

**Relationship and mother-infant bonding
outcomes following a psychological intervention
for antenatal anxiety**

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:



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Date: June 2017

Overview

This thesis focuses on anxiety during pregnancy and the development of interventions to treat antenatal anxiety.

Part One reports on a meta-analysis investigating the effectiveness of psychological interventions on reducing anxiety, depression and stress (combined to create a composite “distress” score) during pregnancy. A random-effects meta-analysis on the reduction of “distress” was conducted, as well as subgroup analyses and meta-regressions investigating the differential effectiveness of preventative and treatment trials, of individual and group interventions, of different therapeutic models, and of number of intervention sessions.

Part Two reports on a feasibility Randomised Control Trial (RCT) that investigated the impact of a group cognitive behavioural therapy (CBT) intervention to treat antenatal anxiety on pregnant women’s self-reported intimate relationship functioning and bonding with their child. Relationship functioning was assessed at three antenatal time-points and once postnatally and mother-infant bonding was assessed at postnatal follow-up. Analyses compared scores on the measures of relationship functioning and bonding in the intervention group with a “Treatment As Usual” control group.

Part Three provides a critical reflection on the research project presented in Part Two, focusing on some of the challenges faced while conducting this research. The experience of being involved in an RCT as both a researcher and a clinician is discussed, as well as further reflections on the research and clinical implications of this project.

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Part 1: Literature review

A systematic review and meta-analysis of prenatal interventions
for distress during pregnancy

Abstract

Aims: Antenatal depression, anxiety and stress (conceptualised as “maternal distress”) can have serious negative implications for maternal and child health. This review aimed to assess the effectiveness of psychological interventions in reducing distress during pregnancy.

Method: Pubmed, EMBASE, PsycInfo, and Cochrane Central Register of Controlled Trials (CENTRAL) databases were searched to identify Randomised Control Trials (RCTs) of psychological interventions for antenatal distress; reference lists of relevant papers and other reviews were also examined. A random-effects meta-analysis assessed the reductions in composite “distress” scores at the final antenatal time-point across studies.

Results: 29 trials met inclusion criteria and 27 trials (n=3,240) provided data for the meta-analysis, revealing a beneficial effect of psychological interventions on reducing maternal distress (SMD=.42, 95% CI [.24, .61]). Subgroup analyses indicated beneficial effects of both preventative and treatment trials. Both individual and group interventions lead to improvements in distress. There were significant beneficial effects of CBT and mindfulness/relaxation interventions, but no beneficial effect of IPT or antenatal group education interventions; however, there were no significant differences between therapeutic modality in terms of effectiveness at reducing distress. A meta-regression revealed no significant association between intervention effect size and number of intervention sessions.

Conclusion: Psychological interventions that target prevention and treatment of antenatal distress show small to moderate reductions in distress, and are effective in both group and individual formats. CBT and mindfulness interventions are effective at reducing distress, whereas IPT interventions require further investigation.

Introduction

Pregnancy, childbirth and early parenthood, defined as the “perinatal” period, are a time when a great number of physical, psychological and social changes occur. During this significant period of transition, new stresses and worries are common for women and their partners; it is a time of uncertainty, coupled with a desire to make the “right decisions” in the best interest of the developing baby. Women are often faced with demands from health professionals to make physical health changes, as well as experiencing significant social and relationship changes (NHS Choices, 2017; Stone et al., 2015). They are also undergoing cognitive and emotional shifts in preparation for motherhood (Laxton-Kane & Slade, 2002). Labour and childbirth can also create anxiety over pain management and worries about what might go wrong (Geissbuehler & Eberhard, 2002). Given these stressors, high anxiety levels and changes in mood are experienced by many women during the perinatal period and women can be vulnerable to mental health difficulties (Bauer, Parsonage, Knapp, Lemmi, & Adelaja, 2014; Heron et al., 2004). Research suggests that between 10 and 20% of women develop a mental illness during pregnancy or within the first year after giving birth (Bauer et al., 2014; National Institute for Health and Care Excellence (NICE), 2014a). The most commonly experienced mental health difficulties are depression and anxiety, but other examples include obsessive compulsive disorder, post-traumatic stress disorder (PTSD) and postnatal psychosis (Jomeen, 2004; Jomeen & Martin, 2014). These conditions can develop suddenly and range from mild to severe in presentation. Women with pre-existing or a history of mental health difficulties are particularly at risk of becoming unwell (Milgrom et al., 2008; NICE, 2014a; O’Hara & Swain, 1996).

Research into perinatal mental illnesses has mainly focused on a broad conceptualisation of illness, such that studies describe symptoms of anxiety and depression more generally, with pregnancy and the early postnatal period representing a “risk factor” for distress due to the significant role change this time of life entails (Evans et al., 2015; Yali & Lobel, 2002). Only a minority of studies explicitly investigate “pregnancy-specific distress” or “pregnancy-related distress” (i.e., anxiety where the focus of current concerns is on the pregnancy itself), as this idea is not yet well-conceptualised and does not represent a diagnostic category (Guardino & Dunkel Schetter, 2014; Evans et al., 2015). Furthermore, there are very few measures of pregnancy-specific/related distress available and those that have been developed are limited by a lack of evidence of their reliability, validity, and clinical utility (Evans et al., 2015). However, there is some evidence that “pregnancy-related anxiety” may be a discrete construct that is not fully captured by more general anxiety or depression symptoms (Bayrampour et al., 2016; Huizink et al., 2004). One study attempted to clarify the concept of pregnancy-related anxiety by reviewing qualitative and quantitative studies of anxiety during pregnancy (Bayrampour et al., 2016). They were unable to identify an underlying theory specific to pregnancy-related anxiety, with the key antecedents of pregnancy-related anxiety fitting more generally with Beck’s cognitive theory of anxiety (Beck et al., 1998). They also found that the critical attributes of pregnancy-related anxiety (affective responses, cognitions, and somatic symptoms) and consequences (negative attitudes, reassurance-seeking behaviours, and avoidance) were similar to those defined for general anxiety disorders (Bayrampour et al., 2016). However, the content of the anxiety and worry was somewhat different to more general anxiety, with commonly reported worries including those about foetal health and wellbeing,

foetal loss, childbirth, and caring for a newborn (Bayrampour et al., 2016).

Therefore, while pregnancy-related distress may comprise a set of specific worries and concerns, the vast majority of studies do not distinguish anxiety related to pregnancy from anxiety (of all forms) occurring during pregnancy. Further, the core characteristics of depression and anxiety and their consequences, regardless of the focus of current concerns, may be captured by models of anxiety or depression developed for the general population.”

If perinatal mental illnesses go untreated they can have serious consequences for women and their families. Mental health problems are one of the leading causes of maternal death in the UK and there has been no significant change in the maternal death rate since 2003 (Cantwell et al., 2011; Knight et al., 2016). Mental health conditions can also affect pregnancy and birth outcomes; it has been shown that depression and anxiety during pregnancy are associated pre-eclampsia (Harville, Savitz, Dole, Herring, & Thorp, 2009; Kurki, Hiilesmaa, Raitasalo, Mattila, & Ylikorkala, 2000; Qiu, Williams, Calderon-Margalit, Cripe, & Sorensen, 2009), pregnancy-induced hypertension (Cardwell, 2013), pre-term labour/delivery (Dayan et al., 2006; Grigoriadis et al., 2013; Grote et al., 2010), increased risk of operative or instrumental delivery (Andersson, Sundström-Poromaa, Wulff, Aström, & Bixo, 2004; Chung, Lau, Yip, Chiu, & Lee, 2001), and more difficulties initiating and maintaining breastfeeding (Dennis & McQueen, 2009). Furthermore, research has shown that perinatal depression and anxiety can affect the foetus during pregnancy, as stress hormones can pass through the placenta and affect foetal development (Glover, 2014). Associated outcomes include low birth weight (Bussi eres et al., 2015; Grote et al., 2010) and admission to neonatal care units (Alder, Fink, Bitzer,

Hösli, & Holzgreve, 2007), with mixed evidence for effects on foetal movements and heart rate (Alder et al., 2007).

However, the implications of poor mental health during pregnancy can go beyond foetal and birth outcomes. Pregnancy is a key developmental period for the foetus, whose brain and central nervous system are developing, thus maternal mental health during this time has the potential to exert critical influences on the development of the child for the rest of his/her life (Slade & Cree, 2010). There is considerable observational evidence that depression, anxiety and stress during pregnancy are associated with a range of adverse neurodevelopmental outcomes for the child, including emotional, behavioural and cognitive difficulties (Austin, Hadzi-Pavlovic, Leader, Saint, & Parker, 2005; Bergman, Sarkar, O'Connor, Modi, & Glover, 2007; Buitelaar, Huizink, Mulder, de Medina, & Visser, 2003; Glover, 2011; Huizink, Robles de Medina, Mulder, Visser, & Buitelaar, 2003; Mennes, Stiers, Lagae, & Van den Bergh, 2006; O'Connor, Heron, Golding, Beveridge, & Glover, 2002; Rice et al., 2010; Talge, Neal, Glover, & Early Stress, Translational Research and Prevention Science Network: Fetal and Neonatal Experience on Child and Adolescent Mental Health, 2007; Van den Bergh, Mennes, et al., 2005; Van den Bergh & Marcoen, 2004; Van den Bergh, Mulder, Mennes, & Glover, 2005; Van den Bergh, Van Calster, Smits, Van Huffel, & Lagae, 2008).

After birth, maternal mental health can influence the way a mother interacts with and cares for her baby. In particular, postnatal depression has well-documented consequences for offspring due to reduced maternal responsiveness and less sensitive parenting (Field, 2010; Lovejoy, Graczyk, O'Hare, & Neuman, 2000). Research has shown that depressed mothers show less engagement with their children, display more negative responses to infant communication, and show more intrusive or

conversely more withdrawn and rejecting parenting (Cohn, Campbell, Matias, & Hopkins, 1990; Field, 2010; Murray, Fiori-Cowley, Hooper, & Cooper, 1996; Pearson et al., 2012; Weinberg & Tronick, 1998). The effects of depression on parenting behaviour are associated with a range of adverse outcomes for the child, including insecure attachment, poor academic performance and internalising and externalising problems (e.g. Barker, Jaffee, Uher, & Maughan, 2011; Goodman et al., 2011; Kim-Cohen, Moffitt, Taylor, Pawlby, & Caspi, 2005; Murray et al., 2011; Murray & Cooper, 1997, 2003; Murray, Woolgar, Cooper, & Hipwell, 2001). Although research in to perinatal anxiety has received less research attention (Marchesi et al., 2016), there is evidence that mothers experiencing anxiety display less sensitive and more intrusive parenting (Feldman, Greenbaum, Mayes, & Erlich, 1997; Weinberg & Tronick, 1998). Again, there are implications for child outcomes, with effects of maternal anxiety on child emotional and behavioural difficulties (Barker et al., 2011; Beidel & Turner, 1997; Van den Bergh, Mulder, et al., 2005).

Given the significant implications of perinatal mental health difficulties for maternal and child health, maternal mental health has become a major public health concern (Lewis, 2007). Evidence suggests that the long-term costs of perinatal depression and anxiety are substantial; in the UK one case of perinatal depression is estimated to cost society approximately £74,000, of which £23,000 relates to the mother and £51,000 relates to impacts on the child. Perinatal anxiety (when it exists alone and is not co-morbid with depression) costs about £35,000 per case, of which £21,000 relates to the mother and £14,000 to the child (Bauer et al., 2014). This obviously creates significant burden on public services, with a large proportion of the cost falling on the NHS and social services. Given the significant emotional, social and financial costs of perinatal mental health difficulties, there is a call for more

specialist services and interventions for women during this time (Bauer et al., 2014; Joint Commissioning Panel for Mental Health (JCPMH), 2012; Slade & Cree, 2010).

Despite evidence that perinatal mental health can have long-term negative implications, there has been limited research on the impact of antenatal interventions (NICE, 2014a). There has traditionally been a focus on postnatal mental health, despite evidence that symptoms of depression and anxiety are at least as common during pregnancy as postnatally (Heron et al., 2004). Furthermore, it has been shown that depression and anxiety during pregnancy are risk factors for ongoing poor emotional functioning in the postnatal period (Grant, McMahon, & Austin, 2008; Leigh & Milgrom, 2008). Therefore, interventions for perinatal mental health difficulties should be targeted during pregnancy to maximise psychological wellbeing during this time and beyond.

In terms of what types of interventions that may be most appropriate, it has been reported that women show a preference for psychological support during the perinatal period, rather than more medicalised interventions such as psychotropic drugs (Arch, 2014; Buist, O'Mahen, & Rooney, 2015). Furthermore, NICE guidelines (2014) recommend that psychological therapies should be offered as the front-line treatment rather than medication due to the potential impact of medication on the baby during pregnancy and later breastfeeding (Myles, Newall, Ward, & Large, 2013; Palmsten, Setoguchi, Margulis, Patrick, & Hernández-Díaz, 2012; Udechuku, Nguyen, Hill, & Szego, 2010). Psychological interventions, such as cognitive behavioural therapy, third-wave behavioural therapy and interpersonal therapy, among others, are commonly used for mental health difficulties outside of the perinatal period and are found to be effective for depression and anxiety, psychosis, OCD, personality disorders, post-traumatic stress disorder (PTSD) and

bipolar disorder (British Psychological Society (BPS), 2000; NICE, 2005a, 2005b, 2009b, 2009a, 2011b, 2011a, 2014c, 2014b). It is recommended that these interventions should also be offered during the perinatal period, however the use of such therapies during this time is less well studied (BPS Division of Clinical Psychology (DCP) Faculty of Perinatal Psychology, 2016; JCPMH, 2012; Jomeen, 2004; NICE, 2014a). Currently, interventions designed for the perinatal period are based on the same underlying theoretical models as proposed for non-perinatal populations, with adaptations for pregnancy in terms of content in some cases (e.g. targeting worries common to perinatal women) and practical adaptations such as time-limited delivery (given the length of pregnancy) and the possibility of embedding interventions within standard antenatal care such that it is more feasible for women to be screened and receive any intervention (Goodman et al., 2014; Lemon, Vanderkruik & Dimidjian, 2015; Milgrom et al., 2011).

Aims of this review

Given the need for high quality, evidence-based interventions for perinatal mental health difficulties, the purpose of this review was to investigate what types of psychological therapies have been studied in perinatal populations. There has been an increased interest in “alternative” therapies for perinatal mental health that focus on mind-body connections, such as yoga, massage, hypnotherapy and acupuncture, and several systematic reviews have investigated these (Beddoe & Lee, 2008; Dennis & Dowswell, 2013; Lavender, Ebert, & Jones, 2016; Marc et al., 2011). For the purposes of the current review there is a focus on psychological interventions as these are what NICE (2014a) and the BPS DCP (2016) currently recommend. It was decided to review interventions for anxiety, stress and depression, as these conditions

are the most common and are significantly correlated, such that it is difficult to truly disentangle symptoms of and the effects of each (Barker et al., 2011; DiPietro, Costigan, & Sipsma, 2008; Fontein-Kuipers, Nieuwenhuijze, Ausems, Budé, & de Vries, 2014; Heron et al., 2004; Jomeen, 2004; Matthey, 2010). Due to the high level of correlation between symptoms of anxiety, stress and depression across the perinatal period, a composite “distress” score was calculated for each study where multiple outcomes including anxiety, stress or depression were reported, and used as a combined effect size. The use of a combined effect size follows a previous meta-analysis of interventions for psychological distress during the perinatal period (Fontein-Kuipers et al., 2014), and avoids the problem of analysing multiple, correlated outcomes and maximises the number of trials available for analysis.

This review was concerned with interventions that targeted anxiety, stress or depression during pregnancy, rather than those interventions delivered postnatally. There have been previous systematic reviews that have looked at antenatal interventions, but these have all included studies that specifically targeted postnatal outcomes and often conflated antenatal and postnatal distress (e.g. Fontein-Kuipers et al., 2014). Although antenatal distress is related to and predictive of postnatal distress, it is also clear that there are distinct stresses and worries pre- and postnatally (Heron et al., 2004; Jomeen, 2004). Therefore, this systematic review and meta-analysis aimed to review and evaluate the evidence for effectiveness of psychological interventions for antenatal anxiety, depression and stress.

Method

Search strategy

A systematic search was conducted on 6th February 2017 to identify published literature on psychological interventions to treat anxiety, depression and/or stress during pregnancy. Electronic databases Pubmed, EMBASE, PsycInfo, Cochrane Central Register of Controlled Trials (CENTRAL) were searched using a search strategy that combined keywords, MeSH terms and text words, limited to the title and abstract of papers. The search terms were: ((prenatal OR perinatal OR antenatal OR pregnant OR pregnancy OR antepartum OR prepartum) AND (anxi* or depress* or stress) AND (intervention? OR therapy OR therapies OR “randomi?ed control trial” OR “randomi*ed controlled trial”)). The search terms were first developed in PubMed and then adapted to use in the other databases. The reference lists of relevant articles and other published reviews were screened for any additional studies missed by the database search.

Types of studies and participants

This review only included references that were full, original, peer-reviewed articles published in English. Only randomised control trials (RCTs) were considered for inclusion; quasi-experimental trials and studies without a control group were not included. Conference abstracts, study protocols, theses and dissertations were not included but further searches were made to locate any published papers that may have come from these. Participants in the studies were required to be pregnant women, in any stage of pregnancy and of any age. Trials that included women with low or non-problematic baseline levels of distress were considered (“preventative

trials”) as well as trials that targeted women with high baseline levels of distress (“treatment trials”).

Types of interventions

All interventions aimed at reducing psychological distress (depression, anxiety and/or stress) during pregnancy were considered. Studies that aimed to treat or prevent postnatal distress were included only if they included a follow-up time-point with outcome measures that occurred during pregnancy. It was decided to focus specifically on interventions that were psychological in nature, including “third wave” and “Eastern-inspired” therapies such as mindfulness and relaxation. Interventions could be delivered by any health professional, paraprofessional or lay person as long as the facilitator(s) were appropriately trained in delivering the intervention and/or providing care. Studies were required to have at least one control group, with the control conditions not providing a psychological intervention (e.g. “treatment as usual”, “waiting list control”, or other non-psychological intervention).

Types of outcome measures

Outcome measures of included studies were required to assess depression, anxiety and/or stress on a continuous scale at least at two time-points. Studies that only assessed psychological distress using physiological measures such as cortisol were not considered.

Selection of studies

Identified studies were reviewed for eligibility by first screening titles and removing clearly irrelevant papers. Then abstracts were reviewed for further details

regarding each study and removed or included for further assessment per inclusion criteria. Finally, the full text of remaining articles was reviewed and relevant data extracted from articles that met all inclusion criteria.

Data extraction

The required information was identified and extracted from the studies in a consistent manner and entered in to Microsoft Excel. To assess study quality and conduct meta-analysis and sub-analyses, the following data were extracted from each study and put in to a table (see Table 1): First author; year published; country study conducted in; participant information, including numbers and demographics; outcome measures used; intervention information, including number of sessions and format; control group information.

Assessment of risk of bias in included studies

Selected studies were assessed for quality and risk of bias using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011). These criteria include: 1) Random sequence generation (checking for possible selection bias); 2) Allocation concealment (checking for possible biased allocation to interventions); 3) Blinding of participants/personnel (checking for possible performance bias; as psychological interventions cannot blind participants to treatment arm, this criterion was assessed on whether researchers were blind to participant treatment arm); 4) Blinding of outcome assessment (checking for possible detection bias due to knowledge of intervention arm by outcome assessors); 5) Incomplete outcome data (checking for possible attrition bias due to the amount,

nature and handling of incomplete data); 6) Selective reporting of outcomes; 7) Other possible sources of bias. Studies were not removed based on quality assessment.

Data analysis

The primary outcome of the pooled analyses was a composite “distress” score reported at the final antenatal assessment of the trial, as long as this was after the intervention had been completed. This was calculated by combining antenatal end points of outcome measurements within any single study (e.g. combining final “anxiety”, “depression” and “stress” scores to create a composite “distress” score) using the formulae presented in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011; table 7.7.a). If studies included two control groups, then these were combined to create a single control comparison group using the same formulae. Likewise, if studies included a second intervention group with a non-psychological additive component (e.g. inclusion of partners in treatment) then these groups were combined using the same formulae.

The meta-analysis was conducted using OpenMeta[Analyst] software (Wallace et al., 2012). Pooled estimates were calculated using standardised mean differences (SMDs) with 95% confidence intervals (95% CIs). An initial overall analysis was conducted, before performing sub-group analyses. Three sub-group analyses were planned; the first was type of trial (preventative or treatment), the second was for type of intervention therapeutic modality (e.g. CBT, mindfulness etc.), and the third was for intervention format (group or individual/one-on-one delivery). Heterogeneity was assessed by forest plots and by the I^2 statistic, which provided a quantitative assessment of the degree of statistical inconsistency across the studies. The I^2 statistic is expressed as a percentage of the total variation across

studies that is attributed to statistical heterogeneity rather than sampling error (Lipsey & Wilson, 2001). A value of 0% indicates no observed heterogeneity beyond that expected from sampling error; larger values show increasing heterogeneity, with values over 40% considered to be a potentially concerning level of heterogeneity (Higgins & Green, 2011).

Results

Results of the search

The search found 4,429 reports after removing duplicates (see Figure 1). These titles were screened; after removing those that were clearly irrelevant, 455 papers were left. Reasons for removing included: not an intervention (e.g. report on epidemiology, service descriptions, model descriptions, screening), not focused on maternal psychological outcomes (e.g. report on birth outcomes, infant data), not focused on depression, anxiety or stress, or paper was a systematic review, meta-analysis or narrative review.

The abstracts were then searched for 455 papers; 64 were reviews, 18 were book chapters, 64 were post-natal outcomes only, 45 were conference abstracts, 6 were correspondence or replies to journal articles, 30 were not an intervention, 17 were protocol only, 2 were screening studies, 5 were dissertations, 31 did not obtain psychological outcomes measures. Of these remaining 173 intervention papers, 92 were initially identified as non-RCTs and 81 were identified as RCTs.

Full text was obtained and screened for these 81 papers, as well as three papers added from screening published reviews and searching for published data from protocols. Of these 84 papers, 20 were removed as they only reported postnatal

outcomes, 7 were removed as they focused on only child or childbirth outcomes rather than maternal outcomes, 7 were removed due to using non-psychological interventions, 4 were removed as they were sub-studies of a trial (using the same data) already included in the review, 4 were removed as participants were not pregnant at baseline, 4 were removed as the full text was not available in English, 2 were removed as they focused on feasibility of the intervention rather than psychological outcomes, 1 was removed as participants were fathers rather than pregnant women, 1 was removed as the trial was an open trial rather than randomised, and 1 paper was removed as there was no access to the journal (author was emailed with no response).

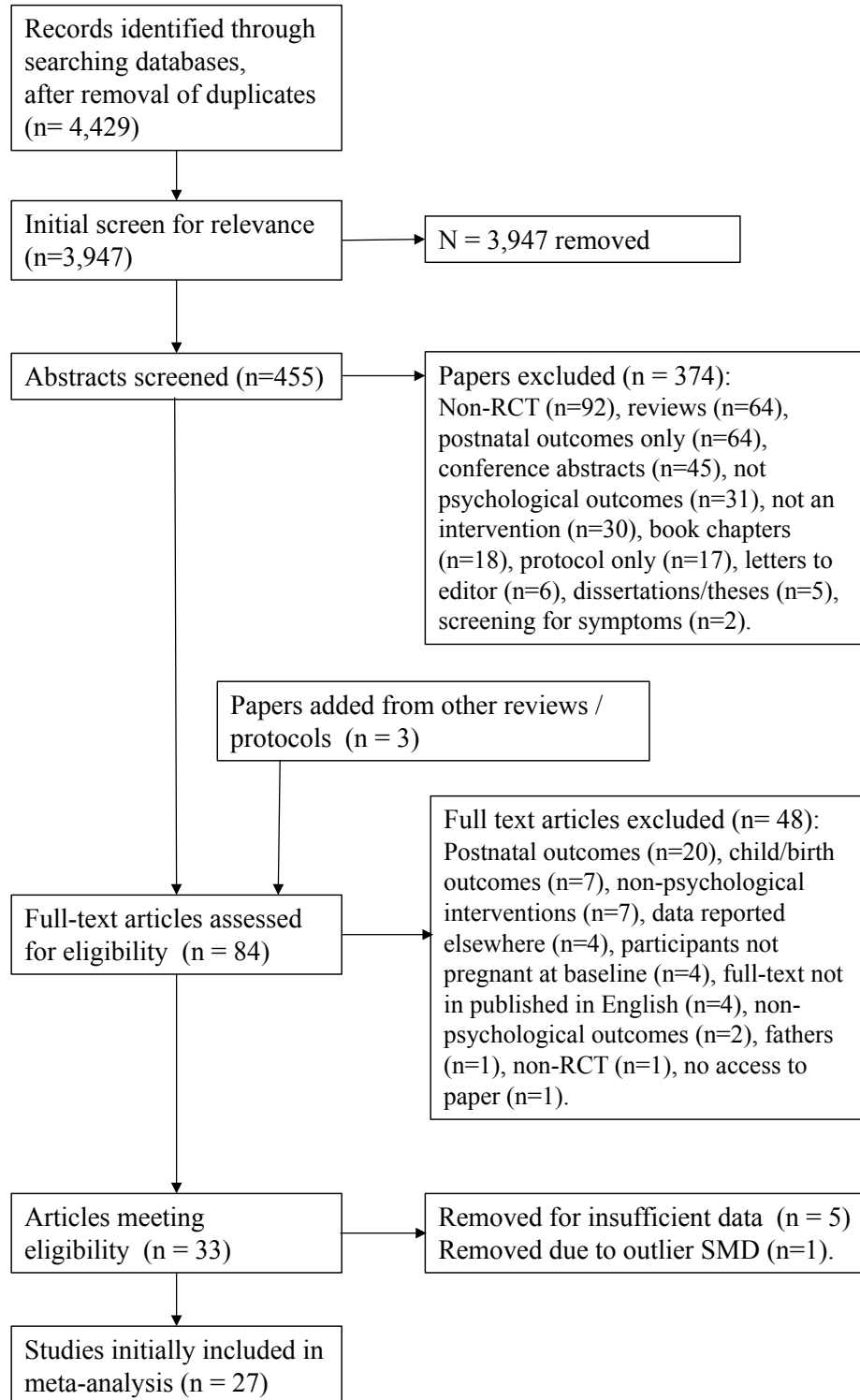


Figure 1. Flow chart showing process of study selection, following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline.

Included studies

After excluding studies as described above, 33 studies met inclusion criteria for review, but five of these did not provide adequate data for meta-analysis. Therefore, 28 studies were considered for the review and meta-analysis. See Table 1 for characteristics of studies. The included studies were published between 2005 and 2017. Thirteen studies were conducted in the USA, six in Iran, two in the UK, two in China, two in Australia, one in Hong Kong, one in Greece and one in Germany. Collectively, included studies had a total of 3,300 participants in their final post-intervention antenatal analysis (1,524 in control groups and 1,776 in intervention groups), with a range from 22 to 934 participants per study. The average age of participants ranged from 20.4 to 33.9 years old and women were recruited across all trimesters of pregnancy. Most of the studies included both primiparous¹ and multiparous women (n=18); 6 studies recruited only primiparous women, 1 recruited only multiparous women, and 3 studies did not report this information. Seven of the trials included women who could be considered “high risk” for distress due to social disadvantage and two of the trials focused on women who could be considered “high risk” due to mild to moderate obstetric complications (nausea/vomited and pre-eclampsia). Inspection of the funnel plot (Figure 2) did not suggest that there was evidence of publication bias.

¹ The literature is mixed as to whether first-time mothers are called “nulliparous” or “primiparous”. This review uses the term “primiparous” to refer to women who are pregnant with their first child.

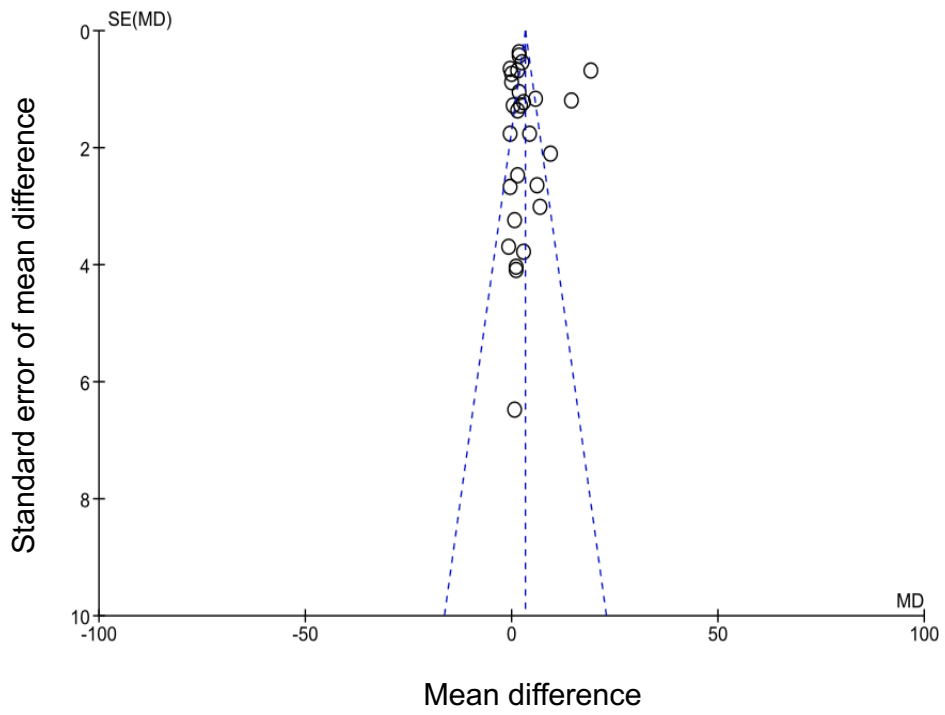


Figure 2. Funnel plot of included studies (n=28).

Table 1. *Descriptive details of included studies (n=28)*

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Akbarzadeh	2016	Iran	Primiparous women; 28-34 weeks pregnant, uncomplicated singleton pregnancy. No health or mental health conditions. Mean age 23.9 years. Low/ average anxiety levels at baseline. Follow-up after intervention completed. N=42 in each group at follow-up.	STAI	Two intervention groups; relaxation and relaxation + attachment training; four 60-90 minute classes held once a week. Intervention groups combined for analysis.	Routine antenatal care
Asghari	2016	Iran	Multiparous women with mild/moderate pre-eclampsia; 28-34 weeks pregnant. Participants aged 20-39. Not selected for baseline levels of distress. Follow-up after intervention completed. N=30 in each group at follow-up.	HADS, PDQ	12 sessions of group CBT over four weeks (3 sessions a week); each session lasting for 90 minutes. 10 women in each group. Delivered by psychotherapist.	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Bastani	2005	Iran	Primiparous women; 14-28 weeks pregnant, uncomplicated singleton pregnancy. No health or mental health conditions. Mean age 23.8 years. Moderate to high anxiety during on STAI. Follow-up after intervention complete. N=52 in each group at follow-up.	STAI, PSS	Applied relaxation training delivered by instructor. Seven 90-minute group sessions over 7 weeks. Asked to practice regularly at home. Different relaxation methods, including progressive muscle relaxation & deep breathing.	Routine antenatal care
Bittner	2014	Germany	Primiparous and multiparous women screened at 10-15 weeks of pregnancy for maternal distress (above clinical cut-off on at least one of PDQ, STAI or BDI). All women married or in long term relationship. Women with severe mental health conditions excluded. Follow-up after intervention completed. Mean age = 29.5. N=53 in control group and N=21 in intervention group at follow-up.	STAI, BDI	CBT group program (4-6 women in each group) adapted for second and third trimester of pregnancy; 8 sessions of 90 minutes each. Homework between sessions. Delivered by clinical psychologist.	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Brugha	2016	UK	Primiparous and multiparous women screened at approx. 12 weeks gestation (<18 weeks gestation) and followed up at 34 weeks. Recruited women who were "high risk" and "low risk" for depression. Excluded women receiving mental health services. 84.6% of women living with a partner, 80.5% white British. N=103 in control group and N=126 in intervention group at follow-up.	STAI, EPDS	Community midwives given training in CBT techniques. Women received "Cognitive Behavioural Approach" care as part of their routine antenatal care. Does not state how many contacts this involved, but high risk women received at least three one-to-one psychological informed contact sessions. Clusters of community midwives were the unit of randomisation.	Routine antenatal care
Burns	2013	UK	Primiparous and multiparous women recruited between 8-18 weeks pregnant if screened positive on 3-question depression screen. Women excluded if receiving other mental health care. Follow-up at 15 weeks post-randomisation. Mean age =29.2 years. Majority of sample White and living with partner. N = 13 in control and N=16 in intervention at follow-up.	CIS-R, PHQ-9, EPDS	12 individual sessions of CBT delivered by CBT therapist in the woman's own home (unless wanted to be seen elsewhere). CBT adapted for pregnancy (e.g. role of maternal beliefs, improving communication).	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Chan	2014	Hong Kong	Chinese women (primiparous and multiparous) recruited at 12-28 weeks pregnant. Not selected for scores on distress measures. All married, majority had college education or above. Majority had planned the pregnancy. Mean age = 33.6 years. Follow-up at 36 weeks pregnant. N=56 in control and N=64 in intervention at follow-up.	EPDS	Six sessions of "Eastern-Based Meditative Intervention", based on mindfulness and delivered by study author. Content included mindful eating, walking, pre- and post-natal exercises, body scan, breathing space, and other meditative exercises.	One introductory lecture and then routine antenatal care.
Dimidjian	2016	USA	Primiparous and multiparous pregnant women (before 32 weeks gestation; mean of 16 weeks) with history of depression. Excluded if met criteria for major depressive disorder in past 2 months, any other mental health problem, high risk pregnancy. Mean age= 29.8 years. Majority of participants White, college graduates, and married. Follow-up after intervention complete. N=31 in control and N=24 in intervention group at follow-up.	EPDS	Eight sessions of MBCT, modified for pregnancy; formal and informal mindfulness practices and cognitive-behavioural skills to teach mindful responses to thoughts, emotions and sensations. Psychoeducation on perinatal depression, anxiety and worry. Given audio files for home practice. Group sizes ranged from 3-9 participants. Delivered by clinical psychologists trained in MBCT.	Routine antenatal care. Recommended other services if depression symptoms were elevated.

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Dimidjian	2017	USA	Recruited primiparous & multiparous women with depression symptoms (PHQ-9>10). Excluded if had major mental health problem. Did not exclude for concurrent psychotropic medication or psychotherapy. Mean age 28.75 years. 58.2% White, 27.6% Black, 4.3% Asian, 9.8% 'other'. 69.9% married/cohabiting. Majority had some college education. Outcome measured at 10 weeks post-randomisation. N= 68 in control and 70 in intervention at follow-up.	GAD-7, PHQ-9, PSS	Ten session BA protocol, delivered either in clinic, by telephone, or in women's homes. Flexible about spacing of and number of sessions. Clinicians were nurses, midwives, nurse practitioners, occupational therapists who all received training in BA. Sessions involved case conceptualisation, self-monitoring, activity scheduling, problem-solving and increasing social support. Given between-session homework.	Routine antenatal care. Recommended other services if depression symptoms were elevated.
Faramazi	2015	Iran	Primiparous & multiparous women with moderate nausea/vomiting (mean gestation = 7.7 weeks). Excluded if using psychotherapy or relaxation or if high risk pregnancy. Not selected for high baseline scores. Mean age = 24.2 years. Majority had less than university education. Follow-up at one month post-treatment. N=40 in each group at follow-up.	HADS, PDQ	Medical therapy for nausea and vomiting and MBCT. MBCT was delivered intensively via 8 individual sessions lasting 50 minutes each over 3 weeks. Delivered by female MBCT therapist. Focus on mindful awareness and responses to thoughts, emotions and sensations. Also included guided meditation.	Medical therapy for nausea and vomiting (pyridoxine hydrochloride, 40mg daily for 3 weeks).

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Gambrel	2015	USA	Pregnant women & partners recruited; 12-34 weeks pregnant (mean=21 weeks). Not selected for high baseline scores, excluded if mental health problem or history of trauma. Follow-up after intervention complete. Mean age of women= 31.6 years. Majority had planned pregnancies, majority had Bachelor's degree or above, 90.9% white, & mean number of years of relationships was 4.9 years. N=17 in each group at follow-up.	DASS	Four week "Mindful Transition to Parenthood" programme, based on MBSR. Each group had 3-5 couples, lasted 2 hours, occurred once a week for four weeks. Psychoeducation on transition to parenthood and small group and dyadic experiential learning activities. Homework of weekly couple activities and 15-minute daily mindfulness practice (e.g. body scan, mindful breath).	Wait-list control
Grote	2015	USA	Recruited pregnant women (average 22 weeks gestation, 67.5% multiparous) scoring >10 on PHQ-9. Excluded if history of suicide attempts, major mental health difficulty, partner violence, or currently receiving psychotherapy. Average age=27 years. 58% non-white, 71% unmarried, 65% had probable PTSD. Follow-up at 3 months post-baseline. N= 71 in control and n=80 in intervention at follow-up.	SCL-20	Involved pre-therapy engagement sessions and offered 8 sessions of brief and culturally-tailored IPT, with in-person and telephone contacts and active outreach if sessions were missed. Could also be offered antidepressants concurrently if symptoms not improving. Weekly monitoring of symptoms. Delivered by doctoral-level and masters-level clinicians.	Intensive maternity support services & depression booklet. Promoted mental & physical health, but did not provide evidence-based depression care or outreach.

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Grote	2009	USA	Pregnant women (10-32 weeks gestation) with EPDS>12. Excluded if major mental health problem, suicidality, substance abuse, medical problem or high-risk pregnancy. 62.3% African-American. Majority low income, unemployed. At baseline moderately depressed according to EPDS and BDI. Follow-up at three-months post-baseline. >50% met criteria for anxiety disorder. N=28 control and 25 intervention at follow-up.	BAI, EPDS, BDI	Enhanced brief IPT with cultural adaptations and pre-therapy engagement using motivational interviewing. Delivered by doctoral-level and masters-level clinicians with experience of IPT and following treatment manuals. Eight individual sessions of IPT. Between-session BA activities with an interpersonal focus.	Enhanced usual care - given written information about depression, encouraged to seek treatment for depression, more monitoring of mood than would usually receive.
Guardino	2014	USA	Recruited pregnant women (10-25 weeks pregnant; mean=17.8 weeks) with high levels of perceived stress (>34 on PSS) and anxiety (> 11 on PSA). 66% participants white, 89% had Bachelor's degree, 78% primiparous, 93.5% married or living with partner. Mean age = 33.13 years. Follow-up at 6 weeks post-intervention. N=21 in control and 20 in intervention at follow-up.	PRA, PSA, PSS	Six-week mindfulness based intervention. Classes were 2 hours long, once a week. Led by a trained instructor following a manual. Classes involved instructor-led meditations, lectures about mindfulness practice and group discussions. Given audio recording to listen to at home and asked to complete diary regarding home practice.	Given a book about pregnancy, childbirth and caring for a newborn. Included information on stress management.

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Huang	2015	China	Primiparous pregnant Chinese women recruited at approx. 31 weeks gestation with singleton pregnancy. Baseline PHQ-9 assessment, but not selected for high scores. Excluded if had obstetric complications or current or previous mental health difficulty. Average age = 28.7 years. Over 60% had university degree. Follow-up at 36 weeks gestation. N=88 control, N=98 intervention.	PHQ-9	Emotional management groups based on CBT, targeting pregnancy and childbirth anxiety. Components included relaxation, cognitive restructuring, exposure to childbirth scenes, couple communication, antenatal education and coping skills, and visits to the delivery room. Six sessions delivered to women and their partners by obstetrician and psychiatrist.	Routine antenatal care
Ickovics	2011	USA	Pregnant women aged 14-25 (mean age 20.4 years) recruited at approx. 18 weeks pregnant. Excluded if had medical problems/high risk pregnancy. 48% primiparous, 80% African-American, 13% Latina, 38% completed high school, 36% still in high school, 26% dropped out of school. Follow-up at approx. 35 weeks gestation. N=355 control group, n=292 first intervention group, n=287 in second intervention group (total intervention n=579).	CES-D, PSS	Antenatal care for groups of 8-12 women, led by midwife or obstetrician; provided in English and Spanish. Ten sessions lasting 2 hours. Content: antenatal education, HIV prevention, mental health and psychosocial functioning, communication, goal-setting. Both intervention groups received the same content, with the second group having more content on HIV and sexual risk. Intervention groups combined for analysis.	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Jallo	2014	USA	Pregnant African-American women between 14-17 weeks gestation (mean=15.4 weeks; 29% primiparous). Excluded if high risk pregnancy, severe mental health difficulties, or current use of guided imagery. Not selected for high stress/anxiety. Mean age 24.3 years. 60% unemployed, 68% low income, 86% not married. Follow-up approx. 12 weeks after baseline (26-29 weeks gest.). N=31 control and N=29 intervention.	STAI, PSS	A 12-week Guided Imagery (GI) intervention which consisted of a CD with 4 GI tracks, each 20-minutes long. CD recorded by an author certified in GI. Key components included relaxation, focused breathing, and multisensory imagery to promote stress and anxiety reduction. Participants instructed to listen to CD once a day for 12 weeks. Contacted once a week to measure stress.	Routine antenatal care and contacted once a week to measure stress over course of study.
Jokar	2015	Iran	Pregnant women recruited at 31-32 weeks; not selected for high anxiety. Excluded if had recent major stressor, physical illness, history of psychiatric problems. All participants were married, 50% at least a Bachelor's degree, 34.4% had Master's degree. Mean age = 28.7 years. Follow-up after intervention complete. N=16 in each group at follow-up.	BAI	Seven sessions of Stress Inoculation Training (SIT); once a week for 60-90 minutes. Group sessions with approx. 15 people per group. SIT intervention based on CBT approach designed to help people cope with past and potential future stressors. Involved cognitive restructuring techniques, problem solving, and planning.	Not described; assumed routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Jesse	2015	USA	Recruited and screened rural, low-income pregnant women between 6-30 weeks gestation for depression using EPDS; stratified by high (score >10) and low-moderate risk (score of 4-9). Excluded if had severe mental health difficulty, suicidality, high-risk pregnancy. Mean age=25.1 years, 49% primiparous, 67.8% African American and 32.8% white. 57.5% living alone, 13.7% married. 61.6% unemployed. Follow-up after treatment complete. N= 72 in control and 39 in intervention at follow-up.	BDI, EPDS	Culturally-tailored CBT intervention, provided in English/Spanish. Delivered to groups of 2-6 women; 6 sessions, once a week for two hours. Content: identifying negative thoughts, psychoeducation, goal-setting, activity scheduling, relaxation, communication, problem-solving, and role transitions. Given MP3 player with playlist of homework activities, guided visualisations, positive affirmations and motivational music. Delivered by social workers, counsellors, family therapist. A paraprofessional co-facilitated groups and offered weekly telephone support.	Routine antenatal care; interviewed on a similar schedule to intervention group.

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Le	2011	USA	<p>Pregnant Latina women (majority from Central or South America); CES-D score >16 and/or history or family history of depression, recruited at approx. 24 weeks gestation. Excluded if smoked, used alcohol/drugs, had serious mental health problem, or significant psychosocial problems. 90% classed as lower income, 42% primiparous, 63.4% married or cohabiting and 59% of participants' partners were employed. Mean age = 25.4 years old. Follow-up in late pregnancy. N=92 in control and 94 in intervention at follow-up.</p>	BDI	<p>Eight weekly two-hour long CBT psychoeducational group sessions. Content included teaching mood regulation skills to prevent perinatal depression. Cultural modifications made to content, including being delivered by multilingual staff. Facilitators were post-bachelor research staff who received CBT training and monitoring.</p>	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Lenze	2017	USA	Primiparous & multiparous women (12-30 weeks gestation; mean=24.6 weeks) recruited if EPDS>10 and met depressive disorder criteria. Exclusion = psychosis, substance use, high-risk pregnancy. 73.8% single, 78.6% African-American, 83% had incomes below poverty level. Many reported severe psychosocial problems (homelessness, food insecurity), 50% PTSD symptoms. Mean age=26.6 years. Follow-up at 37-39 weeks gestation. N=19 in each group.	EDS, EPDS, STAI	Engagement session followed by 8 individual sessions of IPT, delivered by a clinical psychologist with 15 years of IPT experience and two masters-level clinicians with regular supervision. Women also offered diapers and baby supplies at each therapy session.	Enhanced usual care - referred to community resources & mental health services. Offered baby supplies. Received telephone call to monitor symptoms every 2 weeks.
Mao	2012	China	Primiparous pregnant women & partners recruited at approx. 32 weeks gestation. Excluded if an "older" mother, high-risk pregnancy or personal/family history of psychiatric problems. Mean age=28.7 years old. All married, around two thirds had >12 years education, 11.9% had history of miscarriage. Follow-up at 36 weeks gestation. N=120 in each group at follow-up.	PHQ-9	Emotional self-management group program based on CBT; four weekly group sessions (90 minutes) and one individual session. 10 couples per group. Content: problem solving, communication, relaxation, cognitive restructuring, improving self-confidence, childbirth education. Groups run by an obstetrician.	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Milgrom	2015	Australia	Women < 30 weeks pregnant (on average 20.5 weeks, 63% primiparous), EPDS>13 or SCID for DSM-IV diagnosis. 72% had Major Depressive Disorder. Excluded: concurrent major psychiatric problem, suicidality, or receiving other psychological programmes. Mean age=31.8 years. 8.8% of participants married or 'de facto' married, majority "good income", 50% Bachelor's degree or above. Follow-up 9 weeks after baseline. N=21 in control and n=23 in intervention group.	BAI, BDI	Eight one-hour CBT sessions; seven of these delivered one-on-one and one was a couple's session. Participants and their partners given booklets that summarised session content. Content included psychoeducation, activity scheduling, relaxation, assertiveness, communication, self-esteem, cognitive restructuring, preparing for parenthood, including partners and asking for support/giving support. Delivered by psychologists.	Routine antenatal care
Sheikh-Azadi	2016	Iran	Primiparous women recruited 20-25 weeks gestation. Excluded high-risk pregnancy, serious medical problems, major mental health difficulties, substance use, or problems reading/writing. Mean age=24.5 years. 41.7% were college graduates, 88.3% housewives, 63.3% classified as 'low income'. Follow-up after intervention complete. N=30 in each group at follow-up.	STAI	Six 90-minute group discussions facilitated by study researchers. Content included education and discussion of physiological changes in pregnancy, self-care, goal-setting, diet, psychological health, the impact of a baby on family life, sexual health, routine testing for foetal and maternal health, physical activity, newborn care and breastfeeding.	Routine antenatal care

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Tragea	2014	Greece	Primiparous women (14-28 weeks gestation; average 17 weeks). Excluded if had history of medical complications, insufficient understanding of Greek, use of medications, and if already using relaxation techniques. Median age=32 years old. 85% married, 73.3% planned pregnancy, median number years of education =16, 33.3% low income. Follow-up after intervention (6 weeks after baseline). N=29 in control and n=31 in intervention at follow-up.	STAI, PSS	Lecture on stress and management techniques, brochure on stress, diet and exercise, brochure on time management and adopting routines. Given CD (20 minutes long with clear instructions) with two relaxation techniques: 1) Progressive muscle relaxation; 2) Diaphragmatic breathing. Group was asked to practice 1-2 times per day for 6 weeks. Participants given a diary to record the frequency of practice. Participants monitored via weekly meetings or telephone calls	Lecture on stress management techniques, given brochures on stress & benefits of diet/ exercise. Weekly telephone call (contact matched to intervention group). Received relaxation CD at end of study.

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Vieten	2008	USA	Pregnant women (12-30 weeks gestation; mean=25 weeks) who responded "yes" to the question "Have you had a history of mood concerns for which you sought some treatment?". 52% scored >14 on PSS and 31% scored >16 on CES-D. Excluded if had history of psychosis. Mean age=33.9 years, all were married, 74% were White, 13% Hispanic. Mean household income was above national average, mean educational level was 17 years. Intervention delivered during second/third trimester. Follow-up at end of intervention (8-10 weeks after baseline assessment). N=18 in control and n=13 in intervention at follow-up.	STAI, CES-D, PSS	"Mindful Motherhood" intervention based on MBSR, MBCT, and ACT, adapted for pregnancy/postnatal period. Group format (12-20 women in each group); 8 weekly sessions, 2 hours each. Delivered by Clinical Psychologist and Yoga Instructor. Content involved mindful awareness of thoughts, emotions, breath, body and developing baby (via meditation and yoga), discussion of childbirth anxiety. Equal parts education, discussion and experiential exercises. Participants given weekly readings relevant to class material and CD with three 20-minute guided mediations; encouraged to use daily.	Wait-list control

First Author	Year Published	Country	Participants	Outcome Measures	Intervention	Control
Woolhouse	2014	Australia	Pregnant women (10-34 weeks gestation, 84.4% primiparous). Excluded: substance abuse, suicidal ideation, poor English. Mean age=32.39 years. 90.6% employed, 50% had university degree, 85% had English as first language, 65.6% married, 31.3% living with partner. Follow-up at completion of intervention (6-8 weeks after baseline). N=10 in control and 13 in intervention.	STAI, DASS, CES-D, PSS	Mindfulness developed for pregnancy. Six weekly sessions (2 hours each) facilitated by psychiatrist and psychologist trained in mindfulness. Content: formal (e.g. body scan) and informal mindfulness practices (e.g. mindfulness skills in motherhood), mindfulness of physical/emotional pain, cognitive exercises, and weekly discussion topics. Encouraged to practice at home.	Routine antenatal care
Zhang	2015	USA	Pregnant African-American women; 12-31 weeks gestation (mean=21.5 weeks; 84.6% multiparous). Excluded: history of psychosis, current use of psychotropic medication. Not selected for distress, but had elevated PSS / BDI scores. Mean age=25.3 years, 32.3% had pregnancy complications, 29.4% were single, 19.1% were not living with their partner, 38.2% cohabiting. 84.6% unemployed. Follow-up was approx. 8 weeks after baseline. N=11 in both groups at follow-up.	BDI, PSS	"Mindful Motherhood" intervention (see Vieten & Astin, 2008) led by clinical psychology Ph.D. student. Eight-session mindfulness- and acceptance-based intervention program for pregnant and postpartum women, as described above. Two sessions each week over four weeks; each session consisted of 1–6 participants. Only a small percentage completed a full course of training (3 out of 34 participants completed all sessions).	Routine antenatal care

Interventions

Studies included in the review employed a range of psychological interventions: 11 interventions used CBT techniques (9 of these used a range of CBT techniques, one used Behavioural Activation (BA) specifically, and one used Stress Inoculation Training (SIT)); nine interventions used mindfulness techniques (five used a broad definition of “mindfulness”, two specifically used Mindfulness-Based Cognitive Therapy (MBCT), one used Guided Imagery (GI) specifically, and one specifically used Mindfulness-Based Stress Reduction (MBSR)); three used relaxation techniques such as progressive muscle relaxation and deep breathing; three studies used Interpersonal Therapy (IPT) techniques; and two used group psychoeducation/antenatal education care approaches. Two of the interventions were delivered via a CD that participants used at home with weekly telephone support, whereas the other 26 interventions were delivered face-to-face; 18 of these were in a group format and 8 studies used one-to-one sessions. All face-to-face interventions involved at least 4 formal sessions (the modal number of sessions was 8). Four of the interventions included women’s partners. Fifteen of the interventions were “preventative” in nature; that is, the authors did not specifically select participants for high distress scores. Eleven of the studies screened for high distress scores or current diagnosable depression or anxiety and thus were classified as “treatment interventions”. Two of the studies recruited women who scored both above and below clinical cut-offs on outcome measures and stratified them across intervention and control groups; scores were averaged across high and low scorers within each intervention arm, thus these studies were both preventative and treatment interventions. Seventeen of the studies recruited women who could be considered “high risk”, either due to socioeconomic disadvantage (n=3), current or history of

mental health difficulties (n=3), current symptomatology (n=7), history of trauma (n=1), young age (<25 years old; n=1), or due to medical complications (n=2; pre-eclampsia and moderate-severe nausea/vomiting).

Control groups

Interventions in the experimental groups were compared with routine antenatal care (n=19), waiting-list controls (n=2), medication (n=1), and other non-psychological interventions (n=5; e.g. given bibliotherapy or enhanced antenatal care due to high risk).

Outcome measures used

Twenty-one of the studies reported outcome measures for depression, 18 reported anxiety measures and 12 reported stress measures. Seventeen studies reported more than one outcome measure: five reported both depression and anxiety measures; four reported on anxiety and stress; two reported depression and stress; and six reported depression, anxiety and stress measures. All outcome measures were self-completed questionnaires with scales measuring in the same direction.

Depression was measured using the Beck Depression Inventory (BDI; Beck, Steer, & Brown, 1996), Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden, & Sagovsky, 1987), Clinical Interview Schedule (CIS-R; Lewis, Pelosi, Araya, & Dunn, 1992), Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001), Depression Anxiety Stress Scales (DASS; Lovibond & Lovibond, 1995), the 20-item Symptom Checklist (SCL-20; Derogatis, Lipman, & Covi, 1973), and Centre for Epidemiologic Studies Depression Scale (CES-D Radloff, 1977). Anxiety was

measured using the State-Trait Anxiety Inventory (STAI; Spielberger, 1989), Beck Anxiety Inventory (BAI; Beck & Steer, 1990), DASS, HADS, Generalized Anxiety Disorder 7-item scale (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006), PRA (PRA; Rini, Dunkel-Schetter, Wadhwa, & Sandman, 1999), Pregnancy-Specific Anxiety measure (PSA; Roesch, Dunkel Schetter, Woo, & Hobel, 2004). Stress was measured using the Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983), DASS and Prenatal Distress Questionnaire (PDQ; Yali & Lobel, 1999). Although all studies measured maternal distress at least at two time-points during pregnancy, the timing of the assessments varied among the trials. The final antenatal follow-up time-point (included in the meta-analysis) differed across studies, but all occurred during second and third trimester after the intervention was delivered (majority in third trimester).

Risk of bias in included studies

Overall, the studies were of mixed methodological quality. Figure 3 provides a summary of risk of bias in each domain and Table 2 provides a summary for each study. The majority of studies were low risk for randomisation procedures, as it is standard practice for RCTs to report how they randomly assigned participants to treatment arms (Schulz, Altman, & Moher, for the CONSORT Group, 2010). Most studies were also low risk for attrition bias, as they typically reported reasons for attrition at various time-points and/or accounted for attrition in analyses. Nine of the trials were registered with national trial databases and these trials reported on all outcome measures listed in their trial protocols. Most of the other studies reported results for all outcomes measures listed in their methods sections, even if they were not significant. However, many trials were of unclear or high risk for blinding of

participants/personnel and for blinding of outcome assessments. As previously discussed, while participants cannot be blinded to treatment arm, research staff and study authors can be by using other professionals to deliver the interventions, administer outcome measures, or use online outcome measure assessments. However, many of the trials in this review did not blind study staff, usually because the authors were part of delivering the intervention.

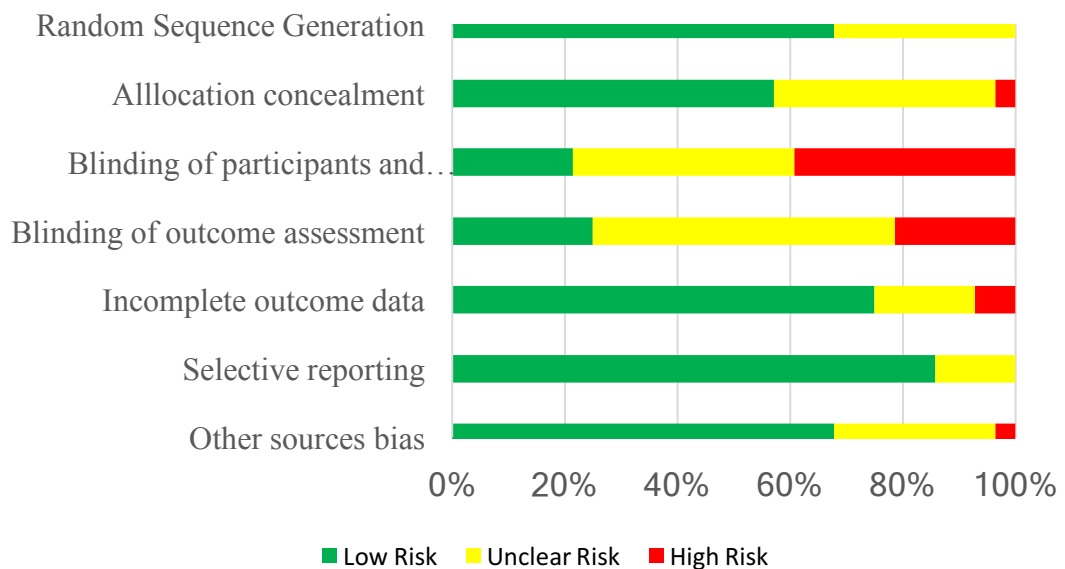


Figure 3. "Risk of bias" graph; judgements about each risk of bias criterion expressed as a percentage across all included studies.

Table 2. *Quality assessment of included studies.*

First Author	Year	Random Sequence Generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources bias
Akbarzadeh	2016	Low Risk	Unclear Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Unclear Risk
Asghari	2016	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	Low Risk	Unclear Risk
Bastani	2005	Low Risk	Unclear Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Unclear Risk
Bittner	2014	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Brugha	2016	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Burns	2013	Low Risk	Low Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Low Risk
Chan	2014	Unclear Risk	High Risk	High Risk	High Risk	High Risk	Unclear Risk	Low Risk

First Author	Year	Random Sequence Generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources bias
Dimidjian	2016	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Dimidjian	2017	Low Risk	Low Risk	Low Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Faramazi	2015	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk
Gambrel	2015	Low Risk	Unclear Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk
Grote	2015	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Unclear Risk
Grote	2009	Low Risk	Unclear Risk	High Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Guardino	2014	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk
Huang	2015	Unclear Risk	Unclear Risk	High Risk	High Risk	Low Risk	Low Risk	Low Risk

First Author	Year	Random Sequence Generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources bias
Ickovics	2011	Low Risk	Low Risk	High Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Jallo	2014	Low Risk	Low Risk	High Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Jokar	2015	Unclear Risk	Unclear Risk	High Risk	High Risk	Unclear Risk	Unclear Risk	Unclear Risk
Jesse	2015	Low Risk	Low Risk	High Risk	High Risk	High Risk	Low Risk	Low Risk
Le	2011	Unclear Risk	Low Risk	High Risk	High Risk	Unclear Risk	Unclear Risk	Unclear Risk
Lenze	2017	Low Risk	Low Risk	Low Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk
Mao	2012	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Milgrom	2015	Low Risk	Low Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Unclear Risk

First Author	Year	Random Sequence Generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other sources bias
Sheikh-Azadi	2016	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	High Risk
Tragea	2014	Low Risk	Unclear Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Vieten	2008	Unclear Risk	Low Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk
Woolhouse	2014	Low Risk	Low Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Unclear Risk
Zhang	2015	Unclear Risk	Unclear Risk	Unclear Risk	Unclear Risk	Low Risk	Low Risk	Low Risk

Assessment of heterogeneity

Assessment of heterogeneity using the I^2 statistic revealed that there was considerable heterogeneity among the included studies ($I^2 = 88.6\%$, $p < .001$). One trial (Sheik-Azadi et al., 2016) had a SMD that was considerably larger than all the other studies (SMD=7.15 as compared to next largest SMD of 2.31). Further inspection of this study revealed that it had the most questionable methodological quality, as it did not report its randomisation methods. Therefore, this study was removed from analysis. Removing this study only slightly reduced heterogeneity ($I^2 = 82.7\%$, $p < .001$). As it is not recommended to keep removing studies until heterogeneity is reduced, due to there being no set “cut-off” for heterogeneity (Higgins, 2008), it was decided to continue the meta-analysis with the remaining 27 studies. Considerable between study variability is somewhat expected given that the trials included in this review studied different populations of women, different interventions, and used different outcome measures. Therefore, analysis was conducted using a random-effects model (DerSimonian-Laird) to address the considerable between study variance.

Effects of interventions

The pooling of results from all 27 trials indicated a small to medium beneficial effect of interventions for reducing maternal distress ($n=3,240$, SMD=.42, 95% CI [.24, .61], $p < .001$, Figure 4).

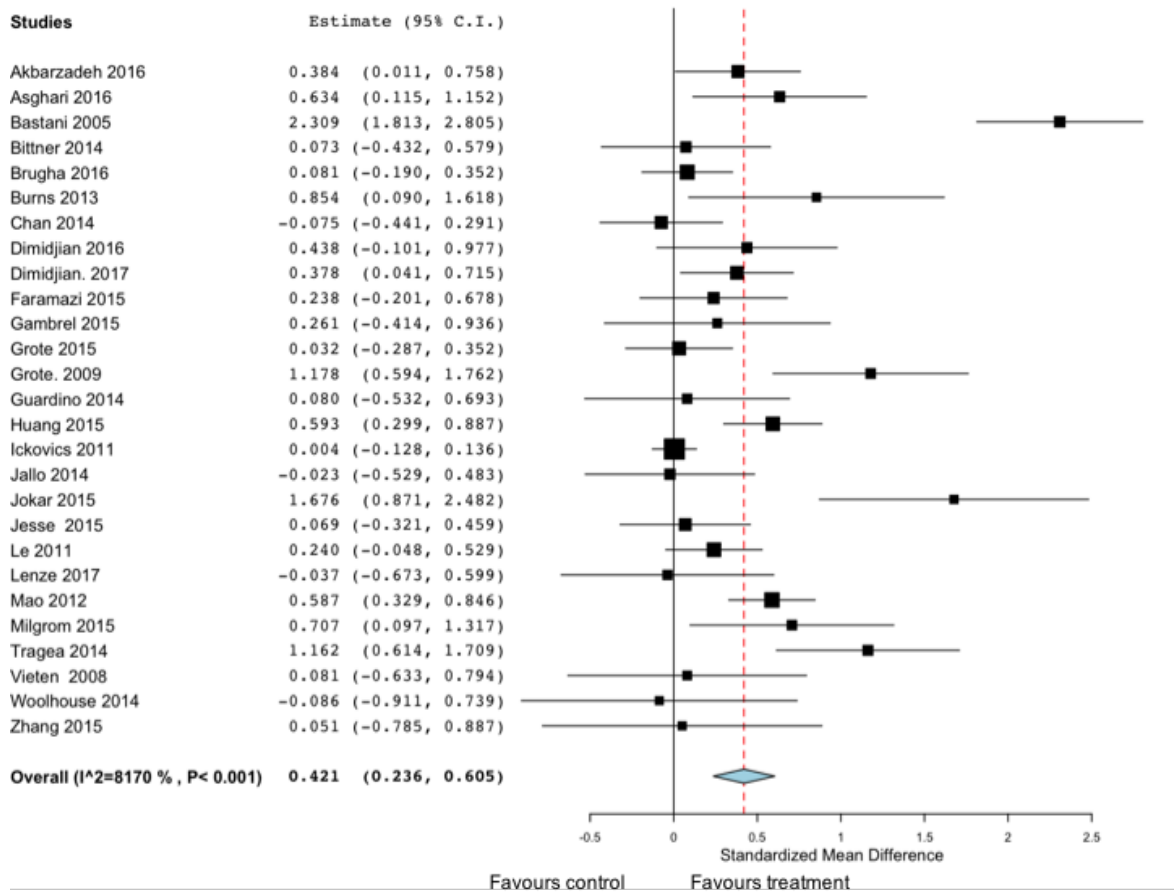


Figure 4. Forest plot of effect sizes of all studies included in meta-analysis.

As part of a pre-planned sensitivity analysis, three subgroup analyses were conducted. In the first subgroup analysis, separate analyses were run for prevention and intervention trials (see Figure 5). Two trials reported data on women who scored both high and low on measures of maternal distress, so these were also analysed separately. Fourteen trials were classified as preventative and pooling these results indicated a small beneficial effect in reducing maternal distress (n=1,952, SMD=.39, 95% CI [.17, .62], $p<.001$; $I^2 = 76.7\%$, $p<.001$). These trials included the following interventions; relaxation (n=2), CBT (n=4), mindfulness (n=7), group antenatal education (n=2). Eleven trials were classified as treatment trials and pooling these results indicated a medium-sized positive effect in reduction in maternal distress

($n=889$, $SMD=.53$, 95% CI [.13, .93], $p<.01$; $I^2 = 87.1\%$, $p<.001$). The treatment trials included the following interventions; relaxation ($n=1$), CBT ($n=5$), IPT ($n=3$), mindfulness ($n=2$). One of the treatment trials (Bastini et al., 2005) had an effect size that appeared to be an outlier as compared to the other trials ($SMD=2.31$ as compared to next largest SMD of 1.18) and confidence intervals for this effect did not overlap with confidence intervals for the other treatment trials. The subgroup analysis for treatment trials was re-run with this trial excluded; the results indicated that treatment trials had a small positive effect in the reduction of maternal distress ($n=785$, $SMD=.32$, 95% CI [.10, .54], $p<.01$; $I^2 = 50.4\%$, $p<.05$). Two trials could be considered both preventative and treatment interventions, as they recruited high and low risk women based on current distress symptomatology. These studies (both CBT) showed no beneficial effect of the interventions in reducing distress ($n=323$, $SMD=.08$, 95% CI [-.15, .30], $p=.50$; $I^2 = 0\%$, $p=.96$).

A post-hoc meta-regression analysis was run to compare the effect of prevention trials ($n=14$) and treatment trials ($n=10$; Bastini et al. trial excluded). As only two trials were categorised as being both preventative and treatment, these were excluded from this analysis (see Hempel et al., 2013). This analysis showed that the intervention effect in treatment trials was not significantly different from the effect of prevention trials ($b=-.06$, 95% CI [-.37, .25], $p=.72$).

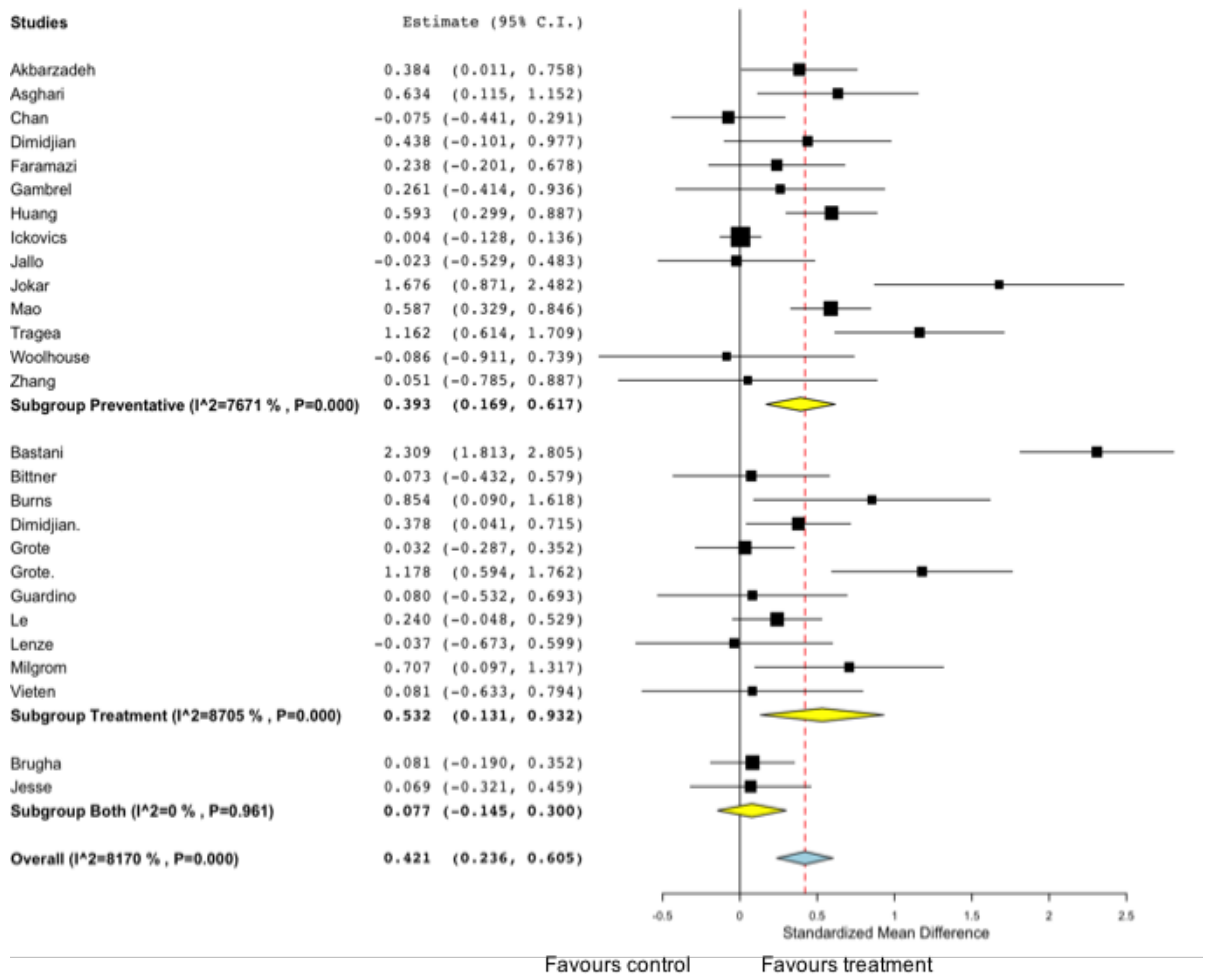


Figure 5. Forest plot of effect sizes for studies categorised as “prevention trials”, “treatment trials”, or “both prevention and treatment”.

In the second subgroup analysis, separate analyses were run for the different intervention types (see Figure 6). Interventions were categorised as either “CBT”, “Mindfulness and Relaxation”, “IPT”, or “Group Antenatal Education”. Eleven trials were categorised as CBT and pooling the results of these trials found a small to medium beneficial effect of CBT interventions on reducing maternal distress (n=1,312, SMD=.44, 95% CI [.24, .64], $p < .001$; $I^2 = 63.4%$, $p < .01$). Twelve trials were categorised as using mindfulness and relaxation-type techniques; one of these trials (Bastini et al., 2005) appeared to be an outlier (had an effect size with

confidence intervals that did not overlap with confidence intervals from other studies) and so was removed from subgroup analysis. Pooling results of the eleven remaining trials indicated a small beneficial effect on reducing maternal distress (n=648, SMD=.25, 95% CI [.03, .46], $p < .05$; $I^2 = 41.6\%$, $p = .07$). Three trials used IPT techniques and pooling the results of these indicated no beneficial effect in reducing maternal distress (n=242, SMD=.38, 95% CI [-.35, 1.10], $p = .31$; $I^2 = 83.7\%$, $p < .01$). Finally, only one trial used group antenatal education and this trial alone showed no beneficial effect on maternal distress levels (n=934, SMD=.004, 95% CI [-.13, .14]).

A post-hoc meta-regression analysis was run to compare the effect of CBT (n=11), mindfulness/relaxation (n=11), and IPT (n=3). Group antenatal education was not included in this analysis as it was only studied in one trial. This analysis showed that the effect of mindfulness and relaxation-based interventions was not significantly different from the effect of CBT interventions (b=-.20, 95% CI [-.50, .10], $p = .43$). It was also found that the effect of IPT interventions was not significantly different from the effect of CBT interventions (b=-.11, 95% CI [-.56, .35], $p = .64$).

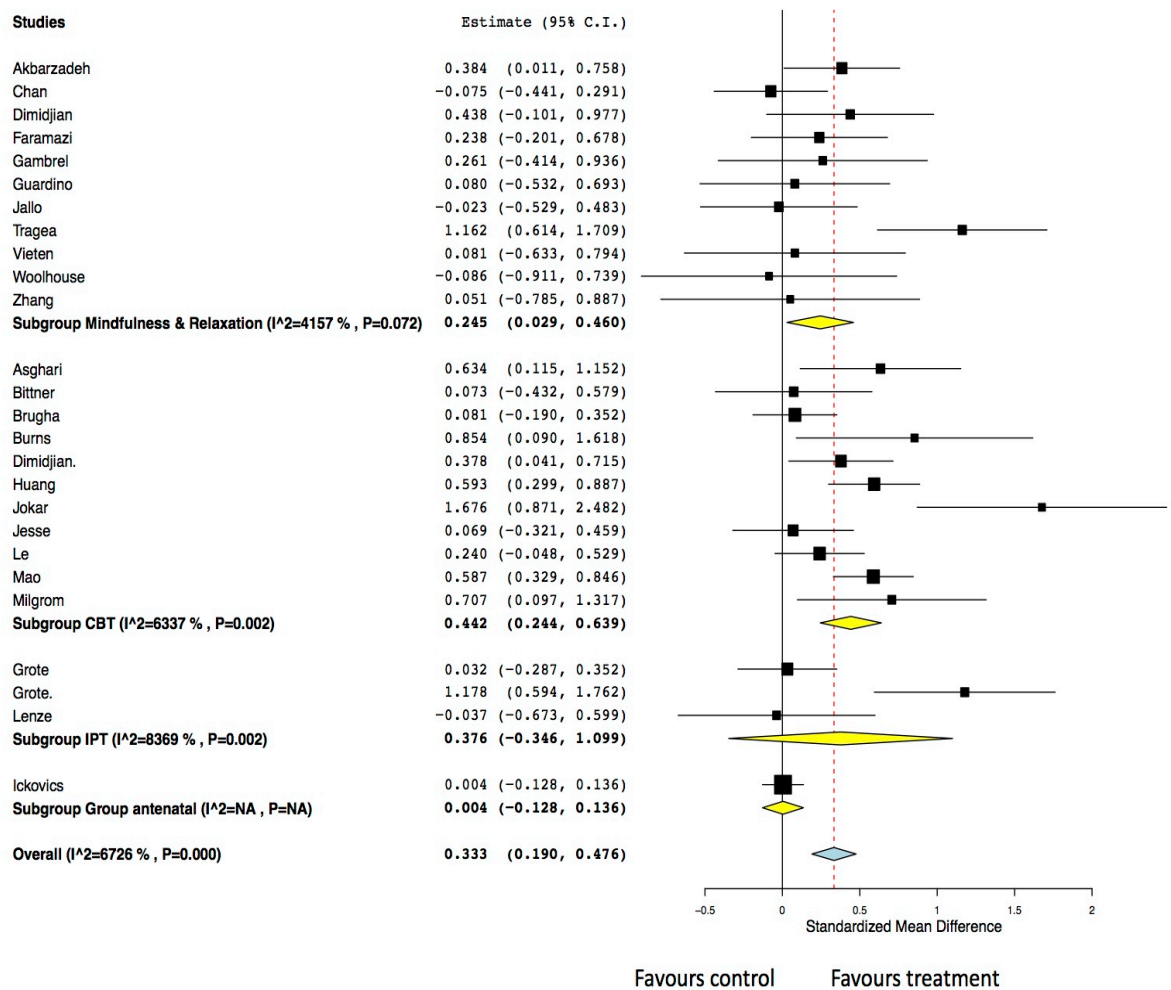


Figure 6. Forest plot of effect sizes for studies categorised according to intervention therapeutic modality.

In the third subgroup analysis, separate analyses were run for group-delivered and individual/one-on-one interventions (see Figure 7). Pooled analysis of 17 studies reporting group interventions found a small to medium beneficial effect of these interventions in reducing maternal distress (n=2,375, SMD=.42, 95% CI [.17, 0.68], $p<.001$; $I^2 = 85.7\%$, $p<.01$). The analysis of 10 studies that delivered interventions individually to women also showed a small to medium beneficial effect of these interventions in reducing maternal distress (n=865, SMD=.41, 95% CI [.15, 0.67], $p<.001$; $I^2 = 70.1\%$, $p<.01$).

A post-hoc meta-regression analysis was run to compare the effect of interventions delivered to participants individually (n=10) as compared to group based interventions (n=16). This analysis showed that the intervention effect of individual interventions was not significantly different from the effect of group interventions (b=.10, 95% CI [-.19, .39], $p=.50$).

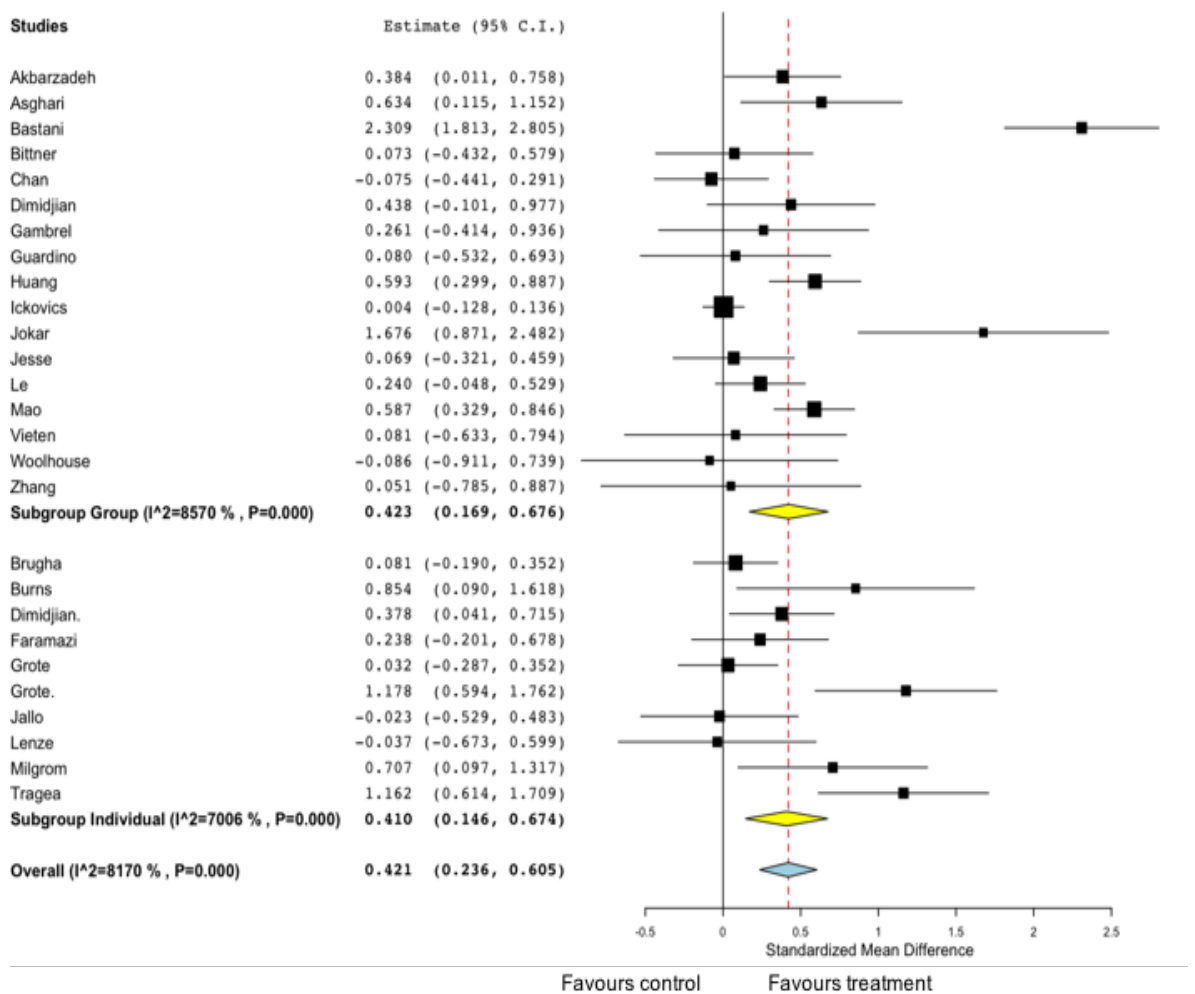


Figure 7. Forest plot of effect sizes for studies categorised according to whether delivered in a group or individual format.

Finally, a post-hoc exploratory meta-regression was run to see if intervention effects differed according to the number of sessions offered. This revealed no significant effect of number of sessions on intervention effect ($b=.01$, 95% CI $[-.09, .12]$, $p=.85$; see Figure 8).

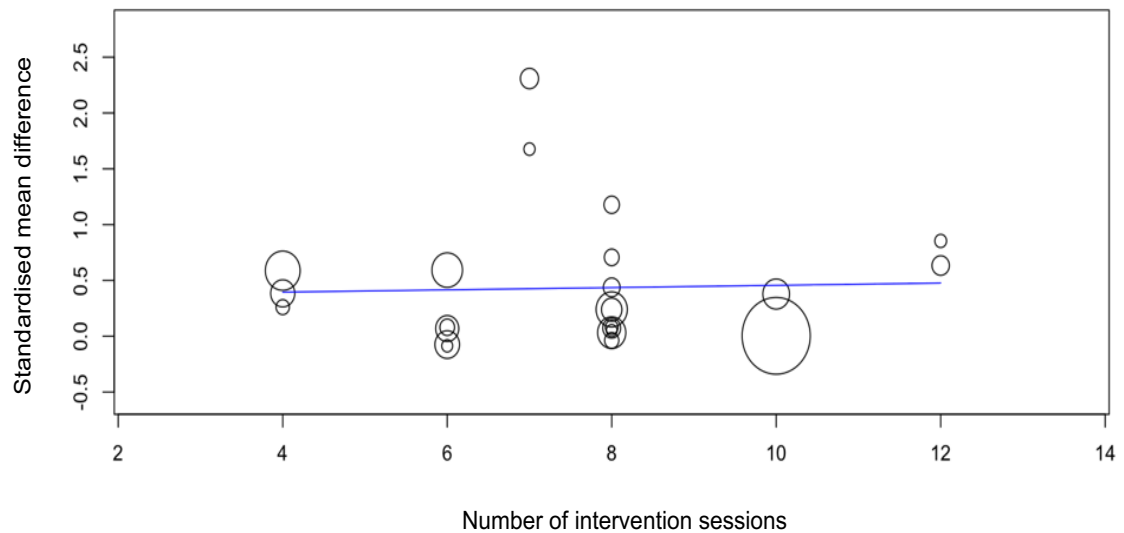


Figure 8. Meta-regression plot of effect of number of sessions on intervention effect size.

Discussion

Summary of main results

This meta-analysis summarised the results of 27 RCTs with 3,240 pregnant women. All the RCTs investigated the effects of psychologically-informed interventions on reducing symptoms of maternal distress, such as depression, anxiety and stress. Overall, it was found that these interventions were moderately effective at reducing maternal distress. As the scope of this review was quite large, three pre-planned sub-analyses were conducted according to: whether the trials aimed to

prevent or treat symptoms of maternal distress; what intervention type the trials used; and how the interventions were delivered to the women. It was found that both prevention and treatment trials had positive effects in reducing maternal distress. This result is different to that reported in a previous meta-analysis of pre- and postnatal maternal distress, which found no beneficial effect of prevention trials (Fontein-Kuipers et al., 2014). This may be because the previous meta-analysis included only six prevention trials, whereas the current analysis found fourteen prevention trials. It was also found that both CBT and mindfulness/relaxation interventions reduced distress, whereas IPT and group antenatal education did not show beneficial effects in reducing distress. However, CBT and mindfulness/relaxation were also the most common interventions, whereas only three trials using IPT were found and only one group antenatal education programme was eligible for inclusion in the meta-analysis. Conclusions regarding these interventions should therefore be tentative at this stage. Finally, it was found that both group and individual interventions had beneficial effects in reducing maternal distress. A post-hoc meta-regression revealed no effect of number of intervention sessions on effect size of reduction in distress levels.

Quality of evidence

This review and meta-analysis included only RCTs as these are considered the “gold-standard” scientific method for studying the effectiveness of interventions (Akobeng, 2005; Spring, 2007). Although all the studies included in this review were self-defined as RCTs and all included control groups, some trials did not report information on their randomisation procedures which led to questions about their quality. If adequate randomisation techniques (e.g. referring to a random number

table, computer-generated random number system, coin tossing, etc.) were not employed, these trials could be considered quasi-experimental rather than true RCTs. This is problematic as it introduced the possibility of selection bias. It may have been preferable to calculate “change scores” for the interventions without clear randomisation procedures rather than only comparing between group post-intervention outcome assessments, but this data was not consistently available.

The domains with the most mixed methodological quality were “blinding of participants and personnel” and “blinding of outcome assessment”. Although in psychological studies it is not possible to blind participants to treatment arm, it is possible to blind research personnel by, for example, having staff who are not involved in data analysis or write up delivering the intervention and outcome measures. However, this is more difficult with smaller and less well-funded studies that may not have the resources to recruit other staff. One potential option for blinding outcome assessments without having to recruit other staff is to use online software to collect outcome data, which a few studies did do. However, this can also be problematic if participants require help filling in the questionnaires, if there are problems with the software or internet connection, and participants may also be less motivated to fill in questionnaires without explicit reminders from staff.

Five trials were excluded from the meta-analysis due to incomplete reporting of outcome data, such that there was not enough information to generate data for the pooled analysis. Attempts were made to contact the authors of these trials without success. With one of these trials there was the option to gather some outcome data from a previous meta-analysis (Fonetin-Kuipers et al., 2014), but the previous meta-analysis did not focus specifically on the prenatal period and used a post-natal endpoint in their analysis, whereas the focus for the current meta-analysis was prenatal

outcomes. The trials included in the current meta-analysis were mostly judged as “low risk” for “incomplete outcome data” and “selective reporting” domains of quality assessment. Nine of the trials were registered with national trial databases and most of the trials reported results for all outcome measures listed in their protocols or methods sections within the paper. Most studies were low risk for other sources of bias. Studies of unclear or high risk of other sources of bias were judged to be so due to the paper being difficult to read/understand due to poor translation in to English.

Strengths and limitations

This review and meta-analysis took a broad approach to examining various psychologically-informed interventions which targeted different constructs of distress during pregnancy. The decision was taken to conceptualise prenatal depression, anxiety and stress as a single multidimensional “distress” construct due to the evidence that women reporting psychological distress during pregnancy often report difficulties in multiple domains of affective functioning (Heron et al., 2004). Outside of perinatal populations, there is evidence for significant comorbidity of depression, anxiety and stress (Caspi et al., 2014; Hirschfeld, 2001; Kessler, Chiu, Demler, Merikangas, & Walters, 2005; Newman, Moffitt, Caspi, & Silva, 1998). It has also been reported that different measures of maternal distress converge both at any one time-point of measurement and over time, suggesting a lack of precision in outcome measures designed for specific constructs and that compiling scores from different measures provides more reliable and interpretable data (DiPietro et al., 2008). Furthermore, previous meta-analysis also focused on a broad definition of “distress” rather than one specific symptom domain (Fontein-Kuipers et al., 2014).

Notably, the current meta-analysis found 19 more studies than this previous meta-analysis. However, the Fontein-Kuiper meta-analysis and other previous systematic reviews on this topic (e.g. Beddoe & Lee, 2008; Dennis, 2005; Dennis & Dowswell, 2013; Lavender et al., 2016; Lavender, Richens, Milan, Smyth, & Dowswell, 2013; Marc et al., 2011) were all performed before or during 2013. In the current meta-analysis, 21 of the papers found were published after 2013.

Taking a broad and multidimensional approach allowed evidence to be examined from several different countries, different populations of women (e.g. primiparous, multiparous, low and high socioeconomic status, typical pregnancies and those with minor/moderate complications), different intervention types, different modes of intervention delivery, and different measures of psychological distress. Unlike the Fontein-Kuipers and colleagues (2014) meta-analysis, the maternal populations were not limited to “low risk” women or countries or cultures. The advantage of such a broad approach is that it allows the generalisability and consistency of findings to be assessed across a wide range of different settings, populations and presentations, reducing the risk of bias and chance results (Gøtzsche, 2000; Grimshaw et al., 2003).

However, this broad approach may also have resulted in the high level of heterogeneity observed across study results. It has been argued that heterogeneity in meta-analyses is not necessarily problematic and should indeed be expected, as long as it is explored appropriately (Higgins, 2008). There are several different options for dealing with heterogeneity; initially, the current analysis opted to remove one study with a clear outlying SMD and questionable methodological quality from the analysis, but this did not have a large effect on reducing the heterogeneity statistic. It is not recommended to continue to remove studies until an arbitrary “acceptable”

level of heterogeneity is reached, but rather to perform sensitivity analyses to see if certain factors are contributing to heterogeneity (Higgins, 2008; Higgins & Green, 2011). This meta-analysis conducted three planned subgroup analyses based on a priori ideas about what may contribute to heterogeneity, but substantial heterogeneity was found within these subgroups. Inspecting studies with larger SMDs did not reveal any consistent factors that may be affecting heterogeneity. As this took such a broad approach, there are too many variables with too few studies to inspect every single factor that could affect heterogeneity. Other differences between studies that could have introduced inconsistency include: Who delivered intervention and how much training and monitoring was provided; study methodological quality; whether women were high or low risk on measures of social disadvantage; obstetric risk; whether partners are included or not; parity of the women; study sample size. As more studies are conducted, future meta-analyses may want to consider some of these factors. Due to the heterogeneity present across studies, a random effects model was used to perform the meta-analysis, which results in wider confidence intervals and thus possible a less precise measure of effects than fixed-effect models.

Another limitation of conceptualising antenatal distress as a single construct is that it is not possible to investigate whether an intervention is having a specific effect on a particular set of symptoms or whether an intervention is more or less effective for certain types of symptoms. Furthermore, by analysing all the studies together with a single outcome variable of “distress”, it is not possible to differentiate between samples where one symptom cluster is more prevalent or severe than others or where there is greater or lesser comorbidity among different types of symptoms. It may be particularly important to further specify and target more specific “pregnancy-related” anxiety symptoms for perinatal populations and taking a broad approach to

conceptualising distress does not allow investigation of whether pregnancy-related anxiety is a meaningfully discrete construct (Bayrampour et al., 2016). Taking a broad approach to conceptualising antenatal distress also has implications for the design and refinement of future interventions, as by focusing on a more generalised measure of distress, one is less able to target particular symptom types and it is more difficult to identify mechanisms of change. This means that treatment may be broad rather than targeted, which has potential implications for the cost and length of treatment. There are also funding implications, as intervention trials are typically funded for discrete disorders rather than for “distress” (Clark, 2009).

However, it has been argued that before National Institute of Mental Health (NIMH) funding priorities emphasised clinical trials for Diagnostic and Statistical Manual (DSM) disorders, treatment approaches used to more commonly be transdiagnostic in nature and thus conceptualise distress more broadly (Clark, 2009; Goldfried & Wolfe, 1996; Meier & Meier, 2017). There has recently been a resurgence of interest in transdiagnostic approaches, which have been shown to be effective treatments (Harvey et al., 2004; Meier & Meier, 2017; Newby et al., 2015; Norton, 2012). It has been argued that transdiagnostic approaches can treat comorbid disorders more effectively than diagnosis-specific treatments (Norton, Hayes, & Hope, 2004; Norton et al., 2013). Indeed, many psychological interventions developed for general populations are multicomponent treatments and research often does not focus on which components of treatment are responsible for symptom improvement (Clark, 2009). Meier and Meier (2017) argue that CBT and mindfulness interventions are transdiagnostic approaches, although they acknowledge that there are some content differences for anxiety and depression (e.g. behavioural activation for depression, tolerating uncertainty for GAD, exposure and

response prevention for OCD, targeting avoidant behaviour / behavioural experiments for anxiety and specific phobias). Clark (2009) states that transdiagnostic approaches may be more cost-effective, as they can be delivered in group formats and do not require several different disorder-specific treatment manuals.

Another potential limitation of this meta-analysis is that the outcome measures used in the included studies were self-report and thus not clinically objective. Although most of the measures used have been reported to be reliable and valid in different populations, most were not specific to measuring distress during pregnancy. It has been reported that the BDI and the CES-D tend to produce higher scores in pregnant women, which may result in more false-positives (Holcomb, Stone, Lustman, Gavard, & Mostello, 1996; Myers & Weissman, 1980; Salamero, Marcos, Gutiérrez, & Rebull, 1994; Sharp & Lipsky, 2002). Furthermore, the BDI has been considered to be unreliable at detecting depression during pregnancy due to its focus on somatic symptoms (Ryan, Milis, & Misri, 2005). Although the EPDS was developed for assessing postnatal depression, it had been found to be effective at identifying women with depression during pregnancy (Murray & Cox, 1990; Ryan et al., 2005). Although the GAD-7 is not a pregnancy-specific measure of anxiety, it has been found to have good internal consistency, sensitivity and specificity in perinatal populations. A minority of the studies included in this meta-analysis measured pregnancy-specific/related anxiety, which is probably because these measures are not yet well validated and the concept of pregnancy-relates anxiety is not well specified (Evans et al., 2015). The inclusion of many different outcome measures may make the results of this meta-analysis less reliable; the different scales used may affect disparity in scores and it is argued that using several different

measures may lead to selective reporting of the most interesting findings (Higgins & Green, 2011). However, the use of continuous scores and SMDs for the meta-analysis limits the concerns about differences in the instrument scales (Higgins & Green, 2011) and there was limited evidence of reporting biases in the studies included in this review. Another limitation is that there was not consistency in time-points of assessments across studies, with baseline and follow-up assessments conducted across the three trimesters of pregnancy. This could be another factor to consider as a potential covariate in future analyses.

Although this review and meta-analysis took a broad approach to measuring distress during pregnancy, it was more focused in terms of what types of interventions were included (psychological) and when the interventions were delivered and outcomes assessed (prenatally). It was decided to focus on outcomes during pregnancy as the prenatal period is distinct from postnatal with different types of stresses and demands (Heron et al., 2004; Jormeen, 2004; Slade & Cree, 2010). Many studies, and consequently previous reviews and meta-analyses, have focused on postnatal psychological distress (in particular, depression) with prenatal interventions focusing on preventing poor postnatal outcomes. Yet, there are difficulties and complications that arise from being distressed during pregnancy that are distinct (yet linked) to postnatal outcomes (Slade & Cree, 2010). By focusing on outcomes in pregnancy this review could specifically assess whether interventions were influencing distress during pregnancy, although this often resulted in using immediate post-intervention time-points for pooled analysis at the expense of examining the longer-term effects of the intervention (i.e. did distress scores remain lower several weeks after the intervention was over?).

As for intervention types, the initial search revealed several other types of interventions designed to target distress during pregnancy which were excluded from this review, such as acupuncture, acupressure, yoga, bright light therapy, and food supplements. Some of these have been reported in previous systematic reviews that focused on mind-body interventions (e.g. Beddoe & Lee, 2008; Dennis, 2013; Marc, 2011). The wide range of intervention types that can be used during pregnancy may be reflective of the fact that pregnant women have contact with many different health professionals and they often favour non-pharmaceutical interventions (Buist et al, 2015). These interventions were excluded as this review focused only on psychological interventions. However, it was a subjective judgement as to what was deemed “psychological”; it could be argued that yoga is as much a mind-body intervention as mindfulness or relaxation and perhaps should also have been included. Indeed, Vieten and Astin’s (2008) mindfulness intervention included in this review incorporated elements of yoga. Furthermore, with the emergence of third-wave CBT therapies, some of the interventions in this review that were categorised as “mindfulness”, such as MBCT, could also potentially be categorised under the CBT umbrella (Hunot et al., 2013). A limitation of this review and meta-analysis is that only one author performed the search, data extraction and analysis. This meant that decisions regarding whether studies met inclusion criteria and how to categorise studies were the subjective opinion of one person, and thus the review process itself may have been biased.

Research and Clinical implications

This meta-analysis found that both “preventative” and “treatment” interventions were effective at reducing symptoms of distress during pregnancy. This

contrasts with a previous meta-analysis which found that only treatment interventions were effective (Fontein-Kuipers et al., 2014). It may be that as the analysis presented here included more studies it was more powered to find an effect. However, it should be mentioned that although studies were categorised as preventative interventions when women were not selected for high scores at baseline (thus the studies took a “general population” approach), inspection of baseline data revealed that for some of the studies the women did have slightly elevated baseline distress scores at or above the clinical cut-offs. This may have influenced the findings, such that interventions may have been more effective for the preventative studies that included higher scoring women. Future studies may wish to plan subgroup analyses to investigate further whether preventative interventions are more effective for higher risk women. Although it has previously been argued that preventative interventions offer no or only limited benefit in reducing maternal distress (Fontein-Kuipers et al., 2014; John, 2011; National Collaborating Centre for Mental Health, 2007), the results of the current meta-analysis suggest that this may not be the case and thus this issue warrants further investigation. Future studies should also investigate whether preventative interventions are more effective for women who are at high risk for developing symptomatology even if they are not currently experiencing elevated symptoms, i.e. due to social disadvantage, history of trauma, young age, or obstetric or medical complications. It would also be prudent to study whether certain interventions are more or less effective according to the severity of levels of reported distress, as this would allow interventions to be developed in line with the NICE recommended stepped-care approach (NICE, 2011a).

Subgroup analysis revealed that CBT and mindfulness/relaxation techniques had small to moderate positive effects in reducing distress, whereas IPT and group antenatal education did not show significant beneficial effects. However, as only three trials of IPT and one trial of antenatal group education were included in this analysis, it would be premature at this stage to suggest that certain intervention types should be favoured over others in clinical practice, especially as many of the studies included in the meta-analysis had small sample sizes. Furthermore, post-hoc moderator analysis using meta-regression found no significant differences in pooled effect sizes between the different intervention types. Future research should investigate a variety of intervention types using larger samples so that more reliable comparisons can be made. It would also be interesting to investigate what the “active” components of interventions may be; for instance, do mindfulness-type interventions need to include content regarding mindful awareness of thoughts, or are more basic relaxation exercises adequate? Are group interventions effective due to the social support aspect of contact with other pregnant women, or are there specific exercises that have beneficial effects? Is there an “ideal” number of sessions/contacts? Investigations such as these would again require large samples as well as different control groups that matched the intervention except for one particular component. Studies such as these would help delineate the most effective forms of interventions.

It was also found that both individual and group interventions were effective at reducing maternal distress. Group interventions have several advantages over individual interventions, including: gaining support from others; vicarious learning from others; normalisation that others share similar difficulties, and a safe space to practice interpersonal skills (Gidron, 2013). Furthermore, in the context of funding

pressures within the NHS as well as difficulties obtaining research funding, group interventions are more cost-effective as they allow more service users to be seen with fewer therapist resources being used. However, some individuals prefer to not be treated in a group context and therefore it is important to continue to develop effective individual interventions. It is also important to develop interventions that allow partners of pregnant women to participate and offer support; only two studies in this meta-analysis included partners, yet there is growing recognition of the importance of involving partners in the care of pregnant women (Panter-Brick et al., 2014). It would be interesting to investigate further how partners could be more involved in perinatal psychological interventions and what effect including partners has on intervention effectiveness.

Future studies should also consider what impact measurement strategies have on outcomes; the broad approach adopted by this meta-analysis, evidence of substantial symptom overlap across different diagnostic categories such as “depression”, “anxiety” and “stress”, and a trend towards transdiagnostic treatment approaches in general populations suggests that multidimensional measures could be employed rather than using several different measures. For example, the EPDS and the DASS look at symptoms of both depression and anxiety (Matthey, 2008). The use of multidimensional measures could save time and resources, as well as leading to more consistency in measures used across different studies, although this may be at the expense of gaining insight in to more specific mechanisms of change. It would be interesting for a future review to perform a more in-depth analysis of the content of antenatal interventions in order to investigate more thoroughly if and how they are adapted for perinatal populations. It will also be important for researchers and clinicians to develop and evaluate interventions for other potentially more serious

forms of psychological distress that can develop or be exacerbated by pregnancy and the postnatal period, including psychosis and personality disorders. The NICE guidance on mental health care during pregnancy and postpartum has called for more research in to these areas (NICE, 2014a). Finally, although the current review has focused on outcomes in pregnancy, which is a relatively short time period, it would be interesting to investigate further the effect of the timing of delivery of interventions (e.g. how early during pregnancy should interventions be delivered? Are prenatal interventions more effective at reducing long-term levels of distress than postnatal interventions, or do interventions need to cross the pre- and postnatal periods?).

Conclusions

This meta-analysis investigated RCTs that targeted preventing and/or treating symptoms of depression, anxiety and stress in pregnancy. A broad approach was taken to conceptualising distress during pregnancy, allowing several different intervention types to be included in the analyses, which increases the completeness, generalisability and applicability of the evidence. It was found that it is effective to both treat and prevent maternal distress, that both CBT and mindfulness interventions were effective at reducing distress, and that both group and individual interventions were effective at reducing distress. The implications of these findings are valuable for both clinicians working to treat perinatal women and clinical researchers working to develop and investigate the effectiveness of perinatal psychological interventions.

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Part 2: Empirical Paper

Relationship and mother-infant bonding outcomes following a psychological intervention for antenatal anxiety

Abstract

Aims: Anxiety during pregnancy is associated with negative maternal and child outcomes, such as poorer relationship functioning and mother-infant bonding. This study therefore investigated the impact of a pilot group cognitive behavioural therapy (CBT) intervention to treat antenatal anxiety on pregnant women's self-reported intimate relationship functioning and mother-infant bonding.

Method: 114 pregnant women were randomly assigned to either the intervention or "treatment as usual" group. The intervention involved three antenatal group sessions and postnatal follow-up, delivered by a trainee clinical psychologist and midwife. Relationship functioning and anxiety were measured at each group session and mother-infant bonding was assessed postnatally.

Results: Analyses revealed a slight decline in relationship functioning over time, with no significant effect of the intervention. Follow-up regression analyses revealed that improvements in anxiety scores at postnatal follow-up were associated with improvements in relationship functioning at postnatal follow-up for the intervention group only. However, comparison of the regression slopes between the two-groups was not significantly different. Between group comparisons of mother-infant bonding found no group differences, but follow-up analyses revealed that improved anxiety scores at postnatal follow-up were associated with higher mother-infant bonding for the intervention group only. Again, comparison of the regression slopes between the two-groups was not significantly different.

Conclusions: This small-scale study found no reliable effect of the intervention on relationship functioning or mother-infant bonding. As this was a feasibility trial,

definitive conclusions about the effectiveness of the intervention and subsequent clinical recommendations cannot yet be made.

Introduction

The journey through pregnancy and into new parenthood involves many changes; many of these are positive and exciting, but others can be experienced as more stressful and anxiety-provoking. This time involves huge role transitions and can impact on all areas of life, including on relationships. Two of the most significant relationships during this time are the relationship that a mother has with her intimate partner and that which she has with her (unborn or newborn) child. The experience of stress and anxiety during this time can negatively affect these relationships, which in turn has implications for the mother's longer term mental health and for the child's future development. It may therefore be important for interventions developed to treat antenatal anxiety to include components addressing intimate partner and parent-infant relationship functioning. Taking this in to consideration, the aim of this study was to investigate the effect of a brief, low-intensity psychological intervention targeting anxiety symptoms during pregnancy on self-reported intimate relationship functioning and mother-infant bonding.

Mental health difficulties during the perinatal period

Mental health problems during the perinatal period are a leading public health issue because of their negative effect on both maternal and child outcomes (Glover, 2014; Howard et al., 2014; Slade & Cree, 2010; Stein et al., 2014). Despite studies showing that antenatal anxiety is more common than depression across all trimesters

of pregnancy, anxiety has received limited attention from researchers and clinicians as compared to depression (Dennis, Falah-Hassani, & Shiri, 2017; Lee et al., 2007). Many women are diagnosed with anxiety disorders during pregnancy and one study found that clinically significant symptoms of anxiety were reported by up to half of all pregnant women (Andersson, Sundström-Poromaa, Wulff, Aström, & Bixo, 2004; Goodman, Chenausky, & Freeman, 2014; Heron et al., 2004; Lee et al., 2007). In a recent meta-analysis, the prevalence for self-reported anxiety symptoms (measured using self-report instruments such as the State-Trait Anxiety Inventory) was found to be 18.2% in the first trimester, 19.1% in the second trimester and 24.6% in the third trimester (Dennis et al., 2017). The overall prevalence for a clinical diagnosis (using diagnostic interviews such as the Structural Clinical Interview for DSM) of any anxiety disorder during pregnancy was 15.2% (4.1% generalised anxiety disorder [GAD]). In the postnatal period the prevalence for self-reported anxiety symptoms was 17.8% at 1-4 weeks postnatally and was 15% between 1-24 weeks postnatally, with 9.9% of women having a clinical diagnosis of any anxiety disorder between weeks 1-24. These prevalence rates are higher in the maternal population than in the general adult population (Alonso, Lépine, & ESEMeD/MHEDEA 2000 Scientific Committee, 2007; Wittchen & Jacobi, 2005). This meta-analysis also suggests that antenatal anxiety may be more prevalent than postnatal anxiety and therefore interventions to treat these symptoms should be provided during the antenatal period.

Despite pregnancy being a time of increased vulnerability for the development of anxiety disorders, symptoms of anxiety during pregnancy have sometimes been overlooked. It has been reported that medical professionals often assume that somatic symptoms such as fatigue, sleep difficulties, irritability, restlessness and muscle tension are due to pregnancy rather than symptoms of an anxiety disorder such as

GAD (Simpson, Glazer, Michalski, Steiner, & Frey, 2014). It may also be assumed that some of the pregnancy-specific concerns, such as worrying about the baby's health, the course of pregnancy, and childbirth, are "normal", potentially resulting in the under-detection of anxiety disorders during the perinatal period and thus a missed opportunity to offer support and/or interventions (Harpel, 2008; Simpson et al., 2014; Weisberg & Paquette, 2002).

Studies of anxiety during the perinatal period have typically used instruments that were designed to measure general psychological functioning, such as the GAD-7, rather than pregnancy-specific measures, due to the lack of such specific measures (Evans, Spiby, & Morrell, 2015; Hewitt et al., 2009; NICE, 2017). The few pregnancy-specific measures that do exist are limited by a lack of evidence of their concurrent and predictive validity against diagnostic tools, a lack of guidance for clinical use, and ultimately a lack of clear theoretical underpinning (Evans et al., 2015). A recent study attempted to clarify the concept of pregnancy-specific / pregnancy-related anxiety, finding that the critical attributes of pregnancy-related anxiety (affective responses, cognitions, and somatic symptoms) and consequences (negative attitudes, reassurance-seeking behaviours, and avoidance) are similar to those defined for general anxiety disorders (Bayrampour et al., 2016). This concept analysis was also unable to find a theory specific to pregnancy-related anxiety; they identified three antecedents of pregnancy-related anxiety including the identification of a potential risk, low perceived control, and the activity of negative cognitions, which fit with Beck's cognitive theory of anxiety (Beck et al., 1998). These authors concluded that pregnancy-related anxiety may not be conceptually different from anxiety that can be experienced at any time of life, although the content of the

cognitions/worries may be different; e.g. anxiety about foetal health, childbirth, and parenting (Bayrampour et al., 2016).

The experience of anxiety during pregnancy is a strong predictor of postnatal anxiety and depression, and has also been associated with an increased risk of suicide (Cooper, Murray, Hooper, & West, 1996; Farias et al., 2013; Heron et al., 2004; Lee et al., 2007; Robertson, Grace, Wallington, & Stewart, 2004). In turn, postnatal anxiety is associated with negative parenting outcomes, such as disengaged parenting and over-controlling maternal behaviours (Barker, Jaffee, Uher, & Maughan, 2011; McLeod, Wood, & Weisz, 2007; Williams, Kertz, Schrock, & Woodruff-Borden, 2012). Other research has shown that anxiety during pregnancy is associated with adverse obstetric outcomes (Glover & O'Connor, 2002), including preterm birth (Dole et al., 2003; Grote et al., 2010; Ibanez et al., 2012; Sanchez et al., 2013), shorter length at birth (Broekman et al., 2014), increased childbirth fear and preference for caesarean section (Hall et al., 2009; Rubertsson, Hellström, Cross, & Sydsjö, 2014). There is also growing evidence that antenatal anxiety is associated with a range of poor child outcomes (Glover, 2014), such as difficulties with temperament (Davis et al., 2007; Field et al., 2004), sleep (O'Connor et al., 2007), cognitive functioning (Bergman, Sarkar, O'Connor, Modi, & Glover, 2007; Van den Bergh, Mulder, Mennes, & Glover, 2005), and emotional and behavioural problems (O'Connor, Heron, Golding, Beveridge, & Glover, 2002; Talge, Neal, Glover, & Early Stress, Translational Research and Prevention Science Network, 2007).

Given the potentially serious negative consequences of mental health difficulties during the antenatal period, national guidelines are beginning to state the importance of identifying and treating anxiety and depression during this time (Akkerman et al., 2012; BeyondBlue, 2011; National Institute for Health and Care Excellence (NICE),

2014; Williams et al, 2014; Yonkers et al., 2009). These guidelines recommend screening all pregnant women for mental health difficulties as part of routine antenatal care, as well as providing services for assessment and treatment, including psychological interventions. These recommendations have been made despite a lack of evidence to guide the direction of treatment for anxiety during pregnancy and the absence of systematic research examining the impact of treating antenatal anxiety on maternal and infant outcomes. Pregnancy is a crucial time for intervention due to the substantial neural, cognitive and socio-emotional developments that occur during the foetal and early postnatal period, and given that poor mental health during this time can have ongoing consequences for later maternal mental health and the mother-infant relationship (Glover, 2014; Heron et al., 2004; Slade & Cree, 2010; Talge et al., 2007). Therefore, it is vital that effective treatments are developed for treating anxiety symptoms during pregnancy.

Research into anxiety-related treatment preference among women has shown that pregnant women have a preference for psychotherapy, particularly in group-based settings, over pharmacotherapy (Arch, 2014; Buist, O'Mahen, & Rooney, 2015; Nolan, 2009). As many symptoms of anxiety occurring during pregnancy do not centre on pregnancy-related concerns, studies have focused on developing psychological interventions for anxiety during pregnancy based on treatments available for anxiety in the general population, with adaptations made for pregnancy. These adaptations are important, as research has suggested that perinatal populations have unique concerns and thus tailoring interventions for pregnancy may maximise engagement and treatment effectiveness (Buist, O'Mahen, & Rooney, 2015; Henshaw et al., 2011; O'Mahen et al., 2012; Reck et al., 2013; Wilkinson et al., 2016).

For example, a recent pilot study of a group mindfulness-based cognitive therapy intervention delivered during pregnancy focused on anxieties commonly experienced by pregnant women, such as anxieties regarding foetal/infant health, labour, and the responsibilities of new parenthood, as well as making practical adaptations to some of the exercises to allow maximum physical comfort for the participants (Goodman et al., 2014). However, the core model of proposed change remained the same as it would for general anxiety disorders; namely, the intervention included psychoeducation about anxiety and depression, the discussion of alternative ways of responding to anxiety symptoms using cognitive approaches (e.g. psychoeducation about cognitive distortions, thought challenging; Beck, 1972) and mindfulness approaches (e.g. observing thoughts, emotions and body sensations objectively and in the present moment; Kabat-Zinn, 1990), and the use of homework practice. This intervention led to statistically and clinically significant improvements in anxiety, worry, and depression, and significant increases in self-compassion (Goodman et al., 2014).

Another example of a CBT-based intervention designed for pregnancy women and their partners used guided self-help methodology. The “Towards Parenthood” intervention aimed to help couples manage anxiety, stress and depression during the transition to parenthood, based on the principles of CBT for anxiety and depression but with content adapted for pregnancy and early parenthood (Milgrom, Schembri, Erickson, Ross, & Gemmill, 2011). Participants were given a self-help workbook and asked to complete one unit of material a week (8 prenatal and one postnatal), as well as receiving weekly telephone calls from a psychologist. The intervention content included: 1) Preparing for motherhood/fatherhood by reflecting on own childhood/family and how this might impact relationship with own child; 2)

Psychoeducation on changes commonly experienced during pregnancy and early parenthood; 3) Problem-solving skills training; 3) Behavioural strategies for managing anxiety and depression: self-care and behavioural activation; 4) Communication skills training to manage changes in relationships; 5) Cognitive strategies for managing anxiety and depression: psychoeducation on cognitive distortions and worksheets for thought challenging. Following the intervention, there was a reduction in symptoms of depression and anxiety and a trend towards reduced parenting stress (Milgrom et al., 2011).

Although these interventions show promise, further research is needed to examine treatment options during the antenatal period, particularly for anxiety difficulties (Lemon, Vanderkruik & Dimidjian, 2015). These authors have called for further investigation of CBT-based treatments, as they are considered the “gold standard” in treating anxiety disorders in the general population (NICE, 2011a,b). Lemon and colleagues hypothesise that research into CBT-based interventions for antenatal anxiety may be lacking due to apprehension about potential risks associated with treatment content such as exposure, as physiological stress reactivity has been linked with adverse birth outcomes (Lemon et al., 2015). However, other research has suggested that stress reactivity from psychological treatment is potentially less harmful for the mother and foetus than leaving anxiety untreated (Arch et al., 2012). Furthermore, Arch (2014) reported that pregnant women expressed a willingness to try CBT and had only minimal concerns about the possible effects of treatment after reading a detailed description of what the therapy would entail. CBT-based interventions for the antenatal period may thus be based on the same underlying theoretical model and use the same techniques as those used in

general treatment protocols, with some perinatal-focused adaptations in terms of the topics discussed.

Given the call for further development of interventions to treat antenatal anxiety, the current study reports on a small-scale feasibility RCT of a brief psychological intervention developed specifically for pregnant women experiencing high levels of anxiety. The intervention, based on CBT, was designed to be low-cost, scalable, acceptable to pregnant women and feasible within an NHS setting. This paper specifically investigates treatment outcomes for couple functioning and postnatal bonding, as previous research has shown that antenatal distress impacts on these areas of functioning.

Perinatal mental health and intimate relationship functioning

It has been found that women who experience perinatal distress are more likely to have difficulties in intimate relationship functioning (e.g. Ayers, Jessop, Pike, Parfitt, & Ford, 2014; Bonari et al., 2004; Iles, Slade, & Spiby, 2011; Kerstis et al., 2014; O'Hara, 1986; Røsand, Slinning, Eberhard-Gran, Røysamb, & Tambs, 2011; Speier, 2015; Whisman, Davila, & Goodman, 2011). Relationship stress and dissatisfaction with support during pregnancy and birth are cited as risk factors for perinatal mood and anxiety disorders, with relationship dissatisfaction the strongest predictor of psychological distress during pregnancy (Iles et al., 2011; Røsand et al., 2011; Speier, 2015). One study found that women reporting distress during pregnancy were four times more likely to be dissatisfied in their partner relationship, with women reporting more symptoms of anxiety than depression (Jonsdottir et al., 2017). Furthermore, relationship satisfaction appears to buffer the effects of other stressful life events (Røsand et al., 2011) and higher levels of social support are

associated with lower perinatal depression and anxiety (Beck, 2001; Robertson et al., 2004; Stapleton et al., 2012). Systematic reviews and meta-analyses have supported the findings that poor-quality relationships are a risk factor for perinatal anxiety, whereas emotional closeness and high levels of support are protective factors for both depression and anxiety in the perinatal period (Leach, Poyser, & Fairweather-Schmidt, 2017; Pilkington, Milne, Cairns, Lewis, & Whelan, 2015; Pilkington, Milne, Cairns, & Whelan, 2016).

However, many of the reported studies are cross-sectional, making it difficult to disentangle whether relationship functioning predicts psychological symptoms or whether pre-existing or latent psychological distress predicts poorer quality relationships. Studies of relationships in non-parent populations have suggested that poor relationship functioning contributes to later negative affect (e.g. DeLongis, Capreol, Holtzman, O'Brien, & Campbell, 2004). One longitudinal study of women at risk for perinatal mental health difficulties due to prior history of depression found that relationship adjustment was predictive of subsequent anxiety symptoms but not depressive symptoms in time-lagged analyses. However, depressive symptoms were predictive of subsequent relationship adjustment (Whisman et al., 2011). Another study measured symptoms of depression, parental stress, and “dyadic consensus” (the extent to which a person agrees with their partner) in the postnatal period and then followed the parents up 6-8 years later. They found that 20% of couples had separated 6-8 years after childbirth and separation was associated with more symptoms of depression, more parental stress, and less dyadic consensus in the first 18 months after childbirth. While depression was a risk factor for separation for both mothers and fathers, dyadic consensus was a risk factor for separation for fathers, whereas parental stress was a risk factor for mothers (Kerstis et al., 2014).

Regardless of whether perinatal psychological distress causes or is a consequence of relationship dysfunction, decades of research have shown that having a baby itself can have a negative impact on romantic relationships (Belsky & Pensky, 1988; Cowan & Cowan, 1995; Doss, Rhoades, Stanley, & Markman, 2009; Huston & Holmes, 2004). Studies have suggested that the vast majority of couples experience declines in relationship satisfaction after having children (Carrère, Buehlman, Gottman, Coan, & Ruckstuhl, 2000; Cowan & Cowan, 1999; Gottman & Gottman, 2008; Twenge, Campbell, & Foster, 2003), with the decline in satisfaction over time nearly twice as steep for couples who have children as compared to childless couples (Doss et al., 2009). One study found that parents reported sudden deteriorations in relationship functioning after the birth of their children (small to medium effect sizes), with these deteriorations persisting over the eight-year course of the study (Doss et al., 2009). In comparison, couples without children did not experience the sudden and rapid decline in relationship functioning, suggesting that the poorer functioning in the parent group was due to having a child (Doss et al., 2009).

In contrast, another study reported that both women and men experienced an increase in marital adjustment at one month postnatally, although this then declined at six months postnatally (Wallace & Gotlib, 1990). A meta-analysis of studies that tracked couples' relationship satisfaction longitudinally across pregnancy and the postnatal period found significant but small declines in relationship functioning for both men and women (Mitnick, Heyman, & Smith Slep, 2009). However, a sub-analysis of studies that tracked newlywed couples over time, comparing those who did and did not go on to have children, found that childless couples showed similar decreases in relationship satisfaction over time, suggesting that decreased

relationship satisfaction and functioning may not indicate anything unique about the transition to parenthood (Mitnick et al., 2009).

It has also been found that several variables moderate the decrease in relationship satisfaction, including being younger, non-white, unmarried, and shorter relationship length (Mitnick et al., 2009). Studies have reported a more negative impact of having children on relationship satisfaction if the pregnancy was unplanned (Lawrence, Rothman, Cobb, Rothman, & Bradbury, 2008), if relationship adjustment was poor during pregnancy, and if there is a high level of parenting stress (Wallace & Gotlib, 1990). Other studies have reported that parenthood has a greater negative impact on relationship satisfaction for women than for men (Belsky & Rovine, 1990; Lawrence et al., 2008).

Evidence thus supports the notion that having a child is likely to have at least some impact on relationship satisfaction. Having a baby involves large and relatively abrupt changes to the relationship; the way couples interact and communicate with each other changes as they negotiate their new role arrangement (a change from lovers to parents) and the stresses involved, such as childcare, housework, and balancing employment and leisure activities (Belsky & Kelly, 1995; Belsky & Pensky, 1988; Cowan et al., 1985; Cowan & Cowan, 1999; Cowan & Cowan, 1988; Kerstis et al., 2014). The degree of these relationship changes will vary among different couples according to their ability to adapt to the challenges of parenthood, which is likely impacted by the presence of symptoms anxiety and depression (Belsky & Rovine, 1990; Cast, 2004; Cox, Paley, Burchinal, & Payne, 1999; Kerstis et al., 2014; Speier, 2015). Furthermore, it has been found that relationship quality following the arrival of a baby and thereafter has important implications for the child's development, including physiological arousal (Gottman, Driver, & Tabares,

2002), attachment (De Wolff & van Ijzendoorn, 1997; Howes & Markman, 1989; Lickenbrock & Braungart-Rieker, 2015), language development (Horwitz et al., 2003), and later psychosocial and educational functioning (Amato, 2001; Davies & Cummings, 1994; Gable, Belsky, & Crnic, 1992; Harold, Acquah, Sellers, & Chowdry, 2016).

Given the potential consequences of relationship functioning on wellbeing for the whole family, it is important for interventions designed for the perinatal period to also address relationship functioning and to include partners in interventions (Coleman, Houlston, Casey, Purdon, & Bryson, 2015; Coleman, Mitcheson, & Lloyd, 2013; Panter-Brick et al., 2014; Simons, Reynolds, Mannion, & Morison, 2003; Speier, 2015). It has been suggested that antenatal interventions could include topics such as preparing together for relationship and role changes, sharing expectations, managing relationship conflict, joint problem-solving, and fostering connectedness (Hewison, 2013; Kerstis et al., 2014; Milgrom, Schembri, Ericksen, Ross, & Gemmill, 2011; Pilkington et al., 2016; Speier, 2015). One RCT of a psychoeducation and communication skills intervention for couples experiencing the transition to parenthood found that it was effective at protecting against marital dissatisfaction, postnatal depression and observed hostile affect for both men and women (Shapiro & Gottman, 2005). Another RCT found that prenatal parenting communication classes had a significant impact on postnatal anxiety and postnatal marital satisfaction (Midmer, Wilson, & Cummings, 1995). It has also been found that an intervention designed to treat antenatal anxiety had better outcomes when partners also participated in the intervention (Sanaati, Mohammad-Alizadeh Charandabi, Farrokh Eslamlo, Mirghafourvand, & Alizadeh Sharajabad, 2017). Recently, the UK Government recognised that a high number of relationships break

down in the first few years after the birth of a child and thus pregnancy represents an important opportunity to engage partners (Prime Minister's Office, 2012; Department of Health, 2004). Policy documents have recommended that antenatal classes include relationship education and counselling for couples and that interventions for maternal mental health also consider the inclusion of partners (Harold et al., 2016; Prime Minister's Office, 2012; Royal College of Midwives, 2011). The intervention reported in the current study therefore included content specifically designed to target relationship functioning and aimed to recruit both pregnant women and their partners.

Postnatal bonding

It is well-established that postnatal depression is associated with impaired mother-infant bonding, both early in the postnatal period and throughout childhood, with consequences for sensitive parenting and child attachment security (Brockington et al., 2001; Edhborg, Nasreen, & Kabir, 2011; Field, 1998; Field, 2010; Kumar, 1997; O'Higgins, Roberts, Glover, & Taylor, 2013; Reck et al., 2004; Waters, Merrick, Treboux, Crowell, & Albersheim, 2000). Maternal bonding refers to affectionate and protective feelings from the mother towards the infant which facilitate the beginning of the mother-infant relationship and serve the function of securing nurturing and protection (Ainsworth & Bell, 1970; Ainsworth, Bell, & Stayton, 1974; Bowlby, 1973, 1980, 1982; Brockington, 2004; Brockington et al., 2001; Carter Porges & Keverne, 2002; Cranley, 1981; Muller, 1993). Mothers with depression have been shown to struggle with developing affectionate feelings towards their infants (Kumar, 1997). Research has also shown that maternal depression is associated with more passive, unresponsive and/or intrusive parenting

styles and expressing more negative feeling towards their children (Field, 1998, 2010; Reck et al., 2004). Even mild and subclinical postnatal depressive symptoms are reported to be associated with lower quality mother-infant bonding (Moehler, Brunner, Wiebel, Reck, & Resch, 2006; Reck et al., 2006). Furthermore, one recent study found that a group CBT intervention designed to treat postnatal depression also led to moderate improvements in mother-infant bonding, suggesting that effectively treating symptoms of depression may lead to increased bonding (Van Lieshout, Yang, Haber, & Ferro, 2017).

Maternal anxiety has been less extensively researched and so the impact of anxiety on maternal bonding and subsequent child development is less clear (Figueiredo & Costa, 2009). There is evidence that high levels of pre- and postnatal anxiety interfere with mother-infant bonding, impair sensitive maternal interactions and increase intrusive maternal behaviour (Feldman, Greenbaum, Mayes, & Erlich, 1997; Figueiredo & Costa, 2009; Kaitz & Maytal, 2005; Murray, Cooper, Creswell, Schofield, & Sack, 2007; Warren et al., 2003; Weinberg & Tronick, 1998).

Much of this research has focused on mood and anxiety difficulties in the postnatal period; however, the bond between mother and baby begins during pregnancy (DiPietro, 2010; Dubber, Reck, Müller, & Gawlik, 2015; Kumar, 1997; Müller, 1996; Raphael-Leff, 2001; Siddiqui & Hägglöf, 2000; van Bussel, Spitz, & Demyttenaere, 2010). Research has shown positive correlations between prenatal and postnatal bonding (Dubber et al., 2015; Müller, 1996; van Bussel et al., 2010) and that prenatal bonding is a strong predictor for the quality of the mother-infant relationship (Siddiqui & Hägglöf, 2000). It has been shown that during pregnancy parents begin to ascribe characteristics to their baby, based partly on foetal rhythms and responses and partly from their imaginations; this mental image of their child

strengthens their bond with them (Ammaniti, Tambelli, & Odorisio, 2013; Raphael-Leff, 2001). The development of this bond during pregnancy is important as it influences maternal health practices during pregnancy (e.g. nutrition, avoiding harmful substances, obtaining healthcare), which has implications for neonatal outcomes (Alhusen, Gross, Hayat, Woods, & Sharps, 2012). One study found that children of women who reported lower levels of maternal bonding during pregnancy were more likely to demonstrate early childhood developmental delays (Alhusen, Hayat, & Gross, 2013).

However, just as postnatal depression and anxiety can impact maternal bonding, so too can prenatal psychological distress. Both depression and anxiety during pregnancy have a negative association with maternal-foetal bonding (Alhusen, 2008). Studies found that both maternal-foetal bonding and prenatal depression are significant predictors of postnatal bonding (Dubber et al., 2015; Rossen et al., 2016). Pearson and colleagues found that depression during pregnancy was associated with lower maternal responsiveness when the infant was 12 months old, even if the mothers were no longer depressed after giving birth (Pearson et al., 2012). Studies are mixed with regards to the impact of perinatal anxiety on mother-infant bonding; some studies have found no correlation (Gaffney, 1986; Mercer & Ferkehch, 1990; Stanton & Golombok, 1993) while others have reported inverse correlations between anxiety/stress and mother-infant bonding (Alhusen, 2008; Armstrong & Hutti, 1998; Cranley, 1981). It has been suggested that there may be a disruptive effect of depression and/or anxiety during pregnancy on the development of preparations for maternal responsiveness, which may then have long-term implications for maternal bonding and parenting behaviour (Alhusen, Gross, Hayat, Rose, & Sharps, 2012; Pearson et al., 2012).

As research has typically focused more on the association between postnatal distress and mother-infant bonding, there is currently a lack of research as to whether treating antenatal distress could help protect against potential bonding difficulties. A recent study found that a nine-session cognitive behavioural therapy (CBT) group treatment for pre- and postnatal depression also demonstrated improvements in mother-infant bonding (Van Lieshout et al., 2017). Given this finding and considering previous research showing that anxiety and depression during pregnancy can impair maternal bonding, both pre- and postnatally, it seems pertinent to that mother-infant bonding is considered when developing interventions to treat antenatal distress.

Aims of current study

Given evidence that there are associations between anxiety symptoms during pregnancy and relationship functioning with both partners and children, there is a need for effective interventions targeting these issues. This paper reports on outcomes of a small-scale feasibility study of a brief, psychologically-informed, low-intensity group intervention designed to treat symptoms of anxiety during pregnancy. This intervention was based on CBT and mindfulness principles, with content adapted for pregnancy, based on the adaptations made and topics covered in the “Towards Parenthood” intervention (Milgrom et al., 2011). The overall aim of the study was to assess the feasibility and acceptability of this newly developed intervention (reported in full elsewhere; Ramchandani et al., *in preparation*); however, the focus of this paper was to conduct an initial evaluation of whether the intervention had any impact on romantic relationship functioning and mother-child bonding. Pregnant women who scored highly on an anxiety questionnaire were

assigned to either an intervention or control group and assessed at four time-points for anxiety symptoms and romantic relationship functioning. After the birth of their child, at the final time-point, women were asked to fill in a questionnaire measuring bonding with their child.

As a feasibility study, we aimed to assess the extent to which postnatal follow-up is possible, and to determine initial estimates of treatment effects on the postnatal outcomes. It was hypothesised that the intervention would have a positive effect on relationship functioning, such that scores on the measure of romantic relationship functioning would improve over time for the intervention group as compared to the control group. It was also hypothesised that changes in anxiety scores from pre- to post-intervention would be associated with changes in scores on the measure of relationship functioning. In terms of postnatal mother-infant bonding, it was hypothesised that the intervention group would have less difficulties in bonding than the control group. It was also hypothesised that changes in anxiety over the course of the intervention would be associated with scores on the mother-infant bonding measure.

Method

Setting

This study was part of a small-scale preliminary RCT called the ACORN study (ISRCTN95282830) which aimed to explore the acceptability and feasibility of a new group therapy for antenatal anxiety (Wilkinson et al., 2016). Originally, funding was obtained to recruit 60 participants. However, additional funding was later awarded, allowing the inclusion of a second study site and a larger number of participants. The trial took place within an NHS setting at two study sites; one in

London and the other in Exeter. Ethical approval was given by NRES Committee London (14/LO/0339; see Appendix A).

Inclusion/exclusion criteria

Eligible participants were pregnant women over 18 years old who did not have any other children and were entering their second trimester. Women were screened for anxiety symptoms using the GAD-7 (Spitzer, Kroenke, Williams & Löwe, 2006; see below) and were invited to participate in the study if they scored in the top quartile. Women were excluded from participating if they had insufficient understanding of English to complete the intervention or outcome measures (as the study was too small-scale to include interpreters) and/or if they had a significant illness or disability that would make it difficult for them to participate.

Recruitment and randomisation

Women were approached at their 12-week scan at antenatal clinics in London and Exeter by a research assistant and asked to complete the anxiety screen and some demographic information. Overall, 1,249 women were screened for eligibility; of these, 240 met the screening criteria for elevated levels of anxiety (defined as a GAD-7 score of 7 or above) and were eligible and contactable. Of these, 114 women consented to participate in the study (70 at the London site and 44 at the Exeter site; see Appendices B and C for participant information sheet and consent form). These participants were then randomised on a 1:1 basis to either the ACORN intervention (N=57) or the treatment-as-usual control (TAU; N=57). Randomisation was conducted using an online randomisation programme and a sealed envelope method and was managed by a staff member in a separate research group. Participants were

informed of their group allocation by a researcher over the telephone. If the women had a partner, then they were also invited to participate in the study.

Participants

In total, 114 pregnant women consented to take part in the study; 57 received the ACORN programme and 57 continued with care as usual. Eight (7%) women withdrew from the study (2 in TAU and 6 in intervention); one due to miscarriage and seven due to no longer wishing to participate. There were no significant differences between those who participated in the study and those who withdrew in terms of age, ethnicity, employment status, years in education, number of previous pregnancies, and alcohol use ($p=.127 - p=.972$). However, participants who withdrew from the study were more likely to be smokers ($p<.001$) and differed in marital status ($p<.005$; cell count too small to make pairwise comparisons).

The remaining 106 participants were aged between 19 and 46 years old (mean age = 31.56). The majority of the sample identified as White British (63.2%), were married (56.6%) or living with a partner (33%), and worked full time (72.6%). Table 1 lists participant demographics by group. There were no significant differences between the ACORN intervention group and TAU group on baseline/demographic measures.

Data collection

Recruitment, intervention delivery and data collection took place between October 2014 and December 2016. Participants completed several questionnaire measures throughout the study (four time-points); of interest to the study reported here are those measures concerned relationship functioning and mother-infant

bonding (see below). Questionnaires were completed at each group session (and approximately similar intervals for the control group), with the last questionnaires completed 3 months postnatally. Figure 1 shows the flow of participant through the study.

Table 1.

Participant demographics.

	TAU			Intervention			<i>p</i>
	Mean (SD)	Median	Range	Mean (SD)	Median	Range	
Age	31.04 (5.30)	30	19-41	32.35 (4.62)	32	21-46	0.18 <i>a</i>
Number previous pregnancies	.56 (.94)	0	0-3	.68 (1.19)	0	0-5	0.79 <i>b</i>
<i>Marital status</i>	n	%		n	%		0.98 <i>c</i>
Married	31	56.36		29	56.86		
Living with partner	18	32.73		17	33.33		
Separated	0	0.00		0	0.00		
Single	6	10.91		5	9.80		

	TAU		Intervention		<i>p</i>
	n	%	n	%	
<i>Highest level qualification</i>					0.29 <i>c</i>
GCSE / O Level or equivalent	3	5.45	6	11.76	
A Level or equivalent	8	14.55	4	7.84	
Vocational qualification	0	0.00	2	3.92	
Cert of HE	2	3.64	1	1.96	
Diploma of HE	7	12.73	2	3.92	
Undergraduate degree	16	29.09	17	33.33	
Postgraduate degree	16	29.09	18	35.29	
Other	3	5.45	1	1.96	

	TAU		Intervention		<i>p</i>
	n	%	n	%	
<i>Employment</i>					0.43 <i>c</i>
Full-time	38	73.08	39	78.00	
Part-time	3	5.77	4	8.00	
Self-employed	1	1.92	3	6.00	
Homemaker	1	1.92	0	0.00	
Carer	0	0.00	0	0.00	
Student	3	5.77	2	4.00	
Long-term sick leave	1	1.92	0	0.00	
Unemployed	5	9.62	1	2.00	
Other	0	0.00	1	2.00	

	TAU		Intervention		<i>p</i>
	n	%	n	%	
<i>Ethnicity</i>					0.44 <i>c</i>
White	33	67.35	34	75.56	
Asian / Asian British	5	10.20	5	11.11	
Black/ African/ Caribbean/ Black British	2	4.08	2	4.44	
Mixed / multiple ethnicities	1	2.04	2	4.44	
Other	8	16.33	2	4.44	

	TAU		Intervention		<i>p</i>
	n	%	n	%	
<i>Smoking</i>					1.00 <i>d</i>
No	51	98.08	50	100.00	
< 5 a day	1	1.92	0	0.00	
6-10 a day	0	0.00	0	0.00	
<i>Alcohol</i>					0.61 <i>d</i>
No	51	98.08	48	96.00	
1-5 units per week	1	1.92	2	4.00	

^a = Independent groups t-test; ^b = Mann-Whitney U test; ^c = Pearson chi-squared test; ^d = Fisher's Exact statistic

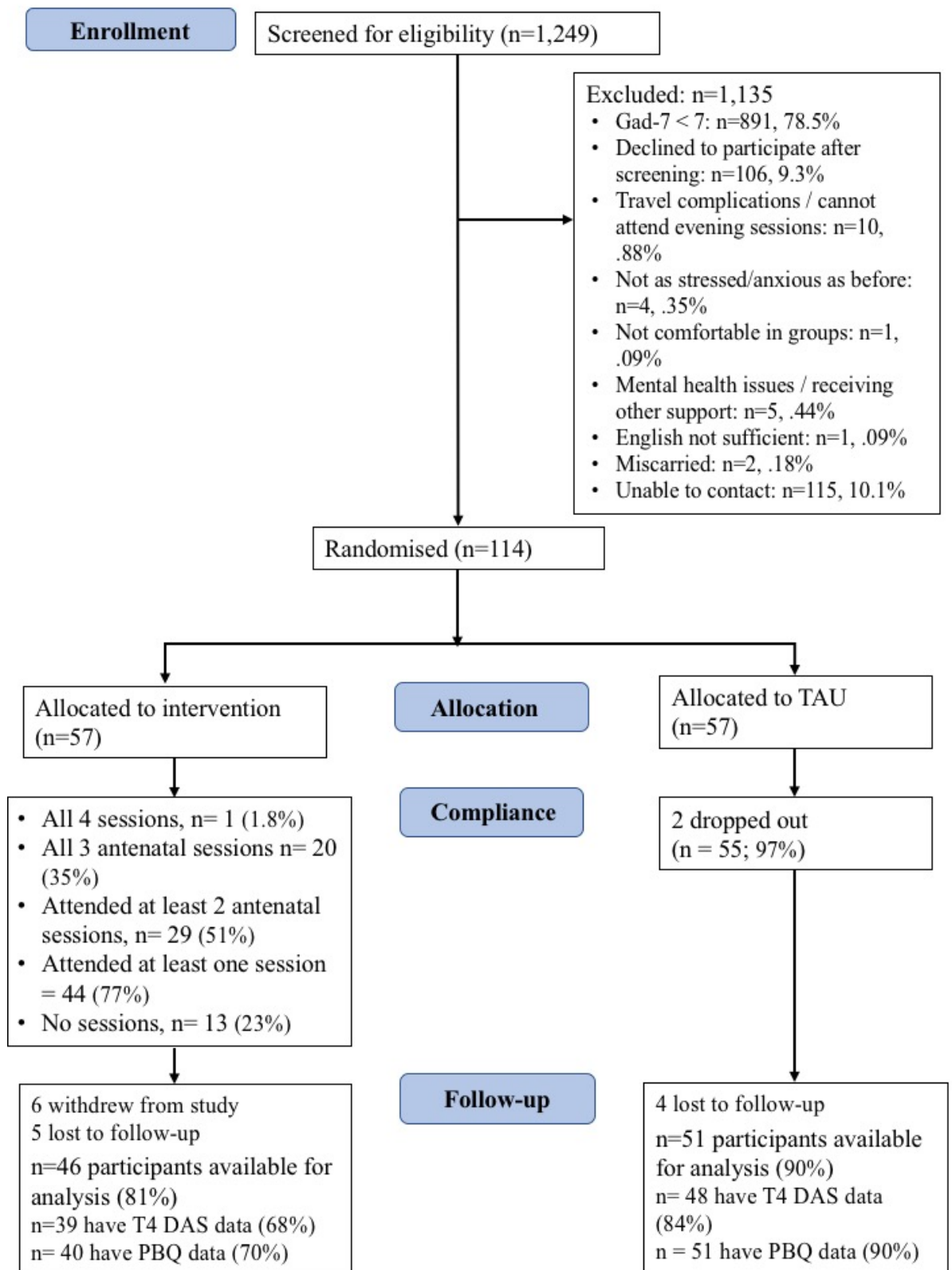


Figure 1. CONSORT diagram of flow of participants through the study

Questionnaire measures

GAD-7

The GAD-7 (Spitzer et al., 2006; see Appendix D) is a self-report questionnaire that measures anxiety and is commonly used in health care settings. It asks respondents to report on symptoms of generalised anxiety disorder (GAD) experienced in the previous two-weeks. There are seven items which are scored on a four-point scale; “not at all” (0), “several days” (1), “more than half the days” (2), and “nearly every day” (3). Summing the responses to all seven items gives a total score. Scores of 5, 10, and 15 are typically taken as the cut-off points for mild, moderate and severe anxiety respectively. Among clinical and general population samples, the GAD-7 has demonstrated good reliability, internal consistency, and criterion, construct, factorial and procedural validity (Löwe et al., 2008; Spitzer et al., 2006). In perinatal populations, the GAD-7 has shown good internal consistency and has yielded a sensitivity of 73.3% and specificity of 67.3% using a cut-off score of 7 (Zhong, Gelaye, Zaslavsky, Fann, Rondon, Sanchez & Williams, 2015), and a sensitivity of 61.3 % and specificity of 72.7 %, using a cut-off score of 13 (Simpson, Glazer, Michalski, Steiner, & Frey (2014). Cronbach alpha for GAD-7 in this study ranged from .82 to .91 across the four time-points.

Dyadic Adjustment Scale

The Dyadic Adjustment Scale (DAS; Spanier, 1976; see Appendix E) is a 32 item self-report measure of relationship adjustment and satisfaction. It comprises four subscales: the “Dyadic consensus” subscale has thirteen items which assess the level of agreement between partners on topics such as handling finances, managing household tasks, social and leisure activities, and making important decisions. The

“Dyadic cohesion” subscale has five items which assess the amount of time couples spend together doing different activities. The “Affective expression” subscale has four items and assesses expressions of love. Finally, the “Dyadic satisfaction” subscale has ten items and assesses how often the couple spend arguing, discussing separation, or the perception that things are generally going well in the relationship. These four subscales can be summed to produce a total “Dyadic Adjustment” score. The DAS is a well validated measure that has been used in over 1,000 published studies. If given to both members of a couple, it is completed by each partner separately. A higher score on the DAS indicates greater relationship satisfaction. Cronbach alpha for all DAS items in this study ranged from .92 to .96 across the four time-points.

Postpartum Bonding Questionnaire

The Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2001; see Appendix F) is a self-report questionnaire with 25 items which measures parent-infant bonding. There are six response options to each item, ranging from “never” to “always”. Positive responses, such as “I love to cuddle my baby” are scored from zero (“always”) to 5 (“never”). Negative responses, such as “I regret having this baby” are scored from 5 (“always”) to zero (“never”). The items are summed to produce a total score (from zero to a possible 125), with higher scores indicating the presence of bonding difficulties. The items can also be divided into four subscales: Impaired bonding (12 items, e.g. “The baby does not seem to be mine”); Rejection and anger (seven items, e.g. “My baby annoys me”); Infant-focused anxiety (four items, e.g. “I am afraid of my baby”); and the risk of abuse (two items, e.g. “I feel like hurting my baby”). The lowest possible score on all scales is 0, whereas the

highest possible score is 125 for the total PBQ. (Brockington et al., 2001; Brockington, Fraser, & Wilson, 2006) also provide thresholds to identify probable cases of bonding disorders. Cronbach alpha for all PBQ items in this study was .91.

Intervention development

The intervention was developed based on CBT principles as well as incorporating elements of mindfulness and communication skills. It was based on the Towards Parenthood intervention (Milgrom et al., 2011). The purpose of the intervention was to reduce elevated levels of anxiety in pregnant women and to focus on the specific needs of perinatal populations in terms of both the content and delivery of the intervention. The intervention was designed to be brief such that it fit with the antenatal education pathway in the UK and could potentially reach a large number of individuals (i.e., a targeted universal intervention). The development of the intervention involved three main stages; identification of key areas to address, initial development of the intervention, and running a pilot group, after which adaptations were made to form the final intervention.

Key target areas for the intervention to address were established in consultation with an expert group and a public involvement (PPI) group, as well as via interviews with five women who had experienced antenatal anxiety. The expert group included two developmental psychologists, three perinatal clinical psychologists and one child and adolescent psychiatrist, all with substantial research and clinical experience in perinatal mental health. The PPI group included one pregnant woman and her partner and two postnatal women with experience of antenatal anxiety. Developing intervention content was done through an iterative process, such that content, exercises and examples were initially developed by the

expert group, based on learning from the Towards Parenthood intervention (Milgrom et al., 2011), and feedback was sought from the working PPI group. Meetings were held with the PPI group before the development of the intervention, before the pilot group and after the pilot group. The content and structure of each session was documented in an intervention manual, which was sent to the PPI group prior to meetings and feedback was sought in face-to-face meetings.

It was agreed that the intervention would be action-oriented with a focus on coping skills and strategies. Between the expert and PPI group (with feedback from women with lived experience of antenatal anxiety) it was agreed the key intervention concepts would be: 1) Understanding anxiety and stress; 2) Self-care, engaging in meaningful activities, and self-compassion; 3) Problem-solving; 4) Relationships and communication. Group exercises were developed for the intervention using perinatal specific examples, for example: discussing support with family members, avoidance of putting together a birth plan, and communication relating to the different needs of parents once the baby is born.

A pilot group of six women and their partners were recruited from NHS antenatal scanning clinics in London at their 12-week scan. Women were eligible if they were primiparous pregnant women entering their second trimester, aged 18 and over, and if they scored in the top quartile of scores on the Generalised Anxiety Disorder 7-item scale (GAD-7 = 7 or more; Spitzer et al., 2006) at screening. These participants received the group intervention during three antenatal sessions and one postnatal session and the group facilitators were a midwife and trainee clinical psychologist (author of this paper). Semi-structured qualitative interviews were carried out with women and partners who took part in the pilot group and with the group facilitators. Several themes emerged from these interviews, which were used

to further refine and adapt the final intervention structure and content. These themes included: 1) Worries and concerns during pregnancy, such as managing uncertainty around pregnancy and childbirth, coping with work-life balance, concerns about changes in their relationships, and feeling lonely during pregnancy with limited support; 2) Intervention expectations, including wanting to meet other expectant parents, receiving professional and knowledgeable support about anxiety difficulties, to understand anxiety and stress better and learn ways to manage it; 3) Experience of the intervention and suggestions for change – both women and their partners described positive experiences of the intervention, in particular sharing their experiences with other couples, acknowledging their worries and anxiety and being able to share these with their partners, learning simple and practical coping strategies, and taking the time to relax and engage in self-care activities that they might have otherwise avoided. Suggested changes to the intervention included further discussion and exercises around managing uncertainty and extra mindfulness exercises. Both women and partners expressed a wish for the group to be longer, however acknowledged that this would have been likely to put them off initially signing up and felt that the group was comprehensive in terms of content and strategies offered.

Intervention content

The final intervention programme consisted of three group sessions which were delivered during pregnancy and aimed to provide women and their partners with skills to manage anxiety more effectively. The groups were led by a midwife and a trainee clinical psychologist (author of this paper) who received a full day of training on the intervention and regular supervision. The facilitators followed a

manual that described the protocol for each session and sessions were videotaped to ensure adherence to the treatment protocol. The intervention content was based on principles of CBT, mindfulness and communication/support and developed by perinatal mental health experts and a PPI group (see above). The content of each group included psychoeducation about anxiety, strategies to manage anxiety symptoms, problem-solving skills and communication skills. More information about the content of each session can be found in Table 2. Up to ten pregnant women (and their partners) were invited to attend each group. Each session took place in the evening at three-week intervals and lasted approximately 1.5 hours. During the initial part of the sessions, women and their partners would meet with the group facilitators to introduce the session topics and review any homework practice given during the previous session. The women and partners would then separate for part of the session, with one facilitator working with the women and the other with the partners. Towards the end of the session the women and partners would reunite and a mindfulness exercise would be completed with the whole group. Participants were given homework exercises to complete between each session (see Table 2) and could access worksheets and mindfulness exercises from a dedicated ACORN study website. The group facilitators would send weekly check-in emails to enquire whether participants were struggling with any of the homework exercises and remind them of the date of the next session.

At the final session, participants were given copies of a workbook that was developed and evaluated in previous studies ('Towards Parenthood Workbook': Milgrom et al., 2009, 2011). This workbook covered topics such as coping with the demands of parenting, problem-solving, enhancing self-esteem, self-care, dealing with relationship changes, bonding with baby and understanding baby cues. It was

given to participants to take away to continue to support the skills learned during the ACORN group sessions. Participants who did not attend the final antenatal session were sent the workbook in the post. Three months after delivery, participants were invited to attend an informal postnatal meet-up session where they could socialise, give any feedback about how they had used the skills they had learned, and complete a final set of questionnaires.

Attendance and follow-up

Of those participants randomised to the intervention group, attendance at each session was as follows: Session 1 n=38; Session 2 n=33; Session 3 n=22; Session 4 (postnatal) n=5. Twenty participants (35%) attended all three of the sessions during the antenatal period, 29 (51%) attended at least two of the antenatal sessions, 44 (77%) attended at least one group session, and 5 participants attended the postnatal follow-up session. Twelve partners participated in at least one ACORN intervention session: Session 1 n=11; Session 2 n=9; Session 3 n=9; Session 4 (postnatal) n=3. When participants missed a session, they were sent the worksheets and information about the exercises through the post or via email and could also access information and exercises from the ACORN study website. They were also asked to complete the questionnaire measures for the relevant time-point even if a session was missed. At the final postnatal follow-up, 46 (81%) of intervention group participants provided data for the GAD-7, 39 (68%) provided data for the DAS, and 40 (70%) provided data for the PBQ.

Treatment as usual

Women randomised to the TAU group continued to receive their standard maternity care. All women in the study were given an information leaflet signposting them to other sources of help, including their GP, midwife, health visitor, and local mental health services. Across the study period six of the women in the TAU group were lost to follow-up, leaving 51 participants (90%) in this group.

Table 2.

Content of each session of the ACORN intervention.

Session	Overview of session	Home practice exercises
One	Introductions, psychoeducation on stress and anxiety during pregnancy, discussion about self-care and meaningful activities, breathing space exercise.	Stressful events diary, breathing space exercise, scheduling meaningful activities
Two	Homework review and barriers to home practice, problem-solving exercise, psychoeducation on avoidance, reflective listening exercise, managing uncertainty exercise, loving-kindness exercise.	Problem-solving and trying out solutions, managing uncertainty, mindfulness, partners to practice reflective listening. Asked to continue exercises from week 1.
Three	Homework review and barriers to home practice, communication skills exercise as a group and in partner pairs, review of all three sessions, self-compassion exercise, video clip of MRI of a baby in womb, given copy of "Towards Parenthood" workbook.	All previous exercises plus continue with Towards Parenthood book
Postnatal	Informal catch-up, completion of questionnaires.	None

Statistical analysis

Power calculations were made using G*Power software (Faul, Erdfelder, Lang, & Buchner, 2007) to estimate the size of the effect that this study could detect. Given the sample size of $n=57$ in each group, using two-tailed tests with $\alpha=.05$ and $\beta=.20$, this study was powered to detect medium effects ($d=.53$). The outcome measures of interest in this study were the DAS (collected at four time-points) and the PBQ (postnatal only). For missing data within a questionnaire at any time point, mean scores were calculated from the items that were completed (as long as an individual had completed at least 75% of the questionnaire items) and substituted for the missing data point. Data for both measures were checked outliers and for normality (variables and residuals). The DAS data was analysed using hierarchical linear modelling (HLM; also called mixed model or mixed level modelling) to assess the effects of the ACORN intervention on changes in relationship satisfaction over time. This technique allows for the determination of between-subjects differences (i.e. group assignment) in within-subject trajectories (i.e. changes in relationship satisfaction over time). HLM procedures are advantageous for longitudinal data as they allow for missing data; all cases are included when estimating effects (complete cases are weighted more heavily) which allows the utilisation of data from all participants even if they did not provide data for every time-point (Kwok et al., 2008; Lininger, Spybrook, & Cheatham, 2015; Snijders, 1996). The PBQ data was found to be positively skewed and so a natural log transformation was completed on the data. As this data was only collected at one time-point it was analysed using independent-samples t-tests, with intervention group (ACORN or TAU) entered as the between-groups variable. Follow-up analyses were run using linear regression to explore the association between changes in anxiety scores from baseline to follow-

up, changes in relationship functioning from baseline to follow-up, and postnatal bonding. Analyses were performed using Stata version 12 and SPSS version 22.

Results

Baseline descriptive statistics and comparisons

Table 3 shows GAD-7, DAS and PBQ scores over time for the women. There were no differences in baseline GAD-7 ($t(100)=-.74, p=.46$) or baseline DAS scores ($t(97)=.72, p=.47$). Chi-square analyses using Fisher's Exact test revealed that there were no between-group differences in terms of completion of the DAS questionnaire at T1 ($p=.11$), T2 ($p=.77$), T3 ($p=1.00$) or T4 ($p=.14$). There were also no between-group differences for completion of the PBQ ($p=.19$). There was no significant difference between study completers and non-completers on either baseline GAD-7 scores ($t(106)=.941, p=.35$) or baseline DAS scores ($t(103)=-.94, p=.35$). There was also no association between change in anxiety scores and baseline anxiety scores ($r=.03, p=.76$).

Table 3.

Descriptive statistics for questionnaire measures across time-points for the TAU and ACORN intervention groups.

	TAU			Intervention		
	n	Mean (SD)	Range	n	Mean (SD)	Range
GAD-7 T1	52	9.64 (9.63)	4-20	50	10.29 (4.44)	1-20
GAD-7 T2	51	7.61 (4.66)	1-19	45	6.42 (3.47)	2-14
GAD-7 T3	48	6.56 (.78)	0-20	44	5.96 (4.33)	0-16
GAD-7 T4	50	5.76 (4.76)	0-18	46	5.17 (4.12)	0-17
DAS T1	51	120.08 (15.38)	69 - 144	54	118.67 (16.80)	60-150
DAS T2	49	120.94 (19.97)	16-144	44	118.25 (23.29)	20-151
DAS T3	44	119.84 (16.84)	56-148	41	118.17 (23.30)	5-142
DAS T4	48	117.63 (22.29)	9-149	39	117.79 (20.34)	42-145
PBQ	51	10.37 (9.47)	0-50	40	12.05 (11.02)	1-49
Log PBQ	51	.919 (.37)	0-1.71	40	.974 (.37)	.30-1.7

Relationship functioning data analysis

DAS data met assumption criteria for HLM. Outliers were identified in the data; three at T1, three at T2, one at T3, and two at T4. Analyses were run both including and excluding these outliers to test the sensitivity of the analysis to the inclusion/exclusion of these cases.

Both linear and quadratic models were fitted for DAS data. HLM analysis found a linear effect of time-point ($\beta=-1.97, p<.05, 95\% \text{ CI } [-3.83, -.11]$), suggesting that DAS scores decreased over time. The quadratic effect of time was not significant ($\beta=-1.07, p=.15, 95\% \text{ CI } [-2.53, .39]$). There was no main effect of group ($\beta=-3.86, p=.28, 95\% \text{ CI } [-10.87, 3.15]$) and no significant interaction effect of linear time x group; the confidence interval included small to medium effect sizes ($\beta=-1.08, p=.15, 95\% \text{ CI } [-2.54, .37]$). There was also no interaction effect of quadratic time x group ($\beta=.62, p=.57, 95\% \text{ CI } [-1.50, 2.74]$). Removing outliers did not alter this pattern of results, although the interaction term for group x linear time was now at trend ($\beta=-1.57, p=.09, 95\% \text{ CI } [-.23, 3.37]$); the confidence interval again included small to medium effect sizes.

A second linear model was fitted to the DAS data, with baseline (T1) anxiety score included as a covariate in the model, which was not statistically significant ($\beta=-.65, p=.25, 95\% \text{ CI } [-1.760, .455]$) and did not have a statistically significant interaction effect with either group ($\beta=.35, p=.67, 95\% \text{ CI } [-1.24, 1.93]$) or time ($\beta=-.10, p=.65, 95\% \text{ CI } [-.51, -.32]$). There was also no three-way interaction between baseline anxiety, group and time ($\beta=.31, p=.33, 95\% \text{ CI } [-.31, .93]$). The inclusion of baseline anxiety did not change the relationship between group and time ($\beta=-1.98, p=.56, 95\% \text{ CI } [-8.67, 4.71]$).

A sub-analysis was conducted for the intervention group only in which a linear model was fitted for DAS data across time-points with the number of intervention sessions attended added as a covariate in the model. There was no effect of attendance on relationship satisfaction outcomes ($\beta=-.1.55, p=.50, 95\% \text{ CI } [-6.11, 3.00]$). A further sub-analysis was conducted for the intervention group to investigate whether DAS scores differed for participants who attended session three (which focused on relationship functioning) as compared to those who did not attend. Again, there was no effect on the DAS slope for attendance at session three vs. non-attendance ($\beta=-.26, p=.96, 95\% \text{ CI } [-10.80, 10.29]$). The results of these sub-analyses did not differ when a quadratic model was fitted.

Changes in DAS scores from baseline to postnatal follow-up were examined in relation to changes in maternal anxiety using linear regression models. A change in anxiety score variable was created by subtracting T4 anxiety score from T1 anxiety score, such that positive numbers indicate improvement in anxiety. A change in DAS score variable was created by subtracting T1 DAS score from T4 DAS score, such that positive numbers indicate an improvement in relationship functioning. Checks were made to ensure that data conformed to assumptions necessary for linear regression, including formal tests of heteroscedasticity (Koenker test $p=.89$). An improvement in anxiety scores was associated with an improvement in DAS scores ($b=.96, p<.05, 95\% \text{ CI } [.24, 1.67]$). When the TAU and ACORN groups were further explored separately (Figure 2), these associations were significant for the ACORN group ($b=1.33, p<.05, 95\% \text{ CI } [.12, 2.53]$) but were not significant for the TAU group ($b=.59, p=.19, 95\% \text{ CI } [-.03, .17]$). However, the regression coefficients for the ACORN group and the TAU group were not significantly different from each other ($p=.32$).

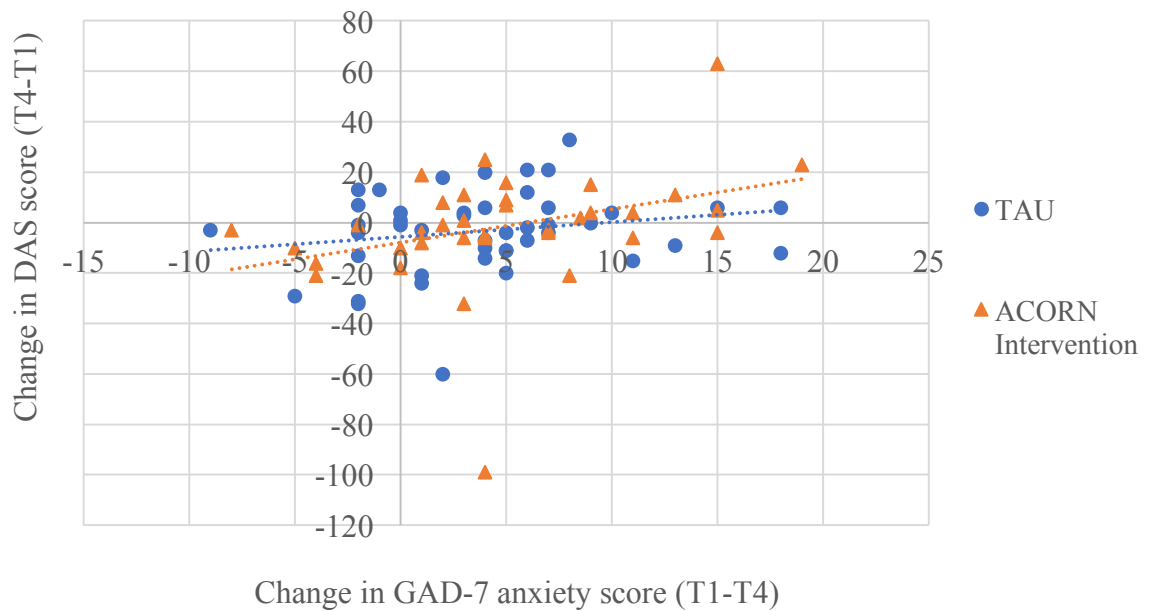


Figure 2. Linear relationship between change in anxiety scores from baseline to postnatal follow-up and change in relationship functioning from baseline to postnatal follow-up for TAU and ACORN intervention groups.

Postnatal bonding data analysis

Independent-samples t-tests on log-transformed PBQ data found no differences between the ACORN and TAU group ($t(89)=-.706, p=.482, d=-.149$).

Table 4 displays both transformed and untransformed descriptive data for the PBQ measure for each group.

Associations between changes in maternal anxiety scores from baseline to postnatal follow-up and PBQ scores were examined using linear regression models. A change in anxiety score variable was created by subtracting T4 anxiety score from T1 anxiety score. Checks were made to ensure that data conformed to assumptions

necessary for linear regression, including formal tests of heteroscedasticity (Koenker test $p=.14$). As the PBQ variable had normally distributed residuals, untransformed PBQ data were entered into the model.

An improvement in anxiety scores was associated with lower scores on the PBQ ($b=-.48, p<.01, 95\% \text{ CI } [-.85, -.12]$). When the TAU and ACORN groups were further explored separately (Figure 3), these associations were significant in the ACORN group ($b=-.60, p<.05, 95\% \text{ CI } [-1.17, -.02]$) but were not apparent in TAU group ($b=-.40, p=.10, 95\% \text{ CI } [-.88, .08]$). However, the regression coefficients for the ACORN group and the TAU group were not significantly different from each other ($p=.59$).

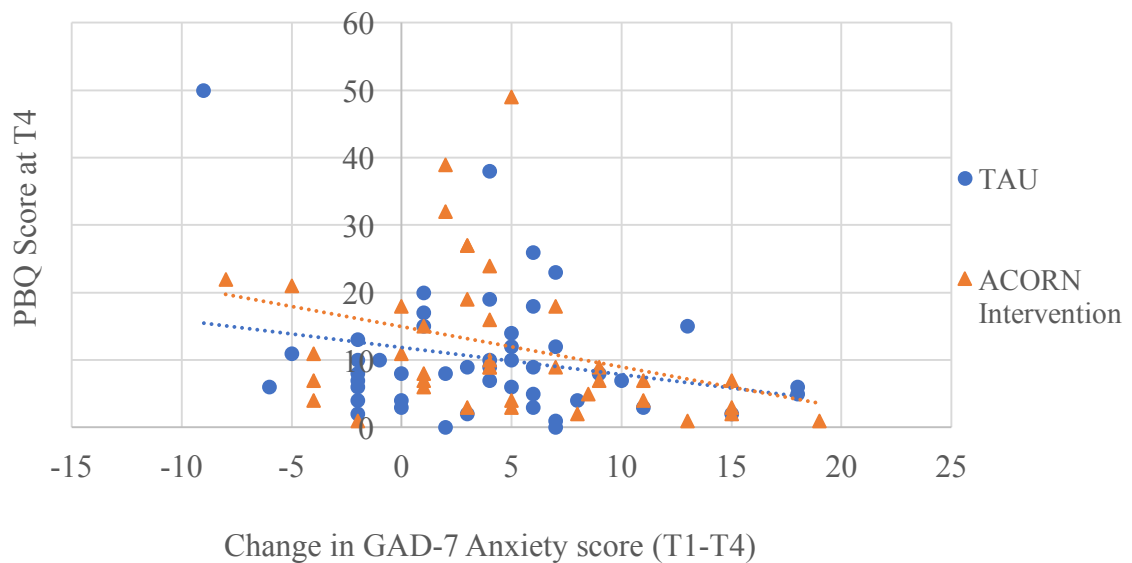


Figure 3. Linear relationship between change in anxiety score from baseline to postnatal follow-up and untransformed PBQ Score measured at postnatal follow-up.

Discussion

This study investigated the impact of a small-scale, brief and low-intensity group antenatal intervention designed to treat anxiety symptoms and improve intimate relationship functioning and postnatal mother-infant bonding. Although this study was first and foremost a feasibility study, the comparatively large sample size (for a feasibility study) allowed us to examine preliminary estimates of treatment impact. There was found to be no statistically significant effect of the intervention on changes in relationship functioning over time and no between group differences on postnatal bonding. The average treatment effect was small to medium. While the study was only powered to reliably detect large treatment effects, it indicates, as might be expected in brief low intensity intervention such as this, that treatment effects are likely to be small to medium in size. Any future trials of this intervention would therefore most likely need to be comparatively large. It is not possible from this investigation to conclude confidently whether or not the intervention would be effective. It was notable that follow-up analyses revealed improvements in anxiety scores at the postnatal time-point (as compared to baseline) were associated with improvements in relationship functioning at postnatal follow-up (as compared to baseline) for the intervention group, but not for the control group, although the regression slopes for the two groups were not significantly different. Another follow-up analysis revealed that improvements in anxiety scores at the postnatal time-point were associated with better postnatal bonding for the intervention group, but not for the control group, although again the regression slopes for the two groups were not significantly different. These results will be discussed in more detail below, including suggestions for future research.

Relationship functioning

Analysis of the measure of relationship functioning across time revealed a significant negative linear relationship, suggesting that relationship functioning decreased over time. This finding fits with previous studies that have reported a decrease in relationship functioning over the perinatal period (Cowan & Cowan, 1999; Doss et al., 2009; Mitnick et al., 2009; Twenge et al., 2003). However, this decline in relationship functioning is not necessarily a consequence of pregnancy and parenthood, as there will be other unmeasured variables changing over time too. This study did not have a non-parent comparison group, so it is not possible to infer that these changes are an effect of pregnancy; although note that Huston and Holmes (2004) argue non-parents do not necessarily represent an appropriate control group, as parents and non-parents are not equivalent groups and parents may be less satisfied in their relationships for several other reasons.

There was no interaction between treatment arm and scores on the DAS over time, suggesting that, within the limits of the modest power of this study, the ACORN intervention did not have a reliable impact on relationship functioning. When outliers were removed from the DAS dataset, the interaction between group and time was at trend. The statistical literature is mixed as to whether to remove outliers from analyses or not (Osborne & Overbay, 2004), but as this study already had a relatively small sample size such that it was only powered to detect medium to large effects, it was decided to leave outliers in the analysis. Additional analysis suggested that improvements in anxiety scores at postnatal follow-up as compared to baseline were associated with small improvements in relationship functioning for the intervention group, but not for the control group. Therefore, it may be that improvements in relationship functioning occur as a function of improved anxiety for

those women receiving the intervention, or vice versa; it is not possible in these exploratory analyses to conclude whether changes in relationship functioning are a consequence of anxiety change, or whether there are other moderating or mediating factors influencing this association. Furthermore, although the association between change in anxiety and change in DAS score was significant in the intervention group but not the control group, the regression slopes for each group were not significantly different from each other. In order to detect significant differences between groups for these regression slopes, a substantially larger study is required. A larger study would also be able to use mediation analysis to investigate whether interventions targeting antenatal anxiety lead to improvements in relationship functioning indirectly via changes in anxiety levels.

There may be several explanations for the observed lack of a direct effect of the intervention on changes in DAS scores over time. Firstly, scores on the DAS were relatively high across time-points. It has been suggested that DAS scores under either 100 (Spanier, 1976) or 97 (Jacobson et al., 1984) indicate relationship distress; in this study mean scores were well above these thresholds at all time-points. It is therefore possible that there may be larger intervention effects for couples experiencing greater levels of relationship dysfunction and dissatisfaction. It is also possible that given that the trial recruited couples and the intervention had a focus on relationships, couples with lower relationship functioning may not have taken part. However, it is also possible that the ACORN intervention did not include enough content on relationships to have a direct effect on improving relationship quality, as only one of the sessions specifically focused on couple functioning and communication. Future interventions may therefore wish to include more content focused on couple functioning. Another possibility is that the intervention did not

have an impact on relationship functioning due to the low number of partners that took part in the intervention; only twelve partners participated in any one intervention session, and only 9 attended the session that focused on couple communication. Future studies may wish to investigate further the impact of partner attendance on relationship functioning outcomes; one previous study compared women who received an antenatal anxiety intervention either alone or with their partner and found that the group who participated with their partner had better outcomes (Sanaati et al., 2017).

Further follow-up analysis showed that baseline anxiety was not a significant covariate in the linear model of relationship functioning and intervention group and did not affect the association between relationship functioning and group, suggesting that baseline anxiety was not influencing this pattern of results. For the intervention group, the effect of session attendance did not interact with relationship functioning. Further analysis looked at whether attendance at the third intervention session, which specifically focused on relationship changes and couple communication, influenced relationship satisfaction changes over time; this was also not significant. This suggests that attending more sessions or specifically attending the session focusing on relationships did not protect against the slight decline in relationship functioning over time.

Postnatal bonding

Intervention effects on postnatal bonding were also investigated. It should be noted that this appears to be the first trial of an antenatal intervention to look at postnatal bonding, with other studies focusing on postnatal symptomatology and interventions. Initial analyses revealed no differences between the intervention and

control group on postnatal bonding, suggesting that the intervention did not have a direct effect on bonding. However, follow-up analyses comparing postnatal outcomes to baseline found evidence that improvements in anxiety scores were associated with better postnatal bonding. Furthermore, this association was only present for the intervention group, suggesting that improvements in anxiety for the intervention group were related to better postnatal bonding. It should be noted that although improvements in anxiety were associated with higher postnatal bonding for the intervention group but not the control group, the regression slopes were not significantly different between the two groups. A larger study is required to investigate further group differences in the relationship between changes in anxiety and postnatal bonding.

It is not possible in the current study to conclude that postnatal bonding was a direct effect of the reduction in anxiety; it may be that lower levels of anxiety lead to better postnatal bonding, or it may be that the intervention better prepared women for motherhood, increasing maternal feelings and bonding, and consequently led to reductions in anxiety. Future studies may wish to conduct longitudinal mediation analysis to reach more definitive conclusions. It may also be interesting for future studies to do a further postnatal follow-up, as studies have shown that postnatal bonding continues to grow over the postnatal period (Kumar, 1997) and this would allow for time-lagged analyses of anxiety, bonding and any intervention effects. It would also be interesting for future research to investigate whether relationship functioning has any effects on parent-infant bonding in the context of anxiety, as previous research has shown that social support and marital relationships are positively related to prenatal bonding (Cranley, 1981; Yarcheski, Mahon, Yarcheski, Hanks, & Cannella, 2009).

Strengths, weaknesses and implications

This study had several strengths; firstly, it employed an RCT design, which is considered to be the most scientifically rigorous method and is regarded as the “gold standard” design for assessing the effectiveness of interventions (Akobeng, 2005; Spring, 2007). RCT methodology allows researchers to avoid selection bias (through randomisation) and avoid bias related to confounding factors (through a control group), such that any differences in outcomes can be explained only by the treatment rather than by baseline systematic differences (Akobeng, 2005). The design of this study also allowed for anxiety and relationship data to be studied at several time-points across the perinatal period, including both pre- and postnatal assessments, which is an advantage as compared to cross-sectional designs used by many previous studies of relationship functioning (e.g. Jonsdottir et al., 2017; Lancaster et al., 2010; Leach et al., 2017; Pilkington et al., 2015; Røsand et al., 2011).

Another strength of this study was the intervention itself; this intervention was designed to specifically address elevated levels of anxiety in pregnant women and to focus on the specific needs of perinatal populations in terms of both the content and delivery of the intervention. There has been a call for the development of perinatal-specific interventions to address mental health difficulties during the perinatal period, as this is a time of life with unique concerns (Division of Clinical Psychology’s Faculty of Perinatal Psychology BP8 Revision Working Group for the BPS, 2016; Joint Commissioning Panel for Mental Health (JCPMH), 2012; Lemon et al., 2015; Slade & Cree, 2010). The ACORN intervention was based on evidence-based CBT techniques that have been effective in general populations (NICE, 2011a,b), with appropriate adaptations for a perinatal population based on a

previously published intervention (Milgrom et al., 2011), clinical expertise in working with perinatal populations, and consultation with a PPI group and service users. Involving service users in intervention design has been shown to make interventions and services more acceptable to service users and is central to the UK Department of Health strategy for modernising the NHS and improving the quality of care (Department of Health, 1999; Nilsen et al., 2006).

Another strength of the intervention was the method of delivery. The groups were co-facilitated by a trainee clinical psychologist and a midwife, allowing a complimentary skill-set of expertise in psychological knowledge and antenatal care. Furthermore, the use of a group intervention may be less resource-intensive and potentially more cost-effective than individual psychotherapy, which is an important consideration in the context of healthcare settings and for delivering targeted prevention programmes. There is also evidence to suggest that pregnant women have a preference for treatments to be delivered in peer group environments as this supports the development of social networks and provides opportunities for discussion and practice of skills (Hillier & Slade, 1989; Nolan, 2009).

However, there are some limitations to note. Firstly, there was quite a high drop-out rate across the time-points. This is a common difficulty with longitudinal studies (Fergusson, Aaron, Guyatt, & Hébert, 2002; Hogan, Roy, & Korkontzelou, 2004; Schulz & Grimes, 2002). Participants are lost to follow-up for many different reasons, including preferring to no longer participate, moving home or changing number such that researchers cannot trace them, or changes in life circumstances. These factors are likely to be even more pertinent for new families who have experienced a major change in life circumstances and are busy caring for a baby. In this study, the amount of data available from participants at the final time-point

(ranging from 68% for DAS data to 81% for GAD-7 data) was similar to that obtained by Milgrom and colleagues (2011) in their Towards Parenthood intervention for pregnant women (66% provided follow-up data), suggesting that the attrition rate observed in the current study is not uncommon for an antenatal intervention. Schulz and Grimes (2002) argue that loss to follow-up of 20% or greater is cause for concern as it may lead to biased results if those who drop out share common characteristics, whereas an attrition rate of less than 5% is not problematic. In the current study the attrition rate ranged from 5-32% across time-points for the intervention group and 11-23% for the TAU group. Although there was no difference in baseline anxiety or relationship functioning scores between study completers and non-completers, the attrition does limit generalisability of the findings. As attrition is a difficult problem to address in terms of study design, different statistical procedures have been developed to deal with missing data. For instance, the DAS data was collected at all four time-points and was analysed with HLM procedures which allow for missing data. Nonetheless, the study would have had more power to detect any effects if fewer data-points were missing, as the study was only powered to detect medium to large effects based on the initial sample size of 57 participants. As the final number of participants was lower, this study was underpowered to detect changes in relationship functioning and postnatal bonding.

As the PBQ was only measured postnatally, the relatively high drop-out rate would have reduced the power to detect any effects of the intervention on postnatal bonding. A previous study reported a medium-sized change in PBQ scores after completion of a CBT intervention using a small sample size ($n=34$; Van Lieshout et al., 2017), but this study used a within-subjects design (no control group); within-subject designs have more power to detect effects with smaller sample sizes, but are

unable to conclude whether changes are due to intervention effects. Although the PBQ is designed to be used postnatally, it might have been interesting to also measure bonding across the whole study period, which would allow within-group comparisons to be made. Future studies may wish to employ maternal-foetal bonding measures (e.g. Maternal Antenatal Attachment Scale; Condon, 1993) to investigate the development of bonding over time and any impact of perinatal anxiety and interventions aiming to target anxiety and/or bonding difficulties.

The relatively high attrition rate across the time-points also limits the conclusions that can be made about the effectiveness of the intervention. As only 35% of participants attended all three antenatal sessions, the majority of the participants were not receiving the entire intervention. By not fully participating in an intervention that was already brief, participants may have been missing out on core content that could have impacted on change. Although the majority of participants (77%) received at least one intervention session and over half attended at least two sessions, it is not clear whether this constitutes “enough” intervention to enable change to occur. When participants missed sessions, efforts were made to re-engage them; they were sent worksheets from the sessions, “catch-up” phone calls and emails were offered and exercises were available from the study website, but data was not collected on whether participants actually accessed the information. All participants in the intervention group also received the Towards Parenthood workbook at the end of the three antenatal sessions (through the post for non-attenders), but again data was not collected on whether participants actually used the book. Any future development of this intervention (or others) should make efforts to collect information on whether non-attenders completed the exercises from missed sessions. Furthermore, it will be important to establish whether there is a “minimum

dose” required of the intervention to enable change to occur. Ultimately, further work will be needed on developing the best way to maintain engagement with the intervention and making it as accessible to participants as possible.

The measures of anxiety, relationship-functioning and parental bonding used in this study were well-validated, have been frequently used in previous research, and had very good internal consistency in the current study. Although the GAD-7 was not specifically developed for use during pregnancy, several studies have suggested that it is a reliable, valid and clinically useful scale for detecting anxiety symptoms in perinatal women and that it is useful in differentiating clinically significant anxiety from “normal” increases in pregnancy-related anxiety (NICE, 2017; Simpson, Glazer, Michalski, Steiner, & Frey, 2014; Zhong, Gelaye, Zaslavsky, Fann, Rondon, Sanchez & Williams, 2015).

Although this study was interested in reducing generalised anxiety symptoms experienced during pregnancy, it may have been interesting to also include a more specific measure of pregnancy-related distress in order to try to capture a fuller picture of distress experienced during pregnancy (be that more generalised distress or pregnancy-specific). There is currently a lack of research in to and availability of pregnancy-specific instruments to assess psychological distress associated with pregnancy (Bayrampour et al., 2016; Evans, Spiby, & Morrell, 2015; Hewitt, Gilbody, Brealey, Paulden, Palmer, Mann, Green, Morrell, Barkham, Light, & Richards, 2009). Pop and colleagues (2011) attempted to develop an instrument to specifically measure pregnancy-related distress using in-depth interviews with pregnant women, new parents, and perinatal health specialists (the Tilburg Pregnancy Distress Scale [TPDS]; Pop, Pommer, Pop-Purceanu, Wijnen, Bergink, & Pouwer, 2011). The TPDS consists of two scales; a pregnancy-specific negative

affect scale (e.g. “I worry about the delivery”) and a partner involvement scale (e.g. “The pregnancy has brought me and my partner closer together”). The authors of the TPDS found that it had a moderate correlation with the GAD-7 and that is also assessed dimensions other than more general depression and anxiety in pregnant-women (Pop et al., 2011). However, this and other scales measuring pregnancy-specific distress are not yet widely used or well validated (Evans, Spiby, & Morrell, 2015). Nonetheless, although the intervention was not designed to selectively address pregnancy-related anxiety per se, including a measure specifically measuring distress associated with pregnancy or the early postnatal period within the current study would have allowed the investigation of any changes in worries or concerns specific to pregnancy over time, and whether any of these changes were associated with relationship functioning and post-natal outcomes. It may have been interesting to have included the TPDS and investigated whether any changes in scores of the partner subscale were associated with changes in relationship functioning on the DAS. Furthermore, inclusion of a scale such as the TPDS may have allowed further investigation of the content of pregnant women’s worries, which may have helped to further refine the intervention in terms of basing example exercises around common pregnancy-specific worries.

It should also be noted that this study relied on self-report measures to assess anxiety, relationship functioning and bonding. Self-report measures are vulnerable to reporting biases, due to a reliance on memory and introspection, as well as possible response biases and ability to understand the questions (Austin, Deary, Gibson, McGregor, & Dent, 1998; Tanaka-Matsumi & Kameoka, 1986). However, they are also easy, quick and affordable to administer, which is especially important when conducting research trials with limited time and funding or when working in

healthcare settings where healthcare professionals have limited clinical expertise and time for diagnostic interviews. Furthermore, administering too many measures may put undue burden on study participants. With more funding, future studies may wish to also include other assessment methods, such as observational measures of parent-infant bonding and parenting behaviour.

As mentioned earlier, only a small number of partners took part in the intervention sessions. As so few partners took part, it was not possible to investigate whether partner-involvement made a difference to intervention effectiveness. Partners' reasons for not participating were not investigated, so it is not clear why this occurred. One potential reason may be that partners thought a pregnancy-specific intervention would not apply to them; traditionally, antenatal classes are delivered to women. However, many men now do take part in antenatal classes and the UK Government have mandated that fathers and partners now have the right to take unpaid time off work to accompany expectant mothers to up to 2 antenatal appointments (Department for Business, Innovation & Skills, 2014; <https://www.gov.uk/government/news/new-right-for-fathers-and-partners-to-attend-antenatal-appointments>). Although much of the ACORN intervention content was targeted for pregnant women, there were many exercises that could be completed as a couple and separate material had also been developed for partners to help them to support their pregnant partner. Although the role of fathers has been less extensively studied in the child development literature, there is emergent evidence showing that fathers have a vital role to play too (Fatherhood Institute, 2013, 2014; Feldman, Bamberger, & Kanat-Maymon, 2013; Lamb, 2010; Lamb & Lewis, 2013; Panter-Brick et al., 2014; Ramchandani et al., 2013). Despite this, antenatal and parenting interventions fail to explore how to best engage with fathers (Panter-Brick et al.,

2014). Furthermore, given research showing that partner support is a key risk/protective factor with regards to perinatal mental health difficulties for the mother, it follows that interventions should be delivered to the couple to foster a family environment for the child to thrive (Speier, 2015). Outside of the perinatal period, couple's therapy is commonly used to treat depression and other mental health problems, and thus treatment for perinatal mental health concerns should follow similarly, with appropriate adaptations for specific pregnancy-related concerns (e.g. Beach, Fincham, & Katz, 1998; Cerny, Barlow, Craske, & Himadi, 1987; NICE, 2009; O'Farrell & Clements, 2012). It therefore important to investigate how to make antenatal interventions more acceptable and accessible to fathers.

Conclusions

The analysis reported in this paper should be interpreted in the context of the main trial being a feasibility study which was not sufficiently powered to detect any smaller effects of the intervention on outcomes. Furthermore, attrition lead to a smaller number of participants available for analysis, such that this study was underpowered to detect changes in relationship functioning and postnatal bonding. The results showed that this brief group intervention for antenatal anxiety had no reliable effect on changes in relationship functioning over time and no between group differences on postnatal bonding. There was evidence of an association between improvements in anxiety symptoms and improvements in relationship functioning for the intervention group at postnatal follow-up. It was also found that there was an association between improvements in anxiety symptoms and higher postnatal bonding for the intervention group. However, direct comparisons between the intervention and control group were not significant, so it is not possible to

conclude that participation in the intervention lead to better relationship and mother-infant bonding outcomes when anxiety symptoms also improved.

As this was a feasibility trial, there is a plan to formally test the effectiveness and cost-effectiveness of the intervention in a larger-scale RCT. The intervention was designed to be brief and low-intensity such that it might eventually be embedded within NHS antenatal care in order to reach as many people was possible. However, given that the majority of participants did not complete all three antenatal group sessions in what was already a brief intervention, it will be important to consider what factors would lead to an improvement in participation before a larger RCT is conducted. One idea would be to conduct interviews with participants and perform a qualitative analysis of factors that lead to drop-out and what might have helped improve attendance. It will also be important for future studies to focus on how to effectively engage partners in perinatal interventions. Furthermore, there may be a need for further refinement of the concept of antenatal anxiety and the inclusion of more specific pregnancy-related anxiety measures in order to fully capture the difficulties experienced during this time and more effectively target interventions. Future studies may also wish to investigate further how parent-infant bonding develops across the perinatal period and the impact of perinatal anxiety and interventions targeting anxiety on the development of the parent-infant relationship.

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Part 3: Critical Appraisal

Introduction

This chapter provides a critical reflection on the research study presented in Part Two of this volume. Initially I will provide the context which prompted me to choose to investigate relationship satisfaction and mother-infant bonding in the context of antenatal anxiety. I will then reflect on some of the experiences of being involved in an RCT, both in terms of delivering the intervention and investigating the outcomes of the study. I will also comment on some of the challenges I faced while conducting the research. Finally, I will discuss some of the research and clinical implications of this research project.

Research interests and choice of topic

I began to develop an interest in perinatal mental health before starting doctoral training. My previous role was working in a child development research department (Developmental Risk and Resilience Unit, UCL) as a PhD student, where I was investigating cognitive mechanisms involved in parenting. My research involved recruiting first-time mothers with children under three years old and administering computerised experiments of cognitive processing as well as several self-report measures of psychological and social functioning, as I was interested in investigating risk factors that might disrupt cognitive processes thought to be important for parenting. I had been interested in studying child development from what I believed was the “beginning”, i.e. from the start of life. However, during the process of my research I realised the importance of the fact that cognitive, social and emotional development begins even before birth (e.g. Glover, 2014; Heron et al., 2004; Slade & Cree, 2010). Furthermore, the development of the identity of a

“parent” begins during pregnancy when preparations are made in anticipation of parenthood (e.g. Hennekam, 2016; Lothian, 2008). When I would speak with my participants who reported high levels of psychological distress, parenting stress and difficulties bonding with their child, they would often tell me that they felt their low mood or anxiety or worries about coping motherhood began during pregnancy.

During this time, a research paper was published showing that pregnant women experiencing symptoms of depression showed less attentional processing of pictures of distressed infant faces than non-depressed women, suggesting that depression is associated with differential cognitive processing of infant stimuli even before the child is born (Pearson, Cooper, Penton-Voak, Lightman, & Evans, 2010). The same research group later found that individual differences in this cognitive processing of infant distress during pregnancy was associated with later mother-infant relationship functioning (Pearson, Lightman, & Evans, 2011). They also reported outcomes from a longitudinal birth cohort study where they found that women who had higher depression scores mid-pregnancy showed lower maternal responsiveness when their infants were one-year old, even if they were no longer reporting symptoms of depression (Pearson et al., 2012). These authors argued that prenatal depression may disrupt preparations for maternal responsiveness. These studies along with my own experiences of working with postnatal women influenced my interest in studying mental health across the perinatal period and piqued in my interest in the antenatal period. Therefore, during the process of selecting a research topic at the end of my first year of the clinical doctorate, I approached a professor at UCL who is well-known for his research of socio-emotional development with interests in parenting, attachment, and maternal mental health. He agreed to

supervise me as he and colleagues were about to begin a small randomised controlled trial (RCT) of an intervention targeting prenatal anxiety which I was invited to join.

Change in scope of project

When my supervisor and I originally discussed what my role in the RCT might be there were several options. One was to investigate the effect of the proposed intervention on secondary outcome measures (i.e. measures other than anxiety, depression, and feasibility and acceptability of the intervention), and another was to run a small diary study alongside the RCT using Experience Sampling Methodology (ESM) via a smart-phone app. I initially focused on the latter option and planned to develop a smart-phone app that trial participants would use to record their daily levels of stress. The aim was to describe the profile of the experience of stress during pregnancy in women reporting high and low levels of anxiety. A second aim was to investigate whether the trial intervention targeting prenatal stress and anxiety would lead to a reduction in daily reported stressors and improved mood. I contacted the RCT team to discuss my proposed study, who agreed to allow the project to go ahead. An initial concern was how we might fund this smart-phone study, as it would require more money than available from the clinical course. A co-investigator in the RCT team was willing to provide funding and one of her colleagues initially offered to program the smart-phone application (“app”) free-of-charge. I wrote my research proposal based on this study being my D.Clin.Psy project, with considerable background research into ESM/diary studies, and conducted a power-analysis to find out how many participants I would need to ensure that the study was feasible in the context of the RCT. I was required to write an ethics amendment for the addition of the smart-phone diary study, including

proposed information sheets and consent forms, and design the content of the app. Unfortunately, it later transpired that our co-investigator was no longer able to help fund the study and her colleague was not able to help with programming within the required time-frame. This was very disappointing as myself and my supervisors had put considerable time and effort in to the conceptualisation of this project.

On reflection, the proposed study may have been too ambitious for a D.Clin.Psy project given that it required a significant amount of work and development in the context of a very short time-frame and limited funding. The project required more funding than we had anticipated, as we underestimated the costs involved in data handling and storage and the amount of payment participants would require given that a diary study demands responding several times per day. Also, we became unsure as to whether it was possible to develop the smart-phone app before the trial began, as it would have required a great deal of piloting due to possible programming glitches; it is reported that “bugs and glitches” are inevitable in app development and they often require a “beta” phase of testing and development before full functionality is possible (e.g. Ben-Zeev et al., 2015; Nimbalkar, 2013; Nistor & Ravindranath, 2014). Although it was not possible to conduct this smart phone diary study, I learned a lot from the process of designing the study and app, such as collaborating with colleagues from other disciplines and universities, how to cost a study, and how to be flexible and responsive when realising that this project would no longer be possible. If an opportunity arises in the future to pursue a similar line of enquiry in the context of more time and money, I would certainly be interested in exploring this type of research again.

Although my original plan was not possible, this presented a new opportunity for me in terms of where I would focus my research. I decided to focus my

investigation on some of the secondary outcome measures we had decided to include in the main RCT. I was particularly interested in the associations between prenatal mental health and relationship quality, both with intimate partners and with children. This was partly influenced by my previous research experience in which I had studied mother-infant bonding and by my knowledge of the importance of social support in protecting against perinatal anxiety and depression (e.g. Beck, 2001; Robertson, Grace, Wallington, & Stewart, 2004; Stapleton et al., 2012).

Reflections on the research process

Study design

Joining the research team presented an exciting opportunity for me to be part of an RCT. Although it was a small-scale trial, the research team were spread across several different universities and were from different disciplines (psychology, psychiatry, and midwifery), which gave me experience of multidisciplinary team (MDT) working within a research context. Working in this team also enabled me to experience feedback and external supervision from several senior researchers/clinicians. There were also disadvantages to this, as some of my decisions and questions in the early part of designing my study needed to be agreed upon by several members of the research team; however, the team were very busy with several concurrent commitments which meant that my questions in the early part of designing my study could not always be answered immediately. There was also a reduction in autonomy in designing and conducting my study, as I had to work within the constraints of the wider RCT. My biggest concern was the sample size, which had been decided upon according to the needs and funding of the RCT which

was focusing on acceptability and feasibility of the intervention rather than clinical outcomes and as such only needed to recruit a small sample. However, part of the way in to the research the sample size was doubled as another site joined the RCT, which put some of these worries to rest. I felt very lucky to be joining a study that was funded by NIHR as I did not have to worry about finding money to pay for participant time or other resources; this also meant that despite my initial concerns about sample size, I was able to recruit more participants and investigate the outcomes of the intervention more thoroughly than if I had to rely on clinical course funding sources alone, as these were limited. Without joining this team, I would not have had the opportunity to use an RCT design, which is considered the most rigorous of scientific methods in health research.

Delivering the intervention

My favourite part of the research process was delivering the intervention, which was a three-session group-based intervention for pregnant women (and their partners) who were experiencing high levels of anxiety. As a group facilitator, I received training in the intervention, which was based on principles of CBT and IPT. I also received regular supervision from a clinical psychologist who developed the intervention manual. It was a new experience to deliver an intervention by strictly adhering to a protocol, as it was obviously important for all trial participants to have a similar experience of the intervention. By facilitating the groups, I feel I have further developed my clinical skills. As I come to the end of clinical training I am even more grateful for this experience, as I hope to work in the field of perinatal mental health and did not have a perinatal placement during training; my experience of delivering the intervention therefore provided me with clinical experience in this

area. Another exciting part of delivering the intervention was that my co-facilitators were midwives; this allowed me to develop further skills in MDT working and is particularly pertinent considering my career plans, as perinatal mental health involves significant MDT working and skill-sharing across professions (Division of Clinical Psychology's Faculty of Perinatal Psychology BP8 Revision Working Group for the BPS, 2016).

During my time working on the research project I became pregnant, which created a unique experience of delivering the intervention to expectant couples while being pregnant myself. Several clinical and research considerations were discussed between myself and my research and clinical supervisors, such as if, when and how to tell participants that I was pregnant, how to deal with participants' reactions to this, and creating a contingency plan regarding who else might co-facilitate the groups and how I could stay actively involved with the research while I was on maternity leave. A lot of the literature on therapist pregnancy is from the psychoanalytic discipline with a focus on transference/countertransference, the disruption to the therapeutic frame, and the disruption to the length of therapy (Anderson, 1994; Cullen-Drill, 2009; Futa, 2002; Haber, 1993; Schmidt, Fiorini, & Ramires, 2015). As I was not working from this theoretical position and the intervention being delivered was short-term and in a group format, some of these issues were less pertinent to my situation. For example, I planned to ensure that I finished delivering the intervention to all the groups that I had begun with (although this meant that I ended up working until I was over 38 weeks pregnant!). Although CBT therapists do not specifically create a neutral therapeutic frame and have fewer "rules" regarding self-disclosure (Farber, 2003, 2006; Goldfried, Burckell, & Eubanks-Carter, 2003) there were still some boundary issues to negotiate. For

example, one participant touched my stomach and commented on how “big” I was getting, something she would most likely not do if I was not pregnant and instead had simply put on weight! I received more questions about my personal life and comments on my wellbeing than I have experienced in clinical work before my pregnancy. I also received comments from one client such as “I bet you never get anxious about pregnancy because you have all the tools to deal with it, your baby is so lucky”, suggesting that this client had a somewhat idealised version of my experience of pregnancy and motherhood (see Gottlieb, 1989). I discussed the issues of boundary setting and judicious self-disclosure in supervision.

However, my pregnancy could also have had some positive effects on the therapeutic relationship and the intervention. I think that I received more questions and comments from study participants because I was seen as “one of them”. Several participants commented that they liked the fact that I was also pregnant as they felt it meant I understood what their experiences. Research has shown that often clients prefer a therapist who is “like them” in terms of demographics, with research typically focusing on race/ethnicity (Cabral & Smith, 2011). Research has also shown that when therapists are similar to their clients in terms of personality, attitudes, behaviours, cognitions, and biological and physical factors they have better therapeutic outcomes (Herman, 1998; Mendelsohn & Geller, 1967; Norcross & Wampold, 2011; Smith, Rodríguez, & Bernal, 2011), perhaps because this facilitates rapport building (Dormaar, Dijkman, & de Vries, 1989). This is important to hold in mind in terms of the effects of the intervention, as it is possible that my pregnancy affected the therapeutic relationship and perhaps had some influence on outcomes. However, at our other research site the group facilitators were not pregnant and no obvious differences in study outcomes were evident between sites. Furthermore,

some research has proposed that the effect of therapeutic alliance may be less important for group therapy (Gurman & Gustafson, 1976; Woody & Adessky, 2002).

Data-analysis

As the RCT began at our London site several months before the other research site in Exeter joined, there was a time-lag in waiting for all the outcome data, and I was faced with choosing whether to begin data analysis without all the completed data. There were also several decisions to make regarding which analysis methods to use to look at the data, as previous intervention studies have used a variety of different techniques. Ultimately, it was decided between myself and my supervisor to use Hierarchical Linear Modelling (HLM) as it makes fewer assumptions of the data and allows the handling of missing data-points. This meant that I was required to learn a new data analysis technique as well as a statistical software package that I had not used before. Although this meant that the data analysis part of my project took longer than I had initially anticipated, overall it was a worthwhile learning experience.

I had hoped to include data from partners' outcome measures in my analysis, but was not able to as only six partners had completed outcome data. I felt especially disappointed by the lack of data from partners, as I had been involved in delivering the intervention to them and was keen to see if data suggested that they had found it helpful. Likewise, any drop-outs in this study were felt keenly as I had become very invested in the effectiveness of the intervention because I had been part of delivering it. For example, I noticed that I felt surprised and disappointed when my analysis showed that the intervention was not associated with changes in relationship functioning, as I had received anecdotal feedback from participants that they had

found participating together and doing tasks together beneficial for their relationship, but this was not reflected in the quantitative data. As discussed in Part 2, this lack of effect may be because most participants reported high functioning relationship in first place. However, it may also reflect a limitation of relying solely on self-report outcome measures; no matter how reliable and valid a measure has been shown to be, it is always possible that there is a question that has not been asked, that a scale does not adequately capture the concept it purports to measure, or that participants misunderstand questions (Kazdin, 2002; Willig, 2013).

Clinical and research implications

Although the intervention delivered in this RCT was at the pilot stage, it nonetheless has shown some promising results in terms of feasibility and acceptability to participants and reduction in symptoms of anxiety (P. Ramchandani, personal communication; data in preparation). The study reported in Part 2 of this thesis has shown that the intervention may have some effect on relationship functioning and mother-infant bonding in the context of improvements in anxiety. It would be premature to make clinical recommendations based on the outcomes of this RCT due to the small sample size, thus a full-scale trial that is fully powered will be necessary. This area of research is currently pertinent as the BPS and NICE have called for more research into interventions addressing perinatal mental health concerns (BPS DCP, 2016; NICE, 2014). It can be particularly difficult to design and adapt interventions for the prenatal period, as it is a unique time in life with special concerns (Slade & Cree, 2010). As has been discussed in previous chapters, there are a multitude of factors that can affect mental wellbeing during the perinatal period

and disentangling causal relationships and moderating and mediating factors is extremely complex, requiring longitudinal study designs with large sample sizes. For example, risk factors for parenting difficulties overlap with risk factors for depression, anxiety and stress (which also share risk factors and are often comorbid) and with other relationship and socio-economic risk factors (Banyard, Williams, & Siegel, 2003; Buist, 1998; Gottlieb & Pancer, 1988; Heron et al., 2004; Kettinger, Nair, & Schuler, 2000; Lancaster et al., 2010; Milgrom & Beatrice, 2003; Speier, 2015).

It will also be important for future research to focus on how prenatal interventions can be made more acceptable, feasible and convenient for partner participation, given the importance of the role of social support (e.g. Beck, 2001; Robertson et al., 2004; Stapleton et al., 2012) and the call for fathers/partners to be more involved in prenatal interventions (e.g. Panter-Brick et al., 2014). Indeed, rather than simply providing psychoeducation on how to support pregnant women, interventions may also want to consider offering psychological support to partners, as research has shown that 1 in 3 new fathers worry about their mental health, with concerns regarding the pressures of fatherhood, financial concerns, and poor quality sleep (National Childbirth Trust (NCT), 2015). Furthermore, 73% said they felt stressed due to worrying about their partner's mental health (NCT, 2015). Other research has shown that around 1 in 20 men experience antenatal depression and between 1 in 5 and 1 in 10 new fathers experience postnatal depression (Condon, 2006; Condon, Boyce, & Corkindale, 2004; Davé, Petersen, Sherr, & Nazareth, 2010; Kim & Swain, 2007).

Conclusions

In this critical appraisal, I have reflected on the development of the project reported in Part Two of this thesis and the challenges I faced throughout the research process. In particular, I have focused on choice of topic, study design, the delivery of the intervention, data-analysis, and the clinical implications of the research. I have also reflected on how my personal circumstances impacted on my involvement in delivering the intervention and on the research process. I hope this will be of interest to other trainees who are due to begin their research projects and may be able to learn from my experiences. I also hope it may be of interest to researchers or clinicians who may be considering or may be pregnant and are wondering what the impact of this might be on their work. Overall, I feel that my experiences during this research project have been valuable, enjoyable and interesting; I have learned the importance of good MDT working in both a clinical and research context, the pressures that are involved in conducting a multi-site study in a short time-frame, and the flexibility that is required to manage unexpected challenges. I am most grateful for the opportunity to work as both a researcher and a clinician on this project, as this has enabled me to develop my skills and experience in both areas. This experience will also be directly applicable to my future career plans, as I hope to continue to balance clinical and research work in the context of perinatal mental health.

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Appendices

Appendix A

Ethics committee approval letter



Health Research Authority

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15 April 2014

Dr Paul Ramchandani
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Dear Dr Ramchandani

Study title: **Adapting and testing a brief intervention to reduce maternal anxiety during pregnancy.**
REC reference: **14/LO/0339**
IRAS project ID: **137253**

Thank you for your letter of 27 March 2014, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-committee of the REC at a meeting held on 31st March 2014. A list of the sub-committee members is attached.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Miss Tina Cavaliere, nrescommittee.london-riverside@nhs.net

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Advertisement	Poster. 1.3	30 January 2014	
Advertisement	1.1. Internet sites	15 January 2014	
Covering Letter		27 March 2014	
GP/Consultant Information Sheets	1.1	09 December 2013	
Interview Schedules/Topic Guides	1.1. Acceptability Interview schedule	13 February 2014	
Interview Schedules/Topic Guides	1.1.Towards parenthood programme synopsis	13 February 2014	
Investigator CV	Paul Ramachandani		
Letter of invitation to participant	Phase 1. Version 1.1	22 January 2014	
Letter of invitation to participant	Phase 2. Version 1.1	22 January 2014	
Other: Towards Parenthood Programme			
Participant Consent Form: Consent Form 1	1.2	20 March 2014	
Participant Consent Form: Consent Form 2	1.2	20 March 2014	
Participant Information Sheet: Participant Information Sheet 1	1.1	21 January 2014	
Participant Information Sheet: Participant Information Sheet 2	1.2	20 March 2014	
Participant Information Sheet: Participant Information Sheet 3	1.2	20 March 2014	
Protocol	1.4	14 January 2014	
Questionnaire: Edinburgh postnatal depression scale			
Questionnaire: GAD-7			

Questionnaire: Pregnancy related worries			
Questionnaire: Dyadic adjustment scale			
Questionnaire: IBQ 270314			
REC application			
Referees or other scientific critique report		19 July 2013	
Response to Request for Further Information		27 March 2014	

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “*After ethical review – guidance for researchers*” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

14/LO/0339	Please quote this number on all correspondence
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We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely

Pp 

Dr Sabita Uthaya
Chair

Email: nrescommittee.london-riverside@nhs.net

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

“After ethical review – guidance for researchers”

Copy to: Ms Lynis Lewis, Central and North West London NHS Foundation Trust

Appendix B

Participant information sheet



Address

Xxxx

Xxxx

Email: xxxxxx

Telephone: xxxxxx

Website: www.acornstudy.org

The ACORN Study: Coping and Relaxation in Pregnancy

Participant Information Sheet

You are being invited to take part in a research study of a programme which aims to help with anxiety and stress in pregnant women. The study is being run by a team of researchers led by Dr Paul Ramchandani.

What is the study for?

In this study we are looking at a programme which aims to help reduce anxiety and stress in pregnant women. The programme involves three group sessions led by midwives. We are in the early stages of this research and so the purpose of this study is to do the sessions with a small number of women, and their partners where possible. We will then ask for your feedback on all aspects of the programme and how we run the study. This will help us to work out what works best for women and their partners and will help us to design a larger study involving more participants.

Why have I been invited to take part?

We are inviting you to take part because you are in the second trimester of your pregnancy, and have indicated that you are experiencing some stress or anxiety. We would like to see a range of women, as we are interested in finding out about different concerns and worries that arise during pregnancy and how we can best help with these.

Do I have to take part?

Participation in the study is entirely voluntary, so it is up to you to decide whether or not to take part. Before you decide it is important that you know what the study is for and what it would involve. We will describe the study and go through this information sheet, which is for you to keep. You may wish to discuss the study and taking part with your partner, family, friends, GP or midwife. If you have any questions or concerns you are welcome to discuss them with one of the research team. If you decide to take part you will be asked to sign a consent form. If you do decide to take part and later change your mind, you are free to withdraw from the study at any time and without giving a reason. Taking part will not affect your healthcare, or that of your baby, in any way.

What will I have to do?

If you agree to take part you will be allocated randomly to one of two groups. One group will undertake the programme, in addition to their usual antenatal care, and the other group will continue to receive their usual antenatal care. The programme involves attending three group sessions led by midwives. The sessions will be in the evening at three-week intervals. Each session



will last about 1.5 hours and will take place at St Mary's Hospital in Paddington or Queen Charlotte's and Chelsea Hospital, London [or the University of Exeter]. We would like to involve partners as well where this is possible, but are very happy for women to come on their own if not. In these sessions you will receive information about anxiety and stress during pregnancy, and you will learn a variety of techniques and strategies to help with these feelings. You will receive a workbook called 'Towards Parenthood', which includes details of the information and techniques. If you are allocated to the usual care group you will continue to receive your usual medical care.

We will ask participants in both groups to complete some short questionnaires at the beginning and end of the study so we have an idea of how you are getting on. Some of these questionnaires may feel personal or may make you feel anxious or upset. Trained and experienced members of the study team will be available to talk to you about any concerns you have and you are welcome to contact them at any time.

At the end of the study we would also like to have a talk with you about your experience of taking part. We will be keen to get your feedback on all aspects of the programme and the research. We will audiotape and transcribe these discussions in order that we can later look at everyone's feedback and use it to improve the way in which we run the programme and the research. We would also like to film the group sessions in order that we can review the way we run the programme and make any changes for future delivery of the sessions if necessary. The recordings and films will be stored securely and will only be accessed by members of the study team, and will be destroyed after the research is completed.

You will be given a £10 voucher, per couple, for the questionnaires you and your partner complete before the study starts, at the end of the group programme, and at a follow up after your baby is born, in recognition of the time and effort you put in to the study. You will also be reimbursed for travel costs to and from the group sessions and refreshments will be available.

What are the possible benefits of taking part?

We are in the early stages of this research and therefore we cannot say with certainty that taking part will be of benefit to you. However, the programme has been used in research studies previously and parents have found it helpful. It has been shown to reduce stress and anxiety in expectant parents.

What are the possible disadvantages and risks of taking part?

The disadvantages of taking part are likely to be small. If you are allocated to do the programme you would need to put aside time for the group sessions (about 1.5 hours), which will be in the evening. The midwives and researchers are experienced and specially trained for the study, and if during the sessions or discussions you were to feel uncomfortable or distressed for any reason, they would respond sensitively and only continue if you were happy to do so.

Will my taking part in the study be kept confidential?

We will keep all information in the strictest confidence. Only certain members of the research team will have access to your information. We will give you a unique 'participant number' so that your name and contact details are not stored with any information from the study.

If you decide to take part we will write to your GP with your permission, but only to let him/her know that you are taking part in the study. Otherwise everything you say will be treated with



utmost confidentiality. The only exception to this would be if something you said or wrote suggested that there was a serious risk to yourself, your family, or other people. In this case we would contact your GP or other care provider and would endeavour to gain your permission before doing so. Whether or not you take part will not in any way affect the healthcare you or your baby receives.

What will happen to my information?

All of your information will be stored securely and will only be accessible by certain members of the research team. In accordance with NHS Trust policy we will keep your information and the recordings we make during the study for 5 years after the study has finished, after which time they will be destroyed.

If you give us permission to do so we may use some clips of you or some quotes from your feedback in research presentations. Quotes would be anonymised and your personal details would not be disclosed.

What will happen to the results of the study?

We will use the feedback and information gained from this study to design a larger study of the programme, to test further how helpful and beneficial it is to expectant parents. We will publish the results of the current study in scientific journals and may present them at conferences. All information will be anonymised and you will not be identifiable in the results or publications. We will also send all participants a summary of our findings at the end of the study.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, in order to protect your wellbeing, rights and dignity. This study has been reviewed and given favourable opinion by the London – Riverside National Research Ethics Committee.

What if there is a problem or something goes wrong?

It is unlikely that anything will go wrong, but it is important that you have this information in case it does. If you wish to make a complaint, or have any concerns about any aspect of the way in which you have been treated during the course of this study, then you should contact the chief investigator, Dr Paul Ramchandani, by phoning 0203 383 4161 or emailing p.ramchandani@imperial.ac.uk. The normal National Health Service complaints mechanisms are also available to you.

What happens next?

If you would like to take part in the study please contact the study team using the details above. If we do not hear from you soon we will also try to contact you to see whether you would like to take part.

If you would like more information about the study or would like to discuss it with one of our researchers, please phone or email us using the contact details above.

**Thank you for taking the time to read this information and for your
interest in our research**

Appendix C

Participant consent form



The ACORN Study: Coping and Relaxation in Pregnancy

Consent Form

Please initial box:

I confirm that I have read and understood the Information Sheet (version xxx dated xxxx)

I have had the opportunity to consider the information and ask any questions, which have been answered satisfactorily.

I understand that participation is voluntary and that I am free to withdraw from the study at any time, without having to give a reason and without it affecting my or my baby's medical care.

I agree to my GP being informed of my involvement in this study.

I agree to the audio-taping of conversations with the researcher.

I agree to the researcher filming me in group sessions and keeping the recordings for the duration of this research. The recordings will only be used for this research project and will be stored in a secure place.

I agree to the researchers using quotes and/or video clips of me in research presentations. Yes / No (You may say no to this at any time and still take part in the study).

I understand that sections of any of my medical/research notes may be looked at by responsible individuals from the NHS Trust or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research.

I agree to participate in this study.

.....
YOUR NAME

.....
SIGNATURE

.....
DATE

.....
RESEARCHER'S NAME

.....
SIGNATURE

.....
DATE

When completed: 1 copy for participant, original copy to be retained in research file.

Appendix D
GAD-7 Questionnaire

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
<i>Add the score for each column</i>	+	+	+	
Total Score (<i>add your column scores</i>) =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

- Not difficult at all _____
- Somewhat difficult _____
- Very difficult _____
- Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Intern Med.* 2006;166:1092-1097.

Appendix E
Dyadic Adjustment Scale

DYADIC ADJUSTMENT SCALE

Most persons have disagreements in their relationships. Please indicate below the approximate extent of agreement or disagreement between you and your partner for each item on the following list.

	Always Agree	Almost Always Agree	Occa- sionally Disagree	Fre- quently Disagree	Almost Always Disagree	Always Disagree
1. Handling family finances	○	○	○	○	○	○
2. Matters of recreation	○	○	○	○	○	○
3. Religious matters	○	○	○	○	○	○
4. Demonstrations of affection	○	○	○	○	○	○
5. Friends	○	○	○	○	○	○
6. Sex relations	○	○	○	○	○	○
7. Conventionality (correct or proper behavior)	○	○	○	○	○	○
8. Philosophy of life	○	○	○	○	○	○
9. Ways of dealing with parents or in-laws	○	○	○	○	○	○
10. Aims, goals, and things believed important	○	○	○	○	○	○
11. Amount of time spent together	○	○	○	○	○	○
12. Making major decisions	○	○	○	○	○	○
13. Household tasks	○	○	○	○	○	○
14. Leisure time interests and activities	○	○	○	○	○	○
15. Career decisions	○	○	○	○	○	○

	All the time	Most of the time	More often than not	Occa- sionally	Rarely	Never
16. How often do you discuss or have you considered divorce, separation, or terminating your relationship?	○	○	○	○	○	○
17. How often do you or your mate leave the house after a fight?	○	○	○	○	○	○
18. In general, how often do you think that things between you and your partner are going well?	○	○	○	○	○	○
19. Do you confide in your mate?	○	○	○	○	○	○
20. Do you ever regret that you married? (<i>or lived together</i>)	○	○	○	○	○	○
21. How often do you and your partner quarrel?	○	○	○	○	○	○
22. How often do you and your mate "get on each other's nerves?"	○	○	○	○	○	○

Appendix F
Postnatal Bonding Questionnaire

Factor	Scoring	Statement	Always	Very often	Quite often	Some-times	Rarely	Never
1	0 → 5	I feel close to my baby						
1	5 → 0	I wish the old days when I had no baby would come back						
2	5 → 0	I feel distant from my baby						
2	0 → 5	I love to cuddle my baby						
2	5 → 0	I regret having this baby						
1	5 → 0	The baby does not seem to be mine						
1	5 → 0	My baby winds me up						
1	0 → 5	I love my baby to bits						
1	0 → 5	I feel happy when my baby smiles or laughs						
1	5 → 0	My baby irritates me						
2	0 → 5	I enjoy playing with my baby						
1	5 → 0	My baby cries too much						
1	5 → 0	I feel trapped as a mother						
2	5 → 0	I feel angry with my baby						
1	5 → 0	I resent my baby						
1	0 → 5	My baby is the most beautiful baby in the world						
1	5 → 0	I wish my baby would somehow go away						
4	5 → 0	I have done harmful things to my baby						
3	5 → 0	My baby makes me feel anxious						
3	5 → 0	I am afraid of my baby						
2	5 → 0	My baby annoys me						
3	0 → 5	I feel confident when caring for my baby						
2	5 → 0	I feel the only solution is for someone else to look after my baby						
4	5 → 0	I feel like hurting my baby						
3	0 → 5	My baby is easily comforted						