



Effect of participatory women's groups facilitated by Accredited Social Health Activists on birth outcomes in rural eastern India: a cluster-randomised controlled trial

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Summary

Background A quarter of the world's neonatal deaths and 15% of maternal deaths happen in India. Few community-based strategies to improve maternal and newborn health have been tested through the country's government-approved Accredited Social Health Activists (ASHAs). We aimed to test the effect of participatory women's groups facilitated by ASHAs on birth outcomes, including neonatal mortality.

Methods In this cluster-randomised controlled trial of a community intervention to improve maternal and newborn health, we randomly assigned (1:1) geographical clusters in rural Jharkhand and Odisha, eastern India to intervention (participatory women's groups) or control (no women's groups). Study participants were women of reproductive age (15–49 years) who gave birth between Sept 1, 2009, and Dec 31, 2012. In the intervention group, ASHAs supported women's groups through a participatory learning and action meeting cycle. Groups discussed and prioritised maternal and newborn health problems, identified strategies to address them, implemented the strategies, and assessed their progress. We identified births, stillbirths, and neonatal deaths, and interviewed mothers 6 weeks after delivery. The primary outcome was neonatal mortality over a 2 year follow up. Analyses were by intention to treat. This trial is registered with ISRCTN, number ISRCTN31567106.

Findings Between September, 2009, and December, 2012, we randomly assigned 30 clusters (estimated population 156 519) to intervention (15 clusters, estimated population n=82 702) or control (15 clusters, n=73 817). During the follow-up period (Jan 1, 2011, to Dec 31, 2012), we identified 3700 births in the intervention group and 3519 in the control group. One intervention cluster was lost to follow up. The neonatal mortality rate during this period was 30 per 1000 livebirths in the intervention group and 44 per 1000 livebirths in the control group (odds ratio [OR] 0.69, 95% CI 0.53–0.89).

Interpretation ASHAs can successfully reduce neonatal mortality through participatory meetings with women's groups. This is a scalable community-based approach to improving neonatal survival in rural, underserved areas of India.

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Introduction

Every year 2.7 million infants die in the first month of life, 2.6 million are stillborn, and 303 000 women die of consequences of pregnancy and childbirth.^{1,2} Most of these deaths can be prevented by increased access to known interventions before conception and during the perinatal period.² A recent analysis estimated that community and primary care strategies to increase the coverage of such interventions could prevent a third of neonatal deaths worldwide in the next 5 years.^{3,4} WHO and UNICEF's Every Newborn Action Plan⁵ recommends two main community-based strategies to improve survival: postnatal home visits for mothers and newborn infants and participatory women's groups. During postnatal home visits, health workers counsel families on essential newborn care, and examine, treat, or refer infants with health problems.⁶ Visits have led to 30–60%

reductions in neonatal mortality in proof-of-principle trials, and smaller effects in larger studies embedded within government programmes.⁷ In the women's group approach, a female facilitator supports a group through a four-phase participatory learning and action cycle. Groups identify and prioritise problems in pregnancy, delivery, and the postnatal period, decide on strategies to address these problems, implement the strategies, and assess their progress.⁸ A meta-analysis⁹ of seven trials noted that women's groups led to an overall 20% reduction in neonatal mortality, rising to 33% when more than a third of pregnant women participated in groups. Effective strategies such as postnatal home visits and participatory women's groups need to be scaled up through government systems, with a focus on high mortality areas.⁴

A quarter of the world's neonatal deaths (696 000) and 15% (45 000) of maternal deaths occur in India.^{1–10} The

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See [Comment](#) page e74

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Research in context

Evidence before this study

We updated a search done for a systematic review published in 2013. Specifically, we searched for interventions with participatory women's groups in low-income and middle-income countries using PubMed, Embase, the Cochrane Library, CINAHL, African Index Medicus, Web of Science, the Reproductive Health library, and the Science Citation Index using the inception date for each database and November, 2014, as inclusion dates. The search terms used were combinations of "community mobilisation", "community participation", "participatory action", "participatory learning and action*" and "women*group*". There were no language restrictions. We included studies if they met the following four criteria: they were randomised controlled trials; study participants were women of reproductive age (15–49 years); interventions contained stages of participatory learning and action; study outcomes included maternal mortality, neonatal mortality, and stillbirths. Before this study, the evidence on the effect of participatory women's groups on birth outcomes only included studies with lay facilitators trained by non-government organisations rather than government-approved workers. A meta-analysis from seven trials found that women's groups led to an overall 20% reduction in neonatal mortality, rising to 33% when more than a third of pregnant women participated in groups.

Added value of this study

This study is the first trial of participatory women's groups done with government-approved workers. We updated a meta-analysis published in 2013 with the results of this trial (appendix). No additional, recent trials of participatory women's groups were identified; a study from Vietnam by Persson and colleagues used participatory learning and action, but this was done with local stakeholder groups based in health facilities rather than by women in the community. We compared the results of our updated meta-analysis with those

of the meta-analysis of home visiting interventions published by Gogia and Sachdev, and updated by Kirkwood and colleagues. Including this latest trial, the meta-analysis of participatory women's groups found an overall 22% reduction in neonatal mortality (OR 0.78, 95% CI 0.67–0.92) in areas with participatory women's groups, albeit with high heterogeneity between trials (I^2 69.8%; $p=0.002$).

How does this compare with the effect of home visiting interventions tested in proof-of-concept and effectiveness studies? Kirkwood and colleagues' updated review found a reduction of 45% (RR 0.55, 95% CI 0.48–0.52) in neonatal mortality rate in proof-of-concept studies and 12% (0.88, 0.82–0.95) in programme settings.

Implications of all the available evidence

Both participatory women's groups and postnatal home visits have been shown to reduce neonatal mortality, with slightly reduced effects of home visits in programme settings. Our trial, as well as the Shivgarh (India) and Hala (Pakistan) trials, suggest that participatory group meetings and home visits can complement each other effectively. The decision of how best to implement a combination of these two strategies through government health systems is likely to depend on context, particularly on mortality levels and the workloads of community health workers or volunteers. We now need operational and effectiveness research to understand the best ways to retain the effects of women's groups and home visits at scale, and to understand their impact. These community-based strategies need to be complemented by efforts to improve the quality of maternal and newborn care in health facilities. Participatory learning and action with women's groups could be used to address problems beyond the perinatal period, and further research is needed to examine its potential to improve women, children and adolescent's health across the lifecourse.

neonatal mortality rate in rural areas is twice that in urban areas (33 vs 16 per 1000 livebirths, respectively).¹¹ Several community-based strategies have reduced neonatal mortality in rural India, including home visits, participatory women's groups, and combinations of both.^{12–14} Only one strategy, the Integrated Management of Neonatal and Childhood Illness (IMNCI), has been tested with government-approved workers. Its assessment found small effects on neonatal mortality.¹⁵ Accredited Social Health Activists (ASHAs), a group of more than 900 000 trained and incentivised female community volunteers working under the National Health Mission, are an important resource to improve maternal and newborn health in India.¹⁶ They are responsible for encouraging women to access antenatal care and give birth in health facilities. They also conduct home-based newborn care through postnatal home visits, and are mandated to provide health education with local women's groups. The evidence that

women's groups can reduce neonatal mortality in rural, high-mortality settings is strong, but all trials up to now have been done with incentivised lay facilitators or volunteers rather than with community health workers working in government systems.⁹ Additionally, most rural areas in India receive a range of health systems and community interventions to improve maternal and newborn health, including the *Janani Suraksha Yojana* maternity incentive scheme and home visits for newborn care. Understanding the effect of an additional intervention such as participatory women's groups required a randomised controlled design to isolate its contribution to mortality reduction from that of other interventions.

We aimed to test the effect of participatory women's groups facilitated by ASHAs on birth outcomes, including neonatal mortality. We hypothesised that ASHAs could help with participatory group meetings, that these would lead to improvements in practices for mothers and

newborn infants, and that such changes would result in a measurable reduction in neonatal mortality.

Methods

Study design and participants

We did this cluster-randomised controlled trial in 30 geographical clusters covering five rural districts of Jharkhand and Odisha, two large states in eastern India. About half of the residents in these five districts belong to indigenous (*adivasi*), or Scheduled Tribe communities.¹⁷

We chose a cluster-randomised design because the intervention was implemented at community level. The unit of randomisation was a purposively selected geographical cluster of a population of about 5000, which was made up of three to five villages and their adjoining hamlets. We sought the permission of village leaders to enrol their villages into one of 30 clusters, with roughly ten ASHAs per cluster. We estimated the study population in these 30 clusters at 156 519 using Indian Census data. Study participants were women of reproductive age (15–49 years) who gave birth between Sept 1, 2009, and Dec 31, 2012. We collected baseline data from Sept 1, 2009, to Aug 30, 2010, before implementing the intervention. Because we expected the group intervention to show an effect after a few months, we designated the period Sept 1, 2010, to Dec 31, 2010, as a window period *a priori*.¹⁸ We then recorded outcomes during a 2 year assessment (Jan 1, 2011, to Dec 31, 2012), which corresponded to phases 3 and 4 of the meeting cycle (implementation of strategies and evaluation). We excluded women who declined to be interviewed or migrated out of the study clusters for birth outcomes, and, for care-seeking and home care practices, women who gave birth in the study area but who could not be traced after 9 months. The trial was led by Ekjut, a non-governmental organisation (NGO) working in Jharkhand and Odisha since 2003, in collaboration with the Institute for Global Health, University College London (UK).

Approval for the study was obtained through an independent ethical research committee chaired by Alok K Debdas in Jamshedpur, India, and through University College London's Research Ethics Committee (UK). Before randomisation, we obtained permission from local community representatives (village headmen in Jharkhand and *Panchayati Raj* institution leaders in Odisha) to work with women's groups and ASHAs, and to collect data in their areas. We sought individual informed consent from all participants and recorded it through a signature or thumbprint.

Randomisation and masking

Randomisation was stratified by district, with six clusters in each district allocated to either control or intervention in a public randomisation meeting (appendix). In each district, we invited local stakeholders, allocated a number to each cluster, wrote these numbers on small plastic balls, and placed the balls in a dark bag. We asked each

participant to draw one ball from the bag and read out the cluster numbers out until all balls had been picked. We wrote the cluster numbers on a sheet of paper in order of selection. Participants then placed 20 pieces of paper numbered 1 to 20—each corresponding to a unique allocation sequence generated by an independent statistician—in the dark bag, and asked a participant to select a paper and read out the number. The corresponding sequence was then used to publicly allocate each cluster to one of two groups. Because of the nature of the intervention being tested, the intervention team could not be masked to allocation. The data collection team was masked to allocation, both at the cluster and at the individual level.

The participatory learning and action cycle

The intervention was a cycle of women's group meetings led by ASHAs. It followed rules of participatory learning and action and had a four-phase structure, like previous women's groups interventions, and as recommended by WHO.^{9,10,14,19} In the first phase, ASHAs helped the groups identify and prioritise maternal and newborn health problems using picture cards and a participatory voting game. In the second phase, groups listened to stories with local motifs featuring the causes of their prioritised problems and potential solutions. They discussed these stories, then identified and prioritised feasible strategies to address each prioritised problem. At the end of this phase, the groups held a community meeting in which they talked about their problems and strategies with other community members, and sought their support. In phase 3, the groups implemented their chosen strategies and learned about other practical actions to improve maternal and newborn health (eg, how to prepare for emergencies in pregnancy). Finally, in phase 4, the groups evaluated the meeting cycle and progress against their strategies. Meetings were held fortnightly for the first four months (phases 1 and 2), and every month thereafter, following a sequence described in the appendix. Although the intervention was originally planned for 24 months, it lasted for 31 months (Sept 1, 2010, to March 30, 2013), because the groups chose to hold additional meetings in phase 3. Specific adaptations from previous women's group interventions included actively encouraging pregnant women to join the groups, and ensuring that meetings about thermal care for newborn infants were held during winter starting from the first year, as previous analyses had shown strong increases in neonatal mortality during this season.²⁰

Recruitment, training, and supervision of ASHAs

In each cluster, we approached ASHA supervisors, village health sanitation and nutrition committees, and existing women's groups, and asked them to identify ASHAs to facilitate group meetings. The 152 ASHAs selected through this process were typical of ASHAs working in the study area; they had undergone at least

See Online for appendix

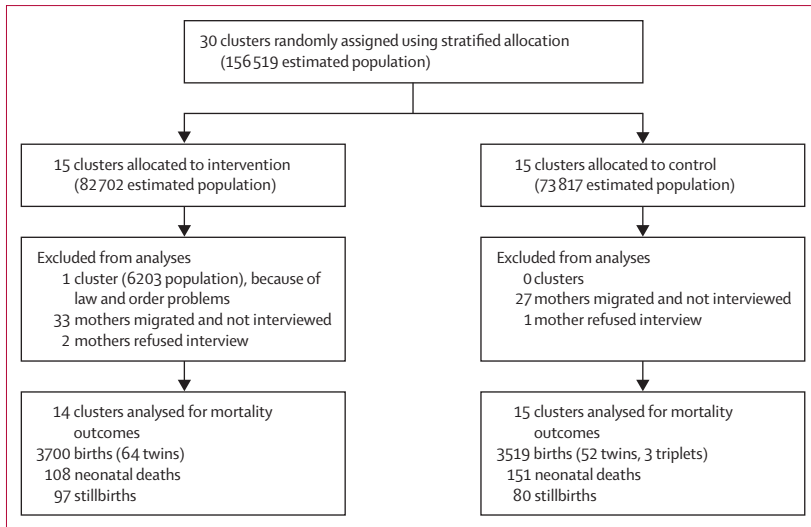


Figure: Trial profile

three government-approved training sessions and were all village-based. About 60% of them had between 6 and 9 years of education, and 70% of them were *adivasi* (indigenous). ASHAs received 11 days of training by Ekjut staff in addition to their own government training. The training was divided into four phases of 3–4 days each, which was acceptable to National Health Mission staff. Coordinators employed by Ekjut supervised about ten ASHAs each through bimonthly meetings in the first 3 months of the intervention, and meetings every month thereafter. ASHAs were given an incentive of INR 100 (US\$2) during training and INR 200 for each woman’s group meeting.

Strengthening village health, sanitation, and nutrition committees

Village health sanitation and nutrition committees are mandated by the National Health Mission to monitor the availability of services at the village level; disseminate information about rights and entitlements related to health, sanitation, and nutrition; design an annual village health plan; and use an untied fund to finance relevant activities.²¹ In both intervention and control areas, we endeavoured to carry out at least one village health sanitation and nutrition committee meeting about rights and entitlements per village. We also organised meetings with government officials and hospital management committees to inform the provision of appropriate care for mothers and newborn infants in facilities located in the study districts. The control group received these activities but did not have participatory women’s groups facilitated by ASHAs.

Data collection and management

A monitoring team was set up independently from the intervention team to monitor birth outcomes in the study population. One key informant per 250 population

	Intervention group (n=1635)	Control group (n=1609)	All (n=3244)
Maternal age (years)	24.5 (5.1)	24.4 (4.8)	24.7 (5.2)
Caste/tribe distribution			
Scheduled tribe	1141 (70%)	1159 (72%)	2300 (71%)
Scheduled caste	137 (8%)	115 (7%)	252 (8%)
Other backward class	327 (18%)	315 (20%)	642 (20%)
Other	31 (2%)	15 (<1%)	46 (1%)
Asset wealth*			
1st (poorest) wealth quintile	472 (29%)	472 (29%)	944 (29%)
2nd	254 (16%)	278 (17%)	532 (16%)
3rd	257 (16%)	211 (13%)	468 (14%)
4th	335 (20%)	331 (21%)	666 (21%)
5th (richest) wealth quintile	322 (20%)	320 (20%)	642 (20%)
Below poverty line card ownership			
Own a card	952 (58%)	861 (53%)	1813 (56%)
Does not own a card	657 (40%)	708 (44%)	1365 (42%)
Applied for a card	20 (1%)	23 (1%)	43 (13%)
Maternal literacy			
Can read	388 (24%)	463 (29%)	851 (26%)
Can read with difficulty	129 (8%)	139 (9%)	268 (8%)
Cannot read	1118 (68%)	1002 (62%)	2120 (65%)
Maternal schooling			
Has not attended school	1022 (62%)	853 (53%)	1875 (58%)
Primary education	226 (14%)	234 (15%)	460 (14%)
Secondary education or higher	392 (24%)	525 (33%)	917 (28%)

Data are mean (SD) or n (%). *Assets included in principal component analysis: chair, table, watch, electricity, fan, television, radio, telephone, bicycle, animal cart, and motorcycle. The principal component analysis was done in Stata (version 13) using methods described by Vyas and Kumaranayake.²⁶

Table 1: Characteristics of mothers at baseline, by allocation (excludes mothers with multiple pregnancies)

reported all births and deaths to women of reproductive age in the past month to an interviewer who visited them once a month. The interviewer checked all reports, paid the informant an incentive of INR 30 (US\$0.5) for each correct identification after verification, and conducted an interview with every mother about 6 weeks after delivery using a previously described system.²² The interview documented birth outcomes and events during the antenatal, delivery, and postnatal periods. Additionally, monitoring supervisors conducted verbal autopsies for any suspected deaths of women of reproductive age, neonatal deaths, and stillbirths. Supervisors were present during 8% of interviews. District-based monitoring supervisors examined all questionnaires every 2 weeks for completeness and accuracy. We cross-checked birth records with local Anganwadi registers for triangulation. Questionnaire and verbal autopsy data were entered into relational

	Baseline (September, 2009–August, 2010)			Window period (September, 2010–December, 2010)			Year 1 (January, 2011–December, 2011)			Year 2 (January, 2012–December, 2012)			Years 1 and 2 (January, 2011–December, 2012)		
	Intervention	Control	All	Intervention	Control	All	Intervention	Control	All	Intervention	Control	All	Intervention	Control	All
Births (infants)	1670	1634	3304	621	609	1230	1877	1735	3612	1823	1784	3607	3700	3519	7219
Livebirths	1608	1568	3176	600	591	1191	1821	1691	3512	1782	1748	3530	3603	3439	7042
Stillbirths	62	66	128	21	18	39	56	44	100	41	36	77	97	80	177
Neonatal deaths (0–8 days)	102	81	183	30	28	58	62	82	144	46	69	115	108	151	259
Early neonatal deaths (0–6 days)	80	61	141	24	20	44	55	75	130	41	53	94	96	128	224
Late neonatal deaths (7–28 days)	22	20	42	6	8	14	7	7	14	5	16	21	12	23	35
Perinatal deaths	142	127	269	45	38	83	111	119	230	82	89	171	193	208	401
Maternal deaths	6	13	19	3	2	5	5	9	14	3	3	6	8	12	20
Stillbirth rate per 1000 births	37.1	40.4	38.7	33.8	29.6	31.7	29.8	25.4	27.7	22.5	20.2	21.3	26.2	22.7	24.5
Neonatal mortality rate per 1000 livebirths	63.4	51.7	57.6	50	47.4	48.7	34	48.5	41	25.8	39.5	32.6	30	43.9	36.8
Early neonatal mortality rate	49.8	38.9	44.4	40	33.8	36.9	30.2	44.4	37	23	30.3	26.6	26.6	37.2	31.8
Late neonatal mortality rate	13.7	12.8	13.2	10	13.5	11.8	3.8	4.1	4	2.8	9.2	5.9	3.3	6.7	5
Perinatal mortality rate per 1000 births	85	77.7	81.4	72.5	62.4	67.5	59.1	68.6	63.7	45	49.9	47.4	52.2	59.1	55.5
Maternal mortality ratio per 100 000 livebirths	373.1	829.1	598.2	500	338.4	419.8	274.6	532.2	398.6	168.4	171.6	170	222	348.9	284

Data are n. *Up to 42 days after delivery.

Table 2: Births, deaths, and crude mortality rates during the study period

Access databases. Data cleaning involved range and frequency checks, as well as comparing mortality data from the main questionnaire with those from verbal autopsies to ensure that neonatal deaths and stillbirths were correctly classified.

We reported interim results to a Data Safety Monitoring Board in December, 2011. The Board noted that areas in one of the study districts (Khunti, Jharkhand) had experienced severe law and order problems during the baseline and evaluation periods. In one cluster, we could not do any data quality checks. Because of our inability to verify the accuracy of data collection in this cluster, the Board voted to exclude it from the final trial analyses at its final meeting in December, 2013.

Outcomes

The primary outcome of the trial was neonatal mortality. Secondary outcomes included stillbirths, perinatal mortality, maternal mortality, and home care and care-seeking practices. All outcomes were measured at the individual-level (ie, for each mother and child) within study clusters.

Statistical analyses

We did a sample size calculation in June, 2010, using 11 months of data for birth outcomes from the study areas. These data suggested a baseline neonatal mortality rate of 66 per 1000 livebirths (higher than the national rural average of 33, which could be explained by the fact that national averages hide wide inter-state and intra-state disparities in neonatal mortality). We estimated k (the between-cluster correlation coefficient) at 0.1 on the basis of data from an earlier study and baseline data from the trial areas.¹⁴ We expected around 100 livebirths per year in each cluster of 5000. Using formulae from Hayes and Bennett²³ and assuming a more conservative baseline neonatal mortality rate of 55 per 1000 livebirths, we estimated that the study would have between 77 and 80% power to detect a 30% reduction in the neonatal mortality rate (from 55 per 1000 to 38.5 per 1000 livebirths) during 24 months.¹⁸

We compared the characteristics of participants between groups at baseline using descriptive statistics. We then used logistic regression with random effects to estimate the effect of the intervention on mortality

outcomes, adjusting for clustering. We used generalised estimating equations to estimate effects on home care and care-seeking practices, because these had high intraclass correlation coefficients.²⁴ We repeated analyses for the primary and secondary outcomes adjusted for baseline differences by fitting an interaction term between study period (baseline vs intervention) and allocation in each model. All analyses were done in Stata (version 13.1). Analyses for the primary and secondary outcomes were by intention to treat, and analysts were masked to allocation by removing identifying labels from relevant variables, including the main allocation variable.

In previous work, we noted that the women's group intervention had the strongest effects among the most marginalised women.²⁵ Therefore, in addition to the prespecified analyses described above, we studied the effect of the intervention on neonatal mortality according to mothers' marginalisation status.

This trial is registered with ISRCTN, number ISRCTN31567106.

Role of the funding source

The funder had no role in designing the study, data collection and analysis, the decision to publish, or the preparation of this manuscript. The corresponding author had full access to all the data in the study and final responsibility for the decision to submit for publication.

Results

Recruitment for this trial took place between September, 2009, and December, 2012. 30 clusters (estimated population 156 519) were randomly assigned to intervention (15 clusters, estimated population n=82702) or control (15 clusters, n=73 817; figure). One cluster in the intervention group was lost to follow-up due to law and order problems. 11753 births in 29 clusters were identified during the study period: 3304 during the baseline, 1230 during the window period, and 7219 during the study period. Loss to follow-up as a result of migration or refusal to be interviewed was 35 (<1%) of 3735 births

in the intervention clusters and 28 (<1%) of 3547 births in the control clusters.

Table 1 describes the characteristics of participants at baseline. Mothers in intervention and control groups had similar socioeconomic characteristics, although slightly more had received secondary education in the control group (525/1609 [33%]) than in the intervention group (392/1635 [24%]).

137 of the 152 ASHAs trained to support women's groups completed the meeting cycle. These 137 ASHAs supported 161 groups, achieving coverage of one group per 475 population. An average of 26 women participated in each meeting. The population coverage of pregnant women was high: 66% (2357/3539) of women who had given birth to a singleton infant during the assessment period in the intervention group reported ever attending a women's group meeting. 59 (2%) of 3519 women who had recently given birth in the control group also reported ever attending a meeting, suggesting that contamination between intervention and control groups was low.

Overall, ASHAs had 4903 meetings, 32% (1588) of which were attended by other front-line workers such as auxiliary nurse midwives and Anganwadi workers. The appendix offers a case study about a women's group in Odisha, which shows group discussions and dynamics.

The appendix shows the coverage of women's groups and of the other salient intervention to improve neonatal survival (postnatal home visits in the first week after delivery) by allocation and wealth quintile. The coverage of the group intervention was uniformly high (>60%) across all wealth quintiles. By contrast, there was a 16·1 percentage point difference in the coverage of postnatal visits by ASHAs between the wealthiest and the poorest quintile.

Table 2 shows the births and deaths identified during the study period, and crude mortality rates. The intention-to-treat analysis for the primary outcome included 7219 births during 24 months of intervention (Jan 1, 2011, to Dec 31, 2012). During this period, the neonatal mortality rate was 30 per 1000 livebirths in the intervention group and 44 per 1000 livebirths in the control group. These findings corresponded to a 31% reduction in neonatal mortality when data were adjusted for clustering and stratification by district (OR 0·69, 95% CI 0·53–0·89; table 3). The effect was more pronounced when results were adjusted for baseline differences in neonatal mortality (adjusted OR 0·54, 95% CI 0·36–0·80). The intraclass correlation coefficient for neonatal mortality was 0·00282. The appendix shows a trend of falling cluster-median neonatal mortality rates from baseline to year 2 in the intervention group, and a concurrent, but smaller downward trend in the control group. The intervention effect varied by state; the unadjusted effect on neonatal mortality was OR 0·62 (95% CI 0·44–0·89) in Jharkhand (where 4520 [63%] of births occurred) and OR 0·79 (0·51–1·21) in Odisha (with 2699 [37%] of births). We recorded no differences in stillbirths,

	Odds ratio (95% CI)*	Odds ratio (95% CI)†
Neonatal mortality	0·69 (0·53–0·89)	0·54 (0·36–0·80)
Early neonatal mortality	0·72 (0·55–0·95)	0·54 (0·35–0·84)
Late neonatal mortality	0·51 (0·24–1·08)	0·47 (0·18–1·18)
Stillbirths	1·18 (0·77–1·80)	1·27 (0·80–2·01)
Perinatal mortality	0·90 (0·66–1·22)	0·79 (0·57–1·09)
Maternal Mortality	0·63 (0·25–1·42)	‡

*Adjusted for stratification by district and clustering only (excludes window period). †Adjusted for stratification by district, clustering, and baseline mortality differences (excludes window period). ‡Results for maternal mortality are not presented adjusted for baseline differences due to the small number of deaths in the baseline period.

Table 3: Odds ratios for effects on mortality outcomes during the evaluation period

	Baseline		Evaluation period		Odds ratio (95% CI)*	Odds ratio (95% CI)†
	Intervention	Control	Intervention	Control		
Home care practices						
Singleton home births	846	909	1272	1521
Birth attendant washed hands with soap	321 (38%)	225 (25%)	590 (46%)	741 (49%)	1.22 (0.31–4.91)	0.85 (0.31–2.32)
Birth attendant used a safe delivery kit	17 (2%)	54 (6%)	45 (4%)	30 (2%)	0.99 (0.43–2.23)	5.06 (1.86–13.7)
All liveborn singleton infants	1573	1542	3543	3384
Infant wiped within one hour of birth‡	1329 (85%)	1415 (92%)	3234 (91%)	3035 (90%)	0.81 (0.37–1.79)	3.14 (2.30–4.30)
Infant wiped within 10 min of birth	140 (9%)	62 (4)	1597 (45%)	945 (28%)	2.42 (0.89–6.54)	0.95 (0.68–1.35)
Infant wrapped within 1 h of birth‡	1249 (79%)	1314 (85%)	3176 (90%)	2933 (87%)	1.18 (0.47–3.01)	2.35 (1.80–3.07)
Infant wrapped within 10 min of birth	169 (11%)	83 (5%)	1230 (35%)	520 (15%)	2.84 (0.98–8.25)	1.60 (1.16–2.20)
Infant not bathed in first 24 h	990 (63%)	893 (58%)	2778 (78%)	2364 (70%)	1.16 (0.43–3.13)	1.18 (0.94–1.49)
Infant placed on mother's skin within 1 h of birth‡	912 (58%)	895 (58%)	2311 (65%)	2019 (60%)	1.07 (0.50–2.29)	1.36 (1.09–1.70)
Infant put to breast within 1 h	1207 (77%)	1056 (69%)	2620 (74%)	2212 (65%)	1.62 (0.67–3.94)	0.81 (0.62–1.05)
Infants alive at 6 weeks	1478	1468	3452	3254
Infant exclusively breastfed for first 6 weeks	1205 (82% ⁵)	1165 (79%)	2934 (85%)	2846 (88%)	0.88 (0.30–2.58)	0.65 (0.27–1.56)
Care-seeking practices						
Singleton births	1640	1612	3636	3464
Three or more antenatal check-ups by a skilled provider‡	594 (36%)	497 (31%)	1580 (43%)	1651 (48%)	0.81 (0.35–1.92)	0.63 (0.35–1.16)
Health problem in pregnancy*	619 (38%)	893 (54%)	2709 (75%)	2524 (73%)	1.30 (0.64–2.64)	0.56 (0.21–1.50)
Care sought for problem in pregnancy¶	504 (56%)	382 (62%)	2283 (84%)	2090 (83%)	0.92 (0.54–1.57)	1.38 (0.73–2.62)
Plan made for:						
Place of delivery	531 (32%)	385 (24%)	2408 (66%)	2061 (60%)	1.15 (0.51–2.57)	1.67 (0.61–4.57)
Delivery attendant	363 (22%)	194 (12%)	2011 (55%)	1479 (43%)	1.46 (0.64–3.35)	1.26 (0.47–3.41)
Money for the delivery	559 (34%)	350 (22%)	2546 (70%)	1936 (56%)	1.58 (0.70–3.58)	1.73 (0.81–1.70)
Transport	260 (16%)	198 (12%)	1781 (49%)	1336 (39%)	1.15 (0.49–2.70)	2.02 (0.71–5.76)
Safe delivery kit	191 (12%)	124 (8%)	1051 (29%)	746 (22%)	1.27 (0.37–4.36)	1.47 (0.59–3.65)
Health facility births	786 (48%)	692 (43%)	2364 (65%)	1943 (56%)	1.23 (0.58–2.60)	1.20 (0.81–1.78)
Mothers alive 48 h after delivery	1634	1600	3629	3454
Mother received check-up in first 6 weeks after delivery‡	429 (26%)	445 (28%)	1109 (31%)	962 (28%)	0.98 (0.37–2.55)	1.31 (0.79–2.18)
Liveborn infants with mothers alive 48 hours after delivery	1576	1542	3539	3380
Newborn health problem¶	362 (23%)	146 (10%)	1416 (40%)	1145 (34%)	1.45 (0.74–2.85)	0.45 (0.16–1.30)
Care sought for newborn health problem	165 (46%)	88 (60%)	1024 (72%)	884 (77%)	0.77 (0.43–1.37)	2.20 (0.49–9.94)
Infant and mother visited by an ASHA	2253 (64%)	1961 (58%)	1.16 (0.50–2.69)	..
Infant and mother visited by an ASHA in the first week after birth	2172 (61%)	1851 (55%)	1.19 (0.49–2.90)	..

Data are n or n (%) unless otherwise stated. ASHA=accredited social health activist. ANM=auxiliary nurse midwife. *Odds ratios for differences between intervention and control during the evaluation period, adjusted for stratification by district and clustering only. †Odds ratios for differences between intervention and control during the evaluation period, adjusted for stratification by district, clustering, and baseline differences. ‡Wiping and wrapping within one hour of birth were outcomes pre-specified in the trial protocol.¹⁸ We present additional data on wiping and wrapping within 10 min of birth to further understand the effect of the intervention on thermal care practices. ‡From doctor, ANM, or ASHA Newborn health problems. ¶Fever for more than 24 h, cough or diarrhoea more than three times a day.

Table 4: Home care and care-seeking practices at baseline and during the evaluation period

perinatal deaths, or maternal deaths between intervention and control groups (table 3). We estimated the cost-effectiveness of the intervention, and this will be reported separately.

Table 4 describes home care and care-seeking practices for mothers and newborn infants during the study period. Most care practices improved over time in both intervention and control groups. There were significant increases in the proportion of infants being wrapped within 10 min (adjusted OR 1.60, 95% CI 1.16–2.20) or 1 h of birth (2.35, 1.80–3.07) and placed on mother's skin within 1 h (1.36, 1.09–1.70) in the intervention group during the study period.

In a supplementary analysis, we assessed the effect of the intervention on neonatal mortality according to mothers' marginalisation status. Marginalisation was defined as belonging to a scheduled tribe, being in the first or second lowest asset quintile, and being unable to read. Effects among the most marginalised were at least as strong as among the less marginalised (OR_{marginalised} 0.38, 95% CI 0.17–0.86; OR_{less marginalised} 0.67, 95% CI 0.40–1.11; p value for difference 0.207; appendix). The appendix shows that the proportion of mothers giving birth in health facilities stagnated below 40% among marginalised mothers in the control group during the study period, but was greater than 60% in the intervention group.

Discussion

ASHAs successfully supported women's groups through a cycle of participatory learning and action meetings at high coverage, achieving a 31% reduction in neonatal mortality rate during 2 years, and with especially strong reductions among the most marginalised mothers. Wrapping, skin-to-skin care, birth preparedness, and health facility births seemed to have higher coverage in the intervention areas, although the confidence intervals around these estimates were wide, and, for the last two indicators, included one.

This is the first cluster randomised controlled trial of a community intervention to improve maternal and newborn health involving ASHAs, India's largest group of financially incentivised community health workers. The size of the effect on neonatal mortality we recorded in this trial was similar to that in other rural South Asian trials in which at least a third of pregnant women attended groups, and in two previous assessments of women's groups led by Ekjut in Jharkhand and Odisha.⁹ The first, a cluster randomised controlled trial noted a 32% (OR 0.68, 95% CI 0.59–0.78) reduction in neonatal mortality over 3 years, followed by a 31% (0.69, 0.57–0.83) reduction post-trial, when the intervention was introduced in the control areas.^{14,19} The effect on neonatal mortality rate in this trial with ASHAs was lower than in other Indian proof-of-principle studies, for example the 10-year analysis of home-based newborn care implementation in Gadchiroli, Maharashtra (70% reduction in neonatal mortality rate, 95% CI 59–81), or the Shivgarh trial, which tested a combination of home visits and social mobilisation in rural Uttar Pradesh (RR 0.46, 95% CI 0.35–0.60).^{12,13} However, the effect recorded was greater than that of the only other intervention tested in a larger programmatic setting with Indian government health workers, the Integrated Management of the Newborn and Childhood Illnesses programme (AHR 0.91, 95% CI 0.80–1.03).¹⁵

The pathways to mortality reduction in this study could have been different to those in previous assessments of women's groups interventions in south Asia, which mainly documented increases in clean delivery practices during home births and exclusive breastfeeding.^{14,19,27} We hypothesise that there were three main pathways to the effect on neonatal mortality in this study: improvements in thermal care practices (particularly early wrapping and skin to skin care), and increased birth preparedness and facility births in the most marginalised mothers. Increases in thermal care practices might have led to gains in neonatal survival among births in the community and in health facilities, in a setting where about a third of newborn infants are low birthweight and many are premature. The Shivgarh trial team have shown the importance of thermal care for newborns in rural India, and the effect that improving thermal care can have on neonatal mortality.¹³ Similarly, our earlier work in Jharkhand documented peaks in

neonatal mortality during winter months, and showed how these can be reduced through timely discussion of thermal care.²⁰ Thermal care was discussed in the women's groups fourth meeting in October 2010 (year 1), and this might account for some of the mortality effect recorded in the first year of the trial. Additionally, women who delivered in health facilities and attended group meetings might have been better prepared to follow early and exclusive breastfeeding and thermal care practices both before and after their usually prompt discharge, thereby preventing complications and deaths in low birthweight and preterm infants. Data from our analyses also suggest that the most marginalised mothers benefited at least as much from the intervention as other mothers. The gap in health facility deliveries between marginalised and less marginalised mothers decreased over time in the intervention group, but remained wide in the control group. Group meetings might have enabled ASHAs to increase their contact with the most marginalised women in the perinatal period. Participatory group meetings enable "soft-targeting" of the poorest women because they are open to all, occur at a time decided by women themselves, and also take place in remote hamlets where the poorest women live.^{25,28} This could have enabled ASHAs to better promote birth preparedness and facility births among those who needed it the most, thereby contributing to mortality reduction.

The study had four main limitations. First, the intervention was not fully embedded within government systems, as Ekjut-employed coordinators and district managers still supported it. However, partnerships between civil society organisations and government are commonly used to scale up interventions, the training scheme we used in this trial was acceptable to the National Health Mission, and the high coverage achieved by ASHAs suggests that the intervention could be accommodated within their existing workload. Second, this study was smaller than an earlier trial of women's groups done in eastern India with Ekjut facilitators, and was probably underpowered to detect changes in care practices.¹⁴ For example, our effective sample size allowed us to detect a 30% increase in health facility births, assuming a baseline of 45% and a *k* value of 0.3. Such a large increase was probably unrealistic for a 2-year intervention, and was also made more difficult to detect by the high coefficients of variation between clusters typically found for outcomes related to care-seeking.²⁹ Third, one intervention cluster was lost to follow-up, and this could have affected our results by either overestimating or underestimating the intervention's effect. Finally, the effects seen on thermal care, while offering a plausible explanation for the mortality reduction, are relatively small; additionally, behaviours such as early wiping and wrapping are difficult to measure accurately, although such measurement bias would have affected intervention and control areas equally.

Further work is needed to understand whether the intervention can now be fully embedded within the National Health Mission and scaled up. This trial shows that ASHAs can be trained to do participatory meetings, and a recent study found that ASHAs' motivation and earnings are strongly influenced by the support and recognition given to them in the community.³⁰ Our own process evaluation data also suggest that the recognition given to ASHAs by their communities for facilitating meetings was a strong incentive for them to continue the intervention. India's flagship National Health Mission programme is now working on strategies to incorporate participatory learning and action into ASHAs' training curriculum in order to enable scale up in rural India.

WHO's global strategy for women's, children's, and adolescents' health set a target to reach a neonatal mortality rate of 12 per 1000 livebirths by 2030.³¹ India's neonatal mortality burden could be reduced by 41% if community and health facility efforts successfully closed the gap in the coverage of protective interventions between the poorest and richest mothers.² With two positive randomised evaluations of participatory women's groups in rural eastern India, important equity benefits, and a global WHO recommendation, scaling up is justified, particularly in underserved rural areas where neonatal mortality remains high.^{8,14}

Contributors

PT, NN, AC, TAJH, and AP came up with the idea for the study and developed the methods with ShR, RKG, SuR, SSR, SA, AKK, DC, SKG, RS, and RM. AP, SSR, and NN analysed the data. ShR, RKG, SSR, AB, VS, SA, AKK, DC, SG, SKG, SK, VN, and RM supported the data collection and cleaning. AP wrote the first draft of the article and collated subsequent inputs. AC acquired the funding and EF and TAJH oversaw the grant that funded the study.

Declaration of interests

We declare no competing interests.

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References

- UN inter-agency group for child mortality estimation. Levels and trends in child mortality: report 2015. UNICEF, WHO, World Bank Group, United Nations, 2015. http://www.unicef.org/media/files/IGME_report_2015_child_mortality_final.pdf (accessed Dec 14, 2015).
- Lawn JE, Blencowe H, Oza S, et al, and the Lancet Every Newborn Study Group. Every Newborn: progress, priorities, and potential beyond survival. *Lancet* 2014; **384**: 189–205.
- Lassi ZS, Haider BA, Bhutta ZA. Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes. *Cochrane Database Syst Rev* 2010; **11**: CD007754.
- Bhutta ZA, Das JK, Bahl R, et al, and the Lancet Newborn Interventions Review Group, and the Lancet Every Newborn Study Group. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? *Lancet* 2014; **384**: 347–70.
- UNICEF/World Health Organization. Every Newborn: an action plan to end preventable newborn deaths, 2014. <http://www.everynewborn.org/Documents/Full-action-plan-EN.pdf> (accessed Nov 1, 2014).
- WHO. WHO recommendations: postnatal care of mother and newborn. Geneva: World Health Organization, 2013. <http://www.healthynewbornnetwork.org/resource/who-recommendations-postnatal-care-mother-and-newborn-2013> (accessed Oct 3, 2015).
- Kirkwood BR, Manu A, ten Asbroek AHA, et al. Effect of the Newhunts home-visits intervention on neonatal mortality rate and care practices in Ghana: a cluster randomised controlled trial. *Lancet* 2013; **381**: 2184–92.
- WHO. WHO recommendation on community mobilization through facilitated participatory learning and action cycles with women's groups for maternal and newborn health. Geneva: World Health Organization, 2014. http://www.who.int/maternal_child_adolescent/documents/community-mobilization-maternal-newborn/en/ (accessed Oct 3, 2015).
- Prost A, Colbourn T, Seward N, et al. Women's groups practising participatory learning and action to improve maternal and newborn health in low-resource settings: a systematic review and meta-analysis. *Lancet* 2013; **381**: 1736–46.
- WHO. Trends in maternal mortality: 1990 to 2015. Estimates by WHO, UNICEF, UNFPA, The World Bank and the United Nations Population Division, 2015. http://apps.who.int/iris/bitstream/10665/194254/1/9789241565141_eng.pdf (accessed Dec 14, 2015).
- Zodpey S, Paul VK, eds. State of India's Newborns (SOIN) 2014. New Delhi: Public Health Foundation of India, All India Institute of Medical Sciences, Save the Children, 2014.
- Bang AT, Bang RA, Reddy HM. Home-based neonatal care: summary and applications of the field trial in rural Gadchiroli, India (1993 to 2003). *J Perinatol* 2005; **25** (suppl 1): S108–22.
- Kumar V, Mohanty S, Kumar A, et al, and the Saksham Study Group. Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet* 2008; **372**: 1151–62.
- Tripathy P, Nair N, Barnett S, et al. 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. *Lancet* 2010; **375**: 1182–92.
- Bandhari N, Mazumder S, Taneja S, et al. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ* 2012; **344**: e1634.
- Government of India, Ministry of Health and Family Welfare. About Accredited Social Health Activist (ASHA). <http://nrhm.gov.in/communitisation/asha/about-asha.html>. (accessed Oct 3, 2015).
- Government of India. Census of India 2011. <http://censusindia.gov.in> (accessed Oct 3, 2015).
- Tripathy P, Nair N, Mahapatra R, et al. Community mobilisation with women's groups facilitated by Accredited Social Health Activists (ASHAs) to improve maternal and newborn health in underserved areas of Jharkhand and Orissa: study protocol for a cluster-randomised controlled trial. *Trials* 2011; **12**: 182.
- Howard-Grabman L, Snetro G. How to mobilize communities for health and social change. Baltimore, MD: Health Communication Partnership, USAID, 2003.
- Roy SS, Mahapatra R, Rath S, et al. Improved neonatal survival after participatory learning and action with women's groups: a prospective study in rural eastern India. *Bull World Health Organ* 2013; **91**: 426–433B.
- Government of India, National Health Mission. Guidelines for Village Health Sanitation and Nutrition Committees. http://nrhm.gov.in/images/pdf/communitisation/vhsnc/order-guidelines/vhsnc_guidelines.pdf (accessed Oct 3, 2015).

- 22 Barnett S, Nair N, Tripathy P, Borghi J, Rath S, Costello A. A prospective key informant surveillance system to measure maternal mortality - findings from indigenous populations in Jharkhand and Orissa, India. *BMC Pregnancy Childbirth* 2008; **8**: 6.
- 23 Hayes RJ, Bennett S. Simple sample size calculation for cluster-randomized trials. *Int J Epidemiol* 1999; **28**: 319–26.
- 24 Hayes RJ, Moulton LH. Cluster randomised trials. London: CRC Press, 2009.
- 25 Houweling TA, Tripathy P, Nair N, et al. The equity impact of participatory women's groups to reduce neonatal mortality in India: secondary analysis of a cluster-randomised trial. *Int J Epidemiol* 2013; **42**: 520–32.
- 26 Vyas S, Kumaranayake L. Constructing socio-economic status indices: how to use principal components analysis. *Health Policy Plan* 2006; **21**: 459–68.
- 27 Fottrell E, Azad K, Kuddus A, et al. The effect of increased coverage of participatory women's groups on neonatal mortality in Bangladesh: a cluster randomized trial. *JAMA Pediatr* 2013; **167**: 816–25.
- 28 Houweling TA, Morrison J, Azad K, et al. How to reach every newborn: three key messages. *Lancet Glob Health* 2014; **2**: e436–37.
- 29 Pagel C, Prost A, Lewycka S, et al. Intracluster correlation coefficients and coefficients of variation for perinatal outcomes from five cluster-randomised controlled trials in low and middle-income countries: results and methodological implications. *Trials* 2011; **12**: 151.
- 30 Gopalan SS, Mohanty S, Das A. Assessing community health workers' performance motivation: a mixed-methods approach on India's Accredited Social Health Activists (ASHA) programme. *BMJ Open* 2012; **2**: e00155.
- 31 WHO. Global strategy for women's, children's and adolescents' health (2016–2030). <http://www.who.int/life-course/partners/global-strategy/en/> (accessed Oct 3, 2015).