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Lassi ZS, Bhutta ZA

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Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes.

*Cochrane Database of Systematic Reviews* 2015, Issue 3. Art. No.: CD007754.

DOI: 10.1002/14651858.CD007754.pub3.

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Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes (Review)

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[Intervention Review]

# Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

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**Editorial group:** Cochrane Pregnancy and Childbirth Group.

**Publication status and date:** New search for studies and content updated (conclusions changed), published in Issue 3, 2015.

**Review content assessed as up-to-date:** 25 May 2014.

**Citation:** Lassi ZS, Bhutta ZA. Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes. *Cochrane Database of Systematic Reviews* 2015, Issue 3. Art. No.: CD007754. DOI: 10.1002/14651858.CD007754.pub3.

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## ABSTRACT

### Background

While maternal, infant and under-five child mortality rates in developing countries have declined significantly in the past two to three decades, newborn mortality rates have reduced much more slowly. While it is recognised that almost half of the newborn deaths can be prevented by scaling up evidence-based available interventions (such as tetanus toxoid immunisation to mothers, clean and skilled care at delivery, newborn resuscitation, exclusive breastfeeding, clean umbilical cord care, and/or management of infections in newborns), many require facility-based and outreach services. It has also been stated that a significant proportion of these mortalities and morbidities could also be potentially addressed by developing community-based packaged interventions which should also be supplemented by developing and strengthening linkages with the local health systems. Some of the recent community-based studies of interventions targeting women of reproductive age have shown variable impacts on maternal outcomes and hence it is uncertain if these strategies have consistent benefit across the continuum of maternal and newborn care.

### Objectives

To assess the effectiveness of community-based intervention packages in reducing maternal and neonatal morbidity and mortality; and improving neonatal outcomes.

### Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 May 2014), World Bank's JOLIS (25 May 2014), BLDS at IDS and IDEAS database of unpublished working papers (25 May 2014), Google and Google Scholar (25 May 2014).

### Selection criteria

All prospective randomised, cluster-randomised and quasi-randomised trials evaluating the effectiveness of community-based intervention packages in reducing maternal and neonatal mortality and morbidities, and improving neonatal outcomes.

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**Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes (Review)**

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## Data collection and analysis

Two review authors independently assessed trials for inclusion, assessed trial quality and extracted the data. Data were checked for accuracy.

## Main results

The review included 26 cluster-randomised/quasi-randomised trials, covering a wide range of interventional packages, including two subsets from three trials. Assessment of risk of bias in these studies suggests concerns regarding insufficient information on sequence generation and regarding failure to adequately address incomplete outcome data, particularly from randomised controlled trials. We incorporated data from these trials using generic inverse variance method in which logarithms of risk ratio (RR) estimates were used along with the standard error of the logarithms of RR estimates.

Our review showed a possible effect in terms of a reduction in maternal mortality (RR 0.80; 95% confidence interval (CI) 0.64 to 1.00, random-effects (11 studies,  $n = 167,311$ ; random-effects,  $\text{Tau}^2 = 0.03$ ,  $I^2 = 20\%$ ). However, significant reduction was observed in maternal morbidity (average RR 0.75; 95% CI 0.61 to 0.92; four studies,  $n = 138,290$ ; random-effects,  $\text{Tau}^2 = 0.02$ ,  $I^2 = 28\%$ ); neonatal mortality (average RR 0.75; 95% CI 0.67 to 0.83; 21 studies,  $n = 302,646$ ; random-effects,  $\text{Tau}^2 = 0.06$ ,  $I^2 = 85\%$ ) including both early and late mortality; stillbirths (average RR 0.81; 95% CI 0.73 to 0.91; 15 studies,  $n = 201,181$ ; random-effects,  $\text{Tau}^2 = 0.03$ ,  $I^2 = 66\%$ ); and perinatal mortality (average RR 0.78; 95% CI 0.70 to 0.86; 17 studies,  $n = 282,327$ ; random-effects  $\text{Tau}^2 = 0.04$ ,  $I^2 = 88\%$ ) as a consequence of implementation of community-based interventional care packages.

Community-based intervention packages also increased the uptake of tetanus immunisation by 5% (average RR 1.05; 95% CI 1.02 to 1.09; seven studies,  $n = 71,622$ ; random-effects  $\text{Tau}^2 = 0.00$ ,  $I^2 = 52\%$ ); use of clean delivery kits by 82% (average RR 1.82; 95% CI 1.10 to 3.02; four studies,  $n = 54,254$ ; random-effects,  $\text{Tau}^2 = 0.23$ ,  $I^2 = 90\%$ ); rates of institutional deliveries by 20% (average RR 1.20; 95% CI 1.04 to 1.39; 14 studies,  $n = 147,890$ ; random-effects,  $\text{Tau}^2 = 0.05$ ,  $I^2 = 80\%$ ); rates of early breastfeeding by 93% (average RR 1.93; 95% CI 1.55 to 2.39; 11 studies,  $n = 72,464$ ; random-effects,  $\text{Tau}^2 = 0.14$ ,  $I^2 = 98\%$ ), and healthcare seeking for neonatal morbidities by 42% (average RR 1.42; 95% CI 1.14 to 1.77, nine studies,  $n = 66,935$ , random-effects,  $\text{Tau}^2 = 0.09$ ,  $I^2 = 92\%$ ). The review also showed a possible effect on increasing the uptake of iron/folic acid supplementation during pregnancy (average RR 1.47; 95% CI 0.99 to 2.17; six studies,  $n = 71,622$ ; random-effects,  $\text{Tau}^2 = 0.26$ ;  $I^2 = 99\%$ ).

It has no impact on improving referrals for maternal morbidities, healthcare seeking for maternal morbidities, iron/folate supplementation, attendance of skilled birth attendance on delivery, and other neonatal care-related outcomes. We did not find studies that reported the impact of community-based intervention package on improving exclusive breastfeeding rates at six months of age. We assessed our primary outcomes for publication bias and observed slight asymmetry on the funnel plot for maternal mortality.

## Authors' conclusions

Our review offers encouraging evidence that community-based intervention packages reduce morbidity for women, mortality and morbidity for babies, and improves care-related outcomes particularly in low- and middle-income countries. It has highlighted the value of integrating maternal and newborn care in community settings through a range of interventions, which can be packaged effectively for delivery through a range of community health workers and health promotion groups. While the importance of skilled delivery and facility-based services for maternal and newborn care cannot be denied, there is sufficient evidence to scale up community-based care through packages which can be delivered by a range of community-based workers.

## PLAIN LANGUAGE SUMMARY

### Community-based intervention packages for preventing maternal and newborn illness and death so that newborn outcomes are improved

While maternal, newborn and under-five child death rates in developing countries have decreased in the past two to three decades, newborn death rates have hardly changed. It is now recognised that almost half of newborn deaths can be prevented by tetanus toxoid immunisation of the mothers; clean and skilled care at the birth; newborn resuscitation; clean umbilical cord care; exclusive breastfeeding; and management of infections in the newborns. In developing countries, almost two-thirds of births occur at home and only half are attended by a trained birth attendant. A large proportion of these maternal and newborn deaths and diseases can potentially be addressed by developing community-based packaged interventions to integrate with local health systems.

The review authors found 26 randomised and quasi-randomised controlled studies evaluating the impact of community-based intervention packages for the prevention of maternal illness and death and in improving newborn health outcomes. These studies were mostly conducted in developing countries (India, Bangladesh, Pakistan, Nepal, China, Zambia, Malawi, Tanzania, South Africa, Ghana) with one additional study in Greece. Women in areas assigned to receive a community-based intervention package and with health workers receiving additional training had less illness and fewer complications during pregnancy and birth and there were fewer stillbirths, infant deaths around the time of birth and maternal ill-health. Community-based intervention packages were associated with improved uptake of tetanus immunisation, usage of clean delivery kits for home births and institutional deliveries. They also improved early initiation of breastfeeding and health-care seeking (by the mothers) for illnesses related to (their) babies. Whether these translate into improved newborn outcomes is unclear. This review highlights the value of integrating maternal and newborn care in community settings through a range of interventions which can be packaged effectively for delivery through a range of community health workers and health promotion groups. There is sufficient evidence to scale up community-based care through packages which can be delivered by a range of community-based workers. Most of the reviewed studies did not document the complete description and characteristics of the community health workers, especially the initial level of education and training, the level and amount of supervision provided, and the community ownership of these workers. This information would be of great relevance to policy and practice.

## BACKGROUND

### Description of the condition

The Millennium Development Goal for maternal health (MDG-5) calls for a reduction in maternal mortality by two-thirds by the year 2015 (Sachs 2005). The estimates of maternal mortality suggest that 287,000 maternal deaths occurred worldwide in 2010, and that 85% (245,000) of these deaths occurred in sub-Saharan Africa (56%) and Southern Asia (29%) (WHO 2012). Most of these maternal deaths seem to occur between the third trimester and the first week after the end of pregnancy (Ronsmans 2006). Mortality has also been found to be extremely high on the first and second days after birth (Hurt 2002).

Almost 80% of maternal deaths are due to direct obstetric causes, including severe bleeding (haemorrhage), infection, complications of unsafe abortion, eclampsia, and obstructed labour; with other causes being related to the unfavourable conditions created by lack of access to health care, illiteracy and factors related to poverty (Hoj 2003). Many women are estimated to suffer pregnancy-related illnesses (9.5 million), near-miss events, which are the life-threatening complications that women survive (1.4 million), and other potentially devastating consequences after birth (Ashford 2002; Say 2004; WHO 2000). The consequences of near-miss events on women themselves and their families can be substantial, and recovery can be slow, with lasting sequelae. An estimated 10 to 20 million women develop physical or mental disabilities every year as a result of complications or poor management (Ashford 2002; Murray 1998). The long-term consequences are not only

physical, but are also psychological, social, and economic (Filippi 2006).

Pregnancy-related illnesses and complications during pregnancy and delivery are associated with a significant impact on the fetus, resulting in poor pregnancy outcomes (Campbell 2006). Around the world, 50 million births occur at home without the presence of skilled birth attendance (UNICEF 2008). In the 1970s the World Health Organization promoted training of traditional birth attendants (TBAs) as a major public health strategy to reduce the burden of mortality and morbidities related to pregnancy and childbirth. However, the evidence of the impact of this strategy on maternal and neonatal outcomes is still limited (Sibley 2007). Deaths occurring in the neonatal period (aged 0 to 27 days) account for 41% (3.575 million) of all deaths in children younger than five years (Black 2010). In developing countries, most of the maternal, perinatal and neonatal deaths and morbidities occur at home. The reasons are multi-factorial, including poverty; poor health status of women; illiteracy; lack of information regarding the availability of health services/providers; lack of control on household resources and decision-making authority; poor antenatal and obstetric care both within the community and health facilities; absence of a trained attendant at delivery; inadequate referral system for emergency obstetric care; inadequacy/absence of transportation facilities; and absence of/poor linkages of health centres with the communities (Ensor 2004). The majority of maternal and neonatal deaths could be prevented with early recognition and proper implementation of required skills and knowledge (Campbell 2006; Ray 2004).

### Description of the intervention

Soon after the Alma-Ata Declaration, arguments for selective rather than comprehensive primary health care dominated and it was then recognised that community participation was important in supporting the provision of local health services and in delivering interventions at the community level (Rosato 2008). Community participation has long been advocated to build links with improving maternal and child health and there are several trials from south Asia which have evaluated the role of women's groups on maternal and neonatal health. The Makwanpur trial, Nepal implemented a participatory learning cycle (in which they identify, prioritise a problem, select and implement relevant interventions and evaluate the results) through developing women's groups and found a reduction in maternal mortality by 88% and neonatal mortality by 30% but the same strategy in other trials has shown variable non-significant impacts on maternal and neonatal outcomes (Azad 2010; Tripathy 2010). Another set of studies in which services were provided to women and children in the community indicated that, at full coverage, 41% to 72% of newborn deaths could be prevented by available interventions such as tetanus toxoid immunisation to mothers; clean and skilled care at delivery; newborn resuscitation; prevention of hypothermia; exclusive breastfeeding; clean umbilical cord care; management of pneumonia and sepsis. Around half of this reduction is possible with community-based Interventions (Darmstadt 2005). It has also been stated that a significant proportion of these mortalities and morbidities could also be potentially addressed by developing community-based intervention packages (package is defined as delivering more than one intervention via different set of strategies such as community support groups/women groups, community mobilisation and home visitation and training TBAs/community health workers (CHWs), which should also be supplemented by developing and strengthening linkages with the local health systems.

Some prior reviews have also generated evidences from reviewing community-based maternal and neonatal interventions trials (Bhutta 2005; Haws 2007), but those were not subjected to meta-analyses. Therefore, in this review we not only assess the effectiveness of community-based intervention packages in reducing maternal and neonatal morbidities and mortality and improving neonatal outcomes, but also the impact of different strategies (home visitation, home-based care, community-support groups/women's groups etc.) on the reported outcomes. This review did not evaluate the impact of training TBAs alone (Sibley 2007), or the effectiveness of a health education strategy designed for mothers and other family members on newborn survival (Thaver 2009), as these are being evaluated in other reviews.

## OBJECTIVES

To assess the effectiveness of community-based intervention packages in reducing maternal and neonatal morbidity and mortality

and improving neonatal outcomes.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We included community-based, randomised or quasi-randomised controlled trials, irrespective of language or publication status in this review. We included both individually-randomised and cluster-randomised designs.

#### Types of participants

Women of reproductive age, particularly pregnant women at any period of gestation.

#### Types of interventions

Intervention packages that included additional training of outreach workers (residents from the community who are trained and supervised to deliver maternal and newborn care interventions to her target population) namely, lady health workers/visitors, community midwives, community/village health workers, facilitators or TBAs in maternal care during pregnancy, delivery and in the postpartum period; and routine newborn care.

Additional training was defined as training other than the usual training that health workers received from their governmental or non-governmental organisation (NGO) and could include a combination of training in providing basic antenatal, natal and postnatal care; preventive essential newborn care, breastfeeding counselling; management and referral of sick newborns; skills development in behaviour change communication; and community mobilisation strategies to promote birth and newborn care preparedness. The training sessions included lectures, supervised hands-on training in a healthcare facility and/or within the community.

The control group in these studies was one in which women received their usual maternal and newborn care services from local government and non-government facilities.

#### Types of outcome measures

We included studies if they assessed any of the following primary and secondary outcomes.

## Primary outcomes

1. Maternal mortality was defined as the number of maternal deaths per live births. Maternal death is defined as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and delivery site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management.

2. Neonatal mortality was defined as the number of neonatal deaths from any cause among total live births:

- early neonatal mortality: neonatal deaths in the first week of life;
- late neonatal mortality: neonatal deaths from seven to 28 days of life.

## Secondary outcomes

1. Perinatal mortality was defined as stillbirths and early neonatal deaths (i.e. neonatal deaths in the first week of life) among all stillbirths and live births.

2. Stillbirth was defined as fetal death after 28 weeks of gestation but before delivery of the baby's head per all births.

3. Low birthweight was defined as birthweight less than 2500 g.

4. Complications of pregnancy, including prolonged or obstructed labour, eclampsia, postpartum haemorrhage, postpartum depression (as defined by the authors).

5. Referral to a health facility for any complication during pregnancy, delivery, or the postpartum period.

6. Iron/folate supplementation.\*

7. Tetanus toxoid immunisation.\*

8. Use of clean delivery kits.\*

9. Institutional delivery/delivery at a health facility.

10. Birth attended by a health provider (doctor, nurse, midwife or a trained health worker).

11. Initiation of breastfeeding within one hour of birth.

12. Wrapping babies within 30 minutes.\*

13. Delayed bathing for six hours.\*

14. Clean cord care.\*

15. Exclusive breastfeeding at six months of age.

16. Health care seeking for maternal and/or neonatal morbidities.

17. Infant's weight for age and height for age Z scores at six months of age.

\*These outcomes were not specified in the protocol or earlier version of review (Lassi 2010) and have been added in the 2014 update (refer to [Differences between protocol and review](#)).

## Search methods for identification of studies

The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

## Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (31 May 2014).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);

2. weekly searches of MEDLINE (Ovid);

3. weekly searches of Embase (Ovid);

4. handsearches of 30 journals and the proceedings of major conferences;

5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and Embase, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the [Cochrane Pregnancy and Childbirth Group](#).

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched the World Bank's JOLIS, British Library for Development Studies BLDS at IDS and IDEAS database of unpublished working papers, Google and Google Scholar. We carried out our search on May 25, 2014. See: [Appendix 1](#) for search strategy.

We did not apply any language or date restrictions.

## Data collection and analysis

For methods used in the previous version of this review, see [Lassi 2010](#).

For this update, the following methods were used for assessing the new reports that were identified as a result of the updated search. The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

## Selection of studies

Two review authors, Zohra Lassi (ZSL) and Zulfiqar Bhutta (ZAB), independently assessed for inclusion of all the potential studies we identified as a result of the search strategy. We resolved disagreement through discussion and, if required, we consulted a third assessor.

## Data extraction and management



We designed a form to extract data. For eligible studies, two review authors (ZSL and ZAB) independently extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third review author. We entered data into Review Manager software (RevMan 2014) and checked for accuracy. When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

### **Assessment of risk of bias in included studies**

Two review authors (ZSL and ZAB) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion.

#### **(1) Random sequence generation (checking for possible selection bias)**

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

#### **(2) Allocation concealment (checking for possible selection bias)**

We described for each included study the method used to conceal the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

#### **(3.1) Blinding of participants and personnel (checking for possible performance bias)**

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

#### **(3.2) Blinding of outcome assessment (checking for possible detection bias)**

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes. We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

#### **(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)**

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), and if reasons for attrition or exclusion were reported. We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

#### **(5) Selective reporting bias**

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

#### **(6) Other sources of bias**

We described for each included study any important concerns we have about other possible sources of bias. We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

### (7) Overall risk of bias

We made explicit judgement about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias. We explored the impact of the level of bias through undertaking sensitivity analyses for primary and some secondary mortality outcomes.

### 'Risk of bias' assessment for cluster-randomised trials

For cluster-randomised trials, we considered the following biases: (i) recruitment bias; (ii) baseline imbalance; (iii) loss of clusters; (iv) incorrect analysis; and (v) comparability with individually-randomised trials.

- Recruitment bias: We assessed if individuals were recruited to the trial after the clusters have been randomised, as the knowledge of whether each cluster is an 'intervention' or 'control' cluster could affect the types of participants recruited.
- We assessed the number of clusters that were randomised as there is a possibility of chance baseline imbalance between the randomised groups, in terms of either the clusters or the individuals. We assessed if trials reduced the risk of baseline differences by using stratified or pair-matched randomisation of clusters.
- Occasionally complete clusters are lost from a trial, and have to be omitted from the analysis. Just as for missing outcome data in individually-randomised trials, this may lead to bias. In addition, missing outcomes for individuals within clusters may also lead to a risk of bias in cluster-randomised trials.
- We assessed if trials considered adjustment in results taking clusters into account.

### Measures of treatment effect

We carried out statistical analysis using the Review Manager software (RevMan 2014).

### Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

### Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measured the same outcome, but used different methods, if necessary.

## Unit of analysis issues

### Cluster-randomised trials

We included cluster-randomised/quasi-randomised trials in the analyses along with individually-randomised trials. We incorporated the data of cluster-randomised/quasi-randomised trials using generic inverse variance method in which logarithms of risk ratio estimates were used along with the standard error of the logarithms of risk ratio estimates.

We acknowledged heterogeneity in the randomisation unit and performed a subgroup and sensitivity analysis to investigate the effects of the randomisation unit.

### Dealing with missing data

For included studies, we noted levels of attrition. For all outcomes we carried out analyses, as far as possible, on an intention-to-treat basis; i.e. we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

### Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau<sup>2</sup>, I<sup>2</sup> and Chi<sup>2</sup> statistics. We regarded heterogeneity as substantial if the Tau<sup>2</sup> was greater than zero and either an I<sup>2</sup> was greater than 30% or there was a low P value (less than 0.10) in the Chi<sup>2</sup> test for heterogeneity. We also undertook exploratory subgroup analyses (described under the heading of subgroup analysis) of subsets of studies to generate hypotheses regarding the reasons for high levels of statistical heterogeneity where applicable.

### Assessment of reporting biases

Where there were 10 or more studies in the meta-analysis, we investigated reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually. If asymmetry was suggested by a visual assessment, we performed exploratory analyses to investigate it.

### Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2014). We used fixed-effect meta-analysis for combining data where trials were examining the same intervention, and

the trials' populations and methods were judged sufficiently similar or when heterogeneity was not sufficient on statistical grounds. On occasions where we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials, or when tests for heterogeneity found heterogeneity, we used random-effects meta-analysis. If we identified substantial heterogeneity in a fixed-effect meta-analysis, we noted this and repeated the analysis using a random-effects method (Deeks 2001).

Where we used random-effects analyses, the results were presented as the average treatment effect with 95% confidence intervals, and the estimates of  $\tau^2$  and  $I^2$ .

### Subgroup analysis and investigation of heterogeneity

We prespecified the following subgroup analysis to investigate heterogeneity.

- Content of intervention.
- Duration of training.
- Continued education after initial training.
- Baseline mortality (maternal, perinatal and neonatal).
- Presence/absence of community mobilisers, advocacy or support groups.
  - Involvement of other family members through community mobilisation (husband, mother-in-law).
  - Linkages to healthcare system.

The review's mortality outcomes were used in subgroup analyses. We assessed subgroup differences by interaction tests available within RevMan (RevMan 2014). We reported the results of subgroup analyses quoting the  $\chi^2$  statistic and P value, and the interaction test  $I^2$  value.

### Sensitivity analysis

We performed sensitivity analyses based on the randomisation process, with quasi-randomised studies being excluded. We performed sensitivity analyses assessing the presence of adequate sequence generation and allocation concealment in the primary outcomes.

## RESULTS

### Description of studies

#### Results of the search

We identified a total of 32,904 (after removing duplicates) titles and abstracts, written in English and other languages. We considered 99 (52 original) full-text papers for inclusion in this review, and eventually determined that 26 were eligible for inclusion (see [Characteristics of included studies](#)). Sixty-six studies were excluded (see [Characteristics of excluded studies](#)); seven studies are ongoing (see [Characteristics of ongoing studies](#)) and 10 studies are awaiting classification.

### Included studies

We included 26 studies, see [Characteristics of included studies](#). Twenty-four of those are cluster-randomised controlled trials, one study (Bang 1999) is a controlled clinical trial which uses a cluster design and one trial (Syed 2006) is a quasi-randomised cluster trial. We included results from two intervention arms (two subsets) of Baqui - Sylhet 2008, Kumar 2008 and Midhet 2011. We have provided a comparison of the characteristics of the included studies in [Table 1](#) and [Table 2](#).

In the section below we have summarised important elements of the included studies.

### Cluster-randomised controlled trials

This study from Florina, Greece (Kafatos 1991) was a cluster-randomised controlled trial. Clinics were randomised to minimise contamination. Florina's 20 clinics were randomly divided into intervention and control arms, and 300 women from intervention clinics and 268 from control clinics were selected. Nurses were intensively trained for health and nutrition counselling. Women and newborns were targeted at homes because of non-attendance and infrequent attendance. During home visits, emphasis was given on nutrition counselling along with general hygiene, preparation of pregnancy. They also covered topics like appropriate feeding, breastfeeding, infant hygiene, clothing, immunisation, and stimulation exercises to improve psychomotor development in infants. Furthermore, each mother was given picture booklets which provided the above mentioned information in a simplified manner. In the other arm, women from control clinics received care from government health services. The characteristics of women in terms of age, parity, socioeconomic status was similar in the intervention and control arms.

The trial conducted in India (Srinivasan 1995) was a cluster-randomised controlled trial from Tamil Nadu, India. Three subcentres were selected at random from among those beyond 10 km of primary health care (PHC) centre. One each was randomly allocated to high-risk package, Tamil Nadu Government (TNG) package and control. All packages were implemented by female ancillary nurse midwives (ANMs), who were trained for six weeks on a general training programme, and for six weeks on a special training programme to detect and treat maternal and neonatal infections. In the high-risk package, ANMs detected pregnancies,

registered them, and measured height, weight, haemoglobin and performed urine analysis testing, etc. They also distributed folic acid tablets, and administered two doses of tetanus toxoid as recommended under the universal immunisation programme. High-risk mothers were advised to have delivery at hospitals, and three postnatal visits were made by ANMs to detect and treat infections in mothers and neonates. In the TNG package, a set of routine antenatal care services recommended by local provincial government was implemented. The characteristics of the study population at registration were broadly similar in the three groups. A total of 45,154 participants were covered in these packages; however, analysis was performed on only 1623 women.

The study conducted by [Manandhar 2004](#) in Makwanpur district of Nepal was a cluster-randomised controlled trial. The study was conducted with the aim of reducing neonatal deaths with community-based participatory interventions. As the first step of intervention, issues around childbirth and care behaviours in the community were discussed. On the basis of a baseline service audit, primary health centres in the study areas were equipped with resuscitators, phototherapy units, warm cots and neonatal resuscitation equipment and essential neonatal drugs. Furthermore, they trained all cadres of government health staff and for community health workers (CHWs) and traditional birth attendants (TBAs) on essential newborn care. CHWs also received a basic newborn care kit. Equipment in health centres and training for government staff were also provided in control areas. Baseline characteristics in the intervention and control arms were similar except the median number of households per cluster was lower in the control arm. The total numbers of pregnancies, deliveries, live births and breast fed infants in the intervention clusters were 3190, 2945, 2899, and 2864, respectively, while those in control clusters were 3524, 3270, 3226, and 3181.

The study conducted in Pakistan ([Jokhio 2005](#)) was a cluster-randomised controlled trial involved seven subdistricts of rural district of Larkana, Sind, Pakistan. The intervention designed for the study was to facilitate care based in the available infrastructure and to be low cost and substantial. TBAs in the intervention arm were trained by obstetricians and female paramedics. TBAs were trained for three days; training involved the use of pictorial cards containing advice on antepartum, intrapartum and postpartum care, how to conduct clean delivery, use of disposable delivery kits, when to refer women for emergency obstetric care, and care of the newborn. They also visited women in the antenatal and postnatal periods to check for danger signs and to encourage women with such signs to seek emergency obstetrical care. TBAs were instructed to register all pregnant women in their catchment areas and to inform the lady health workers (LHWs) about the pregnant women under their care. In the control arm, LHWs followed up all pregnant women in their catchment area in the course of their monthly home visits to women and children. A total of 19,525 women completed follow-up, while the total number of singleton births during the trial period was 18,699. Baseline maternal

characteristics were similar for the study groups across the clusters except for the years of education, which was slightly greater among women in the control group.

The study from Bangladesh ([Bari 2006](#)) was a cluster-randomised controlled trial with two arms: an intervention arm with CHWs delivering a package of maternal and newborn-care interventions in the home, and a comparison arm. For this study, 36 CHWs were recruited and provided with one month of training to equip them to provide a package of maternal and newborn care. These CHWs had education equivalent to grade 10 and were residing in the population they would serve. Each CHW was responsible for a population of 4000, and they assessed 794 sick children during this period. In the control arm, interventions by CHWs were not delivered while they were served by the same hospital.

[Kumar 2008](#), conducted in Shivgarh, Uttar Pradesh, India was a cluster-randomised controlled trial. This study was conducted with the aim that an intervention based in a socioculturally contextualised approach of behaviour management with an emphasis of hypothermia, within a community with a high neonatal mortality rate, could lead to improved care practices and reduced mortality. The intervention package of essential newborn care was broadly categorised into birth preparedness, hygienic delivery, and immediate newborn care including skin-to-skin care, breastfeeding and care seeking from trained providers. They hired community-based health workers, known as *Saksham Sahayak* to facilitate behaviour change. *Saksham Sahayak* were given a combination of classroom and apprenticeship-based field training over seven days related to essential newborn care. They also targeted community stakeholders (community leaders, priests, and teachers), newborn stakeholders (birth attendants, unqualified medical care providers, and healthcare workers) and household target groups (father-in-law, husbands, mother-in-law, pregnant women or mother, neighbours, and relatives). Control clusters received the usual services of governmental and non-governmental organisations (NGOs) working their areas. The key baseline characteristics for the three study arms were similar. Total number of deliveries analysed at the end were 3837, and the total of 3859 births and 3688 live births in intervention and control clusters were reported during the study period. At baseline, stillbirth per 1000 births in the control arm was 27.2 and in intervention arm was 24.4. The neonatal deaths in the control arm were 54.2/1000 live births and 64.1/1000 live births in the intervention arm. Perinatal deaths among the control arm were 60/1000 births and in the intervention arm 68.4/1000 births.

Another study from Pakistan ([Bhutta 2008](#)) was a pilot phase of a cluster-randomised controlled trial (eight clusters). The study was conducted in Hala and Matiari subdistricts located 250 km from Karachi. An intervention package was developed that involved the community and the two main providers of primary care: LHWs and *Dais* (local name for TBAs). LHWs in addition to the standard LHW training programme were given six days' training on antenatal care and were linked with *Dais* to identify births and

visit mothers twice during pregnancy, within 24 hours of birth and on days three, seven, 14, and 28 after delivery. *Dais* were given three days' voluntary training programme in basic newborn care which included basic resuscitation and immediate newborn care. They also identified community volunteers who helped to develop committees for maternal and newborn care in their villages, conducted three-monthly group education sessions in the intervention villages and helped to establish an emergency transport fund for mothers and newborns. In the communities where the intervention package was not implemented, the LHW training programme continued as usual, but there was no attempt made to link *Dais* with LHWs. Special training in basic and intermediate newborn care was offered to all public-sector rural health centre and hospital-based medical and nursing staff. Baseline characteristics of intervention and control clusters on perinatal, neonatal and stillbirths were similar. Groups differed on provision of electricity and hand pumps; a higher number of households in the intervention arm had those facilities as compared to control. A total of 5134 total births and 4815 live births were identified in the intervention and control clusters during the pilot period. The baseline neonatal mortality rates among the intervention cluster was 57.3/1000 live births, and in control clusters was 52.2/1000 live births. Perinatal mortality rate per 1000 births in the intervention arm was 110.8 and in the control was 94.6, while stillbirth rates per 1000 birth were 65.9 and 58.1 in the intervention and control arms respectively.

The study (Projahnmo-I) conducted in Sylhet district, Bangladesh (Baqui - Sylhet 2008) was a cluster-randomised controlled trial. They basically developed an intervention package to promote birth and newborn-care preparedness, including pregnancy care, birth planning, essential newborn care, and awareness of when to seek emergency care for maternal and newborn illnesses. The group had two intervention arms: a home-care study arm and a community-care arm. In the home-care arm, they recruited female CHWs, who received six weeks of hands-on supervised training in a tertiary care hospital and in households. The intervention in this arm included skills development for behaviour change, communication, provision of essential newborn care, clinical assessment of neonates and management of sick neonates with an algorithm adopted from the integrated management of childhood illness. They treated newborns with injectable procaine benzylpenicillin and gentamicin, when families were unable to go to health facilities. In the community-care study arm, families received the usual health services provided by the government, NGOs and private providers. In both these arms male and female community mobilisers held group meetings for the dissemination of birth and newborn care preparedness messages. Families in the comparison arm received the usual health services provided by the government, NGOs, and private providers. Refresher training sessions for management of maternal and newborn complications were provided for government health workers in all three study arms. Projahnmo staff ensured adequate supplies of antibiotics for treatment of new-

born infections at government subdistrict hospitals, which served residents in all three study arms. The end line survey identified 47,158 women with 58,588 pregnancies, 7160 (15%) of whom declined to participate or were absent during data collection. Survey participants reported a total of 46,444 live births, of which 44,380 survived the neonatal period. Outcomes were reported from 1760, 1661 and 1689 births from the home care, community care and control arms, respectively. Baseline characteristics across all study arms were similar. In the analysis we treated them as two subsets.

We also included the unpublished work (cluster-randomised controlled trial) which is under progress by Bhutta 2011 in Hala, Pakistan. The data included in this review were from their eighth surveillance of the intervention and control arms. In this study LHWs and TBAs were trained to deliver Intervention packages and community mobilisation services to women and others members of community. In control clusters, the LHW training programme continued as usual, with regular refresher sessions, but no attempt was made to link LHWs with the *Dais*. Baseline characteristics among intervention and control arm were similar on statistical grounds. Total number of births in intervention and control clusters were 24,085, and the live births were 23,033. The rate of stillbirths in the intervention arm was 36.57/1000 compare to 47.81/1000 in the control arm. Neonatal mortality in the intervention arm was 47.99 compared to 51.25/live births in the control arm. Perinatal mortality in the intervention arm was 67.79 compared to 72.06/births in the control arm.

We included a published work by Tripathy 2010, which is from their cluster-randomised controlled trial conducted in Orissa and Jharkhand, India. From 36 clusters in Jharkhand and Orissa (mean cluster population: 6338), 18 clusters were randomly assigned to either intervention or control using stratified allocation. In intervention clusters a woman facilitator convened 13 groups every month to support participatory action and learning for women, and facilitated the development and implementation of strategies to address maternal and newborn health problems. No participatory intervention activities were conducted in control areas. A total of 19,030 births in intervention and control clusters were reported during the trial period, among which 18,449 were live births. Baseline characteristics of identified pregnancies in the intervention and control clusters were similar; however, differences were found in household assets, maternal education, literacy and trial membership, with women in the intervention clusters tending to be poorer and more disadvantaged.

The study by Azad 2010 was a cluster-randomised controlled trial conducted in Bangladesh. They carried out two trials in the same study area using a factorial design: first, a community-based intervention involving participatory women's groups and health services strengthening to improve maternal and newborn health outcomes; second, an intervention involving training TBAs in bag-valve-mask resuscitation of newborns with symptoms of birth asphyxia. Women's groups were facilitated by a local female peer



facilitator who acted as a catalyst for community mobilisation. Each facilitator was responsible for a total of 18 groups. Facilitators received five training sessions covering participatory modes of communication and maternal and newborn health issues. The role of the facilitator was to activate and strengthen groups, to support them in identifying and prioritising maternal and newborn problems, to help to identify possible strategies, and to support the planning, implementation and monitoring of strategies in the community. Locally recruited supervisors supported facilitators in preparing for meetings and liaising with community leaders. The control group was not provided with participatory learning groups. A total of 30,952 births and 29,889 live births were reported during the trial period in the intervention and control clusters. The intervention and control clusters were similar in terms of their baseline characteristics. However, stillbirths and neonatal deaths (in numbers) were higher in the control clusters as compared to those in the intervention clusters.

A cluster-randomised controlled trial by [Midhet 2011](#) was implemented during 1998 to 2002 in 32 village clusters in Khuzdar, a rural district of Balochistan province in Pakistan. Sixteen of the 32 village clusters were assigned to the intervention arm while the remaining clusters served as the control arm. The IEEC (Information and Education for Empowerment and Change) for women was designed to increase awareness of safe motherhood and neonatal health. The project staff identified 10 female volunteers from each village cluster and trained them as IEEC facilitators. Each facilitator initially invited 10 to 12 women from close villages to participate in a support group. Local TBAs were trained in clean home delivery and in recognising common obstetric and newborn emergencies. The husbands' IEEC was implemented in eight village clusters randomly selected from the 16 intervention clusters. Husbands' booklets and audiocassettes were designed after formative research with married men. Then in each village cluster, 20 to 30 male community volunteers were identified who distributed the materials among husbands of the women who had participated in the support groups. The intervention and control arms were similar in terms of baseline characteristics. However, they did not report P values.

[Bhandari 2012](#) is a cluster-randomised controlled trial from Haryana, India in which intervention was designed according to the IMNCI (Integrated Management of Newborn and Child interventions). All CHWs, auxiliary nurses, and physicians working in the nine intervention areas were trained in improving case management skills by using the Government of India's IMNCI training modules. CHWs (Anganwadi workers) made postnatal home visits on days one, three, and seven to promote early and exclusive breastfeeding, delaying bathing, keeping the baby warm, cord care, and care seeking for illness. They assessed newborns for signs of illness at each visit and treated or referred them. Baseline characteristics were similar across intervention and control clusters. The primary outcomes reported are perinatal mortality, neonatal mortality, infant mortality and other newborn care-re-

lated outcomes.

A cluster-randomised controlled trial by [Darmstadt 2010](#) was conducted in Mirzapur, Bangladesh. Twelve unions were randomised to intervention or comparison arm. All women of reproductive age were eligible to participate. In the intervention arm, CHWs identified pregnant women; made two antenatal home visits to promote birth and newborn care preparedness; made four postnatal home visits to negotiate preventive care practices and to assess newborns for illness; and referred sick neonates to a hospital and facilitated compliance. Primary outcome measures were antenatal and immediate newborn care behaviours, knowledge of danger signs, care seeking for neonatal complications, and neonatal mortality.

A cluster-randomised controlled trial by [Gill 2011](#) used an unblinded design, birth attendants were cluster-randomised to intervention or control groups. The intervention had two components: training in a modified version of the neonatal resuscitation protocol, and single-dose amoxicillin coupled with facilitated referral of infants to a health centre. Control birth attendants continued their existing standard of care (basic obstetric skills and use of clean delivery kits). The groups were well balanced except that control birth attendants had lower schooling rates than the intervention birth attendants and more intervention than control birth attendants were divorced. The characteristics of infants and their mothers were similar between the groups, and were also similar to the birth attendants.

A cluster-randomised controlled trial was conducted in rural county of China ([Wu 2011](#)). The trial investigators developed and implemented a community-based prenatal care package to 1) test the optimal content of prenatal care for the context of rural China; 2) evaluate the effectiveness of such prenatal care on infant and maternal outcomes; 3) to describe the process of conducting a controlled study using community resources.

[Colbourn 2013](#) evaluated a rural participatory women's group community intervention and a quality improvement intervention at health centres via a two-by-two factorial cluster-randomised controlled trial conducted in rural areas of Malawi. The trial included pregnant women who were followed-up to two months after birth using key informants. Primary outcomes were maternal, perinatal and neonatal mortality.

[Fottrell 2013](#) is a cluster-randomised controlled trial conducted in nine intervention and nine control clusters of rural Bangladesh. The trial included women permanently residing in 18 unions and who gave birth during the months of the intervention. The intervention formed women's groups, which proceeded through a participatory learning and action cycle in which they prioritised issues that affected maternal and neonatal health and designed and implemented strategies to address these issues. The primary outcome assessed was neonatal mortality.

The Newhints cluster-randomised trial by [Kirkwood 2013](#) was undertaken in 98 zones in seven districts in the Brong Ahafo Region, Ghana. The trial trained community-based surveillance vol-

unteers to identify pregnant women in their community and to make two home visits during pregnancy and three in the first week of life to promote essential newborn-care practices, weigh and assess babies for danger signs, and refer as necessary. Primary outcomes were neonatal mortality and coverage of key essential newborn-care practices.

[Lewycka 2013](#) is a two-by-two factorial, cluster-randomised trial conducted in Mchinji district of Malawi. The trial randomly allocated 48 equal-sized clusters to four groups with a computer-generated number sequence. Twenty-four facilitators were trained and guided groups through a community action cycle to tackle maternal and child health problems. The trial further trained 72 volunteer peer counsellors who made home visits at five time points 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.

The cluster-randomised trial in Arusha, Tanzania ([Magoma 2013](#)) involved 16 health units (eight per arm). Nine hundred and five pregnant women at 24 weeks of gestation and above were recruited and followed up to at least one month postpartum. The intervention involved the introduction and promotion of birth plans by care providers during antenatal care (ANC) to prepare women and their families for birth and complication readiness. This included discussions on planned place of delivery, the importance of skilled delivery care for all women, transport arrangements to the delivery site or during an emergency, funding arrangements for delivery or emergency care services if needed, identification of possible blood donors, identification of a birth companion if desired and appropriate, and support in looking after the household while the woman was at the health facility. The primary outcomes included were skilled delivery care uptake, postnatal care utilisation.

[More 2012](#) is a cluster-randomised controlled trial conducted in 24 intervention and 24 control settlements in slums in Mumbai, India. In each intervention cluster, a facilitator supported women's groups through an action learning cycle in which they discussed perinatal experiences, improved their knowledge, and took local action. The primary outcomes assessed were perinatal care, maternal morbidity, and extended perinatal mortality.

The Good Start Saving Newborn Lives by [Nsibandwe 2013](#) conducted in KwaZulu-Natal, South Africa, was a community randomised trial that assessed the effect of an integrated home-visit package delivered to mothers by CHWs during pregnancy and post-delivery on uptake of PMTCT (Prevention of Mother to Child Transmission) interventions and appropriate newborn care practices. CHWs were trained to refer babies with illnesses or identified danger signs. The aim of this substudy was to assess the effectiveness of this referral system by describing CHW referral completion rates as well as mothers' health-care seeking practices. The cluster-randomised controlled trial by [Persson 2013](#) randomised maternity and health workers from a province in northern Vietnam into a participatory learning approach group or a control group. These people had, in their different professions,

important roles in their community's health and welfare. The trial looked at the impact of these participatory learning sessions on stillbirths, perinatal mortality and neonatal mortality over a three-year period. The main aim was to analyse the effect of facilitation of local maternal-and newborn stakeholder groups on neonatal mortality.

#### **Quasi-randomised/controlled clinical cluster trials**

[Bang 1999](#), was a cluster-controlled trial conducted in the Gadchiroli district of India (Maharashtra state) with the aim of assessing the impact on the neonatal mortality rate of a home-based neonatal care package for the management of sepsis. Female village health workers were trained to take histories of pregnant women, observe the process of labour, examine neonates, and record finding. Furthermore, they were given colour photographs of various neonatal signs for visual reference. In the first year of intervention they listened to pregnant women in the village, collected their data by home visits, observed labour and neonates. In the second year, female village health workers were trained in home-based management of neonatal illnesses, and in the last year, health education of mothers and grandmothers about care of pregnant women and of neonates was added to the programme. Training of TBAs and management of pneumonia in children was not given by the project team in the control area, where these tasks were done by the government health services and the Integrated Child Development Service (ICDS) workers. The crude birth rate in the last year was 24.4/1000 population in the intervention cluster and 23.7/1000 population in the control cluster. The total live births in intervention and control clusters were 1108 and 979 respectively. Baseline characteristics of intervention and control arms were similar statistically. The neonatal mortality rates at the baseline in the intervention arm were 62/1000 live births and among the control group was 57.7/1000 live births. On the other hand, perinatal mortality rates among the intervention and control arms were 68.3/1000 births and 64.9/1000 births, respectively.

[Syed 2006](#) was a cluster quasi-randomised controlled study that evaluated the impact of essential newborn-care interventions in Saving Newborn Lives project areas of Dhaka, Bangladesh. The projects targeted primarily pregnant mothers and family decision-makers, such as husbands, mothers-in-law, caregivers (both formal and informal), and village leaders. The study gathered data from 6435 women. The primary activities for the programme included: training, service-delivery behaviour change communication, advocacy to improve care during delivery, postnatal and neonatal periods, and referral of sick newborns. The frontline health workers, paramedics, and local TBAs were trained on newborn care following the cadre-specific training modules. A behaviour change-communication strategy was developed based on findings of formative research and interventions-targeted messages on key 'healthful' behaviours, such as birth-preparedness, clean delivery, early and exclusive breastfeeding, immediate drying and warming, and major

danger signs. The postnatal visit strategy included two or more contacts with the mother and newborn by the health workers at home within the first week of delivery, with the first visit within three days. Programme planning, development of materials, implementation, and routine monitoring were carried out jointly by Save the Children-USA, partner NGOs, and professional bodies to ensure adequate support and sustainability. On the other hand, no such interventions were delivered in control clusters. The baseline characteristics of women and newborn in the project-implemented areas were similar to control areas, except for mothers' education.

### Settings

Six studies were conducted in Bangladesh (Azad 2010; Bari 2006; Baqui - Sylhet 2008; Darmstadt 2010; Fottrell 2013; Syed 2006), six in India (Bang 1999; Bhandari 2012; Kumar 2008; More 2012; Srinivasan 1995; Tripathy 2010), four in Pakistan (Bhutta 2008; Bhutta 2011; Jokhio 2005; Midhet 2011), two in Malawi (Colbourn 2013; Lewycka 2013), one each in Tanzania (Magoma 2013), Ghana (Kirkwood 2013), Nepal (Manandhar 2004), Zambia (Gill 2011), China (Wu 2011), South Africa (Nsibande 2013), Vietnam (Persson 2013), and Greece (Kafatos 1991). In total, 19 studies were from Asia (Azad 2010; Bang 1999; Baqui - Sylhet 2008; Bari 2006; Bhandari 2012; Bhutta 2008; Bhutta 2011; Darmstadt 2010; Fottrell 2013; Jokhio 2005; Kumar 2008; Manandhar 2004; Midhet 2011; More 2012; Persson 2013; Srinivasan 1995; Syed 2006; Tripathy 2010; Wu 2011), six from Africa (Colbourn 2013; Gill 2011; Kirkwood 2013; Lewycka 2013; Magoma 2013; Nsibande 2013), and one from Europe (Kafatos 1991).

### Outcomes

These studies reported multiple effect measures and many did not specify a primary outcome. We extracted relevant outcomes (reported as events and population size along with risk ratio (RR) and odds ratio and categorised them for the analysis according to the results detailed below and in Table 1; Characteristics of included studies.

### Excluded studies

We excluded 66 studies because they did not meet our criteria for inclusion.

Eleven studies (Carlo 2010; Dongre 2009; Hounton 2009; Kawuwa 2007; Le 2009; Meegan 2001; Moran 2006; McPherson 2006; McPherson 2007; O'Rourke 1998; Xu 1995) were neither randomised nor quasi-randomised controlled trials. Janowitz 1988 and Rotheram-Borus 2011a did not mention randomisation process. Five trials were quasi-experimental studies (Alisjahbana 1995; Baqui-CARE INDIA 2008; Foord 1995; Greenwood 1990;

Ronsmans 1997). In addition, one study (Mosha 2005) was excluded as it employed stepped wedge randomisation in which the intervention is provided to all the participants (either in intervention and control) by the end of the trial.

We excluded a further 47 studies because the types of interventions were not related to scope of this review.

Baqui 2009 was a validation study in which newborns were assessed to validate trained CHWs' recognition of signs and symptoms of newborn illness during home visits in rural Bangladesh. In Bashour 2008, registered midwives visited mothers at home during the postpartum period. Miller 2012 studies the impact of TBA training. Althabe 2012 studies the impact of corticosteroid; and it was a published protocol. Owais 2011 studies the impact of mother knowledge on the uptake of immunisation.

Bolam 1998 studied the impact of maternal health education on infant care and postnatal family planning. In the Cooper 2002 study, mothers were given interventions relating to infant management, including sleep regimens, crying and feeding. The El-Mohandes 2003 study was a parenting education program. The Johnson 1993 study was a parenting intervention during the first year of a child's life and the impact on child development. The Katz 2001 study investigated strategies for retaining low-income mothers in a parenting intervention study.

In three studies, women received behavioural interventions (Joseph 2005; Joseph 2006) or behavioural and psychosocial interventions (Joseph 2009) for reducing risk factors affecting reproductive outcome (such as smoking, intimate partner violence, or depression). Similarly, Kiely 2007 employed behavioural interventions for reducing depression and smoking during pregnancy. Subramanian 2005 looked at the impact of psychosocial risks on pregnancy and infant outcomes. Wiggins 2004 measured the impact of postnatal social support on the incidence of child injury, maternal smoking and maternal depression. In El-Mohandes 2005, the intervention related to decreasing intimate partner violence during pregnancy and in El-Mohandes 2008, the intervention related to psychosocial and behavioural risks during pregnancy.

The purpose in Koniak-Griffin 1991 was to evaluate the effects of a nursing intervention program on affecting behavioural dimensions of maternal role attainment in adolescents. Similarly, in Koniak-Griffin 2000, adolescent mothers received interventions and the impact of the interventions was observed during the first year of the infant's life.

The Lumley 2006 study, mothers received interventions to decrease depression and improve their physical health and in MacArthur 2003, the use of symptom checklists and the Edinburgh postnatal depression scale (EDPS) was used to identify and manage the clinical and psychological needs of postpartum women.

The Mullany 2007 trial was carried out in urban Nepal and examined whether involving male partners in antenatal health education had an impact on birth preparedness and maternal healthcare



utilisation. In the [Omer 2008](#) study, LHWs visited women before and after birth to discuss safe maternal practices, such as attending antenatal check ups, not doing heavy work during pregnancy, and giving colostrum to the baby after it was born. In [Gokcay 1993](#), the performance of midwives was compared with the performance of LHWs and in the study by [Mannan 2008](#), CHWs visited postpartum women in order to promote breastfeeding.

[Rahman 2008](#) and [Rahman 2012](#) measured the impact of adding cognitive behavioural therapy (CBT) to the usual care provided by CHWs on maternal depression and infant outcomes. [Roman 2009](#) investigated whether a combination of Medicare-enhanced prenatal service and nurse CHW care reduced depressive symptoms and stress compared with usual community care. In [Turan 2003](#), interventions were given to nulliparous women at the healthcare facility level. In [Turan 2001](#), the authors presented the results of three studies investigating methods for including men in antenatal education in Istanbul, Turkey. [Basinga 2011](#) evaluated the effect of performance-based payment of healthcare providers (payment for performance) on use and quality of child and maternal care services in healthcare facilities in Rwanda.

The [Purdin 2009](#) and [Jennings 2010](#) studies focused their interventions in healthcare facility settings. [Shaheen 2003](#), measured the effectiveness of CHWs' second visit at home for postpartum women. [Borghi 2005](#) and [Morrell 2000](#) measured the cost-ef-

fectiveness analysis of participatory interventions with women's groups to improve birth outcomes. There were studies that delivered single interventions only, for example, to improve exclusive breastfeeding among expectant mothers ([Bhandari 2004](#); [Bhandari 2003](#); [Haider 2000](#); [McInnes 2000](#)). [Gloyd 2001](#), assessed the model of TBA deployment in the community. [Hartley 2011](#) presented the results of three studies investigating methods for including men in antenatal education in Istanbul, Turkey. On the other hand, [Thompson 2011](#) and [Dix-Cooper 2012](#) studied the effect of wood smoke on neonatal and perinatal outcomes.

[Nassar 2014](#) assessed the impact of automated call monitoring for flu in pregnancy and [Ramsey 2013](#) assessed the impact of a referral system on CHWs.

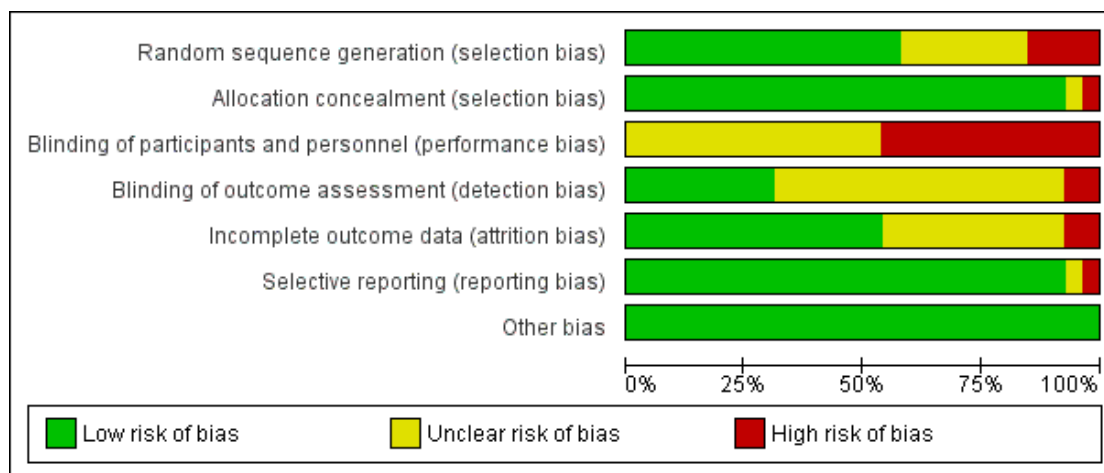
Please refer to the [Characteristics of excluded studies](#) table for more details.

### Risk of bias in included studies

Of these 26 included studies, one was quasi-randomised (a research design in which participants are assigned to treatment (i.e. they receive the intervention being studied and comparison groups through a process that is not random) and one was a controlled trial.

Please refer to [Figure 1](#) and [Figure 2](#) for more details.

**Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.**



**Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Azad 2010	?	+	-	?	+	+	+
Bang 1999	-	+	?	?	?	+	+
Baqui - Sylhet 2008	+	+	-	+	+	+	+
Bari 2006	?	?	?	?	?	+	+
Bhandari 2012	+	+	?	+	+	+	+
Bhutta 2008	?	+	?	+	?	+	+
Bhutta 2011	+	+	?	+	+	+	+
Colbourn 2013	+	+	-	-	-	+	+
Darmstadt 2010	+	+	-	-	+	+	+
Fottrell 2013	?	+	?	?	?	+	+
Gill 2011	+	+	-	?	+	+	+
Jokhio 2005	+	+	-	?	+	+	+
Kafatos 1991	+	+	?	?	?	+	+
Kirkwood 2013	+	+	?	+	+	+	+
Kumar 2008	+	+	-	?	+	+	+
Lewycka 2013	+	+	-	+	+	+	+
Magoma 2013	+	+	-	?	+	+	+
Manandhar 2004	-	+	-	?	+	+	+
Midhet 2011	+	+	?	?	?	+	+
More 2012	?	+	?	+	+	+	+
Nsiband 2013	?	+	?	?	?	-	+
Persson 2013	+	+	-	?	-	?	+
Srinivasan 1995	-	+	?	?	?	+	+
Syed 2006	-	-	?	?	?	+	+
Tripathy 2010	?	+	-	?	+	+	+
Wu 2011	+	+	?	+	?	+	+

## Allocation

In this review, 14 (Baqui - Sylhet 2008; Bhandari 2012; Bhutta 2011; Colbourn 2013; Darmstadt 2010; Gill 2011; Jokhio 2005; Kirkwood 2013; Kumar 2008; Lewycka 2013; Magoma 2013; Midhet 2011; Persson 2013; Wu 2011) had no issues with sequence generation while allocation concealment was not an issue as all clusters were randomised at once. While, individually-randomised controlled trials also reported method of selection and allocation concealment (Kafatos 1991; Srinivasan 1995). Srinivasan 1995 was at high risk for method of random sequence generation.

## Blinding

Among these studies, six clearly mentioned that masking was unachievable because of the nature of study (Azad 2010; Baqui - Sylhet 2008; Colbourn 2013; Manandhar 2004; Persson 2013; Tripathy 2010), while one study (Jokhio 2005) mentioned that the CHWs who recorded outcomes could not be blinded to the intervention status of the women but were not made aware of the main study objective or the outcome measured for the planned comparison. In Baqui - Sylhet 2008 Bhutta 2008; Bhutta 2011; Bhandari 2012; Kirkwood 2013; Lewycka 2013; More 2012; Tripathy 2010 data collectors were independent of implementers.

## Incomplete outcome data

Among all studies, attrition and exclusion were clearly mentioned in 14 studies (Azad 2010; Baqui - Sylhet 2008; Bhandari 2012; Bhutta 2011; Darmstadt 2010; Gill 2011; Jokhio 2005; Kirkwood 2013; Kumar 2008; Lewycka 2013; Magoma 2013; More 2012; Manandhar 2004; Tripathy 2010).

## Selective reporting

We found the majority of the included studies to be free from selective reporting. In two studies (Nsibande 2013; Persson 2013) they did not report outcomes based on intervention and control group and in Nsibande 2013, they did not report if any cluster was lost from the trial and the study did not report adjusted results.

## Other potential sources of bias

We found all of the included studies Azad 2010; Bang 1999; Baqui - Sylhet 2008; Bari 2006; Bhandari 2012; Bhutta 2008; Bhutta 2011; Colbourn 2013; Darmstadt 2010; Fottrell 2013; Gill 2011; Jokhio 2005; Kafatos 1991; Kirkwood 2013; Kumar 2008; Lewycka 2013; Magoma 2013; Manandhar 2004; Midhet 2011; More 2012; Nsibande 2013; Persson 2013; Srinivasan 1995; Syed 2006; Tripathy 2010; Wu 2011) to be free from other biases.

## Cluster-randomised trials

Cluster-randomised trials were assessed for additional biases such as recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually-randomised trials, which further helped in identifying the quality of the trials. All the factors for biases were reported adequately except for baseline imbalances observed in a few trials. In Azad 2010, baseline imbalances were measured in terms of mothers education and age. In Gill 2011, the educational status of TBAs was different. The majority of the trials did not mention if any clusters were lost from the trial at the end.

## Effects of interventions

There are a few additional secondary outcomes reported in this update which were not the part of the protocol or earlier version of the review (Lassi 2010). These outcomes are:

- iron/folate supplementation;
- tetanus toxoid immunisation;
- use of clean delivery kits;
- wrapping babies within 30 minutes;
- delays bathing for six hours;
- clean cord care.

## Primary outcomes

### Maternal mortality

Community-based intervention packages showed a possible effect on reducing maternal mortality (average risk ratio (RR) 0.80; 95% confidence interval (CI) 0.64 to 1.00; 11 studies, n = 167,311; random-effects,  $\text{Tau}^2 = 0.03$ ,  $I^2 = 20\%$ ,  $\text{chi}^2$  P value 0.06 (Analysis 1.1)) and the results were heterogeneous.

We also looked for the effect of different modalities and interventions delivered at varying time periods on reducing maternal mortalities. We found a non-significant impact on maternal mortality for intervention packages that consisted of building support groups (average RR 0.83; 95% CI 0.56 to 1.22, six studies, n = 101,198; random-effects,  $\text{Tau}^2 = 0.11$ ,  $I^2 = 52\%$ ), packages that mobilised the community and made home visits during antenatal and postnatal periods (average RR 0.72; 95% CI 0.49 to 1.06; three studies, n = 43,233; random-effects,  $\text{Tau}^2 = 0.00$ ,  $I^2 = 0\%$ ); or packages that provided training to TBAs, who then made home visits during the antenatal and intrapartum period (average RR 0.74; 95% CI 0.45 to 1.21; two studies, n = 22,880; random-effects,  $\text{Tau}^2 = 0.00$ ,  $I^2 = 0\%$ ).

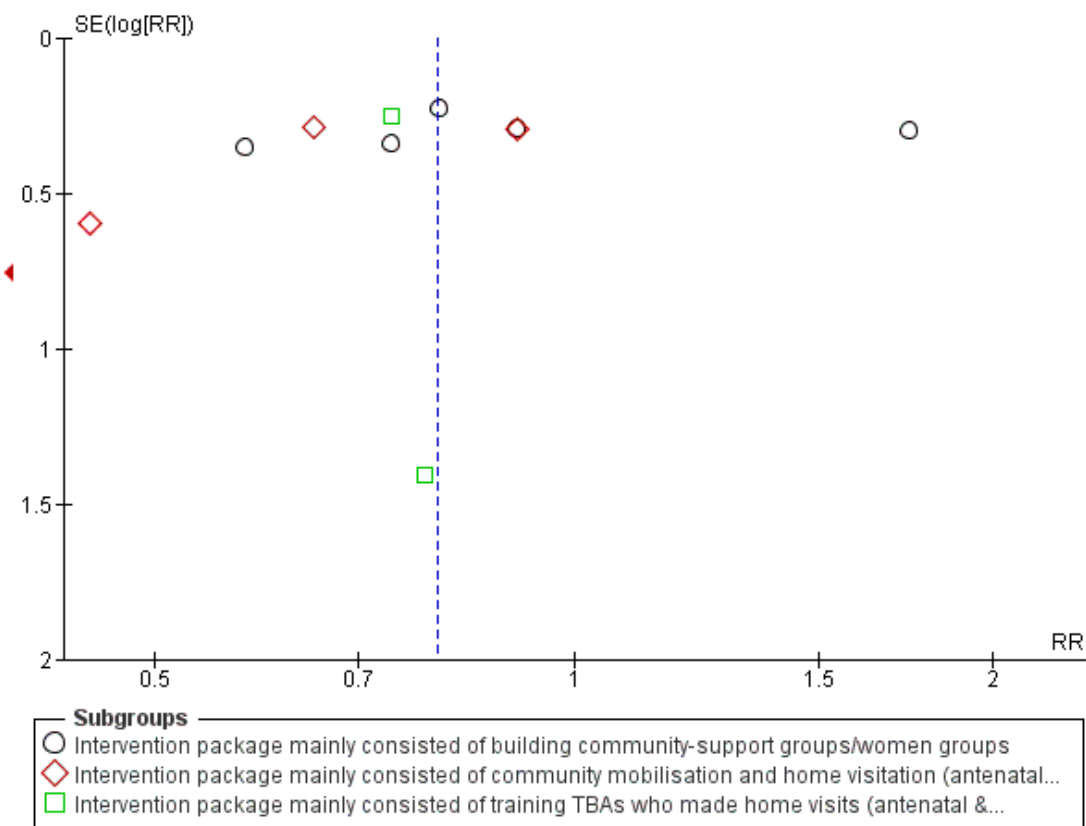
No subgroup differences or interactions were found ( $\text{Chi}^2$  P value 0.86,  $I^2 = 0\%$ ).

We performed a sensitivity analysis of low risk of bias studies, which had used adequate sequence generation and allocation con-

cealment methods, and again, found a significant impact of a community-based intervention package on maternal mortality (average RR 0.76; 95% CI 0.57 to 1.00; five studies, n = 95,946; random-effects,  $\text{Tau}^2 = 0.00$ ,  $I^2 = 0\%$  (Analysis 1.26)).

We found 11 studies that reported maternal mortality, so we assessed them for small-study effect (publication bias). For maternal mortality, we observed that the majority of studies fell at the top, however, only at the left on the lower side that indicates slight risk of publication bias. (Figure 3).

**Figure 3. Funnel plot of comparison: I Community-based intervention versus control, outcome: I.I Maternal mortality.**



**Neonatal mortality**

Community-based intervention packages were associated with a significant reduction in neonatal mortality by 25% (average RR 0.75; 95% CI 0.67 to 0.83; 21 studies, n = 302,464) and the results were heterogenous ( $\text{Tau}^2 = 0.06$ ,  $I^2 = 85\%$  and  $\text{Chi}^2$  P value

< 0.001 (Analysis 1.2)).

When the impact was evaluated separately for packages that built support and advocacy groups, and those that provided home visitation along with community mobilisation, there was a significant impact on reducing average neonatal mortality by 16% (av-

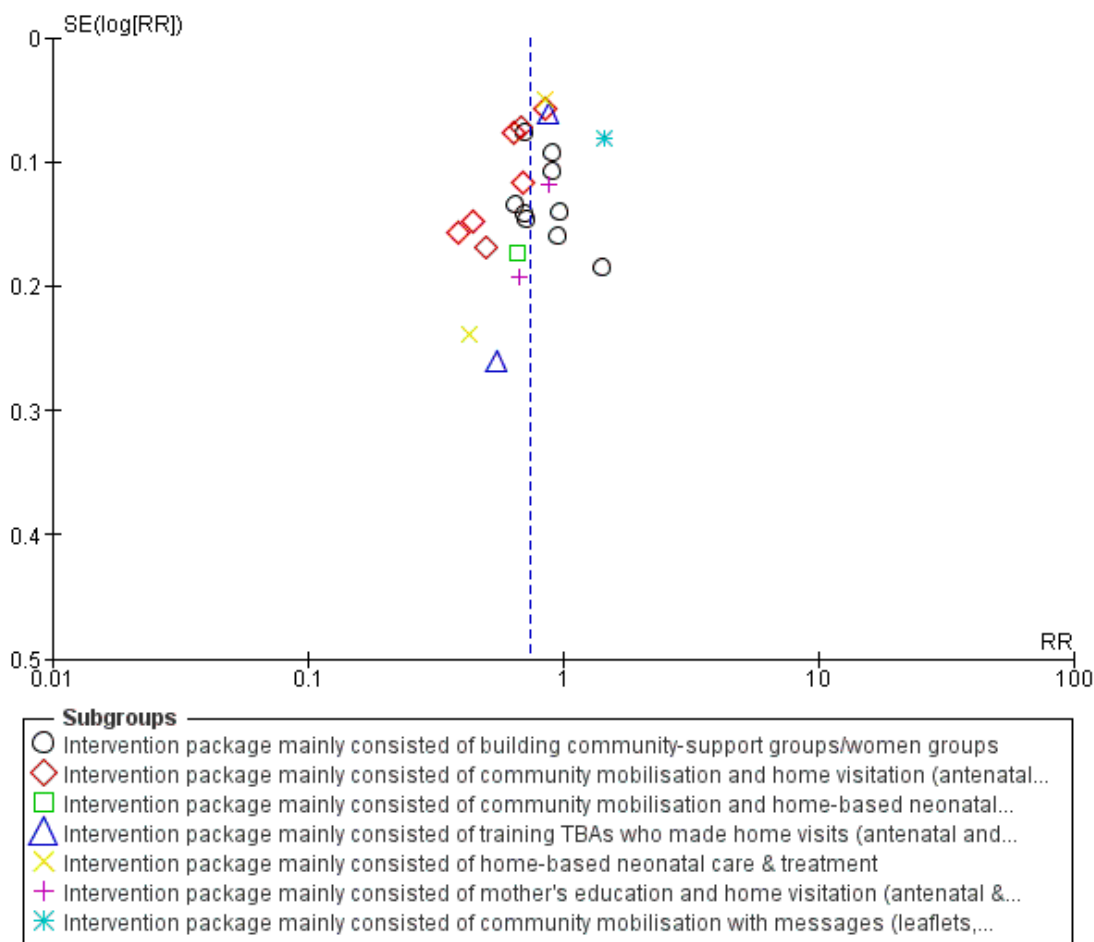
average RR 0.84; 95% CI 0.73 to 0.96; 9 studies, n = 155,509; random-effects,  $\text{Tau}^2 = 0.02$ ,  $I^2 = 62\%$  and  $\text{Chi}^2$  P value 0.006) and 40% (average RR 0.60; 95% CI 0.49 to 0.72, random-effects (five studies, n = 50,052), ( $\text{Tau}^2 = 0.05$ ,  $I^2 = 85\%$  and  $\text{Chi}^2$  P value < 0.001)). We found no evidence of reduced neonatal mortality when home-based neonatal care and sepsis management were delivered as a part of a package (average RR 0.63; 95% CI 0.32 to 1.22; two studies, n = 62,567; random-effects); however, significant impact was found when packages provided community mobilisation along with home-based neonatal treatment (RR 0.66; 95% CI 0.47 to 0.93; one study, n = 4248). Conversely, no impact was found when TBAs were trained and asked to make home visits (average RR 0.74; 95% CI 0.48 to 1.16; two studies, n = 22,860; random-effects,  $\text{Tau}^2 = 0.07$ ,  $I^2 = 67\%$ ), when mothers were given

health education at home (average RR 0.80; 95% CI 0.63 to 1.02; two studies, n = 3072; random-effects,  $\text{Tau}^2 = 0.01$ ,  $I^2 = 25\%$ ), and also when community mobilisation was added with messages in the form of leaflets, and banners (RR 1.44; 95% CI 1.23 to 1.69; one study, n = 4156).

Significant subgroup differences or interactions were found ( $\text{Chi}^2$  P value < 0.001,  $I^2 = 89.8\%$ ).

We performed a sensitivity analysis of low risk of bias studies, which had used adequate sequence generation and allocation concealment methods, and also found a significant 30% reduction in neonatal mortality (average RR 0.70; 95% CI 0.59 to 0.83; eight studies, n = 115,262; random-effects,  $\text{Tau}^2 = 0.06$ ,  $I^2 = 83\%$  (Analysis 1.27)). We did not find any obvious asymmetry in the funnel plot for total neonatal mortality (Figure 4).

**Figure 4. Funnel plot of comparison: I Community-based intervention versus control, outcome: 1.2 Neonatal mortality.**



### Early neonatal mortality

Results were also significant when impact was estimated for early neonatal mortality (average RR 0.67; 95% CI 0.58 to 0.77; 11 studies,  $n = 131,017$ ; random-effects) although the results were heterogenous ( $Tau^2 = 0.04$ ,  $I^2 = 75\%$  and  $Chi^2$  P value  $< 0.001$ ) (Analysis 1.3).

On subgroup analysis, we found significant impact of community-support groups/women's groups (average RR 0.76; 95% CI 0.64 to 0.90; five studies,  $n = 92,022$ ; random-effects,  $Tau^2 = 0.02$ ,  $I^2 = 61\%$ ); community mobilisation along with antenatal and postnatal home visitation (average RR 0.63; 95% CI 0.49 to 0.79; four studies,  $n = 34,433$ ; random-effects,  $Tau^2 = 0.06$ ,  $I^2 = 84\%$ ); home-based neonatal care (RR 0.45; 95% CI 0.28 to 0.72; one study,  $n = 2087$ ) and training of TBAs who made home visits during antenatal and intrapartum period (average RR 0.56; 95% CI 0.32 to 0.98; one study,  $n = 2475$ ) on early neonatal mortality. No subgroup differences or interactions were found ( $Chi^2$  P value 0.14,  $I^2$  44.6%).

### Late neonatal mortality

Results were significant when impact was estimated for late neonatal mortality (average RR 0.74; 95% CI 0.65 to 0.86; 11 studies,  $n = 148,822$ ; random-effects,  $Tau^2 = 0.02$ ,  $I^2 = 32\%$ ) (Analysis 1.4). On subgroup analysis, we found a significant impact of packages that consisted of training TBAs who made home visits during the antenatal and intrapartum period on the reduction of late neonatal deaths (average RR 0.67; 95% CI 0.48 to 0.92; three studies,  $n = 31,759$ ; random-effects,  $Tau^2 = 0.04$ ,  $I^2 = 34\%$ ); and community mobilisation along with antenatal and postnatal home visitation by CHWs (average RR 0.70; 95% CI 0.62 to 0.80; two studies,  $n = 22,054$ , random-effects,  $Tau^2 = 0.00$ ,  $I^2 = 0\%$ ). Whereas, community-support groups and women's groups (average RR 0.84; 95% CI 0.67 to 1.05; five studies,  $n = 92,922$ ; random-effects,  $Tau^2 = 0.02$ ,  $I^2 = 33\%$ ) and home-based neonatal care (RR 0.31; 95% CI 0.09 to 1.07; one study,  $n = 2087$ ) had no impact on late neonatal mortality.

No subgroup differences or interactions were found ( $Chi^2$  P value 0.27,  $I^2$  23.5%).

### Secondary outcomes

#### Perinatal mortality

The community-based intervention package also played a role in reducing perinatal mortality. The percentage reduction for perinatal mortality was 22% (average RR 0.78; 95% CI 0.70 to 0.86, 17 studies,  $n = 282,327$ ; random-effects,  $Tau^2 = 0.04$ ,  $I^2 = 88\%$ ) (Analysis 1.5)) and the results were heterogenous.

There was a significant direction of effect when packages included community mobilisation through building community support and advocacy groups (average RR 0.88; 95% CI 0.82 to 0.95, eight studies,  $n = 155,585$ ; random-effects,  $Tau^2 = 0.00$ ,  $I^2 = 36\%$ ), community mobilisation and home visitation (average RR 0.64; 95% CI 0.54 to 0.77; four studies,  $n = 35,946$ ; random-effects,  $Tau^2 = 0.04$ ,  $I^2 = 89\%$ ), and home visitation by trained TBAs (average RR 0.71; 95% CI 0.65 to 0.78; two studies,  $n = 23,022$ ; random-effects,  $Tau^2 = 0.00$ ,  $I^2 = 0\%$ ). Conversely, home visitation for home-based neonatal care (RR 0.69; 95% CI 0.41 to 1.17; two studies,  $n = 62,644$ ,  $Tau^2 = 0.13$ ,  $I^2 = 90\%$ ), and home visitation by trained midwives (average RR 1.08; 95% CI 0.95 to 1.23; one study,  $n = 5130$ ) had no impact on perinatal deaths. Significant subgroup differences or interactions were found ( $Chi^2$  P value  $< 0.001$ ,  $I^2$  89.6%).

We also performed a sensitivity analysis of low risk of bias studies, which had used adequate sequence generation and allocation concealment methods, and found a significant 27% average reduction in perinatal mortality (RR 0.73; 95% CI 0.65 to 0.82; six studies,  $n = 87,629$ , random-effects,  $Tau^2 = 0.01$ ,  $I^2 = 65\%$ ) (Analysis 1.28)).

#### Stillbirths

Community-based intervention packages showed a 19% reduction in stillbirths (average RR 0.81; 95% CI 0.73 to 0.91; 15 studies,  $n = 201,181$ ; random-effects) and the results were heterogenous ( $Tau^2 = 0.03$ ,  $I^2 = 66\%$  and  $Chi^2$  P value  $< 0.001$ ) (Analysis 1.6).

On subgroup analysis, we found significant impact of packages that consisted of community mobilisation and home visitation during antenatal and postnatal period (average RR 0.76; 95% CI 0.68 to 0.85; three studies,  $n = 33,689$ ; random-effects,  $Tau^2 = 0.0$ ,  $I^2 = 0\%$ ); training midwives who made home visits (RR 0.54; 95% CI 0.41 to 0.72; one study,  $n = 5,130$ ) and home-based neonatal care (average RR 0.59; 95% CI 0.38 to 0.93; one study,  $n = 2164$ ). Results were non-significant when packages consisted of building support groups or women's groups for community mobilisation (average RR 0.94; 95% CI 0.84 to 1.06; seven studies,  $n = 136,646$ ; random-effects,  $Tau^2 = 0.01$ ,  $I^2 = 44\%$ ); training TBAs and their home visitation (average RR 0.79; 95% CI 0.54 to 1.14; two studies,  $n = 23,022$ ; random-effects,  $Tau^2 = 0.05$ ,  $I^2 = 50\%$ ); and home visitation and mother's education (RR 0.45; 95% CI 0.11 to 1.84; one study,  $n = 530$ ).

Significant subgroup differences or interactions were found ( $Chi^2$  P value 0.003,  $I^2$  72.3%).

We also performed a sensitivity analysis of low risk of bias studies, which had used adequate sequence generation and allocation concealment methods, and found a significant 26% reduction in stillbirths (average RR 0.75; 95% CI 0.69 to 0.82; four studies,  $n = 67,948$ ; random-effects,  $Tau^2 = 0.00$ ,  $I^2 = 0\%$ ) (Analysis 1.29)).

### Maternal morbidity and complications during pregnancy

Community-based intervention packages managed to reduce maternal morbidity on average by 25% (RR 0.75; 95% CI 0.61 to 0.92; four studies, n = 138,290; random-effects,  $\text{Tau}^2 = 0.02$ ,  $I^2 = 28\%$  (Analysis 1.8)).

When the effect of community-based intervention was estimated for complications of pregnancy, it had no impact in reducing any of the complications during pregnancy, including eclampsia (RR 0.74; 95% CI 0.43 to 1.27; one study, n = 19,525 (Analysis 1.12)), puerperal sepsis (average RR 0.84; 95% CI 0.65 to 1.08; one study, n = 19,525; (Analysis 1.11)), and spontaneous abortion (RR 0.81; 95% CI 0.55 to 1.18; one study, n = 19,525 (Analysis 1.13)). However, community-based packages decreased the incidence of haemorrhage (average RR 0.63; 95% CI 0.52 to 0.76; one study, n = 19,525 (Analysis 1.9)), and increased the incidence of obstructed labour (average RR 1.19; 95% CI 1.05 to 1.35; one study, n = 19,525 (Analysis 1.10)).

### Iron/folate supplementation and tetanus toxoid immunisation

Community-based intervention packages showed a possible effect on iron/folate supplementation in women during pregnancy (average RR 1.47; 95% CI 0.99 to 2.17; six studies, n = 71,622; random-effects,  $\text{Tau}^2 = 0.26$ ;  $I^2 = 99\%$  (Analysis 1.15)), however, significant impact was observed on tetanus immunisation (average RR 1.05; 95% CI 1.02 to 1.09; seven studies, n = 71,279; random-effects,  $\text{Tau}^2 = 0.00$ ;  $I^2 = 52\%$  (Analysis 1.16)).

### Referral to health facility

No impact was observed for referral to health facility for any complication during pregnancy (RR 1.50; 95% CI 0.95 to 2.36; one study, n = 19,525 (Analysis 1.14)). We also found that community-based intervention packages had a non-significant impact on healthcare seeking for maternal morbidities (average RR 1.63; 95% CI 0.39 to 6.85; two studies, n = 25,059; random-effects,  $\text{Tau}^2 = 0.95$ ,  $I^2 = 89\%$  (Analysis 1.24)); however, it had a positive impact on healthcare seeking for neonatal morbidities (average RR 1.42; 95% CI 1.14 to 1.77, random-effects (nine studies, n = 66,935)), ( $\text{Tau}^2 = 0.09$ ,  $I^2 = 92\%$  (Analysis 1.25)).

### Skilled birth attendance and institutional deliveries

Interventions had no impact on increasing birth attendance by a healthcare provider overall (average RR 1.45; 95% CI 0.66 to 3.17; eight studies, n = 96,302; random-effects,  $\text{Tau}^2 = 1.23$ ,  $I^2 = 99\%$  (Analysis 1.18)), but had significant impacts on improving rates for institutional deliveries (average RR 1.20; 95% CI 1.04 to 1.39; 14 studies, n = 147,890; random-effects,  $\text{Tau}^2 = 0.05$ ,  $I^2 = 80\%$  (Analysis 1.17)).

### Use of clean birth delivery kits

Intervention packages improved the usage of clean delivery kits by 82% in home births (average RR 1.82; 95% CI 1.10 to 3.02; four studies, n = 54,254; random-effects,  $\text{Tau}^2 = 0.23$ ,  $I^2 = 90\%$  (Analysis 1.19)).

### Birthweight and breastfeeding rates and other neonatal care outcomes

Community-based intervention packages failed to show any impact on improving mean birthweight (mean difference (MD) 0.01 kg; 95% CI -0.04 to 0.06; two studies, n = 1050; fixed-effects,  $I^2 = 0\%$  (Analysis 1.7)). However, it showed a statistically significant impact on initiation of breastfeeding within an hour of birth (average RR 1.93; 95% CI 1.55 to 2.39; 11 studies, n = 72,464; random-effects,  $\text{Tau}^2 = 0.14$ ,  $I^2 = 98\%$  (Analysis 1.21)). Exclusive breastfeeding rates at six months of age were not reported in any study.

Community-based intervention packages did not improve other neonatal care outcomes such as wrapping the baby within 30 minutes (average RR 0.95; 95% CI 0.76 to 1.19; four studies, n = 54,274; random-effects,  $\text{Tau}^2 = 0.00$ ,  $I^2 = 0\%$  (Analysis 1.20)); delayed bathing within six hours (average RR 1.22; 95% CI 0.77 to 1.92; two studies, n = 9826; random-effects,  $\text{Tau}^2 = 0.10$ ,  $I^2 = 94\%$  (Analysis 1.22)); and clean cord care (average RR 0.99; 95% CI 0.77 to 1.27; two studies, n = 20,888; random-effects,  $\text{Tau}^2 = 0.01$ ,  $I^2 = 42\%$  (Analysis 1.23)).

### Infant's weight for age and height for age

Infant's weight for age and height for age Z scores at six months of age were not reported in any of the included studies.

## DISCUSSION

This updated review evaluates the effectiveness of community-based intervention packages and reported its impact on maternal, perinatal and neonatal outcomes. Prior to this review, other reviewers have generated evidence from reviewing community-based antenatal, intrapartum and postnatal intervention trials from developing countries and recommended their inclusion in community-based neonatal programs based on their effectiveness (Bhutta 2005). Another review by Haws et al evaluated neonatal care packages in terms of their content, impact, efficacy (implementation under ideal circumstances), effectiveness (implementation within health systems), and cost (Haws 2007) with no attempt to look at their direct effects on reducing neonatal mortality and morbidity outcomes. Recently, a review by Christopher et al (Christopher



2011) has evaluated the impact of community-based curative interventions (via community health workers (CHWs)) on child mortality.

### Summary of main results

This systematic review of cluster-randomised, randomised controlled trials and quasi-randomised controlled trials aimed to provide evidence of the effectiveness of community-based interventions packages on maternal, perinatal and neonatal morbidities, mortality and improving health outcomes.

We found a paucity of eligible studies that implemented interventions (generally as care packages) specifically addressing and reporting maternal outcomes. Our meta-analysis found that community-based intervention packages may have a possible effect on reducing maternal mortality, although the pooled result just crossed the line of no effect. The possible reason for these insignificant findings might be inadequate sample size to detect meaningful change in maternal mortality. In addressing maternal mortality impacts, very large sample sizes are required for producing reliable estimates; as in this comparatively rare event, omission of only a few cases can have a disproportionately distorting effect on the maternal mortality ratio. However, significant reductions were also seen in maternal morbidity (by 25%) as a consequence of the implementation of community-based interventional care packages.

The evidence of the impact of community-based intervention packages is robust, with consistent evidence of reduction in neonatal deaths. We observed a 25% reduction in overall neonatal deaths from the studies reviewed. The findings from this pooled analysis also demonstrate an impact of community interventions on reducing stillbirths by 19% and perinatal mortality by 22%.

In our subgroup analysis, we found that community-based packages that disseminated education and promoted awareness related to birth and newborn care preparedness based on building community-support groups/women's groups were best for reducing total and early neonatal deaths. On the other hand, packages that comprised community mobilisation and education strategies and home visitation by CHWs managed to reduce neonatal, perinatal deaths and stillbirths, possibly with the reason that these strategies focused on women in the antenatal period and on early newborn care, management and referrals of sick newborns. On similar grounds, when community mobilisation was added to home-based neonatal care, it significantly reduced total neonatal deaths by 44% (one study). This is not surprising as it focused on therapeutic aspects of management of neonatal illnesses and infections and the majority (more than 50%) of planned neonatal visits was within the first week of life. The visitation of traditional birth attendants (TBAs) with midwives showed significant impact on reducing stillbirths by 46%, whereas when TBAs made home visits alone it did not show any impact on reducing stillbirths. The result, at the same time, should be interpreted with caution as the evidence for midwife is derived from one study compared to two

studies on TBAs.

Packaged interventional care also improved neonatal care outcomes like breastfeeding, and healthcare seeking for neonatal morbidities, etc; however, the paucity of studies precluded robust estimation of pooled effects. We managed to conduct a meta-analysis of studies reporting initiation of breastfeeding within an hour of birth (early breastfeeding), which showed that interventions consisting of antepartum newborn care and breastfeeding education to mothers doubled rates of initiation of breastfeeding. A commentary (Jana 2009) on review findings for interventions for promoting the initiation of breastfeeding also suggested that educational strategies during the antenatal period (including breastfeeding education, along with other components of essential newborn care) and maternal support are likely to have the greatest impact on early initiation of breastfeeding.

### Overall completeness and applicability of evidence

Notably, most of the reviewed studies, when implemented, neglected to document the complete description and characteristics of the CHWs deployed, especially the level and amount of supervision provided to those workers, which could have helped us in identifying the importance of this factor and its association with other outcomes. This information would be of great relevance to policy and practice. Additional information on the initial level of education of CHWs, midwives and TBAs, provision of refresher training, mode of training (balance of practical/theoretical sessions) would have provided greater assistance in understanding the threshold effect, if any, of these factors on CHW performance in community settings. Importantly, community ownership and supervision of CHWs and midwives is a key characteristic that is insufficiently described and analysed in the available literature.

### Quality of the evidence

The review included 26 randomised or quasi-randomised controlled trials, covering a wide range of intervention packages and settings. Assessment of risk of bias in these studies suggests concerns regarding insufficient information on sequence generation and regarding failure to adequately address incomplete outcome data, particularly from cluster/individually randomised controlled trials. We therefore performed sensitivity analyses for the primary outcomes based on the randomisation process. For cluster-randomised trials, we considered the additional biases such as recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually-randomised trials; which further helped in identifying the quality of the trials.

### Potential biases in the review process

We planned an a-priori subgroup analysis for mortality outcomes, but the majority of the heterogeneity was found in mortality out-



comes. Therefore, findings need to be interpreted with caution. A number of groups showed significant statistical heterogeneity and the sources of this remain unclear.

Many of the factors for subgroup analysis mentioned at the very outset of the review, could not be performed as the majority of the studies failed to provide this information.

### Agreements and disagreements with other studies or reviews

This review is an updated version of an earlier review (Lassi 2010) and in this version we strictly limited our data to randomised and quasi-randomised studies. A recent review that assessed women's groups practising participatory learning and action cycle also reported its beneficial impact on reducing neonatal (23%) as well as maternal deaths (37%) (Prost 2013). Our findings also agreed with the findings reported on home visitation by CHWs and reduction in neonatal deaths by Gogia 2010.

## AUTHORS' CONCLUSIONS

### Implications for practice

We believe that our review offers encouraging evidence of the value of integrating maternal and newborn care in community settings through a range of strategies that work, many of which can be packaged effectively for delivery through a range of CHWs. While the importance of skilled delivery and facility-based care for maternal care cannot be denied, our review provides encouraging evidence that the benefits of community-based strategies may extend across the continuum of maternal and newborn care. The most successful packages were those that emphasised involving family members through community support and advocacy groups and community mobilisation and education strategies, provision of care through trained CHWs via home visitation, and strengthened proper referrals for sick mothers and newborns.

### Implications for research

Notwithstanding these findings, this analysis largely derives from a limited number of effectiveness trials, as most studies were conducted in efficacy settings. Also, the bulk of the data was from studies conducted in Asia, with very limited information from sub-Saharan and central African settings. Thus, there is a clear need for additional research at an appropriate scale and in the right settings. There is also a need for high-quality randomised controlled trials that employ stringent methods to ensure quality.

Given the rapid rise in healthcare costs, and the imperative of reaching hard-to-reach communities, it has become crucial to focus on developing cost-effective and affordable ways to prevent disease and promote health in community settings. Although this was not one of the main objectives of this review, it plays a fundamental role in selecting and bundling intervention packages for scaling up and particularly in tailoring interventions to available health system resources. Only a few studies reported the actual costs incurred for providing interventions for saving one life or the cost of one averted death. Therefore, cost-effectiveness is a priority area for research for the future and researchers should facilitate cost-effectiveness meta-analysis by collecting and reporting cost-effectiveness data in a standardised format (e.g. costs per lives saved or disability-adjusted life years averted).

## ACKNOWLEDGEMENTS

We would like to acknowledge Dr Batool A Haider (BAH), who drafted the protocol, designed the original eligibility and the data extraction forms and also took part in the first review publication.

As part of the pre-publication editorial process, this review has been commented on by two peers (an editor and referee who is external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies *[ordered by study ID]*

#### Azad 2010

Methods	This was a cluster-randomised controlled trial conducted in Bangladesh. 18 clusters in 3 districts were randomly assigned to either intervention or control. Analysis was by intention-to-treat	
Participants	Women of reproductive age, mothers-in-law, adolescents. Total of 30,952 births and 29,889 live births were reported during the trial period	
Interventions	<p><b>Intervention arm</b> In intervention clusters a woman facilitator convened 18 groups monthly to support action learning for women, and to develop and implement strategies to address maternal and newborn health problems. Implemented a participatory learning and action cycle in which they identified and prioritised problems, then formulated strategies, implemented, monitored and finally evaluated the process. Intervention group was again divided into 2 according to the trained TBAs for asphyxia or not</p> <p><b>Control arm</b> Control group was not provided with participatory learning groups</p>	
Outcomes	Miscarriage, stillbirth, neonatal mortality and maternal mortality	
Notes		
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "Within each district, the intervention team randomly allocated unions 4 to intervention or control, with three intervention and three control unions per district" Comment: insufficient information to permit judgement.
Allocation concealment (selection bias)	Low risk	Quote: "Table 1 shows baseline characteristics of intervention and control clusters gathered in a retrospective survey. We noted differences in maternal education, maternal age, and household assets between intervention and control unions, with a greater proportion of mothers in the intervention unions with no education and no household assets. Mothers in intervention unions were also more likely to be younger than mothers in control unions"

**Azad 2010** (Continued)

		Comment: since it was a cluster-randomised trial, allocation concealment should not be an issue as in this design all the clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "The intervention and participants were not blinded to group allocation"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exclusion (0%) and attrition (14.2%) was reported along with their reasons None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	The study appears to be free of selective reporting.
Other bias	Low risk	Study appears to be free from other biases

**Bang 1999**

Methods	This was a clustered-controlled trial done in Gadchiroli district of India. Intervention was implemented in 39 villages and 47 villages were kept as control. Village women with 5 to 10 years of schooling who were willing were chosen to be VHW. Population characteristics at baseline in intervention and control area were similar
Participants	All pregnant women, neonates and grandmothers in study villages. Total numbers of live births during the trial period were 8192
Interventions	<p><b>Intervention arm</b></p> <p>Training of female VHWs to take histories, observe labour, examine neonate and record findings with the help of colour photographs for visual reference</p> <p>Training of VHWs in home-based management of neonatal illnesses including pneumonia</p> <p>Health education of mothers and grandmothers about care of pregnant women and of neonates (nutrition in pregnancy, initiating early and exclusive breastfeeding, prevention of infection, temperature maintenance, importance of weight gain, recognising danger signs or symptoms in neonates and seeking immediate help from a health worker</p> <p><b>Control arm</b></p> <p>Training of TBAs and management of pneumonia in children was not given by project team in the control area, where these tasks were done by the government health services and the ICDS workers</p>
Outcomes	Neonatal mortality rate, infant mortality rate, perinatal mortality rate, stillbirth rate

Notes	Supplementary feeding was provided to children, pregnant and lactating women, diarrhoea and ARI infection in children by ICDS. For this review we will compare the outcomes of 3rd year with the control	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Quote: "Intervention was implemented in 39 villages and 47 villages were kept as control" Comment: probably not done.
Allocation concealment (selection bias)	Low risk	Quote: "Population characteristics at baseline in the intervention and the control area were similar" Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information about to permit any judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information about to permit any judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Number of pregnant women excluded and attrition not mentioned nor their reasons
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study appears to be free from other biases.

## Baqui - Sylhet 2008

Methods	This was a cluster-randomised controlled trial done in 3 rural subdistricts (Beanibazar, Zakiganj, Kanaighat) of Sylhet district of Bangladesh. 24 clusters were randomly assigned to 1 of 2 intervention arms. Baseline household survey to enumerate ever-married women, maternal and newborn care knowledge and practices and neonatal mortality was done. CHW identified pregnancies and provided intervention package. Interim sample household surveys were done to measure intervention inputs, coverage and changes in key newborn care practices in all 3 study arms	
Participants	All pregnant women during the intervention were eligible to participate. Baseline characteristics of participants in all arms were similar. Data were reported from 1760 live births in home-care arm	
Interventions	<p><b>Intervention arm</b></p> <p>Intervention 1: HC model with training of CHWs in BCC and ENC. CHWs visited pregnant women in antenatal and postnatal period to promote birth/newborn care preparedness, provide iron folate supplements and to counsel on breastfeeding issues. Also included home screening/management/referral of sick newborns</p> <p>TBA training on cleanliness during delivery, maternal danger signs, and newborn care. Specific recruitment of volunteer community-resource people to improve attendance at community meetings, and care seeking for maternal and neonatal complications</p> <p>Intervention 2: CC model: community facilitators (males and females mobilisers separately) mobilised community for issues related to mother and child</p> <p><b>Control arm</b></p> <p>Families in the comparison arm received the usual health services provided by the government, non-government organisations, and private providers. Refresher training sessions for management of maternal and newborn complications were provided for GHWs in all 3 study arms. Projahnmo staff ensured adequate supplies of antibiotics for treatment of newborn infections at government subdistrict hospitals, which served residents in all 3 study arms. For tetanus-toxoid vaccination in all study arms and for provision of iron and folic acid supplements in the community-care and comparison arms, they relied on existing government mechanisms</p>	
Outcomes	Change in rate of neonatal mortality, stillbirth, abortion, antenatal visits from trained providers, use of iron and folic acid supplements, use of clean cord cutting instruments, delays in newborn first bath, and breastfeeding within 1 hour of birth and tetanus-toxoid immunisation coverage	
Notes	Refresher training sessions for management of maternal and newborn complications were provided GHWs in all 3 study arms In this review, HC and CC models are separately analysed with control arm	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "each cluster [was] randomly assigned to one of the two intervention arms to the comparison arm with computer-generated pseudo-random number sequence

**Baqui - Sylhet 2008** (Continued)

		without stratification or matching” Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: “Mother’s age and education, birth order, child’s sex, and household wealth were similar at baseline across study arms for a sample of all women who had a live-birth during 2002” Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design as all clusters are randomised
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: “the nature of intervention meant masking was unachievable” Comment: not done.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “team of data collectors, supervisors, and researchers who had no role in the implementation of the intervention mapped and listed...”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exclusion data were not reported nor reasons. Attrition (15%) was mentioned but reasons were not mentioned None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study appears to be free from other biases

**Bari 2006**

Methods	The cluster-randomised trial has 2 arms: an intervention arm with CHWs delivering a package of maternal and newborn-care interventions in the home and a comparison arm. Mirzapur upazila has 13 unions, with a population of around 24,000 each; of these, 6 were randomly allocated to each study arm, excluding the 1 urban union
Participants	Pregnant women, mother of neonates and sick newborns participated. The total of 792 sick newborns were assessed during the study period
Interventions	<b>Intervention arm</b> 36 CHWs were recruited and provided 1 month of initial training to equip them to provide a package of maternal and newborn care. These CHWs had a minimum of 10th grade education and resided in the population they would serve. Each CHW was responsible for about 4000 people. The CHWs carried out bi-monthly pregnancy



	surveillance and registration of MWRA and made home-visits in the third and the eighth month of pregnancy to counsel families on BNCP. After delivery, the CHWs made home-visits to promote evidence-based domiciliary newborn care and to identify and refer sick newborns and mothers on day 0 (day of birth), 3, 6, and 9. Care-seeking for sick newborns through health education of families, identification and referral of sick newborns in the community by CHWs, and strengthening of neonatal care in Kumudini Hospital, Mirzapur <b>Control arm</b> In the control arm, interventions by CHW were not intervened while they were served by the same hospital	
Outcomes	Newborn sickness and referrals to newborn sickness.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "Mirzapur upazila has 13 unions, with a population of around 24,000 each; of these, 6 were randomly allocated to each study arm, excluding the one urban union" Comment: insufficient information to permit judgement.
Allocation concealment (selection bias)	Unclear risk	Comment: since it is a cluster trial, allocation concealment should not be an issue as in this design as all clusters are randomised. Study did not report if baselines characteristics across intervention and control clusters were similar
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Bhandari 2012**

Methods	A cluster-randomised trial was conducted in catchment areas of 18 Primary Health Centres in Haryana, India	
Participants	Women including pregnant women, neonates and children.	
Interventions	<p><b>Intervention arm</b>  <b>IMNCI training</b> AWW, ANMs, TBAs and private practitioners.            These sessions covered neonatal conditions requiring referral, pre-referral treatment, problems that can be managed at home and components of ENC. The management of diarrhoea, pneumonia, conditions requiring referral, and pre-referral treatment as well as appropriate complementary feeding practices for older children were also covered.  <b>Improved availability of medicines</b> was achieved by establishing medicine stores with the VLCs which were replenished every 3 months by a study supply officer.  <b>Supervision of health workers and CHWs</b> was strengthened in the intervention areas. The study recruited 2 supervisors per 30,000 population in consultation with the local government; they conducted monthly visits to the ASHAs and AWWs, observed women's group meetings, and attended monthly government review meetings</p> <p><b>Control arm</b>            AWWs and ANMs were in place in the control areas and continued to provide the usual services. However, they were not trained to conduct IMNCI activities such as home visits for newborns and community management of sick infants and children. Management of sick infants and children remained in the hands of private providers and physicians at government facilities</p>	
Outcomes	Perinatal deaths, neonatal deaths, post neonatal deaths, infant deaths, danger signs of severe illness, local infections, diarrhoea, general danger signs, pneumonia, diarrhoea	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "An independent epidemiologist generated 10 stratified randomisation schemes to allocate the clusters to intervention or control groups." .. "We selected one of the remaining seven allocation schemes by a computer generated random number" Comment: adequately done.
Allocation concealment (selection bias)	Low risk	Quote: "Table 2. shows the characteristics of the intervention and control clusters; the top half of the table shows the characteristics obtained from the baseline survey done in 2006. Whereas the proportion of mothers who had never been to school and the population of the clusters were similarly distributed between inter-

		<p>vention and control groups, the intervention clusters were further away from the highway (15.3 v 7.0 km, P = 0.045) and had a somewhat higher proportion of home births (71.9% v 65.9%, P = 0.272) than the control clusters. The bottom half of the table shows the characteristics of the families of recruited births. These were similar in the intervention and control groups, except that a higher proportion of families in the intervention group had a below poverty line card (18.4% v 10.6%, P = 0.004) suggesting a lower economic status, and the proportion of illiterate mothers was lower in the intervention group (37.8%v 41.7%, P = 0.374)”</p> <p>Comment: since it is a cluster trial, allocation concealment should not be an issue as in this design as all clusters are randomised. Although differences were there in the baseline characteristics, study stratified clusters on randomisation</p>
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “We allocated all households in the intervention and control areas to one of the 110 study field workers who were not involved with IMNCI implementation. The workers visited the allocated households every month to identify new pregnancies and inquire about the outcome of previously identified pregnancies”
Incomplete outcome data (attrition bias) All outcomes	Low risk	12.3% were lost to follow up in intervention clusters and 14% were lost to follow up in control clusters None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Reported all the outcomes defined in methods.
Other bias	Low risk	Study seems to be free from other biases.

**Bhutta 2008**

Methods	This was a pilot clustered-randomised trial from Hala and Matiari subdistricts of Sindh, Pakistan. 24 village clusters were identified of primary care facility. Out of those, 8 clusters were randomly selected for this pilot study. 4 districts chosen to receive intervention were matched with 4 control clusters for population size, and birth and neonatal mortalities rates. More household in intervention clusters and electricity (87% vs 70%) and water pumps (67% vs 56%). All other baseline characteristics were comparable	
Participants	Women of reproductive age and pregnant women participated. Total number births during the trial period were 5134 among which 4815 were live births	
Interventions	<p><b>Intervention arm</b></p> <ul style="list-style-type: none"> <li>- Standard curriculum (for all villages): promotion of antenatal care, iron and folate use during pregnancy, immediate newborn care, cord care, promotion of exclusive breast-feeding</li> <li>- Additional curriculum (for intervention village clusters): promotion of maternal nutrition and rest, early breastfeeding (within first hour) and colostrum administration (avoidance of prelacteal feeds), thermoregulation, HC of LBW infants, treatment of pneumonia with oral TMP-SMX, recognition of danger signs, training in group counselling and communication strategies</li> <li>- LHWs were encouraged to visit all pregnant women twice during pregnancy, within 24 hours of birth and 4 times in the first postnatal month and were encouraged to link up with local <i>Dais</i>.</li> <li>- LHWs were supported by the creation of voluntary community health committee which helped in conducting community education group sessions</li> </ul> <p><b>Control arm</b></p> <p>In communities in which the intervention package was not implemented, the LHW training programme continued as usual, with regular refresher sessions, but no attempt was made to link LHWs with the <i>Dais</i>.</p>	
Outcomes	Stillbirths, early neonatal deaths, late neonatal deaths, total neonatal deaths, perinatal deaths	
Notes	Intervention was supported by the creation of voluntary community health committees. Special training in basic and intermediate newborn care was offered to all public-sector rural health centre and hospital-based medical and nursing staff, irrespective of whether the intervention was implemented in their community. All healthcare facilities were provided with basic and intermediate newborn care equipment courtesy of the United Nations Children's Fund (UNICEF) in Sindh	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "eight clusters were randomly selected". Comment: insufficient information to permit judgement.

**Bhutta 2008** (Continued)

Allocation concealment (selection bias)	Low risk	Quote: “On average, more households in the intervention clusters had electricity (87% versus 70% in the control clusters) and water pumps (67% versus 56%, respectively) but overall stillbirth, perinatal and neonatal mortality rates were comparable” Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collectors were independent of implementers.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Bhutta 2011**

Methods	This is a cluster-randomised trial of community-based interventions to reduce neonatal deaths due to birth asphyxia, neonatal sepsis and prematurity in rural areas of Pakistan
Participants	Pregnant women, other family members. Total number of births in trial period were 24,095 and live births were 23,033
Interventions	<p><b>Intervention arm</b></p> <p>LHWs = along with the basic training (for control group) they received additional training on recognition of high-risk pregnancies and referrals to LBW infants. TBAs = along with the basic training (for control group) they received additional training on promotion of LHW attendance at births</p> <p>To create awareness in the community and at the household level in control and intervention clusters, female and male support groups (health committees) were formed/strengthened. The LHW formed female health committee and male activists formed male health committees in the LHW catchment area. Meetings of both groups were arranged with the assistance of the community health committee and LHWs on monthly basis for dissemination of health messages and education related to maternal and newborn health and problems. Separate community group education sessions for mothers, mothers-in-laws, married women especially with pregnancy and fathers, fathers-in-laws</p>

	<p>for health education of the communities were conducted through the support groups in the LHW catchment area using educational material such as flip charts on antenatal care, identification of danger signs related to pregnancy and recognition of simple risk factors for high-risk pregnancies and births (these include severe maternal malnutrition, illness, short stature, previous perinatal deaths etc), birth preparedness (transport, money, skilled birth attendant, facility), essential and immediate newborn care and recognition of danger signs and sepsis with early and appropriate referral</p> <p><b>Control Arm:</b> LHW training programme continued as usual, with regular refresher sessions, but no attempt was made to link LHWs with the <i>Dais</i>. They were however provided with regular refresher training according to the standard national LHW program curriculum including monthly debriefing sessions in public sector health facilities</p>	
Outcomes	<p>Neonatal mortality rates, perinatal mortality rates, birth asphyxia-related neonatal mortality rates, neonatal mortality rates in LBW infants, neonatal mortality rates due to sepsis</p>	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>Quote: "Twenty-six such clusters with available LHWs were identified in the district, 8 of which were involved in the pilot study. Two further clusters were excluded as they had very few LHWs. The full cluster-RCT was thus implemented in the remaining 16 clusters"; "used restricted, stratified randomisation to allocate clusters to the intervention and control arms (21). Three strata (comprising 2, 6 and 8 clusters) were identified based on their size and the number of LHWs per 1000 population. We identified 126 random allocations which resulted in similar population sizes in the 2 arms....From this list of "balanced" allocations we selected one scheme at random"</p> <p>Comment: probably done.</p>
Allocation concealment (selection bias)	Low risk	<p>Quote: "The overall population covered by the LHW programme in the study area at baseline was 77%, and the number of resident LHWs per 10 000 population was similar in intervention and control clusters (table 3). Baseline stillbirth and neonatal mortality rates were slightly lower in the intervention group than in the control group"</p> <p>Comment: since it is a cluster-randomised</p>

**Bhutta 2011** (Continued)

		trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “established 13 independent data collection teams who undertook quarterly visits to all villages in intervention and control clusters” Comment: data collectors were independent of implementers.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was 12.4% in intervention clusters and 10.8% in control clusters None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Colbourn 2013**

Methods	The interventions were tested by 2 trials combined in a factorial design producing 4 different groupings of intervention combinations conducted in Malawi	
Participants	Pregnant women and their newborns.	
Interventions	<p><b>Intervention arm</b> Community mobilisation: to identify and prioritise maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies</p> <p><b>Control arm</b> No interventions.</p>	
Outcomes	Neonatal mortality, perinatal mortality, stillbirths, early neonatal mortality, late neonatal mortality, maternal mortality, institutional deliveries	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>

**Colbourn 2013** (Continued)

Random sequence generation (selection bias)	Low risk	Quote: "clusters were allocated to each, both or no intervention with a random number sequence generated in Stata" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "To ensure concealment of intervention allocation, identification numbers were assigned for each cluster and a random number generated for each. The random numbers were sorted in ascending order, and a new 'order' variable generated. This sequence was used to allocate to each of the four intervention groups in each district. The sequence was concealed until interventions were assigned" Comment: probably done; however baseline differences in characteristics table were not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Given the nature of the interventions, neither participants nor those administering the interventions were blinded to group assignment"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Those assessing the outcomes were also not blinded to group assignment"
Incomplete outcome data (attrition bias) All outcomes	High risk	Insufficient information to permit judgement. 9 clusters from control and 10 in total from intervention arms were excluded. Reported adjusted results
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Darmstadt 2010**

Methods	A cluster-randomised controlled trial was conducted in Mirzapur, Bangladesh. 12 unions were randomised to intervention or comparison arms
Participants	All women of reproductive age were eligible to participate.



Interventions	<p><b>Intervention arm:</b> in the intervention arm, CHWs identified pregnant women; made 2 antenatal home visits to promote BNCP; made 4 postnatal home visits to negotiate preventive care practices and to assess newborns for illness; and referred sick neonates to a hospital and facilitated compliance</p> <p><b>Control arm:</b> newborns in the comparison arm received the usual health services provided by the government, non-governmental organisations and private providers</p>	
Outcomes	Antenatal and immediate newborn care behaviours, knowledge of danger signs, care seeking for neonatal complications, and neonatal mortality	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "The remaining population of about 292,000 was divided into 12 rural unions, which were randomly allocated to either comparison or intervention arm using a computer-generated pseudo-random number sequence without stratification or matching" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: ".....which were randomly allocated to either comparison or intervention arm using a computer-generated pseudo-random number sequence without stratification or matching"; "There were no differences in the rates of miscarriage and still-birth between the two arms. Enrolment rates did not vary across unions" Comment: probably done.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Blinding was unachievable given the nature of the intervention"
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "data...were collected by separate interviewers who were trained..."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was 3.8% and 4.2% from intervention and control arm respectively and their reasons were given None of the clusters were lost from the trial and study reported adjusted results

**Darmstadt 2010** (Continued)

Selective reporting (reporting bias)	Low risk	Study seems to be free from selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Fottrell 2013**

Methods	A cluster-randomised controlled trial in 9 intervention and 9 control clusters conducted in rural Bangladesh	
Participants	Women permanently residing in 18 unions in 3 districts and accounting for 19,301 births during the final 24 months of the intervention	
Interventions	<p><b>Intervention arm</b> Women's groups at a coverage of 1 per 309 population that proceed through a participatory learning and action cycle in which they prioritise issues that affected maternal and neonatal health and design and implement strategies to address these issues</p> <p><b>Control arm</b> No intervention.</p>	
Outcomes	Neonatal mortality, cause specific mortality, hygienic home delivery practices, newborn thermal care, and breastfeeding practices	
Notes		

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomised". Comment: insufficient information to permit judgement.
Allocation concealment (selection bias)	Low risk	Quote: "Table 1 shows cluster-level summaries of the baseline characteristics of the study population, including cluster size. Sociodemographic indicators and primary and secondary outcome indicators were similar in both arms, irrespective of the inclusion of tea-garden residents. Baseline comparisons did not significantly change with the inclusion of tea-garden residents, except that more women with a primary education were in the intervention clusters than in the control clusters and that fewer Hindus were in the intervention clusters (10.4%) than in the control clusters (17.6%)"

**Fottrell 2013** (Continued)

		Comment: since it was a cluster-randomised trial, allocation concealment should not be an issue as in this design all the clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement. None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	The study appears to be free of selective reporting.
Other bias	Low risk	Study appears to be free from other biases

**Gill 2011**

Methods	This is a prospective, cluster-randomised and controlled effectiveness study conducted in Lufwanyama, an agrarian, poorly developed district located in the Copperbelt province, Zambia	
Participants	Birth attendants were randomly allocated (1:1) to intervention or control groups	
Interventions	<p><b>Intervention arm:</b> the intervention had 2 components: training of TBAs in a modified version of the neonatal resuscitation protocol, and single dose amoxicillin coupled with facilitated referral of infants to a health centre</p> <p><b>In control arm:</b> control birth attendants continued their existing standard of care (basic obstetric skills and use of clean delivery kits)</p> <p><b>Both arms:</b> both intervention and control birth attendants were issued with 1 clean delivery kit per birth. Each kit contained a plastic delivery sheet, a cord cutter, cotton cord ties, 1 pair of latex gloves, soap, and a candle with matches (for deliveries at night)</p>	
Outcomes	Stillbirths, all cause mortality, cause specific neonatal mortality	
Notes		
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>

Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was done by generating 120 allocation slips (60 intervention and 60 control), which were placed in an opaque container" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "Randomisation was done by generating 120 allocation slips (60 intervention and 60 control), which were placed in an opaque container"; "Table 1 summarises the baseline characteristics of the birth attendants. The groups were well balanced except that control birth attendants had lower schooling rates than the intervention birth attendants and more intervention than control birth attendants were divorced. The characteristics of infants and their mothers were similar between the groups (table 2)." Comment: probably done.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "unblinded". Comment: blinding is not an issue in cluster-randomised control trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition was 1.74% and reasons were given. None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study seems to be free from selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

## Jokhio 2005

Methods	This was a cluster-randomised controlled trial in Larkana, Sind, Pakistan. Larkana's 7 talukas were allocated to intervention or control groups using computer-generated procedure. TBAs registered pregnant women in their catchment area. TBAs were issued delivery kits from primary care centres. TBA visited each enrolled woman at least 3 times during pregnancy to check for danger signs. LHWs were trained to support the traditional attendants and data recording
Participants	19,525 pregnant women participated. The Larkana city and its immediate environs were excluded because of better access to healthcare services. Baseline maternal characteristics were similar for the study groups and across clusters with respect to all measured variables except years of education which were slightly greater among women in the control group
Interventions	<p><b>Intervention arm</b></p> <ul style="list-style-type: none"> <li>- Training of TBAs by obstetricians and female paramedics using picture cards containing advice on antepartum, intrapartum and postpartum care, conducting clean delivery, use of disposable delivery kit, referring women to emergency obstetrical care and care of the newborn</li> <li>- Reinforcement by TBAs to pregnant women to seek emergency obstetrical care if need arise</li> </ul> <p><b>Control arm</b></p> <ul style="list-style-type: none"> <li>- In controlled clusters TBAs were not provided any training and were not supplied with delivery kits. LHW provided normal monthly home visits to pregnant women and children</li> </ul>
Outcomes	Perinatal mortality, maternal mortality, major complication of pregnancy (haemorrhage, obstructed labour, puerperal sepsis, eclampsia, abortion), referral by TBA for emergency obstetrical care, type and place of delivery and delivery attendants
Notes	Obstetrical consultation was also provided by 2 teams from public-sector tertiary care centres in Larkana city. The delivery kit included sterilised disposable gloves, soap, gauze, cotton balls, antiseptic solution, an umbilical-cord clamp and a surgical blade. Maternal deaths were ascertained by LHW on the basis of oral reports

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "with a computerized-generated procedure Larkana's seven talukas were allocated to intervention or control groups" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "The baseline maternal characteristics were similar for the study groups and across clusters with respect to all measured variables except years of education, which were slightly greater among women in the control group (Table 2)" Comment: since it is a cluster-randomised

**Jokhio 2005** (Continued)

		trial, allocation concealment should not be an issue as in this design all clusters are randomised
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "LHW who recorded outcomes could not be blinded to the intervention status of the women but were not made aware of the main study objective or the outcome measured for the planned comparison" Comment: probably done.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgment
Incomplete outcome data (attrition bias) All outcomes	Low risk	21 women from intervention arm and 11 women from control arm loss to follow-up, (attrition: 0.16%), reasons for attrition not mentioned. Exclusion (18.5%) reasons were not reported Not mentioned if any of the cluster were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measure as per objectives
Other bias	Low risk	Study seems to be free from other biases.

**Kafatos 1991**

Methods	This is RCT conducted in Florina, Greece. 20 clinics were randomly divided into intervention and control. An intensive training course in nutrition counselling was established for the 10 nurses employed at intervention group clinics. Baseline biosocial data and anthropometric measurements were collated for each participant and each participant was given a standardised clinical examination. Dietary habits and nutrient intake were studied in depth in a subsamples. Food intake was assessed in both the groups by 24-hour dietary recall and food weighing inventory method at the beginning and every 4 weeks until delivery. Comparison was made for biochemical measurements between those participants tested during early pregnancy (< 21 weeks) and those tested during late pregnancy (> 32 weeks)
Participants	All pregnant women irrespective of their gestational age. Both groups differed in their baseline characteristics with respect to maternal height (greater in control group $P < 0.001$ ). 300 women from intervention clinics and 268 from control clinics were selected

Interventions	<p><b>Intervention arm</b> Nutrition education for women in intervention group was provided through home visits every 2 weeks. Women were educated about basics of nutrition during pregnancy for maternal and fetal health, including food sources, methods for selecting a balanced diet, practical techniques for improving their diet quality, encouragement to consume locally grown foods and to prepare and preserve foods</p> <p><b>Control arm</b> Health services were provided by government health services.</p>	
Outcomes	Biochemical measures: HB, serum iron, total iron binding capacity, $\beta$ -carotene, vitamin A, vitamin C, RBC glutathione reductase. Maternal and pregnancy outcomes: weight gain during pregnancy, birthweight, length at birth, head circumference, thoracic circumference, small-for-gestational age, gestational age, morbidity and mortality	
Notes	To ensure accuracy and consistency program's nurse coordinator accompanied each nurse on their home visits to observe data gathering and any associated problems	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "the county's 20 clinics were randomly divided into an intervention and a control group" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measure as per objectives
Other bias	Low risk	Study seems to be free from other biases.

**Kirkwood 2013**

Methods	The Newhints cluster-randomised trial was undertaken in 98 zones in 7 districts in the Brong Ahafo Region, Ghana.
Participants	Pregnant women and their newborns.
Interventions	<p><b>Intervention arm</b></p> <p>The core component is training the existing CBSVs to identify pregnant women and to conduct 2 home visits during pregnancy and 3 in the first week of life to address essential care practices, and to assess and refer very low birthweight and sick babies. CBSVs are supported by a set of materials, regular supervisory visits, incentives, sensitisation activities with TBAs, health facility staff and communities, and providing training for essential newborn care in health facilities</p> <p><b>Control arm</b></p> <p>Standard care.</p>
Outcomes	Neonatal deaths, coverage of key essential newborn care behaviours, antenatal-care visits, baby delivered in a facility, care-seeking, money saved for delivery or emergency, transport arranged in advance for facility, birth assistant for home delivery washed hands with soap, initiation of breastfeeding in less than 1 hour of birth, skin to skin contact, first bath delayed for longer than 6 hours, exclusive breastfeeding, and baby sleeping under bed net for 8 to 56 days

Notes

***Risk of bias***

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated restricted randomisation was then done in a one-to-one ratio by an independent epidemiologist using stratified sampling to ensure balance within districts and the four large towns" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "The Newhints zones were similar to the control zones at baseline for key outcomes (table 1) and for the socio-demographic characteristics of pregnant women" Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.



**Kirkwood 2013** (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “The surveillance consisted of home visits to all women of reproductive age (15-45 years) every 4 weeks by an independent group of resident research field workers”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approximatelt 10% of the participants were loss to follow up and the reason were similar Not mentioned if any of the cluster were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measure as per objectives
Other bias	Low risk	Study seems to be free from other biases.

**Kumar 2008**

Methods	This was a 3-arm cluster-randomised trial done in Shivgarh, India. A control group received usual services of government of India and NGO. In intervention areas community stakeholders, newborn stakeholders and households with immediate support groups were targeted. CHWs were recruited and received classroom-based and apprenticeship based field training on Knowledge, attitudes and practices about ENC, behaviour change management and trust building. Pregnant women were identified by <i>Saksham Sahayak</i> and 2 antenatal visits (60 and 30 days before expected delivery) and 2 postnatal visits (within 24 hours of birth and day 3) were carried out to implement intervention
Participants	Pregnant women, mother-in-law, other female members who played supportive role, male members including father-in-law and husband, family’s immediate support group included neighbours and relatives who influenced family behaviours and helped with delivery. Baseline characteristics of all 3 arms were comparable. Total of 3837 deliveries were analysed at the end
Interventions	<b>Intervention arm</b> <b>ENC:</b> intervention package consisted of home visits and group meetings of stake holders about birth preparedness, hygienic delivery and immediate newborn care including clean umbilical cord, skin care, thermal care including skin-to-skin care, breastfeeding and care seeking from trained providers. Messages were designed to promote newborn care practices to align with existing cultural values and traditions <b>ENC + Thermospot arm:</b> all intervention given in ENC arm plus thermo spot used to detect temperature of newborn <b>Control arm</b> Received the usual services of governmental and NGOs in the area
Outcomes	Miscarriages, stillbirths, neonatal deaths and maternal mortality (combined from both the intervention arms)

Notes	Volunteers from within the community called <i>Saksham Karia</i> played a key part in program advocacy, trust building and social legitimisations of changes in behaviour. No treatment was offered to sick neonates; however, they were advised to seek care at nearest health facility In this review, ENC and ENC +thermo spot arms were separately analysed with control arm	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "stratified cluster randomisation was done at John Hopkins University to allocate 39 clusters units randomly to the three study groups" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "Key baseline characteristics for the three study arms were similar (table 1)" Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "allocation was not masked; however, boundaries to limit communication between the two teams were closely monitored"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition (4.1%) was given along with its reasons. None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measure as per objectives
Other bias	Low risk	Study seems to be free from other biases.

Lewycka 2013

Methods	It was a 2 × 2 factorial, cluster-randomised trial in conducted in Rural Malawi
Participants	Women of child bearing age.
Interventions	<p><b>Intervention arm</b> 207 women's groups were established. Each was supported by a cluster facilitator through a community mobilisation action cycle of 20 meetings in 4 phases. 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</p> <p><b>Control arm</b> No intervention/routine care.</p>
Outcomes	Maternal mortality, neonatal mortality, perinatal mortality, infant mortality, exclusive breastfeeding and neonatal care outcomes
Notes	

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Random number generation was done in STATA 7.0, and each of the 48 clusters was allocated to one of four possible combinations of interventions" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "Due to the nature of the interventions, blinding of study participants to their allocation was not possible."; "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 primi gravidae in areas with women's group intervention only" Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Due to the nature of the interventions, blinding of study participants to their allocation was not possible"
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Analysts and trial monitors will be blinded to the study allocation until the definitive analysis is performed. Data will be

Lewycka 2013 (Continued)

		collected independently from intervention implementation, and no results will be fed back to inform the interventions”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Approximately 20% of the participants were loss to follow-up None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measure as per objectives
Other bias	Low risk	Study seems to be free from other biases.

Magoma 2013

Methods	Cluster-randomised trial in Ngorongoro district, Arusha region, Tanzania	
Participants	Pregnant women and their newborn.	
Interventions	<p><b>Intervention arm</b> The intervention involved the introduction and promotion of birth plans by care providers during ANC to prepare women and their families for birth and complication readiness. This included discussions on planned place of delivery, the importance of skilled delivery care for all women, transport arrangements to the delivery site or during an emergency, funding arrangements for delivery or emergency care services if needed, identification of possible blood donors, identification of a birth companion if desired and appropriate, and support in looking after the household while the woman was at the health facility. Strategies for overcoming barriers to accessing skilled delivery care and recognising danger signs during pregnancy, labour and the postpartum period were also discussed. Providers in the intervention units were given a birth plan implementation guide with instructions on how to assist women to formulate and achieve their birth plans</p> <p><b>Control arm</b> Standard care.</p>	
Outcomes	Skilled delivery care, postnatal care, care satisfaction.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: “The facilities were randomly assigned to the intervention or control arms in a 1:1 ratio using computer-generated random numbers by a statistician in Lon-

		don who had never visited the study district or study health units” Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: “All recruited women were successfully followed up. Approximately, 60% of women in both the intervention and control arms lacked formal education (Table 1) . Utilisation of health units for delivery in the antecedent pregnancy was also low (12.8% in the intervention vs. 14.3% in the control). Most women initiated ANC late in the second trimester.” Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: “The study did not allow blinding of either providers or women who participated in the study to the treatment allocation”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 1 participants from each arm was loss to follow-up. None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measure as per objectives
Other bias	Low risk	Study seems to be free from other biases.

## Manandhar 2004

Methods	This was a cluster-RCT conducted in Makwanpur district of Nepal. A VDC was taken as a unit of randomisation. 42 rural VDCs were matched into 21 pairs on the basis of geography, ethnicity and population. Between 1998-2000 local community leaders and interested parties were taken into confidence. MWRA were identified through a door-to-door baseline survey. A community surveillance system was put in place. It was responsible for monthly visits by local women for enumerations and to monitor pregnancy status of women in cohort. After identification of pregnancy interviews were carried out by VDC interviewer at 7 months of gestation and 1 month postpartum. All pregnancies occurring within the cohort were followed at least 6 weeks after delivery. In the first year facilitation team's skills were developed and groundwork was laid by exploring ideas about childbirth.
Participants	Inclusion criteria included age between 15 to 49 years, married, and potential to conceive within the period of study. Exclusion criteria were age under 15 or over 49 years, unmarried, permanently separated or widowed and no potential for conception within period of study. Total of 28,931 women were allocated in the intervention and control arms, among which 6053 pregnancies were reported while 6215 deliveries were analysed
Interventions	<p><b>Intervention arm</b> Monthly meetings of mother's groups to identify maternal and neonatal problems, prioritisation of problems, identification of possible solution, planning, implementation and monitoring those solutions and sharing information with others. Primary cycle consisted of series of 10 meetings</p> <p><b>Control arm</b> Participatory activities were not conducted in the control areas</p>
Outcomes	Neonatal mortality rate, perinatal mortality rate, antenatal care services usage, perinatal illness, birthing practices, healthcare seeking behaviour, newborn care practices, breast-feeding practices, infant mortality
Notes	Perinatal birth attendants were available in all localities. Health-service strengthening activities were undertaken in both intervention and control areas

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "allocated one cluster in each pair to either intervention or control on the basis of a coin toss" Comment: probably not done.
Allocation concealment (selection bias)	Low risk	Quote: "Table 2 presents baseline characteristics of intervention and control clusters. Although the median number of households per cluster was lower in control clusters, the total numbers of households and participants who became preg-

**Manandhar 2004** (Continued)

		nant were similar” Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: “because of the nature of intervention the trial allocation was not masked”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Exclusion (77%) was mentioned but reasons were not mentioned in the text. Attrition (7.4%) was mentioned along with its reasons None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study has mentioned data regarding all outcome measures as per objectives
Other bias	Low risk	Study seems to be free from other biases.

**Midhet 2011**

Methods	This was a cluster-randomised controlled trial implemented during 1998 to 2002 in 32 village clusters in Khuzdar, a rural district of Balochistan province in Pakistan
Participants	Women of reproductive age and their husbands.
Interventions	The IEEC for women was designed to increase awareness of safe motherhood and neonatal health. Each facilitator initially invited 10 to 12 women from close villages to participate in a support group. Local TBAs - who deliver over 90% of all births in the project area - were trained in clean home delivery and in recognising common obstetric and newborn emergencies. The project also facilitated timely referral and transportation of obstetric and newborn emergencies to the district hospital. A typical support group started with a discussion of the problems faced by women during pregnancy and childbirth. Participants were then asked to look at their booklets while listening to a cassette tape that guided them through the pictures in the booklet. The pictures formed part of the dramatised stories recorded on the tape, thus creating an audio-visual effect. The booklet covered the following topics: family planning; nutrition; preparation for pregnancy and delivery; and danger signs during pregnancy, delivery and postpartum. Typically, the booklet was finished in 6 sessions of 1 to 2 hours each, after which the participants were entitled to have their personal copy of booklet and audiocassette. The husbands’ IEEC was implemented in 8 village clusters randomly selected from the

	16 intervention clusters. Husbands' booklets and audiocassettes were designed after formative research with married men. Then in each village cluster, 20 to 30 male community volunteers were identified who distributed the materials among husbands of the women who had participated in the support groups	
Outcomes	Neonatal mortality, iron supplementation, tetanus immunisation	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: "Randomization took place separately within each of the three zones; equal numbers of village clusters were randomly allocated to the intervention or control sites (by blindly drawing village cluster names written on folded chits)" Comment: probably done.
Allocation concealment (selection bias)	Low risk	Quote: "Randomization took place separately within each of the three zones; equal numbers of village clusters were randomly allocated to the intervention or control sites (by blindly drawing village cluster names written on folded chits)"; "At the baseline survey, socioeconomic and demographic characteristics of married women in the three arms were similar (e.g., age, age at marriage, parity, number of living children and education levels of the woman and her husband) (Additional file 1). The three arms were also similar in socioeconomic variables at the follow-up survey, except that a higher proportion of households had electricity and telephone in the women's only IEEC intervention arm (not shown)" Comment: probably done.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit any judgement. However, blinding is not an issue in cluster-randomised trial
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit any judgement. However, blinding is not an issue in cluster-randomised trial



**Midhet 2011** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit any judgement. Not reported if any cluster were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study seems to be free from selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**More 2012**

Methods	A cluster-randomised controlled trial in 24 intervention and 24 control settlements covered a population of 283,000 in urban slums of Mumbai, India	
Participants	Pregnant, non-pregnant women and their newborn.	
Interventions	<p><b>Intervention arm</b></p> <p>The trial trained sakhi (friend) - a local woman with secondary education and leadership skills, preferably married with children. Her role was to conduct meetings with women, attend planning and supervision meetings, and support group action. After training, she began by profiling her settlement and building rapport with local stakeholders. She also attended regular training on a range of healthcare topics. Over about 6 months, she set up 10 women's groups, formative work having shown that women's mobility tended to be confined to their own alley. The groups met fortnightly and she met weekly with other sakhis and her supervisor. The intervention followed a 36-meeting cycle that was predetermined in general but developed iteratively in detail</p> <p><b>Control arm</b></p> <p>Standard care.</p>	
Outcomes	Stillbirth, neonatal mortality, perinatal mortality, antenatal care, institutional delivery, early and exclusive breastfeeding, or care-seeking	
Notes		

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "For equity across the wider initiative, randomisation was stratified by municipal ward. Eight slum clusters in the catchment areas of each of the 24 health posts involved in the City Initiative for Newborn Health were selected randomly from each of the 6 wards in the sampling frame, giving a total of 48 clusters. Four clusters per ward were allocated randomly

**More 2012** (Continued)

		to the intervention group, and four to the control group” Comment:insufficient information.
Allocation concealment (selection bias)	Low risk	Quote: “Allocation was not concealed because of the nature of the intervention”; “Table 1 summarizes cluster size and participant characteristics. There were insufficient births in nine clusters and we expanded their perimeters for subsequent years. Two clusters were reduced because of excess births. Numbers of households, population, and births were similar in intervention and control arms” Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: “Analysts were blind to allocation”.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Arround 16.5% of the participants from each arm was lost to follow up and the reasons for loss to follow-up were similar None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study seems to be free from selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Nsibande 2013**

Methods	Cluster-randomised unblinded active controlled trial from South Africa
Participants	All pregnant women aged 16 to 49 years who give informed consent for study participation
Interventions	<b>Intervention arm</b> 1. Antenatal visit 1 at home (which included provision of immunisations/micronutrient supplementation, highlighted the importance of VCT (linking this with the PMTCT programme and the benefits of testing to the mother), emphasise the importance of an-

	<p>tenatal care, appropriate infant feeding, exclusive breastfeeding in HIV negative women or women of unknown HIV status, for HIV positive women, assist with thinking about infant feeding options and provision of input regarding infant communication and the mother-infant relationship).</p> <p>2. Antenatal visit 2 at home (which included birth plans, place of birth, support during labour, care plans if returning to work; danger signs and emergency plans; follow up and re-emphasis on VCT, PMTCT, the key messages on appropriate infant feeding that were provided in antenatal visit 1; further discussion in terms of assisting with the implementation of chosen feeding option; and additional input on infant communication and the warning signs of postnatal depression).</p> <p>3. Postnatal visit 1 at home: 24-48 hours, 3-4 days, 10-14 days, 3-4 weeks, 7-8 weeks. (these included assessment of newborn? breathing, thermal care, colour, bleeding, neonatal eye care, checklist of danger signs, early recognition of illness (superficial or systemic) and help seeking).</p> <p>All intervention visits were delivered by community health workers targeting pregnant women and postnatal women and their newborns to provide essential maternal and newborn care</p> <p><b>Control arm</b> CBHW's in control clusters provide key information and support to the mother on how to obtain social welfare grants, particularly the Child Support Grant. The grant package in the control arm comprises 1 visit during the antenatal period to provide the necessary information regarding requirements for a grant application</p>	
Outcomes	HIV-free infant survival at 12 weeks postpartum, levels of exclusive and appropriate infant feeding at 12 weeks postpartum, better uptake of a postnatal clinic visit within 7 days of life, coverage of care and behavioural indicators (antenatal HIV testing, uptake of cotrimoxazole amongst HIV-exposed infants at 6 weeks, family planning uptake at 6 weeks), levels of maternal depression at 12 weeks postpartum	
Notes	The study reported comparison of infant completed referrals with those who did not complete	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "The trial consists of 30 randomized clusters (15 in each arm)" Comment: insufficient information to permit judgment.
Allocation concealment (selection bias)	Low risk	Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once. Study did not report if any of the baseline characteristic was different among intervention and control clusters at baseline

**Nsibande 2013** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit any judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit any judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit any judgement.
Selective reporting (reporting bias)	High risk	Study did not report outcomes based on intervention and control group Not reported if any cluster was lost from the trial and study did not report adjusted results
Other bias	Low risk	Study seems to be free from other biases.

**Persson 2013**

Methods	This is cluster-randomised controlled trial conducted in Quang Ninh province, located in the northeast of Vietnam	
Participants	Maternal and Newborn Health Groups (MNHG) were constituted in each intervention commune (by directives from the Provincial Health Bureau). These groups consisted of 8 members: 3 CHC staff (physician, midwife, nurse); 1 of the VHWs of the commune; 1 population collaborator, the chairperson, or vice chairperson of the commune (having responsibility for health in the commune); and 2 WU representatives (from village and commune levels). The facilitators primarily used the plan-do-study-act cycle in mobilizing the groups in identifying and prioritising local perinatal health problems and accomplishing improvement cycles that included concrete actions on prioritised problems	
Interventions	The intervention consisted of facilitated work of maternal-and child stakeholder groups on the commune level that included identification of local perinatal health problems followed by a problem-solving cycle	
Outcomes	Stillbirths, perinatal mortality, neonatal mortality.	
Notes		
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>

**Persson 2013** (Continued)

Random sequence generation (selection bias)	Low risk	Quote: "A random number list was used to subsequently allocate "intervention" or "control" to the list of communes, and 44 out of the 90 communes were allocated to intervention and 46 to control" Comment: Adequately done.
Allocation concealment (selection bias)	Low risk	Quote: "The sequence was concealed until the intervention was assigned; otherwise the allocation was not masked."; "Ethnicity, economic situation, education, and utilisation of health services were similar among delivering women in randomized intervention and control communes (Table 1). Pregnancy outcomes and neonatal mortality rates in interventions and control communes had been similar in the 2005 baseline (Table 2)"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "...otherwise the allocation was not masked".
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement
Incomplete outcome data (attrition bias) All outcomes	High risk	Insufficient information to permit judgement No communes were lost to follow-up. 1 intervention commune stopped the facilitation meetings after 21 months, i.e, 15 months before the end of trial, while all others completed the intervention
Selective reporting (reporting bias)	Unclear risk	Study did not report outcomes based on intervention and control group
Other bias	Low risk	Study seems to be free from other biases.

## Srinivasan 1995

Methods	This RCT was conducted in Karur health district in Tamil Nadu from July 1987 to July 1990. 4 PHC centres were selected within 100 km radius of Karur; 3 subcentres were selected at random from among those beyond 10 km of PHC. 1 each was randomly allocated to high-risk package, Tamil Nadu government package and control. All packages were implemented by trained female ANMs. Baseline characteristics of all groups were comparable
Participants	Total of 45,154 newly diagnosed pregnant women was covered; analyses were performed on 1623 pregnant women
Interventions	<p><b>Intervention arm</b></p> <p>High-risk package: assessment of women's general condition, abdominal examination, blood pressure monitoring, measurement of height, weight and Hb, urine analysis for analysis of albumin and sugar, history taking for other associated illnesses. Screening was done at the time of registration and at 20, 28, 34 and 38 weeks of gestation. Visits included clinical examination to check height of uterus, presentation of fetus. Supplementation of folic acid (1 tablet if Hb &gt; 11 g/dL, 2 tablets if Hb &lt; 11 g/dL till delivery) and 700-1000 mg of parenteral iron if Hb &lt; 8 mg/dL. 2 doses of tetanus toxoid. 3 postnatal visits on 3, 10, 40 postnatal days. ANMs were responsible to detect maternal and neonatal illness and refer if required. ANMs were trained for 6 weeks by special training program and for 6 weeks by general training program.</p> <p>Tamil Nadu Government package: screening was done at the time of registration and at 20, 28, 34 and 38 weeks of gestation. 5 postnatal visits on 1, 3, 7, 15 and 30 postnatal days. Clinical examination by ANM for serious morbidity, Hb estimation and tetanus toxoid immunisation. A total dosage of 100 tablets of iron and folic acid were provided uniformly to all women from 20 weeks of gestation. ANMs were given 6 weeks of training.</p> <p><b>Control arm</b></p> <p>The implementation of Tamil Nadu Government services were the responsibility of the general health services</p>
Outcomes	Maternal infections, anaemia (Hb < 8 g/dL), eclampsia, delayed labour, maternal distress, puerperal sepsis, perinatal infection, birthweight, birth injuries, birth asphyxia, neonatal sepsis, diarrhoea, ARI, umbilical sepsis, other infections.
Notes	High-risk mothers were referred to project medical officer. In Tamil Nadu Government package 1 examination by medical officer anytime after registration was also stipulated. Women with severe morbidity in Tamil Nadu Government package were referred to Taluk hospital directly. Data were recorded at 14 and 34 weeks of pregnancy

### *Risk of bias*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Each PHC was randomly allocated to intervention and control groups" Comment: probably not done.

**Srinivasan 1995** (Continued)

Allocation concealment (selection bias)	Low risk	Comment: since it is a cluster-randomised trial, allocation concealment should not be an issue as in this design all clusters are randomised at once
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Syed 2006**

Methods	A rural upazila is divided into unions and then into mauzas. An urban upazila is divided into wards and then mahallas. 30 mauzas/mahallas were selected from each of the survey domains with PPS using the census frame of the respective upazila. A randomly-selected segment of approximately 120 households of a selected mauza/mahalla constituted a cluster. From each cluster, 12 mothers with children aged less than 1 year were selected using the systematic random procedure with the expectation that at least 10 respondents would be available for interview successfully from a cluster. Only 1 mother from a household was selected for interview. In total, 3325 mothers in the baseline and 3110 mothers in the end line survey from 10 upazilas were successfully interviewed
Participants	Pregnant women and mothers of children less than 1 year of age. Data were gathered from 6435 women in intervention and control clusters
Interventions	<b>Intervention arm</b> Increased coverage of CHWs, trained healthcare providers and TBA, use of clean delivery kit, antenatal and postnatal visits <b>Control arm</b> No such interventions were delivered in control areas.
Outcomes	Newborn care outcomes, initiation of early breastfeeding.
Notes	
<b>Risk of bias</b>	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Thirty mauzas/mahallas were selected from each of the survey domains with probability proportionate to size (PPS) using the census frame of the respective upazila. A randomly-selected segment of approximately 120 households of a selected mauza/mahalla constituted a cluster. From each cluster, 12 mothers with children aged less than one year were selected using the systematic random procedure with the expectation that at least 10 respondents would be available for interview successfully from a cluster" Comment: not clearly described but seems they randomly selected cluster and can be labelled as quasi-randomised controlled trial
Allocation concealment (selection bias)	High risk	This is a quasi-randomised study.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgement.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgement. Not reported if any cluster was lost from the trial and study did not report adjusted results
Selective reporting (reporting bias)	Low risk	Study appears to be free of selective reporting.
Other bias	Low risk	Study seems to be free from other biases.



**Tripathy 2010**

Methods	This is a cluster-randomised controlled trial. From 36 clusters in Jharkhand and Orissa (mean cluster population: 6338), 18 clusters were randomly assigned to either intervention or control using stratified allocation. Analysis was by intention-to-treat	
Participants	Pregnant women. Total number of 19,030 births in intervention and control clusters were reported during the trial period	
Interventions	<p><b>Intervention arm</b></p> <p>In intervention clusters a woman facilitator convened 13 groups every month to support participatory action and learning for women, and facilitated the development and implementation of strategies to address maternal and newborn health problems</p> <p>Implemented a participatory learning cycle, through developing women's groups where they identify and prioritise maternal and newborn health problems in their community, collectively selected relevant strategies to address those problems, implemented the strategies, and evaluated the results</p> <p><b>Control arm</b></p> <p>Participatory activities were not conducted in control areas</p>	
Outcomes	Miscarriages, stillbirths, neonatal mortality and maternal depression scores	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Quote: "Used stratified randomisation to allocate clusters to intervention and control using a two-step process" Comment: insufficient information to permit judgement.
Allocation concealment (selection bias)	Low risk	Quote: "Table 1 shows the baseline characteristics of identified births during 9 months of data gathering from Nov 21, 2004, to July 30, 2005. Numbers of births were similar in intervention and control clusters, but differences were noted in household assets, maternal education, literacy, and tribal membership, with women in the intervention clusters being generally poorer and more disadvantaged than those in the control clusters (table 1)" Comment: since it was cluster-randomised trial, allocation concealment should not be an issue in this design as all clusters are randomised at once

**Tripathy 2010** (Continued)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: “Due to the nature of the intervention, neither the intervention team nor the participants were blinded to group assignment”
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to permit judgment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition (19%) was reported along with its reasons. None of the clusters were lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study seems to be free from selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

**Wu 2011**

Methods	This was a cluster-randomised controlled trial that was conducted from August 2000 to March 2003 in rural county of China; pregnant woman were enrolled in the study up until July 2002
Participants	Pregnant women.
Interventions	The intervention consisted of 1) training township midwives, 2) informing women and men in the community of the importance of prenatal care, 3) providing intervention township hospitals with basic medical instruments used in prenatal care (i.e. blood pressure monitors, weighing scales for mothers and newborns, stethoscopes)
Outcomes	Perinatal mortality, neonatal mortality, stillbirths, institutional deliveries
Notes	

***Risk of bias***

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Quote: “One township was assigned to the intervention and one to control group in each matched pair by the toss of a coin” Comment: probably done.
Allocation concealment (selection bias)	Low risk	1 township was assigned to the intervention and 1 to control group in each matched pair by the toss of a coin

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information to permit judgment
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The field research assistant visited the intervention township hospital and their midwives at least once a month" Comment: data collectors were independent of implementers.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to permit judgment. Not mentioned if any of the cluster was lost from the trial and study reported adjusted results
Selective reporting (reporting bias)	Low risk	Study seems to be free from selective reporting.
Other bias	Low risk	Study seems to be free from other biases.

ASMR: asphyxia-specific mortality rate  
 ARI: acute respiratory infection  
 AWW: Anganwadi Workers  
 BCC: behaviour change communication  
 BNCP: birth and newborn care preparedness  
 CBSV: community-based surveillance volunteers  
 CHW: community health worker  
 CHC: community health centre  
 CC: community care  
 ENC: essential newborn care  
 GHW: government health worker  
 Hb: haemoglobin  
 HC: home care  
 ICDS: Integrated Child Development Service  
 IEEC: Information and education for empowerment and change  
 IMNCI: Integrated Management of Newborn and Child interventions  
 LBW: low birthweight  
 LHW: lady health worker  
 MWRA: married women of reproductive age  
 NGO: non-governmental organisation  
 PHC: primary health care  
 PPS: probability proportionate to size  
 RBC: red blood cell  
 RCT: randomised controlled trial  
 TBA: traditional birth attendant  
 TMP-SMX: Trimethoprim - Sulfamethoxazole

VCT: voluntary counselling and testing

VDC: village development committee

VHW: village health worker

VLC: village level committees

vs: versus

WU: women union

### Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Alisjahbana 1995	This is a quasi-experimental design and therefore excluded.
Althabe 2012	This is a protocol of a multi-country cluster-randomised trial, in which the effect of multifaceted intervention to increase the use of antenatal corticosteroids will be assessed
Baqui 2009	Not in the scope of this review. It was a validation study. In this study, newborns were assessed independently by a CHW and a study physician to validate trained CHW's' recognition of signs and symptoms of newborn illnesses and classification of illnesses using a clinical algorithm during routine home visits in rural Bangladesh
Baqui-CARE INDIA 2008	This is a quasi-experimental design and therefore excluded.
Bashour 2008	Not in the scope of this review. In this study, home visits were made by registered midwives during the postpartum period
Basinga 2011	This was an evaluation of the effect of performance-based payment of healthcare providers (payment for performance) on use and quality of child and maternal care services in healthcare facilities in Rwanda
Bhandari 2003	In this study, nutrition workers provided mothers with promotion of exclusive breastfeeding teaching and then afterwards impact of exclusive breastfeeding practices was observed on the development of diarrhoeal illnesses and growth of a child
Bhandari 2004	Not in the scope of this review. In this study, health and nutrition workers in the intervention communities were trained to counsel mothers at multiple contacts on breastfeeding exclusively for 6 months and on appropriate complementary feeding practices thereafter
Bolam 1998	In this study, the impact of health education of mothers were observed on infant care and postnatal family planning practices
Borghi 2005	This is a cost-effectiveness analysis of a participatory intervention with women's groups to improve birth outcomes in rural Nepal.
Carlo 2010	The package of essential newborn care was assessed as a before-and-after design and therefore excluded from review
Cooper 2002	Not in the scope of this review. Interventions to mothers were given related to infant management that includes sleep regimen, crying, and feeding

(Continued)

Dix-Cooper 2012	This study investigated whether early life chronic exposure to wood smoke is associated with children's neurodevelopmental and behavioural performance
Dongre 2009	Not a RCT or quasi-RCT.
El-Mohandes 2003	Intervention is related to parenting education program.
El-Mohandes 2005	The Interventions are related to decreasing intimate partner violence during pregnancy
El-Mohandes 2008	In this study, interventions addressed psychosocial and behavioural risks during pregnancy
Foord 1995	This is a quasi-experimental design and therefore excluded.
Gloyd 2001	In this study, investigators assessed the model of traditional birth attendant training
Gokcay 1993	In this study, the performance of midwives were compared with that of lady home visitors
Greenwood 1990	This is a quasi-experimental design and therefore excluded.
Haider 2000	In this study, education on exclusive breastfeeding was only provided to mothers through peer counsellors
Hartley 2011	This study determined the prevalence and correlates of depressed mood in pregnancy in Cape Town peri-urban settlements
Hounton 2009	Randomisation into the 2 groups was not addressed.
Janowitz 1988	Randomisation into the group is not addressed at all.
Jennings 2010	Health facilities were randomised into intervention and control arms and all interventions were delivered at facility set up
Johnson 1993	Study was about parenting intervention in the first year of child's life and their impact on child development
Joseph 2005	Not in the scope of this review. Mothers were provided with behavioural interventions
Joseph 2006	Not in the scope of this review. Mothers were provided with behavioural interventions
Joseph 2009	Not in the scope of this review. Mothers were given psychosocial and behavioural interventions
Katz 2001	In this study, the strategies of retention efforts were employed and compared the population that completed the study versus those that terminated prior to study completion. Comparison was made of those mothers terminating before study completion versus those retained, and of those terminating early in the study period versus later
Kawuwa 2007	Not a RCT or quasi-RCT.

(Continued)

Kiely 2007	Not in the scope of this review. In this abstract behavioural interventions were delivered to reduce depression and smoking during pregnancy
Koniak-Griffin 1991	Not in the scope of this review. The purpose of this study was to evaluate the effects of a nursing intervention program on affective and behavioural dimensions of maternal role attainment in adolescents
Koniak-Griffin 2000	Interventions were given to adolescent mothers only and impact was observed in first year of infant life
Le 2009	Not a RCT or quasi-RCT.
Lumley 2006	Not in the scope of this review. Interventions were given to decrease depression and improve physical health of mothers
MacArthur 2003	Not in the scope of this review. In this study, midwives used symptom checklists and the Edinburgh postnatal depression scale (EPDS) to identify health needs and guidelines for the management of these needs
Mannan 2008	Only provided interventions to promote breastfeeding.
McInnes 2000	It is not a intervention packaged study. In this study, only intervention related to promotion of breast-feeding was employed
McPherson 2006	Not a RCT or quasi-RCT.
McPherson 2007	Not a RCT or quasi-RCT.
Meegan 2001	Randomisation into the 2 groups was not addressed.
Miller 2012	In this study, investigator assessed the model of traditional birth attendant training
Moran 2006	Not a RCT or quasi-RCT.
Morrell 2000	Cost-effectiveness analysis of postnatal interventions for mothers and newborns
Mosha 2005	They employed stepped wedge design. In a stepped wedge design, an intervention is rolled-out sequentially to the trial participants (either as individuals or clusters of individuals) over a number of time periods, so by the end of the random allocation, all individuals or groups will have received the intervention
Mullany 2007	In this study, women who received education alone were compared with no education and those who attended with their husbands. Antenatal education was given in the hospital
Nassar 2014	The study used automated call-monitoring system for women in second and third trimesters predominantly Medicaid-eligible pregnant women in an urban free standing birth centre to promptly detect symptoms of influenza and assure rapid treatment to prevent adverse outcomes from influenza
O'Rourke 1998	Not a RCT or quasi-RCT.

(Continued)

Omer 2008	Not a community intervention package. In this study, the embroidery depicted maternal practices like attending and not attending antenatal check-ups, giving colostrum after birth and not doing heavy work
Owais 2011	This study selected mother and infant pair and assessed the impact of mother's knowledge on uptake of immunisation for an infant
Purdin 2009	Intervention was implemented at healthcare facility level.
Rahman 2008	This study measured the impact of adding CBT to the usual care provided by community health workers on maternal depression and infant outcomes
Rahman 2012	This study assessed poverty and lack of empowerment as moderators of a CBT-based intervention for perinatal depression in rural Pakistan
Ramsey 2013	This study randomised CHWs and the intervention was related to referral improvements
Roman 2009	Interventions delivered by nurse CHW was compared with usual community care that includes Medicaid enhanced prenatal services delivered by professionals. The study investigated whether a combination of Medicare enhanced prenatal service and nurse CHW care reduces depressive symptoms and stress
Ronsmans 1997	This is a quasi-experimental design and therefore excluded.
Rotheram-Borus 2011a	This was not a RCT.
Shaheen 2003	Assessed the effectiveness of second visit of CHWs.
Subramanian 2005	Not in the scope of this review. It was only a published abstract, and in this trial impact of psychosocial risks were observed on pregnancy and infant outcomes
Thompson 2011	The study examined the effect of reduced wood smoke exposure in pregnancy on LBW of Guatemalan infants
Turan 2001	In this study the authors presented the results of 3 studies investigating methods for including men in antenatal education in Istanbul, Turkey
Turan 2003	Interventions were delivered to first time expectant women at healthcare facility level
Wiggins 2004	None of the outcomes reported are of interest to this review. In this study Investigator measured the impact of postnatal social support on occurrence of child injury, maternal smoking or maternal depression
Xu 1995	Not a RCT or quasi-RCT.

CBT: cognitive-behavioural therapy

LBW: low birthweight

CHW: community health worker

RCT: randomised controlled trial

## Characteristics of studies awaiting assessment *[ordered by study ID]*

### Kamm 2012

Methods	Randomised controlled trial.
Participants	Pregnant women.
Interventions	The behavioural impact of safe birthing and neonatal care messages delivered to primiparous women in the third trimester. The study also promoted delivery at a medical facility, use of a clean delivery kit for a home delivery, recognition of maternal and neonatal danger signs, and essential neonatal care to all participants and their families
Outcomes	Prenatal visit to a healthcare provider, planned to deliver at a medical facility, cord care, delayed bathing of newborn
Notes	This was just an abstract which presented before and after results of an intervention. Investigator contacted to inquire about the results from intervention and control arms of the trial

### Kestler 2013

Methods	A matched pair cluster-randomised trial of this intervention package will be conducted in 4 rural and indigenous districts (Huehuetenango, Quiche, Alta Verapaz and San Marcos) of the Republic of Guatemala, using the health clinic as the unit of randomisation
Participants	Women aged 10 to 49 years.
Interventions	The package includes 3 interventions: 1) To train healthcare professionals in emergency obstetric and perinatal care using an innovative high-fidelity, low-tech, in situ, multidisciplinary simulation training curriculum (PRONTO). 2) To design and implement a social marketing strategy that promotes institution-based delivery. 3) To integrate the role of obstetric nurse and professional midwife in intervention communities to act as liaisons between traditional birth attendants (TBA) and public health units. A fourth, cross-cutting component involves ongoing analysis, monitoring, surveillance and evaluation to strengthen information systems and monitor perinatal outcomes throughout the 2 years of the study
Outcomes	Primary outcomes: proportion of institutional deliveries. Secondary outcome measures: perinatal death rate.
Notes	This is a published protocol for an ongoing study.



**Khan 2012**

Methods	This is pragmatic cluster-randomised trial, with qualitative and economic studies, conducted in Jhang, Chiniot and Khanewal districts of Punjab, Pakistan, from February 2011 to May 2013
Participants	1. Eligibility criteria for population is the availability of safe birthing and EmONC services (made available through the Maternal Newborn and Child Health (MNCH) Programme) and a functioning network of lady health workers (through the National Programme for Primary Health Care and Family Planning). 2. All pregnancies in the selected clusters will be eligible
Interventions	1. Arm 1: structured planning for safe birthing/EmONC. 2. Arm 2: structured planning for safe birthing/EmONC plus transport facilitation. 3. Arm 3: no transport facilitation or structured birth planning-education for safe birthing/EmONC (current/routine practice)
Outcomes	Neonatal mortality rate and neonatal morbidity.
Notes	This is a published protocol for an ongoing study.

**Morrison 2011**

Methods	Single-centre unmasked cluster-randomised controlled trial from Nepal
Participants	1. Measurement of outcomes: 1.1. For trained birth attendance within intervention and control clusters, women who deliver infants at gestation 28 complete weeks or greater. 1.2. For mortality, women of reproductive age (12 to 49 years old) who die. 1.3. Infants born within the study period. 2. Intervention: the intervention involves community mobilisation through women's groups and health management committee (HMC) strengthening. Participation in women's groups and their activities is voluntary, and there are no pre-determined intervention inclusion criteria. Participation in HMC strengthening is also voluntary. Participants will usually be HMC members, but may also be community members whom HMCs invite to participate
Interventions	The intervention has 2 components, community mobilisation through women's groups, and health management committee (HMC) strengthening. Both interventions will be implemented for 2 years in 21 intervention clusters.  Community mobilisation through women's groups: A government health cadre, the female community health volunteer (FCHV) runs 1 women's group per month. There are at least 9 FCHVs running 9 women's groups per cluster (n = 189). FCHVs are supported by 7 supervisors, who provide general field support, and conduct monthly training and feedback meetings with FCHVs to discuss the upcoming women's group agenda, and monitor their progress. Women's groups work through a participatory action cycle to identify local problems preventing women from delivering in an institution, or at home with a trained health worker, and then implement and evaluate strategies to address these problems.  Health Management Committee Strengthening: There is 1 health institution per cluster and each institution has a health management committee. 4 Appreciative Inquiry facilitators and trained representatives from the District Public Health Office conduct 3-day workshops with HMCs of each health facility (n = 21). Other participants such as community representatives and health workers may also join workshops. The workshops take an Appreciative Planning and Action approach, where participants are encouraged to build on their strengths to take action to improve health facilities. Facilitators will follow-up on

**Morrison 2011** (Continued)

	progress at HMC meetings approximately 2 months after they have completed their planning workshop, and at regular intervals thereafter
Outcomes	<p>Primary outcomes:</p> <ol style="list-style-type: none"> <li>1. Deliveries conducted by a trained health worker.</li> <li>2. Institutional deliveries.</li> </ol> <p>Secondary outcomes:</p> <ol style="list-style-type: none"> <li>1. Neonatal deaths.</li> <li>2. Stillbirths.</li> <li>3. Maternal morbidities.</li> <li>4. Care behaviours.</li> </ol>
Notes	This is a published protocol for an ongoing study.

**Rodriguez-Angulo 2012**

Methods	Effect of a community-based intervention to improve the knowledge on the warning signs of maternal complications among Mayan women from Yucatan randomised controlled trial
Participants	Pregnant women.
Interventions	Participatory strategies to improve women's knowledge on alarm signs for preeclampsia-eclampsia, obstetrical haemorrhage, and puerperal sepsis
Outcomes	Knowledge increase on preeclampsia-eclampsia, obstetrical haemorrhage, and puerperal sepsis.
Notes	The study was in Spanish and therefore waiting for study to get translated

**Rotheram-Borus 2011b**

Methods	This is a cluster-randomised controlled trial conducted in the KwaZulu-Natal (KZN) province
Participants	Female 18 years and older, pregnant, and HIV+.
Interventions	<p>In the intervention arm, participants will receive the Department of Health-delivered Prevention of Mother to Child Transmission (PMTCT) program plus the Project Masihambisane mentor mothers support program. HIV positive mentor mothers, who have been through the PMTCT program, will be recruited and trained to deliver the intervention to pregnant mothers living with HIV</p> <p>Behavioural: peer support and mentoring The intervention will be delivered in 4 non-consecutive visits during pregnancy and 4 visits postpartum. The sessions will be delivered to mothers living with HIV on the days of their healthcare appointments either individually or in groups that can accommodate up to 30 mothers living with HIV. The intervention will focus on enhancing the mother-baby relationship through increasing the health of the mother and baby, maintaining the mother's mental health, and reducing HIV transmission</p> <p>No Intervention: control mothers living with HIV in the standard of care control clinics will receive the Department of Health-delivered PMTCT program</p>

**Rotheram-Borus 2011b** (Continued)

Outcomes	Primary outcome measures: baby's health status. Secondary outcome measures: maternal adherence: baby's and mother's health
Notes	This is a published protocol for an ongoing study.

**Shrestha 2011**

Methods	The study design is a cluster-randomised controlled trial involving 60 village-development committee clusters allocated 1:1 to 2 interventions in a factorial design conducted in Nepal
Participants	Women and newborns.
Interventions	MIRA Dhanusha community groups: FCHVs are supported in convening monthly women's groups. 9 groups per cluster (270 in total) work through 2 action research cycles in which they (i) identify local issues around maternity, newborn health and nutrition, (ii) prioritise key problems, (iii) develop strategies to address them, (iv) implement the strategies, and (v) evaluate their success. Cycle 1 focuses on maternal and newborn health and cycle 2 on nutrition in pregnancy and infancy and associated postpartum care practices. MIRA Dhanusha sepsis management: FCHVs are trained to care for vulnerable newborn infants. They (i) identify local births, (ii) identify low birthweight infants, (iii) identify possible newborn infection, (iv) manage the process of treatment with oral antibiotics and referral to a health facility to receive parenteral gentamicin, and (v) follow up infants and support families
Outcomes	Neonatal mortality rates. <b>MIRA Dhanusha community group:</b> stillbirth, infant and under-2 mortality rates, care practices and health care seeking behaviour, maternal diet, breastfeeding and complementary feeding practices, maternal and under-2 anthropometric status <b>MIRA Dhanusha sepsis management:</b> identification and treatment of neonatal sepsis by community health volunteers, infection-specific neonatal mortality
Notes	This is a published protocol for an ongoing study.

**Tripathy 2011**

Methods	Cluster-randomised controlled trial in India.
Participants	1. Women who give birth in 30 geographic clusters during the study period. 2. Women and their newborn infants are included after birth, or, if a woman dies during pregnancy, at her death
Interventions	Participation in learning action cycle with women's groups. 1. In each intervention cluster, trained and incentivised Accredited Social Health Activists and convene women's groups. 2. Accredited Social Health Activists are government appointed volunteers incentivised to mobilise communities for improved health outcomes, assist women to access institutional deliveries and delivery a range of primary healthcare services. 3. The participatory learning and action cycle has 4 phases. 4. In the first phase, groups identify and prioritise maternal and newborn health problems, then plan strategies to address these problems.

**Tripathy 2011** (Continued)

	<p>5. In the second phase, they discuss and prioritise strategies to address these problems.</p> <p>6. In the third and fourth phases, groups put these strategies into practice, and evaluate their progress.</p> <p>7. The role of the Accredited Social Health Activists as part of the intervention being tested is to activate and strengthen groups, support them in identifying problems related to maternal and newborn health, help to plan possible solutions and support the implementation and monitoring of strategies to address identified problems in the community.</p> <p>8. Accredited Social Health Activists support group meetings alongside their other activities.</p> <p>9. In all clusters, control and intervention, activities are implemented to strengthen Village Health Committees.</p> <p>10. We do not use patient information sheets because this was a community trial of a social intervention (i.e. not a clinical trial). The intervention consists of women's groups that discuss and design their own strategies to improve newborn and maternal health. All the women in these women's groups participate voluntarily. At the start of the women's groups, there was extensive discussion of what the aims and structure of the women's groups are. By voluntarily joining a women's group, the participants consent to the intervention (i.e. women's groups). Oral consent was obtained from the respondents in the monitoring and surveillance interviews</p>
Outcomes	<p>Primary outcomes: neonatal mortality (deaths in the first 28 complete days after birth per 1000 live births), during the last 24 months of the study</p> <p>Secondary outcomes:</p> <ol style="list-style-type: none"> <li>1. Early and late neonatal mortality rate</li> <li>2. Stillbirth rate</li> <li>3. Maternal mortality ratio</li> <li>4. Pregnancy related mortality</li> <li>5. Health care seeking</li> <li>6. Home care practices</li> </ol>
Notes	This is a published protocol for an ongoing study.

**Waiswa 2012**

Methods	Randomised controlled cluster trial from Uganda.
Participants	<ol style="list-style-type: none"> <li>1. Women of childbearing age.</li> <li>2. Pregnant women.</li> <li>3. Newly delivered women.</li> <li>4. Neonates and infants.</li> </ol>
Interventions	<p>Through formative research around evidence-based practices, and dialogue with policy and technical advisors, we will construct a home-based neonatal care package implemented by the responsible Village Health Team member, effectively a Community Health Worker (CHW). This CHW will be trained to identify pregnant women and make 4 home visits: 2 before and 2 just after birth. Linkages will be made to facility care and targeted messages for home-care and care-seeking delivered. The project will improve care in health units to provide standardised care for the mother and the newborn in both intervention and comparison areas.</p> <p>The control area is being given the current standard of care provided by the Government. However, health facility quality improvement initiatives are being provided in both control and intervention areas in order to standardise care but also for ethical reasons. This will enable sick newborns in the control area to access care</p>
Outcomes	<p>Primary outcome:</p> <ol style="list-style-type: none"> <li>1. In ANC: <ol style="list-style-type: none"> <li>1.1. % of pregnant women attending ANC 2, 4 or more times.</li> </ol> </li> </ol>

**Waiswa 2012** (Continued)

	<p>1.2. % of pregnant women who know at least 2 danger signs of pregnancy. 1.3. % of pregnant women who prepare for birth.</p> <p>2. In the intrapartum period: 2.1. % of pregnant women who have a skilled attendant at delivery. 2.2. % of women who went to the HC in an emergency.</p> <p>3. In the postnatal period: 3.1. % of babies who are initiated on breastfeeding in the first 6 hours of birth. 3.2. % of babies who are exclusively breast fed during the neonatal period. 3.3. % of babies whose first bath was delayed for 6 and 24 hours. 3.4. % of mothers who put nothing on the cord. 3.5. % of mothers who know at least 3 neonatal danger signs. 3.6. % women whose children were managed in skin to skin contact after delivery. 3.7. Effectiveness of sepsis management (special studies to determine: maternal and CHW knowledge, compliance and timing of referral, and adequacy of treatment following referral)</p> <p>Secondary outcome: 1. Neonatal mortality. 2. Perinatal mortality.</p>
Notes	This is a published protocol for an ongoing study.

**Wallin 2011**

Methods	A single-centre, cluster-randomised, population-based community intervention trial
Participants	Districts in Quang Ninh province in Northern Vietnam with a neonatal mortality rate (NMR) higher than 15/1000 have been selected for the intervention, resulting in a study involving 8 districts composed by 87 communities with a corresponding community health centre (CHC). In 2005 there were 6227 births and 150 neonatal deaths in these districts resulting in a NMR of 24/1000
Interventions	<p>The facilitation intervention targets CHC staff and key persons at the community level. Each CHC is accountable for the health care in the community, including all villages. For each village the CHC has 1 Village Health Worker (VHW) who is responsible for the basic health care. At each CHC, there are 3-6 staff working, of whom a midwife or a medical doctor provides perinatal care. Key persons in the community are the vice chairman and the Women Union leader, who both are in decision-making positions. The basic feature of the study intervention is that individuals from the Women Union are acting as facilitators in supporting CHC staff and key persons in their efforts to improve healthcare practice. Individuals from local Women Union organisations have been recruited and trained for 1 week to be able to act as facilitators. A locally recruited person act as supervisor of the facilitators; i.e. supporting the facilitators, assisting and coordinating in the facilitation process, and report back to the research team</p> <p>Controls are communities without intervention.</p> <p>The total duration of the intervention will be 2 years. Follow-up will be done 3 years after the end of intervention</p>
Outcomes	<p>Neonatal mortality. Effects on home visits by midwives. Exclusive breastfeeding. Temperature control.</p>

**Wallin 2011** (Continued)

	Knowledge among health staff. Care-seeking behaviour. Other indicators for neonatal health.
Notes	This is a published protocol for an ongoing study.

ANC: antenatal care  
 CBSV: community-based surveillance volunteers  
 CHW: community health worker  
 EmONC: Emergency Obstetric and Neonatal Care  
 FCHV: female community health volunteers  
 TBA: traditional birth attendant

**Characteristics of ongoing studies** [ordered by study ID]

**Bhandari 2014**

Trial name or title	Overcoming barriers to scaling skilled birth attendants' utilization in improving maternal, newborn and child health in Nepal
Methods	Cluster-randomised controlled trial from Nepal.
Participants	Pregnant women who visit or do not visit health institutions for childbirth in the 36 clusters in a given period of time
Interventions	The intervention involves health facility management committees, mothers' groups, female community health volunteers and youth groups. The interventions are increasing family support for pregnant women to reach the health facility, making funds available to remove financial barriers faced by families for using institutional childbirth care, making transport options available to reach a health facility for childbirth, developing women-friendly health services by improving providers' communication skills, and reducing security problems of SBAs so that care can be available 24/7. The control group do not receive any intervention.
Outcomes	Primary: Utilisation of SBA services by pregnant women for childbirth Secondary: 1. Antenatal check-up 4 times by pregnant women (% of pregnant women who had 1 and who had 4 antenatal checkups during pregnancy) 2. Postnatal check-up of mothers and babies (% of mothers who received at least 1 postnatal check of mother and newborn baby) 3. Availability of transport to the women to visit a health institution for childbirth (% of women who used services and % of women who informed they did not receive SBA services because of transport problems) 4. Functional operation of emergency fund (% of women who perceived lack of finances as a problem in utilising SBA services; % of women who received a loan from emergency fund and % of women who paid back the loan) 5. Security of SBA (% of SBAs who perceived security as a problem in work)

	<p>6. Support from family to the women for childbirth at health institution (% of women who perceived they had support from their family to use SBA services; % of women who informed lack of support from their family as a reason for not using SBA services)</p> <p>7. Women-friendly health facility environment (% of women who inform that health workers were supportive at the facility; % of women who informed that they did not use SBA services because of unsupportive behaviour of health workers)</p>
Starting date	01/04/2014
Contact information	<p><b>Prof Sharad Onta</b>  Nepal Public Health Foundation  Dhara Marga 101/2, Maharajgunj  <a href="mailto:sharadonta@gmail.com">sharadonta@gmail.com</a></p>
Notes	

**ISRCTN63294155**

Trial name or title	Does training non-physician clinicians, in Malawi, have an impact on new-born baby and maternal survival?
Methods	The study design is a cluster-randomised controlled trial with the unit of randomisation being the 14 districts of central and northern Malawi (1 large district was divided into 2 giving an overall total of 15)
Participants	A non-physician clinician in Malawi who is receiving ETATMBA training
Interventions	<p>15 districts (clusters) of the Central and Northern Regions of Malawi will be randomly assigned to either receive the intervention or to be a control district.</p> <p>The Training package  The intervention is the training of NPCs in specific skills. Module 1 will consist of in depth theoretical review and demonstration of prevention and management of the 5 major killers of mothers and the 3 most common causes of neonatal death, e.g. resuscitation of the newborn, treatment of maternal and neonatal sepsis, etc. with facilitated referral in delivery. Module 2 will deal with leadership and module 3 will be on the job training in surgical skills for the management of emergency obstetric complications. The control Districts/Hospitals will continue with their usual EmONC services.</p> <p>Briefly, the training package is an 18 to 24 month programme of skills training and practice. The programme will involve 3 week-long intensive training sessions (over a year) in advanced obstetrics and neonatal care, combined with in-service training of 2, 6-month periods to apply enhanced teaching, training and audit. Assessment of knowledge, competence and performance will be examined at the start of the programme and satisfaction, assessment of knowledge, competence and performance will be examined at the end. Trainees will have to successfully complete and pass a number of tasks (e.g. audits, training others, reflective practice) and will be asked to complete a short feedback questionnaire at the end of each days training noting what they feel they have learned and how valuable the training was to them.</p> <p>The training programme will comprise the major causes of maternal and neonatal mortality, how to teach, and research and leadership skills.</p>

ISRCTN63294155 (Continued)

	Practical and operative skills in the intervention districts will be supported by a specialist registrar in obstetrics working for a period of 4 weeks with NPCs to reinforce training, and rotating over the first year to all intervention hospitals. This on the job supervision and support will be supplemented by cell phone and electronic communication between trainees and specialist consultants
Outcomes	<p><b>Primary outcome</b> will be maternal and perinatal (defined as until discharge from health facility) mortality</p> <p><b>Secondary outcomes</b></p> <ol style="list-style-type: none"> <li>1. Maternal death rates (case specific).</li> <li>2. Recorded data (e.g. still births, postpartum haemorrhage, caesarean section, eclampsia, sepsis, neonatal resuscitation).</li> <li>3. Availability of resources (e.g. are drugs/blood available).</li> <li>4. Use of available resources (e.g. are drugs being used).</li> </ol>
Starting date	01/11/2011
Contact information	<p><b>Dr Paul O'Hare</b> Warwick Medical School University of Warwick</p>
Notes	

**NCT01022788**

Trial name or title	Improving Newborn Survival In Southern Tanzania (INSIST).
Methods	Randomised controlled trial.
Participants	Men and women up to 49 years.
Interventions	Primary outcome measures: household behaviours for essential newborn care
Outcomes	Behavioural: home-based counselling.
Starting date	January 2010.
Contact information	Joanna Schellenberg, London School of Hygiene and Tropical Medicine
Notes	

**NCT01073488**

Trial name or title	Emergency Obstetric and Neonatal Care: The EmONC Trial.
Methods	Cluster-randomised open-label trial.
Participants	Pregnant women living in and/or delivering within the study cluster



NCT01073488 (Continued)

Interventions	Community mobilisation Intervention: Behavioural: Community Mobilisation Home-based life saving skills Intervention: Behavioural: Home-based Life Saving Skills Facility improvement Intervention: Behavioural: Facility improvement
Outcomes	Primary outcome measures: composite of either > 28 week /> 1000 g stillbirth or 7 day neonatal mortality rate.  <b>Secondary outcome measures:</b> Maternal mortality rate. Maternal morbidity rates. Stillbirth rate. 7-day neonatal mortality rate. 28-day neonatal mortality rate. Rates of mothers transported to a referral hospital. Rates of neonates/infants transported to a referral hospital
Starting date	December 2008.
Contact information	Linda Wright. <a href="mailto:wrightl@exchange.nih.gov">wrightl@exchange.nih.gov</a> Elizabeth McClure. <a href="mailto:mcclure@rti.org">mcclure@rti.org</a>
Notes	

NCT01350765

Trial name or title	Naushero Feroze neonatal survival project (AKU).
Methods	Cluster-randomised trial.
Participants	Children of ages 1 day to 28 days, within the catchment area of the preformed research Exclusion criteria: those who are not willing to participate in the study
Interventions	<b>Behavioural intervention:</b> the LHWs of the selected intervention areas would receive additional training on ENC for identification, management and referral for birth asphyxia, LBW and neonatal sepsis <b>Control:</b> the LHWs in the control areas would perform their routine tasks as assigned to them by their program
Outcomes	Primary outcomes: neonatal mortality rate, perinatal mortality rates, neonatal mortality rates Secondary outcomes: cause-specific mortality rates (due to birth asphyxia, neonatal sepsis and low birthweight)
Starting date	March 2010.
Contact information	Zulfiqar A Bhutta, <a href="mailto:zulfiqar.bhutta@aku.edu">zulfiqar.bhutta@aku.edu</a>
Notes	

**NCT01751945**

Trial name or title	Improved accessibility of EmONC services for maternal and newborn health: a community based project
Methods	A cluster-randomised controlled trial from Rural area of Pakistan
Participants	Women of 15 years to 49 years.
Interventions	<p>Experimental: EmONC package The EmONC package consists of: maternal and neonatal health pack (clean delivery kit, emollient, chlorhexidine, SMS messages) for safe motherhood and newborn well being. Enhanced training's of community-level healthcare providers to provide effective maternal and neonatal health services and referral of complicated cases to health facilities and creation of linkages amongst healthcare providers. Community mobilisation</p> <p>Behavioural: EmONC package The EmONC package consists of: maternal and neonatal health pack (clean delivery kit, emollient, chlorhexidine, SMS messages) for safe motherhood and newborn well being. Enhanced training of community-level healthcare providers to provide effective maternal and neonatal health services and referral of complicated cases to health facilities and creation of linkages amongst healthcare providers. Community mobilisation</p>
Outcomes	Perinatal mortality.
Starting date	November 2012.
Contact information	Dr. Sajid Soofi, MBBS, FCPS
Notes	

**NCT01941264**

Trial name or title	Community-based scheduled screening and treatment of malaria in pregnancy for improved maternal and infant health: a cluster-randomized trial in The Gambia, Burkina Faso and Benin (COSMIC)
Methods	Double-blind randomised controlled trial.
Participants	Females 16 years and older.
Interventions	<p>Primary outcome: placental malaria.</p> <p>Secondary outcomes:</p> <p>Birthweight</p> <ul style="list-style-type: none"> <li>● Antenatal care clinic attendance</li> <li>● Resistance to sulphadoxine-pyrimethamine (SP)</li> <li>● Peripheral malaria infection</li> <li>● Haemoglobin</li> </ul>
Outcomes	<p>Primary outcome: placental malaria</p> <p>Secondary outcomes:</p> <ul style="list-style-type: none"> <li>● Birthweight</li> <li>● Antenatal care clinic attendance</li> <li>● Resistance to sulphadoxine-pyrimethamine (SP)</li> <li>● Peripheral malaria infection</li> <li>● Haemoglobin</li> </ul>

NCT01941264 (Continued)

Starting date	October 2013
Contact information	Umberto D'Alessandro, professor
Notes	

EmONC: Emergency Obstetric and Neonatal Care

ENC: essential newborn care

LBW: low birthweight

LHW: lady health workers

NPC: non-physician clinician

SBA: skilled birth attendant

## DATA AND ANALYSES

### Comparison 1. Community-based intervention versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Maternal mortality	11	167311	Risk Ratio (Random, 95% CI)	0.80 [0.64, 1.00]
1.1 Intervention package mainly consisted of building community-support groups/women groups	6	101198	Risk Ratio (Random, 95% CI)	0.83 [0.56, 1.22]
1.2 Intervention package mainly consisted of community mobilisation and home visitation (antenatal & postnatal)	3	43233	Risk Ratio (Random, 95% CI)	0.72 [0.49, 1.06]
1.3 Intervention package mainly consisted of training TBAs who made home visits (antenatal & intrapartum)	2	22880	Risk Ratio (Random, 95% CI)	0.74 [0.45, 1.21]
2 Neonatal mortality	21	302464	Risk Ratio (Random, 95% CI)	0.75 [0.67, 0.83]
2.1 Intervention package mainly consisted of building community-support groups/women groups	9	155509	Risk Ratio (Random, 95% CI)	0.84 [0.73, 0.96]
2.2 Intervention package mainly consisted of community mobilisation and home visitation (antenatal /postnatal)	5	50052	Risk Ratio (Random, 95% CI)	0.60 [0.49, 0.72]
2.3 Intervention package mainly consisted of community mobilisation and home-based neonatal treatment	1	4248	Risk Ratio (Random, 95% CI)	0.66 [0.47, 0.93]
2.4 Intervention package mainly consisted of training TBAs who made home visits (antenatal and intrapartum)	2	22860	Risk Ratio (Random, 95% CI)	0.74 [0.48, 1.16]
2.5 Intervention package mainly consisted of home-based neonatal care & treatment	2	62567	Risk Ratio (Random, 95% CI)	0.63 [0.32, 1.22]
2.6 Intervention package mainly consisted of mother's education and home visitation (antenatal & postnatal)	2	3072	Risk Ratio (Random, 95% CI)	0.80 [0.63, 1.02]

2.7 Intervention package mainly consisted of community mobilisation with messages (leaflets, banners) and training midwives who made home visits	1	4156	Risk Ratio (Random, 95% CI)	1.44 [1.23, 1.69]
3 Early neonatal mortality	11	131017	Risk Ratio (Random, 95% CI)	0.67 [0.58, 0.77]
3.1 Intervention package mainly consisted of community-support groups/women groups	5	92022	Risk Ratio (Random, 95% CI)	0.76 [0.64, 0.90]
3.2 Intervention package mainly consisted of community mobilisation and home visitation (antenatal & postnatal)	4	34433	Risk Ratio (Random, 95% CI)	0.63 [0.49, 0.79]
3.3 Intervention package mainly consisted of training TBAs who made home visits (antenatal & intrapartum)	1	2475	Risk Ratio (Random, 95% CI)	0.56 [0.32, 0.98]
3.4 Intervention package mainly consisted of home-based neonatal care	1	2087	Risk Ratio (Random, 95% CI)	0.45 [0.28, 0.72]
4 Late neonatal mortality	11	148822	Risk Ratio (Random, 95% CI)	0.74 [0.65, 0.86]
4.1 Intervention package mainly consisted of community-support groups/women groups	5	92922	Risk Ratio (Random, 95% CI)	0.84 [0.67, 1.05]
4.2 Intervention package mainly consisted of community mobilisation and home visitation (antenatal & postnatal)	3	31759	Risk Ratio (Random, 95% CI)	0.67 [0.48, 0.92]
4.3 Intervention package mainly consisted of training TBAs who made home visits (antenatal & intrapartum)	2	22054	Risk Ratio (Random, 95% CI)	0.70 [0.62, 0.80]
4.4 Intervention package mainly consisted of home-based neonatal care	1	2087	Risk Ratio (Random, 95% CI)	0.31 [0.09, 1.07]
5 Perinatal mortality	17	282327	Risk Ratio (Random, 95% CI)	0.78 [0.70, 0.86]
5.1 Intervention package mainly consisted of community-support groups/women groups	8	155585	Risk Ratio (Random, 95% CI)	0.88 [0.82, 0.95]
5.2 Intervention package mainly consisted of community mobilisation and home visitation (antenatal and postnatal)	4	35946	Risk Ratio (Random, 95% CI)	0.64 [0.54, 0.77]

5.3 Intervention package mainly consisted of training TBAs who made home visits (antenatal & intrapartum)	2	23022	Risk Ratio (Random, 95% CI)	0.71 [0.65, 0.78]
5.4 Intervention package mainly consisted of home-based neonatal care	2	62644	Risk Ratio (Random, 95% CI)	0.69 [0.41, 1.17]
5.5 Intervention package mainly consisted of community mobilisation with messages (leaflets, banners) and training midwives who made home visits	1	5130	Risk Ratio (Random, 95% CI)	1.08 [0.95, 1.23]
6 Stillbirths	15	201181	Risk Ratio (Random, 95% CI)	0.81 [0.73, 0.91]
6.1 Intervention package mainly consisted of community-support groups/women groups	7	136646	Risk Ratio (Random, 95% CI)	0.94 [0.84, 1.06]
6.2 Intervention package mainly consisted of community mobilisation and home visitation (antenatal & postnatal)	3	33689	Risk Ratio (Random, 95% CI)	0.76 [0.68, 0.85]
6.3 Intervention package mainly consisted of training TBAs who made home visits (antenatal & intrapartum)	2	23022	Risk Ratio (Random, 95% CI)	0.79 [0.54, 1.14]
6.4 Intervention package mainly consisted of home-based neonatal care	1	2164	Risk Ratio (Random, 95% CI)	0.59 [0.38, 0.93]
6.5 Intervention package mainly consisted of mother's education and home visitation (antenatal & postnatal)	1	530	Risk Ratio (Random, 95% CI)	0.45 [0.11, 1.84]
6.6 Intervention package mainly consisted of community mobilisation with messages (leaflets, banners) and training midwives who made home visits	1	5130	Risk Ratio (Random, 95% CI)	0.54 [0.41, 0.72]
7 Mean birthweight (kg)	2	1050	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.04, 0.06]
8 Maternal morbidity	4	138290	Risk Ratio (Random, 95% CI)	0.75 [0.61, 0.92]
9 Complication of pregnancy: haemorrhage	1	19525	Risk Ratio (Random, 95% CI)	0.63 [0.52, 0.76]
10 Complication of pregnancy: obstructed labour	1	19525	Risk Ratio (Random, 95% CI)	1.19 [1.05, 1.35]
11 Complication of pregnancy: puerperal sepsis	1	19525	Risk Ratio (Random, 95% CI)	0.84 [0.65, 1.08]
12 Complication of pregnancy: eclampsia	1	19525	Risk Ratio (Fixed, 95% CI)	0.74 [0.43, 1.27]
13 Complication of pregnancy: spontaneous abortion	1	19525	Risk Ratio (Fixed, 95% CI)	0.81 [0.55, 1.18]

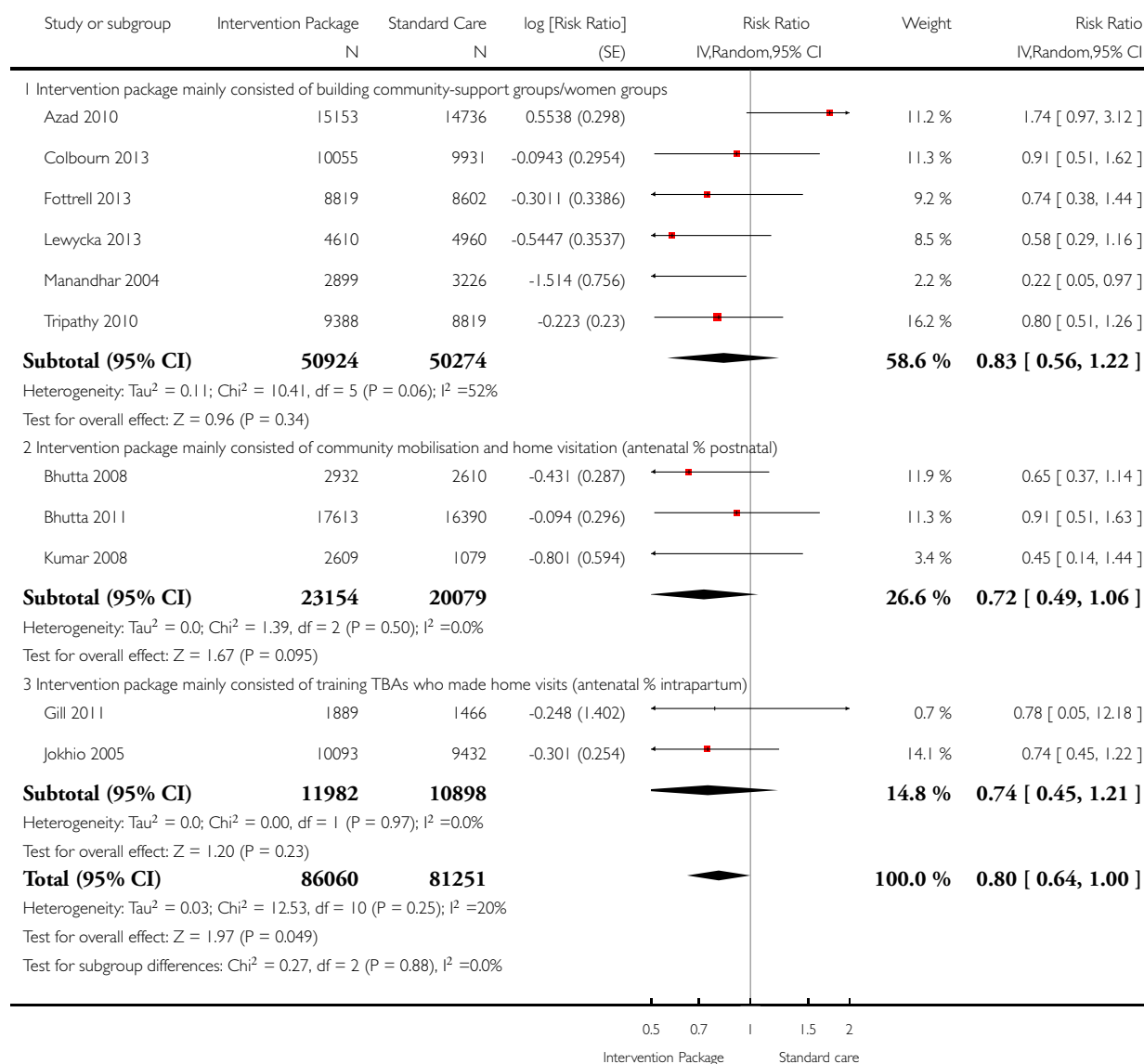
14 Referral to health facility for any complication during pregnancy	1	19525	Risk Ratio (Fixed, 95% CI)	1.50 [0.95, 2.36]
15 Iron/folate supplementation (not pre-specified)	6	71622	Risk Ratio (Random, 95% CI)	1.47 [0.99, 2.17]
16 Any Tetanus toxoid immunisation (not pre-specified)	7	71279	Risk Ratio (Random, 95% CI)	1.05 [1.02, 1.09]
17 Institutional deliveries	14	147890	Risk Ratio (Random, 95% CI)	1.20 [1.04, 1.39]
18 Birth attended by healthcare provider	8	96302	Risk Ratio (Random, 95% CI)	1.45 [0.66, 3.17]
19 Use of clean delivery kits (not pre-specified)	4	54254	Risk Ratio (Random, 95% CI)	1.82 [1.10, 3.02]
20 Baby wrapped within 30 minutes (not pre-specified)	4	54274	Risk Ratio (Random, 95% CI)	0.95 [0.76, 1.19]
21 Initiation of breastfeeding within 1 hour of birth	11	72464	Risk Ratio (Random, 95% CI)	1.93 [1.55, 2.39]
22 Delayed bathing for up to 6 hours (not pre-specified)	2	9826	Risk Ratio (Random, 95% CI)	1.22 [0.77, 1.92]
23 Clean cord care (not pre-specified)	2	20888	Risk Ratio (Random, 95% CI)	0.99 [0.77, 1.27]
24 Healthcare seeking for maternal morbidities	2	25029	Risk Ratio (Random, 95% CI)	1.63 [0.39, 6.85]
25 Healthcare seeking for neonatal morbidities	9	66935	Risk Ratio (Random, 95% CI)	1.42 [1.14, 1.77]
26 Maternal mortality: low risk of bias studies	5	95946	Risk Ratio (Random, 95% CI)	0.76 [0.57, 1.00]
27 Neonatal mortality: low risk of bias studies	8	115262	Risk Ratio (Random, 95% CI)	0.70 [0.59, 0.83]
28 Perinatal mortality: low risk of bias studies	5	87629	Risk Ratio (Random, 95% CI)	0.73 [0.65, 0.82]
29 Stillbirths: low risk of bias studies	4	67948	Risk Ratio (Random, 95% CI)	0.75 [0.69, 0.82]

## Analysis 1.1. Comparison 1 Community-based intervention versus control, Outcome 1 Maternal mortality.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 1 Maternal mortality



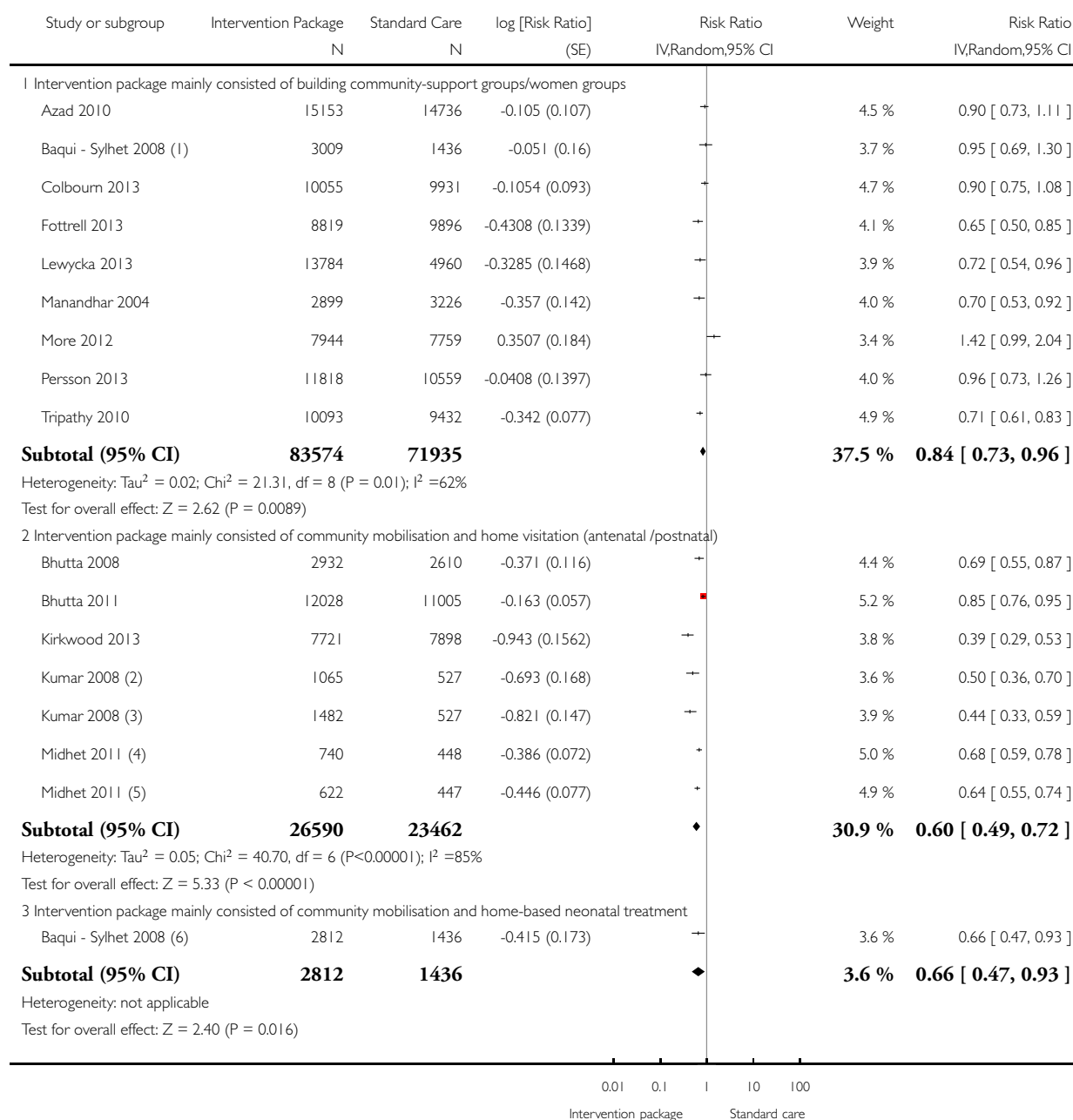


## Analysis 1.2. Comparison 1 Community-based intervention versus control, Outcome 2 Neonatal mortality.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

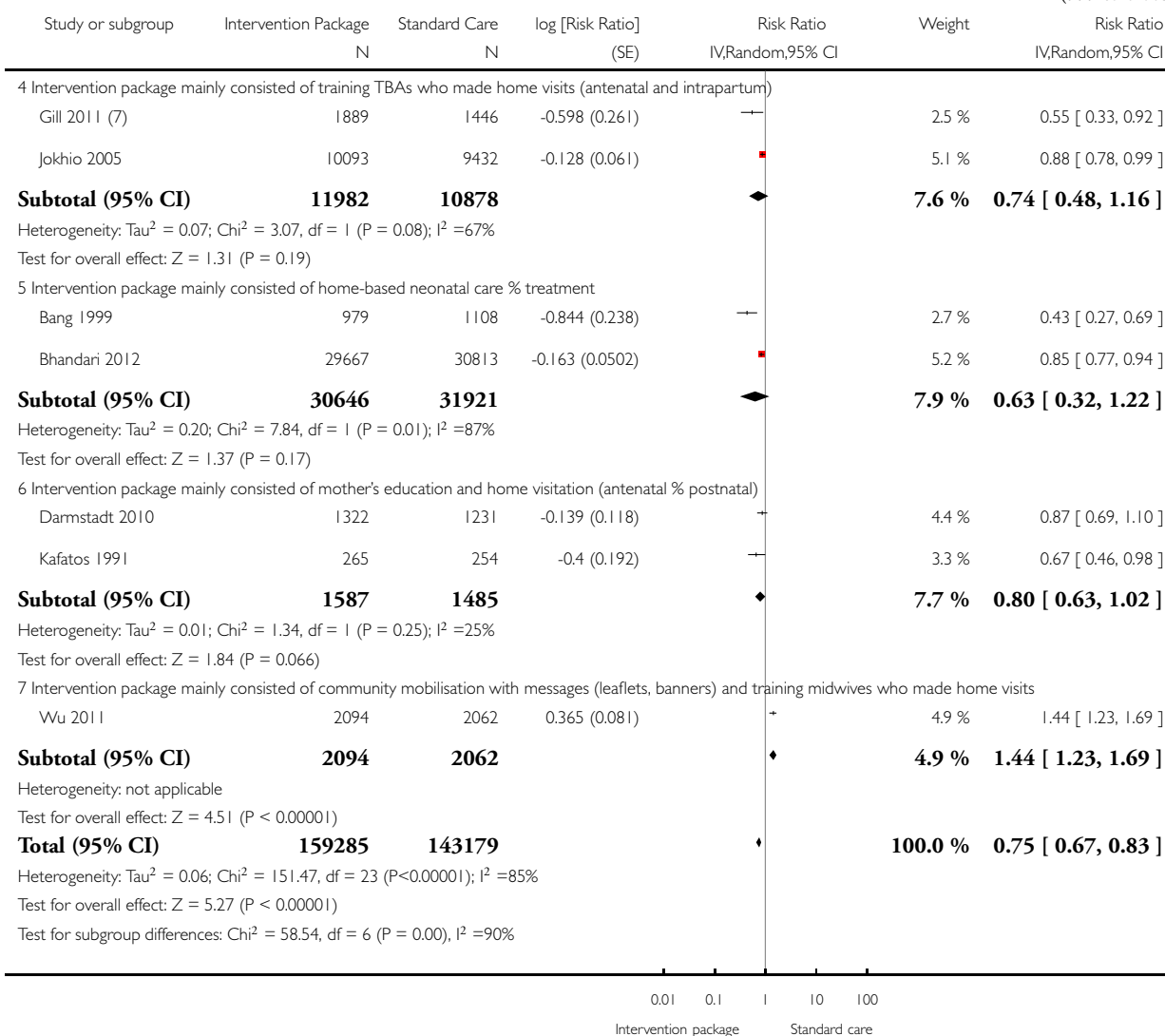
Comparison: 1 Community-based intervention versus control

Outcome: 2 Neonatal mortality



(Continued ...)

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(1) Community care arm

(2) ENC + thermospot

(3) ENC

(4) W-IECC

(5) C-IECC

(6) Home care arm

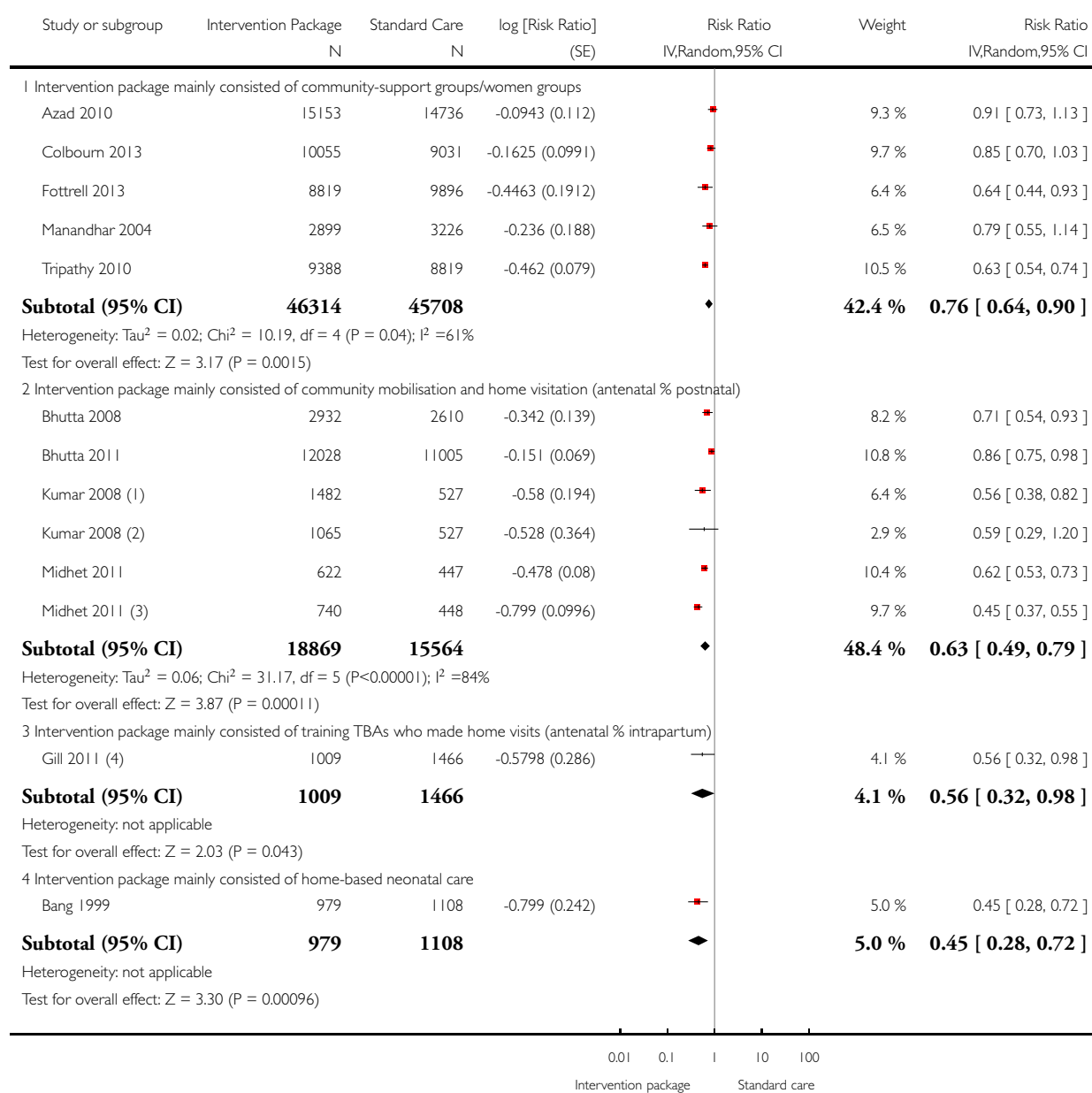
(7) TBAs were trained for management of birth asphyxia and neonatal sepsis (first dose of antibiotic with referral)

### Analysis 1.3. Comparison 1 Community-based intervention versus control, Outcome 3 Early neonatal mortality.

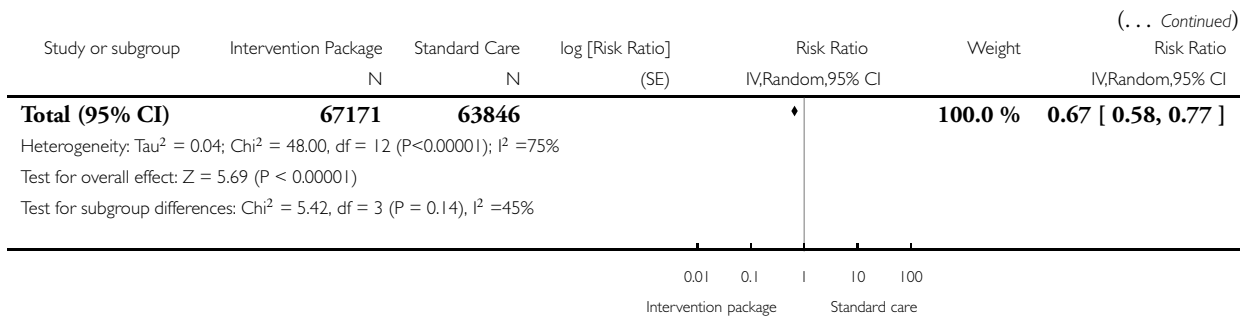
Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 3 Early neonatal mortality



(Continued ...)



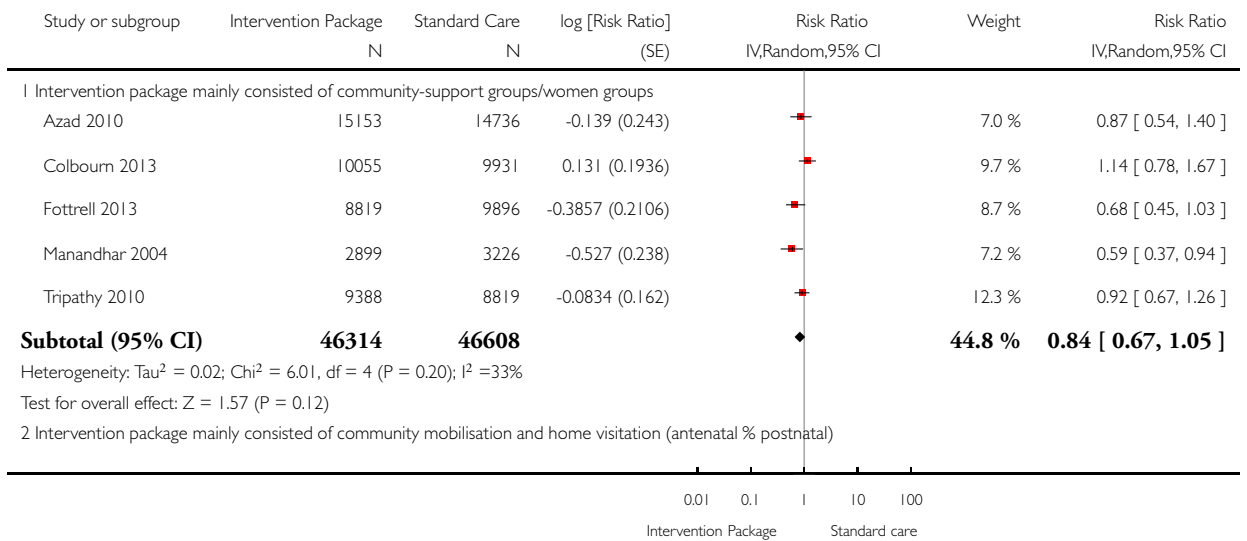
- (1) ENC
- (2) ENC + thermospot
- (3) C-IECC
- (4) TBAs were trained for management of birth asphyxia and neonatal sepsis (first dose of antibiotic with referral)

#### Analysis 1.4. Comparison 1 Community-based intervention versus control, Outcome 4 Late neonatal mortality.

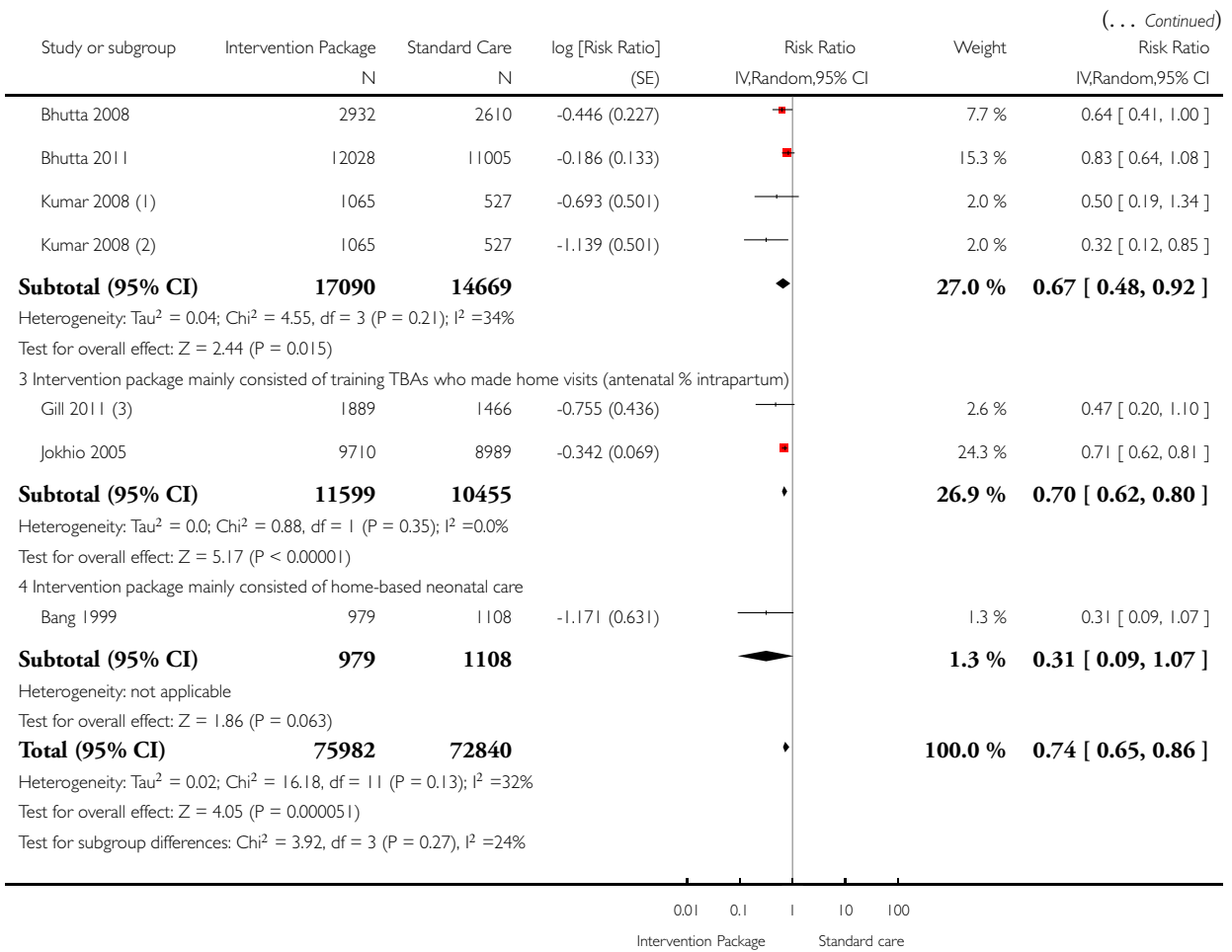
Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 4 Late neonatal mortality



(Continued . . .)



(1) ENC + thermospot

(2) ENC

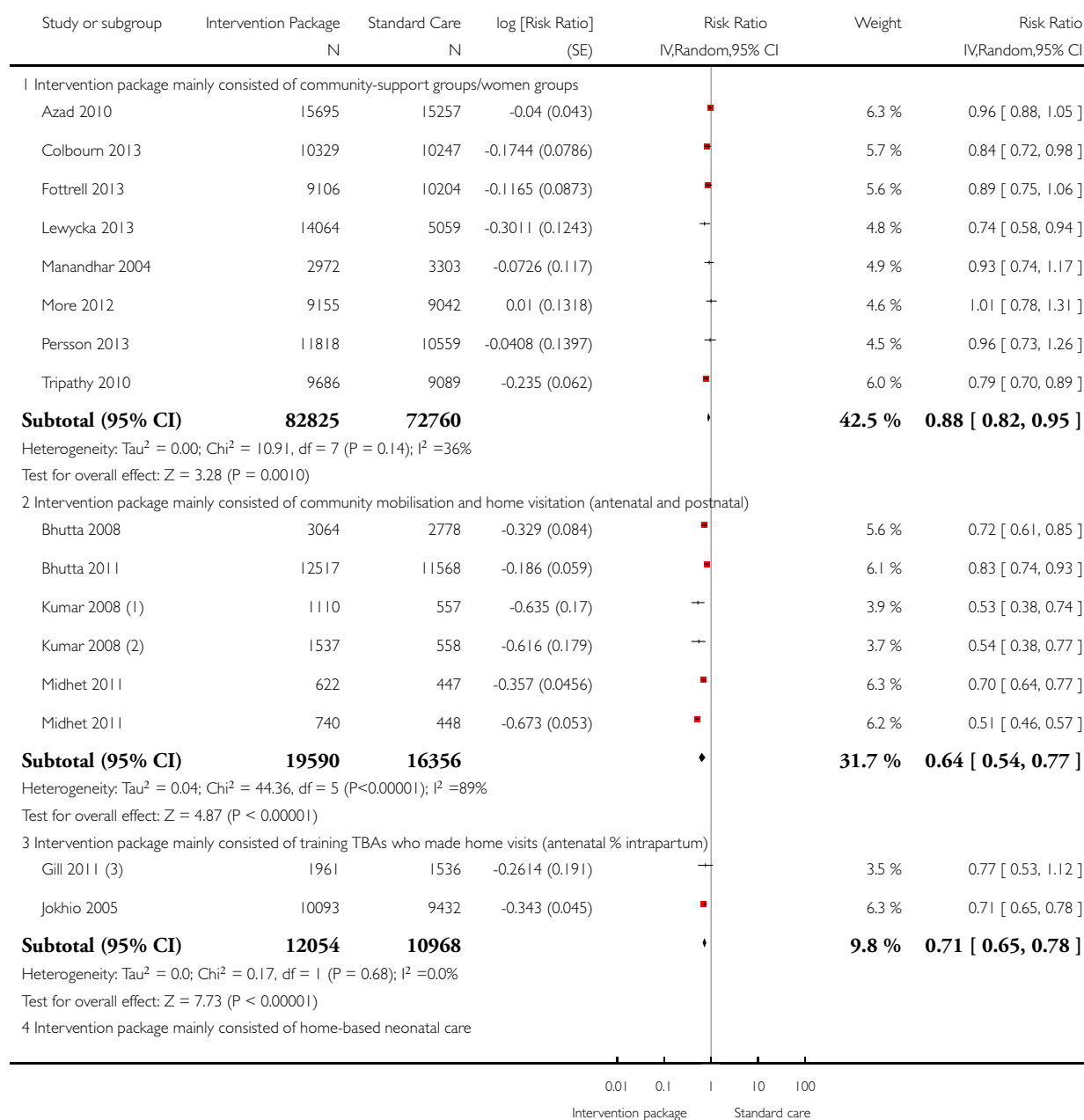
(3) TBAs were trained for management of birth asphyxia and neonatal sepsis (first dose of antibiotic with referral)

## Analysis 1.5. Comparison 1 Community-based intervention versus control, Outcome 5 Perinatal mortality.

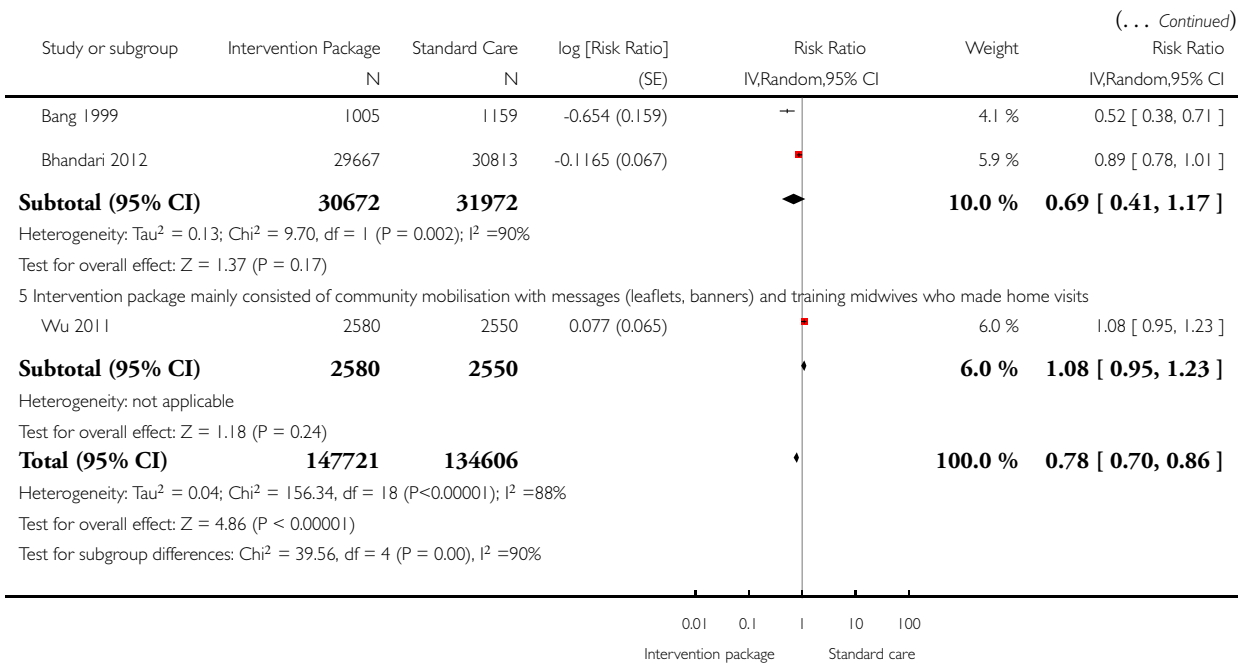
Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 5 Perinatal mortality



(Continued ...)



(1) ENC + thermospot

(2) ENC

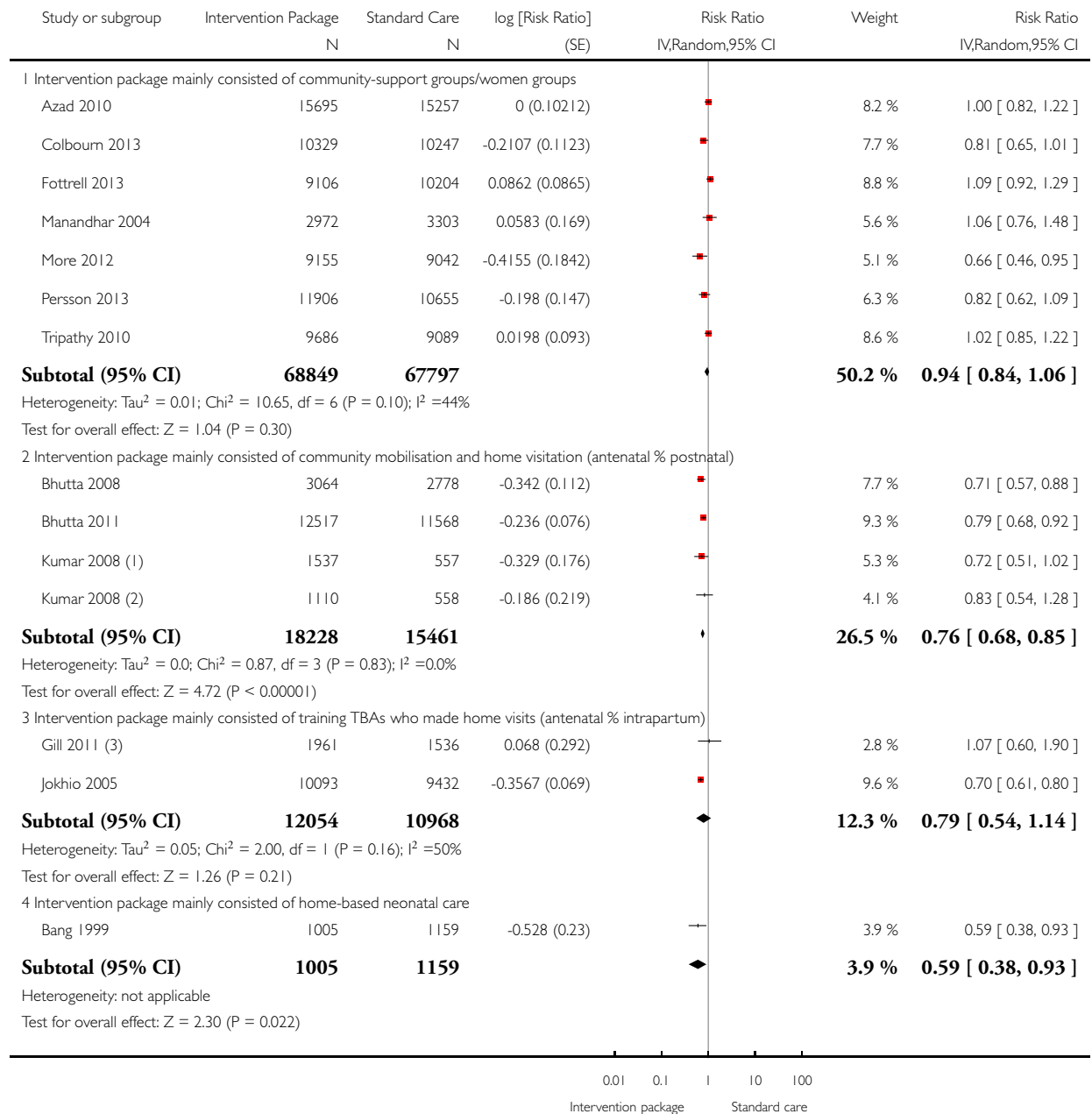
(3) TBAs were trained for management of birth asphyxia and neonatal sepsis (first dose of antibiotic with referral)

## Analysis 1.6. Comparison 1 Community-based intervention versus control, Outcome 6 Stillbirths.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

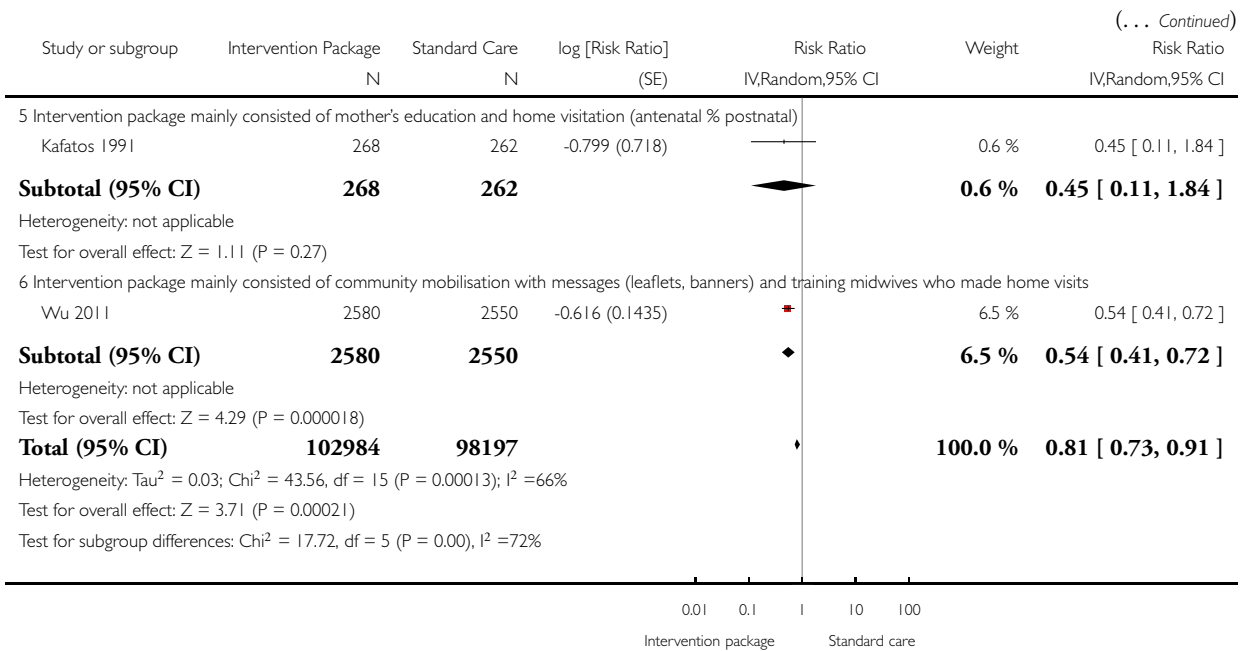
Comparison: 1 Community-based intervention versus control

Outcome: 6 Stillbirths



(Continued ...)





(1) ENC

(2) ENC + thermospot-0.18

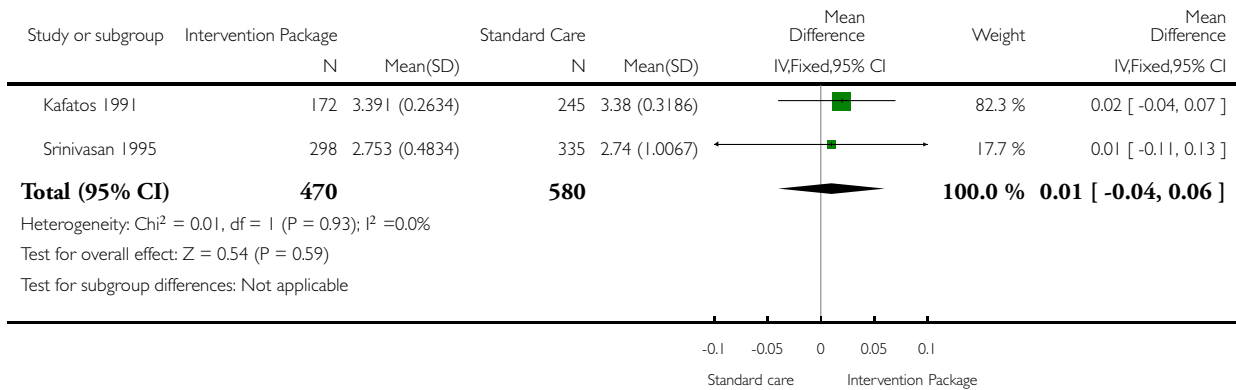
(3) TBAs were trained for management of birth asphyxia and neonatal sepsis (first dose of antibiotic with referral)

### Analysis 1.7. Comparison 1 Community-based intervention versus control, Outcome 7 Mean birthweight (kg).

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 7 Mean birthweight (kg)

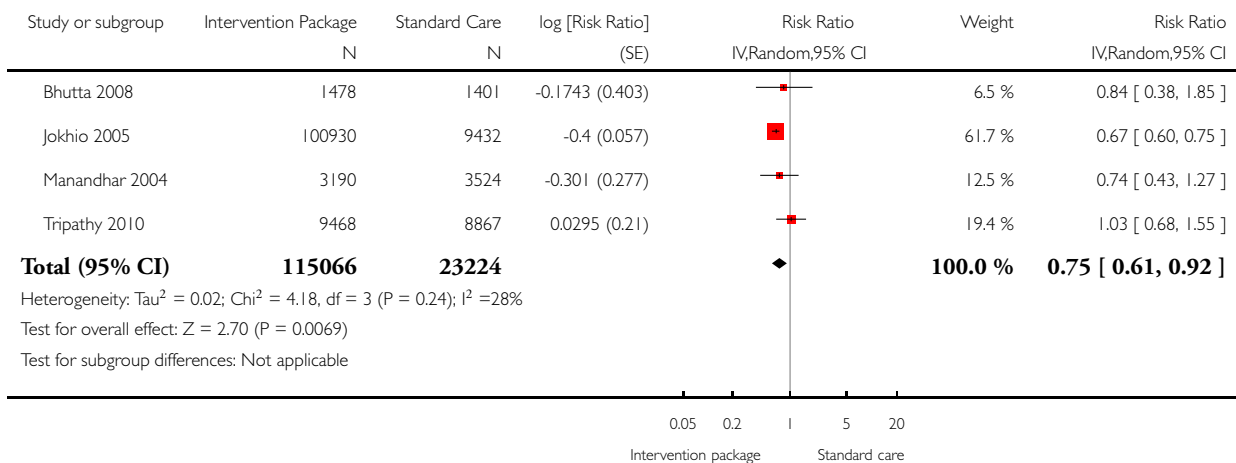


### Analysis 1.8. Comparison 1 Community-based intervention versus control, Outcome 8 Maternal morbidity.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 8 Maternal morbidity

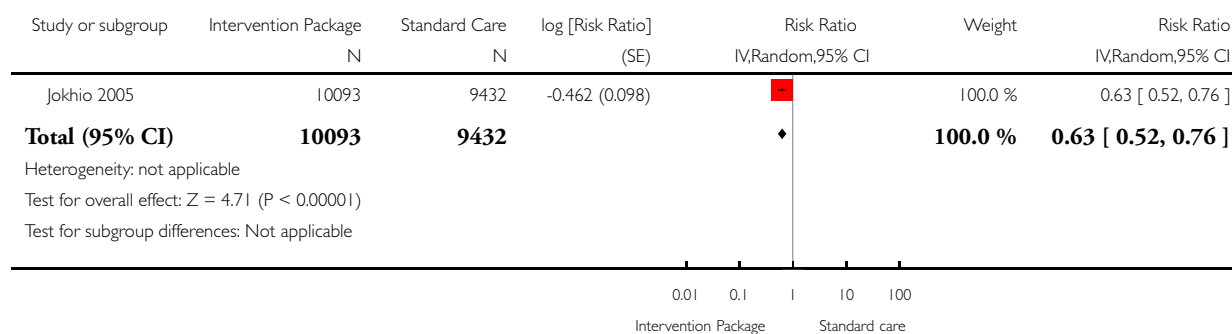


### Analysis 1.9. Comparison 1 Community-based intervention versus control, Outcome 9 Complication of pregnancy: haemorrhage.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 9 Complication of pregnancy: haemorrhage

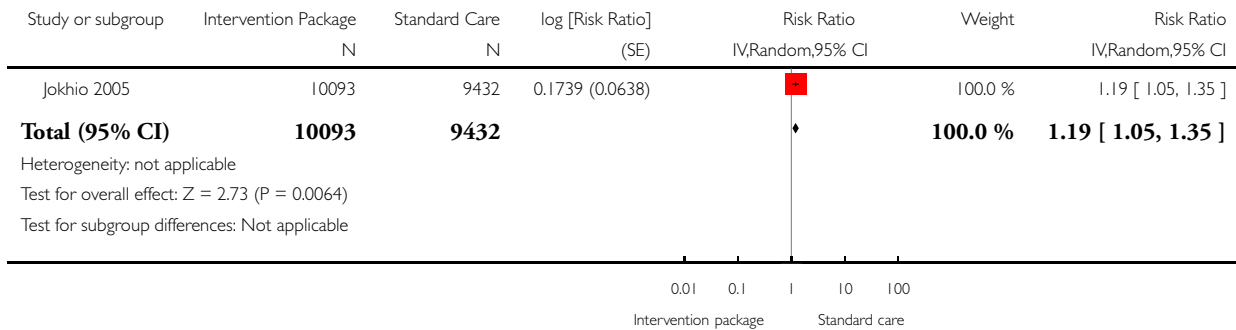


### Analysis I.10. Comparison I Community-based intervention versus control, Outcome I0 Complication of pregnancy: obstructed labour.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: I Community-based intervention versus control

Outcome: I0 Complication of pregnancy: obstructed labour

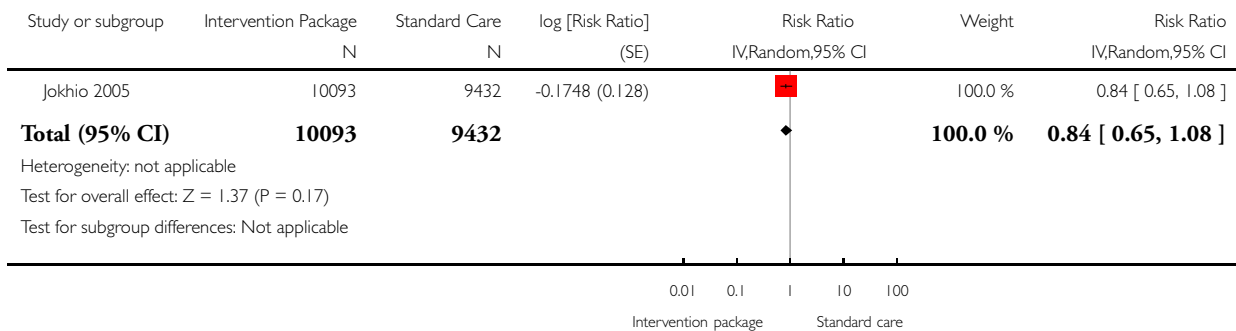


### Analysis I.11. Comparison I Community-based intervention versus control, Outcome I1 Complication of pregnancy: puerperal sepsis.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: I Community-based intervention versus control

Outcome: I1 Complication of pregnancy: puerperal sepsis

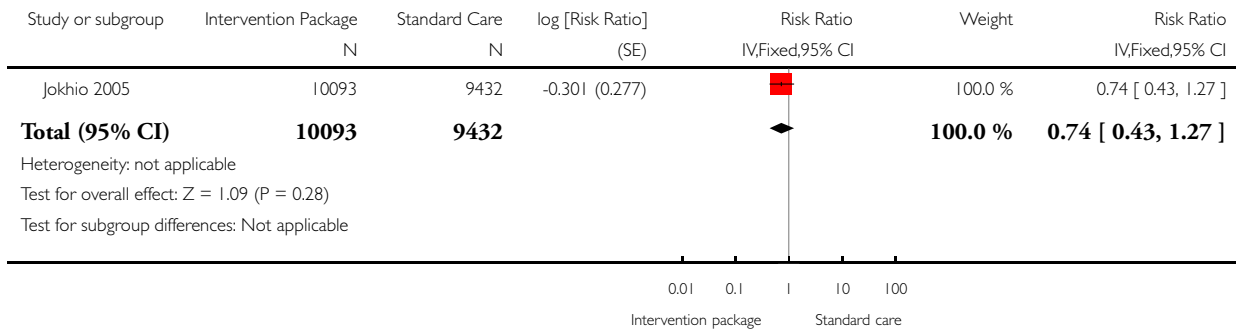


### Analysis I.12. Comparison I Community-based intervention versus control, Outcome I2 Complication of pregnancy: eclampsia.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: I Community-based intervention versus control

Outcome: I2 Complication of pregnancy: eclampsia

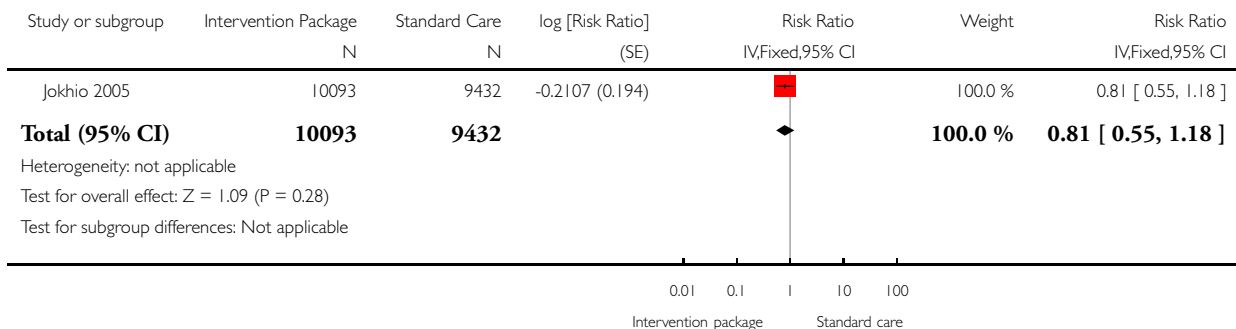


### Analysis I.13. Comparison I Community-based intervention versus control, Outcome I3 Complication of pregnancy: spontaneous abortion.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: I Community-based intervention versus control

Outcome: I3 Complication of pregnancy: spontaneous abortion

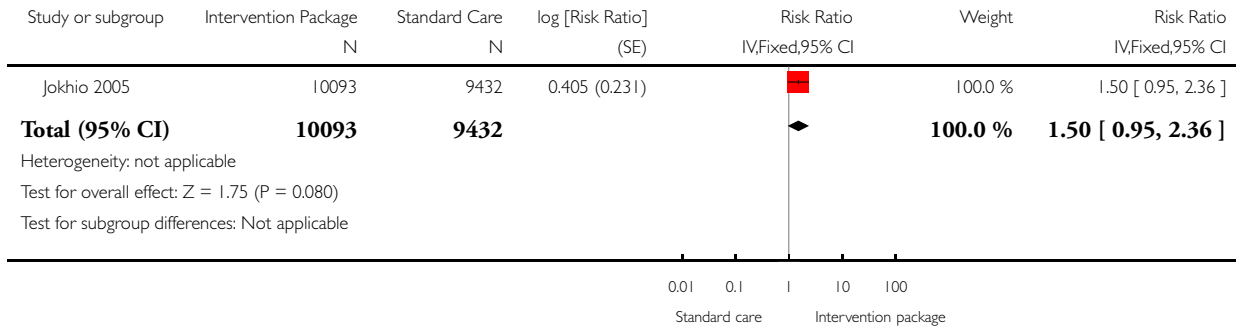


**Analysis 1.14. Comparison 1 Community-based intervention versus control, Outcome 14 Referral to health facility for any complication during pregnancy.**

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 14 Referral to health facility for any complication during pregnancy

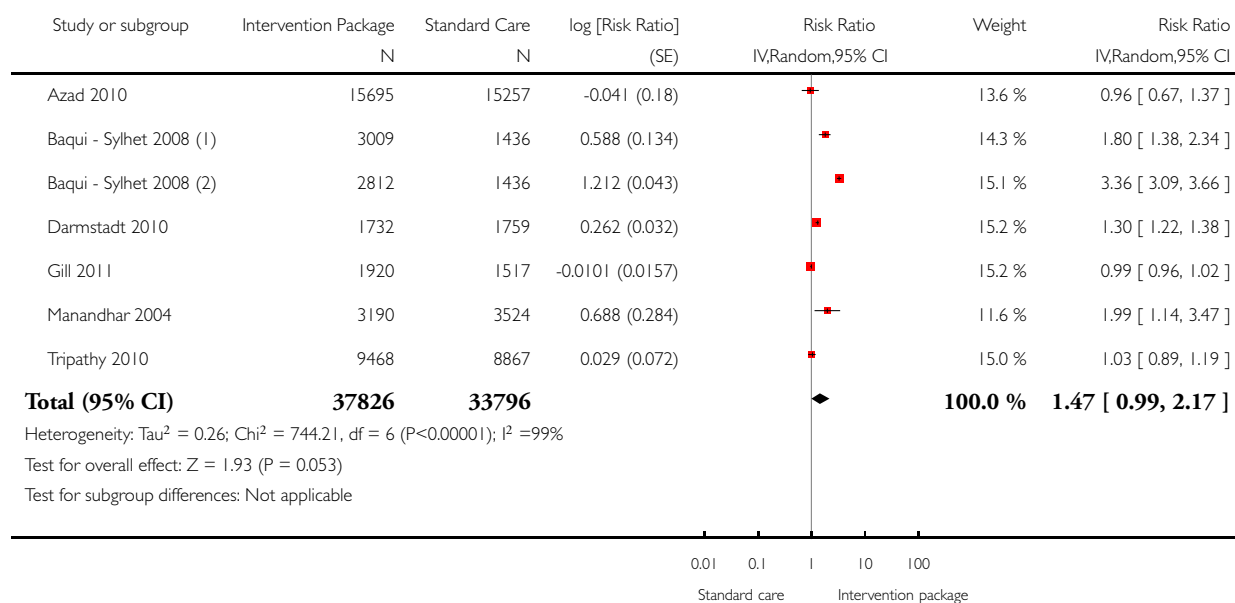


### Analysis 1.15. Comparison 1 Community-based intervention versus control, Outcome 15 Iron/folate supplementation (not pre-specified).

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 15 Iron/folate supplementation (not pre-specified)



(1) Community care arm

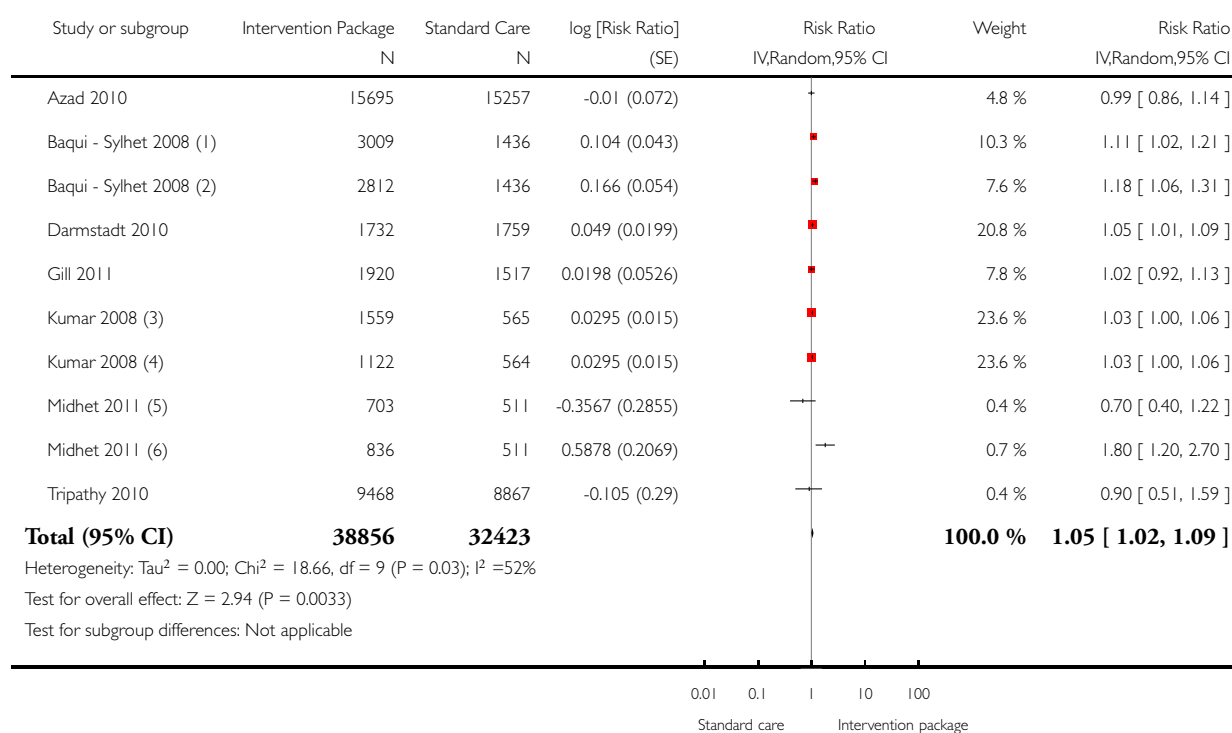
(2) home care arm

## Analysis 1.16. Comparison 1 Community-based intervention versus control, Outcome 16 Any Tetanus toxoid immunisation (not pre-specified).

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 16 Any Tetanus toxoid immunisation (not pre-specified)



- (1) community care arm
- (2) home care arm
- (3) ENC + thermospot
- (4) ENC
- (5) C-IECC
- (6) W-IECC

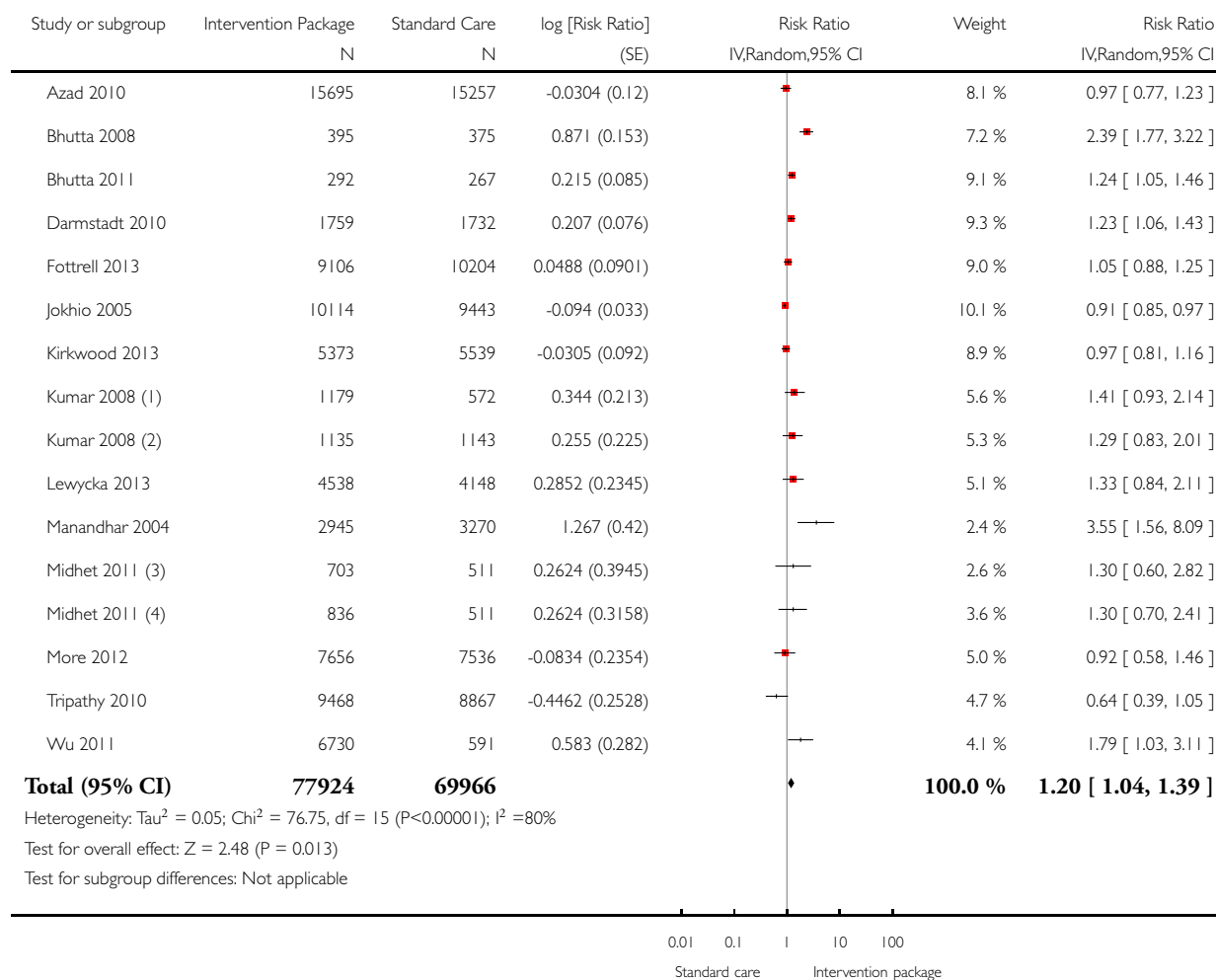


### Analysis 1.17. Comparison 1 Community-based intervention versus control, Outcome 17 Institutional deliveries.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 17 Institutional deliveries



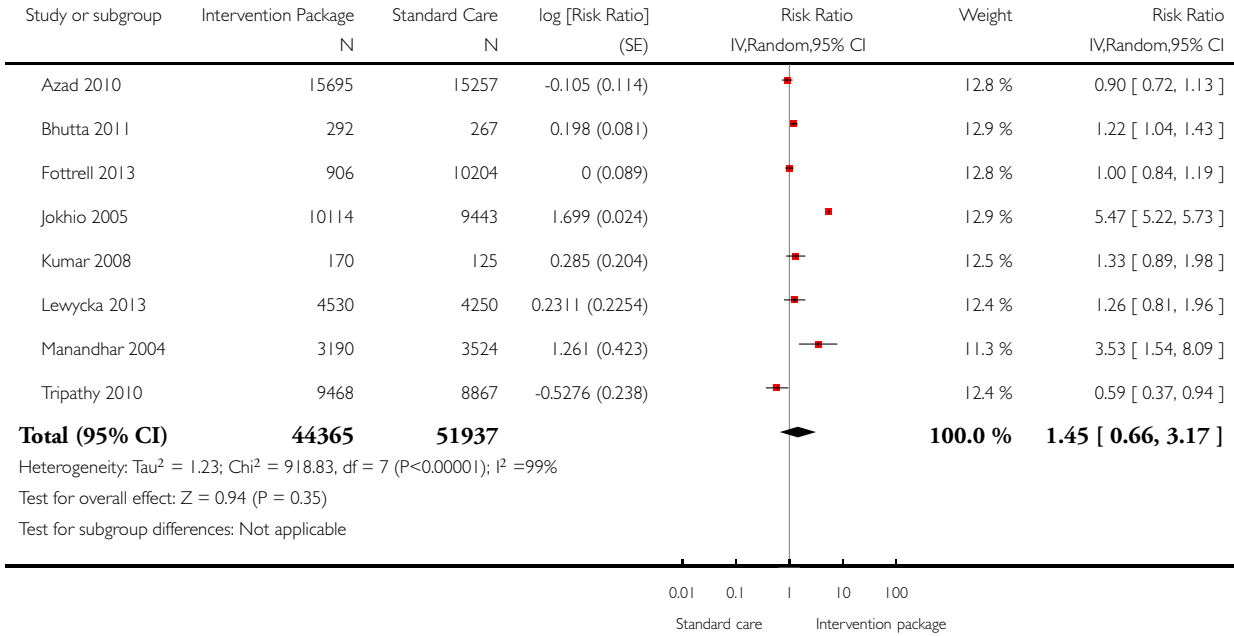
- (1) ENC + thermospot
- (2) ENC
- (3) C-IECC
- (4) W-IECC

**Analysis 1.18. Comparison 1 Community-based intervention versus control, Outcome 18 Birth attended by healthcare provider.**

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 18 Birth attended by healthcare provider

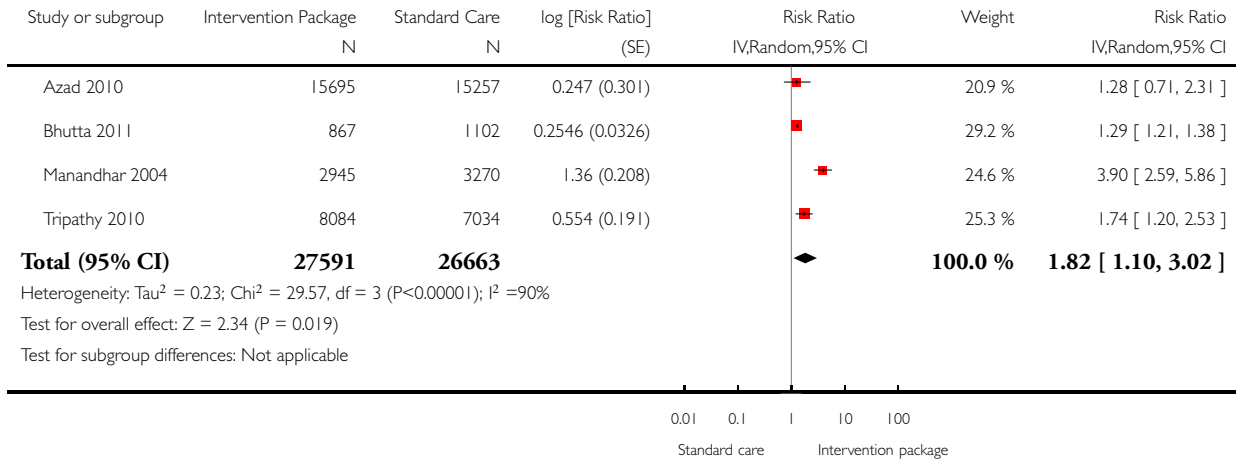


**Analysis 1.19. Comparison 1 Community-based intervention versus control, Outcome 19 Use of clean delivery kits (not pre-specified).**

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 19 Use of clean delivery kits (not pre-specified)

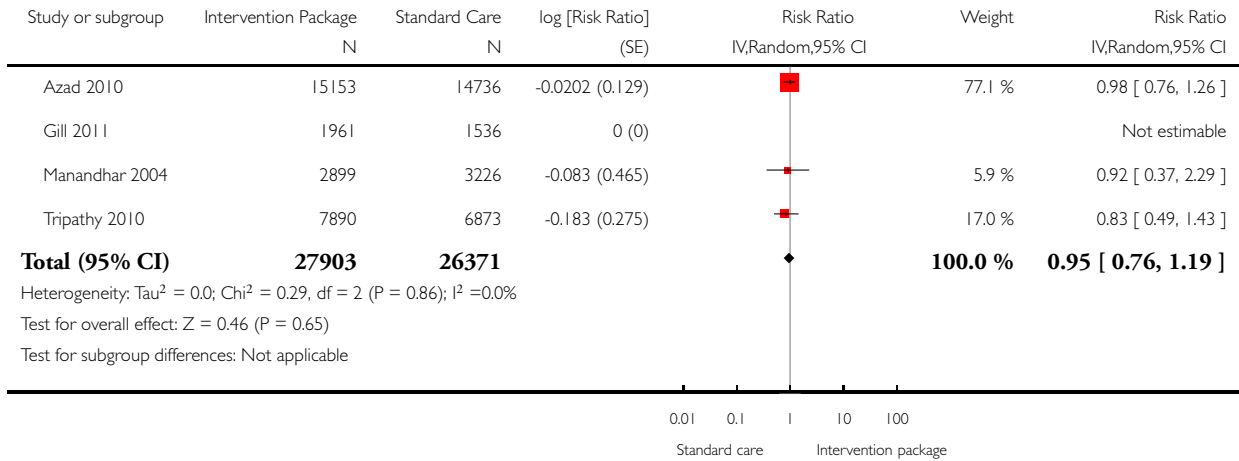


**Analysis 1.20. Comparison 1 Community-based intervention versus control, Outcome 20 Baby wrapped within 30 minutes (not pre-specified).**

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 20 Baby wrapped within 30 minutes (not pre-specified)

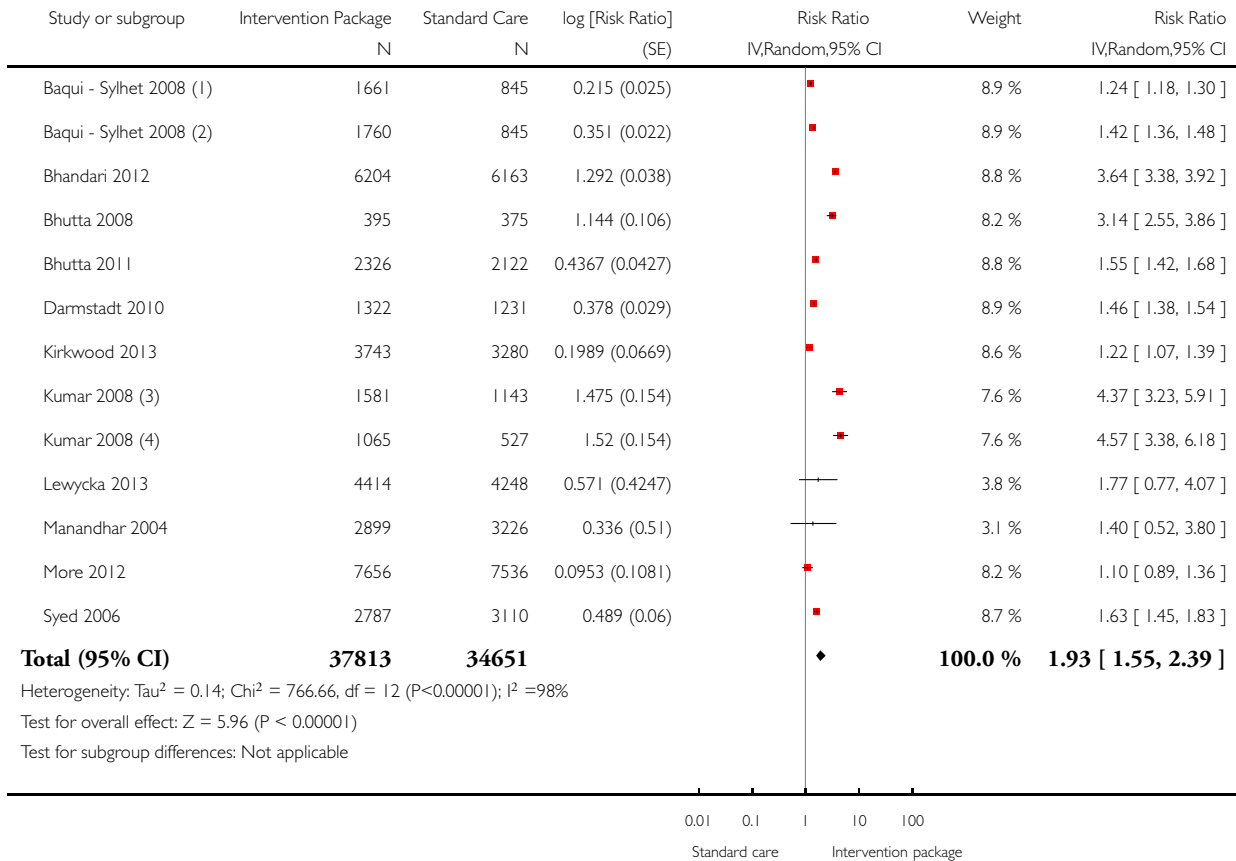


## Analysis 1.21. Comparison 1 Community-based intervention versus control, Outcome 21 Initiation of breastfeeding within 1 hour of birth.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 21 Initiation of breastfeeding within 1 hour of birth



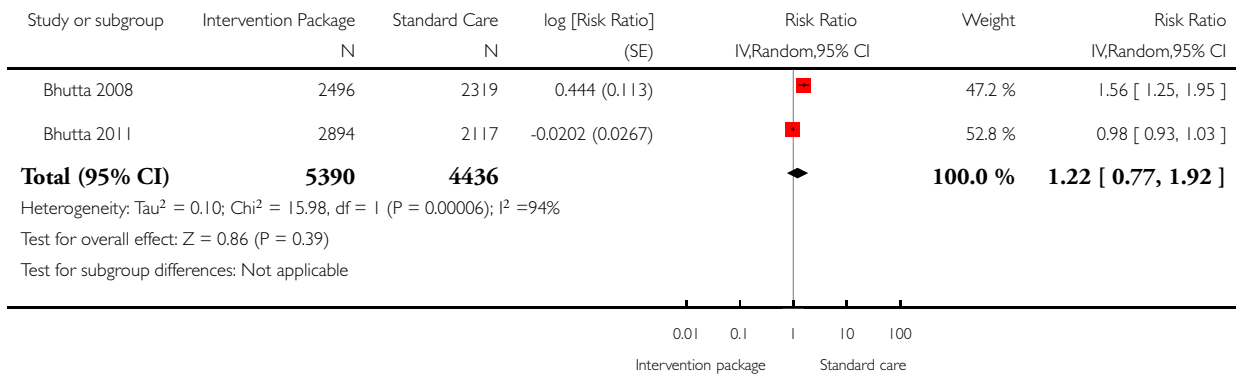
- (1) home care arm
- (2) Community care arm
- (3) ENC
- (4) ENC + thermospot

### Analysis I.22. Comparison I Community-based intervention versus control, Outcome 22 Delayed bathing for up to 6 hours (not pre-specified).

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: I Community-based intervention versus control

Outcome: 22 Delayed bathing for up to 6 hours (not pre-specified)

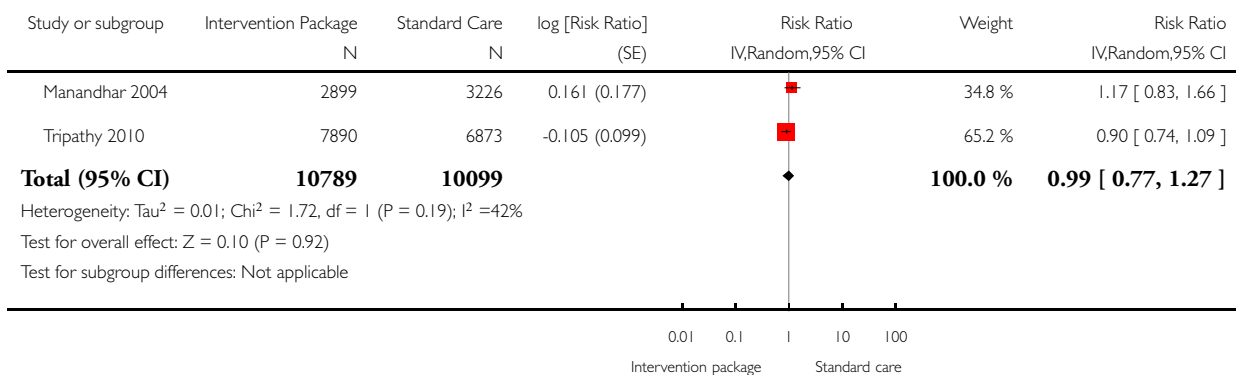


### Analysis I.23. Comparison I Community-based intervention versus control, Outcome 23 Clean cord care (not pre-specified).

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: I Community-based intervention versus control

Outcome: 23 Clean cord care (not pre-specified)

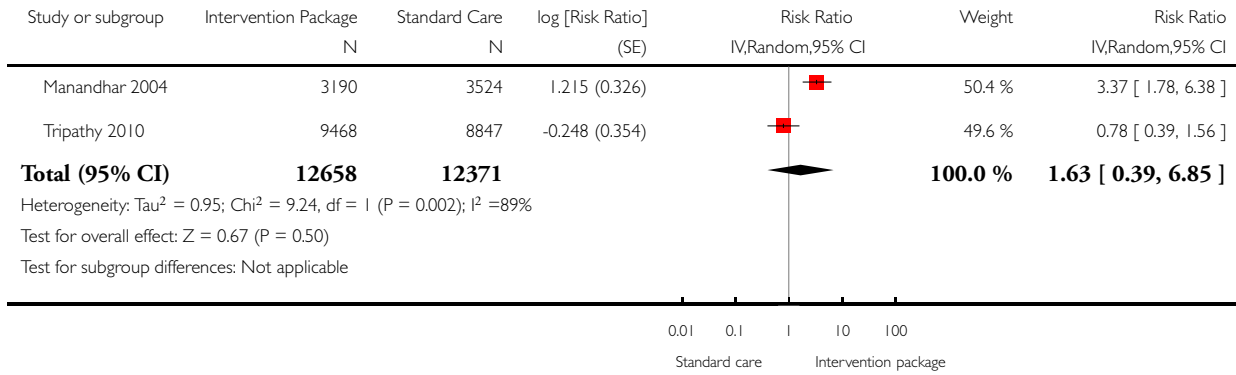


**Analysis 1.24. Comparison 1 Community-based intervention versus control, Outcome 24 Healthcare seeking for maternal morbidities.**

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 24 Healthcare seeking for maternal morbidities

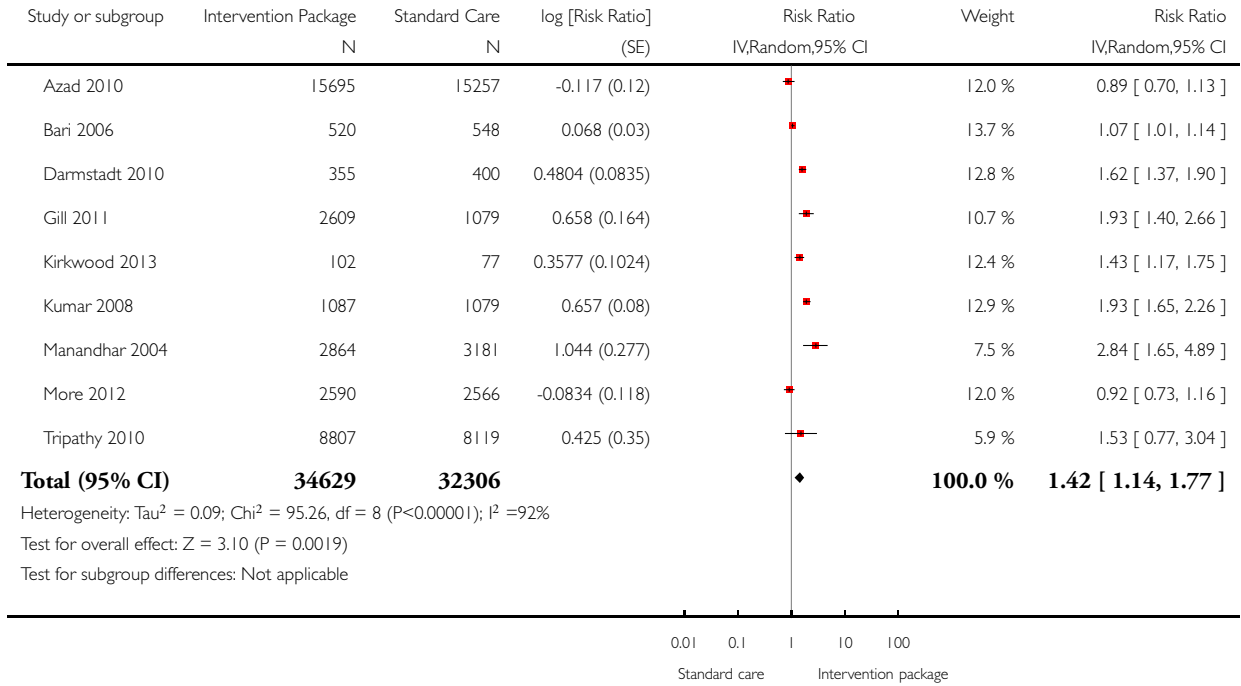


**Analysis 1.25. Comparison 1 Community-based intervention versus control, Outcome 25 Healthcare seeking for neonatal morbidities.**

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 25 Healthcare seeking for neonatal morbidities



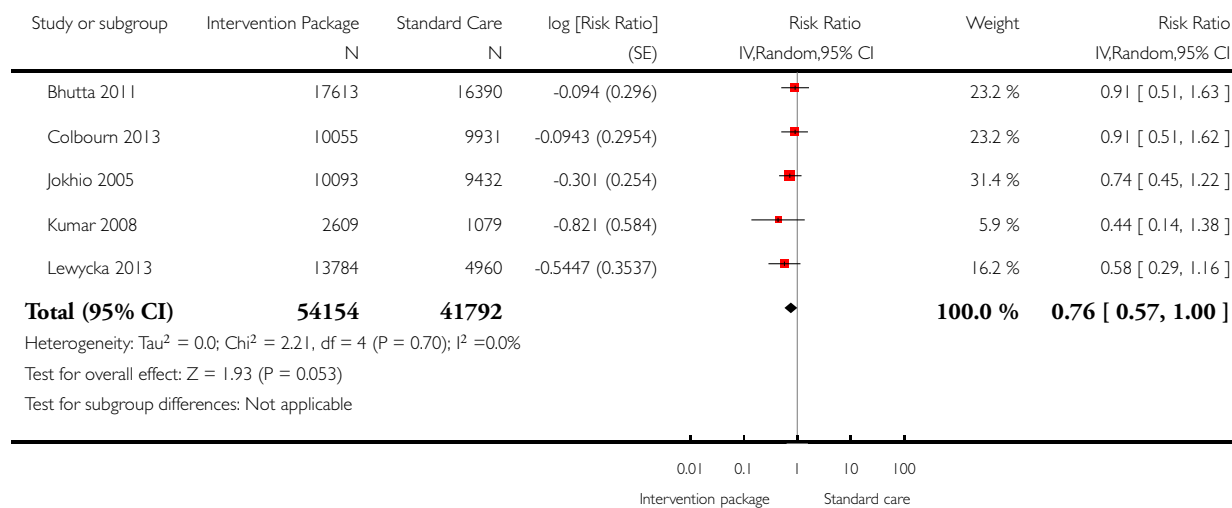


### Analysis 1.26. Comparison 1 Community-based intervention versus control, Outcome 26 Maternal mortality: low risk of bias studies.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 26 Maternal mortality: low risk of bias studies

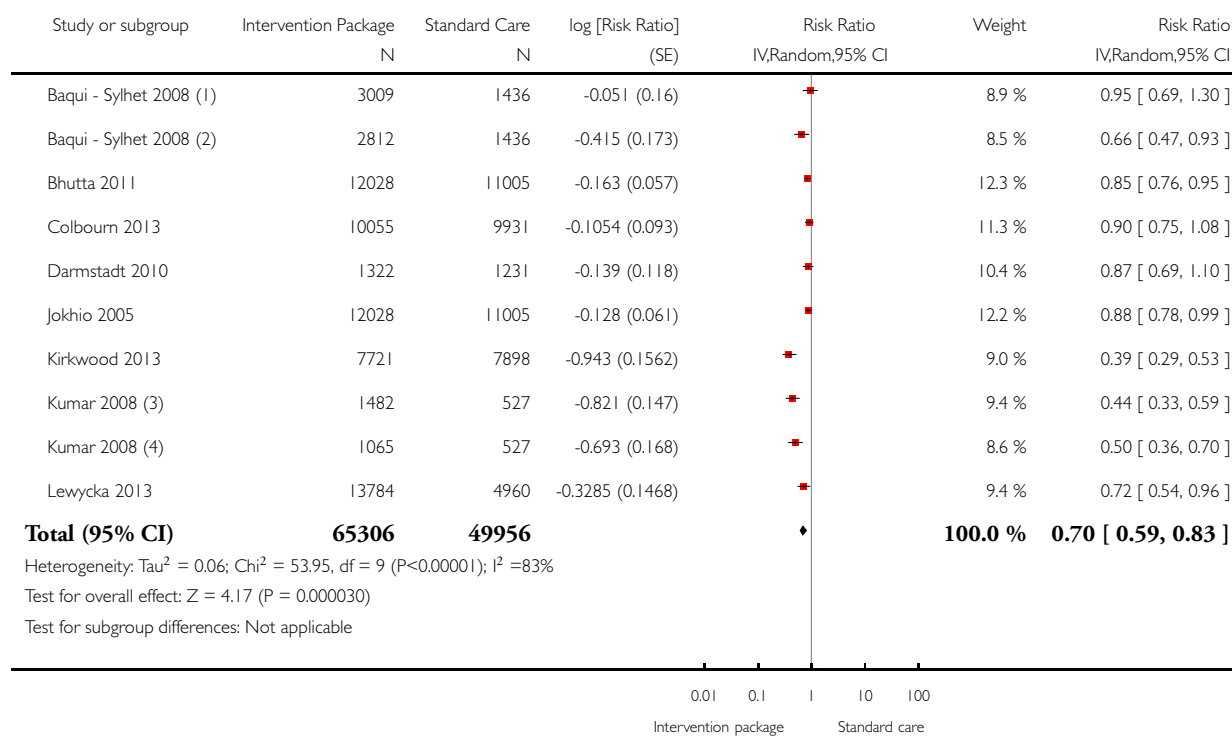


## Analysis 1.27. Comparison 1 Community-based intervention versus control, Outcome 27 Neonatal mortality: low risk of bias studies.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 27 Neonatal mortality: low risk of bias studies



(1) community care arm

(2) home care arm

(3) ENC

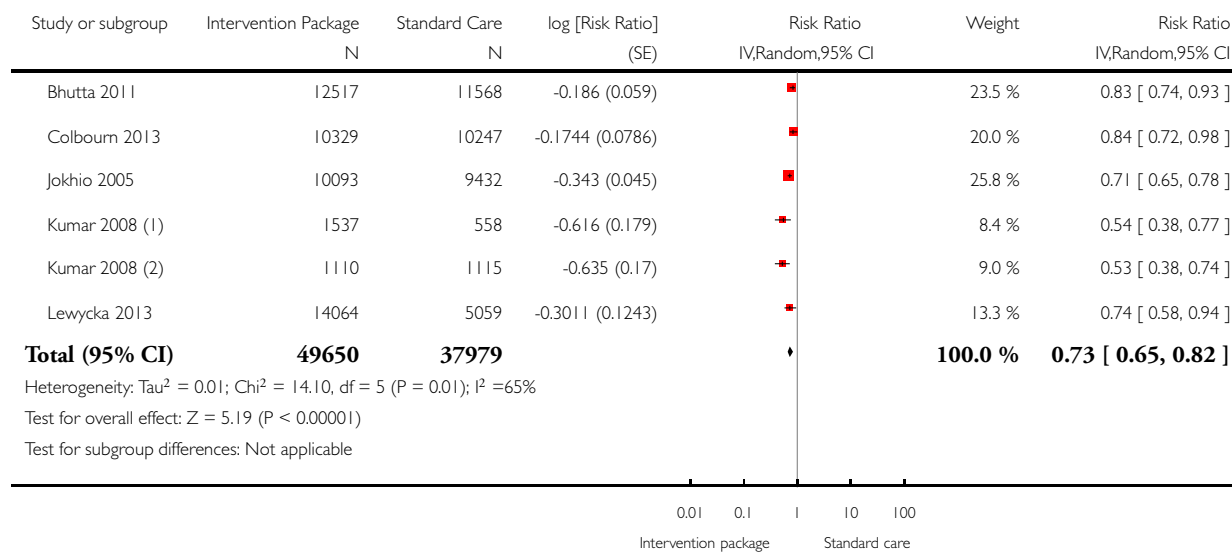
(4) ENC + thermospot

### Analysis 1.28. Comparison 1 Community-based intervention versus control, Outcome 28 Perinatal mortality: low risk of bias studies.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 28 Perinatal mortality: low risk of bias studies



(1) ENC

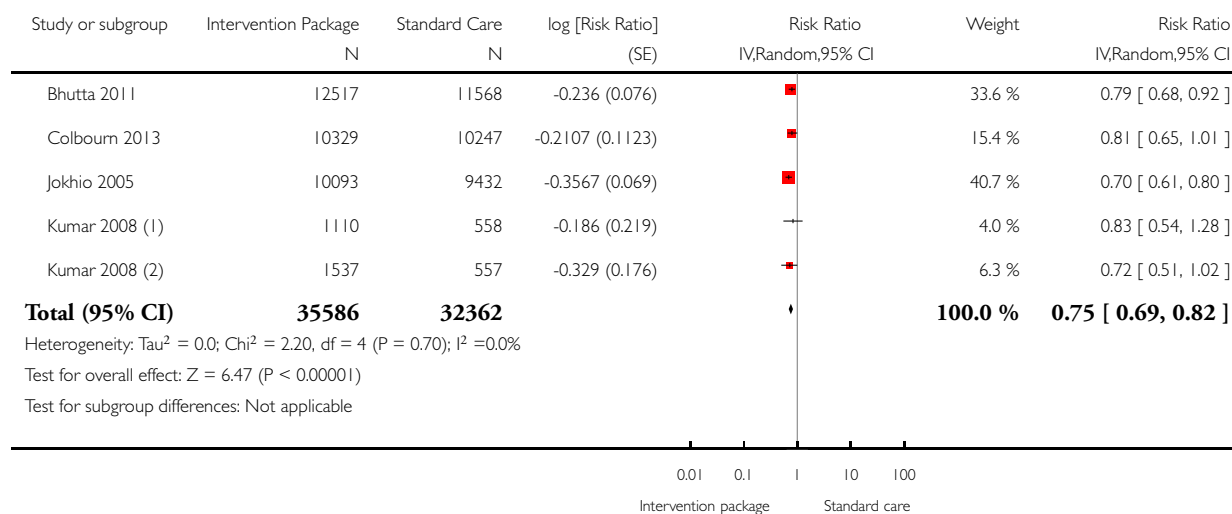
(2) ENC + thermospot

### Analysis 1.29. Comparison 1 Community-based intervention versus control, Outcome 29 Stillbirths: low risk of bias studies.

Review: Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes

Comparison: 1 Community-based intervention versus control

Outcome: 29 Stillbirths: low risk of bias studies



(1) ENC + thermospot

(2) ENC

## ADDITIONAL TABLES

Table 1. Predominant community-based intervention package in included studies

Studies	Predominant intervention factor in package						Health worker characteristics		Coverage in experimental group (n)
	Community-support groups/ community mobilisation)	TBA training	Home visitation	Home-based neonatal care and treatment	Health education to mothers (one-to-one counselling)	Type of health worker involved	Training duration		
<a href="#">Azad 2010</a>	Yes					CHW TBA	5 sessions	15,695 births and 15,153 live births	

**Table 1. Predominant community-based intervention package in included studies** (Continued)

Bang 1999			Yes (AN + PN)	Yes	Yes	CHW TBA	3 days	1108 live births
Baqui - Sylhet 2008 (Home- based model)	Yes		Yes (AN + PN)	Yes		CHW	6 weeks	1760 total births
Baqui - Sylhet 2008 (Com- munity care model)	Yes		Yes (AN + PN)			CHW	6 weeks	1661 total births
Bari 2006			Yes (AN + PN)			CHW		794 sick newborns
Bhandari 2012			Yes (PN)	Yes	Yes	CHW and Midwife	8 days	29667 live births
Bhutta 2008	Yes		Yes (AN + PN)			CHW TBA	6 days 3 days	2672 total births and 2496 live births
Bhutta 2011	Yes		Yes (AN + PN)			CHW TBA	6 days 3 days	12,517 total births and 12,028 live births
Colbourn 2013								
Darmstadt 2010		Yes	Yes (AN + PN)	Yes		CHW	36 days	5031 preg- nancies
Fottrell 2013								
Gill 2011		Yes	Yes (AN and IP and PN)	Yes		TBA	7 days	2007 deliv- eries
Jokhio 2005		Yes	Yes (AN + IP)			TBA	3 days	10,093 women
Kafatos 1991			Yes (AN + PN)		Yes	CHN		300 women

**Table 1. Predominant community-based intervention package in included studies** (Continued)

Kirkwood 2013			Yes (AN + PN)	Yes		CHW	-	7859 pregnancies and 7673 live births
Kumar 2008	Yes		Yes (AN + PN)			CHW	7 days	1110 births and 1065 live births (thermo spot arm)
Lewycka 2013	Yes					CHW	over 11 days	5901, 5670 pregnancies respectively in women group and volunteer peer counselling
Magoma 2013		Yes						
Manandhar 2004	Yes					CHW		3190 pregnancies, 2972 births and 2899 live births
Midhet 2011	Yes	Yes	Yes (AN + PN)	Yes		TBA and CHW		1362 live births
More 2012	Yes					CHW	-	7656 births
Nsibandé 2013			Yes (AN + PN)	Yes		CHW		2423 mothers
Persson 2013	Yes							
Srinivasan 1995			Yes (AN)			CHN		573 pregnancies
Syed 2006						CHW	6 days	3110 women
Tomlinson 2014			Yes (AN + PN)	Yes		CHW	over 10 days	4137 mothers

**Table 1. Predominant community-based intervention package in included studies** (Continued)

Tripathy 2010	Yes					CHW	7 days	9770 births and 9469 live births
Wu 2011			Yes (AN+PN)		Yes	Midwives	3 days	5130 pregnancies and 4156 live births

AN: antenatal

CHW: community health worker (we used this term for all kinds of CHWs that include lady health worker, female health volunteer, maternal and child health worker, *anganwadi* worker, etc.)

CHN: community health nurse

IP: intrapartum

PN: postnatal

TBA: traditional birth attendant

**Table 2. Characteristics of Traditional Birth Attendants (TBAs)**

Characteristics of TBAs (interventions predominantly delivered by TBAs)			
Study	Trained/Untrained	Training duration	Supported/supervised
Gill 2011	TBAs were given training	1 week	Quote: "TBAs had been trained in basic obstetric and newborn care (including how to do mouth to-mouth assisted breathing) and clean delivery techniques, and used clean delivery kits for every delivery. After enrolling in the study, all TBAs received training on basic record keeping and the reporting aspects of the trial, and on the importance of maintaining regular contact with the mother/infant pair even after the delivery".
Jokhio 2005	Quote: "obstetricians and female paramedics trained all traditional birth attendants in the taluka who performed at least one delivery per month. The training lasted three days"	3 days training	Quote: "Lady Health Workers were trained to support the traditional attendants"

## APPENDICES

### Appendix I. Search Strategies and Search Results

**Search Date: 18 September 2011**

#### Google Scholar

["community-based nutrition program" OR "community-based primary health care" OR "community-based program" OR "community-based perinatal care" OR "community-based neonatal care" OR "community health" OR "health worker" OR "community involvement" OR "community participation" OR "community program" OR package OR "behaviour change"] AND [pregnancy OR women OR infant OR neonate OR perinatal OR newborn]

**Search results:** 17,200

#### Google

"community-based nutrition programs" OR "community -based primary health care" OR "community-based programs" OR "community health" OR "community health workers" OR "village health workers" OR "community involvement" OR "community participation" OR "community programs"

**Search results:** 18,600

FOR IDEAS, BLDS and World Bank JOLIS, the individual keywords were added into the search engines and search results were screened. We cumulatively added hits for each searched keyword and added into our total number of hits.

**Revised search: May 25, 2014**

Reviewed: 5009

## WHAT'S NEW

Last assessed as up-to-date: 25 May 2014.

Date	Event	Description
25 May 2014	New citation required and conclusions have changed	This updated review now has 26 included studies. There is now evidence that community-based intervention packages are also associated with increased use of clean delivery kits and rates of institutional deliveries
25 May 2014	New search has been performed	Search updated. Thirteen new studies included (Bhandari 2012; Colbourn 2013; Darmstadt 2010; Fottrell 2013; Gill 2011; Kirkwood 2013; Lewycka 2013; Magoma 2013; Midhet 2011; More 2012; Nsiband 2013; Persson 2013; Wu 2011) and 19 excluded (Althabe 2012; Basinga 2011; Carlo 2010; Dix-Cooper 2012; Nassar 2014; Gloyd 2001; Hartley 2011; Hounton 2009; Janowitz 1988; Jennings 2010; Meegan 2001; Miller 2012; Mosha 2005; Owais 2011; Rahman 2012; Ramsey 2013; Roman 2009; Rotheram-Borus 2011a; Thompson 2011). Ten studies are currently in Studies awaiting classification (Kamm 2012; Kestler 2013; Khan 2012; Morrison 2011; Rodriguez-Angulo 2012; Rotheram-Borus 2011b; Shrestha 2011; Tripathy 2011; Waiswa 2012; Wallin 2011) and seven are ongoing trials (Bhandari 2014; ISRCTN63294155; NCT01022788; NCT01073488; NCT01350765; NCT01751945; NCT01941264). For this update, five studies which were previously included



(Continued)

have now been reclassified as excluded because they were quasi-experimental studies ([Alisjahbana 1995](#); [Baqui-CARE INDIA 2008](#); [Foord 1995](#); [Greenwood 1990](#); [Ronsmans 1997](#)).

## HISTORY

Protocol first published: Issue 2, 2009

Review first published: Issue 11, 2010

Date	Event	Description
9 May 2009	Amended	The Background section has been expanded and additional secondary outcomes identified. The name of funding agency for the review has been added. Additional databases to be searched have also been added

## CONTRIBUTIONS OF AUTHORS

This update was conducted by Zohra S Lassi (ZSL) under the guidance of Zulfiqar A Bhutta (ZAB).

## DECLARATIONS OF INTEREST

Dr Zulfiqar A Bhutta is the principal investigator of two included studies evaluating community care perinatal care package in Pakistan ([Bhutta 2008](#); [Bhutta 2011](#)) but he was not involved in assessing these trials for inclusion in this review, assessing trial quality, or data extraction. These tasks were carried out by other members of the review team who were not involved with the original studies (ZSL and BAH).

## SOURCES OF SUPPORT

### Internal sources

- The Aga Khan University, Pakistan.

## External sources

- International Initiative for Impact Evaluation (3ie), Global Development Network, India.
- Funding for this review was provided by a grant from the International Initiative for Impact Evaluation

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For this update we added the following additional secondary outcomes which were not prespecified in the protocol or earlier version of the review (Lassi 2010). Community-based intervention packages have an important implications in terms of care delivery and improving maternal and neonatal care related outcomes:

- iron/folate supplementation;
- tetanus toxoid immunisation;
- use of clean delivery kits;
- wrapping babies within 30 minutes;
- delays bathing for six hours;
- clean cord care.

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Infant Mortality [trends]; \*Maternal Mortality [trends]; \*Perinatal Mortality [trends]; Cause of Death; Community Health Services [\*organization & administration; statistics & numerical data]; Maternal Health Services [organization & administration; statistics & numerical data]; Morbidity; Randomized Controlled Trials as Topic

### MeSH check words

Female; Humans; Infant; Infant, Newborn; Pregnancy