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A cluster randomised trial to determine the efficacy of the “feeding buddies” programme in improving exclusive breastfeeding rates among HIV-infected women in rural KwaZulu-Natal, South Africa

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Abstract

This cluster randomised trial in KwaZulu-Natal South Africa, evaluated the implementation of a *Feeding Buddies (FB)* programme to improve exclusive breastfeeding (EBF) amongst human immunodeficiency virus (HIV) infected mothers. Eight clinics were randomly allocated to intervention and control arms respectively. Pregnant women attending the prevention of mother-to-child transmission program and intending to EBF were enrolled: control ($n=326$), intervention ($n=299$). Intervention mothers selected FBs to support them and they were trained together (four sessions). Interviews of mothers occurred prenatally and at post-natal visits (day 3, weeks 6, 14 and 22). Breastfeeding results were analysed (Stata) as interval-censored time-to-event data, with up to four time intervals per mother. EBF rates at the final interview were similar for control and

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Compliance with ethical standards

Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

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) and all procedures performed were in accordance with the ethical standards of the institution and with the 1964 Helsinki declaration and its later amendments. Approval was also obtained from local stakeholders, which included the Provincial Department of Health as well as the Manager of the Maternal and Child Health Program, KZN. Informed written consent was obtained from all participants.

Informed consent

Informed consent was obtained from all individual participants included in the study.

intervention groups: 44.68% (105/235) and 42.75% (109/255) respectively ($p=0.67$). In Cox regression analysis better EBF rates were observed in mothers who received the appropriate training ($p=0.036$), had a community care giver visit ($p=0.044$), while controlling for other factors. Implementation realities reduced the potential effectiveness of the FBs.

Keywords

HIV/AIDS; prevention of mother-to-child transmission; exclusive breastfeeding; feeding buddy

Introduction

The World Health Organization's prevention of mother-to-child transmission (PMTCT) guidelines are intended mainly for countries with high HIV prevalence in limited resource settings. The guidelines recommend that all infants be exclusively breastfed (EBF) for six months, and continue breastfeeding, with the introduction of nutrient-dense complementary foods, for up to 24 months while antiretroviral prophylaxis is taken, to prevent associated MTCT of the human immunodeficiency virus (HIV) [1]. The National Department of Health through the Tshwane Declaration (2011), adopted breastfeeding as the default method of infant feeding for all HIV-infected women in South Africa [2].

Antenatal prevalence of HIV in KwaZulu-Natal (KZN) province where this study was carried out, is 37.4%, the highest in South Africa [3]. Existing data at the time of this study estimated national EBF rates at < 6 months to be 25.7% (21.3–30.8) [4]. Mixed feeding, defined as feeding infant under six months of age with other liquids and/or foods together with breast milk, has been documented to increase risk of HIV transmission substantially [5,6]. South African data report that over 64% of children under 6 months are fed solids [5], partly due to cultural practice and mothers' concerns of insufficient breast milk [7].

A meta-synthesis of 16 qualitative studies on infant feeding practices (in the context of HIV) in sub-Saharan Africa identified maternal knowledge, health care support, family resources, and cultural expectations as key factors which influenced breastfeeding [8]. In addition, in South Africa, EBF is often associated with being HIV positive and may thus be stigmatizing, as it is not the norm within many communities [9].

Another key element found to be strongly predictive of breastfeeding initiation and duration is self-efficacy, or a woman's confidence in her ability to breastfeed successfully. Psychosocial dynamics have also been shown to be more predictive of EBF than other demographics combined [10–12].

Although many low-income countries utilize community care-givers (CCGs) as a cost-effective mechanism to support mothers, the roll out of CCGs in South Africa has been slow, a lack of funding and confidentiality cited as reasons [13–17]. Therefore, alternative strategies for home-based support are needed. Pregnant women navigating the journey along the PMTCT cascade require support to negotiate and overcome the challenges and hazards they encounter [18]. HIV stigma impedes disclosure, acceptance and adherence to clinic guidelines, which include EBF [19]. Facility-based interventions are often inadequate to

affect sustained behavioural changes that enhance PMTCT guidelines in the face of multiple contextual factors [20]. These guidelines include EBF, disclosure of their status and adherence to ART [21]. The WHO research priorities are to investigate approaches to increase exclusive and sustained breastfeeding in the context of HIV, and find ways to support EBF rates in those women who are on ART [1]. The Feeding Buddy (FB) could potentially provide this timely and cost-effective help to women, to improve maternal and infant health outcomes and reduce the risk of transmission. An RCT evaluation of the Feeding Buddy programme would provide necessary evidence for the adoption of this programme on a national level. A pilot study found integrating a FB system into current PMTCT programs in SA could be a feasible option to encourage adherence to clinic visits and breastfeeding [22]. The *Windows of Opportunity Project* implemented such a programme in the uThungulu District of KZN, as part of their overall plan to improve maternal and child health in the first two years of the child's life [23]. The aim of this study was to evaluate the impact of this *Feeding Buddy* programme on improving the rates of EBF. Details of the protocol of the study have been described elsewhere [24].

Methods

The design was a cluster randomised control trial conducted in uThungulu District, KZN, in the sub-districts uMhlatuze and uMlalazi, which account for 58% of the district population, 78% of people receiving antiretroviral therapy and high numbers of women attending antenatal clinics during pregnancy.

Sample Size Estimation

Assuming a 25% EBF rate at 22 weeks [9], it was estimated that 16 clusters (8 per arm) with 41 women per cluster ($n=656$) were required to detect an assumed increase to 44%, with 80% power. The estimation, calculated in Stata 13 [25] using the Satterthwaite approximate F test for two-sample comparison of proportions with clustering, assumed an alpha-type-one error of 5% (two-tailed), a 0.25 coefficient of variation to account for within-group variation between clusters, and allowed for 20% loss to follow up.

Participants and Randomisation Procedure

Sixteen of the possible 27 clinics in these two sub-districts were available for selection, based on antenatal attendance rates and accessibility. Clinics with low antenatal bookings and a low attendance for well-baby clinics were excluded from randomisation. Local infrastructure and demographics were also considered to ensure the clinics were accessible to research staff. The clinics were stratified by locale (urban/rural/peri-urban), and within each stratum randomly allocated to intervention and control arm by the study statistician using a random number generated within Stata. This ensured that each arm of the trial contained one urban, three peri-urban and four rural clinics. Rural communities are characterised by traditional homesteads consisting of several mud houses, unpaved roads and minimal infrastructure such as sewage. Urban communities typically have formally constructed homes from brick and mortar with better infrastructure.

Women who were 26–34 weeks pregnant, 18 years or older, with documented HIV infection and were attending the PMTCT programme, who intended to deliver and remain within the area for at least six months after delivery, were planning to EBF, and were willing to participate, were included in the study. Informed consent was obtained from all participants.

S.A. has adopted a unified national message around breastfeeding in the context of HIV and all HIV-infected mothers are strongly encouraged to exclusively breastfeed their infants for the first six months of life, while taking ART. So when women were asked if they intended to breastfeed, they assumed this meant exclusive breastfeeding, as mixed feeding is discouraged due to increased risks of transmission. A clarification of what was meant by EBF was provided upon enrolment.

An additional criteria for mothers in the intervention clusters was the selection of a feeding buddy (partner, family member, friend or other) who they had disclosed their status to. The FB had to be willing to participate in the evaluation, support the mother to adhere to PMTCT recommendations, and accompany her on clinic visits, where possible. Seriously ill women were excluded from the study and referred for services and support.

Intervention

The *Feeding Buddy Programme* launched in March 2014. A FB was selected by the HIV-positive mother to accompany her on PMTCT clinic sessions and provide on-going support to adhere to the PMTCT guidelines, including psycho-social support [22].

The mother/buddy training was conducted by a professional company working in the field of public health, the messaging was based on materials developed by the provincial Department of Health to promote maternal and child health. This ensured consistent messaging within the Feeding Buddy Programme. Mothers and buddies were trained simultaneously, key messages on PMTCT included pregnancy, safe delivery and post-natal care. In addition, the training covered the importance of disclosure. The role of the FB was to encourage disclosure to family members to facilitate adherence to the PMTCT EBF recommendations and inform families of the reasons for doing this. Training covered exclusive breastfeeding and safe complementary feeding and discussed common barriers to EBF encountered in the community. Adherence to daily medication for both mother and infant was stressed, as was monitoring the growth of the baby and the importance of immunization. Illness and danger signs for which children need urgent medical attention, were also included. A take home booklet was produced so that mothers and their buddies had these messages as reminders. Further details are published in the RCT profile [24]. Two training sessions (each lasting an hour) were scheduled prior to delivery at regular ANC visits. Two follow-up training sessions occurred at the three day and six week well-baby clinic visits; again, where possible, the mother and her buddy were trained together. If the buddy missed the clinic visit, another date was set to train the buddy alone.

Data Collection

Control group enrolment commenced in August 2013, prior to the launch of the Feeding Buddy Programme to prevent ‘spill over effect’, and ended in June 2014. Intervention enrolment occurred from May to December 2014 and was initiated several months after the

program began, to allow for adequate roll-out. Some eligible women declined to participate as they had not disclosed their status to anyone, since disclosure was a criterion of enrolment.

Quantitative interviews in the intervention clinics took place with mothers and their chosen buddies, at enrolment during pregnancy and routine post-natal visits at day 3, week 6, 14 and week 22. These visits were scheduled at routine PMTCT, child health, and immunization visits and were conducted by trained research assistants. Women in the control clinics were followed using the same evaluation schedule.

Participants who missed scheduled visits were contacted twice over a period of a month, before being considered lost to follow-up. The primary outcome measure was exclusive breastfeeding, defined as no other food or drink (including water) other than breastmilk or expressed breast milk, with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines. At each interview mothers (and buddies) were asked a 24-hour recall of what they had been feeding their infants and if they had given the infant anything other than breastmilk in the period since their last visit. From this information, the classification of EBF was made for that visit and also used to calculate the duration of EBF

Socio-demographic data were collected concerning mothers, infants and buddies. In the intervention arm, the degree of contact between mother and buddy (exposure) was expressed as (1) 'buddy lives with mother' (yes or no), and (2) in those who did not, how often they spoke, recorded on 3 occasions (0 = never, 1 = at least twice per week and 2 = every day, during the past 2 weeks). A summary score was calculated as 1 (average over the three occasions = 1 or 2) or 0 (average < 1).

Exposure to training was calculated from information on training times and participant lists recorded by the implementer. Since the training did not proceed as planned, a simple binary variable was not appropriate. Instead a training score was calculated in retrospect, to reflect different levels of training received. Mothers scored higher if they attended more sessions, if the sessions were received earlier rather than later, and if sessions were administered as planned, rather than all at once or too late. It was calculated as follows:

$$\text{Total training score} = \text{weighted total sessions} * \text{spread score}$$

weighted total sessions = number of sessions received by 3d*3 + by 42d*2 + by 98d

spread score = 7 if training was received on all three occasions as planned (yes before 3 days, yes during 4–42 days and yes during 43–98 days), 6 (yes-yes-no), 5 (y-n-y), 4 (y-n-n), 3 (n-y-y), 2 (n-y-n), 1 (n-n-y) and 0 (n-n-n).

Data Analysis

Baseline characteristics of control and intervention groups were compared, while accounting for the clinic-level cluster design. For continuous variables, the means were compared with a two-sample t-test where the standard deviation (SD) was derived from the cluster-adjusted standard error (SE): $SD = \text{adjusted SE} * \sqrt{n}$. For categorical variables, the probability that the odds ratio between groups differed significantly from one was calculated using the Wald

chi-squared adjusted for clustering. The same approach was used when comparing baseline characteristics between mothers who completed the study and those who dropped out early. Breastfeeding results were analysed as interval-censored time-to-event data, with up to four time intervals per mother. Infant age (in days) at the post-natal interviews was used as the interval start and end points. An 'event' was defined as EBF having ceased.

Potential explanatory variables were explored in univariate Cox regression, fitting proportional hazards models via maximum likelihood (stcox command in Stata, using Breslow method for ties), and using interval mid-points as time variable. Standard errors were adjusted for intragroup correlation at clinic level. Variables with Wald chi-square probability <0.2 were explored further in multivariate Cox regression as follows: Mixed backward-forward stepwise variable selection was carried out on 1000 bootstrap samples drawn from the full dataset (with replacement). Starting with a full list of potential predictors and confounders, the procedure removed non-significant variables, one by one, highest p-values first, always checking whether previously-removed variables should be reintroduced. Entry and removal thresholds were $p=0.1$ and 0.2 respectively. The main intervention variable (study group), was always included. Variables were ranked based on how often they were selected into the 1000 separate multivariate models.

Using the full data set a multivariate model was derived, by adding variables in decreasing order of their selection frequency from the bootstrap procedure, as long as p-values remained below 0.2 .

The final model was developed in a stepwise manner as above, but on half the data only (a random 'training' subset), and predicted for all observations. Harrell's concordance C was calculated for predicted vs observed values in the remaining 'validation' data [26]. An increase of C exceeding 10% is usually used as cut-off, but since overall model fit was weak, variables were included if they led to *any* increase in concordance. Interaction terms were then calculated for all variables included in the model, added one-by-one, and then together, to the full model, and assessed using Harrell's C as described above. Proportional hazards assumptions were tested using Schoenfeld residuals [27].

Results

Participant Flow

From 619 mothers enrolled, 277 control and 273 intervention mothers (89%) remained for analysis (Figure 1). In the intervention group 95 pre-enrolled mothers were unable to find FBs and so were unable to continue to enrolment as they did not meet the selection criteria. Two rural clinics in the control group, where only two and three mothers were enrolled, were excluded. Thus, control mothers were over-represented in peri-urban clinics and intervention mothers in rural clinics. On average 39 women were enrolled per clinic, ranging from 17 to 87.

Baseline Data

The two groups were similar in most respects at baseline (Table I), but control mothers were more likely have breastfed their last born and less likely to have tertiary education or electricity in their home.

Outcomes and Estimation

EBF rates at the final interview (approximately 22 weeks post- delivery) were similar for the control and intervention group: 44.68% (105/235) and 42.75% (109/255) respectively ($p = 0.67$).

In the time-to-event data the difference in EBF duration between groups was also non-significant (log-rank test for equality of survivor functions: $\chi^2 = 0.9$, $p = 0.34$). Median survival time (infant age where probability of EBF = 50%) was 139.5 days (119.5–144.5) and 144.5 days (133–151.5) for the control and intervention group respectively.

A number of variables were significantly correlated with EBF, (Table II). Mean hazard ratios across the 1000 multivariate regression models were generally similar to those in univariate regression. There were some reversals, where a variable was positively associated with EBF duration on its own, but negatively once other co-variables were accounted for.

Selection frequency in the bootstrap procedure (Figure 2) ranged from nearly 100% (previous breastfeeding experience) to as low as 17% (buddy lives with mother). The most frequently selected variables had a stable effect, either positive or negative: the 1–99% quantile range did not straddle 1 (Table II).

The top eleven were selected manually into the semi-final multivariate model, based on variable-specific p -values (Table II). With the more rigorous method, which demanded increasing concordance in the validation data set, three of these variables failed to be included (Table III).

In the final model (Table III) the main intervention (having a Feeding Buddy) remained non-significant. However, training had a significant effect on prolonging EBF ($HR = 0.992$, $p = 0.036$). Every extra point in the training score reduced the risk of stopping EBF by 0.8%, to a maximum reduction of 46% for the highest score of 66. Figure 3 shows the intervention group EBF survival curves stratified by training score quantiles (Figure 3).

An urban setting and being employed increased the risk that mothers would stop EBF by 66 and 64% respectively ($p < 0.0001$), and having over 5 rooms increased the risk by 27% ($p = 0.024$). Having breastfed a previous child, having a caesarean section, and being visited at least once by a CCG were each significantly associated with a longer duration of EBF or a 25–30% reduction in the hazard ratio. (Table III).

Mothers who did not complete the study ($n=60$) compared to those who did ($n=490$) were similar in all baseline characteristics except in the fact that they were significantly less likely to have had a CCG visit ($p < 0.0001$) and transport access to the clinic ($p = 0.006$).

Discussion

Interpretation

The main finding, that there was no significant difference in EBF rates between and control and intervention groups, was unexpected, since previous systematic reviews reported that support by lay peer counsellors (PCs) improved initiation and duration of EBF in various low or middle-income countries [28–31]. The PROMISE-EBF randomised control trial (RCT) conducted in sub-Saharan Africa [32] which aimed to determine the effect of PCs on rates of exclusive breastfeeding, found that PCs almost doubled the rate of EBF in the South African site, albeit from a very low baseline rate of six percent. In this study five counselling sessions were provided – one prior to delivery and then at 1, 4, 7, and 20 weeks post-delivery. Results from the qualitative sub-study however revealed that there was not a high level of acceptance of PCs by South African mothers [16]. In this qualitative sub-study, 17 of the mothers supported by PCs were interviewed about their infant feeding choices, and results reported that 75% of mothers voiced a distrust of PCs. In addition, the PC had little impact on the mother's views of infant feeding, neither on overcoming barriers associated with it [16]. Tomlinson et al. [33] however found that professional community health workers doubled the rate of EBF in a RCT conducted in South Africa. In this study, unlike the PROMISE-EBF study, the intervention began during pregnancy (two visits) and early postnatal follow-up was prioritized, with a total of seven home visits being conducted. The discrepancies in these findings seem to indicate that these are complex, multifactorial issues.

Another Kenyan study found no increase in EBF rates following a counselling intervention, suggesting that local barriers and the context in which women breastfeed need to be addressed [34]. In addition to the context, the other crucial element however appears to be the training, supervision and remuneration of PCs as indicated in a systematic review conducted by Chapman et al. [29]. Tuthill et al. [8] suggested the Behavioural Change Model be used to ground future training of health care professionals around infant feeding, as their research found most of the challenges identified in counselling had a psychosocial basis. These findings appear to reinforce suggestions that training received and context in which PCs operate are key to successful, meaningful and relevant counselling around EBF. Inadequately trained PCs are not perceived as 'experts' or as having sufficient authority to provide the necessary support to improve EBF.

The timing and quality of training provided by the Feeding Buddy Programme - which was being evaluated - varied, as there appeared to be insufficient trainers to cover all the participating clinics, so the sessions were often not executed timeously. Higher training scores, as assigned in data analysis to allow for dose-response, were associated with longer EBF duration. This supports a link by association that well-timed and repeated training can be effective.

Unlike PC's in other studies, Feeding Buddies in this study were chosen by mothers. They were family members or friends whom they trusted, and they were trained together with the mother and encouraged to attend the clinic with her. Despite this support, sustained EBF remained difficult in the face of their own traditional belief system, as well as those who had influence over them [35]. Comprehensive reviews have found that early mixed feeding is

deeply engrained in African culture. This, together with socio-economic factors and pressure from families, make it difficult for women to adhere to EBF recommendations, even when supported [36].

In addition, the frequent changing of official PMTCT guidelines have left women and health care workers doubtful concerning the safety of breastfeeding [37]. Stigma associated with EBF and HIV remains an issue within communities and outweighs all recommendations and health benefits for HIV positive women [9]. More openness around HIV issues within communities and families is needed to reshape norms around infant feeding [7]. Including family members in antenatal training and raising community awareness should form an essential part of PMTCT [38].

Despite these difficulties, EBF duration was significantly higher in women who had breastfed before. The proficiency of previous breastfeeding experiences has been reported before, and provides the confidence to successfully breastfeed again [39].

In our data, caesarean section was associated with increased EBF duration. Previous studies have been divided on this issue: one systematic review and two other studies found elective caesarean section to be associated with lower breastfeeding rates and early breastfeeding cessation, while another systematic review found no association with negative breastfeeding outcomes [40–43]. In our study, local health care facilities emphasize skin-to-skin contact post-surgery and early initiation of breastfeeding; which may well lead to increased EBF. These mothers had longer contact with the health workers/facility compared with mothers having an uncomplicated vaginal delivery, who are typically discharged within six hours of delivery.

EBF duration was slightly lower in urban areas and in women who had five or more rooms in their home. The reason for the effect of rooms is not very clear, but may have something to do with large extended families seen in mainly rural settings. Here several people may be involved in the role of caregiving, thus affecting the mother's practice of EBF. Of the other factors considered, being employed was the most significant predictor of EBF cessation. In our qualitative study (in press) despite knowing the advantages of breastfeeding and the promotion through multiple avenues, mothers indicated they would choose to formula feed if they had the funds. Reasons for this could be the fear of HIV transmission while breastfeeding, especially if there was non-adherence to their antiretroviral regime, but could also be due to the prevailing belief of the insufficiency of breastmilk to meet the needs of the growing infant [44, 45].

Finally, in 15% of mothers in this study who received even a single visit by a CCG during the observation period, EBF duration was significantly higher and loss to follow-up lower. Over half the CCG visits occurred in rural areas, the urban clinics did not have CCGs attached to them.

EBF is a complex issue, which is multi-factorial, and therefore programmes to improve EBF rates need to take cognisance of all the factors which influence it.

Limitations

The Demographic Health Survey data on populations attending clinics was inaccurate, which affected our assumptions of the number of mothers attending the clinics. This resulted in two of the control clinics having to be excluded due to insufficient enrolment. Both were rural clinics which reduced the number of rural clusters in the control group, compared with the intervention group. Despite randomization, the intervention and control groups differed in the following variables: education; having breastfed their last child; electricity in the home. However, taking account of clustering in the analyses compensates for these differences.

A further limitation of the study was the lack of adequate training which affected outcomes as planned, resulting in the analysis plan being changed. The findings may not be generalizable to other HIV prevalent contexts, due to the specific situation in South Africa as outlined in the discussion.

Conclusion

As an implementation science research study, operationalizing the feeding buddies program was out of the researchers' control. Practical realities typical of programme implementation, such as delays stated, as well as irregular training scheduling potentially compromised the effectiveness of the feeding buddies to improve EBF. Similar programs should prioritize these key components to achieve community and health care worker awareness and maintain quality. However, these are and remain the challenges of implementing actual PMTCT programmes.

This study suggests that, possibly due to multiple complex factors discussed earlier (social, psychological, cultural and economic barriers) FBs on their own did not improve EBF duration. However, importantly, when the level and timing of training was considered, better and timeously trained mothers were found to EBF up to 45% longer than badly-trained or untrained mothers. This is an encouraging finding that has potential to guide the development of future EBF support programmes. Well trained community or professional support appear to be key to successfully improving EBF rates as opposed to untrained peer support.

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Figure 1.
Study enrolment, retention and loss to follow-up.

Figure 2.

Frequency with which potential explanatory variables got selected into cox regression models, during step-wise selection on 1000 bootstrap samples, with group always included.

Figure 3.

Probability that control and intervention mothers are still EBF at increasing infant age. The Kaplan-Meier survival estimates are stratified by training score (score of <30, 30–60 and >60) and adjusted for employment, previous breastfeeding experience, caesarean delivery, over 5 rooms, urban setting and at least one CCG visit, as in final cox regression model.

Table 1

Baseline Characteristics of women included in analysis. For continuous variables: mean with confidence interval (adjusted for clustering at clinic level); two-sample t-test using standard deviation (SD) based on adjusted standard error (SE): SD=adjusted SE*sqrt(n); probability that the two means are equal. For categorical variables: count; proportion with confidence interval (adjusted for clustering at clinic level); odds ratio (OR); Wald chi-squared adjusted for clustering; probability that odds ratio = 1.

Characteristic	n	Control, N= 277/mean or prop	n	Intervention, N= 273/mean or prop	Test t / OR	Wald chi ²	p-value
Mother							
Age (years) range=18–44		28.8 (27.5–30.0)		28.4 (27.5–29.2)	0.62		0.54
Married	21	7.6% (5.4–9.8%)	24	8.8% (3.8–14%)	1.2	0.25	0.62
Living with partner ^a	63	24.1% (12–36%)	68	25.5% (17–34%)	1.1	0.04	0.84
Education							
None	7	2.5% (0.1–4.9%)	6	2.2% (0.2–4.2%)	0.87	0.05	0.82
Primary	37	13.4% (4.6–22%)	34	12.5% (–0.7–26%)	0.92	0.01	0.90
Secondary	226	81.6% (72–92%)	196	71.8% (57–86%)	0.57	1.5	0.22
College	5	1.8% (–0.8–4.5%)	30	11.0% (1.3–21%)	6.7	5.3	0.02
University	2	0.7% (–0.9–2.3%)	7	2.6% (0.2–4.9%)	3.6	1.4	0.24
Employment							
None	199	71.8% (59–84%)	181	66.3% (61–71%)	0.52	2.9	0.09
Employed	63	22.7% (12–33%)	65	23.8% (19–29%)	1.1	0.04	0.85
Self-employed	9	3.2% (1.4–5.1%)	12	4.4% (2.2–6.6%)	1.4	0.73	0.39
Student	6	2.2% (0.0–4.3%)	15	5.5% (1.7–9.2%)	2.6	2.8	0.10
Pregnancy outcomes							
Primiparous	55	19.9% (12–27%)	57	20.9% (16–25%)	1.1	0.06	0.80
Breastfed last child ^b	187	84.2% (79–89%)	161	74.5% (68–81%)	0.55	6.8	0.01
Infant							
Caesarean delivery	79	28.5% (20–37%)	72	26.4% (23–30%)	0.90	0.26	0.61
Birth weight (kg) range=1.1–8		3.14 (3.07–3.21)		3.13 (3.05–3.21)	0.13		0.90
Gestational age (weeks) range=26–39		29.0 (28.5–29.6)		28.9 (28.6–29.2)	0.49		0.63
Socio economic							
Clinic Setting							
Urban	52	18.8% (–19–57%)	46	16.8% (–17–51%)	0.88	0.01	0.93

Characteristic	n	Control, N= 277/mean or prop	n	Intervention, N= 273/mean or prop	Test t / OR	Wald chi ²	p-value
Peri-urban	255	58.1% (11–100%)	161	34.4% (–4–73%)	0.38	0.66	0.42
Rural	64	23.1% (–12–59%)	133	48.7% (7.7–90%)	3.2	0.93	0.34
Children <5 in house							
None	102	36.8% (29–45%)	106	38.8% (30–48%)	1.1	0.13	0.72
1 child	97	35.0% (30–40%)	90	33.0% (28–38%)	0.91	0.43	0.81
2 children	41	14.8% (8.6–21%)	43	15.8% (10–21%)	1.1	0.06	0.81
3+ children	37	13.4% (9.9–17%)	34	12.5% (8.5–16%)	0.92	0.14	0.71
More than 5 rooms	81	29.2% (13–45%)	94	34.4% (22–47%)	1.3	0.31	0.58
Running water	203	73.3% (56–91%)	196	71.8% (53–91%)	0.93	0.02	0.90
Flushing toilet	62	22.4% (7.4–37%)	70	25.6% (10–41%)	1.2	0.11	0.75
Electricity	170	61.4% (34–89%)	233	85.4% (76–95%)	3.7	4.0	0.045

^a among 528 women whether married or not who did have a partner

^b among 438 women who had a previous child and responded to the question

Table II

Hazard ratios, z-scores and p-values of potential predictors and confounders of exclusive breastfeeding, in cox regression on interval-censored time-to-event data, with clustering at the clinic level: results from univariate regression; mean hazard ratios, with 1% and 99% quantiles, from the bootstrap models; results for the semi-final model derived in manual forward stepwise regression., are also shown.

Variable	Univariate Cox regression	Multivariate Cox regression	
	Hazard ratio (z-score, p value)	Bootstrap results Mean hazard ratio (1 – 99% quantiles)	Final model Hazard ratio(z-score, p-value)
Group	0.90 (−0.49, p=0.62)	0.97 (0.37–2.01)	1.12 (0.96, p=0.34)
Intervention variables			
Buddy lives with mother	0.922 (−0.45, p=0.65)	1.16 (0.63–1.48)	
Buddy talks to mother at least once a week	0.923 (−0.36, p=0.72)	1.38 (0.37–3.24)	
Training score (ordinal, 0–66)	0.9924 (−2.2, p=0.03)	0.991 (0.976–0.997)	0.992 (−2.1, p=0.036)
CCG visit, at least one	0.636 (−2.7, p=0.006)	0.64 (0.43–0.82)	0.730 (−1.8, p=0.073)
Infant			
Caesarean delivery	0.835 (−1.9, p=0.06)	0.71 (0.53–0.86)	0.734 (−3.0, p=0.003)
Mother			
Education, vs Primary or None:			
Secondary	1.52 (1.6, p=0.11)	1.54 (0.72–2.84)	
Tertiary	2.03 (2.3, p=0.02)	1.73 (0.46–4.09)	
Employment, vs Unemployed:			
Employed	1.62 (4.5, p=0.000)	1.79 (1.33–2.53)	1.71 (4.5, p=0.000)
Self-employed / student	1.38 (1.6, p=0.11)	1.72 (1.28–2.85)	1.35 (1.3, p=0.19)
Married	1.33 (1.6, p=0.11)	1.64 (0.53–2.62)	1.29 (1.3, p=0.18)
Live with partner	1.10 (0.90.37)	1.35 (0.57–1.9)	
No partner	0.637 (−1.2, p=0.21)	0.61 (0.21–2.09)	
Live births (count)	0.913 (−1.5, p=0.13)	0.83 (0.69–0.93)	
Breastfed lastborn	0.673 (−2.9, p=0.004)	0.63 (0.42–0.82)	0.694 (−3.8, p=0.000)
Primigravid	0.813 (−1.1, p=0.25)	0.58 (0.35–0.77)	
Socio-economic			
Setting of clinic, vs Rural:			
Peri-urban	0.963 (−0.2, p=0.85)	0.85 (0.46–2)	
Urban	1.90 (3.3, p=0.001)	1.82 (0.63–3.14)	1.57 (3.4, p=0.001)
Number of children <5 in house			
Categorical, vs No children:			
1 child	1.21 (1.4, p=0.17)	1.33 (1.13–1.73)	
2 children	0.940 (−0.3, p=0.75)	0.92 (0.62–1.78)	
3+ children	1.24 (1.2, p=0.24)	1.52 (0.76–2.32)	
Number of rooms in household			
Categorical, vs 1–2 rooms:			
3–5 rooms	1.03 (0.3, p=0.78)	1.09 (0.7–1.42)	
6+ rooms	1.21 (1.6, p=0.11)	1.41 (1.19–1.92)	1.28 (2.2, p=0.024)
Running water in home	1.11 (1.0, p=0.32)		

Variable	Univariate Cox regression	Multivariate Cox regression	
	Hazard ratio (z-score, p value)	Bootstrap results Mean hazard ratio (1 – 99% quantiles)	Final model Hazard ratio(z-score, p-value)
Flush toilet	1.29 (2.4, p=0.017)	1.16 (0.59–1.93)	
Electricity	0.743 (–2.0, p=0.05)	1.38 (1.14–1.84)	1.28 (2.4, p=0.017)

Table III

Results of the Cox proportional hazards regression model, showing effect of selected variables, robust standard error (SE), z-scores, p-values, and hazard ratios with confidence intervals (CI). $N = 1459$, Wald $\chi^2 = 160$, $p = <0.0001$.

Variable	Coefficient	Robust SE	z-score	p-value	Hazard Ratio (95% CI)
Intervention group	0.191	0.15	1.6	0.113	1.21 (0.96–1.53)
Employed	0.506	0.19	4.4	<0.001	1.66 (1.32–2.08)
Previous BF	−0.354	0.070	−3.5	<0.001	0.7 (0.58–0.85)
Caesarean	−0.292	0.077	−2.8	0.005	0.75 (0.61–0.91)
Training score	−0.0082	0.0038	−2.1	0.033	0.992 (0.984–0.999)
6+ rooms	0.242	0.14	2.3	0.024	1.27 (1.03–1.57)
Urban	0.492	0.20	4.0	<0.001	1.64 (1.29–2.08)
CCG visit	−0.362	0.12	−2.0	0.044	0.7 (0.49–0.99)