

**The effectiveness of an ice pack, a menthol based cooling gel, a menthol based cooling gel with extracts and a placebo gel in the treatment of acute ankle sprain**

By

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A dissertation submitted to the Faculty of Health at the Durban University of Technology in partial compliance with the requirements for the Master's Degree in Technology: Chiropractic.

I, Shaun Michael Harper do declare that this dissertation is a representation of my own work in both conception and execution.

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## **DEDICATION**

*This dissertation is dedicated to:*

My Lord and Saviour Jesus Christ  
Through whom anything is possible

To my Mom and Dad, I cannot thank you enough for all your support in making this dissertation possible. I hope I have made you proud. Both of you have dedicated your lives to my education and my future. I could never have achieved anything without you, and am truly grateful for all that you have done for me

Mr William Wyndham Quinn. Founder of Healthtech Laboratories, who sadly passed away on 07/03/2010 before the completion of this dissertation. His commitment to his work and to his friends, as well as the volunteering he was involved in will be greatly missed. Williams love and devotion to his family will always be clearly remembered. His example of caring and determination lives as an inspiration to all who knew him.

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# **ABSTRACT**

## **Background**

Cryotherapy is commonly used to decrease pain, swelling and disability in acute injury. The most common form traditionally used is ice packs, with menthol based cooling gels being increasingly used by physicians in place of ice. More recently companies are experimenting with adding herbs containing anti-inflammatory properties to these menthol based gels to enhance their effectiveness. There is a paucity of literature comparing different forms of cryotherapy to one another, and more experiments are necessary to determine if cooling gels containing menthol and cooling gels with menthol and anti-inflammatory herbs are comparable to that of conventional ice pack cryotherapy.

## **Objectives**

To determine the relative effectiveness of an ice pack, a menthol based gel, a menthol based gel with herbal extracts (combination gel) and placebo gel in the treatment of an acute grade 1 or 2 inversion ankle sprains, in terms of subjective and objective measurements. Any adverse reactions were also noted.

## **Method**

A placebo controlled randomised, single blinded clinical trial (n=48) was conducted. Participants were randomly allocated into one of the four groups. Each group consisted of 12 people between the ages of 18 and 45. Each participant had a case history, physical and ankle examination prior to being accepted to ensure that they met the inclusion and exclusion criteria. On the initial consultation the respective treatments were administered and participants were instructed on how to apply the gel or ice pack, which they were required to utilise at home three times per day for 3 days. Those receiving the gels were blinded as to which gel they were receiving, all gels looked and smelt the same. On the 4th day the participants returned for data collection and were instructed to stop using the treatment and return 7 days later for further data collection.

Statistical analysis consisted of repeated measures of ANOVA and Bonferroni post hoc tests, with a  $p$ -value of  $<0.05$  considered statistically significant.

### **Results**

Intra-group and inter-group analysis showed that all four groups had statistically significant improvements in terms of subjective and objective measurements. The results of the study demonstrated that the effects produced by the two cooling gels containing menthol, are comparable with those of conventional/traditional ice pack cryotherapy in the treatment of acute grade 1 or 2 inversion ankle sprains. No adverse reactions were reported.

### **Conclusion**

This study found that all four treatment interventions were effective and safe in treating acute grade 1 and 2 inversion ankle sprains, however the ice pack and both cooling gel groups appear to statistically significantly improve treatment outcomes at a similarly higher rate when compared to the placebo gel group.

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# **Chapter One**

## **Introduction**

### **1.1 The problem and its setting**

Acute injury is common in the musculoskeletal system with the ankle being one of the most commonly injured sites in the body (Fong, Chan, Mok, Yung and Chan, 2009 and Hertel, 2002). The subtalar joint of the ankle is most often affected which results in the tearing of the anterior talofibular ligament (ATFL), which is the weakest of the lateral ankle ligaments and results in pain swelling and reduced mobility (Fong et al., 2009).

Acute injury management varies widely, with the focus being more on treating the symptoms of the injury (Denegar and Miller, 2002). Treatments that produce cold are known as cryotherapy modalities, and are usually the primary intervention for acute musculoskeletal injuries (Collins, 2008 and Hubbard, Aronson and Denegar, 2004) with various modes of cryotherapy being available (Bleakley, McDonough and MacAuley, 2004).

The purpose of applying cryotherapy after an acute injury is to reduce pain, and decrease swelling (Airaksinen, Kyrkland, Latvala, Kouri, Gronbled, and Kolari, 2003 and Knight, 1995). According to Collins (2008) and Wilkerson and Horn-Kingery (1993), there are few studies examining the effectiveness of different treatment methods on acute ankle sprains. This study aims to compare the overall effect of different modes of cryotherapy for pain relief, its effectiveness for reducing localised swelling as well as improved function.

Ice packs are the most frequently used form of cryotherapy, and are a popular and established method for treating acute soft tissue injuries (Airaksinen et al., 2003). According to Herrera, Sandoval, Camargo and Salvini (2010) it decreases pain, swelling and disability by decreasing tissue temperature, altering neuromuscular action and having an anti-inflammatory effect on the tissues being treated.

Other forms of cryotherapy include menthol gels (Airaksinen et al., 2003). Menthol when topically applied is believed to work on a similar principle as ice and produces similar physiological effects (Page, 2007), by stimulating the same cold sensing receptors as ice packs (Patel, Ishiujji and Yosipovitch, 2007). However, menthol only produces the sensation of cold without lowering the actual temperature of the tissue (Airaksinen et al., 2003 and McKemy, Neuhausser and Julius 2002).

Recently menthol gels have also been combined with herbal extracts containing anti-inflammatory properties. The mixture of herbs and menthol in these gels are thought to be superior to the effects of menthol alone (Quinnn, 2009). These combination cooling gels are readily available over the counter, although their efficacy against conventional ice has not yet been determined.

In this study, a placebo gel specifically designed to look the same as the other active gels but without the active ingredients, was used to determine the effectiveness of the other three treatments compared to the placebo group.

## **1.2 Aims and Objectives of the study**

This study aims to determine the relative effectiveness of an ice pack, menthol based cooling gel, menthol based cooling gel with herbal extracts and a placebo gel in the treatment of acute grade 1 and 2 inversion ankle sprains.

### **1.2.1 The first Objective**

To determine the effectiveness of each of the four treatments in terms of objective measurements.

Null hypothesis One: It is hypothesized that all four treatment groups will not show an improvement in terms of objective findings (Algometer and Figure of eight method).



### **1.2.2 The second Objective**

To determine the effectiveness of each of the four treatments in terms of subjective measurements.

Null hypothesis Two: It is hypothesized that all four treatment groups will not show an improvement in terms of subjective findings (VAS and Foot function index).

### **1.2.3 The third Objective**

To compare the four treatments in terms of the objective and subjective measurements.

Null hypothesis Three: It is hypothesized that all 4 treatments will not show improvement in terms of objective and subjective findings.

### **1.2.4 The fourth Objective**

To identify any adverse reactions that may be caused by the treatment methods.

Null hypothesis Four: It is hypothesized that there will be no adverse reactions to the administered treatments by the participants.

## **1.3 Limitations**

- 1) The subjective recordings of the responses by participants were received as honest reflections of how the participants were feeling at the time of recording.
- 2) Participants in the ice pack group were fully aware they were receiving an ice pack treatment because they could not be blinded against the cold.

# **Chapter Two**

## **Literature Review**

### **2.1 Introduction**

This chapter discusses cryotherapy, the different modes used in this study and their mechanism of action, and how they function to reduce pain and swelling after acute injury. This chapter also explains ankle sprains of the ankle joint complex and common treatments utilized for this condition.

### **2.2 Acute ankle sprain**

#### **2.2.1 Introduction**

The ankle joint complex is one of the most common sites for acute musculoskeletal injury (Fong et al., 2009; Hertel, 2002 and Barker, Beynnon and Renstron, 1997). Sprains account for 75% of these injuries (Barker et al., 1997), and are the most common injury in sports accounting for 14% of all sports related injuries (Fong et al., 2009). An analysis by Woods, Hawkins, Hulse and Hodson (2003) of ankle sprains sustained in football, found that ankle sprains accounted for 11% of all injuries over two seasons.

Holmer, Sondergaard, Konradsen, Nielsen and Jorgensen (1994) in a comprehensive prospective study of the incidence of lateral ankle and midfoot sprains in the general population, found that of the injuries treated, 45% were sports related, 20% occurred during play and 16% were work related. The overall sprain incidence was 7/1000 per year. Incidence was higher in the younger age groups and especially in young males, although after the age of forty the incidence becomes higher in women than men. With increasing age sport related ankle sprains become far less, with other daily activities dominating the cause of injury (Holmer et al., 1994).

The majority of ankle sprains are due to inversion (lateral) sprains occurring during plantarflexion of the ankle (Richards, 2007 and Woods et al., 2003) and involve the three parts of the lateral collateral ligament: The anterior talofibular ligament (ATFL) which accounts for 65% of inversion sprains is the most often injured (Richards, 2007). Medial ligament injuries are less likely to occur, and involve excessive eversion of the foot, caused mainly from a direct blow to the medial ankle region, or secondary to a wider foot stance as found in sports such as wrestling (Reid, 1992).

### 2.2.2 Anatomy and biomechanics of the ankle joint complex

The ankle joint complex is made up of three functional joints, the talocrural (ankle), subtalar and distal tibiofibular joints (Hertel, 2002). This joint complex is stabilized by how the articular surfaces, ligamentous and musculotendinous components work together (Hertel, 2002).

#### 2.2.2.1 Talocrural joint

The talocrural or ankle joint is a modified hinge type of synovial joint, which it is located between the distal ends of the tibia and fibula, and the superior part of the talus (Moore and Dalley, 1999 and Denegar and Miller, 2002). The talus is about 2.4mm wider anteriorly than posteriorly, and is concave from side to side. The lateral malleolus extends to about the level of the subtalar joint and is longer than the medial malleolus, which only extends halfway down the talus (Magee, 2002).

The talocrural joint allows mainly for plantarflexion and dorsiflexion (Moore and Agur, 2002). During foot dorsiflexion, the shape of the talus causes it to become wedged between the malleoli ("locked position"), which causes little to no inversion or eversion at the ankle joint, this allows for more ankle stability in dorsiflexion compared to when the foot is in plantarflexion where the talus moves into an "unlocked" position causing the ankle to become unstable (Magee, 2002).

According to Moore and Agur (2002) a fibrous capsule surrounds the ankle joint and provides stability. It is thin anteriorly and posteriorly but is reinforced each side by strong

ligaments. The fibrous capsule is reinforced laterally by the lateral collateral ligament, and reinforced medially by the stronger medial collateral ligament.

The lateral collateral ligament consists of three parts (Figure 2.1):

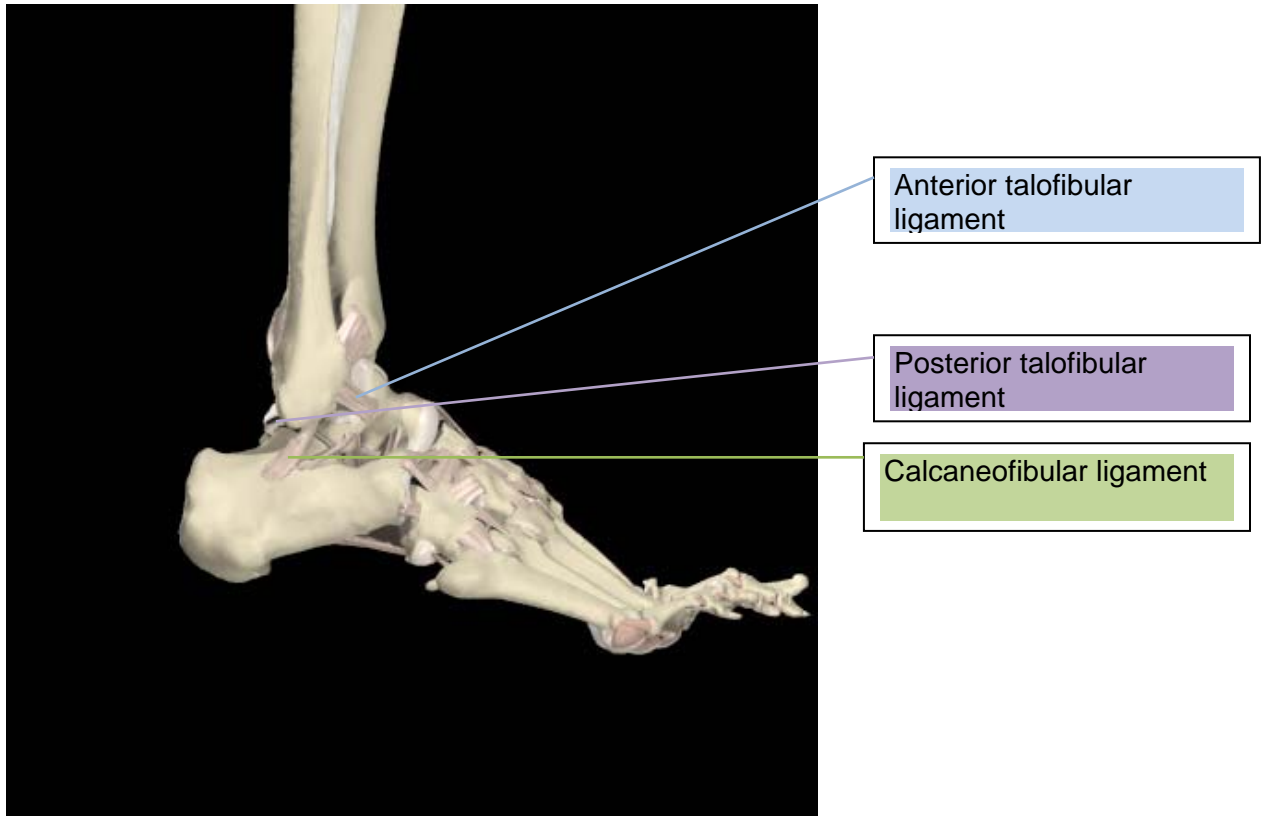
- The anterior talofibular ligament (ATFL): A weak flat band extending in an anteriomedially direction from the lateral malleolus to the neck of the talus.
- The posterior talofibular ligament (PTFL): The strongest of the lateral ligaments, is a thicker band that runs horizontally, medially and slightly posteriorly from the malleolar fossa to the lateral tubercle of the talus.
- The calcaneofibular ligament (CFL): A round cord that passes in a posteroinferiorly direction from the tip of the lateral malleolus to the lateral surface of the calcaneus (Moore and Agur, 2002).

These three lateral ligaments function in resisting inversion and internal rotation of the ankle (Moore and Dalley, 1999).

The medial collateral ligament has fibers that fan out from the malleolus and attach distally to the talus, calcaneus and navicular. These form the four parts of the ligament:

- The tibionavicular ligament,
- The anterior and posterior Tibiotalar ligaments,
- The tibiocalcaneal ligament.

These stronger medial ligaments stabilize the ankle during eversion and helps prevent partial dislocation of the joint (Moore and Dalley, 1999).



Interactive Foot and Ankle 2 © 2001 Primal Pictures Ltd

**Figure 2.1: Lateral foot and ankle ligaments**

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#### 2.2.2.2 Subtalar joint

The subtalar (talocalcaneal) joint is a synovial joint surrounded by an articular capsule. It is located where the talus articulates with the calcaneus, and allows for inversion and eversion movements of the foot (Moore and Agur, 2002 and Hertel, 2002). The ankle and subtalar joints work together as a functional unit in absorbing pressures placed on the foot and stabilizing the foot during movement (Reid, 1992).

#### 2.2.2.3 Distal tibiofibular joint

This fibrous joint helps stabilize the ankle by firmly holding the lateral malleolus against the lateral surface of the talus, which is essential for ankle stability when slight movement of the distal tibiofibular joint is needed to accommodate the talus during foot

dorsiflexion. The strong interosseous ligament is the main connection between the distal tibia and fibula, and the anterior and posterior tibiofibular ligaments strengthen and support the joint anteriorly and posteriorly (Moore and Agur, 2002 and Moore and Dalley, 1999).

#### 2.2.2.4 Arterial and nerve supply

The blood supply to the ankle joint comes from the fibular artery and malleolar branches of the anterior and posterior tibial arteries. The ankle joint is innervated by the tibial nerve, the deep and superficial fibular nerves, as well as the saphenous nerve (Moore and Agur, 2002 and Hertel, 2002).

### **2.3 Grading of ankle sprains**

As shown in table 2.1, ankle sprains are classified into three grades according to their severity of injury, with grade one injuries being less severe than grade three injuries. For the purpose of this study the West Point Ankle Sprain Grading System (Kaplan, 2005) was used.

**Table 2.1: West Point Ankle Sprain Grading System**

<b>Criteria</b>	<b>Grade 1</b>	<b>Grade 2</b>	<b>Grade 3</b>
<b>Location of tenderness</b>	Often only around the ATFL	ATFL or ATFL and CFL	ATFL, CFL and PTFL
<b>Edema and Ecchymosis</b>	Slight	Moderate	Diffuse
<b>Weight bearing ability</b>	Full or partial	Becomes difficult without crutches	Impossible without significant pain
<b>Ligament damage</b>	Stretched	Partial tearing	Complete ligament tear
<b>Instability</b>	None	None to slight	Definite instability

(Kaplan, 2005)

It is important to note however that pain and swelling are not always proportional to the amount of injury (Reid, 1992).

#### **2.4 Mechanism of injury of ankle sprains**

Inversion ankle sprains are usually the result of an excessive plantarflexion inversion injury caused when the foot strikes the ground (Ranawat and Positano, 1999 and Reid, 1992). Although, according to Hyde and Gengenbach (2007) the most common mechanism of injury is when there is plantarflexion, rotation and inversion of the ankle occurring all at once, usually when a person running in a straight line makes a sudden change in foot direction. This is made worse in patients with tight ankle ligaments, a cross over gait, as well as patients with poor balance and proprioception (Hyde and Gengenbach, 2007 and Fong et al., 2009). Most sprains are a result of contact injury of the ankle (Woods et al., 2003) occurring at the subtalar joint (Fong et al., 2009), and as a result the ATFL is usually the first ligament to be injured because it functions as the primary stabilizer of the ankle during plantarflexion (Ranawat and Positano, 1999).

Acute injury to an area results in an increase in local metabolism, which causes oxygen to be used up at a faster rate. As this oxygen is depleted the tissue cells begin to die, resulting in inflammation (Hubbard et al., 2004) contributing to the pain, swelling and joint dysfunction experienced by the patient (Denegar et al., 2002). Chemicals released from injured tissue cells result in pain by directly damaging nerves, and by pressure on uninjured nerves caused by localized swelling. This pain then results in muscle spasm which is the body's protective mechanism in preventing further injury (Knight, Brucker, Stoneman and Rubley, 2000).

Treatment should therefore aim to control pain, swelling and inflammation (Hubbard et al., 2004). However, even without treatment an acute ankle injury usually regains function after a few days or months depending on the severity of the injury (Hertel, 2002). In a systematic literature review by van Rijn, van Os, Bernsen, Luijsterburg, Koes and Bierma-Zeinstra (2008) on the clinical course of an acute ankle sprain, they noted

that after an ankle injury the pain naturally improves rapidly over the first 2 weeks and then at a slower rate after that. According to Reid (1992) the natural history of an ankle sprain depends on the grade, with grade 1 ankle sprains usually recovering anytime over a range of 2-10 days and grade 2 ankle sprains over a range of 10-30 days.

#### 2.4.1 Gate control theory

The perception of pain is controlled by the interaction between both pain transmitting and non pain transmitting neurons, where nerves that don't transmit pain signals can interfere with and prevent signals from pain transmitting fibers, decreasing the individuals perception of pain (Melzack and Wall, 1965). Perception of pain depends on the balance in activity of the large myelinated mechanoreceptive fibers (A-alpha and A-beta fibers) and the small myelinated and unmyelinated nociceptive fibers (A-delta and C fibers). The small fibers comprise of not only pain transmitting fibers but also thermoreceptive and mechanoreceptive fibers (Melzack and Wall, 1965).

### **2.5 Common treatment method for ankle sprains**

The goal for the treatment of acute ankle sprains is to limit tissue damage (Knight et al., 2000), control pain and spasm, and reduce the edema that occurs after an acute injury (Knight et al., 2000 and Ranawat and Positano, 1999).

The protocol for the treatment of an acute grade one or two ankle sprain consists of a period of protection, rest, ice, compression and elevation, commonly referred to by its acronym PRICE (Bleakley, O'Connor, Tully, Rocke, MacAuley and McDonough, 2007 and Ivans, 2006). This PRICE programme promotes fewer a faster recovery time, with fewer complications (Ranawat and Positano, 1999). As cryotherapy is the modality being investigated, the PRICE program was not followed in order to isolate the independent variable.



## **2.6 Cryotherapy**

### **2.6.1 Introduction**

Cryotherapy means “cold therapy” (Knight, 1995), or the use of any cold application for therapeutic purposes (Swenson, Sward and Karlsson, 1996 and Knight, 1995). Cryotherapy is one of the simplest and oldest modalities used to decrease swelling and control pain after acute injury, and considered the treatment of choice (Bleakley, McDonough and MacAuley, 2006 and Bleakley et al., 2004), with many variations in the timing of the therapy and modes available for use (Bleakley et al., 2004 and Hubbard et al., 2004).

Cryotherapy can be applied anywhere from ten to twenty minutes, two to four times a day, starting within the first few days of injury (Greenstein, 2007 and Kellett, 1986). Acute injury begins initially after injury and can last for several days (Gulur, Soldinger and Acquadro, 2007 and Reid, 1992), with cryotherapy usually being used up to a week after an injury (Fong et al., 2009). Cryotherapy is not only used in the acute phase of injury, but also throughout all treatment phases to prevent edema and inflammation (Knight et al., 2000 and Ranawat and Positano, 1999).

The physiological effects of cryotherapy when applied to the treatment area are (Hubbard et al., 2004 and Knight, 1995):

- A decrease in local metabolism,
- Localized neural inhibition,
- Localized decrease and later increase in circulatory effects,
- Localized decrease in inflammatory mediators.

According to Swenson et al. (1996) these physiological effects are due to the localized decrease in tissue temperature and relaxation of the muscles at the site of application, although according to Hubbard et al. (2004), its exact effect has not yet been fully established.

### 2.6.2 Cryotherapy mechanism of action

After an injury, the initial inflammatory response occurs, which includes vasodilation of blood vessels, resultant edema and stimulation of pain receptors. This response leads to pain, swelling and loss of function in the injured area (Knight, 1995 and Reid, 1992).

The application of cold reduces the tissue temperature, usually through conduction (Merrick, Jutte and Smith, 2003), producing a cold sensation which slows down the rate of chemical reactions and the demand for Adenosine Triphosphate (ATP) and thus decreases the cells demand for oxygen, leading to a longer tissue survival rate during hypoxia (Hubbard et al., 2004). This oxygen deprivation indirectly promotes neurovascularisation in both the reactive and regeneration phases of connective tissue healing (Reid, 1992).

The acute inflammatory phase after an injury can last several days (Gulur et al., 2007), so the decreases in metabolic and chemical reactions according to Knight (1995), are the most important effects of cold. Chemical reactions taking place during the inflammatory response are slowed down during cryotherapy, thereby decreasing inflammation and its associated pain (Cameron, 1999).

The analgesic effect is one of the main reasons cryotherapy is used when treating acute musculoskeletal injuries (Hubbard et al., 2004). It reduces nerve excitability and conduction velocity (Bleakley et al., 2004) in both sensory and motor nerves, with the greatest decrease in conduction velocity occurring in the pain transmitting A-delta fibers, as well as gating of pain transmission by cutaneous thermal receptors (Cameron, 1999). According to the gate control theory of Melzack and Wall (1965), the perception of pain is controlled by the interaction between both the small (A-delta and C fibers) pain transmitting (nociceptive) and large (A-alpha and A-beta fibers) non pain transmitting neurons (antinociceptive), where nerves that do not transmit pain signals can interfere with and inhibit signals from pain transmitting fibers, decreasing the individuals perception of pain (Melzack and Wall, 1965). This cold induced neural inhibition can last up to 30 minutes after application (Hubbard et al., 2004). In a randomized clinical trial (n=20) Hayward, Landorf and Redmonds (2006) found that a six minute ice application

prior to two lignocaine injections into the hallux significantly reduced the pain caused by the injections compared to the group not receiving ice application.

The resultant edema after an injury seems to control the amount of initial pain and the ability to restore normal range of motion (Reid, 1992), and is a significant factor in the recovery of ankle sprains (Ranawat and Positano, 1999). According to Reid (1992) decreasing the edema is the key to minimizing the pain caused from the injury. Cryotherapy when applied to the skin constricts cutaneous blood vessels at the site of application for as long as it is being applied (Cameron, 1999), with cryotherapy treatments continuing to decrease the rate of blood flow after application (Topp, Winchester, Sannes, Mink, Kaufman and Jacks, 2009 and Fiscus, Kaminski and Powers, 2005). This cold induced vasoconstriction is activated by two mechanisms. The direct mechanism where cold stimulates the smooth muscles of the blood vessel walls to contract, and the indirect mechanism where cold application decreases the production of vasodilator mediators and so reducing vasodilation (Cameron, 1999).

This resultant vasoconstriction reduces localized blood flow resulting in a reduced rate of inflammation, and together with the decreased metabolism, helps in limiting the pain associated with an acute injury (Cameron, 1999). This reduced blood flow also reduces intravascular fluid pressure, decreasing the amount of fluid moving into the interstitium of the body's cells, which leads to the decrease in swelling (Cameron, 1999). In a systemic review by Bleakley et al. (2004) it was noted that vasoconstriction of blood vessels was effective in decreasing pain and swelling immediately after application to one week after the injury.

For inflammation to be reduced and the beneficial effects of cryotherapy to take effect, the temperature should be reduced to between 10 to 15 degrees Celsius, which usually takes anywhere between 10 to 20 minutes to occur depending on tissue depth (Greenstein, 2007). However when cold is applied for longer periods of time such as 15 minutes or more, or the temperature reaches less than 10°C, a phenomenon known as

cold-induced vasodilation occurs, which increases blood flow to the area (Cameron, 1999).

According to Airaksinen et al (2003) the mechanisms by which we sense cold are poorly understood. Recently a family of sensory neurons, thought to be the primary transducers for sensing thermal stimuli in the mammalian somatosensory system (McKemy et al., 2002), have been discovered. These are collectively known as the transient receptor potential (TRP) channels. A member of this family of channels known as transient receptor potential melastatin 8 (TRPM8) is activated by cold temperatures and cooling compounds such as menthol (Bandell, Dubin, Petrus, Orth, Mathur, Hwang and Patapoutian, 2006; McKemy et al., 2002 and Peier, Moqrich, Hergarden, Reeve, Andersson, Story, Early, Dragoni, McIntyre, Brevan and Patapoutian, 2002). When cold or menthol is applied to the skin, it results in shifting the voltage of the cell membrane which activates an inward current, this inward current is carried by an influx of sodium ions through the TRPM8 channel. This together with the induced action potential induces voltage gated calcium ion entry (Mahieu, Owsianik, Verbert, Janssens, Smedt, Nilius and Voets, 2007; Voets, Owsianik, Janssens, Talavera and Nilius, 2007 and Reid, Babes and Pluteanu, 2002). After being activated, these sensory neurons send signals to the spinal cord and then to the brain, where the signals are deciphered to produce the sensation of cold (Dragoni, Guida and McIntyre, 2006).

### 2.6.3 Types of cryotherapy

Common modes of cryotherapy include:

- Ice bag or cold pack application,
- Ice massage,
- Ice towels (Swenson et al., 1996),
- Cryokinetics (Alternating cold application with active exercise),
- Cryostretch (Alternating cold application with muscle stretching),
- Cold water baths (Knight, 1995),
- Cooling gels containing menthol (Bishop, Greenstein and Topp, 2009 and Airaksinen et al., 2003).

Various modes of cryotherapy are commonly used which have different thermodynamic properties resulting in different rates of cooling (Knight, 1995). The most common form of cryotherapy used in acute injuries is ice bags/ice packs (Airaksinen et al., 2003).

## **2.7 Ice pack cryotherapy**

### **2.7.1 Introduction**

Ice packs are considered traditional cryotherapy (Knight, 1995) used to cool tissues effectively and easily (Greenstein, 2007), and are commonly used by clinicians and lay persons in the treatment of acute musculoskeletal injuries (Enwemka, Allen, Avila, Bina, Konrade and Munns, 2002). Conventional ice packs are usually filled with either a silica based gel or a mixture of saline and gelatin, allowing it to easily conform to the body contours when it is semi solid, which is between 0 and 5 degrees Celsius (Cameron, 1999).

### **2.7.2 Ice pack mechanism of action**

According to Merrick et al. (2003) and Enwemka et al. (2002), the ice pack treatment does not transfer cold to the tissues, but instead the deeper tissues are cooled by losing their heat to the more superficial tissues which warm the ice pack by losing heat to it. This is known as conduction of heat, with the variant of temperature change being smaller in the deeper tissue layers compared to the more superficial tissue layers. This hemodynamic interchange between the tissue levels produces the cold sensation and adds to the reduction in pain, muscle spasm and edema.

Initially the area of ice pack application will feel cold followed by a burning and aching sensation which is followed by the area feeling numb (Reid, 1992). The treatment should be stopped soon after the area becomes numb (Brown and Hahn, 2009) because according to Christensen (2006) this will avoid adverse reactions and should not be more than 5 to 10 minutes for the ankle joint.

### 2.7.3 Clinical research

In a review of the literature Hubbard et al (2004) found that applying ice was more beneficial in reducing pain after injury than applying no ice, and that continuous cryotherapy application was better than intermittent application in decreasing the amount of pain the patient experienced.

A study by Algafly and George (2007) was conducted to determine the effect of applying ice on nerve conduction velocity (NCV), pain threshold (PTH) and pain tolerance (PTO) in the treatment of ankle sprains using one group receiving cryotherapy and another group receiving no cryotherapy (control group) (n=23). The NVC, PTH and PTO values in the group not receiving cryotherapy did not change. In the group receiving ice application, the NCV was reduced significantly compared to the control group, with the PTH and PTO of the subjects increasing in the cryotherapy group ( $p<0.05$ ).

Herrera et al. (2010) also found that ice packs were effective in reducing sensory nerve conduction velocity and thus slowing down the action potential, as well as resulting in a decrease in skin temperature and the inflammatory effect (Herrera et al., 2010 and Nemet, Meckel, Bar-Sela, Zaldivar, Cooper and Eliakim, 2009). The resultant decrease in inflammation results in a decrease in swelling (Reid, 1992).

Skiveren, Kjaerby and Larsen (2008) examined whether applying an ice pack to the axilla for 5 minutes before treatment involving injections, could reduce pain. Patients were their own controls, and a 14% to 19% reduction in pain was recorded after treatment with an ice pack as opposed to none ( $p<0.01$ ), indicating that ice packs can reduce pain.

In a study by Cheing, Wan and Lo (2005) to determine the efficacy of ice and pulsed electromagnetic field (PEMF) in the treatment of distal radial fractures (n=83), group 1 receiving ice and PEMF; group 2 receiving ice and sham PEMF; group 3 receiving only PEMF; and group 4 receiving sham PEMF. The results of their study showed that the

two groups receiving ice improved significantly ( $p=0.005$ ) more in terms of reduction in perceived pain and swelling than those not receiving ice.

These studies show that cryotherapy in the form of an ice pack is beneficial in decreasing pain and swelling in the treatment of ankle sprains.

#### 2.7.4 Advantages of ice packs

According to Nemet et al (2009) ice packs are the cryotherapy treatment modality of choice in the treatment of traumatic injuries. Ice packs are also easy to use, requiring only a low level of skill to apply. They are inexpensive and readily available, covering large to moderate areas on the skin surface (Airaksinen et al., 2003 and Cameron, 1999).

#### 2.7.5 Disadvantages of ice packs

The patient may not tolerate the weight of the ice pack during treatment as well as the pack may not maintain good contact with the treatment area and must sometimes be removed to visualize the treatment area (Cameron, 1999). It may also cause discomfort or even pain when applied to patients (Skiveren et al., 2008). According to Topp et al (2009) ice packs are more “messy” when applied compared to the topical cold gels, and require access to a refrigerator (Airaksinen et al., 2003). Patients can also not be blinded to the treatment of ice packs (Herrera et al., 2010).

#### 2.7.6 Side effects of ice packs

Bleakley et al. (2004) found that some case studies reported the occurrence of nerve damage and skin burns after 20 to 30 minutes of cooling. Excessive cold application can also cause frostbite (Brown and Hahn, 2009).

## **2.8 Menthol cold gel**

### **2.8.1 Introduction**

Menthol is lipid-soluble and found naturally in plants of the *Mentha* species (Zhang, Enix, Snyder, Giggey and Tepe, 2008). It is found in a variety of topical pain relief medications due to its localized anaesthetic (pain reduction) properties, and has been used for many years for medicinal purposes (Patel et al, 2007) to decrease pain in soft tissue injuries (Airaksinen et al., 2003).

### **2.8.2 Menthol cold gel mechanism of action**

Menthol's mechanism of action was initially thought to work according to the gate control theory of pain highlighted by Melzack and Wall (Page, 2007), however, it has only recently been discovered that menthol stimulates the specific cold receptor known as TRPM8 (Page, 2007 and Patel et al., 2007). These TRP channels are expressed by small diameter sensory neurons (Dragoni et al., 2006) found in the trigeminal and dorsal root ganglion (Mahieu et al., 2007 and McKemy et al., 2002).

In mammals, sensing temperature depends on voltage dependent gating of these TRPM8 receptors (Voets, Droogmans, Wissenbach, Janssens, Flockerzi and Nilius, 2004), which are activated by both cold temperatures and menthol (Bandell et al., 2006; McKemy et al., 2002 and Peier et al., 2002), which is how menthol can produce the same sensation as cold (Patel et al., 2007). However, how the underlying gating mechanisms function is poorly understood (Voets et al., 2007 and Bandell et al., 2006). When applied topically, menthol stimulates these cold receptors, which become depolarized (Voets et al., 2004), causing a tingling sensation and perception of cold, resulting in a short term reduction in pain (Liu, Ye, Feng, Zhou, Rong, Fang and Chen, 2005) in much the same way as other modes of cryotherapy, as discussed earlier in section (2.6.2).



Unlike other cryotherapy modalities which result in a decrease in tissue temperature (Cameron, 1999), menthol is unique in that it gives rise to a cooling sensation without lowering the tissue temperature (Airaksinen et al., 2003 and Mckemy et al., 2002).

### 2.8.3 Clinical research

In a study by Airaksinen et al. (2003), a cold producing gel with menthol (3.5%) as the active cold forming agent and ethanol was compared to a placebo gel in a study of patients with acute sports injuries (n=74). After 1 week, results showed that the active cold group had pain relief at rest and with activity, together with decreased disability compared to the placebo group. This study supports the use of menthol based gels in the treatment of musculoskeletal injuries.

In a double blinded placebo controlled study by Hatem, Attal, Willer and Bouhassira (2006) on the effects of topically applied menthol gel in healthy volunteers (n=39), participants received either a menthol or placebo solution applied for 10 minutes at an interval of one week between treatments. The results ( $p>0.05$ ) showed that 90% (n=35) of the subjects experienced the cooling sensation of menthol, with only one subject reporting the same sensation as menthol after the placebo treatment. The remaining 10% of participants (n=4) felt a warm sensation after the application of menthol, which was not observed in the placebo group (Hatem et al., 2006). According to McKemy et al (2002) this perceived warm sensation may occur because a portion of menthol sensitive receptors is also activated by capsaicin which is categorized as heat responsive, and so there are less cold receptors available to sense cold.

### 2.8.4 Advantages of menthol cold gel

Cold gels containing menthol can be carried more conveniently by athletes, and don't require access to a refrigerator as with ice packs (Bishop et al., 2009 and Airaksinen et al., 2003). Cold gels can also be used easily for localized conditions in patients who can't tolerate other forms of treatment (McGee, 2008).

### 2.8.5 Disadvantages of menthol cold gel

According to Hatem et al (2006), not all individuals perceive the cooling sensation after menthol application, indicating that it may be possible for certain individuals to have less menthol sensitive receptors than others, or have an over expression of A-delta fibers. This may indicate that not all subjects will respond similarly to the cold gels used in this study.

### 2.8.6 Side effects of menthol cold gel

Hatem et al (2006) found no side effects to menthol application, with subjects showing no signs of skin irritation and inflammation, and concluded that menthol was suitable for treating patients. External application of menthol at concentrations up to 16% has been approved by the food and drug administration (FDA) as safe, and can be purchased as over the counter (OTC) medication (Patel et al., 2007).

## **2.9 Combination cold gel with menthol and herbal extracts**

### 2.9.1 Introduction

Some menthol cooling agents contain active ingredients such as herbal extracts that have anti-inflammatory properties.

The herbal extracts used in this study are unique and for proprietary reasons remain confidential. The gel component H8000 (less than 0.5% of the total formula) consists of 248 various chemical compounds and organic herbal extracts, which work together to produce an anti-inflammatory effect. The combination gel of menthol and herbal extracts was also designed to be non toxic and a non irritant, with the main effects being that of analgesia and cooling (Quinn, 2009).

### 2.9.2 Combination gel mechanism of action

The two main ingredients in H8000 are Arnica and Echinacea. Arnica is commonly used in the treatment of minor musculoskeletal injuries such as sprains, where it has an anti-inflammatory effect, reducing swelling and pain (Lee, Kim, Lee, Lee and Hong, 2007

and Sumara, 2006). Echinacea is known for its prevention of infection (Quinn, 2009 and Barrett, 2003), and when combined with the other herbs in H8000 it has a synergistic effect, resulting in tissue repair by inhibiting of the enzyme hyaluronidase, this inhibition reduces the inflammatory processes thereby maintaining cell integrity (Quinn, 2009).

The mechanism of action of the combination gel would be the same as that of the menthol gel above with the addition that the patient would benefit from both the cooling sensation and reduction in inflammation (Quinn, 2009). According to Quinn (2009) the herbalist, founder and developer of the gel used in this study, stated that the cooling effect can last up to 10 minutes. Menthol also acts as a penetration enhancer, which when combined with other ingredients, enhances the treatment outcome (Patel et al., 2007). It is also believed that the TRPM8 channels may also interact with commercial anti-inflammatory products, expanding its range of temperature sensitivity (McKemy et al., 2002).

### 2.9.3 Clinical research

There has been no formal research into the combination gel used in this study. However, some studies have researched similar gels. Zhang et al. (2008) comparing the combination of a cooling gel containing menthol and a blend of botanical ingredients including Arnica and Echinacea (Biofreeze™) combined with lumbar spinal manipulation to lumbar spinal manipulation alone (n = 36), found that there was a significant reduction in pain and disability of acute lower back pain in the combination treatment group as opposed to the group that received spinal manipulation alone.

Bishop et al. (2009) in a study on the effects of Biofreeze™ versus ice on acute non complicated neck pain, found that the same topical analgesic as used in the above studies had a greater effect on decreasing the amount and duration of the pain experienced, as compared to ice application. These studies highlight the potential of combination gels aiding in the treatment of musculoskeletal conditions.

Topp et al (2009) compared a topical analgesic gel (Biofreeze™) to ice on blood flow, pain and muscle function, it was found that the analgesic gel decreased blood flow

faster than ice application, which was more beneficial in the early stages of treatment, however the decreased blood flow did not last as long compared to normal ice application. The gel also resulted in greater muscle function compared to the ice group, with similar decreases in pain between the two groups.

#### 2.9.4 Advantages of the combination gel

Topical cold gels because of their analgesic effect, prevent the need to use prescription medication and other anti-inflammatory medication (Topp et al., 2009), and allow for faster pain relief from injury (Bishop et al., 2009). According to Bishop et al. (2009) these combination gels should be used by chiropractors before and after treatment to reduce any pain or apprehension the patient may be feeling, and can also be used together with other modalities.

#### 2.9.5 Disadvantages of the combination gel

As highlighted by Topp et al. (2009), although combination gels appear to decrease the rate of blood flow, the result does not last as long, and therefore the long term effects are lost.

#### 2.9.6 Side effects of the combination gel

According to Airaksinen et al. (2003) it was noted that the composition of the gel itself may cause minimal adverse reactions such as skin irritation, although not enough to discontinue use. According to Quinn (2009), there have been no recorded reports to date of adverse reactions in the combination gel used in this study, therefore any adverse reactions experienced by subjects in this study were documented. According to Topp et al (2009) and Argoff (2002) the similar gels used in their studies produced no systemic side effects and no risk of tissue damage with repeated applications.

## **2.10 The placebo effect**

### **2.10.1 Introduction**

The placebo effect can be defined as “the measurable, observable, or felt improvement in health or behaviour not attributable to the medication or treatment that has been given” (Carroll, 1994). Placebos are mainly used in drug trials as “sugar pills” with the aim to test the efficacy of the active drug compared with the inactive placebo drug (Friedman and Dubinsky, 2008 and de Craen, Kaptchuck, Tijssen and Kleijnen, 1999).

### **2.10.2 Placebo mechanism of action**

How placebos work is largely unknown (Friedman et al., 2008 and Turner, Deyo, Loeser, Von Korff, and Fordyce, 1994). In a review of the literature, Carroll (1994) stated that the placebo effect is commonly thought to be psychological, although some studies had found objective improvements in patient health after placebo treatment.

It is thought that the placebo effect works through pathways closely connected with the patients cognitive and emotional state (Brody, 2000), and that patients belief and expectations that they will get better is activated by the same pathway in the brain as medications (Friedman et al., 2008), although how these pathways function is unknown (Brody, 2000).

This psychological belief that the placebo treatment is working can also be attributed to the Hawthorne effect where people change their behaviour, attitude and treatment response when more interest and attention is paid to them, as in the case of a clinical trial where it is considered a non-specific effect outcome (McCarney, Warner, Iliffe, van Hasselen, Griffin and Fisher, 2007). However, the researchers state that most clinical trials maintain similar standards in both the treatment and placebo controlled groups (McCarney et al., 2007).

In the research setting, placebos are used as controls to mimic other treatment interventions being tested (de Craen et al., 1999) in order to compare the effectiveness

of these other treatments compared to that of the placebo (Friedman et al., 2008). In this study placebo was used in this context. For a new treatment to be deemed effective it has to have a larger effect than the placebo, as it becomes harder to demonstrate the effect of a certain treatment used if there is a strong placebo effect (Friedman et al., 2008).

Individuals respond to placebo treatment at various rates and consistencies, with the individual's response rate being usually higher than expected (Turner et al., 1994). According to Friedman et al. (2008), in a clinical trial it is advisable for the physician to be blinded to what treatment the patient is receiving until after the study, keeping non-specific effects consistent and allow outcomes to be assessed independently. However in this study blinding was limited to only the groups receiving the gels, as subjects cannot be blinded to the cold pack (Hubbard et al., 2004).

### 2.10.3 Clinical research

According to Hrobjartsson and Gotzsche (2001) in an analysis of 130 clinical trials comparing placebo treatment to no treatment, it was found that in studies measuring pain, placebo treatment showed small levels of improvement, and although improvements were seen in both subjective and objective measurements, only subjective outcomes showed significant differences favouring the placebo. It was also noted that as the sample size of the studies increased, the effect of the placebo decreased.

Coudreuse and de Vathaire (2010) in their study on the effect of a plaster containing diclofenac epolamine (DHEP) and heparin compared to a placebo plaster in the treatment of acute ankle sprains (n=233), found objective improvements in terms of ankle pain and swelling in the placebo group, although this improvement was not as significant as the active treatment.

## **2.11 Conclusion**

Cryotherapy has been used for many years in the treatment of soft tissue injuries. The physiological effects of cryotherapy are well known, however according to the review of the literature by Bleakley et al (2004) and Hubbard et al (2004) they noted that the modes, duration and frequency of cryotherapy treatments are inconsistent with many insufficiencies noted in terms of outcome. It has already been established that tissues and ligaments are damaged as a result of an ankle sprain, and thus cryotherapy should be applied as soon as possible in order to decrease the resultant pain, swelling and inflammation associated with the injury. The aim of this study was to determine the effectiveness of an ice pack, menthol based cooling gel, menthol based cooling gel with herbal extracts (combination gel) and a placebo gel in the treatment of acute ankle sprains, and to compare the different modes of treatment with each other.

# **Chapter Three**

## **Material and Methods**

### **3.1 Introduction**

This chapter discusses the study design, sampling procedure, interventions used and data collected. The statistical analysis applied to the data will also be discussed.

### **3.2 Study design**

The research was a double blinded, randomized, comparative, controlled clinical trial, using convenience sampling (Brink, 2006). The objective was to determine the effect of four modes of treatment: An ice pack, a menthol based cooling gel, a menthol based cooling gel with herbal extracts and a placebo gel, for reducing pain, swelling and disability in acute grade 1 or 2 inversion ankle sprains.

The research as outlined in this document was passed by the Faculty of Health Sciences ethics committee. This committee aligns itself with the declaration of Helsinki (Carlson, Boyd and Webb, 2004), ensuring that any ethical issues have been addressed (Appendix L).

### **3.3 Study limitations**

Recommendations were made with regards to the home application of the treatments; however it was not know if the participants followed the instructions accordingly. Blinding was limited to those participants who received the gels as there is no suitable placebo for an ice pack.



### **3.4 Advertising and Subject Recruitment**

The participants of the study were recruited by advertisements in the form of posters (Appendix F) placed around local sports/athletic clubs, around the Durban University of Technology and the University of Kwa-Zulu Natal. The relevant permission was obtained prior to advertising. Advertisements were placed in newspapers that circulate in and around the greater Durban area. Word of mouth was also used to recruit patients.

### **3.5 Sampling technique**

The respondents to the advertisements contacted the researcher and were interviewed telephonically with the following questions to ensure their eligibility.

- Have you sprained your ankle?
- How old are you?
- How long have you had the ankle sprain?
- Can you bear weight on the injured ankle?
- What is the pain rating of the ankle sprain between 1–100?

The participants had to be between 18-45 years of age, with a mild grade 1 or 2 inversion ankle sprain of less than one week duration (Bleakley et al., 2004). The participant must have been able to partially bear weight on the injured ankle and have a pain rating between 40-80 for sample homogeneity.

A total of 48 respondents were recruited via non-probability convenience sampling (Brink, 2006). If the participant met the above criteria, an appointment was made at the Durban University of Technology Chiropractic Day Clinic, permission was obtained from the clinic director and the participants were given a verbal explanation as well as a Letter of Information and Consent form (Appendix A) which they were required to read and sign. Participants were given the opportunity to ask questions and made aware that

they may withdraw from the study at any time. A case history (Appendix B), physical examination (Appendix C) and ankle regional (Appendix D) were done to determine inclusion and exclusion criteria.

### 3.5.1 Inclusion Criteria:

- 1) Participants were only accepted once they had given their informed consent in writing.
- 2) Participants had to be between the ages of 18 and 45 years of age to be accepted into this study (Pellow and Brantingham, 2001 and Parker, 2005). According to Parker (2005) acute ankle sprains occur at younger ages compared to chronic sprains which occur in older age groups, and there is a greater prevalence of ankle injuries in younger people because of higher physical demand in sport activities (Richards, 2007). From about the age of 50 the incidence and prevalence of systemic disorders makes patients conditions more chronic and difficult to treat, with patient's clinical feedback being less accurate (Youdas, Carey and Garrett, 1991).
- 3) Only patients diagnosed by the researcher as having a grade 1 or 2 acute inversion ankle sprain according to the West Point Ankle Sprain grading system (Richards, 2007) were eligible for the study (Appendix G). Both grades of sprains were used to increase the available population for the study.
- 4) A Visual Analogue Scale score between 40-80. The subject's worst pain score and their least pain score were added together and divided by two to give the final score which would have to have been between 40-80, for a homogenous sample.

- 5) Those participants taking non-steroidal anti-inflammatory medication were required to discontinue their medication for twenty-four hours (Leak, Richter, Clemens, Hall and Ansell, 1998) before joining the study.

### 3.5.2 Exclusion Criteria:

- 1) Individuals with a fracture, or history of surgery to the injured ankle.
- 2) Any patient where cryotherapy was contraindicated, according to Cameron (1999):
  - Cardiac and arterial disease,
  - Skin diseases,
  - Raynauds disease,
  - Cold urticaria,
  - Post local hydrocortisone injection,
  - Anaesthetized skin and regenerating peripheral nerves,
  - Emotional sensitivity to cold.
- 3) Any participant with open wounds, sensitive skin areas, occlusive dressings and bandages were excluded.

### 3.5.3 The sample group

Based on the methodology of previous studies (Kohne, 2005; Parker, 2005; Joseph, 2005; Pellow and Brantingham, 2001) a total of 48 participants were allocated into one of four groups of 12. Participants were randomly assigned to a group via the hat method (Brink, 2006). Each participant drew a number and was placed into the corresponding group.

### 3.5.4 Blinding and Sponsorship

Blinding refers to withholding information from those involved in the trial in order to prevent bias (Brink, 2006). In this case the researcher and participants were both

blinded as to which treatments the participants were receiving. However, those participants in the ice pack group could only have single blinding.

Healthtech Laboratories (Pty) Ltd. sponsored the necessary gels and ice packs. The menthol based cooling gel, the menthol based cooling gel with herbal extracts and the placebo gel were manufactured so that they all looked and smelt the same. This means that those receiving the gel would be blinded to which gel they were receiving. Healthtech Laboratories (Pty) Ltd. packaged the gels and the ice packs into identical packaging and allocated a designation for each group. This designation was then given along with all the packages to the Chiropractic Clinic reception staff.

Registration of combination of menthol and herbal extract gel.

Registration holder: HEALTHtech Investments (Pty) Ltd / (Edms) Bpk

Co. /Mpy. Reg.No. 1999/018375/07

Healthtech House, Cnr. Douglas and Old Pretoria Rd

Midrand, South Africa; PO Box 12285, Voma Valley, 1686

### 3.5.5 Drop-out rate

Six participants were excluded before treatment had begun for not meeting the inclusion criteria, and another for being unable to make any future appointments. There were no drop outs after the participants were accepted into the study.

### 3.5.6 Treatment groups/Interventions

Group (1): Ice pack.

Group (2): Menthol gel – Which contains only the active ingredient (Menthol) and no herbal extracts.

Group (3): Combination of menthol and herbal extracts - In this study a menthol gel with herbal extracts was utilized (the herbal component is referred to as H8000). It consists

primarily of menthol from the species *Mentha* (Labiatae) dissolved in isopropyl alcohol, with a unique formula of herbal extracts (H8000), which make up less than 0.5% of the total formula (Quinn, 2009). H8000 consists of 248 chemical compounds, of which the two main ingredients are Arnica and Echinacea.

Group (4): Placebo gel – Which contains none of the active ingredient or herbal extracts.

### **3.6 Clinical procedure**

This study made use of a research assistant in order to bring in the blinding procedure.

At the initial consultation the participant was accepted into the study and placed in one of the four groups. The history, physical examination and ankle regional examination were carried out. After the diagnosis of an acute grade one or two ankle sprain was made, the participant was positioned supine on the examination bed. The researcher held the foot in its neutral position and marked the tenderest area on the lateral side of the ankle with a henna marker. Keeping the foot in its neutral position the initial objective measurements were then taken by the researcher.

Once the measurements had been completed, the researcher left the room and informed the research assistant, who then collected the treatment package from the chiropractic clinic reception staff with the corresponding number the participant had been allocated to. The research assistant then administered the treatment, and before leaving, explained to the participant how to apply the treatments at home and asked them to note any adverse reactions. Each participant was taught a standard protocol, which was exactly the same as the initial treatment given by the research assistant. The participants were required to administer the self treatment two more times on day one, and then three times a day on both day two and day three. It was assumed that the participants would be compliant with the recommendations made. The researcher then came back in and made the two follow up appointments.

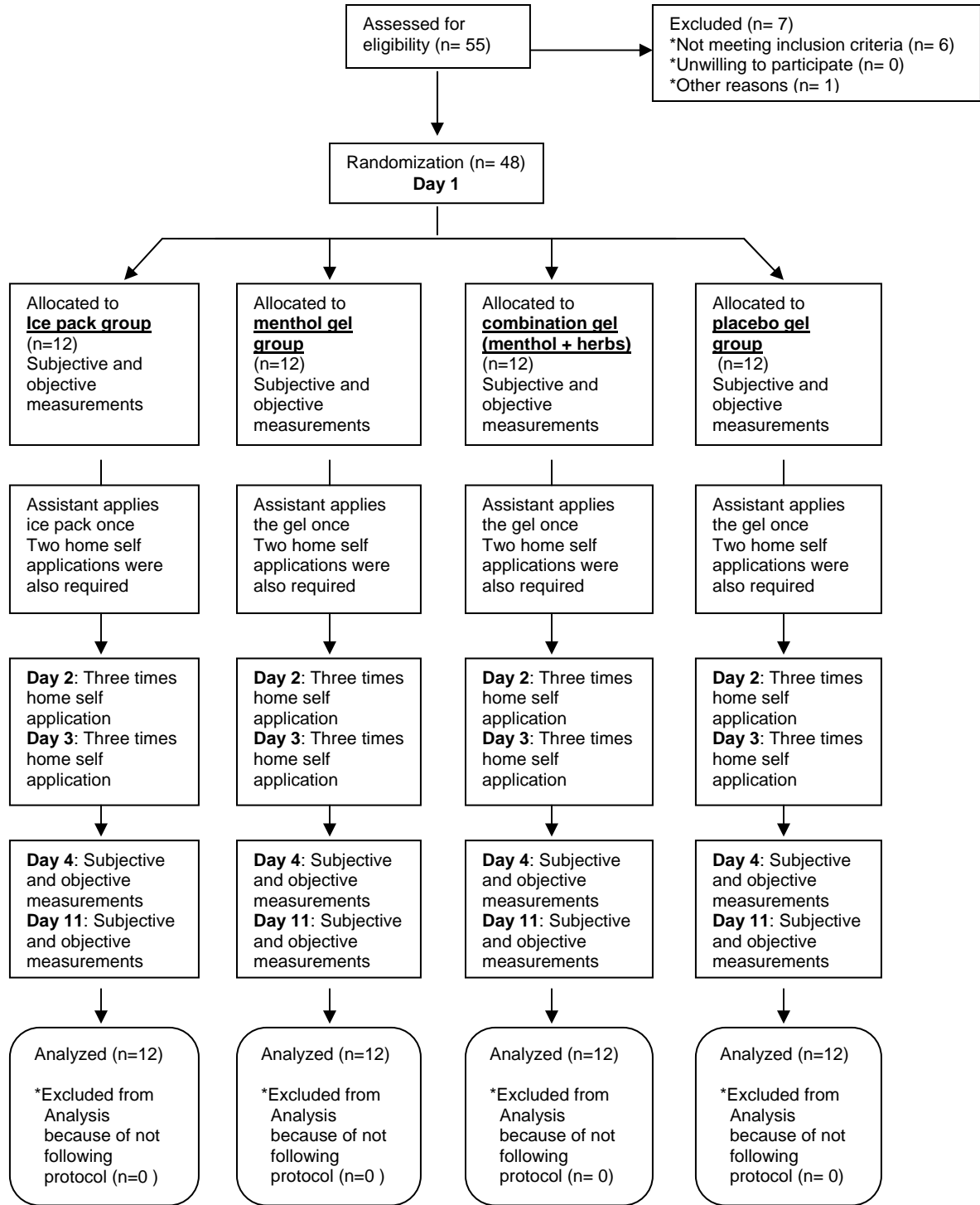
The second consultation took place on day 4, where the researcher took subjective and objective measurements, and the third and final consultation a week after the second consultation (day 11), where the researcher took the last subjective and objective measurements.

### 3.6.1 The interventions

- Ice pack application: The ice pack was placed centrally over the mark left by the henna marker, and was applied directly to the skin and held in place for 10 minutes.
- Gel application: A full table spoon of the gel was applied by the research assistant to the area using gentle massage, taking no longer than a minute to apply (Zhang et al., 2008), with a thin 2-3mm layer left on the skin surface. The participant was then requested to keep the area exposed to light if possible for the following 10 minutes. According to Lee and Whincup (1983) where there is a joint sprain, a 15 minute localised massage to the injured area is generally sufficient. Massage sessions usually range from 15 to 90 minutes, the average being 60 minutes, and require specialised techniques with the aim of enhancing the healing process by mechanically reducing spasm and increasing circulation (Braun, Simonson, Howard and Sinclair, 2007). Therefore, a gentle massage of less than one minute should have minimal effect on the injury.

### 3.6.2 Intervention frequency

Treatment was administered over three consecutive days, three times a day. Two home treatments on day one after the initial visit and thereafter three times a day at home for two days. On the fourth day the participants were required to return to the clinic for the subjective and objective measurements to be taken. A third consultation took place 1 week later to assess the long-term effect.



**Figure 3.1: Study procedure outline**

### 3.6.3 Precaution

All the gels used in this study were for external use only and the participants were informed to stop application if the product caused irritation, or if excessive redness was experienced on the participant's skin. If any adverse reaction did occur the participant was asked to inform the researcher and was to immediately stop using the gel. A record of any adverse reactions was kept.

## **3.7 Measurements**

Subjective and objective data was collected prior to treatment on day 1, and at each consecutive follow up.

### 3.7.1 Objective measurements

The objective data was obtained using the:

- Algometer – This hand held instrument was used to assess the level of pain the participant could withstand (pain threshold). This pain threshold was measured by the amount of force by square centimeter (Kg/cm<sup>2</sup>) the participant could withstand before perceiving pain (Fischer, 1987). According to Kinser, Sands and Stone (2009) this instrument is considered valid and reliable in testing pressure pain threshold.

The algometer was used in the following way:

1. The same algometer was used throughout the study. The dial was set to zero and the procedure of the researcher slowly increasing the pressure (Kinser et al., 2009), and the participant indicating when the pain was felt, was explained.
2. The researcher located the area of maximal tenderness over the lateral ankle and marked it with a henna marker.
3. The rubber application surface of the algometer was placed over the marker at a 90 degree angle to the skin. Pressure was then applied slowly until the participant indicated pain.
4. The algometer reading was then recorded in Kg/cm<sup>2</sup> (Appendix H).



- Figure-of-eight measure of ankle swelling – (Figure 3.2). The figure-of-eight method, using a measuring tape, is considered a reliable and valid method of measuring ankle swelling after an ankle sprain (Henschke, Boland and Adams, 2006 and Mawdsley, Hov and Erwin, 2000).

The measuring tape was wrapped around the ankle in the following way:

1. The researcher instructed the participant to be seated on the examination bed with the knee in full extension and the foot to be measured off the bed, and maintained in the neutral position.
2. The measurement began with the zero of the tape measure being kept midway between the anterior tibial tendon and the lateral malleolus.
3. The tape measure was then drawn toward the middle of the medial longitudinal arch of the foot on the navicular bone.
4. The tape was then pulled lightly across the plantar surface toward the lateral malleolus, then around the Achilles tendon to the medial malleolus.
5. The measurement was completed from the medial malleolus to the zero point of the tape measure and recorded (Appendix I).  
(Dos Reis, Ribeiro, de Tarso, de Carvalho, Belchior, Arakaki and de Vasconcelos, 2004).

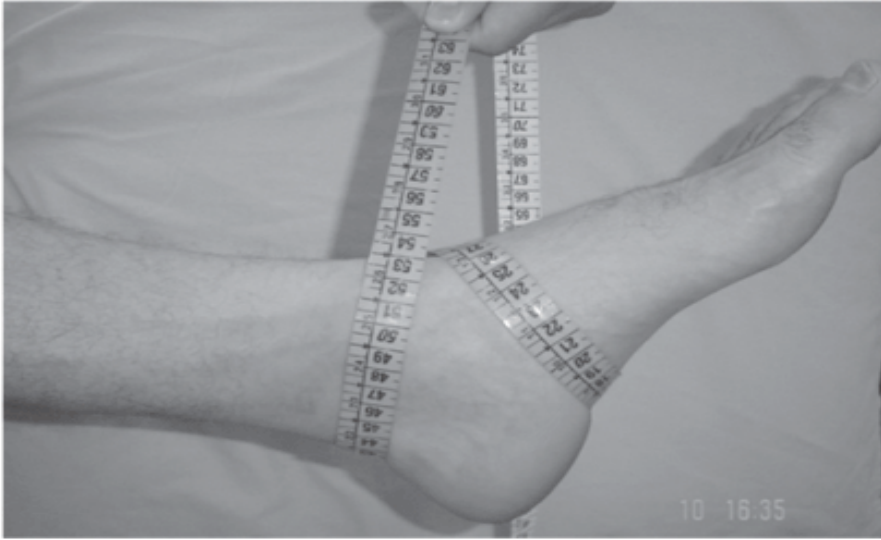


Figure 3.2: Figure of Eight method using tape measure  
Picture adapted from Dos Reis et al. (2004)

### 3.7.2 Subjective measurements

The subjective data was obtained using the:

- Visual Analogue Scale (VAS) – (Appendix J). An easy and simple to understand scale established by Jensen, Karoly and Braver (1986) for its reliability and validity when providing subjective information on the levels of pain perceived by the patient. The participants rate their perceived pain intensity levels on a scale from 0 to 100, with 0 being no pain, and 100 being the worst pain. The participant then gives two values a) when pain is at its worst, and b) when pain is at its least, over the past 24 hours. The average of these two results was taken as the pain intensity experienced.

- Foot function index (FFI) – (Appendix K). The FFI was originally designed to measure pain, disability and activity restriction in elderly people with rheumatoid arthritis, and is known to be a reliable and valid tool for gathering information on the impact of foot pathology on daily activities (Budiman-Mak, Conrad and Roach, 1991).

### **3.8 Statistical Analysis**

SAS version 9.1 (SAS, North Carolina, USA) was used to analyse the data, with a  $p$ -value of  $<0.05$  considered statistically significant. Both Intra-group and Inter-group analysis was achieved using repeated measures of ANOVA to assess the time effect for each outcome separately. Bonferroni adjusted post hoc tests were also done to perform all pair wise comparisons of groups, with profile plots used to assess the direction of the effect as well as any trends (Grobler, 2010).

# **Chapter Four**

## **The Results**

### **4.1 Introduction**

This chapter presents the results from the analysis of the data collected in the study. The data has been analysed in order to make inter- and intra-group comparisons in order to meet the study objectives. Inter-group analysis will indicate any significant difference ( $p < 0.05$ ) between all four treatment groups, with an additional analysis of any adverse reactions.

### **Key**

**Treatment groups** - ice pack, menthol gel, combination gel and placebo gel.

**n** - number of people in sample group

**p-value** -  $< 0.05$

### **4.2 Drop-out rate**

There was a zero drop-out rate in this study.

### **4.3 Demographics**

#### **4.3.1 Gender**

Table 4.1 shows that there was no statistical significant difference ( $p = 0.7283$ ) between the groups in terms of gender, however overall there were more male than female participants.

Table 4.1: Cross-tabulation of gender by group (n=48)

		Group					Total
			Ice pack	Menthol gel	Combination gel	Placebo gel	
Gender	Males	Count	6	9	7	7	29
		% within group	50.0%	75.0%	58.3%	58.3%	60.4%
	Females	Count	6	3	5	5	19
		% within group	50.0%	25.0%	41.7%	41.7%	39.6%

Fishers exact test,  $p=0.7283$

#### 4.3.2 Ethnicity

There were no statistically significant differences between the groups in terms of ethnicity. Table 4.2 shows that there was a predominance of white participants.

Table 4.2: Cross-tabulation of race by group (n=48)

		Group					Total
			Ice pack	Menthol gel	Combination gel	Placebo gel	
Ethnic Group	White	Count	7	5	10	6	28
		% within group	58.3%	41.7%	83.3%	50.0%	58.3%
	Black	Count	5	6	2	5	18
		% within group	41.7%	50.0%	16.7%	41.7%	37.5%
	Indian	Count	0	1	0	1	2
		% within group	0.0%	8.3%	0.0%	8.3%	4.2%

Fishers exact test,  $p=0.3237$

### 4.3.3 Age

There was no statistical significant difference in mean age between the four groups ( $p=0.7648$ ). Table 4.3 shows that the youngest participant was 18 and the oldest was 42 years of age.

Table 4.3: Summary statistics for age distribution (n=48)

Group	n	Mean	Median	Minimum	Maximum
Ice pack	12	24.1	23.0	20	29
Menthol gel	12	26.8	24.0	19	42
Combination gel	12	23.8	21.5	19	32
Placebo gel	12	23.6	23.5	18	29

Mean age = 24.6

Wilcoxon rank sum test,  $p=0.7648$

## **4.4 Baseline measurements**

### **4.4.1 Objective baseline measurements**

#### 4.4.1.1 Algometer

Table 4.4 Shows that there was no statistical difference between groups in terms of Algometer measurements at baseline.

Algometer		Ice pack	Menthol gel	Combination gel	Placebo gel	$p$ -value
Readings	Mean	2.43	2.18	2.79	2.43	0.2957
	Median	2.35	2.10	2.65	2.45	
	Standard Deviation	0.56	0.47	0.97	0.58	

Wilcoxon rank sum test,  $p=0.2957$

#### 4.4.1.2. Figure of Eight

Table 4.5 Shows that there was no statistical difference between groups in terms of Figure of Eight measurements at baseline.

Fig. of 8		Ice pack	Menthol gel	Combination gel	Placebo gel	<i>p</i> -value
Readings	Mean	52.80	54.12	53.02	50.08	0.1324
	Median	53.70	54.00	53.00	50.20	
	Standard Deviation	4.76	3.76	4.37	3.78	

Wilcoxon rank sum test,  $p=0.1324$

#### 4.4.2 Subjective baseline measurements

##### 4.4.2.1. Visual Analogue Scale

Table 4.6 shows a statistically significant difference between groups in terms of Visual Analogue Scale measurements at baseline.

VAS		Ice pack	Menthol gel	Combination gel	Placebo gel	<i>p</i> -value
Readings	Mean	56.25	52.92	47.50	49.79	0.0053
	Median	55.00	52.50	48.75	50.00	
	Standard Deviation	4.33	9.93	4.13	7.11	

Wilcoxon rank sum test,  $p=0.0053$

The Bonferroni adjusted post hoc test (table 4.7) showed that the ice pack group was not statistically significantly different from the menthol and placebo groups but was statistically significantly different from the combination group.

Table 4.7 shows the mean Bonferroni post hoc test measurements at baseline in terms of the Visual Analogue Scale.

<b>Group</b>	<b>Mean</b>	<b>n</b>
Ice pack	56.250	12
Menthol gel	52.917	12
Placebo gel	49.792	12
Combination gel	47.500	12

#### 4.4.2.2 Foot Function Index (FFI)

Table 4.8 shows a statistically significant difference between groups in terms of Foot Function Index measurements at baseline.

FFI		Ice pack	Menthol gel	Combination gel	Placebo gel	<i>p</i> -value
Readings	Mean	55.83	50.50	42.92	38.00	0.0012
	Median	55.00	48.50	44.00	41.00	
	Standard Deviation	8.97	11.93	11.08	11.27	

Wilcoxon rank sum test,  $p=0.0012$

The Bonferroni adjusted post hoc test (Table 4.9) showed that there was no statistically significant difference between the ice pack and menthol group, menthol group and the combination group and combination and placebo group but there was a statistically significant difference between the group receiving the ice pack and those receiving the combination treatment and placebo. Similarly there was a statistical significant difference between the menthol and placebo group.

Table 4.9 shows the mean Bonferroni post hoc test measurements at baseline in terms of the Foot Function Index.

<b>Group</b>	<b>Mean</b>	<b>N</b>
Ice pack	55.833	12
Menthol gel	50.500	12
Combination gel	42.917	12
Placebo gel	38.000	12

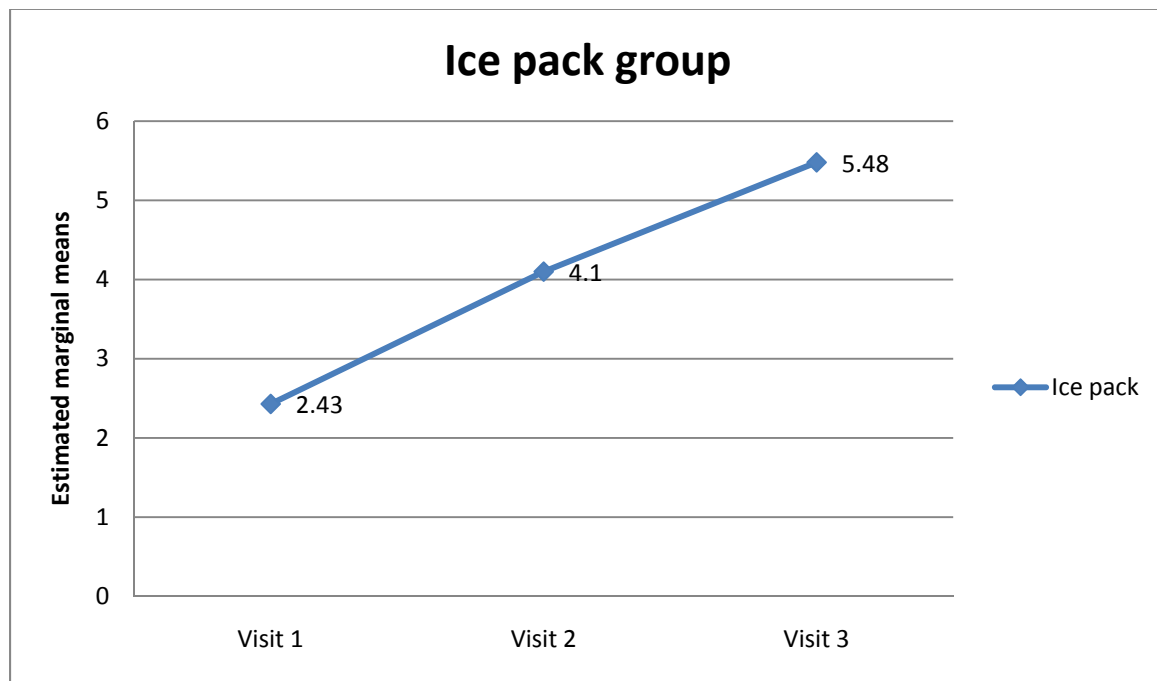


**4.5. Objective one: To determine the effectiveness of each treatment in terms of objective measurements:**

**4.5.1. Group 1 – Ice pack**

**4.5.1.1. Algometer:**

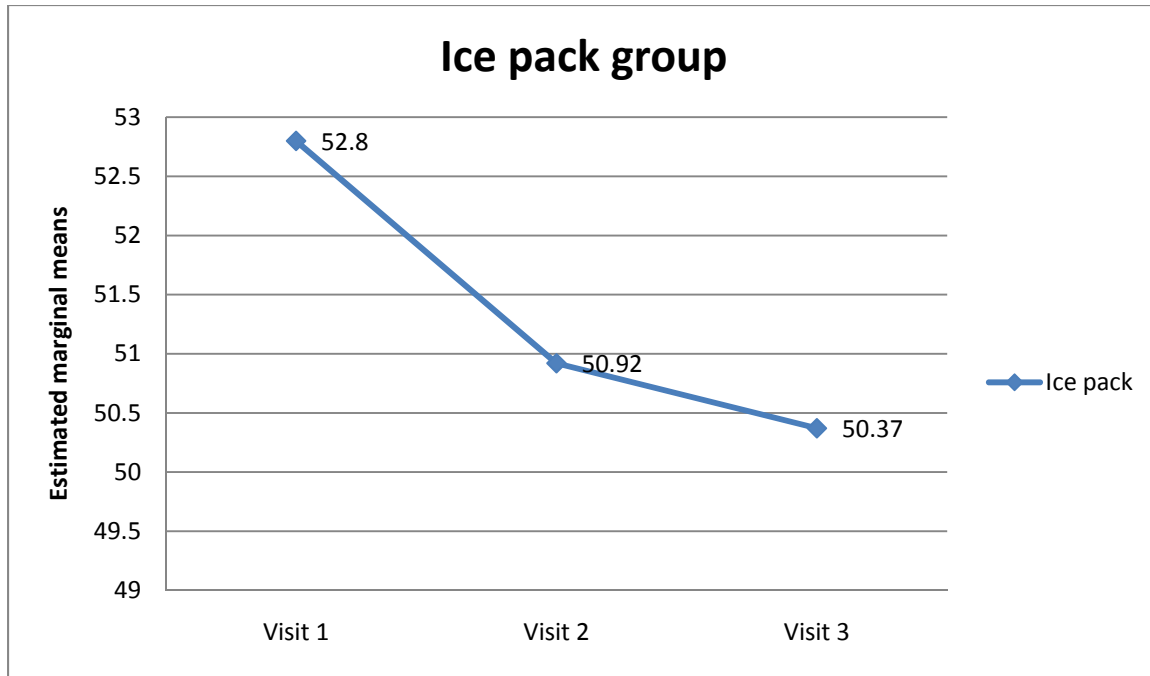
Figure 4.1: shows that there was a highly statistically significant ( $p < 0.0001$ ) increase over time in algometer readings in the ice pack group.



**Figure 4.1: Mean Algometer readings by visit in the Ice pack group**

**4.5.1.2 Figure of eight method:**

Figure 4.2: shows a highly statistical significant ( $p < 0.0001$ ) decrease in the Figure of Eight readings in the Ice pack group.

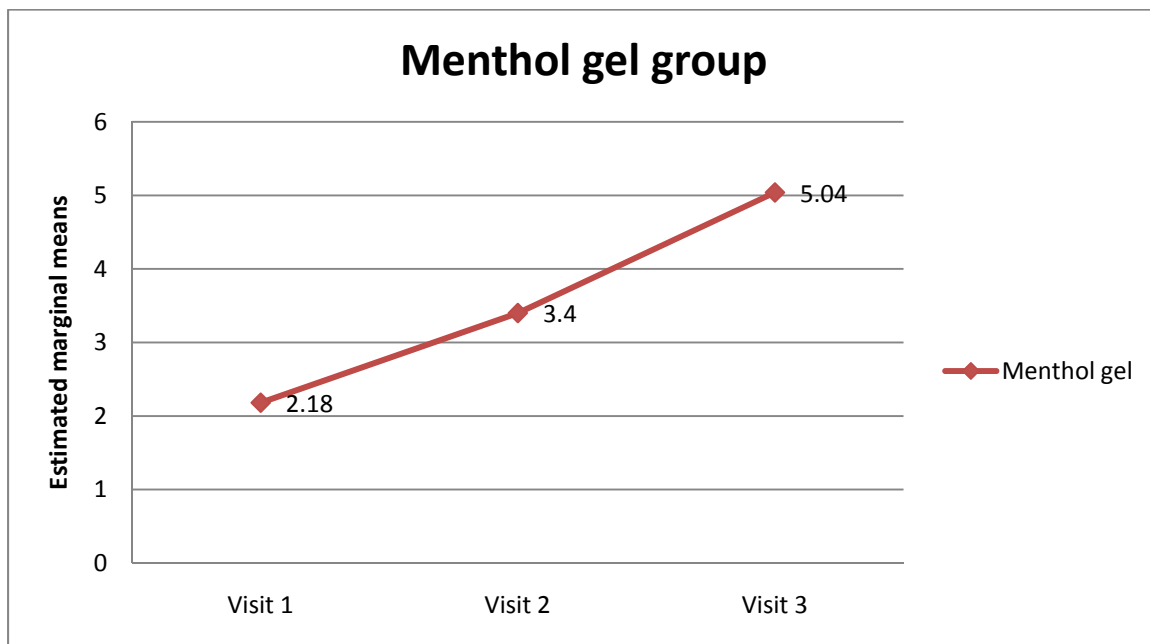


**Figure 4.2: Mean figure of eight readings by visit in the ice pack group**

#### **4.5.2 Group 2 – Menthol gel**

##### **4.5.2.1 Algometer:**

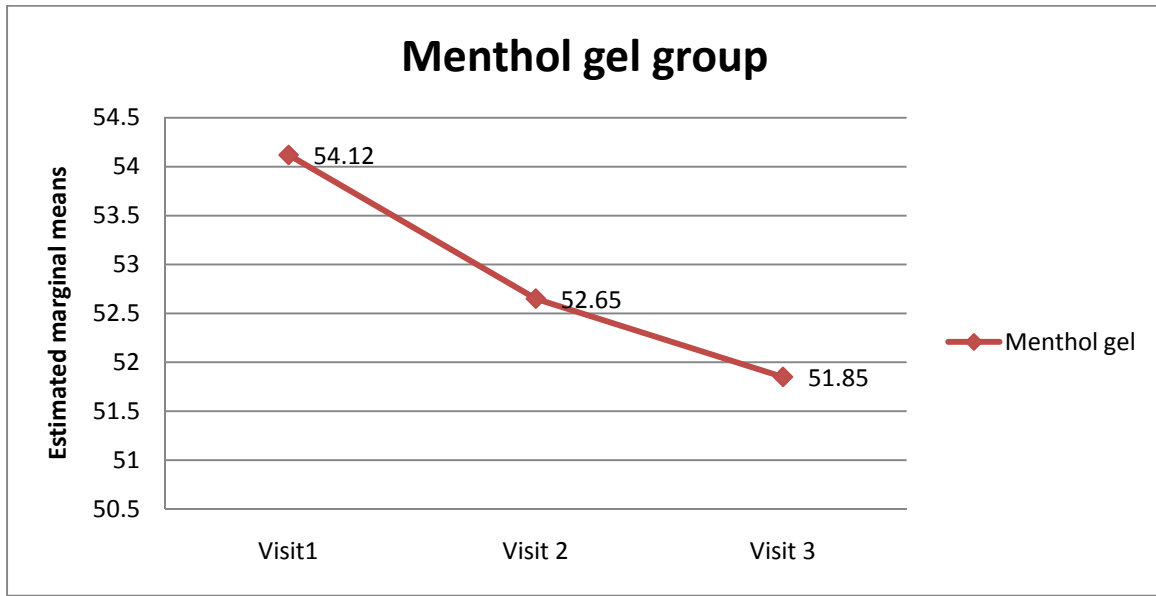
The menthol gel group showed a highly statistical significant ( $p < 0.0001$ ) increase in algometer readings over time (Figure 4.3).



**Figure 4.3: Mean Algometer readings by visit in the Menthol gel group**

#### **4.5.2.2 Figure of eight method:**

The menthol gel group showed a highly statistical significant ( $p < 0.0001$ ) decrease in algometer readings over time (Figure 4.4).

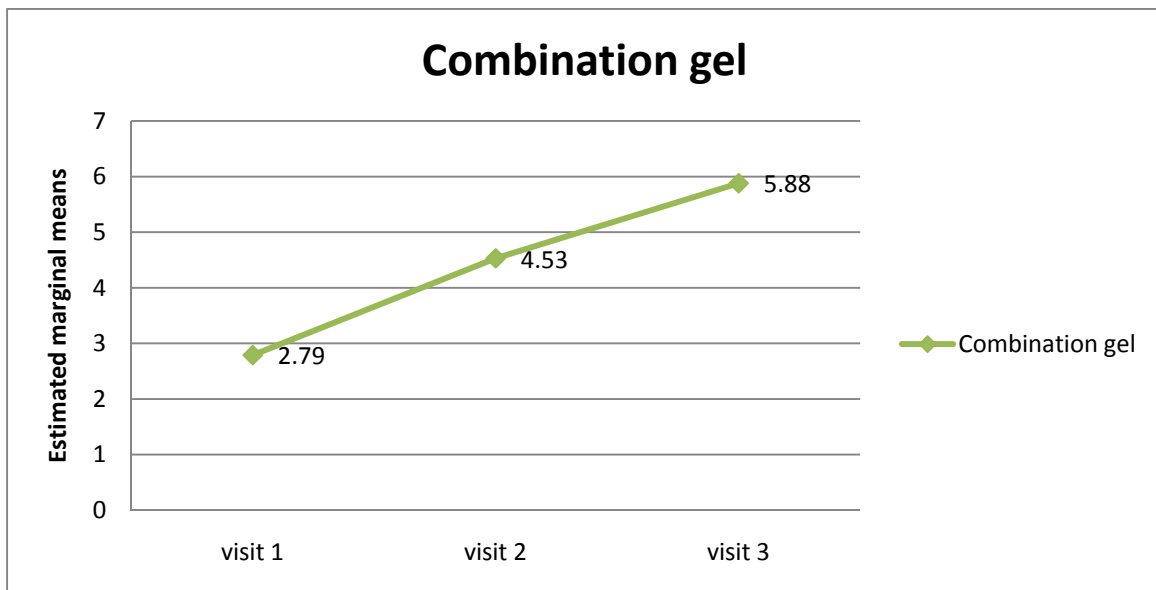


**Figure 4.4: Mean Figure of eight readings by visit in the Menthol gal group**

#### **4.5.3 Group 3 – Combination group**

##### **4.5.3.1 Algometer:**

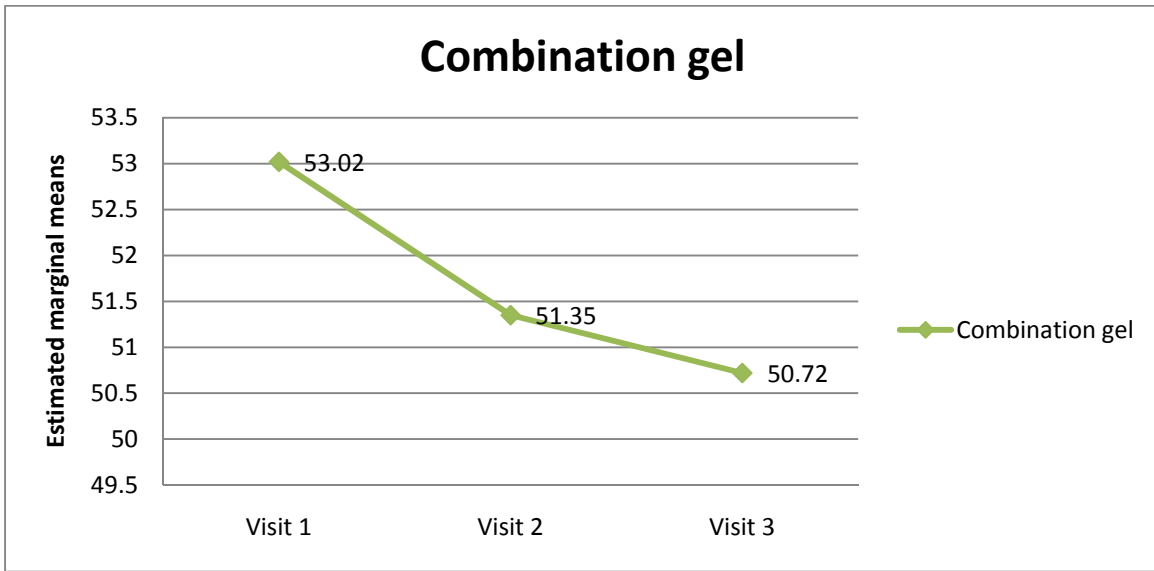
Figure 4.5: shows that there was a highly statistical significant ( $p < 0.0001$ ) increase in algometer readings over time for the combination gel group.



**Figure 4.5: Mean Algometer readings by visit in combination gel group**

#### **4.5.3.2 Figure of eight method:**

Figure 4.6: shows a highly statistical significant ( $p < 0.0001$ ) decrease over time for Figure of Eight readings in the combination group.

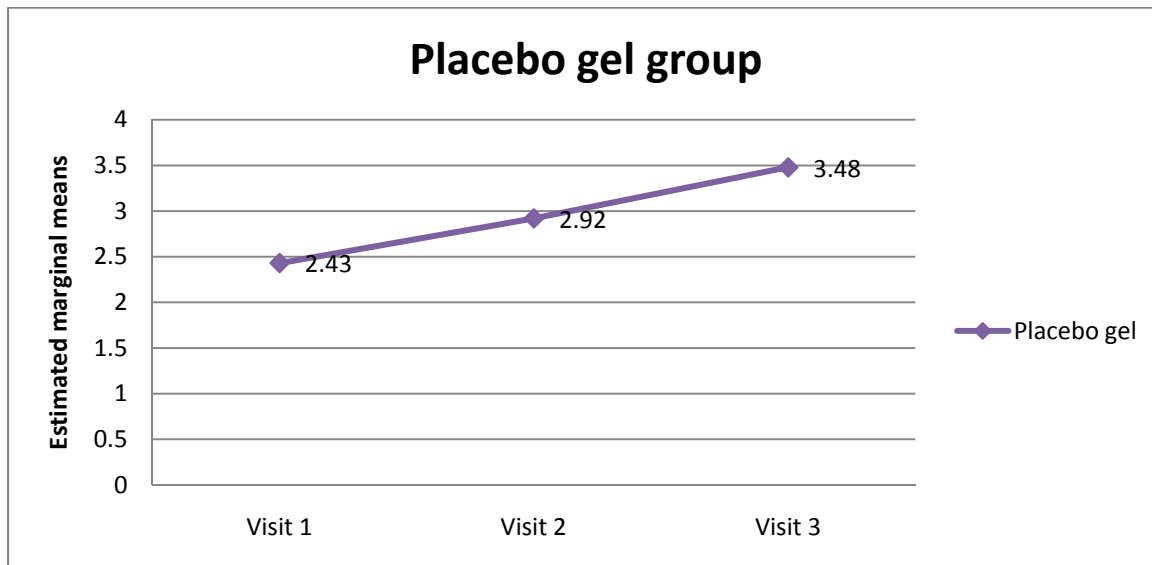


**Figure 4.6: Mean Figure of eight readings by visit in combination gel group**

#### **4.5.4 Group 4 – Placebo gel**

##### **4.5.4.1 Algometer:**

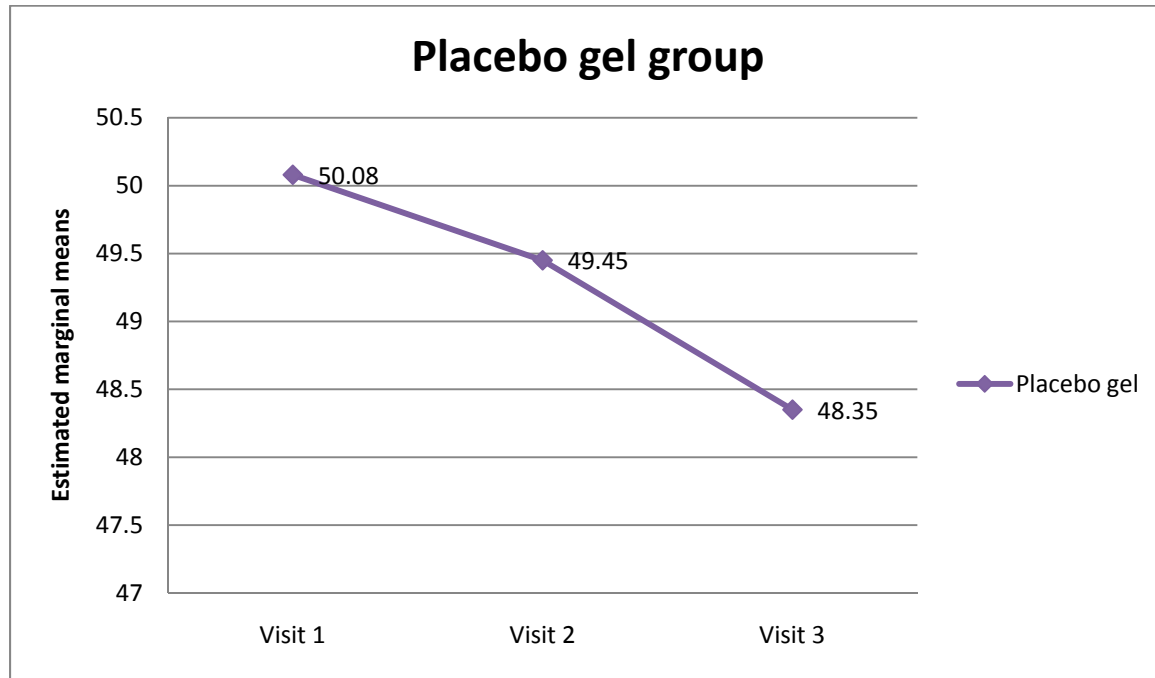
Figure 4.7 shows that there was a highly statistical significant ( $p < 0.0001$ ) increase over time for algometer readings in the placebo gel group.



**Fig 4.7: Mean Algometer readings by visit in the Placebo gel group**

#### **4.5.4.2 Figure of eight method:**

The placebo gel group showed a highly statistical significant ( $p < 0.0001$ ) decrease in Figure of Eight readings over time (Figure 4.8).



**Figure 4.8: Mean Figure of eight readings by visit in the Placebo gel group**

#### **4.5.5 Conclusion**

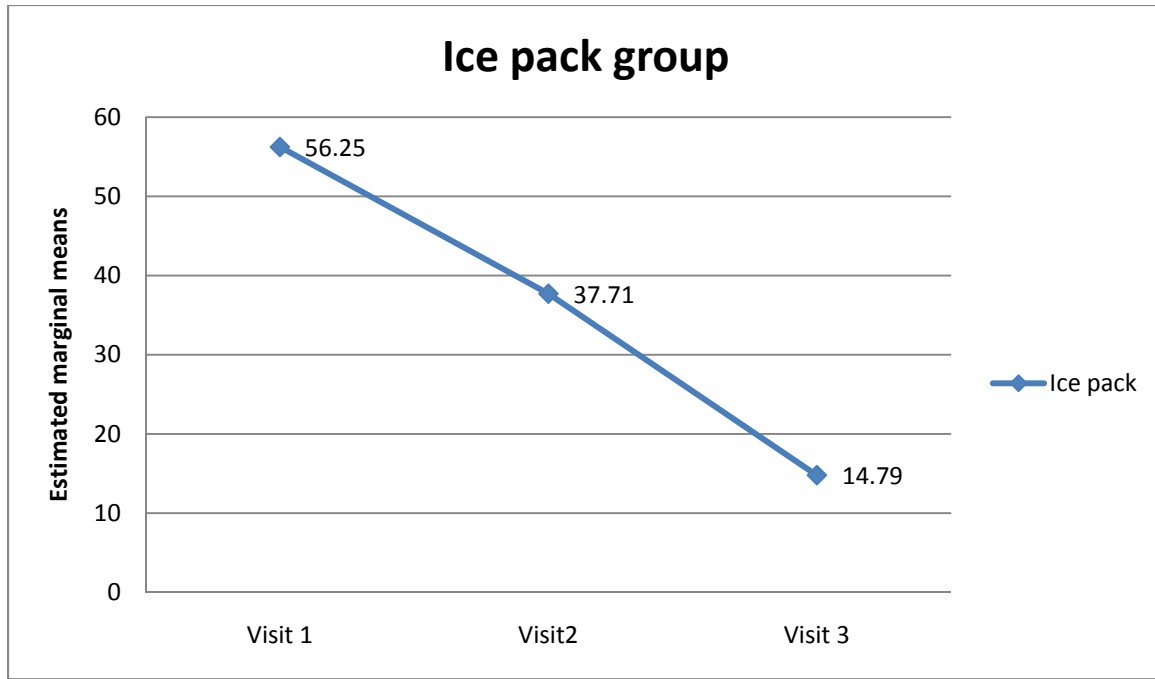
All four groups showed a statistically significant improvement in terms of objective measurements (Algometer and Figure of Eight method) over time.

### **4.6 Objective Two: To determine the effectiveness of each treatment in terms of subjective measurements:**

#### **4.6.1 Group 1 – Ice pack**

##### **4.6.1.1 Visual Analogue Scale;**

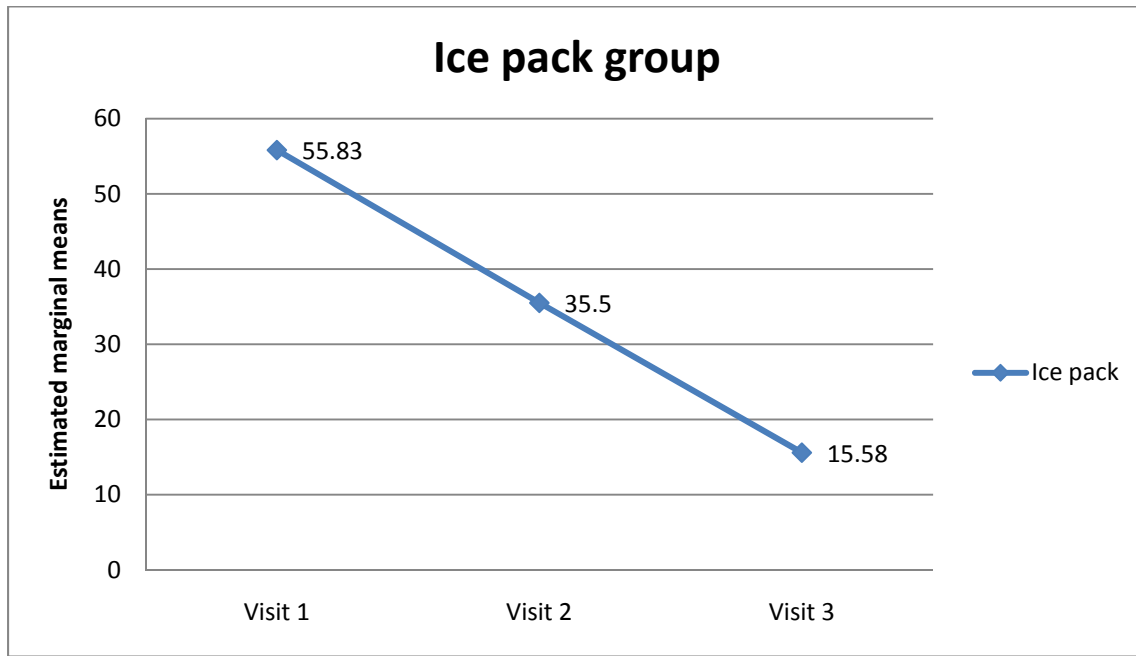
The VAS score showed a highly statistically significant decrease ( $p < 0.0001$ ) over time in the Ice pack group (Figure 4.9).



**Figure 4.9: Mean VAS score by visit in the Ice pack group**

**4.6.1.2 Foot Function Index:**

Similarly the mean FFI score showed a highly statistically significant ( $p < 0.0001$ ) decrease over time in the Ice pack group (Figure 4.10).

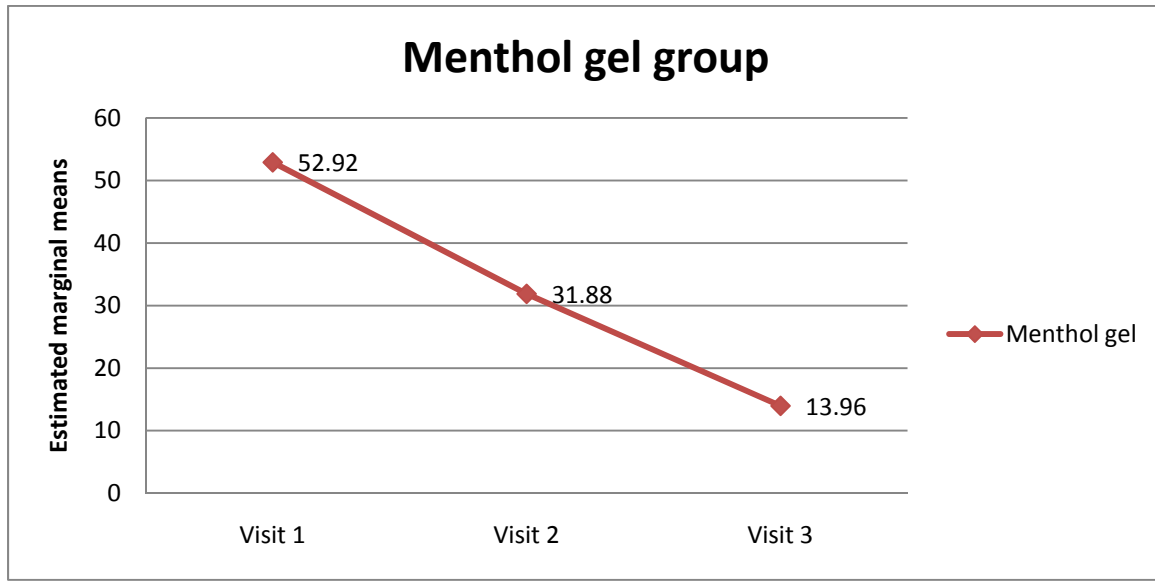


**Figure 4.10: Mean FFI score by visit in the Ice pack group**

#### **4.6.2 Group 2 – Menthol gel**

##### **4.6.2.1 Visual Analogue Scale:**

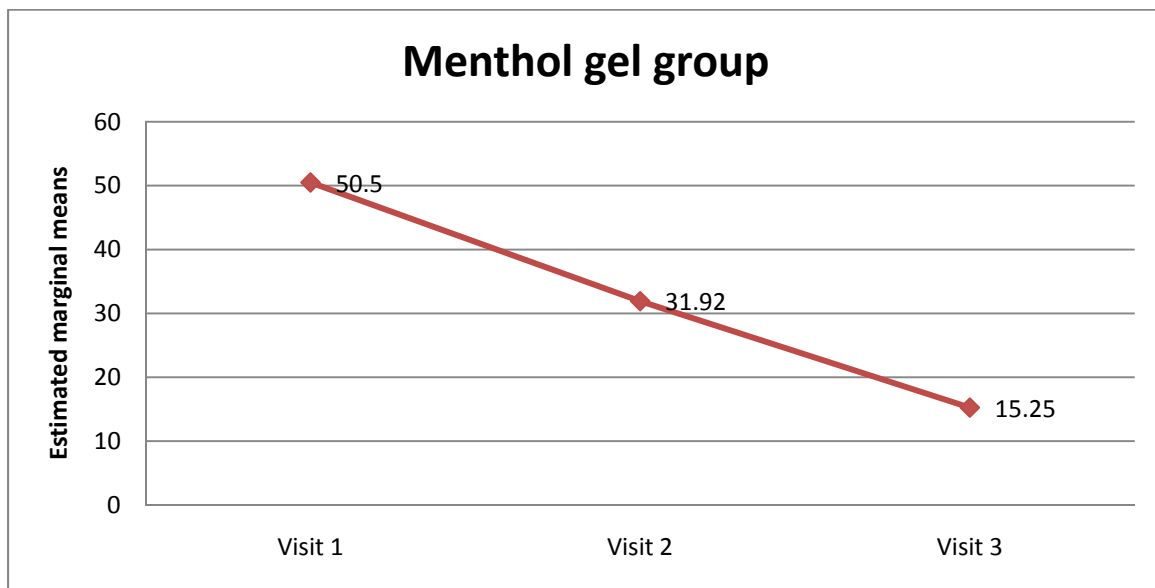
The VAS score showed a highly statistically significant decrease ( $p < 0.0001$ ) over time in the menthol gel group (Figure 4.11).



**Figure 4.11: Mean VAS score by visit in the Menthol gel group**

##### **4.6.2.2 Foot Function Index:**

Similarly the mean FFI score showed a highly statistically significant ( $p < 0.0001$ ) decrease over time in the menthol gel group (Figure 4.12).

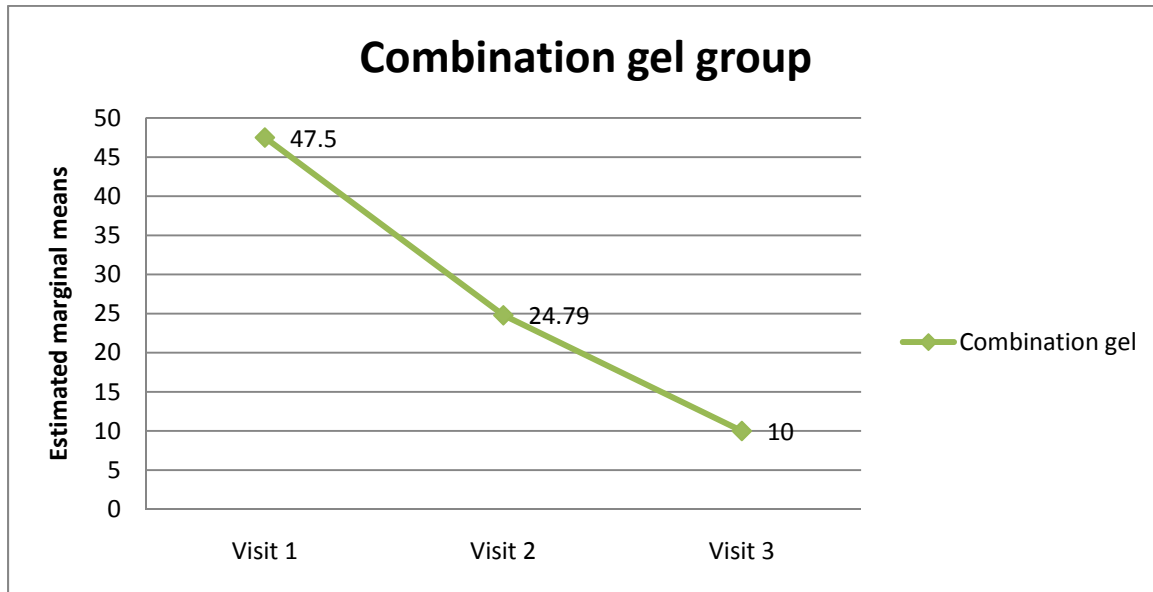


**Figure 4.12: Mean FFI score by visit in the menthol gel group**

### **4.6.3 Group 3 – Combination gel**

#### **4.6.3.1 Visual Analogue Scale:**

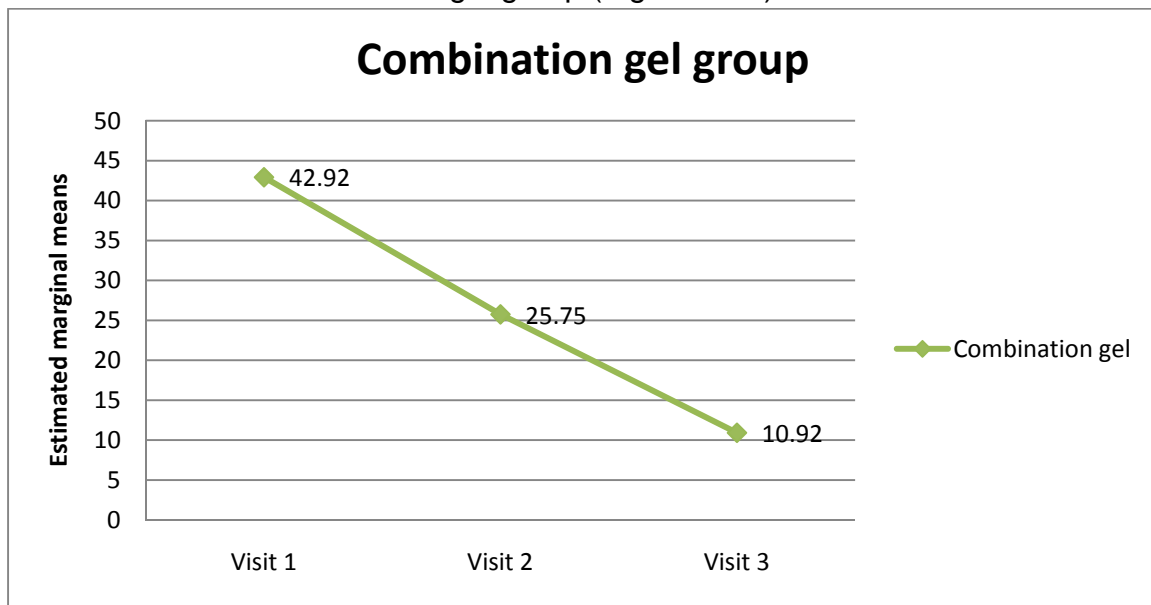
The VAS score showed a highly statistically significant decrease ( $p < 0.0001$ ) over time in the combination gel group (Figure 4.13).



**Figure 4.13: Mean VAS score by visit in the Combination gel group**

#### **4.6.3.2 Foot Function Index:**

Similarly the mean FFI score showed a highly statistically significant ( $p < 0.0001$ ) decrease over time in the menthol gel group (Figure 4.14).



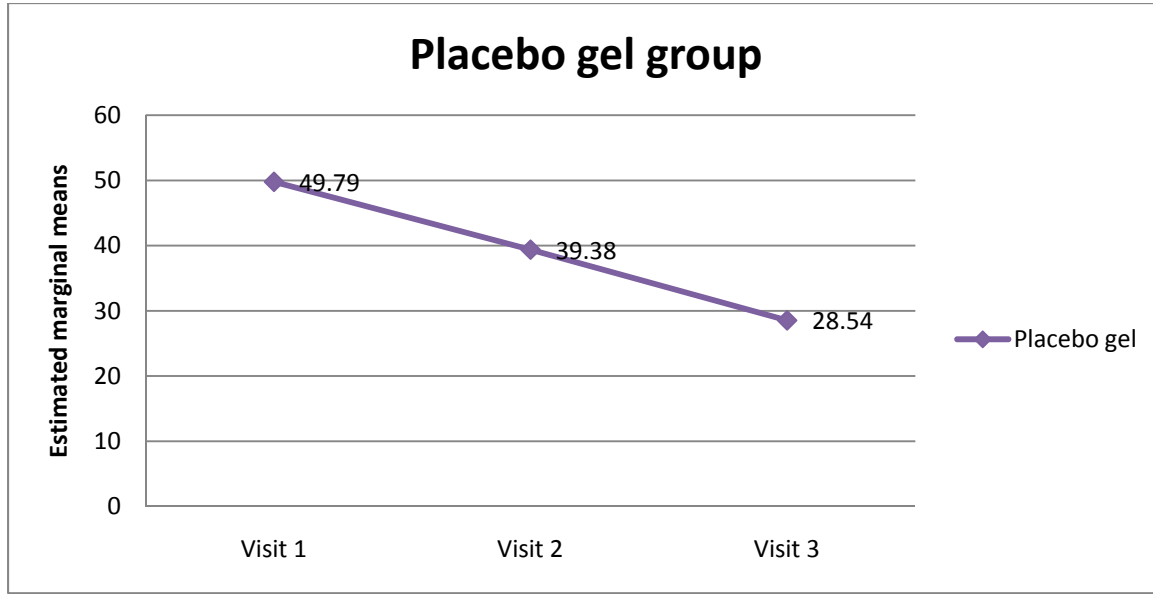
**Figure 4.14: Mean FFI score by visit in the combination gel group**



#### **4.6.4 Group 4 – Placebo gel**

##### **4.6.4.1 Visual Analogue Scale:**

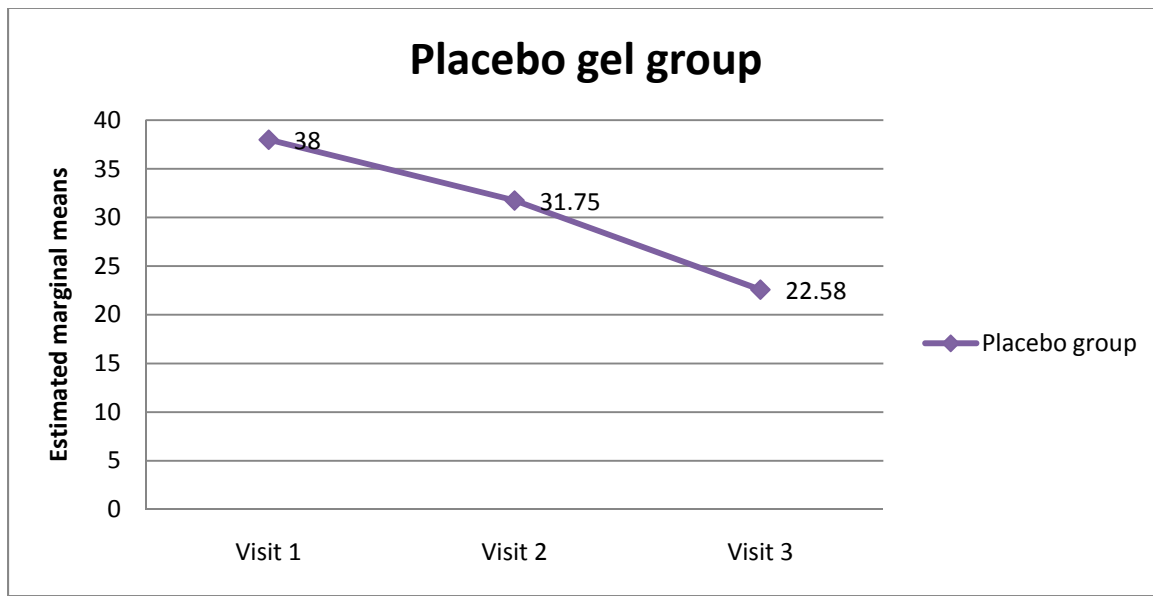
The VAS score showed a highly statistically significant decrease ( $p < 0.0001$ ) over time in the combination gel group (Figure 4.15).



**Figure 4.15: Mean VAS score by visit in the placebo gel group**

##### **4.6.4.2 Foot Function Index:**

The FFI score showed a statistically significant decrease ( $p < 0.0002$ ) over time in the placebo gel group (Figure 4.16).



**Figure 4.16: Mean FFI score by visit in the placebo gel group**

#### **4.6.5 Conclusion**

All four groups showed a statistically significant improvement in terms of their subjective measurements (VAS and FFI) over time.

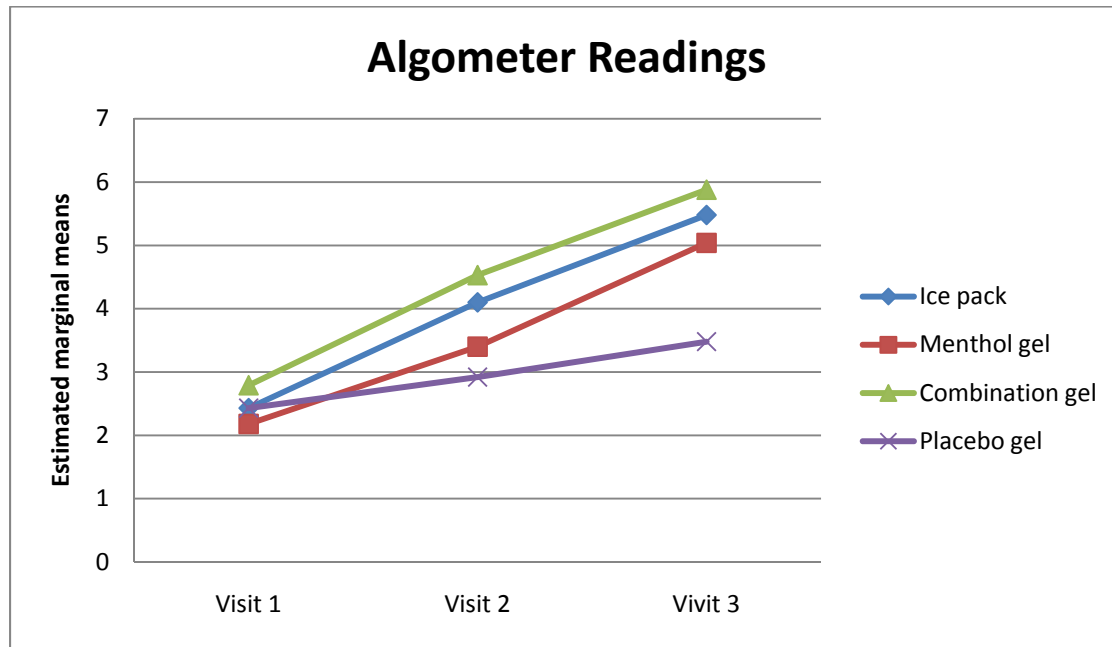
#### **4.7 Objective Three: To compare the four treatments in terms of the Objective and Subjective measures**

The Inter-group comparison of the four different treatments was measured time by group effect using repeated measures ANOVA model.

##### **4.7.1 Objective measurements**

###### **4.7.1.1 Algometer:**

Fig 4.17: represents a statistically significant difference between all the groups from baseline to visit 2 ( $p=0.0003$ ) and from visit 2 to visit 3 ( $p=0.0054$ ). A highly statistically significant change occurred from baseline to visit 3 ( $p<0.0001$ ) between the groups (time by group effect  $p<0.0001$ ).



**Figure 4.17: Mean Algometer readings by group per visit**

The Bonferroni adjusted post hoc test showed that between baseline and visit 2 (Table 4.10), the change in the group receiving the combination treatment was not statistically significantly different from the change in the groups receiving the ice pack or menthol gel; but the change in the placebo group was statistically significantly different from the change in the combination and ice pack group.

Table 4.10: Bonferroni post hoc test assessing change from baseline to visit 2:

<b>Group</b>	<b>Mean</b>	<b>N</b>
Combination gel	1.7333	12
Ice pack	1.6750	12
Menthol gel	1.2167	12
Placebo gel	0.4917	12

The Bonferroni adjusted post hoc test was used to assess changes from visit 2 to visit 3 (table 4.11) showing that the group receiving menthol gel was not statistically significantly different to the groups receiving ice pack or combination therapy but the change in the group receiving placebo was statistically significantly different to the group receiving menthol.

Table 4.11: Bonferroni post hoc test assessing change from visit 2 to visit 3:

<b>Group</b>	<b>Mean</b>	<b>N</b>
Menthol gel	1.6417	12
Ice pack	1.3750	12
Combination gel	1.3583	12
Placebo gel	0.5583	12

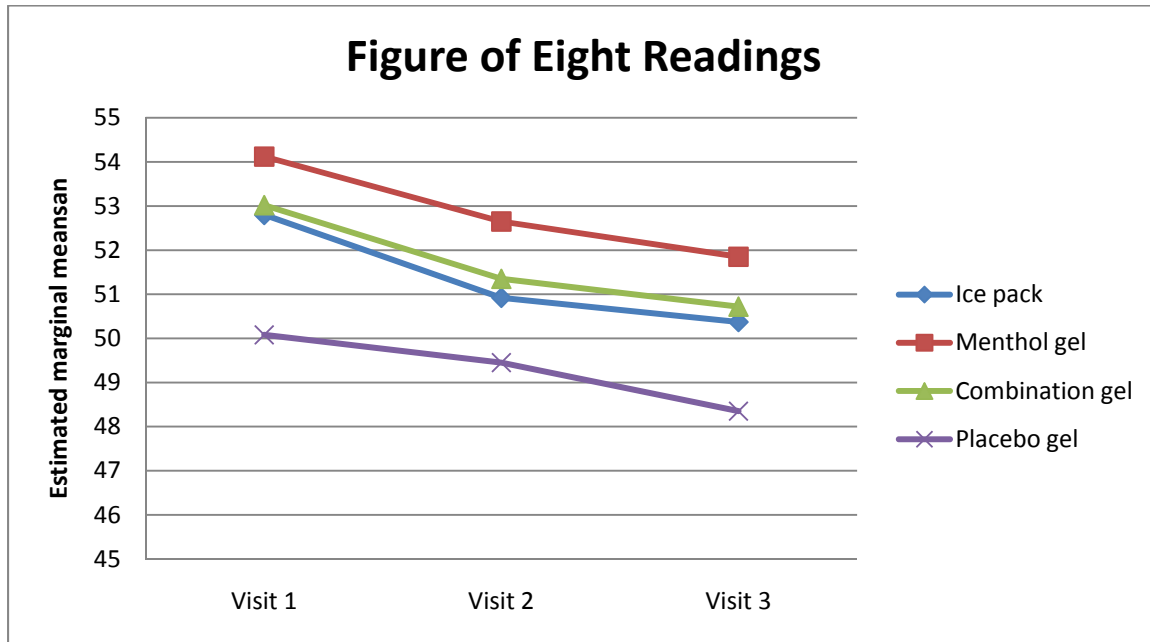
The bonferroni adjusted post hoc test showed that between baseline and visit 3 (table 4.12), the group receiving combination treatment was not statistically significantly different from those groups received ice pack and menthol gel; but the change in the placebo group was statistically significantly different from the change in the combination, ice pack and menthol groups.

Table 4.12: Bonferroni post hoc test assessing change from baseline to visit 3:

Group	Mean	N
Combination gel	3.0917	12
Ice pack	3.0500	12
Menthol gel	2.8583	12
Placebo gel	1.0500	12

**4.7.1.2 Figure of eight method:**

Figure 4.18: shows a statistically significant difference between all four groups at baseline to visit 2 ( $p=0.0033$ ), with no significant statistical difference between the four groups from visit 2 to visit 3 ( $p=0.2026$ ) and baseline to visit 3 ( $p=0.6546$ ) (time by group effect  $p=0.0006$ ).



**Figure 4.18: Mean Figure of Eight readings by group per visit**

Bonferroni adjusted post hoc test from baseline to visit 2 (Table 4.13) showed that change in the groups receiving combination gel, ice pack and menthol gel were not statistically significant, but the change in the placebo group was statistically significantly different to that in the other three groups.

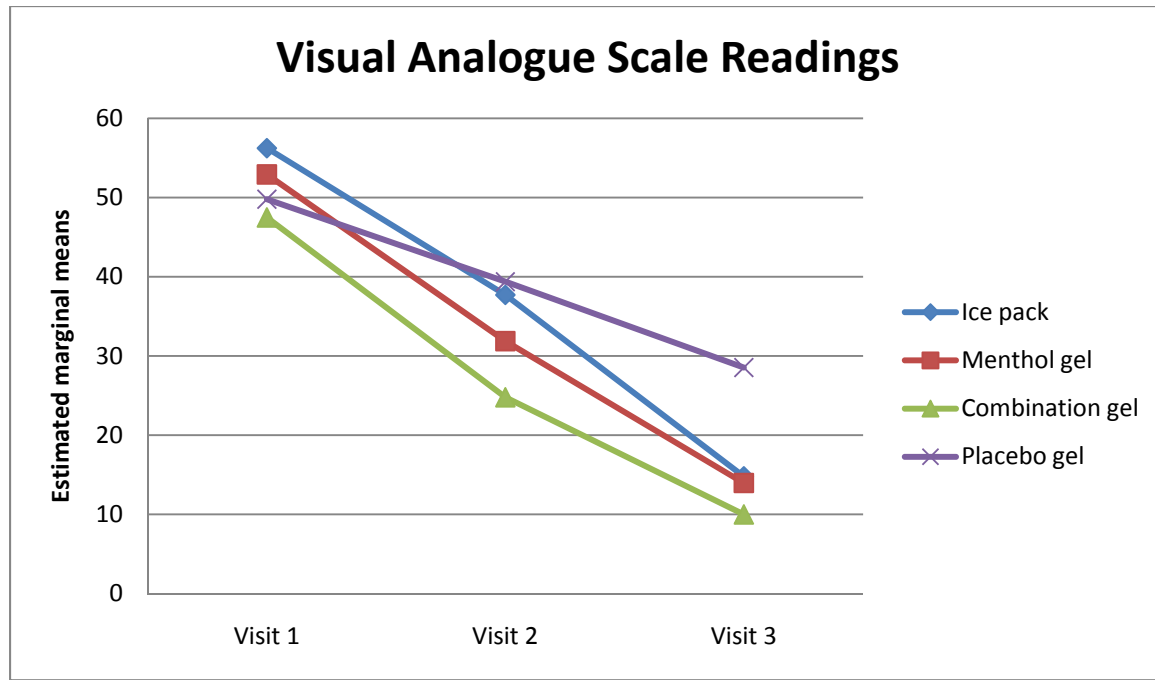
Table 4.13: Bonferroni post hoc test change from baseline to visit 2:

Group	Mean	N
Placebo gel	-0.6333	12
Menthol gel	-1.4667	12
Combination gel	-1.6667	12
Ice pack	-1.8833	12

#### 4.7.2 Subjective measurements

##### 4.7.2.1 Visual Analogue Scale:

In Figure 4.19: the four groups were not comparable at baseline ( $p=0.0053$ ). However, there was a statistically significant difference between all four groups from baseline to visit 2 ( $p=0.0144$ ) and a highly significant difference from baseline to visit 3 ( $p=0.0001$ ). There was no statistical difference from visit 2 to visit 3 ( $p=0.1101$ ) (time by group effect  $p=0.0005$ ).



**Fig 4.19: Mean VAS readings by group per visit**

The Bonferroni adjusted post hoc test from baseline to visit 2 (Table 4.14) showed that the change in the group receiving placebo was not statistically significantly different from the change in the ice pack and menthol gel groups; but was statistically significantly different from the change in the combination group.

Table 4.14: Bonferroni post hoc test assessing change from baseline to visit 2:

<b>Group</b>	<b>Mean</b>	<b>N</b>
Placebo gel	-10.417	12
Ice pack	-18.542	12
Menthol gel	-21.042	12
Combination gel	-22.708	12

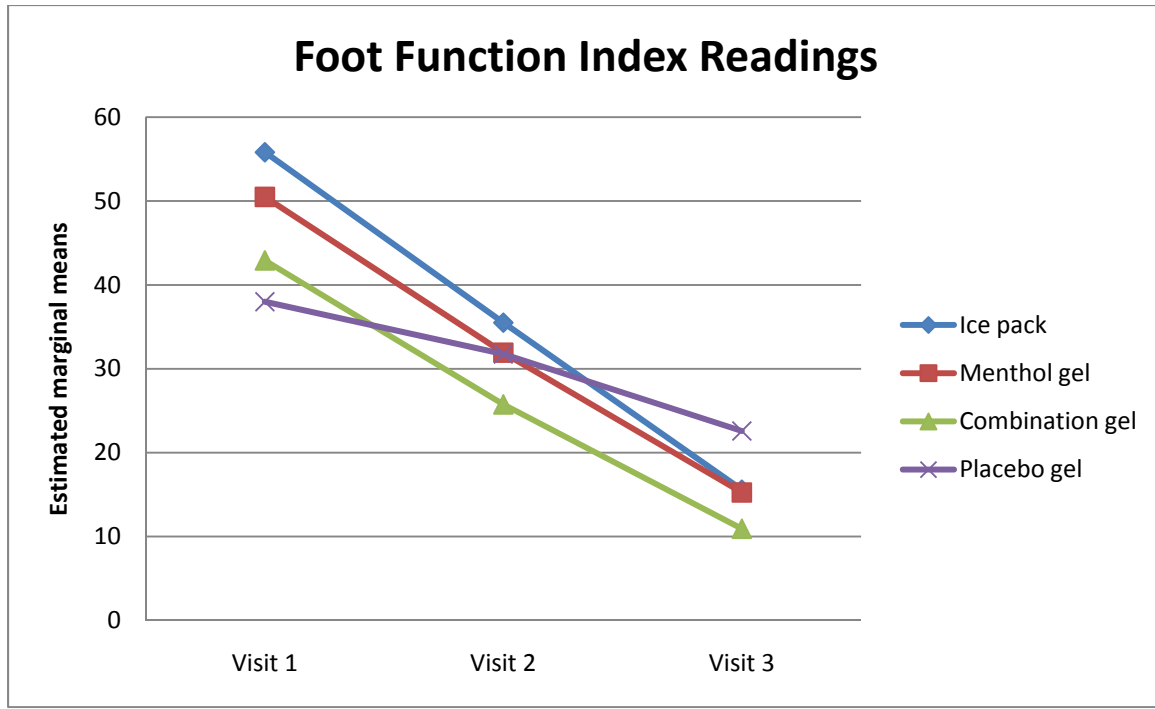
The Bonferroni adjusted post hoc test from baseline to visit 3 (Table 4.15) showed the change in the placebo group was statistically significantly different from the change in the combination, ice pack and menthol gel groups.

Table 4.15: Bonferroni post hoc assessing test change from baseline to visit 3:

<b>Group</b>	<b>Mean</b>	<b>N</b>
Placebo gel	-21.250	12
Combination gel	-37.500	12
Menthol gel	-38.958	12
Ice pack	-41.458	12

#### **4.7.2.2 Foot Function Index:**

In Figure 4.20: The four groups were not comparable at baseline ( $p=0.0012$ ), and results should be interpreted with care. There was a statistical difference in all four groups from baseline to visit 2 ( $p=0.0392$ ) and from baseline to visit 3 ( $p=0.0005$ ). There was no statistically significant difference noted between groups from visit 2 to 3 ( $p=0.2897$ ) (time by group effect  $p<0.0001$ )



**Figure 4.20: Mean FFI readings by group per visit**

The Bonferroni adjusted post hoc tests showed that from baseline to visit 2 (Table 4.16) and from baseline to visit 3 (Table 4.17) that the group receiving the placebo gel was statistically significantly different from those groups receiving combination, ice pack and menthol gel.

Table 4.16: Bonferroni post hoc test change from baseline to visit 2:

Group	Mean	N
Placebo gel	- 6.250	12
Combination gel	-17.167	12
Menthol gel	-18.583	12
Ice pack	-20.333	12

Table 4.17: Bonferroni post hoc test change from baseline to visit 3:

Group	Mean	N
Placebo gel	-15.417	12
Combination gel	-32.000	12
Menthol gel	-35.250	12
Ice pack	-40.250	12

### **4.7.3 Conclusion**

Both subjective measurements showed that the four groups were not comparable at baseline, and all changes should be interpreted with care. However, the results showed that the change in the placebo group was not statistically significant as the changes occurring in the ice pack, combination and menthol gel groups.

### **4.8 Objective Four: To identify any adverse reactions that may be caused by the treatment methods**

There were no reports of any adverse reaction by the participants in this study in any of the four treatment groups.



# Chapter Five

## Discussion of Results

### 5.1 Introduction

In this chapter the results of the demographic, objective and subjective data that was presented in chapter four will be discussed, with the discussion of the data following the objectives of the study.

### 5.2 Demographics

#### 5.2.1 Gender:

There were 48 participants in this study, 29 were male and 19 were female (Table 4.1). This is in keeping with Pellow and Brantingham (2001) and Holmer et al. (1994) who found that lateral ankle sprains occur more frequently in males. In this study the ratio of male to female was similar for each group ( $p=0.7283$ ), indicating that gender had little influence on the results of the study.

#### 5.2.2 Ethnicity:

There were no statistical significant differences between the four groups ( $p=0.3237$ ) in terms of ethnicity (Table 4.2), with a majority of White participants ( $n=28$ ) followed by Black participants ( $n=18$ ), and only 2 Indian participants. The advertisements for the study were placed in multiracial areas such as universities, sports clubs and local newspapers. Ethnicity has not been indicated as factor influencing healing of musculoskeletal injuries therefore the lack of equal representation of the race groups would not have impacted negatively on the results of the study.

#### 5.2.3 Age:

The age distribution across the four groups was similar (Table 4.3) with no statistical difference between the groups in terms of age ( $p=0.7648$ ). The overall mean age of the participants was 24.6 years (Table 4.3). The study location was at the Chiropractic Day

Clinic at the Durban University of Technology (DUT), with advertising being placed mainly around local sports clubs and universities, thus it was more readily accessible to people of a younger age group. This is in keeping with Pellow and Brantingham (2001) and Parker (2005) where ankle sprains were more likely to occur in younger age groups.

#### 5.2.4 Conclusion:

The demographics of the participants showed no statistically significance differences regarding gender, age and race, indicating that these factors did not affect the results of the study.

### **5.3 OBJECTIVE ONE: TO DETERMINE THE EFFECTIVENESS OF EACH TREATMENT IN TERMS OF OBJECTIVE MEASUREMENTS**

#### **5.3.1 Group 1 – Ice pack**

##### 5.3.1.1 Algometer readings and Figure of Eight measurements

The ice pack group showed a highly statistically significant ( $p < 0.0001$ ) improvement over the duration of the study in terms of algometer and Figure of Eight readings (Figures 4.1 and 4.2 respectively).

##### 5.3.1.2 Discussion

Similar results were found by Algaflly et al. (2007) in their study comparing ice application to a control group in the treatment of an ankle injury ( $n=23$ ), where they showed that pain pressure threshold improved statistically significantly more than the control group ( $p<0.05$ ) after ice application. The application of ice has been shown to decrease the excitability and conduction velocity of neural tissue in both sensory and motor nerves (Algaflly et al., 2007 and Bleakley et al., 2004), with the pain transmitting A-delta fibers being primarily affected (Cameron, 1999). Ice application decreases blood flow resulting in a decrease in inflammation and metabolism which helps limit the pain associated with an acute injury (Cameron, 1999).

Bleakley et al. (2006) had similar findings to this study when they investigated changes in swelling using the Figure of Eight method to determine the effect of ice application either through an intermittent or standard application procedure in the treatment of acute ankle sprains. There was a statistically significant ( $p < 0.05$ ) decrease in Figure of Eight readings for both groups. According to Cameron (1999) ice packs reduce blood flow and intravascular fluid pressure, decreasing the amount of fluid moving into the interstitium of the body's cells, leading to a decrease in swelling. In a systemic review of clinical trials by Bleakley et al. (2004) it was noted that vasoconstriction of blood vessels was effective in decreasing swelling immediately after application to one week after the injury. Cheing et al. (2005) also noted in their study that groups receiving ice as part of their treatment protocol following a radial fracture had statistically significant ( $p = 0.005$ ) decreases in swelling than those groups not receiving ice.

### **5.3.2 Group 2 – Menthol gel**

#### **5.3.2.1 Algometer readings and Figure of Eight measurements**

The Algometer and Figure of Eight readings showed a highly significant statistical ( $p < 0.0001$ ) improvement over the study period (Figures 4.3 and 4.4).

#### **5.3.2.2. Discussion**

In respect to pain pressure threshold levels, similar findings were found by Hatem et al. (2006) where they investigated the effect of a menthol pad versus a placebo pad, held in place for 10 minutes on the right forearm of healthy individuals. It was shown that there was a statistically significant ( $p < 0.001$ ) improvement in pain pressure thresholds after menthol application when compared to placebo. To this author's knowledge, no studies were found utilising an objective measurement for determining the effect of menthol on swelling. Therefore, the findings of this study show that menthol is effective in reducing swelling after an acute injury, as the participants improved faster than the natural history which according to Bierma-Zeinstra (2008) is just over two weeks (section 2.4)

The effectiveness of a menthol gel in increasing pain threshold and decreasing swelling lies within its ability to stimulate the specific cold receptor known as TRPM8. Menthol stimulates these receptors which produces a sensation of cold (Liu et al., 2005), thereby reducing pain and swelling in a similar manner as other modes of cryotherapy. However, menthol application does not lower the actual tissue temperatures like other methods of cold application (Mckemy et al., 2002).

### **5.3.3 Group 3 – Combination gel**

#### **5.3.3.1 Algometer measurements and Figure of Eight readings**

The Algometer and Figure of Eight readings were analysed in Figures 4.5 and 4.6 respectively. Both showed a highly statistically significant ( $p < 0.0001$ ) improvement over the study period.

#### **5.3.3.2 Discussion**

The combination gel used in this study is unique in its constituents, no other studies utilising this particular gel were found. In terms of pain pressure thresholds no similar studies where a combination gel was utilised were comparable, therefore the results of this study show that the combination gel used in this study was effective in increasing pain threshold levels, as participant improvement was greater than the natural history following an ankle sprain (Bierma-Zeinstra, 2008 and Reid, 1992).

The combination gel in this study contains the active ingredient menthol, and so was expected to work on the same mechanism of action as menthol (Section 2.2.2 and 2.2.4) in reducing pain and swelling. However, the combination gel differs from the menthol gel in that it also contains anti-inflammatory products (H8000) (Quinn, 2009). The two main ingredients of this H8000 are Arnica and Echinacea as discussed earlier, which directly reduces pain by decreasing the inflammation associated with an injury, which in turn leads to a decrease in swelling (Lee et al., 2007 and Sumara, 2006).

In terms of reduction in swelling, decreased blood flow has been indicated as a mechanism to aid decreased tissue swelling (Cameron 1999). It was shown in this study

that the combination group showed a highly statistically significant ( $p < 0.0001$ ) improvement in swelling. One of the ingredients in the combination group was Arnica. In a study by Lee et al. (2007) local application of Arnica decreased facial swelling in patients with facial trauma without external wounds. Arnica has been reported in the literature to have an anti-inflammatory effect, resulting in a decrease in pain and swelling (Lee et al., 2007 and Sumara, 2006).

Topp et al. (2009) conducted a study comparing a combination gel (Biofreeze™), ice and a control group in terms of blood flow. They found that there was a trend in the data that the combination gel and ice pack groups decreased blood flow, compared to the control group which did not.

### **5.3.4 Group 4 – Placebo gel**

#### **5.3.4.1 Algometer measurements and Figure of Eight readings**

The Algometer and Figure of Eight readings both showed a highly statistically significant ( $p < 0.0001$ ) improvement over the study period (Figures 4.7 and 4.8 respectively).

#### **5.3.4.2 Discussion**

According to Carroll (1994) it is possible for a placebo treatment to produce objective outcomes, as seen in this study where the placebo group responded favourably by showing statistically significant improvements in both objective measurements. The placebo is known to have a powerful effect (Friedman et al., 2008) observed by Pellow and Brantingham (2001), in a placebo controlled study investigating ankle manipulations versus placebo ultrasound in the treatment of an subacute and chronic ankle inversion sprain ( $n=30$ ). The placebo group showed statistical significant ( $p < 0.05$ ) improvements over the four week treatment period. Coudreuse and de Vathaire (2010) in their study on the effect of a plaster containing DHEP and heparin compared to a placebo plaster in the treatment of acute ankle sprains ( $n=233$ ), found that although the active treatment improved statistically ( $p < 0.01$ ) better than the placebo group, the placebo group did show statistical ( $p < 0.05$ ) improvement in terms of ankle pain and swelling after days 3 and 7 of the study period.

### **5.3.5 Conclusion**

All four treatment groups were effective in increasing pain pressure threshold, and decreasing swelling of an acute ankle sprain.

## **5.4 OBJECTIVE TWO: TO DETERMINE THE EFFECTIVENESS OF EACH TREATMENT IN TERMS OF SUBJECTIVE MEASUREMENTS**

### **5.4.1 Group 1 – Ice pack**

#### **5.4.1.1 VAS and FFI scores**

In the ice pack group both the VAS and FFI scores showed a statistically significant improvement over the study period ( $p < 0.0001$ ) (Figures 4.9 and 4.10 respectively).

#### **5.4.1.2 Discussion**

The results of this study are in keeping with Skiveren et al. (2008) who conducted a study to determine if a cold gel pack applied 5 minutes before injection with Botulinum Toxin A was more effective in decreasing pain than receiving an ice pack ( $n=36$ ). There was a statistically significant ( $p < 0.01$ ) improvement in pain reduction in the group receiving the cold gel pack. Similarly Bleakley et al. (2006) and Cheing et al (2005) found that following ice application participants reported less pain.

In respect to ankle disability, Bleakley et al. (2006) assessed ankle function (using Binkley's lower extremity functional scale) to determine the effectiveness of two icing protocols (intermittent versus standard icing protocol) in the treatment of acute ankle sprain, it was found that both procedures showed statistically significant ( $p < 0.05$ ) improvement in ankle function after icing. This is in keeping with the results of this study where participant's ankle function improved after receiving treatment with an ice pack.

### **5.4.2 Group 2 – Menthol gel**

#### **5.4.2.1 VAS and FFI scores**

Both the VAS and FFI scores showed a statistically significant improvement over the study period ( $p < 0.0001$ ) (Figures 4.11 and 4.12 respectively).

#### 5.4.2.2 Discussion

Similar results were found by Airaksinen et al. (2003) in their study comparing menthol gel to placebo gel in the treatment of soft tissue injury of the ankle, leg, knee or hand. There was a highly statistically significant ( $p < 0.001$ ) improvement seen in the menthol group compared to the placebo group in terms of pain. Hatem et al. (2006) found that when comparing the effects of menthol gel to a placebo gel in healthy volunteers, the menthol gel produced a cooling sensation which the placebo gel did not. According to Bandell et al. (2006), this cooling sensation is how menthol activates the TRPM8 receptors, which leads to the improvement of the pain experienced after an injury.

Airaksinen et al. (2003) in their study comparing menthol gel to placebo gel in the treatment of soft tissue injuries showed a statistically significant ( $p < 0.001$ ) improvement in functional ankle disability in the menthol gel group when compared to the placebo gel group. This supports the results found in this study that menthol gel application after an ankle injury improves ankle function and disability.

### **5.4.3 Group 3 – Combination gel**

#### 5.4.3.1 VAS and FFI scores

Both the VAS and FFI scores showed a highly statistically significant ( $p < 0.0001$ ) improvement over the study period in the combination gel group (Figures 4.13 and 4.14 respectively).

#### 5.4.3.2 Discussion

In a study by Zhang et al. (2008) comparing a combination gel (Biofreeze™) combined with chiropractic manipulation to chiropractic manipulation alone in the treatment of acute back pain, it was found that the group receiving the combination gel showed statistically significant pain reduction ( $p < 0.05$ ) when compared to the group which did not receive the combination gel. Similarly Bishop et al. (2009) found that when comparing a combination gel (Biofreeze™) with ice, the combination gel significantly reduced the participant's pain after an acute neck injury, with the Biofreeze™ gel reducing pain almost double to that of the ice application. This is in keeping with the

results found in this study that a combination gel with menthol as the main ingredient can improve pain after acute injury.

Higashi, Kiuchi and Furuta (2010) compared the efficacy of a topical patch containing methyle salicylate (10%) and menthol (3%), to a placebo patch containing no active ingredients, in the treatment of mild to moderate muscle strain. They noted that the combination patch provided statistically significant ( $p = 0,005$ ) pain relief after a single eight hour application.

In contrast to the results found in this study regarding disability after treatment, Zhang et al. (2008) in a pilot study comparing Biofreeze™ combined with chiropractic adjustments to chiropractic adjustments alone, found using the Roland Morris Disability Questionnaire that there was no significant ( $p>0.05$ ) changes in both groups regarding functional disability scores over the four week treatment period. However it was noted in their study that the disability scores did improve after the second week. It must be noted however, that cold gels containing menthol have been shown to significantly improve ankle disability following an injury (Airaksinen et al., 2003). The menthol and herbal component of the combination gel used in this study act together to produce an anti-inflammatory effect (Quinn, 2009), which results in decreased pain and disability (Bleakley et al., 2004).

#### **5.4.4 Group 4 – Placebo gel**

##### **5.4.4.1 VAS and FFI scores**

The VAS score was analysed in Figure 4.15 and showed a statistically significant improvement ( $p<0.001$ ) over the duration of the study. The FFI also showed a statistically significant improvement ( $p<0.002$ ) over the study period, and was analysed in Figure 4.16.

##### **5.4.4.2 Discussion**

Hrobjartsson et al. (2001) in an analysis of 130 clinical trials comparing placebo with no treatment, noted that when measuring perceived pain, the placebo group almost always



showed an improvement in terms of subjective measurements. Airaksinen et al. (2003) found that the pain perceived by participants as well as participants functional ankle disability in the placebo gel group significantly improved ( $p < 0.001$ ) at each of the three treatments over the three weeks. These results are in keeping with the results seen in this study where a placebo gel is seen to be beneficial in reducing pain and disability after soft tissue injury. Similarly, Higashi et al. (2010) showed that when comparing a patch containing menthol to a placebo patch, the participant's pain levels in the placebo group decreased significantly over the study period.

Regarding ankle function, Pellow and Brantingham (2001) in their study found statistically significant ( $p < 0.05$ ) improvements in overall ankle function in the placebo group, supporting the results seen in this study where participants' ankle function improved following an ankle injury. The placebo is thought to work through psychological mechanisms (Carroll, 1994), although the exact mechanisms of action are largely unknown (Friedman et al., 2008 and Turner et al., 1994).

#### **5.4.5 Conclusion**

All four treatment groups were effective in improving the participant's pain and disability after an acute ankle sprain.

### **5.5 OBJECTIVE THREE: TO COMPARE THE FOUR TREATMENTS IN TERMS OF THE OBJECTIVE AND SUBJECTIVE MEASURES**

#### **5.5.1 Objective measurements**

##### **5.5.1.1 Algometer readings**

There were no statistically significant ( $p=0.2957$ ) differences at baseline measurements between the 4 groups (Table 4.4), with a statistically significant difference noted between the groups from baseline to visit 2 ( $p < 0.0003$ ) where the combination and ice group showed a statistically significant difference compared to the placebo group. From visit 2 to 3 ( $p < 0.0054$ ) the menthol group showed statistically significant difference when

compared to the placebo group and from baseline to visit 3 ( $p < 0.0001$ ) where the combination, menthol and ice pack groups were statistically significantly different to the placebo group. This indicates that in terms of pain pressure threshold the ice pack, menthol and combination groups were superior to the placebo group in improving pain threshold levels.

#### 5.5.1.2 Figure of Eight measurements

There were no statistically significant ( $p = 0.1324$ ) differences between the 4 groups at baseline measurements (Table 4.5). There was a statistically significant difference noted between the groups from baseline to visit 2 ( $p < 0.0033$ ), where the Bonferroni post hoc test (Table 4.13) showed that there was a statistically significant difference between the ice pack, menthol and combination groups when compared to the placebo group. This indicates that at visit 2 the active treatments were superior to placebo in decreasing swelling. There was no statistically significant difference noted between the four groups from visit 2 to 3 ( $p = 0.2026$ ), and from baseline to visit 3 ( $p = 0.6546$ ) in terms of decreasing swelling.

#### 5.5.1.3 Discussion

All groups showed statistical improvement overall. An explanation as to why the ice pack, menthol and combination groups improved so significantly may be due to their similar mechanism of action. According to the literature, an ice pack and menthol gel have been shown to work in a similar manner by reducing nerve excitability and conduction velocity, which decreases pain transmission and therefore reduces pain threshold. Ice packs as well as gels containing menthol have also been shown to decrease local blood flow after application, which according to Bleakley et al. (2004) ultimately leads to a decrease in swelling. The combination gel used in this study contains menthol, which would also have a similar mechanism of action. By this mechanism of action the increase in pain threshold levels and the decrease in swelling advocate these therapies in the treatment of acute ankle injuries. These effects were superior to placebo indicating that the three active treatments used in this study are recommendable as treatments for acute ankle sprains.

According to van Rijn et al. (2008), the clinical course of pain experienced after an acute lateral ankle sprain improves rapidly within 14 days and then at a slower rate thereafter. This may account for the reason the placebo gel used in this study improved more than expected. However, all groups were subject to the same study specifications and this together with the time period of this study rule out natural history as an important factor.

## **5.5.2 Subjective measurements**

### **5.5.2.1 VAS scores**

At baseline measurements the four groups were statistically significantly different ( $p=0.0053$ ) (Table 4.6), indicating that the following results must be interpreted with care. When comparing baseline to visit 2 ( $p<0.0144$ ) there was a statistically significant difference between the groups with the combination group being statistically significantly different to the ice pack, menthol and placebo groups. This may highlight that at visit 2 the combination group had superior improvements in pain when compared to the other three groups. From baseline to visit 3 ( $p<0.0001$ ) there was a statistically significant difference noted between the groups with the placebo group being statistically significantly different from the ice pack, menthol and combination groups. This may propose that the placebo group did not respond as favourably as the other three groups in terms of pain over the course of the treatment. There was no statistical difference noted between the groups from visit 2 to 3 ( $p<0.1101$ ).

### **5.5.2.2 FFI scores**

There was a statistically significant ( $p=0.0012$ ) difference noted between the four groups at baseline measurements (Table 4.8), indicating that the results must be interpreted with care. A statistically significant difference was noted between the groups from baseline to visit 2 ( $p=0.0392$ ), and baseline to visit 3 ( $p=0.0005$ ), with the placebo group being statistically significantly different to the combination, menthol and ice pack groups at each of these measurements. Indicating that the active treatment groups were superior to the placebo in resulting in a change in the ankle function and disability. There was no statistical difference noted between groups from visit 2 to 3 ( $p=0.2897$ ).

### 5.5.2.3 Discussion

According to Herrera et al. (2010) and Cameron (1999) the decrease in pain and disability scores are due to the mechanism of action of applying cold after a soft tissue injury. Cold packs have been shown to decrease tissue temperature through conduction, which results in a reduction of pain and muscle spasm (Enwemka et al., 2002), which has also been shown to improve disability and recovery time following an injury (Bleakley et al., 2006). Menthol although it does not decrease tissue temperature, it still produces a cold sensation by stimulating specific cold receptors (TRPM8), which are the same receptors stimulated by cold packs (Patel et al., 2007 and Bandell et al., 2006), causing a reduction in pain sensation. The combination gel was made up of menthol combined with herbal extracts (0.5%) having anti-inflammatory properties. By their nature anti-inflammatory properties result in decreased inflammation and therefore reduce pain, and are thought to further improve outcomes when combined with the cold producing properties of menthol, compared to using menthol alone (Quinn, 2009).

Bishop et al (2009) showed that ice, and a combination gel containing menthol as the active ingredient (Biofreeze), both decreased pain levels following an acute injury, with their study finding that the combination gel had twice the improvement when compared to the group receiving ice. This is similar to the results found in this study.

The placebo gel used in this study did not contain any active ingredient nor was it cold, and so did not work along the same mechanism of action as the other three groups, but rather through highly subjective psychological mechanisms. The results of this study are in keeping with Hrobjartsson et al. (2001) where they found subjective outcomes favouring placebo when comparing it to control groups.

Studies by Hatem et al. (2006) and Airaksinen et al. (2003) found similar results to the ones found in this study, where although the placebo gel improved treatment outcomes, the menthol based gel produced statistically better results overall when compared to a placebo gel group in terms of pain and disability scores.

The results of this study show that the three active treatments were effective in decreasing pain and disability more so than placebo. Although care must be taken as the groups were not equal at baseline.

### **5.5.3 Conclusion**

The overall results of this study are in keeping with the review of the literature by Bleakley et al. (2004) and Hubbard et al. (2004) where it was noted that application of cryotherapy after an acute injury reduced pain, swelling and disability at the site of injury.

This study found that all four treatment interventions were effective and safe in treating acute grade 1 and 2 ankle sprains, but the ice pack and active cold gel groups appear to significantly improve treatment outcomes, and at a similarly higher rate when compared to the placebo gel group.

## **5.6 OBJECTIVE FOUR: TO IDENTIFY ANY ADVERSE REACTIONS THAT MAY BE CAUSED BY THE TREATMENT METHODS**

No adverse reactions were reported or noted in any of the four treatment groups used in this study.

## **5.7 REVIEW OF HYPOTHESIS:**

- The first and second hypotheses are rejected since there were statistically significant changes in all objective and subjective measurements for all four treatment groups.
- The third hypothesis was rejected since the placebo gel group was found to be less effective than the other three groups.

- The fourth hypothesis was accepted since none of the participants in any of the four groups reported any adverse reactions during and after the treatment period.

# **Chapter Six**

## **Conclusion and Recommendations**

### **6.1 Conclusion**

All four treatment groups in this study showed an improvement in terms of objective and subjective findings over the 3 visits, indicating that they were all effective in decreasing pain, swelling and ankle disability and increasing pain pressure thresholds. However when compared to each other the ice pack, menthol and combination groups showed a similar rate of improvement that was superior to the placebo group. Proposing that the three active treatments can be recommended in the treatment of acute ankle sprains. It appears from the results that there were no added benefits in using the combination gel, with it being equal in effect to both the ice pack and menthol gel.

In all four groups there were no reports of any adverse reactions, indicating that these treatments were safe.

In conclusion, the results of the study demonstrated that the effects produced by the two cooling gels containing menthol, are comparable with those of conventional/traditional ice pack cryotherapy in the treatment of acute grade 1 or 2 inversion ankle sprains.

### **6.2 Recommendations**

- A sample size of 48 was used in this study, with 12 in each group. A larger sample size would have strengthened the results of this study.
  
- A future study could include another group, receiving no treatment, to rule out the effect of natural history of acute ankle sprains.

- Measurements should be taken after 24 hours to assess in the short term the effectiveness of the four different treatments.
- It would be interesting to note for future research, which treatment the patient preferred and which was easier to apply and felt more comfortable.
- An ideal situation would have been to be able to apply the treatment immediately after the injury occurred, when cryotherapy is at its most effective.
- In future studies it would be recommendable to only treat grade 1 or 2 ankle sprains rather than combining them as was done in this study.



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# **APPENDIX A**

## **Letter of Information and Consent**

Dear Participant,

Thank you for volunteering to be part of my study. I am a student currently pursuing my M. Tech: Chiropractic qualification at the Durban University of Technology

**Research title:** The effectiveness of an ice pack, a menthol based cooling gel, a menthol based cooling gel with herbal extracts and a placebo gel in the treatment of acute ankle sprains.

**Researcher:** Shaun Harper  
**Supervisor/s:** Dr. Laura Wilson (supervisor) M. Tech: Chiropractic, CCEP  
Prof. David Gerber (co-supervisor) BVSc, PhD

The ankle is one of the most common sites of acute injury, with ankle sprains being the most common injury. Many people use ice or cooling gels when they have acute musculoskeletal injuries. Very few studies have assessed the effectiveness of various methods of cold application. Therefore this study aims to determine the effectiveness of an ice pack; menthol based cold gel, a cooling gel based on a combination of menthol and herbal extracts and placebo gel in the treatment of acute ankle sprains.

### **Outline of procedure:**

You will be required to have a case history, physical and ankle examination done at the chiropractic day clinic. The examination will determine your eligibility to join the study. Once accepted you will be required to sign an informed consent form after a full explanation of what the research involves. You will have the opportunity to ask questions about the procedures. This study consists of four groups comprising of three treatment groups and one placebo group. There is a one in four chance that you may be allocated to the placebo group. Should you fall into the placebo group you will be offered two free treatments at the chiropractic day clinic at the end of the treatment. By partaking in the study you will need to apply a gel or ice pack to your ankle three times per day for three days. On the fourth day you will be required to attend the clinic for an appointment. After that appointment a follow up consultation will be scheduled for one week later. During that week no gel or ice pack must be used.

Please ensure that while you are on this study that you do not apply any other creams/gels to your ankle sprain. In order for the research results to be accurate you are asked to follow the instructions given to you in terms of the treatments.

**Benefits:** This study will help health care practitioners determine the most effective means of applying cold to an ankle sprain.

**Risks/Discomforts to the Subject and Product info:** One of the products used in this study was traditionally used in animals with sore aches and pains however today it is sold by pharmacies country wide for human application. The product was found to be non-irritant however should you develop any skin irritation or dryness please discontinue using the gel immediately, wash the area with water and contact the researcher or the supervisor. Do not use the gels in this study over open wounds or sensitive skin. Avoid exposure to the eyes and use the gels for external use only.

**Reason/s why the Subject May Be Withdrawn from the Study:** You are free to withdraw at any time and it will not affect future treatments at the chiropractic clinic should you return.

**Remuneration:** By participating in this study there will be no cost to you nor will you receive any remuneration except for the free treatment.

**Confidentiality:** This will be maintained as only the researcher and supervisor will have access to the patient files, in the dissertation no personal information will be disclosed only the demographics and results of each group will be discussed.

Should you have any questions regarding the research please contact the researcher (Shaun Harper) on 031 3732205 or 0832299098. If the researcher cannot be contacted please contact the supervisor (Dr Wilson) on 031 3732923 or the Mr V. Singh the faculty research coordinator at the Faculty of Health Sciences on 031 3732701.

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

I,..... (Full name) .....(I.D), have read this document in its entirety and understand its contents. Where I have had any questions or queries, Shaun Harper has explained these to me to my satisfaction. Furthermore, I fully understand that I may withdraw from this study at any stage without any adverse consequences and my future health care will not be compromised. I, therefore, voluntarily agree to participate in this study.

Subject's name:..... Subject's signature.....

Date.....

Researcher's name:..... Researcher's signature.....

Date.....

Witness name..... Witness signature.....

Date.....

Thank you for your participation.

# APPENDIX B

## DURBAN UNIVERSITY OF TECHNOLOGY CHIROPRACTIC DAY CLINIC CASE HISTORY

Patient: \_\_\_\_\_ Date: \_\_\_\_\_  
File # : \_\_\_\_\_ Age: \_\_\_\_\_

Sex: \_\_\_\_\_ Occupation: \_\_\_\_\_  
Intern : \_\_\_\_\_ Signature: \_\_\_\_\_

FOR CLINICIANS USE ONLY:

Initial visit

Clinician: \_\_\_\_\_ Signature : \_\_\_\_\_

Case History:

--

Examination:

Previous:

Current:

X-Ray Studies:

Previous:

Current:

Clinical Path. lab:

Previous:

Current:

CASE STATUS:

PTT: _____	Signature: _____	Date: _____
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CONDITIONAL:

Reason for Conditional:

--

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Signature: \_\_\_\_\_

Date: \_\_\_\_\_

--

Conditions met in Visit No:	Signed into PTT:	Date:
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Case Summary signed off:	Date:
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Intern's Case History:

1. Source of History:
2. Chief Complaint : (patient's own words):
3. Present Illness:

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

4. Other Complaints:
5. Past Medical History:
  - < General Health Status
  - < Childhood Illnesses

- < Adult Illnesses
- < Psychiatric Illnesses
- < Accidents/Injuries
- < Surgery
- < Hospitalizations
- 6. Current health status and life-style:
  - < Allergies
  - < Immunizations
  - < Screening Tests incl. x-rays
  - < Environmental Hazards (Home, School, Work)
  - < Exercise and Leisure
  - < Sleep Patterns
  - < Diet
  - < Current Medication
    - Analgesics/week:
    - < Tobacco
    - < Alcohol
    - < Social Drugs
- 7. Immediate Family Medical History:
  - < Age
  - < Health
  - < Cause of Death
  - < DM
  - < Heart Disease
  - < TB
  - < Stroke
  - < Kidney Disease
  - < CA
  - < Arthritis
  - < Anaemia
  - < Headaches
  - < Thyroid Disease
  - < Epilepsy
  - < Mental Illness
  - < Alcoholism
  - < Drug Addiction



- < Other
- 8. Psychosocial history:
  - < Home Situation and daily life
  - < Important experiences
  - < Religious Beliefs
- 9. Review of Systems:
  - < General
  - < Skin
  - < Head
  - < Eyes
  - < Ears
  - < Nose/Sinuses
  - < Neurologic
  - < Mouth/Throat
  - < Neck
  - < Breasts
  - < Respiratory
  - < Cardiac
  - < Gastro-intestinal
  - < Urinary
  - < Genital
  - < Vascular
  - < Musculoskeletal
  - < Neurologic
  - < Haematologic
  - < Endocrine
  - < Psychiatric

## APPENDIX C

### PHYSICAL EXAMINATION: SENIOR

<b>Patient Name :</b> _____	<b>File no :</b> _____
<b>Date :</b> _____	
<b>Student :</b> _____	<b>Signature :</b> _____

<b>VITALS:</b>			
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

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

<b>SYSTEM SPECIFIC EXAMINATION:</b>
<b>CARDIOVASCULAR EXAMINATION</b>
<b>RESPIRATORY EXAMINATION</b>
<b>ABDOMINAL EXAMINATION</b>
<b>NEUROLOGICAL EXAMINATION</b>
<b>COMMENTS</b>

<b>Clinician:</b> _____	<b>Signature :</b> _____	92
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# APPENDIX D

## Foot and ankle regional examination

Patient: \_\_\_\_\_ File no: \_\_\_\_\_ Date: \_\_\_\_\_

Intern / Resident \_\_\_\_\_ Signature: \_\_\_\_\_

Clinician: \_\_\_\_\_ Signature: \_\_\_\_\_

### Observation

Gait analysis (antalgic limp, toe off, arch, foot alignment, tibial alignment).

\_\_\_\_\_

Swelling \_\_\_\_\_

Heloma dura / molle \_\_\_\_\_

Skin \_\_\_\_\_

Nails \_\_\_\_\_

Shoes \_\_\_\_\_

Contours (achilles tendon, bony prominences) \_\_\_\_\_

\_\_\_\_\_

### Active movements

**Weight bearing:**                      (R)                      (L)                      **Non weight bearing:**                      (R)                      (L)

	(R)	(L)		(R)	(L)
Plantar flexion			50°		
Dorsiflexion			20°		
Supination					
Pronation					
Toe dorsiflexion			40°(mtp)		
Toe plantar flexion			40° (mtp)		
			Big toe dorsiflexion (mtp) (65-70°)		
			Big toe plantar flexion (mtp) 45°		
			Toe abduction + adduction		
			5° first ray dorsiflexion		
			5° first ray plantar flexion		

### Passive movement motion palpation (Passive ROM quality, ROM overpressure, joint play)

	(R)	(L)		(R)	(L)	(L)
Ankle joint: <i>Plantarflexion</i>			Subtalar joint: <i>Varus</i>			

<i>Dorsiflexion</i>			<i>Valgus</i>		
Talocrural: <i>Long axis distraction</i>			Midtarsal: <i>A-P glide</i>		
First ray: <i>Dorsiflexion</i>			<i>P-A glide</i>		
<i>Plantarflexion</i>			<i>Rotation</i>		
Circumduction of forefoot on fixed rearfoot			Intermetatarsal glide		
Interphalangeal joints: <i>L/A dist</i>			Tarso metatarsal joints: <i>A-P</i>		
<i>A-P glide</i>			Metatarsophalangeal dorsiflexion (with associated plantar flexion of each toe)		
<i>lat and med glide</i>					
<i>rotation</i>					

### Resisted Isometric movements

	Ⓡ	Ⓛ		Ⓡ	Ⓞ
Knee flexion			Pronation (eversion)		
Plantar flexion			Toe extension (dorsiflexion)		
Dorsiflexion			Toe flexion (plantar flexion)		
Supination (inversion)					

### Neurological

	Ⓡ	Ⓞ
Dermatomes		
Myotomes		
Reflexes		
Balance/proprioception		

### Special tests

	Ⓡ	Ⓞ
Anterior drawer test		
Talar tilt		
Thompson test		
Homan sign		
Tinel's sign		
Test for rigid/flexible flatfoot		
Kleiger test (med. deltoid)		

### Alignment

	Ⓡ	Ⓞ
Heel to ground		
Feiss line		
Tibial torsion		
Heel to leg (subtalar neutral)		
Subtalar neutral position:		
Forefoot to heel (subtalar & Midtarsal neutral)		
First ray alignment		
Digital deformities		
Digital deformity flexible		

**Palpation**

	<b>R</b>	
Medial malleoli	○	○
Med tarsal bones, tibial (post) artery		
Lat.malleolous, calcaneus, sinus tarsi, and cuboid bones		
Inferior tib/fib joint, tibia, mm of leg		
Anterior tibia, neck of talus, dorsalis pedis artery		
Calcaneus, Achilles tendon, Musculotendinous junction		
Plantar muscles and fascia		

# APPENDIX E

## SOAPE NOTE

### DURBAN INSTITUTE OF TECHNOLOGY

<b>Patient Name:</b>		<b>File #:</b>	<b>Page:</b>
<b>Date:</b>	<b>Visit:</b>	<b>Intern:</b>	<b>Signature:</b>
<b>Attending Clinician:</b>			
<b>S:</b> Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		<b>Intern Rating</b> <input type="checkbox"/>	<b>A:</b>
<b>O:</b>			<b>P:</b>
			<b>E:</b>
<b>Special attention to:</b>		<b>Next appointment:</b>	
<b>Date:</b>	<b>Visit:</b>	<b>Intern:</b>	<b>Signature:</b>
<b>Attending Clinician:</b>			
<b>S:</b> Numerical Pain Rating Scale (Patient) Least 0 1 2 3 4 5 6 7 8 9 10 Worst		<b>Intern Rating</b> <input type="checkbox"/>	<b>A:</b>
<b>O:</b>			<b>P:</b>
			<b>E:</b>
<b>Special attention to:</b>		<b>Next appointment:</b>	
<b>Date:</b>	<b>Visit:</b>	<b>Intern:</b>	<b>Signature</b>
<b>Attending Clinician:</b>			

## APPENDIX F

### ADVERT

Are you between the ages of

**18 – 45?**

And

# **Have a recently injured/sprained ankle?**

Research is currently being done at the Chiropractic  
Day Clinic at the Durban University of Technology

Should you qualify for the research, you will receive

## **FREE TREATMENT**

This will include an assessment and treatment.



For more information, please contact

**Shaun**

(031) 373 2205 or (031) 373 2512

## **APPENDIX G**

### **West Point Ankle Sprain Grading System**

Criterion	Grade 1	Grade 2	Grade 3
Location of tenderness	ATFL	ATFL, CFL	ATFL, CFL, PTFL
Edema, Ecchymosis	Slight	Moderate	Diffuse
Weight bearing ability	Full or partial	Difficult without crutches	Impossible without significant pain
Ligament damage	Stretched	Partial tear	Complete tear
Instability	None	None or slight	Definite



## APPENDIX H

### Algometer readings.

	FIRST	SECOND	THIRD
DATE			
READING			

## APPENDIX I

### Figure of Eight measurements

	FIRST	SECOND	THIRD
DATE			
READING			

# APPENDIX J

## Visual Analogue Scale

Date: \_\_\_\_\_

File No: \_\_\_\_\_

Visit No: \_\_\_\_\_

Patient Name \_\_\_\_\_

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **when it is at its worse**. A zero (0) would mean “no pain at all”, and one hundred (100) would mean “pain as bad as it could be”  
Please write only one number

0 \_\_\_\_\_ 100

Please indicate on the line below, the number between 0 and 100 that best describes the pain you experience **when it is at its least**. A zero (0) would mean “no pain at all”, and one hundred (100) would mean “pain as bad as it could be”  
Please write only one number

0 \_\_\_\_\_ 100

# APPENDIX K

## Foot Function Index

Section 1: To be completed by patient      Name: \_\_\_\_\_  
Age: \_\_\_\_\_      Date: \_\_\_\_\_      Occupation: \_\_\_\_\_  
Number of days of foot pain: \_\_\_\_\_

Section 2: To be completed by patient  
This questionnaire has been designed to give your therapist information as to how your foot pain has affected your ability to manage in everyday life.  
For the following questions, we would like you to score each question on a scale from 0 (no pain) to 10 (worst pain imaginable) that best describes your foot over the past WEEK

Please read each question and place a number from 0-10 in the corresponding box.  
No Pain 0 1 2 3 4 5 6 7 8 9 10 Worst Pain Imaginable

1. In the morning upon taking your first step?
2. When walking?
3. When standing?
4. How is your pain at the end of the day?
5. How severe is your pain at its worst?

Answer all of the following questions related to your pain and activities over the past WEEK, how much difficulty did you have?

No Difficulty 0 1 2 3 4 5 6 7 8 9 10 So Difficult unable to do

6. When walking in the house?
7. When walking outside?
8. When walking four blocks?
9. When climbing stairs?
10. When descending stairs?
11. When standing tip toe?
12. When getting up from a chair?
13. When climbing curbs?
14. When running or fast walking?

Answer all the following questions related to your pain and activities over the past WEEK. How much of the time did you

None of the time 0 1 2 3 4 5 6 7 8 9 10 All of the time

15. Use an assistive device (cane, walker, crutches, etc) indoors?
16. Use an assistive device (cane, walker, crutches, etc) outdoors?
17. Limit physical activities?

Section 3: To be completed by physical therapist/provider  
SCORE: \_\_\_\_\_/170 x100= \_\_\_\_\_% (SEM 5, MDC 7)  
SCORE: Initial \_\_\_\_\_ Subsequent \_\_\_\_\_ Subsequent \_\_\_\_\_ Discharge \_\_\_\_\_

# APPENDIX L

## ETHICS CLEARANCE CERTIFICATE

Student Name	Shaun Harper	Student No	20402321
Ethics Reference Number	FHSEC	Date of FRC Approval	
Qualification	M-Tech Chiropractic		
Research Title:	The effectiveness of an ice pack, a menthol based cooling gel, a menthol based cooling gel with herbal extracts and a placebo gel in the treatment of acute ankle sprains.		

*In terms of the ethical considerations for the conduct of research in the Faculty of Health Sciences, Durban University of Technology, this proposal meets with Institutional requirements and confirms the following ethical obligations:*

1. The researcher has read and understood the research ethics policy and procedures as endorsed by the Durban University of Technology, has sufficiently answered all questions pertaining to ethics in the DUT 186 and agrees to comply with them.
2. The researcher will report any serious adverse events pertaining to the research to the Faculty of Health Sciences Research Ethics Committee.
3. The researcher will submit any major additions or changes to the research proposal after approval has been granted to the Faculty of Health Sciences Research Committee for consideration.
4. The researcher, with the supervisor and co-researchers will take full responsibility in ensuring that the protocol is adhered to.
5. ***The following section must be completed if the research involves human participants:***

	YES	NO	N/A
❖ Provision has been made to obtain informed consent of the participants	X		
❖ Potential psychological and physical risks have been considered and minimised	X		
❖ Provision has been made to avoid undue intrusion with regard to participants and community	X		
❖ Rights of participants will be safe-guarded in relation to:	X		
- Measures for the protection of anonymity and the maintenance of Confidentiality.			
- Access to research information and findings.	X		
- Termination of involvement without compromise	X		
- Misleading promises regarding benefits of the research	X		

\_\_\_\_\_  
SIGNATURE OF STUDENT/RESEARCHER

\_\_\_\_\_  
DATE

\_\_\_\_\_  
SIGNATURE OF SUPERVISOR/S

\_\_\_\_\_  
DATE

\_\_\_\_\_  
SIGNATURE OF HEAD OF DEPARTMENT

\_\_\_\_\_  
DATE

\_\_\_\_\_  
SIGNATURE: CHAIRPERSON OF RESEARCH ETHICS COMMITTEE

\_\_\_\_\_  
DATE