Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial

Prasanta Tripathy, Nirmala Nair, Sarah Barnett, Rajendra Mahapatra, Josephine Borghi, Shibanand Rath, Suchitra Rath, Rajkumar Gope, Dipnath Mahto, Rajesh Sinha, Rashmi Lakshminarayana, Vikram Patel, Christina Pagel, Audrey Prost, Anthony Costello

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Ekjut, Chakradharpur, Jharkhand, India (P Tripathy MSc, N Nair MBBS, R Mahapatra MSc, Sh Rath MA, Su Rath MA, R Gope PGDRD, D Mahto DCHM, R Sinha); **University College London Centre for International Health and Development, Institute of Child Health, University College London, London, UK** (S Barnett PhD, A Prost PhD, Prof A Costello FRCP); **Effective Intervention, Centre for Economic Performance, London School of Economics and Political Science, London, UK** (R Lakshminarayana DNB); **London School of Hygiene and Tropical Medicine, London, UK** (J Borghi PhD, Prof V Patel PhD); **Sangath, 841/1 Alto Porvorim, Goa, India** (Prof V Patel); **and Clinical Operational Research Unit, University College London, London, UK** (C Pagel PhD)

Correspondence to: Dr Prasanta Tripathy, Ekjut, Ward Number 17, Plot 556B, Potka, Po-Chakradharpur, District West Singhbhum, Jharkhand, 833102, India
prasanta.ekjut@gmail.com

Summary

Background Community mobilisation through participatory women's groups might improve birth outcomes in poor rural communities. We therefore assessed this approach in a largely tribal and rural population in three districts in eastern India.

Methods From 36 clusters in Jharkhand and Orissa, with an estimated population of 228 186, we assigned 18 clusters to intervention or control using stratified randomisation. Women were eligible to participate if they were aged 15–49 years, residing in the project area, and had given birth during the study. In intervention clusters, a facilitator convened 13 groups every month to support participatory action and learning for women, and facilitated the development and implementation of strategies to address maternal and newborn health problems. The primary outcomes were reductions in neonatal mortality rate (NMR) and maternal depression scores. Analysis was by intention to treat. This trial is registered as an International Standard Randomised Controlled Trial, number ISRCTN21817853.

Findings After baseline surveillance of 4692 births, we monitored outcomes for 19 030 births during 3 years (2005–08). NMRs per 1000 were 55·6, 37·1, and 36·3 during the first, second, and third years, respectively, in intervention clusters, and 53·4, 59·6, and 64·3, respectively, in control clusters. NMR was 32% lower in intervention clusters adjusted for clustering, stratification, and baseline differences (odds ratio 0·68, 95% CI 0·59–0·78) during the 3 years, and 45% lower in years 2 and 3 (0·55, 0·46–0·66). Although we did not note a significant effect on maternal depression overall, reduction in moderate depression was 57% in year 3 (0·43, 0·23–0·80).

Interpretation This intervention could be used with or as a potential alternative to health-worker-led interventions, and presents new opportunities for policy makers to improve maternal and newborn health outcomes in poor populations.

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Introduction

Every year, an estimated 3·7 million children worldwide die in the first month of life.[1,2] Global progress in reduction of maternal and child mortality rates is insufficient—only 16 of 68 countries are on track to achieve Millennium Development Goal 4 (reduction of mortality rate in children <5 years by two-thirds between 1990–2015).[3] India accounts for 20% of maternal deaths worldwide, 21% of all child (<5 years) deaths, and 25% of all neonatal deaths.[4] Urgent efforts are needed to reduce these mortality rates quickly through cost-effective and scalable interventions.

Large improvements were noted in birth outcomes in a poor rural population in Makwanpur, Nepal, after a low-cost, potentially sustainable, and scalable participatory intervention with women's groups.[5] Newborn mortality rates were 30% lower in intervention areas than in control areas (odds ratio 0·70, 95% CI 0·53–0·94).[5] Local female facilitators assisted women's groups every month to consider the causes and underlying problems leading to maternal and newborn deaths, develop practical strategies with community leaders and men, and implement and assess the outcomes of these strategies. This community-action cycle, adapted from a programme developed in Bolivia, created health and non-health benefits at low cost.[6]

Maternal depression is an increasing public health concern in low-income countries because of its high prevalence and wide-ranging implications for the health of the mother and infant.[7] Delivery of appropriate interventions to prevent or treat maternal depression through health workers is a major challenge in countries with under-resourced health systems, and community groups assisted by non-health-care workers might have some advantage in helping the poorest women.[8]

Jharkhand and Orissa are two of the poorest states in eastern India. About 40% of their total combined population lives below the poverty line.[9] The average life expectancy among women in both states is about 60 years, and an estimated 63% are illiterate.[10] Neonatal mortality

rate (NMR) per 1000 livebirths is 49 in Jharkhand and 45 in Orissa, and maternal mortality ratio per 100 000 livebirths is 371 and 358, respectively.[11,12] These are disproportionately higher than India's national estimates of 39 per 1000 for NMR and 301 per 100 000 for maternal mortality ratio.[11,12]

More than 20% of Jharkhand and Orissa's population is affiliated with Scheduled Tribes (or Adivasi—ie, indigenous groups), and about 12% with scheduled castes.[13] Despite calls for inclusive development, Adivasi communities remain underserved—their employment rate is roughly half that of non-indigenous people, and nearly a third of Adivasi children in Jharkhand and Orissa do not receive primary education.[12,13] Indigenous communities also have higher mortality rates and poorer access to health services than do the non-indigenous populations.[14]

We hypothesised that a participatory intervention with women's groups could reduce neonatal mortality by at least 25% in underserved tribal communities of eastern India, and improve home-care practices and health-seeking behaviour of pregnant and postnatal women, and their family members; and that the women's group intervention could reduce maternal depression in the intervention areas by 30%.

Methods

Study location and population

Our study was done in three contiguous districts of Jharkhand and Orissa—Saraikela Kharswan, West Singhbhum, and Keonjhar (figure 1). The proportion of Adivasis within the study clusters was 58–70%. Eligible participants were women aged 15–49 years, residing in the project area, and who had given birth during the study (July 31, 2005, to July 30, 2008). 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. Women who chose to participate gave their consent (written or left-thumb print) and were free to decline an interview at any time. Women who were identified by interviewers as having symptoms of severe depression were referred to the nearest tertiary mental health centre at Ranchi. Ethical approval was obtained from an independent ethical committee in Jamshedpur, India.

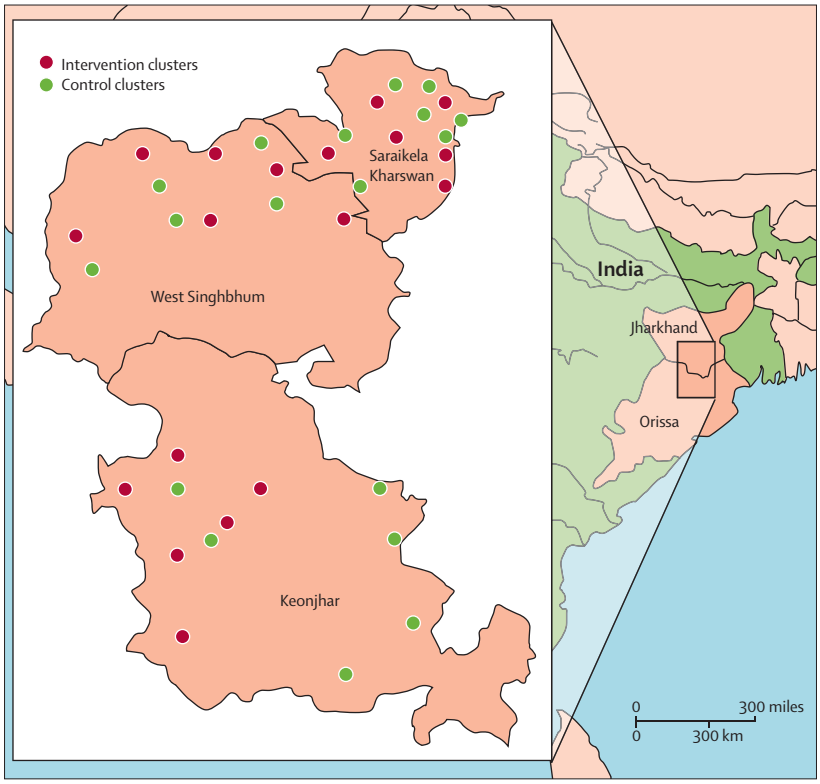

Figure 1: **Map of districts and distribution of clusters**

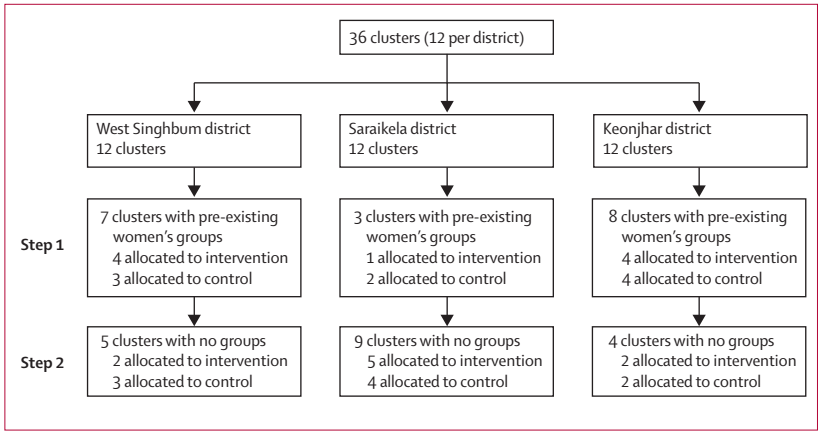

Figure 2: **Randomisation process**

Randomisation

We identified 12 rural clusters per district, with a mean population of 6338 per cluster (range 3605–7467). The estimated population in these 36 clusters was 228 186 (on the basis of the 2001 Indian census projections).[15] In 18 clusters, existing women's groups were involved in savings and credit activities (seven in West Singhbhum, three in Saraikela Kharswan, and eight in Keonjhar). In the first district (West Singhbhum), an external observer from a partner non-governmental organisation (Professional Assistance for Development Action) drew folded papers with numbers corresponding to clusters with existing groups from a basket. The first four clusters were allocated to the intervention group, the rest to the control group. This process was repeated for clusters without women's groups and in the other two districts in the presence of external observers (figure 2). We chose this method because of simplicity and visibility, which were necessary to convince local communities that the process was transparent. Because of the nature of the intervention, neither the intervention team nor the participants were masked to group assignment during the trial.

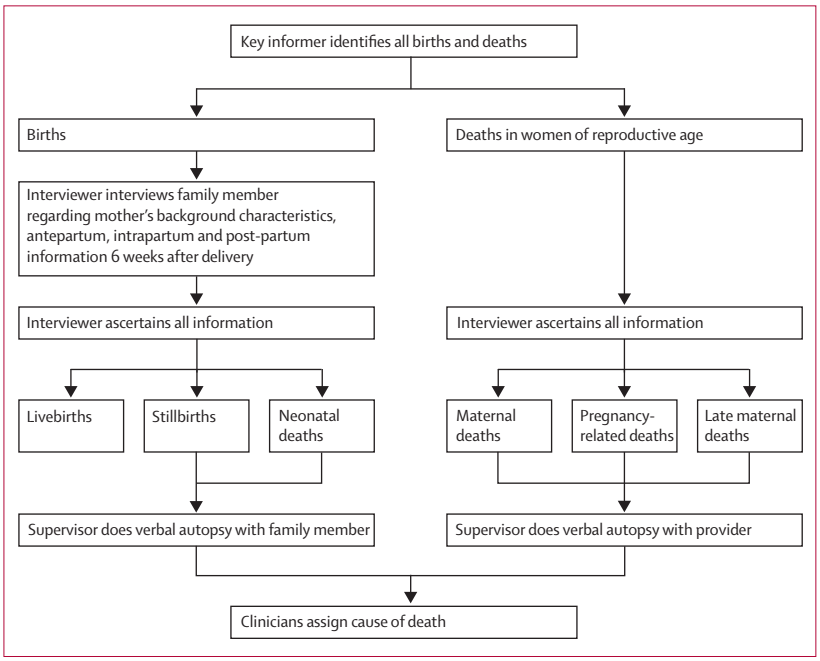

Figure 3: **Surveillance system**

***Panel 1:* Definitions**

- Miscarriage: cessation of a presumptive pregnancy before 22 weeks of gestation before delivery of the baby's head[17]
- Neonatal death: death of a liveborn infant within 28 completed days of birth
- Early neonatal deaths: deaths arising within 6 completed days
- Late neonatal deaths: deaths arising from 7 to 28 completed days of birth
- Perinatal death: a stillbirth or an early neonatal death
- Maternal death: death of a woman while pregnant or within 42 days of cessation of pregnancy from any cause related to the pregnancy or its management, but not from accidental causes

In September, 2004, we met with gram sabhas (village councils), headmen, and representatives from panchayats (elected representatives for basic governance) in the three districts. These representatives granted permission to start surveillance of births and deaths, and to work with women's groups.

Surveillance

A surveillance system with key informants was established in the three districts. Figure 3 shows this system, and Barnett and colleagues[16] describe it in detail. One key informant, usually a traditional birth attendant or active village member, was responsible for about 250 households, and reported any births, maternal or newborn deaths, and deaths in women of reproductive age every month within their allocated area. The key informant met with an interviewer once a month who verified births and interviewed all identified mothers to gather information about their sociodemographic characteristics, pregnancy, delivery, and postnatal period through a structured questionnaire about 6 weeks after delivery. As additional checks for the identification stage, all women identified were asked to locate any others of reproductive age who had recently given birth or died in the study area. Every district had 12 interviewers, one interviewer supervisor, and a district manager. The monitoring manager supervised field-based activities in all three districts and data entry at the head office. The intervention and surveillance teams were partitioned—interviewers and facilitators belonged to different villages, their training was done separately, and they had review meetings on separate days.

In the event of a stillbirth or neonatal death (panel 1), the interviewer administered a questionnaire and did a verbal autopsy with the mother and other individuals present at the time of death; the verbal autopsy included free text in which the mother was asked to narrate the details of events leading to the death of the neonate. For deaths among women of reproductive age, the interviewer spoke to family members to ascertain the age of the woman, cause of death, and whether she was pregnant or had recently given birth. In the event of a maternal death, the monitoring supervisors, initially accompanied by a physician, did verbal autopsies with a relative who was present at the time of the death. Supervisors completed a standard questionnaire with free text for elaboration of the sequence of events before the death. Verbal autopsies for maternal deaths were done by a physician (n=11), interviewer supervisor (n=96), or district manager (n=2).

Maternal depression was included as a trial outcome in the second year of the study because of delays in identification of a contextually appropriate scale. We used the Kessler-10 item scale (K10), a questionnaire for the detection of common mental disorders in community settings, that has been used in India and World Mental Health Surveys.[18–20] A psychiatrist (RL) did three training sessions of 2 days each for groups of 12–15 interviewers that consisted of administration of the K10 questionnaire, aspects of understanding depression and body language, association between physical health and mental health, active listening skills, and confidentiality.

Clusters and coverage of women's groups

In the 18 intervention clusters, we used a participatory action cycle with 172 existing groups and created an additional 72 groups. Coverage of Ekjut groups was one group per 468 population. In year 1, 546 (18%) of 3119 newly pregnant women attended the groups, rising to 1718 (55%) of 3126 in year 3. We recorded 111 006 group attendances over 3 years. 74 715 (67%) of these were from married women of reproductive age, 15 030 (14%) from

adolescent girls, 10 452 (9%) from men, and 10 809 (10%) from elderly women.

Women's group intervention

Every group met monthly for a total of 20 meetings, and a local woman, selected on the basis of criteria (including speaking the local language and having the ability to travel to meetings) identified by the community, facilitated the meetings. After a 7-day residential training course to review the cycle's contents, and to practice participatory communication techniques, facilitators were given support through fortnightly meetings with district coordinators. Facilitators coordinated an average of 13 meetings every month with as many groups.

Groups took part in a participatory learning and action cycle (figure 4). Community members who were not regular group members were also encouraged to participate in discussions. Information about clean delivery practices and care-seeking behaviour was shared through stories and games, rather than presented as key messages. By discussion of case studies imparted through contextually appropriate stories, group members identified and prioritised maternal and newborn health problems in the community, collectively selected relevant strategies to address these problems, implemented the strategies, and assessed the results. Although some strategies were common, each group was free to implement its own combination of strategies. The intervention team adapted facilitation materials from the study in Makwanpur, Nepal, to guide the meetings.[5] Groups used methods such as picture-card games, role play, and story-telling to help discussions about the causes and effects of typical problems in mothers and infants, and devised strategies for prevention, home-care support, and consultations (figure 5).

Health-service inputs

We formed health committees in all intervention and control clusters so that community members would have the opportunity to express their opinions about the design and management of local health services. About ten village representatives within every cluster met once every 2 months and used a structured action cycle to discuss maternal and newborn health entitlement issues. As a result, committee members became more knowledgable about the government health system and assisted with the formation of village health committees as part of the National Rural Health Mission programme.[21] In addition to the creation of cluster-level health committees, we provided workshops for appreciative inquiry with frontline government health staff from seven clusters per district in Jharkhand.[22] Participants assessed the programme qualitatively at the end of every training session. We expected that any improvement in performance or service quality would be equal in intervention and control clusters.

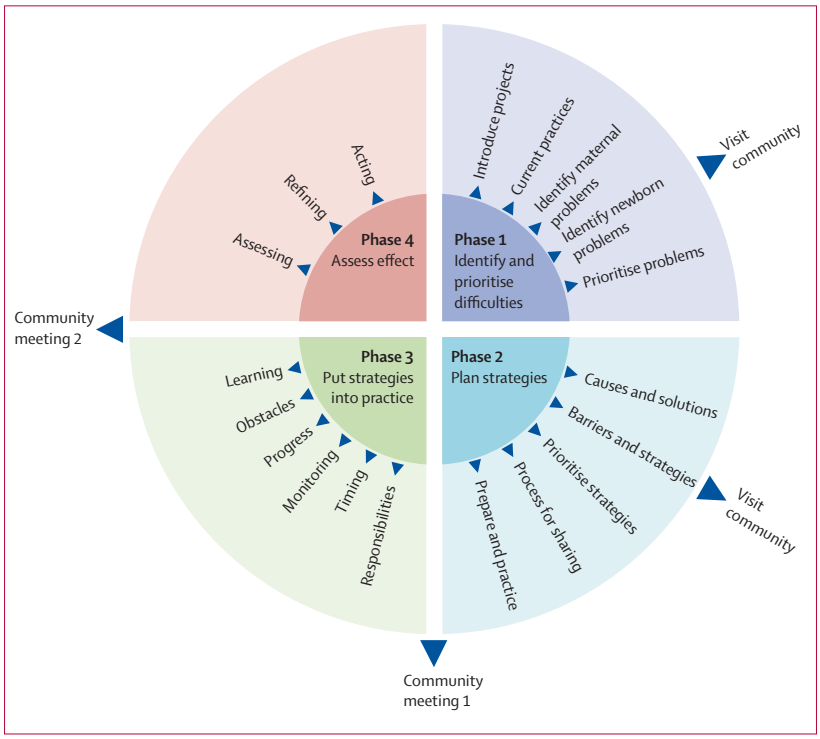

Figure 4: **Meetings in women's group cycle**

Figure 5: **Women's group meeting in Jharkhand, India**
Individuals in the photo provided permission (written or thumb print) for publication of image.

Primary and secondary outcomes

The primary outcomes were reductions in NMR and maternal depression scores. Secondary outcomes were stillbirths, maternal and perinatal deaths, uptake of antenatal and delivery services, home-care practices during and after delivery, and health-care-seeking behaviour (seeking care from qualified providers in the

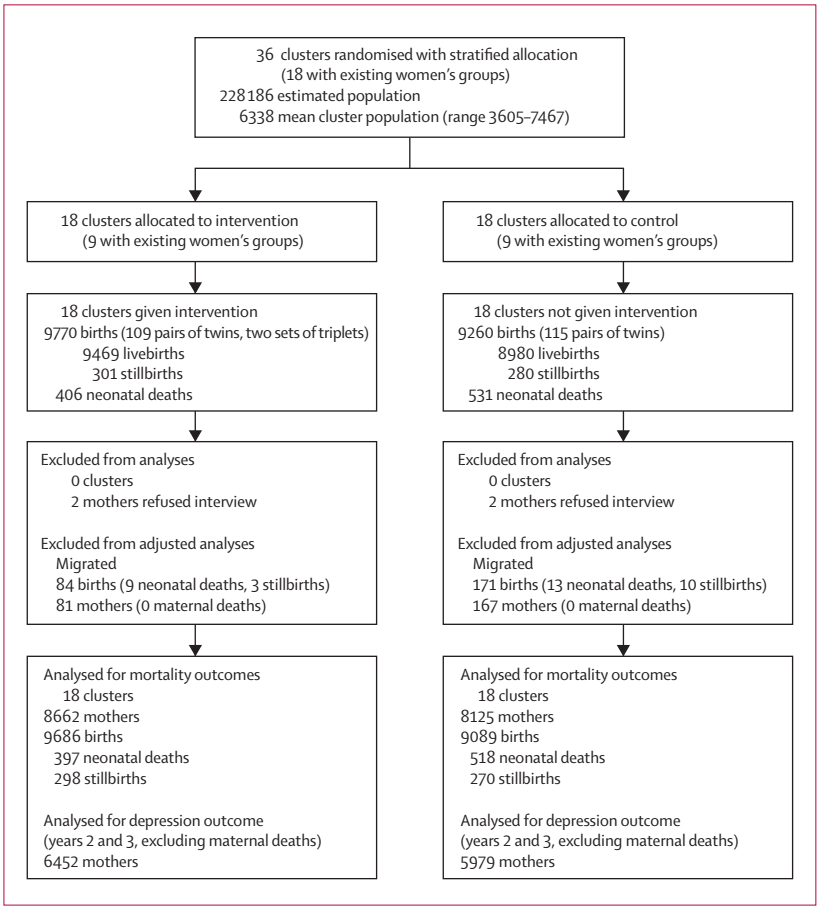

Figure 6: **Trial profile**

antenatal, delivery, and postnatal period, for checkups and problems).

Quality control of data

Data were double-entered in an electronic database. Surveillance supervisors manually checked information provided by key informants and interviewers. The field surveillance manager, data input officer, and data manager undertook manual and systematic data checks.

Statistical analysis

We did not expect the intervention to have adverse effects at cluster or participant level, and therefore did not have any rules for stopping the intervention. In December, 2007, we presented findings from a preliminary analysis to an independent data safety committee. After an interim analysis in 2007, the committee recommended that the trial continue for a total of 3 years to enable comparison with the Makwanpur study,[5] in which the effect was measured from 9 months after the beginning of the intervention to allow exposure to the women's groups in pregnancy. The data safety committee also noted that 3 years would allow analysis of possible seasonal variations in NMR. The committee undertook a final review of the data in December, 2008.

Our prospective surveillance from Nov 21, 2004, to July 30, 2005, showed a baseline NMR of 58 per 1000 livebirths (261 deaths per 4509 livebirths) and maternal mortality ratio of 510 per 100 000 (23 deaths per 4509 livebirths). The trial was planned for 3 years and was originally powered, like the Makwanpur trial,[5] for a 2-year analysis of birth outcomes, after allowing a period of up to 1 year for the women's groups to be established and for pregnant women to be given the intervention. We assumed a between-cluster correlation coefficient of variation (k) of 0·15–0·25, and about 324 births per cluster during 2 years. On the basis of 10% loss to follow-up, a sample size of 18 clusters per group resulted in 64–81% power to detect a 25% reduction in NMR. With an estimated baseline prevalence of 15% and k of 0·3, the study had 79–81% power to detect a 30% reduction in maternal depression over 1 year. We used data for recorded births during the study to estimate that the study had a power of 92% to detect a 25% reduction in NMR.

Analysis was by intention to treat at cluster and participant levels. We excluded data from mothers who migrated out of the region and their infants from intention-to-treat analyses since many of these women probably came into the clusters at the time of delivery and would therefore not have been exposed to the intervention in pregnancy. We aimed to do the tests of significance for our primary and secondary outcomes on the basis of previously agreed hypotheses about the likely effect of the intervention. For comparison of mortality outcome, we used multivariate logistic regression with random effects on individual-level data in Stata (version 10.0).[23] We compared secondary indicators using generalised estimating equations models with semirobust SEs at the cluster level.[23] Generalised estimating equations models were used for secondary indicators and categorical scores of maternal depression because these outcomes had high intracluster correlation coefficients (>0·30). We compared K10 scores grouped in three categories (none/mild, moderate, or severe) during years 2 and 3 of the trial. This method was chosen in favour of linear regression to address the data's strong positive skewness. We adjusted for stratification by including strata as variables in the regression analyses, and for multiple hypothesis testing by adjusting the p values for the primary outcomes using the Holm correction in the results tables. We did not adjust for clustering at the level of the mother. All results are presented as odds ratios with 95% CIs.

Cost-effectiveness analysis

We used a similar method of cost-effectiveness analysis as used by Borghi and colleagues.[24] Costs were estimated at 2007 prices, and were calculated separately for the

women's group intervention and activities for health-service strengthening. These were the financial and economic costs of setting up the intervention, and running costs during the trial. Costs were estimated from the perspective of a provider to give an indication of the potential costs of replication for the government and interested agencies, and discounted at 3%. Incremental cost effectiveness was measured in relation to a do-nothing alternative.

This study is registered as an International Standard Randomised Controlled Trial, number ISRCTN21817853.

Role of the funding source

The funders had no role in the design of the study, data collection, data analysis, interpretation, or writing up of the findings, although they made a site visit early in the study implementation. The corresponding author had access to all the data and had final responsibility for the decision to submit for publication.

Results

Figure 6 shows the trial profile. All 18 selected clusters had the intervention. Loss to follow-up after birth as a result of migration or refusal of interview was 86 (<1%) of 9770 women in intervention clusters and 173 (2%) of 9260 in control clusters. In the study areas, 5661 (37%) of 15 118 home deliveries were by a relative, friend, or neighbour, 5368 (36%) by traditional birth attendants, and 1913 (13%) by husbands.

Table 1 shows the baseline characteristics of identified births during 9 months of data gathering from Nov 21, 2004, to July 30, 2005. Numbers of births were similar in intervention and control clusters, but differences were noted in household assets, maternal education, literacy, and tribal membership, with women in the intervention clusters being generally poorer and more disadvantaged than those in the control clusters (table 1).

NMRs unadjusted for clustering decreased from year 1 to year 3 in the intervention clusters compared with an increase in the control clusters (table 2).

We noted a 32% reduction in NMR during the 3-year trial when data were adjusted for clustering, stratification, and baseline differences (table 3). NMR was reduced by 45% in intervention clusters compared with control clusters during the last 2 years (table 3). The reduction in NMR was still significant when migrated mothers and their babies were excluded from the intention-to-treat analyses during the 3 years (table 3). *k*, estimated from retrospective data from control clusters, was 0·10 when we took stratification into account, and corresponded to an intracluster correlation coefficient of 0·0005.[23] In the analysis of neonatal mortality data at the cluster level, the risk ratio was 0·71 (95% CI 0·57–0·90, p=0·0011) for years 1 to 3 when adjusted for multiple hypothesis testing with the Holm procedure and unadjusted for baseline differences.

	Intervention area	Control area
Identified births	2457	2235
Socioeconomic characteristics		
Household assets		
Radio, cassette tape, bicycle, or electricity	1752 (71%)	1771 (79%)
More costly items (television, generator, battery, fan, fridge)	167 (7%)	225 (10%)
Ownership of agricultural land		
None	345 (14%)	364 (16%)
Own less than 2 bighas (<0·27 hectares)	1157 (47%)	969 (43%)
Own between 2–4 bighas (0·27–0·54 hectares)	653 (27%)	593 (27%)
Caste or tribal group		
Scheduled tribe*	1849 (75%)	1557 (70%)
Scheduled caste*	80 (3%)	64 (3%)
Other backward caste*	520 (21%)	606 (27%)
Maternal age		
<20 years	147 (6%)	253 (11%)
20–29 years	1370 (56%)	1385 (62%)
≥30 years	345 (14%)	348 (16%)
Not known	933 (38%)	592 (26%)
Maternal school education		
None	1908 (78%)	1533 (69%)
Primary	143 (6%)	125 (6%)
Secondary or higher	405 (16%)	577 (26%)
Maternal literacy		
Cannot read	1906 (78%)	1566 (70%)
Can read	550 (22%)	669 (30%)
Care-seeking behaviour and home-care practices		
Any antenatal care	1460 (59%)	1532 (69%)
Three or more antenatal visits	539 (22%)	701 (31%)
Any iron tablets during pregnancy	1571 (64%)	1497 (67%)
Institutional delivery	277 (11%)	326 (15%)
Home delivery	2118 (86%)	1858 (83%)
Delivery attended by traditional birth attendant†	778 (37%)	717 (39%)
Birth attendant washed hands†	609 (29%)	471 (25%)
Birth attendant used safe delivery kit†	195 (9%)	197 (11%)
Birth attendant used plastic sheet†	163 (8%)	141 (8%)
Cord cut with new or boiled blade†	1493 (70%)	1294 (70%)
Cord tied with boiled thread†	276 (13%)	232 (13%)
Infant wiped within 30 min‡	1247 (61%)	1130 (63%)
Infant wrapped within 30 min‡	787 (39%)	782 (43%)
Infants alive at 1 month	2202 (90%)	2046 (92%)
Exclusive breastfeeding for 6 weeks§	1387 (63%)	1168 (57%)

Data are number or number (%). *Standard terms used in Indian demographic surveys. †Home deliveries only (stillbirths were not excluded from the count). ‡Stillbirths excluded. §Number of infants alive at 6 weeks were 2202 in intervention clusters, and 2046 in control clusters.

Table 1: **Baseline characteristics of identified births in intervention and control areas**

After year 1, NMRs were considerably lower in the intervention clusters than in the control clusters (figure 7). In the third year of the study, NMR was almost half in the intervention clusters compared with the control clusters (odds ratio 0·53, 95% CI 0·41–0·68, adjusted for clustering and stratification only), much larger than the findings of the Makwanpur trial in Nepal.[5] Figure 8 shows the cluster-level changes in NMR between baseline and

	Baseline*			Year 1†		Year 2†		Year 3†		Years 1–3†			Years 1–3*		
	Inter-vention	Control	All	Inter-vention	Control	Inter-vention	Control	Inter-vention	Control	Inter-vention	Control	All	Inter-vention	Control	All
Births	2457	2235	4692	3171	3052	3404	3135	3195	3073	9770	9260	19 030	9686	9089	18 775
Livebirths	2347	2162	4509	3073	2960	3286	3035	3110	2985	9469	8980	18 449	9388	8819	18 207
Stillbirths	109	73	183	98	92	118	100	85	88	301	280	581	298	270	568
Neonatal deaths	145	116	261	171	158	122	181	113	192	406	531	937	397	518	915
Early (0–6 days)	100	80	180	116	107	76	135	67	138	259	380	639	253	368	621
Late (7–28 days)	45	36	81	55	51	46	46	46	54	147	151	298	144	150	294
Perinatal deaths	209	153	362	214	199	194	235	152	226	560	660	1220	551	638	1189
Maternal deaths	16	7	23	20	30	22	18	7	12	49	60	109	49	60	109
Stillbirth rate per 1000 births	44·4	32·7	39·0	30·9	30·1	34·7	31·9	26·6	28·6	30·8	30·2	30·5	30·7	29·7	30·2
Neonatal mortality rate per 1000 livebirths	61·8	53·6	57·9	55·6	53·4	37·1	59·6	36·3	64·3	42·9	59·1	50·8	42·3	58·7	50·2
Early neonatal mortality rate per 1000 livebirths (0–6 days)	42·6	37·0	40·0	37·8	36·1	23·1	44·4	21·5	46·2	27·3	42·3	34·6	26·9	41·7	34·1
Late neonatal mortality rate per 1000 livebirths (7–28 days)	19·1	16·6	18·0	17·9	17·2	14·0	15·1	14·7	18·0	15·5	16·8	16·1	15·3	17·0	16·1
Perinatal mortality rate per 1000 births	85·1	68·4	77·1	67·4	65·2	57·0	75·0	47·5	73·5	57·3	71·2	64·1	56·8	70·1	63·3
Maternal mortality ratio per 100 000 livebirths	681·7	323·8	510·1	650·8	1013·5	669·5	593·0	225·1	402·0	517·5	668·1	590·8	521·9	680·3	598·7

Data are unadjusted. *Excluding migrated mothers and infants. †Including migrated mothers and infants.

Table 2: **Births and deaths in intervention and control clusters at baseline and during trial**

	Years 1–3 (including migrated)*	p value	Years 1–3 (excluding migrated)*	p value	Years 1–3†	p value	Years 2 and 3†	p value
Neonatal mortality rate per 1000 livebirths‡	0·71 (0·61–0·83)	<0·0005	0·69 (0·60–0·81)	<0·0005	0·68 (0·59–0·78)	<0·0005	0·55 (0·46–0·66)	<0·0005
Early neonatal mortality rate (0–6 days)	0·63 (0·54–0·75)	<0·0005	0·62 (0·53–0·74)	<0·0005	0·62 (0·52–0·73)	<0·0005	0·46 (0·37–0·57)	<0·0005
Late neonatal mortality rate (7–28 days)	0·92 (0·67–1·26)	0·476	0·89 (0·65–1·22)	0·463	0·84 (0·64–1·12)	0·236	0·80 (0·56–1·14)	0·217
Stillbirth rate per 1000 births	1·02 (0·85–1·23)	0·833	1·04 (0·85–1·25)	0·773	1·05 (0·86–1·28)	0·656	1·01 (0·80–1·28)	0·914
Perinatal mortality rate per 1000 births	0·79 (0·70–0·90)	<0·0005	0·79 (0·69–0·90)	<0·0005	0·79 (0·69–0·91)	<0·0005	0·68 (0·58–0·79)	<0·0005
Maternal mortality ratio per 100 000 livebirths	0·80 (0·51–1·24)	0·180	0·80 (0·51–1·24)	0·180	0·70 (0·46–1·07)	0·104	0·50 (0·48–1·49)	0·563

Data are odds ratio (95% CI). *Adjusted for stratification (by district and pre-existing women's groups) and clustering only. †Adjusted for stratification, clustering, maternal education, assets, and any tribal affiliation. ‡p values adjusted for multiple hypothesis testing with Holm correction were <0·001.

Table 3: **Comparison of mortality rates in intervention and control clusters**

year 3—the NMRs fell below their baseline level in most intervention clusters. Between 2005 and 2008, perinatal mortality rates in the intervention clusters decreased compared with those in the control clusters when adjusted for clustering (table 2; table 3). Stillbirth rates did not differ between intervention and control clusters (table 2). Maternal mortality ratio was generally lower in intervention than in control clusters, but the study was not powered to detect significant differences (table 3). Qualitative evidence from the assessment of the trial's process showed that community mobilisation through women's groups might have contributed to avoidance of some maternal deaths (panel 2).

There was no detectable difference in maternal depression K10 scores, when measured about 6 weeks after delivery, between intervention and control clusters in year 2 of the study or overall (table 4). However, in year 3, when 55% of all pregnant women in the intervention clusters had joined a group, a 57% reduction was noted in moderate depression among mothers in the intervention clusters compared with control clusters (table 4).

No significant differences were noted in health-care-seeking behaviour between control and intervention clusters (table 5). However, home-care practices showed substantial improvements—in intervention clusters, birth attendants were more likely to wash their hands, use a safe delivery kit and a plastic sheet, and boil the thread used to tie the cord than were those in the control clusters. The proportion of infants exclusively breastfed at 6 weeks was higher in intervention areas in adjusted analyses for years 2 and 3.

Cause-specific differences in mortality rate as a percentage of all causes—septicaemia, birth asphyxia, hypothermia, and prematurity—during the 3 years were not clearly discernable because there was a reduction in all causes (table 6). The incremental cost of the women's group intervention was US$910 per newborn life saved, increasing to $1308 (in 2007 prices) when health-service strengthening activities were included. The incremental cost per life-year saved was $33 for the women's group intervention ($48 inclusive of health-service strengthening activities). The women's group intervention in this setting was therefore more cost effective than that reported in Nepal[5] as a result of the greater effect of women's groups on NMR combined with lower operating costs in the current context.

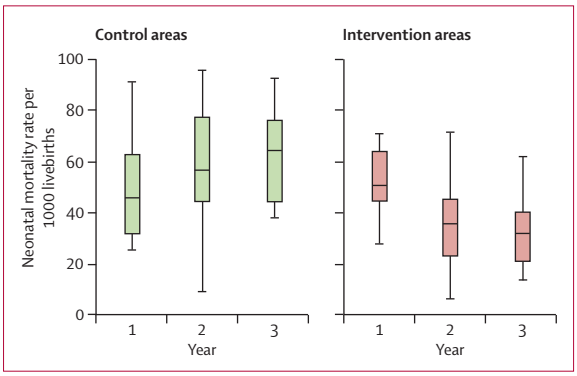

Figure 7: **Boxplot of cluster-level neonatal mortality rates by allocation and study year**

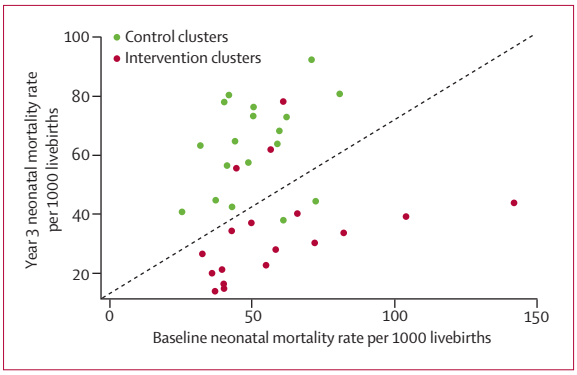

Figure 8: **Scatterplot of cluster-specific neonatal mortality rates in year 3 with rates at baseline**

Discussion

Women's groups led by peer facilitators reduced NMR and moderate maternal depression at low cost in largely tribal, rural populations of eastern India. Our data show that mortality reduction in underserved rural settings was not associated with increased care-seeking behaviour or health-service use. The most likely mechanism of mortality reduction was through improved hygiene and care practices. The availability of safe delivery kits increased in both control and intervention areas, but women's groups seemed to generate more demand in intervention clusters than in control clusters. In places where kits were not provided, group members made them and provided information about their contents to mothers, then visited pregnant women during the eighth month of pregnancy to ensure that they had received kits and would use them. Birth outcomes might have been affected by the fact that these community members attended the groups or were advised by group members, thus generating increased social awareness and support for clean delivery practices.

The most striking reduction in mortality rate was noted in early neonatal deaths, which might be explained by the strong focus on intrapartum and early neonatal periods in several case studies and stories discussed during the cycle. Attribution of cause of newborn death on the basis of verbal autopsy is an imperfect science, and deaths might arise from several and overlapping causes. Early septicaemia could have been reduced with clean delivery practices, and premature babies might have survived with improved care. The reason for this combined reduction of asphyxia, prematurity, and septicaemia could also be improved intrapartum care. Potential mechanisms for reduction of mortality rate will be further assessed in future analyses of verbal autopsies and seasonal mortality trends.

Our findings also show that a low-cost intervention involving non-health-care workers might affect maternal

Panel 2: Case-study effect of women's groups on strategies to avoid maternal deaths

A woman in the eighth month of her pregnancy, and her mother-in-law attended a monthly women's group meeting where they participated in a drill based on what to do in the event of post-partum bleeding. After a month, when the woman delivered at home and had severe bleeding, her mother-in-law remembered what had been said in the group, and, without wasting time, asked her daughter-in-law to breastfeed the baby while she rushed to get money from the group and asked her son to arrange for a vehicle. The daughter-in-law was immediately taken to the district hospital, where she was given medicines, intravenous fluid, and two pints of blood, and was discharged after 15 days.

	Year 2			Year 3			Years 2 and 3		
	Intervention	Control	Adjusted odds ratio (95% CI)*	Intervention	Control	Adjusted odds ratio (95% CI)*	Intervention	Control	Adjusted odds ratio (95% CI)*
Mothers (n)	3332	3016	..	3120	2963	..	6452	5979	..
No or mild depression (10–15)	2922 (88%)	2612 (87%)	0·91 (0·41–2·01)	2962 (95%)	2665 (90%)	2·33 (1·25–4·38)	5884 (91%)	5277 (88%)	1·29 (0·68–2·44)
Moderate depression (16–30)	383 (11%)	382 (13%)	1·04 (0·50–2·16)	154 (5%)	293 (10%)	0·43 (0·23–0·80)	536 (8%)	676 (11%)	0·74 (0·40–1·37)
Severe depression (31–50)	28 (<1%)	21 (<1%)	1·53 (0·47–5·05)	4 (<1%)	5 (<1%)	0·70 (0·15–3·31)	32 (<1%)	26 (<1%)	1·29 (0·46–3·64)

Data are number (%), unless otherwise indicated. *Results adjusted for clustering, stratification, maternal education, tribe affiliation, and household assets by use of generalised estimated equations with semirobust SEs for individual-level data.

Table 4: **Kessler-10 depression scores in mothers in intervention and control clusters**

	Intervention clusters	Control clusters	Odds ratio (95% CI) for years 1–3*	Odds ratio (95% CI) for years 1–3†	Odds ratio (95% CI) for years 2 and 3†
Births‡	9468	8867	..	..	..
Any antenatal care	6990 (74%)	6623 (75%)	0·97 (0·48–1·97)	1·60 (0·65–3·92)	1·86 (0·80–4·34)
≥3 antenatal care visits	3001 (32%)	3621 (41%)	0·63 (0·37–1·06)	0·69 (0·37–1·26)	0·68 (0·37–1·24)
Iron tablets	6997 (74%)	6293 (71%)	1·12 (0·71–1·76)	1·31 (0·62–2·75)	1·34 (0·77–2·35)
Maternal tetanus-toxoid injection	7767 (82%)	7377 (83%)	0·90 (0·51–1·54)	1·39 (0·85–2·28)	1·40 (0·85–2·29)
Illness in pregnancy	5206 (55%)	4983 (56%)	1·03 (0·68–1·58)	1·10 (0·71–1·72)	1·01 (0·67–1·52)
Visited health facility in case of illness during pregnancy	945 (10%)	922 (10%)	0·78 (0·39–1·56)	0·86 (0·46–1·60)	0·80 (0·39–1·65)
Institutional deliveries	1364 (14%)	1811 (20%)	0·64 (0·39–1·04)	0·89 (0·51–1·53)	0·94 (0·50–1·76)
Birth attended by formal provider (doctor or nurse)	1490 (16%)	2067 (23%)	0·59 (0·37–1·94)	0·81 (0·50–1·31)	0·82 (0·47–1·43)
Home deliveries	8084	7034	..	..	..
Birth attended by traditional birth attendant	2692 (33%)	2676 (38%)	0·82 (0·43–1·60)	0·84 (0·43–1·64)	0·85 (0·44–1·65)
Birth attendant washed hands with soap	3291 (41%)	1583 (23%)	2·05 (1·14–3·73)	2·07 (1·24–3·45)	2·50 (1·35–4·62)
Safe-delivery kit used	2594 (32%)	1284 (18%)	2·08 (1·25–3·44)	1·87 (1·11–3·14)	2·28 (1·27–4·09)
Plastic sheet used	2088 (26%)	560 (8%)	3·85 (2·51–5·89)	3·74 (2·48–5·65)	2·98 (1·84–4·81)
Cord tied with boiled thread	2559 (32%)	786 (11%)	3·9 (1·82–6·30)	3·02 (1·61–5·65)	4·33 (2·06–9·11)
Cord cut with new or boiled blade	6679 (83%)	5570 (79%)	1·24 (0·82– 1·87)	1·35 (0·86–2·12)	1·55 (0·96–2·51)
Livebirths (home deliveries)	7890	6873	..	..	..
Cord undressed or dressed with antiseptic	6600 (84%)	6115 (89%)	0·52 (0·24–1·12)	0·58 (0·27–1·26)	1·01 (0·39–2·62)
Infant wiped within 30 min	4741 (60%)	4227 (62%)	0·90 (0·38–2·14)	1·01 (0·43–2·36)	1·06 (0·44–2·57)
Infant wrapped within 30 min	2846 (36%)	2980 (43%)	0·74 (0·35–1·59)	0·78 (0·36–1·66)	0·81 (0·37–1·80)
Infant not bathed in first 24 h	2107 (27%)	1509 (22%)	1·06 (0·52–2·17)	0·95 (0·44–2·10)	1·22 (0·56–2·65)
Infants alive at 1 month	8807	8119	..	..	..
Any of three infant illnesses (cough, fever, diarrhoea)	1739 (20%)	2388 (29%)	0·62 (0·37–1·03)	0·67 (0·40–1·12)	0·61 (0·35–1·06)
Care-seeking behaviour in event of infant illness	940 (54%)§	1050 (44%)§	1·53 (0·77–3·05)	0·88 (0·97–3·61)	1·55 (0·79–3·04)
Infant put to breast within 4 h	5390 (61%)	4942 (61%)	1·01 (0·48– 2·14)	0·90 (0·38– 3·11)	1·11 (0·45–2·76)
Exclusive breastfeeding for first 6 weeks	7022 (80%)	5611 (69%)	1·82 (1·14–2·92)	1·44 (0·89–2·35)	1·74 (1·03–2·94)

Data are number (%), unless otherwise indicated. *Adjusted for clustering and stratification only. †Adjusted for clustering, stratification, maternal education, assets, and any tribal affiliation. ‡Excludes births to migrated mothers and twins. §Denominators are number of infants with any of three infant illnesses: 1739 for intervention clusters and 2388 for control clusters.

Table 5: **Process indicators in intervention and control clusters**

mental health. We hypothesise that the large reduction in moderate depression seen in the third year could have occurred through improvements in social support and problem-solving skills of the groups. Adequate social support reduces the risk of depression during pregnancy and is an important social determinant of mental health.[25] In meetings, information was shared about the difficulties encountered by mothers in the community, and practical ways to collectively address them were established. Group meetings also strengthened problem-solving skills, a component of psychotherapeutic interventions that has been shown to affect depression in other settings.[26] The intervention seemed to have no effect on severe depression, perhaps

because it was more similar to primary prevention rather than treatment, or because severe depression is less amenable to psychotherapeutic interventions. A complete analysis and discussion of these findings will be presented in the future.

Two potential effect modifiers in this trial, on the basis of evidence, were differences in maternal education, and tribal membership and assets between the intervention and control populations. These were taken into account in adjusted analyses and mainly provided an advantage for the control areas. Additionally, the high significance of some of our results could be a result of an increase in mortality rate in the control areas between 2005–08. The control and intervention clusters were in similar geographic areas, so factors that affected NMR should have affected both groups equally, but further investigation is needed.

We believe that the study had two main weaknesses. First, as in several other community-based randomised control trials, the intervention and surveillance teams were not unaware of allocation. However, there were no incentives or disincentives for over-reporting or under-reporting births and deaths, and several process mechanisms were in place to detect errors. Second, although migration out of districts was common, we cannot rule out some intercluster migration when women married out of their home cluster. Our intention-to-treat analysis might have affected the results positively or negatively.

In the Shivgarh study,[27] in Uttar Pradesh, India, the effect of an intensive behaviour-change programme involving community meetings and home visits by a new cadre of paid, non-governmental community workers in a population of 104123 during 15 months resulted in a 54% reduction (relative risk 0·46, 95% CI 0·35–0·60) in NMR with changes in home-care practices, but no real change in care-seeking behaviour. No overall differences in NMR were noted during 30 months of intervention in the Projahnmo trial,[28] in Bangladesh, but a 34% reduction (0·66, 0·47–0·93) was noted in the home-care group in the last 6 months of the programme. The investigators of the Projahnmo study[28] noted that "Availability of referral services and a strong supervisory system were crucial to this intervention and would be a necessary feature of scaling up the intervention."

Interventions with health-worker home visits have rarely achieved adequate coverage, quality, or effectiveness when taken to scale in poor populations.[29] Participatory groups have the advantage of helping the poorest, being scalable at low cost, and producing potentially wide-ranging and long-lasting effects. By addressing critical consciousness,[30] groups have the potential to create improved capability in communities to deal with the health and development difficulties arising from poverty and social inequalities.[31] The intervention requires a training and support structure to manage facilitators in charge of 12–14 groups per month, with every group responsible for a population of about 500 and for recruiting up to half of newly pregnant women. Costs are lower than for most other primary health-care interventions, and these interventions can complement existing self-help groups in the community.

	Intervention		Control	
	Years 1–3	Years 2 and 3	Year 1–3	Years 2 and 3
Early neonatal deaths	253	140	367	264
Birth asphyxia	92 (36%)	53 (38%)	142 (39%)	104 (39%)
Prematurity	85 (34%)	46 (33%)	110 (30%)	77 (29%)
Septicaemia	38 (15%)	15 (11%)	47 (13%)	29 (11%)
Hypothermia	16 (6%)	12 (9%)	26 (7%)	22 (8%)
Other	22 (9%)	14 (10%)	42 (11%)	32 (12%)

Data are number or number (%).

Table 6: **Cause-specific mortality for early neonatal deaths during study**

Two other issues arising from our study are cost effectiveness and the effect on maternal mortality ratios. The interventions in the Ekjut trial were more cost effective than those in the Makwanpur study[5] because of lower operating costs and greater effect of the intervention. In the Nepal trial, effect of women's groups on maternal mortality ratios was significant, although the number of deaths was small and maternal mortality ratio was not a stated primary outcome. In our trial the maternal mortality ratio was higher in the intervention areas at baseline, and 20% lower after 3 years of intervention, but this difference was not significant and the trial was not powered to measure differences in maternal mortality. Reduction in maternal mortality will depend mainly on improved access to health services and to life-saving drugs, but community mobilisation could help through improvement in hygiene at delivery and early care-seeking behaviour for complications by addressing the first-delay component.

This participatory intervention with women's groups could complement or be a potential alternative to health-worker led interventions, two examples of which have been discussed here. Our findings raise several important issues for policy makers in India. Could federal and state governments invest in this programme? Should government or non-government organisations be responsible for its scale-up? Could such a participatory intervention support and strengthen the National Rural Health Mission's mandate of communitisation of health and the Accredited Social Health Activist programme?[32] Further assessments of this approach will involve a scale-up in large populations with little access to health services, and different delivery mechanisms of the intervention will need to be tested in partnership with government and non-government organisations.

Contributors

All authors contributed to the design of the study and criticised drafts of the report. PT, NN, SB, and AC were responsible for the conception and overall supervision of the trial. PT and NN managed the project, data

gathering, data entry, and administration with assistance from ShR, SuR, RM, RG, and DM. SB and AC were technical advisers for the study. JB provided technical assistance with gathering and analysis of cost data. AC, PT, and SB helped design the original trial protocol. SB designed the methods for data gathering and epidemiological surveillance system. VP and RL provided technical advice about the K10 scale and commented on drafts of the report. RL trained interviewers to administer the K10 scale. NN, AP, CP, and SB did the quantitative analysis. AC, AP, PT, NN, and SB wrote the first draft of the report, and were responsible for subsequent collation of inputs and redrafting. PT and AC are guarantors for the report.

Conflicts of interest

We declare that we have no conflicts of interest.

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