Promotion of exclusive breastfeeding is not likely to be cost effective in West Africa. A randomized intervention study from Guinea-Bissau

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INTRODUCTION
There is no doubt that breastfeeding is the ideal food for infants and it has been documented that an infant needs no supplement and does well easily on breast milk alone up to the age of 6 months (1,2). Therefore exclusive breastfeeding is promoted worldwide by WHO to improve infant and child health (3,4). However, evidence obtained from randomized studies showing that exclusive breastfeeding is beneficial to child health is limited. Only two randomized study, in which mothers were randomized to receive counselling about the benefits of exclusive breastfeeding, have been conducted to evaluate the direct effect of promotion of exclusive breastfeeding on infant morbidity and growth, one from Belarus (5) and one from India (6). A study from Mexico examined, as a secondary outcome, the effect of exclusive breastfeeding promotion on diarrhoea morbidity (7).

The ultimate decision of how to feed an infant is taken by its mother or its family and is a product of culture and traditions as well as socioeconomic conditions and well-being of mother and child. It is therefore always a question whether the observed impact of exclusive breastfeeding on child health is due to reverse causality, selection bias, confounding or a causal effect. Several randomized studies have demonstrated that the proportion of exclusive breastfeeding mothers and children can be increased by counselling (7–9). However the knowledge of the impact of exclusive breastfeeding on child health is based mainly on observational studies (10–16).

In most low-income countries, health situation of infants is poor and there is a need for effective interventions that are carefully evaluated in order to achieve improvements in infant health. Very few settings in low-income countries have the possibility of evaluating the impact of health interventions on mortality. However, in Guinea Bissau, West Africa, the Bandim Health Project maintains a demographic health surveillance system making longitudinal follow-up possible.

As in most Sub-Saharan countries the population in Guinea Bissau is characterized by high infant mortality and high prevalence of infectious diseases. Almost 100% of the mothers start breastfeeding but only few percent are breastfeeding exclusively. Nonetheless, the tradition is prolonged breastfeeding with a median length of more than 22 months (9). The present randomized study with longitudinal follow-up was designed to examine whether promotion of exclusive breastfeeding is effective in reducing infant morbidity and mortality in Guinea-Bissau.

SUBJECTS AND METHOD
Study area
The Bandim health project
The study was conducted at the Bandim Health Project in Guinea-Bissau, West Africa, one of the poorest countries in the world (17). The infant mortality rate is 100/1000 (18) and the case fatality rate among children admitted to the only paediatric ward in the country is almost 15% for children under 5 years of age (19). In the study area, suburban districts...
in the capital, people are living mainly in clay houses. Most houses have no access to electricity, and water is collected at public standpipes or wells.

Since 1978, the Bandim Health Project has maintained a demographic health surveillance system, at the time of the study covering around 46 000 people in four suburban districts. All houses in the study area are visited monthly to record new pregnancies and new births. Children under 3 years of age are followed with three-monthly home visits at which breastfeeding status, arm-circumference, vaccine status, residence and survival are ascertained. Measurements of weight and height are collected by specific teams visiting every month for children less than 6 months of age. The project also registers all admissions at the paediatric ward of the national hospital. The study was registered as a clinical trial and ethically approved by the Ministry of Health in Guinea Bissau and by the Danish Central Ethical Committee.

**Intervention design**

**Study population.** A cohort of infants born between 1 March 2000 and 28 February 2001 were eligible for the study. Infants were enrolled in the study if the mother was recorded as living in the area during pregnancy and present when mother and child were visited by the field assistant during the study period. Further in order to avoid birth-related deaths only children who were alive at 7 days of age were included; for the majority of children dying within the first few hours of life we do not have any information on whether they were fed anything before dying. Exclusive breastfeeding for the first 4–6 months is the official policy in Guinean Bissau. Hence, we did not obtain informed consent at enrolment for the information campaign.

**Follow-up of enrolled infants**

Infants and mothers in both the intervention group and the control group were visited every two weeks. During these visits, health information was given to mothers in the intervention group. The health information was provided individually to the mother. As many mothers are illiterate it was given orally in the local language Criolo by a local female health worker. We have previously performed focus group discussions with different groups of mothers. The local beliefs about why and when to introduce water and weaning food were used as basis for the intervention message, i.e. an infant can satisfy its thirst by breast milk and sexual activity does not harm the breast milk. The health education focused on encouraging the mothers to postpone introduction of water and weaning food until the age of 4–6 months according to the WHO recommendation at the time the study was conducted. As breastfeeding is rarely stopped before 12 months of age, the intervention focused on avoiding early introduction of water and weaning food. Furthermore, it was part of the intervention to explain that breast milk is sufficient as the only nutrient up to 6 months of age and that breast milk has protective effect against illnesses. At the visits it was monitored whether the infant had received any water or weaning food during the preceding two weeks. Children in the control group were visited by the same health worker and at the same intervals as in the intervention group. Only during these visits no health education was given and only the information on introduction of water and weaning food was obtained. These biweekly visits were conducted from birth to 6 months of age or until the infant was reported to have started both water and weaning food.

**Background information**

Apart from the visits in which the intervention was delivered and information on feeding practices was obtained all enrolled infants were followed with weekly morbidity interview and monthly monitoring of anthropometric data. All study children were further followed from birth to 6 months of age, death, migration or weaning whichever came first through the routine registration system. Further the information included birth dates as well as background information such as residence, mother’s age, schooling, ethnic group and vaccination status. Information on hospitalization was obtained from the Bandim Health Project’s routine registration system. HIV infection status was not available but the prevalence of HIV-1 in the country was low at the time of the study. All information from these different routines was collected by field assistants unrelated to the intervention part of the study.

Cluster versus individual randomization. With information interventions there is always a problem of communication between members of control and intervention groups and therefore ‘contamination’ of the control group. To address the question of contamination of the intervention message, we previously conducted a study in the same population randomizing mothers and children into clusters. In that study we found that the variation in how intervention mothers changed feeding habits was the same within the clusters as between the clusters. We therefore concluded that contamination of that type of intervention message in the population was not a major problem (9). In order to increase the power of the present study, we choose to randomize at the individual level.

**Randomization procedure.** All pregnancies detected by the demographic surveillance system at Bandim Health Project are allocated an ID number at the time the mother is recorded as pregnant. ID numbers are allocated sequentially within each subdistrict by an independent assistant who was blind to the enrolment criteria for the present trial. All recorded pregnancies were randomized according to the last two digits of their ID. On a list with numbers from 00 to 99, 50 numbers were randomly allocated to the intervention group and 50 to the control group.

Non-enrolled children. Stillborn children and children who died during the first 7 days after birth were not enrolled in the study.

Among the enrolled infants born in the study area in the study period, a group of 425 mother and child pairs were never present in the study area during the study (Fig. 1). This was mainly due to the mother giving birth outside the study area, the infant moving or dying shortly after birth or being hospitalized shortly after delivery. We were therefore not able to provide intervention to this group and...
enrol them in the study. However, due to the demographic health surveillance system, we know whether these children were alive, had moved or died during the study period. The overall mortality in the group of 425 noneligible children was considerably higher compared with enrolled infants (38/425 (8.94%) vs. 23/1296 (1.77%)) (log rank test for equality of survivor functions $\chi^2 = 7.19, p = 0.007$). There was no difference in total number (197 interventions and 228 controls [risk ratio: 0.91; 95% CI: 0.81–1.02]), and no difference in mortality between the intervention group and control group (HR 0.97 [0.51–1.86]). Significantly more mothers of non-enrolled infants had low educational level (data not shown).

**Statistical methods**

Time to introduction of water and weaning food, hospitalization and death were calculated using a hazard regression model with age as underlying time scale. If the proportional hazard assumption was not fulfilled, log-rank test for equality of survivor functions was used. Testing proportional hazard assumptions was based on Schoenfeld’s assumptions. Mortality ratios were compared using Cox proportional hazard regression model with age as underlying scale. If weaned before 6 months of age the children were censored at the time of weaning. Weight-for-age was computed using the NCHS/WHO growth reference and Anthro software. Weight-for-age $z$-scores above $+3$ or below $-6$ were considered unreliable and included as unknown. If a child had more than one measurement in each age group only the first measurement has been counted (Table 3).

A child was defined as having diarrhoea if the mother reported the child to suffer from diarrhoea independently of the frequency and consistency of the stool. The incidence of diarrhoea was estimated as number of initiated episodes per 100 days at risk. To be counted as independent the episodes should be separated by at least two diarrhoea free days. Diarrhoea incidence rates were compared in a Poisson regression model adjusting for age.
Weight was measured to the nearest 100 g using a Salter scale. Length was measured to the nearest millimetres using a locally manufactured measure board of wood.

The original sample was based on the calculation that it would require a population of 2000 infants to detect a 50% reduction in mortality with 95% confidence limits and 80% power given that the expected mortality rate was 6% for children between 2 and 12 months of age. However, the study took place during a postwar period with political and social turmoil and many labour conflicts. The population was even more mobile than usual, many people staying out of the city that had been hit by the war one year earlier. We therefore enrolled fewer children than originally planned making it unlikely that we would be able to measure any effect on mortality. Hence, we have emphasized the result for morbidity, hospitalizations and growth in the first 6 months of life which would require much fewer children.

RESULTS

Study population

A total of 1721 infants were born in the study period and fulfilled the criteria for inclusion in the study; 857 (49.8%) belonging to the intervention group and 864 (50.2%) to the control group. A total of 1296 infants provided information on either introduction of water and weaning food and were enrolled in the intervention study (Fig. 1). As described above the remaining 425 children were not seen in the area at the time of enrolment and were not eligible for the intervention.

Except for maternal education and birth order, the distribution of different socioeconomic indicators was similar for the intervention group and the control groups (Table S1). The present study is randomized and all results are therefore presented uncontrolled. However, in analyses adjusting all results for maternal education and birth order, we found no effect of these imbalances (data not shown).

Introduction of water and weaning food

As a process indicator for the intervention, we analyzed the time to introduction of water and weaning food. More than 70% of the children received water during the first month of life and at the age of 4 months only 1.2% had not started receiving water (Table 1). Overall water was introduced significantly later in the intervention group compared with the control group (log-rank test for equality of survivor functions: \( p = 0.003 \)). At 2 months of age 19.8% versus 13.2% were receiving water (Table 1). Overall water was introduced significantly later in the intervention group compared with the control group (log-rank test for equality of survivor functions: \( p = 0.003 \)). At 2 months of age 19.8% versus 13.2% from the intervention and control groups, respectively, were not yet introduced to water.

For weaning food, 395 children (31.8%) were not yet introduced at the age of 4 months and at 6 months of age the number was 48 children (4.0%). Overall, weaning food was significantly delayed in the intervention group compared with the control group (Hazard ratio [HR]: 0.79; 95% CI: 0.70–0.91) (Table 1).

Morbidity

A total of 588 episodes of diarrhoea were observed following 58 001 diarrhoea free days (1.01 episodes per 100 days). In the intervention group the incidence was 1.00 per 100 diarrhoea free days and in the control group the incidence was 1.01 per 100 (Poisson regression rate ratio: 0.99 [95% CI: 0.84–1.17]) (Table 2).

Hospitalization

During the first 6 months of life, a total of 20 (2.9%) children from the intervention group and 18 (2.7%) from the control group were hospitalized at least once. No difference in time to hospitalization was revealed between the two groups; median time to first hospitalization was 119 days for the intervention group and 123 days for the control group (Log-rank test for equality of survivor functions: \( p = 0.79 \)). Four children were hospitalized twice; 1 from the intervention group and 3 from the control group.

Anthropometry

A total of 763 infants (386 intervention and 377 control infants) had their weight measured at least once during the study period. There was no difference in median time to first measurement between the two groups (64 days vs. 70 days HR: 0.95; 95% CI: 0.83–1.10). Median number of measurements per child was 7 in both the intervention group and the control group. Among children 4–6 months of age,
Exclusive breastfeeding and infant health

Table 2  Mortality and morbidity. Comparing intervention with control groups. Follow-up from 7 days to 5 months (diarrhoea) and 7 days to 12 months (mortality)

<table>
<thead>
<tr>
<th>Age group</th>
<th>Mortality rate per 100 person-years (number of deaths)</th>
<th>Hazard ratio Comparing I and C (95% CI)</th>
<th>Diarrhoea morbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I</td>
<td>C</td>
<td>Hazard ratio</td>
</tr>
<tr>
<td>7–30 days</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1.43 (0.30–6.77)</td>
</tr>
<tr>
<td>51–60</td>
<td>3.7 (2)</td>
<td>1.9 (1)</td>
<td>1.43 (0.30–6.77)</td>
</tr>
<tr>
<td>61–120 days</td>
<td>5.7 (6)</td>
<td>3.9 (4)</td>
<td>2.11 (0.73–6.15)</td>
</tr>
<tr>
<td>121–180 days</td>
<td>6.5 (7)</td>
<td>2.8 (3)</td>
<td>2.62 (0.93–7.39)</td>
</tr>
<tr>
<td>Overall (7–180 days)</td>
<td>4.7 (15)</td>
<td>2.6 (8)</td>
<td>1.86 (0.79–4.39)</td>
</tr>
<tr>
<td>181–274 days</td>
<td>2.4 (7)</td>
<td>1.4 (4)</td>
<td>1.49 (0.60–3.65)</td>
</tr>
<tr>
<td>275–365 days</td>
<td>2.8 (4)</td>
<td>2.8 (4)</td>
<td>1.05 (0.34–3.29)</td>
</tr>
</tbody>
</table>

Table 3  Median weight for age and median z-score. Comparison between intervention and control groups for different age groups

<table>
<thead>
<tr>
<th>Age group (in days)</th>
<th>Total number of measurements (I/C)</th>
<th>Median weight (kg)</th>
<th>Wilcoxon two-sample test (p-value)</th>
<th>Weight for age (median z-scores)</th>
<th>Wilcoxon two-sample test (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–60</td>
<td>176/151</td>
<td>4.7</td>
<td>0.58</td>
<td>0.44</td>
<td>0.42</td>
</tr>
<tr>
<td>61–120</td>
<td>254/260</td>
<td>6.0</td>
<td>0.23</td>
<td>0.45</td>
<td>0.59</td>
</tr>
<tr>
<td>121–150</td>
<td>210/202</td>
<td>6.8</td>
<td>0.01</td>
<td>0.19</td>
<td>0.47</td>
</tr>
<tr>
<td>151–180</td>
<td>350/349</td>
<td>7.5</td>
<td>0.04</td>
<td>−0.16</td>
<td>0.08</td>
</tr>
</tbody>
</table>

those in the intervention group had a significantly lower weight compared with the control group (Table 3).

Mortality

Among the 1296 children enrolled in the intervention study, 1.7% (23/1296) died between 7 days and before 6 months of age; 2.3% (15/660) died in the intervention group and 1.3% (8/636) in the control group. Mortality was slightly, though not significantly higher in the intervention group, the HR being 1.86 (95% CI: 0.79–4.39) (Table 2).

Using the demographic surveillance of the Bandim Health Project, we followed the study population to the age of 12 months (Table 2). There might still have been some difference at 6–9 months but after 9 months there was no longer any difference between the two groups. In the age group 2–12 months of age specified in the protocol, the HR between the intervention and control group was 1.58 (95% CI 0.85–2.95).

DISCUSSION

In the present study, we randomly allocated the infants to promotion of intensive information on the benefits of exclusive breastfeeding according to WHO recommendation. To our knowledge only two randomized studies undertaken in a low-income countries (India and Mexico) (6,7) have examined the impact of promoting delayed introduction of water and weaning food on morbidity. No studies have been conducted in Africa where breastfeeding is often more intensive and no studies have evaluated the effect on overall mortality.

In the present randomized intervention study with longitudinal follow-up we did not find any beneficial health effects of promoting late introduction of water and weaning food in the intervention group. There was no difference in diarrhoea morbidity and hospitalization rates, the nutritional status was lower in the intervention group between 4 and 6 months of age. Although the sample was smaller than originally planned, there was no tendency towards reduction in mortality – if anything mortality tended to be higher in the intervention group. The intervention was designed to reflect a realistic community situation and our results demonstrate that the benefits of such an intervention are likely to be of limited impact and probably not cost effective.

When investigating the impact of promotion of exclusive breastfeeding on child health, maternal change of behaviour becomes an important process indicator. The intervention appeared to be a success in the sense that the introduction of water and weaning food was significantly postponed in the intervention group compared with the control group. As the study was randomized, the reported delay is unlikely to be a result of socioeconomic bias. Some socioeconomic indicators were not equally distributed between the two groups, but control for these indicators did not influence the estimated difference between the two groups. In this kind of study, change of behaviour is not objective but we have to rely on what the mother reports. The risk of reporting bias must therefore be considered. Collection of information on introduction of water and weaning food was performed by the same health worker and at the same time as the intervention was given, which potentially could give rise to reporting bias as mothers may not want to admit starting water and weaning food. However, the reported change was far from being fully compliant with the WHO
recommendations. It is therefore reasonable to believe that the delay in introduction of water and weaning food was due to a partial acceptance of the intervention message. Contamination of the control group with the intervention message could be a possible source of bias as intervention and control mother might meet and communicate about the intervention. However, we consider it unlikely as data from a previous study with a similar intervention message showed that such a contamination did not take place.

The fact that the mothers only seemed to postpone the introduction rather than to follow the advice and avoid introduction of water and weaning food until the age of 4–6 months might lead to speculations whether the intervention was too weak. In Guinea-Bissau, the introduction of, especially, water is associated with supernatural beliefs. It is even believed that late introduction of water may harm the child. It is understandable that a mother in a society with an infant mortality of 100 per 1000 and poor public health care might not be willing to take the chance of potentially harming her child by delaying introduction of water. Even if the difference in time to introduction of water and weaning food was significant later in the intervention group the difference was small. Health resources in most low-income countries are limited. It must be taken into consideration whether it is sensible to use the limited financial resources to change the mother’s behaviour towards exclusive breastfeeding if it is not improving mortality and morbidity rates considerably.

Exclusive breastfeeding is promoted worldwide with the purpose of improving infant health (4,20). However, the impact on infant health has to our knowledge only been documented in three randomized studies. All three studies report a significant positive impact on infant health. In the study from Belarus (5) exclusive breastfeeding was promoted at hospital level. At 3 months of age 43.3% of the children in the intervention group were exclusively breastfed versus 6.4% in the control group; at 6 months of age, the numbers were 7.9% in the intervention group and 0.6% in the control group. Any breastfeeding at 12 months of age was 19.7% in the intervention group versus 11.4% in the control group. A significant decrease in gastrointestinal disease and atopic eczema was observed in the intervention group. However, in the Belarus study, only around 50% of the children were breastfed at 6 months thus the beneficial effect of the intervention is not solely the effect of exclusive breastfeeding but also the effect of breastfeeding versus no breastfeeding. In Guinea-Bissau, weaning before the age of 12 months is an unusual event and often associated with serious events as death or severe illness of the mother. In our analysis we are therefore only comparing children who are breastfed.

In the study from India, exclusive breastfeeding was promoted in the community (6). At 3 months of age, 79% of the infants in the intervention group were exclusively breastfed compared with 48% in the control group. At 6 months of age, the numbers were 42% versus 4%, respectively. The 7-day diarrhoea prevalence was significantly lower in the intervention communities compared with controls at both 3 and 6 months of age. No difference was seen in anthropometric status. In our study, the diarrhoea incidence was 1 episode per 100 days of observation. This is in line with a previous study from Guinea-Bissau (21). This observational study did not find any difference in diarrhoea morbidity between exclusively breastfed infants and infants introduced to weaning food.

In one randomized study from Mexico diarrhoea morbidity was found to be significantly lower in the intervention group from 0 to 3 months (7). However, 15% of the children in the control group in this study were weaned before 3 months of age, and it is not possible from the numbers to see whether it is exclusive breastfeeding or any breastfeeding that accounts for the lower diarrhoea morbidity in the intervention group.

The beneficial effect of breast milk is often considered to be dose–response related (12,16,21). It could be that early introduction of water and weaning foods is less dangerous in a society with intensive breastfeeding, while the children are still protected by a very high content of immune competent factors in the milk and by maternal antibodies. Alternatively, other factors could be more important than the time of introduction of weaning food e.g. provision of primary health care and the quality of hospital treatment and medication. A recent observational multicentre study from Ghana, Peru and India (22) supports this hypothesis. They found a significant higher morbidity and mortality comparing breastfed infants with no breastfeeding. However there were no significant difference in mortality and morbidity comparing infants who were exclusively breastfed with predominantly breastfed children.

Anthropometric measurements took place in the afternoon when mother and child were often away from the house for visits and we therefore had a relatively large group of children who were not examined anthropometrically. However, missing measurements were equally common in the intervention group and control group. It is unlikely that the children not seen in the control group were more ill than the children not seen in the intervention group. In our study infants from 4 to 6 months of age in the intervention group had a significantly lower weight. None of the study children were malnourished and median z-score were mainly above 0. It is well described that breastfed infants have a lower nutritional status compared with formula-fed children (23,24). Our findings are therefore not likely to be an indication of poor growth or health among the breastfed children but merely a result of different growth patterns for breastfed and formula-fed children.

In Guinea Bissau it is local practice to introduce, especially, water very early although the amounts given usually are small. There is evidence that exclusive breastfeeding may be especially important for the first few weeks of life (25). This important aspect is not covered by the present study as we do not have information on both breastfeeding and morbidity and mortality in the first 7 days of life.

Mothers and children were followed as soon as possible after the birth. However, the study was community based, leading to a delay in the identification of new deliveries. The fact that infant mortality is very high in first 7 days of life makes it an important issue to investigate. There seems to
be no major advantages on the health of infants more than 7-day old when combining the efforts to change mother’s behaviour towards exclusive breastfeeding and the effect on infant health.

International recommendations are generally believed to be beneficial for all infants with the expectation of equal access to the intervention for all groups. It is worth noting that mortality was highest in the group of children who were not even reached by the intervention program. We do not know if promotion of exclusive breastfeeding would decrease mortality in this subgroup, but it would demand considerable and more specific efforts to reach this vulnerable group.

Hence, it is questionable whether large-scale promotion of exclusive breastfeeding will lead to any improvement in infant health in countries with strong breastfeeding practices. It would demand a great effort to change current behaviour patterns. Although we cannot conclude that exclusive breastfeeding does not have a beneficial effect on child health under different circumstances, there would seem to be little reason to discourage local practices unless there are strong data justifying such a change. A more appropriate approach might be to avoid premature (< 1 year) stop of breastfeeding (21), to maintain breastfeeding during illness and hospitalization and to supply secure birth control methods to avoid short intervals between pregnancies (26).

ACKNOWLEDGEMENTS

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References

Supplementary material
The following supplementary material is available for this article:

Table S1 Distribution of socioeconomic indicators between intervention and control groups.

This material is available as part of the online article from: http://www.blackwell-synergy.com/doi/abs/10.1111/j.1651-2227.2007.00532.x
(This link will take you to the article abstract).

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