THE EFFICACY OF A HOMOEOPATHIC PROTOCOL AS AN ADJUNCT TO STANDARD CARE OF THE POST-SURGICAL EFFECTS OF CIRCUMCISION

By

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DECLARATION

I, Euvette Cardian Taylor, do declare that this dissertation is representative of my own work, both in conception and execution, unless explicitly acknowledged (including citation of published and unpublished sources). The work has not previously been submitted in any form to the Durban University of Technology or to any other institution for assessment or for any other purpose.

Signature of Student **Date of signature**

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RN, RM, D Tech: Nursing

DEDICATION

I dedicate this dissertation to:

- The **Almighty God** for affording me the privilege of life and for allowing me to make this contribution towards health care. Thank you for the granting me strength to press on, even though all odds seemed to be against me. Thank you for granting me a loving heart, May you give me the strength and meekness to treat all mankind with respect, compassion and dignity.

- To my late Grandmother, **Maggie Taylor** “maThwala”. Thank you for making me the man I am today. Thank you for showing the definition of love. Death can never come between the connections we both share. Rest in peace Ngiyohlala ngikuthanda ntombi ka Sobhuza.

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- To my brother **Tyronne Taylor**, “Tyo”, I hope this inspires you to reach for the stars. Please respect life and tread in this world carefully. I hope God keeps you safe khehla. I wish you success. I Love you.

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ABSTRACT

INTRODUCTION

This research study investigated the efficacy of a homoeopathic protocol in the post-surgical wound management of medical male circumcision (MMC) in the KwaZulu-Natal region. The study had 30 male participants from 10 of the 11 district municipalities of the KwaZulu-Natal province. The study consultations took place at the Durban University of Technology Health Sciences Clinic.

AIM OF THE STUDY

The aim of the study was to determine the efficacy of a topical application of a homoeopathic protocol using; *Calendula officinalis* (mother tincture (M.T.)), *Hypericum perforatum (*M.T.) and *Delphinum staphysagria* 30CH (orally) as an adjunct to the standard care of the post-surgical effects of circumcision and to assess the wounds post-surgically in terms of time taken to heal and associated signs and symptoms.

METHODOLOGY

The data for this study was collected from 30 male participants who had undergone MMC from various hospitals within KwaZulu-Natal. The participants were aged between 18 to 30 years. All participants underwent a medical examination and were given a pain rating scale and a pain and sleep diary. They were instructed to keep a daily record using the data collection tools mentioned above for the study period of six weeks. Descriptive statistics were employed in the form of tables and graphs. The data analysis methods used in the study are: independent samples t-test and the non-parametric Spearman's Correlation test.

RESULTS

Group statistics in relation to ‘time to heal’ showed a statistically significant reduction in the time taken for the group on the homoeopathic protocol. Analysis of ‘time to heal’ by group shows that on average, Group 1 (active group: homoeopathic protocol + standard care) (M = 31.4, SD = 7.49) healed in a significantly shorter time than Group 2 (control group: standard care) (M = 38.6667, SD = 1.99), t (28) = -2.617, p=.014. There was no other statistical significance noted except for the results of the Spearman’s rho, where table 4.8 shows there is a significant positive correlation between average quality sleep until healing and the proportion of days across healing NOT feeling refreshed (rho = .676, p<.0005).

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GLOSSARY OF TERMS

Adjunct

An accessory or auxiliary agent or measure, it is an additional substance, treatment, or procedure (Stedman and Dirckx 2001).

Adverse events

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product (Stedman and Dirckx 2001).

Analgesic

An agent that provides pain relief (Martin 2002).

Angiogenesis

The formation of new blood vessels, a process controlled by chemicals produced in the body that stimulate blood vessels or form new ones. Angiogenesis plays an important role in the healthy body for healing of wounds and restoring blood flow to tissues after injury (Stedman and Dirckx 2001).

Antibacterial

An agent that destroys bacteria or suppresses their growth or their ability to reproduce (Venes 2013).

Antiparasitic

Destroying or inhibiting the growth and reproduction of parasites (Marton 1994).

Antipyretic

An agent that reduces fever or quells it (Martin 2002).

Circumcision

The removal of the prepuce of the male penis or labia of the female vagina (Venes 2013).

Efficacy

The quality of being successful in producing an intended result; effectiveness (Stedman and Dirckx 2001).

Mother tincture

Mother tinctures for homoeopathic preparations may also be obtained from plant juices, with, or without the addition of a vehicle. For some preparations, the matter to be extracted may undergo a preliminary treatment (Royal London Homeopathic Hospital. Faculty of Homeopathy 2009).

Post-surgical effects

These are the signs and symptoms that are that are experienced after the surgery has been done (Rech *et al.* 2014).

Time taken to heal

Measurement of the duration taken for the wound to heal over a certain period (Larke *et al.* 2011).

LIST OF ACRONYMS

Acronym	Full Word
ABC	: Abstain, Be Faithful, Condomise
AIDS	: Acquired immunodeficiency syndrome
DoH	: Department of Health
DUT	: Durban University of Technology
HIV	: Human Immune Virus
KZN	: KwaZulu-Natal
MMC	: Medical Male Circumcision
PHC	: Primary Health Care Clinic
UNAIDS	: Joint United Nations Programme on HIV/AIDS
USA	: United States of America
VMMC	: Voluntary Medical Male Circumcision
WHO	: World Health Organization

CHAPTER 1 : OVERVIEW OF THE STUDY

1.1 BACKGROUND TO THE STUDY

Male circumcision is probably one of the oldest cultural rituals and surgical procedures, performed since before recorded history (Doyle 2005). Historically, the procedure was practiced as a ritual by South Sea Islanders, Australian Aborigines, Sumatrans, Incas, Ancient Egyptians, Aztecs and Mayans (Doyle 2005). In retrospect, medically the procedure was justified for various male related sexual health issues ranging from reducing masturbation (Alanis and Lucidi 2004) to more serious conditions like phimosis in neonates (Weiss *et al.* 2010). Ritual circumcision is still practiced by Jews, Muslims and many societies in Africa, like the AmaXhosa of South Africa. However, in contemporary society circumcision is not performed primarily as a ritual but as a surgical procedure. To date, male circumcision is probably the most widespread surgical procedure globally (Doyle 2005), and this is in part due to the global HIV epidemic.

In the past two decades, the HIV epidemic has contributed to widespread advocacy for male circumcision, primarily as a preventative biomedical method (Aggleton 2007). Early studies on male circumcision suggested that uncircumcised men were at a higher risk of sexually transmittable infections (STIs) when compared to their circumcised counterparts (Van Howe 1999; Turner *et al.* 2007; Herman-Roloff *et al.* 2011; Tian *et al.* 2013). The uncircumcised penis is at an increased risk of STIs “because of a larger surface area, thinner epidermal barriers and the warm, moist niche under the foreskin favouring the persistence of fastidious microorganisms” (Donovan, Bassett and Bodsworth 1994).

While circumcision continues as a medical procedure in the more developed countries such as the United States of America (USA) and the United Kingdom

(UK), its popularity has declined over time (Duffin 2011). For instance, in Australia, circumcision procedures have dropped to a 10% point (Richters *et al.* 2006) in the last ten years. Likewise, in the USA the recorded annual medical male circumcision (MMC) procedures were over 70% of neonates in the year 1996 but declined to 43% procedures per year in 2007 (Weiss *et al.* 2010). These reduced rates in medical male circumcision procedures are perhaps testament to the belief among people in developed countries that it is a primitive and outdated medical procedure that is comparable to corporal punishment (Duffin 2011).

In developing countries, like those in the African continent, medical circumcision is primarily practiced today as a response to the incidence rate of HIV (Bertrand *et al.* 2011; Curran *et al.* 2011; Gow and George 2013). Owing to the HIV epidemic, the use of this medical service has increased in the last decade. In Kenya, for example, medical male circumcision procedures went up from 84% in 2006 (Johnson and Way 2006) to above 90% between 2009 and 2011 (Meyer and Struthers 2012). In Uganda MMC procedures increased from 43% in 2006 to 73% in 2011 (World Health Organization [WHO] 2012). There is evidence in the literature which suggests that MMC reduces the likelihood of an HIV infection by up to 60% (Larke *et al.* 2011; Albero *et al.* 2012). For example, in 2007 a study conducted in three African countries (namely Kenya, Lesotho and Tanzania) found that the incidence rate of HIV was three times less amongst males that were circumcised when compared to their uncircumcised counterparts (Brewer *et al.* 2007).

In South Africa circumcision has gained momentum not just as a cultural procedure but also as a biomedical method of preventing HIV and other STIs (World Health Organization and Unicef 2010). The South African Department of Health (DoH) reported that there has been over 170 000 MMC procedures performed since 2010. The DoH has made plans to increase the uptake of MMC to up to 500 000 in 2016 (Department of Health 2013). This increased uptake is a result of nationwide programmes aimed at encouraging young men to get

circumcised as a prevention method for HIV and other STIs (WHO 2011; Joint United Nations Programme on HIV/AIDS [UNAIDS] 2011).

MMC was launched in South Africa in 2010 following guidelines from the WHO (2010). The launch was hosted in the KwaZulu-Natal (KZN) province since it recorded the highest prevalence of men living with HIV and a smaller number of circumcised men when compared to men from the other eight provinces (Meyer *et al.* 2011). To date, MMC continues to be promoted vigorously by the DoH as a means to reaching about 80% of HIV negative men in the 15-49 year age (Colvin 2011).

While there is great enthusiasm around MMC in the country, certain challenges still persist. For example, Jennings *et al*. (2014) reports insufficient public healthcare resources to accommodate the influx of patients reporting for MMC. Moreover, other studies report poor quality of services rendered in relation to MMC (Mahler *et al.* 2011; Gray, Wawer and Kigozi 2013; Rech *et al.* 2014). A major point of concern is poor post-operative management of circumcision wounds at specific healthcare sites (Jennings *et al*. 2014). This research study attempted to address the concerns of poor wound management post surgically and also explore the benefits of the homoeopathic protocol being researched.

1.2 PROBLEM STATEMENT AND OBJECTIVES OF THE DISSERTATION

Although circumcision is currently advocated as a biomedical intervention in the scourge of HIV, little research has been conducted in South Africa on the post-operative management of circumcision wounds. The poor management of circumcision wounds can have negative consequences if not addressed adequately. Complications include poor wound healing, continued bleeding and infections (Rech *et al.* 2014). A number of controversies and speculations have been observed around MMC in terms of the minimum quality criteria of post-operative wound management and studies show that the main reason for adverse effects has been the poor post-surgical wound management of circumcision (Curran *et al.* 2011; Dickson *et al.* 2011; Edgil *et al.* 2011).

South Africa is doing an excellent job in the expansion of its MMC programme with the highest numbers of new circumcisions recorded globally. However, recent studies have revealed that South Africa has the poorest post-surgical management and reporting of adverse events when compared to other African countries (Mahler *et al.* 2011; Rech *et al.* 2014). There is a paucity of studies to date that have looked at the factors that contribute to wound healing such as hygiene, wound care and nutrition; rather, studies tend to focus on MMC as a preventative strategy for STIs (and HIV in particular). This is particularly worrying since a majority of the men that require MMC and its associated post-operative care services fall within the demographic of the poor, undernourished and under-served population (Statistics South Africa 2013). Likewise, there is little reflected in the literature to address issues of general compliance of patients taking medication related to circumcision in the South African public healthcare (PHC) system.

1.3 AIM OF THE STUDY

The aim of the study was to determine the efficacy of a homoeopathic protocol, which included the topical application of *Calendula officinalis* (mother tincture (M.T.), *Hypericum perforatum (*M.T.) and *Delphinum staphysagria* 30CH (orally) as an adjunct to the standard care of the post-surgical effects of circumcision and to assess the wounds post-surgically in terms of time taken to heal and the associated signs and symptoms.

1.4 OBJECTIVES OF THE STUDY

The objectives of the study were to:

a) Determine the efficacy of the standard treatment of circumcision with regards to pain, sleep, discomfort, inflammation, bleeding, pus formation and exudation, using the pain rating scale and the pain and sleep diary.
b) Determine the efficacy of the standard treatment of circumcision in conjunction with the homoeopathic protocol with regards to pain, sleep,

discomfort, inflammation, bleeding, pus formation and exudation, using the pain rating scale and the pain and sleep diary.

c) Assess the statistical differences between the two groups of treatment, namely standard treatment and the homoeopathic protocol, in terms of post-surgical wound healing with regards to time taken to heal and the differences in associated signs and symptoms.

1.5 RESEARCH QUESTIONS

Contextualizing all of the above factors, this study answers three key research questions that bear directly on the management of post-operative circumcision wounds. The questions were as follows:

a) What is the efficacy of the standard treatment of circumcision with regards to pain, sleep, discomfort, inflammation, bleeding, pus formation and exudation, using the pain rating scale and the pain and sleep diary?

b) What is the efficacy of the standard treatment of circumcision in conjunction with the homoeopathic protocol with regards to pain, sleep, discomfort, inflammation, bleeding, pus formation and exudation, using the pain rating scale and the pain and sleep diary?

c) Are there any statistical differences between the two groups of treatment (namely standard treatment and homoeopathic protocol) for medical male circumcision with regards to time taken to heal and the differences in associated signs and symptoms?

1.6 SIGNIFICANCE OF THE STUDY

The province of KZN has historically recorded the highest prevalence of HIV and is said to be the epicentre of HIV/AIDS in South Africa (Statistics South Africa 2013). DoH (2010) stated that the high HIV prevalence in KZN was

inversely proportional to the number of circumcised males. It was for this reason that the DoH launched a campaign for MMC in 2010. The focal point was increasing the number of circumcised men in the province and in turn decreasing the high prevalence rate of HIV infection, as studies have drawn a correlation between circumcision and heterosexual HIV infection (Weiss, Hankins and Dickson 2009; Dinh, Fahrbach and Hope 2011; Gray, Wawer and Kigozi 2013). To date, little research has been conducted to evaluate the quality of services rendered in relation to MMC. Recent studies have noted that there has been a decrease in the quality of services since the launch of MMC in 2010 (Mahler *et al.* 2011; Rech *et al.* 2014).

1.7 OVERVIEW OF THE RESEARCH METHODOLOGY

The data for this study was collected from participants who had undergone MMC from various hospitals within KZN. All participants underwent a medical examination and were given a pain rating scale and a pain and sleep diary. They were instructed to keep a daily record on the data collections tools mentioned above, over six weeks of the study period, using a pain and sleep diary and pain rating scale. The pain and sleep diary had an adapted form of the Pittsburg sleep quality index. Descriptive statistics were employed in the form of tables and graphs. The data analysis methods used in the study are: independent samples t-test and the non-parametric Spearman's Correlation test.

1.8 DELIMITATIONS

a) The study recruitment group was only 30 participants.
b) The study was limited to the KZN district.
c) The study was limited to males that had undergone MMC only, not those who had been traditionally circumcised.

1.9 OUTLINE OF THE DISSERTATION

This dissertation is structured as follows:

Chapter 1

This chapter introduced the study providing the background and rationale of the study in order to contextualize it. A presentation of the research problem, research rationale, research objective as well as research design and methodology has been included.

Chapter 2

This chapter focuses on a comprehensive literature review on the subject under investigation, and includes the rationale of circumcision from both national and international literature.

Chapter 3

This chapter explains and summarizes the research methodology used in this study and the inclusion and exclusion criteria used to recruit participants.

Chapter 4

This chapter presents the research findings or results.

Chapter 5

This chapter presents the discussion of the results.

Chapter 6

This chapter presents the conclusion, limitations and recommendations.

1.10 CONCLUSION

This chapter focused on providing the basic overview of the dissertation and explained the pertinence of the research. This chapter encompasses the introduction and background, research problem, research rationale, research objective and research design and methodology.

CHAPTER 2 : LITERATURE REVIEW

2.1 INTRODUCTION

This chapter provides local and international literature available on circumcision as a mode of addressing the high incidence and prevalence of HIV. Inspiration will be drawn from the various forms of circumcision practiced globally and in the local arena; as a rite of passage, as a religious necessity and other historic norms related to circumcision. This chapter will focus on the treatment protocols available and the literature that speaks to the role of homoeopathic medication as part of the post-surgical treatment protocol. There will be a discussion on the issues pertaining to policy, ethics and the legal inferences surrounding circumcision. In this chapter there will also be a discussion around the determinants contributing to wound healing and its implications in the scaling up of MMC. The research methodology consists of the collection, analysis, critical evaluation and use of secondary data collected from relevant literature, databases and internet sources and covers various sources such as:

- A desktop review of annual/quarterly work plans, progress reports and research reports.
- A desktop review of medical male circumcision research and services in South Africa.
- Health statistics from hospital and clinics with a primary focus being KZN.
- HIV and AIDS preventative strategies in Africa.
- Articles from journals and newspaper reports.
- Internet sources and publications from WHO and UNAIDS.

Key search terms used:

- Circumcision (Global, Africa, South Africa, Statistics)
- Medical Male Circumcision / Voluntary Male Circumcision (VMMC)
- Circumcision and HIV

- Homoeopathic philosophy, homoeopathy and HIV
- Skin healing/tissue healing.
- Primary healthcare South Africa constraints

2.2 HISTORY OF CIRCUMCISION

Over the centuries, circumcision has been conducted for various reasons. In western cultures the predominant themes include: as a rite of passage into adulthood (Knight 2001), for religious identification (Weinfeld 1993), as a means of controlling sexuality and fertility (Gollaher 2001; Laqueur 2003), for cultural beliefs around health and hygiene (Laqueur 1990).

Historical evidence of ritual circumcision exists in relation to South Sea Islanders, Australian Aborigines, Sumatrans, Incas, Aztecs, Mayans and Ancient Egyptians (Gollaher 2000). Circumcision with a ritual motivation continues in current times by the Jews, Muslims and in South Africa, most prominently amongst the Xhosa in the Eastern Cape region (Kacker and Tobian 2013). The spread and popularity of the procedure over time has been more as a surgical procedure rather than as a ritual. The rationale for the procedure has varied over time and has included reasons such as a means of treating conditions like gout, rectal prolapse, rheumatism, kidney stones and to decrease the urge to masturbate. The Jews and Muslims circumcise as part of their religious culture which stemmed from their leader Abraham being circumcised. In South Africa, circumcision has an interesting history with King Shaka Zulu who stopped the practice as he felt the recovery time of his warriors was of concern and not good for battles (Caldwell and Caldwell 1994). In recent times, for the Zulus, it is no longer a cultural necessity, but many people still undergo the procedure for health reasons. Another big tribe to practice circumcision is the Xhosa people that does it as a rite of passage (Ntsaba 2002).

2.3 CULTURAL CIRCUMCISION

In South Africa, circumcision is practiced by many cultural groups; an example being the AmaXhosa, who performs this procedure as a rite of passage for young boys transcending into manhood (Ntsaba 2009). The implications of this age long rite of passage is very serious as uncircumcised Xhosa men are considered as 'boys' no matter their age and cannot participate in cultural activities that are meant for 'men' (Nkosi 2013).

Nkosi (2013) further elaborates the cultural significance of circumcision. Among the Xhosa, a boy-child is not viewed as an adult. The status of 'adult' is achieved only through an initiation ceremony, which marks the end of a carefree childhood and the acceptance of adult responsibilities. The man must prove that he is suited for the role of provider and protector of his family, while the woman is to accept marriage and the role of homemaker. The senior boy reaches manhood by undergoing the established ritual called *ukweluka* (circumcision).

This old traditional ritual in the amaXhosa has had many fatalities and complications attributed to it (Ntsaba 2009). Over 30 initiates died in one month in 2010 (Wilcken, Keil and Dick 2010). In 2013 the Department of Health in the Eastern Cape Province (2013) reported that over 25 young initiates died in circumcision camps in the province, due to post-operative complications of circumcision. Complications included dehydration, sepsis, gangrene and ischemia (Wilcken, Keil and Dick 2010). The biggest challenge in cultural circumcision is often the absence of aseptic techniques and surgical skills, leading to poor wound management.

2.4 MEDICAL MALE CIRCUMCISION

Circumcision for medical reasons was cited as early as 150 years ago, it was believed that it could decrease the urge to masturbate in men (Hodges 1996). Over the years, South Africa has embarked on different campaigns to try to decrease the high incidence rate of new HIV infections. There may be as many

as 1500 new infections per day (Ramkissoon *et al.* 2010). In the earlier years of these campaigns, the emphasis was placed in behavioural changes. These campaigns focused on abstinence as shown by the 'Abstain, Be Faithful, Condomise' (ABC) campaign (Karim and Karim 2010). This campaign placed the government under great scrutiny and criticism, from both the local and international community due to the high HIV infection rate and the poor management (Butler 2005). The reason for this criticism was that, at that time, the international focus was on the provision of antiretroviral treatment in state facilities (Butler 2005). This was only implemented in South Africa at a much later date.

In recent years, the South African Government has adopted the WHO and UNAIDS campaign to increase circumcision; especially in Sub-Saharan Africa. These countries have a higher prevalence of HIV-related infections and mortality. In 2010, South Africa instituted an aggressive roll-out of MMC, targeting to reach 80% of uncircumcised HIV negative males (Colvin 2011). Over 170 000 MMC have been accomplished in 2013 alone and according to Dr. Thobile Mbengashe (Chief Director of HIV/AIDS, Department of Health) over R100 million from the USA government was made available to support MMC. Many studies and clinical trials have been carried out to assess whether any correlation exists between male circumcision and HIV/AIDS and other STIs. A study conducted by Albero (2012) suggests a definite relationship between circumcision and a decrease in genital HPV infection in men. Auvert (2009) also conducted a study in South Africa that showed that there was a reduction of 36% in sexually related infections in males who are circumcised.

The main theory around MMC was that it will help decrease the incidence of HIV infections according to the studies cited above. However, some studies have questioned the change in behaviour after circumcision. Seed *et al.* (1995) revealed that circumcised men had more sexual partners and acquired more STI's in-contrast to the uncircumcised group. Another study suggested that after men have been circumcised they develop a false sense of security and a

passport to having unprotected sex with multiple sexual partners (Lagarde *et al.* 2003).

The above discussions show that there are both advantages and disadvantages of circumcision. This research is not attempting to debate whether medical circumcision is beneficial or not per se, but it recommends that the best post-operative treatment should be made available to the patients undergoing the procedure.

2.5 POLICY, ETHICS AND THE LEGAL FRAMEWORK

Circumcision is seen as the most controversial procedure of all time, as its benefits versus the ethical inferences generally are inconclusive, and each case needs to be weighed up on its merits. The practice of medical circumcision has many pending ethical implications (Gollaher 2000). The medical rationale for this procedure is to promote hygiene and decrease the infection rate for HIV/AIDS and other related sexually transmitted diseases (WHO 2010). Gollaher (2000) questions the reasons why the procedure is practiced more in developing countries than in developed countries. He postulated that the reason is that the developing countries are more ignorant and do not scrutinize the implications of this procedure thus are more submissive in undergoing procedures than developed countries. This was confirmed by Myers, Leong and Phillips (2007) who also questioned the ethical inferences surrounding a non-consenting neonate.

The legal framework that monitors the South African healthcare fraternity acknowledges and contextualises the different reasons why circumcision occurs so as to protect mainly the rights of children. The children's Act (8/2005, as amended) recognises that circumcision can occur for the following reasons:

a) As a cultural necessity. The guidelines and requirements are stipulated under the section 306 of the Children's Act, which were published in *government gazette 33076.*
b) For medical reasons. Legally boys under the age of 16 are prohibited to be circumcised, under the Section 12(8) of the Children's Act. However

the procedure can be performed on the recommendation of a medical physician or for religious purposes.

c) If the child has given consent. Section 12(9) gives the child over the age of 16 the right to consent to the procedure. However, counselling needs to be conducted prior to circumcision.

When looking at the Children's Act, the most contentious element is Section 12(8) which prohibits the circumcision of boys under the age of 16. This could conflict directly with the South African Constitution (Republic of South Africa 1996) Section 30 which states that "Everyone has the right to use the language and participate in the cultural life of their choice." Section 31 states that "Persons belonging to a cultural, religious or linguistic community may not be denied the right, to enjoy their culture and its practices." This includes boys who undergo cultural circumcision in the mountains, with particular reference to the amaXhosa of the Eastern Cape region of South African, where many young initiates die. These young men are "participating" in their cultural practice, point taken, but what about the provision made by the Children's Act which is meant to protect the interest of children? When one undergoes cultural circumcision, is the best interest of the child paramount?

The debate continues when taking into account the premise around medical circumcision, which, for boys under the age of 16, can only occur on recommendation of a medical practitioner. This is guided by the Constitution (Republic of South Africa 1996) Section 28(2) which states that "A child's best interests are of paramount importance in every matter concerning the child." Male medical circumcision has been conceived as a preventative strategy in relation to the high incidence rate of HIV/AIDS and other sexually transmitted infections (Gray, Wawer and Kigozi 2013) in sexually active adults. The big point of debate is: are the best interests of the child, who is not sexually active at the time that the procedure is done, paramount?

2.6 CELL AND MOLECULAR BIOLOGY

A possible reason why male circumcision is seen to reduce the chance of HIV transmission in males is that once the foreskin is removed, the exposed skin becomes hyperkaritinised, hence reducing tissue susceptibility to HIV.

Clark and Fua (2002) describe the anatomical morphology of the cervix and the foreskin having squamous cells. The author describes that internal foreskin as having a significant number of HIV-1 target cells, which in turn supports the notion of circumcision as being an aid in decreasing the susceptibility rate of the foreskin post circumcision.

2.7 BIOLOGY OF WOUND HEALING

Tissue healing occurs in three stages as seen below in Figure 2.1 and Figure 2.2. It is hypothesized that that the homoeopathic protocol will stimulate this process to occur at a faster rate, hence, decreasing the time taken for wound healing and decreasing the probability of complications.

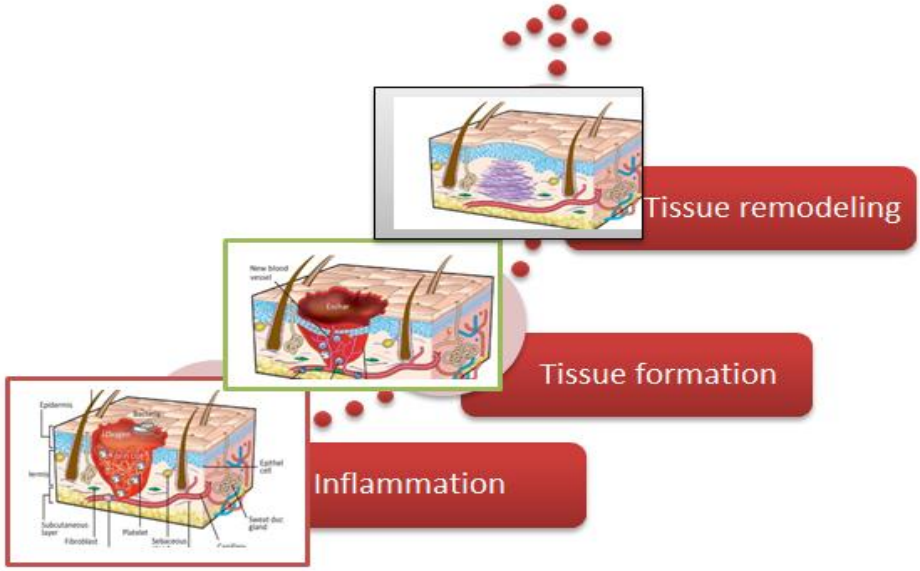

Figure 2.1: Image illustrating the process of wound healing
(Taylor 2014)

Initially there will is blood clotting and formation of fibrin network (Koria 2012; Melchionna *et al.* 2012; Crowley and Crowley 2014) involving the following stages:

- **Inflammation:** There is activation of neutrophils, then phagocytosis of foreign bodies and release of hyaluronic acid and glycosaminoglycan (chemoattractants) into the extracellular matrix (ECM).
- **Tissue formation:** Initially there is an influx of fibroblasts into the ECM then beginning of granulation tissue formation, generation of new blood vessels, deposition of type III collagen fibres (thin and randomly oriented) then the fibrin clot is dissolved, enzymes released and phagocytosis continues.
- **Tissue remodelling:** Type III collagen is replaced by type I collagen: collagen bundles are larger and oriented with principal lines of stress in tissue. Increased amounts of chemicals such as chrondroitin and dermatan sulfate are brought in. Scar tissue continues to form for several months. Blood vessels that are unattached are resorbed and lastly the scar becomes pale and avascular.

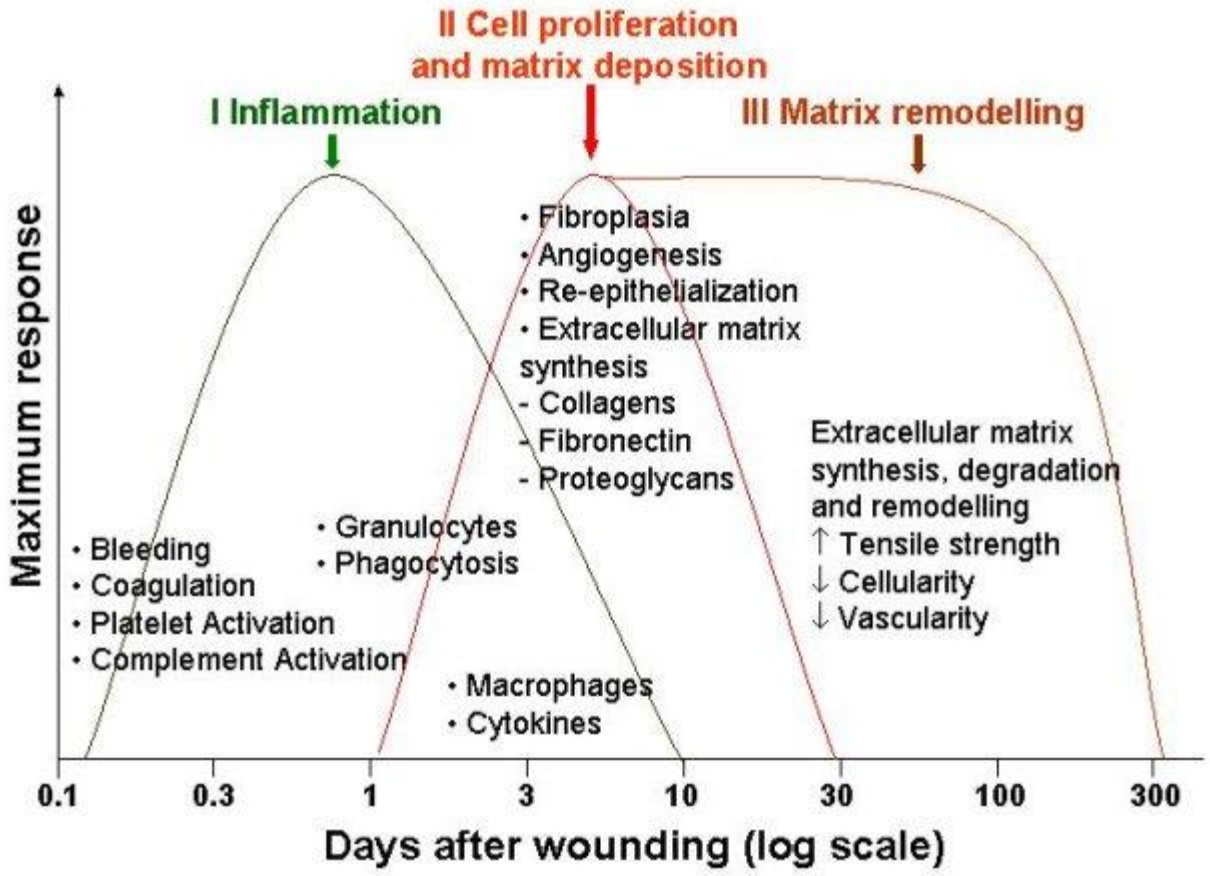

Figure 2.2: Graph illustrating the phases of tissue healing over time
(Clark 1996)

2.8 COMPLICATIONS OF CIRCUMCISION

There are physical complications associated with circumcision, and these are usually related to incorrect wound treatment post-surgically. The most common complication is infection, which if left untreated can lead to septicemia. The most common complications included: urinary retention, scarring, dehydration, gangrene and ischemia (Muula *et al.* 2007; Lagarde *et al.* 2009; Weiss *et al.* 2010).

A recent study conducted to evaluate the complications of VMMC or MMC reported 56% of the participants in the study reported complications which included: bleeding, severe pain and wound infection (Ngo and Obhai 2012).

However, circumcision does not only cause physical complications. Evidence has shown that some patients develop psychological complications as well. Gollaher (2000) found that many young men underwent emotional trauma due to being circumcised as a neonate. This is confirmed by Vivian (2008) who reported that there was an increase in psychiatric aberrance in males after traditional circumcision.

2.9 CURRENT CIRCUMCISION PROCEDURE

According to the WHO (2012), the scaling up of medical male circumcision in Sub-Saharan Africa is still in its early days. The devices used and their regulations are primarily regulated by the Medicines Control Council of South Africa. The WHO states that the laws that govern the use of a device are based on each country's regulatory body, and it is suggested that Africa is less strict when it comes to the regulation of devices. The WHO (2011) has published a set of regulatory guidelines on how the use of the devices can be implemented (World Health Organization and HIV/AIDS 2011). However, few studies have been conducted in South Africa to evaluate if the devices are suitable for its population (World Health Organization and Unicef 2010).

South Africa uses various tools for circumcision. The procedure that is the most recommended, but the least performed in South Africa, is surgical (Brunner, Suddarth and Smeltzer 2008). The reason that this is not utilized as much as it should be is due to the expense. Surgery involves the use of skilled labour and this incurs more comprehensive post-operative costs.

As the majority of people in South Africa rely on public health care in primary health care (PHC) clinics, there has been an influx of various devices that have been introduced into the market for the performance of circumcision that do not require hospitalisation or the use of highly skilled labour (Department of Health 2010). In June 2014, the Department of Health and the Southern African Clothing and Textile Workers Union (SACTWU) launched the 'Clever Dick Campaign' in Cape Town, which aimed to have fully fitted mobile clinics that

would travel around the townships in the area and provide surgical male circumcision.

The Department of Health introduced the Tara Klamp in 2010 (Department of Health 2010). The principle mode of action of this device is ischemia. The clamp is attached to the foreskin of the penis and left on until there is ischemia, and then the foreskin simply sloughs off. This device has obvious disadvantages such as discomfort and using this technique leads to a significant increase in the risk of complications. Despite these disadvantages, the Tara Klamp is extensively used in the MMC campaign primarily in KZN (Department of Health 2010).

A recent tool announced by the Department of Health is the PrePex®. A study was conducted to determine the efficacy of this instrument where 625 subjects underwent the PrePex circumcision. The results of the study revealed that 12 moderate adverse events occurred among 10 participants (1.9%); five participants had device displacement; one had an averted foreskin; five had bleeding after the device was removed and one had voiding difficulties. Adverse events of a moderate or severe nature associated with PrePex were low and reversible. PrePex was found to be feasible for male circumcision scale up (Galukande *et al.* 2014a). This tool is a non-surgical intervention for circumcision which can be easily used by trained circumcision counselors, even if they do not have a medical qualification (Galukande *et al.* 2014b). This tool works by causing pressure on the foreskin, which in turn causes tissue ischemia. This then causes the foreskin to slough off, and with it the device also falls off. This tool is said to be more cost effective than surgical circumcision and would be essential for the scaling up of MMC (Kigenyi, Kusiima and Silas 2013).

As can be seen from the above discussion, the tools used in the MMC campaigns can lead to complications. However, this study only recruited participants who were surgically circumcised.

2.10 COMPLIANCE

The lack of proper guidance and counseling has been reported as being the primary reason for non-compliance for patients post-operatively in public health, as suggested by Duse (2003). Another contributing factor is hygiene during the recovery periods. The City Press newspaper (2011) reported on horrific hygiene practices or lack thereof, in public health. These poor practices lead to a high incidence of post-surgical, as well as healthcare associated, infections in South Africa, which Duse (2003) has found to be at around 9.7%.

2.11 TREATMENT METHODS USED IN THIS RESEARCH

2.11.1 Homoeopathic protocol

Calendula officinalis (M.T.) is excellent as an antiseptic and it can prevent serious infection. It is also well indicated in pus forming wounds after surgical incisions and is a primary remedy for healing surface wounds (Kent and Savage 1993). Studies have shown that *Calendula officinalis* has antioxidant (Chakraborthy 2009), anti-inflammatory (Flausino *et al.* 2002), antibacterial and anti-parasitic (Szakiel *et al.* 2008) properties and improves wound healing (Hoffmann 2006; Leach 2008). A recent study has proven that *Calendula officinalis* is effective for a healthy skin in general as it contains antiglycation and antioxidation properties (Ahmad, Khan and Wahid 2012). *Calendula officinalis* is essential as it plays an important role during all the phases of wound healing illustrated in Figure 2.1 and Figure 2.2. It acts as a blood coagulant, and, as stated above, has antibacterial, anti-parasitic antiglycation and antioxidation properties. All these properties of *Calendula officinalis* play a collective role increasing the rate of tissue healing.

Hypericum perforatum has been shown to have an antimicrobial, antibacterial action on the body (Lion and Henry 2013) and to help in depression (Stevinson and Ernst 1999). This will be essential since a study has been cited (Vivian 2008) that suggests that an association between depression and circumcision exists. *Hypericum perforatum* has been seen to have its chief action on the

nerves, especially if there is nerve end damage (Kent 1994). Jouanny (1984) states that “aspirin and morphine only blunt the sensation, they never cure the pain”, but *Hypericum perforatum* does. Shooting, lacerating, burning and stinging pain are typical symptoms seen in the drug picture of *Hypericum perforatum* (Phatak, Bhagat and Kashlak 2005).

Delphinum staphysagria is a very powerful remedy homoeopathically in laceration wounds, as seen in the Materia Medica (Boericke 2008). Vithoulkas (1998) describes the wounds of *Delphinium staphysagria* as hypersensitive wounds, with cutting pain. This remedy is excellent for open wounds that suppurate and take long to heal (Clarke 1991; Hoffmann 2006). It also has a remarkable action on nerve damage (Boericke 2007) as seen in circumcision. Hahnemann said that an infinitesimal dose can have an excellent action in treating disease, and this was supported by Morrison when he described *Delphinium staphysagria* as being excellent in wounds, which are red and angry occurring after surgical incisions (Morrison, Reekie and Jensen 1998). A study conducted by Hoffmann (2006) showed that the combination (*Hypericum perforatum* and *Calendula officinalis*) was effective in the treatment of venous leg ulcers. Dos Ramos (2000) attested to the therapeutic use of *Calendula officinalis* as part of combination remedies and was successful in pain management.

2.11.2 Standard care

According to the Guidelines of the DoH (2010) postoperative instructions for men who have been circumcised are as follows:

- After the operation, rest at home for one or two days. This will help the wound to heal.
- You may bathe on the day after surgery, but do not let the dressing get wet.
- Remove the dressing 24-48 hours after surgery.
- Do not pull or scratch the wound while it is healing.

- Do not have sexual intercourse or masturbate for 4-6 weeks, and use condoms to protect the wound for every act of sexual intercourse for at least six months until the wound has healed completely.
- You may have a little pain or swelling around the wound. This is normal. Check occasionally to make sure that it does not get worse.
- Take any medicines provided or recommended by the clinic. Be sure to follow the instructions given to you.
- Return to the clinic or call: if you notice increased bleeding from the surgical wound; if the pain or swelling at the surgical wound gets progressively worse; if you have difficulty in passing urine; if you develop a fever within one week of surgery; if you have severe pain in the lower abdomen; if the wound is discharging pus.
- If you have any of these problems, return to the clinic for a follow-up visit about one week after the operation.

Standard care is primary based on symptom presentation and is unique to the presenting case:

- Antibiotics are used if there is an infection.
- Antipyretics and analgesics for inflammation and pain respectively.
- The treatment is primarily symptomatic based on the presenting case.

2.12 MEASUREMENT TOOLS

The measurement tools that were used in this research were the pain rating scale and the pain and sleep diary. These tools captured the essential symptoms of each male that had undergone circumcision.

2.12.1 Pain rating scale

The pain rating scale (Appendix 6) is a tool that is used to determine the level of pain intensity in wounds (Hartrick, Kovan and Shapiro 2003). The efficacy of the numerical pain rating scale has been proven over many studies that show that the scale can be used and is statically credible (Turk and Melzack 1992;

Leong 2001; Mowzer 2004). Each participant was given a pain rating scale and was required to rate their pain on a scale of zero to ten:

- Zero means you have no pain at all.
- Ten means the worst possible pain you can imagine.

2.12.2 Pain diary

This is a diary (Appendix 7) where the subjects were required to record the various pain related symptoms on a daily basis. The assessment of pain is very complex, as pain is both a sensory and emotional experience hence the use of a pain diary is vital to capture the full essence of pain (Evans *et al.* 2007). This tool captures the essence of the pain that would primarily be neglected by the pain rating scale, as this allows the participant to express their pain intensity using words. The scale has been used in a few studies (for example, Maunsell *et al.* 2000). The pain diary can be used to measure various aetiologies of pain; one study measured the pain experienced by cancer patients (Zaza and Baine 2002). It has been adjusted by the researcher to accommodate the research aims and objectives.

2.12.3 Adapted form of the Pittsburgh Sleep Quality Index (PSQI)

Sleep (Appendix 7) plays a role in maintaining the body's circadian rhythm and preventing depression, falls, accidents, impaired cognition, and a poor quality of life (Monk *et al.* 1994; Backhaus *et al.* 2002). The sleep diary captures any aberrance in sleep quality that might be presenting in a patient with any psychiatric and sleep disorders as well as disorders due to somatic diseases (Buysse *et al.* 1989; Monk *et al.* 1994; Backhaus *et al.* 2002). This tool was essential in capturing the effect that circumcision had on sleep quality and energy in the morning on waking. The Pittsburgh sleep diary was adapted by the researcher to meet the objectives of the research study.

2.13 CONCLUSION

The main point of contention interrogated in this chapter was addressing the gap in literature when it comes to the postoperative management of circumcision in the South African setting, considering the massive undertaking to perform MMC as an essential strategic approach in the prevention of HIV in South Africa. The next chapter presents the research methodology which guided the study.

Jennings *et al*. (2014) recommended that the scaling up of MMC must not bypass efforts to strengthen health systems or hinder the quality of existing health services (Jennings *et al.* 2014). This chapter explored the various aspects of circumcision and its history. The current protocol of MMC was discussed. The homoeopathic medicines used in the research study were presented. The subsequent chapters will discuss the methods used in this study, the results, discussion of the results and recommendations for further studies.

CHAPTER 3 : RESEARCH METHODOLOGY

3.1 INTRODUCTION

This chapter outlines the research design that was used to guide this study. The study setting and population and sample size is highlighted and the ethical aspects of the study are presented. The process used to collect and analyse the data is explained.

3.2 RESEARCH DESIGN

The research design is defined as the blueprint of any research study. The research design forms the operational framework within which the researcher will accomplish the intended study (Van Wynsberghe and Khan 2008). This research was a clinical trial that is both descriptive (using the pain and sleep diary) and quantitative (pain rating scale and medical case history). This study was not blinded and there was no placebo given. There was a verum group and a control group.

3.3 STUDY SETTING AND POPULATION

This comprised 18-30 year old men who met the inclusion criteria. The 30 participants were the general public and DUT students who attended the campus health clinics. All the consultations were conducted at the homoeopathic day clinic. The study comprised 15 participants in group 1 (verum group) and 15 participants in group 2 (control group). This made the total sample size of 30 participants, as this is was deemed sufficient for a course work master's degree.

3.4 SAMPLING PROCESS

The participants were selected according to whether they met certain inclusion and exclusion criteria.

3.4.1 Inclusion criteria

- Males who had undergone circumcision.
- Males between 18-30 years old.
- Participants that were recently surgically circumcised.

3.4.2 Exclusion criteria

- Males that had already been circumcised and their wounds healed.
- Males younger than 18 years or above 30 years.
- Any underlying or pre-existing diseases, endocrine pathology, HIV/AIDS or clotting disorders.
- On any other chronic medication.

3.4.3 Randomisation

As the participants came into the study, they were randomly allocated a number according to a randomisation sheet that was drawn up by an independent party. This randomisation sheet divided the patients into two groups – standard treatment and homoeopathic treatment (verum group 1) and standard treatment only (control group 2). The homoeopathic medication was dispensed by an independent qualified homoeopathic doctor, according to the randomisation sheet (Appendix 13) drawn up by an independent party.

3.5 HOMOEOPATHIC TREATMENT

3.5.1 Manufacturing

All the medication was manufactured by Comed Health® using the German Homoeopathic Pharmacopoeia (Appendix 9).

3.5.2 Treatment

Participants in the verum group received:

- A cream composed of *Calendula officinalis* MT and *Hypericum perforatum* MT (equal parts) combined in a ratio of 1:6 with aqueous cream to apply directly to the wound – ½ teaspoon per occasion;
- An 8ml vial of *Delphinum staphysagria* 30CH – ¼ capful of granules three times a day (Appendix 10).

3.6 STANDARD CARE

Standard care is primary based on symptom presentation and is unique to the presenting case:

- Antibiotics are used if there is an infection.
- Antipyretics and analgesics for inflammation and pain respectively

3.7 CONSULTATION PROTOCOL

The participants were subjected to four consultations. All consultations took place at the Homoeopathic Day Clinic at the Durban University of Technology. Both groups were required to attend all the consultations. The consultations were the same for both groups. All participants were already on standard care from after the circumcision procedure, as dispensed and managed by the clinic or health care provider where they underwent the procedure. Each participant followed the same protocol, the only difference being that the verum group also used the homoeopathic medication. Each participant completed the pain and sleep diary and the pain rating scale and it was evaluated at each consultation. All participants were assessed by physical examination using the medical case history form (Appendix 8) at each consultation.

➢ *First consultation*

Pre counseling: a briefing on the research and a question and answer session before circumcision. A full medical case history (Appendix 8) was taken to

evaluate if the volunteers met the inclusion criteria. If they met the inclusion criteria, the letter of information (Appendix 4) was presented and explained, and consent forms (Appendix 4) were signed. All the participants were given the researcher's contact details and the supervisor/s, in case of inquiries or emergencies.

Participants were randomly allocated a unique participant number that determined which group they were in, whether the verum or the control group (Wolff, Sherman and ebrary Inc. 2007). The randomization sheet was kept at the clinic reception by the secretary and the medication was kept at the DUT Homoeopathic Day Clinic dispensary.

- *Second consultation*

This consultation occurred after the participants had undergone the circumcision procedure. Participants in the verum group were given the medication and an instruction guideline on how to administer the medication (Appendix 10). All participants were advised to continue with the standard care as prescribed by the clinic or health care provider where they underwent the circumcision. All participants were given a pain rating scale (Appendix 6) a pain and sleep diary, which included the adapted form of the PSQI (Appendix 7) and taught how to use them.

- *Third consultation*

The third consultation occurred two weeks after the procedure. This consultation was to assess the wound and check the recordings on the pain rating scale and pain and sleep diary of all participants. A brief clinical case was taken and the readings on the dairies were checked. The wound was assessed in terms of inflammation, bleeding, infection and exudation. The progress was evaluated by a physical examination.

- *Fourth consultation*

Six weeks after circumcision to assess the wound and read and collect all the research documentations given at the second consultation. The researcher then took a final medical case history and got general feedback from the participants.

3.8 ETHICAL CONSIDERATIONS

The researcher completed an online course on Ethical Principles for Medical Research Involving Human Subjects. The researcher also attained full ethical clearance from the Institutional Research Ethics Committee (IREC) (IREC number 71/14, Appendix 1). Permission to conduct the study was also attended from the following gate keepers:

- DUT Homoeopathy Day Clinic director (Appendix 3a and 3b);
- Director of the Research Office (Appendix 2b);
- Manager of Campus Health Clinics under the Department of Student Counselling and Health (Appendix 3b).

All participants were treated with confidentiality and anonymity; no names were used in the final dissertation. Each participant was given a number and referred to as that number. All consultations were confidential with only the researcher and the supervisor having access to the files. The participants were free to withdraw at any time during the study with no consequences. The participants were provided with contact numbers for the researcher and the supervisor for if they encountered any complications. If emergency intervention was required the researcher would have withdrawn the participant and referred them to the appropriate medical personnel. After the completion of the study, those on the control group were offered the homoeopathic protocol free of charge. Both the verum and the control group received the standard care as prescribed by the health care provider, so all participants did receive treatment.

3.9 DATA COLLECTING TOOLS

3.9.1 The Numeric Pain rating scale (NRS)

This tool (Appendix 6) was used to monitor rate of pain experienced by the participants. NRS is a questionnaire consisting of a numerical scale from 0-10, with 0 representing one extreme (no pain) and 10 representing the other extreme (pain at its worst). Pain is indicated by means of a percentage, both at its worst and least. The average of these two scores is the level of pain intensity experienced by the patient. This scale is a practical index which can be administered in a written or verbal fashion and is simple to score and is suitable for various medical conditions (Jensen, Karoly and Braver 1986; Breivik, Björnsson and Skovlund 2000; Breau 2010; Chuang *et al.* 2014). Each participant was allocated an NRS sheet to score on a daily bases. Their progress was monitored over the period of the study.

3.9.2 The pain and sleep diary

This is a diary (Appendix 7) where the subjects were required to record a comprehensive written pain profile on a daily basis. The assessment of pain is very complex. As pain is both a sensory and emotional experience, the use of a pain and sleep diary is vital to capture the full essence of pain (Evans *et al.* 2007). This tool captures the essence of the pain that cannot be expressed in the pain rating scale, so this allows the participant to express their pain intensity using words. The scale has been used in a few studies (for example, Maunsell *et al.* 2000). The pain diary can be used to measure various aetiologies of pain; one study measured the pain experienced by cancer patients (Zaza and Baine 2002). It has been adjusted by the researcher to accommodate the research aims and objectives; therefore it fully assesses the newly circumcised wound and allows the participants to describe their wound with regards to:

1. Pain;
2. Bleeding;
3. Exudates/oozing;

4. Swelling;
5. Pus.

The research used both subjective (NRS) and objective tools (pain and sleep dairy and physical examination) to denote their overall post-surgical wound healing experience. With regard to the sleep diary (Appendix 7) this tool was essential in capturing the effect, if any, that circumcision had on sleep quality and energy in the morning on waking. The Pittsburgh sleep diary was adapted by the research and included into the pain and sleep diary.

3.10 DATA ANALYSIS

The data was reduced and analysed with the help of a statistician, using the statistical software SPSS version 21.0. Descriptive statistics using frequency and cross-tabulation tables and various types of graphs were used. Numerical analysis included the use of the arithmetic mean and standard deviations. Inferential statistics using Spearman's correlations at a significance level of 0.05 were used.

Descriptive statistics were used to describe the entire population while inferential statistics is used to make inferences from the sample with reference to the population that it was selected from (Kumar and Phrommathed 2005). Once data was correctly entered into an Excel spreadsheet, the case taking forms, pain and sleep diaries and pain rating scales, were stored accordingly to ensure safekeeping in a steel locker. The data captured was checked to make sure that the correct codes were used appropriately.

3.11 VALIDITY AND RELIABILITY

3.11.1 Validity

Validity is the extent to which the research outcomes accurately represent what is really happening in that specific situation. Editing of the documentation related to the data collection tools was done in order to ensure valid responses

were received. Construct validity ensures that the instrument used in the measurement of the variable, should measure what it is intended to measure (Welman, Kruger and Mitchell 2005). The data collection tools were pre-tested on the participants who were not included in the study. Apart from typographical errors, no other changes were suggested, hence the documentation remained unchanged.

3.11.2 Reliability

Reliability refers to the degree to which the instrument can be depended upon to yield consistent results, if used repeatedly on the same person or if used by two separate researchers (Brink *et al*. 2008: 163). All the participants received the same amount of attention; they all received a minimum of four consultations and had an option of more consultations in case of emergencies. All the instruments have been used in previous research and have been verified:

- Pain Rating Scale (Universal pain rating tool) (Wilkie *et al.* 1990; Breivik, Björnsson and Skovlund 2000; Dixon *et al.* 2011).
- Pain diary (Tursky, Jamner and Friedman 1982; Maunsell *et al.* 2000; Ichiseki 2002; Ferrari 2015)
- Sleep diary (Buysse *et al.* 1989; Monk *et al.* 1994; Backhaus *et al.* 2002; Smyth 2008).

3.12 CONCLUSION

This chapter provided an overview of the research methodology used to guide the study. The data analysed will be presented in the chapter that follows.

CHAPTER 4 : PRESENTATION OF RESULTS

4.1 INTRODUCTION

This chapter presents the results and findings from the data collected in the study. Data was obtained from 30 male participants from most of the districts in the KZN province. The participants were separated into two groups: Group 1 was the experimental group which received standard care plus the homoeopathic research medications and Group 2 was the control group received the standard care only. The participants recorded all the symptoms over a period of 49 days, however if the participants did not experiences any further symptoms they stopped recording and came in for a consultation. All the measurement instruments given had space to record for over 49 days, however due to the length of the data capturing instruments, it was shortened in this report to show only 16 days as an example but all participants had the complete version with 49 days.

Key terms in the context of this chapter:

- p value: is the probability of results being due to chance or random error and if the p value <.05 then one can conclude that the results are significant (Hicks 2009).
- N: sample size (Hicks 2009).
- SD: is the average amount of deviation and is computed by taking the square root of the variance score (Hicks 2009).

The methods used in the study were:

1 Independent samples t-test: A test that compares means for two independent groups in cases of one variable (Brink *et al*. 2008).

2 Spearman's rank correlation coefficient test: This is a non- parametric measure of statistical dependence between two variables. It assesses how well the relationship between two variables can be described using a monotonic function (Schmid and Schmidt 2007).

4.2 DEMOGRAPHIC PROFILE

4.2.1 Age

Figure 4.1 illustrates the age demographics of the participants from group 1.

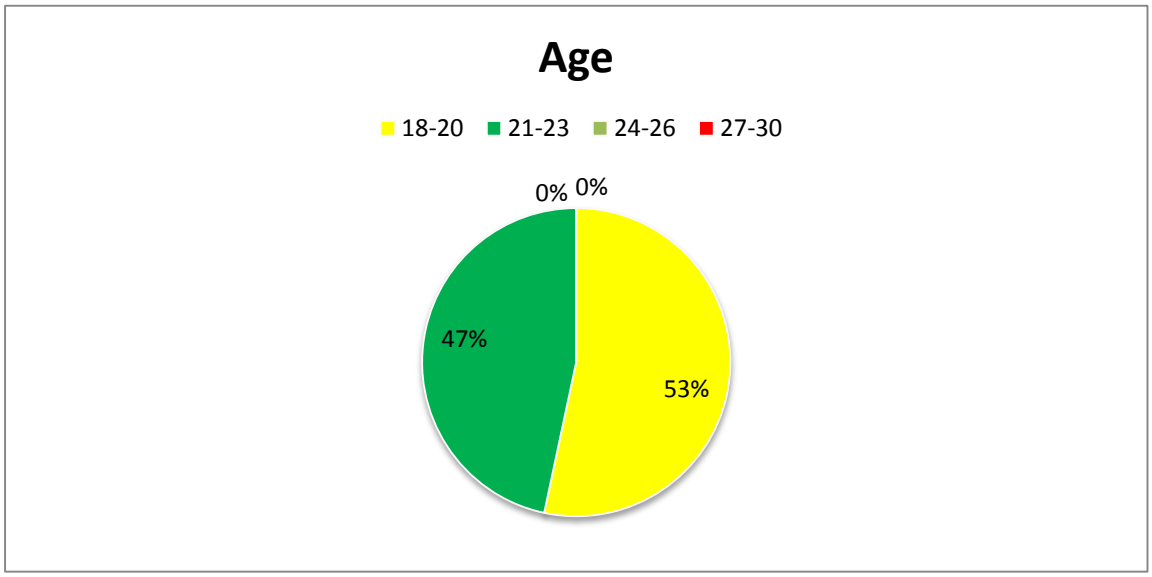

Figure 4.1: Age distribution of the participants from group 1

Figure 4.2. Illustrates the age demographics of the participants from group 2.

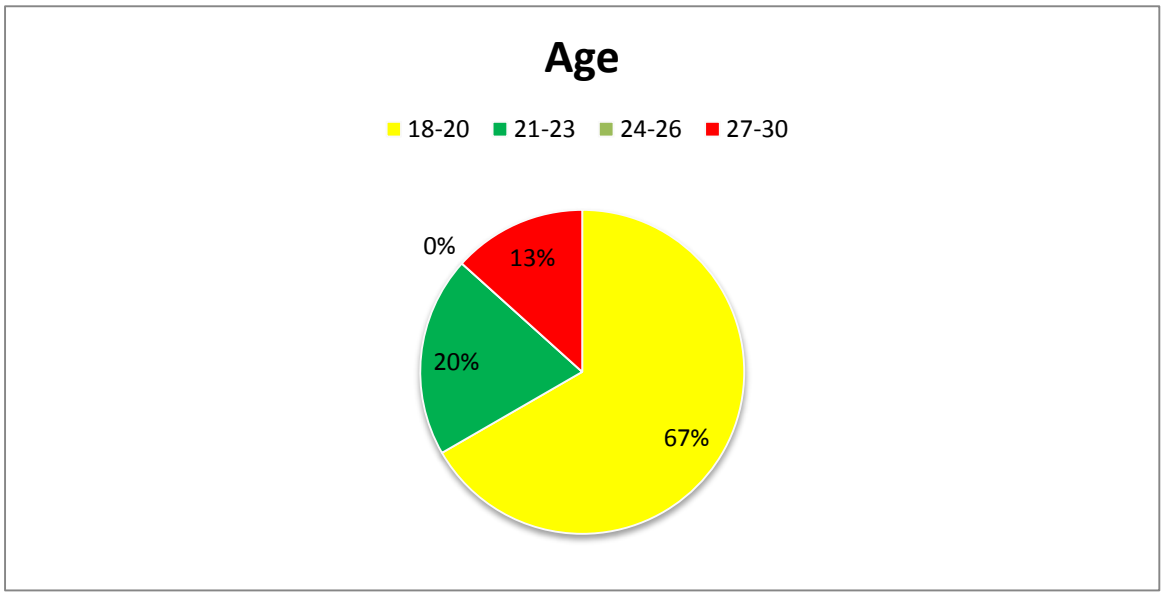

Figure 4.2: Age distribution of the participants from group 2

4.2.2 Geographical area of participants

Figure 4.3 illustrates the geographical area from which the participants in group 1 came, within the health districts of the KZN province.

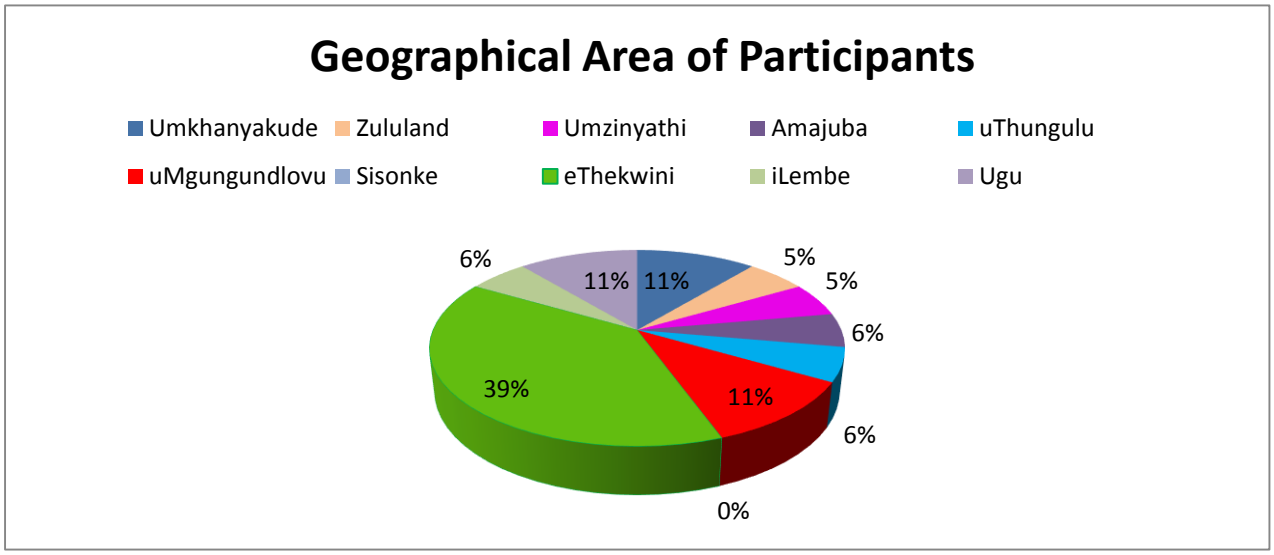

Figure 4.3: Geographical area of the participants from group 1

Figure 4.4 illustrates the geographical area from which the participants in group 2 came, within the health districts of the KZN province.

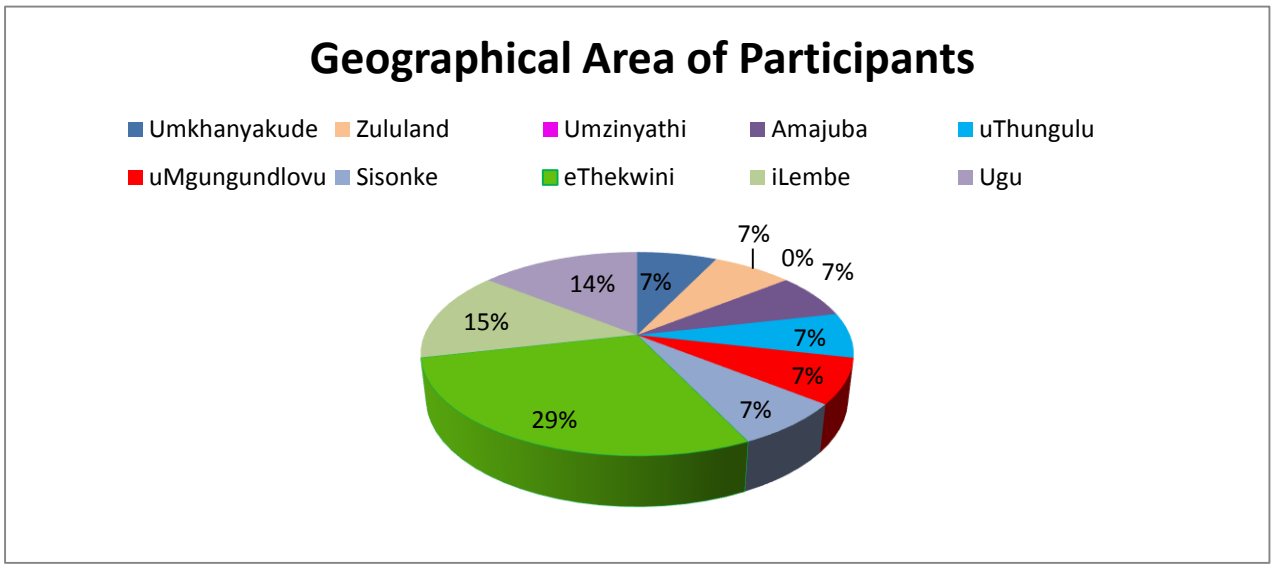

Figure 4.4: Geographical area of the participants from group 2

4.3 GROUP STATISTICS IN RELATION TO TIME TAKEN TO HEAL

Tables 4.1 and 4.2 show the analysis of time taken to heal in both groups. Analysis of 'time to heal' by group shows that, on average, Group 1 (M = 31.4, SD = 7.49) healed in a significantly shorter time than Group 2 (M = 38.6667, SD = 1.99), t (28) = -2.617, p = .014, n = 30. These results are taken as being statistically significant as a p value of less than 0.05 is declared as a significant result.

Table 4.1: Results of the group analysis measuring time taken to heal

	Group	N	Mean	Std. Deviation	Std. Error Mean
time to heal	Standard Care + Homeopathy	15	31.4000	7.49095	1.93415
	Standard Care	15	38.6667	7.71517	1.99205

Table 4.2: Results of the Independent Sample Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	T	Df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
time to heal	Equal variances assumed	.685	.415	-2.617	28	.014	-7.26667	2.77655	-12.95416	-1.57917
	Equal variances not assumed			-2.617	27.976	.014	-7.26667	2.77655	-12.95439	-1.57895

4.4 GROUP ANALYSIS OF RECORDED SYMPTOMS OVER TIME

4.4.1 Average number of days that symptoms were recorded

Figure 4.5 illustrates the results of the average number of days that symptoms were recorded. No statistical significance was derived from the results below. However the Figure below shows that the participants in Group 1 had slightly fewer days of recorded symptoms as compared to Group 2.

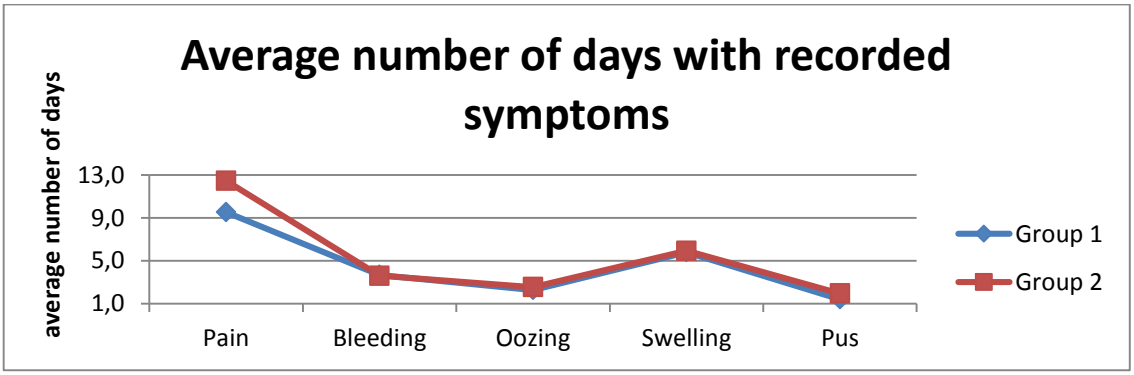

Figure 4.5: Average number of days with recorded symptoms

4.4.2 Average score for the first 18 days for both the study groups

Figure 4.6 illustrates the results of the average score of the first 18 days that symptoms were recorded. For accuracy, the data was analysed using the following scale; 0= none, 1=mild, 2=moderate, 3=severe. An average of 18 was taken a benchmark time where all the participants were still filling in their diaries, as some participants had healed on 18 days, hence they stopped recording. No statistical significance was derived from the results. However, Figure 4.6 shows that the participants in Group 1 had a slightly lower average score (n=30).

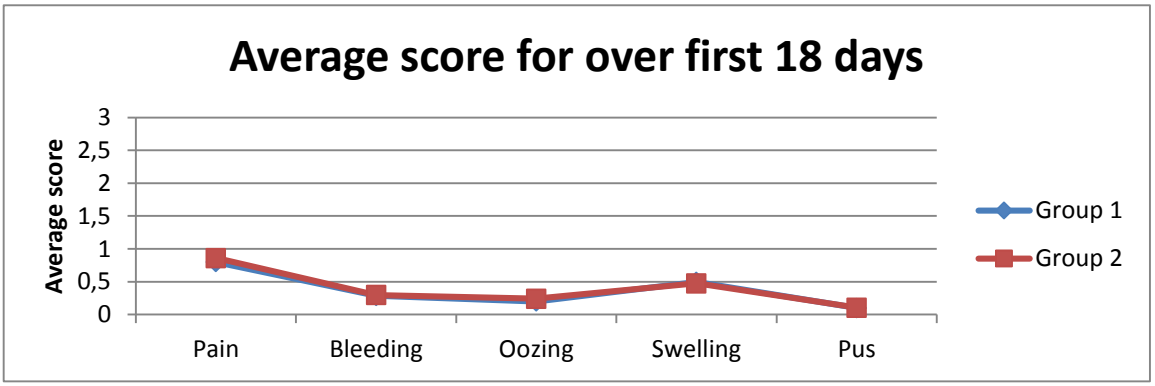

Figure 4.6: Average score over the first 18 days

4.4.3 Average number of days until symptoms ceased completely

Figure 4.7 illustrates the results of the average number of days until symptoms ceased completely. The results show that, on average, the symptoms of participants in Group 1 ceased quicker than that of Group 2, but there was no significant difference.

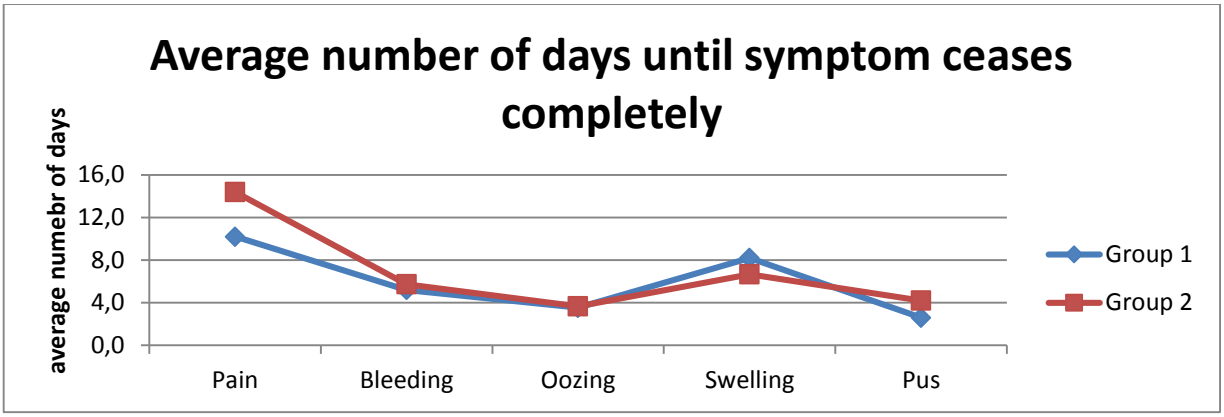

Figure 4.7: Average number of days until symptoms ceases completely.

4.5 SLEEP DATA ANALYSIS

4.5.1 Average hours sleeping during healing period

Tables 4.3 and 4.4 show the average hours sleep in both groups (below). The results show no significant difference between groups in this measure. However, with regards to this specific sample, the mean in Group 1 was lower than that of Group 2.

Table 4.3: Groups Statistics Analysis

Group Statistics

	Group	N	Mean	Std. Deviation	Std. Error Mean
average hours sleep during healing	Homeopathy + standard care	15	6.1489	1.85736	.47957
	Standard care	15	6.8818	1.20658	.31154

Table 4.4: Independent Samples Test

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	T	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
average hours sleep during healing	Equal variances assumed	2.049	.163	-1.282	28	.210	-.73293	.57187	-1.90437	.43850
	Equal variances not assumed			-1.282	24.030	.212	-.73293	.57187	-1.91315	.44728

4.5.2 Average quality of sleep across the healing period

Table 4.5 below shows the results of the average quality of sleep during healing of circumcision. The results show that there is no difference in the quality of sleep during the healing period across the two groups.

Table 4.5: Average quality of sleep till healing

Group Statistics

	Group	N	Mean	Std. Deviation	Std. Error Mean
Average quality sleep till healing	Homeopathy + standard care	15	1.6575	.42783	.11046
	Standard care	15	1.6847	.35992	.09293

4.5.3 Feel in the morning

Results of an independent samples t-test show that no significant differences exist between Group 1 and Group 2. However, for this sample, it is evident in Table 4.6 that group 2 were on average not as refreshed as Group 1 as there were more days that they indicated not being refreshed.

Table 4.6: Group Statistics of proportion days across healing NOT refreshed and number of days unrefreshed

Group Statistics

	Group	N	Mean	Std. Deviation	Std. Error Mean
proportion days across healing NOT refreshed	Homeopathy + standard care	15	.3715	.26365	.06808
	Standard care	15	.3665	.28261	.07297
number days unrefreshed	Homeopathy + standard care	15	11.5333	8.01665	2.06989
	Standard Care	14	14.5000	10.81132	2.88945

4.5.4 Statistics of the pain rating scale

Table 4.7 depicts the average pain rating while healing and the average pain rating over the first 18 days. The results show that there is no significant difference across groups for either of these measures.

Table 4.7: Group Statistics analysing the pain rating scale

	Group	N	Mean	Std. Deviation	Std. Error Mean
average pain intensity while healing	Homeopathy + Standard care	15	1.1944	.84026	.21695
	Standard care	15	1.3822	.81944	.21158
average pain intensity for first 18 days	Homeopathy + standard care	15	2.0000	1.42028	.36671
	Standard care	15	2.5444	1.56420	.40388

4.5.5 Spearman's Correlation Test

Table 4.8 below, demonstrates that poor sleep quality is significantly correlated with worse pain and there is a significant positive correlation between average quality sleep till healing and the proportion of days across healing NOT feeling refreshed (rho = .676, p<.0005). We see that the quality of sleep says: 1 =very good and 4 = very bad, so a low score is good quality sleep. In essence good quality sleep is associated with fewer days unrefreshed and worse quality sleep is associated with more days feeling unrefreshed.

Table 4.8: Spearman's Correlation results

Correlations

			proportion days across healing NOT refreshed	average pain intensity while healing
Spearman's rho	Average quality sleep till healing	Correlation Coefficient	.676**	.484**
		Sig. (2-tailed)	.000	.007
		N	30	30
	average hours sleep during healing	Correlation Coefficient	.060	.041
		Sig. (2-tailed)	.754	.830
		N	30	30

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

CHAPTER 5 : DISCUSSION OF RESULTS

5.1 INTRODUCTION

This chapter will provide a discussion around the presented results in chapter 4. The aim of the study was to determine the efficacy of a topical application of *Calendula officinalis* (mother tincture (M.T), *Hypericum perforatum (*M.T) and *Delphinum staphysagria* 30CH (orally) as an adjunct to the standard care of the post-surgical effects of circumcision. This study assessed both the groups, in terms to the recovery period as well as the signs and symptoms associated with the post-surgical wounds of circumcision. The study setting was in the eThekwini District Municipality, in the province of KZN, South Africa. Thirty participants were recruited and randomly placed into two groups, Group 1 (Homoeopathy + standard care) and Group 2 (Standard care), each group having 15 participants.

5.2 DISCUSSION OF RESULTS

The age distribution of the participants was between the ages of 18 and 30 (Figure 4.1 and 4.2), as stated by the inclusion criteria. The figures illustrate that 53% of the participants in group 1 were aged between 18-20 years and 47% were aged between 21-23 years. Group 2 (figure 4.2) had a similar age distribution, with 67% of participants aged between 18-20, 20% aged between 21-23 and ages 27-30 made up 13% of the study group. The main reason for the 18-20 being the biggest proportion of participants is that the study was conducted in KwaZulu-Natal where most of the men belong to the Zulu ethic group (Scott, Weiss and Viljoen 2005). The Zulus no longer practice cultural circumcision and most opt for the medical male circumcision (Curran *et al.* 2011; Mantell *et al.* 2013). The participants came from 10 of the 11 districts of KZN. It was interesting to note that, though Zulu men no longer see it as part of their culture to be circumcised, the community from the Vulindela district had a different opinion. As their neighbours are Xhosa and Basotho, many

participants withdrew from the study when they were informed that only medically circumcised males were to be included. The reason many of them gave was that their family opted to take them for cultural circumcision. (Khumalo-Sakutukwa *et al.* 2013: 6).

When looking at statistics of circumcision; it is estimated that 30% of the males around the world are circumcised and it is stated that Muslims make up the majority of this percentage (WHO 2009b: 10); WHO and UNAIDS 2007: 7).

When the Independent samples t-test was carried out (Table 4.1 and Table 4.2), it was shown that there was a significant difference in healing time between Group 1 and Group 2 (p=0.14), which is evidence that the homoeopathic protocol was effective in producing a shorter healing time than standard care on its own.

Further analysis by group did not yield any further significant results. However, looking at the results in the Figures 4.5, 4.6, 4.7 and Tables 4.1, 4.2, 4.3, 4.4 and 4.5, and relating them specifically to this sample it is apparent that in general Group 1 had smaller mean scores than Group 2. The reason for such results may be due to the fact that both groups received similar attention, each participant was given the researchers contact details and had to attend four compulsory consultations to check their progress and monitor their wounds. This constant attention and care given to the participants might have played a vital role in there being minimal adverse events as generally seen in circumcision patients. Research has found a link between patient-doctor interaction and the rate of compliance and outcome of clinical cases (Finkler and Correa 1996; Roblin *et al.* 2004). The patient-doctor phenomenon is evident in this research, as many of the general complications post-surgically of circumcision are due to non-compliance on the patient's side and lack of proper guidance post-surgically.

Looking at the intergroup comparisons (Figures 4.5, 4.6 and 4.7) it is evident that the mean score of the homoeopathic group is lower, although it was not significant per se. The low mean scores as well as the statistically significant

faster healing time of the homoeopathic protocol with a p value of 0.14 can be attributed to the constituents of the homoeopathic protocol, which contained: *Calendula officinalis, Hypericum perforatum* and *Delphinum staphysagria.*

Past research studies have demonstrated that *Calendula officinalis* has antibacterial (Mabuza 2002; Faria *et al.* 2011; Tosun *et al.* 2012), and angiogenic (Gazim *et al.* 2008) effects. Recent studies indicate that *Calendula officinalis* also has anti-HIV properties (Kalvatchev, Walder and Garzaro 1997; Ukiya *et al.* 2006; Okoh *et al.* 2008; Muley, Khadabadi and Banarase 2009).

Hypericum perforatum is particularly known for its antifungal (Fenner *et al.* 2005) effect, and nerve injury pain calming effect (Boericke, Savage and Boericke 1990; Boericke 2007) as well as being indicated for depression and anxiety (Vermeulen 1994; Schule *et al.* 2004; Francis 2005; Brattstrom 2009). The lack of *Hypericum perforatum* topical application may explain why Group 2 were on average less refreshed than Group 1 (Table 4.6) and experienced more pain (Table 4.8). Many of the participants in this study had very demanding lifestyles (some are university students and some are at their first jobs) and they hence need to be productive during the day. Research has found that maintaining a good quality of sleep is essential to this productivity and if not maintained, can lead to poor academic performance (Steiger 2003; Ahrberg *et al.* 2012).

The *Delphinum staphysagria* played an essential role in relation to pain, as it possesses analgesic properties (Boericke 1927; William 2002; Boericke 2007). Its effect is evident in Figures 4.5, 4.6 and 4.7 which show that the pain rating was lower in Group 1 than in Group 2. This is turn meant Group 1 had more days waking up refreshed and energetic, compared to Group 2 which had more days waking up feeling unrefreshed.

5.3 CONCLUSION

In conclusion it was interesting to note that the group receiving the homoeopathic protocol had better results and lower mean scores generally across the board. However there was only one result that was statistically significant with a p-value= 0.14, this was the time taken to heal. The other scores were not statistically significant.

CHAPTER 6 : CONCLUSION

This chapter will discuss the study as a whole and the conclusion and then present recommendations for future study.

6.1 INTRODUCTION

The aim of the study was to determine the efficacy of a topical application of *Calendula officinalis* (mother tincture (M.T), *Hypericum perforatum (*M.T) and *Delphinum staphysagria* 30CH (orally) as an adjunct to the standard care of the post-surgical effects of circumcision.

6.2 STUDY FINDINGS

This study assessed both the groups, in terms to the recovery period as well as the signs and symptoms associated with post-surgical wounds of circumcision. The study results revealed that there was one notable significance between the two study groups which was the recovery period, the most important variable. The homoeopathy group healed faster. Research indicates that good post-surgical healing time after circumcision is about 42 days (Rogers *et al.* 2013). The average time to healing for the homoeopathy group was 31.4 days. Any intervention that can shorten the healing period and enable the individual to return to normal activities sooner, as was the case in the homoeopathic group, is to be welcomed.

The rest of the comparisons did not show any significance; however the homoeopathy group had a smaller mean generally. The possible reasons why there was no statistical difference in the symptomatology of the groups may be due to the extensive post-surgical care that both groups received The main reason why there are adverse events and other infections post-surgically is due to neglected hygiene in the newly circumcised, which was not the case in this research as the participants had to report in a diary daily on their wounds, which may have motivated them to keep their wounds clean. In addition, the

researcher was communicating with the participants on a daily bases via cell phone to ensure that participants were complying with the instructions. As discussed in Chapter 5 the doctor patient relationship is an important factor in the road to recovery and when the doctor has good communication with their patients, patients are more compliant and heal quicker (Finkler and Correa 1996; Roblin *et al.* 2004).

Another possible reason that there no other statistical significance noted might be the small sample size of the study; increasing the size would increase it power and may yield a different set of results.

6.3 LIMITATIONS OF THE STUDY

a) The study recruitment group was only 30 participants.
b) The study was limited to the KZN province.
c) The study was limited to males that had undergone MMC only, not those who had been traditionally circumcised.
d) Only males that were surgically circumcised were recruited.

6.4 CONCLUSION

Looking at the results and discussion in the previous two chapters. The original aims and objects were to test if there is any statistical difference that exists in the treatment protocols that were tested in the study namely; the Homoeopathic plus standard care versus the standard care only. Statistical analysis was carried out to assess various variables in both groups, namely, pain, bleeding, pus, exudates, swelling and, more importantly, statistical analysis was carried out to assess whether there was any significant difference in the healing time or period between the groups. As noted in the discussion above, there was one major statistical difference which was in relation to time taken to heal, as seen in Tables 4.1 and 4.2. However the rest of the scores which measured the pain, bleeding, swelling, pus and exudate formation did not reveal any significant differences. It was interesting to note that the homoeopathy group had smaller mean scores across the board.

It is important to note an emerging theme in this study, which is the importance of an effective human resources management protocol in caring for patients. This is an essential tool to assure a high compliance rate and positive outcome. Thus, effective communication and the physician-patient relationship is pertinent in promoting post-surgical healing. This is relevant because the MMC drive in South Africa is under resourced in terms of the post-surgical management faculties, and some researchers have suggested that the main reason for post-surgical adverse events was due to poor post-operative wound management (Mahler *et al.* 2011; Jennings *et al.* 2014; Rech *et al.* 2014).

The overall results are pleasing and they support the homoeopathic protocol as having a relative degree of efficacy in the treatment of post-surgical wounds of circumcision.

6.5 RECOMMENDATIONS

a) Repeat the study with a larger sample group.

b) Repeat the study in different provinces of South Africa.

c) Cultural circumcision; It would be very interesting to conduct this study in an unsterile environment, like that of cultural circumcision. This would be a challenging environment as many deaths and post-procedural complications are noted here (Ntsaba 2002; Wilcken, Keil and Dick 2010; Khumalo-Sakutukwa *et al.* 2013).

d) Do a study in the rural areas as part of the MMC campaign to see if geographical demographics have any relation to recovery period post-surgically.

e) Consider using different potencies, suited more to the individual, rather than standardizing the potency and dose.

f) Consider using similimum, suited more to the individual presenting symptoms.

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APPENDICES

APPENDIX 1: DUT ETHICS CLEARANCE

DUT
DURBAN UNIVERSITY OF TECHNOLOGY

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

P O Box 1334, Durban, South Africa, 4001

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

www.dut.ac.za

13 November 2014

IREC Reference Number: **REC 71/14**

Mr E C Taylor
4574 Bellair Road
Cato Manor
Mayville
Durban
4091

Dear Mr Taylor

The efficacy of a homoeopathic protocol as an adjunct to standard care of the post-surgical effects of circumcision

I am pleased to inform you that Full Approval has been granted to your proposal REC 71/14.

The Proposal has been allocated the following Ethical Clearance number **IREC 082/14**. Please use this number in all communication with this office.

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

Any adverse events [serious or minor] which occur in connection with this study and/or which may alter its ethical consideration must be reported to the IREC according to the IREC SOP's. In addition, you will be responsible to ensure gatekeeper permission.

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

Yours Sincerely

[redacted]

Professor J K Adam
Chairperson: IREC

APPENDIX 2A: PERMISSION LETTER TO THE DUT RESEARCH DIRECTOR

4574 Bellair Road
Cato Manor, Mayville
Durban
4091

Director of Research and Postgraduate Directorate
P.O Box 1334
Durban
4000

Dear Prof. S. Moyo

RE: PERMISSION LETTER TO USE DUT STUDENTS AS PARTICIPANTS IN A RESEARCH STUDY

I am currently registered for M Tech: Homoeopathy and I am requesting to conduct a research study at DUT Homoeopathic Clinic as my consultation site and use Isolempilo Clinic to recruit the newly circumcised males and provide free treatment to them using the Homoeopathic complex that I be instigating. The title of the study is: The efficacy of a homoeopathic protocol as an adjunct to standard care of the post-surgical effects of circumcision. The aim of the study is to evaluate the efficacy of a topical application of *Calendula officinalis, Hypericum perforatum* and *Delphinium staphysagria 30CH* as an adjunct to standard care of the post-surgical effects of circumcision. This study will consist of a verum group receiving the above mentioned complex and a control group receiving just the standard care as prescribed by the Department of Health. The above remedies have been fully credited and clinically verified and they form part of the Homoeopathic Materia Medica and Pharmacopoeia.

Participants will be required to attend 5 consultations at the DUT Homoeopathy Clinic during the course of the clinical trial and a pain rating scale and diary will be collected once they are done.

Yours Sincerely.

……..
Mr E.C Taylor (Student)
Tel: 079 398 9994
Email address: euvettetaylor@yahoo.com

……
Prof M.N Sibiya (Co-Supervisor)
Tel: 031-373 2606
Email address: nokuthulas@dut.ac.za

……..
Dr. I.M.S Couchman (Supervisor)
Tel: 031-373 2514
Email address: ingridc@dut.ac.za

APPENDIX 2B: APPROVAL LETTER FROM THE DUT RESEARCH DIRECTOR

Directorate for Research and Postgraduate Support
Durban University of Technology
Tromso Annexe, Steve Biko Campus
P.O. Box 1334, Durban 4000
Tel.: 031-3732576/7
Fax: 031-3732946
E-mail: moyos@dut.ac.za

27th November 2014

Mr Euvette C Taylor
c/o Department of Homeopathy
Durban University of Technology

Dear Mr Taylor

PERMISSION TO CONDUCT RESEARCH AT THE DUT

Your email correspondence in respect of the above refers. I am pleased to inform you that the Institutional Research Committee (IRC) has granted full permission for you to conduct your research at the Durban University of Technology.

We would be grateful if a summary of your key research findings can be submitted to the IRC on completion of your studies.

Kindest regards.
Yours sincerely

[redacted]

PROF. S. MOYO
DIRECTOR: RESEARCH AND POSTGRADUATE SUPPORT

APPENDIX 3A: PERMISSION LETTER TO THE DIRECTOR OF THE DUT CLINIC

4574 Bellair Road
Cato Manor, Mayville
Durban
4091

Homoeopathic Clinic Director
Homoeopathic Day Clinic
P.O Box 1334
Durban
4000

Dear Dr. D. Naude

RE: PERMISSION LETTER TO USE DUT HOMOEOPATHIC CLINIC

I am currently registered for M Tech: Homoeopathy and I am requesting to conduct a research study at DUT Homoeopathic Clinic as my research/consultation station. The title of the study is: The efficacy of a homoeopathic protocol as an adjunct to standard care of the post-surgical effects of circumcision. The aim of the study is to evaluate the efficacy of a topical application of *Calendula officinalis, Hypericum perforatum* and *Delphinium staphysagria 30CH* as an adjunct to standard care of the post-surgical effects of circumcision. This study will consist of a verum group receiving the above mentioned complex and a control group receiving just the standard care as prescribed by the Department of Health. All cost will be credited to the researcher and not the clinic.

Participants will be required to attend 5 consultations at the DUT Homoeopathy Clinic during the course of the clinical trial and a pain rating scale and diary will be collected once they are done.

Yours Sincerely

……..
Mr E.C Taylor (Student)
Tel: 079 398 9994
Email address: euvettetaylor@yahoo.com

……
Prof M.N Sibiya (Co-Supervisor)
Tel: 031-373 2606
Email address: nokuthulas@dut.ac.za

……..
Dr. I.M.S Couchman (Supervisor)
Tel: 031-373 2514
Email address: ingridc@dut.ac.za

APPENDIX 3B: APPROVAL LETTER FROM THE DIRECTOR OF THE DUT CLINIC

4574 Bellair Road
Cato Manor, Mayville
Durban
4091
15 November 2014

Homoeopathic Clinic Director
Homoeopathic Day Clinic
P.O Box 1334
Durban
4000

Dear Dr. D. Naude

RE: PERMISSION LETTER TO USE DUT HOMOEOPATHIC CLINIC

I am currently registered for M Tech: Homoeopathy and I am requesting to conduct a research study at DUT Homoeopathic Clinic as my research/consultation station. The title of the study is: The efficacy of a homoeopathic protocol as an adjunct to standard care of the post-surgical effects of circumcision. The aim of the study is to evaluate the efficacy of a topical application of *Calendula officinalis, Hypericum perforatum* and *Delphinium staphysagria 30CH* as an adjunct to standard care of the post-surgical effects of circumcision. This study will consist of a verum group receiving the above mentioned complex and a control group receiving just the standard care as prescribed by the Department of Health. All cost will be credited to the researcher and not the clinic.

Participants will be required to attend 5 consultations at the DUT Homoeopathy Clinic during the course of the clinical trial and a pain rating scale and diary will be collected once they are done.

Yours Sincerely

.....
Mr E.C Taylor (Student)
Tel: 079 398 9994
Email address: euvettetaylor@yahoo.com

.....
Dr. I.M.S Couchman (Supervisor)
Tel: 031-373 2514
Email address: ingridc@dut.ac.za

.....
Prof M.N Sibiya (Co-Supervisor)
Tel: 031-373 2606
Email address: nokuthulas@dut.ac.za

Approved
15/11/2014

APPENDIX 4A: PERMISSION LETTER TO THE ISOLEMPILO CAMPUS DUT CLINIC

4574 Bellair Road
Cato Manor, Mayville
Durban
4091

Isolempilo Campus Health Clinic Director
Durban University of Technology
Durban
4000
P.O Box 1334

Dear Director / Manager of DUT Isolempilo clinic.

RE: PERMISSION LETTER TO USE DUT ISOLEMPILO CAMPUS HEALTH CLINIC

I am currently registered for M Tech: Homoeopathy and I am requesting to conduct a research study at DT Isolempilo Campus Health Clinic as my recruitment station. The title of the study is: The efficacy of a homoeopathic protocol as an adjunct to standard care of the post-surgical effects of circumcision. The aim of the study is to evaluate the efficacy of a topical application of *Calendula officinalis, Hypericum perforatum* and *Delphinium staphysagria 30CH* as an adjunct to standard care of the post-surgical effects of circumcision. This study will consist of a verum group receiving the above mentioned complex and a control group receiving just the standard care as prescribed by the Department of Health. All cost will be credited to the researcher and not the clinic.

Participants will be required to attend 5 consultations at the DUT Homoeopathy Clinic during the course of the clinical trial and a pain rating scale and diary will be collected once they are done.

Yours Sincerely

……..
Mr E.C Taylor (Student)
Tel: 079 398 9994
Email address: euvettetaylor@yahoo.com

…….
Prof M.N Sibiya (Co-Supervisor)
Tel: 031-373 2606
Email address: nokuthulas@dut.ac.za

……..
Dr. I.M.S Couchman (Supervisor)
Tel: 031-373 2514 Email address: ingridc@dut.ac.za

APPENDIX 4B: APPROVAL LETTER FROM THE ISOLEMPILO CAMPUS DUT CLINIC.

On Mon, Nov 17, 2014 at 1:53 PM, Sooriagandhi Wardthen <sooriagandhiw@dut.ac.za> wrote:

> Dear Euvette
>
> I have perused the information submitted and am pleased to inform you that the Isolempilo Campus Health Clinic can be utilized as a recruitment station for your research.
>
> Regards
>
> Soori Wardthen
>
> Manager: Campus Health Services
>
> Department : Student Counselling and Health
>
> Durban University of Technology
>
> 0313732267/0313732223

APPENDIX 5: INFORMATION LETTER AND CONSENT

LETTER OF INFORMATION

Greetings and thank you for taking your time to be a participant in this study.

Title of the Research Study:

The efficacy of a homoeopathic protocol as an adjunct to standard care of the post-surgical effects of circumcision.

Principal Investigator/s/researcher:

Euvette Cardian Taylor (B.Tech: Homoeopathy)

Co-Investigator/s/supervisor/s:

Dr. I.M.S. Couchman (M. Tech. Homoeopathy).

Prof. M.N. Sibiya (D. Tech: Nursing).

Brief Introduction and Purpose of the Study:

This study is of great significance in South Africa as circumcision has become popular in our country as an intervention in the spread of disease like HIV and other related STI's. This procedure however can have discomforts and other surgery related signs and symptoms. Hence this research aims to investigate whether the homoeopathic medication will increase wound healing and alleviate the other related discomforts.

Outline of the Procedures:

You are kindly requested to attend 5 consultations during which the researcher will guide and monitor your progress. May you please record in a pain and sleep diary and pain rating scale daily. I will arrange all the consultations telephonically and via email. The venue will be the Homoeopathic Day Clinic on Ritson road campus. Clinic contact details: (031) 373 2041 or the Researcher cell 079 398 9994 / email: euvettetaylor@gmail.com. In order to be considered in the study, you will need to meet the inclusion criteria.

Treatment:
You will be randomly divided into 2 groups: one of these groups will receive the active treatment (homoeopathic complex + the standard treatment as prescribed by the primary health care facility) and the others receiving the standard treatment only as prescribed by the primary health care facility). The homoeopathic treatment is safe to administer and has been fully tested on humans before. You will be provided with all the information on how to take the medication.

Risks or Discomforts to the Participant:
If you develop any complication/s in the course of the study you will be immediately referred for treatment and withdrawn from the study.

Benefits:
The rate of wound healing may be increased. It is hypothesized that this medication would decrease the rate of wound infection and discomfort. This may form part of treatment plans within the department of health and other countries that encourage the voluntary medical male circumcision or medical male circumcision. Those in the control group will also receive the treatment once the research is concluded. The research could be published and may form part of literature to further expand on the understanding of circumcision as its implications thereof.

Reason/s why the Participant May Be Withdrawn from the Study:
There will be no adverse consequences should you choose to withdraw from the study. You may withdraw from this study anytime.

Remuneration:
There is no remuneration for participating in this study.

Costs of the Study:
You will not be expected to cover any costs towards the study.

Confidentiality:
Only the researcher and the supervisor will see the patient's files. You will be allocated a research number, so no names will be used.

Research-related Injury:
There will be no injury expected.

Persons to Contact in the Event of Any Problems or Queries:
Researcher: Euvette Taylor - 079 398 9994
Supervisor: Dr. Ingrid Couchman - 031 373 2514

Co-Supervisor: Prof. M. N. Sibiya - 031-373 2606
The Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za.

CONSENT

Statement of Agreement to Participate in the Research Study:

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

Full Name of Participant _____ **Right Thumbprint**

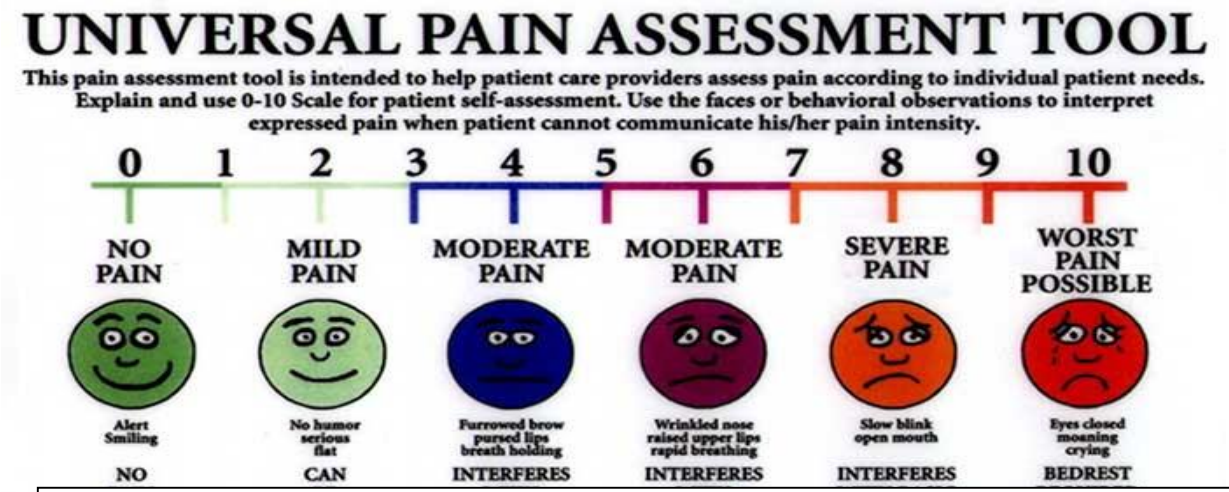
Date:_____ Time: _____Signature: _____

I, Euvette Cardian Taylor herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

Full Name of Researcher **Date** **Signature**

Full Name of Witness (If applicable) **Date Signature**

APPENDIX 6: PAIN RATING SCALE AND INSTRUCTIONS



HOW TO USE PAIN RATING SCALE.

As the participant you will be required to keep a **daily** record on the pain rating scale which will be given to you. The instructions of using the numeric pain rating scale are as follows;

1. I would like you to rate your pain on a scale from zero to ten.
2. ‘Zero’ means you have no pain at all.
3. ‘Ten’ means the worst possible pain you can imagine.
4. What number would you give to your pain?

APPENDIX 7: PAIN AND SLEEP DIARY AND INSTRUCTIONS

DATE:_____ **Day Number** (since you started the medication):

PARTICIPANTS NUMBER:_____

The Pain Perception Profile: Lists of Pain Descriptors

INTENSITY	UNPLEASANTNESS	FEELING
Just Noticeable	Tolerable	Stinging
Moderate	Distressing	Grinding
Mild	Noticeable	Squeezing
Excruciating	Awful	Burning
Very Strong	Unpleasant	Shooting
Very Intense	Unbearable	Numbing
Severe	Uncomfortable	Throbbing
Intense	Intolerable	Stabbing
Very Weak	Bearable	Itching
Strong	Agonizing	Aching
Weak	Miserable	Cramping
Not Noticeable	Distracting	
Pressure	Not Unpleasant	

Please state what did you take for the wound?

Prescribed medication	How often	Dosage size	How many

Please state any other discomfort noted?_____

_____.

Has your wound healed (Yes/NO)_____?

If **YES** how long did it take for your wound to completely heal in days__.

Please note that ONCE HEALED you may stop filling in the table/s above. You will need to contact the researcher and submit all the information/data at the next scheduled consultation.

1. Please indicate the box that best describes your wound **(TODAY)** with regards to;

INDICATE WHAT BEST DESCRIBES YOUR WOUND USING THE FOLLOWING CODES: **(Rate the pain, bleeding, exudates or oozing, swelling, pus).**

1= none
2=mild
3=moderate
4=severe

Wound description today																
Day ->	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
1.PAIN																
2.BLEEDING																
3. EXUDATES/ OOZING.																
4.SWELLING																
5.PUS																

2. If you are still experiencing the following symptoms please tick**(x)** the box that best describes your wound **TODAY** as **compared** to **YESTERDAY** in terms of: Rate the pain, bleeding, exudates or oozing, swelling, pus. **Using the following codes:**

1= same as yesterday

2=slightly better than yesterday

3=Better than yesterday

4=No

5=severely worse than yesterday.

Wound description																	
Day ->	**1**	**2**	**3**	**4**	**5**		**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
1.PAIN																	
2.BLEEDING																	
3. EXUDATES/ OOZING.																	
4.SWELLING																	
5.PUS																	

3. In the SLEEP table below, please answer the following questions regarding your sleeping patterns:

1 How many hours of sleep did you get last night?

2 Indicate the quality of your sleep last night using the following codes:

1 = very good

2= fairly good

3= fairly bad

4= very bad

3 Select the option below that BEST describes how you felt this morning on waking:

1 = refreshed and energetic

2 = tired

3 = I don't feel like waking up (SLEEPY)

4 = Other – please describe how you feel

SLEEP																
Day ->	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
1 Hours of sleep last night?																
2 Quality of sleep																
3 Feel in the morning																

APPENDIX 8: CASE TAKING FORM

Case history

Subject No:_____

Date of consultation:_____

Marital status:_____

Age:_____

Site of consultation:_____

Source of History:_____

Occupation:_____

History of Main Complaint:

Onset:_____

Setting/Cause:_____

Duration:_____

Frequency/Timing:_____

Progression:_____

Aggravating Factors:_____

Relieving Factors:_____

Associated signs & symptoms:_____

Past Treatment:_____

Previous Medical History:

Childhood Illnesses:_____

Adult Illnesses:_____

Psychiatric Illnesses:_____

Injuries/ Accidents:_____

Surgery/Operations:_____

Circumcised previously:_____

Current Health Status:

Current Medication:_____

Allergies: _____

Diet:_____

Tobacco: _____

Alcohol:_____

Social Drugs:_____

Immediate Family History:

Social History:

Systemic History:

General_____
Skin:_____

Head: _____
Eyes: _____
Ears: _____
Nose/Sinuses: _____
Mouth/Throat: _____
Respiratory: _____
Cardiac: _____
GIT: _____
Urinary: _____
Vascular: _____
Musculoskeletal: _____
Endocrine: _____

Vitals

Pulse: _____
Breathing Rate: _____
Temperature: _____
Blood Pressure: _____
Height: _____
Weight: _____
BMI: _____
GCS: _____

Cursory Examination

1. **General Observation**

State of awareness and level of consciousness: _____

Apparent state of health: _____

Signs of distress: _____

Skin colour and possible lesions: _____

Stature and habitus: _____

Weight: _____

Motor activity: _____

Dress, grooming and personal hygiene: _____

Odours of body/ breath:_____

Facial expression:_____

Manner, affect, and relationships to persons and things:_____

Speech:_____

CURSORY EXAMINATION

1. Head

Hair: _____

Scalp: _____

Skull: _____

Face: _____

Eyes: _____

Nose and Para nasal Sinuses: _____

Mouth: _____

Pharynx: _____

Ears:_____

2. Neck

3. Upper Limbs

Hands:_____

Forearm and Upper Arm:_____

4. Thorax

Shape and Movement:_____

Skin_____

Heart:_____

Lungs (Anterior): _____

Lungs (Lateral):_____

5. Abdomen

Inspection:

Auscultation:

Percussion;

Palpation:

6. **Inguinal region :**
7. **Lower Limbs**

Feet:
Lower Limb and Thigh:

8. **Back**

Inspection:
Auscultation:

9. **Axillae**

Deep:
Distal:
Pectoral:
Posterior:

10. **Last Check- JACCOLD**

APPENDIX 9: HOMOEOPATHIC PROTOCOL INGREDIENTS AND BATCH NUMBERS.

THE HOMOEOPATHIC PROTOCOL

The Unmedicated granules were purchased from Comed Health
Batch no: 13RO8002
Expiry date: 08/2016

Calendula officinalis
Batch no: 12RA45
Expiry Date: 04/2016

Hypericum perforatum
Batch no: 12RH35
Expiry date: 02/2016

Aqueous Cream
Purchased from Reitzer's Pharmaceuticals (PTY) LTD
Batch no 133038
Expiry date: 10/2017

Batch no 131621
Expiry date 08/2017

APPENDIX 10: INSTRUCTIONS ON HOW TO TAKE THE MEDICATION

PARTICIPANTS INSTRUCTIONS: How to take the medication.

PARTICIPANTS INSTRUCTIONS

May you please follow the guidelines below as they are important to the research and your steady recovery:

1. Always **THOROUGHLY WASH HANDS** with warm-hot water and SOAP **before** and **after** touching the genital area (PENIS), and then dry the hands using paper towel or clean towel.
2. When taking the cream make certain that your **HANDS** have been **THOROUGHLY WASHED** as instructed above.
3. Wash a stainless steel teaspoon with HOT water and scoop ½ a teaspoon of cream from the bottle of medication (DON'T TOUCH THE INSIDE OF BOTTLE WITH HANDS) place on your clean washed palm and close the bottle of cream, then start to gently apply the cream around the newly circumcision wound. When done, Wash hands again.
4. Taking the GRANULES, take a ¼ capful of the vial given to you three times a day (DO NOT TAKE WITH WATER). Before taking the granules avoid eating for about 30 minutes and 30 minutes after the dose. RISE MOUTH WITH WARM WATER BEFORE TAKING THE GRANULES
5. When taking the remedies avoid CAMPHOR, MINT.
6. If you drink coffee postpone for 30 minutes after and before the GRANULES have been taken.
7. STORE all medication in a DRY and DARK AREA (KEEP AWAY FROM LIGHT AND ELECTROMAGNETIC RADIATION e.g. T.V., computers, cell phones.)

APPENDIX 11: ADVERT

DUT DURBAN UNIVERSITY OF TECHNOLOGY

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF HOMOEOPATHY

HOMOEOPATHIC DAY CLINIC
(Ritson Campus)
1st Floor New Clinic Building
Corner Steve Biko and Ritson Roads
Berea, Durban. Access and secure off street parking via Gate 6 in Steve Biko Road. Lift provided to access 1st floor.

MMC CLINICAL RESEARCH...

Are you planning to get circumcised any time soon?

Research is being conducted on post-surgical wound healing of circumcision at the

Faculty of Health Sciences; Homoeopathic Day Clinic.

To be considered for the study, you must be:

- Between 18-30 years old.
- And planning to be medically circumcised.

Should you meet the **inclusion criteria** for the study, you will receive medical consultations and circumcision wound treatment.

079 398 9994

mmcdut@gmail.com

Contact Researcher
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Email: mmcdut@gmail.com
http://www.dut.ac.za/clinics/homoeopathy

APPENDIX 12: EDITORS REPORT

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EDITING CERTIFICATE

Re: **Euvette Cardian Taylor**

THE EFFICACY OF A HOMOEOPATHIC PROTOCOL AS AN ADJUNCT TO STANDARD CARE OF THE POST-SURGICAL EFFECTS OF CIRCUMCISION

I confirm that I have edited this dissertation and the references for clarity, language and layout. I am a freelance editor specialising in proofreading and editing academic documents. My original tertiary degree which I obtained at UCT was a B.A. with English as a major and I went on to complete an H.D.E. (P.G.) Sec. with English as my teaching subject. I obtained a distinction for my M.Tech. dissertation in the Department of Homeopathy at Technikon Natal in 1999 (now the Durban University of Technology). In my capacity as a part-time lecturer in the Department of Homoeopathy I have supervised numerous Master's degree dissertations.

Dr Richard Steele
24 June 2015
electronic

APPENDIX 13: RANDOMISATION SHEET

RANDOMISATION SHEET FOR MR E.C. TAYLOR
DRAWN UP BY DR M MAHARAJ ON 12/01/2014

PARTICIPANT NUMBER	GROUP ONE VERUM AND STANDARD TREATMENT	GROUP TWO STANDARD TREATMENT ONLY
1	√	
2	√	
3		√
4	√	
5		√
6		√
7	√	
8	√	
9		√
10	√	
11		√
12	√	
13		√
14		√
15	√	
16		√
17	√	
18		√
19		√
20	√	
21	√	
22		√
23	√	
24		√
25	√	
26	√	
27		√
28	√	
29		√
30		√