The efficacy of a homoeopathic complex (*Angelica sinensis* 6cH, *Dioscorea villosa* 6cH, *Matricaria chamomilla* 6cH, *Viburnum opulus* 6cH and *Zingiber officinalis* 6cH) compared to a homoeopathic similimum (30cH plussed) in the treatment of primary dysmenorrhoea

By

CAROLE MONGA NGOIE

Mini-dissertation submitted in partial compliance with the requirements of the Master's Degree in Technology in Homoeopathy

In the

Department of Homoeopathy
Faculty of Health Sciences
Durban University of Technology
Durban, South Africa

June 2017

Mini-dissertation submitted in partial compliance with the requirements of the Master's Degree In Technology: Homoeopathy in the Faculty of Health Sciences at the Durban University of Technology.

I, Carole Monga Ngoie, do declare that this dissertation is representative of my own work, both in conception and excution. Where use of other's work is made, it has been acknowledged in the text.

The research described in this dissertation was supervised by

Dr Cornelia Maria Hall

Senior lecturer in the Department of Homoeopathy

Faculty of Health Sciences

Durban University of Technology

Durban, South Africa

Carole Monga Ngoie _____

Approved for final submission:

Dr Cornelia Maria Hall (B.Sc., M. Tech: Hom) _____

Supervisor

DEDICATION

To my Lord and Saviour Jesus Christ, for his unconditional love, his faithfulness and guidance. You protected me and gave me joy and peace when I no longer had strength to persevere.

To my late Father, Alain Monga, for your unconditional love, support and encouragement. You were always there for me when I needed you, leading me with your strength, wisdom and kindness.

To my wonderful Mum, Christiane Monga, for your love, support and patience. Your continued understanding, encouragement and guidance are truly appreciated.

To my siblings, for being there for me, supporting me and encouraging me through it all. You guys have been my biggest help through the challenging moments of this journey.

The Lord is my strength and my shield; my heart trusts in Him, and I am helped. Therefore my heart greatly rejoices, and with my song I shall thank Him and praise Him.

Psalm 28:7.

ACKNOWLEDGEMENTS

I would like to extend my sincerest gratitude and appreciation to the following people:

Dr C. Hall, for your guidance, assistance and patience as my supervisor throughout this long journey. You never gave up on me despite the many challenges and setbacks that I faced.

All the lecturers and clinicians in the Department of Homoeopathy, for sharing your knowledge, supporting and encouraging me throughout my studies.

Dr Gangaram and Dr Sigcu, for their assistance with the ultrasound examinations of the participants.

Mr S. Eche, for helping with the statistical aspects of this research.

Dr R. Steele, for editing my chapters.

Dr J. Ngobese, Dr S. Brijnath and Mrs G. Clarke, for always having a kind word of encouragement.

To my friends and colleagues who stood by me throughout this journey and for always bringing laughter.

To all the wonderful women who took part in this study. All this would not have been possible without you. Thank you.

ABSTRACT

Dysmenorrhoea is the term used to describe painful menstrual cramps, and is the most commonly encountered gynaecological disorder. It affects more than 50% of women of reproductive age, of which 10% to 12% experience severe dysmenorrhoea that interferes with their daily lives by incapacitating them for 1 to 3 days each month. Dysmenorrhoea is estimated to be the single greatest cause of working hours lost by women and school absence in teenage girls (Dawood 2008; Lindeque 2015: 6-9).

Primary dysmenorrhoea is defined as painful, spasmodic cramping in the lower abdomen just before and/or during menstrual bleeding, in the absence of any identifiable macroscopic pathology. It is related to increased levels of inflammatory markers such as vasopressin, prostaglandins (PGF2α) and leukotrienes from the secretory endometrium. These induce ischaemia due to excessive prolonged uterine contractions, increased the sensitivity of pain fibres, and cause vasoconstriction (Iacovides, Avidon and Baker 2015: 1-17; Stewart and Deb 2014: 296-302).

This double-blinded randomised study aimed to establish the efficacy of a homoeopathic complex (consisting of *Angelica sinensis* 6cH*, Dioscorea villosa* 6cH*, Matricaria chamomilla* 6cH*, Viburnum opulus* 6cH and *Zingiber officinalis* 6cH*)* compared to a homoeopathic similimum in 30cH plussed potency in the treatment of the symptoms of primary dysmenorrhoea, in terms of the participants' perception of the treatment.

Thirty female students, who signed the inform consent forms (Appendices B and D), from the Durban University of Technology were selected based on specified inclusion and exclusion criteria after they underwent an abdominal ultrasound examination (Appendix D) by a gynaecologist. They were randomly divided by means of convenience sampling according to a randomisation sheet into two groups. There were 20 in the experimental group which received the homoeopathic complex, and 10 in the control group which received the homoeopathic similimum.

The study took place at the Homoeopathic Day Clinic, located at the Durban University of Technology. It was conducted over a period of three menstrual cycles per participant. The initial consultation took place prior to a menstrual period and the subsequent three follow-ups took place once a month, a week after each menstrual period. During each consultation, a detailed homoeopathic case history was conducted and a physical examination including an abdominal examination was performed. In addition, the participants were required to complete the Moos Menstrual Distress Questionnaire (Moos 1968) (Appendix G) and the Pain Rating Scale (British Pain Society 2006) (Appendix H).

SPSS version 23.0 software was used to analyse the data collected from these questionnaires. The quantitative variables across the groups were compared using the Kruskal-Wallis test since the captured data was non-parametric. The one-way analysis of variance (ANOVA) was used to compare intra-group data. Quantitative variables were expressed as a mean ± standard deviation. A p-value less than 0.05 was considered significant.

The intra-group analysis using the PRS and the MDQ scales (Appendices G and H) showed statistically significant changes in the subcategories of pain in the simillimum group, while these changes were noticed in the complex group only with the PRS scale, when different follow up mean pain score was compared to that at baseline. The different comparisons and p-values can be found in the Appendix G1. The homoeopathic complex group showed more statistically significant changes in the subcategories of behaviour change, negative affect, and control (Appendix G1); while the homoeopathic similimum also revealed other statistically significant changes in the autonomic response and appetite change subgroups (Appendix G1). The inter-group analysis did not reveal any statistically significant change between the groups, although a decrease in the majority of the various mean scores was observed throughout the study.

The study's results led to the conclusion that both the homoeopathic complex and homoeopathic similimum were effective (Appendix G1) in the treatment of symptoms

of primary dysmenorrhoea during various follow-ups, as well as reducing the need for allopathic pain medications in the participants during the study. However that efficacy shown by the presence of statistically significant results could not been maintained throughout the study from the baseline to the third follow-ups, this could be due to the smaller sample size of the participants, the need for a better suited similimum remedy with a higher potency for the control group; or the need for another complex remedy, It was also noted that there was no evidence that one treatment was more beneficial than the other even though a decrease in the mean scores was observed in both groups.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

DEFINITION OF TERMS

ADHESIONS: A band of scar tissue that binds anatomical surfaces that normally are separated from each other. Adhesions most commonly form in the abdomen after abdominal surgery, inflammation, or injury (Mosby's Medical Dictionary 2013: 42).

ANOVA: The one-way analysis of variance (also known as ANOVA) is used to determine whether there are any statistically significant differences between the means of two or more independent (unrelated) groups (although you tend to only see it used when there are a minimum of three, rather than two groups) (Laerd Statistics 2013a).

ATRESIA:

1. Absence or closure of a natural passage of the body.
2. Absence or disappearance of an anatomical part (such as an ovarian follicle) by degeneration.

(Merriam-Webster Dictionary 2017a).

BIOPSY: The removal of a small piece of living tissue from an organ or another part of the body for microscopic examination to confirm or establish a diagnosis, estimate prognosis, or follow the course of a disease (Mosby's Medical Dictionary 2013: 208-209).

COMPLETE BLOOD COUNT (CBC): A determination of the number of red and white blood cells per cubic millimetre of blood. A CBC is one of the most routinely performed tests in the clinical laboratory and one of the most valuable screenings and diagnostic technique (Mosby's Medical Dictionary 2013: 411).

CONVENIENCE SAMPLING: Convenience sampling (also known as availability sampling) is a specific type of non-probability sampling method that relies on data collection from members who are conveniently available to participate in the study (Saunders, Lewis and Thornhill 2012).

CORPUS ALBICANS: A pale white spot on the surface of the ovary that arises from the corpus luteum if conception does not occur (Mosby's Medical Dictionary 2013: 444).

CORPUS LUTEUM: A yellowish mass of progesterone-secreting endocrine tissue that consists of pale secretory cells derived from granulosa cells, that forms immediately after ovulation from the ruptured graafian follicle in the mammalian ovary, and that regresses rather quickly if the ovum is not fertilised but persists throughout the ensuing pregnancy if it is fertilised (Merriam-Webster Dictionary 2017b).

CHRONIC PELVIC INFLAMMATORY DISEASE: This manaifests as chronic pain, menstrual irregularities, and recurrent and exacerbation of acute symptoms (lower abdominal pain with guarding and rebound tenderness, fever, copious purulent cervical discharge, nausea and vomiting, malaise). Diagnosis is made through a clinical exam that reveals typical symptomatology coupled with elevated white blood cells and erythrocyte sedimentation rate plus a positive culture of secretions (Mosby's Medical Dictionary 2013: 1353-1354).

CULTURE: A laboratory test involving the cultivation of microorganisms or cells in a special growth medium (Mosby's Medical Dictionary 2013: 468).

CURETTAGE: Scraping off the material from the wall of a cavity or other surface, performed to remove tumours or other abnormal tissue or to obtain tissue for microscopic examination (Mosby's Medical Dictionary 2013: 469).

DNA PROBE: A labelled segment of DNA or RNA used to find a specific sequence of nucleotides in a DNA molecule. Probes may be synthesised in the laboratory, with a sequence complementary to the target DNA sequence (Mosby's Medical Dictionary 2013: 553).

ENDOMETRIOSIS: Is an abnormal gynaecological condition characterised by ectopic growth and the function of endometrial tissue (Mosby's Medical Dictionary 2013: 615).

ENZYME IMMUNOASSAY: An immunoassay (as an enzyme-linked immunosorbent assay) in which an enzyme bound to an antigen or antibody function as a label- abbreviation EIA (Merriam-Webster Dictionary 2017c).

OESTROGEN: Any of various natural steroids (as estradiol) that are formed from androgen precursors, that are secreted chiefly by the ovaries, placenta, adipose tissue, and testes, and that stimulate the development of female secondary sex characteristics and promote the growth and maintenance of the female reproductive system; also**:** any of various synthetic or semisynthetic steroids (as ethynyl estradiol) that mimic the physiological effect of natural oestrogens (Merriam-Webster.com 2017d).

FIBROID: A benign tumour especially of the uterine wall that consists of fibrous and muscular tissue (Merriam-Webster Dictionary 2017e).

FIBROSIS:

1. A proliferation of fibrous connective tissue that occurs normally in the formation of scar tissue lost through injury or infection.
2. An abnormal condition in which fibrous connective tissue spreads over or replaces normal smooth muscle or other normal organ tissue.

(Mosby's Medical Dictionary 2013: 696).

FOLLICLE-STIMULATING HORMONE (FSH): A hormone produced by the anterior lobe of the pituitary gland that stimulates the growth of the ovum-containing follicles in the ovary and activates sperm-forming cells (Merriam-Webster Dictionary 2017f). A gonadotropin that stimulates the growth and maturation of graafian follicles in the ovary and promotes spermatogenesis in the male. It is secreted by the anterior pituitary gland. Increasing amounts of FSH are secreted in the postmenstrual or resting phase of the menstrual cycle, causing a primordial follicle to develop into a mature graafian follicle containing a mature ovum. The graafian follicle produces

oestrogen, which reaches a high level before ovulation and suppresses the release of FSH (Mosby's Medical Dictionary 2013: 715).

FOLLICLE-STIMULATING HORMONE-RELEASING FACTOR: A hormone from the hypothalamus that stimulates the synthesis and release of FSH and luteinising hormone from the anterior pituitary (Mosby's Medical Dictionary 2013: 715).

FOLLICULAR PHASE: The long phase constituting the first half of the human menstrual cycle. As the menstrual flow ceases, the ovarian follicle continues its development started at the end of the previous cycle and increases its production of inhibin B and estradiol (Mosby's Medical Dictionary 2013: 715-716).

GASTROINTESTINAL BLEEDING: This is when bleeding occurs in any part of the gastrointestinal tract. The gastrointestinal tract includes the oesophagus, stomach, small intestine, large intestine (colon), rectum, and anus (Cunha and Anand 2016).

GONADOTROPIN-RELEASING HORMONE (GnRH): A hormone secreted by the hypothalamus that stimulates the anterior lobe of the pituitary gland to release gonadotropins (as luteinising hormone and follicle-stimulating hormone) – also called luteinising hormone-releasing hormone (Merriam-Webster Dictionary 2017g).

GUAIAC TEST: A test, using guaiac as a reagent, formerly performed on faeces and urine for detecting occult blood in the intestinal and urinary tracts (Mosby's Medical Dictionary 2013: 793)**.**

HUMAN CHORIONIC GONADOTROPHIN (hCG): A glycoprotein hormone similar in structure to luteinising hormone that is secreted by the placenta during early pregnancy to maintain corpus luteum function and stimulate placental progesterone production, is found in the urine and blood serum of pregnant women, is commonly tested for as an indicator of pregnancy, is used medically to induce ovulation and to treat male hypogonadism and cryptorchidism, and is produced in certain cancers (as of the testes) (Merriam-Webster Dictionary 2017h).

HCG BLOOD TEST – QUANTITATIVE (QUANTITATIVE HUMAN CHORIONIC GONADOTROPIN LEVEL): A quantitative human chorionic gonadotropin (hCG) test measures the specific level of hCG in the blood. HCG is a hormone produced in the body during pregnancy (White 2014).

HYMEN: A fold of mucous membrane partly or wholly closing the orifice of the vagina (Merriam-Webster Dictionary 2017i).

HYSTEROSCOPY: Direct visual inspection of the cervical canal and uterine cavity through a hysteroscope. Hysteroscopy is performed to examine the endometrium, to secure a specimen for biopsy, to remove an intra-uterine device, or to excise cervical polyps. The endoscope is passed through the vagina and into the uterus, and the surrounding tissues are examined (Mosby's Medical Dictionary 2013: 890-891).

ISCHAEMIA: A decreased supply of oxygenated blood to a body part. The condition is often marked by pain and organ dysfunction. The condition is often marked by pain (Mosby's Medical Dictionary 2013: 965).

LAPAROSCOPY: A technique to examine the abdominal cavity with a laparoscope through one or more small incisions in the abdominal wall, usually at the umbilicus. The procedure is used for inspection of the gallbladder, ovaries, and fallopian tubes; diagnosis of endometriosis, intestinal conditions, and hernias; destruction of the uterine leiomyomas; and myomectomy (Mosby's Medical Dictionary 2013: 1009-1010).

LEUKOTRIENES: A class of biologically active compounds that occur naturally in leukocytes and produce allergic and inflammatory reactions similar to those of histamine (Mosby's Medical Dictionary 2013: 1035).

LUTEAL PHASE: The third phase of the human menstrual cycle, when the ovarian follicle that has recently discharged an ovum ruptures and transforms into the corpus luteum, which secretes progesterone. Progesterone acts on the endometrium to build up tissue with a supply of blood for the nourishment of the potential embryo. If

fertilisation and conception do not take place, the oestrogen level falls and the menstrual phase begins (Mosby's Medical Dictionary 2013:1066).

LUTEINISING HORMONE (LH): A glycoprotein hormone that is secreted by the adenohypophysis that in the female stimulates ovulation and the development of the corpora lutea, and, together with FSH, the secretion of oestrogen from developing ovarian follicles. In the male LH stimulates the development of interstitial tissue in the testis and the secretion of testosterone (Merriam-Webster Dictionary 2017j).

LEUKOTRIENES: A class of biologically active compounds that occur naturally in leukocytes and produce allergic and inflammatory reactions similar to those of histamine. They are thought to play a role in the development of auto-allergic diseases such as asthma, rheumatoid arthritis, inflammatory bowel disease, and psoriasis (Mosby's Medical Dictionary 2013: 1035).

MENARCHE: The first menstruation and the commencement of cyclic menstrual function. It usually occurs between 9 and 17 years of age (Mosby's Medical Dictionary 2013: 1117).

MENORRHAGIA: Abnormally heavy or long menstrual periods. Menorrhagia occurs occasionally during the reproductive years of most womens' lives. If the condition becomes chronic, anaemia from recurrent excessive blood loss may result (Mosby's Medical Dictionary 2013: 1121).

MENSTRUAL PHASE: The fourth phase of the human menstrual cycle, following the luteal phase and occurring only if fertilisation has not taken place. The corpus luteum regresses and is shed through menstruation, and growth begins for the ovarian follicle, leading to the follicular phase of the next menstrual cycle (Mosby's Medical Dictionary 2013: 1121).

METRORRHAGIA: Uterine bleeding other than that caused by menstruation. It may be caused by uterine lesions and may be a sign of a urogenital malignancy, especially cervical cancer (Mosby's Medical Dictionary 2013: 1135).

MYOMETRIUM: The muscular layer of the wall of the uterus (Mosby's Medical Dictionary 2013: 1189).

OESTRADIOL: The most potent naturally occurring human oestrogen (Mosby's Medical Dictionary 2013: 648).

OOCYTE: A primordial or incompletely developed ovum (Mosby's Medical Dictionary 2013:1268)

OVARIAN CYST: A globular sac filled with fluid or semisolid material that develops in or on the ovary. It may be transient and physiological or pathological (Mosby's Medical Dictionary 2013: 1302).

OVARIAN FOLLICLE: A general name for oocytes (immature ova) in any stage of development, along with their surrounding epithelial cells (Tortora and Derrickson 2009: G19).

OVARY: Female gonad that produces oocytes and the estrogens, progesterone, inhibin, and relaxin hormones (Tortora and Derrickson 2009: G19).

OVULATION: The rupture of a mature ovarian follicle with the discharge of secondary oocytes into the pelvic cavity (Tortora and Derrickson 2009: G19).

OVULATORY PHASE: The second phase of the human menstrual cycle, during which the LH surges, the FSH surges, and ovulation occur. It is followed by the luteal phase (Mosby's Medical Dictionary 2013: 1304).

OVUM:

1. An egg.
2. The secondary oocyte (female germ cell) extruded from the ovary at ovulation.

(Mosby's Medical Dictionary 2013: 1304).

PELVIC CONGESTION SYNDROME: An abnormal gynaecological condition characterised by chronic low back pain, dysuria, dysmenorrhoea, vague lower abdominal pain, vaginal discharge, and dyspareunia. The cause of the symptoms is not understood; formerly it was thought that the vascular bed of the area was distended with blood, but this has not been demonstrated. Women between 25 and 45 years of age are most often affected (Mosby's Medical Dictionary 2013:1352).

PELVIC INFLAMMATORY DISEASE (PID): Any inflammatory condition of the female pelvic organs, especially one caused by bacterial infection. Characteristics of the condition include fever; foul-smelling vaginal discharge; pain in the lower abdomen; abnormal uterine bleeding; pain with coitus; and tenderness or pain in the uterus, affected ovary, or fallopian tube on bimanual pelvic examination (Mosby's Medical Dictionary 2013: 1353-1354).

PLUSSED POTENCY: The process of succussing a remedy to slightly increase the potency level so that the patient does not receive the same potency many times (O'Reilly 1996: 219).

POLYCREST REMEDIES: Polycrest remedies are those which have been known and established to have a wide domain of sphere of action and have produced a wide variety of symptoms that are similar and common to many diseases. This implies that they have their action on multiple organs and organ systems and a repetition of a dose of a Polycrest remedy is done after the action of a previous dose is exhausted (Tamhane 2014).

POLYCYSTIC OVARIAN SYNDROME: An endocrine disturbance characterised by anovulation, amenorrhea, hirsutism, and infertility. It is caused by increased levels of testosterone, oestrogen, and LH, and decreased secretion of FSH. The increased level of LH associated with this disorder may be the result of an increased sensitivity of the pituitary to stimulation by releasing hormone or of excessive stimulation by the adrenal gland. It may also be associated with a variety of problems in the hypothalamic-pituitary-ovarian axis, with extragonadal sources of androgens, or with androgen-producing tumours (Mosby's Medical Dictionary 2013: 1418).

POLYPS: A small tumour-like growth that projects from a mucous membrane surface (Mosby's Medical Dictionary 2013: 1421).

PREMENSTRUAL TENSION SYNDROME: Also known as premenstrual syndrome (PMS) is a syndrome of nervous tension, irritability, weight gain, oedema, headache, mastalgia, dysphoria, sleep changes, and lack of coordination occurring during the last few days of the menstrual cycle before the onset of menstruation. Several theories attempt to explain the cause of the syndrome, including nutritional deficiency, stress, hormonal imbalance, and various emotional disorders (Mosby's Medical Dictionary 2013: 1444).

PROLIFERATION PHASE: The proliferation phase (also called proliferative phase) is the phase of the menstrual cycle after menstruation. Under the influence of folliculating hormone from the pituitary, the ovary produces increasing amounts of oestrogen, causing the lining of the uterus to become dense and richly vascular. The phase is terminated by rupture of a mature follicle and subsequent ovulation (Mosby's Medical Dictionary 2013: 1464-1465).

PROGESTERONE: A female steroid sex hormone $C_{21}H_{30}O_2$ that is secreted by the corpus luteum to prepare the endometrium for implantation and later by the placenta during pregnancy to prevent rejection of the developing embryo or foetus; also**:** a synthetic steroid resembling progesterone in action (Merriam-Webster Dictionary 2017k).

PROSTAGLANDIN $F_{2\alpha}$ ($PGF_{2\alpha}$): Prostaglandin F2-alpha: One of the prostaglandins, a group of hormone-like substances that participate in a wide range of body functions such as the contraction and relaxation of smooth muscle, the dilation and constriction of blood vessels, control of blood pressure, and modulation of inflammation. Prostaglandin F2-alpha (PGF-2 alpha) is a stable prostaglandin that stimulates the contraction of uterine and bronchial smooth muscle and produces vasoconstriction (tightening) in some blood vessels (Medicine Net 2016).

REPERTORY: An index, list, or catalogue. This method embraces a variety of techniques whereby a repertory is employed to determine a small group of remedies, from which the most similar one to the case may be chosen (Watson 2009).

SIMILIMUM: In homoeopathy, the remedy indicated in a certain case because the same drug, when given to a healthy person, will produce the symptom complex most nearly approaching that of the disease in question (The Free Dictionary 2017).

STENOSIS: An abnormal condition characterised by the constriction or narrowing of an opening or narrowing of an opening or passageway in a body structure (Mosby's Medical Dictionary 2013: 1688).

SUCCUSSION: The process of potentisation; vigorously shaking with impact the properly diluted homoeopathic remedy (Navab 2014).

THE HYPOTHALAMIC-PITUITARY-OVARIAN AXIS: The events of the menstrual cycle are controlled by the interplay of five hormones secreted by three organs known as the hypothalamic-pituitary-ovarian-axis (HPO).
The three organs are:

1. The hypothalamus at the base of the brain which secretes gonadotropic releasing hormone (GnRH).
2. A tiny gland called the pituitary gland just below the hypothalamus which secretes FSH and LH.
3. The ovary which secretes the steroid hormones oestrogen and progesterone. The interplay of hormones in the HPO axis is regulated by a feedback mechanism (O'Hara 2014).

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS): Electrodes are placed on the skin and different electrical pulse rates and intensities are used to stimulate the area. Low-frequency TENS (also referred to as acupuncture-like TENS) usually consists of pulses delivered at 1 Hz to 4 Hz at high intensity, so they evoke visible muscle fibre contractions. High-frequency TENS (conventional TENS) usually consists of pulses delivered at 50 Hz to 120 Hz at a low intensity, so there are no muscle contractions (Proctor and Farquhar 2007: 0813).

TRITURATION: The reduction of a substance to a minute state or division by means of long, continued rubbing or grinding (Navab 2014).

URINALYSIS: A physical, microscopic, or chemical examination of urine. The specimen is physically examined for colour, turbidity, and specific gravity. Then it is spun in a centrifuge to allow collection of a small amount of sediment, which is examined microscopically for blood cells, casts, crystals, pus, and bacteria. Chemical analysis may be performed to measure the pH and to identify and measure the levels of ketones, sugar, protein, blood components, and many other substances (Mosby's Medical Dictionary 2013: 1844).

UTERINE FIBROID: A growth of fibrous tissue in the uterus, usually a fibroma, fibromyoma, or leiomyofibroma (Mosby's Medical Dictionary 2013: 1849).

VASOPRESSIN: A hormone secreted by cells of the hypothalamic nuclei and stored in the posterior pituitary for release as necessary; it constricts blood vessels raising the blood pressure, increases peristalsis, exerts some influence on the uterus, and influences resorption of water by the kidney tubules, resulting in concentration of urine (Dorland's Medical Dictionary for Health Consumers 2007).

CHAPTER 1 : INTRODUCTION

Primary dysmenorrhoea is defined as menstrual pain which is characterised by the absence of existent pathology with normal pelvic anatomy and ovarian function. It usually appears within a year after menarche when ovulatory cycles are established (Stewart and Deb 2014: 296-302). This condition is the most common gynaecological complaint in young women (Calis 2016). It affects 50% of menstruating women every month and is characterised by physical pain with associated psychological distress, leading to considerable disruption in their daily lives (Dmitrovic, Kunselman and Legro 2012: 1143-1150; Sturpe 2013: 23-26).

Primary dysmenorrhoea is thought to result from the increased production and release of prostaglandins which in turn cause increased myometrial contraction during the menstrual bleed and subsequent uterine ischaemia (Stewart and Deb 2014: 296-302). Orthodox medical treatments involved mostly the use of non-steroidal anti-inflammatory drugs and oral contraceptives, which are effective in providing symptomatic relief. However, these drugs have been reported to have many adverse effects such as nausea, dizziness, indigestion, gastroduodenal ulcer, abdominal pain, headaches, breast tenderness, weight gain and depression (Stewart and Deb 2014: 296-302; Wong *et al*. 2009).

Homoeopathy has a gentle approach to disease and is intended to activate a patient's own capacity for self-healing by stimulating the organism’s regulatory system (Koehler 1989: 16; Richberg 1997: 12). According to Witt, Lüdtke, and Willich (2009: 603-611) homoeopathy is used in Germany in 83% of hospital associated clinics for gynaecological and obstetrical complaints, and is widely chosen as an alternative treatment; hence the need to increase the knowledge of homoeopathic remedies that can be offered as a treatment for these complaints.

This study aimed at evaluating the efficacy of two different methods of homoeopathic treatment: the complex, which is a more generalised approached to treatment, versus the similimum, which is tailored to the patient's need (i.e. individualised). Small studies conducted by Tsolakis (1995), Christie (2005) and Mokabane (2009) showed the efficacy of the homoeopathic similimum as a treatment for primary dysmenorrhoea.

This study further attempted to provide information on the effect of the complex (*Angelica sinensis* 6CH*, Dioscorea villosa* 6CH*, Matricaria chamomilla* 6CH*, Viburnum opulus* 6CH and *Zingiber officinalis* 6CH) in the treatment of primary dysmenorrhoea. Although a vast amount of information is known about the individual remedies making up this homoeopathic complex as a treatment for primary dysmenorrhoea, no studies were found on the combined effect of these remedies when used in a homoeopathic complex.

1.1 AIM OF THE STUDY

The aim of this double-blind randomised study was to establish the efficacy of the homoeopathic complex (*Angelica sinensis* 6cH*, Dioscorea villosa* 6cH*, Matricaria chamomilla* 6cH*, Viburnum opulus* 6cH and *Zingiber officinalis* 6cH) and compare it to homoeopathic similimum (30cH plussed) in the treatment of primary dysmenorrhoea.

1.2 OBJECTIVES

1.2.1 First objective

The first objective was to determine the efficacy of the homoeopathic complex in the treatment of primary dysmenorrhoea symptoms, in terms of the participants' perceptions.

1.2.2 Second objective

The second objective was to compare the effectiveness of the homoeopathic complex against that of a homoeopathic similimum (30cH plussed) in the treatment of the primary dysmenorrhoea symptoms, in terms of the participants' perceptions.

1.3 HYPOTHESES

1. The homoeopathic complex (*Angelica sinensis* 6cH*, Dioscorea villosa* 6cH*, Matricaria chamomilla* 6cH*, Viburnum opulus* 6cH and *Zingiber officinalis* 6cH) will be more effective than the homoeopathic similimum in a 30cH plussed potency in the treatment of primary dysmenorrhoea symptoms in terms of the participants' perception.
2. The homoeopathic complex will be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea symptoms in terms of the participants' perception.
3. The null hypothesis that states that the homoeopathic complex will not be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea symptoms in terms of the participants' perceptions.

1.4 ASSUMPTIONS

It was assumed that:

- The participants adhered to the protocol with regards to taking the medication (complex or similimum) in the correct dosage and frequency as was prescribed by the researcher.
- The participants maintained a similar lifestyle during the duration of the study than before, including taking the usual painkillers whenever the pain was unbearable and not being improved by the prescribed medication.
- The participants were truthful in terms of recalling their symptoms and grading them while filling in the questionnaires.
- The correct similimum was given based on the symptoms recorded during case taking.

1.5 CONCLUSION

The results of the intra-group analyses concluded that both the homoeopathic complex and homoeopathic similimum were statistically effective in reducing the pain of primary dysmenorrhoea with the PRS (British pain society 2006) (AppendixH).The the similimum group showed greater improvement with both measurement scales, i.e. Moos Menstrual Distress Questionnaire (MDQ) (Moos 1968) (Appendix G) and Pain Rating Scale (PRS) (British Pain Society 2006) (Appendix H). In addition, they both decreased the participants' need for allopathic pain medication throughout the study. These treatments also improved the participants' behaviour change, negative affect, control; and autonomic response and appetite change respectively (Appendix G1).

The inter-group analyses failed to show any statistically significant difference between the two treatments approaches, even though an overall decrease in the mean scores of the majority of the subgroups of symptoms found within the MDQ (Moos 1968) (Appendix G) was observed within the individual groups during the study. Therefore, there was no evidence that one treatment was more effective than the other in the treatment of primary dysmenorrhoea.

CHAPTER 2 : REVIEW OF THE RELATED LITERATURE

2.1 INTRODUCTION

Primary dysmenorrhoea, also known as spasmodic dysmenorrhoea is denoted by painful uterine contractility without underlining causes that begin just before or with the onset of menstruation. It invariably prevails in adolescents and women in their twenties with established ovulatory cycles (Deb and Raine-Fenning 2008: 294-299; Lindeque 2015: 6-9; Stewart and Deb 2014: 296-302). The cause of primary dysmenorrhoea is biochemical and the diagnosis is suggested by history which is supported by the absence of physical abnormalities (Smith 2015; Stewart and Deb 2014: 296-302).

2.2 PHYSIOLOGY OF THE MENSTRUAL CYCLE

The menstrual cycle describes the monthly changes that occur in the ovaries and the endometrial lining of the uterus (Magowan, Owen and Drife 2009: 55-59). The average duration of menstrual cycles is 21 to 35 days (mean 28 days). Its extent differs in women based on the variability in the length of their follicular phase. Hence, some may present with polymenorrhoea which is defined as regular menstrual cycles that are 21 days long or less; while others may have oligomenorrhoea which is irregular menstrual cycles that are longer than 35 days in duration. The cycle extends from the first day of the flow, which can last 2 to 6 days of an average blood flow of 20 ml to 60 ml, to the next first day of flow. The hormones produced by the hypothalamic-pituitary-ovarian axis control the menstrual cycle (Berek 2007: 162-184; Beshay and Carr 2013: 31-42; Tortora and Derrickson 2009: 1095-1127).

Figure 2.1 illustrates the fluctuation of the hormonal concentration levels and the changes they influence within the uterus and the ovaries during the menstrual cycle:

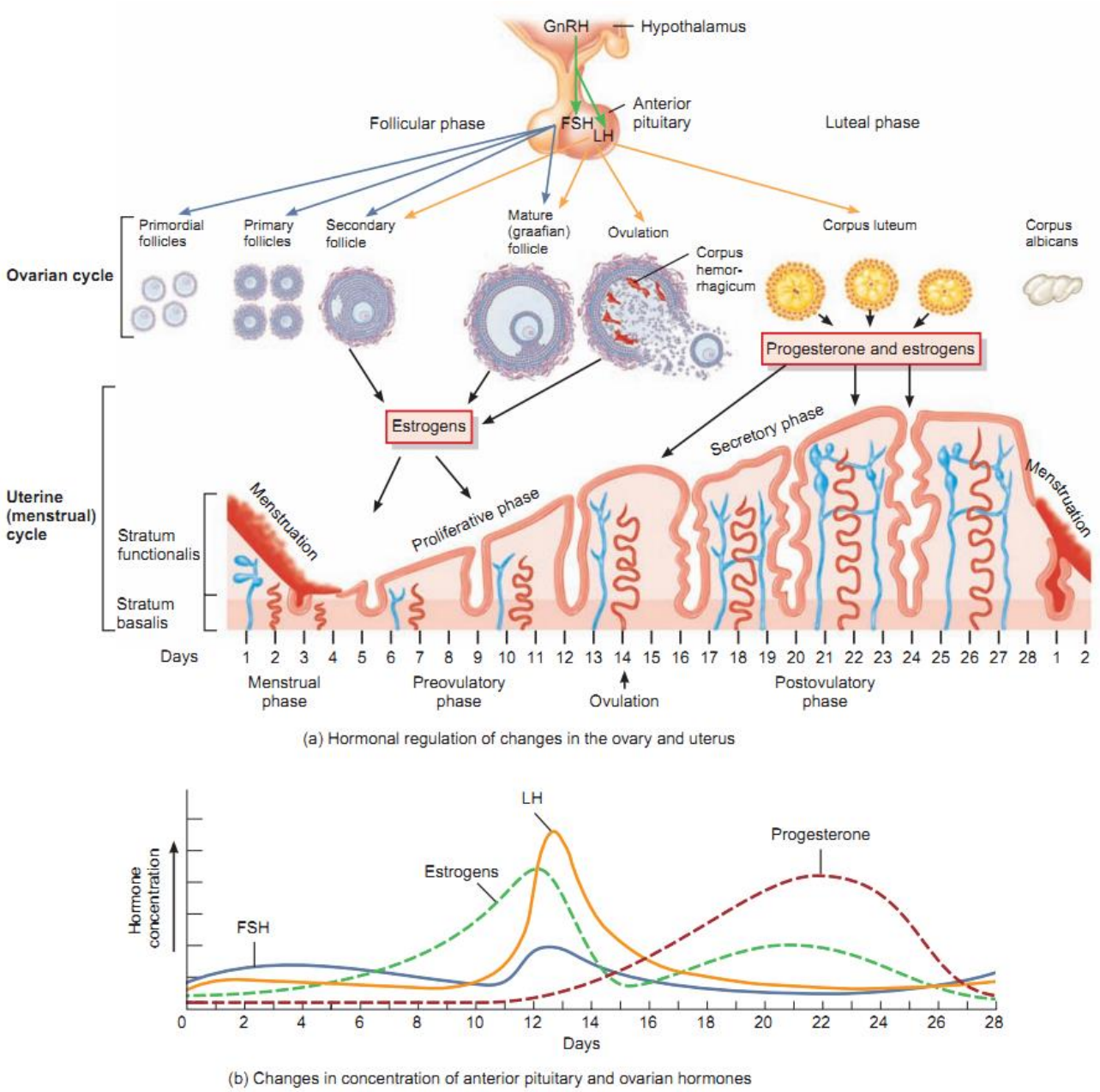

Figure 2.1: The female reproductive cycle
Source: Tortora and Derrickson (2009: 1095-1127)

Berek (2007: 162-184) states that the normal menstrual cycle can be divided into two segments namely the ovarian cycle and the uterine cycle.

2.2.1 The phases of the ovarian cycle

The ovarian cycle is a sequence of events in the ovaries that occurs during and after maturation of an oocyte. The ovarian cycle is often described in terms of a 28-day period of time in which the rise and decline of the follicle-stimulating hormone (FSH)

and the luteinising hormone (LH) levels regulate the changes observed in the ovarian follicle. These hormones are synthesised and released by the anterior pituitary gland in response to the stimulation of the gonadotropin-releasing hormone (GnRH) released by the hypothalamus (Magowan, Owen and Drife 2009: 55-59; Tortora and Derrickson 2009: 1112).

The ovarian cycle has three phases:

- **Follicular phase**

This phase fluctuates between the 10th to 14th days of the cycle. At the beginning of each cycle, the levels of FSH and LH are higher in response to the fall of oestrogen and progesterone at menstruation which results in the follicles being stimulated to develop and mature (Berek 2007: 162-184; Magowan, Owen and Drife 2009: 55-59). The follicular maturation causes the oestrogen (mainly oestradiol) level to rise resulting in negative feedback suppressing both FSH and LH, which prevents hyperstimulation of the ovary and the maturation of multiple follicles (Magowan, Owen and Drife 2009: 55-59).

- **Ovulatory phase**

Ovulation occurs on the 14th day of the cycle following a mid-cycle surge of LH, it is associated with rapid enlargement of the follicle and its rupture from the follicular attachment. The final rise of oestradiol concentration acts as a positive feedback loop which stimulates the surge of LH levels and to a lesser extent, of FSH (Magowan, Owen and Drife 2009: 55-59).

- **Luteal phase**

This postovulatory phase takes place from the 15th to the 28th days of the cycle. The corpus luteum, which is the remnant of the follicle with its LH-sensitised granulosa cells, is responsible for the continued production of the sex steroid hormones, namely oestrogen and progesterone (Magowan, Owen and Drife 2009: 55-59). Reed and Carr (2015) state that the corpus luteum reaches maximal production of estradiol (which is the naturally occurring oestrogen) and progesterone at about eight or nine days after ovulation and if conception has not occurred, the corpus luteum

experiences luteolysis, which is described as its regression resulting in the formation of scar tissue known as corpus albicans. This regression can only be prevented if conception and implantation occur as human chorionic gonadotrophin (hCG) is being secreted by the trophoblast that will maintain it (Magowan, Owen and Drife 2009: 55-59).

2.2.2 The phases of the uterine cycle

The inner layer of the uterus is called the endometrium and it is composed of a superficial layer, which is shed in the course of menstruation, and a basal layer, which does not undergo changes during this process but is responsible for the regeneration of the superficial layer during the subsequent cycle (Magowan, Owen and Drife 2009: 55-59).

The uterine cycle has three phases:

- **Proliferative phase**

The changes observed during this phase are maintained by the oestrogen produced by the ovaries during the follicular stage, which brings about repair and regeneration of the endometrium. The continued exposure to this hormone ensures growth and proliferation of glands and blood vessels (Magowan, Owen and Drife 2009: 55-59).

- **Secretory phase**

This phase takes place after ovulation, where progesterone production by the corpus luteum induces the changes in the endometrial glands, preparing the endometrium for implantation (Magowan, Owen and Drife 2009: 55-59). The following changes are also observed: swelling of the stromal cells, a rich blood supply with the spiral arteries extending into the superficial layer of the endometrium and becoming convoluted (Hacker, Gambone and Hobel 2010: 34-45).

- **Menstrual phase**

Magowan, Owen and Drife (2009: 55-59) state that at the end of the ovarian luteal phase, which normally lasts 14 days, the corpus luteum would regress if conception

and implantation did not happen. This is associated with a decline in ovarian oestrogen and progesterone production. This decline is followed by intense spasmodic contraction of the endometrial arterioles, resulting in ischaemic necrosis, shedding of the superficial layer of the endometrium and bleeding. The prostaglandins locally produced are responsible for causing the vasospasm as well as the increased uterine contractions at the time of the menstrual flow; they are also responsible for removing the endometrial lining during this time (Wright, Willacy and Gronow 2014).

2.3 CLASSIFICATION OF DYSMENORRHOEA

Dysmenorrhoea is a word derived from Greek and means painful menstruation or difficult monthly flow. It is the most common gynaecologic complaint in young women who present to clinicians (Calis 2016; Stewart and Deb 2014: 296-302). It is commonly divided into two broad classifications, namely primary and secondary dysmenorrhoea.

- **Primary dysmenorrhoea**

Primary dysmenorrhoea is defined as intermittent, cramping pain that occurs with menses once ovulatory cycles are established in the absence of observable pelvic pathology (De Sanctis *et al.* 2016).

- **Secondary dysmenorrhoea**

Secondary dysmenorrhoea, also known as congestive dysmenorrhoea, is defined as menstrual pain associated with underlying pelvic pathologies such as: endometriosis, pelvic inflammatory disease (PID), fibroids, ovarian cysts and pelvic congestion syndrome. In this type of dysmenorrhoea, there is an increased blood flow to the pelvic region which results in the patient complaining of fullness, dull pelvic pain and a distended lower abdomen that is sensitive to touch. The pain occurring with secondary dysmenorrhoea often increases continually throughout the luteal phase until it peaks around the onset of menstruation. This type of dysmenorrhoea mostly happens in women in the group age of thirty to forty-five years (Cowperthwaite 2001: 408-418; Deb and Raine-Fenning 2008: 294-299; Jana 2002: 48-54; Stewart and Deb 2014: 296-302).

- **Membranous dysmenorrhoea**

This is a further division of primary dysmenorrhoea and presents as painful menstruation that is accompanied by the discharge of larger or smaller pieces of the complete hypertrophied endometrium. These casts may also appear as tube-shaped sacs or tube-shaped portions.

- **Neuralgic dysmenorrhoea**

This is dysmenorrhoea with hypersensitivity of the uterine nerves due to the congestion of the corresponding uterine vessels. Between menstrual periods, the sufferer experiences other nervous affections, such as irritability, the tendency to melancholy, hysteria, and weakness. Intense pain in the uterine region, loins, and the back are typical symptoms experienced during the menstrual flow.

- **Obstructive dysmenorrhoea**

This is also referred to as congenital or mechanical dysmenorrhoea. This type of painful menstruation is characterised by the partial or complete obstruction of the normal flow of the menstrual blood through the genital canal. This is caused by ailments such as fibroids, cancer, and polyps in cases of mechanical dysmenorrhoea, and by conditions such as atresia of the cervix, vagina or the hymen; stenosis of the cervix, and excessive flexure of the uterus in cases of congenital dysmenorrhoea. The sensation of fullness or distention is only felt after enough blood has collected within the uterus above the obstruction. The blood is then discharged through forceful spasmodic contractive pains.

2.4 AETIOLOGY AND PATHOPHYSIOLOGY OF PRIMARY DYSMENORRHOEA

Primary dysmenorrhoea is thought to result from the increased production and release of prostaglandins and other inflammatory modulators such as vasopressin and leukotrienes that can be found in the endometrial fluid. There is a three-fold rise in these substances starting at the onset of the follicular phase and continuing into the luteal phase. The decline in the level of progesterone at the end of the luteal phase further contributes to the increased level of these substances (Calis 2016; Deb and Raine-Fenning 2008: 294-299). Deb and Raine-Fenning (2008: 294-299),

and Stewart and Deb (2014: 296-302), assert that the pain experienced by the dysmenorrhoea sufferer is due to the increased myometrial activity and contraction during the menstrual bleed, which is also caused by prostaglandins and the subsequent uterine ischaemia caused by the reduced blood blow. Despite the progress in understanding the roles of these inflammatory markers, it is not clearly understood why women with primary dysmenorrhoea produce these substances in excessive amounts as compared to those without this condition.

These substances individually act to affect changes happening during the menses:

- Prostaglandin PGF2α is a vasoconstrictor and also acts as a potent myometrial stimulant.
- Leukotrienes are vasoconstrictors which increase myometrial stimulation and are also responsible for increasing the sensitivity of pain fibres.
- Vasopressin works by stimulating uterine activity as well as decreasing uterine blood flow.
- The prostaglandins PGF2 and PGE2 are believed to cause contractions of the bowel and vascular smooth muscle resulting in nausea, vomiting, and diarrhoea (Stewart and Deb 2014: 296-302).

2.5 CLINICAL FEATURES

Dysmenorrhoea is described as labour-like pain, spasmodic or cramping in nature. This pain usually begins just before or with the onset of menstruation and it is commonly felt in the lower abdomen or suprapubic area and radiates into the inner aspects of the thighs and lower back. The symptoms of primary dysmenorrhoea last for 48 to 72 hours (2-3 days) (Berek 2007: 516-520; Deb and Raine-Fenning 2008: 294-299; Dmitrovic, Kunselman and Legro 2012: 1143-1150). The intensity of the pains is acute on the first or second day of the menses. These are correlated with the time of maximal prostaglandins release into the menstrual fluid (Beckmann *et al.* 2010: 277-282; De Sanctis *et al.* 2016: 1). Primary dysmenorrhoea is often associated with the following symptoms: malaise, fatigue, irritability, dizziness, headache, diarrhoea, nausea and vomiting (Stewart and Deb 2014: 296-302).

2.6 INCIDENCE AND PREVALENCE

Stewart and Deb (2014: 296-302) state that it is difficult to establish the true incidence of dysmenorrhoea when gathering information from various studies and publications. This is due to the variety of the populations being studied, the differences in the perceived symptoms and the inconsistency in the definitions used in those studies. However, they indicate that its prevalence is age-related with a noted increase from 40% in 12 year old girls to 70% in 17 year old girls.

It is estimated that 50% of menstruating females suffer from primary dysmenorrhoea (Dawood 2008) and up to 10% to 45% of them experience a disruption in their daily activities resulting in time lost at school or work (Stewart and Deb 2014: 296-302). Dysmenorrhoea is the most common symptom of all menstrual ailments and represents the single greatest source of lost productivity in the United States. The estimated annual economic loss amounts to 600 million work hours and 2 billion dollars (Hailemeskel, Demissie and Assefa 2016; Ju, Jones and Mishra 2014; Stewart and Deb 2014: 296-302).

According to Deb and Raine-Fenning (2008: 294-299), the effect and importance of dysmenorrhoea are not limited to its socio-economic impact. It also results in significant psychological distress, which may be manifested in the form of anxiety and depression. Deb and Raine-Fenning (2008: 294-299) have reported that 40% to 70% of women of reproductive age suffer from the physical, behavioural, social and psychological impact of dysmenorrhoea in their lives. Despite its greater incidence in young women, women can be affected at any age, regardless of their ethnicity or number of viable pregnancies carried to term (Adegbite *et al*. 2016: 21-31).

2.7 RISK FACTORS

The severity of dysmenorrhoea is associated with longer menstrual periods, earlier menarche, heavy menstrual flow, smoking and a positive family history of dysmenorrhoea (Calis 2016). In addition, null parity, high body mass index or low body mass index, alcohol consumption, anxiety, and depression are also

exacerbating factors (De Sanctis *et al.* 2016: 1; Ju, Jones and Mishra 2014; Hailemeskel, Demissie and Assefa 2016).

2.8 INVESTIGATIONS

Beckmann *et al.* (2010: 277-282) and Deb and Raine-Fenning (2008: 294-299) stressed the need to distinguish between primary and secondary dysmenorrhoea once a history of menstrual pain has been established.

2.8.1 Menstrual history and diagnosis

The patient's history is an important factor to consider in the diagnosis of dysmenorrhoea (Calis 2016). This is especially the case for primary dysmenorrhoea which may be suspected by history alone since it is fundamentally a diagnosis of exclusion emphasised by the absence of any physically identifiable cause (Deb and Raine-Fenning 2008: 294-299; Stewart and Deb 2014: 296-302).

The following should be included when taking a thorough menstrual history:

- Age at menarche.
- Menstrual frequency, length of menses, estimate of menstrual flow, and presence or absence of inter-menstrual bleeding.
- Associated symptoms, namely nausea, vomiting, bloating, diarrhoea and fatigue.
- The severity of pain and its relationship to the menstrual cycle.
- Impact on physical and social activity.
- Progression of symptom severity.
- Sexual history (Calis 2016).

2.8.2 Imaging

Magowan, Owen and Drife (2009: 140-141) state that transabdominal ultrasound scans will reveal normal pelvic organs in primary dysmenorrhoea sufferers and provide considerable reassurance to young women that there is no physical pathology causing their symptoms.

2.8.2.1 Ultrasound imaging

Jurkovic, Valentin and Vyas (2009: 1-5) assert that ultrasound imaging allows a quick non-invasive assessment of the pelvis and abdomen in women with a history of acute or chronic pelvic pain. It may be used as the first line investigation, to confirm or exclude provisional diagnosis based on clinical history. This can be performed transabdominally (through the abdominal wall) or transvaginally (where the probe is place inside the vagina).

Ultrasound imaging can be used to:

- Detect pelvic lesions or masses such as fibroids and endometrial polyps, as it provides a clear view of the endometrium and the myometrium.
- Investigate abnormal vaginal bleeding.
- Diagnose pelvic inflammatory disease (PID) and pelvic abscesses.
- Assess female fertility.
- Determine the location and viability of an early pregnancy (Jurkovic, Valentin and Vyas 2009:1-5).

2.8.2.2 Other imaging studies

These are more invasive procedures:

- Biopsy of the endometrium may be indicated to confirm the diagnosis of endometriosis.
- Hysteroscopy and dilation and curettage may be indicated to evaluate intra-uterine pathology found on imaging.
- Laparoscopy is the gold standard in the investigation of peritoneal endometriosis, adhesions, and chronic PID. It is indicated when initial interventions fail to relieve symptoms (Jurkovic, Valentin and Vyas 2009: 1-5; Stewart and Deb 2014: 296-302).

2.8.3 Laboratory studies

Calis (2016) states that there are no specific tests that can be used to diagnose primary dysmenorrhoea, but the laboratory studies mentioned below may be indicated to establish or exclude organic causes of secondary dysmenorrhoea:

- Complete blood count with differential to search for evidence of infection or a neoplastic process.
- Gonococcal and chlamydial cultures, enzyme immunoassay, and DNA probe testing to exclude sexually transmitted infections and (PID).
- Quantitative human chorionic gonadotropin level to exclude ectopic pregnancy.
- Urinalysis to exclude urinary tract infection.
- Stool guaiac to rule out gastrointestinal bleeding.

These laboratory studies should be performed as secondary measures to support a proper clinical assessment in the process of diagnosing the different types of dysmenorrhoea.

2.9 TREATMENT FOR PRIMARY DYSMENORRHOEA

DeCherney *et al.* (2007: 572-573) indicate that the term dysmenorrhoea is reserved for women whose menstrual pain prevents normal activity and necessitates medication, whether an over-the-counter or a prescription drug.

2.9.1 Allopathic treatment

Allopathic therapy is aimed at relieving the symptoms of primary dysmenorrhoea and is achieved by reducing the production or action of the causative prostaglandins (Deb and Raine-Fenning 2008: 294–299). Allopathic treatments include:

- **Non-steroidal anti-inflammatory drugs**

Several families of non-steroidal anti-inflammatory drugs (NSAIDs) are prescribed for the relief of dysmenorrhoea including aspirin, indomethacin, ibuprofen (Advil, Motrin), naproxen and fenamanic acid (Romm 2010: 130-138). Non-steroidal anti-

inflammatory drugs are inhibitors of prostaglandin synthesis and work by decreasing uterine prostaglandin levels which result in reduced uterine contractility, vasoconstriction, and anoxia (Deb and Raine-Fenning 2008: 294-299). Although they may bring quick and temporary relief, they often require increasing doses to maintain efficacy. Gastric bleeding is a problematic side effect (Romm 2010: 130-138). Stewart and Deb (2014: 296-302) found one systematic review that found aspirin less effective than ibuprofen but more effective than placebo in the treatment of primary dysmenorrhoea.

Paracetamol is often self-administered by the dysmenorrhoea sufferers. They may also be prescribed as a starting point in the management of primary dysmenorrhoea in cases where NSAIDs are contraindicated (Calis 2016; Sturpe 2013: 23-26). Stewart and Deb (2014: 296-302) found two systematic reviews which found paracetamol (acetaminophen) unable to provide more pain relief than placebo, aspirin or naproxen.

- **Prostaglandin synthetase inhibitors**

Prostaglandin synthetase inhibitors prevent the synthesis of prostaglandins, hence reducing uterine hypercontractility, pressure, ischaemia, and pain. Although they are effective in 80% of cases, their side effects include gastrointestinal upset, oedema and skin rash (Romm 2010: 130-138).

- **Combined oral contraceptive pill**

Most of the combined oral contraceptive pills used today are made of two synthetic hormones, namely oestrogen and progesterone. These are usually prescribed as second-line therapy for primary dysmenorrhoea where NSAIDs are contraindicated, or inadequate to relieve the symptoms. These pills, when taken, maintain a steady hormonal state, which inhibits the natural fluctuation of oestrogen and progesterone levels in the body hence preventing the menstrual flow from occurring. The synthetic oestrogen prevents ovulation, i.e. the release of an egg from the ovary, while the synthetic progesterone (also called progestin) induce changes in the cervical mucus (i.e. inhibiting sperm motility) and in the endometrial lining by decreasing the quantity of prostaglandins produced which diminishes the blood flow and cramps in the

uterus (Carey and Allen 2012: 223- 2282; Beckmann *et al.* 2010: 277-28; Stewart and Deb 2014: 296-302). Their efficacy in reducing pain has been reported by over 90% of adolescents after taking them for three months (Stewart and Deb 2014: 296-302). Weight gain and depression are the side effects with short and long-term use. Oral contraceptives are contraindicated in women who smoke, have high blood pressure or have blood clotting problems (Romm 2010: 130-138).

2.9.2 Complementary and alternative medicine (CAM)

Many women affected by primary dysmenorrhoea are using allopathic treatment as a means to relieve their monthly pain and discomfort, as mentioned above, but these medications have many side effects which in turn impact the health of these patients. This has led to the need to find a gentler and safer alternative treatment for primary dysmenorrhoea. Examples of these include:

- **Dietary supplements**

Omega 3 fatty acids (fish oil) alone taken in capsule (comprising 180mg of eicosapentaenoic acid plus 120mg of docosahexaenoic acid) daily for three months form or in association with vitamin B12 has been found to be effective in reducing the pain. It also lessens the need for additional pain relief, when compared to placebo, although authors mention that more research studies need to be conducted to support this information. Mild side effects such as nausea, vomiting and worsening of acne have been reported (Khan, Champaneria and Latthe 2012: e3011; Rahbar, Asgharzadeh and Ghorbani 2012: 45-47; Stewart and Deb 2014: 296-302).

Magnesium was reported to be more effective than placebo in relieving menstrual pain, as well as reducing the need for additional pain medication (Deb and Raine-Fenning 2008: 294-299). Vitamin B6 (pyridoxine) (200mg/day) was reported to be more effective at relieving the pain in dysmenorrhoea than placebo, as well as compared to a combination of magnesium (500mg/day) and Vitamin B6 (200mg/day) (Stewart and Deb 2014: 296-302; Alsiyabi, Mullaicharam and Halligudi 2016: 241-259).

Other vitamins like B1 (thiamine) and E have been proposed as a conservative treatment for primary dysmenorrhoea. Vitamin B1 showed positive response in 87% of patients after taking 100mg daily for two consecutive months when compared to placebo. Vitamin E was shown to be beneficial after taking 200mg twice daily forty-eight hours prior to the start of menstrual bleeding and three days thereafter when compared to placebo (Stewart and Deb 2014: 296-302).

- **Herbal treatment (phytotherapy)**

Phytotherapy is defined as the use of medicinal products made solely from plant material and or vegetable drug preparations used to treat various health conditions. It is reported as a substantial form of therapy used by 70% of the world's population (Mosby's Medical Dictionary 2013: 833). The treatment is aimed at providing physiological support or correction, rather than just compensating for the chemical deficiencies or excess resulting from an abnormal physiology (Mills and Bone 2007: 126).

The following phytotherapeutic substances have been recommended in the treatment of dysmenorrhoea:

Angelica sinensis (Donq quai) has a general analgesic and anti-inflammatory effect. It has the ability to relax smooth muscles and it reduces tissue congestion through enhanced blood and lymph circulation (Romm 2010: 130-138, Low Dog 2014). McCraken (2016: 143-155) mentions randomised controlled trials on Angelica sinensis which yielded mixed data on its efficacy.

Dioscorea villosa (Wild Yam) continues to be one of the primary uterine antispasmodics used for treating dysmenorrhoea with spasmodic, colicky pain (Romm 2010: 130-138). Low Dog (2014) states that there is no current research available to prove or dispute the historical use of this remedy for dysmenorrhea.

Matricaria chamomilla (Chamomile) is an effective antispasmodic and anti-inflammatory substance, useful in the treatment of menstrual discomfort. It possesses weak oestrogenic and progesteronic activity. It is also used as a mild

sedative (Romm 2010: 130-138). A systematic review reported on many studies that showed that *Matricaria chamomilla* was more effective in decreasing the severity of the pain of primary dysmenorrhoea when compared to mefenamic acid; as well as being more effective than placebo when it was taken before the pain starts (Mirabi *et al* 2014: 757-767).

Pulsatilla pratensis (Pulsatilla). The dried herb is used to treat uterine pain and nervous tension accompanying dysmenorrhoea due to its sedative and analgesic activity (Romm 2010: 130-138, Low Dog 2014). Even though Pulsatilla pratensis demonstrated the ability to decrease uterine contractionsnin-vitro; there were no randomized, controlled studies accessible for this plant (Low Dog 2014).

Viburnum opulus (Cramp bark) is an effective uterine antispasmodic and uterine tonic used for sedating pain (Romm 2010: 130-138). *Virburnum opulus* was reported to be one of the most effective herbs for decreasing uterine spasm and cramping (Kashani *et al.* 2015:1-5).

Zingiber officinalis (Ginger) is recommended for women having cramps relieved by heat and a light flow of blackish-red blood during menstruation (Nissim 1996: 16-23). It relieves nausea and vomiting, making it useful when these are concomitant symptoms of dysmenorrhoea (Romm 2010: 130-138). Jenabi (2013: 8-10) demonstrated the effectiveness of *Zingiber officinalis* in alleviating the severity of the pain and improving the symptoms of primary dysmenorrhoea in 82,85% of participants in this treatment group as opposed to those in the placebo group. Several studies were also mentioned in Jenabi (2013: 8-10)’s article supporting his findings.

Stewart and Deb (2014: 296-302) mention one small study that investigated the efficacy of the combination herbal remedies Toki-shakuyaku-san, a Japanese herbal medicine, which was compared to placebo and was found to be more effective than placebo in relieving the pain of dysmenorrhoea.

- **Exercise**

Exercise (10 minutes of stretching exercises, 20 minutes of aerobic exercise [walking or cycling], and 10 minutes of relaxation exercises) was reported to be effective in improving the quality of life for women with primary dysmenorrhoea by reducing the intensity of pain, and the number of other symptoms and complaints such as stress and anxiety, that usually accompany this condition (Daley 2008: 659-670; Onur *et al.* 2012).

Gupta, Kaur and Singh (2013: 168-177) assert that the combined effect of ginger and active exercises which included few muscles strengthening and stretching exercises was found more effective than exercise alone in decreasing the severity of primary dysmenorrhoea.

- **Topical heat treatment**

Murray (2015) reviewed three single-blinded randomised controlled trials in which the efficacy of heat patch to relieve menstrual pain and its associated symptoms was compared with that of an over-the-counter NSAID (either ibuprofen 400mg taken orally every 8 hours or acetaminophen 500mg taken orally every 6 hours). A statistically significant pain relief in favour of the heat patch was reported in two studies, while the third study showed no significant statistical improvement between the two interventions. The reviewer concluded that the results were indecisive; she recommended that more studies be conducted on topical heat treatment.

- **Transcutaneous electrical nerve stimulation**

Smith (2015) believes that transcutaneous electrical nerve stimulation (TENS) is effective in providing pain relief in dysmenorrhoea, by altering the body's ability to perceive or receive pain signals rather than by having a direct effect on the uterine contractions. A Cochrane database systematic review concluded that high-frequency TENS was found to be more effective than placebo TENS in relieving menstrual pain. The review also states that the effectiveness of the TENS therapy combined with drugs is greater than when it is used alone; this will ultimately help women who cannot tolerate oral analgesics by reducing their intake. Muscle vibrations, tightness, headaches, and slight burning or redness are reported side effects (Proctor and Farquhar 2007).

2.10 HOMOEOPATHY

The term homoeopathy is derived from the Greek words *homoios,* meaning similar, and *pathos*, meaning suffering (Bloch and Lewis 2003: 24). Homoeopathy is a holistic system of medicine that was founded by Samuel Hahnemann in 1790; it is based on the principles of like cures like (*Similia similibus curentur)*. It has a gentle approach to health problems, and is intended to activate a patient's own capacity for self-healing. This is achieved by returning the disturbed vital force or body's regulatory force to its normal healthy state by using remedies that are highly diluted (Cook 1989: 31-44, Richberg 1997: 12; Owen 2007: 3-17; Homoeopathyplus 2014a). The principles of homoeopathy include the following:

- **Law of Similars**

The prescription of a homoeopathic remedy relies on "the Law of Similars" or "like cures like" which means that the remedy for any individual illness is the very substance that can produce a similar symptom picture and pattern of the illness in a healthy person. The drug picture or the knowledge of the actions of each homoeopathic remedy are acquired through a process called "proving", where non-toxic doses of a substance are given to a healthy individual and the resulting symptoms experienced are recorded in the materia medica (Kayne 2006: 50-57; Owen 2007: 3-17; Rohrer 2008).

- **The minimum dose and potentisation**

Hahnemann reduced the concentration of remedies with the goal of increasing their safety, and he developed a preparation procedure called potentisation that involved serial dilution and vigorous shaking (referred to as succussion). This process makes the remedies more potent. The Arndt-Schulz Law is used to explain the the effect of levels (low or high) of potentisation of remedies as it states that the administration of the minimal dose is required to bring about the cure. It also stipulates that a drug's small stimuli or small doses encourage the organism's systems, moderate doses interfere or inhibit, and large doses destroy (Kayne 2006: 50-57).

- **Single remedy**

Hahnemann recommended the administration of one remedy at a time when treating the patient. The medication should be the one that closely resembles, or covers all or most of the symptoms present in the sufferer when compared with the remedy's drug picture (Kayne 2006: 50-57; Richberg 1997: 17-18).

- **Drug Proving**

Drug proving is used in homoeopathic pharmacy to discover a substance's ability to heal a patient according to the law of similars. Substances are given in safe amounts to healthy human volunteers and the symptoms produced will be recorded in the materia medica as the remedies' drug picture (Homoeopathyplus 2014b).

2.10.1 The potency scale

The procedure of potentisation takes out the mechanical and chemical aspect of the drug and simultaneously enhances its dynamic properties. The potency is the unit of the drug strength. There are three different scales of potency to suit the patient sensitivity; these are the centesimal, decimal and 50 millesimal scales (Chauhan and Gupta 2007: 50-53), described as follows:

- The centesimal scale is the original scale developed by Hahnemann. Its serial dilutions are prepared using the ratio of 1:100 and the resulting potencies are denoted by the letter "C". It is prepared by adding 99ml of alcohol and water mixture to 1ml of the mother tincture; the final mixture is succussed 100 times, giving a potency of 1C.
- The decimal scale is denoted by the suffix "X" and was developed by Hering. The serial dilutions are prepared using the ratio of 1:10. It is prepared by adding 9ml of alcohol and water mixture to 1ml of mother tincture; the final mixture is succussed 10 times, giving a potency of 1X.
- The 50 millesimal or LM scale was developed by Hahnemann in the last years of his life. The ratio of 1:50 000 is used when preparing this scale and the resulting potency is denoted by the letter "Q" or the symbols "0/…". The preparation of LM scale is more complex than that of the centesimal or decimal scale, and involves steps of trituration and dilution followed by 100 succussions (Chauhan and Gupta 2007: 50-53; Bhatia 2009b; Hpathy 2009).

2.10.2 Similimum

The homoeopathic practitioner's ideal goal is to reach the similimum by prescribing a single remedy that closely matches the patient's symptom picture in its totality. In doing so he/she takes into account the mental and emotional state of the patient, as well as their physical symptoms (Owen 2007: 210). This method is carefully observed in classical homoeopathy and allows the practitioner to individualise the treatment.

For the purpose of this study, the similimum was prescribed in 30cH plussed potency and at the follow-up consultations the researcher either repeated the previous prescription or changed the remedy in the light of the new presenting symptoms.

This study compared two methods of treatment namely the complex which is generalised versus the similimum which is tailored to the patient's needs (i.e. individualised).

2.10.3 Complex remedies prescribing

This is a method that has been developed by homoeopaths based on their clinical experiences in an attempt to provide the best care for patients (Kayne 2006: 180-182; Owen 2007: 409-413). These remedies are combined based on their specific indications, making them easier to prescribe (Kayne 2006: 180-182), and to complement and reinforce one another's therapeutic activity (Cook 1989: 73-75). The use of a homoeopathic combination of remedies has always been controversial in the homoeopathic community, pitting those who prescribe a single remedy at a time (unicists) against those who prescribe several remedies concurrently (pluralists) (Bhatia 2009a; Owen 2007: 409-413).

Morley and Bartlett (2001) state that complex prescribing targets the patient's specific stress factors rather than his or her constitutional type. Remedies in low potencies are chosen and combined with the goal to cover the highest number of

toxic and functional disturbances. The authors mention two main principles governing remedy combination and the use of low potencies to manufacture them:

1. Low potencies remedies are chosen because they are well indicated to specifically act within a structure or function. They need to be repeated often because their time of activity is short.
2. Their action is synergistic as each strengthens the therapeutic efficacy of the others without disturbing or stopping their own isolated activity.

Kayne (2006:180-182) contends that there are three main reasons why some practitioners choose to use complexes: “The uncertainty of the appropriate remedy (similimum) to prescribe, hence by giving a complex the prescriber increases the chance of a correct prescription; to treat more than one symptom of the same condition or more than one complaint at the same time; for convenience, to save time and trouble”.

Although complex remedies are becoming very popular as they are readily available over-the-counter, they do not follow “the law of similars” because they are mixed to treat one or two common symptoms of a disease and do not match the patient as a whole. All the single remedies making up any particular complex have been individually proven and their drug pictures recorded. Mixture remedies as such when proven have demonstrated an extensive number of new symptoms that are peculiar to the complex, indicating that they function differently then the constituent parts. The administration of more than one remedy at a time goes against Hahnemann’s recommendation concerning single remedy prescription. Further, this one remedy should not be repeated until specifically indicated – following this rule ensures that the practitioner knows with certainty if the particular remedy was successful or not (Bhatia 2009b; Kayne 2006: 180-182, Owen 2007: 411-412, Sanjit 2016).

2.10.3.1 The homeopathic complex investigated in this study

The homoeopathic complex investigated in this study consisted of the following remedies: *Angelica sinensis, Dioscorea villosa, Matricaria chamomilla, Viburnum opulus* and *Zingiber officinalis* all in 6cH potency.

- *Angelica sinensis* (Donq quai)

Dysmenorrhoea indications:

Stimulates the uterine muscles (Murphy 1995 and 2006: 158-160). It also has an affinity for the genital organs especially female. This substance is well indicated in female hormonal imbalances. There are pain and congestion in the left ovary; a feeling of discomfort during menses with vomiting and frequent stools. Menses is scanty with a feeling of wanting to faint, breast congestion, diarrhoea, and occasional vomiting.

General indications:

Mind: Difficulty in concentrating. Reading is difficult because she needs to move, to walk about. There is general restlessness and she lacks courage while being restless. Feels well, calm, a little tired. She may present with a state of euphoria, which is mixed with a state of indifference. She feels more dynamic but also more nervous.

Female: Amenorrhoea (long interval between menses). She experiences premenstrual syndrome, which manifests as premenstrual swelling, breast congestion, and heavy legs. There may be irritable discharge.

Abdomen: Pain in solar plexus with pulsations in the abdominal aorta, flatulence.

Back: Lumbar pain, lumbago as after exertion. She easily feels tired with a backache.

Food: Loss of appetite, worse after eating sweets, pastries, sugar.

Rectum: Diarrhoea, worse after eating sweets, pastries, sugar. There is diarrhoea after any meal; and the tendency to periods of constipation, alternating with soft stools, diarrhoea.

Pelvis: Pain in the hip and sacroiliac joint, appearing especially in the late afternoon. She complains of pain in all joints of the pelvis; with a feeling of stretching of the pelvic joints as after birth (Murphy 1995 and 2006: 158-160).

- *Dioscorea villosa* (Wild Yam)

Dysmenorrhoea indications:

Violent, paroxysmal pains, which radiate from the uterus to distant parts. There is spasmodic uterine colic, which is better from bending backward. The sensation is that of twisting, cutting, sharp and unbearable pains. There are cramps in the fingers

and toes alternating with uterine pains. It is useful for painful disorders of abdominal or pelvic viscera (Jouanny *et al.* 1997: 144, Murphy 1995 and 2006: 708-712).

General indications:

This remedy acts on the nerves, sciatic and spinal cord. It is also indicated in severe painful affections of abdominal and pelvic viscera.

Mind: Cross, nervous and easily troubled.

Abdomen: Constant aching, gripping, sharp, cutting pains and colic that start in the region of the umbilicus and radiate all over the abdomen to the back. The pains in the abdomen, stomach, and uterus are accompanied by vomiting and cramps.

Stomach: Violent, colicky pains, with the desire to bend double, which makes her worse, she must walk erect to get relief. There may be vomiting, heartburn, and gastralgia during menses.

Back: The pain and lameness are felt in the lumbar region, making turning in bed almost impossible. There is a severe backache and drawing pains in the sacrum and sacroiliac joint (Vermeulen 2001: 396-398 and 2004; Murphy 1995 and 2006: 708-712).

- *Matricaria chamomilla* (Chamomile)

Dysmenorrhoea indications:

Menstruation is disordered; the discharged blood is dark and clotted. The pain is unbearable and associated with numbness. The severe menstrual cramps make her a very irritable patient. Anger and emotions aggravate the pain of dysmenorrhoea. There is membranous dysmenorrhoea, especially at puberty. It presents as irregular labour-like pains, which are going up and down the inner thighs. This remedy is suitable for persons who are hypersensitive to pain (Murphy 1995 and 2006: 512-516).

General indications:

Affinities with mind, nerves, emotions, mucous membrane and sexual organs.

Mind: Irritable, fussy, whining and moaning. She is extremely sensitive to every type of pain, always complaining. Sensitivity to music and any noise. There is an aversion to talking, and irritability when spoken to during menses. She cannot bear anyone near her and becomes violent from the pains. Despair with the pains. She is cross

and uncivil, quarrelsome; and has sensitive nerves. Women become suddenly capricious, quarrelsome, and obstinate, before menses.

Abdomen: Feels distended. There are spells of colic from time to time. The pain moves from side to side. She complains of diarrhoea, pain in the region of navel and pain in the small of the back. She experiences cutting pains that are ameliorated by warm applications.

Back: Severe pains in the loins and hips (Gibson 1987: 153-157; Murphy 2006: 512-516; Phatak 1988: 148-150; Vermeulen 2004: 421-428).

- *Viburnum opulus* (Cramp bark)

Dysmenorrhoea indications:

This is a remedy for general cramps and colicky pains in the pelvic organs. There are spasmodic and congestive affections of ovarian or uterine origin. Pains make her so nervous she cannot keep still. Conscious of the internal sexual organs. There is a sick feeling all over in pelvic complaints. The patient needing this remedy present with heavy aching and bearing-down pains before the onset of menses. It is well indicated for spasmodic and membranous dysmenorrhoea (Murphy 1995 and 2006: 2031-2033).

General indications:

Affinity: The female organs, nerves, rectum, and bladder.

Mind: The person needing this remedy feels restless, nervous and irritable especially before and during menses.

Abdomen: Cramps and colicky pains in the lower abdomen during menses. The abdomen feels tender, worse for pressure around the umbilicus.

Back: The pains begin in the back and go around, ending in cramps in the uterus or go down the thighs. There is a bruised feeling in the back as after severe exertion. She complains of a headache during menstruation.

Food: No appetite. Stomach feels full (Murphy 1995 and 2006: 2031-2033; Phatak 1988: 548; Vermeulen 2001: 997-998 and 2004: 1405-1409).

- *Zingiber officinalis* (Ginger)

Dysmenorrhoea indications:

There is painful menstruation with cramps. Menstruation is too early and too profuse. The blood is dark and clotted (Murphy 1995 and 2006: 2076-2077).

General indications:

Affinity: This remedy is particularly useful for states of debility in the digestive tract, sexual system, and respiratory troubles.

Mind: She is irritable and chilly in the evening and during menses.

Abdomen: She complains of colic, diarrhoea, and extremely loose stools.

Back: A backache with a stiff feeling as from weakness, aggravated by sitting and leaning against something.

Extremities: She feels weakness in all her joints.

Rectum: Colic, diarrhoea and very loose stools (Vermeulen 2001: 1016-1017; Murphy 1995 and 2006: 2076-2077).

2.11 HOMOEOPATHIC CASE HISTORY AND REPERTORISATION

The homoeopathic case history is a process that involves the recording of the patients' symptoms or complaints by considering their mental and physical symptoms; their unique modalities (what make the symptoms better or worse, for example rest, motion, cold or warmth), as well as important past or present experiences affecting them. The practitioner will accomplish that by using observation, perception and clinical examination as tools to gather the information and form the totality of the symptoms' picture in order to achieve the similimum (Richberg 1997: 16-17 and Bhatia 2009c).

The growing knowledge of the homoeopathic remedies recorded in the materia medica requires the need to use a repertory to guaranty a quick and easy reference between the numerous remedies. Hence Repertorisation helps the practictioner to match the patients' totality of symptoms to the drug picture in the materia medica (Watson 2009). Watson (2009) states that "a successful repertorisation takes the prescriber to those few remedies bearing close similarity to the case, which may then be studied and compared in the materia medica to determine the final choice".

2.12. HOMOEOPATHIC TREATMENT OF PRIMARY DYSMENORRHOEA

Christie (2005) conducted a qualitative study to determine the effectiveness of the homoeopathic similimum in the treatment of primary dysmenorrhoea symptoms' severity and the need of orthodox pain medication during menstruation in terms of participants' perception using a questionnaire on a scale of 0 to 10, with 0 indicating no pain and 10 indicating extreme pain. There was no placebo group as the researcher chose to treat all the participants (n = 10) due to the pain they were experiencing with dysmenorrhoea. The outcome showed a significant improvement of the severity of the symptoms after three months of treatment, specifically lower backache, irritability, abdominal discomfort and mild depression as well as a significantly reduced need for allopathic pain medication.

Witt *et al.* (2009: 520-528) conducted a two-year prospective multicenter observational study that evaluated homoeopathic treatment of dysmenorrhoea. Fifty-seven physicians treated 139 participants (128 women and 11 girls) and used a *"*quality of life" questionnaire to assess the severity of the condition and its impact on their daily lives. Although the study's design (namely lack of control group, randomisation, and blinding) did not allow the researchers to conclusively support the effectiveness of the homoeopathic remedies; they reported a significant improvement in the dysmenorrhoea symptoms in 50% of women and 45.5% of girls, and recommended that controlled studies should be done to investigate the efficacy and effectiveness of the homoeopathic remedies prescribed during the study.

A study was conducted at the University of Johannesburg to evaluate the effect of the homoeopathic similimum in black females (n = 10) suffering from primary dysmenorrhoea; who were selected by means of convenience sampling. The researcher used the "*evaluation of symptoms"* form to gather data for statistical evaluation and the qualitative clinical information obtained from individual cases were analysed to find the similimum. The results showed that the homoeopathic similimum is statistically and clinically had a positive impact on primary dysmenorrhoea and its associated symptoms in black females (Mokabane 2009).

CHAPTER 3 : MATERIALS AND METHODOLOGY

3.1 DESIGN OF THE STUDY

The purpose of this quantitative double-blinded randomised controlled clinical study (ethic clearance number IREC 033/13) was to compare the efficacy of a homoeopathic complex with a homoeopathic similimum in the treatment of primary dysmenorrhoea in terms of the participant's perception of the treatment using the Moos Menstrual Distress Questionnaire (MDQ) (Moos 1968) (Appendix G) as well as the Pain Rating Scale (PRS) (British Pain Society 2006) (Appendix H) which they were required to complete at each consultation. The study was conducted over a period of three menstrual cycles for each participant.

3.2 SAMPLE GROUP

A total of 37 women, who signed the informed consent forms (Appendices B and D), were selected for the study, according to the inclusion and exclusion criteria listed below. Only 30 participants were required for statistical analysis, but the researcher included 37 to allow for participants who were excluded due to a positive secondary dysmenorrhoea diagnosis and for the two that did not come back for treatment after the transabdominal ultrasound examination. Participants were recruited through advertisements (Appendix I) placed on notice boards at the Durban University of Technology's campuses.

At the end of the screening, 30 participants met the inclusion criteria for the study, and they were randomly placed by means of convenience sampling within two groups (Appendix K), namely 20 participants in the experimental group receiving the homoeopathic complex and 10 participants in the control group receiving the homoeopathic similimum. There was no placebo group involved, as this condition is mainly described by the monthly pain it causes and the suffering and discomfort that these women experience. Of the 30 participants selected, only 26 completed the study due to drop outs (four). This was a double-blinded clinical study; therefore,

neither the researcher nor the participants knew which group they belonged to, only the supervisor and the clinician who dispensed the medications were aware of the grouping.

3.3 SELECTION CRITERIA

3.3.1 Inclusion criteria

- The participants in this study had to be between the ages of 18 years to 30 years. This is because primary dysmenorrhoea commonly occurs in 20-year-old women or younger shortly after menarche (6 to 12 months) when ovulatory cycles are established. While secondary dysmenorrhoea can occur at any time after menarche, it is more frequent in 30 to 40-year-old women with existing underlying pathologies (Deb and Raine- Fenning 2008: 294-299; Ju, Jones and Mishra 2014: 104-113).

- Clinical features of primary dysmenorrhoea must be present during most menstrual cycles. These include lower abdominal or pelvic pain which is described as cramping or labour-like. It radiates to the back and along the thighs, occurring just before or during menstruation. The pain lasts an average of 48 hours. Associated symptoms such as malaise, fatigue, irritability, dizziness, headache, lower backache, diarrhoea, nausea, and vomiting may be present (Stewart and Deb 2014: 296-302).

- Participants who are not currently using any form of hormonal contraception. Participants needed to discontinue the use of any hormonal contraception in order to be included in the study. They needed to have discontinued the use of the oral contraceptive pill for at least one month in order to be allowed into the study.[*]

[*] According to Davis *et al.* (2008) it takes one month or a median time of 32 days for the return to normal menstrual cycles after the discontinuation oral contraceptives. Participants who are sexually active were advised on and educated about the use of other forms of contraceptives, such as condoms, to prevent unwanted pregnancy. No participants were asked to discontinue the use of other contraceptive methods (e.g. the implant, injection, intra-uterine device, oral contraceptive pill etc.) if they wanted to take part in this study. This needed to be a personal decision that was not imposed on them by the researcher.]

3.3.2 Exclusion criteria

- Any person older than 30 years. Stewart and Deb (2014: 296-302) state that common causes of secondary dysmenorrhoea are more frequent in this age group.
- Persons with underlying conditions leading to secondary dysmenorrhoea e.g. endometriosis.
- Previous pelvic surgery or any underlying physical abnormality / pelvic diseases such as endometriosis, fibroids, polycystic ovarian syndrome.
- Persons with religious objections to alcohol used in medicinal preparations.
- Persons on hormonal contraceptives or intra-uterine devices.
- Persons with a family history of hormonal cancer (e.g. breast cancer or ovarian cancer).
- Pregnancy – being pregnant, or becoming pregnant during the course of this study.

3.4 RECRUITMENT AND SCREENING PROCESS

As the participants responded telephonically to advertisements (Appendix I) placed at the Durban University of Technology's campuses, they were scheduled for a first appointment that took place at the Homoeopathic Day Clinic. On the day of the appointment, they were given the following documents:

1. The study's information letter and consent form (Appendix B) to read and sign.
2. The ultrasound procedure's information letter and consent form (Appendix D) to read and sign.
3. A short questionnaire (Appendix A) was used in order to determine if patients qualify for the study.

The first appointment took 45 minutes as the participants were given a chance to ask questions about the study. Participants were asked to inform the researcher if they fell pregnant during the course of the study, this would have meant exclusion and referral to the appropriate health care providers for their future health care needs. No participants fell pregnant during the course of the study

Participants who qualified were sent to the gynaecologist. The participants' menstrual history was an important component in establishing the diagnosis of dysmenorrhoea (Calis 2016). Participants who complied with the inclusion criteria were scheduled for an abdominal ultrasound at the Durban University of Technology's radiography clinic. This examination was performed by two registered gynaecologists (who were collaborators in the study), and the purpose of this was to rule out any abnormalities which indicate secondary dysmenorrhoea and therefore exclude the participant from the study. Five participants were diagnosed with pelvic pathologies, namely polycystic ovarian syndrome in four and fibroids in one; and therefore were excluded. They received an explanation of these conditions and advice from the gynaecologists and were referred to a medical doctor for their future health care needs. The participants were scheduled at any time during their menstrual cycle as this had no impact on the findings (Streicher 2013). The participants were only required to have a full bladder in order for the examination to give clear results.

3.4.1 Details of the Ultrasound examination:

The gynaecologist took a brief menstrual history prior to the transabdominal ultrasound examination. The following questions were asked:

- The date of their recent menstrual cycle.
- The regularity of their menstrual cycle.
- The onset and duration of dysmenorrhoea symptoms.
- Any previous gynaecological pathology.

A transabdominal ultrasound examination was performed. No transvaginal ultrasound examination was performed.

3.5 STUDY PROCEDURE

The clinical study was conducted over three menstrual cycles for each participant, during which the impact of the treatments on their menstrual pain was assessed using two questionnaires (Appendices G and H). After the baseline or initial

consultation, there were three follow-up consultations that were scheduled after each consecutive menstrual cycle while patients were taking their respective treatments. All consultations took place at the Durban University of Technology Homoeopathic Day Clinic under the supervision of a qualified homoeopath.

3.5.1 Baseline consultation

This was scheduled after the transabdominal ultrasound screening (Appendix D) was performed and the diagnosis of primary dysmenorrhoea confirmed. At every examination, a detailed homoeopathic case history was taken, followed by a complete physical examination (Appendix F) that included blood pressure readings, checking the pulse rate, temperature, respiratory rate and abdominal examination.

Participants were required to complete the Moos MDQ (Moos 1968) (Appendix G) as well as the PRS (British Pain Society 2006) (Appendix H). The data collected constituted the baseline information on the participants' menses prior to the treatments.

This was a double-blinded study; therefore, neither the researcher nor the patient knew to which group the patient belonged. A complete homoeopathic case history (Appendix F) was gathered from every participant at each consultation, therefore collecting sufficient information from each participant to be able to find a similimum for them, even though only those in the similimum group would receive it. The researcher holistically analysed the symptoms for every participant and repertorised these, using the Radar computerised repertory (Radar, Version 9 – Archibel, Belgium) and the most suitable remedy, i.e. the similimum, was chosen for each participant, according to the totality of their symptoms. The clinician on duty at the Homoeopathic Day Clinic dispensed the relevant medication to the respective groups according to the randomisation sheet drawn up by the clinic director. The participants were sent to the reception desk to collect their medication.

Each participant received a 25ml amber droppler bottle containing the treatment in liquid form which was either the similimum in 30cH plussed potency or the homoeopathic complex (*Angelica sinensis*, *Dioscorea villosa*, *Matricaria chamomilla*,

Viburnum opulus and *Zingiber officinalis* all in 6cH potency). They were required to take 20 drops three times daily on the tongue for the first three days of their menses. The participants were asked to return for a first follow-up a week after their next menstruation.

3.5.2 First follow-up consultation

This was a follow-up consultation that included feedback on the effects of the respective treatments using the two measurement tools that were completed. A homoeopathic case history was taken to re-evaluate the participant's symptoms from their recent menses. Vital signs were checked and an abdominal examination was performed.

The participants in the treatment group received a repeat of the complex remedy, while those in the control group were either prescribed the previous similimum remedy or a new similimum remedy considering the new presenting symptoms experienced during the previous month. They collected their remedies at the reception and were asked to take the same dosage as previously instructed. The participants were asked to return for the second follow-up consultation a week after their next menses.

3.5.3 Second follow-up consultation

The same procedures as for the first consultation were followed. The participants were asked to return for the third follow-up consultation a week after their next menses.

3.5.4 Third follow-up consultation

A homoeopathic case history was taken to see any lasting effects of the treatments in both groups. The vital signs were checked and the abdominal examination was performed. The MDQ (Moos 1968) (Appendix G) and the PRS (British Pain Society 2006) (Appendix H) were completed in relation to the symptoms experienced during their recent menses. The participants completed the study and were not prescribed remedies on this last consultation.

3.6 MONITORING OF THE PARTICIPANTS

The follow-ups were scheduled once a month, a week after their menstruation. The researcher phoned the participants once a week for the duration of the study. This was done in order to keep in touch with them and to avoid any drop-outs.

3.7 TREATMENT

The medication dispensed was identical in both experimental and control groups, in that it took the form of a colourless liquid in a 25ml amber glass bottle, with identical labels. All participants received three bottles of the respective medications. The experimental, i.e. dysmenorrhoea complex; and the control, i.e. the similimum, were prepared according to the German Homoeopathic Pharmacopoeia (British Homoeopathic Association 1991).

3.7.1 Complex preparation

The complex was made up using five remedies, namely, *Angelica sinensis*, *Dioscorea villosa*, *Matricaria chamomilla*, *Viburnum opulus* and *Zingiber officinalis*. These remedies were individually prepared from mother tinctures up to the 5cH potency, as per German Homoeopathic Pharmacopoeia Method 4a prior to being mixed. This method states that the mother tinctures of dried plants or parts of plants are prepared by maceration or percolation, using a ratio of plant part to the appropriate concentration of alcohol, as prescribed in their individual monograph (Benyunes 2005; Sahani 2007: 121-125):

Table 3.1 Preparation of 1cH potency from the mother tincture

Plants' name	**Drug strength**	**Parts used**	**Maceration**	**10 succussions —› 1cH potency**
Angelica sinensis	1:2	Roots		2 parts of MT mixed to 98 parts of alcohol
Dioscorea villosa	1:6	Bulb		6 parts of MT mixed to 94 parts alcohol
Matricaria chamomilla	1:2	Whole plant		2 parts of MT mixed to 98 parts of alcohol
Viburnum opulus	1:6	Bark		6 parts of MT mixed to 94 parts of alcohol

Zingiber officinalis	1:10	Dried rhizome		10 parts of MT mixed to 90 parts alcohol

Table 3.1 shows the preparation of the first potency from the various remedies' mother tinctures that made up the homoeopathic complex.

Preparation of 2cH potency:

One part of the 1cH was mixed to ninety-nine parts of alcohol, then succussed 10 times to obtain the 2cH potency.

Preparation of 3cH to 5cH potencies:

The same process as the one used to make the 2cH potency was repeated for the 3cH to 5cH, but one part of the preceding potency was always used for the next one.

Preparation of 6cH potency:

The final potentisation stage was obtained by combining one part of each remedy in equal volume (3ml) to ninety-nine parts of 20% alcohol, then succussed 10 times to obtain the dysmenorrhoea complex in 6cH potency. This co-potentisation of the mixture was conducted according to the Method 40a of the German Homoeopathic Pharmacopoeia (Benyunes 2005). Co-Med Health Pty Ltd. prepared the homoeopathic complex.

The participants in the complex group received a 25ml amber droppler bottle that contained 20ml of the dysmenorrhoea complex made of five remedies in 6cH potency. They were advised to take 20 drops directly on their tongue three times daily starting on the first day of their menstruation until the third day. This was decided upon based on the statement by Dmitrovic, Kunselman and Legro (2012: 1143-1150) that dysmenorrhoea sufferers experience symptoms during the first three days of menstruation. The same remedy and dosage were repeated for the second and third follow-up consultations.

3.7.2 Homoeopathic Similimum

The similimum was dispensed in 30cH plussed potency and for the follow-up consultations the researcher either repeated the previous prescription or changed the remedy in the light of the new presenting symptoms.

The plussing of potency refers to the process of succussing a remedy to slightly increase the potency level so that the patient does not receive the same potency many times (O'Reilly 1996: 219). In the 5th edition of the Organon, Hahnemann advised the use of this method in cases where a patient will receive the repeated dose of the same potency, that is, many doses of the same potency, this may lead to an aggravation of the symptoms as well as decrease the body's response to the treatment, hence challenge the progress towards cure (O'Reilly 1996: 219-220). The participants succussed their remedies before they took it.

The participants in the control group received a 25ml amber droppler bottle which contained 20ml of the homoeopathic similimum in a 30cH plussed potency. The similimum was prepared according to Method 5a of the German Homoeopathic Pharmacopoeia: 10 granules of the chosen remedy, i.e. the similimum, were placed in a 25ml bottle, then 18ml of water were added to it. The granules were slowly swirled until completely dissolved, then 2ml of 30% alcohol was added to the mixture. The bottle was closed securely and succussed 10 times. The bottle was labelled with appropriate information for prescription. The quantity was sufficient to last for the first three days of each menstrual cycle. The similimum was prepared at the Homoeopathic Day Clinic at the Durban University of Technology by the clinician on clinic duty.

3.8 MEASUREMENT TOOLS

Various studies on dysmenorrhoea and other menstrual disorders have used patient self-reporting measurement tools such as pain rating scales, quality of life scales such as menstrual distress or menstrual symptom questionnaires to collect data (Deb and Raine-Fenning 2008: 294-299). The Moos MDQ (Moos 1968) (Appendix

G) and the PRS (British Pain Society 2006) (Appendix H) were used in this study, and were completed by participants at each consultation.

3.8.1 Moos Menstrual Distress Questionnaire

According to Moos (1968) (Appendix G), the "Moos Menstrual Distress Questionnaire (MDQ) can be used to screen and identify patients suffering from menstrual distress". The MDQ (Appendix G) can be used to measure the effectiveness of treatment as well as to observe each patient's progress. It has 46 symptoms, that are rated from 1 (no symptoms present) to 5 (acute or partially disabling symptoms). This tool helps to identify the type and intensity of symptoms experienced by individual participants during their menstrual cycle phases, namely the four days prior to menstrual flow, during menstruation, and the remainder of the cycle, as well as help to differentiate cyclical from noncyclical changes in physical symptoms, mood, behaviour, and arousal (Moos 1968 and 2010). The MDQ (Appendix G) was used to determine the difference between the two groups in term of the efficacy of treatments (Dmitrovic *et al*. 2012). During the development of the MDQ (Appendix G), Moos (1968) divided the 46 symptoms into subcategories that contain clusters of other symptoms (Appendix G).

3.8.2 Pain Rating Scale

The Pain Rating Scale (British Pain Society 2006) (Appendix H) also known as the Numerical Rating Pain Scale and the Verbal Rating Scale are among the most commonly used measurement tools of pain intensity in research and clinical settings (Ferreira-Valenta, Pais-Ribeiro and Jensen 2011). This type of pain rating scale consists of a set of numbers ranging from 0 (no pain) to 10 (excruciating pain) represented along a vertical or horizontal line and may include words or descriptions to better label the patient's symptoms. This is a quick and simple test to administer and does not require a higher degree of understanding or literacy from the patient. This scale can be used before, during and following treatment to evaluate participants' perception of treatment. This variety of combination scale may be most sensitive to gender and ethnic differences in describing pain (Echternach 1996; Wood 2004; Graham 2009).

Gupta, Kaur and Singh (2013: 168-177) used both the MDQ and PRS measurement tools to assess the severity of primary dysmenorrhoea in 64 nursing students. Their representation of the statistically analysed data was used as a model for this study.

3.9 ALLOPATHIC PAIN MEDICATION

Stewart and Deb (2014: 296-302) stated that 5% to 20% of women with dysmenorrhoea experience severe pain during their menstruation which interferes with their daily routines. It was suggested in this study that research participants could take the necessary allopathic medication that usually helps them. They were required to inform the researcher telephonically or in person about this for the purposes of record keeping.

3.10 STATISTICAL ANALYSIS

The MDQ (Moos 1968) (Appendix G) and the PRS (British Pain Society 2006) (Appendix H) were used to record and grade the participants' primary dysmenorrhoea symptoms as these were completed once a month after each of three consecutive menstrual cycles. Participant records were captured and documented electronically using a Microsoft EXCEL® spreadsheet. Demographics and primary dysmenorrhoea symptoms data were analysed using SPSS version 23.0 software (IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp). Four participants dropped out of the study; therefore, the statistical analysis was conducted on the results of the remaining 26 participants.

The quantitative variables across the groups were compared using the Kruskal-Wallis test since the captured data was non-parametric. The one-way analysis of variance (ANOVA) was used to compare intra-group data. Participant demographic data were graphically expressed. Quantitative variables were expressed as a mean ± standard deviation. A p-value of less than 0.05 was considered significant.

Kruskal-wallis test

The Kruskal-wallis H test (sometimes also called the “one-way ANOVA on ranks”) is a non-parametric test. It is considered as an extension of the Mann-Whitney U test to allow the comparison of more than two independent groups. This test is also used to establish if there are statistically significant differences between two or more groups of independent variable (Laerd Statistics 2013b).

Paired t-test

The paired t-test, also known as the dependent t-test is used to compare the mean of two related groups to establish whether there is a statistically significant difference between these means (Laerd statistics 2013c).

3.11 ETHICAL ISSUES

The nature and design of the study (IREC 033/13) were explained to the participants and their questions were answered prior to the transabdominal ultrasound examination and the initial consultation. Those that agreed to take part in the study signed the two informed consent forms (Appendix B) and (Appendix D). They were assured that all information provided during the course of the study was strictly confidential. Furthermore, no explanation was required if a participant decided to withdraw from the study as participation was voluntary. The participants were informed that there was a possibility for them to be prescribed either the complex or the similimum medication. They were allowed to take their usual painkillers in cases where they received no relief from their respective prescriptions, this is due to the fact that the pain and discomfort experienced as a result of dysmenorrhoea are real and can interfere with daily activities (Stewart and Deb 2014: 296-302). All the participants’ personal informations provided throughout the study were kept strickly confidential at the homoeopathic day clinic and will be destroyed after five years. The results of the study were made available to the participants.

CHAPTER 4 : RESULTS

4.1 PARTICIPANTS' FLOW DIAGRAM

Figure 4.1 shows the enrollment process.

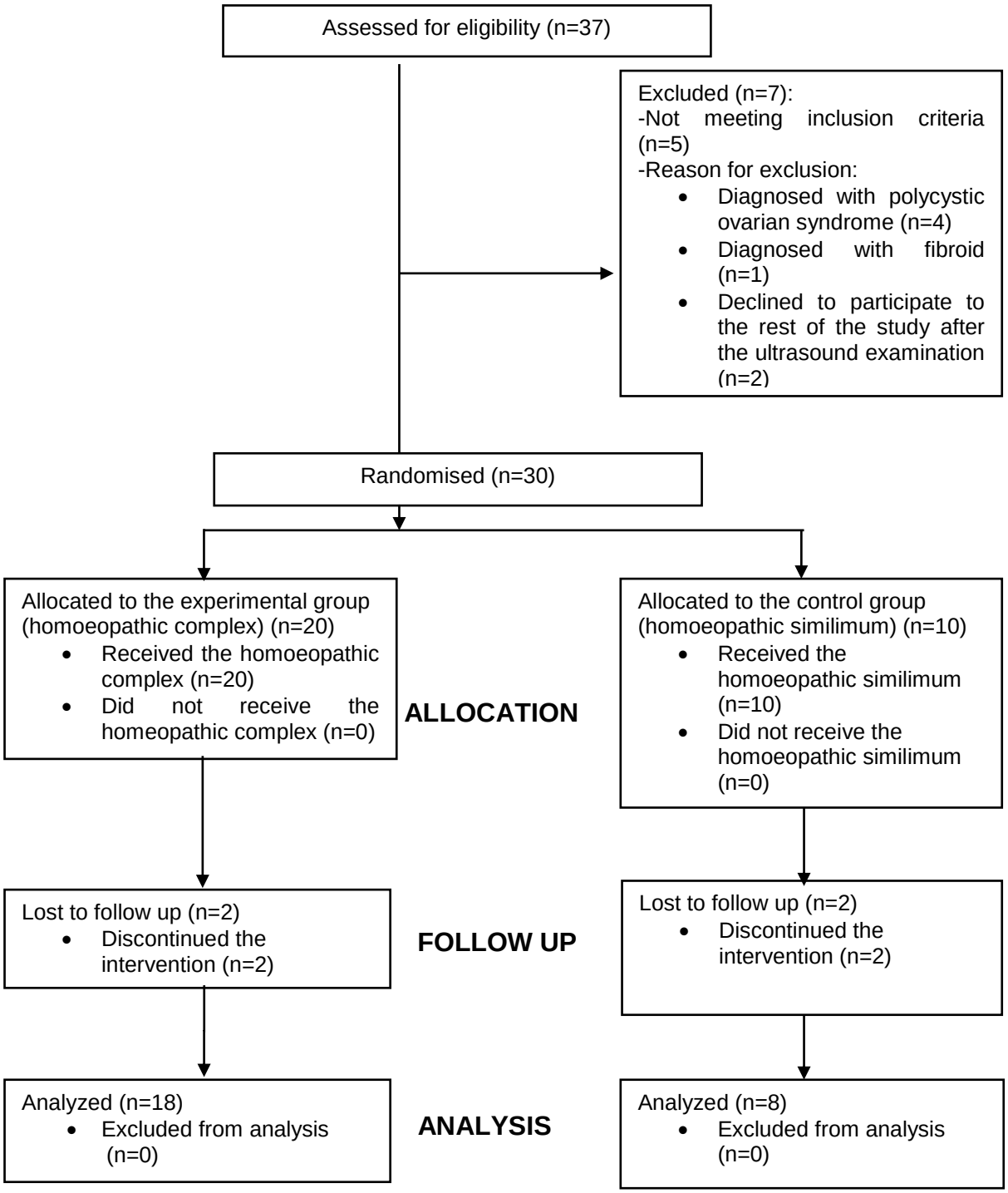

Figure 4.1: Flow chart diagram of participants in this study

4.2 DEMOGRAPHIC DATA

The study consisted of 26 women that were recruited by means of convenient sampling and randomly placed into two groups. There were 18 participants in the treatment group receiving the complex and eight in the control group receiving the similimum. All participants were African students of the Durban University of Technology.

Table 4.1: Demographic data table of participants

Variables	Complex group	Similimum group
	n = 18	**n = 8**
	n (%)	**n (%)**
Age during the study		
18 - 21 years	**13 (72.2%)**	**7 (87.5%)**
22 - 25 years	**4 (22.2%)**	**1 (12.5%)**
26 - 30 years	**1 (5.6%)**	**N/A**
Age at menarche		
11 - 13 years	**8 (44.4%)**	**4 (50%)**
> 13 years	**10 (55.5%)**	**4 (50%)**
BMI		
<18 Kg/m²	**2 (11.1%)**	**N/A**
18.5 - 24.9 Kg/m²	**8 (44.4%)**	**7 (87.5%)**
25 - 29.9 Kg/m²	**5 (27.8%)**	**1 (12.5%)**
≥30 Kg/m²	**3 (16.7%)**	**N/A**

BMI: Body mass index
n: Number
N/A: Not applicable

Table 4.1 shows the demographic data of participants. The age of participants enrolled in this study ranged between 18 and 30 years. There were more participants in the age group of 18 years to 21 years in both the complex and similimum groups, with 13 (72.2%) and 7 (87.5%) respectively. The remaining were distributed between 22 years to 25 years and 26 years to 30 years for the complex group, with 4 (22.2%) and 1 (5.6%) respectively. Only 1 (12.5%) was found to be within the 22 years to 25 years age gap for the similimum group.

Most of the participants in the complex group 10 (55.5%) had their menarche after 13 years old, with the remaining participants between 11 years and 13 years old. In

the similimum group, the distribution was equal between the ranges of 11-13 years old 4 (50%), and more than 13 years old 4 (50%).

The majority of participants in both groups were found within the normal range of weight according to their body mass index (BMI) (BMI = 18.5 Kg/m² to 24.9 Kg/m²), i.e. 8 (44.4%) and 7 (87.5%) in the complex group and similimum group respectively. In addition, there were 5 (27.8%) in the complex group and 1 (12.5%) in the similimum that were overweight (BMI = 25 Kg/m² to 29.9 Kg/m²). The remaining participants within the complex group 3 (16.7%), were overweight (BMI ≥ 30 Kg/m²) and 2 (11.1%) were underweight (BMI < 18.5 Kg/m²).

4.2.1 The mean age of participants during the study and age at menarche

The age during the study and age at menarche of participants are shown in Figure 4.2. The mean age of participants during the study in the complex group was 20.4 while that in the similimum group was 20.3. The mean age at menarche of participants in both the complex and similimum groups was 13.8. Participants' age during the study and the age at menarche for both the complex and similimum group showed no difference ($p > 0.05$).

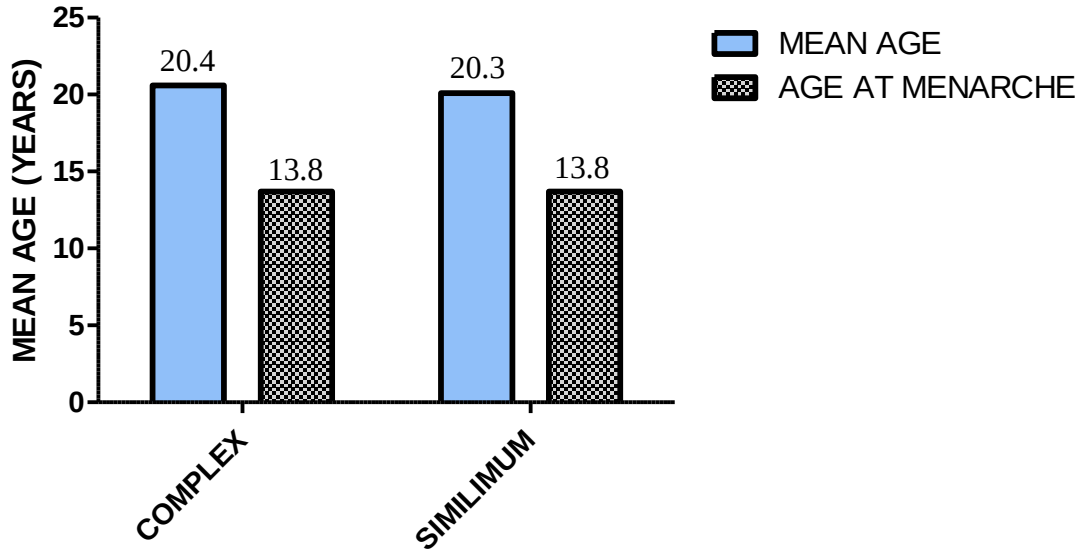

Figure 4.2: Graphical representation of the participants' mean age during the study and their age at menarche

4.2.2 The mean body mass index at baseline

The participants' BMI at baseline were recorded. The mean BMI in the complex group was 24.1 while that in the similimum group was 23.5. There was no significant difference in the mean BMI between the complex and similimum group ($p > 0.05$).

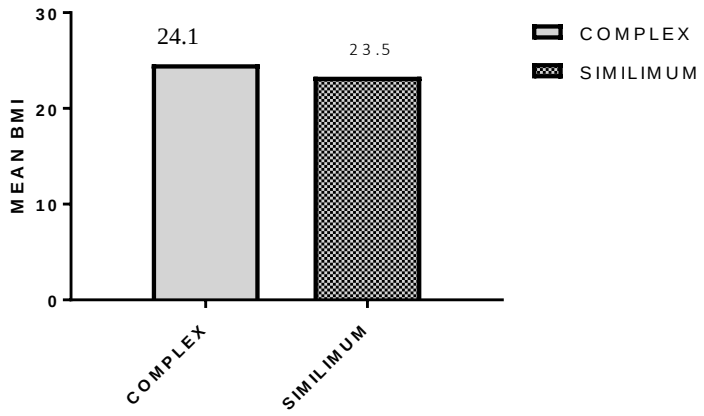

Figure 4.3: Graphical representation of the participants' means BMI at baseline

4.3 MEAN PAIN SCORE

This symptom group has six cluster symptoms; i.e muscle stiffness, headache, cramps, fatigue, general aches, pains and backache (Moos 1968) (Appendix G).

4.3.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean pain score values in the homoeopathic complex and homoeopathic simillimum groups when using the MDQ scale (Appendix G).

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:

The homoeopathic complex will be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.2: Intra-group comparison of the mean pain score in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	32.8 ± 8.5	29.9 ± 5.4
FU1	30.8 ± 7.5	29.5 ± 9.2
Mean difference (Baseline – FU1)	2.0 ± 9.7	0.4 ± 11.4
Df; T-test; P- value	17; 1.33; 0.20	7; 0.09; 0.93
Baseline	32.8 ± 8.5	29.9 ± 5.4
FU2	27.9 ± 7.0	23.3 ± 4.5
Mean difference (Baseline – FU2)	4.8 ± 10.8	6.6 ± 6.3
Df; T-test; P- value	17; 1.91; 0.07	7; 3.0; 0.02*
Baseline	32.8 ± 8.5	29.9 ± 5.4
FU3	29.8 ± 9.4	28.1 ± 7.6
Mean difference (Baseline – FU3)	3.4 ± 10.9	1.8 ± 9.8
Df; T-test; P- value	17; 1.34; 0.20	7; 0.5; 0.62
FU1	30.8 ± 7.5	29.5 ± 9.2
FU2	27.9 ± 7.0	23.3 ± 4.5
Mean difference	1.8 ± 8.6	6.3 ± 7.3
Df; T-test; P- value	17; 0.87; 0.39	7; 2.4; 0.04*
FU1	30.8 ± 7.5	29.5 ± 9.2
FU3	29.8 ± 9.4	28.1 ± 7.6
Mean difference	0.4 ± 9.5	1.4 ± 6.8
Df; T-test; P- value	17; 0.17; 0.86	7; 0.5; 0.58
FU2	27.9 ± 7.0	23.3 ± 4.5
FU3	29.8 ± 9.4	28.1 ± 7.6
Mean difference	-1.4 ± 9.5	-4.9 ± 4.8
Df; T-test; P- value	17; 0.63; 0.54	7; 2.9; 0.02*

*Statistically significant
FU1: First follow-up
FU2: Second follow-up
FU3: Third follow-up

Table 4.2 shows that the MDQ (Moos 1968) (Appendix G) mean pain score at baseline in the complex group was 32.8 ± 8.5 and decreased to 30.8 ± 7.5 at the first

follow-up (FU1), 27.9 ± 7.0 at the second follow-up (FU2) and 29.8 ± 9.4 at the third follow-up (FU3). The difference at all the levels is not statistically significant as per t-test when a comparison is made within baseline and FU1 (p=0.20), baseline and FU2 (p=0.07), baseline and FU3 (0.20), FU1 and FU2 (0.39), FU1 and FU3 (0.86) and FU2 and FU3 (0.54). In the similimum group, the mean pain score reduced from 29.9 ± 5.4 at baseline to 29.5 ± 9.2 at FU1, 23.3 ± 4.5 at FU2 and 28.1 ± 7.6 at FU3. The difference is statistically significant when a comparison is made within baseline and FU2 (p = 0.02), FU1 and FU2 (p = 0.04) and FU2 and FU3 (p = 0.02) which shows that the homoeopathic similimum has the ability to reduce the pain of the respondents. Based on these results, the first hypothesis can be rejected and the second one is rejected as the homoeopathic simillimum was more effective than the homoeopathic complex.

Table 4.3: Intra-group comparison of the mean pain score in the complex and similimum groups in terms of the PRS (Appendix H)

	Complex	**Similimum**
Baseline	5.4 ± 1.6	6.6 ± 2.0
FU1	4.2 ± 1.7	3.8 ± 2.2
Mean difference (Baseline – FU1)	1.2 ± 1.3	2.9 ± 2.0
Df; T-test; P- value	17; 3.6; 0.002*	7; 4.0; 0.004*
Baseline	5.4 ± 1.6	6.6 ± 2.0
FU2	2.6 ± 1.8	2.8 ± 1.6
Mean difference (Baseline – FU2)	2.7 ± 2.5	3.8 ± 1.7
Df; T-test; P- value	17; 4.7; 0.002*	7; 6.2; 0.004*
Baseline	5.4 ± 1.6	6.6 ± 2.0
FU3	3.2 ± 2.4	2.7 ± 2.0
Mean difference (Baseline – FU3)	2.1 ± 2.8	3.9 ± 2.3
Df; T-test; P- value	17; 3.3;0.004*	7; 4.9; 0.02*
FU1	4.2 ± 1.7	3.8 ± 2.2
FU2	2.6 ± 1.8	2.8 ± 1.6
Mean difference	1.6 ± 2.3	0.9 ± 1.7
Df; T-test; P- value	17; 2.9; 0.009*	7; 1.6; 0.16
FU1	4.2 ± 1.7	3.8 ± 2.2
FU3	3.2 ± 2.4	2.7 ± 2.0
Mean difference	1.0 ± 2.3	1.0 ± 1.6
Df; T-test; P- value	17; 1.9; 0.07	7; 1.9; 0.10

FU2	2.6 ± 1.8	2.8 ± 1.6
FU3	3.2 ± 2.4	2.7 ± 2.0
Mean difference	-0.6 ± 2.9	0.10 ± 1.4
Df; T-test; P- value	17; 0.9; 0.39	7; 0.19; 0.9

*Statistically significant.

Table 4.3 indicates that the PRS (Appendix H) mean pain score at baseline in the complex group was 5.4 ± 1.6 and reduced to 4.2 ± 1.7 at FU1, 2.6 ± 1.8 at FU2 and 3.2 ± 2.4 at FU3. The difference is statistically significant as per t-test when the comparison is made within baseline and FU1 (p = 0.002), baseline and FU2 (p = 0.002), baseline and FU3 (p = 0.009). There is no statistical significant as per t-test when a comparison is made within FU1 and FU3 (0.07) and Fu2 and FU3 (0.39). When looking at the PRS (Appendix H) mean score in the similimum group, the mean pain score decreased from 6.6 ± 2.0 at baseline to 3.8 ± 2.2 at FU1, 2.8 ± 1.6 at FU2 and 2.7 ± 2.0 at FU3. The difference is significant when the comparison is made within baseline and FU1 (p-value 0.004), baseline and FU2 (p-value 0.004) and baseline and FU3 (p = 0.02). The difference is not statistically significant when the comparison is made within FU1 and FU2 (0.16), FU1 and FU3 (0.10) and FU2 and FU3 (0.9). When looking at the results of the PRS (Appendix H), both treatments are proven to have a positive impact on the pain of the participants. Hence, the second hypothesis can be accepted; while the first can be rejected. The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean pain score values measured with the PRS (Appendix H) in both the complex and the similimum groups.

4.3.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoepathic simillimum in the treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.4: Comparison of mean pain score of respondents in terms of the MDQ (Appendix G) and PRS (Appendix H)

Time period		Measurement scale	Pain score		p-value
			Complex	Similimum	
Before treatment	Baseline	MDQ	32.8 ± 8.5	29.9 ± 5.4	0.55
		PRS	5.4 ± 1.6	6.6 ± 2.0	0.09
After intervention	1st follow up	MDQ	30.8 ± 7.5	29.5 ± 9.2	0.74
		PRS	4.2 ± 1.7	3.8 ± 2.2	0.76
	2nd follow up	MDQ	27.9 ± 7.0	23.3 ± 4.5	0.15
		PRS	2.6 ± 1.8	2.8 ± 1.6	0.75
	3rd follow up	MDQ	29.8 ± 9.4	28.1 ± 7.6	0.76
		PRS	3.2 ± 2.4	2.7 ± 2.0	0.72

The comparison of the mean pain score of the MDQ (Appendix G) and PRS (Appendix H) is shown in Table 4.4. The paired t-test was employed to compare the mean pain score values in the complex and similimum groups. The mean pain score before intervention at baseline showed no significant difference with the MDQ (Appendix G) (p=0.55) and PRS (Appendix H) (p=0.09). After the intervention, respondents mean pain score at first follow-up with the MDQ (AppendixG) (p=0.74) and PRS (Appendix H) (p=0.76), second follow-up with the MDQ (Appendix G) (p=0.15) and PRS (Appendix H) (p=0.75) and third follow-up with MDQ (Appendix G) (p=0.76) and PRS (Appendix H) (p=0.76) did not show any significant statistical difference, despite the evident decrease in the mean pain score throughout the study. Hence, the null hypothesis is rejected.

4.4 MEAN CONCENTRATION SCORE

The concentration symptom has eight cluster symptoms, namely insomnia, forgetfulness, confusion, lowered judgement, difficulty concentration, distractibility, accident prone and lowere motor coordination (Moos 1968) (Appendix G).

4.4.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean concentration score values in the complex and the similimum groups.

Hypothesis 1:

The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:

The homoeopathic complex will be as effective as the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.5: Intra-group comparison of mean concentration score in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	28.0 ± 10.7	30.9 ± 5.9
FU1	25.2 ± 6.8	29.0 ± 8.0
Mean difference (Baseline – FU1)	2.8 ± 8.3	1.9 ± 8.9
Df; T-test; P- value	17; 1.4; 0.17	7; 0.6; 0.57
Baseline	28.0 ± 10.7	30.9 ± 5.9
FU2	25.4 ± 8.5	25.9 ± 9.6
Mean difference (Baseline – FU2)	2.6 ± 9.9	5.0 ± 12.2
Df; T-test; P- value	17; 1.1; 0.12	7; 1.2; 0.28
Baseline	28.0 ± 10.7	30.9 ± 5.9
FU3	26.8 ± 9.2	27.1 ± 7.2
Mean difference (Baseline – FU3)	1.2 ± 7.5	3.8 ± 9.7
Df; T-test; P- value	17; 0.6; 0.51	7; 1.1; 0.31
FU1	25.2 ± 6.8	29.0 ± 8.0
FU2	25.4 ± 8.5	25.9 ± 9.6
Mean difference	-0.2 ± 5.7	3.1 ± 10.6
Df; T-test; P- value	17; 0.1; 0.90	7; 0.8; 0.43
FU1	25.2 ± 6.8	29.0 ± 8.0
FU3	26.8 ± 9.2	27.1 ± 7.2
Mean difference	-1.6 ± 4.9	1.9 ± 8.4
Df; T-test; P- value	17; 1.4; 0.18	7; 0.6; 0.55
FU2	25.4 ± 8.5	25.9 ± 9.6
FU3	26.8 ± 9.2	27.1 ± 7.2
Mean difference	-1.4 ± 5.4	-1.3 ± 5.9
Df; T-test; P- value	17; 1.1; 0.27	7; -0.6; 0.57

Table 4.5 shows the Intra-group comparison for mean concentration score in the complex and similimum groups. The concentration score in the complex group slightly reduced from 28.0 ± 10.7 to 25.2 ± 6.8 at FU1, 25.4 ± 8.5 at FU2, and 26.8 ± 9.2 at FU3. The same was noticed in the similimum group, with the concentration score reducing from 30.9 ± 5.9 to 29.0 ± 8.0 at FU1, 25.9 ± 9.6 at FU2, and 27.1 ± 7.2 at FU3. These results show that both treatments slightly improved the participants' concentration. Despite that, there was no significant difference in the mean concentration score at baseline compared to the level of the first follow-up in both complex (p=0.17) and similimum (p=0.57) groups. During the second follow-up in the complex group (p=0.12) and the similimum group (p=0.28); and third follow-up in the complex group (p=0.51) and similimum group (p=0.31), no significant difference in the mean concentration score was observed in both complex and similimum groups when compared to the baseline levels. The mean concentration score in the complex and similimum groups did not vary when the first and second follow-ups were compared (p=0.90) and (p=0.43) respectively. Comparison of the first and third follow-up mean concentration level also did not show any variation after comparison in both the complex group (p=0.18) and the similimum group (p=0.55). When the mean concentration levels in the second and third follow-up were compared in both the similimum (p=0.57) and complex (p=0.27) groups, no significant difference was observed. Hence, the first and second hypotheses have been rejected.

4.4.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea.

Table 4.6: Mean concentration score of respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Concentration score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	28.0 ± 10.7	30.8 ± 5.9	0.12

After intervention	1st follow up	MDQ	25.2 ± 6.8	29.0 ± 8.0	0.24
	2nd follow up	MDQ	25.4 ± 8.5	25.9 ± 9.6	0.91
	3rd follow up	MDQ	26.8 ± 9.2	27.0 ± 7.2	0.80

The mean concentration score of respondents using the MDQ (Appendix G) is shown in Table 4.6. The paired t-test was used to compare the mean concentration score values in the complex and similimum groups. The mean concentration score of respondents showed no statistically significant difference at baseline for the complex and similimum groups (P=0.12). The value also did not differ between the two groups after intervention at the first follow-up (p=0.24), second follow-up (p= 0.91) and third follow-up (p=0.80), despite the evident decrease in the mean pain score throughout the study. Hence the null hypothesis is rejected.

4.5 MEAN BEHAVIOURAL CHANGE

This symptom group comprises the following cluster symptoms; lowered school/ work performance, take naps, stay in bed, avoid social activities and decreased efficiency (Moos 1968) (Appendix G).

4.5.1 Intra-group analysis

The ANOVA was used to compare the intr-group data. The paired t-test was used to compare the mean behavioral change score values in the complex and the similimum groups

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:
The homoeopathic complex will be as effective as the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.7: Intra-group comparison of mean behavioural change of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	40.4 ± 13.9	39.3 ± 12.6
FU1	36.5 ± 12.3	33.4 ± 7.9
Mean difference (Baseline – FU1)	3.9 ± 10.4	5.9 ± 11.8
Df; T-test; P- value	17; 1.6; 0.13	7; 1.4; 0.20
Baseline	40.4 ± 13.9	39.3 ± 12.6
FU2	31.6 ± 10.3	29.9 ± 7.4
Mean difference (Baseline – FU2)	8.9 ± 12.8	9.4 ± 12.3
Df; T-test; P- value	17; 2.9; 0.09	7; 2.3; 0.07
Baseline	40.4 ± 13.9	39.3 ± 12.6
FU3	35.2 ± 13.2	32.4 ± 9.0
Mean difference (Baseline – FU3)	5.2 ± 11.7	6.9 ± 13.7
Df; T-test; P- value	17; 1.9; 0,08	7; 1.4; 0.20
FU1	36.5 ± 12.3	33.4 ± 7.9
FU2	31.6 ± 10.3	29.9 ± 7.4
Mean difference	4.9 ± 11.9	3.5 ± 8.3
Df; T-test; P- value	17; 1.8; 0.1	7; 1.2; 0.27
FU1	36.5 ± 12.3	33.4 ± 7.9
FU3	35.2 ± 13.2	32.4 ± 9.0
Mean difference	1.3 ± 9.1	1.0 ± 9.2
Df; T-test; P- value	17; 0.6; 0.56	7; 0.3; 0.77
FU2	31.6 ± 10.3	29.9 ± 7.4
FU3	35.2 ± 13.2	32.4 ± 9.0
Mean difference	-3.7 ± 7.0	-2.5 ± 6.1
Df; T-test; P- value	17; -2.2; 0.04*	7; -1.2; 0.28

* Statistically significant

Table 4.7 shows the intra-group comparison for a mean behavioural change of respondents in the complex and similimum groups. The intra group analysis for both the complex and similimum groups at baseline, first follow up, second follow up and third follow up was compared using paired t-test. The behavioural change score in the complex group reduced from 40.4 ± 13.9 at baseline to 36.5 ± 12.3 at FU1, 31.6 ± 10.3 at FU2 and 35.2 ± 13.2 at FU3. The same can be seen in the similimum group where the score reduced from 39.3 ± 12.6 at baseline to 33.4 ± 7.9 at FU1, 29.9 ±

7.4 at FU2 and 32.4 ± 9.0 at FU3. Although a constant decrease in the score throughout the study is noted, there was no significant difference in the mean behavioural change of respondents at baseline compared to the level of the first follow-up in both complex (p=0.13) and similimum (p=0.20) groups. No significant difference in the mean behavioural change of respondents was observed in both the complex and similimum groups when compared to the baseline levels at the second follow-up (p=0.09) and (p=0.07) respectively and third follow-up consultations (p=0.08) and (p=0.20) respectively. When first and second follow-ups were compared, mean behavioural change of score of respondents in the complex (p=0.1) and similimum (p=0.27) groups did not vary. Comparison of the first and third follow-up of the mean behavioural change of respondents also did not show any variation after comparison. When the mean behavioural change of respondents in the second and third follow-up was compared in both the similimum (p=0.77) and complex (p=0.56) groups, a significant difference was observed in the complex group (p=0.04), while no significant difference was observed in the similimum group (p=0.28). Hence, the first hypothesis is accepted while the second one is rejected. The complex has shown to have the ability to improve the behaviours (lowered motor coordination, lowered school / work performance, take naps, stay in bed, stay at home, avoid social activities and decreased efficiency) of the respondents.

4.5.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic similimum will be effective in the treatment of primary dysmenorrhoea.

Table 4.8: Mean score for behavioural change of respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Behavioural change score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	40.4 ± 13.9	39.3 ± 12.6	0.91
After intervention	1st follow up	MDQ	36.5 ± 12.3	33.4 ± 7.9	0.45
	2nd follow up	MDQ	31.6 ± 10.3	29.9 ± 7.4	0.78
	3rd follow up	MDQ	35.2 ± 13.2	33.4 ± 9.0	0.95

Table 4.8 shows the mean scores for behavioural change of respondents in terms of the MDQ (Appendix G). The paired t-test was used to compare the mean behavioural change score values in the complex and the similimum groups. The mean of behavioural change of respondents showed no significant difference at baseline for the complex and similimum groups (p=0.91). The MDQ (Appendix G) score was reduced slightly in both groups from the baseline consult to the first and the second follow-ups from 40.4 ± 13.9 to 36.5 ± 12.3, and from 36.5 ± 12.3 to 31.6 ± 10.3 in the complex group; and from 39.3 ± 12.6 to 33.4 ± 7.9, and from 33.4 ± 7.9 to 29.9 ± 7.4 in the similimum group. This means that both treatments could not provide long-term relief to the cluster of complaints found under behavioural change as demonstrated by the p-value which did not differ between the two groups after intervention at the first follow-up (p=0.45), second follow-up (p=0.78) and third follow-up (p=0.95). Hence, the null hypothesis was rejected.

4.6 MEAN AUTONOMIC SCORE

The autonomic symptom has four cluster symptoms; namely dizziness, hot flushes cold sweats, nausea and vomiting (Moos 1968) (AppendixG).

4.6.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean autonomic score values in the complex and similimum groups.

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:
The homoeopathic complex will be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.9: Intra-group comparison of the mean autonomic response of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	19.7 ± 5.9	18.1 ± 5.4
FU1	17.9 ± 5.3	14.3 ± 2.4
Mean difference (Baseline – FU1)	1.7 ± 6.1	3.9 ± 5.3
Df; T-test; P- value	17; 1.2; 0.25	7; 2.1; 0.08
Baseline	19.7 ± 5.9	18.1 ± 5.4
FU2	16.9 ± 4.4	13.8 ± 2.3
Mean difference (Baseline – FU2)	2.8 ± 6.6	4.4 ± 5.2
Df; T-test; P- value	17; 1.8; 0.09	7; 2.4; 0.04*
Baseline	19.7 ± 5.9	18.1 ± 5.4
FU3	18.5 ± 5.1	16.0 ± 4.8
Mean difference (Baseline – FU3)	1.2 ± 6.7	2.1 ± 4.6
Df; T-test; P- value	17; 0.7; 0.47	7; 1.3; 0.23
FU1	17.9 ± 5.3	14.3 ± 2.4
FU2	16.9 ± 4.4	13.8 ± 2.3
Mean difference	1.1 ± 4.5	0.5 ± 3.2
Df; T-test; P- value	17; 1.0; 0.33	7; 0.4; 0.67
FU1	17.9 ± 5.3	14.3 ± 2.4
FU3	18.5 ± 5.1	16.0 ± 4.8
Mean difference	-0.6 ± 5.5	-1.8 ± 4.5
Df; T-test; P- value	17; -0.4; 0.67	7; -1.1; 0.31
FU2	16.9 ± 4.4	13.8 ± 2.3
FU3	18.5 ± 5.1	16.0 ± 4.8
Mean difference	-1.6 ± 6.4	-2.3 ± 3.5
Df; T-test*; P- value	17; -1.1; 0.30	7; -1.8; 0.11

Table 4.9 shows the intra-group comparison for the mean of autonomic response in the complex and similimum groups. The autonomic response score in the complex group decreased from 19.7 ± 5.9 at baseline to 17.9 ± 5.3 at FU1, 16.9 ± 4.4 at FU2 and 18.5 ± 5.1 at FU3. In the similimum group, it decreased from 18.1 ± 5.4 at baseline to 14.3 ± 2.4 at FU1, 13.8 ± 2.3 at FU2 and 16.0 ± 4.8 at FU3. There was no significant difference in the mean autonomic response score of respondents at baseline compared to the level of the first follow-up in both complex (p=0.25) and similimum (p=0.08) groups. No significant difference in the mean autonomic

response of respondents was observed in the complex (p=0.09) group during the second follow-ups, while a significant difference was seen in the similimum group (p=0.04). Comparison of the baseline score and third follow-up score in both the complex (p=0.47) and similimum (p=0.23) groups showed no significant difference. When the first and second follow-ups were compared the mean autonomic response of respondents in the complex (p=0.33) and similimum (p=0.67) groups did not vary. Comparison of the first and third follow-up mean autonomic response of respondents also did not show any variation after comparison in both the complex (p=0.67) and the similimum (p=0.31) groups. When the mean autonomic response of respondents in the second and third follow-up was compared in both the similimum (p=0.11) and complex (p=0.30) groups, no significant difference was observed. Hence, the first and second hypotheses were rejected.

4.6.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea.

Table 4.10: Mean score for the autonomic response of respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Autonomic response score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	19.6 ± 5.9	18.1 ± 5.4	0.50
After intervention	1st follow up	MDQ	17.9 ± 5.3	14.3 ± 2.4	0.06
	2nd follow up	MDQ	16.9 ± 4.4	13.8 ± 2.3	0.09
	3rd follow up	MDQ	18.5 ± 5.1	16.0 ± 4.8	0.14

The paired t-test was employed to compare the mean score values in the complex and the similimum groups. The mean score of the autonomic response of the respondents in terms of the MDQ (Appendix G) measurements is shown in Table 4.10. This table also shows the reduction in the mean autonomic response score throughout the various follow-ups. The mean autonomic response score showed no statistically significant difference at baseline for the complex and similimum groups (p=0.50). The autonomic response score also did not differ between the two groups

after intervention at the first follow-up (p=0.06), second follow-up (p=0.09) and third follow-up (p=0.14). Hence, the null hypothesis is rejected.

4.7 MEAN WATER RETENTION SCORE

The water retention symptom comprises weight gain, skin disorders, painful breasts and swelling as cluster symptoms (Moos 1968) (Appendix G).

4.7.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean water retention score values complex and the similimum groups

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:
The homoeopathic complex will not be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.11: Intra-group comparison of mean water retention score of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	20.4 ± 7.0	20.6 ± 7.3
FU1	18.3 ± 6.8	19.4 ± 5.3
Mean difference (Baseline – FU1)	2.1 ± 6.1	1.3 ± 3.1
Df; T-test; P- value	17; 1.5; 0.16	7; 1.2; 0.23
Baseline	20.4 ± 7.0	20.6 ± 7.3
FU2	18.2 ± 7.5	18.8 ± 5.2
Mean difference (Baseline – FU2)	2.2 ±7.1	1.9 ± 2.6
Df; T-test; P- value	17; 1.3; 0.21	7; 2.0; 0.08
Baseline	20.4 ± 7.0	20.6 ± 7.3
FU3	19.1 ± 6.2	18.4 ± 4.3
Mean difference (Baseline – FU3)	1.3 ± 5.1	2.3 ± 5,4

Df; T-test; P- value	17; 1.1; 0.28	7; 1.2; 0.23
FU1	18.3 ± 6.8	19.4 ± 5.3
FU2	18.2 ± 7.5	18.8 ± 5.2
Mean difference	0.1 ± 3.6	0.6 ± 2.6
Df; T-test; P- value	17; 0.1; 0.95	7; 0.7; 0.52
FU1	18.3 ± 6.8	19.4 ± 5.3
FU3	19.1 ± 6.2	18.4 ± 4.3
Mean difference	-0.8 ± 5.0	1.0 ± 4.2
Df; T-test; P- value	17; -0.7; 0.52	7; 0.7; 0.53
FU2	18.2 ± 7.5	18.8 ± 5.2
FU3	19.1 ± 6.2	18.4 ± 4.3
Mean difference	-0.8 ± 5.2	0.4 ± 4.8
Df; T-test; P- value	17; -0.7; 0.51	7; 0.2; 0.83

Table 4.11 shows the intra-group comparison for mean water retention score in the complex and similimum groups. The water retention score reduced in the complex group from 20.4 ± 7.0 at baseline to 18.3 ± 6.8 at FU1, 18.2 ± 7.5 at FU2 and 19.1 ± 6.2 at FU3. In the similimum group, it reduced from 20.6 ± 7.3 at baseline to 19.4 ± 5.3 at FU1, 18.8 ± 5.2 at FU2 and 18.4 ± 4.3 at FU3. There was no significant difference in the mean water retention score at baseline compared to the level of the first follow-up in both complex (p=0.06) and similimum (p=0.23) groups. During the second follow-up in the complex group (p=0.21) and in the similimum (p=0.08) and third follow-up in the complex group (p=0.28) and the similimum group (p=0.23), no significant difference in the mean water retention score was observed when compared to the baseline levels. The mean water retention score in the complex (p=0.95) and similimum (p=0.52) groups did not vary when the first and second follow-ups were compared. Comparison of the first and third follow-up mean water retention score also did not show any variation after comparison in both the complex group (p=0.52) and the similimum group (p=053). When the mean water retention score in the second and third follow-up was compared in the similimum (p=0.83) and complex group (p=0.51), no significant difference was observed. Hence, both hypotheses have been rejected.

4.7.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic simillimum in the treatment of primary dysmenorrhoea.

Table 4.12: Mean water retention score of respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Water retention score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	20.3 ± 7.0	20.6 ± 7.3	0.85
After intervention	1st follow up	MDQ	18.3 ± 6.8	19.4 ± 5.3	0.60
	2nd follow up	MDQ	18.2 ± 7.5	19.0 ± 5.2	0.40
	3rd follow up	MDQ	19.0 ± 6.2	18.4 ± 4.3	0.91

Table 4.12 shows the mean water retention score of respondents before and after intervention in terms of the MDQ (Appendix G) as well as the decrease in the constant score throughout the study. At baseline, there was no statistically significant difference in the mean water retention score of respondents in the complex and similimum (p=0.85) groups. After the intervention, respondents mean water retention at first follow-up (p=0.60), second follow-up (p=0.40) and third follow-up did not show any difference (p=0.91). Hence the null hypothesis is rejected. The paired t-test was used to compare the mean water retention score values in the complex and the similimum groups.

4.8 MEAN NEGATIVE AFFECT SCORE

The negative affect symptoms is made up of eight cluster symptoms, namely crying, loneliness, anxiety, restlessness, irritability, mood swings, depression and tension (Moos 1968) (Appendix G).

4.8.1 Intra-group analysis

The ANOVA was used to intra-group data. The paired t-test was employed to compare the mean negative affect in the complex and the similimum groups.

Hypothesis 1:

The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:

The homoeopathic complex will be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.13: Intra-group comparison of mean negative affect score of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	44.4 ±16.7	42.0 ± 8.3
FU1	41.2 ± 15.1	39.4 ± 10.8
Mean difference (Baseline – FU1)	3.8 ± 6.7	2.6 ± 14.7
Df; T-test; P- value	17; 2.4; 0.03*	7; 0.5; 0.63
Baseline	44.4 ±16.7	42.0 ± 8.3
FU2	35.1 ± 14.3	37.9 ± 13.5
Mean difference (Baseline – FU2)	9.3 ± 12.4	4.1 ± 13.3
Df; T-test; P- value	17; 3.2; 0.01*	7; 0.9; 0.41
Baseline	44.4 ±16.7	42.0 ± 8.3
FU3	40.9 ± 21.6	33.4 ± 9.8
Mean difference (Baseline – FU3)	3.5 ± 16.6	8.6 ± 10.8
Df; T-test; P- value	17; 0.9; 0.38	7; 2.6; 0.06
FU1	41.2 ± 15.1	39.4 ± 10.8
FU2	35.1 ± 14.3	37.9 ± 13.5
Mean difference	5.6 ± 9.0	1.5 ± 14.0
Df; T-test; P- value	17; 2.6; 0.02*	7; 0.3; 0.77
FU1	41.2 ± 15.1	39.4 ± 10.8
FU3	40.9 ± 21.6	33.4 ± 9.8
Mean difference	-2.8 ± 14.9	6.0 ± 11.3
Df; T-test*; P- value	17; -0.1; 0.94	7; 1.5; 0.18
FU2	35.1 ± 14.3	37.9 ± 13.5
FU3	40.9 ± 21.6	33.4 ± 9.8
Mean difference	-5.8 ± 12.4	4.5 ± 8.8
Df; T-test*; P- value	17; -2.0; 0.06	7; 1.5; 0.19

* Statistically significant

Table 4.13 shows the intra-group comparison of mean negative affect score in the complex and similimum group in terms of the MDQ (Appendix G). The negative affect score reduced in the complex group from 44.4 ±16.7 at baseline to 41.2 ± 15.1 at FU1, 35.1 ± 14.3 at FU2 and 40.9 ± 21.6 at FU3. In the similimum group, it reduced from 42.0 ± 8.3 at baseline to 39.4 ± 10.8 at FU1, 37.9 ± 13.5 at FU2 and 33.4 ± 9.8 at FU3. There was a significant difference in the mean negative affect score at baseline compared to the level of the first follow-up in the complex group (p=0.03), while that in the similimum group showed no difference (p=0.63). A significant difference in the mean negative affect score was observed in the complex group (p=0.01) during the second follow-up, while the similimum group showed no difference (p=0.41) when the baseline level was compared to that of the second follow-up. There was no significant difference when the baseline level was compared to that of the third follow-up in both the complex (p=0.38) and the similimum (p=0.06) groups. In the complex group, there was a significant difference when the mean negative affect score of the first follow-up was compared to that of the second follow-up (p=0.02). In the similimum group, no difference was observed (p=0.77). There was no significant difference in mean negative affect score at the second follow-up when compared with that at the third follow-up. Comparison of the first and third follow-up mean negative affect score also did no show any significant difference in both the complex (p=0.94) and the similimum (p=0.18) groups. When the mean negative score in the second and third follow-up was compared the similimum (p=0.19) and the complex (p=0.06) groups, no significant difference was observed. Hence, the first hypothesis is accepted while the second one is rejected, despite the similimum group showing a constant decrease in the mean negative affect score throughout the study.

4.8.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea.

Table 4.14: Mean negative affect score of respondents using in terms of the MDQ (Appendix G)

Time period		Measurement scale	Negative affect score		p-value
			Complex	Similimum	
Before intervention	Baseline	MDQ	44.4 ±16.7	42.0 ± 8.3	0.85
After intervention	1st follow up	MDQ	41.2 ± 15.1	39.4 ± 10.8	0.93
	2nd follow up	MDQ	35.1 ± 14.3	37.9 ± 13.5	0.49
	3rd follow up	MDQ	40.9 ± 21.6	33.4 ± 9.8	0.43

Table 4.14 shows the mean negative affect score of respondents before and after intervention in terms of the MDQ (Appendix G). A slight decrease in the score can be identified in both groups at the different follow-ups. At baseline, there was no statistically significant difference in the mean negative affect score of respondents in the complex and similimum groups (p=0.85). After the intervention, respondents' mean negative affect score at first follow-up (p=0.93), second follow-up (p=0.49) and third follow-up (p=0.43) did not show any difference. Hence, the null hypothesis is rejected. The paired t-test was employed to compare the mean negative affect in the complex and the similimum groups.

4.9 MEAN AROUSAL SCORE

Affectionate, Orderliness, excitement, feeling of well-being, and burst of energy and activity form the cluster of symptoms grouped under in the arousal symptoms (Moos 1968) (Appendix G).

4.9.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean arousal score values in the complex and the similimum groups.

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:
The homoeopathic complex will be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.15: Intra-group comparison of mean arousal score of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	26.9 ± 12.0	23.1 ± 6.0
FU1	25.7 ± 10.6	22.0 ± 5.7
Mean difference (Baseline – FU1)	1.2 ± 10.0	1.1 ± 6.5
Df; T-test; P- value	17; 0.5; 0.61	7; 0.5; 0.64
Baseline	26.9 ± 12.0	23.1 ± 6.0
FU2	25.7 ± 9.0	21.5 ± 8.2
Mean difference (Baseline – FU2)	1.2 ± 7.6	1.6 ± 8.7
Df; T-test; P- value	17; 0.7; 0.53	7; 0.5; 0.61
Baseline	26.9 ± 12.0	23.1 ± 6.0
FU3	24.7 ± 9.9	22.0 ± 10.8
Mean difference (Baseline – FU3)	2.2 ± 11.9	1.1 ± 10.4
Df; T-test; P- value	17; 0.8; 0.45	7; 0.3; 0.76
FU1	25.7 ± 10.6	22.0 ± 5.7
FU2	25.7 ± 9.0	21.5 ± 8.2
Mean difference	-0.1 ± 6.6	0.5 ± 7.0
Df; T-test; P- value	17; -0.03; 0.97	7; 0.2; 0.85
FU1	25.7 ± 10.6	22.0 ± 5.7
FU3	24.7 ± 9.9	22.0 ± 10.8
Mean difference	0.9 ± 9.5	0.0 ± 9.4
Df; T-test; P- value	17; 0.4; 0.68	7; 0.0; 1.0
FU2	25.7 ± 9.0	21.5 ± 8.2
FU3	24.7 ± 9.9	22.0 ± 10.8
Mean difference	1.0 ± 7.6	-0.5 ± 7.9
Df; T-test; P- value	17; 0.6; 0.58	7; -0.2; 0.86

Table 4.15 shows the intra-group comparison for mean arousal (affectionate, orderliness, excitement, feeling of well-being and burst of energy, activity) score in the complex and similimum groups. The mean arousal score decreased in the complex group from 26.9 ± 12.0 at baseline to 25.7 ± 10.6 at FU1, 25.7 ± 9.0 at FU2 and 24.7 ± 9.9 at FU3. In the similimum group, it reduced from 23.1 ± 6.0 at baseline to 22.0 ± 5.7 at FU1, 21.5 ± 8.2 at FU2 and 22.0 ± 10.8 at FU3. There was no significant difference in the mean arousal score at baseline compared to the level of

the first follow-up in both complex (0.61) and similimum (p=0.64) groups. No significant difference in the mean arousal score was observed in either complex (p=0.53) or similimum (p=0.61) groups when compared to the baseline levels during the second and third follow-up (p=0.45) and (p=0.76) respectively. The mean arousal score in the complex (p=0.97) and similimum (p=0.85) groups did not vary when the first and second follow-ups were compared. Comparison of the first and third follow-up mean arousal score also did not show any variation after comparison in both the complex (p=0.68) and similimum (p=0.10) groups. When the mean arousal score in the second and third follow-up was compared in the similimum (p=0.86) and complex (p=0.58) groups, no significant difference was observed. Hence, the first and the second hypotheses have been rejected.

4.9.2 Inter-group analysis

Hypothesis 3:
The null hypothesis states that the homoeopathic complex will no be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea.

Table 4.16: Mean arousal score for respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Arousal score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	26.9 ± 12.0	23.1 ± 6.0	0.89
After intervention	1st follow up	MDQ	25.7 ± 10.6	22.0 ± 5.7	0.66
	2nd follow up	MDQ	25.7 ± 9.0	21.5 ± 8.2	0.36
	3rd follow up	MDQ	24.7 ± 9.9	22.0 ± 10.8	0.72

Table 4.16 shows the mean arousal score of respondents before and after intervention in terms of the MDQ (Appendix G) measurements. In both groups, a slight decrease in the mean arousal score can be identified from the baseline through to the third follow-up (FU3). At baseline, there was no statistically significant difference in the mean arousal score of respondents in the complex and similimum groups (p=0.89). After the intervention, respondents' mean arousal score at the first follow-up (p=0.66), second follow-up (p=0.36) and third follow-up (p=0.72) did not show any difference. Hence, the null hypothesis was rejected. The paired t-test was

used to compare the mean arousal score values in the complex and the similimum groups.

4.10 MEAN CONTROL SCORE

The control symptom comprises six cluster symptoms; namely feeling of suffocation, chest pain, ringing in the ears, heart pounding, blind spots and fussy vision (Moos 1968) (Appendix G).

4.10.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean control score values in the complex and the similimum groups.

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:
The homoeopathic complex will be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.17: Intra-group comparison of mean control score of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	24.1 ± 5.5	22.4 ± 8.3
FU1	23.6 ± 40	22.4 ± 4.8
Mean difference (Baseline – FU1)	0.5 ± 4.1	0.0 ± 6.8
Df; T-test; P- value	17; 0.5; 0.61	7; 0.0; 1.00
Baseline	24.1 ± 5.5	22.4 ± 8.3
FU2	21.4 ± 4.6	22.5 ± 4.6
Mean difference (Baseline – FU2)	2.6 ± 5.0	-0.1 ± 8.6
Df; T-test; P- value	17; 2.2; 0.04*	7; -0.04; 0.97
Baseline	24.1 ± 5.5	22.4 ± 8.3
FU3	26.5 ± 9.7	22.4 ± 5.0
Mean difference (Baseline – FU3)	-2.4 ± 6.9	0.0 ± 7.2

Df; T-test; P- value	17; -1.5; 0.15	7; 0.0; 1.00
FU1	23.6 ± 40	22.4 ± 4.8
FU2	21.4 ± 4.6	22.5 ± 4.6
Mean difference	2.1 ± 4.3	-0.1 ± 3.5
Df; T-test; P- value	17; 2.1; 0.04*	7; -0.1; 0.92
FU1	23.6 ± 40	22.4 ± 4.8
FU3	26.5 ± 9.7	22.4 ± 5.0
Mean difference	-2.9 ± 8.6	0.0 ± 2.3
Df; T-test; P- value	17; -1.4; 0.17	7; 0.0; 1.00
FU2	21.4 ± 4.6	22.5 ± 4.6
FU3	26.5 ± 9.7	22.4 ± 5.0
Mean difference	-5.1 ± 8.8	0.1 ± 2.9
Df; T-test; P- value	17; -2.4; 0.03*	7; 0.1; 0.91

* Statistically significant

Table 4.17 shows the intra-group comparison for mean control score in the complex and similimum groups. The mean control score in the complex group decreased from 24.1 ± 5.5 at baseline to 23.6 ± 40 at FU1, 21.4 ± 4.6 at FU2 then increased to 26.5 ± 9.7 at FU3. This was similar in the similimum group, where the score slightly decreased from 22.4 ± 8.3 at baseline to 22.4 ± 4.8 at FU1, then increased to 22.5 ± 4.6 at FU2, and then decreased slightly to 22.4 ± 5.0 at FU3. There was no significant difference in the mean control score at baseline compared to the level of the first follow-up in both the complex (p=0.61) and similimum (p=1.00) groups. A significant difference was observed when the mean control score at baseline was compared to the second follow-up in the complex group (p = 0.04), while in the similimum group no difference was observed (p=0.97). No significant difference in the mean control score was observed during the third follow-up in both the complex (p=0.15) and similimum (p=1.00) groups when compared to the baseline score. The mean control score showed a significant difference in the complex group when the first follow-up was compared to the second follow-up (p = 0.04). In the similimum group no significant difference was observed (p=0.92). Comparison of the first and third follow-up mean control score also did not show any variation after comparison in both the complex (p=0.17) and the similimum (p=1.00) groups. The mean control score in the second and third follow-up showed a significant difference in the

complex group (p = 0.03). No significant difference was observed in the similimum group (p=0.91). The complex treatment showed more statistically significant values than the similimum treatment, when various comparisons are made at different levels throughout the study, which indicates that it has a positive impact on control of the respondents. Hence, the first hypothesis is accepted and the second one is rejected.

4.10.2 Inter-group analysis

Hypothesis 3:
The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea.

Table 4.18: Mean control score of respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Control score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	24.1 ± 5.5	22.4 ± 8.3	0.29
After intervention	1st follow up	MDQ	23.6 ± 40	22.4 ± 4.8	0.60
	2nd follow up	MDQ	21.4 ± 4.6	22.5 ± 4.6	0.49
	3rd follow up	MDQ	26.5 ± 9.7	22.5 ± 5.0	0.35

Table 4.18 shows the mean control score of respondents before and after intervention using in terms of the MDQ (Appendix G). The mean control scores slightly decreased from the baseline to the first and second follow-ups in the complex group, then it increased greatly in the third follow-up. In the similimum group, the decrease can only be seen in the first follow-up, and then a minor increase is noted at the second and third follow-ups. At baseline, there was no statistically significant difference in the mean control score of respondents in the complex and similimum groups (p=0.29). After the intervention, the respondents' mean control score at first follow-up (p=0.60), second follow-up (p=0.49) and third follow-up (p=0.35) did not show any significant difference. Hence, the null hypothesis is rejected. The paired t-test was used to compare the mean control score values in the complex and the similimum groups.

4.11 MEAN APPETITE CHANGE SCORE

This group does not have cluster symptoms (Moos 1968) (Appendix G).

4.11.1 Intra-group analysis

The ANOVA was used to compare the intra-group data. The paired t-test was used to compare the mean appetite change score values in the complex and the similimum groups.

Hypothesis 1:
The homoeopathic complex will be more effective than the homoeopathic similimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Hypothesis 2:
The homoeopathic will be as effective as the homoeopathic simillimum in treating primary dysmenorrhoea in terms of participants' perceptions.

Table 4.19: Intra-group comparison of mean appetite score of respondents in the complex and similimum groups in terms of the MDQ (Appendix G)

	Complex	**Similimum**
Baseline	6.4 ± 2.8	6.5 ± 2.9
FU1	5.6 ± 3.0	5.4 ± 2.5
Mean difference (Baseline – FU1)	0.9 ±3.2	1.1 ± 3.5
Df; T-test; P- value	17; 1.2; 0.25	7; 0.9; 0.39
Baseline	6.4 ± 2.8	6.5 ± 2.9
FU2	5.6 ± 2.5	4.4 ± 2.5
Mean difference (Baseline – FU2)	0.8 ± 2.8	2.1 ± 2.2
Df; T-test; P- value	17; 1.3; 0.22	7; 2.7; 0.02*
Baseline	6.4 ± 2.8	6.5 ± 2.9
FU3	5.7 ± 3.1	5.3 ± 2.1
Mean difference (Baseline – FU3)	0.8 ± 4.3	1.3 ± 2.0
Df; T-test; P- value	17; 0.8; 0.45	7; 1.8; 0.12
FU1	5.6 ± 3.0	5.4 ± 2.5
FU2	5.6 ± 2.5	4.4 ± 2.5
Mean difference	-0.1 ± 2.8	1.0 ± 3.8

Df, T-test, P- value	17, 0.1, 0.93	7, 0.7, 0.48
FU1	5.6 ± 3.0	5.4 ± 2.5
FU3	5.7 ± 3.1	5.3 ± 2.1
Mean difference	-0.1 ± 4.0	0.1 ± 2.9
Df; T-test; P- value	17; -0.1; 0.90	7; 0.1; 0.90
FU2	5.6 ± 2.5	4.4 ± 2.5
FU3	5.7 ± 3.1	5.3 ± 2.1
Mean difference	-0.1 ± 2.7	-0.9 ± 1.4
Df; T-test; P- value	17; -0.1; 0.93	7; -1.8; 0.11

* Statistically significant

Table 4.19 shows the intra-group comparison for mean appetite score in the complex and similimum groups. The mean appetite score reduced in the complex group from 6.4 ± 2.8 at baseline to 5.6 ± 3.0 at FU1, 5.6 ± 2.5 at FU2 and 5.7 ± 3.1 at FU3. In the similimum group, it reduced from 20.6 ± 7.3 at baseline to 19.4 ± 5.3 at FU1, 18.8 ± 5.2 at FU2 and 18.4 ± 4.3 at FU3. There was no significant difference in the mean appetite score at baseline compared to the level of the first follow-up in both complex (p=0.25) and similimum (p=0.39) groups. During the second and third follow-ups, no significant difference in the mean appetite score was observed in the complex group (p=0.22) and (p=045) respectively. In the similimum group, there was a difference in the mean appetite score when the baseline score is compared to the second follow-up score (p = 0.02) but when the comparison was made with during the third follow-up (p=0.12). Comparison of the first and second follow-up score as well as the first and third follow-up score did not show any variation for both the complex group (p=0.93) and (p=0.90), and the similimum group (p=0.48) and (p=0.90). Comparison of the mean appetite score in the second and third follow-up for both the similimum (p=0.11) and the complex (p=0.93) groups showed no significant difference. Hence, the first hypothesis is rejected. The similimum treatment showed a single positive effect on the participants' appetite; therefore the second hypothesis is also rejected.

4.11.2 Inter-group analysis

Hypothesis 3:

The null hypothesis states that the homoeopathic complex will not be as effective as the homoeopathic similimum in the treatment of primary dysmenorrhoea.

Table 4.20: Mean appetite score of respondents in terms of the MDQ (Appendix G)

Time period		**Measurement scale**	**Appetite score**		**p-value**
			Complex	**Similimum**	
Before intervention	Baseline	MDQ	6.4 ± 2.8	6.5 ± 2.9	0.84
After intervention	1st follow up	MDQ	5.6 ± 3.0	5.4 ± 2.5	0.98
	2nd follow up	MDQ	5.6 ± 2.5	4.4 ± 2.5	0.20
	3rd follow up	MDQ	5.5 ± 3.1	5.3 ± 2.1	0.86

Table 4.20 shows the mean appetite score of respondents before and after intervention in terms of the MDQ (Appendix G). Both groups show a decrease in their mean scores from baseline to the third follow-up. At baseline, there was no statistically significant difference in the mean appetite score of respondents in the complex and similimum groups (p=0.84). After the intervention, respondents mean appetite score at first follow-up (p=0.98), second follow-up (p=0.20) and third follow-up (p=0.86) did not show any difference. Therefore, the null hypothesis is rejected. The paired t-test was used to compare the mean appetite change score values in the complex and the similimum groups.

4.12 ALLOPATHIC PAIN MEDICATION ANALYSIS

The mean painkillers (Appendix L) used by the participants in the different groups are shown in Figure 4.4. In the complex group the mean painkillers used at baseline by the participants was 3.3, and 0.7 at first follow-up, 1.0 at second follow-up and 0.9 at third follow-up. While in the similimum group, the mean painkillers used at baseline by the participants was 2.3, and 0.8 at first follow-up, 0.9 at second follow-up and 0.6 at third follow-up.

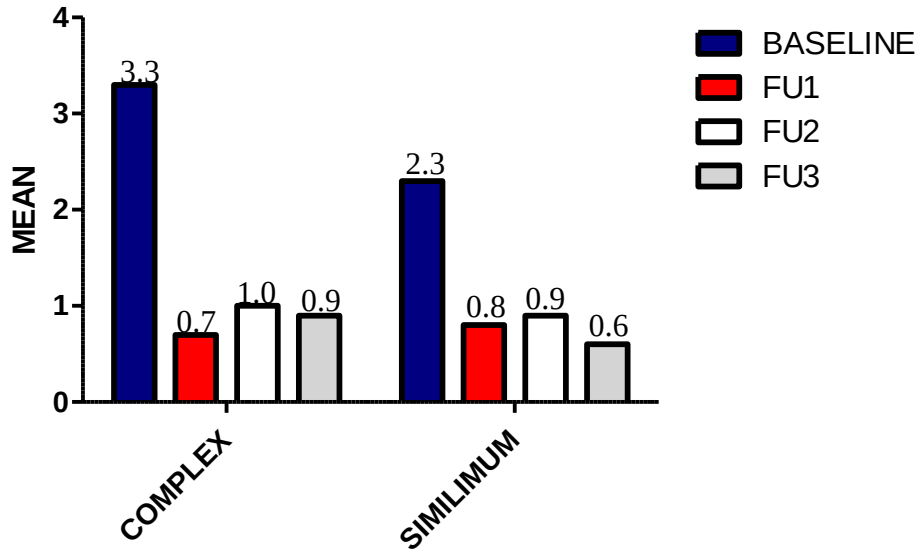

Figure 4.4: Graphical representation of the participants' use of allopathic pain medication in the complex and similimum groups

As can be seen from Figure 4.4, both complex and similimum groups demonstrated a reduction in allopathic pain medication use across the trial. This was mainly seen in the change from baseline to first follow-up.

4.13 HOMOEOPATHIC REMEDIES PRESCRIBED

4.13.1 Total homoeopathic remedies prescribed

Homoeopathic remedies were prescribed for both the homoeopathic complex (but not dispensed) and the similimum groups; as this was a double-blinded study and the homoeopathic case histories for all the participants (Appendix F) were taken the same. These remedies were prescribed at the baseline, the first and second consultations for each participant; therefore there were three remedies prescribed per participant in both groups.

Table 4.21: Frequency of remedies prescribed throughout the study

Arsenicum album	5
Bryonia alba	5
Calcarea carbonica	4
Matricarea chamomilla	6
Cimicifuga racemosa	3
Colocynthis	2

Conium maculatum	2
Cyclamen europaeum	2
Elaps corallinus	3
Kali carbonicum	3
Lachesis mutas	1
Lilium tigrinum	2
Magnesia muriatica	2
Natrum muriaticum	4
Nux moschata	2
Nux vomica	8
Phosphorus	3
Pulsatilla pratensis	8
Sepia officinalis	13

Table 4.21 reveals that the six most prescribed remedies in the study were *Sepia officinalis, Nux vomica, Pulsatilla pratensis, Matricaria chamomilla, Bryonia alba* and *Arsenicum album.*

4.13.2 Remedies prescribed in the complex group

Table 4.22: Remedies prescribed in the complex group

Arsenicum album	2
Bryonia alba	5
Calcarea carbonica	1
Matricarea chamomilla	3
Cimicifuga racemosa	3
Colocynthis	1
Conium maculatum	2
Cyclamen europaeum	2
Elaps corallinus	3
Kali carbonicum	3
Lachesis mutas	1
Lilium tigrinum	2
Natrum muriaticum	1
Nux moschata	2
Nux vomica	5
Pulsatilla pratensis	6
Sepia officinalis	12

Table 4.22 reveals that the four most common remedies found in repertorisation but not dispensed in the complex group were *Sepia officinalis, Pulsatilla pratensis, Nux vomica, Bryonia alba.*

4.13.3 Remedies prescribed in the similimum group

Table 4.23: Remedies prescribed in the similimum group

Arsenicum album	3
Calcarea carbonica	3
Matricarea chamomilla	3
Colocynthis	1
Magnesia muriatica	2
Natrum muriaticum	3
Nux vomica	3
Phosphorus	3
Pulsatilla pratensis	2
Sepia officinalis	1

Table 4.23 reveals that the most common remedies found in Repertorisation and dispensed in the similimum group were *Arsenicum alsbum, Calcarea carbonica, Matricaria chamomilla,Natrum muriaticum and Nux vomica.*

CHAPTER 5 : DISCUSSION

The use of homoeopathic remedies as a means of treatment for ailments helps to activate the patient's own ability for self-healing by activation of regulatory systems in the body (Richberg 1997: 12; Koehler 1989: 16). This study was designed to evaluate the efficacy of two methods of treatment commonly used in homoeopathy, namely, the complex (generalised) and the similimum (tailored to the patient's need, i.e. individualised). This study employed the use of two measurement tools (MDQ and PRS) (Appendices G and H) to assess pain experienced during the menstrual period in participants, as this is the main complaint with the condition (primary dysmenorrhoea) (Steward and Deb 2014: 296-302), while the associated symptoms were measured using only the MDQ scale (Appendix G).

A quantitative double-blind randomised control study was conducted and 37 potential participants were assessed for elligibily of which seven were excluded. Four were diagnosed with polycystic ovarian syndrome, one was diagnosed with fibroid and two declined to continue the study after the transabdominal ultrasound examination (Appendix J). The remaining participants (n=30) were randomised and allocated into two groups; namely the experimental group (homoeopathic complex) which had 20 participants who received the homoeopathic complex remedy and those in the control goup (the similimum group) which had 10 received the homoeopathic similimum. Throughout the study, four participants were lost to follow-up (two in each group). This resulted at the end in having 18 cases analysed in the complex group versus eight cases in the similimum group (Figure 4.1).

Table 4.1, Figures 4.1 and 4.2 showed the demographic data of the participants who took part in the study. The mean ages of participants during the study were 20.4 for the complex group and 20.3 for the similimum group. The majority of the participants, 13 (72.2%) and 7 (87.5%), in the complex and similimum groups, respectively, were in the 18 year to 21 year age group. Many research articles which mention the prevalence and severity of primary dysmenorrhoea focus on the fact that age plays a

role. Steward and Deb (2014), Lindeque (2015: 6-9), and Hailemeskel, Demissie and Assefa (2016: 489-496), state that primary dysmenorrhoea is predominantly found in adolescence and in the 20s, as it increases at approximately 17 years of age and then decreases with advancing age. The participants' age during the study showed no statistically significant difference between the complex and the similimum group. This result may be due to the small sample size.

The mean age at menarche in the study group was 13.8. Early age at menarche, within the 11 year to 13 year age group is a common presentation, as well as a risk factor, for primary dysmenorrhoea (Davis and de Costa 2011: 36-37). In this study, the participants' age at menarche showed no statistically significant difference between the complex group and the similimum group, leading to the conclusion that the age at menarche was not strongly associated with primary dysmenorrhoea. This may be due to the fact that most of the participants in the complex group, 10 (55.5%), and half of those in the similimum group, 4 (40%), had their menarche after the age of 13. This finding correlated with the result reported by Hailemeskel, Demissie, and Assefa (2016: 489-496) which revealed that 82.6% of the participants in their study also had their menarche after 13 years and that age at menarche younger than 13 years was not significantly associated with primary dysmenorrhoea.

The BMI at baseline revealed that the majority of the participants that took part in this study were within the normal range of weight in both groups. The mean BMI in the complex group was 24.1, while in the similimum group it was 23.5. The difference in the mean BMI between the two groups was not significant, therefore it was not considered to be a factor for primary dysmenorrhoea in this study, although higher BMI, i.e. being overweight and/or lower BMI, i.e. being underweight are commonly reported as of significance in primary dysmenorrhoea in various research studies (Lindeque 2015: 6-9; Hailemeskel, Demissie and Assefa 2016: 489-496).

Tables 4.2 and 4.3 show the intra-group analysis of the mean pain score recorded in terms of the MDQ (Appendix G) and PRS (Appendix H) respectively. In the complex group, the intra-group analysis did not show any significant difference when comparing the baseline and the FU1 ($p=0.20$), the baseline and the FU2 ($p=0.07$),

baseline and FU3 (p=0.20), FU1 and FU2 (p=0.39), FU! And FU3 (p=0.86) and FU2 and FU3 (p=0.54) when using the MDQ (Appendic G). There was a significant difference in the mean pain score when the level at the second follow-up was compared to the baseline level in the similimum group (p=0.02). In addition, the intra-group analysis in the similimum group showed a significant difference between the levels at first follow-up and second follow up (p=0.04), just as the second follow-up and the third follow-up also showed differences when compared (0.02) when using the MDQ (Appendix G). From the results obtained with the MDQ (Appendix G), the similimum was effective in treating the pain of the respondents in this study. In the complex and similimum groups, the intra-group analysis using the PRS (Appendix H) showed a significant difference in this score when the levels at the first, second and third follow-up were compared with the baseline, which contradicted the results observed in the MDQ scale (Appendix G). This may be due to the difference in sensitivity between the tests, as the PRS (Appendix H) is a simple test that does not necessitate a high degree of understanding or literacy from the patient (Echternach 1996; Wood 2004; Graham 2009).

The inter-group analysis of the mean pain score of the respondents in the complex and similimum groups using the MDQ (Appendix G) and PRS (Appendix H) measurement scales is shown in Table 4.4. There was no statistically significant difference in the inter-group analysis of the mean pain score in the complex group versus the similimum group, before treatment (p=0.55) with the MDQ (Appendix G) and PRS (Appendix H) (p=0.09). The same was observed after intervention at the first, second and third follow-up (p=0.74, p=0.15 and p=0.76 respectively) with MDQ (Appendix G) and (p=0.76, 0.75 and 0.72 respectively) with thr PRS (Appendix H). Despite the lack of significant statistical significance a decrease in this score was observed in the complex group from the baseline to the second follow-up and a slight increase was observed in the third follow-up. A similar trend was observed in the similimum group in terms of the MDQ (Appendix G). While the similimum group showed a consistent decrease throughout (from baseline to third follow-up), the complex group only showed this decrease from the baseline to the second follow-up in terms of the PRS (Appendix H). The results obtained using both measurement tools showed that treatment using the complex and similimum remedies may help

relieve primary dysmenorrhoea since the mean pain score decreased from baseline to the third follow-up, though not statistically significantly. If there were more research participants in each group, statistical results could have potentially shown a significant difference.

The mean concentration score of respondents in the complex and similimum groups showed no statistically significant difference in both the intra-group and inter-group analyses for all the follow-up consultations as shown in Tables 4.5 and 4.6. These were the values observed in the intra-group analysis in the complex and the similimum groups, when comparing the baseline to the first follow-up (p=0.17) and (p=0.57) respectively; to the second follow-up (p=0.12) and (p=0.28) respectively and to the third follow-up (0.51) and (p=0.31) repsectively. The same same lack of significant statistical difference was noted when the comparison was done between the first and the second follow-ups (p=0.90) and (p=0.43) respectively; and with the third follow-up (p=0.18) and (p=0.55) respectively; as well as between the second and the third follow-ups (p=0.27) and (p=0.57). Although a slight decrease in the mean concentration score was observed in the complex group (from the baseline to the FU1) and similimum group (from baseline to FU2). These indicated that both treatments had a minor impact on concentration (insomnia, forgetfulness, confusion, lowered judgement, difficulty concentrating, distractibility and accident-prone) of the respondents even though, it was not consistent throughout the study and showed no statistical significance.

Table 4.8 showed the inter-group analysis for the mean behavioural change score in the complex and similimum groups. These analyses indicated no statistically significant difference before intervention (p=0.91) and after intervention in the first (p=0.45), the second (p=0.78) and third (p=0.95) follow-up consultations. Both treatments showed a slight effect on the mean behavioural change score, which decreased in both groups from the baseline to the second follow-up. Table 4.7 showed the intra-group analysis, which also displayed no significant difference in all follow-ups for the similimum group when the comparison was made between the baseline and the first (p=0.20), the second (p=0.07) and the third (p=0.20) follow-ups. The same was noted when the first follow-up was compared to the second

(p=0.27) and the third (p=0.77) follow-ups; as well as beween the second and third follow-ups (p=0.28). Although in the complex group a statistically significant difference was seen when the second follow-up was compared to the third follow-up (p=0.04), this was not the case when the comparison was made between the baseline and the first (p=0.13), the second (p=0.09) and the third (p=0.08) follow-ups; neither when the first follow-up was compared the second (p=0.1) and third follow-up (p=0.56); nor when the. That one statistical significant difference found in the complex group promising and could mean that the complex may be effective to treat behavioural changes associated with primary dysmenorrhoea over a period of time. Both methods of treatment have shown an almost equal effect on behavioural changes associated with primary dysmenorrhoea (accident-prone, lowered motor coordination, lowered school or work performance, take naps or stay in bed, stay at home, avoid social activities and decreased efficiency) by decreasing the mean scores during few follow-ups. These results, however, were not sufficient to be statistically significant in the similimum group and showed only one statistically significant difference in the complex group.

In this study, the inter-group analysis for the mean autonomic response score (Table 4.10) did not show any statistically significant difference before intervention (p=0.50); after intervention in the first (p=0.06), second (p=0.09) and third (p=0.14) follow-ups. Although from the observed scores during the different follow-ups it is evident that there was a slight reduction in the mean autonomic response score at first and second follow-ups in both groups. Both treatments had the same impact on the autonomic response (cold sweats, nausea, vomiting and hot flushes) and none was found to be statistically more effective than the other. The intra-group analysis seen in Table 4.9 showed only one statistically significant difference (p=0.04) in the similimum group only when the autonomic response score at baseline was compared to the second follow-up. And none of the other levels showed a statistical significant difference when the comparison was made between the baseline and the first (p=0.08), the third (p=0.23) and the third (p=0.23) follow-ups; neither when the first follow-up was compaired to the second (p=0.67) and the third (p=0.31) follow-ups; nor between the second and the third follow-ups (p=0.11). The presence of that one statistically significant result in the similimum group, showed that its impact was

slightly better than that of the homoeopathic complex, which showed no statistically significant difference in the complex group throughout the study when comparison was made between the baseline and the first (p=0.25), the second (p=0.09) and with the third (p=0.47) follow-ups. And the same was noted when the comparison was made between the first follow-up and the second (p=0.33) and the third follow-ups (p=0.67); as well as when the second and third (p=0.30) follow-ups were compared.

The mean water retention score of respondents in the complex and similimum groups (Tables 4.11 and 4.12) displayed no statistically significant difference in both inter-group and intra-group analyses for all follow-ups. In the inter-group analysis, it was noted that the mean water retention score berfore intervention had a p-value of (p=0.85); and after intervention at the first (p=0.60), second (p=0.40) and third (p=0.91) follow-ups were not statistically significant. The intra-group analysis showed the same trend in both the complex and the similimum groups, when the baseline was compared to the first (p=0.16) and (p=0.23) respectively, to the second (p=0.21) and p=0.08) respectively, and to the third follow-ups (p=0.28) and (p=0.23) respectively. The same lack of statistical significant difference is seen when the first follow-up is compared to the second (p=0.95) and (p=0.52) respectively; and to the third follow-ups (p=0.52) and (p=0.53) respectively; as well as when the second and third follow-ups are compared (p=0.51) and (p=0.83) respectively. A slight decrease in the mean water retention score was observed in both the complex and similimum groups. These indicated that both treatments had a very small impact on water retention (weight gained, skin disorders, painful breasts, and swelling) of the respondents even though, it was not consistent throughout the study and showed no statistical significance.

Table 4.13 shows the intra-group analysis for the mean negative affective score in the complex and the similimum groups. In the complex group, a statistically significant difference was noted when the baseline is compared to the first follow-up (p = 0.03), and the second follow-up (p = 0.01) as well as when the first follow-up was compared to the second follow-up (p = 0.02). There was no statistical significant difference when the baseline was compared to the third follow-up (p=0.38); neither when the first and third follow-ups were compared (p=0.93), nor when the second

and third follow-ups were compred (p=0.06). The similimum group did not show any statistically significant difference throughout the study. This finding was noted when looking at the comparison between the baseline and the first (p=0.63), the second (p=0.41) and third (p=0.06) follow-ups. This was also noted when the first follow-up was compared to second (p=0.77) and the third (p=0.18) follow-ups; as well as when the second and the third follow-ups (p=0.19). Although a consistent decrease in the mean negative affect score was noted in both groups, the inter-group analysis displayed in Table 4.14 did not show any statistically significant difference throughout the study when looking at the mean negative score before the intervention (p=0.85); and after the intervention in the first follow-up (p=0.93), second follow-up (p=0.49) and the third follow-up (p=0.43).

Tables 4.15 and 4.16 displaying the mean arousal score of respondents in the complex and similimum groups showed no significant difference in both inter-group and intra-group analyses through all the follow-ups. This result can be seen in the inter-group analysis before intervention (p=0.89); after intervention in the first (p=0.66), second (p=0.36) and third (p=0.72) follow-ups. The intra-group analysis also showed the same in both the complex and the similimum groups, when the baseline was compared to the first follow-up (p=0.61) and (p=0.64) respectively, to the second follow-up (p=0.53) and (p=061) the third follow-up.61) respectively, and to third follow-up (p=0.45) and (p=0.76) respectively. And when the first follow-up was compared to the second follow-up (p=0.97) and (p=0.85) respectively, and to the third follow-up (p=0.68) and (p=1.0) respectively; as well as when the second follow-up and the third follow-ups were compared (p=0.58) and (p=0.86) respectively. A slight decrease in the mean arousal score was observed in both groups, with the complex group showing a constant decrease throughout the study and similimum group only from the baseline until the second follow-up. These indicated that both treatments had an impact on the arousal (affectionate, orderliness, excitement, feeling of well-being and burst of energy, activity) of the respondents even though, it was not consistent throughout the study in the similimum group unlike in the complex group and showed no statistically significant difference.

Table 4.17 displays the intra-group analysis of the mean control score of the complex and similimum groups. The complex group showed statistically significant differences when the baseline was compared to the second follow-up (p=0.04), when the first follow-up was compared to the second (p=0.04), as well as when the second follow-up was compared to third follow-up (p=0.03). There was no significant difference when the baseline was compared with the first follow-up (p=0.6), and with the third follow-up (p=0.15). The same was noted when comparing the first and the third follow-up (p=0.17). There was no significant difference at all the various follow-ups in the similimum group, i.e when comparing the baseline to the first (p=1.00), the second (p=0.97) and the third follow-ups (p=1.00). This was also noted when the comparison was made between the first follow-up, to the second (p=0.92) and to the third follow-ups (p=0.100), as well as when comparing the second follow-up to the third follow-up (p=0.91) , This implied that the complex treatment was more effective than the similimum to improve the control (feeling of suffocation, chest pain, ringing in the ears, heart pounding, numbness, tingling, blind spots and fuzzy vision) of the participants. Although the inter-group analysis (Table 4.18) showed no statistically significant difference throughout the study, before treatment (p=0.29) and after treatment at the first (p=0.60), second (p=0.49) and thirsd follow-up (p=0.35), a greater decrease in the mean control score was observed in the complex group compared to the similimum group, and it extended from the baseline to the second follow-up. The score increased earlier in the similimum group, namely from the second follow-up to the third follow-up compared to the complex group, which showed the increase only in the third follow-up. This implied that both treatments had an impact on the control of the participants, but the complex showed it might be beneficial than the similimum for this particular aspect.

The intra-group analysis depicted in Table 4.19 revealed that the mean appetite score in the complex group did not show any statistically significant difference throughout the study; when the comparison was made between the baseline and the first follow-up (p=0.25), the second follow-up (p=0.22) and the third follow-up (p=0.45). No statistical significant difference was also noted when the comparison was made between the first follow-up and the second (p=0.93) as well as when compared with the third follow-up (p=0.90) and between the second follow-up and

the third (p=0.93). While the similimum group only showed one statistically significant difference when the baseline was compared to the second follow-up (p=0.02). The other comparisons did not show the same result when comparing the baseline and the first follow-up (p=0.39), and the third follow-up (p=0.12). Neither when first follow-up was compared to the second follow-up (p=0.48), first follow-up and second (0.90) nor when the second follow-up was compared to the third follow-up (p=0.11). This implied that the similimum treatment had a slight positive impact on appetite than the complex treatment, and this effect might have been greater with a higher potency. Table 4.20 displays the inter-group analysis which did not show any statistically significant difference from the baseline to all follow-ups when comparing this finding before intervention (p=0.84), affter intervention at the first follow-up (p=0.98), second follo-up (p=0.20), and the third follow-up (p=0.86), even though both groups showed a constant decrease in the mean appetite score.

The participants were allowed to take their usual allopathic pain medication during the study, due to the fact that women suffering with dysmenorrhoea experience severe pain with their menses (Stewart and Deb 2014: 296-302). Figure 4.4 shows the mean of the allopathic pain medication taken throughout the study. It is interesting to notice the constant decrease in the need for allopathic pain medication (Appendix L) in the complex and similimum groups throughout the study, with the main change visible from the baseline to the first follow-up.

Homoeopathic case histories for each participant in both the complex and the simillimum groups were taken (Appendix F). The symptoms recorded were analysed and repertorized, using the Radar computerized repertory (Radar, Version 9 – Archibel Belgium). The most suitable remedy, i.e similimum was chosen based on the totality of their symptoms. This was a double blind study, which required that the researcher conducted the homoeopathic case takings and prescriptions of remedy the same for all the participants; this .meant that the researcher prescribed the similimum to all the participants during the baseline to the second follow-up, but only the participants in the control group, i.e the similimum group received the homoeopathic similimum remedy while those in the experiment group, i.e the complex group received the homoeopathic complex remedy. The most common

remedies prescribed in this study as similimum were *Sepia officinalis, Nux vomica, Pulsatilla pratensis, Matricaria chamomilla, Bryonia alba* and *Arsenicum album*.

Sepia officinalis (cuttlefish ink)

Murphy (2006: 1765-1774) describes *Sepia officinalis* as a woman's remedy that mainly affects the reproductive organs. The majority of the symptoms occurring in the *Sepia officinalis* patient are related to the area of reproduction and female organs. This remedy is also well indicated for problems with the venous circulation, especially of the female pelvic organs and of the digestive tract, the portal venous system with venous congestion.

Female – Hormonal disorders, sexual disorders, amenorrhoea, dysmenorrhoea, menstrual and premenstrual syndromes. The menses is irregular, early and profuse, but can also be too late and scanty. Menstrual pains in women with scanty menses. There is dryness of the vagina and vulva after menses. The pelvic organs feel relaxed, with a weak uterus. There is a dragging or bearing-down sensation as if everything would escape through the vagina (Bell., Lil-T., Nat-c.) she must cross her limbs to prevent protrusion or press against her vulva. She complains of violent stitches upward in the vagina from the uterus to umbilicus. Griping, burning or stitching pains in the uterus. Sharp clutching pains. There may be mania from profuse menses, dullness causing numbness in the left ovary.

Mind – She feels mentally and physically worn-out. Depression related to pregnancy, menses or menopause. She is indifferent to those loved best. She is averse to occupation, to family, to husband, to company, is irritable and easily offended (Murphy 2006: 1765-1774; Vermeulen 2001: 871-878).

Pulsatilla pratensis **(**Wind flower)

This remedy is useful for the period from puberty to menopause, including menstruation, pregnancy, and the puerperium and breastfeeding. The mucous membranes are all affected; their discharges are profuse, bland, thick, and yellowish. There are haemorrhages that are passive, vicarious, with dark blood that easily coagulates. She may present with varicose veins and anaemia.

Female - *Pulsatilla pratensis* is indicated for dysmenorrhoea that begins in puberty. The menses is delayed at puberty, intermittent, irregular or suppressed. The blood is dark, thick, clotted, and changeable and flows more during the day while walking about. There is a pain, bearing down in nature, that is worse for lying. The mucus membranes are all affected. Menstrual cramps with chills and weeping. She may have epilepsy with absent or irregular menses. Never well since puberty. During menses and with uterine troubles, heavy, pressing pain in abdomen and small of back; as from a stone; limbs go to sleep; ineffectual urging to pass a stool.

Mind- She has changeable moods, is timid, irresolute and craves affection and sympathy. She has a tendency to be mild, emotional and tearful. Oversensitive to pain and consolation will improve all symptoms. She desires company, is capricious and weeps easily (Murphy 2006: 1596-1604; Vermeulen 2001: 796-804).

Nux vomica (Poison nut)

Nux vomica is the greatest of polychrest remedies because the bulk of its symptoms correspond in similarity with those of the commonest and most frequent of diseases. The typical Nux patient is rather thin, spare, quick, active, nervous, and irritable. This remedy is useful to those who lead a sedentary life doing much mental work, or to those who remain under stress and strain of prolonged office work, business cares and worries. The person needing it is hypersensitive, over-impressionable and has an irritable nervous system. There are digestive disturbances, portal congestion. She complains of nausea, vomiting.

Female – The menses is irregular, too early, and too long. The menstrual blood is black with fainting spells, it ceases flowing at night. Dysmenorrhoea with pain experienced in the sacrum and there is a constant urge to pass a stool. There is a strong desire to urinate and increased frequency, as well as burning in the vulva. Cramping in the uterine region causes her to double up and cry, she must stay in bed. Prolapse of the uterus from straining or lifting. The pain in the uterus feels as if it is bruised; she feels pressure towards the genitals in the morning. There are contraction and spasms in the uterus with the discharge of clots, and pressure on bladder and rectum. Cramping pains cause nausea and fainting, twisting, moving

about in abdomen, soreness across pubes, cramps in the bladder. She complains of soreness of the nipples, nausea in the morning during menses and may present with metrorrhagia with sensation as if the bowels wanted to move.

Mind – The person needing this remedy has an overactive mind, is very irritable and is sensitive to all impressions. She is ambitious and competitive. She cannot stand the pain, so mad, she cries. She wants to be quiet, desires repose and tranquillity. There is anger when consoled (Murphy 2006: 1403-1411; Vermeulen 2001: 709-717).

Bryonia alba (Wild hops)

Bryonia alba is one of the polychrest remedies of the homoeopathic materia medica. It acts on all serous membranes and the internal organs they contain causing inflammation and exudation. The general character of the pain experienced is stitching (sharp pain), tearing made worse by motion and better for rest. There is aversion to least motion, even to distant parts; this is due to its action on nerves and muscles. The pains are bursting, stitching or heavy, sore; going backward. It is recommended for disorders of circulation causing congestion, it alters the blood giving rise to bilious, rheumatic and remitted types of fever.

Female – There is complaining of menstrual irregularities with gastric symptoms. The menses is dark, foul, and may be too early, too profuse, and made worse from motion due to tearing pains in legs. The menses may also be suppressed with vicarious discharge or splitting headache. The mucous membranes are all dry which results in the discharges being scanty and adherent. Stitching pains in the ovaries on taking a deep inspiration; very sensitive to touch. She complains of inter-menstrual pain with a great abdominal and pelvic soreness. Pain in the right ovary as if torn, extending to thigh.

Mind – The person needing this remedy is easily angered, with biliousness, headache, and dyspepsia and is exceedingly irritable especially during menses. She suffers from effects of anger, fright, chagrin or pain. She is capricious, very hard to please and desires for things that are rejected when offered. There is weeping mood, with a headache and other complaints. There is an aversion to being disturbed,

wanting to be left alone and wanting to go home (Murphy 2006: 371-377 and Vermeulen 2001: 190-197).

Arsenicum album (Arsenic trioxide)

This is profoundly acting remedy on every organ and tissue. *Arsenicum album* is recommended for debilitating conditions presenting with great exhaustion that is aggravated by exertion, and restlessness that are worse at night. It is characterised by irritable weakness, burning pains, and unquenchable thirst. The pains are maddening, burning like fire and may feel like hot needles or wires; they are better for heat. The haemorrhages are black, offensive. She complains of weakness, low vitality, emaciation, and gradual loss of weight.

Female – The menses is too profuse and too soon. There is burning in the ovarian region. Pain experienced feels as if from red hot wires that are worse from least exertion. The menses is suppressed in weak, tired, careworn women. She complains of stitching in the rectum during menses. The menorrhagia presents with black blood, and there may be dark haemorrhages between menses. There is stitching and or pressing pain in the pelvis, especially the right ovary; this pain extends down the thigh which feels numb and lame, and it is worse for motion or bending. There may be lancinations from the abdomen into the vagina. The pain of dysmenorrhoea is better for heat.

Mind – The person needing this remedy is extremely nervous and anxious. There is anxiety about the future and health. She has deep insecurities and fears, including fears of death, disease, suffocation, starvation, financial loss and poverty. She desires company, and fears to be left alone. She is restless and changes places continually. She may suffer from obsessive compulsive disorder and cannot stand disorder, dirt, and germs. She is obsessed with order and tidiness (Murphy 2006: 226-235; Vermeulen 2001: 115-122).

The homoeopathic complex used in this study was made of five remedies, namely *Angelica sinensis, Dioscorea villosa, Matricaria chamomilla, Viburnum opulus* and *Zingiber officinalis* in a 6cH potency. These remedies were chosen for their effect on

the female reproductive organs, menstrual cycle and the mind symptoms accompanying the menses.

Angelica sinensis (Donq quai)
This remedy has an affinity for the female genital organs and stimulates the uterine muscles. It is well indicated for female hormonal imbalances.

Female – She experiences pain and congestion in the left ovary; and complains of a uncomortable feeling during menses with vomiting and frequent stools. The person needing this remedy may present with premenstrual syndrome with congested breasts, premenstrual swelling, and heavy legs. The menses is scanty and there are pain and congestion in the left ovary.

Mind – She alternates between a state of euphoria and that of indifference. There is a general restlessness with a lack of courage. She has difficulty concentrating (Murphy 2006: 158-160).

Dioscorea villosa (Wild yam)
This remedy is well indicated for dysmenorrhoea presenting with menstrual cramps and neuralgia, and for painful disorders of abdominal or pelvic organs. The pains are colicky in nature and are better from bending backward.

Female – She experiences violent pain with the dysmenorrhoea, with pains radiating from the uterus. There may be spasmodic uterine colic with pains moving to distant parts. She complains of cramps in fingers and toes alternating with uterine pains.

Mind – She is cross, nervous and easily troubled. She is aggravated by conversations, fears crowd and people. There is restlessness that is better for walking. She may feel tired, yet still keeps walking around the room (Murphy 2006: 708-712).

Matricaria chamomilla (Chamomile)
It is interesting to note that *Matricaria chamomilla* is the only ingredient from this study's homoeopathic complex that has been commonly prescribed as a similimum.

Matricaria chamomilla has affinities for the mind, nerves, emotions, mucous membrane and sexual organs. It is well indicated when menstruation is disordered, and the discharged blood is dark and clotted. The severity of the menstrual cramps makes her irritable.

Female – There is menstrual cramps with a lot of pain and irritability. She complains of irregular labour-like pains, going up and down the inner thighs, with the profuse discharge of clotted, dark blood. There may be menorrhagia with black clots, profuse coldness of limbs and much thirst. This is a remedy for membranous dysmenorrhoea at puberty and menstrual pain from anger or emotions.

Mind – The person needing this remedy is highly emotional, temperamental and oversensitive. Her senses are too acute. She is sensitive to every type of pain; she cannot bear it and is always complaining. She is averse to talking and cannot bear anyone near her (Murphy 2006: 512-516).

Viburnum opulus (Cramp bark)

This is a remedy that is useful for painful spasmodic conditions like dysmenorrhoea. It is also well indicated for general cramps and colicky pains in the pelvic organs. She is conscious of internal sexual organs.

Female – There are violent, spasmodic, nervous effects dependent upon the ovarian or uterine origin. She complains of a heavy aching feeling or excruciating cramps in the pelvis that is better from menses. She experiences bearing-down pains before menses. The menses is too late, scanty, lasting a few hours; it is offensive in odour with cramping pains that extends down the thighs. She may have spasmodic and membranous dysmenorrhoea. The ovarian region feels heavy and congested and there is uterine haemorrhage.

Mind – The pains make her very nervous and she cannot keep still. She is nervous and irritable (Murphy 2006: 2031-2033).

Zingiber officinalis (Ginger)

This remedy is particularly useful for states of debility in the digestive tract, sexual system, and respiratory troubles. It is also indicated for menstrual cramps.

Female – She experiences painful cramps during her menses. The menstruation is too early, too profuse with dark blood and clots.

Mind – She is forgetful and has a weak memory. She is irritable and chilly in the evening and during menses. She is cheerful, good-humoured and has a pleasing sensation in her system (Murphy 2006: 2076-2077).

CHAPTER 6 : CONCLUSION AND RECOMMENDATIONS

This study aimed to introduce the homoeopathic complex made up of the combination of five remedies, namely *Angelica sinensis, Dioscorea villosa, Matricaria chamomilla, Viburnum opulus* and *Zingiber officinalis* all in a 6cH potency as a readily accessible treatment for primary dysmenorrhoea and its associated symptoms. It also aimed at establishing its efficacy by comparison to a homoeopathic similimum in the 30cH plussed potency.

6.1 CONCLUSION

The intra-group analyses results demonstrated that both the homoeopathic complex and the homoeopathic similimum had varied degrees of effect on the participants' pain, with the similimum showing statistically significants results with both measurement tools; while the complex demonstrated those results only with the PRS (British pain society 2006) (Appendix H) These analyses further showed statistically significant results for the behaviour change, negative affect, and control for the homoeopathic complex; while the homoeopathic similimum showed positive results for the autonomic response and the appetite change of the participants when looking at their reduced mean scores and the statistically significant differences that were seen throughout the study for some follow-up consults.The lack of constant statistical significant differences from the baseline to the third follow-up could be due to the need for a better suited simillimum remedy to the totality of symptoms with a higher potency for those in the control group, i.e the similimum group; or a different complex remedy for those in the experimental group. The small sample size could have affected the results, as a bigger group could have shown more statistical significant differnces.

6.1.1 First objective

The first objective was to determine the efficacy of the homoeopathic complex in the treatment of primary dysmenorrhoea symptoms, in terms of the participants' perceptions.

The results of the intra-groups analyses concluded that both the homoeopathic complex and homoeopathic similimum were statistically effective in reducing the pain of primary dysmenorrhoea when using the PRS (British pain society 2006) (Appendix H), while the similimum group showed greater improvement with both measurement scales, i.e. MDQ (Moos 1968) (AppendixG) and PRS (British pain society 2006) (Appendix H). In addition, there was a decrease in the need for allopathic pain medication throughout the study. The intra-group analyses also showed that the homoeopathic complex effectively ameliorated the behavioural change, negative affect and the control of the participants; as it showed more statistically significant differences than the homoeopathic similimum in these instances. On the other hand, the homoeopathic similimum had a greater effect on pain, concentration, autonomic response, and appetite; as it showed more statistically significant differences than the homoeopathic complex for this specific subgroup of symptoms. The first and second hypotheses were therefore rejected alternatively since both treatments were effective in treating the above symptoms of primary dysmenorrhoea.

6.1.2 Second objective

The second objective was to compare the effectiveness of the homoeopathic complex against that of a homoeopathic similimum in the treatment of the primary dysmenorrhoea symptoms, in terms of the participants' perceptions.

Although the inter-group analyses failed to show any statistically, significant difference between the two treatments approaches; an overall decrease in the mean scores of the majority of the subgroups of symptoms found within the MDQ (Moos 1968) (Appendix G) was observed within the individual groups during the study. Therefore, there was no evidence that one treatment was more effective than the

other in the treatment of primary dysmenorrhoea. Therefore, the third hypothesis has been accepted.

6.2 LIMITATIONS OF THE STUDY

- The participants' compliance during the study was crucial; as the study extended over a period of three menstrual cycles per participant. The researcher relied heavily on them to be able to recall their symptoms while taking the homoeopathic case history; as well as when filling in the questionnaires. It was assumed that they followed the instructions with regards to taking their respective prescriptions. Non-adherence to these instructions could have affected the results of the study.

- The flexibility in accessing the rooms at the Homoeopathic Day Clinic. The majority of the participants were students at the Durban University of Technology with busy lectures' schedules that only allowed them to come for the follow-ups at times were the clinic was closed (i.e. early morning before 8h00, during the lunch break at 12h00 and/or near closing time or after 16h00 in the afternoon).

- Due to the length of the study, a few participants failed to remember their third and final follow-up consultations, as their menstrual cycles happened during the holidays while they were away from Durban. The researcher gave them journals and copies of the two questionnaires to fill in.

- The sample size of the study was small and the study may have produced better data from a larger sample group with greater statistical significant results. This is the reason why the researcher tried to achieve and maintain the minimum required participant number (30) by recruiting more participants (37) at the beginning of the study began. This resulted in the use of two different qualified gynaecologists as the screening process took longer than expected and the first gynaecologist could no longer commit to the study.

- The uncertainty of the impact of the allopathic pain medication taken by the participants on their symptoms, as this could have influenced the final outcome of the homoeopathic complex and homoeopathic similimum

treatments. The compliance of the participants in informing the researcher about it for record keeping.

- The researcher's relative inexperience (due to still being a student) in taking the homoeopathic case history may have affected the choice and prescription of the correct similimum. This limited knowledge could have also affected the choice of better acting remedies to make up the homoeopathic complex. Both these variables could have impacted the overall results.

6.3 BENEFITS OF THE STUDY

- The participants benefitted from this study. Most of them reported experiencing a decrease in the severity of their clinical symptoms of primary dysmenorrhoea and associated complaints.
- The transabdominal ultrasound performed by the qualified gynaecologists helped reassure the participants, as they all received a diagnosis and were able to gain knowledge on the causes of their menstrual ailments (i.e. primary or secondary dysmenorrhoea).
- The participants acquired knowledge about homoeopathy as an alternative treatment for primary dysmenorrhoea.

6.4 RECOMMENDATIONS

These recommendations are made for future research studies:

- The study should be conducted using a larger sample group to increase the power of the statistical interpretation of results.
- The flexibility in the potency prescribed to adapt to the physical and/or emotional need of the participants, for both the similimum and the complex. As most participants reported that their treatments worked but it needed to be stronger as it seemed to stop their effect around the second follow-up consultations.

- A different complex that may include the remedies that were commonly prescribed during this study.
- The use of daily journals to record the symptoms and changes happening during the menstrual cycle and the menstrual flow; as the participants met the researcher once a month, a week after their menses. This will also help with recalling the symptoms while completing the questionnaires and with participant compliance.
- Modifying the PRS (Appendix H) to include the recording of the allopathic pain medication.

REFERENCES

Adegbite, O. A., Omolaso, B., Seriki, S. A. and Akpabio, N. 2016. Prevalence of dysmenorrhea and menstrual bleeding in relation to packed cell volume among female students of Bingham University. *International invention journal of medicine and medical sciences*, 3(2): 21-31.

Alsiyabi, A. Z. S., Mullaicharam, A. R. and Halligudi, N. 2016. A review on evaluation, management and pathophysiology of dysmenorrhea. *World journal of pharmaceutical research*, 5(5): 241-259.

Beckmann, C. R. B., Ling, F. W., Barzansky, B. M., Herbert, W. N. P., Laube, D. W. and Smith, R. P. 2010. *Obstetrics and gynecology*. 6th edition. Baltimore, MD: Lippincott Williams and Wilkins.

Benyunes, S. 2005. *German homoeopathic pharmacopoeia supplement 2005*. London: Medpharm Scientific Publishers.

Berek, J. S. 2007*. Berek and Novak's gynecology*. 14th ed. Philadelphia: Lippincott Williams and Wilkins.

Beshay, V. E and Carr, B. R. 2013. *Hypothalamic-pituitary-ovarian axis and control of the menstrual cycle*. New York: Springer.

Bhatia, M. 2009a. *ABC of homeopathy. Homeopathy principles* (online), Available: http://hpathy.com/abc-homeopathy/homeopathy-principles/ (Accessed 18 April 2017).

Bhatia, M. 2009b. *Homeopathic potency selection* (online), Available: http://hpathy.com/organon-philosophy/homeopathic-potency-selection/ (Accessed 30 October 2016).

Bhatia, M. 2009c. *Homeopathic case taking* (online). Available: https://hpathy.com/organon-philosophy/case-taking/ (Accessed 14 March 2018).

Bloch, R. and Lewis, B. 2003. *Homoeopathy for the home*. Cape Town: Struik Publishers.

British Pain Society. 2006. *Pain Rating Scale* (online). Available: www.britishpainsociety.org (Accessed 25 July 2012).

Calis, K.A. 2016. *Dysmenorrhoea* (online). Available: http://emedicine.medscape.com/article/253812-overview -2011-03-08 (Accessed 13 November 2016).

Carey, M. S. and Allen, R. H. 2012. Non-contraceptive uses and benefits of combined oral contraception. *The obstetrician and gynaecologist*, 14(4): 223-228.

Chauhan, V. K. and Gupta, M. 2007. *Homeopathic principles and practice of medicine: a textbook for medical students and homeopathic practitioners.* New Delhi: B. Jain Publishers.

Christie, L. 2005. A qualitative study on the effect of the homoeopathic similimum in the treatment of primary dysmenorrhoea (online). M.Tech, University of Johannesburg. Available: https://ujdigispace.uj.ac.za/handle/10210/4598 (Accessed 5 June 2012).

Cook, T. M. 1989. *Homoeopathic medicine today*. New Canaan, CT: Keats Publishing, Inc.

Cowperthwaite, A. C. 2001. *A textbook of gynaecology*. New Delhi: B. Jain Publishers.

Cunha, J. P. and Anand, B. 2016. Gastrointestinal bleeding (online). Available: http://www.emedicinehealth.com/gastrointestinal_bleeding/article_em.htm **(**Accessed: 21 February 2017).

Daley, A. J. 2008. Exercise and primary dysmenorrhoea: a comprehensive and critical review of the literature. *Sports medicine,* 38(8): 659-670.

Davis, N and de Costa, C. 2011. Primary dysmenorrhoea. *O & g magazine (online)*, 13(1): 36-37. Available: https://www.ranzcog.edu.au/RANZCOG_SITE/media/DOCMAN-ARCHIVE/OG-Dysmenorrhoea_Davis_deCosta_Autumn_2011.pdf (Accessed 23 July 2016).

Davis, A. R., Kroll, R., Soltes, B., Zhang, N., Grubb, G. S. and Constantine, G. D. 2008. Occurrence of menses or pregnancy after cessation of a continuous oral contraceptive. *Fertility and sterility*, 89(5): 1059-1063.

Dawood, Y. 2008. Dysmenorrhea. *Global library of women's medicine* (online), Available: DOI 10.3843/GLOWM.10009.

Deb, S. and Raine-Fenning, N. 2008. Dysmenorrhoea. *Obstetrics, gynaecology and reproductive medicine*, 18(11): 294-299.

DeCherney, A. H., Goodwin, T.M., Nathan, L. and Laufer, N. 2007. *Current diagnosis and treatment: obstetrics and gynecology*. 10th ed. New York: McGraw-Hill.

De Sanctis, V., Soliman, A. T., Elsedfy, H., Soliman, N.A., Elalaily, R. and El Kholy, M. 2016. Dysmenorrhea in adolescents and young adults: A review in different countries. *Acta bio-medica*, 87(3): 233-246.

Dmitrovic, R., Kunselman, A. and Legro, R. S. 2012. Continuous compared with cyclic oral contraceptives for the treatment of primary dysmenorrhoea: a randomized controlled trial. *Obstetrics & gynecology*, 119(6): 1143-1150.

Dorland's Medical Dictionary for Health Consumers. 2007. Vasopressin (online). Available: http://medical-dictionary.thefreedictionary.com/vasopressin (Accessed: 26 February 2017).

Echternach, J. L. 1996. *Management of the individual with pain: Parts 1 and 2.* (online), Available: http://learningcenter.apta.org/shared/assetDownload.aspx?id=29 (Accessed 10 June 2015).

Ferreira-Valente, M. A, Pais-Ribeiro, J. L and Jensen, M. P. 2011. *Validity of four pain intensity rating scales* (online) 152(10): 2399-2404. Available: http://www.ncbi.nlm.nih.gov/pubmed/21856077 (Accessed: 16 August 2015).

Gibson, D. 1987. *Studies of homoeopathic remedies*. Beaconsfield, Buks: Beaconsfield Publishers.

Graham, R. B. 2009. *The purpose of pain scales: these easy-to-use tools offer valuable insight into the experience of pain* (online). Available: http://www.intelihealth.com/IH/ihtIH/WSIHW000/29721/32087.html-2009-03-23 (Accessed: 29 February 2012).

Gupta,R., Kaur, S. and Singh, A. 2013. Comparison to assess the effectiveness of active exercises and dietary ginger versus active exercises on primary dysmenorrhoea among adolescent girls. *Nursing and midwifery research* (Online), 9: (4): 168-177.

Hacker, N. F., Gambone, J. C. and Hobel, C. J. 2010. *Hackers and Moore's essentials of obstetrics and gynecology*. 5th edition. Philadelphia: Saunders Elsevier.

Hailemeskel, S., Demissie, A. and Assefa, N. 2016. Primary dysmenorrhea magnitude, associated risk factors, and its effect on academic performance: evidence from female university students in Ethiopia. *International journal of women's health*, 8:489-496.

Homoeopathyplus. 2014a. The vital force (online). Available: http://homeopathyplus.com/tutorial-7-the-vital-force/ (Accessed 27 September 2016)

Homoeopathyplus. 2014b. *Provings* (online). Available: http://homeopathyplus.com/tutorial-6-provings/ (Accessed 27 September 2016)

Hpathy. 2009. *Preparation of drugs and homeopathic scales of dilution* (online), Available: http://hpathy.com/pharmacology/preparation-of-drugs-homeopathic-scales-of-dilution/ (Accessed 18 April 2017).

Human Chorionic Gonadotropin. Merriam-Webster.com. 2017. Available: https://www.merriam-webster.com/dictionary/human chorionic gonadotropin. (Accessed: 26 February 2017).

Hymen. 2017. *Merriam-Webster.com* (online), Available: https://www.merriam-webster.com/dictionary/hymen#medicalDictionary (Accessed 12 Mar. 2017).

Iacovides, S., Avidon, I. and Baker, F. C. 2015. What we know about primary dysmenorrhea today: a critical review. *Human Reproduction,* 21(6): 762-768.

Jana, B. 2002. *Textbook of gynaecology and obstetrics*. New Delhi: B. Jain Publishers.

Jenabi, E. 2013. The effect of ginger for relieving of primary dysmenorrhoea. *Journal of Pakistan medical association,* 63 (1): 8-10.

Jouanny, J. Demarque, D. Poitevin, B. Saint-Jean, Y. 1997. *Pharmacology and homoeopathic materia medica*. Lyon: Boiron-C.E.D.H.

Ju, H., Jones, M. and Mishra, G. 2014. The prevalence and risk factors of dysmenorrhoea. *Epidemiology reviews,* 36: 104-13.

Jurkovic, D. Valentin, L. and Vyas, S. 2009. *Gynaecological ultrasound in clinical practice: Ultrasound imaging in the management of gynaecological conditions*. London: Royal college of obstetricians and gynaecologists.

Khan, K. S., Champaneria, R. and Latthe, P. M. 2012. How effective are non-drug, non-surgical treatments for primary dysmenorrhoea? *BMJ* (clinical research edition) 344: e3011.

Kashani, L., Mohammadi, M., Heidari, M. and Akhondzadeh, S. 2015. Herbal medicine in the treatment of primary dysmenorrhea. *Journal of medicinal plants*, 14 (53):1-5.

Kayne, S. 2006. *Homoeopathic pharmacy theory and practice*. 2nd ed. Edinburgh: Elsevier Churchill Livingstone.

Koehler, G. 1989. *The handbook of homoeopathy: its principles and practice*. Rochester, VT: Healing Arts Press.

Laerd statistics. 2013a. *One–way ANOVA in SPSS statistics* (online), Available: https://statistics.laerd.com/spss-tutorials/one-way-anova-using-spss-statistics.php (Accessed 11 March 2017).

Laerd statistics. 2013b. Kruskal Wallis h test using SPSS statistics (online), Available: https://statistics.laerd.com/spss-tutorials/kruskal-wallis-h-test-using-spss-statistics.php (Accessed 11 March 2018).

Laerd statistics. 2013c. Dependent t-test for paired samples (online), Available: https://statistics.laerd.com/statistical-guides/dependent-t-test-statistical-guide.php (Accessed 11 March 2018).

Lindeque, B. G. 2015. Dysmenorrhoea. *South African family practice*, 57(2): 6-9.

Low Dog, T. 2014. Menstrual cramps (online). Available: http://foundationsinherbalmedicine.com/assets/pdf_files/FIHM_online_docs/fihm_part_3/fihm_13_womens_health_1/Handouts/LowDog_MenstrualCramps_Chapter.pdf (Accessed: 29 November 2017).

Magowan, B., Owen, P. and Drife, J. 2009. *Clinical obstetrics and gynecology*. 2nd ed. Edinburgh: Elsevier

McCracken, K. 2016. Gynecologic pain in adolescents. *Current treatment options in pediatrics,* 2(3): 143-155.

Mirabi, P., Alamolhoda, S. H. Esmaeilzadeh, S. and Mojab. F. 2014. Effect of medicinal herbs on primary dysmenorrhoea – A systematic review. Iran journal of pharmaceutical research, 13 (3): 757-767.

Medicine Net. 2016. Prostaglandin F2-alpha (online). Available: http://www.medicinenet.com/script/main/art.asp?articlekey=39804 (Accessed: 27 February 2017).

Merriam-Webster Dictionary. 2017a. Atresia (online). Available: https://www.merriam-webster.com/dictionary/atresia (Accessed 12 March 2017).

Merriam-Webster Dictionary. 2017b. Corpus Luteum (online). Available: https://www.merriam-webster.com/dictionary/corpus luteum. (Accessed 26 February 2017).

Merriam-Webster Dictionary. 2017c. Enzyme Immunoassay (online). Available: https://www.merriam-webster.com/medical/enzyme%20immunoassay (Accessed: 27 Mar. 2017).

Merriam-Webster Dictionary. 2017d. Estrogen (online). Available: https://www.merriam-webster.com/dictionary/estrogen. (Accessed: 26 February 2017).

Merriam-Webster Dictionary. 2017e. Fibroid (online). Available: https://www.merriam-webster.com/dictionary/fibroid (Accessed 26 February 2017).

Merriam-Webster Dictionary. 2017f. Follicle–stimulating Hormone (online). Available: https://www.merriam-webster.com/dictionary/follicle–stimulating hormone (Accessed: 27 February 2017).

Merriam-Webster Dictionary. 2017g. Gonadotropin–releasing Hormone (online). Available: https://www.merriam-webster.com/dictionary/gonadotropin–releasing hormone (Accessed: 26 February 2017).

Merriam-Webster Dictionary. 2017h. Human Chorionic Gonadotropin (online). Available: https://www.merriam-webster.com/dictionary/human chorionic gonadotropin. (Accessed: 26 February 2017).

Merriam-Webster Dictionary. 2017i. Hymen (online). Available: https://www.merriam-webster.com/dictionary/hymen#medicalDictionary (Accessed 12 Mar. 2017).

Merriam-Webster Dictionary. 2017j Luteinizing hormone (online). Available: https://www.merriam-webster.com/dictionary/luteinizing hormone (Accessed: 26 February 2017).

Merriam-Webster Dictionary. 2017k. Progesterone (online). Available: https://www.merriam-webster.com/dictionary/progesterone (Accessed: 26 February 2017).

Mills, S and Bone, K. 2007. *Principles and practice of Phytotherapy*. Edinburgh Churchill Livingstone.

Mokabane, M. E. 2009. The efficacy of the homoeopathic similimum in the treatment of the symptoms of primary dysmenorrhoea in black females (online). M.Tech. University of Johannesburg. Available: https://ujdigispace.uj.ac.za/bitstream/handle/10210/3775/Mokabane.pdf?sequence=1&isAllowed=y (Accessed 13 July 2012).

Moos, R. H. 1968. The development of a menstrual distress questionnaire. *Psychosomatic medicine*, 30: 853-867.

Moos, R. H. 2010. *Menstrual distress questionnaire* (online). Available at: http://www.mindgarden.com/products/mdq.htm (Accessed 31 August 13).

Mosby. 2013. Mosby's medical dictionary. 9th ed. St Louis, Missouri: Mosby Elsevier.

Morley, J. and Bartlett, P. 2001. *Homeopathy 3: complex remedies* (online). Available http://www.wholisticresearch.com/info/artshow.php3?artid=124 (Accessed 21 June 2012).

Murray, S. R. 2015. Are topical heat patches more effective at relieving pain associated with dysmenorrhea than OTC NSAIDs (Ibuprofen 400mg PO Q8h or Acetaminophen 500 mg PO Q6h) in menstruating women 18 and over? *PCOM Physician Assistant Studies Student Scholarship* (online). 238. Available: http://digitalcommons.pcom.edu/cgi/viewcontent.cgi?article=1236&context=pa_systematic_reviews (Accessed 12 April 2017).

Murphy, R., 1995. *Lotus materia medica: homeopathic and spagyric medicines*. Colorado: Lotus Star Academy.

Murphy, R. 2006. *Nature's materia medica: 1400 homeopathic and herbal remedies*. 3rd ed. Blacksburg, VA: Lotus health institute.

Navab, I. 2014. Trituration and succussion in the history of medicine (online), Available: http://hpathy.com/pharmacology/trituration-succussion-history-medicine/ (Accessed 23 April 2017).

Nissim, R. 1996. *Natural healing in gynaecology: a manual for women*. London: Pandora Press.

O'Hara, B. 2014. *The hypothalamic-pituitary-ovarian axis* (online). Available: http://www.naturalfamilyplanning.ie/the-hpo-axis/ (Accessed 14 February 2017).

Onur, O., Gumus, I., Derbent, A., Kaygusuz, I., Simavli, S., Urun, E., Yildirim, M., Gok, K. and Cakirbay, H. 2012. Impact of home-based exercise on quality of life with primary dysmenorrhoea. *South African journal of obstetrics and gynaecology*, 18(1).

O'Reilly, W. B. 1996. *Organon of the Medical Art by Dr Samuel Hahnemann.* California: Birdcage Books.

Owen, D. 2007. *Principles and practice of homoeopathy: the therapeutic and healing process*. London: Churchill Livingstone.

Phatak, S. R. 1988. *Phatak's material medica of homoeopathic medicines*. London: S. White and M. Johnson.

Proctor, M. L., and Farquhar, C. M. 2007. Dysmenorrhoea. *BMJ clinical evidence* 2007, pii: 0813.

Rahbar, N., Asgharzadeh, N. and Ghorbani, R. 2012. Effect of omega-3 fatty acids on the intensity of primary dysmenorrhea. *Obstetrics and gynecology*, 117(1): 45-47.

Reed, B. G. and Carr, B. 2015. The normal menstrual cycle and the control of ovulation. In: De Groot, L. J. et al., editors. Endotext (online). South Dartmouth (MA): MDText.com, Inc. Available: https://www.ncbi.nlm.nih.gov/books/NBK279054/ (Accessed 7 March 2017).

Richberg, I. M. 1997. *Gentle healing with homoeopathy: a practical primer to self-treatment of common ailments*. New York, NY: Sterling Publishing Company, Inc.

Rohrer, A. 2008. *Basic laws of homoeopathy* (online). Available: http://www.hahnemann.at/en/laws.html (Accessed 27 March 2015).

Romm, A. J. 2010. *Botanical medicine for women's health*. Missouri, MO: Churchill Livingstone Elsevier.

Sahani, M. K. 2007. *Principles and practice of homeopathic pharmacy for students*. New Delhi: B. Jain Publishers.

Sanjit, R. 2016. A repertorial comparison of the proving of a homoeopathic complex to the rubrics of the constituent parts. M. Tech, Durban University of Technology. Available: https://ir.dut.ac.za/bitstream/handle/10321/1780/SANJIT_2016.pdf?sequence=1&isAllowed=y (Accessed 24 July 2017).

Saunders, M., Lewis, P., and Thornhill, A. 2012. *Research methods for business students*. 6th Edition: Pearson Education Limited.Available: http://research-methodology.net/sampling-in-primary-data-collection/convenience-sampling/ (Accessed 25 February 2017).

Smith, R. P. 2015. Managing dysmenorrhea (online). Available: http://contemporaryobgyn.modernmedicine.com/contemporary-obgyn/news/managing-dysmenorrhea?page=full (Accessed 14 June 2016).

Stewart, K. and Deb, S. 2014. Dysmenorrhea. *Obstetrics, gynaecology and reproductive medicine*, 24(10): 296-302.

Streicher, L. F. 2013. Ultrasound: gynecology (online). Available: http://www.mygyne.info/ultrasoundGyne.htm (Accessed 07/09/2014)

Sturpe, D. A. 2013. The management of primary dysmenorrhea. *US Pharmacist*, 38 (9): 23-26.

Tamhane, A. 2014. *Complete cure in homeopathy by polycrest remedies* (online). Available: http://www.kasakaru.com/240-complete-cure-in-homeopathy-by-polycrest-remedies/#Definition_of_Polycrest_in_English (Accessed: 17 May 2017).

The Free Dictionary. 2017. *Similimum* (online). Available: http://medical-dictionary.thefreedictionary.com/similimum (Accessed 23 April 2017).

Tortora, G. J. and Derrickson, B. 2009. *Principles of anatomy and physiology*. 12th ed. New York, NY: John Wiley and Sons, Inc.

Tsolakis, N. 1995. The homoeopathic treatment of primary dysmenorrhoea. M.Tech, Durban University of Technology.

Vermeulen, F. 2001. *Concordant of the materia medica.* Haarlem: Emryss bv Publishers.

Vermeulen, F. 2004. *Prisma: The arcane of materia medica illuminated*. 3rd ed. Haarlem: Emryss bv Publishers.

Watson, I. 2009. *Repertorisation* (online), https://hpathy.com/homeopathy-repertory/repertorisation/ (Accessed 14 March 2018).

Witt, C. M., Lüdtke, R., and Willich, S. N. 2009. Homeopathic treatment of patients with dysmenorrhoea: a perspective observational study with 2 years follow-up. *Archives of Gynecology and Obstetrics*, 280(4): 603-611.

White, C. D. 2014. *HCG blood test – quantitative* (online). Available: https://medlineplus.gov/ency/article/003510.htm (Accessed: 27 March 2017).

Wong, C. L., Farquhar, C., Roberts, H. and Proctor, M. 2009. Oral contraceptive pill for primary dysmenorrhoea (online). *Cochrane database systematic reviews.* Oct 7 (4). DOI:10.1002/14651858.CD002120.pub3

Wood, S. 2004. *Factors influencing the selection of appropriate pain assessment tools*, 100(35): 42-47.

Wright, M., Willacy, H. and Gronow, H. 2014. *Primary dysmenorrhoea* (online). Available: http://www.patient.co.uk/health/period-pain-dysmenorrhoea (Accessed 12 September 2014).

APPENDICES

APPENDIX A: SCREENING QUESTIONAIRE

QUICK SCREENING QUESTIONNAIRE

Participant's Name: _____

Age: _____ Telephone: _____

1. Age at menarche (First period)? _____
2. Are your periods regular (Yes/No)? _____ How long does it last (length)? _____ Days
3. Do you usually experience pain with your periods (Yes/No)? _____
    - When does the pain occur? _____
    - How often do you experience the pain? _____
4. Is there anyone else in your family suffering with period pain (Yes/No)? _____
5. When did you experience period pain for the first time? _____
    - How long have your periods been painful? _____
6. What do you use to relieve your pain (painkillers or others)?
    - Name: _____
    - How many? _____
    - How often? _____
    - When do you take them?

      Before your period starts _____

      Throughout your period _____
7. Do you experience any other symptoms with your pain?
8. Are you using any contraceptive methods (Yes/No)? _____

APPENDIX B: PARTICIPANTS' LETTER OF INFORMATION AND CONSENT FORM (ENGLISH)

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

LETTER OF INFORMATION

Title of the Research Study:

The efficacy a homoeopathic complex (*Angelica sinensis* 6cH*, Dioscorea villosa* 6cH*, Matricaria chamomilla* 6cH, *Viburnum opulus* 6cH and *Zingiber officinalis* 6cH) compared to a homoeopathic similimum (30cH plussed) in the treatment of primary Dysmenorrhoea.

Principal Investigator/s/researcher: Carole Monga Ngoie (B.Tech. Hom.)

Co-Investigator/s/supervisor/s: Dr. Corné Hall (B.Sc.); (M. Tech. Hom)

Dear Participant,

The purpose of this study is to investigate the efficacy of the homoeopathic complex compared to a homoeopathic similimum in the treatment of primary dysmenorrhoea. Primary dysmenorrhoea is defined as painful menstruation or period with no associated pelvic malformation or pelvic diseases and every month, with your period, you may experience lower abdominal pain and discomfort that disturb your daily life.

Thank you for your interest taken in this study. In order to determine if you are suffering with primary dysmenorrhoea and therefore to have a chance to take part in this study, you will be required to have an ultrasound examination of your abdomen. This examination will be performed by a qualified gynaecologist to rule out any pelvic diseases or malformation that might be causing your period pain. This will be an abdominal ultrasound which means that it is not an internal exam. An ultrasound examination is a procedure that has been used in gynaecology practice since the 1970's as a diagnostic tool that helps identify possible causes of acute or chronic pelvic and abdominal pain (Jurkovic *et al*. 2009). This examination will take place at the radiography department at the Durban University of Technology.

Exclusion criteria:

You will be excluded from this study:

- If you are older than 30 years old as common causes of painful period are more frequent in this age group.
- If any pelvic or abdominal malformation or diseases are diagnosed during the ultrasound examination.
- If you are taking medication for any chronic disease.
- If there is a history of cancer in your family.
- If your religious beliefs oppose the use of alcohol in medical preparation.
- If you are currently taking oral contraceptives (the pill) or using intra-uterine devices.
- If you are currently pregnant or if you fall pregnant during the course of the study.
- **The researcher will not ask you to stop the pill for the purpose of this study; this is a personal decision that will not be required for you to take.** For those who have already stopped using the pill and are sexually active and desire to be part of the study; the researcher will advise you to use condoms, to prevent unwanted pregnancy.
- This clinical study will run for three menstrual cycles during which the impact of the treatment on your period pain will be assessed using two questionnaires. There will be one meeting which will be used to explain the study's procedures; this will take 45 minutes as you will be given the opportunity to ask questions about the study. There will be four consultations, the first one will be scheduled after the ultrasound examination and the three follow-up consultations will take place once a month at the end of your menstrual period. At every consultation you will be required to fill in the two questionnaires that will be used find out the efficacy of the treatment on your symptoms, all information given will be regarded as strictly confidential and will only be viewed by the researcher's supervisor. The first consultation will be one hour long while the follow-ups will be 45 minutes long; you will receive treatment at each consultation. These consultations will take place at the Homoeopathic Day Clinic at the Durban University of Technology, under the supervision of a qualified homoeopath.

- There is a chance that you will be randomly placed within either of the two groups which will receive two different treatments, namely the homoeopathic complex which will be repeated for the all duration of the study or in the other group will receive the homoeopathic similimum, this remedy may or may not be repeated for the second and third month of the study, this means that it could be changed for a remedy that will best cover your presenting symptoms at these follow-ups consultations. The medicine will be taken orally and you will be advised to put 20 drops on your tongue as soon as your period pain starts and the dosage will be repeated every three hours for the first three days of your menstrual period. You may experience symptom's relief with either treatment. In cases where you still experience pain, despite the treatment, you will be allowed to take the conventional pain medication that normally helps you and you will be required to record the dosage (how many, how often) in the diary that will be given to you for record keeping. The researcher will phone you once a week for the duration of the study.
- Please be aware that confidentiality will be maintained throughout the study. On completion of this study any identifiable data will be removed and destroyed. Your recorded symptoms will only be published using a code.
- Your participation in this study is voluntary, and will not cost you anything, and you are free to refuse treatment or withdraw from the study at any time, no reason needs to be given.
- In case of any queries or problems that may arise during the study, please contact:

The researcher:	My research supervisor:
Carole Monga Ngoie:	**Dr. Cornelia Maria Hall**:
Cellular: **082 8664306**	Cellular: **082 9216149**
M.Tech. Hom student	B.Sc.; M.Tech. Hom

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

CONSENT

Statement of Agreement to Participate in the Research Study:

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

_____ _____ _____ _____

Full Name of Participant **Date** **Time** **Signature / Right Thumbprint**

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____ _____ _____

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

_____ _____ _____

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

_____ _____ _____

Full Name of Legal Guardian (If applicable) **Date** **Signature**

APPENDIX C (INDIKIMBA) C: PARTICIPANTS' LETTER OF INFORMATION AND CONSENT FORM (ISIZULU)

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

INCWADI YESAZISO NGOCWANINGO

Isihloko socwaningo:

Ukuhlola impumelelo yokusebenza kwalenxubevange noma inhlanganisela yemithi yehomoeopathy (*Angelica sinensis* 6cH*, Dioscorea villosa* 6cH*, Matricaria chamomilla* 6cH*, Viburnum opulus* 6cH ne *Zingiber officinalis* 6cH) uma uyiqhathanisa nomuthi ngamunye oyi similimum (30cH plussed) yehomoeopathy ekwelapheni isilumo noma ubuhlungu bokuya esikhathini okubizwa nge primary Dysmenorrhoea.

Umcwaningi oqavile: CAROLE MONGA NGOIE (umfundi owenza i M.Tech. Hom.)

Umhloli omkhulu wocwaningo: Dkt.. CORNÉ HALL (M. Tech. Hom)

Ngiyakubingelela,

Injongo yalolucwaningo ukuhlola imiphumela yemikhakha emibili yendlela yokwelapha yehomoeopathy kuzimpawu zesilumo noma ubuhlungu bokuya esikhathini okubizwa nge primary dysmenorrhoea.

I-Primary dysmenorrhoea/ isilumo noma ubuhlungu bokuya esikhathini:

I-Primary dysmenorrhoea/ isilumo noma ubuhlungu bokuya esikhathini obungenazo ezinye izinkinga zesibeletho noma ukukhubazeka kokungakhekhi ngendlela kwesibeletho noma izifo ezinye zesibeletho, lobubuhlungu bokuya esikhathini bubekhona njalo nyangazonke uma uya esikhathini futhi izinhlungu zibasezansi impela kwesisu ngasesinyeni, lezizinhlungu ziyakukhinyabeza ziphazamise nempilo yakho ngalezozinsuku.

I-Homoeopathy:

Iyindlela yokwelapha ngemvelo nesiza ukuba umzimba uzilwele wona futhi uzame ukuzilapha wona. Iyindlela enesineke futhi ephephile ekwelapheni isilumo noma ubuhlungu bokuya esikhathini**.**

Izindlela zokwelapha:

- Inhlanganisela noma inxubevange yemithi yehomoeopathy ebizwa ngehomoeopathic complex :

  Lomuthi uyokwenziwa ngokudidiyela inhlanganisela yemithi ehlukene eyisihlanu.

- Umuthi owodwa ofana nezimpawu zesifo obizwa iHomoeopathic similimum:

  I- homoeopathic similimum yona iwumuthi owodwa ongaxutshiwe neminye.

Ukuxilongwa kwesisu ngomshini i-ultrasound:

Loluxilongo luyokwenziwa udokotela ogogodele izifundo zezifo noma izitho zabesifazane ukuze kuhluzwe ezinye izifo zesibeletho noma ukungakheki kahle kwesibeletho okungase kube nomuthelela ekubeni ubenesilumo noma ubuhlungu uma uya esikhathini.

Ukuxilongwa kwesibeletho ngomshini i-ultrasound iyona ndlela esisetshenziswe kusukela ngo 1970 njengendlela edalula ukuthi ingabe yini imbangela yobuhlungu sezifo zesisu kanye nobuhlungu besikhashana kanye nobuhlungu besikhathi eside (Jurkovic *et al*. 2009). Loluxilongo luyothatha indawo kumnyango wezeradiography esikhungweni sezemfundo ephakeme i Durban University of Technology.

- Ukungatholakali kwembangela yezinhlungu zesilumo ngesikhathi saloluxilongo kuyokwenyusa amathuba akho okuba ubandakanyeke kulolucwaningo, njengalokhu lolucwaningo luqonde ukwelapha isilumo noma ubuhlungu uma uya esikhathini i-primary dysmenorrhoea okuwubuhlungu obungenambangela esobala neyaziwayo.
- Labo abayotholakala benesifo esithize noma isigulo sesibeletho bayodluliselwa kudokotela ukuze bathole uhlengo olufanelekile, kepha abayukuba ingxenye yalolucwaningo.

Imigomo yokungafaneleki ukuba ubeyingxenye yalolucwaningo:

Awuyukuba ingxenye yalolucwaningo:

- Uma ungaphezu kweminyaka engu 30 ubudala njengoba imbangela yobuhlungu uma uya esikhathini ivamile kulesigaba seminyaka.

- Uma ngabe kukhona izifo zesibeletho noma ukungakheki kahle kwaso kanye nezinye izicubu ezinobudlelwano nesibeletho ezitholakalayo ngesikhathi uxilongwa ngomshini we ultrasound.
- Uma ngabe kukhona imithi oyithathatyo yesifo esinesikhathi eside.
- Uma ngabe kunokhondolo lwesifo somdlavuza emndenini.
- Uma ngabe inkolo noma isiko lakho lingakuvumeli ukuphuzwa noma ukusetshenziswa kwemithi enobutshala ekwenziweni kwayo.
- Uma ngabe uthatha amaphilisi okuhlela umndeni noma ngabe usebenzisa isivikeli nzalo esibelethweni esishuthekwayo..
- Uma ngabe ukhulelwe noma kwenzeka ukhulelwa ngesikhathi salolucwaningo.

Umcwaningi angeke akucele ukuba uyeke ukuthatha amaphilisi okuhlela umndeni ukuze ubeyingxenye yalolucwaningo; lokhu kuyisinqumo sakho ongeke wacelwa ukuba usenze. Kulabo asebewayekile vele amaphilisi okuvikela inzalo kwaze kwaba amaviki amane kodwa bebe besazibandakanya ocansini kepha benothando lokuzibandakanya kulolucwaningo; umncwaningi uyoniluleka ukuba nisebenzise amajazi abakhenyana noma ama condoms, ukuvikela ukukhulelwa okungahleliwe.
Uma ukhulelwa ngesikhathi salolucwaningo uyocelwa ukuba wazise umcwaningi ngalokho.

Isiphetho:
Kuyoba nomhlangano owodwa kanye nokubonana nomcwaningi izihlandla ezine.lokhukubonwa kuyothatha indawo kumtholampilo weze Homoeopathy owaziwa ngokuthi i-Homoeopathic Day Clinic kwisikhungo sezemfundo ephakeme i-Durban University of Technology, ngaphansi komhloli ozigogodele izifundo zehomoeopathy obizwa ngokuthi i-homoeopath.

- Umhlangano:
  Lomhlangano uyobe uhlose ukuchazelwa ngemigomo nagemibandela yalolucwaningo.
  .
- Ukubonwa:

- Okokuqala: kuyohlelwa emveni kokuhlolwa ngomshini we- ultrasound.
- Okulandelayo: kuyohlelwa kanye ngenyanga emveni kokuya khwakho esikhathini.

Uhla lwemibuzo yocwaningo:

Uyothola uhla lwemibuzo yocwaningo emibili okuyomele ukuba uyigcwalise njalo uma uzobonwa.

Loluhla lwemibuzo yocwaningo luyosiza umcwaningi ukuba abone impumelelo yohlengo lwemithi ekwelapheni ubuhlungu bakho uma uya esikhathini.

Ubude besikhathi socwaningo:

Lolucwaningo luyothatha isikhathi esingangezihlandla ezintathu zakho zokuya esikhathini.

Ukungaziswa ngokuphindapindiwe okubizwa nge-Double blind:

Lokhu kusho ukuthi wena nomacwaningi aniyukwazi ukuthi yiluphi uhlobo lwemithi olutholayo noma inxubevange yemithi noma umuthi ongaxutshiwe (i- complex noma i-similimum).

Umuthi:

Uyothola umuthi uyisilinganiso sika 20ml ongamanzi noma ukutshezi. Lomuthi uyophuzwa ngomlomo uyobe usululekwa ukuba uphuze amaconsi angu 20 olimini masishane nje emveni kokuqala kwezinhlungu zesikhathi sakho bese uphinda njalo emveni kwamahora amathathu kuze kuphele izinsuku ezintathu uqalile ukuya esikhathini.

Ungazizwela ukudamba kwezimpawu kunoma iluphi uhlobo lalokhukwelashwa. Ezimweni lapho uqhubeka ukuzizwela izinhlungu yize uphuza lemithi uyovumeleka ukuba uthathe amaphilisi okudambisa izinhlungu ovamile ukuwaphuza uma usuvukwe izinhlungu kepha kuyomele nje ukuthi ukuqhophe phansi konke lokho kwibhukwana lezigameko lansuku zonke (ukuthi uphuze amaphiliai amangaki nezihlandla ezingaki).

Ibhukwana lezigameko zansukuzonke i-diary:

Uyonikwa lelibhukwana ngosuku lokuqala lokubonana.

Uyolisebenzisela ukuqopha izimpawu obanazo ngesikhathi sokuya esikhathini. Kanye nesikalo samaphilisi ezinhlungu (ukuthi uphuze amaphiliai amangaki nezihlandla ezingaki) owaphuzile lapho ubuhlungu bungasabekezeleki.
Umcwaningi uyobe esxhumana nawe ngocingo kanye njalo ngeviki kusenziwa lolucwaningo.

Imfihlo nokungadalulwa kwemininingwane:

Yonke imininingwane oyinikezayo mayelana nalolucwaningo iyoba imfihlo engenakudalulwa eyokwaziwa nje kuphela umcwaningi kanye nomhloli wocwaningo.

Uyacelwa ukuwa uqondisise ukuthi ukuvikelwa kolwazi olucobelelayo mayelana nawe luyongadalulwa kuze kuphele lolucwaningo. Emveni kokuphothulwa kwalolucwaningo lolo lwazi olungaveza ukuthi ungubani wena luyobe selucinywa noma lususwa beselyabhujiswa ukukuvikela wena. Izimpawu ezibhalwe phansi kuphela eziyosetshenziswa zishicilelwe nazo ziyobe zinamakhodi azo.

Ukuzibandakanya kulolucwaningo kuwukuvolontiya qha, akuyukukukhokhisa lutho, futhi uvumelekile ukuba ungenqaba ukuthatha imithi noma ukwelashwa noma ukuyeka phakathi uma uzizwela ukuthi ufuna ukuyeka nanoma ingasiphi isikhathi, awuyukudingeka ukuba unikeze isizathu.
Uma ngabe unemibuzo noma izinkinga ezivelayo usengaphansi kwalolucwaningo, **uyacelwa ukuba uxhumane**:

Umcwaningi:	Umhloli wocwaningo:
Carole Monga Ngoie:	**Dkt. Cornelia Maria Hall**:
Umakhalekhukhwini: **082 8664306**	Umakhalekhukhwini: **082 9216149**
M.Tech. umfundi we M.Tech. kweze Homoeopathy	B. Sc., M.Tech. Hom

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC) - IGUNYA

Izitatimende zokuvuma ukuzibandakanya kulolucwaningo:

Ngimilana ngiyavuma ukuthi ngazisiwe umcwaningi u, _____ (igama lomcwaninginame), mayelana nohlobo, indlela, inzuzo kanye nencuphephe yalolucwaningo- inombolo ye Research Ethics Clearance: _____,

- Ngiyitholile, futhi ngiyifundile incwadi yokwazisa ngokuzibandakanya kulolulcwaningo ngaba nokuqondisisa okuphelele mayelana nalolucwaningo.
- Nginakho ukuqonda ngemiphumela yalolucwaningo, ukubandakanya ubulili, iminyaka, unyaka wokuzalwa, ama-inishiyali ami nokudalulwa kwesigulo sami ukuthi kuyobe sekudidiyelwa ukwenza umbiko ngalolucwaningo.
- Ekwazini ngezidingo zalolucwaningo ngiayanikeza igunya lokuba ulwazi ngami olutholakalayo ludidiyelwe beseluhlaziywa ngekhompuyutha nguye umcwaningi.
- Ngingahoxa ukuba ngizibandakanye kulolucwaningo noma inini, ngaphandle kokuba ngicwaswe kulolucwaningo.
- Sengibenesikhathi nethuba elanele lokuba ngibuze imibuzo (futhi ngentando yami) ngizikhethele mina ukuba ngizibandakanye kulolucwaningo.
- Ngiyaqonda ukuthi kusangatholakala ulwazi olubalulekile olusha oluphathelene nalolucwaningo, lolo lwazi ngiyokwazi ukuluthola uma ngiludinga.

_____ _____ _____ _____

Igama eliphelele lalona ozibandakanyayo **Usuku Date** **Isikhathi** **Uphawu lokusayina / isithupha sangasesandleni sokudla**

Mina, _____ (igama lomcwaningi) ngiyavuma ukuthi lona ongenhla ozibandakanya kucwaningo ngimazisile ngokuphelele mayelana nohlobo, indlela, inzuzo kanye nencuphephe yalolucwaningo.

_____	_____	_____
Igama eliphelele lomcwaningi	**Usuku**	**Uphawu lokusayina**
_____	_____	_____
Igama eliphelele llkafakazi (uma ekhona)	**Usuku**	**Uphawu lokusayina**
_____	_____	_____
Igamaeliphelele likamqaphi uma lidingeka	**Usuku**	**Uphawu lokusayina**

APPENDIX D: ULTRA-SOUND EXAMINATION'S INFORMATION LETTER AND CONSENT FORM (ENGLISH)

ULTRA-SOUND EXAMINATION'S INFORMATION

Dear participants,

This study will be investigating the efficacy of a homoeopathic complex to treat period pains. An ultrasound examination of your lower abdomen performed by a registered gynaecologist will be used to identify the cause of your period pains.

You will be required to fill in a quick screening questionnaire which will be used to gather information on your period (menstrual history). After a successful completion of the screening process, you will be scheduled for an abdominal examination using the ultra-sound machine.

These are the procedures:

1. The following **questions** will be asked:
    - Last menstrual period.
    - Is your period regular (every month)?
    - When did the first pain started?
    - How long did it last?
    - Have you suffered from previous pelvic diseases (endometriosis, pelvic masses or infections…)?
2. **Physical examination**

    Abdominal examination:
    - The gynaecologist will palpate/ touch your abdomen to look for any masses.
    - *No pelvic examination will be performed.*
3. **Ultrasound examination procedure**
    - You will be asked to lie on your back on the examination table and expose your lower abdomen.

- A clear water-based gel will be applied to the area and a transducer (part of the ultrasound machine) will be pressed against the skin and moved back and forth to obtain the desired image of your organs.
- The transducer will send and receive the sound waves through the body. The echoing waves will create images of your underlying organs. These images will be recorded on a computer (part of the ultrasound machine).

4. Requirement

- You will be required to drink a lot of liquid before the examination is performed in order to fill up your bladder.

5. **Location**: This examination will take place at the Radiographic Clinic at the Durban University of Technology.

6. Important notice

- This examination is painless, fast and easy.
- There is usually no discomfort from pressure as the transducer is pressed against the area being examined.
- You may feel pressure or minor pain only if the scanning is performed over an area of tenderness.
- The gel can easily be wiped off your skin.
- This examination will be 30 minutes long.
- The ultrasound examination will not interfere with the rest of your day.
- **You will be referred to a doctor if any abnormality is found during this examination.**

7. You will be excluded from the study if:

- You are on any medication for any chronic condition.
- You are older than 30 years.
  (Common causes of secondary dysmenorrhoea are more frequent in this age group).
- Any underlying causes of period pain are found during this examination. e.g. endometriosis, fibroids, abdominal masses.
- You had a pelvic surgery.
- You currently have an underlying physical abnormality/ pelvic diseases such as endometriosis, fibroids, polycystic ovarian syndrome.

- You have religious objections to alcohol used in medicinal preparations.
- You are on hormonal contraceptives or intra-uterine devices.
- You have a family history of cancer (e.g: hormonal cancer).
- You are currently pregnant or become pregnant during the course of this study.

Thank you for your interest in this research.

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

CONSENT

Statement of Agreement to Participate in the Research Study:

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

_____ _____ _____

_____

Full Name of Participant **Date** **Time** **Signature / Right Thumbprint**

I, _____ (name of researcher) herewith confirm that the above participant has been fully informed about the nature, conduct and risks of the above study.

_____ _____ _____

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

_____ _____ _____

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

_____ _____ _____

Full Name of Legal Guardian (If applicable) **Date** **Signature**

APPENDIX E (INDIKIMBA) E: ULTRASOUND EXAMINATION'S INFORMATION LETTER AND CONSENT FORM (ISIZULU)

INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

IGUNYA

ISAZISO NGOKUXILONGWA NGOMSHINI WE ULTRA-SOUND

Ngiyakubingelele,

Lolucwaningo luhlola indlela yemiphumela yokusebenza kwengxubevange yemithi yemithi yehomoeoepathy ekwelapheni isilumo noma izinhlungu uma uya esikhathini. **Ukuhlolwa ngomshini we ultrasound esiswini kwizicubu eziphathelene nezinobudlelwane nesibeletho** kuyokwenziwa udokotela okufundele futhi nonegunya lokwenza lomsebenzi wezicubu zabesifazane. Lomshini uyobe usudalula imbangela yezinhlungu uma uya esikhathini.

Nansi imigudu nemigomo eyolandelwa:

8. Nansi **imibuzo** elandelayo eyobuzwa:
    - Ugcine nini ukuya esikhathini.
    - Ingabe uya njalo nyangazonke esikhathini?
    - Ingabe ubuhlungu/ isilumo saqala nini?
    - Ubuhlungu buthatha isikhathi esingakanani bukhona?
    - Ingabe usuke waba nazo izifo noma inkinga yesibeletho noma izicubu ezinobudlelwane nesibeletho ezinjenge (endometriosis, pelvic masses or infections…)?

9. **Ukuhlolwa komzimba**

    Ukuhlolwa kwesisu:

    - Udokotela oyigynaecologist uyobe esetoboza isisu sakho/ ebheka ukuthi zikhona yini izigaxa.
    - *Akukho ukuhlolwa kwangaphakathi nangaphansi okuyokwenziwa.*

10. **Ukuhlolwa ngomshini weUltrasound:**
    - Uyocelwa Ukuba ulale phansi ngomhlane kwitafula lokuhlola, bese uveza ingxenye engezansi yesisu sakho.
    - Uketshezi olushubile olungamanzi luyobe seluputshuzelwa lapho kwisisu sakho lapho kuzobe kuhamba khona lomshini nakwikhanda lalomshini i-

transducer (okuyingxenye yezicubu zalomshini i-ultrasound) lomshini uyobe usucindezelwa esiswini sakho uhanjiswa uyephambili nasemuva ukuze ukwazi ukuthwebula izicubu zakho ngaphakathi ukuze ukhiphe izithombe zazo.

11. <u>Okudingekayo:</u>

- Kuyodingeka Ukuba uphuze amanzi noma ujusi omningi ngaphambi kokuba uxilongwe ngalomshini ukuze isinye sakho sigcwale.

12. **<u>Indawo</u>**: lokhukuxilongwa kuyothatha indawo kumtholampilo we Radiography kwisikhungo sezemfundo ephakeme i-Durban University of Technology.

13. <u>Isaziso esibalulekile:</u>

- Lokhukuxilongwa akunabo ubuhlungu, kuyashesha futhi kulula.
- Ngokuvamisile akuze kungaba khona ubuhlungu uma lomshini ucindezelwa kuleyo ndawo exilongwayo.
- Ungazizwela ubuhlungwana obuncane uma ngabe lomshini ucindezelwa endaweni enobuhlungu vele.
- Uketshezi lusuleka kalula esikhunjeni sakho.
- Lokhukuxilongwa ngalomshini angeke kuphazamise usuku lwakho lonke.
- **Uyokwedluliselwa kudokotela uma ngabe kukhona okungahambi kahle okutholakalayo kusenziwa lokhukuxilongwa.**

14. <u>Uyongabandakanywa kulolucwaningo uma:</u>

- Kukhona imithi oyiphuzayo yesigulo sesikhathi eside.
- Uma uneminyaka engaphezulu kuka30 ubudala njengoba imbangela yobuhlungu uma uya esikhathini ivamile kulesigaba seminyaka.
- Uma kukhona ezinye izinkinga eziyimbangela yesilumo uma kusenziwa loluxilongo ezitholakalayo njenge. e.g. i-endometriosis, amafibroids, nezigaxa -abdominal masses.
- Usuke wahlinzwa isibeletho.
- Uma unezinye izifo ezinjenge-endometriosis, amafibroids, i-polycystic ovarian syndrome.
- Uma unenkolelo noma usiko olungahambisani nokusetshenziswa kotshwala ekuthakweni kwemithi ezobe iphuzwa.

- Uma ngabe uphuza amaphilisi okuhlela umndeni noma ufake isivikelinzalo ngaphakathi esibelethweni sakho.
- Uma ngabe unokhondolo lomdlavuza emndenini njengo (umdlavuza wama homoni).
- Uma ngabe ukhulelwe njengamanje noma uyakhulelwa ngokuhamba kwesikhathi kusaqhubeka lolucwaningo.

Ngiyabonga ngokuzinikela kwakho ekubambeni iqhaza kulolucwaningo.

Izitatimende zokuvuma ukuxilongwa isisu sonke nezicubu zangaphakathi ngomshini i-ultrasound

- Ngimilana ngiyavuma ukuthi ngazisiwe umcwaningi u, _____ (igama lomcwaninginame), mayelana nohlobo, indlela, inzuzo kanye nencuphephe yalolucwaningo- inombolo ye Research Ethics Clearance: _____,
- Ngiyitholile, futhi ngiyifundile incwadi yokwazisa ngokuzibandakanya kulolulcwaningo ngaba nokuqondisisa okuphelele mayelana nalolucwaningo.
  - Nginakho ukuqonda ngemiphumela yalolucwaningo, ukubandakanya ubulili, iminyaka, unyaka wokuzalwa, ama-inishiyali ami nokudalulwa kwesigulo sami ukuthi kuyobe sekudidiyelwa ukwenza umbiko ngalolucwaningo.
  - Ekwazini ngezidingo zalolucwaningo ngiayanikeza igunya lokuba ulwazi ngami olutholakalayo ludidiyelwe beseluhlaziywa ngekhompuyutha nguye umcwaningi.
  - Ngingahoxa ukuba ngizibandakanye kulolucwaningo noma inini, ngaphandle kokuba ngicwaswe kulolucwaningo.
  - Sengibenesikhathi nethuba elanele lokuba ngibuze imibuzo (futhi ngentando yami) ngizikhethele mina ukuba ngizibandakanye kulolucwaningo.
  - Ngiyaqonda ukuthi kusangatholakala ulwazi olubalulekile olusha oluphathelene nalolucwaningo, lolo lwazi ngiyokwazi ukuluthola uma ngiludinga.

_____ _____ _____ _____

Igama eliphelele lalona ozibandakanyayo **Usuku Date** **Isikhathi** **Uphawu lokusayina / isithupha sangasesandleni sokudla**

Mina, _____ (igama lomcwaningi) ngiyavuma ukuthi lona ongenhla ozibandakanya kucwaningo ngimazisile ngokuphelele mayelana nohlobo, indlela, inzuzo kanye nencuphephe yalolucwaningo.

Igama eliphelele lomcwaningi	**Usuku**	**Uphawu lokusayina**
Igama eliphelele lIkafakazi (uma ekhona)	**Usuku**	**Uphawu lokusayina**
Igamaeliphelele likamqaphi uma lidingeka	**Usuku**	**Uphawu lokusayina**

APPENDIX F: CASE HISTORY QUESTIONAIRE

Tsolakis, N.1995. The Homoeopathic Treatment of Primary Dysmenorrhoea. M.Tech., Homoeopathy, Durban University of Technology.

Date: _____

Participant Number: _____

Surname: _____

First Names: _____

Age: _____

Sex: _____

Occupation: _____

Marital Status: _____

Children: _____

Religion: _____

Address:

_____

_____

_____

_____

_____

Telephone: _____

(Duration)

Main Complaint: What seems to be the problem today?

(Onset, Location, Aetiology, Duration, Character, Modalities, Concomitants, Radiation, Patient's response to symptoms and incapacities)

History of the Main complaint:

(Onset, Location, Aetiology, Duration, Character, Modalities, Concomitants, Radiation, Patient's response to symptoms and incapacities)

Principal symptoms

Social History:

1. Hobbies, exercise and leisure activities?
2. Any travelling (i.e. out Durban)?
3. Any recent shock or grief?
4. Sleep patterns?
5. Diet?

Psychosocial History:

1. Home situation and significant others?
2. Daily life?
3. Import experiences?
4. Religious beliefs?
5. The Patient's outlook?

Past Surgical History:

Any operations since you were born?

Past Medical History:

(Rheumatic fever, Pneumonia, Tuberculosis, Jaundice, High Blood Pressure, Diabetes)

1. Have you ever had any serious medical problems?

(Mumps, Measles, Chicken Pox, German Measles, Tuberculosis)

2. Can you remember your childhood illness?

3. Have you ever been in hospital for anything?

4. Do you have any allergies?

5. What vaccinations/immunisations have you had recently or previously?

(Tetanus, Pertusis, Diphtheria, Polio, Measles, Rubella, Mumps, Influenza, Hepatitis B, Haemophilus influenza type B)

6. Are you taking any medication?

(Onset, duration, dosage - How often, how many, when during your period?) (Pills, Vitamins, homoeopathic medicine, minerals, herbs, **PAINKILLERS**)

7. Do you smoke?

(Onset, Amount/Day, type)

8. Do you drink any form of alcohol?

Family History:

1. Are both your parents alive?

    1.1. Did/ Do any of them have any medical problems?

    1.2. If either of them died, why? And when?

    1.3. Is there a history of cancer in your family (hormonal cancer/ others)?

2. Do you have any siblings and are they all alive?

    2.1. If not how did they die and when?

    2.2. Did your siblings have any medical problems?

3. Do you have any children, and are they all alive?

    3.1. Do any of your children have any medical problems?

Possible family medical problems: Diabetes, Tuberculosis, Heart Diseases, High Blood Pressure, stroke, Kidney Disease, Cancer, Dysmenorrhoea, Hormonal cancer, Arthritis, Anaemia, Headaches, Epilepsy, Mental illness.

Systems review:

1. *General*:

(Usual weight, Recent weight change, weakness, Fatigue, Fever)

2*. Skin:*

(Rashes, Lumps, Sores, Itching, Dryness, Colour change, Changes in hair and nails)

3*. Head:*

(Headaches, Head injuries)

4. *Eyes:*

(Vision, Glasses, Contact lenses, Pain, Extensive tearing, Redness, Double vision, Cataracts)

5*. Ears:*

(Hearing problems, Tinnitus, Vertigo, Earache, Infection, Discharge)

6*. Nose & sinuses:*

(Frequency of colds, Nasal stuffiness, Discharge or itching, Hayfever, Nose bleeds, Sinus trouble)

7*. Mouth & throat:*

(Bleeding gums, Sore tongue, Frequency or sore throat, Hoarseness)

8*. Neck:*

(Swollen glands, Pain or stiffness in neck)

9. *Respiratory system:*

(Cough, Sputum, Haemoptysis, Wheezing, Asthma, Bronchitis, Emphysema, Pneumonia, Tuberculosis, Pleurisy)

10. *Cardiac system:*

(Heart trouble, High Blood Pressure, Rheumatic fever, Heart murmurs, Chest pain or discomfort, Palpitations, Dyspnea, Orthopnea, Paroxysmal nocturnal dyspnea, Oedema, Any heart tests)

11*. Gastrointestinal system:*

(Any trouble swallowing, Heartburn, Loss of appetite, Nausea, Vomiting, Regurgitation, Vomiting of blood, Indigestion, Haemorrhoids, constipation, Diarrhoea, Abdominal pain, Food intolerance, Excessive belching or passing of gas, jaundice, Liver or gall bladder trouble, hepatitis)

12*. Urinary system:*

(Polyuria, Nocturia, Burning or pain on urination, haematuria, Urgency, Hesitancy, Incontinence, Urinary infection, Stones)

13*. Genitoreproductive system*

(Hernias, Genital discharge or sores, History of venereal disease, sexual interest)

14*. Peripheral vascular system;*

(Intermittent claudication, Leg cramps, Varicose veins, Thrombophlebitis)

15*. Musculoskeletal system:*

(Muscular and joint pains, Stiffness, Arthritis, Gout, Backache)

16*. Neurological system:*

(Fainting, Blackouts, seizures, weakness, Paralysis, Numbness, Tingling, tremor or other involuntary movements)

17*. Haematologic system:*

(Anaemia, Easy bruising or bleeding, past transfusion and possible reactions)

18*. Endocrine system:*

(Thyroid trouble, Heat or cold intolerance, Excessive sweating, Diabetes, Excessive thirst or hunger, Polyuria)

19*. Psychiatric:*

(Nervousness, Tension, Depression, Memory loss)

<u>On Examination (O/E):</u>

Vital Signs:

Pulse:

Respiration:

Blood pressure:

Temperature (°C):

Weight & Height:

General inspection:

(Observe the state of health, Stature, Sexual development, Posture, Motor activity & gait, Dress, Grooming & personal hygiene, Odours of body or breath, Facial expression, Manner, Affect, Reaction to person and things in the environment. Listen to patient's speech, note state of awareness and level of consciousness)

General examination: (Inspection, Auscultation, Palpation, Percussion)

1. *Position the patient on their backs at 45°*
(Note: Muscle condition, Colour, Nails [clubbing, spooned, splinter haemorrhage], Sweat, Temperature, Circulation, Any nodules, Any lesions, Joint pain)

2*. Hands:*
(Hair distribution, Colour, Temperature, Muscle condition, Skin lesions, any pain)

3*. Forearm-> Arm-> Shoulder:*

4*. Neck:*
(Neck stiffness, Thyroid gland, Tracheal deviation, Jugular venous pressure, Glands, any pain)

5*. Face:*
(Twitches of facial muscles, Drooping, Swellings, Lesions, Inflammation, Skin, Hair distribution, Colour, any pain)

6*. Eyes:*
(Ophtalmoscopic examination, Visual acuity, Pupil reaction to light, Extra-ocular muscle movement, any pain)

7*. Nose:*
(Anosmia, any pain, Epistaxis, Runny nose, Hayfever, Lesions)

8*. Sinuses:*
(Pain, Headaches, Post nasal drip)

9*. Lips:*

(Colour, Lesions, Pain)

10*. Mouth:*

(Bad breath, Taste, Lesions, Pain)

11*. Teeth:*

(Condition, Pain, Colour, Caries Types of fillings)

12*. Gums:*

(Bleeding, Colour)

13*. Tongue:*

(Indentations, Colour, Mapped, Pain, Lesions, Taste)

14*. Throat:*

(Inflammation, Pain, Tonsils, Deposits, Voice)

15*. Ears:*

(Hearing, Lesions, Pain, Tympanic membrane, Wax colour)

16*. Thorax and Lungs:*

(Skin, Lesions, Hair distribution, Chest wall movement and shape, Respiratory rate, Depth, Rhythm & Effort; Tender areas, Tactile fremitus, Percussion, Auscultation)

17*. Heart:*

(Rate, Rhythm, Amplitude, Contour, Bruits, Thrills)

18*. Abdomen:*

(Pain, Tender areas, Skin, Spider nevi, Distention, Borborygmi, Liver, Kidneys, Spleen, Rebound tenderness, Muscle guarding)

19*. Back:*

(Skin, Lesions, Pain, Contour, of spine, Moles, Kidney pain)

20*. Pelvis & perineum:*

(Only if indicated, Glands, Sexual development, Lesions, Skin, Pain)

21*. Lower limbs:*

(Pain, Skin, Hair distribution, oedema, Varicose veins, Temperature, Colour/Filling, Sensory)

22. Feet:

(Nails, Temperature, Colour, Skin, Pain, Lesions, Warts, Athletes foot, Odour)

Additional Homoeopathic questions:

Mind

1. Fears
2. Sleep (Position, type, dreams, on waking)
3. Confusion/cloudiness
4. Excitement
5. Anxiety
6. Speech (Hurried, nasal, lost/difficult, slow/monotonous)
7. Imagination
8. Memory

Emotions

1. Depression
2. Melancholy
3. Mood

Physical

(Cravings, aversion, add salt, drink in gulps or sips, hot or cold drinks, love eggs)

1. Diet
2. Best time of day
3. Coast or inland
4. Particular
5. Brittle hair
6. Modalities

-cold/ Warmth:

-Movement/ Rest:

-Touch:

-Inside/ Outside:

-Riding in car:

-humidity/ Dryness:

-Sitting still/ Changing position:

-time of day:

-thirsty/ Not thirsty:

-Itchy/ Not itchy:

-Seaside/ inland:

-Consolation/ No consolation:

-Morning upon awakening:

-after meals:

-Winter/ Summer:

-Strong pressure:

-Dark:

-Standing:

Differential diagnosis:

APPENDIX G: MOOS MENSTRUAL DISTRESS QUESTIONNAIRE

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE (MDQ)

Moos, R. H. 1968. The development of a menstrual distress questionnaire. *Psychosomatic medicine* (online), 30: 853-867. Available: http://www.psychosomaticmedicine.org/ (Accessed 22 February 2012).

Participant:

_____

Entry

N°:_____

Write the appropriate date of your recent menstrual flow:

A. Most recent flow from_____ to _____

Write the date of the menstrual flow that preceded the most recent flow

B. Flow preceding the most recent menstrual flow _____ to _____

On the following pages is the list of symptoms that women sometimes experience. Please describe your experience of these symptoms during the three different periods listed below:

Column 1: During the most recent menstrual flow (A)
Column 2: one week before the menstrual flow (B)
Column 3: During the remainder of your most recent menstrual cycle (C)

Note: The answers you put in column 1, 2 and 3 should describe your experience specifically during your **most recent menstrual cycle**. Please do not report your

general symptoms. Please report if the symptoms are related to your menstrual cycle or not.

For each answer choose the category listed below which best describes your experience of each symptoms during that particular time. Write the number of that category in the space provided below. If none of the options acutely describe the symptoms, please choose an option that is closest to your experience.

CATEGORIES:

1= no experience of symptoms
2= barely noticeable
3= present, mild
4= present, strong
5= acute or partially disabling.

	Most recent flow (A)	**The week before (B)**	**Rest of the month (C)**
Muscle stiffness			
Headaches			
Cramps			
Backache			
Fatigue			
General aches and pains			
Insomnia			
Forgetfulness			
Confusion			
Lowered judgement			
Difficulty concentrating			
Distractible			
Accident prone			
Lowered motor coordination			
Lowered school / work performance			

Take naps; stay in bed			
Stay at home			
Avoid social activities			
Decreased efficiency			
Dizziness, faintness			
Cold sweats			
Nausea, vomiting			
Hot flushes			
Weight gained			
Skin disorders			
Painful breasts			
Swelling			
Crying			

	Most recent flow (A)	**The week before (B)**	**Rest of the month (C)**
Loneliness			
Anxiety			
Restlessness			
Irritability			
Mood swings			
Depression			
Tension			
Affectionate			
Orderliness			
Excitement			
Feeling of well-being			
Burst of energy, activity			
Feeling of suffocation			
Chest pain			
Ringing in the ears			

Heart pounding			
Numbness, tingling			
Blind spots, fuzzy vision			
Change in eating habits			

SYMPTOMS SCALES ON THE MOOS MENSTRUAL DISTRESS QUESTIONNAIRE

PAIN
Muscle stiffness
Headache
Cramps
Fatigue
General aches and pains
Backache

CONCENTRATION
Insomnia
Forgetfulness
Confusion
Lowered judgement
Difficulty concentrating
Distractible
Accident prone
Lowered motor coordination

BEHAVIOURAL CHANGES
Lowered school/ work performance
Take naps, stay in bed
Stay at home
Avoid social activities
Decreased efficiency

AUTONOMIC REACTIONS
Dizziness
Nausea, vomiting
Hot flushes
Cold sweats

WATER RETENTION
Weight gain
Skin disorders
Painful breasts
Swelling

NEGATIVE AFFECT
Crying
Loneliness
Anxiety
Restlessness
Irritability
Mood swings
Depression
Tension

AROUSAL
Affectionate
Orderliness
Excitement
Feeling of well-being
Burst of energy, activity

CONTROL
Feeling of suffocation
Chest pain
Ringing in the ears
Heart pounding
Blind spots, fuzzy vision.

APPETITE CHANGES

APPENDIX H1: STATISTICALLY SIGNIFICANT P-VALUES

The intra-group analysis using the PRS and the MDQ scales showed statistically significant changes in the subcategories of pain in the simillimum group (MDQ: Baseline-FU2: 0.02; FU1-FU2: 0.02 and FU2-FU3: 0.02; PRS: Baseline-FU1: 0.004, Baseline-FU2: 0.004 and Baseline-FU3: 0.02) and these changes were noticed in the complex group only with the PRS scale (Baseline-FU1: 0.002; Baseline-FU1: 0.002; Baseline-FU3: 0.004 and FU1-FU2: 0.009), when different follow up mean pain score was compared to that at baseline. The homoeopathic complex group showed more statistically significant changes in the subcategories of behaviour change (FU1-FU3: 0.04), negative affect (Baseline-FU1: 0.03; Baseline– FU1: 0.01 and FU1–FU2: 0.02), and control (Baseline-FU2: 0.04; FU1-FU2: 0.04 and FU2-FU3: 0.03); while the homoeopathic similimum also revealed other statistically significant changes in the autonomic response (Baseline-FU2: 0.04) and appetite change (Baseline-FU2: 0.02) subgroups. The inter-group analysis did not reveal any statistically significant change between the groups, although a decrease in the majority of the various mean scores was observed throughout the study.

FU1: First follow-up
FU2: Second follow-up
FU3: Third follow-up

APPENDIX I: PAIN RATING SCALE

PAIN RATING SCALE (PRS)

(English)

Title:..... Date:.....

First Name:..... Patient number:.....

Surname:..... Clinic:.....

Please mark the scale below to show how intense your pain is.

A zero (0) means no pain, and ten (10) means extreme pain.

How intense is your pain now?

I I I I I I I I I I I I I I I I I I I I I

0 1 2 3 4 5 6 7 8 9 10

no pain -- extreme pain

How intense was your pain on average last week?

I I I I I I I I I I I I I I I I I I I I I

0 1 2 3 4 5 6 7 8 9 10

no pain --- extreme pain

Now please use the same method to describe how distressing your pain is.

How distressing is your pain now?

I I I I I I I I I I I I I I I I I I I I I

0 1 2 3 4 5 6 7 8 9 10

not at all --- extremely distressing

How distressing was your pain on average last week?

I I I I I I I I I I I I I I I I I I I I I

0 1 2 3 4 5 6 7 8 9 10

not at all --- extremely distressing

Now please use the same method to describe how much your pain interferes with your normal everyday activities.

I I I I I I I I I I I I I I I I I I I I I

0 1 2 3 4 5 6 7 8 9 10

does not interfere --- interferes completely

If you have had treatment for your pain, how much has this relieved (taken away) the pain?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

no relief --- complete relief

The Pain Society
An alliance of professionals advancing the understanding and management of pain for the benefit of patients

APPENDIX J: ADVERTISEMENT

Do you suffer from

Painful periods?

If you are between the ages of 18 and 30 and you suffer from painful periods, you are invited to participate in research being conducted at the Durban University of Technology Homoeopathic Day Clinic.

Treatment is available should you qualify for the study.

For more information,

Please contact Carole on

0828664306

Research Ethics Clearance Number: IREC 033/13

APPENDIX K: RESULTS OF THE TRANSABDOMINAL ULTRASOUND SCREENING OF THE PARTICIPANTS

PARTICI-PANTS' NUMBERS	DATES OF EXAMINATION	AGE years	INCLUDED	EXCLUDED		LEFT THE STUDY
GYNAECOLOGIST: DR. GANGARAM						
1	20/08/2013	25	Participant #1		√	
2	20/08/2013	21	Participant # 11		√	
3	20/08/2013	22		PCOS	**X**	
4	20/08/2013	30	Participant # 2		√	
5	20/08/2013	18	Participant # 3		√	Left the study after the second follow-up.
6	02/09/2013	22	Participant #4		√	
7	02/09/2013	20	Participant # 5		√	
8	09/09/2013	19	Participant #6		√	
9	09/09/2013	22	Participants # 7		√	
10	09/09/2013	20	Participants # 8		√	Left the study after the baseline consultation.
11	09/09/2013	23	Participants # 9		√	Was unable to continue the study due to time constraint.
12	09/09/2013	20	Participant # 10		√	
13	09/09/2013		Participant # -		√	Did not come back for treatment after the ultrasound examination.
GYNAECOLOGIST: DR. SIGCU						
14	02/06/2014	24	Participant # 12		√	
15	02/06/2014	19	Participant # 13		√	
16	02/06/2014	23	Participant # 14		√	
17	02/06/2014	19	Participant # 15		√	
18	02/06/2014	20	Participant # 16		√	
19	09/06/2014	20		PCOS	**X**	
20	09/06/2014	19	Participant # 17		√	
21	04/08/2014	18		PCOS	**X**	

22	25/08/2014	19	Participant # 18		√	
23	25/08/2014	19	Participant # 19		√	
24	25/08/2014	19	Participant # 20		√	
25	25/08/2014	21	Participant # 21		√	
26	25/08/2014	18	Participant # 22		√	
27	25/08/2014	20	Participant # 23		√	
28	25/08/2014	20	Participant # 24		√	
29	25/08/2014	18	Participant # 25		√	
30	25/08/2014	19	Participant # 26		√	
31	25/08/2014	28		Fibroids	**X**	
32	01/09/2014	19		PCOS	**X**	
33	01/09/2014	18	Participant # 27		√	
34	01/09/2014	19	Participant # 28		√	
35	01/09/2014	19	Participant # 29		√	
36	01/09/2014	20	Participant # 30		√	
37	01/09/2014	27	-			Did not come back for treatment after the ultrasound examination.

Note: Appendix J: Thirty-seven participants were screened using the transabdominal ultrasound. Five participants were diagnosed with pelvic pathology, i.e. polycystic ovarian syndrome in four and fibroids in one participant.

APPENDIX L: RANDOMISATION LIST

PARTICIPANTS' NUMBERS	HOMOEOPATHIC COMPLEX	HOMOEOEPATHIC SIMILIMUM
1.	X	
2.	X	
3.		X
4.	X	
5.	X	
6.		X
7.	X	
8.	X	
9.		X
10.	X	
11.	X	
12.		X
13.	X	
14.	X	
15.		X
16.	X	
17.	X	
18.		X
19.	X	
20.	X	
21.		X
22.	X	
23.	X	
24.		X
25.	X	
26.	X	
27.		X
28.	X	
29.	X	
30.		X

APPENDIX M: RAW DATA

Moos menstrual distress questionnaire, Pain rating scales and Painkillers tables

PARTICIPANT NUMBER 1
Age: 25 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL QUESTIONNAIRE TABLE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	18	9	15	17	16	10	13	10	10	10	11	6
2.Concentration	14	6	6	8	12	6	9	8	6	10	11	6
3.Behavioral change	23	7	7	18	19	7	15	11	7	11	13	8
4.Autonomic reaction	13	4	6	12	9	4	9	10	4	9	8	4
5.Water retention	9	7	6	7	7	4	6	6	4	8	6	4
6.Negative affect	14	9	8	11	10	8	8	8	10	13	12	8
7.Arousal	9	5	5	7	5	5	10	9	13	12	9	6
8.Control	12	7	6	10	7	6	6	6	8	13	11	7
9.Appetite changes	3	2	1	2	1	1	1	1	1	3	2	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE TABLE				
	Baseline 1st consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	10	6	2	1
How intense was it the week before your periods started?	4	3	1	1
How distressing was it during your recent periods?	8	5	1	1
How distressing was it the week before your periods started?	3	2	0	0
How did it interfere with your daily life?	7	4	2	1
How much has the treatment relieved the pain?	50%	80%	90%	90%

PAINKILLERS TABLE			
Baseline 1st consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
Panado: 6 to 8 pills 2 pills X4 daily As soon as her menses started	Panado: Took 2 pills on the first day only.	Panado: 6 pills Took 2 pills every 4 hours on the first day only.	None

PARTICIPANT NUMBER 2
Age: 30
Race: African
Occupation: Lab technician
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	11	9	7	10	11	7	11	9	8	8	7	6
2.Concentration	8	7	6	8	6	6	7	6	6	6	6	6
3.Behavioral change	16	13	7	15	13	10	9	9	9	11	10	7
4.Autonomic reaction	13	8	4	9	4	4	8	8	8	4	4	4
5.Water retention	8	6	4	5	4	4	4	4	4	5	5	5
6.Negative affect	26	22	14	22	18	11	9	8	8	8	8	8
7.Arousal	12	10	9	15	12	8	12	6	6	15	11	6
8. Control	6	6	6	10	10	8	7	7	7	6	6	6
8.Appetite changes	4	3	2	4	2	1	3	3	3	2	2	2

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	8	5	5	3
How intense was it the week before your periods started?	1	0	2	0
How distressing was it during your recent periods?	1	4	6	3
How distressing was it the week before your periods started?	7	0	4	0
How did it interfere with your daily life?	5	0	3	3
How much has the treatment relieved the pain?	90%	90%	70%	80%

PAIN RATING SCALE			
Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
Panado: 3 pills Took them on the first and third day	None	Panado: 3 pills Took them on the first and last day	None.

PARTICIPANT NUMBER 3: Dropped out of study

Age: 18 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	12	6	6	15	7	6	6	8	8	-	-	-
2.Concentration	14	6	6	12	6	6	12	6	6	-	-	-
3.Behavioral change	25	7	7	19	7	7	22	9	9	-	-	-
4.Autonomic reaction	9	4	4	4	4	4	7	4	4	-	-	-
5.Water retention	5	5	5	4	4	4	4	4	4	-	-	-
6.Negative affect	20	8	8	17	8	8	20	8	8	-	-	-
7.Arousal	5	17	17	5	20	20	20	5	20	-	-	-
8. control	9	6	6	6	6	6	6	6	6	-	-	-
9. Appetite changes	4	1	1	1	1	1	4	1	1	-	-	-

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	8	3	10	-
How intense was it the week before your periods started?	7	7	0	-
How distressing was it during your periods?	9	2	8	-
How distressing was it the week before your periods started?	8	8	3	-
How did it interfere with your daily life?	9	10	10	-
How much has the treatment relieved the pain?	100%	60%	20%	-

PAINKILLERS TABLE			
Baseline 1st consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Grandpa: 6 pills Took 2 pills daily for three days.	None	None	------

PARTICIPANT NUMBER 4

Age: 22 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline consultation 1ST			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	24	6	6	10	8	8	6	6	6	6	6	6
2.Concentration	6	6	6	7	6	6	6	6	6	6	6	6
3.Behavioral change	22	15	7	15	6	6	11	7	7	7	7	7
4.Autonomic reaction	4	4	4	6	5	5	4	4	4	4	4	4
5.Water retention	10	9	4	4	4	4	4	4	4	4	4	4
6.Negative affect	20	8	8	18	8	8	8	8	8	8	8	8
7.Arousal	5	5	5	5	5	5	5	5	5	5	5	5
8. control	6	6	6	6	6	6	6	6	6	6	6	6
9. Appetite changes	6	1	1	1	1	1	1	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	10	5	0	0
How intense was it the week before your periods started?	0	1	0	0
How distressing was it during your recent periods?	10	5	0	0
How distressing was it the week before your periods started?	0	1	0	0
How did it interfere with your daily life?	8	7	0	0
How much has the treatment relieved the pain?	50%	70%	100%	100%

PAINKILLERS TABLE			
Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
Grandpa: 6pills Took 2pills daily for three days	None	None	None

PARTICIPANT NUMBER 5

Age: 20 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	14	6	6	16	10	01	10	8	9	27	7	6
2.Concentration	11	7	7	10	7	9	9	6	6	17	6	6
3.Behavioral change	16	7	7	17	10	11	14	8	8	26	9	9
4.Autonomic reaction	7	4	4	9	4	4	8	4	4	16	4	4
5.Water retention	9	6	4	8	4	9	7	4	4	14	4	4
6.Negative affect	15	10	8	14	8	9	10	8	8	25	8	8
7.Arousal	6	5	5	6	5	5	6	5	5	10	6	5
8. control	9	6	6	8	6	6	8	6	6	23	6	6
9. Appetite changes	2	2	1	3	1	4	2	1	1	5	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	9	5	3	10
How intense was it the week before your periods started?	3	0	0	2
How distressing was it during your recent periods?	8	5	3	10
How distressing was it the week before your periods started?	3	0	0	1
How did it interfere with your daily life?	8	8	0	10
How much has the treatment relieved the pain?	70%	20%	90%	10%

PAINKILLERS TABLE			
Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
Ibuprofen: 2 pills Ablex: 2 pills Took 4 pills on the first day	Ibuprofen: 2 pills Took them on the first day	Ibuprofen: 1 pill Ablex: 2 pills Took 3 pills X 2 daily on the first day	Ibuprofen: 4 pills Took 2 pills on the first day and second day

PARTICIPANT NUMBER 6

Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	8	9	6	19	16	8	8	8	8	19	12	7
2.Concentration	14	11	6	18	15	9	7	6	6	15	8	6
3.Behavioral change	11	9	7	19	16	7	10	7	7	17	7	7
4.Autonomic reaction	4	4	4	6	5	4	4	4	4	4	4	4
5.Water retention	5	7	4	7	6	4	9	4	4	8	6	4
6.Negative affect	19	10	8	26	17	8	12	10	8	6	8	8
7.Arousal	9	9	5	13	11	5	5	5	5	6	6	4
8. control	6	6	6	9	8	6	6	6	6	7	6	6
9. Appetite changes	4	2	1	4	4	1	1	1	1	4	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	10	8	9	3
How intense was it the week before your periods started?	7	7	0	7
How distressing was it during your	10	5	8	7
recent periods?				
How distressing was it the week before your periods started?	5	4	0	3
How did it interfere with your daily life?	4	6	8	3
How much has the treatment relieved the pain?	90%	80%	50%	80%

PAINKILLERS TABLE			
Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
Pain block: 4 pills Took 2X 2 pills daily depending on the intensity of the pain.	Pain block: 2 pills Took 2 pills in the morning on the first day.	Pain block: 4 pills Took 2 X 2 pills in the morning and the afternoon on the first day.	Pain block: 2 pills Took 2 pills in the morning on the first day only.

PARTICIPANT NUMBER 7

Age: 22 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	13	6	6	11	6	6	8	6	6	7	6	6
2.Concentration	16	6	6	9	6	6	6	6	6	6	6	6
3.Behavioral change	25	7	7	13	7	7	13	7	7	10	7	7
4.Autonomic reaction	12	4	4	6	4	4	4	4	4	7	4	4
5.Water retention	9	4	4	10	4	4	10	5	4	4	4	4
6.Negative affect	18	8	8	14	8	8	8	8	8	8	8	8
7.Arousal	12	5	5	11	5	5	10	5	5	5	5	5
8. control	10	6	6	9	6	6	9	6	6	6	6	6
9. Appetite changes	5	1	1	3	1	1	4	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	10	6	2	2
How intense was it the week before your periods started?	5	5	0	0
How distressing was it during your recent periods?	10	6	0	0
How distressing was it the week before your periods started?	4	5	0	0
How did it interfere with your daily life?	8	4	0	2
How much has the treatment relieved the pain?	60%	50%	80%	90%

PAINKILLERS TABLE			
Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
Grandpa: 3 pills Took 1 pill every 3 hours throughout her menstrual cycle.	None	None	None

PARTICIPANT NUMBER 8- Dropped out of the study.
Age: 20 years
Race: African
Occupation: Student
Group: Homoeopathic complex
.
PARTICIPANT NUMBER 9- Dropped out of the study.
Age: 23 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

PARTICIPANT NUMBER 10
Age: 20 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			1st Follow-up			2nd Follow-up			3rd Follow-up		
	A	B	C	A	B	C	A	B	C	A	B	C
1.Pain	18	10	9	9	8	6	7	8	9	14	14	13
2.Concentration	11	21	17	9	8	8	12	6	6	12	8	8
3.Behavioral	30	18	14	17	14	14	23	21	21	27	19	19
change												
4.Autonomic reaction	4	4	4	4	4	4	4	6	6	5	7	7
5.Water retention	4	7	5	4	4	4	4	4	5	4	8	4
6.Negative affect	26	25	24	27	22	19	21	22	22	37	37	37
7.Arousal	13	9	8	10	12	16	11	10	9	5	5	5
8. control	10	13	12	9	9	9	8	8	8	18	18	18
9. Appetite changes	1	1	1	1	1	1	5	2	2	5	5	5

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	1st Follow-up	2nd Follow-up	3rd Follow-up
How intense was your pain during your recent periods?	6	6	1	2
How intense was it the week before your periods started?	3	3	1	1
How distressing was it during your recent periods?	6	6	2	3
How distressing was it the week before your periods started?	3	3	1	0
How did it interfere with your daily life?	9	2	1	3
How much has the treatment relieved the pain?	40%	80%	90%	90%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Stop pain or Pain block: 2pills on the last day	None	None	None

PARTICIPANT NUMBER 11
Age: 21 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE											
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**	
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	15	6	6	22	6	6	21	6	6	24	6	6
2.Concentration	3	6	6	20	6	6	20	6	6	19	6	6
3.Behavioral change	18	7	7	27	7	7	22	7	7	25	7	7
4.Autonomic reaction	12	4	4	13	4	4	11	4	4	16	4	4
5.Water retention	8	4	4	12	4	4	9	7	7	12	4	4
6.Negative affect	34	8	8	30	8	8	7	17	17	32	8	8
7.Arousal	16	5	5	7	5	5	15	6	6	9	17	17
8. control	13	6	6	16	6	6	17	6	6	16	6	6
9. Appetite changes	4	1	1	2	1	1	3	1	1	3	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	7	10	9	10
How intense was it the week before?	7	0	1	0
How distressing was it during your recent periods?	7	10	0	9
How distressing was it the week before?	1	0	1	0
How did it interfere with your daily life?	10	9	8	9
How much has the treatment relieved the pain?	10%	50%	40%	70%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Mybulen: 2 pills Took them throughout her menstrual cycle.	Pain block: 2 pills Took them on the first day only.	Pain block: 2 pills Took them on the first day only.	Pain block: 4 pills Took 2 pills on the first day and the second day.

PARTICIPANT NUMBER 12
Age: 24 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	16	13	7	10	6	9	14	7	6	10	10	10
2.Concentration	9	8	6	11	8	12	18	11	16	16	11	11
3.Behavioral change	10	10	8	9	8	9	12	9	8	15	15	12
4.Autonomic reaction	8	7	6	4	4	6	8	5	5	7	8	8
5.Water retention	8	9	7	7	5	6	9	6	6	8	7	7
6.Negative affect	24	19	9	8	8	15	23	18	19	13	13	13
7.Arousal	8	7	14	12	11	6	13	11	11	16	16	16
8. control	5	5	5	5	6	8	10	8	7	6	6	6
9. Appetite changes	4	4	3	1	1	1	4	3	3	3	3	3

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	5	2	5	0
How intense was it the week before your periods started?	4	0	1	0
How distressing was it during your recent periods?	6	1	5	0
How distressing was it the week before your periods started?	6	1	1	0
How did it interfere with your daily life?	8	0	4	0
How much has the treatment relieved the pain?	0%	80%	100%	100%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
None She prefers exercising and drinking water.	None	None	None

PARTICIPANT NUMBER 13
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENTSRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	8	6	6	8	6	9	7	6	10	7	7	9
2.Concentration	9	6	6	8	6	8	6	6	7	6	6	6
3.Behavioral change	10	8	7	15	14	13	11	10	10	7	9	12
4.Autonomic reaction	6	5	4	10	5	8	7	5	10	4	4	6
5.Water retention	5	4	4	4	4	5	4	4	5	4	4	5
6.Negative affect	12	8	8	11	9	12	10	8	15	8	8	12
7.Arousal	5	5	5	5	8	8	6	7	7	6	7	8
8. control	6	6	6	7	6	6	6	6	6	8	6	7
9. Appetite changes	2	1	1	4	4	4	3	1	3	1	2	2

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	10	10	8	3
How intense was it the week	0	0	0	0
before your periods started?				
How distressing was it during your recent periods?	10	8	8	2
How distressing was it the week before your periods started?	0	0	0	0
How did it interfere with your daily life?	10	5	1	0
How much has the treatment relieved the pain?	100%	60%	50%	50%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Neurofen or Mybulen: 4 pills daily. 2 pills X 2 daily throughout her menstrual cycle (7 days).	Grandpa powder: 1pill. Took it on the first day only.	None "The patient was not that bad"	Panado: 2 pills Took them on the first day only

PARTICIPANT NUMBER 14
Age: 23 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	9	6	6	6	6	6	6	6	6	8	6	6
2.Concentration	6	6	6	6	6	6	6	6	6	6	6	6
3.Behavioral change	10	7	7	7	7	7	7	7	7	7	7	7
4.Autonomic reaction	4	4	4	4	4	4	4	4	4	4	4	4
5.Water retention	4	4	4	4	4	4	4	4	4	4	4	4
6.Negative affect	11	8	8	10	9	8	8	8	8	8	8	8
7.Arousal	5	5	5	5	5	5	5	5	5	5	5	5
8. control	6	6	6	6	6	6	9	6	6	6	6	6
9. Appetite changes	1	1	1	1	1	1	1	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	7	3	4	3
How intense was it the week before your periods started?	0	0	0	0
How distressing was it during your recent periods?	8	3	4	1
How distressing was it the week before your periods started?	0	0	0	0
How did it interfere with your daily life?	0	0	10	0
How much has the treatment relieved the pain?	100%	70%	50%	60%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Panado: 3 pills Took them at once.	None She didn't feel the need to take the as the pain was decreased	None The pain was not present.	None Pain was bearable.

PARTICIPANT NUMBER 15
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic similimum.

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	16	6	6	28	6	6	18	6	6	26	6	6
2.Concentration	23	6	6	22	6	6	24	6	6	24	6	6
3.Behavioral change	28	7	7	26	7	7	28	7	7	27	7	7
4.Autonomic reaction	10	4	4	11	4	4	7	4	4	13	4	4
5.Water retention	7	4	4	7	4	4	7	4	4	8	4	4
6.Negative affect	32	8	8	32	8	8	32	8	8	32	8	8
7.Arousal	8	5	5	11	5	5	8	5	5	14	5	5
8. control	18	6	6	12	6	6	12	6	6	14	6	6
9. Appetite changes	1	1	1	4	1	1	1	1	2	2	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	10	9	9	10
How intense was it the week before your periods started?	2	0	0	0
How distressing was it during your	10	10	9	10
recent periods?				
How distressing was it the week before your periods started?	8	0	0	0
How did it interfere with your daily life?	10	10	8	10
How much has the treatment relieved the pain?	40%	40%	70%	30%

PAINKILLERS TABLE			
Baseline 1ST consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Grandpa or Dispirin: 2 pills Took them on the first day only.	Grandpa: 1 pill. Took it on the first day only.	Dispirin: 1 pill Took it on the first day only.	None

PARTICIPANT NUMBER 16
Age: 20 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	15	12	13	8	15	15	11	7	7	17	17	12
2.Concentration	19	17	14	14	16	11	14	14	14	15	16	16
3.Behavioral change	29	21	15	24	24	20	12	11	11	21	22	15
4.Autonomic	13	10	8	12	12	8	8	8	7	8	9	7
reaction												
5.Water retention	10	9	5	10	11	7	10	8	5	11	11	6
6.Negative affect	23	20	12	28	26	13	20	16	15	25	22	14
7.Arousal	11	13	20	10	12	17	14	9	13	9	9	14
8. control	11	10	10	9	10	8	9	6	6	11	11	13
9. Appetite changes	4	4	2	5	5	2	4	3	3	4	4	2

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	8	8	6	9
How intense was it the week before your periods started?	6	1	0	0
How distressing was it during your recent periods?	7	0	0	8
How distressing was it the week before your periods started?	7	7	7	1
How did it interfere with your daily life?	7	7	7	7
How much has the treatment relieved the pain?	60%	60%	60%	50%

PAINKILLERS TABLE			
Baseline consultation 1ST	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Paracetamol: 1pill daily for 4 days	None The pain was bearable	None The pain was better or no too painful	None

PARTICIPANT NUMBER 17
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	11	10	10	20	11	7	18	12	12	22	12	12
2.Concentration	17	6	6	11	6	6	10	6	6	16	7	7
3.Behavioral change	18	7	7	12	7	7	11	9	7	18	7	7
4.Autonomic reaction	19	4	4	9	4	4	4	4	4	16	4	4
5.Water retention	4	4	4	6	4	4	4	4	4	6	4	4
6.Negative affect	21	8	8	19	8	8	11	8	8	29	9	9
7.Arousal	5	5	5	6	18	18	5	12	16	6	14	16
8. control	14	6	6	15	7	7	6	6	6	21	6	6
9. Appetite changes	5	1	1	4	1	1	1	1	1	3	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	8	5	5	10
How intense was it the week before your periods started?	0	0	0	0
How distressing was it during your recent periods?	7	4	5	10
How distressing was it the week before your periods started?	0	0	0	0
How did it interfere with your daily life?	0	6	4	9
How much has the treatment relieved the pain?	90%	80%	90%	0%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Adcodol: 6 pills Took them at once on the first day.	None The pain was bearable	None The pain was present only on the first day.	None

PARTICIPANT NUMBER 18
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	14	12	11	11	7	6	10	6	6	11	8	6
2.Concentration	8	10	10	9	6	6	9	6	6	12	9	6
3.Behavioral change	20	20	22	18	10	7	18	7	7	18	9	9
4.Autonomic reaction	9	9	9	5	5	4	5	4	4	9	6	6
5.Water retention	6	4	4	7	6	4	6	4	4	7	6	4
6.Negative affect	20	8	10	20	13	8	18	8	8	21	12	8
7.Arousal	7	5	5	5	5	5	5	5	7	7	6	5
8. control	11	6	6	9	9	5	9	6	6	10	7	5
9. Appetite changes	2	1	1	1	1	1	1	1	1	3	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	9	7	3	3
How intense was it the week before your periods started?	9	7	3	4
How distressing was it during your recent periods?	8	5	4	4
How distressing was it the week before your periods started?	9	5	3	2
How did it interfere with your daily life?	9	4	5	2
How much has the treatment relieved the pain?	70%	50%	80%	80%

PAIN RATING SCALE			
Baseline 1ST consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Panado or Disprin: 2 pills per menstrual cycle. Took 1 pill on the first day and the second one on the third day.	None The pain was bearable.	Pain blocks: 2 pills	Panado: 2 pills

PARTICIPANT NUMBER 19
Age: 29 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	30	9	11	9	7	9	9	7	7	20	7	8
2.Concentration	17	10	10	9	9	13	6	7	11	17	10	9
3.Behavioral change	21	14	15	11	15	18	9	12	14	20	12	11
4.Autonomic reaction	16	4	4	4	5	5	5	4	4	14	6	5
5.Water retention	7	9	13	11	8	14	9	10	11	11	6	5
6.Negative affect	28	9	13	11	8	14	9	10	11	19	8	13
7.Arousal	7	22	22	10	13	16	13	15	14	12	10	14
8. control	13	7	9	7	8	9	8	7	7	7	7	8
9. Appetite changes	5	1	1	2	1	2	2	1	1	4	2	2

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	7	4	2	8
How intense was it the week before your periods started?	0	0	0	0
How distressing was it during your recent periods?	8	3	2	8
How distressing was it the week before your periods started?	0	0	0	2
How did it interfere with your daily life?	10	5	0	9
How much has the treatment relieved the pain?	70%	80%	90%	30%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Painblocks: 6 pills daily for the first three days	None The pain was bearable	None There was no pain, she only felt a discomfort	Painblocks: 4Pills She took one pill twice daily for the first two days.

PARTICIPANT NUMBER 20
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	17	17	10	20	9	9	8	9	9	14	6	6
2.Concentration	14	14	7	17	7	7	7	8	8	13	6	6
3.Behavioral change	31	31	9	27	10	11	10	9	7	21	7	7
4.Autonomic reaction	12	11	5	7	4	4	4	4	4	5	5	4
5.Water retention	14	14	10	7	8	5	5	6	4	8	12	5
6.Negative affect	27	27	11	29	10	9	8	10	8	14	9	8
7.Arousal	17	13	13	10	6	6	13	9	11	5	5	6
8. control	9	9	6	13	7	6	6	6	6	7	7	6
9. Appetite changes	5	5	3	5	2	2	4	2	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	6	9	2	3
How intense was it the week before your periods started?	0	6	0	3
How distressing was it during your recent?	7	9	0	4
How distressing was it the week before your periods started?	0	5	0	4
How did it interfere with your daily life?	10	1	5	5
How much has the treatment relieved the pain?	40%	30%	80%	40%

PAINKILLERS TABLE			
Baseline 1ST consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Grandpa: 2 pills Took them on the first day	None Doesn't like to take pain killers unless the pain is unbearable.	None The pain was only present for few hours.	None

PARTICIPANT NUMBER 21
Age: 21 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	16	10	6	6	6	6	6	6	6	12	6	8
2.Concentration	13	6	6	6	6	6	6	6	6	6	6	6
3.Behavioral change	17	7	7	7	7	7	7	7		11	7	7
4.Autonomic reaction	6	4	4	4	4	4	4	4	4	4	4	4
5.Water retention	4	4	4	4	4	4	4	4	4	4	4	4
6.Negative affect	16	8	8	8	8	8	8	8	8	8	8	8
7.Arousal	9	6	6	13	6	6	14	10	10	9	5	5
8. control	5	5	5	5	5	5	6	6	6	6	6	6
9. Appetite changes	5	1	1	5	1	1	1	1	1	3	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	10	1	3	3
How intense was it the week before your periods started?	0	0	0	0
How distressing was it during your recent periods?	7	0	0	3
How distressing was it the week before your periods started?	0	0	0	0
How did it interfere with your daily life?	6	0	0	3
How much has the treatment relieved the pain?	30%	90%	60%	80%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Nurofen: 6 Pills Took 1 pill X3 daily for two days	Nurofen: 1 pill Took it on the first day.	None She wanted to see how well the remedy worked without taking painkiller.	Nurofen 1 Pill Took it on the first day.

PARTICIPANT NUMBER 22
Age: 18 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	13	14	12	8	8	8	15	13	14	14	12	12
2.Concentration	18	13	13	13	10	10	16	14	13	19	14	
3.Behavioral change	19	11	15	15	14	14	19	14	14	23	16	16
4.Autonomic reaction	5	5	5	7	6	6	7	8	7	8	8	8
5.Water retention	8	8	8	6	6	6	8	8	7	11	9	10
6.Negative affect	19	18	16	18	16	16	23	20	17	20	16	19
7.Arousal	11	14	14	13	14	16	12	14	14	12	15	15
8. control	11	11	11	12	9	9	12	12	12	12	12	12
9. Appetite changes	3	2	2	3	2	2	4	2	2	2	2	2

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1ST consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	8	7	9	4
How intense was it the week before your periods started?	4	4	4	2
How distressing was it during your recent periods?	6	6	8	5
How distressing was it the week before your periods started?	3	3	5	1
How did it interfere with your daily life?	9	3	6	3
How much has the treatment relieved the pain?	30%	60%	0%	0%

PAIN RATING SCALE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Paracetamol: She used to take 2 pills at once. They stopped working, so she no longer takes them.	None The pain was not that bad.	None.	None

PARTICIPANT NUMBER 23
Age: 20 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	17	9	6	26	8	7	11	8	7	14	9	7
2.Concentration	12	6	6	20	6	6	18	13	8	12	11	6
3.Behavioral change	25	7	7	24	14	8	15	8	7	16	10	8
4.Autonomic reaction	11	4	4	8	7	4	8	4	4	8	4	4
5.Water retention	12	9	7	14	11	8	16	15	8	12	9	8
6.Negative affect	37	24	14	32	29	11	31	20	11	26	22	11
7.Arousal	8	15	17	8	10	11	5	7	17	6	7	12
8. control	8	11	9	9	9	6	6	6	6	6	6	6
9. Appetite changes	5	3	1	1	1	1	4	3	1	4	2	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	10	10	6	7
How intense was it the week before your periods started?	7	6	4	4
How distressing was it during your recent periods?	9	10	6	7
How distressing was it the week before your periods started?	6	4	3	4
How did it interfere with your daily life?	10	10	7	8
How much has the treatment relieved the pain?	70%	10%	50%	50%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Panado: 2 pills Took them on the first day.	Panado: 2 Pills Took them on the first day.	Panado: 2 pills Took them on the first day.	Panado: 2 Pills Took them on the first day.

PARTICIPANT NUMBER 24
Age: 20 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	7	8	8	7	6	7	7	6	6	8	7	6
2.Concentration	18	13	7	11	5	6	8	6	6	15	6	6
3.Behavioral change	12	10	8	12	7	7	13	7	8	12	7	7
4.Autonomic reaction	8	9	6	6	6	4	4	4	4	4	4	4
5.Water retention	12	10	8	12	7	7	13	7	8	8	4	4
6.Negative affect	16	15	10	15	8	8	10	8	8	8	8	8
7.Arousal	5	5	7	5	5	5	5	5	5	5	5	5
8. control	8	7	6	6	6	6	6	6	6	6	6	6
9. Appetite changes	3	3	2	2	1	1	1	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	10	5	3	1
How intense was it the week before your periods started?	8	3	1	2
How distressing was it during your recent periods?	9	2	3	0
How distressing was it the week before your periods started?	6	3	0	0
How did it interfere with your daily life?	5	3	4	1
How much has the treatment relieved the pain?	30%	90%	90%	80%

PAINKILLERS TABLE			
Baseline 1st consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Grandpa: 2Pills Took them on the first day.	None The pain wasn't too intense.	None She only felt little pain.	None

PARTICIPANT NUMBER 25
Age: 18 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	15	12	15	14	6	6	15	8	6	9	6	6
2.Concentration	8	6	6	6	6	6	8	6	6	10	6	6
3.Behavioral change	12	7	9	11	7	7	8	7	7	10	6	6
4.Autonomic reaction	12	4	6	4	4	4	12	4	4	5	4	4
5.Water retention	6	4	4	5	4	4	5	4	4	7	4	4
6.Negative affect	11	8	9	12	8	3	12	8	8	14	13	8
7.Arousal	7	6	8	8	5	5	5	5	5	5	5	5
8. control	10	7	8	9	6	6	11	6	6	15	7	9
9. Appetite changes	3	1	2	1	1	1	4	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	8	7	3	2
How intense was it the week before your periods started?	0	0	1	0
How distressing was it during your recent periods?	5	6	4	2
How distressing was it the week before your periods started?	0	0	0	0
How did it interfere with your daily life?	5	2	2	1
How much has the treatment relieved the pain?	30%	20%	70%	80%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Ibuprofen: 2 Pills She took them on the first day.	None	None The pain wasn't too bad	None

PARTICIPANT NUMBER 26
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic complex

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st Consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	17	7	7	12	15	8	16	13	8	11	7	7
2.Concentration	8	6	6	6	6	6	7	6	6	6	6	6
3.Behavioral change	13	7	7	8	8	7	9	8	7	9	7	7
4.Autonomic reaction	11	4	4	8	8	7	5	5	5	9	7	7
5.Water retention	6	5	4	5	5	4	5	5	4	6	5	4
6.Negative affect	18	10	8	11	12	8	12	12	8	8	8	8
7.Arousal	5	5	5	5	5	5	5	5	5	5	5	5
8. control	9	5	5	7	7	6	7	7	6	7	6	6
9. Appetite changes	1	1	1	1	1	1	1	1	1	1	2	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	5	5	7	5
How intense was it the week before your periods started?	3	4	4	4
How distressing was it during your recent periods?	7	0	3	6
How distressing was it the week before your periods started?	3	5	2	3
How did it interfere with your daily life?	8	3	3	5
How much has the treatment relieved the pain?	10%	50%	40%	40%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
None She drinks a lot of cold or hot water	None	Panado: 2 Pills Took them on the first day.	None

PARTICIPANT NUMBER 27
Age: 18 years
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1ST consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	12	12	12	12	10	10	7	6	6	7	6	6
2.Concentration	13	13	13	11	11	11	12	7	7	9	6	6
3.Behavioral change	17	17	17	17	11	11	12	6	6	12	7	7
4.Autonomic	6	6	6	4	4	4	6	5	5	6	5	4
reaction												
5.Water retention	8	8	8	9	9	6	11	4	4	10	6	4
6.Negative affect	18	18	18	13	11	11	13	8	8	13	8	8
7.Arousal	9	9	9	7	8	9	8	6	6	8	5	5
8. control	13	13	13	10	9	9	11	7	7	13	7	7
9. Appetite changes	3	3	3	2	4	2	2	2	2	3	2	2

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	8	8	3	4
How intense was it the week before your periods started?	9	0	0	1
How distressing was it during your recent periods?	8	7	3	3
How distressing was it the week before your periods started?	8	7	0	2
How did it interfere with your daily life?	6	0	2	3
How much has the treatment relieved the pain?	60%	40%	70%	80%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Disprin or panado: 2pills Took them at once on the first day.	Panado: 2Pills Took them on the first day.	None	None

PARTICIPANT NUMBER 28
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic complex
Homoeopathic remedies prescribed but not dispensed

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1ST consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	10	10	10	14	6	6	13	13	13	14	6	6
2.Concentration	8	8	8	6	6	6	11	11	11	8	8	8
3.Behavioral change	14	14	14	7	7	7	10	10	10	10	10	10
4.Autonomic reaction	5	5	5	7	4	4	5	5	5	7	5	5
5.Water retention	9	9	9	9	4	4	8	8	8	9	8	8
6.Negative affect	8	8	8	8	8	8	9	9	9	9	9	9
7.Arousal	9	9	9	10	5	5	7	7	7	8	8	8
8. control	6	6	6	7	8	6	6	6	6	8	7	7
9. Appetite changes	1	1	1	1	1	1	1	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	7	7	2	3
How intense was it the week before your periods started?	9	2	1	1
How distressing was it during your recent periods?	8	8	3	2
How distressing was it the week before your periods started?	7	0	1	1
How did it interfere with your daily life?	5	4	5	4
How much has the treatment relieved the pain?	80%	30%	40%	50%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
Panado: 2 Pills She took them at once.	None	None	None

PARTICIPANT NUMBER 29 - Dropped out of the study
Age: 19 years
Race: African
Occupation: Student
Group: Homoeopathic complex

PARTICIPANT NUMBER 30
Age: 20
Race: African
Occupation: Student
Group: Homoeopathic similimum

MOOS MENSTRUAL DISTRESS QUESTIONNAIRE												
	Baseline 1st consultation			**1st Follow-up**			**2nd Follow-up**			**3rd Follow-up**		
	A	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**	**A**	**B**	**C**
1.Pain	14	14	6	16	11	7	10	9	8	12	9	8
2.Concentration	10	12	6	13	11	7	8	7	7	8	7	6
3.Behavioral change	19	13	11	16	12	10	14	13	12	14	11	7
4.Autonomic reaction	4	4	4	4	4	4	4	4	4	4	4	4
5.Water retention	12	10	8	11	8	7	10	7	7	10	8	8
6.Negative affect	12	14	8	20	19	15	19	18	15	16	13	11
7.Arousal	11	11	11	6	6	6	6	6	6	6	6	6
8. control	6	6	6	10	10	9	11	11	9	11	11	9
9. Appetite changes	1	1	1	1	1	1	1	1	1	1	1	1

A: Most recent flow.
B: The week before the flow.
C: the rest of the month.

PAIN RATING SCALE				
	Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
How intense was your pain during your recent periods?	5	6	3	5
How intense was it the week before your periods started?	0	0	0	1
How distressing was it during your recent periods?	4	2	4	4
How distressing was it the week before your periods started?	0	4	0	1
How did it interfere with your daily life?	6	8	1	2
How much has the treatment relieved the pain?	60%	20%	20%	50%

PAINKILLERS TABLE			
Baseline 1st Consultation	**1st Follow-up**	**2nd Follow-up**	**3rd Follow-up**
None	None	None	None