Articles

Effect of women's groups and volunteer peer counselling on rates of mortality, morbidity, and health behaviours in mothers and children in rural Malawi (MaiMwana): a factorial, cluster-randomised controlled trial

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Summary

Background Women's groups and health education by peer counsellors can improve the health of mothers and children. We assessed their effects on mortality and breastfeeding rates in rural Malawi.

Methods We did a 2×2 factorial, cluster-randomised trial in 185 888 people in Mchinji district. 48 equal-sized clusters were randomly allocated to four groups with a computer-generated number sequence. 24 facilitators guided groups through a community action cycle to tackle maternal and child health problems. 72 trained volunteer peer counsellors made home visits at five timepoints during pregnancy and after birth to support breastfeeding and infant care. Primary outcomes for the women's group intervention were maternal, perinatal, neonatal, and infant mortality rates (MMR, PMR, NMR, and IMR, respectively); and for the peer counselling were IMR and exclusive breastfeeding (EBF) rates. Analysis was by intention to treat. The trial is registered as ISRCTN06477126.

Findings We monitored outcomes of 26 262 births between 2005 and 2009. In a factorial model adjusted only for clustering and the volunteer peer counselling intervention, in women's group areas, for years 2 and 3, we noted non-significant decreases in NMR (odds ratio 0·93, 0·64–1·35) and MMR (0·54, 0·28–1·04). After adjustment for parity, socioeconomic quintile, and baseline measures, effects were larger for NMR (0·85, 0·59–1·22) and MMR (0·48, 0·26–0·91). Because of the interaction between the two interventions, a stratified analysis was done. For women's groups, in adjusted analyses, MMR fell by 74% (0·26, 0·10–0·70), and NMR by 41% (0·59, 0·40–0·86) in areas with no peer counsellors, but there was no effect in areas with counsellors (1·09, 0·40–2·98, and 1·38, 0·75–2·54). Factorial analysis for the peer counselling intervention for years 1–3 showed a fall in IMR of 18% (0·82, 0·67–1·00) and an improvement in EBF rates (2·42, 1·48–3·96). The results of the stratified, adjusted analysis showed a 36% reduction in IMR (0·64, 0·48–0·85) but no effect on EBF (1·18, 0·63–2·25) in areas without women's groups, and in areas with women's groups there was no effect on IMR (1·05, 0·82–1·36) and an increase in EBF (5·02, 2·67–9·44). The cost of women's groups was US$114 per year of life lost (YLL) averted and that of peer counsellors was $33 per YLL averted, using stratified data from single intervention comparisons.

Interpretation Community mobilisation through women's groups and volunteer peer counsellor health education are methods to improve maternal and child health outcomes in poor rural populations in Africa.

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Background

Worldwide, the mortality rate in children younger than 5 years is still unacceptably high at 7·7 million to 8·8 million per year, and includes 3·6 million deaths in newborn babies.[1,2] In Malawi, the mortality rate in children younger than 5 years during 2005–10 was 112 per 1000 livebirths, of which 30% were neonates.[1,3] In south Asia, community mobilisation through women's groups reduced the rate of neonatal mortality, probably through improved solidarity, decision making, preventive care, care-seeking, and health-service accountability.[4,5]

Exclusive breastfeeding helps development of the immune system,[6] improves survival of children born to HIV-infected mothers,[7] and reduces the risk of mother-to-child transmission (MTCT) of HIV compared with mixed feeding.[7,8] The findings from systematic reviews[9,10] suggest that peer advice and support for mothers improve hygiene, recognition of illness in infants, and breastfeeding. Evidence that exclusive breastfeeding as a result of peer counselling leads to a reduction in the mortality rate is scarce. The results of research suggest that peer counselling increases the rates of breastfeeding and reduces those of diarrhoea, with little effect on mortality rates.[11–17] According to the findings of a Cochrane review,[10] further trials are needed to assess the cost-effectiveness of lay and professional support for breastfeeding.

Most births in African countries occur at home, especially in rural areas, and many deaths in infants might be prevented if mothers are given advice about

feeding, infant care, danger signs, MTCT, HIV testing and treatment, and care-seeking. In Africa, no trials of community mobilisation through women's groups, and only one trial of counselling for exclusive breastfeeding, have been done to assess effects on child mortality. The effects of community mobilisation through women's groups, and health education through female volunteer peer counsellors on rates of infant care, feeding, morbidity, and mortality were assessed in the MaiMwana Project, a collaboration between the Malawi Ministry of Health and University College London, London, UK.

Methods

Study location and population

90% of Malawi's population live on less than US$2 a day.[18] Mchinji district, in the central region, has a population of 455 000, of which 90% live in rural areas and are dependent on subsistence farming.[19] In 2006, 99% of women in this district attended antenatal care at least once during pregnancy and 58% delivered at a health facility.[20] Health care is provided by one district hospital, four rural hospitals, nine health centres, and private clinics. Quality is compromised by a severe shortage of personnel, low morale, and irregular drug supplies.

Participants

A cohort of 43 719 women of childbearing age was defined in 2004 during a baseline household survey. All women aged 10–49 years who consented to participate were enrolled. Cohort members were entered in an open master list to which new participants were added if they moved into the study area. Women's migrations within and outside the study area were recorded to allow for both intention-to-treat and per-protocol analyses.[21] Women who had terminal family planning procedures were enumerated but excluded from the final sample. They were not excluded from participating in the interventions.

The study was approved by the Malawi National Health Sciences Research Committee in January, 2003, and the ethics committee of the University College London Institute of Child Health and Great Ormond Street Hospital, London, UK.

Written consent for the random allocation of interventions to communities was obtained from the district commissioner, district health officer, and leaders of participating communities. Most women enrolled were not literate, and verbal consent was obtained for each data gathering episode after explaining the purpose of the visit. Women were free to decline to be interviewed at any time.

Randomisation and masking

We did a cluster-randomised controlled trial using a 2×2 factorial design to assess the effects of two interventions on specific outcome indicators. The study design has been described in detail elsewhere.[21] 48 clusters were defined on the basis of census enumeration areas (appendix p 1). Each cluster had a population of about 3000 people, with a surrounding buffer area to reduce contamination between intervention and control areas; villages in the buffer area were excluded. Clusters of villages, rather than individual villages, were used as the unit of randomisation to further reduce rates of travel across cluster boundaries and the possibility of contamination. The urban district administrative centre was excluded.

The 48 clusters were allocated randomly to one of four groups (appendix p 1). 12 were allocated to the women's group and volunteer peer counselling, 12 women's group only, 12 volunteer peer counselling only, and 12 no intervention. SL and DO allocated clusters with a random number sequence generated in Stata (version 7.0). Neither was involved in the implementation of the interventions. Although the interventions made masking of allocation impossible at the participant level, allocation was masked for data analysis. Data were gathered independently of programme implementation and could not be used to inform the implementation of the interventions, and thus bias them.

Surveillance

From December, 2004, to December, 2010, each cohort member was visited once a month by a cluster enumerator and data were gathered; the interventions are still in progress, with data (not related to this trial) being gathered. All pregnancies, births, and neonatal, infant, and maternal deaths were identified, and surviving mothers and infants were followed up to 1 year. Trained interviewers administered questionnaires about the demographic characteristics, maternity history, care and care-seeking, and maternal and infant morbidity at 1 month and 6 months after delivery. Feeding practices were ascertained through 24 h and 7 day recall at both interviews. Deaths were verified by a supervisor, through a verbal autopsy interview 2–6 weeks later. When respondents were temporarily unavailable, they were followed up by the interviewers until an outcome was ascertained. If respondents were permanently unavailable, information about dates and timings of events was sought from other community members.

Women's group intervention

From May, 2005, 207 women's groups were established. Each was supported by a cluster facilitator through a community mobilisation action cycle of 20 meetings in four phases (appendix p 2), adapted from cycles used in Bolivia and Nepal.[4,22–24] Facilitators (n=24) were local women aged 20–49 years, literate and with at least one child, selected from the community. They were trained over 11 days, with refresher training every 4 months. The facilitators were paid a salary, and given a bicycle, T-shirt, umbrella, field bag, and monitoring forms. They were supported by four supervisors who visited them at least twice a month, observed meetings, and provided training

and feedback. The facilitators used a manual to implement the cycle, with participatory rural appraisal methods and picture cards of maternal and newborn health problems to guide discussion. Through the four phases of the cycle, members identified and prioritised maternal and child health problems, identified strategies to implement, planned and implemented them, and assessed them and made plans for the future. Criteria for membership were decided by the groups. Initially restricted to women (phases 1 and 2), membership was expanded to include men (phase 3). More than 12 000 people attended at least once.

Volunteer peer counselling intervention

From December, 2004, 72 female volunteer peer counsellors (two to four per cluster) implemented the intervention.[25] Counsellors were selected with communities, and were literate women aged 23–50 years with breastfeeding experience. They identified pregnant women and made five home visits during and after pregnancy: in the third trimester, in the week after birth, and at 1 month, 3 months, and 5 months (appendix p 3). They provided health education about exclusive breastfeeding, infant care, immunisations, prevention of MTCT (PMTCT), and family planning. They also supported women with breast problems and raised awareness of timely care-seeking. Counsellors used an intervention manual describing visit content, and a simple picture book (adapted from manuals published by WHO,[26] Save the Children,[27] and Linkages[28]). They were given an initial 5 day and annual refresher training, and attended monthly meetings. They were also given a bicycle, meeting allowances, registers, calendars, and supervision forms. Peer counsellors lived in the same communities, so informal contacts to make arrangements for visits were common. Because the content was time dependent (eg, birth preparedness, immunisations, and weaning), counsellors stopped trying to arrange missed counselling visits after the appropriate time had elapsed, but would still attempt to make the next scheduled visit. No prespecified number of attempted visits were made before giving up. Counsellors only stopped attempting meetings if a woman expressed a lack of interest or refused. If a woman was not identified during pregnancy, counsellors would try to enrol her after delivery to attend the remaining four visits. Reasons for missed visits or discontinued counselling were recorded in their register.

To promote sustainability, planning, and management, the Mchinji district health office was involved. Counsellors were supervised by 24 government health surveillance assistants, who visited quarterly, documenting progress, achievements, and challenges, and by three MaiMwana officers. Health surveillance assistants received initial and yearly refresher training, attended monthly and quarterly meetings, and were given calendars and a supervisory checklist.

Health service inputs

All study clusters benefited from strengthening of health services. Health workers from every facility were trained in essential newborn care, lifesaving skills and safe motherhood, and discussed the MaiMwana interventions. Bulb syringes, resuscitation tables, ambubags, artery forceps, cord clamps, and sphygmomanometers were donated by University College London and UNICEF to all facilities. MaiMwana project and district health staff, with funding from UNICEF, introduced PMTCT to the district in 2005 and all health facilities were covered by 2008.

Outcomes

Primary outcomes were maternal, perinatal, neonatal, and infant mortality rates (MMR, PMR, NMR, and IMR, respectively) for the clusters assigned to the women's group intervention; and IMR and rates of exclusive breastfeeding (EBF) in the first 6 months for those assigned to the volunteer peer counselling intervention (panel 1). PMR was reported as deaths per 1000 births (perinatal), NMR and IMR were reported as deaths per 1000 livebirths, and MMR was reported as deaths per 100 000 livebirths.

Secondary outcomes for the women's group intervention were maternal and infant morbidity, skilled antenatal, delivery, and postnatal care, tetanus toxoid immunisation, use of malaria prophylaxis, insecticide-treated bednets during pregnancy, and PMTCT services, infant immunisations, early EBF, and reduced use of prelacteal feeds. For the volunteer peer counselling intervention, neonatal mortality and infant morbidity rates were secondary outcomes, and caretaker practices included duration of EBF, time to initiating breast-feeding, use of prelacteal feeds, time to weaning, management of breast problems, and family planning uptake, including condom use. We excluded dietary recall data if they were incomplete or gathered more than 2 weeks after expected interview dates. Care-seeking behaviour included awareness and use of PMTCT and HIV testing services and uptake of immunisations (three doses of pentavalent immunisation and four

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Panel 1: **Definitions of primary outcomes**

- Perinatal death: stillbirth after 28 weeks of gestation, or death of a liveborn infant within 7 completed days of birth
- Neonatal death: death of a liveborn infant within 28 completed days of birth
- Early neonatal death: death arising within 7 completed days of birth
- Late neonatal death: death arising after 7 days but within 28 completed days of birth
- Infant death: death arising within the first year of life
- Maternal death: death of a woman while pregnant or within 42 days of cessation of the pregnancy from any cause related to the pregnancy or its management, but not from accidental causes
- Exclusive breastfeeding: infants receiving only breastmilk and no prelacteal feeds or other liquids or solids except for vitamins, minerals, or medicines

doses of polio vaccine by 6 months). Birth preparedness was a prespecified outcome assessed indirectly through reported handwashing or use of gloves at delivery and early wrapping of the newborn baby. Use of nevirapine, expressing breastmilk, and infant growth were also prespecified, but data for these outcomes were gathered through different systems and will be investigated in future analyses. Uptake of antenatal, skilled delivery, and postnatal care were included as post-hoc outcomes because they were promoted by peer counsellors. Data for recognition of danger signs, though this was a prespecified secondary outcome for

both interventions, were not gathered because showing participants pictures of major danger signs and asking for responses for each would have substantially lengthened the interview.

Statistical analysis

The main analyses were factorial analyses, for comparison of the 24 clusters given the women's group intervention (ie, alone or with volunteer peer counselling) with 24 control clusters (ie, volunteer peer counselling only or no intervention), and the 24 clusters given volunteer peer counselling (ie, alone or with the women's
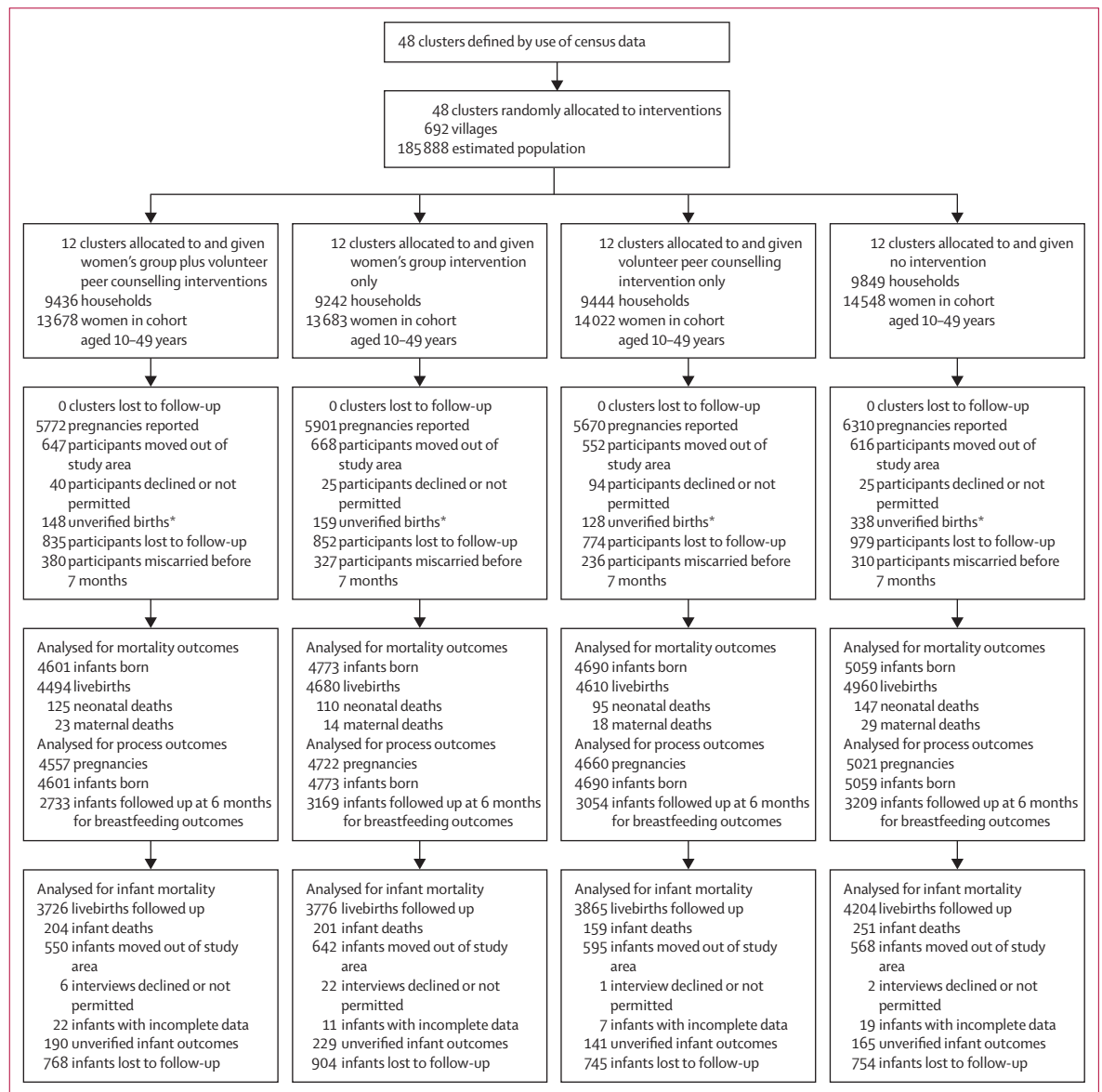
Figure: Trial profile

Data correspond to study period for the women's group intervention because intervention study periods overlap; 26 262 births were followed up (analysis dataset). *Pregnancies reported in monthly registers but not followed up with an interview could also include women who moved away permanently, declined, or were temporarily out of the cluster, reporting errors, or some missed interviews; some pregnancies might have resulted in miscarriage, but the miscarriage was not reported.

group intervention) with 24 control clusters (ie, women's group alone or no intervention). The volunteer peer counselling intervention was established more rapidly than was the women's group intervention, so the interventions were assessed over different timeframes (appendix p 4). After exclusion of the baseline and establishment periods, the study ran from Feb 1, 2006, to Jan 31, 2009, for the women's group intervention and July 1, 2005, to June 30, 2008, for the volunteer peer counselling intervention.

We did not expect the interventions to have adverse effects at cluster or participant level, and did not institute stopping rules. In October, 2008, we presented preliminary findings to an independent data monitoring committee,[29] which recommended further data gathering for 1 year, and consideration of the delays in the first year of the women's group intervention. The committee undertook a final review of the volunteer peer counselling intervention in August, 2009, and of the women's group intervention in March, 2010.

	Total	Intervention groups				Pairs of intervention groups			
		Women's group + volunteer peer counselling (A)	Women's group only (B)	Volunteer peer counselling only (C)	No intervention (D)	Women's group (A+B)	No women's group (C+D)	Volunteer peer counselling (A+C)	No volunteer peer counselling (B+D)
Pregnant mothers	3033	728	755	777	773	1483	1550	1505	1528
Age (years; mean, SE)	26·2 (0·12)	26·3 (0·24)	26·3 (0·25)	26·1 (0·23)	26·2 (0·23)	26·3 (0·17)	26·1 (0·16)	26·2 (0·16)	26·2 (0·17)
Tribe									
Chewa	2679 (88%)	655 (91%)	594 (79%)	702 (90%)	728 (94%)	1249 (84%)	1430 (92%)	1357 (90%)	1322 (87%)
Ngoni	194 (6%)	42 (6%)	86 (11%)	43 (6%)	23 (3%)	128 (9%)	66 (4%)	85 (6%)	109 (7%)
Senga	57 (2%)	8 (1%)	41 (5%)	4 (<1%)	4 (<1%)	49 (3%)	8 (<1%)	12 (<1%)	45 (3%)
Other	71 (2%)	15 (2%)	28 (4%)	20 (3%)	8 (1%)	43 (3%)	28 (2%)	35 (2%)	36 (2%)
Religion									
Catholic	1377 (45%)	283 (39%)	310 (41%)	427 (55%)	357 (47%)	593 (40%)	784 (51%)	710 (47%)	667 (44%)
Non-Catholic Christian	1529 (50%)	419 (58%)	399 (53%)	323 (42%)	388 (50%)	818 (55%)	711 (46%)	742 (49%)	787 (52%)
Muslim	47 (2%)	13 (2%)	19 (3%)	11 (1%)	4 (<1%)	32 (2%)	15 (1%)	24 (2%)	23 (2%)
Other	48 (2%)	5 (<1%)	21 (3%)	8 (1%)	14 (2%)	26 (2%)	22 (1%)	13 (<1%)	35 (2%)
Education									
None	634 (21%)	149 (20%)	147 (19%)	164 (21%)	174 (23%)	296 (20%)	338 (22%)	313 (21%)	321 (21%)
Primary (1–8 years)	2154 (71%)	525 (72%)	551 (73%)	539 (69%)	539 (70%)	1076 (73%)	1078 (70%)	1064 (71%)	1090 (71%)
Secondary or higher (9–12 years)	230 (8%)	52 (7%)	55 (7%)	71 (9%)	52 (7%)	107 (7%)	123 (8%)	123 (8%)	107 (7%)
Occupation									
Farming	2494 (82%)	595 (82%)	635 (84%)	604 (78%)	660 (85%)	1230 (83%)	1264 (82%)	1199 (80%)	1295 (85%)
Piece work*	31 (1%)	9 (1%)	10 (1%)	7 (<1%)	5 (<1%)	19 (1%)	12 (<1%)	16 (1%)	15 (<1%)
Salaried	30 (1%)	6 (<1%)	6 (<1%)	8 (1%)	10 (1%)	12 (<1%)	18 (1%)	14 (<1%)	16 (1%)
Business	180 (6%)	43 (6%)	37 (5%)	66 (8%)	34 (4%)	80 (5%)	100 (6%)	109 (7%)	71 (5%)
Student	116 (4%)	32 (4%)	25 (3%)	28 (4%)	31 (4%)	57 (4%)	59 (4%)	60 (4%)	56 (4%)
No work	150 (5%)	35 (5%)	36 (5%)	56 (7%)	23 (3%)	71 (5%)	79 (5%)	91 (6%)	59 (4%)
Marital status of woman									
Married	2809 (93%)	681 (94%)	700 (93%)	721 (93%)	707 (91%)	1381 (93%)	1428 (92%)	1402 (94%)	1407 (92%)
Never married	61 (2%)	18 (2%)	14 (2%)	15 (2%)	14 (2%)	32 (2%)	29 (2%)	33 (2%)	28 (2%)
Divorced, widowed, or other	116 (4%)	23 (3%)	29 (4%)	28 (4%)	36 (5%)	52 (4%)	64 (4%)	51 (3%)	65 (4%)
Socioeconomic quintile									
1 (poorest)	612 (20%)	150 (21%)	156 (21%)	147 (19%)	159 (21%)	306 (21%)	306 (20%)	297 (20%)	315 (21%)
2	617 (20%)	130 (18%)	172 (23%)	162 (21%)	153 (20%)	302 (20%)	315 (20%)	292 (19%)	325 (21%)
3	610 (20%)	146 (20%)	145 (19%)	160 (21%)	159 (21%)	291 (20%)	319 (21%)	306 (20%)	304 (20%)
4	605 (20%)	148 (20%)	125 (17%)	164 (21%)	168 (22%)	273 (18%)	332 (21%)	312 (21%)	293 (19%)
5 (least poor)	542 (18%)	140 (20%)	151 (20%)	135 (17%)	116 (15%)	291 (20%)	251 (16%)	275 (18%)	267 (17%)
Parity									
Non-primigravida	2328 (78%)	572 (79%)	566 (75%)	599 (77%)	591 (76%)	1138 (77%)	1190 (77%)	1171 (79%)	1157 (76%)
Primigravida	595 (20%)	134 (18%)	167 (22%)	155 (20%)	139 (18%)	301 (20%)	294 (19%)	289 (19%)	306 (20%)

(Continues on next page)

	Total	Intervention groups				Pairs of intervention groups			
		Women's group + volunteer peer counselling (A)	Women's group only (B)	Volunteer peer counselling only (C)	No intervention (D)	Women's group (A+B)	No women's group (C+D)	Volunteer peer counselling (A+C)	No volunteer peer counselling (B+D)
(Continued from previous page)									
Antenatal	3033	728	755	777	773	1483	1550	1505	1528
Any antenatal care at a health facility	2765 (91%)	680 (93%)	672 (89%)	718 (92%)	695 (90%)	1352 (91%)	1413 (91%)	1398 (93%)	1367 (89%)
Any HIV testing at antenatal care visit	374 (12%)	90 (12%)	83 (11%)	110 (14%)	91 (12%)	173 (12%)	201 (13%)	200 (13%)	174 (11%)
Any perceived antenatal, delivery, or postnatal maternal problem	1569 (52%)	375 (52%)	448 (59%)	372 (48%)	374 (48%)	823 (55%)	746 (48%)	747 (50%)	822 (54%)
Births	3071	739	765	785	782	1504	1567	1524	1547
Institutional delivery	1231 (40%)	255 (35%)	292 (38%)	400 (51%)	284 (36%)	547 (36%)	684 (44%)	655 (43%)	576 (37%)
Birth attended by skilled provider	1210 (39%)	249 (34%)	297 (39%)	374 (48%)	290 (37%)	546 (36%)	664 (42%)	623 (41%)	587 (38%)
Attendant washed hands or wore gloves	2442 (80%)	569 (77%)	606 (79%)	624 (79%)	643 (82%)	1175 (78%)	1267 (81%)	1193 (78%)	1249 (91%)
Livebirths	3002	716	745	765	776	1461	1541	1481	1521
Baby wrapped within 30 min of birth	2699 (90%)	640 (89%)	704 (94%)	662 (87%)	693 (89%)	1344 (92%)	1355 (88%)	1302 (88%)	1397 (92%)
Postnatal care at a health facility	801 (27%)	188 (26%)	158 (21%)	267 (35%)	188 (24%)	346 (24%)	455 (30%)	455 (31%)	346 (23%)
Infant received BCG	1299 (43%)	278 (39%)	377 (51%)	366 (48%)	278 (36%)	655 (45%)	644 (42%)	644 (43%)	655 (43%)
Infant received polio immunisation	1118 (37%)	230 (32%)	317 (43%)	333 (44%)	238 (31%)	547 (37%)	571 (37%)	563 (38%)	555 (37%)
Any perceived neonatal problem (cough, fever, or diarrhoea)	1236 (41%)	279 (39%)	321 (43%)	283 (37%)	353 (45%)	600 (41%)	636 (41%)	562 (38%)	674 (36%)
Breastfed infants at age 1 month	2714	649	673	677	715	1322	1392	1326	1388
Breastfeeding initiated within 1 h of birth	2064 (76%)	466 (72%)	559 (83%)	486 (72%)	553 (77%)	1025 (78%)	1039 (75%)	952 (72%)	1112 (80%)
Infants with 6 months of breastfeeding data	1657	387	408	414	448	795	862	801	856
Infant exclusively breastfed to age 6 months	232 (14%)	100 (26%)	41 (10%)	58 (14%)	33 (7%)	141 (18%)	91 (11%)	158 (20%)	74 (9%)

Data are number (%), unless otherwise indicated. Missing data differ for each variable and are not included in the table. Percentages are calculated from available data for each variable. *Temporary work—usually labouring work or farming for different employers on an occasional and ad-hoc basis, so individual receives a fixed amount for completion of the job.

Table 1: **Characteristics of identified pregnancies in intervention groups during the inception period**

The trial was planned for 3 years, and was powered for an analysis of birth outcomes over 2 years, allowing 1 year for the women's group intervention to be established.[21] We assumed a between-cluster coefficient of variation (k) of 0·15–0·30, and about 240 births per cluster in 2 years. A sample size of 24 clusters per comparison group would detect a 47–50% reduction in MMR, 28–33% reduction in PMR, 31–36% reduction in NMR, and 21–28% reduction in IMR between intervention and control areas at 80% power and 5% significance level (assuming baseline mortality rates of 984 per 100 000 livebirths, 34 per 1000 births, 27 per 1000 livebirths, and 76 per 1000 livebirths, respectively).[30] At the same power and significance levels, it would

detect a 16–30% increase in EBF, assuming baseline levels of 28%.[30]

Analysis was by intention to treat at cluster and participant levels. Data were excluded from analyses when dates of birth or death were not known. We tested the intervention effect on primary and secondary outcomes on the basis of previously agreed hypotheses. We used multivariate logistic regression with random effects on individual-level data in Stata (version 11.0). Main analyses were factorial and adjusted for clustering, stratification by the other intervention, and socioeconomic and demographic variables. Analyses were adjusted for baseline differences in the women's group intervention, but not in the volunteer peer

	Births	Livebirths	Perinatal deaths	Neonatal deaths	Infant deaths*	Maternal deaths	PMR	NMR	IMR	MMR
Factorial analysis, women's group versus no women's group										
Women's group (with and without volunteer peer counselling, 24 clusters)										
Inception (6 months)	1504	1461	76	48	79/1113	8	50·5	32·9	71·0	548
Year 1	3073	2992	142	91	150/2422	20	46·2	30·4	61·9	668
Year 2	3124	3054	130	81	150/2548	8	41·6	26·5	58·9	262
Year 3	3177	3128	99	63	105/2533	9	31·2	20·1	41·5	288
Years 1–3	9374	9174	371	235	405/7503	37	39·6	25·6	54·0	403
Change from inception to year 3	..	..	..	..	..	..	0·51 (0·37–0·71)	0·57 (0·38–0·85)	0·53 (0·39–0·73)	0·55 (0·21–1·43)
No women's group (volunteer peer counselling only and no intervention, 24 clusters)										
Inception (6 months)	1567	1541	50	36	64/1229	8	31·9	23·4	52·1	519
Year 1	3321	3255	125	82	141/2728	14	37·6	25·2	51·7	430
Year 2	3090	3035	116	88	158/2583	21	37·5	29·0	61·2	692
Year 3	3338	3280	116	72	111/2761	12	34·8	22·0	40·2	366
Years 1–3	9749	9570	357	242	410/8072	47	36·6	25·3	50·8	491
Change from inception to year 3	..	..	..	..	..	..	1·09 (0·77–1·55)	0·94 (0·61–1·43)	0·74 (0·53–1·02)	0·61 (0·23–1·64)
Factorial analysis, volunteer peer counselling versus no volunteer peer counselling†										
Volunteer peer counselling (with and without women's group, 24 clusters)										
Inception (6 months)	1524	1481	66	39	68/1172	10	43·3	26·3	58·0	675
Year 1	3156	3084	123	76	120/2483	28	39·0	24·6	48·3	908
Year 2	3048	2974	128	77	120/2508	15	42·0	25·9	47·8	504
Year 3	3113	3062	114	80	140/2550	13	36·6	26·1	54·9	425
Years 1–3	9317	9120	365	233	380/7541	56	39·2	25·5	50·4	606
No volunteer peer counselling (women's group only and no intervention, 24 clusters)										
Inception (6 months)	1547	1521	60	45	75/1170	6	38·8	29·6	64·1	394
Year 1	3390	3314	149	106	172/2630	16	44·0	32·0	65·4	483
Year 2	3374	3307	140	96	167/2728	20	41·5	29·0	61·2	605
Year 3	3088	3031	110	73	136/2503	10	35·6	24·1	54·3	330
Years 1–3	9852	9652	399	275	475/7861	46	40·5	28·5	60·4	476
Intervention group analysis										
Women's group plus volunteer peer counselling (12 clusters)										
Inception (6 months)	739	716	40	28	42/568	3	54·1	39·1	73·9	419
Year 1	1429	1386	64	36	58/1156	11	44·8	26·0	50·2	794
Year 2	1573	1534	78	55	91/1315	7	49·6	35·9	69·2	456
Year 3	1599	1574	56	34	55/1255	5	35·0	21·6	43·8	318
Years 1–3	4601	4494	198	125	204/3726	23	43·0	27·8	54·8	512
Change from inception to year 3	..	..	..	..	..	..	0·56 (0·37–0·87)	0·51 (0·31–0·87)	0·55 (0·36–0·84)	0·76 (0·18–3·21)
Women's group only (12 clusters)										
Inception (6 months)	765	745	36	20	37/545	5	47·1	26·8	67·9	671
Year 1	1644	1606	78	55	92/1266	9	47·4	34·2	72·7	560
Year 2	1551	1520	52	26	59/1233	1	33·5	17·1	47·9	66
Year 3	1578	1554	43	29	50/1278	4	27·2	18·7	39·1	257
Years 1–3	4773	4680	173	110	201/3777	14	36·2	23·5	53·2	299
Change from inception to year 3	..	..	..	..	..	..	0·45 (0·27–0·73)	0·65 (0·35–1·21)	0·52 (0·33–0·82)	0·39 (0·10–1·44)
Volunteer peer counselling only (12 clusters)										
Inception (6 months)	785	765	26	11	26/604	7	33·1	14·4	43·0	915
Year 1	1591	1559	53	30	50/1298	8	33·3	19·2	38·5	513
Year 2	1470	1441	50	32	58/1210	6	34·0	22·2	47·9	416
Year 3	1629	1610	47	33	51/1358	4	28·9	20·5	37·6	248

(Continues on next page)

	Births	Live births	Perinatal deaths	Neonatal deaths	Infant deaths*	Maternal deaths	PMR	NMR	IMR	MMR
(Continued from previous page)										
Years 1–3	4690	4610	150	95	159/3866	18	32·0	20·6	41·1	390
Change from inception to year 3	..	..	..	..	..	..	0·84 (0·51–1·38)	1·40 (0·70–2·82)	0·80 (0·49–1·31)	0·27 (0·08–0·93)
No intervention (12 clusters)										
Inception (6 months)	782	776	24	25	38/625	1	30·7	32·2	60·8	129
Year 1	1730	1696	72	52	91/1430	6	41·6	30·7	63·6	354
Year 2	1620	1594	66	56	100/1373	15	40·7	35·1	72·8	941
Year 3	1709	1670	69	39	60/1403	8	40·4	23·4	42·8	479
Years 1–3	5059	4960	207	147	251/4206	29	40·9	29·6	59·7	585
Change from inception to year 3	..	..	..	..	..	..	1·41 (0·85–2·33)	0·72 (0·42–1·24)	0·69 (0·45–1·07)	3·66 (0·46–29·31)
Total										
All 48 clusters										
Inception (6 months)	3071	3002	126	84	143/2342	16	41·0	28·0	61·1	533
Year 1	6394	6247	267	173	291/5150	34	41·8	27·7	56·5	544
Year 2	6214	6089	246	169	308/5131	29	39·6	27·8	60·0	476
Year 3	6515	6408	215	135	216/5294	21	33·0	21·1	40·8	328
Years 1–3	19 123	18 744	728	477	815/15 575	84	38·1	25·4	52·3	448
Change from inception to year 3	..	..	..	..	..	..	0·74 (0·58–0·93)	0·72 (0·54–0·96)	0·62 (0·50–0·78)	0·58 (0·29–1·15)

Data are numbers, n/N, or adjusted odds ratio (95% CI). The odds ratio was adjusted for socioeconomic quintile and parity. The study years used in this table are for the women's group intervention, except for the factorial analysis of the volunteer peer counselling intervention. PMR=perinatal mortality rate per 1000 births. NMR=neonatal mortality rate per 1000 livebirths. IMR=infant mortality rate per 1000 livebirths. MMR=maternal mortality ratio per 100 000 livebirths. *Prospectively gathered data; denominator is all livebirths followed up at 1 year. †Years 1–3 for women's group and volunteer peer counselling interventions overlap but are not the same; change from inception is not included for the volunteer peer counselling intervention because inception was not a baseline for this intervention, and incremental changes during the course of the study were not expected.

Table 2: Births, deaths, and mortality rates in intervention groups during 2005–09

counselling intervention because this intervention had already started during the 6 month inception and therefore there was a risk of masking early effects. Analysis of year 2 and 3 outcomes was planned because of the potential for delayed effects of the women's group intervention.[4,5,31] Treatment group analysis was pre-specified to investigate any interaction between the interventions, and interaction terms were included in factorial models to assess the strength of interaction.

Cost-effectiveness analysis

Costs were calculated from July, 2004, to January, 2009, separately for women's groups, peer counselling, health-service strengthening, monitoring and evaluation, and process evaluation. Joint costs were shared. Costs from July, to December, 2004, and costs incurred later on that were necessary for implementation, were classified as start-up and running costs (appendix p 4). Costs were estimated from the perspective of a provider in Malawi Kwacha, inflated to 2010 values with the Malawian consumer price index,[32] and converted to US$ on July 2, 2010. Capital costs were converted to yearly costs, assuming constant linear depreciation. Residual assets were deducted from programme costs based on resale value on Jan 31, 2009.

Costs were gathered through project accounting systems, vehicle log-books, and time-allocation interviews. Resource use was assessed retrospectively. Donated resources and other items not captured in the accounting ledger were valued on the basis of best alternative use. Volunteer time was not valued at minimum wage because volunteers received financial allowances and goods, and volunteer work did not replace regular employment. Incremental cost-effectiveness was measured in relation to a do-nothing alternative. Results were calculated as the years of life lost (YLL) component of disability-adjusted life-years (DALYs) with 3% discounting and no age weights. Deaths averted were calculated by subtracting actual from expected numbers and, for infant deaths, by multiplying the difference by the ratio of livebirths (n=9120) to births followed up to 1 year (n=7541). Expected deaths were calculated by use of adjusted odds ratios (ORs) from the stratified analyses to control for individual-level confounding. Maternal YLL averted were calculated from a mean age at death of 28 years.

This study is registered as ISRCTN06477126.

Role of the funding source

The funders had no role in the design of the study, data gathering, analysis, interpretation, or writing up of the

findings. SL and AC had full access to all the data and AC had final responsibility for the decision to submit for publication.

Results

The figure shows the trial profile; 48 clusters were randomly assigned equally to interventions—women's group plus volunteer peer counselling, women's group only, volunteer peer counselling only, or no intervention.

The mean population per cluster was 3873 (range 3083–4933). Intervention implementation started before the trial periods began. The volunteer peer counselling intervention began on Dec 1, 2004, and the women's group intervention on May 1, 2005. We took the 6 months' inception, Jan 1, to June 30, 2005, as a baseline for the women's group intervention, and an establishment period for the volunteer peer counselling intervention. Table 1 shows the characteristics of women and

	Mortality	Model 1, years 1–3		Model 1, years 2–3		Model 2, years 1–3		Model 2, years 2–3	
		Adjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value
Factorial analysis									
Women's groups versus no women's groups									
MMR	37/9174 (403)	0·82 (0·53–1·29)	0·39	0·54 (0·28–1·04)	0·06	0·77 (0·49–1·21)	0·26	0·48 (0·26–0·91)	0·0238*
PMR	371/9374 (39·6)	1·07 (0·86–1·34)	0·54	1·00 (0·28–1·04)	0·98	0·99 (0·82–1·21)	0·95	0·91 (0·70–1·18)	0·47
NMR	235/9174 (25·6)	1·05 (0·78–1·39)	0·76	0·93 (0·64–1·35)	0·70	0·97 (0·74–1·28)	0·83	0·85 (0·59–1·22)	0·39
IMR	405/7503 (54·0)	1·09 (0·89–1·34)	0·42	1·01 (0·80–1·27)	0·95	1·05 (0·86–1·29)	0·60	0·96 (0·77–1·20)	0·72
Peer counselling versus no peer counselling									
IMR†	380/7541 (50·4)	0·82 (0·67–1·00)	0·0499	0·88 (0·71–1·09)	0·23	0·83 (0·68–1·02)	0·08	0·89 (0·72–1·10)	0·30
EBF†	1047/5222 (20·0)	2·42 (1·48–3·96)	0·0004	2·47 (1·40–4·36)	0·0019	2·44 (1·49–3·99)	0·0004	2·46 (1·39–4·34)	0·0019
Stratified analysis									
Women's groups stratified by peer counselling									
MMR (no peer counselling)	14/4722 (296)	0·51 (0·26–1·02)	0·06	0·23 (0·09–0·63)	0·0043	0·51 (0·26–1·02)	0·06	0·26 (0·10–0·70)	0·0074
MMR (peer counselling)	23/4557 (505)	1·31 (0·71–2·43)	0·39	1·18 (0·49–2·86)	0·72	1·21 (0·60–2·45)	0·59	1·09 (0·40–2·98)	0·86
PMR (no peer counselling)	173/4773 (36·2)	0·86 (0·65–1·14)	0·30	0·74 (0·54–1·00)	0·0532	0·83 (0·66–1·04)	0·10	0·67 (0·50–0·88)	0·0046
PMR (peer counselling)	198/4601 (43·0)	1·36 (0·99–1·88)	0·06	1·36 (0·90–2·07)	0·14	1·24 (0·90–1·71)	0·19	1·30 (0·84–2·01)	0·24
NMR (no peer counselling)	110/4680 (23·5)	0·79 (0·57–1·11)	0·17	0·62 (0·40–0·95)	0·0298	0·77 (0·57–1·02)	0·07	0·59 (0·40–0·86)	0·0058
NMR (peer counselling)	125/4494 (27·8)	1·42 (0·91–2·21)	0·12	1·38 (0·79–2·39)	0·25	1·33 (0·83–2·13)	0·23	1·38 (0·75–2·54)	0·31
IMR (no peer counselling)	201/3777 (53·2)	0·89 (0·69–1·17)	0·41	0·75 (0·57–0·99)	0·0423	0·87 (0·68–1·11)	0·26	0·72 (0·56–0·94)	0·0144
IMR (peer counselling)	204/3726 (54·8)	1·35 (1·01–1·81)	0·0429	1·35 (0·97–1·88)	0·07	1·31 (0·96–1·79)	0·08	1·33 (0·94–1·89)	0·11
Volunteer peer counselling stratified by women's group									
IMR (no women's group)†	159/3866 (41·1)	0·65 (0·49–0·85)	0·0017	0·65 (0·49–0·86)	0·0029	0·64 (0·48–0·85)	0·0021	0·67 (0·49–0·91)	0·0107
IMR (women's group)†	204/3726 (54·8)	1·02 (0·78–1·34)	0·87	1·20 (0·93–1·55)	0·16	1·05 (0·82–1·36)	0·68	1·22 (0·95–1·57)	0·12
EBF (no women's group)†	351/2611 (13·4)	1·17 (0·62–2·21)	0·63	1·15 (0·51–2·58)	0·74	1·18 (0·63–2·25)	0·60	1·14 (0·51–2·57)	0·75
EBF (women's group)†	697/2353 (29·6)	4·99 (2·64–9·43)	<0·0001	5·14 (2·55–10·36)	<0·0001	5·02 (2·67–9·44)	<0·0001	5·13 (2·55–10·33)	<0·0001
Treatment group analysis‡									
MMR			0·0386§	··	0·0162§		0·08§		0·0467§
Women's group plus peer counselling	23/4557 (505)	0·87 (0·50–1·51)		0·55 (0·26–1·16)		0·82 (0·46–1·46)		0·47 (0·22–1·00)	
Women's group only	14/4722 (296)	0·51 (0·27–0·97)		0·23 (0·08–0·63)		0·51 (0·26–0·99)		0·26 (0·10–0·68)	
Peer counselling only	18/4660 (386)	0·67 (0·37–1·20)		0·46 (0·21–1·03)		0·69 (0·36–1·30)		0·48 (0·20–1·10)	
No intervention	29/5021 (578)	1·0		1·0		1·0		1·0	
PMR			0·0371§	··	0·0223§		0·0377§		0·0132§
Women's group plus peer counselling	198/4601 (43·0)	1·03 (0·77–1·39)		1·02 (0·72–1·45)		1·01 (0·79–1·31)		1·01 (0·73–1·39)	
Women's group only	173/4773 (36·2)	0·86 (0·64–1·16)		0·73 (0·51–1·06)		0·82 (0·63–1·07)		0·66 (0·47–0·94)	
Peer counselling only	150/4690 (32·0)	0·76 (0·56–1·03)		0·75 (0·52–1·09)		0·82 (0·62–1·08)		0·80 (0·56–1·13)	
No intervention	207/5059 (40·9)	1·0		1·0		1·0		1·0	
NMR			0·0456§	··	0·0317§		0·06§		0·0380§
Women's group plus peer counselling	125/4494 (27·8)	0·95 (0·65–1·38)		0·99 (0·61–1·59)		0·93 (0·65–1·32)		0·98 (0·62–1·54)	
Women's group only	110/4680 (23·5)	0·79 (0·54–1·16)		0·62 (0·38–1·03)		0·76 (0·53–1·09)		0·59 (0·36–0·96)	
Peer counselling only	95/4610 (20·6)	0·67 (0·45–1·00)		0·72 (0·44–1·18)		0·73 (0·50–1·06)		0·78 (0·48–1·27)	
No intervention	147/4960 (29·6)	1·0		1·0		1·0		1·0	
								(Continues on next page)	

	Mortality	Model 1, years 1–3		Model 1, years 2–3		Model 2, years 1–3		Model 2, years 2–3	
		Adjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value	Adjusted odds ratio (95% CI)	p value
(Continued from previous page)									
IMR			0·0440§	..	..		0·0330§		0·0077§
Women's group plus peer counselling	204/3726 (54·8)	0·91 (0·70–1·20)		0·99 (0·74–1·32)		0·91 (0·70–1·17)		0·97 (0·74–1·27)	
Women's group only	201/3777 (53·2)	0·89 (0·68–1·17)		0·75 (0·56–1·02)		0·87 (0·67–1·12)		0·72 (0·54–0·96)	
Peer counselling only	159/3866 (41·1)	0·67 (0·51–0·89)		0·73 (0·54–0·99)		0·68 (0·52–0·89)		0·74 (0·55–0·99)	
No intervention	251/4206 (59·7)	1·0		1·0		1·0		1·0	
EBF			0·0054§	..	..		0·0054§		0·0311§
Women's group plus peer counselling	697/2353 (29·6)	3·72 (1·85–7·48)		5·05 (2·41–10·59)		3·72 (1·86–7·44)		3·50 (1·64–7·46)	
Women's group only	241/2692 (9·0)	0·84 (0·42–1·70)		0·98 (0·46–2·09)		0·84 (0·42–1·69)		0·94 (0·44–2·03)	
Peer counselling only	351/2611 (13·4)	1·02 (0·50–2·08)		1·16 (0·54–2·49)		1·04 (0·51–2·10)		1·11 (0·51–2·39)	
No intervention	274/2752 (10·0)	1·0		1·0		1·0		1·0	

Data are n/N (rate), unless otherwise indicated. 95% CIs were not adjusted. MMR=maternal mortality ratio per 100 000 livebirths. PMR=perinatal mortality rate per 1000 births. NMR=neonatal mortality rate per 1000 livebirths. IMR=infant mortality rate per 1000 livebirths. EBF=exclusive breastfeeding rate per 100 livebirths. Model 1 data were adjusted for clustering and stratification by the other intervention. Model 2 data were adjusted as in model 1, and for cluster-level baseline values, socioeconomic quintile, and parity. *This effect was no longer significant at the 5% level after application of the Holm procedure for multiple testing. †Adjusted for stratification, clustering, socioeconomic quintile, and parity, but not for baseline values, because these could reflect early effects of the volunteer peer counselling intervention. ‡Study years used for this analysis were for the women's group intervention, so that both interventions were active during the period analysed, because the women's group intervention was still in its set-up phase during year 1 of the volunteer peer counselling intervention. §p value for likelihood ratio test for comparison of the model with and without the interaction term.

Table 3: Factorial and treatment group analyses of primary outcomes

pregnancies in intervention groups in this period. Women in the four groups were similar in age, education, and marital status, with small differences in religious and tribal affiliations between groups, fewer farmers in areas with volunteer peer counselling only, and more primigravidae in areas with women's group intervention only. The 24 clusters with volunteer peer counselling had higher uptake of skilled antenatal, delivery, and postnatal care, HIV testing, and exclusive breastfeeding, compared with clusters without peer counselling during this period, and lower frequencies of perceived maternal and neonatal problems, suggesting early intervention effects, though newborn care practices—early wrapping and initiation of breastfeeding—were lower (table 1). The opposite was true for areas with the women's group intervention—lower delivery and postnatal care, and highest perceived maternal problems than in control areas—though early wrapping and breastfeeding were better (table 1). Clusters with only the women's group intervention had the lowest uptake of antenatal and postnatal care and HIV testing, and higher perceived maternal problems (table 1). Exclusive breastfeeding was highest in areas with both interventions, suggesting early effects of volunteer peer counselling (and not an interaction because the women's group intervention had not begun; table 1).

Four women's group facilitators dropped out during the trial and were replaced. Over 3 years in intervention areas, data for coverage were provided by 7815 mothers at 1 month after delivery. 4167 (53%) of these mothers had ever attended a women's group. 2457 (59%) of 4167 had attended groups one to five times, 1267 (30%) six to ten times, and 443 (11%) more than ten times. There was one

women's group per 105 women aged 15–49 years and per 440 population.

Eight volunteer counsellors and six health surveillance assistants dropped out during the trial and were replaced. Over 3 years in intervention areas, data for coverage were provided by 8112 mothers at 1 month after delivery, and 4447 (55%) of these said they had received counselling (8612 individual visits). Reports at 6 months after delivery were available for 5513 mothers in intervention areas, and 3582 (65%) of these were given counselling (8715 visits). There was one volunteer counsellor per 305 women aged 15–49 years and per 1291 population.

Table 2 summarises the numbers of births and deaths in each group. Mortality rates were higher in the women's group (with or without volunteer peer counselling) than in the non-women's group (volunteer peer counselling only or no intervention) clusters at inception, and highest in clusters given both interventions (women's group plus volunteer peer counselling). PMR, NMR, and IMR fell consistently over 3 years in areas given the women's group intervention with or without volunteer peer counselling; MMR also fell, with the largest reductions in years 2 and 3 (table 2). Non-women's group clusters did not show a similar pattern (table 2). Generally, IMR was lower in clusters assigned to volunteer peer counselling (alone or with women's groups) than in those assigned to non-volunteer peer counselling (women's groups or no intervention) and was lowest in volunteer peer counselling only clusters throughout the study.

Table 3 summarises the analyses of the primary outcomes for the women's group intervention. There was no difference between women's group and no

women's group intervention clusters in a factorial model adjusted only for clustering and the presence of volunteer peer counselling intervention. Adjustment for cluster-level baseline values, socioeconomic quintile, and parity lowered the ORs. For years 2 and 3, after exclusion of data from the first year (establishment) of the trial, MMR was reduced by 52% (adjusted OR 0·48, 95% CI 0·26–0·91; table 3). Inclusion of interaction terms in models showed highly significant interactions between the two interventions for almost all primary outcomes, and stratified analyses were done. Strong effects were noted in areas without peer counsellors, with reductions of 33% in PMR, 41% in NMR, 28% in IMR, and 74% in MMR in years 2 and 3 (table 3). No effects were noted in areas with peer counsellors. k for NMR was 0·38 for all

clusters and 0·28 for control clusters only, corresponding with intracluster correlation coefficients of 0·00376 and 0·00237, respectively.

Analysis of secondary outcomes, after adjustment for cluster-level baseline values, socioeconomic quintile, and parity, showed a 50% increase in uptake of antenatal care, and a 30% reduction in births attended by traditional birth attendants (table 4). Exclusive breastfeeding showed an increase of 74% and complete immunisation at 6 months showed a greater than 2·5 times increase (table 4).

For the primary outcomes with the volunteer peer counselling intervention, we noted an 18% reduction in IMR compared with control areas during the 3 years of the trial after adjustment for stratification and clustering

	Intervention	Control	Model 1	Model 2
Women's groups				
Pregnancies	9279	9681		
Any antenatal care at a health facility	8838 (96%)	9126 (94%)	1·44 (0·88 to 2·35)	1·50 (1·03 to 2·19)
Four or more antenatal care visits	2628 (29%)	2788 (30%)	0·91 (0·62 to 1·32)	1·02 (0·74 to 1·42)
Any iron and folate	7841 (89%)	8344 (90%)	0·92 (0·56 to 1·49)	1·11 (0·73 to 1·69)
Iron or folate given for more than 90 days	1628 (18%)	1435 (16%)	1·19 (0·64 to 2·23)	1·58 (0·95 to 2·62)
Any tetanus toxoid immunisation	7748 (88%)	7687 (83%)	1·37 (0·92 to 2·03)	1·22 (0·85 to 1·75)
Adequate tetanus toxoid immunisation*	5960 (68%)	6465 (71%)	0·82 (0·57 to 1·18)	0·82 (0·64 to 1·07)
Any sulfadoxine-pyrimethamine	8421 (93%)	8832 (93%)	1·04 (0·71 to 1·53)	1·19 (0·90 to 1·58)
Two or more doses of sulfadoxine-pyrimethamine	4144 (49%)	4535 (51%)	0·80 (0·43 to 1·50)	0·77 (0·42 to 1·41)
Bednet used every night during pregnancy	5094 (55%)	5230 (52%)	1·03 (0·59 to 1·52)	1·10 (0·78 to 1·55)
Any HIV testing at antenatal care	4666 (51%)	5166 (54%)	0·80 (0·43 to 1·46)	0·87 (0·53 to 1·44)
Any perceived antenatal, delivery, or postnatal maternal problem	4418 (48%)	4349 (45%)	1·02 (0·59 to 1·77)	0·80 (0·55 to 1·18)
Infants with 1 month follow-up data	9374	9749		
Institutional deliveries	4733 (51%)	4891 (50%)	0·98 (0·62 to 1·56)	1·27 (0·95 to 1·71)
Birth attended by skilled provider	4802 (51%)	4955 (51%)	0·99 (0·64 to 1·54)	1·22 (0·91 to 1·65)
Birth attended by a traditional birth attendant	2736 (29%)	3297 (34%)	0·79 (0·49 to 1·28)	0·70 (0·51 to 0·95)
Attendant washed hands or wore gloves	7010 (90%)	8311 (93%)	0·68 (0·39 to 1·18)	0·67 (0·39 to 1·15)
Baby wrapped within 30 min	8810 (98%)	9274 (98%)	1·11 (0·55 to 2·23)	1·09 (0·53 to 2·22)
Baby bathed after 24 h	5064 (57%)	5456 (58%)	0·99 (0·36 to 2·71)	1·23 (0·56 to 2·71)
Postnatal care at a health facility	2984 (38%)	3235 (40%)	0·85 (0·49 to 1·48)	1·16 (0·80 to 1·68)
Any perceived infant problem (cough, fever, or diarrhoea)	2818 (38%)	2887 (37%)	1·04 (0·67 to 1·62)	1·03 (0·72 to 1·47)
Infants with follow-up data about vaccinations received by age 6 months	5902	6263		
Infant received BCG, four doses of oral polio, and three doses of diphtheria, pertussis, and tetanus vaccines by age 6 months	358 (6%)	724 (12%)	1·17 (0·35 to 3·97)	2·66 (1·05 to 6·75)
Infants with 6 months of breastfeeding data	5045	5363		
Infant exclusively breastfed to age 6 months	938 (19%)	625 (12%)	1·76 (1·03 to 3·02)	1·74 (1·02 to 2·98)
Breastfeeding initiated within 1 h of birth	4226 (84%)	4228 (79%)	1·28 (0·47 to 3·47)	1·29 (0·48 to 3·49)
Use of prelacteal feeds	340 (7%)	505 (10%)	0·78 (0·50 to 1·23)	0·78 (0·50 to 1·23)
Any breastfeeding problem	96 (2%)	74 (1%)	1·34 (0·73 to 2·46)	1·31 (0·71 to 2·41)
Volunteer peer counselling				
Family planning	9242	9578		
Ever used modern method (pill, norplant, depo, condom, loop, intrauterine device)	4342 (47%)	4200 (43%)	1·18 (0·96 to 1·45)	1·28 (0·96 to 1·70)
Ever used condom	223 (2%)	234 (2%)	1·12 (0·63 to 2·01)	1·07 (0·57 to 1·89)
Used condom during or after pregnancy	139 (2%)	129 (1%)	1·17 (0·68 to 2·01)	1·09 (0·62 to 1·91)
				(Continues on next page)

	Intervention	Control	Model 1	Model 2
(Continued from previous page)				
Pregnancies	9242	9578		
Any antenatal care at a health facility	8730 (95%)	9021 (93%)	1·34 (0·82 to 2·20)	1·29 (0·79 to 2·10)
Any antenatal HIV counselling and testing	4015 (44%)	3432 (36%)	1·54 (0·82 to 2·87)	1·52 (0·81 to 2·85)
Any perceived antenatal, delivery, or postnatal maternal problem	4176 (45%)	4926 (51%)	0·76 (0·44 to 1·31)	0·75 (0·44 to 1·30)
Infants with 1 month follow-up data	9317	9852		
Institutional deliveries	4538 (49%)	4148 (42%)	1·33 (0·84 to 2·12)	1·28 (0·82 to 2·00)
Birth attended by skilled provider	4530 (49%)	4250 (43%)	1·26 (0·81 to 1·98)	1·21 (0·79 to 1·86)
Attendant washed hands or wore gloves	7517 (94%)	7808 (90%)	1·70 (0·99 to 2·93)	1·66 (0·97 to 2·85)
Baby wrapped within 30 min	8741 (98%)	9173 (97%)	1·89 (0·94 to 3·79)†	1·94 (0·94 to 3·98)†
Postnatal care at a health facility	3064 (38%)	2602 (30%)	1·48 (0·86 to 2·54)	1·43 (0·84 to 2·43)
Infant received BCG	4915 (54%)	4973 (52%)	1·07 (0·64 to 1·79)	1·03 (0·62 to 1·71)
Infant received polio vaccine	4250 (47%)	4698 (49%)	0·92 (0·54 to 1·55)	0·89 (0·53 to 1·49)
Any perceived infant problem (cough, fever, or diarrhoea)	2560 (33%)	3529 (43%)	0·59 (0·39 to 0·88)	0·58 (0·39 to 0·88)
Infants with follow-up data at age 6 months	5891	6568		
Infant received BCG by age 6 months	5713 (98%)	6203 (95%)	2·15 (1·07 to 4·30)	1·98 (1·00 to 3·90)
Infant received any polio vaccine doses by age 6 months	5727 (98%)	6259 (96%)	2·00 (0·98 to 4·09)	1·85 (0·92 to 3·70)
Infant received four polio vaccine doses by age 6 months	423 (7%)	888 (14%)	0·33 (0·11 to 0·99)	0·32 (0·11 to 0·94)
Infant received any pentavalent vaccine (diphtheria, pertussis, tetanus, hepatitis B, *Haemophilus influenzae* type b) dose by age 6 months	5508 (94%)	5928 (91%)	1·62 (0·70 to 3·77)	1·59 (0·68 to 3·74)
Infant received three pentavalent vaccine (diphtheria, pertussis, tetanus, hepatitis B, *Haemophilus influenzae* type b) doses by age 6 months	3573 (61%)	3379 (52%)	1·47 (0·66 to 3·28)	1·45 (0·65 to 3·23)
Infants with 6 months of breastfeeding data	5222	5824		
Infant exclusively breastfed to age 6 months	1047 (20%)	458 (8%)	2·42 (1·48 to 3·96)	2·44 (1·49 to 3·99)
Breastfeeding initiated within 1 h of birth	4414 (85%)	4248 (73%)	1·77 (0·77 to 4·05)	1·73 (0·76 to 3·97)
Time to first breastfeed (min)	82 (267)‡	128 (362)‡	–39·8 (–74·7 to –4·9)§	–37·7 (–67·5 to –7·9)§
Use of prelacteal feeds	362 (7%)	755 (13%)	0·50 (0·33 to 0·77)	0·51 (0·33 to 0·78)
Age at starting porridge (months)	5·0 (1·14)‡	4·8 (1·21)‡	0·26 (0·04 to 0·48)§	0·24 (0·03 to 0·46)§
Any breastfeeding problem	103 (2%)	83 (1%)	1·30 (0·78 to 2·16)	1·38 (0·83 to 2·30)
Seeking help for breastfeeding problem	37 (39%)	35 (48%)	0·65 (0·28 to 1·52)	0·62 (0·24 to 1·59)

Data are number (%) or adjusted odds ratio (95% CI), unless otherwise indicated. Model 1 data were adjusted for clustering and stratification by the other intervention. Model 2 data: as model 1, with adjustment for socioeconomic quintile and parity. Women's group analyses were adjusted for cluster-level baseline values due to imbalance at baseline. Volunteer peer counselling analyses were not adjusted for baseline values as the intervention had already started. Denominators used for calculating percentages do not include missing data, which differ for each variable. p values for secondary outcomes were not corrected for multiple testing, and exact significance levels should be interpreted with caution. Care practices and care-seeking behaviour were secondary outcomes for the peer counselling intervention, but antenatal care, health facility delivery, type of birth attendant, and postnatal care were not directly prespecified and were analysed post hoc. *A woman received two or three doses of tetanus toxoid vaccine during her current pregnancy or a complete course of five immunisations during her lifetime. †Only data for study period for women's group intervention used because models 1 and 2 failed to run with the data for the study period for the volunteer peer counselling as a result of numerical overflow. ‡Mean (SD). §Linear regression coefficients.

Table 4: Secondary outcomes in intervention and control clusters for the two interventions (women's groups and volunteer peer counselling)

(table 3). This effect was not significant after adjustment for socioeconomic quintile and parity, and the effect size was not increased when the first year was excluded (table 3). Stratified analysis showed large effects on IMR in areas without women's groups (adjusted OR 0·64, 0·48–0·85), but no effect in areas with women's groups. k for IMR was 0·26 for all clusters and 0·14 for control clusters, corresponding with intracluster correlation coefficients of 0·00385 and 0·00120, respectively. Improvements were also noted in exclusive breastfeeding rates (tables 3 and 4); however, stratified analysis showed that these effects were not significant in areas without women's groups. k for exclusive breastfeeding was 0·91

for all clusters and 0·62 for control clusters only (intracluster correlation coefficients 0·14703 and 0·04263, respectively).

Analysis of secondary outcomes for the peer counselling intervention, after adjustment for socioeconomic quintile and parity, showed much lower use of prelacteal feeds, shorter mean time to first breastfeed, and higher mean age of starting porridge (the main complimentary feed; table 4). Immunisation rates were already high in all study areas at inception, and though coverage was generally higher in peer counselling areas during the study, only the effect on BCG was significant (table 4), and the number of infants fully vaccinated for

poliomyelitis was lower. Reported breastfeeding problems and associated care-seeking did not differ between control and intervention groups, but reported infant cough, fever, or diarrhoea was 42% lower in intervention areas (table 4).

No differences were noted in use of family planning, or other antenatal, delivery, and postnatal care-seeking (table 4). Uptake of HIV testing was much higher in all areas than it was at inception, but there was no difference between volunteer peer counselling and control areas during the study (table 4).

The presence of both interventions in a cluster improved coverage, with 2192 (57%) of 3874 women with available attendance data having ever attended a women's group by 1 month post partum, compared with 1975 (50%) of 3941 in clusters with women's group only. 2552 (63%) of 4055 women with available visit data had ever been visited by a peer counsellor in areas with both interventions, compared with 1895 (47%) of 4057 in areas with only volunteer peer counselling. Despite this, the effects on mortality rates were lower than in areas with one intervention.

Comparisons were made between control areas and the three intervention groups (table 3). Striking effects were noted on MMR with women's groups only, and on IMR with volunteer peer counselling only in years 1–3. Table 2 shows that IMR remained the lowest in peer counselling only areas throughout the study. Outcomes in years 2 and 3 showed striking effects on all mortality rates in areas with women's group intervention only (table 3). With the exception of MMR, adjusted ORs in areas with both interventions were near to 1·00 (table 3). All interaction effects were significant, except for MMR and NMR for model 2, years 1–3, though these treatment group effects showed a similar pattern (table 3). Treatment group analysis of EBF showed much higher rates in double intervention areas than in control areas, and non-significant effects in areas with either intervention alone (table 3). This pattern was the same as at inception, before the women's groups had started, and could not have been due to interaction (table 1).

Significant interactions were not noted for secondary outcomes, though treatment group analysis showed larger effects in areas with both interventions. Adjusted (for clustering, stratification, socioeconomic quintile, parity, and baseline values) ORs for skilled birth attendance were 1·36 (0·89–2·06) for areas with both interventions, 1·21 (0·80–1·83) for women's group only, and 1·10 (0·72–1·67) for volunteer peer counselling only.

The total economic cost of the women's group intervention was $698459. The cost of the volunteer peer counselling intervention was $263544. In years 2–3, 48·4 maternal deaths and 157·5 infant deaths were averted by the women's group intervention. In years 1–3, 258·5 infant deaths were averted by the volunteer peer counselling intervention. The cost of the women's groups was $114 per YLL averted (infant and maternal deaths),

and was of similar magnitude to other studies.[4,5] The average cost of volunteer peer counselling was $33 per YLL averted.

The mean costs per year were $16·6 per infant (women's group), $6·3 per infant (volunteer peer counselling), and $5·6 per woman of childbearing age (women's group). Health service strengthening added $1·6 and monitoring and assessment $5·4 per woman of childbearing age. $601019 (86%) of the cost of the women's group and $205446 (78%) of the cost of the volunteer peer counselling group were for implementation.

Discussion

Our results suggest that, in rural Malawi, a women's group intervention mobilising communities for improved maternal and child health reduced MMR (74%), PMR (33%), NMR (41%), and IMR (28%) in years 2 and 3, in adjusted, stratified models in areas without a peer counselling intervention, but had no effects in areas with peer counselling. In areas without women's groups, where volunteer peer counsellors advised mothers about feeding and infant care, IMR fell by 36% (table 3), and overall infant morbidity by 42% (table 4). EBF rates increased more than two times, but after stratification the effect was only significant in areas with women's group intervention. Both interventions were highly cost effective, averting 1 YLL for less than the per head gross domestic product of Malawi.[33] Despite the lower than expected coverage and attendance, the effect of both interventions was impressive. Increasing coverage would have increased costs, making the interventions difficult

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Panel 2: Research in context

Systematic review

We searched PubMed and the Cochrane Library for relevant papers published from Jan 1, 2000, to Dec 31, 2011. We also searched key internet sites, including those of UNICEF, WHO, and the World Bank. Search terms were "community participation", "community mobilisation", "newborn mortality", "maternal mortality", "breastfeeding", and "peer counsellor". Searches were restricted to reports published in English. We assessed the quality of the evidence by critically reviewing the methods used in each study and focusing on randomised controlled trials.

Interpretation

The results from our study add to existing evidence because we report, as far as we know, the first population-based trial of a community action cycle for birth outcomes in an African country led by a participatory women's group, and the first trial of the effect of a volunteer peer counselling intervention on infant mortality rates. We compared our results with those of other studies with similar methods that have been done mainly in south Asian countries. Our findings allow us to draw firmer conclusions that women's groups with a community action cycle are a generalisable method for improving survival of newborn babies and mothers in poor rural communities. The work with volunteer counsellors takes forward the evidence that community peer education on infant care and feeding not only improves feeding behaviours but also might have a direct effect on infant mortality. Demand-side interventions are a crucial, yet neglected, component of strategies to improve maternal and child health and to achieve the Millennium Development Goals.

to implement on a larger scale. Secondary outcomes suggested changes toward improved care and care-seeking behaviour, though few indicators showed conclusive effects. Reductions in morbidity and mortality rates might have been due to small changes in many behaviours (panel 2).[34]

Our study had some limitations. Although surveillance of births and deaths was prospective and quality controlled, errors probably arose in ascertainment and classification of outcomes. Delays in implementation of activities by the women's groups in year 1 diluted the effects noted overall. Breastfeeding status was ascertained by use of self-report at two timepoints, raising the possibility of misclassification. The low exclusive breastfeeding proportion (14%) compared with Malawi Demographic and Health Survey estimates (28%),[30] suggests it was not over-reported. Losses to follow-up for breastfeeding outcomes are largely explained by the exclusion of incomplete or delayed dietary recall data. Because women knew their intervention allocation, behavioural answers were open to best behaviour bias. However, corresponding reductions in mortality outcomes suggest that changes in behaviour were real.

The factorial design introduced the possibility of interaction between the two interventions, confirmed by the analyses. The greater effect on mortality rates seen in single intervention areas than in those with both was noteworthy. One explanation might be negative synergy, where both interventions might have been saving the same lives, thus restricting the potential for combined effect. Another explanation is that combined delivery led to reduced efficiency, but this was not supported by improved coverage in areas with both interventions. Furthermore, outcomes such as EBF and skilled birth attendance were greater in areas with both interventions. For EBF, this apparent interaction existed at inception, before the women's group intervention started, suggesting that areas with both interventions differed in ways that were not compensated for by the adjusted analyses. They were either more urbanised, making interventions less easy to implement, or more remote from health facilities. They had higher IMR, NMR, and PMR at inception, but improved more than areas with no intervention during the study period (table 2).

Our results, though complicated by the factorial design and baseline imbalances after randomisation, confirm the findings from women's group trials in south Asia that reductions in mortality rates result from mobilisation of women and communities.[4,5] Of particular note is the effect on MMR, also noted in the Makwanpur trial,[4] but in this case a specified primary outcome. Previous trials of breastfeeding counselling showed variable effects in sub-Saharan Africa and elsewhere.[7,10,20] The contribution of improvements in feeding to infant survival in rural Malawi is plausible, but difficult to ascertain in this study. We did not see changes in individual home-care practices or uptake of routine primary care interventions, although 22 of 26 process variables were better in areas with volunteer peer counsellors. Infant morbidity rate from cough, fever, and diarrhoea was lower in these areas, and better recognition of illness and timely care-seeking might have contributed to a reduction in IMR.

Our study is the first trial of women's groups and volunteer peer counsellors in a rural African population and showed substantial effect on MMR, NMR, and IMR. The interventions were uncomplicated and inexpensive, and could achieve further savings at scale. Counsellors were supervised through the government public health system, and women's groups linked to government health surveillance assistants during strategy implementation, so both could be scaled up and sustained through these systems. Slow progress towards Millennium Development Goal 4 in Africa, and a lack of community trials with population mortality rates as outcomes, means that women's groups and peer counsellors deserve serious policy consideration for scale-up.

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