The effect of a lumbar support pillow on low back pain in long distance truck drivers in the eThekweni District.

By

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I, Brittany Van Wyk, do hereby declare that this dissertation is representative of my own work in both conception and execution (except where acknowledgements indicate to the contrary).

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DEDICATION

I dedicate this dissertation to:

My mom and dad who have made this all possible. I cannot thank you enough for the love, encouragement and support you have both given me throughout this journey of pursuing my dreams. When I thought I couldn't do it, you were the ones who kept me going. The many sacrifices and hard work you have put in towards my education will forever be appreciated.

"At the end of the day, the most overwhelming key to a child's success is the positive involvement of parents." – **Jane D. Hull**

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"No eye has seen, no ear has heard, and no mind has IMAGINED what God has prepared for me." - **1 Corinthians 2:9**

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ABSTRACT

BACKGROUND

A lack of adequate lumbar support when driving has been said to be an important causative factor of low back pain (LBP) in long-distance truck drivers. Health practitioners prescribe a lumbar support pillow even though the findings of several studies are uncertain. EnVision Tomorrow After Pain (ENTAP) claims that its lumbar support pillows result in an improved posture, a decrease in pain and an increase in comfort (ENTAP 2016). The *'ENTAP Lumbar Support'* has not yet been tested on participants and, therefore, these claims cannot be currently validated. Therefore, this study intended to determine the effectiveness of the *'ENTAP Lumbar Support Pillow'* in decreasing LBP in long-distance truck drivers.

OBJECTIVE

To determine the effect of the *'ENTAP Lumbar Support Pillow'* on LBP in long-distance truck drivers in terms of pain parameters (intensity and duration of pain), activities of daily living and disability when compared with a polyester lumbar support pillow and no lumbar support pillow.

METHODS

Sixty-three long-distance truck drivers experiencing LBP were recruited from a trucking company by random allocation. The study was a quantitative paradigm, double blinded, true experimental study design. Participants had to fill out a general questionnaire to determine whether they met the inclusion criteria. A baseline, three-week and six-week questionnaire, consisting of the Numerical Pain Rating Scale (NPRS), the Oswestry LBP Scale and the Patients' Global Impression of Change (PGIC) Scale. Statistical Package for the Social Sciences (SPSS) version 25.0 was used to analyse the data. The mean body mass and height were compared between the three treatment groups using one-way Analysis of Variance (ANOVA) tests. Repeated measures ANOVA testing was used to assess the treatment effect of the intervention group compared to the other groups (Esterhuizen 2018). Post hoc comparison of the intervention effect between time points and between treatment groups was done using a Bonferroni correction for multiple testing (Esterhuizen 2018).

RESULTS

The NPRS within the subjects' contrast showed a progressive variation from baseline testing to the three week ($p=0.04$) and the six week ($p=0.001$). The profile plot revealed that the mean pain score decreased much faster in Group B *'ENTAP Lumbar Support Pillows'* compared with both the other groups. The Oswestry LBP Disability Questionnaire score revealed that the score tests within the subjects' contrasts showed that the interaction of time x group was significant only at six weeks ($p<0.001$) compared with baseline. The profile plot showed that the mean Oswestry LBP Disability Questionnaire score decreased (improved) much faster in Group B *'ENTAP Lumbar Support Pillow'* compared with both the other groups. There was a highly significant treatment effect overall (time x group $p<0.001$) for the PGIC Scale, indicating that the change in score over time was different in the two groups ($p<0.001$). The profile plot showed that the mean PGIC score increased (improved) in the Group B *'ENTAP Lumbar Support Pillow'* while it decreased (worsened) in the polyester group. There was a highly significant treatment effect overall (time x group $p<0.001$) for the degree of change score, meaning that the change in score over time was different in the two groups. The profile plot showed that the mean degree of change score decreased (improved) in Group B *'ENTAP Lumbar Support Pillow'* while it increased (worsened) in the Group C (polyester-filled lumbar support). All participants in both lumbar support groups answered "yes" to the question on whether they found the support comfortable at both three weeks and six-week time points.

CONCLUSION

The *'ENTAP Lumbar Support Pillow'* was effective in decreasing LBP in long-distance truck drivers. It was considered to decrease LBP, improve activities of daily living and decrease disability, and it was also considered as comfortable. Therefore, the Alternate Hypothesis (H_a) which states that there will be a statistically significant ($p<0.05$) improvement in LBP in the participants who use *the 'ENTAP Lumbar Support Pillow'* compared to no lumbar support pillow and the polyester-filled lumbar support pillow is accepted and the Null Hypothesis is rejected.

LIST OF SYMBOLS AND ABBREVIATIONS

°:	Degree
≤:	Less than or equal to
<:	Less than
%:	Percent
=:	Equals
α:	Alpha
B:	Beta Coefficient
t:	t statistic from a t-test
f:	f statistic for the ANOVA test
H_{a}:	Alternate Hypothesis
n:	Sample size or count
LBP:	Low Back Pain
ENTAP:	EnVision Tomorrow After Pain
NPRS:	Numerical Pain Rating Scale
PGIC:	Patients’ Global Impression of Change
NDI:	Neck Disability Index
ANOVA:	The Analysis of Variance
NAPPI:	Non-Abusive Psychological and Physical Intervention
SPSS:	Statistical Package for the Social Sciences
IREC:	Institutional Research Ethics Committee
DUT:	Durban University of Technology
RHDC:	Research Higher Degrees Committee
VAS:	Visual Analogue Score
SSAS:	Somatosensory Amplification Scale
ROM:	Range of Motion
IVD’s:	Intervertebral Discs
WBV:	Whole-Body Vibration
MSK:	Musculoskeletal
BMI:	Body Mass Index
EMG:	Electromyography

km:	Kilometres
g:	Grams
mm:	millimetres
m:	metres
cm:	centimetres
kg:	Kilograms
OR:	Odds Ratio
CI:	Confidence Interval
ICC:	Intraclass Correlation Coefficient
L1:	First lumbar vertebra
L2:	Second lumbar vertebra
L3:	Third lumbar vertebra
L4:	Fourth lumbar vertebra
L5:	Fifth lumbar vertebra
S1:	First sacral vertebra

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

TABLE OF CONTENTS

CHAPTER ONE

INTRODUCTION

1.1 INTRODUCTION

Low back pain is the leading cause of activity limitation and absenteeism from work globally. This imposes a high economic burden on individuals, families, communities, industries and governments (Katz 2006). In 2013, 71% of the 734-million tons of freight moved in South Africa was moved by road (Grey 2015); therefore, making truck driving an important, but tedious job (Benstowe 2008). Two South African studies, both by Ramroop, have investigated LBP amongst truck drivers. In his study on occupational LBP in a sample of 450 truck drivers, Ramroop (2013) reported that 86% (n=385) of the individuals currently suffered from LBP, of which 18% (n=68) rated their pain as '10' on the NPRS. Ramroop (2005) also investigated LBP amongst refuse truck drivers in the eThekweni Municipality, reporting a one-year prevalence of 79%, a one-week prevalence of 64%, and 69% of subjects reported experiencing LBP after driving.

Long-distance truck drivers are uniquely positioned to be at high risk for the development of occupational LBP as they are exposed to a number of risk factors associated with LBP. These include prolonged sitting, whole body vibration (WBV), physical and psychological fatigue, static work posture, awkward work posture, poor truck ergonomics, monotony, and stress. They are also expected to load and unload heavy cargo as well as put on and remove the heavy tarpaulins (Van Dyne and Christiansen 2006; Benstowe 2008; Kresal *et al.* 2017; Lis *et al.* 2007; Blood *et al.* 2015; Ramroop 2005; Mitsuhiko *et al.* 2004: 119-124). Other risk factors associated with LBP include age, gender, genetics, sedentary lifestyle, excess weight, poor posture and smoking (Hochschuler 2008).

In a laboratory vehicle mock-up research on the seat position and posture of truck drivers without proper lumbar support, it was found that truck drivers were not satisfied with the limited range of adjustability. The limitations of not being able to adjust the seat to a desirable position could lead to musculoskeletal injuries and other symptoms (Fatollahzadeh 2006). These include persistent stiffness or aching of the lower back, sharp localised pain in the low back, chronic ache in the back after sitting for prolonged periods of time, LBP that radiates from the low back to the buttock, into the hamstring, can extend into the calf and down to the toes and muscle spasms (DerSarkissian 2017). Since truck drivers sit for prolonged periods nearly daily, it is very important to reconsider the types of seats they are using (Key 2013). One way of addressing the limitations of not being able to adjust the seat is to provide an adequate back support pillow for the drivers.

Hagiwara *et al.,* (2017) reported the effects of a lumbosacral support for LBP amongst hospital workers. The Visual Analogue Score (VAS), the Somatosensory Amplification Scale (SSAS) scores and the lumbar spinal range of motion (ROM) within the experimental group decreased significantly. Low back pain (OR=0.401, 95% CI=0.168-0.954) decreased significantly (Hagiwara *et al.* 2017: 201-209). Chen *et al.* 2005 reported that seat inclination, use of a lumbar support on symptomatic LBP among Taiwanese taxi drivers reduced prevalence of LBP (p=0.00001*)*. These encouraging findings support the need for robust trials on the effectiveness of lumbar supports on reducing LBP in long-distance truck drivers (van Duijvenbode *et al.* 2008). It is with this in mind, that the current research seeks to explore the effectiveness of a locally-developed lumbar support pillow for long-distance truck drivers.

It is said that without a proper lumbar support pillow, the natural "S" shape of the spinal column straightens and becomes a "C" shape, resulting in a slouched posture, causing tension and stress on the lower back (Gale, 2011). The basis of all lumbar support pillows is to achieve the correct seating position. To obtain the optimum seating position, the lumbar support must provide support to the pelvis, preventing it from rotating, support to the lumbar vertebra and vertical support to the upper body (Gale 2011). The ergonomic benefits of lumbar support pillows include a decrease in muscle activation, decreased tension on ligaments, decreased pressure on the discs and increased comfort (Hedge 2005).

Ergonomists believe that sitting can be beneficial in decreasing the fatigue experienced from standing but can in turn cause increased intradiscal pressure and flatten the lumbar lordosis (Lueder 2004). Lueder (2004) reported that truck drivers are four times more at risk of developing a herniated disc. A good lumbar support pillow will result in a decrease in muscle activity, decrease tension on ligaments, decrease pressure on Intervertebral Discs IVD's and increase the comfort of drivers (Buss 2009).

The lumbar support pillows that will be used in this study are the *'ENTAP Lumbar Support Pillow'* (ENTAP 2016) and the polyester-filled lumbar support pillow. The *'ENTAP Lumbar Support Pillow'* is made from foam which is moulded to correct the users seating posture. The ENTAP lumbar support pillow is compact and firm, therefore it is an ideal pillow to be used in car seats or office chairs. This pillow has a Non-Abusive Psychological and Physical Intervention (NAPPI) code which enables the purchaser to apply for reimbursement from a medical aid scheme (ENTAP 2016). The lumbar support pillow will not cure LBP but is said to be palliative in contributing to a decrease in LBP. *'ENTAP'* anecdotally claims that their lumbar support pillow results in an improved posture, a decrease in pain and an increase in comfort (ENTAP 2016). However, the *'ENTAP Lumbar Support Pillow'* has not yet been tested on participants and, therefore, these claims cannot currently be validated. The polyester-filled pillow was made by the *'ENTAP'* company only for the purpose of this study. The reason for the testing of the polyester pillow versus the *'ENTAP Lumbar Support Pillow'* was to determine the effects of a simple polyester-filled lumbar pillow in comparison to the high-quality foam filled *'ENTAP Lumbar Support Pillow'.*

1.2 STUDY AIMS, OBJECTIVES AND HYPOTHESES

1.2.1 Aim

The aim of the study was to determine the relative effects of an *'ENTAP Lumbar Support Pillow',* a polyester-filled lumbar support pillow and no support pillow on low back pain in long-distance truck drivers over a six-week period.

1.2.2 The objectives of the study were:

Objective one:

To determine the effect of the *'ENTAP Lumbar Support Pillow'* on LBP in long-distance truck drivers in terms of pain parameters (intensity and duration of pain), activities of daily living and disability.

Objective two:

To investigate the effect of no lumbar support fitted in the trucks on LBP in long-distance truck drivers in terms of pain parameters (intensity and duration of pain), activities of daily living and disability.

Objective three:

To determine the effect of the polyester-filled lumbar support pillow on LBP in long-distance truck drivers in terms of pain parameters (intensity and duration of pain), activities of daily living and disability.

Objective four:

To establish the effect of the polyester-filled lumbar support pillow on low back pain in long-distance truck drivers in order to determine the efficacy of the *'ENTAP Lumbar Support Pillow'* in reducing LBP in terms of pain parameters (intensity and duration of pain), activities of daily living and disability.

1.2.3 Hypothesis

1.2.3.1 The Null hypothesis:

The Null hypothesis states that there will be no statistically significant ($p<0.05$) improvement in LBP in the participants who use the *'ENTAP Lumbar Support Pillow'* when compared to no lumbar support pillow and the polyester-filled lumbar support pillow.

1.2.3.2 The Alternate hypothesis:

The Alternate Hypothesis (H_a) states that there will be a statistically significant ($p<0.05$) improvement in LBP in the participants who use the *'ENTAP Lumbar Support Pillow'* compared to no lumbar support pillow and the polyester-filled lumbar support pillow.

1.3 THE SCOPE OF THE STUDY

The results of 63 participants aged between 18 and 65, working as long-distance truck drivers, experiencing LBP and meeting the inclusion criteria were reported in this dissertation. This study adopted a quantitative paradigm and a true experimental study design over a period of six weeks. A signed informed consent was used throughout. The participants were each randomly allocated to one of three groups by drawing a piece of paper marked either A, B or C from a small box. Group A used no lumbar support pillow during the six-week experimental period, Group B use the *'ENTAP Lumbar Support Pillow'* and Group C used a polyester lumbar support pillow. The subjective outcome measures used were the NPRS (Hawker 2011), the Oswestry LBP Disability Questionnaire (Fairbank and Pynsent 2000) and the PGIC scale (Hurst and Bolton 2004). They were each administered at the start of the study and after three and six weeks.

1.4 LIMITATIONS OF THE STUDY

The participants were driving their trucks most days and therefore the researcher was unaware whether the participants were wearing their lumbar support pillow as well as whether the lumbar support was always positioned correctly while driving. The researcher went to the transport company once a week to check on the drivers in the yard at that time and whether they were wearing their lumbar support pillows and whether they were wearing them correctly. The researcher was at the work place once a week also to get an update on whether any truck drivers were experiencing problems with the lumbar support pillows. It is assumed that the participants answered all questions truthfully. Due to human resource, time and financial constraints this study is limited to participants from one company only.

1.5 FLOW OF DISSERTATION

Chapter one has provided an introduction and rationale for the study, together with the aims, objectives and study hypotheses.

Chapter two, the literature review, has provided an overview of the anatomy of the low back and the diagnosis and management of LBP. This was followed by a critical analysis of the literature on the use of lumbar support pillows used for low back pain.

Chapter three explains the methodology utilised in this study to achieve the aims and objectives. The study design, methods, techniques and instruments used are outlined and explained.

Chapter four presents the results of the study. The demographic and anthropometric characteristics of the sample - with the data collected through the Oswestry LBP Disability Questionnaire, the NPRS and the PGIC Scale - will be presented using figures and tables. IBM SPSS version 25.0 was used to analyse the data. A p value <0.05 was considered as statistically significant. The mean body mass and height were compared between the three treatment groups using the one-way ANOVA tests. Repeated measures of ANOVA testing were used to assess the treatment effect of the intervention group (*'ENTAP Lumbar Support Pillow'* – Group B) when compared with the other groups (no lumbar support pillow – group A and a polyester-filled lumbar support pillow – group C). A significant time x group interaction effect indicated a significant treatment effect. The direction of the effect was assessed using profile plots. Post hoc comparison of the intervention effect between time points and between the treatment groups was done using a Bonferroni correction for multiple testing (Esterhuizen 2018).

Chapter five provides the discussion of the results in relation to the current literature.

Chapter six concludes the study discussing the study limitations and recommendations.

CHAPTER TWO
LITERATURE REVIEW

This chapter will investigate and explain the anatomy of the lumbar-pelvic region of the spine, occupational low back pain and its implications, the epidemiology, aetiology, risk factors, treatment, long-distance truck driving and review of the literature related to the effect of a lumbar support pillow on LBP.

2.1 INTRODUCTION

According to Manga *et al.* (1993), LBP is an "ubiquitous and economically costly problem", affecting most people at a point in their lives. Ergonomists believe that conventional seating, even though it's beneficial to decrease the fatigue experienced from standing, causes an increase in the intradiscal pressure and flattens the normal lumbar lordosis. Musculoskeletal (MSK) complaints are common in truck drivers, especially the complaint of LBP (Amiditis and Bekiaris 2002). With regards to MSK complaints, truck drivers are common victims of back problems, being four times more likely to contract a herniated disc (Milosevic 1997: 381-389). Several authors have reported long-distance truck drivers to be at risk of experiencing back pain, fatigue and leg pain (Milosevic 1997: 381-389; Gale 2011: 21-22; Lueder 2004: 12-13). An hour of WBV whilst seated may result in weakened muscles, muscle fatigue and therefore cause the truck driver to be more at risk of developing LBP (Amiditis and Bekiaris 2002). It is said that absenteeism amongst occupational drivers is due to MSK complaints that are the result of an unhealthy seating posture whilst driving (van der Meulen *et al.* 1999). These problems arise due to the out-of-date and insufficient data used when designing the workspace in a truck (Fatollahzadeh 2006). Although research states that the use of a lumbar support decreases intradiscal pressure in the lumbar spine, the advantages of backrest lumbar support pillows are not yet reliable because not enough research has been done (Lueder 2004). Therefore, a greater understanding of the use of a lumbar support pillow as an intervention to prevent LBP in long-distance truck drivers is necessary.

2.1.1 Method of literature search

Various search engines such as Google Scholar, Summon, PubMed, eMedicine, and the Durban University of Technology Institutional Repository have been used.

Key terms used include: “epidemiology of LBP,” “incidence and prevalence of LBP,” “occupational LBP,” “lumbar support pillow,” “risk factors for LB in truck drivers,” “LBP in long-distance truck drivers,” “pathophysiology of LBP,” “effect of a lumbar support pillow on LBP,” “long-distance truck drivers,” “implication on the low back of long term sitting,” “treatments for LBP,” and “condition of roads in South Africa.”

2.2 LOW BACK PAIN

Hartvigsen *et al.* (2004: 2) stated there was no homogenous definition for LBP that serves as a gold standard. Kravitz and Andrews (2007) defined LBP as a pain within the lumbosacral region which includes the first lumbar vertebra to the first sacral vertebra of the spine. This definition covers a smaller region and does not include a vast number of cases where there had been symptoms of higher and lower regions. Shiel (2017) stated that LBP was a pain of the low back region which could be caused by an issue within the intervertebral discs (IVD’s), the lumbar spine, the spinal cord, nerves and muscles, spinal ligaments, or the skin over the area of the low back. This definition is adequate as it covers a bigger area of the low back and includes the structure within the low back. The limitation of the aforementioned definition, is that it fails to demarcate the anatomical region.

2.2.1 Incidence and prevalence of low back pain

Low back pain is defined as muscle or ligament tension, pain or stiffness as well as bone pain that is localised below the costal margin and above the inferior gluteal folds, with or without sciatica (Chou 2011: 437-438). Low back pain is very common, and most individuals will experience it in their lifetime.

Hoy *et al.* (2010: 769-781) concluded that the one-year incidence of first time LBP ranges between 6.3% and 15.4%. The estimated one-year incidence of any episode of LBP ranges between 1.5% and 36% found in a clinic-based study, the episode of remission at one-year ranges between 54% and 90%. These studies did not state whether the LBP was continuous between the baseline and follow up time of the study. The majority of individuals who experience activity-limiting LBP will have recurrent episodes of LBP. It is estimated that recurrence of LBP at one-year ranges from 24% to 80% (Hoy *et al.* 2010:

769-781). Hoy *et al.* (2010: 769-781) stated that there was a considerable amount of information on LBP prevalence, and estimated a point prevalence ranging from 1.0% to 58.1% with a mean of 18.1% and median of 15.0%, and a one-year prevalence ranging from 0.8% to 82.5% with a mean of 38.1% and a median of 37.4%. Hodges and Richardson (1999: 1005-1012) stated that recurring LBP was caused by the inability to recruit the transverse abdominal muscles which work to stabilise the low back and this can lead to an overload of the joints during everyday activity. Roatta et al. (2002: 237-248) showed that high sympathetic activity, such as excessive mental stress causes an increase in the sensitivity of the muscle spindle system therefore causing chronic pain. Another cause of chronic and recurrent pain is the fear-avoidance model **(refer to Figure 2.2)** (Vlaeyen and Linton, 2012: 1144).

A global review on the prevalence of LBP within the adult population estimated the point prevalence of LBP to be 12%, a one-month prevalence of 23%, a one-year prevalence of 38% and a lifetime prevalence of 40%. As individuals age over the decades, the number of people with LBP is expected to increase substantially (Manchikanti *et al*. 2014: 3-10).

The point prevalence of LBP among Africans was substantially higher than estimates provided for Canada, Denmark and Sweden, and it was comparable to Germany and Belgium (Hoy D *et al.* 2010). The one-year prevalence of LBP among Africans was considerably higher than Spain, and on par with Denmark and Ukraine (Hoy D *et al.* 2010). The findings of this review therefore reiterates the fact that LBP is a burden and is therefore a public health concern among developing nations in Africa (Hoy D et al. 2010; Woolf et al. 2012; March L 2011). Despite the high burden, LBP remains a lower priority compared to epidemics such as HIV/AIDS in Africa (Hoy D et al. 2010; Woolf et al. 2012; March L 2011). African healthcare budgets and systems may be generally ill-prepared to deal with the management of LBP which could partly explain the high LBP prevalence among African populations (Hoy D et al. 2010; Woolf et al. 2012; March L 2011). The successful development and implementation of strategies and policies to address the burden of LBP in poorer countries or countries with emerging economies, like those in Africa, is therefore warranted (Hoy D et al. 2010; Woolf et al. 2012; March L 2011).

Louw *et al.* (2007) reported the mean LBP point prevalence amongst African adolescents was 12% and amongst adults, 32% respectively. Louw et al. (2007) review included 27 suitable epidemiological studies. 63% of the studies took place between Nigeria (26%) and South Africa (37%). Most of the sample group included workers (48%) and scholars (15%), the other 37% were unemployed. The average one-year prevalence of LBP amongst adolescents was 33% and amongst adults, 50%. The average lifetime prevalence of LBP amongst adolescents was said to be 36% and 62% amongst adults (Louw *et al.* 2007).

2.2.2 Prevalence of low back pain in truck drivers

Andrusaitis *et al.* (2006: 1807-1810) researched the risk factors and prevalence of LBP in truck drivers in the state of São Paulo, Brazil. Fifty-nine percent of the cohort sustained LBP. It was further discovered that individuals who worked one additional hour longer experienced more LBP than their contemporaries. The protection risk factor was reduced number driving. Sekkay et al. (2018) concurs with prevalence of LBP among truck drivers.

Miyamoto *et al.* (2000) has reported a high prevalence among Japanese trucker drivers, whose predisposing mechanism of pain was poorly designed ergonomic seats.

Ramroop (2005) and Ramroop (2013) recorded LBP among South African truck drivers to range from 79% to 86%. This is a startling static because the occurrence of LBP among South African drivers increasing. The risk factors for LBP in truck drivers in South Africa are heavy physical work, static work posture, frequent bending and twisting, lifting pushing and pulling, repetitive work, whole-body vibrations and psychological and psychosocial risk factors (Ramroop 2013).

2.2.3 Classification of low back pain

There are several classifications of LBP. Low back pain can be clinically classified into three different groups. These groups are predominant neuropathic, nociceptive or the central sensitisation pain. These classifications help determine the correct treatment of the LBP.

Neuropathic pain is caused by a disease or a primary lesion of the somatosensory nervous system (Nijs *et al.* 2015: 333-346). An example of neuropathic pain could be a lumbar radiculopathy. Nociceptive pain arises from a threatening or an actual damage to non-neural tissue. This pain is due to nociceptor activation or is attributable to the activation of primary afferent neurons because of mechanical, noxious chemical or thermal stimuli. Myofascial tissue and lumbar ligaments contain nociceptors which are therefore capable of causing nociceptive pain. Both neuropathic and nociceptive pain are classified as specific LBP when there is a distinct patho-anatomical diagnosis (Nijs *et al.* 2015: 333-346). It is said that a clear patho-anatomic diagnosis cannot be given to 85% of patients with LBP and therefore this LBP will be labelled as non-specific LBP (Nijs *et al.* 2015: 333-346).

Central sensitisation is defined as an increase in the neuronal repose or neural signalling within the central nervous system which then causes pain hypersensitivity. Central sensitisation of pain can be caused by an increase in the responsiveness to a variety of stimuli such as mechanical pressure, chemical substances, sound, light, cold, stress, heat and electricity (Nijs *et al.* 2015: 333-346). Low back pain can also be classified as acute, sub-acute and chronic LBP. Acute pain lasts less than four weeks, sub-acute pain lasts four to 12 weeks and chronic LBP lasts more than 12 weeks (Qaseem *et al.* 2017: 514-530). Low back pain can also be mechanical LBP, non-mechanical LBP and can also be caused by a visceral disease **(Table 2.1).**

Table 2.1 Classifications and causes of LBP

Mechanical LBP (97%)	**Non-mechanical LBP (1%)**	**Visceral Disease (2%)**
Lumbar strain or sprain or idiopathic pain or no pathoanatomic confirmation (70%)	Neoplasia (0.7%)	Pelvic organ involvement
Degeneration of discs and facets (10%)	Multiple Myeloma	Prostatitis
Herniated disc (4%)	Metastatic carcinoma	Chronic pelvic inflammatory disease
Spinal stenosis (3%)	Lymphoma and leukaemia	Endometriosis
Osteoporotic compression fracture (4%)	Spinal cord tumours	Nephrolithiasis
Spondylolisthesis (2%)	Retroperitoneal tumours	Pyelonephritis
Traumatic fractures (1%)	Primary vertebral tumours	Prostatitis
Congenital disease (1%)	Infection (0.01%)	Perinephric abscess
Severe scoliosis	Septic discitis	Aortic aneurysm
Transitional vertebrae	Shingles	Gastrointestinal involvement
Severe kyphosis	Osteomyelitis	Pancreatitis
Spondylosis	Paraspinal abscess	Cholecystitis
Instability	Inflammatory arthritis (0.3%)	Penetrating ulcer
Internal disc disruption or discogenic back pain	Ankylosing Spondylitis	Renal Involvement
	Psoriatic Spondylitis	
	Inflammatory bowel disease	

	Scheuermann disease	
	Reiter syndrome	
	Paget disease	
	Ankylosing Spondylitis	

(Deyo and Diehl 1998: 230-238)

2.3 RISK FACTORS FOR LOW BACK PAIN

It is said that five to 15% of LBP can be due to a specific cause such as osteoporotic fractures, infection or a neoplasm. The cause of the remaining 85% to 95% is unclear (Duthey 2013).

2.3.1 Individual's Kinanthropometry

An increase in a person's Body Mass Index (BMI) can be a risk factor for lumbar sacral radicular pain and LBP. Individuals with anorexia nervosa are at risk for developing osteoporosis which can lead to an increase in the risk of vertebral fractures and because of this, the person will experience LBP (Lionel 2014: 1-4). It is said that increased height can increase the risk for disc instability under external loading. In taller people it was more evident that there was an alteration in the facet joints in patients with a lumbar disc herniation (Duthey 2013). Duthey (2013) also stated that studies had shown clearly that individuals with a high BMI have an increased rate of developing LBP. An analysis that included 33 research studies found that an obese individual will have an increased prevalence of LBP in the past one year with an OR of 1.33 (95% Confidence Interval (CI): 1.14-1.54) (Duthey 2013; Asher 2018). The spine is designed to carry an individual's body's weight and then distributes the loads that are encountered during rest and activity. When the body carries excess weight, the spine is forced to assimilate the burden, this can lead to structural compromise and damage. The region of the spine that is mostly affected by obesity is the low back – the lumbar spine (Silveri 2017).

2.3.2 Psychosocial factors

Psychosocial factors such as job dissatisfaction, low levels of social support in the work place, stress, anxiety, depression, low levels of job control and persons with negative affectivity have an increased risk of developing LBP (Duthey 2013; Hartvigsen *et al.* 2004; Hoogendoorn *et al.* 2000; Davis and Heaney 2000).

2.3.3 Occupational factors

It is said that 37% of cases of LBP are attributed to occupational factors (Duthey, 2013). Individuals who are exposed to vibration or long periods of standing or sitting in a workplace are more likely to experience LBP. These occupations include health-care workers, professional drivers, and construction workers. LBP can be higher in some occupations in which workers do a lot of heavy physical work and have abnormal working postures (Duthey 2013; Yilmaz and Dedeli 2018). Other factors such as job dissatisfaction, manual handing of goods or material, lack of social support in the workplace, working night shifts, bending and twisting and monotonous work can increase the risk of developing LBP (Yilmaz and Dedeli 2018).

2.3.4 Age and Gender

According to Kostova and Koleva (2001: 17-25), there is a gradual increase in LBP after the age of 40 years. As an individual ages, the height of the intervertebral disc which lies between each vertebral body decreases this can lead to pain and stiffness as there is no cushioning between the vertebral bodies and therefore the vertebral bodies rub against each other. With age, there is a decrease in the intervertebral foramen and this leads to spinal stenosis which causes pressure on the spinal nerves, causing referring pain. Osteoporosis (decreased bone mass) can also cause the vertebrae to be more vulnerable to fractures. The spine can also degenerate as a person ages and therefore lead to spinal arthritis (very common in the facet joints) (Orenstein 2016). A study done in Johannesburg, South Africa investigated the risk factors associated with LBP in hospital workers. This study found that LBP is more prevalent in females between the ages of 41 and 60 years of age with an OR of 2.06 and CI of 0.85; 4.98 (Olivier 2008).

2.4 AETIOLOGY OF LOW BACK PAIN

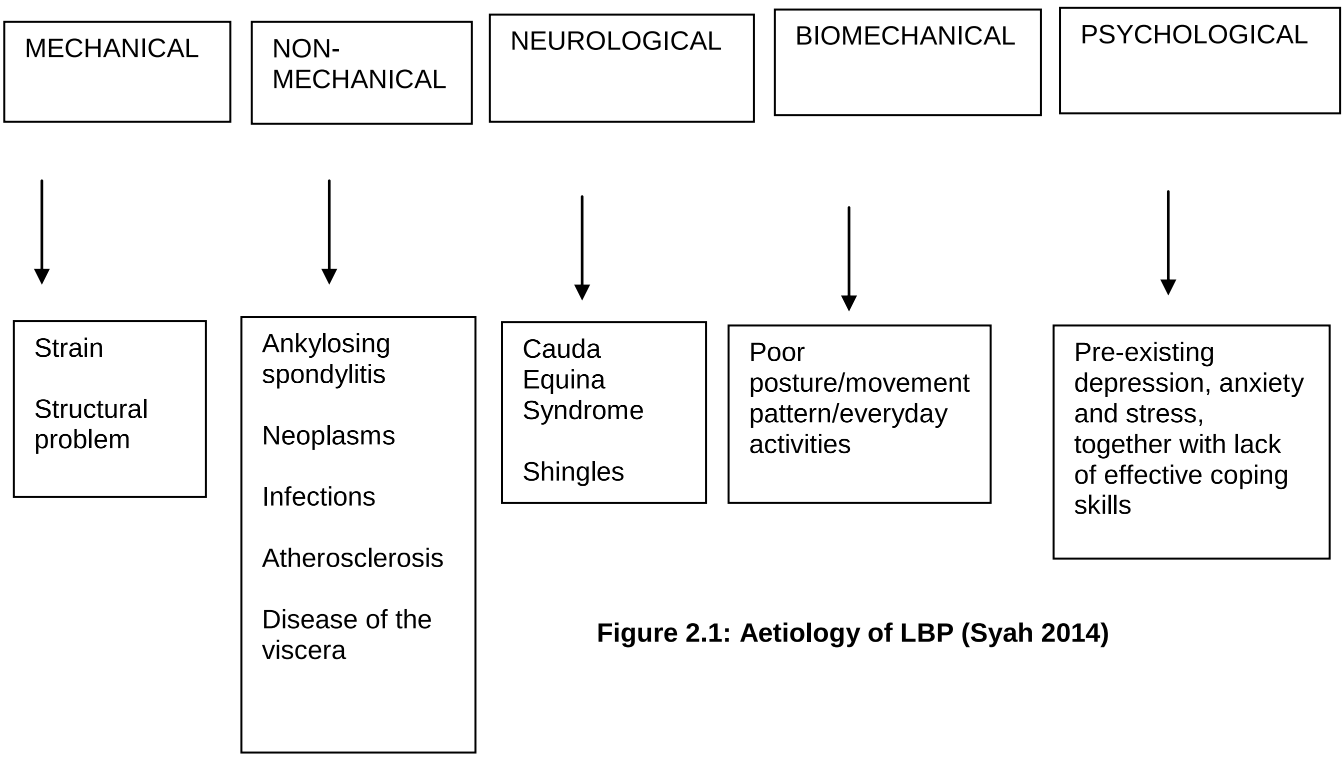

Figure 2.1: Aetiology of LBP (Syah 2014)

2.4.1 Anatomical and biomechanical aetiology

The aetiology of LBP is complex and multifaceted. Low back pain is usually due to an acute traumatic event, but cumulative trauma may also be an aetiology (Hills 2018). Anatomical structures such as bones, discs, ligaments, muscles and tendons play a role in LBP (Hills 2018). Many of these components of the lumbar spine have sensory innervation, which can then generate nociceptive signals, representing a response to a tissue damaging stimuli. Another cause of LBP is a neuropathic signal as in sciatica. Chronic LBP is usually due to mixed nociceptive and neuropathic signals (Hills 2018).

A poor sitting posture involves fixed femurs in relation to the mobile pelvis and vertebrae. A prolonged poor sitting posture causes the posterior rotation of the pelvis in relation to the pair of fixed femurs. However, the truck driver may lean forward to have a better view of the road or to clasp the steering wheel, this thereby elicits lumbar vertebral flexion. This is clinically known as short arc pelvis on femoral hip extension (Mansfield and Neumann 2008). The posterior pelvic rotation occurs due to concentric contraction of the gluteal muscles and eccentric contraction of the iliopsoas in a closed kinetic chain. Similarly, lumbar vertebral flexion is caused by the concentric contraction of the rectus abdominis and eccentric contraction of the erector spinae in a closed kinetic chain. Muscle action in closed kinetic chain actions moves the muscles' origin to the insertion (Prentice 2004). It is postulated that prolonged posterior pelvic orientation alters the length of the anterior and posterior intervertebral and pelvic muscles that could produce vertebral pain (Ellapen *et al.* 2014).

Authors have concluded that the apophyseal joints are commonly a cause of LBP (Adams 2004: 178-188). The sacroiliac joints are a major source of LBP in about 30% of individuals with chronic LBP below the level of L5 and S1 (Adams 2004: 178 -188). Biomechanically, there are physiological forces that act on the lumbar spine, most commonly on the disc which can contribute to mechanical damage and therefore causing LBP (Bogduk *et al.* 2004: 71-83).

2.4.2 Psychosocial aetiology

The psychosocial risk factors for LBP are cognitions, attitudes, fear-avoidance behaviour, anxiety, depression and distress (Bodguk 2006: 49–53). There is no evidence that psychosocial factors can cause LBP (Bodguk 2006: 49-53). The fear avoidance model shows the predictions of the interventions that can address this certain psychosocial factor of LBP (Bogduk 2006: 49-53).

Figure 2.2: Fear Avoidance Model
(Vlaeyen and Linton 2012: 1144)

2.5 ASSOCIATED FEATURES OF LOW BACK PAIN

Low back pain is a symptom and is not a specific disease. LBP is usually a discomfort that is felt in the lumbosacral region of the back, this pain may or may not radiate to the legs, hips, and buttock. As many as 90% of individuals who experience LBP, do not have a clear diagnosis as to what the problem is, and a small percentage may have a serious disease that is not low back related (Shiel 2018).

Associated features of LBP include a dull aching pain, numbness and tingling, a sharp pain, a pulsating pain, pain that occurs with certain movements of the spine, pins and needles sensation, muscle spasms, tenderness, sciatica with shooting pain down one or both lower extremities, and loss of continence of bladder or bowel (Shiel 2018). Low back pain may increase with activity or it may be worse at night or with prolonged sitting. An individual may have weakness or numbness in their lower extremities and this could indicate a nerve compression (Shiel 2018).

Red flags of LBP can possibly indicate a serious pathology and when these are present it is necessary for further investigations to be done. The red flags are seen below (**Table 2.2).**

Table 2.2: Red flags for low back pain

Possible Fracture	**Possible tumour/infection**	**Possible significant neurological deficit**
Major trauma	Age <20 or >50 years	Severe or progressive sensory alteration or weakness
Minor trauma in an elderly or osteoporotic individual	History of cancer	Bladder or bowel dysfunction
	Constitutional symptoms (fever, chills, weight loss).	On physical examination: evidence of neurological deficit (in legs or perineum in the case of LBP)
	Recent bacterial infection	
	Intravenous drug use	
	Immunocompromised	
	Pain worse at night	

(Henschke *et al.* 2009: 3072-3080)

2.6 OCCUPATIONAL LOW BACK PAIN DUE TO TRUCK DRIVING

Compared with the standing posture, the sitting posture decreases the lumbar lordosis, increases muscle activity in the low back, increases the pressure on the disc and the pressure put on the ischium. These are all associated with occupation LBP (Roffey *et al.* 2010).

2.6.1 Long-distance truck driving

A long-distance truck driver is defined as a person who drives a truck over a 200- to 300-kilometre (km) radius, or greater, from their home terminal each day for 26 days each month (Complete School of Truck Transportation 2014; Supergroup 2017). In South Africa, truck driving can be very stressful for a number of reasons, including drivers having to master the diverse skill of controlling and managing a heavily loaded trailer and dealing with many hazards on South African roads such as accidents, traffic congestion and road construction (Van Niekerk 2016). In South Africa, a draft was compiled which truck drivers are meant to comply with (Barry 2012). The draft is summarised as follows:

1. A maximum of five hours of continuous driving time.

2. A maximum total of 15 hours driving time in a period of 24 hours.
3. A resting period for a minimum of 15 minutes AND a total minimum of 30 minutes in a period of five and a half hours (Barry 2012).

Compared to the driving rules of the European Union where truck drivers drive nine to ten hours a day twice a week, truck drivers in South Africa work much longer hours (15 hours driving time in a period of 24 hours) (Barry 2012).

2.7 BIOMECHANICAL RISK FACTORS FOR LBP IN TRUCK DRIVERS

2.7.1 Static work posture

Truck drivers are exposed to many risk factors that contribute to developing LBP. When sitting in a fixed position while driving, they are exposed to WBV, forced positions and handling of heavy goods (Kresal *et al.* 2017: 151-162). Low back pain is more common in truck drivers than in those professions where workers change their body positions on a regular basis (Kresal *et al.* 2017: 151-162). Ergonomic factors such as uncomfortable truck seats are commonly stated as causes for LBP (Kresal *et al.* 2017: 151-162).

Ergonomists believe that conventional seating, even though it's beneficial to decrease the fatigue experienced from standing, it causes an increase in the intradiscal pressure and flattens the normal lumbar lordosis. The IVD's are meant to expand and contract as an individual moves, allowing for absorption of blood and nutrients in to the discs. When sitting, the discs are compressed and lose flexibility over time which can increase the risk of a herniated disc (Mercola 2015). This could possibly be a cause of LBP and trauma as the discs are being displaced anterior, leading to a prolapsed disc with steady damage to the nucleus pulposus as well as the possibility of nerve root compression (Gale 2011).

2.7.2 Awkward work posture

The sitting posture has been said to be a risk factor for developing LBP for many years (Lis *et al.* 2007: 283-298). The posture of an individual changes the magnitude of the loads on the lumbar spine. The magnitude of the load on the lumbar spine increases when compared with standing posture and well-supported reclining posture. There was much controversy around this finding even though laboratory studies supported it, other researchers found different results (Lis *et al.* 2007: 283-298). Wilke *et al.* (1999) documented that sitting caused an increase in the intradiscal pressure when compared to the erect standing posture. It was also said that the intradiscal pressure is ten percent more when sitting and ten percent less when standing.

Studies have shown that the OR is as low as 0.7 for individuals working in occupations which entail prolonged periods of sitting (Lis *et al.* 2007: 283-298). This shows that these individuals who sit for prolonged periods of time have a lower chance of developing LBP when compare to those whose occupations entail major physical activity or more strenuous occupations (Lis *et al.* 2007: 283-298). Lee *et al.* (2001: 2029-2035) stated that the individuals who sit for prolonged periods of time have the highest hospitalisation rate for LBP. This indicates that when these workers get low back injuries, they are more severe than those in other occupations. This shows that the risk of prolonged sitting in the work place should be addressed.

Prolonged periods of sitting in itself does not suggest an increased association with the occurrence of reported or examined LBP. It was concluded that there was a strong association when prolonged sitting was combined with WBV and/or awkward postures (Lis *et al.* 2007: 283-298).

2.7.3 Whole Body Vibration (WBV)

Truck drivers spend prolonged periods seated in heavy trucks, where they are subjected to WBV. Two of the most common risk factors for the development of LBP are manual handling of heavy material and WBV exposure. Blood *et al.* (2015) researched professional drivers in Europe and revealed that there is a strong connection between WBV exposure and the development of LBP, however there is evidence of a dose-dependent pattern. Low back injuries have been seen to increase with an increase in the duration and dose of exposure of WBV while driving in heavy trucks (Blood *et al.* 2015).

According to the United States Bureau of Labour Statistics, truck drivers that work in the transport and warehousing industry have recorded 5.5 injuries per year per 100 full-time workers. This number of injuries is higher than the total private industry rate which is 3.5 injuries per year per 100 full-time workers and other jobs which involve prolonged periods of time in the seated position (2.7 injuries per a year per 100 full-time workers). The extended hours that professional truck drivers work, cause them to be at an increased risk of developing LBP. Whole-body vibration and prolonged sitting in the static position increase the truck drivers' risk for developing LBP, degenerative disc disease and sciatic pain (Blood *et al.* 2015). According to Ramroop (2005), there is a link between WBV from the trucks and the LBP prevalence ($p < 0.05$).

2.7.4 Ergonomics of the truck cab

There was an increase in the prevalence of LBP among drivers driving older trucks. Truck drivers of the older Nissan trucks indicated a 100% prevalence of suffering with LBP. This finding was predicted as the newer trucks were superiorly designed with technological advancements (Ramroop 2005). Since the drivers will be in their vehicles for extended periods, adequate seats are necessary. The study found that the drivers' seats were adequate, except for the padding of the seats. Only 58% of the drivers considered that their refuse truck seats were well padded (Ramroop 2005).

2.8 PSYCHOSOCIAL RISK FACTORS

2.8.1 Monotony and Stress

Mitsuhiko *et al.* (2004: 119-124) revealed the relationship between work stress and LBP in drivers who drive prolonged periods of time, the age adjusted OR was 2.19 (CI of 0.98-5.16). Bongers (1993) revealed the relationship between psychosocial risk factors and MSK disease. He concluded that high workloads, monotonous work, time pressure, low control of job and a lack of social support by others in the work place are related to the development of musculoskeletal diseases such as LBP. Olivier (2008) investigated risk factors that are associated with LBP in workers and showed a positive correlation between work stress and LBP.

2.9 SOUTH AFRICAN ROAD CONDITIONS

In South Africa, truck driving can be very stressful for a number of reasons, including drivers having to master the diverse skill of controlling and managing a heavily loaded trailer. In addition to this, the truck driver has to deal with the many hazards on South African roads such as accidents, traffic congestion and road construction (Van Niekerk 2016). In Gauteng, it was identified that in a space of six years, the number of roads considered to be in a poor to very poor condition increased from 20% to 46%. To improve safety on the roads, the pothole-pandemic in South Africa needs to be addressed (Hippo 2014).

2.10 TREATMENT OF LOW BACK PAIN

The 2007 LBP guidelines worldwide - prepared by the American Pain Society and American College of Physicians - say that spinal manipulation (90% is done by Chiropractors) is an effective treatment for both acute and chronic types of LBP. A systematic review of the cost-effectiveness of treatments endorsed by the American Pain

Society and American Pain Society guidelines, established that spinal manipulation as a treatment for sub-acute and chronic LBP was cost-effective, as well as other methods such as interdisciplinary rehabilitation and exercise within the Chiropractor's scope of practice (Lin *et al*. 2011: 1024-1038). Many health care professionals use different methods to help improve the patient's seated posture. Commonly, lumbar support devices are prescribed (Grondin *et al.* 2013: 30-34). Biokineticists prescribe rehabilitative exercises to increases the asymmetrical weak lower back and create symbiotic force couple relationship among the lumbopelvic hip muscles (Ellapen et al 2017).

Aota *et al.* (2007) stated there was a notable improvement in participants' subjective measurements of stiffness, LBP and fatigue when using a lumbar support in the dynamic and static states. Low back pain management was reported by 33% of the studies included in Louw et al. (2007) review paper on management of lower back pain. Louw et al. (2007) found that in Africa, the most common health professionals used for management of LBP were general practitioners (medical doctors) and physiotherapists, which differs from international trends Lin et al. (2007). The most used management strategies in Africa were analgesics and rest (Louw *et al.* 2007).

2.11 LUMBAR SUPPORT PILLOWS

When using a lumbar support pillow, it is meant to allow for a correct seating posture anatomically. The seating posture is obtained by providing support to the pelvic region (to prevent backward rotation of the pelvis), the lumbar vertebrae and vertical support of the trunk of an individual. Support to these three areas of the body is commonly known as the "Three-Fold Effect." If the individual has an incorrect seating position, this can lead to LBP which will result in a decrease in concentration, discomfort during driving and therefore a decrease in driving safety. A good lumbar support pillow will provide a decrease in muscle activity, decrease in tensile and shear stresses on ligaments, decrease pressure on the IVD's and increase the comfort of the driver (Buss 2009). There is limited literature on the effect of lumbar support pillows on LBP in drivers, however, the effect of lumbar support braces are investigated widely (Jellema *et al.* 2001: 377-386).

2.11.1 Positive effects of a lumbar support pillow

In laboratory vehicle mock-up research on the seat position and posture of truck drivers, it was found that they were not satisfied with the limited range of adjustability. The limitations of not being able to adjust the seat to a desirable position could lead to MSK injuries and other symptoms (Fatollahzadeh 2006). Since truck drivers sit for prolonged periods nearly daily, it is very important for them to reconsider the types of seats they are using (Key 2013). One way to address the limitations of not being able to adjust the seat is to provide adequate back support pillows for the drivers. Chen *et al.* (2005) researched seat inclination, use of a lumbar support and LBP among Taiwanese taxi drivers who reported a LBP prevalence of 18% for driver using lumbar support and 34% without lumbar support. This lumbar support was simply a commercialised cushion pad or pillow made of various materials, but their positions could be easily adjusted to individual preference.

Grondin *et al.* (2013: 30-34) studied 28 male participants with and without a history of LBP. These individuals sat in a standard office chair and in a chair with the lumbar support pillow for 30 minutes. Grondin et al. (2013) recorded the effect of a lumbar support pillow on lumbar posture and comfort during a prolonged seated task. The results showed that the use of a lumbar support pillow, that has a space for the posterior pelvic bulk, caused a decrease in lumbar flattening during sitting in healthy individuals and patients with LBP. However, the thoracic kyphosis was increased. The difference found in the angular change was small and further studies are needed to determine the clinical relevance over a long-term period. The study also found that the measure of comfort had improved with the use of the pillow. When looking at the lumbar spine, the standard chair and the lumbar support angle had a 2.88° difference (95% CI: 1.01; 4.75). This study showed that the lumbar support was closer to neutral than the normal chair was. The pressure put on the spine during sitting was significantly improved ($p = 0.017$), however participants noted that there were no changes in comfort when using subjective measures. Roelofs *et al.* (2010: 1619-1626) researched the effect of lumbar supports in preventing recurrent LBP in home care workers. study was done over a period of 12 months and the individuals in the group using lumbar support pillows stated an average of -52.7 days of LBP (CI, -59.6 to -45.1 days). The total number of days the participants in the lumbar support group were absent did not decrease (-5 days [CI, -21.1 to 6.8 days]). There was small, but statistical significance in the levels of pain and function, and the lumbar support group was favoured. Low back posture with the support is said to be healthier for the user (De Carvalho and Callaghan 2012: 876-882).

Hekmatfard *et al*. (2017: 1-8) researched the use of Lumbar Support in Patients with Chronic Nonspecific LBP. The subjects had the lumbar supports in place for a period of six weeks. Using the Oswestry LBP Disability questionnaire, the NPRS and the fear-avoidance beliefs questionnaire, it was found that wearing the lumbar support decreased pain intensity, improved the disability index score and improved the fear-avoidance beliefs in the participants with LBP.

These encouraging findings support the need for robust trials on the effectiveness of lumbar supports. It is with this in mind, that the current research seeks to explore the effectiveness of a locally-developed back support for long-distance truck drivers (Van Duijvenbode *et al.* 2008).

2.11.2 Adverse effects of a lumbar support pillow

Grondin *et al. (*2013: 30-34) studied the effect of a lumbar support pillow on lumbar posture and comfort during a prolonged seated task and the results showed that the use of a lumbar support pillow that has a space for the posterior pelvic bulk caused a decrease in lumbar flattening during sitting in healthy individuals and patients with low back pain. However, the thoracolumbar curvature was increased. This occurred because the participants adopted a short arc pelvis on the femur extended posture, which increased the IVD pressure causing the nucleus pulposus to displace posteriorly (Mansfield and Neumann 2014). The difference that was found in the angular change was small and further studies are needed to determine the clinical relevance over a long-term period. The study also found that the measure of comfort had improved with the pillow. De Carvalho and Callaghan (2012: 876-882) found that lumbar supports prevented vertebral rotations of the lumbar spine yet had no effect on the posture of the pelvis. Increasing support from the current maximum of two centimetres to four centimetres resulted in increased lumbar lordosis. The changes were mostly imparted at the upper lumbar spine joints with the most marked change exhibited at the approximate level of the lumbar support apex: in the L2/L3 joint. In this study all individuals who participated showed a remarkable increase (p=0.003) in pelvic discomfort throughout the two-hour trial (De Carvalho and Callaghan 2012: 876-882).

De Carvalho and Callaghan (2012: 876-882) studied the effect of a lumbar support in a motor vehicle seat radiologically. It was found that there was increased support in the spine and this was noted to increase the extension in the intervertebral joints within the lumbar spine. It could not be stated whether comfort of the participant was affected (De Carvalho and Callaghan 2012: 876-882).

The expectations behind the philosophy of lumbar support pillows have never been researched thoroughly (Zacharkow 1988). Zacharkow (1988) stated that the use of a lumbar support can result in the deep lower abdominal muscles relaxing and overstretching. These are critical postural muscles used in both the sitting and standing posture. The upper trunk is displaced posteriorly in relation to the hips, causing the individual to move further away from the work station. Trying to keep the correct posture of the lumbar support may put extra stress on the neck and upper back (Zacharkow 1988).

2.12 THE *'ENTAP LUMBAR SUPPORT PILLOW'*

The lumbar support pillows that will be used are the *'ENTAP Lumbar Support Pillow'* and a polyester-filled lumbar support pillow. The *'ENTAP Lumbar Support Pillow'* is made from foam which is moulded into the correct shape to support the low back. The *'ENTAP Lumbar Support Pillow'* is compact and firm. The lumbar support pillow is protected with a cotton cover which is zipped for removal. The pillow is intended to keep the person upright, alert and productive throughout the day while maintaining the correct spinal alignment and therefore decreasing back pain and muscle fatigue. This pillow also has a NAPPI Code which enables the purchaser to apply for reimbursement from a medical aid scheme (ENTAP 2016). The lumbar support pillow will not cure low back pain but will be palliative in contributing to a decrease in low back pain.

'ENTAP' claims that their lumbar supports result in an improved posture, a decrease in pain and an increase in comfort (ENTAP 2016). The *'ENTAP Lumbar Support Pillow'* has not yet been tested on participants and, therefore, these claims cannot currently be validated. Without a proper lumbar support, the natural "S" shape of the spinal column straightens and becomes a "C" shape resulting in a slouched posture, causing tension and stress on the lower back. The basis of all lumbar supports is to achieve the correct seating position. To obtain the optimum seating position, the lumbar support must provide support to the pelvis preventing it from rotating, support to the lumbar vertebra and vertical support to the upper body (Gale 2011). The ergonomic benefits of a lumbar support include a decrease in muscle activation, decreased tension on ligaments, decreased pressure on the discs and increased comfort (Hedge 2005).

The effectiveness of the *'ENTAP Lumbar Support Pillow'* has not been researched. The *'ENTAP Lumbar Support Pillow'* is 6.5 centimetres (cm) thick, 36.5 cm wide, 30.0 cm in height and weighs 370 grams (g). These pillows contain moulded foam and was specially designed in Australia to create an orthopaedic cushion with lower lumbar support (Botha 2018).

Figure 2.3: ***'ENTAP Lumbar Support Pillow'***

(ENTAP 2016)

2.13 THE POLYESTER-FILLED LUMBAR SUPPORT PILLOW

The polyester-filled lumbar support pillow was made only for the purpose of this research by the *'ENTAP'* company. This pillow had a poly-filling usually used in normal scatter cushions. This filling was used as customers who purchase lumbar support pillows usually use a similar cushion for back support (Botha 2018). The pillows had the same dimensions as the foam-filled *'ENTAP Lumbar Support Pillows'*.

2.14 SUMMARY OF RELEVANT ANATOMY OF THE LUMBAR SPINE

When discussing the lumbar spine, it is important to have an overview of the bony anatomy and the soft tissue found in this region. The lumbar spine is made up of five vertebrae which are L1 to L5. The anatomy of the lumbar spine comprises of the vertebrae, linked together by joint capsules, ligaments, tendons and muscles with a widespread innervation. The flexibility of the lumbar spine allows for movement in different planes. The zygapophyseal joints are between the vertebral bodies and allow for mobility of the vertebral column. The stability of the lumbar spine is provided by the facet joints which are found at every spinal level between and behind the adjacent vertebrae (Allegri *et al*. 2016).

2.14.1 Typical lumbar vertebra

A typical lumbar vertebra consists of a vertebral body, a vertebral arch, as well as seven processes i.e. one spinous process, two transverse processes, two superior articular processes and two inferior articular processes **(Figure 2.4).**

The vertebral body takes most of the force placed on the lumbar vertebrae. Vertebral bodies increase in size as the vertebral column descends. The vertebral body consists of trabecular bone which contains the red marrow and is surrounded by a thin external layer of compact bone. The arch and the posterior aspect of the vertebral body form the vertebral or spinal canal, and this contains the spinal cord within. The spinal cord ends between L1 and L2. The distal bulbous part of the spinal cord is known as the conus medullaris which then tapers and ends as the filum terminale. Distal to the filum terminale is a collection of nerve roots which is called the cauda equina (Dawodu 2018).

A typical lumbar vertebra also contains four articular processes, two superior and two inferior, which contact the inferior and superior articular processes of adjacent vertebrae, respectively. The point at which superior and inferior articular processes meet is known as a facet, or a zygapophyseal joint. Facet joints or zygapophyseal joints are synovial, diarthrodial joints which are encircled by connective tissue which provides fluid to lubricate and supply nutrients to the joint (Bridwell 2018; Welch *et al*. 2011: 1-24). The diarthrodial joint and orientation of the facet joint allow for limited translation and rotation of adjacent vertebrae (Welch *et al.* 2011: 1-24). The facet joint surface is made up of cartilage which allows the joint to articulate smoothly against each other (Bridwell 2018). These joints help keep the vertebra aligned, control the range of motion, and are weight-bearing in several positions. The spinous process projects posteriorly and inferiorly from the vertebral arch and overlaps the inferior vertebrae to a certain degree, dependent on the region of the spine. Lastly, the two transverse processes project laterally from the vertebral arch in a symmetric fashion.

A typical lumbar vertebra has several features that are distinct from those typical of the cervical or thoracic vertebrae. The most notable difference is the presence of a much larger vertebral body. The spinous process is shorter and thicker in relation to the size of the vertebra, and it projects perpendicularly from the vertebral body. The articular facets are distinctly vertical, with the superior facets directed posterior-medially and medially. The facets also have the unique feature of a curved articular surface. This is one feature that differentiates lumbar vertebrae from thoracic. There is also the addition of the mammillary process on the posterior aspect of the superior articular process. The facet joints, IVD's and spinal ligament link adjacent vertebrae of the spinal column, it provides support, it also limits load and allows for transfer of loads on the spine (Welch *et al.* 2011). The thickness of the intervertebral discs is dependent on location in the spine. Compression forces are greater within the lumbar region and therefore the discs are between nine and 17 millimetres in thickness (White e*l al.* 1990: 1-8).

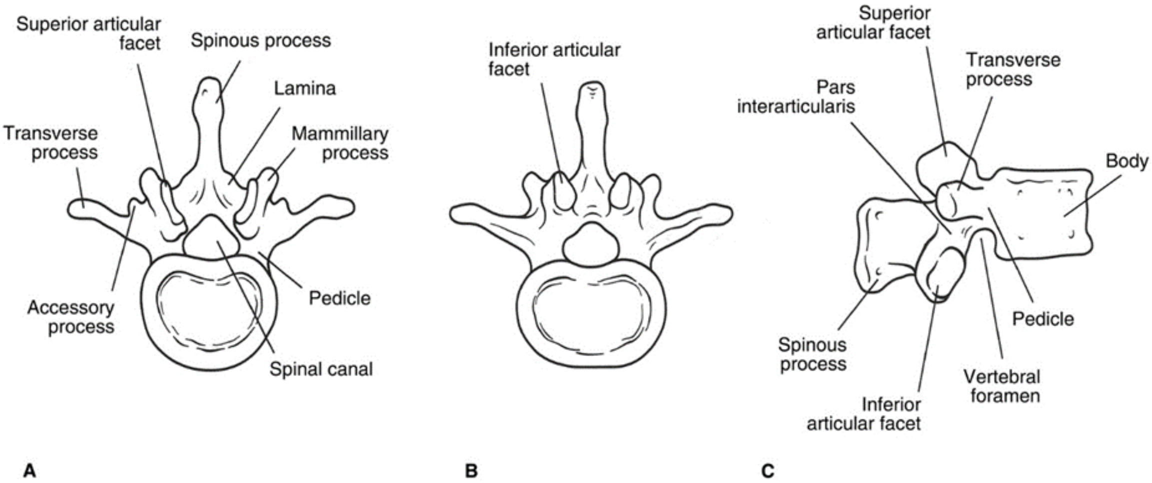

Figure 2.4: A typical lumbar vertebra

(Fandom 2017)

2.14.2 Atypical lumbar vertebra

There is only one lumbar vertebra that may be considered atypical. This lumbar vertebra is L5 which has the largest body and transverse processes of all the other vertebrae. The anterior aspect of the body is greater in height when compared to the posterior aspect. This creates the lumbosacral angle between the lumbar region of the vertebrae and the sacrum (Waxenbaum and Futterman 2017).

2.14.3 Lumbar lordosis

Lumbar lordosis is defined as the normal, convex curvature of the lumbar spine. This secondary curvature is developed postnatally when one learns to walk which results in the upright posture (Mosby's Medical Dictionary 2009). The lumbar lordosis is measured on a radiograph, with the Cobb method is most commonly used. When using the Cobb method, the normal lumbar lordosis may range from 20° to 40° (Ayad *et al.* 2013: 1-4; Tuzun *et al.* 1999: 308-312). Hyperlordosis is determined when there is an increase in the lordotic angle (more than 40 degrees) and hypolordosis is when there is a decrease in the lumbar lordosis (less than 20 degrees) (Tuzun *et al.* 1999: 308-312). Lumbar lordosis by effect of sitting versus standing posture was studied by radiographic evaluation. The study revealed that the lumbar lordosis decreased by 50% when sitting, compared with standing. This finding was clinically significant as it may explain the reason for the increased intradiscal pressure when seated and the benefit of a lumbar support pillow that will increase the lumbar lordosis (Dinsay *et al.* 1997: 2571-2574; Cho *et al.* 2015: 1983-1985).

2.14.4 Intervertebral discs (IVD)

There are five discs in the lumbar spine. These discs are fibrocartilaginous and separate all the lumbar vertebrae. They are responsible for two inches of the overall height in the adult human. The IVD's are an important component of the vertebral column. The discs have a dual purpose - to allow for proper absorption and distribution of stress during compressive load bearing of the spine. The IVD comprises part of a joint complex which allows various movements of the spine such as flexion, extension, rotation and lateral flexion. The individual components of the disc are each unique in their molecular composition and work in conjunction to be able to resist the forces that they are subjected to.

The lumbar discs are taller and wider compared to the cervical and thoracic discs. Yet, the lumbar discs are more vulnerable to injury. This occurs because the discs in the lumbar spine have a greater range of motion while under great axial load (a downward force caused by gravity and the weight of the body) (Liu and Benzel 2015). Billy et al. (2014) investigated lumbar disc changes associated with prolonged sitting, who revealed that the biggest decrease in the height of the disc was found at L4 to L5 after sitting for prolonged periods of time without taking breaks intermittently (Billy *et al.* 2014: 790-795).

The lumbar discs share one unique anatomical difference when compared with the cervical and thoracic discs. This anatomical oddity is that the lumbar discs are completely avascular and therefore rely on simple diffusion for their waste removal and nourishment. The poor blood supply in the lumbar spine is the origin for many of the causes of low back pain. Understanding the mechanism by which the disc performs its task, is mandatory to understand the anatomy of the IVD.

There are three anatomical regions in the lumbar discs. These include:

1. The gelatinous nucleus (nucleus pulposus).
2. The fibrous annulus fibrosus.
3. The cartilaginous vertebral endplates (Choi 2009: 39-44).

2.14.4.1 The Nucleus Pulposus

The nucleus pulposus is made up of gelatinous material. It is centrally located and is made up of collagen fibres which are randomly arranged and elastin fibres which are radially organised (KenHub 2018). The nucleus pulposus is surrounded by the anulus fibrosus and the endplates **(Figure 2.5).** The cells of the nucleus produce two types of molecules and these create the substance of the nucleus pulposus. The substances of the nucleus pulposus are type II collagen (17%) and proteoglycan (65%). Proteoglycans are important as they have a high affinity for water and are responsible for the high water-content in a healthy young intervertebral disc. This high water-content is needed for proper spinal biomechanics. A decrease in proteoglycans can start degenerative disc disease which can then cause symptomatic annular tears, herniations, collapse and chronic disc-related pain (Gillard 2017).

2.14.4.2 The Annulus Fibrosus

The annulus fibrosis a tough circular exterior of the intervertebral disc which surrounds the soft gelatinous nucleus pulposus. The annulus fibrosus is made up of a ring of ligament fibres that encloses the inner core of the disc (the nucleus pulposus) and connects the spinal vertebrae above and below the disc securely (Veritashealth 2018). The annulus fibrosus is not as water rich as the nucleus pulposus, it still is made up of 65% water as one of its cells still produce the substance proteoglycans (20%). The annulus has two cells, one being chondrocytes which produce proteoglycans and the other being fibroblasts which mainly produces type I collagen. Type I collagen is the strongest type of collagen, therefore making the annulus fibrosus stronger than the nucleus pulposus. The main function of the annulus is to contain axial-load related deformation of the nucleus and therefore preventing herniation of the nucleus pulposus (Bogduk 2008: 11-28).

2.14.4.3 The Vertebral Endplates

The vertebral endplates are positioned above and below most of the annulus fibrosus and the whole of the nucleus pulposus (Gillard 2017). The superior and inferior cartilaginous vertebral endplate (each are 0.6 to one millimetre (mm) thick) cover the inferior and superior portions of the discs. The endplates bind the discs to their respective vertebral bodies (Gillard 2017; Newell *et al.* 2017: 420-434). The endplates contain molecules which are proteoglycan, water and collagen. The endplates are biochemically similar to the annulus and nucleus and are therefore considered part of the disc and not part of the vertebral body. The nucleus and anulus are attached to the endplate firmly, except at the periphery. Therefore, separation of the nucleus and annulus from the vertebral endplate is difficult. The main function of the vertebral endplate is to act as a semi-permeable membrane. This allows metabolites and nutrients to enter the disc through diffusion and waste products to diffuse out of the disc. It also stops bigger molecules such as the proteoglycans from exiting the nucleus pulposus and the annulus fibrosus (Gillard 2017).

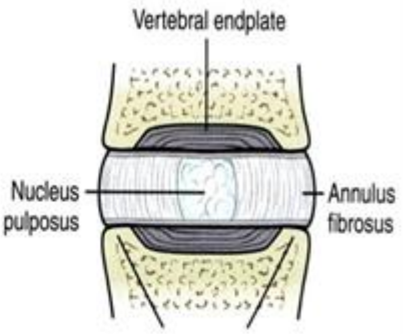

Figure 2.5: A typical intervertebral disc

(Marianne 2014)

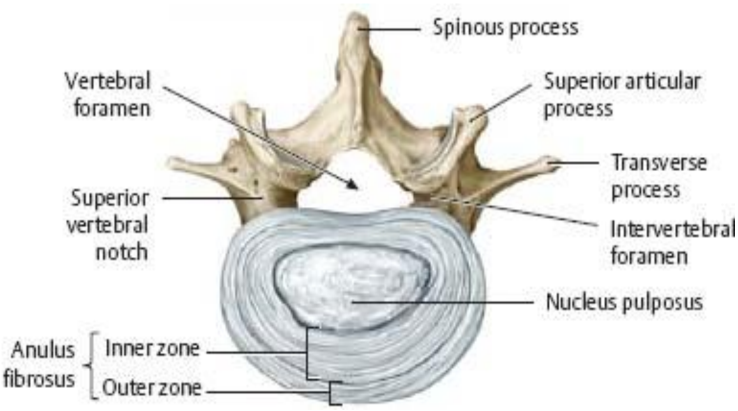

Figure 2.6: Structures of an intervertebral disc

(Doctorlib 2015)

2.15 THE HAWTHORNE EFFECT

The Hawthorne Effect refers to the concept of a changed behaviour due to the participant being singled out to participate in the research. A hallmark of the Hawthorne Effect would be an effort by the participants to improve productivity, thereby creating improved results

(Macefield 2007: 145-154). The Hawthorne Effect has been a factor in numerous clinical studies. However, there has been much critique of its validity or its place in research.
The Hawthorne Effect does not require direct observation, nor does it require feedback to influence experimental subjects (Campbell *et al.* 1995: 590-594). If the Hawthorne Effect is taken into consideration, the following should be considered:

- The truck drivers feel the need to please the researcher as a result of being chosen or singled out to take part in the research trial.
- Any form of perceived compensation by the researcher to the participants – such as the possibility of the transport company buying them lumbar support pillows (Jagarnath 2012).

2.16 CLINICAL USEFULNESS OF MEASUREMENT TOOLS

Vianin (2008: 161-163) researched the clinical usefulness of the Oswestry Low Back Disability Questionnaire and found that the questionnaire showed an effective construct validity due to its consistency with other measurement tools and due to it being used to compare other measures that assess LBP disability. Internal consistency is achieved by the questionnaire. Cronbach alpha (*α)* varies from 0.71 to 0.87 (Fairbank and Pynsent 2000; Roland and Fairbank 2000: 2940-2952). The test-retest reliability has shown to be effective, the values vary depending on the time between the measurements from r = 0.83 to 0.99 (Fairbank and Pynsent 2000; Roland and Fairbank 2000: 2940-2952; Davidson and Keating 2002: 8-24). The score is lower when there is a longer period between repeated measurements and responsiveness to the questionnaire is said to be high (Vianin 2008: 161-163).
Rice (2018) researched the NPRS as an effective measurement tool and found that at four weeks, the NPRS revealed moderate reliability (Intraclass Correlation Coefficient (ICC), 0.72) when compared with the Neck Disability Index (NDI) (ICC, 0.92). At three months follow-up, the NPRS revealed fair and poor reliability (ICC, 0.48) when compared with the NDI which showed effective reliability (ICC, 0.95). The NPRS showed effective responsiveness (region under curve varied from 0.78 to 0.93) and effective construct validity ($p<0.001$).

When looking at the PGIC scale, there is a high test-retest reliability (ICC 0.9) (Costa *et al.* 2008: 2459-2463). There is a strong link between the PGIC and the participants' ratings of the significance of change (Pearson's r = 0.90) show that there is face validity (Watson *et al.* 2005). There is also satisfaction measured by the patient when using this scale (Spearman's rho 0.56-0.70) (Fischer *et al.* 1996).

2.17 CONCLUSION

Despite the high incidence and prevalence of LBP in truck drivers, little attention has been focused on addressing the factors contributing to this condition as well as ensuring mechanisms are put in place to reduce the morbidity associated with the condition. This study will be one of the first in South Africa to determine the impact of a lumbar support in reducing LBP and worker absenteeism in long-distance truck drivers.

CHAPTER THREE

MATERIALS AND METHODS

The methodology describes the exact steps that were undertaken to address the hypotheses and research question. This chapter will discuss the study design; the method of approval to conduct the study; the study population; the sample size; the study setting, the sample characteristics; the inclusion and exclusion criteria; the research procedure; a description of the lumbar support pillows that were used; the measurement tools that were used; limitations that were experienced in the study; the statistical analysis used and the ethical considerations that were put in to place.

3.1 STUDY DESIGN

This study was designed as a quantitative, double blinded, true experimental study trial, conducted at a large trucking company in the eThekweni area. The company gave the researcher permission to conduct the research **(Appendix K).** Individuals were randomly allocated to one of three groups - group A having no lumbar support pillow, group B wearing an *'ENTAP Lumbar Support'* and group C wearing a polyester-filled lumbar support pillow. Approval to conduct this study was obtained by the Institutional Research Ethics Committee (IREC) **(IREC Reference Number: REC148/17) (Appendix L).**

3.2 APPROVAL TO CONDUCT THE STUDY

Contracts were drawn up between the researcher and the *'ENTAP Lumbar Support Pillow'* company **(Appendix G)**; and between the researcher and the research assistant **(Appendix F).** Approval for this study was then obtained from the Research Higher Degrees Committee (RHDC) and the Institutional Research Ethics Committee (IREC) of the Durban University of Technology (DUT) **(IREC Reference Number: REC148/17) (Appendix L)**.

3.3 STUDY POPULATION

The study population was 132 long-distance truck drivers working for a large transport company in the eThekwini Municipality of KwaZulu-Natal. A long-distance truck driver is defined as a person who drives a truck in a 200 to 300 km radius or greater from their home terminal for 26 days in a month (Complete School of Truck Transportation 2014; Supergroup 2017). The participants age, race and gender were recorded.

3.4 PARTICIPANT RECRUITMENT

The participants were the employees of a large transport company in KwaZulu-Natal. The directors at the company agreed to allow their drivers to participate in the study **(Appendix K)**. The participants were recruited by the researcher during a meeting with twenty truck drivers, explaining what the research entailed and the rest of the participants were recruited by word of mouth. All 132 truck drivers were invited but not all of them were in the same place at that given time of the meeting, therefore only twenty truck drivers were able to attend. Participation in the study was voluntary.

3.5 SAMPLE SIZE AND ALLOCATION

Purposive sampling was used to select long-distance truck drivers with LBP working at the selected company. The sample size was based on a total population of 132 long-distance truck drivers within the company. The sample size for this study only included truck drivers with current LBP. The sample size (n = 63) of long-distance truck drivers with current LBP was determined after consultation with a statistician to be a total of 63 participants. This was worked out by a power analysis using the F-test with an effect size of 0.35, an α of 0.05 and a power of 80.64%, showed that a minimum of 21 participants were required per group (Singh 2017). The researcher did endeavour to recruit more than 63 participants as this would have increased the power of results. These 63 participants were divided into three groups, allowing for 21 participants per group. The participants were randomly allocated into one of three groups: Group A, Group B or Group C. Random allocation was done by the participant drawing a piece of paper marked either A, B or C from a small box. The researcher was blinded as to which lumbar support pillow was in which group and assistance was provided by the research assistant **(Appendix F).** Group A included participants who had no lumbar support pillow, group B included participants wearing an *'ENTAP Lumbar Support Pillow'* and group C included individuals wearing a polyester-filled lumbar support.

3.6 STUDY SETTING

The research took place at a company in an industrial area, Westmead in Durban. The company is a leading transport logistics and mobility group, providing end-to-end supply chain solutions, fleet management and dealership services to a diversified global customer base. The business combines the skills of a team with more than 20 years of supply chain experience.

3.7 SAMPLE CHARACTERISTICS

The truck drivers are predominantly Black males who work 26 days in a month and are all South African Citizens. The truck drivers get 15 working days leave in a year and are actively working for 14 hours a day. This includes duties such as loading and unloading trucks as well as driving the trucks (Supergroup 2016). This excludes one hour of lunch and nine hours of consecutive rest; therefore, they spend 364 hours in their trucks every month. All the drivers drive the same type of trucks with the same set-up inside each. Each of the trucks are 22 metres (m) long, they all have a sleeping compartment and the features of the truck driver seats are:

- Height adjustable
- Weight adjustable
- Horizontal adjustment
- Seat cushion depth adjustment
- Mechanical suspension function (Supergroup 2016).

Figure 3.1: Inside a truck cabin
(Truck&Trailer 2019)

3.8 INCLUSION AND EXCLUSION CRITERIA

a. Inclusion criteria

1. The driver must currently be experiencing LBP which is defined as pain, muscle tension, or stiffness localised below the costal margin and above the inferior gluteal folds (Chou 2011).

2. Drivers who drive more than 200-km radius from their home terminal for 26 days a month.
3. The drivers need to be literate in order to complete and understand the questionnaire.

b. Exclusion criteria

1. Truck drivers not willing to take part in the study.
2. Participants already using any type of lumbar support.
3. If the participant had any organic causes of LBP for example tumours or tuberculosis related spine pain.
4. Truck drivers who do not currently have LBP.

3.9 RESEARCH PROCEDURE

3.9.1 Initial approach to prospective participants

The prospective participants were approached by the researcher and research assistant where the purpose of the research was verbally explained to them. Those expressing willingness to participate were asked the following questions **(Appendix A):**

1. Will you be willing to take part in my study?
2. Do you suffer from LBP? This can be pain that is always there or LBP that comes and goes.
3. What distance do you drive monthly?
4. Do you already have a lumbar support pillow in your truck?
5. Do you have any organic causes of LBP such as tuberculosis of the spine, tumours in the spine?
6. How long have you had LBP for?
7. Is the pain always there or does it come and go?

They would have needed to answer "Yes" to Questions One and Two; they must have driven more than a 200 to 300 km radius from their home terminal for 26 days a month (Complete School of Truck Transportation 2014; Supergroup 2017); they must not be using a lumbar support pillow in their trucks; and they must not have any organic causes of LBP to be eligible to participate in this study. This was kept on paper record **(Appendix A)**.

3.9.2 Informed Consent and Briefing Session

At their workplace, participants were given a detailed explanation of the study, both verbally and through a letter of information **(Appendix H)**. The truck drivers were allowed to ask any questions and withdraw from the study at any time.

After obtaining written informed consent **(Appendix I)**, the researcher assessed if the participants met the inclusion criteria **(Appendix A).**

3.9.3 Random allocation of the participants into one of three groups

A research assistant coded the two different lumbar support pillows (Group A was individuals who received no lumbar support pillow, the *'ENTAP Lumbar Support Pillow'* was group B and polyester-filled lumbar support pillow was Group C) without the researcher being aware. The coding of the pillows and grouping was done by a research assistant prior to the start of the study. To minimise researcher bias, the researcher was unaware of the numbering system. Random allocation was done by the participant drawing a piece of paper marked either A, B or C from a small box. The research assistant then distributed the lumbar support pillows to the participants and the study took place over a period of six weeks. The researcher was blinded as to which lumbar supports are within which group. A contract was signed by the research assistant who was also fluent in isiZulu and was able to translate if needed **(Appendix F).**

3.9.4 Baseline assessment and procedure

The participants completed the Oswestry Low back Disability Questionnaire (Fairbank and Pynsent 2000) and NPRS (Childs *et al.* 2005: 1331-1334) for this study. The lumbar support pillows were given to the participants depending on which group they were in. The research assistant demonstrated to the truck drivers how to fit the lumbar support pillow onto the truck seats. The participants who received the lumbar support pillows were informed not to reveal which pillow they received to the researcher throughout the study. Both the lumbar support pillows looked the same to prevent the researcher from identifying them. Only at the end of the study the researcher was made aware of the groupings of the participants. The participants always drove with the lumbar support pillows in place and the researcher visited the work place once a week to check whether the truck drivers who were in the yard had the lumbar support pillows in their trucks. The truck drivers were also told to report any discomfort whilst using the lumbar support pillow to the driver trainer who would then report it to the researcher and the participant would be excluded from the study.

3.9.5 Three-week procedure

Participants completed the Oswestry low back Disability Questionnaire, the NPRS and PGIC Scale.

3.9.6 Six-week procedure

Participants completed the Oswestry low back Disability Questionnaire, the NPRS and the PGIC Scale. The participants were thanked and advised on low back maintenance care.

3.9.7 Control of work factors

All truck drivers drove the same type of trucks with the same seats and had the same sleeping arrangements inside each of the trucks. The truck drivers were all long-distance truck drivers, transporting heavy loads, and all drove similar distances and routes. This would therefore expose the truck drivers to the same risk factors for LBP.

3.10 DESCRIPTION OF THE TWO LUMBAR SUPPORT PILLOWS

The lumbar support pillows that will be used are*: 'ENTAP Lumbar Support Pillow'* and the polyester-filled lumbar support pillow.

3.10.1 ENTAP foam-filled lumbar support pillow

The *'ENTAP Lumbar Support Pillow'* is made from high-quality foam moulded into the correct shape to support the low back. The *'ENTAP Lumbar Support Pillow'* is compact and firm, therefore it is ideal for car seats or office chairs. The lumbar support pillow is protected with a pure cotton cover which is zipped for easy removal and has a velcro strap to secure the support to the seat. The pillow is designed to keep the person upright, alert and productive throughout the day whilst maintaining the correct spinal alignment and decreasing LBP and muscle fatigue. This pillow also has a Non-Abusive Psychological and Physical Intervention (NAPPI) Code which enables the purchaser to apply for reimbursement from a medical aid scheme (ENTAP 2016). The lumbar support pillow will not cure LBP but will be palliative in contributing to a decrease in LBP.

3.10.2 Polyester-filled lumbar support pillow

The polyester-filled lumbar support pillow was shaped the same as the *'ENTAP Lumbar Support Pillow'* and was protected with the same luxury pure cotton cover, had a zip and a velcro strap to secure the support to the seat. The only difference between the two was that this lumbar support pillow was filled with polyester instead of foam. The participants were not able to tell the difference between the two. This lumbar support pillow was made by the '*ENTAP'* company for the purposes of this research study only.

3.11 MEASUREMENT TOOLS

3.11.1 The Numerical Pain Rating Scale (NPRS)

Participants used the NPRS to rate their LBP levels at baseline, three weeks and at six weeks. Numerical Pain Rating Scale (NPRS) has a high test-retest reliability which has been observed in both literate and illiterate patients (Hawker 2011).

3.11.2 The Oswestry LBP Disability Questionnaire

The Oswestry Low Back Disability Questionnaire is an important tool that disability evaluators and researchers use to measure a patient's functional disability (Fairbank and Pynsent 2000). This questionnaire is known as the 'gold standard' of low back functional outcome tools. This questionnaire was used in the research to determine the participant's disability at baseline, at three weeks and after using the lumbar support pillow for six weeks.

3.11.3 Patients' Global Impression of Change (PGIC) scale

The self-report measure, PGIC reflects a patient's belief about the efficacy of treatment. Patient Global Impression of Change (PGIC) is a seven-point scale depicting a patient's rating of overall improvement (Hurst and Bolton 2004: 26-35). This scale was used after three weeks and six weeks of using the lumbar support pillow. It helped determine whether there was an improvement in the participants' LBP after using the lumbar support pillow.

3.12 A SUMMARY OF THE RESEARCH PROCEDURE

Permission was obtained from Directors **(Appendix K)** of the selected company. Approval to conduct the study was obtained from RHDC and IREC **(Appendix L).**

↓

The sample population of 63 participants with current LBP was obtained from a trucking company at Westmead, Pinetown in Durban.

↓

Participants were selected using purposive, random sampling.

↓

Informed consent was obtained from the participants at a briefing session.

↓

Participants filled out a general questionnaire to determine whether they met the inclusion criteria **(Appendix A).**

↓

Participants were divided into three groups. This allocation was blinded for the researcher. Group A received no lumbar support pillow, Group B received an *'ENTAP Lumbar Support Pillow'* and Group C received a polyester-filled lumbar support pillow.

↓

Those included, completed a baseline questionnaire which included the NPRS and the Oswestry LBP Scale **(Appendix C).**

↓

After three weeks, participants completed the NPRS, the Oswestry LBP Scale and the PGIC **(Appendix D).**

↓

After six weeks, participants completed the NPRS, the Oswestry LBP and the PGIC **(Appendix E).**

↓

Data was coded on an EXCEL spread sheet and was thereafter analysed by a statistician using SPSS version 25.0.

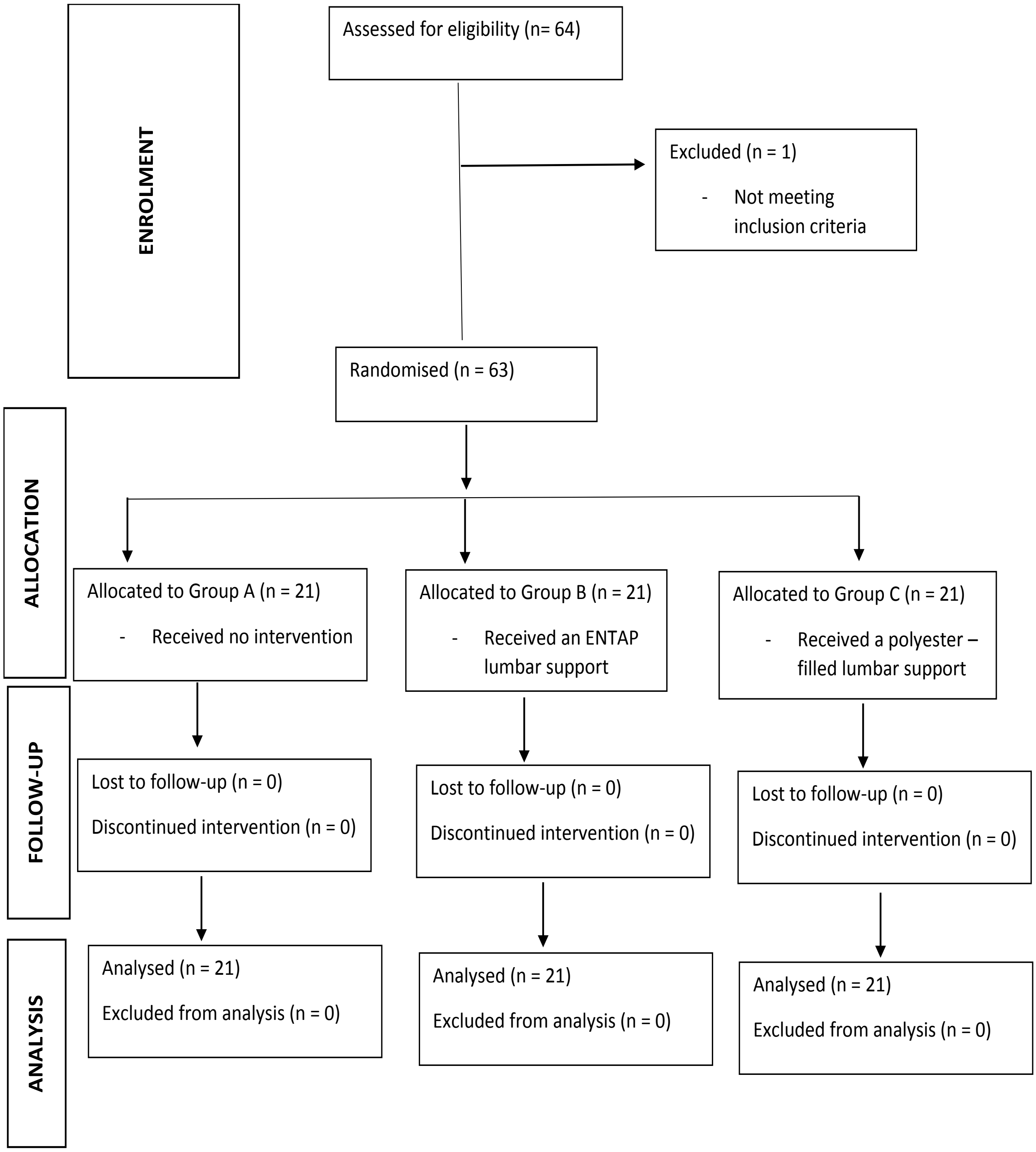

Figure 3.2: Flow diagram showing the research process from enrolment to analysis of the sample population

3.13 LIMITATIONS

The participants were driving their trucks most days and therefore the researcher was unaware whether the participants were always wearing their lumbar support pillows as well as having the lumbar support positioned correctly when driving. Once a week the researcher checked up on the truck drivers in the yard at that time. Unfortunately, not all truck drivers were in the yard when the researcher was there. It is assumed that the participants answered all questions truthfully. Due to human resource, time and financial constraints this study was limited to participants from one company only.

3.14 STATISTICAL ANALYSIS

Data Synthesis and Analysis

IBM Statistical Package for the Social Sciences (SPSS) version 25.0 was used to analyse the data. A p value <0.05 was considered as statistically significant. The mean body mass and height were compared between the three treatment groups using the one-way ANOVA tests. Repeated measures ANOVA testing was used to assess the treatment effect of the intervention group when compared with the other groups. A significant time x group interaction effect indicated a significant treatment effect. The direction of the effect was assessed using profile plots. Post hoc comparison of the intervention effect between time points and between treatment groups was done using a Bonferroni correction for multiple testing (Esterhuizen 2018).

3.15 ETHICAL CONSIDERATIONS

- Permission had been received from the company and directors to conduct the study **(Appendix K).**
- Participants were given a letter of information to inform them of the study **(Appendix H)** and the drivers were required to sign both the letter of consent **(Appendix I)** and the letter of information.
- A letter of confidentiality was signed by each participant and the researcher. It stated that the information was to be kept between the researcher and the participant and would not be discussed with their employer **(Appendix J).**
- A memorandum of understanding between the manufacturer and the researcher was signed **(Appendix G).**
- A contract was signed by the research assistant stating that s/he would help throughout the data collection and abide by the blinding process by not telling the researcher which lumbar support was used by which group **(Appendix F).**
- All information obtained was only used and seen by the researcher, the supervisor and the statistician. It was kept in safe storage during the research study.
- The data will be kept safely at the Durban University of Technology – Chiropractic Programme for five years and will then be shredded and disposed of.
- The participants were informed that taking part in the research was optional and that they should not feel compelled to participate.

- Participation was voluntary, and no remuneration was given to the participants.
- **Autonomy –** the participants were able to make their own decisions without any influence from others.
- **Non-maleficence** – the intervention did not harm the participants***.***
- **Beneficence** - if the intervention proved to be beneficial, the company would be advised by the researcher to purchase the lumbar support pillows for all their trucks – this would benefit the truck drivers. This study will also benefit Chiropractors as lumbar support pillows can possibly assist in the management of a patient with LBP.
- **Justice –** every truck driver who took part in the research study had an opportunity to give his own opinions without discrimination.
- There was a research assistant to avoid researcher bias.
- The welfare of the participant was the goal of this clinical trial.
- The researcher visited the company once a week during the data collection process and the participants informed the researcher if their LBP got worse. If the LBP increased, the lumbar support was removed from the participant's truck.

CHAPTER FOUR
RESULTS

This chapter describes the analysis of the data collected in this dissertation. The findings are related to the research question and hypotheses that guided this study.

4.1 INTRODUCTION

Sixty-three long-distance truck drivers with LBP were selected by purposive sampling from the 132 drivers working for a South African' transport company. The 63 participants were randomly allocated to three equal groups, with 21 participants in each group. 'Group A' had no lumbar support; while 'Group B' had the '*ENTAP Lumbar Support Pillow*' and 'Group C' had a polyester-filled lumbar support whenever driving for the duration of the six-week study period. Participants completed the Oswestry Low Back Disability Questionnaire, the NPRS and PGIC Scale at the start of the study, at three weeks and at six weeks (the end of the study).

4.2 DEMOGRAPHICS (APPENDIX A)

4.2.1 Age

Table 4.1: Age distribution within groups

AGE (years)	GROUP A (n=21)		GROUP B (n=21)		GROUP C (n=21)	
	Count	**%**	**Count**	**%**	**Count**	**%**
20-25	0	0.0	0	0.0	1	4.8
26-30	2	9.5	2	9.5	1	4.8
31-35	3	14.3	5	23.8	4	19.0
36-40	4	19.0	3	14.3	4	19.0
41-45	3	14.3	4	19.0	3	14.3
46-50	3	14.3	4	19.0	2	9.5
51-55	5	23.8	2	9.5	2	9.5
56-60	1	4.8	1	4.8	3	14.3
61-65	0	0.0	0	0.0	1	4.8
TOTAL	21	100	21	100	21	100

The median age group in all groups was 41-45 years (the median age in Group A was 43.5 years, in Group B 41.6 years and in Group C 41.8 years). The mode for Group A was 51-55, for Group B 31-35 years and for Group C 31-35 and 36-40 years of age. The mean age group for Group A, B and C was 41-45 years of age. In Groups A and B 85.7% (n=18) of subjects were aged 31-55 years and in Group C, 71% (n=15) fell into this age range. Group C had the greatest number of participants (n=3, 14%) in the 56-60 age group. The table suggests that the age of subjects was similarly distributed in the three study groups, with the majority of subjects in each group aged between 31 and 55 years.

4.2.2 Height and Body Mass

Table 4.2: Height and body mass distribution within groups

	GROUP A (n=21)		**GROUP B** (n=21)		**GROUP C** (n=21)		**p value**
	Mean	**Standard Deviation**	**Mean**	**Standard Deviation**	**Mean**	**Standard Deviation**	
Height (metres)	1.7	.1	1.7	.1	1.8	.0	0.103
Weight (kilograms)	79.1	7.9	81.0	8.4	83.9	8.0	0.173

One-way analysis of variance (ANOVA) determined that there was no statistically significant difference between groups for the height (p=0.103) and body mass (p=0.0173) of participants.

4.2.3 Distance driven monthly by truck drivers

The information below was obtained from Question number three of the initial general questionnaire **(Appendix A).**

Table 4.3: Distance driven monthly per group

DISTANCE DRIVEN MONHTLY (kms)		**GROUP A** (n=21)	**GROUP B** (n=21)	**GROUP C** (n=21)	**TOTAL** (N=63)
6000-7000	**Count**	1	0	0	1
	%	4.8	0.0	0.0	1.6
8000-9000	**Count**	5	3	8	16
	%	23.8	14.3	38.1	25.4
10 000 +	**Count**	15	18	13	46
	%	71.4	85.7	61.9	73.0
TOTAL	**Count**	21	21	21	63
	%	100	100	100	100

The majority of individuals in all three groups travelled a distance of 10 000 kilometres or more per month. There was no statistically significant difference between groups for distance driven monthly (Pearson's Chi Square=5.2 and p=0.267).

4.2.4 Length of time the participants had been experiencing LBP

The information below was obtained from Question number six **(Appendix A).**

Table 4.4: Length of time participants had been experiencing LBP per group

How long have you had low back pain for?		GROUP A (n=21)	GROUP B (n=21)	GROUP C (n=21)	TOTAL
1 month to 1 year	**Count**	6	8	6	20
	%	28.6	38.1	28.6	31.7
2 - 3 years	**Count**	6	5	4	15
	%	28.6	23.8	19.0	23.8
4 - 5 years	**Count**	2	2	4	8
	%	9.5	9.5	19.0	12.7
6 - 7 years	**Count**	4	3	6	13
	%	19.0	14.3	28.6	20.6
8 - 9 years	**Count**	2	1	1	4
	%	9.5	4.8	4.8	6.3
9 - 10 years	**Count**	0	2	0	2
	%	0.0	9.5	0.0	3.2
Over 10 years	**Count**	1	0	0	1
	%	4.8	0.0	0.0	1.6
TOTAL	**Count**	21	21	21	63
	%	100.0	100.0	100.0	100.0

As seen in the table above, most of the participants (n=20, 31.7%) in all three groups had been experiencing LBP for a period of between one month and one year. The mean for group A was three years duration, it was 2.5 years duration for group B and was 2.7 years duration for group C. The mode for Group A was one month to one year and two years to three years; B was one month to one year; and the mode for Group C was one month to one year and six to seven years.

4.3 SUBJECTIVE MEASURE OUTCOMES

4.3.1 THE NUMERICAL PAIN RATING SCALE (NPRS)

4.3.1.1 Overall treatment effect

Table 4.5: The overall treatment effect measured using the NPRS

Effect	Wilk's lambda	p value
Time	0.290	<0.001
Time x group	0.122	<0.001
Group	F=40.39	<0.001

There was a highly significant treatment effect overall (time x group p<0.001) for the NPRS, indicating that the change in NPRS scores over time were different in the three groups. This allowed the results of the NPRS to be compared between groups.

4.3.1.2 Tests of NPRS within subjects' contrasts

Table 4.6: Tests of NPRS within subjects' contrasts overall

Tests Within Subjects Contrasts							
Measure: NPRS							
Source	**Time**	**Type III Sum of Squares**	**Df**	**Mean Square**	**F**	**Significance**	**Partial Eta Squared**
time x group	Level 2 vs. Level 1	20.698	2	10.349	6.324	0.003	0.174
	Level 3 vs. Level 1	421.556	2	210.778	157.895	<0.001	0.840

The tests within subjects' contrasts overall showed that the interaction of the time x group within the three groups overall was significant interaction at both three weeks (Level 2) (p=0.003) and six weeks (Level 3) (p<0.001) compared with the baseline (Level 1).

4.3.1.3 Comparison of NPRS between the groups

Table 4.7: Comparison of the NPRS between Group A (no lumbar support pillow) and Group B (‘*ENTAP Lumbar Support Pillow*’)

Dependent Variable	Parameter	B	Std. Error	T	Significance
NPRS baseline	Intercept	6.571	.223	29.489	<0.001
	[Group A]	-.429	.315	-1.360	0.181
	[Group B]	0	.	.	.
NPRS 3 weeks	Intercept	5.000	.253	19.755	<0.001
	[Group A]	.905	.358	2.528	0.016
	[Group B]	0	.	.	.
NPRS 6 weeks	Intercept	1.286	.233	5.523	<0.001
	[Group A]	5.524	.329	16.778	<0.001
	[Group B]	0	.	.	.

There was no statistically significant difference between the groups at baseline (p=0.181), but there was a significant difference between the groups at three weeks (p=016) and six weeks ($p < 0.001$). This, therefore means that the NPRS score in the *‘ENTAP Lumbar Support Pillow’* Group was lower than the no lumbar support group.

Table 4.8: Comparison of the NPRS between Group B (‘*ENTAP Lumbar Support Pillow*’) and Group C (polyester-filled lumbar support pillow)

Dependent Variable	Parameter	B	Std. Error	T	Significance
NPRS baseline	Intercept	6.524	.214	30.520	.000
	[Group B]	.048	.302	.158	.876
	[Group C]	0[a]	.	.	.
NPRS 3 weeks	Intercept	6.000	.249	24.115	.000
	[Group B]	-1.000	.352	-2.842	.007
	[Group C]	0[a]	.	.	.
NPRS 6 weeks	Intercept	6.095	.218	27.899	.000
	[Group B]	-4.810	.309	-15.566	.000
	[Group C]	0[a]	.	.	.

Table 4.8 compared the *‘ENTAP Lumbar Support Pillow’* group with the polyester-filled lumbar support group. There was no difference between the groups at baseline (p=0.876), therefore making this data insignificant. There was a difference between the two groups at three weeks (p = 0.007) and at six weeks (p = 0.000).

4.3.1.4 The mean NPRS score within the three groups

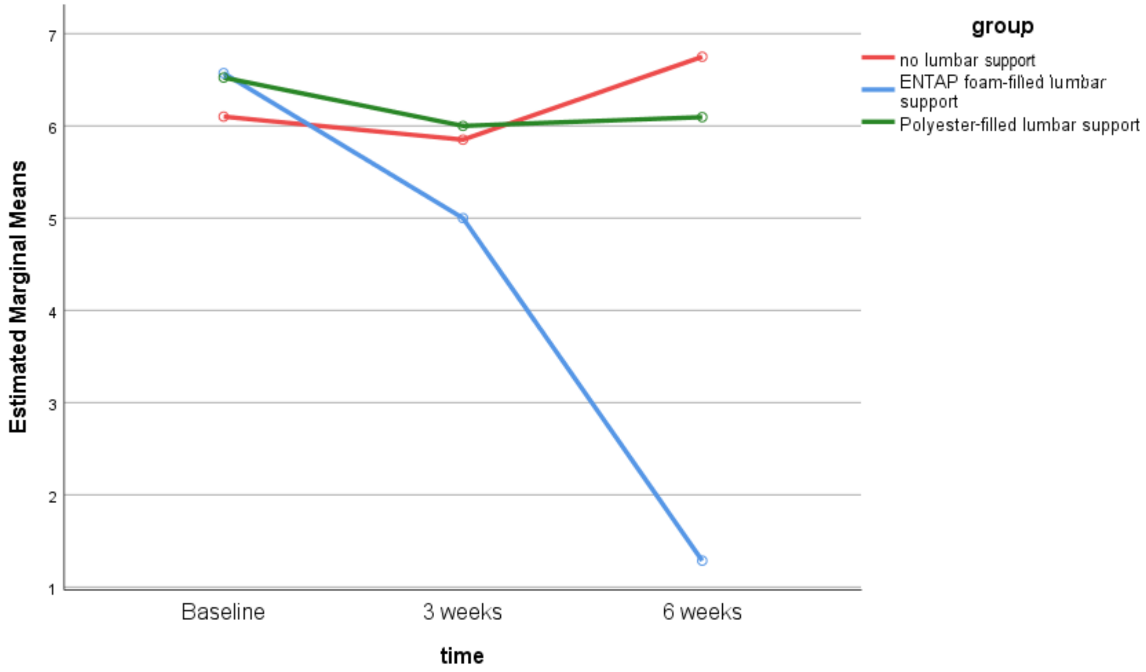

Figure 4.1: Profile plot showing the mean NPRS score within the three groups

The mean NPRS score in the *'ENTAP Lumbar Support Pillow'* group decreased from 6.57 to 5.0 on the NPRS at three weeks and then decreased significantly to 1.28 on the NPRS at the six-week follow-up. In the polyester-filled lumbar support group, the mean NPRS decreased from about 6.52 on the NPRS scale to 6.0 at three weeks, it then slightly increased to 6.09 at the six-week follow-up. In the no lumbar support group, the Oswestry LBP Disability Questionnaire score decreased slightly from 6.14 on the scale to 5.90 at three weeks and then increased to 5.57 on the NPRS at the six-week follow up.

Therefore, the findings revealed that the NPRS score in the *'ENTAP Lumbar Support Pillow'* group decreased LBP in long-distance truck drivers to a greater extent when compared with the other two groups.

4.3.2 OSWESTRY LBP DISABILITY QUESTIONNAIRE SCORE

4.3.2.1 The overall treatment effect

Table 4.9: The overall treatment effect when using the Oswestry LBP Disability Questionnaire

Effect	Wilk's lambda	p value
Time	0.626	<0.001
Time x group	0.475	<0.001
Group	F=1.69	0.053

There was a highly significant treatment effect overall (time x group p<0.001) for the Oswestry LBP Disability Questionnaire score, therefore the change in the score over time was different in the three groups.

4.3.2.2 Tests of Oswestry LBP Disability Questionnaire score within subjects' contrasts

Table 4.10: Tests of Oswestry LBP Disability Questionnaire within subjects' contrasts overall

Tests of Within-Subjects Contrasts							
Measure: Oswestry LBP Disability Questionnaire							
Source	**Time**	**Type III Sum of Squares**	**Df**	**Mean Square**	**F**	**Significance**	**Partial Eta Squared**
time x group	Level 2 vs. Level 1	6.095	2	3.048	1.593	0.212	.050
	Level 3 vs. Level 1	391.079	2	195.540	29.542	<0.001	.496

The tests within subjects' contrasts overall showed that the interaction of the time x group within the three groups was significant only at six weeks (Level 3) (p<0.001) compared with baseline (Level 1).

4.3.2.3 Comparison of the Oswestry LBP Disability Questionnaire Score between the groups

Table 4.11: Comparison of the Oswestry LBP Disability Questionnaire score between Group A (no lumbar support pillow) and Group B *('ENTAP Lumbar Support Pillow')*

Dependent Variable	Parameter	B	Std. Error	T	Significance
Oswestry baseline	Intercept	6.429	.721	8.913	.000
	[Group A]	-1.333	1.020	-1.307	.199
	[Group B]	0[a]	.	.	.
Oswestry 3 weeks	Intercept	5.333	.646	8.257	.000
	[Group A]	-.571	.913	-.626	.535
	[Group B]	0[a]	.	.	.
Oswestry 6 weeks	Intercept	1.095	.496	2.207	.033
	[Group A]	4.476	.702	6.377	.000
	[Group B]	0[a]	.	.	.

Table 4.11 compared the no lumbar support group with the *'ENTAP Lumbar Support Pillow'* group. It can be seen that there was no difference between these two groups at baseline (p=0.199) or at three weeks (0.535) and therefore this data was statistically insignificant. However, at six weeks there was a difference between the two groups (p=0.33) and therefore, this would be statistically significant.

Table 4.12: Comparison of the Oswestry LBP Disability Questionnaire score between Group B *('ENTAP Lumbar Support Pillow')* and Group C (polyester-filled lumbar support pillow)

Dependent Variable	Parameter	B	Std. Error	T	Significance
Oswestry baseline	Intercept	6.381	.821	7.773	.000
	[Group B]	.048	1.161	.041	.967
	[Group C]	0[a]	.	.	.
Oswestry 3 weeks	Intercept	5.667	.703	8.059	.000
	[Group B]	-.333	.994	-.335	.739
	[Group C]	0[a]	.	.	.
Oswestry 6 weeks	Intercept	5.571	.533	10.446	.000
	[Group B]	-4.476	.754	-5.934	.000
	[Group C]	0[a]	.	.	.

Table 4.12 compared the polyester-filled lumbar support group with *the 'ENTAP Lumbar Support Pillow*' group. There was no difference between the two groups at baseline (p=0.967) and at three weeks (p=0.739), therefore this data is statistically insignificant. At six weeks, a difference between the two groups can be seen (p=0.000), therefore this data is significant.

In conclusion, the difference lies between the *'ENTAP'* group and both the no support group and the polyester groups. It shows an improvement in activities of daily living and disability in the truck drivers' wearing the *'ENTAP Lumbar Support Pillow'* (Group B) and either a worsening of LBP disability and activities of daily living or no improvement in activities of daily living and LBP disability group A and C.

4.3.2.4 The mean Oswestry LBP Disability Questionnaire score within the three groups

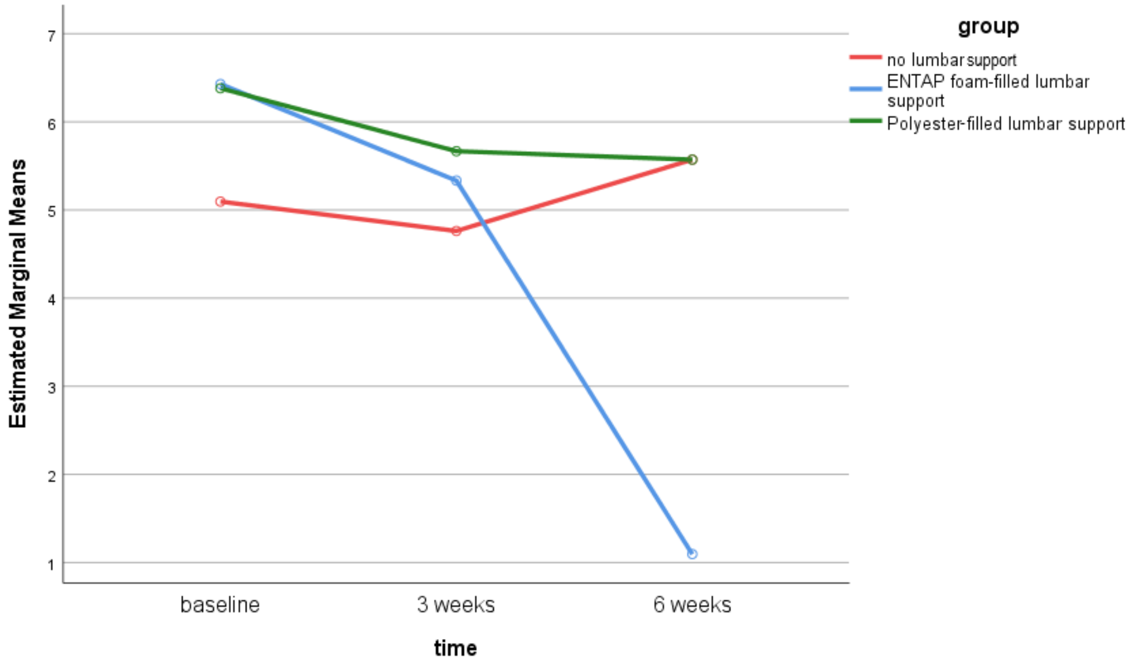

Figure 4.2 Profile plot showing the mean Oswestry LBP Disability Questionnaire score within the three groups

The mean Oswestry LBP Disability Questionnaire score in the *'ENTAP Lumbar Support Pillow'* group decreased from 6.43 to 5.33 at three weeks and then decreased significantly to 1.09 at the six-week follow-up. In the polyester-filled lumbar support group, the mean Oswestry LBP Disability Questionnaire score decreased from 6.38 to 5.67 at three weeks, it then slightly increased to 5.8 at the six-week follow-up. In the no lumbar support group, the Oswestry LBP Disability Questionnaire score decreased slightly from 5.1 on the scale to 4.76 at three weeks and then increased to just below 5.57 at the six-week follow up.

Therefore, the results of the Oswestry LBP Disability Questionnaire revealed a decrease (improvement in disability caused from LBP) in the score when the long-distance truck driver used the *'ENTAP Lumbar Support Pillow'* when compared with the other two groups.

4.3.3 PGIC SCALE

4.3.3.1 The overall treatment effect when using the PGIC Scale

Table 4.13: The overall treatment effect when using the PGIC Scale

Effect	Wilk's lambda	p value
Time	0.820	0.005
Time x group	0.595	<0.001
Group	F=31.7	<0.001

There was a highly significant treatment effect overall (time x group p<0.001) for the PGIC scale, revealing that the change in the score over time was different in the groups.

4.3.3.2 The mean PGIC score

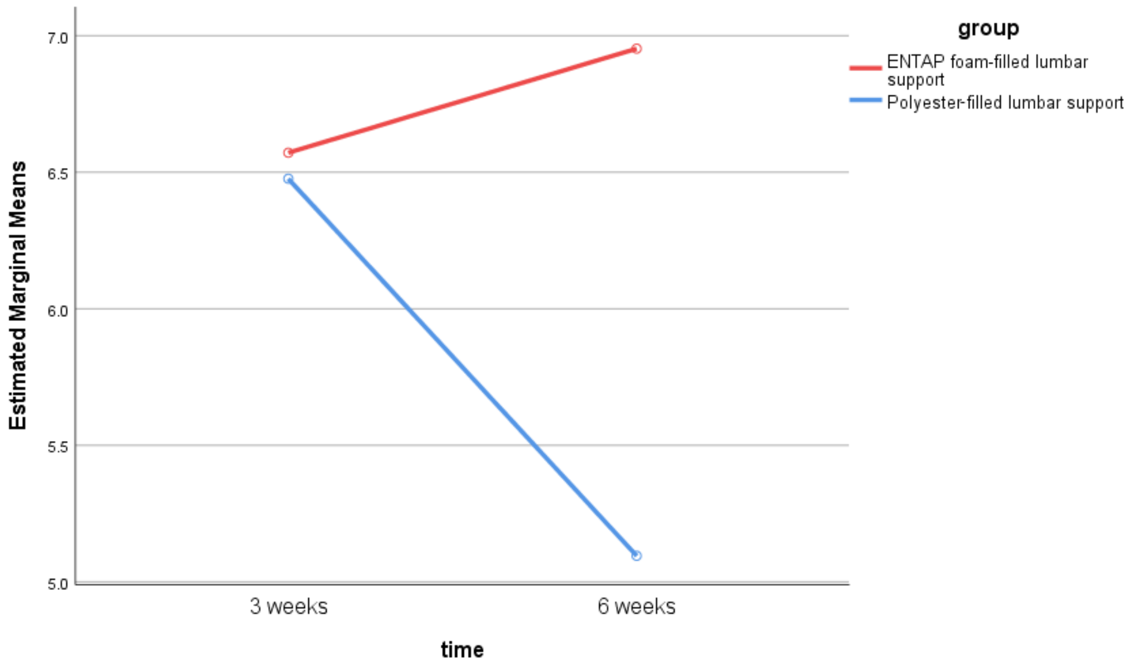

Figure 4.3: Profile plot showing the mean PGIC Scale score within Group B and Group C

As seen in figure 4.3, the mean PGIC Scale score in the *'ENTAP Lumbar Support Pillow'* group went from 6.56 at three weeks to 6.9 at six weeks, therefore showing an improvement in LBP whilst using the '*ENTAP Lumbar Support Pillow.'* The polyester-filled lumbar support pillow group went from 6.45 at three weeks to 5.10 and therefore decreased (worsened) in this group.

The profile plot shows that the mean PGIC score increased (improved) in the *'ENTAP Lumbar Support Pillow'* group while it decreased (worsened) in the polyester-filled lumbar support group.

4.3.4 DEGREE OF CHANGE

4.3.4.1 The overall treatment effect

Table 4.14: The overall treatment effect when using the Degree of Change Scale

Effect	Wilk's lambda	p value
Time	0.889	0.031
Time x group	0.639	<0.001
Group	F=21.6	<0.001

There was a highly significant treatment effect overall (time x group p<0.001) for degree of change score, meaning that the change in score over time was different in the groups and therefore, one is able to compare data collected.

4.3.4.2 The mean degree of change score

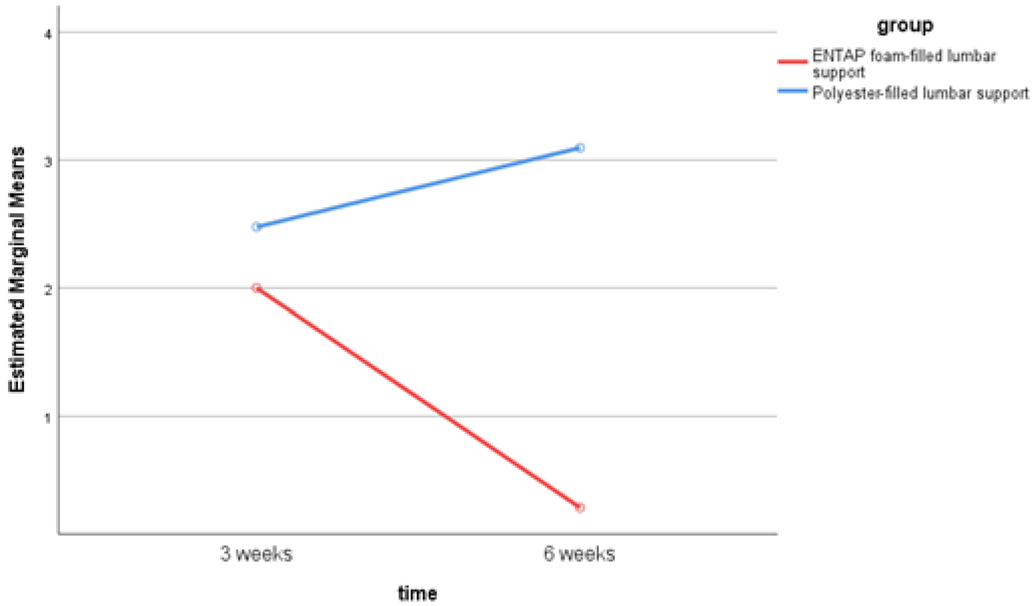

Figure 4.4: Profile plot showing the mean degree of change within Group B and Group C

The mean degree of change score in the *'ENTAP Lumbar Support Pillow'* group went from 2.0 at three weeks to 0.29 at six weeks. In the polyester-filled lumbar support group, the mean degree of change score went from 2.48 at three weeks to 3.10 at six weeks.

Therefore, the profile plot shows that the mean degree of change score decreased (improved) in *the 'ENTAP Lumbar Support Pillow'* Group while it increased (worsened) in the polyester-filled lumbar support group.

4.3.5 LUMBAR SUPPORT PILLOW COMFORT

All participants in both lumbar support pillow groups (Group B and C) replied "yes" to the question on whether they found the lumbar support pillow comfortable at both the three-week and six-week follow-up questionnaires.

4.4 CONCLUSION

It can be concluded that the *'ENTAP Lumbar Support Pillow'* effectively reduced LBP in long-distance truck drivers in terms of pain parameters (intensity and duration of pain), activities of daily living and disability, compared with the polyester pillow and no lumbar support. Therefore, the Alternate Hypothesis (H_a) which states that there will be a statistically significant ($p < 0.05$) improvement in LBP in the participants who use the *'ENTAP Lumbar Support Pillow'* compared to no lumbar support pillow and the polyester-filled lumbar support pillow is accepted and the Null Hypothesis is rejected.

CHAPTER FIVE

DISCUSSION OF RESULTS

This chapter discusses in detail the results found in this dissertation. Demographic data and subjective outcomes are discussed.

5.1 DEMOGRAPHIC DATA OF PARTICIPANTS

5.1.1 Gender

The groups were uniform with regards to gender (100% male) as all the truck drivers within the transport company studied were male.

5.1.2 Height and Body Mass

There was no statistically significant difference between groups for the height (p=0.103) and body mass (p=0.0173) of participants, which suggests that height and body mass are not confounding factors in this study. Calculation of the mean Body Mass Index (BMI) indicates that the average individual in each group was overweight (National Heart, Lung, and Blood Institute, 2018). The BMI was 25.9 kg/m² in Group A (no lumbar support), 25.9 kg/m² Group B (*'ENTAP Lumbar Support Pillow')* and 28.0 kg/m² in Group C (polyester-filled lumbar support). The BMI's of all the participants in the three groups were very similar and therefore this did not influence the outcome of the study. It is interesting to note that truck drivers in this study tended to be overweight, as there is evidence to support this as a trend in the industry. For example, a survey of 1670 long-distance truck drivers across the United States reported that 69% of the drivers were obese (National Institute for Occupational Safety and Health 2014). This is also true for the other demographic characteristics (age, gender, distance travelled per month and duration of LBP).

5.1.3 Distance travelled within a month

The distance travelled by the truck drivers within a month was similar in all three groups **(p = 0.267 and Pearson's chi square = 5.2)**, with the majority of drivers in each group travelling 10 000km or more every month. According to the definition of a long-distance truck driver (Complete School of Truck Transportation 2014; Supergroup 2017), this distance travelled monthly is in the high range. The average distance travelled per month is thus not a confounding factor.

The presence of LBP in the sample population of 63 truck drivers is not surprising in light of literature reporting that sitting and driving for prolonged periods is associated with LBP (Gale 2011; Kerkar 2018); possibly related to a decrease in lumbar lordosis, increased muscle activity, muscle fatigue and increased intra-discal pressure (Roffey *et al.* 2010) while sitting. The long distances travelled - an average of 10 000 kilometres by subjects in all groups and consequently the length of time spent sitting in the cab - may explain the results. Considering the literature, it is not surprising that LBP in Group A (no lumbar support) tended to get worse over the 6-week study period (71.4% of the participants in this group travelled more than 10 000 kms a month). In contrast, LBP in Group B with 85.7% of participants travelling more than 10 000 kms a month (‘*ENTAP Lumbar Support Pillow’*), improved significantly, possibly as the support used (100% of the time during many hours of driving) mitigated against further deterioration by supporting and maintaining the lumbar lordosis, reducing muscle overload and pressure on intervertebral discs. The poor/mixed LBP response in Group C (polyester lumbar support) with 61.9% of the participants travelling more than 10 000kms, may point to its inferior ability to provide the support offered by the polyester-filled lumbar support. It had the smallest population of participants within the group driving more than 10 000 kms.

5.1.4 Length of time having LBP

The majority of the study population had been experiencing LBP of less than one-year duration. The mean for Group A was three years duration, it was 2.5 years duration for Group B and was 2.7 years duration for Group C. The duration of having LBP was similar in all three groups and therefore did not influence the outcome of this research study.

5.2 SUBJECTIVE OUTCOMES

The subjective outcome results were as follows - the NPRS score decreased more and at a faster rate in Group B (*‘ENTAP Lumbar Support Pillow’)* Group, the Oswestry LBP Disability Questionnaire score decreased in Group B, the mean PGIC score increased (improved) in Group B, while it decreased (worsened) in Group C (polyester-filled lumbar support) and the mean degree of change score decreased (improved) in the *‘ENTAP Lumbar Support Pillow’* group while it increased (worsened) in the polyester-filled lumbar support group.

5.2.1 The effectiveness of the lumbar support pillows

There is limited literature on the effect of lumbar support pillows on LBP in drivers, however, the effect of lumbar support braces are investigated widely (Jellema *et al.* 2001:

377-386). Grondin *et al. (*2013: 30-34) documented the effect of a lumbar support pillow on lumbar posture and comfort during a prolonged seated task for 30 minutes at a time. The results showed that the use of a lumbar support pillow that has a space for the posterior pelvic bulk caused a decrease in lumbar flattening which is usually resultant when sitting. However, the thoracic kyphosis was increased. Future studies are needed to investigate the clinical benefits of using a lumbar support over a longer period in both males and females.

The 'ENTAP *Lumbar Support Pillow'* was effective in decreasing pain, disability, activity limitation and LBP symptoms of the long-distance truck drivers in this study. This was measured using the NPRS, the Oswestry LBP Questionnaire, the PGIC and the degree of change scale. The finding in this study is consistent with many other studies which proved that a lumbar support pillow decreases LBP (Chen *et al.* 2005). Chen *et al.* (2005) concluded that when using the lumbar support pillow, the prevalence of LBP decreased in the taxi drivers. Similar findings by Hekmatfard *et al*. (2017: 1-8) and Roelofs et al. (2010) concur with this study's findings. The *'ENTAP Lumbar Support Pillow'* used in the study was found to be effective in decreasing LBP, improving the Oswestry LBP Disability Questionnaire score and the PGIC score when compared with the no lumbar support group and the polyester-filled lumbar support group. The polyester-filled lumbar support pillow showed a worsening of the PGIC score and the degree of change scale at the six-week follow-up.

5.2.2 Comfort

It is essential to determine what comprises an effective lumbar support pillow. One of the essential factors would be to provide a level of comfort which enables a healthy sitting posture. Grondin *et al. (*2013: 30-34) reported that the measure of comfort of the lumbar support is associated decreased LBP. This was consistent with this study which revealed all participants in both lumbar support groups (Group B and C) replied "yes" to the question on whether they found the support comfortable at both three weeks and six-week time points.

Both the *'ENTAP Lumbar Support Pillow'* and polyester lumbar support improved comfort during sitting. This could be due to both lumbar supports providing some degree of support whilst seated for long periods of time. The *'ENTAP Lumbar Support Pillow'* would have provided a greater amount of support due to moulded foam within and this would therefore cause a decrease in the NPRS score, a decrease (improvement) in the Oswestry LBP Disability Questionnaire score and an increase (improvement) in the PGIC score when compared to the polyester-filled lumbar support pillow which showed an increase (worsening) of the Oswestry LBP Disability Questionnaire score and a decrease (worsening) of the PGIC score.

5.2.3 Physiological factors

There are multiple causes of LBP which have a physiological origin. When the spine is not adequately aligned, it puts the muscles, ligaments, spinal joints and discs under pressure. The low back is more susceptible to pain caused by poor posture due to the lower back supporting most of the body weight (Robinson 2004).

The *'ENTAP Lumbar Support Pillow'* was assessed for reducing LBP at baseline, at three weeks and at six weeks. Each participant had to be experiencing LBP. When the participants used the '*ENTAP Lumbar Support Pillow,'* there was a significant decrease in the NPRS **(Table 4.5 - 4.8 and Figure 4.1).** The findings in this study were consistent with literature where Rosenthal and Spencer (2011: 1-8) concluded that a back support might affect the size of the muscle fibre, but rather decreased the patients' pain, allowing for greater mobility.

The improvement in the NPRS could be related to the change in the dynamics of the lumbar facet joints, muscles and ligaments as these could be a source of the LBP (Bogduk 2004: 79-83). Bogduk (2004: 79-83), stated that the mechanoreceptors found within the facet joints may be activated as a result of biomechanical stress due to inadequate lumbar support of the lumbar spine when seated. This could eventually cause facet joint dysfunction, which is a common cause of LBP (Kirpalani and Mitra 2008). An adequate lumbar support pillow would have a positive effect on decreasing the stress on the facet joints, thereby decreasing the irritation of the mechanoreceptors (Bogdanovic *et al.* 2011: 21-24). This would lead to a resultant decrease in the pain rating, as observed in this study **(Table 4.5 - 4.8 and Figure 4.1).**

5.2.4 Occupational factors

According to Duthey (2013), 37% of LBP cases are due to occupational factors. Individuals who are exposed to WBV and long periods of standing or sitting in a workplace are more likely to experience LBP. These occupations include health-care workers, professional drivers, and construction workers. It has been said that LBP can be higher in some occupations where workers do a lot of heavy physical work and have abnormal working postures (Duthey 2013).

Truck drivers are exposed to many risk factors that contribute to developing LBP. When sitting in a fixed position while driving, they are exposed to whole body vibration, forced positions and handling of heavy goods. Low back pain is more common among truck drivers than in those professions where workers change their body positions on a regular basis. Ergonomic factors such as uncomfortable truck seats are commonly stated as causes for LBP (Kresal *et al.* 2017).

The findings in this study were consistent with literature as a change in the truck driver's seating position by using a correct '*ENTAP Lumbar Support Pillow'* allowed for a decrease (improvement) in pain, a decrease (improvement) in the Oswestry LBP disability Questionnaire score and an increase (improvement) in the PGIC and an improvement in the comfort of their truck seats.

5.2.5 Hawthorne effect

The *'ENTAP Lumbar Support Pillow'* is a branded pillow and is an established company, this may have caused the participants to record greater improvements in both lumbar support pillow groups as both the researcher and participant were blinded as to which pillow was the *'ENTAP Lumbar Support Pillow.'* Furthermore, the participants that were included in the research study may have felt the need to please the researcher. The participants were also told that if the lumbar support pillow resulted in a decrease of their LBP, the trucking company would consider purchasing the *'ENTAP Lumbar Support Pillow'* for them. This form of compensation may have influenced their responses.

The Hawthorne Effect was taken in to consideration as a factor that contributed to the positive results. However, the Hawthorne Effect would have had a minimal impact due to the double blinded effect of the study. The researcher and the participants were unaware of which pillow was being used.

5.2.6 Hypothesis

The alternate hypothesis was accepted. The *'ENTAP Lumbar Support Pillow'* was effective in decreasing LBP in long-distance truck drivers in terms of the objective measurements. The '*ENTAP Lumbar Support Pillow'* was more effective in decreasing LBP when compared with the polyester-filled lumbar support pillow and no lumbar support pillow used over a period of six weeks.

5.3 CONCLUSION

The researcher concludes that the *'ENTAP Lumbar Support Pillow'* could be an integral part of a Patient-Centred Care (PCC) approach in the management of LBP. The findings of this research study provide health-care professionals, professional drivers and trucking companies with the knowledge of the importance of correct seating posture whilst driving. It also reinforces the importance of a lumbar support pillow in an individual's vehicle to help decrease LBP. It can be used by practitioners for their patients as part of a holistic plan of management. The positive effects to the patient or individual using such an approach include:

- Supplementation of intervention or treatment plans.
- Correct support of the lumbar lordosis and lumbar musculature whilst driving.
- Correct posture when in a seated position whilst driving.
- An improvement in performing activities of daily living.
- A decrease in LBP.
- Due to a decrease in LBP, the driver may become more attentive and this could lead to a decrease in accidents.
- An improvement in the psychological status of an individual.
- An approach which is cost-effective in reducing LBP in professional drivers.

The results seen in this research study support the *'ENTAP Lumbar Support Pillow'* company's claim. The *'ENTAP Lumbar Support Pillow'* was effective in decreasing pain, disability, activity limitation and symptoms; and an improvement in emotions, quality of life and comfort whilst driving. Furthermore, the *'ENTAP Lumbar Support Pillow'* was more effective in reducing the symptoms LBP when compared with the polyester-filled lumbar support or when the participant wore no lumbar support.

The degree of support and its effect on keeping the correct lumbar lordosis or lumbar posture was not investigated. Even though there were positive results seen in this study, caution needs to be taken when an individual over-generalises the results of the study because of the small sample size and the study being performed in one transport company. A study needs to be done to investigate the effect of the *'ENTAP Lumbar Support Pillow'* in a larger population with both males and females, and on individuals from more than one transport company to verify the findings of this research study.

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

This chapter concludes the entire dissertation and explains any limitations that were experienced in this study and any recommendations that could be put in place for any future related studies.

6.1 CONCLUSION

The study investigated the effect of the *'ENTAP Lumbar Support Pillow'* when compared with the polyester-filled lumbar support and no lumbar support on LBP in long-distance truck drivers. In conclusion, individuals in Group B ('*ENTAP Lumbar Support Pillow')* experienced a decrease (improvement) in pain, a decrease (improvement) in the Oswestry LBP disability Questionnaire score, an increase (improvement) in the PGIC and an improvement of the comfort of their truck seats. This could be due to the pillow changing the lumbar posture whilst sitting and therefore preventing or altering the causative agents such as myofascial trigger points and facet syndrome of the lumbar spine. A good lumbar support pillow that improves comfort levels and decreases LBP is important to individuals who drive long-distances and experience LBP and to health-care professionals who can recommend the lumbar support pillow to their LBP patients. In Group A (no lumbar support pillow), the participants' LBP increased over the six weeks. This may suggest that driving long distances, WBV and associated risk factors have a cumulative or progressive impact on LBP. In Group C (polyester-filled lumbar support pillow), the NPRS did not decrease at the rate the *'ENTAP Lumbar Support Pillow'* did, the Oswestry LBP Disability Questionnaire Score decreased at a much slower rate than the *'ENTAP Lumbar Support Pillow'* group, the PGIC score decreased (worsened) and the degree of change increased (worsened).

The use of the *'ENTAP Lumbar Support Pillow'* may allow home treatment options to be implemented in individuals who experience LBP whilst driving long-distances or sitting in a position for a prolonged period. The evidence of this study allows health-care professionals to advise on the use of a lumbar support pillow which could therefore make up an integral part of a management programme.

6.2 LIMITATIONS

The following limitations were taken into consideration:

- The sample size (n = 63) used was moderately a small sample size and therefore limited the validity of the research results.
- The long-term effect of the lumbar support pillow was not investigated and therefore is unknown. This study was only done over a period of six weeks.
- The biomechanical effects of the *'ENTAP Lumbar Support Pillow'* on the lumbar lordosis was not tested and therefore the effect of the lumbar support pillow on the biomechanical and anatomical structures are not known.
- The Hawthorne Effect may have come into play due to participants feeling the need to please the researcher and the fact that the trucking company may consider purchasing the lumbar support pillow if the truck drivers found a decrease in their LBP.
- It was not possible to know whether the truck drivers wore the lumbar support pillows at all times in their trucks whilst driving. The researcher did go once a week to the company to check whether the truck drivers who were in the yard at that particular time were wearing their lumbar support pillow. Unfortunately, the researcher was unable to determine whether all the truck drivers were wearing their lumbar support pillows as they were not all in the same place at the same time as the researcher.
- The study was only done on males as there were no female truck drivers within this company.
- The truck drivers' posture was not evaluated with and without the lumbar support pillow whilst sitting in their trucks.

6.3 RECOMMENDATIONS

The recommendations that arose from this study were as follows:

- A similar study should be performed with a bigger sample size and at more than one trucking company. This would allow for the results of the research study to be more comprehensive.
- A study should be conducted to determine the truck drivers' posture when using the *'ENTAP Lumbar Support Pillow'* and when not using it whilst sitting in the truck.

- A study should be done to determine the efficacy when comparing the *'ENTAP Lumbar Support Pillow'* with other brands of lumbar support pillows in terms of pain parameters and biomechanical parameters such as lumbar lordosis and the degree of lumbar support in the seated position.

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APPENDIX A

NAME: ____

AGE: ___________________________

GENDER: MALE ___ FEMALE ___

RACE: BLACK ___ WHITE ___ INDIAN ___ COLOURED ___ OTHER ___

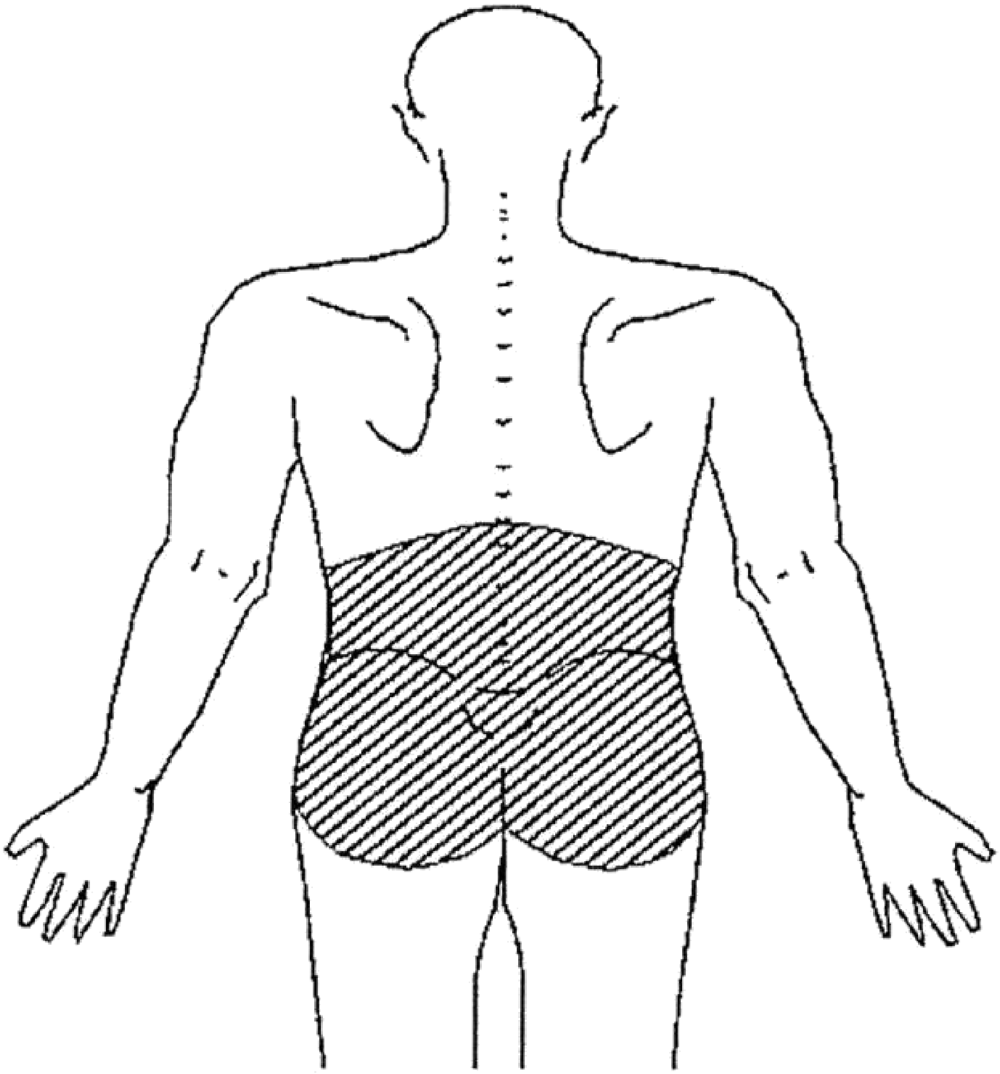
HEIGHT: __________ metres

WEIGHT: __________ kilograms

1. Will you be willing to take part in my study? **Yes___ No___**
2. Do you suffer from low back pain? This can be pain that is always there or low back pain that comes and goes. **Yes___ No___**
3. What distance do you drive monthly? ________________
4. Do you already have a lumbar support pillow in your truck? **Yes___ No___**
5. Do you have any organic causes of low back pain such as tuberculosis of the spine or tumours of the spine? **Yes___ No___**
6. How long have you had low back pain for? ________________
7. Is the pain always there or does it come and go? ________________

APPENDIX B

Low back is the area that is coloured in this diagram.



(Onofrio. A et al., 2012)

APPENDIX C

Numerical Pain Rating Scale at Baseline

Please rate the severity of your pain by circling a number below:

No pain	0 1 2 3 4 5 6 7 8 9 10	***Unbearable pain***

Name ______________________________ **Date** ________________

Participant Number ________________________

Oswestry Low Back Pain Scale at Baseline

Instructions: Please circle the **ONE NUMBER** in each section which most closely describes your problem.

Section 1 – Pain Intensity
0. The pain comes and goes and is very mild.
1. The pain is mild and does not vary much.
2. The pain comes and goes and is moderate.
3. The pain is moderate and does not vary much.
4. The pain comes and goes and is severe.
5. The pain is severe and does not vary much.

Section 2 – Personal Care (Washing, Dressing, etc.)
0. I would not have to change my way of washing or dressing in order to avoid pain.
1. I do not normally change my way of washing or dressing even though it causes some pain.
2. Washing and dressing increase the pain but I manage not to change my way of doing it.
3. Washing and dressing increase the pain and I find it necessary to change my way of doing it.
4. Because of the pain I am unable to do some washing and dressing without help.
5. Because of the pain I am unable to do any washing and dressing without help.

Section 3 – Lifting
0. I can lift heavy weights without extra pain.
1. I can lift heavy weights but it gives extra pain.
2. Pain prevents me lifting heavy weights off the floor.
3. Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
4. Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
5. I can only lift very light weights at most.

Section 4 – Walking
0. I have no pain on walking.
1. I have some pain on walking but it does not increase with distance.
2. I cannot walk more than 1 kilometre without increasing pain.
3. I cannot walk more than 500 metres without increasing pain.
4. I cannot walk more than 250 metres without increasing pain.
5. I cannot walk at all without increasing pain.

Section 5 – Sitting
0. I can sit in any chair as long as I like.
1. I can sit only in my favourite chair as long as I like.
2. Pain prevents me from sitting more than 1 hour.
3. Pain prevents me from sitting more than ½ hour.
4. Pain prevents me from sitting more than 10 minutes.
5. I avoid sitting because it increases pain immediately.

Section 6 – Standing
0. I can stand as long as I want without pain.
1. I have some pain on standing but it does not increase with time.
2. I cannot stand for longer than 1 hour without increasing pain.
3. I cannot stand for longer than ½ hour without increasing pain.
4. I cannot stand for longer than 10 minutes without increasing pain.
5. I avoid standing because it increases the pain immediately.

Section 7 – Sleeping
0. I get no pain in bed.
1. I get pain in bed but it does not prevent me from sleeping well.
2. Because of pain my normal night's sleep is reduced by less than one-quarter.
3. Because of pain my normal night's sleep is reduced by less than one-half.
4. Because of pain my normal night's sleep is reduced by less than three-quarters.
5. Pain prevents me from sleeping at all.

Section 8 – Social Life
0. My social life is normal and gives me no pain.
1. My social life is normal but it increases the degree of pain.
2. Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
3. Pain has restricted my social life and I do not go out very often.
4. Pain has restricted my social life to my home.
5. I have hardly any social life because of the pain.

Section 9 – Traveling
0. I get no pain when traveling.
1. I get some pain when traveling but none of my usual forms of travel make it any worse.
2. I get extra pain while traveling but it does not compel me to seek alternate forms of travel.
3. I get extra pain while traveling which compels to seek alternative forms of travel.
4. Pain restricts me to short necessary journeys under ½ hour.
5. Pain restricts all forms of travel.

Section 10 – Changing Degree of Pain
0. My pain is rapidly getting better.
1. My pain fluctuates but is definitely getting better.
2. My pain seems to be getting better but improvement is slow.
3. My pain is neither getting better or worse.
4. My pain is gradually worsening.
5. My pain is rapidly worsening.

TOTAL ____________

APPENDIX D

Numerical Pain Rating Scale at 3 weeks

Please rate the severity of your pain by circling a number below:

No pain	0 1 2 3 4 5 6 7 8 9 10	*Unbearable pain*

Name ______________________________ **Date** ______________

Participant Number______________________________

Oswestry Low Back Pain Scale at 3 weeks.

Instructions: Please circle the **ONE NUMBER** in each section which most closely describes your problem.

Section 1 – Pain Intensity
0. The pain comes and goes and is very mild.
1. The pain is mild and does not vary much.
2. The pain comes and goes and is moderate.
3. The pain is moderate and does not vary much.
4. The pain comes and goes and is severe.
5. The pain is severe and does not vary much.

Section 2 – Personal Care (Washing, Dressing, etc.)
0. I would not have to change my way of washing or dressing in order to avoid pain.
1. I do not normally change my way of washing or dressing even though it causes some pain.
2. Washing and dressing increase the pain but I manage not to change my way of doing it.
3. Washing and dressing increase the pain and I find it necessary to change my way of doing it.
4. Because of the pain I am unable to do some washing and dressing without help.
5. Because of the pain I am unable to do any washing and dressing without help.

Section 3 – Lifting
0. I can lift heavy weights without extra pain.
1. I can lift heavy weights but it gives extra pain.
2. Pain prevents me lifting heavy weights off the floor.
3. Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
4. Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
5. I can only lift very light weights at most.

Section 4 – Walking
0. I have no pain on walking.
1. I have some pain on walking but it does not increase with distance.
2. I cannot walk more than 1 kilometre without increasing pain.
3. I cannot walk more than 500 metres without increasing pain.
4. I cannot walk more than 250 metres without increasing pain.
5. I cannot walk at all without increasing pain.

Section 5 – Sitting
0. I can sit in any chair as long as I like.
1. I can sit only in my favourite chair as long as I like.
2. Pain prevents me from sitting more than 1 hour.
3. Pain prevents me from sitting more than ½ hour.
4. Pain prevents me from sitting more than 10 minutes.
5. I avoid sitting because it increases pain immediately.

Section 6 – Standing
0. I can stand as long as I want without pain.
1. I have some pain on standing but it does not increase with time.
2. I cannot stand for longer than 1 hour without increasing pain.
3. I cannot stand for longer than ½ hour without increasing pain.
4. I cannot stand for longer than 10 minutes without increasing pain.
5. I avoid standing because it increases the pain immediately.

Section 7 – Sleeping
0. I get no pain in bed.
1. I get pain in bed but it does not prevent me from sleeping well.
2. Because of pain my normal night's sleep is reduced by less than one-quarter.
3. Because of pain my normal night's sleep is reduced by less than one-half.
4. Because of pain my normal night's sleep is reduced by less than three-quarters.
5. Pain prevents me from sleeping at all.

Section 8 – Social Life
0. My social life is normal and gives me no pain.
1. My social life is normal but it increases the degree of pain.
2. Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
3. Pain has restricted my social life and I do not go out very often.
4. Pain has restricted my social life to my home.
5. I have hardly any social life because of the pain.

Section 9 – Traveling
0. I get no pain when traveling.
1. I get some pain when traveling but none of my usual forms of travel make it any worse.
2. I get extra pain while traveling but it does not compel me to seek alternate forms of travel.
3. I get extra pain while traveling which compels to seek alternative forms of travel.
4. Pain restricts me to short necessary journeys under ½ hour.
5. Pain restricts all forms of travel.

Section 10 – Changing Degree of Pain
0. My pain is rapidly getting better.
1. My pain fluctuates but is definitely getting better.
2. My pain seems to be getting better but improvement is slow.
3. My pain is neither getting better or worse.
4. My pain is gradually worsening.
5. My pain is rapidly worsening.

TOTAL ______________

Patients' Global Impression of Change (PGIC) Scale at 3 weeks

Since using the lumbar support pillow, how would you describe the change (if any) in **ACTIVITY LIMITATION, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE,** related to your low back pain? (Tick **ONE** box).

No change (or condition has got worse)	☐	1
Almost the same, hardly any change at all	☐	2
A little better, but no noticeable change	☐	3
Somewhat better, but the change has not made a real difference	☐	4
Moderately better, and a slight but noticeable change	☐	5
Better and a definite improvement that has made a real and worthwhile difference	☐	6
A great deal better and a considerable improvement that has made all the difference	☐	7

In a similar way, please circle the number below that matches your degree of change since using the lumbar support pillow:

Much Better **No Change** **Much Worse**

0 1 2 3 4 5 6 7 8 9 10

Did you find the lumbar support pillow comfortable? **Yes** _____ **No** _____

APPENDIX E

Numerical Pain Rating Scale at 6 weeks

Please rate the severity of your pain by circling a number below:

No pain	0 1 2 3 4 5 6 7 8 9 10	*Unbearable pain*

Name ______________________________ **Date** ______________

Participant Number______________________________

Oswestry Low Back Pain Scale at 6 weeks.

Instructions: Please circle the **ONE NUMBER** in each section which most closely describes your problem.

Section 1 – Pain Intensity
0. The pain comes and goes and is very mild.
1. The pain is mild and does not vary much.
2. The pain comes and goes and is moderate.
3. The pain is moderate and does not vary much.
4. The pain comes and goes and is severe.
5. The pain is severe and does not vary much.

Section 2 – Personal Care (Washing, Dressing, etc.)
0. I would not have to change my way of washing or dressing in order to avoid pain.
1. I do not normally change my way of washing or dressing even though it causes some pain.
2. Washing and dressing increase the pain but I manage not to change my way of doing it.
3. Washing and dressing increase the pain and I find it necessary to change my way of doing it.
4. Because of the pain I am unable to do some washing and dressing without help.
5. Because of the pain I am unable to do any washing and dressing without help.

Section 3 – Lifting
0. I can lift heavy weights without extra pain.
1. I can lift heavy weights but it gives extra pain.
2. Pain prevents me lifting heavy weights off the floor.
3. Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
4. Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
5. I can only lift very light weights at most.

Section 4 – Walking
0. I have no pain on walking.
1. I have some pain on walking but it does not increase with distance.
2. I cannot walk more than 1 kilometre without increasing pain.
3. I cannot walk more than 500 metres without increasing pain.
4. I cannot walk more than 250 metres without increasing pain.
5. I cannot walk at all without increasing pain.

Section 5 – Sitting
0. I can sit in any chair as long as I like.
1. I can sit only in my favourite chair as long as I like.
2. Pain prevents me from sitting more than 1 hour.
3. Pain prevents me from sitting more than ½ hour.
4. Pain prevents me from sitting more than 10 minutes.
5. I avoid sitting because it increases pain immediately.

Section 6 – Standing
0. I can stand as long as I want without pain.
1. I have some pain on standing but it does not increase with time.
2. I cannot stand for longer than 1 hour without increasing pain.
3. I cannot stand for longer than ½ hour without increasing pain.
4. I cannot stand for longer than 10 minutes without increasing pain.
5. I avoid standing because it increases the pain immediately.

Section 7 – Sleeping
0. I get no pain in bed.
1. I get pain in bed but it does not prevent me from sleeping well.
2. Because of pain my normal night's sleep is reduced by less than one-quarter.
3. Because of pain my normal night's sleep is reduced by less than one-half.
4. Because of pain my normal night's sleep is reduced by less than three-quarters.
5. Pain prevents me from sleeping at all.

Section 8 – Social Life
0. My social life is normal and gives me no pain.
1. My social life is normal but it increases the degree of pain.
2. Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
3. Pain has restricted my social life and I do not go out very often.
4. Pain has restricted my social life to my home.
5. I have hardly any social life because of the pain.

Section 9 – Traveling
0. I get no pain when traveling.
1. I get some pain when traveling but none of my usual forms of travel make it any worse.
2. I get extra pain while traveling but it does not compel me to seek alternate forms of travel.
3. I get extra pain while traveling which compels to seek alternative forms of travel.
4. Pain restricts me to short necessary journeys under ½ hour.
5. Pain restricts all forms of travel.

Section 10 – Changing Degree of Pain
0. My pain is rapidly getting better.
1. My pain fluctuates but is definitely getting better.
2. My pain seems to be getting better but improvement is slow.
3. My pain is neither getting better or worse.
4. My pain is gradually worsening.
5. My pain is rapidly worsening.

TOTAL ______________

Patients' Global Impression of Change (PGIC) Scale at 6 weeks

Since using the lumbar support pillow, how would you describe the change (if any) in **ACTIVITY LIMITATION, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE,** related to your low back pain? (Tick **ONE** box).

No change (or condition has got worse)	☐	1
Almost the same, hardly any change at all	☐	2
A little better, but no noticeable change	☐	3
Somewhat better, but the change has not made a real difference	☐	4
Moderately better, and a slight but noticeable change	☐	5
Better and a definite improvement that has made a real and worthwhile difference	☐	6
A great deal better and a considerable improvement that has made all the difference	☐	7

In a similar way, please circle the number below that matches your degree of change since using the lumbar support pillow:

Much Better **No Change** **Much Worse**

0 1 2 3 4 5 6 7 8 9 10

Did you find the lumbar support pillow comfortable? **Yes** _____ **No** _____

APPENDIX F

Durban University of Technology

Agreement with research assistant

This is to certify that I agree to assist the Researcher, Brittany Van Wyk with her study in testing the effect of a lumbar support pillow on low back pain in long distance truck drivers in the eThekweni district. I acknowledge that the lumbar support pillows are to be kept at the trucking company and to ensure that the blinding process is adequate until the end of the data collection. I am fluent in isiZulu and I will be able to translate the questionnaire for the truck drivers, if they are having difficulties understanding. I will be available at all times to assist in the data collection process and will be transported to the trucking company by the researcher.

Name of the research assistant: [redacted]

Signature: [redacted]

Date: 08/11/2017

Name of the Researcher: Brittany Van Wyk

Signature: [redacted]

Date: 8/11/2017

APPENDIX G

Durban University of Technology

Memorandum of understanding between:

The "RESEARCH INSTITUTION' - Durban University of Technology (this includes the respective research student and research supervisor, Department of Chiropractic. The Faculty of Health Sciences Research Committee, The Institutional Research Committee and any other related DUT employees.

AND

The "MANUFACTURER" – ENTAP lumbar support (including all members, employees, associates).

This Memorandum of Understanding pertains to the following research project and must be read in conjunction with:

APPENDIX A-Detailed Research Proposal (PG4a)
APPENDIX B-Durban University of Technology Research Committee Research Ethics Policy and Guidelines

Title of the study:
The effect of a lumbar support pillow on low back pain in long distance truck drivers in the eThekweni District.

Research Supervisor: Dr A. van der Meulen (M.Tech. Chiro).

This study is a Master's Mini Dissertation conducted in partial compliance with the Master's Degree in Technology in the Department of Chiropractic - Faculty of Health Sciences - Durban University of Technology. This study will obtain ethical approval from the Faculty of Health Sciences Research & Ethics Committee (FRC) of Durban University of Technology.

Please be aware the brand name will be told to the participants and will be included in the letters of information as well as the dissertation.

Section 1-Funding of the study and financial commitment

1.1 A research allowance of R5000.00 has been awarded by the Dept. Post-graduate Development & Support –The details of the funds approved are described in Section A of the Research Proposal (PG4a) attached.

1.2 The 'MANUFACTURER'- acknowledges that THE RESEARCH INSTITUTION' will have no financial obligations or commitments to the 'MANUFACTURER' whatsoever as a result of conducting this study.

1.3 The 'MANUFACTURER'- may not award or incentivize the study or its related parties in any manner whatsoever, nor remunerate, award or offer any financial or other donation or gift to any of those involved with the study.

1.4 It is noted however that the 'MANUFACTURER' will be providing a Foam ENTAP lumbar supports and are making polyester lumbar supports for the purposes of completing the research project referred to in this document.

[redacted]

Section 2-Academic processes and outcome

2.1 The FRC has approved the above mentioned Research Supervisor and co-supervisor who in conjunction with the Research Student are the sole contributors to the academic content, procedures, results and findings of the study based on the prescribed data analysis in the research proposal, barring amendments required by the approved research examiners appointed by the RESEARCH INSTITUTION.

2.2 The 'MANUFACTURER' acknowledges that the findings upon completion of the study (as determined by the Research Student and Research Supervisors and according to the protocol stated in the attached research proposal) will be final and non-negotiable.
The 'MANUFACTURER' acknowledges further that it has no authority over the outcome of this study and may not influence the findings or the reporting thereof in any matter.

2.3 Any modification or deviation from the approved research proposal, must be applied for in writing, endorsed by both the Research Student & Supervisors and Head of Department before serving before the FRC/IREC, the final say therein will be determined by the FRC/IREC.

2.4 The 'MANUFACTURER' acknowledges that it may not influence or make any change to the approved research protocol/proposal.

Section 3-Publication of findings

3.1 The findings and outcome of the above mentioned study remain the intellectual property of the 'RESEARCH INSTITITION' indefinitely. The study will be published in the format of a hard bound dissertation which will be placed in the DUT library.

3.2 Publication of the findings of this study in a journal or other scholarly medium will be at the discretion of the Research student and /or Research Supervisors who will determine the appropriate medium and place of publication as well as content of the publication. Authorship of any scholarly output originating from this study of the Research Student and Research Supervisors and other collaborators appointed by the Research Student and/or the Research Supervisors. Such scholarly publication must include the names of the Researcher and the Research Supervisor as well as the 'RESEARCH INSTITUTION'.

3.3 Any reference whatsoever to the findings of this study if quoted or mentioned in any format must make formal reference to the respective dissertation, its official title, and its author(s) and the owners of the intellectual property thereof i.e. the 'RESEARCH INSTITITION'.

3.4 Any reference whatsoever to any secondary publication arising from this original study must make formal reference to the respective dissertation its official title and its author(s) and the owners of the intellectual property thereof i.e. the 'RESEARCH INSTITUTION'

3.5 The 'MANUFACTURER' may make reference to the outcome of this study in the prescribed manner mentioned in section 3.3 and 3.4 undertaking 3.1 and 3.2.

Section 4-Indemnity

4.1 The Research Student, the Research Supervisor and the research facilities and its staff are duly covered by the 'RESEARCH INSTITUTION' insurance policy pertaining to public liability, injury or harm which may occur as a result of conducting this study.

[redacted]

4.2 The 'MANUFACTURER' undertakes to indemnify the 'RESEARCH INSTITUTION' with regard to any outcome, incidents, injury or harm which occurs as a result of the conduction of this study including the results of the study and publication thereof.

4.3 The 'MANUFACTURER' will not be held liable for any incidents, injury or harm which may occur as a result of the study, use or misuse of the product.

Section 5- Ethical considerations

5.1 Ethical clearance of the proposed study will be granted by the DUT IREC (such ethical clearance will become invalid should there be any deviation from the approved research methodology described in the research proposal attached).

5.2 The 'MANUFACTURER' undertakes to abide by the DUT Research Committee Research Ethics Policy and Guidelines (APPENDIX B).

5.3 In addition to 5.2 the 'MANUFACTURER should note and refer to **Section 1,2 & 3** of this document.

[redacted]____ **(name of representative of the 'MANUFACTURER')** [redacted] representative of **ENTAP lumbar support** hereby agree to abide by the regulations stated in this memorandum of understanding.

[redacted]______________ **ITAP lumbar support**

6-12-2017
Date

[redacted]____ **(name of representative of the 'THE RESEARCH** [redacted]cial capacity as representative of **Durban University of** [redacted]de by the regulations stated in this memorandum of understanding

[redacted]______________

2017 -12- 0 8
Date

Si[redacted]
Durban University of Technology

I **Brittany Van Wyk** in my capacity as **the research student** hereby agree to abide by the regulations in this memorandum of understanding between the **ENTAP lumbar support company** (the "MANUFACTURER") and **Durban University of Technology** (the "RESEARCH INSTITUTION")

[redacted]______________

7/12/2017.
Date

[redacted]

Attachment: Information regarding ENTAP (the "MANUFACTURER").

Information regarding the **"MANUFACTURER" – ENTAP-** gleaned from their website: https://www.entap.co.za/

Founder and Chief Executive Officer at ENTAP is Margaret Botha.

ENTAP which stands for ENvision Tomorrow After Pain was started in 1996 by Margaret Botha. Margaret worked as a textile manager before starting ENTAP and therefore knows a lot about the industry. Combined with ENTAP's patented technology in back support, Margaret has helped over 350 people manage their back pain. It is said that the ENTAP lumbar support pillows will improve posture, decrease pain and increase comfort. This pillow also has a NAPPI Code which enables the purchaser to apply for reimbursement from a medical aid scheme. It also has a 30 day money-back guarantee if you don't feel improvement to your back pain while using the lumbar support pillow.

ADDRESS:
102 12th Avenue, Fairland, Randburg, Johannesburg, 2030, South Africa

EMAIL:
info@entap.co.za

PHONE:
(011)-476-5240

[redacted]

APPENDIX H

<u>Durban University of Technology</u>

<u>Main Study: Letter of Information:</u>

Dear Participant, welcome to my research study.

Title of the Research Study:
The effect of a lumbar support pillow on low back pain in long-distance truck drivers in the eThekweni District.

Principle Investigator/s/researcher: Brittany Van Wyk (Chiropractic student and main researcher)

Supervisor: Dr A van der Meulen (M. Tech. Chiro)

Brief Introduction and purpose of the Study:

Low back pain is very common in truck drivers. Low back support during driving may be beneficial. Therefore, the purpose of the study is to determine whether a lumbar support will decrease low back pain in truck drivers. The lumbar support pillow will not cure low back pain but will be palliative in contributing to a decrease in low back pain.

Outline of the Procedures:

Participation in this study is voluntary. If you are interested in participating in this study, you will then be asked to read letter of information and sign the consent form and the statement of confidentiality. You will then receive a short questionnaire which you will then complete. You will be allocated in one of three groups in a random manner. These groups include for example group A receiving an ENTAP lumbar support for a period of six weeks, group B receiving no lumbar support and group C receiving a polyester-filled lumbar support. Another questionnaire will be done after three weeks and the last questionnaire will be done after six weeks of taking part in the study. The researcher will visit the company every week, and you must inform the researcher if your low back pain is getting worse. If the low back pain is increasing, the lumbar support will be removed from your truck.

Risks or Discomforts to the Participant:

If you receive a lumbar support pillow, you might experience a slight discomfort as it will take time for you to get used to it. If the pain gets worse and you cannot tolerate it, please let the researcher know and you can withdraw from the study.

Benefits:

The lumbar support pillow may help reduce your back pain. If the lumbar support pillow allows for the improvement of low back pain in the truck driver, the researcher will then advise the trucking company to purchase lumbar support pillows for their drivers. They are not obliged to do so, if they don't feel the need for it.

Reason/s why the Participant May be Withdrawal from the Study:

You may be withdrawn from the study due to non-compliance, illness or an adverse reaction to the device being tested. You may withdraw from the study at any time for any reason, without any consequences. This will be documented.

Remuneration:

You will receive no remuneration.

Costs of the study:

You are not expected to cover any costs towards the study.

Confidentiality:

All completed questionnaires are kept in complete confidence and will not be discussed with the employers or any individual outside of the research proposal. Questionnaires will be kept in a locked cupboard and all research data will be submitted to DUT Chiropractic program for five years where it will stored and then disposed of by shredding.

Research-related Injury:

Should your low back pain increase when using a lumbar support pillow, please inform the researcher immediately.

Person to Contact in the Event of Any Problems or Queries:

Should you have any queries, feel free to contact the researcher (Brittany) on 031 373 2205. If the researcher cannot be contacted please contact the supervisor, Dr. van der Meulen on 031 262 0776 or the Institutional Research Ethics administrator on 031 373 2375. Complaints can be reported to the Director: Research and Postgraduate Support, Prof S Moyo on 031 373 2577 or moyos@dut.ac.z

APPENDIX I

CONSENT

Statement of Agreement to Participate in the Research Study:

- I hereby confirm that I have been informed by the researcher, **Brittany Van Wyk,** about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: ___________.
- I have also received, read and understood the above written information (Participant Letter of Information) regarding the study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the researcher.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.
- I understand that significant new findings developed during the course of this research which may relate to my participation will be made available to me.

____________________	__________	______	_______________
Full Name of Participant	**Date**	**Time**	**Signature**

I, **Brittany Van Wyk** herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

________________	__________	__________________
Full Name of Researcher	**Date**	**Signature**
________________	__________	__________________
Full Name of Witness (If applicable)	**Date**	**Signature**
________________	__________	__________________
Full Name of Legal Guardian (If applicable)	**Date**	**Signature**

APPENDIX J

Durban University of Technology

CONFIDENTIALITY STATEMENT – IMPORTANT NOTICE:

THIS IS TO BE FILLED IN AND READ BY EVERY MEMBER TAKING PART IN THE RESEACRH STUDY, BEFORE THE STUDY COMMENCES.

DECLARATION:

1. All information in the research documents and any information discussed during the study will be kept private and confidential. This is especially binding to any information that may identify any of the participants in the research process.
2. The returned questionnaires will be coded and kept anonymous in the research process.
3. None of the information shall be communicated to any one of your employers outside of the study.
4. The information from this research study will be made public in terms of a journal publication, which in no way will identify any participants of this research.

Once this has been agreed upon and read, please fill in the suitable information below and sign to acknowledge agreement.

Research participant: ____________________________ Signature: ____________________

Witness Name: ____________________________ Signature: ____________________

Researcher's Name: ____________________________ Signature: ____________________

Supervisor's Name: ____________________________ Signature: ____________________

Co-Supervisor's Name: ____________________________ Signature: ____________________

APPENDIX K

28 July 2017

To whom it may concern,

PRINCIPLE PERMISSION TO CONDUCT RESEARCH AT OUR COMPANY

This letter will serve as principle permission for Brittany Van Wyk to conduct the research project entitled "The effect of a lumbar support pillow on low back pain in long distance truck drivers" at Super Group Freight Division.

All truck drivers are trained in the English language and therefore most should be literate in English. However, if needed, the driver trainer will be available to translate.

Super Group Freight Division are not obliged to purchase the lumbar support pillows after the research has been conducted.

Yours sincerely,

[redacted]

Sam Hamann
Chief Executive Officer
[redacted]

APPENDIX L

Institutional Research Ethics Committee
Research and Postgraduate Support Directorate
2nd Floor, Berwyn Court
Gate 1, Steve Biko Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

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12 December 2017

IREC Reference Number: **REC 148/17**

Ms B Van Wyk
3 Overdale Road
Berea
Durban
4001

Dear Ms Van Wyk

The effect of a lumbar support pillow on low back pain in long distance truck drivers in the eThekwini District.

I am pleased to inform you that Full Approval has been granted to your proposal REC 148/17.

The Proposal has been allocated the following Ethical Clearance number **IREC 119/17**. Please use this number in all communication with this office.

Approval has been granted for a period of two years, before the expiry of which you are required to apply for safety monitoring and annual recertification. Please use the Safety Monitoring and Annual Recertification Report form which can be found in the Standard Operating Procedures [SOP's] of the IREC. This form must be submitted to the IREC at least 3 months before the ethics approval for the study expires.

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's.

Please note that any deviations from the approved proposal require the approval of the IREC as outlined in the IREC SOP's.

Yours Sincerely

[redacted]

Professor J K Adam
Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY
2017 -12- 12
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

APPENDIX M

4948	IREC119/17	The effect of a lumbar support pillow on low back pain in long-distance truck drivers in the eThekweni district.	2018/01/30	View	DOH-27-0118-5948