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Appendix 1. Focus Group Discussion guides for the different groups

A. With peer counsellors

We have all been invited for training as peer counsellors for support of exclusive breast feeding. Though we had already introduced our selves earlier in the classroom, let us introduce ourselves again so that each one of us knows who they are discussing with. (Each one can tell us your name, home parish and village, the number of children you have and your marital status and what you do i.e. occupation).

1. You have all been invited for training as peer counsellors for exclusive breastfeeding. Lets us discuss what exclusive breastfeeding is.
2. How are babies fed in our communities?
(Probe about when initiation of breast feeding done use of prelacteal feeds duration of exclusive breastfeeding, introduction of complementary feeds.)
3. What challenges do mothers experienced while breast feeding.
(Probe for problems with the mother for example breast health problem, other social and family challenges faced.)
4. How are breast feeding mothers supported?
(Probe for support at family level health unit.)
5. What do you hope to gain from this training?
(Probe for how they hope to utilise the knowledge and skills they acquire.)
6. How do you view your role as a trained peer counsellor in your community?
7. What challenges do you anticipate to encounter as you help mothers with breastfeeding?
Additional questions for after training session:-
8. How do you think this training has affected you with regard to feeding of younger babies?
9. Is there any thing else you wish to add or talk about?

With Supported mothers:

We are gathered here today because we have some things in common: We are all mothers, we live in this village and we have been visited by a peer counsellor who has shared some information with us about feeding our babies. Am I right?

Lets us first introduce our selves (give our names, what we do, how many children we have, age of our youngest child and marital status.)

1. We are going to have a discussion about feeding babies.
How are younger babies fed in our community?
(Probe for when invitation of breastfeeding done, use of prelacted feeds, duration of exclusive breastfeeding, and introduction and types of complementary feeds given.)
2. What do we understand by exclusive breastfeeding?
3. What challenges do breast feeding mothers face?
(Probe for breast health problem, socio-cultural barriers.)
4. How are breast mothers supported in our community?
(Probe for support at family, community and health unit level.)
5. What were your experiences with the peer counselling visits?
(Probe for usefulness, new knowledge gained and whether would wish for similar visits with another child.)
6. Who would you consider as the best person to offer support to a breast feeding mother?
7. Is there any thing else you would like to add or discuss?

Thank you very much.

With the husbands of the supported mothers.

You are welcome to this discussion. Thank you for accepting to come despite your very busy schedules. We are gathered here because we have some things in common for example: We are all men (except for me and my colleague) we live in this community and our wives have small babies and our wives have been visited by a peer counsellor for support of exclusive breastfeeding.

Lets us start by introducing ourselves so that we know who we are seated with (give your name, what you do, and age of your youngest baby.)

1. We are going to have a discussion about feeding babies. How are younger babies fed in our community?
(Probe for when initiation of breastfeeding done, use of prelacted feeds, duration of exclusive breastfeeding, and introduction and types of complementary feeds given.)
2. What do we understand by exclusive breastfeeding?
3. What challenges do breast feeding mothers face?
(Probe for breast health problem, socio-cultural barriers.)
4. How are breast mothers supported in our community?
(Probe for support at family, community and health unit level.)
6. What are your feedings about having had a peer counsellor helping your wife with exclusive breastfeeding?

Thank you very much.

Appendix 2.

Pre-test/ Post-test questionnaire for the Peer Supporters on knowledge, attitudes and practices towards EBF (Exclusive Breast Feeding)

Date Time

Interviewer's Initials/Code

Peer Supporter's Initials/Code

Peer Supporter's Characteristics:

1. How old are you?(Complete years)
2. When were you born (Date of Birth)
3. What is your highest level of education?
4. Marital Status
 - Single
 - Married
 - Widowed
 - Divorced/Separated
 - No response
5. What is your occupation?
6. How many children have you given birth to?
7. How old is your youngest child?
8. Did you breast feed any of your children?
 - Yes
 - No
9. After how long after birth did you put your baby on the breast feed?
 - Immediately after birth

- Within the 1st 1 hour
- After one hour
- After one day

10. How long did you breast feed only without adding anything, not even water?

11. How old was your baby when you first gave other drinks/foods apart from breast milk?

12. What did you do with your colostrum when you gave birth to you last baby?

Peer Supporter’s Knowledge, Beliefs and attitude

13. What do you understand by the term exclusive breastfeeding?

14. After how long after birth should a baby be put on the breast?

- Within 1st 30 minutes
- 30 min – 1 hour
- After 1 hour
- After one day

15. What is the best feed to give to give a baby as first feed after birth?

- Breast milk
- Water
- Glucose
- Tea
- Other (Specify).....

16. For how long should a baby be kept on the breast?

- For as long as a baby wants
- 5 minutes
- 10 minutes

17. How should a baby be put off the breast?

- Baby left to release the breast
- Baby should be pulled off
- Other, Specify

18. For how long should a baby feed on one breast before changing to the other one?

- 5 minutes
- 10 minutes
- More than 10 minutes
- Other, specify

19. What would make you change a baby from one breast to the other?

.....
.....
.....

20. What signs will show that a mother has enough breast milk?

.....
.....

21. Does breastfeeding have any benefits?

- Yes
- No

22. If yes, what are the advantages of breastfeeding?

.....
.....

23. What in your opinion affects breast milk production?

.....
.....

24. What helps to increase breast milk production in a mother?

.....
.....

25. What do you think can cause a mother to have painful breasts during breast feeding?

.....
.....

26. Do you think a baby can refuse the mother's breast?

Yes

No

27. If yes, what would cause it?

.....
.....
.....

28. For how long should a baby receive breast milk only, without even water?

6 months

4 months

8 months

2 months

29. If a mother has to leave her baby home, how can she ensure that the baby will continue to have her breast milk?

.....
.....
.....

30. Do you think a mother who works away from home can continue to give her baby breast milk only?

Yes

No

31. If a baby spends a day or more without breastfeeding can it breast feed again?

Yes

No

32. Do you think an exclusively breastfed baby needs extra water?

Yes

No

33. When a baby is sick, should the mother continue to breast feed it?

Yes

No

34. If a mother is sick, should she continue breastfeeding her baby?

Yes

No

35. When a baby is too sick to suck on the mother's breast, what should you do to feed the baby?

Express breast milk and feed by baby by cup

Express breast milk and feed baby by spoon and cup

Other, specify

36. Have you ever heard about expressing breast milk?

Yes

No

37. If yes, in what situations can a mother express breast milk?

.....
.....
.....
.....
.....

38. What is your opinion/feelings about expressing breast milk?

.....
.....
.....

39. Do you think expressed breast milk can be fed to a baby?

Yes

No

40. Do you know anything that can reduce breast milk production?

Yes

No

41. What would you tell a mother who says her baby wants to feed all time?

Put baby on breast as often as it wants

- Give baby extra milk
- Baby not getting satisfied with breast milk
- Baby is greedy
- Other, specify

42. Should a mother clean her breasts before each breastfeed?

- Yes
- No

43. If yes what should she use to clean?

- Water only
- Water and soap
- Other, specify

44. What do you call the first milk a mother produces soon after delivery (Local term)

.....

45. Is this first milk good for the baby?

- Yes
- No

46. What would you tell a mother to do with this first milk?

- Feed the baby with it
- Express it and pour it
- Other, specify

47. If it is good, in what way is it good for the baby?

.....

48. If it is bad, in what ways is bad for the baby?

.....

.....
.....

49. In your opinion what causes leaking of milk from the mother's breasts?

.....
.....

50. If a mother's breasts leak milk, is it a good sign?

Yes

No

51. If yes, why?

.....
.....
.....
.....

52. If no, why?

.....
.....
.....
.....

Thank you so much for your time and cooperation.

Appendix 3. Exit interview for mothers counselled by peer supporters

Date Time

Interviewer's Initials/Code

Mother's Initials/Code Village

Mother's Characteristics:

1. How old are you?(*completed years*)
2. When were you born (dd/mm/yy)
.....
3. What is the highest level of formal education you attained? (*circle correct response*)
 - A. University
 - B. Tertiary institution
 - C. S5- S6
 - D. S1-S4
 - E. P 5- P7
 - F. P.1-P4
 - G. None
4. Marital Status (*circle correct response*)
 - A. Single
 - B. Married
 - C. Co habiting
 - D. Widowed
 - E. Divorced/Separated
 - F. No response
5. How many children do you have?.....
6. What is your occupation? (*circle correct response*)
 - A. Full-time housewife
 - B. Subsistence farmer
 - C. Trader
 - D. Civil servant
 - E. Self employed
 - F. Other (Specify)
.....

7. How many visits did you receive from the peer supporter?.....
8. What do you feel about the time the peer supporter spent with you during her visits? (*Choose and circle one*)
 - A. Definitely not enough
 - B. Somehow enough
 - C. Just enough
 - D. More than enough

(*Please explain the reason for your answer*).....

9. Were you satisfied with the peer supporter's explanations about breastfeeding your baby? (*Choose and circle one*)
 - A. Not satisfied at all
 - B. A little satisfied
 - C. Just satisfied
 - D. Very satisfied
 - E. Extremely satisfied

(*Please explain your answer*).....

10. Did you find the peer supporter's visits useful? (*Choose and circle one*)
 - A. Not useful at all
 - B. A little useful
 - C. Just useful
 - D. Very useful
 - E. Extremely useful

11. If useful, of what use were the peer supporter's visits to you?

12. If not useful, why?

13. Did you learn anything new about breastfeeding from the peer supporter? (*Choose and circle one*)

- A. No
- B. Yes

14. If yes, what new information about breastfeeding did you learn from the peer supporter? (*circle whichever is mentioned*)

- A. Advantages of exclusive breastfeeding
- B. Initiation of breastfeeding after birth
- C. Why colostrum (first milk) is good for the baby
- D. How to position a baby on the breast
- E. How a baby holds the breast for effective suckling
- F. What increases breast milk production
- G. Why babies cry
- H. Expressing breast milk for the baby
- I. Normal frequency of urination
- J. Other (*specify*)

.....
.....

15. What else would you have liked the peer supporter to tell you about breastfeeding that she did not?

.....
.....
.....
.....

16. Did you feel free to discuss openly with the peer supporter during her visits? (*Choose and circle one*)

- A. Not free at all
- B. A little free
- C. Somewhat free
- D. Very free
- E. Extremely free

(*Please give reasons for your answer*)

.....
.....
.....

17. Did you feel the peer supporter gave you opportunity to ask questions and clarify doubts? *(Choose and circle one)*

- A. Not at all
- B. A little opportunity
- C. Just enough opportunity
- D. A lot of opportunity

(Please give reasons for your answer)

.....

.....

.....

18. Did the peer supporter treat you with respect during her visits? *(Choose and circle one)*

- A. Not at all
- B. A little respect
- C. Just enough respect
- D. Lots of respect

(Explain your answer)

.....

.....

.....

19. What did you feel about the whole exercise of being visited by a peer supporter?

.....

.....

.....

20. If you become pregnant again, would you like the peer supporter to visit and help you with breastfeeding? *(Choose and circle one)*

- A. Definitely no
- B. Maybe no
- C. Maybe yes
- D. Definitely yes

(Give reasons for your answer)

.....

.....

.....

21. If your friend became pregnant, would you recommend a peer supporter for her? *(Choose and circle one)*

- A. Definitely no
- B. Maybe no
- C. Maybe yes
- D. Definitely yes

(Give reasons for your answer)

.....
.....
.....
.....

22. In your opinion, who do you think can best help mothers with breastfeeding? *(Choose and circle one)*

- A. Peer supporters
- B. Health workers
- C. Grandmothers
- D. Friends
- E. Fathers
- F. Traditional birth attendant
- G. Other *(specify)*

(Please give reasons for your answer)

.....
.....
.....
.....
.....

23. For how long did you exclusively breastfeed this baby (that is breastfed only without giving anything else, not even water)?

.....

24. Is there any thing else you would like to tell me or ask me?

.....
.....
.....

Thank you very much for your participation



Exclusive breastfeeding promotion by peer counsellors in sub-Saharan Africa (PROMISE-EBF): a cluster-randomised trial

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Summary

Background Exclusive breastfeeding (EBF) is reported to be a life-saving intervention in low-income settings. The effect of breastfeeding counselling by peer counsellors was assessed in Africa.

Methods 24 communities in Burkina Faso, 24 in Uganda, and 34 in South Africa were assigned in a 1:1 ratio, by use of a computer-generated randomisation sequence, to the control or intervention clusters. In the intervention group, we scheduled one antenatal breastfeeding peer counselling visit and four post-delivery visits by trained peers. The data gathering team were masked to the intervention allocation. The primary outcomes were prevalence of EBF and diarrhoea reported by mothers for infants aged 12 weeks and 24 weeks. Country-specific prevalence ratios were adjusted for cluster effects and sites. Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, number NCT00397150.

Findings 2579 mother–infant pairs were assigned to the intervention or control clusters in Burkina Faso (n=392 and n=402, respectively), Uganda (n=396 and n=369, respectively), and South Africa (n=535 and 485, respectively). The EBF prevalences based on 24-h recall at 12 weeks in the intervention and control clusters were 310 (79%) of 392 and 139 (35%) of 402, respectively, in Burkina Faso (prevalence ratio 2.29, 95% CI 1.33–3.92); 323 (82%) of 396 and 161 (44%) of 369, respectively, in Uganda (1.89, 1.70–2.11); and 56 (10%) of 535 and 30 (6%) of 485, respectively, in South Africa (1.72, 1.12–2.63). The EBF prevalences based on 7-day recall in the intervention and control clusters were 300 (77%) and 94 (23%), respectively, in Burkina Faso (3.27, 2.13–5.03); 305 (77%) and 125 (34%), respectively, in Uganda (2.30, 2.00–2.65); and 41 (8%) and 19 (4%), respectively, in South Africa (1.98, 1.30–3.02). At 24 weeks, the prevalences based on 24-h recall were 286 (73%) in the intervention cluster and 88 (22%) in the control cluster in Burkina Faso (3.33, 1.74–6.38); 232 (59%) and 57 (15%), respectively, in Uganda (3.83, 2.97–4.95); and 12 (2%) and two (<1%), respectively, in South Africa (5.70, 1.33–24.26). The prevalences based on 7-day recall were 279 (71%) in the intervention cluster and 38 (9%) in the control cluster in Burkina Faso (7.53, 4.42–12.82); 203 (51%) and 41 (11%), respectively, in Uganda (4.66, 3.35–6.49); and ten (2%) and one (<1%), respectively, in South Africa (9.83, 1.40–69.14). Diarrhoea prevalence at age 12 weeks in the intervention and control clusters was 20 (5%) and 36 (9%), respectively, in Burkina Faso (0.57, 0.27–1.22); 39 (10%) and 32 (9%), respectively, in Uganda (1.13, 0.81–1.59); and 45 (8%) and 33 (7%), respectively, in South Africa (1.16, 0.78–1.75). The prevalence at age 24 weeks in the intervention and control clusters was 26 (7%) and 32 (8%), respectively, in Burkina Faso (0.83, 0.45–1.54); 52 (13%) and 59 (16%), respectively, in Uganda (0.82, 0.58–1.15); and 54 (10%) and 33 (7%), respectively, in South Africa (1.31, 0.89–1.93).

Interpretation Low-intensity individual breastfeeding peer counselling is achievable and, although it does not affect the diarrhoea prevalence, can be used to effectively increase EBF prevalence in many sub-Saharan African settings.

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Introduction

Promotion of exclusive breastfeeding (EBF) for the first 6 months of life has been estimated to be the most effective preventive strategy for saving the lives of young children in low-income settings,¹ and could contribute towards the Millennium Development Goal 4 of reducing child mortality. High coverage of promotion and support of breastfeeding could prevent 22 million (8.6%) disability adjusted life years.²

WHO recommends EBF for 6 months.³ However, in sub-Saharan Africa, initiatives to promote EBF are hampered by the HIV epidemics.⁴ Only one randomised facility-based study has been done in Ghana;⁵ no trials of community-based EBF promotion had been undertaken in sub-Saharan Africa at the time our trial was initiated. A recent review of breastfeeding promotion summarised the small amount of evidence from Africa.⁶ In the past decade, most studies in which EBF was promoted in

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sub-Saharan Africa had been undertaken within the framework of prevention of mother-to-child transmission of HIV 1 to assess whether EBF could increase HIV-free survival.⁴ The results indicated that intensive interventions could lead to near-universal adherence to EBF. Investigation of whether less intensive community-based interventions can achieve substantial benefits in feeding patterns is important.⁷

PROMISE-EBF is the first trial undertaken in Africa to assess the effect of individual home-based EBF peer counselling. We report here the results of the analysis of the primary outcomes in Burkina Faso, Uganda, and South Africa only because severe floods midway through the study site in Zambia disrupted the data gathering.

Methods

Study sites

The study was undertaken in rural Banfora, southwest Burkina Faso, Mbale District, eastern Uganda, and Paarl (a periurban site close to Cape Town), Umlazi (periurban site near Durban), and Rietvlei (rural Kwa Zulu Natal), South Africa. Further details of the study sites are provided in the webappendix pp 2–7).

Study design

PROMISE-EBF was a multicentre community-based cluster-randomised behavioural-intervention trial that was done in sub-Saharan Africa (webappendix pp 2–7). To assess the potential for scale up of the EBF intervention, we randomly assigned clusters rather than mother–infant pairs, thereby avoiding the potential contamination between intervention and control groups, and more accurately mimicking an intervention that is to be undertaken on a full scale. Peer counsellors provided breastfeeding support in intervention clusters. Mothers and infants in control clusters in Burkina Faso and Uganda were given standard health care only, and those control clusters in South Africa were visited by peer counsellors, with the same schedule as in the intervention clusters, but who assisted families in obtaining birth certificates and social welfare grants. The peer counsellors for the intervention and control clusters in South Africa were kept separate during the study.

Inclusion in the study was a two-stage process, starting with the assessment of pregnant women (preinclusion) and then the inclusion of the mother–infant pairs (inclusion). Pregnant women intending to breastfeed were assessed for study participation, after being identified by community-based recruiters (for further details, see webappendix pp 8–9). Almost all mothers in the clusters were reached, irrespective of birth place. The preinclusion criteria were that the woman resided in the selected cluster; was 7 months or visibly pregnant; had no plans to move in the forthcoming year; and provided informed consent. At the 3-week post-partum assessment a preincluded mother–infant pair was included if there was a singleton

livebirth with no severe malformation that could interfere with breastfeeding. Exclusion criteria for the women were severe psychological illness, which could interfere with consent and study participation; giving birth more than 1 week before preinclusion; or a plan to replacement feed. Unless a clear reason for non-participation in a scheduled visit was given, three attempts to visit the mother–infant pair were made before a visit was judged to be missed and this increased the number of untimely visits. A recruited mother was revisited until the last scheduled visit, irrespective of the number of missed visits, unless there was a clear reason for termination.

Randomisation and masking

We used simple computer-generated randomisation, with clusters assigned in a 1:1 allocation ratio. The allocation sequences for Burkina Faso and Uganda were generated by HS and Rajiv Bahl, and for South Africa by CL. HS, Rajiv Bahl, and CL also assigned clusters to the trial groups. In Burkina Faso, randomisation was not stratified; in Uganda, it was stratified according to urban and rural location, and in South Africa according to the three sites. Clusters were mapped based on criteria of accessibility, population size, health system, and health data. Within each stratum, the clusters were randomly assigned to intervention or control on the basis of numbers generated in Excel 97. Only the data collectors were masked to the allocation assignment—ie, they were not informed about the cluster allocation and were kept separate from the intervention team; they enrolled the eligible participants. The success of this masking was not formally assessed. Further details about the randomisation and masking are provided in the webappendix p 8.

Because of fairly large clusters in Burkina Faso and South Africa, all eligible women in the intervention clusters were enrolled in the study for peer counselling, whereas a randomly selected subset were approached for data gathering. The recruitment interview was scheduled antenatally or within 1 week after birth. Visits for data gathering were scheduled at weeks 3, 6, 12, and 24 after birth. We defined timely visits (9–18 weeks for the visit at 12 weeks, and 18–28 weeks for the visit at 24 weeks) to be included in the prevalence estimates for EBF and diarrhoea. The figure shows the total and timely visits. In all countries, peer support was offered to all women in intervention clusters irrespective of whether they were enrolled for data gathering, and women were approached for data gathering irrespective of whether they agreed to participate in peer-support visits, consistent with a community-based study for measurement of the effect of an intervention when undertaken on full scale.

Study approval was obtained by the institutional review board of Centre Muraz (number 013/2005/CE-CM) and by the Ministry of Health at national and regional levels

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See Online for webappendix



Figure: Trial profile
 (A) Burkina Faso. (B) Uganda. (C) South Africa. *One infant death and one maternal death combined.

in Burkina Faso; Faculty of Medicine, Makerere University, and Research and Ethics Committee, Uganda National Council for Science and Technology; ethics committee for the Medical Research Council, South Africa; and regional committees for Medical and Health

Research Ethics in Norway. Women provided verbal informed consent for participation in the peer-counselling programme, which was regarded as a service, whereas signed or thumb-printed informed consent was obtained before data were gathered.

Peer counselling

We recruited peer counsellors who were living in or near the intervention clusters. Peer counsellors were identified and trained for 1 week by the national research teams. The counsellors offered home-based-breastfeeding peer support to the mothers in the intervention clusters. Peer counsellors received continuous mentoring (fortnightly to monthly) by study-appointed supervisors. All mothers were offered at least five visits, starting with a visit in the third trimester. In Burkina Faso, mothers were scheduled to have home visits during the first week postnatally, and thereafter at weeks 2, 4, 8, 16, and 20. In Uganda and South Africa, home visits were scheduled within the first week and thereafter at weeks 4, 7, and 10. Detailed descriptions of the intervention are provided in the webappendix pp 12–14 and elsewhere.^{8–10} The course material was based on the WHO courses: Breastfeeding counselling: a training course, and HIV and infant feeding counselling: a training course. The courses were integrated and adapted at sites for local circumstances. The intervention was piloted in Uganda.¹¹ Peer counsellors provided information, and encouraged and supported EBF for 6 months. Mothers with any breastfeeding difficulties were referred to a health worker with training in lactation management (Burkina Faso and Uganda) or to a public health provider who was aware of the HIV status of the participant (South Africa).

Data capture and management

Study questionnaires were developed and adapted from Bland and colleagues¹² and Pwosz,¹³ and previous work undertaken in participating countries.^{14–17} The questionnaires were piloted in Uganda in 2005.¹⁸ Data were gathered in the mothers' homes from 2006 to 2008 by trained data gatherers. In Burkina Faso and Uganda, data were gathered with hand-held computers by use of EpiHandy (version 165.528-142 RC; webappendix p 15). In South Africa, the data were gathered by use of paper questionnaires that were entered by use of EpiData (version 3.1).

Definitions

Current breastfeeding was assessed at all scheduled postpartum visits with past 24-h and 7-day recalls. Additionally, dietary recalls consisted of 22 specified items and one open question. Babies who did not receive any other food or liquids other than breast milk were classified as exclusively breastfed, even if they had been administered drugs.¹³ Prevalence of diarrhoea was based on the mothers' reports of the past 2 weeks. A socioeconomic index was created with Multiple Correspondence Analysis (Stata SE, version 11.0), based on a set of country-specific assets that included house type and toilet facilities.¹⁹ Every country-specific index was divided into quintiles.

Statistical analysis

Sample size calculation was done independently for the two primary outcomes EBF and diarrhoea at ages

12 weeks and 24 weeks, with 95% CIs and 80% power. The cluster sizes corresponded to an estimated average of 35 deliveries per year. The coefficient of variation between the clusters used in the sample size calculation was 0.4 for EBF prevalence. To detect an increase from 20% to 40% in EBF prevalence in each country, we needed a minimum of 12 clusters per group per country. For the diarrhoea prevalence sample size calculation, the coefficient of variation was assumed to be 0.3. To detect a 33% reduction in diarrhoea prevalence from 12% to 8%, a total of 48 clusters in each group were needed. 106 clusters—34 in South Africa, 24 in Burkina Faso, 24 in Uganda, and 24 in Zambia—were randomly assigned. To compensate for the loss of the Zambian site, we combined the observations at 12 weeks and 24 weeks of infant age to obtain an adequate precision for effects of the intervention on diarrhoea prevalence.

All eligible mother–infant pairs were analysed with Stata SE (version 11.0). The models of EBF and diarrhoea were country specific. We calculated prevalence ratios for EBF and diarrhoea with a generalised linear model for the binomial family with a log link taking the design effect and stratification into account. Additionally, for diarrhoea only, we used Poisson regression to estimate the event ratio between the intervention and the control groups of the trial, combining the number of reported periods of 2 weeks with diarrhoea at age 12 weeks and 24 weeks, in a pooled estimate of Burkina Faso, Uganda, and South Africa. This variable could accordingly have the values 0, 1, or 2.

The analysis presented in this report included all mother–infant pairs in the denominator, implying that we recorded missing, lost to follow-up, and death as non-events—ie, not having exclusively breastfed or not having had diarrhoea. We also undertook an analysis excluding individuals without valid information (webappendix pp 21–22).

This study is registered with ClinicalTrials.gov, number NCT00397150.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing 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

Overall, 4984 women were approached for participation in the study from May, 2006, to July, 2008 (figure). The final sample for data gathering and analysis was 2579 mother–infant pairs. Few baseline differences were noted between the intervention and control clusters at the country level (table 1). Burkina Faso had the poorest participants with the lowest education, whereas the participants from South Africa were the richest with the highest education.

In all three countries, prevalence of EBF at 12 weeks of age in the intervention cluster was about twice that in the control cluster (table 2) whether based on a 24-h

For Breastfeeding counselling: a training course see http://www.who.int/child_adolescent_health/documents/who_cdr_93_3/en

For HIV and infant feeding counselling: a training course see http://www.who.int/child_adolescent_health/documents/fch_cah_00_2/en/index.html

	Burkina Faso		Uganda		South Africa	
	Intervention	Control	Intervention	Control	Intervention	Control
Categorical data						
Eligible mother-infant pairs	392	402	396	369	535	485
Marital status	390	402	392	366	533	484
Married	333 (85%)	351 (87%)	244 (62%)	234 (64%)	134 (25%)	114 (24%)
Cohabiting	32 (8%)	34 (8%)	119 (30%)	104 (28%)	36 (7%)	30 (6%)
Single, widowed, separated, or divorced	25 (6%)	17 (4%)	29 (7%)	28 (8%)	363 (68%)	340 (70%)
Socioeconomic-status quintile	392	401	396	369	535	485
1 (poorest)	82 (21%)	81 (20%)	91 (23%)	62 (17%)	111 (21%)	85 (18%)
2	77 (20%)	77 (19%)	97 (24%)	86 (23%)	100 (19%)	87 (18%)
3	76 (19%)	85 (21%)	76 (19%)	49 (13%)	103 (19%)	100 (21%)
4	76 (19%)	85 (21%)	71 (18%)	84 (23%)	111 (21%)	113 (23%)
5 (least poor)	81 (21%)	73 (18%)	61 (15%)	88 (24%)	110 (21%)	100 (21%)
Electricity in house	389	402	391	361	535	485
Yes	18 (5%)	5 (1%)	53 (14%)	70 (19%)	409 (77%)	445 (92%)
Water source	388	400	392	363	535	484
Surface water and other	117 (30%)	161 (40%)	136 (35%)	97 (27%)	121 (23%)	105 (22%)
Borehole or tap	271 (70%)	238 (60%)	244 (62%)	246 (68%)	68 (13%)	58 (12%)
Piped yard or home	0	1 (<1%)	12 (3%)	20 (6%)	346 (65%)	321 (66%)
Toilet	168	232	339	328	515	456
None or open	165 (98%)	229 (99%)	84 (25%)	59 (18%)	82 (16%)	67 (15%)
Pit or ventilated improved pit	3 (2%)	3 (1%)	245 (72%)	266 (81%)	262 (51%)	238 (52%)
Flush	0	0	10 (3%)	3 (<1%)	171 (33%)	151 (33%)
Parity	391	402	392	366	535	485
Primipara	64 (16%)	65 (16%)	81 (21%)	85 (23%)	261 (49%)	247 (51%)
Multipara	327 (84%)	337 (84%)	311 (79%)	281 (77%)	274 (51%)	238 (49%)
Previous child death	325	337	307	277	395	362
Yes	190 (58%)	201 (60%)	109 (36%)	80 (29%)	29 (7%)	23 (6%)
Attendance at antenatal clinic (index child)	389	401	376	352	532	481
Yes	284 (73%)	285 (71%)	272 (72%)	274 (78%)	527 (99%)	470 (98%)
Place of birth (index child)	372	370	381	351	514	461
Out of facility	229 (62%)	241 (65%)	208 (55%)	146 (42%)	28 (5%)	38 (8%)
Facility	143 (38%)	128 (35%)	173 (45%)	205 (58%)	486 (95%)	423 (92%)
Continuous data						
Maternal age	292	318	394	368	533	485
Years	25 (20-30)	25 (20-30)	25 (20-30)	24 (20-30)	23 (19-29)	23 (19-28)
Maternal education	377	379	391	365	535	485
Years	0 (0-0)	0 (0-0)	6 (4-8)	6 (5-9)	10 (9-12)	10 (9-12)
Maternal body-mass index	247	214	343	312	432	398
At 6 weeks (kg/m ²)*	21 (20-22)	22 (20-23)	22 (20-24)	22 (20-24)	26 (23-29)	25 (22-30)
Monthly income	318	330	116	121	508	452
2007 euros	3 (2-8)	3 (3-8)	14 (5-28)	10 (5-23)	101 (63-158)	105 (63-162)
Data are number, number (%), or median (IQR). *At 6 weeks' post partum.						
Table 1: Baseline characteristics of study population						

or 7-day recall of feeding practices. The prevalence ratios for EBF obtained with the 24-h and 7-day recalls were also similar (table 2). The prevalence of EBF was lower at 24 weeks of age than at 12 weeks in the intervention and control clusters in Burkino Faso, Uganda, and South Africa, whereas the differences (prevalence ratios) were higher (table 2).

No differences were noted for the prevalence of diarrhoea at age 12 weeks or 24 weeks between the clusters within the countries (data not shown) or all the clusters (prevalence ratio 0.95, 95% CI 0.71-1.26, at 12 weeks, and 0.96, 0.75-1.23, at 24 weeks; table 3). The ratio of the prevalence of reported diarrhoea for 2 weeks at age 12 weeks and 24 weeks in the intervention

	12 weeks			24 weeks		
	Intervention	Control	Prevalence ratio (95% CI)	Intervention	Control	Prevalence ratio (95% CI)
Burkina Faso						
24-h recall	310/392 (79%)	139/402 (35%)	2.29 (1.33–3.92)	286/392 (73%)	88/402 (22%)	3.33 (1.74–6.38)
7-day recall	300/392 (77%)	94/402 (23%)	3.27 (2.13–5.03)	279/392 (71%)	38/402 (9%)	7.53 (4.42–12.82)
Uganda						
24-h recall	323/396 (82%)	161/369 (44%)	1.89 (1.70–2.11)	232/396 (59%)	57/369 (15%)	3.83 (2.97–4.95)
7-day recall	305/396 (77%)	125/369 (34%)	2.30 (2.00–2.65)	203/396 (51%)	41/369 (11%)	4.66 (3.35–6.49)
South Africa						
24-h recall	56/535 (10%)	30/485 (6%)	1.72 (1.12–2.63)	12/535 (2%)	2/485 (<1%)	5.70 (1.33–24.26)
7-day recall	41/535 (8%)	19/485 (4%)	1.98 (1.30–3.02)	10/535 (2%)	1/485 (<1%)	9.83 (1.40–69.14)

Data are n/N (%), unless otherwise indicated. Data were adjusted for clustering and site. EBF=exclusive breastfeeding.

Table 2: EBF prevalence at ages 12 weeks and 24 weeks based on 24-h recall and 7-day recall

	12 weeks			24 weeks		
	Intervention	Control	Prevalence ratio (95% CI)	Intervention	Control	Prevalence ratio (95% CI)
Burkina Faso	20/392 (5%)	36/402 (9%)	0.57 (0.27–1.22)	26/392 (7%)	32/402 (8%)	0.83 (0.45–1.54)
Uganda	39/396 (10%)	32/369 (9%)	1.13 (0.81–1.59)	52/396 (13%)	59/369 (16%)	0.82 (0.58–1.15)
South Africa	45/535 (8%)	33/485 (7%)	1.16 (0.78–1.75)	54/535 (10%)	33/485 (7%)	1.31 (0.89–1.93)

Data are n/N (%), unless otherwise indicated. Data were adjusted for clustering and site.

Table 3: Diarrhoeal morbidity by 2-week recall at ages 12 weeks and 24 weeks

versus the control clusters in all three countries was 0.95 (0.78–1.17).

Similar results were obtained when the analysis with missing information set as non-events was compared with the analysis omitting subjects with missing information (webappendix pp 21–22). Socioeconomic status did not confound the associations in any of the countries (data not shown).

Discussion

Overall, peer counselling was an effective strategy to increase the practice of EBF in Burkina Faso, Uganda, and South Africa. This effect was particularly important in Burkina Faso and Uganda. At infant age of 12 weeks, about a third of mothers breastfed exclusively in the control clusters in these two countries compared with about 80% in the intervention clusters. The situation in South Africa was quite different with EBF being rare at baseline, and even though the intervention also had a significant effect, the absolute increase was small. Prevalence of diarrhoea before 12 weeks and 24 weeks of age was not significantly different between the intervention and control clusters between these three countries.

The findings of this study are similar to those of similar intervention studies in other parts of the world (panel). Frequent counselling has been associated with a large effect on EBF practices, including two larger studies in Bangladesh²¹ and India,²² and a gradient between counselling frequency and EBF prevalences was shown

in Mexico.²³ The results of our study are also similar to those of a meta-analysis of breastfeeding interventions² in which individual counselling nearly doubled any breastfeeding at age 6 months. The results of the meta-analysis of breastfeeding promotion suggest that facility-based group counselling has a larger effect than does individual counselling. This strategy might, however, not reach women who rarely use health facilities.

The contexts of the countries need to be taken into account during the interpretation of the findings of our trial. Rural and urban diets are similar in South Africa, with most people in rural farming areas purchasing most of their food, whereas subsistence farming is common in rural Uganda and Burkina Faso. Furthermore, the South African Department of Health's routine child health services have a history of promoting commercial infant formula as part of the protein energy malnutrition scheme.²⁴ Additionally, the national programme for prevention of mother-to-child transmission of HIV-1 provided free formula to HIV-infected mothers. Furthermore, the International Code of Marketing of Breast-milk Substitutes²⁵ is not yet legislated in South Africa, allowing the uncontrolled marketing of infant formula throughout the country. Mixed messages are likely to undermine EBF.²⁶ Burkina Faso and Uganda do not provide free formula through the health system and EBF is much more common, as suggested by the data from our control communities in these two countries.

Panel: Research in context**Systematic review**

We searched PubMed up to April 26, 2011, with the search terms “Randomized Controlled Trial” and Breast Feeding*, and “Health Promotion/methods*” for randomised trials in which exclusive breastfeeding (EBF) was promoted in low-income countries, and with Breast Feeding* only for reviews published in the past 5 years. EBF has been widely promoted in other contexts by use of facility-based group counselling, individual counselling, community outreach, and campaigns with differing effects on EBF acceptance and practice. A recent meta-analysis² of 30 studies (of which none was done in Africa) showed a positive effect of EBF on breastfeeding at 6 months of age (odds ratio 1.93, 95% CI 1.18–3.15). Diarrhoea has been the most frequently reported child health outcome related to breastfeeding peer counselling. In a review⁶ done in 2010, five randomised trials were identified in which diarrhoea prevalence or incidence was reduced by peer support promotion of EBF. Two studies were undertaken in Latin America, two in Asia, and one in Africa. The African trial was a smaller facility-based trial of diarrhoea re-occurrence. In another African trial, in Guinea-Bissau,²⁰ no effect of peer counselling was noted on diarrhoea incidence in a birth cohort that was followed up for 6 months (Poisson regression rate ratio 0.99 (0.84–1.17)). In this study, breastfeeding was widely practised and the intervention delayed the introduction of other foods and drinks.

Interpretation

The results of PROMISE EBF show that EBF promotion by peer counsellors more than doubled the proportion of mothers who reported to have exclusively breastfed their infants. Our results for diarrhoea prevalence are similar to those of the trial in Guinea-Bissau. Moreover, epidemiological, behavioural, and other contextual differences are likely to vary greatly between different population groups and, although too early to draw conclusions about the effect of EBF promotion on diarrhoea morbidity from EBF promotion in sub-Saharan Africa as a whole, one hypothesis would be that a shift from a predominantly breastfed infant population to exclusively breastfed does not reduce the diarrhoea-associated morbidity.

Results of qualitative studies associated with our trial showed a high degree of satisfaction with the intervention among mothers in Uganda¹⁰ and Burkina Faso (data not shown). By contrast, in South Africa,^{9,27} targeted concerted actions seem to be needed. These include support to mothers while ensuring that marketing of formula milk is regulated and that health systems harmonise their approaches to infant feeding to avoid giving mothers conflicting messages.

We accordingly undertook a pooled analysis across these three countries that, with a high precision, showed that the intervention did not affect diarrhoea prevalence. In a cluster randomised trial in Guinea-Bissau, a similarly high precision showed that delayed introduction of water and weaning foods had no effect on diarrhoeal morbidity.²⁰

However, breastfeeding might have less effect on the incidence than on the duration and severity of diarrhoea. Our 2-week prevalence assessment includes incident episodes and episodes that started just before but continued into the 2-week observation. So although diarrhoeal duration contributed to our diarrhoeal disease burden estimate, it was not measured as a separate entity. Notably, in a cluster-randomised trial in India, with

roughly the same effect on the prevalence of reported EBF, promotion of EBF substantially reduced the prevalence of diarrhoea.²² In an observational prospective study in Bangladesh, babies exclusively breastfed in the first few months of life had an almost four times lower risk of diarrhoeal deaths than did those who received no breast milk or were partly breastfed.²⁸

In communities where predominant breastfeeding is common, such as Guinea-Bissau,²⁰ and Burkina Faso and Uganda with mainly predominant breastfeeding, a shift to EBF might not generate large differences in diarrhoeal morbidity or mortality. In a multicountry cohort study, although not being breastfed was associated with a substantially increased diarrhoeal mortality risk, babies who were exclusively breastfed were not at a lower risk of dying from diarrhoea than were those predominantly breastfed.²⁹

Our trial was a large community-based and cluster-randomised intervention with an intervention-intensity appropriate for scale-up within national health services. The community-based approach could possibly have resulted in socially desirable answers, and the results were based on self-reports. A bias towards desirable answers and thereby an increased effect size cannot be ruled out. However, the very large effects on reported EBF are unlikely to be attributable to information bias. We also noted some questionnaire fatigue in the Ugandan site—ie, reluctance to fully engage in answering similar questions after a few interviews.¹⁸

Overall, a fairly low-intensity peer-counselling intervention to promote EBF for infants aged up to 6 months in Burkina Faso, Uganda, and South Africa resulted in an increase in EBF prevalence ratios at age 12 weeks and 24 weeks. With the success of increasing EBF prevalence elsewhere,² our findings suggest that the prevalence of EBF can be increased in many sub-Saharan African settings. However, the intervention did not lead to a reduction in diarrhoeal prevalence, and additional studies are needed to assess its effect on other child health and development outcomes.

From a policy-perspective, to achieve the Millennium Development Goal 4, when initiating interventions with specially trained community peers interacting with parents before and after delivery about infant-feeding counselling, the opportunity to undertake other interventions to reduce maternal and neonatal mortality that target mother–infant pairs during pregnancy and early childhood should not be missed—at least not in the 68 countdown countries³⁰ where maternal and infant mortality remains high.

Contributors

TT, DJ, NM, IMSE, MC, TD, AG, CK, JIK, JKN, PvdP, DS, HS, HW, and JKT designed the study and intervention. TT, DJ, IMSE, MC, AHD, TD, E-CE, JIK, CL, HS, and JKT elaborated the data gathering methods and database architecture. TT, DJ, NM, IMSE, MC, AHD, TD, E-CE, JIK, VN, JKN, HS, and JKT implemented the study at the different sites. TT, DJ, IMSE, AHD, TD, LTF, JIK, CL, VN, RS, HS, and HW did the data management and statistical analysis. All authors, except MC, CK, and

JIK, were active in the interpretation of the results. The report was prepared by TT, DJ, and IMSE, and reviewed by AHD, TD, LTF, AG, CL, VN, JKN, PvdP, DS, and HS. All authors have approved the final report.

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Conflicts of interest

We declare that we have no conflicts of interest.

Acknowledgments

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Eratta

Introduction:

Page 13: paragraph 2, last sentence, “This thesis -----to undertake exclusively breastfeeding---.” now reads as, “This thesis-----to undertake exclusive breastfeeding.”

Page 18, paragraph 3, 2nd sentence: “These mothers tend -----because of the t health problem----.” now reads as “These mothers tend -----because of the breast health problem----.”

Page 19, paragraph 3, 3rd sentence: “The MPC No. 183 covers different -----and non-discrimination and ----.” The word “and” has been replaced by “of”

Page 20, paragraph 2, last sentence, “The introduction of the -----undertake successful to breastfeeding.” Now ends as “-----undertake successful breastfeeding.”

Page 21, last paragraph, last sentence: “The question remains -----they would more easily be approach than health workers.” The word “approach” has been changed to approachable.

Page 22, last paragraph, first sentence: “Studies that evaluated -----or social support ore than -----” The word “ore” now reads as “more”

Page 36, last paragraph, 2nd sentence reads, “Mbale is a small district comprised -----” now reads as “Mbale is a small district currently comprised -----”

Page 37 line 5, Sentence which reads, “Mbale district had an estimated -----per square kilometre.” now reads as, “Mbale district had an estimated -----per square kilometre before it was split into smaller districts.”

Page 37, line 5, second sentence “The study was carried out in 2 of the 7 counties of the district:----” should read as “The study was carried out in 2 of the 7 counties of the former district:----”

Page 57, line 13, the words, (appendix 4), has been added after the last sentence.

Page 69, paragraph 4, the word (appendix 4) has been added after the second sentence.