Article type : Review

Systematic review and meta-analysis of non-pharmacological interventions to reduce the symptoms of mild to moderate anxiety in pregnant women

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Abstract

Aim: To assess the effectiveness of non-pharmacological interventions for pregnant women with symptoms of mild to moderate anxiety.

Background: Many pregnant women experience mild to moderate symptoms of anxiety and could benefit from additional support. Non-pharmacological interventions have been suggested for use during pregnancy.

Design: A systematic review of randomised controlled trials.

Data sources: Randomised controlled trials published since 1990, identified from electronic databases: Medline; CINAHL; Maternity and Infant Care; PsycINFO; Cochrane Database of Systematic Reviews; CENTRAL; EMBASE; Centre for Reviews and Dissemination; Social Sciences Citation Index; ASSIA; HTA Library; Joanna Briggs Institute Evidence-Based Practice database; Allied and Complementary Medicine.

Review methods: Conducted according to the Centre for Reviews and Dissemination procedure. Papers were screened (N=5,222), assessed for eligibility (N=57) and selected for inclusion (N=25). The Cochrane Collaboration’s tool for assessing risk of bias was used. Papers were assessed for clinical and statistical heterogeneity and considered for meta-analysis. Descriptive analysis of the data was conducted.

Results: Psychological, mind-body, educational and supportive interventions were delivered individually and to groups of pregnant women over single or multiple sessions. The State-Trait Anxiety Inventory was the most commonly used anxiety measure. In 60% of studies there were fewer than 40 participants. Meta-analysis of three studies indicated no observed beneficial effect in the reduction of anxiety.

Conclusion: There was insufficient evidence from which to draw overall conclusions regarding the benefit of interventions. Results were predominantly based on small samples.

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Many papers provided an inadequate description of methods which prevented a full assessment of methodological quality.

**Keywords**

anxiety, pregnancy, antepartum, systematic reviews and meta-analyses, nurses, nursing, midwifery

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<table>
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<th>Summary</th>
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| **Why is this review needed?** | • The prevalence of anxiety disorders in pregnancy is reported between 10-15%. Severe symptoms of anxiety are associated with negative health outcomes for women and infants.  
• Interventions to reduce symptoms of anxiety in pregnancy have the potential to improve health outcomes by developing coping strategies and preventing an escalation of symptoms.  
• Research is required to confirm the effectiveness of interventions to improve symptoms of mild to moderate anxiety in pregnancy. |
| **What are the key findings?** | • A variety of interventions were evaluated which included: psychological, educational, supportive interventions and mind-body interventions.  
• Most studies had small sample sizes and inadequate procedural reporting. |
• The review provides a discussion of the intervention components in the included studies: duration, recruitment, eligibility criteria and attrition.

How should the findings be used to influence policy / practice / research / education?

• The findings identify where improvements can be made in further research in anxiety in pregnancy.
• The findings have relevance for healthcare professionals and researchers for service delivery and research design.

INTRODUCTION

Anxiety disorders are the sixth leading cause of disability globally, in terms of Years Lived with Disability (YLD) and accounted for 390 Disability Adjusted Life Years (DALYs) per 100,000 persons in 2010 (Baxter et al. 2014). Symptoms of generalised anxiety disorder (GAD) are associated with significant distress or impairment in social and occupational functioning and include: feeling restless or on edge; having difficulty concentrating; irritability; fatigue; muscle tension and sleep disturbance (American Psychiatric Association 2013). A high proportion of DALYs caused by anxiety disorders were experienced by females (65%) and DALY rates peaked for men and women in the 15–34 year age groups (Baxter et al. 2014). Symptoms of GAD below the diagnostic threshold (Diagnostic and Statistical Manual of Mental Disorders (DSM) and International Classification of Diseases (ICD) criteria) were found to increase the risk of developing co-morbid mental health problems and somatic disorders. They were associated with high levels of distress; poor perceived physical health; impairment in psychosocial functioning and more primary health care use than in non-anxious individuals (Haller et al. 2014). Haller et al. (2014) reported the median point prevalence rate of sub-threshold GAD symptoms was 4.4% in two general
population studies (Angst et al. 2006, Kessler et al. 2005). In these studies anxiety symptoms were assessed via structured clinical interviews (SPIKE: Angst & Dobler-Mikola 1985, WMH-CIDI: Kessler & Ustün 2004). The prevalence of sub-threshold anxiety symptoms were double the rate of the full disorder and prevalence rates were higher for women than men. In postpartum women, the prevalence of one or more anxiety disorders (assessed via structured diagnostic interview) has been reported as 8.5% (Goodman et al. 2016). The prevalence of anxiety disorders in pregnancy varies widely in different reports, from 10 to 15% (National Institute for Health and Care Excellence (NICE) 2014, Rubertsson et al. 2014, Goodman et al. 2014). In a UK community sample of pregnant women at 18 weeks gestation, the prevalence was reported as 14.6% (Heron et al. 2004). Symptoms of self-report anxiety in pregnancy have been reported to be higher in the first and third trimesters with a notable decrease in the second trimester (Öhman et al. 2003, Statham et al. 1997).

Elevated and prolonged anxiety in pregnancy has been associated with pre-term birth, fetal growth restriction (Ding et al. 2014, Littleton et al. 2007, Rich-Edwards & Grizzard 2005) and severe behavioural problems in developing children (Blair et al. 2011, Cardwell 2013, Davis & Sandman 2010, Glover 2014, Stein et al. 2014). Mild to moderate psychological distress can be extremely debilitating for pregnant women and can affect a woman’s general functioning (Furber et al. 2009). Anxiety during pregnancy has been reported to predict post-traumatic stress disorder (Czarnocka & Slade 2000, Iles et al. 2011) and depression in the postnatal period (Heron et al. 2004, Coelho et al. 2011).

Background

The Healthy Child Programme (Department of Health (DOH) 2009) highlights possible interventions to support women with anxiety in pregnancy, including social support, assisted self-help and Cognitive Behavioural Therapy (CBT). For pregnant women with a diagnosed
anxiety disorder, CBT has been suggested as the first line treatment option (Marchesi et al. 2016). The maternal mental health guidance (DOH 2012) stated that all women identified with mild to moderate mental health issues should be offered a range of support tailored to the needs of those women. The NICE guideline for perinatal mental health (NICE 2014) suggested that low intensity psychological interventions may benefit women with symptoms of mild to moderate anxiety which significantly interfere with personal or social functioning. However, services to support the emotional wellbeing of women are not always readily available and need to be strengthened (Maternal Mental Health Alliance (MMHA) 2013). The aim of interventions for pregnant women with symptoms of mild to moderate anxiety is to provide suitable and timely support and treatment to prevent an escalation of symptoms and improve a woman’s ability to cope (NICE 2007, MMHA 2013). However, the evidence of the effectiveness of interventions for mild to moderate symptoms of anxiety in pregnancy has not yet been determined (Ryan 2013, Glover 2014) and further research is required.

THE REVIEW

Aim

The aim was to conduct a systematic review to establish the effectiveness of non-pharmacological interventions for pregnant women with symptoms of mild to moderate anxiety. It addressed the following research questions:

1. What non-pharmacological interventions to reduce the symptoms of anxiety in pregnant women have been tested?

2. How effective are non-pharmacological interventions in reducing the symptoms of mild to moderate anxiety in pregnant women?
Design

A scoping review was undertaken to identify appropriate parameters for the development of the PICOS (Population, Intervention, Comparators, Outcomes, Study designs) process for the systematic review (Centre for Reviews and Dissemination (CRD) 2009). The review protocol was registered on the PROSPERO database at the CRD (Evans et al. 2015: CRD42015017841). A systematic review was conducted according to the Centre for Reviews and Dissemination guidelines for a quantitative systematic review (CRD 2009). The report follows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement guidelines (Moher et al. 2009).

Search methods

A systematic search of the following 13 electronic databases was undertaken in January 2015 and updated in August 2016: Medline (Medical Literature Analysis and Retrieval System Online), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Maternity and Infant Care database from MIDIRS (Midwives Information and Resource Service), PsycINFO, The Cochrane Database of Systematic Reviews (CDSR) and The Cochrane Register of Controlled Trials (CENTRAL), EMBASE (Excerpta Medica Database), CRD (Centre for Reviews and Dissemination), SSCI (Social Sciences Citation Index), ASSIA (Applied Social Sciences Index and Abstracts), HTA (Health Technology Assessment) Library, JBI (Joanna Briggs Institute) Evidence-Based Practice Database and AMED (The Allied and Complementary Medicine Database). Visually scanning reference lists from relevant primary studies and reviews identified three additional studies for inclusion.
**Inclusion and exclusion criteria**

The studies had to meet the following criteria to be included in the review:

Papers written in English and published since 1990. This period reflects the time since non-pharmacological interventions were recommended to support women’s mental health during pregnancy (DOH 1999).

**Population**

Studies with pregnant women of all parities across the three trimesters of pregnancy were included (including pregnant women from general populations and women with symptoms of mild to moderate anxiety). Studies with pregnant women with severe symptoms of anxiety and/or depression; under the care of specialist mental health services; less than 18 years of age; who lack capacity to provide informed consent and pregnant women with complex social factors (NICE 2010) were excluded.

**Intervention**

Studies of non-pharmacological interventions were included. Non-pharmacological interventions include: physical; cognitive; behavioural and other complementary methods. Studies were included if the evaluation focused on the effects on symptoms of anxiety alone or anxiety and other psychosocial outcomes.

**Comparators**

Studies with comparison groups which comprised any form of usual maternity care or other pharmacological or non-pharmacological interventions were included.

**Outcomes**

Studies were included where the primary or secondary outcome measure included symptoms of anxiety identified by various self-report measures or clinical interview measured at any time in the antenatal period prior to the onset of labour. Studies that did not include
symptoms of anxiety as an outcome measure or where symptoms of anxiety were only measured in the intrapartum or postnatal period were excluded.

**Study design**

Randomised Controlled Trials (RCTs) and pilot RCTs of non-pharmacological interventions, systematic reviews and meta-analyses were included. Non-randomised studies were excluded. Key search terms were: pregnancy; antenatal; prenatal; perinatal; antepartum; childbearing; intervention; anxiety; randomised controlled trial; clinical trial, review. A full search strategy is included in Appendix 1.

**Search outcome**

After 45 duplicates were deleted, the search identified 5,222 potentially eligible papers which were individually assessed on the information provided in the study title and abstract. From these 5,168 records were excluded using the inclusion and exclusion criteria. Following inclusion of 3 additional papers identified through scanning reference lists of relevant studies, 57 papers were retrieved and the full text assessed. From these, 32 papers were excluded and the remaining 25 papers were selected for inclusion. A research supervisor independently read the potentially relevant papers and the papers identified for inclusion were agreed with any disagreements resolved through discussion with a second research supervisor. The literature search and inclusion process are detailed in the PRISMA Flow Diagram in Figure 1 (Moher et al. 2009).

The twenty-five included randomised controlled trials were reported between 1992 and 2016 (Table 1) and were conducted in Australia, Belgium, Canada, Germany, Greece, India, Iran, New Zealand, Portugal, Switzerland, Taiwan, the UK and the US. Six studies were pilot...
RCTs. The components of the interventions are detailed in Table 1. The total number of participants included in the 25 studies was 5,156.

**Quality appraisal**

Twenty-five included RCTs were independently assessed by two reviewers (KE, JM). The studies were quality assessed using the Cochrane Collaboration’s tool for assessing risk of bias (CRD 2009, Higgins *et al.* 2011) to evaluate six quality domains: sequence generation; allocation concealment; blinding; incomplete data; selective outcome reporting; and other sources of bias. Many domains included in the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach are assessed in the review (Guyatt *et al.* 2008), however an overall rating using the GRADE approach was not undertaken as: 1. anxiety symptoms was not the sole outcome measure in many included studies; 2. anxiety symptoms were assessed using different measurement tools; 3. many studies were small studies or pilot studies; 4. most studies were assessed as having ‘unclear risk of bias’; 5. there was considerable clinical heterogeneity between the included studies. Therefore, it was not possible to draw overall conclusions for making recommendations based on confidence of the current evidence.

**Data extraction and synthesis**

Data were extracted using a predesigned and piloted template which included the following headings: study design; intervention design; recruitment rate; number of participants; setting; outcome measures; control/comparators; results and comments. Data extraction tables were produced to present the study characteristics, results and risk of bias. A narrative description of the data was conducted.
Where outcome data were available, the studies were assessed for methodological, clinical and statistical heterogeneity and considered for meta-analysis. Assessment of clinical heterogeneity was informed by the findings from the scoping review (CRD 2009) and considered the types of participants (women with obstetric complications, general antenatal population, women with symptoms of or risk factors for mild to moderate anxiety), duration of interventions (single or multiple sessions), delivery of interventions (delivered to individuals or groups) and types of intervention (psychological, mind/body, educational, supportive interventions) in the included studies.

To evaluate statistical heterogeneity, the Chi-squared test was performed to generate the $Q$-statistic and the $I^2$ statistic was calculated (CRD 2009, Higgins & Green 2011). A random effects model was considered to be the most appropriate method of analysis as it involves an assumption that the effects being estimated in the different studies are not identical, but follow some random distribution (CRD 2009, Higgins & Green 2011). The standardised mean difference was used as the summary statistic for the self-report anxiety scores, with 95% confidence intervals and two-tailed $p$-tests conducted for each outcome where possible. The criteria for conducting sub-group analysis were pre-specified in the review protocol.

**RESULTS**

**Quality of randomised controlled trials**

One study was assessed to have an overall ‘low risk of bias’ (Faramarzi et al. 2015). One study was assessed as having an overall ‘high risk of bias’ (Korol & Von Baeyer 1992). Twenty-three studies were assessed as having an overall ‘unclear risk of bias’. The risk of bias assessment summary for all included randomised controlled trials is presented in Figure 2. The sample sizes ranged from 25 participants (Côté-Arsenault et al. 2014) to 2,212 participants (Dodd et al. 2016).
Participants

Seven studies recruited women from a general pregnant population and four studies included nulliparous pregnant women. Six studies recruited pregnant women with a history of mood concerns or elevated anxiety / depression scores. Other studies included women who were not selected due to anxiety / depression symptoms but women who: had obstetric complications (high BMI, nausea, gestation diabetes mellitus); had social risk factors (single pregnant women or with unemployed partners); were African American pregnant women; were pregnant women attending for amniocentesis and pregnant women with a history of previous pregnancy loss.

Recruitment

Twelve studies reported a power calculation to determine the correct sample required to detect significant changes in the primary outcome where one exists. This comprised self-report measures of anxiety in seven of the studies (Bastani 2015, Bastani et al. 2005, Bittner et al. 2014, Chang et al. 2008, Milgrom et al. 2015, Newham et al. 2014, Satyapriya et al. 2013).

In the included studies, pregnant women were mainly recruited from hospital antenatal clinics. Five studies recruited women from community locations (Bullock et al. 1995, Newham et al. 2014, Brugha et al. 2015, Côté-Arsenault et al. 2014, Davis et al. 2015). In most studies, a healthcare professional approached potential participants during a clinic appointment. Pregnant women were also recruited by: posting flyers in clinic locations (Vieten & Astin 2008, Woolhouse et al. 2014, Guardino et al. 2014); via antenatal classes (Korol & Von Baeyer 1992, Vieten & Astin 2008, Woolhouse et al. 2014); support groups (Côté-Arsenault et al. 2014), attendance at ultrasound scan (Snaith et al. 2014) and physiotherapy appointments (Woolhouse et al. 2014).
Psychological screening was used to assess participant eligibility in five studies:

- Bittner et al. (2014): STAI, BDI and PDQ followed by a diagnostic interview (Wittchen & Pfister 1997). Following screening procedures, 160 (21%) women were eligible and consented to participate.
- Teixeira et al. (2005): STAI
- Davis et al. (2015): STAI and EPDS
- Guardino et al. (2014): PSA and PSS
- Milgrom et al. (2015): EPDS and a Structured Clinical Interview for DSM-IV (SCID). From an initial sample of 169 women referred to the study with an EPDS score of 12 or more, 54 (32%) women were finally eligible and consented to participate in a SCID.

**Interventions**

Various types of interventions were tested in the included studies. Interventions have been categorised as 1. mind-body: hypnosis, meditation, yoga, biofeedback, tai chi and visual imagery (Wahbeh et al. 2008); 2. psychological: CBT, motivational interviewing, psychotherapy (Australian Psychological Society 2010); 3. supportive: social, emotional or practical support provided by healthcare professionals or peer groups. 4. Educational: health education and advice. Categories were defined with reference to the main interventional approach reported in the included studies. Some studies have included multiple components in the intervention design therefore a description of the intervention is included in Table 1.
Fourteen studies evaluated mind-body interventions including:


Four studies evaluated psychological interventions including:

- CBT (Bittner et al. 2014, Milgrom et al. 2015); CBA (Brugha et al. 2015) and MCBT (Faramarzi et al. 2015)

Three studies evaluated supportive interventions, including:

- peer telephone support (Bullock et al. 1995)
- midwifery telephone support (Snaith et al. 2014)
- Home visits by nurses (Côté-Arsenault et al. 2014).

Two studies tested educational interventions focused on health, diet and exercise


Knight et al. (2001) evaluated an acupuncture intervention.

Bastani et al. (2015) evaluated an acupressure intervention.

**Theoretical basis**

Some authors described the theoretical basis for CBT interventions (Bittner et al. 2014, Milgrom et al. 2015), psychological support / CBA interventions (Brugha et al. 2015, Côté-Arsenault et al. 2014) and mind-body interventions such as acupressure (Bastani 2015), mindfulness (Guardino et al. 2014, Woolhouse et al. 2014, Vieten & Astin 2008), guided imagery (Jallo et al. 2014), yoga (Newham et al. 2014, Satyapriya et al. 2013) and relaxation

**Participation**
Studies which reported that 40% or more of the eligible target population declined participation in interventions were:

- Educational intervention for pregnant women with a high BMI (Dodd et al. 2016), 60% (N=3262) declined due to lack of interest, too busy to participate or were unable to be contacted.
- Group CBT intervention (Bittner et al. 2014), following initial anxiety/depression screening 45% (N=209) declined further participation/screening or could not be contacted.
- CBT intervention (Milgrom et al. 2015), 47% (N=79) declined or could not be contacted to complete further SCID screening.
- Yoga intervention (Newham et al. 2014), 43% (N=44) declined or did not make further contact with the researchers.
- Telephone support intervention (Bullock et al. 1995), 41% (N=90) declined or could not be contacted.

Studies which reported that 80% or more of the eligible target population agreed and consented to participation included:

- Educational intervention for women with a high BMI (Bogaerts et al. 2012), 87% (N=205) agreed
- Supportive intervention for pregnant women who had previously experienced pregnancy loss (Côté-Arsenault et al. 2014), 89% (N=24) agreed.
• Guided imagery intervention for pregnant African American women (Jallo et al. 2014), 97% (N=72) agreed.

• Mindfulness intervention for women with high pregnancy anxiety scores on the PRA and PSA scales (Guardino et al. 2014), 94% (N=50) agreed.

Interventions delivered to general populations of pregnant women which reported that 80% or more of the eligible target population agreed participation included:

• Yoga intervention (Satyapriya et al. 2013), 86% (N=105) agreed.

• Relaxation intervention (Chang et al. 2008), 100% (N=136) agreed.

Outcome measures and outcome time points

The STAI (Spitzer et al. 2006) was the most commonly used scale, being used in 21 studies.

Attrition

In four multi-session interventional studies, more than 20% of the IG did not complete the intervention (Bittner et al. 2014, Knight et al. 2001, Newham et al. 2014, Woolhouse et al. 2014).

Results of individual studies

Studies which reported significant differences in anxiety scores (p<0.05) between the control group (CG) and intervention group (IG) at post-intervention are presented in Table 1 alongside studies which reported no significant between group differences.

Meta-analysis of STAI post-intervention scores

Studies used different versions of the STAI (Spielberg et al. 1970, Spielberger et al. 1983) and included other anxiety measures (HAD-A, BAI, MAQ, STAI-short) therefore the Standardised Mean Difference (SMD) was used as the summary statistic (Higgins & Green 2011). Four studies (Newham et al. 2014, Teixeira et al. 2005, Tragea et al. 2014, Knight et al. 2001) reported anxiety scores as median and inter-quartile ranges (IQR) due to the non-normal distribution of the data, so were excluded from the meta-analysis. Four studies with insufficient details of post-intervention scores (Côté-Arsenault et al. 2014, Ventura et al. 2012, Bogaerts et al. 2012, Bullock et al. 1995) were excluded from the meta-analysis.

The results from 17 studies included 1,928 participants in the IG and 1,914 participants in the CG. Pooling of results indicated considerable statistical heterogeneity among the studies ($I^2=92\%$; p<0.001). There was also clinical heterogeneity between the intervention type, timing and duration of the interventions and the characteristics of participants. Sub-group analyses were conducted on studies of interventions with similar characteristics, such as educational, mind-body, psychological and supportive interventions. Only interventions...
which included mindfulness group interventions were assessed as having sufficient clinical and statistical homogeneity to perform a meta-analysis (Figure 3) (Higgins & Green 2011). There was no observed beneficial effect in relation to the reduction of self-report STAI state anxiety score (median=0.09; 95% CI=-0.32 to 0.49), with low statistical heterogeneity among the studies ($I^2=0\%$; $p=0.85$). However, the pooled number of participants in these three studies is small ($N=95$), all were assessed to have an unclear risk of bias and therefore the results of the meta-analysis should be interpreted with caution.

**DISCUSSION**

The aim of the systematic review was to identify and assess the effectiveness of non-pharmacological interventions for pregnant women with symptoms of mild to moderate anxiety.

**Strengths of the review**

A comprehensive search strategy maximised the potential to identify relevant studies and the review used a robust, independent and appropriate assessment method. The review assessed a wide range of non-pharmacological interventions to improve mild to moderate symptoms of anxiety in pregnancy and included different populations of pregnant women across the three trimesters of pregnancy. Previous systematic reviews have sought evidence of the effectiveness of interventions to support women with symptoms of distress in pregnancy (depression, anxiety, stress, fear, self-efficacy and self-esteem) (Fontein-Kuipers et al. 2014), mind-body interventions for women with symptoms of anxiety in pregnancy (Marc et al. 2011) and pharmacological and non-pharmacological treatments for pregnant and postpartum women with a diagnosed anxiety disorder (Marchesi et al. 2016). The findings highlight
points for consideration in the practical aspects of delivering non-pharmacological interventions in maternity care contexts including training needs for intervention providers.

Limitations of the review

Studies not published in English were not included in the review. Most of the included RCTs had relatively small sample sizes and thirteen studies did not include a sample size calculation. As a meta-analysis of post-intervention anxiety scores was only achievable for a small sub-group of studies, the aim of the study to assess the effectiveness of interventions was only partially achieved.

Quality of the included RCTs

Most of the included studies were assessed as having an unclear risk of bias. Details of allocation concealment, blinding of study personnel, sampling methods and outcome assessors were not reported in many of the studies.

Participants and eligibility screening

The studies included women from general pregnant populations or pregnant women with obstetric, social or psychological symptoms or risk factors. Attention to recruitment rates and recruitment strategies in the included studies has revealed the possibility of selection bias and highlighted limitations to the reach, generalisability and relevance of the findings. Therefore, addressing the limitations to recruitment processes will assist the design of future studies (Dzewaltowski et al. 2004, Toerien et al. 2009, Tarquinio et al. 2014). Studies which targeted women with obstetric complications or risk factors or where women had an option to self-select into the study reported higher percentages of women recruited from the initial sample. Most studies which reported lower participation rates from the initial sample population used...
Intervention components

The studies included in the review evaluated psychological, educational and mind-body interventions. Many interventions were complex and combined psychological or mind-body approaches with elements of education, discussion, professional support and peer support. Women who have psychological or obstetric risk factors may feel especially isolated during pregnancy and may benefit from discussing their situation and feelings with healthcare professionals. Women who are socially isolated may benefit from interventions which act as a proxy for enhanced social support. The Boots Family Trust Alliance (2013) reported that women who experienced mental health problems in pregnancy stated the main cause as being
isolation and lack of support. Interventions delivered to pregnant women which combine education, professional support, peer support and psychological approaches are suggested as approaches to improve women’s postnatal psychological outcomes and health outcomes for infants (Glover 2014, Marchesi et al. 2016, Morrell et al. 2016). The Acorn and First steps trials are currently being conducted to evaluate multi-component interventions delivered to pregnant women (Barnes et al. 2013, Wilkinson et al. 2016).

**Intervention providers**

Most mind-body interventions were delivered by trained instructors (mindfulness, yoga, acupuncture, relaxation), while mindfulness and CBT interventions were delivered by psychologists or psychotherapists. Four studies recruited healthcare professionals (nurses and midwives) to deliver interventions and provided additional training in psychological and motivational interviewing techniques. Only one study recruited and trained peer volunteers to deliver a telephone support intervention (Bullock et al. 1995). Details of intervention provider skills and additional training provided to deliver interventions were underreported in the included studies. The Medical Research Council (MRC 2000) advise that variations in levels of skills across providers may affect delivery of the intervention and/or outcomes. The training and practitioner skills required to deliver RCTs is valuable information for researchers, practitioners and service providers reviewing and potentially implementing interventions.

**Attrition and compliance**

Five studies reported attrition rates of greater than 20% for the IG and/or CG (Tragea et al. 2014, Woolhouse et al. 2014, Newham et al. 2014, Bittner et al. 2014, Knight et al. 2001) and only four studies indicated the numbers of sessions attended by participants (Davis et al.
2015, Milgrom et al. 2015, Guardino et al. 2014, Bittner et al. 2014). Bittner et al. (2014) excluded women from final analysis who did not attend more than 74% of the sessions. Delgadillo et al. (2014) suggested that non-pregnant participants in low intensity psychological interventions for anxiety and/or depression report the highest attrition rates by session four, implying that sessions 1–3 are key periods to maximise engagement and retention. They suggest that at least 4 therapy sessions are required to achieve reliable and clinically significant improvement rates. Three studies which evaluated single-session relaxation interventions (Teixeira et al. 2005, Urech et al. 2010, Ventura et al. 2012) measured anxiety symptoms directly following the intervention and recommend that the psychobiological effects of the interventions are evaluated over a longer follow-up period.

Outcome measures

Two studies were solely focused on evaluating the effects of the intervention on symptoms of anxiety with other studies including anxiety alongside other psychosocial outcomes. It is recognised that multidimensional psychosocial aspects of pregnancy are important in developing models of care to promote the psychological wellbeing of women (Jomeen 2004). This multidimensional approach was employed in six of the included studies which included anxiety in a composite of primary outcome measures alongside depression, stress, positive and negative affect and social support. However, the presence of anxiety may reduce the effectiveness of the treatment of depression or vice versa. Interventions targeting one condition may not be effective for the other co-morbid condition (Garber & Weersing 2010). Interventions that focus on improving symptoms of anxiety and depression need to have a proposed logic and theory of change before testing the mechanism by which an improvement in symptoms is likely to occur for each condition. Studies of interventions which aim to
CONCLUSION

The introduction of interventions to reduce symptoms of mild to moderate anxiety in pregnant women has the potential to improve health outcomes for pregnant women and their infants. The results of the review were inconclusive and need to be interpreted with caution as many of the included studies provided an inadequate description of their methods to allow a full assessment of methodological quality and the results of the review were predominantly based on small samples. Future RCTs should be adequately powered and reported in accordance with the CONSORT guidance (Schulz et al. 2010). Including an assessment of the recruitment process, level of engagement with interventions and the criteria for completion will assist researchers to maximise recruitment and identify the optimal duration of interventions, balancing resources and commitment required with potential beneficial effects.

The review found insufficient evidence to draw overall conclusions regarding the benefit of non-pharmacological interventions for pregnant women with anxiety and future studies are required to develop the current evidence base.

Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

* http://www.icmje.org/recommendations/
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affective disorders, 80 (1), 65–73.


Maternal Mental Health Alliance, NSPCC & Royal College of Midwives (2013) *Specialist Mental Health Midwives*. Maternal Mental Health Alliance.


the clinical effectiveness, the cost-effectiveness, safety and acceptability of interventions to prevent postnatal depression. *Health Technology Assessment*, 20 (37), 1–414.


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Interview; Interviewheft.


**Appendix 1**

Search strategy for: **AMED, Medline, EMBASE, Psycinfo and Maternity and Infant care.**

| Anxiety disorders/ OR anxious.mp OR Anxiety/ | Intervention studies/ OR intervention*.mp OR Randomized Controlled Trials as Topic/ OR rct.mp OR randomi*ed controlled trial.mp OR Clinical trial/ OR clinical trial.mp OR trial.mp OR randomi*.mp OR systematic review.mp OR Meta analysis/ or meta analysis.mp | pregnan*.mp OR Pregnancy/ OR Peripartum period/ OR peripart*.mp OR childbearing.mp OR Perinatal care/ OR perinat*.mp OR antenatal.mp OR ante-natal.mp OR antepartum.mp OR ante-partum.mp OR Prenatal care/ OR prenat*.mp |
Table 1. Data extraction from the randomised controlled trials and pilot randomised controlled trials included in the review

<table>
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<tr>
<th>First author</th>
<th>Country</th>
<th>Year</th>
<th>Intervention, control and comparison group.</th>
<th>Included women</th>
<th>Primary outcome (secondary outcome)</th>
<th>Gestation at start/post intervention (weeks of pregnancy)</th>
<th>Analysed n=</th>
<th>Main anxiety measure mean score: Baseline/post-intervention</th>
<th>Key anxiety results as reported in the included RCTs/pilot RCTs</th>
<th>Risk of bias assessed as:</th>
</tr>
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<tbody>
<tr>
<td>Bogaerts</td>
<td>Belgium</td>
<td>2013</td>
<td>Educational (4 group sessions)</td>
<td>Pregnant women: BMI 29 or more</td>
<td>Maternal weight gain (Depression, anxiety, birthweight, prematurity)</td>
<td>115 / (SD 34)</td>
<td>IG: 75 / 78 CG: 63 / 63 Comp: 58 / 64 (Direct likelihood model)</td>
<td>STAI-S: IG: 36.5 / 34.0 CG: 35.0 / 38.0 Comp: 35.9 / 37.6</td>
<td>RCT: reported STAI-S scores significantly decreased in the IG and increased in the CG post-intervention (p=0.02, n=141) (multivariate linear mixed effects model, time by group interaction)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Dodd</td>
<td>Australia</td>
<td>2016</td>
<td>Educational (5 individual sessions, 20-30 weeks)</td>
<td>Pregnant women: BMI 25 or more</td>
<td>1. Birthweight (Quality of life, depression, anxiety)</td>
<td>(12-17) / 36</td>
<td>IG: 1108 / 1108 CG: 1104 / 1104 (ITT analysis)</td>
<td>STAI short: IG: 10.7 (SD 3.8) / 10.6 (SD 3.6) CG: 10.8 (SD 3.9) / 10.4 (SD 3.6)</td>
<td>RCT: reported no significant differences in STAI-S scores between groups post-intervention (p=0.51, n=2122) (multivariate linear mixed effects model, time by group interaction, 95% CI=0.19-0.38)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Bastani</td>
<td>Iran</td>
<td>2005</td>
<td>Mind body (7 group sessions)</td>
<td>Nulliparous pregnant women</td>
<td>1. Anxiety 2. Stress</td>
<td>18 (mean) / 25 (approx)</td>
<td>IG: 55 / 55 CG: 55 / 55 (ITT analysis)</td>
<td>STAI-S: IG: 37.2 (SD 5.4) / 22.7 (SD 7.4) CG: 38.6 (SD 6.5) / 38.5 (SD 5.7)</td>
<td>RCT: reported significant reductions in STAI-S scores for the IG compared with the CG post-intervention (p&lt;0.001, n=110) (1 independent samples t-test, post-intervention between group scores)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Chang</td>
<td>Taiwan</td>
<td>2008</td>
<td>Mind body (daily exercises via audio CD, 2 weeks)</td>
<td>General pregnant population</td>
<td>1. Anxiety 2. Depression 3. Stress</td>
<td>(18-34) / NR</td>
<td>IG: 116 / 120 CG: 120 / 121 (Analysis NR)</td>
<td>STAI-S: IG: 37.9 (SD 9.8) / 35.8 (SD 10.9) CG: 37.1 (SD 10.0) / 37.8 (SD 12.1)</td>
<td>RCT: reported no significant differences in STAI-S scores between groups post-intervention (mean change = +1.5, 95%CI=−2.7 to 1.7, n=60) (ANCOVA, baseline STAI-S score as co-variate)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Tragea</td>
<td>Greece</td>
<td>2014</td>
<td>Mind body (6 individual sessions)</td>
<td>Nulliparous pregnant women</td>
<td>1. Anxiety 2. Stress 3. Locus of control</td>
<td>(14-21) / (21-28)</td>
<td>IG: 31 / 44 Comp: 29 / 41 (Per-protocol analysis)</td>
<td>STAI-S (median/QR): IG: 38.0 (35-42) / 36.6 (29-42) CG: 30.4 (30.0-32.5) / 28.9 (25-30)</td>
<td>RCT: reported no significant difference for STAI-S scores between groups post-intervention (mean change = −1.85, 95%CI=−2.6 to −1.0, n=26)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Teixeira</td>
<td>UK</td>
<td>2005</td>
<td>Mind body (1 individual session)</td>
<td>General pregnant population</td>
<td>1. Cortisol 2. Uterine artery resistance 3. Anxiety</td>
<td>(28-32) / (28-32)</td>
<td>IG: 29 / 29 Comp: 29 / 29 (ITT analysis)</td>
<td>STAI-S (median/95%): IG: 38.5 (35-42) / 24.5 (23-27) CG: 27.0 (30.2-42) / 27.5 (25-30)</td>
<td>RCT: reported both IG and Comp groups had reduced STAI-S scores, which were significantly greater in the IG (95% CI, p&lt;0.001, n=38) (7 independent samples t-test, comparison of deltas p=0.01, pre/post intervention between groups change score)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Urech</td>
<td>Switzerland</td>
<td>2010</td>
<td>Mind body (1 individual session)</td>
<td>General pregnant population</td>
<td>1. Relaxation 2. Anxiety 3. Endocrine parameters 4. Cardiovascular responses</td>
<td>32 (mean) / 32 (mean)</td>
<td>IG: 13 / 13 CG: 13 / 13 Comp: 13 / 13 (ITT analysis)</td>
<td>STAI-S: IG: 37.7 / 30.9 CG: 31.5 / 29.9 Comp: 30.9 / 28.1</td>
<td>RCT: reported no significant change of STAI-S scores from baseline to post-intervention. Anxiety scores decreased equally in all groups (p&lt;0.03, F=13.5, p=0.001) (ANOVA, time by group interaction)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Ventura</td>
<td>Portugal</td>
<td>2012</td>
<td>Mind body (1 individual session)</td>
<td>Pregnant women attending for amniocentesis</td>
<td>1. Anxiety (Maternal cortisol levels)</td>
<td>17 / 17</td>
<td>IG: NR / 61 CG: NR / 47 Comp: NR / 46 (ITT analysis)</td>
<td>STAI-S: IG: MD -7.6 (SD 8.3) CG: MD -4.5 (SD 5.7) Comp: MD -5.5 (SD 6.4)</td>
<td>RCT: reported STAI-S scores decreased in all groups (p=0.058). IG scores were significantly different from the comp and CG (F2,150=7.3, p=0.001, n=108) (ANOVA, baseline STAI-S score as co-variate)</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>First author Country Year</th>
<th>Intervention category (duration)</th>
<th>Intervention, control and comparison group. * Description of intervention ** Facilitator / facilitator training</th>
<th>Included women</th>
<th>Primary outcome (secondary outcome)</th>
<th>Gestation at start / post intervention (weeks of pregnancy)</th>
<th>Analyzed n as post-intervention / baseline (method)</th>
<th>Main anxiety measure mean score (baseline / post-intervention)</th>
<th>Key anxiety results as reported in the included RCTs / pilot RCTs</th>
<th>Risk of bias assessed as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Korol Canada 1992</td>
<td>Mind body (group sessions, number NR)</td>
<td>IG: Guided imagery; Comp: Antenatal classes * Information about the birth process and relaxation techniques with birth visualisation. ** Instructor / NR</td>
<td>General pregnant population</td>
<td>1. Knowledge of childbirth (Anxiety, depression)</td>
<td>NR</td>
<td>IG: 30 / 30 Comp: 30 / 30 (Analysis NR)</td>
<td>STAI-S</td>
<td>RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (n=60) (values not reported)</td>
<td>High</td>
</tr>
<tr>
<td>Jallo US 2014</td>
<td>Mind body (daily exercises via audio CD, 12 weeks)</td>
<td>IG: Guided imagery; CG: Standard care * Relaxation; focused breathing and multisensory images to promote reduction of stress and anxiety and restore levels of energy. ** Audio CD / authored by a trained guided imagery instructor</td>
<td>Pregnant African American women</td>
<td>1. Stress (Anxiety, fatigue)</td>
<td>15 (mean) / (26-29)</td>
<td>IG: 36 / 36 CG: 36 / 36 (ITT analysis)</td>
<td>STAI-S</td>
<td>RCT: reported no significant differences in STAI-S scores between the groups post-intervention (p=0.606, n=72) (multivariate linear mixed effects model, time by group interaction)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Vieten US 2008</td>
<td>Mind body (8 group sessions)</td>
<td>IG: Mindfulness, CG: Wait list (postnatal period) * Mindfulness: meditation; Hatha yoga. Adaptations for pregnancy: awareness of the developing fetus and body; explanations and discussions about coping with anxiety in labour ** Psychologist / Mindfulness and yoga</td>
<td>Pregnant women: history of mood concerns</td>
<td>1. Stress 2. Depression 3. Anxiety 4. Positive / negative affect</td>
<td>25 (mean) / (35 approx)</td>
<td>IG: 13 / 15 CG: 18 / 19 (Analysis NR)</td>
<td>STAI-S</td>
<td>Pilot RCT: reported significantly reduced STAI-S scores in the IG in comparison to the CG post-intervention (F2,24=4.32, p=0.04, d=0.58, n=31), (ANCOVA, baseline STAI-S score as co-variate)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Guardino US 2014</td>
<td>Mind body (8 group sessions)</td>
<td>IG: Mindfulness, Comp: Pregnancy book * Mindfulness meditation, lectures, discussions and sharing experiences. Guided meditations to use at home. ** Mindfulness instructor / Curriculum outlined in a standardised instructor's manual.</td>
<td>Pregnant women with elevated anxiety / stress scores</td>
<td>1. Mindfulness 2. Stress 3. Anxiety 4. Adherence</td>
<td>18 (mean) / (23 mean)</td>
<td>IG: 24 / 24 Comp: 23 / 23 (ITT analysis)</td>
<td>STAI-S</td>
<td>Pilot RCT: reported significant between group differences for the PSA and moderately significant for the PRA (p=0.01, p=0.07 respectively, n=47), no significant differences for STAI-S scores (multivariate linear mixed effects model, time by group interaction)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Woolhouse Australia 2014</td>
<td>Mind body (6 group sessions)</td>
<td>IG: Mindfulness, CG: Standard care * MindBabyBody*: breathing practice; body scan (communicating with babies); mindfulness of pain and thoughts; meditation; self-compassion; mindfulness skills in motherhood. ** Psychologist and Psychiatrist / Facilitation of mindfulness groups</td>
<td>General pregnant population</td>
<td>1. Stress 2. Depression 3. Anxiety</td>
<td>(11-34) / (17-40)</td>
<td>IG: 13 / 17 CG: 15 / 20 (Analysis NR)</td>
<td>STAI-S</td>
<td>Pilot RCT: reported significant changes on the DASS-21 anxiety subscale for the IG (Cohen’s d=0.9). No significant between group differences for the IG and CG for the STAI-S or DASS-21 anxiety post-intervention sub-scale scores (values not reported n=23) (independent samples t-test)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Satyapriya India 2013</td>
<td>Mind body (12 group sessions and daily home exercises, 16-18 weeks)</td>
<td>IG: Yoga, CG: Standard care * Integrated approach of yoga therapy (JAYT): physical postures; exercises; stretches; relaxation; breathing techniques and meditation. Audio cassette for home use. ** Trained yoga instructor / NR</td>
<td>General pregnant population</td>
<td>1. Anxiety 2. Depression</td>
<td>(18-20) / 36</td>
<td>IG: 51 / 53 CG: 45 / 52 (Analysis NR)</td>
<td>STAI-S</td>
<td>RCT: reported STAI-S and HADS-A scores reduced in the IG and increased in the CG with significant difference between groups post-intervention (p&lt;0.01, n=105) (Mann-Whitney U test, post-intervention between group scores)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Newman UK 2014</td>
<td>Mind body (8 group sessions)</td>
<td>IG: Yoga, CG: Standard care * Hatha yoga at each class. Sessions themed to aid common pregnancy ailments, optimal positioning of the fetus and stages of labour. ** Yoga instructor / British Wheel of Yoga</td>
<td>Nulliparous pregnant women</td>
<td>1. Pregnancy specific anxiety (Anxiety, depression)</td>
<td>21 (mean) / (29-30)</td>
<td>IG: 29 / 31 CG: 22 / 28 (Per-protocol analysis)</td>
<td>STAI-S (median/QQR) IG: 28.0 (24-42) / 27.0 (22-36) CG: 32.0 (24-37) / 34.0 (25-38)</td>
<td>RCT: reported no significant difference in STAI-S scores between the groups post-intervention (p=0.5, r=-0.09, n=51) (Mann-Whitney U test, post-intervention between group scores)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Davis US 2015</td>
<td>Mind body (8 group sessions)</td>
<td>IG: Yoga, CG: Standard care * Ashanga Vinyasa yoga modified for pregnancy. Instructional video for home use.</td>
<td>Pregnant women with elevated anxiety /</td>
<td>1. Depression 2. Anxiety 3. Positive and</td>
<td>21 (mean) / (28-29)</td>
<td>IG: 23 / 23 CG: 23 / 23 (ITT analysis)</td>
<td>STAI-S</td>
<td>RCT: reported no significant effect of group or the interaction between group and time, STAI-S scores decreased over time in both groups (p=0.05, 95%)</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>First author</th>
<th>Country</th>
<th>Year</th>
<th>Psychological category (duration)</th>
<th>Intervention, control and comparison group.</th>
<th>Included women</th>
<th>Primary outcome (secondary outcome)</th>
<th>Gestation at start / post intervention. (weeks of pregnancy)</th>
<th>Analysed as</th>
<th>Main anxiety measure: mean score: baseline / post-intervention</th>
<th>Key anxiety results as reported in the included RCTs / pilot RCTs</th>
<th>Risk of bias assessed as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milgrom</td>
<td>Australia</td>
<td>2014</td>
<td>Psychological (8 individual sessions)</td>
<td>IG: CBT, CG: Standard care</td>
<td>Pregnant women with elevated depression scores</td>
<td>1. Depression 2. Anxiety (Infant outcomes)</td>
<td>20 (mean) / 29 (approx)</td>
<td>IG: 27 / 27  CG: 27 / 27 (ITT analysis)</td>
<td>BAI</td>
<td>Pilot RCT: reported anxiety scores decreased in the IG but not in the CG. Between group differences for anxiety scores represented moderately large effect sizes post-intervention (p=0.006, d=0.67, 95% CI:0.33–1.01, n=54) [ANCOVA, baseline scores as co-variate]</td>
<td>Unclear</td>
</tr>
<tr>
<td>Bittner</td>
<td>Germany</td>
<td>2014</td>
<td>Psychological (8 group sessions)</td>
<td>IG: CBT, CG: Standard care</td>
<td>Pregnant women with elevated anxiety and depression scores</td>
<td>1. Depression 2. Anxiety (Fear of childbirth, social support)</td>
<td>16 (mean) / 24</td>
<td>IG: 21 / 80  CG: 53 / 80 (Analysis NR)</td>
<td>STAI-S</td>
<td>RCT: reported no significant difference between groups for the STAI-S scores post-intervention (p=0.246, r²=0.019, n=74) (2-way repeated measures ANOVA)</td>
<td>Unclear</td>
</tr>
<tr>
<td>Faramarzi</td>
<td>Iran</td>
<td>2015</td>
<td>Psychological Group MBCT (8 group sessions)</td>
<td>IG: MBCT, CG: Standard care</td>
<td>Pregnant women with moderate nausea and vomiting</td>
<td>1. Nausea and vomiting (Anxiety, depression, distress)</td>
<td>8 (mean) / 11 (approx)</td>
<td>IG: 43 / 43  CG: 43 / 43 (ITT analysis)</td>
<td>HADS-A</td>
<td>RCT: reported significant effect for group by time on HADS-A scores (p&lt;0.001, d=0.53, n=86) (mixed effect ANOVA, time by group interaction)</td>
<td>Low</td>
</tr>
<tr>
<td>Brughia</td>
<td>UK</td>
<td>2015</td>
<td>Psychological (up to 3 individual sessions, 22 weeks)</td>
<td>IG: Midwife psychological training, CG: Standard care</td>
<td>General pregnant population</td>
<td>3. Depression (Anxiety and satisfaction)</td>
<td>22 / 34 (approx)</td>
<td>IG: 118 / 165  CG: 94 / 133 (Pilot study – descriptive statistics)</td>
<td>STAI-S</td>
<td>Pilot RCT: Anxiety results not discussed in the paper</td>
<td>Unclear</td>
</tr>
<tr>
<td>Bullock</td>
<td>New Zealand</td>
<td>1995</td>
<td>Supportive interventions (individual sessions 10+ weeks)</td>
<td>IG: Telephone support, Comp. Pregnancy leaflets</td>
<td>Pregnant women who were single or with an un-employed partner</td>
<td>1. Depression 2. Anxiety 3. Stress 4. Social support</td>
<td>&lt;20 / 34</td>
<td>IG: 59 / 65  Comp: 63 / 66 (Analysis NR)</td>
<td>STAI-S</td>
<td>RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (p=0.05, n=122) [ANCOVA, baseline STAI-S score as co-variate]</td>
<td>Unclear</td>
</tr>
<tr>
<td>Snath</td>
<td>UK</td>
<td>2014</td>
<td>Supportive interventions (3 individual sessions, 17 weeks)</td>
<td>IG: Telephone support / Doppler, CG: Standard care, Comp: Telephone support</td>
<td>Nulliparous pregnant women</td>
<td>1. Number of antenatal visits (Anxiety)</td>
<td>20 / 36</td>
<td>IG: 170 / 275  CG: 159 / 283  Comp: 166 / 282 (ITT analysis)</td>
<td>STAI-S</td>
<td>RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (p=0.68, n=495) [one-way ANOVA]</td>
<td>Unclear</td>
</tr>
<tr>
<td>Côte-Arsenault</td>
<td>US</td>
<td>2014</td>
<td>Supportive interventions (approx 5 individual sessions, 20 weeks)</td>
<td>IG: Home visits, Comp: Information booklets</td>
<td>Pregnant women with a history of at least one spontaneous</td>
<td>3. Anxiety 2. Depression (Intervention evaluation)</td>
<td>14 (mean) / NR</td>
<td>IG: 12 / 13  Comp: 11 / 11 (Analysis NR)</td>
<td>NR</td>
<td>RCT: reported no significant difference between the STAI-S scores between the groups post-intervention (p=0.66, n=23) [multivariate linear mixed effects model, time by group interaction]</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

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depression and promote prenatal attachment. Based on the caring process (Swanson, 1993).

** Nurses with additional training / NR

### First author

** Country

** Year

### Intervention category (duration)

** ** Facilitator / facilitator training

### Included women

### Primary outcome (secondary outcome)

### Gestation at start / post intervention (weeks of pregnancy)

### Analysed as Post-intervention / baseline / post-intervention

### Main anxiety measure mean score: baseline / post-intervention

### Key anxiety results as reported in the included RCTs / pilot RCTs

### Risk of bias assessed as:

#### Anxiety measures:

- **ASI** - Anxiety Sensitivity Index
- **BAI** - Beck Anxiety Inventory
- **DASS** - Depression Anxiety Stress Scale
- **HADS-A** - Hospital Anxiety and Depression Scale
- **MAQ** - Maternal Anxiety Questionnaire
- **PRA** - Pregnancy Related Anxiety Scale
- **PSA** - Pregnancy Specific Anxiety Scale
- **STAI** - State Trait Anxiety Inventory
- **VASA** - Visual Analogue Scale for the Severity of Anxiety

*(For all of the self-report measures a decrease in scores indicated an improvement in anxiety symptoms)*

#### Intervention descriptions:

- **BMI** - body mass index
- **BP** - Blood pressure
- **CBA** - Cognitive behavioural approach
- **CBT** – Cognitive behavioural therapy
- **CG** - control group
- **Comp** - comparison group
- **CTG** - Cardiotocograph
- **GDM** - Gestational diabetes mellitus
- **IG** - intervention group
- **MBSR** - Mindfulness-based stress reduction
- **MCBT** - Mindfulness cognitive based therapy
- **NR** - Not reported

#### Analysis descriptions:

- **CI** - confidence interval
- **IQR** - Inter quartile range
- **ITT** - Intention to treat analysis
- **MD** - mean difference
- **MC** - mean change
- **NR** - Not reported
- **SD** - standard deviation
- **SE** - standard error

† - test not clearly stated in the paper and has been inferred from the information provided

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Figure 1. PRISMA study flow diagram (Moher et al. 2009), Systematic Review of Randomised Controlled Trials

Records identified through database searching (n=5267)
Following removal of duplicates (n=5222)

Records Screened (n=5222)

Records excluded (n 5168)

Full-text articles assessed for eligibility (n=57)

Records identified through scanning reference lists (n=3)

Full-text articles excluded as ineligible on the basis of relevance (n=32):
- Did not report post-intervention data in pregnancy (n=13)
- Did not measure anxiety (n=7)
- Included participants with severe symptoms of anxiety and/or depression (n=6)
- Study design not an RCT or systematic review (n=5)
- Included participants less than 18 years of age (n=1)

Studies included in the review (n=25)
Figure 2. Cochrane Risk of Bias summary (Higgins et al. 2011): judgements about each risk of bias item for each included study

<table>
<thead>
<tr>
<th>Study</th>
<th>Random sequence generation (selection bias)</th>
<th>Allocation concealment (selection bias)</th>
<th>Blinding of participants and personnel (performance bias)</th>
<th>Blinding of outcome assessment (detection bias)</th>
<th>Incomplete outcome data (attrition bias)</th>
<th>Selective reporting (reporting bias)</th>
<th>Other bias</th>
</tr>
</thead>
</table>

† low risk of bias
?
unclear risk of bias
- high risk of bias
### Figure 3. Meta-analysis of mindfulness group interventions on self-report symptoms of anxiety

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Std. Mean Difference</th>
<th>Std. Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>Guardino 2014</td>
<td>39.47</td>
<td>6.7</td>
<td>21</td>
<td>37.35</td>
</tr>
<tr>
<td>Vieten 2008</td>
<td>35.4</td>
<td>9.1</td>
<td>13</td>
<td>35.6</td>
</tr>
<tr>
<td>Woolhouse 2014</td>
<td>32.83</td>
<td>7.8</td>
<td>13</td>
<td>33</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>47</td>
<td>48</td>
<td>100.0%</td>
<td>0.09 [-0.32, 0.49]</td>
</tr>
</tbody>
</table>

Heterogeneity: \( \tau^2 = 0.00; \chi^2 = 0.34, \text{df} = 2; P = 0.85; I^2 = 0\%

Test for overall effect: \( Z = 0.41 \) (\( P = 0.68 \))

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