

**EFFECTS OF PEER COUNSELLING ON FEEDING PRACTICES OF HIV
POSITIVE AND HIV NEGATIVE WOMEN IN SOUTH AFRICA: A
RANDOMISED CONTROLLED TRIAL**

PELISA DANA

A mini thesis submitted in partial fulfillment of the requirements for the degree of
Masters in Public Health at the School of Public Health, University of the Western Cape



Supervisor: Prof. Debra Jackson

Co-supervisors: Dr. T. Doherty & Dr. B. van Wyk

February 2011

DECLARATION

I declare that “Effects of peer counselling on feeding practices of HIV positive and HIV negative women in South Africa: A randomised controlled trial” is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.



Pelisa Dana



February 2011

ACKNOWLEDGEMENTS

First, I would like to pass my sincere gratitude to my supervisor, Prof. Debra Jackson and my co-supervisors, Dr. Tanya Doherty & Dr. Brian van Wyk for all their support during my studies. Without them, this work would not have come to fruition. I would also like to thank the MRC biostatistician, Ms. Sonia Swanevelder for her help with the data analysis.

I would also like to thank the Human Sciences Research Council for providing me with financial assistance and time to study while still working for them. Once more, thanks to my supervisor for securing a bursary for my final year of studies.

To my fellow colleagues whom I started the MPH journey with, thank you for all your support, the constant reminders you sent me of when assignments were due and just for being there when I needed you most.

To my dear family, especially my son, thank you for encouraging me to go on even when things seemed not to be going according to plan. Your love and support has helped shape me into the person I am today.

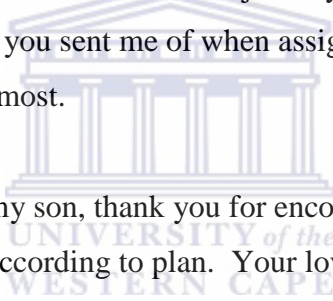
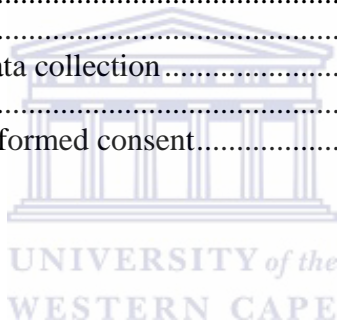


TABLE OF CONTENTS

DECLARATION	i
ACKNOWLEDGEMENTS	ii
TABLE OF CONTENTS	iii
LIST OF TABLES	v
LIST OF FIGURES	vi
KEYWORDS USED	vii
ACRONYMS USED	viii
ABSTRACT	1
CHAPTER 1	3
1.1 INTRODUCTION	3
1.2 RATIONALE	7
CHAPTER 2	8
2.1 LITERATURE REVIEW	8
2.1.1 International and national recommendations for infant feeding	8
2.1.2 Advantages and disadvantages of breastfeeding	11
2.1.3 Disadvantages of mixed Feeding	13
2.1.4 Advantages and disadvantages of formula feeding	15
2.1.5 Factors influencing choice of feeding method	17
2.1.6 Peer counseling/support for infant feeding	24
2.1.7 Feeding practices amongst HIV positive and HIV negative women	25
2.2 AIM	27
2.3 OBJECTIVES	27
Infant feeding practices	27
Infant feeding intention and infant feeding practice	28
High and Low risk infant feeding in HIV-positive mothers	28
Disclosure and infant feeding intention and practice	28
CHAPTER 3	29
3.1 METHODOLOGY	29
3.1.1 Study design for the cluster randomised trial in South Africa	29
3.1.2 Sample	31
3.1.3 Data Collection Method	32
3.2 ETHICAL CONSIDERATIONS	33
3.3 DATA MANAGEMENT	33
3.4 DATA ANALYSIS	34
3.5 VALIDITY, RELIABILITY & LIMITATIONS	36
3.6 CONTRIBUTION OF THE STUDENT	36
CHAPTER 4	38
4.1 RESULTS	38
4.1.1 Study profile	38
4.1.2 Infant feeding practices	41
4.1.2.1 Type of counselling and infant feeding method chosen	42
4.1.2.2 Intention to feed at recruitment versus chosen or practised feeding plan	50
4.1.2.3 Infant feeding methods regarded as high risk for HIV transmission	54

4.1.2.4 Disclosure of women’s HIV positive status and their infant feeding plans at recruitment	55
4.1.2.5 HIV disclosure and infant feeding practices	56
4.1.2.6 Disclosure of women’s HIV positive status and their choice of high or low risk infant feeding methods.....	57
CHAPTER 5	60
5.1 DISCUSSION	60
5.1.1 Impact of counselling on infant feeding practices	61
5.1.2 Adherence to antenatal infant feeding intention	64
5.1.3 HIV status disclosure and adherence to antenatal infant feeding intention	66
5.2 LIMITATIONS	67
CHAPTER 6	69
6.1 CONCLUSION	69
6.2 RECOMMENDATIONS	70
REFERENCES	73
APPENDICES	86
APPENDIX 1	86
Peer support recruitment	86
APPENDIX 2	88
Sampling Procedure for data collection	88
APPENDIX 3	90
Procedure for obtaining informed consent.....	90



LIST OF TABLES

Table 1a: Study profile of all women who were recruited into the study.....	39
Table 1b: Study profile of women recruited into the control group	40
Table 1c: Study profile of women recruited into the intervention group	41
Table 2: Outcomes on Exclusive Breastfeeding (EBF) at 12 and 24 weeks	41
Table 3: Infant feeding outcomes at 3, 6, 12 & 24 weeks amongst all women receiving peer support (intervention) and those receiving standard ANC counselling (control)	43
Table 4: Infant feeding outcomes for HIV positive women at 3, 6, 12 & 24 weeks	46
Table 5: Infant feeding outcomes for HIV negative women at 3, 6, 12 & 24 weeks	48
Table 6: Adherence of HIV negative women to the infant feeding method chosen at recruitment when visited at 3 weeks after birth in the intervention and control groups...	51
Table 7: Adherence of HIV positive women to the infant feeding method chosen at recruitment during visits at 3, 6, 12 & 24 weeks after birth in the intervention and control groups.....	53
Table 8: High and low risk infant feeding methods in the intervention and control groups	55
Table 9: Women's disclosure of their HIV status and their planned infant feeding choices at recruitment	56
Table 10: HIV disclosure and infant feeding methods	57
Table 11: Disclosure of HIV status and choice of high or low risk infant feeding method	59

LIST OF FIGURES

Figures 1(a) and 1(b): Feeding practices amongst HIV positive women in the intervention and control groups, respectively	47
Figures 2(a) and 2(b): Feeding practices amongst HIV negative women in the intervention and control groups, respectively	49



KEYWORDS USED

HIV/AIDS

Infant feeding practices

Exclusive breastfeeding

Exclusive formula feeding

Predominant breastfeeding

Mixed feeding

Peer support

Intervention group

Control group

Cluster randomized trial.



ACRONYMS USED

AFASS	Acceptable, Feasible, Affordable, Sustainable and Safe
AIDS	Acquired Immunodeficiency Syndrome
ANC	Antenatal care
ARV	Antiretroviral
ART	Antiretroviral treatment
CBOs	Community-based organisations
DCS	Data Collector Supervisor
DQM	Data Quality Manager
EBF	Exclusive breastfeeding
EFF	Exclusive Formula Feeding
HIV	Human Immunodeficiency Virus
IMR	Infant Mortality Rate
INP	Integrated Nutrition Programme
IYCF	Infant and Young Child Feeding
IYCN	Infant and Young Child Nutrition
LC	Lay counsellor



MF	Mixed Feeding
MRC	Medical Research Council
MTCT	Mother-to-child transmission of HIV
NDOH	National Department of Health
PBF	Predominantly Breastfeeding
PMTCT	Prevention of mother-to-child transmission of HIV
PC/PS	Peer counsellor/Peer Supporter
PSS	Peer Support Supervisor
RNA	Ribonucleic Acid
VCT	Voluntary counselling and testing (for HIV)
WHO	World Health Organisation
QC	Quality Control
UNAIDS	The Joint United Nations Programme on HIV/AIDS



ABSTRACT

Background: Promotion of exclusive breastfeeding (EBF), (giving breast milk only without any solids or liquids), has proved to be very challenging in the South African context, although this infant feeding practice has been found to protect babies against diarrhoea and respiratory tract infections and to carry a lower risk of HIV infection than mixed feeding (breastfeeding combined with formula or solids).

Study design: The PROMISE-EBF study is a multi-country cluster randomised trial to examine peer support to promote exclusive breastfeeding in Africa. For the South African site in the PROMISE-EBF study, three sites, Paarl, Rietvlei and Umlazi, were selected because of their different geographic settings and each site operated as a separate stratum for cluster selection and randomisation purposes. The clusters were then randomised into intervention and control arms making a total of 17 clusters in each arm. HIV positive and negative women in the intervention arm received support on their choice of infant feeding from the peer supporters who visited them at their homes while the women in the control group only received the standard infant feeding counselling and support provided by health care workers at health facilities.

Data collection: Mothers were interviewed at recruitment during the antepartum period to establish eligibility, obtain informed consent and data on socio-economic status. Home visits were scheduled for data collection by trained data collectors at 3, 6, 12 and 24 weeks after birth.

Analysis of results: This mini-thesis was a secondary analysis of the PROMISE-EBF data focusing on the South African data only. The data was adjusted for clustering and

analysed using SAS. Comparison of variables between the intervention and control groups within sites was done.

Results: A significant difference, regarding counselling and infant feeding practices, was observed among all women who received peer support compared to those who received the standard antenatal counselling, with more women in the intervention group (20.5%) practising EBF than those in the control group (12.8%) by Week 3. When the women's HIV status was considered, more than 65% of HIV positive and 40% of HIV negative women practised MF and EFF (giving formula milk only with no breast milk) throughout the study, respectively, regardless of the group they were in. For women who had intended to practise EBF at recruitment, 33% in the control group and 20% in the intervention group actually practised EBF by Week 3. Regarding disclosure and feeding choice, 77.4% of women who had disclosed their HIV status actually practised MF versus 8.6% who practised EBF by Week 3.

Conclusion: Community peer counselling should be strengthened as the results from this study showed that a high percentage of women who practised EBF were those who had received counselling, irrespective of their HIV status. The high percentage of HIV positive women who practised high risk feeding, despite receiving infant counselling, is of concern. Disclosure of the women's HIV status did not translate to them practising low risk infant feeding methods, which may suggest that there are other issues that determine the women's choice of infant feeding.

CHAPTER 1

1.1 INTRODUCTION

Mother-to-child transmission (MTCT) of HIV has been identified as the most common means by which children get infected (Horvath, Madi, Luppa, Kennedy, Rutherford & Read, 2009). According to WHO (2003), the risk of HIV transmission without ARV prophylaxis is 5 – 10% during pregnancy, 10 – 15% during labour and delivery, 5 – 20% during breastfeeding, 15 – 25% overall without breastfeeding, 20 – 35 % overall with breastfeeding up to six months, 30 – 45% overall with breastfeeding up to 18 – 24 months. Exclusive breastfeeding (EBF) decreases the risk of infant HIV infection by three to four times if EBF is practised for less than six months (WHO, 2006). Despite the advantages of breastfeeding, it also results in more than 200 000 global infant infections each year (de Kock, Fowler, Mercier, Vencenzi, Saba, Hoff et al., 2000). In South Africa, an estimated 38 000 children acquired HIV infection through MTCT around birth while 26 000 were infected through breastfeeding (DoH, 2007). A WHO, UNICEF, UNFPA & UNAIDS (2004) report estimated an HIV transmission rate of 5 – 20% through breastfeeding in the absence of no ARV prophylaxis. However, in a study conducted in Cato Manor in Durban, where EBF was supported, only 2.6% of HIV transmission through breastfeeding was observed by nine months postpartum (Coutsoudis, 2005).

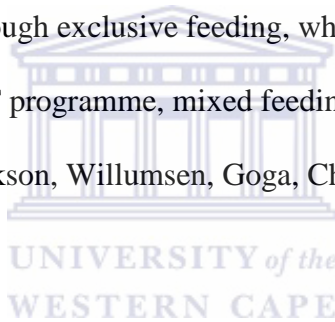
The choice of feeding method has an impact on an infant's nutritional status, growth, health status and ultimately survival (Shisana, Simbayi, Rehle, Zungu, Zuma, Ngogo et al., 2010). In certain cultures, where breastfeeding is a norm, non-breastfeeding women may be worried that this may somehow reveal their HIV status and hence live in constant fear of being stigmatised, abandoned and ostracized (UK Department of Health, 2004). This sentiment was also shared by Thairu, Pelto, Rollins, Bland and Ntshangase (2005), who conducted a study on socio-cultural factors that influence the choice of infant feeding practised by HIV positive women in Kwa-Zulu Natal. According to these authors, even prior to HIV being an epidemic, practising any other form of feeding other than breastfeeding in a community where breastfeeding is a norm would be regarded as abnormal and practising formula feeding these days would be tantamount to disclosing one's HIV positive status. Similar findings were shown in a study conducted in Tanzania, where mothers participating in focus group discussions explained that breastfeeding is heavily culturally embedded in their communities and refusal to breastfeed without a valid reason might lead to rejection, loss of respect and even withdrawal of assets provided to a woman after birth (Leshabari, Koniz-Booher, Åstrøm, de Paoli & Moland, 2006). In South Africa, breastfeeding is a norm with 88% of mothers reporting initiating breastfeeding after birth, although only 8% of infants are exclusively breastfed by six months of age (Shisana et al., 2010).

Health care workers find themselves in a dilemma when trying to implement the UNAIDS guidelines on replacement feeding as they face difficulties in deciding when replacement feeding meets the AFASS criteria (Coutsoudis, 2005), which means that the

replacement feeding is acceptable, feasible, affordable, sustainable and safe to use. This was shown in a study conducted amongst nurse-counselors in Tanzania, where high levels of stress and frustration among the counsellors was observed (Leshabari, Blystad, de Paoli & Moland, 2007). In that study, the nurse-counselors admitted to being unable to give qualified and relevant advice on appropriate infant feeding to an HIV positive mother and perceived both exclusive breastfeeding (EBF) and exclusive formula feeding (EFF) as culturally and socially unsuitable.

In a study conducted in Kenya to determine the feeding practices and the nutritional status of babies born to HIV positive women, 31% of the mothers, despite being counseled, practiced mixed feeding six weeks after delivery (Kiarie, Richardson, Mbori-Ngacha, Nduati, & John-Stewart, 2004). In South Africa, counselling on suitable infant feeding by trained lay counsellors is an integral part of the Prevention of Mother-to-Child Transmission (PMTCT) programme (Matji, Wittenberg, Makin, Jeffery, MacIntyre & Forsyth, 2008), although according to Jackson, Chopra, Doherty and Ashworth (2004), it is suboptimal. In a study conducted in three geographically and resource-diverse areas in South Africa on infant feeding and decision making by HIV positive women, disclosure of one's HIV status and having a supportive husband or partner were key factors in these women's maintenance of EBF (Doherty, Chopra, Nkonki, Jackson, & Persson, 2006). These authors cite lack of support from health workers as one of the challenges that may lead to HIV positive women changing their minds about practising EBF, even if that was their intended infant feeding practise.

In South Africa, the Global Strategy for Infant and Young Children Feeding (IYCF) guidelines developed jointly by WHO and UNICEF in 2003 state that for the first six months of life, exclusive breastfeeding should be practiced to achieve optimal growth, development and health (WHO, 2003a), have been adopted by the National Department of Health 's (NDoH) infant and young child feeding policy (NDOH, 2008) . Despite the efforts on infant feeding counselling, Coutsoadis (2005) points out that for many HIV positive women, replacement feeding does not always meet the AFASS criteria and as a result most women end up practising mixed breastfeeding. The cultural norms and societal expectations on new mothers to introduce liquids and other foods to infants, results in mixed feeding. Although exclusive feeding, whether breast or formula feeding, is recommended in the PMTCT programme, mixed feeding is the most commonly practiced form of feeding (Jackson, Willumsen, Goga, Chopra, Doherty, Colvin et al., 2005).



Exclusive breastfeeding improves infants' survival by protecting them against gastrointestinal, respiratory and other infections (WHO, 2000) while providing nutritional and psychosocial benefits (Thairu et al., 2005). It is also estimated that it can prevent 13% of deaths in children under five years of age with universal coverage (Coovadia, Rollins, Bland, Little, Coutsoadis, Bennish et al., 2007). However, promotion of EBF has proved to be a challenge and needs to be scaled up to a far greater extent (PROMISE-EBF Study Group, 2009). The PROMISE-EBF study set out to test an EBF promotion intervention utilising peer counsellors in four countries: Burkina Faso, Uganda, Zambia and South Africa. In South Africa this intervention was HIV sensitive and also supported

exclusive formula feeding in HIV-positive women who chose the formula feeding option (PROMISE-EBF Study Group, 2009).

1.2 RATIONALE

This mini-thesis seeks to find out if there is an increase in mothers who adhere to WHO- and NDOH- recommended exclusive infant feeding practices (exclusive breastfeeding or exclusive replacement feeding) as a result of being provided with peer counselling on infant feeding and also to compare the impact of a peer counselling intervention in HIV positive and HIV negative women.



CHAPTER 2

2.1 LITERATURE REVIEW

A major challenge facing countries with high HIV prevalence is improving feeding of infants and young children, irrespective of their mothers' HIV status (WHO, 2003a). Stigma, discrimination, cultural norms and beliefs put HIV positive women in awkward positions when deciding on infant feeding choices and influence actual infant feeding practices.

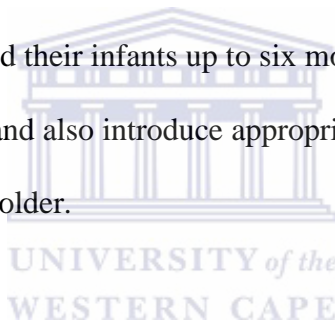


2.1.1 International and national recommendations for infant feeding

The Global Strategy for Infant and Young Child Feeding (IYCF) was adopted by the World Health Assembly (WHA) in May 2002 and endorsed by the UNICEF Executive Board in September 2002 (Safi, Wahdati & Hamid, Undated). A multi-country survey consisting of 14 countries, conducted to determine IYCF in the context of HIV, found that South Africa has the national IYCF policies and that it recommends that exclusive breastfeeding for HIV-exposed infants be practised from 0 – 6 months of age if the mother does not meet the AFASS criteria, otherwise replacement feeding can be used if the mother meets the AFASS criteria (Mazzeo, 2009). In 2004, the USAID/South Africa asked the LINKAGES project to provide technical assistance to the Department of Health's Nutrition Directorate (DoH, USAID, AED & LINKAGES, 2006). Some of the AED/LINKAGES recommendations were that PMTCT and IYCF be linked to other child

survival interventions, knowledge and counselling skills of health providers in maternal nutrition and IYCF be strengthened and that lay counsellors and community health workers be trained on maternal nutrition and IYCF in the context of HIV/AIDS.

The Integrated Nutrition Programme (INP) was developed from the recommendations of the Nutrition Committee in 1994 to develop an integrated approach to nutrition in order to replace the fragmented food-based approach used in the past (DoH, 2003). The INP was implemented as an integral part of the Primary Health Care system and at different levels of the Health management structures. One of the aims of the INP is to enable all women to exclusively breastfeed their infants up to six months of age and thereafter to be able to continue breastfeeding and also introduce appropriate complementary foods, until twenty-four months of age and older.



Previously, the WHO (2003b) recommended that HIV positive women who choose to breastfeed, whether by choice or because they do not meet the AFASS criteria, should only do so for the first six months of the baby's life, it is also encouraged that a woman should be given information about the risks associated with each feeding choice so as to make an informed decision (WHO/UNAIDS/UNICEF/UNFPA, 2008). The previous South African national guidelines on PMTCT also recommended that an HIV positive woman who chooses to exclusively breastfeed her child should stop this practice between 12 to 24 weeks (DoH, 2008) although this is no longer recommended in the 2010 guidelines. Although the WHO and the DoH recommended that HIV positive mothers should completely stop breastfeeding by six months, a study conducted by Goga, van

Wyk, Doherty, Colvin, Jackson and Chopra (2009) showed that stopping breastfeeding at six months was not easy and that if this is to be successful, interventions at health facility level, individual level and at family level should be implemented to minimise adverse effects on both the mother and child's health. This was in contrast to a study by Coovadia et al. (2007) who found that rapid cessation of breastfeeding at six months was possible with the help of a good support system. Goga et al. (2009) suggested that counselling on stopping breastfeeding was in a way effective but that family support and advice to HIV positive women on how to completely stop breastfeeding were needed.

The latest 2010 WHO guidelines recommend that counselling and support in appropriate infant feeding practices and ARV interventions be provided to all pregnant women and mothers. The guidelines also recommend that HIV positive mothers or HIV-exposed infants should take a course of ARVs during the breastfeeding period (WHO, 2010). The new guidelines also encourage HIV positive mothers to exclusively breastfeed their infants for the first six months of life, then introduce appropriate complementary foods but still continue breastfeeding up until 12 months after birth, even if ARVs are not available. In such cases, breastfeeding beyond six months is recommended unless environmental and social circumstances are safe and support replacement feeding. In cases where ARVs are unlikely to be available, breastfeeding is recommended to increase the infant's chances of survival. Mothers who are HIV negative or of unknown HIV status should be counselled to practise EBF for the first six months of the infant's life and then introduce complementary foods while continuing with breastfeeding.

The latest 2010 South African ART guidelines recommend that HIV positive pregnant women whose CD4 count is at or below 350 cells / μ l or at clinical stage 3 or 4 be started on lifelong ART within two weeks and their infants be given single dose NVP (sdNVP) at birth and then daily for six weeks irrespective of the infant feeding method used (DoH, 2010). Those with CD4 counts above 350 cells / μ l and not eligible for ART must be started on AZT at 14 weeks of pregnancy, be given sdNVP + AZT every three hours during labour and their infants be given NVP at birth and then daily for six weeks continued for as long as breastfeeding is practised. For HIV positive mothers who did not receive any ARVs before or during delivery, they should be given sdNVP + AZT after every three hours, TDF + FTC single dose post-delivery and their infants should be given sdNVP and then daily for six weeks continued for as long as breastfeeding is practised. Infants of mothers of unknown status should have an HIV antibody test done, be given sdNVP if HIV antibody positive, followed by a daily dose for six weeks when Polymerase Chain Reaction (PCR) test will be done.

2.1.2 Advantages and disadvantages of breastfeeding

In most African societies, breastfeeding is supported and encouraged as it is seen as part of the traditional culture (Simondon, Costes, Delaunay, Diallo & Simondon, 2001).

Breastfeeding has many benefits which include a decrease in infant morbidity and mortality rates through optimal nutrition and protection against common childhood infections such as gastrointestinal and respiratory tract infections (WHO, 2000; Coovadia et al., 2007). A study conducted by Patel, Bland, Coovadia, Rollins, Coutsooudis and Newell (2010) showed that optimal feeding practices used during the first six weeks of an

infant's life neutralize the effect of being born to an HIV positive mother, as was shown by breastfed HIV infected infants who had higher z-scores for weight. Sellen (2009) concurs that starting exclusive breastfeeding within an hour after birth until six months of an infant's life promotes optimal growth and development. Not breastfeeding, especially in developing countries, is associated with a six fold increase in infant mortality from infectious diseases (WHO, 2003b).

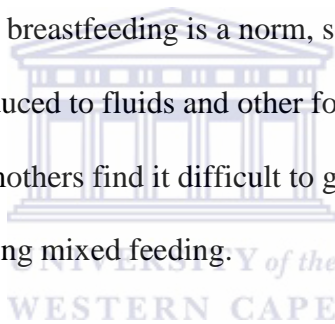
Even so, breastfeeding by HIV positive women is a major route of HIV transmission (WHO, 2003c). The risk through breastfeeding persists as long as breastfeeding continues (Nduati et al., 2000), a fact shared by Becquet, Bland, Leroy, Rollins, Ekouevi, Coutoudis et al. (2009) from a pooled analysis of West and South African cohorts, where they found that the duration of breastfeeding was a major determinant of postnatal HIV transmission. This was also shown in a study conducted in Côte d'Ivoire, where breastfeeding for more than six months was associated with a more or less 7.5 times likelihood of postnatal transmission of HIV (Becquet, Ekouevi, Menan, Amani-Bosse, Bequet, Dabis et al (2008) . According to Thorne and Newell (2004), the rates of Mother-to-Child-Transmission (MTCT) of HIV, without antiretroviral treatment, are estimated to range between 15 to 30% in the absence of breastfeeding, 25 to 45% if breastfeeding continues through six months and 30 to 45% if breastfeeding continues through 18 to 24 months (De Cock, Fowler, Mercier, Vincenzi, Saba, Hoff et al., 2000). Infection of infants, whose mothers were not infected with HIV during pregnancy or at delivery but who became infected while breastfeeding, has been observed (WHO, 2003c). Also, infants with HIV negative mothers may get infected by breast milk expressed by

HIV positive wet nurses, as was shown in a study conducted in the Free State by Shisana, Mehtar, Mosala, Zungu-Dirwayi, Rehle, Dana et al. (2005), which showed that 30% of expressed breast milk had at least 50 copies/ml of HIV Ribonucleic acid (RNA).

Although these findings show the adverse side of breastfeeding by HIV positive women, the benefits gained, e.g., bonding of the mother with the child, the nutrients found only in breastmilk, the cheap and readily available source of food for babies, more than make up for the risks, as long as the mothers do not mix breastfeeding with other forms of feeding.

According to Lunney, Illiff, Mutasa, Ntozini, Magder, Moulton et al. (2010) exclusive breastfeeding protects the infant against postnatal transmission of HIV compared to MF.

Although in some communities breastfeeding is a norm, some families and communities encourage that infants be introduced to fluids and other food stuffs from an early age, and because of lack of disclosure, mothers find it difficult to go against such norms (Doherty et al., 2006) and end up practicing mixed feeding.



2.1.3 Disadvantages of mixed Feeding

The disadvantages of MF before six months of age are that it damages the lining of the intestines, making it easy for the HI virus in the breastmilk to pass through to the infant's circulation; it stimulates immune cells making them susceptible to HIV infection and induces sub-clinical mastitis (Kasonka & Filteau, 2009). The study conducted in Côte d'Ivoire by Becquet et al. (2008) showed that mixed feeding during the first month of an infant's life exposed them to a 6.3 fold increased risk of contracting HIV. A study conducted on feeding patterns in Zimbabwe, the ZVITAMBO study, showed that if mixed feeding, breastfeeding mixed with solids or animal milks, was practiced in the first

three months of a baby's life, the risk of HIV contraction at six months was four-times higher compared to exclusive breastfeeding (Iloff et al., 2005). In South Africa, Coutsooudis, Pillay, Kuhn, Spooner, Tsai and Coovadia (2001) reported that MF was associated with a high risk of infant HIV infection in the first three months of life compared to exclusive breastfeeding. These authors found that non-exclusive breastfeeding may be a risk factor as infants exclusively breastfed for at least three months had a lower transmission risk at 6 months (19.4%) than those who also received other foods and fluids in addition to breast milk (26.1%).

Although breastmilk remains an important source of nutrients and immune protection, complementary feeding is necessary to increase the daily dietary intake of an infant (Sellen, 2009) and to ensure satisfactory growth and development, especially after the age of six months (Hop, Gross, Giay, Sastroamidjojo & Schultink, 2000). The inconsistencies in defining infant feeding methods led to the WHO in 1991 setting up definitions and indicators for studying infant feeding practices using a 24 hour recall method (WHO, 1991). According to the WHO's definition, complementary feeding is when an infant is given both breast milk and semi-solid or solid foods, including non-human milk. It is when the breast milk is no longer enough to meet the nutritional needs of an infant that complementary foods should be added to the infant's diet (WHO, 2005). This should be done when the infant is six months old and the complementary food should at least have the same nutritional value as the breast milk. UNICEF's key IYCF definition of complementary feeding also defines it as when a child is given breast milk and solid or semi-solid or soft foods when the child is above six months of age whereas

giving breast milk and other liquids or solids while a child is below six months as mixed feeding (UNICEF, 2008). According to UNICEF, mixed feeding, especially giving other liquids, can cause a decrease in breast milk supply to the child as he suckles less. This report goes further to state that babies do not need water, even in hot climates, in the first six months of their lives as they get it all from the breast milk.

2.1.4 Advantages and disadvantages of formula feeding

Regarding formula feeding, HIV positive women should avoid breastfeeding from the onset if they meet the AFASS criteria, i.e., replacement feeding is acceptable, feasible, affordable, sustainable and safe (WHO, 2003d; Linkages, 2004). A study on infant feeding choices conducted by Coutsooudis, Pillay, Spooner, Kuhn and Coovadia (1999) showed no higher rates of HIV transmission between mothers who exclusively breastfed their babies and those who formula-fed theirs. A follow-up study by Coutsooudis et al. (2001) showed that infants who were breastfed exclusively for three to six months were not at a higher risk of HIV infection than those who were never breastfed. Another study conducted by Mbori-Ngacha, Nduati, John et al. (2001) in Nairobi did not find an increased risk of mortality amongst formula feeders compared to breast feeders. This is in contrast to what WHO (2000) suggests, that replacement feeding in resource poor settings could increase the infants' risk of morbidity and mortality from other infections. This fact is shared by Jackson, Goga, Doherty and Chopra (2009), who acknowledge that although exclusively feeding an infant with replacement feeds may reduce the risk of HIV transmission from the mother to the child in developing countries, this infant feeding

choice should not be an automatic option in poor socio-economic areas where safety of the replacement feed may be compromised.

Complete avoidance of breastfeeding prevents MTCT but has significant morbidity associated with it, especially if the formula is not prepared with clean water (Hovarth et al., 2009). Sturt, Dokubo & Sintt (2010) showed that prevention of MTCT can be achieved if EBF is practised for the first few months of the infant's life and antiretroviral treatment is provided to the infant, and also to the mother.

A study conducted in KwaZulu-Natal clinics showed the mortality rate of replacement fed infants was more than double in their first three months of life compared to exclusively breastfed infants (Coovadia et al., 2007). In a study conducted in India, a high risk of repeat hospitalisation of formula-fed infants born to HIV positive women was observed (Phadke, Gadgil, Bharucha, Shrotri, Sasrty, Gupta et al., 2003). In that study, formula-fed infants born to HIV positive mothers were hospitalised within six months of their lives, some of them repeatedly, as a result of gastroenteritis (48.1%), pneumonia (18.5%), septicemia (11.1%) and jaundice (11.1%). In Uganda, HIV transmission rates of 3.7% in exclusively formula fed babies, 16% in exclusively breast fed and 20.4% in mixed fed babies at six months were shown (Magoni, Bassani, Okong, Kituuka, Germinario, Giuliano et al., 2005). The question arises whether these mothers really practice exclusive breastfeeding or only say so when interviewed. A study conducted by Doherty et al. (2006) showed that mothers who were sampled because they had reported exclusive feeding practices only maintained this practice for a short period

because of constraints they encounter in the community and in the health system. The reasons given by the mothers in that study showed that their family members, especially mothers and sisters, together with the healthcare workers, had a huge influence on which feeding option the women ended up choosing. Another disadvantage of formula feeding is that in South Africa, HIV positive women who chose to practice formula feeding were faced with shortage of formula milk at the clinics and lack of support after giving birth, which made them feel incapable to raise their babies (Doherty, Chopra, Nkonki, Jackson & Greiner, 2006).

2.1.5 Factors influencing choice of feeding method

Every woman has a right to decide on the choice of infant feeding method they would like to practice (WHO, 2003c). This is particularly important for HIV positive women who, in essence, should be counseled on the different infant feeding methods, the advantages and disadvantages of the different methods, the impact they will have on their and babies' health and should be supported in whatever decision they make for the duration of their choice. Many influences on both infant feeding choice and actual infant feeding practices have been documented in the literature.

2.1.5.1 Influence of family Members

As family members, especially spouses/partners and parents-in-law, have a huge influence of the infant feeding methods used by the mothers. They should be involved in the infant feeding decision making process because of both financial implications and societal/cultural norms that dictate what is acceptable or expected of a new mother and

because of the support the HIV positive mother will need from them, even though the final decision is hers. The inclusion of male partners in promotion of and education about breastfeeding, as well as providing the fathers with knowledge and skills for optimal breastfeeding practices was found to have a positive impact on EBF rates (Susin & Giugliani, 2008). A study conducted in Kenya by the Infant and Young Child Nutrition (IYCN) project on HIV positive men attending support groups, that tried to engage men to increase support for optimal infant feeding, showed that although men felt that their role was to provide shelter, food, security and education, they could be more involved, open and willing to discuss the nutrition concerns of both women and children and that they could be more involved in infant feeding by sharing responsibility with their partners (Martin & Mukuria, 2010). A cohort study conducted in six clinics in rural KwaZulu-Natal showed that negotiating with a spouse on infant feeding may make it easy for the woman to adhere to her chosen form of infant feeding (Thairu, Pelto, Rollins, Bland & Ntshangase, 2005). In this study, an HIV positive woman had negotiated with her husband to formula-feed her child and because her husband knew her HIV status, she did not mind what the community said about her.

The influence of family members, especially partners, seems to be a universal phenomenon. This was observed in a study conducted in Perth, Australia, where higher rates of women who perceived their own mothers or their partners as pro-breastfeeding, were observed practicing breastfeeding compared to those who perceived their partners to prefer formula feeding or were undecided about the infant feeding method to be used (Scott, Binns, Oddy & Graham, 2006). Besides family members being perceived to have

tremendous influence on the choice of infant feeding that mothers practise, the environment in which a mother is in, i.e., community and the media she is exposed to, also plays a role. A study conducted to determine the sources of influence on infant feeding practices amongst Chinese mothers with infants aged between 4 weeks to six months of age in Hong Kong (Hung, Ling & Ong, 2002) found that mothers who practised bottle feeding were influenced more by health professionals who did not support breastfeeding, which was reinforced by infant formula milk advertisements in the media. On the other hand, mothers who successfully breastfed their babies were influenced by their social networks through which they were told about the dangers of formula feeding while those who failed were found not to have support from relatives and friends.



Many HIV positive women practise MF because they are afraid of their families' disapproval (HST, 2002). The age of the woman and social dependency also play a role in choosing the form of infant feeding, as was shown in the study conducted by Thairu et al. (2005), where young mothers mentioned that older people at their homes expected them to feed their babies whenever they cried and that breastmilk alone is not enough and they should give their babies other foods for them to grow. Although there are such pressures on mothers, mixed feeding an infant during their first month of life should be avoided as it is a strong determinant of HIV transmission (Becquet et al., 2008).

In a longitudinal qualitative study of infant feeding decision-making and practices among HIV positive women conducted in three sites in South Africa, the mother's own beliefs

about breastfeeding and ANC counseling experiences influenced their choice of infant feeding during the antenatal period (Doherty, Chopra, Nkonki, Jackson & Persson, 2006b). This study showed that the pressure experienced by breastfeeding and formula feeding mothers within the first two weeks after birth, from both the health care workers and family members, caused them to change their intended infant feeding method. As a result, a mother who had intended to practise EBF changed to EFF because the health care worker told her that she may infect her child with the HIV. Among those who had intended to practise EFF, one mother was just given her baby by a health care worker and asked to start breastfeeding without being asked what infant feeding choice was while another switched to EBF for fear of her family associating formula feeding with HIV, and she had not disclosed her HIV status to anyone at home. Similar findings have been observed in other countries as well, where in Tanzania, despite counseling on replacement feeding being the best option to prevent MTCT, HIV positive women who had initially practiced formula feeding ended up practising breastfeeding for fear of being labeled as bad mothers and because they did not have full control on infant feeding as the mothers-in law had more power over infant feeding issues (Leshabari et al., 2006).

2.1.5.2 Social Norms and Stigma

Stigmatisation of HIV infected pregnant women, or even those perceived to be HIV positive, is a common occurrence. Bond, Chase and Aggleton (2002), in a study conducted in rural Zambia, found that the forms of stigmatisation of HIV positive women ranged from subtle to extreme actions where these women were subjected to rejection, degradation and in some cases abandonment. Besides the fear of being stigmatised,

young age and low socio-economic status of the women sometimes makes them powerless to stick to decisions they have taken about feeding their infants. This was shown in a study conducted in rural Kwa-Zulu Natal, where young, unemployed and single HIV positive mothers could not stand up to their older family members regarding their infant feeding choices (Doherty, Chopra, Nkonki, Jackson & Greiner, 2006).

Although community members may empathize with HIV positive people and may be aware that they need to treat them with compassion, the opposite is often true, as was shown by a focus group discussion study on community attitudes to HIV in KwaZulu-Natal (Ndinda, Chimbwete, McGrath, Pool & Group, 2007). The same adverse treatment was shown in a study conducted by Doherty et al. (2006), where some HIV positive women mentioned that they were laughed at by community members when seen with tins of formula milk. This lack of empathy presents big challenges for PMTCT, especially with regard to infant feeding (Leshabari, Blystad & Moland, 2007c).

2.1.5.3 Disclosure of HIV Status

The negative community attitudes make decision making for HIV positive women difficult on whether to disclose their HIV status or not (Thairu et al., 2005). Studies from developing countries show lower rates of disclosure (49%) compared to developed countries (79%) (WHO, 2004). According to this source, only 16.7% - 32% of pregnant ANC-tested women disclose their HIV status to their current or steady partners in sub-Saharan Africa. Most of the women in a cohort study conducted by Thairu et al. (2005) on socio-cultural influences on infant feeding decisions by women in KwaZulu-Natal

mentioned that they had not disclosed their HIV positive status, even to their families. A study conducted by Doherty, Chopra, Nkonki, Jackson and Greiner (2006) on the effect of HIV disclosure on infant feeding showed that only half of the participants (mothers) had disclosed their HIV status to someone, usually the baby's father. Another study conducted in Cape Town by Simbayi, Kalichman, Strebel, Cloete, Henda and Nqeketo (2007) showed a significant relationship between fear of potential adverse reactions and non-disclosure to sex partners.

It is not only at community level where fear of HIV disclosure impacts on the women's choice of infant feeding but also at health care facilities just after delivery. A study conducted in rural KwaZulu-Natal revealed that most women perceived the health care providers as pro-breastfeeding and when a new mother does not breastfeed, they ask why and because some women do not want their status known, they opt to breastfeed (Thairu et al., 2005). Similar findings were shown in a study conducted by Doherty et al. (2006), where health care workers had more power and influence over women who were undecided about which infant feeding method to use and because they had control over resources like formula milk.

2.1.5.4 Costs of Replacement Feeding

Although the current UNAIDS guidelines recommend avoidance of breastfeeding if replacement feeding meets the AFASS criteria, some HIV positive women, although counseled on replacement feeding as the best option to prevent MTCT, may not follow this advice because of high costs of the formula milk and fuel, poor access to clean water

and storage facilities may deter women from practising this form of feeding (Abiona, Onayade, Ijadunola, Obiajunwa, Aina & Thairu, 2010). Similar findings were shown in a study conducted in India, where infant formula feeding was identified as one of the least likely feeding methods because of the costs involved (Shankar, Sastry, Erande, Joshi, Suryawanshi, Phadke et al., 2005).

2.1.5.5 Knowledge of MTCT

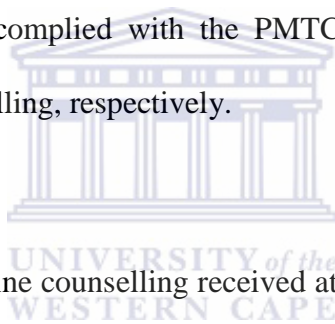
Results from a study conducted in Kenya showed that it is the mother's knowledge about MTCT that has an influence on the choice of alternative feeding but not on breastfeeding (Omwega, Oguta & Sehmi, 2006). In that study, women with high MTCT knowledge were more receptive to giving their infants expressed milk or milk from the milk bank rather than cow milk, a socially acceptable and easily available alternative. In an operations research study conducted in the Kilimanjaro area in Tanzania amongst HIV positive and HIV negative women in intervention and comparison groups, 16 (80%) out of 20 HIV positive women in the intervention group chose breastfeeding despite the fact that they knew the risks involved (Leshabari, Koniz-Booher, Burkhalter, Hoffman & Jennings, 2007c). Out of that 16, eight (50%) of them chose breastfeeding to hide their HIV status, four (25%) because they could not afford formula milk, and four (25%) because of the both reasons combined. Only three of the 20 (15%) HIV positive women in that study chose formula feeding to protect their infant from being infected with HIV. In South Africa, an evaluation of PMTCT and infant feeding conducted on health professionals showed that most health care providers overestimated the HIV transmission through breastfeeding and downplayed the risks associated with formula feeding, a cause

for concern since health care providers are a source of information for pregnant women and new mothers and are therefore expected to provide accurate information to ensure safe and appropriate infant feeding choices (Tint, Doherty, Nkonki, Witten & Chopra, 2003).

2.1.6 Peer counseling/support for infant feeding

HIV-positive women need education, counselling and support during pregnancy (Besser, 2002). According to Besser, education ensures adherence to the chosen feeding practices, while counselling and support ensure that the quality of life of these women is improved. HIV-positive mothers who have recently given birth may expect support from family, friends, partners and the health care system in making informed decisions about feeding and family planning but may not get such support (Besser, Ebdon, Engelbrecht, Ntshanga and Qolo, 2004). In such cases, peer support groups may act as a safe haven for such women to share their experiences, talk about HIV, and to learn from other infected individuals (Summers, Robinson, Zisook, Atkinson, McCutchan, Deutsch et al., 2000). Peer counselling has been proven to be a possible way of changing people's behaviours (Hutton, Wyss & N'Diekhor, 2003). A study conducted by Coovadia et al. (2007) showed that home visits by infant feeding counsellors and field monitors encouraged HIV positive women to choose appropriate and optimum feeding options. Although peer counseling has been found to increase the duration of breastfeeding, it does not increase exclusivity in populations who, traditionally, do not breastfeed (Merewood, Chamberlain, Phillip, Cook, Malone & Bauchner, 2005). Until recently, counselling on infant feeding has not been at the forefront of PMTCT programmes

resulting in misunderstanding of the risks involved in breastfeeding (Chopra, Doherty, Mehattru & Tomlinson, 2009). This was shown in a study conducted by the Human Sciences Research Council (HSRC) in the Kouga Local Service Area in the Eastern Cape Province in twenty PMTCT-providing sites where only 81.8% of the sites had infant feeding counselling guidelines and only 50.4% of health care workers in those facilities had been trained on infant feeding for the PMTCT programme (Peltzer, Phaswana-Mafuya, Ladzani, Davids, Mlambo, Phaweni, et al., 2009a). In a similar study conducted by the HSRC in 75 health facilities in Gert Sibande District in the Mpumalanga Province, only 26 facilities had the National guidelines on infant feeding (Peltzer et al., 2009b) and only 66 and 69 of the sites complied with the PMTCT guidelines on antenatal and postnatal infant feeding counselling, respectively.

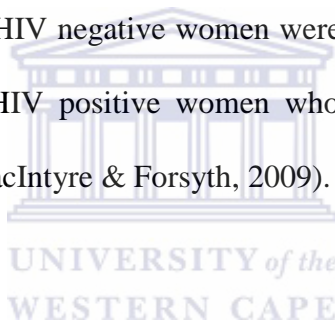


In some instances, despite routine counselling received at antenatal clinics during routine checkups, most HIV positive women may still be uncertain of the appropriate infant feeding method to use and pressure from family and friends may lead them to using infant feeding methods that may expose their babies to HIV infection (Leshabari et al., 2007).

2.1.7 Feeding practices amongst HIV positive and HIV negative women

A study conducted in Uganda showed that exclusive breastfeeding of infants below the age of six months was less common amongst HIV positive women (24%) compared to the general population of mothers (45%) and that solids were introduced to half of the

HIV positive mothers' infants compared to a quarter of the general population (Fadnes, Engebretsen, Wamani, Semiyaga, Tylleskär & Tumwine, 2009). The same study also showed that 27% of HIV positive mothers stopped breastfeeding their infants before they reached 12 months of age compared to 1% of the general population mothers. A different scenario was seen in Kenya where a high percentage of HIV positive women (67%) practised EBF compared to 47% of HIV negative women (Kaai, Baek, Geibel, McOdida, Benson, Muthumbi et al., 2005). It was also found that mixed feeding was a common infant feeding practice, with 50% of the HIV negative women reporting mix feeding their infants compared to 22% of HIV positive women. In South Africa, a study conducted in Tshwane showed that 94% of HIV negative women were breastfeeding their infants at 6 weeks compared to 69% of HIV positive women who were formula feeding (Matji, Wittenberg, Makin, Jeffery, MacIntyre & Forsyth, 2009).

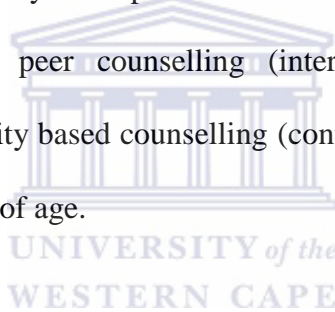


In a study conducted in rural Qaukeni District in the Eastern Cape by Peltzer, Mosala, Dana and Fomundam (2008), 41.2% of the HIV positive women chose to exclusively formula feed their babies while only 8% chose to exclusively breastfeed. On the contrary, a study conducted by Bland, Little, Coovadia, Coutsoodis, Rollins & Newell (2008) showed higher exclusive breastfeeding rates in HIV positive women compared to negative women contrary to studies conducted by Coutsoodis, Pillay, Spooner, Kuhn and Coovadia (1999) and Doherty, Chopra, Jackson, Goga, Colvin and Persson (2007). Bland et al (2008) attribute these higher rates of exclusive breastfeeding to visits made by lay counselors to pregnant women and new mothers up to six months after birth.

The current study was conducted to determine whether there were any differences in the feeding practices in women with strong support and counselling by community based counsellors compared to those women only exposed to the routine health facility provided counselling.

2.2 AIM

The study aims to describe the differences in infant feeding practices and adherence to chosen infant feeding practice by HIV positive and HIV negative mothers who have undergone community based peer counselling (intervention arm) versus mothers provided with only health facility based counselling (control arm) in practising exclusive feeding from birth to 24 weeks of age.



2.3 OBJECTIVES

Infant feeding practices

1. To compare infant feeding practices of all women, irrespective of their HIV status, who received peer support (intervention) and those who received standard infant feeding counselling (control) at 3, 6, 12 and 24 weeks.
2. To compare the infant feeding practices of HIV positive women in the intervention arm with those of HIV positive women in the control arm at 3, 6, 12 and 24 weeks after birth.

3. To compare the infant feeding practices of HIV negative women in the intervention arm with those of HIV negative women in the control arm at 3, 6, 12 and 24 weeks after birth.

Infant feeding intention and infant feeding practice

4. To determine adherence to chosen infant feeding options based on intention at recruitment among HIV negative women in the intervention and control arms.
5. To determine adherence to chosen infant feeding option based on intention at recruitment among HIV positive women in the intervention and control arms.

High and Low risk infant feeding in HIV-positive mothers

6. To determine the high and low risk infant feeding methods practised by HIV positive women in the intervention and control arms.

Disclosure and infant feeding intention and practice

7. To determine disclosure of HIV positive women's status and their infant feeding intention.
8. To determine the effect of disclosure on infant feeding method amongst HIV positive women at 3, 6, 12 and 24 weeks after birth.
9. To determine the effect of disclosure and the choice of high risk or low risk infant feeding method amongst HIV positive women at 3, 6, 12 & 24 weeks after birth.

CHAPTER 3

3.1 METHODOLOGY

This is a secondary analysis from a large multi-country cluster randomised trial examining the effect of peer support on exclusive breastfeeding. The multi-country study included sites in Burkina Faso, Uganda, Zambia and South Africa. HIV-positive women who intended to formula feed were excluded from enrolment in the other three countries. However in South Africa HIV-positive women regardless of feeding intention were included in the trial and were supported to exclusively breastfeed or replacement feed whichever they indicated as their selected feeding choice. The data on the HIV-positive mothers in the South African study is not being analysed as part of the multi-country study and will therefore distinguish this mini-thesis analysis and report from the primary PROMISE-EBF analyses. The study methods reflect the overall cluster randomised trial design. The data analysis section of this chapter reflects the work of the student.

3.1.1 Study design for the cluster randomised trial in South Africa

The South African component of the study was conducted in three sites, Paarl, Rietvlei and Umlazi, which were selected because of their different geographic settings and variation in their socio-economic indicators and health care infrastructure. Another advantage was that these areas already had an established research structure and their communities were familiar with the research team as a result of previous research work

conducted in those areas. Paarl is a well resourced peri-urban commercial farming area in the Western Cape with an average of 289 antenatal care (ANC) bookings per month, 9% ANC client HIV prevalence, and 40/1000 Infant mortality Rate (IMR). Rietvlei is one of the poorest rural areas in the Eastern Cape Province with 28% ANC client HIV prevalence and 99/1000 IMR. The hospital in this area has an ANC clinic that delivers approximately 170 women per month. Umlazi is a peri-urban area in Durban in the KwaZulu-Natal Province with a mixture of formal and informal settlements. It has, on average, 248 women who book for ANC per month, a 44% ANC clients HIV prevalence and 60/1000 IMR. For the purposes of this study, each site operated as a separate stratum for cluster selection and randomisation purposes. Census units in each site were delineated and the number of childbearing women, from the 2001 census data, was noted. Based on estimated local fertility rates to obtain approximately seven pregnant women per month, rational distinct geographic units containing 1500-3000 women of child bearing age were identified. Fourteen clusters were identified in Umlazi, 10 in Rietvlei and Paarl, respectively. The clusters were then randomised into intervention and control arms, i.e., 7 per arm in Umlazi and 5 per arm each in Rietvlei and Paarl, making a total of 17 clusters in the intervention arm and 17 clusters in the control arm (PROMISE-EBF Study Group, 2009).

Peer counsellors were then recruited. Selection criteria included women who had at least 12 years of schooling, who lived in the study area and had no intentions to move for at least three years, had similar backgrounds to other women in the community, spoke English and had a good reputation in the community, committed and interested in helping

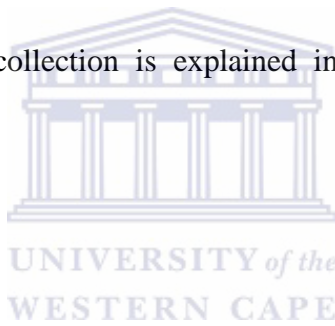
women feed their children appropriately. The peer counsellors were interviewed, given a proficiency of written English test and subjected to an observation of counselling skills during a role play. The peer counsellors were then trained over five days on infant feeding counselling and study specific activities (recruitment of women and completion of home visit forms). In the intervention clusters to support infant feeding and child health, the peer counsellors visited the women five times, i.e., once antenatally, 1 week post delivery, 4 weeks post delivery, 7 weeks post delivery and 10 weeks post delivery. In the control clusters the peer counsellors were trained to assist families to obtain birth certificates and child support grants and other social welfare grants using the same schedule as the infant feeding peer supporters. The control group counsellors did not discuss infant feeding so the control group only received standard infant feeding counselling as offered by the routine health services. The two groups of peer supporters were kept separate during the course of the study to avoid contamination of training and support (PROMISE-EBF Study group, 2009).

3.1.2 Sample

In the Umlazi and Paarl sites, women were identified using a census approach, in which every house was visited starting from the peer counsellor's house. Pregnant women in their last trimester or if they were early on their pregnancy and scheduled for a repeat visit were immediately recruited. In the Rietvlei site, pregnant women were identified through a snowballing approach through word of mouth, informal meetings in the streets and recruitment from the ANC clinics. As participation in the study was not dependent on participation in the peer intervention, women who agreed to peer support were

included in the intervention but those who refused peer support were still approached for data collection, but only after obtaining their informed consent. The procedure followed to get the sample for peer support is explained in Appendix 1 (PROMISE-EBF Study group, 2009).

In each cluster, all pregnant women or those who delivered babies in each month were eligible and approached for peer support. These women formed the sample list from which women were selected for data collection. Three to four women were then selected per cluster per month for data collection with 1 – 2 backups in case of refusals. The selection procedure for data collection is explained in Appendix 2 (PROMISE-EBF Study group, 2009).



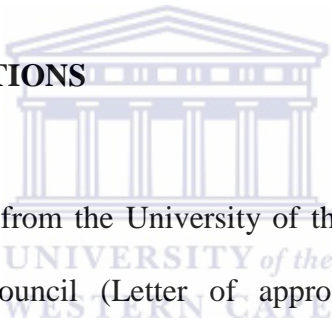
3.1.3 Data Collection Method

At each site, the interviewers were trained in data collection and questionnaires were piloted. Data collection was scheduled in the following manner:

1. Recruitment interview when the mother is not less than 7 months pregnant
2. Interview when the infant is 3 weeks old
3. Interview when the infant is 6 weeks old
4. Interview when the infant is 12 weeks old
5. Interview when the infant is 24 weeks old

The questionnaires were conducted during pregnancy (around seven months), 3, 6, 12 and 24 weeks after delivery. All mothers were interviewed at recruitment to establish eligibility and to obtain informed consent and data on socio-economic status. Further data collection visits were scheduled for 3, 6, 12 and 24 weeks after birth, where feeding patterns were determined. A separate team of data collectors not involved in counselling mothers was used so as to separate the intervention from data collection. Data collectors were also kept blind as to which were the intervention or control clusters (PROMISE-EBF Study group, 2009).

3.2 ETHICAL CONSIDERATIONS



Ethical approval was obtained from the University of the Western Cape and the South African Medical Research Council (Letter of approval attached – Note title of PROMISE-EBF in South Africa was “Good Start Community-Based Infant Feeding Intervention Study” to align with local research group name). Verbal informed consent to participate in the peer support programme was obtained while written informed consent was obtained for participation in data collection. The Standard Operating Procedure for informed consent is explained in Appendix 3.

3.3 DATA MANAGEMENT

Paper based data collection tools were used. Data collectors who had worked previously at the three sites in a PMTCT of HIV cohort study during 2002 – 2005 were trained. An

additional 1 – 2 data collectors with a Matric pass (Grade 12) were recruited. The data entry team comprised of data capturers and a data manager at a central centre (MRC Durban), with Epidata used as the data entry platform. At each site, quality control of data collection was done on a daily basis by the Data Collection Supervisor (DCS). The DCS, together with the Data Quality Manager (DQM), were responsible for data cleaning. Quality Control (QC) reports were generated by MRC Biostatistics Unit and were reviewed by the DQM. Copies of the QC reports were sent to DCS in each site to address any queries picked up. The corrected data and CRFs were then sent to the Biostatistics unit for recapturing. The corrections were documented on the original forms and kept in locked cabinets at the site and in the logs kept at the central unit (PROMISE-EBF Study group, 2009).



3.4 DATA ANALYSIS

For this sub study analysis was done on four groups:

- i) HIV positive mothers who received infant feeding peer support -
(Intervention)
- ii) HIV positive mothers who did not receive infant feeding peer support -
(Control)
- iii) HIV negative mothers who received infant feeding peer support -
(Intervention)
- iv) HIV negative mothers who did not receive infant feeding peer support -
(Control)

The data was adjusted for clustering and analysed using SAS, with a focus on outcomes from the 3, 6, 12 and 24 weeks visits. Comparison of variables between the intervention and control groups within sites was done. Comparisons amongst the infant feeding practices followed will be determined according to recognised WHO categories: exclusive breastfeeding, predominant breastfeeding, mixed feeding and replacement feeding (WHO, 1991). Also, analysis was done to determine the impact peer counselling had on adherence to feeding methods amongst intervention and control mothers.

The data was analysed either adjusted by cluster and strata (site) or analysed without being adjusted. In the case of data analysed unadjusted, three scenarios emerged as a result of the small numbers in the cells:

- i) The Chi square p-value was used where there was no warning of 38% of cells having expected counts less than 5. For purposes of clarity, this p-value will be depicted by one star (*).
- ii) In cases where such a warning was given that some cells have an expected count less than 5, the Fischer's Exact p-value was then used. This p-value will be shown by two stars (**).
- iii) In cases where the Fischer's Exact could not be run, the Monte Carlo Estimate for the Exact Test was used. This p-value will be shown by three stars (***)

In the case of the cluster adjusted data, the Rao-Scott p-value was used. This p-value will be shown by four stars (****).

3.5 VALIDITY, RELIABILITY & LIMITATIONS

The likelihood of selection bias was addressed by randomisation of participants into intervention arm and control arm. Also, the peer supporters were not aware of the participants' HIV status. Randomisation of clusters should reduce confounding due to baseline differences. A low percentage (20%) of participants was lost to follow up due to them moving away from the study areas. Information bias emanating from the participants' infant feeding recall was given extra attention, literature was reviewed and precise definitions on what 24 hour recall and 1 week recall entail were defined. A separate team of data collectors who were not involved in counselling mothers collected the data.



3.6 CONTRIBUTION OF THE STUDENT

As the PROMISE-EBF study was conducted in four countries, i.e., Burkina Faso, Uganda, Zambia and South Africa, I only analysed the data that was specific to South Africa. The data analysis included HIV positive women and their babies who are otherwise excluded from the multi-country analysis. I created variables to define my exposure groups in my analysis and also to define a four category feeding outcome, instead of the two category outcome that has been used by PROMISE-EBF, i.e., Exclusive Breastfeeding and not Exclusive Breastfeeding. I performed analytic data analyses to determine whether, by being part of a peer support group, HIV positive and HIV negative mothers are more able to adhere to exclusive infant feeding. The work

generated from this mini thesis will be submitted for publication in a peer-reviewed scientific journal.



CHAPTER 4

4.1 RESULTS

4.1.1 Study profile

A total of 1276 women were recruited into the study although 139 of them were only seen at recruitment, resulting in 1137 women being the final sample (Table 1a). The total number of women lost to follow up was 186 women, which resulted in 951 as the final number of women who were in the study until the end. Loss to follow up excludes deaths which is a study outcome. The women were scheduled to be visited for data collection at 3, 6, 12 and 24 weeks after birth but in cases where women were visited earlier or later than the stipulated visit time, that resulted in the visit being Out of Range (OOR). In this sub study the outcome is infant feeding practices, therefore it is important to know at what infant age a mother practised a certain feeding option and that is why the OOR data is important. Infants whose mothers moved around with them and could only be reached later when they came back to the study site contributed to the OOR data as well as infants visited after the age of 3 weeks for the first time after birth. At week 3, 191 women were out of range, 114 at Week 6, 36 at Week 12 and 169 at Week 24. The final sample at 24 weeks, after removing the OOR from the initial sample (1276) was 782.

Table 1a: Study profile of all women who were recruited into the study

SOUTH AFRICA					
	Recruitment	3	6	12	24
all vis	745	745	745	745	745
R	139				
R,3	27	27			
R,3,6	50	50	50		
R,3,6,12	78	78	78	78	
R,6	4		4		
R,12	5			5	
R,24	4				4
R,3,12	18	18		18	
R,3,24	15	15			15
R,6,12	4		4	4	
R,6,24	0	0	0	0	0
R,12,24	7			7	7
R,3,6,24	59	59	59		59
R,3,12,24	103	103		103	103
R,6,12,24	18		18	18	18
Total	1276	1095	958	978	951
Out of range visits	0	191	114	36	169
sample removing OOR	1276	904	844	942	782

In the control group, a total of 608 women were recruited into the study with 70 of them only seen at recruitment, resulting in 538 as the final sample (Table 1b). Due to loss to follow up, 89 women were lost resulting in 449 as the number of women who were in the study from recruitment to week 24. When the OOR data was removed, the final sample was 361.

Table 1b: Study profile of women recruited into the control group

SOUTH AFRICA - CONTROL					
	Recruitment	3	6	12	24
all vis	351	351	351	351	351
R	70				
R,3	11	11			
R,3,6	26	26	26		
R,3,6,12	39	39	39	39	
R,6	2		2		
R,12	2			2	
R,24	3				3
R,3,12	8	8		8	
R,3,24	6	6			6
R,6,12	3		3	3	
R,6,24	0	0	0	0	0
R,12,24	6			6	6
R,3,6,24	27	27	27		27
R,3,12,24	45	45		45	45
R,6,12,24	9		9	9	9
Total	608	513	457	463	447
Out of range visits	0	93	63	18	86
sample removing OOR	608	420	394	445	361

UNIVERSITY of the
WESTERN CAPE

In the intervention group, a total of 668 women were recruited into the study with 69 of them only seen at recruitment, leaving 599 women in the final sample (Table 1c). As a result of loss to follow up, 93 women were lost resulting in 506 women left as the final number of women who were in the study from recruitment to the end. After excluding OOR 421 remained in sample for this analysis.

Table 1c: Study profile of women recruited into the intervention group

SOUTH AFRICA - INTERVENTION					
	Recruitment	3	6	12	24
all vis	394	394	394	394	394
R	69				
R,3	16	16			
R,3,6	24	24	24		
R,3,6,12	39	39	39	39	
R,6	2		2		
R,12	3			3	
R,24	1				1
R,3,12	10	10		10	
R,3,24	9	9			9
R,6,12	1		1	1	
R,6,24	0	0	0	0	0
R,12,24	1			1	1
R,3,6,24	32	32	32		32
R,3,12,24	58	58		58	58
R,6,12,24	9		9	9	9
Total	668	582	501	515	504
Out of range visits	0	99	51	18	83
sample removing OOR	668	483	450	497	421

4.1.2 Infant feeding practices

South African results from the main Promise EBF study show that EBF rates were higher in the intervention group than in the control group, both at 12 weeks and at 24 weeks.

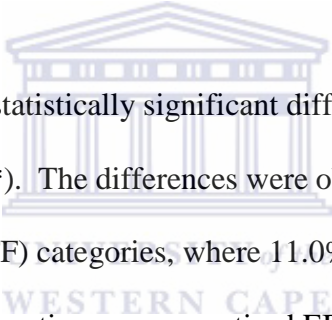
Despite the small numbers, these differences were statistically significant (Table 2).

Table 2: Outcomes on Exclusive Breastfeeding (EBF) at 12 and 24 weeks

	Intervention n (%)	Control
EBF outcomes at 12 weeks (n)	517	466
	57 (11%)	31 (7%)
EBF outcomes at 24 weeks	458	410
	12 (3%)	3 (0%)

4.1.2.1 Type of counselling and infant feeding method chosen

For this study, the overall infant feeding practices of all women in the three sites are shown in Table 3. The p-value (0.0412*) shows that there is a statistically significant difference between women in the control and intervention groups with regard to the four feeding practices. The most relative difference is seen in the Exclusive Breast Feeding (EBF) category (n=118), where 20.5% (n=77) of women in the intervention group were practising this form of infant feeding compared to 12.8% (n=41) in the control group at the 3 week visit after birth. In the other feeding categories, the results between the intervention and control groups showed no substantial difference.



At Week 6, the results show a statistically significant difference between the intervention and control groups ($p = 0.0077^*$). The differences were observed in the EBF and Exclusive Formula Feeding (EFF) categories, where 11.0% of women in the control group versus 18.1% in the intervention group practised EBF while in the EFF category, 45.4% of women in the control versus 36.2% in the intervention group practised this form of infant feeding.

The results at Week 12 show a statistically significant difference between the intervention and control groups ($p = 0.0241^*$). The differences are again observed in the EBF and EFF categories, where in the EBF category, 6.7% of women in the control group practised this form of feeding compared to 11.6% in the intervention group while in the EFF category, 53.9% of women in the control group versus 47.9% in the intervention group practised this form of feeding.

At Week 24, the results show a statistically significant difference between the intervention and control groups ($p = 0.0338^*$). The difference is seen in the Mixed Feeding (MF) and EFF categories, where in the MF category, 37.9% of women in the control group practised this form of feeding compared to 42.1% in the intervention group while in the EFF category 59.2% of women in the control group practised this form of feeding versus 52.9% in the intervention group. There is also a difference in EBF with 3.1% in the intervention and only 0.6% in the control, however this level of EBF is extremely low in both groups.

Table 3: Infant feeding outcomes at 3, 6, 12 & 24 weeks amongst all women receiving peer support (intervention) and those receiving standard ANC counselling (control)

	Exclusive Breastfeeding n (%)	Predominant Breastfeeding n (%)	Mixed Feeding n (%)	Exclusive Formula Feeding n (%)	TOTAL n (%)
Outcomes at 3 weeks					
Intervention	77 (20.5%)	81 (21.5%)	85 (22.6%)	133 (35.4%)	376 (53.9%)
Control	41 (12.8%)	82 (25.6%)	70 (21.8%)	128 (39.9%)	321 (46.1%)
TOTAL	118 (16.9%)	163 (23.4%)	155 (22.2%)	261 (37.5%)	697 (100%)
Outcomes at 6 weeks					
Intervention	81 (18.1%)	101 (22.5%)	104 (23.2%)	162 (36.2%)	448 (53.5%)
Control	43 (11.0%)	79 (20.3%)	91 (23.3%)	177 (45.4%)	390 (46.5%)
TOTAL	124 (14.8%)	180 (21.5%)	195 (23.3%)	339 (40.5%)	838 (100%)
Outcomes at 12 weeks					
Intervention	56 (11.6%)	50 (10.3%)	146	232 (47.9%)	484

			(30.2%)		(52.8%)
Control	29 (6.7%)	33 (7.6%)	137 (31.7%)	233 (53.9%)	432 (47.2%)
TOTAL	85 (9.3%)	83 (9.1%)	283 (30.9%)	465 (50.8%)	916 (100%)
Outcomes at 24 weeks					
Intervention	13 (3.1%)	8 (1.9%)	175 (42.1%)	220 (52.9%)	416 (54.1%)
Control	2 (0.6%)	8 (2.3%)	134 (37.9%)	209 (59.2%)	353 (45.9%)
TOTAL	15 (1.9%)	16 (2.1%)	309 (40.2%)	429 (55.8%)	769 (100%)

Table 4 and Figures 1(a) and 1(b) show the infant feeding outcomes at 3, 6, 12 and 24 weeks after birth amongst HIV positive women. The results from the 3 week interview show no statistically significant difference between women in the intervention and control groups ($p = 0.7416^{**}$) regarding the infant feeding methods they were practising. Although there was no statistically significant difference shown, a relative difference was shown in the exclusive breast feeding (EBF) category, where 6.9% of women in the intervention group were practising this form of infant feeding compared to 12.2% in the control group.

The results from week 6 also show no statistically significant difference ($p = 0.4814^*$) between the intervention and control groups. Relative differences were seen with intervention subjects having slightly higher EBF and Mixed feeding and control subjects showing slightly higher Predominant breastfeeding and EFF.

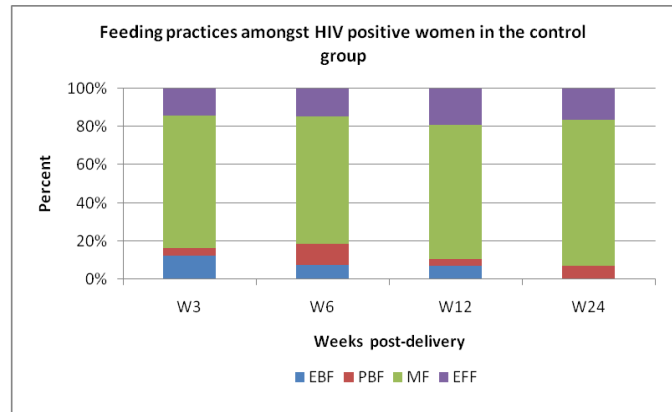
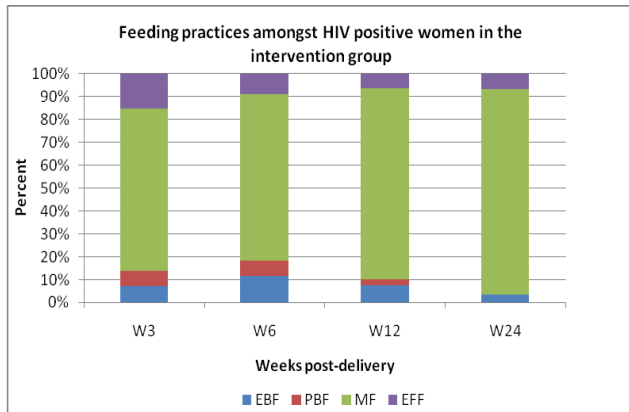
In the 12 week results, there was a non significant difference was shown between the intervention and control groups ($p = 0.1253^{**}$). A relative difference was shown in the MF and EFF categories, where a considerably higher proportion of women in the intervention group in the MF category were practising this form of feeding (83.8% compared to 70.7% in the control group). In the EFF category, 6.3% of women in the intervention group practised this form of feeding compared to 18.9% in the control group.

The 24 week results did show a statistically significant difference between the intervention and control groups ($p = 0.0229^{**}$). Big differences were again observed in the MF and EFF categories, where in the MF category, a higher percentage of women in the intervention group (90.2%) practised this form of feeding compared to the control (76.7%) group. In the EFF category, a lower percentage in the intervention group (6.6%) practised this form of feeding compared to 16.3% in the control group. There were also slightly higher rates of EBF in the intervention and slightly higher rates of Predominant breastfeeding in the control, similar to the pattern at 6 weeks.

At all weeks, the most common form of infant feeding amongst HIV positive women was mixed feeding, regardless of whether the women were in the intervention or control group.

Table 4: Infant feeding outcomes for HIV positive women at 3, 6, 12 & 24 weeks

	Exclusive Breastfeeding n (%)	Predominant Breastfeeding n (%)	Mixed Feeding n (%)	Exclusive Formula Feeding n (%)	TOTAL n (%)
Outcomes at 3 weeks					
Intervention	5 (6.9%)	5 (6.9%)	52 (71.2%)	11 (15.1%)	73 (59.8%)
Control	6 (12.2%)	2 (4.1%)	34 (69.4%)	7 (14.3%)	49 (40.2%)
TOTAL	11 (9.0%)	7 (5.7%)	86 (70.5%)	18 (14.8%)	122 (100%)
Outcomes at 6 weeks					
Intervention	9 (11.7%)	5 (6.5%)	56 (72.7%)	7 (9.1%)	77 (58.8%)
Control	4 (7.4%)	6 (11.1%)	36 (66.7%)	8 (14.8%)	54 (41.2%)
TOTAL	13 (9.9%)	11 (8.4%)	92 (70.2%)	15 (11.5%)	131 (100%)
Outcomes at 12 weeks					
Intervention	6 (7.5%)	2 (2.5%)	67 (83.8%)	5 (6.3%)	80 (57.9%)
Control	4 (6.9%)	2 (3.5%)	41 (70.7%)	11 (18.9%)	58 (42.0%)
TOTAL	10 (7.3%)	4 (2.9%)	108 (78.3%)	16 (11.6%)	138 (100%)
Outcomes at 24 weeks					
Intervention	2 (3.3%)	0 (0.0%)	55 (90.2%)	4 (6.6%)	61 (58.7%)
Control	0 (0.0%)	3 (6.9%)	33 (76.7%)	7 (16.3%)	43 (41.4%)
TOTAL	2 (1.9%)	3 (2.9%)	88 (84.6%)	11 (10.6%)	104 (100%)



Figures 1(a) and 1(b): Feeding practices amongst HIV positive women in the intervention and control groups, respectively

Table 5 and Figures 2(a) and 2(b) show the feeding outcomes of HIV negative women at 3, 6, 12 and 24 weeks after birth. The results from week 3 show a statistically significant difference between the intervention and control groups ($p = 0.0098^*$). A difference is shown in the EBF feeding group, where 12.9% of women in the control group practised this form of feeding compared to 23.8% in the intervention group.

At week 6, a statistically significant difference in EBF and EFF rates between study arms can be seen ($p = 0.0064^*$) with 11.6% of women in the control group practising EBF compared to 19.4% in the intervention group. The relatively high percentages of women practising EFF in both the control (50.3%) and intervention (41.8%) groups remained, as was observed in week 3.

Table 5: Infant feeding outcomes for HIV negative women at 3, 6, 12 & 24 weeks

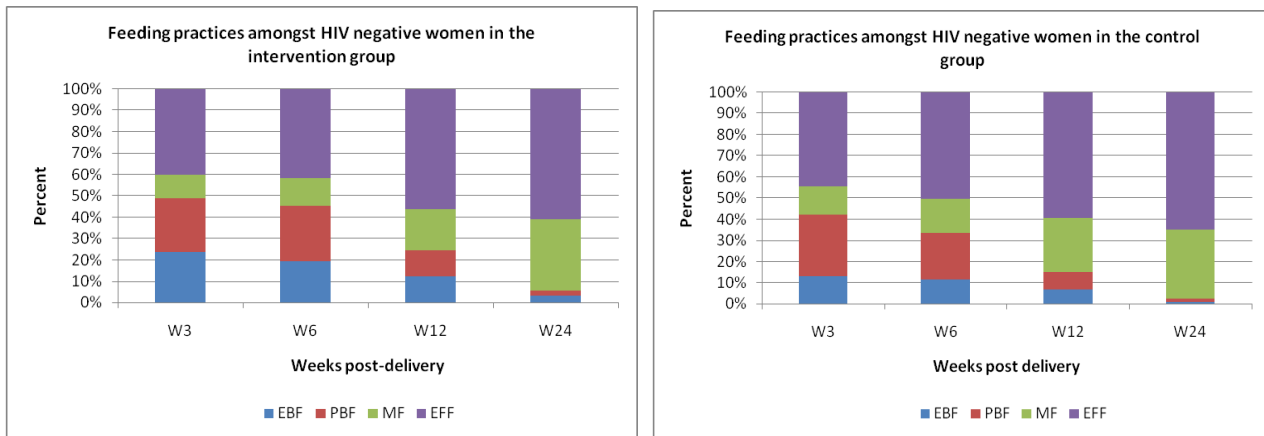
	Exclusive Breastfeeding n (%)	Predominant Breastfeeding n (%)	Mixed Feeding n (%)	Exclusive Formula Feeding n (%)	TOTAL n (%)
Outcomes at 3 weeks					
Intervention	72 (23.8%)	76 (25.1%)	33 (10.9%)	122 (40.3%)	303 (52.7%)
Control	35 (12.9%)	80 (29.4%)	36 (13.2%)	121 (44.5%)	272 (47.3%)
TOTAL	107 (18.6%)	156 (27.1%)	69 (12.0%)	243 (42.3%)	575 (100%)
Outcomes at 6 weeks					
Intervention	72 (19.4%)	96 (25.9%)	48 (12.9%)	155 (41.8%)	371 (52.5%)
Control	39 (11.6%)	73 (21.7%)	55 (16.4%)	169 (50.3%)	336 (47.5%)
TOTAL	111 (15.7%)	169 (23.9%)	103 (14.6%)	324 (45.8%)	707 (100%)
Outcomes at 12 weeks					
Intervention	50 (12.4%)	48 (11.9%)	79 (19.6%)	227 (56.2%)	404 (51.9%)
Control	25 (6.7%)	31 (8.3%)	96 (25.7%)	222 (59.4%)	374 (48.1%)
TOTAL	75 (9.6%)	79 (10.2%)	175 (22.5%)	449 (57.7%)	778 (100%)
Outcomes at 24 weeks					
Intervention	11 (3.1%)	8 (2.3%)	120 (33.8%)	216 (60.9%)	355 (53.4%)
Control	2 (0.7%)	5 (1.6%)	101 (32.6%)	202 (65.2%)	310 (46.6%)
TOTAL	13 (1.9%)	13 (1.9%)	221 (33.2%)	418 (62.9%)	665 (100%)

The week 12 results show a statistically significant difference between the intervention and control groups ($p = 0.0057^*$). In the EBF category, a higher percentage of women in

the intervention group (12.4%) compared to 6.7% in the control group practised this form of feeding. In the MF category, it was more women in the control group (25.7%) than in the intervention group (19.6%) who practised this form of feeding. Again, EFF seems to be the preferred form of feeding, with 59.4% of women in the control group and 56.2% in the intervention group practising this form of feeding.

At 24 weeks there was no significant difference observed ($p = 0.1112^*$). A relatively small difference was observed in the EFF category, where 60.9% of the women in the intervention group practised this form of infant feeding compared to 65.2% in the control group.

Figures 2(a) and 2(b) below clearly show EFF as the most preferred infant feeding method by HIV negative women in both the intervention and control groups.



Figures 2(a) and 2(b): Feeding practices amongst HIV negative women in the intervention and control groups, respectively

4.1.2.2 Intention to feed at recruitment versus chosen or practised feeding plan

HIV negative women or of unknown status

At recruitment, women were asked how they intended to feed their infants and Table 6 shows the infant feeding method HIV negative women or those of unknown status intended to use versus the feeding method that they ultimately practiced. Only results from Week 3 are looked at since the women are not likely to go back to practising EBF once they have started on EFF or MF.

In the control group, the results of HIV negative or unknown status women on their intention to feed and the feeding practices they actually engaged in show a statistically significant difference amongst feeding practices ($p = 0.000^{***}$). For women who had intended to practise EBF at recruitment, at week 3, only 17.7% actually followed through with it, 40.3% practised PBF while 37.8% practised EFF. A low percentage (4.2%) of these women practised MF. For those who had intended to practise MF and complimentary feeding (CF) at recruitment, only 4.9% followed through with it while a higher proportion of women (58.3%) practised EFF versus 11.7% who practised EBF.

For the women who had intended on practising EFF, 20.6% followed through with this form of feeding, 2.9% practised EBF while a large proportion (64.7%) practised MF. For women who did not know what their infant feeding intentions were at recruitment, 50.0% practised MF while 25.0% of them practised EBF and EFF, respectively. Overall, very few HIV negative women practised MF during this period in the control group.

Table 6: Adherence of HIV negative women to the infant feeding method chosen at recruitment when visited at 3 weeks after birth in the intervention and control groups

Intention to feed at recruitment	Exclusive breastfeeding n (%)	Predominant breastfeeding n (%)	Mixed Feeding n (%)	Exclusive formula feeding n (%)	TOTAL n (%)
At 3 weeks					
Control					
EBF	21 (17.7%)	48 (40.3%)	5 (4.2%)	45 (37.8%)	119 (45.8%)
MF & CF	12 (11.7%)	26 (25.2%)	5 (4.9%)	60 (58.3%)	103 (39.6%)
EFF	1 (2.9%)	4 (11.8%)	22 (64.7%)	7 (20.6%)	34 (13.1%)
Do not know yet	1 (25.0%)	0 (0.0%)	2 (50.0%)	1 (25.0%)	4 (1.5%)
TOTAL	35 (13.5%)	78 (30.0%)	34 (13.1%)	113 (43.5%)	260 (100%)
Intervention					
EBF	50 (32.7%)	46 (30.1%)	8 (5.2%)	49 (32.0%)	153 (52.8%)
MF & CF	15 (14.9%)	24 (23.8%)	7 (6.9%)	55 (54.5%)	101 (34.8%)
EFF	2 (6.7%)	4 (13.3%)	16 (53.3%)	8 (26.7%)	30 (10.3%)
Do not know yet	2 (33.3%)	0 (0.0%)	1 (16.7%)	3 (50.0%)	6 (2.1%)
TOTAL	69 (23.8%)	74 (25.5%)	32 (11.0%)	115 (39.7%)	290 (100%)

In the intervention group, a statistically significant difference in the feeding practices that the HIV negative or unknown status women actually chose was shown ($p = 0.000^{***}$).


For women who had intended to practise EBF at recruitment, 32.7% actually practised this form of feeding, 32.0% practised EFF while only 5.2% practised MF. For women who had intended to practise MF & CF, only 6.9% of the women followed through compared to 54.5% who practised EFF and 14.9% who practised EBF. For the women

who had intended on practising EFF, 26.7% of them practised this form of feeding during this period compared to 53.3% who practised MF and 6.7% who practised EBF.

Regarding the women who, at recruitment, did not know which feeding method they were going to use, half of them (50%) practised EFF, 33.3% practised EBF and 16.7% of them practised MF. Overall, MF and EFF seem to be the commonly practised infant feeding methods.

Table 7 shows the infant feeding method HIV positive women intended to use versus the feeding method that they actually practised after birth. The numbers of the HIV positive women in the study was very small.

HIV positive women



In the control group, the differences in the feeding methods the HIV positive women chose were statistically significant ($p = 0.000***$). For HIV positive women who had intended to practise EBF at recruitment, 33.3% actually practised this form of feeding. Also, 44.4% of the women in this group practised EFF while 11.1% practised PBF and MF, respectively. For the women who had intended to practise MF and CF, half of them (50.0%) practised EBF while the other half practised EFF. A comparison of women who had intended to practise EFF at recruitment showed that only 5.3% of them actually practised EFF. In this EFF-intended group, as high as 86.8% of HIV positive women practised MF.

In the intervention group, there was a statistically significant difference in the feeding methods chosen by the HIV positive women ($p = 0.000^{**}$). For HIV positive women who had intended to practise EBF at recruitment, 20.0% of them actually practised this form of feeding during Week 3 compared to 26.7% who practised MF and 33.3% who practised EFF. For the HIV positive women who had intended to practise MF and CF at recruitment, all of them (100%) chose to practise EFF. For those who had intended to practise EFF at recruitment, 3.9% practised this form of feeding while 90.4% practised MF.

Table 7: Adherence of HIV positive women to the infant feeding method chosen at recruitment during visits at 3, 6, 12 & 24 weeks after birth in the intervention and control groups

Intention to feed at recruitment	Exclusive breastfeeding n (%)	Predominant breastfeeding n (%)	Mixed Feeding n (%)	Exclusive formula feeding n (%)	TOTAL n (%)
At 3 weeks					
Control					
EBF	3 (33.3%)	1 (11.1%)	1 (11.1%)	4 (44.4%)	9 (18.4%)
MF & CF	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (50%)	2 (4.1%)
EFF	2 (5.3%)	1 (2.6%)	33 (86.8%)	2 (5.3%)	38 (77.6%)
TOTAL	6 (12.2%)	2 (4.1%)	34 (69.4%)	7 (14.3%)	49 (100%)
Intervention					
EBF	3 (20.0%)	3 (20.0%)	4 (26.7%)	5 (33.3%)	15 (21.1%)
MF & CF	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (100%)	4 (5.6%)
EFF	2 (3.9%)	1 (1.9%)	47 (90.4%)	2 (3.9%)	52 (73.2%)
TOTAL	5 (7.0%)	4 (5.6%)	51 (71.8%)	11 (15.5%)	100%

4.1.2.3 Infant feeding methods regarded as high risk for HIV transmission

The percentages of HIV positive women who practised feeding methods regarded as high risk (MF) for transmission of HIV from the mother to the infant and those practising low risk feeding methods with regards to HIV transmission (EBF, PBF and EFF) in both the intervention and control groups were examined (Table 8).

Week 3

The results of HIV positive women practising high risk infant feeding method and those practising low risk infant feeding method in both the intervention and control groups showed no statistically significant differences between the two groups ($p = 0.8266$ *). Although there was no statistical significant difference between the two groups, high percentages of women in both groups practised the high risk infant feeding method, 69.4% in the control group and 71.2% in the intervention group. Since these women practised MF from the onset, a high risk infant feeding method, chances of them changing to a safer feeding method in the future were highly unlikely, as shown in Table 8.

Table 8: High and low risk infant feeding methods in the intervention and control groups

	HIGH RISK n (%)	LOW RISK n (%)	TOTAL n (%)
Week 3			
Control	34 (69.4%)	15 (30.6%)	49 (40.2%)
Intervention	52 (71.2%)	21 (28.8%)	73 (59.8%)
TOTAL	86 (70.5%)	36 (29.5%)	122 (100%)
Week 6			
Control	36 (66.7%)	18 (33.3%)	54 (41.2%)
Intervention	56 (72.7%)	21 (27.3%)	77 (58.8%)
TOTAL	92 (70.2%)	39 (29.8%)	131 (100%)
Week 12			
Control	41 (70.7%)	17 (29.3%)	58 (42.0%)
Intervention	67 (83.8%)	13 (16.3%)	80 (57.9%)
TOTAL	108 (78.3%)	30 (21.7%)	138 (100%)
Week 24			
Control	33 (76.7%)	10 (23.3%)	43 (41.4%)
Intervention	55 (90.2%)	6 (9.8%)	61 (58.7%)
TOTAL	88 (84.6%)	16 (15.4%)	104 (100%)

UNIVERSITY of the
WESTERN CAPE

4.1.2.4 Disclosure of women's HIV positive status and their infant feeding plans at recruitment

The possibility that the women's knowledge and disclosure of their HIV status had an effect on them choosing a certain form of infant feeding was examined. A statistically significant difference in the women's status and their choice of infant feeding method was observed ($p = 0.0199^{****}$). Table 9 shows the infant feeding choices the HIV positive women who either had disclosed or did not disclose their HIV status had, at recruitment, had made.

More than half of the HIV positive women consulted at recruitment who had disclosed their status (54.7%) had planned on practising MF compared to 16.0% who had not disclosed. Regarding EBF, 14.4% of women who had disclosed their status had planned on using this form of infant feeding compared to 5.5% who had not disclosed.

Table 9: Women's disclosure of their HIV status and their planned infant feeding choices at recruitment

DISCLOSED	EBF	PBF	MF	EFF	TOTAL
Yes	26 (19.6%)	8 (6.0%)	99 (74.4%)	0 (0.0%)	133 (73.5%)
No	10 (20.8%)	9 (18.8%)	29 (60.4%)	0 (0.0%)	48 (26.5%)



4.1.2.5 HIV disclosure and infant feeding practices

The effect of disclosure or non-disclosure of the women's HIV status on their actual infant feeding method was also examined.

The results of women who disclosed their HIV status and those who did not disclose show a significant difference on the feeding practices that they actually practised ($p = 0.0046^{**}$). For the women who practised EBF, only 8.6% had disclosed their status while 11.5% had not. Very low percentages of women who practised PBF (2.2%) had disclosed their HIV status compared to 19.2% who had not disclosed. On the other hand, a high percentage of women who practised MF in the disclosed group (77.4%) was observed. In the EFF category, 11.8% of the women who practised this form of feeding had disclosed their status while 4.2% had not. Overall, the majority of women practised

MF, irrespective of their HIV disclosure. The same trend was observed for Week 6, 12 and 24 (Table 10).

Table 10: HIV disclosure and infant feeding methods

Disclosed their HIV status to at least one person	Exclusive breastfeeding n (%)	Predominant breastfeeding n (%)	Mixed Feeding n (%)	Exclusive formula feeding n (%)	TOTAL n (%)
Week 3					
Yes	8 (8.6%)	2 (2.2%)	72 (77.4%)	11 (11.8%)	93 (78.2%)
No	3 (11.5%)	5 (19.2%)	13 (50.0%)	5 (19.2%)	26 (21.8%)
TOTAL	11 (9.2%)	7 (5.9%)	85 (71.4%)	16 (13.5%)	119 (100%)
Week 6					
Yes	6 (6.6%)	7 (7.7%)	70 (76.9%)	8 (8.8%)	91 (72.2%)
No	6 (17.1%)	2 (5.7%)	20 (57.1%)	7 (20.0%)	35 (27.8%)
TOTAL	12 (9.5%)	9 (7.1%)	90 (71.4%)	15 (11.9%)	126 (100%)
Week 12					
Yes	8 (7.6%)	3 (2.8%)	87 (82.1%)	8 (7.6%)	106 (78.5%)
No	2 (6.9%)	1 (3.5%)	19 (65.5%)	7 (24.1%)	29 (21.5%)
TOTAL	10 (7.4%)	4 (2.9%)	106 (78.5%)	15 (11.1%)	135 (100%)
Week 24					
Yes	2 (2.4%)	(2.4%)	75 (88.2%)	6 (7.1%)	85 (83.3%)
No	0 (0.0%)	0 (0.0%)	13 (76.5%)	4 (23.5%)	17 (16.7%)
TOTAL	2 (1.9%)	2 (1.9%)	88 (86.3%)	10 (9.8%)	102 (100%)

4.1.2.6 Disclosure of women's HIV positive status and their choice of high or low risk infant feeding methods

The disclosure or non-disclosure of the HIV positive women's status and the choice of high or low risk infant feeding method as a result was looked at (Table 11). A statistically significant difference was observed in the risk levels of the feeding practices

of women who had disclosed their HIV status and those who had not disclosed ($p = 0.0062^*$). At Week 3, 77.4% of the HIV positive women who chose an infant feeding method that could put their babies at high risk of HIV infection had disclosed their HIV status compared to 50% who had not disclosed. At Week 6, the difference on risk levels of infant feeding practised by women who had disclosed and those who had not remained statistically significant ($p = 0.0277^*$). Amongst the women who had disclosed their status, 76.9% of them practised high risk feeding compared to 57.1% who had not disclosed. At Week 12, a borderline difference amongst women who had disclosed their HIV status versus those who had not regarding risk levels of feeding methods used was observed ($p = 0.0544^*$). There was an increase in women who practised high risk infant feeding, with 82.1% of the women who had disclosed their HIV status and 65.5% who had not disclosed their HIV status practising high risk infant feeding methods. At Week 24, no statistical significant difference was observed ($p = 0.2438^{**}$). An increase in high risk feeders was observed, with 88.2% of those who had disclosed their status compared to 76.5% who had not disclosed practising high risk infant feeding methods.

Table 11: Disclosure of HIV status and choice of high or low risk infant feeding method

HIV status disclosed to at least one person	HIGH RISK n (%)	LOW RISK n (%)	TOTAL n (%)
Week 3			
Yes	72 (77.4%)	21 (22.6%)	93 (78.2%)
No	13 (50.0%)	13 (50.0%)	26 (21.9%)
TOTAL	85 (71.4%)	34 (28.6%)	119 (100%)
Week 6			
Yes	70 (76.9%)	21 (23.1%)	91 (72.2%)
No	20 (57.1%)	15 (42.9%)	35 (27.8%)
TOTAL	90 (71.4%)	36 (28.6%)	126 (100%)
Week 12			
Yes	87 (82.1%)	19 (17.9%)	106 (78.5%)
No	19 (65.5%)	10 (34.5%)	29 (21.5%)
TOTAL	106 (78.5%)	29 (21.5%)	135 (100%)
Week 24			
Yes	75 (88.2%)	10 (11.8%)	85 (83.3%)
No	13 (76.5%)	4 (23.5%)	17 (16.7%)
TOTAL	88 (86.3%)	14 (13.7%)	102 (100%)

CHAPTER 5

5.1 DISCUSSION

The following summarises the primary findings of this analysis.

- Counselling on infant feeding practices for all women, irrespective of their HIV status, showed a significant difference amongst women receiving peer support in the peer counselling intervention group and those receiving standard infant feeding counselling in the control group, with more women practising EBF in the intervention group than in the control group.
- HIV negative women appeared to benefit most from the intervention, with a higher EBF rate at 3 weeks observed amongst HIV negative women compared to HIV positive women (24% versus 7%).
- Regarding MF, more than 65% of the HIV positive women practised MF throughout the study period, irrespective of the group they were in.
- For HIV negative women, more than 40% of them practised EFF throughout the study period regardless of the group they were in.
- When the infant feeding intentions the HIV positive women had at recruitment were looked at in relation to what they practised, the results showed that for women who had intended to practise EBF at recruitment, 33.3% of them in the control group compared to 20.0% in the intervention group at Week 3 actually practised EBF. Regarding women who had intended on practising EFF at recruitment, 5.3% of them in the control group versus 3.9% in the intervention

group followed through with it. The difference amongst women who intended to practise MF all of them (100%) ended up practising EFF.

- The high risk infant feeding method (MF) was found to be the most practised feeding method by HIV positive women in both the control group (69.4%) and the intervention group (71.2%).
- More than half (54.7%) of the HIV positive women who had disclosed their HIV status had planned on practising MF at recruitment which became a reality when 77.4% of the women who disclosed their HIV status practised MF. When the different infant feeding methods were combined into high risk and low risk infant feeding methods, 76.9% of those who had disclosed their HIV status practised high risk feeding.



5.1.1 Impact of counselling on infant feeding practices

The positive effect of intense counselling and support is seen in the Promise EBF study, where there was a higher proportion of women who practised EBF in the intervention arm, irrespective of their HIV status, throughout the study period. This was also observed when the women were stratified according to their HIV status, with more HIV positive women in the intervention group practising EBF compared to those in the control group. Exclusive breastfeeding, especially in developing countries, has been found to offer HIV positive women with an affordable, effective and culturally acceptable means of infant feeding that has a lower HIV risk infection rate than mixed feeding (Coutsoudis, Pillay, Spooner, Kuhn & Coovadia, 1999). This sentiment is shared by Rollins, Meda, Becquet, Coutsooudis, Humphrey, Jeffrey, et al. (2004) as they found out that EBF was

more acceptable and feasible for HIV positive women, especially if they were in a supportive environment. This was shown in a non-randomised intervention study conducted in KwaZulu Natal amongst HIV positive and negative women attending ANC clinics, where it was found that rates of EBF improved with extensive home support (Bland, Little, Coovadia, Coutsoodis, Rollins & Newell, 2008).

Regarding EFF, irrespective of the women's HIV status, higher percentages of women who practised this form of infant feeding were those in the control group throughout the study period. This trend continued even after the women were stratified by their HIV positive status. Regarding MF, despite being counselled on the different infant feeding options, high percentages of all women, irrespective of their HIV status, practised this form of infant feeding with percentages increasing throughout the study.

When the HIV status of the women was taken into consideration, it was disturbing to see that amongst the HIV positive women, the highest numbers were those of women who practised MF, an infant feeding practice which is regarded as posing the highest risk for HIV transmission, regardless of study arm. This may be attributed to the women only disclosing their HIV status to the health care professionals at the health facilities and not to the community health workers. The reason for this non-disclosure may be because of fear of being stigmatised, isolated and discriminated against by community members once their HIV positive status is known (Thairu et al., 2005). Stigmatisation as a result of being HIV positive is considered a major barrier to effective response to the pandemic and the little consensus amongst policy makers on how to define, measure and reduce

stigmatisation is of concern (Mahajan, Sayles, Patel, Remien, Ortiz et al., 2008). In addition to having a negative effect on an individual's familial, social and economic life, it also deters individuals from seeking care and treatment services (Kalichman & Simbayi, 2003).

Counselling of HIV positive mothers should be interactive and provide an opportunity for the mothers to ask questions and ascertain their knowledge (Doherty et al., 2006b).

Individual circumstances of the women and the environment in which they live should be considered to ensure appropriate infant feeding choice (Doherty, et al., 2007). It should not just be about educating them on risks but should be about assessing each individual woman's circumstances on what is feasible and practical for her (Coutsoudis, 2005).

Lack of disclosure to peer supporters would have hampered the peer supporters ability to provide appropriate counseling based on the woman's circumstances.

Another aspect to take into account is that of the number of infant feeding counselling sessions received by the study woman. While it was enough to double the rate of EBF, due to the low baseline this still left a substantial percentage of women practising sub-optimal feeding and the intensity of visits in this study did not have a large population based impact. In a cohort study conducted in urban, semi-urban and rural areas of KwaZulu-Natal amongst HIV positive and HIV negative women, the number of antenatal infant feeding counselling visits was associated with the exclusive infant feeding choice made antenatally and adhered to even postnatally, where mothers who had less than the maximum number of visits (four) were more likely to change their feeding method

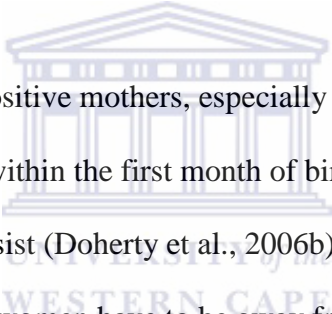
postnatally (Bland, Rollins, Coovadia, Coutsooudis, & Newell, 2007). Similar findings were observed in the ZVITAMBO trial conducted in Zimbabwe, where mothers who had received group education or individual education and/or both group and individual education were more likely to practise EBF compared to those who had not been exposed to any of the education programmes (Piwoz, Iliff, Tavengwa, Gavin, Marinda, Lunney et al. 2005).

5.1.2 Adherence to antenatal infant feeding intention

In the current Promise EBF study, the results based on intent to feed in the antenatal period by HIV positive women showed that high percentages of women who had intended to practise a certain form of infant feeding and adhered to it were those found in the control group and practised EBF, 33.3%. This is of concern as the highest percentages of women, both in the control and intervention group, were those who practised MF, 86.8% and 90.4%, respectively, although at recruitment they had intended to practise EFF. Although in this study the women's reasons for choosing a particular feeding method were not determined, their knowledge of the benefits of breastfeeding and or fear of being stigmatised if they did not breastfeed may have led to them practising MF. Even when the different infant feeding practices were grouped together according to low risk and high risk, the highest percentages were those of women who practised high risk infant feeding, regardless of whether they were in the intervention or control group.

Although breastfeeding is promoted because of its many benefits, both to the mother and the baby, it carries the risk of HIV transmission and discovering that HIV can be

transmitted through breastmilk has created a public health dilemma (Thairu et al. 2005) while formula feeding negates that risk but increases infant morbidity and mortality (Coutsoudis, Goga, Rollins, Coovadia, Child Health Group, 2002). In a study conducted in Ibadan in Nigeria, although emphasis was placed on EBF during counselling of HIV positive women, most of them ended up practising EFF (Oladokun, Brown & Osinusi, 2010). Similar results were observed in a study conducted in India, where a higher percentage of HIV positive women were more likely to feed modified animal milks to their infants in the first week postpartum as a result of the mothers being too sick to breastfeed (Shankar et al., 2005).

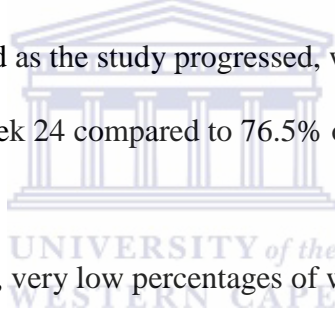


The pressure exerted on HIV positive mothers, especially by mothers and mothers-in-law, to introduce other liquids within the first month of birth and their lack of disclosure makes it difficult for them to resist (Doherty et al., 2006b). The problem is compounded by the third month, when these women have to be away from home, probably to go back to work, and they do not have the skills and support to sustain EBF during their absence. In a study conducted in rural Kwa-Zulu Natal, the age of the mother and financial and emotional dependency on the family were noted as possible reasons that may have made younger mothers hesitant to contradict their families when advised to practise MF (Thairu, 2005). Another study on infant feeding decision making by HIV positive women in South Africa showed that just under one-half of women who started on EBF at birth continued practising this method of infant feeding while over two-thirds who started on EFF maintained that infant feeding practise (Doherty et al., 2006b). Although the age of the participants in the Promise EBF study was not looked into, this may explain why

most of the participants who had intended to practise EBF at recruitment ended up practising MF.

5.1.3 HIV status disclosure and adherence to antenatal infant feeding intention

Regarding the intention to feed and HIV disclosure, a high percentage of HIV positive women who had disclosed their HIV status at recruitment (74.4%) and those who had not disclosed (60.4%) had intended to practise MF. By Week 3, high percentages of these women, regardless of their HIV status disclosure, were practising MF or high risk feeding, 77.4% of them being those who had disclosed to at least one person and 50.0% of them being those who had not disclosed their HIV status. The percentages of the women practising MF increased as the study progressed, with 88.2% of those who had disclosed practising MF by Week 24 compared to 76.5% of those who had not disclosed.



Regarding disclosure and EBF, very low percentages of women who had disclosed their HIV status (19.6%) and those who had not disclosed their HIV status (20.8%) intended to practise EBF at recruitment while none (0.0%) of the women intended to practise EFF regardless of whether they had disclosed their HIV status or not. By Week 3, less than 10% of the women who had disclosed their HIV status were practising EBF, with the percentages dropping further by Week 24 (2.4%). A similar trend was observed amongst those who had not disclosed their HIV status, with only 11.5% of them practising EBF by Week 3 and none (0.0%) by Week 24. Regarding EFF, none of the women (0%) had any intentions of practising this form of feeding at recruitment, irrespective of whether they had disclosed their HIV status or not. As a result, very low percentages of women, whether they had disclosed their HIV status or not, practised this form of feeding, with

the numbers decreasing as the study progressed. These results are of concern as the expectation would be that, after all the counselling, the majority of HIV positive women would intend to, and actually practise either EBF or EFF.

Although some studies have looked at HIV positive women's infant feeding practices and their intention to feed while still attending antenatal clinic, and between infant feeding and disclosure, none have looked at a combination of the three aspects, i.e., HIV disclosure, the intended infant feeding method while still pregnant, and adherence to that feeding method after the child is born.

5.2 LIMITATIONS

The loss of participants to follow up in this study, with a total of 139 of the women recruited to be part of the study last seen at recruitment while a further 186 were lost to follow up during the course of the study, resulted in a small sample size. The dropping out of participants during the study period limits the scope of analysis and that influences the findings. A small sample size makes it difficult to make definite conclusions about an observed result and to make inferences to other situation.

The reasons for the choice of feeding practised by participants were not determined in this study and therefore it is difficult to make a conclusion on whether it was because of fear of stigmatisation, lack of knowledge about safe infant feeding or cultural norms that determined their choice of feeding.

Peer counsellors had no way of knowing the participants' HIV status and that non-disclosure of the participants' HIV status to the peer-counsellors could be the reason why

most participants practised MF as they may have received different messages from the health care workers in the health facilities and peer counsellors.



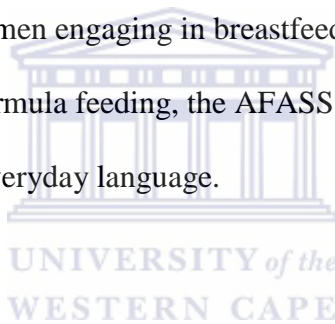
CHAPTER 6

6.1 CONCLUSION

This study suggests that community-based peer support can positively influence exclusive breastfeeding rates as the results show that a higher percentage of women who practised EBF were those who received peer counselling in the intervention group although the intervention effect was still low and the population level benefit on child health may not be significant. Regarding the intention to feed at recruitment, although the HIV positive mothers may have understood what they need to do during infant feeding counselling received from the health care providers, fear of being stigmatised by both their families and community members may have contributed to them deviating from the intended infant method chosen at recruitment. Also, the fact that very high percentages of women, irrespective of whether they received standard counselling or peer counselling, engaged in high risk infant feeding practices, was of concern and this may be attributed to mixed messages that the women may have received from both the health care workers who knew their HIV status and therefore gave them informed advise versus advise from peer counsellors who were not aware of their HIV status. Another cause for concern was that of HIV positive women who, although they had disclosed their HIV status and the expectation would be that they would practise safer infant feeding methods, still practised high risk infant feeding methods.

The 2010 WHO/UNICEF infant feeding guidelines recommend that the authorities in each country be the ones who decide on which infant feeding to be adopted, i.e., breastfeeding with an antiretroviral intervention to reduce MTCT or to avoid

breastfeeding altogether (WHO, UNAIDS, UNFPA & UNICEF, 2010). This means that HIV positive mothers would no longer have the burden of making a difficult infant feeding choice and since this would be a government policy, it would remove the challenges of stigmatisation and discrimination these women face within their families and the society at large. In areas where ARVs are available, HIV positive mothers are encouraged to breastfeed for 12 months, a move that would ensure that the infant receives the necessary nutrition found in breastmilk, thereby ensuring optimal growth, health and protection from preventable illnesses and also helps the mother continue to practise the most common and society-acceptable form of infant feeding. These recommendations would, hopefully, see more women engaging in breastfeeding and moving away from formula feeding. Regarding formula feeding, the AFASS criteria still apply but in a common and understandable everyday language.



6.2 RECOMMENDATIONS

Extensive infant feeding counselling training of both the health care workers in health facilities and peer counsellors working in the communities should be provided in and around all PMTCT-providing centres. This kind of training should be standardised to ensure that the same information is provided to pregnant and new mothers to avoid conflicting messages from health care workers and peer counsellors. Counselling of pregnant women, especially HIV positive mothers, should be strengthened both in health facilities and community health workers. HIV positive women, especially, should be encouraged to attend at least four of the infant feeding counselling sessions, where they

will receive information about the advantages and disadvantages of the different feeding methods and then make informed decisions. Extensive counseling of mothers may reduce the number of women who practise MF.

The 2010 WHO/UNICEF infant feeding guidelines, which recommends that the national authorities in each country should decide on the infant feeding choice, whether breastfeeding with ARVs or avoidance of breastfeeding altogether, should be adopted and implemented. These guidelines will ensure standardisation all across and remove the burden of individual counseling of HIV positive mothers by health care workers and then leaving the onus on the mothers to make a decision. Since the AFASS feeding model is still recommended for women who choose formula feeding, extensive training on this model should be provided to both health care workers and peer counselor or home-based workers, in a simple and easy to understand language. This will translate to easy guidance and information sharing with HIV positive mothers.

Home-based carers or peer counsellors should be encouraged to make at least weekly visits to the new mothers in the first two weeks after delivery to check on the new mothers and encourage them to adhere to their chosen infant feeding practice and to provide support. Since the peers come from the same communities as the mothers, the peers have a better understanding of what the mothers are going through in their familial and community settings and may offer better support than the health care providers at the health facilities, who, currently, only offer advice and counselling according to the Department of Health's guidelines.

HIV positive mothers should be linked with or encouraged to join community support structures like Mothers-to-Mothers. This will be to ensure continuous support to their

choice of infant feeding method and to share information with women in the same situation.

Disclosure of HIV status to family members should be encouraged so that HIV positive can get support from their families. Awareness programmes on PMTCT, with specific focus on infant feeding and the consequences of MF as part of dealing with cultural barriers, should be developed for both HIV mothers and their families at large. Peer counselors should be trained on confidentiality which may result in HIV positive women feeling comfortable to disclose their HIV status to them, thereby ensuring that they receive appropriate infant feeding information and support. Women who have already disclosed their HIV status should be encouraged to practise low risk infant feeding methods.

Further studies on the determinants of the HIV positive women's choice of infant feeding need to be done as these may give some perspective on whether the practised infant feeding methods are a result of age of the mother, cultural norms, fear of stigmatization or unmet AFASS criteria.

REFERENCES

- Abiona, T.C., Onayade, A.A., Ijadunola, K.T., Obiajunwa, P.O., Aina, O.I. & Thairu, L.N. (2010). Acceptability, feasibility and affordability of infant feeding options for HIV positive women: A qualitative study in South-west Nigeria. *Maternal & Child Nutrition*, 2 (3): 135 – 144.
- Becquet, R., Ekouevi, D.K., Menan, H., Amani-Bosse, C., Bequet, L., Dabis, I. et al (2008). Early mixed feeding and breastfeeding beyond beyond 6 months increase the risk of postnatal HIV transmission: ANRS 1201/1202 Ditrane Plus, Abidjan, Côte d'Ivoire. *Prev Med*, 47 (1): 27 – 33.
- Becquet, R., Bland, R., Leroy, V., Rollins, N.C., Ekouevi, D.K., Coutsoydis, A. et al (2009). Duration, pattern of breastfeeding and postnatal transmission of HIV: Pooled analysis of individual data from West and South African cohorts. *PLoS One*, 4 (10): e7397.
- Besser, M.J. (2002). *Mothers-to Mothers-to-be: Peer counseling, education and support for women in pregnancy in Cape Town, South Africa*. International Conference on AIDS, July 7-12, abstract no. Mo0rF1031.
- Besser, M.J., Ebdon, M., Engelbrecht, L., Ntshanga, N. & Qolo, P. (2004). *The mothers' programs: Mothers 2 Mothers – continued education and support for PMTCT mothers after delivery*. International Conference on AIDS, July 11-16, abstract no. ThPeD7671.
- Bland, R.M., Rollins, N.C., Coovadia, H.M., Coutsoydis, A. & Newell, M-L. (2007). Infant feeding counselling for HIV-infected and uninfected women: appropriateness of choice and practice. *Bulletin of the World Health Organization*, 85: 289 – 296.

- Bland, R.M., Little, K.E., Coovadia, H.M., Coutsoodis, A., Rollins, N.C. & Newell, M-L. (2008). Intervention to promote exclusive breastfeeding for the first 6 months of life in a high HIV prevalence area. *AIDS*, 22: 883 – 891.
- Bond, V., Chase, E., Aggleton, P. (2002). Stigma, HIV/AIDS and prevention of mother-to-child transmission in Zambia. *Evaluation and Program Planning*, 25 (4): 347 – 356.
- Chopra, M., Doherty, T., Mehatru, S. & Tomlinson, M. (2009). Rapid assessment of infant feeding support to HIV-positive women accessing prevention of mother-to-child transmission services in Kenya, Malawi & Zambia. *Public Health Nutr.*, 12 (12): 2323 – 2328.
- Coovadia, H.M., Rollins, N.C., Bland, R.M., Little, K., Coutsoodis, A., Bennish, M.L. & Newell, M-L. (2007). Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: An intervention cohort study. *Lancet*, 369: 1107 – 1116.
- Coutsoodis, A. (2005). Infant feeding dilemmas created by HIV: South African experiences. *The Journal of Nutrition*, 1315: 956 – 959.
- Coutsoodis, A., Pillay, K., Spooner, E., Kuhn, L., & Coovadia H.M. (1999). Influence of infant feeding patterns on early mother-to-child transmission of HIV-1 in Durban, South Africa: A prospective cohort study. *The Lancet*, 354 (9177): 471 – 476.
- Coutsoodis, A., Pillay, K., Kuhn, L., Spooner, E., Tsai, W-Y., Coovadia, H.M. (2001). Method of feeding and transmission of HIV-1 from mothers to children by 15 months of age: Prospective cohort study from Durban, South Africa. *AIDS*, 15: 379 – 387.
- Coutsoodis, A., Goga, A.E., Rollins, N., Coovadia, H.M. & Child Health Group (2002). Free formula milk for infants of HIV-infected women: Blessing or curse? *Health Policy Plan*, 17 (2): 154 – 160.

- David, S., Abbas-Chorfa, F., Vanhems, P., Vallin, B., Iwaz, J. & Ecochard, R. (2008). Promotion of WHO feeding recommendations: A model evaluating the effects on HIV-free survival in African children. *Journal of Human Lactation*, 24 (2): 140 – 149.
- De Cock, K.M., Fowler, M.G., Mercier, E., de Vincenzi, I., Saba, J., Hoff, E., Alnwick, D.J., Rogers, M., Shaffer, N. (2000). Prevention of mother-to-child HIV transmission in resource-poor countries – Translating research into policy and practice. *Journal of American Medical Association*, 283 (9): 1175 – 1182.
- Department of Health (DoH) (2003). *The Integrated Nutrition Programme (Nutritional Status)*. [Online] Available: <http://www.doh.gov.za/programmes/nutrition.html> downloaded 2010/11/03.
- DoH, USAID, AED & LINKAGES (2006). *AED/LINKAGES/South Africa: Final Report 2003 – 2006*. [Online] Available: http://www.linkagesproject.org/publications/Finalreport_SAfrica.pdf downloaded 2010/11/03.
- Department of Health (DoH) (2007). *HIV and AIDS and STI strategic plan for South Africa, 2007-2011 (draft 9)*. Pretoria: Department of Health.
- Department of Health (2008). *National Department of Health protocol for providing a comprehensive package of care for the prevention of mother-to-child transmission of HIV (PMTCT) in South Africa*. [Online] Available: www.doh.gov.za Downloaded 2009/09/02.
- Department of Health (DoH) (2010). *The South African antiretroviral treatment guidelines*. [Online] Available: <http://www.sanac.org.za/documents/2010%20art%20guideline-short.pdf> downloaded 2010/11/03.

- Doherty, T., Chopra, M., Nkonki, L., Jackson, D. & Greiner, T. (2006a) Effect of the HIV epidemic on infant feeding in South Africa: “When they see me coming with the tins they laugh at me”. *Bulletin of World Health Organisation*, 84 (2): 90-96.
- Doherty, T., Chopra, M., Nkonki, L., Jackson, D. & Persson, L-A. (2006b). A longitudinal qualitative study of infant-feeding decision making and practices among HIV-positive women in South Africa. *The Journal of Nutrition*, 136 (9): 2421 – 2426.
- Doherty, T., Chopra, M., Jackson, D., Goga, A., Colvin, M. & Persson, L. (2007). Effectiveness of the WHO/UNICEF guidelines on infant feeding for HIV-positive women: Results from a prospective cohort study in South Africa. *AIDS*, 21: 1791 – 1797.
- Fadnes, L.T., Engebretsen, I.M.S., Wamani, H., Semiyaga, N.B., Tylleskär, T. & Tumwine, J.K. (2009). Infant feeding among HIV positive mothers and the general population mothers: Comparison of two cross-sectional surveys in Eastern Uganda. *BMC Public Health*, 9:124. Published online 2009 May 7.
- Goga, A.E., van Wyk, B., Doherty, T., Colvin, M., Jackson, D.J. & Chopra, M. (2009). Operational effectiveness of guidelines on complete breast-feeding cessation to reduce mother-to-child transmission of HIV: Results from a prospective observational cohort study routine prevention of mother-to-child transmission sites, South Africa. *Journal of Acquired Immune Deficiency Syndrome*, 50 (5): 521 – 528.
- Hop, L.T., Gross, R., Giay, T., Sastroamidjojo, S., Schultink, W & Lang, N.T. (2000). Premature Complementary Feeding Is Associated with Poorer Growth of Vietnamese Children. *The Journal of Nutrition*, 130: 2683 – 2690.

- Horvath, T., Madi, B.C., Luppa, I.M., Kennedy, G.E., Rutherford, G & Read, J.S. (2009). Interventions for preventing late postnatal mother-to-child transmission of HIV. *Cochrane Database System Rev.*, 21 (1): CD006734.
- HST (2002). South Africa: Focus on Nevirapine programme. [Online] Available: <http://www.hst.org.za/news/20020228> Downloaded 2008/10/28.
- Hung, B. K.M., Ling, L. & Ong, S.G. (2002). *Sources of influence on infant feeding practices in Hong Kong*. doi:10.1016/0277-9536(85)90191-1.
- Hutton, G., Wyss, K. & N'Diekhon, Y. (2003). Prioritization of prevention activities to combat the spread of HIV/AIDS in resource constrained settings: A cost effective analysis from Chad, Central Africa. *International Journal of Health Planning and Management*, 18: 117 - 136.
- ICRW (2010). Reducing HIV stigma could decrease mother-to-child transmission: Exploratory analysis attempts to quantify benefits of stigma reduction. [Online] Available: www.icrw.org/media/news Downloaded 2010/7/25.
- Ilf, P.J., Piwoz, E.G., Tavengwa, N.V., Zunguza, C.D., Marinda, E.T., Nathoo, K.J., Moulton, L.H., Ward, B.J., the ZVITAMBO study group & Humphrey, J.H. (2005). Early exclusive breastfeeding reduces the risk of postnatal HIV-1 transmission and increases HIV-free survival. *AIDS*, 19: 699 – 708.
- Jackson, D.J., Willumsen, J., Goga, A., Chopra, M., Doherty, T., Colvin, M. et al. (2005). *Infant feeding patterns in the context of HIV in South Africa*. Philadelphia: American Public Health Association, 133rd Annual Meeting and Exposition.
- Jackson, D.J., Goga, A.E., Doherty, T. & Chopra, M. (2009). An update on HIV and infant feeding issues in developed and developing countries. *JOGNN*, 38: 219 – 229.

- Kaai, S., Baek, C., Geibel, S., McOdida, P., Benson, U., Muthumbi, G., N’Katha-Matiko, C. & Rutenberg, N. (2005). "HIV serostatus and infant feeding counseling and practice: Findings from a baseline study among the urban poor in Kenya," *Horizons Research Update*. Washington, D.C.: Population Council.
- Kalichman, S.C. & Simbayi, L. (2003). HIV testing attitudes, AIDS stigma, and voluntary counselling and testing in a black township in Cape Town, South Africa. *Sexually Transmitted Infections*, 79: 442 – 447.
- Kasonka, L., & Filteau, S. (2009). *Exclusive breastfeeding and HIV infection*. In: Goldberg, G., Prentice, A., Prentice, A., & Filteau, S., Simondon, K. (Eds). *Breastfeeding: Early influences on later life*. Springer Science + Business Media
- Kiarie, J.N., Richardson, B.A., Mbori-Ngacha, D., Nduati, R.W. & John-Stewart, G.C. (2004). Infant feeding practices of women in a perinatal HIV-1 prevention study in Nairobi, Kenya. *Journal of Acquired Immune Deficiency Syndrome*, 35 (1): 75 – 81.
- Leshabari, S.C., Koniz-Booher, P., Åström, A.N., de Paoli, M.M., & Moland, K.M. (2006). Translating global recommendations on HIV and infant feeding to the local context: the development of culturally sensitive counselling tools in the Kilimanjaro Region, Tanzania. *Implementation Science*, 1 (22): 1 – 14
- Leshabari, S.C., Blystad, A., de Paoli, M. & Moland, K.M. (2007a). HIV and infant feeding counseling: Challenges faced by nurse-counsellors in northern Tanzania. *Human Resources for Health*, 5 (18) doi: 10.1 186/1478 4491-5-18.
- Leshabari, S.C., Blystad, A. & Moland, K.M. (2007b). Difficult choices: Infant feeding experiences of HIV-positive mothers in northern Tanzania. *Journal of Social Aspects of HIV/AIDS*, 4 (1): 544 – 555.

- Leshabari, S., Koniz-Booher, P., Burkhalter, B., Hoffman, M. & Jennings, L. (2007c). *Testing a PMTCT infant-feeding counselling program in Tanzania: Operations Research Results*. Published for the U.S. Agency for International Development (USAID) by QAP.
- Linkages (2004). *Infant feeding options: In the context of HIV*. Washington D.C.: Academy for Educational Development.
- Lunney, K.M., Illiff, P., Mutasa, K., Ntozini, R., Magder, L.S., Moulton, L.H. & Humphrey, J.H (2010). Association between breastmilk viral load, mastitis, exclusive breastfeeding, and postnatal transmission of HIV. *Clin Infect Dis*, 50 (5): 762 – 769.
- Mahajan, A.P., Sayles, J.N., Patel, V.A., Remien, R.H., Ortiz, D., Szekeres, G. & Coates, J. (2008). Stigma in the HIV/AIDS epidemic: A review of the literature and recommendations for the way forward. *AIDS*, 22 (2): S67 – S79.
- Magoni, M., Bassani, L., Okong, P., Kituuka, P., Germinario, E.P., Giuliano, M. & Vella, S. (2005). Mode of infant feeding and HIV infection in children in a program for prevention of mother-to-child transmission in Uganda. *AIDS*, 19 (4): 433 – 437.
- Martin, S. & Mukuria, A. (2010). *Engaging men to increase support for optimal infant feeding in Western Kenya*. 5th breastfeeding and feminism symposium, March 2010.
- Matji, J.N., Wittenberg, D.F., Makin, J.D., Jeffery, B., MacIntyre, U.E. & Forsyth, B.W.C. (2008). Psychosocial and economic determinants of infant feeding intent by pregnant HIV-infected women in Tshwane/Pretoria. *South African Journal of Child Health*, 2 (3): 114 – 118.

- Matji, J.N., Wittenberg, D.F., Makin, J.D., Jeffery, B., MacIntyre, U.E. & Forsyth, B.W.C. (2009). Factors affecting HIV infected mothers' ability to adhere to antenatally intended infant feeding choice in Tshwane. *South African Journal of Child Health*, 3 (1): 20 – 23.
- Mazzeo, C. (2009). *Infant and young child feeding in the context of HIV: Findings from a foundation-wide survey*. Elizabeth Glaser Pediatric AIDS Foundation: IAS Satellite Session, 19 July 2009.
- Mbori-Ngacha, D., Nduati, R., John, G., Reilly, M., Richardson, B., Mwatha, A., Ndinya-Achola, J., Bwayo, J. & Kreiss, J.(2001). Morbidity and mortality in breastfed and formula-fed infants of HIV-1–infected women: a randomized clinical trial. *Journal of American Medical Association*, 286 (19): 2413-2420.
- Merewood, A., Chamberlain, L.B., Phillip, B.L., Cook, J.T., Malone, K. & Bauchner, H (2005). *Peer counselors increase breastfeeding rates in the neonatal intensive care unit: Final data from a randomized controlled trial*. Philadelphia: American Public Health Association, 133rd Annual Meeting and Exposition.
- National Department of Health (2008). *Policy and guidelines for the implementation of the PMTCT programme*. South Africa: Pretoria.
- Ndinda, C., Chimbwete, C., McGrath, N., Pool, R. & Group, M.D.P. (2007). Community attitudes towards individuals living with HIV in rural KwaZulu-Natal, South Africa. *AIDS Care*, 19 (1): 92 – 101.
- Oladokun, R.E., Brown, B.J. & Osinusi, K. (2010). Infant-feeding pattern of HIV-positive women in a prevention of mother-to-child transmission (PMTCT) programme. *AIDS Care*, 1 – 7 (EPub ahead of print).

- Omwega, A.M., Oguta, T.J. & Sehmi, J.K. (2006). Maternal knowledge on mother-to-child transmission of HIV and breast milk alternatives for HIV positive mothers in Homa Bay District Hospital, Kenya. *East Afric. Med. Journal*, 83 (11): 610 – 618.
- Patel, D., Bland, R., Coovadia, H., Rollins, N., Coutsooudis, A. & Newell, H. (2010). Breastfeeding, HIV status and weights in South African children: A comparison of HIV-exposed and unexposed children. *AIDS*, 24 (3): 437 – 445.
- Peltzer, K., Mosala, T., Dana, P. & Fomundam, H. (2008). Follow-up survey of women who have undergone a Prevention of Mother-to –Child Transmission program in a resource-poor setting in South Africa. *Journal of the Association of Nurses in AIDS Care*, 19 (6): 450 – 460.
- Peltzer, K., Phaswana-Mafuya, N., Ladzani, R., Davids, A., Mlambo, G., Phaweni, K., Dana, P. & Ndabula, M. (2009). Programme to Improve Implementation of the Prevention of Mother to Child Transmission of HIV in Gert Sibande District in Mpumalanga, South Africa. Pretoria, HSRC.
- Phadke, M.A., Gadgil, B., Bharucha, K.E., Shrotri, A.N., Sastry, J., Gupte, N.A. et al (2003). Replacement-fed infants born to HIV-infected mothers in India have a high early postpartum rate of hospitalization. *The Journal of Nutrition*, 133 (10): 3153 – 3157.
- Piwoz, E.G., Iliff, P.J., Tavengwa, N., Gavin, L., Marinda, E., Lunney, K. et al. (2005). An education and counseling program for preventing breast-feeding associated HIV transmission in Zimbabwe: Design and impact on maternal knowledge and behaviour. *The Journal of Nutrition*, 135 (4): 950 – 955.
- Rollins, N.G., Meda, N., Becquet, R., Coutsooudis, A., Humphrey, J., Jeffrey, B. et al. (2004). Preventing postnatal transmission of HIV-1 through breast-feeding: Modifying infant feeding practices. *Journal of Acquired Immune Deficiency Syndrome*, 35 (2): 188 – 195.

- Safi, Z., Wahdati, M. & Hamid, B.A. (Undated). *Assessment of status of infant and young child feeding (IYCF): Practice, policy and program achievements and gaps. Afghanistan Report*. [online] Available: <http://www.worldbreastfeedingtrends.org/report/Afghanistan.pdf> downloaded 2010/11/03.
- Scott, J.A., Binns, C.W., Oddy, W.H. & Graham, K.I. (2006). Predictors of breastfeeding duration: Evidence from a cohort study. *Pediatrics*, 117: e646 – e655.
- Sellen, D.W. (2009). *Evolution of human lactation and complementary feeding: Implications for understanding contemporary cross-cultural variation*. In: Goldberg, G., Prentice, A., Prentice, A., & Filteau, S., Simondon, K. (Eds). *Breastfeeding: Early influences on later life*. Springer Science + Business Media
- Shisana, O., Mehtar, S., Mosala, T., Zungu-Dirwayi, M., Rehle, T., Dana, P. et al. (2005). *HIV risk exposure in children: A study of 2 – 9 year olds served by public health facilities in the Free State, South Africa*. Cape Town: HSRC Press.
- Shisana, O., Rehle, T., Simbayi, L. C., Zuma, K., Jooste, S., Pillay-van-Wyk, V. et al. (2009). *South African national HIV prevalence, incidence, behaviour and communication survey 2008: A turning tide among teenagers?* Cape Town: HSRC Press.
- Simbayi, L.C., Kalichman, S.C., Strebel, A., Cloete, A., Henda, N. & Nqeketo, A. (2007). Disclosure of HIV status to sex partners and sexual risk behaviours among HIV-positive man and women, Cape Town, South Africa. *Sexually Transmitted Infections*, 83: 29 – 34.
- Simondon, K.B., Costes, R., Delaunay, V., Diallo, A. & Simondon, F. (2001). Children's height, health and appetite influence mothers' weaning decisions in rural Senegal. *International Journal of Epidemiology*, 30 (3): 476–481.

- Sturt, A.S., Dokubo, E.K. & Sint, T.T. (2010). Antiretroviral therapy (ART) for treating HIV infection in ART-eligible pregnant women. *Cochrane Database System Rev.*, 17 (3): CD008440.
- Summers, J., Robinson, R.C.L., Zisook, S., Atkinson, J.H., McCutchan, E., Deutsch, R., Patterson, T. & Grant, I. (2000). The influence of HIV-related support groups in survival in women who lived with HIV: A pilot study. *Psychosomatics*, 41: 262 – 268.
- Susin, L.R. & Giugliani, E.R. (2008). Inclusion of fathers in an intervention to promote breastfeeding: Impact on breastfeeding rates. *Journal of Human Lactation*, 24(4):386–392.
- Thairu, L.N., Pelto, G. H., Rollins, N.C., Bland, R. M. & Ntshangase, N. (2005). Sociocultural influences on infant feeding decisions among HIV-infected women in rural Kwa-Zulu Natal , South Africa. *Maternal and Child Nutrition*, 1: 1- 10.
- Tint, K., Doherty, T., Nkonki, L., Witten, C. & Chopra, M. (2003). An evaluation of PMTCT and infant feeding training in seven provinces of South Africa. [Online] Available: http://www.hst.org.za/uploads/files/pmtct_training.pdf downloaded 2010/11/04.
- UK Department of Health (2004). *HIV and infant feeding: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS*. Department of Health, London, UK.
- UNAIDS (2006). *UNAIDS fact sheet: Sub-Saharan Africa*. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS.
- UNAIDS (2008). *Report on the global AIDS epidemic*. Geneva, Switzerland: Joint United Nations Programme on HIV/AIDS.

- UNESCO (2010). Violence, gender, culture and HIV: Overview and abstracts from UNESCO upcoming publications. [Online] Available: <http://www.stop-stoning.org/node/833> downloaded 2010/07/12.
- UNICEF (2008). *Breastfeeding: Impact on child survival and global situation*. [Online] Available: http://www.unicef.org/nutrition/index_24824.html downloaded 2010/11/03
- WHO (1991). *Indicators for assessing breastfeeding practices: Report of an informal meeting*. Geneva: World Health Organisation.
- WHO (2000). Collaborative study team on the role of breastfeeding on the prevention of infant mortality. Effect of breastfeeding on infant and child mortality due to infectious diseases in less developed countries: A pooled analysis. *The Lancet*, 355: 451 – 455.
- WHO (2003a). Global strategy for infant and young child feeding. [Online] Available: <http://www.who.int/nutrition/publications/infantfeeding/9241562218/en/index.html> downloaded 2010/10/12.
- WHO (2003b). *HIV and infant feeding: Framework for priority action*. Geneva: World Health Organisation.
- WHO (2003c). *HIV and infant feeding: A guide for health-care managers and supervisors*. Geneva: World Health Organisation.
- WHO (2003d). *HIV and infant feeding: Guidelines for decision-makers*. Geneva: World Health Organisation.
- WHO (2004). *HIV status disclosure to sexual partners: Rates, barriers and outcomes for women*. Geneva: World Health Organisation.
- WHO (2005). *Guiding principles for feeding non-breastfed children 6 – 24 months of age*. Geneva: World Health Organisation.

WHO (2006). HIV and infant feeding technical consultation held on behalf of the inter-agency task team on prevention of HIV infections in pregnant women, mothers and their infants. [Online] Available: http://www.who.int/child-adolescent-health/New_Publications/Nutrition/Consensus_Statement downloaded 2010/07/31.

WHO/UNICEF/UNFPA/UNAIDS (2004). *HIV transmission through breastfeeding: Review of available evidence*. Geneva: World Health Organisation.

WHO/UNAIDS/UNICEF/UNFPA (2008). *HIV transmission through breastfeeding: A review of available evidence*. Geneva: World Health Organisation.

WHO (2010). *Guidelines on HIV and infant feeding 2010: Principles and recommendations for infant feeding in the context of HIV and a summary of evidence*. Geneva: World Health Organisation.



APPENDICES

APPENDIX 1

Peer support recruitment

1. Peer Supporters found women in their clusters and submitted lists to PS Supervisors.
2. For women who refused peer support, the peer supporter completed as much information on the refusal form as possible. She also asked the woman if she was interested in being involved in a study and being visited by a data collector. If she said yes then she completed a directions to home form so that the woman could be found by the data collectors if she was selected to be in the study.
3. PS supervisors checking of clinic ANC records (1-2 times per month as they went by the clinic). PS Supervisors planned to stop by local clinics when out in the field visiting PS. Cross-checked their lists with the ANC clinic records/registers or whatever they were keeping for records. While there they also checked in with the sister to see if there were any problems with the study or just generally to improve communication about the project and the work of the PS in their area to improve community-clinic collaboration.
4. Finally, the peer supporter supervisor checked delivery registers at primary hospitals (Paarl, Rietvlei, Prince Mshyeni) daily/every other day or so for women from our clusters even if they were not previously identified by peer supporters. The supervisor asked the women if they were interested in receiving peer support and if they were, then she completed a 'directions to home

form' so that the peer supporter could make the one week visit. If they were not interested in peer support, the supervisor still asked if they were interested in being visited by a data collector for a study. If they were, then the directions to home form were still completed. If they were not, then a refusal form was completed.

5. In Umlazi there were additional activities such as regular household census - a separate procedure was developed for this as it only pertained to Umlazi.

6. In Paarl and Rietvlei, a census was done periodically during the study period to ensure that we were capturing 98% of the pregnant women in our clusters.



APPENDIX 2

Sampling Procedure for data collection

1) Each month the PS Supervisor drew up a list of new women identified in the previous month from any of the above methods for each cluster. Women were identified as early as possible after 7 months to reduce deliveries prior to sampling. For women who were identified who were not yet 7 months their names were written on a back up list and put onto the selection list in the month that they were 7 months pregnant.

2) This list was then given to the DC Supervisor for sample selection.

3) Sampling was then done one cluster at a time to achieve 3 women selected/recruited per cluster per month with 1-2 back-ups in case of refusal as follows:

a. Count and number the women in the cluster

b. Open the envelope with the random sampling lists for the current month

c. For each cluster go to the random sampling list with the corresponding number of women in the cluster, i.e. if there were 9 women in a cluster then use the 9 women random sampling list

d. Rank the women on the cluster list for the current month according to the random selection - e.g. if the random selection list numbers are 3, 7 & 4 then woman #3 on the list would be 1st for that month and indicated by A, woman #7 would be 2nd and indicated by B, woman #4 would be the 3rd one selected and indicated by C. Also select the two potential replacements D and E according to the last two random numbers of the selection list and indicate them.

e. The three (ABC) women were approached for consent for data collection.

f. If one of the ABC women refused participation in data collection, this was *noted* on the master cluster list, completed a refusal to participate form and selected women D as replacement

g. If a second woman from the ABC women refused participation in data collection, this was *noted* on the master cluster list, completed a refusal to participate form and selected women E as replacement.

h. If a third woman from the ABC women refused, this was *noted* on the master cluster list, completed a refusal to participate form.

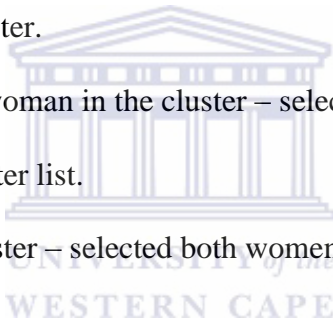
i. If the ABC women all refused to participate the supervisors reviewed the recruitment strategy of that cluster.

j. Special cases: Only one woman in the cluster – selected the woman and indicated her by A. Noted refusal on master list.

Only two women in the cluster – selected both women and indicated them by A and B. Noted refusals on master list.

Only three women in the cluster – selected all three women and indicated them by A, B and C. Noted refusals on master list.

Only four women in the cluster – followed the steps b to i above with only one woman selected as potential replacement (D).



APPENDIX 3

Procedure for obtaining informed consent

1. The informed consent procedure took place in a private space to ensure confidentiality.
2. The field researcher sat down with the woman, gave her an information sheet and read through the Informed Consent Form with her in her chosen language.
3. The language used in the oral and written information about the study, including the written informed consent form, was to be non-technical and practical and be understandable to the participant.
4. Both the informed consent discussion and the written informed consent form and any other written information provided to participants included explanations of the following:
 - That the study involves research.
 - The purpose of the study: to understand how mothers feed their babies in the area.
 - That participation was voluntary.
 - The participant was free to withdraw at any time, without losing the benefits of her routine medical care
 - The length of study/visit schedule and procedures (interview, blood pricks, urine tests, anthropometry)
 - The participant's responsibilities.
 - The reasonably foreseeable risks or inconveniences to the participant (emotional nature of the topic, pain associated with blood pricks)
 - The reasonably expected benefits (home visits, support for feeding, referral to hospital if necessary)

- The compensation and/or treatment available to the participant in the event of study-related injury.
- The anticipated prorated payment, if any, to the participant for participating in the study (amount per visit).
- That the monitor (MRC), would be granted direct access to the participant's personal information forms for verification of study procedures and/or data, without violating the confidentiality of the participant, and that by signing a written informed consent form, the participant was authorizing such access.
- That records identifying the participant would be kept confidential and, would not be made publicly available. If the results of the study were published, the participant's identity would remain confidential.
- The person(s) to contact for further information regarding the trial and the rights of trial participants, and whom to contact in the event of trial-related injury.
- The foreseeable circumstances and/or reasons under which the participant's participation in the trial might be terminated.
- The approximate number of participants involved in the trial.

5. All participants would receive the same information, and all of the above points must be covered.

6. During the information session the women would be given the opportunity to ask questions about any part of the study.

7. Ask the woman to repeat things periodically to be sure she understood the information.

8. The field researcher would never coerce or unduly influence a participant to participate or to continue to participate in the study.

9. Once the field researcher was convinced the woman could give informed consent for participation in the study, the potential participant would sign the Informed Consent Form. After the participant signed the form, the study staff member conducting the consenting process had to sign and date the form.

10. Once the forms were signed, the participant would be given a copy. She would also be offered a copy of the information sheet to take home and read before her first visit.

Ongoing consent: Participants were enrolled in this study for a long period of time, therefore it was important that time be taken at each study visit to ensure the participants know:

- a. The purpose of study: to understand the feeding methods of women in the area.
- b. That their participation was voluntary and they could leave the study at any time

