

# Support during pregnancy for women at increased risk of low birthweight babies (Review)

Hodnett ED, Fredericks S



**THE COCHRANE  
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2007, Issue 4

<http://www.thecochranelibrary.com>



## TABLE OF CONTENTS

ABSTRACT . . . . .	1
PLAIN LANGUAGE SUMMARY . . . . .	2
BACKGROUND . . . . .	2
OBJECTIVES . . . . .	2
CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW . . . . .	3
SEARCH METHODS FOR IDENTIFICATION OF STUDIES . . . . .	3
METHODS OF THE REVIEW . . . . .	3
DESCRIPTION OF STUDIES . . . . .	4
METHODOLOGICAL QUALITY . . . . .	4
RESULTS . . . . .	5
DISCUSSION . . . . .	5
AUTHORS' CONCLUSIONS . . . . .	6
POTENTIAL CONFLICT OF INTEREST . . . . .	6
ACKNOWLEDGEMENTS . . . . .	6
SOURCES OF SUPPORT . . . . .	6
REFERENCES . . . . .	6
TABLES . . . . .	10
Characteristics of included studies . . . . .	10
Characteristics of excluded studies . . . . .	18
ANALYSES . . . . .	19
Comparison 01. Additional support versus usual care during at-risk pregnancy . . . . .	19
INDEX TERMS . . . . .	20
COVER SHEET . . . . .	20
GRAPHS AND OTHER TABLES . . . . .	21
Analysis 01.01. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 01 Miscarriage . . . . .	21
Analysis 01.02. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 02 Termination of pregnancy . . . . .	22
Analysis 01.03. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 03 Antenatal anxiety score . . . . .	22
Analysis 01.04. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 04 Less than very satisfied with antenatal care . . . . .	23
Analysis 01.05. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 05 Antenatal depression . . . . .	23
Analysis 01.06. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 06 Antenatal hospital admission . . . . .	24
Analysis 01.07. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 07 Antenatal hypertension . . . . .	24
Analysis 01.08. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 08 Intrapartum analgesia/anaesthesia . . . . .	25
Analysis 01.09. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 09 Induction of labour . . . . .	25
Analysis 01.10. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 10 Caesarean birth . . . . .	26
Analysis 01.11. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 11 Instrumental vaginal birth . . . . .	27
Analysis 01.12. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 12 Gestational age < 37 weeks at birth . . . . .	27
Analysis 01.13. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 13 Gestational age at birth . . . . .	28
Analysis 01.14. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 14 Birth weight < 1500 gm . . . . .	29

Analysis 01.15. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 15 Birth weight < 2500 gm . . . . .	29
Analysis 01.16. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 16 Birth weight (gm) . . . . .	30
Analysis 01.17. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 17 Small for gestational age . . . . .	31
Analysis 01.18. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 18 Stillbirth/neonatal death . . . . .	31
Analysis 01.19. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 19 Apgar score < 7 at 1 minute . . . . .	32
Analysis 01.20. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 20 Apgar score < 7 at 5 minutes . . . . .	32
Analysis 01.21. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 21 Newborn respiratory distress . . . . .	33
Analysis 01.22. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 22 Admission to neonatal intensive care nursery . . . . .	33
Analysis 01.23. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 23 Absence of other help at home . . . . .	34
Analysis 01.24. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 24 Postnatal physical problems . . . . .	34
Analysis 01.25. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 25 Postnatal re-hospitalization . . . . .	35
Analysis 01.26. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 26 Poor postnatal health . . . . .	35
Analysis 01.27. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 27 Prefer hospitalization in at-risk pregnancy . . . . .	36
Analysis 01.28. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 28 Feeling low control postnatally . . . . .	36
Analysis 01.29. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 29 Feeling worried about baby . . . . .	37
Analysis 01.30. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 30 Postnatal depression . . . . .	37
Analysis 01.31. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 31 Additional health service use . . . . .	38

# Support during pregnancy for women at increased risk of low birthweight babies (Review)

Hodnett ED, Fredericks S

## This record should be cited as:

Hodnett ED, Fredericks S. Support during pregnancy for women at increased risk of low birthweight babies. *Cochrane Database of Systematic Reviews* 2003, Issue 3. Art. No.: CD000198. DOI: 10.1002/14651858.CD000198.

**This version first published online:** 21 July 2003 in Issue 3, 2003.

**Date of most recent substantive amendment:** 16 May 2003

## ABSTRACT

### Background

Studies consistently show a relationship between social disadvantage and low birthweight. Many countries have programs offering special assistance to women thought to be at risk for giving birth to a low birthweight infant. These programs may include advice and counseling (about nutrition, rest, stress management, alcohol and recreational drug use), tangible assistance (eg transportation to clinic appointments, help with household responsibilities), and emotional support. The programs may be delivered by multidisciplinary teams of health professionals, by specially trained lay workers, or by a combination of lay and professional workers.

### Objectives

The objective of this review was to assess the effects of programs offering additional social support for pregnant women who are believed to be at risk for giving birth to preterm or low birthweight babies.

### Search strategy

We searched the Cochrane Pregnancy and Childbirth Group trials register (30 September 2005).

### Selection criteria

Randomized trials of additional support during at-risk pregnancy by either a professional (social worker, midwife, or nurse) or specially trained lay person, compared to routine care. Additional support was defined as some form of emotional support (eg counseling, reassurance, sympathetic listening) and information or advice or both, either in home visits or during clinic appointments, and could include tangible assistance (eg transportation to clinic appointments, assistance with the care of other children at home).

### Data collection and analysis

We independently assessed trial quality and extracted data. Double data entry was performed. We contacted study authors to request additional information.

### Main results

Eighteen trials, involving 12,658 women, were included. The trials were generally of good to excellent quality, although three used an allocation method likely to introduce bias. Programs offering additional social support for at-risk pregnant women were not associated with improvements in any perinatal outcomes, but there was a reduction in the likelihood of caesarean birth and an increased likelihood of elective termination of pregnancy. Some improvements in immediate maternal psychosocial outcomes were found in individual trials.

### Authors' conclusions

Pregnant women need the support of caring family members, friends, and health professionals. While programs which offer additional support during pregnancy are unlikely to prevent the pregnancy from resulting in a low birthweight or preterm baby, they may be helpful in reducing the likelihood of caesarean birth.

## PLAIN LANGUAGE SUMMARY

Programs offering additional support during pregnancy were not effective in reducing number of babies born too early and babies with low birthweights

Babies born to mothers in socially disadvantaged situations are more likely to be small and so have health problems. Programs providing emotional support, practical assistance, and advice have been offered in addition to usual care. Women who received additional support during pregnancy were less likely to have a caesarean birth and some were more likely to choose to terminate the pregnancy. However, the additional support did not reduce the likelihood of giving birth too early or that the baby was smaller than expected. There may be benefits in terms of lower anxiety and feeling better about their care.

## BACKGROUND

Low birthweight, usually defined as weight less than 2500 grams, is a major health problem for a baby and the baby's family, and one which consumes significant healthcare resources. In high-income countries preterm birth is the major reason for low birthweight. In low- to middle-income countries, chronic maternal malnutrition leads to large numbers of babies who are small for gestational age at birth (Kramer 1987). Thus "low birthweight" is an outcome that includes both infants that are born early (less than 37 weeks) and/or who are small for their gestational age (SGA). Combining babies who are born preterm with those who are SGA is problematic from a research perspective, since the underlying causes of the two problems are believed to be quite different (Kramer 1987), and treatment is different. Effective prevention of low birthweight may depend in part on its cause. Nevertheless, many countries have programs offering special assistance to women thought to be at risk of giving birth to an infant weighing less than 2500 grams. These programs may include advice and counseling (about nutrition, rest, stress management, alcohol and recreational drug use), tangible assistance (eg transportation to clinic appointments, help with household responsibilities), and emotional support. The programs may be delivered by multidisciplinary teams of health professionals, by specially trained lay workers, or by a combination of lay and professional workers. This Review includes all acceptably controlled trials of such programs.

Epidemiological studies consistently show a strong relationship between social disadvantage and low birthweight (Kramer 1987; Wilkins 1991; Berkowitz 1993). The underlying causal pathways are unclear, but several theoretical mechanisms have been proposed that link the physiological and psychological stress associated with social disadvantage to an increased likelihood of complications during pregnancy, fetal growth restriction, intrapartum complications, preterm birth, and poor maternal and neonatal health. Chronic poverty can lead to malnutrition, unhealthy living environments, increased risk of infection, and increased stress in daily life. The social stigma associated with being marginalized in society is also a source of chronic stress. Observational studies (eg Norbeck 1983) have suggested that social support may have a mediating influence on the relationship between life stress (regard-

less of the causes of the stress) and the development of pregnancy complications.

The current Review focuses on evaluations of programs, for pregnant women believed to be at high risk for giving birth to a preterm or SGA baby, that have the provision of support as a major component. Readers are referred to Cochrane Reviews that have evaluated other forms of care to prevent preterm birth, small-for-gestational-age birth, and/or low birthweight. These Reviews have evaluated nutritional supplements, nutritional advice, interventions to assist pregnant women to stop smoking, plasma volume expansion, and various medications (Brocklehurst 2003; Cuervo 2003; Kramer 2003a; Kramer 2003b; Kramer 2003c; Kramer 2003d; Kramer 2003e; Lumley 2003; Mahomed 2003; Say 2003a; Say 2003b; Say 2003c; Say 2003d; Smail 2003).

Debates have arisen regarding the relative benefits of 'professional' versus 'peer' support. Social support from a woman in one's community, who has a similar socioeconomic background and is experiencing similar life stresses, may be qualitatively different from support from a healthcare professional, who has broad professional knowledge and experience, but may not share the same socioeconomic background or life concerns, and who often provides other professional services as well as support. This Review includes studies of support by providers with varying backgrounds and qualifications.

## OBJECTIVES

The primary objective was to assess the effects of programs offering additional social support compared with routine care, for pregnant women who are believed to be at high risk for giving birth to babies that are either preterm or weigh less than 2500 gm, or both, at birth. Secondary objectives were to determine whether effectiveness of support was mediated by timing of onset (early versus later in pregnancy) or type of provider (a healthcare professional or a lay woman).

## CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

### Types of studies

Inclusion criteria were: randomized controlled trial comparing a program of additional support during at-risk pregnancy by either a professional (social worker, midwife, or nurse) or a specially trained lay person, or both; random allocation to treatment and control groups.

'Additional support' was defined as some form of emotional support (eg counseling, reassurance, sympathetic listening) with or without additional information or advice, or both, occurring during home visits, clinic appointments, and/or by telephone. The additional support could also include tangible assistance (eg transportation to clinic appointments, assistance with the care of other children at home). Studies were included if the additional support was provided during pregnancy and continued until the birth of the baby, or into the postnatal period.

Trials were excluded if the intervention was solely an educational intervention or if the intervention was of brief duration (eg two to three weeks) and not intended to continue until the birth of the baby. Trials of smoking cessation programs for pregnant women were also excluded, as they are part of another Review (Lumley 2003).

### Types of participants

Pregnant women judged to be at risk of having preterm or growth-restricted babies, or both.

### Types of intervention

Standardized or individualized programs of additional social support, provided in either home visits, during regular antenatal clinic visits, and/or by telephone on several occasions during pregnancy.

### Types of outcome measures

The primary outcomes of interest were gestational age less than 37 weeks and birthweight lower than 2500 gm. However, the Review also includes a wide variety of neonatal and maternal outcomes that are potentially influenced by social support, including:

- miscarriage;
- pregnancy termination;
- complications during pregnancy, including fetal growth restriction and fetal distress;
- hospitalization during pregnancy;
- psychological distress during pregnancy and in the postpartum period;
- intrapartum obstetric interventions;
- operative birth;

- length of hospital stay;
- pregnancy that results in stillbirth or neonatal death;
- pregnancy that results in other adverse neonatal outcomes, including need for specialized care and treatment;
- indicators of poor postnatal physical or mental health.

## SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

We searched the Cochrane Pregnancy and Childbirth Group trials register (30 September 2005).

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. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 37 journals.

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 'Search strategies for identification of studies' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords.

## METHODS OF THE REVIEW

We evaluated trials under consideration for methodological quality and appropriateness for inclusion, without consideration of their results. We processed included trial data as described in Higgins 2005. We assigned quality scores for allocation concealment to each trial, where A = adequate, B = unclear, C = inadequate, and D = not used. Studies rated as a D were excluded. Wherever necessary, we requested unpublished data from the trial authors. For all data analyses in this Review, we entered data based on the principle of intention to treat. To be included in a given comparison, outcome data had to be available for at least 80% of those who were randomized.

In trials in which some participants have interventions such as prenatal and infancy home visitation prior to enrollment, only

those interventions which occurred after randomization were included in the data tables. In trials that included women with multiple pregnancies (eg twins), the pregnancy was the unit of analysis. Thus, an adverse outcome for one baby was counted as an adverse outcome of that pregnancy, and if both babies had an adverse outcome (eg preterm birth), it was counted as a single outcome.

We performed double-data entry, and the results were compared until 100% agreement was achieved.

We calculated relative risks as the measures of effect size for binary outcomes. We used weighted mean differences for most continuous outcome measures. If trials had used different ways of measuring the same outcome, standardized mean differences were to be used. Scores from rating scales were either analysed as continuous variables, if the scale was sufficiently long for this to be reasonable, or converted to dichotomous variables. Fixed-effect meta-analysis was used for combination of studies if the trials were sufficiently similar in their design and interventions that a fixed-effect summary would be meaningful. When there were differences between the trials that were likely to lead to differences in their treatment effects, we used a random-effects meta-analysis. We performed tests for heterogeneity, and when heterogeneity was identified, either by a significant result ( $P < 0.1$ ) or obvious inconsistency of the effect sizes of the trials in the analysis, a random-effects analysis was preferred. We investigated biases in the studies included in the analyses by means of funnel plots and through sensitivity analyses comparing the results when lower quality trials were excluded.

A subgroup analysis was planned to compare support provided by lay women versus support by healthcare professionals, because another Review of support for childbearing women (Hodnett 2003) found differences in the effects of support by hospital staff (nurses, midwives) versus support by lay women.

The pre-specified outcomes for inclusion in the subgroup analysis were:

- gestational age less than 37 weeks;
- birthweight less than 2500 gm;
- perinatal death;
- postpartum depression;
- maternal re-admission to hospital in the first month after childbirth; and
- infant re-admission to hospital in the first month after birth.

## DESCRIPTION OF STUDIES

Eighteen trials, involving 12,658 women, met the inclusion criteria. See table of 'Characteristics of included studies'. While all

participants were judged to be at risk for giving birth preterm or to a low birthweight baby, the inclusion criteria defining risk status was variable. Most trials used a combination of social and obstetrical factors. The trials were conducted in Australia, Great Britain, France, Latin America, the Netherlands, South Africa, and the United States. No single outcome was reported in all 18 trials. For example, data were available from 13 trials ( $n = 10235$  participants) for birthweight lower than 2500 gm, from 11 trials ( $n = 10237$  participants) for gestational age less than 37 weeks, but from only one to two trials ( $n = 509$  and  $n = 559$ ) for maternal psychosocial outcomes.

The descriptions of the additional support were generally consistent across all trials. Five trials included specific mention of education or client teaching as a component of the support (Heins 1990; McLaughlin 1992; Moore 1998; Klerman 2001; Brooten 2001). In 15 trials (Olds 1986; Spira 1986; Dawson 1989; Spencer 1989; Blondel 1990; Heins 1990; Oakley 1990; Bryce 1991; Rothberg 1991b; Villar 1993; Iedema-Kuiper 1996; Norbeck 1996; Moore 1998; Brooten 2001; Dawson 1999) the intervention consisted of one-to-one support, while in three trials (Rothberg 1991a; McLaughlin 1992; Klerman 2001), the intervention consisted of both one-to-one and group sessions. Three trials (Spira 1986; Dawson 1989; Iedema-Kuiper 1996) compared care and support during home visits with inpatient hospital care.

In 12 of the 16 trials, in which the support intervention was provided by a health professional (Olds 1986; Spira 1986; Dawson 1989; Blondel 1990; Heins 1990; Oakley 1990; Bryce 1991; Iedema-Kuiper 1996; Moore 1998; Norbeck 1996; Dawson 1999; Brooten 2001), the provider of support was a midwife or a nurse, and in four trials (Rothberg 1991a; Rothberg 1991b; Villar 1993; Klerman 2001) the providers were social workers. In one trial (McLaughlin 1992) the support was provided by a multi-disciplinary team consisting of nurses, psychologists, midwives, and specially trained lay women. In one trial (Spencer 1989) specially trained lay women provided all of the additional support.

## METHODOLOGICAL QUALITY

### Allocation concealment

The included trials varied in the extent to which selection bias posed a threat to validity. In one trial (McLaughlin 1992) the method of random allocation was an open list of random numbers, thus neither centrally controlled nor concealed. In one trial (Olds 1986) women drew their treatment assignments from a deck of cards, and the decks were reconstituted periodically to over represent those treatments with smaller numbers of participants. In eight trials (Blondel 1990; Klerman 2001; Spira 1986; Bryce 1991; Norbeck 1996; Rothberg 1991a; Rothberg 1991b; Spencer 1989) the method for randomization was not fully described and thus was unclear. Three trials (Spencer 1989; Bryce 1991; Norbeck 1996) used the Zelen method, in which random allocation

to groups is performed before seeking group members' consent to participate. This approach could have introduced bias because of losses to follow up (higher in the experimental groups) of women who declined to participate. In five trials (Dawson 1989; Heins 1990; Oakley 1990; Villar 1993; Iedema-Kuiper 1996) randomization was both centrally controlled and concealed.

#### **Performance bias**

Women and their care providers could not be blinded to the presence or absence of additional support during pregnancy.

#### **Attrition bias**

Follow up for outcomes that were measured prior to hospital discharge was generally excellent, but follow up for longer-term outcomes was variable. All data entered in this Review were reported for a minimum of 80% of those originally enrolled.

## **RESULTS**

Eighteen trials, involving 12,658 women, met the inclusion criteria. Social support interventions for at-risk pregnant women have not been associated with reductions in the numbers of preterm babies (11 trials,  $n = 10237$ , relative risk (RR) = 0.96, 95% confidence interval (CI) 0.86 to 1.07), low birthweight babies (13 trials,  $n = 10235$ , RR = 0.98, 95% CI 0.89 to 1.08), or perinatal mortality (11 trials,  $n = 9507$ , RR = 1.15, 95% CI 0.89 to 1.51). The only improvement in any medical outcome of pregnancy was a decreased likelihood of caesarean birth (9 trials,  $n = 5108$ , RR = 0.88, 95% CI 0.79 to 0.98). Results of four trials indicate women who received additional social support were almost three times more likely to have their pregnancies terminated ( $n = 4195$ , RR = 2.96, 95% CI 1.42 to 6.17). There was a possible small reduction in the use of analgesia or anaesthesia during labour and birth (3 trials,  $n = 4032$ , RR = 0.94, 95% CI 0.89 to 1.00); although the 95% confidence interval included 1.00, there is consistency in the results of the three trials.

Individual trials have found other psychosocial benefits. Dawson 1989 reported reduced antenatal anxiety ( $n = 60$ , weighted mean difference (WMD) = -7.85, 95% CI -13.14 to -2.56). Oakley 1990 found that mothers who received additional support were less likely to report being worried about their babies (RR = 0.57, 95% CI 0.39 to 0.82). Blondel 1990 reported that mothers who received additional support were less likely to be dissatisfied with their antenatal care ( $n = 158$ , RR = 0.42, 95% CI 0.25 to 0.73) and less likely to report they had no help at home ( $n = 158$ , RR = 0.39, 95% CI 0.21 to 0.73).

Because in one trial 58.6% of those randomized to additional support did not accept it (Spencer 1989), funnel plots were used to explore sources of bias, and sensitivity analyses were conducted, comparing the results with and without inclusion of the trial. The funnel plots did not suggest the trial (or any other included trial)

was a source of bias, and the results did not change materially when the trial was excluded.

Because there was only one trial in which the support was provided by lay women (Spencer 1989), and in another trial the support was provided by a multidisciplinary team that included lay women (McLaughlin 1992), the planned subgroup analysis was not performed. However, the results of these two trials were remarkably consistent with those of the other trials.

## **DISCUSSION**

In general the social support intervention was comprehensive and intensive, although timing of onset varied from the first to third trimester, with the majority of women enrolled at about mid-pregnancy. Despite the comprehensiveness of the intervention, the number and diversity of outcomes, and despite the solid theoretical rationale for linking stress, social support, and pregnancy outcome, there was no significant reduction in the likelihood of pregnancy complications, low birthweight, preterm birth, or medical complications for mother or baby in the weeks after birth. While the theoretical rationale for links between social support, stress, and health is strong, it may be that social support (regardless of the quality and quantity) is not sufficiently powerful to improve the outcomes of the pregnancy during which it is provided. An argument could be made that, given the immense social deprivation experienced by most of the women in these trials, it would be surprising if social support could have such an immediate and powerful effect.

An alternate, or complementary, explanation for the lack of effect of social support on preterm birth or low birthweight is that our abilities to identify women who are at high risk of preterm birth or low birthweight babies are seriously limited, and thus many women were included in these trials who were not actually at higher risk of these outcomes. Furthermore, the underlying causal mechanisms linking social disadvantage to adverse pregnancy outcomes have not been identified.

Two outcomes were significantly associated with enhanced social support during pregnancy, in meta-analyses that involved several trials and over 4000 women: increased likelihood of termination of pregnancy and decreased likelihood of caesarean birth. On the assumption that the results did not occur by chance, the following interpretations are offered.

#### **(1) Termination of pregnancy**

The additional support may have resulted in women's increased awareness of the added social risk to themselves or their families, and/or their increased awareness of an increased medical risk to the baby, and thus more women were likely to take action to avoid additional problems. Also, an important aspect of social support is the provision of information. Thus, it is possible that women in



the additional support group sought or received additional information, or both, about the option of pregnancy termination.

## (2) Caesarean birth

It is noteworthy that the effect size is very similar to that in the Cochrane Review of support during labour (Hodnett 2003), and it is consistent with an observational study that linked social support to reduced likelihood of intrapartum complications and operative birth (Norbeck 1983).

Psychosocial outcomes were reported in few of the trials. Despite small numbers, these trials were methodologically sound and reported clear benefits in some outcomes (ie antenatal state anxiety, satisfaction with antenatal care, reported absence of other help at home, and feeling worried about the baby) but not in others (ie antenatal or postnatal depression, feeling low control postnatally). Given the number of outcomes included in the trials, it is possible that the differences occurred by chance. Alternatively, effects on psychosocial outcomes are real but the sample sizes were too small to detect important differences.

## AUTHORS' CONCLUSIONS

### Implications for practice

Pregnant women need and deserve to have the help and support of caring family members, friends, and health professionals. However, such support is unlikely to be powerful enough to overcome the effects of a lifetime of poverty and disadvantage, or a long-standing pregnancy complication, and thereby influence the remaining course of a pregnancy. Pregnant women and their caregivers should be informed that programs which offer additional support during pregnancy are unlikely to prevent the pregnancy from resulting in a low birthweight or preterm baby, but they may be helpful in reducing the likelihood of caesarean birth.

### Implications for research

There appears to be no need for further trials evaluating the medical effects of social support during pregnancy on immediate pregnancy and maternal or neonatal outcomes, or both. The possibility of improved psychosocial outcomes requires confirmation by larger trials that ensure adequate follow up of participants. Qualitative studies conducted concurrently with such trials would provide valuable information about women's evaluations of the additional support. There is an urgent priority for studies which identify the cause(s) of preterm birth. Future studies of forms of care to prevent low birthweight should differentiate between the two distinct causes of low birthweight: being born preterm and being small for gestational age.

## POTENTIAL CONFLICT OF INTEREST

None known.

## ACKNOWLEDGEMENTS

We are grateful to Rita Iedema-Kuper, RM, PhD, for providing us with a copy of her PhD thesis and English summary of the trial, and to Winnie Chu, who assisted with double-data entry and with preparation of the included and excluded trials tables, for the previous version of this Review.

## SOURCES OF SUPPORT

### External sources of support

- No sources of support supplied

### Internal sources of support

- University of Toronto CANADA
- Ryerson University CANADA

## REFERENCES

### References to studies included in this review

#### Blondel 1990 {published data only}

\* Blondel B, Breart G, Llado J, Chartier M. Evaluation of the home-visiting system for women with threatened preterm labor: results of a randomized controlled trial. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 1990;**34**:47–58.

Blondel B, Llado J, Breart G. Prevention of preterm deliveries by home visiting system: results of a French randomized controlled trial. *Proceedings of International Symposium on Advances in the Prevention of Low Birthweight*; 1988 May 8-11; Cape Cod, Massachusetts,

USA. 1988:141–50.

#### Brooten 2001 {published data only}

\* Brooten D, Youngblut JM, Brown L, Finkler SA, Neff DF, Madigan E. A randomized trial of nurse specialist home care for women with high-risk pregnancies: outcomes and costs. *American Journal of Managed Care* 2001;**7**(8):793–803.

#### Bryce 1991 {published data only}

Bryce R. Support in pregnancy. *International Journal of Technology Assessment in Health Care* 1991;**7**(4):478–84.

\* Bryce RL, Stanley FJ, Garner JB. Randomized controlled trial of

antenatal social support to prevent preterm birth. *British Journal of Obstetrics and Gynaecology* 1991;**98**:1001–8.

Stanley F, Bryce R. The pregnancy home visiting program. In: PapiernikE, BreartG, SpiraN editor(s). *Prevention of preterm birth*. Vol. 138, Paris: Colloque INSERM, 1986:309–28.

**Dawson 1989** {published data only}

\* Dawson AJ, Middlemiss C, Coles EC, Gough NAJ, Jones ME. A randomized study of a domiciliary antenatal care scheme: the effect on hospital admissions. *British Journal of Obstetrics and Gynaecology* 1989;**96**:1319–22.

Middlemiss C, Dawson A, Gough N, Jones M, Coles E. A randomised study of a domiciliary antenatal care scheme: maternal psychological effects. *Midwifery* 1989;**5**:69–74.

**Dawson 1999** {published data only}

\* Dawson A, Cohen D, Candelier C, Jones G, Sanders J, Thompson A, et al. Domiciliary midwifery support in high-risk pregnancy incorporating telephonic fetal heart rate monitoring: a health technology randomized assessment. *Journal of Telemedicine & Telecare* 1999;**5**(4):220–30.

**Heins 1990** {published data only}

Heins H, Nance N. A statewide randomized clinical trial to reduce the incidence of low birth weight/very low birth weight infants in South Carolina. In: PapiernikE, BreartN, SpiraN editor(s). *Prevention of preterm birth*. Vol. 138, Paris: Colloque INSERM, 1986:387–410.

Heins H, Nance N, McCarthy B, Efird C, Collaborative Group. The South Carolina multicentered randomized controlled trial to reduce low birthweight. Proceedings of International Symposium on Advances in the Prevention of Low Birthweight; 1988 May 8–11; Cape Cod, Massachusetts, USA. 1988:87–99.

\* Heins HC, Nance NW, McCarthy BJ, Efird CM. A randomized trial of nurse-midwifery prenatal care to reduce low birth weight. *Obstetrics & Gynecology* 1990;**75**:341–5.

**Iedema-Kuiper 1996** {unpublished data only}

Iedema-Kuiper HR. *Geïntegreerde Thuiszorg bij Risicozwangeren [Domiciliary care in high risk pregnancies] [PhD thesis]*. Utrecht: University of Utrecht, 1996.

\* Iedema-Kuiper HR, Bruinse HW, Peddemors HE, Reuwer HM, Merkus WN, v.d. Salm PCM, et al. The Utrecht domiciliary care in high risk pregnancies study: the effect of hospital admission days, fetal and maternal outcome, maternal well being and cost-effectiveness: a randomized study. *Prenatal and Neonatal Medicine* 1996;**1 Suppl 1**: 10.

**Klerman 2001** {published data only}

\* Klerman LV, Ramey SL, Goldenberg RL, Marbury S, Hou J, Cliver SP. A randomized trial of augmented prenatal care for multiple-risk, medicaid-eligible African American women. *American Journal of Public Health* 2001;**91**(1):105–11.

**McLaughlin 1992** {published data only}

\* McLaughlin FJ, Altemeier WA, Christensen MJ, Sherrod KB, Dietrich MS, Stern DT. Randomized trial of comprehensive prenatal care for low-income women: effect on infant birth weight. *Pediatrics* 1992;**89**(1):128–32.

**Moore 1998** {published data only}

Moore ML, Meis PJ, Ernest JM. Reducing low birthweight birth through intensive nursing intervention via telephone. *American Journal of Obstetrics and Gynecology* 1994;**170**:383.

\* Moore ML, Meis PJ, Ernest JM, Wells HB, Zaccaro DJ, Terrell T. A randomized trial of nurse intervention to reduce preterm and low birth weight births. *Obstetrics & Gynecology* 1998;**91**:656–61.

Muender MM, Moore ML, Chen GJ, Sevcik MA. Cost-benefit of a nursing telephone intervention to reduce preterm and low-birth-weight births in an African American clinic population. *Preventive Medicine* 2000;**30**(4):271–6.

**Norbeck 1996** {published data only}

\* Norbeck JS, DeJoseph JF, Smith RT. A randomized trial of an empirically-derived social support intervention to prevent low birth-weight among African American women. *Social Science and Medicine* 1996;**43**:947–54. [MedLine: 1997043266].

**Oakley 1990** {published data only}

Oakley A, Rajan L. The social support and pregnancy outcome study. Proceedings of International Symposium on Advances in the Prevention of Low Birthweight; 1988 May 8–11; Cape Cod, Massachusetts, USA. 1988:123–38.

\* Oakley A, Rajan L, Grant AM. Social support and pregnancy outcome. *British Journal of Obstetrics and Gynaecology* 1990;**97**:155–62.

Rajan L, Oakley A. Infant feeding practice in mothers at risk of low birth weight delivery. *Midwifery* 1990;**6**:18–27.

Rajan L, Oakley A. Low birth weight babies: the mother's point of view. *Midwifery* 1990;**6**:73–85.

**Olds 1986** {published data only}

Olds D, Henderson C, Phelps C, Kitzman H, Hanks C. Effect of prenatal and infancy nurse home visitation on government spending. *Medical Care* 1993;**31**(2):155–74.

Olds D, Henderson C, Tatelbaum R, Chamberlin R. Improving the life-course development of socially disadvantaged mothers: a randomized trial of nurse home visitation. *American Journal of Public Health* 1988;**78**:1426–45.

\* Olds D, Henderson R, Chamberlin R, Tatelbaum R. Preventing child abuse and neglect: a randomized trial of nurse home visitation. *Pediatrics* 1986;**78**(1):65–78.

Olds DL, Henderson CR, Tatelbaum R, Chamberlin R. Improving the delivery of prenatal care and outcomes of pregnancy: a randomized trial of nurse home visitation. *Pediatrics* 1986;**77**:16–28. [Med-Line: 1986066978].

**Rothberg 1991a** {published data only}

\* Rothberg AD. *Effects of stress and counselling on birthweight in two Johannesburg communities [PhD thesis]*. Johannesburg, South Africa: University of Witwatersrand, 1991.

Rothberg AD, Lits B, Shuenyane E. Effects of counselling on birth-weight in two Johannesburg communities. Proceedings of the 10th Conference on Priorities in Perinatal Care; 1991; South Africa. 1991: 103–6.

Rothberg AD, Shuenyane E, Sefuba M. Psychosocial support for mothers with pregnancy-related hypertension: effect on birthweight. *Pediatric Reviews and Communications* 1991;**6**:13–20.

Rothberg AD, Shuenyane EI, Lits B, Strebel PM. Effect of stress on birth weight in two Johannesburg populations. *South African Medical Journal* 1991;**79**:35–8.

**Rothberg 1991b** {published data only}

Rothberg AD. *Effects of stress and counselling on birthweight in two Johannesburg communities [PhD thesis]*. Johannesburg, South Africa: University of Witwatersrand, 1991.

Rothberg AD, Lits B, Shuenyane E. Effects of counselling on birthweight in two Johannesburg communities. Proceedings of the 10th Conference on Priorities in Perinatal Care; 1991; South Africa. 1991: 103–6.

\* Rothberg AD, Lits B. Psychosocial support for maternal stress during pregnancy: Effect on birth weight. *American Journal of Obstetrics and Gynecology* 1991;**165**:403–7. [MedLine: 1991336337].

**Spencer 1989** {published data only}

Spencer B. The family workers project: evaluation of a randomized controlled trial of a pregnancy social support service. Proceedings of International Symposium on Advances in the Prevention of Low Birthweight; 1988 May 8–11; Cape Cod, Massachusetts, USA. 1988: 109–21.

Spencer B, Morris J. The family worker project: social support in pregnancy. In: Papiernik E, Breart G, Spira N editor(s). *Prevention of preterm birth*. Vol. 138, Paris: Colloque INSERM, 1986:363–82.

\* Spencer B, Thomas H, Morris J. A randomized controlled trial of the provision of a social support service during pregnancy: the South Manchester Family Worker Project. *British Journal of Obstetrics and Gynaecology* 1989;**96**:281–8.

**Spira 1986** {published and unpublished data}

Spira N. Evaluation of prenatal home visiting midwives program. In: Papiernik E, Breart G, Spira N editor(s). *Prevention of Preterm Birth*. Vol. 138, Paris: Colloque INSERM, 1986:291–308.

\* Spira N, Audras F, Chapel A, Debuisson J, Jacquelin C, Kirchhoffer C, et al. Domiciliary care of pathological pregnancies by midwives. Comparative controlled study on 996 women. *Journal de Gynecologie, Obstetrique et Biologie de la Reproduction (Paris)* 1981;**10**:543–8.

**Villar 1993** {published data only}

Belizan JM, Barros F, Langer A, Farnot U, Victora C, Villar J. Impact of health education during pregnancy on behavior and utilization of health resources. Latin American Network for Perinatal and Reproductive Research. *American Journal of Obstetrics and Gynecology* 1995;**173**:894–9. [MedLine: 1996013412].

Langer A, Garcia C, Leis T, Reynoso S, Hernandez B. Psychosocial support in pregnancy as a strategy to promote the newborn's health (translation). *Revista de Investigacion Clinica* 1993;**45**:317–28.

Langer A, Victora C, Victora M, Barros F, Farnot U, Belizan J, et al. The Latin American trial of psychosocial support during pregnancy: a social intervention evaluated through an experimental design. *Social Science and Medicine* 1993;**36**(4):495–507.

Victora CG, Langer A, Barros F, Belizan J, Farnot U, Villar J. The Latin American multicenter trial on psychosocial support during pregnancy: methodology and baseline comparability. Latin American Network for Perinatal and Reproductive Research (LANPER). *Controlled Clinical Trials* 1994;**15**:379–94.

\* Villar J, Farnot U, Barros B, Victora C, Langer A, Belizan J. A randomized trial of psychosocial support during high-risk pregnancies. *New England Journal of Medicine* 1992;**327**:1266–71.

## References to studies excluded from this review

**Boehm 1996**

Boehm FH, Glass CA, Reed GW. Prevention of preterm birth. Role of daily telephone contact. *Journal of Reproductive Medicine* 1996;**41**(8):595–601.

**Bullock 1995**

Bullock LFC, Wells E, Duff GB, Hornblow AR. Telephone support for pregnant women: outcome in late pregnancy. *New Zealand Medical Journal* 1995;**108**:476–8.

**Dance 1987**

Dance J. A social intervention by linkworkers to Pakistani women and pregnancy outcome. M.A. Sociological Research in Health Care, Marston Green Maternity Hospital: Birmingham, University of Warwick July 1987; Vol. 1:1–85.

**Ford 2002**

Ford K, Weglicki L, Kershaw T, Schram C, Hoyer PJ, Jacobson ML. Effects of a prenatal care intervention for adolescent mothers on birth weight, repeat pregnancy, and educational outcomes at one year postpartum. *Journal of Perinatal Education* 2002;**11**(1):35–8.

**Goulet 2001**

Goulet C, Gevry H, Gauthier RJ, Lepage L, Fraser W, Aita M. A controlled clinical trial of home care management versus hospital care management for preterm labour. *International Journal of Nursing Studies* 2001; Vol. 38:259–69.

Goulet C, Gevry H, Lemay M, Gauthier RJ, Lepage L, Fraser W. A randomized clinical trial of care for women with preterm labour: home management vs. hospital management. *CMAJ: Canadian Medical Association Journal* 2001;**164**(7):985–91.

**Graham 1992**

Graham A, Frank S, Zyzanski S, Kitson G, Reeb K. A clinical trial to decrease the rate of low birth weight in an inner-city black population. *Family Medicine* 1992;**24**(6):439–46.

**Graham 2003**

Graham M, Stabile S, Powell A, Pruett R, Zervigon Hakes A, Butler B. Serving pregnant women within early head start: lessons from the panhandle healthy start and early head start. <http://www.ehsnrc.org/InformationResources/ResourceArticles/ftpreg.htm> (accessed 15 July 2003).

**Hamilton 2002**

Hamilton MS, Broton D, Youngblut JM. High-risk pregnancy: postpartum rehospitalization. *Journal of Perinatology* 2002;**22**:566–71.

**Hobel 1994**

Hobel C, Ross M, Bennis R, Bragonier J, Nessim S, Sandhu M, et al. The West Los Angeles preterm birth prevention project: I. Program impact on high-risk women. *American Journal of Obstetrics and Gynecology* 1994;**170**:54–62.

Hobel C, Siega-Riz A. The West Los Angeles Preterm Birth Prevention Project: a reassessment of interventions. *Prenatal and Neonatal Medicine* 1998;**3**:161–4.

Hobel CJ, Bemis RL. The West Area Los Angeles prematurity prevention demonstration project. In: Papiernik E, Breart G, Spira N editor (s). *Prevention of preterm birth*. Vol. 138, Paris: Colloque INSERM, 1986:205–22.

Hobel CJ, Bragonier R, Ross M, Bear M, Bemis R, Mori B. West Los Angeles premature prevention program: significant impact. *Journal of Perinatal Medicine* 1987;**15**:112.

Ross M, Sandhu M, Bemis R, Nessim S, Bragonier J, Hobel C. The West Los Angeles preterm birth prevention project: II. Cost-effectiveness analysis of high-risk pregnancy interventions. *Obstetrics & Gynecology* 1994;**83**:506–11.

Ross MG, Sandhu M, Bemis R, Nessim S, Bragonier JR, Mori B, et al. West Los Angeles preterm birth prevention project (LAPPP): cost benefit of high risk pregnancy interventions. *American Journal of Obstetrics and Gynecology* 1992;**166**:367.

#### Kitzman 2000

Kitzman H, Olds DL, Sidora K, Henderson CR Jr, Hanks C, Cole R, et al. Enduring effects of nurse home visitation on maternal life course: a 3-year follow-up of a randomized trial. *JAMA* 2000;**283** (15):1983–9.

#### Koniak-Griffin 2000

\* Koniak-Griffin D, Anderson NLR, Verzemnieks I, Brecht ML. A public health nursing early intervention program for adolescent mothers: outcomes from pregnancy through 6 weeks postpartum. *Nursing Research* 2000;**49**(3):130–8.

#### Little 2002

Little M, Saul G, Testa K, Gaziano C. The influence of telephonic nursing care coordination on patient satisfaction in a predominantly low-income, high-risk pregnancy population. *Lippincott's Case Management* 2002;**7**:15–23.

\* Little M, Saul GD, Testa K, Gaziano C. Improving pregnancy outcome and reducing avoidable clinical resource utilization through telephonic perinatal care coordination. *Lippincott's Case Management* 2002;**7**:103–12.

#### Oakley 1996

Oakley A, Hickey D, Rajan L, Rigby A. Social support in pregnancy: does it have long-term effects?. *Journal of Reproductive and Infant Psychology* 1996;**14**:7–22.

### References to studies awaiting assessment

#### Beazley 2001

Beazley D, Mercer B, Meyer N, Carr T. The Memphis preterm birth project: prediction and prevention of preterm birth in extremely high risk women [abstract]. *American Journal of Obstetrics and Gynecology* 2001; Vol. 185, issue 6:S86–7.

Mercer B, Beazley D, Klesges L, Meyer N, Carr T. Weekly nurse contact to prevent preterm birth: impact of maternal stressors and perceived stress [abstract]. *American Journal of Obstetrics and Gynecology* 2002;**187**(6 Pt 2):S128.

#### Nguyen 2003

Nguyen JD, Carson ML, Parris KM, Place P. A comparison pilot study of public health field nursing home visitation program interventions for pregnant hispanic adolescents. *Public Health Nursing* 2003;**20**(5):412–8.

### Additional references

#### Berkowitz 1993

Berkowitz G, Papiernik E. Epidemiology of preterm birth. *Epidemiologic Reviews* 1993;**15**(2):414–43.

#### Brocklehurst 2003

Brocklehurst P, Hannah M, McDonald H. Interventions for treating bacterial vaginosis in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1.

#### Cuervo 2003

Cuervo LG, Mahomed K. Treatments for iron deficiency anaemia in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1.

#### Higgins 2005

Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5 [updated May 2005]. In: The Cochrane Library, Issue 3, 2005. Chichester, UK: John Wiley & Sons, Ltd.

#### Hodnett 2003

Hodnett E, Gates S, Hofmeyr GJ, Sakala C. Continuous support for women during childbirth (Cochrane Review). *The Cochrane Library* 2003, Issue 2. Art. No.: CD003766. DOI: [10.1002/14651858.CD003766.pub2](https://doi.org/10.1002/14651858.CD003766.pub2).

#### Kramer 1987

Kramer M. Determinants of low birth weight: methodological assessment and meta-analysis. *Bulletin of the World Health Organisation* 1987;**65**:663–737.

#### Kramer 2003a

Kramer MS. Balanced protein/energy supplementation in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1.

#### Kramer 2003b

Kramer MS. Isocaloric balanced protein supplementation in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000118. DOI: [10.1002/14651858.CD000118](https://doi.org/10.1002/14651858.CD000118).

#### Kramer 2003c

Kramer MS. Nutritional advice in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000149. DOI: [10.1002/14651858.CD000149](https://doi.org/10.1002/14651858.CD000149).

#### Kramer 2003d

Kramer MS. High protein supplementation in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000105. DOI: [10.1002/14651858.CD000105](https://doi.org/10.1002/14651858.CD000105).

#### Kramer 2003e

Kramer MS. High protein supplementation in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000105. DOI: [10.1002/14651858.CD000105](https://doi.org/10.1002/14651858.CD000105).

#### Lumley 2003

Lumley J, Oliver S, Waters E. Interventions for promoting smoking cessation during pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD001055. DOI: [10.1002/14651858.CD001055.pub2](https://doi.org/10.1002/14651858.CD001055.pub2).

#### Mahomed 2003

Mahomed K, Gulmezoglu AM. Vitamin D supplementation in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000228. DOI: [10.1002/14651858.CD000228](https://doi.org/10.1002/14651858.CD000228).

**Norbeck 1983**

Norbeck JS, Tilden VP. Life stress, social support, and emotional disequilibrium in complications of pregnancy: a prospect, multivariate study. *Journal of Health and Social Behaviour* 1983;**24**:30–6.

**Say 2003a**

Say L, Gülmezoglu AM, Hofmeyr GJ. Betamimetics for suspected impaired fetal growth (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000036. DOI:[10.1002/14651858.CD000036](https://doi.org/10.1002/14651858.CD000036).

**Say 2003b**

Say L, Gülmezoglu AM, Hofmeyr GJ. Calcium channel blockers for potential impaired fetal growth (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000049. DOI:[10.1002/14651858.CD000049](https://doi.org/10.1002/14651858.CD000049).

**Say 2003c**

Say L, Gülmezoglu AM, Hofmeyr GJ. Maternal nutrient supplementation for suspected impaired fetal growth (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000148. DOI:[10.1002/14651858.CD000148](https://doi.org/10.1002/14651858.CD000148).

**Say 2003d**

Say L, Gülmezoglu AM, Hofmeyr GJ. Plasma volume expansion for suspected impaired fetal growth (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000167. DOI:[10.1002/14651858.CD000167](https://doi.org/10.1002/14651858.CD000167).

**Smaill 2003**

Smaill F. Antibiotics for asymptomatic bacteriuria in pregnancy (Cochrane Review). *The Cochrane Library* 2003, Issue 1. Art. No.: CD000490. DOI:[10.1002/14651858.CD000490.pub2](https://doi.org/10.1002/14651858.CD000490.pub2).

**Wilkins 1991**

Wilkins R, Sherman G, Best P. Birth outcomes and infant mortality by income in urban Canada, 1986. *Health Report* 1991;**3**:7–31.

**References to other published versions of this review****CDSR 2003**

Hodnett ED. Support during pregnancy for women at increased risk of low birthweight babies (Cochrane Review). *The Cochrane Library* 2003, Issue 2. Art. No.: CD000198. DOI:[10.1002/14651858.CD000198](https://doi.org/10.1002/14651858.CD000198).

*\*Indicates the major publication for the study*

**T A B L E S****Characteristics of included studies**

Study	Blondel 1990
Methods	RCT. Stratified by maternity unit. Random allocation was performed using sealed envelopes (no other details provided).
Participants	158 pregnant French women with moderate threatened preterm labour between 26–36 weeks' gestation, no IV betamimetics.
Interventions	Control group: routine care from obstetricians or midwives at outpatient clinics, no home visits, and hospitalization if necessary.  Experimental: 1–2 home visits/week by midwives and access to domiciliary midwives via telephone, in addition to the same routine care received by control group.
Outcomes	Hospital admission, < 37 weeks gestation at delivery, tocolytics, length of hospital stay, at least 4 antenatal visits at outpatient clinic, number remaining in bed all day, number with help at home, perinatal death, and number who preferred home visiting system.
Notes	
Allocation concealment	B – Unclear
Study	Brooten 2001
Methods	RCT. Random assignment using sealed envelopes prepared in advance by a statisticians using a list of random numbers. After receiving informed consent, a research assistant opened each envelope in turn. (No other details provided.)
Participants	173 pregnant women at a tertiary care hospital in Philadelphia, Pennsylvania, USA, at varying gestations, who were either judged to be at high risk for preterm labour or had gestational or nongestational diabetes, chronic hypertension or an episode of preterm labour.

### Characteristics of included studies (Continued)

Interventions	Control group: standard prenatal and postpartum care by residents and staff physicians, for high-risk patients at the hospital clinic. No routine home visits.  Experimental group: Alternate standard clinic visits were replaced with home visits by nurse specialists with master's degrees. Home visits included discussion of lifestyle and psychosocial issues, as well as individualized teaching and counseling
Outcomes	Antenatal hospitalization; length of antenatal and postpartum hospital stay; postpartum rehospitalization.
Notes	No neonatal outcomes are included in the Review because all results are reported with the infant as the unit of analysis, and there were unequal numbers of twins in the two groups (12 in the control group and 9 in the intervention group).
Allocation concealment	A – Adequate

#### Study Bryce 1991

Methods	RCT via Zelen method (randomization prior to consent). No details provided regarding how the random allocation was performed, other than that it was done using computer-generated random numbers.
Participants	1970 women entered the trial in Perth, Australia. Women were eligible for the trial if they had a history of one or more preterm births, one or more low birthweight births, one or more perinatal deaths, three or more first trimester miscarriages, one or more second trimester miscarriages, or an antepartum hemorrhage in a previous pregnancy.
Interventions	Control group: routine antenatal care (not described).  Experimental group: routine care plus home visits to provide sympathy, understanding, acceptance, and affection at approximately 4-6 week intervals (more frequently if the woman desired) and in-between telephone calls by midwives.
Outcomes	Gestational age at delivery, stillbirths, neonatal deaths, postneonatal deaths, number of babies discharged alive, method of birth.
Notes	88% of women randomized to the experimental group agreed to participate in the trial. Outcome data were available for all but 3 subjects originally randomized (one control and two experimental).
Allocation concealment	B – Unclear

#### Study Dawson 1989

Methods	RCT. 2:1 random allocation scheme. A sealed envelope was opened by a third party to reveal treatment allocation.
Participants	60 pregnant women at varying stages of pregnancy, with a risk factor for low birthweight baby, e.g. hypertension, IUGR, isolated small antepartum bleeds, or previous perinatal loss, which would ordinarily have led to hospital admission but not to immediate intervention.
Interventions	Control group: conventional hospital care (not described).  Experimental group: an average of 11 home visits by midwives plus a telephone domiciliary fetal monitoring system.
Outcomes	Number of hospital admissions, mean gestation at delivery, days under observation, numbers of nights spent in hospital, obstetric interventions (inductions, caesarean delivery), maternal anxiety, postnatal depression, perinatal mortality
Notes	
Allocation concealment	A – Adequate

#### Study Dawson 1999

Methods	RCT. Randomization by consecutively numbered, sealed envelopes.
---------	---

## Characteristics of included studies (*Continued*)

Participants	81 pregnant women at varying gestations, at two areas in South Wales, believed to be at high risk for adverse pregnancy outcome but not with complications likely to require acute intervention. Risk factors included a poor obstetric history, hypertension, weight loss, IUGR, diminished fetal movement, and minor antepartum hemorrhage.
Interventions	Control group: usual care, including frequent hospital clinic visits and serial ultrasound scans and CTG monitoring of the fetal heart rate, fetal movement, and uterine contractions.  Experimental group: domiciliary fetal monitoring, transmitted over the phone, plus home support from community midwives.
Outcomes	Mean gestation at delivery, induction of labour, method of birth, birthweight, Apgar Scores, depression, anxiety, and satisfaction.
Notes	No usable outcome data regarding depression and anxiety outcomes. Satisfaction outcomes were only reported for the intervention group, and response rate was only 67%.
Allocation concealment	A – Adequate

### Study **Heins 1990**

Methods	RCT. Computer-generated random numbers were put into sequentially-numbered, sealed opaque envelopes at the co-ordinating centre. Upon receipt of a telephone call, a lay person with no contact with patients opened the envelope.
Participants	1458 low-income pregnant women who attended state-funded antenatal clinics, at varying gestations, free of known medical or pregnancy complications, score > 9 on a risk factors scale for low birthweight baby or had a low birthweight infant in the previous pregnancy, in South Carolina, USA.
Interventions	Control group: usual antenatal care (not described).  Experimental group: weekly or biweekly antenatal care by a nurse-midwife, including education, counseling, assessment of the cervix, and screening.
Outcomes	Fetal death, birthweight.
Notes	The Institutional Review Board of the university determined that no formal consent was necessary for entry into the study.
Allocation concealment	A – Adequate

### Study **Iedema-Kuiper 1996**

Methods	RCT. Randomization centrally controlled using sealed, opaque envelopes. Randomization to groups in the first half of the study was 1:1; in the second half, 2:1 in favour of the experimental group.
Participants	415 high-risk pregnant women requiring daily evaluation of maternal and/or fetal condition, at three hospitals in the Netherlands, between 1992 and 1995. The main reasons for high-risk status were pregnancy induced hypertension (60% of both groups), fetal growth retardation, and threatened preterm birth.
Interventions	Control group: admitted to hospital for daily evaluations of maternal and/or fetal condition.  Experimental group: daily domiciliary care by a midwife, supervised by a gynaecologist; care included monitoring blood pressure, urine analysis and other laboratory tests, cardiotocography, and support.
Outcomes	Induction of labour, gestational age at delivery, mode of delivery, birthweight, 5 minute Apgar score, arterial cord pH, patient satisfaction, costs.
Notes	Information was obtained from the English summary. Efforts to obtain translation of other important details are ongoing.  There were 46 sets of twins (20 control, 26 experimental), and analyses of neonatal outcome data were based on the individual baby, rather than the pregnancy, as the unit of analysis.

**Characteristics of included studies (Continued)**

Allocation concealment A – Adequate

<b>Study</b>	
<b>Klerman 2001</b>	
Methods	RCT. After written informed consent was obtained, the nurse opened a sealed envelope revealing the participants' assignment to experimental or control group (with approximately equal monthly assignments to both groups).
Participants	656 African American women who sought prenatal care from the Jefferson County (Alabama) Department of Health from March 1994 to June 1996 were eligible if they were: (1) African American, (2) eligible for Medicaid, (3) less than 26 weeks' gestation, (4) at least 16 years old, (5) score of 10 or higher on a risk assessment scale. Exclusion criteria were alcoholism and substance abuse, asthma, cancer, diabetes, epilepsy, high blood pressure, sickle cell disease, and HIV/AIDS.
Interventions	Control group: usual care by the county health department or the university's obstetrics dept. No specific educational or support programs.  Experimental: care aimed at informing pregnant women of their risks and what behaviours might improve pregnancy outcome. Women were given prenatal vitamins, offered a structured smoking cessation/reduction program, and offered regular meetings with a social worker, to reduce stress and strengthen existing social support networks. Prenatal appointments were every two weeks, with minimum waiting times, on-site child care, evening hours, and transportation. In addition, each visit included a group educational session.
Outcomes	Maternal outcomes: number of cesarean deliveries.  Neonatal outcomes: fetal death, mean birthweight, birthweight of liveborn infants < 2500 g, mean gestational age at delivery, preterm births, IUGR, Apgar score < 7 at 1 min and at 5 min, NICU stay.
Notes	Outcome data not available on 37 enrolled participants (no reason provided).
Allocation concealment	B – Unclear

<b>Study</b>	
<b>McLaughlin 1992</b>	
Methods	RCT. After informed consent and initial interview, women were randomly assigned to groups by a research assistant using a computer-generated list of random numbers.
Participants	428 low-income women, < 28 weeks gestation, with singleton pregnancies, judged to be at risk for child maltreatment.
Interventions	Control group: standard medical services provided by obstetrical residents at a hospital clinic.  Experimental: prenatal care by a multi-disciplinary team, focused on psychosocial support, education, and health promotion, as well as offers of individual meetings with a psychologist and prenatal support groups.
Outcomes	Neonatal: mean birthweight, birthweight < 2500 g.  Maternal: miscarriage, termination of pregnancy.
Notes	n = 34 (15.7%) lost to follow up from intervention group and 44 (20.9%) from control group due to spontaneous and elective abortions, twin deliveries, and/or withdrawal. For an additional 13 in the experimental group and 30 in the control group, only birthweight data were available. Participants, healthcare providers, and data collectors were blind to design and hypotheses of study. Data collectors were kept blind to treatment group assignment of mothers.
Allocation concealment	C – Inadequate

<b>Study</b>	
<b>Moore 1998</b>	
Methods	RCT. Random assignment using sequentially numbered, sealed, opaque envelopes. Clinic personnel were blinded to study group assignment, as was the nurse who collected outcome data. 121 (7.8%, 57 experimental



## Characteristics of included studies (Continued)

	and 64 control) were dropped from final data analyses, because they had either a multiple gestation, moved, or transferred to private care.
Participants	1554 women, between 22-32 weeks' gestation, believed to be at risk for birth of a low birthweight baby, receiving prenatal care in a public clinic in North Carolina, USA. All spoke English and had access to a telephone. 775 were randomized to the experimental group and 779 to the control group.
Interventions	Control: A booklet about preventing preterm labour, available in the clinic.  Experimental: Instruction about the signs of preterm labour, a booklet about preventing preterm labour, and 3 telephone calls/week until the 37th week of gestation, by a nurse who was otherwise uninvolved with the woman's care.
Outcomes	Low birthweight, gestational age < 37 weeks. Additional analyses were performed on subgroups (younger versus older black women, younger versus older white women).
Notes	Data are included in this Review only for outcomes of the groups originally randomized, not for subgroups.
Allocation concealment	A – Adequate

<b>Study</b>	<b>Norbeck 1996</b>
Methods	RCT. Random allocation was performed using consecutively numbered, sealed envelopes. Zelen method was used: only those participants randomized to the experimental group were asked for consent. Analysis was based on intent-to-treat.
Participants	114 adult low-income African American women in California, USA, in mid-pregnancy who were identified as having inadequate social support, defined as low support from mothers or male partners. The tool used to assess eligibility was the Norbeck Social Support Questionnaire; if the support score from either the woman's mother or husband/partner was < 28 or the combined score for the two sources was < 36, women were judged to have low support. Women were excluded if they had major mental illness, therapeutic or spontaneous abortion prior to 20 weeks, or were pregnant with twins.
Interventions	Control group: standard prenatal care (not described).  Experimental: 4 standardized face-to-face sessions at 2 week intervals in their homes, given by nurses, and telephone contacts in the intervening weeks. The sessions focused on identification of problem areas and successful aspects of each woman's life, her social supports, her feelings about her pregnancy, and the types of relationships that foster or limit self-esteem.
Outcomes	Rates of low birthweight (< 2500 gm).
Notes	5 (8.9%) in the experimental group refused to participate, 12% received only one of the formal intervention sessions, and 77% received 3 or 4 sessions.
Allocation concealment	B – Unclear

<b>Study</b>	<b>Oakley 1990</b>
Methods	RCT. Random allocation, stratified by centre, via telephone call to the co-ordinating centre.
Participants	509 women with a history of a low birthweight (< 2500 gm) baby, < 24 weeks gestation, singleton pregnancy, fluent in English, attending antenatal booking clinics at 4 UK hospitals. The sample was socially disadvantaged: 77% were working class, 18% had unemployed partners, and 41% were smoking on entry.
Interventions	Control group: usual antenatal care.  Experimental group: usual antenatal care plus social support by the research midwife at her hospital. The social support intervention consisted of, at a minimum, 3 home visits - at 14, 20, and 28 weeks' gestation - plus 2 telephone contacts or brief home visits between these times. The midwife was also on-call to the mothers 24 hours/day. Semi-structured interview guides provided the basis for flexible and open-ended communication between midwives and mothers.
Outcomes	Antenatal hospital admission, > 1 ultrasound scan, days in hospital antenatally, admission for threatened preterm delivery, antenatal hypertension, antenatal depression, method of labour onset, epidural anaesthesia,

## Characteristics of included studies (Continued)

	labour length, type of delivery, birthweight, gestational age, 5-minute Apgar score < 7, neonatal respiratory distress, admission to special care nursery, days ventilated, days receiving oxygen, days totally tube-fed, breastfed at discharge, neonatal problems at discharge, health service use postdischarge, mother's health, mother returning to hospital for non-routine postnatal care, visit to/from family doctor, postnatal depression, mother feeling low/loss of control over life, worried about baby, partner helpful.
Notes	After excluding twins (3 in the intervention group and 2 in the control group) and spontaneous abortions (6 per group) and pregnancy terminations (2 per group), data on the medical and psychosocial outcomes of pregnancy, labour, and birth were available for between 225-243 per group (88%-96%). However, the comparisons in this review are based on the numbers originally randomized to each group. Data from a 7-year follow-up survey of the participants (Oakley 1996) are not included because responses were received from < 50% of the original sample (126 of 255 in the intervention group and 115 of 254 in the control group).
Allocation concealment	A – Adequate

<b>Study</b>	<b>Olds 1986</b>
Methods	RCT. Eligible women were stratified by marital status, race, and geographic region. Women drew their treatment assignments from a deck of cards. The decks were reconstituted periodically to over represent those treatments with smaller numbers of participants. Also, in 6 instances women who were living with other women already enrolled were assigned the same treatment condition as their housemates, and in the last 6 months of the 30-month enrolment period, the number of cards for treatment 4 was increased.
Participants	379 pregnant women in a semi-rural area in upstate New York, USA, who had no previous live births, were < 30 weeks' gestation, and had one or more of the following: age < 19, single parent, low socioeconomic status, or nulliparous and wanting to participate.
Interventions	Four groups: (1) no additional services during pregnancy, at ages 1 and 2 children screened for sensory and developmental problems; (2) free transportation for regular prenatal and well-child care, sensory and developmental screening of the children at ages 1 and 2; (3) nurse-home visitor during pregnancy plus transportation service and screening; (4) the same services as in group 3, and in addition the nurse continued to visit until the child was age 2.
Outcomes	Child abuse/neglect; mothers' reports of babies' moods, eating problems, amount of crying and wakefulness at night; mothers' reports of worry/concern, conflict, scolding, and hitting babies; number of and reasons for emergency room visits for the babies; nurses' home observations of mothers' avoidance of restriction and punishment and mothers' provision of appropriate play materials; number of mothers who graduated from or remained in high school; birthweight, length of gestation, stillbirth.
Notes	Most of the reported results were unusable because they compared small subgroups or were derived from multivariate statistical procedures.  For most of the comparisons of treatments, groups 1 and 2 were combined and groups 3 and 4 (nurse-visited) were combined.  Data were not provided for 46 non-white women and 20 cases with maternal or fetal conditions predisposing to preterm delivery and/or aberrations in fetal growth, who were excluded by the authors prior to data analyses.
Allocation concealment	C – Inadequate

<b>Study</b>	<b>Rothberg 1991a</b>
Methods	RCT. Random allocation via sealed envelopes which contained a green or pink slip of paper.
Participants	80 poor black pregnant women with hypertension and < 26 weeks' gestation, attending obstetric clinics serving Soweto, South Africa and booked for delivery at Baragwanath Maternity Hospital, Johannesburg.
Interventions	Control group: routine care (not described) at the hypertension clinic and routine antenatal care.

## Characteristics of included studies (Continued)

	Experimental group: counseling by a social worker either at the time of a clinic visit, in a group session, or in a home visit (or hospital visit if the mother was hospitalized), on average approximately 4 times during the remainder of the pregnancy. The social worker provided psychosocial support and counseling, help with problems at home and at work, and encouragement to comply with clinic staff instructions/advice.
Outcomes	Birthweight, gestational age at delivery, number hospitalized in pregnancy for urgent BP control, number with proteinuria, caesarean delivery, abortion/stillbirth, low birthweight rate.
Notes	
Allocation concealment	B – Unclear

<b>Study</b>	<b>Rothberg 1991b</b>
Methods	RCT. Random allocation via sealed envelopes which contained a green or pink slip of paper.
Participants	104 Caucasian women in Johannesburg, South Africa, with a singleton pregnancy between 18-25 weeks' gestation, free of medical or obstetric problems known to be associated with prematurity or low birthweight, and with high scores on a scale measuring life stress.
Interventions	Control group: usual clinic care, in which personnel were largely unaware of mothers' personal problems.  Experimental group: a minimum of 20 minutes of individualized counseling from an assigned social worker at each antenatal visit or by telephone shortly thereafter.
Outcomes	Birthweight < 3000 gm, number of LBW babies, preterm rate, birthweight categorized in 500 gm increments.
Notes	Of the original 104 randomized, 18 women (8 experimental and 10 control) were dropped from the analyses. 8 mothers (4 per group) were excluded for complications or because they transferred to other centres. Data collection was stopped when 43 in each group had completed the study. The 4 remaining mothers in the experimental group and 6 in the control group continued on the study protocol, but data from these 10 mothers were not included in the published reports.
Allocation concealment	B – Unclear

<b>Study</b>	<b>Spencer 1989</b>
Methods	RCT. Random allocation "using random number tables" prior to seeking consent to participate from women allocated to the experimental group (Zelen method).
Participants	1288 pregnant women < 20 weeks' gestation and at increased risk of giving birth to a low birthweight baby, booked for delivery in either of 2 maternity units within the South Manchester Health District, England. Asian women were excluded from the trial. Risk was defined as at least 2 of the following: previous LBW baby, interpregnancy interval ≤ 6 months, underweight, previous perinatal death, > 1 previous midtrimester spontaneous abortion, parity > = 3, previous neonatal/infant death, single parent, woman's social class IV/V/unemployed.
Interventions	Control group: routine antenatal care (not described).  Experimental: client-centred approach in which social support was provided by a family worker during pregnancy. The tasks of the worker varied according to the individual situation, and ranged from providing help in obtaining state benefits, with housing, shopping, and other domestic work and child care, to promoting appropriate use of health and social services and community facilities, and acting as a confidante. An average of 1-2 visits/week was provided.
Outcomes	Birthweight, length of gestation, proportions of low birthweight, small-for-gestational age, and preterm births, pregnancy terminations, miscarriages, still births, live births.
Notes	Of 655 women randomized to the experimental group, 384 (58.7%) refused the social support intervention. Comparisons of experimental and control groups included all women originally randomized, except for 25 controls and 27 experimentals for whom outcome data were unavailable.  Secondary analyses comparing those who accepted the family worker in the experimental group, with those who did not accept combined with the control group, showed no statistically significant differences between

## Characteristics of included studies (Continued)

the two groups. Reasons for refusal of the family worker included: "already well supported" (21.8%), "not in when visited" (13.9%), "not interested" (8.4%), employed full time (6.3%), moving away (6.0%).

Allocation concealment C – Inadequate

Study	Spira 1986
Methods	RCT. Method of random allocation not described.
Participants	996 women with pregnancy complications that put them at risk for preterm delivery, in France.
Interventions	Control group: hospitalized. Experimental group: domiciliary care by midwives.
Outcomes	Birthweight, gestational age at delivery, perinatal mortality, birth weight < 2500 gm, < 37 weeks' gestation at birth.
Notes	113 of the 996 (11.3%) who were randomized were subsequently excluded: 43 in the domiciliary and 70 in the hospital group. However, the comparisons in this review are based on the numbers originally allocated to each group.

Allocation concealment B – Unclear

Study	Villar 1993
Methods	RCT. Random allocation was carried out by the central data co-ordinating centre, which produced sealed, opaque envelopes containing computer-generated codes within balanced blocks of 20 women, stratified by centre.
Participants	2235 pregnant women at risk for giving birth to a low birthweight baby, between 15-22 weeks' gestation, in centres in: Rosario, Argentina; Pelotas, Brazil; Havana, Cuba; and Mexico City. Risk was defined as 1 or more of the following: previous LBW or preterm infant, previous fetal or infant death, age < 18, body weight < = 50 kg, height < = 1.5 m, low family income according to locally adapted cutoff points, < 3 years of school, smoking or heavy alcohol consumption, residence apart from the child's father.
Interventions	Control group: standard antenatal care (not described)  Experimental: aimed at increasing social support and reducing stress and anxiety in pregnancy. A minimum of 4 home visits by specially trained female social workers or obstetrical nurses. The aims of the visits were to strengthen the woman's social network, and to provide direct emotional support and health education. In addition, a special support office - for women to visit without prior appointments or to telephone - was available at each study hospital for all women in the experimental group.
Outcomes	Low birthweight, preterm delivery, IUGR, forceps delivery, caesarean delivery, anaesthesia during labour, stillbirth, perinatal death, Apgar score < 7 at 5 minutes, admission to neonatal intensive care unit.

Notes

Allocation concealment A – Adequate

BP: blood pressure

IUGR: intrauterine growth restriction

IV: intravenous

LBW: low birthweight

min: minutes

NICU: neonatal intensive care unit

PHNs: public health nurses

RCT: randomized controlled trial

## Characteristics of excluded studies

Study	Reason for exclusion
Boehm 1996	Not a randomized trial. The 'control group' had education, frequent prenatal visits, and cervical examinations. The 'study group' also had daily telephone contact. 'Group 3' had education but refused to participate in the study.
Bullock 1995	Not a trial of women judged to be at risk for preterm birth or low birthweight baby. The purpose was to improve pregnant women's health behaviours during pregnancy. No usable or clinically interpretable outcome data. Published data are mean scores (without standard deviations) on measures of stress, social support, self-esteem, depression, and anxiety at baseline (< 20 weeks' gestation) and 34 weeks' gestation. Comparisons were performed using analysis of covariance.
Dance 1987	Strong likelihood of selection bias: "Randomisation into intervention and control groups was decided by 'the toss of a coin' in the order in which they presented for 'booking', case, control, case etc until the 50 women had been recruited into the study", and 25 women were in each study group.
Ford 2002	Strong likelihood of selection bias. A table of random numbers was used to create an open list of group assignments. Approximately the first 5 subjects at each of 5 clinics were assigned to the experimental group., resulting in 282 in the experimental group and 165 in the control group. Number of losses to follow up in each group are not known.
Goulet 2001	Not a trial of support during pregnancy. The intervention lasted 2 weeks and consisted of home uterine activity monitoring and additional information.
Graham 1992	Strong likelihood of selection bias, and large loss to follow up in experimental group. An open table of random numbers was used, with odd versus even digits determining group assignment, prior to seeking consent from subjects. Of the original sample of 145 women, 87 (60%) were allocated to the experimental group and 58 to the control group. Twenty-four women (27.6%) in the experimental group were lost to follow up, compared to 5 women (8.6%) in the control group.
Graham 2003	Not a report of an RCT. A description of a program.
Hamilton 2002	Not an RCT. A secondary analysis of Brooten 2001; analysis is not by group but by diagnostic category.
Hobel 1994	<p>The unit of randomization was the clinic and the unit of analysis was the patient, thus interfering with the estimates of effect by creating the potential for confidence intervals to be misleadingly narrow. No intraclass correlation co-efficient is reported.</p> <p>Five clinics were randomized to the experimental group and three to the control group. Women in the experimental clinics who met eligibility criteria and consented to participate were offered additional prenatal visits, education on prevention of preterm birth, screening for psychosocial and nutritional problems, and crisis intervention. Women in the experimental clinics were further randomized to 1 of 5 intervention groups: bedrest, psychosocial support, Provera, placebo, or nothing further. Women in the control clinics received usual care, which did not include education on preterm birth.</p> <p>Analyses are based on a subset of women, who met eligibility criteria and were not subsequently excluded or lost to follow up. Women in the experimental group differed significantly from those in the control group; the experimental group had a lower proportion of Hispanic women and women who had not completed high school, and averaged more high-risk problems. Approximately 15% in each group (336/2110 in the experimental group) and 154/1034 in the control group) were excluded from analyses or lost to follow up. Among the reasons for exclusion were stillbirth and multiple gestation.</p> <p>It is noteworthy that the study results were comparable to those of the included studies in this Review: no significant differences in preterm birth rate, rates of low birthweight, and mean gestational age.</p>
Kitzman 2000	This study compared two groups of women who had received prenatal and infancy home visitation 3 years ago, and was a follow up to determine the effectiveness of the program on their maternal life course. The purpose was not to evaluate the immediate impact of provision of additional support to high-risk pregnant women during prenatal and postpartum care.

## Characteristics of excluded studies (Continued)

Koniak-Griffin 2000	Not a trial of additional pregnancy support. Both study groups received 1-2 antenatal home visits by a nurse. The experimental group received additional visits during the year after birth. Also, although the sample was small (n = 144), there was prognostic stratification on 5 variables. And there may have been some attrition bias: 144 adolescents were originally enrolled, with no information about how many were in each group, and outcomes are reported for 95%-98% of the 121 who complied through the first 6 postpartum weeks, with no information about how many of the 23 withdrawals were in each group.
Little 2002	Large losses to follow up; outcome data available for just 70% of those originally randomized.
Oakley 1996	This report describes the results of a 7-year follow-up postal survey of the participants in an earlier trial (Oakley 1990). Data were available for fewer than 50% of the trial participants (126 of 255 in the intervention group and 115 of 254 in the control group).
RCT: randomized controlled trial	

## ANALYSES

### Comparison 01. Additional support versus usual care during at-risk pregnancy

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Miscarriage	4	4195	Relative Risk (Fixed) 95% CI	0.99 [0.73, 1.35]
02 Termination of pregnancy	4	4195	Relative Risk (Fixed) 95% CI	2.96 [1.42, 6.17]
03 Antenatal anxiety score	1	60	Weighted Mean Difference (Fixed) 95% CI	-7.85 [-13.14, -2.56]
04 Less than very satisfied with antenatal care	1	158	Relative Risk (Fixed) 95% CI	0.42 [0.25, 0.73]
05 Antenatal depression	1	509	Relative Risk (Fixed) 95% CI	0.77 [0.50, 1.19]
06 Antenatal hospital admission	6	1933	Relative Risk (Random) 95% CI	0.86 [0.68, 1.08]
07 Antenatal hypertension	1	509	Relative Risk (Fixed) 95% CI	0.95 [0.55, 1.66]
08 Intrapartum analgesia/ anaesthesia	3	4032	Relative Risk (Fixed) 95% CI	0.94 [0.89, 1.00]
09 Induction of labour	4	1065	Relative Risk (Fixed) 95% CI	0.91 [0.77, 1.07]
10 Caesarean birth	9	5108	Relative Risk (Fixed) 95% CI	0.88 [0.79, 0.98]
11 Instrumental vaginal birth	6	5533	Relative Risk (Fixed) 95% CI	1.01 [0.89, 1.14]
12 Gestational age < 37 weeks at birth	11	10237	Relative Risk (Fixed) 95% CI	0.96 [0.86, 1.07]
13 Gestational age at birth	5	2152	Weighted Mean Difference (Fixed) 95% CI	0.17 [-0.06, 0.40]
14 Birth weight < 1500 gm	3	2428	Relative Risk (Fixed) 95% CI	0.72 [0.47, 1.09]
15 Birth weight < 2500 gm	13	10235	Relative Risk (Fixed) 95% CI	0.98 [0.89, 1.08]
16 Birth weight (gm)	6	3029	Weighted Mean Difference (Random) 95% CI	20.88 [-53.35, 95.11]
17 Small for gestational age	2	3523	Relative Risk (Fixed) 95% CI	1.05 [0.88, 1.26]
18 Stillbirth/neonatal death	11	9507	Relative Risk (Fixed) 95% CI	1.15 [0.89, 1.51]
19 Apgar score < 7 at 1 minute	3	1209	Relative Risk (Fixed) 95% CI	0.81 [0.60, 1.09]
20 Apgar score < 7 at 5 minutes	4	3444	Relative Risk (Fixed) 95% CI	0.99 [0.61, 1.61]
21 Newborn respiratory distress	1	509	Relative Risk (Fixed) 95% CI	0.54 [0.22, 1.32]
22 Admission to neonatal intensive care nursery	4	3467	Relative Risk (Fixed) 95% CI	0.92 [0.77, 1.09]
23 Absence of other help at home	1	158	Relative Risk (Fixed) 95% CI	0.39 [0.21, 0.73]
24 Postnatal physical problems	1	509	Relative Risk (Fixed) 95% CI	0.93 [0.85, 1.03]
25 Postnatal re-hospitalization	2	682	Relative Risk (Fixed) 95% CI	0.91 [0.56, 1.49]
26 Poor postnatal health	1	509	Relative Risk (Fixed) 95% CI	0.77 [0.59, 1.00]
27 Prefer hospitalization in at-risk pregnancy	1	158	Relative Risk (Fixed) 95% CI	0.88 [0.33, 2.30]
28 Feeling low control postnatally	1	509	Relative Risk (Fixed) 95% CI	0.78 [0.59, 1.03]

29 Feeling worried about baby	1	509	Relative Risk (Fixed) 95% CI	0.57 [0.39, 0.82]
30 Postnatal depression	1	509	Relative Risk (Fixed) 95% CI	0.86 [0.69, 1.06]
31 Additional health service use	1	509	Relative Risk (Fixed) 95% CI	0.88 [0.76, 1.02]

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Infant, Low Birth Weight; Infant, Newborn; Infant, Premature; \*Pregnancy, High-Risk; Pregnancy Outcome; Randomized Controlled Trials; \*Social Support

### MeSH check words

Female; Humans; Pregnancy

## COVER SHEET

<b>Title</b>	Support during pregnancy for women at increased risk of low birthweight babies
<b>Authors</b>	Hodnett ED, Fredericks S
<b>Contribution of author(s)</b>	Ellen Hodnett had overall responsibility for every aspect of the Review. Suzanne Fredericks performed the second data entry for the new trials in the updated Review, helped to write a draft of a revised Background, and participated in decisions regarding eligibility of trials, interpretations of the results and all other aspects of the Review.
<b>Issue protocol first published</b>	1995/1
<b>Review first published</b>	1995/1
<b>Date of most recent amendment</b>	06 February 2006
<b>Date of most recent SUBSTANTIVE amendment</b>	16 May 2003
<b>What's New</b>	September 2005 Updated literature search resulted in addition of two included trials (Brooten 2001; Dawson 1999) and two excluded studies (Ford 2002; Graham 2003). The additions led to minor modifications in test statistics but did not lead to changes in the conclusions of the Review. Two trials await assessment (Beazeu 2001; Nguyen 2003), one because only a brief abstract was available and the other because the reported results are for a portion of the final sample. Typos were corrected. One study ID was changed to reflect the name of the primary author (Middlemiss 1989 is now identified as Dawson 1989).
<b>Date new studies sought but none found</b>	Information not supplied by author
<b>Date new studies found but not yet included/excluded</b>	Information not supplied by author
<b>Date new studies found and included/excluded</b>	30 September 2005
<b>Date authors' conclusions section amended</b>	14 March 2003
<b>Contact address</b>	Prof Ellen Hodnett Professor Lawrence S. Bloomberg Faculty of Nursing University of Toronto

155 College Street  
Suite 130  
Toronto  
Ontario  
M5T 1P8  
CANADA  
E-mail: ellen.hodnett@utoronto.ca  
Tel: +1 416 9468676  
Fax: +1 416 9468681

**DOI** 10.1002/14651858.CD000198  
**Cochrane Library number** CD000198  
**Editorial group** Cochrane Pregnancy and Childbirth Group  
**Editorial group code** HM-PREG

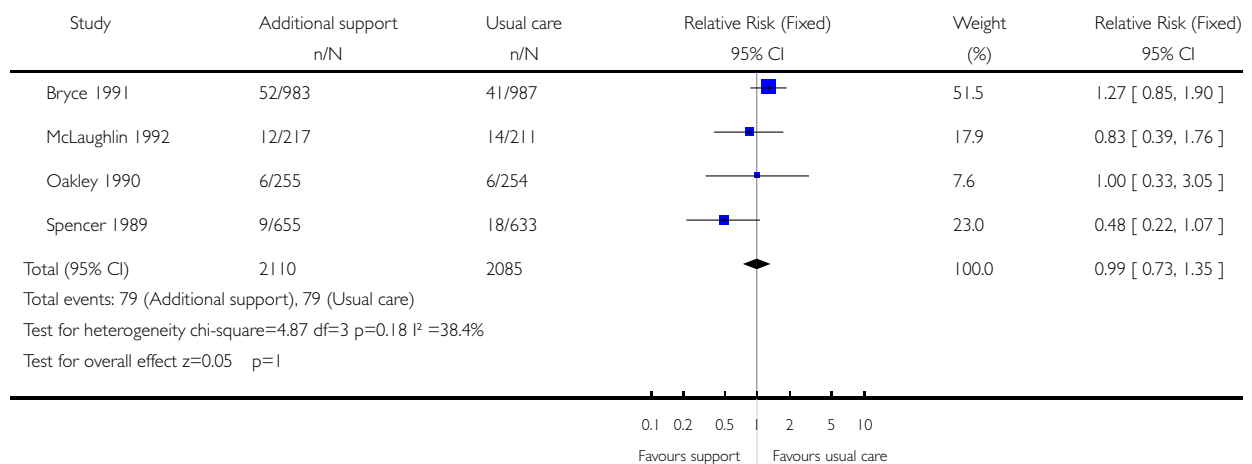
## GRAPHS AND OTHER TABLES

### Analysis 01.01. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 01 Miscarriage

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 01 Miscarriage



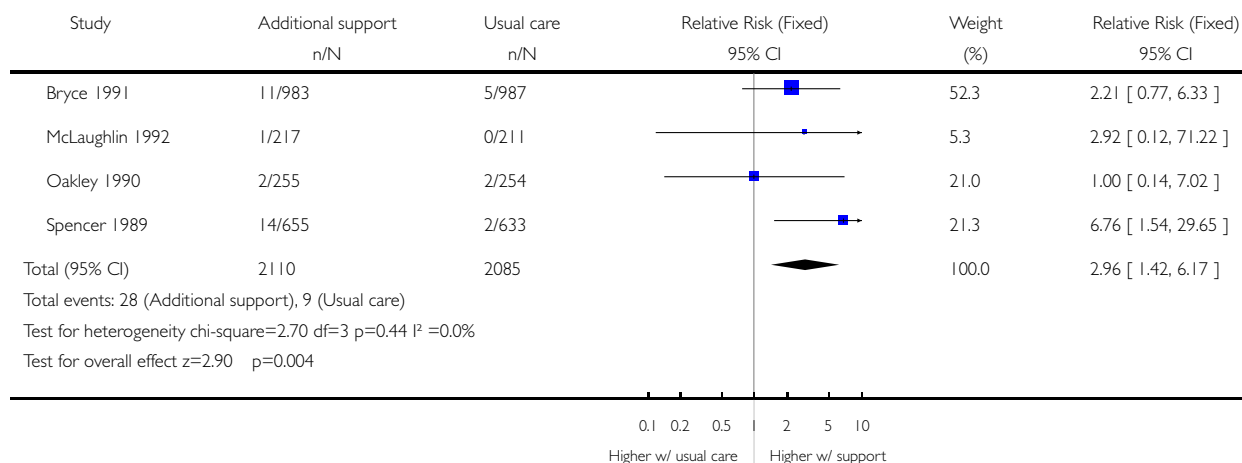


## Analysis 01.02. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 02 Termination of pregnancy

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 02 Termination of pregnancy

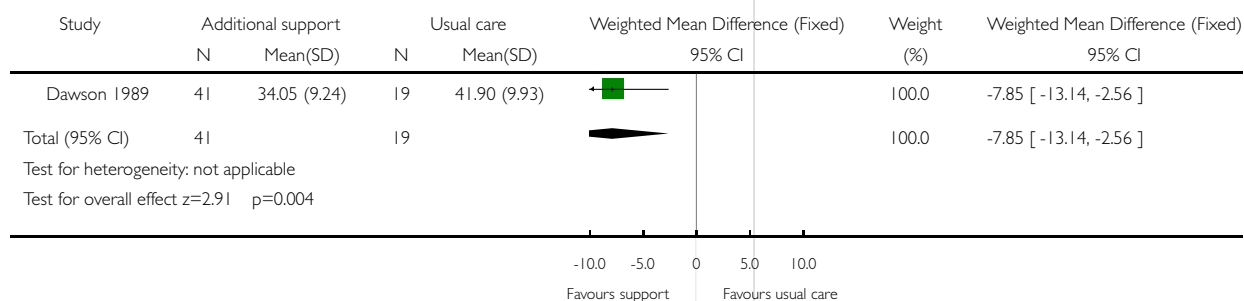


## Analysis 01.03. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 03 Antenatal anxiety score

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 03 Antenatal anxiety score

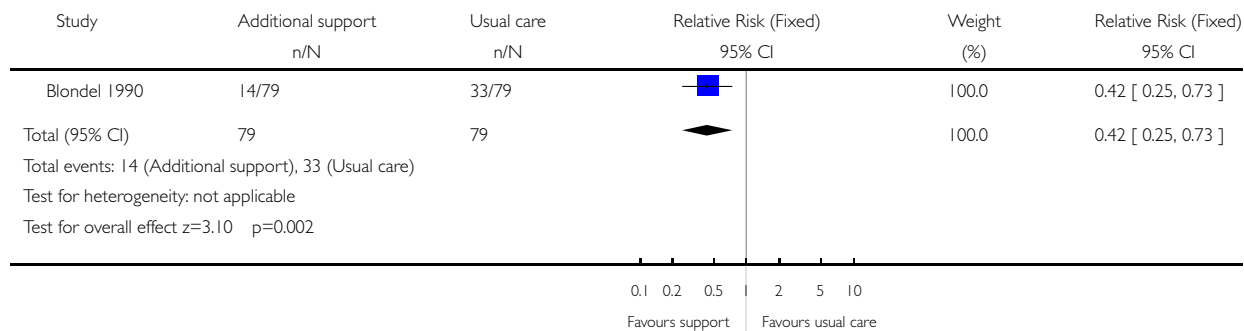


#### Analysis 01.04. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 04 Less than very satisfied with antenatal care

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 04 Less than very satisfied with antenatal care

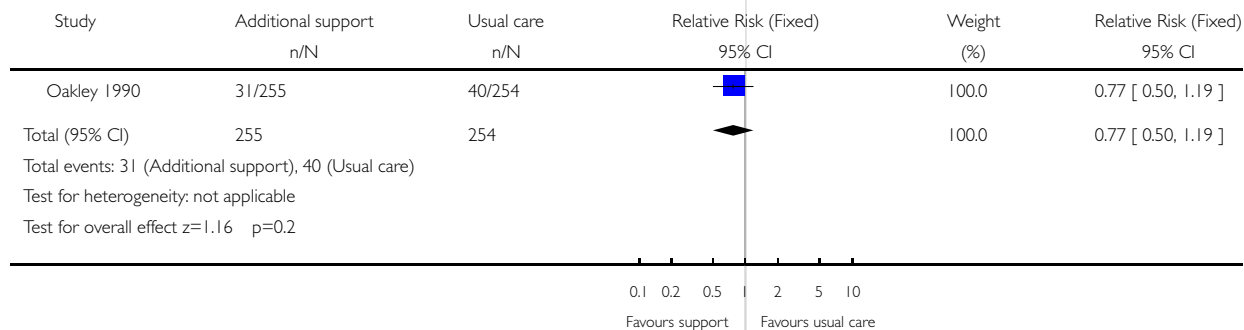


#### Analysis 01.05. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 05 Antenatal depression

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 05 Antenatal depression

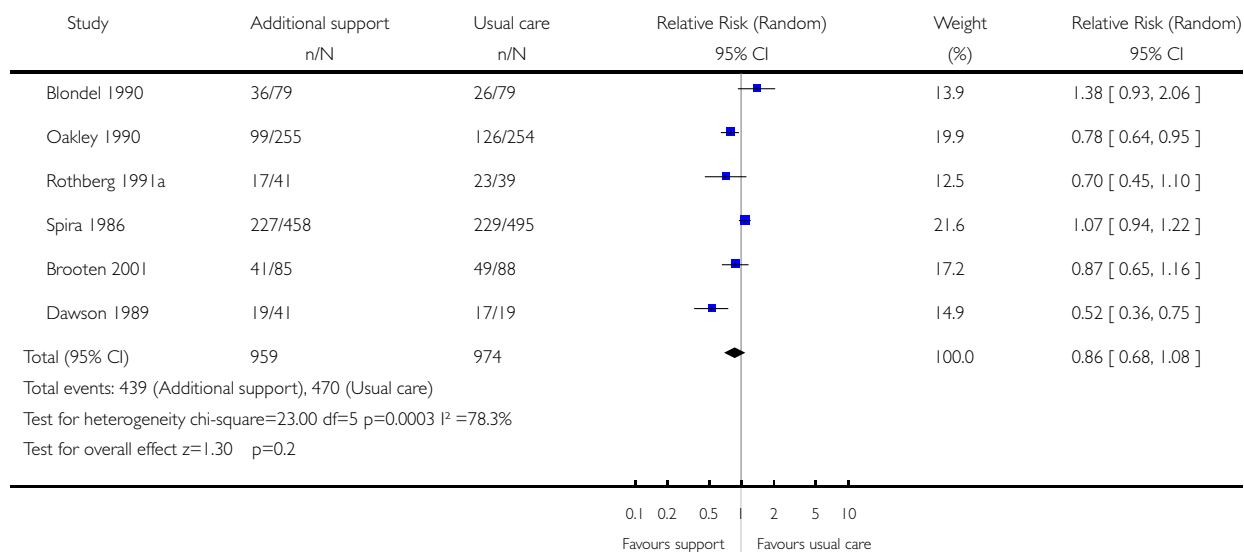


### Analysis 01.06. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 06 Antenatal hospital admission

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 06 Antenatal hospital admission

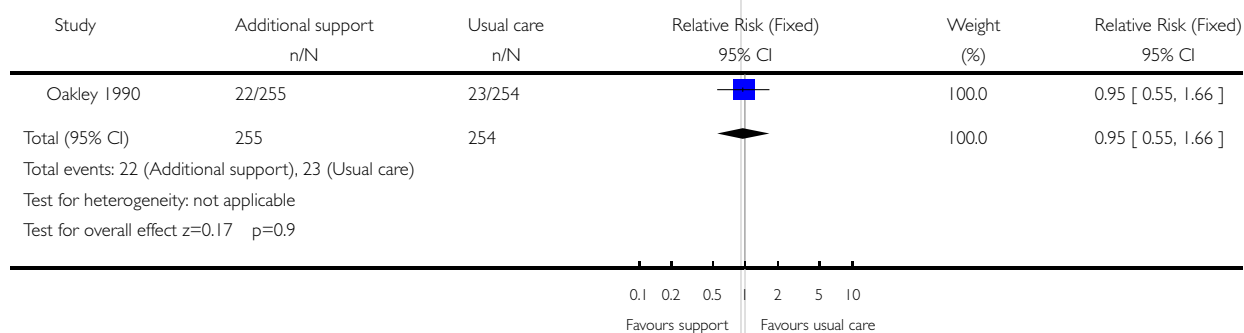


### Analysis 01.07. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 07 Antenatal hypertension

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 07 Antenatal hypertension

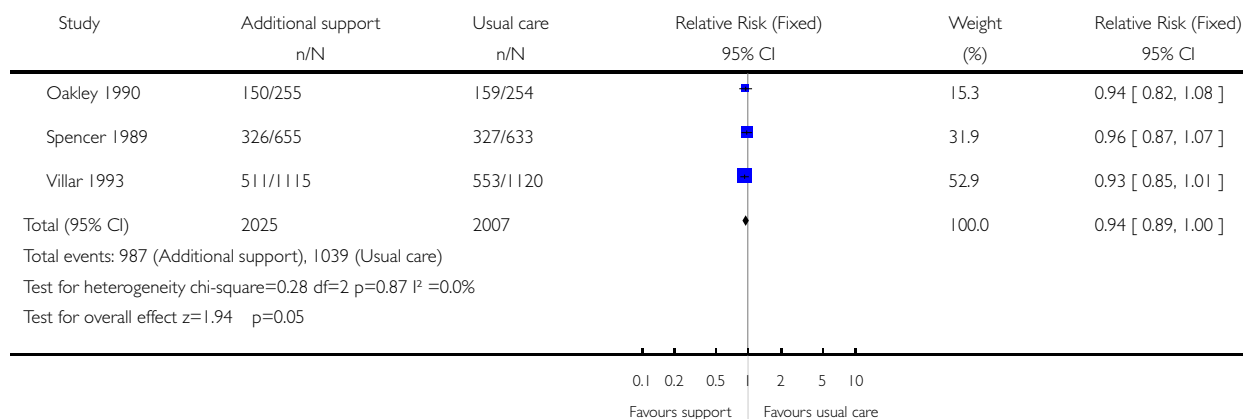


### Analysis 01.08. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 08 Intrapartum analgesia/anaesthesia

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 08 Intrapartum analgesia/anaesthesia

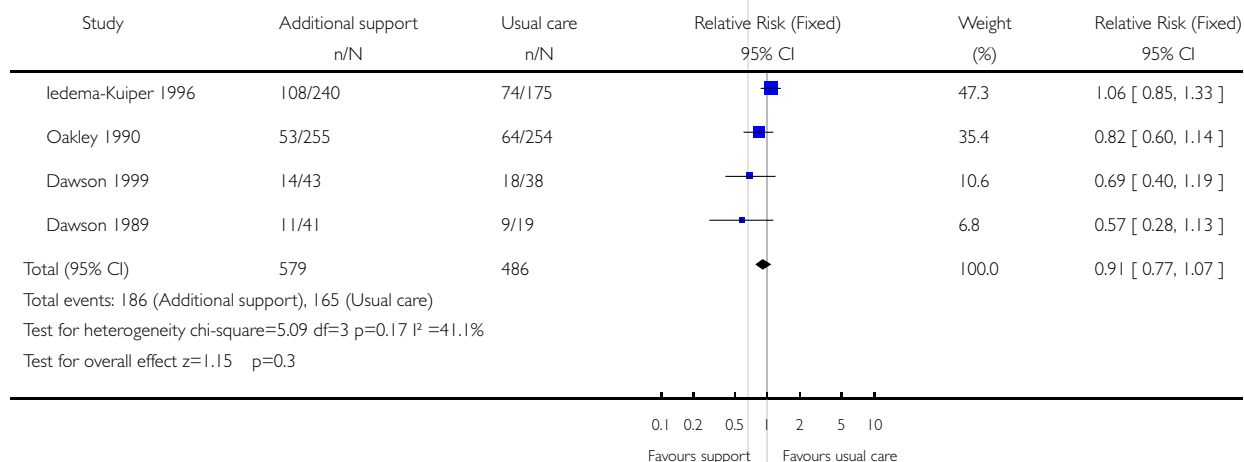


### Analysis 01.09. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 09 Induction of labour

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 09 Induction of labour

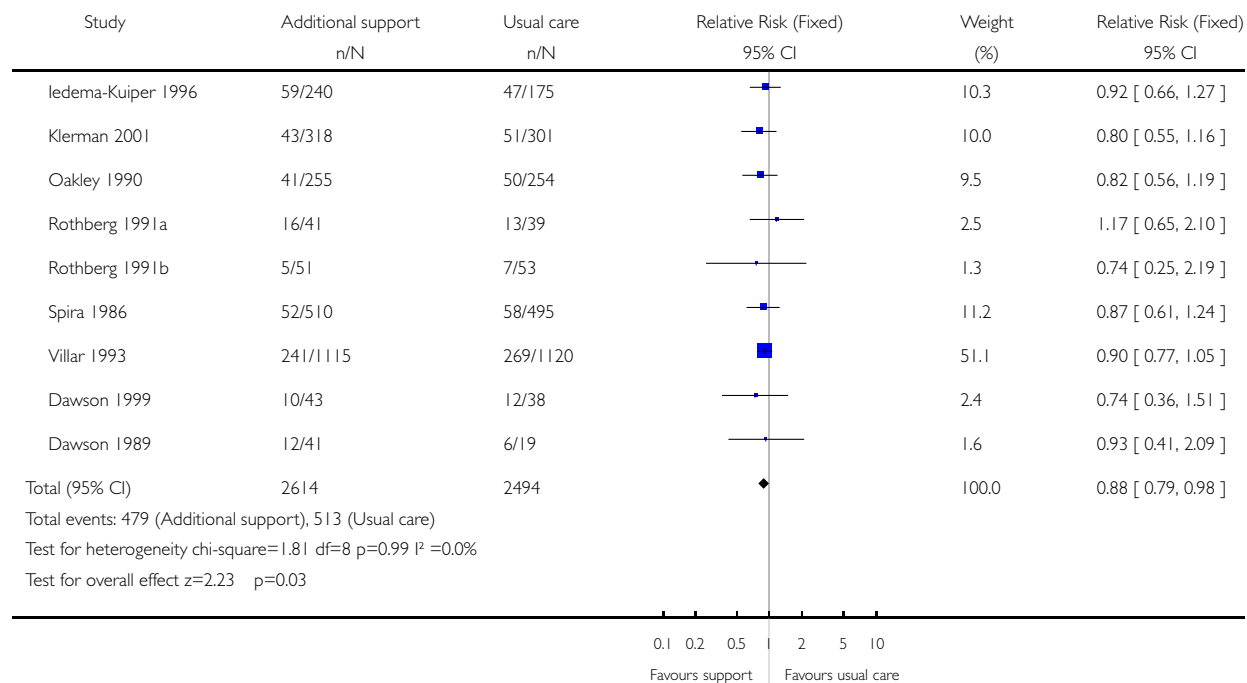


# **Analysis 01.10. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 10 Caesarean birth**

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 10 Caesarean birth

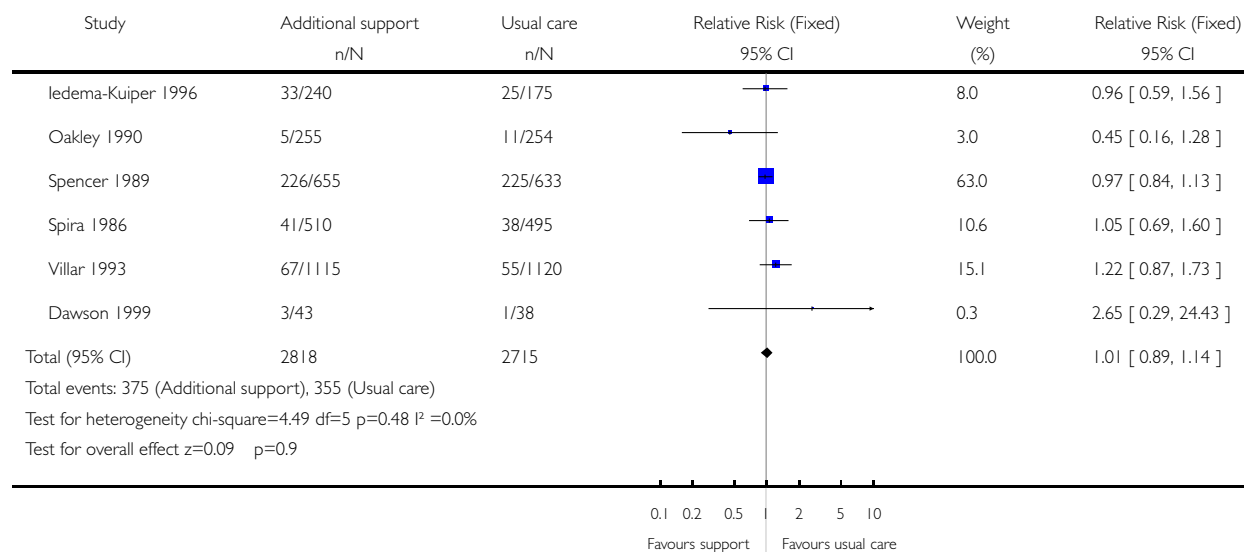


### Analysis 01.11. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 11 Instrumental vaginal birth

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 11 Instrumental vaginal birth

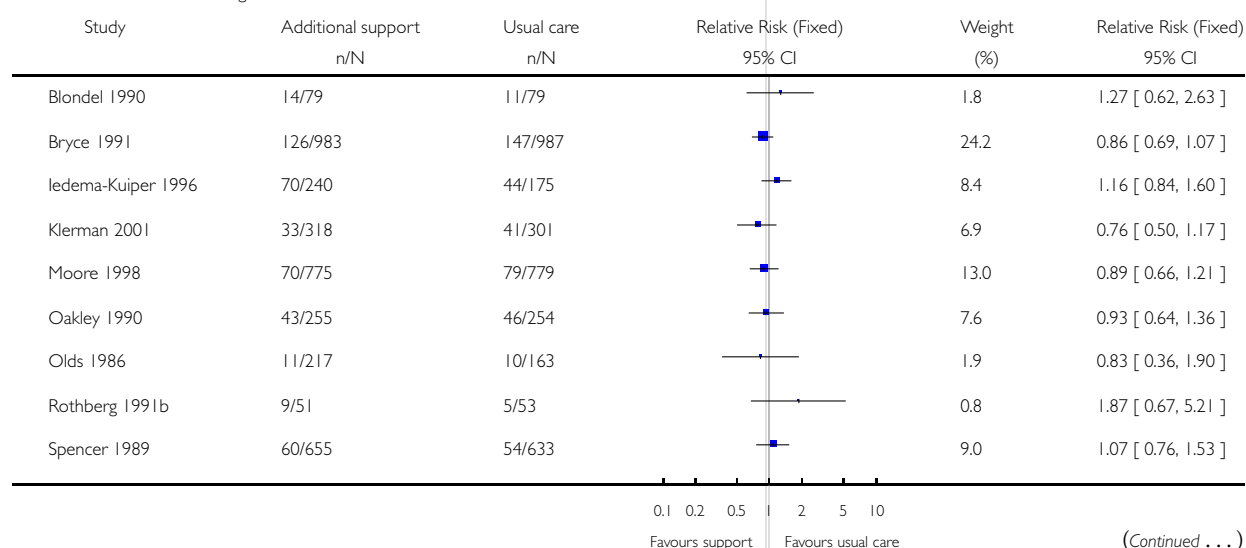


### Analysis 01.12. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 12 Gestational age < 37 weeks at birth

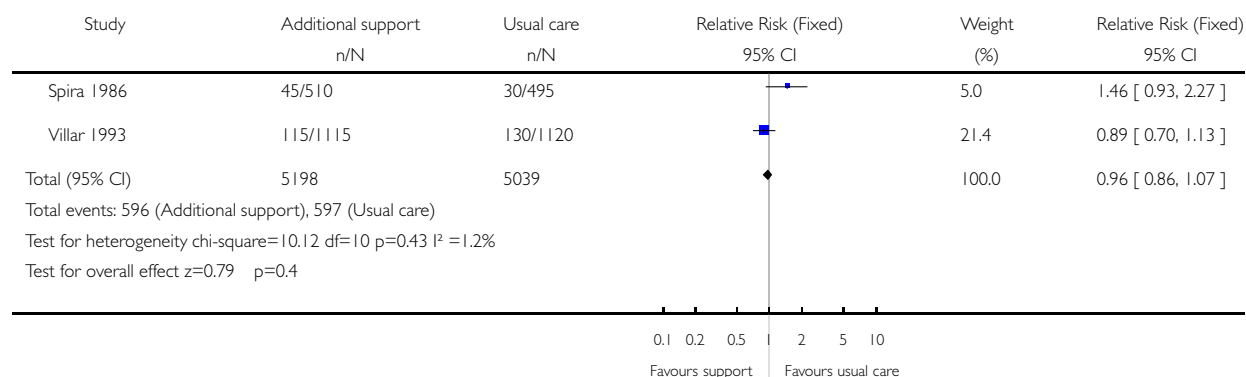
Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 12 Gestational age < 37 weeks at birth



(... Continued)

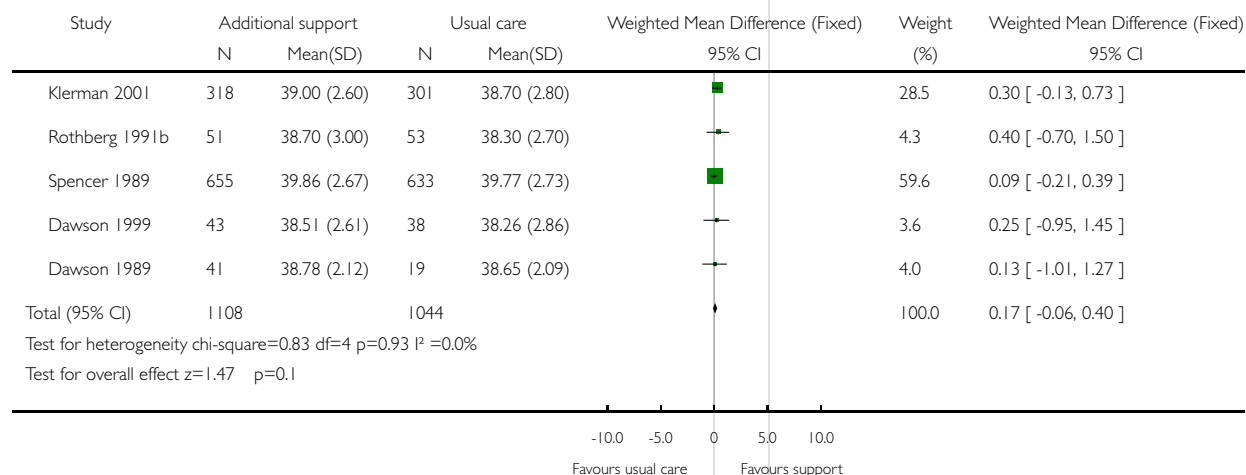


### Analysis 01.13. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 13 Gestational age at birth

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 13 Gestational age at birth

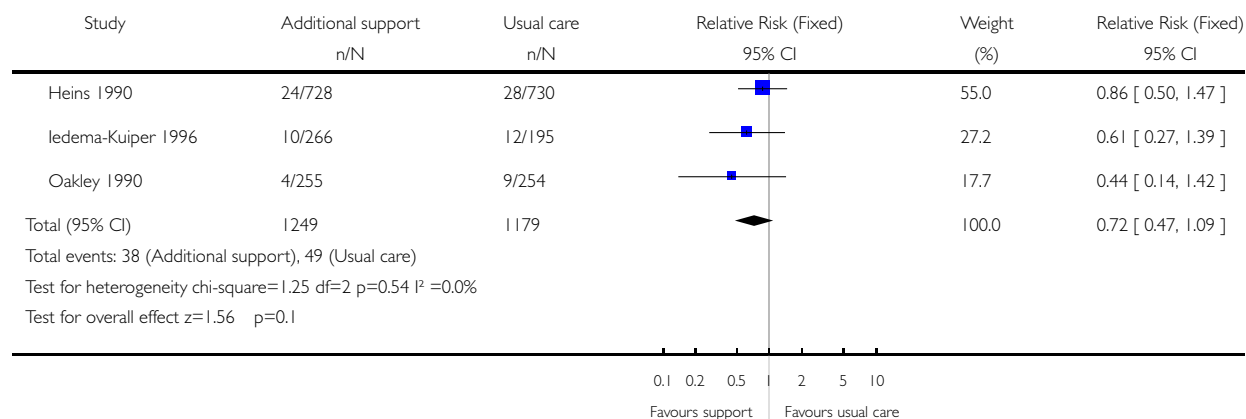


### Analysis 01.14. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 14 Birth weight < 1500 gm

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 14 Birth weight < 1500 gm

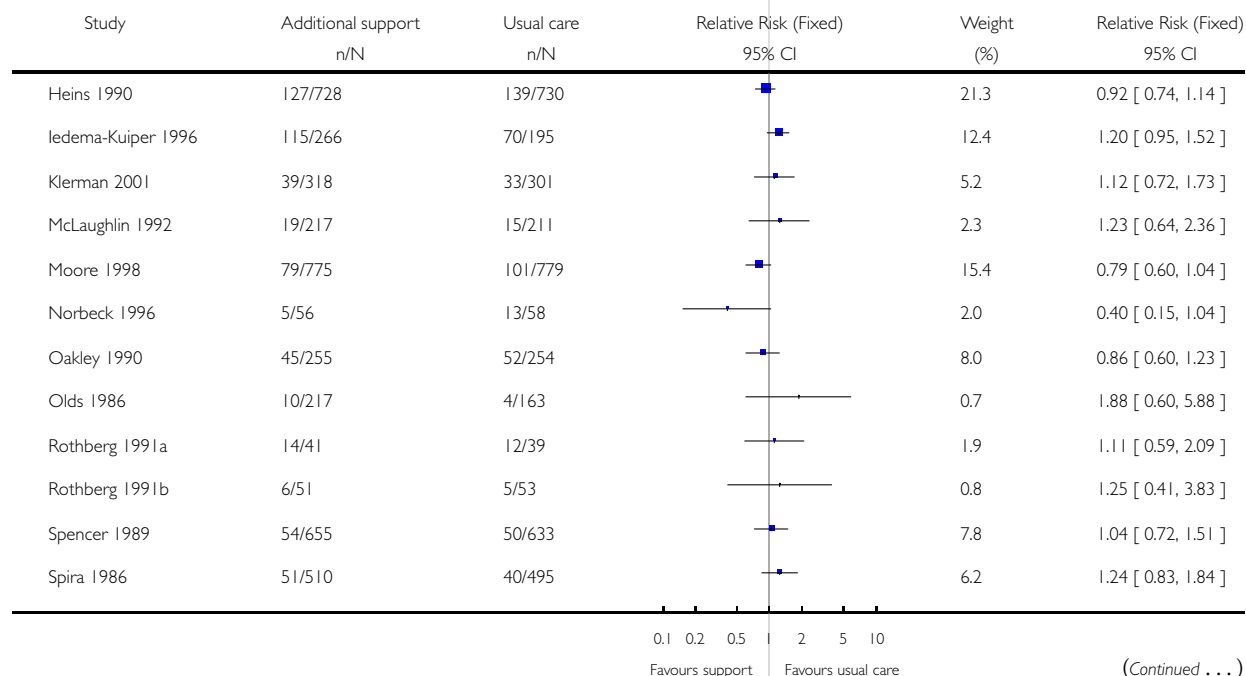


### Analysis 01.15. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 15 Birth weight < 2500 gm

Review: Support during pregnancy for women at increased risk of low birthweight babies

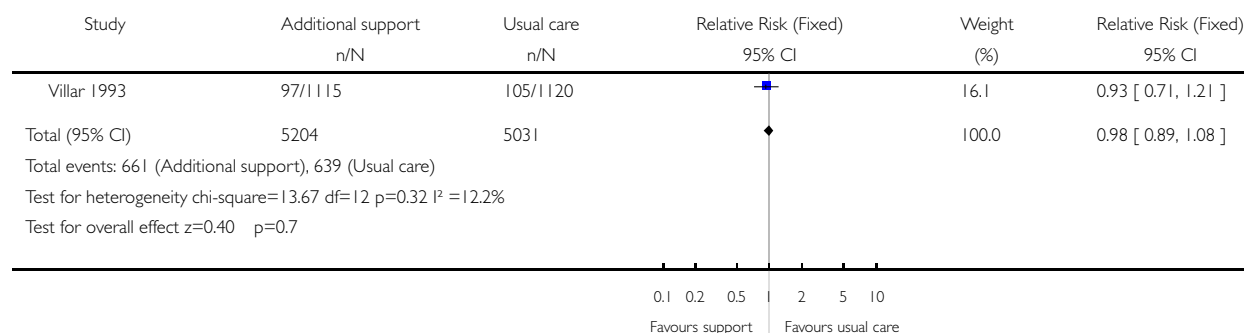
Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 15 Birth weight < 2500 gm





(... Continued)

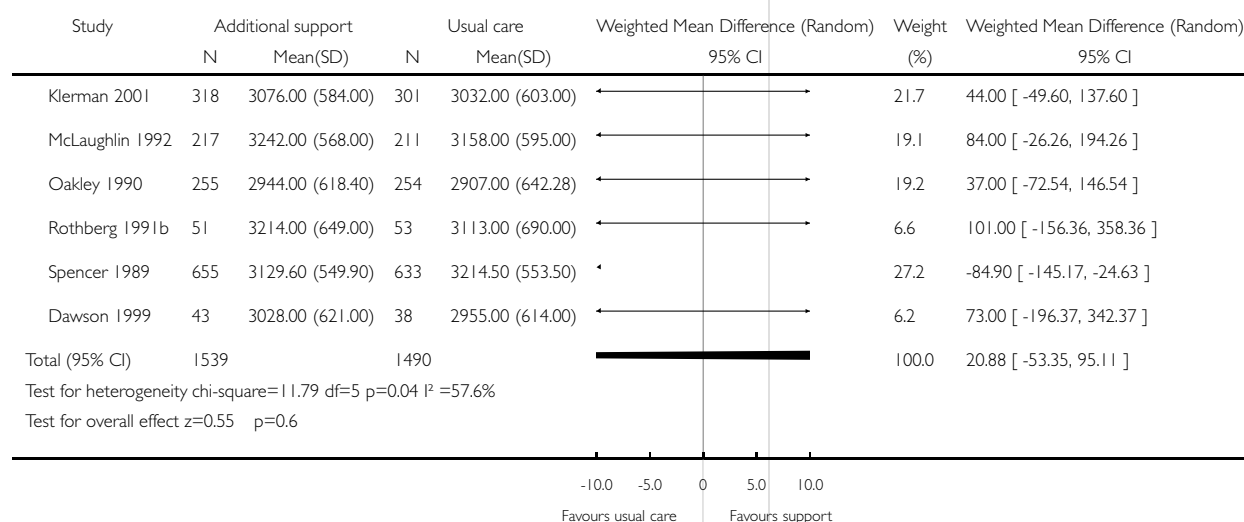


### Analysis 01.16. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 16 Birth weight (gm)

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 16 Birth weight (gm)

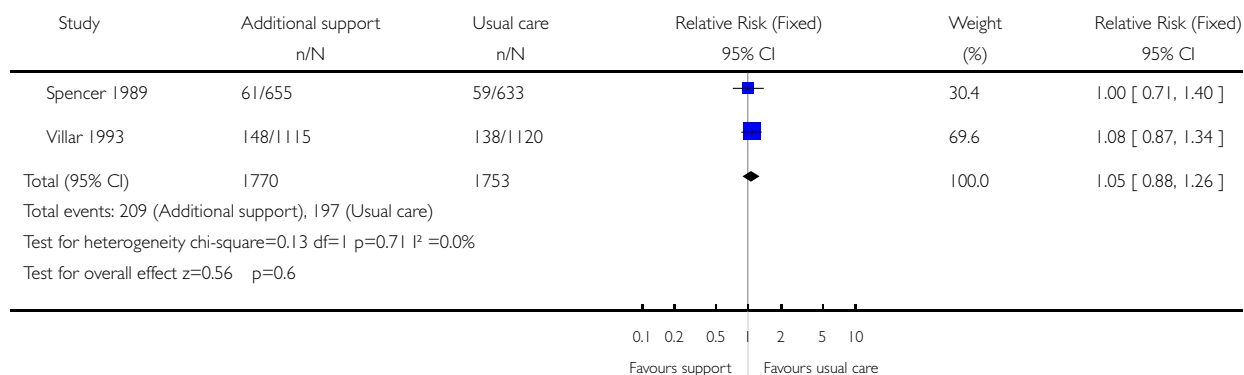


### Analysis 01.17. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 17 Small for gestational age

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 17 Small for gestational age

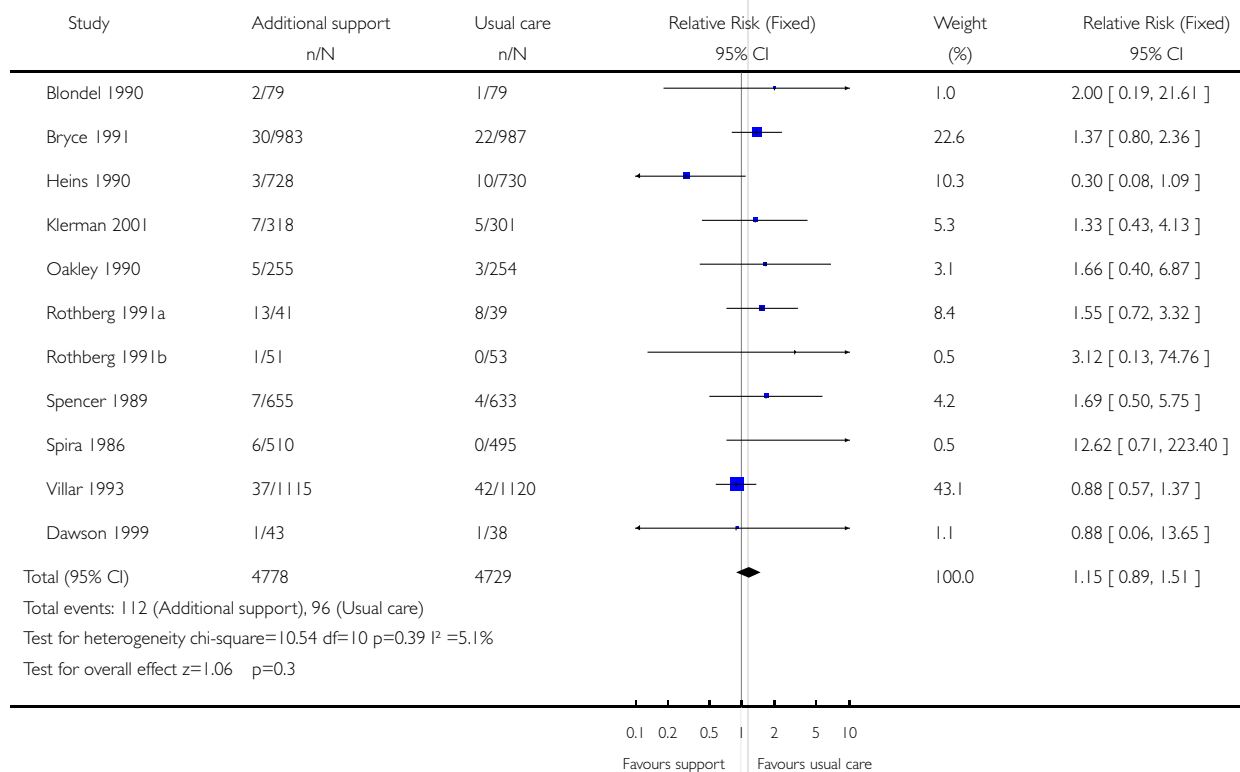


### Analysis 01.18. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 18 Stillbirth/neonatal death

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 18 Stillbirth/neonatal death

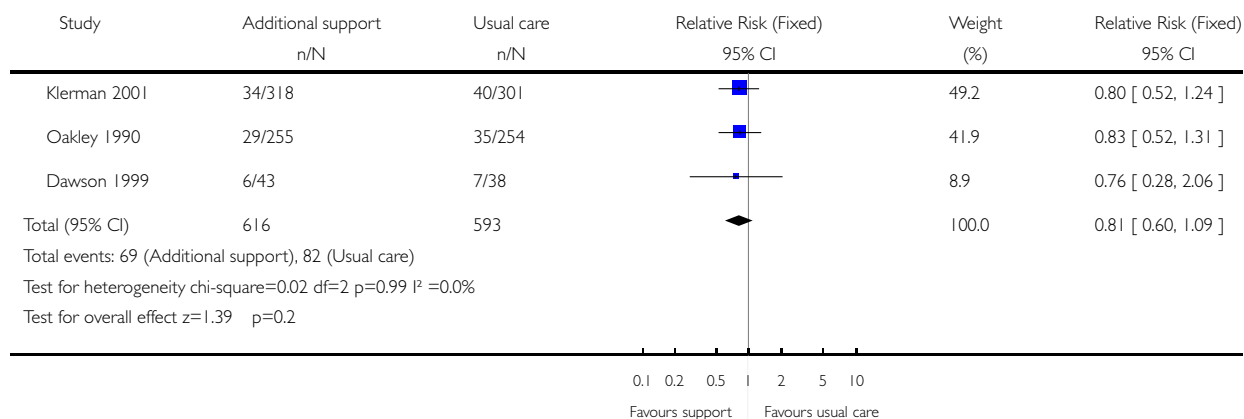


### Analysis 01.19. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 19 Apgar score < 7 at 1 minute

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 19 Apgar score < 7 at 1 minute

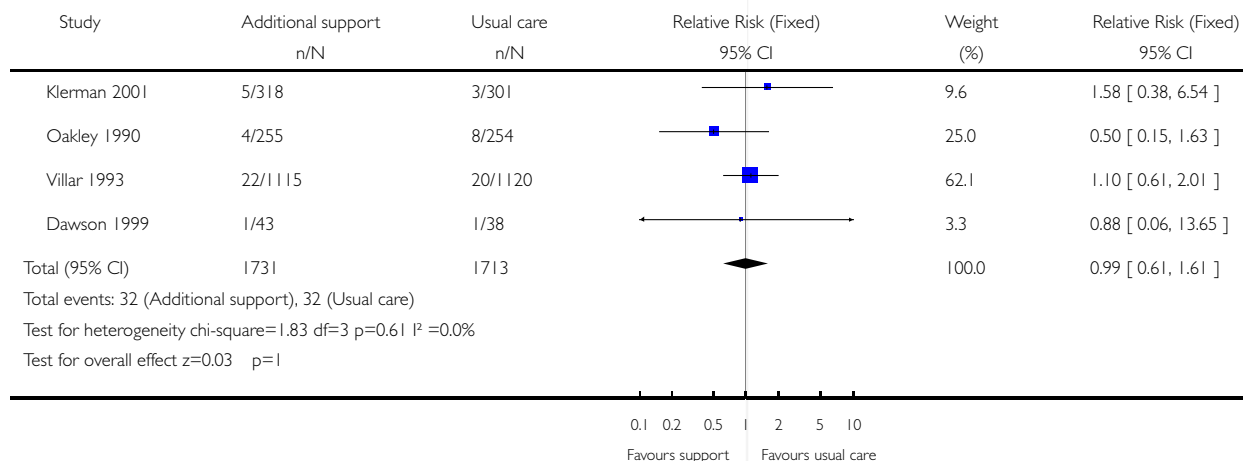


### Analysis 01.20. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 20 Apgar score < 7 at 5 minutes

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 20 Apgar score < 7 at 5 minutes

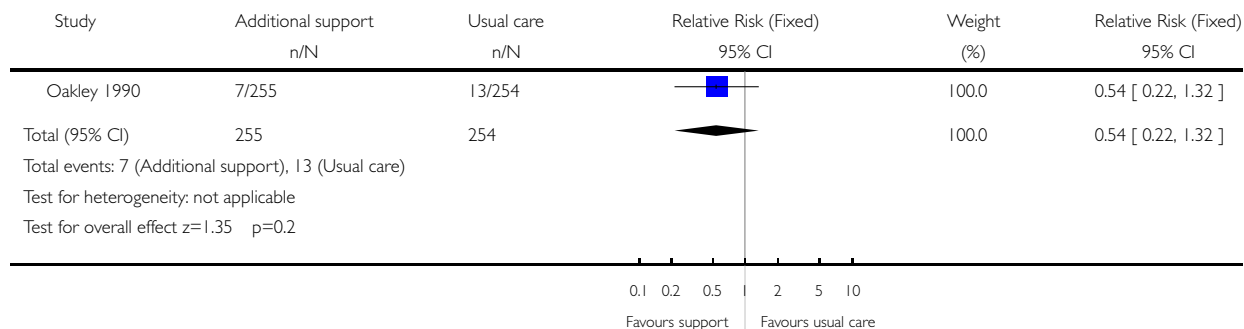


### Analysis 01.21. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 21 Newborn respiratory distress

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 21 Newborn respiratory distress

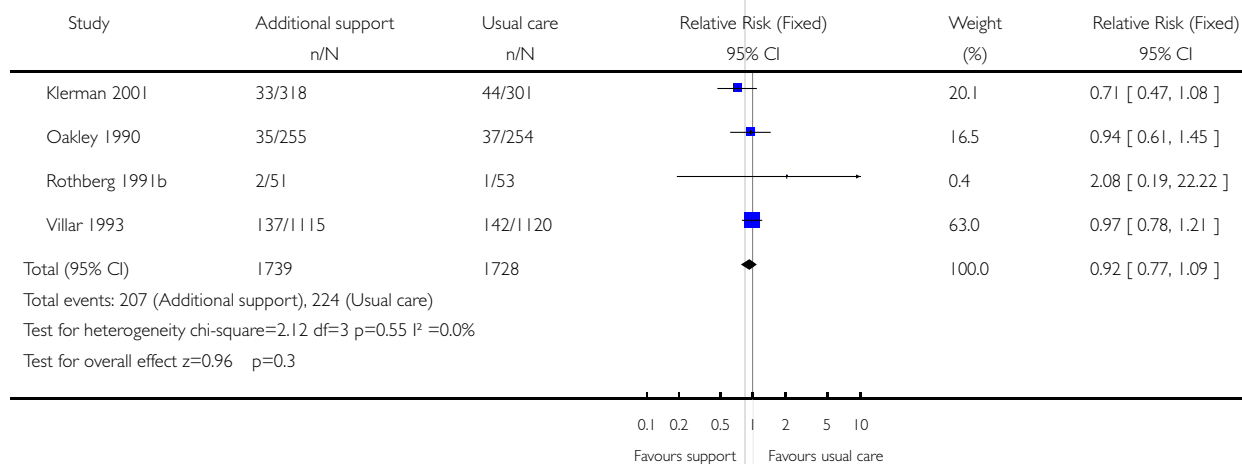


### Analysis 01.22. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 22 Admission to neonatal intensive care nursery

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 22 Admission to neonatal intensive care nursery

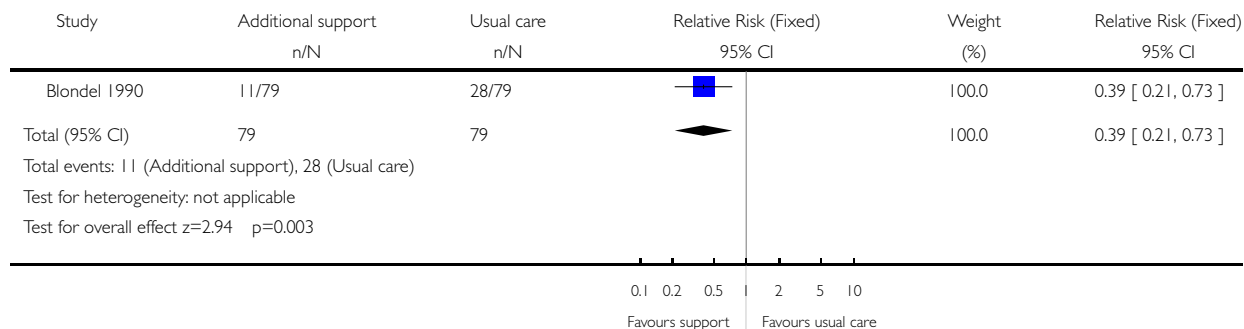


### Analysis 01.23. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 23 Absence of other help at home

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 23 Absence of other help at home

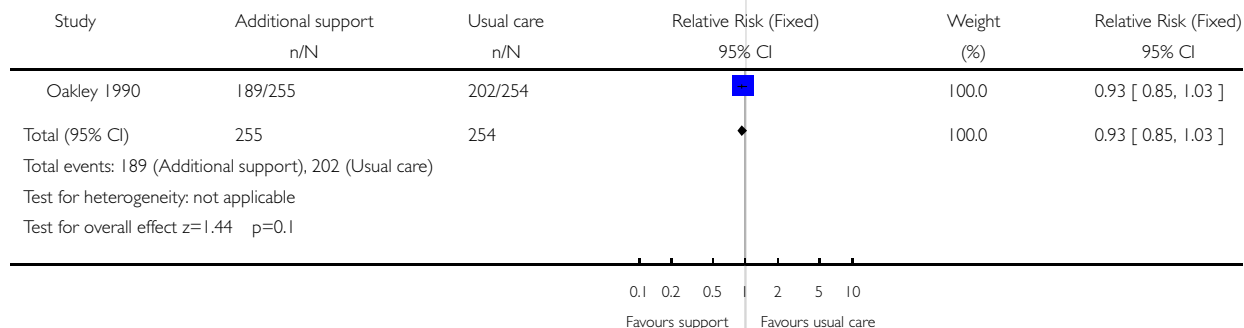


### Analysis 01.24. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 24 Postnatal physical problems

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 24 Postnatal physical problems

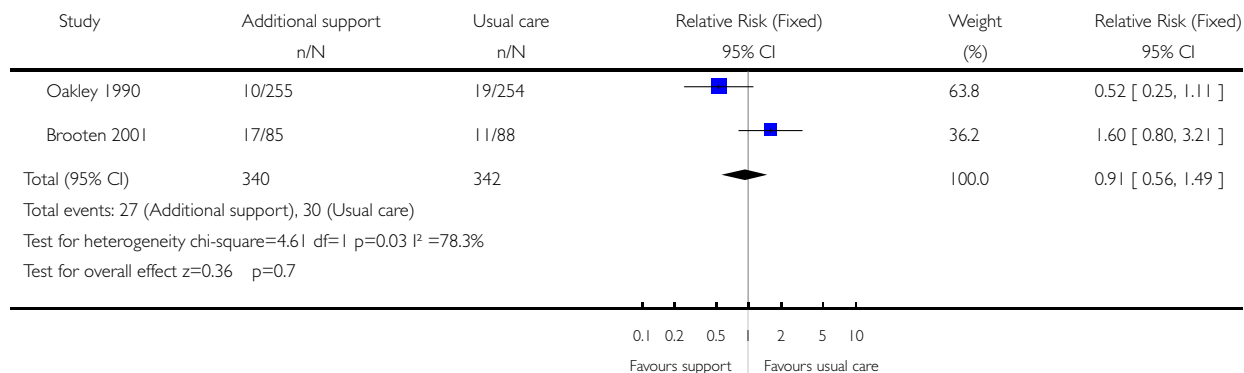


### Analysis 01.25. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 25 Postnatal re-hospitalization

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 25 Postnatal re-hospitalization

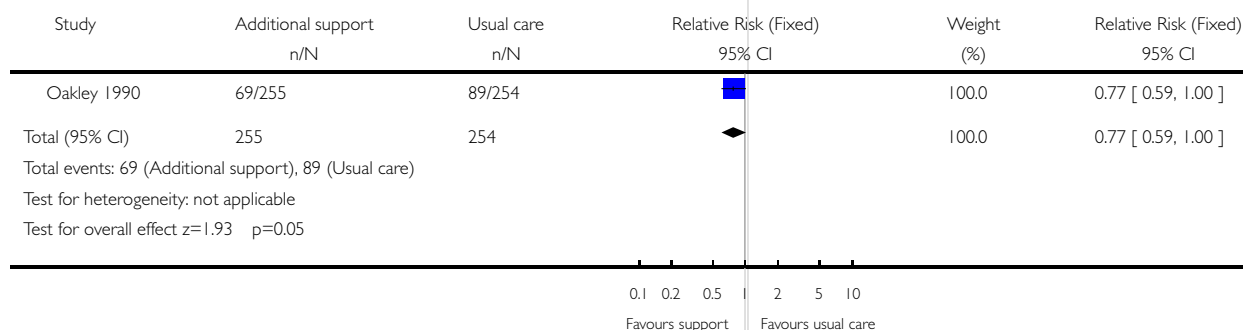


### Analysis 01.26. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 26 Poor postnatal health

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 26 Poor postnatal health

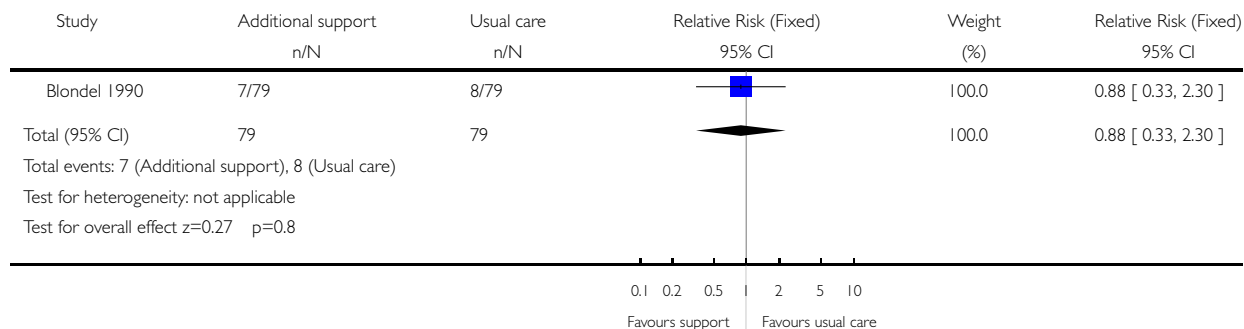


### Analysis 01.27. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 27 Prefer hospitalization in at-risk pregnancy

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 27 Prefer hospitalization in at-risk pregnancy

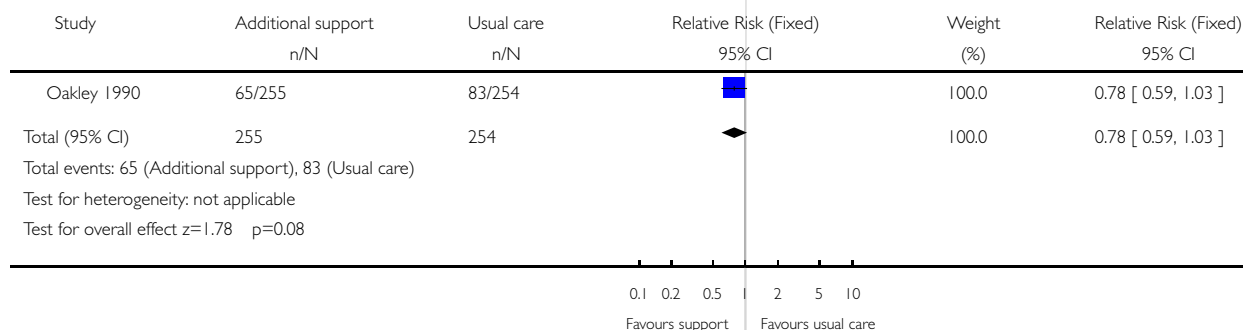


### Analysis 01.28. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 28 Feeling low control postnatally

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 28 Feeling low control postnatally

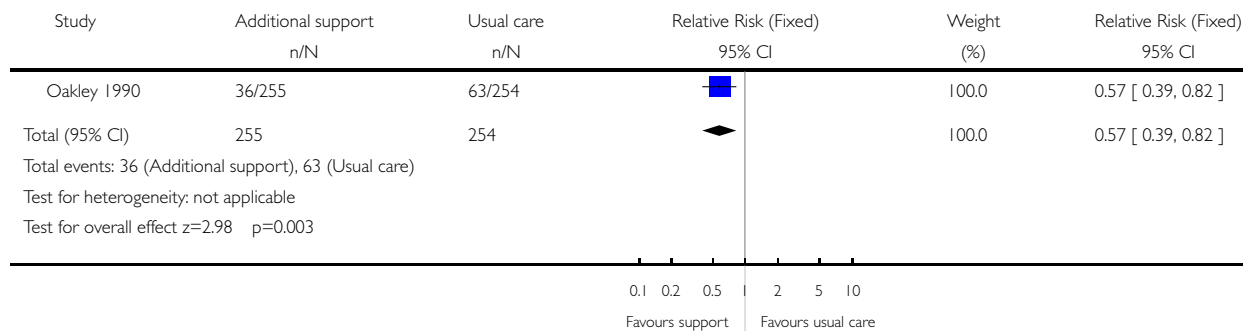


### Analysis 01.29. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 29 Feeling worried about baby

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 29 Feeling worried about baby

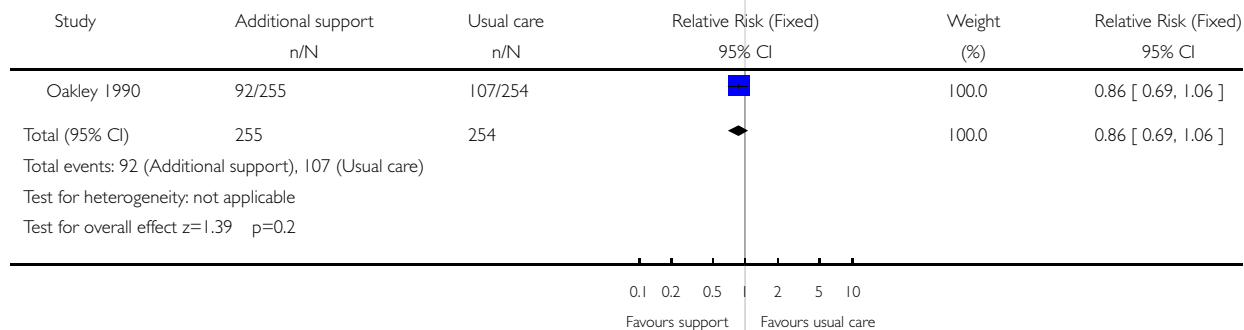


### Analysis 01.30. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 30 Postnatal depression

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 30 Postnatal depression





### Analysis 01.31. Comparison 01 Additional support versus usual care during at-risk pregnancy, Outcome 31 Additional health service use

Review: Support during pregnancy for women at increased risk of low birthweight babies

Comparison: 01 Additional support versus usual care during at-risk pregnancy

Outcome: 31 Additional health service use

