

School of Psychology Ysgol Seicoleg

## Does Mindfulness Based Cognitive Therapy improve Perinatal Mental Health Outcome? A Systematic Review.

## The Impact of Dispositional Mindfulness and Social Support on the Risk of Prenatal Depression and Anxiety among Women with Hyperemesis Gravidarum.

Thesis submitted in partial fulfilment of the requirement for

the degree of:

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#### Preface

The perinatal period is known to be a time of heightened risk for the onset or relapse of mental health difficulties. Given the potential impact of psychological distress for perinatal women, evidence-based interventions that are effective and acceptable to this group are important.

Paper one of this thesis presents a systematic review that aimed to contribute to the evidence-base relating to the effectiveness of Mindfulness-based Cognitive Therapy (MBCT) (Segal, Williams, and Teasdale, 2002) for perinatal women. MBCT is an 8-week group programme which combines elements of Cognitive Behavioural Therapy (CBT) (Beck et al., 1979) with components of Mindfulness Based Stress Reduction (MBSR) (Kabat-Zinn, 1990). The effect of this intervention upon anxiety, depression, and stress levels for women during pregnancy and postpartum was of interest. The acceptability of MBCT interventions to perinatal women was also examined. The review found that there is initial evidence to suggest that MBCT has positive effects on depression and anxiety outcomes for perinatal women. Few studies investigated benefits in terms of mindfulness, however existing evidence suggests that mindfulness levels potentially increase over the course of MBCT. Currently, MBCT effects on stress outcomes have been inadequately tested and so the interventions impact in terms of women's stress levels is unknown. Overall, the review indicated that MBCT is a potentially beneficial intervention that may be both effective and highly acceptable to perinatal women. However, the review highlights the need for further high-quality studies particularly with postpartum women, as well as the need for further examination of the effect of MBCT for anxiety, stress, and mindfulness outcomes.

Paper two presents an empirical paper which aims to contribute understanding of the factors that influence anxiety and depression for women with a pregnancy-related condition known as Hyperemesis Gravidarum (HG). HG is characterised by persistent nausea and vomiting and can be extremely debilitating for women, often affecting many aspects of their lives. Women with this condition are known to have an elevated risk of anxiety and depression. However, this population is under researched and currently there is a lack of understanding of the factors that impact upon anxiety and depression within this group. This study aimed to examine the impact of specific aspects of social support and mindfulness upon anxiety and depression for prenatal women affected by HG. A crosssectional survey design was used with a sample of 190 pregnant women with HG. Women had completed questionnaires relating to their backgrounds, HG factors, anxiety, depression, mindfulness, and social support. The findings indicate elevated levels of anxiety and particularly depression, therefore highlighting the need for routine screening for women affected by HG. It was also found that women with lower levels of social support and mindfulness had higher levels of anxiety and depression. This suggests value in assessing social support and mindfulness to identify women most likely to benefit from psychosocial interventions. When the distinct dimensions of mindfulness and social support were examined together in a model, some unique relationships emerged. Results indicate that the mindfulness facets of 'non-judging' and 'describing' may be important targets within interventions for women with HG. Social support was also found to be important. When considered together with mindfulness, 'positive social interaction' showed a direct path with depression. Furthermore, a direct path between 'affectionate support' and anxiety also emerged. These findings highlight the potential importance of support from

others characterised by enjoyment, relaxation and behavioural expressions of love and affection in preventing mood disturbance and anxiety for prenatal women affected by HG.

Taken together, these findings have important clinical implications in guiding assessment and screening procedures, as well as informing intervention protocols for women with HG. There are also important theoretical implications, as the presented model indicates that some important factors are likely to be missing. Therefore, continued research will be important to help identify the factors that directly and indirectly impact upon anxiety and depression for women affected by HG.

# Does Mindfulness Based Cognitive Therapy improve Perinatal Mental Health Outcome? A Systematic Review.

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For ease of reading, figures and table have been included within the text rather than in the appendices.

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#### Abstract

**Background:** The perinatal period represents a time of heightened risk for the onset or relapse of mental health conditions. Given the potential impact of perinatal mental health conditions on women, infants, and families, acceptable and evidence-based interventions are needed. Mindfulness-based Cognitive Therapy (MBCT) shows promise in its application to a variety of populations, however, its efficacy and acceptability for perinatal women is less clear.

**Methods:** A systematic literature search was conducted using five databases to identify studies reporting standardised MBCT interventions with pregnant and postpartum women. Clinical outcomes included anxiety, depression, stress, and mindfulness. Acceptability of MBCT interventions to perinatal populations was also examined. The 'Quality Assessment Tool for Quantitative Studies' was used to quality assess the included articles, and a narrative synthesis was undertaken to summarise the findings.

**Results:** The search identified twelve studies across ten cohorts (total *n*=480). Methodological quality of studies varied but was generally low. Preliminary evidence indicates that MBCT reduces the severity of perinatal depression and anxiety. Evidence that MBCT increases mindfulness levels is limited. The impact of MBCT on stress related outcomes during the perinatal period has been inadequately tested. Findings support the acceptability of MBCT interventions within this population.

**Conclusion:** The study of MBCT for perinatal populations is still in its infancy, but preliminary findings indicate the intervention the be highly acceptable to perinatal populations and to have promising effects for perinatal depression and anxiety. Recommendations for future research and clinical practice are made.

#### Introduction

The perinatal period is a time of increased vulnerability for the onset and relapse of anxiety and depression (Howard et al., 2014; Woody et al., 2017). An estimated 18% and 19% of women suffer with depression during pregnancy and postpartum respectively (Gavin et al., 2005). Prevalence of perinatal anxiety is less clear (Dunkel Schetter & Tanner, 2012), but studies suggest rates as high as 19% during pregnancy and 20% during postpartum (George et al., 2013). Comorbidity of anxiety and depression is common, with an estimated antenatal prevalence of 9.5% and postnatal prevalence of 8.2% (Falah-Hassani et al., 2017). Perinatal women may experience an array of psychosocial stressors that increase their risk of mental health problems including relational difficulties, inadequate social support, bodily changes, fear of childbirth, and anxiety around the infant's wellbeing (Woods et al., 2010; Yali & Lobel, 1999). Women who experience anxiety and depression during pregnancy are more likely to experience mood disturbance postnatally (Heron et al., 2004), and subsequently during their child's lifetime (Halligan et al., 2007; Pawlby et al., 2009).

Perinatal mental health problems have been associated with poor maternal, birth, and infant outcomes, particularly if left untreated (Dunkel Schetter & Tanner, 2012; Glover, 2014; Waters et al., 2014). Associated consequences include premature birth, low gestational weight, and emotional-behavioural difficulties in infants (Cardwell, 2013; Closa-Monasterolo et al., 2017). Perinatal mental health issues are a major public health problem necessitating attention (Rees et al., 2019). Given the potential risks of pharmacological treatment on foetal development (Howard & Khalifeh, 2020), and the reluctance of many expectant mothers to take medication (Dimidjian & Goodman, 2009), evidence-based interventions that are safe, effective, and acceptable to perinatal women are required.

Psychological interventions are advised for the treatment of perinatal mental health difficulties (NICE, 2014); however, the evidence-base requires expansion.

Mindfulness is defined as "the awareness that emerges through paying attention on purpose, in the present moment, and non-judgementally" (Kabat-Zinn, 2003, p. 145). Emerging research indicates mindfulness-based interventions (MBIs) to be both acceptable and beneficial to perinatal women (Dhillon et al., 2017). One of the most widely dispersed MBIs, Mindfulness Based Cognitive Therapy (MBCT), is a manualised 8-week group program (Segal et al., 2002). MBCT has a basis in information processing theories (Teasdale et al., 1995), and integrates standard Cognitive Behavioural Therapy (CBT) (Beck et al., 1979) with components of Mindfulness Based Stress Reduction (MBSR) (Kabat-Zinn, 1990). Through systematic training and practice, MBCT aims to develop mindful awareness of mental events, and encourages a novel approach to thoughts, emotions, and bodily sensations. Distinct from CBT, MBCT places little focus on challenging cognitive distortions, but aims to foster metacognitive awareness whereby participants are increasingly enabled to recognise automatic activation of dysfunctional cognitive processes (Chartier et al., 2010).

Although originally developed in the context of major depression, accelerating interest has seen MBCT applied to varied clinical and non-clinical populations (Chiesa & Serretti, 2011; Piet & Hougaard, 2011; Querstret et al., 2020), and more recently, perinatal mental health. Preliminary results are encouraging with reported benefits including reduced worry, anxiety, and depression alongside enhanced emotion regulation, self-compassion, mindfulness, and psychological wellbeing for prenatal women (Dimidjian et al., 2016; Goodman et al., 2014; Zemestani & Fazeli Nikoo, 2020). Positively, benefits have been shown to extend into the postpartum, a time of particularly heightened risk of mental health onset and relapse

(Dimidjian et al., 2015; Luberto et al., 2018). Furthermore, recent evidence indicates MBCT potentially reduces risk of preterm birth for those with initially heightened psychological distress through reduction of pregnancy-anxiety in early gestation (Mackinnon et al., 2021). Manualised MBIs including MBCT have been documented as having larger effect sizes than other MBIs that focus solely on meditation (Lever Taylor et al., 2016). Thus, MBCT may have therapeutic benefits beyond mindfulness, and is a potential alternative to pharmacological treatment within perinatal care.

Reviews of MBIs (not specific to, but inclusive of MBCT) within perinatal populations report mixed findings. A meta-analysis found MBIs to produce moderate pre-post effects for depression, and smaller effects for anxiety (Lever Taylor et al., 2016). However, betweengroup analyses found no significant difference, a finding supported by a subsequent metaanalysis (Dhillon et al., 2017). In contrast, a synthesis by Shi and Macbeth (2017) reported MBIs to have more pronounced effects for anxiety than for depression and stress. However, consistent with previous reviews, when comparisons were made with a control group, results were non-significant. Reviews consistently observe high heterogeneity in intervention content across MBIs, along with widespread methodological shortcomings including small samples, inadequately powered studies, and a lack of RCTs. Taken together, these factors have confounded attempts to clarify the effect of MBIs for perinatal populations. Therefore, despite encouraging preliminary results, clear recommendation around the utility of MBIs within perinatal care is lacking.

Whilst existing reviews provide broad insight of MBI effects, there is yet to be a focused synthesis of evidence to distinguish the value of MBCT programmes within perinatal mental healthcare. The tendency of MBIs to integrate varied practices and diverse cognitive and

affective skills under an umbrella term "mindfulness" makes it difficult to tease apart intervention components, acting mechanisms, and ultimately their effects. The disentanglement of MBIs is often a topic of contention. However, significant distinctions exist between MBIs in terms of their philosophical backgrounds, techniques, psychological mechanisms, and conceptualisations of mindfulness (Chiesa & Malinowski, 2011). Discerning the evidence for distinct MBIs is essential to inform clinical recommendations and commissioning of services, for which clarification regarding the therapeutic approach being employed and the relevant evidence-base is important. Despite the broad similarities between MBCT and MBSR, and the frequent interchangeable use of these terms, MBCT is distinct in its theoretical features with its basis in a model of ongoing risk engrained in major depression (Segal et al., 2002). MBCT uniquely incorporates a curriculum drawn from CBT and has its strongest evidence-base in relation to its effects within recurrent depression (Dryden & Crane, 2017). To achieve an understanding of the utility and acceptability of MBCT for perinatal populations, a focused synthesis of empirical studies of MBCT interventions is required.

The aforementioned blending of varied mindfulness practices within the literature can present difficulty for researchers and clinicians to decipher quality MBCT interventions that maintain integrity with standardised procedures. As such, a quality tool that supports identification of the core MBCT components of interventions would be valuable both within clinical practice and research to aid contribution to, and dissemination of, the MBCT evidence-base. The development of such a tool is an aim of the current review.

In summary, preliminary evidence indicates that MBCT may be effective in improving mental health outcomes for perinatal women (Dhillon et al., 2017). Given the expanding evidence-

base, an update on the topic of MBIs within perinatal mental health is required. A synthesis of MBCT evidence would be advantageous to aid recommendations around the clinical utilisation of this approach. Such recommendations are particularly pertinent given the increased emphasis on evidence-based psychological interventions within perinatal mental healthcare in the UK (Health and Social Care Committee, 2019). The recent publication of several MBCT studies makes it possible to inspect the impact of this programme more closely. To the authors knowledge there is yet to be a synthesis of several recent MBCT studies (Evans et al., 2021; Latendresse et al., 2021; Mackinnon et al., 2021). The aim of the current review is to explore the evidence of MBCT for psychological distress (particularly anxiety, depression, and stress) within pregnancy and the postpartum period. Little is known about the acceptability of MBCT to perinatal women, and so a further aim of this review is to examine acceptability through findings of standard acceptability measures and possible proxy indicators of acceptability, including dropout rates and usability. Findings relating to potential moderating variables such as practice, therapist expertise, delivery, and programme fidelity are also synthesised.

#### Methods

#### **Protocol and Registration**

This systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions and follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Higgins et al., 2021; Page et al., 2021). The protocol was registered with PROSPERO (CRD42021242427).

#### **Eligibility Criteria**

Included samples were perinatal women (*see* Appendix 2). Traditionally, the term 'perinatal' refers to women during pregnancy and up to one-year following childbirth. The current study expanded this definition to include women up to two-years after childbirth. This is in accordance with UK-wide service changes that aim to extend perinatal mental healthcare to women and infants up to two-years following childbirth (Health and Social Care Committee, 2019).

MBCT was the intervention of interest. To be included, studies had to: (1) state the reported mindfulness intervention to be MBCT and describe its basis in a standardised MBCT manual; *or* (2) if the paper did not cite a MBCT manual, papers had to explicitly state the intervention to be MBCT and provide sufficient detail to ascertain consistency with standard MBCT. Due to digital delivery being recognised as an important option (Segal et al., 2020), this review included both MBCT delivered in-person as well as remote MBCT interventions (e.g., video-conferencing groups). Included studies comprised of controlled and uncontrolled quantitative studies. The primary outcome was perinatal mental health, specifically anxiety, stress, and/or depression as measured by standardised measures. Outcomes relating to mindfulness and acceptability were also of interest. Only studies that were available in English, peer-reviewed, and that reported quantitative data were included. Studies examining multicomponent interventions were excluded (e.g., ACT, DBT). Qualitative studies, abstracts, literature reviews, and unpublished dissertations were omitted. No restrictions on publication date were imposed.

#### Search Strategy

Five electronic databases (PsycINFO, Scopus, Web of Science, MEDLINE and CINAHL) were systematically searched from database inception to 8<sup>th</sup> April 2021. Reference lists of relevant papers were also manually screened. Search terms were devised by the author, and a Librarian was consulted to ensure specificity. In the event of full-text papers being unavailable, authors were contacted to request these. Subject headings and search terms focused on: (1) the targeted intervention, MBCT; and (2) the targeted sample, perinatal women (Appendix 3). Literature search results were managed using EndNote (Version X9.2).

#### **Study Selection**

Titles and abstracts of all retrieved citations were screened and the inclusion and exclusion criteria applied. Upon instances when eligibility could not be determined full-text articles were reviewed. An independent reviewer completed screening of all titles and abstracts and a randomly selected 25% of full-text papers. Any uncertainties were discussed by reviewers until a consensus was reached. An interrater reliability analysis using Kappa statistic was performed to determine consistency between reviewers. Level of agreement was 94% and interrater reliability was calculated to be Kappa=0.82, therefore indicating substantial interrater reliability.

#### **Data Extraction Process**

The 'Data Collection Form for Intervention Review – RCTs and non-RCTs' from the Cochrane Collaboration was adapted for the purposes of this review (Appendix 4). Prior to data extraction, the form was piloted on four articles and adapted accordingly.

#### **Quality Assessment**

The 'Quality Assessment Tool for Quantitative Studies' (Effective Public Health Practice Project, 1998) was used to assess quality of the included articles (Appendix 5). This tool was selected due to its ability to evaluate varied quantitative methodologies including RCTs, uncontrolled studies, and pre-post designs. It is considered appropriate for systematic reviews (Deeks et al., 2003), to have content and construct validity (Thomas et al., 2004), and has been shown to have superior inter-reliability in comparison to other tools such as The Cochrane Collaboration Risk of Bias Tool (Armijo-Olivo et al., 2012). Six domains were assessed: (1) selection bias; (2) study design; (3) confounders; (4) blinding; (5) data collection methods; and (6) withdrawals and dropouts. A scoring system is used to designate a quality rating for each domain which together infer a global rating of either *strong*, *moderate*, or *weak*.

#### **MBCT Quality Checklist (MBCT-QC)**

Following a review of the MBCT literature, the Good Practice Guidelines for Mindfulnessbased Approaches (BAMBA, 2021), and discussion with two Clinical Psychologists with expertise in mindfulness approaches, the 'MBCT Quality Checklist' (MBCT-QC) was developed (Appendix 6). The MBCT-QC comprises of 5 domains: (1) delivery format, (2) cognitive-behavioural components, (3) mindfulness components, (4) facilitators competence; and (5) programme adherence. It allows evaluation relating to the inclusion of core MBCT components as indicated by article descriptions. Based on these descriptions, ratings of 'included', 'not included' or 'unclear' are given for each checklist item. Due to the emergence of various MBCT manuals that allow applicability to diverse populations, intervention aspects can deviate from standard MBCT originally proposed by Segal et al., (2002). This is particularly the case for remote delivered MBCT interventions in relation to delivery format. As such, the MBCT-QC allows identification of those intervention components that 'deviate from standard MBCT but remain consistent with a cited manual'. The MBCT also captures adaptations made to MBCT for perinatal populations. The checklist was applied to each of the included studies to evaluate the quality of MBCT interventions. A score was calculated for each study by summing the MBCT-QC items *included* within the description of the MBCT intervention for each study. The maximum possible score is 29, with higher scores indicating greater quality MBCT interventions.

#### Results

#### **Study Selection**

The search resulted in 204 titles and abstracts being screened and 66 papers identified as potentially relevant (Figure 1). After reading the full-text, a further 54 papers were excluded. Multicomponent MBIs that incorporated MBCT alongside other interventions and did not identify the examined intervention as MBCT were excluded (Perez-Blasco et al., 2013; Vieten & Astin, 2008; Vieten et al., 2018; Zhang & Emory, 2015). Two further studies reported a MBCT intervention in the title or abstract but did not cite a MBCT manual and interchangeably referenced MBSR within the intervention description (Hosseinian et al., 2016; Musavi & Narimani, 2014). The authors were contacted but a response was not obtained and so these studies were excluded. A further study was excluded due to including women at pre-conception, pregnancy, and postpartum and results were not presented separately (Miklowitz et al., 2015). Another study reference to the intervention as

'mindfulness training' and outlined a smartphone-based app intervention (Sun et al., 2021). Due to this intervention not being explicitly described as MBCT and the extent to which it deviated from standard MBCT protocol; this study was excluded. One study self-defined the intervention to be MBCT in the absence of a manual citation but provided a sufficiently detailed curriculum for the reviewer to ascertain consistency with MBCT protocol, albeit with adaptations for women with nausea and vomiting in pregnancy (NVP) (Faramarzi et al., 2015).

The final data set consisted of 12 studies across 10 cohorts. Two studies (Goodman et al., 2014; Luberto et al., 2018) reported results from the same cohort but the latter extended outcomes to 3-months postpartum. Additionally, a study by Evans et al., (2021) combined data reported by an open-trial and a RCT (Dimidjian et al., 2015, 2016). In these instances, where more than one paper reported outcomes for the same sample, these were considered as one study/sample. Sample and study characteristics are summarised in Table's 1 and Table 2.





Table 1. Sample Characteristics

Study	Country	Population Description	Mean maternal and Gestational age: Mean (SD)	Race / Ethnicity	Marital Support	Mental health status/history	Additional treatment use during the study
Dimidjian (2015)	United States of America	Pregnant women with prior MDD	Maternal age = 31.83 (4.19), Gestational age = 17.25 (6.90)	82% white, 6% African American, 4% Asian, 4% Hispanic, 4% other	93% married or cohabiting.	All women had history of prior MDD & were at risk of depressive relapse/recurrence.	Utilisation data of additional treatments were available for 94% of participants. Among these, 30% were dispensed psychotropic medication, and 20% had 2+ psychotherapy visits
Dimidjian (2016)	United States of America	Pregnant women with prior MDD	MBCT-PD: Maternal age = 30.98(4.08), Gestational age = 15.29 (5.85) TAU: Maternal age= 28.72 (5.50), Gestational age = 16.65 (6.15)	70.93% white, 18.60% African America, 2.32% Asian, 6.98% Hispanic, and 1.12% other	Married/cohabiting in MBCT-PD group = 38 (88.4%), in TAU group = 35 (81.4%).	All women had history of MDD & were at risk of depressive relapse/recurrence. 1 previous episode (MBCT = 34.88%, TAU = 2 episodes = 34.88%), 2 previous episodes (MBCT = 32.56%, TAU = 46.51%), and 3+ previous episodes (MBCT = 32.56%, TAU = 18.60%). Current or lifetime anxiety disorder in MBCT = 34.88%, TAU = 51.16%.	No limitations in either condition on receiving non- study treatment, including psychotropic medications or psychotherapy. No treatment utilisation data reported.
Dunn (2012)	Australi a	Pregnant women, outpatients of an antenatal clinic	MBCT: Maternal age = 35.33 (4.53), Gestational age = 12-28 weeks TAU: Maternal age = 27.67 (5.34), Gestational age = 17-29 weeks	Not reported.	Committed relationship in MBCT group = 90%, in TAU group = 100%	MBCT = 90% reported history of anxiety and/or depression. Control = 0%	Not reported.
Faramarzi (2015)	Iran	Pregnant women	MBCT plus medication:	Not reported.	Not reported.	Not reported. Women with psychiatric illness were	Women currently practicing any relaxation techniques, or

		diagnosed with moderate NVP	Maternal age = 25.11 (4.60), Gestational age = 7.69 (1.88) <b>Control:</b> Maternal age = 23.27 (5.24), Gestational age = 7.74 (1.27)			excluded.	undergoing any psychotherapy, or taking medication other than that permitted by the study protocol were excluded.
Felder (2017)	United States of America	Pregnant women with history of depressive episode	Maternal age = 30.49 (4.09), Gestational age = 24.53 (7.81)	86.5% white, 10.8% Hispanic, 5.4% African American, 2.7% Asian, 5.4% other	91.9% married or cohabiting.	Women at risk of depressive relapse. Past number of episodes: one = 16.2%, two 24.3%, Three+ = 59.5%. Psychiatric comorbidity: PTSD = 13.5%, OCD = 18.9%, social phobia = 27%, panic disorder 2.7%, Alcohol dependence, 13.5% Drug dependence = 0%	Not reported.
Goodman (2014) Luberto (2018)	United States of America	Pregnant women with diagnosis or prominent symptoms of GAD	Maternal age = 33.5 (4.40), Gestational age = 15.54 (5.83)	75% white/non- Hispanic, 12.5% Asian, 8.3% Hispanic, 4.17% other	4.2% single, 95.8% were married or cohabiting.	70.8% met GAD criteria at baseline (sole diagnosis for 11 p's). 25% had comorbid diagnoses of MDD and specific phobia, dysthymia, PTSD, agoraphobia, specific phobia, dysthymia, social phobia. 29.17% did not meet GAD criteria but had prominent generalised anxiety symptoms.	16.67% had accessed psychotherapy in the past year or longer and were continuing during the current pregnancy. 8.33% were on SSRI's. 29.17% had a history of psychotropic use prior to current pregnancy, and 1 participant had taken medication early in pregnancy but had discontinued it. An additional 37.5% reported past psychotropic use but were not taking medication during study.

Latendres se (2021)	United States of America	Pregnant and postpartum women who either screened positive or showed risk factors for perinatal depression	Maternal age = 30.6 (4.3), Gestational age = 24.4 (8.8)	89% white	91.4% married or cohabiting.	51.1% currently experiencing mild-moderate depression symptoms. 48.9% had EPDS scores less than 10 but were at high risk for developing perinatal depression due to health history and significant life events. Among the 47 participants, 48.9% were asymptomatic but had risk factors at screening, and 51.1% were symptomatic.	None reported. Women already dispensed medication for mental health reasons were excluded.
MacKinn on (2021)	Canada	Pregnant women who self- identified as experiencin g high levels of psychologic al distress	MBCT: Maternal age = 30.43 (5.28), Gestational age = 20.21 (5.16) TAU: Maternal age = 32.91 (4.39), Gestational age = 21.38 (4.71)	78.33% white, Asian 10%, Arab 1.7%, mixed/other 10%	In a relationship, MBCT group =96.43%, in TAU group = 93.75%	Women in use of antidepressant/ anxiolytic medications; a lifetime diagnosis of a psychotic, delusional, or dissociative disorder; a current diagnosis of MDD, suicidality, substance abuse or dependence were excluded.	Raw data not reported. At 3- month follow-up, there were no significant differences between groups when reporting the use of other forms of treatment (e.g., counselling, medication). Since post-intervention, however, more MBCT-PD participants reported engaging in yoga meditation, and deep breathing.
Shulman (2018)	Canada	Postpartum women with a diagnosis of depression /anxiety within the first year following	MBCT: Maternal age = 36.71 (4.29) Control: Maternal age = 34.31 (3.44)	<b>MBCT group:</b> 85.7% white, 14.2% other <b>Control group:</b> 56.3% white, 43.7% other	Married/ cohabiting in MBCT group = 92.9%, in control group = 93.8%	GAD in MBCT = 21.4%, in TAU = 25%; MDD in MBCT = 35.7%, in TAU = 43.8%, Comorbid anxiety and depression in MBCT = 35.7%, in TAU = 25%	Participants excluded if they were attending other groups. All women were on monotherapy with various antidepressant medications whose doses were standardized to fluoxetine 40 mg/day (range 10–80 mg/day) using standardized dose equivalents.

		childbirth					
Zemestan i (2020)	Iran	Pregnant women with comorbid depressive or anxiety disorders	MBCT: Maternal age = 28.63 (3.02), Gestational age = 18.27 (6.71) Control: Maternal age = 30.54 (4.15), Gestational age = 16.85 (5.62)	Not reported.	Not reported.	47.36% met criteria for current or lifetime MDD, and 42.10% had comorbid anxiety disorder (including GAD, social phobia, or PTSD). Current or lifetime MDD in MBCT = 47.36%, in control = 52.63%. comorbid anxiety in MBCT = 42.10%, in control = 47.36%. Current or lifetime OCD in MBCT = 10.52%, in control = 0%.	Women excluded if receiving pharmacological treatment for depression and/or anxiety currently, within past 6 weeks or, had increased dose within past 6 weeks or planned change/increase dose during study. Also excluded if participating in psychotherapy > 2 times per month; had received CBT in the past 12 months; or had participated in formal stress reduction program in past 12 months.

#### Key terms in Table 1

*Mental health terms:* Major mood disorder (MDD), Post Traumatic Stress Disorder (PTSD), Obsessive Compulsive Disorder (OCD), Selective Serotonin Reuptake Inhibitor Other: Treatment as Usual (TAU), Selective Serotonin Reuptake Inhibitor (SSRI's)

*Measures:* Edinburgh Postnatal Depression Scale (EPDS), Patient Heath Questionnaire (PHQ-9).

Other: Standard Deviation (SD), Cognitive Behaviour Therapy (CBT), treatment as usual (TAU)

Study (Author & Year)	Design	Dropout rate (as fraction of total n)/follow- up loss/ number analysed	MBCT intervention description	Psychologic al outcomes	Assessment time-points	Finding's summary
Dimidjian et al., (2015)	Uncontrolled pre-post study	<b>MBCT-PD:</b> Dropout (7/49) No control	8 weekly 2-hr group sessions consistent with standard MBCT (Segal et al., 2002). <i>Perinatal modifications included:</i> increased attention to brief informal mindfulness practices (e.g., driving, washing dishes), mindfulness and yoga practices customised for perinatal period (e.g., "being with baby" informal practice), and modified psychoeducation about perinatal depression and transition to parenthood.	Depression: • EPDS • LIFE	Intake, baseline, weekly during intervention, post intervention, monthly during remainder of pregnancy, and 6- months postpartum.	Large and significant decrease in depressive symptom levels that were sustained throughout the perinatal period. An 18.37 % relapse/ recurrence rate was observed following the first MBCT-PD class across pregnancy and the 6-month postpartum follow-up period.
Dimidjian et al., (2016) Evans et al., (2021)	RCT (pilot)	MBCT-PD: dropout (17/43) Analysed = (n = 43) Control (TAU): dropout (1/43) Analysed (n = 43)	8 weekly 2-hr group sessions based on standard MBCT (Segal et al., 2002). <i>Perinatal modifications included:</i> increased attention to brief informal mindfulness practices, practices customised for perinatal period, modified psychoeducation with emphasis perinatal psychological health, self- care practices and cognitive-behavioural strategies to enhance social support. Optional monthly follow-up class & make-up sessions offered by phone.	Depression: • EPDS • LIFE	Intake, baseline, weekly during intervention, post intervention, monthly during remainder of pregnancy, and 6- months postpartum.	During pregnancy, there was a non-significant difference in time to relapse between MBCT-PD and TAU, but in the postpartum period, there was a significant difference in the rate of relapse/recurrence between MBCT-PD and TAU. MBCT-PD demonstrated a significant preventive effect relative to TAU. MBCT group showed approximately 30% reduction in risk of depressive relapse/recurrence compared to TAU.

## Table 2. Study Characteristics and Study Results

Dunn et al., (2012)	Non- randomised control trial	MBCT: dropout (4/14) Control: dropout (0/9)	8 weekly group sessions based on the standard MBCT programme (Segal et al., 2002). <i>Perinatal modifications included:</i> adaptations to mindful movement component to ensure appropriateness for prenatal women, and some sections relating to depression omitted.	Anxiety, depression, stress: DASS21 EPDS Mindfulness: MAAS	Baseline, post intervention and 6- weeks postpartum.	3 out of 4 MBCT participants (75%) experienced a clinically reliable decrease in stress symptoms from baseline to post-treatment, and 1 participant reported a reliable change on most measures. Little change was observed in outcome scores for controls.
Faramarz i et al., (2015)	Prospective open-labelled RCT	MBCT plus medical therapy (pyridoxine hydrochloride for NVP): Dropout 2/43 Follow-up loss (n = 1) Analysed (n = 43) Control: Dropout 2/43 Follow-up loss (n = 1) Analysed (n = 43)	Intensive MBCT: 8 individual sessions (50 minutes each) over a 3-week period for women with NVP. Shortened duration due to consideration that the mean duration of NVP is short (6 weeks). No manual cited but a protocol outlining components of MBCT described. <i>Perinatal modifications included:</i> NVP adaptations and CBT focused on specific issues pertaining to eating related self-regulatory processes. Includes guided eating meditations.	Anxiety and Depression: • HADS Stress: • PDQ Other: • NVP outcome s: RINVR	Baseline, post intervention, and at follow-up (7 weeks after baseline).	MBCT plus medical therapy group showed significant improvements in NVP symptoms, anxiety, depression, and pregnancy distress, compared with medical therapy alone. Significant benefits continued one month after intervention.
Felder et al., (2017)	Uncontrolled pre-post study	MMB program: Dropout (16/37) Analysed, completed ≥4 sessions (n = 21) Analysed, ITT (n = 37)	An 8-week web-based MBCT programme delivered remotely: MMB (Dimidjian, et al., 2014) augmented with MBCT-PD resources (Dimidjian et al., 2015). Included weekly phone coaching offered individually or in a group. Incorporates videos from an in-person MBCT group, guided mindfulness & yoga practices, CBT strategies, psychoeducation, consistent with standard MBCT.	Depression • EPDS • PHQ-9	Baseline, weekly during intervention and post intervention.	As predicted, participants did not evidence a significant increase in depression symptom severity over the course of the intervention.

		No control	No further perinatal adaptations described.				
Goodma n et al., (2014)	Uncontrolled pre-post study CALM Pregnancy: Dropout (1/24) Follow-up loss (n = 0) No control		CALM: 8-weekly 2-h group sessions following standard MBCT structure (Segal et al., 2002; 2013). 3x groups of 6-12 women. CBT component focuses on anxiety and included depression-related content. <i>Perinatal modifications included:</i> Adaptations to mindful movement exercises for pregnant women, and inclusion of self- compassion meditation. Content focused on anxieties typically experienced by prenatal women, e.g., regarding delivery, health of the foetus/infant, and motherhood responsibilities. Adaptations to mindful yoga and postures for sitting and lying down meditation to accommodate pregnancy. Practice meditations incorporate mindfulness of the developing infant.	Depression: PHQ-9 BDI-II Anxiety: PSWQ BAI GAD-7 The MINI Mindfulness: MAAS Other SCS	Baseline, at weeks 3, 5, ad 7 of intervention, and post intervention.	All outcomes significantly improved from baseline to post intervention including concurrent significant increases in self-compassion and mindfulness. High rate of recovery (93.8%) was found for those who met GAD criteria at baseline. Correlations between the MAAS scores and BDI-II levels at all five time-points demonstrated a quadratic effect. There were no significant relationships at the first 3 time points. However, a statistically significant inverse association was found at week 7.	
Luberto et al., (2018)	Uncontrolled pre-post study	Follow-up loss (n = 3)		Anxiety: BAI PSWQ Depression: BDI-II Mindfulness: MAAS Other: SCS	Baseline, post intervention, and 3-months postpartum.	Significant improvements on outcomes were maintained or further improved into the postpartum period. Significant increases in mindfulness and self-compassion over time.	
Latendre sse et al., (2021)	Uncontrolled pre-post study	2 groups completed UPLIFT programme:	8 weekly 1-h video conference MBCT group following standardised manualised programme (UPLIFT) tailored in this study to pregnant women. Combines CBT and	Depression: • EPDS	Baseline, post intervention, 2- and 4-months follow-up.	No significant increases in depression were observed. Symptomatic group: showed	

		<ol> <li>P's with depressive symptoms: Dropout (8/24)</li> <li>Follow-up loss (n = 6)</li> <li>P's high-risk of perinatal depression: Dropout (6/23)</li> <li>Follow-up loss (n = 10)</li> </ol>	mindfulness-based practices focused on teaching skills to reduce symptoms of depression. No further adaptation described.			significant decrease in depressive symptoms at end of intervention and at 2-month follow-up. Of those that were symptomatic at baseline, 65.2% were symptomatic at postintervention. High-risk group: no significant change observed. Of the 23 that per asymptomatic at screening, 20% were symptomatic postintervention.
MacKinn on et al., (2021)	Single-blind RCT	MBCT-PD: Dropout defined as not attending ≥4 sessions (n = 5/28) Analysed (n = 28) Control (TAU): Dropout (not stated) analysed (n = 32)	MBCT-PD: 8 weekly 2-hr group sessions (3-6 members). <i>Perinatal modifications included:</i> Minor modifications made to include greater emphasis on managing stress and anxiety using mindfulness techniques. Information about preventing postpartum depression was retained. Included practice in mindful, assertive communication (Dimidjian et al., 2015, 2016).	Depression: • EPDS Anxiety: • PRA • GAD-7 Stress: • PSS Birth/labour: • Self- report Other: • The Distress Thermo meter	Baseline, post intervention, and 3-months postpartum.	Multilevel modelling indicated a treatment effect on reducing the overall rating of psychological distress among MBCT-PD but not TAU group. Women with higher initial levels of pregnancy anxiety had the greatest reduction in symptoms There was no moderation by baseline for overall distress, generalized anxiety, depression. A significant group difference in type of birth-delivery was found i.e., the MBCT-PD group reported more vaginal births and less caesarean deliveries than TAU.
Shulman et al., (2018)	Non- equivalent control group quasi- experimental	MBCT: Dropout (0/14) 3-month follow- up loss (n = 4) 3-month follow-	8 weekly group MBCT sessions. MBCT techniques based on a modified version of "The Mindful Way Workbook: an 8-week program to free yourself from depression and emotional distress" (Teasdale et al., 2014).	Depression: • PHQ-9 Anxiety: • GAD-7 Mindfulness:	Baseline, 4 weeks, 8 weeks, and 3 months following baseline.	Depression and anxiety levels decreased, and mindfulness levels increased, in the MBCT group, but not in the control group. Most between-group

design	up analysis (n = 10) <b>Control:</b> Dropout (0/16) 3-month follow- up loss (n =14) 3-month follow- up analysis (n = 0)	Included guided exercises around monitoring thoughts & emotional states, deepening awareness, and becoming mindful of how the mind operates.	■ MAAS		and over time comparisons displayed trends towards significance but were not always statistically significant.
Zemesta RCT ni et al., (2020)	MBCT: Dropout $(2/19)$ Follow-up loss (n = 1) Missed $\geq 4$ sessions $(n = 1)$ Analysis ITT $(n = 19)$ Control: Dropout $(1/19)$ Follow-up loss (n = 0) Analysis ITT $(n = 19)$	8-weekly 2-h group MBCT sessions. <i>Perinatal modifications included:</i> Modifications for perinatal depression and anxiety based on MBCT trials (Dimidjian et al, 2016; Goodman et al, 2014; Luberto et al, 2018).	BAI	Baseline, post- intervention, and 1 month follow-up.	MBCT participants showed greater improvements in levels of depression and anxiety than those in control group. ITT analysis indicated a significant effect of time, and greater improvement in emotion regulation strategies at post and follow-up in MBCT. Anxiety and depression levels remained significantly reduced at follow-up.

#### Key terms in Table 2

*Intervention names*: Mindfulness Based Cognitive Therapy adapted for Perinatal Depression (MBCT-PD), Coping with Anxiety through Living Mindfully (CALM), Mindful Mood Balance (MMB), Using Practice and Learning to Increase Favourable Thoughts (UPLIFT).

*Measures:* Edinburgh Postnatal Depression Scale (EPDS), Longitudinal Interval Follow-up Evaluation (LIFE), The Mindful Awareness Attention Scale (MAAS), Patient Health Questionnaire (PSQ-9), Beck's Depression Inventory (BDI-II), The Penn State Worry Questionnaire (PSWQ), Beck Anxiety Inventory (BAI), The Mini International Neuropsychiatric Interview (M.I.N.I), Generalised Anxiety Disorder Assessment (GAD-7), The Positive and Negative Affect Schedule (PANAS), The depression, anxiety and stress scale (DASS21), Emotion Regulation Questionnaire (ERQ), self-Compassion Scale (SCS), The Pregnancy Related Anxiety (PRA), The Perceived Stress Scale (PSS), Hospital Anxiety and Depression Scale (HADS), Prenatal Distress Questionnaire (PDQ)

*Miscellaneous:* Nausea and vomiting of pregnancy (NVP), Rhodes Index of Nausea, Vomiting and Retching (RINVR), Randomised Control Trial (RCT), Intention-to-Treat (ITT).

#### **Design and Sample Characteristics**

Of the included studies, there were four RCTs, two non-randomised control trials, and four uncontrolled studies. Control groups comprised of treatment-as-usual (N=4), medical therapy for NVP (N=1), and no intervention (N=1). The total sample size was *n*=480 (M=28.24, SD=12.25), with individual sample sizes ranging between 23-86 participants. Five of the included studies were conducted in the United States of America, two in Canada, two in Iran, and one in Australia. Therefore, multi-national data was represented, however, samples were mostly Western. Interventions were most typically delivered within maternal/obstetric settings but also within clinical and academic settings, and through online platforms. A variety of instruments were used to measure mental health outcomes, the most common of which were the EPDS for depression (n=6), the GAD-7 for anxiety (n=3), the MAAS for mindfulness (n=3), and one study measured stress using the PSS. Studies more commonly measured depression and anxiety, with stress and mindfulness being assessed to a lesser extent.

Eight of the ten studies administered MBCT with pregnant women (Dimidjian et al., 2015, 2016; Dunn et al., 2012; Faramarzi et al., 2015; Felder et al., 2017; Luberto et al., 2018; Mackinnon et al., 2021; Zemestani & Fazeli Nikoo, 2020). One study was conducted with postpartum women (Shulman et al., 2018) and another included a mixed sample of prenatal and postpartum women (Latendresse et al., 2021). All but one study reported the mean gestational age which ranged between 7.69 and 24.53 weeks (M=18.47, SD=6.75). Therefore, most participants were in their second trimester of pregnancy at baseline. Samples were predominantly white women (M=76.97%, SD=9.56) who were in a committed relationship, married, or cohabiting (M=90.76%, SD=3.82). All studies reported the mean

maternal age which ranged between 25.11 and 36.71 years (M=30.45 years, SD=3.41). One study included women with the pregnancy-related condition NVP (Faramarzi et al., 2015). None of the studies reported inclusion of high-risk pregnancies.

Studies differed in their mental health inclusion criteria and samples comprised of women with a prior diagnosis of MDD (n=3), current symptoms of perinatal depression/women at risk (n=1); comorbid anxiety and depression (n=1); symptoms consistent with diagnostic criteria for GAD/prominent anxiety symptoms (n=1); MDD, GAD or both (n=1); and women self-identifying as having high levels of psychological distress (n=1). One study excluded women with diagnosed psychiatric illnesses (Faramarzi et al., 2015), and another did not indicate any specific mental health inclusion criteria (Dunn et al., 2012). However, both studies included women with anxiety and depression symptoms as indicated by baseline assessments.

#### **Methodological Quality Assessment**

Administration of the Quality Assessment Tool for Quantitative Studies indicated the overall global ratings of studies to be weak (n=6), moderate (n=3), and strong (n=1) (*see* Table 3). Most studies scoring as weak in quality employed an uncontrolled design with a small sample size or were RCT's that did not describe important research design components such as randomisation and/or blinding procedures. The author conducted all quality assessments and an independent researcher assessed a randomly selected 25% of studies. There was 87% agreeability between reviewers, and any disagreements were resolved through discussion.

Quality Tool	Item	Studies (first author, year)									
Domain		Dimidjian (2015)	Dimidjian (2016)	Dunn (2012)	Faramarzi (2015)	Felder (2017)	Goodman (2014)	Latendresse (2021)	MacKinnon (2021)	Shulman (2018)	Zemestani (2020)
Selection Bias	Representative of population	NL	SL	SL	SL	SL	NL	SL	SL	Unclear	SL
	% agreed to participate	71.01%	89.58%	Unclear	82.56%	95%	67%	77%	<60%	Unclear	>80%
Study Design	RCT or CCT	No	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes
	Randomised	N/A	Yes	No	Yes	N/A	N/A	N/A	Yes	No	Yes
	Randomisation method described	N/A	No	N/A	Yes	N/A	N/A	N/A	No	N/A	Yes
	Appropriate randomisation method	N/A	No	N/A	Yes	N/A	N/A	N/A	Unclear	N/A	Yes
Confounders	Differences between groups	N/A	No	yes	No	N/A	N/A	N/A	Unclear	Unclear	No
	If yes, % confounders controlled for	N/A	80-100%	Unclear	N/A	N/A	N/A	N/A	Unclear	N/A	N/A
Blinding	outcome assessor aware of allocation	N/A	Unclear	Unclear	No	N/A	N/A	N/A	No	Unclear	Unclear
	P's aware of allocation / research question	Unclear	Unclear	Unclear	Yes	N/A	N/A	N/A	Yes	Unclear	Unclear
Data Collection	Valid measures	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Reliable measures	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Withdrawals and	Number(s) <i>and</i> reasons described	Yes	Yes	No	Yes	Yes	No	Yes	No	Unclear	No
Dropouts	% completing study	86%	72%	83%	93.2%	67%	88%	67%	63%	<60%	86%
Rating	1	Weak	Moderate	Weak	Strong	Moderate	Weak	Moderate	Weak	Weak	Weak

Table 3. Quality Assessment Tool for Quantitative Studies (Effective Public Health Practice Project 1998) for included core studies

Key Terms In Table 3: Somewhat Likely (SL), Not Likely (NL)

#### **Summary of Clinical Findings**

The clinical findings of studies are detailed in Table 2. High variability across study designs and outcome measures alongside weak quality rating in studies (N=6) precludes quantitative synthesis. A synthesis of clinical findings is first presented followed by an analysis of MBCT interventions and their acceptability.

#### Depression

All ten studies included in this review measured depression symptoms. Studies varied in their inclusion criteria in relation to women's depression histories and symptomology. Therefore, studies differed in their objectives with some being focused on prevention and others on symptom reduction. Given this, it is important to highlight that not all studies would be expected to document improvements on depression outcome measures due to low scores at baseline.

#### Clinical Samples

All five studies that included participants with baseline depressive symptomology reported significant improvements in depressive symptoms post-treatment (Dunn et al., 2012; Faramarzi et al., 2015; Goodman et al., 2014; Latendresse et al., 2021; Zemestani & Fazeli Nikoo, 2020). One RCT documented MBCT participants to have superior improvements in depression compared to controls, with a significant effect of time as well as a significant time x group interaction (Zemestani & Fazeli Nikoo, 2020). Although this study included an inactive control group, it found benefits to be maintained at one month follow-up. Further
positive results were documented by a RCT undertaken with women with moderate NVP together with mild-moderate levels of anxiety and depression (Faramarzi et al., 2015). Their results indicated significantly reduced depression levels in the MBCT group compared to controls at post-treatment and at 1-month follow-up. However, the authors highlighted potential bias related to a greater quantity of professional attention received by MBCT participants.

Benefits were also reported by a controlled study which included a postpartum sample presenting with high occurrence of MDD diagnosis (35.7%) and comorbid anxiety and depression (35.7%) (Shulman et al., 2018). Analyses indicated that compared with controls, the MBCT group benefited from decreased depression levels from week one to week eight of the intervention, an effect that almost reached significance. It is possible that the small sample sizes of this study impacted the significance of findings. Encouragingly, observed effect sizes were within the 'moderate' range (Cohen, 1992), thus indicating that the MBCT intervention potentially had a clinical impact on depression levels. Similarly, in a small prenatal sample, Dunn et al., (2012) compared outcomes for prenatal women receiving MBCT compared with a control group. They used reliable change indices to determine the number of women in each group who experienced clinically reliable changes in depression scores from baseline to follow-up. Reduced depression scores were found for 50% of participants from baseline to six-weeks postpartum. Such benefits were not observed for any control participants. Despite these positive results, limitations relating to the small sample size are evident, and there were notable baseline differences with more women reporting clinical histories in the MBCT than in the control group.

The two uncontrolled studies support the trend of improved depression following MBCT. In an online group-delivered MBCT intervention for women experiencing mild-moderate depressive symptoms, Latendresse and colleagues (2021) found significantly reduced EPDS scores at post-intervention and at 2-month follow-up. Similarly, women with no greater than moderate depression levels showed significant improvements in depression severity at post-treatment and at 3-months post-partum (Goodman et al., 2014). Overall, results of these studies consistently indicate improved depression symptomology for clinical samples following MBCT, with some evidence to suggest that benefits are sustained beyond the intervention. However, the relatively short durations of follow-up are notable.

# **Prevention Studies**

In focusing upon prevention rather than acute treatment, three studies recruited women with histories of MDD (Dimidjian et al., 2015, 2016; Felder et al., 2017). Additionally, Latendresse and colleagues (2021) included a group of women at risk of perinatal depression without current symptomology. Two uncontrolled studies reported participants to maintain minimal to mild depression severity over the course of MBCT, indicating a stabilising effect (Felder et al., 2017; Latendresse et al., 2021). The remaining two studies reported improved depression levels and reduced relapse rates (Dimidjian et al., 2015, 2016). One of these, an RCT, reported significantly lower relapse rates and depressive symptoms in MBCT-PD participants compared with controls, with superior protection being evident at the postpartum follow-up (Dimidjian et al., 2016). Significant differences were found in relapse/recurrence between MBCT-PD and treatment-as-usual, with rates of 4.6% and 34.6% respectively. Encouragingly, the hazard ratio indicated MBCT-PD to have reduced

risk by 88% compared to controls during the postpartum period. However, whilst a further RCT found MBCT-PD to be associated with improved overall distress beyond treatment-asusual, depression did not improve (Mackinnon et al., 2021). Methodological differences between the study of Mackinnon et al., (2021) and the aforementioned trials are noteworthy due to its community sample of women who self-identified as experiencing high levels of psychological distress. In contrast, studies by Dimidjian et al., (2015, 2016) and Goodman et al., (2014) recruited women with clinical histories of depression and/or GAD suggesting MBCT may have greatest benefit for those with prior psychopathology.

# Anxiety

Anxiety symptoms were measured in six of the ten studies, all of which found some evidence of beneficial effects of MBCT. Of the three RCTs that explored anxiety outcomes, two reported significant symptom improvements beyond those observed in controls (Faramarzi et al., 2015; Zemestani & Fazeli Nikoo, 2020). Interestingly, one RCT documented greatest symptom improvement in women who commenced the intervention with higher levels of pregnancy anxiety (Mackinnon et al., 2021). Furthermore, a moderated mediation effect was found whereby MBCT-PD potentially lengthened gestational age by reducing pregnancy anxiety. However, in contrast to other trials, this study did not observe treatment effects on symptoms of generalised anxiety. As previously noted, the disparity in this studies results could reflect methodological differences. Further MBCT benefit was reported by two control studies. One of these studies did not quantify between-group statistical differences (Dunn et al., 2012), and the other found between-group differences to be non-significant (Shulman et al., 2018). However, Shulman and colleagues (2018) documented marginally

significant pre-post differences in anxiety scores following MBCT, but these results were not maintained at 3-months follow-up.

Promising results were also reported by an uncontrolled trial conducted by Goodman and colleagues (2014) who found significant improvements in anxiety and worry following MBCT treatment. Of the 16 completers who met diagnostic criteria for GAD at baseline, only one was reported to meet criteria at post-intervention. Anxiety gains extended into the postpartum with significant reductions in anxiety and worry being demonstrated from baseline to 3-months postpartum (Luberto et al., 2018). Overall, anxiety outcomes have been examined to a lesser extent than depression, but initial results with small samples indicate MBCT benefits.

### Stress

Three of the ten studies included in this review reported stress/psychological distress as an outcome measure. Only one of the two RCTs to examine stress/psychological distress levels reported significant improvements compared with controls. This study employed MBCT as an adjunctive to NVP medication compared to a medication-only group in a sample of prenatal women with NVP (Faramarzi et al., 2015). Significant reductions in concerns about body-image/weight, childbirth, infant well-being, and relationships were also documented as secondary outcomes in this study. Benefits were also found by a control trial which reported 75% of MBCT participants to have experienced clinically reliable reductions in stress symptoms from baseline to post-intervention (Dunn et al., 2012). No change was observed in the control group. Whilst an additional RCT reported improved overall psychological distress in the MBCT group, there were no significant treatment group by time

interactions on perceived stress (Mackinnon et al., 2021). Overall, the few studies to have examined stress outcomes have yielded mixed results.

# Mindfulness

Three of the ten included studies measured mindfulness, all of which utilised the MAAS and found increased mindfulness following MBCT. A control trial observed significant mindfulness increases in MBCT participants. However, this change was not significantly different to treatment-as-usual (Shulman et al., 2018). The authors report that superior mindfulness scores present within controls at baseline remained constant whilst the MBCT group benefited from increased mindfulness overtime. A second control study with a small sample reported reliable improvements in MAAS scores for 25% of group participants from baseline to post-intervention, and in 50% of group participants from baseline to postpartum, whilst no change was observed for controls (Dunn et al., 2012).

An uncontrolled study by Goodman and colleagues (2014) was the only study to examine the correlation between mindfulness improvements and mental health outcomes. Associations between mindfulness and depression by the seventh intervention week were found, and at post-intervention a significant correlation between mindfulness and anxiety emerged. Although no change from the end of the intervention to 3-months postpartum was evident, overall, mindfulness levels significantly increased from baseline to postpartum (Luberto et al., 2018). Interestingly, despite relatively high rates of formal mindfulness practice, such practice was not associated with any outcomes. Currently, very little evidence relating to mindfulness outcomes following MBCT is available within perinatal populations,

and cautious interpretation of the available data is required, particularly given the small sample sizes and constrained variability in adherence within studies.

## **MBCT Interventions**

MBCT-QC scores ranged from 8-23 with an average score of 16, indicating considerable variability in intervention descriptions (Table 4, *see* Appendix 6 for full MBCT-QC). This variation not only reflects differing intervention components, but also variable degrees of intervention detail within papers. Whilst studies scoring above the MBCT-QC Mean were consistent in their findings of improved psychological outcomes following MBCT, results are more varied for those studies scoring equal to or below the mean. Although all studies report MBCT benefits, some studies with lower MBCT-QC scores (<16) failed to identify benefit for all measured psychological outcomes or did not identify significant differences between MBCT and control groups (Mackinnon et al., 2021; Shulman et al., 2018). Such inconsistencies may be reflective of differential levels of MBCT quality/integrity but should also be considered within the context of study differences and limitations as both studies were also found to be methodologically 'Weak' (Table 3). Findings relating to MBCT adaptations, delivery, facilitators expertise, model fidelity, and acceptability are presented.

Study (First author, year)	MBCT Format							CBT components								Mindfulness						Facilitators					Adherence Score			
	Primarily based on standardised manual / MBCT theory	Pre-course interview	8-week duration	2-hr sessions	Predominantly group sessions	1 x all day session	Home assignments/practice	Relapse/action planning	CBT exercises	Decentring focus	Metaphors / narrative material	Pleasure & mastery exercise(s)	Psychoeducation	Automatic thoughts discussion	Cognitive coping strategies	Behavioural strategies	Daily practice 6+ days weekly	3-min breathing space/mini-med	Formal & informal practice	Awareness establishment	Movement based awareness	MBCT qualification e.g., MSc	MBCT training	Professional qualification	Own mindfulness practice	Supervision	Measure used e.g., MBCT-AS	Use of video/audio recordings	MBI-TAC	
Dimidjian (2015)	۲	۲	۰	۲	۰	۰	۰	•	•	•	•	•	۰	•	•	۰	۰	•	۰	۰	•	0	•	۲	0	0	۲	۲	•	19
Dimidjian (2016)	۰	۰	۰	۰	۰	•	٠	۰	۰	۰	•	۰	۰	۰	•	٠	۰	۰	•	•	٠	0	•	۰	0	0	۲	0	•	23
Dunn (2012)	۲	٠	۲	0	۲	۲	۲	۲	۲	۲	•	•	۰	۲	•	۰	•	•	•		۰	•	۲	۲	0	0	۲	۲	۲	16
Faramarzi (2015)		۲	۲	٠	•	۲	۲	0	۲	۲	0	0	0	۲	•	•	•	۲	۲	۲	۲	0	0	0	0	0	۲	۲	۲	12
Felder et al (2017)		۲	۰	x	•	٠	۰	۰	۰	۰	٠	•	۰	•	•	۰	•	•	۰	•	۰	0	0	0	0	0	•	٠	۰	18
Goodman (2014) & Luberto (2018)	۲	۲	۰	۲	۲	٠	۲	•	۰	•	۰	٠	۲	۲	۲	•	۲		۲	۲	۲	0	۲	۲	0	۰	٠	۲	•	21
Latendresse (2021)	۲	۰	۲	x	۲	۲	۲	•	•	•	۲	٠	۲	•	•	•	•	•	•	•	•	0	۲	۰	0	0	۰	۲	۲	8
MacKinnon (2021)	۰	۰	۲	۲	۰	٠	۰	•	۲	٠	•	•	۰	•	۰	۰	•	٠	•	•	۰	0	0	۲	0	0	٠	۰	•	13
Shulman (2018)	۲	۲	۲	0	۲	۰	۲	۰	۲	۲	٠	•	۲	۰	٠	٠	٠	۲	٠	۲	۲	0	•	۰	0	0	۲	۲	•	15
Zemestani (2020)	۰	۲	۲	۲	۲	0	۲	•	۲	۲	۲	•	۰	۲	•	•	•	•	۲	•	۲	0	۲	۲	0	۲	٠	۲	۲	19

# Table 4. Intervention MBCT-QC ratings and total scores for core studies

Included (1 point)

X Component included *but* is a deviaton consistent with cited protocol to tailor to participant group

Not explicitly stated, but included in cited manual

- Unclear from article
- Not included

### MBCT Adaptations for Perinatal Populations:

All studies described some degree of modification to MBCT for perinatal populations; however, not all studies detailed the nature of these. Described adaptations frequently included increased focus on brief formal and/or informal mindfulness practice alongside modified mindful movement and yoga practices to be suitable for prenatal women. Psychoeducation was commonly adapted to include perinatal worry, stress, anxiety, depression, and/or transition into parenthood. Some studies (N=3) described inclusion of meditational practices intended to nurture mindfulness of the developing foetus. Studies that evaluated the MBCT-PD programme (Dimidjian et al., 2015, 2016) reported greater emphasis on self-compassion, self-care, and cognitive-behavioural strategies targeted at social-support optimisation. Some studies described aspects of action-planning focused upon strategies to enhance mothers' well-being through the remainder of their pregnancy, postpartum and early motherhood. Outlined skill-development sessions included practice and role-play of strategies for mothers to implement following childbirth to enhance management of stressors typically encountered by new mothers (e.g., practical demands, lack of social support). Focus upon the development of a decentring approach to selfjudgments pertinent to perinatal women was also described.

### Facilitator Expertise and Supervision

Most intervention facilitators were reported to be qualified professionals (e.g., Clinical Psychologists, Social Workers, or Mental Health Professional). However, information around facilitator MBCT expertise and training was poorly reported. Whilst seven papers reported facilitators to have completed MBCT training, the formality and degree of this was typically

unclear. Only one study identified the facilitator to have an accredited MBCT qualification. Whilst several studies described peer supervision amongst study therapists, only two studies reported external supervision which in one instance was facilitated by a Clinical Psychologist described as having extensive experience, and in the other, by a professional who had completed professional-level training in MBSR and MBCT. None of the included papers reported use of the 'Mindfulness-based Interventions Teacher Assessment of Competency' (MBI-TAC), a tool used to assess facilitators levels of competence (Crane et al., 2013).

# Model Fidelity

Only two studies reported measurement of treatment fidelity using an adherence measure, both of which employed the MBCT-AS and reported above adequate instructor adherence to the protocol (Dimidjian et al., 2015, 2016). An additional three studies reported use of video/audio session recordings (Goodman et al., 2014; Latendresse et al., 2021; Zemestani & Fazeli Nikoo, 2020). However, levels of adherence achieved are not indicated. The lack of fidelity and adherence data makes it difficult to infer accuracy of interventions included in this review, and on a broader note, limits conclusions around the feasibility of this intervention for perinatal populations.

#### MBCT delivery (remote compared with in-person interventions):

Seven of the ten studies reported real-time, in-person group MBCT, one reported in-person individual MBCT (Faramarzi et al., 2015), whilst two studies described a remote MBCT intervention through: (1) a videoconference MBCT group (Latendresse et al., 2021); and (2)

eight web-sessions alongside either individual or group phone coaching. Both remote interventions were associated with benefits. For women with depression histories and/or at risk of onset/relapse, studies reported no worsening of depression (Felder et al., 2017; Latendresse et al., 2021). For women with depression symptoms, improvements in EPDS scores were evident following a videoconference group at post-intervention and 2-month follow-up (Latendresse et al., 2021).

Dropout rates of the two remote interventions were 13.89% and 43.24% (M=28.57%, SD=5.07). The average completion rate for remote MBCT interventions was 63.61%, which was somewhat lower than the average completion rate for in-person MBCT (86.73%). The web-based intervention that incorporated a pre-recorded group component reported a completion rate of 56.8% based on a completion definition of attendance to  $\geq$ 4 sessions (Felder et al., 2017). This was notably lower than the 70.45% completion rate reported by the study that employed a live videoconference group intervention based on attendance to  $\geq$ 5 sessions. It is conceivable that a lack of real-time delivery and/or a reduced opportunity for social interaction and group learning potentially contributed to this high attrition rate. That being said, the in-person individual MBCT intervention reported 95% completion rate (Faramarzi et al., 2015). However, this was a briefer three-week intervention with fifty-minute sessions, and comparison to other studies is not possible due to the applied completion criterion being unclear.

# Acceptability

## Treatment Satisfaction

Five of the ten studies that measured satisfaction either used the validated acceptability measure: Client Satisfaction Questionnaire (Attkisson et al., 1982) (Dimidjian et al., 2016), an interview (Dunn et al., 2012), or both (Dimidjian et al., 2015; Felder et al., 2017; Goodman et al., 2014). One study developed a usability questionnaire in relation to their remote MBCT intervention (Felder et al., 2017). Encouragingly, findings revealed a high degree of satisfaction across these studies. Dimidjian and colleagues (2015) found that 78% of women experienced the intervention as helpful, with 83% stating that they had noticed a positive change in their coping abilities. Similarly, Goodman et al (2014) found that all women reported MBCT to have been enjoyable, with themes relating to helpfulness including skill-building, non-reactivity, acceptance and self-kindness, cognitive changes, and connection. However, women reported the volume of home practice to be overwhelming at times but also endorsed the usefulness of learning such practices. In an RCT, levels of satisfaction for MBCT were found to be significantly higher than treatment-as-usual (Dimidjian et al., 2016). Whilst satisfaction levels were not reported by Dunn et al (2012), interviews revealed that all women continued to utilise mindfulness skills post-intervention, therefore indicating developed skills to be useful to women beyond the end of intervention. Of the two remote interventions, only one measured satisfaction, which indicated web based MBCT to be acceptable and of value to perinatal women (Felder et al., 2017). However, qualitative data highlighted participants desire for interaction with other perinatal women and indicated that most women had experienced technical issues such as navigation issues. Nonetheless, women endorsed therapeutic benefits of the intervention, reporting

improved ability to identify warning signs, an awareness of negative thoughts and emotions, and improved emotional closeness to friends and family.

# **MBCT Session Completion**

Eight studies reported completion data. Study definitions of completion varied and was specified as attendance to  $\geq$ 4 (*n*=5),  $\geq$ 5 (*n*=2) or  $\geq$ 7 sessions (*n*=1). An overall average of 82.92% (SD=12.01) completion rate was documented according to individual studies completion criterion. Only four studies documented the average number of sessions attended by participants, with an overall average of 6.17 out of 8 sessions attended (SD=1.04). As already noted, the lowest completion rate (56.8%) was observed by a remote web based MBCT intervention that did not involve a real-time group component (Felder et al., 2017). Taken together, generally high completion levels were achieved according to studies self-defined completion criteriors, however lack of detailed attendance data together with differences in study criteria's limit's interpretation.

Mackinnon et al., (2021) found no association between the number of sessions attended and changes in clinical symptomology. In contrast, an analysis by Evans et al., (2021) found that greater engagement defined by class attendance and quantity of home-practice, was associated with superior improvements in depression at post-intervention through to 6months postpartum. These are the only two investigations of the association between MBCT attendance and psychological outcomes.

#### At-home Mindfulness Practice

Six studies measured mindfulness practice, with this data accessible in four studies. Three of four studies (75%) reported participants to have completed an average of 28.33 practice days (SD=5.69) out of a possible 42 days (Dimidjian et al., 2015, 2016; Felder et al., 2017). One study reported participant's to have completed an average of four days of practice out of six allocated days each week (Goodman et al., 2014). As such, although optimal practice was not achieved, reasonably high practice levels were documented within studies reporting this data.

Of the three studies that distinguished between levels of informal and formal practice, greater quantity of formal home practice was reported in one study (Felder et al., 2017), and a greater degree of informal practice in two studies (Dimidjian et al., 2015, 2016). Notably, Felder et al., (2017) reported lower overall engagement in home-practice than observed in the trials of Dimidjian et al., (2015, 2016). These findings may reflect a greater accessibility of informal practice for perinatal women due the ease of weaving such practice into existing daily routines, and a lesser demand on women's time. However, results are mixed.

Some evidence suggests that formal practice may be an important mechanism of MBCT. In combining the data of aforementioned trials of Dimidjian et al., (2015, 2016), an analysis by Evans et al (2021) indicated engagement in both formal-practice and session attendance to be associated with improved depressive symptomology at post-intervention and postpartum. Women who completed an average of  $\geq$ 3 formal practices weekly demonstrated improved depressive outcomes compared with those who completed fewer. Unfortunately, analysis of any associations between informal practice and outcomes is not

presented by this study. Consistent results were reported by Mackinnon et al (2021), who found total duration of home formal practice to be significantly correlated with reductions in generalised anxiety from baseline to post-intervention. Yet, there was no significant association in this study between changes in anxiety symptomology and the number of weeks of homework completion nor with quantity of informal practice. An additional study observed no significant associations between formal practice, practice frequency/duration and any of the measured outcomes during MBCT-PD, at post-intervention, and at follow-up (Luberto et al., 2018). Furthermore, at postpartum, there were no significant differences in outcomes between participants who were continuing and those who had ceased meditation practice. It should be noted that this study potentially lacked adequate power to sufficiently investigate associations. However, qualitative data indicated women to experience development of mindfulness skills as the most helpful intervention component, a theme articulated by 83% of the sample (Goodman et al., 2014). Similarly, an open-label trial found participants to endorse mindfulness practice as a highly valued aspect of the MBCT intervention (Dimidjian et al., 2015).

## Discussion

#### **Summary of Evidence**

This review systematically examined the evidence relating to MBCT applied to perinatal mental health outcomes including anxiety, depression, and stress. There is preliminary evidence of outcome improvements following MBCT for perinatal women. MBCT also appears to be highly acceptable to this cohort. However, research is in its infancy and

currently only four RCTs, two control trials, and four uncontrolled studies have been undertaken to test MBCT efficacy within this population.

Presently, MBCT has the strongest evidence for improvements in depression. Findings indicate MBCT is potentially a beneficial prevention option for perinatal women at risk of depression onset or relapse, as well as a promising treatment for those presenting with mild symptomology. Although relatively few studies have been undertaken, there are also promising indications of the beneficial effects of MBCT for perinatal anxiety. The finding that MBCT may have potential to reduce the risk of premature birth through targeting pregnancy anxiety is encouraging (Mackinnon et al., 2021). However, only a single study has examined birth outcomes associated with MBCT, and further exploration is required. There is a dearth of research examining stress related outcomes, and the few existing studies report mixed results. As such, the effect of MBCT on stress outcomes is yet to be adequately tested.

The clinical findings of this review are broadly supported by meta-analyses of MBIs for perinatal mental health (Dhillon et al., 2017; Lever Taylor et al., 2016). For example, significant within-group effects of moderate size for depression, and smaller effects for anxiety have been observed (Lever Taylor et al., 2016). However, all between-group effects lacked significance and high levels of heterogeneity was evident. The current review indicates that MBCT may be of most benefit for perinatal women with greater psychological symptom burden. This finding is consistent with the broader MBI literature which has found greatest improvements in psychological distress amongst individuals with greater symptom severity (Hofmann et al., 2010). Initial results indicate MBCT to be a promising adjunctive to medication for women with moderate NVP (Faramarzi et al., 2015). However, there is too little research to infer the impact of MBCT for pregnancy-related conditions, which given the

associated risk of anxiety and depression (e.g. Mitchell-Jones et al., 2020), warrants further investigation.

Initial studies identify several modifications to MBCT for perinatal women that may increase prospect of success. Adaptations typically included greater emphasis on brief informal and/or formal mindfulness practices, changes to mindful movement components, inclusion of self-care and/or self-compassion, optimisation of social support, mindfulness components focused upon the foetus, in addition to psychoeducation about perinatal worry, stress, anxiety, depression, and transition to parenthood.

Studies exploring remote distributions of MBCT within perinatal populations have also began to emerge. Given the benefits of digital therapy platforms in terms of costeffectiveness and ease of access/distribution (Andersson & Titov, 2014), examination of digital MBCT is valuable, particularly with perinatal populations that may experience unique barriers to accessing in-person therapies. Despite the finding that remote MBCT is of potential benefit and highly acceptable to perinatal women, the average completion rate was lower for remote compared with in-person MBCT. The nature of remote interventions, particularly those that lack a group/participatory element, may hinder engagement. Inperson group delivery may provide observational learning, emotional support, validation, and may facilitate metacognition (Schroevers et al., 2016). However, another explanation for differences in attrition is the high variation in how adherence was defined across studies. As such, acceptability findings relating to completion and adherence must be interpreted cautiously. Nonetheless, it is widely acknowledged that the completion rates for web-based programs are lower than for face-to-face treatments (Christensen et al., 2009). Given evidence that endorses the potential of web based MBIs to contribute to mental health

improvements (Spijkerman et al., 2016), and their high acceptability amongst perinatal samples (Harrison et al., 2020), the question of how to improve adherence to digital/remote MBCT is important.

# **Treatment Mechanisms**

Despite the mounting evidence of the clinical utility of MBCT within the broader literature, there continues to be little understanding around its mechanisms of action. Home practice of mindfulness is considered a primary vehicle by which participants become aware and relate differently to mental events (Segal et al., 2018). However, few studies have systematically examined the relationship between home-practice and subsequent outcomes for perinatal women, and current data is mixed. The finding that formal practice may be a key MBCT mechanism is important, particularly given the tendency of some MBCT-PD programmes to focus upon brief informal practice. However, evidence in this respect is contradictory and insufficiently assessed due to a reliance on self-report measures and differences in methods of quantifying practice. Difficulties in reliably quantifying informal practice potentially hindered comparisons of formal and informal practice in this review (Carmody & Baer, 2008).

Development of mindfulness skills was experienced as highly valuable amongst perinatal women (Dimidjian et al., 2015; Goodman et al., 2014), and limited evidence indicates increased mindfulness levels over the MBCT course. Preliminary evidence proposes mindfulness as a potential mechanism of action, with increases in mindfulness skills possibly contributing to reductions in anxiety and depression. However, despite mindfulness being considered crucial to the change process (Feldman & Kuyken, 2011), and being a

fundamental skill that MBCT purports to develop, few studies examined mindfulness as a mediating mechanism. Within the mindfulness literature, it has been suggested that a differential pattern of relationships exist between mindfulness facets and psychological outcomes (Brown et al., 2015). As such, not all mindfulness facets may be important targets for modification within MBCT. Future research that contributes greater understanding of the role of mindfulness and its different facets in perinatal mental health would inform refinement of MBCT protocols, and the use of MBIs more broadly within perinatal healthcare.

## **Constraints of Included Studies**

The current findings must be interpreted with consideration of the poor methodological quality of the included studies—generally characterised by a paucity of RCTs, lack of power, presence of bias, and in some cases, inadequate consideration of potential confounding variables. Current research is also limited by high variability in sample characteristics, construct measures, completion definitions, and study designs. As such, there is ambiguity surrounding the conclusions of this review. Most studies did not report use of standardised fidelity measures, and over half did not indicate any fidelity consideration (e.g., use of videos). Additionally, descriptions around facilitator training, competence, and supervision were generally poor. Therefore, overall adherence and integrity to MBCT protocols is unclear, as is the expertise of MBCT facilitators. Finally, there is a reliance on the use of self-reported outcomes, and more comprehensive assessment is required.

#### MBCT-QC

The use of the newly developed MBCT-QC in the current review was invaluable in establishing consistency of identified interventions within standardised MBCT, and in allowing comparison of intervention results based on MBCT-QC scores. This tool may be of benefit to researchers and clinicians seeking to clarify MBCT intervention components, thus indicating the quality of an MBCT.

#### **Limitations of this Review**

The present systematic review has several notable limitations. Quantification of the effects through a meta-analysis has not been completed. Standardised MBCT interventions were chosen for this review to reduce intervention heterogeneity. However, substantial clinical and methodological heterogeneity in studies remains (e.g., variations in: participant mental health history, baseline symptom severity, measures, completion criterions, and designs). Limitations relating to the methodological quality rating tool used in the current study must also be acknowledged. Although the utilised tool offered the benefit of evaluating varied quantitative study designs, not all items were relevant for each study. Finally, it is possible that a different pattern of findings would have emerged if non-English and unpublished articles were included in the review.

# **Implications for Future Research**

MBCT investigations have tended to focus on antenatal rather than postnatal samples, and to measure depressive outcomes more so than any other psychological outcome. Given the

high incidence of mental health difficulties during the postpartum period (Gavin et al., 2005), and evidence to suggest that women would prefer non-pharmacological interventions (Wang et al., 2020), further MBCT research with postpartum samples is essential. Furthermore, considering evidence of the high prevalence of perinatal anxiety and stress (George et al., 2013; Woods et al., 2010), further examination of MBCT for these outcomes is needed. Exploration of specific mechanisms in MBCT for perinatal populations should be a first step in establishing how MBCT may work for this group of women. For example, there is a lack of understanding around the role of mindfulness and how this interacts with other intervention components such as cognitive, behavioural and group process related mechanisms. Furthermore, to aid greater understanding of causal relations, more rigorous study designs are required including a greater number of well-powered RCTs with active control comparisons. Greater insight into the barriers and utility of remote MBCT interventions for perinatal women would also be advantageous. The quality of studies included in the current review was suboptimal, and methodological issues need to be addressed within future research. As the number of high-quality MBCT studies applied to perinatal care increase, meta-analytical evaluation may be an appropriate next step.

# **Clinical Implications**

The study of MBCT applied to perinatal populations is still in its early stages, and there is currently more evidence to support its application with prenatal than postpartum women. The current review indicates that MBCT may be both acceptable and beneficial for depression and anxiety within this cohort. Studies suggest that MBCT has a potential stabilising effect for women with histories or at risk of depression and may have benefits for

those with presenting symptoms. The review raises further questions around the mechanisms by which MBCT achieves change, and more data is required. Whilst digital/remote MBCT deliveries appear beneficial and acceptable to perinatal women, barriers in attrition need to be further addressed.

# Conclusions

Preliminary evidence indicates MBCT to be a promising alternative or adjunctive to pharmacological treatment with evidence to suggest improvements in anxiety and depression. Initial results indicate MBCT to prevent depressive relapse, however further examination is required. There is limited evidence of the effect of MBCT on stress. Initial studies indicate MBCT to increase mindfulness overtime and suggest this trait as a potential mechanism of change. However, a clear conclusion is not possible due to the lack of studies to explore mindfulness outcomes. Future directions for research as well as implications for clinical practice have been outlined.

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# The Impact of Dispositional Mindfulness and Social Support on the Risk of Prenatal Depression and Anxiety among Women with Hyperemesis Gravidarum.

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(See Appendix 7 for submission guidelines)

For ease of reading, figures and table have been included within the text rather than in the appendices.

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#### Abstract

**Background:** Hyperemesis Gravidarum (HG) is a pregnancy-related condition characterised by intractable nausea and vomiting. The condition is known to be associated with elevated levels of anxiety and depression. However, little is known about factors that directly contribute to anxiety and depression within the context of HG. The current study aimed to address gaps in knowledge by examining the unique relationships between the distinct mindfulness facets and aspects of social support with anxiety and depression among prenatal women affected by HG.

**Methods:** This study employed a cross-sectional survey design with a sample of 190 prenatal women affected by HG. Participants were recruited online through liaison with the Pregnancy Sickness Support Charity (PSS). Study variables were measured with self-report questionnaires using a secure online survey platform. Path analysis was conducted using R System for Statistical Computing (R Core Team, 2017) to explore the simultaneous relationship between the five facets of mindfulness (awareness, describing, observing, non-judging, and non-reactivity) and four dimensions of social support (emotional/informational support, tangible support, affectionate support, and positive social interaction) with anxiety and depression.

**Results:** Women with HG reported higher levels of both anxiety and depression than community samples, and greater depression symptomology than clinical samples. Findings indicate that higher levels of mindfulness and social support are associated with lower levels of anxiety and depression among prenatal women affected by HG. Initial bivariate correlations showed three mindfulness facets (describing, awareness and non-judging) and

all dimensions of social support to be inversely related to anxiety and depression. Path analysis revealed differential relationships and highlighted the importance of 'non-judging' and 'describing' for both anxiety and depression, and 'non-reactivity' for anxiety. The social support dimension of 'positive social interaction' was found to have a significant influence on depression, but not anxiety. 'Affectionate support' was directly related with anxiety but not depression. The overall model had predictive utility explaining 29% and 31% of the variance in anxiety and depression, respectively.

**Conclusions:** Findings highlight the importance of screening for anxiety and depression, as well as identifying those low in dispositional mindfulness and social support within HG populations. Results indicate 'non-judging' and 'describing' to be clear targets for interventions, such that woman with higher levels of 'non-judgment' and 'describing' potentially experience lower levels of anxiety and depression. Facets of 'acting with awareness' and 'observing' may be of less utility in treating anxiety and depression for prenatal women affected by HG. Social support appears important for prenatal women with HG. When considered together with mindfulness facets, 'positive social interaction' showed a direct path with depression, whilst 'affectionate support' was directly related to anxiety. Research and clinical implications relating to adaptations to screening procedures and intervention protocols for women with HG are outlined.

#### Introduction

## Background

Nausea and vomiting of pregnancy (NVP) is common with estimates indicating that as many as 91% of pregnancies are affected (Einarson et al., 2013). The severest form of NVP, known as Hyperemesis Gravidarum (HG), is much less common, presenting in 0.2-2% of pregnancies (Einarson et al., 2013; Verberg et al., 2005). However, the true impact of HG may be underestimated due to an absence of well-defined diagnostic criteria (Fiaschi et al., 2019). A universally agreed definition of HG is lacking and the condition is typically diagnosed based on clinical judgment (Mullin et al., 2012). Commonly endorsed criteria include intractable nausea and vomiting prior to twenty-weeks of gestation, loss of at least five-percent of pre-pregnancy bodyweight, and metabolic and electrolyte imbalances (Verberg et al., 2005). The negative implications of HG are well documented including its association with adverse infant outcomes such as prematurity and low birth weight (Lutomski et al., 2014; Veenendaal et al., 2011). The condition often necessitates secondary care intervention and is the leading cause of hospitalisation in the first half of pregnancy (Gazmararian, 2002; Grooten et al., 2015). The associated maternal implications can be long-lasting with the potential for post-pregnancy difficulties including muscle weakness, motion sickness, food aversions, and psychological morbidity (Mitchell-Jones et al., 2020; Mullin et al., 2012).

## **Aetiological Understandings**

Historically, misguided emphasis has been placed upon theories of psychogenic aetiology for HG (Munch, 2002). The condition had been attributed to a range of psychiatric causes

including ill-preparedness for motherhood, pregnancy-related anxiety, maladaptive coping, conversion disorder, and a symbolic rejection of pregnancy by the mother (El-Mallakh et al., 1990; Fairweather, 1968; Ringler & Krizmanits, 1984; Tsoi et al., 2010). Such misconceptions have heavily contributed to the stigmatisation of those affected by HG and continue to impact upon the quality of care and treatment (Dean, 2016; Power et al., 2010).

Although evidence remains inconclusive, it is likely that HG is a multifactorial condition with biological, socioeconomic, and psychological predisposing factors (Verberg et al., 2005). A growing body of evidence indicates a genetic contribution to the condition with data suggesting women with a familial history of HG are at increased risk (Zhang et al., 2011). Although causal roles are yet to be established, studies have identified possible genetic pathways involved in the aetiology of HG (Fejzo et al., 2018). However, a multitude of possible contributory factors have been implicated including abnormalities in the hormonalreceptor pathways, hepatic differences, nutritional deficiencies, autonomic dysfunction, and variations in human chorionic gonadotropin levels (Sonkusare, 2008; Verberg et al., 2005). Furthermore, increased HG incidence has been found for women of younger age, having had multiple pregnancies, carrying female offspring, and with pre-existing gastrointestinal disorders (Fell et al., 2006; Mullin et al., 2012; Roseboom et al., 2011; Schiff et al., 2004). Therefore, there is yet to be a clearly established aetiology for HG, however, increasing evidence suggests that understanding biological contributions is essential to understanding the condition (Fejzo et al., 2018).

## **Psychosocial Implications**

HG can have an extensive psychosocial impact, often affecting daily, social, occupational, and economic functioning (Festin, 2014). A large cohort study found that over 80% of women experienced negative psychosocial or financial consequences such as loss of employment, fear around future pregnancies, and psychological difficulties following a HG pregnancy (Poursharif et al., 2008). For some, the severe psychosocial burden of HG results in elective pregnancy termination (Poursharif et al., 2007). This devastating outcome has been linked to feelings of hopelessness, social isolation, and higher levels of depression (Mazzota et al., 1997; Mazzotta et al., 2001). A clear association between HG and psychological morbidity has been established (Mitchell-Jones et al., 2017). However, this relationship remains poorly understood. Elevated anxiety and depression levels have been observed for women with HG both with and without a history of psychological difficulties (Mccarthy et al., 2011; Mitchell-Jones et al., 2020; Seng et al., 2007; Tan et al., 2010, 2014; Yıldırım & Demir, 2019). Heightened risk of anxiety and depression has been associated with sociodemographic variables including income, education, and social relations, as well as clinical markers of HG severity such as nausea and vomiting (Kramer et al., 2013; Topalahmetoğlu et al., 2017).

## Interventions

Current treatments for HG are primarily focused on the management of physical symptoms, and commonly include nutrient supplementation, intravenous hydration therapy, and electrolyte imbalance correction (Wegrzyniak et al., 2012). Given evidence that psychological distress may be a response to the physical symptoms of HG (Tan et al 2014),

and that current physiological treatments remain suboptimal (Verberg et al., 2005), greater focus on psychological interventions is imperative. The urgent need for a review of the clinical approach to HG to ensure effective assessment and intervention for women's psychological needs has been highlighted (Mitchell-Jones et al., 2017). Considering the elevated risk of anxiety and depression for women affected by HG (Mitchell-Jones et al., 2017, 2020), it is important to understand the factors that directly impact these outcomes to inform evidence-based psychological assessment and intervention. Investigation of psychological outcomes for those affected by HG has been identified as an international priority by the HG Priority Setting Partnership (PSP) (Dean et al., 2021).

# Mindfulness

Mindfulness is commonly defined as "paying attention in a particular way, on purpose, in the present moment, and nonjudgmentally" (Kabat-Zinn, 1994, p. 4). It has been conceptualised as a state, whereby mindfulness is experienced moment-by-moment, and as a disposition which refers to a person's natural tendency to be mindful over time (Brown, Ryan, & Creswell, 2007). Interventions that purport to enhance mindfulness, such as Mindfulness-based Cognitive Therapy (MBCT) (Segal et al., 2002) and Mindfulness Based Stress Reduction (MBSR) (Kabat-Zinn, 1990), have demonstrated improved psychological outcomes including reduced anxiety and depression (Hofmann et al., 2010). Despite small sample sizes, Mindfulness-based intervention (MBI) studies conducted with predominantly healthy pregnant women with low-risk pregnancies have reported improved anxiety and depression (Beddoe et al., 2009; Dunn et al., 2012; Guardino et al., 2014; Muzik et al., 2012). However, currently there is inadequate evidence from high quality research to base any

recommendation about the effectiveness of MBIs within perinatal mental health (Hall et al., 2016).

The reported success of MBIs has prompted theoretical interest in the concept of mindfulness. There has been increased exploration of the potential for dispositional mindfulness (DM) to improve psychological well-being within the general population, and more recently, within perinatal cohorts (Brown et al., 2007; Truijens et al., 2016). Studies suggest DM to be inversely associated with anxiety, depression, and emotional distress in pregnancy (Krusche, Crane, & Dymond, 2019; Mennitto, Ditto, & Da Costa, 2020; Truijens, Nyklíček, Van Son, & Pop, 2016). Additionally, higher levels of DM have been associated with reduced severity of pregnancy symptoms including back-pain, nausea, and vomiting (Mennitto et al., 2020). Therefore, DM may be a protective factor for psychological and physical well-being during pregnancy. However, there is a gap in knowledge about the role of mindfulness within psychological outcomes within the context of HG.

Research indicates that DM is made up of five facets (Baer et al., 2006). 'Observing' refers to a tendency to notice internal and external sensations, and 'awareness' relates to a person's ability to attend to the present moment. 'Non-judgement of experiences' concerns a person's tendency to adopt a non-evaluative position towards thoughts, whilst 'describing' refers to the inclination to label experiences. Finally, 'non-reactivity to inner experience' is the tendency to allow thoughts to come and go without response. Whilst research consistently demonstrates that mindfulness facets do not operate homogeneously within anxiety and depression (Brown et al., 2015; Desrosiers et al., 2013), results are conflicting regarding the nature of their impact. Understanding their distinct effects for specific populations has clinical implications as not all mindfulness facets may be important targets for modification within MBIs.
#### **Social Support**

Social support has consistently been shown to be beneficial to mental health (Taylor, 2011). Although varied definitions exist, social support is considered to be multidimensional with essential aspects including emotional, appraisal, tangible, informational, and instrumental support received from persons in one's social network (Schaefer et al., 1981). Social support may protect mental health both directly through the benefits of relationships, and indirectly by providing a buffer against stressful life experiences (Gariépy et al., 2016). Whilst the protective nature of social support is well-documented, the dimensions that are most protective against anxiety and depression are unclear. One review indicates that emotional and instrumental support are most consistently associated with protection from depression in the general population (Gariépy et al., 2016). However, the most valuable types of social support in protecting psychological wellbeing may fluctuate across the life-course with different dimensions being needed in different contexts (Cohen & Mckay, 2020; Schaefer et al., 1981). For this reason, it is beneficial to investigate the health effects of social support for specific samples experiencing particular stressors (Kessler & McLeod, 1985).

The protective nature of social support against prenatal anxiety and depression has been evidenced, with studies highlighting its likely benefits in providing emotional and cognitive relief and assistance with coping with distress (Biaggi et al., 2016; Elsenbruch et al., 2007). Conversely, inadequate social support is a risk factor for anxiety and depression and is associated with adverse pregnancy outcomes including low birthweight (Elsenbruch et al., 2007; Li et al., 2017; Razurel et al., 2013). Less is known about the role of social support for women with HG. Topalahmetoğlu and colleagues (2017) found greater anxiety and depression among women affected by HG with poorer levels of support from family and friends. This is concerning given reports that many women experience social isolation during

the course of HG (Dean et al., 2018). Although social support is indicated as a protective factor for mental health in HG women (Kara et al., 2016), it is unclear which types of social support are of most importance.

Overall, whilst the internal resource of DM and external resource of social support have been found to have protective qualities against anxiety and depression in perinatal populations, the most valuable aspects of these constructs are unclear, especially among a sample of women with HG. Given the heightened risk of anxiety and depression among HG groups, such an understanding would be advantageous in contributing to the development of assessment and intervention protocols. Currently, some MBIs aim to enhance mindfulness and incorporate strategies aimed at optimising social support. For example, in tailoring MBCT to meet the needs of perinatal women, some adaptations include cognitivebehavioural strategies targeted at social support optimisation. (e.g., Dimidjian et al., 2015, 2016). Furthermore, it has been considered that the in-person group formats of some MBIs may contribute social support benefits that are important for perinatal depression (Felder et al., 2017). A greater understanding of the impact of mindfulness and social support would be beneficial to consider evidence-based adaptations specific to HG.

#### The current study

The current study aimed to address gaps in knowledge by examining the unique relationships between the distinct mindfulness facets and aspects of social support with anxiety and depression among prenatal women affected by HG. These constructs may explain unique patterns of associations with anxiety and depression within bivariate correlations as well as when considered simultaneously, therefore providing relevant information for the development and application of psychosocial interventions for HG

populations in addition to the development of theoretical models. Several hypotheses were formulated:

- H1: There will be a higher incidence of anxiety and depression in HG women compared to age-matched non-clinical samples.
- H2: Sociodemographic variables and HG severity will explain small variance in symptoms of anxiety and depression.
- H3: Higher levels of dispositional mindfulness and social support will be associated with lower levels of anxiety and depression in pregnant women who experience HG.
- *H4:* We expect that the dimensions of mindfulness and social support will be predictive of anxiety and depression for prenatal women with HG. Whilst evidence consistently demonstrates the predictive nature of mindfulness and social support within anxiety and depression, the role of distinct aspects of these constructs is unknown for HG populations due to a lack of research. Due to the exploratory nature of this study, a priori hypotheses relating to specific social support and mindfulness aspects were not formulated. A path model will be constructed to aid understanding of the relationships between facets of mindfulness (describing, awareness, observing, nonjudging, non-reactivity) and dimensions of social support (tangible, emotional, affection support, and positive interaction) within both anxiety and depression.

#### Methodology

#### Participants

Participants were n=259 prenatal women who had experienced HG. For the purposes of the current study, HG was defined as the presence of nausea and vomiting resulting in loss of >5% of pre-pregnancy weight and/or if symptom severity had necessitated inpatient or outpatient care. Inclusion criteria required women to be English-speaking and 18 years of age or older. Of the 259 women who expressed initial interest in the study, 190 women (73.36%) provided consent and completed the questionnaires that measured the constructs of interest (depression, anxiety, social support, and mindfulness). Participants with incomplete data on these construct questionnaires were excluded (n=69). Of the 190 women included in the study, 178 (93.68%) completed all sociodemographic variables, and 177 (93.16%) completed items relating to HG severity. Cases of incompleteness can be attributed to instances of women clicking on the survey but not entering the study, as well as items being missed during survey completion.

Comparisons of completers and non-completers identified no significant differences across any of the constructs (i.e., EPDS, GAD-7, MOSSSS, and FFMQ-15) and HG variables (i.e., nausea duration, vomiting, frequency, duration of hospitalisation, and weight loss). However, completers significantly differed from non-completers in terms of prior mental health history. Whilst completers had a generally equal distribution between those with and without mental health histories, non-completers were skewed such that more women in this group reported no mental health history (*see* Appendix 8 for t-test and chi-square results for all variables).

Due to utilisation of a pre-existing dataset, a priori power analysis could not be performed. Post-hoc power analysis suitable for detecting misspecifications of the path model (Moshagen & Erdfelder, 2016) indicated that the sample of N=190 was associated with a power >87% to reject a model (df=20), and misspecifications corresponding to RMSEA=0.08 with an  $\alpha$  of 0.05. Therefore, a sufficient sample size was indicated.

#### Recruitment

Participants were recruited online through liaison with the Pregnancy Sickness Support Charity (PSS). The study was advertised on social media platforms through the PSS. Study advertisements directed women to the study site which presented study information and guided participants to confirm consent prior to study commencement (Appendix 9). Qualtrics (https://www.qualtrics.com) secure online survey platform was used to collect data. Participants were able to terminate the survey by exiting the browser. An incentive was offered to women who completed the study by offering entry to a prize-draw for an Amazon voucher worth £25. Participation in the wider study was open to women, aged 18 years and older, who were either >3 months pregnant with HG, or within the first 3 months post-partum following a HG pregnancy. The present study extracted data from the wider data set. Inclusion criteria for this study were adult women who were pregnant at the time of assessment and who were experiencing symptoms of HG in their pregnancy. This data has not been presented in any other work to date. Figure 1 outlines the current study's data management process.

#### Figure 1. Flow chart summarising data management process



#### Measures

# Sociodemographic and obstetric variables

All participants were asked to provide information regarding their age, ethnicity, marital status, employment, education level, and annual household income. HG information was also collected including nausea duration, vomiting frequency, weight-loss, number of days hospitalised, healthcare support and medical interventions received.

#### Anxiety

Anxiety was assessed using the Generalised Anxiety Disorder Questionnaire (GAD-7) (Spitzer et al., 2006). The GAD-7 is a seven-item self-report measure shown to be both valid and

efficient in screening for, and assessing severity of generalised anxiety (Spitzer et al., 2006). It enquires about the extent to which the individual has been impacted by worries and feelings of nervousness, anxiety, irritability, fear, restlessness, and difficulties relaxing. Mild, moderate, and severe anxiety levels are indicated by cut-off scores of 5, 10, and 15, respectively, and a cut off score of >10 is recommended to detect a probable anxiety disorder (Spitzer et al., 2006). Hence, this was the cut-off score used by this study. The GAD-7 is extensively used in research with pregnant and postnatal women. In the current sample the scale was internally consistent at .88 level.

#### Depression

The Edinburgh Postnatal Depression Scale (EPDS) (Cox et al., 1987) was used to assess depression. This 10-item measure requires respondents to indicate their feelings over the previous week. The threshold score of >13 is recommended to identify women with higher levels of depressive symptomology (Levis et al., 2020), and was the base-rate used by the current study. The EPDS is extensively used in research with pregnant and postnatal women and has good reliability and validity data (McBride et al., 2014; Murray & Carothers, 1990). In the current sample the internal reliability of the scale was .85.

# Mindfulness

Mindfulness was assessed using the fifteen-item Five Facet Mindfulness Questionnaire (FFMQ-15) (Baer et al., 2008). This is a short-form of the 39-item FFMQ (Baer et al., 2006) which measures the five facets of mindfulness. Facet scores range from 3-15 with higher scores indicating greater mindfulness. The FFMQ-15 has good reliability and validity data (Gu et al., 2016; H. Kim et al., 2021). In the current sample the internal consistency of the subscales was .74 for reactivity, .85 for non-judging, .52 for awareness, .41 for observing,

and .85 for describing. The FFMQ-15 has been shown to perform as well as the longer version as evidenced by Gu et al., (2016).

#### Social Support

The MOS Social Support Survey (MOSSSS) (Sherbourne & Stewart, 1991) was used to measure perceived availability of social support. It has nineteen-items that measure multiple dimensions of support. Total raw scores were transformed into a 0-100 scale, with higher scores indicative of greater levels of perceived social support (Sherbourne & Stewart, 1991). The MOSSSS is widely used with good reliability and validity data (Giangrasso & Casale, 2014; Kim & Mazza, 2014). In the current sample the internal consistency of the subscales was .94 for emotional support, .94 for tangible support, .97 for affectionate support, and .94 for positive social interaction.

#### Procedure

#### **Research Design**

Ethical approval was granted by Cardiff University, School of Psychology, Research Ethics Committee. Data for prenatal women with experience of HG was collected as part of a wider longitudinal study examining the psychological impact of HG during pregnancy and the first three-months postpartum. A cross-sectional study was undertaken to explore the impact of dispositional mindfulness and social support on the risk of prenatal anxiety and depression among women with HG.

#### Data Analysis

Data analyses were conducted using R System for Statistical Computing (Version R-4.0.4) (R Core Team, 2017) with utilised packages including 'Psych' (Revelle, 2021) and 'Lavaan' (Rosseel, 2012). Descriptive statistics were calculated for all variables. All continuous variables were assessed for violations of normality by Shapiro–Wilk, Skewness and Kurtosis statistics, and inspections of Q-Q plots. The GAD-7 and MOSSSS scores were found to violate normality assumptions. Given the small deviation of normality and the large sample size of the current study, two-sample t-tests were considered appropriate to compare completers (n=190) with non-completers (n=67) for continuous variables (Fagerland, 2012). Chi-square tests were used for categorical data. Spearman's Rho was used to assess relationships between all continuous variables, Kendall Tau correlations to analyse ordinal variables, and Eta coefficient for nominal data. Pairwise deletion was used to manage missing data for HG and obstetric variables.

A series of one-sample t-tests were conducted to determine whether levels of anxiety and depression in HG women were different to those of; non-clinical pregnant samples (Krusche et al., 2019); perinatal women referred for psychiatric consultation (Simpson et al., 2014); and to women presenting to Perinatal Community Mental Health Service's (PCMHS) with/at risk of developing a moderate-to-severe mood/anxiety disorder (Waters et al., 2020). Comparison tests were also conducted to compare anxiety and depression levels of participants scoring higher and lower in mindfulness and perceived social support.

Finally, path analysis, a form of Structural Equation Modelling (SEM) (Mitchell, 2001), was utilised to examine the associations between anxiety and depression, the five facets of mindfulness (observing, describing, non-judging, non-reactivity, awareness) and four social support dimensions (tangible, emotional, and affectionate support, and positive social

interaction). Whilst controlling for type-1 error rate inflations, path analysis allows examination of multiple simultaneous regression models, therefore allowing testing of complex models (Kline, 2011). This analysis allowed for a focused examination of the simultaneous relationships between distinct aspects of mindfulness and social support with measures of anxiety and depression.

Whilst the assumption of linearity was met, the assumption of multivariate normality was violated as indicated by inspection of Q-Q plots, Mardia multivariate kurtosis and skewness tests. Therefore, all model testing used Maximum Likelihood estimation and robust statistics were applied. Bivariate correlations were screened and no correlations above r=.85 were identified thus indicating no multicollinearity issues (Kline, 2005). The model was found to be over-identified, a necessary requirement for analysis to proceed (Ullman & Bentler, 2012).

Five measures of fit indices were used to evaluate the goodness of fit between the hypothesised model and the empirical data; the Root Mean Square Error of Approximation (RMSEA) (Steiger, 1990), Comparative Fit Index (CFI) (Bentler, 1990), Tucker-Lewis index (TLI), Standardized Root Mean Square Residual (SRMR), and the relative (normed) chi-square (X<sup>2</sup>/df). There is consensus that a relative chi-square of <3.0 is indicative of a model that is of reasonable fit (Kline, 2005). CFI provides an indication of the model fit in terms of the difference between the observed and predicted covariance matrices, with a value >0.90 (Yu-Ling, 2012) or near 0.95 (Hu & Bentler, 1999) considered acceptable. In terms of the RMSEA, values of 0.01, 0.05, and 0.08 have been considered to infer excellent, good, and medium fit (MacCallum et al., 1996). TLI values of >0.95 and SRMR values <0.10 are also considered to signify adequate model fit (Browne & Cudeck, 1989; Hu & Bentler, 1999).

Based on inspection of the pathway coefficients, factor loadings, and overall goodness of fit indices of the initial path model, a more parsimonious model was developed and a secondary path analysis completed.

#### Results

### **Demographic variables**

Table 1 presents the sample characteristics. Participants were predominantly white with a mean age of 30.53 years (SD=4.71), which is in-line with the UK average age of pregnant women/at childbirth of 30.7 years (ONS, 2020). Most women were in a committed relationship (97.37%) and were either married (63.16%) or cohabiting (28.42%). Women were most commonly either in full-time (45.79%) or part-time employment (20.53%), with a highest education level of either Degree (43.68%) or Postgraduate Degree level (26.32%). Most women reported their annual household income to be between £30,000-£60,000 (40%) or more than £60,000 (35%), which is above the UK average of £30,800 (ONS, 2021).

Table 1 Sample Characteristics (n = 190)					
Characteristics	Value				
Ethnicity, n (%)					
White	178 (93.68)				
Asian or Asian British	2 (1.05)				
Black or Black British	3 (1.58)				
Hispanic (inc. Mexican)	2 (1.05)				
Mixed race	4 (2.11)				
Maori	1 (0.53)				
Age					
Age, mean (SD)	30.53 (4.71)				
Age of first HG experience, mean (SD)	27.92 (5.16)				
Education, n (%)					
Undergraduate Degree	83 (43.68)				
Postgraduate (Master's Degree or above)	52 (27.37)				
A-Levels or equivalent	34 (17.89)				
GCSE's or equivalent	13 (6.84)				
other	8 (4.21)				
Marital status, n (%)					
Married	120 (63.16)				
Single	5 (2.63)				
In a relationship and cohabiting	54 (28.42)				
In a relationship and not living with partner	8 (4.21)				
Employment, n (%)					
Full-time	87 (45.79)				
Part-time	39 (20.53)				
Self-employed	25 (13.16)				
Unemployed or studying	38 (20)				
Household Income, n (%)					
less than £15,000	9 (4.74)				
£15,000 - £30,000	26 (13.68)				
£30,000 - £60,000	76 (40.00)				
£60,000 - £100,000	44 (23.16)				
More than £100,000	24 (12.63)				
Note: range of Nugries due to missing data					

**Table 1** Sample Characteristics (n = 190)

Note: range of N varies due to missing data

# **Obstetric Variables**

All women were currently pregnant with a mean pregnancy stage of 4.92 months (SD=2.07). Most women (91.58%) had received a HG diagnosis from a GP or doctor. Those without a HG diagnosis met the studies a priori HG criteria (i.e., having lost >5% of pre-pregnancy body weight due to nausea and vomiting and/or having required inpatient or outpatient care due to HG symptom severity). The mean age of women at the time of their first HG experience was 27.92 years (SD=5.16). Most women (72.11%) reported no family history of HG, whilst 17.37% confirmed family history and 10.53% were uncertain. Women reported having had an average of 2.31 (SD=1.38) previous pregnancies and having experienced HG in 1.84 (SD=1.38) of these.

On average, women reported 21.28 hours (SD=3.46) of nausea and had 19.70 (SD=14.63) episodes of vomiting per day when their HG symptoms were at their severest. At the time of study participation, women indicated a mean weight-loss of 11.66 lbs (SD=9.40). Most women accessed support through GP's (85.79%) and online-forums (58.95%). 74.74% of women had been admitted to hospital as either an outpatient or inpatient for treatment of HG symptoms, with an average of 5.04 days (SD=12.49) having been spent in hospital.

#### Mental health history

Of the 185 (97.37%) women who provided mental health history information, 46.48% reported no past mental health issues, and 53.51% reported a past mental health difficulty. Self-reported mental health conditions prior to the current pregnancy included depression (37.30%), postnatal depression (9.19%), anxiety (34.59%), panic attacks (11.35%), PTSD (6.49%), OCD (4.86%), social anxiety (3.24%), and health anxiety (2.70%). Over half (56.56%) of women who reported previous mental health history reported two or more psychological difficulties.

#### Anxiety and depression prevalence

Questionnaire scores were examined to establish the prevalence of anxiety and depression (Table 2). For depression, the mean EPDS score was 17.70 (SD=5.25). In terms of clinical caseness, 81.05% of women scored >13. For anxiety, almost half of women (47.9%) reported moderate-severe symptoms, 38.95% reported mild symptoms, and 13.16% reported minimal symptoms. The mean GAD-7 score was 9.93 (SD=5.18) which falls just on the borderline between 'mild' and 'moderate' anxiety. The group mean is just under the cut-off score of 10. Spearman's rho tests showed that anxiety and depression were positively correlated (r=0.67, p<0.01). 39% met cut-off scores on both the GAD-7 (>10) and EPDS (>13), therefore indicating high levels of comorbidity.

depression outcomes.		
Measure	Mean (SD), %	Alpha
EPDS	17.70 (5.25)	.85
>13	81.05%	
GAD-7	9.93 (5.18)	.88
≤ 4, Minimal	13.16%	
5-9 <i>,</i> Mild	38.95%	
10-14, Moderate	27.37%	
15-21, Severe	20.53%	

 Table 2. Descriptive statistics for anxiety and

 depression outcomes

Table 3 shows findings of one-sample t-tests comparing the HG sample with clinical and non-clinical samples. HG women had significantly higher levels of anxiety (t(189)=5.19, p<0.001) and depression (t(189)=18.29, p<0.001) than the community sample. They also had significantly higher levels of depression than perinatal women presenting for psychiatric

consultation (t(189)=8.65, p<0.001), and to women presenting to PCMHS with/at risk of developing a moderate-to-severe perinatal mood/anxiety (t(189)=2.65, p<0.05). However, HG women reported significantly lower anxiety levels than perinatal women referred for psychiatric consultation (t(189)=-2.05, p<0.05). No data for anxiety from the PCMHS sample was available.

**Table 3.** Means (SDs) of EPDS and GAD-7 measures for HG sample compared to clinical and nonclinical populations.

	HG sample	Perinatal women referred for psychiatric consultation (1)	PCMHS (2)	Healthy pregnant women (3)
EPDS	17.70 (5.25)	14.4 (5.9)**	16.69 (4.71) <sup>++</sup>	10.72 (6.05) <sup>+</sup>
GAD-7	9.93 (5.18)	10.7 (6.3) <sup>++</sup>	-	$7.97~(5.31)^{t}$
(2) = (3) = (1	(Simpson et al., 20 (Waters et al., 202 Krusche et al., 2019 <i>e-tailed test</i>	0)		

<sup>*tt*</sup> = two-tailed test

# **Descriptive statistics: study variables**

Descriptive statistics for the constructs of interest are shown below in Table 4.

Variable	Mean	SD
Mindfulness	47.68	7.85
Observing	9.77	2.38
Describing	10.11	2.74
Acting with awareness	9.34	2.00
Non-judging	9.53	2.89
Non-reactivity	8.93	2.61
Social support	60.13	20.10
Emotional support	54.65	24.18
Tangible support	65.00	26.23
Affectionate support	77.98	25.29
Positive social interaction	52.50	26.93

**Table 4.** Means, SDs and Alpha Coefficients of themain study constructs.

# Associations between sociodemographic, HG clinical variables, mindfulness, social support, anxiety, and depression.

Income, education, and age were negatively associated with depression (Table 5). Previous mental health history was positively associated with anxiety but not depression. There was no association between any of the HG variables with anxiety and depression. In terms of mindfulness, an inconsistent pattern of associations between distinct facets and anxiety and depression was identified. Higher levels of mindfulness on the three facets of 'describe' 'awareness' and 'non-judgement' were negatively correlated with both anxiety and depression. However, 'observe' and 'non-reactivity' were not significantly correlated with either depression or anxiety. All four dimensions of social support were inversely associated with both anxiety and depression, such that higher levels of social support were associated with lower levels of prenatal anxiety and depression.

Variable	Anxiety	Depression
Demographic		
Income	-0.14++	-0.17* <i>††</i>
Employment	0†	0.07†
Ethnicity	0†	0.06†
Education	-0.12++	-0.18* <i>††</i>
Age	-0.1	-0.16*
Marital status	0.11†	0.06†
Mental health history	0.17* <i>†</i>	0.03+
Obstetric		
Days hospitalised	0.05	0.05
Weight loss	0.02	0.06
Vomiting frequency	0.05++	0.01++
Nausea duration	0.07++	0.12++
Overall mindfulness	-0.42**	-0.36**
Describe	-0.35**	-0.33**
Observe	-0.13	-0.09
Awareness	-0.31**	-0.23**
Non-reactivity	-0.09	-0.01
Non-judgment	-0.45**	-0.47**
Perceived Social Support	-0.3**	-0.3**
Emotional/informational support	-0.23**	-0.22**
Tangible support	-0.23**	-0.21**
Affectionate support	-0.26**	-0.18*
Positive Social interaction	-0.2*	-0.31**

**Table 5.** Correlation coefficients for associations between

 sociodemographic HG clinical variables, anxiety, and depression

Spearman's Rho Eta correlation coefficients † Kendall Tau correlation coefficient†† \*P < 0.05 \*\*P < 0.01.

# **Dispositional mindfulness**

Two-sample t-tests compared women with DM scores below (n=97) and above (n=93) the FFMQ-15 median (=47). Women scoring higher in DM demonstrated significantly lower levels of anxiety (t(188)=4.52, p<0.001) and depression (t(188)=3.65, p<0.001) than those with lower DM. The mean EPDS score in the high mindfulness group was 16.32 compared to

19.02 in the low mindfulness group. Mean GAD-7 scores in the high mindfulness group was 8.27 compared with 11.52 in the low mindfulness group.

#### Social support

Two-sample t-tests were conducted to compare women with MOSSSS scores below (n=94) and above (n=96) the median (=61.84). Women with higher levels of perceived social support reported lower levels of anxiety (t(188)=3.94, p<0.001) and depression (t(188)=3.29, p<0.01). For anxiety, mean scores for those scoring high in social support was 8.51 compared with 11.37 for those lower in social support. For depression, the high social support group had a mean EDPS score of 16.49 compared with a mean score of 18.94 for low social support group.

# **Path Analyses**

# Examination of the direct impacts of mindfulness and social support on prenatal anxiety and depression

Path analysis was conducted and the factor loadings, explained variance for each factor, and overall model fit were inspected (Figure 2, Table's 6 & 7). Results indicated a differential pattern of associations between mindfulness facets and levels of anxiety and depression. Higher levels of *describing* were associated with lower levels of both anxiety ( $\beta$ =-0.26, p<0.01) and depression ( $\beta$ =-0.23, p<0.01). Higher levels of *non-judging* were also associated with lower levels of anxiety ( $\beta$ =-0.35, p<0.01) and depression ( $\beta$ =-0.42, p<0.01). Conversely, higher levels of non-reactivity were associated with greater levels of depression ( $\beta$ =0.15,

p<0.05) but not anxiety ( $\beta$ =0.03, p>0.05). There were no significant associations between the facets of *awareness* and *observing* and anxiety or depression.

In terms of social support, *positive social interaction* was inversely associated with depression ( $\beta$ =-0.23, *p*<0.01), and *affectionate support* was negatively related to anxiety ( $\beta$ =-0.17, *p*<0.05). No other relationships between dimensions of social support and anxiety and depression were found. Taken together, mindfulness facets and social support dimensions accounted for 31% of the variance in anxiety (adjusted R<sup>2</sup> = 0.31), and 33% of the variance in depression (adjusted R<sup>2</sup> =0.33) when all pathways shown in Figure 2 were included.



**Figure 2.** Initial path diagram describing pathways for mindfulness facets and social support dimensions for anxiety and depression. Path coefficients are indicated above. Bold lines represent significant pathways as indicated by unstandardised coefficients (\*P<0.05, \*\*P<0.01).

Path			coe (stanc	andardised efficient dardisation efficient)	SE	Z	p	95% Cl (Lower, Upper)
Describing	+	Anxiety	-0.48	(-0.26)**	0.13	-3.62	0.00	-0.75, -0.22
Non-reactivity	$\rightarrow$	Anxiety	0.06	(0.03)	0.13	0.50	0.62	-0.19, 0.32
Non-judging	->	Anxiety	-0.62	(-0.35)**	0.13	-4.71	0.00	-0.88, -0.36
Awareness	->	Anxiety	-0.21	(-0.08)	0.18	-1.13	0.26	-0.56, 0.15
Observing	-	Anxiety	0.21	(0.10)	0.16	1.29	0.20	-0.11, 0.53
Tangible support	-	Anxiety	-0.00	(-0.02)	0.02	-0.25	0.80	-0.04, 0.03
Affectionate support	->	Anxiety	-0.04	(-0.17)*	0.02	-2.02	0.04	-0.07, -0.00
Emotional/informational support	->	Anxiety	0.01	(0.05)	0.02	0.59	0.56	-0.02, 0.20
Positive social interaction	->	Anxiety	-0.01	(-0.03)	0.02	-0.41	0.69	-0.04, 0.04
Describing	-	Depression	-0.43	(-0.23)**	0.13	-3.32	0.00	-0.67, -0.18
Non-reactivity	->	Depression	0.29	(0.15)*	0.13	2.23	0.03	0.04, 0.55
Non-judging	->	Depression	-0.75	(-0.42)**	0.12	-6.33	0.00	-0.99 <i>,</i> -0.52
Awareness	->	Depression	0.06	(0.02)	0.18	0.33	0.74	-0.29, 0.41
Observing	->	Depression	0.10	(0.05)	0.15	0.66	0.51	-0.20, 0.40
Tangible support		Depression	-0.01	(-0.03)	0.02	-0.39	0.70	-0.04, 0.03
Affectionate support	->	Depression	-0.01	(-0.02)	0.02	-0.32	0.75	-0.03, 0.02
Emotional/informational support	->	Depression	0.02	(0.08)	0.02	1.09	0.27	-0.01, 0.05
Positive social interaction	->	Depression	-0.05	(-0.23)**	0.02	-3.09	0.00	-0.07, -0.02

Table 6. Path model analysis: Mindfulness facets and social support dimensions as predictors of anxiety and depression

SE = standard error

CI = confidence interval

\*P < 0.05

\*\*P < 0.01.

The model's goodness of fit indices indicates the model to have reasonable, but not excellent fit as some figures did not meet the recommended criterions (TLI, SRMR, RMSEA), indicating room for improvement in the model fit (Table 7).

Table 7. Path analysis: goodness of fit indices

χ²/df	CFI	TLI	RMSEA	SRMR		
2.42	0.95	0.85	0.09	0.11		
RMSEA = Root Mean Square Error of Approximation						
CDMP - Standardiz	ad Boot Moon Squar	o Docidual				

SRMR = Standardized Root Mean Square Residual

 $\chi^2/df$  = relative (normed) chi-square

CFI = Comparative Fit Index

TLI = Tucker-Lewis index

#### **Secondary Path Analysis**

A secondary path analysis examined a more parsimonious path model inclusive only of significant pathways identified in the initial analysis (Figure 3 & Table 8). Results of this analysis revealed a consistent pattern of coefficients with all previously identified pathways continuing to show significant associations with anxiety and/or depression. After removing non-significant pathways, all but one of the pathway coefficients slightly reduced in magnitude. The pathway coefficient for affectionate support and anxiety remained the same. Taken together, mindfulness facets and social support dimensions accounted for 29% of the variance in anxiety (adjusted  $R^2 = 0.29$ ), and 31% of the variance in depression (adjusted  $R^2 = 0.31$ ).



**Figure 3.** Refined path diagram describing pathways for mindfulness facets and social support dimensions for anxiety and depression. Path coefficients are indicated above. Bold lines represent significant pathways as indicated by unstandardised coefficients (\*P<0.05, \*\*P<0.01).

Path		Unstandardised coefficient (standardisation coefficient)		SE	Z	p	95% Cl (Lower, Upper)	
Describing	+	Anxiety	-0.43	(-0.23)**	0.12	-3.60	0.00	-0.66, -0.19
Non-judging		Anxiety	-0.68	(-0.38)**	0.12	-5.48	0.00	-0.93, -0.44
Affectionate support	->	Anxiety	-0.03	(0.17)**	0.01	-3.32	0.00	-0.05, -0.01
Describing	->	Depression	-0.37	(-0.20)**	0.12	-3.16	0.00	-0.59, -0.14
Non-judging	->	Depression	-0.73	(-0.41)**	0.12	-6.07	0.00	-0.97, -0.49
Non-reactivity	->	Depression	0.24	(0.12)*	0.10	2.52	0.01	0.05, 0.43
Positive interaction	->	Depression	-0.04	(-0.21)**	0.01	-3.97	0.00	-0.06, -0.02

# Table 8. Path model analysis: second model

SE = standard error

CI = confidence interval

\*P < 0.05

\*\*P < 0.01.

As seen in Table 9, goodness of fit tests showed the parsimonious model to have improved fit in comparison to the initial model, with all indices now falling within recommendations. The model fit indices indicate this model to have good fit to the data as indicated by the relative (normed) chi-square (<3.0), RMSEA (0.05), SRMR (<0.10), CFI (>0.95), and TLI (>95).

Table 9. Path anal	ysis: goodness	of fit indices
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χ²/df	CFI	TLI	RMSEA	SRMR			
1.50	0.99	0.96	0.05	0.07			
RMSEA = Root Mean Square Error of Approximation							
SRMR = Standardized Root Mean Square Residual							
$\chi^2$ /df = relative (normed) chi-square							
CFI = Comparative	Fit Index						

TLI = Tucker-Lewis index

#### Discussion

The current study aimed to examine the relationship between the distinct mindfulness facets, dimensions of social support and anxiety and depression for pregnant women affected by HG. Findings indicate that anxiety and depression were common in this sample, and comorbidity was high with over a third of participants meeting recommended cut-off criteria for both anxiety and depression. Participants reported anxiety and depression levels that were significantly higher than those found in healthy pregnant women without HG (Krusche et al., 2019), a finding that is consistent with other research (Aksoy et al., 2015; Uguz et al., 2012). When compared to clinical samples including perinatal women with/at risk of anxiety and mood disorders (Simpson et al., 2014; Waters et al., 2020), HG women had significantly lower levels of anxiety but higher levels of depression. Therefore, elevated

levels of anxiety and particularly depression are indicated for pregnant women with HG, thus highlighting the need for routine mental health screening and the development of evidence-based psychological interventions for this vulnerable population.

The present study used weight-loss, vomiting frequency, nausea duration, and number of days hospitalised as markers of HG severity. Our findings indicate no association between these markers of HG severity and prenatal levels of anxiety and depression. Similarly, Tan and colleagues (2010) reported no relationship between HG severity with anxiety caseness. However, they identified crude associations between vomiting leading to hospitalisation, gestational age at vomiting onset and the severity of prenatal depressive symptoms. Therefore, whilst the current study found no relationship between HG severity and prenatal depressive and anxious symptomatology, it is possible that HG variables important to the presentation of anxiety and depression were not captured.

Modest negative associations were identified between income, maternal age, education, and prenatal depressive symptoms, such that younger women with lower levels of income and education experienced higher levels of depressive symptoms. These findings correspond with previous research undertaken with HG women (Topalahmetoğlu et al., 2017). However, it should be noted that the current sample was predominantly employed and most participants (66%) reported a household income above the UK mean (ONS, 2021). As such the current findings may not be representative of unemployed women with lower household incomes.

Prior mental health history was positively associated with anxiety but not depression. Over half of the sample reported having had a previous mental health condition, most commonly depression and/or anxiety. These rates are slightly higher than reported by other studies

such as that of Seng and colleagues (2007) who found 1 in 10 women with HG to have prior psychological difficulties. In the present study, a significant difference was identified between those women who did and did not complete the full set of questionnaires. Completers were significantly more likely to report prior mental health conditions. Given that a prior history of depression and anxiety is frequently identified as a risk-factor for prenatal anxiety and depression (Lancaster et al., 2010; Leach et al., 2017), it is possible that the prevalence rates in the current HG sample represent an overestimation. That being said, anxiety prevalence reported in the current study is in-line with another study undertaken with HG women (Tan et al., 2010). However, depression rates of the present sample were substantially higher than those found by Tan and colleagues (2010).

Consistent with our hypotheses, bivariate correlations indicated greater levels of social support are associated with reduced levels of anxiety and depression for HG women. All four social support dimensions (positive social interaction, tangible, affectionate, and emotional/informational support) were inversely related to prenatal anxiety and depression. Comparative analyses revealed significant differences. On average, women low in social support reported anxiety scores that were above the recommended cut-off indicative of clinical caseness, whilst average scores for those high in social support fell below this clinical cut-off. For prenatal depressive symptoms, the difference between those identified as having high or low perceptions of social support did not translate into any disparity in clinical caseness. This is likely to be linked to the finding that depressive symptomology was particularly elevated for this sample. Nonetheless, women with greater social support levels demonstrated lower depressive symptomology. These findings are consistent with decades of research that indicate greater perceived social support to be

associated with superior psychological wellbeing and reduced anxiety and depression levels (Goodman & Tully, 2008; Hughes et al., 2009; O'hara & Swain, 1996; Taylor, 2011).

As hypothesised, those with higher DM levels reported lower anxiety and depression levels. Again, for anxiety, this difference was enough to deduce that women low in mindfulness had average anxiety scores within the clinical range, whilst those high in mindfulness generally reported anxiety levels below the clinical cut-off. In contrast, average prenatal depression symptoms remained within the clinical range for women scoring high and low in DM. Consistent with other studies undertaken with prenatal women without HG (Krusche et al., 2019; Truijens et al., 2016), bivariate correlations revealed an inverse relationship between DM and prenatal psychopathology. Closer inspection revealed three mindfulness facets to be negatively associated with anxiety and depression, namely describing, acting with awareness, and non-judgement of inner experience.

To extend understanding further, a path analysis was conducted whereby the distinct facets of mindfulness and dimensions of social support were simultaneously examined. This analysis revealed unique relationships between the aspects of mindfulness and social support with anxiety and depression. The overall model had predictive utility explaining 29% and 31% of the variance in anxiety and depression, respectively. Amongst all the examined variables, non-judgement was the strongest direct predictor of anxiety and depression and had a negative association with both psychological outcomes. This is consistent with other literature examining these relationships in non-pregnant (Brown et al., 2015; Cash & Whittingham, 2010; Desrosiers et al., 2013) and pregnant populations (Kantrowitz-Gordon, 2018). An intervention study conducted with prenatal women reported reduced levels of depression following MBI treatment (Lönnberg et al., 2020). In this study, lower prenatal

depressive symptoms were found to be driven by the non-judging mindfulness facet, therefore supporting its potential importance in MBIs for HG populations. Non-judging has been linked to reduced self-criticism and rumination, both of which are known to exacerbate anxiety and depression, particularly in perinatal populations (Barcaccia et al., 2019; O'Mahen et al., 2010). As such, judgements may serve to maintain and worsen negative cognitive processes that underlie prenatal depressive and anxiety symptoms.

The mindfulness facet of describing was the second strongest inverse predictor of prenatal anxiety and depressive symptoms. Whilst several studies have found describing to be unrelated to depression (Cash & Whittingham, 2010), others replicate the current study's findings for depression (Barnhofer et al., 2011; Kantrowitz-Gordon, 2018), anxious arousal (Desrosiers et al., 2013), and pregnancy-anxiety (Kantrowitz-Gordon, 2018). It is possible that the ability to describe and label internal experiences may lead to reductions in experiential avoidance, thereby reducing prenatal anxiety and depression.

In contrast to studies that document negative associations between non-reactivity and psychological outcomes (Brown et al., 2015; Desrosiers et al., 2013), present results indicate a modest positive association between non-reactivity and depression, but no association with anxiety. The reason for this discrepancy is unclear but is possibly related to the specific sample of prenatal HG women. The non-reactivity items of the FFMQ-15 query women about their ability to notice distressing thoughts and images and to let them go without reacting (Baer et al., 2008). It has been hypothesised that these items may be interpreted differently in pregnant populations, such that they may be understood as signifying thoughts relating to pregnancy and the foetus that should be taken seriously rather than

being let go of (Truijens et al., 2016). However, this result should be interpreted cautiously due to having the lowest predictive strength together with a marginal significance level.

No association between the observing facet and prenatal anxiety and depression was found. This contrasts with studies undertaken with other populations that have found the observing facet to be positively related to psychological distress (Desrosiers et al., 2013). It has been postulated that observing may be sensitive to differing levels of previous meditation experience (Baer et al., 2006), a variable not considered in the current analysis. Furthermore, the observing items on the FFMQ-15 are related to paying attention to the body and the influence of external stimuli upon one's bodily state. For this HG group, such awareness might be particularly distressing with the potential to exacerbate nausea. These results suggest that other mindfulness facets, namely describing and non-judging, may be of more value to HG populations.

Bivariate associations indicated acting with awareness to be inversely associated with anxiety and depression, but when all variables were simultaneously examined, these relationships were no longer significant. Similarly, other studies have observed associations between awareness and psychological outcomes to became non-significant when other mindfulness aspects were controlled for (Desrosiers et al., 2013; Kohls et al., 2009). It has been suggested that awareness may be required to cultivate other mindfulness facets, which may then influence symptomology more directly (Desrosiers et al., 2013).

Within the path analysis, of all the social support dimensions, only positive social interaction was found to be inversely associated with depression. Positive social interaction reflects availability of social support from another person characterised by shared enjoyment, fun, and relaxation (Sherbourne & Stewart, 1991). It is conceivable that this type of social

support could provide a sense of social belonging that offers relief and enhances positive affect thereby offering a stress-buffering effect that reduces mood disturbance for women with HG. It is also possible that this direct association is the result of women with lower depressive symptomology being more able to engage in positive social interactions. When considering anxiety, only affectionate support showed a direct path. This suggests that interacting with others that behaviourally demonstrate their love and affection, has an important role within anxiety for HG women. It may be that more intimate or affectionate relationships are of greater value to women with HG when experiencing intense anxiety symptoms (nervousness, irritability, fear) than for depressive symptoms (hopelessness, low mood).

It is surprising that other social support types were not shown to be of importance for prenatal anxiety and depression within the model. A possible reason for this relates to the finding that women in this sample were predominantly married or in a committed relationship and with above average household incomes. Whilst social support is likely to be valuable to all expectant mothers, particularly those experiencing HG, it may be that some women are in greater need than others (e.g., women not in a committed relationship and/or with few economic resources). Further research to investigate for whom specific aspects of social support are most beneficial within the HG context would be advantageous.

#### **Strengths and limitations**

A strength of this study was that we were able to utilise data from a population at risk of anxiety and depression that is not often studied. However, whilst the examined path model was conceptually guided by existing research, the cross-sectional study design impedes any causal assumptions and the possibility of alternate models remains. Furthermore, this study is unable to draw inferences around the trajectory of anxiety and depression symptomology for this cohort, nor around any changes in their relationships with mindfulness facets and social support dimensions over the course of HG pregnancies and beyond. Research suggests that DM may fluctuate during pregnancy (Mennitto et al., 2020), and that the importance of types of social support change according to context and the changing needs of women as they transition from pregnancy through childbirth and into parenthood (Gjerdingen et al., 1991; Schaefer et al., 1981). Therefore, it is possible that associations between mindfulness, social support and mental health outcomes are more accurately explained by non-linear relationships whereby associations fluctuate overtime. An implication of this would be that different dimensions of social support and mindfulness may be helpful at various stages of HG pregnancy. Longitudinal research to examine the role of these constructs at different stages of pregnancy and postpartum would be advantageous.

A further limitation is that the current sample may not be representative of all women affected by HG. Participants were all English-speakers and predominantly comprised of white and highly educated women in committed relationships with above average household incomes. Consequently, there are likely restrictions in the generalisability of these findings. This study also relied on self-report measures which are known to be subject to biases (Furnham & Henderson, 1982). However, previous studies indicate that maternal self-reports are valid and reliable when gathering perinatal outcome data (Gresham et al., 2015).

This study reports some differential results to those documented within the literature, which could reflect differences that exist in the relationship between the variables of interest and prenatal anxiety and depressive symptomatology within HG populations. However, it is also important to note that numerous alternate models could provide equivalent or superior fit to the data. The model statistics indicate that there are unmeasured constructs that could contribute to explaining the associations between mindfulness, social support, and prenatal anxiety and depressive symptoms more fully. Although findings are consistent with research that suggests greater mindfulness and social support are associated with better psychological wellbeing, it is still unknown how these constructs lead to these benefits, and so further work is required. Some studies indicate that mindfulness may have an important role in emotion regulation and in reducing rumination, a cognitive process known to be related to depressive symptomology (Brown et al., 2007; Williams, 2008). It is conceivable that rumination and emotion regulation may mediate the relationship between mindfulness and psychological distress (Alleva et al., 2014). Moreover, multiple pathways through which social support influences psychological health have been suggested including self-efficacy, increased positive affect, appraising circumstances as valuable, and emotional regulation (Feeney & Collins, 2014). Therefore, further investigation inclusive of other factors is necessary to fully understand the psychological processes underpinning prenatal anxiety and depression in HG populations.

#### **Clinical implications**

Despite the summarised limitations, the current study has several important implications relevant to assessment and screening procedures, and to intervention developments to

support the psychological wellbeing of women affected by HG. Firstly, given the finding that HG women not only reported significantly higher levels of anxiety and depression than community samples, but significantly higher depression levels than age-matched clinical samples, the routine screening of anxiety and especially depression is imperative for this group. Routine screening would support identification of women who might benefit from psychological support. Furthermore, screening should include assessment of women's mindfulness levels, available sources of support, and potential needs. It may be valuable to detect women affected by HG who score low on mindfulness and social support, and to offer an intervention focused on the enhancement of DM and the optimisation of social support. For this purpose, valid and brief screening tools for social support and mindfulness characteristics could be beneficial for the HG population.

By determining the unique direct paths by which aspects of mindfulness and social support relate to prenatal anxiety and depression, some insight is gained into how MBIs may be effective for this cohort. Findings suggest that acting with awareness and observing may be of less utility in treating prenatal anxiety and depression for women affected by HG. Conversely, non-judging, and describing appear to be clear targets for interventions, such that woman with higher levels of non-judgment and describing potentially experience lower levels of prenatal anxiety and depression. The current study also highlights the potential utility of targeting reductions in non-reactivity, however further research is needed to understand the role of this facet for HG women. Positive social interaction and affectionate support could be potential protective factors against anxiety and depression that can also be integrated into MBIs, either through group processes or by supporting women's skills in optimising such support from their existing social networks.

#### **Future research directions**

Understanding protective factors within anxiety and depression is particularly pertinent within the HG context given the heightened risk of psychopathology in this cohort (Mitchell-Jones et al., 2020). There is still a lot to learn about the role of social support and mindfulness for women with HG, and further replication and extension of the present study's results is required with more diverse and representative samples. It would be beneficial for future research to build on our findings by utilising longitudinal designs to further examine the role of mindfulness, social support, as well as other potentially important variables (e.g., emotion regulation, self-efficacy, and rumination). Furthermore, investigation at multiple time points both during pregnancy and postnatally would allow for better disentanglement of causal relationships whilst supporting improved understanding of women's changing needs as they progress through pregnancy and transition into parenthood. Finally, research that informs development of valid and brief screening tools for social support and mindfulness characteristics could be beneficial for the HG population.

#### Conclusions

This study explored psycho-social predictors of prenatal anxiety and depression among women affected by HG. It adds to an under-researched area relating to the mental health outcomes and underlying psycho-social processes within a HG population, and also contributes more widely to a large volume of research that has investigated the relationship between DM, social support and mental health outcomes. Research and clinical implications have been outlined, specifically in relation to the need for mental health screening and the potential benefit of interventions aimed at enhancing specific mindfulness facets and aspects of social support for women affected by HG who are at risk/presenting with anxiety and depression. Future research is necessary to verify and expand upon the current findings by further examining the association between these constructs and prenatal anxiety and depression symptoms among women affected by HG.
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## Appendices

## Appendix 1: Journal of Midwifery and Women's Health Author Submission guidelines

# Submitting a Manuscript:

All manuscripts must be submitted via the JMWH online manuscript submission and peer review system. Please visit http://mc.manuscriptcentral.com/jmwh to submit a manuscript. A manuscript may be accepted as a submission with the understanding that: 1) it is an original contribution that has not been published previously; 2) it is not simultaneously under consideration by any other journal; 3) the content is not fraudulent or plagiarized; 4) the material does not infringe or violate any copyright agreements or other personal or proprietary rights; and 5) all financial support for the work described in the manuscript and any conflicts of interest are disclosed. JMWH will consider manuscripts previously available as preprints. Authors must provide information about any preprint postings, including copies of the posted manuscript and a link to it, at the time of submission of the manuscript to JMWH. Authors are requested to update any pre-publication versions with a link to the final published article. All individuals designated as authors should meet all 4 of the following criteria for authorship: 1) substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; 2) drafting the work or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.1 Authors must upload signed Author Disclosure forms for each author. Individuals who do not meet all 4 criteria for authorship should be listed in the acknowledgments. An ORCID iD is required for the submitting author and recommended for all authors. ORCID iDs are unique, persistent, digital identifiers that link authors with their publications and other professional activities.2 All manuscripts submitted to JMWH undergo a preliminary review by the editors to assess their quality and suitability for the Journal. All manuscripts submitted to the Journal are analyzed with plagiarism detection software. Manuscripts that qualify for external peer review will be evaluated using a double-blind process in which neither the authors nor the reviewers know the others' identities. Please contact the editorial office at jmwh@acnm.org with questions about manuscript submission.

# **Types of Articles:**

Submissions for the following types of articles are accepted. Word and reference limits vary by article type as do specific components, such as abstract headings. Table 1 summarizes key requirements for each type of article.

# **Original Research**

Original reports of research should include introduction, methods, results, and discussion sections. State the study objective(s) in the introduction section. Include clinical, and policy if applicable, implications in the discussion section. For qualitative research, choose exemplar quotes judiciously. Readers should be able to clearly see the relationship between the quotes and study findings. Length limit is 4000 words, 50 references. For pilot studies, feasibility studies, and other studies the editors determine warrant a short report, length limit is 2500 words, 30 references. Reports of research involving human participants must state in the methods section of the manuscript that institutional review board (IRB) or independent ethics review committee approval was obtained or an exemption was granted. The name of the IRB or ethics review committee must be included. JMWH may request documentation of the IRB or ethics committee approval or exemption. The methods section should also indicate how informed consent was obtained from all participants (ie, written or oral). Research in which members of the American College of Nurse-Midwives were solicited as participants must be conducted in accordance with the organization's policy regarding soliciting members for research purposes, which is available at www.acnm.org. Adherence to this policy must be noted in the methods section of the manuscript. Clinical trials started after May 2005 must be registered with a central registry.1,3,4 It is acceptable to produce more than one manuscript from a single study or data set; however, each manuscript must represent a clearly unique use of the data and be presented in a manner that avoids any perception of duplicate publication. Authors who submit a manuscript using the same data as a previously published work, work in press (ie, accepted for publication but not yet published), or work under review (i.e., submitted but not yet accepted) must include the following in their cover letter: 1) information about the previously-published work(s), including references for other articles that are published or in press elsewhere; 2) how (or if) the current analysis differs from analysis in the other work(s); 3) how (or if) the participants differ from those in the other work(s); and 4) a clear and specific statement about how the submitted manuscript differs from other works from the study and why the further use of these data is appropriate. Reporting guidelines are used to improve the quality and transparency of research reports.5 Reporting guidelines specify what information should be included in a research report. Many reporting guidelines include checklists, flow diagrams, and other resources that can be valuable for organizing a manuscript and ensuring the content is complete. Following reporting guidelines will improve a manuscript and may enhance its chances for eventual publication.

	Word	Reference				Quick
Article Type	Limit <sup>a</sup>	Limit	Précis	Abstract Headings	Keywords	Points
Original Research	4000	50	Yes	Introduction, Methods, Results,	Yes	Yes
				Discussion		
Original Research:	2500	30	Yes	Introduction, Methods, Results,	Yes	Yes
Pilot or Feasibility Study				Discussion		
Review: Formal	5000	70	Yes	Introduction, Methods, Results,	Yes	Yes
Methodological Process				Discussion		
Review: State of the Science	5000	70	Yes	Unstructured (no headings)	Yes	Yes
Innovations from the Field	3000	30	Yes	Unstructured (no headings)	Yes	Yes
Quality Improvement	3500	35	Yes	Introduction, Process,	Yes	Yes
Report				Outcomes, Discussion		
Clinical Rounds	3000	30	No	Unstructured (no headings)	Yes	No
Commentary	2000	20	No	NA (no abstract)	No	No
Share with Women	1000	NA	No	NA (no abstract)	No	No
Letters to the Editor	600	6	No	NA (no abstract)	No	No

Abbreviation: NA, not applicable. <sup>a</sup>The word limit includes the manuscript text only, exclusive of the précis, abstract, keywords, Quick Points, references, tables, and figure captions.

Use of the following reporting guidelines is encouraged for original research manuscripts:

- Randomized controlled trials: Consolidated Standards of Reporting Trials (CONSORT) Statement
- Observational studies: Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement
- Nonrandomized evaluations of behavioral and public health interventions: • Transparent Reporting of Evaluations with Nonrandomized Designs (TREND).
- Qualitative research: Standards for Reporting Qualitative Research (SRQR)9 and Consolidated Criteria for Reporting Qualitative Research (COREQ)
- Quality improvement studies: Standards for Quality Improvement Reporting • Excellence (SQUIRE)
- Diagnostic accuracy studies: Standards for the Reporting of Diagnostic Accuracy Studies (STARD)
- Online surveys: The Checklist for Reporting Results of Internet E-Surveys (CHERRIES)

Wiley, the publisher of JMWH, will post the accepted version of any manuscript authored by National Institutes for Health (NIH) grant-holders to PubMed Central upon acceptance. This accepted version will be made publicly available 12 months after publication in accordance with NIH Public Access Policy. For further information, the see https://authorservices.wiley.com/ author-resources/Journal-Authors/licensing-openaccess/openaccess/funder-agreements.html. Wiley also offers open access via OnlineOpen (https://authorservices.wiley.com/authorresources/Journal-Authors/licensing-openaccess/open-access/ onlineopen.html). Upon payment of the OnlineOpen fee, the published version of the article will be deposited into PubMed Central, with public availability in PubMed Central and on the Journal's website immediately upon publication.

# **Reviews:**

Reviews may address, but are not limited to, clinical practice; education; health care policy; or legal, ethical, environmental, cultural, historical, or international issues affecting women's health. Two types of reviews are published in JMWH: reviews that follow a formal methodological process and state of the science reviews. Length limit for reviews is 5000 words, 70 references.

Systematic reviews, meta-analyses, integrative reviews, scoping reviews, and other reviews conducted using a formal methodological process should conform to the same format as research reports (ie, introduction, methods, results, and discussion sections). Use of the following reporting guidelines is encouraged for systematic reviews and meta-analyses:

- Systematic reviews and meta-analyses: Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) Statement and related extensions for specific aspects and types of reviews (eg, abstracts, harms, network metaanalysis)
- Systematic reviews of observational studies: Meta-analysis of Observational Studies in Epidemiology (MOOSE)
- Scoping reviews: PRISMA for scoping reviews

State of the science reviews provide an up-to-date review and synthesis of the literature for a clearly defined topic. The purpose is to inform understanding of a specific issue or question by objectively presenting the current, relevant, best knowledge about the review's topic. For example, reviews that address clinical topics may address the scope of a condition (eg, incidence, prevalence), physiology, clinical presentation, assessment (eg, history, physical examination, diagnostic testing), diagnosis, prevention, management, and/or patient education. A formal methodology, such as is performed for a systematic review, is not required for state of the science reviews; however, authors are expected to conduct a search of the relevant literature, including databases with peer-reviewed publications (eg, MEDLINE, CINAHL). A state of the science review presents an integrated synthesis of the available literature and goes beyond simply listing descriptions of studies. Recommendations in state of the science reviews should be supported with reference to well-designed studies, systematic reviews, and evidence-based clinical practice guidelines, if available. When evaluating evidence to formulate recommendations, properly conducted randomized controlled trials, systematic reviews, and meta-analyses are considered higherquality evidence than other types of studies (eg, controlled trials without randomization, cohort studies, case-control studies). Evidence-based guidelines are statements based on

evidence from rigorous review and synthesis of published literature. Expert opinion, clinical experience, editorials, animal studies, and case reports are not considered high-quality evidence, and recommendations based on these should be clearly delineated as such.

# **Conflict of Interest**

Provide full disclosure of any conflicts of interest for all authors. If there are none, note "The author(s) has(have) no conflicts of interest to disclose." The JMWH policy on conflict of interest can be found in the Journal's editorial policies, which are available at <u>www.jmwh.org</u>.

# Acknowledgements

Identify sources of financial or other support that contributed to the manuscript. Acknowledge contributors who are not included as authors. Obtain written permission from any individuals named in the acknowledgements section. JMWH may request the author provide documentation of permission from individuals acknowledged. If material in the manuscript has been read or exhibited at a professional meeting, this should be noted in the acknowledgments section. For example, "This study was presented in part at the American College of Nurse-Midwives 63rd Annual Meeting & Exhibition; May 21, 2018; Savannah, Georgia." If an abstract related to the manuscript has been published, the citation should be included. For example, "The results of this study were presented at the American College of Nurse-Midwives 63rd Annual Meeting & Exhibition; May 21, 2018; Savannah, Georgia (Thumm EB. Developing the midwifery practice climate scale: model misfit and item reduction. J Midwifery Womens Health. 2018;63[5];626)."

# Manuscript style and preparation:

The manuscript components will be uploaded as separate files in the following order: 1) cover letter (optional); 2) title page, including author affiliation(s), conflict of interest disclosure, and acknowledgements; 3) blinded manuscript, including precis, ´ abstract, keywords, Quick Points, text, references, tables, figure captions, and appendices; 4) figures; and 5) supporting information. The title page and manuscript files should be uploaded as Microsoft Word files.

The Journal of Midwifery & Women's Health Manuscript Preparation and Style Guide contains necessary information about manuscript preparation and style specific to JMWH and is available at www.jmwh.org. JMWH has adopted the AMA Manual of Style, 11th ed.18 to inform grammar, punctuation, and style for articles published in the Journal. Manuscripts must be in English. Authors who are not fluent in English should seek assistance to ensure manuscript readability. Authors for whom English is a second language may choose to have their manuscript professionally edited before submission. Wiley's options for editing

services can be found at http://wileyeditingservices.com/en/. Use of an English-language editing service does not guarantee acceptance or preference for publication.

# Abstract

Do not include the same sentences in the abstract that are in the introduction. Do not cite references in the abstract. Manuscripts reporting original research, systematic reviews, integrative reviews, and other reviews conducted using a formal methodological process should include a structured abstract of no more than 300 words with the following headings:

- Introduction: State the purpose of the study or review and why this question is important.
- Methods: For original research, include the study design, setting (for example, location and level of clinical care), population intervention(s), and main outcome measure. For reviews, identify data sources, including years searched; inclusion and exclusion criteria used to select studies; and methods for abstracting data and assessing quality and validity.
- Results: State the key findings of the study or review. Include the response rate for surveys.
- Discussion: Clearly state the conclusions of the study or review, including the implications for clinical practice.

# Text and references

All references, tables, figures, and appendices must be cited in the text of the manuscript in chronologic order. References follow the format in the AMA Manual of Style, 11th ed.18 The JMWH Manuscript Preparation and Style Guide provides detailed information about reference requirements and formatting. Do not blind any references for publications by the author(s) of the submitted manuscript.

# Tables

Tables should not repeat information in the text and vice versa. A table should stand independently, without requiring explanation from text. Make sure there is adequate content for a table. If the information it contains could be reported in 1 or 2 sentences, a table is unnecessary. Type each table on a separate page. Number tables consecutively according to when they are cited in the text. Construct tables using the table function in word processing software. The table title should completely explain the contents and be placed on a line above and outside of the table grid. Footnotes for tables should be identified with superscript lowercase letters placed in alphabetical order as each row is read from left to right starting at the top and moving to the bottom. The JMWH Manuscript Preparation and Style Guide contains detailed instructions for creating tables and includes examples. Additional table examples can be found in the AMA Manual of Style.

If a table is constructed or reprinted from text or a table in another publication, appropriate credit must be given to the original source. Sources should be listed in numeric order of the references (e.g., Smith et al, Jones, and Alvarez). The source wording depends upon the

construction of and permission for the table content. A table constructed from the author's data does not need a source listed. A table constructed from text in another publication needs the source cited (e.g., Source: Smith et al.22). A table constructed from a table in another publication must be accompanied by written permission for its use from the copyright holder. Cite the source and permission (e.g., Adapted with permission from Smith et al22 and Jones.25). A table reprinted from another publication must be accompanied by written permission for its use from Smith et al22 and Jones.25). A table reprinted from another publication must be accompanied by written permission for its use from the copyright holder.

## **Figure captions**

Each figure must have a caption. The figure caption succinctly identifies and describes the figure. It should provide sufficient detail to make the figure comprehensible without reference to the text. The components of a figure caption include: 1) the figure label, 2) title, 3) additional text (optional), 4) abbreviations (optional), and 5) sources (optional). The caption for each figure should be placed on a separate page of text at the end of the Microsoft Word manuscript file. Do not include the figure caption as part of the image itself. Number figures consecutively according to when they are cited in the text. If a figure is constructed or reprinted from text or figures in another publication, appropriate credit must be given to the original source. If a figure includes a photograph of a potentially identifiable person, it must be accompanied by written permission to use the photograph as a figure. This permission must be acknowledged in the figure caption. The source wording depends upon the construction of and permission for the figure content. The instructions for source wording in the preceding section on tables should also be used for figures.

## Appendices

Appendices appear at the end of an article in the print and/or online versions of the Journal. Items better presented as an appendix, as opposed to a table that is typeset within the text, include additional information that is of interest to readers but not necessary to follow the text of the manuscript (e.g., study questionnaires, lists of additional resources). Appendices must be cited in the text of the manuscript. Number appendices consecutively according to where they are cited in the text. Appendix titles follow the same format as table titles. The editors reserve the right to change appendices to online-only supporting information.

# Figures

Figures include diagrams, flow charts, line drawings, and photographs. Figures can highlight patterns or trends in data and display complex relationships. Figure(s) should be high quality and submitted as a TIFF, JPEG, PDF, or EPS electronic file. Do not include the figure caption as part of the figure itself. Figure captions should be placed in the manuscript file. Please save line artwork (vector graphics) as EPS files, and bitmap files (halftones or photographic images) as TIFF files, with a resolution of at least 300 dpi at final size. Please do not send native file formats, such as Microsoft Excel or PowerPoint.

# Appendix 2: PICOSS Table.

	INCLUDE	EXCLUDE
POPULATION:	<ul> <li>Pregnant and postpartum women (up to 2 years after birth).</li> <li>No limit set on age.</li> </ul>	<ul> <li>Women who are not pregnate /postpartum.</li> </ul>
INTER VENTION:	<ul> <li>Mindfulness Based Cognitive Therapy (MBCT). Adapted MBCT interventions for application to perinatal populations are expected.</li> <li>Studies must: 1) state the reported mindfulness intervention to be MBCT and describe its basis in a standardised MBCT manual; or 2) if the paper does not cite a MBCT manual, papers must explicitly state the intervention to be MBCT and provide sufficient detail to ascertain consistency with standard MBCT.</li> <li>In-person and digital delivery of MBCT is included.</li> </ul>	<ul> <li>Interventions other than MBCT.</li> <li>Multicomponent intervention (i.e., studies that have employed other interventions alongside MBCT) will be excluded.</li> <li>Studies that combine MBCT and MBSR will be excluded.</li> </ul>
COMPARATOR(S):	<ul> <li>Might include inactive control such as TAU, and waitlist or active groups, such as medication or other psychological intervention.</li> <li>Pre and post studies are included.</li> </ul>	
OUTCOMES:	<ul> <li>Mental health outcomes (specifically anxiety, depression, and stress).</li> <li>Secondary outcome is mindfulness.</li> </ul>	<ul> <li>Any study that does not specify any outcome specifie in inclusion criteria will be excluded.</li> </ul>
STUDY DESIGN:	<ul> <li>Follow study designs will be included:</li> <li>Control trials that aim to examine the effectiveness of MBCT.</li> <li>Randomised Controlled Trials.</li> <li>Non-randomised design with an intervention group and a control group, waitlist, treatment as usual (TAU).</li> <li>Pre/post designs.</li> </ul>	<ul> <li>Any study design other than those listed in inclusion criteria.</li> <li>Qualitative research.</li> <li>Grey literature (i.e., Doctorat MSc, BSc dissertations, boo chapters, and other unpublished research)</li> </ul>
SETTING:	<ul><li>Any setting.</li></ul>	<ul> <li>No exclusion criteria in terms of setting will be applied.</li> </ul>

Database	Date Search Conducted	Search Terms/Search Strategy (combination of subject headings, MESH terms, key words and search stings using Boolean operators (AND, OR, ADJ3)
PsychInfo	From inception (1806) – 8 <sup>th</sup> April 2021	("MBCT" OR "mindfulness based cognitive therap*" OR "mindfulness based intervention*" OR "cognitive therapy/" or "mindfulness-based interventions/") AND ("perinatal*" OR "antenatal" OR "postnatal" OR "post natal" OR "postpartum" OR "peripartum" OR pregnan* OR "perinatal" OR "puerperal" OR "trimester" OR "childbirth" OR "child birth" OR "maternal" OR mother* Or "prenatal" OR "exp pregnancy/" OR "postnatal period/" OR "maternity" OR "exp perinatal care/")
Web of Science	From inception (1946) – 8 <sup>th</sup> April 2021	TS=("MBCT" OR "mindfulness based cognitive therap*" OR "mindfulness based intervention*") AND TS=("perinatal*" OR "antenatal" OR "postnatal" OR "post natal" OR "postpartum" OR "peripartum" OR pregnan* OR "puerperal" OR "trimester" OR "childbirth" OR "child birth" OR "maternal" OR mother* Or "prenatal")
Medline	From inception (1806) – 8 <sup>th</sup> April 2021	("MBCT" OR "mindfulness based cognitive therap*" OR "mindfulness based intervention*" OR "cognitive therapy/" or "mindfulness-based interventions/") AND ("perinatal*" OR "antenatal" OR "postnatal" OR "post natal" OR "postpartum" OR "peripartum" OR pregnan* OR "perinatal" OR "puerperal" OR "trimester" OR "childbirth" OR "child birth" OR "maternal" OR mother* Or "prenatal" OR "exp pregnancy/" OR "postnatal period/" OR "maternity" OR "exp perinatal care/")
CINAHL	From inception (1937) – 8 <sup>th</sup> April 2021	TS=("MBCT" OR "mindfulness based cognitive therap*" OR "mindfulness based intervention*") AND TS=("perinatal*" OR "antenatal" OR "postnatal" OR "post natal" OR "postpartum" OR "peripartum" OR pregnan* OR "puerperal" OR "trimester" OR "childbirth" OR "child birth" OR "maternal" OR mother* Or "prenatal") Subject Headings: (MH "Cognitive Therapy") AND
		(MH "Mindfulness") AND (MH "Pregnancy")

n inception – 8 <sup>th</sup> I 2021	TITLE-ABS-KEY (("MBCT" OR "mindfulness based cognitive therap*" OR "mindfulness based intervention") AND ("perinatal*" OR "antenatal" OR "postnatal" OR "post natal" OR "postpartum" OR "peripartum" OR "pregnan*" OR "puerperal" OR "trimester" OR "childbirth" OR "child birth" OR "maternal" OR mother* OR "prenatal"))

## Appendix 4 – Data Extraction Form

# **DATA EXTRACTION FORM**

# adapted from the Cochrane Collaboration Data Collection Form

This form is an adapted version of the 'Data Collection from for intervention review – RCTs and non-RCTs' from the Cochrane Collaboration. Some sections have been removed due to irrelevance to the current review, whilst other sections have been added.

Review title or ID	
Study ID	

# **General Information**

Date form completed (dd/mm/yyyy)	
Name/ID of person extracting data	
Reference citation	
Publication type (e.g. full report, abstract, letter)	
Notes:	

# Study eligibility

Study Characteristics	Eligibility criteria [Also Refer to PICOS table for eligibility criteria]	Eligibility criteria met?		Location in text or source (pg & ¶/fig/tabl	
		Yes	No	Unclear	e/other)
Type of study	Randomised Controlled Trial				
	Quasi-randomised Controlled Trial				
	Controlled Before and After Study Contemporaneous data collection				

	Comparable control sites		
	At least 2 x intervention and 2 x control clusters		
	Interrupted Time Series		
	At least 3 time points before and 3 after the intervention		
	Clearly defined intervention point		
	Other design (specify):		
Participants	Pregnant or postpartum women (up to 2- years after childbirth)		
Types of intervention	Standard MBCT		
Types of comparison			
Types of outcome measures	Anxiety, depression, and/or stress		
	EXCLUD	E 🗌	
Reason for exclusion			
Notes:			

# DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

# **Characteristics of included studies**

Methods

	Descriptions as stated in report/paper	Location in text or source (pg & ¶/fig/table/o ther)
Aim of study		
Design		
Duration		
Duration of participation		
Ethical approval needed/ obtained for study	Yes No Unclear	
Notes:		

# Participants

	Description Include comparative information for each intervention or comparison group if available	Location in text or source (pg & ¶/fig/tabl e/other)
Population description		
Setting		
Inclusion criteria		

Exclusion criteria							
Method of recruitment of participants							
Informed consent obtained	U Yes	□ No	 Unclear				
Total no. randomised							
Clusters							
Baseline imbalances							
Withdrawals and exclusions							
Age							
Sex							
Race/Ethnicity							
Severity of illness							
Co-morbidities							
Other relevant sociodemographic							
Subgroup's measure							
Subgroups reported							
Notes:							

# Intervention groups

Copy and paste table for each intervention and comparison group.

# Intervention Group: MBCT

	Description as stated in report/paper	Location in text or source (pg & ¶/fig/table/o ther)
Group name	МВСТ	
No. randomised to group		
Theoretical basis		
Description		
Duration of treatment period		
Timing (e.g., frequency, duration of each session, timing in relation to pregnancy)		
<b>Delivery</b> (e.g., mechanism, medium, intensity, fidelity)		
<b>Providers</b> (e.g., profession, MBCT training, supervision)		
Co-interventions		
Integrity of delivery		
Compliance		
Notes:		

# **Outcomes**

Copy and paste table for each outcome reported in study

## Outcome 1

	Description as stated in report/paper	Location in text or source (pg & ¶/fig/tabl e/other)
Outcome name		
Time points measured		
Time points reported		
Outcome definition		
Person measuring/ reporting		
Scales: upper and lower limits (indicate whether high or low score is good)		
Is outcome/tool validated?	Yes No Unclear	
Imputation of missing data (e.g. assumptions made for ITT analysis)		
Assumed risk estimate (e.g. baseline or population risk noted in Background)		
<b>Power</b> (e.g. power & sample size calculation, level of power achieved)		
Notes:		

# Other

Study funding sources (including role of funders)	
Possible conflicts of interest	
Notes:	

## Appendix 5: Methodology quality assessment tool

# QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES



## COMPONENT RATINGS

#### **SELECTION BIAS** A)

#### Are the individuals selected to participate in the study likely to be representative of the target population? (01)

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

#### (02) 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. Yes

No

No

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

Yes

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

Yes

No

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

# (02) 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

## (02) 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

### (02) 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

#### WITHDRAWALS AND DROP-OUTS F)

- Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group? (Q1)
  - 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).

- 80 100% 1
- 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

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

- 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) individual

community organization/institution practice/office

#### (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

#### (Q4) 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.

Α	SELECTION BIAS	STRONG	MODERATE	WEAK	
		1	2	3	
в	STUDY DESIGN	STRONG	MODERATE	WEAK	
		1	2	3	
С	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

1

If yes, indicate the reason for the discrepancy

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

Final decision of both reviewers (circle one):

2 MODERATE 3 WEAK

STRONG

1

Appendix 6: MBCT Quality Checklist (MBCT-QC)

# **MBCT QUALITY CHECKLIST (MBCT-QC)**

This MBCT Quality Checklist was developed following review of several relevant sources (see end of document for references) and through discussion with the research team.

Although studies are not required to fulfil all intervention components, they are required to fulfil sufficient elements particularly in relation to intervention format and, CBT and mindfulness components to be included in the review (particularly if citation of a standardised MBCT manual is absent).

tudy name/ID
--------------

# **MBCT Quality Checklist**

	Criteria	<b>Described</b> Included	<b>in paper?</b> Not included	Unclear	Cited in utilised manual	Location in text or source
Standardised MBCT	1) MBCT manual cited (e.g., Segal et al., 2002)					
Format	2) Pre-course interview					
	3) 8-session/week duration					
	4) Weekly 2-hr sessions					
	5) Group delivery					
	6) 1x all day session (at approx. week 6)					
	7) Homework assignments / review					
	8) Relapse prevention/action planning.					

Cognitive- behavioural components	9) CBT exercises: linking thoughts, emotions, physical sensations, and behavioural responses (e.g., walking down street/ thoughts & feelings exercise).			
	10) Focus on decentring approach (e.g., thoughts are not facts).			
	11) Use of metaphors and narratively oriented material to communicate the core themes of MBCT.			
	12) Pleasure & mastery exercise(s).			
	13) Automatic thoughts discussion/exercise.			
	14) Psychoeducation (i.e., cognitive model, depression).			
	15) Cognitive coping strategies (i.e., for responding to negative thoughts).			
	16) Behavioural strategies for mood regulation.			
Mindfulness components	17) Once daily mindfulness practice x6 days a week.			
	18) Both formal and informal practice included described			
	19) 3-minute breathing space (also called mini-meditation).			
	20) Movement-based awareness exercises.			
	21) Stepping out of autopilot & establishing awareness (i.e., attentional control).			
Facilitator factors	22) MBCT qualification (e.g., certificate, MSc).			

	23) Attended MBCT training.			
	24) Professional qualifications (e.g., clinical psychologist, social worker).			
	25) Own regular mindfulness practice.			
	26) Supervision.			
Adherence monitoring	27) Measure used e.g., MBCT- AS (Segal et al., 2002).			
	28) Use of recordings.			
	29) Use of MBI-TAC			

TOTAL SCORE:
(number of checklist items included in the paper description)

<b>Description of any adaptations made for</b> <b>perinatal population</b> (e.g., changes to mindful movement components, psychoeducation, meditation, etc.,)
t components, psychoeducation,
ss components listed in the above checklist altered.

# EXCLUDE

Reason for exclusion		
Have any linked citations been inspected? And/or has the author been contacted?		

# Appendix 7: Psychological Medicine Author Submission guidelines

# Submission of manuscripts

Please see the below table for the types of papers accepted:

Article Type	Usual Max Word count*	Abstract	References	Tables/figures**	Supplementary material online only
Original article	4500	250 words, structured, using subheadings Background, Methods, Results, Conclusions	APA style – see elsewhere in this document for full details	Usually up to 5 total	Yes
Review article	4500	250 words, not structured	APA style	Usually up to 5 total	Yes
Editorial	3500	No	APA style	Usually up to 5 total	Yes
Correspondence***	1500	No	max 20 APA style	Max 1	No
Commentary	2000 By invitation of editor	No	max 20 APA style	Not usually	Yes

\* Editors may request shortening or permit additional length at their discretion in individual cases

- \*\* May be adjusted in individual cases at Editors' discretion
- \*\*\* Please note, Correspondence papers must be in response to content published in PSM

Figures should be submitted as discrete files, not embedded in the text of the main document. Supplementary material for online only should be submitted as discrete files, not as part of the main text.

Generally, papers should not have text more than 4500 words in length (excluding abstract, tables/figures, and references) and should not have more than a combined total of 5 tables and/or figures. Papers shorter than these limits are encouraged. For papers of unusual importance, the editors may waive these requirements. Articles require a structured abstract of no more than 250 words including the headings: Background; Methods; Results; Conclusions. Review Articles require an unstructured abstract of no more than 250 words. The name of an author to whom correspondence should be sent must be indicated and a

full postal address given in the footnote. Any acknowledgements should be placed at the end of the text (before the References section).

Contributors should also note the following:

- 1. S.I. units should be used throughout in text, figures and tables.
- 2. Authors should spell out in full any abbreviations used in their manuscripts.
- 3. Foreign quotations and phrases should be followed by a translation.
- If necessary, guidelines for statistical presentation may be found in: Altman DG., Gore SM, Gardner, MJ. Pocock SJ. (1983). Statistical guidelines for contributors to medical journals. British Medical Journal 286, 1489-1493.

# References

The guidelines set forth in the Publication Manual of the American Psychological Association (6th ed.) should be used in the text and a complete list of References cited given at the end of the article. The References section should be in alphabetical order.

# **Figures and Tables**

Only essential figures and tables should be included and should be provided in black and white except in exceptional circumstances, eg PET scan images etc. If you request colour figures in the printed version, you will be contacted by CCC-Rightslink who are acting on our behalf to collect Author Charges. Please follow their instructions in order to avoid any delay in the publication of your article. Further tables, figures, photographs and appendices, may be included with the online version on the journal website.

All wording within submitted figures must be Arial, point size 8. To ensure that your figures are reproduced to the highest possible standards and your article is published as quickly and efficiently as possible, Cambridge Journals recommends the following formats and resolutions for supplying electronic figures. Please note that submitting low quality figures may result in a delay in publishing your valuable research

Please ensure that your figures are saved at final publication size (please see the latest issue of the journal for column widths) and are in our recommended file formats. Following these guidelines will result in high quality images being reproduced in both the print and the online versions of the journal. All graphs and diagrams should be referred to as figures and should be numbered consecutively in Arabic numerals. Captions for figures should be typed double-spaced on separate sheets. Tables should be numbered consecutively in the text in Arabic numerals and each typed on a separate sheet after the References section. Titles should be typed above the table.

# **Required statements**

## Acknowledgements
You may acknowledge individuals or organisations that provided advice, support (non-financial). Formal financial support and funding should be listed in the following section.

#### **Financial support**

Authors must include a Funding Statement in their manuscript. Within this statement please provide details of the sources of financial support for all authors, including grant numbers, for example: "Funding Statement: This work was supported by the Medical Research Council (grant number XXXXXXX)". Grants held by different authors should be identified as belonging to individual authors by the authors' initials, for example: "Funding Statement: This work was supported by the Wellcome Trust (AB, grant numbers XXXX, YYYY), (CD, grant number ZZZZ); the Natural Environment Research Council (EF, grant number FFFF); and the National Institutes of Health (AB, grant number GGGG), (EF, grant number HHHH)." Where no specific funding has been provided for research, you should include the following statement: "Funding Statement: This research received no specific grant from any funding agency, commercial or not-for-profit sectors."

## **Conflicts of interest**

Authors are required to include a Conflicts of Interest declaration in their manuscript. Conflicts of Interest are situations that could be perceived to exert an undue influence on an author's presentation of their work. They may include, but are not limited to, financial, professional, contractual or personal relationships or situations. Conflicts of Interest do not necessarily mean that an author's work has been compromised. Authors should declare any real or perceived Conflicts of Interest in order to be transparent about the context of their work. If the manuscript has multiple authors, the author submitting the manuscript must include Conflicts of Interest declarations relevant to all contributing authors. Example wording for your Conflicts of Interest declaration is as follows: "Conflicts of Interest: Author A is employed at company B. Author C owns shares in company D, is on the Board of company E and is a member of organisation F. Author G has received grants from company H." If no Conflicts of Interest exist, your declaration should state "Conflicts of Interest: None".

## **Ethical standards**

Where research involves human and/or animal experimentation, the following statements should be included (as applicable): "The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008." and "The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008." and "The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guides on the care and use of laboratory animals."

Appendix 8: T-tests and Chi-squared tests comparing completers and non-completed

across key constructs, HG, and sociodemographic variables

Figure 1. Comparisons of completers and non-completers (two sample t-tests)					
Variable	Completers	Non-completers	t-value	df	p-value
	Mean	Mean			
Anxiety	9.93	11.26	-1.38	223	0.17
Depression	17.70	17.53	0.18	226	0.85
Social support	3.41	3.22	1.05	214	0.30
Mindfulness	47.68	50.25	-8.21	196	0.37
Vomiting frequency	19.70	20.79	-0.42	228	0.67
Nausea duration	21.28	22.24	-1.6	228	0.10
Weight loss	11.66	12.55	-0.55	228	0.58
Days in hospital	5.04	6.51	-0.65	223	0.51
Education	2.97	2.81	1.06	235	0.29
Income	3.50	3.37	0.60	231	0.55
*P < 0.05					

\*\*P < 0.01.

Figure 2. Comparisons of completers and non- completers (Chi-squared test)				
Variable	X <sup>2</sup>	p-value		
Ethnicity	4.86	0.63		
Marital status	3.80	0.29		
Mental health history	6.16	0.02		

\*P < 0.05

\*\*P < 0.01.

#### **Appendix 9: Participant Informed Consent**

School of Psychology Ysgol Seicoleg

South Wales Doctoral Programme in Clinical Psychology De Cymru Rhaglen Doethuriaeth mewn Seicoleg Glinigol



Wales UK www.cardiff.ac.uk/psych Prifysgol Caerdydd Adeilad y Tŵr Plas y Parc Caerdydd CF10 3AT Cymru Y Deyrnas Unedig

# **Informed Consent**

We, the research team at Cardiff University's school of Clinical Psychology are pleased to have an opportunity to conduct further research into the debilitating and yet often overlooked condition of Hyperemesis Gravidarum (HG) or as most may know it – extreme morning sickness and nausea.

Hyperemesis Gravidarum (HG) is a serious pregnancy condition that affects 0.3-2% of pregnancies and is characterised by extreme and prolonged levels of nausea and vomiting. Medical intervention can only help to manage symptoms associated with HG as HG cannot be cured. Therefore, women who experience HG may have to endure the condition throughout the whole of their pregnancy.

Our aim is to improve people's understanding of the psychological impact of HG and to bring attention to this under-researched area. We are hoping to assess both the impact that HG is having presently on well-being and to also follow women over a nine-month period, to improve understanding of any long-term effects that may be associated with HG.

We hope the findings of this study will improve support for women who have experienced HG and are experiencing psychological distress

# Can I take part in the study?

You are invited to participate in this study if you meet the following criteria:

- a) You are a female over the age of 18
- b) You can speak English
- c) If you are currently experiencing HG or you have experienced HG in the past year

A standard definition of HG is: Losing more than 5% of pre-pregnancy body weight due to severe and prolonged feelings of nausea and vomiting and/or being in receipt of inpatient or outpatient care due to the severity of symptoms associated with nausea and vomiting.

An example of outpatient care is being prescribed medication by your GP to help with symptoms associated with nausea and vomiting in pregnancy or being given intravenous (IV) fluids in hospital. we appreciate that you may not have accessed or had the appropriate medical support, but please still participate in this research

Do you meet the above criteria? YES/NO

If you answered NO, do you consider yourself to have experienced HG in the last 12 months YES/NO

If a woman responds no to the definition adopted by the study for HG, but yes to feeling that she has had HG then they will be re-directed to the following information We're sorry, but you are unable to participate in this particular study as you have not met our study's criteria. This does not mean that you have not had HG. But, we are aware that the definition of HG used by the study or limiting the study to women who have had experienced HG in the past year, will mean some women who have experienced HG are unable to take part.

If you are happy to, we would ask that you describe your thoughts about this definition of HG and whether you feel there are other factors that would be important to consider when identifying HG. If you don't want to comment please write NA.

## Additional criteria:

The following study is split into two parts.

You are able to take part in either **Study 1** or **Study 2** if you meet the following criteria:

- d) You are currently experiencing Hyperemesis Gravidarum (HG) or have experienced HG in the past year. HG is defined by this study as losing more than 5% of her pre-pregnancy body weight due to severe and prolonged feelings of nausea and vomiting and/or if a woman has had been in receipt of inpatient or outpatient care due to the severity of symptoms associated with nausea and vomiting. An example of outpatient care is being prescribed medication by your GP to help with symptoms associated with nausea and vomiting in pregnancy or being given intravenous (IV) fluids in hospital.
- e) If they are not current, your symptoms of HG stopped within the past 12 months. This is to improve the accuracy of answering the questionnaires of the study.

**Study 1:** You are invited to take part in Study 1 if your symptoms of HG stopped <u>4 or more months ago</u>, but you have experienced HG within the past 12 months.

**Study 2:** You are invited to take part in Study 2 if your symptoms of HG stopped within the last 3 months or if you are currently experiencing symptoms of HG.

Thank you, you are eligible to take part in our study. If you would like to participate, please tick the informed consent box at the end the page. Once you have ticked the box, the online questionnaire will open for you to complete.

## Reason for conducting this research

This study is being conducted to find out more about the impact of women's experience of Hyperemesis Gravidarum on their psychological well-being. It is hoped that this research will inform healthcare professionals of the psychological impact of HG and provide some clinical recommendations to improve perinatal psychological support for women who experience HG during pregnancy.

#### What will happen if I take part?

You will be asked to complete a secure online questionnaire. All responses to the questionnaire are confidential and you will be assigned a unique code to protect your anonymity. Only the researchers will have access to these codes.

The study will involve you completing a few select questionnaires again in three, six, and nine months' time. This is to explore how psychological wellbeing may change over time. You will therefore be asked to provide an email address as part of the survey for the research team to contact you on. Your email address and your data will be stored confidentially and if you would like us to delete your data in the future, then we are able to.

At the end of the study, if you agree, you will be entered to a prize draw **to win one of six £25** amazon vouchers. This is to acknowledge the time you have taken out form your day to participate and to show you our appreciation of this.

## Do I have to take part?

No, your participation in this study is entirely voluntary.

## Can I withdraw from the study?

If you wish to stop participating in the study at any point you would be free to do so.

#### What are the risks of taking part?

This research has been reviewed and approved by Cardiff University School of Psychology Ethics Committee. The questionnaire has been tested by several members from the charity Pregnancy Sickness Support.

This research has been reviewed and approved by Cardiff University School of Psychology Ethics Committee. The questionnaire has been tested by several members from the charity Pregnancy Sickness Support.

It is not expected that participating in this study will cause distress. However, if should you find reflecting on this study causes you to feel distressed you are encouraged to seek support from friends and family in the first instance, or your contact your GP or out of hours service for support. The following organisations are also available to offer support in the UK: MIND, Pregnancy Sickness Support, Samaritans etc, if you feel further help would be beneficial. No clinical service is available as part of this research. A list of organisations will be provided at the end of the survey.

#### How long will it take?

Please allow 45 minutes to 60 minutes to complete this survey. You may want to make yourself comfortable and take yourself to a quiet place for this time. Your results will be saved automatically so you can pick up where you left off.

## How will information about me be used?

The findings of the study will be written up as part of a Clinical Psychology Doctorate project and may be published in professional journals and/or shared at relevant conferences. A general summary of the findings will be shared through Pregnancy Sickness Support charity's website. You will not be identified by name in the dissemination of the results. If you would like to receive a copy of the final report when it is completed, please follow the link at the end of the survey.

If you have a difficulty or disability which means that accessing this study online is troublesome for you, then additional paper or telephone access can be made available. Please contact Jerrie for more information.

As this study is conducted over a nine-month period we will need to contact you in the future to collect further information to see if and how things change over time. We will need your email address in order to contact you again in future. Your data will be stored confidentially and anonymised and separated from your email address using a unique code. If you would like us to delete your data in the future, we will be able to.

#### Who will have access to information about me?

Survey responses are confidential as the Qualtrics system automatically generates

numerical code for each participant. All research data will be stored in accordance with national policy ad legislation (The Data Protection Act\_1998) and BPS Ethics guidelines for internet-mediated research (BPS, 2013). Any email addresses provided by participants for follow up studies in the future will be stored in secure password protected file that is not connected to their questionnaire data. The researcher and research supervisors will have access to the electronic research data. Research data will be stored for 15 years after completion of the study for academic purposes in accordance with Cardiff University Policy and destroyed thereafter.

## What if there is a problem, or you have further questions?

If you have any concern or require additional information about any aspect of this study, please contact the researcher of research supervisor. If you would like to complain about this project, please contact Cardiff University School of Psychology Ethics Committee.

#### **Researchers:**

Jerrie Serrell, Trainee Clinical Psychologist Email: richardsj25@cardiff.ac.uk

#### **Research Supervisors:**

Dr Helen Penny, Senior Research Tutor, Doctorate in Clinical Psychology, Cardiff University

Email: <u>pennyH@cardiff.ac.uk</u>

Dr Cerith Waters, Clinical Psychologist, Lecturer at Cardiff University Email: <u>watersCS@cardiff.ac.uk</u>

## **Concerns/comments:**

If you should have any concerns/comments about the study, please contact: Ethics Secretary, Cardiff University School of Psychology Ethics Committee Email: psychethics@cardiff.ac.uk

## Please declare below that you are providing informed consent

# [] I have read the above participant information and I agree to provide my consent to participate in this study

[] I consent to be contacted in the future for follow up research

## **Privacy Notice:**

The information provided will be held in compliance with GDPR regulations. Cardiff University is the data controller and Matt Cooper is the data protection officer (inforequest@cardiff.ac.uk). The lawful basis for processing this information is public interest. This information is being collected by Jerrie Serrell. The research information you provide will be used for the purposes of research only and will be stored securely. Only the principal researcher Jerrie Serrell and her research supervisor's Dr Helen Penny and Dr Cerith Waters, will have access to this information. After 15 years the data collected will be anonymised (any identifying

elements removed) and this anonymous information may be kept indefinitely or published.

I understand that the personal data will be processed in accordance with GDPR regulations

The information on the consent form will be held securely and separately from the research information. After 15 years the data collected will be anonymised (any identifying elements removed) and this anonymous information may be kept indefinitely or published.

I understand that personal data will be processed in accordance with GDPR regulations

[] I understand and consent

[] I do not consent

#### **Appendix 10: Participant Debrief Form**

School of Psychology Ysgol Seicoleg

South Wales Doctoral Programme in Clinical Psychology De Cymru Rhaglen Doethuriaeth mewn Seicoleg Glinigol



Cardiff University Tower Building Park Place Cardiff CF10 3AT Wales UK www.cardiff.ac.uk/psych Prifysgol Caerdydd Adeilad y Tŵr Plac y Parc Caerdydd CF10 3AT Cymru Y Dewnas Unedie

# Psychological Impact of experiencing Hyperemesis Gravidarum

# **Debriefing Information Sheet**

## Thank you very much for taking the time to participate in this study.

#### We hope you found it interesting.

The study aimed to explore women's experiences of Hyperemesis Gravidarum (HG) during pregnancy. It is hoped that this research will inform healthcare professionals of the psychological impact of Hyperemesis Gravidarum (HG) and provide some clinical recommendations to improve support for women who experience HG during pregnancy. In particular the research is investigating whether women who experience of HG in pregnancy develop symptoms indicative of trauma and what factors are associated with the development of trauma symptoms. The findings will be published on Pregnancy Sickness Support website.

#### **Further Support**

Reflecting on your pregnancy or your experiences of having had Hyperemesis Gravidarum may have been difficult. This is understandable and you may find that you feel low after completing the questionnaires. If you do feel upset and feel further support is needed, here are some suggested sources of support you may want to consider calling upon:

- Your friends and family may be able to provide you with immediate support.
- Your GP is also a potential source of support if you feel upset about what has been discussed for longer than you expected to. Please speak with your GP if you have

thoughts of harming yourself in some way, for support. Please contact your GP or local out of hours service if you feel that you are at risk of harming yourself or if you feel that you are unable to keep yourself safe.

 Your GP can refer you to a Clinical Psychologist for support to talk through any difficulties that you experience and support you to cope with these. There are also a number of organisations and charities that offer support. You may find some of these helpful.

# Pregnancy Sickness Support (<u>www.pregnancysicknesssupport.org.uk</u>)

Pregnancy sickness support are a national <u>Support Network</u> for women suffering any degree of nausea and

vomiting in pregnancy to access support and comfort at times of isolation and distress. The network is made up

of volunteers who know first-hand the trials of nausea and vomiting in pregnancy. The website also provides

information on <u>treatments</u> to discuss with your doctor and advice for <u>coping strategies</u> at home. The website

hosts an <u>online forum</u> where you can access support from a number of women at almost any time of the day or

night. PSS has developed leaflets and information for carers and partners and carers can register with their  $\underline{forum}$ 

to access an area specifically for them.

PSS Helpline - 02476382020

Lines are open 9am-4.30pm Monday to Friday.

Mindline (https://www.mind.org.uk/)

Mindline is a confidential listening service to support anybody who is in distress. Mindline can guide you where to get help, discuss medication and alternative treatments, offer advocacy and look for details of help and support in your own area.

Mindline- phone 0300 123 3393 or text 86463

Lines are open 9am to 6pm, Monday to Friday (except for bank holidays).

The Samaritans (<u>www.samaritans.org</u>)

The Samaritans is a national charity and the co-ordinating body for the 201 Samaritans branches across the UK. The Samaritans aims to help alleviate emotional distress- you do not have to be suicidal to call

Samaritans helpline- call 116 123 from any phone for free

Lines are open 24 hours a day, 365 days a year.

# If you have any further questions in relation to this study please contact us on the details below.

#### Contact details:

Name: Jerrie Serrell, Trainee Clinical Psychologist Email: richardsj25@cardiff.ac.uk Address: Doctorate in Clinical Psychology, 11th Floor, Tower Building, School of Psychology, 70 Park Place, Cardiff, CF10 3AT

If you have any concerns/comments that you would like to raise about the research you

can also contact my academic supervisors:

#### Contact details:

Name: Dr Helen Penny, Senior Clinical Tutor Cardiff University Email address: PennyH@cardiff.ac.uk Address: Doctorate in Clinical Psychology, 11th Floor, Tower Building, School of Psychology, 70 Park Place, Cardiff, CF10 3AT.

Name: Dr Cerith Waters, Consultant Clinical Psychologist, Lecturer Cardiff University

Email: watersCS@cardiff.ac.uk Address: 10<sup>th</sup> Floor, Tower Building, School of Psychology, 70 Park Place, Cardiff, CF10 3AT.

Or you can contact The School Research Ethics Committee:

Secretary of the Ethics Committee, School of Psychology, Cardiff University, Tower Building,

Park Place, Cardiff, CF10 3AT

Tel: 029 2087 0360

Email: psychethics@cardiff.ac.uk

## Thank you again for taking the time to participate

# Privacy Notice: All personal data will be processed in accordance with GDPR regulations

The information provided will be held in compliance with GDPR regulations. Cardiff University is the data controller and Matt Cooper is the data protection officer (inforequest@cardiff.ac.uk). The lawful basis for processing this information is public interest. This information is being collected by Jerrie Serrell. The information on the consent form will be held securely and separately from the research information. Only the researchers will have access to this form and it will be destroyed after 7 years.

The research information you provide will be used for the purposes of research only and will be stored securely. Only the principal researcher, Jerrie Serrell, and her research supervisor's Dr Helen Penny and Dr Cerith Waters, will have access to this information.