Impact of Counseling on Breastfeeding Practice and Perinatal HIV-1 Transmission in Nairobi, Kenya

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Abstract

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Background: Breastfeeding is associated with significant reductions in infant mortality rates in developing country settings, and the World Health Organization recommends exclusive breastfeeding (EBF) for 6 months when possible. Where HIV-infected mothers receive anti-retroviral treatment (ART), it is recommended that they also practice EBF. However, exclusive breastfeeding rates remain low throughout Sub-Saharan Africa, irrespective of maternal HIV status. Counseling interventions have been demonstrated to increase EBF rates in a variety of settings, but few studies have designed and evaluated interventions for HIV-infected women in sub-Saharan Africa.

Methods: HIV-positive pregnant women reporting for care at six government health facilities in Nairobi were enrolled into a before-after study. The first cohort of women at each clinic received standard perinatal care and the second group was offered standard care plus three sessions of lactation counseling sessions promoting exclusive breastfeeding for prevention of mother-to-child HIV-1 transmission (PMTCT). Subjects were followed until 14 weeks after delivery, and infants were tested for HIV at six weeks postpartum. The proportion of women practicing EBF at fourteen weeks postpartum was compared between control and intervention groups using binomial regression. Other outcomes included

6-week HIV-free survival, 14-week infant survival, and counts of breast pathology from 0 to 14 weeks postpartum.

Results: Eight hundred thirty-three women were enrolled into the study between 2009 and 2013. Median age was 27 years (Interquartile range [IQR] 23-31 yeas), and median CD4 count was 403 cells/μL (IQR 287-571). The proportion of women practicing EBF at 14 weeks postpartum was high in both groups (>80%) and there was no significant difference between treatment and control group ($p>0.05$). No differences were observed between groups for 6-week HIV-free survival, 14-week infant survival, or prevalence of breast pathology.

Conclusion: The counseling intervention was not associated with increased EBF. However, the proportion of women practicing EBF, irrespective of study arm, was nearly two times higher than the proportion reported nationally in 2008. High rates of EBF in the study population may be attributable to policy changes and a strong national PMTCT program.

I. Introduction

The World Health Organization (WHO) currently recommends exclusive breastfeeding, defined as feeding no other liquids or solids besides breastmilk and medicine, for the first 6 months of an infant's life (WHO 2001, WHO 2013). This is based on evidence that breastmilk provides adequate nutrition for infants during the first 6 months of life and research which suggests that exclusive breastfeeding is associated with reduced infant morbidity and mortality (Butte et al. 2001, WHO 2002, WHO 2000). Compared to formula feeding, exclusive breastfeeding has been demonstrated to diminish infants' risk of respiratory and gastrointestinal infections, including pneumonia and diarrheoa, leading to reduced infant mortality (WHO 2000, Chantry et al. 2006, Cesar et al. 1999, Victoria et al. 1987, Kramer & Kakuma 2012). While this survival benefit is most pronounced in the developing world where avoidance of contaminated water is a major protective factor, it has also been observed in high-income settings, which suggests that the maternal antibodies transferred through breastmilk also play a key protective role.

Although breastmilk is associated with mother-to-child transmission of HIV (MTCT), the WHO breastfeeding recommendations extend to women infected with HIV because the widespread availability of anti-retroviral treatment (ART) has made it possible for HIV-infected women to safely breastfeed (De Cock et al. 2000, WHO 2010). In this context, risk of MTCT can be reduced to less than 5% among HIV-infected populations who breastfeed, while extending the survival benefit of exclusive breastfeeding which reduces infant mortality rates, relative to formula feeding (Lallemant et al. 2004, Dabis et al. 2007, Coovadia et al. 2007, Creek 2006, Natchu et al. 2012, Coutsoudis et al. 2003, WHO 2010). Furthermore, multiple studies have indicated that exclusive breastfeeding is associated with decreased MTCT risk, relative to mixed feeding, which is defined as feeding infants food, animal milk, or formula in addition to breastmilk (Coovadia et al. 2007, Coutsoudis et al. 2000, Iliff et al. 2005**).**

The exact mechanisms whereby EBF reduces risk of MTCT, relative to mixed feeding, have not been fully elucidated, but mixed feeding is associated with breast pathologies, such as mastitis, which occurs as a result of engorgement and failing to empty the breast regularly. Mastitis is associated with increased HIV

viral load in breastmilk, and both mastitis and engorgement have been associated with a 2-3 fold increased risk of MTCT in observational studies (Embree et al. 2000, Semba 2000, Semba & Kumwenda 1999). Therefore, it is important to provide HIV-infected, breastfeeding mothers with education about how to properly feed and avoid breast pathologies as part of exclusive breastfeeding promotion efforts.

Despite the WHO recommendation, exclusive breastfeeding practice remains low throughout sub-Saharan Africa. Cross-sectional evidence in East and Southern Africa indicates that in 2010 only 47% percent of infants under the age of 6 months are breastfed exclusively, but this figure masks substantial variation by country and region with more than 60% of women in Rwanda, Burundi, Uganda, and Malawi exclusively breastfeeding compared to less than 35% in Kenya, Zimbabwe, and Namibia (Cai et al. 2012; Various and ICF International 2014). Additionally, little is known about differences in breastfeeding practice between HIV-infected and HIV-negative mothers. Low rates of exclusive breastfeeding are a significant concern in countries such as Kenya, which has an overall HIV prevalence of 5.6% and a high infant mortality rate (KAIS 2012, World Bank 2014). In Kenya, only 42% of infants less than 3 months old and 32% of infants less than 6 months old were breastfed exclusively in 2008 (Kenya MoH & ICF International 2008), and while this represents a significant increase in exclusive breastfeeding from 2003, further progress is necessary, especially among HIV-infected women and their infants.

No silver bullet intervention exists to improve rates of exclusive breastfeeding, but multi-component counseling interventions are among the most promising. A recent systematic review of interventions to promote exclusive breastfeeding in high-income settings suggested that successful breastfeeding interventions incorporate peer support, have long duration, actively respond to women's difficulties encountered during feeding, and occur primarily postpartum (Skouteris et al. 2014). While much differs between high-income settings and low-income, HIV-endemic regions, these suggestions are supported by recent work in sub-Saharan Africa. In a population of HIV-negative women in Nairobi, a series of seven intensive counseling sessions (1 prenatal, 6 postnatal) by peer mentors was associated with a 4-fold increase in exclusive breastfeeding compared to standard of care, while a single, facility-based intensive counseling session failed to show any impact (Ochola et al. 2012). Similar findings have also

been observed in studies utilizing peer mentors to implement intense, long duration interventions in a largely HIV-negative population in Ghana and a population of mixed HIV-1 serostatus in South Africa (Bland et al. 2008, Aidam et al. 2005).

This study sought to assess the proportion women of exclusive breastfeeding at 14 weeks postpartum among HIV-positive women from six Nairobi clinics and evaluate the impact of a counseling intervention on exclusive breastfeeding, infant HIV free-survival, infant survival, and breast pathology. A before-after study design was used: each study clinic first enrolled women and offered standard-of-care counseling to assess baseline rates of exclusive breastfeeding and thereafter enrolled women into the intervention group.

II. METHODS:

Study Design and Setting: A before-after study design was utilized to investigate the impacts of breastfeeding counseling on exclusive breastfeeding among HIV-positive pregnant women at 6 Nairobi City Council clinics: Kangemi, Riruta, Baba Dogo, Dandora II, Kayole II and Mathare North. These clinics serve a low-income population from densely populated, urban regions around Nairobi, Kenya.

The study was prospective, longitudinal and quasi-experimental in nature. Crossover from control to intervention status was unidirectional. Control groups were continuously enrolled at each clinic, and individuals in the control groups were given the standard-of-care counseling about PMTCT, facility delivery, and other topics. After completion of follow-up in the control cohort at each clinic, women were continuously enrolled into the intervention group, receiving standard-of-care plus additional counseling. Four clinics began enrolling controls in 2009, while the last 2 clinics began enrolling controls in 2011 only as the first four clinics had begun to administer the intervention.

Recruitment and Enrollment Procedures: The study recruited HIV-infected pregnant women who expressed the intention to breastfeed their infants (duration and exclusivity of breastfeeding were not part

of this requirement, only expressed intention). Eligible women were 18 years of age or older, at gestational age no less than 30 weeks, and planning to deliver and reside in Nairobi until 3 months postpartum. Study staff explained the study to pregnant mothers seeking prenatal care, and women interested in participating were required to provide written informed consent before enrollment.

Intervention and Control: The standard of care includes HIV-1 rapid testing and counseling for all pregnant women. If a women tests HIV-positive, additional counseling is offered, and this address prevention of mother to child HIV transmission (PMTCT) and recommends that women practice exclusivity in whatever infant feeding plan a woman chooses. This counseling lasts about 10-15 minutes and is typically provided by a peer counselor who does not have clinical expertise but has trained in PMTCT. This standard of care was provided to women in the control arm by peer counselors from each facility.

The intervention group received this standard of care counseling plus an additional three counseling sessions, one prenatal session around enrollment and two postnatal sessions at 1 week and 6 weeks, respectively. These supplementary sessions each lasted between 15 and 30 minutes and were provided by peer mentors at the clinic, who were given additional training and education about PMTCT, exclusive breastfeeding, and breastfeeding techniques after the control period was completed.

Intervention messages were modeled after WHO infant feeding tools and developed through a formative research component preceding the study. Exclusive breastfeeding was defined, and peer counselors explained the benefits of exclusive breastfeeding for both the infant and mother, namely PMTCT and the adequacy of breastmilk for infant nutrition, growth, and development during the infant's first 6 months of life. In the prenatal session, peer counselors also described the dangers of pre-lacteal feeds and recommended early initiation of breastfeeding. They introduced the need for frequent and on-demand feeding of infants during this first session, and advised mothers on breastfeeding techniques such as, positioning and attachment. During postnatal visits, these messages were re-inforced, and mothers were taught to recognize and prevent lactation problems, namely sore nipples, engorgement, and mastitis.

Study Follow-up Procedures: Participants in both treatment groups were advised to seek prenatal care weekly until delivery and attend four postpartum follow-up visits, at 1, 6, 10 and 14 weeks, respectively. Nurses employed by the study performed clinical evaluations and administered questionnaires each follow-up visit to investigate the current health of women enrolled in the study and the results of clinical examinations. At postpartum visits, questionnaires addressed breastfeeding practices, relationship status, and maternal and infant health.

At enrollment, twenty milliliters of maternal blood were obtained at maternal enrollment by venipuncture for CD4 subset evaluation. Women were referred for HAART, per NASCOP treatment guidelines. Infant dried blood spots were collected by nurses using a heel prick and filter paper HIV-1 DNA PCR assays at 6 weeks postpartum per the standard of care. Children found to be HIV infected were referred for HAART, per NASCOP guidelines.

Statistical Analysis: Data were managed and analyzed in CSPro and Stata 12.0 (StataCorp; College Station, Texas). Baseline characteristics were analyzed using Chi-squared and Fisher's Exact tests for categorical variables and t-tests for continuous variables. The number and proportion of individuals in each category were listed for categorical variables, while the median and interquartile range were reported for continuous variables.

The proportions of women exclusively breastfeeding at 10 and 14 weeks postpartum were each analyzed by study arm using binomial regression with a log-link, while adjusting for clinic. A mother was considered to be exclusively breastfeeding only when the infant was fed no other food or drink, not even water, except medicinal syrups, per the WHO definition. Proportions were calculated out of the number of women who attended each visit, rather than from the total study population in each arm, but those known to be no longer breastfeeding at a previous visit were marked as not exclusively breastfeeding at the next visit, regardless of their attendance.

Cox regression and Kaplan-Meir plots were utilized to assess both 6-week infant HIV-free survival and 14-week infant survival, while adjusting for clinic. The former outcome incorporated all deaths that were recorded before 6 weeks postpartum and HIV PCR test results from routine testing around week 6. The timing of seroconversion was judged to be the midpoint between testing and delivery. The latter outcome included all infant deaths that occurred before 14 weeks.

Counts of breast pathologies were analyzed using Poisson regression adjusted for clinic and offset by the number of post-natal visits a woman attended. Self-reported and clinically-diagnosed breast pathologies, namely breast abscess, mastitis, nipple cracking, and nipple bleeding, were included in the analysis.

Human Subjects: Human subjects approval was granted by the Ethical Review Committee at the Kenya Medical Research Institute and the University of Washington Human Subjects Division.

III. Results

Enrollment: Between March 2009 and February 2012, HIV-infected pregnant women were continuously screened and 420 were enrolled into the control group at 6 study clinics, while 413 women were enrolled into the intervention group between August 2010 and April 2013 (Table 1, Figure 1).

Baseline Characteristics: The control and intervention groups had similar characteristics (Table 2). The median age of women was 27 years (Interquartile Range [IQR] 23-31), and the median CD4 count was 403 cells/μL (IQR 287-571). Overall, 458 (55.1%) women had a primary level education or less, while only 60 (7.2%) had a post-secondary education. 610 women (73.6%) were unemployed at baseline, and greater than 75% of women reported living in a 1-room home.

There were small differences in the proportion of women in a relationship at enrollment. In the control group 57 (13.6%) women were not in a relationship and 362 (86.4%) were in a relationship, while in the intervention group only 37 (9%) were single and 373 (91%) reported a current relationship (p=0.038).

However, the median duration of relationships was similar between groups at 4 years (IQR 2-8 years). Among the 736 women in relationships, 526 (71.5%) had disclosed their HIV status to their male partners, but only 377 (52.1%) had discussed PMTCT methods with their partner. Parity was similar between groups. Overall, 775 (93.8%) of women entered the study with plans to breastfeed exclusively for at least 6 month, and among parous women 277 (98.2%) in the control reported feeding their last infant with breastmilk compared to 282 (92.8%) in the intervention (p=0.001).

Intervention Compliance: 301 women (72.9%) in the intervention group received all the three counseling interventions, one prenatal and two postnatal visits, while 51 women (12.3%) missed all 3 visits. Among women without perfect attendance, 43 (10.2%) missed both postnatal sessions, and 25 (6.1%) missed the prenatal session.

Main Outcomes: High levels of exclusive breastfeeding were observed in both groups at each visit (Table 3). At 14 weeks postpartum 574 (83.2%) of women reporting for visits were practicing exclusive breastfeeding, and significant variation was observed between clinics with the proportion ranging 72% at Baba Dogo to 95% at Mathare North. The adjusted relative risk (aRR) of exclusive breastfeeding was 0.96 (95% Confidence Interval [CI] 0.90-1.02) comparing the intervention and control groups, but there was no significant difference in the proportions (p=0.166). Similarly, at 10 weeks postpartum, 566 (88%) of women were breastfeeding exclusively, and no statistically significant difference was observed between women in the intervention and control (p=0.634).

There was no significant difference in 6-week HIV-free infant survival between groups (Figure 2). The intervention was associated with a non-significant 14% reduction (adjusted hazard rate [aHR] = 0.86, 95% CI: 0.50-1.50) in the risk of HIV acquisition or death before 6 weeks postpartum (p=0.599). Likewise, a non-significant 25% reduction in the risk of infant death (aHR = 0.75, 95% CI: 0.40-1.41) before 14 weeks postpartum was observed (p=0.376).

Women in the intervention group were more likely to have been diagnosed or provided self-report of

breast pathology, but this difference was not statistically significant. Risk of one or more breast pathologies was 21% higher (aRR=1.21, 95% CI: 0.74-2.00) in the intervention versus control (p=0.44). However, this difference was made up exclusively of self-reported pathologies as 27 were self-reported by women in the intervention versus 19 by women in the control group.

IV. Discussion

The counseling intervention was not associated with increased exclusive breastfeeding at 14 weeks postpartum. Additionally, no association was observed between the intervention and infant HIV-free survival to 6 weeks postpartum, infant survival to 14 weeks postpartum, or reduced risk of breast pathology. Nevertheless, the overall proportion of women exclusively breastfeeding was far higher than expected given other data about breastfeeding. The proportions in both arms were nearly double what was observed in the 2008 Kenya Demographic and Health Survey, which included both HIV-positive and negative women, where approximately 43% of infants 3 months old or younger were being exclusively breastfed (Kenya MoH & ICF International 2008). Additionally, the proportion of women exclusively breastfeeding at 14 weeks was much higher than in a recent study of HIV-negative women in Nairobi from 2006 to 2008, where the proportion of women breastfeeding exclusively at 3 months postpartum was 61.4% in the group receiving counseling compared to 36.8% in the control arm (Ochola et al. 20102). The proportions observed here were also somewhat higher than what was observed with high-intensity, long-duration interventions in South Africa (70.7% exclusively breastfeeding at 3 months and 64.7% at 4 months), but it is difficult to compare with this study because it occurred more than five years before the present study and in Southern Africa, where breastfeeding practice, cultural traditions, and other factors likely differ.

Recent studies have suggested that long-duration counseling interventions are among the most successful ways to increase exclusive breastfeeding and indicate that a high number of contacts with mothers after delivery is necessary to promote behavior change (Skouteris et al. 2014, Ochola et al. 2012, Bland et al. 2008). However, despite only three counseling visits in this study, high levels of

exclusive breastfeeding were observed in both intervention and control groups, relative to the aforementioned studies. This may be due to a number of factors. First, there are likely underlying differences between the population in this study and those from Kibera (Ochola et al. 2012), Kenya (Kenya MoH & ICF International 2008), and South Africa (Bland et al. 2008) as this population was constituted by HIV-infected women from Nairobi who already planned to breastfed before enrollment. Moreover, the timeline of this study also coincided with major efforts from the MoH and NASCOP to increase exclusive breastfeeding, which may have washed out any observable impacts, as standard of care counseling likely changed during the course of the study.

This study indicates that high levels of exclusive breastfeeding can be achieved among HIV-infected mothers in Kenya. However, there is uncertainty about the causes of the high proportions of exclusive breastfeeding in this study as these high proportions may be unique to a specific population of HIV-positive women in Nairobi or due to the inclusion of only women who planned to breastfeed. It might also have resulted from temporal trends in PMTCT and breastfeeding policies in Kenya. This latter explanation is particularly convincing because NASCOP has quickly scaled up HIV prevention efforts in recent years and began aggressive promotion of 6-month exclusive breastfeeding early in the course of the study. The counseling may, thus, have been redundant in this context, as it was not being compared to an intervention-naïve population but to a population receiving a variety of other public health messages on exclusive breastfeeding and PMTCT. This is supported by the finding that, at enrollment, approximately 94% of women reported that they planned to breastfeed exclusively for at least 6 months, which suggests that the study population had already been educated about the importance of exclusive breastfeeding.

A variety of limitations of the study design may have impacted results. The study was designed as a stepped-wedge, cluster randomized trial with two clinics in each cluster, which would have balanced time-dependent confounders and temporal trends. However, this design was abandoned in practice due to a number of financial and logistic concerns. Although the before-after design utilized in this study appears to have balanced measured participant characteristics fairly well, it is susceptible to confounding by temporal trend and other unmeasured confounders. The study was also underpowered to assess infant

survival, infant HIV-free survival, and breast pathology outcomes.

Another challenge was differential loss-to follow-up and failure to assess the fidelity of the intervention. At each visit individuals in the intervention arm were more likely to attend than those in the control group ($p<0.01$). This lead to differential ascertainment of outcomes by study arm, but the magnitude of this error is unlikely to have changed the neutral result of this study because an equivalent proportion of women in each arm (72%) were known to be exclusively breastfeeding at 14 weeks, when including all enrollees in the denominator population. Additionally, the researchers were unable to evaluate the fidelity of the intervention due to concerns about the Hawthorne effect, which is a common pitfall for counseling-based interventions (Skouteris et al. 2014). This phenomenon occurs when individuals change their behavior because they know they are being watched or observed, thus, risking that the results of any fidelity assessments are invalid.

The study results indicate that high levels of exclusive breastfeeding at 14 weeks can be achieved among HIV-positive women in Kenya. However, further work is needed to target interventions towards those who would be maximally benefitted by exclusive breastfeeding promotion efforts and assess whether these efforts can sustain high levels of exclusive breastfeeding to 6 months postpartum. These concerns are particularly salient, given indications from the 2008 Kenya DHS and other research in Kenya that exclusive breastfeeding practice declines precipitously between four and six months postpartum (Kenya MoH & ICF International 2008, Ochola et al. 2012).

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Table 1. Number of women enrolled in each clinic and study arm.

Clinic	Control	Intervention	Total
Kangemi	70	70	140
Riruta	70	70	140
Dandora II	70	70	140
Baba Dogo	70	70	140
Kayole II	70	63	133
Mathare North	70	70	140
Total	420	413	833

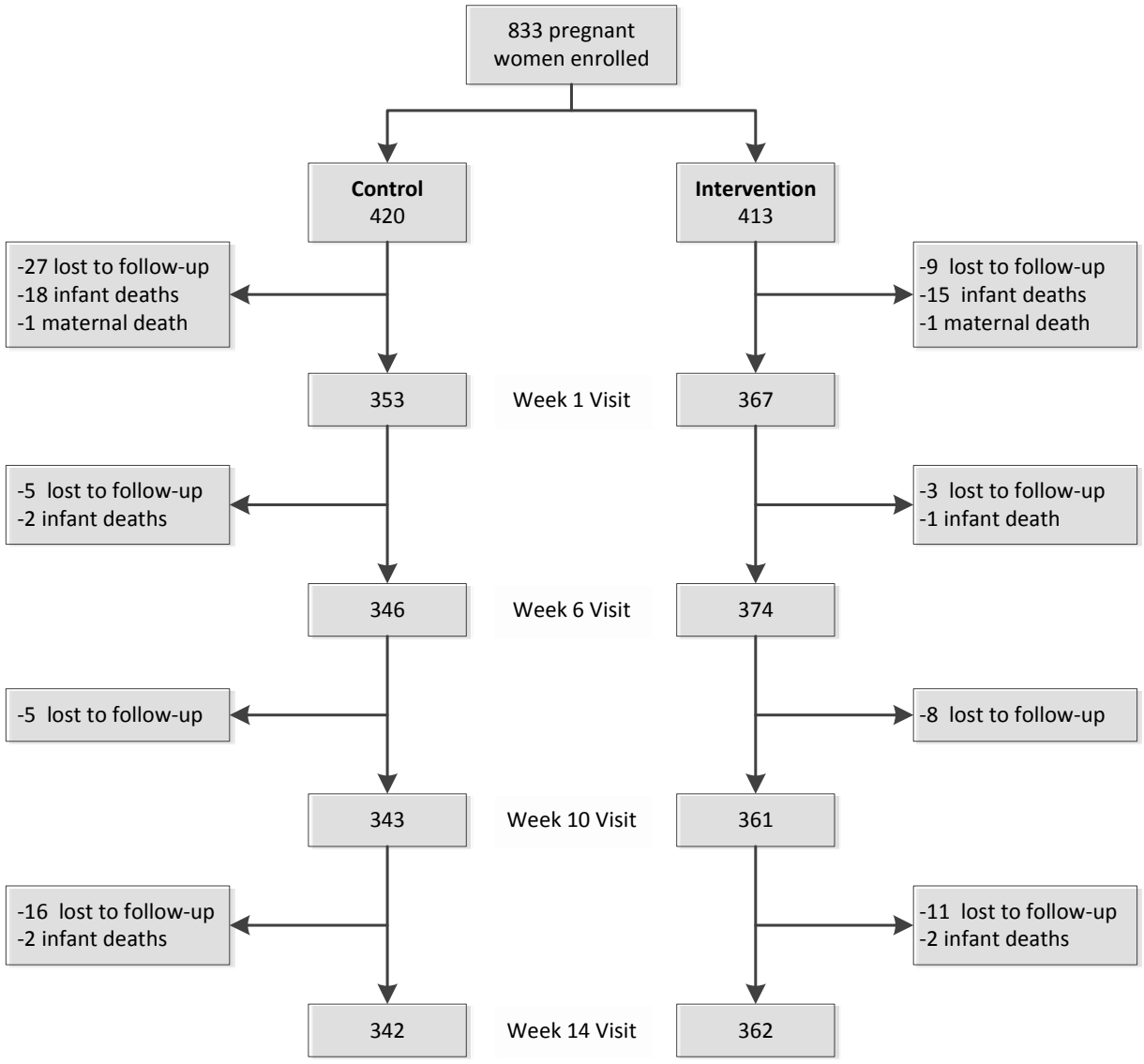

Figure 1. Illustration of enrollment of pregnant women and follow-up after delivery.

Table 2. Description of baseline characteristics.

Characteristic	Control n (%) or Median (IQR) n=420	Intervention n (%) or Median (IQR) n=413	P-value
Age (years)	27 (23-31)	27 (23-31)	0.634
CD4 count			
Median (IQR)	401 (286-560)	405 (293-576)	0.492
<200	46 (11.0)	32 (07.8)	
200-500	198 (47.3)	186 (45.2)	0.149
>500	175 (41.8)	194 (47.1)	
Marital Status			
Single, no partner	57 (13.6)	37 (9.0)	0.038
In relationship	362 (86.4)	373 (91.0)	
Partner duration (years)	4 (2-8)	4 (2-7)	0.999
Education Level			
Primary or less	251 (59.9)	218 (54.0)	
Secondary	145 (34.6)	157 (38.1)	0.098
Post secondary	23 (5.5)	37 (9.0)	
Occupation			
Unemployed	318 (76.1)	292 (71.1)	
Salaried	36 (8.6)	50 (12.2)	0.172
Self-employed	64 (15.3)	69 (16.8)	
No. of rooms in home			
1	320 (76.7)	323 (78.4)	
2	64 (15.4)	54 (13.1)	0.641
3+	33 (7.9)	35 (8.5)	
Flush toilet	184 (44.1)	199 (48.5)	0.203
Shared toilet	376 (90.2)	369 (90.0)	0.936
Had an STI previously	10 (2.4)	22 (5.3)	0.027
Used contraception previously	257 (61.3)	287 (69.7)	0.012
Partner known to be HIV+	90 (38.3)	112 (41.6)	0.446
Disclosed HIV status to partner	250 (69.3)	276 (73.6)	0.192
Discussed PMTCT with partner	172 (45.6)	205 (54.4)	0.072
Number of previous pregnancies			
Median (IQR)	2 (1-3)	2 (1-2)	0.476
0	65 (15.9)	55 (13.7)	
1	125 (30.6)	145 (36.1)	0.230
2+	219 (53.5)	203 (50.3)	
Previous children with partner	143 (53.4)	161 (51.1)	0.588
Feeding method for last child			
Breastmilk	277 (98.2)	282 (92.8)	
Formula/Mixed Feeding	5 (1.7)	22 (7.2)	0.001
Planned duration of exclusive breastfeeding for 6+ months	391 (94.0)	384 (93.7)	0.084

Table 3. Risk of key outcomes by study arm.

Characteristic	**Intervention** n (%)	**Control** n (%)	**Adjusted Rate*** (95%CI)	**p-value**
EBF** at 14 weeks (n_I=354; n_c=336)	286 (80.7)	288 (85.7)	0.96 (0.90, 1.02)	0.166
EBF** at 10 weeks (n_I=328; n_c=315)	283 (86.3)	283 (89.8)	0.99 (0.94, 1.04)	0.634
Infant death or HIV infection by 6 weeks	24	27	0.86 (0.50. 1.50)	0.599
Infant death (n_I=400; n_c=392)	16	20		
HIV infection	8	7		
Infant death by 14 weeks (n_I=399; n_c=392)	17	22	0.75 (0.40, 1.41)	0.376
Breast pathologies (n_I=387; n_c=372)	35	28	1.21 (0.74, 2.00)	0.444
Clinically-diagnosed	8	9	0.88 (0.34, 2.29)	0.796
Self-reported	27	19	1.21 (0.76, 2.46)	0.293

*All estimates were adjusted for clinic.
**Exclusive breastfeeding denoted as EBF.
Note: percent of whole listed only where relevant for calculations.

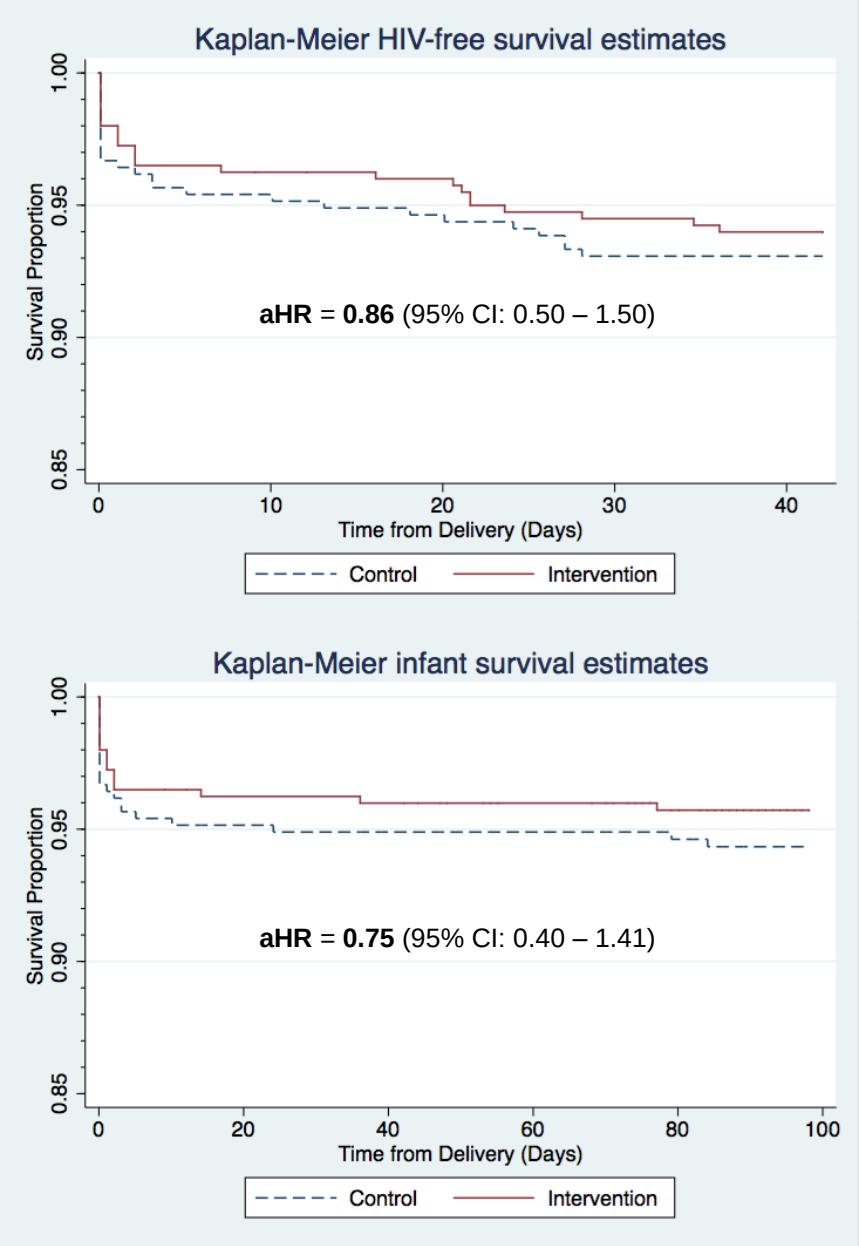

Figure 2. Survival curves and adjusted hazard rates comparing the intervention and control groups for 6-week infant HIV-free survival and 14-week infant survival. Hazard rates were adjusted for clinic. 6-week infant HIV-free survival was calculated using infant mortalities and HIV infections over 42 days, while 14-week infant survival included infant mortalities during the first 98 days of life.