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A Protocol for a Cluster Randomized Trial on the Effect of a "*feeding buddy*" Program on adherence to the Prevention of Mother-To-Child-Transmission Guidelines in a Rural Area of KwaZulu-Natal, South Africa

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Background: The uptake of prevention of mother-to-child-transmission (PMTCT) services has improved in South Africa but challenges remain, including adherence to the World Health Organization's (WHO) PMTCT recommendations of exclusive breastfeeding (EBF), taking antiretroviral medication (ARV); testing for early infant diagnosis; and reducing stigma. Women who practice EBF for the first 6 months are less likely to transmit HIV to their infants, yet only 7% of women EBF for 6 months in South Africa. Adherence to these recommendations remains challenging because of difficulties relating to disclosure and stigma. To address this challenge, the feeding buddy concept was developed based on studies where ARV buddies have proved effective in providing support for women living with HIV. Buddies have demonstrated a positive effect on providing emotional and social support to adhere to PMTCT guidelines.

Methods: A cluster randomized controlled trial was conducted in 16 selected randomly assigned clinics in uMhlathuze and uMlalazi districts of KwaZulu Natal, South Africa. HIV-positive pregnant women (n = 625) who intended to breastfeed were enrolled at 8 control clinics and 8 intervention clinics. The clinics were stratified on the basis of urban/rural/periurban locale and then randomly allocated to either intervention or control. In the intervention clinics, the mother chose a feeding buddy to be enrolled alongside her. Quantitative interviews with mothers and their chosen buddies took place at enrollment during pregnancy and at routine postdelivery visits at day 3 and weeks 6, 14 and 22. Women in the control clinics were followed using the same evaluation schedule. The trial evaluated the effect of a voluntary PMTCT feeding buddy program on HIV-infected women's adherence to PMTCT recommendations and stigma reduction. The proportion of women exclusively feeding at 5.5 months postpartum was the primary end-point of the trial. In-depth interviews were conducted among a convenience sample of PMTCT counselors, community caregivers, mothers, and buddies from intervention clinics and control clinics to document their overall experiences.

Discussion: The information collected in this study could be used to guide recommendations on how to build upon the current South Africa. PMTCT "buddy" strategy and to improve safe infant feeding. The information would be applicable to many other similar resource poor settings with poor social support structures.

Key Words: HIV/AIDS, antiretroviral treatment, prevention of mother -to- child transmission, breastfeeding, feeding buddy

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BACKGROUND

Prevention of mother-to-child transmission services has been available in South Africa for over 10 years. The uptake of these services has improved dramatically since the service was first introduced. In 2012, 98% of women were being tested for HIV during pregnancy and 92% of HIV-positive mothers were receiving ARV for treatment and/or prophylaxis.[1] Regardless, HIV prevalence among pregnant women in South Africa remains high (30%).[1] In the province of KwaZulu Natal (KZN), South Africa, where this study was conducted, prevalence among pregnant women is 37%, the highest in the country.[1]

Many of the steps of the PMTCT cascade are hampered by stigma and other factors that prevent women from accepting their status and accessing appropriate care and treatment.[2] Challenges remain, in particular, with adherence to exclusive breastfeeding (EBF), ARV medication, and early infant diagnosis.[3]

This manuscript outlines the protocol of a randomized control trial designed to assess the impact of the

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feeding buddy (FB) strategy to improve adherence to the PMTCT guidelines.

Exclusive Breastfeeding

Breastfeeding provides immunological support[4] and promotes gut maturation,[5] and thereby has potential to reduce infant mortality in resource-limited settings where formula feeding is not always a safe option.[6,7] Although HIV can be transmitted through breast milk, evidence has shown that EBF, combined with the provision of ARV prophylaxis, significantly reduces the risk of vertical transmission of HIV.[8,9] Yet, the prevalence of EBF in South Africa remains low at an estimated 7% at 6 months.[10]

A landmark study in KwaZulu-Natal Province (KZN), South Africa, found that the cumulative probability of HIV infection by 6 months of age was similar among the exclusively breastfed [0.194 (95% CI: 0.125 to 0.274)] and the never breastfed [0.194 (95% CI: 0.136 to 0.260)] groups, with the highest risk among those who were mixed feeders [0.261 (95% CI: 0.205 to 0.319)].[11] Several additional studies substantiated these findings.[12,13] Supporting women to EBF provides the safest and healthiest outcomes for women and their infants, therefore strategies to provide such support are important interventions that should be implemented.

Antiretroviral Treatment/Prophylaxis

When HIV-positive mothers receive antiretroviral treatment or prophylaxis and exclusively breastfeed, the risk of postnatal transmission at 6 months can be reduced to 0%–1%.[14,15] Based on this clinical evidence, the World Health Organization (WHO) amended its PMTCT and infant feeding guidelines. The WHO states that the risks of HIV transmission through breastfeeding in resource-limited settings should be weighed against the mortality risks associated with not breastfeeding; the guidelines recommend EBF to 6 months and the introduction of complementary feeding thereafter with breastfeeding up to 12 months, with extended ARV prophylaxis for either infant or mother throughout the breastfeeding period.[16,17] Breastfeeding should only stop once a nutritionally adequate and safe diet can be provided.

The South African PMTCT policy broadly adopted these guidelines in 2010 but stopped short of declaring breastfeeding the default feeding choice.[2] After the Tshwane Declaration in 2011, breastfeeding was then clearly adopted as the feeding method of choice for HIV-exposed infants.[18] Before 2011, free formula was provided by the clinics regardless of whether this was the safest infant feeding choice for HIV-positive women. These women were meant to meet certain AFASS criteria (accessibility, feasibility, affordability, sustainability, and safe) to ensure the safe provision of infant formula. But health care workers and mothers were confused about what constituted safe infant feeding practices. The Department of Health phased out the free formula in 2011 and women were encouraged to exclusively breastfeed their infants. The frequent changes in policy created confusion and a feeling of insecurity in mothers and health care workers.[19] In January 2015, yet another policy change was introduced in South Africa with a change to WHO's Option B+.[3] All pregnant women are now placed on lifelong ARV treatment, a single daily dose of triple ARV's (tenofovir, emtricitabine, and efavirenz) and daily nevirapine syrup is supplied to their infants from birth to 6 weeks.

Early Infant Diagnosis

Early infant diagnosis (EID) is critical for ensuring immediate care and treatment for infants who test positive for HIV. At the time of this study, EID testing was routinely done at 6 weeks. Early initiation of ARVs is critical for infant survival because a third of untreated HIV-positive infants die within a year of birth.[20] The coverage of virological testing of HIV-exposed children at 2 months in South Africa in 2010 was 68%.[21] Effective strategies for successful EID have been challenging in resource-limited settings. Many women are unemployed and have insufficient funds to travel to the clinics, the fear of receiving a positive diagnosis acted as a deterrent for taking their infants for testing, as did the lack of disclosure to other family members. Innovative approaches to address difficulties around EID are needed.

Stigma and Discrimination

Disclosure of an HIV status has led to isolation and exclusion of HIV-positive mothers.[22] Stigma prevents women from accessing health services, contributes to their dropping out of PMTCT programs,[23,24] and impacts their overall mental health which is likely to impact on infant health outcomes. Women interviewed in South African Health Care Facilities related the positive benefit of having psycho-social support in the form of a person to confide in and discuss issues with.[25] Given the challenges facing women during the antenatal and postnatal periods (eg, disclosure of HIV status, stigma, health beliefs, and domestic/social issues), a support system is crucial to a woman's well-being.

Defining the Intervention

In this project, a feeding buddy (FB) was selected by the HIV-positive mother to accompany her on PMTCT counseling and clinic sessions and to provide ongoing and continuous support to adhere to the PMTCT guidelines. These include specifically adherence to: ARV treatment, EBF, and overcoming cultural practices linked to mixed feeding. Additionally, to promote infant testing and strategies to reduce stigma and discrimination, the mothers and their selected buddies received training on essential PMTCT and health behaviors and skills.[26] The effects of a treatment buddy on ARV adherence have been previously assessed and linked to higher rates of adherence, but the effects of a FB who focused on several aspects of the PMTCT cascade have not evaluated yet.

Figure 1 Conceptual Model of Feeding Buddy intervention.

Both the mother and buddy received intensive training around key target health messages, which covered pregnancy, safe delivery, and postnatal care. This take-home booklet was produced specifically for the intervention, so that mothers and FBs would have these messages

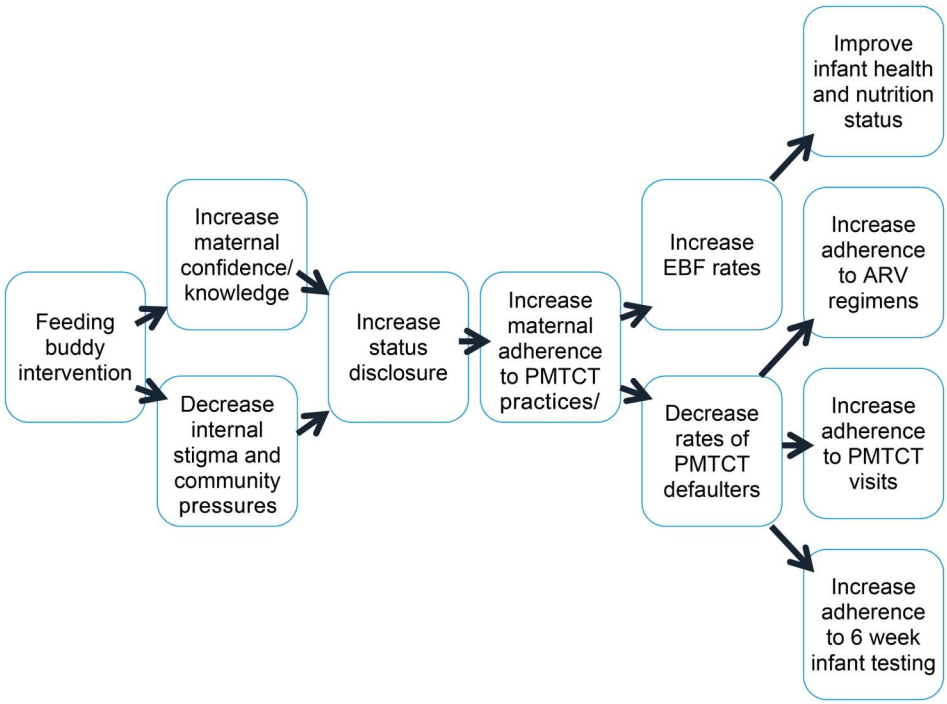

FIGURE 1. Feeding buddy conceptual model.

documented and available at hand. The training covered all aspects of breastfeeding, the importance of EBF, and safe complementary feeding. The importance of taking medication regularly for both mother and baby was stressed, as was monitoring the growth of the baby and the importance of immunization. In addition, the training covered illness and the danger signs for which children need urgent medical attention. The buddy also provided the psycho-social support that disclosing to a trusted person is believed to provide based on other studies. See Figure 1 Feeding buddy intervention conceptual model below.

Feeding Buddy Concept

Facility-based interventions are often inadequate to effect sustained behavioral changes that enhance PMTCT in the face of multiple contextual factors. Several studies in South Africa noted that training peer counselors or community health workers (CHW) to conduct home-based visits have had a positive influence on the uptake of PMTCT services, including a study in KZN[27] and EBF studies,[28–31] such as the PROMISE-EBF trial, where low-intensity, individual home-based counseling was shown to increase the rate of EBF in 3 sub-Saharan countries.[31]

ARV buddies have demonstrated a positive impact as a support mechanism in encouraging disclosure, helping HIV-infected individuals to resist stigma, restoring a sense of social connection,[31] and fostering social goodwill.[32] Researchers in the Free State province of South Africa highlighted the crucial role of community support as a key predictor of ARV adherence.[32] Disclosure to partners has been linked to decreased anxiety, risky behavior, and an increase in informed choices and uptake of health services.[33] The FB strategy is similar to the mother-to-mother approach,[34] the key difference being that it does not only rely on other mothers to be buddies, but anyone that the mother chooses can be trained as a feeding buddy.

A pilot study carried out in the Eastern Cape Province of South Africa examined the acceptability of the FB strategy and found integrating feeding buddies into an existing PMTCT program could be an effective strategy for providing community and home-based support for HIV-positive mothers.[35]

In this study, the FB intervention was implemented as one component of The Window of Opportunity Project (WinOp), a comprehensive and integrated maternal and child health project, being implemented in KZN. The WinOp Project focuses on maternal and infant morbidity and mortality during pregnancy and the first 2 years of the child's life. The goal being to strengthen health and community institutional capacity through training and mentoring, thereby improving the provision of services, community education, generating demand for services, and health-promoting behaviors. Under WinOp, the FB intervention was implemented as part of its community engagement.

STUDY OBJECTIVES

We hypothesized that mothers who chose a FB would have greater adherence to EBF and ARV regimens, they would be more likely to disclose their status, and they would be more likely to take their infant be tested for HIV at 6 weeks.

To test our hypothesis, the primary objectives were to determine the effect of a FB on adherence to EBF. The secondary objectives were to determine the effect of a FB on

adherence to ART regimens, to determine the effect of a FB on adherence to infant HIV testing at 6 weeks, and to determine the effect of a FB on disclosure and stigma.

METHODS

Study Design

Quantitative Data Collection

This study has a cluster randomized controlled trial design and was registered with NIH clinical trials registry: NCT02162498. The study was conducted in the Umlalazi and uMhlatuze subdistricts of the Uthungulu District of KwaZulu-Natal Province in South Africa. Of the 27 clinics in these 2 districts, these 16 clinics were the only 16 found to be eligible for selection for this study in terms of having sufficient numbers of pregnant mothers and accessibility of location. They were then randomly assigned to the control or intervention arm. The clusters consisted of 8 selected and randomly assigned control clinics where the FB intervention was not in place and 8 selected and randomly assigned intervention clinics where the feeding buddy intervention had been implemented. The clinics were stratified on the basis of urban/rural/periurban locale. Clinics were then randomly allocated to either intervention or control with each strata.

The trial evaluated the effect of a voluntary PMTCT FB program on HIV-infected women's adherence to EBF. The trial enrolled HIV-infected women who intended to breastfeed and were between 26 and 34 weeks gestation. The proportion of women exclusively feeding at 5.5 months after delivery was the primary end-point of the trial.

In the study intervention clinics, quantitative interviews with mothers and their chosen buddies took place at enrolment during pregnancy and at routine postdelivery visits at day 3 and then week 6, 14, and 22. These visits were aligned with routine PMTCT, well-child, and immunization visits and were conducted by trained research assistants. Women in the control clinics, those that did not yet have a FB program, who consented to the study, were followed using the same evaluation schedule.

Baseline data collection included household characteristics, maternal factors, FB characteristics, previous feeding history, disclosure of HIV status, and stigma. At follow-up visits, data collection included maternal factors, infant status, ARV adherence, infant feeding, stigma, and disclosure of HIV status. A study visit tracking form was completed for each of the study's scheduled visits. Loss to follow-up and reasons for this were also recorded. Participants who missed scheduled visits were contacted twice by research staff before they were considered lost to follow-up.

Sample Size Estimation

It was assumed that in the control arm, 25% of women would be exclusively breastfeeding up to 5.5 months and that the FB intervention would increase this proportion to at least 44% in the intervention group. Sample size calculations indicated that 16 clusters (8 in each arm), with 41 women in each cluster (N = 656), were required to achieve an 80% power to detect this difference. Estimated power was calculated using the Satterthwaite approximate F test for 2-sample comparison of proportions with clustering implemented within Stata 11. Underlying statistical parameters were as follows: an alpha-type-one error of 5% (2-tailed) and an allowance of 20% of study participants lost to follow-up. A coefficient of variation of 0.25 was assumed to account for within-group variation between clusters. See Figure 2 below.

Study Population Inclusion and Exclusion Criteria

The quantitative study sample was drawn from these 2 subdistricts, which constituted 58% of the district population. Two subdistricts were purposively sampled because they accounted for 78% of the district population on ART and had high proportion of reported ANC coverage. Although they did not represent of the district as a whole, they did represent the populations with the greatest need for intervention and the greatest opportunity for study.

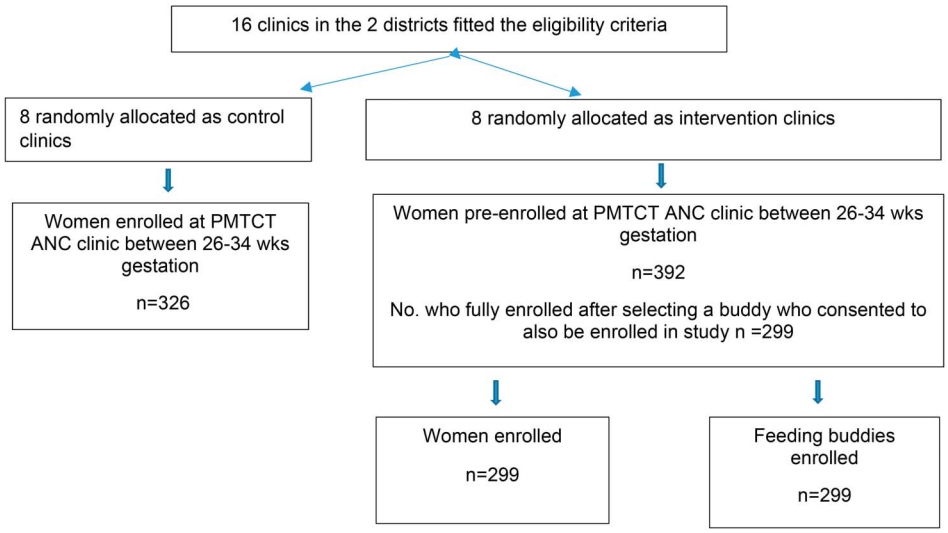

FIGURE 2. Consort profile diagram.

Site Assessments, Selection, and Randomization

Site visits were conducted on all 27 clinics in the 2 subdistricts, uMhlathuze and uMlalazi, and data were collected regarding antenatal clinic numbers and well-baby clinic numbers among other things. Clinics with below 10 first antenatal bookings per month and a very low percentage of follow-up visits for well-baby clinics were excluded from the randomization. Consideration was also given to the local infrastructure and demographics (eg, roads, population density, distribution of urban and rural areas) to enable the assessment to be completed in a feasible timeframe. The clinics were then stratified on the basis of urban/rural/periurban locale and randomization into 8 intervention and 8 control clinics was undertaken.

Qualitative Data Collection

Qualitative data were collected by trained research assistants using in-depth interviews conducted among a convenience sample of 10 PMTCT counselors and 10 Community Care Givers (CCGs) to capture their experiences in implementing the FB strategy (work load, satisfaction and challenges, limitations). Additionally, in-depth interviews were conducted with a random sample of 16 mothers from intervention clinics and 16 FB's and 16 from control clinics to document their differing perspectives and overall experiences around the challenges around breastfeeding; adhering to ARV medication; early infant diagnosis; stigma and having/being a feeding buddy and EBF. Interviews were conducted in the local language isiZulu and recorded for later translation into English before analysis would be commenced.

Inclusion Criteria

Pregnant women included in the study had to be 18 years or age or older; attending one of the study clinics and enrolled in the PMTCT program; were to be at least 26 but not more than 34 weeks pregnant; indicated their intention to deliver and remain within the study area for at least 6 months after delivery; intending to exclusively breastfeed; and had to provide written informed consent.

An additional eligibility criterion applied only to the mothers in the intervention clusters. They had to select a feeding buddy who agreed to attend training and participate in the evaluation. Mothers in the intervention arm were therefore preenrolled until they had selected their FB who attended at least one visit at which time the enrolment was confirmed.

Outcome Measures

Primary Outcomes

Exclusive Breastfeeding

EBF is defined as no other food or drink, including water, apart from breast milk (including expressed breast milk) with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines. The number of months engaged in EBF was calculated from date of birth of the infant to the discontinuation of breastfeeding and introduction of anything other than breast milk.[36]

Secondary Outcomes

Adherence to ARV

Two separate outcomes were examined and included adherence to ART to prevent MTCT among HIV-positive mothers and adherence to infant ARV prophylaxis of infant. Adherence to ARV in each case was defined as taking more than 95% of prescribed dose.[37] Adherence was assessed through self-report at study visits and measured from enrollment to final survey.

Exposure of Interest

The intervention group effectively received 2 separate interventions: having a feeding buddy, and training on breastfeeding. Exposure to the feeding buddy was measured by recording whether buddies attended orientation sessions, the number of antenatal and postnatal visits accompanied by the buddy, and the degree of contact between mother and buddy. Exposure to training was expressed as a numerical training score, calculated as a weighted total number of sessions received, with greater weights for early training, and repeated training. Training dates for each mother will be obtained from the records of the training organization.

Other Covariates

A range of potential explanatory variables were also collected: a urban or rural setting; age of mothers and buddies; infant's gender; education of the mother; maternal employment; water source; toilet type; fuel type; number of people living in the household; number of children under 5 living in the house; the number of children supported by the mother; the number of rooms in the house; the transport mode to the clinic; transport time to the clinic. In addition, if the mother had a partner, was married, lived with the partner; the gestational ages of the infant, type of delivery, birth weight of the infant, the number of live births, frequency of CCG visits, and previous breastfeeding experience.

DATA COLLECTION AND MANAGEMENT

Trained research assistants conducted surveys and collected data using a mobile phone platform that transmitted all data confidentially to an internet-based research console. A data manager managed the research console and weekly quality assurance visits by a field supervisor were made to the clinics sites to troubleshoot any data queries. Refresher trainings were provided to the research assistants during regular team meetings to improve data quality.

Ethical Considerations

Approval for the study was obtained by both the University of KwaZulu Natal's Biomedical Research Ethics Committee (BE001/13) and the PATH Research Ethics Committee (HS721). Approval was also obtained from local stakeholders, which included the Provincial Department of Health and the Manager of the Maternal and Child Health Program in KZN.

Risks

This study involved minimal risk to participants because no novel interventions were introduced. PMTCT guidelines state that routine HIV counseling should include encouraging the client to disclose their status to someone for support. Similarly, the PMTCT guidelines recommend that HIV-positive clients identify a "buddy" who can provide support.

Confidentiality

At enrolment, all participants were assigned a unique study identification number, which was utilized on all nonclinic-based data collection forms in lieu of their names. All forms were kept locked in a secure filing cabinet. All computer records and databases were password-protected to limit their access to feeding buddy personnel and the research assistant consultant only.

DATA ANALYSIS

The qualitative and quantitative work will be analyzed and results will be published separately, but early anecdotal information from the qualitative interviews suggests that multiple challenges remain for women within PMTCT programs. FBs played an encouraging, supportive role in the intervention group, which improved the participant's ability to accept and cope with their HIV status and further reduced feelings of social isolation.

The breastfeeding outcome, which constitutes interval-censored survival data, will be analyzed using Cox regression, assuming the event happens at interval midpoint, allowing for clustering at clinic level. Potential explanatory variables and interactions will be explored for inclusion into a multiple-variable model. Frailty models will also be fitted to assess unobserved heterogeneity in the data. Analysis will be done in Stata.

CHALLENGES AND LIMITATIONS

As an implementation science research study, the intervention and evaluation were led by separate groups. The intervention was led by the WinOp team and the evaluation was conducted by the research team from the University of KwaZulu Natal. The challenges experienced for the evaluation included delays in implementation of the feeding buddy program, which resulted in divergent timelines for control and intervention data collection. The delay in signing the memorandum of understanding between funders and the implementers delayed the appointment of trainers; the development of materials; and the roll out of the community mobilization and FB training. Additionally, there was lack of clear criteria to systematically determine when the FB program had been fully implemented and thus ready for accurate evaluation. Achieving adequate community awareness and support for the FB program may have been avoided with effective quality assurance checks, monitoring of the intervention, enhanced cooperation with the multiple local stakeholders which included policy makers and health facilities.

Although previous pilot data indicated buddies would attend clinic visits for training and data collection, reaching the buddies through clinic visits was a challenge. A revised community-based delivery design may have been more appropriate.

An inherent limitation of the study is the criterion to only enroll mothers in the intervention who actually chose a feeding buddy. There is therefore a possibility for selection bias whereby women who chose a feeding buddy were the more motivated women likely to disclose and follow instructions.

An important challenge of the study was adherence to critical time points for FB trainings for mothers and buddies; as a result, the true effect of key targeted messages per study protocol might not be measured accurately. Only 4 trainers were appointed to train both mothers and buddies in 8 clinics, which were spread over a wide area. Because of time constraints and difficulties with transport, the trainers were often unable to access the clinic at the time the mother and buddy arrived for their clinic visits. Ideally, a trainer should have been based at each of the 8 clinics, so she was readily available to train the mothers and buddies. Training should have been spread over pregnancy and completed by the early postnatal period. Often mothers and buddies ended up receiving all 4 training sessions at one time, sometimes after delivery thereby missing some key and timeous messages.

CONCLUSION

By supporting the current South Africa PMTCT guidelines to encourage EBF; adhere to ARV's; ensure early EID; encourage disclosure and build support systems, this intervention may help to diminish the damaging impact that stigma could potentially have on a mother's ability to safely feed her child and adhere to current recommendations. Safe infant-feeding benefits not only the infant, but also the entire family and community because its impacts on the long-term health of both the mother and her infant ensure the HIV-free survival of HIV-exposed infants.

Stigmatizing of HIV is destructive and addressing this has been a priority for HIV care and treatment programs. Despite the challenges experienced with the implementation, having a trained FB to provide not only social and emotional support but also to walk alongside them provide practical help, reminders, act as a mediator, and encourage disclosure could be a strategy that could be used in similar low resource settings with poor social support structures.

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