

**A randomised controlled trial studying the effects of the copper
intrauterine device and the injectable progestogen contraceptive
on depression and sexual functioning of women in the
Eastern Cape**

By

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Thesis Presented for the Degree of

DOCTOR OF PHILOSOPHY

In the Department of Nursing, Faculty of Health Sciences.

University Of Cape Town

May 2014

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Declaration

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Dedication

To my son, Sandisele Sakhane Madliki, and daughter, Somelezo Siyolise Madliki; you two have inspired me so much to complete this research. Mommy loves you so much.

To my husband, Xolile Madliki, your support, patience, and understanding have made it all possible for me to complete this journey.

Abstract

A lack of contraception use and contraceptive method discontinuation are common causes of unintended pregnancy in the Eastern Cape. The most common reason for method discontinuation among childbearing women is the unacceptable side effects of their contraceptive choices. Both depression and sexual dysfunction are given as side effects of contraceptive use; however, there is little evidence to support these effects. This randomised, single-blind controlled trial conducted in East London, South Africa, investigated the effects of the initiation of a long-acting injectable contraceptive, Depot Medroxyprogesterone Acetate (DMPA), compared with the initiation of a copper Intrauterine Contraceptive Device (Cu-IUD) after childbirth on depression and sexual functioning. After counselling, 242 consenting pregnant women were randomised to receive DMPA or a Cu IUD within 48 hours of childbirth, in a ratio of 1:1. Primary outcome measures were depression and sexual dysfunction evaluated by validated instruments. Questionnaires were administered at baseline, and telephonically at one month and three months after randomisation. The telephonic interviewer was blinded to the participants' group allocation. English and Xhosa versions of the Beck Depression Inventory and the Edinburgh Postnatal Depression Scale were used to assess depression. The Arizona Sexual Functioning Scale was used to assess sexual functioning. For these primary outcomes, median scores between the intervention groups were compared, as well as the number of events (dichotomous data) in each intervention group. The relative effects of these interventions were summarised by calculating risk ratios, with 95% confidence intervals. Statistical tests used included the Shapiro-Wilk test, T-test, and Wilcoxon test. There were not consistently statistically significant differences in the risk of depression or sexual dysfunction between the intervention groups in this study. However, there was a trend towards more depression in the DMPA group which was statistically significant for mean EPDS score at the one month and for the BDI score three month assessments compared with the IUD group. There was also a trend to more sexual dysfunction with DMPA, but the only statistically significant difference was that fewer women in the DMPA group resumed sexual intercourse within the first month of treatment than in the IUD group. The author's recommendations from the study are that, firstly, family planning providers should inform women during contraceptive counselling that there is no certainty that DMPA causes depression and/or sexual dysfunction; however, it may do so in the postpartum period. Secondly, contraceptive users can continue to use DMPA with confidence as a convenient and effective method of preventing unintended pregnancy. Thirdly, the trend towards postpartum depression and sexual dysfunction in the DMPA group of this study justifies further research with a larger sample size, to include women from various social settings, and for a longer period of follow-up. Lastly, the Cu-IUD is a good alternative to DMPA in women who experience intolerable effects with the latter.

Acknowledgments

This thesis is the culmination of a study based on postpartum depression, and sexual functioning. I am indebted to the following for their encouragement, continuous support and assistance:

Professor Doris Khalil, my Advisor, for her comments that moulded this work. Professor Justus Hofmeyr, who believed in me and encouraged me to conduct this study, and to further my studies; Henri Carrara , Biostatistician at UCT for his advice on statistics; Tina Purnat for continuous support and assistance despite her own busy schedule; Professor Cheryl Nikodem without whom I would not have had the invaluable assistance of the research team; and my colleagues at the Effective Care Research Unit: Amwe Aku, Noxanti Nondlwana, Xoliswa Williams, Pamela Njikelana, Angel Phuti,Tapiwa Gundu,Carol Phipson, Mzwabantu Gqoboka, Phumla Mvango, Nolukhanyo Madliki, Nomthandazo Monakali, Thembeke Likota, Ntombekaya Betsha, Nontuthuzelo Toto, Sindiswa Nduneni, Zodwa Fawule, Xoliswa Manyisane, Nomvuyiseko Mbinda and Vuyelwa Mqashane.

Tess Lawrie thank you for your great work, Annette Peters and Ana Pilar Betran, and all the doctors and Midwives of the O&G department (East London Hospital Complex) for their assistance.

I would also like to acknowledge the support of my family and friends and to thank Nowethu Ben, for looking after my children in my absence.

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List of Abbreviations

ASEX	Arizona Sexual Experience Scale
BDI	Beck Depression Inventory
CES-D	Centre for Epidemiology Studies Depression Scale
CHC	Combined hormonal contraception
CIC	Combined injectable contraception
COCs	Combined oral contraceptive pills
Cu-IUD	Copper intrauterine device
DMPA	Depot medroxyprogesterone acetate
DOH	Department of Health
EPDS	Edinburgh postnatal depression scale
IUD	Intrauterine device
LAM	Lactational amenorrhoea method
LNG-IUS	Levonorgestrel releasing intrauterine system
LARC	Long-acting reversible contraception
MDG	Millennium Development Goal
NET-EN	Norethisterone Enanthate
PID	Pelvic inflammatory disease
PPD	Postpartum depression
POC	Progestogen-only contraceptive
RCT	Randomised controlled trial
STI	Sexually transmitted infection

TOP	Termination of pregnancy
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Glossary of Terms

Terms	Definitions
Adverse effects	Unfavourable, unpleasant and potentially harmful effects.
Amenorrhoea	No evidence of monthly menstruation.
Contraception	Methods and ways of avoiding getting pregnant.
Depression	It is a common mental disorder characterized by depressed mood and sleep disturbances.
Depot Provera	An injectable preparation of medroxyprogesterone acetate (DMPA) administered three-monthly for pregnancy prevention.
Norethisterone	An injectable preparation of a 19-nortestosterone derivative administered two-monthly for pregnancy prevention.
Ectopic pregnancy	Type of pregnancy that occurs outside the womb, in either the fallopian tubes or the abdomen.
Endometrial cancer	Cancer of the lining of the uterus
Family planning	Indicates ways and means used to plan or space children during active childbearing period.
Genital tract infection	Infections of any part of the genital organs.
Injectable contraceptives	A method to control or prevent pregnancy by administering hormone preparations in the form of injections.

Intra-uterine device (IUD)	A small plastic device about the size of a five-rand coin, which is inserted into the uterus to prevent pregnancy.
Irregular vaginal bleeding	Any form of bleeding through the vagina that is not part of the monthly period.
Sexual function	The perceived quality of the person's sexual life and relationships.
Menopause	The cessation of the menstrual period in women between the ages of 45-65 years.
Oligomenorrhoea	Infrequent or very light menstruation.
Peri-menopausal women	The period ranging from 5-10 years before the onset of cessation of the menstrual period in women between the ages of 45-65 years.
Randomised trial	A study design where willing people are allocated into groups by chance, to determine the efficacy of an intervention.
Randomisation	Allocation into groups by chance.
Trial	A way of testing the efficacy of a specified intervention.
Unintended pregnancy	A situation where a woman finds herself pregnant without planning to become pregnant.
Unwanted pregnancy	A situation where a woman finds herself pregnant and does not want to keep the baby.
Fibroid	Benign muscular growth in the uterus.
Polyp	Growths (usually benign) inside the uterus which some medical experts believe are linked to infertility.
Nulliparous	A woman who has never given birth to a child.

Chapter 1: Introduction

1.1 Introduction

This chapter gives an overview of the unintended pregnancy burden as the basis for this study. This is followed by purpose of the study; research question and study hypothesis explanation. Thereafter, the significance of the study and overview of the research design used to answer the study question and to test the hypothesis are described.

1.2 Background

There is an epidemic of unintended pregnancy globally, with profound consequences for women, their families, and their communities (Gipson, Koenig & Hindin, 2008a). In 2012, it was estimated that over 222 million women have an unmet need for modern contraception (Singh S and Darroch JE, 2012). This need is greatest where the risks of maternal mortality are highest (Singh S and Darroch JE, 2012).

Two-thirds of pregnancies worldwide are unintended (WHO and Gutmacher Institute, 2007). Unintended pregnancies may have significant risks for women and their families (Cheng et al., 2009; Gipson, Koenig & Hindin, 2008a). Women with unintended pregnancies that are continued to term are more likely to receive inadequate or delayed prenatal care, and have poorer health outcomes such as low infant birth weight, infant mortality, and maternal mortality and morbidity (Cheng et al., 2009; Gipson, Koenig &

Hindin, 2008b; Hook, 1963; Kost, Landry & Darroch, 1998; Najman et al., 1991). The unmet need for modern contraception is a significant contributor to unintended pregnancy (Mqhayi et al., 2004). Two-thirds of unintended pregnancies occur in women not using any method of contraception (WHO and Gutmacher Institute, 2007). Many women at risk of unintended pregnancy may be interested in using contraception, but are unable to do so due to barriers to accessing contraception services; or they may choose not to use contraceptives due to concerns about health consequences and side effects.

Contraceptive failure or non-use of contraception due to lack of access or unacceptable side effects are common causes for unintended pregnancy, many of which end in Termination of pregnancy (TOP) (Bankole, Singh & Haas, 1998). Locally, in East London, (a city in one of nine South African provinces), two-thirds of babies born at Cecilia Makiwane Hospital were results of unplanned pregnancies (Mshweshwe, 2008). Furthermore, examination of records from two TOP clinics at local hospitals (Cecilia Makiwane and Frere Hospitals) reveals that more than 4,000 TOP's are performed annually (author's examination of hospital records). The records demonstrate a high burden of unintended pregnancy within the East London Municipality.

Researchers worldwide have been discussing the issue of contraceptive use, non-use and its effects for many years (Bryant, 2009; Draper et al., 2010; Frost, 2008; Gakidou & Vayena, 2007). In 2005 at the World Summit of the

United Nations, most Governments committed to “achieve universal access to reproductive health by 2015” for their populations (Assembly, 2005). Again in 2010 at the United Nations General Assembly meeting on the Millennium Development Goals, Governments committed to “ensuring that all women, men and young people have information about, access to, and choice of wide possible range of safe, effective and acceptable methods of family planning” (United Nations, 2012).

At the time of writing, the author has been employed at the Effective Care Research Unit of the East London Hospital Complex in the Eastern Cape of South Africa as a Midwife and Researcher for the past twelve years (12) years. In her experience as a midwife, she has come across pregnant women who are still dependant on their parents for financial support, or who are from very poor families... Based on these daily observations, one is forced to ask the question, “How are the available family planning methods failing to meet women’s sexual health needs?”.

To understand why some women continue to choose TOP rather than consistently a reliable method of contraception, the researcher has spoken to women accessing reproductive health care services. Several remarks from informal discussions with women of reproductive age indicated that their non-use of contraceptives was because of the side effects. To quote an example of such comment, one woman stated, “I am not going for the injection again. I cannot lose my boyfriend because he always complains that when I use the injectable contraceptive, he does not enjoy having sex with

me". Another woman, told the researcher "I do not like the altered mood effects of the Depo injection" medroxyprogesterone acetate (DMPA).

Unacceptable side effects are the most common reason for discontinuation of contraception(Barden-O'Fallon et al., 2009; Gilliam et al., 2004; Paul, Skegg & Williams, 1997).While it had been found that hormonal contraception can alter menstruation(Abdel-Aleem et al., 2007; Berenson et al., 2008), limited data exists to support the possible interaction between hormonal contraception and mood or sexual functioning(Folger et al., 2013;World Health Organisation, 2009).

During the development of medical eligibility criteria for contraceptive use, the World Health Organisation and the Centres for Disease Control identified a research gap about the association between hormonal contraception and depressive disorders (WorldHealth Organisation,2009).The question identified was, "Does the use of hormonal contraceptives exacerbate depressive disorders, including postpartum depression?"(Folger et al., 2010).

Hence revised contraceptive guidelines produced by the South African Government Department of Health (2012) do refer to mood swings as a possible side effect of Depo-Provera. The South African Minister of Health, Dr Aaron Motswaledi, made a call in his preamble of the contraceptive guidelines to health workers to prioritise evidence-guided care, by ensuring that policy is informed by local research (Department of Health, 2012).

Unintended pregnancy is a problem in the East London setting; fear of side effects, or side effects actually experienced by users, are likely contributors to unintended pregnancy and the high prevalence of abortion in East London. The question of whether DMPA leads to depression or sexual dysfunction, remain unanswered and of public health importance.

1.1. Statement of the Problem

Contraceptive non-use and method discontinuation are common causes of unintended pregnancy (Paul, Skegg & Williams, 1997). Several studies have reported that unacceptable side effects are a common reason for contraceptive method discontinuation (Barden-O'Fallon et al., 2009; Brunner Huber et al., 2006; Gilliam et al., 2004; Paul, Skegg & Williams, 1997).

Berga and Smith (2012) theorise that depot medroxyprogesterone acetate (DMPA) suppresses endogenous ovarian function as well as producing progestin dominant hormonal exposure. These changes can potentially affect both libido and the functioning of the reproductive tract. The authors hypothesize that decreased oestrogen results in less vaginal lubrication, thereby leading to sexual dysfunction (Berga & Smith, 2012).

This study compares the relative effects of two long acting contraceptive methods (DMPA versus the non-hormonal copper intrauterine device (Copper T380a [Cu-IUD]), on depression and sexual dysfunction in women postpartum for a duration of three months. Both depression and sexual dysfunction are given as potential side effects of hormonal contraceptive use (Westhoff et al., 1998); however, limited evidence exists to support this claim.

The Cu-IUD is a non-hormonal method, with no proven or theoretical risk of depression or sexual dysfunction (Gabalci & Terzioglu, 2010); therefore, the Cu-IUD method provides a good 'control' comparison with the hormonal intervention (DMPA) evaluated in this study. In a double blind placebo controlled study, injectable Progestogen contraception (Norethisterone Enanthate) in the postpartum period was associated with increased depression and reduced serum estradiol and progesterone levels (Lawrie et al, 1998).The majority of women in South Africa who use a modern contraceptive rely on DMPA(Depo-Provera®) for contraception (United Nations, Department of Economic and Social Affairs, Population Division, 2012).Women react differently to different contraceptive methods, and the use of family planning services is directly linked to the variety of contraceptive options offered to women(Hofmeyr, Singata & Lawrie, 2010).As reported by previous researchers studies, "choice of contraceptive methods depends on many factors such as effectiveness, potential adverse effects or convenience as well as the couple's medical condition, sociocultural profile or reproductive intentions and beliefs"(Lopez-del Burgo et al., 2012; Oddens, 1997).

1.2. Purpose of the Study

The purpose of this randomized controlled trial (RCT) is to determine whether the use of DMPA for contraception, compared to the Cu-IUD, is associated with an increased risk of depression and reduced sexual functioning amongst women of reproductive age in the Eastern Cape, South Africa.

1.3. Justifications for the study

An RCT, conducted in South Africa in Gauteng Province, found that the injectable Norethisterone contraceptive (NET-EN), was associated with an increased risk of postpartum depression at six weeks after delivery, when given to women after the birth of their baby (Lawrie et al., 1998b). However, to the researcher's knowledge, no clinical trials have compared the relative effects of DMPA and NET-EN on postpartum depression; neither has the postpartum effects of these drugs on mood and sexual functioning been compared with the non-hormonal IUD

It was important to the researcher to conduct this study in the Eastern Cape Province because the rate of unintended and unwanted pregnancies in the province requires urgent attention (Mshweshwe, 2008). The counselling during the initiation of any contraceptive method includes discussion of possible side effects of the method (WHO, 2012). Therefore, information obtained about the two possible side effects under investigation in this study would be helpful to inform contraceptive users of both DMPA and IUD.

There is evidence and strong advocacy from various studies that the acceptability of a contraceptive method is increased when users are well informed about its side effects (Blumenthal, Voedisch & Gemzell-Danielsson, 2011; Hubacher et al., 1999; Hubacher et al., 2009). In addition, reliable data on the occurrence of known side effects with any contraceptive method is essential for clinicians in managing patients properly (Barden-O'Fallon et al., 2009).

In light of the detected research gap the present study addresses the following questions:

1.4. Research Questions

- Is there any effect of injectable Progestogen on the risk of depression as compared to the Cu-IUD (Copper T 380A)?
- Is there any effect of injectable Progestogen on sexual functioning as compared to the Cu-IUD?

1.4.1. Hypotheses

Null hypothesis

- There is no statistically significant difference in the incidence of depression between women of reproductive age residing in the Eastern Cape allocated to use the Cu-IUD and those allocated to use injectable DMPA.

-
- There is no statistically significant difference in sexual functioning of women of reproductive age residing in the Eastern Cape allocated to use the Cu-IUD and those allocated to injectable DMPA.

Alternative hypothesis

- The use of injectable DMPA given to women of reproductive age, who wish to practice birth control, will result in a statistically significant difference in the incidence of depression compared to women who received the Cu-IUD.
- The use of injectable DMPA given to women of reproductive age, who want to practice birth control, will result in a statistically significant difference in the level of sexual functioning compared to women who received the Cu-IUD.

1.5. Significance of the Study

Firstly, to the researcher's knowledge this study is unique to Southern Africa with special reference to South Africa. It will provide new evidence to determine whether the injectable DMPA as compared to the Cu IUD has causal effects on depressive symptoms and sexual dysfunction.

Secondly, it will contribute to address unmet needs of women who request DMPA by adding information about possible side effects, such as depression and sexual functioning. The knowledge would enable family planning providers to counsel women requesting contraception.

Thirdly, it will assist policy-makers in drawing up informed guidelines and contraceptive policies. Such informed guidelines would ensure evidence-based practice that would allow for a well thought-out, systematic approach in managing patients with specific needs.

Fourthly, this study might be able to contribute to a systematic review that examines depression and/or sexual functioning based on its study design (a RCT) and the quality of the evidence.

1.6. Overview of the design appropriateness

An RCT is the 'gold standard' for evaluating the effects of clinical interventions. The strength of an RCT, when conducted properly, is that it reduces the risk of serious imbalance of known and unknown factors (Stolberg, Norman & Trop, 2004). One example of these factors is trial treatment non adherence that could influence the clinical outcome (Stolberg, Norman & Trop, 2004).

In this RCT, women were randomized to one of two groups: the injectable DMPA or the Cu-IUD. This means that each woman had an equal chance of receiving either contraceptive method. By randomly allocating participating women to intervention groups, the risk of introducing selection bias into the study was minimized. One can, therefore, be more certain that any differences between the interventions are due to the intervention and not due to differences between the study groups. Randomisation should control various confounding factors, such as HIV infection, stillbirth and age (Katzenellenbogen, G Joubert & S S Abdool Karim, 1997). Without proper

control of confounders, bias can alter a study's findings and cause improper conclusions (Schulz & Grimes, 2002).

The aim of a randomized controlled trial is to classify features, count them, and construct statistical models in an attempt to explain observations (Feldblum et al., 2005). The researcher has used the Consort 2010-statement guidance to report the results of the study to give more clarity, completeness, and transparent reporting (Schulz, Altman & Moher, 2010).

1.7. Study Outcomes

1.7.1. Primary Outcomes

Measured at one month and three months postpartum:

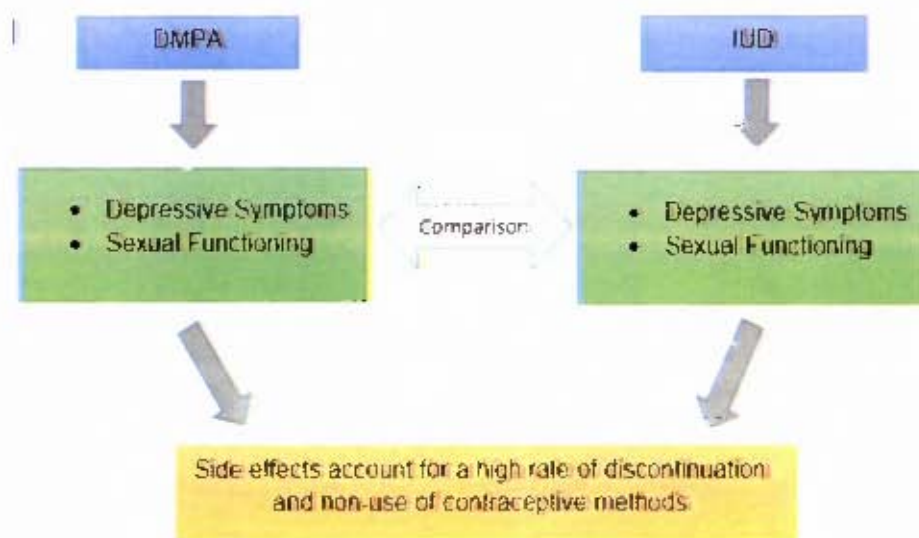
- Mean / median depression scores measured by the EPDS and the Beck Depression Inventory (BDI) (Aaron T. Beck, Robert A. Steer, Gregory K. Brown, 1996).
- Depression (mild to severe) measured by the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden & Sagovsky, 1987).
- Depression (mild to severe) measured by the BDI (Aaron T. Beck, Robert A. Steer, Gregory K. Brown, 1996) at one month and three months postpartum.
- Major depression measured by EPDS and BDI-II.
- Sexual dysfunction as measured by the Arizona Sexual Experience Scale (McGahuey et al., 2000) at one month and three months postpartum.

1.7.2. Secondary Outcomes

Measured at one month and three months postpartum, participants' perceptions about the following outcomes were asked:

- Menstrual flow
- Menstrual pain
- Weight gain
- Weight loss

Figure 1 : Conceptual Framework



1.8. Preview of remaining Chapters of the Thesis

1.8.1. Chapter 2

This chapter describes literature that is relevant to family planning in general. The demographic profile of the Eastern Cape is explored; different contraceptive methods are discussed. Lastly, the literature on the two contraceptive methods evaluated in this study is explored.

1.8.2. Chapter 3

This chapter is divided into two sections. The first section explores literature on depression and, in particular, postpartum depression (PPD). Included is the prevalence of PPD in low and middle income countries, and risk factors of PPD, and the effects of PPD on both mother and baby are discussed. The second section explores literature on sexual functioning, different sexual response cycles, and sexual dysfunction during the postpartum period, and the potential effects of contraception on sexual functioning.

1.8.3. Chapter 4

The chapter presents the hierarchy of study design that led to the need to the selection of a randomised controlled trial methodology to conduct this study. It describes the study design, research sites, study population, sample size calculation, inclusion and exclusion criteria, recruitment and randomisation procedures and the instruments for data collection. It also describes the

results of the pilot study. In addition, this chapter includes the methods for determining validity and reliability of the instruments, data collection, ethical considerations, data management and analysis. Finally, the chapter explains the risks and benefits of taking part in the study, and the referral system put in place to support study participants.

1.8.4. Chapter 5

This chapter presents the flow of participants through the study, baseline characteristics of the sample and the results of primary and secondary outcomes.

1.8.5. Chapter 6

This chapter aims to put into context, discussing associated literature that aids to clarify why the results observed might have been anticipated and how this influence our understanding of DMPA and IUD effect on Depression and Sexual functioning.

Chapter 2: Literature Review

2.1 Introduction

This chapter describes literature that is relevant to family planning in general. The demographic profile of the Eastern Cape is explored; different contraceptive methods are discussed. Lastly, the literature on the two contraceptive methods evaluated in this study is explored.

The choice of birth control method selected by couples depends on several factors. These include factors, such as effectiveness, possible adverse effects and convenience, as well as the couple's medical conditions, sociocultural profile or reproductive intentions and beliefs (Lopez-del Burgo et al, 2012).

2.2 Source of search

A literature search was conducted to gain contextual information and a more in-depth understanding of issues surrounding DMPA and Cu-IUD use internationally and in the Eastern Cape. International and national literature was reviewed to evaluate the existing evidence regarding the impact (if any) of DMPA and the Cu-IUD on depression and sexual function.

The following databases were searched for RCT's comparing progestogen contraceptives with IUD's: MEDLINE, EMBASE, Science Direct, Scopus, Cinahl, Popline, Google scholar and Pascal.

The following keywords were used to search for info:

- Injectable progestogen or DMPA
- Non-hormonal IUD or copper IUD
- "Intra-uterine contraceptive device" OR "Copper T 380A"
- Depression or "mood disorders" or postpartum depression
- Sexual functioning
- Contraceptive side effects

2.3 Demographics of the Eastern Cape

Figure 1: Amatole district Map



2.4 Population profile

According to the mid-year population estimates of 2013 by the South African Statistics Office, the population of South Africa was estimated to be over

fifty-two million (52, 982, 000) and out of this number over forty-two (42, 284, 100) are Black Africans. The Eastern Cape population was estimated at over six million (6, 620 100.00). The Eastern Cape had the third highest population in the nine South African provinces (Statistics South Africa, 2011). The provincial average total fertility rate for the period 2011-2016 was projected as 2.70 for the Eastern Cape, higher than in all other provinces in the country (Stats SA, 2013)..Cross-national quantitative data of seventy-nine (79) low development countries suggest that an economic dependency may have an indirect effect on maternal mortality (Shen & Williamson, 1999).

2.5 *Socio-economics of the Eastern Cape*

Economic conditions are a determinant of most health outcomes(Brennan Ramirez, Baker & Metzler, 2008).A quarterly labour-force survey conducted by Statistics South Africa revealed that the Eastern Cape has an unemployment rate of 30.2% which has increased from 29.3 in the fourth quarter of 2012(Statistics South Africa, 2011).This is an improvement from the unemployment rate of 48.5% which was reported by Zere and McIntyre in their survey 20 years ago before democratic elections in South Africa(Zere & McIntyre, 2003). However, at the time of writing, there are still many women who depend on South African Child Support grants to take care of their families, living below the poverty line of less than R 250 a month, totalling about 8.2 million beneficiaries (Coovadia et al., 2009; Goldblatt, 2005).

Some association has been shown, in a survey conducted in five developed countries, (Canada, France, Great Britain, Sweden and USA), between poverty, unemployment and sexual behaviour as well as use of contraception (Singh, Darroch & Frost, 2001). Despite the high economic status of these countries, high birth rates and lower contraception use were reported in women with socioeconomic disadvantages, compared with the USA, where contraceptive use is high (Singh, Darroch & Frost, 2001). Similarly high birth rates among South African women are associated with socioeconomic disadvantage and minimal education standards (Chopra et al., 2009).

Long-acting reversible contraceptives (LARC) have a low failure rate (Secura et al., 2010) and, by effectively controlling population growth, have the potential to contribute to the eradication of extreme poverty and hunger, “Millennium Development Goal -1(MDG)” (United Nations, 2000; United Nations, 2012).

2.5.1 Rites of passage for women in the Eastern Cape

Transition from childhood varies in different cultural settings; however, biologically a girl converts from being a child to be a woman, ready to bear children, when she has her first menstrual period, as a sign that her body is

now producing eggs for reproduction (Rembeck, Möller & Gunnarsson, 2006)

Amongst the Xhosa's tribes of the Cape of South Africa, there used to be rites of passage (*Intonjane*) for young girls to womanhood (Finlayson, 1998) and virginity testing is undertaken at the end of *intonjane* (Tassiopoulos & Nuntsu, 2005). A difference between a Xhosa girl's initiation and that of girls from other African countries is that it does not involve genital circumcision (Finlayson, 1998; Khalil, 2006). Female genital circumcision is still widely practiced in some African countries although not as high as it used to be (Khalil, 2006).

In other discipline like Anthropology, Silverman (2004) has explored the topic of female circumcision to understand the moral purpose of the practice (Silverman, 2004). Due to increasing migration to South Africa, midwives need to be aware of female circumcision and its impact on maternity care (Berg 2010; Collinet 2004).

2.5.2 Inequalities of role and function between men and women

In some South African communities, there is still the expectation that women are to have children (Wood & Jewkes, 2006), should not go to school, and no investment should be made to educate them (Hari, 1998). These studies support the idea that education is the key for the emancipation of women in South Africa.

This is further supported by the second Millennium Development Goal, which is to achieve universal primary education. MDG-2 cannot be achieved if women continue to have unintended pregnancies (Black, Devereux & Salvanes, 2005). In Norway, larger family size has been shown to have a negative effect on education (Black, Devereux & Salvanes, 2005), as does poor child spacing (Black, Devereux & Salvanes, 2005), (Bates, Maselko & Schuler, 2007). Achieving MDG-2, will contribute towards achieving MDG-3, which is to “Promote gender equality and empower women” (United Nations, 2000). In order to empower women in South Africa and other developing countries, it is necessary to provide confidential reproductive health services to meet their needs, and in order to space pregnancies appropriately.

2.6 *Health services provision in the Eastern Cape*

2.6.1 Health services provision

It is well-recognized that the reproductive health should be accessible, and facilities should provide privacy for women to meet all their reproductive needs (Indigo & Naidoo, 2010; Sheeder, Tocce & Stevens-Simon, 2009). In South Africa, the first point of entry into the health services starts in primary health care settings, which are local clinics that are supposed to be accessible within 10km reach of one’s home (Dookie & Singh, 2012).

In 1996, a policy of an integrated health care approach was adapted by the South African government (Cooper et al., 2004); whereby a reproductive health service should include antenatal services, delivery, postnatal care and family planning (Chopra et al., 2009).

2.7 *Histories of family planning and birth control*

2.7.1 International perspectives

In the early 20th century, use of birth control was disapproved of by the then President of the United States, Theodore Roosevelt. According to Bullough, Roosevelt saw birth control as a weapon to kill the white race (Bullough, 2001). Similarly in South Africa during the apartheid period, emphasis was placed for more vigorous use of contraceptive by blacks than whites population, as black's fertility rate was much higher and this was viewed as a threat to whites population (Burgards & Lee-Rife, 2009).

Margaret Sanger is cited by researchers as the person who established the American Birth Control League in 1921 to open birth control clinics (Chesler, 2007; Sanger, 1920). She managed to set-up the first legal birth control clinic in the US named the Birth Control Clinical Research Bureau (Sanger, 1920). Later on, the American Birth Control League changed its name to the Planned Parenthood Federation, which still exists today (Bullough, 2001).

Reviewing contraceptive use in the USA, Piccinino and Mosher (1998) showed that there was an increase in the use of contraceptives from 56% in

1982 to 64 % in 1995. They also found that female sterilisation increased, from 23.2% in 1983 to 38% 1995(Piccinino & Mosher, 1998). Injectable contraceptives were not used in the 1980's and only 3% used in 1995. Use of the male condom (Piccinino & Mosher, 1998) gradually increased between 1982 and 1995 to 20.4%. Although there were other family planning methods used, IUD usage decrease over time from 7.1% 1982 to 0.8% in 1995 (Piccinino & Mosher, 1998).

History reveals that one of other factors that motivated high fertility was a perception that having a big family is a sign of wealth (Pollak & Watkins, 1993). Findings of WHO and Gutmacher Institute (2007) have showed that in the twentieth century globally two-thirds of pregnancies are unintended as alluded to already in the first chapter.

2.7.2 South Africa

Birth control has been used since 1930 in South Africa(Kaufman et al., 2004). At that time, it was available to the white population group only during the South African apartheid era in the 1970's, modern contraceptives were then promoted among black women (Brown, 1987) and this was perceived by blacks as a political programme to control the population growth of blacks (Brown, 1987; Burgard, 2004). Despite this, South Africa has managed to have a high contraceptive prevalence among all population groups compared to other sub-Saharan African countries(Cooper et al., 2004). The most used contraceptive methods in South Africa are injectable progestogen (mainly DMPA) and oral contraceptives(Mqhayi et al.,

2004).The DOH is, at time of writing, reintroducing other LARC, including the Cu-IUD(Department of Health, 2012).Despite freely available contraceptives, unintended pregnancies are still a challenge (Mqhayi et al., 2004).

2.8 *Types of family planning and birth control methods*

2.8.1 Traditional methods

In the Zulu tribe of KwaZulu Natal province, there is an annual ceremony to check the virginity of girls. This practice discourages girls from engaging in sexual activity until married (Scorgie, 2002).Keeping girls as virgins has an added benefit of birth control and helps in the reduction of new HIV transmission to young girls(Naidu, 2008). However, there are some concerns from researchers who have conducted studies on the practice of *ukuhlolwa* (virginity test) those girls not seen to be good enough to be brides may experience discrimination (Naidu, 2008).

Similarly in Turkey, virginity testing is also conducted. However, the difference with the Zulu practice is that the test is conducted by medical doctors in their private practice, although it is not a legalised practice in Turkey. Some see it as a violation of a woman's freedom to control her own body (Pahinođlu Pelin, 1999).

Withdrawal (*coitus interruptus*) is one of the methods that couples can use to prevent pregnancy but efficacy depends "on the motivation and ability" to

practice the method correctly (WHO, 2012). Its mode of action is the prevention of sperm from entering the vagina. This method has no side effect however it is not protective of HIV and STIs.

The other methods that falls under traditional methods are lactation amenorrhea method (LAM). The mode of action of LAM in preventing pregnancy is ovulation suppression. Reported to be highly effective if a women is fully breastfeeding and has amenorrhoea and less than 6 months postpartum (Trussell, 2011; Van der Wijden, Kleijnen & Van den Berk, 2003; WHO, 2012). Furthermore report from the Eastern Turkey study showed that there was non- adherence to the influential factors of LAM which influence effectiveness , about 82.8% of their participants could not adhere (Türk, Terzioğlu, & Eroğlu, 2010).

LAM has been reported as having the added benefit of preventing mix feeding in a Jordan study (Bongiovanni et al., 2013). Added to that it is reported as a method that has no side effects (Stone-Jimenez, Kouyaté & Bongiovanni).

Fertility awareness-based (FAB) methods are reported to be 75% effective (WHO, 2012). However, women need to be able to identify their fertile window. FAB methods need commitment from both partners as they need to use a condom or abstain from sexual intercourse during the fertile phase period. Although all the traditional contraception need commitment and

discipline but some women use them to avoid side effects of modern family planning methods (Khalaf et al., 2008).

2.8.2 Intrauterine contraception

2.8.2.1 *Copper intrauterine device*

The Cu-IUD is a small device made of plastic and copper, that is placed in the uterus as a method of contraception (Hatcher et al., 2008) . The main mechanism of action of the Cu-IUD is spermicidal (Hatcher et al, 2008). It is one of the most effective forms of contraception available, and is widely used globally (Hatcher et al., 2008; United Nations, 2011).Just like other contraceptive methods, the IUD has some advantages and disadvantages.

Advantages and disadvantages of the Cu-IUD

Advantages include no hormonal effects, no amenorrhoea, and immediate return to fertility on removal of the device (Hatcher et al, 2008). Other advantages of the IUD are that a single insertion lasts up to 12 years, and could be left in place until after the menopause (Bhathena & Guillebaud, 2006; Sivin, 2007). Additionally, the IUD reduces the risk of haemorrhagic stroke compared to combined hormonal methods,(Li et al., 2006) and has a lower rate of discontinuation than other family planning methods (Singh, Roy & Singh, 2010; Winner et al., 2012).In a systematic review Cu-IUD was found to have a lower rate of pregnancy compared to hormonal

contraception (Hofmeyr, Singata & Lawrie, 2010). Also Cu-IUD is safe for use by HIV positive women (Curtis, Nanda & Kapp, 2009; Stringer et al., 2009).

According to El-Hefnawy et al, (2008) the main disadvantages of IUDs are that the first insertion may be painful, and requires a skilled provider to insert. Other disadvantages include increased menstrual flow, painful menstruation, and rare complications include uterine perforation and expulsion of the device (El-Hefnawy et al., 2008).

Nevertheless, modern Cu-IUDs are safe, effective, and quickly reversible LARCs that require little attention after insertion (Salem, 2006). Declining use of the Cu-IUD in Ghana has been attributed to rumour about adverse effects, and worries about vaginal bleeding and weight loss (Osei et al., 2005).

Assessment of research findings, translated into guidance by the World Health Organization (WHO), should help encourage providers that most women can use Cu-IUDs (Salem, 2006; World Health Organization. Reproductive Health, 2010).

According to Zhou & Xiao (2001), the main reasons for requesting removal of the Cu-IUD are heavy menstrual bleeding and pain (Zhou & Xiao, 2001). A randomized trial of prophylactic ibuprofen found no reduction in removal rates with this treatment (Hubacher et al., 2006), while other randomised trials found that the increase in menstrual blood loss with the IUD was prevented with ibuprofen (Grimes et al., 2006), tranexamic acid (Ylikorkala &

Viinikka, 1983) and to a lesser extent diclofenac sodium (Hubacher et al, 2006).

2.8.2.2 *Levonorgestrel releasing intrauterine system*

Levonorgestrel intrauterine system(LNG-IUS),marketed under the brand name Mirena (WHO, 2012), is a T-shaped plastic device that steadily releases small amount of Levonorgestrel (progestin) each day (French et al., 2003).LNG-IUD prevents pregnancy by suppressing the growth of endometrium (WHO, 2012). It a highly effective contraceptive method, with an advantage of high continuation rate similar to the Cu-IUD (Shaamash et al., 2005), and can also be used to reduce heavy menstrual flow (Baldaszi, Wimmer-Puchinger & Lösckke, 2003; French et al., 2004).However, it is much expensive when compared to the Cu-IUD(Trussell et al., 2009).

2.8.3 Hormonal contraception

2.8.3.1 *Combined hormonal contraceptive*

The combined oral contraceptive (COC), vaginal ring and patch all work in the same way by inhibiting follicular development, growth of the endometrial lining, and ovulation (Department of Health, 2012; Edelman et al., 2010). Oral contraceptives improve dysmenorrhea, acne and are reported to lower the risk of pelvic inflammatory disease (PID) (Mishell, 2010).

However, COCs have some disadvantages as well. They have a high rate of method discontinuation (Westhoff et al., 2007a; Winner et al., 2012) and

require daily intake for perfect use or it may result in unintended pregnancy (Blumenthal, Voedisch & Gemzell-Danielsson, 2011). Irregular bleeding is also another adverse event experienced by OC users (Barden-O'Fallon et al., 2009; Gilliam et al., 2004; O'Connell, Davis & Kerns, 2007a; Sabatini & Cagiano, 2006; Westhoff et al., 2007b).

Progestogen only contraceptives

Progestogen-only pills

Progestogen-only pills (POP's) are estrogen-free oral contraceptives containing very low doses of synthetic progestogen. They prevent pregnancy by thickening the cervical mucus and, sometimes preventing ovulation (Amy & Tripathi, 2009). POP can be an alternate option for women who want to use oral contraceptives, but cannot use COC (de Melo, 2010). Some mood changes with POPs (particularly, those with Levonorgestrel) have been reported (Lakha et al., 2007) and irregular bleeding as a side effect (de Melo, 2010).

Injectable Progestogens

There are two injectable Progestogen contraceptive preparations: Depo-Provera® (DMPA 150 mg) which is given every twelve weeks (Hatcher et al, 2008), and NurIsterate ® (Norethisterone Enanthate 200 mg or NET-EN), given every eight weeks and which is effective for a shorter period than DMPA (Rivera, Yacobson & Grimes, 1999).

These two injectable have been in existence since the 1960's (Kaunitz, 2001). At the time of writing, DMPA and NET EN are the most common contraceptives used in South Africa (Department of Health, 2012; Mqhayi et al., 2004). About 80% of contraceptive users in South Africa are on progestogen injectable contraception (Ortayli, 2006).

Injectable progestogens have several mechanisms of action for preventing unintended pregnancy including, blocking ovulation, thinning the lining of the uterus, and thickening cervical mucus to act as a barrier to sperm. (Haider & Darney, 2007; Hatcher et al., 2008; Kaunitz et al., 2009).

Advantages and disadvantages of injectable Progesterone contraceptives

There is general consensus in the literature that DMPA is highly effective as a contraceptive, and convenient, as only needs to be administered once in 12 weeks (Burke, 2011; Draper et al., 2006; Haider & Darney, 2007; Hatcher et al., 2008).

The DMPA pregnancy rate was found to be 0.3 % with perfect use and 3% with typical use (Trussell, 2004). It is probable that pregnancy rates decrease with duration of use (Kaunitz et al., 2009).

DMPA effectiveness is independent of daily intervention as it is for the oral contraceptive as discussed in the previous section. In addition to these other advantages DMPA can be used in various conditions, where there is a contra-indication to estrogen, i.e. coronary artery disease (Guilbert et al., 2009). It has the non-contraceptive benefit of decreasing the risk of

endometrial cancer (Thomas & Ray, 1991; Wernli et al., 2006), iron deficiency anaemia (Cullins, 1996), and uterine leiomyoma's (Lumbiganon et al., 1996).

On the other hand, injectable progestogen has disadvantages, which may lead to discontinuation and thus unintended pregnancies. In a Cochrane systematic review conducted by (Draper et al., 2006), the rate of discontinuing injectable methods within 12 months was found to be 49% for DMPA, and 48% for NET ET. The main reason given for discontinuation was menstrual disturbances (Draper et al., 2006). Similarly, in a retrospective study that was conducted in Iran more than eight hundred previous DMPA users, (41.3%) discontinued after the first injection and 19% discontinued after the second injection. Menstrual disturbances were the primary reasons for discontinuation (Adeyemi & Adekanle, 2012; Hajikazemi, Nikpour & Haghani, 2004; Wood & Jewkes, 2006). Vaginal estrogen supplementation during DMPA initiation may reduce the risk of irregular vaginal bleeding (Dempsey, Roca & Westhoff, 2010).

In a systematic review of a hormonal implant (LNG implant) and DMPA (Hubacher et al., 2009), 12% of 1610 DMPA users had amenorrhea compared with 11% of 1629 LNG implant users in the first 90 days of use (Hubacher et al., 2009).

DMPA has been reported to cause weight gain in users (Haier & Draney, 2007; Nitrade, Abash & Shaffer, 2013; Vickery et al., 2013; Westhoff et al., 2007b). A study by (Beksinska et al., 2010) of new adolescent users of hormonal contraception, non-users and discontinuers reported that weight

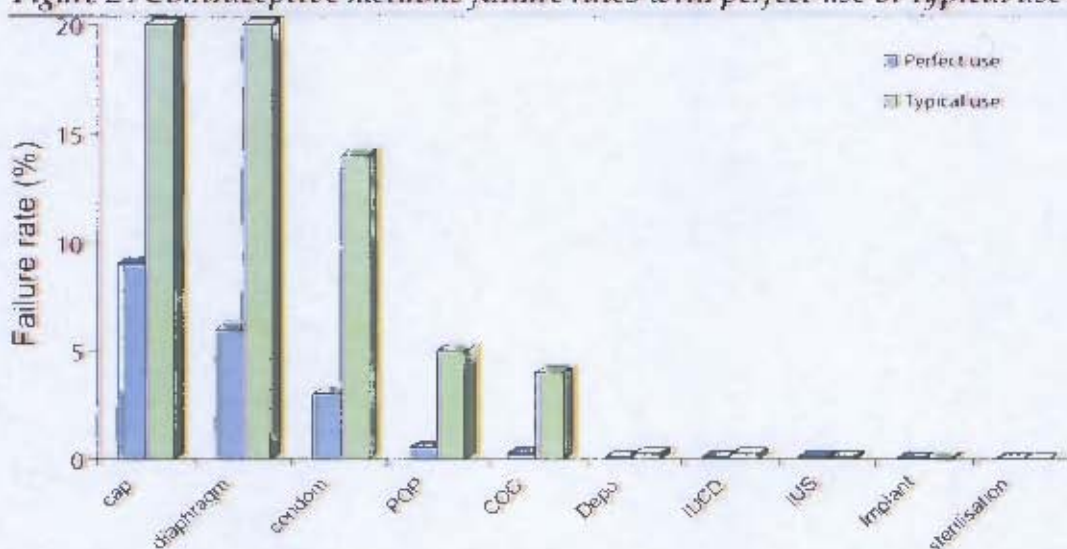
gain among injectable contraceptive users was more than twice that of other methods (Beksinska et al., 2010). Without ready access to alternative methods, many women feel compelled to continue with a method they are not happy with, or to stop contraceptive use altogether (Gilliam et al., 2004).

There are some controversies around initiation of hormonal contraception before 6 week postpartum in breastfeeding mothers and WHO made a recommendation that DMPA and NET-EN can only be used before 6 weeks if other methods are not available (WHO, 2009). But report from other researchers is reassuring that they could not establish negative effects of hormonal contraceptive on lactation (Espey et al., 2012; King, 2007; Truitt et al., 2009). In the South African guidelines (Department of Health, 2012), there is no restriction of the use of progestogen only contraceptives therefore the use of DMPA in this study was possible as it is routinely administered to women before they are discharge postpartum (Hani et al., 2003; Peltzer, Chao & Dana, 2009).

One other controversy about hormonal contraception is an association with HIV transmission and disease progression (Baeten, Lavreys & Overbaugh, 2007; Heffron et al., 2012; Morrison & Nanda, 2012; Polis et al., 2011). In a Cochrane systematic review that compared contraceptive and non-contraceptive benefits and risks of using DMPA as compared with Cu IUD (Hofmeyr, Singata & Lawrie, 2010) HIV disease progression was increased in the depot progestogen group (RR 0.58; 95% CI 0.39 to 0.87). Mixed hormonal contraceptives were used in Stringer (1997), RCT that was included in the

previously mentioned review (Stringer et al., 2007). Systematic reviews that were conducted concluded that evidence about hormonal contraception risk of HIV transmission and disease progression is still limited advocating for more confirmation from (Curtis, Nanda & Kapp, 2009; Polis, Phillips & Curtis, 2013).

Figure 2: Contraceptive methods failure rates with perfect use or typical use



POP: Progestogen only pill; COC: Combined oral contraceptive pills; IUS: Intrauterine system; IUD; Intrauterine contraceptive device. (Fleming, 2009)

2.8.4 Abortion

When services for family planning are not available to young adults and women and in situations where there are barriers to accessing these services, some women resort to abortion (Mqhayi et al., 2004). Abortion is the termination of pregnancy and, in most situations, the pregnancy is

unwanted. An estimation of 45.8 million abortions occurred in 2008 worldwide (Sedgh et al., 2012), nearly half of which are reported to be unsafe (World Health Organization, 2012). In South Africa there has been a growing need for termination of pregnancy services (Cooper et al., 2004).

Women who resort to terminating an unintended pregnancy have been shown to be more able to protect their education opportunities (Fergusson, Boden & Horwood, 2007). South Africa is one of the countries where abortion is legalised, however, abortion is also viewed as a non-Godly act (Patel & Kooverjee, 2009) and some religions are completely against termination of pregnancy, advocating for pro-life (Ellison, Echevarría & Smith, 2005).

2.9 Summary of chapter

This chapter has explored the contexts in which this study is taking place on. Different methods of family planning and contributory factors to contraception non-use have been discussed. DMPA and Cu IUD advantages and disadvantages have been explored.

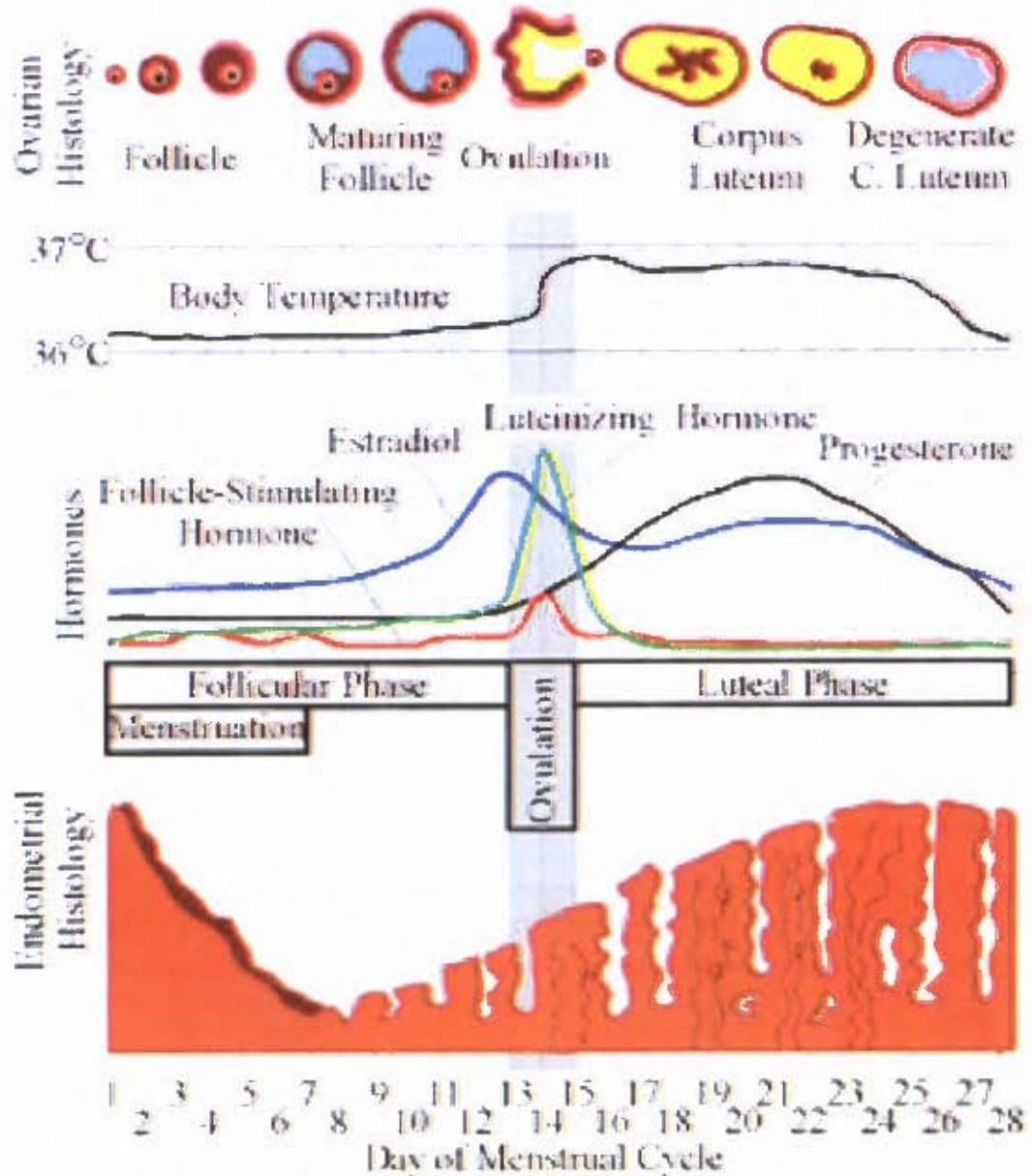
Chapter 3: Depression and Sexual Functioning

3.1 Introduction

This chapter is divided into two sections. The first section explores literature on depression and, in particular, postpartum depression (PPD). Included are the prevalence of PPD in low and middle income countries, and risk factors of PPD, and the effects of PPD on both mother and baby are discussed. The second section explores literature on sexual functioning, different sexual response cycles, and sexual dysfunction during the postpartum period, and the potential effects of contraception on sexual functioning.

3.2 Physiology of Progesterone and estrogen

Figure 3 : Hormonal fluctuation in menstrual cycle



(Average values. Durations and values may differ between different females or different cycles.)

Adapted: with permission from Lippincott Williams and Wilkins/Wolters Kluwer Health. Obstetrical & Gynaecological Survey (Farage, Neill & MacLean, 2009), copyright 2014

3.2 *Depression*

3.2.1 Prevalence of Depression

According to the national representative survey which was conducted between 2002 and 2004, the lifetime prevalence of major depression in South Africa is 9.8% and the twelve month prevalence is 4.9% (Tomlinson et al., 2009).

In comparison, the prevalence estimates for a major depressive episode (MDE) of 10 developing country populations (Belgium, France, Germany, Israel, Italy, Japan, Netherlands, New Zealand, Spain and America) are 14.6% and 5.5% for an average lifetime prevalence and twelve month prevalence, respectively (American Psychiatric Association & American Psychiatric Association. Task Force on DSM-IV., 1994; Bromet et al., 2011). Postpartum depression presents in the same way as major depression; the only difference is the timing of the occurrence of symptoms of depression (Najman et al., 2000).

Women are said to be twice as prone to depression as men, as shown by various studies conducted both internationally and in South Africa; Tomlinson males and females have sex hormones that may influence mood, however levels of these hormones differ. The dominating sex hormones in females are both progesterone and oestrogen (Douma et al., 2005). Postpartum depression presents in the same way as major depression, the only difference is the timing of the occurrence of symptoms of depression (Najman et al., 2000).

3.2.2 Postpartum depression

Postpartum depression (PPD), also known as postnatal depression, is a psychological disorder that occurs after childbirth (American Psychiatric Association & American Psychiatric Association. Task Force on DSM-IV., 1994). It frequently begins with postpartum 'blues', a condition that presents with weeping, sadness, uncontrolled and depressed mood, irritability, anxiety and sleeplessness (Alici-Evcimen & Sudak, 2003). These signs frequently occur around the fourth day after childbirth and the mother's condition gradually improves by the tenth day (Alici-Evcimen & Sudak, 2003).

According to the Diagnostic and Statistical Manual of mental disorder's (DSM-IV), when postnatal blues does not improve within four weeks of childbirth it is then defined as postpartum depression. For postpartum depression to meet the criteria of major depression, depressed mood, or loss of interest or pleasure must be present for at least two weeks (DSM-IV, Pearlstein Teri, 2008). According to the International Classification of Diseases version 10 (ICD-10) postnatal depression is defined six weeks after childbirth (World Health Organization, 1992).

During the postnatal period, women appear to be more vulnerable to depression (Douma et al., 2005; Kessler, 2003). Several risk factors for PPD have been documented, including: a history of depression (both postnatal and non-postnatal) (Alici-Evcimen & Sudak, 2003; Henshaw, 2003); a family history of mood disorders (Milgrom et al., 2008); estrogen deficiency, poor

pregnancy outcomes, societal stresses, and stressful life events (Ramchandani et al., 2009); and a poor marital relationship (Alici-Evcimen & Sudak, 2003; Cooper et al., 1999; Milgrom et al., 2008; Ramchandani et al., 2009; Rich-Edwards et al., 2006).

3.2.3 Prevalence of postpartum depression

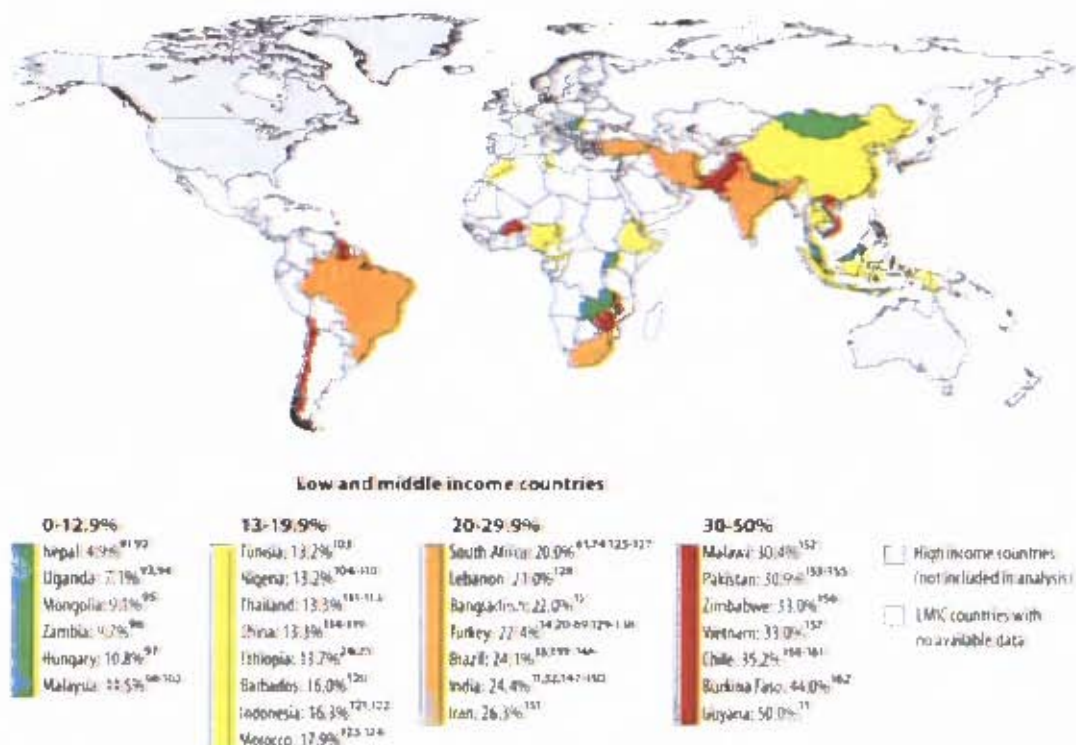
Halbreich and Karkun (2005) reviewed 143 studies from 40 countries reporting PPD prevalence and found much variation, with PPD prevalence ranging from 0% to 60%. Although the overall global prevalence of PPD was considered to be 10 to 15%, these authors considered this not to be globally representative due to the wide variability between countries.

The prevalence of PPD in South Africa is considered to be between 20 and 29% (See Figure 4; Parsons, 2012). In a South African study conducted in 1998, the Edinburgh postnatal depression scale (EPDS) was used to identify women at risk of PPD (defined by an EPDS score > 11). Thirty-six percent and 31% of the study sample (163 women) had EPDS scores > 11 at six weeks and three months after delivery, respectively. Similar rates of PPD were reported (34.7%) in an observational study by Cooper and colleagues (1999) conducted in Khayelitsha Township, Cape Town, was reported in a sample of 147 women using the DSM-IV diagnostic tool to diagnose major depression (Cooper et al., 1999). In the latter study, the majority of participants were Xhosa speaking, similar to participants of this study. Recruitment took place over nine months period and selection of the 147 participants were from a community of ± 329 002 (Statistics South Africa,

2003). Participants in the study were assessed for depression two months after childbirth; however, it was not clear from the report whether all participants were assessed at the same time interval (Cooper et al., 1999).

Lower prevalence rates of PPD have been reported in other sub-Saharan countries, e.g. Zambia (Nakku, Nakasi & Mirembe, 2007). Nakku screened a sample of 523 Zambian women for PPD using a self-report questionnaire and identified only 7.3% to be at risk of PPD.

Figure 4 : Prevalence of postpartum depression in low and middle income countries.



Adapted with permission from Lippincott Williams and Wilkins/Wolters Kluwer Health: British Medical Bulletin (Parsons et al., 2012). Jan 20, 2014.

According to the above map (figure 4) prevalence of PND in South Africa is said to be 20% (Parsons et al., 2012).

3.2.4 Oral contraception and depression

Various researchers have raised concerns about the lack of strong evidence to show a causal effect of oral contraception on depression (Duke, Sibbritt & Young, 2007; O'Connell, Davis & Kerns, 2007b; Toffol et al., 2011).

Robinson et al (2004) conducted a literature review of seven studies in an attempt to demonstrate association between the intrinsic pharmacologic properties of the oral contraceptive pill and mood disturbances. The authors assert that the collective data demonstrated that hormonal contraceptive users, in contrast with non-users, have higher rates of depression, anxiety, fatigue, neurotic symptoms, sexual disturbances, compulsion, anger, and negative menstrual effects. They argued that the cause was a psychological and not pharmacological effect (Robinson et al., 2004).

3.2.5 Injectable hormonal contraception and depression

In a randomised study of subcutaneous DMPA versus intramuscular DMPA, depression was measured using a patient satisfaction questionnaire (PSQ) (Kaunitz et al., 2009). Authors concluded that DMPA was not a causal factor for depression as the study incidence of depression was similar to that found in a cross-national epidemiological data of major depression and bipolar disorders conducted from 10 countries (Weissman et al., 1996).

The findings of Gupta et al., 2001 support the Kaunitz study. In this prospective study conducted in the USA, mood changes were assessed in adolescents using contraception in Boston. The sample size for Gupta's study was 53 and participants were not randomised. The 39 participants that chose DMPA as a method served as the experimental group and 24 that did not use DMPA served as the control group. Participants were followed up for 12 months. The authors reported that the mean depression scores of the experimental and control groups did not differ significantly (Gupta et al., 2001). However the two groups in this study had many differences at baseline (more adolescents in the DMPA group were poor academic achievers, had previously been pregnant and had a history of receiving psychological counselling) and the study methodology did not control for these confounding factors.

Another study conducted in the USA has also reported no differences in depression scores of DMPA users of a high risk population (Westhoff, Wieland & Tiezzi, 1995). In this study, participants were invited to participate by study clinicians after being identified from the clinic records. To meet the inclusion criteria, women had to be English speaking. A total of 80 women were enrolled. These authors reported no difference in the Community Epidemiology Survey-Depression scale (CES-D) score at high exposure of DMPA versus low exposure. The results of this study are limited by the absence of a control group and the small sample size.

Another American study conducted by Westhoff et al (1998) found that more than 50% of DMPA users who discontinued the method had higher depression scores at baseline than continuers (Westhoff et al., 1998).

Civic and colleagues assessed depression symptoms in 457 users and non-users of DMPA, in a study in which the primary outcomes was bone density evaluation. Depression scores measured by the CED-S were assessed in 180 DMPA users and 257 non-users. No explanation is given about how participants were allocated to study groups. DMPA users who continued with the contraceptive method were 40% more likely to report depressive symptoms and 60% of DMPA users who discontinued were more likely to report depression symptoms than the non-users (Civic et al., 2000). This study lacked controlling for confounding factors in their groups and therefore it is difficult to be certain if DMPA was the cause of depression or not.

3.2.6 DMPA and postpartum depression

The postpartum period is a very critical period not just for the mother but for the baby as well. It is important to identify women who are more vulnerable to PPD so that prevention measures can be taken.

Evidence for an association between progestogen contraception and PPD is limited and conflicting. In a South African double-blind placebo-controlled study, the injectable progestogen contraception Nurlsterate® (Norethisterone Enanthate) was associated with increased risk of PPD and reduced serum estradiol and progesterone levels when used during the postnatal period

(Lawrie et al, 1998). In this study of 180 women, mean depression scores for the progestogen group were significantly higher than those of the placebo group (Lawrie et al., 1998b).

A retrospective review was conducted of the clinic records of 55 DMPA users and 192 women not using hormonal contraception at their six week postnatal check-up (Tsai & Schaffir, 2010). EPDS scores were compared and found to be not significantly different between the groups. Ten percent of the DMPA users and 14% of the non-users had PPD defined as an EPDS score of >13 ($P = 0.88$). However, these results of this study are limited by the design and the potential of confounding factors, e.g. the women in the DMPA group were significantly older than the group of non-users.

To the researcher's knowledge, there have been no studies randomizing women to DMPA or non-hormonal contraception to evaluate the effect of DMPA on depression and sexual functioning. Therefore, the design of this study is unique (randomising research participants to either DMPA or the copper IUD), and aims to address the limitations of the existing evidence.

3.2.7 Effects of Postpartum depression

Cooper and colleagues in their study conducted at the Khayelitsha Township (South Africa) on mother-baby pairs showed that major depression had a negative effect on bonding between mother and baby (Cooper et al., 1999).

Similarly, negative effects were reported in an Indian study (Patel, DeSouza & Rodrigues, 2003). The aim of this study was to determine whether PPD contributes to poor growth and development of the infant. They found that PPD was a contributing factor to poor growth and development of babies born to depressed mothers (Patel, DeSouza & Rodrigues, 2003).

3.3 *DMPA and Sexual Function*

It is important to understand normal female sexual function to determine whether contraceptives have an effect on sexual functioning or not.

Meston & Buss (2007) conducted a study to understand why human beings engage in sexual intercourse (Meston & Buss, 2007). However, there are many other factors positively and negatively that can affect sexual functioning such as environmental, cultural, religious and societal norms.

With the help of an existing sexual functioning model researchers and clinicians can identify factors that can cause variation in sexual functioning (Richard D. McAnulty, M. Michele Burnette, 2006). In addition phases of human sexual response to be discussed in this chapter will help to understand normal sexual function as opposed to sexual dysfunction (Davison et al., 2008).

3.3.1 Sexual Functioning.

Kaplan defines sexual function as an emotional ability to experience desire (Kaplan, 1974), arousal and orgasm with a requirement of the integrity of genitalia reliable co-ordination of blood flow (Munarriz et al., 2002)

Different scientists have developed sexual response stages models(Basson, 2000;Kaplan,1974), and all have evolved from the traditional model developed by Master and Johnson in the 1960's with phases of "sexual excitement, plateau, orgasm and resolution" (Masters & Johnson, 1966).

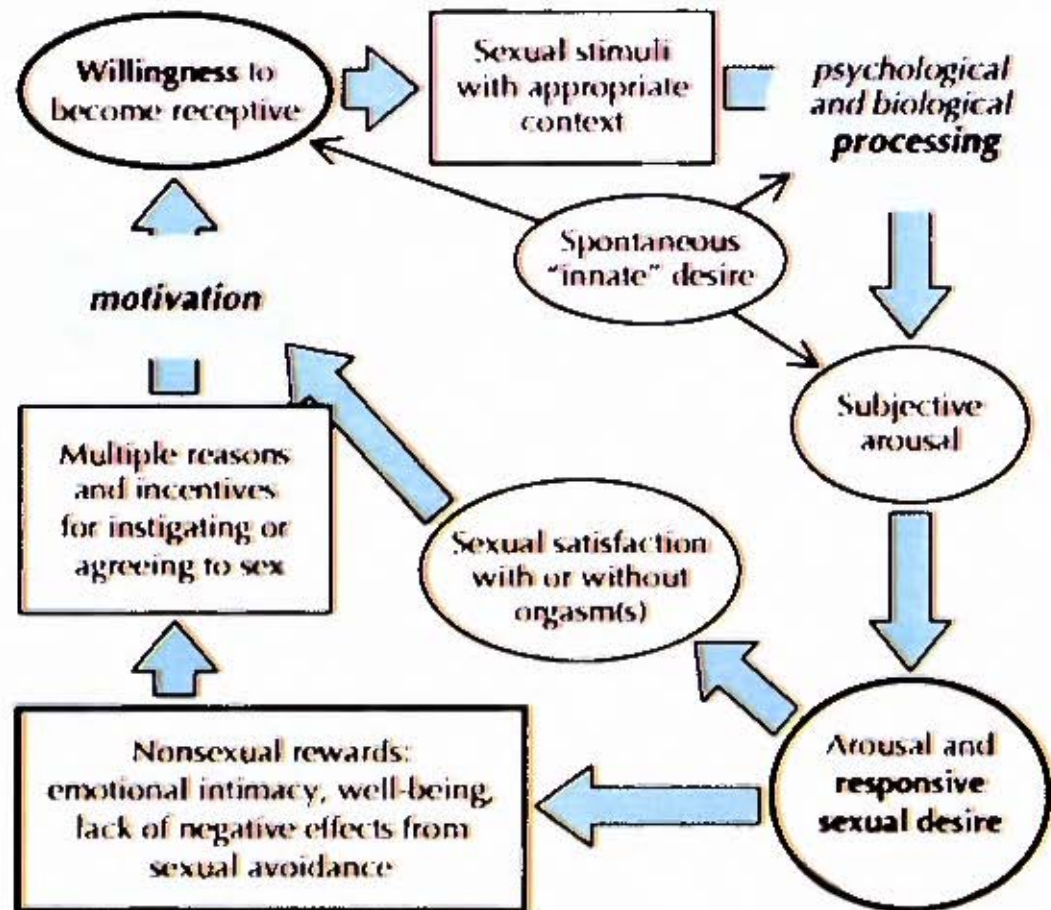
Masters and Johnson developed the sexual response model after laboratory observations of 700 men and women masturbating and engaging in sexual intercourse. Master and Johnson's model suggests that the sexual response phases are linear meaning that the sexual desire phase always comes before arousal phase. Furthermore "excitement" in Masters and Johnson's model is said to be the first phase of sexual response.

On the other hand Kaplan developed a model that contradicted the Master and Johnson's model with the hypothesis that before sexual intercourse one should have a desire to do so and Kaplan produced a sexual function response cycle that has three phases: desire, arousal, and orgasm (Kaplan, 1974).

After Kaplan's model researchers still felt there was a need for another model that could explain normal sexual response in women (Basson, 2000; Whipple & Brash-McGreer, 1997). Whipple and Brach-McGreer developed a circular

model in the 1990s but was not that different from the linear models of Masters and Kaplan.

Figure 5: Sexual response cycle modified model by Basson.



The above model (figure 2) was developed by Basson and illustrates that willingness to become receptive to sexual stimuli is processed biologically and psychologically. Basson hypothesizes that willingness can lead to subjective arousal (Basson, 2005).

McGahuey and colleagues reviewed studies that identified some core elements of sexual function and they produced the following phases “sex drive, arousal, penile erection/vaginal lubrication, ability to reach orgasm and satisfaction” (McGahuey et al., 2000). McGahuey and colleagues then developed a sexual functioning scale called the Arizona Sexual Functioning Scale (ASEX) to quantify the sexual responses and to measure sexual functioning. The ASEX is one of the instruments to be utilised to measure sexual function of women participating in the study.

Sexual desire is a drive or interest to have sexual experience with or without a partner(McGahuey et al., 2000).Neurotransmitters, sex hormones and environmental factors are said to have an influence in sexual desire (Basson, 2006).In an observational study that was conducted by Basson in Vancouver (Canada) the majority of women who had sexual desire dysfunction expressed insufficient emotional intimacy and factors involve stimuli as contributory factors to their problem(Basson, 2000).However, there is poor evidence to support factors that can affect sexual desire Basson have then advocated for randomised control trial to assess the effect of psychological and pharmacological therapies for sexual dysfunction.

It is very important to note that there is a difference between sex desire and sexual arousal and it does not mean arousal takes place after sexual desire(Basson, 2000).Graziottin defines sexual arousal as “a state with specific feelings attached to the genitalia” (Graziottin, 2000). Graziottin’s definition indicates that there is some visible biological changes in the genital

area during sexual arousal. Engorgement of the labia's and clitoris as they are filled up with blood and this elongates the vagina (Meston et al., 2004).Lubrication or vaginal wetness is also evident at this phase of sexual response (Basson, 2005).

Orgasm is a phase in sexual response that manifests itself as an intense pleasure reaching the climax of excitement during sexual intercourse, which varies in individuals and women (Meston et al., 2004).

3.3.2 Sexual Functioning after childbirth

In a study (Leite et al., 2009) that observed a group of pregnant teenagers and adults who were 20 years or more sexual function during the third trimester has been reported to have declined, with adults having higher sexual dysfunction than teenagers. Several researchers have studied return of sexual interest or vaginal intercourse after birth (Ezebialu & Eke, 2012; Hicks et al., 2004; von Sydow, 1999).In the Nigerian study by Ezabialu and Eke only 29.7% had a return of sexual interest/intercourse at 6 weeks postpartum.

Researchers have studied the effect of mode of delivery on sexual function with contradictory results reported(Baksu et al., 2007; Hicks et al., 2004; Safarinejad, Kolahi & Hosseini, 2009).A study conducted in Sweden on women who asked for elective caesarean section without any medical indication compared with elective vaginal delivery reported no difference in the two groups in sexual function at three months postpartum(Wiklund,

Edman & Andolf, 2007). Similarly Safarinejad, Kolahi & Hossein reported in their study that women post caesarean section had a higher quality of life than women who delivered by other means. On the other hand Basku et al (2007) reported a negative effect of vaginal delivery with episiotomy on sexual functioning associated with increased level of pain at 6 months as compared to the caesarean group. Literature review with no meta-analysis by Hicks et al (2004) of 6 studies conducted in developed countries also associated assisted vaginal delivery with some degree of sexual dysfunction.

3.3.3 Sexual functioning and Intra-uterine device - Copper T380A

A study that was conducted in Turkey to examine the effects of family planning methods reported that IUD users expressed no change in their sexual lives (Gabalci & Terzioglu, 2010). However in their study ASEX score for sexual satisfaction was 13.32 and for sexual desire 13.21 showing sexual dysfunction according to their cut off contrary to the cut off for sexual dysfunction given by the producer of ≥ 19 (McGahuey et al., 2000).

3.3.4 Hormonal contraception and sexual functioning

Substantial research (Caruso et al., 2004; Gabalci & Terzioglu, 2010; Greco et al., 2007; Sabatini & Cagiano, 2006; Schaffir, Isley & Woodward, 2010a) has been conducted on the effect of combined oral contraceptive pills and sexual functioning, research reports are discussed below.

Gabalci & Terzioglu, (2010) surveyed differences in sexual experiences for users of different types of contraception, i.e. condoms, withdrawal, IUD and oral contraception. In their study, 366 Turkish women were interviewed (Gabalci & Terzioglu, 2010). Although participants of the study generally reported sexual concerns, there were no significant differences between users of hormonal and non-hormonal contraception (Gabalci & Terzioglu, 2010). Similar results of the Turkish study have been reported in Chinese women of whom no statistical difference was reported from baseline and at four months follow-up(Li et al., 2004).

A study that assessed combined oral contraceptive and injectable progestin (DMPA) effects on sexual function (Schaffir, Isley & Woodward, 2010b), showed a difference in the level of free testosterone in COC group having lower levels of free testosterone compared to the DMPA group and COC group had lower levels of estradiol. However there was no significant difference in the two groups' sexual function regardless of the difference in androgen levels (Schaffir, Isley & Woodward, 2010b).

In contrast, Robinson et. al. (2004) reviewed over seven studies to ascertain whether emotional side effects of hormonal contraceptives were due to pharmacological or physiological causes. Their findings revealed that causes of side effects were due to physiological and not pharmacological effects of the hormonal contraceptives. However, no meta-analysis was conducted as part of their review and the studies that were reviewed were conducted

between the 1960's and the 1980's, however the hormonal contraceptive used during that time had lower levels of ethinyl estradiol (Robinson et al., 2004).

On the other hand (Sabatini & Cagiano, 2006) on their comparison of side effects of three hormonal contraceptives, (20 µg of ethinylestradiol (EE)/100 µg of Levonorgestrel and 15 µg of EE/60 µg of gestodene) compared with vaginal ring (15 µg of EE/120 µg of etonogestrel) found negative influence on sexual desire due to vaginal dryness (Sabatini & Cagiano, 2006).

3.3.5 DMPA - Sexual functioning

DMPA use for treatment of male sexual offenders has been reported to decrease sexual drive (Kiersch, 1990)

Kaunitz and colleagues (2009) on their study of subcutaneous DMPA as compared to intramuscular DMPA reported decreased libido as an adverse event. Similarly low libido among DMPA users was reported by (Matson, Henderson & McGrath, 1997; Paul, Skegg & Williams, 1997).

Berga & Smith alluded to interference of DMPA on sexual interest and generalised that progestin diminishes libido and sexual responsiveness (Berga & Smith, 2012).

3.4 *Summary*

Prevalence of major depression in South Africa is 9.8% and 4.9% for the twelve months prevalence as compared to the estimates from the developing countries which are 14.6% and 5.5% for an average lifetime prevalence and twelve months prevalence.

Several risk factors for postpartum depression have been documented; family history of mood disorders, estrogen deficiency and poor pregnant outcomes. The prevalence of PPD in South Africa is said to be between 20 to 29%, though from low and middle income countries it's given to range from 0% to 50%.

Evidence to associate oral contraceptives with depression in various settings is lacking. However progestogen contraceptive use in the postpartum period has been associated with depression in only one study.

Postpartum depression has showed to have an adverse effect on bonding between mother and baby and it is reported to contribute to poor growth and development of babies born to depressed mothers.

A decline in sexual functioning after childbirth have been associated the mode of delivery (operative/assisted deliveries); old age also was another factor that influence sexual functioning.

Majority of oral contraceptives studies could not find a statistically significant effect of OC no sexual dysfunction.

The DMPA has showed to decrease sex drive when used to treat sexual offenders. Report from observational studies has associated DMPA use for contraception with low libido.

Chapter 4: Methodology

4.1 Introduction

The chapter presents the hierarchy of study designs that led to the need to the selection of a randomised controlled trial methodology to conduct this study. It describes the study design, research sites, study population, sample size calculation, inclusion and exclusion criteria, recruitment and randomisation procedures and the instruments for data collection. It also describes the results of the pilot study. In addition, this chapter includes the methods for determining validity and reliability of the instruments, data collection, ethical considerations, data management and analysis. Finally, the chapter explains the risks and benefits of taking part in the study, and the referral system put in place to support study participants.

4.2 Research Questions

This study posed the following research questions:

- Are there statistical differences in the effects of injectable DMPA on postpartum depression as compared with the Cu-IUD (Copper T 380A) as measured with EPDS and BDI-II?
- Are there statistical differences in the effects of injectable DMPA on sexual functioning as compared with the Cu-IUD as measured with the ASEX?

4.3 *Hypotheses*

4.3.1 Null hypotheses

- There is no statistical difference in the rates of postpartum depression between women using the IUD (Copper T 380A) and those using injectable DMPA contraception in the Eastern Cape.
- There is no statistical difference in sexual functioning between women using the IUD (Copper T 380A) and those using injectable DMPA contraception in the Eastern Cape.

4.3.2 Alternate hypotheses

- The use of injectable DMPA, given to women of reproductive age who wish to practice birth control, will result in a statistically significant difference in the level of depression compared to women who received the Cu-IUD.
- The use of injectable DMPA, given to women of reproductive age who wish to practice birth control, will result in a statistically significant difference in the level sexual functioning compared to women who received the Cu-IUD.

4.4 *Research Design*

4.4.1 Quantitative design

The research approach in this study is an experimental quantitative approach. Ponterotto (2005) describes quantitative methods as having a "...focus on the strict quantification of data and on careful control of empirical variables" (Ponterotto, 2005). Lietz and Zaya, (2010) describe the purpose of quantitative research as seeking". Through measurements to test a hypothesis, to determine outcomes and to draw generalizable conclusions to a defined population" (Lietz & Zayas, 2010).

Experimental study designs focus on testing causality with optimal control. A type of experimental study design is the randomised clinical trial (RCT) which is used in this study.

Filstead (in Ponterotto, p.127-128) defines a research model as "...a set of interrelated assumptions about the social world which provide a philosophical and conceptual framework for the organised study of that world" (Filstead, 1979; Ponterotto, 2005).

Post-positivism stresses objectivity, experimentation and generalizability (Mertens, 2010). Objectivity, experimentation and generalizability support the generation of meaningful and relevant knowledge for action, which was the paradigmatic intent behind this research project. The selected paradigm will inform on selection of tools, instruments, participants, and process of this

study (Denzin & Lincoln, 2005; Norman K. Denzin & Yvonna S. Lincoln, 2005).

4.4.2 Randomised Controlled Trial

The selected study design is randomized controlled trial (RCT) to compare two family planning methods available in South Africa.

Figure 1 "Hierarchy of evidence"



Source: Evidence-Based Practice in the Health Sciences: Evidence-Based Nursing Tutorial Information Services Department of the Library of the Health Sciences-Chicago, University of Illinois at Chicago.(Skinner, 2013)

4.4.3 Advantages and disadvantages of RCT design

RCT methodology makes it possible to allow control of confounding factors is important to be able determine whether the intervention is the causal effect as compared to the control (Jepsen et al., 2004; Kendall, 2003). Control of confounding factors is achieved in RCTs by eliminating bias in method assignment (Schulz & Grimes, 2002). According to Schulz (2002), it then permits the use of probability theory to express the likelihood that any differences in outcome between treatment groups merely indicate chance. Non-randomized study designs such as case-control or observational studies cannot control for unknown confounding factors.

4.5 *Research sites*

The study will be conducted in two tertiary government hospitals that are 23km apart, namely, Cecilia Makiwane hospital located in Mdantsane township ("native units" built by the apartheid government to house Blacks) of East London, and Frere Hospital situated near the central business district (CBD) of East London. Both hospitals have research and diagnostic facilities for conducting the study. The author of this document has the added advantage of access, as she had been working in both hospitals as a midwife-researcher for twelve years.

4.6 *Study population*

Pregnant women (99% Black Xhosa- speaking) were enrolled and invited to participate in the study immediately after childbirth. Whilst still in hospital and prior to discharge. The population for this study was recruited from women who gave birth between 06 December 2012 and 30 March 2013.

Participants for this study had to be of reproductive age (WHO). The eligible age to participate was between 18 and 44 years, as 18 years of age is the minimum age of consent for research participants (World Medical Association, 2008).

4.7 *Pilot study*

A pilot study was conducted with ten (10) postpartum women who consented to participate. And women approached consented to take part. Random allocation of participants to either DMPA or IUD was mostly welcomed by participants. One participant requested to consult her husband after consenting and before IUD insertion and this resulted in non-adherence to the allocated method.

A copy of the study instruments, i.e. EPDS, BDI-II and ASEX was given to all pilot participants at enrolment to refer to during telephonic interviews. All participants were able to answer the questions with ease. Telephonic interviews were feasible and all participants were reachable.

4.8 *Sample size calculation*

Two studies similar to the current study were identified during literature review. The first was a South African study by Lawrie et al (1998) that explored the effect of Norethisterone Enanthate (NET-EN) on PPD and serum hormones. Study instruments used to measure the primary outcome (PPD) was the Edinburg Postnatal Depression Scale. The mean depression score at six weeks was 8.3 [SD 7.5] for the NET-EN group. For the control group the mean depression score was 4.9 [SD 7.5]. The second study of (Gupta et al., 2001) that looked at the mood changes in adolescents using DMPA for contraception in this study the mean BDI scores for the DMPA group at three months was 11.5 (SD 10.2) and for the control group mean was 6.9 (SD 6.5).

STATA statistical software (StataCorp, 2011) was used to calculate sample size. Based on these previous studies, we calculated our sample size as follows: To be able to show a reduction in mean depression score from 11.5 to 6.9, 73 women were required in each group ($\alpha = 0.05$, $\beta = 90\%$). To allow for 25% loss to follow-up, the sample size was increased to 200. The sample size was further increased as there was an unexpected lack of adherence to one of the study methods (IUD) due to requests to postpone insertion by participants after randomisation. The required sample size was increased to allow for some non-compliance, which might have reduced the power of the trial. Finally, a total of 242 women were included in this study.

4.8.1 Inclusion criteria

Inclusion criteria for women to participate in this study:

- Child bearing women between the age of 18-45
- Child bearing women with no contraindications to either method (World Health Organisation, 2009).
- Child bearing women willing to use either DMPA or IUD within 48 hours of childbirth.
- The women must consent in writing to participate in the study.
- The women should be able read English and/or Xhosa

4.8.2 Exclusion criteria

- Women with severe depression defined as a BDI score of 29-63 (Beck, Steer & Brown, 1996).
- Women with no access to a telephone.
- Women who have delivered >48 hours will be excluded as IUDs inserted in the puerperium must be inserted within 48 hours of childbirth (World Health Organisation, 2009).

4.9 *Recruitment procedures*

Gross and Colleagues, (2002) and Wright, (2006) referred to participant recruitment as a process of identifying a target population, reviewing eligibility criteria, and obtaining consent to assemble a study population (Gross et al., 2002; Wright, 2006).

Selection of potential participants was based on the antenatal records from the two hospitals. The Effective Care Research Unit (ECRU) trained fieldworkers were responsible for distributing information leaflets to the pregnant women in the two hospitals. Once the women had read the information leaflet and agreed to take part in the study, the fieldworkers then referred them to the research-midwives for screening to determine eligibility.

If eligible, pregnant women were given further details about the study and invited to participate. Those willing to participate signed the Information and Consent Form. A photocopy of the signed Information and Consent Form was given to each participant for their personal record (Appendix A & B). Copies of the EPDS (Appendix D), BDI-II (Appendix E or F) and ASEX (Appendix G) instruments were given to participants to take home to read as the content would be the focus during the telephonic interviews after randomisation.

4.9.1 Role of the research midwives

Enrolment took place prior to delivery. However, if participants underwent a caesarean section during which an IUD was inserted, they were excluded. Both participants and the researcher were blinded to the allocation sequence to prevent selection bias. The contraceptive methods were allocated to the woman by drawing the next in a series of consecutively numbered, sealed opaque envelopes containing allocation cards. The cards were in a computer-generated random sequence in balanced blocks of variable size which had been prepared by the co-supervisor of the researcher and were packed in envelopes by the data manager of the Effective Care Research Unit based at Cecelia Makiwane Hospital.

Screening, enrolment and baseline interviews were conducted by assisting research midwives; subsequent telephonic interviews were conducted by the principal researcher. Participants were requested during the informed consent process to keep the allocated method of contraceptive confidential during telephonic follow-up interviews at one month and three months to ensure the telephonic interviewer remained blinded to the allocated method (See appendix A&B).

Injectable progestogen group - (DMPA)

The women were fully counselled on the use of injectable DMPA contraception, and the need for repeat injections at three monthly intervals, according to the WHO Family Planning Handbook for Providers (WHO, USAID, Johns Hopkins, 2012). The first injection was administered on the day of enrolment into the study by a midwife employed by the Eastern Cape government as a family planning provider in the postnatal wards. This midwife was aware of the study procedure and worked in consultation with the research midwife. All participating women were then referred to attend a designated appointment at their local clinic every three months for their next dose of DMPA.

Cooper T 380 A- IUD group

All participants allocated to the Cu-IUD group were counselled on the use of the Cu-IUD, according to the WHO Family Planning Handbook for Providers (WHO, 2012). A standard Copper T 380A IUD was inserted using a standard technique by an experienced doctor or midwife employed by the hospital, as would occur for any woman choosing this contraception option after delivery. Immediately after insertion, ultrasound was performed by a trained sonographer employed by the hospital to confirm placement. Study participants were asked to return to the Women's Health Clinic at each hospital for follow-up at six weeks to check the position of the Cu-IUD as is routinely practised at the two study sites.

4.10 *Data collection*

Informed consent, demographic data, medical history, weight, and a brief questionnaire (see Appendix A) were obtained at baseline. In addition, all three study instruments (BDI-II, ASEX and EQ E5) were administered at baseline by research midwives in the form of a face-to-face interview; research midwives completed the study instruments.

Women were followed-up telephonically after one month (high exposure of DMPA) and at three months (low exposure of DMPA), before the next scheduled injection (Westhoff et al., 1995). An interview schedule was arranged with each participant to be contacted telephonically.

Participants were requested to be in a place where they will be comfortable to answer all questions to ensure privacy. The BDI-II was administered first, followed by the EPDS and the ASEX. During the interviews, the researcher read the questions, mostly in English, to the participants. Where necessary, the isiXhosa version of the BDI-II was used, and the EPDS was translated by the interviewer into isiXhosa and the respondent's reply recorded.

Table 1 : Data Collection instruments

Time point in study				
Baseline/Screening	Case Report Form page 1 & 2 (Appendix 3)	BDI-II	EPDS	ASEX
One month postpartum telephone follow-up	Case Report Form page 2 only (Appendix 3)	BDI-II	EPDS	ASEX
Three months postpartum follow-up	Case Report Form page 2 only (Appendix 3)	BDI-II	EPDS	ASEX

4.11 Study instruments

4.11.1 Beck Depression Inventory (BDI-II)

The Beck Depression Inventory was selected to evaluate depressive symptoms. It had been previously validated, used in the same cultural context and translated into the local language IsiXhosa (Somhlaba & Wait, 2009; Segal, et al., 2008).

English and IsiXhosa versions of the BDI-II were used in this study. The BDI-II can be self-administered or verbally administered by a trained administrator. In this study, verbal administration was utilized during telephonic follow-up interviews (BDI-II®, Beck et al, 1996, Somhlaba & Wait, 2009).

The BDI-II has 21 items, and each item is rated on a four-point scale ranging from 0-3. The maximum total score is 63 (Beck, Steer & Brown, 1996). According to the BDI-II manual, scores of 0-13 indicate minimal depression, scores of 14-19 indicate mild depression, scores of 20-28 indicate moderate depression, and scores of 29- 63 indicate severe depression (Beck, Steer & Brown, 1996).

Approach used in this study:

1. One copy was given to the participant at baseline and a research midwife explained the tool to the participant. Each question was read out by the midwife and an explanation was given where needed. The participant's response was recorded by the midwife.
2. At one month and three months after baseline, follow-up telephone interviews were conducted by the researcher. Participants had copies of the questionnaires with them at home, whilst the researcher read out the questions and gave explanation where needed in the participant's language of choice: either English or IsiXhosa. Responses from the clients were recorded by the researcher on the Case Report Form (CRF) and measurement instrument (BDI-II).

4.11.2 Edinburgh Postnatal Depression Scale

The Edinburgh Postnatal Depression Scale (EPDS) was developed by Cox (Cox, Holden & Sagovsky, 1987) and is used to screen postnatal depression globally. It is a 10-item self-report instrument where items are rated on a four-point scale to produce a summative score ranging from 0- 30. For this study, thresholds of 9 and 12 were used to indicate mild and severe depression, respectively.

4.11.3 Arizona Sexual Experience Scale

The Arizona Sexual Experiences Scale (ASEX) by McGahuey and Colleagues (McGahuey et al., 2000) is used to evaluate sexual functioning. This is a five-item rating scale instrument with total scores ranging from 5–30. It has been validated to be independent of the presence of a sexual partner (McGahuey et al., 2000), and can therefore be used even when study participants are not sexually active.

Among the measurement instruments researched, this scale was found to meet the needs of this study best because of its brevity and validity. Gabalci and Terzioglu (2010) in their study of the side-effects of family planning methods used this scale to identify sexual problems on their participants. These authors found the ASEX to be a useful, brief and simple scale. Other validated instruments used to measure sexual functioning were also reviewed by the researcher and found to be longer than the ASEX, with items

ranging from 19-35 (Meston & Derogatis, 2002) as compared to a 5-item ASEX. As the ASEX only exists in an English version, the researcher translated it into IsiXhosa for those participants who did not understand the questions in English.

Questions 4 and 5 of this scale are not ranked if a participant has not engaged in sexual intercourse within a week of the interview.

4.11.4 Questionnaire

A brief questionnaire was developed to collect, weight, medical and menstrual history, for comparison of other side effects as per the secondary objective and for eligibility screening (Appendix 3 case record form). This was a closed-ended questionnaire which covered all possible answers per question. The type of questions enabled the generation of numeric data. Page one of the questionnaire included eligibility check, medical and gynaecological history, and history of contraceptive use. On page two, data about HIV status, weight, menstruation, and feeding options used for the baby was collected.

In addition some of the questions were taken from the EQ E5 (Jelsma et al., 2004) to collect demographic data of the participating women.

4.12 *Reliability and Validity*

Reliability refers to the degree of similarity of the information obtained when the measurements are repeated on the same subject or the same group (Katzenellenbogen et al, 1997). Katzenellenbogen et al, 1997 also define

validity as the extent to which a measure actually measures what it was meant to measure.

4.12.1 One side blinded design

The researcher administered the follow-up telephone interviews only and was not involved in screening and enrolment. The baseline screening for eligibility and enrolment was done by research midwives assisting in this study. The researcher only made contact with the study participants by telephone.

The researcher remained blinded by reminding participants before the start of telephonic interviews not to mention the contraceptive method to which they had been allocated. The researcher was blinded to the allocated method until the end of the study.

Blinding of the researcher in this study was done to reduce differential assessment of outcomes which is often called detection or ascertainment bias (Schulz and Grimes, 2002).

4.12.2 The Beck Depression Inventory

The Beck Depression inventory is widely used in South Africa both clinically and in trials (Lucas, September 2003; Somhlaba, Nceba. Z. & Wait, John. W., 2009; Steele & Edwards, 2008). It has been translated into IsiXhosa, a language that is widely used in the Eastern Cape where this research was

conducted. (XBDI-II, Steele, & Edwards, 2008. This IsiXhosa version has been validated and used by other researchers (Somhlaba, Nceba. Z. & Wait, John. W., 2009; Steele & Edwards, 2008). Steer et al. (2000) reported internal consistency of the BDI-II to be high with coefficient alpha = 0.90, and total score of BDI-II was not significantly related to sex, age, or ethnicity.

4.12.3 Edinburgh Postnatal Depression Scale

The EPDS has been validated in South Africa. Two studies have been conducted in two different sociocultural settings (Cooper et al., 1999; De Bruin et al., 2004; Lawrie et al., 1998b) .

Validation by Lawrie, Hofmeyr and de Jager (1998a) showed that EPDS was able to identify 100% of women with major depression and 70.6% with minor depression. Combined major and minor depression sensitivity was 80%, specificity 76.6%, positive predictive value 52.6% and the negative predictive value 92.2% (Lawrie et al., 1998a). De Bruin reported that the EPDS scores obtained from Xhosa speaking participants showed the EPDS to be reliable for this population (De Bruin et al., 2004).

4.12.4 Arizona Sexual Experience Scale

McGahuey and Colleagues conducted a study to validate and test reliability of the ASEX. They concluded that ASEX was a 'reliable, valid and a sensitive tool for measuring sexual dysfunction'. (McGahuey et al., 2000:35)

4.13 *Ethical considerations*

Ethical approval was obtained before data collection began from the Faculty of Health Sciences Human Research Ethics Committee (FHS HREC: ref number 548/2012) of the University of Cape Town (Appendix I), East London Hospital institutional Ethics Committee (Appendix J) and the Provincial Department of Health was requested for permission to conduct the study (Appendix K). This study adheres to the ethical principles outlined in the Declaration of Helsinki (World Medical Association, 2011) and the Constitution of the Republic of South Africa (Bill of Rights) (Devenish, 1999). Following a baseline screening at recruitment, participants who gave consent and who met eligibility criteria were allocated to either injectable DMPA (Depo-Provera®) or the Cu-IUD (Copper T380A®). As discussed in Chapter Two, hormonal contraceptives have been reported to have depressive and sexual function effects in some studies; therefore, the DMPA group was defined as the treatment (or experimental) group and the Cu-IUD group was defined as the control group.

4.14 *Informed consent*

All participants received information about the trial in the language of their choice, conforming to ethical requirements for research involving human subjects (Appendices A or B). Participant was given enough time to ask questions before obtaining a written confirmation of informed consent.

Participants were asked to sign informed consent to participate in the study, and were informed that they were free to withdraw from the trial at any stage without loss of benefits (Appendix A & B).

4.15 *Confidentiality and Anonymity*

Any information provided during the study by participants was kept confidential (Hewison & Haines, 2006). Full names do not appear on any study document, and only staff participating in the study had access to the information provided (Hewison & Haines, 2006).

4.16 *Autonomy and Right to withdraw*

Participants were informed that they were free to choose whether they wished to participate (Appendix A & B). They were also free to withdraw from the study at any time should they have wished to for any reason. If for any reason they were not eligible for the study, or decide not to participate, they would still receive normal care.

4.17 *Possible risks/benefits from the research*

The study participants were informed of the possible risks and benefits of the methods of contraception used in this study. Both methods of family planning have risks and discomforts.

The discomforts associated with trial procedures included:

- Completing of the questionnaires
- Pain that might be felt during intramuscular injection administering the Depo-Provera
- Pain that might be felt during insertion of the IUD.

In case of adverse events that were reported or noted whilst subjects/participants were in the study (including depression and/or sexual dysfunction), they were referred to the relevant health provider for the management.

4.18 *Data Management*

Data management consists of data preparation and processing steps to produce clean data files (Stouthamer-Loeber & van Kammen, 1995).

All study forms completed at baseline by research midwives were checked by the researcher for completeness and accuracy each day, before data entry onto Epidata statistical software (Lauritsen & Bruus, 2006). In Epidata, electronic data forms were created to be identical with the paper case report forms to prevent data entry errors and to save time. Two data capturers who had been trained by the researcher entered data. If there were any errors

picked up by data capturers, corrections were made before the second data entry. Double entry of data was done to detect inconsistency of data entry (Stouthermer-Loeber and van Kammer, 1995).

The entered data was reviewed by the researcher for accuracy before unblinding the dataset by comparing the two data sets (decoding the randomized group).

4.19 Data analysis

Data was exported from Epidata into Microsoft Excel to enable import of data into Statistica (Statistica version 11). Before data was imported to Statistica it was cleaned and checked. Women were analysed in the group to which they were allocated, including those who did not receive the allocated method (intention-to-treat). Descriptive statistics were calculated for demographic data by the two treatment groups. The statistics included means, standard deviations, frequencies and percentages. Following are the procedures undertaken:

Categorical data were compared as relative risks with 95% confidence intervals, using the Chi square test.

For continuous data, the Shapiro Wilk test was used to test for normal distribution of selected variables (Altman DG, 1991). For normally distributed variables, the mean and the standard deviation were reported, and the t-test was done to compare the mean values and standard deviations for the two groups (Altman DG, 1999). For repeated measures (e.g.

depression score) at baseline, one month and three months, comparisons of one month and three month follow-ups against baseline were considered separately.

- a. For continuous variables: the baseline value for each subject was subtracted from the follow-up value (e.g. at one month) to calculate the change up to that time point. The mean values of the changes for each randomized group were compared using the t-test and the mean difference with 95% CI (using RevMan software).
- b. For categorical variables, the baseline data were compared to confirm that the randomisation produced well-balanced groups. The follow-up variables were compared between groups using the chi-square test, as relative risks with 95% confidence intervals.

If the continuous variables were not normally distributed, analysis was done with the non-parametric Wilcoxon test to compare median and Interquartile Range (IQR) of the two groups (Leedy & Ormrod, 2010). This followed the recommendation described by Altman (1991), that ".parametric methods require the observations within each group to have an approximately normal distribution and the standard deviation in each group should be similar. If the raw data does not satisfy these conditions a non-parametric method should be used".

4.20 *Presentation of findings*

The risk of depression in the two groups is presented with a table and a forest plot to illustrate clearly any difference in risk of depression of the two groups. Both depression scales EPDS and BDI-II are shown in one table, to highlight any differences in the results of the two depression scales. Three different tables are shown at each study point starting with baseline assessment, one month follow-up results and the three months results.

Bar graphs present the different depression categories (mild to severe depression) in each chart for the three time-points. Each tool has its own bar chart.

For sexual functioning a table with a forest plot will present the baseline, one month and three month follow-up results for risk of sexual dysfunction. Any difference between the groups should be easily visualized in this forest plot.

Bar charts presenting events of sexual dysfunction by each item of the ASEX are shown.

Secondary outcomes are presented in frequency tables so that the reader can see the actual number of events occurring in each group.

4.21 *Constraints and limitations*

Some eligible women who would have been enrolled in the study did not consent to participate as they did not wish to receive the IUD. The most frequent reason for this was a fear of pain during insertion, particularly in women who had experienced vaginal tears during delivery.

Follow-up at one month and three months was not possible during the day for all participants, as some were students and others were back at work. It was, therefore, necessary for the researcher to make some calls between 5pm and 21h00pm as per participant request.

The study was expected to finish in June 2013, however, follow-up took longer than expected to complete. One participant, who was randomised on the 20th March 2013, was scheduled to go for a caesarean section on the same day, but the plan was changed and she was only delivered on the 11th April 2013.

4.22 *Summary of chapter*

The purpose of this chapter was to explain the research methodology of this study and to justify the research design and the strengths of the design chosen. Selection of participants and the study process were discussed. The statistical procedure used for the analysis of study data was described.

Chapter 5: Study Results

5.1 Introduction

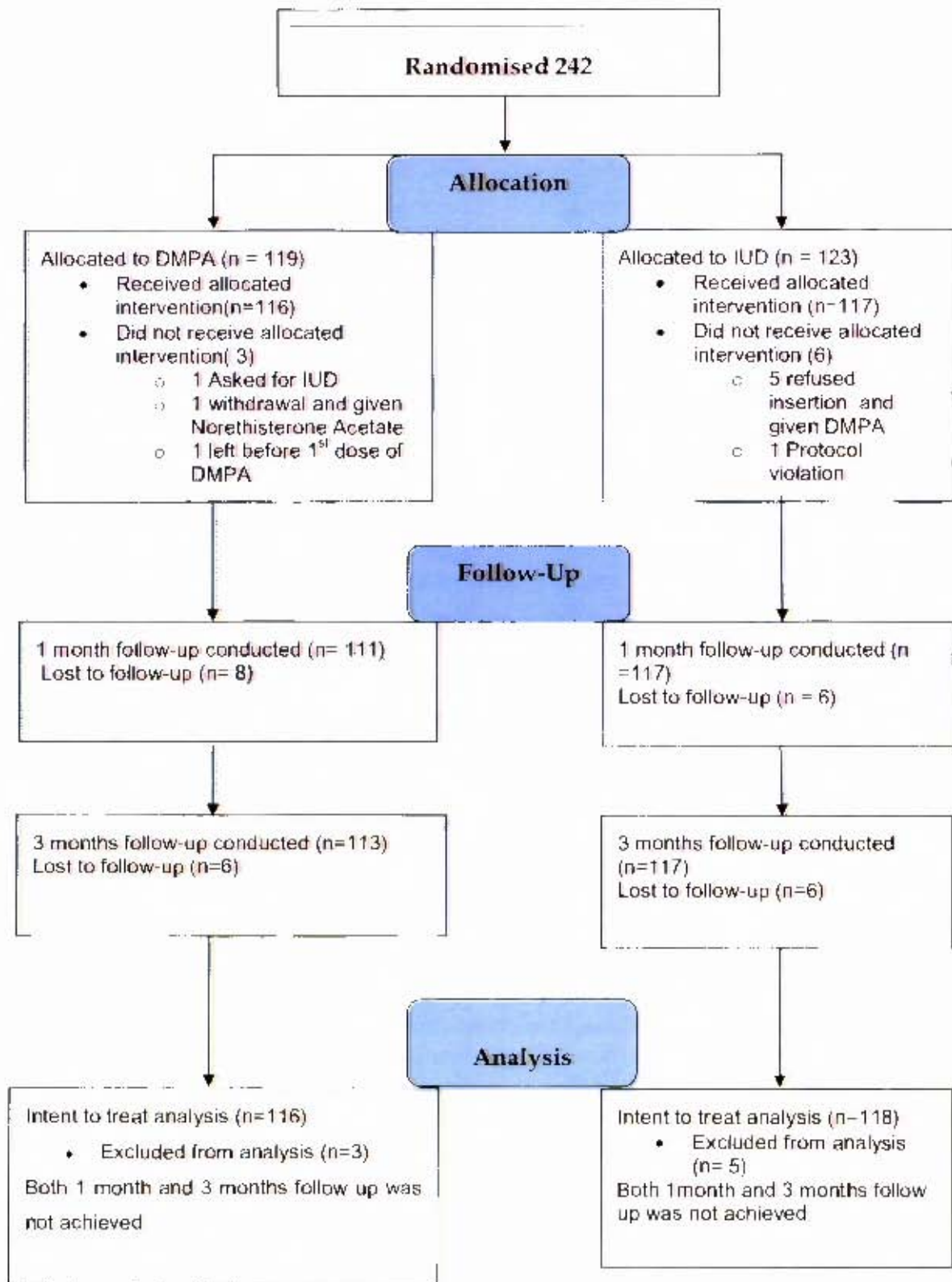
This chapter presents the flow of participants through the study, baseline characteristics of the sample and the results of primary and secondary outcomes.

5.2 Sample Description

Participant flow from randomisation to analysis can be found in Figure 6, in accordance with the recommended CONSORT statement (Schulz, Altman & Moher, 2010).

Recruitment commenced on the 04th of December 2012 and ended on the 20th March 2013. Follow-up continued until 1 July 2013.

Figure 6: Participants flow diagram



The research midwives did not kept records of the number of women screened. However, based on hospital records, the number of women eligible for referral to the research midwives for screening from the two hospitals totalled to 575.

As presented in the flow diagram (Figure 6), two hundred and forty-two (242) participants were randomly allocated to the study methods, i.e. 123 were allocated to the IUD group and 119 to the DMPA group.

There were eight exclusions from analysis; three were from the DMPA group and five from IUD group. All were excluded from the analyses as there were no data for both follow-up end points (1 month and 3 months).

Adherence to the allocated method could not be achieved among all study participants. Three women in the DMPA group did not receive the allocated method because of reasons outlined in the flow diagram (Figure 6). Five participants in the IUD group refused insertion and one could not be inserted due to protocol violation because she was randomised three days after delivery (beyond the time-period for postpartum IUD insertion). Subsequently, this participant was given DMPA. Participants who did not receive the method they were allocated were still included in the analysis, with the "intention-to-treat" approach.

After excluding eight participants from final analysis, a total of 234 participants completed the study follow-up interviews and were included in the analysis (See Table 2).

5.3 *Recruitment and follow-up*

Table 2: Recruitment and follow-up

Baseline - BDI	Baseline - EPDS	Baseline ASEX
Total = 234	Total = 234	Total = 234
DMPA = 116	DMPA= 116	DMPA= 116
IUD = 118	IUD = 118	IUD = 118
One Month Follow-up- BDI	One Month Follow-up- EPDS	One Month Follow-up - ASEX
Total = 228 (94%)	Total = 227 (93%)	Total = 227 (93%)
DMPA=111 (93%)	DMPA=110 (92%)	DMPA=110 (92%)
IUD=117 (95%)	IUD=117 (95%)	IUD=117 (95%)
Three months follow-up: BDI	Three months - EPDS	Three months- ASEX
Total = 230 (95%)	Total = 229 (94%)	Total = 230 (95%)
DMPA = 113 (94%)	DMPA = 113 (94%)	DMPA = 113 (91%)
IUD = 117 (90%)	IUD = 116 (94%)	IUD = 117 (95%)

Telephonic follow-up at one month after enrolment occurred at a mean of 34 days. The second follow-up occurred at a mean of 90 days for the DMPA group and 89 days IUD group. Follow-up at one month was conducted telephonically for 225 participants and by home visit for two (2), which were done by a trained fieldworker, not the researcher. At three months follow-up, home visits were undertaken for 22 women (15 women on DMPA and 7 on IUD), and 208 were followed up telephonically.

Overall, follow-up was 94% for one month and 95% for three months. There was no significant difference in achieved follow-up of groups at one month and three months.

5.4 Baseline results

Baseline characteristics of participants are shown in Table 3. Data are expressed as frequencies (Percentages), mean [\pm standard deviation] and median [Interquartile range].

Table 3: Demographic and clinical characteristics of DMPA & IUD group at baseline.

Characteristics	Total (N= 234)	DMPA (N=116)	IUD (N= 118)	P- value
Medical and gynaecological history				
Age (median)[IQR]	26[11-23]	26 [10-22]	26.5[11-22]	
Diabetics*	2(0.8%)	0	2(1.6%)	p= 0.498
High Blood pressure	16(6.3%)	8(6.7%)	8(6.7%)	P=0.971
Positive HIV ⁺	91 (39%)	39 (33%)	52 (44%)	P=0.102
CD4 count mean [SD]	n=86 M385[177]	n=37 M438[173]	n=49 M344[170]	P=0.01**
Negative HIV ⁻	141(60%)	75(64%)	66(55%)	p= 0.173
Previous pelvic sepsis	5(2.1%)	2(1.7%)	3(2.5%)	p=.9846*
Spontaneous miscarriages	13(5.5%)	6(5%)	7(5.9%)	P=0.78
Previous C/S	19(8%)	11(4%)	8(6.8%)	P= 0.45
A current smoker	4(1.7%)	3(2.5%)	1(0.8%)	P= 0.368*
An ex-smoker	9(3.8%)	4(3.4%)	5(4.2%)	P=1.00*
Never smoked	221(94%)	109(93%)	112(94%)	P=0.75
Previous Contraception				
Injectable	204(87%)	100(86%)	104(88%)	P=0.66
Pill	20(8.5%)	10(8.2%)	10(8.2%)	P=0.97
IUD	0	0	0	
Condom use	164 (70%)	78(67%)	86(72%)	P=0.35
Pregnancy unplanned	181 (77%)	97 (83%)	84 (71%)	P=0.346
Socio-economic status				
Employed	61(26%)	34(31%)	27(22%)	P=0.265
Housework	73(31%)	33(28%)	40(33%)	P=0.37
Student	37(15%)	21(18%)	16(13%)	P= 0.343
Seeking work	63(26%)	28(24%)	35(29%)	P= 0.341
Min school leaving grade 9/standard 7.	178 (76%)	85(73%)	93(78%)	P= 0.321
Degree or Diploma	16 (6.8%)	8(7%)	8 (7%)	P= 0.971
Married	49(20%)	21(18%)	28(23%)	P= 0.33
Single	185 (79%)	95(81%)	90(76%)	P= 0.291

*Fisher's exact two-tailed. ** Significant difference $p < 0.05$ (ANOVA TEST)

5.4.1 Demographic characteristics of study participants

Medical and gynaecological history

There were no statistical significant differences between groups for almost all variables as measured by the Chi square test and Fisher's exact test were appropriate. Only one variable (CD4 count), had a statistical significance difference $p < 0.05$.

The median ages of participants were 27.5 for the total groups, 26 for the DMPA and 26, 5 IUD group. Thirty nine percent of participants were in the 18-24 age group, followed by 25% in the 25-34 age group, 15% 30-34 and 19% 35- 45. Almost all participants were black, Xhosa-speaking women, with only four coloured women included.

Previous Contraception

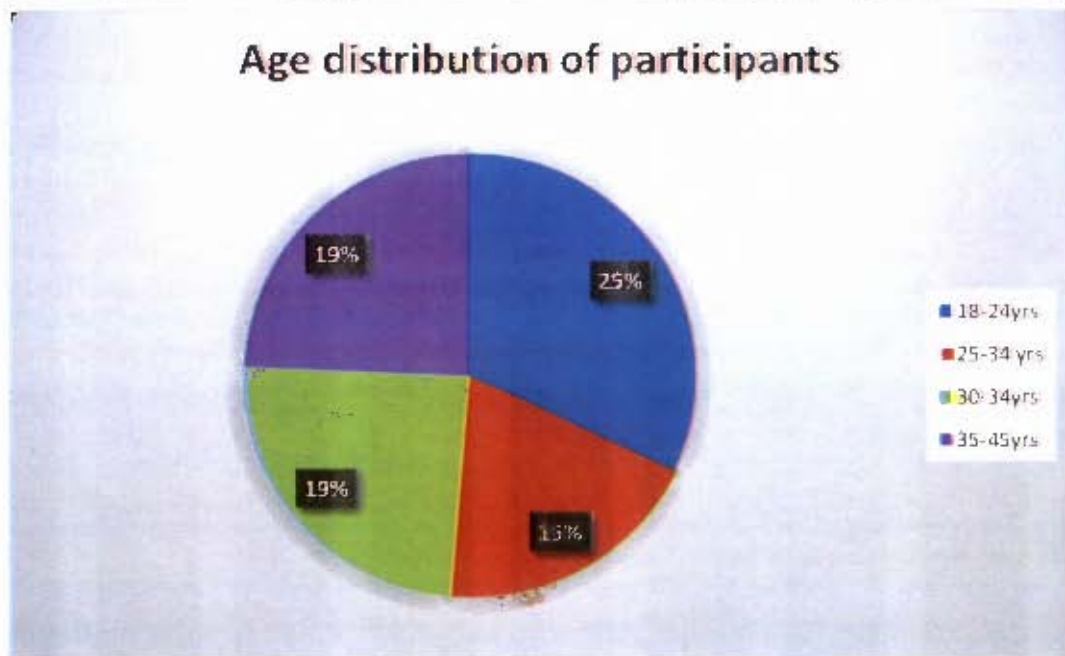
Eighty seven per cent (87%) of the total sample size had previously used injectable progestogen contraception and none in both groups have used IUD before. No statistical significance difference $p < 0.05$ on use of condom.

Socio- economic status

Only 26% of the total sample group was employed and 64% had no source of income and only 7% in each group had a degree or diploma, majority had only grade 9 /standard 7 minimum school leaving qualification (Table 3).

Figure 7 presents the age distribution of the study participants.

Figure 7 : Age distribution of study participants



5.5 Primary outcome results

5.5.1 EPDS and BDI-II continuous data : Depression results

Table 4 presents the depression scores as measured by the EPDS. Data are expressed as median scores [Interquartile range].

Table 4 : EPDS median scores & changes over time by study groups

EPDS					
	DMPA		IUD		
Time	n	Median (IQR)	n	Median (IQR)	p- value
Baseline	116	9(3 to 21)	118	8(2 to 20)	0.2
1Month	110	4(1 to 18)	117	2(0 to 21)	0.04*
Δ 1 month	110	-3 (-7 to 0.5)	117	-4 (-8.5to 0.5)	0.3
three months	113	2 (0.5 to 19)	117	2(0 to 19)	0.1
Δ 3 month	113	-4.5(-7.5 to 11)	117	-4(-6.5 to 16)	0.4

P <0.05 (Wilcoxon test)

There was no statistically significant difference between groups at baseline and at three months after randomisation, nor was there a significant change from baseline at one or three months. However, the median depression score in the DMPA group was significantly higher than in the IUD group at the one month follow-up.

Table 5 presents the depression scores as measured by BDI-II. Data expressed as median [Interquartile range].

Table 5: BDI median and scores change over time by groups

BDI-II					
DMPA			IUD		
Time	N	Median (IQR)	n	Median (IQR)	p-value
Baseline	116	6(2.5 to 12.5)	118	5 (2.5 to 9.0)	0.1
1 month	111	8(4.5 to 19.5)	117	7(4 to 12.5)	0.2
Δ1 month	111	2(-1.5 to 8.0)	117	1(-1.5 to 5.5)	0.2
Three months	113	9 (4.5 to 14.5)	117	5 (2 to 11.5)	0.002*
Δ3 month	113	1(-1.5 to 6.5)	117	0(-3.5 to 4.5)	0.09

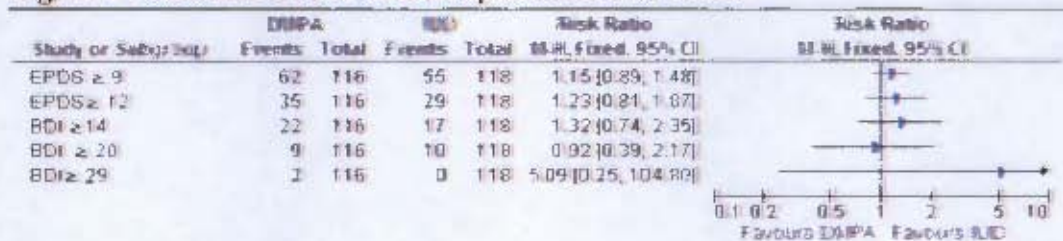
*P< 0.05 (Wilcoxon test)

There were no statistically significant differences between the groups in median BDI-II results for depression at baseline and one month postpartum, either as absolute values or changes from baseline (Table 5). However, at three months the median score for the DMPA group was statistically significantly higher than the IUD group (P = 0.002).

5.5.2 EPDS and BDI-II categorical data : Risk of Depression results

Baseline categorical data for the risk of depression is presented in Figure 8 for all depression thresholds according to EPDS and BDI-II. Data are expressed as risk ratios and 95% confidence intervals.

Figure 8 : Baseline EPDS & BDI depression risk ratios

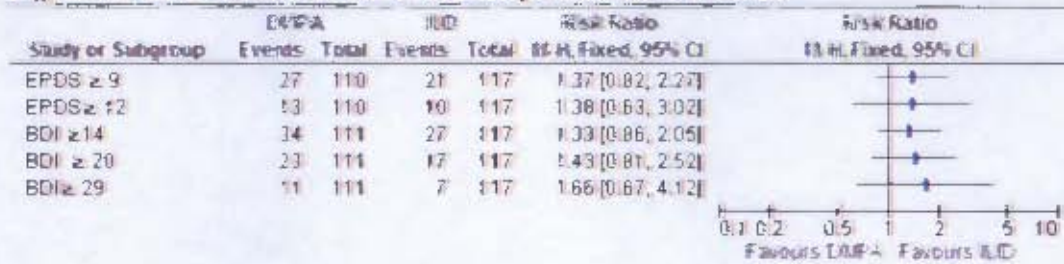


Statistical methods used were the Mantel-Haenszel analyses model, fixed effect measure is the risk ratio with 95% Confidence interval.

There were no differences in baseline depression rates between the groups with respect to mild to severe depression (Risk Ratio of 1.15 and 95% CI 0.89, 1.48) using the EPDS. Similar results were observed for depression rates according to BDI-II scores. Two DMPA group participants had high scores falling in the category of major depression (BDI ≥ 29). These participants met the exclusion criteria for the study, however, due to a protocol violation, were included. This protocol violation was only noticed by the researcher at the time of analysis; therefore, these women were included in the final analysis.

Risk of depression at the one month follow-up is presented in Figure 9 for all depression thresholds according to EPDS and BDI-II. Data are expressed as risk ratios and 95% confidence intervals.

Figure 9: One month EPDS & BDI depression risk ratios

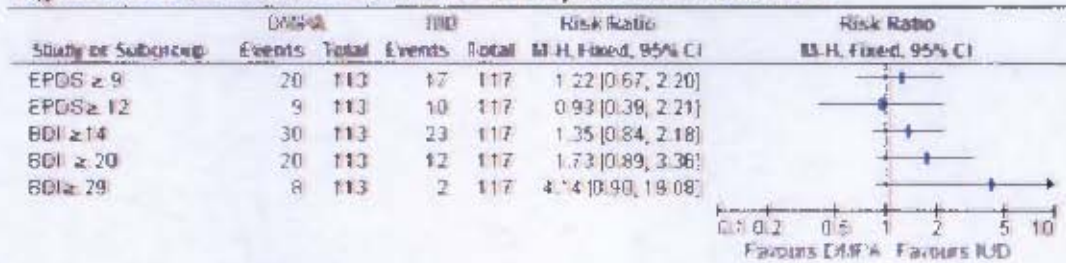


Statistical methods used were the Mantel-Haenzel analyses model, fixed effect measure expressed as the risk ratio with 95% Confidence interval.

At one-month there was a trend towards a greater risk of depression in the DMPA group compared with the IUD group, however, the 95% confidence interval does not cross 1 indicating that this trend was not statistically significant.

The risk of depression at three months is presented in Figure 10 according to EPDS and BDI-II. Data are expressed as risk ratios and 95% confidence intervals.

Figure 10: Three months EPDS & BDI depression risk ratios



Statistical methods were the Mantel-Haenzel analyses model, fixed effect measure expressed as the risk ratio with 95% Confidence interval.

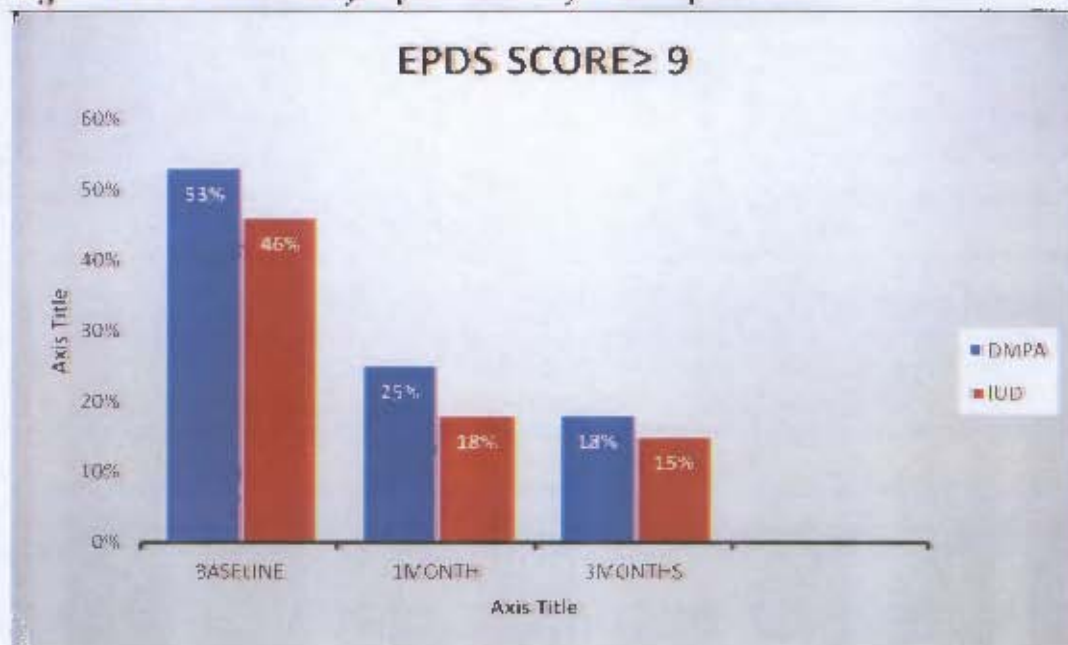
At three months follow-up, there was no statistically significant difference between rates of depression in the DMPA and IUD groups for either depression scales. However, with the BDI-II there was a non-significant trend towards more depression in the DMPA group.

5.5.3 EPDS and BDI-II categorical data : Depression results

5.5.3.1 EPDS score results for mild depression

Figure 11 presents depression rates of mild to severe depression events (EPDS scores of ≥ 9) between DMPA and IUD groups. Data is expressed as percentages.

Figure 11 : EPDS results for prevalence of mild depression

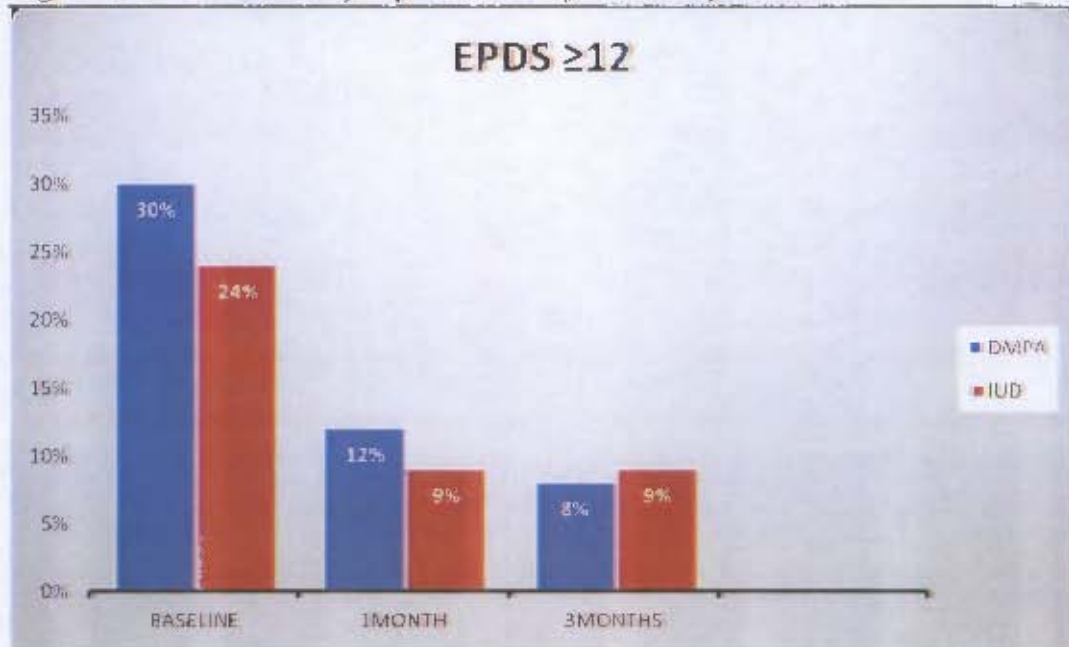


There were no statistically significant differences between the groups in the rates of mild to severe depression according to EPDS scores at baseline $P=0.36$ (Yates corrected Chi-square test), one month ($P=0.29$) (Yates corrected Chi-square test) and three months $P = 0.63$ (Yates corrected Chi-square test).

5.5.3.2 EPDS score results for severe depression

Figure 12 presents depression rates of severe depression events (EPDS scores of ≥ 12) between DMPA and IUD groups. Data are expressed as percentages.

Figure 12 : EPDS results for prevalence of severe depression.

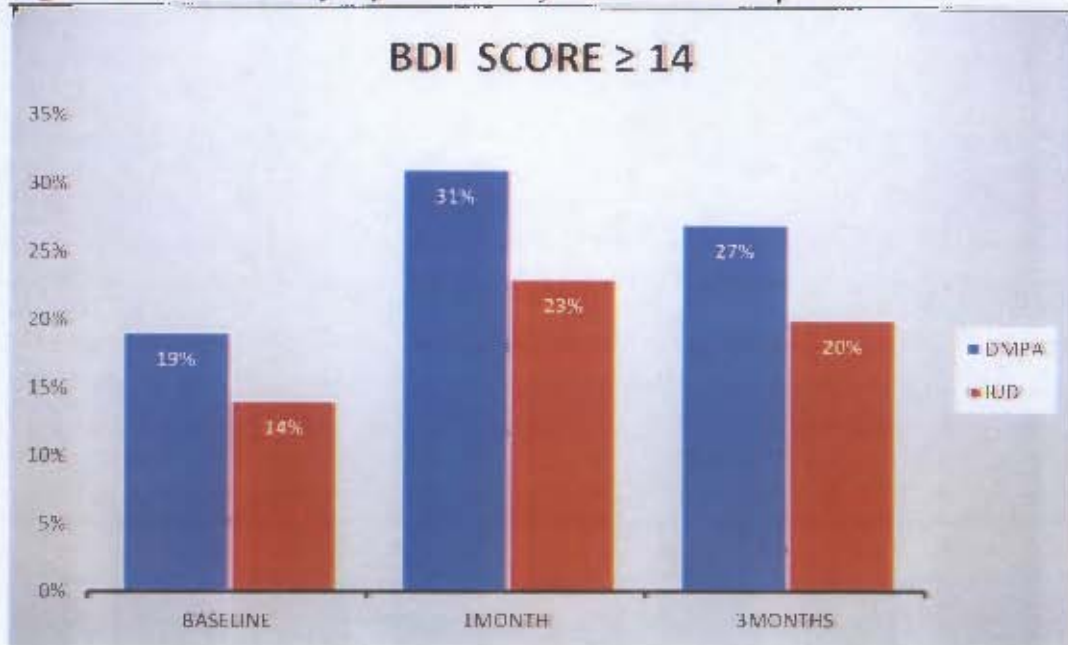


There was no statistically significant difference in the rate of severe depression between the groups at baseline $P= 0.41$ (Yates corrected Chi-square test), one month $P=0.55$ (Yates corrected Chi-square test), and three months $P= 0.93$ (Yates corrected Chi-square test).

5.5.3.3 BDI score results mild – severe

Figure 13 presents depression rates of mild to severe depression events (BDI scores of ≥ 14) between the DMPA and IUD groups. Data are expressed as percentages.

Figure 13 : BDI results for prevalence of mild-severed depression

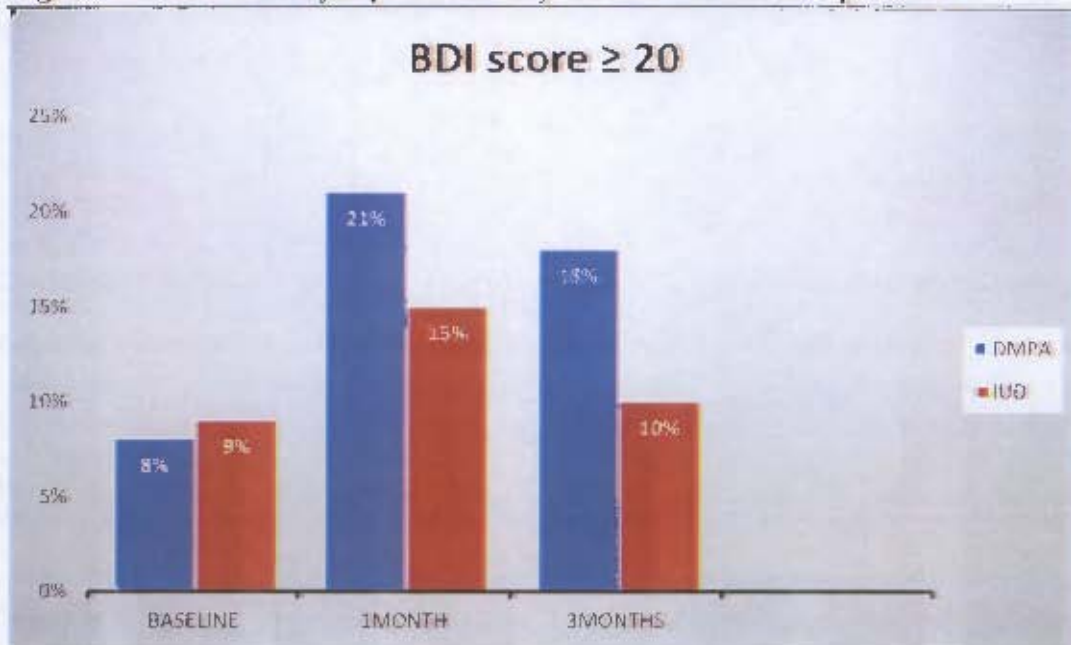


There was no statistically significant difference in the prevalence of mild to severe depression between the groups at baseline $P = 0.44$ (Yates corrected Chi-square test), one month $P = 0.25$ (Yates corrected Chi-square test) and three months $P = 0.13$ (Yates corrected Chi-square test).

5.5.3.4 BDI score results moderate – severe

Figure 14 presents depression rates of moderate to severe depression events (BDI scores of ≥ 20) between DMPA and IUD groups. Data are expressed as percentages.

Figure 14: BDI results for prevalence of moderate - severe depression

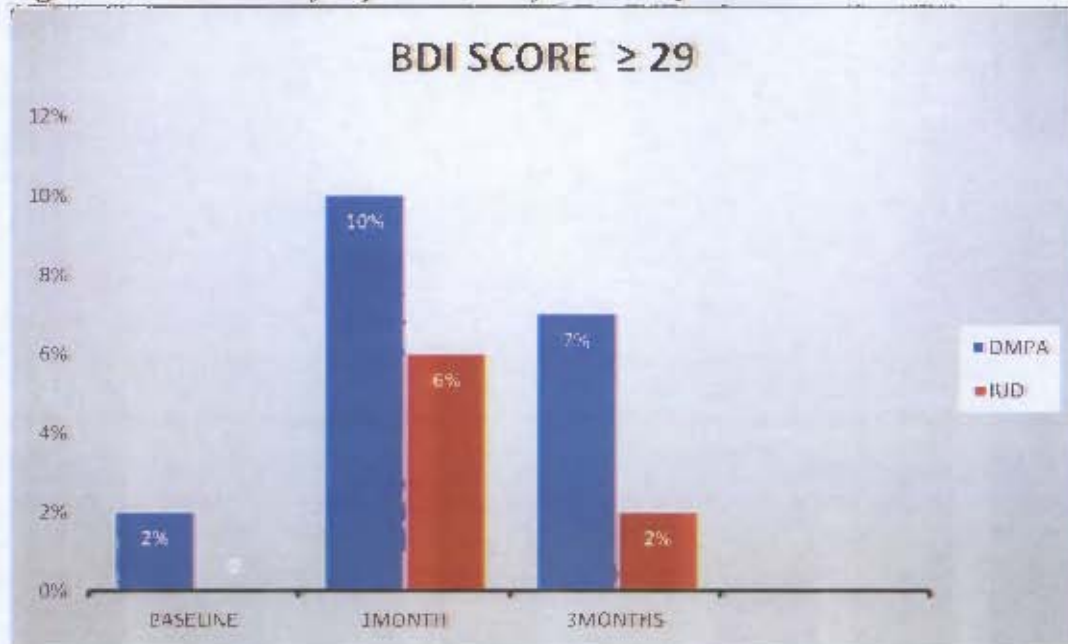


There was no statistically significant difference in the rate of moderate to severe depression between the groups at baseline $P = 0.96$ (Yates corrected Chi-square test), one month $P = 0.29$ (Yates corrected Chi-square test) and three months $P = 0.14$ (Fisher exact two-tailed test).

5.5.3.5 BDI score results severe depression

Figure 15 presents rates of severe depression events (BDI scores of ≥ 29) between DMPA and IUD groups. Data are expressed as percentages.

Figure 15: BDI results for prevalence of severe depression



There was no statistically significant difference in the prevalence of moderate to severe depression between the groups at baseline $P=0.24$ (Fisher exact two-tailed test), one month $P = 0.39$ (Yates corrected Chi-square test). At three months the increase in severe depression in the DMPA group was of borderline statistical significance: $P = 0.05$ (Fisher exact two-tailed test) (8/119 women in the DMPA group and 2/123 women in the IUD group).

5.5.4 ASEX continuous data: Sexual functioning results

Sexual functioning scores as measured by ASEX are presented in Table 6.

Data are expressed as mean \pm standard deviation.

Table 6 : ASEX mean score results and changes over time

ASEX		DMPA		IUD			
Time	n	Mean (SD)	n	Mean (SD)	p-value	Mean diff	95% CI
Baseline	116	9.5 (3.1)	118	9.5(3.1)	0.9	0.00	-0,82 to 0.82
One Month	110	12.9(4.2)	117	12.4(4.5)	0.4	0.48	-0.67 to 1.63
Δ One Month	110	3.4(5.4)	117	3.1(5.3)	0.2	0.8	-0.63 to 2.26
Three months	113	13.9(5.1)	117	13.5(4.3)	0.5	0.38	-0.86 to 1.62
Δ Three Months	113	4.2(6.4)	117	3.8(5.1)	0.7	0.37	-1.14 to 1.90

There was no statistical significant difference in ASEX scores between groups, either in absolute scores or changes from baseline.

5.5.5 ASEX categorical data: Risk of sexual dysfunction results

Baseline categorical data for risk of sexual dysfunction between the groups is presented in Figure 14 for ASEX thresholds of each item score ≥ 5 and for total score ≥ 19 according ASEX. Data are expressed as risk ratios and 95% confidence intervals.

Figure 14: Baseline comparison of DMPA & IUD ASEX items and total events of no sexual intercourse



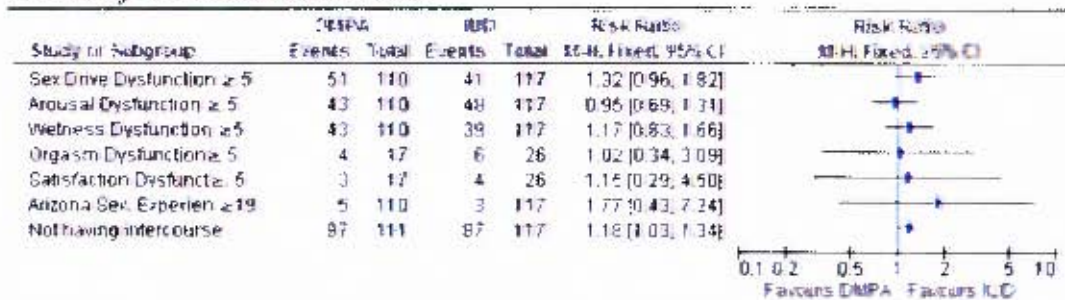
Statistical methods used were the Mantel-Haenszel analyses model, fixed effect measure is the risk ratio with 95% Confidence interval.

There was no statistically significant difference in the risk of sexual dysfunction noted at baseline. However there was a trend for more participants in the DMPA group not having intercourse within the week before enrolment in the study.

5.5.6 ASEX categorical data: Risk of Sexual dysfunction results

One month categorical data for risk of sexual dysfunction between the groups is presented in Figure 16 for ASEX thresholds of each item score ≥ 5 and for total score ≥ 19 according ASEX. Data are expressed as risk ratios and 95% confidence intervals.

Figure 16 : One month comparison of DMPA & IUD ASEX items and total events of no sexual intercourse

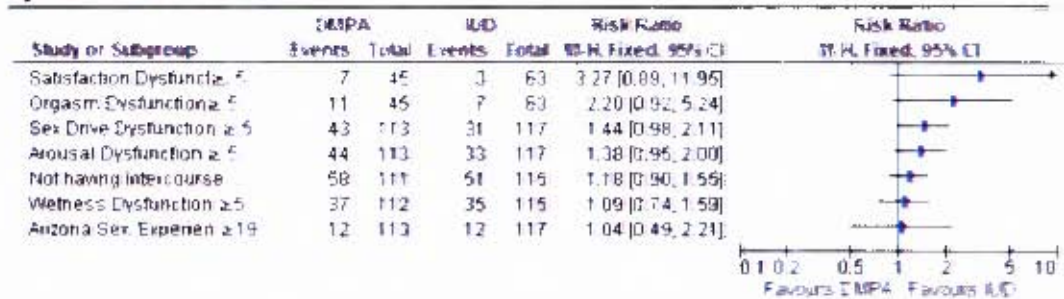


Statistical methods used were the Mantel-Haenzel analyses model, fixed effect measure is the risk ratio with 95% Confidence interval.

There was no statistically significant difference in ASEX scores. However, significantly more women in the DMPA group had not resumed intercourse at one month postpartum. The Yates corrected Chi-square gave us $p=0.00$ ($P<0.05$) showing the difference was statistically significant.

Three month categorical data for risk of sexual dysfunction between the groups is presented in Figure 17 for ASEX thresholds of each item score ≥ 5 and for total score ≥ 19 according ASEX. Data are expressed as risk ratios and 95% confidence intervals.

Figure 17 : Three month comparison of DMPA & IUD ASEX items and events of no sexual intercourse



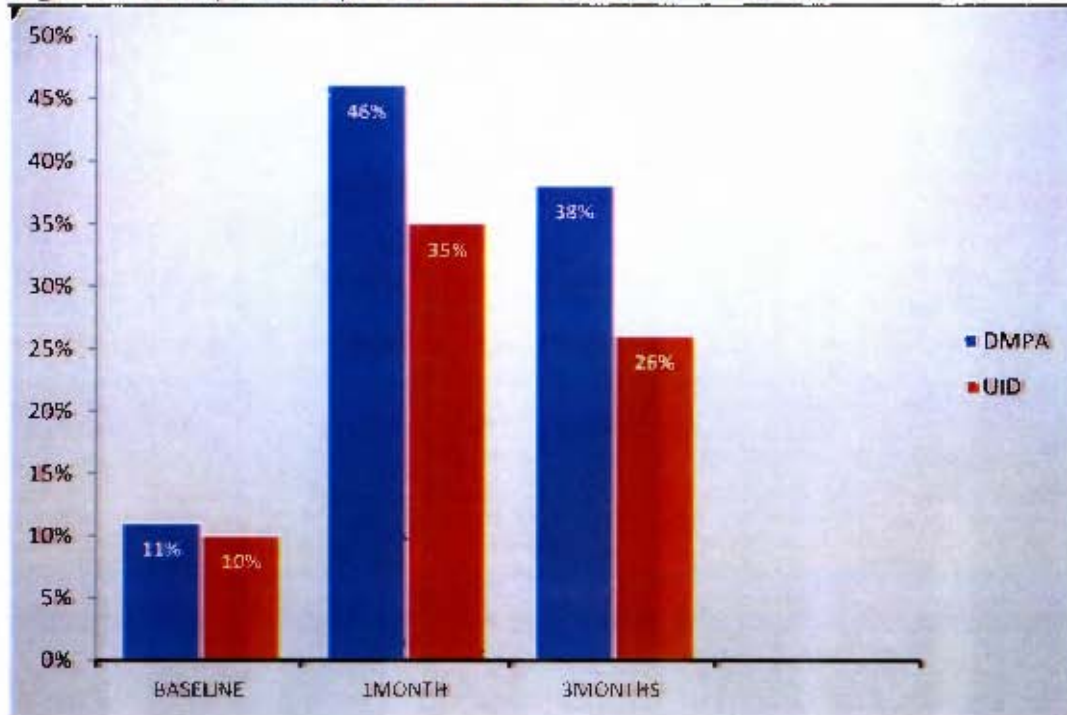
Statistical methods were the Mantel-Haenszel analyses model; fixed effect measure expressed as the risk ratio with 95% Confidence interval.

There was a statistically non-significant trend to more sexual dysfunction with DMPA in the first four categories.

5.5.6.1 ASEX Item 1: Sex drive

Figure 18 presents ASEX item 1 scores for sex drive dysfunction ≥ 5 (representing very weak to no sex drive), between DMPA and IUD groups. Data are expressed as percentages.

Figure 18: Comparison of DMPA & IUD sex drive scores ≥ 5

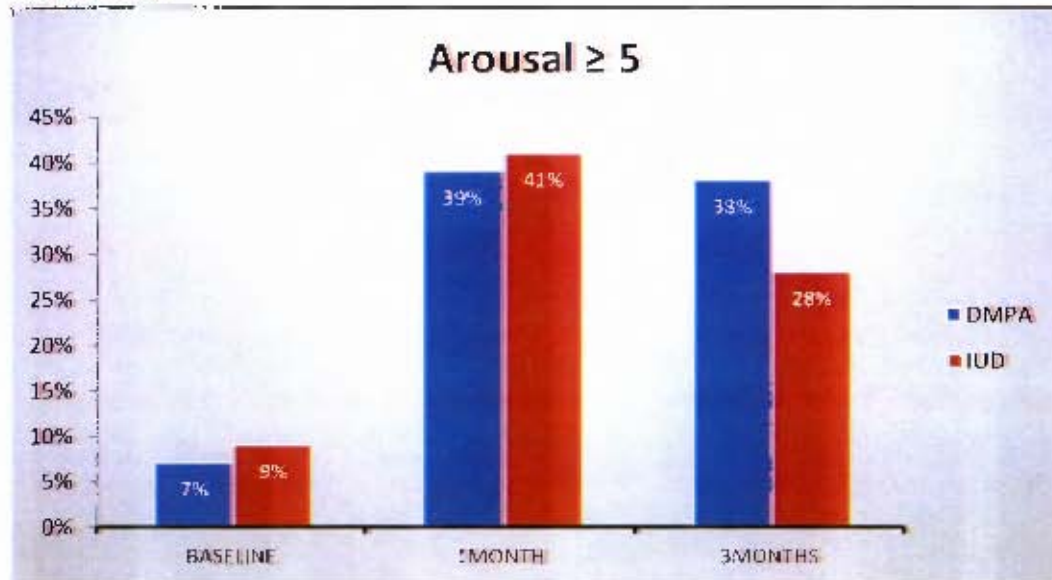


At baseline, 11% of 115 women in DMPA group had a score ≥ 5 for sex drive, and 10% of 118 women in IUD group had the same. At one month follow-up, this proportion increased to 46% of 110 women in DMPA group, and to 35% increase from of 117 women in the IUD group. At three months, this proportion decreases compared to one month follow-up: 38% of 110 women in DMPA group and 26% of 117 women on the IUD group scoring ≥ 5 but remained non-significantly higher in the DMPA group.

5.5.6.2 ASEX Item 2: Arousal

Figure 19 presents ASEX item 2 scores for Arousal ≥ 5 (5 representing low arousal), between DMPA and IUD groups. Data are expressed as percentage

Figure 19: Comparison of DMPA & IUD group events of very difficult to no sex arousal

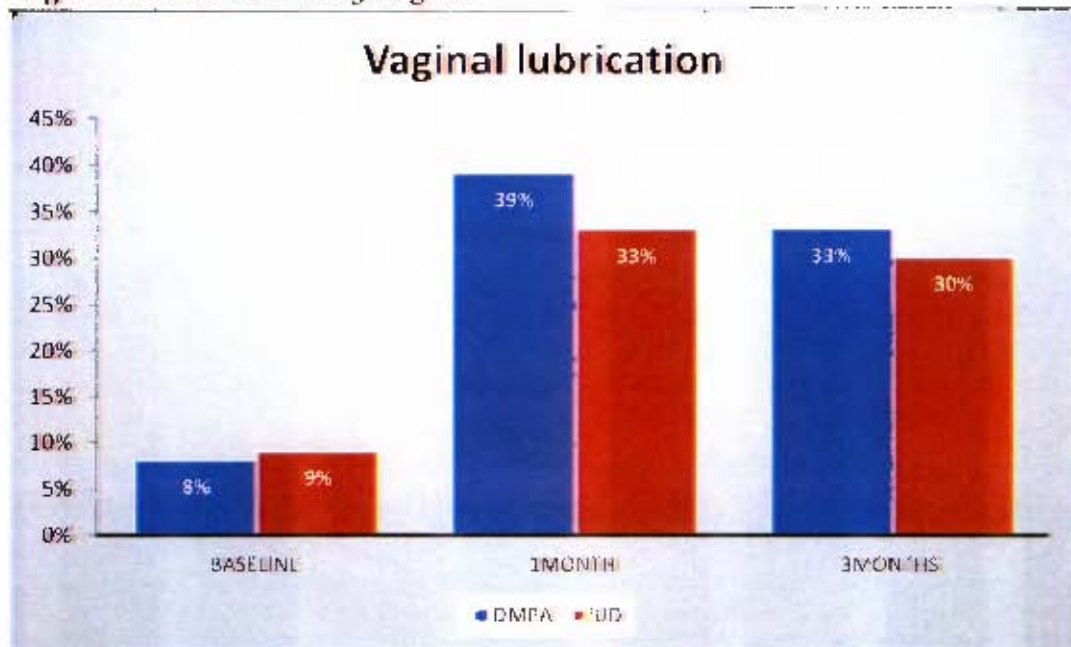


At baseline, 7% of 116 women in DMPA group and 9% of 118 women in IUD group had a score ≥ 5 for arousal. This proportion increased at one month follow-up for both groups, to 39% in DMPA group (total 110 women) and to 41% in the IUD group (total 117 women). There was not much of a difference between the proportion at one month as compared with three months for the DMPA group. However there was a statistically significant difference in the IUD group in the one month and three months rates of sexual arousal dysfunction $P = 0.05$ (Yates corrected Chi-square test).

5.5.6.3 ASEX Item 3: Vaginal wetness

Figure 20 presents ASEX item 3 for vaginal lubrication scores ≥ 5 (representing “very difficult vaginal lubrication” to “never experiencing vaginal wetness”) between DMPA and IUD groups. Data are expressed as percentages.

Figure 20: Comparison of DMPA & IUD events of women with difficult vaginal lubrication to dry vagina



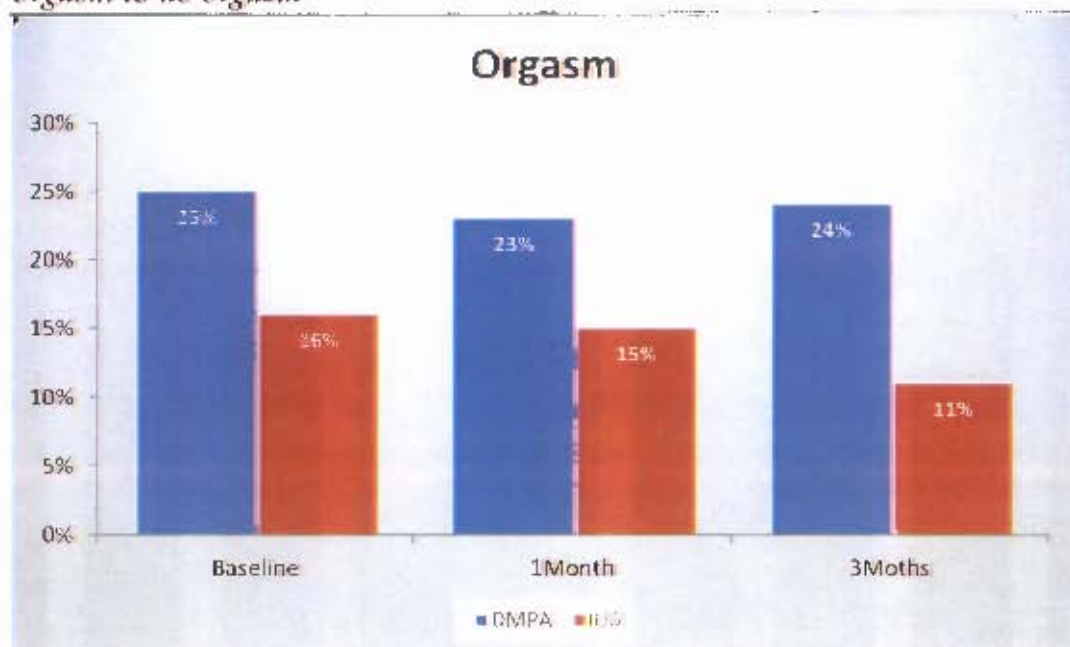
At baseline, 8% of 114 women in DMPA group and 9% of 118 women in IUD group had a score ≥ 5 on the vaginal lubrication item. An increase in this proportion relative to baseline was being observed, similarly to the arousal scores. In the DMPA group, 39% of 110 women, compared with 33% of 117 women in the IUD group, had a score ≥ 5 on the vaginal lubrication. Some decrease in proportions at three months relative to one month follow-up was seen: 33% of 113 women in DMPA group and 30% of 117 women in IUD group had a score ≥ 5 . None of these differences was statistically significant.

The next two ASEX items, orgasm and satisfaction, were only answered by participants who had had sexual intercourse within a week of the interview. Therefore, the numbers presented in the following chart only include those women.

5.5.6.4 ASEX Item 4: Orgasm

Figure 21 presents a comparison of the DMPA and IUD groups with scores ≥ 5 on orgasm dysfunction (very difficult to reach orgasm to never reaching it). Data are expressed as percentages.

Figure 21: Comparison of DMPA & IUD group events of difficulty to reach orgasm to no orgasm



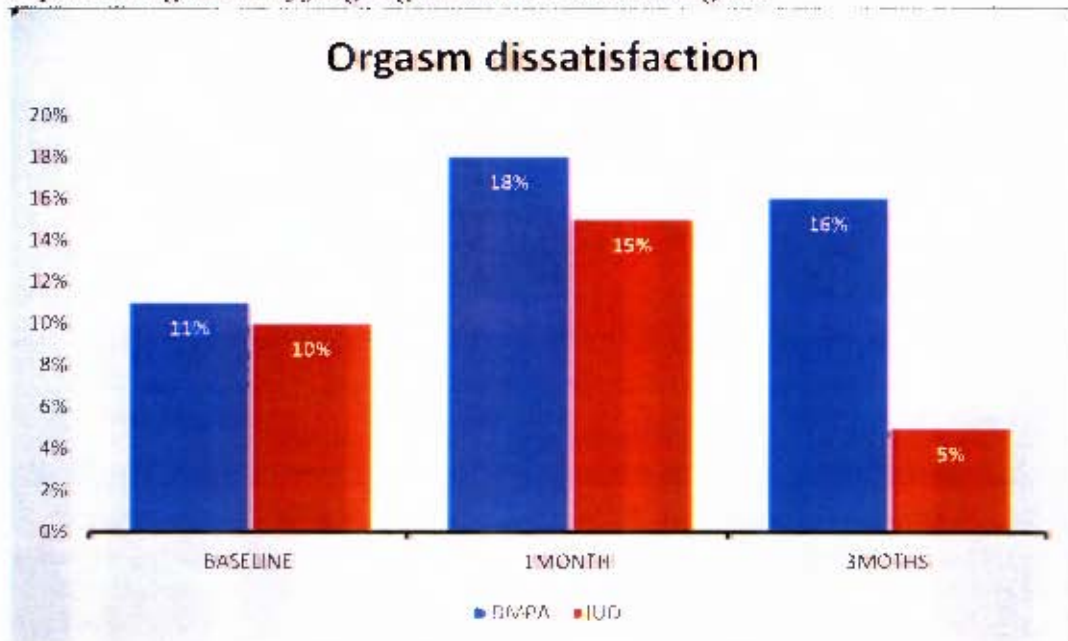
At baseline, only 25% of 12 participants in DMPA group and 16% of 12 participants in IUD group have this score. At one month follow-up 23% of 17 women in DMPA group and 15% of 26 participants in IUD group reported this score on orgasm. At the three month follow-up, 24% of 45 participants in

DMPA and 11% of 63 participants in IUD group reported having difficulties with reaching orgasm. There were no statistically significant differences in scores for each group over time.

5.5.6.5 ASEX Item 5: Satisfaction

Figure 22 presents ASEX item 5 scores for satisfaction ≥ 5 (representing very unsatisfying experience among the women who could not reach orgasm), between DMPA and IUD groups. Data are expressed as percentages.

Figure 22: Comparison of DMPA & IUD group for events of women experiencing unsatisfying orgasm or can't reach orgasm

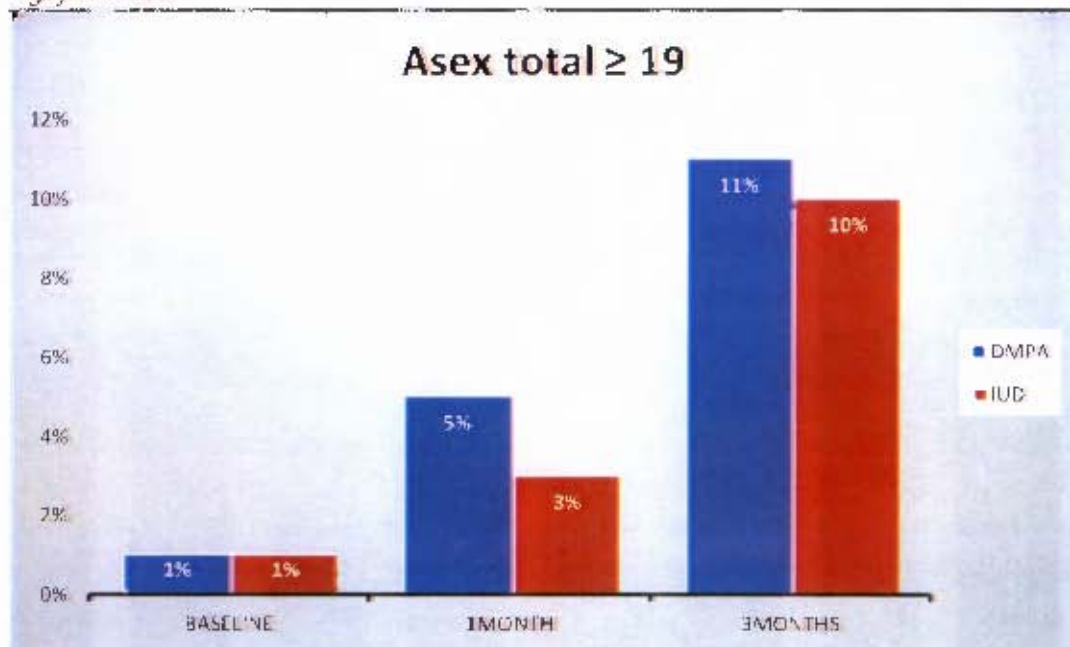


At baseline, there were no participants in both groups who had scores ≥ 5 for sexual satisfaction. At one month follow-up, 18% of 17 participants on the DMPA group had scores ≥ 5 indicating less satisfaction with their orgasm, compared with 15% of 26 participants in IUD group. At three month follow-up, 16% of 45 participants in DMPA group and 5% from of 63 participants in IUD group were also less satisfied with the experience.

5.5.6.6 ASEX total score ≥ 19

Figure 23 presents ASEX total scores ≥ 19 (represents sexual dysfunction), between DMPA and IUD groups. Data are expressed as percentages.

Figure 23: Comparison of DMPA & IUD groups for events of sexual dysfunction

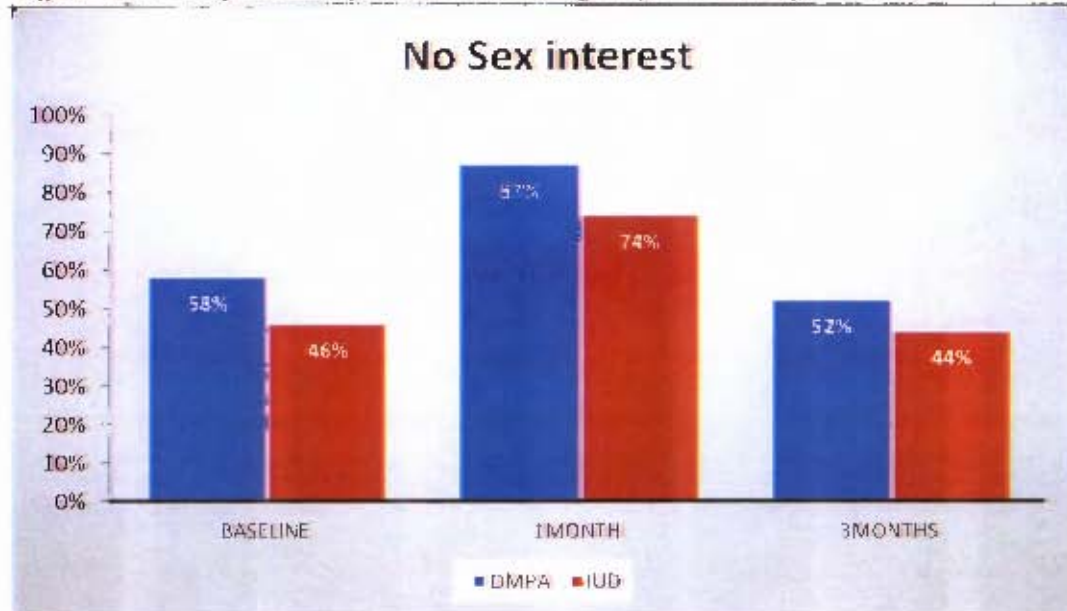


At baseline, each group had only one study participant with a total scores ≥ 19 . At one month, 4.5% of 110 participants in DMPA group and 2.5% of 117 participants in IUD group reported sexual dysfunction. At three months, this proportion increased to 11% of 113 participants in DMPA group and 10% of 117 participants in IUD group. These differences were not statistically significant.

5.5.6.7 Return of sexual interest after birth

Figure 24 presents the rate of return of sexual interest, between DMPA and IUD groups. Data are expressed as percentages.

Figure 24 : Comparison of DMPA & IUD group's return of sex interest



In addition to the ASEX, a question was asked at all study time points (baseline, one month and three months) whether study participants have had sexual intercourse within the past month. At baseline there was no statistically significant difference between the study groups of participants who did not have sexual intercourse. At one month follow-up, more participants in the IUD group (30 of 117 participants) compared with the DMPA group (14 of 111 participants) had engaged in sexual intercourse; this difference was statistically significant $P = 0.02$ (Yates corrected Chi-square test). At three months (64 of 115 participants) IUD group had more participants who had engaged in sexual intercourse as compared to the

DMPA group (53 of 111 participants); this difference was not statistically significant $p=0.29$ (Yates corrected Chi-square test).

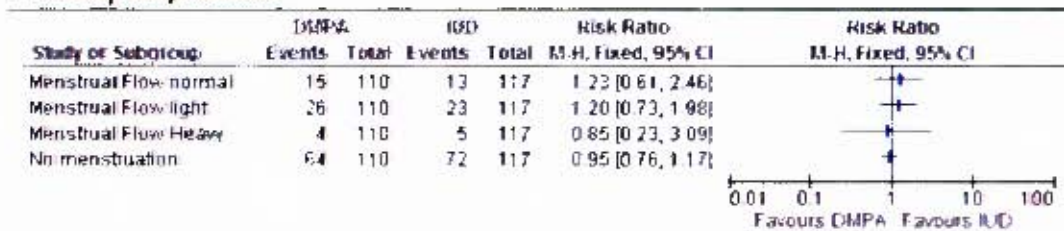
5.6 Secondary outcomes results

5.6.1 Menstrual Flow

Figure 25 presents the risk of menstrual disturbances within the two groups.

Data are expressed as risk ratios and 95% confidence intervals.

Figure 25 : Comparison of DMPA & IUD group's menstrual flow at one month postpartum

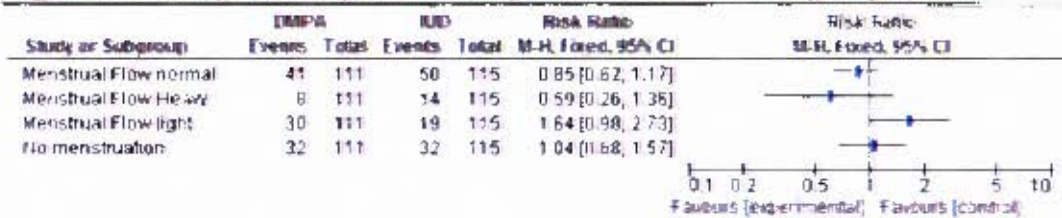


Statistical methods used were the Cochran Mantel-Haenszel analyses model, fixed effect measure is the risk ratio placed at 95% Confidence interval.

There was no statistically significant difference in risk for menstrual disturbances between the groups.

Figure 26 presents the risk of menstrual disturbances between the two groups at three months postpartum. Data are expressed as risk ratios and 95% confidence intervals.

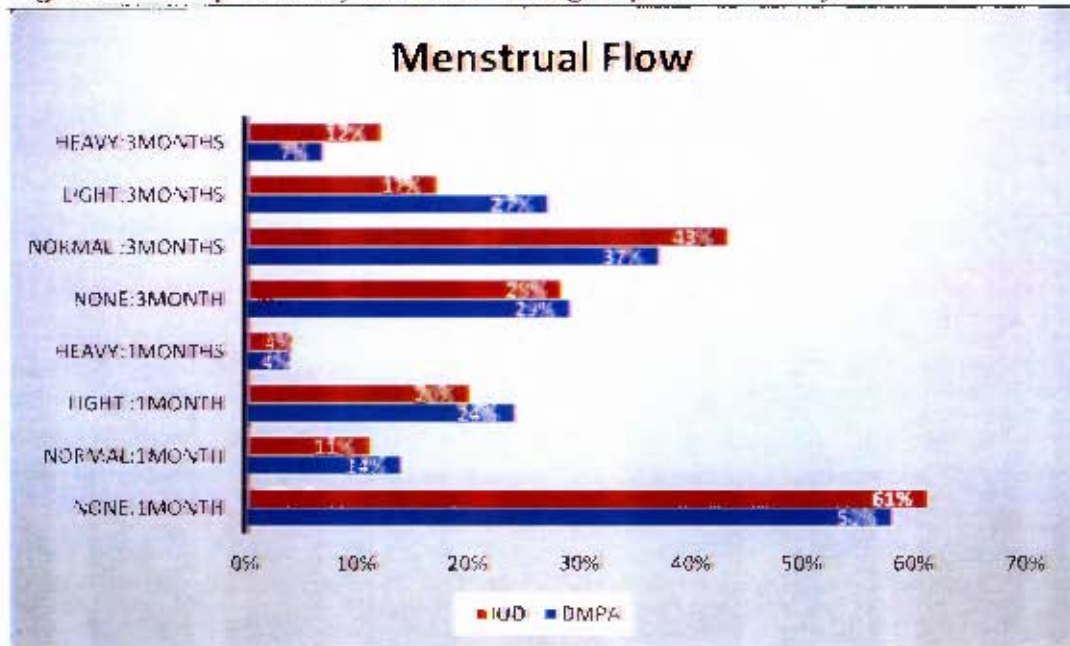
Figure 26 : Comparison of menstrual flow at three months postpartum



There was no statistical significant difference in the risk of menstrual disturbances between the groups. However there was a trend towards more participants in the DMPA group having heavy menstruation compared with the IUD group (RR < 1 means the event is less likely to occur in the DMPA group).

Figure 27 presents prevalence of normal, light and heavy menstruation, as well as amenorrhoea, between DMPA and IUD groups. Data are expressed as percentages.

Figure 27: Comparison of DMPA & IUD groups 'menstrual flow



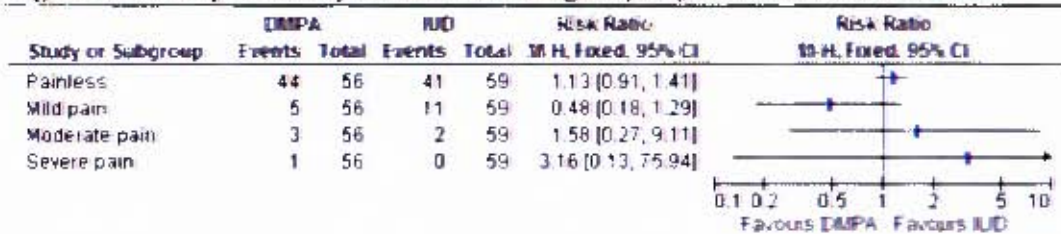
There was no statistical difference in menstrual flow at both follow up study points (one month and three months) for menstrual flow between study participants.

The prevalence of amenorrhea at one month was 59% for the whole sample (136 out of 227 participants), which decreased to 28% (64/225) at three months.

5.6.2 Menstrual Pain

Figure 28 presents the risk of dysmenorrhea within the two groups at one month postpartum. Data are expressed as risk ratios and 95% confidence intervals.

Figure 28: Comparison of DMPA & IUD group: dysmenorrhea at 1month

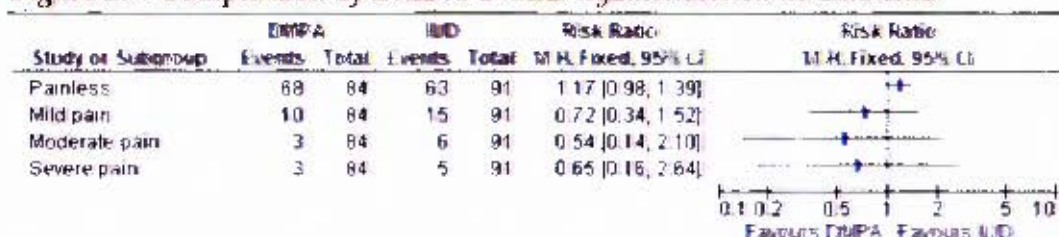


Statistical methods used were the Cochran Mantel-Haenzel analyses model, fixed effect measure is the risk ratio placed at 95% Confidence interval.

There was no significant difference in the risk of dysmenorrhea between the groups at one month postpartum.

Figure 29 presents risk of menstrual pain within the two groups at three months postpartum. Data is expressed as risk ratios and 95% confidence intervals.

Figure 29: Comparison of DMPA & IUD dysmenorrhea at 3months

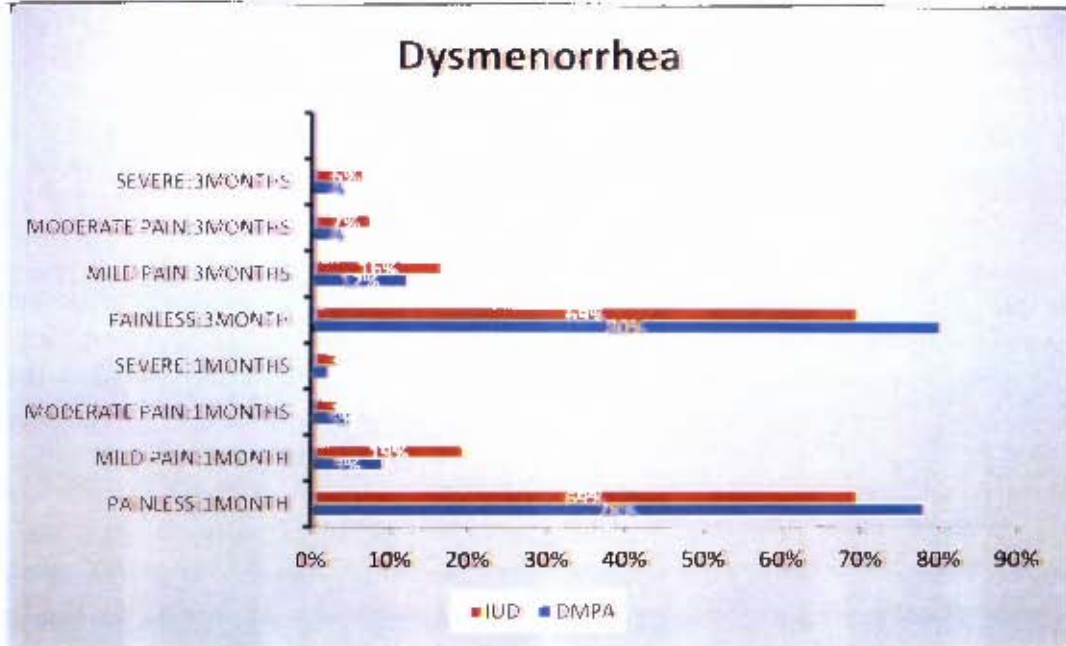


Statistical methods used were the Cochran Mantel-Haenszel analyses model; fixed effect measure is the risk ratio placed at 95% Confidence interval.

There was no significant difference in the risk of dysmenorrhea between the groups at three months postpartum. However, there is a trend for the last three categories (mild, moderate and severe pain) to occur more frequently in the IUD group compared with the DMPA group (RR < 1).

Figure 30 presents prevalence of normal, light and heavy menstruation as well as dysmenorrhea between DMPA and IUD groups. Data are expressed as percentages.

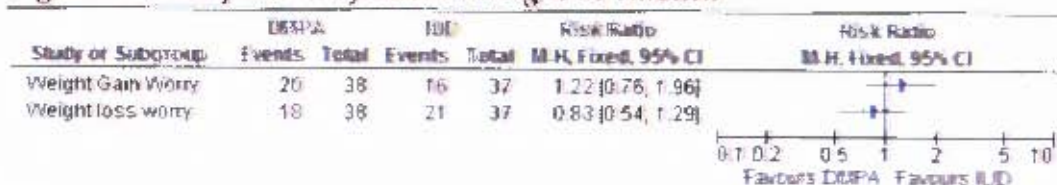
Figure 30 : Dysmenorrhea



Only women who had menstruation at these time points could answer whether they had menstrual pain or not. For both groups, the majority of women had no menstrual pains and there was no significant difference of dysmenorrhea among the two groups. There is just a slight trend of more events in the IUD group for mild pain compared with the DMPA group.

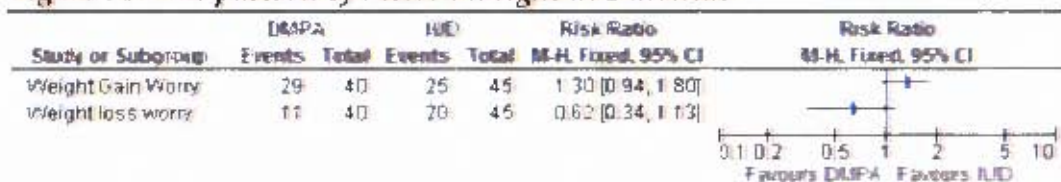
5.6.3 Weight changes

Figure 31 : Comparison of altered weight at 1month



A weight gain index (weight gain minus the number reporting weight loss worry) captured both aspects of changes in weight (DMPA 2/38 versus IUD 5/37).

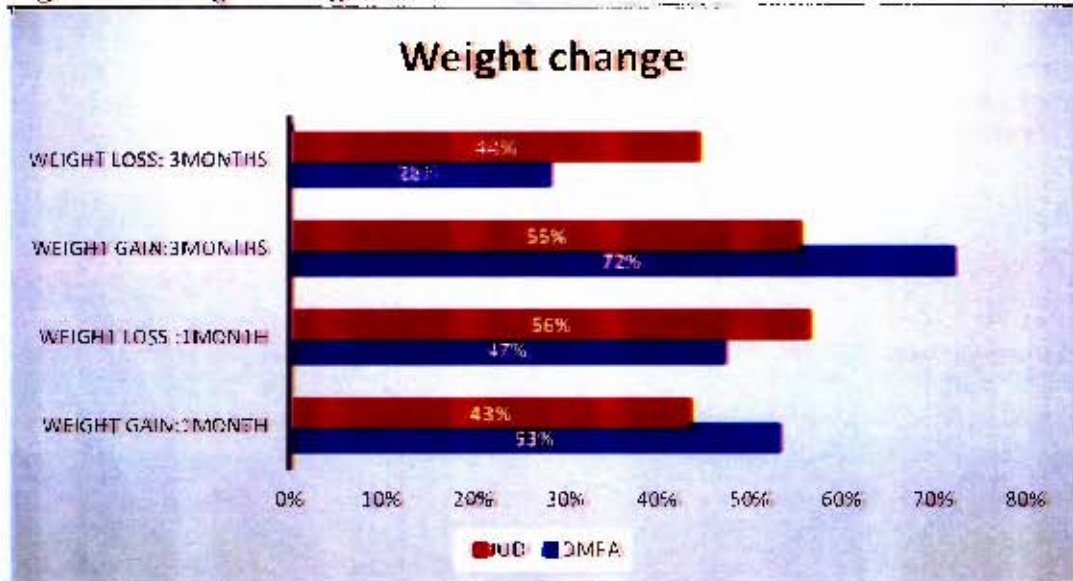
Figure 32: Comparison of altered weight at 3 months



A weight gain index (weight gain minus the number reporting weight loss worry) to capture both aspects of changes in weight changes was undertaken. The Yates corrected Chi-square test showed there was a statistical significant difference in the weight gain index (DMPA 18/40 versus IUD 5/45) between DMPA and IUD, $P = 0.00$ ($P > 0.05$).

Figure 33 presents prevalence of weight loss and weight gain between DMPA and IUD groups. Data are expressed as percentages.

Figure 33 : Weight change chart

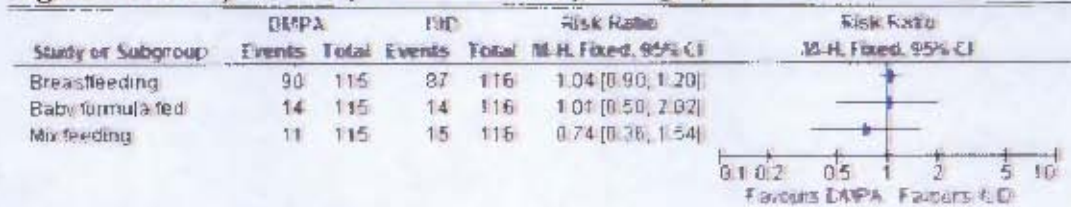


This summary includes those women who said they were worried about their weight. There is no difference in the prevalence of weight gain and weight loss between DMPA and IUD group. More participants in the DMPA complained of weight gain than the IUD group, however, this difference was not statistically significant.

5.6.4 Choices of feeding options

Figures 34, 35, and 36 presents the risk of breastfeeding, formula feeding and mix feeding at baseline, one month and three months. Data are expressed as risk ratios and 95% confidence intervals.

Figure 34 : Comparison of DMPA & IUD feeding options at baseline



Statistical methods were the Mantel-Haenzel analyses model; fixed effect measure expressed as the risk ratio with 95% Confidence interval.

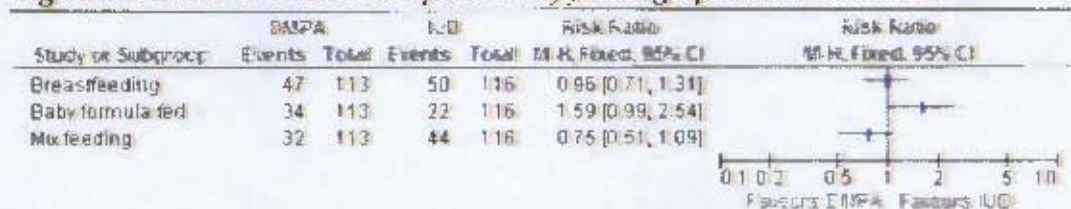
There was no statistically significant difference in the choice of feeding between the two groups at baseline (Figure 34), one month (Figure 35) and three months (Figure 36).

Figure 35 : Comparison of DMPA & IUD group feeding options at 1month



Statistical methods were the Mantel-Haenzel analyses model; fixed effect measure expressed as the risk ratio with 95% Confidence interval.

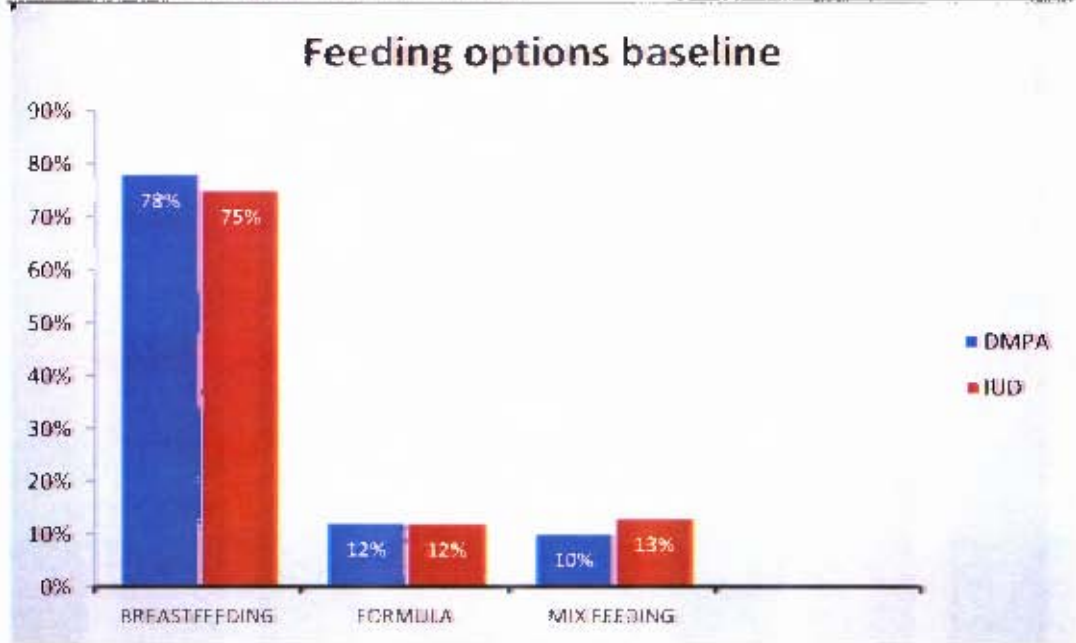
Figure 36 : DMPA & IUD comparison of feeding options at 3months



Statistical methods were the Mantel-Haenzel analyses model; fixed effect measure expressed as the risk ratio with 95% Confidence interval.

Figure 37 presents the rates of feeding options at baseline between DMPA and IUD groups. Data are expressed as percentages.

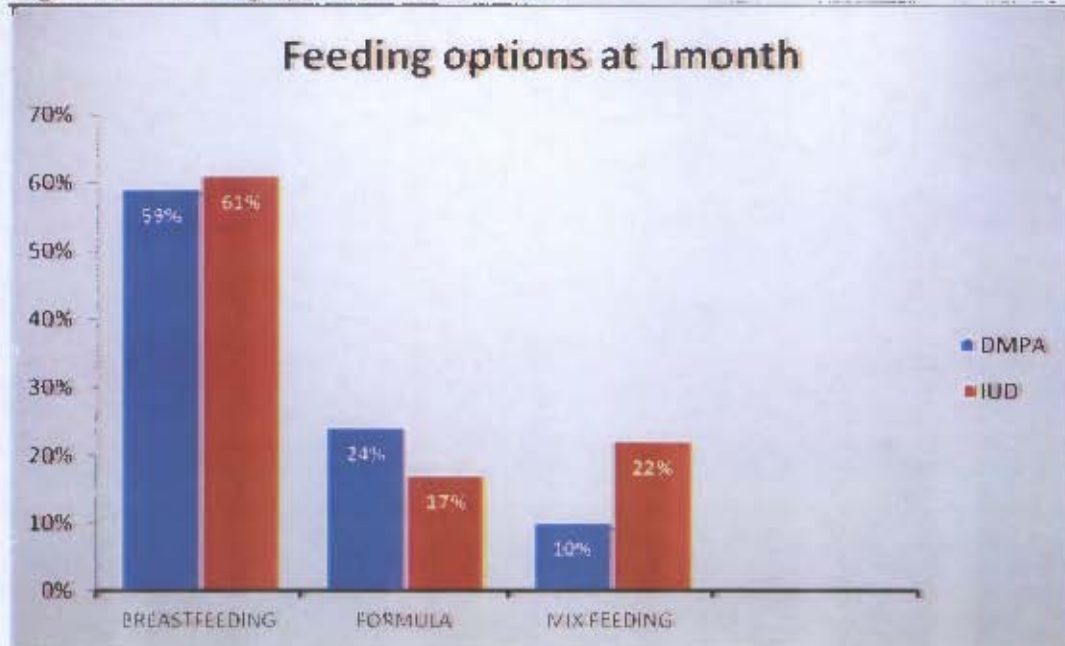
Figure 37 : Feeding options at baseline



At enrolment, women were asked about decisions they had already made about their choice of feeding option. At the two participating study sites, exclusive breastfeeding is encouraged and women are supported to initiate breastfeeding whilst in hospital. No differences were noted between the DMPA and IUD in their feeding options at baseline.

Figure 38 presents the rates of feeding options at one month postpartum between DMPA and IUD groups. Data are expressed as percentages.

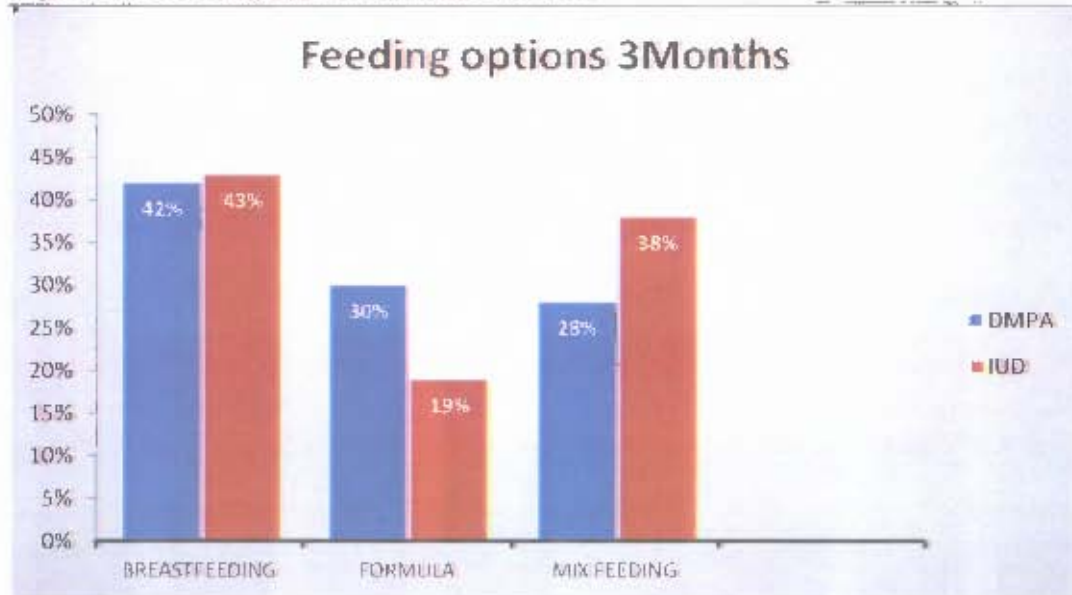
Figure 38 : Feeding options at one month



There was no significant difference between the DMPA and IUD groups with regard to their feeding choices at one month. Although there were more participants in the IUD group who mix fed than the DMPA group, this difference was not statistical significant.

Figure 39 presents prevalence of feeding options at one month postpartum between DMPA and IUD groups. Data are expressed as percentages.

Figure 39: Feeding options at three months



There was no significant difference between the DMPA and IUD groups with regard to their feeding options at one month. Although there were more participants in the DMPA than the IUD group who formula fed their babies, and more participants in the IUD group who mix fed than the DMPA group, these differences were not statistical significant.

5.7 *Summary of Results*

Primary outcomes

The study questions were to ascertain whether:

- There is a statistical difference in the effect of injectable DMPA on depression as compared to the Cu-IUD
- There is a statistical difference in the effect of injectable DMPA on sexual functioning as compared to the Cu-IUD.

To answer the first question, two depression scales were used: the BDI-II and the EPDS. Depression was expressed as continuous (means/medians) and categorical variables (number of events) for each test and the relative risk of depression in each group was calculated to determine whether there was any difference between the groups. A 95% CI which spans from <1 to >1 indicates no statistically significant difference between the groups at the 5% level.

At baseline, group characteristics were similar and the incidence of depression was not significantly different between the two groups using the EPDS (mild or severe depression categories) or the BDI-II (mild-severe, moderate-severe and severe depression categories).

Results at one month after randomisation showed a statistical significant difference between median EPDS scores in favour of the IUD ($P=0.04$). However, there was no statistically significant difference in median BDI-II

scores ($P = 0.2$) at the same time point. For the categorical data the relative risk of depression at one month for both the EPDS and BDI-II scales showed a trend towards more depression in the DMPA group for all depression categories, however, the incidence of depression was not significantly different between DMPA and IUD groups.

At three months, the BDI-II showed a statistically significant difference in median depression scores in favour of the IUD group ($P = 0.002$). However, median EPDS scores were not statistically significantly different ($P=0.1$). The risk of depression at three months was not statistically significantly different using either the EPDS or the BDI-II scale for any of the depression categories.

ASEX was used to answer the second question on sexual functioning. As with depression, data for sexual functioning were analysed as continuous (mean ASEX scores) and categorical data (number with sexual dysfunction), and the risk ratios calculated. In addition, the resumption of sexual intercourse was evaluated and compared between the groups.

At all study time-points, mean ASEX scores were not statistically significantly different for sexual dysfunction between the groups, either in absolute values or in change from baseline. There was no difference in the relative risk of sexual dysfunction when data from all 5-items of the ASEX (sex drive, arousal, vaginal lubrication, orgasm and satisfaction) were combined. The incidence of sexual dysfunction was not significantly different between the groups as well. However, significantly more women in

the DMPA group had not resumed intercourse at one month ($P=0.02$) compared with the IUD group.

Secondary outcomes

For all secondary outcomes incidence rates and relative risks were calculated. There was no significant difference in menstrual flow between the groups at one month and three months. There was a trend towards more menstrual pain (mild, moderate and severe pain) at three months in the IUD compared with the DMPA group. There was statistically significant difference between the groups with regard to complaints of weight gain at three months which were more common in the DMPA group. There were no statistically significant differences between the groups with regard to feeding options at any study time-point.

Chapter 6: Discussion

6.1 Introduction

The previous chapter presented the results of data analysis performed using Statistica and Revman software. This chapter aims to put into context, discussing associated literature that aids to clarify why the results observed might have been anticipated and how this influence our understanding of the effect of DMPA and IUD on depression and sexual functioning.

6.2 DMPA and IUD on depression

The primary outcome on which the sample size calculation was based was the depression score. In general depression scores were higher in the DMPA group, but few analyses of difference between the groups reached statistical significance. Some results that were significant were not consistent across depression scales: For example at one month, the increase in depression according to the EPDS, but not the BDI, was statistically significant. At three months, the difference in BDI scores was statistically significant but not the EPDS scores. The results of the study, therefore, need to be interpreted with caution. Although the results are highly suggestive of higher depression scores with DMPA, this trial in isolation cannot be regarded as conclusive.

However, this study is the second randomised clinical trial to evaluate the effect of injectable progestogen contraception on postpartum depression. In the previous study (Lawrie et al, 1998b), also conducted in South Africa, the

progestogen injectable contraception NET-EN was statistically significantly associated with postpartum depression at six weeks postpartum, compared with placebo ($P = 0.002$). This effect had 'worn off' by the three month assessment, possible because women in this study received only one injection, and NET-EN has a duration of action of approximately two months.

When the results from Lawrie et al (1998b) are considered together with the results of this study, there is some compelling evidence that postpartum injectable progestogen contraception is associated with increased depression.

See the pooled results in exploratory meta-analyses below:

Figure 40: Depression at 4 to 6 weeks (EPDS scores ≥ 12)

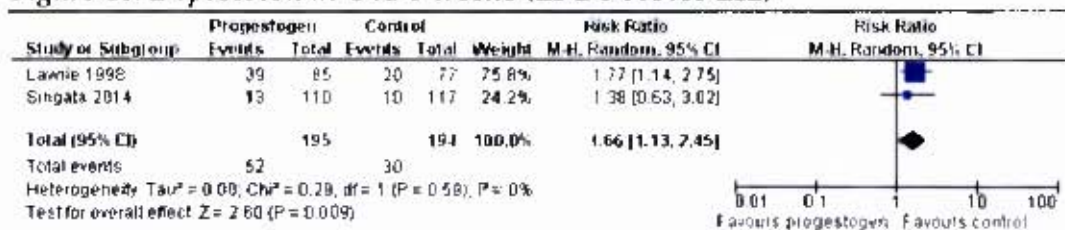
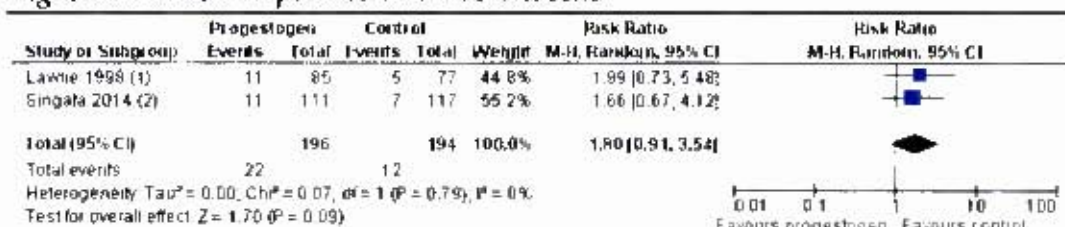


Figure 41: Severe depression at 4 to 6 weeks



(1) MADRS score ≥ 18 at 6 weeks

(2) BDI-II score ≥ 29 at 4 weeks

These pooled results are limited because these studies differ in the type of progestogens used, the duration of contraceptive action of the progestogens (DMPA lasts three months and NET-EN lasts 2 months), the different

depression scales used, and the time-point for follow-up assessed (four weeks and six weeks, respectively).

The only other study of DMPA and postpartum depression is previous retrospective study (Tsai & Schaffir, 2010) that showed no statistically significant difference in depression with DMPA users as compared with non-users in the postpartum period.

However, the quality of the evidence from the current study and the study by Lawrie et al is much higher due to the use of a randomized controlled study design. This study design eliminates selection bias (Schulz & Grimes, 2002). In addition, detection bias was reduced in both randomised studies by blinding the assessor.

The two depression scales (BDI-II & EPDS) did not give equally significant results at the same time points (though the trends were consistent), and this can be expected as these two scales measure different aspects of depression. The BDI-II includes questions about somatic disturbances as opposed to EPDS, and is used to measure the severity of depression rather than to identify depression symptoms as does the EPDS (Čuržik & Begić, 2012).

The incidence of severe depression in Lawrie et al (1998) was approximately 10% (16/162 women) at the six week assessment, measured by the Montgomery-Asberg Depression Rating Scale (MADRS). In this study, the

incidence of severe depression was 8% overall (18/228) in women assessed at four weeks

6.3 DMPA and IUD effects on sexual functioning

These study findings were inconclusive as to whether participants receiving DMPA after delivery have greater risk than those who received the IUD of sexual dysfunction in the postpartum period. Evidence from previous studies is conflicting. Galbaci & Terzioglu (2010) found no significant difference in sexual functioning between hormonal and non-hormonal contraception users. These results were endorsed by Schaffir, Isley and Woodward (2010b), Davis et al (2005) who found that even low androgen levels in hormonal contraceptive users did not introduce negative effects on sexual functioning. However Sabatini & Cagiano (2006) found a negative effect of COCs on vaginal lubrication influencing sexual desire dysfunction.

Results of other studies (Kaunitz, 2009; Matson, Henderson & McGrath, 1997; Paul, Skegg & Williams, 1997; Berga & Smith (2012) suggest that DMPA interferes with sexual interest and breastfeeding with negative effects on sex. Our study did not confirm these findings. However, the methodology of these other studies is limited: most are observational studies; one, (Kaunitz, 2009), randomly allocated participants to intramuscular DMPA or subcutaneous DMPA, therefore this did not have a non-hormonal control group.

Several studies have found negative effects of assisted vaginal delivery compared with caesarean section on sexual functioning, (Safarinejad, Kolahi & Hossein, 2009; Basku 2007; Hicks et al 2004). However, the opportunity to record these data in this study was inadvertently missed.

The results of this study regarding sexual function should be treated with caution because factors affecting sexual function in the postpartum period are complex, including perineal pain, method of delivery (vaginal or caesarean) and adjustment to motherhood, which may override more subtle feelings regarding sexual function. The ASEX questionnaire may therefore not have been sufficiently sensitive to detect differences in feelings between the groups. However the one 'hard' outcome measured, whether or not sexual intercourse was resumed within the first month postpartum, was statistically significantly different; More participants in the IUD group, had sexual intercourse within the 1st month compared with the DMPA group (25% vs. 12%, respectively; $P= 0.02$). This outcome may be a more robust indication of sexual function in the context of the postpartum period, than the more subtle questions which make up the ASEX questionnaire. The 25% recorded in the IUD group is similar to the proportion of women who had a return of sexual interest in a Nigerian study which reported a rate of sexual intercourse at six weeks postpartum of 29.7% (Ezebialu & Eke, 2012)". By contrast, in a Canadian study, a high percentage of postpartum women (47%) had resumed sexual intercourse at 6 weeks (Rowland et al.,

2005). In the latter study, breastfeeding was reportedly associated with the delay in the resumption of sexual intercourse.

Current practice of clinician in the two research sites is education of women not to resume intercourse until six weeks postpartum; in this study their lack of sexual activity at six weeks postpartum may not be all significant.

6.4 DMPA and IUD effects on menstrual disturbances.

There was a significant difference in the menstrual flow index between the groups in this study, with cu-IUD group having a greater risk of heavy menstruation than the DMPA group. Therefore this study adds to the existing evidence that IUD users experience heavier menstrual flow than DMPA users and non-users (Grimes et al., 2006; Zhou & Xiao, 2001). DMPA is known to cause menstrual irregularities; however, it is likely that the three months duration of this study was too short to demonstrate this effect among users. In women who discontinue injectable progestogen contraception due to menstrual irregularities, the cu-IUD may be offered as alternative (Adeyemi & Adekanle, 2012; Hajikazemi, Nikpour & Haghani, 2004; Wood & Jewkes, 2006).

Significant difference in the rate of amenorrhea menstruation would have been expected under normal circumstances in these two groups, as amenorrhea is more common with DMPA use (Draper et al, 2007, Hubacher et al, 2008) as discussed in Chapter two. Again, it is likely that the three

months duration of this study was too short to demonstrate differences between the groups with regard to amenorrhea as this effect tends to occur with duration of use greater than one year.

6.5 DMPA and IUD effect on weight changes

This study has showed that DMPA users are more likely to experience weight gain than cu- IUD users. The weight index of the DMPA group was statistically significantly difference from the IUD group, ($P = 0.00$) These findings are in agreement with the previous studies that have reported weight gain as one of the disadvantages or complaints from DMPA users (Haider & Darney, 2007; Nyirati, Habash & Shaffer, 2013; Vickery et al., 2013; Westhoff et al., 2007b). Furthermore these findings of weight changes with DMPA use add to evidence that was shown in a South African study as well (Beksinska et al., 2010). This effect on weight may be particularly undesirable in the postpartum period when women are eager to get back to their pre-pregnancy weight and, arguably, might adversely affect mood.

6.6 DMPA and IUD effects on feeding options

This study did not show any difference in the rate of different feeding options between the two groups. However, a decline over time in the prevalence of exclusively breastfeeding is observed with an increase in either formula feeding or mix feeding. The reason for including this secondary outcome was to establish if there is an effect of hormonal contraception on milk quantity and mother -infant bonding.

In this study assessment of milk volume was done by assessing the need for supplemental infant feeds, and there was no difference in the two groups. This finding is in agreement with previous studies that could not establish effects of hormonal contraception on milk quantity (Espey et al., 2012; King, 2007; Truitt et al., 2009).

The second intention was to assess mother and child bonding as demonstrated by breastfeeding. The extent of mother and child bonding was intended to evaluate if postpartum depression had a negative effect on mother and child relationship. However, unlike the study of Cooper et al (2009), that reported major depression to have negative effects on mother-infant bonding, this found no association between type of contraception and mother-infant bonding.

6.8 Strengths of current study

The main strength of this study is the use of random allocation to the treatment groups with allocation concealment. Random allocation greatly reduces the risk of spurious results due to confounding factors which may occur with any non-randomized methodology.

Other strengths are the high follow-up rate, and the use of intention to treat analysis. The latter means that effects attributed to the interventions are unlikely to have been over-estimated.

6.9 *Weaknesses of current study*

There are several weaknesses in this study. The first was that the study was powered to detect differences in mean depression scores; it was not powered to detect differences in the categorical depression outcomes nor the other secondary outcomes. It is therefore possible that the study failed to demonstrate important differences in these outcomes (type 2 error).

The second weakness was non-compliance. Six women in the IUD group received DMPA. This deviation from the protocol would cause systematic under-estimation of any differences in outcome between the groups. A per protocol analysis would reduce this underestimation, but would lose the benefit of randomisation and introduce the possibility of bias which would be unpredictable both in direction and size. For this reason, the analysis has been limited to the more conservative 'intention to treat' analysis, acknowledging the potential for under-estimation of effects.

The third limitation is the duration of follow-up which was short and certain outcomes such as menstrual flow, and sexual dysfunction were not easily assessed as participating women were still in the postpartum period. Another limitation was the inconsistency in methods of data collection. The majority of women were interviewed telephonically as per protocol; however, for those who could not be reached by phone, home visits were undertaken. The data collection forms were completed by a trained fieldworker during these interviews.

Self-reported screening tools (EPDS and BDI-II) were used to measure the primary outcomes, no clinical diagnosis was made.

There was no measure for confounding factors that may be associated with the risk of depression, such as unemployment and relationship conflicts; however, randomisation should have ensured that these unknown factors were evenly distributed between the study groups.

Only women who came from Amatole district of the Eastern Cape took part in this study. As participants only received one injection and were followed up for only three months, it is possible that these results may not be applicable to women who have been using these contraception methods for a longer duration. Also, women in this study were recruited postnatal; therefore these results may not be applicable to women at other times of their reproductive lives, e.g. adolescents or women without young babies.

6.10 Conclusion

Statistically significant differences in depression scores and rates of depression between women allocated to DMPA or the cu-IUD were limited to one continuous measure each at one and three months on different depression scales.

No statistically significant differences in sexual functioning between the study groups were found, however, women in the IUD group were more likely to have resumed sexual intercourse by three months postpartum, compared with the DMPA group. Therefore, the results for this study are

inconclusive with respect to the primary outcomes and we are unable to robustly reject the null hypotheses.

Although, the trend towards more depression in the progestogen group needs to be interpreted with caution, previous robust research on NET-EN (Lawrie et al, 1998), this study contributes to the body of evidence suggesting that long-acting progestogen contraception probably increases the risk of postpartum depression. As only one progestogen injection was administered to women in these studies, it is not clear whether this effect is likely to be transient.

Postpartum women are particularly vulnerable to depression; therefore these results may not be generalizable to women at other times of their reproductive lives. However, it is important to bear these potential effects on mood in mind when offering contraception to postpartum women and women who may be depressed, or at risk of depression, until more evidence becomes available.

6.11 *Implications of this study*

- Family planning providers should inform women during contraceptive counselling that there is no certainty but a possibility that DMPA injections may cause depression and/or sexual dysfunction. This implies that enough time must be allocated by

provider for method counselling during antenatal care when for choosing a suitable contraceptive method.

- Using DMPA immediately after delivery may be associated with less than desired postpartum weight loss than non-hormonal methods.
- Women using injectable progestogens should be screened for depression at their six week follow-up visit and, if found to be at risk of depression, an additional follow-up visit's should be scheduled, with appropriate referral if indicated.
- The IUD is a useful alternative contraceptive method for DMPA contraceptive users who cannot tolerate side effects if they occur. DMPA users can continue to use DMPA with confidence as a convenient and effective method of preventing unintended pregnancy.
- Policy makers and governments can promote the use of long acting contraceptive methods with the knowledge that the risk of side effects outweighs the burden of unintended pregnancies.

6.12 *Implication for research*

The findings of the study raise sufficient concerns to justify further research with larger sample size and adequate power to answer several of the supplemental aims. Such a randomised controlled trial should ideally be a multicentre trial conducted over a longer period of time.

A large sample would be able to clarify whether the trend to more depression found with injectable progestogen is significant. In addition, it might enable greater understanding of the course of depressive symptoms in postnatal women using injectable progestogen contraceptives, and whether depressive symptoms in these women are sustained or transient.

Further research is needed to determine which groups of women, if any, are more vulnerable to becoming depressed on long-acting progestogen contraceptives, in the postnatal period or at other times.

A Cochrane systematic review and meta-analysis of available high-quality data for long-acting progestogen contraception compared to the IUDs methods should be conducted to provide women with the best possible information regarding relative benefits and risks of these two important reversible methods of contraception.

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APPENDICES

Appendix A: (English) Information and consent form

UNIVERSITY OF CAPE TOWN



School of Health & Rehabilitation Sciences

Faculty of Health Sciences

Name of Researcher : Mandisa Singata

Name of Organization : University of Cape Town

Name of Sponsor : Effective Care Research Unit, Eastern Cape

Department of Health

Name of Proposal : "A randomised control trial studying effects of
Intrauterine-device and Injectable Progestogen contraceptive on depression
and sexual functioning of child-bearing women in the Eastern Cape

Version and date: July 2012

Ethics approval number: FHS HREC: ref number 548/2012

This informed consent form has two parts. The first part is an information sheet containing brief outline of the study. The second is a certificate of

consent that you are required to sign indicating your willingness to take part in the study.

Part 1 Information sheet

To be read by or to each prospective participant in her language of choice.

One copy of a signed form to be given to participant.

Introduction

Good day....., my name is Mandisa Singata. I work for the Effective Care Research Unit. I am inviting you to participate in a research study to find out more about the advantages and disadvantages of different methods of contraception. I understand that you are requesting family planning method to prevent pregnancy.

This study is part of Mandisa Singata's research for a PhD degree at the University of Cape Town. Title: "A randomised control trial studying the effects of the copper intrauterine device and injectable Progestogen contraceptive on depression and sexual functioning of women in the Eastern Cape".

I would like to share some information with you and invite you to participate in this research study. Before you decide to participate you can talk to anyone you feel comfortable with about the research, including your family if you wish to do so. There may be some words in this form that you do not understand. Please ask me to stop as we go through the information and I

will take time to explain. If you have any questions later, you can ask me or any other member in the research team.

Background

Contraceptive non-use and method discontinuation are common causes of unintended pregnancy. The most common reason for method discontinuation is unacceptable side effects. This study will examine the potential association between two highly effective forms of contraception, the copper intrauterine device (IUD) and injectable Progestogen, and mood disorders. The study will specifically investigate the impact that initiation of an IUD or injectable Progestogen has on depressive symptoms and sexual functioning. Both depression and sexual dysfunction are given as side effects of contraceptive use; however, limited data exists to substantiate this claim.

Purpose:

The overall purpose is to ascertain the impact, if any, of the IUD and injectable Progestogen contraceptives on depression and sexual functioning, amongst reproductive age women. The study will also compare the side effects of two methods of family planning: the 3 monthly depot injection (depot Provera), and the copper T380A intrauterine device (IUD). The results of this study will guide the choice, as we will have sound data on side effects of the two methods to enable us to be able to give women the best advice in the future

Procedure:

The 'depot' injection is a hormone injection, which lasts for 3 months. The IUD is a small plastic and copper device, which is placed in the uterus during a gynaecological examination. It has two thin nylon threads attached, which are used to pull it out when the woman wishes to stop using this method.

Both the methods (the 'depot' injection and the IUD) are considered safe and effective methods of family planning and are recommended by the World Health Organization. All contraceptive methods have advantages and disadvantages. For both these methods, serious complications are very rare, and are less than the complications of unintended pregnancy. These methods do not protect against sexually transmitted diseases. To be protected against sexually transmitted diseases you need to use condoms as well.

If you agree to participate in this study, I will provide contraceptive method for you either by means of the 'depot' injection, or by means of the IUD. The choice will be made by opening an envelope to find out which group you belong to. In addition, for the purpose of

This study, I will ask you to complete a brief questionnaire at the start, and to complete the questionnaire by phone after 1 month and at 3 months. If adequate resources are available, we may contact you again after 6, and/or 12 months. You will be free to contact our research staff at any time should you have any worries or questions.

Benefits of participating in this study:

All women in the trial will receive a safe and effective method of contraceptive, and will be offered careful follow-up and advice from the research staff should they have any worries or questions. If there is any health problem identified during the study, I will refer you for the necessary care. The main benefit will be the knowledge that you will be helping to provide more knowledge about these methods of contraceptive, which will help to provide the best possible information for women in the future. I will also provide you with the results of the research, and assist you to choose a contraceptive method after completing the study.

Will you be paid to take part in this study and are there any costs involved?

No you will not be paid. There are no costs expected from you as a participant, if you do take part.

Risks & possible discomforts:

Both contraceptive methods have risks and discomforts, but these are related to your need for family planning, not to the research. The Depot Provera need to have repeat injection every 3 months and might experience the following, menstruation may be irregular or stop, and there may be some nausea and weight gain. Disadvantages of IUD Putting in the 'IUD' may be painful, there may be increased menstrual flow and menstrual pain, rare complications such as infection or the 'IUD' penetrating the wall of the uterus (These complications are less than the complications of unintended pregnancy)

The strings may be felt in the vagina. If you prefer not to have the strings able to be felt they may be shortened, but this has disadvantages: not being able to check easily that the IUD is still present, and more difficult to remove it.

It is not known whether one method is overall better or safer than the other is. The World Health Organization recommends both methods for widespread use.

Confidentiality:

Any information you provide during the study will be kept confidential. Your name will not appear on any report of the study, and only staff participating in the study will have access to the information you provide.

Right to Refuse or Withdraw:

You are free to choose whether you wish to participate. You are also free to withdraw from the study at any time should you wish to do so for any reason. If for any reason you are not eligible for the study, or decide not to participate, you will still receive normal care.

Duration

The interview that you will take part in will last approximately 30 minutes. During the telephonic interviews that are to be done at 1month and 3 months, you are requested not to inform the interviewer which family planning method you are on. The study, on the other hand, will last until we complete the number required.

Ethical clearance

This proposal has been reviewed and approved by the Faculty of Health Sciences Human Research Ethics Committee (FHS HREC) of the University of Cape Town, as well as the East London Complex Ethics committee. The purpose of these committees is to ensure that research participants are protected. If you wish to find out more about the FHS HREC, contact Prof Blockman at 021 4066492 (University Of Cape Town). Dr Alexander at 043 708 2100 is the chair person for the ELHC ethics.

We hope you will participate and thank you if you do.

Whom to Contact:

If you have any questions you may ask now or later during the study. You may contact ECRU Research team anytime at 073 7777753 or 043 709 2482 (Frere Hospital) or 073 7778606 or 043 708 2302 (Cecilia Makiwane)

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this survey and understand that I have the right to withdraw from the research at any time without in any way affecting my or my infant's future health care.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Print Name of Researcher _____

Signature of Researcher _____

Date _____

Day/month/year

If participant, cannot read or write the form to be completed by either the researcher or research assistant. A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____ AND

Thumb print of participant

Date _____

Day/month/year

Signature of witness _____

Date _____

Day/month/year

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print Name of Researcher _____

Signature of Researcher _____

Date _____

Day/month/year

An original copy of this Informed Consent Form has been provided to participant.

An original copy of this Informed Consent Form will be filed in a secure place in the research unit _____ (Initialed by the researcher)

Appendix B: (Xhosa) Information and consent form.

UNIVERSITY OF CAPE TOWN



School of Health & Rehabilitation Sciences

Faculty of Health Sciences

Igama lomphandi : Mandisa Singata

Igama lombutho : Idyunivesithi YaseKapa

Igama lomxhasi ngezimali :Effective Care Research Unit, Eastern Cape
Department of Health.

Igama lesiphakamiso : "A randomised control trial studying effects of
Intrauterine-device and Injectable Progestogen contraceptive on depression
and sexual functioning of child-bearing women in the Eastern Cape"

Umhla: July 2012

Inombolo yophunyezo lwentsulugeko: FHS HREC: ref number 548/2012

Icandelo 1**Uxwebhu lolwazi**

Kufanele ifundwe ngumntu wonke onokuthatha inxaxheba eyifunda ngolwimi afunangalo. Elinye iphepha mvume izakuba lelakho elinye lishike kuthi,

Molo. Igama lam ngu Mandisa Singata. ndisebenzela isebelezempilo apha kwimpuma koloni. Siyakumema ukuba uthathe inxaxheba kuphando esilenzayo lokujonga ukuba zeziphi na izinto ezixhamlekayo anezingathandekiyo kwintlobontlobo zendlela zokucwangcisa. Siyaqonda ukuba unqwenela ukucwangcisa ukhusele umitho.

Intsusa

Ukungasebenzisi ucwangciso kunye nokungaqhubeki nedlela yocwangciso ngo nobangela abaxhaphakileyo bomitho obungakhange bucwangciswe. Esona sizathu sixhaphakileyo sokungaqhubeki nedlela yocwangciso zizinto ezithi zenzeke zingathandeki. Oluphando luzakuphonononga ukuba ikhona na phakathi kwezintlobo zimbini zocwangciso iDepe kunye ne(IUD) enza kupekho ukunxunguphala ngokwasemoyeni. Oluphando luzakugxininisa ekujongeni ukuba iIUD Okanye isitofu se Depo sinenalo na igalelo kwimpawo zokubanomoya ophantsi(Depression) kunye nokungasebenzi kakuhle kwemizwa ngokwase ncantsini. Zombini iDepression kunye nedlela umzimba osebenza ngayo ngokwacecantsini zichazwa ngokuba ngezinye nezinto ezinokuthi zenziwe

yi Depo nangona kunjalo ingxelo izixhala lonto zimalwa azikwazi ukuxhasa ncakasana.

Injongo zoluphando

Oluphando lunenjogo zokuqonda ukuba I IUD ne Depo ingaba zinegalelo naokanye azinalo kwi(Depression kunye nedlela obusebenda ngayo ubume bukasisi .Sifuna ukuvula amathuba okuba abantu babe nalo ithuba lokufumana intlobo ezangeziweyo zokucwangcisa ebezingafumaneki kuqala.Oluphando luzakunceda ukuba sazi izinto esinokuzizuzanezingathandekiyo xa siqathanisa ezintlobo zimbini oluqhelekileyo olusetyenziswayo lokucwangcisa inaliti ye Depo kunye ne IUD(intrauterine device) yona ke ayikho kumasebe ethu empilo.Iziphumo zoluphando ziyakusinceda ukuba sikwazi ukucebisa abantu ababhinqileyo ngolona hlobo olunokumsebenzela unmtu lokuncwangcisa kwixesha elizayo.

Indlela ekuqhutywa ngayo oluphando

Inaliti yeDepo inechiza elihlala emzimbeni inyanga ezithathu .

IUD yona yinto yeplastic anentwana yekopa eyenzela ukuthintela umitho.Ifakwa apha phakathi esibelekweni ngexesha uhlolwa ngalo ngaphantsi.Inemisonto ebityileyo elapha kuyo ekusentyenziswa yona xa ikhutshwa xa sele ufuna ukuyeka ukucwangcisa nge IUD.

Zombini ke ezintlobo zokucwangciswa zaziwa zingenabungozi kwaye zikhusela umitho.Umbutho wezempilo elizweni lonke (WHO) uyakukhuthaza ukusentyenzisaw kwazo.

-
- Zonke intlobo ezisentyenziswayo zokucwangcisa zinezinto esizizuzayo kunye nezingathandekiyo
 - Kuzo zombini ezindindi akukhonto enokuxhalisa ngazo. Iziphumo ezinokuthi zothose zinqabile kakhule kwaye zingaphantsi kwengxaki enokuthi yenziwe lumitho obelingalinelekanga.
 - Zombine ezintlobo azikukhuseleli ekosulelekeni kwizifo zocantsi. Kubalulekile ukuba uzikhusele ngokusebenzisa I “condom”.

Inaliti ye Depo

Izinto ezixhamlekayo kuyo

- Kulula ukuyiniezelela uncutswa ngenaliti

Izinto onongazithandi

- Kufuneka uzokuhlaba inali qho kwinyanga ezintathu
- Kungenzeka uyeke ukuya exesheni okanye ungayi ngohlobo obukhele

ngalo

- Kungenzeka ubenisicefesefe ufune ukugabha
- Ubunzima bomzimba wakho bungongezeleka
- Kundenzeka ubenamaxesha okuziva unxunguphele
- Kunqabile ke kodwa ukuba ungo phuka lula amathambo okanye

ufunyanwe

sistroke. (Qaphela ezingxaki zingaphantsi kwengxaki yokukhulelwa ungafuni)

-
- Emva kokuyeka ukucwangcisa kungathatha ixesha ukuba ukhulelwe xasele ufuna.

IUD

Izinto ezixhamlekayo kuyo

- Akukho sizathu sokuba uquqe ubuya ihlala ithuba elide elinokufika kwiminyaka elishumi

elinesibini(12 years) iphakathi kuwe

- Ayinamachiza anokukhathaza umzimba wakho
- Awuyeki ukuya exesheni
- Umitha kwangoko emvakokuyikhupha

Izinto onokuthi ungazithandi

- Xa kufakwa iIUD kungabakho intlungu
- Kungenzeka ukuba wophe kakhulu xa usexesheni
- Inqabile into yokupa leplastiki yeIUD inga kuhlaba esibelekweni (nangona kunjalo ayinaku qathaniswa nobunzima onoba kubo xa uthe wamitha ungafuni)
- Imisonto le yeIUD ungakwazi ukuyiva apha kuwe ngaphakathi kunosisi wakho xa ufake isandla. Kodwa ukuba ufuna ingavakali ingasikwa ibemifutshane kodwa ke kungangabilula ukuba uzihlole uve ukuba isekhona na I IUD.Lonto ingenza kubenzima ukuyikhupha iIUD.

Ukuba uyavuma ukuthatha inxaxheba koluphando,Wokufumana nokuba loluphi uhlobo kula sesiwasacisile ngentla.Sobabini sokwazi ukuba ungena koluphi uhlobo ngokuthi sivule imvulophu eyakuthi isixelele ukuba sikunike oluphi uhlobo.

Njengokuqhelekileyo uzakufumana ingcaciso unikwe nethuba lokuba ungahlolwa kujongwe intsholongwane yengculazi xa ufuna.Yinto ke le eyenziwa kumntu wonke nokuba akazokuthatha inxaxheba koluphando.Njengenxalenye yoluphando sicela ukugcina ngokufihlakeleyo ingxelo zegazi lakho lokuhlolwa ingculazi.

Ngaphezulu sisela ukuba usiphendulele imibuzo thile ngoku xa uqala ukungena koluphando naxa usiza okokungqibela socela uphinde usiphendulele lemibuzo.

Sothi ke emva kwenyanga yokuqala nakweyesithathu sikutsalele umnxeba s kubuze imibuzo ethile.Ukuba sithe sakwazi ukuphumelela sicela ukuba sikutsalele nakwixesha lenyanga ezintandathu,ezisithoba kunye naye tshumi elinambini.

Uvumelekile nangalo naliphina ixesha ukuba usibuze imibuzo ukuba kukho into ekhukhathazayo.

Okuyinzuzo kuwe

Wonke usisi okuluphando wofumana unyango olukhuselekileyo lohlobo lokucangcisa.Siyakuku landelela ngokunonophelekileyo sikuhlola.Maxa onke ukuba unemibuzo wofumana ingcebiso kwiqela elisebenzela

oluphando.Ukuba kunokwenzeka kubekho ingxaki ngokwasempilweni yakh siyakukuthumela kwinawo efanelekileyo yokukunyanga.Eyona nzuzo iyakuba lulwazi oyakuthi isityhilele lona ngezindidi zimbine zoncwangciso,olwakuthi luncede xa sicebisa abantu ababhinqileyo kwixesha elizayo ngocwangcoso ntsapho.

Ukuba uyafuna siyakukunika iziphumo zoluphando ekupheleni kwesisifundo.

Ingaba kukhona na intlawulo oyakuthi uyifumane ngokuthatha inxaxheba nencitho elindelekileyo.

Akukho ntlawulo oyakuyifumana..Akukho ncitho ilindelekileyo kuwe ukuba uthathe inxaxheba.

Okwenzeka kube kungeyonjongo

Zombini ezintlobo zinezinto onongazithandi,kodwa ke zizinto ezenziwa kukuba ufuna ukucwangcisa hayi ngokuba uthatha inxaxheba koluphando.Asiyazi ukuba ngeyiphi kwezi ntlobo sikunikazona enzono ukwadlula enye nekwakhuseleke kakhulu kunenye.Undlunkulu kazwelonke wesebe lezempilo (WHO) ukhuthaza ukuba zombini ezintlobo zisentyenziswe ukukhusela ukukhulelwa.Ngokudibanisele nokuthatha kwakho inxaxheba inye qha into enokuthi ikudube kukuphendula imibuzo yethu emalungelana nesisifundo.

Okuyimfihlelo

Yonke inkcazelo oyinikileyo kwesi sifundo iya kugcinwa iyimfihlelo. Igama lakho aliyikuvela kwincadana zesi sifundo yaye ngabasebenzi ababandakanyekayo kwesisifundo kuphela abakubanegunya kwinkcazelo oyinikileyo. Igama lakho alizokubakho nakumagazi esiwathathileyo.

Unelungelo lokungavumi okanye uyeke sele uqalile

Akunyanzelekanga ukuba uthathe inxaxheba koluphando uvemelekile kananjalo ukuba uyeke nanagaliphi na ixesha nokuba sithini na isizathu sakho. Ukuba kuyenzeka ukuba akuku lungelanga ukungena koluphando lonto ayithi akuzokufumana unyango olufunayo kweliziko.

Siyathemba uyakuyithatha inxanxeba ,siyabulela ngokwenje njalo

Intloso yoluphando iye yapicotwa kwaye yafunyanwa ukuba kungile iqhube oluphando licandelo le (Faculty of Health Sciences Human Research Ethics Committee (FHS HREC) ye Ndzunivesiti yase Kapa. Kananjalo ne komiti ye East London hospital Complex Ethics committee (ELHCE). Injongo zezikomiti kukuqiniseka ukuba abathathi nxanxheba koluphando bakhuselekile. Ukuba unqwenela ukwazi banzi unga tsalela umnxena usihlalo wekomiti (FHS HREC) Prof Blockman 0214066492. Xa ufuna le yalapha Emonti kwi (ELHCE) tsalela usihlalo wayo Dr Alexander 043 708 2100

Ngubani onokuthetha naye xa unemibuzo nokuba usekhaya

Ukuba unemibuzo ofuna iphendulwe ngexesha siqhuba oluphano ungatsalela umnxeba Umphandi owenza esisifundo.

Abangikazi abasebenza kwa ECRU ngalo lonke ixesha ungabafumana kwezinamba 073 7777753 okanye 043 709 2482 (Frere hospital) kunye no 073 7778606 okanye 043 708 2302 (Cecilia Makiwane)

Icandelo II:IPHEPHA-MVUME LOKUTHATHA INXAXHEBA

MNANdifundile iphepha lenkcazelo malunga nesi sifundo kwaye ndicacelwe kwendizakwenza ukuba ndithathe inxaxheba . Imibuzo yam iphenduliwe kwaye ndiyayazi ukuba ndingayeka nanini na ndifuna ndinganiki sizathu. Oko akusayi kuchaphazela inkathalo endifaneleyo.

Ndiyavuma ukuthatha inxaxheba kwesi sifundo.

Tyikitya..... Umhla.....

Igama lengqina..... Umhla.....


Tyikitya(ingqina).....

Umhla.....

Ndingathanda ukufumano iziphumo zoluphando/Nokuba anindazisanga iziphumo zoluphando (Yenza isangqa koyikhethayo)

Oqhuba uphando(umongikazi / ugqirha).....Umhla

Appendix C: Study questionnaire

 Effective Care Research Unit in collaboration with Eastern Cape Department of Health East London Hospital Complex Obs & Gynae Department and University of Cape Town		Revised version 1
UNIVERSITY OF CAPE TOWN		
Identification		
1 Hospital identification code	<input type="text"/>	2 Today's date
2 Hospital record number	<input type="text"/>	Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>
3 Randomisation number	<input type="text"/>	3 Date of birth
Inclusion Criteria		Day <input type="text"/> Month <input type="text"/> Year <input type="text"/>
1 Is the women 18 years or older?	<input type="checkbox"/> Y <input type="checkbox"/> N	Exclusion Criteria
2 Does she requests contraception?	<input type="checkbox"/> Y <input type="checkbox"/> N	1 Is she now pregnant?
3 Is she prepared to use either the progesterone injectable or the IUCD ?	<input type="checkbox"/> Y <input type="checkbox"/> N	2 Is there currently any evidence of an active pelvic infection?
4 Has she signed the consent form?	<input type="checkbox"/> Y <input type="checkbox"/> N	3 Has she recently noticed vaginal bleeding that is unusual?
Name	<input type="text"/>	4 Is there any contraindication for depot injection or IUCD?
Surname	<input type="text"/>	5 Has she given birth > 48 hours ago
Cell #	<input type="text"/>	6 Baseline depression score ≥ 20
Home	<input type="text"/>	7 Does she has access to a telephone
Work	<input type="text"/>	Eligible
Additional #	<input type="text"/>	<input type="checkbox"/> Y <input type="checkbox"/> N
Name of above	<input type="text"/>	
Baseline data	Gynaecological history	Previous contraception
Pregnant now <input type="checkbox"/> Y <input type="checkbox"/> N	Pregnancies >24 weeks	Injectable: <input type="checkbox"/> Y <input type="checkbox"/> N
Medical history	Spontaneous abortions <input type="checkbox"/> Y <input type="checkbox"/> N	Duration used <input type="text"/> Months
Diabetes <input type="checkbox"/> Y <input type="checkbox"/> N	Requested terminations <input type="checkbox"/> Y <input type="checkbox"/> N	PIU <input type="checkbox"/> Y <input type="checkbox"/> N
High bloodpressure <input type="checkbox"/> Y <input type="checkbox"/> N	Other <input type="checkbox"/> Y <input type="checkbox"/> N	Duration used <input type="text"/> Months
Previous PID <input type="checkbox"/> Y <input type="checkbox"/> N		IUCD <input type="checkbox"/> Y <input type="checkbox"/> N
Surgical history		Duration used <input type="text"/> Months
Previous cs <input type="checkbox"/> Y <input type="checkbox"/> N		Other <input type="checkbox"/> Y <input type="checkbox"/> N
Allerges		Other <input type="checkbox"/> Y <input type="checkbox"/> N
If yes, what?		If yes what?

Serology	<input type="checkbox"/> P <input type="checkbox"/> IN	Day: <input type="text"/> <input type="text"/> <input type="text"/> Month: <input type="text"/> <input type="text"/> <input type="text"/> Year: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Weight	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Day: <input type="text"/> <input type="text"/> <input type="text"/> Month: <input type="text"/> <input type="text"/> <input type="text"/> Year: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
CC4	<input type="text"/> <input type="text"/> <input type="text"/>	Day: <input type="text"/> <input type="text"/> <input type="text"/> Month: <input type="text"/> <input type="text"/> <input type="text"/> Year: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	kg	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Day: <input type="text"/> <input type="text"/> <input type="text"/> Month: <input type="text"/> <input type="text"/> <input type="text"/> Year: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Viral load	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Day: <input type="text"/> <input type="text"/> <input type="text"/> Month: <input type="text"/> <input type="text"/> <input type="text"/> Year: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Enrolment date	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Day: <input type="text"/> <input type="text"/> <input type="text"/> Month: <input type="text"/> <input type="text"/> <input type="text"/> Year: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Enrolment time	<input type="text"/> <input type="text"/> <input type="text"/>	

	Baseline	1 month	3 months
	Today's date	Today's date	Today's date
	Day Month Year	Day Month Year	Day Month Year
Was this pregnancy planned?	<input type="checkbox"/> Y <input type="checkbox"/> N		
In the last months/2 months			
1 Has your menstruation been?			
1= Normal 3= Light	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2= Heavy 4= None			
In the last months/2 months			
2 Has your menstruation been?			
1= Painless 3= Moderate pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2= Mild pain 4= Severe pain			
In the last months/2 months			
3 Have you been worried about your weight? If yes why?			
1= Too fat	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
2= Too thin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the last months/2 months			
4 Have you had intercourse? If yes	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
1= One partner only	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2= More than one partner			
5 Are you breastfeeding?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N
Investigator's Name	<input type="text"/>		
Date	<input type="text"/>		

Appendix D: Edinburgh Postnatal Depression Scale

Edinburgh Postnatal Depression Scale¹ (EPDS)

Name: _____ Address: _____

Your Date of Birth: _____

Baby's Date of Birth: _____ Phone: _____

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

Here is an example, already completed.

I have felt happy

- L. Yes, all the time
- B. Yes, most of the time This would mean: "I have felt happy most of the time" during the past week.
- C. No, not very often Please complete the other questions in the same way.
- D. No, not at all

In the past 7 days

- | | |
|---|---|
| <p>1. I have been able to laugh and see the funny side of things</p> <ul style="list-style-type: none"><input type="radio"/> a. As much as I always could<input checked="" type="radio"/> b. Not quite so much now<input type="radio"/> c. Definitely not so much now<input type="radio"/> d. Not at all <p>2. I have looked forward with enjoyment to things</p> <ul style="list-style-type: none"><input type="radio"/> a. As much as I ever did<input type="radio"/> b. Rather less than I used to<input type="radio"/> c. Definitely less than I used to<input type="radio"/> d. Hardly at all <p>3. I have blamed myself unnecessarily when things went wrong</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, most of the time<input type="radio"/> b. Yes, some of the time<input type="radio"/> c. Not very often<input type="radio"/> d. No, never <p>4. I have been anxious or worried for no good reason</p> <ul style="list-style-type: none"><input type="radio"/> a. No, not at all<input type="radio"/> b. Hardly ever<input type="radio"/> c. Yes, sometimes<input type="radio"/> d. Yes, very often <p>5. I have felt scared or panicky for no very good reason</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, quite a lot<input type="radio"/> b. Yes, sometimes<input type="radio"/> c. No, not much<input type="radio"/> d. No, not at all | <p>6. Things have been getting on top of me</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, most of the time I haven't been able to cope at all<input type="radio"/> b. Yes, sometimes I haven't been coping as well as usual<input type="radio"/> c. No, most of the time I have coped quite well<input type="radio"/> d. No, I have been coping as well as ever <p>7. I have been so unhappy that I have had difficulty sleeping</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, most of the time<input type="radio"/> b. Yes, sometimes<input type="radio"/> c. Not very often<input type="radio"/> d. No, not at all <p>8. I have felt sad or miserable</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, most of the time<input type="radio"/> b. Yes, quite often<input type="radio"/> c. Not very often<input type="radio"/> d. No, not at all <p>9. I have been so unhappy that I have been crying</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, most of the time<input type="radio"/> b. Yes, quite often<input type="radio"/> c. Only occasionally<input type="radio"/> d. No, never <p>10. The thought of harming myself has occurred to me</p> <ul style="list-style-type: none"><input type="radio"/> a. Yes, quite often<input type="radio"/> b. Sometimes<input type="radio"/> c. Hardly ever<input type="radio"/> d. Never |
|---|---|

Administered/Reviewed by _____ Date _____

¹Source: Cox, J.L., Holden, J.M., and Sagovsky, R. 1987. Detection of postnatal depression: Development of the 10-item Edinburgh Postnatal Depression Scale. *British Journal of Psychiatry* 150:782-786.

²Source: K.L. Wisner, B.L. Parry, C.M. Ploniek, Postpartum Depression N Engl J Med vol. 347, No 3, July 16, 2002, 194-199

Users may reproduce the scale without further permission providing they respect copyright by quoting the names of the authors, the title and the source of the paper in all reproduced copies.

BDI-II ENGLISH

Date: _____

Name: _____ Marital Status: _____ Age: _____
 Gender: _____

Beck Inventory: On this questionnaire are groups of statements. Please read each group of statements carefully. Then pick out the one statement in each group which best describes the way you have been feeling in the PAST WEEK, INCLUDING TODAY! Circle the number beside the statement you picked. If several statements in the group seem to apply equally well, circle each one. Be sure to read all the statements in each group before making your choice.

<p>1. Sadness 0 I do not feel sad. 1 I feel sad. 2 I feel sad all the time and I can't snap out of it. 3 I am so sad or unhappy that I can't stand it.</p> <p>2. Pessimism 0 I am not particularly discouraged about the future. 1 I feel discouraged about the future. 2 I feel I have nothing to look forward to. 3 I feel that the future is hopeless and that things cannot improve.</p> <p>3. Past Failure 0 I do not feel like a failure. 1 I feel I have failed more than the average person. 2 As I look back on my life, all I can see is a lot of failures. 3 I feel I am a complete failure as a person.</p> <p>4. Loss of Pleasure 0 I get as much satisfaction out of things as I used to. 1 I don't enjoy things the way I used to. 2 I don't get real satisfaction out of anything anymore. 3 I am dissatisfied or bored with everything.</p> <p>5. Guilty Feelings 0 I don't feel particularly guilty. 1 I feel guilty a good part of the time. 2 I feel quite guilty most of the time. 3 I feel guilty all of the time.</p>	<p>6. Punishment Feelings 0 I don't feel I am being punished. 1 I feel I may be punished. 2 I expect to be punished. 3 I feel I am being punished.</p> <p>7. Self-Dislike 0 I feel the same about myself as ever. 1 I have lost confidence in myself. 2 I am disappointed in myself. 3 I dislike myself.</p> <p>8. Self-Criticalness 0 I don't criticize or blame myself more than usual. 1 I am more critical of myself than I used to be. 2 I criticize myself for all of my faults. 3 I blame myself for everything bad that happens.</p> <p>9. Suicidal Thoughts or Wishes 0 I don't have any thoughts of killing myself. 1 I have thoughts of killing myself, but I would not carry them out. 2 I would like to kill myself. 3 I would kill myself if I had the chance.</p> <p>10. Crying 0 I don't cry any more than usual. 1 I cry more now than I used to. 2 I cry all the time now. 3 I used to be able to cry, but now I can't cry even though I want to.</p>
	<p>Subtotal Page 1</p>

Please turn over...

11. Agitation

- 0 I am no more restless or wound up than usual.
- 1 I feel more restless and wound up than usual.
- 2 I am so restless or agitated that it's hard to stay still.
- 3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

- 0 I have not lost interest in other people or activities.
- 1 I am less interested in other people or things than before.
- 2 I have lost most of my interest in other people or things.
- 3 It's hard to get interested in anything.

13. Indecisiveness

- 0 I make decisions about as well as ever.
- 1 I find it more difficult to make decisions than usual.
- 2 I have greater difficulty in making decisions than I used to.
- 3 I have trouble making any decisions.

14. Worthlessness

- 0 I do not feel I am worthless.
- 1 I don't consider myself as worthwhile and useful as I used to.
- 2 I feel more worthless as compared to other people.
- 3 I feel utterly worthless.

15. Loss of Energy

- 0 I have as much energy as ever.
- 1 I have less energy than I used to have.
- 2 I don't have enough energy to do very much.
- 3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

- 0 I have not experienced any changes in my sleeping pattern.
- 1a I sleep somewhat more than usual.
- 1b I sleep somewhat less than usual.
- 2a I sleep a lot more than usual.
- 2b I sleep a lot less than usual.
- 3a I sleep most of the day.
- 3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

- 0 I am no more irritable than usual.
- 1 I am more irritable than usual.
- 2 I am much more irritable than usual.
- 3 I am irritable all the time.

18. Changes in Appetite

- 0 I have not experienced any changes in my appetite.
- 1a My appetite is somewhat less than usual.
- 1b My appetite is somewhat greater than usual.
- 2a My appetite is much less than before.
- 2b My appetite is much greater than before.
- 3a I have no appetite at all.
- 3b I crave food all the time.

19. Concentration Difficulty

- 0 I can concentrate as well as ever.
- 1 I cannot concentrate as well as ever.
- 2 It's hard to keep my mind on anything for very long.
- 3 I cannot concentrate on anything.

I am purposely trying to lose weight by eating less. Yes No

20. Tiredness or Fatigue

- 0 I am no more tired or fatigued than usual.
- 1 I get more tired or fatigued more easily than usual.
- 2 I am too tired or fatigued to do a lot of things I used to do.
- 3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

- 0 I have not noticed any recent change in my interest in sex.
- 1 I am less interested in sex than I used to be.
- 2 I am much less interested in sex now.
- 3 I have lost interest in sex completely.

_____ Subtotal Page 2

_____ Subtotal Page 1

_____ **Total Score**

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Appendix F: BDI-II Xhosa version

XBDI-II XHOSA

Date: _____

Igama/Name: _____ Ushushie/Mental Status: _____ Iminyaka/Age: _____ Ubomi/ Gender: _____

Imigqo: Le fom u yemibuzo inaniqela eentetho ezingamashumi amabini ananye 21. Nceda fundisa iqela ngalinye lentetho, uze ukhethe intetho ibe nye kwiqela ngalinye enokuthi ichaze indlela obe uziva ngayo kwiveki ezimbini ezidluliyayo udibanisa nonamhlanje. Yenza isangqa kwinombolo esecaleni kwentetho oykhethileyo. Ukuba intetho ezikhulenteyo kwiqela ngalinye zibonakala zikuchaphazela ngokufanayo yenza isangqa kuleyo menani eliphakamileyo kwiqela elo. Qiniseka ukuba akukhethi ngaphezulu kwentetho enye kwiqela ngalinye, ngokuquka no 16 (Umehluko kwindlelayokulala) okanye u18 (Umehluko Kokucacelelo Ukutya)

<p>1. ANDONWABANGA</p> <p>0 Andiziva ndigonwabanga.</p> <p>1 Ndiziva ndigonwabanga amaxesha amaninzi</p> <p>2 Andonwabanga ngalo lonke ixesha.</p> <p>3 Andonwabanga kangokokuba andikwazi ukunyamezela.</p> <p>2. UKUTHANDA UKUBONA UBUBI KUYO YONKE INTO</p> <p>0 Andiziva ndingakhuthazekanga ngekamva lam.</p> <p>1 Ndiziva ndityhafise kakhulu ngekamva lam ngaphezulu kunokuba bendinjalo ngaphambili</p> <p>2 Andilindelanga ukuba izinto zondibambele kakuhle.</p> <p>3 Ndiziva ndingenathemba kwikamva lam kananjalo izinto ziya zaiba nandundu</p> <p>3. UKUNGAPUMELELI OKUDLULILEYO</p> <p>0 Andiziva ndingenampumeleli.</p> <p>1 Andiphumelelanga nangaphezulu kunokuba bekufanele.</p> <p>2 Xa ndikhangela emva ndibona ukungapumeleli okuninzi.</p> <p>3 Ndiziva ndingumntu ongenampumeleli ngokupheleleyo.</p> <p>4. UKUPHULUKANA NOLONWABO</p> <p>0 Ndifumana ulonwabo ngokufanayo kwizinto endizithandayo.</p> <p>1 Andizonwabeli izinto njenqesiqhelo.</p> <p>2 Ndifumana ulonwabo oluncinci kakhulu kwizinto endaye ndizonwabela.</p> <p>3 Andifumani lonwabo lu kwizinto endaye ndizonwabela.</p> <p>5. ISAZELA</p> <p>0 Andiziva ndinesazela.</p> <p>1 Ndiziva ndinesazela malunga nezinto ezininzi endzenzileyo okanye ebekufanele ndibe ndizenzele.</p> <p>2 Ndiziva ndinesazela ixesha elininzi.</p> <p>3 Ndiziva ndinesazela ngalo lonke ixesha</p>	<p>6. UKUZIVA USOHLWAYWA</p> <p>0 Andiziva ndisoohwaywa.</p> <p>1 Ndiziva ngathi ndingohwaywa</p> <p>2 Ndukulindele ukoohwaywa.</p> <p>3 Ndiziva ndingowohwayweyo.</p> <p>7. UKUNGAZITHANDI</p> <p>0 Ndiziva njenqesiqhelo ngesiqu sam.</p> <p>1 Ndiphetelewe kukuzithemba ngesiqu sam.</p> <p>2 Ndidanile ngesiqu sam.</p> <p>3 Andizithandi.</p> <p>8. UKUZIGXEKA</p> <p>0 Andizigxeki okanye ndizisole ngaphezulu kunesiqhelo</p> <p>1 Ndizigxeka ngaphezulu kunokuba ndandinjalo</p> <p>2 Ndizigxeka ngazo zonke iimpazamo zam.</p> <p>3 Ndizisole ngazo zonke izinto ezimbi ezenzekayo.</p> <p>9. IINGCINGA OKANYE IMINQWENO YOKUZIBULALA</p> <p>0 Andinazo tu iingcinga zokuzibulala.</p> <p>1 Ndinazo iingcinga zokuzibulala, kodwa andingekhe ndiziphumeze.</p> <p>2 Ndingathanda ukuzibulala.</p> <p>3 Bendingazibulala ukuba bendinganethuba</p> <p>10. UKULILA</p> <p>0 Andilili ngaphezulu kunesiqhelo</p> <p>1 Ndilila ngaphezulu kunesiqhelo.</p> <p>2 Ndililela yonke into nokuba incinci.</p> <p>3 Ndiziva ndiluna ukulila, kodwa andikwazi</p>
---	--

Subtotal Page 1

Nceda gqula iphepha

11. UKUYALUZELA

- 0 Andiziva ndingazinzanga okanye ndibambekile ngaphezulu kunesiqhelo.
- 1 Ndziva ndingazinzanga okanye ndibambekile ngaphezulu kunesiqhelo.
- 2 Ndziva ndingazinzanga okanye ndiyaluzela kakhulu kangangokuba kuzima ukuhlala ndizole.
- 3 Ndziva ndingazinzanga okanye ndiyaluzela kakhulu kangangokuba kufuneka ndjikeleze okanye kubhekisela into enolenzayo.

12. UKUPHELELWA NGUMDLA

- 0 Andiphelelwanga ngumdlwa kwabanye abantu okanye kwizintu endiqhele ukuzenza. Uhle umdlwa wam kwabanye abantu okanye izintu kunangaphambili.
- 1 Ndiphelele ngumdlwa omkhulu kwabanye abantu okanye izintu.
- 2 Kunzima ukuba nomdlwa na weyiphi na into.

13. UKUNGAFIKELELI KWISIGQIBO

- 0 Ndenza izigqibo njengaphambili.
- 1 Ndiva kunzima kakhulu ukwenza izigqibo kunesiqhelo.
- 2 Nandibuzima obugqibileyo ukwenza izigqibo kunangaphambili.
- 3 Ndingaxaki yokwenza naziphi na izigqibo.

14. UKUNGA XABISEKI

- 0 Andiziva ndingaxabisekanga sekanga.
- 1 Andiziboni njengomntu oxabisekileyo oancedo njengohlobo endandilulo.
- 2 Ndziva ndingaxabisekanga ngaphezulu xanandizithelekisa nabanye abantu.
- 3 Ndziva ndingaxabisekanga ngokupheleleyo.

15. UKUPHELELWA NGAMANDLA

- 0 Ndinamandla kangangoko njengesiqhelo.
- 1 Ndinamandla amancinci kunohlobo endandinawo ngoko.
- 2 Andinamandla aneleyo okwenza okuninzi.
- 3 Andinamandla aneleyo okwenza nantwana.

16. UMEHLUKO KWINDLELAYOKULALA

- 0 Andiboni mehluko kwindlela endlela ngayo.
- 1a Ndilala ngaphezulu kunesiqhelo noko.
- 1b Ndilala ngaphantsi kunesiqhelo noko.
- 2a Ndilala ngaphezulu kakhulu kunesiqhelo.
- 2b Ndilala ngaphantsi kakhulu kunesiqhelo.
- 3a Ndiyavala ixesha elininzi emini.
- 3b Ndivuka phambi kwexesha kangangeyure enye okanye ezimbini (1hr-2hrs) ndingakwazi ukuphinde ndilala.

17. UKUCAPHUKA

- 0 Andicaphuki kunesiqhelo.
- 1 Ndicaphuka ngaphezulu kunesiqhelo.
- 2 Ndicaphuka kakhulu ngaphezulu kunesiqhelo.
- 3 Ndicaphuka ngalo lonke ixesha.

18. UMEHLUKO KOKUCA CELO UKUTYA

- 0 Andikazifumaniki ndinimehluko kwindlela yam yokutya.

1a Umda wam wokutya noko ungaphantsi kunesiqhelo.

1b Umda wam wokutya noko ungaphezulu kunesiqhelo.

2a Umda wam wokutya ungaphantsi kakhulu kunangaphambili.

2b Umda wam wokutya ungaphezulu kakhulu kunesiqhelo.

3a Andinamandla wokutya kwaphela.

3b Ndivawela ukutya ngalo lonke ixesha.

19. UBUNZIMA BOKUZIKISA-INGQONDO

- 0 Ndiyakwazi ukuzikisa ingqondo kakuhle njengesiqhelo.
- 1 Andikwazi ukuzikisa ingqondo kakuhle njengesiqhelo.
- 2 Kunzima ukugqona ingqondo yam nakwintoni na ngaphezulu kwexesha elingephi.
- 3 Ndifumanisa ndingakwazi ukuzikisa ingqondo nakwintoni na.

20. UKUZIVA UKUDINWA

- 0 Andiziva ndidinwe ndidinwe ingqondo kunesiqhelo.
- 1 Ndininwe okanye ndidinwe ingqondo luthi kakhulu ngaphezulu kunesiqhelo.
- 2 Ndininwe okanye ndidinwe ingqondo kangangokuba andikwazi nokwenza inkoliso yezinto ebendiqhele ukuzenza.
- 3 Ndininwe okanye ndidinwe ingqondo kangangokuba andikwazi ukwenza ezininzi yezinto ebendiqhele ukuzenza.

21. UKUPHELELWA NGUMDLA KWISONDO

- 0 Andikaphawuli nguqulelo isandla ukwenzeka kumda wam kwisondo.
- 1 Uhle umdlwa wam kwisondo kunesiqhelo.
- 2 Uhle kakhulu umdlwa wam kwisondo ngoko.
- 3 Ndiphelele ku ngumdlwa kwisondo.

Subtotal Page 2

Subtotal Page 1

Total Score

Appendix G: ASEX

Arizona Sexual Experiences Scale (ASEX)

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For each item, please indicate your **OVERALL** level during the **PAST WEEK**, including **TODAY**.

1. How strong is your sex drive?

1	2	3	4	5	6
extremely strong	very strong	somewhat strong	somewhat weak	very weak	no sex drive

2. How are you sexually aroused (turned on)?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never aroused

FOR MALE ONLY

3. Can you easily get and keep an erection?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never

FOR FEMALE ONLY

3. How easily does your vagina become moist or wet during sex?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never

If you have had any sexual activity in the past week, please also answer the following two questions. If not, leave questions 4 and 5 blank.

4. How easily can you reach an orgasm?

1	2	3	4	5	6
extremely easily	very easily	somewhat easily	somewhat difficult	very difficult	never reach orgasm

No Sexual activity in past week

5. Are your orgasms satisfying?

1	2	3	4	5	6
extremely satisfying	very satisfying	somewhat satisfying	somewhat unsatisfying	very unsatisfying	can't reach orgasm

COMMENTS:

Appendix H: University of Cape Town ethics approval



UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Human Research Ethics Committee
Room E52-24 Grooto-Schoor Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
e-mail: sunmyah.ariofd@uct.ac.za

08 November 2012

HREC REF: 548/2012

Ms M Singata
Health & Rehabilitation Sciences
1-Floor
GME

Dear Ms Singata

PROJECT TITLE: A RANDOMISED CONTROL TRIAL STUDYING THE EFFECTS OF THE COPPER INTRAUTERINE DEVICE AND INJECTABLE PROGESTOGEN CONTRACEPTION ON DEPRESSION AND SEXUAL FUNCTIONING OF WOMEN IN THE EASTERN CAPE

Thank you for addressing the issues raised by the Human Research Ethics Committee.

It is a pleasure to inform you that the Ethics Committee has **formally approved** your collaboration in the above mentioned study.

Approval is granted for one year till the 15 November 2013.

Please submit a progress form, using the standardised Annual Report form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please include contact details of HREC in informed Consent form.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC REF in all your correspondence.

Yours sincerely

PROFESSOR M BLOESMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.

Amelia

Appendix I: UCT protocol amendment approval



UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES

Human Research Ethics Committee

Form FHS006: Protocol Amendment

Note: All amendments should include a 5-synopsis for the amendment (please see notice dated 23 April 2012)

HREC office use only (FWA00001037; IRB00001038)

Approved Type of review: Expedited Full committee

This serves as notification that all changes and documentation described below are approved

Signature: Chairperson of the HREC of T. Burgess Date: 29 July 2013

Principal Investigator to complete the following:

1. Protocol information

Date	21 January 2013
HREC REF Number	5/8/2012
Protocol title	Title: "A randomised controlled study of the effects of the copper intrauterine device and norgestrel progestogen contraceptives on depression and sexual functioning of women in the Eastern Dapu"
Protocol number (if applicable)	
Principal investigator	Mandisa Sigala
Department / Office Internal Mail Address	Health & Rehabilitation Sciences
1.1 Does this protocol receive US Federal funding?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
1.2 Is this a major or a minor amendment, see FHS000hip?	<input type="checkbox"/> Major <input checked="" type="checkbox"/> Minor

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval. This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

1. To add the Edinburgh Perinatal Depression Scale as a revised (1) amendment revised version number 1
2. To add a question on breastfeeding during follow-up revised version number 1

Appendix J: East London Hospital Complex ethics clearance.

Ethics Committee: E. L. HOSPITAL COMPLEX

Postal Address:

C/o East London Health Resource Centre

PO Box 12882

Amalinda

5250

Telephone : 045 709 2032

Fax no.: 045 7092386

Physical Address:

Cheltenham Road

East London

5201 South Africa

18th November 2012

Ms M Singato
East London Hospital Complex
Amalinda
East London
5200

Dear

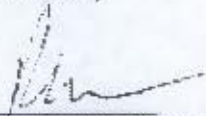
RE: A randomized control trial studying the effects of the coxist intrauterine device and injectable norgestrel contraceptive on depression and sexual functioning of women in the Eastern Cape

We acknowledge receipt of the above mentioned proposal.

Having gone through your proposal, the committee has no ethical problems noted.

Please be advised that the committee has granted you the consent to do the research.

Yours sincerely



**Dr P Alexander – Chairman Region C Ethics Committee
Ophthalmologist EL Hospital Complex**

Appendix K: Eastern Cape Department of Health study approval



Eastern Cape Department of Health

Enquiries:	Zurwabele Meme	Tel No:	040 638 0830
Date:	29th November 2012	Fax No:	043 542 1409
e-mail address:	zurwabele.meme@mpilo.ecdoh.gov.za		

Dear Ms M. Singata

Re: The effects of the copper intrauterine device and injectable progestogen contraceptive on depression and sexual functioning of women in the Eastern Cape

The Department of Health would like to inform you that your application for conducting a research on the abovementioned topic has been approved based on the following conditions:

1. During your study, you will follow the submitted protocol with ethical approval and can only deviate from it after having a written approval from the Department of Health in writing.
2. You are advised to ensure, observe and respect the rights and culture of your research participants and maintain confidentiality of their identities and should remove or not collect any information which can be used to link the participants.
3. The Department of Health expects you to provide a progress of your study every 3 months (from date you received this letter) in writing.
4. At the end of your study, you will be expected to send a full written report with your findings and implementable recommendations to the Epidemiological Research & Surveillance Management. You may be invited to the department to come and present your research findings with your implementable recommendations.
5. Your results on the Eastern Cape will not be presented anywhere unless you have shared them with the Department of Health as indicated above.

Your compliance in this regard will be highly appreciated.

DEPUTY DIRECTOR, EPIDEMIOLOGICAL RESEARCH & SURVEILLANCE MANAGEMENT



Appendix K: Letter requesting permission to use the BDI-II

[Basic HTML view](#)

Move to Inbox
More

4. BDI-II

Mandisa Singata mandisa.singata@gmail.com 3/8/12

to abeck

Dear Dr Beck

I'm a PhD Nursing student with University of Cape Town(South Africa) and would love to use your BDI-II revised inventory to see if hormonal contraceptive versus Intra-uterine contraceptive device has effects on depression.

I'm in South Africa and the study population is mostly Xhosa speaking. I fortunately got the Xhosa validated BDI-II from Gary Steel and David Edwards(Rhodes University)

I have tried to search online and I saw that I have to pay.

I humble request a sponsored copy and the permission to use the scale for my research

Yours truly

Mandisa Singata

Reply Forward

Aaron

T. I will be out of the office until further notice. I will respond to any Beck, messa ... 3/8/12

MO

I will be out of the office until further notice. I will respond to any messa ...

Appendix L: Request to use the BDI-II Xhosa version

From: Dave Edwards [mailto:d.edwards@ru.ac.za]

Sent: 23 February 2012 09:42 PM

To: g.steele@ru.ac.za

Cc: mandisa.singata@gmail.com

Subject: FW: Xhosa translated version of the Beck inventories

Hi Gary

Please see the enquiry below from Mandisa Singata. Can you assist?

Thanks

Dave

Professor David Edwards - Clinical Psychologist (Health Professions Council SA & Health Professions Council UK)

Diplomate and Founding Fellow, Academy of Cognitive Therapy; Associate Fellow of the British Psychological Society; Certified Schema Therapist (ESST)

Cell/mobile phone: 083 304 2238, Fax: 086 647 0956; UK mobile (only when I am in Europe) 07594 342 957 (+44)

Department of Psychology, Rhodes University, Grahamstown, 6140 - phone: 046 603 7085

From: Mandisa Singata [mailto:mandisa.singata@gmail.com]

Sent: 23 February 2012 12:23 PM

To: d.edwards@ru.ac.za

Subject: Xhosa translated version of the Beck inventories

Dear Prof

I'm conducting a study amongs Xhosa speaking and I will be using the Beck's depression inventory.

Will you kindly help me with your validated Xhosa translation.

I'm measuring depression amongs women who are on progestogen injectable contraceptive and IUD.

Yours truly,

Mandisa Singata

0624201743

Appendix M: Approval for protocol registration with PACTR



SOUTH AFRICAN COCHRANE CENTRE

PO Box 2906, Durban, 4001, South Africa
E: epienaar@mrc.ac.za
T: +27 21 938 0835
F: +27 21 938 0835
C: 011 234 1000



23 October 2012

To Whom It May Concern:

RE: Effects of the copper intrauterine device and injectable progestogen contraceptive on depression and sexual functioning

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201209000419241**

Please be advised that you are responsible for updating your trial, or for informing us of changes to your trial.

Additionally, please provide us with copies of your ethical clearance letters as we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835

