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Maternity waiting facilities for improving maternal and neonatal outcome in low-resource countries

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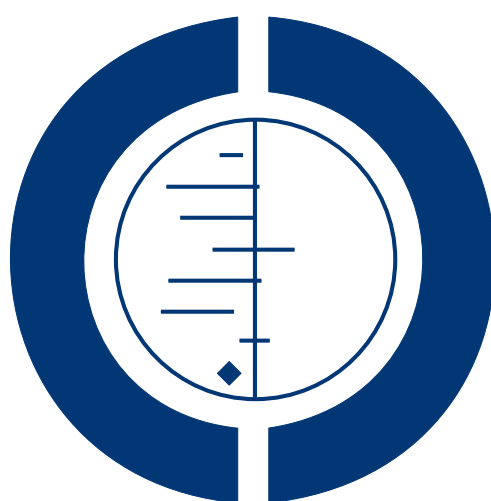
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Maternity waiting facilities for improving maternal and neonatal outcome in low-resource countries (Review)

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[Intervention Review]

Maternity waiting facilities for improving maternal and neonatal outcome in low-resource countries

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ABSTRACT

Background

A Maternity Waiting Home (MWH) is a facility, within easy reach of a hospital or health centre which provides Emergency Obstetric Care (EmOC). Women may stay in the MWH at the end of their pregnancy and await labour. Once labour starts, women move to the health facility so that labour and giving birth may be assisted by a skilled birth attendant. The aim of the MWH is to improve accessibility and thus reduce morbidity and mortality for mother and neonate should complications arise. Some studies report a favourable effect on the outcomes for women and their newborn. Others show that utilisation is low and barriers exist. However these data are limited in reliability.

Objectives

To assess the effects of a maternity waiting facility on maternal and perinatal health.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (April 2009), CENTRAL (*The Cochrane Library* 2009, Issue 1), MEDLINE (1966 to April 2009), EMBASE (1980 to April 2009), CINAHL (1982 to April 2009), African Journals Online (AJOL) (April 2009), POPLINE (April 2009), Dissertation Abstracts (April 2009) and the National Research Register archive (March 2008).

Selection criteria

Randomised controlled trials including quasi-randomised and cluster-randomised trials that compared perinatal and maternal outcome in women using a MWH and women who did not.

Data collection and analysis

There were no randomised controlled trials or cluster-randomised trials identified from the search.

Main results

There were no randomised controlled trials or cluster-randomised trials identified from the search.

Authors' conclusions

There is insufficient evidence to determine the effectiveness of Maternity Waiting Facilities for improving maternal and neonatal outcomes

PLAIN LANGUAGE SUMMARY

Maternity waiting facilities for improving maternal and neonatal outcome in low-resource countries

The chances of women dying because of complications of pregnancy and childbirth are still high in many parts of the world. The main direct causes of maternal and perinatal deaths are unsafe abortion, eclampsia, haemorrhage, obstructed labour, infections and sepsis. Most of these deaths can be prevented with early identification and treatment of complications. The poor utilisation of maternal health services and antenatal care in areas where deaths are high is mainly the result of barriers to access.

A maternity waiting home is a facility that is within easy reach of a hospital or health centre that provides antenatal care with skilled birth attendants and emergency obstetric care. They may also provide women with health education about pregnancy, giving birth and infant care. It is mostly women with high-risk pregnancies or those that are living far away that are encouraged to stay in these facilities at the end of their pregnancy. The extent to which women are cared for in the homes and the help that is available to them differs from country to country. A further difficulty is that home delivery is less expensive and that women may not be willing to leave their families whom depend on their care, or their farms which are their means of existence.

The review authors could not find any individual or cluster-randomised controlled trials that evaluated the outcomes for women using a maternity waiting facility in low-resource countries. The fact that women who develop a serious obstetric complication need appropriate care in order to survive is clear. The effectiveness of maternity waiting homes in decreasing maternal deaths and stillbirths has been described in general terms in six retrospective population cohort studies. These are likely to describe women who were referred to stay in maternity waiting homes because of risk factors and compared to women who came to the hospitals for other reasons. The control groups may have been self selected by disaster or women's ability to access to the hospitals in time. The outcomes of births for the women who stayed at home were not known. There is insufficient evidence on which to base recommendations about the effectiveness of Maternity Waiting Homes, and well controlled trials are needed.

BACKGROUND

The chances of women dying as a result of complications during pregnancy, delivery or the postpartum period remains high in many parts of the world. In 2005 the worldwide maternal mortality ratio was 402 deaths per 100,000 live births (Confidence Interval (CI) 216 to 654) Of the estimated 535,900 women who died that year, 50.5% (270,500) lived in sub-Saharan Africa and 45% (240,600) in Asia. These numbers have remained essentially unchanged since 1990 (Hill 2005).

Haemorrhage, eclampsia, sepsis, unsafe abortion and obstructed labour are the five main direct obstetric causes of maternal death (Khan 2006). It is well recognised that most of these maternal deaths can be prevented when appropriate treatment is started in time, and given by a trained health professional in an adequate environment (WHO 2004).

In areas with high maternal mortality ratios, utilisation of maternal health services is low. Low utilisation of maternal health services is mainly a result of barriers to access and leads to high maternal

and perinatal mortality and morbidity. Differences in utilisation between high- and low-income countries are enormous, but differences are also encountered within countries. Access to maternity health services is a key indicator of maternal mortality. Besides the per capita gross national product, access to maternal health services is the only important predictor. Therefore, reaching a health facility that can provide emergency obstetric care, is the best tool for reducing maternal mortality, and will also lead to a significant reduction of perinatal morbidity and mortality (Bulatao 2003).

Since the 1960s, maternity waiting homes have been advocated to bridge the geographical gap - the difference in care received by women living in remote areas compared to women living in urban areas. Women with high-risk pregnancies have been encouraged to go and stay close to the clinic at the end of their pregnancy (AbouZahr 1998; Fawcus 1996; Greenwood 1987, Kambarami 1999; Mahony 1995; Stewart 1968; WHO 1991).

What is a Maternity Waiting Home?

A Maternity Waiting Home (MWH) is a facility within easy reach of a hospital or health centre, which provides Emergency Obstetric Care (EmOC). Women stay in the MWH at the end of their pregnancy and await labour. Once labour starts, women move to the health facility so they may be assisted by a skilled birth attendant (WHO 1991; WHO 2004).

There are many ways in which this concept is being implemented. In Zimbabwe and Ethiopia traditional style huts are used (Millard 1991; Poovan 1990), but also modern houses with toilet, bathroom and kitchen facilities (Cardoso 1986; Knowles 1988); old hospital wards (Wilson 1997); or, as in Papua New Guinea, a house on stilts may function as a MWH (Barss 1985).

The way women are cared for differs from country to country. Some facilities are completely self-catering and women provide their own food, water and firewood. Others are completely catered for and sometimes the economic status of the women determines whether she is provided with food or not.

When staying in the MWH, women often have access to antenatal care. They may visit the routine antenatal care program in the health facility, but more often the MWH is visited regularly by a nurse, midwife or doctor. Often, the time women spend in the MWH is also used to give health education about pregnancy, giving birth and neonatal care.

The costs of a MWH are covered in different ways. Communities have been involved in building huts while ministries of health or Non Governmental Organisations contribute to building costs. Running costs may be partly covered by user fees, and by fundraising projects co-ordinated by the waiting women (Eckermann 2008; Poovan 1990; Wessel 1990; Wilson 1997).

Risk selection

The concept of risk selection and the aim to use resources effectively played an important role in the early descriptions of MWH (Thaddeus 1994). Consequently, selection of women for referral to a maternity waiting home is important. Selection takes place during antenatal clinics by the attending health professional, either within the hospital or in health centres/clinics without labour facilities. Several studies suggest that risk assessment should play a central role in reducing maternal mortality (Essex 1977; Larsen 1978; Lennox 1984). It was believed that by selecting women with risk factors such as a poor obstetric history, high parity or anaemia and advising them to stay near a hospital could prevent poor outcome. Selection of women with high-risk pregnancies, however, has not always been successful. A study in Tanzania showed very poor risk selection by healthcare workers: only risk factors such as previous caesarean section and first pregnancy lead to more referrals towards health facilities with emergency obstetric care (Jahn 1998). Even in a low-risk population, it is estimated that 20% of pregnancies will result in complications requiring treatment at a

facility with skilled attendants providing emergency obstetric care consisting of intravenous or intramuscular antibiotics, oxytocics and anticonvulsants, assisted delivery and manual removal of placenta (WHO 1994).

Consequently, although risk selection played an important role, MWHs usually also allow women without formal risk factors to stay there, especially if they live far from health facilities. In Nicaragua, Honduras and Papua New Guinea, another reason why women came to stay was the availability of postpartum tubal ligation (Barss 1985; Danel 2004; Wessel 1990).

We systematically searched the literature for studies describing the use and effectiveness of the MWH. The literature describing MWH comes from many different low-income countries: Zimbabwe, Zambia, Tanzania, former Zaire, Ghana, Ethiopia, Nigeria, Liberia, Malawi, Mozambique, Papua New Guinea, Nicaragua, Cuba, Peru, Honduras and Lao. But also in the USA, certain groups of pregnant homeless adolescents were admitted to a waiting home (LaGuardia 1989).

Factors in success and utilisation of a MWH

Several authors have investigated the factors that play a role in the success of a MWH. In Zimbabwe, a cluster survey (including 235 respondents) examined the use of maternal care services and found that nearly all (97%) women attended antenatal care during their last pregnancy at least once and 66% gave birth in hospital. The use of a MWH increased the likelihood of hospital delivery nearly six fold. Only one third of all respondents, however, did use the MWH. Complaints mentioned about the MWH were that the houses were too small and crowded, the toilets needed improvement and there was shortage of water and firewood (Van den Heuvel 1999). Five years earlier, in a survey in the same district, two thirds of the women stated that they would use a MWH if provided. The other third mentioned the absence of food provision and no help with cooking, the necessity to collect own water and firewood, poor hygiene and lack of transport for referrals, as important factors for their refusal to use a MWH (Nhindiri 1996). In a rural district in Ghana, 83% of women attended antenatal clinics at least once and 90% of respondents were willing to stay in a MWH when advised to do so (Martey 1995). In another district in Ghana the introduction of a MWH failed. This MWH was located in a refurbished ward in an old hospital. In the first year, 25 women were referred and only one spent one night there. After the first year, attitudes and barriers were assessed, through focus group discussions with the people involved. There appeared to be strong financial barriers: home delivery is less expensive. Costs of living are higher in a MWH. In addition, women could not take care of their families and their farms. The location of the MWH was also considered problematic because it was still some way from the hospital and arranging transport at night was difficult. It was not considered safe at night and no healthcare personnel were available (Wilson 1997). In Nicaragua, being away from the family was

also considered the main drawback of staying in a MWH (Wessel 1990).

In southern Malawi not all hospitals have MWHs. In those hospitals without a MWH women may be lodged in the antenatal or postnatal ward, or in the guardian shelter. In interviews, 55% of women who had used a MWH were satisfied with their stay. They perceived the easy access to skilled attendance during delivery, receiving treatment during ANC, and the development of new companionship, as important advantages of using a MWH. However, concerns were raised about lack of supervision by midwives and poor staff attitude during ANC and delivery (Touray-Daffeh 2003). In Zaire, MWHs near a hospital were rarely used. During focus group discussions it emerged that many women felt that the risk associated with staying in the MWH, with no food and no one to help, was greater than the risk of staying at home (Sambe 1990). Focus group discussions also took place in Lao before a MWH was established. Many potential barriers were identified such as lack of privacy, inability to use traditional birthing practices, lack of respect from health staff, and cost of reaching the hospital (Eckermann 2008). In Peru, MWHs are reported to be successful. Women are allowed to bring their families with them and introduction of the MWH was combined with a 'cultural adaptation' of the health care services, including the option of vertical delivery which was set down in a nationwide protocol (Fraser 2008).

From these studies it is clear that careful planning is required for successful introduction of a MWH. Even when women have a positive attitude towards staying in a MWH, barriers might prevent them from doing so. Direct and indirect costs might be too high. Also, the perceived level of care in both the MWH and the facility in which they are going to give birth is an important factor that will influence decision making.

The effect of the MWH

The effectiveness of Maternity Waiting Homes has been described in general terms. Cardoso 1986 reports how Cuba has improved its national health system since 1961. MWHs were part of an extensive project to improve the care for women giving birth. The first MWH opened in 1962, and by 1984 there were 85 facilities. In the same period, the proportion of deliveries in health institutions increased from 63% to 99%. A continuous audit of all cases of maternal death showed that between 1960 and 1984 maternal deaths from haemorrhage decreased dramatically from 32 per 100,000 birth to 2 per 100,000 births (Cardoso 1986).

In Honduras, the introduction of MWH was part of a strategy to improve maternal health. It consisted of improving the referral of obstetric emergencies through the training of traditional birth attendants. Secondly, it aimed to identify women with high-risk pregnancies and encourage them to give birth in hospital. MWHs were built, and maintained with help from the communities, to allow those women living far away to go and stay near the hospital. With this risk approach, hospitals with a MWH (compared to

hospitals without a MWH) had more women who were older than 34 or had more than 4 deliveries (Danel 2004).

In Malawi, the introduction of a MWH is thought to have contributed to the reduction of maternal mortality in the area to zero. Knowles 1988 suggests that all women should be referred to a MWH so that they may all give birth in hospital.

In Nigeria, the establishment of MWHs has contributed to reducing the maternal mortality ratio in hospital from 10 per 1000 deliveries to less than 1 per 1000 deliveries, and the stillbirth rate from 116 per 1000 deliveries to 20 per 1000 deliveries (Stewart 1968).

In Papua New Guinea, it was observed that many complications occurred in grand multiparas. A policy of early referral of these grand multiparas to a MWH, combined with the advocacy of tubal ligation for these women after giving birth, has led to a reduction of emergency referrals by air from 25 to 9 per year. Nevertheless, the authors also observed that few stillbirths have occurred in women staying in the MWH when mothers failed to inform the nurses that their labour had started (Barss 1985).

We found six studies that evaluated the effect of a maternity waiting home. In Zimbabwe, Chandramohan 1994 evaluated a MWH over a two year period. They compared the outcome of delivery in 1573 women who had stayed in the MWH to 2915 women who had not. They found that non-users were more likely to have obstructed labour (1% versus 0.06%). Non-users were also less likely to have a caesarean section (15% versus 18%). Among the non-users there were six craniotomies and four hysterectomies, compared to zero amongst the MWH users (Chandramohan 1994). The authors found that only 31% of the women with high risk pregnancies had stayed in the MWH. They conclude that the success of a MWH depends on the risk selection, but that this may implicate a high patient load for the hospital which may overstretch its resources.

In the same study population the effect on perinatal outcome was recorded. The perinatal death rate per 1000 births was 19.1 in the users group compared to 32.2 amongst the non-users (Risk Ratio (RR) 1.7, 95% CI 1.1 to 2.6). In the subgroup with antenatal high-risk pregnancies, the difference was 21 compared to 43 (RR 2.1, 95% CI 1.2 to 3.6). When adjusted for other risk factors the RR was 1.9 (95% CI 1.1 to 3.9). In the group with low-risk pregnancies without any antenatal risk factors, no difference in perinatal deaths was found (Chandramohan 1995).

In a second study in Zimbabwe, including 854 births, the authors found no significant difference in risk status, perinatal and maternal outcome between women who had stayed in a MWH and women who had not but came to hospital to deliver (Millard 1991).

The third study in Zimbabwe, including 1053 births over a 2 year period, did not find any significant difference in risk status or in pregnancy outcome between users and non-users. In total, four maternal deaths occurred (Maternal Mortality Ratio 380 per 100,000 live births): three among non-users and one in the users

group (Tumwine 1996). In 1997, Zimbabwe had 1335 health facilities, with a MWH available in 255 of these. However not all of these MWH had a midwife to supervise the shelter, nor the means of communication with a referral unit (Feresu 2003).

In Zambia, risk selection worked well. The women in the MWH group had maternal, antenatal and intrapartum risk factors. As a consequence, more caesarean sections and vacuum extractions were performed in the MWH group compared to the non-MWH group. There was no difference in the Maternal Mortality Ratio and Perinatal death rate (van Lonkhuijzen 2003).

While these studies only looked at institutional births, Spaans 1998 also included home births in his analysis of 1041 deliveries in Zimbabwe. Of these, 22% occurred at home and 78% in hospital. MWHs were used by 59% of all women. The two most frequent reasons for women delivering at home were lack of money (35%) and unsure gestational age (26%). Two women died at home due to postpartum haemorrhage and one died in hospital due to cerebral malaria. Primiparae and women with a previous caesarean section more frequently delivered in hospital. The authors conclude that the MWH improved access to hospital care (Spaans 1998).

Current sources are limited in evaluating the effect of the use of a MWH on maternal mortality and morbidity and neonatal outcome. These available data consist of retrospective cohort studies with significant potential for bias. Women that have stayed in the maternity waiting home and that may have been referred because of risk factors are compared to women that came to hospital for other reasons. This last population might be selected by disaster or might be women who were able to reach hospital in time. Birth outcomes for the women who stayed at home is not known.

The conclusions of these studies should therefore be interpreted with caution. Evidence from randomised controlled trials at the level of the individual or at the level of a geographical area (cluster-randomised trial) would be better to assess the effect of the MWH.

OBJECTIVES

To assess the effects of a maternity waiting facility on maternal and perinatal health.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials including quasi-randomised and cluster-randomised trials.

Types of participants

All pregnant women.

Types of interventions

All types of facilities within easy reach (as defined by trial authors) of a medical facility, that are designated for the lodging of pregnant women who await labour, with the purpose of being assisted by skilled attendants during delivery. We only included facilities in which women at least receive the antenatal care that is also available to all other women in the community.

Types of outcome measures

Primary Outcomes

Maternal

- Maternal death
- Sepsis
- Uterine rupture
- Postpartum haemorrhage
- Prolonged/obstructed labour
- Use of antiretrovirals during labour (in HIV-positive women)

Neonatal

- Perinatal mortality
- Respiratory distress syndrome
- Neonatal infection/sepsis

Secondary Outcomes

Maternal

- No skilled birth attendant at delivery
- Delivery at a health care facility
- Pre eclampsia/eclampsia
- Chorioamnionitis/endometritis (as defined by trialists)
- Serious placental abruption
- Mode of birth
- Prolonged postpartum hospital stay (as defined by trialists)
- Satisfaction with care

Neonatal

- Apgar score less than 7 at five minutes
- Intrauterine death
- Neonatal death

- Birth weight less than 2500 g
- Prolonged hospital stay (as defined by trialists)
- Breastfeeding not established

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (April 2009).

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

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

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

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

In addition, we searched CENTRAL (*The Cochrane Library* 2009, Issue 1), MEDLINE (1966 to April 2009), EMBASE (1980 to April 2009), CINAHL (1982 to April 2009), African Journals Online (AJOL) (April 2009), POPLINE (April 2009), Dissertation Abstracts (April 2009) and the National Research Register archive (March 2008).

See [Appendix 1](#) for search strategies.

Searching other resources

We contacted the librarians of the following institutions in March 2008:

- Royal Tropical Institute Amsterdam
- Prince Leopold Institute of Tropical Medicine Antwerp
- Liverpool School of Tropical Medicine (Donald Mason Library)
- London School of Hygiene and Tropical Medicine

We retrieved any additional relevant references referred to in papers identified through the above search strategy, and assessed their suitability for inclusion in the review.

We did not apply any language restrictions.

Data collection and analysis

If RCTs are identified in subsequent updates of this review we will collect and analyse the data using the methods outlined in [Appendix 2](#).

RESULTS

Description of studies

See: [Characteristics of excluded studies](#).

There were no randomised controlled trials or cluster-randomised trials identified from the search strategy.

Risk of bias in included studies

There were no randomised controlled trials or cluster-randomised trials identified from the search strategy.

Effects of interventions

There were no randomised controlled trials or cluster-randomised trials identified from the search strategy.

DISCUSSION

There were no randomised controlled trials or cluster randomised controlled trials that evaluated outcomes for women using a maternity waiting facility in low-resource countries.

The fact that women who develop a serious obstetric complication need appropriate care in order to survive is clear. But from the literature we reviewed it is also clear that in many places a large number of women are unable to deliver in a health care facility. Antenatal care attendance might be good but when labour starts, many barriers may prevent women from reaching a hospital. So, building a maternity waiting home may be a solution for some but not for all women. If women manage to stay in a MWH, immediate access to emergency obstetric care, if required, should be guaranteed.

There is an urgent need for studies to provide evidence to assess the effect of a MWH on pregnancy outcomes for women and neonates in low-resource countries. This information will be best obtained from RCTs.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence upon which to base recommendations for practice.

Implications for research

The available literature describing the effect of MWH provides limited insight into the potential benefit of these facilities. Randomised controlled trials are required to provide the most reliable evidence of the effect of improving outcome in low-resource countries.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), one or more members of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Chandramohan 1994	Hospital-based cohort study comparing maternal outcome for women admitted to the MWH and women delivering in hospital after self referral or referral by a traditional birth attendant.
Chandramohan 1995	Hospital-based cohort study comparing perinatal outcome for women staying in the MWH and women who presented after onset of labour.
Millard 1991	Hospital-based cohort study comparing pregnancy outcome for women staying in a MWH and women admitted directly from the community.
Spaans 1998	Community-based cohort study describing outcome for women who gave birth at home, in hospital, or in hospital after having stayed in a MWH.
Tumwine 1996	Hospital-based cohort study comparing risk factors and pregnancy outcome for women staying in a MWH and women who gave birth in hospital without staying in the MWH.
van Lonkhuijzen 2003	Hospital-based cohort study comparing risk factors and pregnancy outcome for women staying in a MWH and women who gave birth in hospital without staying in the MWH.

MWH - Maternity Waiting Home.

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Search Strategies

CENTRAL (*The Cochrane Library* 2009, Issue 1):

(waiting next facilit* or waiting next home* or hut* or shelter*) near (antenatal* or prenatal* or pregnan* or mother* or matern* or birth* or childbirth).

MEDLINE (1966 to April 2009), **EMBASE** (1980 to April 2009) and **CINAHL** (1982 to April 2009):

We adapted the CENTRAL search strategy by changing the truncation symbol and proximity operator.

African Journals Online (AJOL) (April 2009):

(maternity OR maternal OR pregnant OR pregnancy OR birth OR childbirth OR antenatal OR antenatally OR prenatal OR prenatally) AND (waiting OR shelter OR shelters OR hut OR huts).

POPLINE (April 2009):

(maternity OR maternal OR pregnant OR pregnancy OR birth OR childbirth OR antenatal OR antenatally OR prenatal OR prenatally) AND (waiting OR shelter OR shelters OR hut OR huts).

Dissertation Abstracts (April 2009) and **The National Research Register Archive** (March 2008):

We used similar terms as for searches listed above, adapted for each of the databases.

Appendix 2. Data collection and analysis methods for subsequent updates of this review

Selection of studies

Two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third person.

Data extraction and management

We will design a form to extract data. For eligible studies, at least two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third person. Data will be entered into Review Manager software ([RevMan 2008](#)) and checked for accuracy.

When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions ([Higgins 2008](#)). Any disagreement will be resolved by discussion or by involving a third assessor.

(I) Sequence generation (checking for possible selection bias)

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

We will assess the method as:

- adequate (any truly random process e.g. random number table; computer random number generator);
- inadequate (any non random process e.g. odd or even date of birth; hospital or clinic record number);
- unclear.

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

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

We will assess the methods as:

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

(3) Blinding (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Studies will be judged at low risk of bias if they were blinded, or if we judge that the lack of blinding could not have affected the results. Blinding will be assessed separately for different outcomes or classes of outcomes.

We will assess the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

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

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake. We will assess methods as:

- adequate (less than 20% of data is missing);
- inadequate (more than 20% of data is missing);
- unclear.

(5) Selective reporting bias

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We will assess the methods as:

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

(6) Other sources of bias

We will describe for each included study any important concerns we have about other possible sources of bias.

We will assess whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the Handbook ([Higgins 2008](#)). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider

it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* 'Sensitivity analysis'.

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually randomised trials. We will adjust their sample sizes using the methods described in [Gates 2005](#), using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), or from another source. If ICCs from other sources are used, we will report this, and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely. We will include cluster-randomised trials for which the unit of allocation is a health facility or geographical area.

We will also acknowledge heterogeneity in the randomisation unit and perform a separate meta-analysis. Therefore the meta-analysis will be performed in two parts as well.

Dealing with missing data

For included studies, levels of attrition will be noted. The impact of including studies with high levels of missing data in the overall assessment of treatment effect will be explored by using sensitivity analysis.

For all outcomes analyses will be carried out, as far as possible, on an intention to treat basis i.e. we will attempt to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will use the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identify substantial heterogeneity (> 50%) we will explore it by prespecified subgroup analysis and perform sensitivity analysis. A random-effects meta-analysis will be used as an overall summary if this is considered appropriate.

Assessment of reporting biases

Where we suspect reporting bias (*see* selective reporting bias above), we will attempt to contact study authors asking them to provide missing outcome data. Where this is not possible, and the missing data are thought to introduce serious bias, the impact of including such studies in the overall assessment of results will be explored by a sensitivity analysis.

Data synthesis

We will carry out statistical analysis using the Review Manager software ([RevMan 2008](#)). We will use fixed-effect inverse variance meta-analysis for combining data where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. Where we suspect clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials we will use random-effects meta-analysis.

If substantial heterogeneity is identified in a fixed effect meta-analysis this will be noted and the analysis repeated using a random-effects method.

Subgroup analysis and investigation of heterogeneity

For fixed effect meta-analyses we will conduct planned subgroup analyses classifying whole trials by interaction tests as described by [Deeks 2001](#). For random effects meta-analyses we will assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

We will carry out sensitivity analysis to explore the effect of trial quality. This will involve analysis based ratings of selection bias and attrition bias. We will exclude studies of poor quality in the analysis in order to assess for any substantive difference to the overall result. Or, we will carry out sensitivity analysis to explore the effect of trial quality assessed by concealment of allocation, by excluding studies with clearly inadequate allocation of concealment.

HISTORY

Protocol first published: Issue 4, 2007

Review first published: Issue 3, 2009

CONTRIBUTIONS OF AUTHORS

All authors participated in the writing of the protocol. LvL conducted the searches, LvL and JS reviewed the literature identified by the search, LvL wrote the first draft of the review, all authors contributed to writing the final document.

DECLARATIONS OF INTEREST

None known.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The latest PCG methods have been incorporated into this review ([Appendix 2](#)).