic Day Clinic is:

Initial visit: **R60.00**
Subsequent visits: **R50.00**
Research visits: **No Charge**

X-rays and other services: Varies with procedures

Most **Medical Aid** schemes pay for Chiropractic Services. Please check with your scheme for the extent of such coverage. Statements for submission to you Medical Aid will be forwarded to you at the **end of the month.**

The terms of payment at this clinic are **strictly cash**, to be paid for **in advance** of any services rendered.

Please note: No Medico/Legal Reports will be generated here.

I accept full financial responsibility for consultations and/or services

Date: ……. **Signature: ……..**

TO BE COMPLETED IN THE CASE OF PATIENTS UNDER THE AGE OF 18

I, …….. , Parent/Guardian of: ……...
Who is a minor, have been fully informed of the treatment protocols to be implemented and hereby consent to the commencement of this treatment plan at the this Chiropractic Day Clinic.

Name of Guardian: ……

Signature of Guardian: …….

Relationship of Guardian to Minor: ……..

Appendix O

pg1 12-9-03
Dr. H. Pooke

Waiting Room: - friendly pleasand receptionist
- light well like room with reception desk and comfortable chairs for patients
- Adequet upto date magazines
- Radio playing in background
- Interesting articles + postes on the walls related to chiropractics
- Patients Paid for Treatment prior or Post appointment (prior if patient Volunteered it)
- Atmosphere very relaxed and pleasent

Doctor : - Very friendly + Accomidating, Confident
- Dressed Smart Casual (no clinic jacket)
- Meet and Greet patient, Socialises with other patients invits patient through to his Treatment Room.

Treatment Room: - Plinth, chiro Table, Dr., Desk, Book Shelf Postevs,
- Desk faces Patient, Dr. Personal effects eg: Photos, Diagnostic equipment etc on Desk
- Walls Covered with postes, Qualifications
- Personal photos achievments etc
- Room spaciously arranged
- Extra Therapeutic equipment on display eg: IR lamp, Vibration massage, TENS IFC etc

pg2

Consultation :
- Basic info captured by receptionist
- Vitals initially done
- Pt History captured while examination done (5 - 10 min)
- Problem area Tackled immediately
- Diagnosis + Proposed Treatment given as soon as Dr. was sure of Diagnosis + Plan.
- Dr. looked at and examined Multiple areas
- Dr. spoke and socialized throughout consultation there was no set regime or Structure

Treatment :
- Multiple areas Treated
- Multiple modalities used eg: IFC, adjcm Ice. or Acupuncture, STT, adj, ICE.
- IVI Voltarene used in Acute cases
- 7 Treatment were observed 5 female, 2 Male
- Consultation + Treatment Time on average 27min
- Home exercise + advice given
- for LBP suggested Rx 4 appointment in 2 week period

Pg3 15-9-03
Dr. G. Haswell

Waiting Room :
- Small But pleasant
- Very light + welcoming
- Very Proffetional + comfortable
- clean + neat
- plants to decorate
- Usual Selection of Magazines
- friendly Helpful Receptionist o

Doctor :
- friendly, Confident, firm
- Well presented
- Dressed smart Casual
- Very welcoming

Treatment Room :
- More clinical (painted White)
- fewer personal effects
- Very Proffesional looking
- Posties + Qualifications on Walls

Consultation :
- Tackled problem area imediately following Vital check
- Brief Notes made during Consultation
- Constant Communication with patient on findings
- History done while examination Took place (10-15min).

Treatment :
- 4 Treatments observed 1 Female 3 Male
- Multiple areas Treated
- Multiple Modalities Used
- Average Rx Time 40min

pg4 30-9-03
Dr A. Jones

Waiting Room :
- Very light and Comfating, Warm
- (Yellow + white Combination)
- Very Spacious
- Usual Magazines
- pot plants decorate office making it look fresh + proffesional.
- Patients pay for Treatment on arrival

Doctor :
- Very friendly easy to approach
- Soft spoken
- Confident
- Dressed Smart Casual (No white coat)
- Socialises with patient
- Invites pt through to Rx Room.

Treatment Room :
- Very proffesional looking
- Books, posters, Personal effects etc
- plinth, adjustable chiro Table
- Host of modalaties, Ultra Sound, TENS
- IFC, Needles
- Pleasant Relaxing Proffessional atmosphere

Consultation :
- Basic info captured by receptionist
- Vitals Done by Practicus
- History (Brief) completed followed by examination of affected area (5-12)
- Diagnosis given after examination
- looked at Multiple areas.

Pg 5

Treatment :-
- Average consult with Treatment was approximitly 30 mi
- Multiple area Treated
- Multiple modalities used
- 6 Treatments observed
- 3 males, 2 Geriatric ladies, 1 Infant
- advise + Home exercises were given
- Constant Reassurance and communication between Dr. + Patient.

Appendix P

Telephonic Interview Questions

1. Where is your back pain situated?
2. Is your pain one sided or do you have pain on both sides?
3. How long have you had the pain for?
4. Was there any trauma involved in causing your pain?
5. Do you have any knee, foot, or leg pain?
6. Do you have pins and needle sensation anywhere or loss of sensation?
7. How old are you?
8. Are you Pregnant?
9. Have you been taking anti-inflamatories or painkillers?
10. Do you have any congenital Low back problems?
11. Have you had any recent Low Back Surgery?