Lay health workers in primary and community health care: A systematic review of trials

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Abstract

Background
Increasing interest has been shown in the use of lay health workers (LHWs) for the delivery of a wide range of maternal and child health (MCH) services in low and middle income countries (LMICs). However, robust evidence of the effects of LHW interventions in improving MCH delivery is limited.

Objective
To review evidence from randomized controlled trials (RCTs) on the effects of LHW interventions in improving MCH and addressing key high burden diseases in LMICs.

Methods
Search strategy: multiple databases and reference lists of articles were searched for RCTs of LHW interventions in MCH. RCTs identified in an earlier systematic review were included in this report where appropriate.

Selection criteria: a LHW was defined by the authors of this report as a health worker delivering health care, who is trained in the context of the intervention but has no formal professional certificate or tertiary education degree. RCTs were included of any intervention delivered by LHWs (paid or voluntary) in primary or community health care and intended to promote health, manage illness or provide support to patients. Interventions needed to be relevant to MCH and/or high burden diseases in LMICs. No restrictions were placed on the types of consumers.

Data collection and analysis: data were extracted for each study and study quality assessed. Studies comparing broadly similar types of interventions were grouped together. Where feasible, the results of the included studies were combined and an estimate of effect obtained.

Results
48 studies met the review's inclusion criteria. There was evidence of moderate to high quality of the effectiveness of LHWs in improving immunisation uptake in children (RR 1.22, p = 0.0004); and in reducing childhood morbidity (RR 0.81, p = 0.001) and mortality (RR 0.74, p = 0.04) from common illnesses, compared with usual care. LHWs are also effec-

tive in promoting exclusive breastfeeding up to six months of age in LMICs (RR 3.67, p = 0.001, evidence of moderate quality), and had some effect on promoting any breastfeeding (RR 1.22, p = 0.02) and exclusive breastfeeding up to six months (RR 1.5, p=0.04) in high income countries. However, this evidence was of low quality. LHWs appear to be effective in improving TB treatment outcomes compared with institution-based directly observed therapy (RR 1.21, p = 0.05, evidence of moderate quality). Evidence related to the effects of using LHWs for other health interventions is unclear.

Conclusions

The use of LHWs in health programmes shows promising benefits, compared to usual care, in promoting immunization and breastfeeding uptake; in reducing mortality and morbidity from common childhood illnesses; and in improving TB treatment outcomes. Little evidence is available regarding the effectiveness of substituting LHWs for health professionals or the effectiveness of alternative training strategies for LHWs.

1. Background

Lay health workers (LHWs) perform diverse functions related to health care delivery. While LHWs are usually provided with informal job-related training, they have no formal professional or paraprofessional tertiary education, and can be involved in either paid or voluntary care. The term 'LHW' is thus necessarily broad in scope and includes, for example, community health workers, village health workers, cancer supporters and birth attendants.

In the 1970s the initiation and rapid expansion of LHW programmes in low and middle income settings was stimulated by the primary health care approach adopted by the WHO at Alma-Ata (Walt 1990). However, the effectiveness and cost of such programmes came to be questioned in the following decade, particularly at a national level in developing countries. Several evaluations were conducted (Walt 1990; Frankel 1992) but most of these were uncontrolled case studies that could not produce robust assessments of effectiveness. The 1990s saw further interest in community or LHW programmes in low and middle income countries (LMICs). This was prompted by the AIDS epidemic; the resurgence of other infectious diseases; and the failure of the formal health system to provide adequate care for people with chronic illnesses (Maher 1999; Hadley 2000). The growing emphasis on decentralisation and partnership with community based organisations also contributed to this renewed interest.

In industrialised settings, a perceived need for mechanisms to deliver health care to minority communities and to support consumers for a wide range of health issues (Witmer 1995) led to further growth in a wide range of LHW interventions.

More recently, growing concern regarding the human resource crisis in health care in many LMICs has renewed interest in the roles that LHWs may play in extending services to 'hard to reach' groups and areas and in substituting for health professionals for a range of tasks (WHO Task Force on Health Systems Research 2005). This cadre of health workers, as Chen (2004) and Filippi (2006) suggest, may be able to play an important role in achieving the Millennium Development Goals for health

The growth of interest in LHW programmes, however, has generally occurred in the absence of robust evidence of their effects. Given that these interventions have consider-

able direct and indirect costs, such evidence is needed to ensure they do more good than harm.

In 2005, Lewin published a Cochrane systematic review examining the global evidence from randomised controlled trials (RCTs) published up to 2001 on the effects of LHW interventions in primary and community health care (Lewin, 2005). This review indicated promising benefits, in comparison with usual care, for LHW interventions for immunisation promotion; improving outcomes for selected infectious diseases; and for breastfeeding promotion. For other health issues, the review suggested that the outcomes were too diverse to allow statistical pooling.

This document updates the 2005 systematic review, focusing on the effects of LHW interventions in improving maternal and child health (MCH) and in addressing key high burden diseases such as tuberculosis (TB). To our knowledge, this constitutes the only global systematic review of rigorous evidence of the effects of LHW interventions.

2. Objective

To review evidence from randomized controlled trials (RCTs) on the effects of LHW interventions in improving MCH and in addressing key high burden diseases in LMICs.

3. Criteria for considering studies for this review

3.1 TYPES OF STUDIES

Individual and cluster randomized controlled trials.

3.2 TYPES OF HEALTH CARE PROVIDERS

Any lay health worker (paid or voluntary) including community health workers, village health workers, birth attendants, etc.

For the purposes of this review, the term 'lay health worker' was defined as any health worker who:

- Performed functions related to health care delivery
- Was trained in some way in the context of the intervention, but
- Had received no formal professional or paraprofessional certificate or tertiary education degree

3.3 EXCLUSIONS

Interventions in which a health care function was performed as an extension to a participants' profession were excluded. The term 'profession' was defined in this study as remunerated work for which formal tertiary education (e.g. teachers providing health promotion in schools) was required.

Formally trained nurse aides, medical assistants, physician assistants, paramedical workers in emergency and fire services and other self-defined health professionals or health paraprofessionals were not considered. Trainee health professionals and trainees of any of the cadres listed above were also excluded.

Other exclusions were also made:

- Interventions involving patient support groups only as these interventions were seen as different to LHW interventions
- Interventions involving teachers delivering health promotion or related activities in schools. The authors of this report reasoned that this large and important system of LHWs constitutes a unique group (teachers) and setting (schools) that, due to its scale and importance, would be better addressed in a separate review
- Interventions involving peer health counselling programmes in schools, in which pupils teach other pupils about health issues as part of the school curriculum. Again, we reasoned that this type of intervention contains a unique group and setting better suited to a separate review
- LHWs in non-primary level institutions (e.g. referral hospitals)
- RCTs of interventions to train self-management tutors who were health professionals rather than lay persons. Furthermore, RCTs that compared lay self-management with other forms of management (i.e. those that did not focus on the training of tutors etc.) were also excluded as these were concerned with the effects of empowering people to manage their own health issues rather than with the effects of interventions using LHWs. RCTs of interventions to train self-management tutors who were lay persons themselves were eligible for inclusion in this review
- Studies which solely measured consumers' knowledge, attitudes or intentions were also excluded. Such studies assessed, for example, knowledge of what constituted a 'healthy diet' or attitudes towards people with HIV/AIDS. These measures were not considered to be useful indicators of the effectiveness of LHW interventions
- Interventions in which the LHW was a family member trained to deliver care and provide support only to members of their own family (i.e. in which LHWs did not provide some sort of care/service to others or were unavailable to other members of the community). These interventions were assessed as qualitatively different from other LHW interventions included in this review given that parents/spouses have an established close relationship with those receiving care which could affect the process and effects of the intervention
- Comparisons of different LHW interventions
- Multi-faceted interventions that included LHWs and professionals working together or LHWs implementing several activities that did not include a study arm to enable us to separately assess the effects of the LHW intervention were also excluded

3.4 TYPES OF CONSUMERS

There were no restrictions on the types of patients/recipients for whom data were extracted.

3.5 TYPES OF INTERVENTIONS

Curative and/or preventive interventions delivered by LHWs and intended to promote health, manage illness, or support people. Interventions were included if descriptions of the intervention were adequate to allow the reviewers to establish that it was a LHW in-

tervention. Where such detail was unclear, authors were contacted whenever possible, to verify if the personnel described were LHWs.

Interventions also needed to addresss MCH issues, as defined below, and/or to target high burden diseases in LMICs. For the purposes of this review, a MCH intervention was defined as follows:

- Child health: any interventions aimed at improving the health of children aged less than five years
- Maternal health: any interventions aimed at improving reproductive health or ensuring safe motherhood or directed at women in their role as carers for children aged less than five years.

3.6 TYPES OF OUTCOME MEASURES

Studies were included if they assessed any of the following primary and secondary outcomes:

Primary outcomes:

1. Health behaviours such as the type of care plan agreed, and adherence to care plans (medication, dietary advice etc.)
2. Health care outcomes as assessed by a variety of measures. These included physiological measures (e.g blood pressure or blood glucose levels) as well as patients' self reports of symptom resolution, or quality of life, or patient self-esteem
3. Harms or adverse effects

Secondary outcomes:

1. Utilization of LHW services
2. Consultation processes
3. Consumer satisfaction with care
4. Costs
5. Social development measures such as the creation of support groups for the promotion of other community activities.

4. Search methods for identification of studies

For the original review (Lewin et al, 2005), the following electronic databases were searched:

MEDLINE (1966-August 2001)
CENTRAL and specialised Cochrane Registers (EPOC and Consumers and Communication Review Groups) (to August 2001)
Science Citations (to August 2001)
Embase (1966-August 2001)
CINAHL (1966-August 2001)
Healthstar (1975-2000)
AMED (1966-August 2001)
Leeds Health Education Effectiveness Database (www.hubley.co.uk)

For this update, the following electronic databases were searched:
MEDLINE (2004-August 2006)
CENTRAL and specialized Cochrane Registers (EPOC and Consumers and Communication Review Groups) (2001-August 2006)
Science Citations (up to August 2006)
Embase (2005-August 2006)
CINAHL (2001-August 2006)
AMED (2001-August 2006)
POPLINE (2004-August 2006)

Because most RCTs indexed in MEDLINE and Embase are also included in the CENTRAL and specialized Cochrane registers, it was decided to search MEDLINE from 2004 to August 2006, and Embase from 2005 to August 2006 only. This ensured that articles that may not have been uploaded into the Cochrane databases by the start of the study could still be retrieved.

Retrieved documents included one or more terms relating to LHWs (e.g. community health aides, home health aides, or voluntary workers), and one or more terms suggesting a RCT (e.g. clinical trial, randomized controlled trial, or controlled clinical trial, among others). Search strategies from the original review were revised to reflect our knowledge refinement following the first review, of terms used in the literature to de-

scribe LHW interventions. The search strategy was tailored to each database and a sensitivity analysis done to ensure that most of the relevant studies retrieved during the last review were retrieved again. The strategy used for MEDLINE is described in Appendix I. Given the volume of articles retrieved and the deadline for the IDEAHealth meeting, MCH filters were used to retrieve only those studies relevant to the IDEAHealth focus. Reference Manager software was used to search titles and abstracts, as well as all indexed fields and all non-indexed fields, using the following terms: 'child' or 'children' or 'infant' or 'infants' or 'maternity' or 'maternal' or 'mother' or 'mothers'.

Bibliographies of the studies assessed for inclusion were also searched. However, not all of these referenced articles were retrieved in time for inclusion in this review, and authors still need to be contacted for details of additional studies.

5. Methods of the review

5.1 SELECTION OF TRIALS

Two reviewers assessed independently the potential relevance of all titles and abstracts identified from the electronic searches. Full text copies of the articles identified as potentially relevant by either one or both reviewers were retrieved.

Assessment of the eligibility of interventions can vary between reviewers. Therefore, each full paper was evaluated independently for inclusion by at least two reviewers. When reviewers disagreed, a discussion was held to obtain consensus. If no agreement was reached, a third reviewer was asked to make an independent assessment. Where appropriate, authors were contacted for further information and clarification.

5.2 ASSESSMENT OF METHODOLOGICAL QUALITY

Two reviewers assessed independently the quality of all eligible trials using the methodological quality criteria for RCTs listed in the Cochrane EPOC Review Group module. Further analysis of methodological quality was done using the GRADE approach (see www.gradeworkinggroup.org for further information). Studies were assessed as high quality if they reported allocation concealment, higher than 80% patient follow up and intention to treat analysis. Studies were assessed as 'low quality' if the information necessary for assessment was not reported. 'High quality' studies had no limitations in terms of consistency, directness or other considerations (such as sparse data, etc.) according to the GRADE approach.

5.3 DATA EXTRACTION

Reviewers extracted data from the studies included using a standard form. Not all articles were extracted in duplicate owing to time limitations, but outcome data were checked by a second reviewer. It was not feasible to contact study authors to obtain any missing information.

Data relating to the following were extracted from all the studies included:

1. Participant (LHWs and consumers) information. For LHWs this included terms used to describe the LHW, selection criteria, basic education and tasks performed. For consumers, data included the health problems/treatments received, their age and demographic details and their cultural background
2. The health care setting (home, primary care facility or other); the geographic setting (rural, formal urban or informal urban settlement) and country
3. The study design and its key features (e.g. whether the allocation to groups was at the level of individual health care provider or at the village/suburb level)
4. The intervention (specific training and ongoing monitoring and support –including duration, methods, who delivered the training etc. – and the health care tasks performed with consumers). A full description of each intervention was extracted
5. The number of LHWs who were approached, trained and followed up; the number of consumers enrolled at baseline and the number and proportion followed up.
6. The outcomes assessed and timing of the outcome assessment
7. The results (effects), organized into seven areas (consultation processes, utilization of lay health worker services, consumer satisfaction with care, health care behaviours, health status and well being, social development measures, cost and harms/adverse effects)
8. Any consumer involvement in the selection, training and management of the LHW interventions.

5.4 DATA SYNTHESIS

We grouped together studies that compared broadly similar types of interventions (n = 45), as listed below. The remaining three studies were extremely diverse and could not be usefully grouped.

1. LHW interventions to promote breastfeeding compared with usual care. Analysis was undertaken for the following subgroups as part of exploration of the causes of statistical heterogeneity in effect estimates:
    1.1. LHW interventions to promote initiation of breastfeeding in LMICs compared with usual care
    1.2. LHW interventions to promote any breastfeeding up to six months postpartum in LMICs compared with usual care
    1.3. LHW interventions to promote exclusive breastfeeding up to six months postpartum in LMICs compared with usual care
    1.4. LHW interventions to promote initiation of breastfeeding in high income countries compared with usual care
    1.5. LHW interventions to promote any breastfeeding up to six months postpartum in high income countries compared with usual care
    1.6. LHW interventions to promote exclusive breastfeeding up to six months postpartum in high income countries compared with usual care.
2. LHW interventions to promote immunization uptake in children compared with usual care.
3. LHW interventions to reduce mortality in children under five compared with usual care.

4. LHW interventions to reduce morbidity from common infectious diseases in children under five compared with usual care.
5. LHW interventions to provide support to mothers of sick children compared with usual care.
6. LHW interventions to prevent/reduce child abuse compared with usual care
7. LHW interventions to promote parent-child interaction/health promotion compared with usual care.
8. LHWs to support women with a higher risk of low birth weight babies or other health conditions in pregnancy compared with usual care.
9. LHW interventions to improve TB treatment outcomes compared with institution-based directly observed therapy.

Where feasible, the results of the included studies were combined and an estimate of effect obtained. This was possible for the subgroups 1 to 4 and 9 listed above. Outcome comparisons for LHW interventions to promote the uptake of breastfeeding and immunization are expressed as adherence to beneficial health behaviour. Outcomes for the subgroups including LHW interventions to reduce morbidity and mortality in children and for improving TB treatment outcomes are expressed as the number of events (mortality and morbidity; number of patients cured respectively). Only dichotomous outcomes were included in meta-analysis owing to the methodological complications involved in combining and interpreting studies in which different continuous outcome measures had been used. Differences in baseline variables were rare and not considered influential. Data were reanalysed on an intention-to-treat basis where possible.

Adjustment for clustering was made for 16 studies that used a cluster randomized design (see Appendix VI), assuming an intracluster correlation coefficient (ICC) of 0.02 which is typical of primary and community care interventions (Campbell, 2000).

Log relative risks and standard errors of the log relative risk were then calculated for both individual and adjusted cluster RCTs and analysed using the generic inverse variance method in Review Manager 4. Relative risks were preferred to odds ratios because event rates were often high and, in these circumstances, odds ratios can be difficult to interpret (Altman, 1998). Random effects meta-analysis was preferred because the studies were heterogeneous.

For the remaining four study subgroups (LHW interventions to provide support for mothers of sick children; to prevent/reduce child abuse; to promote parent-child interaction/health promotion; and to support women with a higher risk of low birth weight babies or other health conditions in pregnancy), the outcomes assessed and the settings in which the studies were conducted were very diverse. Consequently, we judged it inappropriate to combine the results of included studies quantitatively, given that an overall estimate of effect would have little practical meaning. A brief descriptive review of these subgroups is presented in the main text (Sections 8.4-8.8).

6. Description of studies

6.1 SEARCHING

A total of 5,013 titles and abstracts (excluding duplicates), written in English and other languages, was identified (see Appendix II). When MCH filters were added, 1,231 titles and abstracts were identified as relevant. Approximately 316 articles were considered potentially eligible for inclusion and full text articles were obtained. Subsequent to the original review in 2005 (Lewin et al), an additional 129 potentially eligible titles and abstracts were collected by the lead author and full papers for these retrieved. 445 full text papers were therefore considered for inclusion into this review. 59 studies met our criteria for inclusion. When the RCTs from the last review (42 in total) were included, a total of 101 articles were eligible for inclusion in this review. However, given the focus of the IDEAHealth brief and the limited time scale, the following groups of studies are not reported here: cancer screening, chronic diseases management including diabetes, mental illness and hypertension, and studies focusing on care of the elderly. This report therefore includes a total of 48 studies (29 from the original review) that are relevant to MCH and high burden diseases. Studies conducted among low income groups in high income countries have been included based on the premise that low income groups across different countries share similar constraints in accessing health care.

6.2 SETTING

Most trials took place in North America: 25 in the USA and 1 in Canada. A further three studies were conducted in the United Kingdom and one in Ireland. Three studies were undertaken in South America: Brazil (Leite, 2005; Coutinho, 2005) and Mexico (Morrow, 1999). One study was based in New Zealand (Bullock,1995) and one in Turkey (Gockay, 1993). Six studies were implemented in Africa: South Africa (Zwarenstein, 2000; Clarke,2005), Tanzania (Lwilla, 2003; Mtango, 1986), Ethiopia (Kidane, 2000), Ghana (Pence, 2005); and seven in Asia: Bangladesh (Haider, 2000), Thailand (Chongsuvivatwong, 1996), Vietnam (Sripaipan, 2002), Nepal (Manandhar, 2004), India (Bhandari, 2003), Pakistan (Luby, 2006) and the Philippines (Agrasada, 2005).

6.3 MODE OF DELIVERY OF THE INTERVENTIONS

In 37 studies the intervention was delivered to patients in their own homes. Five interventions were delivered from primary care facilities (Barnes,1999; LeBaron, 2004; Merewood, 2006; Caulfield, 1998; Korfmacher, 1999) and four combined home and primary care interventions (Stevens-Simmons, 2000; Malchodi, 2003; Rodewald, 1999; Anderson, 2005). In Manandhar (2004), the intervention was delivered through community meetings and in the studies by Dennis (2002), Graffy (2004) and Singer (1999), the interventions were delivered by telephone.

The modes of intervention delivery adopted in the study subgroups varied considerably. These included:

1. *LHW interventions to promote immunization uptake*: these studies employed systems of tracking individuals whose immunizations were not up to date or who had not received any vaccinations. Reminders were sent by telephone or postcard and occasionally home visits made to non-responders. Methods used to 'identify those at risk' in Gockay 1993 were not clarified.
2. *LHW interventions to reduce mortality/morbidity in children under five*: home visits or community meetings for health education, case identification and management were undertaken.
3. *LHW interventions to promote breastfeeding*: in some studies, the interventions were initiated during the antenatal period, usually during hospital visits by pregnant women. During the postnatal period, most interventions were delivered during home visits by LHWs but occasionally were delivered by telephone. This was the main mode of delivery in Dennis (2002) and Graffy (2004).
4. *LHWs providing support to mothers of sick children*: Interventions were delivered by telephone (Singer,1999) or during home visits. Some studies also included group events for mothers or parents (Ireys,1996; Ireys, 2001; and Silver,1997).
5. *LHWS to promote parent-child interaction/health promotion*: interventions were delivered in the home during visits and in primary health centres (Olds 2002).
6. *LHWs to prevent/reduce child abuse*: all the interventions involved some form of home visiting to provide support to parents.
7. *LHWs to support women with a higher risk of low birth weight babies or other health conditions in pregnancy*: the mode of delivery used was primarily home visitations
8. *LHW interventions to improve TB treatment outcomes*: interventions involved face to face contact with patients in their own homes or in the homes of LHWs

6.4 PARTICIPANTS

6.4.1 Lay Health Workers

Only 15 studies documented the number of LHWs delivering care. Within these, considerable differences in numbers were reported (ranging from 2 LHWs in Graham (1992) and Schuler (2000), to 150 in Chongsuvivatwong (1996). It was difficult to group such studies in terms of either LHW selection or training. In some cases, individuals had been recruited for their familiarity with a target community or because of their experience of a particular health condition.

The level of education of the LHWs was described in 11 (23%) of the studies. LHWs had primary school education in two studies; secondary school education in seven studies; and college education in two. Another study mentioned that the LHWs selected had similar education levels to mothers participating in the trial, but provided no further details. Data on the duration of training were available in 28 of the 48 studies. The median duration was six days (range 0.4 to 146 days; inter-quartile range 13.7 days). The longest period (146 days) included six months of practical field training.

The training approaches varied greatly between studies and were not described in the same level of detail in all of them. The terms used included: courses, classes, seminars, sessions, workshops, reading, discussion groups, meetings, role play, practical training, field work, video-taped interviews and in-class practice.

6.4.2 Recipients

Different recipients were targeted in the study subgroups:

1. *LHW interventions to promote immunisation uptake*: Krieger (2000) included people over 65 years of age and aimed to increase immunization levels against influenza and pneumococcal pneumonia. Other studies targeted children and intended to minimize immunization dropouts (Rodewald, 1999; LeBaron, 2004); provide guidance on immunization as part of other MCH services (Gockay, 1993); or target non-immunized children (Barnes,1999)
2. *LHW interventions to promote breastfeeding*: studies implemented in high income countries focussed primarily on low income groups. In contrast, Muirhead (2006) detailed female participants who were 'white' and mostly middle-class. The Merewood (2006) study offered support to mothers with pre-term babies. Studies from LMICs focused mainly on younger mothers from low income settings. There was considerable variation within these studies with regard to the parity of the mothers
3. *LHW interventions to reduce mortality/morbidity in children under five*: children were targeted for the prevention and treatment of common ailments such as malaria, ARI and diarrhoea. In Luby (2004), whole neighbourhoods were targeted for the prevention of diarrhoea through various hygiene interventions. In the Manandhar study (2004), married women of reproductive age were targeted for the prevention of various perinatal conditions
4. *LHWs providing support to mothers of sick children*: recipients were varied, with most trials including a mix of low and higher income families and ethnic groups
5. *LHWs to prevent/reduce child abuse*: in three studies recipients were low income women while in two others little information was available (Duggan, 2004; Siegel, 1980). Three of the studies (Bugental, 2002; Siegel, 1980 and Stevens-Simon, 2001) included a high proportion of women from ethnic minority groups and in three of these the intervention was directed mainly at teenage or young mothers (Barth 1998, Siegel 1980, Stevens-Simon 2001). In Bugental (2002) and Stevens-Simon (2001) participants were assessed as having a higher risk of abusing children in their care

6. *LHWS to promote parent-child interaction/health promotion*: in all four studies the recipients were young women (mean age range = 19.7-27 years), many of whom were single and were drawn mainly from low income groups
7. *LHWs to support women with a higher risk of low birth weight babies or other health conditions in pregnancy*: in Spencer (1989) and Graham (1992), recipients of the intervention were women at higher risk of giving birth to a low birth weight baby. Most women came from low income groups and were younger mothers, with a mean age of 23 and 24 years in the respective studies. In the study reported by Graham, participants were of African-American origin while in Spencer, women from a range of ethnic backgrounds were included. The study by Rohr (2004) described women selected on the basis of having phenylketonuria and being pregnant or planning a pregnancy. The mean age for this group was 29 years
8. *LHW interventions to improve TB treatment outcomes*: consumers were adults with pulmonary TB (including both clinically diagnosed and sputum/culture AFB positive TB patients). All of the studies were conducted in low income communities, with Clarke (2005) drawing recipients from rural farms

6.5 OUTCOMES

Most studies reported multiple effect measures and many did not specify a primary outcome. Primary, and occasionally secondary outcomes, were extracted and were categorised for the analysis according to the results detailed below and in the summary tables in Appendix VII.

7. Methodological quality

Assessments of the methodological quality of included studies are shown in Appendix V. 15 studies were assessed as 'high quality', with a low susceptibility to bias. The remaining 33 studies were considered to be 'low quality', meaning that potential inherent bias was of greater concern. Allocation concealment was 'done' in 32 studies, 'not done' in one study and in the remaining studies was scored as 'unclear'. Loss to follow up was scored 'done' in 32 studies (i.e. more than 80% of patients followed up), unclear in eight studies and not done in eight studies. Intention to treat analysis was performed in 26 studies, in 13 the procedure was not described and in nine it was 'not done'. The grouping of studies according to methodological quality is not intended as a platform for deciding which studies should be included in the meta-analysis. Instead, it is intended to illustrate the quality range for research on the effects of LHW interventions. Further information on quality is provided in the GRADE tables for each LHW subgroup for which meta-analysis was undertaken (Appendix IV).

8. Results

LHWs have been employed to deliver a wide range of interventions in many health care settings. Attempting to group studies by intervention type is therefore problematic; a more useful discussion can be generated by concentrating on the intended outcome or objective of each study. For the purposes of this discussion, the meta-analysis studies have been arranged into groups, each containing studies that used broadly similar methods to influence a single health care outcome. Meta-analysis was performed for four of the groups, and included a total of 23 studies. In the majority of cases the analysis included the primary study outcome. Forest plots and GRADE tables for all meta-analyses discussed below are shown in Appendix III and IV respectively.

For the remaining groups, outcomes were considered too diverse to be usefully pooled. The outcomes for studies not included in the meta-analysis are listed in Appendix VII.

8.1 LHW INTERVENTIONS TO PROMOTE IMMUNISATION UPTAKE IN CHILDREN UNDER FIVE COMPARED WITH USUAL CARE

Setting and recipients

Four of the six studies identified were undertaken in the USA (Barnes, 1999; Krieger, 2000; LeBaron, 2004; Rodewald. 1999); one was conducted in Turkey (Gockay, 1993) and one in Ireland (Johnson 1993). The studies conducted in the USA were among ethnically diverse groups (see, for example, Kreiger, 2000) and in predominantly Hispanic (Barnes, 1999) or African American populations (Rodewald, 1999; LeBaron 2004). All were implemented in urban formal or informal low income communities. In the case of Gockay (1993), the research was undertaken within squatter communities.

Description of interventions

These studies employed systems to track patients that were either not up-to-date or not vaccinated. Reminders were made by telephone or by postcard. Occasionally home visits made to non-responders during which parents were educated about vaccination and compliance encouraged. Methods used to 'identify those at risk' in Gockay (1993) were not clarified. In the Johnson (1993) study, first time mothers were given guidance on child development, including immunisation.

LHWs

Krieger (2000) utilized peers selected from senior centres. In all other studies the LHWs were volunteers serving as outreach workers or home visitors and recruited from the community. Information on educational background was available from three studies and indicated that the LHWs were college educated (LeBaron, 2004; Rodewald, 1999) or primary school graduates (Gockay, 1993). Only three studies provided specific information related to training: in Johnson (1993), LHWs were trained for four weeks on early childhood development principles, while Krieger (2000) reported training for just four hours. Both studies indicated that monitoring during implementation was provided. In Gockay (1993), LHWs were trained for three weeks on MCH, communication skills and for tasks undertaken during home visits. The methods used to monitor or evaluate were not specified.

Results

When outcomes from the six studies were combined in a meta-analysis, the result favoured the intervention group (RR 1.23,p = 0.009) but with strong evidence of heterogeneity (p = 0.005, I^2 = 70%). To address this, Krieger (2000) – a study focusing on adults - and Gockay (1993) – which had been implemented in a very different setting to the other studies – were removed from the analysis. The subsequent findings show strong evidence that LHW based promotion strategies can increase immunization uptake in children (RR 1.22, [1.10, 1.37] p=0.0004) but with some evidence of heterogeneity remaining (p = 0.07, I^2 = 57.9%). The control group risk was 49.5% (range 18.9–74%).

8.2 LHW INTERVENTIONS TO REDUCE MORTALITY/MORBIDITY IN CHILDREN UNDER FIVE COMPARED WITH USUAL CARE

Setting

Seven studies implemented in LMICs were identified, three conducted in Africa (Kidane, 2000; Mtango, 1986; Pence, 2005), and four in Asia (Sripaipan, 2002; Luby, 2006; Manandhar, 2004; Chongsuvivatwong, 1996) among rural or urban informal populations (Luby 2006). All were community level interventions.

LHWs

These were nominated by village health committees/leaders in two studies (Pence 2005, Manandhar 2004) or by community members in the case of Kidane (2000). No information was provided on the educational background of the LHWs. Six studies indicated that training was provided which ranged from two days in in the case of Chongsuvivatwong (1996) to six weeks in Pence (2005). Supervision was performed by village committee in two studies (Pence, 2005; Sripaipan, 2002); by the trainer in Kidane (2000); or not specified.

Description of interventions

The main purpose of these interventions was to promote health and in some cases to manage/treat illness, including acute respiratory infections (ARI), malaria, diarrhoea, malnutrition and other illnesses during the neonatal period. In four of the studies, LHW tasks included mainly visiting homes to educate mothers about ARI or malaria; early

recognition of symptoms; first line treatment of cases by tepid sponging, with antimalarials or antibiotics; and referral of severe cases to health facilities (Chongsuvivatwong, 1996; Kidane, 2000; Mtango, 1986; and Pence, 2005). In Pence's study (2005), education about immunization, hygiene and other childhood illnesses was also given and LHWs distributed multivitamins, deworming tablets and vaccines in addition to antimalarials and antibiotics. In Manandhar (2004), LHWs facilitated meetings where local perinatal health problems were identified and local strategies formulated to promote maternal and child health. Both Pence (2005) and Manandhar (2004) improved general health care services in the intervention and control areas.

In the research undertaken by Luby (2006) the LHWs arranged neighbourhood meetings and provided education concerning health problems associated with hand and water contamination. LHWs provided a broad range of interventions at household level including bleach, hand washing, flocculant-disinfectant and flocculant-disinfectant plus hand washing for the prevention of diarrhoea. LHWs in Sripaipan (2002) provided growth monitoring, nutrition education and referral to health facilities of those who were ill or failing to gain weight. They conducted rehabilitation programmes and made home visits to malnourished children.

Five studies utilised an extension of services to communities not previously served (Kidane, 2000; Mtango, 1986; Luby 2006; Manandhar 2004; Chongsuvivatwong 1996), including 'hard to reach' communities in the case of four studies (Kidane, 2000; Mtango,1986; Pence, 2005; Manandhar, 2004). Pence 2005 compared LHWs with care delivered by health professionals.

Results

Child mortality: four studies (Kidane, 2000; Mtango, 1986; Pence, 2005; Manandhar, 2004) measured mortality among children under five years. Results from three of these studies (Kidane,2000; Mtango, 1986; Manandhar 2004) were included in a meta-analysis. This showed a significant reduction in mortality favouring the intervention (RR 0.74, [95% CI 0.55, 0.99] p = 0.04). There was no evidence of heterogeneity (p = 0.71, I^2 = 0%). The control group risk was 4.4% (range 3.7–4.6%). Data from Pence (2005) were excluded from this analysis due to the measurement approach used in this study and its poor methodological quality. However, it should be noted that the study reported an increase in mortality among children randomized to the LHW arm (RR 1.11, 95%CI 0.95, 1.30) when compared with care delivered by health professionals.

Child morbidity: four studies measured morbidity from fever, ARI or diarrhoea among children under five years. Three studies were included in a meta-analysis which showed a 29% reduction in morbidity in favour of the LHW interventions, compared with usual care (RR 0.81, 95%CI 0.71, 0.92), p=0.001). There was no evidence of heterogeneity (p=0.81, I^2=0%). The control group risk was 39.2% (range 24.7 – 53.8%). Luby (2006) presented insufficient raw data to warrant the inclusion of this study in the meta-analysis but did document a lower prevalence of diarrhoea among children under five in the LHW arm.

8.3 LHW INTERVENTIONS TO PROMOTE BREASTFEEDING COMPARED WITH USUAL CARE

All studies were intended to promote health and/or offer psychosocial support for breastfeeding through the provision of counselling, education and support to mothers.

Setting

13 studies were identified of which seven were implemented in high income countries (Caulfield 1998, Dennis 2002, Chapman 2004, Graffy 2004, Anderson 2005, Muirhead 2006, Merewood 2006) and six in LMICs (Haider 2000, Morrow 1999, Bhandari 2003, Coutinho 2005, Agrasada 2005, Leite 2005). All (except Agrasada 2005 where this was not clarified) were implemented in urban formal settings.

LHWs

These were commonly peers (documented in nine studies) or volunteers selected from the community. In two studies (Coutinho, 2005; Morrow, 1999) previous breastfeeding experience was not a pre-requisite while in all others instances, LHWs had previous breastfeeding experience as mothers. In some studies LHWs had similar educational backgrounds to those of the participating mothers (see Coutinho, 2005; Agrasada, 2005)

Training of the LHWs varied in terms of intensity and content. For studies implemented in high incomes countries training varied from 2.5 hours of orientation (Dennis, 2002) to 40 hours of training (Anderson, 2005). In two studies, training was by board-certified lactation consultants (Anderson, 2005; Chapman, 2004) while in Graffy (2004) training was given by National Childbirth-accredited counsellors. In studies implemented in LMICs, the training duration varied from eight months (Morrow 1999) to three days (Bhandari 2003). Trainers were specialists in lactation management in three of the studies (Coutinho, 2005; Agrasada, 2005; Morrow, 1999).

Description of interventions

In some studies, LHWs initiated contact during the antenatal period (Anderson, 2005; Chapman, 2004; Muirhead, 2006; Morrow, 1999; Haider, 2000; Caulfield, 1998; Graffy, 2004) and this varied from one visit (Graffy 2004, Muirhead 2006, Chapman 2004) to three or more visits (Anderson 2005, Caulfield 1998). During this time discussions focused on ways to overcome potential obstacles to breastfeeding as well as on the importance and benefits of breastfeeding.

Activities implemented during postnatal visits included counselling to promote exclusive breast feeding (Coutinho 2005, Haider 2000, Morrow 1999, Anderson 2005, Bhandari 2003, Agrasada 2005) and address barriers to breastfeeding; observation of baby positioning and mother-child interaction; and health education. Support was mainly by telephone in Dennis 2002 and Graffy 2004. Postnatal contact also varied in intensity.

Results

Findings for each meta-analysis subgroup are reported below:

LHW interventions to promote initiation of breastfeeding in low and middle income countries compared with usual care

Three studies were included in this analysis (Bhandari, 2005; Haider, 2000; Morrow, 1999). Breastfeeding promotion did not appear to have a significant impact on the initiation of breastfeeding; studies showed a relative risk range from 0.80 to 4.89. The heterogeneity of the studies' outcomes raises doubts about the suitability of a pooled estimate ($p=0.00001$; $I^2=95.8\%$). This heterogeneity cannot easily be explained, but may relate to differences in inputs provided to women who delivered in hospital rather than home settings.

LHW interventions to promote any breastfeeding up to 6 months postpartum in low and middle income countries compared with usual care

This meta-analysis included four studies (Agrasada, 2005; Bhandari, 2005; Leite, 2005; Morrow, 1999). The results suggest that breastfeeding promotion has a small, but non-significant impact on any breastfeeding up to six months postpartum in these settings (RR = 1.17 [95% CI 0.98, 1.40] p = 0.09). The control group risk was 65.7% (range 28.9–84.6%). Heterogeneity between study outcomes raises doubts about the suitability of a pooled estimate ($p = 0.005$; $I^2 = 76.5\%$) and cannot easily be explained.

LHW interventions to promote exclusive breastfeeding up to 6 months postpartum in low and middle income countries compared with usual care

Five studies were included in this analysis (Agrasada, 2005; Bhandari, 2005; Haider, 2000; Leite, 2005; Morrow; 1999). Meta-analysis indicated that breastfeeding promotion had a significant impact on exclusive breastfeeding up to six months (RR = 3.67 [95% CI 1.66, 8.11] p=0.001). The control group risk was 21.9% (range 0–41.6%). Although between study heterogeneity was substantial ($p = 0.00001$; $I^2 = 93.7\%$), the effect is large and the individual study results all favoured the intervention.

LHW interventions to promote initiation of breastfeeding in high income countries compared with usual care

The pooled RR for the five studies that examined the influence of breastfeeding promotion interventions on the initiation of breastfeeding in high income countries (Anderson, 2005; Caulfield, 1998; Chapman, 2004; Graffy, 2004; Muirhead, 2006) was 1.13 [95% CI 0.95, 1.35] p = 0.16), indicating a non-significant effect. The control group risk was 71.5% (range 26.3– 92.5%). Between-study heterogeneity was substantial ($p = 0.004$; $I^2 = 74.1\%$) and cannot easily be explained.

LHW interventions to promote any breastfeeding up to 6 months postpartum in high income countries compared with usual care

Six studies were included in this analysis (Anderson 2005, Caulfield 1998, Chapman 2004, Dennis 2002, Graffy 2004, Muirhead 2006). Breastfeeding promotion had a significant impact on any breastfeeding up to six months postpartum (RR=1.22[95% CI 1.07, 1.39] p=0.002). The control group risk was 34.3% (range 14 – 65.9%). Between study heterogeneity was not significant ($p=0.31$; $I^2=16.4\%$).

LHW interventions to promote exclusive breastfeeding up to 6 months postpartum in high income countries compared with usual care.
This meta-analysis included four studies (Anderson, 2005; Dennis, 2002; Graffy, 2004; Muirhead, 2006). The results suggest that breastfeeding promotion has a significant impact on exclusive breastfeeding in these settings (RR = 1.53[95% CI 1.01, 2.30] p = 0.04). The control group risk was 20.3% (range 0–39.7%). Heterogeneity between study outcomes was of borderline significance (p.0.05; I^2 = 62.4%).

8.4 LHWS PROVIDING SUPPORT TO MOTHERS OF SICK CHILDREN COMPARED WITH USUAL CARE

This group included five studies in which LHWs provided differing kinds of support to mothers of sick children (Black,1995; Ireys, 1996; Ireys, 2001; Silver, 1997; Singer, 1999).

Setting
All studies in this group were based in urban settings within the United States (Silver, 1997; Ireys, 1996; Ireys, 2001; Black, 1995; Singer, 1999). The interventions were delivered both in the home and the community in three studies (Silver, 1997; Ireys, 1996; Ireys, 2001). Black (1995) provided only home-based intervention while for Singer (1999) the intervention was delivered telephonically.

Description of interventions
The interventions intended to provide psycho-social support and to promote health. In four of the trials, the LHWs were parents or grandparents of children with the illnesses of interest. The intensity of the intervention varied from four telephone calls over a two month period (Singer, 1999) to nineteen one-hour home visits (Black, 1995). In addition, some studies included group events for mother or parents (Ireys, 1996; Ireys, 2001; Silver, 1997). In four of the studies the LHWs received considerable supervision. No information regarding the nature of the supervision was provided in Singer (1999).

Results
These studies measured a wide range of maternal, parent and child health outcomes. Three studies (Ireys, 1996; Ireys, 2001; Silver, 1997) reported maternal health outcomes following interventions to provide support for mothers of sick children. Two studies (Ireys,2001; Silver, 1997) reported that maternal anxiety was lower in the intervention group but this was the only significant outcome of many reported. The same two studies also reported child mental health scores. Three scores (hostility; anxiety/depression; summary score of mental health) favoured the intervention group in one study (Ireys, 2001). Other differences were not significant. Black (1995) reported a large number of child growth and development outcomes.

No differences between the intervention and control groups were found for growth outcomes. However, outcomes measuring cognitive development, motor development, task engagement and negative affect showed significant differences in favour of the intervention group. Other differences in developmental measures were not significant. Singer (1999) reported four outcome measures: scores for parental acceptance of family and

disability and the extent to which primary needs were met favoured the intervention group while those for empowerment showed no significant differences between the intervention and control group. Scores on the parental coping measure favoured the intervention, but only for parents who entered the study with low perceived coping skills.

Due to the heterogeneity of settings, interventions and outcomes, it is not possible to draw overall conclusions regarding the effects of LHWs providing support to mothers of sick children, compared with usual care. There are some suggestions of benefits for child health and development.

8.5 LHWS TO PREVENT/REDUCE CHILD ABUSE COMPARED WITH USUAL CARE

This group included five studies (Barth,1988; Bugental, 2002; Duggan, 2004; Siegel, 1980; Stevens-Simon, 2000) concerned with preventing child abuse.

Setting

All studies were conducted in the USA, with three delivered in formal urban settings (Barth,1988; Siegel, 1980; Stevens-Simon, 2000) and two in rural settings (Bugental, 2002; Duggan, 2004).

Description of interventions

All the interventions involved some form of home visitation to provide support to parents. In Barth (1988) and Steven-Simons (2000), the interventions included both pre- and post-natal contact with LHWs whereas post-natal contact only was provided in Duggan (2004) and Siegel (1980).1 All attempted to assist parents in solving problems or dealing with stresses or crises and several also tried to improve access to or referral to local services (Duggan, 2004; Siegel, 1980; Stevens-Simon, 2000).

Results

Most studies measured a wide range of health care behaviour, health status and social development outcomes. Two of the studies reported outcomes favouring the intervention group for measures of child abuse or neglect. Bugental (2002) showed a decrease in harsh parenting and in physical abuse in the cognitive appraisal group while Stevens-Simon (2000) reported a decrease in the number of children removed due to child neglect in the intervention group compared with the control group. The remaining studies showed no difference between the intervention and control groups for measures of child abuse. However, Duggan (2004) reported that in families receiving a high dose of the intervention only, significant differences in favour of the intervention were measured for maternal problem alcohol use and physical abuse of women by partners. Stevens-Simon (2000) also reported a significant increase in the use of a reliable form of hormonal contraception in the intervention group compared with control.

Overall, these studies indicated variable success regarding the effects of LHWs in preventing child abuse.

[1] No information was available from Bugental (2002) on the timing of home visits.

8.6 LHWS TO PROMOTE PARENT-CHILD INTERACTION/HEALTH PROMOTION COMPARED WITH USUAL CARE

Four studies examined the effect of LHWs on mother-child health promotion (Bullock, 1995; Johnson, 1993; Olds, 2002; Schuler, 2000).

Setting

All studies in this group were conducted in urban formal settings in high income countries, including Ireland, New Zealand and the USA (n = 2). In three, the LHW interventions were delivered in the home, while in the fourth study, care was delivered in primary health centres (Olds, 2002).

Description of interventions

In all four studies the intervention was intended to promote health, particularly child development, and to provide psychosocial support. In two studies, participants were encouraged as well to make use of local health and social service resources (Bullock, 1995; Olds, 2002). Schuler (2000) also provided information on drug use and treatment to encourage maternal empowerment and infant development while Olds (2002) encouraged mothers to build social networks.

Results

The results of these studies were highly variable, with many of the studies reporting multiple outcome measures. The effects are presented in the attached tables (see Appendix VII).

8.7 LHWS TO SUPPORT WOMEN WITH A HIGHER RISK OF LOW BIRTH WEIGHT BABIES OR OTHER HEALTH CONDITIONS IN PREGNANCY COMPARED WITH USUAL CARE

In this group, two studies examined LHW support for pregnant women who were at higher risk of low birth weight (LBW) babies (Graham, 1992; Spencer, 1989) and one focused on support for pregnant women with phenylketonuria (Rohr, 2004), with the aim of supporting dietary changes to protect the foetus from the effects of the illness.

Setting

All three studies were conducted in urban formal settings in high income countries, including the United States of America (Graham, 1992; Rohr, 2004) and the United Kingdom (Spencer, 1989).

Description of interventions

All three studies involved the provision of psychosocial support to pregnant women. In addition, LHWs provided help with daily tasks (Rohr, 2004) and with obtaining benefits, housing etc. (Spencer, 1989). Graham (1992) also provided health education and information on pregnancy health risks, antenatal care and childbirth while Spencer promoted the appropriate use of health and social services.

Results

For both Graham (1992) and Spencer (1989), no differences were apparent in the proportion of LBW babies born to high risk mothers in the LHW group compared with the control. In Graham (1992), women in the intervention group showed a higher frequency of clinic attendance and a dose-response relationship with the number of LHW visits was noted. A large number of birth-related outcomes, none of which showed significant differences between intervention and control, were measured by Spencer (1989). Rohr (2004) measured a number of birth and maternal metabolic outcomes, none of which demonstrated statistically significant differences between intervention and control groups.

Overall, these studies suggest that LHW interventions may not be useful in reducing the frequency of LBW babies in women at higher risk. However, the number of studies included in this group is small and the results should therefore be interpreted with caution.

8.8 LHW INTERVENTIONS TO IMPROVE TB TREATMENT OUTCOMES COMPARED WITH INSTITUTION-BASED DIRECTLY OBSERVED THERAPY

Setting

Three studies (Clarke,2005; Lwilla, 2003; Zwarenstein, 2000) were included in this subgroup. Two were conducted in South Africa and one in Tanzania (Lwilla, 2003). Zwarenstein (2000) was conducted in an urban formal setting, while the remaining two were located in rural settings.

Description of the intervention

LHW-supervised directly observed therapy (DOT) for TB patients was compared to institution-based therapy that would typically be supervised by a nurse. Other tasks implemented by the LHWs included follow up of patients who had failed to adhere to treatment; referral of patients with TB-like symptoms; and in the study by Lwilla (2003), the provision of drug refills. The LHWs were previous TB patients (Zwarenstein, 2000) or volunteers from the same community as the TB patients (Clarke 2005). In both Clarke (2005) and Lwilla (2003), consumers themselves participated in the selection of the LHWs.

Training of LHWs

In Clarke (2005), training consisted of 25 hours per week and focused on TB, primary health care and community development principles. This training was conducted by a nurse and two LHW trainers. In Zwarenstein (2000), five mornings of interactive health promotion were delivered by a nurse who was also the project leader. Details of the training given were not reported in Lwilla (2003).

Results

The pooled RR for the three studies was 1.21[95% CI 1.00, 1.47], providing positive evidence of a beneficial effect ($p = 0.05$) of using LHWs to supervise DOT when compared to institution based/supported DOT. The control group risk was 44% (range 28–41%). There was little heterogeneity [$p = 0.31$, $I2 = 15.3\%$].

Owing to the range of interventions described and outcomes measured, three studies (Gielen, 2002; Malchodi, 2003 and Sullivan, 2002) could not be assigned to subgroups. The outcomes for these individual studies are reported in Appendix VII.

9. Discussion

This review highlights evidence of moderate to high quality of the effectiveness of LHWs in promoting immunisation uptake in children; promoting breastfeeding; reducing mortality and morbidity from common health conditions in children; and improving TB treatment outcomes, when compared to usual care. For other health issues, evidence is insufficient to draw conclusions regarding effectiveness. There is also inadequate evidence to enable the identification of specific LHW training or intervention strategies likely to be most effective.

9.1 STRENGTHS AND WEAKNESSES OF THE REVIEW

9.1.1 Strengths

- The review is the only global–scale evaluation,, based on RCTs, of the effectiveness of LHW interventions

- It uses a systematic approach to identifying and selecting studies; extracting data from eligible studies; synthesizing data across studies; and assessing the quality of the evidence obtained

- The review highlights the effectiveness of LHW interventions for health issues that contribute substantially to the burden of disease in LMICs

- Finally, the review highlights areas where further work is needed to explore the effects of LHW interventions

9.1.2 Weaknesses

- Many of the studies were conducted in high income settings. This necessarily raises questions regarding the applicability of the findings of such research to low and middle income settings where health systems are often less developed (see further discussion below – Section 9.3)

- LHW RCTs are poorly indexed in electronic databases. Further, time constraints precluded the option of contacting authors to obtain references for further studies. It is therefore possible that some relevant RCTs were not identified. Evidence for publication bias was not explored

- Because the number of studies in each analysis subgroup was small, it was not always possible to:
  - Explore differential effects across different socio-economic settings
  - Examine the impact of different forms of LHW training and support, and different intensities of intervention, on outcomes

- Studies included in this review did not always compare LHW interventions with similar services delivered by professionals (substitution). Instead, many compared LHW interventions with 'usual care'. The five studies comparing LHW programmes with similar services delivered by professionals (Black,1995; Korfmacher, 1999; Lwilla, 2003; Olds, 2002; Pence, 2005) presented mixed findings, with different outcomes favouring either professional or LHW interventions. It is possible therefore that replacing professional care with LHWs may, in some circumstances, do harm rather than good, and this should be considered more carefully in future studies. We would suggest that the available data allow no overall conclusions to be drawn regarding the effectiveness of LHWs in substituting for professional providers

- The review does not assess the sustainability of the effects of LHW interventions. Most trials have relatively short follow-up periods and may involve higher levels of support and supervision than may be available in non-experimental settings. Reviews including other study designs may be necessary to address the question of sustainability

- For a number of important health issues, such as providing home-based support to families caring for people living with HIV/AIDS, no eligible studies have been identified thus far

- It is also difficult to assess whether the lack of association measured in some trials was due to the intervention itself or due to other effects such as, for example, poor programme delivery. Information in the individual publications did not provide sufficient detail to enable us to evaluate process/intervention fidelity in this way

In the following sections, we discuss considerations of equity in relation to the review findings; the applicability of the findings in other settings; and factors to be considered in scaling up these programmes. As these factors are interlinked, there is some overlap in the discussion points raised in each section.

9.2 EQUITY CONSIDERATIONS

This section considers the effects of the interventions discussed above on health inequities i.e. on differences in health that are avoidable and unfair in relation to dimensions such as income, gender etc.

- Overall, the included studies provide little data regarding differential effects of the interventions for disadvantaged populations

- Some differences in the effectiveness of LHW interventions to promote breastfeeding were found between high and low and middle income settings, possibly related to different baseline levels of breastfeeding in these settings and cultural norms or traditions (see results above in Section 8.3). However, the differences among study findings within the LMIC and high income country groups were larger than those between such groups. These reasons for this heterogeneity are unclear and require further exploration

- Some interventions relied on technologies (e.g. telephone-based support) that may not always be appropriate when attempting to contact low income households. Implementation of interventions in such setting utilising such technologies may exacerbate health inequities, or fail to address them adequately

- Many of the interventions evaluated in this review were directed at low income groups (37 of the 48 studies), even where the studies were conducted in high income countries. Based on the premise that low income groups across different countries share similar constraints in accessing health care, it may be concluded that these interventions could potentially be extrapolated to other settings, be effective in reaching low income groups, and contribute to reducing health inequalities. However, the degree to which the findings from studies in high income settings can be generalised to low income settings remains unclear and requires further empirical research. This is a particularly important consideration in the context of the two analysis subgroups (LHWs providing support to mothers of sick children; and LHWs to prevent child abuse), where all the studies were conducted in the United States. Given the high socio-economic diversity within the USA, generalisation may well be possible, but using such location-specific research findings as a basis for programmes in other settings should be undertaken with caution

9.3 APPLICABILITY CONSIDERATIONS

Based on the information available in the trial reports, this section considers the extent to which the LHW interventions discussed above could be applied to other settings; the factors that need to be taken into account when considering how and when such interventions should be applied in other settings; and the potential benefits and harms

9.3.1 Could these interventions be applied to other settings?

- Although 26 of the included studies were conducted in North America, the RCTs reviewed here also covered an extensive range of other settings, including 16 from LMICs. The range of study settings included in some of the review subgroups (i.e. LHWs to promote breastfeeding and to deliver treatment), and the consistent pattern of findings across these studies, suggests that the measured effects may be transfer-

able across settings for these health issues

- For other subgroups where most studies were conducted in the USA or other high income settings (e.g. LHWs to promote immunization uptake and to provide support to mothers of sick children), it is unclear whether the intervention effects are likely to be transferable to other settings with different systems of health care delivery. Factors (among others) which need to be considered include: the availability of routine data on who might benefit from the intervention (e.g. children whose immunization is not up-to-date); resources to provide clinical and managerial support for LHWs; accessible referral centres (e.g. for those at risk of child abuse or requiring developmental assessment); the availability of drugs (e.g. for the treatment of TB or malaria); and financial support for LHWs, and the programmes in which they are located

- A number of the interventions described in this report rely and build on the expertise of lay people who have experienced particular health problems, such as caring for a child with a chronic illness. If applied in other settings, LHWs with similar experiential expertise would probably need to be recruited

- It should be noted that most of the LHW interventions shown to be effective in this review were focused on very specific health issues, such as the promotion of breastfeeding or immunization uptake. Little evidence was identified regarding the effectiveness of 'generalist' LHWs who are given responsibility for delivering a range of primary health care interventions. Further research in this area is needed before such programmes can be supported

9.3.2 Will these interventions work in other settings?

- This review provides strong evidence for the effectiveness of using LHWs for particular health issues. However, the attitudes of health policy makers and managers towards LHWs varies across settings. In some contexts, LHWs are still seen as a second rate care option for the poor by governments, and by international agencies and NGOs who may be reluctant to invest or participate in these programmes. The remuneration of LHWs may also be a controversial issue. In some settings, changes to the legal frameworks governing health care delivery may be necessary to enable LHWs, for example, to distribute medicines or refer patients to health professionals. Such policy issues need to be discussed before programmes are initiated

- The attitudes of frontline health professionals, and their professional organisations, to lay health workers are also important issues to consider. This issue was not examined in this review, but it is likely that these interventions will not be effective in settings where health professionals are reluctant to work with, or supervise, lay people

- The positive effects of LHW programmes reported here may not materialise or be possible to sustain, in settings where clinical and supervisory support is inadequate. While this review cannot draw conclusions regarding the relationship between the level of support provided and the effectiveness of these programmes, it is likely that

adequate support will not be available in areas with the greatest for these interventions. This is a significant consideration, for in such contexts LHWs may do harm by, for example, failing to identify health problems requiring referral or by implementing interventions that have not been shown to be effective

9.3.3 What would it take to make it work?

This review did not consider evidence on this question. However, some of the factors that may need to be addressed are outlined above

9.3.4 Is it worth it?

- This review indicates that LHWs can be effective for specific health issues. LHWs could potentially reduce the costs of health care if substituted for professionals, by providing care at a level closer to local consumers. However, as others have noted, there is a conspicuous lack of data on the cost effectiveness of interventions across different settings (Walker, 2005). As we have noted, where such data are available, they have not yet been reviewed systematically. Such information is needed to inform policy decisions on implementation

- Most of the studies included in this review did not report on the possible harms or adverse effects of these interventions, either to individual patients or the health system. It is therefore difficult to draw conclusions regarding the trade-off between benefits and harms; this is likely to vary according to the focus of the intervention, the setting in which it is implemented, and other services provided within the health system

9.4 IMPORTANT CONSIDERATIONS REGARDING SCALING UP

This section considers the factors likely to influence the widespread implementation of LHW interventions.

- LHWs are most likely to be useful as a cadre of health care providers when they have an effective health care intervention to deliver. Before these programmes are scaled up, robust evidence is needed regarding both the effectiveness of the intervention to be delivered and of LHWs as a delivery mechanism

- The findings presented here are based on RCTs in which the levels of organisation and support were potentially higher than those available outside of research settings. Providing adequate support to programmes is likely to be vital to intervention effectiveness when scaling up. This review did not consider how best such support should be provided. However, it should be noted that where health system management capacity is weak, support for LHW interventions may be very limited

- Few studies reviewed here described how LHW-provided services were linked to other health system components. This may necessarily create difficulties and uncertain-

ties when scaling up the interventions described above

- Consumer participation in the selection, training and management of LHW programmes, was generally poorly described in the RCTs included in this review. If such participation is seen as important to programme success, considerable resources may need to be invested in this process. Participation may be particularly important where the LHW interventions involve some form of community mobilisation or the utilisation and development of social networks

- Widespread implementation of these programmes may result in increased demand for services such as immunization or TB treatment. Planners need to consider how this increased demand will be managed. If the services promoted by LHWs are not available, the activities of LHWs may be undermined

9.5 KEY CONSIDERATIONS FOR POLICY DECISIONS REGARDING LHW INTERVENTIONS

- Further systematic reviews are needed that will focus on:
  - Factors affecting the sustainability of LHW interventions when scaled up
  - The effectiveness of different approaches to ensure programme sustainability
  - The cost-effectiveness of LHW interventions for different health issues
  - Mechanisms for integrating LHW programmes into the formal health system
  - Factors that determine the effectiveness of LHW interventions in different settings

- The acceptability of LHW programmes to consumers and health professionals may need to be evaluated in some settings before such programmes are taken to scale. The effects of consumer involvement in these programmes require further research

Where LHW programmes are implemented for health issues for which good evidence for effectiveness is, as yet, unavailable, robust mechanisms of evaluation should be built into programme implementation

10. Conclusions

LHWs show promising benefits, compared to usual care, in promoting immunization and breastfeeding uptake; in reducing mortality and morbidity from common childhood illnesses; and in improving TB treatment outcomes. There is little evidence available regarding the effectiveness of LHWs in substituting for health professionals or the effectiveness of alternative training strategies for LHWs

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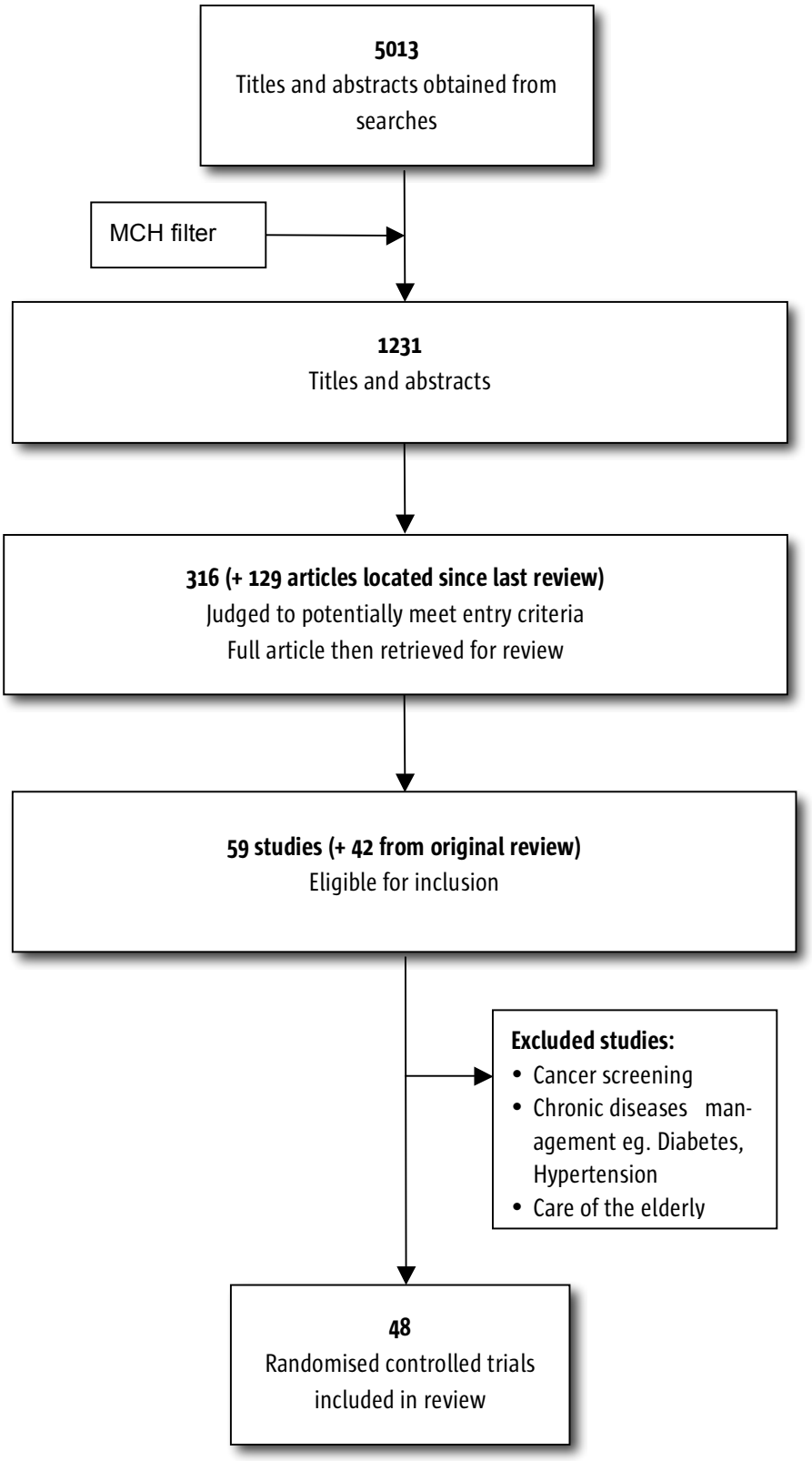
Appendix I: Search Strategy for Medline

1. Community Health Aides/
2. Home Health Aides/
3. Voluntary Workers/
4. Home Nursing/
5. Community Networks/
6. Peer Group/
7. Caregivers/
8. Social Support/
9. ((lay or voluntary or volunteer? or untrained or unlicensed or nonprofessional? or non professional?) adj5 (worker? or visitor? or attendant? or aid or aides or support$ or personnel or helper? or carer? or caregiver? or care giver? or consultant? or assistant? or staff or visit$ or midwife or midwives)).tw.
10. lay volunteer?.tw.
11. paraprofessional?.tw.
12. (paramedical adj (person$ or staff or aid or aides or assistant?)).tw.
13. (trained adj3 (volunteer? or lay person$ or health worker? or mother?)).tw.
14. ((community or primary or village?) adj3 (health worker? or health care worker? or healthcare worker?)).tw.
15. (community adj3 (volunteer? or aid or aides or support)).tw.
16. ((birth or childbirth or child birth or labor or labour) adj (attendant? or assistant?)).tw.
17. (doula? or douladural?).tw.
18. monitrice?.tw.
19. (peer adj (volunteer? or counsel$ or outreach or support)).tw.
20. "peer to peer".tw.
21. "mother to mother".tw.
22. "family to family".tw.
23. (church based adj3 (intervention$ or program$ or counsel$)).tw.
24. (linkworker? or link worker?).tw.
25. barefoot doctor?.tw.
26. (home adj (care or aid or aides or nursing or support or intervention? or treatment? or visit$)).tw.
27. ((care or aid or aides or nursing or support or intervention? or treatment? or visit$) adj3 (lay or volunteer? or voluntary)).tw.
28. 26 and 27
29. or/1-25,28
30. clinical trial.pt.
31. randomized controlled trial.pt.
32. controlled clinical trial.pt.
33. randomized.ab.
34. placebo.ab.
35. Clinical Trials/
36. randomly.ab.

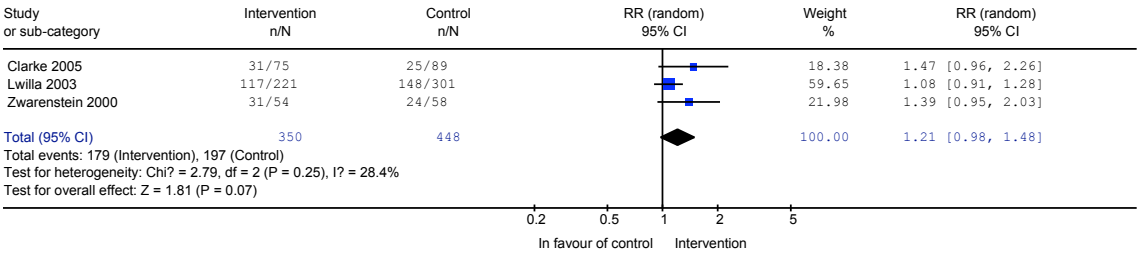
37. trial.ti.
38. or/30-37
39. Animals/
40. Humans/
41. 39 not (39 and 40)
42. 38 not 41
43. letter.pt.
44. editorial.pt.
45. comment.pt.
46. or/43-45
47. 42 not 46
48. 29 and 47

Appendix II: Quorum flow chart

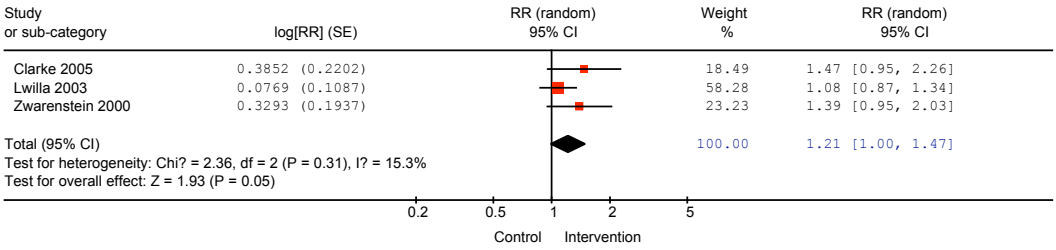


Appendix III: Meta-analysis – Forest plots[2]

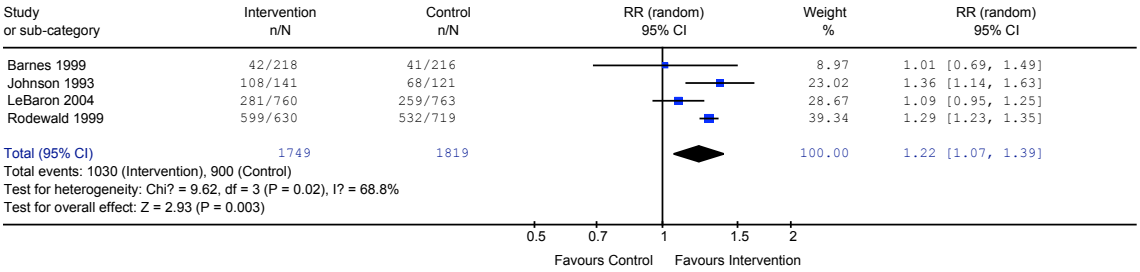
Review: Lay Health Workers
Comparison: 01 Tuberculosis - Lay Health Workers vs. Institution based DOTS
Outcome: 01 Cure rates for smear positive pulmonary tuberculosis patients - unadjusted



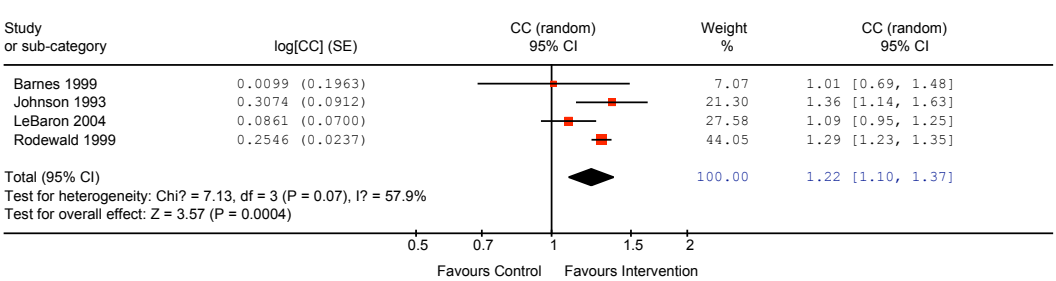
Review: Lay Health Workers
Comparison: 01 Tuberculosis - Lay Health Workers vs. Institution based DOTS
Outcome: 02 Cure rates for smear positive pulmonary tuberculosis patients



Review: Lay Health Workers
Comparison: 04 Vaccination - Lay Health Workers vs. standard procedure
Outcome: 04 Vaccination complete according to schedule (excl. Gökcay and Krieger) - unadjusted

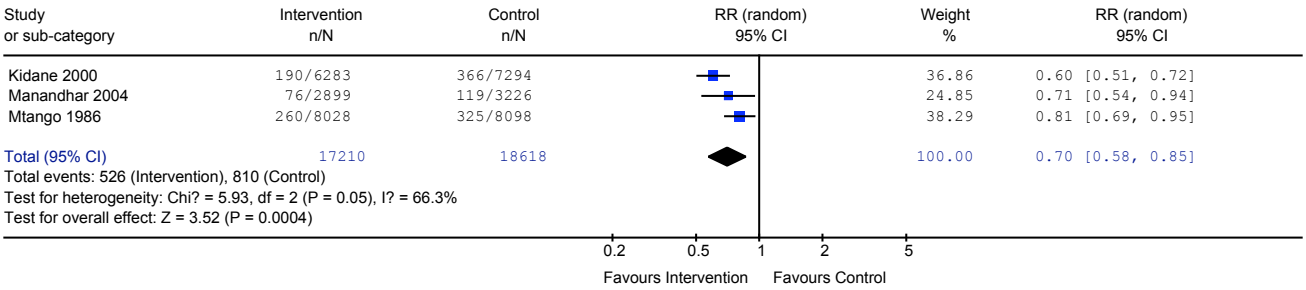


Review: Lay Health Workers
Comparison: 04 Vaccination - Lay Health Workers vs. standard procedure
Outcome: 08 Vaccination complete according to schedule (excl. Gökcay and Krieger)

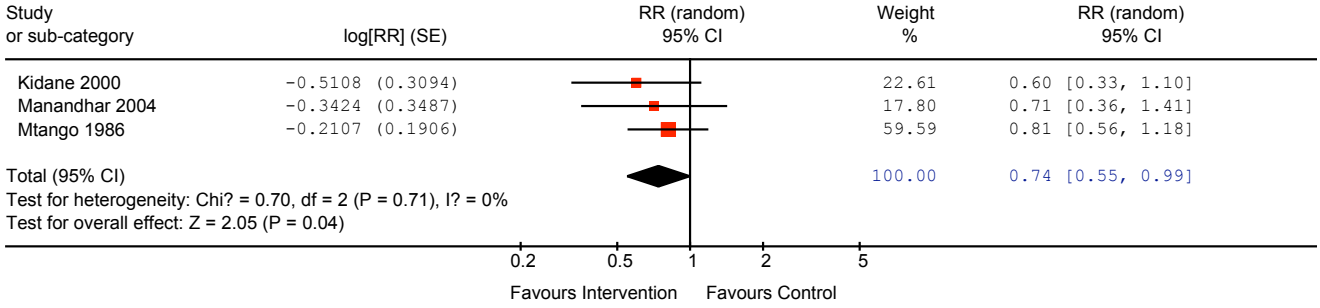


[2] Please note that both unadjusted and adjusted data are presented for each meta-analysis group.

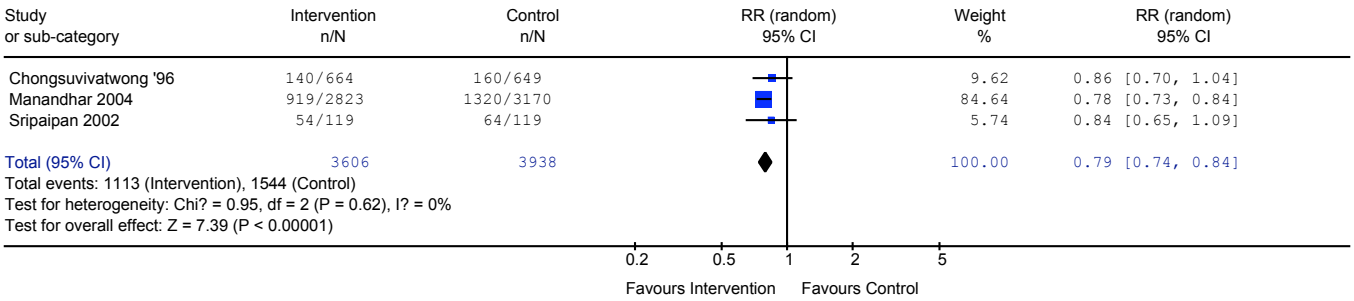
Review: Lay Health Workers
Comparison: 03 Treatment/Medical Services - Lay Health Workers vs. Standard services
Outcome: 07 Mortality among children < 5 years old - unadjusted (Excl. Pence)



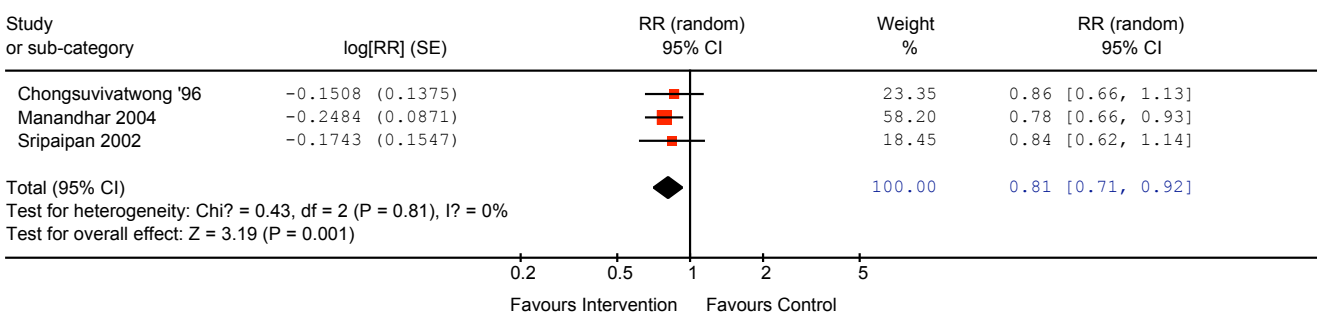
Review: Lay Health Workers
Comparison: 03 Treatment/Medical Services - Lay Health Workers vs. Standard services
Outcome: 08 Mortality among children < 5 years old (Excl. Pence)



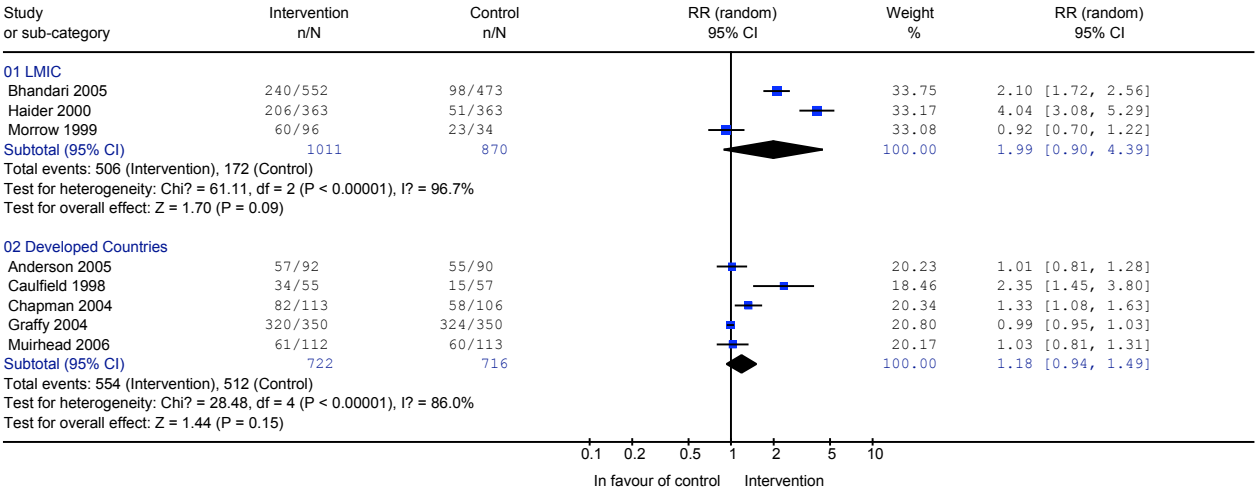
Review: Lay Health Workers
Comparison: 03 Treatment/Medical Services - Lay Health Workers vs. Standard services
Outcome: 03 Morbidity - unadjusted



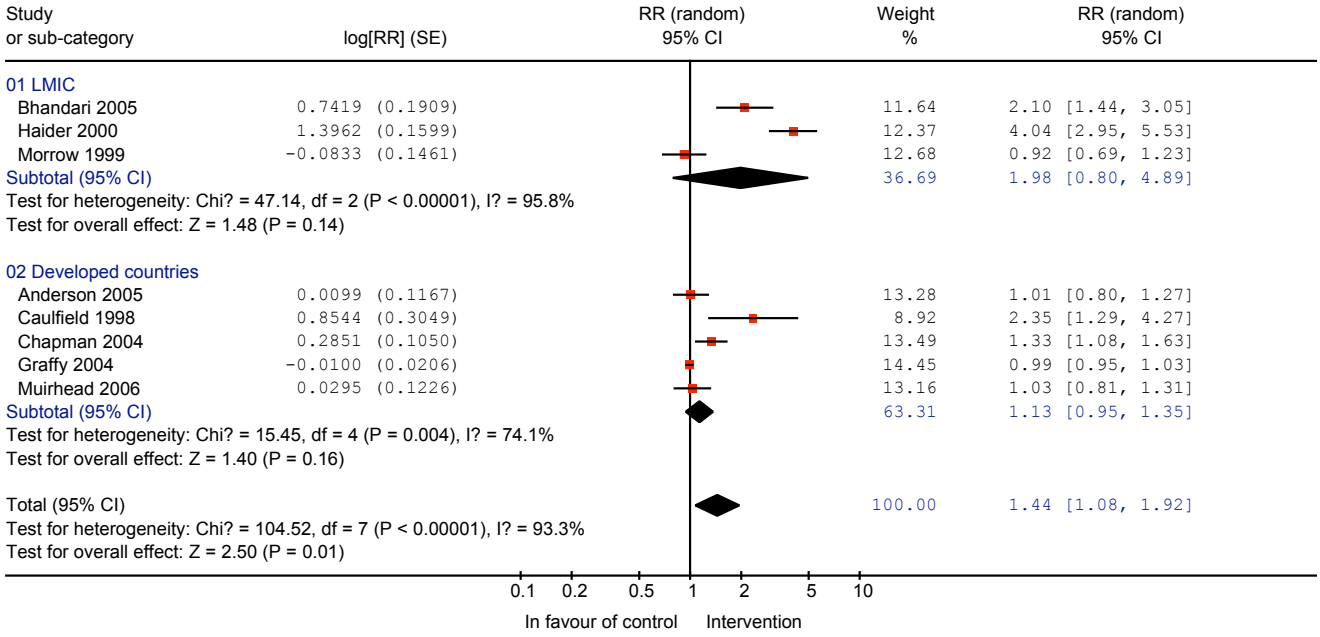
Review: Lay Health Workers
Comparison: 03 Treatment/Medical Services - Lay Health Workers vs. Standard services
Outcome: 04 Morbidity



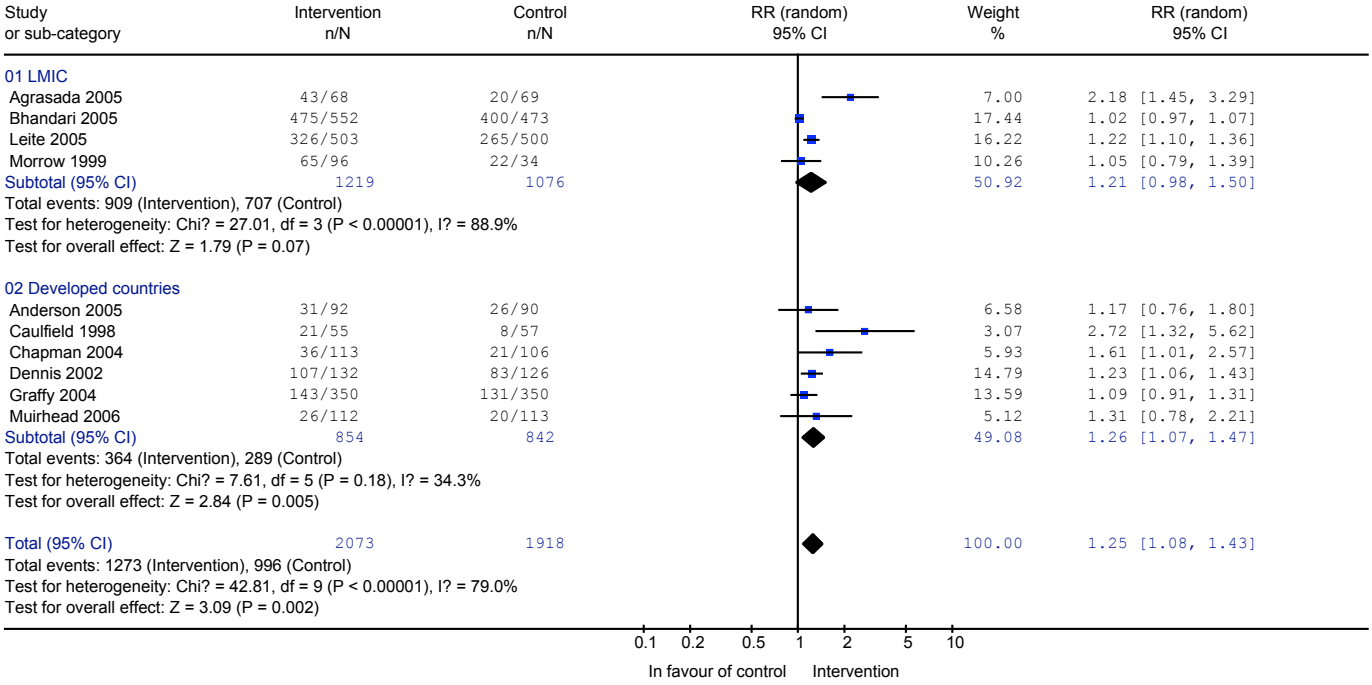
Review: Lay Health Workers
Comparison: 02 Breast-feeding - Lay Health Workers vs. conventional support/care
Outcome: 07 Initiated breast-feeding - unadjusted subgroups



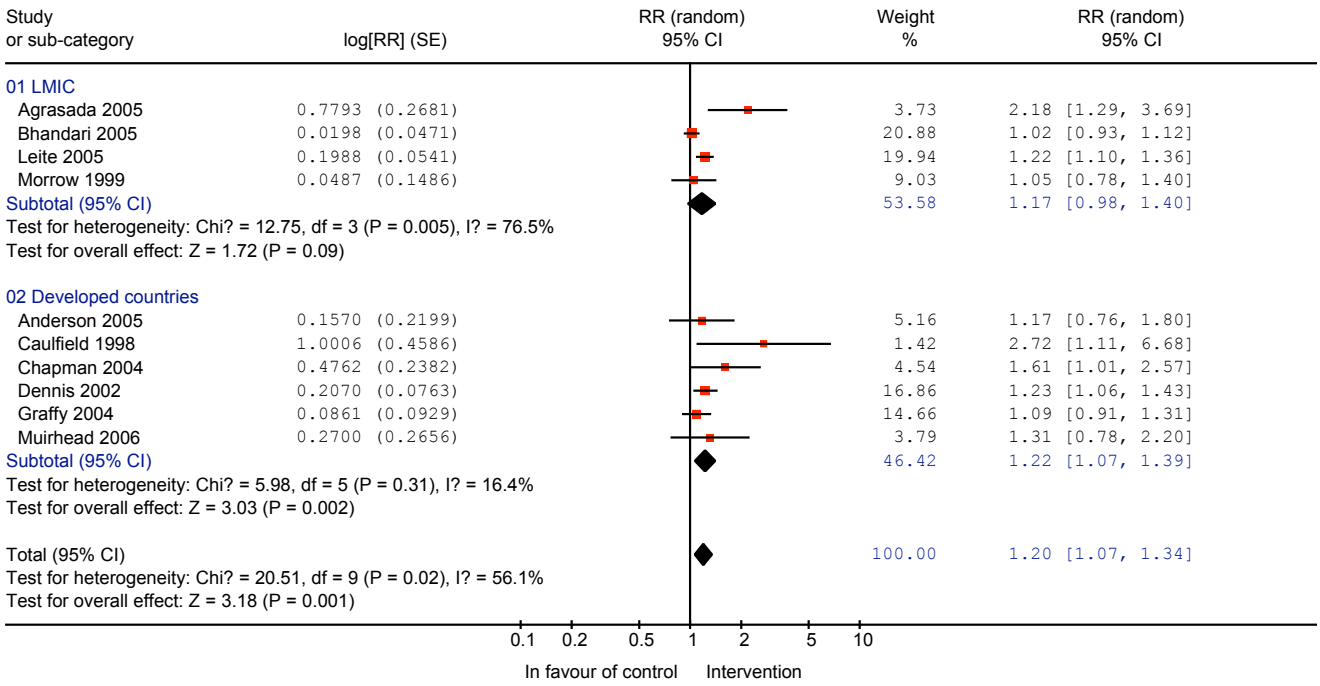
Review: Lay Health Workers
Comparison: 02 Breast-feeding - Lay Health Workers vs. conventional support/care
Outcome: 08 Initiated breast-feeding



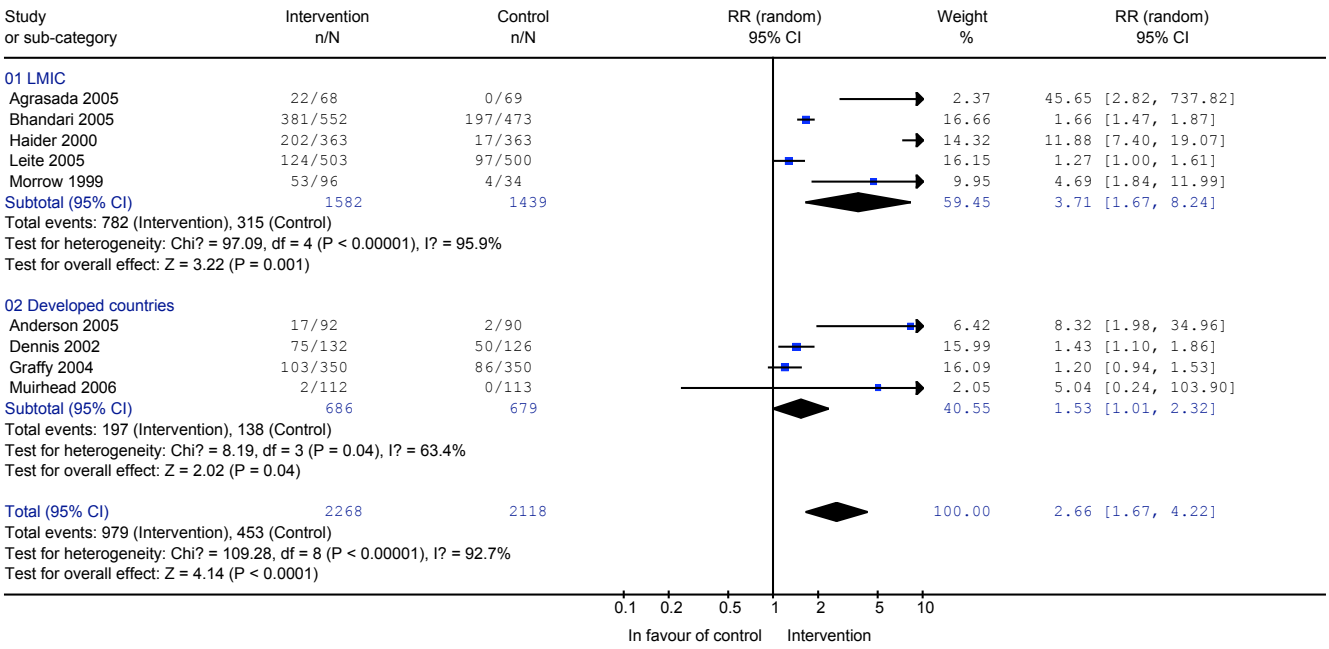
Review: Lay Health Workers
Comparison: 02 Breast-feeding - Lay Health Workers vs. conventional support/care
Outcome: 09 Any breast-feeding up to 6 months - unadjusted



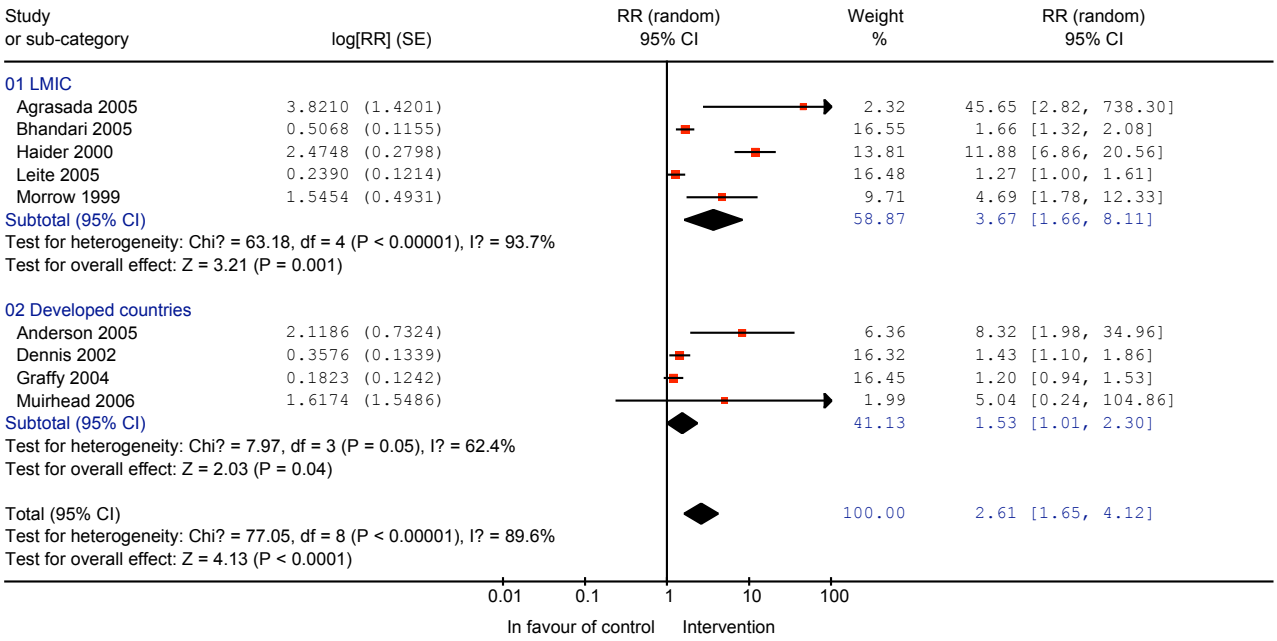
Review: Lay Health Workers
Comparison: 02 Breast-feeding - Lay Health Workers vs. conventional support/care
Outcome: 10 Any breast-feeding up to 6 months



Review: Lay Health Workers
Comparison: 02 Breast-feeding - Lay Health Workers vs. conventional support/care
Outcome: 11 Exclusive breast-feeding 6 weeks to 6 months - unadjusted



Review: Lay Health Workers
Comparison: 02 Breast-feeding - Lay Health Workers vs. conventional support/care
Outcome: 12 Exclusive breast-feeding 6 weeks to 6 months



Appendix IV: GRADE Evidence Profile Tables

Meta-analysis subgroup: LHW interventions to reduce mortality / morbidity in children under five years, compared with usual care
Patient or population: Children less than five years of age
Settings: Ethiopia, Tanzania, Nepal, Ghana, Thailand, Viet Nam

Summary of findings

Outcome	No of Participants (No of trials)	Control group risk (Range)	Relative effect (95% CI)	Illustrative absolute effect	Quality
Mortality	35828 (3)[1,2,5]	4.4% (3.7 to 4.6%)	RR 0.74 (0.55 to 0.99)	11 fewer/1 000	⨁⨁⨁⨁ High
Morbidity	7544 (3)[3,4,6]	39,2% (24.7 to 53.8%)	RR 0.81 (0.71 to 0.92)	8 fewer/1 000	⨁⨁⨁◯ Moderate

Footnotes:

1. Mtango (1986), Kidane (2000), Manandhar (2004).
2. Kidane reported a 40% reduction in under 5 mortality; Manandhar reported a 29% reduction; and Mtango a 27.2% reduction.
3. Chongsuvivatwong (1996), Sripaipan (2002), Manandhar (2004).
4. For all three studies it is not clear whether or not the assessors were blinded. Intention to treat analysis was not conducted in Sripaipan (2002).
5. All three studies offered some form of treatment or management of illness at community level. In Manandhar, the interventions focused on general perinatal health and the effects on morbidity may be indirect.
6. Length of follow-up: 1 year in Siripaipan (2002); 2years in Manandhar (2004); 5 years in Chongsuvivatwong (1996).

Meta-analysis subgroup: LHW interventions to promote immunization uptake in children compared with usual care.
Patient or population: Children less than five years
Settings: Included trials from USA (3) and Ireland (1)

Sumary of findings

Outcome	No of Participants (No of trials)	Control group risk (Range)	Relative effect (95% CI)	Illustrative absolute effect	Quality
Vaccination complete according to schedule	3568 (4)[1,2,3]	49,5% (18.9 to 74%)	RR 1.22 (1.10 to 1.37)	109 more/1 000	⨁⨁⨁◯ Moderate

Footnotes:

1. Barnes (1999), Johnson (1993), LeBaron (2004), Rodewald (1999).
2. In Barnes (1999), only 37.5% of eligible families consented to participate.21.2% refused to participate and 14.3% were living out of the country or in another state. A significantly greater percentage of non-enrolled children were covered by Medicaid insurance than enrolled children (p=0.02). Intention to treat analysis was not done and allocation concealment was not clear.
3. Intention to treat analysis was not done in Rodewald (1999) and Johnson (1993).

Meta-analysis subgroups: LHW interventions to promote the initiation of breastfeeding, any breastfeeding and exclusive breastfeeding up to six months of age
Patient or population: Breastfeeding mothers
Settings: Included trials done in USA, UK, Canada, Scotland, Mexico, Bangladesh, Philippines, India

Summary of findings

Outcome	No of Participants (No of trials)	Control group risk (Range)	Relative effect (95% CI)	Illustrative absolute effect	Quality
Initiated breastfeeding – LMIC	1881 (3)[1,2]	19.8% (14% to 67.6%)	RR 1.98 (0.80 to 4.89)	194 more/1 000	⨁⨁⨁◯ Moderate
Any breastfeeding up to 6 months – LMIC	2295 (4)[6,8]	65,7% (28.9 to 84.6%)	RR 1.17 (0.98 to 1.40)	138 more/1 000	⨁⨁◯◯ Low[7]
Exclusive breastfeeding 6 weeks to 6 months – LMIC	3021 (5)[11,12]	21,9% (0 to 41.6%)	RR 3.67 (1.66 to 8.11)15	584 more/1 000	⨁⨁⨁◯ Moderate[7]
Initiated breastfeeding – Developed countries	1438 (5)[4,5]	71,5% (26.3 to 92.5%)	RR 1.13 (0.95 to 1.35)	93 more/1 000	⨁⨁⨁◯ Moderate
Any breastfeeding up to 6 months – Developed countries	1696 (6)[9,10]	34,3% (14 to 65.9%)	RR 1.22 (1.07 to 1.39)	76 more/1 000	⨁⨁◯◯ Low[7]
Exclusive breastfeeding 6 weeks to 6 months – Developed countries	1365 (4)[13,14]	20,3% (0 to 39.7%)	RR 1.53 (1.01 to 2.30)	108 more/1 000	⨁⨁◯◯ Low[7]

Footnotes:

1. Haider (2000), Morrow (1999), Bhandari (2005).
2. Length of follow up: 3 months (Morrow 1999, Bhandari 2003), 5 months (Haider 2000).
3. Strong evidence of heterogeneity, source is not clear.
4. Caulfield 1998, Anderson 2005, Chapman 2004, Graffy 2004, Muirhead 2006.
5. Length of follow up: 1.5 weeks (Caulfield 1998), 6 weeks (Graffy 2004), 3 months (Anderson 2005), 4 months (Muirhead 2006), 6 months (Chapman 2004).
6. Agrasada (2005), Bhandari (2005), Leite (2005), Morrow (1999).
7. Assessment of outcome is thorugh interviews with mothers who gave reports of breastfeeding.
8. Length of follow up: 3 months (Morrow 1999, Bhandari 2003), 6 months (Leite 2005, Agrasada 2005).
9. Includes all studies listed in footnote 4 plus Dennis (2002).
10. See footnote 5 for length of follow up. Follow up was 3 months in Dennis (2002).
11. Includes all studies listed in footnote 6 plus Haider (2000).
12. See footnote 8 for length of follow up. Follow up in Haider (2000) was for 5 months.

13. Anderson 2005, Dennis 2002, Graffy 2004, Muirhead 2006.
14. Length of follow up: 1.5 months (Graffy 2004), 3 months (Dennis 2002, Anderson 2005), 4 months (Muirhead 2006).
15. Large effect size is unlikely to be due to chance.

Meta-analysis subgroup: LHW interventions to improve TB treatment outcomes compared with institution-based directly observed therapy
Patient or population: Patients with sputum or culture positive pulmonary tuberculosis
Settings: Included trials conducted in South Africa (2) and Tanzania

Summary of findings

Outcome	No of Participants (No of trials)	Control group risk (Range)	Relative effect (95% CI)	Illustrative absolute effect	Quality
Cure rates for smear positive pulmonary tuberculosis patients[1,2,3,4]	798 (3)	44% (28 to 41%)	RR 1.21 (1.00 to 1.47)	92 more/1 000	⊕⊕⊕◯ Moderate

Footnotes:
1. Clarke (2005): Followed up 46% and 54% of patients in the intervention and control arms respectively.
2. Lwilla (2003): 68% follow up of patients after 8 months of treatment. Overall loss to follow up was higher in community than in institution based DOTS (OR 1.92, 95% CI 1.29-2.8).
3. Clarke (2005) was implemented among farm dwellers in South Africa but there are no obvious signs of inconsistency in relation to the other study populations.
4. Length of follow up varied from 5 months (Clarke 2005) to 7 months (Lwilla 2003).

Appendix V: Methodological quality summary scores for all included studies

Study	Summary score1
Agrasada 2005	Low
Anderson 2005	High
Barnes 1999	Low
Barth 1998	Low
Bhandari 2003	Low
Black 1995	Low
Bugental 2002	Low
Bullock 1995	High
Caulfield 1998	Low
Chapman 2004	Low
Chongsuvivatwong 1996	Low
Clarke 2005	Low
Coutinho 2005	Low
Dennis 2002	High
Duggan 2004	Low
Gielen 2005	Low
Gockay 1993	Low
Graffy 2004	High
Graham 1992	Low
Haider 2000	Low
Ireys 1996	Low
Ireys 2001	High
Johnson 1993	Low
Kidane 2000	High
Krieger 2000	Low
LeBaron 2004	High
Leite 2005	High
Luby 2006	High
Lwilla 2003	Low
Malchodi 2003	Low

Study	Summary score1
Manandhar 2004	High
Merewood 2006	Low
Morrow 1999	High
Mtango 1986	Low
Muirhead 2006	High
Olds 2002/Korfmacher 1999	Low
Pence 2005	Low
Rodewald 1999	Low
Rohr 2004	Low
Schuler 2000	High
Siegel 1980	Low
Silver 1997	High
Singer 1999	Low
Spencer 1989	Low
Sripaipan 2002	Low
Stevens- Simons 2001	Low
Sullivan 2002	Low
Zwarenstein 2000	High

[1] Studies were assessed as high quality if they reported allocation concealment, higher than 80% patient follow up and intention to treat analysis. Studies were assessed as low quality if they did not meet these criteria or if they did not report the information necessary for assessment.

Appendix VI: Summary tables of included studies

Author, year								Tasks performed by LHWs		Health issues of participants / consumers
	Analysis subgroup	*Reach (1)*	*Substitution (2)*	*Extension (3)*	*Geographic setting*	*Location of intervention*	*Country*	*Task category*	*Details*	
Clarke 2005*	TB	Yes	No	Yes	Rural	Home	South Africa	Treatment of illness	For TB patients on DOT by LHW, recorded treatment adherence. Monthly weighing and TB screening, Referral of patients with symptoms suggestive of TB. LHW mentoring role in case of self-supervision group. Addressed non-adherence promptly.	Tuberculosis patients who had commenced treatment
Lwilla 2003*	TB	No	Yes	No	Rural	Home	Tanzania	Treatment of illness	Supervise TB drug intake, collect drugs from nearby health facility depending on patients condition	Tuberculosis treatment
Zwarenstein 2000	TB	No	No	Yes	Urban formal	Home	South Africa	Treatment of illness		Treatment of Pulmonary tuberculosis
Barnes 1999	Immunisation	No	No	Yes	Urban formal	PHC	USA	Health Promotion		Children who were not immunised that enrolled in one of two ambulatory clinics
Krieger 2000	Immunisation	No	No	Yes	Urban formal	Home	USA	Health Promotion		Immunisation against influenza and pneumococcal pneumonia
LeBaron 2004	Immunisation	No	No	Yes	Urban informal	PHC	USA	Other	Intervention to prevent missed immunization opportunities	Reminder-recall intervention to minimise immunisation missed opportunities
Rodewald 1999	Immunisation	No	No	Yes	Urban formal	PHC	USA	Health Promotion	Reduce immunisation dropouts	Reduce immunisation dropouts

Author, year								Tasks performed by LHWs		Health issues of participants / consumers
	Analysis subgroup	*Reach (1)*	*Substitution (2)*	*Extension (3)*	*Geographic setting*	*Location of intervention*	*Country*	*Task category*	*Details*	
Gockay 1993*	Immunisation	No			Urban informal	Home	Turkey	Health Promotion	Identified high risk families, educated and referred them for immunization	Guidance on MCH related issues including family planning, ANC, well-child control, immunisation
Chongsuvivatwong 1996*	Treatment	No	No	Yes	Rural	Home	Thailand	Treatment of illness		Acute Respiratory Infection
Mtango 1986*	Treatment	Yes	No	Yes	Rural	Home	Tanzania	Treatment of illness	Utilisation of LHWs to include higher levels of primary care by referral to dispensaries, health centres and hospitals. Training courses on ARI management.	ARI in children<5yrs
Kidane 2000*	Treatment	Yes	No	Yes	Rural	Home	Ethiopia	Treatment of illness	Training of mothers to manage malaria	Malaria in children
Pence 2005*	Treatment	Yes	Yes	No	Rural	Home	Ghana	Treatment of illness		Reduction of under 5 mortality
Luby 2006*	Treatment	No	No	Yes	Urban informal	Home	Pakistan	Health Promotion		Diarrhoea prevention through drinking water treatment and hand washing
Sripaipan 2002*	Treatment				Rural	Home	VietNam	Health Promotion		Managed malnutrition using nutrition intervention based on the positive deviant approach
Manandhar 2004*	Treatment	Yes	No	Yes	Rural	Other	Nepal	Health Promotion	Organised monthly meetings to discuss issues around childbirth and care in the community	Perinatal health issues
Bhandari 2003*	Breastfeeding	No	No	Yes	Rural	Home	India	Health Promotion	Given to mothers of non-exclusively breastfed children	Promote exclusive breastfeeding

Author, year								Tasks performed by LHWs		Health issues of participants / consumers
	Analysis subgroup	*Reach (1)*	*Substitution (2)*	*Extension (3)*	*Geographic setting*	*Location of intervention*	*Country*	*Task category*	*Details*	
Coutinho 2005	Breastfeeding	No	No	Yes	Urban formal	Home	Brazil	Support		Support for breastfeeding mothers
Agrasada 2005	Breastfeeding	No	No	Yes		Home	Phillipi-nes	Health Promotion	Counselling	Exclusive breastfeeding of low birth-weight infants
Anderson 2005	Breastfeeding	No	No	Yes	Urban formal	Home	USA	Health Promotion	Peer counselling and support for mothers before and after commencing breastfeeding	Breastfeeding counselling, education and support
Chapman 2004	Breastfeeding	No	No	Yes	Urban informal	Home	USA	Health Promotion		Education regarding breast-feeding
Muirhead 2006	Breastfeeding	No	No	Yes	Urban formal	Home	Scotland	Health Promotion		Infant feeding counselling
Merewood 2006	Breastfeeding	No	No	Yes	Urban formal	PHC	USA	Health Promotion	Infant feeding counselling with empha-sis on encouraging breastfeeding among mothers with pre-term babies	Infant feeding counselling with emphasis on encourag-ing breastfeeding among mothers with pre-term babies
Leite 2005	Breastfeeding	No	No	Yes	Urban formal	Home	Brazil	Health Promotion	Home visits that included interviews with mothers, observation of home environment and observation of breast-feeding. Identification of the breast-feeding difficulties.	Breastfeeding
Morrow 1999*	Breastfeeding	No	No	Yes	Urban informal	Home	Mexico	Health Promotion		Breastfeeding promotion and support for women
Haider 2000	Breastfeeding	No	No	Yes	Urban informal	Home	Bangla-desh	Health Promotion		Promotion of exclusive breastfeeding among pregnant women
Dennis 2002	Breastfeeding	No	No	Yes	Urban formal	Home	Canada	Support		Telephone based social support for breastfeeding

Author, year								Tasks performed by LHWs		Health issues of participants / consumers
	Analysis subgroup	*Reach (1)*	*Substitution (2)*	*Extension (3)*	*Geographic setting*	*Location of intervention*	*Country*	*Task category*	*Details*	
Caulfield 1998*	Breastfeeding	No	No	Yes	Urban formal	PHC	USA	Health Promotion		Breastfeeding promotion and support
Graffy 2004	Breastfeeding				Urban formal	Home	UK	Health Promotion		Breastfeeding promotion and support
Barth 1998	Prevention of child abuse	No	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	This was a perinatal prevention program to prevent abuse to children
Bullock 1995	Parent-child	No	No	Yes	Urban formal	Home	New Zealand	Health Promotion	Psychosocial support	
Johnson 1993	Parent-child	No	No	Yes	Urban formal	Home	Ireland	Health Promotion	Psychosocial support	Provide parents guidance on health and encourage early child development
Korfmacher 1999*	Parent-child	No	Yes	No	Urban formal	PHC	USA			Maternal/child health
Siegel 1980	Prevention of child abuse	No	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	Mothers coping with situational crises
Duggan 2004*	Prevention of child abuse				Rural	Home	USA	Health Promotion	Home visits were guided by an individual family support plan (family goals and steps to achieve them) prepared conjointly with family. Supervisor and home visitor identify key issues by examining the family's stress checklist	Child abuse
Bugental 2002	Prevention of child abuse				Rural	Home	USA	Physical care	Prevent harsh parenting	Child abuse
Sullivan 2002	Not classified	No	No	Yes	Urban formal	Home	USA	Health Promotion		Women's partners physical violence

Author, year								Tasks performed by LHWs		Health issues of participants / consumers
	Analysis subgroup	*Reach (1)*	*Substitution (2)*	*Extension (3)*	*Geographic setting*	*Location of intervention*	*Country*	*Task category*	*Details*	
Stevens-Simons 2001	Prevention of child abuse	No	No	Yes	Urban informal	Home	USA	Health Promotion	Psychosocial support	Teenage mothers at risk of abusing or neglecting their children
Ireys 1996	Mothers	No	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	Social support for mothers with children who have juvenile rheumatoid arthritis who had been active patients of the paediatric rheumatology clinic at John Hopkins Hospital
Ireys 2001	Mothers	No	No	Yes	Urban formal	Home	USA	Support		Women with children aged 7 to 11 yrs with one of the following chronic illnesses: diabetes (40%), sickle cell anaemia (19%), cystic fibrosis (9%), moderate to severe asthma (32%)
Silver 1997	Mothers	Yes	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	Children with a variety of ongoing health conditions / social support and increased access to relevant information, services and knowledgeable advisors for mothers
Black 1995	Mothers	No	Yes	No	Urban formal	Home	USA	Health Promotion	Psychosocial support	Non-organic failure to thrive (NOFTT) especially among children of low socio-economic families
Spencer 1989	Child outcomes	No	No	Yes	Urban informal	Home	UK	Support	Psychosocial support	Social support to pregnant women at above average risk of giving birth to a low-weight baby

Author, year								Tasks performed by LHWs		Health issues of participants / consumers
	Analysis subgroup	*Reach (1)*	*Substitution (2)*	*Extension (3)*	*Geographic setting*	*Location of intervention*	*Country*	*Task category*	*Details*	
Malchodi 2003	Child out-comes	No	No	Yes	Rural	Home	USA	Health Promotion		Smoking cessation
Graham 1992	Child out-comes	No	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	Prevention of low birth weight babies (<2500g). NB Only high risk participants initially identified by a medi-cal / psychosocial screening questionnaire
Schuler 2000	Parent-child	No	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	Mother infant interaction among drug-using women
Rohr 2004	Child out-comes	No	No	Yes	Urban formal	Home	USA	Health Promotion	Psychosocial support	Women (pregnant or plan-ning pregnancy) with phen-ylketonuria
Singer 1999	Mothers	No	No	Yes	Urban formal	Other	USA	Support		Support for parents/foster parents/grandparents of children with disabilities or chronic health problems
Gielen 2005*	Not classified	No	No	Yes	Urban formal	Home	USA	Health Promotion		To enhance parents' home safety practices through paediatric safety counselling

* Cluster randomised trials

(1) LHWs intended to extend an intervention to 'hard-to-reach' group/s (e.g. geographically remote or do not usually access health services etc.)

(2) LHWs undertaking activities usually performed by health professionals (intervention group) compared to the same activities performed by health professionals (control group) [i.e. substitution or replacement]

(3) LHWs undertaking activities not usually undertaken by health professionals OR in addition to those usually undertaken by health professionals (intervention group) compared to no intervention / usual care [i.e. an extension of services]

Appendix VII: Summary tables of outcomes for studies not included in meta-analysis subgroups

Author year	Category	Control	Intervention1	Intervention2	Effect Size	Comments
Barth 1998	Prevention of child abuse	Prenatal Care: Summary score 1) Eating unhealthy items Mean =8.28(SD 2.88); 2) Eating healthy items: Mean=6.10 (SD 2.83); 3) Frequency of visits to doctor in 2nd and 3rd trimesters Mean=9.73, (SD 3.48)	1) Mean =8.12 (SD2.38) 2) Mean=6.2, (SD 2.81) 3) Mean=9.90, (SD 3.17)		F(3,38)=5.69, P<0.01	
		Parent well-being:1) Depression: Mean =41.4, (SD 12.38); 2) Anxiety: Mean=40.41, (SD 13.23); 3) Perlin scale: Mean =20.28, (SD=3.52); 4) Child abuse potential: Mean=93.37(SD 46.61); 5)Goal level: Mean=2.98 (SD1.02)	1) Mean=39.54 (SD12.30); 2) Mean = 39.25 (SD 12.98); 3) Mean = 19.98 (SD 3.73); 4) Mean=99.76 (SD 45.82); 5) Mean=2.29 (SD 1.03)		NS	1) Center for Epidemiological Studies depression scale (CES-D) 2)The state-trait anxiety inventory (STAI) 3)The Pearlin Mastery scale 4)The Child abuse potential inventory (CAPI)
		Birth Outcomes: 1) Pregnancy problems(adverse events during delivery) Mean=1.36 (SD 1.09); 2)Total days mother and newborn were in hospital around delivery: Mean=9.80(SD 4.57); 3) Birthweight (g):Mean=3255 (SD 625); 4) Score of discrepancy between expected and actual discomfort during pregnancy and delivery: Mean=1.36 (SD 0.45); 5) Score of degree to which client worried about issues related to having a newborn: Mean =24.19(SD 6.48)	1) Mean=1.49, (SD 1.06) 2) Mean=8.41(SD 3.88) 3) Mean 3396 (SD 683) 4) Mean=1.31(SD 0.19) 5) Mean 25.04 (SD 7.55)		F(5,29)=2.59, p<0.05	

Author year	Category	Control	Intervention1	Intervention2	Effect Size	Comments
(Barth 1998 continued)		Child temperament: 1) Activity: Mean=50.18 (SD 8.75); 2) Mood: Mean=23.91 (SD 4.93); 3) Distractability: Mean=24.59 (SD 6.44)	1) Mean=48.05(SD 9.35) 2) Mean=22.05 (SD 4.54) 3) Mean =24.11(SD6.50)		F(3,17)=5.84, P<0.01	Subscales of infant temperament questionnaires
Barth 1998	Prevention of child abuse	Prenatal Care: Summary score 1) Eating unhealthy items Mean =8.28(SD 2.88); 2) Eating healthy items: Mean=6.10 (SD 2.83); 3) Frequency of visits to doctor in 2nd and 3rd trimesters Mean=9.73, (SD 3.48)	1) Mean =8.12 (SD2.38) 2) Mean=6.2, (SD 2.81) 3) Mean=9.90, (SD 3.17)		F(3,38)=5.69, P<0.01	
		Parent well-being:1) Depression: Mean =41.4, (SD 12.38); 2) Anxiety: Mean=40.41, (SD 13.23); 3) Perlin scale: Mean =20.28, (SD=3.52); 4) Child abuse potential: Mean=93.37(SD 46.61); 5)Goal level: Mean=2.98 (SD1.02)	1) Mean=39.54 (SD12.30); 2) Mean = 39.25 (SD 12.98); 3) Mean = 19.98 (SD 3.73); 4) Mean=99.76 (SD 45.82); 5) Mean=2.29 (SD 1.03)		NS	1) Center for Epidemiological Studies depression scale (CES-D) 2)The state-trait anxiety inventory (STAI) 3)The Pearlin Mastery scale 4)The Child abuse potential inventory (CAPI)
		Birth Outcomes: 1) Pregnancy problems(adverse events during delivery) Mean=1.36 (SD 1.09); 2)Total days mother and newborn were in hospital around delivery: Mean=9.80(SD 4.57); 3) Birthweight (g):Mean=3255 (SD 625); 4) Score of discrepancy between expected and actual discomfort during pregnancy and delivery: Mean=1.36 (SD 0.45); 5) Score of degree to which client worried about issues related to having a newborn: Mean =24.19(SD 6.48)	1) Mean=1.49, (SD 1.06) 2) Mean=8.41(SD 3.88) 3) Mean 3396 (SD 683) 4) Mean=1.31(SD 0.19) 5) Mean 25.04 (SD 7.55)		F(5,29)=2.59, p<0.05	

Author year	Category	Control	Intervention1	Intervention2	Effect Size	Comments
(Barth 1998 continued)		Child temperament: 1) Activity: Mean=50.18 (SD 8.75); 2) Mood: Mean=23.91 (SD 4.93); 3) Distractability: Mean=24.59 (SD 6.44)	1) Mean=48.05(SD 9.35) 2) Mean=22.05 (SD 4.54) 3) Mean =24.11(SD6.50)		F(3,17)=5.84, P<0.01	Subscales of infant temperament questionnaires
		Child Health Score: -0.30	0.25	-0.05	F(2.70)=4.01, p=0.02	Score from information reported by parents
		Changes in BDI depression	-6.23(SD 9.67)	3.29(SD 12.05)	P<0.05	Beck Depression Inventory (BDI)
		Changes in STAI anxiety	6.69 (SD 16.80)	3.29 (SD 12.05)	NS	State trait anxiety inventory(STAI)
		Adult control factor(ACF): High and low	High ACF: Mean =0.46(SD 1.28), Low ACF Mean =0.28(SD 1.32)	High ACF: Mean =-0.15(SD 1.75), Low ACF Mean =-0.10(SD 2.13)	High ACF p>0.05. Low ACF NS	High ACF: Importance attributed to causes controllable by self) Low ACF, same as High ACF but not controllable
		Child control factor: High and Low	High CCF: Mean =0.35(SD 1.21), Low ACF Mean =0.35(SD 1.63)	High CCF: Mean =0.24(SD 1.88), Low ACF Mean =0.24(SD 1.67)	Both NS	High CCF: importance attributed to causes controllable by child. Low CCF: same as High CCF but not controllable
Duggan 2004	Prevention of child abuse	Prevalence of depressive symptoms at 1 yr 23%, 2yr 18%, 3yr 16%	Prevalence of depressive symptoms at 1yr 235, 2yr 16%, 3yr 16%		Adjusted OR 0.97[0.70-1.33] p=0.84	Follow up at 1, 2 3 yrs for all outcomes. Center for Epidemiological Studies depression scale(CES-D) using a cutoff of >24 as a positive score
		Prevalence of severe parenting stress : 10%, 9%, 8%	Prevalence of sever parenting stress : 11%, 8%, 8%		Adjusted OR 1.04[0.65 - 1.67] p=0.86	Abidins Parenting stress Index (PSI)
		Prevalence of poor general mental health : 46%, 38%, 32%	Prevalence of poor general mental health : 36%, 35%, 29%		Agency B: Adjusted OR0.52 [0.33-0.81] P<0.01. Agency A and C: Adjusted OR 0.93[0.67-1.31] p=0.69	5-item version of the Mental health index (MHI-5)
		Maternal illicit drug use: 9%, 11%, 9%	Maternal illicit drug use: 9%, 10%, 11%		Adjusted OR 1.06[0.69 - 1.61] p=0.80	

Author year	Category	Control	Intervention1	Intervention2	Effect Size	Comments
(Duggan 2004 continued)		Maternal problem alcohol use: 10%, 9%, 10%	Maternal problem alcohol use: 10%, 9%, 10%		Adjusted OR 0.76[0.48 - 1.21] p=0.25	Self report of alcohol use in the past year together with a history of alcohol problems, as measured by 2 or more positive responses to the four CAGE questions
		Partner psychological abuse: 49%, 42%, 38%	Partner psychological abuse: 49%, 42%, 42%		Adjusted OR 1.05[0.81 - 1.36] p=0.69	
		Partner physical abuse: 42%, 32%, 30%	Partner physical abuse: 37%,26%, 29%		Adjusted OR 0.83[0.63 - 1.09] p=0.19	Conflict Tactics Scale (CTS)
		Parent incident resulting in injury:26%, 20%, 18%	Parent incident resulting in injury:24%, 14%, 17%		Adjusted OR 0.81[0.59 - 1.10] p=0.19	
		Maternal problem alcohol use: all families included	Maternal problem alcohol use: only families with high dose of service		Adjusted OR 0.45 [0.18-0.94] p<0.05	
		Partner physical abuse: all families included	Partner physical abuse: only families with high dose of service included		Adjusted OR 0.51 [0.29-0.88] p<0.05	
		Partner physical abuse: women without partner + women in a non-violent relationship, 3 or more incidents reported	Partner physical abuse: women without partner + women in a non-violent relationship, 3 or more incidents reported		Adjusted OR 0.58 [0.33-1.00] p=0.05	
		Mothers with poor mental health who wanted services:26%, 31%, 59%	Mothers with poor mental health who wanted services:26%, 36%, 52%		Adjusted OR 0.96[0.70-1.33] p=0.82	
		Mothers with poor mental health who succeeded in obtaining services:20%, 27%, 55%	Mothers with poor mental health who succeeded in obtaining services:18%, 28%, 48%		Adjusted OR 0.92[0.65-1.31] p=0.64	
		Mothers with maternal substance abuse who wanted services: 48%, 41%, 59%	Mothers with maternal substance abuse who wanted services: 35%, 44%, 61%		Adjusted OR 0.85[0.50-1.44] p=0.54	
		Mothers with maternal substance abuse who succeeded in obtaining services: 35%, 32%, 56%	Mothers with maternal substance abuse who succeeded in obtaining services: 25%, 36%, 56%		Adjusted OR 0.90[0.51-1.58] p=0.71	

Author year	Category	Control	Intervention1	Intervention2	Effect Size	Comments
(Duggan 2004 continued)		Mothers with partner violence who wanted services:24%, 44%, 70%	Mothers with partner violence who wanted services:30%, 41%, 63%		Adjusted OR 0.0.99[0.66-1.47] p=0.95	
		Mothers with partner violence who succeeded in obtaining services:18%, 31%, 50%	Mothers with partner violence who succeeded in obtaining services:17%, 30%, 50%		Adjusted OR 1.01[0.66-1.53] p=0.97	

Author year	Category	Control	Intervention 1	Intervention 2	Intervention 3	Effect Size	Comments
Siegel 1980	Prevention of child abuse	Acceptance: 4 months 0.217; 12 months: 0.084	Home Visit and extended contact: Acceptance score at 4 months:0.258; 12 months:0.091	Extended contact only: Acceptance score at 4 month 0.245; 12 months 0.085	Home visit only at 4 months 0.221; 12 months 0.085	Acceptance score: 4 months p<0.0001; 12 months p=NS	
		Interaction/stimulation: 4 months 0.198; 12 months:0.190	Interaction/stimulation score 2) 4months: 0.209, 12 months0.203	Interac-tion/stimulation at 4 month 0.203; 12 months 0.201	Interac-tion/stimulation at 4 months 0.198; 12 months 0.193	Interac-tion/stimulation: 4 months p<0.0002; 12months p<0.004	
		Consoling: 4 months 0.102	Consoling score at 4 months:0.136	Consoling score at 4 months 0.135	Consoling score at 4 months 0.110	Consoling score: p<0.02	
		Positive/negative:12 months 0.046	Positive/negative at 1 2months 0.078	Positive/negative score at 12 months 0.078	Posi-tive/negative score at 12 months 0.046	Positive/negative score: p=NS	
		Child abuse/neglect:3/52	Child abuse/neglect:4/47	Child abuse/neglect: 3/50	Child abuse/neglect: 7/53		

(Siegel 1980 continued)		Health care utilisation by infants 1) Hospitalisations = 3	Health care utilisation by infants 1) Hospitalisations = 4	Health care utilisation by infants 1) Hospitalisations = 1	Health care utilisation by infants 1) Hospitalisations = 4	
		ER visits 13	ER visits 9	ER visits 13	ER visits 11	
		Preventive care visits = 4.1	Preventive care visits =3.8	Preventive care visits =3.8	Preventive care visits =34.1	
		Immunisations = 4.5	Immunisations = 4.7	Immunisations = 4.4	Immunisations = 5.1	

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
Stevens-Simons 2001	Prevention of child abuse	Any maltreatment:19.4%	18.2%			Not specified how was measured. Could be based on how many children were taken into care because of different forms of maltreatment.
		Abuse (physical, sexual, emotional):0%	3.6%			
		Neglect (failure to provide basic shelter, supervision, medical care or support): 15.3%	3.6%			
		Abandonment (the mother left the home, putting a friend or relative in charge of the child's care): 4.6%	10.9%			
		Immunisation				
		Health care utilisation (no. of CAMP clinic, emergency dept visits, hospitalisations)				
		Teenagers next pregnancy				
		Use of hormonal contraception: 87.4%	96.5%			

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Stevens-Simons 2001 continued)		Childs mental and motor development				Bayley's Scales for Mental and Motor development
		Qualities of home environment and parental care				home screening questionnaire
		Postpartum school return				not specified
Graham 1992	High risk mothers	Frequency of clinic attendance (n=48): 0.93	4 visits: Frequency of clinic attendance (n=49):1.17	Some visits: Frequency of clinic attendance(n=49):1.12	Intervention 1(4 visits): p=0.007 Intervention 2 (some visits):p=0.029	Ratio of actual to expected visits calculated using American College of Obstetrics and Gynecologists' routine pre-natal care visitation standards
		Proportion of low birth weight babies born to high risk mothers (n=53): 7.5%	4 visits :Proportion of low birth weight babies born to high risk mothers (n=52): 7.7%	Some visits: Proportion of low birth weight babies born to high risk mothers (n=62): 12.9%	Intervention 1 (4 visits): p=0.98 Intervention 2 (some visits): p=0.51	Extracted from hospital medical records
Rohr 2004	High risk mothers	Weeks gestation after which blood Phe remained <360micromol/L: Mean 20.5(SD16.1), Median 14	Mean 20.5(SD16.6), Median 9		NS	
		Birth weight z-score: Mean -0.1+/-1.3 (SD -1.6 to 2.2)	Mean -0.2+/-1.5 (SD -3.4 to 1.3)		NS	
		Birth length z-score: Mean 0.7+/-1.3 (SD -1.4 to 2.5)	Mean -0.4+/-2.0 (SD -3.9 to 3.1)		NS	
		Birth head circumference z-score: Mean 0.5+/-1.2 (SD -3.6 to 1.2)	Mean -0.9+/-2.5 (SD -5.8 to 2.5)		NS	
		Treatment initiated prior to pregnancy: Wks gestation after which blood Phe remained<360micromol/L. Mean 12.4 (SD13.3) Range 0-28	Mean 17.7(SD17.6)Range 0-40		NS	

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Rohr 2004 continued)		Treatment initiated during pregnancy: Wks gestation after which blood Phe remained<360micromol/L. Mean 29.8 (SD15.8) Range 6-40	Mean 22.4(SD15.7)Range 5-40			
		Mean blood Phe during pregnancy when treatment initiated prior to pregnancy. Mean 4.7+/- 1.6(2.9-8.3)	Mean 5.2+/- 2.2(2.4-9.9)			
		Mean blood Phe during pregnancy when treatment initiated during pregnancy. Mean 6.5+/- 2.0(3.8-9.1)	Mean 8.1+/- 5.7(2.5 - 18.9)			
Spencer 1989	High risk mothers	Mean birth weight(g) all:3214.5	3179.6		p=0.03 [-97.8 - 28.0]	Hospital records
		Mean birth weight(g) femalesl:3146.3	3113.3		p=0.4[-90.5 - 24.5]	
		Mean birth weight(g) males:3289.3	3232.0		p=0.3[-143.8 - 41.2]	
		Termination for social reasons	0.2%	1.8%		
		Mean gestational age(days)	278.4	279	p=0.6[-1.6 - 2.8]	
		Low birth weight(<2500g)	8.6%	8.8%	OR 1.0 [0.7-1.5]	
		Small for gestation age	10.2%	10 %	OR 1.0 [0.7-1.6]	
		Pre-term birth:9.3%	10 %		OR 1.1[0.7-1.6]	
		Termination for medical reasons: 0.2%	0.5%			
		Miscarriage<12weeks:1%	0.5%			
		Miscarriage>12weeks:1.8%	1 %			
		Stillbirth antepartum:0%	0.8%			

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Spencer 1989 continued)		Stillbirth intrapartum:0%	0 %			
		Stillbirth gestation age not known:0.2%	0.2%			
		Early neonatal death (1-7days): 0.5%	0.2%			
		Late neonatal death 88-28days): 0%	0 %			
		Survivors at 1 month: 99.5%	99.8%			

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments	Author year
Black 1995	Mothers of sick children	Older Control: Growth weight for age -1.7 (SD 0.7), Weight for height -1.3 (SD 0.6), Height for age -0.9 (SD 1.0)	Younger Control: Growth weight for age -1.1(SD 1.0), Weight for height -0.8 (SD 1.1), Height for age -1.0 (SD 1.0)	Intervention for Older Children: Growth weight for age -1.8 (SD 0.6), Weight for height -1.5 (SD 0.5), Height for age -0.7 (SD 1.1)	Intervention for younger children: Growth weight for age -1.3 (SD 1.1), Weight for height -1.0 (SD 1.4), Height for age -0.8 (SD 1.1)	p=NS	Determined using age/gender specific charts. Childs height for age adjusted by parents' weight.
		Cognitive development 80.8 (SD=15.2)	Cognitive development 86.1 (SD=18.7)	Cognitive development 81.9 (SD=12.5)	Cognitive development 89.3 (SD=17.4)	P=0.02	Bayley's scales of infant development
		Motor development 91.6 (SD 14.2)	Motor development 91.5 (SD 18.7)	Motor development 92.0 (SD 12.2)	Motor development 92.0 (SD 14.6)		Bayley's scales of infant development
		Language development: receptive 82.7 (SD 17.2); Expressive 83.3 (SD 19.0)	Language development: receptive 88.0 (SD 15.9); Expressive 86.1 (SD 18.2)	Language development: receptive 83.2 (SD 10.2); Expressive 83.4 (SD 11.7)	Language development: receptive 88.5 (SD 14.0); Expressive 86.1 (SD 16.9)	p=0.05	REEL scale
		Parent-child interaction: Child interactive competence 3.64 (SD=0.69) Parent nurture 2.42 (SD 0.78) Negative control 3.77 (SD 0.72)	Parent-child interaction: Child interactive competence 3.31 (SD=0.48) Parent nurture 2.21 (SD 0.71) Negative control 3.89 (SD 0.61)	Parent-child interaction: Child interactive competence 3.66 (SD=0.51) Parent nurture 2.46 (SD 0.85) Negative control 3.66 (SD 0.59)	Parent-child interaction: Child interactive competence 3.33 (SD=0.66) Parent nurture 2.24 (SD 0.65) Negative control 3.78 (SD 0.69)	p=NS	Modified version of parent child early relational assessment

(Black 1995 continued)		Home 30.3 (SD 5.7)	Home 29.3(SD 4.2)	Home 32.4 (SD 5.1)	Home 31.6 (SD 3.6)	p=0.05	Home Observation for measurement of Environmental scales

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
Ireys 1996	Mothers of sick children	Maternal mental health: 1) PSI scale a) Total=20.7; 15months=20.3; change=-0.4	1) PSI scale a)Total=24.0;15months=18.9; change=-5.1			Difference in change in mean PSI score from baseline to 15months was NS. Psychiatric symptom index with 4 subscales. depression, anxiety, anger and cognitive disturbance
		a) Depression baseline=18.2; 15months=17.2; change=-1.0	a) Depression baseline = 23.9; 15months = 17.8; change = -6.1			
		b) Anxiety: baseline=15.3; 15months=15.6; change=0.3	b) Anxiety: baseline = 16.9; 15months = 11.6; change = -5.3			
		c) Anger: baseline=31.1; 15months=35.5; change=4.4	c) Anger: baseline=35.1; 15months=31.1; change=4.0			
		d) Cognition disturbance: baseline=31.1; 15months=25.4; change= -5.7	d) Cognition disturbance: baseline = 33.0; 15months=29.3; change= -3.7			
		2) Perceived availability of social support: a) Index of overall availability of social support. Baseline score=3.9; 15 months = 4.3; b) Propn. indicating that 'no one understands my burden': baseline = 15.8%; 15months=15.8%; c) Propn. indicating support some/none of the time. Baseline=26.3%; 15months=31.6% d)No. of sources of support: Baseline=5.1;15months=6.5	2) Perceived availability of social support: a) Index of overall availability of social support. Baseline score=3.5; 15 months = 4.3; b) Propn. indicating that 'no one understands my burden': baseline = 30.4%; 15months=4.4%; c) Propn. indicating support some/none of the time. Baseline = 26.3%; 15months = 31.6%; d) No. of sources of support: Baseline = 4.3; 15 months = 7.0		2 a) NS b) NS c)NS for between group differences and change scores; d) NS for between group differences and change scores	5 question index on overall availability of social support. a) one question from impact on family scale asking respondents to agree or disagree with the statement 'Nobody understands the burden i carry' referring to the child's condition. b) one item from a multidimensional inventory asking 'Overall, do you get the support you need all, most, some or none of the time?' c) Assessment of no. of sources of social support. This was calculated from questions following the 5 question questionnaire. If the mother replied yes to any of the five items, she was asked to identify that person and their role. Up to 2 persons could be names for each item.

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
Ireys 2001	Mothers of sick children	Maternal anxiety: i)Mean baseline score for all conditions: 19.2 (SD 13.2); Mean at 12months =21.5 (SD 16.4); ii) Mean anxiety score for highly anxious control group at baseline=31.9, at 12months Mean=31.6; iii) Mean score for low anxiety group at baseline =9.9, at 12 months=14.1	Maternal anxiety: Mean baseline score for all conditions: 18.9 (SD 14.2); Mean at 12months =16.8 (SD 14.9); ii) Mean anxiety score for highly anxious control group at baseline = 33.3, at 12months Mean=26.4; iii) Mean score for low anxiety group at baseline = 10.5, at 12 months = 11.1		i) p=0.03. Multivariate analysis also suggested the intervention was successful in reducing anxiety in the experimental group (p</= 0.05). Mothers who reported good, fair or poor health benefited particularly from the intervention (p<0.01) compared to those who reported very good or excellent health.	11 item anxiety subscale of the Psychiatric Symptom Index(PSI)
		Maternal depression: figures not given	Maternal depression: figures not given		No effect	21-item Beck Depression Inventory
		Stressful life events: figures not given	Stressful life events: figures not given		No effect	Items from the Psychiatric Epidemiology Research Interview Life events scale

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Ireys 2001 continued)		Child psychosocial adjustment: 1 a) baseline total mean score=89.27 (SD10.0); follow-up mean score=86.98 (SD 11.23); b) Hostility: baseline total Mean=22.47 (SD 3.95);follow-up mean score=22.0 (SD 4.45); c) Peer: baseline total mean=12.21 (SD 2.66); follow-up total mean score=11.53 (SD 2.92); d) Dependency: baseline total mean=11.86 (SD 2.14); follow-up total mean score=12.05 (SD 2.00); e) Withdrawal: baseline total mean=14.76 (SD 1.43); follow-up total mean score=14.80 (SD 1.47); f) Anxiety/depression: baseline total mean=16.52 (SD 2.26); follow-up total mean score=16.05 (SD 2.48); g) Productivity: baseline total mean=11.24 (SD 2.70); follow-up total mean score=10.33 (SD 2.80). 2. Propn. of children falling below cutoff score of total group mean at baseline minus 1 SD: baseline=15%; follow-up=21%	Child psychosocial adjustment: 1 a) baseline total mean score=88.35;(SD9.91); follow-up mean score=90.21 (SD 9.27); b) Hostility: baseline total Mean=22.22 (SD 3.63); follow-up mean score=23.23 (SD 3.41) c) Peer: baseline total mean=12.00;(SD 3.10); follow-up total mean score=12.22(SD 2.59) d) Dependency: baseline total mean=11.45(SD 2.56); follow-up total mean score=11.81 (SD 2.59); e) Withdrawal: baseline total mean=15.01(SD 1.31); follow-up total mean score=14.95 (SD 1.50); f) Anxiety/depression: baseline total mean=16.29 (SD 2.52); follow-up total mean score=17.08 (SD 2.14); g) Productivity: baseline total mean=11.03 (SD 2.74); follow-up total mean score=10.78 (SD 2.72). 2. Propn. of children falling below cutoff score of total group mean at baseline minus 1 SD: baseline = 19%; follow-up = 10%		1a) p=<0.01 using analysis of variance controlling for pre-intervention scores. Multiple regression analysis controlling for baseline scores showed that the intervention had significant effects on the hostility (t= -2.56, p=0.01) and anxiety/depression (t= -3.28;p=0.001) subscales. b). not stated; c) Mulitple regression of follow-up adjustment scores, controlling for baseline adjustment scores: p<0.01, and adding baseline physical self-esteem scores p<0.001; f) Child depression NS, Childs report of general anxiety NS	Personal Adjustment and Roles Skill scale (PARS)III. This 28 item measure completed by mothers and exploring children's normative roles and activities as well as mile problem behaviours. Children's depression inventory: 27 item self report measure that assesses recent affective, cognitive and behavioural symptoms of childhood depression. Revised children's manifest anxiety scale:28 item self report measure that assessed psychological anxiety, worry/oversensitivity and concentration problems

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Ireys 2001 continued)		Childs self esteem a) Overall – no data provided; b)effect on children with low physical self-esteem at baseline: Mean=86.67; follow-up Mean=81.24	Childs self esteem a) Overall – no data provided; b) effect on children with low physical self-esteem at baseline: Mean=85.45; follow-up Mean=88.07		a) NS on overall measure b)effect on children with low physical esteem at baseline – effect of intervention more pronounced as compared with children with moderate to high self esteem (bivariate analysis)	4 subscales from the Self-perception profile for children including physical appearance, social acceptance, athletic and global self-worth.
Silver 1997	Mothers of sick children	Children's illness related functional impairment: no data provided	Children's illness related functional impairment: no data provided		NS at baseline, not measured post intervention	Children's illness related functional impairment.14item Functional Status II(R) scale
		Stressful life events=3.0	Stressful life events=3.4		NS	Modification of the list used in the Psychiatric epidemiology research interview
		Among mothers with greater life stress(5 or more SLE): post intervention Anxiety score=29.1	Among mothers with greater life stress (5 or more SLE): post intervention Anxiety score=23.1		F(1.94)=4.61, p<0.05	Modification of the list used in the Psychiatric epidemiology research (PERI) interview. Respondents asked to indicate if any of 46 listed events had been experienced in the previous year and to rate whether each experienced event had been a good or bad event. The score was the number of 'bad' events reported.
		Maternal capacity to provide care: Psychiatric symptom index. Baseline =20.3 (SD14.3), postintervention = 20.1(SD 14.7), adjusted=21.4	Psychiatric symptom index. Baseline = 24.1 (SD15.5), postintervention = 22.1 (SD 15.4), adjusted = 20.9		All NS. There was no pattern of post-intervention differences in PSI scores based on level of mothers participation in the intervention	PSI measures 29 common symptoms including depression, anxiety, anger and cognitive disturbance
		Depression baseline = 20.8 (SD 16.6), postintervention = 9.6 (SD16.9); adjusted20.5	Depression baseline = 23.8 (SD 17.5), postintervention = 22.1 (SD17.5); adjusted 21.3			

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Silver 1997 continued)		Anxiety baseline = 17.6 (SD 17.4), postintervention = 17.3 (SD18.0); adjusted 18.5	Anxiety baseline = 21.4 (SD 18.0), postintervention = 19.4 (SD17.5); adjusted 18.2			
		Anger baseline=23.9 (SD 16.5), postintervention =25.8 (SD19.0); adjusted 27.3	Anger baseline = 29.0 (SD 19.8), postintervention = 26.7 (SD19.2); adjusted 25.3			
		Cognitive disturbance baseline=22.7 (SD 18.7), postintervention =28.2 (SD18.3); adjusted 24.5	Cognitive disturbance baseline=27.1 (SD 19.7), postintervention = 25.0 (SD19.5); adjusted 23.8			
Singer 1999	Mothers of sick children	Measure of acceptance of family and disability/Cognitive adaptation: Mean Pretest 3.16(SD 0.44), Mean Posttest 3.11 (SD 0.50)	Mean Pretest = 2.89 (SD0.56) Mean Post test 3.13 (SD 0.47)		ANCOVA test, F(1,121)=8.974, p=0.003	Source of strength and family closeness subscale of the Kansas Inventory of Parental Perceptions
		Perceptions of coping efficacy measure: Mean Pretest = 3.65 (SD 0.77), Mean posttest =3.72 (SD 0.72)	Mean Pretest = 3.44 (SD 0.70), Mean Posttest =3.77 (SD 0.60)		For parents entering the study with levels of perceived coping skills below 3.07value, there were statistically significant differences on the Posttest. Not significant for those who scored above 3.07 at the pretest.	Parent Efficacy Coping Scale consisting of 24 items
		Measure of empowerment			F(1,122)=1.78, p=0.184	Family Empowerment scale
		Parents progress in meeting the primary need. Mean Pretest = 2.39 (SD 0.73), Mean Postest =2.34 (SD0.89))	Mean Pretest = 2.33(SD 0.90), Mean Posttest =2.81 (SD 0.97),		F(1,112)=9.49, p=0.003	Measured by asking 'How much progress have you made in meeting this need?'
Bullock 1995	Parent-child	No. of smokers: Baseline 35(56%), 34 weeks 30 (48%)	Smokers: Baseline 31 (53%), 34 weeks 29 (49%)			

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Bullock 1995 continued)		No. women drinking alcohol in last month: Baseline 17 (27%), 34 weeks 18 (29%)	No. women drinking alcohol in last month: Baseline 15 (25%), 34 weeks 19 (32%)			
		> 3 drinks on any one occasion: Baseline 17 (27%), 34 weeks 6 (10%)	> 3 drinks on any one occasion: Baseline 6 (10%), 34 weeks 3 (5%)			
		Marijuana use: Baseline 5 (8%), 34 weeks 4 (6%)	Marijuana use: Baseline 4 (7%), 34 weeks 2 (3%)			
		<3meals per day: Baseline 23 (37%), 34weeks 23 (37%)	<3meals per day: Baseline 15 (25%), 34 weeks 10 (17%)		p=0.03	
		Not utilising any community resources: Baseline 45 (71%), 34weeks 35 (52%)	Not utilising any community resources: Baseline 35 (59%), 34 weeks 17 (29%)		p=0.02	
		Stress: Baseline=19.3, 34 weeks=18.4	Stress: Baseline=18.8, 34 weeks=16.5		p=0.02	Prenatal psychological profile to measure stress, support from partner, support from others and self esteem
		Social support from partner: Baseline 52.7, 34 weeks 52.7; ii) support from other: Baseline 51.3, 34 weeks 49.7	Social support from partner: Baseline 54.4, 34 weeks 56.9; ii) support from other: Baseline 54.3, 34 weeks 52.5		partner p=0.09, other support p=0.49	
		Self esteem: Baseline 32.0, 34 weeks 32.5	Self esteem: Baseline 33.3, 34 weeks 34.9		p=0.008	
		Depression: i) Somatic: Baseline 3.9, 34 weeks, 4.4; ii) mood: Baseline:7.2, 34 weeks 8.1; iii) other: Baseline 4.0, 34 weeks 4.1; iv) Overall: Baseline 15.3, 34 weeks 34.1;	Depression: i)Somatic: Baseline 3.9, 34 weeks, 4.3; ii) mood: Baseline:7.2, 34weeks 6.6; iii) other: Baseline 3.9, 34 weeks 4.4; iv) Overall: Baseline 14.8, 34 weeks 15.3;		somatic p=0.86, mood p=0.02, other p=0.84, overall p=0.10	
		State anxiety: Baseline 34.3, 34 weeks 34.1	State anxiety: Baseline 32.8, 34 weeks 30.0		p=0.05	Spielberger's state trait anxiety inventory
		Trait anxiety: Baseline 41.8, 34 weeks 39.4	Trait anxiety: Baseline 40.3, 34 weeks 35.2		p=0.04	Modified Levine Pilowsky depression inventory

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
Johnson 1993	Parent-child	Propn. of children who received all 3 shots of primary immunisations by 1st birthday (n=68):65%	Propn. of children who received all 3 shots of primary immunisations by 1st birthday (n=108):85%		p<0.001; RR 1.31[CI 1.12-1.54]	Questionaire administered to the mothers by the family development nurse
		Propn. of children who received at least one shot of their primary immunisation schedule who received the DPT vaccine (n=71):68%	Propn. of children who received at least one shot of their primary immunisation schedule who received the DPT vaccine (n=98):77%		NS	
		No. of children in each trial arm admitted to hospital during the study (n=21): 20%	No. of children in each trial arm admitted to hospital during the study (n=24): 19%		NS	
		Mean no. of days spent in hospital for children: 1.3days	Mean no. of days spent in hospital for children: 2.6 days		p=0.88	
		Mean length of hospital stay in days: 7	Mean length of hospital stay in days:14.0		p<0.05	
		Length of time child kept on formula feeds:28weeks (SD 15.2)	Length of time child kept on formula feeds:38.1weeks(SD 13.5)		P=<0.001 [95% CI 6.4 - 13.8]	
		Proportion of mothers who gave their child cows milk before 26 weeks (n=49):47%	Proportion of mothers who gave their child cows milk before 26 weeks (n=24):19%		RR= 0.40, [95% CI 0.27 - 0.61]; P<0.0001	
		24hr dietary nutrition intake - child 6 measures, mother: 6 measures	see control		Child: all significant in favour of the intervention at p=0.001 level (page 1451). Mother: all significant in favour of the intervention group at p=<0.01 level	Nutrition assessed by 24 hr recall. Advice from dietician allowed responses to be categorised as appropriate or inappropriate. Inappropriate refers to not enough or too much of a particular food.
		No. of mothers who read to their child (n=57):54%	No. of mothers who read to their child (n=125):98%		RR 1.81 [95% CI 1.52 - 2.16] p<0.0001;	

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Johnson 1993 continued)		Developmental score: Cognitive games: Mean=1.62 (SD 1.39) Motor games mean=0.76 (SD9.84)	Cognitive games Mean=3.75 (SD 2.11); Motor games =0.83 (SD 0.76)		Cognitive games: 95%CI 1.65 – 2.60; Motor games: 95% CI 0.13 – 0.28.	Each game mentioned by mother was recorded and divided to cognitive and motor. Each game was given a score of one and these were totalled.
		The extent to which mothers used song and nursery rhyme with their child: Mean=3.50 (SD 3.24)	Nursery rhymes: Mean=7.74 (SD 1.65)		Nursery rhymes:95% CI 3.59 – 4.88	Measured on a 10cm analogue scale(Barker 1984)
		Mothers self esteem: Tired (n=105) Yes 90%, Headaches Yes 50%, Miserable 76%, stay in Yes 54%	Mothers self esteem (n=127): Tired Yes 78%, Headaches Yes 49%, Miserable 57%, stay in Yes 31%		Mothers self esteem: Tired RR 0.86; P<0.01[95% CI 0.77 – 0.97], Headaches: RR 0.99; P=0.92 [95%CI 0.76 -1.28], Miserable RR 0.75;P<0.003 [95%CI 0.63 – 0.90], Staying in RR 0.58;p<0.001; [95% CI 0.43 – 0.79]	Questionnaire on four aspects of mothers esteem
		Relative risk of having an accident: no data			RR=0.3 [95% CI 0.08 – 1.14]	
		Mothers feelings in the year since their child was born: Positive, Mean:1.17 (SD 1.01), Negative, Mean 1.42(SD 1.25)	Mothers feelings in the year since their child was born: Positive, Mean:2.61 (SD 1.28), Negative, Mean 0.93 (SD 0.87)		Difference in means: Positive = 1.44 [95%CI 1.14 – 1.75], p<0.01. Negative= – 0.5 [95%CI – 0.77 – – 0.23]	Mothers were asked about their feelings and replies noted 'positive' or 'negative'. Each positive feeling was given a score, as was each negative feeling. Scores were totalled separately, so that total positive and negative scores were derived for each mother.
Korfmacher 1999 / Olds 2002	Parent-child	i) Length of visit pregnancy: 77.25; ii) Length of visit infancy: 71.82%; iii) Total visit time pregnancy:503; iv) Total visit time infancy 1498	i) Length of visit pregnancy: 85.24; ii) Length of visit infancy: 78.49; iii) Total visit time pregnancy: 542; iv) Total visit time infancy 1299		i) p<0.001 ii) p<0.001	Nurse intervention as control

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Korfmacher 1999 / Olds 2002 continued)		Contact area: i) Personal health pregnancy: 38.11; ii) Personal health infancy:14.87; iii) Environmental health: 7.30; iv) Environmental health infancy: 7.93; v) Life course development pregnancy: 13.97; vi) Life course development infancy: 16.23; vii) Parental care giving pregnancy: 25.03; viii) Parental care giving infancy: 46.09; ix) Friends and family pregnancy: 15.42; x) Friends and family infancy: 14.76	Contact area: i) Personal health pregnancy: 26.56; ii) Personal health infancy: 15.30; iii) Environmental health pregnancy: 15.14; iv) Environmental health infancy:15.16; v) Life course development pregnancy: 15.43; vi) Life course development infancy:19.41; vii) Parental care giving pregnancy: 23.70; viii) Parental care giving infancy: 31.51; ix) Friends and family pregnancy:18.78; x) Friends and family infancy: 18.39		i) p<0.001 iii) p<0.001 iv) p<0.001 v) p<0.05 vi) p<0.001 viii) p<0.001 ix) p<0.001 x) p<0.001	
		Program drop out: 38%	Program drop out: 48%		P=0.004	
		Relationship continuity: 6.51	Relationship continuity:6.32		NS	% mothers seen by>1 visitor (disrupted or undisrupted)
		No. infancy visits: 21.34	No. infancy visits:16.49		p<0.001	
		Attempted visits i) pregnancy:1.33, Attempted visits ii) infancy:5.25	Attempted visits pregnancy:1.73, Attempted visits infancy:7,63		i) p<0.05 ii)p<0.001	
		Relationship disruption: 11%	Relationship disruption:35%		P<0.001	
		Mothers rating of relationship: 4.14	Mothers rating of relationship:4.06		NS	27 item Helper-Client relationship inventory
Schuler 2000	Parent-child	Drug Use:1) Cocaine/heroin 44.0; 2) Marijuana 37.8; 3) Alcohol 68.0	Drug Use:1) Cocaine/ heroin 45.6; 2) Marijuana 25.4; 3) Alcohol 64.8			Mothers asked about prior/current use

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Schuler 2000 continued)		Mother-infant interaction: 1) Maternal responsiveness 3.3; 2) Infant warmth 2.5	Mother-infant interaction: 1) Maternal responsiveness 3.6; 2) Infant warmth 2.5			Videotaped observation of mothers/infants during breastfeeding, scored using rating scales. Hierarchical multiple responsiveness for Maternal responsiveness. F(8,136)=3.8,p<0.01, Infant warmth: F(8,136)=3.2,p<0.01
		Families receiving services in past 6 months: 1) AFDC 85.1; 2) Medical assistance 93.1; 3) WIC 89.7; 4) Food stamps 87.4; 5) Protective services 31.0	Families receiving services in past 6 months 1) AFDC 89.3; 2) Medical assistance 91.7; 3) WIC 95.2; 4) Food stamps 91.7; 5) Protective services 11.9		5) p<0.05	
Coutinho 2005	Breast-feeding (Not possible to include in meta-analysis)	Rates of exclusive breast-feeding from 10 to 180 days: 13%	Rates of exclusive breastfeeding from 10 to 180 days: 45%		p<0.001	
		Rates of any breastfeeding from 10-180 days: 62%	Rates of any breastfeeding from 10-180 days: 78%		p<0.0001	
		At 6 months propn. of babies given: water (n=134) 83%	At 6 months propn. of babies given: water (n=91) 54%		p<0.0001	
		At 6 months propn. of babies given: tea (n=21) 13%	At 6 months propn. of babies given: tea (n=8) 5%		p=0.013	
		At 6 months propn. of babies given: milk (n=139) 86%	At 6 months propn. of babies given: milk (n=109) 65%		p<0.0001	
		At 6 months propn. of babies given: pacifier (n=116) 72%	At 6 months propn. of babies given: pacifier (n=90) 53%		p=0.0006	
		At 6 months propn. of babies given: bottle (n=145) 90%	At 6 months propn. of babies given: bottle (n=110) 65%		p<0.0001	

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
Merewood 2006	Breast-feeding (Not possible to include in meta-analysis)	Odds of mothers giving any breast milk at 12 weeks follow-up			OR 2.81, P=0.03[95%CI 1.11 – 7.14]	
		Odds of mothers giving mostly breast milk at 12 weeks follow-up			OR 2.49, P=0.006[95%CI 0.97 – 6.40]	
		Odds of mothers giving breast milk at 12 weeks follow-up – all			OR 1.30, P=0.72[95%CI 0.30 – 5.65]	
		Subgroup Analysis: Odds of Africa American mothers giving any breast milk at 12 weeks			OR 3.59, P=0.03[95%CI 1.16 – 11.03]	
		Subgroup Analysis: Odds of Africa American mothers giving mostly breast milk at 12 weeks			OR 1.94, P=0.24 [95%CI 0.64 – 5.86]	
		Subgroup Analysis: Odds of Africa American mothers giving breast milk at 12 weeks – all			OR 0.23, P=0.21 [95%CI 0.02 – 2.26]	
Luby 2006	Mortality / morbidity (Not included in meta-analysis)	Propn. of children <5yrs with longitudinal prevalence of diarrhoea>10% =34.4%	Propn. of children <5yrs with longitudinal prevalence of diarrhoea>10%: Bleach water treatment =19.3%		Percent difference versus control -44% (2% – -75%)	n=2273 children. Reports of diarrhoea based on caregivers reports. LHW were in each of the four intervention arms. Field workers provided materials e.g. children's books and collected data in the control arm

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Luby 2006 continued)			Propn. of children <5yrs with longitudinal prevalence of diarrhoea>10%: Soap and hand washing promotion = 15.6%		Percent difference versus control -55% (-14% - -83%)	
			Propn. of children <5yrs with longitudinal prevalence of diarrhoea>10%: Flocculent-disinfectant water treatment = 10.4%		Percent difference versus control -70% (-35% - -96%)	
			Propn. of children <5yrs with longitudinal prevalence of diarrhoea>10%: Flocculent-disinfectant plus soap =13.0%		Percent difference versus control -62% (-25% - -89%)	
Gielen 2002	Not classified	Hot water temperature</= 48.9degrees centigrade (n=27): 47%	Hot water temperature</= 48.9degrees centigrade (n=27): 47%		NS	
		Working smoke alarms (n=47): 84%	Working smoke alarms (n=47): 81%		NS	
		Stairs protected by gate or door(11):23%	Stairs protected by gate or door(n=13):27%		NS	
		Poisons kept latched or locked up (n=7):12%	Poisons kept latched or locked up (n=6):10%		NS	
		Homes with ipecac syrup (n=16):27%	Homes with ipecac syrup (n=19):31%		NS	
Malchodi 2003	Not classified	Change in number of cigarettes per day:-4.5+/-5.9	-9.1 +/-7.3		p=0.03	Self reporting and urinary cotinine screening (by immunoassay with 200ng/ml as cut off for a positive screen)
		Quit rates retained sample: 33%	42 %		p=0.50	
		Quit rates intention to treat: 21%	24 %		p=0.84	

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Malchodi 2003 continued)		Carbon monoxide at 36weeks, raw scores retained sample: 5.2 +/- 7.23	3.11 +/- -4.41%		p=0.13	<8 parts per million in expired air when abstinent
		Carbon monoxide at 36 weeks, retained sample (transformed for severe positive skew): 0.38 +/- -0.34	0.54 +/- -0.40%		p=0.05	
		Subjects abstinent at 36 weeks:21%	24 %		NS	
Sullivan 2002	Not classified	Child wellbeing, Self competence score 1 to 4 Global self worth (n=33): 3.26, 3.37, 3.22	(n=45): 3.11,3.42, 3.44		Polynomial contrasts(directional t tests) Linear quadratic and mu2: 1.89(p<0.05); 0.13; 0.05	Pre-, post- and 4 months follow-up. Several scales
		Child wellbeing, Self competence score 1 to 4 Physical appearance: 3.27, 3.31, 3.18	3.07, 3.33, 3.44		2.27(p<0.05); 0.05;0.07	Overall multivariate effects (MANCOVA). Main effect of condition F(8.65)=0.52, p=0.84. Main effect for time F (16.57)=1.29; p=0.24. Condition x time interaction F(16,57)=2.30, p<0.01
		Child wellbeing, Self competence score 1 to 4 athletic : 2.74, 2.88, 2.75	2.65, 2.74, 3.12		2.21 (p<0.05); 1.73(p<0.05); 0.10	
		Child wellbeing, Self competence score 1 to 4 Scholarstic : 2.79, 2.79, 2.85	2.74, 2.87, 3.03		1.01, 0.05, 0.01	
		Child wellbeing, Self competence score 1 to 4 Social acceptance : 2.88, 2.91, 3.13	2.91, 2.97, 3.05		0.55, 0.46. 0.01	
		Child wellbeing, Self competence score 1 to 4 Behavioural conduct : 2.99, 2.97, 3.24	3.09,3.12, 3.21		0.64;0.74:0.01	

Author year	Category	Control	Intervention 1	Intervention 2	Effect Size	Comments
(Sullivan 2002 continued)		Children well-being: Assailant abuse witnessed:1.36,0.67,0.47	1.62, 0.43, 0.44		1.36; 20.4(p<0.05);0.08	
		Children well-being: Assailant abuse of children:1.51,0.85,0.79	1.30, 0.55, 0.62		0.32, 0.42, 0.01	
		Mother wellbeing: Depression score (1 to 4): 2.27, 2.30, 2.35	2.31, 2.04, 2.09		2.13(p<0.05), 1.24;0.08	Centre for Epidemiological Studies- Depression scale (CES-D). 20 items
		Self esteem score (1 to 4): 2.97, 2.97, 2.96	2.92, 3.18, 3.22		2.32(p<0.05) 1.02; 0.08	Rosenberg self-esteem inventory, 10 item measure
		Quality of life score (1 to 4): 4.55, 4.48, 4.40	4.55, 4.63, 4.80		1.46(p<0.10);0.18;0.03	9 item scale mothers responses
		Social support score (1 to 4):4.81, 4.67, 4.88	4.70, 4.93, 4.76		0.05;1.58(p<0.10);0.03	9 item scale mothers responses
		Assailant abuse score (1 to 4):1.65, 0.83, 0.58	1.91, 0.67, 0.60		1.07, 1.72(p<0.05),0.05	
						Overall multivariate effects (MANCOVA). Main effect of condition F (8.68) = 0.46, p=0.80. Main effect for time F (10,63) = 2.13; p<0.04. Condition x time interaction F(10,63)=1.82, p<0.08