Ten Steps to Successful Breastfeeding programme to promote early initiation and exclusive breastfeeding in DR Congo: a cluster-randomised controlled trial

Marcel Yotebieng, Miriam Labbok, Heidi M Soeters, Jean Lambert Chalachala, Bruno Lapika, Bineti S Vitta, Frieda Behets

Summary

Background Optimisation of breastfeeding practices could reduce high mortality rates in children younger than 5 years, but in DR Congo, despite near-universal breastfeeding initiation and nine of ten children still breastfeeding at 1 year of age, exclusivity remains a difficulty. We assessed the effect on breastfeeding outcomes of a short-cut implementation of a programme called the Ten Steps to Successful Breastfeeding, the key component of the Baby-Friendly Hospital Initiative (BFHI).

Methods We did a cluster-randomised controlled trial and randomly assigned health-care clinics in Kinshasa, DR Congo, to standard care (control group), BFHI steps 1–9 (steps 1–9 group), or BFHI steps 1–9 plus additional support during well-child visits (steps 1–10 group) with computer-generated random numbers used to assign matched pairs to study groups. Mothers at these clinics who had given birth to one healthy baby during enrolment, and who expressed their intentions of visiting a well-baby session at the same clinic, were eligible and received the treatment assigned to their clinic. Mother–infant pairs that were excluded if the mothers intended to attend well-baby clinic visits at a different health facility, or to travel before the child was aged at least 6 months. Participants and independent interviewers were masked to group assignment (ie, they were recruited after randomisation and training of the clinical staff and were not informed of the study scheme), but clinical staff were unmasked. BFHI steps 1–9 and 1–10 were given by health-care staff trained with the WHO/UNICEF BFHI course. The primary outcomes were breastfeeding initiation within 1 h of birth and exclusive breastfeeding at age 14 and 24 weeks, assessed at face-to-face interviews in the clinic. Analysis was by intention to treat. Prevalence ratios (PR) were adjusted for cluster effects and baseline characteristics. This trial is registered at ClinicalTrials.gov, number NCT01428232, and is closed to new participants.

Findings Between May 24, and Aug 25, 2012, we randomly assigned two eligible clinics to control, two to BFHI steps 1–9, and two to BFHI steps 1–10. We enrolled 975 eligible mother–infant pairs (304 in the control group, 363 in the steps 1–9 group, and 308 in the steps 1–10 group). 230 (76%) of infants in the control group, 263 (72%) in the steps 1–9 group, and 220 (71%) in the steps 1–10 group were breastfed within 1 h of birth; these results did not differ significantly between groups. Prevalence of exclusive breastfeeding at age 14 weeks was 89% (95% CI 88–90) in the control group, 237 (65%) in the steps 1–9 group (adjusted PR 2.20, 95% CI 1.73–2.77), and 129 (42%) in the steps 1–10 group (1.40, 1.13–1.74). At age 24 weeks, the prevalence of exclusive breastfeeding was 36% (12%) in the control group, 131 (36%) in the steps 1–9 group (3.50, 2.76–4.43), and 43 (14%) in the steps 1–10 group (1.31, 0.91–1.89).

Interpretation In the setting of health-care clinics in DR Congo with a high proportion of mothers initiating breastfeeding, implementation of basic training in BFHI steps 1–9 had no additional effect on initiation of breastfeeding but significantly increased exclusive breastfeeding at 6 months of age. Additional support based on the same training materials and locally available breastfeeding support materials, offered during well-child visits (ie, step 10) did not enhance this effect, and might have actually lessened it.

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The predominant role of diarrhoea, pneumonia, and malaria in mortality and poor growth during the post-neonatal period, suggest suboptimum infant feeding practices. Best breastfeeding practices, including immediate post-partum initiation of skin-to-skin contact and breastfeeding within 1 h of birth, exclusive breastfeeding for 6 months, and continuation of breastfeeding up to 24 months and beyond in accordance with age-appropriate feeding, have great potential for reducing mortality in children younger than 5 years. In DR Congo, despite near-universal initiation of breastfeeding and nine of ten children still breastfeeding at age 1 year, poor exclusivity of breastfeeding remains a problem. National surveys show that in 2010, only 69% of babies aged 0–1 month and 35% of those aged 2–3 months (about 10–14 weeks) were exclusively breastfed. Since 1990, global initiatives to improve breastfeeding practices have focused on maternity-level policies and practices known as the Ten Steps to Successful Breastfeeding (panel), which are the basis for the Baby-Friendly Hospital Initiative (BFHI). However, successful implementation of BFHI resulting in certification is a challenge, and many countries in sub-Saharan Africa have not been able to scale it up nationwide. In DR Congo, UNICEF led the main attempt to implement BFHI in the early 2000s as part of a national campaign to promote breastfeeding. Overall, only 25 health facilities in DR Congo, including 13 in the capital Kinshasa, of more than 6000 eligible health facilities were certified through this effort. The need for additional resources to organise the implementation warrant further investigation, efforts should be renewed to provide health-care personnel with the appropriate skills they need to support optimum breastfeeding, especially in countries with a high prevalence of child mortality.

Evidence before this study
The rationale for our investigation was based on a 2007 Cochrane review of 44 trials in 14 countries and a review by the US Agency for Healthcare Research and Quality, which both showed that all forms of extra support had a positive effect on the duration of exclusive breastfeeding, and that the treatment effect was greater when the intervention was delivered by non-professionals (lay support). But whether those findings were applicable in Africa was unclear because no study of healthy mothers from this region was included in the reviews. The Cochrane review was updated in 2011, but only two of the 52 studies included in the update were from low-income countries and only one was from Africa. In a study called PROMISE, undertaken in Burkina Faso, Uganda, and South Africa, breastfeeding counselling by peer counsellors (lay support) had a substantial positive effect on the prevalence of exclusive breastfeeding. On Jan 24, 2015, we searched PubMed for English-language publications with the terms “randomized control trial”, “breastfeeding”, and “promotion”, and identified results from four trials that were reported since the updated Cochrane review published in 2011. Again, only one of those trials was done in Africa (Nigeria), which showed that monthly group counselling by trained peer educators (lay support) combined with text and voice messages sent every week had a positive effect on timely initiation of breastfeeding and on exclusive breastfeeding at 6 months. Additionally, diarrhoea and infections of the respiratory tract have been the most frequently reported child-health outcomes related to breastfeeding peer counselling. Five studies from the updated Cochrane review have reported about diarrhoea and two about infections of the respiratory tract. In each investigation, the number of babies with reported diarrhoea or infections was reduced in the intervention groups.

Added value of this study
A short-cut implementation of the Ten Steps to Successful Breastfeeding by training health personnel with the WHO/UNICEF training course in Democratic Republic of the Congo (DR Congo) resulted in effects similar to those noted from interventions with lay workers in previous studies. This low-intensity, non-technical intervention, which is very suitable for rapid scale-up, raised the prevalence of exclusive breastfeeding and decreased the rate of diarrhoea at age 6 months in our context of high breastfeeding initiation, and high prevalence of mortality in children younger than 5 years in DR Congo. However, additional support during well-child visits did not increase these effects, and might actually have lessened them.

Implications of all the available evidence
Although the scalability and cost-effectiveness of this short-cut implementation warrant further investigation, efforts should be renewed to provide health-care personnel with the appropriate skills they need to support optimum breastfeeding, especially in countries with a high prevalence of child mortality.
serve as an easy-to-implement alternative for step 10 of the BFHI.

The objectives of our study were therefore to compare against standard of care the effectiveness of implementation of steps 1–9 and steps 1–10 (additional breastfeeding support provided during well-child clinic visits), of the BFHI on initiation and exclusivity of breastfeeding in a health-care setting in DR Congo.

**Methods**

**Study design and participants**

We did a cluster-randomised controlled trial, with health-care facilities as the unit of randomisation, in Kinshasa, DR Congo. We selected six health facilities from a network of 44 that, at the time, were being supported by the University of North Carolina at Chapel Hill and Kinshasa School of Public Health partnership to implement activities to prevent mother-to-child transmission of HIV. To inform the selection, study staff (two medical doctors) visited all 44 facilities between October, and November, 2011, and collected information about factors that might affect the quality of care provided in each facility, including the type of management, location, number of deliveries, number and type of personnel, presence of a separate well-child clinic and a maternity clinic, and proportion of mothers who return for the 1 week post-partum visit. Health-care facilities were then stratified by location (urban or periurban) and type of management (government, confessional, or private for-profit). Government and private for-profit health facilities were excluded because they were almost all exclusively located in the urban area. Within each stratum, facilities were sorted by the number of deliveries and the proportion of mothers returning for the 1 week post-partum visit and matched across strata for the average workload (number of deliveries divided by number of personnel), Three pairs of facilities with relatively similar workloads, number of deliveries per month, and proportion of mothers returning for the 1 week visit were selected. This selection scheme was chosen to ensure, for example, that health-care facilities at the centre of the city, which might have lower patient volumes and more patients with a higher socioeconomic status than facilities in periurban areas, were included in the final sample while reducing the overall heterogeneity among the selected facilities.

All mothers who gave birth to one healthy child in one of the participating facilities between May 24, and Aug 25, 2012 and who intended to attend well-baby clinic visits in the same facility were eligible. Mother–infant pairs were excluded if they intended to attend well-baby clinic visits in a different health facility, or to travel before the child was aged at least 6 months. To recruit suitable participants, we approached eligible mothers in the post-partum wards of each participating clinic 1–2 days after delivery, and invited them to participate in our study. All participants provided written informed consent. The study was approved by the Institutional Review Board of the University of North Carolina at Chapel Hill and the Ethical Committee of the Kinshasa School of Public Health.

**Randomisation and masking**

The three pairs of facilities were ranked alphabetically and a computer was used to generate three random numbers. The randomisation was done by the study statisticians who had no involvement in enrolment or follow-up of participants. A priori, the pair with the highest number was assigned to the standard of care (control group), the second to the implementation of BFHI steps 1–9 alone (steps 1–9 group), and the last pair with the lowest number to the implementation of BFHI steps 1–9 plus additional support provided in well-child clinics (steps 1–10 group). We assigned the facilities rather than mother–infant pairs to the implementation of BFHI steps 1–9 plus additional support provided in well-child clinics (steps 1–10 group).

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For the study protocol see http://cph.osu.edu/sites/default/files/biopage/docs/BFHI_Promotion_and_Support_of_Exclusive_Breastfeeding_5_Months_May_18_11.docx

For more on the Baby-Friendly Hospital Initiative see http://www.unicef.org/programme/breastfeeding/baby.htm

**Panel: Ten Steps to Successful Breastfeeding**

The Ten Steps to support successful breastfeeding serve as the basis for the Baby-Friendly Hospital Initiative. The steps are:

1. Having a written breastfeeding policy that is routinely communicated to all health-care staff
2. Training all health-care staff in skills necessary to implement this policy
3. Informing all pregnant women about the benefits and management of breastfeeding
4. Helping mothers to initiate breastfeeding within 30 min of birth
5. Showing mothers how to breastfeed and maintain lactation, even if they are separated from their infants
6. Giving newborn infants no food or drink other than breastmilk, unless medically indicated, and not accepting free or low-cost breastmilk substitutes, feeding bottles, or teas
7. Allowing mothers and infants to remain together 24 h per day
8. Encouraging breastfeeding on demand
9. Giving no artificial teats or pacifiers to breastfeeding infants
10. Fostering the establishment of breastfeeding support groups and referring mothers to them on discharge from a hospital or clinic

Additional material on the Baby-Friendly Hospital Initiative can be accessed on the UNICEF website.
Procedures
For implementation of steps 1–9 in clinics randomly assigned to the steps 1–9 and 1–10 groups, we trained health-care staff from antenatal and maternity care (ie, delivery rooms and post-partum wards) in the intervention facilities using the WHO/UNICEF course12 (for more detail of training, see appendix). No organised breastfeeding support system, whether informal or formal, where mothers can be referred to get support when needed, is available in Kinshasa. Therefore Session 14 of the training on “Ongoing support for mothers” was limited only to “Describe how to prepare a mother for discharge”. Session 15 on “Making your hospital baby-friendly” was not covered. For facilities in the steps 1–10 group, staff from well-child clinics also received the same training. Although the development of community groups where women could be referred for support after discharge from the postpartum ward was not fostered, the well-baby clinic and its trained staff was to serve as a clinic-based alternative. Additionally, for the steps 1–10 facilities, we distributed flyers containing locally developed materials with culturally appropriate messages addressing behaviours identified in a pretrial survey as main contributors to sub-optimal breastfeeding practices, in French (the official language of DR Congo) and Lingala (the main spoken language in Kinshasa) to mothers before discharge. We also provided additional material in French developed in part by the Linkages project for clinic staff.

We obtained outcome information through face-to-face interviews at enrolment (in the post-partum ward 2–3 days after birth), age 1 week (at the post-partum clinic visit), and age 6, 10, 14, 18, and 24 weeks (at well-child visits). In addition to sociodemographic characteristics of the mother–infant pair that we obtained at enrolment, we assessed infant feeding practices at each timepoint, and asked mothers whether their infant had had any diarrhoea, fever, or cough since the last interview. For mother–infant pairs who did not return for a visit, interviewers traced them and visited them at home, interviewing them within 2 weeks of the missed visit. We double-entered questionnaire data for assessment and regularly compared them, to correct for inconsistencies.

Outcomes
We assessed two coprimary outcomes: the proportion of mothers who initiated breastfeeding within 1 h of birth and the prevalence of exclusive breastfeeding at 14 and 24 weeks post partum. WHO definitions17 and two timeframes (the past 24 h and past 7 days) were used for maternal recall of exclusive breastfeeding. We also assessed two secondary outcomes: the prevalence of infants with reported diarrhoea and the prevalence with reported respiratory illness (fever with cough) between 10 and 14 weeks and between 18 and 24 weeks post partum.

Statistical analysis
We calculated sample sizes for exclusive breastfeeding at age 14 and 24 weeks. We assumed a coefficient of

| Where or to whom intervention was delivered | Standard of care group | Steps 1–9 group | Steps 1–10 group |
|-------------------------------------------|------------------------|----------------|-----------------|
| Training                                  | None                   | ANC clinic staff | ANC clinic staff |
|                                           |                        | Delivery room staff | Delivery room staff |
|                                           |                        | Post-partum ward staff | Post-partum ward staff |
| Documentation                              | None                   | ANC clinics       | ANC clinics      |
|                                           |                        | Delivery room    | Delivery room   |
|                                           |                        | Post-partum ward | Post-partum ward |
|                                           |                        | Well-baby clinic | Well-baby clinic |
| Community support                          | None                   | None             | None            |
|                                           |                        | Post-partum ward | Post-partum ward |
|                                           |                        | Well-baby clinic | Well-baby clinic |

BFHI=Baby-Friendly Hospital Initiative. ANC=antenatal care.

Table 1: Interventions by study group
Table 2: Demographic characteristics of mothers at enrolment

| Feature                                      | Overall (310 [100%]) | Control (304 [31%]) | BFHI steps 1–9 (363 [37%]) | BFHI steps 1–10 (308 [32%]) |
|----------------------------------------------|-----------------------|----------------------|-----------------------------|-----------------------------|
| Age (years)                                  | 27 (23–32)            | 28 (24–33)           | 26 (23–32)                  | 26 (22–31)                  |
| Marital status                               |                       |                      |                             |                             |
| Married/live-in boyfriend                    | 847 (87%)             | 269 (88%)            | 322 (89%)                   | 256 (83%)                   |
| Never married/separated/divorced             | 127 (13%)             | 35 (12%)             | 41 (11%)                    | 51 (17%)                    |
| Education (years)                            | 10 (8–12)             | 11 (8–12)            | 9 (7–12)                    | 10 (8–12)                   |
| Owns the house where she lives?              |                       |                      |                             |                             |
| Yes                                          | 415 (43%)             | 146 (48%)            | 130 (36%)                   | 139 (45%)                   |
| No                                           | 557 (57%)             | 158 (52%)            | 230 (63%)                   | 169 (55%)                   |
| Electricity in house?                        |                       |                      |                             |                             |
| Yes                                          | 947 (94%)             | 279 (92%)            | 346 (95%)                   | 292 (95%)                   |
| No                                           | 58 (6%)               | 23 (8%)              | 17 (5%)                     | 16 (5%)                     |
| Water source                                 |                       |                      |                             |                             |
| Piped yard or home                           | 852 (87%)             | 246 (81%)            | 318 (87%)                   | 288 (94%)                   |
| Borehole/tap/surface water                   | 122 (13%)             | 59 (19%)             | 45 (13%)                    | 19 (6%)                     |
| Type of toilet                               |                       |                      |                             |                             |
| Flush                                        | 418 (43%)             | 81 (27%)             | 179 (49%)                   | 158 (51%)                   |
| Pit/open/none                                | 557 (57%)             | 223 (73%)            | 184 (51%)                   | 150 (49%)                   |
| Parity                                       |                       |                      |                             |                             |
| Primiparous women                            | 238 (24%)             | 81 (27%)             | 78 (21%)                    | 79 (26%)                    |
| Multiparous women                            | 737 (76%)             | 223 (73%)            | 285 (79%)                   | 229 (74%)                   |
| Previously had a child who died?             |                       |                      |                             |                             |
| Yes                                          | 191 (20%)             | 67 (22%)             | 78 (21%)                    | 46 (15%)                    |
| No                                           | 784 (80%)             | 257 (88%)            | 285 (79%)                   | 262 (85%)                   |
| Place of attendance of antenatal clinic visit|                       |                      |                             |                             |
| Facility                                     | 888 (93%)             | 278 (93%)            | 329 (91%)                   | 281 (91%)                   |
| Outside facility                             | 80 (8%)               | 24 (8%)              | 29 (8%)                     | 27 (9%)                     |
| No antenatal care                            | 7 (<1%)               | 2 (<1%)              | 5 (1%)                      | 0                           |

Data are mean (%) or median (IQR). *Type of toilet, electricity in the house, and water sources were highly correlated. Thus, of these three categories, only type of toilet was included in the adjusted models. Not all variables were available for each mother–infant pair.

Table 2: Demographic characteristics of mothers at enrolment

 variation of 25% and a 15% prevalence of exclusive breastfeeding in the control group at 6 months, and calculated that a minimum of two clusters with 150 mother–infant pairs per group was needed to detect a minimum increase of 20% compared with standard of care with 90% power (appendix).

We did an intention-to-treat analysis that included all mother–infant pairs irrespective of whether or not they continued to visit the facility after enrolment and for which all missing information was set to non-event (not exclusive breastfeeding, not having diarrhea or respiratory infection) whatever the reason for missing information (eg, death of the baby or mother, loss to follow-up, or missed visit); a complete-case analysis with data restricted to participants with available information; and a per-protocol analysis restricted to participants who attended the clinic for a particular visit (because to receive the intervention, the mother had to attend the clinic), thus excluding data from mothers who were interviewed at home.

We entered questionnaire data into the Epi Info program. All analyses were done with SAS 9.3 (SAS Institute, Cary, NC, USA). We used generalised estimating equations and log-binomial models to estimate the prevalence ratios (PR) and 95% CIs, comparing intervention groups with the control group while accounting for clustering. We adjusted final results for any maternal baseline characteristic that was imbalanced between groups.

This trial is registered at ClinicalTrials.gov, number NCT01428232.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

We randomly assigned six eligible clinics to treatment groups (of 44 assessed); 975 mother–infant pairs (of 1340 assessed) were enrolled in the study and received treatment according to the clinic they were in (304 to control, 363 to steps 1–9, and 308 to steps 1–10). 855 pairs completed the 24-week interview (figure). Few imbalances in baseline characteristics were noted between the intervention and control groups. Mothers in the control group were slightly older and more likely to have attended at least four antenatal visits compared with mothers in the two intervention groups (table 2). Most participants in each group missed no more than one follow-up visit (figure 1). Except for week 1 post partum, when attendance was lower in the control group, attendance was consistently higher in the control group than in the intervention groups throughout the study. This difference was significant only at the week 6 visit when 77% (control), 63% (steps 1–9), and 70% (steps 1–10) of participants returned to their respective health facility for well-child services (appendix). Baseline characteristics did not differ between mother–infant pairs who attended follow-up visits and those who did not.

In the intention-to-treat analysis, the proportions of children breastfed within 1 h of birth in the intervention groups were not significantly different from those of the control group: 230 (76%) of infants in the control group, 263 (72%) who received steps 1–9, and 220 (71%) who received steps 1–10 (table 3). However, the prevalence of exclusive breastfeeding at age 14 weeks, calculated on the basis of 24 h recall, was more than twice as high in the steps 1–10 group than in control (table 3).

The prevalence of exclusive breastfeeding at age 24 weeks, calculated on the basis of 24 h recall, was about three times higher in group 1 than in the control group, but not significantly different from control in the steps

See Online for appendix
1–10 group (table 3). 7 day recall raised the estimated PRs, but not substantially (table 3).

The prevalence of diarrhoea at age 14 weeks was similar between the control and steps 1–9 groups, but significantly higher than control in the steps 1–10 group. Prevalence increased between week 14 and week 24 in all groups, but was significantly lower than control in the steps 1–9 group and significantly higher than control in the steps 1–10 group (table 4). No significant differences between groups were noted in the prevalence of reported respiratory infections (fever with cough) at age 14 or 24 weeks (table 4).

In the complete-case analysis with only available information, similar results were obtained for each of the outcomes (table 4). As expected, restriction of the analysis to participants who attended the clinic visit in the per-protocol analysis resulted in stronger effects and the PRs for exclusive breastfeeding at 24 weeks in the steps 1–10 group versus control became significant (table 3). Additional results for each timepoint when the outcomes were assessed and the calculated intraclass correlation coefficients are in the appendix.

**Discussion**
Overall, our results show that provision of training in the Ten Steps to Successful Breastfeeding for health professionals is an effective strategy to enhance the practice of exclusive breastfeeding, even in settings with high breastfeeding initiation such as DR Congo. The intervention was also associated with a significantly reduced prevalence of diarrhoea in the infants by age 24 weeks. However, the combination of this intervention with training of staff at well-child clinics and provision of educational flyers (the steps 1–10 group) did not increase the effect in this setting and actually seemed to lessen the effect of the training, resulting in a smaller effect than the implementation of steps 1–9 alone.

**Findings from a systematic review and meta-analysis** of breastfeeding support show that training health-care professionals with the WHO BFHI course raised the prevalence of exclusive breastfeeding compared with a control group. However, none of the studies in the meta-analysis included specific additional training for the clinic visits or were from the African region. Implementation of steps 1–9 in our investigation tripled the prevalence of

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### Table 3: Primary outcomes

| Intervention | Control | BFHI steps 1–9 | BFHI steps 1–10 |
|--------------|---------|----------------|-----------------|
|              | n/N (%) | n/N (%)        | Crude prevalence ratio (95% CI)* | Adjusted prevalence ratio (95% CI)** |
|              |         |                |                 |                                |
| Initiation of breastfeeding within 1 h | 230/304 (76%) | 263/363 (72%) | 0.99 (0.78–1.26) | 1.01 (0.79–1.30) |
| 24 h recall | 89/304 (29%) | 233/363 (65%) | 2.23 (1.79–2.75) | 2.20 (1.73–2.77) |
| 7 day recall | 78/304 (26%) | 231/363 (64%) | 2.45 (1.93–3.10) | 2.46 (1.94–3.18) |
| exclusive breastfeeding at 14 weeks | 230/304 (76%) | 263/363 (72%) | 0.99 (0.78–1.26) | 1.01 (0.79–1.30) |
| 24 h recall | 89/304 (29%) | 233/363 (65%) | 2.23 (1.79–2.75) | 2.20 (1.73–2.77) |
| 7 day recall | 78/304 (26%) | 231/363 (64%) | 2.45 (1.93–3.10) | 2.46 (1.94–3.18) |
| exclusive breastfeeding at 24 weeks | 230/304 (76%) | 263/363 (72%) | 0.99 (0.78–1.26) | 1.01 (0.79–1.30) |
| 24 h recall | 89/304 (29%) | 233/363 (65%) | 2.23 (1.79–2.75) | 2.20 (1.73–2.77) |
| 7 day recall | 78/304 (26%) | 231/363 (64%) | 2.45 (1.93–3.10) | 2.46 (1.94–3.18) |
| complete-case analysis† | 230/304 (76%) | 263/363 (72%) | 0.99 (0.78–1.26) | 1.01 (0.79–1.30) |
| 24 h recall | 89/304 (29%) | 233/363 (65%) | 2.23 (1.79–2.75) | 2.20 (1.73–2.77) |
| 7 day recall | 78/304 (26%) | 231/363 (64%) | 2.45 (1.93–3.10) | 2.46 (1.94–3.18) |
| per-protocol analysis¶ | 230/304 (76%) | 263/363 (72%) | 0.99 (0.78–1.26) | 1.01 (0.79–1.30) |
| 24 h recall | 89/304 (29%) | 233/363 (65%) | 2.23 (1.79–2.75) | 2.20 (1.73–2.77) |
| 7 day recall | 78/304 (26%) | 231/363 (64%) | 2.45 (1.93–3.10) | 2.46 (1.94–3.18) |
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| 7 day recall | 78/304 (26%) | 231/363 (64%) | 2.45 (1.93–3.10) | 2.46 (1.94–3.18) |

*For all 95% CIs, generalised estimating equations were used to account for clustering. †Adjusted for mother’s age, maternal education, ownership of the house in which they live, type of toilet, having had a previous child who died, and the number of visits to an antenatal clinic made before delivery. ‡The main assumption especially for steps 1–10 was that mothers would return to the facility for their well-child visit. Therefore, for the intention-to-treat analysis, all missing outcomes were treated as a failure (ie, not exclusively breastfeeding). §For the complete-case analysis, only individuals with outcome data available were included. ¶For the per-protocol analysis, only participants who returned for the scheduled visit to a well-child clinic were included.
exclusive breastfeeding at age 6 months (24 weeks) compared with the control group (36% vs 12%). A similar effect was shown in PROMISE, a large community trial of promotion of exclusive breastfeeding in three sub-Saharan African countries, in which individual peer counselling resulted in a prevalence, based on 24 h recall at age 24 weeks, of 73% in the intervention group versus 22% in the control group (PR 3.33 [95% CI 1.74–6.38]) in Burkina Faso and 59% versus 15% (3.83 [2.97–4.95]) in Uganda. The consistency of the results between the two studies suggest that, in settings with high breastfeeding initiation, the provision of quality breastfeeding support to mothers in clinical settings might be as effective as the provision of community support through peer counselling.

Although the prevalence of exclusive breastfeeding in our study was similar in both intervention groups at 1 h after birth, by the age of 24 weeks, it had reduced by about 29 percentage points in the steps 1–10 group, compared with 7 percentage points in the steps 1–9 group, suggesting that the addition of educational flyers starting at maternity discharge and training staff in the ten steps for well-child clinic settings might have produced an effect opposite to what was postulated (ie, they discouraged continuation of breastfeeding rather than encouraging it). The motivation behind the distribution of flyers was to engage family members to support optimum breastfeeding and tackle the social customs that might encourage some suboptimum practices. The lower prevalence of exclusive breastfeeding in the steps 1–10 group suggest that the materials used might not have provided the accurate or necessary messages for this setting, or that engagement of family members might have led to misunderstandings or incorrect advice that were not sufficiently countered by group counselling from nurses during well-child visits. This theory is at least partly evident because the PRs comparing the steps 1–10 and control groups at 6 months was larger and significant when the analysis was restricted to mother–infant pairs who attended well-child clinics. Good breastfeeding practices might also have been inappropriately changed by engaged family members in the steps 1–10 group suggest that the materials used might not have provided the accurate or necessary messages for this setting, or that engagement of family members might have led to misunderstandings or incorrect advice that were not sufficiently countered by group counselling from nurses during well-child visits. This theory is at least partly evident because the PRs comparing the steps 1–10 and control groups at 6 months was larger and significant when the analysis was restricted to mother–infant pairs who attended well-child clinics. Good breastfeeding practices might also have been inappropriately changed by engaged family members in the steps 1–10 group.

### Table 4: Secondary outcomes

|                     | Control | BFHI steps 1–9 | BFHI steps 1–10 |
|---------------------|---------|----------------|-----------------|
|                     | n/N (%) | Crude prevalence ratio (95% CI)* | Adjusted prevalence ratio (95% CI)** |
|                     | n/N (%) | Crude prevalence ratio (95% CI)* | Adjusted prevalence ratio (95% CI)** |
| **Intention-to-treat analysis** |         |                 |                 |
| Age at 14 weeks     |         |                 |                 |
| Diarrhoea since last visit | 14/204 (5%) | 18/363 (5%) | 1.01 (0.59–1.70) | 1.03 (0.63–1.67) |
| Fever with cough    | 36/204 (12%) | 20/363 (6%) | 0.51 (0.19–1.36) | 0.66 (0.31–1.40) |
| Age at 24 weeks     |         |                 |                 |
| Diarrhoea since last visit | 45/304 (15%) | 28/363 (8%) | 0.52 (0.32–0.84) | 0.50 (0.34–0.73) |
| Fever with cough    | 70/304 (23%) | 47/363 (13%) | 0.60 (0.30–1.18) | 0.84 (0.43–1.62) |
| **Complete-case analysis** |         |                 |                 |
| Age at 14 weeks     |         |                 |                 |
| Diarrhoea since last visit | 14/271 (5%) | 18/315 (6%) | 1.02 (0.61–1.70) | 1.05 (0.67–1.64) |
| Fever with cough    | 36/271 (13%) | 20/315 (6%) | 0.54 (0.20–1.41) | 0.73 (0.34–1.54) |
| Age at 24 weeks     |         |                 |                 |
| Diarrhoea since last visit | 45/271 (17%) | 28/304 (9%) | 0.54 (0.37–0.78) | 0.53 (0.40–0.71) |
| Fever with cough    | 70/271 (26%) | 47/304 (15%) | 0.62 (0.34–1.14) | 0.62 (0.35–1.11) |
| **Per-protocol analysis** |         |                 |                 |
| Age at 14 weeks     |         |                 |                 |
| Diarrhoea since last visit | 7/231 (3%) | 17/272 (6%) | 1.09 (0.75–1.58) | 2.16 (0.84–5.54) |
| Fever with cough    | 27/231 (12%) | 20/272 (7%) | 0.68 (0.28–1.64) | 0.88 (0.47–1.67) |
| Age at 24 weeks     |         |                 |                 |
| Diarrhoea since last visit | 3/201 (1%) | 24/220 (11%) | 0.56 (0.42–0.73) | 0.62 (0.50–0.79) |
| Fever with cough    | 52/202 (26%) | 45/220 (20%) | 0.84 (0.45–1.58) | 0.84 (0.43–1.62) |

*For all 95% CIs, generalised estimating equations were used to account for clustering. †Adjusted for mother’s age, maternal education, ownership of the house in which they live, type of toilet, having had a previous child who died, and the number of visits made to an antenatal clinic before delivery. ‡For the complete-case analysis, only individuals with outcome data available were included. §§For the per-protocol analysis, only participants who returned for the scheduled visit to the well-child clinic were included.
on post-partum practices than support from a lay counsellor. Furthermore, a study in Australia, where similarly most women initiate breastfeeding, showed that the practices, rather than the BFHI designation per se, were associated with improvements, as did a US study in several non-designated hospitals where a lower percentage initiated breastfeeding.12,21

Another possible explanation is that the WHO materials are designed to promote initiation of breastfeeding, rather than to address common difficulties with breastfeeding that occur in later weeks and months. If the clinic staff tried to use the interventions designed for newborn babies at these later ages, without the ability to address breastfeeding issues for mothers of older children, this might have led to inappropriate advice being offered by well meaning clinicians.

Our results show that receiving antenatal, labour, and delivery care, and immediate post-partum care from health professionals who had received the training was associated with a significant rise in optimum breastfeeding and associated with a significant reduction in diarrhoea at 24 weeks compared with standard of care. The PROBIT study,23 done in Belarus with a similar ten-step approach, showed that infants from the intervention sites who were more likely to be exclusively breastfed at 3 months and 6 months, had a significant reduction in the risk of one or more infections of the gastrointestinal tract, but no significant reduction in infections of the respiratory tract, similar to our investigation. Moreover, a review published in 201024 identified five randomised trials in which prevalence or incidence of diarrhoea at 3 months and 6 months, had a significant reduction in diarrhoea prevalence by half at this age. The large-scale implementation of steps 1–9 in similar settings could help to quickly reduce mortality in children younger than 5 years and increase the likelihood of meeting MDG 4.

Implementation of BFHI steps 1–9 by training health personnel with the WHO/UNICEF training course—a fairly low-intensity low-tech intervention which is very suitable for rapid scale-up in maternity settings—significantly raised the proportion of infants exclusively breastfeeding at age 6 months and decreased diarrhoea prevalence by half at this age. The large-scale implementation of steps 1–9 in similar settings could help to quickly reduce mortality in children younger than 5 years and increase the likelihood of meeting MDG 4.

Contributors
MY, FB, BL, and ML designed the study. MY and JLC obtained the data. MY and HMS analysed the data and wrote the report. HMS created the figures. MY, FB, BL, ML, and BSV interpreted the data.

Declaration of interests
We declare no competing interests.

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