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Effect of home-based childcare on childhood mortality in rural Maharashtra, India: a cluster randomised controlled trial

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ABSTRACT

Background Melghat, an impoverished rural area in Maharashtra state, India; has scarce hospital services and low health-seeking behaviour. At baseline (2004) the under-five mortality rate (U5MR) (number of deaths in children aged 0–5 years/1000 live births) was 147.21 and infant mortality rate (IMR) (number of deaths of infants aged under 1 year/1000 live births) was 106.6 per 1000 live births. We aimed at reducing mortality rates through home-based child care (HBCC) using village health workers (VHWs).

Methods A cluster-randomised control trial was conducted in 34 randomly assigned clusters/villages of Melghat, Maharashtra state, between 2004 and 2009. Participants included all under-five children and their parents. Interventions delivered through VHWs were patient–public involvement, newborn care, disease management and behaviour change communications. Primary outcome indicators were U5MR and IMR. Secondary outcome indicators were neonatal mortality rate (NMR) (number of neonatal deaths aged 0–28 days/1000 live births) and perinatal mortality rate (PMR) (number of stillbirths and early neonatal deaths/1000 total births). Analysis was by intention-to-treat at the individual level. This trial was extended to a service phase (2010–2015) in both arms and a government replication phase (2016–2019) only for the intervention clusters/areas (IA).

Findings There were 18 control areas/clusters (CA) allocated and analysed with 4426 individuals, and 16 of 18 allocated IA, analysed with 3230 individuals. The IMR and U5MR in IA were reduced from 106.60 and 147.21 to 32.75 and 50.38 (reduction by 69.28% and 65.78%, respectively) compared with increases in CA from 67.67 and 105.3 to 86.83 and 122.8, respectively, from baseline to end of intervention. NMR and PMR in IA showed reductions from 50.76 to 22.67 (by 55.34%) and from 75.06 to 24.94 (by 66.77%) respectively. These gains extended to villages in the service and replication phases.

Interpretation This socio-culturally contextualised model for HBCC through VHWs backed up with institutional support is effective for significant reduction of U5MR, IMR and NMR in impoverished rural areas. This reduction was maintained in the study area during the service phase, indicating feasibility of implementation in large-scale public health programmes. Replicability of the model was demonstrated by a linear decline in all the mortality rates in 20 new villages during the government phase.

Trial registration number NCT02473796.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ A Cochrane review of integrated community case management programmes revealed scarcity of effective, replicable, scientifically sound, community health worker driven, intervention model in the rural tribal community of India and developing countries for reducing very high under-five mortality rate (U5MR) and infant mortality rate (IMR).

WHAT THIS STUDY ADDS

⇒ This cluster randomised controlled trial with robust study design, sound scientific base, using an integrated approach of home-based newborn care, post-neonatal infectious disease management, antenatal care and behaviour change communication in the intervention arm had a significant impact on U5MR, IMR, neonatal mortality rate and perinatal mortality rate in an impoverished area that was sustained for 10 years following the trial, compared with the standard of care clusters.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Government policies can be framed for wider, long-term and sustainable replication of this community-based childcare model via community health workers for reducing U5MR and IMR in rural, difficult to access, impoverished areas of world with scarcity of health services and low health-seeking behaviour.

INTRODUCTION

Globally it has been estimated that there were 5.2 million under-5 years childhood deaths in 2019[1] of which 20% occurred in India.[2] In India in 2004, the mortality rates/1000 live births were U5MR (number of deaths

in children aged 0–5 years/1000 live births): 76,[1] IMR (number of deaths of infants aged under 1 year/1000 live births): 58[1] and NMR (number of neonatal deaths aged 0–28 days/1000 live births): 38.8[2] and NMR in 2001 was 37.9.[3] In contrast the IMR for industrialised countries was 5.0 in 2005.[4] Infant mortality remains an important measure of social well-being. While diarrhoea, pneumonia, malaria and under nutrition are common preventable causes of post-neonatal deaths in rural India, the major reason for these high rates are persistent difficulties in access to treatment and in navigation of the referral pathways.[1 5] Even after accessing health facilities, the quality of care in most rural areas in low-income and middle-income countries (LMICs) is poor.[6] Despite the development of the WHO guidelines for care at first level facilities and hospitals,[7] most countries in LMICs, do not have well-functioning health systems that reach rural areas where mortality is highest.[8] The cost of even outpatient care can push marginalised families into poverty, since 'free care' is rarely available.[9] Health facilities alone are ineffective at averting a large proportion of childhood deaths in rural areas.[10] Quality neonatal care is not available to most neonates in LMICs because hospitals are inaccessible and costly.[11] A combination of community outreach and health system strengthening would be necessary to reduce child deaths in rural India.[12]

Though the Indian U5MR and NMR have declined between 2000 and 2015 (U5MR=46.6, NMR=27),[13] there are remarkable disparities between rural and urban areas, between poorer and richer districts.[14] We found that IMR in India reduced from around 80 to 34 per 1000 live births at the national level from 1990 to 2016.[15] In 2004, just prior to start of the study, the rural population in India constituted 71.1% of Indian population and the U5MR varied between 8 and 131.5, while NMR varied between 3.8 and 84, in New Delhi and Odisha (tribal dominated state), respectively.[16] HBNC interventions have been shown to prevent 30%–60% of newborn deaths in high-mortality settings,[17] and the WHO recommends community-based preventive and curative care for high risk and poor populations by CHWs supported by the health system with focused training.[18 19]

We present results of a 15 years HBCC study in a rural area of India that started as a cluster randomised control trial (cRCT) (2004–2010), had a service phase (2011–2015) and a replication phase (2016–2019).

METHODS

Study design and participants

We conducted a community based, cRCT of HBCC, in rural Melghat, Maharashtra, India. Since interventions were administered by VHWs at the village level, a village was defined as a cluster unit to minimise treatment contamination between intervention and control groups.[20]

The study area, Melghat is spread over 4000 km^2, in 320 villages, with a population of 280 000. A baseline survey revealed widespread faulty child-rearing practices, large family sizes, treatment by traditional faith healers and low health-seeking behaviour.[21] The government healthcare system consists of: (a) subcentre staffed with one paramedical worker per 4–5 villages, (b) a primary health centre (PHC) for 30 villages manned by a physician. (The physician to population ratio was >1:10 000). The average distance of PHCs from villages was 19 km. Every village participated in the Integrated Child Development Scheme (ICDS) providing food supplementation, immunisation, deworming and oral rehydration solution (ORS) to all under-fives.[22]

Hypothesis

Cluster-level objectives were to reduce the U5MR and IMR from 147.21 to 106.60/1000 live births, respectively, by at least 35% in the usual resident population of 14 120 in 16 villages of Melghat over 5 years.

Patient and public involvement

Aim of patient and public involvement in the study

Our survey-based analysis (year 2002–2003) of very high U5MR in Melghat revealed that the existing policies, healthcare system and government interventions were malaligned to the community's needs and socio-cultural practices, resulting in low healthcare seeking behaviour. A survey was done to understand the underlying causes of the very high U5MR in Melghat. Hence, we included community participation and patient and public involvement (PPI) as a critical part of the intervention to reduce U5MR and IMR.

Description of the methods used for PPI

The public was first involved through gramsabha/community meetings with >60% of adults in the villages in attendance. We obtained informed written consent from the community members present at these meetings, that were designed to explain the aims and methods to be used in the research study. The principal investigator and the study team conducted these meetings to understand the community's needs, their demand for health services, as well as acceptable and approachable methods for service delivery. Our team conducted door-to-door surveys to understand the health problems, priorities, along with the most important and common causes of deaths. After this, we discovered that the community wanted easily accessible, free, culturally acceptable services from a person who knew the local language and traditions and who respected the community and understood its problems. They identified HBCC as the most urgent need. Thus the experience, preferences and health needs of community members were used to design the methodology of the study. We worked in close association with the traditional health system (ie, birth attendants, community leaders and traditional faith healers).

We conducted all our interventions in the community in accordance with their requests, respecting their culture, traditional practices, language and socioeconomic conditions. The women showed reluctance for hospital-based delivery and newborn care. They preferred delivery by

traditional birth attendants (TBAs). Hence, the HBCC programme was implemented by trained tribal, socially sensitive, female VHWs who provided culturally acceptable good quality care and BCC in the local dialect. Our trained TBAs provided safe and hygienic home deliveries.

Subsequently informed written consent was obtained from parents of all study children who participated in the trial, prior to any study related interventions.

Recruitment in the study

Local tribal VHWs recruited study participants from the community in which they lived.

Outcome selection by PPI

After intensive community meetings and surveys, we realised that the high under-five mortality was a health priority of the community. Hence, we kept U5MR and IMR as the primary outcome measures.

The extent to which PPI influenced the study overall

With the help of PPI, we could plan culturally acceptable, easily accessible and affordable interventions following community needs. Community participation played a crucial role in understanding the problems and appropriate solutions to solve them. PPI also helped to sustain our study for 17 years. The government assisted in replication of our PPI model in the 20 new villages.

PPI involvement in dissemination of the study results to participants and linked communities

The community selected VHWs, TBAs and key persons in the villages to implement our interventions and share results during gramsabhas once every 4 months and to mobilise the community for our programme.

Inclusion and exclusion criteria

The participants were under-five children, their parents and pregnant women who were permanent residents of 34 study villages in Melghat. Children migrating with parents and leaving the study area for more than 6 months were considered as having migrated permanently, and were excluded from the analyses.

Randomisation and masking

Dharni block of Melghat, consisting of 160 villages, was divided into five zones. The sample size required 36 villages (clusters). Eight villages from each zone were randomly selected and two more villages from neighbouring Chikhaldara block were randomly added using a lottery method by a member of the study community in order to generalise the results beyond our block and to understand the impact on different blocks, with a different administrative structure. Out of these 42 clusters, 36 clusters were selected based on their willingness to participate. The clusters were block stratified according to their distances from the base hospital (<5 km, 5–25 km and >25 km). A random allocation sequence assigned clusters to the intervention arm (IA) and control arm (CA) by an external person. The allocation was masked, concealed and based on clusters and not on individuals. Participants were blinded after assignment to interventions. Infants and children in both the CA and IA received standard care following Government of India guidelines at its village, PHC and hospitals. In addition, IA received supervised HBCC assigned by investigators.

The de-facto method[23] was used for calculation of mortality rates. All births and deaths actually occurring in the clusters or hospitals from IA and CA were included. A complete enumeration methodology was used to include all under-fives and pregnant women in clusters. The VHWs collected the vital events in the two arms by prospective door-to-door surveys of the households within 24 hours of the event. They filled the death and birth forms, confirmed by the parents or near relatives in the absence of parents, who signed the forms. Each vital event was confirmed by a data collection supervisor (within 15 days) and a retrospective surveyor (within 6 months) by door-to-door visits to the household. All vital events were further confirmed by a sarpanch (elected village head) and a police patil (government appointed village key person) within 15 days of the event. We also collected vital data from government health and the ICDS records, to supplement any missing vital data. Verbal autopsies were conducted to by data collection supervisors and VHWs. Deaths were verified by the, sarpanch and police patil. While implementation could not be masked due to the visible nature of the intervention, boundaries to limit communication between the two arms were closely monitored. Patients living in the CA were not treated in the IA during the research phase.

After obtaining community consent to do the trial, approval from the MAHAN independent ethical committee was obtained. Informed written consent was obtained from the parents of all infants and children who participated in the study. The study was registered with ClinicalTrials.gov.

Study phases

Baseline phase: January 2004–December 2004

Microplanning

Participatory community meetings were held at the start of the study (online supplemental annexure-1) that provided an introduction of the study to the community, invited their collaboration, identified resources for child health and finally resulted in obtaining written community consent from village elders at both IA and CA. Interventions were based on inputs from qualitative focus group discussions and surveys regarding high-risk behaviours for child mortality, potential barriers to implementation and taking into consideration factors affecting behaviour change. The study team activities in CA were: (a) consent of villagers, (b) census, (c) village mapping at the beginning of the research phase, (d) collection of vital statistics, for example, death, birth, verbal autopsies to define the causes of deaths during the entire research and service phases and (e) anthropometry at the baseline and at the end of the research phase (online

supplemental annexure-1). Consent was needed in the control area as we were collecting (a) census data, (b) personal vital data of birth, deaths and cause of deaths and (c) anthropometry of children.

Selection and trainings of field workers

VHWs, data collection supervisors, medical supervisor, BCC supervisors, programme manager, retrospective surveyors and TBAs as external stakeholders (online supplemental annexure-2) formed the field team in IA. External stakeholders were from the clusters but were not paid workers of MAHAN trust. They assisted our HBCC programme to achieve its objectives. VHWs, data collection supervisors, programme manager and retrospective surveyors formed the field team in CA. The VHWs were local, tribal, married, semiliterate, socially sensitive women selected through community meetings. VHW's received monthly trainings, details of which are provided in online supplemental annexure-2.

Data collection

VHWs conducted a census and baseline survey regarding births, under-five deaths, maternal and child healthcare practices and demographic information in January 2004. They were supervised by data collection supervisors. Similar information was verified from government agencies, parents, cluster heads and independent retrospective surveyors to detect any missed events. Verbal autopsies of all under-five deaths were conducted by supervisors and VHWs, and reviewed by two physicians using standard methods.[24] A third physician adjudicated discrepancies.

Baseline data verification was done by the Rajmata Jijau Mother and Child Health and Nutrition Mission (RJMCHNM) of the state government and UNICEF.[25] Data monitoring and safety was performed by the State Tribal Department. Finally, a third-party evaluation was conducted by the Government Medical College, Aurangabad, India.

In the implementation arm of the study, the population size was 13 150 during the implementation/research phase, 10 932 during the service phase and 29 335 during the replication phase. The number of VHWs in the implementation arm were 24 during the research phase, 20 during the service phase and 42 during the replication phase.

Intervention phase: January 2005–December 2009

Interventions were delivered by VHWs, implemented in a sequential phase-wise manner and continued subsequently. All VHWs were trained monthly in the first year with refresher trainings 2 monthly until the end of the study (online supplemental annexure-2).

Subphase 1: January 2005–December 2009

Community-based management of acute respiratory infections, diarrhoeal illness and malaria, in post-neonatal under-fives was done using co-trimoxazole (for pneumonia), ORS (for diarrhoea) and Furoxone/norfloxacin (for unresponsive diarrhoea), metronidazole (for dysentery) and chloroquine syrup (for malaria) respectively, as per guidelines (online supplemental annexure-3).

Subphase 2: November 2006–December 2009

Implementation of antenatal, natal and newborn care was added to the above post-neonatal management (online supplemental annexure-4). Briefly, VHW's conducted three home visits and examined each pregnant mother, encouraged her to avail facility care and provided iron and calcium supplements. Tetanus immunisation was given by the auxiliary nurse midwife. Pregnancy-induced hypertension and pedal oedema were monitored and paid special attention. Clean and safe home deliveries[26 27] were conducted by trained TBAs assisted by trained VHWs. High-risk pregnant women were referred to hospitals.[28–30] At birth the VHWs recorded neonatal observations and the birth weight, kept the baby warm, applied Gentian violet (1%) to the umbilical cord, administered 1 mg vitamin K_1 intramuscularly and initiated early breast feeding. Subsequently VHW's did 7 or 13 household visits to normal or high-risk newborn, respectively, within 28 days of birth and weekly thereafter. At subsequent household visits, breast feeding was observed, advise was given to mothers to keep babies warm and babies were observed for danger signs of illness and received care as outlined below. VHWs provided high-risk newborn care for low-birth weight and premature babies and for hypo–hyperthermia and breast-feeding problems. They maintained asepsis and provided referral if required. VHWs identified babies with prematurity defined as a gestational age at birth of <37 weeks.[31–35] Expected date of delivery (EDD) was calculated from last menstrual period. VHWs maintained an EDD calendar. Low birth weight was defined as a birth weight of ≤2500 g.[36] The weight was measured by VHWs and confirmed by medical supervisors using a salter or electronic weighing scale.

Subphase 3: May 2007–December 2009 online supplemental annexure-4

Birth asphyxia was managed by mouth–nose suction using an oral mucus sucker, tactile stimulation, Ambu bag and mask ventilation.[37]

Neonatal sepsis was diagnosed clinically[38 39] by the simultaneous presence of two of seven signs (poor sucking; weak cry; limp extremities; vomiting or abdominal distension; convulsions, altered consciousness; severe chest indrawing; umbilical infection) and babies were referred immediately to the hospital. When hospital referral was not accepted, syrup cotrimoxazole and intramuscular gentamicin were administered by the VHW following WHO guidelines.[40 41]

BCC was conducted for health, hygiene, infant and young child feeding, malnutrition, antenatal and newborn care, breast feeding, diarrhoea, malaria, pneumonia and growth.

We extended the intervention to only the intervention areas during the service phase and the replication phase.

Service phase: January 2010–December 2015

The healthcare delivery by VHWs was continued in the IA with supervision by supervisors. We continued data collection in CA and IA.

Replication phase: September 2016–August 2019 (Only for the IA)

The Government of Maharashtra (India) validated the replicability of interventions for reducing NMR, IMR and U5MR by randomly adding 20 new villages (population: 19 437) from Dharni block. The government adopted the same methods used in the service phase for these villages with our collaboration. An integrated accelerated approach of simultaneous implementation of all interventions was adopted following a 2-month training for VHW's and supervisors in the government villages. Due to a successful outcome of the trial, it was stopped after 31 August 2019. It was evaluated by measuring reduction in IMR, U5MR, NMR and perinatal mortality rate (PMR) (total number of stillbirths and early neonatal deaths per 1000 total births) from baseline to the end (figure 5). The tribal development department of government of Maharashtra appointed a committee from one of the medical schools for its evaluation.

Outcomes

The primary outcome measures are comparisons between IA and CA, at both individual and cluster levels, for IMR and U5MR at baseline (2004) and subsequent years. The secondary outcome measures are NMR and PMR.

Statistical analysis

Sample size was estimated to detect a reduction of at least 50% in U5MR in the IA. Preliminary data from Melghat in 2004 estimated the U5MR at 140/1000 live births. The intracluster correlation coefficient (ICC) for U5MR was assumed to be 0.01, and the average live births per cluster per year was 20, which resulted in a variance inflation factor or design effect of 1.19. Hence, to detect a desired mortality reduction of 50% in IA with 95% confidence and 80% power, a sample size of 359 live births was needed per arm, with 18 clusters per arm.

Participants fulfilling the inclusion criteria were recruited and observed in each year of the study periods. The data on cluster characteristics from control and intervention areas, defined on a nominal scale, were summarised in frequencies and percentages and compared using the Pearson's χ^2 test. Since the number of characteristics at the cluster level was large, an approach based on wealth quintiles was used to classify clusters into homogeneous subsets. The characteristics were dichotomised into 0 and 1 indicating absence or presence of the attribute, while distances (continuous) were retained in the same format. This mixed data set was subjected to principal component analysis (PCA) using the PCA mix function in the R-programming tool. A weighted index was obtained for each cluster referred to as the cluster-status index. On similar lines, the analysis was performed at the household level, based on household level characteristics, to generate a wealth index. Each index array was categorised into five quintiles forming five homogeneous subsets, with level (I) indicating a weaker cluster or household, while (V) indicated better placement. 'Weaker cluster' indicates a village with poor infrastructure. Similarly, a weaker household indicates a lack of essential facilities at the domestic level. 'Better placement' suggests villages with required infrastructure, and households with necessary amenities. Table 1 and online supplemental table 1S provide the cluster and household level factors determining their status.

To assess the change in the mortality rates in different age categories, the crude incidence rate ratios (cIRR) were obtained for primary and secondary outcomes, for each intervention year (2005–2009) with reference to the base year (2004), independently for each of the two arms. In this year-wise comparison, the distribution of cluster-status index was altered due to the varying number of live births and the household level wealth index within clusters across years. Therefore, in the individual-level analysis the incidence rate ratios for each outcome were adjusted for each year with respect to the base year using a log-binomial regression (the adjusted incidence rate ratio (aIRR)). The analysis was performed independently for the two arms. The convergence issue of log-binomial regression was not met for any of the outcomes.

The difference between crude and adjusted incidence rate-ratios between the two arms was obtained for each year along with 95% CIs.[42] The effect on mortality rates during the intervention and service and replication phases were assessed through the magnitude of these differences and the associated statistical significance.

To determine whether the effect of the intervention was uniform across clusters, a cluster level analysis was performed and ICCs were obtained for the primary outcomes.

All analyses were performed using R-3.4.3 (R-Core Team 2017), and statistical significance was tested at the 5% level. The statistician was masked to treatment groups while analysing the data. Interim analyses were not done.

Role of the funding source

Funding source: Stichting Geron, Caring Friends (MAHN 1) and Bajaj Holdings and Investment Limited (2242/BHIL).

The funding sources had no role in study design, data collection, analysis, interpretation, report writing and in the decision to submit the paper for publication.

We have included an author reflexivity statement as online supplemental material/appendix S1.

RESULTS

Out of 36 equally randomised clusters in two study arms, two clusters from the IA did not participate due

Table 1 Cluster characteristics in control and intervention areas

Characteristics	Control (N=18)	Intervention (N=16)	P value
Subcentres (no. (%))	14 (77.8)	5 (31.3)	**0.006**
Primary health centre (no. (%))	0	0	–
Distance from primary health centre (km) (mean (SD))	11.5 (9.9)	17.1 (12.7)	0.166
Distance from base hospital (km) (mean (SD))	31.1 (14.9)	30.7 (20.0)	0.958
Distance from subdistrict hospital (km) (mean (SD))	29.1 (14.1)	33.7 (16.1)	0.393
Village council (no. (%))	8 (44.4)	3 (18.8)	0.109
Emergency health facilities (no. (%))	8 (44.4)	3 (18.8)	0.109
ANM workers (no. (%))	9 (50.0)	5 (31.3)	0.268
ASHA workers (no. (%))	2 (11.1)	0	0.169
Anganwadi workers (no. (%))	17 (94.4)	15 (93.8)	0.999
Major source of water in the village (no. (%))			
Well	5 (27.8)	5 (33.3)	0.693
Hand pump	7 (38.9)	7 (46.7)	
Others*	6 (33.3)	3 (20.0)	
Road facility (no. (%))			
Tar	8 (44.4)	4 (25.0)	0.106
Dirt	7 (38.9)	12 (75.0)	
Government transport facility present (no. (%))	11 (61.1)	4 (25.0)	**0.034**
Private transport facility present (no. (%))	15 (83.3)	10 (62.5)	0.169
Mobile/telephone connectivity present (no. (%))	10 (55.6)	8 (50.0)	0.746
Anganwadi present (no. (%))	15 (83.3)	15 (93.8)	0.347

Bold p values indicate statistical significance.
*Tap, pond and river.
anganwadi worker, grassroot worker of the integrated child development scheme covering food supplementation to under-five children and preschool education; ANM, auxiliary nurse midwife trained for two academic sessions to conduct deliveries and minor ailments like oral rehydration solution for diarrhoea, deworming and routine immunisation; ASHA, Accredited Social Health Worker placed in every village who assist ANM's for management of deliveries and referral of high-risk mothers and children.

to non-cooperation of health workers. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram modified for cRCT is presented in figure 1. Out of 4426 total infants and children included in the CA, 2316 were live births and there were 378 deaths (163.21 deaths per 1000 live births), while in the IA, there were 3230 infants and children with 2299 live births and 267 deaths (116.13 deaths per 1000 live births). The male: female ratios were 1.018 and 1.058 in CA and IA, respectively. The cluster-level characteristics were compared between the two study groups (table 1). The number of subcentres (p=0.0064) and the presence of government transport facility (state government transport bus services) (p=0.0343) were significantly better in the CA.

The 34 clusters were classified into five levels (quintiles) based on the cluster-status index. The distribution of clusters in these levels was almost uniform (ie, seven in each level, except level 3 with six clusters). The household variables of under-five children, (online supplemental table 1S), were used to obtain a Wealth Index and thus classify subjects into quintiles, mirroring their economic status. The year-wise distribution of live births into five quintiles based on their cluster-status and wealth index and their comparison with the base year are given in table 2 for both the arms. The cluster-status index quintile distribution for the years 2008 and 2009 were significantly different from the base year ($p<0.05$) in the IA, while the Wealth Index distribution differed significantly from the base year for the years 2008 and 2009 in the CA and for 2009 in the IA. In the IA, the cluster status index distribution for 2008 and 2009 were significantly different compared with the baseline year, 2004. During 2008 and During, 2009, there were increased cases of cluster status I and status IV and V compared with the baseline year. Due to higher proportions in the extreme cluster levels, the difference was significant.

There was significantly higher proportion of subjects in wealth index level I in 2008 and 2009 compared with year 2004. In the IA, in 2009, the proportions increased in level I and decreased in levels II and III, resulting in significant differences.

Table 3 shows the IRR computed for different infant and under-five children categories across years in the two arms, and the per cent reduction between the two arms.

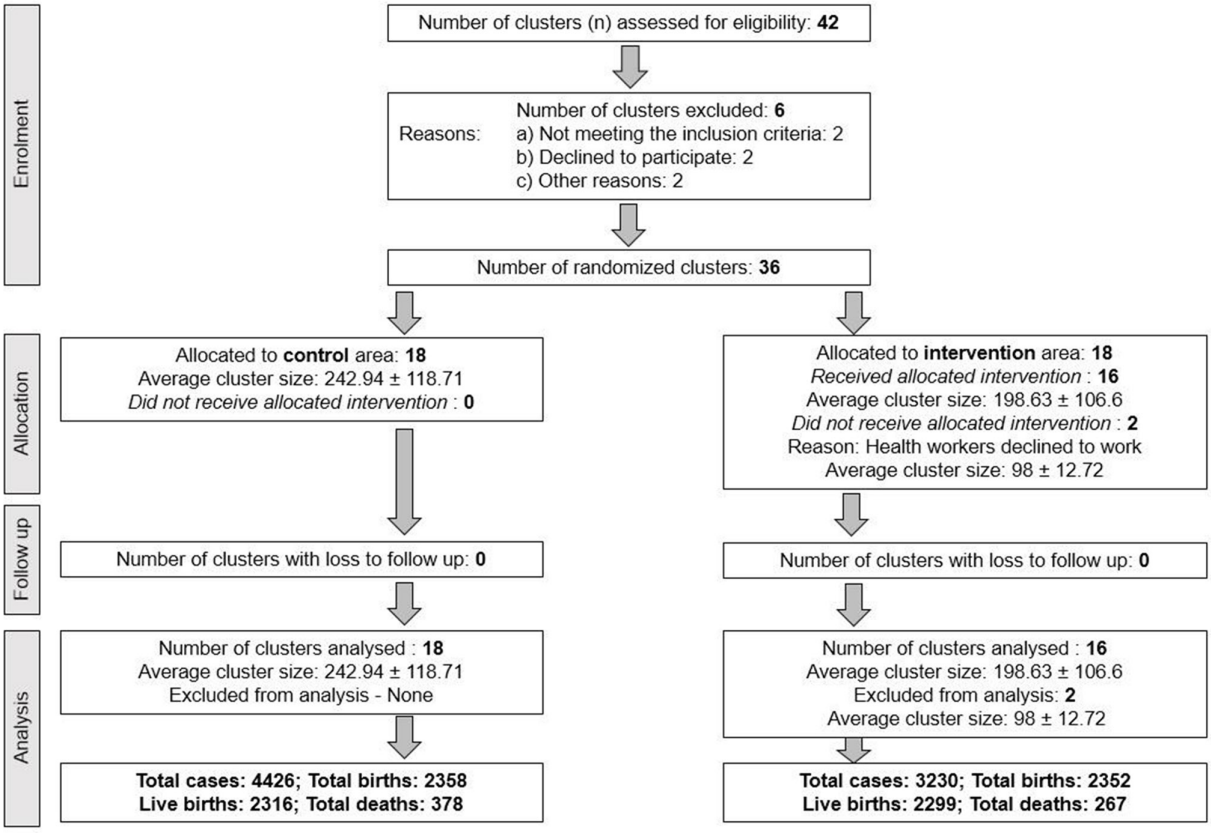

Figure 1 Cluster randomised control trial flow diagram.

In the CA, the IMR and U5MR for the period 2005–2009 were significantly higher than the baseline year, as indicated by cIRR >1. The differences in the distribution of cluster level and household level status in these years compared with the baseline year (table 2), were adjusted for and presented as aIRR (table 3). The effect of covariates on the crude rate ratios were marginal until the year 2007, but thereafter the reduction in the aIRR was noticeable (>10%) compared with their respective cIRR although the effects were statistically insignificant. The wealth index differentials primarily contributed to the difference in aIRRs for the years 2008–2009 (table 2).

In the IA clusters, for the IMR and U5MR, both IRRs were reduced for the each of the years 2005–2009 compared with the reference. The effects of covariates were noticeable as indicated by the change in IRRs (>10%) for the above years for the IMR. However, this covariate effect was not observed for the U5MR.

The IMR and U5MR in IA were reduced from 106.60 and 147.21 to 32.75 and 50.38 (reduction by 69.28% and 65.78%, respectively) compared with increases in CA from 67.67 and 105.26 to 86.83 and 122.75, respectively, from baseline to end of intervention. The >50% relative reduction in both IMR and U5MR in the IA were significantly different when comparing the crude rate ratios for CA and IA, for each of the years 2005–2009, culminating in a >70% reduction in both in 2009. The relative reduction in adjusted IRRs while not significant in the first year after introduction of the intervention for the IMR, were significantly reduced in each of the subsequent years for both IMR and U5MR with at least a sustained >50% relative reduction after 2007.

NMR in IA showed reductions from 50.76 to 22.67 (by 55.34%) and PMR from 75.06 to 24.94 (by 66.77%) respectively. The secondary outcomes on NMR and PMR are presented in online supplemental table 2. Consistently in the CA, except for the PMR in 2006, both rates were consistently higher in years subsequent to the baseline year (increased with an average of 28.5% during the research phase). In contrast, for the IA for most years there was a reduction in both parameters. This resulted in significant relative reductions in both the cIRR and aIRR in the IA compared with the CA that were consistently above 50% after 2007.

A cluster-level analysis was performed in the two arms independently, using ICCs. Table 4 shows IMR and U5MR along with ICCs at baseline year (2004) and at the end of study year (2009) for the two arms. In both the arms, ICCs for IMR and U5MR were higher at baseline compared with end of study period. This indicates that the between-cluster variability was higher at baseline, which declined at the end of the intervention period in both the arms. For infant mortality, in the IA, the per cent ICC change was 82.95% (95% CI 77.76% to 88.13%), which was significantly higher than that of CA (45.83%) (95% CI 24.52% to 67.13%). For the U5MR, in IA the reduction of ICC was 46.15% (95% CI 26.83% to 65.47%), which was better than CA 31.85% (95% CI 5.99% to 57.70%).

Table 2 Year wise categorisation of live born infant families based on cluster level infrastructure (cluster-status index) and economic status of household (wealth index) in two study areas

Year	Live births	Control area											
		Cluster-status index—quintiles (n (%))						Wealth index—quintiles (n (%))					
		I	II	III	IV	V	P value*	I	II	III	IV	V	P value*
2004	399	18 (4.5)	116 (29.1)	63 (15.8)	76 (19.1)	126 (31.6)	Base year	54 (13.5)	87 (21.8)	87 (21.8)	91 (22.8)	80 (20.1)	Base year
2005	398	11 (2.8)	100 (25.1)	78 (19.6)	84 (21.1)	125 (31.4)	0.301	56 (14.1)	86 (21.6)	84 (21.1)	87 (21.9)	85 (21.4)	0.987
2006	376	19 (5.1)	103 (27.4)	43 (11.4)	79 (21.0)	132 (35.1)	0.394	49 (13.0)	80 (21.3)	87 (23.1)	95 (25.3)	65 (17.3)	0.828
2007	335	18 (5.4)	84 (25.1)	49 (14.6)	60 (17.9)	124 (37.0)	0.523	52 (15.5)	80 (23.9)	65 (19.4)	77 (22.9)	61 (18.2)	0.795
2008	474	16 (3.4)	138 (29.1)	96 (20.3)	82 (17.3)	142 (29.9)	0.457	139 (29.3)	76 (16.0)	100 (21.1)	87 (18.4)	72 (15.2)	<0.001
2009	334	10 (2.9)	99 (29.6)	52 (15.6)	59 (17.7)	114 (34.1)	0.796	97 (29.0)	48 (14.4)	47 (14.1)	76 (22.8)	66 (19.8)	<0.001
Year	Live births	Intervention area											
		Cluster-status index—quintiles (n (%))						Wealth index—quintiles (n (%))					
		I	II	III	IV	V	P value**	I	II	III	IV	V	P value**
2004	394	95 (24.1)	51 (12.9)	57 (14.5)	107 (27.2)	84 (21.3)	Base year	86 (21.8)	93 (23.6)	75 (19.0)	57 (14.5)	83 (21.1)	Base year
2005	363	81 (22.3)	32 (8.8)	40 (11.0)	109 (30.0)	101 (27.8)	0.067	107 (29.5)	63 (17.4)	64 (17.6)	59 (16.3)	70 (19.3)	0.066
2006	406	109 (26.9)	42 (10.3)	37 (9.1)	115 (28.3)	103 (25.4)	0.087	96 (23.6)	80 (19.7)	76 (18.7)	67 (16.5)	87 (21.4)	0.689
2007	333	80 (24.0)	33 (9.9)	33 (9.9)	99 (29.7)	88 (26.4)	0.143	81 (24.3)	68 (20.4)	48 (14.4)	63 (18.9)	73 (21.9)	0.213
2008	406	110 (27.1)	36 (8.9)	38 (9.4)	125 (30.8)	97 (23.9)	0.047	109 (26.9)	79 (19.5)	65 (16.0)	66 (16.3)	87 (21.4)	0.273
2009	397	129 (32.5)	30 (7.6)	31 (7.8)	99 (24.9)	108 (27.2)	0.0002	109 (27.5)	62 (15.6)	62 (15.6)	60 (15.1)	104 (26.2)	0.013

Bold p values indicate statistical significance. Cluster-status index was derived based on characteristics listed in table 1, while wealth index was derived based on household level characteristics listed in online supplemental table 1S. The quintiles I–V indicate gradient towards improved cluster status or household economic status.
*Obtained using Pearson's χ^2 test between base year and subsequent years

Table 3 Comparison of mortality rates in control and intervention groups from 2004 to 2009 (primary outcomes)

		Control				Intervention				Absolute reduction in IRR between intervention and control arms	
				Incidence rate ratio (95% CI), p value				Incidence rate ratio (95% CI), p value		(95% CI), p value	
	Year	Deaths/ live births	Incidence rate/1000 live births	Crude (cIRR)	Adjusted (aIRR)*	Deaths/ live births	Incidence rate/1000 live births	Crude (cIRR)	Adjusted (aIRR)*	Crude	Adjusted
Infant mortality	2004	27/399	67.7	Ref.	Ref.	42/394	106.6	Ref.	Ref.	Ref.	Ref.
	2005	43/398	108.0	1.60 (0.99 to 2.58), 0.054	1.24 (0.80 to 1.94), 0.332	22/363	60.6	0.57 (0.34 to 0.95), 0.029	0.75 (0.48 to 1.17), 0.214	0.36 (0.18 to 0.72), 0.002	0.60 (0.32 to 1.13), 0.056
	2006	43/376	114.4	1.69 (1.04 to 2.74), 0.031	1.55 (1.03 to 2.38), 0.044	35/406	86.2	0.81 (0.52 to 1.27), 0.352	0.83 (0.54 to 1.26), 0.367	0.48 (0.24 to 0.93), 0.028	0.54 (0.29 to 0.97), 0.018
	2007	47/335	140.3	2.07 (1.29 to 3.33), 0.002	1.75 (1.16 to 2.68), 0.011	18/333	54.1	0.51 (0.29 to 0.88), 0.014	0.48 (0.27 to 0.82), 0.010	0.24 (0.12 to 0.51),<0.001	0.27 (0.14 to 0.55), <0.001
	2008	49/474	103.4	1.53 (0.96 to 2.44), 0.075	0.99 (0.64 to 1.56), 0.972	21/406	51.7	0.49 (0.29 to 0.82), 0.006	0.43 (0.25 to 0.72),<0.001	0.32 (0.16 to 0.64),<0.001	0.43 (0.22 to 0.87), 0.011
	2009	29/334	86.8	1.28 (0.75 to 2.18), 0.350	0.80 (0.49 to 1.31), 0.367	13/397	32.8	0.31 (0.16 to 0.57),<0.001	0.26 (0.13 to 0.48),<0.001	0.24 (0.10 to 0.55),<0.001	0.32 (0.14 to 0.74), <0.001
Under-five mortality	2004	42/399	105.3	Ref.	Ref.	58/394	147.2	Ref.	Ref.	Ref.	Ref.
	2005	55/398	138.2	1.31 (0.88 to 1.96), 0.183	1.26 (0.87 to 1.83), 0.218	31/363	85.4	0.58 (0.38 to 0.90), 0.013	0.58 (0.38 to 0.86), 0.011	0.44 (0.25 to 0.79), 0.006	0.46 (0.26 to 0.79), <0.001
	2006	65/376	172.9	1.64 (1.11 to 2.42), 0.011	1.57 (1.11 to 2.24), 0.010	44/406	108.4	0.74 (0.50 to 1.09), 0.124	0.76 (0.52 to 1.08), 0.136	0.45 (0.26 to 0.78),<0.001	0.48 (0.29 to 0.80), <0.001
	2007	60/335	179.1	1.70 (1.15 to 2.53), 0.007	1.64 (1.16 to 2.36), 0.012	29/333	87.1	0.59 (0.38 to 0.92), 0.019	0.59 (0.38 to 0.89), 0.013	0.35 (0.19 to 0.63),<0.001	0.36 (0.21 to 0.63), <0.001
	2008	62/474	130.8	1.24 (0.84 to 1.84), 0.276	1.06 (0.73 to 1.55), 0.759	30/406	73.9	0.50 (0.32 to 0.78), 0.002	0.51 (0.33 to 0.76),<0.001	0.40 (0.22 to 0.73),<0.001	0.48 (0.27 to 0.84), <0.001
	2009	41/334	122.8	1.17 (0.76 to 1.79), 0.483	0.92 (0.62 to 1.37), 0.668	20/397	50.4	0.34 (0.21 to 0.57),<0.001	0.36 (0.21 to 0.57),<0.001	0.29 (0.15 to 0.56),<0.001	0.39 (0.21 to 0.74), <0.001

*Adjusted for sex, wealth index of individual and village/cluster status using log-binomial regression.
aIRR, adjusted IRR; cIRR, crude IRR; IRR, incidence rate ratio.

Table 4 Intracluster correlation coefficient for primary outcomes at baseline (2004) and end of intervention period (2009) in the two study groups

	Control				Intervention			
Parameters	IMR—2004	IMR—2009	U5MR—2004	U5MR—2009	IMR—2004	IMR—2009	U5MR—2004	U5MR—2009
Live births	399	334	399	334	394	397	394	397
Deaths	27	29	42	41	42	13	58	20
Mortality rate/1000 live births	67.7	86.8	105.3	122.8	106.6	32.8	147.2	50.4
ICC* (95% CI)	0.16 (0.05 to 0.28)	0.09 (0.01 to 0.18)	0.11 (0.02 to 0.21)	0.08 (0.00 to 0.16)	0.13 (0.03 to 0.23)	0.02 (0.00 to 0.06)	0.10 (0.02 to 0.19)	0.06 (0.00 to 0.12)
ICC (% change w.r.t 2004) (95% CI)	45.8% (24.5% to 67.1%)		31.9% (5.9% to 57.7%)		82.9% (77.8% to 88.1%)		46.2% (26.8% to 65.5%)	

*The intracluster correlation coefficient (ICC) for binary data.
IMR, infant mortality rate per 1000 live births; U5MR, under-five mortality rates per 1000 live births.

The reduction in primary outcomes in the IA during the intervention phase was maintained during the service phase for the next 6 years (figure 2). In the CA, there was a reduction in IMR and U5MR from 2014 onwards when the government started an HBNC intervention. The IRRs and relative reductions for primary outcomes for all phases are shown in figure 3. In the service period, the reductions for IMR and U5MR were consistently below

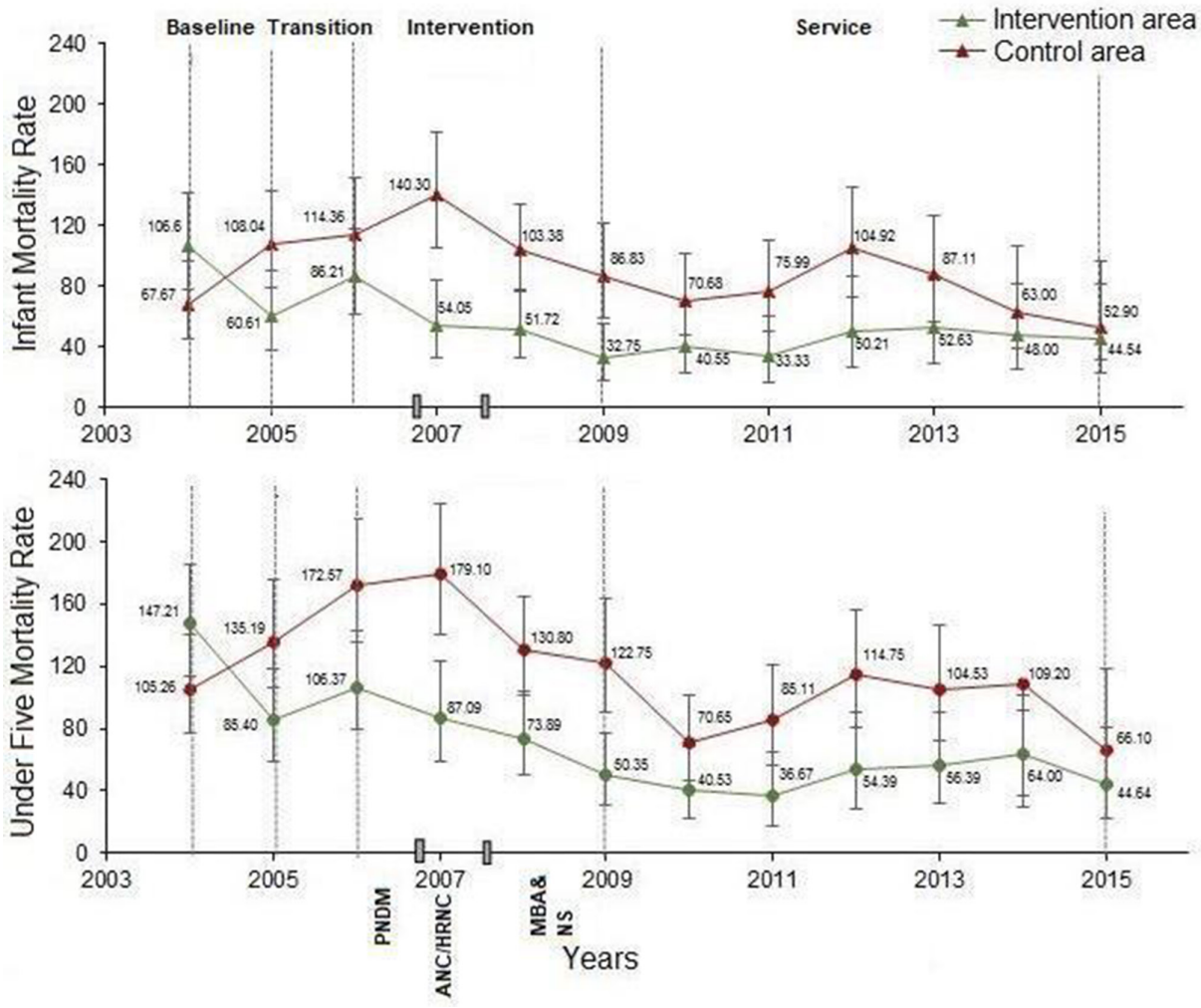

Figure 2 Line plots showing infant and under-five mortality rates in intervention and control areas in different phases across time. ANC, antenatal care; HRNC, high-risk newborn care; MBA, management of birth asphyxia; NS, neonatal sepsis; PNDM, post-natal disease management.

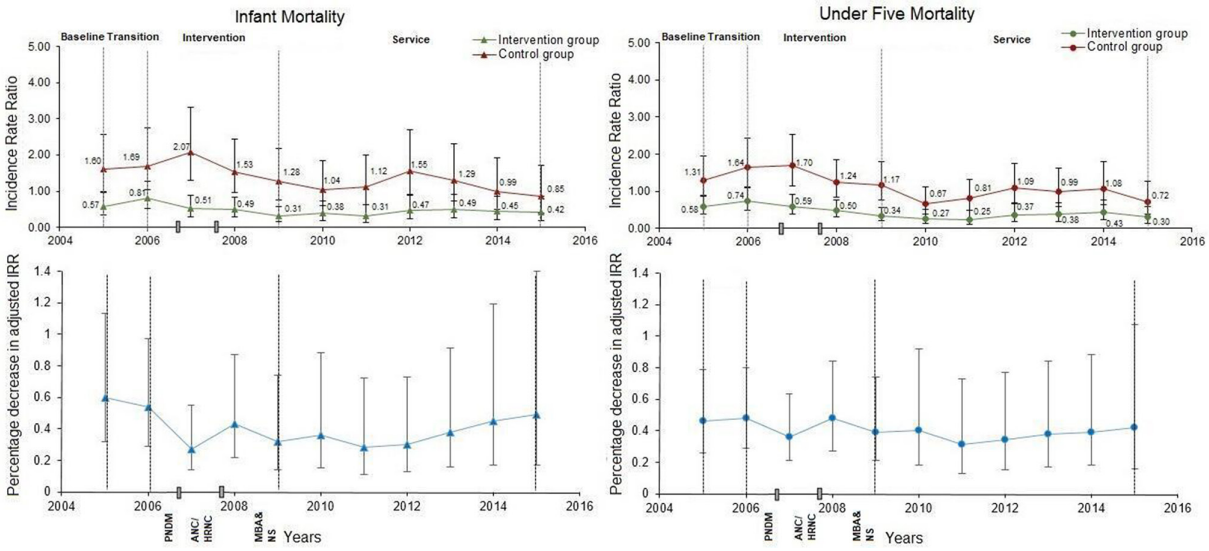

Figure 3 Line plots showing incidence rate ratio (IRR) and percentage decrease in IRR for infant and under-five mortalities in intervention and control areas in different phases across time. ANC, antenatal care; HRNC, high-risk newborn care; MBA, management of birth asphyxia; NS, neonatal sepsis; PNDM, post-natal disease management.

50% in the IA. Figure 4 shows the reduction in NMR and PMR in the IA, which was maintained during the service period.

During the replication phase, the baseline IMR and U5MR were reduced from 71.63and 85.96 to 28.50 and 45.13, respectively (figure 5). The NMR and PMR were reduced from 51.58 and 48.02 to 16.63 and 23.47, respectively, in 2 years. The reduction in IMR and NMR were statistically significant (p=0.022 and p=0.019, respectively). The reductions for U5MR and PMR were not significant (p=0.071 and p=0.1763, respectively). There were no harms or unintended effects in either group.

Results of PPI in the study. Focus group discussions with PPI improved community participation.

DISCUSSION

Our study shows a major reduction in primary and secondary outcomes in the IA compared with the CA at the end of the Research Phase. The integrated multipronged approach to HBCC resulted in significant reductions of U5MR and IMR in this high-mortality area. The reduction in intercluster correlation coefficients for both IMR and U5MR in the IA shows that variability of outcomes between clusters declined at the end of the intervention period. The per cent change for IMR in the IA was highest, indicating that the significant reduction in IMR was nearly consistent across all clusters by the end of study. This consistency was much higher than the CA. Similarly, the per cent reduction in ICC for U5MR in the IA was higher than that of CA, indicating uniform effectiveness of the intervention in the IA. The increased mortality rate in the control arm might have occurred due to changing priorities of senior district administrators (as a part of government policy)

After completion of the Research Phase, the reduction in mortality indicators was maintained during the Service Phase of the next 6 years in the IA, mimicking the situation of large-scale public health programmes. This indicates the feasibility of programme implementation at scale. The consistency of reduction in IMR and U5MR prompted the Government of Maharashtra in India to extend the methodology using government resources. The replicability of the model was then proven by the decline in all the mortality rates in the 20 new villages during the Replication Phase. This series of sequential studies has now been instrumental in driving subsequent governmental programmes.

We provide the following example directly related to this study, to empower the many non-governmental organisations and researchers in India and other countries with carefully collected, verified data of their own, to challenge data collected by less vigorous, transparent collection methods and work with local, state and national governments to effect policy changes.

This study has a significant impact on state government policies. (a) In Melghat, the MAHAN study, found an IMR of 96 per 1000 live births whereas the ICDS data recorded IMR at 31. The government and UNICEF verified this discrepancy by actual field visits and approved MAHAN findings. (b) The government could not ignore this more reliable MAHAN survey data as it generated more attention to combating U5MR in the state, especially in the poorer rural districts.[25] This lead to the formation of the 'RJMCHNM',[25] by the state government to work in collaboration with UNICEF for reduction of U5MR in Maharashtra. (c) Subsequently the Indian and Maharashtra State Government funded and replicated HBCC, in 33 villages of Melghat. (d) Before 2013, grassroot front line health workers were not allowed to use antibiotics for the treatment of post-neonatal childhood infections, which policy was changed by a state government committee, based in part on this study by MAHAN and another one by SEARCH.

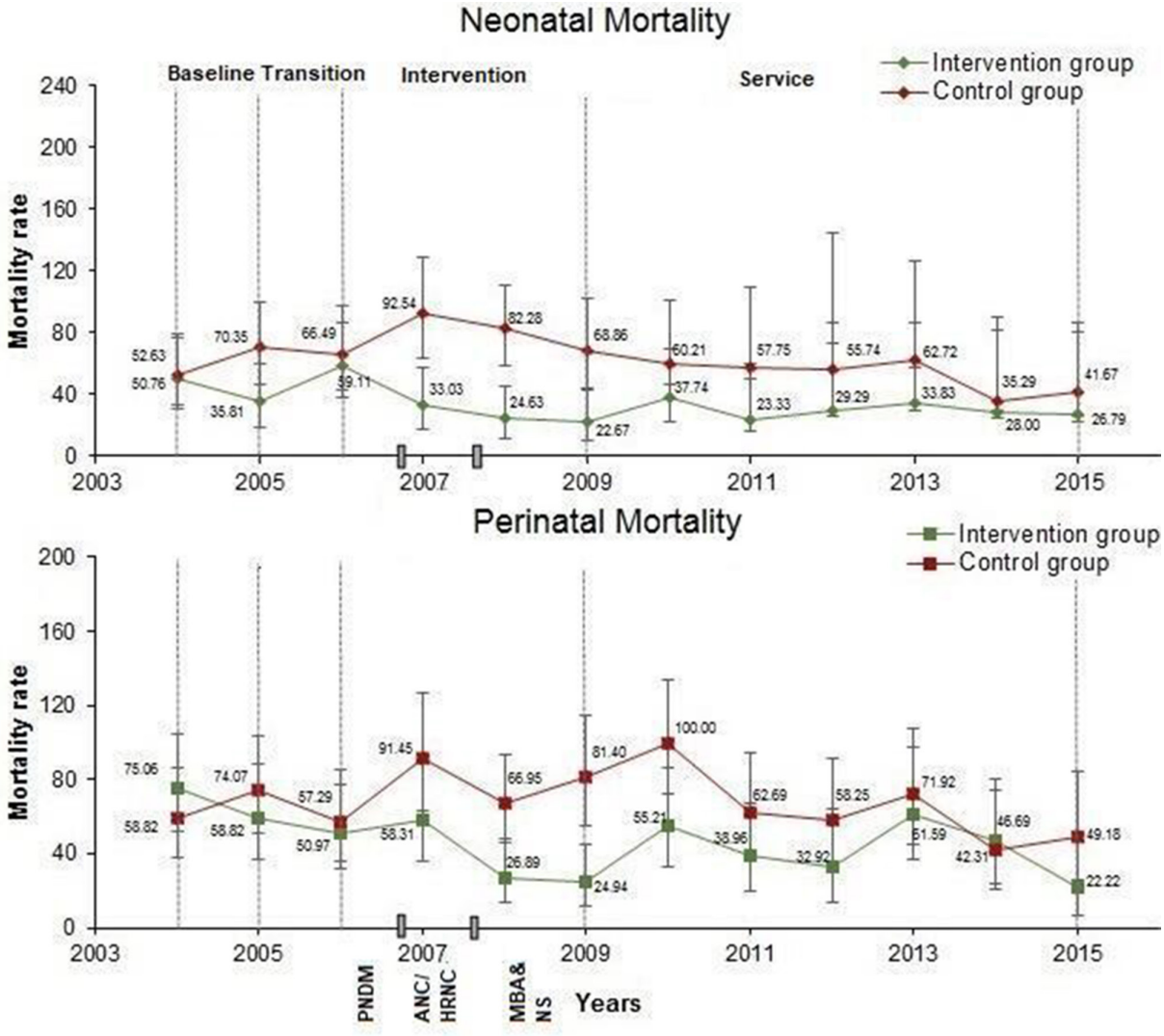

Figure 4 Line plots showing neonatal and perinatal mortality rates in intervention and control areas in different phases across time. ANC, antenatal care; HRNC, high-risk newborn care; MBA, management of birth asphyxia; NS, neonatal sepsis; PNDM, post-natal disease management.

The Government of India has empowered Accredited Social Health Worker for HBNC. However, this does not include management of neonatal sepsis or birth asphyxia, which is still a lacuna. Today, 33% of deliveries are home deliveries in rural India. The facilities for treatment of neonatal diseases are available at an average distance of 32 km from villages. Trauma due to transport of sick neonates in suboptimal conditions endanger lives, reflecting high NMR, as also proved by Mori *et al*.[43]

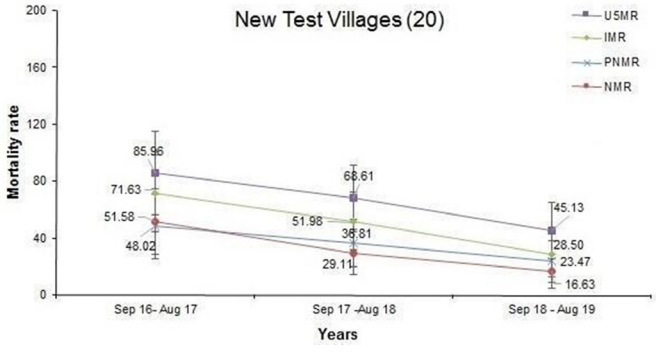

Figure 5 Line plots showing different mortality rates in a new set of test villages (government villages) exposed to intervention during the observation period 2016–2019. IMR, infant mortality rate; NMR, neonatal mortality rate; PNMR, perinatal mortality rate; U5MR, under-five mortality rates.

Our model is cost-effective as the average cost of treatment of each child including the research cost in this project was Indian National Rupees (Rs.) 592 (US$8) per year (unpublished data). In comparison the National Sample Survey Organisation revealed that the average total treatment expenditure per patient in rural and urban areas for outpatient management is Rs.509 (US$6.8) and Rs.639 (US$8.6), and hospitalisation Rs.16 956 (US$229.1) and Rs.26 455 (US$357.5) respectively. We plan to conduct a formal cost-effectiveness analysis.

Our study follows many of the principles of the census-based, impact-oriented approach.[44] These principles included the following:

1. We developed a cooperative partnership with local communities.
2. We worked together with the local community, identified and decided their heath priorities. We planned and implemented the programme as per need of the community.
3. Our interventions included regular planned home visits.
4. We regularly measured the impact of our interventions on health of the children until the age of 5 years.

Our study highlights the importance of community sensitisation, acceptance and participation. Our active and effective system of community-based VHWs made this programme successful.

Integrated management of childhood illnesses (IMCI)[45] has been implemented in India from 2003 onward for wider community coverage and impact. The original IMCI was primarily first level facility based, did not include care of the sick early newborn (the time when one in three child deaths occurs) and it did not emphasise HBNC. The newborn component was added to the integrated management of neonatal and childhood illnesses (IMNCI) programme in India in 2004.[46] Unfortunately, IMNCI has not been successful in India, despite having sound principles. It was the implementation of the programme that faltered not only in India but in many other countries. The reasons for the failure of the programme were: irregular funding, lack of refresher trainings of fieldworkers, poor supervision/mentorship,[47] irregular availability of key supplies, weak referral hospitals and frequent transfer of staff.[48] _ENREF_34 A 2017 review of community IMCI found only one RCT that showed a reduction of 8% in under-five mortality after 2 years using cIMCI.[49]

Recognising these challenges globally, WHO in conjunction with UNICEF and USAID launched iCCM, iCCM in Africa (2012). A Cochrane review of iCCM programmes found no impact on child mortality due to poor study design of the trials.[50] These faced critical challenges due to lack of integration into national health systems, lack of political commitment and non-coordination with funding agencies. Funding was largely dependent on development partners, and sustainability of funding remained a critical concern for delivery of iCCM services. The problems in supply of commodities, utilisation, scale, quality, financing and monitoring of services were not resolved. A strong referral system for facility-based treatment was not developed simultaneously, and, finally, iCCM policy did not include treatment of neonatal sepsis.[51]

In India at present, complete HBCC has not been implemented by the government. The major obstacles in implementing community-based health programmes in India are: poor trainings and monitoring of grassroot workers, poor referral support for quality treatment, the rigid hierarchical structure of the health system, failure to incorporate community participation into large-scale primary healthcare programmes[52] and opposition from professional bodies such as the Indian Medical Association and the Indian Academy of Pediatrics. Nevertheless, the Government of Maharashtra has taken many steps to implement HBNC in high mortality rural areas. Critically, the HBCC programme did not require strengthening of the primary healthcare facilities or of the referral facilities, which are still a major obstacle in most developing countries. Empowering community workers to provide basic and advanced care for the well and sick child and the provision of basic essential medicines obviates the need for the most part for referral and will decrease the burden on these facilities if widely implemented, making it a much more cost-effective strategy.

VHWs played a critical role to reduce the mortality in the community and provided appropriate grassroots healthcare. Community health workers (CHWs) are essential for achieving the health-related Sustainable Development Goals.[53] A significant increase in continuous funding for CHW programmes is needed. National and state governments should increase political support for prioritising CHW programmes during economic growth and make additional health-related funding available. This paradigm shift will be an essential step in escalating development in achieving current global health goals and in reaching the goal of Health for All.[54]

The limitations of this trial include possible spillover effects as the CA and the IA were in contiguous areas. There were differences in between IA and CA for baseline IMR, U5MR and the household level characteristics, although they were adjusted during analysis by obtaining a wealth index. Finally, this strategy might not be applicable for the urban setting. Malaria rapid diagnostic tests (RDTs) were not used for malaria diagnosis during research and service phase. It was based on a clinical diagnosis after excluding other causes of fever. Our VHWs used malaria RDTs during the government replication phase. This was a relatively small study and it might be difficult to scale up this complex HBCC approach. However, the principles, methods, VHW monitoring, simple treatment modalities and collaboration with government makes this a feasible modality for reductions of IMR and U5MR in the Indian subcontinent and other LMICs.

In conclusion, progressive policies on CHW programmes must be backed up by concrete institutional support to enable CHWs to fulfil their role.[55] While VHWs are not a panacea for weak health systems, they can make a major contribution to health system strengthening if they have focused tasks, adequate remuneration and the active involvement of the communities in which they work.[19] Thus the prerequisites for successful programme delivery are: (a) Selection of a VHW through a transparent community participatory process based on merit, (b) Intensive, focused regular trainings and monitoring of VHWs, (c) Maintenance of the supply chain, (d) The programme must be backed up by concrete institutional support. HBCC is possible with local resources. It is affordable, acceptable, measurable, safe, achievable and effective. It should be replicable in other impoverished

areas of the world having inadequate medical facilities and a high U5MR.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval Name of Ethics Committee: MAHAN Institutional Review Board (IRB), Reference ID 1/2004. IRB meets standard of BMJ. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Aggregate data that underlie the results reported in this article, after de-identification (text, tables, figures and appendices) will be shared. Study protocol has been added in the supplementary materials. As per guidelines of Government of India (GOI), individual participant data will not be available. Data will be made available: The beginning 9 months and ending 36 months following article publication. Data will be shared with investigators whose proposed use of the data has been approved by an independent review committee, the GOI and ethical review by the ICMR and Government of Maharashtra (India), Tribal Section clearance, identified for this purpose. Proposals may be submitted up to 35 months following article publication. After 36 months the data will be available with investigator support.

Author note The reflexivity statement for this paper is linked as an online supplemental file1.

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