LITERATURE REVIEW: Psychological interventions for perinatal ethnic minority populations: A systematic review

EMPIRICAL PAPER: Intolerance of Uncertainty and Emotion Regulation in Pregnant Women

Submitted by Claire Treleaven, to the University of Exeter

as a thesis for the degree of Doctor of Clinical Psychology, 15th June 2020

Signature: 

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SCHOOL OF PSYCHOLOGY DOCTORATE

IN CLINICAL PSYCHOLOGY

LITERATURE REVIEW

Psychological interventions for perinatal ethnic minority populations: A systematic review

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Abstract

Purpose

Ethnic minority women are at a higher risk of mental health problems during the perinatal period. However, they are less likely to receive or to be able to engage with mental health services and interventions, due to many personal and systemic factors, including a lack of cultural adaptations made within services. The current review aims to investigate the efficacy of interventions targeting perinatal mental health for ethnic minority women, and the factors that may improve engagement and/or efficacy.

Methods

Five databases (Psychinfo, EMBASE, MEDLINE, Global Health and Psychology and Behavioural Science) were searched to identify articles examining interventions for perinatal mental health conditions, with a sample of at least 60% of ethnic minority participants. Initially 2311 papers were identified, and 17 papers met the final inclusion criteria for the review.

Results:

Overall levels of engagement were high, although more so when an intervention was ‘culturally’ tailored, although this does not impact on the efficacy of interventions. The efficacy of preventative interventions at post-treatment were inconsistent, but at follow-up points there were significantly more improvements made in the intervention groups than controls. Interpersonal Psychotherapy was the most effective intervention for treating perinatal depression.

Conclusion:

Perinatal interventions are effective at preventing and treating mental health problems within ethnic minority populations. Culturally adapting interventions

improves engagement, but not efficacy. Further research is required to expand upon the literature within different countries, a postnatal population and alternative diagnoses.

Keywords: Ethnic minority, Perinatal, Psychological interventions, Cultural adaptations.

Declarations: Not applicable

Introduction

One in five women experience a mental health problem during pregnancy and in the first year postnatally (Royal College of Obstetricians & Gynaegologists, 2017). Together, perinatal mental health conditions cost an estimated £8.1 billion to the UK each year, with 72% of this cost being attributed to the adverse impacts upon the infant (Bauer et al., 2014), including difficulties with psychological, behavioural, biological, and neurophysiological functioning, both as an infant and later in life (Aktar et al., 2019; Surkan et al., 2011).

Research has shown considerable variation in the prevalence of perinatal mental health conditions among ethnic minority groups; for those who have a different national, racial or cultural identity to the general population (e.g. Asian in a UK context, or White within an Asian context). Between 33-38% of ethnic minority women experience perinatal depression (Gress-Smith et al., 2012), almost double that of the general population (Gavin et al., 2005). Prevalence rates specific to ethnic minority populations, are rarely reported within other perinatal mental health conditions, including anxiety disorders, Obsessive-Compulsive Disorder (OCD), post-traumatic stress disorder, fear of childbirth (tokophobia), bipolar disorder and psychosis. Although, the latter is not as common, it can have a debilitating impact on a mother, infant and wider family (O'Hara & Wisner, 2014).

In the UK, there are many ethnic disparities in pregnancy and maternal outcomes. For example, when compared to White women, Asian women are twice as likely to die during childbirth, and Black women are five times more likely (MBRRACE-UK, 2018). In addition, there are significantly higher risks of low-birth weight and infant mortality for Black women specifically, and for Asian women (Office for National Statistics, 2015). Similarly, it is well-documented that these women are at a

significantly greater risk of developing perinatal mental health problems (Gavin et al., 2011; Howell et al., 2012; Onozawa et al., 2003; Roomruangwong & Epperson, 2011; Segre et al., 2006). A number of factors have been attributed to these increased risks, for example ethnic minority populations are more likely to have experienced racism and discrimination (Synergi Collaboration Centre, 2018), social and economic disadvantage (Equality and Human Rights Commission, 2016; Memon et al., 2016), and mental health stigma (Memon et al., 2016).

Despite these risks, ethnic minority women have less access to services, both during pregnancy and postnatally, are less likely to be correctly identified through early screening, and to receive appropriate treatment (Edge, 2010a; Prady et al., 2016). A number of barriers to ethnic minority women accessing mental health services have been reported. Notably, personal factors include; not recognising or accepting mental health problems, adopting alternative explanations for symptoms, a reluctance to discuss psychological distress, cultural identity, and cultural stigma against mental health issues (Memon et al., 2016; Watson et al., 2019). Furthermore, a lack of English language proficiency, knowledge of local services (Nilaweera et al., 2014), a lack of time, transportation, child-care or finances, and experiencing current mental health crises are reported (Davis et al., 2008).

Service-level factors also contribute to these barriers. For example, ethnic minority individuals are less likely to be asked about their emotional well-being and about their social support networks, despite engaging in equivalent amount of antenatal and postnatal care (Almeida et al., 2013).

Additionally, a systemic lack of attention to mental health and cultural factors (Nilaweera et al., 2014), long waiting times, language barriers, poor communication between providers and service users, an imbalance of power and authority, and

cultural incompetence or discrimination create further barriers (Memon et al., 2016). It is suggested that as a result, there are often minority women left feeling isolated, fearful, stigmatised and suffering in silence (Watson et al., 2019).

When engaging in services, ethnic minority women often experience culturally inappropriate and/or insensitive services which demonstrate bias towards them. For example care being provided by men without consideration of the cultural impact; a lack of representation of ethnic minorities within the staff group; or interpreters not being provided (Watson et al., 2019). However, steps can be taken to improve the cultural acceptability. Miranda et al (2003), demonstrated that efficacy of interventions can be improved through providing translated material, ensuring ethnic minority individuals and their cultures feature within any materials used, and facilitators receive supervision from minority supervisors.

Commonly, services focus their efforts on language and translation in an attempt to act in a culturally sensitive way. However, whilst this may reduce a physical barrier, it does little to address the individual cultural needs (Edge, 2010b). Lau (2006), states that for interventions to be culturally acceptable, two factors need to be considered; engagement and outcome. They state that cultural adaptations should be selective (a focus on specific areas where there is a poor fit between the intervention and target community) and directed (guided by the evidence base). This suggests that cultural adaptations cannot use a universal approach, and only when the needs of the specific population are known, can cultural acceptability be achieved.

There is a lack of evidence regarding facilitators to help-seeking within perinatal population. However, it is noted that perinatal women tend to seek help more frequently from informal sources, such as friends and family or printed resources (Jones, 2019; O'Mahen & Flynn, 2008; Shivakumar et al., 2014; Thomas et al., 2014)

and this is particularly used when there is a cultural distrust of mental health services (Memon et al., 2016). In addition to this, some women seek support through religion or spirituality (Thomas et al., 2014), which is more common within African-American women, who have greater confidence in religious leaders as treatment deliverers (O'Mahen & Flynn, 2008).

A growing body of research describes therapeutic interventions that are effective in preventing and treating mental health issues within a general perinatal population. However, little is known about the efficacy of these within ethnic minority populations. For the general population, Cognitive-Behavioural Therapy (CBT) and Interpersonal Psychotherapy (IPT) have been found to be effective treatments (O'Connor et al., 2019), which, along with Behavioural Couples Therapy, are the recommended psychological intervention for perinatal mental health problems in the UK (National Institute for Health and Care Excellence, 2014).

The main aim of this systematic literature review is to examine the evidence for perinatal psychological interventions for ethnic minority populations, as defined as samples containing more than 60% of an ethnic minority population within the country of completion (e.g. Asian within a UK context). The research questions for this review are; "how effective are psychological interventions for perinatal mental health in ethnic minority populations?" and "what, if any, are the barriers and facilitators to engaging and adhering with perinatal mental health interventions within ethnic minority populations?"

Method

Both the PRISMA-P reporting protocol (Moher et al., 2015; Shamseer et al., 2015) and the Cochrane Handbook for Systematic Review of Interventions (Higgins & Thomas, 2019) were used to conduct and structure this review.

Eligibility Criteria

Eligibility criteria for the study were constructed looking at population, intervention, comparator, outcome and study design (PICOS). The full inclusion and exclusion criteria can be found in Table 1.

Table 1

PICOS Criteria

	Inclusion Criteria	Exclusion criteria
Population	‣ Total sample aged 18 years and above. ‣ Women currently pregnant or up to one year postpartum. ‣ Women who have had multiple pregnancies and/or previous children. ‣ At least 60% of the sample were populations from minority ethnic backgrounds. ‣ Clinical and/or elevated symptoms of psychological distress. ‣ Women “at risk” of developing mental health problems, by either experiencing sub-threshold symptoms or by meeting subthreshold cut-off points on a validated outcome measures. ‣ Women with a diagnosed mental health problem.	‣ Fathers. ‣ Populations with no current, or history of pregnancy (nulligravida) or birth (nulliparous). ‣ The sample’s ethnicity was not described. ‣ Populations with physical health conditions only. ‣ No evidence of current or historical elevated symptoms or psychological distress.

Intervention	‣ Interventions specifically targeting psychological well-being. ‣ Preventative interventions. ‣ Treatment interventions.	‣ Pharmacological or medical intervention or any other intervention, which is not based upon any psychological model or theory. ‣ Interventions that target non-clinical distress resulting from termination, miscarriage, stillbirth, or infant loss.
Comparator	‣ Any clinical or non-clinical population.	‣ Neither group related to psychological wellbeing.
Outcomes	‣ Change in mood, cognition, physiology or behaviour associated with psychological wellbeing.	‣ Outcomes unrelated to psychological wellbeing. ‣ Change in the outcome of pregnancy; i.e. miscarriage or stillbirth.
Study design	‣ Peer-reviewed ‣ Quantitative designs ‣ Mixed-methods designs ‣ Randomised-controlled trials ‣ Single case designs ‣ Experimental designs ‣ Naturalistic designs ‣ Small-scale research designs ‣ Longitudinal studies	‣ Qualitative design ‣ Clinical case studies where n<5 and/or no data analysis has been conducted. ‣ Discussion or opinion papers ‣ Conference abstracts ‣ Review articles ‣ Systematic reviews and meta-analyses ‣ Editorials ‣ Papers published in a foreign language where the translation to English is unavailable

Information Sources

To identify eligible studies, the following electronic databases were searched: PsycINFO, EMBASE, MEDLINE, GlobalHealth and Psychology and Behavioural Science. Databases were not restricted by date of publication because there had

not yet been a review of intervention efficacy within this population. Reference lists of studies that were included following the full text screening were also scanned for any papers that were not identified in the original search. Grey literature was not included in this review due to limited resources.

Search Strategy

All databases were searched on the 15th October 2019. Key search terms were used (Table 2). Truncation symbols were included to increase the sensitivity of the search strategy. All articles identified in the search were exported into Mendeley, a reference management software programme, by 31st October 2019.

Table 2

Search terms

	Perinatal Section 1 "OR"	Ethnic Minority Section 2 "OR"	Mental Health Section 3 "OR"	Intervention Section 4 "OR"
Individual Search Terms (In title and abstracts)	Perinatal Postnatal Antenatal Pregnan*	Ethni* Culture Minority Race Black African Caribbean Asian Indian Pakistani Bangladeshi Chinese Arab Mixed Latin* Hispanic	Depress* Anxiety PTSD OCD Dysthymia Phobia Panic GAD	Psychological Intervention CBT Therapy Psychotherap* Counselling Complimentary therapy
Combined Search (In title and abstracts)	Section 1 "AND" Section 2 "AND" Section 3 "AND" Section 4			

Study Records

Selection process

An initial screen by title was completed against the criteria, followed by a screen by abstract. The studies identified as appropriate at this stage were then included in a full-text screen to assess against the eligibility criteria.

Three studies were randomly selected to be reviewed by a second-rater, who was asked to make an independent yes/no decision regarding whether the studies were appropriate for inclusion based on the PICOS criteria. Consensus meetings were held until 100% agreement was achieved.

Data collection process

A data extraction form was used to independently extract all data from the included papers, in accordance with guidance from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Thomas, 2019).

Data Items

Information was extracted from each study based on their study characteristics, including the title and author, the study design, participant characteristics and a description of the primary outcomes.

Quality Appraisal

The Quality Assessment Tool for Quantitative Studies, developed by the Effective Public Health Practice Project (1998), was used to assess the quality of each study. This tool evaluates studies based on the selection, study design,

confounding variables, blinding data collection methods and attrition rates. All papers were rated by the author, with three chosen at random being second-rated by an independent researcher. Although disagreements existed within individual items on the measure, there were no disagreements on global QAT quality ratings (100% inter-rater reliability).

Data Synthesis

A systematic narrative synthesis was conducted on the data collected as recommended by the Centre for Reviews and Dissemination (2009).

Results

Search Results

During the initial search, 4111 articles were identified, which reduced to 2305 once duplicates were removed. 74 papers were retained after title and abstract screening, of which 57 papers did not meet PICOS criteria and were excluded. A further 6 eligible papers were identified by screening the reference lists of retained papers. These were not identified in initial searching due to them being hosted by alternative databases, and not featuring “ethnicity” or “culture” within their title or abstract. Following screening, a total of 17 full-text articles were retained for synthesis. See Figure 1 for PRISMA-P diagram. All extracted data for the 17 included papers can be found in Table 3.

Figure 1

PRISMA-P Diagram

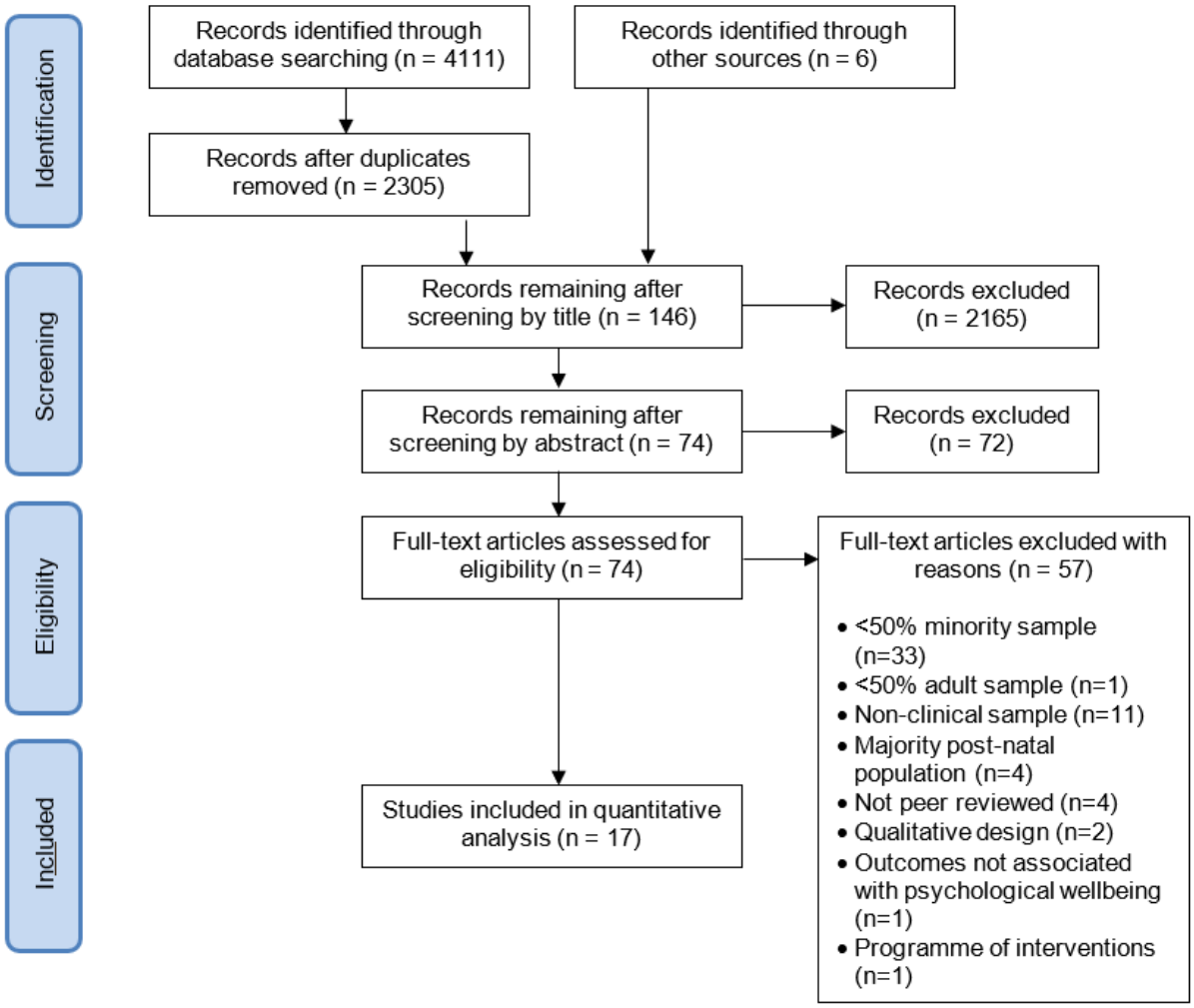

Table 3

Extracted data from included papers

Author	Population	Design	Measures	Intervention & Comparator	Results & Conclusion	QAT Rating & Strengths/ Limitations
1.Crockett, Zlotnick, Davis, Payne, and Washington (2008)	36 African-American (100%) pregnant women at risk of postnatal depression; scoring clinical cut-off (>27) on the Cooper Survey Questionnaire Minority within Mississippi, USA	Controlled Clinical Trial Prevention study	**Primary:** Edinburgh Postnatal Depression Scale (EDPS) **Secondary:** Social Adjustment Scale Self-Report (SAS-SR) Postpartum Adjustment Questionnaire (PPAQ) Parenting Stress Index (PSI)	**Intervention:** The ROSE Programme - 4 x 90mins group psychoeducation sessions based upon interpersonal psychotherapy, targeting social adjustment and role transition, plus 1 x 50min individual telephone session **Focusses on:** • Enhancing social support • Familial communication • Managing transitions • Perinatal depression **Comparator:** Treatment as Usual – prenatal obstetric care and educational pamphlets.	**Results:** No significant differences were found between the intervention and control group on degree of depressive symptoms, or level of parenting stress at post-intervention, 2 weeks postpartum or 3 months postpartum. A significant between-group difference was found on postpartum adjustment at 3 weeks and 3 months post-partum (F (1,25) = 5.43, p=0.028). Significant change in depression scores over time for intervention group (F (3, 39) =4.44, p=0.009, d=0.26).	**QAT Rating:** Moderate **Strengths:** Intervention and control groups mostly equally weighted. Robust research design. No known confounding variables between groups. Low drop-out rates. **Weaknesses:** Sample taken from one antenatal clinic – cannot be generalised to wider population.

					No significant difference in parenting stress across time. Mean number of sessions attended was 4.58 out of 5. Transportation cited as a barrier to attending. Dropouts were due to relocation of participants. **Conclusion:** The ROSE programme is an effective intervention for improving postpartum functioning in this population.	Randomisation method not described. Effect sizes reported for depression scores over time, but not for group differences in postpartum adjustment. No fidelity checks carried out.
2. Zlotnick, Miller, Pearlstein, Howard, and Sweeney, (2006)	99 Hispanic (45%), Caucasian (28%), African American (17%), Asian (2%), and Other (8%) pregnant women at risk of postnatal depression as measured by the Cooper Survey Questionnaire, with scores	Randomised Controlled Trial Prevention study	**Primary:** Beck Depression Inventory II **Secondary**: Range of Impaired Functioning Tool Longitudinal Interval Follow-up Evaluation.	**Intervention:** The ROSE Programme - 4 x 60mins psychoeducational group sessions (with between 3-5 women) based upon an interpersonal psychotherapy model, focussed on social adjustment and role transition, plus 1 x 50min individual telephone session **Focusses on:**	**Results:** Participants in the intervention group were significantly less likely to develop postpartum depression within 3 months after delivery than those in the control group (p=.04). Calculated effect size – Cohen's d = 0.08 (small) There was no significant difference between groups on BDI scores of	**QAT Rating:** Strong **Strengths:** High retention rate of participants. Robust study design. No confounding variables between groups. **Limitations:** Blinding not described.

	above clinical threshold (>27). Minority within Rhode Island, USA			• Enhancing social support • Familial communication • Managing transitions • Perinatal depression **Comparator:** Treatment as Usual – antenatal care at health clinic.	functioning at 3 months postpartum. Mean number of sessions attended was 3.3 out of 5. Dropouts were due to relocation of participants. **Conclusion:** A brief intervention for pregnant women may reduce the incidence of depression at three months postpartum.	Limited analysis conducted and reported (Fishers exact test). No effect sizes reported. No fidelity checks carried out.
3. Jesse et al., (2010)	26 African-American (81%) and Caucasian (19%) pregnant women at risk of antepartum depression as measured by the EPDS (score >10). Minority within North Carolina, USA.	Mixed-methods Cohort study Prevention study	**Primary:** Edinburgh Postnatal Depression Scale **Secondary:** Beck Depression Inventory	**Intervention:** Insight Plus – 6 x 2-hour group intervention based upon a CBT model. **Focusses on:** • Identifying symptoms of depression • Coping and relaxation • Identifying and modifying cognitive distortions • Developing supportive and open communication within the partner relationship. • Dealing with loss and grief	**Results:** Significant reductions in both EPDS ($p<.01$) and BDI ($p<.01$) scores at post-intervention, and at one-month follow-up (EPDS = $p<.001$, $\eta^2 = .82$) (BDI = $p<.001$, $\eta^2 = .53$). 41% of initial sample declined to participate due to; lack of interest, relocation, illness, and not maintaining telephone contact. **Conclusion:** A CBT intervention can improve antepartum	**QAT Rating:** Weak **Strengths:** Use of valid and reliable measures. Moderate and large effect sizes found. **Limitations:** Small sample size. No comparator group. Small proportion of participants from initial numbered

				• Relapse prevention **Comparator:** No comparator	depressive symptoms for those at risk.	completing the intervention. No fidelity checks carried out.
4. Jesse et al. (2015)	146 African-American (68%) Caucasian (32%) pregnant women identified as high risk for postpartum depression as measured by EPDS. Those scoring above >10 allocated to the "high-risk" group, and those scoring between 4-9 were allocated to the low/moderate group. Minority within North Carolina, USA	Randomised-Controlled Trial Prevention study	**Primary:** Edinburgh Postnatal Depression Scale **Secondary:** Beck Depression Inventory Dolphin EDC – diagnostic evaluation for clinical depression Client Satisfaction Questionnaire	**Intervention:** Insight Plus - 6 x 2 hours group intervention based upon a CBT model, with 2-6 women per group. **Focusses on:** • Identifying symptoms of depression • Coping and relaxation • Identifying and modifying cognitive distortions • Developing supportive and open communication within the partner relationship. • Dealing with loss and grief • Relapse prevention **Comparator:** Treatment as Usual – prenatal care from midwives, health	**Results:** Both intervention and TAU had significant reductions in EPDS and BDI scores immediately after intervention, and at one-month follow-up. Significant reduction in BDI-II scores in low-moderate risk intervention group compared with controls, from baseline to post-intervention (4.92 vs 0.59, *P* = .18) and baseline to 1-month follow-up (5.67 vs 1.51, *P* =.04). Calculated effect size – Cohen's d = 0.73 (medium) Intervention successfully reduced EPDS scores for high-risk African-American women immediately after intervention (5.59 to 2.18, p=.02) and at one-month	**QAT Rating:** Moderate **Strengths:** Robust methodological design, with randomisation of participants clearly described. No confounding variables between groups. All therapists underwent culturally sensitive training and supervision. **Limitations:** Higher level of attrition within intervention group (35%) compared to TAU group (3%). Neither researchers nor participants were

				visitors and doctors, as necessary.	follow-up (6.32 to 3.14, p=.04), compared with controls. 35% of initial sample declined to participate due to; work and school conflicts, not maintaining telephone contact, lack of transportation, or miscarriage. **Conclusion:** A CBT intervention can improve depressive symptoms for African-American women at high-risk for postnatal depression, and for the full-sample of women at low/moderate risk.	blinded to study aims/conditions. Participants were only rural, low-income minority women as cannot be generalised to other groups. Effect sizes not reported. No fidelity checks carried out.
5. Le, Perry, and Stuart (2011)	217 Latina (100%) pregnant women who reached clinical cut-off (>16) on the Center for Epidemiologic Studies Depression Scale	Randomised-Controlled Trial Prevention study	**Primary:** Beck Depression Inventory-II **Secondary:** Center for Epidemiologic Studies Depression Scale	**Intervention:** Mothers and Babies Course - 8 x 2-hour psychoeducational group sessions based upon a CBT model. 3 x individual booster sessions postnatally to review group concepts and generalize skills to parenting. **Focusses on:**	**Results:** Intervention participants had significantly lower depressive symptoms immediately after intervention compared to controls (Cohen's *d* = -0.28, *p* = .03). The incidence of major depression postnatally was not significantly different between groups.	**QAT Rating:** Moderate **Strengths:** Robust methodological design, with randomisation of participants clearly described. A high proportion of potential confounding

	Minority within Washington DC, USA		The Mood Screener	• Understanding mood and health • Relaxation • Identifying and modifying cognitive distortions • Increasing positive social networks • Developing a positive mother-child attachment • Parenting skills Supported by a participant's workbook and homework tasks. **Comparator:** Treatment as Usual – prenatal care at a community hospital/hospital clinic.	**Conclusion:** A CBT intervention for low-income, high-risk Latina women is effective in reducing depressive symptoms during pregnancy, but not postnatally.	variables controlled for within design. Measures used were reliable and valid. Missing data was accounted for using a multiple imputation approach. Fidelity checks carried out. **Limitations:** The comparator, "Usual Care" is not described with any detail. A high level of participants lost prior to randomisation. High level of participants attending less than half of the intervention.
6. McKee, Zayas, Fletcher, Boyd, and Nam (2006)	187 Hispanic (57%) African-American (43%) pregnant	Controlled Clinical Trial Treatment study	**Primary:** Beck Depression Inventory-II	**Intervention:** 8 x 2-hour individual sessions of manualised CBT programme, with four additional	**Results:** BDI-II scores decreased significantly from third trimester to three months postpartum in both	**QAT Rating:** Weak **Strengths:** Participants

women who reached clinical cut off (>14) on the BDI-II Minority within New York, USA	**Secondary:** Norbeck Social Support Questionnaire Interaction Rating Scales	psychoeducational modules focussing on child development. Further social support building sessions were delivered twice monthly in person or over the phone. Focusses on: Depressive symptoms Addressing cognitive distortions Relaxation Mother-infant interaction Child development Maternal social support **Comparator:** Treatment as Usual – routine antenatal care and access to psychosocial support offered by health centres. And A comparator intervention group of non-depressed individuals.	intervention group (F = 8.4, p <0.05) and control group (F = 9.8, p <0.05). No significant difference found in depressive symptoms between intervention and TAU group. No significant change in total functional support scores between groups. Medium effect size (f^2 =.0625). 54.5% of initial sample declined to participate. Those who dropped out of the intervention group were more likely to live <1 year at current address, and to be Hispanic (p<.05). **Conclusion:** Intervention and TAU offered by health centres was equally as effective.	randomised to intervention and control groups, with no known confounding variables between groups. Measures used were reliable and valid. **Limitations:** High attrition rates within TAU and intervention group. Final numbers in non-depressed group not described. Blinding was not described. No fidelity checks carried out.

7. Stevens, Lillis, Wagner, Tirone, and Hobfoll, (2019)	45 African-American (53%) Hispanic/Latina (42%) White (4%) pregnant women experiencing at least three symptoms of post-traumatic stress. Minority within Chicago, USA	Mixed-methods cohort study Prevention study	**Primary:** PSTD Symptom Checklist for Civilians (PCL-C) **Secondary:** Childhood Trauma Questionnaire (CTQ) Trauma History Questionnaire (THQ) Patient Health Questionnaire (PHQ-9)	**Intervention:** TO-CARE Programme – 6 x 60min group CBT sessions to develop coping skills, and trauma-sensitive obstetric care provided by trained clinicians. 6-week postpartum follow-up visit. **Focusses on:** • Psychoeducation • Developing coping strategies • Self-care • Relaxation • Assertiveness • Applying skills to pregnancy, childbirth, and postpartum concerns. **Comparator:** No comparator	**Results:** Participants reported high satisfaction following completion of the programme. Post intervention, reliable change was demonstrated in post-traumatic symptoms (n=4), and depression symptoms (n=2), (RCI values > -1.96). At follow-up reliable change was demonstrated in depression symptoms (n=2) and post-traumatic symptoms (n=1), (RCI values > -1.96). 48% of initial sample declined to participate or were lost to follow-up. Reasons for dropouts were cited as lack of transportation, difficulty in finding childcare, lack of time to schedule appointments and lost to follow-up. Women with pregnancy complications were more	**QAT Rating:** Weak **Strengths:** Therapists adherence to treatment manuals was measured and reported. **Limitations:** Sample taken from one antenatal clinic – limited generalisability. Lack of consistency in format of intervention delivery (group and individual CBT), and those receiving the trauma-sensitive obstetric care. No control group was used. High rates of drop-out. Effect sizes not reported and means not available for calculation.

					likely to stay in treatment (χ^2 = 6.11, *p* >0.5). **Conclusion:** TO-CARE programme may help to reduce trauma related symptoms, or to enable a stability of symptoms during transition to motherhood which is a recognised risk period for exacerbation in distress.	No fidelity checks carried out.
8. Upshur, Wenz-Gross, Weinreb, and Moffitt, (2016)	149 African-American (14%), Hispanic (66%), Caucasian (12%) and Other (8%) pregnant women experiencing sub-threshold levels of PTSD, as measured by the Primary Care PTSD Screen (score greater than >2), and comorbid substance misuse.	Mixed-methods controlled clinical trial Prevention study	**Primary:** Posttraumatic Stress Scale **Secondary:** Primary Care PTSD Screen Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) Drug Abuse Screening Test (DAST-10)	**Intervention:** Seeking Safety Programme – 8 x individual sessions of a manualised psychosocial education programme based on the model of CBT. **Focuses on:** • Improving coping skills • Understanding PTSD • Safety • Self-care • Setting boundaries in relationships. Supported by a participant's workbook and weekly homework.	**Results:** Negative coping skills were reduced in the intervention group (*p*<0.5, *d* = 0.39) but PTSD symptoms were not. 57.3% of women attended all intervention sessions. Cohen's d = 0.39 (small) Intervention group attended significantly more prenatal care appointments (*M*=11.7 versus 8.9; p<.001) than controls. 1.8% of eligible sample declined to participate. Women declining were	**QAT Rating:** Weak **Strengths:** All measures used were valid and reliable, with details given for each. All confounding variables were controlled for during analysis. Fidelity checks carried out. **Limitations:** Testing sites were randomised, rather

	Minority within Massachusetts, USA		Edinburgh Postnatal Depression Scale Adequacy of prenatal care utilization index Brief COPE Questionnaire	**Comparator:** Treatment as Usual – routine antenatal care and access to psychosocial support offered by health centres.	more likely to be White (p = .02). 8% of total sample dropped out due to, declining intervention, early miscarriage, relocation, and a language barrier. **Conclusion:** Providing Seeking Safety sessions to women screening positive for PTSD symptoms increased participation in routine antenatal care and may reduce the use of negative coping strategies.	than individuals, leading to differences in sample characteristics between groups. Drop-out rates not described. Blinding was not described.
9. Tandon, Perry, Mendelson, Kemp, and Leis (2011)	98 African-American (85%) Caucasian (8%) Other (7%) pregnant (36%) or postpartum women (64%) who reached clinical cut-off (>16) on the Center for Epidemiologic Studies Depression Scale	Controlled-Clinical Trial Prevention study	**Primary:** Beck Depression Inventory (BDI-II) **Secondary:** Maternal Mood Screener (MMS) Center for Epidemiologic Studies Depression Scale	**Intervention:** Mother & Babies Course - 6 x 2-hour group sessions run by a clinical social worker or clinical psychologist, based on a CBT model. Transportation, childcare, a meal was provided at each session. **Focusses on:** • Understanding mood and health • Relaxation	**Results:** A significant effect for time, (F (2,112) = 6.0, p< .01, η^2=.10). A significant interaction between time X condition, (F (2,112) = 4.1, p= .02, η^2=.07). No significant difference between groups (F (1,56) = 0.62, p=.43, η^2=0.1). Only 9% of participants in the treatment condition met clinical cut off for	**QAT Rating:** Strong **Strengths:** Participants were randomised to intervention and control groups with no identified confounding variables between groups. Measures used are known to be valid and reliable.

	Minority within Baltimore, USA			• Identifying and modifying cognitive distortions • Increasing positive social networks • Developing a positive mother-child attachment • Parenting skills Supported by a participant's workbook and homework tasks. **Comparator:** Treatment as Usual – Home visiting services plus information on perinatal depression	depression at 3 months post-intervention, compared to 33% of controls (X^2 (1, N = 59) = 5.18, p<.05). Mean number of sessions attended was 4.8 out of 6. **Conclusion:** Preventative interventions such as CBT are effective in reducing perinatal depression, or to prevent symptoms worsening.	Fidelity checks carried out. **Limitations:** Blinding not described.
10. Mendelson, Leis, Perry, Stuart, and Tandon (2013)	78 African American (83%) Caucasian (12%) Other (5%) Pregnant women (28%) or women up to 6 months postpartum (56%) with elevated symptoms on the Center for Epidemiological	Controlled Clinical Trial Prevention study	**Primary:** Negative Mood Regulation Scale **Secondary:** Center for Epidemiological Studies Depression Scale	**Intervention:** Mother and Babies Course – 6 x 2-hour psychoeducational (and relaxation) group sessions with 3-8 women per group, based on a cognitive behavioural therapy model. Plus, individual booster sessions at 3 and 6 months postpartum. **Focusses on:**	**Results:** No significant difference in mood regulation between groups from baseline to 3 months postpartum. Significant growth in mood regulation from baseline to 6 months (β=0.16, SE=0.03, p<.001). No significant difference between active coping between groups over time.	**QAT Rating:** Strong **Strengths:** High retention rate of participants. Robust study design. No confounding variables between groups. Measures shown to be reliable.

	Studies Depression Scale and the Maternal Mood Screener Minority within Baltimore, USA		Maternal Mood Screener Interpersonal Support Evaluation List. Brief COPE Questionnaire	• Understanding mood and health • Relaxation • Identifying and modifying cognitive distortions • Increasing positive social networks • Developing a positive mother-child attachment • Parenting skills Supported by a participant's workbook and homework tasks. **Comparator:** Standard antenatal care or home visiting services	**Conclusion:** The MB course enhances mood regulation, which may facilitate prevention of depression over time.	**Limitations:** Randomisation procedure not outlined. Blinding not described. Effect sizes not reported and means to provided for calculation. No fidelity checks carried out.
11. Muñoz et al., (2007)	41 Latina (100%) pregnant women at-risk for postnatal depression as scored on the Maternal Mood Screener (score >16). Minority within California, USA	Randomised-Controlled Trial Prevention study	**Primary:** The Center for Epidemiologic Studies Depression Scale **Secondary:** Edinburgh Postnatal Depression Scale	**Intervention:** Mother and Babies Course – 12 x psychoeducational (and relaxation) group sessions with 3-8 women per group. Plus, four individual booster sessions a 1, 3, 6 and 12 months postpartum. **Focusses on:**	**Results:** No significant differences in depressive symptoms were found between groups post-intervention. At follow-up, incidence of postnatal Major Depressive episodes was reduced in the intervention group (14%) compared to controls (25%), (χ^2 (2) = 11.90, p=.003, *h* = 0.28).	**QAT Rating:** Strong **Strengths:** High retention rate of participants. Robust study design. No confounding variables between groups.

			The Maternal Mood Screener	• Understanding mood and health • Relaxation • Identifying and modifying cognitive distortions • Increasing positive social networks • Developing a positive mother-child attachment • Parenting skills Supported by a participant's workbook and homework tasks. **Comparator:** Treatment as Usual – routine antenatal care and access to psychosocial support offered by health centres.	31% of eligible sample declined to participate. Reasons for drop out are cited as miscarriage of pregnancy and lost to follow-up. **Conclusion:** The intervention may be effective in reducing the incidence of post-natal depression.	All measures used are reliable and valid. **Limitations:** Low retention for follow-up booster sessions (1.4 out of 4 attended on average). Randomisation procedure not outlined. Blinding not described. No fidelity checks carried out.
12. Urizar and Munoz (2011)	86 Hispanic/Latina (78%) Other (22%) pregnant women at high risk for postpartum	Controlled Clinical Trial Prevention study	**Primary:** Salivary cortisol using a Salivette sampling device **Secondary:**	**Intervention:** Mothers and Babies Course - 12 x sessions with approx. 6 women per group. In addition, four booster sessions were delivered at 1, 3, 6 and 12 months	**Results:** At 6 months postpartum, infants of women in the intervention group had significantly lower cortisol levels than control group (F=9.6, p<.001).	**QAT Rating:** Strong **Strengths:** Robust study design. Use of active control group.

depression as measured by the Maternal Mood Screener Minority within California, USA	Maternal Mood Screener Perceived stress measured on an analogue rating scale from 0-100. Center for Epidemiological Studies – Depression scale The Positive and Negative Affect Scale (PANAS)	postpartum to review group material. **Focusses on:** • Understanding mood and health • Relaxation • Identifying and modifying cognitive distortions • Increasing positive social networks • Developing a positive mother-child attachment • Parenting skills Supported by a participant's workbook and homework tasks. **Comparator:** Treatment as Usual – routine antenatal care and access to psychosocial support offered by health centres. **And** A comparator group of non-depressed individuals.	Women in the intervention group had significantly lower cortisol at 18months postpartum than controls (r= -0.36, p<.01). Effect size calculated – Cohen's d = 0.53 (medium) **Conclusion:** Cognitive Behavioural Stress Management group programmes may effectively regulate biological markers of stress among mothers and their infants, therefore decreasing risk for developing health complications.	Use of reliable and valid measures. **Limitations:** Participants are limited to low-income Latina, Spanish-speaking women, and therefore cannot be generalised to alternative populations. Effect sizes not reported No fidelity checks carried out.

13. Grote, Bledsoe, Swartz, and Frank (2004)	9 x African America (75%), Caucasian (17%) and Latina (8%) pregnant women reaching clinical cut-off (>10) on the Edinburgh Postnatal Depression Scale. Minority within Pennsylvania, USA	Cohort Study Treatment study	**Primary:** Edinburgh Postnatal Depression Scale. **Secondary:** Diagnostic Interview Schedule Conflict Tactics Scale Hamilton Rating Scale for Depression Beck Anxiety Inventory Social and Leisure Domain of the Social Adjustment Scale Inventory of Interpersonal problems Medical Outcomes	**Intervention:** Brief Interpersonal Psychotherapy (IPT-B) - 1 x engagement individual session and 8 x individual sessions of brief Interpersonal psychotherapy (IPT-B) for depression with a focus on role transition, role dispute, grief, and interpersonal deficits. Monthly maintenance sessions for six-months postpartum. **Focusses on:** Resolving interpersonal problems from one of the following areas. • Grief • Interpersonal disputes • Role transition • Complicated pregnancy **Comparator:** No comparator.	**Results:** Significant reduction in scores on the EPDS from pre to post intervention ($t(11) = 4.0$, $p<0.1$, ES = 1.5), and at six months postpartum ($t(11) = 2.9$, $p<.05$, ES=.8). Effect size calculated – Cohen's d = 2.29 (large) Similar reductions and statistical significance on BDI, HRSD & BAI at pre to post intervention and 6 months postpartum. 25% of sample dropped out. Reasons cited include; unstable home environment, didn't feel treatment was warranted, and lost to follow-up. **Conclusion:** Providing brief interpersonal psychotherapy to pregnant women can be effective in reducing symptoms of depression for up to six months postpartum.	**QAT Rating:** Moderate **Strengths:** Measures were shown to be reliable and valid. Moderate retention of participants. Considerable adaptations made to ensure a culturally relevant intervention. Fidelity checks carried out. **Limitations:** Small sample size. No comparator group.

			Study Social Support Survey New Baby subscale of Postpartum Adjustment Questionnaire			
14. Grote et al. (2009)	53 African-American (62%) White (15%) Latina (2%) Mixed (3%) pregnant women scoring above clinical cut-off (>12) on EPDS. Minority within Pennsylvania, USA	Randomised-Controlled Trial Treatment study	**Primary:** Edinburgh Postnatal Depression Scale **Secondary:** Beck Depression Inventory (BDI) Beck Anxiety Inventory (BAI) Social and Leisure Doman of the Social Adjustment Scale (SAS) Postpartum Adjustment	**Intervention:** Brief Interpersonal Psychotherapy (IPT-B) - 1 x engagement individual session and 8 x individual sessions of brief Interpersonal psychotherapy (IPT-B) for depression with a focus on role transition, role dispute, grief, and interpersonal deficits. Monthly maintenance sessions for six-months postpartum. **Focusses on:** Resolving interpersonal problems from one of the following areas; • Grief • Interpersonal disputes • Role transition	**Results:** Significant differences in depression symptoms during pregnancy and before childbirth within treatment group compared to controls (X^2 = 9.06, df=1, p<.003; Cohen's h= .96). Significantly improved social functioning at six months postpartum in treatment group (X^2 = 21.16, df=1, p<.001, Cohen's h = 1.17). Engagement was higher in the intervention group with 68% completing a full course of treatment, compared with only 7% of comparator.	**QAT Rating:** Moderate **Strengths:** Considerable adaptations made to ensure a culturally relevant intervention. Participants randomised to intervention and control groups, with no identified confounding variables between groups. Reliable and valid measures used. Fidelity checks carried out.

			Questionnaire (PPAQ)	• Complicated pregnancy **Comparator:** Enhanced usual care	25% of eligible sample declined to participate. Main reasons cited was a lack of time. **Conclusion:** Enhanced IPT-B ameliorates depression symptoms during pregnancy, prevents postpartum relapse and improves postpartum social functioning.	**Limitations:** Sample referred by professionals from one antenatal clinic – limited generalisability. Researchers were not blinded to conditions.
15. Spinelli (1997)	13 Black (15%), Caucasian (31%), Hispanic (54%) pregnant women who met clinical cut-off score (>12) on the Hamilton Depression Ratings Scale. Minority within New York, USA.	Cohort Study Treatment study	**Primary:** Beck Depression Inventory **Secondary:** Hamilton Depression Rating Scale Edinburgh Postnatal Depression Scale Clinical Global Impression	**Intervention:** 16 x 50-minute sessions of individual interpersonal psychotherapy sessions. **Focusses on:** Resolving interpersonal problems from one of the following areas; • Grief • Interpersonal disputes • Role transition • Complicated pregnancy **Comparator:** No comparator	**Results:** Significant decrease in mean depression scores after intervention on Hamilton Depression Rating Scale (*t*=11.0, p<0.01), BDI (t=4.9, p<0.01), EPDS (t = 4.3, p<0.01), and Clinical Global Impression (t=6.8, p<0.01). Effect size calculated – Cohen's d = 3.06 (large) **Conclusion:** Interpersonal psychotherapy may be an effective intervention for individuals with antepartum depression.	**QAT Rating:** Moderate **Strengths:** Measures used were reliable and valid. **Limitations:** No comparator group. Small number of participants. No details regarding dropouts. Effect sizes not reported. No fidelity checks carried out.

16. Spinelli and Endicott (2003)	38 Latina (66%) White (29%) African American (5%) pregnant women scoring above clinical cut off (> 12) on Hamilton Depression Rating Scale Minority within New York, USA	Controlled Clinical Trial Treatment study	**Primary:** Edinburgh Postnatal Depression Scale **Secondary:** Hamilton Depression Rating Scale Beck Depression Inventory (BDI) Clinical Global Impression Maudsley Mother Infant Interaction Scale	**Intervention:** 16 x 45minute individual interpersonal therapy sessions with a trained therapist. **Focusses on:** Resolving interpersonal problems from one of the following areas; • Grief • Interpersonal disputes • Role transition • Complicated pregnancy **Comparator:** 16 x 45 minutes individual sessions of didactic educational material	**Results:** Significantly greater improvement in EPDS scores for the treatment group, compared to the control (t=2.99, df=36, p=0.005). Similar significant improvement on Hamilton Depression Rating Scale (t=2.42, df=36, p<0.03), BDI-II (t=2.72, df=31, p<0.02). 25% of initial sample entered the study. 76% of the eligible sample completed at least one session. **Conclusion:** Interpersonal psychotherapy is an effective intervention for depression during pregnancy.	**QAT Rating:** Moderate **Strengths:** Robust study design No significant differences between group characteristics. All measures were valid and reliable. **Limitations:** A high attrition rate as from a reported figure of “over 200”, only 38 completed the study. Researchers were not blinded to treatment conditions. Effect sizes not reported and means not provided for calculation. No fidelity checks carried out.

17. Stevens et al., (2018)	67 African-American (31%), Hispanic/Latina (33%), Caucasian (36%) pregnant (31%) and postpartum women (69%) referred to an outpatient psychotherapy clinic for mental health treatment. Minority within Chicago, USA.	Cohort study Treatment study	**Primary:** Beck Depression Inventory-II (BDI-II) **Secondary:** Personality Assessment Inventory Patient Health Questionnaire (PHQ-9) Generalised Anxiety Disorder (GAD-7) PTSD Symptom Checklist (PCL-5)	**Intervention:** Coordinated care model - Individually tailored treatment plan, which may include individual psychotherapy (CBT, IPT, DBT, ACT, MI, PE, CPT), psychiatric medication, group therapy, or reproductive health support. Number of sessions and combination of above is led by clinical need. All interventions are informed by intersectionality theory. **Focusses on:** Each intervention was person-focussed. **Comparator:** None.	**Results:** 65.9% of participants demonstrated reliable change in symptoms on one measure (RCI lower than 1.96). No significant difference between ethnicity groups. 16.4% of total sample dropped out. Mean number of sessions attended was 17.79. White women had lowest rates of returning to therapy postpartum (57.1%; $\chi^2 = 6.11$, $p = 0.47$). No ethnic disparities between treatment engagement. **Conclusion:** This model may be a promising approach to reducing perinatal mental health disparities	**QAT Rating:** Strong **Strengths:** All measures used are reliable and valid. High uptake and low drop-out rates. **Limitations:** No control group. Effect sizes not reported.

Study Characteristics

Study characteristics of the 17 papers included in the review can be found in Table 3.

Research aims

Efficacy of interventions within a perinatal population were assessed within ten papers (2, 4, 5, 6, 9, 10, 12, 14, 17), and seven examined the feasibility of the intervention (1, 3, 7, 8, 11, 13, 15, 16).

Design

Based upon the EPHPP Quality assessment tools specified research designs, five studies used a randomised controlled trial (RCT) design (2, 4, 5, 11, 14), with clear details regarding the randomisation process. A further seven used a controlled clinical trial (1, 6, 8, 9, 10, 12, 16) randomising their sample, but not describing the randomisation process, and five used a cohort study design (3, 7, 13, 15, 17), using pre-post outcomes for one group.

Sample size

There was considerable variability in sample sizes between studies; from 9 to 217 participants. As expected, cohort design studies had smaller sample sizes, ranging from 12 to 45. Sample sizes for the feasibility studies ranged from 9 to 149. Notably four studies had under 40 participants, which is under the limits recommended for a feasibility study (n=30/condition, 1, 3, 9, 16). Sample sizes for the efficacy studies were between 53 and 217, with only one study being fully powered, according to their reported sample size calculations (6). One study failed to gain statistical power based

upon their calculations (4), and seven efficacy studies did not report any power calculation.

Sample sizes for treatment studies (6, 13, 14, 15, 16, 17) was between 9 and 187, which was typically smaller than those for prevention studies (1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12), which ranged from 26 to 217, consistent with the smaller effect sizes normally found in prevention studies. The majority of studies had less than 60 participants (1, 3, 7, 11, 13, 14, 15, 16), although in a notable exception, three prevention studies (4, 5, 8), and one treatment study (6) had samples over 100.

Participants

All studies were completed and published within the USA, thus all participants were minorities within the same country.

Nine studies recruited participant groups that were “at-risk” of postnatal depression (PND; 1, 2, 3, 4, 5, 9, 10, 11, 12) or currently meeting clinical criteria for depression (6, 7, 13, 14, 15, 16). Two focused on the treatment of post-traumatic stress disorder (PTSD) in women with elevated symptoms (7, 8), and one paper included women with depression, anxiety and trauma symptoms (17).

Three studies focused specifically on one minority ethnic group; African-American (1) and Latina (5, 11). Two focused on using one population of minority participants (e.g. Black), alongside Caucasian participants (3, 4). Twelve studies had a multi-ethnic population of Black, Hispanic, Latino, Asian, Caucasian and Other women (2, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17). Nine studies purposefully recruited minority women as their target population (1, 3, 4, 5, 6, 7, 11, 13, 14), but three recruited low-income women only as their target population (2, 9, 12), and met criteria for this review by chance.

A total of fourteen studies recruited women during pregnancy only (1, 2, 3, 4, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16). Eleven completed the intervention within the pregnancy period (1, 2, 3, 4, 5, 7, 8, 11, 12, 13, 14), although eight went on to provide ‘”booster sessions” or “maintenance sessions” during the postnatal period (1, 2, 5, 7, 11, 12, 13, 14). An additional three papers recruited women during pregnancy or postnatally (9, 10, 17). None of the identified studies recruited postpartum women only.

Intervention

Descriptions of all interventions can be found in Table 3. Of all 17 studies, twelve specifically describe the intervention as ‘culturally tailored” (1, 2, 3, 4, 5, 6, 9, 10, 11, 12, 13, 14). However, only six of these describe the process of tailoring the intervention (4, 5, 8, 11, 13, 14). Characteristics of each intervention are reported in Table 3.

Comparators

Overall, eleven studies compared the intervention to treatment-as-usual within the clinics they had recruited from (1, 2, 4, 5, 6, 8, 9, 10, 11, 12, 14), with two of these including a further comparator of a non-depressed intervention group (6, 12). Additionally, one study compared the intervention to another non-therapeutic intervention which provided individual sessions of didactic parenting education (16), and 5/17 (29%) studies did not include a comparator (3, 7, 13, 15, 17).

Measures

In the assessment of depression symptoms, the Edinburgh Postnatal Depression Scale (EPDS) was the most widely used primary outcome measure,

documented within seven studies (1, 3, 4, 13, 14, 15, 16). The Beck Depression Inventory-II (BDI-II) was used by five studies (2, 5, 6, 9, 17). Other primary measures used to assess depression symptoms were the Center for Epidemiological Studies Depression Scale; used by one paper (11). One study did not assess mood, and instead opted to use a measure of mood regulation, known as the Negative Mood Regulation Scale (10). Additionally, one study used salivary cortisol levels as their primary outcome (12). The primary outcome measures used in the assessment of PTSD, were the PTSD Symptom Checklist (7), and the PTSD Scale (8).

Quality Appraisal

The quality of the studies are presented in Table 3. Overall, the preventative studies demonstrated more methodological rigour, with seven of the nine preventative interventions adopting a randomised controlled approach. A total of six studies received an overall rating of “strong” (2, 9, 10, 11,12, 17), six received a “moderate” rating (1, 4, 5, 13, 14, 16) and five received a “weak” rating (3, 6, 7, 8, 15).

Synthesis of results

The results can be found in Table 3, including a description of each intervention, the studies’ main findings and conclusions.

Efficacy of interventions

Prevention interventions.. The Seeking Safety programme (8), was the only individual preventative intervention, and was based on a CBT model. Materials were presented in both English and Spanish, and these were translated into alternative languages where requested. 57% of participants received all sessions, with 81%

attending at least half. Individuals in the treatment group had significantly greater improvement in PTSD symptoms, compared with controls, with a small between group effect size. Additionally, there were significant between group differences on secondary outcomes, including a reduction in negative coping strategies and more antenatal care appointments being attended than controls.

The further eight studies investigating a preventative CBT intervention were delivered in a group format. Insight Plus (3, 4), was developed following an initial focus group (4) and tailored for the specific needs of the targeted ethnic minority group by making a number of adaptations. These included, reading material being presented at the reading age of a 10-year-old, and translated into Spanish; facilitators aiming to be positive, and non-judgmental, and to be open to "spirit[ually]-related resources". Furthermore, transportation and child-care were provided. A range of completion rates were reported from 76% (4) to 94% (3) of participants completing the trial and follow-up points. Both papers reported significant improvement in depressive mood at post-intervention, compared with controls, with a large (3) and medium (4) between-group effect size. Additionally, when compared with controls, significant improvements in depressive mood were reported at one-month post-intervention by both papers. A specific ethnic variance was found by paper 4, reporting that African-American women had significantly improved mood at post-intervention, and at one-month follow-up, when compared to controls.

The Mother and Babies course (5, 9, 10, 11, 12), also known as Mamas y Bebes, was originally developed by the authors of paper 11 for Latina women as a prevention for depression. However, papers 9 and 10 applied this to a multi-ethnic population. Paper 5 reported that specific adaptations were made in response to a focus group. The course was taught in Spanish, with bi-lingual and/or bi-cultural

research staff. Sessions were recorded and reviewed by a bilingual and bi-cultural author, who also provided supervision to the facilitators. Paper 11 described delivering the intervention in Spanish, and weaving particular features of the Latina culture within the content, using culturally relevant examples and touching on specific cultural values, such as religion. A range of retention rates were reported, with 54% (11) to 80% (9) of sessions being fully attended. Engagement with booster sessions were also varied, from 35% (11) to 69% (5). Paper 5 reported significant improvement in depressive mood at post-intervention, compared with controls, with a small effect size. However, paper 11 failed to find a significant difference between groups in mood, with a small reported effect size. Additionally, paper 10 failed to find a significant difference between groups in active coping immediately after the intervention. Significant improvements in mood were reported at the follow-up points; 3-months (9; small effect), 6 months (10, 12), and 12 months (12), with significantly lower cortisol levels in the infant at 6 months, and within the mother at 18 months, compared to controls (12), with a medium effect. The one study that assessed mood regulation found no significant difference between groups (10). Two studies report that the incidence of PND was significantly lower in the intervention group compared to controls (9, 11), both with a small effect size. Additionally, one study failed to find a significant difference in incidence rates between groups, and also reported a low effect size (5).

The TO-CARE programme (7) for individuals with sub-threshold PTSD was attended by 47% of participants. Women with pregnancy complications were more likely to stay in treatment (7) than those without. Reliable change was demonstrated at post-intervention, and again at 1-month follow-up.

Two papers described a group intervention based on the model of Interpersonal Psychotherapy (IPT) to prevent PND (1, 2). The ROSE programme did not describe

any specific cultural adaptations. A range of 66% (2) to 92% (1) of all sessions were fully attended. The reason for drop-out was commonly ‘relocation’. Improvement in mood immediately following the intervention was not statistically different to controls, with a low reported effect size (1). However, compared to controls there was a significant improvement in the secondary outcome of postpartum adjustment (1; small effect size) and improvements in depression scores over-time, as measured at 3-month follow-up (1), and less incidence of post-natal depression at 3-month follow-up (2; small effect size).

Overall, papers describing preventative interventions demonstrated rigour within their methodological approach. Seven utilised a randomised controlled design or a controlled clinical trial (1, 2, 4, 5, 8, 9, 10, 11, 12), three made use of fidelity testing (5, 8, 9), two used intent-to-treat analysis (5, 8) and six reported effect sizes (3, 5, 8, 9, 11). Three papers included both an active control group and treatment-as-usual as a comparator (1, 2, 12) whereas six used treatment-as-usual only as a control (4, 5, 8, 9, 10, 11). Overall, the quality of studies investigating preventative interventions was variable, with four rated as strong, two as moderate, and three as weak. Therefore, there remains to space for increased rigour within these.

Treatment interventions. All treatment interventions were delivered within an individual format. Only one traditional CBT treatment intervention with no cultural adaptations was described (6). 57% completed the study, with slightly more non-depressed women dropping out (non-significant). Non-completers were more likely to live less than 1-year at their current address, and to be Hispanic. This study reported a significant decrease in mood/symptoms at post-intervention, and at follow up, with a medium within-group effect size. However, no significant difference was found

between controls.

A further four papers described an intervention for depression, based upon an IPT model (13, 14, 15, 16). A manualised version of Brief Interpersonal Psychotherapy (IPT-B) was described by two papers (13, 14). Both papers described including using the engagement interview prior to intervention, to elicit sociocultural information so that individual cultural needs could be met by the therapist. Sessions were run in a women's health clinic to promote accessibility. If sessions were not attended, telephone sessions could be supplemented. Participants were reimbursed for financial costs incurred for travel and childcare. Paper 13 reports 75% of participants completing the trial, with 66% engaging in at least one session by telephone. Paper 14 reports higher rates of treatment engagement in the intervention condition (68%) compared to controls (7%). Both papers reported significant reductions in mood, when compared to controls, with large effect sizes. Mood was also significantly improved (13), along with social functioning (14) at 6 months follow-up.

Two additional papers focused on a traditional approach to IPT (15, 16). No cultural adaptations were described. Paper 16 described 76% of randomised participants completed at least one session. Both papers reported significant improvements in mood, when compared to controls, with a large effect size (15).

The final treatment study provided a 'coordinated perinatal mental health care model' with a cohort design. This is described as an individually tailored treatment plan, which may include individual psychotherapy (such as, Cognitive-Behavioural Therapy, Interpersonal Therapy, Dialectical Behaviour Therapy, Acceptance & Commitment Therapy, Motivational Interviewing etc), psychotropic medication, group therapy, or reproductive health support. The number of sessions and combination of the above is led by clinical need, and informed by intersectionality theory. No cultural

adaptations are described. 84% of participants completed at least 6 sessions, with an average of 17.79 (SD = 13.05) sessions completed. 65.9% of participants demonstrated reliable change in symptoms at post-intervention. No significant differences were found between ethnic groups, but effect sizes were not reported. This study did not measure at follow-up, or against a comparator.

There is variability in the methodological rigour reported within the treatment papers describing treatment interventions. Three papers described a randomised controlled or controlled clinical trial design (6, 14, 16), three reported effect sizes (6, 13, 14), three used intent-to-treat analysis (6, 13,14), two utilised fidelity checks (13, 14) and two used an active control group (6, 16). The quality of all the IPT treatment studies were rated as moderate, the one CBT intervention paper was rated as weak (6).

Barriers and Facilitators

Studies reported a range of participants that did not enter the studies from the initial pool of potential participants, or dropped-out; from 2% (8) to 75% (16). Reasons reported included; not maintaining telephone contact/lost to follow-up (3, 4, 7, 11, 13), relocation of participants (1, 2, 3, 8), miscarriage (4, 8, 11), a lack of transportation (1, 4, 7), and a lack of time (7, 14). Other papers reported individual reasons such as lack of childcare (7), or language barriers (8), an unsafe home environment (13). One study found that individuals who had lived at their current address for less than one year were more likely to drop out of the intervention (6).

Preventative interventions were generally well attended, with almost all studies retaining above 50% of participants until post-intervention. However, paper 4 described specific attrition within the intervention group, compared to controls. Trial

completed rates were generally lower for the two interventions aimed at preventing PTSD (7, 8). Highest completion rates were reported within the IPT group intervention, with up to 92% completion rate.

Engagement with treatment interventions was encouraging, with between 57% (6) and 76% (16) of all sessions being completed, with IPT-B being more well attended than CBT interventions. Interestingly, paper 13 reported significantly more participants dropping out of treatment-as-usual, compared to the IPT-B intervention.

Studies found varied results regarding which ethnic group were more likely to decline or drop-out of treatment. Overall, only three papers reported drop-out rates by ethnicity, all of which described individual interventions. However, each described a different approach. Paper 8, providing CBT for PTSD, found that White women were more likely to drop-out than minority groups (8); another CBT intervention for depression found that Hispanic women were more likely (6); and the paper describing the coordinated care programme (17) found no ethnic differences in drop-outs, but did describe that White women were significantly less likely to return to therapy during the postpartum period compared to other ethnic groups.

Discussion

The purpose of this review was to evaluate the current evidence base for interventions for perinatal mental health disorders within ethnic minority populations and to explore the barriers and facilitators to care. Seventeen studies were included for review, which included both preventative and treatment interventions. CBT and IPT were the most commonly tested interventions in this population, conducted in both group and individual formats.

Preventative interventions

Preventative interventions for depression and PTSD included both CBT and IPT approaches. The overall methodological rigour of these studies was generally good, with 64% utilizing a randomised controlled design or a controlled clinical trial. Overall, both the CBT and IPT studies for perinatal depression demonstrated that, although improvements were made at post-intervention there was minimal short-term between-group effects. However, at longer-term follow-up points there were consistently greater effects in the intervention versus control group. Interestingly, one of the studies reporting a CBT intervention for postpartum depression described the greatest duration of sessions (5), with 16 hours plus three additional "booster sessions", showed the smallest impact despite having a large sample size. This may have been a result of high attrition rates within the intervention group, pointing to the importance of attending to the acceptability of the intervention and addressing issues related to access.

The results of the review provided preliminary evidence that CBT may be effective for preventing PTSD within an antenatal ethnic minority population, however engagement was lower in this population than within studies for postnatal depression. This may have been due to the nature of PTSD, with avoidance being characteristic of the condition. Therefore, further research is required to investigate ways in which these populations can be engaged further in interventions.

Papers describing preventative interventions measuring against a control group, generally report a significant within-group improvement at post-intervention (55%), but one that was no different to the effects of treatment-as-usual. This lack of findings could be reflective of the nature of preventative work, where women with sub-threshold symptoms are recruited with the aim of preventing these from worsening,

resulting in small effect sizes. It is notable that this approach would require a large sample size, and the majority of these studies were small to medium in size. However, it is notable that at longer-term follow-up (6 months after the intervention) there were greater improvements and less incidence of PND, compared with controls. This demonstrates that indeed these interventions have been effective at preventing, or at least reducing, perinatal mental health problems in the longer-term.

Treatment interventions

Of all treatment interventions, three models of intervention were reported (CBT, IPT and coordinated care), by six papers. These were variable in their methodological rigour, with 50% utilising a randomised controlled or controlled clinical trial design. Only one study investigated a CBT treatment intervention and described a significant within group improvement in mood, but no difference between groups. Although this study had a relatively large sample size, it had notably high rates of attrition, which would have affected its ability to detect between-group differences.

More promising results were found with the three studies investigating IPT treatments, despite having a significantly lower sample size, all papers reported large effect sizes and a significant reduction in mood at post-intervention and/or follow-up. The two studies utilising a control group also reported significant between-group differences. This suggest that IPT may be especially appropriate intervention for the ethnic minority groups described.

The one paper examining the coordinated mental health care model, demonstrated reliable change in 65.9% of participants. However, in this complex intervention, it wasn’t possible to ascertain which aspects of the interventions were most effective, e.g. the psychological intervention, psychopharmaceuticals or case

management, or whether these would be more effective than treatment-as-usual, due to a lack of a comparator group. Further, the lack of control group or follow-up data limits the conclusions one can draw regarding long-term impact. It is perhaps possible that reliable change was brought about by the person-centred aspects of this model, and the flexibility in duration and content of intervention. However, given the difficulties that persons from ethnic minorities have with engaging and completing interventions, and the high levels of document engagement within this treatment, further research is required to replicate this approach using a large-scale between-group design.

In consideration of all treatment interventions described, it is possible to conclude that individual IPT is more effective as a treatment for depression within the perinatal period for minority women, which is interestingly similar to reports within a general population (Sockol et al., 2011). However, it is important to note that the CBT treatment and coordinated care model were only represented by one paper each, and so there is a need for further research within these areas.

In sum, the results of this review point to the promise of psychological treatment interventions for ethnic minorities experiencing perinatal mental health problems. However, they also highlight the importance of treatment acceptability and improving access and adherence to interventions. Recent research in the UK using large scale clinical data has shown that perinatal ethnic minorities are less likely to access care earlier on in their mental health problems and this may be related to their higher than expected rates of admissions to inpatient mental health hospitals (Jankovic et al., 2020). Such results highlight the critical importance of ensuring equality of access across ethnic groups, and the importance of understanding the needs of ethnic minorities and how to best engage these groups.

Barriers and facilitators

In this review, many studies were able to retain a vast range of ethnic minority participants, with the most commonly cited reason for drop-out being “not maintaining telephone contact/lost to follow-up”. It appears that the home environment and lifestyle had a large impact on a participants’ ability to engage, with relocation being a frequent reason, as well as living at their home address for less than a year being a predictive factor for trial drop-outs. Other reasons such as lack of transportation and childcare were cited, despite a number of studies offering financial support to enable them to attend.

Of the interventions describing a specifically culturally tailored intervention, trial completion was generally high, ranging from 54% to 92%. Interventions that specifically designed their interventions for ethnic minority populations (such as the Mothers and Babies Course, and the Rose programme) were particularly high across the representing papers, with the majority reporting above 75% engagement. This was generally higher than rates reported by papers not describing specific tailoring of the intervention for ethnic minority groups, with around 40-50% engagement being reported.

The adaptations described were; providing written materials in the population’s first language, providing or reimbursing child-care and transportation costs, and intervention facilitators being either bi-lingual or bi-cultural themselves, or considerations being made around how to respond to the cultural needs of attendees. Although from the results it is not possible to point to which specific adaptations were responsible, it appears that these measures contribute to women feeling more able to engage with these therapies. However, surprisingly there appears to be little evidence that it improves the efficacy of these interventions, with similar results found across

those interventions that do not describe being culturally tailored. These results demonstrate that cultural adaptations may improve the acceptability and adherence to interventions for ethnic minority populations, and in doing so may reach individuals that would otherwise have dropped-out of treatment. With this in mind, it is imperative that services consider culturally appropriate adaptations for those individuals they may be hoping to engage in treatment.

Strengths and Limitations

To date, this is the first systematic review of the evidence surrounding interventions for perinatal populations from ethnic minorities. This review is strengthened by the utilisation of a systematic approach and adherence to the priori protocol. This included a comprehensive search strategy and did not limit the eligibility of studies by date, country of origin, or quantitative design. Furthermore, the inclusion of a second rater for both data extraction and quality assessment of a proportion of studies enhances the reliability of the findings.

Whilst this review developed a number of noteworthy conclusions regarding the efficacy of interventions for this population, a number of limitations exist. Surprisingly, whilst there were no restrictions on geographical area, only American studies were identified. The experience of being an ethnic minority in the UK will be different to that of one within the USA, with varying cultures and health care systems, and therefore this review presents a biased view and limits the ability to generalise these findings internationally, including within a UK context. Further, this review was limited to studies carried out where participants were a minority ethnicity within a majority population, which therefore excluded several studies carried out internationally, which may have provided further insight into this topic. Future research may benefit from including

these papers within their criteria. Furthermore, some papers investigated low-income populations, and met criteria for this review by chance. It is therefore difficult to draw conclusions regarding which factor; socio-economic status, or ethnicity, or the interaction that impacts on the efficacy of an intervention. Further research is required to draw upon these.

There was an overwhelming focus on depression in this review, with fourteen of the included studies exploring this diagnosis only. Low mood and depression are one of the most common perinatal mental health problems (Royal College of Obstetricians & Gynaegologists, 2017) and so a large emphasis on this diagnosis was to be expected within the literature. However, other common perinatal mental health problems, such as anxiety disorders, have been entirely overlooked, and is an area that may be of interest to future research.

A limitation of this review is the lack of representation of a postnatal population. This may be due to the majority of studies making use of “at-risk” populations and evaluating preventative interventions, rather than treatments of existing mental health problems. However, this limits the ability to generalise the findings to a postnatal population, in which alternative interventions may be more efficacious.

Only two psychological models were represented within this review; CBT and IPT. Whilst a preference towards this was expected, it is surprising that no other psychological models have been represented. The coordinated care model for example describes the use of a number of additional psychological models, such as ACT and DBT. Whilst the study demonstrated overall reliable change it is not possible to include this in drawing conclusions about the efficacy of individual models as this was not measured. Further research is required to investigate models of care within this population.

Conclusion

This systematic review aimed to explore the efficacy of interventions for ethnic minority women within the perinatal period. Findings suggest that both CBT and IPT are effective interventions for preventing and treating perinatal mental health conditions within this population, in both a group and individual format. A coordinated care model looks to be promising, with a need for further research.

Overall engagement was high and was improved further when interventions were specifically tailored for ethnic minority groups. Although it appeared unnecessary to tailor this to one specific ethnic group. Although this increased engagement, it appeared to do little to impact the efficacy of studies.

Preventative studies reported inconsistencies at post-intervention when compared with controls. However, at follow-up there were greater differences between controls, and less incidence of post-natal depression, suggesting that in the long-term these interventions are effective at preventing PND within this population. Further to this, results showed that IPT was a more effective as a treatment for depression within this population, although further research is required to confirm this.

Given the challenges and barriers to care faced by minority groups, and the substantial positive impact perinatal interventions can have for both mother and the infant, this is an area of great importance and further research is required. It would specifically be helpful for research to examine the efficacy of interventions with alternative diagnoses, therapeutic models other than CBT and IPT, and to be carried out within countries other than the USA.

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Appendices

Appendix A - EPHPP Quality assessment tool

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(01) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(02) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(01) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(02) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(03) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(01) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(02) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(03) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(04) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one):

1 STRONG
2 MODERATE
3 WEAK

Appendix B - EPHPP Quality assessment tool dictionary

Quality Assessment Tool for Quantitative Studies Dictionary

EPHPP
Effective Public Health Practice Project

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)
An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and** the study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or** blinding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix C – Archives of Women's Mental health – Authors Guidance

Instructions for Authors

Types of papers

Original Contributions / Research Articles should be arranged into sections conforming to standard scientific reporting style, i.e. under the following headings: Abstract: Should not exceed 150–250 words and be structured as follows: Purpose, Methods, Results, ConclusionsKeywords: Not more than five, separated by semicolons - Introduction: A brief outline of the background literature leading to the objective(s) of the study - Materials and Methods: Describe the basic study design. State the setting (e.g., primary care, referral center). Explain selection of study subjects and state the system of diagnostic criteria used. Describe any interventions and include their duration and method of administration. Indicate the main outcome measure(s). Specify the dates in which data were collected (month/year to month/year). - Results: Include the key findings. Give specific data and their statistical significance, if possible. Subset Ns should accompany percentages if the total N is ‹100. - Discussion and Conclusions:Discuss your findings critically in comparison to existing literature and considering your methodological and other limitations. Conclusions should highlight the potential meaning for the field given the limitations.The main text (i.e. without abstract, references, figures, tables, or supplementary material) should not exceed 3000 words.

Reviews should be comprehensive, fully referenced expositions of subjects of general interest, including background information and detailed critical analyses of current work in the field and its significance. They should be designed to serve as source materials.Meta-analyses or systematic reviews according to the PRISMA style are preferred.Reviews are not meant to be encyclopedic and should not exceed 4000 words. Reviews may contain figures and tables.

Short Communications should be prepared as described above except for the following: The average length of Short Communications should not exceed 1500 words and may include a maximum of two figures or tables and up to 12 references. The summary should not exceed 80 words.

Letters to the EditorLetters to the Editor should be a maximum of 750 words and may include one table or figure and up to five references.

Case Reports will not be accepted.

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Manuscript Submission

Manuscript Submission

Submission of a manuscript implies: that the work described has not been published before; that it is not under consideration for publication anywhere else; that its publication has been approved by all co-authors, if any, as well as by the responsible authorities – tacitly or explicitly – at the institute where the work has been carried out. The publisher will not be held legally responsible should there be any claims for compensation.

Permissions

Authors wishing to include figures, tables, or text passages that have already been published elsewhere are required to obtain permission from the copyright owner(s) for both the print and online format and to include evidence that such permission has been granted when submitting their papers. Any material received without such evidence will be assumed to originate from the authors.

Online Submission

Please follow the hyperlink "Submit online" on the right and upload all of your manuscript files following the instructions given on the screen.

Please ensure you provide all relevant editable source files. Failing to submit these source files might cause unnecessary delays in the review and production process.

Reviewer Suggestion

Authors will be kindly asked to suggest up to 5 potential reviewers for their papers. These recommendations will be of help to ensure the journal's high scientific level and will support a quick review process and thus shorten the time from manuscript submission to publication.

Please note that only reviewer suggestions from institutions of international reputation other than the institution of the corresponding author will be taken into consideration and you should not have published common articles with the suggested reviewers previously.

Please note that the journal does not offer pre-evaluation. Therefore please directly submit your manuscript to EditorialManager at the below link. The Editorial Office will then contact you.

EditorialManager

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Title page

Title Page

Please use this **template title page** for providing the following information.

The title page should include:

The name(s) of the author(s)

A concise and informative title

The affiliation(s) of the author(s), i.e. institution, (department), city, (state), country

A clear indication and an active e-mail address of the corresponding author

If available, the 16-digit ORCID of the author(s)
If address information is provided with the affiliation(s) it will also be published.
For authors that are (temporarily) unaffiliated we will only capture their city and country of residence, not their e-mail address unless specifically requested.

Abstract

Please provide a structured abstract of 150 to 250 words which should be divided into the following sections:
Purpose (stating the main purposes and research question)
Methods
Results
Conclusion
For life science journals only (when applicable)
Trial registration number and date of registration
Trial registration number, date of registration followed by "retrospectively registered"

Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations'.
If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.
To be used for non-life science journals
Funding (information that explains whether and by whom the research was supported)
Conflicts of interest/Competing interests (include appropriate disclosures)
Availability of data and material (data transparency)
Code availability (software application or custom code)
Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)
To be used for life science journals + articles with biological applications
Funding (information that explains whether and by whom the research was supported)
Conflicts of interest/Competing interests (include appropriate disclosures)
Ethics approval (include appropriate approvals or waivers)
Consent to participate (include appropriate statements)
Consent for publication (include appropriate statements)
Availability of data and material (data transparency)
Code availability (software application or custom code)
Authors' contributions (optional: please review the submission guidelines from the journal whether statements are mandatory)
Please see the relevant sections in the submission guidelines for further information as well as various examples of wording.
Please revise/customize the sample statements according to your own needs.

Important note:

Please ensure your authorship is correct, check spelling of authors' names, line up, etc.
No changes can be made once copyright has been transferred to us.

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Text

Text Formatting

Manuscripts should be submitted in Word.
Use a normal, plain font (e.g., 10-point Times Roman) for text.
Use italics for emphasis.
Use the automatic page numbering function to number the pages.
Do not use field functions.
Use tab stops or other commands for indents, not the space bar.
Use the table function, not spreadsheets, to make tables.
Use the equation editor or MathType for equations.
Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).
Manuscripts with mathematical content can also be submitted in LaTeX.
LaTeX macro package (Download zip, 188 kB)

Headings

Please use no more than three levels of displayed headings.

Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.
Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.
Always use footnotes instead of endnotes.

Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

Important note:

Authors are requested to use **automatic continuous line numbering** throughout the manuscript and in double space.

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References

Citation

Cite references in the text by name and year in parentheses. Some examples:

Negotiation research spans many disciplines (Thompson 1990).

This result was later contradicted by Becker and Seligman (1996).

This effect has been widely studied (Abbott 1991; Barakat et al. 1995a, b; Kelso and Smith 1998; Medvec et al. 1999, 2000).

Reference list

The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

Reference list entries should be alphabetized by the last names of the first author of each work. Order multi-author publications of the same first author alphabetically with respect to second, third, etc. author. Publications of exactly the same author(s) must be ordered chronologically.

Journal article

Gamelin FX, Baquet G, Berthoin S, Thevenet D, Nourry C, Nottin S, Bosquet L (2009) Effect of high intensity intermittent training on heart rate variability in prepubescent children. Eur J Appl Physiol 105:731-738. https://doi.org/10.1007/s00421-008-0955-8

Ideally, the names of all authors should be provided, but the usage of "et al" in long author lists will also be accepted:

Smith J, Jones M Jr, Houghton L et al (1999) Future of health insurance. N Engl J Med 965:325–329

Article by DOI

Slifka MK, Whitton JL (2000) Clinical implications of dysregulated cytokine production. J Mol Med. https://doi.org/10.1007/s001090000086

Book

South J, Blass B (2001) The future of modern genomics. Blackwell, London

Book chapter

Brown B, Aaron M (2001) The politics of nature. In: Smith J (ed) The rise of modern genomics, 3rd edn. Wiley, New York, pp 230-257

Online document

Cartwright J (2007) Big stars have weather too. IOP Publishing PhysicsWeb. http://physicsweb.org/articles/news/11/6/16/1. Accessed 26 June 2007

Dissertation

Trent JW (1975) Experimental acute renal failure. Dissertation, University of California

Always use the standard abbreviation of a journal's name according to the ISSN List of Title Word Abbreviations, see ISSN LTWA

If you are unsure, please use the full journal title.

For authors using EndNote, Springer provides an output style that supports the formatting of in-text citations and reference list.

EndNote style (Download zip, 3 kB)

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Tables

All tables are to be numbered using Arabic numerals.

Tables should always be cited in text in consecutive numerical order.

For each table, please supply a table caption (title) explaining the components of the table.

Identify any previously published material by giving the original source in the form of a reference at the end of the table caption.

Footnotes to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data) and included beneath the table body.

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Artwork and Illustrations Guidelines

Electronic Figure Submission

Supply all figures electronically.

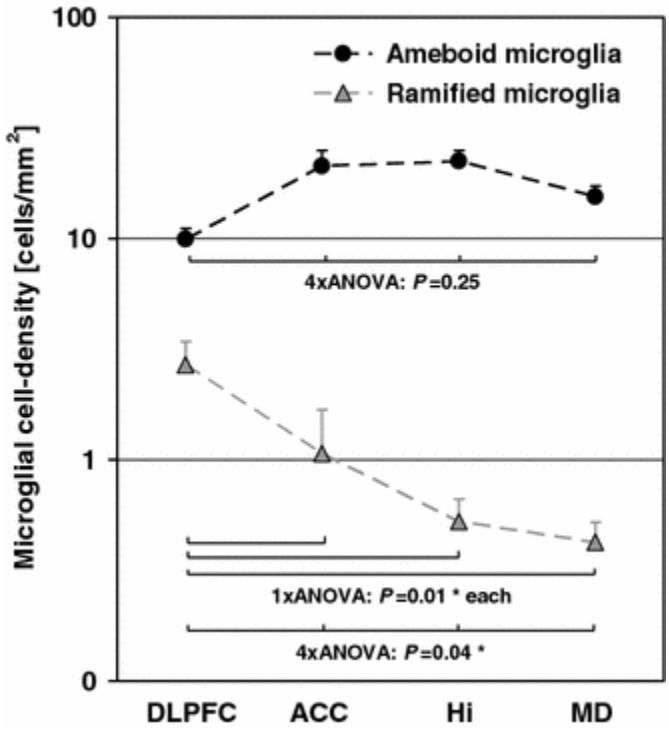
Indicate what graphics program was used to create the artwork.

For vector graphics, the preferred format is EPS; for halftones, please use TIFF format. MSOffice files are also acceptable.

Vector graphics containing fonts must have the fonts embedded in the files.

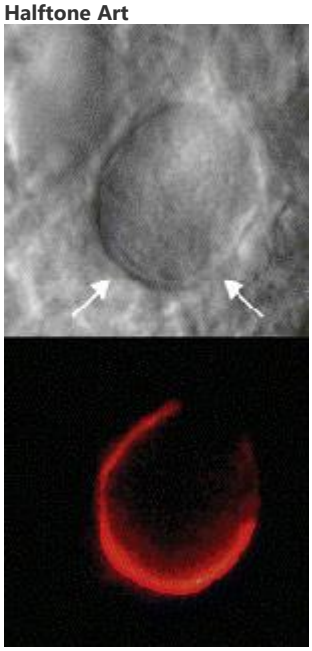
Name your figure files with "Fig" and the figure number, e.g., Fig1.eps.

Line Art



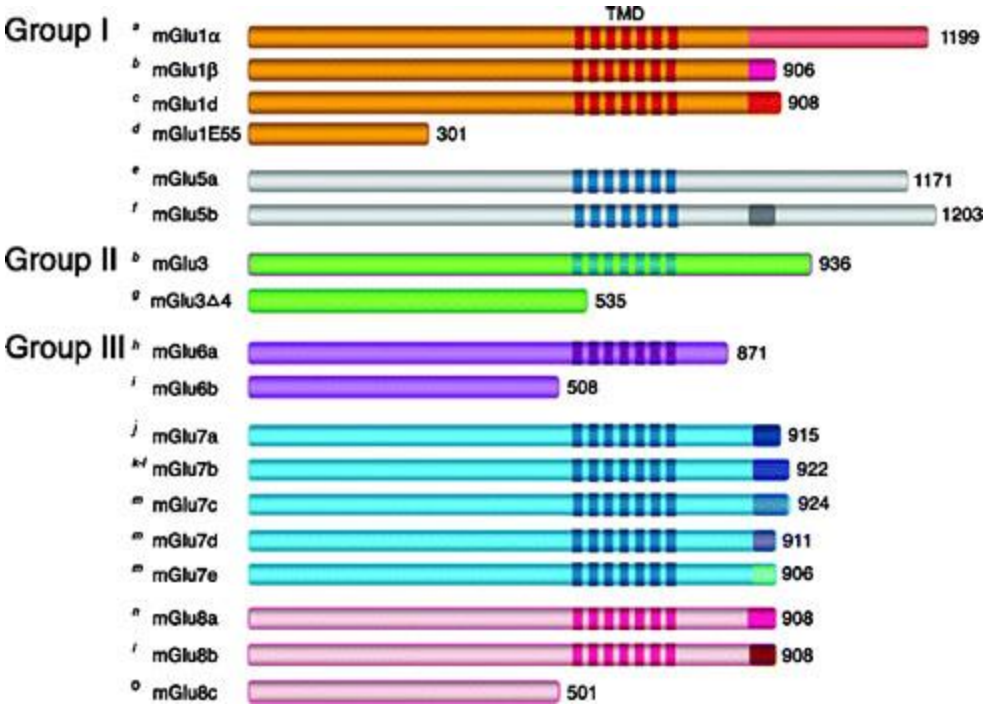
Definition: Black and white graphic with no shading.
Do not use faint lines and/or lettering and check that all lines and lettering within the figures are legible at final size.
All lines should be at least 0.1 mm (0.3 pt) wide.
Scanned line drawings and line drawings in bitmap format should have a minimum resolution of 1200 dpi.
Vector graphics containing fonts must have the fonts embedded in the files.

Halftone Art



Definition: Photographs, drawings, or paintings with fine shading, etc.
If any magnification is used in the photographs, indicate this by using scale bars within the figures themselves.
Halftones should have a minimum resolution of 300 dpi.

Combination Art



Definition: a combination of halftone and line art, e.g., halftones containing line drawing, extensive lettering, color diagrams, etc. Combination artwork should have a minimum resolution of 600 dpi.

Color Art

Color art is free of charge for online publication.

If black and white will be shown in the print version, make sure that the main information will still be visible. Many colors are not distinguishable from one another when converted to black and white. A simple way to check this is to make a xerographic copy to see if the necessary distinctions between the different colors are still apparent.

If the figures will be printed in black and white, do not refer to color in the captions.

Color illustrations should be submitted as RGB (8 bits per channel).

Figure Lettering

To add lettering, it is best to use Helvetica or Arial (sans serif fonts).

Keep lettering consistently sized throughout your final-sized artwork, usually about 2–3 mm (8–12 pt).

Variance of type size within an illustration should be minimal, e.g., do not use 8-pt type on an axis and 20-pt type for the axis label.

Avoid effects such as shading, outline letters, etc.

Do not include titles or captions within your illustrations.

Figure Numbering

All figures are to be numbered using Arabic numerals.

Figures should always be cited in text in consecutive numerical order.

Figure parts should be denoted by lowercase letters (a, b, c, etc.).

If an appendix appears in your article and it contains one or more figures, continue the consecutive numbering of the main text. Do not number the appendix figures,"A1, A2, A3, etc." Figures in online appendices (Electronic Supplementary Material) should, however, be numbered separately.

Figure Captions

Each figure should have a concise caption describing accurately what the figure depicts. Include the captions in the text file of the manuscript, not in the figure file.

Figure captions begin with the term Fig. in bold type, followed by the figure number, also in bold type.

No punctuation is to be included after the number, nor is any punctuation to be placed at the end of the caption.

Identify all elements found in the figure in the figure caption; and use boxes, circles, etc., as coordinate points in graphs.

Identify previously published material by giving the original source in the form of a reference citation at the end of the figure caption.

Figure Placement and Size

Figures should be submitted separately from the text, if possible.

When preparing your figures, size figures to fit in the column width.

For large-sized journals the figures should be 84 mm (for double-column text areas), or 174 mm (for single-column text areas) wide and not higher than 234 mm.

For small-sized journals, the figures should be 119 mm wide and not higher than 195 mm.

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sources should be used.

Accessibility

In order to give people of all abilities and disabilities access to the content of your figures, please make sure that
All figures have descriptive captions (blind users could then use a text-to-speech software or a text-to-Braille hardware)
Patterns are used instead of or in addition to colors for conveying information (colorblind users would then be able to distinguish the visual elements)
Any figure lettering has a contrast ratio of at least 4.5:1

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Electronic Supplementary Material

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Submission

Supply all supplementary material in standard file formats.
Please include in each file the following information: article title, journal name, author names; affiliation and e-mail address of the corresponding author.
To accommodate user downloads, please keep in mind that larger-sized files may require very long download times and that some users may experience other problems during downloading.

Audio, Video, and Animations

Aspect ratio: 16:9 or 4:3
Maximum file size: 25 GB
Minimum video duration: 1 sec
Supported file formats: avi, wmv, mp4, mov, m2p, mp2, mpg, mpeg, flv, mxf, mts, m4v, 3gp

Text and Presentations

Submit your material in PDF format; .doc or .ppt files are not suitable for long-term viability.
A collection of figures may also be combined in a PDF file.

Spreadsheets

Spreadsheets should be submitted as .csv or .xlsx files (MS Excel).

Specialized Formats

Specialized format such as .pdb (chemical), .wrl (VRML), .nb (Mathematica notebook), and .tex can also be supplied.

Collecting Multiple Files

It is possible to collect multiple files in a .zip or .gz file.

Numbering

If supplying any supplementary material, the text must make specific mention of the material as a citation, similar to that of figures and tables.
Refer to the supplementary files as "Online Resource", e.g., "... as shown in the animation (Online Resource 3)", "... additional data are given in Online Resource 4".
Name the files consecutively, e.g. "ESM_3.mpg", "ESM_4.pdf".

Captions

For each supplementary material, please supply a concise caption describing the content of the file.

Processing of supplementary files

Electronic supplementary material will be published as received from the author without any conversion, editing, or reformatting.

Accessibility

In order to give people of all abilities and disabilities access to the content of your supplementary files, please make sure that
The manuscript contains a descriptive caption for each supplementary material
Video files do not contain anything that flashes more than three times per second (so that users prone to seizures caused by such effects are not put at risk)

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Ethical Responsibilities of Authors

This journal is committed to upholding the integrity of the scientific record. As a member of the Committee on Publication Ethics (COPE) the journal will follow the COPE guidelines on how to deal with potential acts of misconduct.
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The manuscript should not be submitted to more than one journal for simultaneous consideration.
The submitted work should be original and should not have been published elsewhere in any form or language (partially or in full), unless the new work concerns an expansion of previous work. (Please provide transparency on the re-use of material to avoid the concerns about text-recycling ('self-plagiarism').
A single study should not be split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (i.e. 'salami-slicing/publishing').

Concurrent or secondary publication is sometimes justifiable, provided certain conditions are met. Examples include: translations or a manuscript that is intended for a different group of readers.
Results should be presented clearly, honestly, and without fabrication, falsification or inappropriate data manipulation (including image based manipulation). Authors should adhere to discipline-specific rules for acquiring, selecting and processing data.
No data, text, or theories by others are presented as if they were the author's own ('plagiarism'). Proper acknowledgements to other works must be given (this includes material that is closely copied (near verbatim), summarized and/or paraphrased), quotation marks (to indicate words taken from another source) are used for verbatim copying of material, and permissions secured for material that is copyrighted.
Important note: the journal may use software to screen for plagiarism.
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Research articles and non-research articles (e.g. Opinion, Review, and Commentary articles) must cite appropriate and relevant literature in support of the claims made. Excessive and inappropriate self-citation or coordinated efforts among several authors to collectively self-cite is strongly discouraged.
Authors should avoid untrue statements about an entity (who can be an individual person or a company) or descriptions of their behavior or actions that could potentially be seen as personal attacks or allegations about that person.
Research that may be misapplied to pose a threat to public health or national security should be clearly identified in the manuscript (e.g. dual use of research). Examples include creation of harmful consequences of biological agents or toxins, disruption of immunity of vaccines, unusual hazards in the use of chemicals, weaponization of research/technology (amongst others).
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*All of the above are guidelines and authors need to make sure to respect third parties rights such as copyright and/or moral rights.
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EMPIRICAL PAPER

Intolerance of Uncertainty and Emotion Regulation in Pregnant Women

Trainee Name:	**Claire Treleaven**
Primary Research Supervisor:	**Professor Heather O'Mahen** University of Exeter
Secondary Research Supervisor:	**Dr Janet Smithsen** University of Exeter
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Abstract

Anxiety during pregnancy is common, with up to 25% of women reporting anxiety symptoms. This has implications for the mother, feotus and for birth outcomes. When anxiety is specifically related to the pregnancy, these risks increase. The current study aimed to investigate the relationship between Intolerance of Uncertainty (IU) and Emotion Regulation (ER) in pregnancy-related anxiety. A convenience sample of 40 pregnant women were randomised into an experimental induction of pregnancy specific versus general uncertainty. Participants completed a Vertical Arrow Technique (VAT) procedure to induce uncertainty. General Anxiety and Distress increased significantly in both groups, but Pregnancy-related anxiety was significantly higher in the pregnancy-specific group only. Neither trait IU nor trait ER moderated this relationship, suggesting that uncertainty related to pregnancy uniquely predicted pregnancy-related anxiety. Furthermore, pregnancy-specific uncertainty may lead to less adaptive ER strategies being used. Although further research is required to examine what is driving the relationship between uncertainty and pregnancy-related anxiety, this research has implications for antenatal services, as well as perinatal mental health assessments and interventions.

Key words: Intolerance of Uncertainty; pregnancy-related anxiety; emotion regulation

Introduction

Pregnancy is a period in a woman's life which is full of uncertainty, fear and joy (Rovas et al., 2017), and one which presents the challenge of adapting to physiological, psychological and social changes (Hodgkinson et al., 2014). Anxiety during pregnancy is common, with 19% of women reporting anxiety symptoms in their first trimester, raising to 25% in the third trimester (Dennis et al., 2017). Lower levels of anxiety may serve an adaptive function during an otherwise healthy pregnancy, with mild stress or anxiety triggering the nervous system to develop more quickly, and positively impacting the cognitive and motor development of the foetus (DiPietro et al., 2006). However, if the mother suffers from high levels of chronic stress and anxiety, cortisol (otherwise blocked by the placenta) is able to reach the baby. This leads to negative consequences for foetal neurological development (Sandman & Davis, 2012), birth outcomes (Ding et al., 2014; Dunkel-Schetter & Glynn, 2011), the development of the child (Dunkel-Schetter & Glynn, 2011) and their physical health (Beijers et al., 2010). Children of mothers who experienced high levels of prenatal anxiety are more likely to have emotional and behavioural difficulties (Blair et al., 2011; O'Connor et al., 2002), and to have higher levels of cortisol themselves at pre-adolescence (O'Connor et al., 2005).

A growing body of research demonstrates that when anxiety is specific to the pregnancy, this risk increases further (Dunkel-Schetter, 2011; Lobel et al., 2008). It is yet unclear the exact reasons why pregnancy specific anxiety is particularly critical, although work with maternal cortisol and epigenetics suggest that pregnancy-specific stress and anxiety is a more potent process, that triggers greater physiological arousal than general anxiety (Huizink et al., 2004; Lobel et al., 2008).

Research has found that pregnancy-specific anxiety is highest within the first

and third trimesters (Costa et al., 1999) and loads onto three factors; worry about the birth and labour, worry about the child being unwell, and concern regarding one's own appearance (Huizink et al., 2004). Although research exists around the content of pregnancy-specific worries, little is understood about the processes underlying and driving the anxiety. This is important to understand because it may help to specify which elements of the experience of pregnancy are particularly problematic, and why pregnancy-specific anxiety is particularly potent.

Intolerance of Uncertainty

In the broader anxiety literature, there has been some interest in the concept of Intolerance of Uncertainty (IU). Carleton (2016) describes IU as "an individual's dispositional incapacity to endure an aversive response triggered [and sustained] by the perceived absence of salient, key or sufficient information" (p. 31). Individuals higher in IU are likely to appraise uncertain situations as threatening, and to adopt more negative cognitive, emotional and behavioural responses (Dugas & Ladouceur, 2000). Berenbaum, Bredemeier and Thompson (2008) suggest that IU encompasses several different dimensions, including a desire for predictability; a tendency to become paralysed by uncertainty; a tendency to respond to uncertainty with distress; and inflexible beliefs about uncertainty. IU has been shown to have physiological effects, with studies reporting greater neural activity and skin conductance (Feldmanhall et al., 2016; Tanovic et al., 2018) when making decisions in uncertain circumstances. Further studies have also demonstrated a significant increase in cortisol levels when individuals are faced with uncertainty regarding occupational role (Wirtz et al., 2013) or relationship uncertainty (Priem & Solomon, 2011). When applying the theory of IU to the experience of pregnancy, it is unsurprising that women

may find this difficult. Pregnancy is a sustained period of uncertainty (approximately 40 weeks), with limited or inconsistent information/feedback (e.g., foetal movement), and little actual control over the pregnancy and birth outcomes. Further, there are typically no ways to escape many of the feared situations (e.g., childbirth/pain). Additionally the pregnancy is likely to be especially meaningful, and some of the feared consequences, (e.g. perinatal loss), are particularly significant. In support of the importance of IU in pregnancy, research has found that pregnant women with higher trait IU are significantly more likely to report lower levels of psychological well-being (Çevik & Yağmur, 2018).

The literature describing IU has focussed largely on its role in Generalised Anxiety Disorder (GAD). Dugas et al (1998) propose the Intolerance of Uncertainty Model, which suggests that uncertainty drives worry. The worrier perceives this as an effective way to cope; as a motivator for preparation, problem-solving and avoidance of feared outcomes occurring, this then increases the individual's propensity to worry and a 'worry chain' develops. This is impacted further when there is low perceived control over either external events or internal states (Ruggiero et al., 2012). Research into the function of worry supports the idea that worry is a cognitive avoidance response to perceived future threat (Borkovec, 1994; Borkovec et al., 2004).

It has been well documented that IU is a transdiagnostic maintaining factor underlying a range of other mental health conditions, such as depression, Obsessive Compulsive Disorder (OCD), social phobia, panic disorder and agoraphobia (Boswell et al., 2013; Mcevoy & Mahoney, 2012). Mahoney and Mcevoy (2011), found that the more comorbid diagnoses one has, the higher the level of IU the individual will experience. Specific interventions have been developed focussing on IU using a Cognitive-Behavioural Therapy (CBT) model (Robichaud, 2013). This entails working

towards a treatment goal of recognising and accepting uncertainty, and developing strategies to manage uncertain situations (Ladouceur, Freeston, et al., 2000). These have shown to be effective in treating GAD (Torbit & Laposa, 2016), along with other anxiety disorders (Boswell et al., 2013; Talkovsky & Norton, 2016) and various populations including adolescents (Wahlund et al., 2020), older adults (Hui & Zhihui, 2017) and individuals with diabetes (Amoako et al., 2008). Surprisingly, despite pregnancy involving significant uncertainty, and anxiety being so highly prevalent within this population, little research has examined either the concept of IU or IU-based interventions in this population.

Much of the IU research is based upon survey designs, or experimental methodologies, which lack ecological validity, such as gambling procedures (Carleton et al., 2016; Luhmann, Ishida, & Hajcak, 2011; Ladouceur, Gosselin, & Dugas, 2000). Grenier and Ladouceur (2004) developed an experimental induction of uncertainty by adapting the Vertical Arrow Technique (VAT); a strategy initially described by Burns (1999) for use in CBT. The VAT procedure within Grenier and Ladouceur's (2004) study called for participants to consider the consequences of ingestion of a drug, with unpredictable effects. After which, they read statements designed to either increase or decrease uncertainty. Grenier and Ladouceur (2004) successfully induced uncertainty using this methodology. This was later supported by Mosca, Lauriola, and Carleton, (2016) who aimed to develop a more ecologically valid experimental induction of uncertainty by asking students to complete the VAT in relation to an idiosyncratic negative life event. The VAT procedure therefore may be a valid tool with which to adapt to studies of pregnancy-related IU.

Uncertainty in pregnancy

Uncertainty within pregnancy has only recently become an interest within research, with much of this being based upon women with high-risk pregnancies. This is defined as any pregnancy in which a medical condition exists that has potential to adversely affect the health of the mother, her foetus, or both (Ricci, 2016). The emotional and psychological experience of a high-risk pregnancy is complex, with associated feelings of shock, fear, grief, isolation, loneliness, anger, sadness, and guilt (Isaacs & Andipatin, 2020). Significantly higher levels of stress and distress has been documented within those with high-risk pregnancies (Rodrigues et al., 2016). Women who are at higher risk of miscarriage, experience higher levels of IU than those with low risk pregnancies (Çevik & Yağmur, 2018). Similarly, pregnant women above 35 years of age, experience heightened anxiety relating to the uncertainty of pregnancy viability and the additional tests they may be offered (Sun et al., 2008). Stress and anxiety relating to uncertainty increases when women have experienced previous perinatal loss (Moore & Côté-Arsenault, 2018), when they are required to rest due to early contractions (Höglund & Dykes, 2013), or if they are hospitalised (Richardson et al., 2017; Rodrigues et al., 2016). However, Clauson (1996) reports that throughout a hospital admission, and at discharge, uncertainty levels reduce as they receive care and their concerning symptom patterns stabilise.

Despite the majority of research being carried out in high-risk pregnancies, uncertainty is a feature of all pregnancies, from conception to birth and there may be individual differences in the ability to tolerate uncertainty. Ross (2018) describes home pregnancy testing as a source of uncertainty, where women may not fully trust in her interpretation of the symptoms, or in the reliability and accuracy of the test; placing her “in between being a pregnant and non-pregnant woman” (p. 98). They further describe

the uncertainty within the first trimester, and the ways in which women monitor and interpret bodily symptoms and sensations in the absence of the recognised characteristics, such as a “bump”. According to Moore and Côté-Arsenault (2018), until confidence in the viability of pregnancy develops in later weeks, women may often avoid bonding with their baby. There appears to be particular periods of anxiety around foetal health, such as in anticipation of the routine ultrasounds, however once positive feedback and a visual image of their baby is received anxiety reduces (Harpel, 2008). Towards the end of pregnancy the focus of anxiety turns more towards childbirth (Borrelli et al., 2018), with IU and pain catastrophisation being recognised as predictors of fear of childbirth (Rondung et al., 2018). Rovas et al (2017) reported that anxiety rises toward the end of pregnancy, at the same time as the desire to have a baby. Furthermore, a women’s readiness to experience birth increases over time, with first-time mothers wanting to be more prepared for labour than those on their second or subsequent pregnancies.

Emotion regulation and coping

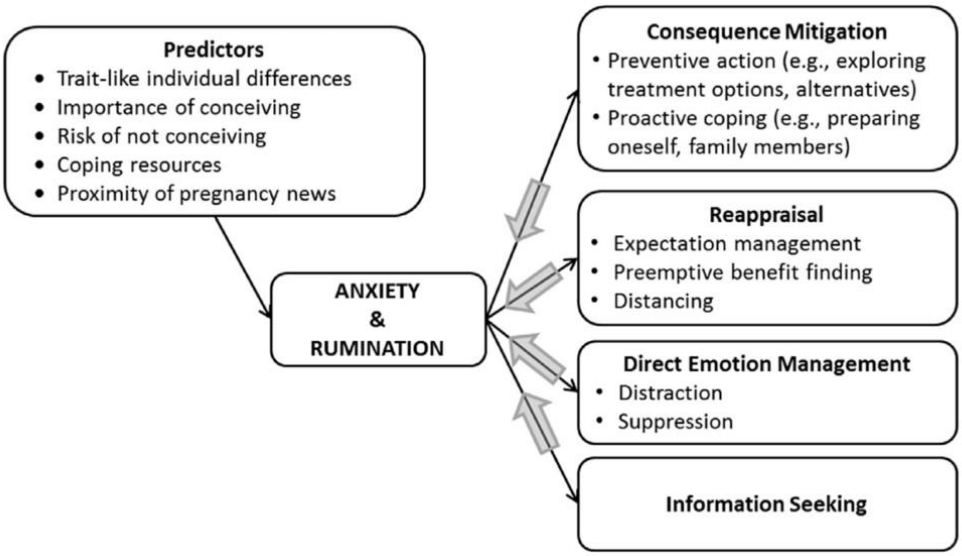
Sweeny and Cavanaugh (2012) propose the Uncertainty Navigation Model, which suggests that varying individual and situational factors (e.g. individual traits, associated risks etc), are associated with the experience of anxiety and cognitive rumination in uncertain situations. This is supported by literature, recognising that IU is strongly related to both anxiety (Jensen et al., 2016) and rumination (Jong-meyer et al., 2009; Liao & Wei, 2011; Yook et al., 2010), with IU and rumination together accounting for up to 30% of worry. Repetitive thought, which encompasses both rumination and worry, is reported to have both constructive and unconstructive consequences. The outcome depends on the valence of thought content, the

interpersonal and situational context, and level of abstract vs. concrete processing that is adopted (Watkins, 2008). For example, more unconstructive consequences are likely if one uses more negative valency and abstract thought within a situation in which they feel inexperienced and/or have a no command over.

The experience of anxiety and rumination, according to the model, then initiates the use of strategies to navigate the associated uncertainty. These strategies include consequence mitigation (minimising the consequences of the feared outcome), reappraisal (of the likelihood of outcomes, the value and validity of information, and finding benefits), information seeking (searching for information from various sources), and direct emotion management (strategies to avoid, distract or suppress emotions). The model was applied to the experience of trying to conceive (Figure 1), when Sweeny, Andrews, Nelson, and Robbins, (2015) found that those who were higher in trait IU recalled more anxiety, rumination, and more use of uncertainty navigation strategies when trying to conceive, compared to those who were lower in IU.

Figure 1

Application of the Uncertainty Navigation Model to conceiving a baby *(Sweeny et al., 2015)*



Findings from further research describe similar emotion regulation (ER) strategies to cope in the face of uncertainty during pregnancy. For example, Borrelli et al, (2018), found that women who were pregnant for the first time used strategies such as preparing and reading information; avoiding and distracting themselves; considering childbirth as a shared experience among women; relying on maternal instinct; relying on pain relief; and relying upon their birthing partners to be a voice of reason. Women recognised the need to be flexible and open-minded in regard to their birthing plans, which is associated with more positive reporting of a labour experience (Whitburn et al., 2014). Furthermore, Moore and Côté-Arsenault (2018), analysed entries from pregnancy journals completed by women who had experienced previous pregnancy loss. Themes emerged around a need to monitor physical symptoms, the expression of both positive and negative emotions, and the need for social support. Social support commonly appears in the literature describing coping strategies, with some women choosing to withdraw from their social support network, whilst others

use social support as a distraction (Schmuke, 2019). Interestingly, Giurgescu et al (2006) reported that women who experience high levels of IU, were more likely to report less social support available to them. Seeking support from healthcare services also helped women to cope with uncertainty overall, although when information is perceived to be inadequate (Schmuke, 2019) or information-seeking becomes excessive it can have a negative impact (Bayrampour et al., 2016). Those who are higher in trait IU being more likely to request additional testing and screening to mitigate the uncertainty, or even to request terminations if there are significant risks to the health of the foetus (Edwards et al., 2017).

The current study

With the presence of uncertainty having such a vast psychological impact, and the potential implications for both the pregnancy and the infant, this is an important area in research. The main aim of the empirical study was to explore the impact of pregnancy-specific versus general uncertainty on pregnant women's intolerance of uncertainty, anxiety and distress. Research questions and hypothesis are outlined below.

Research Question 1

Do levels of state pregnancy-related anxiety, general anxiety/distress and state IU in pregnant women vary by the type of uncertainty they are exposed to?

Hypothesis. It was hypothesised that exposure to the uncertainty situations would increase general anxiety and distress, but the type of uncertainty would moderate the relationship between the increase in pregnancy-specific anxiety. Specifically, it was expected that pregnant women who are exposed

to pregnancy-specific uncertainty would have a greater increase in pregnancy-related anxiety than women exposed to general uncertainty. It was not expected that state IU, general anxiety, or distress would differ based on whether women were exposed to pregnancy-specific or general uncertainty.

Research Question 2

Does trait IU moderate the relationship between pregnancy versus general uncertainty and pregnancy-related anxiety?

Hypothesis. It was hypothesised that individuals who are high in trait IU who are exposed to pregnancy-specific uncertainty will have a greater increase in pregnancy related anxiety than those who are low in trait IU and exposed to both pregnancy related uncertainty and general uncertainty.

Research Question 3

Does trait emotion-regulation moderate the relationship between pregnancy versus general uncertainty and pregnancy-related anxiety?

Hypothesis. It was hypothesised that individuals who were low in their use of cognitive ER strategies would demonstrate greater distress/anxiety than those who endorsed high levels of cognitive ER strategies, and this relationship would be stronger in the pregnancy-specific uncertainty condition than in the general uncertainty condition.

Research Question 4

Does pregnant women's use of ER strategies vary based on the type of uncertainty (pregnancy-specific or general) they are exposed to?

Hypothesis. It was hypothesised that women in the pregnancy-specific uncertainty condition would use rumination and ER strategies less adaptively than those in the general uncertainty condition.

Method

Design

The current study utilised a between-within experimental design, adapting the method developed by Mosca, Lauriola, and Carleton (2016). This method aims to induce uncertainty in a perinatal population, representing the independent variable. Dependent variables include IU, anxiety, distress, and ER at two-time points; before and after the uncertainty induction.

Ethics

Ethical considerations were made around the potential impact to both mother and baby whilst taking part in an experimental induction of uncertainty. A focus group of pregnant women initially gave feedback on the acceptability of the procedure, and measures were put into place through the selection process, and the induction to limit this risk and prioritise the well-being of all participants. The research was granted ethical approval by the University of Exeter Ethics Committee on the 9th July 2019 (see appendix A).

Sample

Inclusion and exclusion criteria

Participants were eligible to take part if they were above the age of 18 and were in their second or third trimester of pregnancy with their first child. Their pregnancy

was required to be considered as ‘low risk’, with all antenatal care being led by a midwife. Women were excluded only if they associated distress with previous experiences of miscarriage, or termination of pregnancy. Participants with a previous history of mental health problems more than one year prior to participation were included. However, if they had a mental health diagnosis that is current or within the previous year they were excluded, along with any participant scoring within clinical ranges on the Patient Health Questionnaire-9 (PHQ-9), or Generalised Anxiety Disorder-7 (GAD-7).

Participants

Participants for this study were a non-clinical sample of adult pregnant women. All participants were between 12- and 40-weeks’ gestation and were having a low-risk single pregnancy. Participants responded to an advert (see appendix B), which was displayed on social media, at antenatal events and through word of mouth. A total of 234 potential participants made contact to express an interest in the research. 111 (47%) women went on to be assessed for eligibility. Of these, 66 (59%) did not meet the inclusion criteria, 5 (5%) declined to participate, and 40 (36%) women were enrolled after reading the participant information sheet (see appendix C) and completing the informed consent process (see appendix D). Participants were randomly allocated by survey software, Qualtrics, to one of two conditions: pregnancy-specific uncertainty (n=20) or general uncertainty (n=20). Participants completed the study at the University of Exeter (n=13), in their home (n=10) or via a video call (n=17). This variation in format was offered at the convenience of participants to improve access and to enable nationwide recruitment. However, in doing so a lack of control over the environment in which the procedure took place may have impact upon

baseline anxiety levels (e.g. participants may have felt more comfortable completing the procedure in their own home, as opposed to a university laboratory). The benefit of maximising recruitment however, outweighed the risks of this potential confounding variable.

Measures

Participants completed a battery of counterbalanced measures both before and after the uncertainty induction. These are outlined, along with their psychometric properties. Full measures can be found within appendix E.

Intolerance of Uncertainty Scale (IUS). The IUS (Freeston, Rhéaume, Letarte, Dugas, & Ladouceur, 1994), English version (Buhr & Dugas, 2002) is a 27-item questionnaire specifically measuring trait IU, regarding beliefs, functioning and distress relating to uncertainty. The IUS was administered prior to induction as a measure of trait IU. Items are scored on a 5-point Likert scale ranging from 1 (not at all characteristic of me) to 5 (entirely characteristic of me). The IUS achieves excellent internal reliability (Cronbach's alpha = .88; Mcevoy & Mahoney, 2010; .= 94; Buhr & Dugas, 2002).

The Pregnancy Related Anxiety Questionnaire – Revised (PRAQ-R). The PRAQ-R (Huizink et al., 2004) is a reliable measure of pregnancy-specific anxiety (Cronbach's alpha = 0.83; Huizink et al., 2016). This is a 10-item measure, adopting a Likert scale of 1-5. It is widely validated for use within pregnancy as a predictor of birth outcome (Reck et al., 2013) and has been validated to measure change in pregnancy (Huizink et al., 2016). The PRAQ-R was administered before and after induction to assess change in pregnancy-specific anxiety.

The Cognitive Emotion Regulation Questionnaire – Short version (CERQ-S). The

CERQ-S (Garnefski & Kraaij, 2006) consists of 18-items measuring nine subscales; self-blame; other blame; rumination; catastrophising; putting into perspective; positive refocusing; positive reappraisal; acceptance; and planning. The measure achieved good reliability (Cronbach's alpha = .87; Garnefski & Kraaij, 2007). This measure was used before and after the uncertainty induction procedure to assess changes in ER following uncertainty induction.

Intolerance of Uncertainty Scale - Situation Specific (IUS-SS). The IUS-SS (Mahoney & Mcevoy, 2012) is an adapted version of the IUS to specifically measure state IU and has achieved excellent internal consistency (Cronbach's alpha = 0.94; Mahoney & Mcevoy, 2012). This measure was used after the uncertainty induction procedure to measure variations in state IU.

General anxiety and distress. To measure general anxiety and distress the question, "how anxious/distressed do you feel now?" was asked at baseline, and again after the uncertainty induction. This was measured on a Likert scale, where "1 = not at all", "2 = not very", "3 = slightly", "4 = somewhat", and "5 = highly".

ER and Coping. All participants were asked to describe the ways in which they would cope within the uncertain situation. Responses to these questions were coded for the ER strategies described, and how adaptive these were within the context.

Procedure

All participants completed an initial eligibility screening questionnaire online. If criteria were satisfied, participants met with the researcher either face-to-face or via a video call to complete the computerised task. All participants completed the PHQ-9 and GAD-7 to screen for anxiety and/or depression. If either specified clinical cut-off scores (19 and 14 respectively) were met they were excluded from the study and

signposted onto additional support services.

Initial measures were completed (IUS, PRAQ-R, and CERQ-S) and each participant was asked to read a scenario depending on the condition they were allocated to. Both scenarios were matched for length, detail, and degree of potential uncertainty. Because the pregnancy specific condition could represent a very relevant domain (well-being of feotus), the general uncertainty condition was written to balance the intensity of the relevance of the domain by emphasising a negative outcome with a meaningful relationship without stating why the outcome had occurred;

Pregnancy-specific uncertainty condition. You are at an ultrasound appointment, and your baby has just been pictured on the screen. The sonographer looks concerned, but won't tell you what is wrong. They tell you that they need to get their manager, and quickly leave the room and you are left on your own for a very long time.

General uncertainty condition. You are walking down the street and see a close friend who looks very upset. They tell you that you have deeply offended them, but they won't tell you what you have done. They tell you that they don't want to see you again, and demand that you don't contact them, and they will not answer if you try. They quickly leave and don't look back.

All participants were then asked to complete a vertical arrow technique (VAT), originally developed by Burns (1999) and adopted by both Mosca et al., (2016) and Grenier and Ladouceur, (2004). In turn, they were asked to consider the consequences of the identified situation (see appendix F). Following completion of the VAT, participants were asked to read a list of eight statements developed by Grenier and Ladouceur (2004) and validated by Mosca et al., (2016) as effective in

experimentally inducing uncertainty (appendix G). Participants then completed the post-induction measures before being asked to describe the ways in which they would cope in the scenario described. Finally, a mood induction procedure was completed to reduce the emotional effects of the uncertainty induction and participant debriefing took place (see appendix H).

Statistical Analyses

All analyses were conducted using SPSS Statistics Version 25. Descriptive statistics and correlation analyses were initially performed to characterise the data and inspect zero-order relationships between the mood and psychological variables. Repeated-measures ANCOVA's were conducted to examine change in distress and anxiety over the induction period, and whether condition moderated this relationship. Multiple regression was performed to assess whether trait IU and trait ER moderated the relationship between condition and distress/anxiety.

All qualitative responses to the VAT were reviewed for content relating to the emotion regulation strategies described by Sweeny et al (2015); rumination, consequence mitigation, reappraisal, information seeking and direct emotion management. A copy of the coding scheme can be found in Appendix I. Each strategy identified was rated on how adaptive it was within the context (-1 = not adaptive, 1 = somewhat adaptive, 2 = very adaptive). 10% of the data was coded by a second rater, and the Krippendorff's alpha test (Hayes & Krippendorff, 2007) was used to estimate the inter-rater reliability within the coding scheme. One-way ANCOVA's controlling for PHQ9, and trait IU were performed to examine between-groups differences.

One-way ANCOVA's, controlling for baseline PHQ-9 scores were performed to assess whether a difference existed in the way in which coping strategies were used

between conditions.

Results

Participants were on average 30.80 years old (SD = 3.52), with an average gestational age of 26.45 weeks (SD = 8.51). Participants were White British (92.5%), White European (5%) and Asian (2.5%). There were no significant differences in baseline characteristics between groups on any of the demographic characteristics, but there were higher PHQ-9 scores in the pregnancy-specific uncertainty group (M = 2.90, SD = 1.83) compared to that of the general uncertainty group (M = 1.65, SD = 1.18), F (1, 38) = 6.57, p = .01. PHQ-9 scores were therefore controlled for in all subsequent analyses.

Table 1

Baseline demographics and measures

Variable	Pregnancy Specific uncertainty (N = 20)	General uncertainty (N =20)	Total (N = 40)
	Mean (SD)	Mean (SD)	Mean (SD)
Gestational age (wks)	26.9 (9.03)	26.00 (8.16)	26.45 (8.51)
GAD	2.05 (1.79)	2.30 (2.31)	2.18 (2.05)
PHQ-9	2.90 (1.83)	1.65 (1.18)	2.28 (1.65)

Bivariate correlations between trait and state IU, trait ER and state ER, pregnancy-related anxiety, distress, and general anxiety, are presented in Table 2. There was a strong positive correlation between trait and state IU, and between trait

ER and state ER. Pregnancy-related anxiety was moderately correlated with trait IU, state IU, and state ER, whilst there was a moderate positive correlation between general distress and general anxiety.

Table 2

Bivariate Pearson correlation between baseline measures

	1	2	3	4	5	6	7
1. Trait IU	-						
2. State IU	.855**	-					
3. Pregnancy-related anxiety	.468**	.380*	-				
4. Trait ER	.258	.264	.285	-			
5. State ER	.298	.365*	.323*	.887*	-		
6. Distress	.160	.064	.143	.049	.138	-	
7.General anxiety	.093	-.032	.174	-.268	-.225	.458**	-

*$p < .05$. **$p < .01$.

Hypothesis 1

Repeated measures ANCOVAs, with the emotional variable (general distress, anxiety or pregnancy related anxiety as the within-participants factor), controlling for baseline PHQ-9, were conducted to examine whether general distress and anxiety and pregnancy-related anxiety increased from baseline to post-induction, and whether condition moderated the change in pregnancy-related anxiety. A one-way ANCOVA, controlling for PHQ9 and trait IU was conducted to explore whether there was a

difference in state IU between groups.

All ANCOVA statistics for pre-to-post measures are reported within Table 3. As expected, there was a significant within-subject effect with both general distress and general anxiety increasing significantly from baseline to post-induction. Condition did not moderate the relationship of the change in distress, or anxiety from pre-to-post induction. There were no other significant effects.

Regarding pregnancy-related anxiety, there was no main effect of time on change in pregnancy-related anxiety, nor was there a main effect of condition. However, as hypothesised, there was a significant interaction effect. Post-hoc repeated measures ANCOVAs were conducted on each group separately, and revealed that there was a significant increase in pregnancy-related anxiety for those in the pregnancy-specific uncertainty condition, but there was no increase in pregnancy-related anxiety for those in the general uncertainty condition (See table 3). There were no significant differences in state IU between the two groups, when controlling for PHQ9 and trait IU, F (1, 37) = 36.37, p = *.44*.

Table 3

ANCOVA statistics for pre to post induction measures

Variable	Pre	Post	*F*	*p*	η_p^2
General Distress	Mean (SD)	Mean (SD)			
Pregnancy-specific	1.15 (.37)	1.90 (1.02)			
General	1.05 (.22)	1.75 (.85)			
Within Groups			14.41	.001	.28
Between Groups			1.28	.27	.03
Interaction			.39	.53	.01
General Anxiety	Mean (SD)	Mean (SD)			
Pregnancy-specific	1.30 (.47)	1.95 (.89)			
General	1.30 (.57)	2.05 (.89)			
Within Groups			9.95	.003	.21
Between Groups			86.32	.736	.00

Variable	Pre	Post	*F*	*p*	η_p^2
Interaction			.05	.82	.00
Pregnancy-related anxiety	Mean (SD)	Mean (SD)			
Pregnancy-specific	27.75 (6.34)	30.45 (7.65)			
General	25.80 (8.75)	25.90 (9.58)			
Within Groups			4.06	.051	.09
Between Groups			124.75	.000	.77
Interaction			6.98	.012	.16
Pregnancy-specific			6.06	.024	.25
General			1.19	.29	.06

Hypothesis 2

Hierarchical multiple linear regression was used to examine whether trait IU, condition, and the interaction of trait IU with condition predicted general distress and anxiety, and pregnancy related anxiety, after controlling for PHQ-9 and the baseline mood variable. Depressive symptoms (PHQ-9) were entered into the first step. In the second step, the baseline general distress/anxiety measure was entered. Condition and trait IU were entered on the third step, with the interaction of condition and trait IU in the fourth step.

Model 1 examined general distress as the dependent variable. The overall model was not significant, F (1, 39) = .78, p = .59, and none of the individual predictors were significant. Model 2 examined general anxiety as the dependent variable. Although baseline anxiety was a significant predictor of anxiety at post-induction, B (1, 39) = .40, p = .01, the overall model was not significant, F (5, 34) = 1.49, p = .22, and none of the other variables were significant predictors of anxiety. Model 3 examined pregnancy-related anxiety. The overall model was significant, F (5, 34) = 56.41, p <.001 and explains 87.7% of the variance. Condition was a significant predictor of pregnancy-related anxiety, but the main effect of trait IU and the interaction of trait IU with condition were not significant, F = (5, 34) 56.41, p = .99, and F (5, 34) = 56.41, p = .60, respectively.

Table 4

Multiple regression for variables predicting pregnancy-related anxiety

Variable	*B*	*SE B*	β	Adjusted R^2	Significance
Step 1					
PHQ-9	1.09	.85	.20	.02	p = .21

Variable	*B*	*SE B*	β	Adjusted R^2	Significance
Step 2					
Baseline PRAQ-R	1.08	.07	.93	.86	$p < .001$
Step 3					
Trait IU	.06	.04	.08	.88	$p = .19$
Condition	-2.87	1.06	-.16		$p = .01$
Step 3					
Trait IU X Condition	.04	.08	.15	.88	*p = .60*

Hypothesis 3

To examine whether trait ER, condition and the interaction of trait ER and condition predicted pregnancy related anxiety, after controlling for PHQ-9 and the baseline measure, a multiple linear regression was completed. Again, the PHQ-9 was entered into the first step. Baseline pregnancy-specific anxiety was entered into the second step. In the third step, condition and trait ER were entered, and the interaction between condition and trait ER was entered into the fourth step. The overall model was significant F (5, 34) = 55.22, p <.001 and explains 87.4% of the variance. Baseline PRAQ-R was a significant predictor, along with condition. The main effects of trait ER and the interaction of trait ER with condition were not significant, F = (4, 35), = 70.56, p = .29, and F (4, 35, = 70.56, p = .65, respectively.

Table 5

Multiple Regression analysis for variables predicting emotion regulation

Variable	*B*	*SE B*	β	Adjusted R^2	Significance
Step 1	1.09	.85	.20	0.2	$p = .21$

Variable	*B*	*SE B*	β	Adjusted R^2	Significance
PHQ-9					
Step 2					
Baseline PRAQ-R	1.08	.07	.93	.86	$p < .001$
Step 3					
Trait ER	.08	.08	.07	.88	$p = .29$
Condition	-2.65	1.07	-.15		$p = .02$
Step 3					
Trait ER X Condition	-.07	.15	-.21	.87	$p = .65$

Hypothesis 4

To determine state ER coding of all qualitative data took place, with a second independent rater coding 10% of responses. Krippendorff's alpha statistic demonstrated high inter-rater reliability (α = 0.8468).

One-way ANCOVA's, controlling for PHQ-9, and trait IU were conducted to inspect the between-groups differences in the adaptivity of ER strategies used. All ANCOVA statistics are reported within Table 6. There was a significant difference in the use of consequence mitigation, with participants in the pregnancy-specific uncertainty group using this strategy less adaptively than the general uncertainty group. A further significant difference was found in the use of information seeking, with those in the pregnancy-specific uncertainty group using this strategy more adaptively than those in the general uncertainty group. No other significant differences were found.

Table 6

One-way ANCOVA analysis for emotion regulation strategies

Variable		*F*	*p*	η_p^2
Rumination	Mean (SD)			
Pregnancy-specific	-.15 (.59)	3.29	.07	.08
General	-1.05 (1.85)			
Reappraisal	Mean (SD)			
Pregnancy-specific	.55 (1.43)	3.02	0.9	.07
General	1.55 (2.26)			
Consequence mitigation	Mean (SD)			
Pregnancy-specific	1.30 (2.90)	5.69	0.02	.137
General	3.00(2.03)			
Reappraisal	Mean (SD)			

Variable		*F*	*p*	η_p^2
Pregnancy-specific	.55 (1.43)	3.02	0.90	.07
General	1.55 (2.26)			
Direct Emotion Management	Mean (SD)			
Pregnancy-specific	.45 (1.15)	.08	.775	.00
General	.30 (.66)			
Information Seeking	Mean (SD)			
Pregnancy-specific	4.60 (4.35)	6.59	.015	1.55
General	1.75 (1.71)			

Discussion

This study found that although uncertainty inductions increased both general anxiety and distress, only a pregnancy-specific uncertainty induction increased pregnancy-related anxiety. These results remained even when controlling for trait IU and trait ER, and despite there being a strong significant correlation between trait IU and state IU at baseline. Further, neither trait IU nor trait ER moderated the relationship between condition and emotional distress or anxiety. Together, these results suggest that pregnancy-related anxiety is associated with uncertainty, but only pregnancy-specific uncertainty, not general uncertainty. Further, despite the fact critical factors of uncertainty were controlled for between the two conditions (i.e., relevance of domain, level of uncertainty), the *type* of uncertainty resulted in the use of different emotion regulation strategies. Individuals in the pregnancy-specific uncertainty condition used more adaptive information-seeking responses and less adaptive management of consequences skills than those in the general uncertainty condition. Pregnancy specific uncertainty therefore seems to drive both a particular way of coping and responding to uncertainty when compared to general uncertainty, as is an important contributor to pregnancy-related anxiety.

The results support the first hypothesis, that general distress and anxiety would increase after both the general and pregnancy-specific uncertainty inductions, but pregnancy-related anxiety would only increase for those in the pregnancy-specific uncertainty condition. Although the effect sizes were small, these results point to the importance of pregnancy-specific uncertainty within the perinatal period, and the potential potency of this variable. This is important to consider because research has demonstrated that risks of negative pregnancy and birth outcomes are significantly increased when anxiety is specific to pregnancy (Dunkel-Schetter & Glynn, 2011;

Lobel et al., 2008). As expected, there were no differences between groups in relation to state IU, which suggests that the two conditions were equally matched in regard to the levels of uncertainty presented. There was also a large positive correlation between trait IU and state IU measures. This suggests that although trait IU is an important contributor to state IU, such that individuals who are higher in trait IU are more likely to find uncertain situations intolerable (Mahoney & Mcevoy, 2012), it is also the case that whether this state IU has a further impact on pregnancy-related anxiety depends on the *specific content* the individual fears is uncertain. Thus, general trait IU may lower the threshold at which a person feels uncertain about any topic (general or pregnancy-specific), but only pregnancy specific, not general, uncertainty is causally related to increases in pregnancy-related anxiety. This is further supported in the fact that there was no support for the second or third hypothesis that trait IU or trait ER would moderate the relationship between type of uncertainty and pregnancy-related anxiety. It was also the case that, contrary to previous literature, trait IU was not correlated with general anxiety or distress within this sample (Dugas & Ladouceur, 2000), although it is possible that it may have been indirectly related via state IU, but this study was not powered to test this. It may also be a result of general anxiety and distress being measured on a Likert scale, as opposed to a validated measure.

The fourth hypothesis, that women in the pregnancy-specific uncertainty condition would use rumination and ER strategies less adaptively, was partially supported. No significant difference was found between groups in adaptiveness of rumination strategies, which is surprising given the body of research supporting the ideas that both trait IU and anxiety increase rumination (Jong-meyer et al., 2009; Liao & Wei, 2011; Yook et al., 2010). It is possible that the experimental design was not sensitive enough to detect the process of rumination, and more direct questions about

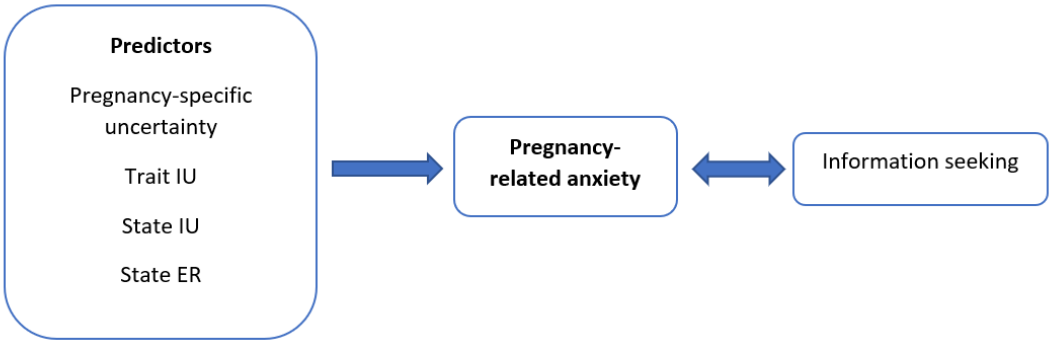
this would have elicited differences. However, differences were found in the use of consequence mitigation, and information-seeking. Participants in the pregnancy-specific uncertainty group used information-seeking more adaptively than those in the general uncertainty group. These results are interesting, given that this is an active strategy, as opposed to cognitive one. However, it may be understood as a way for women to regain some control, in a situation in which they have no control over. Further, the notion that women might seek information is supportive of previous literature (Schmuke, 2019). The finding that consequence mitigation is used less adaptively by those exposed to pregnancy-specific uncertainty is also interesting. Despite relational uncertainty having shown to increase cortisol levels in previous research (Priem & Solomon, 2011), it is perhaps the inherent importance and value placed on a pregnancy that makes mitigating the consequences challenging; e.g. the consequences of losing a baby, may be much more significant than that of losing a friend.

Theoretical Implications

The current study investigated specific factors described within the Uncertainty Navigation Model (Sweeny et al., 2015), namely the individual predictor of IU, and the use of emotion regulation strategies. Results from the current study have been used to define the model within an antenatal population (see Figure 2). This model suggests that both trait IU, state IU and pregnancy-specific uncertainty are related to the experience of pregnancy-related anxiety. The ER strategy of information seeking is used to reduce anxiety, but also in turn are likely to maintain the anxiety, as no amount of information can entirely remove the uncertainty of pregnancy.

Figure 2

Application of the Uncertainty Navigation Model to pregnancy



Strengths and limitations

The current study has several limitations to note. Firstly, a manipulation check was not completed, largely due to a desire to limit the load upon participants to maximise recruitment. It is therefore not possible to say with confidence that the uncertainty induction was successful. However, it is possible to infer that it was due to the significant increases in both anxiety and depression from baseline to post-induction procedure. Regrettably, general anxiety was measured on a five-point Likert scale only, with pregnancy-related anxiety being assessed with a valid and reliable measure. This decision was made following feedback from the initial pilot group that the procedure felt cumbersome to complete due to the number and length of measures initially chosen. It was important to maximise recruitment to ensure that the procedure was acceptable to participants, and to ensure they had the ability to become emotionally engaged in completion for the procedure to successfully induce uncertainty. In hindsight, a validated measure of general anxiety was important, and excluding this means it is not possible to make reliable conclusions about the impact of the induction on general anxiety, or its relationship with pregnancy-related anxiety. If this methodology were to be repeated, a validated measure of uncertainty would be

necessary, and alternative amendments to the procedure should be made, such as a shorter measure of emotion regulation.

The use of the VAT procedure, described originally by Grenier and Ladouceur (2004) was translated into English by Mosca et al (2016). Unfortunately, participants of the current study reported some confusion whilst completing the procedure, asking for clarification on the meaning of words such as “consequences” and “outcome” within the context of the VAT. This confusion, along with my involvement to provide clarity may have influenced the success of the induction, creating some emotional separation from the uncertainty scenario. Future researchers using this methodology would benefit from piloting different expressions of the statements within their population.

Furthermore, the CERQ-S was also used to explore change in emotion regulation over the two time points. No significant results were found, which may have been due to the CERQ-S being a measure of trait characteristics, and therefore not having the necessary sensitivity to detect change. Future studies of a similar design should ensure the use of a validated trait and state measure of emotion regulation.

Unfortunately, the sample size was smaller than anticipated, which impacts upon the internal and external validity of findings. Only 17% of those who originally responded to the advert took part, and 59% of those who completed the screening questionnaire were ineligible to take part. This is largely due to restrictions on eligibility criteria due to risk, such as the exclusion of those with previous distressing perinatal loss or miscarriage, high-risk pregnancies, or current mental health diagnoses. This was because at the time the emotional impact of the induction was unknown due to a lack of previous research using this type of methodology, and their exclusion was deemed a more ethical decision. However, individuals within these groups reported they were particularly drawn to the content of the research at the advertising stage, in

part because of its relevance to their current experience of uncertainty and anxiety within their pregnancy. Anecdotally, many of these individuals commented on how difficult they were finding pregnancy due to these risk factors, which is consistent with previous research reporting that those in high-risk pregnancies experience higher levels of distress (Rodrigues et al., 2016). Including these individuals within research could not only improve recruitment rates significantly, but also would represent a population in which anxiety is more prevalent, and therefore results would present higher clinical significance. Interestingly, the mean gestational age of participants was 26 weeks, which is within the second trimester. As previously described, anxiety is highest within the first and third trimester of pregnancy (Costa et al., 1999), and so it would also be interesting to explore the impact of an uncertainty induction within individuals within these periods.

The sample was not limited in regard to location and represented a national UK population due to the ability to conduct the induction procedure online. Unfortunately, despite this, there remained to be heterogeneity of baseline characteristics across the sample. This lack of sample diversity is disappointing and limits the ability for conclusions to be made regarding the experience of uncertainty in pregnancy cros-culturally. Future research would benefit from taking additional measures to recruit from ethnic minority populations and from both rural and urban areas. Unfortunately, this was not possible within this study due to limited resources.

To improve recruitment rates within future research, it would be important to maintain the use of a variety of social media platforms (which was the most successful source of recruitment for this study), but also to attend antenatal events where both direct recruitment and networking is able to take place.

Despite the limitations, the findings of the current study expand upon the current

evidence base, and to our knowledge is the first to use an experimental procedure to induce and explore uncertainty within a population of pregnant women. It has been able to adapt a validated and effective method of inducing uncertainty to provide a more ecologically valid manipulation within the antenatal period.

Methodologically, all participants were randomised by the survey software into either the pregnancy-specific or general uncertainty group and the researcher was blind to condition at the time of participation, helping to reduce bias within the data. Furthermore, measures were delivered using counterbalancing to reduce order effects.

Clinical Implications

This study has demonstrated the importance of uncertainty within pregnancy, and the potential for higher levels anxiety when uncertainty is specific to pregnancy. This has a number of implications for services, and the interventions they deliver.

Service implications

Previous research has shown that anxiety that is specific to pregnancy increases the risk of implications or adverse outcomes for the pregnancy, birth and child (Dunkel-Schetter & Glynn, 2011; Huizink et al., 2004; Lobel et al., 2008). It is crucial that this is addressed within antenatal services. Much of the clinical process women go through when pregnant increases uncertainty, for example, initial testing (Ross, 2018), ultrasounds and anomaly testing (Harpel, 2008), or if she were to require hospitalisation (Richardson et al., 2017; Rodrigues et al., 2016). These experiences may be particularly anxiety provoking and carry a risk of impacting negatively on the pregnancy or child outcomes. This consideration should undoubtedly be extended to

perinatal mental health services. Although not possible to conclude here, it is possible that clinical populations of women experience greater pregnancy-related anxiety, and therefore would be at increased risk of negative outcomes (Dunkel-Schetter & Glynn, 2011; Lobel et al., 2008).

Furthermore, research supports the finding that pregnant women may use information seeking as a strategy to cope with uncertainty and/or anxiety (Schmuke, 2019). It is important to note that in a health care context, it is likely to be midwifery services that receive the vast majority of this. It may also be likely that for those higher in trait IU, the responses midwives are able to give may not provide enough resolution to the uncertainties experienced. It may therefore be helpful for midwives to be supported with recognising when information-seeking becomes excessive and is possibly contributing to the uncertainty and anxiety experienced (Bayrampour et al., 2016; Schmuke, 2019). In these circumstances, signposting to mental health services may be a more appropriate response.

Assessment and intervention implications

It is essential that services consider uncertainty and pregnancy-related anxiety as unique, and in need of specific assessment and treatment. By neglecting to address these issues, and only addressing general anxiety, treatment outcomes could be negatively impacted. Where possible, psychological interventions should feature components of managing uncertainty. Interventions, such as CBT with uncertainty components have been found to be effective for individuals with GAD (Dugas et al., 2010; Ladouceur, Freeston, et al., 2000), with a treatment goal of recognising and accepting uncertainty, and developing strategies to manage uncertain situations. It would be beneficial for further research to investigate the application of this within an

antenatal population.

Future directions

As previously stated, a high proportion of participants did not take part due to stringent exclusion criteria around risk, however it is possible that the excluded group were expressing an interest in the research due to their current lived experience of uncertainty within their pregnancies. As stated, this group of individuals are more likely to experience anxiety and distress, and so it would be particularly important for future research to investigate the impact of uncertainty of this group, perhaps by applying the current induction procedure within these higher-risk populations. Alternatively, exploration of diary entries throughout pregnancy may access levels of uncertainty across all trimesters in all types of pregnancy (high-risk etc.) and would perhaps be another way to investigate the relationship between IU, ER and anxiety. Furthermore, this would be an opportunity to examine the specific anxieties that women describe at various stages in their pregnancy, as these are suggested to transition from initial anxiety relating to the viability of the pregnancy, and health of the baby, to the birth and ability to be an effective parent in later weeks (Borrelli et al., 2018; Rovas et al., 2017). Addionally, it would also be interesting for research examining uncertainty within this population to explore whether cortisol levels vary according to the type of uncertainty they are exposed to.

Although the current study found that anxiety for both groups was significantly raised following the induction, future research would benefit from using a reliable and valid measure of anxiety and distress before and after the induction, along with additional manipulation checks. Furthermore, a valid and reliable measure of general anxiety should be used, alongside the use of the PRAQ-R to provide confidence that

uncertainty has such a distinctive difference within these two types of anxiety.

IU is clearly an important component of pregnancy-related anxiety, given that there are moderate correlations between the measure of trait IU and pregnancy-related anxiety. However, what is not clear is what is driving this relationship. Further investigation is required to explore this, and to understand the factors involved, perhaps by manipulating the degree of uncertainty, the consequences, or amount of time before a resolution is reached. Furthermore, it may be interesting to investigate the impact of the felt sense of responsibility on the ways in which uncertainty is experienced and dealt with.

Although the current study did not find a significant result, a specific relationship within IU and cognitive rumination has been previously documented, it would therefore be beneficial for further investigation into the use of rumination within this population, perhaps by specifically assessing changes within this.

Conclusion

The current study aimed to explore the impact of uncertainty on pregnant women's intolerance of uncertainty, anxiety and distress. Participants were randomised into either pregnancy-specific, or general uncertainty conditions, where they were presented with a scenario and asked to complete a VAT procedure to elicit their responses to the scenario and to induce uncertainty. The findings from this study suggest that the induction procedure significantly increased anxiety and distress for both groups, but only the pregnancy-specific uncertainty group reported significantly higher levels of pregnancy related anxiety. Although trait IU was positively correlated with state IU and pregnancy-related anxiety, this did not moderate the relationship, nor did trait ER. Therefore, it is concluded that pregnancy-specific uncertainty has a

unique relationship with pregnancy-related anxiety. Moreover, individuals used information-seeking as an ER strategy more adaptively than those in the general uncertainty group, and consequence mitigation less adaptively. The findings from the current study are important to consider for all services offering pregnant women clinical support. Involving uncertainty modules within antenatal interventions may help to reduce pregnancy-specific anxiety, however more research is required in this area.

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APPENDICES

Appendix A – Ethical approval and amendments

CLES – Psychology
Psychology
College of Life and Environmental Sciences
University of Exeter
Washington Singer Building
Perry Road
Exeter
EX4 4QG
Web: www.exeter.ac.uk

CLES – Psychology Ethics Committee

Dear Claire Treleaven

Ethics application - eCLESPsy000575
Intolerance of Uncertainty and Emotion Regulation in Pregnant Women

Your project has been reviewed by the CLES – Psychology Ethics Committee and has received a Provisional opinion.

The Committee has made the following comments about your application:
This application referred back to Applicant because : 1. Provide more explanation as to how partici pants will be recruited from antenatal support organisations or online support groups. 2. Please explain how r isk will be handled (e.g., participants scoring as suicidal on the PHQ-9. How will this be followed up? 3. Please provide signposting information (for people who are excluded due to high scores on anx iety/depression). 4. Add name of Chair of Psychology Ethics: Lisa Leaver.
- Please view your application at https://eethics.exeter.ac.uk/CLESPsy/ to see comments in full.
If you have received a Favourable with conditions, Provisional or unfavourable outcome you are required to re-submit for full review and/or confirm that committee comments have been addressed before you begin your research.

If you have any further queries, please contact your Ethics Officer.

Yours sincerely

Date: 31/01/2019

CLES – Psychology Ethics Committee

Dear marker,

Thank you for your feedback regarding my ethics application. I have considered the comments you have made and responded to these with the changes below;

1. Provide more explanation as to how participants will be recruited from antenatal support organisations or online support groups.
Potential participants will be approached in person during their attendance at antenatal classes (with permission from the facilitators), and will be given the opportunity to discuss the study with the researcher. Posters advertising the study will be given to all members (example attached), with posters left with facilitators who are happy to distribute them to their clients. The poster will also be distributed on relevant social media pages (e.g. "Exeter/Devon Mums and Mums to be" facebook group) and online forums (eg. mumsnet), with a request for interested individuals to contact the researcher for further information. All participants will be asked to advertise the research to others they may know to create a snowballing sample.

2. Please explain how risk will be handled (e.g., participants scoring as suicidal on the PHQ-9. How will this be followed up?

The Mood Disorders Centre Guidelines will be followed for managing the risk. GP details are collected prior to any participation, along with consent to contact the GP, if required. After the initial screening, if item nine on the PHQ-9 identifies any level of suicidal ideation the risk to self will be clinically assessed, including any plans of intention to end their life. Telephone or written contact will be made with the GP to express concerns regarding the individual's safety. The individual will be provided with a signposting information sheet.

This statement has been added to the consent form;
"If the researcher has concerns regarding my physical or emotional wellbeing they will inform my GP and provide me with details of relevant local services that may help."

3. Please provide signposting information (for people who are excluded due to high scores on anxiety/depression).
A signposting information sheet has been created and attached to the application. This contains all local signposting information taken from Devon Partnership Trust website; https://www.dpt.nhs.uk/i-need-help-now

4. Add name of Chair of Psychology Ethics: Lisa Leaver.
Lisa Leavers details have been added to debriefing form.

I look forward to hearing from you.
Yours Sincerely

Claire Treleaven

Dear Marker,

Thank you for reviewing my application again and providing further feedback. I have considered the comments myself, and with my supervisor, and responded to these in the following ways;

- a high "severe" threshold is used for exclusion based on PHQ/GAD even though the procedure is likely to be upsetting. How do you justify not excluding people with moderate (yet clinically significant) levels of anxiety/depression given that you are likely to cause them distress through a worry procedure? At the very least, please consider further safeguards that you can put in place if participants show excessive distress at this time.

(1) Firstly, we hold that we (a) are not presenting anxious material that people in the study would not encounter in their own lives. The inductions are based on commonly occurring anxieties. (b) we are presenting the materials in a controlled fashion, and we are taking steps at the end of the study to help people manage their anxieties in terms of engaging them in meaningful mood repair and providing them with helpful strategies to manage uncertainty in their day-to-day life. These are strategies that would be employed in a therapeutic setting as well, so we think these may be useful to participants. We will also provide information to participants about who they can contact if they continue to experience anxiety/distress at the end of the study. We therefore hold that we have taken steps to ameliorate distress or the negative effects of distress should it occur.

(2) We think that this study could have important and clinically useful outcomes. There is evidence that anxiety is high during the perinatal period, but the mechanisms driving these increased rates/risk of anxiety are unclear. It is critical to understand these mechanisms in order to clearly address this problem clinically.

This study is one of the first studies to examine intolerance of uncertainty in pregnancy versus non-perinatal topics. We posit that pregnancy may create especially difficult to manage problems for tolerating uncertainty (e.g., because the domain is very important/relevant to the individual). If this is true, then people who already struggle with tolerating uncertainty may find that they become clinically anxious, where previously they were not. This may help to explain increased risks for anxiety during the perinatal period. Knowing this would help to point to clear targets for perinatal intervention.

We are recruiting anxious people because people high in intolerance for uncertainty are more likely to be anxious. If we exclude all anxious people, then we are likely significantly reducing the range of intolerance for uncertainty in our sample, and we will have less power to detect meaningful differences where those differences exist. It would ultimately obscure an effect where there actually may be an effect, and this would ultimately serve to harm pregnant women with anxiety – because we would not be able to adequately examine a phenomena that may be causing problems for women, and would not therefore be able to provide the logic for clinically targeting this effect.

Together with the scientific logic for the study (there is less merit in conducting a study that has a significantly reduced chance of actually studying the phenomena of interest), and the steps we have taken to ameliorate any distress participants might experience as a result, we think that it is reasonable to include women with moderate (but not severe) levels of anxiety.

- what will you do if participants' levels of distress are discovered to be high at the end of the study?

If the participant is still distressed after debriefing and all levels of the mood induction procedure (uncertainty reducing statements, mindfulness exercise, and a video clip) are completed, the clinical cover will be contacted immediately. All advice given will be followed and signposting information provided to the participant. Their GP will be notified, and a follow-up telephone call will be provided within 24 hours to check on their wellbeing.

- please confirm that you are screening participants (PHQ/GAD) in person and ensure that you arrange clinical cover for these times.
Screening will take place face to face and the following statement has been added to the ethics application; “During all face to face contact with participants, a clinical cover will be provided. I will make contact with the clinical cover to ensure that any distress or clinical issues can be discussed and acted upon immediately.”

- I may have missed this in the application, but please confirm that participants will read the information sheet and complete the consent form *before* they complete the demographics/medical history/PHQ/GAD (so they understand about confidentiality etc.).
Yes, all participants will be asked to read the participant information and consent form before completion of any forms. This has now been made clear within the ethics application.

On the information sheet:
DPA (1998) is obsolete and has been superseded by DPA (2018) and GDPR. Please correct.
This has been corrected.

- in the section on Confidentiality, state more clearly how names/emails/medical details (on demographics and consent form) will be stored securely (ideally after scanning and shredding paper copies), who will have access to these details, whether these personal details will be stored separately from other data, and whether these are linked to the other data by, e.g., code number.
The following statement has been added to the participant information sheet; “During participation you will be allocated a code, against which all data will be stored, in order to protect your identity and ensure that nobody else can trace the information back to you. All data collected in paper form will be scanned into digital format, and paper copies will be shredded immediately. Digital data will be saved securely on password-protected computers and stored securely in accordance with the Data Protection Act 2018, and General Data Protection Regulation (GDPR). All personal details will be stored separately from data collected for the purpose of the study; and linked only by your allocated code (as above).”

- Personal data should be deleted shortly after the end of testing to protect anonymity, unless there is a good reason not to.
The information sheet has been changed to reflect this, with the following statement; “All personal data will be destroyed immediately following the completion of your involvement in the study”.

- add contact details for the Chair of PREC (NM) at the end.
Details have been added.

I hope that these changes are satisfactory. I look forward to hearing from you.
Yours Sincerely

Claire Treleaven

FURTHER AMENDMENTS:

17/10/2019 – Reduction in the elements of the mood induction following feedback from a pilot run with colleagues.
25/10/2019 – Amendments to eligibility criteria, to allow individuals who have experienced previous perinatal loss, if it is rated as not distressing, and to allow individuals with a historical mental health diagnoses.
08/11/2019 – Amendment to allow for data collection to take place via video call.

Appendix B – Research advertising

Research Participants Required

Are you pregnant with your first child?

Are you over 18, and having a "low-risk pregnancy"?

i.e. your care is provided by a midwife, not a consultant?

Do you want to help us to understand how women manage uncertainty in pregnancy?

Pregnancy is a time which is full of uncertainties. Many women report feeling anxious about these throughout their pregnancy, which impacts upon their mental wellbeing. This study aims to investigate the uncertainty that women experience, and how they manage their emotions around this.

Every participant will be entered into a prize draw to win up to £100 in vouchers!

Interested?

Please contact Claire Treleaven

Call or Text: 07506861140

Email: ct495@exeter.ac.uk

fb.me/uncertaintyinpregnancy

UNIVERSITY OF EXETER

Appendix C – Participant information sheet

Participant Information Sheet

Intolerance of Uncertainty and Emotion Regulation in pregnant women

Researcher: Claire Treleaven (Trainee Clinical Psychologist, University of Exeter)

Supervised ~~by:~~ Dr Heather O'Mahen (University of Exeter)

I am a trainee clinical psychologist, currently carrying out a research project, investigating how pregnant women experience uncertainty; and how they manage their emotions around this. This is an important piece of research because, as you know, there are so many uncertainties associated with being pregnant, and some women may struggle to manage their emotions around these. Very little research has been done in this area, and it is my hope that I can begin to highlight the importance of this. I would like to invite you to take part in this study, but before you decide whether you would like to participate, please read this information sheet carefully. If you have any questions after reading this, please do not hesitate to contact me on the details below.

What will participation involve?

I will firstly have to check that you meet criteria to take part. To do this, I will send you a link to an online questionnaire which will provide you with a consent form, and ask you some questions about your pregnancy and current health. If you meet all criteria, we will need to arrange a one-off appointment either in person at the University of Exeter, or via video call. To meet over video call, you will need a computer with internet access, and you will be required to be undisturbed for the duration of the call. The appointment (whether face to face, or via video call) will take no longer than one hour. At the meeting, I will ask you to complete two short online questionnaires about how you are feeling to make sure that there are no reasons why you shouldn't take part. You will then be asked to work through a series of three online questionnaires relating to how you usually manage uncertainty and difficult situations, and how you feel about pregnancy. Following this, you will be shown a scenario of an uncertain situation and asked to think about some of consequences of that situation. Finally, you will be asked to read some statements; and to re-complete the initial questionnaires.

How will my information be kept confidential?

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing dataprotection@exeter.ac.uk or at www.exeter.ac.uk/dataprotection.

During participation you will be allocated a code, against which all data will be stored, in order to protect your identity and ensure that nobody else can trace the information back to you. All data collected in paper form will be scanned into digital format, and paper copies will be shredded immediately. Digital data will be saved securely on password-protected computers and stored securely in accordance with the Data Protection Act 2018, and General Data Protection Regulation (GDPR). All personal details will be stored separately from data collected for the purpose of the study; and linked only by your allocated code (as above). All personal data will be destroyed immediately following the completion of your involvement in the study. The final report will be submitted to the University of Exeter in May 2020, with a plan for future publication within a journal.

Data will be accessed only by the researcher, and research supervisor. However, if at any point during your participation, I become aware of any issues regarding the safety of yourself, or others, with your consent, I will share this with individuals at the University, your GP and relevant local services if appropriate. However, I will endeavour to inform you of this if concerns are raised.

What are the possible disadvantages of taking part?

For some women, actively considering some of the uncertainties relating to pregnancy may be upsetting. However, the task involved asks you to consider common concerns that pregnant women express, and is therefore likely to be asking you to consider things you are already aware of. The task will take no longer than one hour, after which you will be offered the opportunity to discuss your experience of the task. Your participation is completely voluntary, and you therefore have the right to withdraw at any stage of your participation. Every opportunity to reduce any upset caused will be taken.

What are the possible advantages of taking part?

You will have the opportunity to support research into a highly valuable area. If we are able to gain more understanding about how pregnant women experience uncertainty; more can be done to support them at this time. Also, as a result of taking part you will be offered the opportunity to be entered into a prize draw, with the top prize of £100 in vouchers!

Do I have to take part in this research?

No, you are under no obligation to take part in this research; all participation is voluntary. You can withdraw at any time without giving a reason. If after taking part, you would like to withdraw your information, you are able to request this at any time, and your information will be removed immediately. If you have any concerns regarding your participation, at any point during the study, you are invited to discuss these with the researcher, the research supervisor, or the Chair of Psychology Ethics (details are supplied at the end of this information sheet, and on the post-study information sheet).

Who has reviewed this study?

This project has been reviewed by the Research Ethics Committee at the University of Exeter (Reference Number: eCLESPsy000575).

What happens now?

If you are interested in taking part in this project, please let me know on the contact details provided (ct495@exeter.ac.uk / 07506861140). Following this, I will contact you to make an appointment to check you meet criteria, and if eligible to carry out the research activity.

Alternatively, if you are not happy with any aspect of this project, please contact either Dr Heather O'Mahen (Research supervisor; h.omahen@exeter.ac.uk / 01392 724651), Gail Seymour (Research Ethics and Governance Manager; g.m.seymour@exeter.ac.uk / 01392 726621) or Dr Nick Moberly (Chair of Psychology Research Ethics Committee ; N.J.Moberly@exeter.ac.uk / 01392 724656).

Claire Treleaven
Trainee Clinical Psychologist

Telephone: 07506861140
Email: ct495@exeter.ac.uk
Facebook: fb.me/uncertaintyinpregnancy

Appendix D – Participant consent form

Consent Form

Intolerance of Uncertainty and Emotion Regulation in Pregnant Women

Claire Treleaven (Trainee Clinical Psychologist)

1.	I understand that this is a project run by a Trainee Clinical Psychologist, studying at the University of Exeter.	☐
2.	I confirm that I have read and understood the Participant Information Sheet for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
3.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, and without my legal rights being affected in any way.	☐
4.	I understand that the data collected during the study, may be looked at by members of the research team and other individuals from the University of Exeter. I give permission for these individuals to have access to these records.	☐
5.	I understand that taking part involves data from my anonymised questionnaire responses to be used for the purpose of reports published in an academic publication.	☐
6.	I understand that if the researcher has any concerns regarding my safety, or the safety of anyone else, they will discuss this with members of the University of Exeter, inform my GP and/or other relevant agencies, and provide me with details of local services that may be of help to me.	☐
7.	I understand that if I have any concerns following my participation, I can contact the researcher, the research supervisor, or members of the ethics committee at the University of Exeter.	☐
8.	I agree to take part in the research project.	☐

Print Name: _____

Signature: _____

Date: _____

Appendix E – Measures

Patient Health Questionnaire-9 (PHQ-9), Kroenke et al., (2001)

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

Generalised Anxiety Disorder Assessment (GAD-7), Spitzer, Kroenke, Williams, & Löwe, (2006)

GAD-7 Anxiety

Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✔" to indicate your answer"*	Not at all	Several days	More than 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 is 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

Column totals: ___ + ___ + ___ + ___

= *Total Score* _____

If you checked off any problems, how difficult have these problems 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
☐	☐	☐	☐

Pregnancy Related Anxiety Questionnaire (PRAQ-R) - (Huizink et al., 2004)
Please circle each answer that applies most accurately to your situation
Answer categories;

1. Absolutely not relevant
2. Hardly ever relevant
3. Sometimes relevant
4. Reasonably relevant
5. Very relevant

I am worried about the pain of contractions and the pain during delivery

m worried about the fact that I shall not regain my figure after delivery

ɔmetimes think that our child will be in poor health or will be prone to illnesses

m concerned about my unattractive appearance

m worried about not being able to control myself during labour and fear that I will scream

m worried about my enormous weight gain

m anxious about the delivery because I have never experienced one before

m afraid the baby will be mentally handicapped or will suffer from brain damage

m afraid our baby will be stillborn, or will die during or immediately after delivery

m afraid that our baby will suffer from a physical defect or worry that something will be physically wrong with the baby

Intolerance of Uncertainty Scale (IUS) - Buhr & Dugas, (2002)

IUS

You will find below a series of statements which describe how people may react to the uncertainties of life. Please use the scale below to describe to what extent each item is characteristic of you. Please circle a number (1 to 5) that describes you best.

	Not at all characteristic of me			Somewhat characteristic of me		Entirely characteristic of me
1. Uncertainty stops me from having a firm opinion.	1	2	3	4	5	
2. Being uncertain means that a person is disorganized.	1	2	3	4	5	
3. Uncertainty makes life intolerable.	1	2	3	4	5	
4. It's unfair not having any guarantees in life.	1	2	3	4	5	
5. My mind can't be relaxed if I don't know what will happen tomorrow.	1	2	3	4	5	
6. Uncertainty makes me uneasy, anxious, or stressed.	1	2	3	4	5	
7. Unforeseen events upset me greatly.	1	2	3	4	5	
8. It frustrates me not having all the information I need.	1	2	3	4	5	
9. Uncertainty keeps me from living a full life.	1	2	3	4	5	
10. One should always look ahead so as to avoid surprises.	1	2	3	4	5	
11. A small unforeseen event can spoil everything, even with the best of planning.	1	2	3	4	5	
12. When it's time to act, uncertainty paralyses me.	1	2	3	4	5	
13. Being uncertain means that I am not first rate.	1	2	3	4	5	

	Not at all characteristic of me			Somewhat characteristic of me			Entirely characteristic of me
14. When I am uncertain, I can't go forward.	1			2			3			4			5
15. When I am uncertain I can't function very well.	1			2			3			4			5
16. Unlike me, others always seem to know where they are going with their lives.	1			2			3			4			5
17. Uncertainty makes me vulnerable, unhappy, or sad.	1			2			3			4			5
18. I always want to know what the future has in store for me.	1			2			3			4			5
19. I can't stand being taken by surprise.	1			2			3			4			5
20. The smallest doubt can stop me from acting.	1			2			3			4			5
21. I should be able to organize everything in advance.	1			2			3			4			5
22. Being uncertain means that I lack confidence.	1			2			3			4			5
23. I think it's unfair that other people seem sure about their future.	1			2			3			4			5
24. Uncertainty keeps me from sleeping soundly.	1			2			3			4			5
25. I must get away from all uncertain situations.	1			2			3			4			5
26. The ambiguities in life stress me.	1			2			3			4			5
27. I can't stand being undecided about my future.	1			2			3			4			5

Intolerance of Uncertainty Scale – Situation Specific - Mahoney & Mcevoy, (2012)

Initials/ID #: _____

Date: _____

Intolerance of Uncertainty Scale – Situation Specific

Please circle the number that best corresponds to how much you agree with each

	Not at all characteristic of me	A little characteristic of me	Somewhat characteristic of me	Very characteristic of me	Entirely characteristic of me
1. Unforeseen events upset me greatly regarding this situation	1	2	3	4	5
2. It frustrates me not having all the information I need about this situation	1	2	3	4	5
3. Uncertainty in this situation keeps me from living a full life	1	2	3	4	5
4. One should always look ahead so as to avoid surprises in this situation	1	2	3	4	5
5. A small unforeseen event can spoil everything in this situation, even with the best of planning	1	2	3	4	5
6. When it's time to act in this situation, uncertainty paralyses me	1	2	3	4	5
7. When I am uncertain of this situation I can't function very well	1	2	3	4	5
8. I always want to know what the future has in store for me in this situation	1	2	3	4	5
9. I can't stand being taken by surprise in this situation	1	2	3	4	5
10. The smallest doubt can stop me from acting in this situation	1	2	3	4	5
11. I should be able to organize everything in advance of the situation	1	2	3	4	5
12. I must get away from all uncertainties in this situation	1	2	3	4	5

Cognitive Emotion Regulation Questionnaire (CERQ-S) - Garnefski & Kraaij, (2006)
Everyone gets confronted with negative or unpleasant experiences and everyone responds to them in his or her own way. By the following questions, you are asked to indicate what you generally think, when you experience negative or unpleasant events. Please read the sentences below and indicate how often you have the following thoughts by circling the most suitable answer.

1. Almost never
2. Sometimes
3. Regularly
4. Often
5. Almost always

1	I think that I have to accept that this has happened	1	2	3	4	5
2	I often think about how I feel about what I have experienced	1	2	3	4	5
3	I think I can learn something from the situation	1	2	3	4	5
4	I feel that I am the one who is responsible for what has happened	1	2	3	4	5
5	I think that I have to accept the situation	1	2	3	4	5
6	I am preoccupied with what I think and feel about what I have experienced	1	2	3	4	5
7	I think of pleasant things that have nothing to do with it	1	2	3	4	5
8	I think that I can become a stronger person as a result of what has happened	1	2	3	4	5
9	I keep thinking about how terrible it is what I have experienced	1	2	3	4	5
10	I feel that others are responsible for what has happened	1	2	3	4	5
11	I think of something nice instead of what has happened	1	2	3	4	5
12	I think about how to change the situation	1	2	3	4	5
13	I think that it hasn’t been too bad compared to other things	1	2	3	4	5
14	I think that basically the cause must lie within myself	1	2	3	4	5
15	I think about a plan of what I can do best	1	2	3	4	5
16	I tell myself that there are worse things in life	1	2	3	4	5
17	I continually think how horrible the situation has been	1	2	3	4	5
18	I feel that basically the cause lies with others	1	2	3	4	5

Appendix F – Vertical arrow technique

If this scenario were to happen to you, what are the three most personally meaningful outcomes?

Outcome 1:
Outcome 2:
Outcome 3:

What are the consequences of OUTCOME 1 occurring?

1)
2)
3)

What are the consequences of OUTCOME 2 occurring?

1)
2)
3)

What are the consequences of OUTCOME 3 occurring?

1)
2)
3)

Appendix G – Uncertainty inducing statements

1. It is disturbing to not know what is going to happen to me
2. I don’t feel good in anything that is uncertain
3. This is exactly what bothers me, I love to have everything in control, and I can’t control this…
4. Its difficult to live with a lot of possibilities
5. It is unacceptable to live like this
6. It is unfair to have no guarantees in life
7. I should be able to organize and plan everything beforehand, but I don’t know what will happen…
8. It is difficult to not know what will happen to me

Appendix H - Participant debriefing form

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Participant Debriefing Information

Thank you very much for taking part in the research project. The aim of your participation was to gain an understanding of how pregnant women experience uncertainty, and how they manage their emotions around this.

What did my participation involve?

You asked to consider the consequences of one of two scenarios. One of these scenarios was relating specifically to an uncertainty within your pregnancy, and the other to an uncertainty in a friendship. Whilst completing the task, you were asked to think carefully about the scenario and rate how this made you feel, along with how you would manage your emotions around it. This was important because now it will be possible to explore whether there are specific differences in the way pregnant women feel about two different scenarios, and how they manage these feelings.

What happens next?

It is possible that for some women, specifically thinking about uncertainties may have caused some upset. It is important to remember that the uncertainties specified within the tasks are very common concerns that pregnant women express. The task was completely hypothetical and fictional. If you feel that your participation has caused upset, please let the researcher know at the end of your appointment. Alternatively, please feel free to make contact on the details below to discuss the impact of your involvement.

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University of Exeter
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Email: N.J.Moberly@exeter.ac.uk

Can I withdraw my information from the research after I have taken part?

Yes. You can withdraw your information from the study at any time until the research is completed. If you would like to withdraw your information from this project, please contact me and it will be arranged with immediate effect.

Can I see what happens with my information?

If you are interested in receiving a copy of the final report, please register your interest on the details below, and I will ensure that this is sent to you once complete.

If you have any further questions or would like to discuss your involvement further, please do not hesitate to contact me on the details above.

Appendix I – Data coding scheme

Coping Strategy	Description	Count Total	How adaptive? (Each count must have their own adaptive rating) -1 = Not at all helpful 0 = not mentioned 1 = somewhat helpful 2 = Very helpful	Total adaptive score
Consequence mitigation - Objective - Psychological	Minimising the objective or non-psychological consequences of a bad outcome. Minimising the emotional and cognitive consequences of a bad outcome by preparing effective coping responses.			
Reappraisal - Expectation management - Invalidating feedback - Benefit-finding	Reappraising the likelihood of good and bad outcomes. Reappraising the value of feedback by finding fault with the nature or source of the information itself Reappraising the relative value of good and bad health outcomes			
Information seeking	Seeking information from various sources (e.g., online, from friends etc)			
Direct emotion management	Using strategies to avoid, distract from or supress emotions			
Rumination	Focussing on the feelings and thoughts associated with the negative event and supressing competing activities			

Appendix J – Dissemination statement

The literature review will be submitted for publication to the Archives of Women's Mental Health, and empirical paper will be submitted to Behaviour Research and Therapy. Details of the empirical study will also be shared at the South West Regional Perinatal Network Meeting, and presented as a poster at the annual BABCP conference. Participants who registered interest will also receive a copy of the paper via email.

Appendix K – Behaviour Research and Therapy – Authors guidance

GUIDE FOR AUTHORS

INTRODUCTION

The major focus of *Behaviour Research and Therapy* is an experimental psychopathology approach to understanding emotional and behavioral disorders and their prevention and treatment, using cognitive, behavioral, and psychophysiological (including neural) methods and models. This includes laboratory-based experimental studies with healthy, at risk and subclinical individuals that inform clinical application as well as studies with clinically severe samples. The following types of submissions are encouraged: theoretical reviews of mechanisms that contribute to psychopathology and that offer new treatment targets; tests of novel, mechanistically focused psychological interventions, especially ones that include theory-driven or experimentally-derived predictors, moderators and mediators; and innovations in dissemination and implementation of evidence-based practices into clinical practice in psychology and associated fields, especially those that target underlying mechanisms or focus on novel approaches to treatment delivery. In addition to traditional psychological disorders, the scope of the journal includes behavioural medicine (e.g., chronic pain). The journal will not consider manuscripts dealing primarily with measurement, psychometric analyses, and personality assessment.

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Contact details
Any questions regarding your submission should be addressed to the Editor in Chief:
Professor Michelle G. Craske
Department of Psychology
310 825-8403
Email: brat@psych.ucla.edu

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