Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial

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Summary

Background Two recent trials have shown that women's groups can reduce neonatal mortality in poor communities. We assessed the effectiveness of a scaled-up development programme with women's groups to address maternal and neonatal care in three rural districts of Bangladesh.

Methods 18 clusters (with a mean population of 27 953 [SD 5953]) in three districts were randomly assigned to either intervention or control (nine clusters each) by use of stratified randomisation. For each district, cluster names were written on pieces of paper, which were folded and placed in a bottle. The first three cluster names drawn from the bottle were allocated to the intervention group and the remaining three to control. All clusters received health services strengthening and basic training of traditional birth attendants. In intervention clusters, a facilitator convened 18 groups every month to support participatory action and learning for women, and to develop and implement strategies to address maternal and neonatal health problems. Women were eligible to participate if they were aged 15–49 years, residing in the project area, and had given birth during the study period (Feb 1, 2005, to Dec 31, 2007). Neither study investigators nor participants were masked to treatment assignment. In a population of 229 195 people (intervention clusters only), 162 women's groups provided coverage of one group per 1414 population. The primary outcome was neonatal mortality rate (NMR). Analysis was by intention to treat. This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN54792066.

Findings We monitored outcomes for 36 113 births (intervention clusters, n=17 514; control clusters, n=18 599) in a population of 503 163 over 3 years. From 2005 to 2007, there were 570 neonatal deaths in the intervention clusters and 656 in the control clusters. Cluster-level mean NMR (adjusted for stratification and clustering) was 33·9 deaths per 1000 livebirths in the intervention clusters compared with 36·5 per 1000 in the control clusters (risk ratio 0·93, 95% CI 0·80–1·09).

Interpretation For participatory women's groups to have a significant effect on neonatal mortality in rural Bangladesh, detailed attention to programme design and contextual factors, enhanced population coverage, and increased enrolment of newly pregnant women might be needed.

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Introduction

An estimated 3·7 million neonatal deaths occur worldwide every year,[1] 98% of which are in developing countries. In Bangladesh, the neonatal mortality rate (NMR) declined from 63 per 1000 livebirths in 1985–89 to 34 per 1000 in 2002–06.[2–4] A recent survey showed that around 85% of births occur at home.[5] Since around 45% of deaths in children under 5 years of age in Bangladesh occur in the first month of life, further progress in reducing neonatal mortality is essential to achieve Millennium Development Goal 4 (to reduce child mortality by two-thirds by 2015).[6] This progress would require community-based interventions to improve the supply and demand for maternal and neonatal care.

We tested a low-cost, participatory, community-based approach to improving birth outcomes in rural areas in two cluster-randomised controlled trials: the first in Makwanpur, Nepal (2001–03),[7] and the second in Jharkhand and Orissa, India (2005–08).[8] Participatory women's groups reduced neonatal mortality by 30% in Nepal over years 2 and 3 and by 32% in rural India over the 3-year study period. We also assessed a similar approach in a larger population within three rural districts of Bangladesh.[9] We recruited local female peer facilitators who undertook twice as many meetings than did facilitators in the Nepal trial (18 *vs* nine) and covered a population two to five times larger. We also introduced a key informant system to monitor maternal and neonatal mortality rates with detailed interviews or verbal autopsies for all births, neonatal deaths, and maternal deaths.[10] Our aim was to test the generalisability and scalability of this community-based participatory approach with women's groups. A cluster-randomised design was used in the trial because the women's group

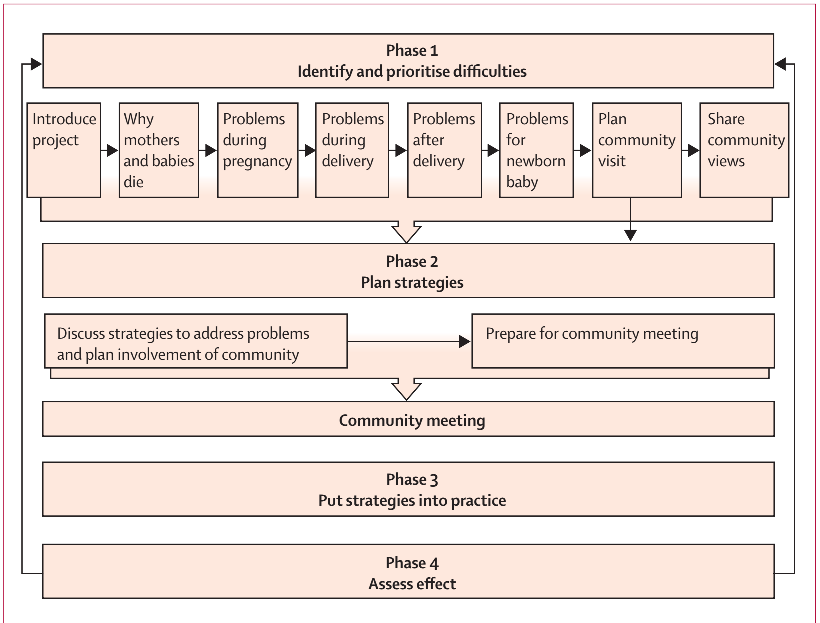

Figure 1: **Description of women's group meetings in the community action cycle**

intervention was implemented at a community rather than individual level.

Methods

Study design, location, and population

We assessed two interventions in the same study area using a factorial design against a common background of health services strengthening: first, a community-based intervention with participatory women's groups to improve maternal and neonatal health outcomes; second, an intervention that involved training traditional birth attendants in bag-valve-mask resuscitation of neonates with symptoms of birth asphyxia.

Three districts, Bogra, Faridpur, and Moulavibazar, were selected by use of purposive sampling from three different divisions in Bangladesh on the basis of the districts having active Diabetic Association of Bangladesh (BADAS) offices (webappendix p 1). Within these districts, subdistricts (upazilas) and unions (the lowest-level administrative units in rural Bangladesh) were also purposefully sampled by use of recommendations from BADAS representatives, the main criteria being perceived limited access to perinatal health care in those unions, and a feasible travelling distance from BADAS district headquarters.

See Online for webappendix

We approached community leaders and obtained their permission to establish women's groups in the intervention clusters in 2004. 451 community orientation meetings were undertaken with the chairmen and members of union councils and community members. The team also undertook 451 village mapping exercises to identify the location of health facilities and social and religious meeting places.

Women were eligible to participate in the study if they were aged 15–49 years, residing in the project area, and had given birth during the study period (Feb 1, 2005, to Dec 31, 2007). The study population was an open cohort—ie, women could enter the study at any time during the trial period if they had given birth. Data was obtained for all eligible women throughout the study period.

Ethics approval was obtained from the ethics committees of BADAS and the University College London Institute of Child Health. Women who chose to participate in the study during the baseline survey and the period of prospective surveillance gave verbal consent and were free to decline an interview at any time.

Randomisation and masking

Each district constituted one stratum and each union a cluster (see webappendix p 2). 18 unions (six per district) were selected. The total population within these 18 unions was 503 163 people, with union sizes ranging from 15 441 to 35 110. Unions were randomly allocated to either intervention or control groups by district in the presence of four project staff (including the project director and project manager) and two external individuals (Nazmun Nahar, Department of Paediatrics, Dhaka Medical College, Dhaka, and Azad Khan, BADAS, Dhaka). For each district, cluster names were written on pieces of paper, which were folded and placed in a bottle. The first three cluster names drawn from the bottle were allocated to the women's group intervention and the remaining three to control. The project manager drew the papers from the bottle. The allocation sequence was decided upon by the project team before drawing the papers and was based on clusters rather than individuals. Clusters had been pre-identified by the team on the basis of previously mentioned criteria.

The control clusters included three tea garden estates that had substantially worse health and socioeconomic indicators than did the rest of the study area. In these areas, surveillance started late because of entry restrictions. We did not know about the entry difficulties and high mortality rates before the recruitment and allocation of clusters and therefore did not exclude these areas before allocation. Additionally, about 10% of mothers in our study area were temporary residents and mainly came into the cluster areas to give birth, since the tradition is for women to go to their mothers' home just before delivery. These temporary residents were not exposed to the women's group intervention, and often had returned to their marital homes outside the study area before the post-natal interview.

In a second-level randomisation, the randomised clusters were further randomly assigned by the same method to traditional birth attendant intervention or control groups. Of the nine women's group intervention clusters, five became traditional birth attendant intervention clusters and four became controls. The nine women's group control clusters were randomised so that four received the traditional birth attendant intervention and five became controls. Overall, for this second-level randomisation, there were nine traditional birth attendant intervention groups and nine control clusters (webappendix p 2).

The randomisation process was done before the collection and analysis of baseline data, and none of the staff attending the randomisation process had any previous knowledge of the health and socioeconomic status of the chosen union clusters. Neither the study investigators nor the participants were masked to group allocation.

Women's group intervention

Women's group facilitators visited every tenth household within the intervention clusters and invited married women of reproductive age to join the groups. The groups initially only included women of reproductive age but others joined later because group members requested that mothers-in-law, adolescents, and other women should also attend.

Women's groups were facilitated by a local female peer facilitator who acted as a catalyst for community mobilisation. Every facilitator was responsible for 18 groups. Facilitators received five training sessions that covered participatory modes of communication and maternal and neonatal health issues. The role of the facilitator was to activate and strengthen groups, to support them in identifying and prioritising maternal and neonatal problems, to help to identify possible strategies, and to support the planning, implementation, and monitoring of strategies in the community. Locally recruited supervisors supported facilitators in preparing for meetings and liaising with community leaders. Groups took part in a participatory learning and action cycle consisting of four phases (figure 1 and webappendix p 3). Control and intervention clusters all received health services strengthening and basic training of traditional birth attendants.

Traditional birth attendant intervention

In clusters assigned to the traditional birth attendant intervention, 482 attendants were given basic training in undertaking clean and safe deliveries, providing safe delivery kits, recognising danger signs in mothers and infants, making emergency preparedness plans, accompanying women to facilities, and undertaking mouth-to-mouth resuscitation. They also received additional training in neonatal resuscitation with bag-valve-mask. A pre-test and post-test questionnaire was done for every traditional birth attendant at the start and end of the initial training session and at subsequent training sessions. Control clusters were given basic training but no training in bag-valve-mask resuscitation.

Health service inputs

The project did not have resources to improve service delivery intensively at all levels of government health

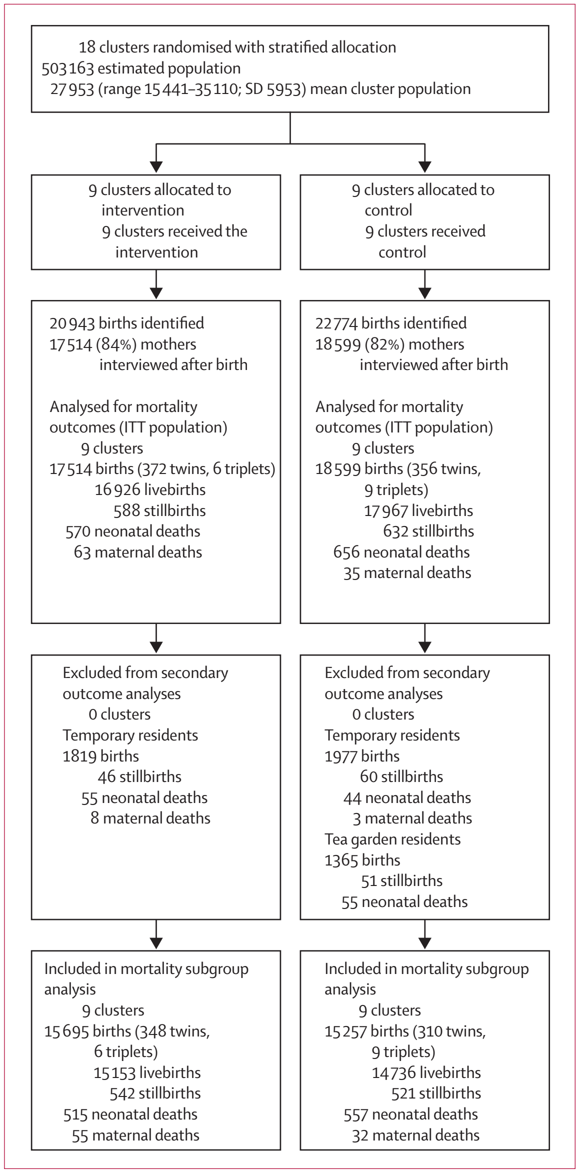

Figure 2: **Trial profile**
ITT=intention to treat.

services. Activities undertaken in both intervention and control clusters focused on improving referral systems, links between the community and health services and between different levels of health services, efficient use of available resources, basic and refresher clinical training relating to essential neonatal and maternal care, in addition to information, education, and communication materials. The training was provided to doctors, nurses, and paramedical staff working at district, upazila, and union levels. This training consisted mainly of refreshing knowledge about antenatal, natal, and postnatal care, recognition of danger signs in the mother and newborn baby, essential care of the newborn baby, the five cleans (clean delivery surface, clean perineum,

	Intervention area	Control area
Births		
Total	3162	3227
Livebirths	3054	3069
Stillbirths	42	73
Neonatal deaths	66	85
Neonatal mortality rate (per 1000 livebirths)*	21·6	26·9
Stillbirth rate (per 1000 births)*	13·3	22·6
Socioeconomic characteristics		
Household characteristics		
Own agricultural land	1558 (49%)	1566 (49%)
Own house	3095 (98%)	3110 (96%)
Own one of almyrah (wardrobe), radio or tape recorder, sewing machine, or bicycle	941 (30%)	1429 (44%)
Own none of the appliances on the list	322 (10%)	248 (8%)
Use of sanitary latrine	1007 (32%)	1476 (46%)
Access to tubewell† water	3061 (97%)	3072 (95%)
Religion		
Islam	2794 (88%)	2621 (81%)
Hinduism	368 (12%)	601 (19%)
Maternal age (years)		
<20	520 (16%)	417 (13%)
20–29	2044 (65%)	1930 (60%)
≥30	591 (19%)	851 (26%)
Maternal education		
None	1589 (50%)	1560 (48%)
Primary	1011 (32%)	901 (28%)
Secondary or higher	560 (18%)	761 (24%)
NGO membership‡	853 (27%)	1046 (32%)
Health-care-seeking and home-care practices		
Antenatal care by formal provider at last pregnancy	1148 (36%)	1085 (34%)
Four or more antenatal check-ups by formal provider at last pregnancy	211 (7%)	284 (9%)
Health facility visit in case of illness during pregnancy	330 (10%)	406 (13%)
Institutional delivery	226 (7%)	302 (9%)
Home delivery	2924 (92%)	2891 (90%)
Home delivery attended by trained TBA§	529 (18%)	424 (15%)
Home delivery attended by untrained TBA§	1058 (37%)	1245 (43%)
Birth attendant washed hands§	1959 (67%)	1847 (63%)
Blade boiled during delivery§	1767 (60%)	1733 (60%)
Appropriate cord care§	2044 (70%)	1891 (65%)
Infant wiped immediately after delivery§	1405 (48%)	1540 (53%)
Infant wrapped immediately after delivery§	1640 (56%)	1658 (57%)
Infant not bathed in first 24 h§	625 (21%)	777 (27%)
Health-care provider seen in first 24 h after delivery	978 (31%)	1434 (44%)
Infant put to breast within 1 h	1611 (51%)	1672 (52%)

Data are number or number (%). 6389 mothers were interviewed, 3213 from intervention unions and 3176 from control unions. NGO=non-governmental organisation. TBA=traditional birth attendant. *Baseline mortality rates were lower than expected when compared with district and national estimates. Unlike the trial data, the baseline mortality estimates were based on retrospective recall rather than prospective identification of births and deaths, which might account for under-reporting. †Well made by driving a tube into the earth to a stratum that bears water. ‡NGO membership is defined as belonging to a microcredit or savings organisation. §Home deliveries only.

Table 1: **Baseline characteristics of mothers and their most recent birth in intervention and control areas**

clean hands of attendant, clean blade to cut cord, clean umbilical stump without anything applied to it), safe delivery kits (soap, a blade, gauze, polythene, and a thread), and safer motherhood.

Surveillance

A prospective monitoring system was developed to record all births and their outcomes within the 18 control and intervention clusters during the project. The system was similar to the one implemented in the India trial and consisted of two stages (webappendix p 4).[10] First, traditional birth attendants (ie, key informants) in the study area identified all births, irrespective of whether they attended them, and deaths in all women during pregnancy or up to 6 weeks after delivery. Each traditional birth attendant was responsible for about 200 households, and was paid an incentive of 60 Taka (US$0·87 on June 8, 2009) for each accurate identification. Surveillance monitors met with traditional birth attendants once a month to gather the information. Second, when births were identified, women were interviewed once 6 weeks after delivery. Interviewers verified the births and deaths identified by key informants and completed a questionnaire that covered background characteristics and the antenatal, delivery, and postpartum periods. All eligible women identified were also asked if they could identify any other pregnant women. In the event of a stillbirth or neonatal death, a verbal autopsy was done with the mother. In the event of a maternal death up to 6 weeks after delivery, a verbal autopsy was done with a close friend or relative. Surveillance started in August, 2004, and covered all clusters by January, 2005.

Primary and secondary outcomes

The primary outcome of the women's group study was NMR (deaths in the first 28 days per 1000 livebirths). Secondary outcomes were maternal deaths (death of a pregnant woman or within 42 days of cessation of pregnancy from any cause related to the pregnancy or its management, but not from accidental causes), stillbirths (fetal death after 28 weeks of gestation but before delivery of the baby's head), uptake of antenatal and delivery services, home-care practices during and after delivery, infant morbidity, health-care seeking behaviour (seeking care for any maternal or newborn illness or complication), perinatal mortality, and early and late NMR. We used the International Classification of Diseases version 9 definition of stillbirth because it was appropriate for this setting.[11]

The primary outcome of the traditional birth attendant study was early NMR. This outcome is presented in this report, but a more detailed analysis of the intervention will be reported in a separate publication. Early neonatal deaths refer to deaths within 6 completed days after birth and late neonatal deaths from 7–28 completed days after birth. Miscarriage was defined as cessation of a presumptive pregnancy before 28 weeks of gestation. Perinatal death describes either a stillbirth or an early neonatal death. We obtained background demographic

	Year 1 (2005)		Year 2 (2006)		Year 3 (2007)		Years 1–3 (2005–07)		All
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	
Births*	4620 (4706)	4586 (4924)	5495 (6183)	5250 (6426)	5580 (6625)	5421 (7249)	15 695 (17 514)	15 257 (18 599)	30 952 (36 113)
Livebirths	4457 (4538)	4441 (4770)	5296 (5961)	5062 (6200)	5400 (6427)	5233 (6997)	15 153 (16 926)	14 736 (17 967)	29 889 (34 893)
Stillbirths	163 (168)	145 (154)	199 (222)	188 (226)	180 (198)	188 (252)	542 (588)	521 (632)	1063 (1220)
Neonatal deaths	138 (139)	175 (196)	187 (215)	202 (233)	190 (216)	180 (227)	515 (570)	557 (656)	1072 (1226)
Early (0–6 days)	108 (109)	128 (144)	159 (184)	158 (184)	143 (167)	149 (186)	410 (460)	435 (514)	845 (974)
Late (7–28 days)	30 (30)	47 (52)	28 (31)	44 (49)	47 (49)	31 (41)	105 (110)	122 (142)	227 (252)
Perinatal deaths	271 (277)	273 (298)	358 (406)	346 (410)	323 (365)	337 (438)	952 (1048)	956 (1146)	1908 (2194)
Maternal deaths	14 (14)	11 (11)	23 (28)	9 (11)	18 (21)	12 (13)	55 (63)	32 (35)	87 (98)
Stillbirth rate per 1000 births	35·3 (35·7)	31·6 (31·3)	36·2 (35·9)	35·8 (35·1)	32·2 (29·9)	34·7 (34·8)	34·5 (33·6)	34·1 (33·9)	34·6 (33·8)
NMR per 1000 livebirths	30·9 (30·6)	39·4 (41·1)	35·3 (36·1)	39·9 (37·5)	35·2 (33·6)	34·4 (32·4)	34 (33·7)	37·8 (36·5)	35·9 (35·1)
Early NMR per 1000 livebirths (0–6 days)	24·2 (24·0)	28·9 (26·8)	30 (30·9)	31·2 (29·7)	26·5 (26·4)	28·5 (26·6)	27·0 (27·1)	29·5 (28·6)	28·3 (27.9)
Late NMR per 1000 livebirths (7–28 days)	6·7 (6·1)	10·6 (10·9)	5·3 (5·2)	8·7 (7·9)	8·7 (7·6)	5·9 (5·8)	6·9 (6·7)	8·3 (7·9)	7·6 (7·2)
Perinatal mortality rate per 1000 births	58·6 (58·8)	59·5 (60·5)	65·1 (65·6)	65·9 (63·8)	57·8 (55·0)	62·2 (60·4)	60·6 (59·8)	62·6 (61·6)	62·4 (60·7)
Maternal mortality ratio per 100 000 livebirths	314·1 (308·5)	247·7 (230·6)	434·3 (469·7)	177·8 (177·4)	333·3 (326·7)	229·3 (185·7)	363 (372·2)	217·1 (188·1)	291·1 (280·8)

Data in parentheses include temporary and tea garden residents. NMR=neonatal mortality rate. *Includes all births for which interviews were completed from Feb 1, 2005, to Dec 31, 2007.

Table 2: **Births, deaths, and crude mortality rates in intervention and control clusters during the trial period (2005–07)**

and socioeconomic information to investigate cluster comparability.

Quality control of data

Data were double-entered in an electronic database. Quality checks were undertaken by district-based surveillance supervisors who manually checked information provided by the traditional birth attendants and monitors. The field surveillance manager, data input officer, and data manager undertook manual and systematic data checks. Additionally, we cross-checked a subsample of our data with government records.

Statistical analysis

We undertook a cross-sectional baseline survey for the women's group study from January to March, 2003, in more than 6000 mothers who had delivered a baby within the past year, to obtain data for household and demographic characteristics, in addition to data for pregnancy, delivery, and neonatal outcomes. Details of the sampling method used for this survey have been published elsewhere.[9] The baseline survey was undertaken to gather data for neonatal care practices and behaviour, but not to provide precise NMRs in view of its limited sample size. We based our original sample size calculations on the national estimate of neonatal mortality from Bangladesh Demographic and Health Survey data from 2004, which gave a value of 41 deaths per 1000 livebirths for the 1999–2003 period. With an estimated 1600 livebirths per cluster over 3 years, a k value of 0·3, and a baseline NMR of 41 deaths per 1000 livebirths, the study had a power of 56% to detect a 30% reduction in NMR at the 95% significance level. After the end of the trial, we undertook a retrospective calculation to understand whether our inability to detect an effect of the intervention could be caused by a lack of power. From our study data, the harmonic mean of the number of recorded livebirths per cluster over the study period was 1467 (range 1081–2708). The stratum-average intracluster correlation coefficient was 0·00056, corresponding to a between-cluster coefficient (k) of 0·12 with the observed NMR in the control groups of 38 deaths per 1000 livebirths.[12] On the assumption of a baseline NMR of 38 deaths per 1000 livebirths, the study had a power of 88% to detect a reduction in neonatal mortality of 25% at the 95% significance level.

We did not expect the intervention to have adverse effects at cluster or participant level and therefore did not have any stopping rules. A preliminary analysis was undertaken in July, 2008, and findings were presented to an independent data safety monitoring board. The board recommended a final analysis of data for all births in the study area between Feb 1, 2005, and Dec 31, 2007.

Analysis was by intention to treat (ITT) at cluster and participant levels. Temporary and tea garden residents were included in the analysis for mortality outcomes. However, they were excluded from analyses for secondary outcomes since they were unlikely to have been exposed to the intervention.

We compared NMRs, stillbirth rates, and maternal mortality ratios between control and intervention groups by use of stratified cluster-level analysis because of the small number of clusters in each group. These analyses involved calculating risk ratios for each stratum and then

	Intention-to-treat population			Excluding temporary and tea garden residents			
	Intervention cluster	Control cluster	Unadjusted* risk ratio (95% CI)	Intervention cluster	Control cluster	Unadjusted risk ratio* (95% CI)	Adjusted risk ratio† (95% CI)
NMR per 1000 livebirths	33·9	36·5	0·93 (0·80–1·09)	34·2	37·7	0·92 (0·75–1·12)	0·90 (0·73–1·10)
Early NMR per 1000 livebirths (0–6 days)	27·2	28·8	0·95 (0·78–1·16)	27·1	29·5	0·93 (0·75–1·15)	0·91 (0·72–1·14)
Late NMR per 1000 livebirths (7–28 days)	6·7	7·7	0·87 (0·59–1·29)	7·0	8·1	0·90 (0·57–1·41)	0·87 (0·54–1·38)
Stillbirth rate per 1000 births	33·6	34·3	0·97 (0·82–1·15)	34·5	33·8	1·01 (0·82–1·21)	1·00 (0·82–1·21)
Perinatal mortality rate per 1000 births	59·9	62·2	0·96 (0·87–1·07)	60·7	62·3	0·97 (0·90–1·05)	0·96 (0·88–1·04)
Maternal mortality ratio per 100 000 livebirths	388·9	189·1	2·02 (1·11–3·68)	375·2	211·4	1·73 (0·98–3·05)	1·74 (0·97–3·13)

Data are mean rate. NMR=neonatal mortality rate. *Adjusted for stratification and clustering only. †Adjusted for stratification, clustering, maternal age (continuous), maternal education (categorical 1–5), and having no household assets.

Table 3: **Comparison of mortality rates in intervention and control clusters (2005–07)**

an overall weighted mean of these, testing the null hypothesis that the true overall risk ratio is 1 by use of a stratified *t* test.[13] We noted baseline differences in maternal education, maternal age, and household assets between intervention and control clusters: mothers in the intervention clusters were slightly younger, less educated, and had fewer household assets. We adjusted for these covariates by use of the two-stage method described by Hayes and co-workers[13] for cluster-level analysis. First, a logistic regression model was fitted to the individual-level data, which incorporated the stratum, maternal age, education, and household assets, but excluded any information about trial group. The resulting regression model was used to calculate ratio residuals for each cluster, which were then used in place of cluster-level observations for a stratified *t* test described above for unadjusted analysis. Results are presented as risk ratios with 95% CIs.

In the assessment of the traditional birth attendant intervention, only home deliveries were included in the analysis. Analysis was at cluster level and adjusted for stratification as described for the women's group assessment, but in this analysis the strata were clusters in which the women's group intervention was implemented, and clusters in which no women's groups were implemented. We undertook tests to check for interactions between the traditional birth attendant and women's group interventions and did not find any. We therefore analysed the women's group data as if from a single trial with two groups.

This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN54792066.

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. Representatives from the Big Lottery Fund and Saving Newborn Lives visited the project during the trial implementation. All authors had access to all the data in the study. KA and AC had final responsibility for the decision to submit for publication.

Results

Figure 2 shows the trial profile. The estimated population size was 503 163 people. All nine selected clusters had the intervention. All women's groups had finished their first meeting by September, 2004. The traditional birth attendant intervention started in March, 2005, with all attendants completing their training in May, 2005. We monitored births and deaths in the study area between Feb 1, 2005, and Dec 31, 2007. Interviews were completed for 17 514 births in the intervention clusters and for 18 599 births in control clusters (including temporary and tea garden residents). These data correspond with 84% of 20 943 births registered by key informants in intervention areas and 82% of 22 774 births in control areas (figure 2). The main reason for failure to interview was maternal migration.

Table 1 shows baseline characteristics of intervention and control clusters gathered in a retrospective survey. 6389 mothers were interviewed, 3213 from intervention unions and 3176 from control unions. The number of mothers to be interviewed in each union was weighted according to the total union population based on the 1991 Bangladesh census.[14] Women who had delivered a baby within the past 12 months were selected for interview by use of random sampling. We noted differences in maternal education, maternal age, and household assets between intervention and control unions, with a greater proportion of mothers in the intervention unions with no education and no household assets. Mothers in intervention unions were also more likely to be younger than mothers in control unions. Further results from this survey are reported elsewhere.[9]

In a total population of 229 195 people in the nine clusters, 162 women's groups provided a coverage of one group per 1414 population. In 2007, 2363 (9%) women of reproductive age in the intervention clusters (n=27 614) were group members. Almost half the members (1158 women, 49%) were between 25 years and 34 years old with fewer (378 women, 16%) younger members (<24 years old). The groups held meetings once a month and completed a cycle of 20 meetings. The mean attendance during the first ten meetings was 73% (1735 women) of registered members. Only 477 (3%) of 15 695 women who gave birth and were interviewed during the study period reported attending a group.

Unadjusted NMRs per 1000 livebirths were 30·6 in 2005, 36·1 in 2006, and 33·6 in 2007 in the intervention clusters (including all residents), and 41·1, 37·5, and 32·4 in the control clusters, respectively (table 2). The risk ratio for neonatal mortality, taking into account clustering and stratification, for the 3-year period was 0·93 (95% CI 0·80–1·09; table 3). The difference in maternal mortality ratio between intervention and control clusters was based on fairly small numbers of deaths but reached significance when temporary and tea garden residents were included in the analysis (table 3). Although this finding is of concern, 46 of the 55 maternal deaths in the intervention clusters (excluding tea garden or temporary residents) were to women who had neither heard of nor attended groups and there were no maternal deaths in members of women's groups, which suggests that the intervention did not have a direct adverse effect. Additionally, maternal mortality was a secondary outcome of the study and the sample size only gave us power to detect large differences.

In intervention clusters, neonatal mortality increased during year 2 then stabilised in year 3. In control clusters, neonatal mortality decreased over time, although the differences were not significant (figure 3). Stillbirth rates did not differ between intervention and control clusters.

No significant differences were noted in most home-care practices or health-care-seeking behaviours between intervention and control clusters (table 4). However, we did see higher frequencies of delayed bathing and exclusive breastfeeding in the intervention clusters than in the control clusters. The proportion of institutional deliveries was slightly higher in control clusters than in intervention clusters, which might have contributed to the difference noted in maternal mortality.

To further examine the effect of the women's group intervention, we compared birth outcomes and selected home-care and health-care-seeking practices in women's group members and non-group members in the intervention clusters (webappendix pp 5–6). The proportion of women with hygienic delivery practices was higher in group members than in non-group members. Additionally, group members were more likely to avoid bathing in the first 24 h and to undertake exclusive breastfeeding for the first 6 weeks than were non-group members.

Data from our process assessment showed that the three main strategies implemented by women's groups were the creation of emergency funds managed by the groups, the raising of awareness of maternal and newborn health issues during meetings and in the community by use of materials provided by the groups (such as picture cards and flipcharts), and the fostering of effective communication with health-care providers through meetings with group representatives. These strategies changed over time and varied between groups.

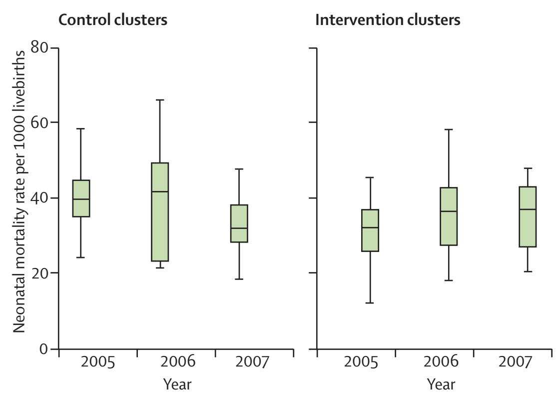

Figure 3: **Mean overall neonatal mortality rates in intervention and control clusters by year (2005–07)**
Boxes include lower and upper quartiles, the lines within boxes represent the median, and the error lines represent the range.

In clusters in which selected traditional birth attendants were trained in bag-valve-mask resuscitation, there were 12 519 home births, of which 8618 were attended by any traditional birth attendant and 2792 by a traditional birth attendant trained in bag-valve-mask resuscitation. In the control clusters, there were 13 195 home births, of which 9171 were attended by any traditional birth attendant and 2536 by a traditional birth attendant trained in mouth-to-mouth resuscitation. Mean early NMRs did not differ significantly between clusters in which traditional birth attendants received training in bag-valve-mask resuscitation (25·4 deaths per 1000 livebirths) and control clusters (26·5 deaths per 1000 livebirths). The risk ratio for early neonatal death was 0·95 (95% CI 0·75–1·21). A more detailed assessment of this intervention will be reported in a separate publication. We did not find any interactions between the traditional birth attendant and women's group interventions.

Discussion

Our study shows that participatory women's groups did not significantly reduce neonatal mortality in poor rural populations of Bangladesh. This finding contrasts with the large reductions in mortality reported in other trials undertaken in Nepal and India.[7,8] This trial monitored birth outcomes in a large population and had fewer clusters than did previous trials; however, the intracluster correlation coefficient was small, thus our inability to detect a difference in NMR between intervention and control clusters cannot be attributed to lack of power. Although neonatal mortality was lower in the intervention clusters than in the control clusters over the 3 years of the trial, there was also a decline in neonatal mortality in the control clusters over time. This finding might reflect underlying secular trends in mortality seen in other parts of Bangladesh, and merits further investigation.[15,16]

	Intervention cluster	Control cluster	Unadjusted risk ratio* (95% CI)	Adjusted risk ratio† (95% CI)
Births‡				
Any antenatal care	58·7%	64·5%	0·88 (0·72–1·09)	0·91 (0·76–1·09)
≥4 ANC visits	13·1%	15·8%	0·74 (0·39–1·39)	0·79 (0·46–1·37)
Any iron tablets	53·7%	57·5%	0·95 (0·69–1·30)	0·96 (0·70–1·31)
Maternal tetanus-toxoid injection	69·1%	69·4%	0·99 (0·86–1·14)	0·99 (0·86–1·14)
Institutional deliveries	14·6%	16·2%	0·91 (0·67–1·24)	0·97 (0·77, 1·24)
Home deliveries	84·3%	82·4%	1·02 (0·96–1·09)	1·01 (0·96–1·06)
Attended by formal provider (doctor or nurse)	2·0%	4·3%	0·85 (0·63–1·14)	0·90 (0·72–1·14)
Attendant washed hands with soap	68·4%	65·3%	1·05 (0·86–1·29)	1·25 (0·88–1·75)
Safe delivery kit used	27·1%	18·4%	1·29 (0·77–2·16)	1·28 (0·71–2·30)
Plastic sheet used	46·7%	41·4%	1·11 (0·87–1·43)	1·12 (0·86–1·47)
Cord cut with new or boiled blade	92·4%	92·1%	1·01 (0·97–1·04)	1·00 (0·97–1·03)
Appropriate cord care	68·1%	67·2%	1·01 (0·80–1·27)	1·00 (0·80–1·26)
Livebirths (home deliveries)				
Infant wiped within 30 min	78·1%	72·7%	1·06 (0·85–1·33)	1·06 (0·85–1·32)
Infant wrapped within 30 min	75·6%	76·1%	0·98 (0·75–1·28)	0·98 (0·76–1·27)
Infant not bathed in first 24 h	70·7%	60·4%	1·14 (0·97–1·33)	1·15 (0·97–1·36)
Infants alive at 1 month				
Any of three infant illnesses (cough, fever, diarrhoea)	27·4%	28·6%	0·93 (0·74–1·17)	0·92 (0·73–1·16)
Health-care-seeking behaviour in event of infant illness	22·5%	24·3%	0·89 (0·70–1·13)	0·89 (0·71–1·13)
Exclusive breastfeeding for first 6 weeks	68·0%	61·5%	1·10 (0·98–1·24)	1·10 (0·98–1·23)

Data are %. Percentages based on cluster means. ANC=antenatal clinic. *Adjusted for clustering and stratification only. †Adjusted for clustering, stratification, maternal education, maternal age, and having no household assets. ‡Excludes births to tea garden and temporary residents; includes births between Feb 1, 2005, and Dec 31, 2007.

Table 4: **Process indicators in intervention and control clusters**

Maternal mortality was higher in intervention clusters than in control clusters during the 3 years of the trial. This difference only reached significance when tea garden and temporary residents were included in the analysis. There are no obvious population, health service, or other contextual factors to explain this finding, and there is no evidence that women's groups discouraged use of health services. Also, there were no deaths in mothers who attended women's groups. We do not wish to over-interpret differences in maternal mortality rates on the basis of low numbers of maternal deaths. The effects of women's group membership on maternal mortality might become evident with meta-analysis of several trials.

Despite the absence of a significant effect of women's groups on neonatal mortality, process data suggested that good perinatal practices in intervention clusters were slightly better than they were in control clusters, such as use of a safe delivery kit, exclusive breastfeeding for the first 6 weeks, and avoidance of early bathing. Nonetheless, none of these findings were significant, and the continuing second phase trial, in which women's group coverage has been increased to one group per 400 population, should clarify questions about any significant effects of women's groups on maternal mortality or perinatal care practices.

We believe that the lack of effect of the intervention in this setting was caused by three main factors. First, the population coverage of women's groups (one group per 1414 population) was less than a third of the coverage achieved in the India trial (one group per 468 population)[8] and less than half that in the Nepal trial (one group per 756 population).[7] Findings from these three trials suggest that population coverage and the proportion of newly pregnant women enrolled in groups might need threshold levels to have an effect on birth outcomes (perhaps of the order of one group per 450–750 population, and between 30% and 50% of newly pregnant women attending groups, respectively). The enrolment of newly pregnant women is likely to be a key determinant of the effectiveness of women's groups.

Second, we believe that the quality of the intervention might have been affected by several factors related to the size of the study. The total population covered by the project was much larger than that covered in the Nepal or India trials, but facilitators in our study had to coordinate more groups than did those in other trials. The project had difficulties in retaining facilitators and supervisors, which might have led to disruptions in meetings and reduced support for community mobilisation. Facilitators also had an increased workload, since they arranged 18 meetings per month compared with nine per month in the trial in Nepal. Although the support structure and ratio of supervisors to facilitators in this study were similar to those in Nepal and India, in practice coordinators often lived further away from women's group facilitators than did those in other sites, and they were not able to provide refresher training and continuing support to facilitators. Facilitators' use of participatory techniques to stimulate community mobilisation is the hallmark of this intervention and lack of support for facilitators might have damaged the quality of the intervention.

Third, local contextual factors could have had a role: adverse climatic conditions affected the facilitators' ability to travel to meetings and one of the intervention unions in Faridpur was entirely flooded in 2007. Additionally, there are signs that gender-based barriers were strong in some of the intervention unions, and might have prevented some women from joining groups, seeking care, or from implementing strategies if they had joined a group. For example, some women reported facing problems when asking for their husbands' or in-laws' permission to join a group. Other women's groups linked to non-governmental organisations (NGOs) operated in our study area, and women were regularly asked to participate in NGO activities for which they could receive financial incentives. Women might therefore have been deterred from investing time in women's group meetings for which no incentives were offered. Despite these problems, all 162 groups continued to meet after the end of the programme's cycle.

The purposive selection of districts and upazilas, and the stratification of sampling, together with the restricted number of clusters, might have limited the effectiveness of randomisation procedures. The participatory approach assessed in this study contrasts with health-worker-led interventions tested in other recent trials of community-based newborn care.[17,18] In Bangladesh, the Projahnmo trial[18] compared home care, consisting of multiple community health worker visits to pregnant mothers, with a community mobilisation group and a control group. The results showed no overall significant differences between groups in NMR over the 3 years of the trial, but there was a 34% reduction in NMR in the final 6 months of the trial in the home-care group. However, the community mobilisation approach used in the Projahnmo trial was not participatory and was less intensive than the approaches used in the Nepal, Indian, and Bangladesh Perinatal Care Project trials. In the Projahnmo community-care group, each female community health worker was responsible for a population of 18 000 people, which was divided so that each geographical area of about 225 people was visited once every 4 months; the male community health workers visited each area every 10 months. Just as we propose for this trial with women's groups, we do not believe that this level of coverage and intensity is sufficient to bring about behaviour change and reduction in mortality.

Few government programmes have managed to provide multiple prenatal or postnatal home visits to mothers and infants when scaled up.[19] By contrast, women's groups, if scaled to an adequate coverage, have the potential to reach the poorest people and bring about substantial health and non-health benefits. Nonetheless, a women's group approach requires adequate human resources support for community mobilisation and appropriate coverage. The threshold coverage or dose effect for the women's group intervention needs to be established for future scale-up programmes. This threshold coverage raises an important new research and policy question: would scaling up the coverage of women's groups in Bangladesh achieve the same effect on mortality as did the intervention in India and Nepal, or is the absence of effect caused by other delivery and social context barriers? We are currently assessing the effect of more intensive scale-up of women's groups in the intervention clusters to increase population coverage and membership of pregnant women to levels similar to those reported in the trial in India. Additionally, we are improving support for facilitators and implementing strategies to counter gender-based barriers, such as the involvement of men and religious leaders. We are closely monitoring contextual factors that might affect the delivery of the intervention through a detailed process assessment. The results of this assessment will establish whether the success of women's groups is dependent on population coverage, or whether specific contextual and delivery factors reduce their effectiveness.

Contributors

All the authors contributed to the design of the study and criticised drafts of the report. KA, SB, and AC were responsible for the conception and overall supervision of the trial. KA and her team managed the project, data collection, data entry, and administration with assistance from BB and SS. SB, ME, and AC were technical advisers to the study. AC, KA, and SB helped design the original trial protocol. SB designed the data collection methods and epidemiological surveillance system. AP, CP, and SB undertook the quantitative analysis. AC, AP, SB, and KA wrote the first draft of the report and were responsible for subsequent collation of inputs and redrafting. KA and AC are guarantors for the report.

Conflicts of interest

We declare that we have no conflicts of interest.

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