THE EFFECT OF INTERFERENTIAL CURRENT TREATMENT DURATION ON CHRONIC LOW BACK PAIN

By

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I, Ahmed Abdul Carim, 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 parents, Ismail and Roshanara Abdul Carim who thought me how to smile and laugh despite all the obstacles I have been through. You have thought me the fundamental basics of what it is to be a chiropractor, to respect others and treat them with kindness. I love you with all my heart.

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ABSTRACT

Background to the study: Chronic low back pain (CLBP) is a common musculoskeletal complaint, which results in increased absenteeism from work and other disabilities. Interferential current (IFC) is one of the treatment modalities used by manual and physical therapists to alleviate CLBP. Interferential current involves electrical stimulation of medium frequency using two currents that cross over each other.

There have been numerous mechanisms proposed on how IFC works with regard to pain inhibition; however, these remain unconfirmed. Common theories include those based on the gate control theory of pain and integrated pain theories.

Although the placement of the electrodes used in the IFC application has been well defined, the optimum treatment time for CLBP has not been well researched. Therefore, this study aimed to determine what protocol regarding the duration of IFC is most appropriate in the treatment of CLBP.

Aim: The aim of this study was to investigate the effect of interferential current in the treatment of chronic low back pain using variable time intervals

Methodology: This study was a randomised single-blinded clinical trial which consisted of 45 participants residing in the eThekwini municipality, divided into three groups of 15 each. The participants were randomly assigned using concealed allocation to one of three treatment groups of 15 each viz. 15, 20 or 30 minutes of interferential current (IFC). Low back pain level was determined using a numerical pain rating scale (NRS-101). Pain pressure thresholds (PPT) were measured with a pain pressure algometer. The effect of low back pain on participants' activities of daily living was assessed using the Oswestry low back questionnaire (OLBQ).The participants received three treatments over a two week period with the fourth consultation being used for the final subjective and objective measurements a week later.

Results: Repeated measures ANOVA testing was used to examine the intra-group effect of time and the inter-group effect of treatment on the outcomes of NRS-101 and algometer readings. Profile plots were used to assess the direction and trends of the effects. An intra-group analysis revealed that, objectively and subjectively, all groups responded positively to treatment over time, with no significant time-group interaction.

Conclusion: This study concluded that neither group is more effective than the other with respect to participants' pain perception and the OLBQ. However, groups one and three showed the largest individual improvement between consultation one and three, compared to group

two which showed consistent improvement throughout for the NRS-101 readings. Based on the results collected from this study, the shortest time frame of 15 minutes of IFC application can be used in the treatment of CLBP.

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LIST OF SYMBOLS AND ABBREVIATIONS

AIDS: Acquired immune deficiency syndrome
ALL: Anterior longitudinal ligament
ANOVA: Analysis of variance
APS: Action potential stimulator
CDC: Chiropractic Day Clinic
CLBP: Chronic low back pain
DJD: Degenerative joint disease
DUT: Durban University of Technology
EMS: Electrical muscle stimulation
HIV: Human immunodeficiency virus
HT: Horizontal therapy
IFC: Interferential current
IREC: Institutional Research and Ethics Committee
$kg.m^{-2}$: Kilograms per meter squared
LBP: Low back pain
MCID Minimally clinically important difference
n: Sample size
NRS-101: Numerical pain rating scale
NSAIDS: Non-steroidal anti-inflammatory drugs
OLBQ: Oswestry low back questionnaire
PLL: Posterior longitudinal ligament
QL: Quadratus lumborum muscle
RA: Research Assistant
SP: Spinous process
SPSS: Statistical package for the social sciences
TA: Therapeutic alliance
TENS: Transcutaneous electrical stimulation
TVP: Transverse process
USA: United States of America
VAS: Visual analogue scale
vs.: Versus

LIST OF DEFINITIONS

Accommodation:

A process whereby the patient gets accustomed to the IFC stimulation and does not feel the sensation anymore (Watson, 2008).

Amplitude-modulated frequency / Beat frequency / Carrier frequency:

The difference between the two currents on a four pole IFC unit (Singh, 2012; Watson, 2008).

Ceiling effect:

A point at which the independent variable no longer has an effect on the dependent variable (Mouton, 2006).

Frequency sweep:

The frequency that can be directly fed to the IFC unit. The frequency of the second current can be changed rhythymically across a range of beat frequencies (Singh, 2012).

Floor effect:

When a data gathering instrument has a lower limit to the data it can reliably specify (Mouton, 2006).

CHAPTER ONE

INTRODUCTION

1.1. INTRODUCTION TO THE STUDY

Chronic low back pain (CLBP) is a common musculoskeletal complaint (Dagenais and Haldeman, 2012), resulting in increased absenteeism from work, morbidity and other disabilities (Dagenais et al., 2008). This results in increased medical expenditure by both the patient and society in general (Manga et al., 1993; Dagenais et al., 2008). Thus, it is prudent to establish effective intervention strategies to ameliorate pain arising from the low back region (Potrias and Brosseau, 2008).

One such intervention used by manual and physical therapists which is useful for alleviating CLBP is an electrotherapy modality known as Interferential current (IFC) (Tabasam and Johnson, 2006). Interferential current involves electrical stimulation of medium frequency using two currents that cross over each other. The currents are set slightly out of phase so that they 'interfere" with each other, thereby, causing electrical stimulation through the skin which reaches the deep musculature (Palmer et al., 1999; Jarit et al., 2003). By penetrating the deep musculature, IFC is able to reach areas that cannot be reached by massage therapy (Beattii et al., 2011). Interferential current, when compared to transcutaneous electrical stimulation (TENS) and action potential stimulator (APS) therapy, was found to have greater peak-to-peak amplitude (Alves-Guerreiro et al., 2001). Therapeutic uses of IFC include reduction of pain and inflammation. Interferential current is also able to reduce tissue restriction and it helps with increased movement and healing through vasodilation and neuro-stimulation (Poitras and Brosseau, 2008).

There have been numerous mechanisms proposed on how IFC works with regard to pain inhibition; however, these remain unconfirmed (Johnson and Tabasam, 2002; Johnson and Tabasam, 2003a, 2003b; Stephenson and Walker, 2003). Common theories include those based on the gate control theory of pain (Melzack and Wall, 1965) and integrated pain theories (Zambito et al., 2006; Apkarian et al., 2009); which suggest that IFC significantly reduces pain and disability in CLBP by overriding pain receptors and increasing electro-mechanical stimulation (Zambito et al., 2006; Apkarian et al., 2009). However, variable clinical outcomes, poorly designed and small studies (viz. insufficient evidence) exist for the inclusion of IFC into

systematic reviews, in order to consolidate the possible mechanisms of action and therefore increase the predictability of clinical outcomes (Poitras and Brosseau, 2008).

Although the placement of the electrodes used in the IFC application has been well defined, the optimum treatment time for CLBP has not been well researched (Tsolakis, 2001; Zambito et al., 2006; Suh et al., 2014). Therefore, it is not possible to determine what protocol regarding the duration of IFC is most appropriate in the treatment of CLBP.

1.2. AIM AND OBJECTIVES OF THE STUDY

1.2.1. Aim of the study

The aim of this study was to investigate the effect of interferential current in the treatment of chronic low back pain using variable time intervals.

1.2.2. Objectives of the study

1. To determine the effect of 15 minutes of application of IFC on CLBP in terms of numerical pain rating scale (NRS-101), Oswestry low back questionnaire (OLBQ) and algometer.

2. To determine the effect of 20 minutes of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

3. To determine the effect of 30 minutes of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

4. To compare the overall effect of the different time intervals of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

1.3 THE HYPOTHESES OF THE STUDY

1.3.1 Null hypothesis

The null hypothesis stated that there will be no difference between the groups in terms of subjective and objective findings.

1.3.2 Alternate hypothesis

It was hypothesised that the 20 minute application of IFC will be statistically significant in improving CLBP *(p* > 0.05*)* when compared to the 15 and 30 minute groups.

1.4. RATIONALE

1.4.1 Rationale one

Chronic low back pain is a frequent but often misunderstood pain disorder (Chevan and Clapis, 2013) which has a mean prevalence of 4.4% amongst middle-aged adults which refers to those between the ages of 24 to 39 years and it has a prevalence of 19.6% in those aged 20 to 59 years (Meucci et al., 2015). The prevalence of CLBP thus increases from the third decade of life and is likely to peak at 50 to 60 years of age (Meucci et al., 2015). Based on the demographics of ageing, CLBP can potentially become an increasingly important problem in the general population in the future (Meucci et al., 2015). This increases the need for an effective treatment for CLBP, which can be administered over a shorter period requiring fewer numbers of visits thereby curbing costs incurred by patients.

1.4.2 Rationale two

Many patients suffering from low back pain (LBP) experience a considerable amount of pain and discomfort which is persistent in nature thereby leading to the development of CLBP (Woolf and Pleger, 2003). Patients also experience acute exacerbations of pain which are episodes or “flare-ups” of LBP while still experiencing CLBP (Woolf and Pleger, 2003). This results in increased absenteeism from work and occasionally allows an individual to return to work. Therefore, studies should be done to determine an effective treatment for CLBP and add to the existing body of literature.

1.4.3 Rationale three

Various non-invasive methods which include stretching, massage, IFC, laser therapy, heat, acupressure, ultrasound, TENS, biofeedback and pharmacological treatments have been utilised in the treatment of CLBP however, no single treatment has been demonstrated to be universally effective (Bogduk and McGuirk, 2002). This study aimed to give practitioners who use IFC clarity on the best treatment protocol. Practitioners can be made aware of alternate treatment options for CLBP, which is noted to be increasing on a global scale. It is hoped that

this study will give better guidelines on the treatment of CLBP, which will invariably decrease treatment costs to the patient and allow for improved recovery.

1.5 SCOPE OF THE STUDY

The results of 45 healthy participants between the ages of 18 to 45 years, who met all the inclusion criteria of this study, are reported in this dissertation. This randomised controlled clinical trial was carried out at the Durban University of Technology (DUT) Chiropractic Day Clinic (CDC). Participants were randomly allocated into one of three treatment groups with varying time intervals for IFC i.e. 15 minute, 20 minute and 30 minute durations (Fuentes et al., 2010). Subjective and objective measurements using the NRS-101, the OLBQ and algometer were recorded at the first consultation, at the third consultation and at the final consultation. Data analysis was performed using SPSS: (2010.IBM SPSS Statistics for Windows, Version 22. Armonk, NY: IBM Corp.). Statistical significance was set at $p < 0.05$ level.

CHAPTER TWO

Literature review

2.1 INTRODUCTION

Low back pain (LBP) is a common condition treated by chiropractors amongst a range of other musculoskeletal disorders (Farabaugh et al., 2010). Low back pain is regarded as one of the four most common conditions worldwide (Vos et al., 2012). Low back pain has reduced the quality of life of individuals because of a number of factors such as treatment interventions that have not worked, medication that has led to dependence and abuse, social isolation, difficulties at work as well as emotional anxiety (Dagenais and Haldeman, 2012). Additionally, LBP adds limitations to an individual's day-to-day activities and reduces the ability of the individual to function at his or her optimum (Dagenais and Haldeman, 2012). Low back pain can also cause erratic mood swings, sleep derangement and reduced appetite. This eventually leads to severe psychological, physiological and social consequences (Blyth et al., 2003; Dagenais and Haldeman, 2012). Studies on the economic impact of LBP revealed that it causes work absenteeism, long-term disability and increased use of the National Health Insurance (Ibrahim et al., 2008; Gore, 2012). Moreover, the prevalence of LBP is expected to rise in the future, making it pertinent that effective treatment is made available to reduce this drastic economic and social burden (Freburger et al., 2009).

2.2 DEFINITION OF LOW BACK PAIN

Low back pain is defined as "pain which can include stiffness or muscle tension that is localised below the twelfth rib and above the gluteal folds" (Anderson, 1986; Galukande et al., 2005). Low back pain is further sub-categorised and defined as stated by Globe et al. (2016):

Acute **:** symptoms of LBP which are present for less than six weeks.
Subacute **:** LBP that is present between six to 12 weeks.
Chronic **:** persistence of LBP for greater than 12 weeks.

2.3 THE EPIDEMIOLOGY OF LOW BACK AND CHRONIC LOW BACK PAIN

Globally, there is evidence indicating that LBP is of growing concern (Dyer, 2012; Coole et al., 2010; Chen et al., 2009). Hoy et al. (2012) conducted a systematic review on the global

prevalence of LBP in the adult population. The study showed that LBP had a point prevalence of 11.9% and a one-month prevalence of 23.2%. The overall mean prevalence was 31.0%, the one-year prevalence was 38% and the lifetime prevalence was 39.9%. A systematic review was conducted reviewing the prevalence of LBP in Africa (Louw et al., 2007) there was a 32% made up the prevalence for the adult population whilst the one-year average prevalence for LBP was 50%. Furthermore, the lifetime prevalence of LBP in Africa was 62%.

A national survey in the USA by Deyo et al. (2006), concluded by saying that LBP was found to be the highest in American-Indians and Alaska natives, however, Asian-Americans had the lowest prevalence. The low prevalence could possibly be due to cases of LBP going unreported or poor access to health care or be directly related to the location in which the studies were done (viz. national reporting mechanisms are usually related to hospitals and patients seen in this context). In the South African context, research on LBP is lacking as more focus is placed on the HIV and AIDS pandemic together with tuberculosis as shown in the strategic plan of the South African Department of Health (2014). There are however, studies that were conducted amongst different race groups in South Africa. Van der Meulen (1997) found a prevalence of LBP amongst Black males to be 53.1%, Docrat (1999) found a prevalence of 45.4% in Indian males and 54.6% in Indian females whilst the prevalence in Coloured males was 42.2% and 57.8% for Coloured females and Dyer (2012) found the point prevalence amongst Whites to be 34%.

These varied prevalence findings may be related to LBP increasing in likelihood from the third decade of life (Patrick et al., 2014; Meucci et al., 2015); with a peak prevalence at 50 to 60 years of age (Meucci et al., 2015). It is found more commonly in women possibly because women have a lower bone density and muscle mass compared to men and women also have increased demands on their bodies from pregnancy and childbirth which could be causative factors in developing CLBP (Woolf and Pfleger, 2003; Meucci et al., 2015). Other factors may include a sedentary lifestyle, obesity, trauma, smoking, genetic factors and psychological stress (Manchikanti et al., 2014).

Given this multivariate aetiology of LBP, it is nevertheless seen as a self-limiting condition where most sufferers will recover and return to their normal day-to-day activities. However, a percentage of these patients do not recover and go on to become chronic pain sufferers (Patrick et al., 2014). Low back pain is susceptible to becoming chronic in 15 to 45% of individuals with a point prevalence of 30% (Manchikanti et al., 2014). This is also supported by Chou and Shekelle (2010), who stated that 20% of LBP sufferers had symptoms after one year in developed countries. From the multivariate aetiology as well as the high rate of conversion to chronicity, it is evident that CLBP is of clinical importance and further research

is warranted to address the efficacy and effectiveness of treatment interventions. In order to investigate the most effective clinical interventions, it is important to understand the clinical anatomy of the low back. Therefore, the next section will cover this aspect before addressing the causes and effects of LBP.

2.4 ANATOMY OF THE LUMBAR SPINE

The lumbar spine is composed of the posterior part of the trunk, inferior to the thoracic cage and just superior to the buttocks (Galukande et al., 2005). The lumbar spine consists of five bones called lumbar vertebrae (Moore et al., 2014).

2.4.1 Bony anatomy

The anterior elements of the lumbar vertebra comprises the vertebral body and the pedicles which are found posterior to the vertebral body on either side. The posterior elements of the lumbar vertebra are made up of laminae arising from the base of the pedicles, where the superior and inferior articular processes (that form the zygapophysial joint, colloquially called the facet joint) are found. The laminae fuse posteriorly to form a centrally placed spinous process (Cramer and Darby, 2005). Two transverse processes arise from the base of the laminae, between the superior and inferior articular processes (one on either side). The distinguishing feature of the lumbar vertebrae is that they are much larger than the thoracic and cervical vertebrae mainly because they support and transmit body weight (Moore et al., 2014). Additionally the lumbar vertebrae does not have transverse foramina and articular facets for ribs, but it does display mammillary processes which are not present in the other regions of the spine (Cramer and Darby, 2005; Standring, 2015).

2.4.2 Ligaments of the lumbar spine

The anterior longitudinal ligament (ALL) extends from the pelvic aspect of the sacrum to the anterior tubercle of the C1 vertebra in a longitudinal fashion (Moore et al., 2014; Standring, 2015). The main function of the ALL is to limit hyperextension of the spine thus maintaining stability of the joints in between the vertebral bodies (Drake et al., 2005; Moore et al., 2014). The posterior longitudinal ligament (PLL) is a narrower ligament found within the vertebral canal posterior to the vertebral bodies, which attaches mainly to the intervertebral discs (Cramer and Darby, 2005). The main function of this ligament is to prevent posterior herniation of the nucleus pulposus and to limit hyperflexion of the vertebral column. The PLL also contains pain nerve endings (Drake et al., 2005; Moore et al., 2014). The ligamentum flavum is a band of pale to yellow elastic tissue that joins the laminae of the vertebral arches together (Moore

et al., 2014). They extend from the lamina above to the lamina below. They are found to be the thickest in structure in the lumbar region. Their function is to limit abrupt flexion by resisting separation of the vertebral lamina, thus preventing injury to the intervertebral discs (Moore et al., 2014; Standring, 2015). The ligamentum flavum also maintains the normal curvature of the vertebral column and assists with straightening post flexion (Moore et al., 2014).

2.4.3 Muscles of the lumbar spine

Muscles are an essential component of the body which allow for various movements (Vizniak, 2010). In particular, the muscles of the low back allow for flexion, extension, lateral flexion and rotation (Moore et al., 2014). Muscles are able to contract and relax to allow for movement and are attached to bone via tendons (Vizniak, 2010; Moore et al., 2014). When the muscle is overused, acutely overloaded or repetitively traumatised, a spasm results (Travell and Simons, 1983; Chaitow and DeLany, 2000). This often leads to LBP (Kirkaldy-Willis and Burton, 1992; Njoo and Van De Does, 1994; Morris, 2006; Vizniak, 2010).

Numerous muscles make up the low back and are divided into the extrinsic and intrinsic muscles. The extrinsic muscles control limb and respiratory movement whilst the intrinsic muscles act directly on the vertebral column to produce movement and maintain posture (Drake et al., 2005; Moore et al., 2014). The intrinsic muscles will be discussed further as they are relevant to this study.

The intrinsic muscles of the lumbar spine can be further divided into the intermediate, deep and minor deep layers. The intermediate layer is made up of erector spinae muscles which is subdivided into three columns i.e. the illiocostalis, longissimus and spinalis. The deep layer is made up of the semispinalis, multifidus and rotatores, which are collectively called the transversospinalis group. The minor deep layer is made up of the interspinales, intertransversarii and levatores costarum (Moore et al., 2014; Standring, 2015).

Other muscles that are involved in movement and maintaining stability are the quadratus lumborum (lateral flexors), iliopsoas, rectus abdominus (forward flexors), internal and external oblique and transverse abdominus (forward flexors and rotators). Details of these muscles can be found in **Table 2.1.**

Table 2.1: Muscles of the lumbar spine: their origin, insertion, innervation, actions and blood supply

Muscle	Origin	Insertion	Innervation	Blood supply	Actions
	Intermediate layer: Erector spinae				
Illiocostalis Lumborum	Broad tendon of iliac crest, posterior surface of sacrum and lumbar SPs	Angles of ribs 8 to 12	Posterior rami of spinal nerves	Dorsal branches of segmental arteries	Unilateral: Lateral flexion of the spine
Longisimus		TVPs and angle of ribs 1 to 12			Bilateral: Extends the vertebral column and head. Controls movement via eccentric contraction
Spinalis		SPs of T3 to T9			
	Deep layer: Transversospinalis				
Semispinalis	TVPs of C4 to T12 vertebra	SPs of 5 to 6 vertebral segments above	Posterior rami of spinal nerves	Posterior intercostal artery and lumbar branches	Bilateral: Extension of the head and neck Unilateral: Controls lateral flexion to side opposite contraction
Multifidus	Mamillary processes of L1 to L5	SPs of 4 to 6 vertebral segments above			Stabilisation of vertebrae during local movement
Rotatores (Brevis and Longus)	TVPs of C4 to L5	Base of SPs and lamina 1 to 2 segments above			Stabilises vertebrae and assists in local extension and rotary movements
	Lateral Flexors				
Quadratus lumborum	Inferior border of twelfth rib and tips of lumbar transverse processes	Iliolumbar ligament and iliac crest; internal lip	Lumbar plexus of T12 to L4 nerves, anterior branches	Subcostal and lumbar arteries	Bilateral: Extends lumbosacral spine Unilateral: Elevates pelvis, laterally flexes the trunk and depresses the twelfth rib
	Flexors				
External oblique	External and inferior borders of ribs 5 to 12	Linea alba and anterior half of Iliac crest	T7 to T12 thoracic spinal nerves and subcostal nerve	Subcostal and intercostal arteries	Compression and support of abdominal viscera. Also flexes and rotates the trunk
Internal oblique	Anterior two thirds of the Iliac crest, lateral half of the inguinal ligament and thoracolumbar fascia	Cartilage of ribs 10 to 12 and linea alba	T8 to T12 thoracic spinal nerves and illioinguinal nerves	Subcostal and intercostal arteries	
Rectus abdominis	Pubic symphysis and pubic crest	Costal cartilages of ribs 5 to 7 and xiphoid process	T7 to T12 thoracic spinal nerves	Epigastric arteries	Flexion of the trunk, stabilisation and control of pelvic tilt
Transversus abdominis	Internal surface of ribs 7 to 12 costal cartilages, Iliac crest and Inguinal ligament	Inferior border of rib 12 and L1 to L4, linea alba and pubic crest	T7 to T12 thoracic spinal nerves	Subcostal and intercostal arteries	Compression and support of abdominal viscera

SP= spinous process; TVP=transverse process; C= cervical; T=thoracic; L=lumbar
Table compiled from Drake et al. (2005), Vizniak, (2010) and Moore et al. (2014)

2.4.4 Blood supply and venous drainage of the lumbar spine

The main artery that supplies blood to the lumbar spine is the abdominal aorta which lies in close relation to the spine (Drake et al., 2005; Moore et al., 2014). The abdominal aorta gives rise to the lumbar arteries, whose anterior branch encircles the vertebra on three sides viz. anteriorly and laterally (right and left) feeding the anterior elements of the vertebra. By contrast the posterior branch feeds the posterior elements of the lumbar vertebra. These arteries occur in pairs, for each of the five lumbar vertebrae (Moore et al., 2014; Standring, 2015).

The lumbar artery positions itself to run along the middle of the vertebral body until it reaches the intervertebral foramen, at which point it gives off its branches (Moore et al., 2014; Drake et al., 2005). The most common branches are the anterior and posterior lumbar arteries, the sinuvertebral artery (supplying the dural layers) as well as the anterior and posterior spinal canal arteries which supply the anterior and posterior aspects of the vertebral canal, respectively (Bogduk and Twomey, 1987; Standring, 2015). Furthermore, these arteries give rise to the ascending and descending branches which anastomose with the spinal branches at their respective levels (Drake et al., 2005; Moore et al., 2014). Nutrient arteries supply the red marrow of the vertebral body and the larger branches of the spinal branches become the radicular or segmental medullary arteries. These supply the nerve root and spinal cord (Drake et al., 2005; Moore et al., 2014). Anteriorly, the vertebral bodies are supplied by the periosteal metaphysial and equatorial branches (Cramer and Darby, 2005).

The venous drainage of the lumbar spine runs parallel to the arterial supply, meaning there is a constant supply and drainage of oxygenated and deoxygenated blood (Cramer and Darby, 2005; Moore et al., 2014). Contained within the vertebral bodies are the basivertebral veins which drain blood into the anterior internal vertebral venous plexus (Cramer and Darby, 2005; Moore et al., 2014). In addition to this, smaller veins drain into the metaphysial and epiphyseal veins that form part of the anterior external vertebral venous plexus (Drake et al., 2005). Posteriorly, the facet joints, laminae and ligamentum flavum are principally drained by the posterior internal vertebral venous plexus and the transverse processes, the posterior aspect of the laminae and the spinous process, along with their related musculature attachments, are drained by the posterior external vertebral venous plexus (Drake et al., 2005; Cramer and Darby, 2005; Moore et al., 2014). Collectively, these two networks of veins called the internal and external vertebral venous plexi (Batson's venous plexus). They coalesce to drain into the ascending lumbar vein and into the azygous (right) / hemi-azygous (left) system or they travel to pass venous blood into the lumbar veins, which drain into the ascending inferior vena cava on its way to the heart (Drake et al., 2005; Moore et al., 2014). The only level that does not follow this pattern is L5, which drains into the median sacral vein, before draining into the

inferior vena cava (at its formation) or one of the common iliac veins (Cramer and Darby, 2005; Drake et al., 2005; Moore et al., 2014). This network of veins is an important aspect of the anatomy of the lumbar spine. They are a potential source for the spread of cancer and infection as a result of their valveless structure and ability to pass blood bi-directionally, within a venous system that responds to external and internal pressure as an indicator for path of least resistance for venous flow back to the heart (Kumar et al., 2007). Other causes of low back pain will be discussed in the next section.

2.5 THE CAUSES OF CHRONIC LOW BACK PAIN

The diagnosis of CLBP have the same limitations as acute LBP as a definitive diagnosis cannot be reached without thorough investigation (Bogduk and McGuirk, 2002). Degeneration of the disc is known to be the source of "pure" LBP (Benoist, 2003). This is due to the annulus fibrosis being susceptible to nociceptor reactivity, however, nociceptor reactivity in muscles, ligaments and facet joints also occur. This makes it difficult to arrive at a definitive diagnosis for the patient (Benoist, 2003). There have been advances in the medical field and there are now specific diagnostic methods to diagnose CLBP (Bogduk and McGuirk, 2002). A brief discussion of the causes of CLBP is presented in **Table 2.2**.

Table 2.2: Causes and description of chronic low back pain

Cause	Description and Clinical features
Ankylosing spondylitis	This is typically found in the younger population group of males. The pain is relieved by exercise and it radiates from the low back toward the thighs and buttocks
Disc herniation	Pain that originates in the low back and radiates dermatomally toward the lower extremities (neurological symptoms possible). Aggravating factors include sitting and relieving factors are standing.
Muscle strain	Generally, an ache in the low back which presents as a spasm. The pain may radiate to the thighs and buttocks.
Spinal stenosis	This type of condition is found with radiculopathy of the spine and the pain is aggravated by extension or standing up. The pain is relieved by sitting or flexion.
Spondylolysis	A common cause of back pain in the younger population. This can occur as a reaction to stress or as a result of a stress fracture to the pars interarticularis.
Spondylosis (lumbar)	Back pain that is usually worse upon waking up. The pain does get better as the day progresses but activity, especially back extension can lead to worsening of the pain.
Trauma	This is very variable and depends on the severity of the injury. Trauma may present with sensory and/or motor loss.
Vertebral compression fracture	This is found in older patients, typically with a history of osteoporosis. Patients who frequently over use corticosteroids are also at risk.

Table adapted from Bogduk and McGuirk (2002) and Patrick et al. (2014)

Low back pain may also be attributed to non-muscular (organic) causes and these should be considered when evaluating a patient presenting with LBP (Patrick et al., 2014). A list of organic causes is highlighted in **Table 2.3**.

Table 2.3: Organic causes of low back pain

Genitourinary	Gastrointestinal	Respiratory	Cardiovascular
Endometriosis	Abdominal infections	Lung cancer	Angina or Cardiac
Nephrolithiasis	Cholecystitis	Lung infections	ischemia
Ovarian cysts	Cholelithiasis		Abdominal or thoracic
Prostatitis	Diverticulitis		aneurysm
Pyelonephritis	Gastritis		Myocardial infarction
	Oesophagitis		
	Liver pathologies		
	Pancreatitis		
	Peptic ulcer		
	Spleen pathologies		

Table adapted from Morris (2006) and Patrick et al. (2014)

2.6 THE CLINICAL PRESENTATION OF MECHANICAL LOW BACK PAIN

Low back pain presents as pain within the region of the low back (Galukande et al., 2005). Chronic low back pain will present in a similar manner as LBP with the only difference being that the duration will be longer as defined (section 2.3). The presentation of LBP or CLBP can be divided into signs and symptoms. A sign is what the practitioner can gauge by the case history and physical examination (Boon et al., 2006). A symptom is the subjective presentation or experience of the patient (Boon et al., 2006). A summary of the signs and symptoms is tabulated in **Table 2.4**.

Table 2.4: The clinical presentation of mechanical low back pain

Signs	Symptoms
Muscular pain upon palpation of the muscles	Pain whilst doing back extension, flexion or lateral flexion
Pain elicited during the straight leg raise test	Pain after prolonged standing or sitting
Pain whilst palpating the spinous processes	Pain while driving for long distances
	Pain while coughing or sneezing
	Pain while getting up from a chair
	Pain that wakes a person up from their sleep or even sitting
	Pain while doing repetitive bending or walking for 50m or more
	Stabbing, constant LBP
	Stiffness or pain after resting or upon awakening
	Pain that gets worse as the day progresses

Table adapted from Walker and Williamson (2009)

2.7 RED AND YELLOW FLAGS ASSOCIATED WITH LOW BACK PAIN

Red flags are associated with a serious underlying pathology and should not be ignored by the practitioner (Farabaugh et al., 2010). The patient should immediately be carefully and thoroughly evaluated and referred for further investigations such as blood tests and other laboratory testing, imaging or referral to a specialist medical provider (Ferri, 2017; Patrick et al., 2014). A list of the red flags for LBP is presented in **Table 2.5.**

Table 2.5: A summary of red flags in patients who present with low back pain

- A history of malignancy
- Age, greater than 50 years especially
- Bacterial infection, particularly that of the urinary tract or skin
- Cauda equina syndrome
- Chronic use of corticosteroids
- Constitutional symptoms which includes unexplained weight loss, pyrexia, night sweats, fatigue, decreased appetite and chills
- History of drug use, particularly intravenously
- Neurological disorders which get worse over time
- Pain that gets worse with rest or wakes a patient up from their sleep
- Patients who are immunosuppressed
- Trauma to the low back region
- Unresponsiveness to initial therapy

Table adapted from Patrick et al. (2014); Farabaugh et al. (2010)

Yellow flags are those risk factors that increase the likelihood of an episode of LBP becoming chronic. These flags include, but are not limited to:

- Family problems that increase stress or suffers as a result of the limitations that the LBP brings to bear (Nielens et al., 2006; van Tulder et al., 2006).
- Fear avoidance behavior (where patients avoid exercise, activity and other recommendations that would assist in decreasing their pain) (Airaksinen et al., 2006; Nielens et al., 2006; van Tulder et al., 2006).
- High job stress, poor job satisfaction or both (Airaksinen et al., 2006; Nielens et al., 2006; van Tulder et al., 2006).
- High pain severity or increasing progressive pain severity (Nielens et al., 2006).
- Inappropriate beliefs about pain, its causes, its impact on life and the manner in which it can be addressed (Australian Acute Musculoskeletal Pain Guidelines Group, 2003; Airaksinen et al., 2006; Nielens et al., 2006; van Tulder et al., 2006).
- Pathological changes and/or neurological involvement impacting on the patient's ability to perform activities of daily living (The Norwegian Back Pain Network, 2002; Nielens et al., 2006).

- Prior episodes of LBP or recurrent episodes of LBP (Accident Compensation Corporation, 1997; Nielens et al., 2006).
- Psychological and emotional stability as a result of the pain or the limitations that it imposes (Australian Acute Musculoskeletal Pain Guidelines Group, 2003; Airaksinen et al., 2006; Nielens et al., 2006; van Tulder et al., 2006).
- Third party pay, injury on duty or other compensation claims related to the patients LBP (Airaksinen et al., 2006; Nielens et al., 2006; van Tulder et al., 2006).
- Unrealistic prognostic and/or treatment expectations (Australian Acute Musculoskeletal Pain Guidelines Group, 2003; Nielens et al., 2006; van Tulder et al., 2006).

2.8 THE TREATMENT OF CHRONIC LOW BACK PAIN

The treatment of CLBP remains extensive (Airaksinen et al., 2006), however, CLBP is a problem of such magnitude that simple treatment guidelines cannot be accepted universally (Bogduk and McGuirk, 2002; Airaksinen et al., 2006; Negrini et al., 2006; NICE, 2009). This also concurs with Patrick et al. (2014) who mentioned that despite the many available treatment options and the advances made in modern medicine, treatment of CLBP remains limited due to the failure of the practitioner to identify and then specify the exact cause of the pain and proceed with the development of an appropriate treatment protocol. Patrick et al. (2014) stated that improvement of functionality of the patient and decreasing the symptoms would be of greater benefit instead of focusing on a “cure” for CLBP. A classification and discussion of the various treatment options for CLBP will follow.

2.8.1 Surgery

With the remarkable advances made in evidence-based medicine, surgery is considered the last option for the treatment of CLBP. Historically, if conservative treatment did not work then surgery was regarded as an option (Bogduk and McGuirk, 2002). Patrick et al. (2014) stated that surgery may be of benefit to CLBP patients to alleviate their symptoms. This, however, cannot be determined as no criteria exist and no approach can determine which patient will benefit from surgery and who will not.

Fusion surgery is a common form of spinal surgery wherein one or more vertebrae are fused with each other to alleviate pain. The rationale as described by Bogduk and McGuirk (2002) is that movement aggravates pain, so by fusing the vertebra, the pain would be alleviated. Other therapies within the surgical realm include but are not limited to spinal injections (epidural, nerve block, sympathetic block, facetal and sacroiliac injections), intrathecal infusion therapy,

intrathecal pumps (with their agents), epidural neuroplasty, subarachnoid or epidural neurolysis, spinal cord stimulation or discal surgery (including intradiscal electro-thermo-nucleoplasty therapy, chemonecleolysis or nuceloplasty). Lastly, vertebroplasty may also be considered (Haldeman, 2005; Morris, 2006; Dagenais and Haldeman, 2012).

2.8.2 Medication

This can be regarded as an option especially in CLBP patients (Dagenais and Haldeman, 2012). Recommendations for medication use, according to known guidelines, have been summarised in **Table 2.6**.

Table 2.6: A summary of recommended medication use in patients with low back pain

Study	Acetaminophen	Muscle relaxants	NSAIDs	Opioid analgesics
The Norwegian Back Pain Network (2002)	Yes	Yes	Yes	Yes
Australian Acute Musculoskeletal Pain Guidelines Group (2003)	Yes	Yes	Yes	Yes
Negrini et al. (2006)	Yes	Yes	Yes	Yes
van Tulder et al. (2006)	Yes	No	Yes	No comment
Chou et al. (2007)	Yes	Yes	Yes	Yes
Dagenais et al. (2010)	No	No	No	No

Adapted from Dyer (2012)

The pitfalls regarding medication involve side effects and dependence (Bogduk and McGuirk, 2002; Dagenais and Haldeman, 2012; Deyo et al., 2015). According to Bogduk and McGuirk, (2002), analgesics and non-steroidal anti-inflammatory drugs (NSAIDS) beyond six weeks is largely unknown owing to the fact that no long-term studies have been done (Dagenais and Haldeman, 2012). According to the World Health Organisation (2000), it is recommended that simple analgesics and NSAIDs be used; thereafter, opioid analgesics may be used if analgesics and NSAIDs fail to provide relief.

2.8.3 Rest

This is essentially bed rest, which means the patient should remain inactive until they recover, however, this has been shown to be partially harmful and may even be of detriment to the patient (Hagen et al., 2000). It is known that rest leads to muscle, ligament and bone changes which make healing time slower (Hagen et al., 2000). There is a type of rest that has been shown to have a positive effect on patient recovery, this is referred to as “active rest” (Hyde and Gengenbach, 2007). Active rest is defined as doing a very light form of exercise which

does not increase the heart rate but rather serves to improve recovery i.e. it is a less intensive form of exercise (Hagen et al., 2000; Hyde and Gengenbach, 2007).

2.8.4 Therapeutic exercise and rehabilitation

Therapeutic exercise essentially means exercise that is performed for the treatment of a specific condition as opposed to recreational purposes (Morris, 2006; Liebenson, 2007; Dagenais and Haldeman, 2012). Therapeutic exercise in CLBP focuses on strengthening the lumbar spine in order to maintain stability (Dagenais and Haldeman, 2012; Hyde and Gengenbach, 2007).

A study conducted by Hayden et al. (2005), which looked at specific exercises to reduce CLBP, found that if the elements of stretching and strengthening are considered in designing a programme, it may be of benefit to CLBP patients, an example of this being the McKenzie extension exercises (Long et al., 2008). Exercise also has its limitations, as a patient in pain will be limited in terms of movement. This overrides the ability for that patient to perform their exercises properly. This has been demonstrated in a systematic review by Chou (2010) which showed that there was an exacerbation of symptoms and soreness in 25% of the individuals who participated in the study. This reported reaction could be associated with a natural process after prolonged inactivity or first time exercise participants (Chou, 2010). However, it may also represent fear avoidance behaviour where individuals are unwilling to do exercises for fear of pain (Nicholas et al., 2011).

2.8.5 Soft tissue techniques

Massage is a common treatment modality used in patients with CLBP. Massage is defined as “manipulation of the soft tissue by a practitioner or therapist using their hands or a device” (Furlan et al., 2002). Some massage techniques have reduced pain, possibly due to the mechanoreceptors, which perceive this as pain relief (Furlan et al., 2002). In a systematic review by Furlan et al. (2002), it was concluded that massage might be of benefit in patients with CLBP. Van Middelkoop et al., (2011) disagrees with this by stating that there is no statistical evidence to prove that massage therapy benefited pain intensity when compared to other passive interventions. According to Chou (2010), in his systematic review, massage may be of benefit to CLBP patients in the short-term.

2.8.6 Joint techniques

There are two types of joint techniques commonly associated with chiropractors (Bergmann and Peterson, 2011) viz. Spinal manipulation and Spinal mobilisation.

Spinal manipulation is a common technique used by chiropractors to treat CLBP (Bogduk and McGuirk, 2002; Dagenais and Haldeman, 2012). Spinal manipulation is typically defined as a high velocity, low amplitude thrust that is applied to extend the joint beyond the passive range of motion limit into the paraphysiological space (Grade V application) (Bergmann and Peterson, 2011; Byfield, 2011). Spinal mobilisation (Grade I – IV application) involves applying a manual force to the joints within its passive range of motion and does not involve a thrust (Bergmann and Peterson, 2011; Byfield, 2011; Dagenais and Haldeman, 2012). This results in “gapping” of the joints (Haldeman, 2005; Bergmann and Peterson, 2011). The benefits of spinal manipulation are decreased muscle spasm with concomitant increased range of motion, increased mechanical stimulation with a resultant reduction of pain, reduction in swelling/oedema and removal of adhesion formation (Leach, 2004; Bergmann and Peterson, 2011; Bronfort et al., 2004; Byfield, 2011).

Although a common treatment option, there are cases wherein spinal manipulation is contra-indicated and other forms of therapy have to be employed (Dagenais and Haldeman, 2012; Globe et al., 2016). Contraindications are of two types viz. absolute - whereby no manipulation can be done due to an underlying problem, and relative - whereby manipulation can be modified to prevent a risk of injury (Bergmann and Peterson, 2011). These contraindications are presented but are not limited to those seen in **Table 2.7** (Bergmann and Peterson, 2011; Byfield, 2011; Farabaugh, 2010).

Table 2.7: A summary of absolute and relative contra-indications in patients who present with low back pain and are considered for manipulative therapy

Category	Absolute	Relative
Articular	Articular instability Infectious arthritis	Anticoagulant therapy Osteoarthritis Inflammatory arthritis Ankylosing spondylitis Spondylolisthesis Joint instability or hypermobility
Bone weakening disorders	Bone tumors	Osteomyelitis Osteoporosis Osteomalacia Bone infections (tuberculosis)
Neurologic	Cauda equina syndrome Progressive neurological disorders Extensive prolapse with neurologic deficit	Severe nerve root compression Vertigo Severe pain/intolerance Space occupying lesion Neuropathies associated with systemic disease
Physiological		Pregnancy Severe functional or structural scoliosis
Psychological		Malingering Hysteria Hypochondriac
Trauma	Disc prolapse with neurologic deficit Fracture - vertebral Dislocation	Severe sprains Severe strains
Vascular	Vertebrobbasilar insuffiency syndrome	Atherosclerosis

Adapted from Haldeman (2005); Bergmann and Peterson (2011); Byfield (2011)

2.8.7 Therapeutic modalities

Therapeutic modalities are viable alternatives in achieving pain control in patients with CLBP and comprise machines and instruments that utilise electricity to achieve this (Alves-Guerreiro et al., 2001). This is particularly advantageous as they are non-invasive (Watson, 2008). These include transcutaneous electrical nerve stimulation (TENS), electrical muscle stimulation

(EMS) and interferential current (IFC) (Watson, 2008, Alves-Guerreiro et al., 2001). A brief explanation of how each of these modalities are used in the treatment of CLBP follows.

2.8.7.1 Galvanic (Direct) and Faradic (Alternating) Current

Galvanic current also known as direct current occurs by passing current through an electrolyte solution (Watson, 2008; Singh, 2012). These electrolytes partially split to form positive and negative ions which in turn act on tissue to produce a chemical reaction (Watson, 2008; Singh, 2012). Galvanic current produces a high voltage, low amplitude current that is thought to alleviate pain and promote wound healing.

Faradic current, otherwise known as alternating current, is a high frequency current that does not use poles (like the IFC). Its action on tissue results in heat formation (Watson, 2008; Singh, 2012). The intact nerve is stimulated by changing the permeability of the cell membrane. In doing so, the muscles are able to contract when the cell membrane reaches an excitatory level (Watson, 2008; Singh, 2012).

2.8.7.2 Transcutaneous electrical nerve stimulation

Transcutaneous electrical nerve stimulation (TENS) is usually applied through the application of TENS units. These are small, portable devices that are battery operated, with four pads attached to electrodes connected to the units (Blincoe, 2007). The handheld controls are then used to apply a mild electrical stimulation through specific frequencies and intensities; this being low to moderate frequency and high intensity for CLBP (Poitras and Brosseau, 2008; Watson, 2008). This application is thought to stimulate the production and release of natural endorphins and enkephalins, which have an analgesic effect (Blincoe, 2007).

TENS produces differing literature results in terms of the treatment of LBP (Beurskens et al., 1995; Van Tulder et al., 1997). The clinical practice guidelines from Belgium (Nielens et al., 2006), Italy (Negrini et al., 2006), Europe (Airaksinen et al., 2006) the USA (Chou et al., 2007) and the United Kingdom (NICE, 2009), indicate limited evidence for its use (Dagenais and Haldeman, 2012) particularly for CLBP.

2.8.7.3 Electrical Muscle Stimulation

Electrical muscle stimulation (EMS) is a form of electrical stimulation that is often used at high intensities to produce muscle contraction. It does this by mimicking the action potential coming from the central nervous system. According to Durmus et al. (2009), in contrast to

TENS, EMS seems to show some positive benefit for patients suffering from LBP.

The limitation of TENS and EMS is that they cover a relatively small area of the low back; resulting in the modalities needing to be moved around the low back region, which can become tiresome for the therapist in a practice setting, which is unlike IFC, which is discussed next.

2.9 INTERFERENTIAL CURRENT

Interferential current (IFC) is superior to the above-mentioned modalities (TENS and EMS) because IFC covers a broad aspect of the low back at once. Therefore, IFC is a commonly used modality by physiotherapists and chiropractors, however, little information is known regarding its clinical use (Watson, 2008; Dagenais and Haldeman, 2012).

Historically, IFC was developed by Dr Hans Nemec in the 1950s who sought to develop a way to pass electrical stimulation to the musculature without encountering discomfort on the skin. The resistance of the skin did not permit the current to pass through it because low frequency currents were being used. This meant that the layers deep to the skin could not be stimulated including the musculature (Ganne, 1976). Skin impedance to electrical stimulation is inversely proportional to the frequency of the current, which is represented in the following equation (Kitchen and Bazin, 1996; Singh, 2012):

$$Z = \tfrac{1}{2}fC$$

Where: Z = skin resistance
f = current frequency
C = skin capacitance

The advent of medium frequency currents was seen as a breakthrough as it passed through the skin to the deeper lying tissue offering very little skin resistance. This application now excluded patient discomfort, which resulted in it becoming a widely used modality for pain relief (Kitchen and Bazin, 1996).

Interferential current has no set duration, and according to Watson (2008), the reason for the accepted duration is based on time constraints in the working environment and anecdotal evidence from clinicians. Moreover, the time durations of IFC have no theoretical basis and this literature review aims to discuss IFC, as it was the focus of this study.

2.9.1 The definition of interferential current

There is no standardised definition of IFC although Watson (2008) has described it as the "transcutaneous application of medium-frequency alternating currents, the amplitude of which is modulated at low frequency for therapeutic purposes."

2.9.2 The mechanism of action of interferential current

The reason for the use of the IFC over TENS is to deliver currents with a kilohertz cycle duration, that overcomes the impedance of the skin (Johnson and Tabasam, 2003a; 2003b), which the TENS is not able to achieve. The arguments in the literature, however, suggest that kilohertz currents do not stimulate nerve endings appropriately or sufficiently. As a result two out of phase kilohertz currents are utilised in order to produce an interference wave in the deep tissues (**Figure 2.1**). This is thought to better stimulate nerve fibres due to the resultant carrier frequency and wave forms that are produced (Alves-Guerreiro et al., 2001; Johnson and Tabasam, 2003a, 2003b).

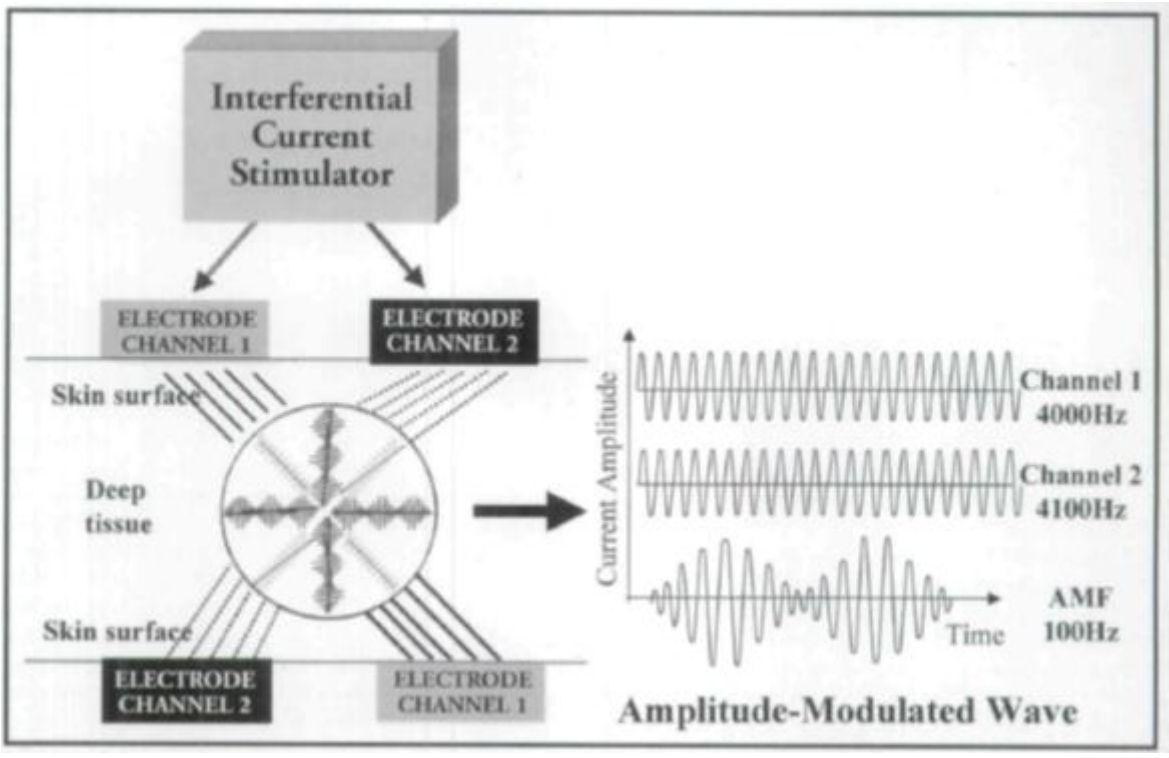

Figure 2.1: Illustration of how wave currents are formed in interferential current
Source: Johnson and Tabasam, (2003b)

This interference wave, according to McManus et al. (2006), has been theorised to be a medium pulsed frequency at 100Hz which stimulates the afferent Aδ nerve fibres and C fibres. Alves-Guerreiro et al. (2001), showed in their study that the IFC group produced significant

differences to their APS and TENS groups, in terms of their peak-to-peak amplitude data, suggesting that the IFC stimulates and "recruits" a larger number of smaller diameter nerve fibres. These fibres stimulate the periaqueductal grey matter, rostral ventral medulla (raphe nuclei), the reticular nuclei and spinal dorsal horn (Noble et al., 2000a, 2000b, 2001). This recruitment of nerve fibres increases the activity in descending fibres from the pain suppression system thereby releasing inhibitory neurotransmitters at the level of the spine (McManus et al., 2006; Noble et al., 2000a, 2000b, 2001); this information then travels down the anterolateral spinothalamic tract to induce an effect (Noble et al., 2000a, 2000b, 2001). The effect of this stimulation is, however, limited to central modulation of pain. The study by Alves-Guerreiro et al. (2001) indicated that there was a limited effect of the intervention (IFC) on changing the recorded negative peak latency (a decrease in the nerve conduction velocity and thus an increase in the manual pressure threshold (algometry)) when testing the peripheral effects of the intervention. This latter system would be related to stimulation of the larger diameter fibres (Aβ) (Noble et al., 2000a, 2000b, 2001).

The theory above differs with another proposed mechanism through which IFC works i.e. the Gate Control Theory of pain pathways and the mediation of pain (Melzack and Wall, 1965; Goats, 1990; Apkarian et al., 2009). Interferential current is thought to be able to stimulate the larger diameter sensory nerve fibres which in turn activates a closure of the gate to pain fibres, limiting their ability to transmit pain "sensation" to the central nervous system (Noble et al., 2000a, 2000b, 2001). This, in turn, causes the release of endogenous opiates (endorphins and enkaphalins) (Forster and Palastanga, 1985; Goats, 1990; Apkarian et al., 2009). This occurs as a result of the sensory nerves being stimulated which in turn inhibits stimulation of the afferent Aδ nerve fibres and C fibres thereby closing the gate to nociception. It is unclear according to the literature whether the Gate Control Theory effects are related to the beat frequency or the carrier frequency (Noble et al., 2000a, 2000b, 2001).

Another theory is that of a "physiological block" that is induced by frequencies above 50Hz, impeding the ability of peripheral C fibres to be able to conduct impulses, thus affecting the ability of the peripheral nerve to conduct pain "sensations" along its length. This effect usually only appears after an initial burst of activity, once the IFC intervention has been applied fully (Noble et al., 2000a, 2000b, 2001). This seems to concur with the Gate Control Theory with the exception that this theory espouses a peripheral block of the C fibres and not a central block of the pain pathways.

Thus, IFC, although able to achieve pain control and analgesia, does not have a mechanism of action that is fully understood (Watson 2008; Venancio et al., 2013).

In addition to the neurological theories surrounding pain control with IFC use, McManus et al. (2006) also suggest that the physiological block of nerve fibres has a depressive effect on Aδ and C fibre activity (Watson, 2008). This results in the sympathetic nerve fibres innervating the muscular walls of small arterioles of the body to decrease their tone resulting in an increase in blood flow. This in turn reduces swelling, increases flushing of oedema and pain producing substances that would otherwise stimulate the nociceptive nerve endings (Noble et al., 2000a, 2000b, 2001; McManus et al., 2006; Watson, 2008) thus speeding up healing and repair (McManus et al., 2006).

From the above, the following physiological properties of IFC become evident (Watson, 2008):

- Limited peripheral analgesia
- Central analgesia
- Increases blood flow
- Reduces swelling and the presence of pain mediators
- Reduces muscle contractions
- Promotes tissue healing

2.9.3 The advantages of interferential current

In terms of IFC as a modality, it is applied transcutaneously, making it a non-invasive modality that significantly reduces the side effects (e.g. adverse reactions to medication) compared to invasive treatment methods. Another advantage is that IFC is applied to a specific area, thereby, isolating treatment to the affected area (Singh, 2012; Watson, 2015).

Singh (2012) concurs with Noble et al. (2000a, 2000b, 2001) by suggesting that IFC does not produce sensory nerve irritation, regardless of amplitude, due to the physiological block it creates. Therefore, it does not produce an unwanted burning sensation over the skin.

Unlike TENS, IFC is better suited for treating layers deep to the skin including the muscles, nerves and tendons (Beatti et al., 2011) making it the treatment of choice. This depth penetration does not result in increased discomfort to the patient (e.g. those produced by low frequency currents) (Watson, 2015).

Although some adverse consequences to the use of the IFC have been reported, these are preventable through appropriate application of the IFC unit and appropriate application of aseptic principles in most cases (Watson, 2008). Those physiological adverse reactions that are not related to application of the unit or aseptic principles and occur as a result of the treatment being mainly transient resolve within relatively short periods of time. Adverse

reactions or effects can include general malaise, vomiting, nausea, dizziness or fainting and/or the presentation of mild headaches (Watson, 2015). These latter effects are also the reason that patients are often asked to be appropriately hydrated before, during and after the treatment session (Casale et al., 2012; Watson, 2015).

2.9.4 Contra-indications to interferential current

Contra-indications (CI) to IFC result in the patient not being able to receive IFC. This is because IFC can cause considerable damage to the patient or worsen their condition. **Table 2.8** lists the CI for IFC.

Table 2.8: Contra-indications to interferential current

General / Systemic	Local
• Blood disorders (predisposed to thrombus formation, blood dyscrasias) • Cancer patients • Centrally mediated neurological conditions (e.g. Parkinsonism, multiple sclerosis) • Epilepsy or any neuropathies (e.g. diabetic patients) • Hyperpyrexia • Hypertensive patients or patients with heart disease (not over the chest wall) • Incoherent or mentally impaired patients • Medication (e.g. heparin, warfarin) • Mental impairment • Pacemakers or metal implants	• Skin abnormalities that prevent electrode placement • Open wounds or/ infection spread • Metals or rods at site of IFC placement • Hypersensitive skin • Loss of skin sensation (anaesthesia) • Pregnancy

IFC= interferential current

Adapted from Vizniak (2007); Watson (2008); Singh (2012)

In addition to the above, the practitioner is required to know the appropriate and correct application of IFC otherwise it is considered a contraindication for application. If there is a possibility that the patient has withheld information or the clinical picture does not fully support the use of IFC and its safety is questioned, then these are also regarded as contraindications (Airaksinen et al., 2006; Casale et al., 2012).

2.9.5 The placement of interferential current electrodes

The literature on IFC shows consensus and standardisation regarding the placement of the IFC pads in a crossover manner to achieve the beat frequency for patients with LBP as is depicted in **Figure 2.2** (Watson, 2008; Johnson and Tabasam, 2003b; Hurley et al., 2001).

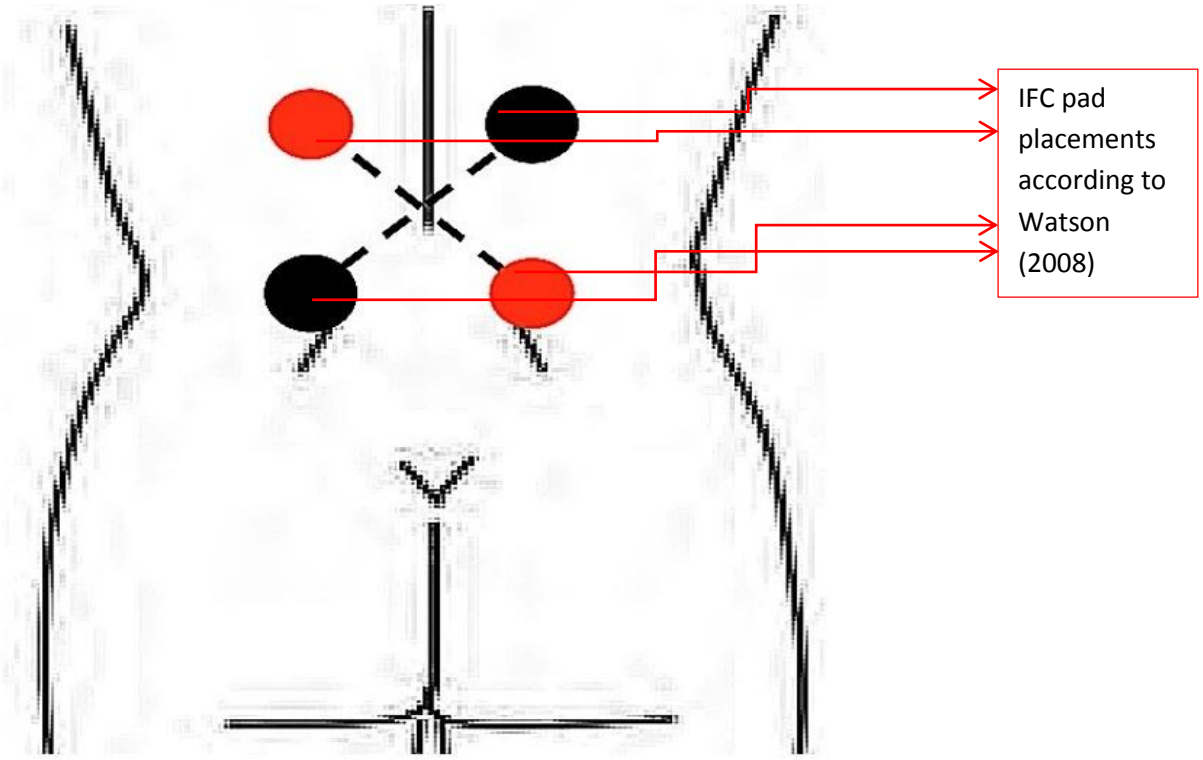

Figure 2.2 Crossover placement of IFC pads

Source: https://www.win-health.com/nexwave-interferential.html

From the electrode placement, it can be seen that IFC current is generated by simultaneously applying two medium frequency currents through two pairs of electrodes. These electrodes are modulated at slightly different frequencies which are thought to “interfere” with each other (Kitchen and Bazin, 1996; Watson, 2008). One electrode pair is set at a frequency e.g. 4000Hz and the second pair is set at an adjustable frequency e.g. 4000 – 4200Hz.

These electrode pairs are placed to ensure the currents are crossed over each other and thus allowed to “interfere” with each other. Since the currents differ slightly in their frequencies, the amplitude of the wave that forms will either increase or decrease in a regular cycle. This is known as “amplitude modulation” (Singh, 2012). The cancelling effect of the two frequencies of current that cross over is known as the amplitude-modulated frequency (AMF) or “beat frequency” (Kitchen and Bazin 1996; Watson, 2008).

The AMF can also be altered over time, which is known as the frequency sweep. The settings can be varied between two AMFs and the pattern of how the frequency changes can also be pre-set. This effectively prevents the patient from accommodating to the IFC whilst it is being used on the patient (Watson 2008; Singh, 2012).

2.9.6 Clinical Application of Interferential Current for the treatment of low back pain

The evidence of studies on IFC and CLBP seem to suggest that IFC does have physiological effects when applied, however, the literature shows no consensus on the treatment parameters for CLBP (Airaksinen et al., 2006). Studies therefore, remain ambivalent toward treatment time and frequency, which has not been established (Hurley et al., 2001; Johnson and Tabasam, 2003a, 2003b; Watson, 2008). This can obscure the research results obtained, as there is no gold standard (Mouton, 2006) and may explain why IFC has been shown to be effective in some studies and ineffective in others. A summary of the literature for IFC in treating CLBP is presented in **Table 2.9.**

Table 2.9: A summary of randomised clinical trials on interferential current and chronic low back pain

Reference	Aim of study	Number of participants	Intervention	Outcome measures	Summary of results
Werners et al. (1999)	To compare IFC with motorised lumbar traction and massage to treat CLBP	152 participants with 20 dropping out at the three month follow-up	Group One: n = 74 received IFC with electrodes placed paravertebrally. Group Two: n = 73 received traction and massage. Each group received six 10 minute sessions over a two to three week period.	OLBQ and VAS at baseline, end of treatment and at three months follow-up.	Both groups improved significantly ($p < 0.05$), but there were no intragroup improvements.
Adedoyin et al. (2005)	To determine the effect of three different swing patterns in CLBP	39 participants with CLBP	Group One: n = 13 with three 1ʃ1* IFC treatments. Group Two: n = 13 with three 6ʃ6* IFC treatments. Group Three: n = 13 with three 6^6* IFC treatments. Group Four: n= 13 with three burst IFC treatments. Each group received 20 minutes of IFC two times daily twice a week over a three week period.	Verbal semantic differential scale.	Significant decrease in pain over time ($p < 0.01$), however, no significance was noted between the groups
Zambito et al. (2006)	Comparison of IFC to HT in CLBP due to DJD or previous vertebral fractures	26 males and 94 females were randomly assigned into one of three groups	Group One: n = 45 received IFC. Group Two: n = 45 received HT. Group Three: n = 30 received Sham HT. Each group received five treatment sessions of 10 minutes each over two weeks.	Backhill questionnaire, VAS and analgesic consumption at baseline. At the end of two weeks, and at a three month follow-up.	Significant improvements noted in all three groups at two weeks from the Backhill, VAS and analgesic intake ($p < 0.05$). At three month follow-up, improvements noted in the VAS and Backhill questionnaire compared to the sham group ($p < 0.01$)

*These parameters refer to differing sweep frequencies between the groups.

Zambito et al. (2007)	Comparison of IFC to HT in CLBP due to multiple vertebral fractures	115 females who had CLBP	Group One: n = 35 received IFC. Group Two: n = 35 received HT. Group Three: n = 30 participants received Sham HT. Each group received five treatment sessions of 30 minutes each over two weeks.	Backhill questionnaire, VAS and analgesic consumption at baseline. At the end of the two weeks and at a three month follow-up.	Significant improvements in the VAS and Backhill scores ($p < 0.01$). Significant improvements at the sixth and fourteenth week when compared to the sham group ($p < 0.01$).
Facci et al. (2011)	To establish the effect of IFC and TENS in CLBP	150 participants randomly allocated into three groups	Group One: n = 50 TENS. Group Two: n = 50 IFC. Group Three: n = 50 Control. Treatment groups received 10 treatments of 30 minutes over two weeks.	VAS, RMDQ, McGill pain questionnaire and use of medication at baseline and at the end of treatment.	No statistical significance between TENS and IFC ($p > 0.05$).
Lara-Palomo et al. (2012)	The short-term effect of IFC combined with massage on participants with non-specific CLBP	62 participants with non-specific CLBP	Group One: n = 32 with IFC and electro massage. One follow-up drop out in the experimental group. Group Two: n = 32 with electro-massage only. All groups received treatment for 30 minutes each for two times a week over 10 weeks.	OLBQ, VAS and RMDQ. All tests were done at baseline and at the end of the study after treatment.	Significant improvements were noted in the experimental group when compared to the control group.
Fuentes et al. (2014)	To establish whether TA between the therapist and the patient has any effect on CLBP patients	117 participants with CLBP randomly allocated into four groups	Group One: n = 30, IFC with limited TA. Group Two: n = 29, Sham IFC with limited TA. Group Three: n = 29, IFC with enhanced TA. Group Four: n = 29, Sham IFC with enhanced TA. Each group received a single treatment of IFC for 30 minutes each.	Baseline: NRS-101, algometer, assessment of expectations Post treatment: NRS-101, therapeutic alliance	Significant improvement in the TA group.

Grabiańska et al. (2015)	Comparison of IFC and TENS	60 patients divided into two groups	Group One IFC. Group Two TENS. Ten 20 minute sessions of either IFC or TENS were applied.	VAS and Latinen scale were done at baseline and post-treatment.	No statistical significance between TENS and IFC (p > 0.05).
Corrêa et al. (2016)	To test the carrier frequency of IFC in CLBP	150 participants randomly allocated into three groups	Group One: n = 50 received 1kHz IFC. Group Two: n = 50 received 4 kHz IFC. Group Three: n = 50 Control. 12 treatment sessions of 30 minutes IFC or sham over four weeks.	Primary outcomes: NRS-101 at baseline, after 30 minutes while the current was still switched on and 20 minutes after the current was switched off at each session. Further measurements took place after four months. Secondary outcomes: Algometer before IFC was applied, after 30 minutes and 20 minutes after IFC. Measurements were done at the first and last sessions. RMDQ was given at the first and last treatment and four months after.	There was a significant reduction of pain in the first session amongst the active groups.
Albornoz-Cabello et al. (2016)	Assessment of the short-term effects of trans-regional IFC on pain perception and disability in CLBP	64 participants, randomly distributed into a control or experimental group	Group One: n = 44 trans-regional IFC administered to the experimental group. Group Two: n = 20 Control group received massage, mobilisation and soft tissue treatment. Ten 25 minute treatments over a two week period.	VAS and OLBQ at baseline and end of treatment	Experimental group had improved significantly on VAS (p = 0.032) and OLBQ (p = 0.002).

IFC=interferential current; CLBP=chronic low back pain; VAS=visual analogue scale; OLBQ=Oswestry low back questionnaire; HT=horizontal therapy; DJD=degenerative joint disease; TENS-transcutaneous electrical stimulation; RMDQ=Roland-Morris disability questionnaire; TA=therapeutic alliance; NRS-101=numerical pain rating scale.

The available evidence of IFC on CLBP seems to suggest that there is ambiguity regarding the frequency. A study conducted on healthy participants who had cold induced pain treated with IFC, found the optimum frequency setting to be 1kHz when compared with frequencies of 2kHz, 4kHz, 8kHz and 10kHz (Venancio et al., 2013). In the 1kHz group, it was observed that the hypoalgesic effects of IFC were most effective after 20 minutes of treatment (Venancio et al., 2013). The study also observed that applying IFC for less than ten minutes resulted in a lowered hypoalgesic effect (Venancio et al., 2013). This concurs with Noble et al. (2000a, 2000b, 2001), who suggested that the peripheral physiological block may first cause irritation before causing a peripheral physiological block to nerve conduction in addition to the slightly longer time period required for the central modulation of pain also blocking the perception of pain (Noble et al., 2000a, 2000b, 2001). The study by Venancio et al., (2013) was limited for the purposes of determining IFC placement, frequency and optimum time interval as the treatment was on healthy patients who had pain induced on the forearm. One could argue that the penetration of the low back and forearm varies in depth and the anatomical structures are markedly different (Beatti et al., 2011).

In the study by Corrêa et al. (2016), the setting of 1kHz was utilised for patients with LBP (**Table 2.9**). This study found no change after the first treatment between the active and placebo group. However, the 1kHz group had a greater reduction in temporal summation (Corrêa et al., 2016). In addition, studies conducted on patients with LBP by Werners et al. (1999), Adedoyin et al. (2005), Facci et al. (2011), Lara-Palomo et al. (2012), Fuentes et al. (2014) and Albornoz-Cabello et al. (2016) (**Table 2.9**) all used a carrier frequency of 4kHz. Zambito et al., (2006 and 2007) did not state what carrier frequencies were used in their studies.

The duration of IFC application differs in the studies reported. Anecdotal evidence points toward the treatment time being between 10 and 15 minutes (but not longer than 20 minutes) (Watson, 2008). Watson (2008) went on to state that there is no theoretical basis for these times and these are limited due to time constraints in practice as opposed to scientific evidence. It should also be noted that IFC machines in the past were large and bulky, however, IFC units are now compact and can be easily transported (Watson, 2008) thus potentially negating the argument of clinical practice constraints.

With respect to CLBP, Werners et al. (1999) and Zambito et al. (2006) applied IFC for a duration of 10 minutes (**Table 2.9**). This is in contrast to Zambito et al. (2007), Facci et al. (2011), Lara-Palomo et al. (2012), Fuentes et al. (2014) and Corrêa et al. (2016) who applied IFC for 30 minutes at each session (**Table 2.9**). Irrespective of the time intervals utilised in these studies, it would seem that they all achieved a significant level of reported pain or

measured pain outcomes. One limitation is that half of the studies have relatively low sample sizes (**Table 2.9**) and several did not have appropriately homogenous treatment groups (wide inclusion criteria); thereby not allowing for optimal statistical analyses of the data and appropriate comparisons. Therefore, there is no indication from this literature that any particular time is optimal for CLBP. This may be related to muscle fatigue, which IFC may reduce (Youn et al., 2016). Youn et al. (2016) used 15 healthy participants to measure the optimum treatment time of IFC in producing induced muscle fatigue. They concluded that treatment time is dependent on the condition of the muscle, thus a standard treatment time is not available as the time should be tailored to the patient and their condition. This latter assertion is also limited by the small sample size of 15 healthy participants. Another possible reason for the similar outcomes at different time intervals may be the congruence between the outcome measures utilised and the point at which these measurements are applied. This is related to the proposed mechanisms by which IFC may induce hypoalgesia (Noble et al., 2000a, 2000b, 2001) through: Central modulation, Peripheral modulation, Physiological Block, Improved circulation with a decrease in the pain mediating substances.

The inducement of hypoalgesia may indicate that patients improved or did not because of a mismatch between the proposed mechanism of IFC and the time the measurement tool was applied. For example, a measurement applied at the 10 minute interval would most likely need to be able to measure changes in physiological blocks i.e. nerve conduction (Noble et al., 2000a, 2000b, 2001). A measurement applied at the 30 minute interval, however, may be required to measure the release of endorphins and enkephalins as result of the central modulation of pain (Noble et al., 2000a, 2000b, 2001). Mismatching the measurement to the time interval may result in the possibility of patients not improving when in fact the measurement tool is not sensitive enough or appropriate to measure the change.

Further research is thus needed to investigate the optimum carrier frequency. Treatment combined with different application times (duration) of IFC along with stricter inclusion criteria in order to begin determining clinical predication rules for the application of IFC in different patient population and clinical presentation groups. This has been done for some subgroups of patients with LBP and the application of manipulation (Flynn et al., 2002). This can only be achieved by consciously considering the appropriate patients, measurement tools and ensuring that they are congruent with the treatment duration and measurement interval.

2.9.7 Clinical measurement of interferential current treatment success

2.9.7.1 Visual Analogue Scale / Numerical Pain Rating Scale-101 / Verbal Semantic Differential Scale

As discussed, IFC is able to reduce pain and Fuentes et al. (2014) and Corrêa et al. (2016) who used the NRS-101 as a subjective measurement of pain (Table 2.9) support this. This is not dissimilar to the other studies (Werners et al. 1999; Zambito et al. 2006; Zambito et al. 2007; Facci et al. 2011; Lara-Palomo et al. 2012; Grabiańska et al. 2015; Albornoz-Cabello et al. 2016) reported in **Table 2.9** who utilised the VAS and found improvement.

Jensen et al. (1986) found the NRS-101 to be the best form of pain measurement in terms of responsiveness to change, ease of administration and sensitivity. The VAS has been criticised due to it being sometimes difficult to understand and is further problematic in participants who are illiterate or have cognitive inabilities. The VAS can also pose a problem for older individuals who have difficulty in comprehending due to mental impairments (Mannion et al., 2007). The verbal semantic differential scale was utilised by Adedoyin et al., (2005). It was described wherein the participant was asked to map out their pain in terms of duration and severity on a 10 point scale.

2.9.7.2 Disability – Roland-Morris disability questionnaire / Oswestry Low Back Questionnaire / BackHill / McGill pain questionnaire.

Studies regarding the treatment of CLBP and IFC reported favourable results in reducing disability (Werners et al., (1999); Adedoyin et al., (2005); Zambito et al., (2006); Zambito et al., (2007); Lara-Palomo et al., (2012); Fuentes et al., (2014); Albornoz-Cabello et al., (2016)) (**Table 2.9**). Werners et al. (1999) and Lara-Palomo et al. (2012) used IFC in conjunction with other treatment modalities and Lara-Palomo et al. (2012) found greater improvement when IFC was combined with massage therapy. Werners et al. (1999) should have included a combination of IFC and lumbar traction group to their study to assess IFC as an adjunct to treatment as combined therapy was shown to be favourable in another study Lara-Palomo et al., (2012).

Some authors have used the RMDQ as a measurement of disability (Facci et al., 2011; Lara-Palomo et al., 2012; Corrêa et al., 2016). This is in contrast to authors that have utilised the OLBQ (Werners et al., 1999; Lara-Palomo et al., 2012; Albornoz-Cabello et al., 2016). The OLBQ has been recommended for use in CLBP and severe disability as it was designed for this purpose, whereas the RMDQ is more suited for patients with mild to moderate disability

(Roland and Fairbank, 2000). Since all studies reported included participants with CLBP, the OLBQ should have been favoured over RMDQ. Interestingly, Lara-Palomo et al. (2012) included both in their study and found significant improvements in both.

The McGill pain questionnaire allows individuals to give an adequate description of the quality and intensity of the pain. This scale was used by Facci et al. (2011). The Backhill questionnaire is essentially an extension of the McGill questionnaire and includes 27 functional questions and four questions which quantify the type of pain. This scale was used by Zambito et al. (2006, 2007) who reported significant improvements.

2.9.7.3 Algometer

An algometer is a device that is used to measure pain-pressure threshold. It serves as a reliable, objective way of measuring pain and is considered valid by Kinser et al. (2009). Studies reported in **Table 2.9** have used this device for measuring pain in CLBP (Fuentes et al., 2014; Corrêa et al., 2016). This is in contrast to the other studies mentioned in **Table 2.9** that did not use any form of objective testing. This could have created a bias in the results as subjective measurements are patient dependent.

2.9.7.4 Other

In **Table 2.9,** studies also compared IFC to different forms of treatment. Fuentes et al., (2014) considered the therapeutic alliance (TA) between the therapist and the patient (**Table 2.9**). Therapeutic alliance was defined as the positive connection between the therapist and the patient, establishing a positive rapport and a healing environment (Fuentes et al., 2014). The study applied IFC for 30 minutes across all the groups. There was no mention as to why 30 minutes was the selected time duration. The question arises as to whether the same therapeutic effect could have been achieved at a lower duration of time.

Interferential current has been found to have variable results in the treatment of LBP (Foster and Palastanga 1990, Shekida Industries, 1993; Sanya, 2000). Thus, the clinical practice guidelines from United Kingdom (NICE, 2009), Europe (Airaksinen et al. 2006) and the USA (Chou et al. 2007) indicate limited evidence for use (Dagenais and Haldeman, 2012), particularly in CLBP. Currently there are no guidelines for the use of IFC in Africa.

2.10 Conclusion

Various studies were conducted looking at IFC and CLBP, however, no commonality regarding the duration of application for IFC was found. It would seem that there is limited agreement on the application of IFC in terms of the duration of application as there are no recommendations given (even with a review of the guidelines) (Dagenais and Haldeman, 2012; NICE, 2009; Chou et al., 2007; Airaksinen et al., 2006). Thus, there remains a paucity of literature with regard to using varied time intervals of IFC on participants with CLBP and the development of clinical prediction rules. This study, therefore, aimed to explore the optimum treatment time of IFC in the treatment of CLBP.

CHAPTER THREE

METHODOLOGY

3.1 INTRODUCTION

This chapter presents the methodology utilised in this study i.e. the design of the study, study location, participant recruitment and allocation, the study procedure, treatment protocols and measurement tools used to document clinical progression. The chapter ends with a discussion around the ethical considerations of the study and the statistical analyses used to analyse the data obtained.

3.2 STUDY DESIGN

The study paradigm was quantitative and the design was a randomised controlled clinical trial.

3.3 PERMISSION TO CONDUCT THE STUDY

Permission to conduct the study was obtained from the Durban University of Technology's Institutional Research and Ethics Committee (DUT IREC) (Rec: 117/15 (Appendix A_1 and A_2).

3.4 STUDY LOCATION

This study was conducted at the Chiropractic Day Clinic (CDC), situated at the Durban University of Technology (DUT).

3.5 SAMPLING

A total of 45 participants who presented with LBP for more than six weeks were included in the study.

3.5.1 Sample Population

The study population comprised individuals residing within the eThekwini Municipality who met the inclusion criteria.

3.5.2 Recruitment

Advertisements (Appendix B) were placed around notice boards of DUT and around the DUT Berea and City campuses. This was after permission had been granted by the relevant authorities (Appendix C). In addition to this, advertisements were placed on free advertisement boards e.g. in spar shops. Participants were also recruited via word of mouth.

Prospective participants were requested to contact the researcher telephonically for more information. All prospective participants who contacted the researcher telephonically were asked questions, tabulated in **Table 3.1**, to establish if they qualified to participate in the study (Appendix D).

Table 3.1: Telephonic screening questions and expected answers for prospective participants

	Question	Required Answer
1	Would you mind me asking you a few simple medical questions to ensure that you have a high likelihood of meeting the inclusion criteria for the study?	**No**
2	"How old are you?"	**18 – 45 years of age**
3	"Do you suffer from any of the following: Heart disease, diabetes, hypertension or any other blood vessel disease?"	**No**
4	Are you currently taking any medication?"	**No**
5	"Do you have a cardiac pacemaker?" (Vizniak, 2007)	**No**
6	"Do you have any mental impairment?" (Vizniak, 2007)	**No**
7	"Do you have any metal rods, plates or other assistive devices that have been implanted?"	**No**
8	"Do you have any open wounds or any recent scar tissue over the low back?"	**No**

The prospective participant had to answer no to questions one and three through eight to be included in the study in addition to meeting the required age range. If they had answered yes to any of the questions asked during the telephonic interview (**Table 3.1**), they were excluded from the study and thanked for their time.

3.5.3 Sample size

The study required a total of 45 participants who were randomly allocated into one of three groups of 15 each viz. group one using 15 minutes of IFC application; group two using 20 minutes of IFC application or group three using 30 minutes of IFC application.

3.5.4 Sample allocation

Once the prospective participant was screened and found to be eligible for the study, a randomisation table generated by a statistician was used to randomly allocate the participant into one of the three groups. This required that 52 numbers, to allow for dropouts, were randomly assigned numbers one to three, with one representing the 15 minute IFC group, two representing the 20 minute IFC group and three representing the 30 minute IFC group. The clinic student administrator of the CDC who performed the allocation to the groups, held this randomisation table (Appendix E). Therefore, the researcher was not privy to the group allocations prior to determining eligibility of a participant in keeping with the blinding procedure.

3.6 PARTICIPANT PROCEDURE

Participants residing in the eThekwini Municipality voluntarily agreed to participate in the study. All participants who were included in the study were given a letter of information to read and sign (Appendix F). Informed consent was also obtained from the participant making sure that the study was explained adequately (Appendix F). The participants were given an opportunity to ask any questions regarding the process of the research prior to them signing the informed consent form.

3.6.1 Participant assessment

After the telephonic interview, an appointment was made at the DUT CDC for the prospective participant. Upon arrival at the CDC, the participant was screened further by means of a case history (Appendix G), a physical examination (Appendix H) and a lumbar spine regional examination (Appendix I) in order to determine if the participant met the inclusion criteria for the study.

3.7 INCLUSION AND EXCLUSION CRITERIA

3.7.1 Inclusion criteria

- Participants between the ages of 18 and 45 years were included in this study. People under the age of 18 years are considered a vulnerable population of research for the purposes of this study (Dagenais and Haldeman, 2012; South Africa Department of Health, 2016) and thus they were excluded; those over 45 years of age were excluded due to the natural age related changes which occur (Jellema et al., 2007; Dagenais and Haldeman, 2012).

- Participants had to have pain present in the quadratus lumborum (QL) muscle.
- Participants had to be symptomatic in terms of CLBP, that is mechanical in origin and included:
    - Pain between the inferior aspect of the twelfth rib bilaterally and the gluteal fold inferiorly. The mid-axillary lines bind this space laterally (Galukande et al., 2005).
    - A pain rating of between four and eight on the NRS-101 (Jellema et al., 2007). This was to increase the homogeneity of the participant's perceived pain scale and to allow for improvements or deterioration of pain symptoms without having a floor or ceiling effect, thereby limiting the recorded pain outcomes (Mouton, 2006).
    - The pain episode could not have been longer than 12 weeks or less than six weeks (Anderson, 1999; Jellema et al., 2007).

3.7.2 Exclusion criteria

- Contraindications to IFC:
    - Any participant who reported or was found to have anesthesia or decreased sensory ability in the region of the low back (Watson, 2008; Rennie, 2010).
    - Participants who reported a history of conditions which are known causative factors of neuropathy, which were found during the physical examination (e.g. diabetes and multiple sclerosis) (Vizniak, 2007; Rennie, 2010).
    - Haematological abnormalities that were found during the case history or the physical examination (e.g. venous thrombosis, emboli and bleeding disorders) (Nelson, 1981; Vizniak, 2007; Rennie, 2010).
    - Any participant who presented with fever and/or signs that they were suffering from an acute infection and would have required alternative treatment to facilitate the improvement of their condition (Watson, 2008; Rennie, 2010).
    - Any skin abnormalities that did not allow placement of the IFC pads (Nelson, 1981; Watson, 2008; Rennie, 2010).
    - Any participant who had a history of recent malignancy that had not been in remission for a period greater than five years (Nelson, 1981; Watson, 2008; Rennie, 2010).
    - Any participant who presented with a history of surgical implants (rods, plates, medically assistive devices (e.g. pacemakers) (Watson, 2008; Rennie, 2010).
    - Pregnant participants and those who suspected that they may be pregnant or had skipped a period were excluded from the study (Watson, 2008; Rennie, 2010).

- Participants who were on medication for pain, muscle relaxation and/or to reduce inflammation and who were not prepared to consider a three day washout period without medication prior to entry into this study (Seth, 1999). The wash out period was used to generate baseline data of the participant and, produce results that are more accurate.
- Participants were excluded if they reported taking any new medication during the course of the study or if it was found out that they were taking any form of medication after the wash out period delineated in the bullet above.
- Participants who had radiating pain to the posterior thigh or leg which could clinically be assigned to neurological origin or involvement (Jellema et al., 2007; Dagenais and Haldeman, 2012).
- Participants who refused or did not agree to sign the letter of information and informed consent.

3.8 RESEARCH ASSISTANT AND BLINDING FOR OBJECTIVE MEASUREMENTS

A blinded research assistant (RA) completed the algometer outcome measurements. The RA was a chiropractic student who was registered for and completing the Master's Degree in Technology for Chiropractic. The RA was responsible for the baseline algometer readings, as well as the repeated measure algometer readings. The RA was trained (Appendix J) to record and accurately document the outcome measure as required for this study (Section 3.9 (algometer)). The RA was shown how to complete the measurement and was then expected to repeat the measurement on three non-study volunteers in order to ascertain whether the RA was able to reliably repeat the measures as demonstrated by the researcher across all three volunteers.

Blinding was achieved by the RA not having access to the randomisation table, being issued with new data recording sheets at each data recording session and not having access to the participant files for the duration of the study (which indicated the treatment group).

It should also be noted that the researcher was not privy to the algometer readings until the end of the fourth visit for each participant.

3.9 INTERVENTION DEVICE

An IFC unit made by Chattanooga, device name: Intelect mobile combo, intl std 5cm^2 Appl was used. The Chattanooga Group is certified / compliant to the ISO13485, EN46001 and FDA-

QSR Quality Manufacturing Systems with the addition of all necessary approvals from the U.S. FDA 510(K). The device used in the study was a new machine and hence did not have a last service date.

3.10 MEASUREMENT TOOLS

3.10.1 Subjective measurements

3.10.1.1 Oswestry low back questionnaire (OLBQ)

The OLBQ (Appendix K) measured the functional disability status of the participant (Fairbank and Pynsent, 2000). It is a short, simple questionnaire that is readily understood by respondents and leads to fewer ambiguous responses, allowing for greater accuracy upon completion of the questionnaire. In addition, the OLBQ is a valuable tool in research, as it has the requisite reliability and validity (Davidson and Keating, 2001). It is also important to consider (for subjective outcomes) that the minimally clinically important difference (MCID) value has an important implication for the evaluation of research outcomes and thus treatment effectiveness. A lower MCID value could potentially place an intervention in a favourable light (e.g. a greater proportion of participants would be able to reach a lower threshold). Conversely, an artificially high MCID would be unable to appropriately rate the clinical value of the intervention. According to Copay et al. (2008), the MCID for LBP is 12.8 (2.92 to 15.36), although Schwind et al. (2013) contends that a score of ≤ 20% should be considered when interpreting data, as the clinical predictive value is more robust above this value. It was found, that below 20%, the baseline measurements and characteristics of the patients had a possibility of influencing the clinical predictive value model that they computed (Schwind et al., 2013).

In this study, the OLBQ was applied as follows:

> At the initial consultation, the participant was presented with an A4 page containing the OLBQ (Appendix K) which they were asked to fill out to the best of their ability. The participant was presented with the same questionnaire at the end of the study and they were asked to fill it out again without having reference to the first OLBQ that they completed. The results were then collected and collated.

3.10.1.2 Numerical pain rating scale (NRS-101)

The NRS-101 is a reliable and valid tool for measuring pain (Bolton and Wilkinson, 1998; Yeomans, 2000; Childs et al., 2005) (Appendix L). It was noted by the same authors that a

two-point change on the NRS-101 was seen as a minimally clinically important difference, indicating that a change of greater than two had a clinically significant effect (Childs et al., 1976; Hawker et al., 2011).

In this study, the NRS-101 was applied as follows:

The participant was asked to rate their average pain from zero to 10. This was contextualized in that 10 was noted as the worst the pain could be and zero being the least the pain could be or no pain. This was done at the initial consultation, third consultation (before treatment was administered) and at the final consultation. These repeated measures are the minimum required to track pain adequately (Hawker et al., 2011).

3.10.2 Objective measurements

The algometer achieved highly reliable scores and is considered a valid measure of subjective tenderness in addition to being a suitable, convenient method of monitoring treatment effects (Potter, et al., 2006; Kinser et al., 2009). Therefore, the algometer could be used to assess tenderness (Carli et al., 2002). Additionally, in a study by Paungmali et al., (2003), it was reported that an algometer may yield reliable measurements and had strong discriminating validity between treatment groups (Paungmali et al., 2012). The MCID noted for algometry is 1.77 kg/cm^2 (Chesterton et al., 2007) for patients with measurements over soft tissue and 1.62 kg/cm^2 (Mutlu and Ozdincler, 2015) for patients with measurements over joints. Therefore, for the purposes of this study, the MCID was pegged at 1.77 kg/cm^2

In this study the algometer was applied as follows:

The researcher marked the participant's most painful trigger point of the (QL) in the low back with Henna dye (to allow repeated measures). The participant was then asked to lie in a prone position (i.e. lying face down). The researcher exited the room, the RA went in and placed the algometer on the most painful trigger point of the QL muscle (noted with Henna dye) and the participant was asked to notify the RA when pain or discomfort was felt (Chesterton et al., 2007). At this point, the algometer was removed and a reading was taken (Appendix M). The algometer was then zeroed before the procedure was repeated and a mean value was calculated. This was done at the initial consultation, third consultation (before treatment was administered) and at the final consultation.

3.11 RESEARCH PROCEDURE

Consultation one

Following the case history (Appendix G), physical examination (Appendix H) and lumbar spine regional examination (Appendix I), subjective measurements were taken viz. the OLBQ (Appendix K) and NRS-101 (Appendix L). Each participant was asked to rate their pain on a scale of 0–10 using the NRS-101 system and thereafter fill in the OLBQ (Yeomans, 2000; Childs et al., 2005). The researcher then left the room and the RA went in to measure the participant's pain threshold over the QL muscle trigger point using an algometer (Appendix M). The QL was selected because it is a common muscle that is involved in LBP (Travell and Simons, 1999). The QL muscle is also easily accessible anatomically since there is no need to palpate through fascia or other muscles (Njoo and Van De Does, 1994; Standring, 2015). Henna dye, which is a dye utilised for the application of temporary tattoos, was applied by the researcher onto the area that the algometer was to be placed for each participant. This facilitated pinpoint accuracy at each measurement taking consultation, which was summarised on a SOAPE note (Appendix N).

The researcher then prepared the IFC unit, making sure the appropriate equipment was present (e.g. leads, electrodes, electrode covers, water bowl, straps, towel and paper towel). Additionally, the air conditioner in the consultation room was set at room temperature i.e. 25 degrees Celsius. This ensured standardisation between all participants and reduced the effect of humid or cold weather.

Once the IFC unit was prepared, a towel was placed on the plinth for hygiene purposes and two pillows were used, the first being at the head and the second being between the participants' abdomen and the plinth for the comfort of the participant. The participant was asked to lie in a prone position (i.e. lying face down) (Watson, 2008; Johnson and Tabasam, 2003). The participant's low back was exposed and cleaned with alcohol. The IFC electrodes were cleaned with alcohol (Watson, 2008). The IFC electrode covers were immersed in cold water and excess water was squeezed out. The IFC electrodes were then inserted into the electrode covers. Following this, the covered electrodes were placed on the participant's low back as demonstrated in **Figure 3.1**. The electrodes were then strapped so as to remain flush against the area (Hurley et al., 2001; Johnson and Tabasam, 2003a, 2003b; Watson, 2008).

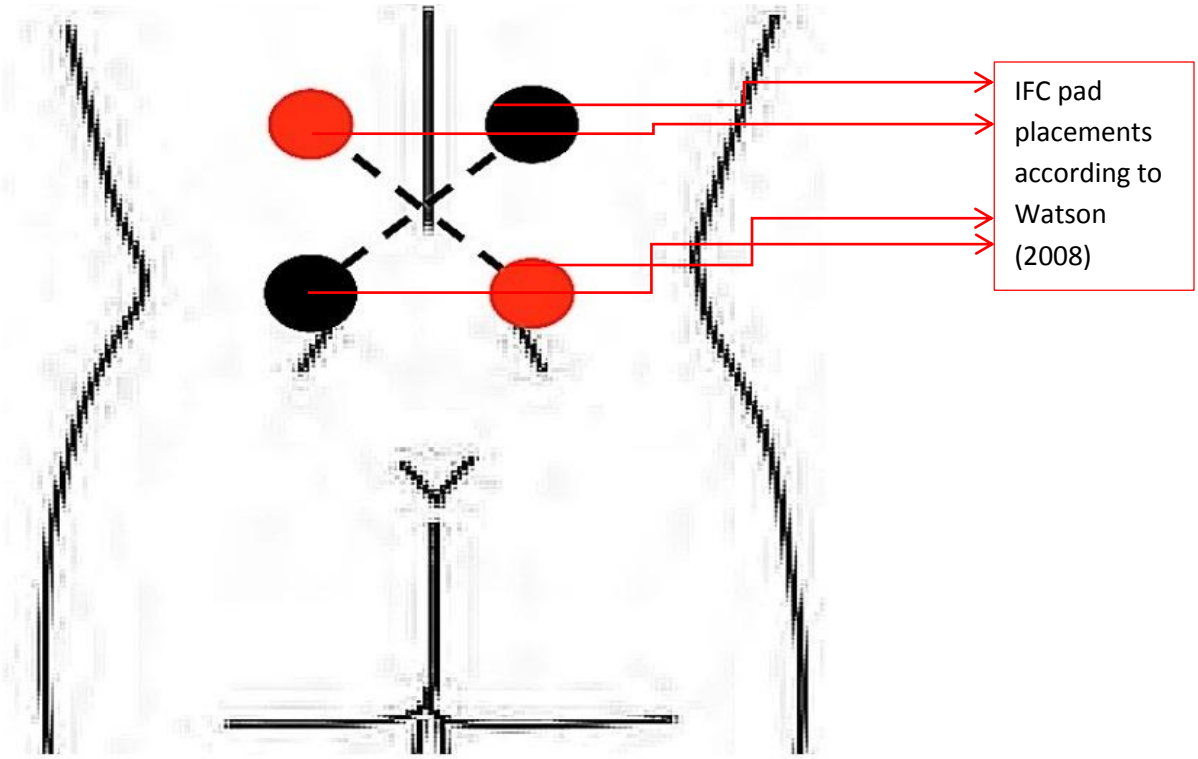

Figure 3.1: IFC pads and placements during the study

Source: https://www.win-health.com/nexwave-interferential.html

The IFC machine was switched on and the settings adjusted according to the group allocation. **Table 3.2** summarises the settings that were used in this study. Essentially, the only variable that differed was the time in which the IFC was applied. It should be noted that the machine did not deliver current unless the start button was pressed; at which time the timer also started.

Table 3.2: Summary of the settings used

Group	Time	Carrier Frequency	Mode
1	15 Minutes	1Khz	Sweep
2	20 Minutes	1Khz	Sweep
3	30 Minutes	1Khz	Sweep

Before the administration of IFC, the researcher explained to the participant that a slight tingling sensation would be felt on their low back (Johnson and Tabasam, 2003a, 2003b; Watson, 2008). This sensation would be gradually increased to the comfort of the participant. This is known as the intensity of the current. The researcher also explained that anything more than a mild discomfort to the participant should be reported to the researcher immediately (Johnson and Tabasam, 2003a, 2003b).

Therefore, the intensity of the IFC was participant dependent and was regulated by the researcher throughout the duration of application. Once treatment was completed, the researcher then switched off the IFC unit, removed the straps and electrodes and wiped off any water from the participant's low back with a paper towel (Hurley et al., 2001; Johnson and Tabasam, 2003a, 2003b; Watson, 2008). Upon completion of the IFC application, the participant was assisted off the plinth and given time to change in privacy. The participant was advised not to apply any form of treatment such as heat or cold therapy or application of pain reducing gels, patches or ointments to the low back. Advice was also given not to use medication for the duration of the study. The participant was taken to the CDC reception to book the next consultation.

Consultation two

A follow-up appointment was made within one week of the initial consultation depending on participant availability. A minimum of one day was given between the first and second consultation. No measurements were taken at this consultation and treatment was administered according to group allocation (**Table 3.2**). The next appointment was scheduled at the end of this consultation.

Consultation three

This took place in week two (at a minimum of seven days after the first consultation). The NRS-101 was done by the researcher and the algometer reading was done by the RA as described before. Treatment was then administered according to the group allocation (**Table 3.2**). The next appointment was scheduled at the end of this consultation.

Consultation four

This took place in week three (at a minimum of fourteen days after the first consultation) depending on participant availability. No treatment was administered at this consultation. Only subjective and objective measurements were taken. The participant was thanked for participating in the research at the end of this consultation.

A summary of the research process in all three groups is indicated in **Table 3.3**.

Table 3.3: Summary of the research process

Week	Visit	Group One: 15 minutes of IFC application	Group Two: 20 minutes of IFC application	Group Three 30 minutes of IFC application
1	1	Screening *Baseline measures* **Treatment**	Screening *Baseline measures* **Treatment**	Screening *Baseline measures* **Treatment**
	2	**Treatment**	**Treatment**	**Treatment**
2	3	*Measures* **Treatment**	*Measures* **Treatment**	*Measures* **Treatment**
3	4	*Measures*	*Measures*	*Measures*

3.12 ADVERSE EVENT TO TREATMENT

There were no adverse events reported during the study, however, if an adverse event was to be reported, the following protocol was delineated prior to the implementation of the study:

The IFC machine would be switched off immediately and the electrodes removed. The participant would have been asked if they were aware of their surroundings and to describe the adverse symptoms they were experiencing. A mini mental exam would have been performed whereby the participant was asked their name, age, what day it was and their current location. The participant's vital signs would have been assessed and reassessed to determine if they were stable. An ambulance would be called to transport the participant to an emergency care facility if they remained unresponsive. These events would additionally have required reporting to the DUT IREC as per their required adverse events reporting procedure.

3.13 STATISTICAL ANALYSES

Data analysis was performed using SPSS: (IBM Corp. 2010. IBM SPSS Statistics for Windows, Version 22. Armonk, NY: IBM Corp.). Statistical significance was set at a $p < 0.05$ level. Summary of the sample was done by means of central tendency and was presented in terms of mean, median, standard deviation, inter quartile range (Q1-Q3), minimum and maximum. This depended on the underlying distribution (non-parametric). ANOVA was done to ensure that the means of the groups were equal at baseline. Inter-group comparisons were done using repeated measures of ANOVA with time and group effects. While there was no difference in treatment application between the groups, the time varied. Therefore, post hoc multiple comparisons were done to compare each of the three groups to each other. This was done separately for each of the outcome measurements. Profile plots were generated to compare the direction and trend of the effect.

CHAPTER FOUR

RESULTS

4.1 INTRODUCTION

This chapter describes the data obtained from each participant in the form of subjective and objective measurements as detailed in chapter three. IBM SPSS version 22 was used to analyse the data as discussed in Chapter Three. A *p* value of < 0.05 was considered as statistically significant. Repeated measures analysis of variant (ANOVA) testing was used to perform within-group and between group comparisons. Within group comparisons included analysing the comparison of treatment at each consultation, whilst the between group comparisons entailed assessing the interaction between the consultation and treatment.

The analyses consisted of:

1. Demographic data which included age and gender.
2. Subjective measurements which consisted of the numerical pain rating scale (NRS-101) and Oswestry low back questionnaire (OLBQ).
3. Objective measurements which were obtained using the algometer device.

4.2 COMPARISON OF SELECTED DEMOGRAPHICS BETWEEN THE GROUPS

The mean and standard deviation of the age of the 45 participants is shown in **Table 4.1**. The range of the age of the participants was 18 to 45 years. There was no significant difference between the groups in terms of age (*p* = 0.224; ANOVA).

Table 4.1: The mean and standard deviation of the age of the participants per group and their means

Age	Group 1 15 min IFC	Group 2 20 min IFC	Group 3 30 min IFC	mean
Mean	25.7	29.5	28.9	28.0
Standard deviation	6.2	7.0	5.9	6.5

4.3 COMPARISON OF GENDER BETWEEN THE GROUPS

The distribution of male and female participants across the three groups is tabulated in **Table 4.2**. There was no significant difference in the gender distribution between the three groups (*p* = 0.537; ANOVA).

Table 4.2: Comparison of gender between the groups

Gender		Group 1 15 min IFC	Group 2 20 min IFC	Group 3 30 min IFC	Total
Male	n	8	6	9	23
	Column n %	53.3%	40%	60%	51.1%
Female	n	7	9	6	22
	Column n %	46.7%	60%	40%	48.9%

4.4 COMPARISON OF BASELINE OUTCOMES BETWEEN THE GROUPS

The baseline measurements are depicted in **Table 4.3**. The baseline outcome measurements did not differ significantly amongst the groups as shown.

Table 4.3: Comparison of baseline outcomes between the groups

		Group 1 15 min IFC	Group 2 20 min IFC	Group 3 30 min IFC	Total	*p* value
NRS-101	Mean	6.5	6.0	6.0	6.2	0.496
	Standard Deviation	1.4	1.6	1.1	1.4	
Algometer ($kg.m^{-2}$)	Mean	7.3	5.9	7.1	6.8	0.253
	Standard Deviation	2.4	2.2	2.9	2.5	
OLBQ (%)	Mean	18.3	19.7	24.9	21.0	0.192
	Standard Deviation	6.8	13.7	9.1	10.4	

NRS-101= Numerical pain rating scale; OLBQ = Oswestry low back questionnaire

4.5 OBJECTIVE ONE

To determine the effect of 15 minutes of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

4.5.1 Numerical rating scale

The mean NRS-101 scores across the three consultations for group one is depicted graphically in **Figure 4.1**. The range of the NRS-101 scores for consultation one was 5 to 10; 0 to 7 for consultation three, and 0 to 7 for consultation four. There was a statistically significant decrease in the NRS-101 scores from baseline to consultation four (p < 0.001, ANOVA). Moreover, the NRS-101 scores for all consultations were significantly different to each other as shown by the pairwise comparison **(Table 4.4)**.

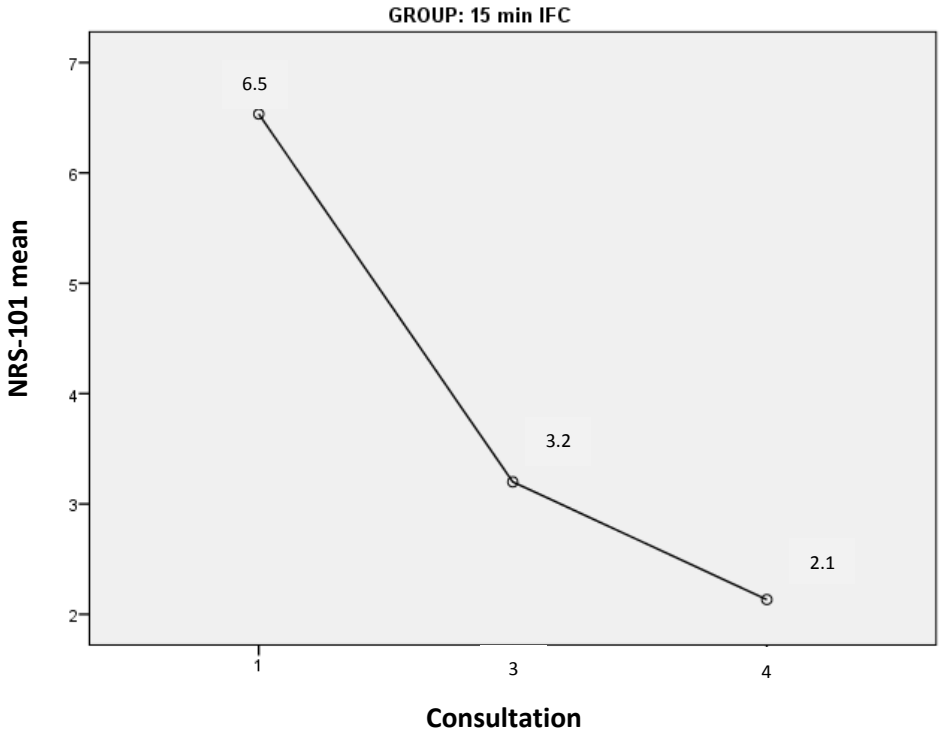

Figure 4.1: The mean NRS-101 scores for participants in Group one: 15 minutes

Table 4.4: Pairwise comparisons between the three time points for NRS-101: 15 minutes

Pairwise Comparisons[a]						
Measure: NRS-101						
(I) time	**(J) time**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[b]**	**95% Confidence Interval for Difference[b]**	
					Lower Bound	**Upper Bound**
1	3	3.333*	0.540	p < 0.001	2.174	4.492
	4	4.400*	0.559	p < 0.001	3.201	5.599
3	1	-3.333*	0.540	p < 0.001	-4.492	-2.174
	4	1.067*	0.345	0.008	.328	1.806
4	1	-4.400*	0.559	p < 0.001	-5.599	-3.201

	3	-1.067*	0.345	0.008	-1.806	-.328

Based on estimated marginal means
***. The mean difference is significant at the .05 level. a. GROUP = 15 min IFC; b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).**

4.5.2 Oswestry low back questionnaire

The mean OLBQ scores across the two consultations for group one is shown graphically in **Figure 4.2**. The range of the OLBQ scores for consultation one was 4 to 30 and it was 0 to 14 for consultation four. There was a statistically significant difference in the OLBQ scores from baseline to consultation four ($p < 0.001$, ANOVA). There was no need for *post-hoc* pairwise comparisons as there were only two consults for this measurement.

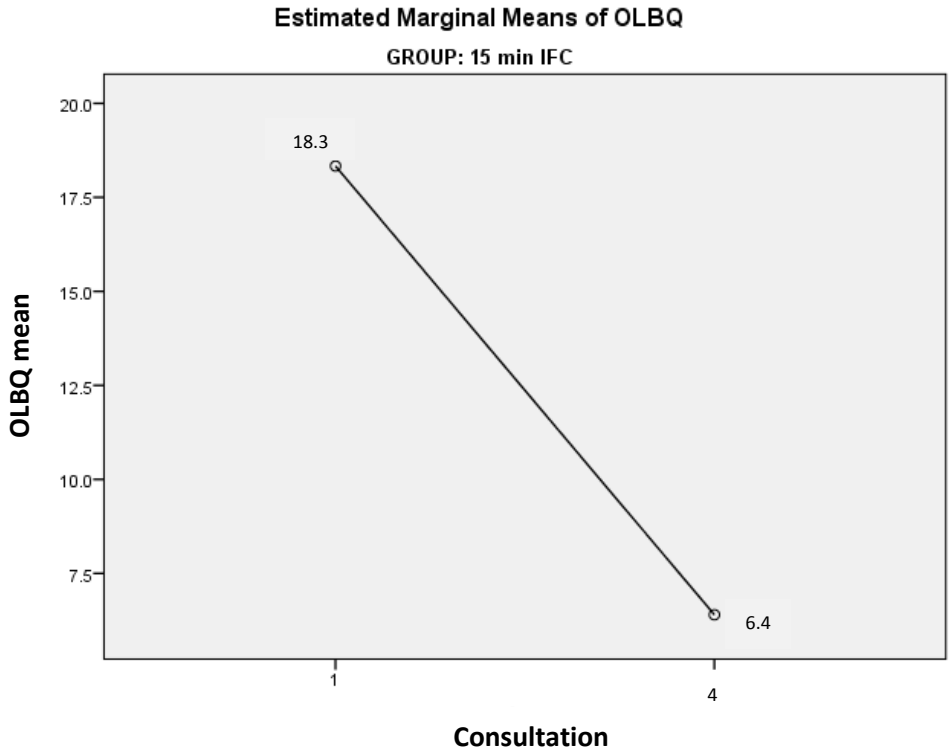

Figure 4.2: The mean OLBQ scores for participants in Group one: 15 minutes

4.5.3 Algometer

The mean algometer scores across the three consultations for group one is shown graphically in **Figure 4.3**. The range of the algometer scores for consultation one was 2.9 to 11.9; 4.3 to 13.7 for consultation three and 2.9 to 15.5 for consultation four. There was no statistically significant difference in algometry measurements between the consultation times in this group ($p = 0.086$, ANOVA). Additionally, the pairwise comparisons showed that consultations one

and four were significantly different to each other but no other comparisons were significant **(Table 4.5)**.

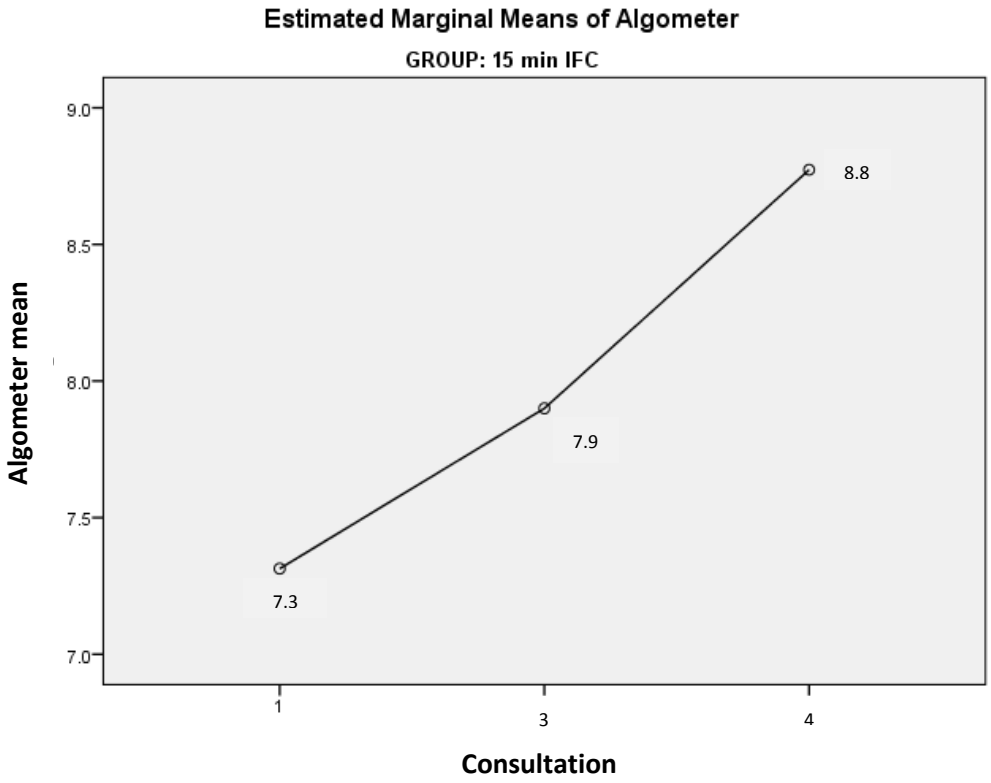

Figure 4.3: The mean Algometer scores for participants in Group one: 15 minutes

Table 4.5: Pairwise comparisons between the three time points for algometer

Pairwise Comparisons[a]						
Measure: Algometer						
(I) time	**(J) time**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[b]**	**95% Confidence Interval for Difference[c]**	
					Lower Bound	**Upper Bound**
1	3	-.587	0.817	0.484	-2.338	1.165
	4	-1.460*	0.579	0.024	-2.702	-.218
3	1	.587	0.817	0.484	-1.165	2.338
	4	-.873	0.902	0.350	-2.809	1.062
4	1	1.460*	0.579	0.024	.218	2.702
	3	.873	0.902	0.350	-1.062	2.809

Based on estimated marginal means
***. The mean difference is significant at the .05 level. a. GROUP = 15 min IFC; b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).**

4.6. OBJECTIVE TWO

To determine the effect of 20 minutes of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

4.6.1 Numerical rating scale

The mean NRS-101 scores across the three consultations for group two is shown in **Figure 4.4**. The range of the NRS-101 scores for consultation one was 4 to 9; 2 to 6 for consultation three and 0 to 6 for consultation four. There was a statistically significant difference in the NRS-101 scores from baseline to consultation 4 ($p < 0.001$, ANOVA). Furthermore, the NRS-101 scores for all consultations were significantly different to each other as shown by the pairwise comparison **(Table 4.6)**.

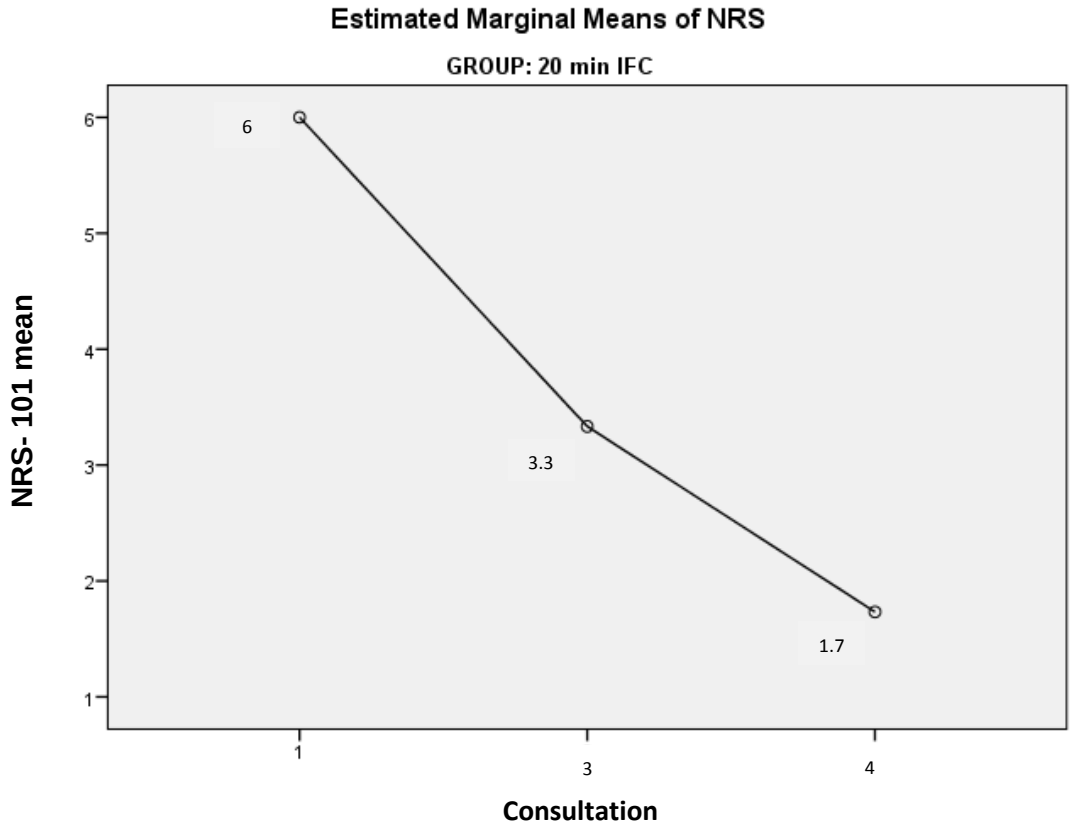

Figure 4.4: The mean NRS-101 scores for participants in Group two: 20 minutes

Table 4.6: Pairwise Comparisons between the three time points for NRS-101: 20 minutes

Pairwise Comparisons[a]						
Measure: NRS-101						
(I) time	**(J) time**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[b]**	**95% Confidence Interval for Difference[c]**	
					Lower Bound	**Upper Bound**
1	3	2.667*	0.422	p < 0.001	1.762	3.571
	4	4.267*	0.502	p < 0.001	3.190	5.343
3	1	-2.667*	0.422	p < 0.001	-3.571	-1.762
	4	1.600*	0.349	p < 0.001	.851	2.349
4	1	-4.267*	0.502	p < 0.001	-5.343	-3.190
	3	-1.600*	0.349	p < 0.001	-2.349	-.851

Based on estimated marginal means
***. The mean difference is significant at the .05 level. a. GROUP = 20 min IFC; b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).**

4.6.2 Oswestry low back questionnaire

The mean OLBQ scores across the three consultations for group two is presented in **Figure 4.5**. The range of the OLBQ scores for consultation one was 2 to 52 and 0 to 28 for consultation four. There was a statistically significant difference in the OLBQ scores from baseline to consultation four (p = 0.003, ANOVA). There was no need for *post hoc* pairwise comparisons as there were only two consultations for this measurement.

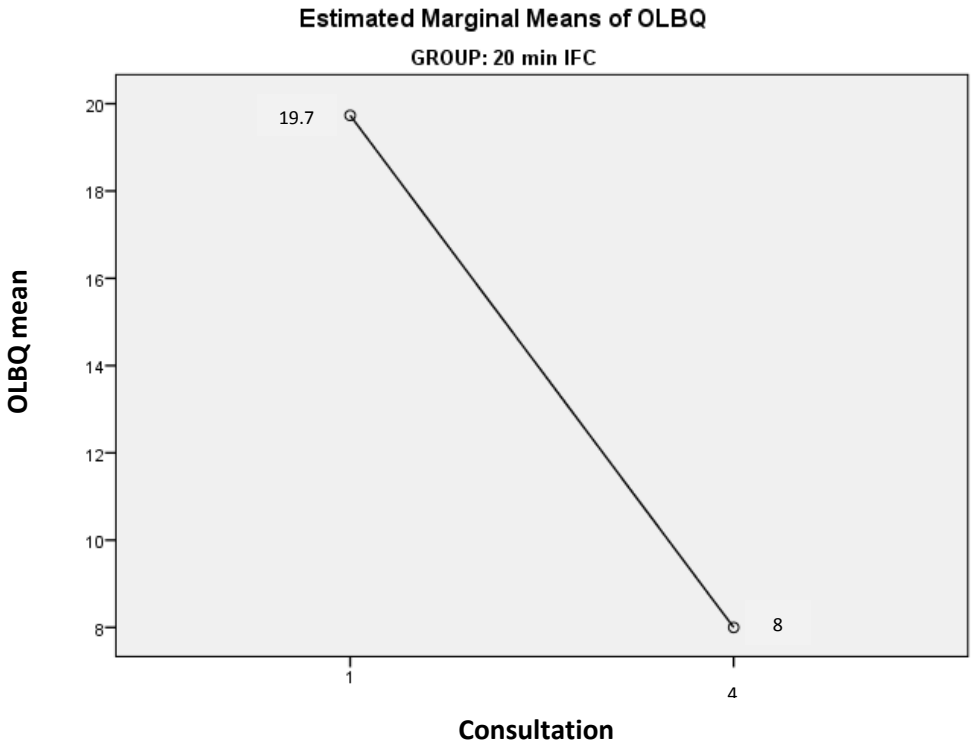

Figure 4.5: The mean OLBQ scores for participants in Group two: 20 minutes

4.6.3 Algometer

The mean algometer scores across the three consultations for group two is graphically illustrated in **Figure 4.6**. The range of the algometer scores for consultation one was 1.8 to 9.3; 2.1 to 13.1 for consultation three and 3.0 to 14.9 for consultation four. There was a statistically significant difference in the algometer measurement between the consultation times in this group (p = 0.046, ANOVA). Moreover, the pairwise comparisons showed that all consultations except 3 versus 4 were significantly different from each other. **(Table 4.7)**.

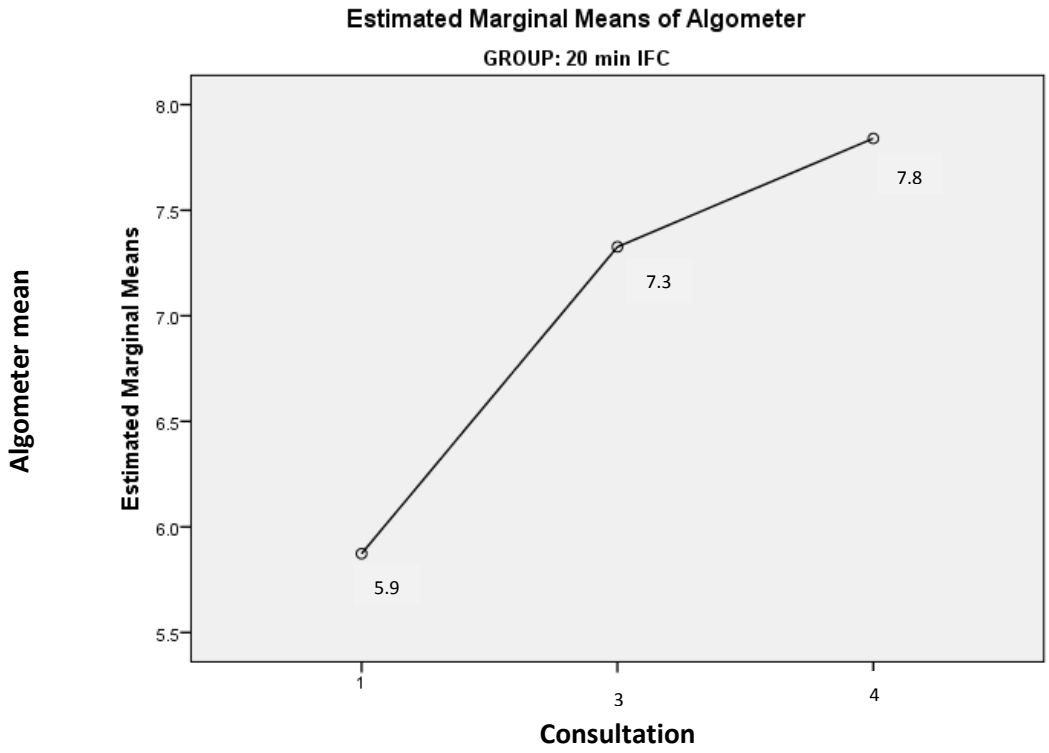

Figure 4.6: The mean Algometer scores for participants in Group two: 20 minutes

Table 4.7: Pairwise Comparisons between the three time points for Algometer: 20 minutes

Pairwise Comparisons[a]						
Measure: Algometer						
(I) time	**(J) time**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[b]**	**95% Confidence Interval for Difference[c]**	
					Lower Bound	Upper Bound
1	3	-1.453*	0.578	0.025	-2.694	-.213
	4	-1.967*	0.676	0.011	-3.416	-.518
3	1	1.453*	0.578	0.025	.213	2.694
	4	-.513	0.322	0.133	-1.204	.177
4	1	1.967*	0.676	0.011	.518	3.416
	3	.513	0.322	0.133	-.177	1.204

Based on estimated marginal means
***. The mean difference is significant at the .05 level. a. GROUP = 20 min IFC; b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).**

4.7 OBJECTIVE THREE

To determine the effect of 30 minutes of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

4.7.1 Numerical rating scale

The mean NRS-101 scores across the three consultations for group three is represented graphically in **Figure 4.7**. The range of the NRS-101 scores for consultation one was 4 to 8; 3 to 7 for consultation three and 0 to 6 for consultation four. There was a statistically significant difference in the NRS-101 scores from baseline to consultation four ($p < 0.001$, ANOVA). The NRS-101 scores for all consultations differed significantly to each other as shown by the pairwise comparison **(Table 4.8)**.

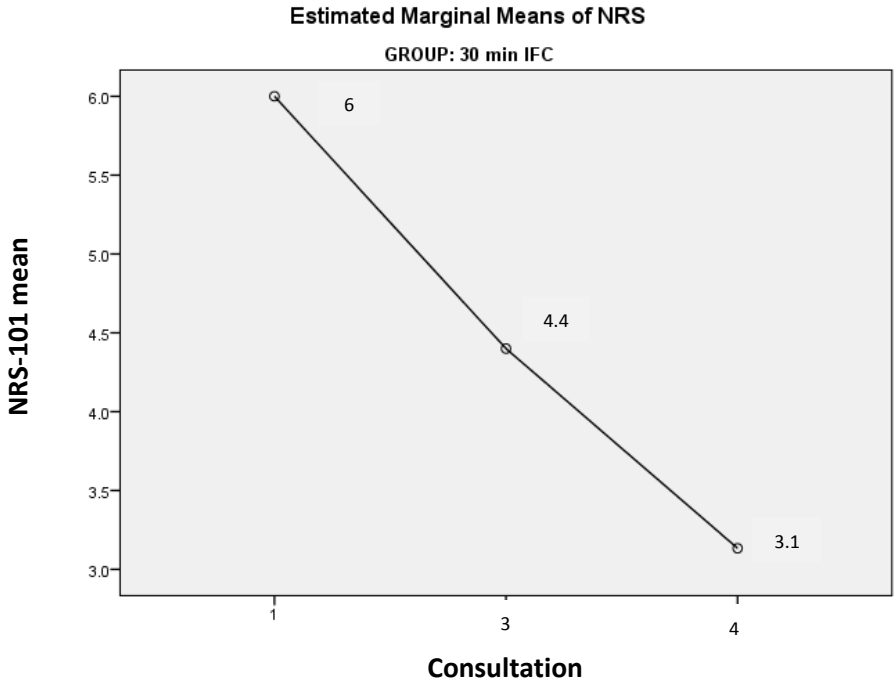

Figure 4.7: The mean NRS-101 scores for participants in Group three: 30 minutes

Table 4.8: Pairwise Comparisons between the time points for NRS-101: 30 minutes

Pairwise Comparisons[a]						
Measure: NRS-101						
(I) time	**(J) time**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[b]**	**95% Confidence Interval for Difference[c]**	
					Lower Bound	**Upper Bound**
1	3	1.600*	0.388	0.001	.768	2.432
	4	2.867*	0.376	p < 0.001	2.060	3.674
3	1	-1.600*	0.388	0.001	-2.432	-.768
	4	1.267*	0.419	0.009	.367	2.166
4	1	-2.867*	0.376	p < 0.001	-3.674	-2.060
	3	-1.267*	0.419	0.009	-2.166	-.367

Based on estimated marginal means
***. The mean difference is significant at the .05 level. a. GROUP = 30 min IFC; b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).**

4.7.2 Oswestry low back questionnaire

The mean OLBQ scores across the three consultations for group three is depicted in **Figure 4.8**. The range of the OLBQ scores for consultation one was 8 to 40, and 0 to 28 for consultation four. There was a statistically significant change in the OLBQ scores from baseline to consultation four (p = 0.001, ANOVA). There was no need for *post hoc* pairwise comparisons as there were only two consultations for this measurement.

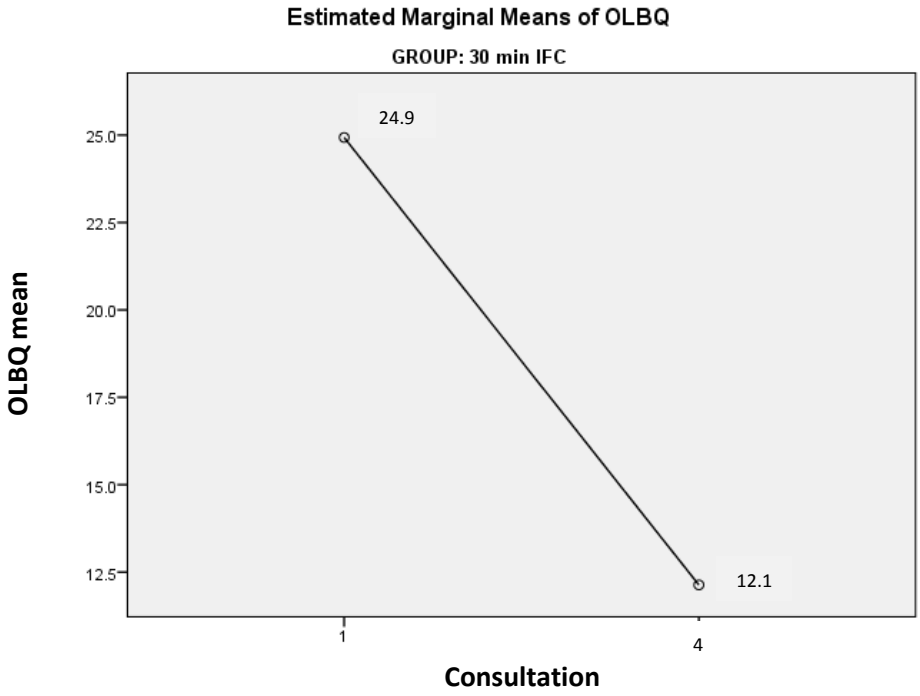

Figure 4.8: The mean OLBQ scores for participants in Group three: 30 minutes

4.7.3 Algometer

The mean algometer scores across the three consultations for Group three is portrayed graphically in **Figure 4.9**. The range of the algometer scores for consultation one was 3.6 to 12.3; 5.1 to 13.7 for consultation three and 3.4 to 16.8 for consultation four. There was a statistically significant difference in the algometer measurement between the consultation times in this group (p = 0.034, ANOVA). Additionally, the pairwise comparisons showed that consultations one versus four and three versus four were significantly different to each other **(Table 4.9)**.

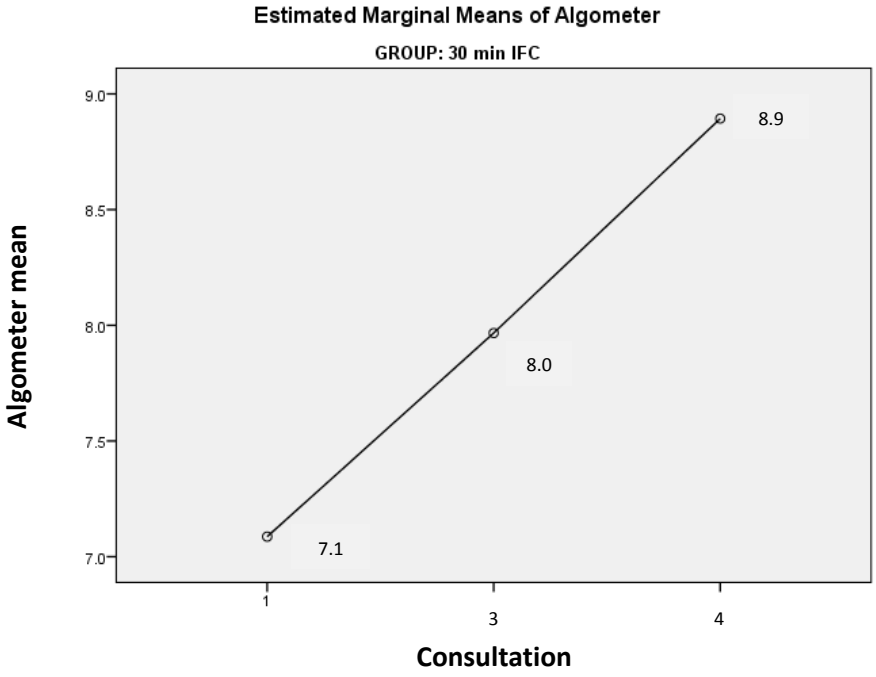

Figure 4.9: The mean algometer scores for participants in Group three: 30 minutes

Table 4.9: Pairwise Comparisons between the three time points for Algometer: 30 minutes

Pairwise Comparisons[a]						
Measure: algometer						
(I) time	**(J) time**	**Mean Difference (I-J)**	**Std. Error**	**Sig.[b]**	**95% Confidence Interval for Difference[c]**	
					Lower Bound	**Upper Bound**
1	3	-.880	0.417	0.053	-1.774	.014
	4	-1.807*	0.588	0.008	-3.069	-.545
3	1	.880	0.417	0.053	-.014	1.774
	4	-.927*	0.388	0.032	-1.760	-.094
4	1	1.807*	0.588	0.008	.545	3.069
	3	.927*	0.388	0.032	.094	1.760

Based on estimated marginal means
***. The mean difference is significant at the .05 level. a. GROUP = 30 min IFC; b. Adjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).**

4.8 OBJECTIVE FOUR

To compare the overall effect of the different time intervals of application of IFC on CLBP in terms of NRS-101, OLBQ and algometer.

4.8.1 Numerical rating scale

There was no significant difference in the mean NRS-101 scores between the three groups over the three time periods (p = 0.086; ANOVA; **Table 4.10**). Post-hoc contrasts showed that the 15 minute and 30 minute groups differed significantly to each other (p = 0.044) only.

Table 4.10: Overall comparison of NRS-101 between the three groups

Effect	**Statistic**	***p*-value**
Time	Wilk's lambda = 0.183	<0.001
Time x group	Wilk's lambda = 0.821	0.086
Group	F = 2.120	0.086

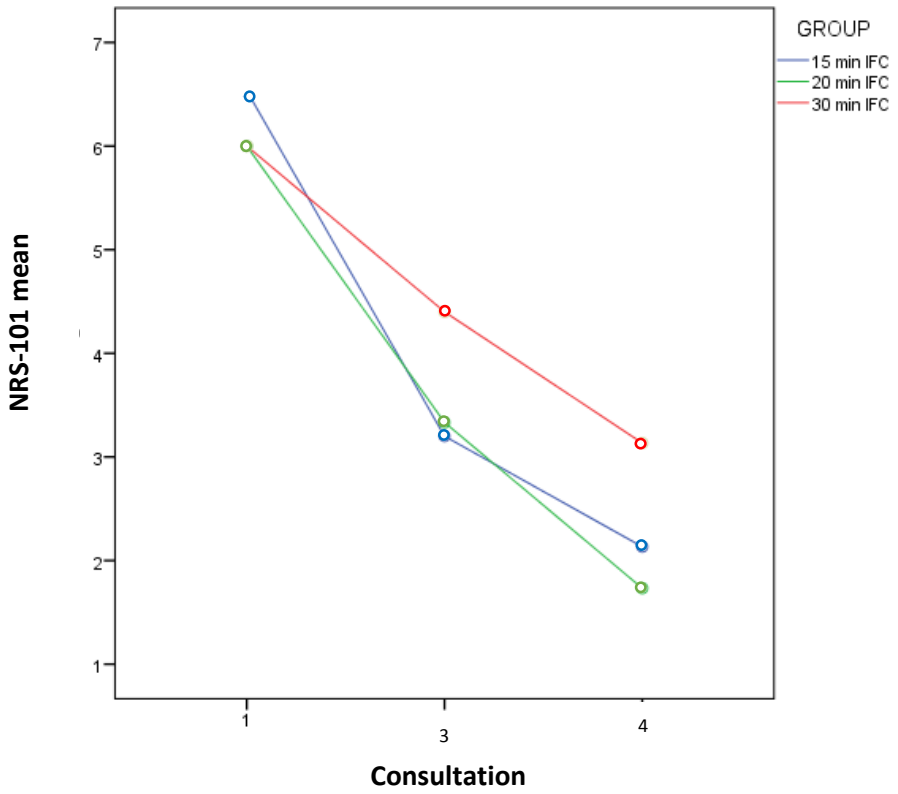

Figure 4.10: The mean NRS-101 scores for participants across the Groups

The trend shown in **Figure 4.10** suggests that the 20 minute group showed the highest level of decrease in NRS-101 score over time while the 30 minute group showed the least effect.

4.8.2 Oswestry low back questionnaire

There was no difference in rate of change over time between the treatment groups (p = 0.950; ANOVA; **Table 4.11**).

Table 4.11: Overall comparison of OLBQ between the three groups

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.371	<0.001
Time x group	Wilk's lambda = 0.998	0.950
Group	F = 0.052	0.950

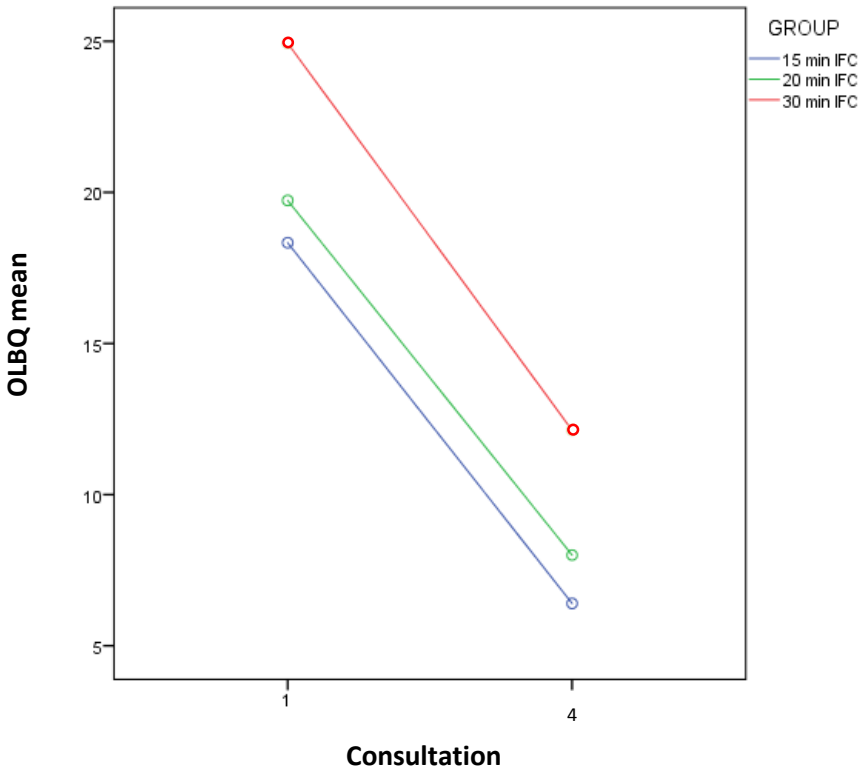

Figure 4.11: The mean OLBQ scores for participants across the Groups

Figure 4.11 shows that the slopes of all the lines are parallel, indicating that the effect was similar in all groups.

4.8.3 Algometer

There was no significant difference in rate of change over time between the groups (p = 0.903).

Table 4.12: Overall comparison of algometer between the three groups

Effect	Statistic	*p*-value
Time	Wilk's lambda = 0.636	<0.001
Time x group	Wilk's lambda = 0.975	0.903
Group	F = 0.259	0.903

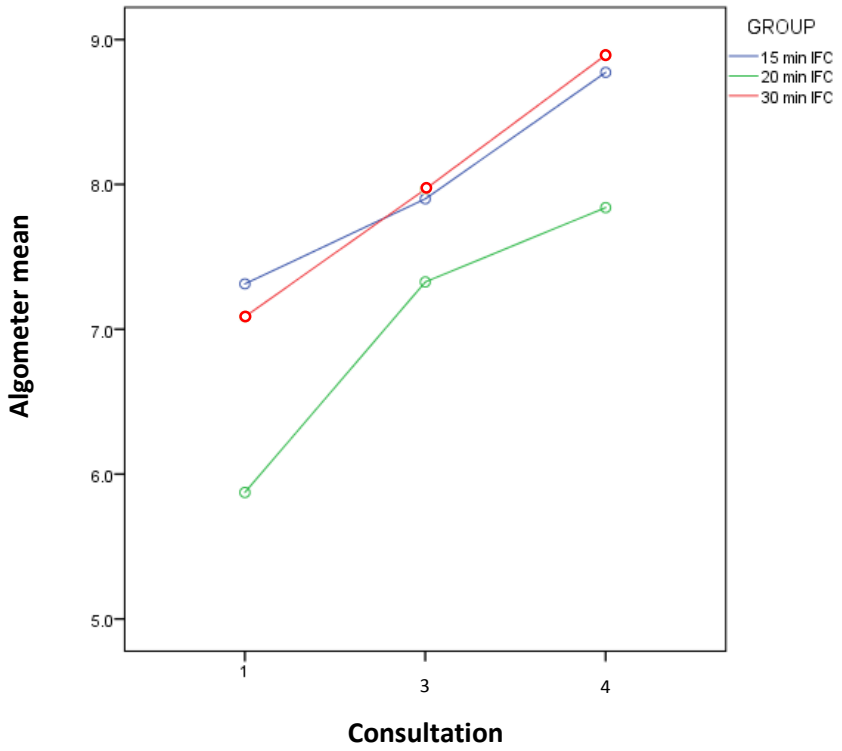

Figure 4.12: The mean algometer scores for participants across the Groups

Figure 4.12 shows that there was an improvement in all three groups over time, however, not enough to bear significance across the three groups.

4.9 CONCLUSION

There was a significant improvement across all three groups for the NRS-101 and OLBQ from the first to the fourth consultation over three weeks. Groups one and three showed the largest individual improvement between consultation one and three, compared to group two which showed consistent improvement throughout for the NRS-101 readings. All groups showed significant improvement over time, but collectively between the groups, there was no significant difference. In terms of the participants' activities of daily living (OLBQ), there was significant improvement for all groups over time, with no difference having been found between the groups. With regards to the algometer, it was found that the groups all improved significantly over time and that there was no significant difference between the groups in terms of this outcome measure.

CHAPTER FIVE

DISCUSSION

5.1 INTRODUCTION

The aim of the study was to investigate the effect of IFC in the treatment of CLBP using variable time intervals.

This chapter comprises a detailed discussion of the results obtained in the study as is reflected in Chapter Four with reference to the literature reviewed in Chapter Two.

These factors are discussed hereunder in relation to the objectives of the study.

5.2. ANALYSIS OF THE DEMOGRAPHIC DATA.

Low back pain is reported to have a higher prevalence in the 30 to 60 year age range (Patrick et al., 2014; Meucci et al., 2015), therefore, an increase in age seems to be directly related to and a prognostic factor for, an increase in the prevalence of LBP (Morris, 2006; Dagenais and Haldeman, 2012). This seems to agree with the larger body of literature regarding age, which follows an algorithm of increasing age having a direct relationship with an increasing likelihood of LBP (Hurwitz and Morgenstein, 1997; Taimela et al., 1997). This, however, contrasts a smaller body of literature where authors like Daltroy et al. (1991) suggested that decreasing age was related to increasing LBP and older age was protective of LBP.

In an African based systematic review by Louw et al. (2007), it was suggested that LBP starts at an early age and then increases with age according to the studies reported in this review (**Table 5.1**).

Table 5.1: Summary of reviewed studies with regards to ages of participants in Africa

Study	Country	Study design	Age (yrs)
Mijiyawa et al., 2000	Togo	Retrospective	17–94
Omokhodion et al., 2000	Nigeria	Cross-sectional	20–60
Wallner- Scholtfeldt et al., 2000	South Africa	Survey	23–59
Omokhodion, 2002	Nigeria	Cross-sectional	20–85
Omokhodion and Sanya, 2003	Nigeria	Cross-sectional	20–60
Igumbor et al., 2003	Zimbabwe	Cross-sectional	23–76
Omokhodion, 2004	Nigeria	Cross-sectional	20–82
Govender, 2004	South Africa	Survey	20–62
Puckree et al., 2004	South Africa	Survey	11–14
Prista et al., 2004	Mozambique	Survey	11–16
Fabunmi et al., 2005	Nigeria	Survey	25–84
Sanya et al., 2005	Nigeria	Cross-sectional	20–60
Bejia et al., 2005	Tunisia	Cross-sectional	11–19
Jordaan et al., 2005	South Africa	Cross sectional	13–18
Bejia et al., 2005	Tunisia	Survey	18–60
Galukande et al., 2005	Uganda	Cross-sectional	19–86

Table adapted from Louw et al., 2007; Dyer 2012

In line with the above literature on LBP, Patrick et al. (2014) and Meucci et al. (2015) indicated that CLBP usually begins in the mature ages of life (30-60). Similar to the smaller body of literature Pellise et al. (2009) and Jones et al. (2004), noted that where LBP was reported to have started at 12.98 years and 10.0-10.9 years, respectively, it resulted in CLBP being reported much earlier. This debate in the literature is influenced by a number of factors including but not limited to, the type of study collecting the data, the inclusion criteria of the study (specifically age ranges and employment type or status), the study location, the definition of LBP and CLBP manner in which the data is recorded and reported (Louw et al., 2007).

When evaluating the data around the population of eThekwini (Dyer 2012), it can be seen that the age at which the respondents first experienced LBP was 25.61 years of age with the result that most of the participants reported LBP as a persistent problem or medical condition by the age of 38.54 years of age. The only other comparable studies by Docrat (1999) and van der Meulen (1997), did not report the age ranges of their participants.

Bound by the inclusion criteria for this study (section 3.6.2), where the participant age was limited to between that of 18 to 45 years of age and based on the literature findings; the findings of this study (**Table 4.1)** indicate that the participants were collectively between 18 to 45 years of age with a mean age of 28.0 years. A principle reason for the age group representation in this study is that the location of this study was at a Higher Education Institution in the greater eThekwini Municipality, thus the target population was predominantly

students or recent graduates or staff of the University. This, although location specific, is therefore consistent with the literature where the reported data on the African continent suggests that individuals are likely to have LBP at a younger age (Louw et al., 2007) and are likely to report CLBP sooner than their international peers (Pellise et al., 2009).

When reviewing the three randomly allocated groups within the study, there was no significant difference between the groups in terms of age (p = 0.224; ANOVA). This indicates that randomisation achieved the desired effect of ensuring that the groups were not significantly different whilst at the same time not being influenced by bias of the researcher (Mouton, 2006). By comparison, to other clinical trials of a similar nature this study had an age group similar to Fuentes et al. (2014) who had conducted their study in a university setting. The authors also had reported lower mean age values with 30.5 years, 30.3 years and 29.7 years in Groups One, Two and Three, respectively.

This is in contrast to studies done by Lara-Palomo et al. (2012), who reported a mean age of 47 in the control group and 50 in the experimental group. This is not dissimilar to a study conducted by Albornoz-Cabello et al. (2016) (**Table 2.9**), where there was a reported mean age of 52 years in the experimental group and 47 years in the control group. The differences may be accounted for because that Lara-Palomo et al., (2012) required their patients to be referred from a primary health care provider to their clinic for possible inclusion into their study. Similarly the study by Albornoz-Cabello et al., (2016) was conducted at a private physiotherapy care center, which may only have been frequented by patients who were employed and had the means to afford the care provided at that facility, thus limiting their patients to those who were older, had a stable income and were possibly health insured. By contrast, this study and the study by Fuentes et al. (2014) targeted a completely different market and explains the different patient populace.

In terms of gender, the literature suggests that the average annual incidence for LBP was noted as 40.5% (age range: 29-55/1000) for men and 54% (age range: 40-41/1000) for women (Hillman et al., 1996). This is not dissimilar to the trends noted in **Table 4.2**, where it can be seen that the lifetime incidence tends to be higher in females (Meucci et al., 2015) irrespective of country (developing or developed) and the period in which the study was done.

Table 5.2: Summary of reviewed studies with regard to ages of participants

Author(s)	Year	Country	Lifetime Prevalence %	Gender
Van Der Meulen	1997	South Africa – Chesterville*	51.8	Male
Picavet et al.	1999	Netherlands	50	Male
			50	Female
Docrat	1999	South Africa – Durban*	45.4	Male
			42.2	Male
			54.6	Female
			57.8	Female
Picavet et al.	2002	Netherlands	50.4	Male
			49.6	Female
Jin et al.	2004	China – Shanghai*	45	Male
			54.2	Female
Bingefors et al.	2004	Sweden	20.9	Male
			24.3	Female
Vindigni et al.	2005	Australia	46	Male
			53	Female
Koley et al.	2008	India – Punjab*	48.32	Male
			53.64	Female
Ferreira et al.	2010	Brazil*	43	Male
			57	Female

***These countries are all third world / developing countries**

Table adapted from Louw et al. (2007); Dyer (2012)

Theories suggest that LBP is found more commonly in women due to a lower bone density and muscle mass compared to men; in addition to women having increased demands on their bodies from pregnancy and childbirth which may be causative factors in developing CLBP (Woolf and Pfleger, 2003; Meucci et al., 2015). Other factors which may affect the genders differentially depend on lifestyle, employment type and socioeconomic standing may include a sedentary lifestyle, obesity, trauma, smoking, genetic factors and psychological stress (Dyer, 2012; Manchikanti et al., 2014).

In contrast to the literature, it was found that this study had an almost equal number of male (n = 23) and female (n = 22) participants (**Table 4.2**). One contributing factor to this equal level of participation may be accounted for by the actual numbers of males and females residing in the eThekwini Municipality. According to Statistics South Africa (2011), the male and female population in the eThekwini municipality was 51.1 % and 48.9%, respectively.

As these participants were randomly allocated to one of three intervention groups, there was a relatively equal distribution of males and females between the groups as shown in **Table 4.2**. As a result, there was no significant difference in the gender distribution between the three groups (p = 0.537; ANOVA).

By comparison to other clinical trials of a similar nature, this study showed a completely different gender profile that was inconsistent with Fuentes et al. (2014), who in their total patient base (n=117) had 71 females (60.6%) and 46 males (39.3%). Lara-Palomo et al. (2012), reported 61 participants in total, with 20 males (31.2%) and 41 females (67.8 %) and Albornoz-Cabello et al. (2016) reported 20 males (31.3%) and 44 females (68.7%) in their total of 64 participants. These latter studies seem to suggest that roughly one third of participants are male and two thirds are female. This may be influenced by females tending to utilise health care to a greater extent (Härtela and Volgera, 2004; National Center for Complementary and Alternative Medicine, 2004) and complementary alternative therapy options, particularly in countries where patients have a higher level of education (Menniti-Ippolito et al., 2002; Tatalias, 2006). This contrasts to the South African population where access to health care is limited, often there is a poor understanding of health care options that are available and access to the health care may be limited by socioeconomic status (Grut et al., 2012; Mayosi and Benatar, 2014)

5.3 SUBJECTIVE DATA ANALYSIS

5.3.1 Numerical pain rating scale

The outcome measure used to assess the subjective pain rating of participants was the NRS-101, the outcomes noted were:

- Intra-group analysis of NRS-101 revealed a significant decrease in pain rating between each visit across all three groups ($p < 0.001$) (**Figures 4.1**, **4.4 and 4.7**). Of interest is the fact that groups one and three found their most significant improvement ($p < 0.001$ and $p = 0.001$, respectively) between visit one (baseline readings) and visit three, as compared to group two that had a significant change between baseline and visit three ($p < 0.001$); and between visit three and visit four ($p = 0.00$). This implies that groups one and three started to plateau in terms of their clinical improvement.
- Notwithstanding the trends seen in bullet one, the pairwise comparisons for the NRS-101 showed significance across all three groups ($p < 0.05$) over time **(Tables 4.4, 4.6 and 4.8)**.
- The inter-group analysis revealed no significant differences in the mean NRS-101 scores between all three groups but post-hoc contrasts showed that the 15 minute and 30 minute groups differed significantly from each other ($p = 0.044$) **(Table 4.10)**. This implies that group one improved to the greatest extent, but not markedly so from group two and group three improved the least.

These results concur with Werners et al. (1999), Zambito et al. (2006), Zambito et al. (2007), Facci et al. (2011), Lara-Palomo et al. (2012), Fuentes et al. (2014) and Corrêa et al. (2016), (**Table 2.9**) who all noted a reduction in pain over time in their study.

When reviewing the physiological principles provided in the literature, it seems possible that the participants in group one (15 minutes of intervention application) only had a physiological block (peripheral modulation) which reduced the nerve conduction (Venancio et al., 2013), thereby decreasing the pain signals to the spinal cord and cortex. This mechanism seems to be able to achieve significant effects in the short-term (Werners et al., 1999; Zambito et al., 2006), however, over time the repeated applications seem to have reduced ability to decrease perceived pain (Werners et al., 1999; Zambito et al., 2006). This may be as a result of peripheral nerve refractory being variable as well as the lack of an enhancing central modulation benefit (Noble et al., 2000a, 2000b, 2001).

By contrast, group two had a 20 minute application of IFC. This application seems to have stimulated the same peripheral modulation (physiological block), as well as a central modulation effect (Noble et al., 2000a; 2000b; 2001; Venancio et al., 2013). This can be seen in **Figure 4.10**, where the drop trajectory in the NRS-101 values for this group remains consistent over time. This reflects that there is not only a short-term, but also a more long-term effect, suggesting that the central modulation enhances the peripheral modulation (which is not seen in group one). The downside, however, is that the degree of change over time, although consistent for group two, is not as rapid as for group one (**Figure 4.10**), considering the small sample size. This outcome supports the assertion of Watson (2008), who suggested that the treatment time should not be more than 20 minutes.

This discussion seems to be reflected in group three, where the participants improved the least (but still significantly). This suggests that the application time of 30 minutes of IFC stimulated the central modulation system (Noble et al., 2000a, 2000b, 2001) more strongly to the detriment of the peripheral stimulation which was seemingly stimulated to the smallest degree (this can be seen by the slope of the trajectory in **Figure 4.10**). Therefore, the participants in this group did not benefit from the physiological nerve block, but had more long lasting effects as befit the stimulation of the central modulation system.

Thus, when assessing the outcomes of the NRS-101, it would seem that the 20 minute IFC application would potentially have had the ability to provide better outcomes if the study had been run over a longer time period or another measurement consultation was scheduled in week four. Therefore, it is recommended that a future study consider this to determine the possibility of the physiological mechanisms of action of IFC as suggested here. This could be

further enhanced by the use of nerve conduction studies or serum endorphin level measures as outcomes to validate the time points at which these occur and whether this would substantiate the results obtained in this study.

Clinically, the NRS-101 achieved minimally clinically important difference levels from baseline to the final readings; group one decreased by 4.4 points, group two decreased by 4.3 points and group three decreased by 2.9 points, all above the minimum of two points (Childs et al., 1976; Hawker et al., 2011). This means that the groups all achieved statistical and clinically important benchmarks, indicating that even without knowing which physiological mechanism underlies the improvement in the clinical presentation of the patient's pain; patients are likely to receive clinical benefit (Childs et al., 1976; Hawker et al., 2011). This may be another reason why previous research into the duration of application of IFC had not rigorously been studied, as patients seemed to gain benefit irrespective of the duration of application.

5.3.2 Oswestry low back questionnaire

There was a significant decrease over time in all three groups **(Figures 4.2, 4.5 and 4.8),** with group one achieving $p < 0.001$, group two achieving $p = 0.003$ and group three achieving a $p = 0.001$ outcome**.** There were no time point intervals other than the baseline and the final readings, therefore, interval discussions are not possible for this outcome measure, which in turn limits comparison to the work of Lara-Palomo et al. (2012).

When compared to the literature, these results corroborate the work of Albornoz-Cabello et al. (2016), who noted a significant improvement on the OLBQ (**Table 2.9**). However, they used 10 sessions of IFC for a 25 minute time interval over a period of two weeks; which is a significantly higher intervention application when compared to this study. The results for the OLBQ also concur with Lara-Palomo et al., (2012) who stated that there was a significant reduction noted in the OLBQ. Similar to Albornoz-Cabello et al., (2016), the study by Lara-Palomo et al., (2012) consisted of 20 treatments over 10 weeks. Therefore, by implication these comparisons seem to imply that the outcomes for IFC application can be achieved through the application of fewer treatments over shorter intervention periods (e.g. three weeks).

The inter-group analysis revealed that the three groups showed similar positive trends with regard to the change over time, there were parallel to each other **(Figure 4.11);** group one noted a reduction of 11.9 points, group two 11.7 points and group three 12.8 points. It would seem that the application of IFC resulted in a relatively equal reduction of disability across all three groups, regardless of the duration of intervention application.

The trend in the improvement of the participants' activities of daily living reporting may suggest the following:

- Those with a sudden immediate reduction in pain (**Figure 4.1**), as noted on the NRS-101 and due to the physiological block mechanism, are likely to report on average in this study an 11.9-point improvement in their activities of daily living (**Table 4.11**). By contrast, those that had lesser pain reduction due to only central modulation (**Figure 4.7**), as noted on the NRS-101 reported an improvement of 12.8 points on the OLBQ (**Table 4.11**). This is a contradiction in terms, in that those who reported lesser pain improvement (NRS-101) also reported a higher ability to participate in activities of daily living (OLBQ).
- This assertion could be aggregated for group two, where the NRS-101 outcome was found to lie between groups one and three (**Figure 4.4**) and yet the OLBQ outcomes (**Table 4.11**) showed the lowest improvement (11.7 points).

This may be related to a balance between the participant's perception of treatment and an association between the length or duration of treatment and the impact on their physical ability versus their pain outcomes (Wand et al., 2004). Therefore, the longer the treatment, the better their post treatment ability irrespective of pain measures and the shorter their treatment, the lower their improvement in the OLBQ. The middle group, knowing that they were not being "short changed" on treatment, but were also not receiving the full treatment, would potentially have been ambivalent in their responses (Jamison, 1998; Richardson, 2007) and potentially more accurate in their recording of the outcomes. In addition, another influencing factor may have been the lack of stratification of the patients in this study in terms of the length of time with which they had been suffering from LBP. This may have influenced the outcome of the study, by either detracting from or enhancing the results (Foster et al., 2008). An example would be that patients who had had LBP for longer would have potentially preferred the longer treatment based on the perception that this would be most beneficial (Jamison, 1998; Richardson, 2007; Foster et al., 2008). Therefore, if such a patient did present as the majority in group three, they would have reported improved outcomes based on their perception even though their pain levels did not necessarily improve to the same extent. The converse would be true of group one.

In terms of the clinical application of the results of this outcome, it is noted that there is debate in the literature about the minimally clinically important difference with regards to the OLBQ. If the suggestions from Copay et al. (2008) are applied then only group three shows a change of 12.8 and would therefore qualify as meeting the MCID benchmark; indicating that the application of the 30 minute IFC protocol would have clinically beneficial outcomes for patients

in terms of their activities of daily living. However, if we applied the standards of Schwind et al. (2013), who suggested and required a more conservative 20-point change, then none of the groups in this study meet their benchmark. In terms of this study and the discussions on the influences such as perception and patient preference, it may therefore be more realistic to apply the suggestions by Schwind et al. (2013), noting that the OLBQ did not achieve clinical significance, even though statistical significance was attained.

5.4 OBJECTIVE DATA ANALYSIS

The algometer was consistently applied by the RA, to the same point at the first, third (before treatment commenced) and at the fourth consultation.

The trend in the algometer readings showed improvements across all three groups (group one: $p = 0.086$, group two: $p = 0.046$, group three: $p = 0.034$). This, however, did not show any significant improvement when the inter-group analysis was performed. These results concur with Fuentes et al. (2014) and Corrêa et al. (2016) who also noted a significant improvement in pain pressure threshold over the period of their studies.

When reviewing the NRS-101 outcomes and physiological principles provided in the literature, in the context of the algometer outcomes, it seems possible that the group one (15 minutes of intervention application) participants only had a physiological block (peripheral modulation) stimulated that reduced the nerve conduction (Venancio et al., 2013). This means that the participants would not have had the benefit of the endorphin release and close of the small C-fibre tracts (McManus et al., 2006), in addition to the benefit of the endorphin stimulation of blood flow with the concomitant reduction in oedema and nerve sensitising substances (Noble et al., 2000a, 2000b, 2001). As a result it would be expected that this group had the least improvement in terms of the change in pressure threshold over time (1.5kg/cm^2, compared to 1.8 kg/cm^2 and 1.9 kg/cm^2 for group three and two, respectively).

The effects for group two and three are similar as they would both have had the central modulation mechanisms stimulated by virtue of the duration of the treatment intervention (Noble et al., 2000a, 2000b, 2001). Thus, they would both have had an increase in blood flow, a reduction in oedema and a reduction in nerve sensitising substances. Their improvement however, may have been limited by muscle fatigue (Youn et al., 2016), which would have decreased the ability to measure only changes due to the IFC, as muscle fatigue has the ability to cause myofascial trigger points (Chaitow and DeLany, 2000) which are responsive to algometry readings.

In addition, the participants who scored the most improvement in the OLBQ was group three, which indicated that they were also more active. This implies that this group is likely to have had the potential to develop delayed onset muscle stiffness if they were utilising muscles to a greater degree (which would normally have been inhibited by pain) (Chaitow and DeLany, 2000; Travell and Simons, 1983). Therefore, this may explain why group three did not improve to a greater extent than group two, who had a lesser improvement recorded on the OLBQ (**Figure 4.12**).

Clinically, both group two and three attained clinically significant levels (1.9 kg/cm^2 and 1.8 kg/cm^2) compared to group one (1.5kg/cm^2). Therefore, it would stand to reason that a longer duration application of IFC would benefit the participant's pain threshold as measured by the algometer.

5.5 CONCLUSION

Based on the results of this study there was:

- A statistically and clinically significant improvement of subjective pain rating across all three consultations.
- A statistically and very limited clinically significant improvement for the OLBQ (only group three when non conservative measures are used as a benchmark).
- A statistically and clinically significant improvement of pain threshold for groups two and three, but not group one.

It seems evident that the use of the 15 minute IFC application has limitations in terms of the of pain pressure threshold (algometry) outcomes and activities of daily living and improving activities of daily living (OLBQ) even though pain recordings on the NRS-101 were significantly different from the baseline to the final readings.

With the application of the 20 or 30 minute IFC intervention, it would seem that group two has the best outcomes in terms of perceived pain (NRS-101) and algometry measures, but not the best outcomes for activities of daily living (OLBQ). This is in contrast to group three that had improved outcomes over group two in only the activities of daily living category (OLBQ readings). This latter outcome, may have been influenced by the perception of the duration of treatment length "making the participant better".

Therefore, based on this study, the pragmatic outcome would suggest a 20 minute IFC application seems to benefit the patient the most; implying that the hypothesis for this study is

not supported by the statistical outcomes obtained. This may be based on the limitations that this study had, which are considered in the next section.

5.6 LIMITATIONS OF THE STUDY

- To consistently identify participants with a similar root origin of their LBP would have required additional clinical measures or special tests that were outside of the budgetary allocation for this study. This may have improved the homogeneity of the participants and aligned to a greater degree with the requirements of utilising specific patient populations (as would be recognised in the use of clinical predication rules) (Flynn et al., 2002). Thus, this study relied heavily on clinical symptoms and signs, which increases the variance and decreases homogeneity of participants. This would also align with the concept of participant stratification in terms of the length of time for which they had had LBP and not just an inclusion that determined the length of their current episode of LBP.
- In terms of the outcome measures; measures with regards to the physiological responses of the patient to treatment (e.g. serum endorphins, nerve conduction studies) would have strengthened the study by supporting the literature that was utilised to explain the results.
- In terms of the perception of participants, it would have assisted in interpreting the data more accurately if the study had recorded and reported on the participants' perception of care, care duration and expectation.
- Analogue instrumentation was utilised in this study instead of digital instrumentation. This may have led to an increased chance of error in reading and recording the. An error in parallax may have been observed during algometer measurements despite all efforts to try to minimise errors.
- As has been reported in the literature and in previous studies, mismatching the measurement to the time interval may result in the possibility that the participants did not improve when in fact the measurement tool is not sensitive enough or appropriate to measure the change (Noble et al., 2000a; Noble et al., 2000b; Noble et al., 2001).

CHAPTER SIX

CONCLUSION AND RECOMMENDATIONS

6.1. CONCLUSION

The primary aim of this study was to investigate the effect of IFC using variable time intervals for the treatment of CLBP.

Based on the results of this study there was:

- A statistically and clinically significant improvement of subjective pain rating across all three consultations. Therefore the null hypothesis is rejected for this outcome measure, as the post-hoc tests indicated that the 15 minute and 30 minute groups differed significantly from each other ($p = 0.044$).
- A statistically and very limited clinically significant improvement for the OLBQ (only group three when non conservative measures are used as a benchmark). Therefore the null hypothesis is not rejected for this outcome measure.
- A statistically and clinically significant improvement of pain threshold for groups two and three, but not group one. Therefore, the null hypothesis is not rejected for this outcome measure.

The results of the study revealed that regardless of the three time intervals used to treat CLBP, all three groups showed significant improvements in the outcome measures assessed. This study shows that the actual treatment times are insignificant in terms of the outcome measures assessed.

The alternate hypothesis (H_a) that was set at commencement of the study stated that the 20-minute application of IFC would be statistically significant in improving CLBP *($p > 0.05$)* when compared to the 15 and 30 minute groups. This H_a was not proven and therefore rejected as all three time intervals were shown to be effective in terms of subjective and objective outcomes.

6.2. RECOMMENDATIONS

The following recommendations may be beneficial for further studies in this field:

- A similar study should be conducted on a larger sample size to determine the generalisability of the results in patients who present with CLBP.
    - With increased sample size, there needs to be increased homogeneity of patients in terms of their presenting low back pain.
    - There needs to be homogeneity of patients in terms of gender and age spread between the groups – perhaps even the intent of utilising a stratification table for ensuring this would allow for negating the impact of these variables on the outcomes of future studies.
- A placebo group should be considered for future studies as a comparative measure to add further validity to the study.
- Future studies should focus on using IFC (i.e. a standard treatment protocol) on patients with different types of low back pain (i.e. acute, subacute, chronic, acute on chronic or low back pain with leg pain versus low back pain without leg pain or groups allocated by duration for which low back pain had been present since initial onset). This would assist in determining clinical prediction rules for different groups of low back pain patients and may also highlight reasons for the variable use of treatment settings in different patient groups.
- In terms of outcomes measurements, a one-month follow-up consultation after the final treatment should be included so as to compare the long-term effects of the treatment therapies. This inevitably means ensuring that there are multiple time points at which measures are taken to allow for determining the neurological effect of the intervention and thus the physiological manifestations (clinical outcomes) that a clinical trial would measure.
- The use of nerve conduction studies and / or serum endorphin levels would help support the previous bullet point by underscoring the mechanism of action of the IFC within particular groups and at particular intervals. The use of these objective measures may also assist in substantiating the more subjective patient outcomes utilised in any clinical study focussing on the IFC.
- Digital instrumentation may also improve the outcomes of a future clinical trial and reduce researcher / assessor bias.
- An additional factor that may also have influenced the outcome of this study was muscle fatigue (Youn et al., 2016). The implication of this is that the muscle fatigability may be related to the duration for which the participants have had CLBP. Therefore, it may be necessary in future studies to standardise the treatment at a set frequency and

duration and vary the durations for which patients have experienced acute LBP, subacute LBP, chronic LBP and acute on chronic LBP and variations in-between. This may allow for the determination of the effect of the pain on muscle fatigue along with determining the most effective duration for specific subgroups of patients.

- Thus the results for this study should be read carefully as there was no stratification of the patients as would have been preferable based on the clinical predication rules (Flynn et al., 2002). There was no recording of the patients' perception as they entered the study, so it was not possible to control for perception influencing the outcomes in terms of the OLBQ. Future studies should look at incorporating these two strategies in order to improve the rigour of their studies and allow for them to control for confounders that were not considered in this study.

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LIST OF APPENDICES

APPENDIX A_1

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site
Gate 8, Ritson Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2900
Fax: 031 373 2407
Email: lavishad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

29 September 2015

IREC Reference Number: **REC 121/15**

Mr A Abdul Carim
13a Beaumont Road
Isipingo Beach
Isipingo

Dear Mr Abdul Carim

The effect of Interferential Current time frame variations in the treatment of chronic low back pain

I am pleased to inform you that Provisional Approval has been granted to your proposal REC 121/15 subject to:

- Obtaining and submitting the necessary gatekeeper permission/s to the IREC.

Full approval is subject to meeting the above condition.

The Proposal has been allocated the following Ethical Clearance number **IREC 117/15.** 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
2015 -09- 29
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

APPENDIX A_2

Institutional Research Ethics Committee
Faculty of Health Sciences
Room MS 49, Mansfield School Site
Gate 8, Ritson Campus
Durban University of Technology

P O Box 1334, Durban, South Africa, 4001

Tel: 031 373 2900
Fax: 031 373 2407
Email: lavishad@dut.ac.za
http://www.dut.ac.za/research/institutional_research_ethics

www.dut.ac.za

8 October 2015

IREC Reference Number: **REC 121/15**

Mr A Abdul Carim
13a Beaumont Road
Isipingo Beach
Isipingo
4133

Dear Mr Abdul Carim

The effect of Interferential Current time frame variations in the treatment of chronic low back pain

The Institutional Research Ethics Committee acknowledges receipt of gatekeeper permission from Professor Moyo.

Please note that Full Approval is granted to your research proposal. You may proceed with data collection.

Yours Sincerely,

[redacted]

Professor J K Adam
Chairperson: IREC

DUT DURBAN UNIVERSITY OF TECHNOLOGY
2015 -10- 08
INSITUTUTIONAL RESEARCH ETHICS COMMITTEE
P O BOX 1334 DURBAN 4000 SOUTH AFRICA

APPENDIX B

Do you have low back pain that has been present for more than 6 weeks?

If you answered yes, you may qualify to take part in a study at the Chiropractic Clinic (Durban University of Technology)

Contact: Ahmed Abdul Carim on 0726786698

Or

0313732205

APPENDIX C

MEMORANDUM

To : Prof Puckree
Chair : RHDC

Prof Adam
Chair : IREC

From : Dr Charmaine Korporaal
Clinic Director : Chiropractic Day Clinic : Chiropractic and Somatology

Date : 13.03.2015

Re : Request for permission to use the Chiropractic Day Clinic for research purposes

---

Permission is hereby granted to :

Mr Ahmed Abdul Carim (Student Number: 20602282)

Research title : "An investigation into the effect of Interferential Current in the treatment of chronic low back pain using variable time intervals".

Mr Abdul Carim, is requested to submit a copy of his RHDC / IREC approved proposal along with proof of his MTech:Chiropractic registration to the Clinic Administrators before he starts with his research in order that any special procedures with regards to his research can be implemented prior to the commencement of him seeing patients.

Thank you for your time.

Kind regards

Dr Charmaine Korporaal

Clinic Director : Chiropractic Day Clinic : Chiropractic and Somatology

Cc: Mrs Pat van den Berg : Chiropractic Day Clinic
Dr L O'Connor : Research co-ordinator
Dr D Varatharajullu : Research supervisor

APPENDIX D

Date: _____

Name of Participant: _____

Contact number: _____

Included/excluded from the study? _____

	Question	**Required Answer**
1	Would you mind me asking you a few simple medical questions to ensure that you have a high likelihood of meeting the inclusion criteria for the study?	**No**
2	"How old are you?"	**18 – 45 years of age**
3	"Do you suffer from any of the following: Heart disease, diabetes, hypertension or any other blood vessel disease?"	**No**
4	Are you currently taking any medication?"	**No**
5	"Do you have a cardiac pacemaker?" (Vizniak, 2007)	**No**
6	"Do you have any mental impairment?" (Vizniak, 2007)	**No**
7	"Do you have any metal rods, plates or other assistive devices that have been implanted?"	**No**
8	"Do you have any open wounds or any recent scar tissue over the low back?"	**No**
9	If female – "Are you pregnant or do you suspect that you may be pregnant?" or "have you skipped a period?"	**No**
10	Now that you have met the inclusion criteria, based on this telephonic screen, would you be prepared to bring your ID document to the clinic on your first visit	
OR 10	Thank you for your telephonic participation, but you do not seem to meet my inclusion criteria and it is likely that you will not be eligible for my study	

APPENDIX: E

Date: _____

Dear Mrs. Linda Twiggs

Would you be willing to assist with patient randomization once you have received the randomization table from the statistician?

Thank you kindly

Signature of Mrs. Linda Twiggs (student administrator): _____

Witness name and signature: _____

Ahmed Abdul Carim (researcher): _____

Appendix F

LETTER OF INFORMATION

Welcome to my study, thank you for agreeing to participate

Title of the Research Study: "The effect of Interferential Current treatment duration on chronic low back pain."

Researcher: Mr Ahmed Abdul Carim (B.Tech: Chiropractic)
Supervisor: Dr Desiree Varatharajullu (M.Tech: Chiropractic)

Brief Introduction and Purpose of the Study:

There are many ways to treat low back pain. Chiropractors often use manual therapy, and electrotherapy. Electrotherapy consists of passing electrical current through the body via electrodes in a very safe manner. Interferential current (IFC) is an example of electrotherapy that is easy to apply and achieves pain control. However, there is limited clinical research to support its use, particularly in terms of how long it should be applied. The main objective and purpose of this study is to determine the best treatment time of IFC in chronic low back pain (CLBP) patients. This randomised single blinded controlled clinical trial will be carried out at the Durban University of Technology Chiropractic Day Clinic.

Outline of the Procedures:

An appointment will be made at the DUT Chiropractic clinic. The first appointment will be a two hours long. During your first consultation, you will be asked to read this letter and sign agreement to participate in this study. You will also be given an opportunity to ask any questions. Thereafter, you will be asked to fill in a questionnaire to measure the extent to which your low back pain affects your life. The researcher will then assess your condition by means of a full case history, a physical examination and a lumbar spine regional examination. This assessment will assess your compliance with the inclusion and exclusion criteria of this study.

If you qualify to be included in the study, you will be randomly allocated into one of three intervention groups. You will then be asked to put on a clinic gown and a pair of shorts. (These items will be provided) and you will then be asked to lie on your stomach. Your name will then be checked on the list to see which group you were allocated to. The relevant treatment will then be performed. You will be given three IFC treatments over a period of two weeks, with the IFC placed on your low back either for 15 minutes, 20 minutes and 30 minutes depending on which group you fall into. Please do not take any muscle relaxants, NSAIDs, or pain medication for the duration of this study. Measurements using a pain measurement device will be taken at the initial, third and final consultation. At the third consultation you will be given the same questionnaire that was presented to you on your first visit to fill out. This will conclude the study and you will be thanked and allowed time to leave.

The benefits of IFC include:
Relief of pain, Stimulation of muscle, increased local blood flow and reduction of oedema.

Risks or Discomforts to the Participant:
You may feel drowsy and fall asleep due to the known effects of IFC. Some patients may also report nausea and fatigue after treatment, which is normal and transient (does not stay for longer than a few hours) in nature.

Benefits:
You will be receiving a treatment modality (IFC) which has previously been used for chronic low back pain. From this study the researcher will be completing a master's thesis.

Reason/s why the Participant May Be Withdrawn from the Study:
You may be withdrawn from the study, if you do not show up for the appointment, if you have an unexpected adverse reaction to the treatment, or if you are involved in an accident or contract /develop a condition that is a stated contra-indication for the application of the IFC modality
Additionally you may withdraw at any time from the study. Your withdrawal will not result in any negative consequences for you from the DUT Chiropractic Clinic or any of its agents.

Remuneration:
There will be no payment due to you based on your participation in the study.

Costs of the Study:
There will be no costs to be borne by you due to your participation in the study.
Confidentiality:

Only the researcher, supervisor and reception staff (as necessary to draw your file) will have access to the personal information of the participant. Confidentiality will be maintained at all times and no personal information will be used in the write up of the dissertation. After a period of five years the data collected will be destroyed through shredding.

Research-related Injury:

The injury will need to be reported to the IREC, as the parent body that oversees the wellbeing of research participants. The DUT chiropractic clinic will bear the costs, should there be an adverse reaction or an injury.

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

Head of Department: Dr. A. Docrat, Contact number: 031 373 2589.

Please contact the researcher, Ahmed Abdul Carim on (0726786698), Supervisor: Dr Desiree Varatharajullu (0313732533) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof S. Moyo on (031) 373 2382 or dvctip@dut.ac.za.

CONSENT : Statement of Agreement to Participate in the Research Study:

I hereby confirm that I have been informed by the researcher, Mr Ahmed Abdul Carim, about the nature, conduct, benefits and risks of this study - Research Ethics Clearance Number: REC117/15,

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 / Right Thumbprint

I, Mr Ahmed Abdul Carim 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 G

DUT DURBAN UNIVERSITY OF TECHNOLOGY | DEPARTMENT OF CHIROPRACTIC AND SOMATOLOGY

CHIROPRACTIC PROGRAMME

CHIROPRACTIC DAY CLINIC CASE HISTORY

Patient: _____ Date: _____

File #: _____ Age: _____

Sex: _____ Occupation: _____

Student: _____ Signature _____

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: Signature:

Case History:

Examination:
Previous: Current:

X-Ray Studies:
Previous: Current:

Clinical Path. lab:
Previous: Current:

CASE STATUS:

PTT: Signature: Date:

CONDITIONAL:
Reason for Conditional:

Signature: Date:

Conditions met in Visit No: Signed into PTT: Date:

Case Summary signed off: Date:

Student's Case History:

1. **Source of History:**

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

3. **Present Illness:**

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

4. **Other Complaints:**

5. **Past Medical History:**

General Health Status

Childhood Illnesses

Adult Illnesses

Psychiatric Illnesses

Accidents/Injuries

Surgery

Hospitalizations

6. Current health status and life-style:

Allergies

Immunizations

Screening Tests incl. x-rays

Environmental Hazards (Home, School, Work)

Exercise and Leisure

Sleep Patterns

Diet

Current Medication
Analgesics/week:
Other (please list):

Tobacco
Alcohol
Social Drugs

7. Immediate Family Medical History:

Age of all family members
Health of all family members
Cause of Death of any family members

	Noted	Family member		Noted	Family member
Alcoholism			Headaches		
Anaemia			Heart Disease		
Arthritis			Kidney Disease		
CA			Mental Illness		
DM			Stroke		
Drug Addiction			Thyroid Disease		
Epilepsy			TB		
Other (list)					

8. Psychosocial history:

Home Situation and daily life
Important experiences
Religious Beliefs

9. Review of Systems (please highlight with an asterisk those areas that are a problem for the patient and require further investigation)

General

Skin

Head

Eyes

Ears

Nose/Sinuses

Mouth/Throat

Neck

Breasts

Respiratory

Cardiac

Gastro-intestinal

Urinary

Genital

Vascular

Musculoskeletal

Neurologic

Haematological

Endocrine

Psychiatric

Appendix H

CHIROPRACTIC PROGRAMME

PHYSICAL EXAMINATION: SENIOR

Patient Name:			**File no:**	**Date:**	
Student:		**Signature:**			
VITALS:					
Pulse rate:			Respiratory rate:		
Blood pressure:	R	L	Medication if hypertensive:		
Temperature:			Height:		
Weight:	Any recent change?	Y / N	If Yes: How much gain/loss	Over what period	

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

SYSTEM SPECIFIC EXAMINATION:
CARDIOVASCULAR EXAMINATION
RESPIRATORY EXAMINATION
ABDOMINAL EXAMINATION
NEUROLOGICAL EXAMINATION
COMMENTS
Clinician: **Signature:**

Appendix I

DUT DURBAN UNIVERSITY OF TECHNOLOGY

DEPARTMENT OF CHIROPRACTIC AND SOMATOLOGY

CHIROPRACTIC PROGRAMME

REGIONAL EXAMINATION
LUMBAR SPINE AND PELVIS

Patient: _____ File#: _____ Date: _____

Student: _____ Clinician: _____

STANDING:

Posture– scoliosis, antalgia, kyphosis
Body Type
Skin
Scars
Discolouration

Minor's Sign
Muscle tone
Spinous Percussion
Schober's Test (6cm)
Bony and Soft Tissue Contours

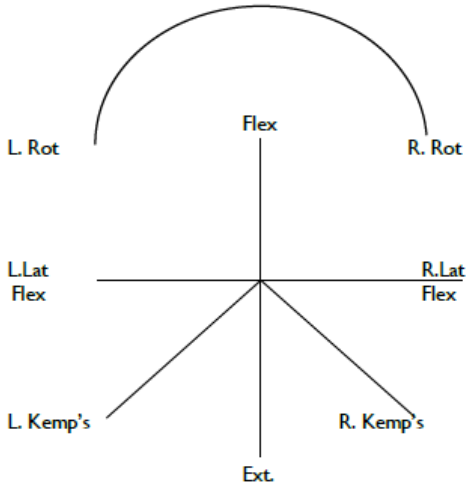
GAIT:

Normal walking
Toe walking
Heel Walking
Half squat

ROM:

Forward Flexion = 40-60° (15 cm from floor)

Extension = 20-35°
L/R Rotation = 3-18°
L/R Lateral Flexion = 15-20°



Which movement reproduces the pain or is the worst?

- Location of pain
- Supported Adams: Relief? (SI)
- Aggravates? (disc, muscle strain)

SUPINE:

Observe abdomen (hair, skin, nails)
Palpate abdomen\groin
Pulses - abdominal
- lower extremity
Abdominal reflexes

		Degree	LBP?	Location	Leg pain	Buttock	Thigh	Calf	Heel	Foot	Braggard
SLR	**L**										
	R										

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

SITTING:

Spinous Percussion
Lhermitte

Valsalva

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

SLUMP 7 TEST											
	L										
	R										

LATERAL RECUMBENT:	**L**	**R**
Ober's		
Femoral n. stretch		
SI Compression		

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

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

NON ORGANIC SIGNS:

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

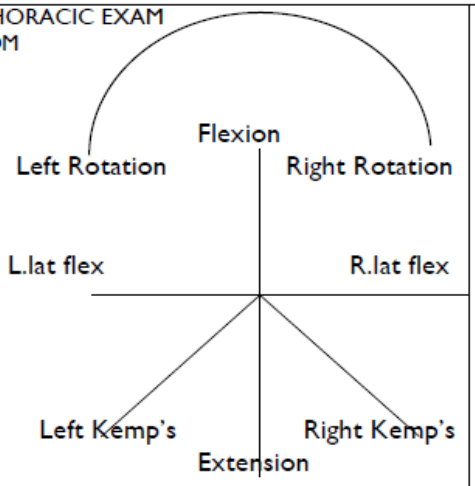
NEUROLOGICAL EXAMINATION

Fasciculations						
Plantar reflex						
level	**Tender?**	**Dermatomes**		**DTR**		
		L	**R**		**L**	**R**
T12				Patellar		
L1				Achilles		
L2						
L3				Proprioception		
L4						
L5						
S1						
S2						
S3						

MYOTOMES

Action	Muscles	Levels	L	R	
Lateral Flexion spine	Muscle QL				
Hip flexion	Psoas, Rectus femoris				5+ Full strength
Hip extension	Hamstring, glutes				4+ Weakness
Hip internal rotation	Glutmed, min, TFL, adductors				3+ Weak against grav
Hip external rotation	Gluteus max, Piriformis				2+ Weak w\o gravity
Hip abduction	TFL, Glut med and minimus				1+ Fascic w\o gross movt
Hip adduction	Adductors				0 No movement
Knee flexion	Hamstring,				
Knee extension	Quad				W - wasting
Ankle plantarflexion	Gastrocnemius, soleus				
Ankle dorsiflexion	Tibialis anterior				
Inversion	Tibialis anterior				
Eversion	Peroneus longus				
Great toe extensor	EHL				

BASIC THORACIC EXAM
Passive ROM



History :

Orthopedic assessment:

BASIC HIP EXAM

History
ROM: Active
Passive: Medial rotation: A) Supine (neutral) If reduced
- hard \ soft end feel

B) Supine (hip flexed):
- Trochanteric bursa

MOTION PALPATION AND JOINT PLAY	L	R
Thoracic Spine		
Lumbar Spine		
Sacroiliac Joint		

Appendix J

Statement of Agreement to Participate in the Research Study as a Research Assistant:

I ……....., ID number…… voluntarily agree to participate in this study: **"The effect of Interferential Current treatment duration on chronic low back pain."**, as a research assistant**.**

I will ensure that I maintain a level of confidentiality with regards to the research data that is collected.

Research assistant's name (print)
…….

Research assistant's signature: ……

Date: ……

Researcher's name (print)……..

Signature: …….

Date: ……

Witness name (print)……..

Signature……

Date: …….

Appendix K

Patient's Name_____ Number_____ Date_____

LOW BACK DISABILITY QUESTIONNAIRE (REVISED OSWESTRY)

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

Section 1 - Pain Intensity

- † I can tolerate the pain without having to use painkillers.
- † The pain is bad but I can manage without taking painkillers.
- † Painkillers give complete relief from pain.
- † Painkillers give moderate relief from pain.
- † Painkillers give very little relief from pain.
- † Painkillers have no effect on the pain and I do not use them.

Section 2 -- Personal Care (Washing, Dressing, etc.)

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

Section 3 – Lifting

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

Section 4 – Walking

- † Pain does not prevent me from walking any distance.
- † Pain prevents me from walking more than one mile.
- † Pain prevents me from walking more than one-half mile.
- † Pain prevents me from walking more than one-quarter mile
- † I can only walk using a stick or crutches.
- † I am in bed most of the time and have to crawl to the toilet.

Section 5 -- Sitting

- † I can sit in any chair as long as I like
- † I can only sit in my favorite chair as long as I like
- † Pain prevents me from sitting more than one hour.
- † Pain prevents me from sitting more than 30 minutes.
- † Pain prevents me from sitting more than 10 minutes.
- † Pain prevents me from sitting almost all the time.

Scoring: Questions are scored on a vertical scale of 0-5. Total scores and multiply by 2. Divide by number of sections answered multiplied by 10. A score of 22% or more is considered significant activities of daily living disability.
(Score__x 2) / (____Sections x 10) = _____ %ADL

Section 6 – Standing

- † I can stand as long as I want without extra pain.
- † I can stand as long as I want but it gives extra pain.
- † Pain prevents me from standing more than 1 hour.
- † Pain prevents me from standing more than 30 minutes.
- † Pain prevents me from standing more than 10 minutes.
- † Pain prevents me from standing at all.

Section 7 -- Sleeping

- † Pain does not prevent me from sleeping well.
- † I can sleep well only by using tablets.
- † Even when I take tablets I have less than 6 hours sleep.
- † Even when I take tablets I have less than 4 hours sleep.
- † Even when I take tablets I have less than 2 hours sleep.
- † Pain prevents me from sleeping at all.

Section 8 – Social Life

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

Section 9 – Traveling

- † I can travel anywhere without extra pain.
- † I can travel anywhere but it gives me extra pain.
- † Pain is bad but I manage journeys over 2 hours.
- † Pain is bad but I manage journeys less than 1 hour.
- † Pain restricts me to short necessary journeys under 30 minutes.
- † Pain prevents me from traveling except to the doctor or hospital.

Section 10 – Changing Degree of Pain

- † My pain is rapidly getting better.
- † My pain fluctuates but overall is definitely getting better.
- † My pain seems to be getting better but improvement is slow at the present.
- † My pain is neither getting better nor worse.
- † My pain is gradually worsening.
- † My pain is rapidly worsening.

Comments_____

Reference: Fairbank, Physiotherapy 1981; 66(8): 271-3, Hudson-Cook. In Roland, Jenner (eds.), Back Pain New Approaches To Rehabilitation & Education. Manchester Univ Press. Manchester 1989: 187-204

Appendix L

Numerical Rating Scale - (NRS-101) Questionnaire

Date: ___________________ File no:______________

Visit no:_______

Participant's name:____

Please indicate on the line below, the number between 0 and 10 that best describes the pain you experience **when it is at its worst**. A zero (0) would mean "no pain at all", and ten (10) would mean "pain as bad as it could be". Please write only **one** number.

0 1 2 3 4 5 6 7 8 9 10

____

No pain | Average pain | Worst pain

Please indicate on the line below, the number between 0 and 10 that best describes the pain you experience **when it is at its worst**. A zero (0) would mean "no pain at all", and ten (10) would mean "pain as bad as it could be". Please write only **one** number.

0 1 2 3 4 5 6 7 8 9 10

____

No pain | Average pain | Worst pain

Please indicate on the line below, the number between 0 and 10 that best describes the pain you experience **when it is at its worst**. A zero (0) would mean "no pain at all", and ten (10) would mean "pain as bad as it could be". Please write only **one** number.

0 1 2 3 4 5 6 7 8 9 10

____

No pain | Average pain | Worst pain

Appendix M

Participant's Code	Date	Initial Algometer Reading	Date	Second Algometer Reading	Date	Final Algometer Reading

Appendix N

CHIROPRACTIC PROGRAMME

Patient Name:			***File number:*** ***Page:***
Date:	***Visit:***	***Student:***	
Attending Clinician:			***Signature:***
S: *Numerical Pain Rating Scale (Patient)* Least 0 1 2 3 4 5 6 7 8 9 10 Worst		*Student Rating* ☐	***A:***
O:			***P:***
			E:
Special attention to:			***Next appointment:***
Date:	***Visit:***	***Student:***	
Attending Clinician:			***Signature:***
S: *Numerical Pain Rating Scale (Patient)* Least 0 1 2 3 4 5 6 7 8 9 10 Worst		*Student Rating* ☐	***A:***
O:			***P:***
			E:
Special attention to:			***Next appointment:***
Date:	***Visit:***	***Student:***	
Attending Clinician:			***Signature***
S: *Numerical Pain Rating Scale (Patient)* Least 0 1 2 3 4 5 6 7 8 9 10 Worst		*Student Rating* ☐	***A:***
O:			***P:***
			E:
Special attention to:			***Next appointment:***