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East CE, Biro MA, Fredericks S, Lau R.
Support during pregnancy for women at increased risk of low birthweight babies.
Cochrane Database of Systematic Reviews 2019, Issue 4. Art. No.: CD000198.
DOI: [10.1002/14651858.CD000198.pub3](https://doi.org/10.1002/14651858.CD000198.pub3).

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[Intervention Review]

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

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Editorial group: Cochrane Pregnancy and Childbirth Group.

Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 4, 2019.

Citation: East CE, Biro MA, Fredericks S, Lau R. Support during pregnancy for women at increased risk of low birthweight babies. *Cochrane Database of Systematic Reviews* 2019, Issue 4. Art. No.: CD000198. DOI: [10.1002/14651858.CD000198.pub3](https://doi.org/10.1002/14651858.CD000198.pub3).

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ABSTRACT

Background

Studies consistently show a relationship between social disadvantage and low birthweight. Many countries have programmes offering special assistance to women thought to be at risk for giving birth to a low birthweight infant. These programmes, collectively referred to in this review as additional social support, may include emotional support, which gives a person a feeling of being loved and cared for, tangible/instrumental support, in the form of direct assistance/home visits, and informational support, through the provision of advice, guidance and counselling. The programmes may be delivered by multidisciplinary teams of health professionals, specially trained lay workers, or a combination of lay and professional workers. This is an update of a review first published in 2003 and updated in 2010.

Objectives

The primary objective was to assess the effects of programmes offering additional social support (emotional, instrumental/tangible and informational) compared with routine care, for pregnant women believed to be at high risk for giving birth to babies that are either preterm (less than 37 weeks' gestation) or weigh less than 2500 g, or both, at birth. Secondary objectives were to determine whether the effectiveness of support was mediated by timing of onset (early versus later in pregnancy) or type of provider (healthcare professional or lay person).

Search methods

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register, [ClinicalTrials.gov](https://www.clinicaltrials.gov), the WHO International Clinical Trials Registry Platform ([ICTRP](https://www.who.int/clinicaltrialsregistryplatform)) on 5 February 2018, and reference lists of retrieved studies.

Selection criteria

Randomised trials of additional social support during at-risk pregnancy by either a professional (social worker, midwife, or nurse) or specially trained lay person, compared to routine care. We defined additional social support as some form of emotional support (e.g. caring, empathy, trust), tangible/instrumental support (e.g. transportation to clinic appointments, home visits complemented with phone calls, help with household responsibilities) or informational support (advice and counselling about nutrition, rest, stress management, use of alcohol/recreational drugs).

Data collection and analysis

Two review authors independently assessed studies for inclusion and risk of bias, extracted data and checked them for accuracy. We assessed the quality of the evidence using the GRADE approach.

Main results

This updated review includes a total of 25 studies, with outcome data for 11,246 mothers and babies enrolled in 21 studies. We assessed the overall risk of bias of included studies to be low or unclear, mainly because of limited reporting or uncertainty in how randomisation was generated or concealed (which led us to downgrade the quality of most outcomes to moderate), and the impracticability of blinding participants.

When compared with routine care, programmes offering additional social support for at-risk pregnant women may slightly reduce the number of babies born with a birthweight less than 2500 g from 127 per 1000 to 120 per 1000 (risk ratio (RR) 0.94, 95% confidence interval (CI) 0.86 to 1.04; 16 studies, $n = 11,770$; moderate-quality evidence), and the number of babies born with a gestational age less than 37 weeks at birth from 128 per 1000 to 117 per 1000 (RR 0.92, 95% CI 0.84 to 1.01, 14 studies, $n = 12,282$; moderate-quality evidence), though the confidence intervals for the pooled effect for both of these outcomes just crossed the line of no effect, suggesting any effect is not large. There may be little or no difference between interventions for stillbirth/neonatal death (RR 1.11, 95% CI 0.88 to 1.41; 15 studies, $n = 12,091$; low-quality evidence). Secondary outcomes of moderate quality suggested that there is probably a reduction in caesarean section (from 215 per 1000 to 194 per 1000; RR 0.90, 95% CI 0.83 to 0.97; 15 studies, $n = 9550$), a reduction in the number of antenatal hospital admissions per participant (RR 0.78, 95% CI 0.68 to 0.91; 4 studies; $n = 787$), and a reduction in the mean number of hospitalisation episodes (mean difference -0.05 , 95% CI -0.06 to -0.04 ; 1 study, $n = 1525$) in the social support group, compared to the controls.

Postnatal depression and women's satisfaction were reported in different ways in the studies that considered these outcomes and so we could not include data in a meta-analysis. In one study postnatal depression appeared to be slightly lower in the support group in women who screened positively on the Edinburgh Postnatal Depression Scale at eight to 12 weeks postnatally (RR 0.74, 95% CI 0.55 to 1.01; 1 study, $n = 1008$; moderate-quality evidence). In another study, again postnatal depression appeared to be slightly lower in the support group and this was a self-report measure assessed at six weeks postnatally (RR 0.85, 95% CI 0.69 to 1.05; 1 study, $n = 458$; low-quality evidence). A higher proportion of women in one study reported that their prenatal care was very helpful in the supported group (RR 1.17, 95% CI 1.05 to 1.30; 1 study, $n = 223$; moderate-quality evidence), although in another study results were similar. Another study assessed satisfaction with prenatal care as being "not good" in 51 of 945 in the additional support group, compared with 45 of 942 in the usual care group.

No studies considered long-term morbidity for the infant. No single outcome was reported in all studies. Subgroup analysis demonstrated consistency of effect when the support was provided by a healthcare professional or a trained lay worker.

The descriptions of the additional social support were generally consistent across all studies and included emotional support, tangible support such as home visits, and informational support.

Authors' conclusions

Pregnant women need the support of caring family members, friends, and health professionals. While programmes that offer additional social support during pregnancy are unlikely to have a large impact on the proportion of low birthweight babies or birth before 37 weeks' gestation and no impact on stillbirth or neonatal death, they may be helpful in reducing the likelihood of caesarean birth and antenatal hospital admission.

PLAIN LANGUAGE SUMMARY

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

What is the issue?

Babies can have a low birthweight if they are born early, before 37 weeks gestational age, or are born small because the mother was poorly nourished through the pregnancy. Poverty can lead to malnutrition, unhealthy living environments, increased risk of infection, and increased stress in daily life. The social stigma associated with being marginalised in society is also a cause of stress. Babies whose growth has been restricted during pregnancy are more likely to die around the time of birth or to suffer from health problems.

Why is this important?

Many countries offer programmes giving special assistance to women thought to be at risk of giving birth to low birthweight babies. These programmes can include emotional support, direct assistance such as home visits, transportation to clinic appointments or help with household responsibilities, and informational support such as guidance and counselling. We set out to assess the effects of programmes offering additional social support compared with routine care, for pregnant women believed to be at high risk of giving birth to low birthweight babies.

What evidence did we find?

We searched for evidence on 5 February 2018. We identified 21 randomised controlled trials from which 11,246 mother-baby pairs contributed results for this review. Examples of the additional social support include information, home visits, telephone calls and stress management. The overall quality of evidence for most outcomes was moderate. It was not possible to blind women to which group they were in.

We found that women who received additional social support during pregnancy may be slightly less likely to have a baby with low birthweight (16 studies, 11,770 babies), or give birth too early (14 studies, 12,282 babies). The number of babies that died around the time of birth was similar for both groups of women (15 studies, 12,091 babies). Women who received the additional social support were, however, probably less likely to be admitted to hospital during their pregnancy (4 studies, 787 women), or to have a caesarean birth (15 studies, 9550 women). Women with additional social support may be less likely to be depressed (1 study, 1008 women). Findings around satisfaction with care were mixed, with one study reporting the support group being more satisfied, whilst another study suggested women in the usual care group were more satisfied. The findings did not appear to be different if the social support was provided by trained lay people or health professionals.

What does this mean?

Although programmes that offer additional social support during pregnancy are unlikely to prevent the pregnancy from resulting in a low birthweight or early birth, before 37 weeks of pregnancy, they may be helpful in reducing the likelihood of antenatal hospital admissions and the need for caesarean births.

Additional social support is not powerful enough to improve the outcomes of the pregnancy during which it is provided, as measured by the outcomes considered in this review. The factors contributing to deprivation require social change in order to bring about improvements in health for mothers and their newborn babies.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Additional support compared to usual care during pregnancy in women at increased risk of low birthweight babies: fetal/neonatal/infant outcomes

Additional support compared to usual care during pregnancy in women at increased risk of low birthweight babies: fetal/neonatal/infant outcomes

Patient or population: women at increased risk of low birthweight babies (fetal/neonatal/infant outcomes)

Setting: studies were conducted in Australia, France, Ireland, Latin America, South Africa, UK and USA

Intervention: additional support

Comparison: usual care during pregnancy

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with usual care during pregnancy	Risk with additional support				
Birthweight < 2500 g	Study population		RR 0.94 (0.86 to 1.04)	11,770 (16 RCTs)	⊕⊕⊕⊖ Moderate ^{a,b}	The effects were consistent when considered as sub-groups of support provided by healthcare professionals or trained lay persons. Studies were conducted in USA, UK, South Africa, France and Latin America. Women in the intervention groups received emotional or informational support provided through home visits and telephone calls compared with clinic/hospital-based care in the control groups.
	127 per 1000	120 per 1000 (109 to 132)				
Gestational age < 37 weeks at birth	Study population		RR 0.92 (0.84 to 1.01)	12,282 (14 RCTs)	⊕⊕⊕⊖ Moderate ^{a,b}	The effects were consistent when considered as sub-groups of support provided by healthcare professionals or trained lay persons. Studies were conducted in USA, UK, France, Australia and Latin America. Women in the intervention groups received emotional or informational support provided through home visits and telephone calls compared with clinic/hospital-based care in the control groups.
	128 per 1000	117 per 1000 (107 to 129)				
Still-birth/neonatal death	Study population		RR 1.11 (0.88 to 1.41)	12,091 (15 RCTs)	⊕⊕⊕⊖ Low ^{a,b,c}	The effects were consistent when considered as sub-groups of support provided by healthcare professionals or trained lay persons. Studies were conducted in USA, UK, Australia, France, Latin America and South Africa. Women in the interven-
	21 per 1000	23 per 1000 (19 to 30)				

tion groups received emotional or informational support provided through home visits and telephone calls compared with clinic/hospital-based care in the control groups.

Long-term morbidity	-	-	-	-	Not reported
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***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: confidence interval; **RCT:** randomised controlled trial; **RR:** risk ratio

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aMany studies did not provide sufficient detail to determine the risk of bias for random sequence generation, allocation concealment or blinding of participants, personnel or outcome assessors (-1).

^bWe have not downgraded evidence for lack of participant blinding.

^cWide confidence interval crossing the line of no effect, so we downgraded one level for imprecision (-1).

Summary of findings 2. Additional support compared to usual care during pregnancy in women at increased risk of low birthweight babies: maternal outcomes

Additional support compared to usual care during pregnancy in women at increased risk of low birthweight babies: maternal outcomes

Patient or population: women at increased risk of low birthweight babies (maternal outcomes)

Setting: studies were conducted in Australia, France, Ireland, Latin America, South Africa, UK and USA

Intervention: should additional support

Comparison: usual care during pregnancy

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with usual care during pregnancy	Risk with additional support				

Caesarean section	Study population		RR 0.90 (0.83 to 0.97)	9550 (15 RCTs)	⊕⊕⊕⊖ Moderate ^{a,b}	Studies were conducted in UK (6), USA (3), South Africa (2), Australia (1), France (1), Ireland (1) and Latin America (1). Women in the intervention groups received home visits, telephone calls, meetings with the social workers and emotional support, compared with clinic-based care for women in the control groups.
	215 per 1000	194 per 1000 (179 to 209)				
Antenatal hospital admissions	Study population		RR 0.78 (0.68 to 0.91)	787 (4 RCTs)	⊕⊕⊕⊖ Moderate ^{a,b}	Studies were conducted in UK (2), South Africa (1) and USA (1). Women in the intervention groups received home visits and telephone calls.
	Number of admissions per woman	524 per 1000 409 per 1000 (356 to 477)				
Antenatal hospital admissions	The mean antenatal hospital admissions was 0.76 occasions	MD 0.05 occasions lower (0.06 lower to 0.04 lower)	-	1525 (1 RCT)	⊕⊕⊕⊖ Moderate ^{a,b}	The study was conducted in the UK. Women in the intervention group received home visits.
Postnatal depression	Study population		RR 0.85 (0.69 to 1.05)	458 (1 RCT)	⊕⊕⊕⊖ Low ^{a,b,c}	The study was conducted in the UK. Women in the intervention group received home visits and telephone calls.
	Self-reported	469 per 1000 399 per 1000 (324 to 493)				
Postnatal depression	Study population		RR 0.74 (0.55 to 1.01)	1008 (1 RCT)	⊕⊕⊕⊕ Moderate ^c	The study was conducted in the UK. Women in the intervention group received home visits.
	Positive EPDS score	168 per 1000 124 per 1000 (92 to 169)				
Satisfaction with pregnancy care	Study population		RR 1.17 (1.05 to 1.30)	223 (1 RCT)	⊕⊕⊕⊖ Moderate ^{b,d}	The study was conducted in the USA. Women in the intervention group received regular visits with the social worker.
	Pregnancy care rated as "very helpful"	800 per 1000 936 per 1000 (840 to 1000)				

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **EPDS:** Edinburgh Postnatal Depression Scale; **MD:** mean difference; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence

High quality: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate quality: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

^aMany studies did not provide sufficient detail to determine the risk of bias for randomisation sequence generation, allocation concealment and/or blinding of participants, personnel or outcome assessors (-1).

^bWe have not downgraded evidence for lack of blinding of participants.

^cWide confidence interval crossing the line of no effect, so we downgraded one level for imprecision (-1).

^dThe one included study included good information about allocation concealment but no detail on random sequence generation (-1).

BACKGROUND

Description of the condition

Low birthweight is defined as weight less than 2500 g at birth irrespective of the weeks of gestation (OECD 2011). In high-income countries preterm birth is the major reason for low birthweight (Blanc 2005). In low- to middle-income countries, chronic maternal malnutrition leads to large numbers of babies who are born weighing less than the 10th percentile, that is, small for their gestational age (Blanc 2005; Walker 2007). Thus 'low birthweight' is an outcome that has potentially different origins, but includes both infants that are born early (less than 37 weeks' gestational age) or who are small for their gestational age, or both (Lee 2013).

More than 20 million low birthweight babies are born worldwide annually and the incidence of low birthweight in low- to middle-income countries (17%) is more than double that of high-income countries (7%) (Lee 2013; UNICEF 2004). Over 95% of all low birthweight babies are born in low- to middle-income countries (UNICEF 2004), the vast majority of small-for-gestational-age infants (87%, 28.2 million) being born in south Asia, southeast Asia, and sub-Saharan Africa, with the highest incidence recorded in south Asia (45%), followed by sub-Saharan Africa (26%) and southeast Asia (24%) (Lee 2013). In low- to middle-income countries, these estimates are biased because more than half of the infants are not weighed (UNICEF 2004).

Pregnant women experiencing psychosocial stress, anxiety and depression, and substance abuse; and who are socioeconomically disadvantaged, including refugees, asylum seekers and those from ethnic minorities; or who are experiencing intimate partner violence, have an increased risk of adverse pregnancy and birth outcomes such as low birthweight, preterm birth, stillbirth or birth by caesarean section (Alder 2007; Blumenshine 2010; Chung 2001; Grote 2010; King-Hele 2009; Lu 2003; McDonald 2017; Nasreen 2010; Ncube 2016; Ogunyemi 2018; Orr 2012; Patra 2011; Staneva 2015). Globally, about 10% of women during pregnancy and 13% of women after they have given birth experience a mental disorder (~16%), predominately depression (~20%) and these rates are higher in low- to middle-income countries (WHO 2015).

Generally low birthweight and, specifically, severe fetal growth restriction (< third centile) is an important cause of perinatal mortality (stillbirths and neonatal deaths), infant and childhood morbidity (Goldenberg 2007; Mandy 2015). These babies, whether born prematurely (before 37 weeks' gestational age) or small for their gestational age, will be referred to as low birthweight throughout this review. They are more susceptible to a range of poor short- and long-term health outcomes, and have a significant impact on healthcare resource usage. Low birthweight babies are at risk of poor neurodevelopment, including cerebral palsy (Baschat 2014). For example, for babies born weighing over 2500 g, the risk of cerebral palsy is 1.3 per 1000 live births, compared with a prevalence of 56.6 per 1000 when the birthweight is less than 1000 g and 10.2 per 1000 for babies weighing between 1500 g and 2499 g at birth (Oskoui 2013). Babies of low birthweight are also at risk for poor neurodevelopment, cardiovascular disease and lung function with aging (Bayman 2014; Pei 2010).

Description of the intervention

We have evaluated a number of interventions designed to improve maternal and fetal outcome, including fetal growth restriction and preterm birth in women at risk of these outcomes. These included, but were not limited to, specialty clinics or other models of pregnancy care, bedrest, nutritional supplements, nutritional advice, interventions to assist pregnant women to stop smoking, plasma volume expansion, oxygen therapy, various medications, and mind-body interventions (Brocklehurst 2012; Lumley 2009; Mahomed 2011; Marc 2011; Ota 2012; Reveiz 2007; Say 2009a; Say 2009b; Say 2009c; Say 2009d; Say 2010a; Say 2010b; Say 2010c; Smaill 2007; Turienzo 2016; Whitworth 2011). Continuity of maternity care, such as provided by midwives in a caseload-type model, has demonstrated reduced rates of preterm birth, compared with standard care, in low- and mixed-risk groups (Sandall 2016). Such findings lend credibility to the potential benefit of social (and other) support in reducing adverse pregnancy outcomes.

Recently the Royal College of Obstetricians and Gynaecologists (RCOG 2014), and the Society of Obstetricians and Gynaecologists of Canada (Lausman 2013), have published new guidelines on the investigation and management of small-for-gestational-age babies. These guidelines provide current evidence on the best practices on detection and prevention of small-for-gestational-age and will better inform health professionals in the management of women at risk of giving birth to a small-for-gestational-age infant.

Many countries have programmes offering additional social support to women thought to be at risk of giving birth to an infant weighing less than 2500 g (Chersich 2016; Coleman 2017). Social support is generally conceptualised as a multidimensional construct and classified into four types, including emotional support, instrumental/tangible support, informational support, and appraisal support (House 1981; Langford 1997). Emotional support involves the provision of caring, empathy, love and trust to others. Instrumental/tangible support involves the provision of goods and services that directly assist a person in need. Informational support involves the provision of advice and information and suggestions that a person can use to deal with problems. Appraisal support involves the provision of information that is helpful for self-evaluation purposes, such as constructive feedback.

For the purposes of this review, the additional social support programmes offered to women at risk of low birthweight infant may include emotional support (e.g. empathy, caring, reassurance), instrumental/tangible support (e.g. transportation to clinic appointments, caseload/continuity of carer models, home visits, telephone calls) and informational support that would be additional to routine care (advice and counselling about nutrition, relaxation, stress management, avoidance of alcohol/recreational drugs). These programmes may be delivered by multidisciplinary teams of health professionals, by specially trained lay workers, or by a combination of lay and professional workers (Finfgeld-Connett 2005).

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 (Finfgeld-Connett 2005). This review includes studies of support by providers with varying backgrounds and qualifications.

How the intervention might work

Studies consistently show a strong relationship between social disadvantage or maternal mental health concerns and low birthweight (Chersich 2016; Staneva 2015; WHO 2010a; Wilkinson 2003). 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 obstetric complications and poor maternal and fetal well-being (Zachariah 2009). These concerns include an increased likelihood of complications during pregnancy, fetal growth restriction, intrapartum complications, operative birth, 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 marginalised in society is also a source of chronic stress (Hatzenbuehler 2013).

One pathway through which social support is thought to mitigate stress is the 'stress buffering' effect (Cohen 1985; Cutrona 1990; Thoits 1986). Stress buffering effect occurs when social support protects individuals from the adverse effects of stress by promoting adaptive appraisals or effective coping or both (Lahey 2011). For instance, social support has a buffering effect against some pregnancy complications, including adolescent maternal mortality and perinatal mental health conditions (McIntyre 2006; WHO 2008; WHO 2010b; Wilkinson 2003). The timing of the intervention may be important. For example, long-term support to address chronic poverty for at-risk women during their childbearing years may be more or less effective than support provided from early pregnancy through to the post partum period, or short-term interventions designed to improve attendance at pregnancy visits, such as those initiated mid- to later pregnancy (Mbuagbaw 2015; McLeish 2017).

Why it is important to do this review

This update of the Hodnett 2010 systematic review will provide evidence to inform the development of appropriate support, provided, for example, through public health initiatives and policy, thus potentially influencing interventions, which may already be in place or in planning, that improve the chances of a healthy start in life.

OBJECTIVES

The primary objective was to assess the effects of programmes offering additional social support (emotional, instrumental/tangible and informational) compared with routine care, for pregnant women believed to be at high risk for giving birth to babies that are either preterm (less than 37 weeks' gestation) or weigh less than 2500 g, or both, at birth. Secondary objectives were to determine whether the effectiveness of support was mediated by timing of onset (early versus later in pregnancy) or type of provider (healthcare professional or lay person).

METHODS

Criteria for considering studies for this review

Types of studies

We included studies if they were: randomised or quasi-randomised controlled trials (RCT), or cluster-randomised trials, comparing a programme of additional social support during at-risk pregnancy by either a professional (social worker, midwife or nurse) or a specially trained lay person, or both, in an effort to reduce the likelihood of preterm birth or low birthweight; random allocation to treatment and control groups. Studies with a cross-over design, or those reported only in abstract form were not eligible for inclusion.

We defined 'additional social support' as some form of emotional support (e.g. reassurance, sympathetic listening), instrumental support such as tangible assistance (e.g. transportation to clinic appointments, assistance with the care of other children at home) and informational support (e.g. counselling, advice). These social supports could be provided during home visits, clinic appointments, by telephone, or a combination of all or some of these. We included studies if the additional support was provided during pregnancy and continued until the birth of the baby, or into the postnatal period.

Consistent with the previous review (Hodnett 2010), we excluded studies if the intervention was solely an educational or behavioural intervention and if the intervention was of brief duration (e.g. two to three weeks) and not intended to continue until the birth of the baby. We also excluded studies of smoking cessation programmes or mind-body interventions for pregnant women, as they are considered in other systematic reviews (Lumley 2009; Marc 2011).

Types of participants

Pregnant women judged to be at risk of having preterm or growth-restricted babies, or both. We included women with a multiple pregnancy, but only reported the outcomes in this review if we were reasonably confident that the unit of analysis was the mother or one of the babies.

Types of interventions

Standardised or individualised programmes of additional social support, provided in either home visits, during regular antenatal clinic visits, by telephone, or a combination of all or some of these, on several occasions during pregnancy in comparison to normal routine care.

Types of outcome measures

Primary outcomes

Fetal, neonatal and infant outcomes

1. Birthweight less than 2500 g
2. Gestational age less than 37 weeks at birth
3. Stillbirth/neonatal death

Secondary outcomes

Maternal outcomes

1. Caesarean section
2. Antenatal hospital admission
3. Postnatal re-hospitalisation

4. Antenatal depression
5. Postnatal depression
6. Satisfaction with pregnancy care

Baby (infant)

1. Long-term morbidity (as defined by study authors)

Search methods for identification of studies

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

Electronic searches

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (5 February 2018).

The Register is a database containing over 25,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this [link](#).

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains studies identified from:

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

Two people screen the search results and review the full text of all relevant study reports identified through the searching activities described above. Based on the intervention described, each study report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that has been fully accounted for in the relevant review sections ([Included studies](#); [Excluded studies](#); [Ongoing studies](#)).

In addition, we searched [ClinicalTrials.gov](#) and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing study reports (5 February 2018) using the search methods detailed in [Appendix 1](#).

Searching other resources

We searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

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

For the 2019 update, the following methods retain elements as used in the previous version and the current standard template used by Cochrane Pregnancy and Childbirth.

Selection of studies

At least two of the three reviewers who joined the authorship team for this update (Rosalind Lau (RL), Mary Anne Biro (MAB) and Christine East (CE)) assessed for inclusion all the potential studies that were identified in the most recent searches. We resolved any disagreements through discussion. If required, we would have consulted a third person from within the authorship (Suzanne Fredericks (SF)).

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. All review authors participated in data extraction for the range of included studies, with two allocated per study, (RL, MAB and CE for the 2019 update). We resolved discrepancies through discussion. If required, we planned to consult a third person, (SF for the 2019 update). We entered data into Review Manager 5 software ([Review Manager 2014](#)) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors, selected from the authorship as described above, independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2017](#)). We resolved any disagreement by discussion and if necessary, we would have involved a third assessor.

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

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

We assessed the method as:

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

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

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

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

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

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

We assessed the methods as:

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

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

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

We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the study authors, we re-included missing data in the analyses which we undertook.

We assessed methods as

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

As per the original protocol, we made an a priori decision to include studies where outcome data were available for at least 80% of those who were originally randomised.

(5) Selective reporting (checking for reporting bias)

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

We assessed the methods as:

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

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

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

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

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

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Assessment of the quality of the evidence using GRADE

For this update, we assessed the quality of the evidence using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following outcomes for the main comparison, Additional support versus usual care (Schünemann 2013). We produced two 'Summary of findings' tables, to distinguish outcomes for the mother and fetal, neonatal and infant outcomes.

Fetal, neonatal and infant outcomes

1. Birthweight less than 2500 g
2. Gestational age less than 37 weeks at birth
3. Stillbirth/neonatal death
4. Long-term morbidity (as defined by study authors) (no data were available to include in the table)

Maternal outcomes

1. Caesarean section
2. Antenatal hospital admission
3. Postnatal depression
4. Satisfaction with pregnancy care

We used the GRADEpro Guideline Development Tool ([GRADEpro GDT 2015](#)), to import data from Review Manager 5 ([Review Manager 2014](#)), in order to create 'Summary of findings' tables. We produced a summary of the intervention effect and a measure of quality for each of the above outcomes using the GRADE approach, which uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. We elected to present the maternal and fetal outcomes in separate tables, to accommodate the different ways in which study authors reported outcomes within the limits of maximum number of outcomes per table.

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data from one study, we used the mean difference. If further studies are identified in future updates and if outcomes are measured in the same way between studies and, we will use mean difference and we will use the standardised mean difference to combine studies that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We planned to include cluster-randomised trials identified in the searches in the analyses along with individually randomised trials. We only identified one such trial, however, as it did not contribute any data to the review, we did not pursue the planned method for including it in meta-analysis. If cluster-randomised trials are included in future updates, we will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population ([Higgins 2011](#)). If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually randomised trials, we will synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and we consider the interaction between the effect of intervention and the choice of randomisation unit to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Cross-over trials

It is unlikely that cross-over designs will be a valid study design for Pregnancy and Childbirth reviews, and so we will exclude them if they are identified in future updates of this review.

Studies with multiple arms

We planned to include studies, if identified, which would contribute to a meta-analysis as follows: if the control group was shared by two or more intervention groups, we would divide the control group between the relevant interventions to create two-arm comparisons and to avoid double-counting of control group participants. If there were two 'control' groups, for example, a placebo group and a no-treatment group, we would combine the findings to enable a two-arm comparison with the intervention group.

Multiple pregnancies

We included studies that enrolled women with multiple pregnancies, in which the unit of analysis for maternal outcomes was the mother. Because the activities in the intervention or control groups applied to the mother, rather than to each individual fetus, the unit of analysis for fetal, neonatal or infant outcomes needed to be for only one baby, rather than each, in a multiple pregnancy. For the remaining studies, where possible, we only included fetal, neonatal or infant outcomes from studies that enrolled multiples if the report allowed for such data to be from one baby only per woman ([Gates 2004](#)). Where this was not possible, we planned to consider the impact of including or not including the data on the overall effects through post-hoc sensitivity analysis.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by considering using sensitivity analysis, although this was not ultimately necessary.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, that is, we attempted to include all participants randomised to each group in the analyses, and all participants analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each study was the number randomised minus any participants whose outcomes were known to be missing.

We retained the a priori decision of the previous version of the review ([Hodnett 2010](#)), to include studies where outcome data were available for at least 80% of those who were originally randomised.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the τ^2 , I^2 ([Higgins 2003](#)) and χ^2 statistics ([Deeks 2017](#)). We regarded heterogeneity as substantial if the I^2 statistic was greater than 50% and either the τ^2 was greater than zero, or there was a low P value (less than 0.10) in the χ^2 test for heterogeneity.

Assessment of reporting biases

Where there were 10 or more studies in the meta-analysis we investigated reporting biases (such as publication bias) using funnel plots ([Sterne 2017](#)). We assessed funnel plot asymmetry visually. If asymmetry was suggested by a visual assessment, we planned to perform exploratory analyses to investigate it. Additionally, had we suspected reporting bias (see 'Selective reporting bias' above), we would have attempted to contact study authors asking them to provide missing outcome data. Where this was not possible, and we thought that the missing data would

introduce serious bias, we would not have included the outcome data from that study.

Data synthesis

We carried out statistical analysis using Review Manager 5 software ([Review Manager 2014](#)). We used fixed-effect inverse variance meta-analysis for combining data. Where we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between studies, we used random-effects meta-analysis.

Subgroup analysis and investigation of heterogeneity

If we identified substantial heterogeneity, we planned to investigate it using subgroup analyses and sensitivity analyses. Where an overall summary was meaningful, we used random-effects analysis to produce it. Additionally, we considered the potential for parents, care providers and policy makers to consider outcomes as they relate to various subgroups, in order to make meaningful choices to implement or not pursue an intervention.

We therefore planned to carry out the following subgroup analyses:

1. timing of onset of support (early in pregnancy versus after the first trimester is completed);
2. type of provider of support (healthcare professional versus lay person).

We chose the primary outcomes to be used in subgroup analyses on the basis of their importance from the perspective of parents, care providers, and policy makers. They were: birthweight less than 2500 g, gestational age less than 37 weeks and stillbirth/neonatal death.

We assessed subgroup differences by interaction tests available within Review Manager 5 ([Review Manager 2014](#)). We reported the

results of subgroup analyses quoting the χ^2 statistic and P value, and the interaction test I^2 statistic value.

In this update, data were only available to carry out subgroup analysis by type of provider support.

Sensitivity analysis

We planned to conduct sensitivity analyses on the primary outcomes, based on the following conditions, which have been clarified and/or added for this update:

1. results when studies with a high risk of bias, specifically related to allocation concealment and/or attrition rates in excess of 20% were included versus excluded;
2. fixed-effect versus random-effects analyses when evidence of statistical heterogeneity was present (defined as an I^2 value greater than 50% and inconsistency between studies in the direction or magnitude of effects (judged visually));
3. results when non-uptake of the support intervention was high versus low. We acknowledge that this is a potentially subjective judgement to make, however, it would seem appropriate to consider that above and below 50% would be a reasonable means of categorising high and low non-uptake.

We also planned to conduct post-hoc sensitivity analyses in this update to explore the potential influence of data included for more than one neonate from a multiple pregnancy.

RESULTS

Description of studies

Results of the search

See: [Figure 1](#).

Figure 1. Study flow diagram

Figure 1. (Continued)

The search for this review update identified 34 unique reports: two of these were related to one of the already excluded studies (El-Mohandes 2011). Ten reports were attributed to four new included studies (Doyle 2014; Kenyon 2016; Lutenbacher 2014; Robling 2016) and 17 reports (13 studies) were added to the excluded studies (Arranz 2017; Chowdhury 2017; Collado 2014; Dykema 2012; Ekhtiari 2014; Jahan 2014; Kakkilaya 2011; Kamalifard 2017; Khoramabadi 2015; Kumar 2014; NCT01997151; Mejdoubi 2014; Nicolson 2013). The remaining five reports relate to three ongoing studies (Denktas 2014; Saville 2016; ISRCTN37733900).

The overall updated review now includes 25 studies (68 reports), excludes 31 studies (50 reports) and notes that there are three ongoing studies.

Included studies

Twenty-five studies that enrolled 19,148 women during pregnancy, met the inclusion criteria; see [Characteristics of included studies](#). Four of these studies did not contribute data to the review (Graham 1992; Hobel 1994; Little 2002; Olds 1986), leaving 21 studies that enrolled 15,297 participants and provided outcomes for 11,246 women. A cluster trial by Hobel 1994 had been excluded in the previous review because of a lack of intracluster coefficient. We included it in this update, as in both versions, the plan was to include cluster trials. Three other studies that had been excluded in the previous review on the basis of high risk of bias were moved to included studies in this update (Dance 1987; Graham 1992; Little 2002): however, only one of these (Dance 1987, n = 50) contributed data to the review. Our decision to move these studies from excluded to included studies did not change the overall conclusions of the review.

Design

All studies in the review involved some form of randomisation. There were 20 individually randomised controlled trials (RCTs). Three studies used the Zelen method, with randomisation prior to seeking consent (Bryce 1991; Norbeck 1996; Spencer 1989); one quasi-RCT used odd versus even numbers from a table of random numbers (Graham 1992); while Hobel 1994 conducted a cluster-RCT (clinic).

Sample sizes

Numbers of women enrolled ranged from 50 to 1554: 11 studies each enrolled fewer than 300 women, while six studies had sample sizes between 307 and 966. Four studies enrolled over 1000 women.

Settings

The studies were conducted in the USA (11), UK (7), France (2), South Africa (2), Australia (1), Ireland (1), and Latin America (1).

Participants

Women were eligible for enrolment in the studies based on their social or obstetric risks, or both, for having a low birthweight baby. Examples of obstetric/medical risks included previous preterm birth, previous birth of a low birthweight baby, previous perinatal loss, maternal hypertension or pre-eclampsia. Social risks were considered for the demographic of the areas served by the health providers, including, for example, being of black or African-American race, being teenaged, having recent experience of a stressful life event, or having low socio economic status. Ten studies included women with medical/obstetric risk factors only, eight enrolled only women who had social risks, while seven studies included women with social and obstetric risk factors (see [Characteristics of included studies](#)).

Outcomes

We performed meta-analyses for the three primary and two secondary outcomes ([Analysis 1.1](#); [Analysis 1.2](#); [Analysis 1.3](#); [Analysis 1.4](#); [Analysis 1.5](#)), with no single outcome being reported in all of the studies. For example, data were available from 16 studies (n = 11,770 participants) for birthweight lower than 2500 g, from 14 studies (n = 12,282 participants) for gestational age less than 37 weeks, but not from the majority of studies, for example, for antenatal depression (one study, n = 486) and postnatal depression (two studies, n = 1466, not meta-analysed as they had different ascertainment properties).

Sources of funding and declarations of interest

Nineteen studies stated their sources of funding (Blondel 1990; Brooten 2001; Bryce 1991; Dawson 1999; Doyle 2014; Graham 1992; Heins 1990; Hobel 1994; Kenyon 2016; Klerman 2001; Lutenbacher 2014; McLaughlin 1992; Moore 1998; Norbeck 1996; Oakley 1990; Olds 1986; Robling 2016; Rothberg 1991a; Villar 1992), one was unclear (Dawson 1989). Five studies provided declarations of interest, noting no competing interests (Kenyon 2016), that the views expressed were those of the authors and not of the funding bodies (Hobel 1994; Lutenbacher 2014), or that the funding bodies did not influence reporting of findings (Doyle 2014; Robling 2016).

Interventions and comparisons

Intervention groups

Additional social support in the intervention groups was provided in a variety of ways, with some studies including more than one form of support.

Emotional support

Ten studies reported emotional support, for example, counselling, acting as a confidante, helping reduce stress and anxiety (Bryce 1991; Doyle 2014; Graham 1992; Hobel 1994; Klerman 2001; McLaughlin 1992; Norbeck 1996; Rothberg 1991a; Rothberg 1991b; Villar 1992).

Instrumental or tangible support

A total of 22 studies provided one or more forms of instrumental or tangible support, including home-visits (17 studies), telephone calls (19 studies), bed rest (one study), home or transport help (three studies), help with obtaining benefits/housing/shopping, etc (one study), and regular meetings with social workers (one study). We excluded studies if they only involved education. However, we did include studies if the overall support included one or more other forms of support as well as education (Brooten 2001; McLaughlin 1992).

Informational support

Nine studies included informational support, such as appropriate use of social services, advice and health education (Blondel 1990; Doyle 2014; Heins 1990; Klerman 2001; Little 2002; Lutenbacher 2014; Moore 1998; Spencer 1989; Villar 1992).

In 21 studies, a health professional provided the additional social support intervention (nurses, midwives, social workers, multidisciplinary teams). Lay persons provided support in the intervention groups of the studies reported by Dance 1987, Graham 1992, Kenyon 2016, and Spencer 1989. The previous version of this review noted that the study reported by McLaughlin 1992 relied on support provided by a multidisciplinary team that included health professionals and specially trained lay workers: we interpret this to be the 'paraprofessionals' mentioned in the report. We retained the McLaughlin 1992 data in the health professionals subgroup, on the basis that the majority of the team were health professionals and the lack of influence that shifting it between the subgroups made on the overall findings.

Many studies provided compliance rates for the intervention group (Blondel 1990; Bryce 1991; Norbeck 1996; Oakley 1990; Rothberg 1991a; Spencer 1989; Spira 1986; Villar 1992) and in these eight studies, 90% to 100% of the participants randomised to receive additional social support did receive it. In Spencer 1989, women were randomised based on assessment of eligibility criteria in their medical records: consent was then sought only for those randomised to the intervention group, and 58.6% refused the intervention but still consented to be part of the study. In one study (Lutenbacher 2014), the sample size was 300, however because of concerns with systemic changes in the study's healthcare birthing environment, an interim analysis was conducted after 200 women had given birth and recruitment was stopped.

Control groups

Women randomised to the control groups received the usual or 'routine care' that was available to all women attending the relevant hospital or clinic for pregnancy care. This might include routine pregnancy assessments, antenatal classes, or, for one study, a booklet available in the clinic about preventing preterm labour (Moore 1998).

Although one study (Brooten 2001), also reported healthcare utilisation information for the first year postpartum, we could not use the data to report on long-term morbidity in this review because of uncertainty about the follow-up rate for this information. This uncertainty stemmed from the following: 1) the one-year follow-up information was included in a table with birth information and no separate denominators were reported; 2) the process for maintaining contact with the participants was not outlined; 3) some loss to follow up would be expected when tracking women for such a long period of time and none was noted; and 4) including the full sample for the one-year follow-up data meant that two participants with spontaneous miscarriages were included.

We made comparisons for outcomes on the basis of group allocation (intervention versus control/usual care) in 23 of the studies. Hobel 1994 involved numerous interventions received by subgroups within the intervention group and that were not reported separately: this resulted in no data contributing to this systematic review. The 'comparison' group findings in the study reported by Olds 1986 included findings that were combined from the true control group and one of the intervention groups (provision of transport to clinical appointments), then compared with the other two treatment groups that were designated as the 'nurse-visited' groups. We were therefore unable to include data from this study in the meta-analysis, as it was not possible to delineate the true intervention and comparison groups.

Data were not available from the included studies to conduct the planned subgroup analysis of timing of the intervention.

Unit of analysis issues

One cluster-randomised trial met the inclusion criteria (Hobel 1994): however, as it did not contribute data to the review, we did not pursue the methods for adjusting for the clusters.

Olds 1986 involved four groups: those with no additional services (group 1), transport to clinic appointments (group 2), nurse-home visiting (group 3) or visiting during pregnancy and until the child turned two (group 4). They presented outcome data as a combination of groups 1 and 2, compared with combined findings from groups 3 and 4. We were therefore unable to elicit the true 'standard care' group to compare with the combined interventions and thus did not include data from this study in the analyses.

Enrollment into some studies occurred relatively early in pregnancy and multiple gestations were subsequently identified. In order to determine the effect of the intervention with the unit of analysis being the mother, several studies excluded multiples after randomisation (Little 2002; McLaughlin 1992; Moore 1998; Oakley 1990; Rothberg 1991a; Spencer 1989). We noted that Bryce 1991 counted each pregnancy only once. We sought and were provided with information on only the singleton pregnancies enrolled in reports by Kenyon 2016 and Robling 2016. Three other studies

probably included the results of twin pregnancies in their reports of fetal and neonatal outcomes ([Analysis 1.1: Brooten 2001](#); [Analysis 1.2: Brooten 2001](#); [Doyle 2014](#); and [Analysis 1.3: Brooten 2001](#); [Bryce 1991](#); [Dawson 1999](#)). We conducted post hoc sensitivity analyses (not reported) including or excluding these studies and found no meaningful change in the overall effect sizes.

Excluded studies

We excluded 31 studies (see [Characteristics of excluded studies](#)), with the majority being excluded as they were not related to social support during pregnancy. Two reports were not RCTs ([Boehm 1996](#); [Graham 2003](#)). In [Beazley 2001](#), only conference abstracts were available (a pre-specified exclusion criteria). In [Bullock 1995](#), the purpose was to improve pregnant women's health behaviours during pregnancy, whilst the trial registration and protocol described by [Chowdhury 2017](#) would involve all pregnant women residing in the district. Several studies were excluded in the previous version of this review ([Hodnett 2010](#)),

on the basis of having a strong likelihood of selection bias. We reviewed these for this update and agreed that there were indeed features that raised concern about bias. As noted above, we identified four that met the review's inclusion criteria: findings from [Dance 1987](#) were subsequently included in this update, while three studies did not contribute data ([Graham 1992](#); [Hobel 1994](#); [Little 2002](#)). We excluded one study as it did not otherwise meet the inclusion criteria ([Ford 2002](#)), and we determined that the publication by Hamilton and colleagues was a report related to [Brooten 2001](#).

Ongoing studies

We identified two study protocols for ongoing studies ([Denktas 2014](#); [Saville 2016](#)), see [Characteristics of ongoing studies](#).

Risk of bias in included studies

We rated the overall risk of bias as low or unclear. Please see [Figure 2](#) and [Figure 3](#) for a summary of all 'Risk of bias' assessments.

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

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Blondel 1990	?	?	?	?	+	+	+
Brooten 2001	+	?	?	?	+	+	+
Bryce 1991	+	?	+	+	+	+	+
Dance 1987	+	?	?	+	?	?	+
Dawson 1989	?	?	?	?	+	+	+
Dawson 1999	?	?	?	?	+	+	+
Doyle 2014	+	+	?	?	+	+	+
Graham 1992	?	-	?	?	-	+	-
Heins 1990	+	+	?	?	+	+	+
Hobel 1994	+	?	?	+	+	+	+
Kenyon 2016	+	+	?	+	+	+	+
Klerman 2001	?	?	?	?	+	+	+
Little 2002	?	?	?	?	-	+	?
Lutenbacher 2014	+	?	?	?	+	+	+
McLaughlin 1992	+	?	+	+	+	+	+
Moore 1998	+	+	+	+	+	+	+
Norbeck 1996	+	?	+	+	+	+	+
Oakley 1990	+	?	?	?	+	+	+
Olds 1986	+	+	?	+	-	-	+
Robling 2016	?	+	?	?	+	+	+

Figure 2. (Continued)

Robling 2016	?	+	?	?	+	+	+
Rothberg 1991a	?	?	?	+	+	+	+
Rothberg 1991b	?	?	?	+	+	+	+
Spencer 1989	+	?	?	?	+	+	+
Spira 1986	?	-	?	?	+	+	+
Villar 1992	+	+	+	+	+	+	+

Figure 3. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies

Allocation

Many of the studies had missing details on the sequence generation or allocation concealment (Blondel 1990; Brooten 2001; Bryce 1991; Dance 1987; Dawson 1989; Dawson 1999; Graham 1992; Hobel 1994; Klerman 2001; Little 2002; Lutenbacher 2014; McLaughlin 1992; Norbeck 1996; Oakley 1990; Robling 2016; Rothberg 1991a; Rothberg 1991b; Spencer 1989; Spira 1986), thus we rated these studies as unclear risk of bias; only the translation of the report by Spira 1986 raised concerns about allocation "by lots". There was sufficient evidence of random sequence generation and allocation concealment provided in the reports by Doyle 2014; Heins 1990; Kenyon 2016; Moore 1998; Olds 1986; and Villar 1992 to rate these as low risk of bias. Graham 1992 reported on a quasi-randomised trial, in which they used an open table of random numbers, with odd versus even digits determining group assignment, prior to seeking consent from participants.

Blinding

Due to the nature of the intervention, it was not possible to blind the participants. Additionally, although many of the studies did not report on blinding of personnel (Blondel 1990; Brooten 2001;

Dawson 1989; Dawson 1999; Doyle 2014; Graham 1992; Heins 1990; Hobel 1994; Kenyon 2016; Klerman 2001; Little 2002; Lutenbacher 2014; Oakley 1990; Olds 1986; Robling 2016; Rothberg 1991a; Rothberg 1991b; Spencer 1989; Spira 1986), such blinding would be problematic to achieve, given the intervention. On the basis that the primary outcomes are all objective measures made by clinical staff, rather than by the participants or researchers, we have elected to classify the lack of blinding as contributing an unclear risk of bias. The ability to apply the findings of pragmatic studies such as these would be limited by rating them as being at high risk of bias, although it is acknowledged that a more conservative approach would be to do so. Fourteen studies did not report on outcome assessor blinding (Blondel 1990; Brooten 2001; Dawson 1989; Dawson 1999; Doyle 2014; Graham 1992; Heins 1990; Klerman 2001; Little 2002; Lutenbacher 2014; Oakley 1990; Robling 2016; Spencer 1989; Spira 1986), hence we also rated these studies as unclear risk of bias. The remaining studies (Bryce 1991; Hobel 1994; Kenyon 2016; McLaughlin 1992; Moore 1998; Norbeck 1996; Olds 1986; Rothberg 1991a; Rothberg 1991b; Villar 1992), achieved blinding of health professionals or those collecting data, or both, making these at low risk of bias.

Incomplete outcome data

More than 20% of the sample in three studies reported incomplete outcome data (Graham 1992 (did not contribute data to the review); Little 2002; Olds 1986). Blondel 1990 reported outcomes for 89.5% of the original sample, with the exception of the questionnaire returned by only 78% of women three to four days postnatally. Data for the latter were not required for inclusion in this review. Olds 1986 did not provide data for 46 non-white women and 20 cases with maternal or fetal conditions predisposing to preterm birth and/or aberrations in fetal growth. The resulting rate of completion for the majority of outcome data was 77.5%. Robling 2016 reported outcome data for over 90% of the sample for birthweight, stillbirth/neonatal death and antenatal hospital admission, however, postnatal depression at six months was only available for 58% of the original sample and therefore we did not include the data in this review.

Selective reporting

Most studies reported all outcomes listed in their methods sections, which we rated as low risk of bias. One study only reported on small subgroups of outcomes and so we assessed this at high risk of bias (Olds 1986). We assessed one study as being at unclear risk of bias because no protocol was available and results were only available in thesis form (Dance 1987).

Other potential sources of bias

Randomisation to the two groups in Graham 1992 was unbalanced: 93.1% of the intervention group were on Medicaid compared to 74.5% of the control group. On the basis of the overall concerns with bias in this study, we did not include any data from this study in the review.

Effects of interventions

See: [Summary of findings for the main comparison](#) Additional support compared to usual care during pregnancy in women at increased risk of low birthweight babies: fetal/neonatal/infant outcomes; [Summary of findings 2](#) Additional support compared to usual care during pregnancy in women at increased risk of low birthweight babies: maternal outcomes

Additional social support versus routine care during at-risk pregnancy

Primary outcomes

Birthweight less than 2500 g

Additional social support interventions for at-risk pregnant women may be suggestive of a reduction, albeit not large, in the proportion of low birthweight babies (risk ratio (RR) 0.94, 95% confidence interval (CI) 0.86 to 1.04, $I^2 = 0\%$; 16 studies, $n = 11,770$; moderate-quality evidence; [Analysis 1.1](#)), though the confidence interval for the pooled effect for this outcome just crossed the line of no effect. We performed the planned sensitivity analysis for [Analysis 1.1](#), comparing the results with and without Spencer 1989, in which 58.6% of those randomised to additional support did not accept it: the results did not change materially.

There were four studies in which the support was provided by lay persons (Dance 1987; Graham 1992 (did not contribute data); Kenyon 2016; Spencer 1989). Subgroup analysis of such providers

did not appear to change the overall measure of effect (test for subgroup differences $\text{Chi}^2 = 0.87$, $P = 0.35$, $I^2 = 0\%$; [Analysis 1.1](#)).

Gestational age less than 37 weeks at birth

There was evidence that the provision of social support for women at risk of a low birthweight baby may have resulted in a small reduction in the proportion of babies born at less than 37 weeks' gestation (RR 0.92, 95% CI 0.84 to 1.01, $I^2 = 0\%$; 14 studies, $n = 12,282$; moderate-quality evidence; [Analysis 1.2](#)), though again the confidence interval for the pooled effect for this outcome just crossed the line of no effect.

The subgroup analysis for provider of the additional support did not suggest evidence of a difference between subgroups ($\text{Chi}^2 = 1.40$, $I^2 = 28.5\%$; [Analysis 1.2](#)).

Stillbirth/neonatal death

The findings did not suggest an influence of additional support on rates of stillbirth or neonatal death (RR 1.11, 95% CI 0.88 to 1.41, $I^2 = 21\%$; 15 studies, $n = 12,091$; low-quality evidence; [Analysis 1.3](#)). There was no apparent difference in this measure of effect when the support was provided by health professionals, compared to provision by lay persons ($\text{Chi}^2 = 1.23$, $I^2 = 19\%$; [Analysis 1.3](#)).

Multiple pregnancies

Four studies enrolled women with multiple pregnancies (Brooten 2001; Bryce 1991; Dawson 1999; Doyle 2014), and it was unclear whether or not the outcomes related to one or more of the babies from each. Post hoc sensitivity analysis, excluding each study for fetal/neonatal outcomes, did not change the measure of effect or 95% CIs meaningfully ([Analysis 1.1](#): Brooten 2001; [Analysis 1.2](#): Brooten 2001; Bryce 1991; Doyle 2014; or [Analysis 1.3](#): Brooten 2001; Bryce 1991; Dawson 1999).

Secondary outcomes

Birth by caesarean section

Social support interventions for at-risk pregnant women were associated with a decreased likelihood of caesarean birth (RR 0.90, 95% CI 0.83 to 0.97, $I^2 = 0\%$; 15 studies, $n = 9550$; moderate-quality evidence; [Analysis 1.4](#)).

Hospital admissions

We excluded data for this outcome from Dawson 1989, as women in the control group were cared for in hospital. There was substantial heterogeneity in the outcome of antenatal hospital admission when we included the five remaining studies ($I^2 = 59\%$), attributed to the unexpected findings by Blondel 1990 that there were more admissions in the intervention group, that was designed to provide domiciliary visits. However, some women were enrolled while hospitalised and remained in hospital. Given the heterogeneity that this study introduced and the uncertainty around why women could be randomised to receiving domiciliary visits whilst continuing their care in hospital, we omitted this study from the final analysis. Thus, [Analysis 1.5](#) contains data from four studies only. Moderate-quality evidence suggests that there is probably a reduction the number of antenatal hospital admissions per participant (RR 0.78, 95% CI 0.68 to 0.91; 4 studies, $n = 787$; [Analysis 1.5](#)), and the mean number of hospitalisation episodes (mean difference -0.05 , 95% CI -0.06 to -0.04 ; 1 study, $n = 1525$; [Analysis 1.6](#)), in the social support group, compared to the controls.

We found no evidence that social support interventions for at-risk pregnant women were associated with a decreased likelihood of postnatal hospital readmission (RR 1.60, 95% CI 0.80 to 3.21; 1 study, $n = 173$; [Analysis 1.7](#)).

Maternal depression

Results of one study indicated that additional social support was not associated with a decreased likelihood of depression during pregnancy (RR 0.78, 95% CI 0.50 to 1.20; $n = 486$; [Analysis 1.8](#)).

We reported the findings for postnatal depression for two studies separately, given that different measurement tools were used. There was evidence of a slight reduction in the number of women who screened positively on the Edinburgh Postnatal Depression Screen, administered eight to 12 weeks postnatally, which [Kenyon 2016](#) used as a surrogate for depression (RR 0.74, 95% CI 0.55 to 1.01; $n = 1008$; moderate-quality evidence), and also a slight reduction to self-report of being depressed when assessed by a questionnaire sent at six weeks postnatally in [Oakley 1990](#) (RR 0.85, 95% CI 0.69 to 1.05; $n = 458$; low-quality evidence), see [Analysis 1.9](#). [Brooten 2001](#) reported a text-only comment that there were no differences in maternal affect, measured for anxiety, depression and hostility, measured several times during and following the pregnancy in each group. [Dawson 1999](#) presented the data in the form of a figure and we were unable to ascertain specific rates to include in the meta-analysis here. Data from two studies ([Blondel 1990](#); [Robling 2016](#)), that reported postnatal depression were missing data for over 20% of the original sample and we did not, therefore, include them in the meta-analysis.

Satisfaction with pregnancy care

Women's satisfaction with their pregnancy care was measured and reported differently by each of the investigators that considered this outcome and were therefore not meta-analysed ([Analysis 1.10](#)). [Villar 1992](#) reported the proportion of women who indicated that their satisfaction with prenatal care was "not good" as 51 of 945 in the additional support group, compared with 45 of 942 in the usual care group. A higher proportion of women in [Klerman 2001](#) reported that their prenatal care was very helpful in the supported group, than in the standard care group (RR 1.17, 95% CI 1.05 to 1.30; $n = 223$, moderate-quality evidence). Some studies provided comment in text-only form, including, "women in the intervention group were significantly more satisfied with care than were controls" ([Brooten 2001](#), p.5), and, "none of the women in the domiciliary group [the intervention] expressed any major dissatisfaction with the service" ([Dawson 1989](#), p.1321). [Oakley 1990](#) reported that 217 of 236 women (92%) in the intervention group considered that the research midwife was helpful, without a comparison with women in the control group. Similarly, although [Dawson 1999](#) sought measures of satisfaction from women in both the intervention and control groups, other than stating that there were no differences, they only reported detail from women in the intervention group.

Long-term morbidity

No studies reported long-term morbidity of the baby.

Funnel plots of those meta-analyses involving 10 or more studies appeared fairly symmetrical ([Figure 4](#); [Figure 5](#); [Figure 6](#); [Figure 7](#)), suggesting that publication bias was not present.

Figure 4. Funnel plot of comparison 1. Additional support versus usual care during at-risk pregnancy, outcome: 1.1 Birthweight < 2500 g

Figure 5. Funnel plot of comparison 1. Additional support versus usual care during at-risk pregnancy, outcome: 1.2 Gestational age < 37 weeks at birth

Figure 6. Funnel plot of comparison 1. Additional support versus usual care during at-risk pregnancy, outcome: 1.3 Stillbirth/neonatal death

Figure 7. Funnel plot of comparison 1. Additional support versus usual care during at-risk pregnancy, outcome: 1.4 Caesarean birth

DISCUSSION

Summary of main results

In general, the additional 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. The additional social support was provided by health professionals in most of the included studies and in one study (McLaughlin 1992), the support was provided by a multi-disciplinary team including specially trained laywomen. In three studies (Dance 1987; Kenyon 2016; Spencer 1989) specially trained laypersons (all women) provided the additional social support. Outcomes did not appear to be influenced by the lay- or professional status of the person(s) providing the support.

Despite the comprehensiveness of the intervention and the solid theoretical rationale for linking stress, social support, and pregnancy outcome, there was only slight evidence to support a reduction in the likelihood of low birthweight, birth prior to 37 weeks' gestation and postnatal depression, but little difference between interventions for other outcomes: perinatal death and postnatal readmission. One study provided evidence of increased satisfaction with pregnancy care in women who received support, whilst a larger study did not. We postulate that additional social support (regardless of the quality and quantity) is not sufficiently powerful to improve the outcomes of the pregnancy during which it is provided, when measured by birthweight, gestation at birth and perinatal death. An argument could be made that, given the

immense social deprivation experienced by most of the women in these studies, it would be surprising if additional social support alone could have such an immediate and powerful effect and that the factors contributing to the background of deprivation require social change, in order to effect improvements in maternal and perinatal health. Such sentiment is supported by the findings in the systematic review of midwifery-led continuity care by Sandall 2016, which may have included elements of social, as well as other, support for women with mixed levels of risk in pregnancy, labour and birth: there was a reduction in preterm birth (RR 0.76, 95% CI 0.64 to 0.91), but no difference in the proportion of infants born weighing less than 2500 g (RR 0.96, 95% CI 0.82 to 1.13).

There was moderate-quality evidence that two outcomes were positively associated with enhanced additional social support during pregnancy: decreased likelihood of caesarean birth, and decreased likelihood of antenatal hospital admission. These analyses involved multiple studies and enrolled 9500 and over 2000 women respectively. On the assumption that the results did not occur by chance, we offer the following interpretations.

For caesarean birth

It is noteworthy that the effect is in the same direction as that in the Cochrane Reviews of support during labour (Hodnett 2013) and midwifery-led continuity of care (Sandall 2016), and it is consistent with an observational study that raised the issue of linking social support to reduced likelihood of intrapartum complications and operative birth over 30 years ago (Norbeck 1983). These reports

describe mechanisms whereby additional support, by lessening anxiety and fear, reduce the likelihood of obstetric complications and thereby increase the likelihood of normal vaginal birth.

For antenatal hospital admission

Additional social support provides information and knowledge related to antenatal care and may allow for early detection of pregnancy complications either by the caregiver or the woman herself. Treatment could then be provided on an outpatient basis rather than requiring hospitalisation. By contrast, however, continuity of midwifery care provider (Sandall 2016) was not shown to influence hospital admissions during pregnancy in seven studies that reported this outcome for over 7700 women and was conducted over a similar time period to those reviewed in this update. We therefore consider that this finding be treated with some caution and not used as a strong outcome for decision making.

Overall completeness and applicability of evidence

In general the additional 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. An alternate, or complementary, explanation for the potential for a small effect of social support on birth prior to 37 weeks' gestation or low birthweight is that our ability to identify women who are at high risk of preterm birth or low birthweight babies is seriously limited, and thus many women were included in these studies 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.

Quality of the evidence

The overall risk of bias of the included studies was low or unclear. While all participants were assessed to be at risk for giving birth preterm or to a low birthweight baby, the inclusion criteria defining risk status was variable. Most studies used a combination of social and obstetric factors. In seven of the studies 90% to 100% of the participants randomised to receive additional support did receive it.

We assessed the quality of the evidence for all fetal/neonatal and infant outcomes as being moderate for birthweight less than 2500 g and gestational age less than 37 weeks at birth; and low for stillbirth/neonatal death (Summary of findings for the main comparison). None of the studies reported long-term morbidity. We downgraded all outcomes by one level for serious limitations in study design. Many studies did not provide sufficient detail to determine the risk of bias for random sequence generation, allocation concealment or blinding of participants, personnel or outcome assessors. We downgraded stillbirth/neonatal death by an additional level due to concerns of imprecision, with a wide confidence interval crossing the line of no effect. We assessed the quality of the evidence for maternal outcomes as being mainly moderate for the following outcomes: caesarean section; antenatal hospital admissions; postnatal depression using the Edinburgh Postnatal Depression Scale; satisfaction with pregnancy care; and low for one outcome, postnatal depression (self-reported) (Summary of findings 2). We downgraded outcomes by one level for serious limitations in study design: many studies did not provide sufficient detail to determine the risk of bias for randomisation

sequence generation, allocation concealment and/or blinding of participants, personnel or outcome assessors and one included study included good information about allocation concealment but not detail on random sequence generation. We downgraded postnatal depression (self-reported) by an additional level due to concerns of imprecision, with a wide confidence interval crossing the line of no effect.

Potential biases in the review process

The review authors are not aware of potential biases that have not already been addressed through the rigorous methods adopted in this review in line with those of Cochrane Pregnancy and Childbirth. The search strategy is believed to be robust in its ability to identify all studies.

Agreements and disagreements with other studies or reviews

This updated review did not change the conclusions of previous versions. We are not aware of any other systematic reviews on the topic. There is potential overlap between this review and systematic reviews of continuity of maternity care in low- or mixed-risk populations (Sandall 2016: reduced preterm birth, which was not the primary outcome of the included studies) or of models of pregnancy care that target women at risk of preterm birth (for example, Turienzo 2016; Whitworth 2011, which demonstrate limited evidence of benefit of specialised clinics as conducted in the USA some decades ago).

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, this review does not provide evidence that such support is likely to be powerful enough to overcome the effects of a lifetime of poverty and disadvantage, or a longstanding pregnancy complication, and thereby influence the remaining course of a pregnancy, in terms of fetal growth. These findings may be influenced by the availability of reports of studies mainly conducted in high-income countries. We await the findings of the large study being conducted in low-income countries (villages in South East Asia; Saville 2016). There is little evidence to support benefit from programmes that offer additional social support only during pregnancy in terms of preventing the pregnancy from resulting in a low birthweight or preterm baby, although such programmes may be helpful in reducing the likelihood of caesarean birth or antenatal hospital admission. Additional support appeared to have little impact on rates of stillbirth or neonatal death. The potential for support through contemporary models of continuity of maternity care provider have not yet been fully explored.

Implications for research

It is important to await the findings from two ongoing studies before abandoning further research into the benefits (or otherwise) of social support. These studies will include women at risk of having low birthweight babies in a low-income country (Saville 2016) and contemporary models of continuity of maternity care provider (midwives) in a high-income country (ISRCTN37733900). Additional research needs to focus on the cause(s) of low birthweight, distinct or related for premature (< 37 weeks) and small-for-gestational age,

to inform further opportunities to improve maternal and infant outcomes in at-risk pregnancies, through social support. Such research could be qualitative in nature or be large quantitative studies with adequate follow up, or both. Further studies may also try to address the chronicity of social deprivation, including for women during their childbearing years ([Lu 2010](#)).

ACKNOWLEDGEMENTS

We are grateful to Rita Iedema-Kuiper, RM, PhD, for providing us with a copy of her PhD thesis and English summary of the study ([Iedema-Kuiper 1996](#)), and to Winnie Chu, who assisted with double-data entry and with preparation of the included and excluded studies tables, for the previous version of this review.

We would like to thank Ellen Hodnett, Suzanne Fredericks and Julie Weston for their contributions as authors on previous versions of this review.

As part of the pre-publication editorial process, the CRG Editorial Team are grateful to the following peer reviewers for their time and comments: Ali Khashan - School of Public Health and INFANT Centre, University College Cork, SM O'Kelly - Ranelagh Medical, one consumer and the Group's Statistical Adviser.

This project was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to Cochrane Pregnancy and Childbirth. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Blondel 1990

Methods	RCT
Participants	158 (79 to the intervention group and 79 to the control group, with loss to follow-up of 6 immediately after enrolment, leaving a total of 73 in the control group) pregnant French women with moderate threatened preterm labour between 26-36 weeks' gestation, no IV betamimetics
Interventions	<p>Control group: routine care from obstetricians or midwives at outpatient clinics, no home visits, and hospitalisation if necessary</p> <p>Intervention group: 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</p>
Outcomes	Hospital admission, < 37 weeks' gestation at birth, tocolytics, length of hospital stay, at least 4 ante-natal visits at outpatient clinic, number remaining in bed all day, number with help at home, perinatal death, satisfaction with prenatal care and number who preferred home visiting system
Notes	<p>95% of women in the experimental group received the intervention.</p> <p>Intervention group: 4 out of 79 had no home visits</p> <p>Control group: 8 out of 73 had home visits</p> <p>ITT analysis</p> <p>Study location: Paris, France</p> <p>Dates of the study: November 1985-August 1987</p>

Blondel 1990 (Continued)

Funding sources: Ministère de la Solidarité, de la Santé et de la Protection Sociale (Direction Générale de la Santé)

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated "allocated to group by randomisation" and that randomisation was stratified by maternity unit. No other information provided
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes were used. No mention if they were consecutively numbered or opaque
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. All participants received pre-natal care from obstetricians or midwives at the clinics and were hospitalised if necessary. It is not clear whether the obstetricians or midwives were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the analysis was performed blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Medical record data were collected for 89.5% of the sample. Questionnaire about satisfaction with prenatal care, administered at 3-4 days postnatal in hospital, had a completion rate of 78%; these data from the questionnaires were not included in the meta-analysis, as the pre-specified methods in the 2010 version of this review only included findings when they were reported on a minimum of 80% of the sample.
Selective reporting (reporting bias)	Low risk	All outcomes were reported on.
Other bias	Low risk	No other sources of bias noted

Brooten 2001

Methods	RCT
Participants	173 pregnant women (85 to intervention and 88 to control) 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 non-gestational diabetes, chronic hypertension or an episode of preterm labour
Interventions	<p>Control group: standard prenatal and postpartum care by residents and staff physicians, for high-risk women at the hospital clinic. No routine home visits</p> <p>Intervention 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 individualised teaching and counselling</p>
Outcomes	Antenatal hospitalisation; length of antenatal and postpartum hospital stay; postpartum rehospitalisation
Notes	<p>Study location: Philadelphia, Pennsylvania, USA</p> <p>Dates of the study: 1 January 1992-1 January 1996</p>

Brooten 2001 (Continued)

Funding sources: National Institutes of Health, Bethesda, MD

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Envelopes prepared in advance by a statistician using a list of random numbers.
Allocation concealment (selection bias)	Unclear risk	A sequence of sealed envelopes were used. A research assistant opened each envelope in turn. No mention if the envelopes were opaque or consecutively numbered
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. Both groups received standard care for high-risk women at the hospital clinic from resident and staff physicians. It is not clear if physicians and midwives were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the analysis was performed blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	There was complete follow-up for medical record data. No return rate was mentioned for a questionnaire completed 1 month after discharge, but no data from it were applicable for this review. Data were presented for postpartum acute care visits and re-hospitalisations within a year of birth, but no methods were described for how these data were collected. The data are reported in the same tables as the birth data (with complete follow-up), but this was not confirmed in the text.
Selective reporting (reporting bias)	Low risk	All maternal outcomes were reported. Neonatal outcomes are reported with the infant as the unit of analysis, and there were unequal numbers of twins in the 2 groups (12 in the control group and 9 in the intervention group). We were unable to include infant outcomes for 1 baby per mother in this review. Questionnaire data were only presented descriptively and thus mentioned in text rather than in a meta-analysis.
Other bias	Low risk	No other sources of bias noted

Bryce 1991

Methods	RCT, using Zelen method (randomisation prior to consent)
Participants	1970 women (983 to intervention and 987 to control) entered the study. Women were eligible for the study if they had a history of ≥ 1 preterm births, ≥ 1 LBW births, ≥ 1 perinatal deaths, ≥ 3 1st trimester miscarriages, ≥ 1 2nd trimester miscarriages, or an antepartum haemorrhage in a previous pregnancy. Women enrolled at a mean gestational age of 18 weeks
Interventions	Control group: routine antenatal care (not described) Intervention 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

Bryce 1991 (Continued)

Outcomes	Gestational age at birth, stillbirths, neonatal deaths, postneonatal deaths, number of babies discharged alive, method of birth
Notes	<p>90.5% of women randomised to the experimental group agreed to participate in the study. All sets of twins were counted once for fetal/neonatal outcomes</p> <p>Study location: Perth, Australia</p> <p>Dates of the study: October 1984-December 1987</p> <p>Funding sources: Commonwealth Department of Community Services and Health - Research and Development grant, Stillbirth and Neonatal Death Support Group of Western Australia, King Edward Memorial Hospital Research Foundation and Department of Medicine, University of Western Australia. "General support" provided by the National Health and Medical Research Council.</p> <p>Declarations of interest among primary researchers: none stated</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Simple randomisation, within blocks with no stratification, was done by a computer programmer
Allocation concealment (selection bias)	Unclear risk	No information was provided
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were unblinded to group allocation. Personnel giving the 'usual care' to all study participants were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Main outcome (gestation at birth) was collected blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcome data were available for all but 3 participants originally randomised (1 control and 2 experimental).
Selective reporting (reporting bias)	Low risk	Maternal outcomes reported on a 'per-case' basis. Neonatal outcomes reported on a 'per baby' case (as twins were included in the study) and thus were not usable for this review.
Other bias	Low risk	No other sources of bias noted

Dance 1987

Methods	RCT
Participants	Women booking in for pregnancy care at the Marston Green Hospital Birmingham (East Birmingham Health District) who were immigrant Pakistani women from rural-agrarian villages in Azad Kashmir and Rawalpindi (≤ 26 weeks of pregnancy), who also had a history of at least 1 LBW baby (not associated with a multiple birth, elective caesarean section, or gross congenital anomaly)
Interventions	Control group: (n = 25) received routine pregnancy care only.

Dance 1987 (Continued)

Intervention group: "Cases" (n = 25) received routine pregnancy care plus support from one of two Asian 'Linkworkers'. These workers were part of a nationwide programme that involved "women aged between 25-40 years of age with some formal 'western' educations, who were fluent speakers of English, as well as being fluent in at least 1 of the languages spoken locally... They received initial training for four weeks... followed by 'on the job training' with midwives and health visitors" (p17). The study Linkworkers received an additional 40 h of discussion and training for their new role as 'independent practitioners' (of support provision). They conducted 3 home visits at 18, 25 and 30 weeks' gestation (or 28, 31 and 34 weeks for 'late-bookers') and 2 phone calls (or home visits if there was no phone), at which they provided information about pregnancy, answered women's questions or problems, advised as required and were able to "generally support, befriend and advocate for them, during the pregnancy" (p27). A third Linkworker, who was on leave at the time of the intervention, conducted the 50 post-natal questionnaires with the participants.

Outcomes	Mode of birth, gestation at birth, birthweight
Notes	<p>This study was excluded in the previous version of the review, on the basis of a "strong likelihood of selection bias" given the coin toss for randomisation. We have included it in the 2018 update to align with contemporary Cochrane methodology.</p> <p>Study location: Birmingham, UK</p> <p>Dates of the study: commenced September 1986 - completion date not stated</p> <p>Funding sources: none stated</p> <p>Declarations of interest among primary researchers: none stated</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Coin toss on women booking to the clinic until 50 women had been enrolled
Allocation concealment (selection bias)	Unclear risk	Not recorded
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Women were unblinded. Clinicians were not aware of the allocation ("Great care ... participation ... never recorded on their Medical Records ...", p.51)
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The clinical outcome measures were routinely recorded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No protocol available
Selective reporting (reporting bias)	Unclear risk	No protocol available. Results available only in thesis form
Other bias	Low risk	None identified

Dawson 1989

Methods	RCT
Participants	60 pregnant women (41 to intervention and 19 to control) at varying stages of pregnancy, with a risk factor for hospital admission but not to immediate intervention, and by implication, risk of premature birth or LBW baby, e.g. hypertension, IUGR, isolated small antepartum bleeds, or previous perinatal loss
Interventions	Control group: conventional hospital care (not described) Intervention group: an average of 11 home visits by midwives plus a telephone domiciliary fetal monitoring system
Outcomes	Number of hospital admissions, mean gestation at birth, days under observation, numbers of nights spent in hospital, obstetric interventions (inductions, caesarean birth), maternal anxiety, postnatal depression, perinatal mortality. Satisfaction with care
Notes	Satisfaction with care was only reported as "None of the women in the domiciliary group expressed any major dissatisfaction with the service." (p. 1321). We did not include findings on the number of hospital admissions, as the control group only included women admitted to hospital. Study location: Cardiff, Wales, UK Dates of the study: January 1986-October 1987 Funding sources: these are not clear. The study authors acknowledge support and collaboration of the following, which may have included funding: the Iolanthe Trust, South Glamorgan Health Authority and Obstetric Consultants, Welsh Scheme for Development of Health and Social Research, the Spastics Society in Wales, British Telecom Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated that 'randomisation' was done. 2:1 random allocation scheme used. No further details provided
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes opened by a third party. It is unclear whether the envelopes were opaque or consecutive
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether obstetric consultants were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Data collection done from case notes. It is not clear whether the data collectors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Medical record data collected on 93% of the sample. No response rate noted for the maternal questionnaire completed at the end of pregnancy. However, no information from this questionnaire was relevant to this review.
Selective reporting (reporting bias)	Low risk	All medical outcomes were reported. Information from the questionnaire was only reported for the intervention group and thus not usable.
Other bias	Low risk	No other sources of bias noted

Dawson 1999

Methods	RCT
Participants	81 pregnant women (38 to intervention and 43 to control) at varying gestations, at 2 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, IU-GR, diminished fetal movement, and minor antepartum haemorrhage
Interventions	<p>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</p> <p>Intervention group: domiciliary fetal monitoring, transmitted over the phone, plus home support from community midwives</p>
Outcomes	Mean gestation at birth, induction of labour, method of birth, birthweight, Apgar scores, depression, anxiety, and satisfaction
Notes	<p>Study location: South Wales</p> <p>Dates of the study: not stated</p> <p>Funding sources: Welsh Office, Programme for the Valleys</p> <p>Declarations of interest among primary researchers: none stated</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention of how allocation sequence was generated
Allocation concealment (selection bias)	Unclear risk	Consecutively-numbered sealed envelopes were opened in order; no mention if envelopes were opaque
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It was not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Medical record data were completed for all participants. A questionnaire was completed at 6-8 weeks postpartum by 76% of the sample. We did not use any data from it.
Selective reporting (reporting bias)	Low risk	All medical record outcomes were reported on. Satisfaction outcomes were only reported for the intervention group. EPDS comparison used a non-study group for comparison. We used only the medical record data for this review.
Other bias	Low risk	No other sources of bias noted

Doyle 2014

Methods	RCT
Participants	233 pregnant women (115 to intervention group; 118 to control group) from a community in Dublin, Ireland, which had above national average rates of unemployment, early school leavers, lone parent households and social housing.
Interventions	<p>Control group: usual care with access to standard antenatal education classes. Contacted once by Pregnancy For Life Programme office and offered widely available pregnancy leaflets</p> <p>Intervention group: The Pregnancy For Life Programme consisted of bi-monthly home visits by trained mentors to a prescribed average of 10 visits. Visits included pre-birth and pregnancy information and support addressing anxieties or concerns around pregnancy. Visits lasted approximately 1 h and continued until the birth of the baby.</p>
Outcomes	Labour onset and method of birth; Apgar cut-off scores (< 7), birthweight, gestational age and prematurity
Notes	<p>Study location: Dublin, Ireland</p> <p>Dates of the study: 2008-2011</p> <p>Funding sources: Northside Partnership - The Atlantic Philanthropies and Department of Children and Youth Affairs</p> <p>Declarations of interest among primary researchers: state that funder had no role in the design, conduct, analysis or decision to prepare and submit the manuscript for publication.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	An unconditional probability randomisation procedure assigned participants to treatment allocation.
Allocation concealment (selection bias)	Low risk	Participants clicked on a randomisation website where they were automatically assigned a number that corresponded to group allocation and they were notified by automatic email with allocation and an ID code. Procedures were in place to ensure that randomisation could only take place once.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were not blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Baseline data were collected by field staff who were blinded to allocation. The paper does not report whether staff who collected outcome data were blinded to group allocation, although lack of blinding would not have affected results of primary outcomes (routinely collected data).
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data analysed for 92.2% of those allocated to experimental group and 84.7% of those allocated to the control group.
Selective reporting (reporting bias)	Low risk	All primary outcomes were reported.
Other bias	Low risk	No other sources of bias noted

Graham 1992

Methods	Quasi-randomised trial
Participants	145 non-white women attending the prenatal clinic at a hospital in Cleveland, USA. Eligible if they were 17-28 weeks' gestation, were low on family functioning and had experienced at least 1 stressful life event
Interventions	Control group: routine pregnancy care with obstetricians at the clinic Intervention group: home visits (2 black women, non-professionals, who were known to have a rapport with patients from this clinic), trained to provide psychosocial support, encourage reduction in family stress through linkage with community services and providing 4 1-h home visits at intervals of 2-4 weeks and pregnancy care with obstetricians at the clinic.
Outcomes	LBW (< 2500 g regardless of gestation); number of prenatal visits
Notes	We did not include the study findings in this review due to the incomplete outcome data (see risk of bias) Dates of the study: March 1987-September 1989 Funding sources: Robert Wood Johnson Foundation and Gerston Family Foundation Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Large table of random numbers - no other information provided
Allocation concealment (selection bias)	High risk	Odd versus even digits determined group allocation. No mention of who accessed these or how
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind the participants Obstetricians providing prenatal care to both groups were unaware of group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Objective outcome data for birthweight was collected from routine sources.
Incomplete outcome data (attrition bias) All outcomes	High risk	Data on the major outcome measure (birthweight) was available for 79% of those randomised and for 28% of the sample overall.
Selective reporting (reporting bias)	Low risk	All primary outcomes were reported.
Other bias	High risk	Unbalanced groups. 93.1% of intervention group on Medicaid compared to 74.5% of control group

Heins 1990

Methods	RCT
Participants	1458 low-income pregnant women (728 to intervention and 730 to control) who attended state-funded antenatal clinics, at varying gestations, free of known medical or pregnancy complications, score > 9 on a risk-factor scale for LBW baby or had a LBW infant in the previous pregnancy, in South Carolina, USA
Interventions	<p>Control group: usual antenatal care - provided by an obstetrician. Regular reviews, with care focused on monitoring maternal weight gain and advising increased rest</p> <p>Intervention group: weekly or biweekly antenatal care by a nurse-midwife, including education, counselling, assessment of the cervix, and screening</p>
Outcomes	Birthweight
Notes	<p>The Institutional Review Board of the university determined that no formal consent was necessary for entry into the study.</p> <p>ITT analysis</p> <p>Fetal deaths were excluded, as the hypothesis was to reduce the rate of LBW live-born infants. However, the numbers of fetal deaths were provided in text and we were therefore able to include them in this review.</p> <p>Dates of the study: July 1983-October 1987</p> <p>Funding sources: March of Dimes, the South Carolina Department of Health and Environmental Control and the Robert Wood Johnson Foundation</p> <p>Declarations of interest among primary researchers: none stated</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation sequence was created centrally, using computer-generated random numbers.
Allocation concealment (selection bias)	Low risk	Treatment allocations were in sequentially numbered, sealed, opaque envelopes stored away from the clinical sites. The centres made a phone call to a lay administrator, who selected the next envelope.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded to group allocation, due to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes were obtained on 93% of the sample.
Selective reporting (reporting bias)	Low risk	All outcomes were reported.
Other bias	Low risk	No other sources of bias noted

Hobel 1994

Methods	Cluster-randomised trial
Participants	<p>Women attending 1 of 8 prenatal clinics in West Los Angeles, considered to be at high risk of preterm birth, were < 31 weeks of gestation at their first visit, spoke English or Spanish, provided written, informed consent</p> <p>Exclusion criteria: women with any disabling condition that could interfere with protocol adherence, medical disorders (cardiac, hyperthyroidism, medicated for asthma, seizures/epilepsy, diabetes, history of thromboembolic disorders, known sensitivity to oral progestin (Provera), liver disease, genital or breast malignancy, attempted suicide in the current pregnancy.</p> <p>Of the 10,394 women screened for risk of preterm birth, 3144 were at high risk and also had their pregnancy prior to 1986 (when financial considerations resulted in ceasing recruitment of women in the control clinics). Limited findings were therefore reported on the 1774 and 880 women in the intervention and controls respectively.</p>
Interventions	<p>Intervention group: (5 clinics) more frequent prenatal visits plus psychosocial and nutritional screening plus crisis intervention. High-risk women in this group who agreed to participate were further randomised to 1 of:</p> <ol style="list-style-type: none"> 1. bed rest; 2. psychosocial support; 3. oral progestin (active); 4. oral placebo (for progestin). <p>Staff at the intervention clinics were supplemented by social worker, health educator and PHN.</p> <p>Control group: (3 clinics) usual "County care" plus psychosocial and nutritional screening plus crisis intervention. Risk assessment not available to clinicians and findings of psychosocial screening only available in crisis situations.</p> <p>All women, if required, were provided with crisis intervention, nutritional advice if at "nutritional risk" and access to Nutritional Service for Women, Infants and Children if income was < 200% of the poverty level.</p>
Outcomes	Preterm birth (< 37 weeks) rates, birthweight < 2500 g
Notes	<p>Data for the primary outcome were reported as all the interventions versus the control and the 4 interventions within the intervention group. The challenge of considering the potential association between each of the secondary interventions and the outcomes led us to not report the outcomes in the meta-analysis.</p> <p>Dates of the study: 1983-1986</p> <p>Funding sources: State of California, Department of Health Services, Maternal and Child Health Branch. Upjohn Company (randomised active and placebo drug)</p> <p>Declarations of interest among primary researchers: state that "interpretations and conclusions ... are those of the authors and are not to be construed as reflecting those of the State of California Department of Health Services"</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Restricted block, grouped by (clinic) size and percentage of black women attending, randomised scheme

Hobel 1994 (Continued)

Allocation concealment (selection bias)	Unclear risk	The unit of randomisation was the clinic. Once randomised, however, it remains unclear how women were referred to each clinic, with the possibility that some bias could have been introduced at this stage. This is not discussed in the publications and therefore remains unclear.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded with regard to attending a control or intervention clinic. This is unavoidable, given the nature of the interventions. Participants and clinicians were only blinded to the secondary intervention of active or placebo oral progestin.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	This is not stated. However, because the primary outcome of preterm birth is routinely recorded data, this is considered to be low risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Post randomisation exclusions (multiple pregnancy, stillbirth, 15% loss to follow-up in both intervention and control groups, major congenital abnormalities) accounted for an overall reporting of 84% of outcomes in the intervention group and 85% of outcomes in the control group.
Selective reporting (reporting bias)	Low risk	The publications do not provide detail that would flag the study as being selectively reported. The availability of the published protocol supports this.
Other bias	Low risk	None identified

Kenyon 2016

Methods	RCT
Participants	Black and ethnic minority nulliparous women < 28 weeks' gestation having social risks from 3 PCTs in Birmingham, UK. The 3 PCTs: 1) Birmingham Women's National Health Service Foundation Trust, 2) Sandwell & West Birmingham NHS Trust, and 3) Heart of England NHS Foundation Trust
Interventions	Lay pregnancy outreach workers provided individualised care including home visits
Outcomes	Primary outcomes: engagement with antenatal care and postnatal depression. Secondary outcomes: maternal and neonatal morbidity and mortality, immunisation, breastfeeding uptake, self-efficacy, mother-infant bonding
Notes	We sought and received data on singletons and multiples from the study authors. We report only data on singleton pregnancies in this review. Dates of the study: July 2010–October 2011 Funding sources: National Institute of Health Research, Birmingham and Black County Collaboration for Leadership and Applied Health Research and Care Declarations of interest among primary researchers: states that there were no competing interests declared

Risk of bias

Bias	Authors' judgement	Support for judgement
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Kenyon 2016 (Continued)

Random sequence generation (selection bias)	Low risk	Randomisation lists were computer-generated using random block sizes and stratified for maternity trust.
Allocation concealment (selection bias)	Low risk	Telephone randomisation using a registered trials unit
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding of women and caregivers was not possible due to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Personnel who collected or entered data remained blind to allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of those who received allocated treatment, antenatal visits data available for 99% (intervention group) and 100% (control group); EPDS data available for 85% (intervention) and 82% (control). Data were available for > 90% of the secondary outcomes.
Selective reporting (reporting bias)	Low risk	Published protocol available. All a priori specified outcomes were reported in the results publication.
Other bias	Low risk	No other sources of bias noted

Klerman 2001

Methods	RCT
Participants	656 African American women in total who sought prenatal care from the Jefferson County Department of Health (Alabama USA) were enrolled from March 1994-June 1996. Women were eligible if they were: (1) African American, (2) eligible for Medicaid, (3) < 26 weeks' gestation, (4) ≥ 16 years old, (5) score of ≥ 10 on a risk assessment scale (social and obstetric: developed for the local region). Exclusion criteria were alcoholism and substance abuse, asthma, cancer, diabetes, epilepsy, high BP, 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 programmes Intervention group: 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 programme, and offered regular meetings with a social worker, to reduce stress and strengthen existing social support networks. Prenatal appointments were every 2 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 caesarean deliveries, perceptions of care and reported behaviour changes Neonatal outcomes: fetal death, mean birthweight, birthweight of liveborn infants < 2500 g, mean gestational age at birth, preterm births, IUGR, Apgar score < 7 at 1 min and at 5 min, NICU stay
Notes	Number of women originally randomised to each group not provided. Outcome data not available on a total of 37 enrolled participants (no reason provided) leaving 318 women in the experimental group and 301 in the control group for whom medical record data were reported. Dates of the study: March 1994-June 1996

Klerman 2001 (Continued)

Funding sources: Federal Agency for Health Care Policy and Research, federal Maternal and Child Health Bureau and Civitan International Foundation

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Assignment to group was done with "approximately equal monthly assignments to both [groups]" (p.106). No further details provided
Allocation concealment (selection bias)	Unclear risk	Nurse enrolling participant opened sealed envelope. No mention as to whether envelopes were opaque or consecutively numbered.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Due to the nature of the intervention, both participants and personnel would have been unblinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the assessors collecting medical record information were blinded to group allocation. Postpartum interviews conducted during the second year of the study were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Medical record data were obtained on 94% of the sample. Postpartum interviews were planned for all participants, but those done during the first year had "inconsistencies in their administration" and were not included in the report. The number of participants recruited in the 2nd year was not stated, and therefore a completion rate for the questionnaire data was not possible. Therefore we used only medical record data in this review.
Selective reporting (reporting bias)	Low risk	All outcomes appeared to be reported.
Other bias	Low risk	No other sources of bias noted

Little 2002

Methods	RCT
Participants	High-risk per the Minnesota Pregnancy Assessment Form (MPAF), low-income pregnant women attending 2 obstetric clinics and giving birth at a tertiary care centre in the Mid-West of the USA. Women could have a singleton or multiple pregnancy, however, outcome data were only analysed for those with a singleton pregnancy.
Interventions	Control group: telephone contact was made for the initial screen and then at the completion of pregnancy to collect information. Intervention group: the ROSEBUD Program: nurse-case-managers made telephone contact with the women every 7-14 days to assess pregnancy status, offer pregnancy-related education and support
Outcomes	Birthweight, gestation at birth, financial costs, women's satisfaction
Notes	This study did not contribute data to the meta-analysis, as there was a high attrition rate and the report did not include any numbers or proportions for the outcomes. Dates of the study: March 1999-March 2001

Little 2002 (Continued)

Funding sources: none stated

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were not blinded due to the nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcome data for satisfaction from both groups were collected by the nurse who had been the case manager for the control groups - followed a strict script. Other outcomes were routinely collected.
Incomplete outcome data (attrition bias) All outcomes	High risk	Data on the main outcome measures were available for 111 of the 175 singleton pregnancies, that is, 63.4% of the participants
Selective reporting (reporting bias)	Low risk	The main outcomes were all reported (but not in the form of numbers or proportions).
Other bias	Unclear risk	No other apparent sources of bias

Lutenbacher 2014

Methods	RCT
Participants	211 pregnant women (109 intervention and 102 control) with previous preterm infant receiving care from a large regional medical centre in the Southeastern part of USA
Interventions	<p>Control group: received standard care (not described)</p> <p>Intervention group: received standard care, home visits and telephone access to assigned nurse-midwife. Each woman received individual protocol, which included risk factors (e.g. depression, substance abuse, smoking), therapeutic relationship, family planning, 17-P usage, domestic violence, dental health, maternal infection, and breastfeeding</p>
Outcomes	Gestational age at birth, change in gestational age from previous preterm birth, maternal length of stay
Notes	<p>During the course of the study, additional resources of a psychiatrist and a social worker in prenatal clinic services. Both groups have access to these services. Intention to recruit 150 in each group. Concerns with systemic changes in the healthcare services, an interim analysis was conducted after 200 women had given birth and recruitment was stopped.</p> <p>Information about the 1 stillbirth and the numbers of babies born with birthweight of < 2500 was sought from and provided by the authors for inclusion in this review.</p> <p>Dates of the study: April 2007-January 2010</p>

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

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Lutenbacher 2014 (Continued)

Funding sources: BlueCross BlueShield Tennessee Health Foundation, National Center for Research Resources and National Center for Advancing Translational Sciences

Declarations of interest among primary researchers: stated that the content was the responsibility of the authors and did not represent official views of the NIH

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Project statistician generated computerised random numbers
Allocation concealment (selection bias)	Unclear risk	RA opened a sealed envelope containing the group allocation. It did not state whether the envelopes were opaque or not.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were blinded. It did not state whether the trained RAs collecting the data were blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No report whether the senior staff who reviewed the data for completeness were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were unavailable for 8.1% of participants because their births were outside the medical centre.
Selective reporting (reporting bias)	Low risk	No evidence of selective reporting
Other bias	Low risk	No sources of other bias noted

McLaughlin 1992

Methods	RCT
Participants	428 low-income women in Tennessee, USA (217 to intervention and 211 to control), < 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. Intervention group: 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
Notes	Dates of the study: not stated Funding sources: National Institute of Mental Health Declarations of interest among primary researchers: none stated

Risk of bias

McLaughlin 1992 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A computer-generated list of random numbers
Allocation concealment (selection bias)	Unclear risk	Randomisation performed by a RA in an off-site research office. Unclear if allocation sequence was concealed
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were unblinded to group allocation. Health care providers were blinded to group allocation
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collectors were kept blind to treatment group assignment of mothers. Medical records were reviewed by 2 data collectors.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Post randomisation exclusions: known miscarriage, known termination of pregnancy, twin pregnancy. Loss to follow-up 18 in intervention group and 27 in control group. Birthweight data available for 82% overall (84% intervention group and 79% of control group). Complete perinatal data reported for 78% in intervention group and 65% in control group, however, none of these outcomes were pre-specified for use in this review.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

Moore 1998

Methods	RCT
Participants	1554 women (775 to intervention and 779 to control), between 22-32 weeks' gestation, believed to be at risk for birth of a LBW baby (based on the Wake Forest University School of Medicine risk assessment tool, which considers social (young maternal age, being of black race) and obstetric/medical factors (previous preterm birth, previous LBW birth, previous still-birth, previous maternal renal disease), receiving prenatal care in a public clinic in North Carolina, USA. All spoke English and had access to a telephone.
Interventions	Control group: a booklet about preventing preterm labour, available in the clinic Intervention group: 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	LBW, 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 randomised, not for subgroups. Dates of the study: not stated Funding sources: National Institute of Nursing Research, NIH

Moore 1998 (Continued)

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random assignment created by biostatistician from computer randomisation table, who placed allocation in numbered opaque envelopes and then sealed them.
Allocation concealment (selection bias)	Low risk	Each nurse enrolling participants carried a box of the sequentially numbered envelopes. After obtaining consent, she opened the next envelope.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were unblinded to group allocation. Clinic personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcome assessor was blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes were obtained on 92.2% of the sample
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

Norbeck 1996

Methods	RCT, used Zelen method, and only those participants randomised to the intervention group were asked for consent.
Participants	114 adult low-income African American women (56 to intervention and 58 to control) 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 2 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) Intervention group: 4 standardised 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 LBW (< 2500 g)
Notes	5 (8.9%) in the experimental group refused to participate, 12% received only 1 of the formal intervention sessions, and 77% received 3 or 4 sessions Dates of the study: October 1990-December 1992

Norbeck 1996 (Continued)

Funding sources: National Institute of Nursing Research, NIH

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A clerical staff person prepared a set of consecutively numbered, sealed envelopes before the study began. The envelopes contained a group designation based on a table of random numbers.
Allocation concealment (selection bias)	Unclear risk	No statement about where or how the envelopes were opened
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were unblinded to group allocation. Research personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The outcome assessor was blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up was completed on all but 1 participant.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

Oakley 1990

Methods	RCT
Participants	509 women (255 to intervention and 254 to control) with a history of a LBW (< 2500 g) 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 Intervention 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 h/d. 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 birth, antenatal hypertension, antenatal depression, method of labour onset, epidural anaesthesia, labour length, type of birth, birthweight, gestational age, 5-min 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 fam-

Oakley 1990 (Continued)

ily doctor, postnatal depression, mother feeling low/loss of control over life, worried about baby, partner helpful. Women's satisfaction with care was only reported in the intervention group.

Notes

98% of those in the intervention group had at least 1 home visit.

Dates of the study: January 1986-May 1987

Funding sources: Department of Health and Social Security

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation organised in balanced blocks, stratified by centre. The allocations were based on a table of random numbers.
Allocation concealment (selection bias)	Unclear risk	Enrolling midwife telephoned the co-ordinating centre to get group assignment. It is unclear whether the envelopes were sealed, opaque and consecutively numbered.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the 507 women for whom case-note information was available, 5 were noted (after randomisation) to have twins: these were excluded from the analyses, as the study authors considered that the study was principally of social support for women with a singleton pregnancy. Medical record data were collected on all but 2 of the remaining cases. The 6-week questionnaire was completed by 94% of the sample. 1-year follow-up was obtained on 71% of the sample and 7-year follow-up on 47% and no data from them were used in this review. The 1-year and 7-year questionnaires were only mailed to those completing the 6-week questionnaire.
Selective reporting (reporting bias)	Low risk	Satisfaction with care was only reported for the intervention group and thus not used in this review. All other outcomes were reported for both groups.
Other bias	Low risk	No other sources of bias noted

Olds 1986

Methods	RCT
Participants	<p>Pregnant women in a semi-rural area in upstate New York, USA, who had no previous live births, were < 30 weeks' gestation, and had ≥ 1 of the following: age < 19, single parent, low socioeconomic status, or nulliparous and wanting to participate.</p> <p>90 women were enrolled to group 1; 94 to group 2; 100 to group 3 and 116 to group 4. This resulted in 184 in the combined control group (groups 1 and 2) and 216 in the combined intervention (nurse-visited group; groups 3 and 4).</p>

Olds 1986 (Continued)

Interventions	<p>4 groups</p> <p>Control groups:</p> <ol style="list-style-type: none"> 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, screening <p>Intervention groups:</p> <ol style="list-style-type: none"> 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	<p>For most of the comparisons of treatments, groups 1 and 2 were combined (which implies 'contamination' of the standard care, through some having transport to clinical visits) and groups 3 and 4 (nurse-visited) were combined. We were therefore unable to elicit the true 'standard care' group to compare with the interventions and thus we included no data from this study in the analyses.</p> <p>Dates of the study: not stated</p> <p>Funding sources: Bureau of Community Health Services, Robert Wood Johnson Foundation, W.T. Grant Foundation, Department of Health and Human Services</p> <p>Declarations of interest among primary researchers: none stated</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Assignment to 4 treatment groups was done at random using a deck of cards. Stratification for marital status, race, and geographic region was handled by having a separate deck of cards for each stratum. The decks were reconstituted periodically to over-represent those treatments with smaller numbers of participants (minimisation). In the last 6 months of the 30-month enrolment period, the number of cards for treatment 4 was increased. In 6 instances women who were living with other women already enrolled were assigned the same treatment condition as their housemates.
Allocation concealment (selection bias)	Low risk	At the end of the intake interview, women drew their own treatment assignment from the deck of cards.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Interviewers and the RA collecting medical record information were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	High risk	Data were not provided for 46 non-white women and 20 cases with maternal or fetal conditions predisposing to preterm birth and/or aberrations in fetal growth. These cases were excluded by the study authors prior to data analyses. The resulting rate of completion for the majority of outcome data was 77.5%. The only useable data for this review was rate of stillbirth, as this was available on the full sample.

Olds 1986 (Continued)

Follow-up was done several times over the first 2 years of life and the attrition rate was reported as "15-21%". No further details were available and no data from these follow-ups were used in this review.

Selective reporting (reporting bias)	High risk	Most of the reported results were unusable because they compared a combination of the usual care group and those provided with transport (support), with the other interventions. Additionally, many results were provided for only small subgroups or were derived from multivariate statistical procedures.
Other bias	Low risk	No other sources of bias noted

Robling 2016

Methods	RCT
Participants	Young, first-time mothers, aged ≥ 19 years, < 24 gestation, able to communicate in English, attending NHS organisations and local authorities in the UK participating in the PCT programme
Interventions	Control group: received usual care, including standard health and social care provided. Intervention group: received visits from a specially trained 'Family Nurse' in the home or somewhere else if they preferred. Visits were every week for the 1st month after they joined the study, and then every other week until the baby was born, weekly until the baby was 6 weeks old and then once every 2 weeks until the child was 20 months old. The last 4 visits were monthly until the child was 2 years old.
Outcomes	Primary outcomes: birthweight, prenatal tobacco use, child emergency attendances and/or admissions within 2 years of age, second pregnancy within 2 years of giving birth
Notes	Study registered, protocol published, peer-reviewed supplementary material available with the study publication and a full study report available on the study's website There were 24 sets of twins: 14 in the intervention group and 10 in the control group. The study authors provided data on request on the outcomes from women with singleton pregnancies: we have included only the singleton data in this review. Dates of the study: June 2009-July 2010 Funding sources: Department of Health (England) Declarations of interest among primary researchers: p7 of 17: "The funder required the inclusion of specified policy-relevant primary outcomes and determined the number of study sites, but played no role in finalising study design, data collection, data analysis, data interpretation, or report writing. The corresponding author had full access to all study data,..., and had final responsibility for the decision to submit for publication."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The allocation programme was created by a programmer at the Bristol Randomised Trials Collaboration, a registered Clinical Trials Unit. No further detail provided
Allocation concealment (selection bias)	Low risk	Allocation was concealed using a remote, computer-based system, accessible via telephone and Internet by the recruiting researcher.

Robling 2016 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Mothers and field-based staff were not blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Routine data were collected by field-based staff, who were not blinded to group allocation, although lack of blinding could not have affected results of primary outcomes. Assessors collecting data by computer assisted telephone interview were blinded to allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The publications and the full report of the study (available at the study's website) provide good detail of the participant flow and losses.
Selective reporting (reporting bias)	Low risk	All primary outcomes reported
Other bias	Low risk	No other sources of bias noted

Rothberg 1991a

Methods	RCT
Participants	80 poor black pregnant women (41 to intervention and 39 to control) with hypertension and < 26 weeks' gestation, attending obstetric clinics serving Soweto, South Africa and booked for birth at Baragwanath Maternity Hospital, Johannesburg, South Africa
Interventions	Control group: routine care (not described) at the hypertension clinic and routine antenatal care Intervention group: counselling 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 hospitalised), on average approximately 4 times during the remainder of the pregnancy. The social worker provided psychosocial support and counselling, help with problems at home and at work, and encouragement to comply with clinic staff instructions/advice.
Outcomes	Birthweight, gestational age at birth, number hospitalised in pregnancy for urgent BP control, number with proteinuria, caesarean birth, abortion/stillbirth, LBW rate
Notes	All women in the intervention group received counselling at least once Dates of the study: March 1987-March 1988 Funding sources: Anglo American Chairman's Fund, Iris Ellen Hodges Trust and Medical Faculty Research Fund Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention of method of how the allocation sequence was generated

Rothberg 1991a (Continued)

Allocation concealment (selection bias)	Unclear risk	Sealed envelopes containing a green or pink slip of paper were used. No mention if they were opaque, consecutively numbered, or the process used to give them out
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collectors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 2 cases were lost to follow-up.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

Rothberg 1991b

Methods	RCT
Participants	104 white 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 LBW, 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 Intervention group: a minimum of 20 min of individualised counselling from an assigned social worker at each antenatal visit or by telephone shortly thereafter
Outcomes	Birthweight < 3000 g, number of LBW babies, preterm rate, birthweight categorised in 500 g increments
Notes	Number of women originally randomised to each group not provided. 8 mothers were excluded after randomisation for complications or because they transferred to another centre, leaving 47 women in the intervention group and 49 in the control group. Dates of the study: not stated Funding sources: not stated Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No description of how this was done

Rothberg 1991b (Continued)

Allocation concealment (selection bias)	Unclear risk	Sealed envelopes containing a green or pink slip of paper were used. No mention if they were opaque, consecutively numbered, or the process used to give them out.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Medical record data were collected blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	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. This resulted in an 83% follow-up rate.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

Spencer 1989

Methods	RCT. Randomisation prior to consent; consent to participate only sought from women allocated to the experimental group (Zelen method)
Participants	1288 pregnant women (655 to intervention and 633 to control) < 20 weeks' gestation and at increased risk of giving birth to a LBW baby, booked for birth in either of 2 maternity units within the South Manchester Health District, England, UK. Asian women were excluded from the study. Risk was defined as ≥ 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 deprivation.
Interventions	Control group: routine antenatal care (not described) Intervention group: 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 LBW, SGA, and preterm births, pregnancy terminations, miscarriages, stillbirths, live births
Notes	Of 655 women randomised to the intervention group, 384 (58.6%) refused the social support intervention. Comparisons of experimental and control groups included all women originally randomised, except for 25 controls and 27 experimental group for whom outcome data were unavailable. Secondary analyses comparing those who accepted the family worker in the intervention group, with those who did not accept combined with the control group, showed no statistically significant differences between the 2 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%). Dates of the study: June 1982-June 1983; June 1984-June 1985 (funding issues)

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

Spencer 1989 (Continued)

Funding sources: North West Regional Health Authority

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random allocation "using random number tables" was done after identifying women that were eligible for the study.
Allocation concealment (selection bias)	Unclear risk	No mention of how group allocation was given out or by whom
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up rate was 95.5%.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other source of bias noted

Spira 1986

Methods	RCT
Participants	996 women in the Seine Saint-Denis region of France with a history of threatened preterm labour, a cervical suture, signs of pre-eclampsia, haemolytic disease, multiple pregnancy, hydramnios, previous history of repeated miscarriages, stillbirths, prematurity, LBW, uterine malformations or other serious complications including psychological. 501 women were randomised to receive the intervention and 495 to the control group.
Interventions	Control group: hospitalised Intervention group: domiciliary care by midwives
Outcomes	Birthweight, gestational age at birth, perinatal mortality, birthweight < 2500 g, < 37 weeks' gestation at birth
Notes	4 women refused the intervention (0.8%) Dates of the study: October 1978-January 1980 Funding sources: not stated Declarations of interest among primary researchers: not stated

Spira 1986 (Continued)

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated that "random selection for the 2 groups was stratified by site". No mention of how the 'random selection' was created.
Allocation concealment (selection bias)	High risk	"Women were divided into two groups, 'by lots'" (translation document)
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded to group allocation. It is not clear whether personnel were blinded to group allocation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear whether outcome assessors were blinded to group allocation.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up rate was 88.7%. 43 women were lost or excluded in the intervention group and 70 in the control group.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

Villar 1992

Methods	RCT
Participants	2235 pregnant women (1115 to intervention and 1120 to control) at risk for giving birth to a LBW baby, between 15-22 weeks' gestation, in centres in: Rosario, Argentina; Pelotas, Brazil; Havana, Cuba; and Mexico City. Risk was defined as ≥ 1 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) Intervention group: 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	LBW, preterm birth, IUGR, forceps birth, caesarean birth, anaesthesia during labour, stillbirth, perinatal death, Apgar score < 7 at 5 min, admission to NICU, psychosocial support
Notes	90% of women in the intervention group received at least 1 home visit. Dates of the study: not stated Funding sources: International Development Research Center, Ottawa, Canada

Villar 1992 (Continued)

Declarations of interest among primary researchers: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The Data Coordinating Centre produced computer-generated numbers in balanced blocks of 20 and stratified by centre.
Allocation concealment (selection bias)	Low risk	A sequence of sealed, opaque envelopes was used by a single investigator in each hospital to assign women to groups.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were unblinded to group allocation. The clinic personnel were not told whether the women were enrolled in the study.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Data collection at 36 weeks' gestation, postpartum in hospital and at 40 days was blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	In-hospital data collection was done for 93% of the sample and follow-up at 40 days postpartum was done for 85%. Data from the follow-up at 36 weeks' gestation was not usable as some of the sample had delivered by that gestation.
Selective reporting (reporting bias)	Low risk	All outcomes were reported
Other bias	Low risk	No other sources of bias noted

BP: blood pressure; **CTG:** cardiotocograph; **EPDS:** Edinburgh Postnatal Depression Scale; **IUGR:** intrauterine growth restriction; **ITT:** intention-to-treat; **LBW:** low birthweight; **NHS:** National Health Service; **NICU:** neonatal intensive care unit; **NIH:** National Institutes of Health; **PCT:** Primary Care Trust; **PHNs:** public health nurses; **RA:** research assistant; **RCT:** randomised controlled trial; **SGA:** small-for-gestational age

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Arranz 2017	The intervention is a mind-body activity, which is an exclusion criteria for this review.
Bastani 2006	This is a not a study of social support during pregnancy. It was a study of applied relaxation training to reduce anxiety and stress in pregnant women.
Beazley 2001	2 abstracts, which are a pre-specified exclusion. If a full study report becomes available, we will re-assess the study for inclusion.
Boehm 1996	Not a RCT. 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	This is not a study of women judged to be at risk for preterm birth or LBW baby. The study was to improve pregnant women's health behaviours during pregnancy. No usable or clinically interpretable outcome data. Published data are mean scores (without SDs) 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.

Study	Reason for exclusion
Chowdhury 2017	Cluster-randomised study of a nutritional intervention, with the primary outcome of infant birth-weight and secondary outcomes that include maternal nutritional behaviours. The intervention does not include social support during pregnancy.
Cohen 2002	This is not a study of additional social support during pregnancy. The intervention combined guided imagery with mindfulness-based stress reduction in a prenatal education programme.
Collado 2014	This is not a study of additional social support. The intervention used a psychosomatic approach for women at risk of postnatal depression, not specifically at risk for SGA baby.
Dykema 2012	This is not a study of additional social support. It examined the effects of incentives on response rates, costs, survey response distributions, and item nonresponse.
Ekhtiari 2014	This is not a study of additional social support. The intervention was solely an education programme.
El- Mohandes 2011	These 11 publications, including conference abstracts, report the findings of a psycho behavioural intervention, rather than social support.
Ford 2002	The support did not meet our definition for the purposes of this review.
Goulet 2001	This is not a study of support during pregnancy. The intervention lasted 2 weeks and consisted of home uterine activity monitoring and additional information.
Graham 2003	This is not a report of a RCT but a description of a programme.
Hoyer 1994	This is a letter to the editor. There is no indication of how many were enrolled and randomised. No usable data in results (test statistics without numbers). Intervention does not appear to be social support; the study compared nurse-led group prenatal care with regular prenatal care by physicians or other clinic practitioners.
Ickovics 2007	This is not a study of social support. The study compared individually-provided prenatal care with prenatal care provided in groups. Group prenatal care was hypothesised to decrease HIV risk behaviours and STD transmission. The report is a secondary analysis to determine whether group prenatal care leads to better reproductive health outcomes.
Iedema-Kuiper 1996	This is not a study of social support. The study compared the same care given at home versus in the hospital.
Jahan 2014	This RCT compared outcomes for women who participated in a 3-month education programme about nutrition and women who did not.
Kakkilaya 2011	This is not a study of social support. The study tested the use of a visual aid in counselling.
Kamalifard 2017	The intervention in this protocol registration is labelled "counselling". This involves small group instruction on physiological aspects of labour and childbirth, rather than emotionally supportive counselling.
Khoramabadi 2015	The intervention in this study was 2 nutritional education sessions based on the Health Belief Model and as such, is not a study of social support.
Kitzman 2000	This study compared 2 groups of women who had received prenatal and infancy home visitation 3 years previously, and was a follow-up to determine the effectiveness of the programme 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.

Study	Reason for exclusion
Koniak-Griffin 2000	This is not a study of social 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.
Kumar 2014	This is not a study of social support. This study compared different counselling methods.
Lee 2009	This is not a study of social support in pregnancy. Report is of a subset of pregnant women who were part of a larger study to evaluate a public health programme in New York, USA, which included pre and postnatal home visits. The purpose of the programme was to prevent child abuse and neglect. Of 1297 originally randomised, only 501 (38.6%) (236 and 265 in each group) were included in this secondary analysis.
Lumley 2006	This is not a study of social support in pregnancy. The intervention was pre-pregnancy advice and counselling.
Mejdoubi 2014	This is not a study of additional social support. The intervention was smoking cessation counselling.
NCT01997151	This is not a study of social support. It tested the effectiveness of an iPad-delivered intervention.
Nguyen 2003	This is not a study of social support. Both groups received home visits in pregnancy, and the difference was in the training of the home visitors. 1 group received visits by a 'traditional' public health nurse and the other by a public health nurse with advanced training. The objective was to increase women's self-efficacy. High risk of bias in method of randomisation.
Nicolson 2013	This is not a study of social support. The intervention was a short attachment intervention on adolescent mother-infant relationship.
Tough 2006	This is not a study of social support. The aim was to improve use of healthcare resources. There were 3 groups, 1 of which received social support by home visitors during pregnancy. No usable clinical outcome data. Primary objective was to measure the use of community-based, pregnancy-related resources, including prenatal and parenting classes, breastfeeding supports, and nutrition counselling.

LBW: low birthweight; **RCT:** randomised controlled trial; **SD:** standard deviation; **SGA:** small for gestational age; **STD:** sexually transmitted disease

Characteristics of ongoing studies [ordered by study ID]

Denktas 2014

Trial name or title	Health pregnancy 4 all study (HP4All).
Methods	There are 2 substudies within the overall programme: 1, not included in this review, relates to customised preconception care in a cohort of high-risk women. The second, which will inform this review, involves pregnancy care. Cluster-RCT (municipalities)
Participants	Women attending pregnancy care in municipalities in the Netherlands that have a high prevalence of perinatal mortality, SGA babies and premature births
Interventions	Control group: conventional risk assessment

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Denktas 2014 (Continued)

Intervention group: women will be screened for medical and non-medical risks using a 70-item 'R4U' scorecard, based on social status, lifestyle, obstetric history, medical history and ethnicity. The risk score then triggers referral for medical or psychosocial care (not described further) in non-medical care pathways.

Outcomes	Primary: SGA (< 10th percentile), preterm birth (< 37 weeks), efficacy of intervention (number of R4U forms filled out) Secondary outcomes: perinatal mortality, antenatal detection of SGA, unexpected preterm births
Starting date	1 April 2012
Contact information	dentkas@abd.eur.nl
Notes	This publication is the protocol for HP4All, conducted in the Netherlands. Trial registration: NTR3367

ISRCTN37733900

Trial name or title	POPPIE: Pilot study Of midwifery Practice in Preterm birth Including women's Experiences
Methods	RCT
Participants	Asymptomatic women with a singleton pregnancy ≤ 24 weeks of pregnancy and at risk of preterm birth (per criteria)
Interventions	Continuity of midwifery care, provided "... in a multi-disciplinary network of consultation and referral with other care providers"
Outcomes	Primary outcome: initiation of [specified] interventions related to prevention and management of preterm labour/birth Secondary outcomes include: women's perceptions/experiences; labour and birth outcomes; health/complications in pregnancy; health economic analysis
Starting date	1 May 2017
Contact information	Mrs Cristina Fernandez Turienzo, cristina.fernandez_turienzo@kcl.ac.uk
Notes	Study website: www.medscinet.net/poppie/

Saville 2016

Trial name or title	Low birthweight South Asia trial (LBWSAT).
Methods	Cluster-RCT. Rural VDC are the unit of randomisation. There are 80 VDCs cluster-randomised to 4 groups of 20 VDC each
Participants	Pregnant women who attend village community meetings in VDCs, from 8 weeks' gestation
Interventions	Control group (Group 1): women receive pregnancy care through the Government of Nepal Health Clinics

Saville 2016 (Continued)

Intervention group (Group 2): enhanced Participatory Learning and Action (PLA) behaviour change strategy (rather than a purely educational activity)

Intervention group (Group 3): enhanced PLA plus a monthly food supplement (10 kg sack of "Super Cereal" from 8 weeks' gestation

Intervention group (Group 4): enhanced PLA plus an unconditional cash transfer (equivalent of USD 7).

Outcomes	<p>Primary outcomes: birthweight, infant weight-for-age Z-score</p> <p>Secondary outcomes: prevalence of LBW; preterm birth; miscarriage, stillbirth or neonatal mortality; maternal weight gain during pregnancy; maternal eating behaviour; illness (mother and infant); infant length-for-age and weight-for-length Z scores; infant head circumference; maternal postnatal mid-upper arm circumference and body mass index</p>
Starting date	13 February 2014
Contact information	Dr Naomi Saville, n.saville@ucl.ac.uk
Notes	<p>This publication is the protocol for LBWSAT, conducted in Nepal.</p> <p>The PLA is facilitated by the female community health and the frontline health volunteers in place in each VDC, trained and supported by the facilitation field co-ordinators.</p> <p>Trial registration: ISRCTN75964374:1</p>

LBW: low birthweight; **RCT:** randomised controlled trial; **SGA:** small-for-gestational age; **VDC:** village development committees

DATA AND ANALYSES

Comparison 1. Additional support versus routine care during at-risk pregnancy

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Birthweight < 2500 g	16	11770	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.86, 1.04]
1.1 Support by healthcare professionals	13	9341	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.83, 1.02]
1.2 Support by lay persons	3	2429	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.82, 1.33]
2 Gestational age < 37 weeks at birth	14	12282	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.84, 1.01]
2.1 Support by healthcare professionals	12	11036	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.83, 1.00]
2.2 Support by lay persons	2	1246	Risk Ratio (M-H, Random, 95% CI)	1.16 [0.79, 1.71]
3 Stillbirth/neonatal death	15	12091	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.88, 1.41]
3.1 Support by healthcare professionals	13	9668	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.84, 1.36]

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Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.2 Support by lay persons	2	2423	Risk Ratio (M-H, Fixed, 95% CI)	1.83 [0.73, 4.57]
4 Caesarean birth	15	9550	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.83, 0.97]
5 Number having antenatal hospital admission	4	787	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.68, 0.91]
6 Mean number of antenatal hospital admissions	1	1525	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.06, -0.04]
7 Postnatal re-hospitalisation of mother	1	173	Risk Ratio (M-H, Fixed, 95% CI)	1.6 [0.80, 3.21]
8 Antenatal depression	1	486	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.50, 1.20]
9 Postnatal depression	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
9.1 Self-reported	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 Positive EPDS score	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Satisfaction with pregnancy care	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
10.1 Pregnancy care rated as 'very helpful'	1		Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 1 Birthweight < 2500 g.

Analysis 1.2. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 2 Gestational age < 37 weeks at birth.

Analysis 1.3. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 3 Stillbirth/neonatal death.

Analysis 1.4. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 4 Caesarean birth.

Analysis 1.5. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 5 Number having antenatal hospital admission.

Analysis 1.6. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 6 Mean number of antenatal hospital admissions.

Analysis 1.7. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 7 Postnatal re-hospitalisation of mother.

Analysis 1.8. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 8 Antenatal depression.

Analysis 1.9. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 9 Postnatal depression.

Analysis 1.10. Comparison 1 Additional support versus routine care during at-risk pregnancy, Outcome 10 Satisfaction with pregnancy care.

APPENDICES

Appendix 1. Search methods - ICTRP and ClinicalTrials.gov

ICTRP

(each line was run separately)

support AND low birthweight

antenatal AND low birthweight

prenatal AND low birthweight

pregnant AND low birthweight

pregnancy AND low birthweight

ClinicalTrials.gov

Advanced search

Interventional studies | low birthweight | pregnancy

Interventional studies | low birthweight | antenatal

Interventional studies | low birthweight | prenatal

WHAT'S NEW

Date	Event	Description
5 February 2018	New citation required but conclusions have not changed	This updated review includes 25 studies, with 21 contributing data (compared with 17 studies in the previous version). Conclusions remain the same.
5 February 2018	New search has been performed	Methods updated. Search updated. New 'Summary of findings' tables added. Two new authors joined the team. The new authorship endeavoured to retain the intent of the original re-

Date	Event	Description
		view whilst updating to current Pregnancy and Childhood Group methods and processes.

HISTORY

Protocol first published: Issue 1, 1995

Review first published: Issue 1, 1995

Date	Event	Description
4 May 2010	New citation required but conclusions have not changed	New author helped to update the review.
11 February 2010	New search has been performed	Search updated. No new trials identified. Revision to every aspect of the Review to bring it up to date in terms of current methodological guidelines, including guidelines about number of pre-specified outcomes. We removed one trial (Iedema-Kuiper 1996) from the review after further translation of the methods indicated that no additional support was provided to the intervention group.
31 March 2009	New search has been performed	Search updated. Eight new studies identified: (Bastani 2006 ; Cohen 2002 ; El-Mohandes 2011 ; Hoyer 1994 ; Ickovics 2007 ; Lee 2009 ; Lumley 2006 ; Tough 2006). None met inclusion criteria. Beazley 2001 and Nguyen 2003 previously in awaiting classification also now excluded. Conclusions of Review unchanged. Edits were made throughout the Review.
12 May 2008	Amended	Converted to new review format.
30 September 2005	New search has been performed	<p>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.</p> <p>Two trials await assessment (Beazley 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.</p> <p>Typos were corrected. One study ID was changed to reflect the name of the primary author (Middlemiss 1989 is now identified as Dawson 1989).</p>

CONTRIBUTIONS OF AUTHORS

In this updated review, Rosalind Lau, Mary Anne Biro and Christine East prepared all aspects of the revised review, including assessing the studies found for inclusion, risk of bias and data extraction. Suzanne Fredickericks read, advised on and approved the drafts of this review. Christine East is the guarantor of the review

DECLARATIONS OF INTEREST

Christine E East: none known

Mary A Biro: none known

Suzanne Fredericks: none known

Rosalind Lau: none known

SOURCES OF SUPPORT

Internal sources

- University of Toronto, Canada.
- Ryerson University, Canada.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In this updated version, we revised the background and the methods section extensively to adhere to the current standards of MECIR and Cochrane Pregnancy and Childbirth, including an additional search of [ClinicalTrials.gov](https://clinicaltrials.gov), and the World Health Organization International Clinical Trials Registry Platform (ICTRP).

Outcomes

Although termination of pregnancy was not listed as an outcome in the methods section of the previous version of the review, results for this outcome were reported. We debated including this outcome, however, we elected not to do so, on the basis of support being offered primarily to reduce births at less than 37 weeks' gestation or small-for-gestational-age birth, rather than assist women in making decisions about continuing a pregnancy. Furthermore, most studies offered support from mid- to late in the second trimester, when termination may be less of a consideration or option for the women.

We also reviewed and revised the order of the primary and secondary outcomes to reflect the objectives of the review.

In the last version of this review, (Hodnett 2010), caesarean section was a primary outcome and this is now a secondary outcome in this update (2018). We have added the outcome antenatal depression to maternal secondary outcomes. We have changed the outcome 'less than highly satisfied with antenatal care' to 'satisfaction with pregnancy care', which required the findings of one study that had been included in a forest plot in previous versions to be reported in text in this update.

Sensitivity analysis

For this update, we added some text about what might be considered high risk of bias or high non-uptake of the proffered intervention, as follows:

1. results when studies with a high risk of bias, specifically related to allocation concealment and/or attrition rates in excess of 20% were included versus excluded;
2. fixed-effect versus random-effects analyses when evidence of statistical heterogeneity was present (defined as an I^2 value greater than 50% and inconsistency between studies in the direction or magnitude of effects (judged visually);
3. results when non-uptake of the support intervention was high versus low. We acknowledge that this is a potentially subjective judgement to make: however, it would seem appropriate to consider above and below 50% would be a reasonable means of categorising high and low non-uptake.

We also conducted post-hoc sensitivity analyses in this update to:

1. explore the potential influence of data included for more than one neonate from a multiple pregnancy; and
2. including or excluding three studies that probably included the results of twin pregnancies in their reports of fetal and neonatal outcomes.

INDEX TERMS

Medical Subject Headings (MeSH)

*Infant, Low Birth Weight; *Social Support; Cesarean Section [statistics & numerical data]; Infant, Premature; Pregnancy Outcome; Pregnancy, High-Risk; Prenatal Care [methods]; Randomized Controlled Trials as Topic; Social Class

MeSH check words

Female; Humans; Infant, Newborn; Pregnancy