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**The delivery of care in perinatal mental health: A systematic review and meta-analysis of psychological interventions for perinatal anxiety and a qualitative exploration of healthcare professionals' experiences of working with women experiencing perinatal mental health difficulties**

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**Doctorate in Clinical Psychology**

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## **Thesis Portfolio Abstract**

**Background:** Perinatal mental health (PMH) is a significant global public health concern. Up to 20% of women will experience mental health difficulties during the perinatal period (conception to one-year post childbirth; Jones et al., 2014). Perinatal mental health difficulties (PMHDs) can have a significant and detrimental impact on women, their infants and families (Silverwood et al., 2019). Improving service provision and care pathways for PMH is regarded as a public health priority for both the UK and Scottish Governments. This thesis aims to extend the current evidence base by providing a systematic review and meta-analysis of the psychological treatments for perinatal anxiety and by qualitatively exploring the personal experiences of healthcare professionals working with women experiencing PMHDs in non-specialist settings.

**Method:** The review involved conducting a systematic search of relevant online databases to identify appropriate articles which were then selected by utilising pre-set inclusion and exclusion criteria. This process led to the identification of 16 articles, 12 of which were included in the meta-analysis. The methodological quality and risk of bias of each included study were independently evaluated by two reviewers using the revised Cochrane risk-of-bias tool for randomised trials. The qualitative empirical study involved conducting in-depth, semi-structured interviews with 13 community-based healthcare professionals. These interviews were digitally recorded and transcribed verbatim. The transcripts were analysed using Interpretative Phenomenological Analysis (IPA).

**Results:** The meta-analysis found that psychological interventions were more effective than control conditions in reducing symptoms of perinatal anxiety, with a medium post treatment effect size. The results also indicated support for the use of group-based and self-guided interventions, and both face to face and online delivery methods. In addition, small but significant effect sizes were found for both Cognitive Behavioural Therapy (CBT) and Mindfulness Based Interventions (MBIs) in the treatment of perinatal anxiety. In the qualitative study, a number of superordinate and subordinate themes emerged from the analysis of the interview transcripts. The five superordinate themes were:

navigating a complex system, two lives to care for, “working at the coalface”, “it’s okay to talk about it” and needs led interventions.

**Conclusions:** From the results of the review, it is suggested that psychological interventions should be made more readily available for women experiencing anxiety during pregnancy and in the postnatal period. Both CBT and MBIs demonstrated effectiveness, as did group-based, self-guided, online and face to face interventions, suggesting that therapeutic modality, type of intervention and mode of delivery could be tailored to meet the individual and perinatal-specific needs of each woman. The results of the empirical study suggest that the delivery of care to women experiencing PMHDs is common across a number of professions and services. Whilst this is a common occurrence, participants indicated that the difficulties women experience are often complex and multifaceted, and practitioners often feel that they have not received sufficient training to confidently address concerns and deliver care. In addition, the findings suggested that there were a number of service and organisational barriers that impacted on their ability to deliver an optimal integrated and multi-disciplinary approach.

## **Thesis Portfolio Lay Summary**

This thesis explores the personal experiences of community-based healthcare professionals working with women experiencing perinatal mental health difficulties (PMHDs) and reviews the existing evidence base for the effectiveness of psychological interventions in the treatment of perinatal anxiety. The perinatal period refers to the period from conception to one-year post childbirth. During this time women are at increased risk of developing mental health difficulties or experiencing a worsening of pre-existing difficulties. PMHDs can be influenced by historical factors (e.g., trauma and adverse childhood experiences), social circumstances (e.g., financial pressures, poor housing, relationship breakdown) and perinatal specific factors (severe nausea, pregnancy complications, birth trauma).

Perinatal anxiety is common, with the rates of anxiety in both pregnancy and post-birth being higher in this population than in non-perinatal populations. An extensive body of research has highlighted that untreated perinatal anxiety can have a detrimental impact on women, their infants, and families. Research has also shown that women prefer to engage in psychological interventions over medication due to the potential risks to them or their infant. Despite the high prevalence and negative consequences of perinatal anxiety, and women's preferences for psychological treatments, the research evidence for such treatments is limited. Therefore, this thesis aimed to conduct a comprehensive review of the use of psychological interventions as a treatment to reduce perinatal anxiety.

Across the UK the identification, assessment and appropriate treatment of women experiencing PMHDs is insufficient. There are several factors influencing the under-recognition and under-treatment of these difficulties, including woman's reluctance to seek help due to shame, fear, and stigma, as well as the lack of appropriate training for professionals. The provision of specialist perinatal mental health services is also inconsistent, meaning that access to appropriate care and treatment can be dependent on the area in which women live. In many areas, especially across rural Scotland, women are simply not able to access such services. The inconsistent provision of perinatal



mental health care has been recognised by both the UK and Scottish governments who have pledged to prioritise improving service provision and access. The aim of the empirical project contained in this thesis was to explore and understand the experiences of those providing perinatal mental health care to women in areas where there are no specialist services. This involved interviewing community-based healthcare professionals (e.g., midwives, GPs, health visitors, nurses, psychologists etc.) in both primary care and secondary mental health care services. The intention was to gain an understanding of their personal experiences and attitudes, levels of knowledge and training and current practices. It was considered that gaining this insight may help to identify areas where improvements to services could be made.

***Journal Article 1: Systematic Review***

***The effectiveness of psychological interventions for anxiety in the perinatal period: A systematic review and meta-analysis***

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**Abstract**

*Background:* Prevalence rates of anxiety during pregnancy are between 11-21% and during the postpartum period between 9-23%. Despite the high prevalence rates, and the well documented adverse outcomes for mother and infant of untreated perinatal anxiety, psychological intervention research for this population is still in its infancy. This systematic review and meta-analysis aimed to comprehensively evaluate the evidence of the effectiveness of psychological interventions for reducing perinatal anxiety.

*Method:* This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Databases searched included EMBASE, MEDLINE, PsychINFO, MIDIRS, CINAHL and the Cochrane Library. Search terms included: Psychological Therapy, Perinatal Period, Antenatal, Postnatal, Anxiety, Obsessive Compulsive Disorder and Phobia.

*Results:* The search strategy identified 1,392 studies. A total of 16 studies published between 2004 and 2020 fulfilled inclusion criteria. Of those, 12 were included in the meta-analysis. Overall results indicated that psychological interventions were more effective than control conditions in reducing symptoms of perinatal anxiety with a medium post treatment effect size. Significant effect sizes were also identified for online, face-to-face, group and guided self-help treatment modalities.

*Limitations:* A small sample of studies are represented and limited to articles published in English. The review was unable to draw specific conclusions about what works (i.e., therapeutic modality/delivery) for whom (i.e., specific diagnoses) due to purposefully broad inclusion criteria. The longer-term effects of psychological interventions for perinatal anxiety and infant outcomes could not be established.

*Conclusions:* This review demonstrates that psychological interventions are effective in reducing symptoms of both anxiety and comorbid anxiety and depression in the antenatal and postnatal periods. The results also demonstrate the efficacy of delivering such interventions in multiple

settings, including online, and in group format. Further research is required to optimise treatment delivery to individual needs.

*Keywords:* Perinatal Anxiety, Pregnancy, Postpartum, Psychological Interventions, Psychological Therapy

## **1. Introduction**

There is a growing body of literature exploring the prevalence and impacts of anxiety in the perinatal period, from pregnancy to one-year post childbirth (Loughnan et al., 2018). It is well established that the perinatal period represents a time of increased risk for the development of mental health problems (Biaggi et al., 2016; O'Hara and Wisner, 2014) and exacerbation of pre-existing conditions (Higgins et al., 2018). Rates of common mental health problems, such as anxiety and depression, are higher in this population than in the general adult population (Dennis et al., 2017). Prevalence rates indicate that clinically elevated symptoms of anxiety are experienced by approximately 9-22% of women during pregnancy and 11-21% of women during the postnatal period (Dennis et al., 2017; Fairbrother et al., 2016). Furthermore, 8.5% of postpartum women meet criteria for one or more anxiety disorders (Goodman et al., 2016).

An extensive range of anxiety disorders are prevalent in the perinatal period (O'Hara and Wisner, 2014). Leach et al. (2017) reported rates of generalised anxiety disorder (GAD) at 1-11%, specific phobia ranging from 7-20%, panic disorder (PD) from 1-8% and agoraphobia 1-17%. Research also suggests that rates of obsessive compulsive disorder (OCD) are more prevalent in the postnatal period (4-9%) than in the general population (1.2%; McGuinness et al., 2011). In addition, evidence suggests that one in 10 women will experience comorbid anxiety and depression during pregnancy and one in 12 during the postnatal period (Falah-Hassani et al., 2017). However, despite the evidence suggesting that prevalence rates for perinatal anxiety are similar to, if not greater than, that of perinatal depression, a substantial body of evidence has focused on treatment of the latter (Sockol, 2015; Sockol et al., 2011), while, until recently, research aimed at understanding and

treating anxiety in this period has been largely neglected (Loughnan et al., 2018; Maguire et al., 2018). This neglect may contribute to the under-recognition and treatment of perinatal anxiety (Bauer et al., 2016; Buist et al., 2011).

Unrecognised and untreated perinatal anxiety has significant consequences for women, their infants and wider family (Maguire et al., 2018). These impacts include a higher likelihood of developing postpartum depression, negative effects on the mother-infant attachment, more risk of obstetric complications and adverse outcomes for fetal and infant development (Dunkel Schetter and Tanner, 2012; Glasheen et al., 2010; Glover, 2014; Milgrom et al., 2008). These impacts are a major concern for clinical and public health (Blackmore et al., 2016; Dennis et al., 2017). As is the considerable economic cost of untreated perinatal anxiety and depression, which is estimated at £6.6 billion per year in the UK (Bauer et al., 2016). The development and evaluation of effective interventions for perinatal anxiety is, therefore, of the utmost importance.

In comparison to that of depression, the literature on the effective treatment and clinical management of perinatal anxiety remains limited (Loughnan et al., 2018; Marchesi et al., 2016). The evidence is growing, however, with particular attention being paid to the development of psychological interventions (Loughnan et al., 2018; Maguire et al., 2018). Psychological interventions are considered preferable to women in this period because of the risks posed to the woman, the fetus and the infant through breastfeeding, associated with pharmacological interventions (Green et al., 2020; Loughnan et al., 2018; Taylor et al., 2016).

In a review comparing psychological and pharmacological interventions, Marchesi et al. (2016) found only three studies investigating the use of Cognitive Behavioural Therapy (CBT) for perinatal anxiety in pregnancy and two in the postpartum period. In contrast, the review found 13 papers reporting on the use of medications (6 in pregnancy, 7 postpartum). This may reflect the widespread use of antidepressant medication in clinical practice (Huybrechts et al., 2014). The review supported the use of CBT for reducing symptoms related to PD, specific phobia and OCD; and the use of selective

serotonin reuptake inhibitors (SSRIs) for those of PD and OCD (Marchesi et al., 2016). Nevertheless, Marchesi et al. argued that psychotherapy, with particular focus on CBT, should be a first line intervention consistent with evidence of its effectiveness and safety. However, no papers exploring interventions for GAD were included. This is concerning, given that research suggests GAD is the most prevalent anxiety disorder in this population (Leach et al., 2017). This review also had a number of methodological flaws which suggest results should be interpreted with caution, in particular, the majority of selected studies (83%) were single case reports and not controlled trials, which means conclusions made cannot be generalised to the wider perinatal population.

Support for the utilisation of CBT for the treatment of perinatal anxiety was found in a meta-analysis of 13 studies examining its efficacy (Maguire et al., 2018). They reported large within groups effect sizes from pre-post treatment ( $d = 0.81$ ) and from pre-treatment to follow up ( $d = 0.82$ ) indicating that CBT is an effective treatment for perinatal anxiety (Maguire et al., 2018). However, smaller effect sizes were reported for between groups analyses ( $d = 0.49$ ) meaning that CBT may not be more effective than non-active control conditions and further research is required to establish the superiority of CBT over alternative interventions (Maguire et al., 2018). This report was also subject to several methodological limitations including small sample sizes, high levels of heterogeneity and overall low scores on quality assessment tools.

There is tentative evidence for the use of mindfulness based interventions (MBIs), including mindfulness based cognitive therapy (MBCT) and mindfulness based stress reduction (MBSR), as an effective treatment for both anxiety and depression in this population (Shi and MacBeth, 2017; Woolhouse et al., 2014). It should be noted, however, that the majority of this research has been conducted with women during pregnancy. In Shi and MacBeth (2017), 17 studies were identified, 16 of which were conducted in pregnancy and only one which involved participants in the first year after childbirth, suggesting gaps in the current literature. Shi and MacBeth found 12 studies exploring the efficacy of MBIs for symptoms of perinatal anxiety, of which seven were Randomised

Controlled Trials (RCTs). The results indicated consistent treatment effects of MBIs on anxiety symptomatology, these effects were larger than those established for both depression and stress (Shi and MacBeth, 2017). Follow up data was not consistently reported for these studies and so it is difficult to know whether these reductions were sustained post-treatment. The methodological characteristics of the included studies varied considerably meaning that in depth between groups analyses could not be made (Shi and MacBeth, 2017). While these results are promising, there is room for more robust evaluation of the contribution of MBIs for the treatment of perinatal anxiety.

In the existing literature the modes of delivery of psychological interventions vary and include individual, group and internet delivered interventions (Bittner et al., 2014; Burger et al., 2020; Loughnan et al., 2019c). There is a paucity of research directly comparing the modes of delivery and so no one method is suggested to be more efficacious than the other. All seem to be acceptable to women based on rates of treatment adherence and patient feedback (Loughnan et al., 2018). It is argued, however, that internet-delivered interventions offer greater flexibility, which may improve access to treatment for women in this period when demands on their time are greater (Loughnan et al., 2019b), and so it is unsurprising that there has been increasing interest in this area (Lau et al., 2017). In a recent review, Loughnan et al. (2019b) identified only seven papers exploring the use of these interventions for anxiety and depression in the perinatal period. Of these papers none were targeted interventions for specific anxiety disorders or comorbid anxiety and depression. However, tentative conclusions were drawn in terms of the utility of these interventions for perinatal anxiety. Namely, that interventions targeted at Major Depressive Disorder (MDD) also showed modest improvements on secondary, self-report anxiety measures (Loughnan et al., 2019b). These results warranted further investigation and since the publication of this review two further papers have been published evaluating the 'MUMmentum' internet based CBT program targeting anxiety and depression for use within both pregnancy and the postpartum period (Loughnan et al., 2019c, 2019a) which will be included in the current review.

Taking the above into consideration, the current review builds on previous evidence evaluating the effectiveness of psychological interventions for reducing anxiety in the perinatal period. The current review is specifically focused on studies where perinatal anxiety, or comorbid anxiety and depression, were the primary intervention targets, regardless of therapeutic modality or mode of delivery. Unlike previous reviews (Maguire et al., 2018), studies of interventions for perinatal depression where anxiety is a secondary outcome will be excluded. In addition, previous reviews have in turn focused only on specific therapies, such as CBT (Maguire et al., 2018), specific modes of delivery (Lau et al., 2017; Loughnan et al., 2019b), or have performed only narrative synthesis due to the methodological limitations of the literature (Loughnan et al., 2018; Marchesi et al., 2016). The current review addressed the following research questions:

- Are psychological interventions associated with reductions in anxiety during the perinatal period?
- Do psychological interventions for perinatal anxiety produce secondary outcomes, i.e., improvement in general wellbeing, mother-infant attachment etc?
- Which psychological interventions are most beneficial, i.e., group versus individual therapy?
- Is there a difference between interventions to reduce anxiety offered in pregnancy versus postpartum?
- Are there methodological sources of bias in the literature?

## **2. Method**

### **2.1 Search Strategy**

The systematic review search was conducted using PRISMA criteria (Moher et al., 2009). Studies were identified by searching the electronic databases EMBASE, MEDLINE, PsychINFO, MIDIRS, CINAHL and the Cochrane Library. The following search terms were developed and combined using MESH terms and key words and adapted for use with each database: Psychological Therapy or Psychological Intervention or Psychotherapy or Cognitive Behavioural Therapy or Cognitive Therapy or Mindfulness or Mindfulness Based Cognitive Therapy or Mindfulness Based Approaches or



Mindfulness Based Stress Reduction or Psychodynamic Psychotherapy or Group Psychotherapy or Interpersonal Psychotherapy or Psychological Treatment or Anxiety Management or Acceptance and Commitment Therapy or Compassion Focused Therapy AND Perinatal Care or Perinatal or Perinatal Period or Antenatal or Postnatal or Postnatal Care or Postpartum or Postpartum Period or Maternal or Pregnancy AND Anxiety or Obsessive Compulsive Disorder or Obsessions or Obsessive Behaviour or Compulsions or Compulsive Behaviour or Panic Disorder or Generalised Anxiety Disorder or Phobia or Fear of Childbirth or Tokophobia or Childbirth Trauma or Birth Trauma or Post-Traumatic Stress Disorder.

Searches were conducted in November 2019. The initial search returned 1,392 articles, after duplicates were removed 995 articles remained. These papers were reviewed using title and abstract and a further 899 were removed. The full text of the remaining 96 articles were reviewed against the inclusion and exclusion criteria, this resulted in the exclusion of a further 80 papers and the remaining 16 were considered in this review, 12 of which were included in the meta-analysis. In addition, a search of grey literature conducted within the last two years was also completed using Google Scholar, OpenGrey and ProQuest Dissertations & Theses Global in March 2020. This process yielded one paper included in the review. This process is outlined in the PRISMA flowchart below (Fig. 1). Identified peer-reviewed studies were published between 2004 and 2020.

## 2.2 Inclusion and Exclusion Criteria

Studies were included if:

- They were investigating the effectiveness of psychological interventions for treating anxiety in the perinatal period
- The reduction of anxiety or comorbid anxiety was a primary target of the intervention\*
- There was a treatment and control group
- Participants were women, over the age of 16, who were pregnant or postpartum (up to one-year post-birth)

- Participants were experiencing elevated levels of anxiety based on valid and reliable self-report outcomes measures or had a clinical diagnosis of an anxiety disorder\*\*

\* In studies where a reduction in other symptoms (e.g., depression) were also targeted, the study was only included if participants were screened for anxiety as an inclusion criterion.

\*\*This also included women with a diagnosis of OCD. Prior to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V; American Psychiatric Association (APA), 2013) OCD was considered an anxiety disorder. Despite the move out of this category, the DSM-V still suggests a close relationship between OCD, anxiety disorders and other related disorders (APA, 2013). In addition, the psychological treatment interventions for OCD are similar to those offered for anxiety disorders and therefore treatment in the perinatal period is likely to be somewhat overlapping (Marchesi et al., 2016).

Studies were excluded if:

- Target of the intervention was not anxiety
- Anxiety was not used as an inclusion criterion
- The design was single case, case series or review
- They were not written in English (due to feasibility issues in accessing translations).

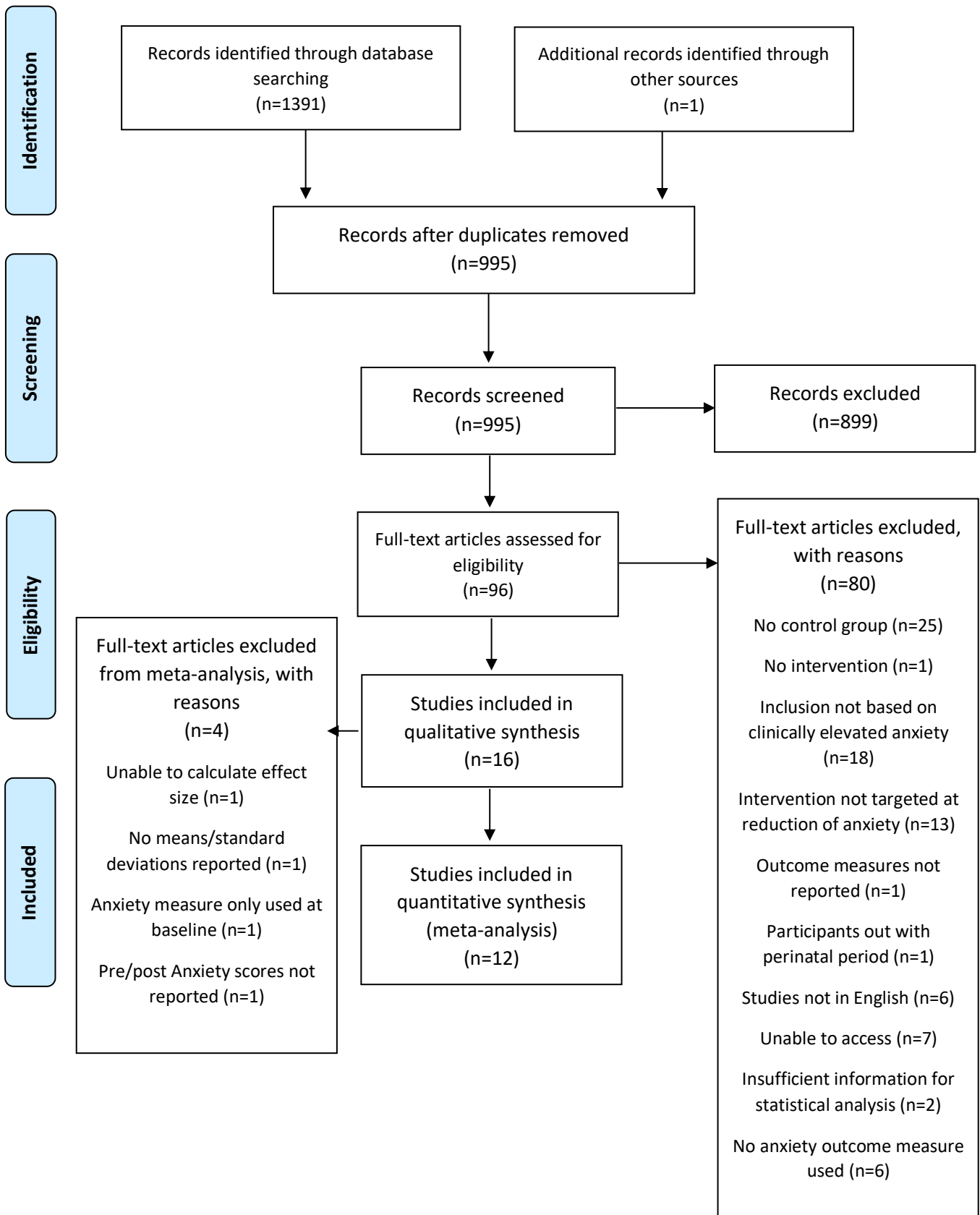


Fig. 1: Flowchart of study selection

## 2.3 Data Extraction

### *2.3.1 Demographics*

A tailored proforma was developed to extract all relevant information from the full text of each eligible paper, including: Citation, Country, Participants Characteristics, Sample Size, Age, Gestational Age at Baseline (weeks) or Infant Age, Study Design, Perinatal Period (Antenatal/Postnatal), Intervention, Clinician, Comparison Group, Diagnosis (Dx), Outcome Measure(s) and Assessment Time Point.

### *2.3.2 Meta-analytic Model*

Analyses were conducted in RStudio (RStudio Version 1.2.5033) using the 'metafor' (Viechtbauer, 2010) and 'meta' (Schwarzer, 2007) packages. It was assumed prior to analysis that the included studies would have a high degree of variability due to high methodological heterogeneity between studies, for example, therapeutic modality used (e.g., CBT vs Mindfulness) and method of intervention (e.g., group vs online). Fixed-effects meta-analytic modelling inflates the possibility of Type one errors, therefore, random effects analyses were conducted applying the inverse variance method (Deeks et al., 2001), using DerSimonian Laird estimators for between-study variance (DerSimonian and Laird, 1986). Effect sizes were converted into Cohens d. Publication bias was investigated using visual inspection of funnel plots, and Egger's test for plot asymmetry (Egger et al., 1997). Influence analyses were run to investigate the impact of outliers and impact of missing data modelled using a trim and fill analysis (Duval and Tweedie, 2000). Heterogeneity estimates were reported using I-squared values with values of 0, 25, 50, and 75% indicating zero, low, moderate, and high heterogeneity, in turn (Higgins et al., 2003).

### *2.3.3 Risk of Bias Assessment*

Risk of bias in the included papers was assessed using the revised Cochrane risk-of-bias tool for randomised trials (RoB2; Higgins et al., 2019). Bias was considered across 5 domains:

- (1) bias arising from the randomisation process
- (2) bias due to deviations from intended interventions
- (3) bias due to missing outcome data

(4) bias in measurement of the outcome

(5) bias in selection of the reported result

The first and second authors both completed the RoB2 template (see Appendix 2) independently for each study, following this both reviewers discussed and agreed their bias ratings for each study.

Intra-class correlation coefficients based on Landis and Koch's heuristics (1977) were conducted to establish level of agreement between reviewers.

### **3. Results**

#### **3.1 Study Characteristics**

Demographic information is displayed in Table 1. A total of 16 studies were identified as meeting inclusion criteria, representing a sample of n=1,333 women (treatment conditions, n=595; control conditions, n=738). All participants were aged between 18-42, with a mean age of 30.8 years in the treatment group and 32.1 years in the control group. Due to inconsistent reporting, it was not possible to calculate the mean gestational/infant age. Of the 16 studies, four were conducted in Iran, four in Australia, two in Canada, and one each in the UK, Germany, China, USA, Sweden, and the Netherlands. The interventions utilised were CBT (n=10), MBIs (n=4), Applied Relaxation (n=1) and a mixed approach self-help (n=1). The methods of intervention delivery comprised of group setting (n=9), online format (n=3), face to face individual therapy (n=3) and guided self-help (n=1). The number of treatment sessions offered varied from two to 14. Anxiety outcomes were measured using the Spielberger State-Trait Anxiety Inventory (STAI; n=4), Generalised Anxiety Disorder 7-item scale (GAD-7; n=3), Beck Anxiety Inventory (BAI; n=2), State-Trait Inventory for Cognitive and Somatic Anxiety, Trait Version (STICSA; n=1), Pregnancy Related Anxiety Questionnaire (PRAQ; n=1) and the Hamilton Anxiety Rating scale (HAM-A; n=1). To measure depression the following outcome measures were used the Edinburgh Postnatal Depression Scale (EPDS; n=8), Patient Health Questionnaire 9-item scale (PHQ-9; n=4), Hamilton Depression Rating scale (HAM-D; n=1) and Beck Depression Inventory-II (BDI-II; n=1). Of the 16 studies, nine completed measures only pre- and post-intervention and seven studies administered follow up measures post intervention at varying

timepoints. Due to the substantial variation in follow up time points meta-analytic modelling was not performed.

**Table 1: Study Demographic Characteristics**

Study	Country	Participants Characteristics	Sample Size	Age	Gestational Age at Baseline (weeks)/ Infant Age	Study Design	Perinatal Period (Antenatal/ Postnatal)	Intervention	Clinician	Comparison Group	Dx	Outcome Measure(s)*	Assessment Time Point
Bastani et al. (2006)	Iran	Pregnant women, with uncomplicated, singleton pregnancies and no identified medical or obstetrical risk factors. Recruited participants demonstrated high levels of anxiety on STAI	Total sample (N=110), Experimental (N=55), Control (N=55)	18-30 (Average 23.8, SD = 3.1)	14-28 weeks (M = 17.8, SD = 1.8)	RCT	Antenatal	CAU with 7-week applied relaxation training sessions	Qualified Nurse	CAU	N	STAI; PSS	Pre-test/Post-test, no follow up
Bittner et al. (2014)	Germany	Women age over 18 years, scoring above cut off on screening measures indicating elevated symptoms of anxiety or depression	Total Sample, N=74; Intervention group (N = 21) control group (N = 53)	M (SD) Intervention 29.4 (3.6); Control 29.7 (4.7)	10-15 weeks; M (SD) Intervention 16.1 (3.1); Control 16.6 (3.9)	RCT	Antenatal	Cognitive Behavioural Group Programme (8x90min sessions)	Clinical Psychologist	TAU	Y	PDQ; STAI; BDI-V; MCIDI; EPDS; FCS; ASI-R; DAS; SSS; QoM/IRS	T1 (preintervention), T2 (antenatal follow up), and T3 (3 months postpartum)
Burger et al. (2019)	Netherlands	Pregnant women with moderate-severe anxiety or depression as per screening measures	Total sample 149; CBT (n=71); CAU (n=78)	Mean (SD) CBT: 33.4 (4.6), CAU: 32.1 (4.5)	10-12 weeks	RCT	Both	10-14 individual CBT sessions,	Licensed Psychologists	CAU	Y	STAI; EPDS; CBC; PBQ; BSID-III	Baseline; 24 weeks gestation; 36 weeks gestation; 6 weeks postnatal; 3,6,12,18 months postnatal
Challacombe et al. (2017)	UK	Postpartum women with a diagnosis of OCD with a baby less than 6 months old	Total Sample 34; iCBT, n=17; TAU, n=17	Mean age (iCBT 32.4 v. TAU 32.7 v. HC 34.6 years)	Not reported	RCT	Postnatal	Participants received 12 h of face-to-face individual iCBT	Qualified Clinician	TAU/ Healthy control group	Y	SCID-IV; YBOCS; OCI-R; DASS; PSSS; G-RIMS; MSES; BITQ	Baseline assessment - 6 months postpartum, follow up at 12 months postpartum
Green et al., (2020)	Australia	Participants were pregnant or up to 6 months postpartum and had an anxiety disorder with or without comorbid depression.	86 participants; CBT group (N=44); WC (N=42)	M(SD) CBT group: 32.46 (3.54) WC: 31.43 (3.66)	N/A: n=31 pregnant. n=55 within the first 6 months postpartum.	RCT	Both	Cognitive Behavioural Group Therapy	Clinical Psychologist and a Psychology trainee	WC	Y	STICSA; PSWQ; PSS-14; EPDS; HAM-A; MADRS; CSQ	Baseline and 6 weeks post-intervention
Guardino et al. (2014)	USA	Women experiencing elevated levels of perceived stress or pregnancy-specific anxiety	Total Sample n = 47; Mindfulness Group (n = 24); RC (n = 23).	Mean 33.13 (SD = 4.79)	10-25 weeks (mean 17.78 weeks; SD = 5.10)	RCPT	Antenatal	6-week mindfulness class	Mindfulness Trained Instructor	RC	N	FFMQ; PSS; PSA; PRAS; STAI	Baseline, post-intervention, 6 week follow up
Karamoozian and Askarizadeh (2015)	Iran	Pregnant women experiencing depression and anxiety based on screening measures	Total Sample n = 29; experimental group (n=14), control group (n=15)	Not reported	4th or 5th month of pregnancy	pretest-posttest control-group design	Antenatal	CBSM; 12 weekly sessions	Not reported	CAU	N	PRAQ; EPDS; Apgar Scale	Pre-test/Post-test, no follow up
Lilliecreutz et al. (2010)	Sweden	Pregnant women with DSM-IV diagnosis of blood-and-injection phobia	Total Sample n = 146; CBT group (n=30), CAU phobia group (n=46), healthy control (n=70)	CBT group 28.5 (SD=5.03), CAU - mean age 30.5 (SD=4.09)	25-30 weeks	OT	Antenatal	Group CBT	CBT-trained Therapist and Midwife	CAU/ healthy control group	Y	BAI; EPDS	Intervention group - before/after each group session, 3 month postpartum follow up, control groups - 25/36 weeks gestation, 6-8 weeks postpartum
Loughnan et al. (2019c)	Australia	Pregnant women aged over 18 years, who met criteria for a probable diagnosis of GAD and/or MDD	Total Sample n = 78; CBT (n=36); TAU (n=41)	31.61 years, SD=4.00	13-30 weeks (mean 21.66, SD=5.93)	RCT	Antenatal	internet CBT intervention (self-guided)	N/A	TAU	N	K-10; PHQ-9; GAD-7; WHO-QoL; MAAS; TCEQ; TSQ	baseline, post-treatment and four-week follow-up

Loughnan et al. (2019a)	Australia	Women within 12 months postpartum; aged over 18 years; self-report symptoms of anxiety and/or depression above clinical threshold	Total Sample n =120 (CBT: n=65, TAU: n=55)	32.56 years (SD=4.53)	mean infant age of 4.55 months, SD=3.05)	RCT	Postnatal	internet CBT intervention (self-guided)	N/A	TAU	N	GAD-7; PHQ-9; EPDS; K-10; MPAS; KPCCS; WHO-QoL; TCEQ; TSQ	Baseline (pre-treatment); Post-treatment (1 week after the active treatment period ended), with follow-up 4 weeks post-treatment
Milgrom et al. (2011)	Australia	Women both with and without symptoms of depression, anxiety and stress were included.	Total Sample n= 143: HS (Intervention n=21; routine care n = 50); LS (Intervention n=22; routine care n = 50)	M (SD) Intervention: 31.96 (5.58); Routine Care 32.63 (5.93)	20-32 weeks; M (SD) Intervention 24.73 (3.71); Routine care; 25.10 (3.63)	RCT	Majority Antenatal with one Postnatal unit	Self-help workbook comprising nine units —weekly telephone support session.	Guided self-help; psychologist or trainee	CAU	N	EPDS; RAC; BDI; DASS; PSI	pre/post treatment, no follow up
Misri et al. (2004)	Canada	Postpartum Women scoring high on screening measures indicating symptoms of postpartum mood and anxiety disorder.	Total Sample (n=35)— paroxetine only monotherapy group (PO; N = 16) or paroxetine plus 12 sessions of CBT group (CBT; N = 19)	18-40 mean age (SD) PO: 30.81 (3.31); CBT: 29.52 (5.85)	Not reported	RCT	Postnatal	1-hour individual CBT session every week for 12 weeks plus paroxetine treatment.	Registered psychologist	Paroxetine Only Group	Y	HAM-A; HAM-D; YBOCS; CGI; EPDS;	Pre-test/Post-test, no follow up
Salehi et al. (2016)	Iran	Women in the second trimester of pregnancy with a mild to moderate anxiety level, and no history of antipsychotic medication.	Total sample: N=91 (CBT group: n=31; IL group n=30; and control group: n=30)	16-39 years (mean 26.04; SD 4.68)	13-26 weeks	quasi experimental trial	Antenatal	Group CBT	Midwife and a Psychiatrist.	CAU	N	STAI	Pre-test/Post-test, no follow up
Shulman et al. (2018)	Canada	Postpartum women who met DSM-V criteria for either MDD, GAD, or both, in the first twelve months post-childbirth	Total Sample n = 30; MBCT group (n = 14); TAU group (n = 16).	27-42 years; Mean age (SD): MBCT group 36.71 (SD = 4.29); TAU 34.31 (SD=3.44)	Not reported	non-equivalent control group quasi-experimental design	Postnatal	8-week group MBCT	Psychiatrist and a Clinical Counsellor	TAU	Y	PHQ-9; GAD-7; Mindful Attention Awareness Scale (MAAS);	baseline, 4, 6, 8 weeks, 3 months
Yang et al. (2019)	China	Pregnant women with elevated depressive or anxious symptoms	Total sample n = 123 (intervention group N=62; control group N=61)	24-30; Mean (SD) Intervention group 31.31 (4.97); control group 30.38 (3.91)	Mean (SD) in weeks Intervention group 25.52 (1.84); control group 26.33 (3.45)	RCT	Antenatal	8-week mindfulness online intervention program	Online intervention	CAU	N	FFMQ; PHQ-9; GAD-7	Pre-test/Post-test, no follow up
Zemestani and Fazeli Nikoo (2019)	Iran	Pregnant women (1-6-month gestation) aged over 18, meeting DSM-5 criteria for depression and anxiety disorders	Total Sample (n = 38); MBCT group (n = 19); control group (n = 19).	M (SD) MBCT 28.63 (3.02); Control 30.54 (4.15)	M (SD) MBCT Group 18.27 (6.71); Control Group 16.85 (5.62)	RCT	Antenatal	8-week MBCT group	Clinical Psychologist	No intervention	Y	BDI-II; BAI; ERQ; SPW	Pre-test/Post-test, 1 month follow up

**Note:** RCT = Randomised Control Trail, RCPT = Randomised Control Pilot Trial, OT = Open Trial, DSM-V = Diagnostic and Statistical Manual of Mental Disorders: Fifth Edition, CAU = Care as usual, TAU = Treatment as usual, WC = Waitlist control, RC = Reading Control, MDD = Major depressive disorder, OCD = Obsessive Compulsive Disorder, GAD = Generalised Anxiety Disorder, CBSM = Cognitive-behavioural stress management, CBT = Cognitive Behavioural Therapy, MBCT = Mindfulness Based Cognitive Therapy, IL = Interactive Lectures, iCBT = time-intensive cognitive-behaviour therapy, HS = High screening scores, LS = Low screening scores; **Outcome Measures:** Spielberger State-Trait Anxiety Inventory (STAI; Spielberger, et al., 1970); The Perceived Stress Scale (PSS-14; Cohen et al., 1983) Prenatal Distress Questionnaire (PDQ; Alderdice and Lynn, 2011); Beck Depression Inventory-short form (BDI-V; Schmitt et al., 2003); Beck Depression Inventory-II (BDI-II; Beck et al., 1996); Beck Anxiety Inventory (BAI; Beck et al., 1988); Munich-Composite International Diagnostic Interview (MCIDI; Wittchen et al., 1998); Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987); Fear of childbirth scale (FCS; Lukesch, 1983); Anxiety Sensitivity Index -revised version (ASI-R; Reiss et al., 1986); Dysfunctional Attitudes Scale (DAS; Weissman and Beck, 1978); Social Support Scale (SSS; Fydrich et al., 2007); Quality of a Marriage or Intimate Relationship Scale (QoM/IRS; Hahlweg, 1996 ); Child Behaviour Checklist (CBC; Achenbach



and Rescorla, 2000); Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2006); Bayley Scales of Infant and Toddler Development, Third Edition (BSID-III; Bayley, 2006); Structured Clinical Interview for DSM-IV (SCID-IV; First et al., 1995); Yale-Brown Obsessive Compulsive Scale (YBOCS; Goodman et al., 2018); Obsessive Compulsive Inventory-Revised (OCI-R; Foa et al., 1998); Depression, Anxiety and Stress Scale (DASS; Lovibond and Lovibond, 1995); Perceived Social Support Scale (PSSS; Marshall and Barnett, 1993); Golombok–Rust Inventory of Marital Satisfaction (G-RIMS; Rust et al., 2007); Maternal Self-Efficacy Scale (MSES; Pedersen et al. 1989); Bates Infant Temperament Questionnaire (ITQ; Bates et al., 1979); Five Factor Mindfulness Questionnaire (FFMQ; Baer et al., 2006); Pregnancy-Specific Anxiety Scale (PSA; Roesch et al., 2004); Pregnancy Related Anxiety Scale (PRAS; Rini et al., 1999). Pregnancy-Related Anxiety Questionnaire (PRAQ; Vandenberg, 1989); Kessler-10 psychological distress scale (K-10; Kessler et al., 2002); Patient Health Questionnaire 9-item scale (PHQ-9; Kroenke et al., 2001); Generalised Anxiety Disorder 7-item scale (GAD-7; Spitzer et al., 2006); World Health Organisation Quality of Life scale (WHO-QoL; Skevington, 2004); Maternal Antenatal Attachment Scale (MAAS; Condon, 1993); Treatment Credibility and Expectancy Questionnaire (TCEQ; Devilly and Borkovec, 2000); Treatment Satisfaction Questionnaire (TSQ; Cox et al., 1994); The Maternal Postnatal Attachment Scale (MPAS; Condon, 1993); The Karitane Parenting Confidence Scale (KPCS; Črnčec et al., 2008); The Risk Assessment Checklist (RAC; Murphy, 2009); Parenting Stress Index (PSI; Abidin, 1995); Hamilton Rating Scale for Depression (HAM-D; Hamilton, 1967); the Hamilton Anxiety Rating Scale (HAM-A; Hamilton, 1959); Clinical Global Impressions scale (CGI; Petkova et al., 2000); Emotion Regulation Questionnaire (ERQ; Gross and John, 2003); Scales of Psychological Well-being (SPWB; Ryff, 1989); State-Trait Inventory for Cognitive and Somatic Anxiety, Trait Version (STICSA; Grös et al., 2007); The Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990); Montgomery–Åsberg Depression Rating Scale (MADRS; Montgomery and Asberg, 1979); The Client Satisfaction Questionnaire (CSQ; Larsen et al., 1979); Mindful Attention Awareness Scale (MAAS; (Brown and Ryan, 2003).

### 3.2 Anxiety Scores Pre/Post Intervention

Results of the meta-analytic modelling of the effect of treatment on perinatal anxiety are displayed in Table 2. The main model (see forest plot, Fig. 2) reported a statistically significant effect size for the effect of intervention vs. control in reducing anxiety ( $d = -0.57$ ; 95%CI = -0.98 to -0.16,  $p=0.006$ ), indicating a medium effect with a broad but significant confidence interval. There was a high degree of heterogeneity between the studies (87.8%) indicating a considerable degree of between-study variance.

To investigate the potential impact of outliers, an influence analysis was also conducted. This analysis suggested that there was little effect of a leave one out analysis, with the exception of Zemestani and Fazeli Nikoo (2019). When this study was omitted, the overall effect size was reduced to a small effect ( $d=-0.36$ ) with reduced, but still significant confidence intervals (-0.69 to -0.04) and a marginal reduction in heterogeneity (80.5%).

With regards to sensitivity analyses, visual inspection of the funnel plot suggested no significant asymmetry, confirmed using Egger's test ( $B = -4.87$ ,  $SE = 2.59$ ,  $p = 0.09$ ). The trim and fill method identified two missing studies. Included estimated missing effects in the analysis, suggested the effect for intervention vs. control in reducing anxiety would no longer be significant  $k = 14$ ,  $d = -0.28$  (95%CI = -0.74 to 0.17,  $p = 0.23$ ).

**Table 2: Results of the meta-analytic modelling of the effect of treatment on perinatal anxiety**

<b>Analysis (k)</b>	<b>Effect size (d) (95% CI)</b>	<b>Significance (p)</b>	<b>I<sup>2</sup> (%)</b>
<i>Anxiety Scores Pre/Post</i>	-0.57 (-0.98; -0.16)	0.006	87.8
<i>Anxiety Measures Subgroup</i>			
<i>STAI (k=4)</i>	-0.13 (-0.59; 0.32)	>.05	74.1
<i>GAD-7 (k=3)</i>	-0.73 (-0.98; -0.48)	<.05	3.1
<i>BAI (k=2)</i>	-1.43 (-5.28; 2.41)	>.05	97.8
<i>Other (k=3)</i>	-0.65 (-1.33; 0.03)	>.05	71.2
<i>Type of Intervention Subgroup</i>			
<i>Group (k=8)</i>	-0.73 (-1.31; -0.15)	<.05	89.3
<i>Self-guided (k=2)</i>	-0.63 (-0.99; -0.27)	<.05	16.8
<i>Individual (k=2)</i>	0.15 (-0.13; 0.43)	>.05	0
<i>Mode of Delivery Subgroup</i>			
<i>Face to face (k=9)</i>	-0.53 (-1.05; -0.01)	<.05	88.7
<i>Online (k=3)</i>	-0.74 (-0.98; -0.49)	<.05	3.1
<i>Therapeutic Modality Subgroup</i>			
<i>CBT (k=9)</i>	-0.36 (-0.72; -0.01)	<.05	79.4
<i>MBI (k=3)</i>	-1.28 (-2.78; 0.22)	>.05	94.6
<i>Antenatal Only Subgroup (k=8)</i>	-0.74 (-1.36; -0.13)	0.017	89.9
<i>Depression Scores Pre/Post (k=11)</i>	-0.69 (-1.14; -0.25)	0.002	88.1

Note: negative effect = reduction in anxiety, favouring treatment group

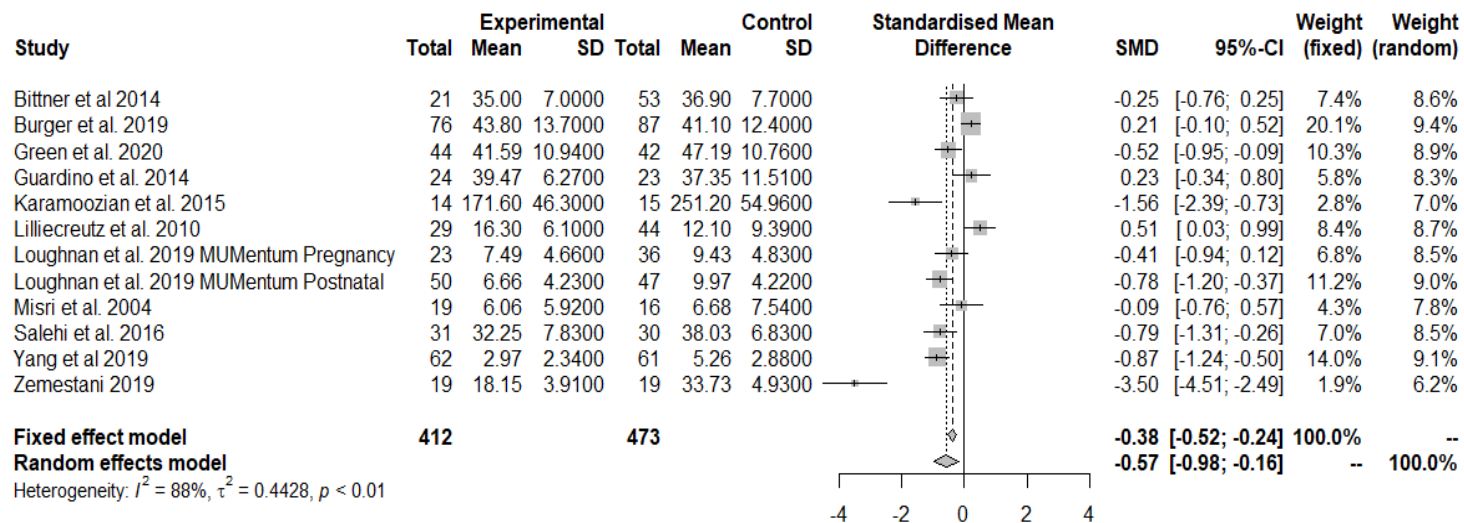


Fig. 2: Forest Plot displaying the meta-analytic modelling of the effect of treatment on perinatal anxiety

### 3.3 Moderator Analyses

#### *3.3.1 Type of anxiety measure*

In order to further explore these results subgroup analyses were conducted; firstly, assessing the impact of different anxiety measures on the effect size. A medium effect ( $d=-0.74$ ) was found for the GAD-7; however, this was based on only 3 studies with a heterogeneity of 3.1%, indicating the effect was likely to be unstable. The test for subgroup differences was non-significant ( $p=0.149$ ) indicating that no one anxiety measure performed better than others as a measure of anxiety outcome in this context. This result should be interpreted with caution given the small sample. Due to the small number of studies in each subgroup bias analyses were not conducted.

#### *3.3.2 Type of intervention*

Next, moderator analyses examined the effect of type of intervention (group, individual or self-guided) on anxiety scores. For group interventions a significant medium effect size was found for the effect of intervention vs. control in reducing anxiety equivalent to  $d = -0.73$  (95%CI = -1.31 to -0.15). This effect was based on eight studies with high heterogeneity (89.3%). A medium effect was also found for use of self-guided interventions vs. control ( $d=-0.63$ , 95% CI=-0.99 to -0.27). No significant effect was found for individual interventions vs. control for reducing anxiety ( $d=0.15$ , 95%CI =-0.13 to 0.43). However, the latter two analyses were based on only two studies per subgroup and effects are likely to be unstable. Overall, the test for subgroup difference between types of interventions was significant ( $p=0.001$ ), suggesting type of intervention may impact upon overall anxiety reduction.

To account for outliers, the above analysis was re-run with the omission of Zemestani and Fazeli Nikoo (2019). For group interventions the overall effect size for the effect of intervention vs. control reduced to  $d=-0.43$  (95% CI = -0.88 to -0.03), indicating a small effect. The effect for individual and self-guided interventions remained unchanged. The test for subgroup differences remained significant ( $p=0.002$ ).

### 3.3.3 Mode of delivery

For face-to-face interventions, a significant medium effect size was found for the effect of intervention vs. control in reducing anxiety equivalent to  $d = -0.53$  (95%CI = -1.05 to -0.01). This effect was based on nine studies with a high degree of heterogeneity (88.7%). A medium effect was also found for online interventions vs. control in reducing anxiety ( $d=-0.74$ , 95% CI=-0.98 to -0.49). However, this effect was based on only three studies. Overall, the test for subgroup differences between mode of delivery was non-significant ( $p=0.48$ ). However, due to difference in sample size between these two groups this result should be interpreted with caution.

Re-running the analyses with the omission of the outlier Zemestani and Fazeli Nikoo (2019), indicated that for face to face interventions the overall effect size for the effect of intervention vs. control reduced to a small effect ( $d=-0.23$ ; 95% CI = -0.61 to 0.16). The effect for online interventions remained unchanged. The test for subgroup differences became significant ( $p=0.02$ ) suggesting that mode of delivery does have some impact on anxiety scores. This result warrants further investigation.

### 3.3.4 Therapeutic modalities

For CBT interventions an overall significant effect size was found for the effect of intervention vs. control in reducing anxiety equivalent to  $d = -0.36$  (95%CI = -0.72 to -0.01), indicating a small effect. This effect was based on nine studies with a high degree of heterogeneity (79.4%). For MBI interventions an overall significant effect size was found for the effect of intervention vs. control in reducing anxiety equivalent to  $d = -1.28$  (95%CI = -2.78 to 0.22), indicating a large effect. This effect was based on only three studies and so this effect is likely to be unstable. Overall, the test for subgroup differences between therapeutic modality was non-significant ( $p=0.24$ ).

To account for outliers, the above analysis was re-run, omitting Zemestani and Fazeli Nikoo (2019). For MBI interventions the overall effect size for the effect of intervention vs. control reduced to  $d=-0.34$  (95% CI = -1.42 to 0.73), indicating a small effect. The effect for CBT interventions remained unchanged.

### 3.3.5 Effect of antenatal treatment

A subgroup analysis was also conducted for psychological interventions for anxiety offered in the antenatal period only. This model demonstrated an overall significant effect size for the effect of intervention vs. control in reducing anxiety in the antenatal period equivalent to  $d = -0.74$  (95%CI = -1.36 to -0.13,  $p=0.017$ ), indicating a medium effect with a broad but significant confidence interval. This result indicates that psychological interventions are effective for reducing anxiety in the antenatal period. A random effects model was used due to the high degree of heterogeneity between the studies (89.9%) to statistically correct for a proportion of this variance.

### 3.4 Depression Scores (Secondary Outcome) Pre/Post Intervention

Although the primary focus of the meta-analysis was on anxiety, the majority of included studies also measured depression, therefore a post-hoc meta-analysis was performed to explore the magnitude of effect of intervention on depressive symptoms. This model demonstrated an overall significant effect size for the effect of intervention vs. control in reducing depression equivalent to  $d = -0.69$  (95%CI = -1.14 to -0.25,  $p=0.002$ ), indicating a medium effect around a broad confidence interval. This result suggests that the psychological interventions were effective in reducing depression scores. There was a high degree of heterogeneity between the studies (88.1%) indicating a considerable degree of variance hence the use of a random effects model to correct for a proportion of the variance.

To investigate the impact of outliers an influence analysis was also conducted. This analysis suggested that there was little effect of a leave one out analysis, with the exception of Zemestani and Fazeli Nikoo (2019). When omitted, the overall effect size was reduced to a small effect ( $d=-0.43$ ) with confidence intervals between -0.73 and -0.13. The study heterogeneity also drops to 74.1%.

A sensitivity analysis was also conducted to explore the influence of bias. A visual inspection of the funnel plot suggested no asymmetry, confirmed using Egger's test ( $B = -4.16$ ,  $SE = 2.52$ ,  $p = 0.13$ ). The trim and fill method was applied and identified no missing studies.

### 3.5 Methodological Risk of Bias

The RoB2 methodological risk of bias tool (Higgins et al., 2019) was completed for each study by the first and second authors independently before consensus agreement was established (see Table 3 for consensus agreement ratings). Intra-class correlation coefficients indicated a fair level of agreement between reviewers (ICC (1) = 0.23) based on Landis and Koch's heuristics (1977).

Overall, four studies were rated as having a high risk of bias, five studies raised some concerns, and seven studies were rated low. For domain one, bias arising from the randomisation process, three studies raised some concerns, namely due to the lack of information regarding the actual randomisation method used. Domain two accounted for risk arising from deviations from intended interventions and is further broken down into two subcategories: a) effect of assignment to intervention and b) effect of adhering to intervention. In domain 2a, six studies raised some concerns, in all cases this related to the lack of intention to treat (ITT) analysis, or other appropriate analysis to estimate the effect of assignment to intervention. However, in these studies small sample sizes may mean there were fewer resources to complete ITT analysis. One study was rated as high in this area (Bittner et al., 2014), this was due to lack of appropriate analysis to estimate the effect of assignment to intervention, along with a large dropout rate, which may have had a substantial impact on results. For domain 2b, the majority of studies (n=13) delivered interventions to protocol and were, therefore, considered low risk of bias. However, three studies were rated as having a high risk of bias, this was primarily due to the lack of information regarding fidelity and adherence to treatment. For Yang et al. (2019) it was reported that adherence to treatment was low but appropriate analysis to estimate the effect of this was not conducted. In domain three, only one study was rated as some concerns, and one rated high, based on missing outcome data. For Karamoozian and Askarizadeh (2015) the risk was considered high due to inconsistent reporting. Overall, the measurement of outcome was appropriate (domain 4), however, Green et al. (2020) were flagged as having some concerns as the only study to use a waitlist control group, which may have influenced self-reported outcomes. Overall, the selection of reported results (domain 5) was



appropriate for the majority of studies, indicating a low risk of bias. However, Karamoozian and Askarizadeh (2015) raised concerns due to lack of information regarding planned analysis.

**Table 3: Consensus ratings between first and second reviewer on the RoB2**

Study	Domain 1: randomisation process	Domain 2a: deviations from intended interventions (effect of assignment to intervention)	Domain 2b: deviations from intended interventions (effect of adhering to intervention)	Domain 3: Missing outcome data	Domain 4: measurement of outcome	Domain 5: selection of reported results	Overall Risk of Bias
*Bastani et al. (2006)	Low	Some concerns	Low	Low	Low	Low	Some concerns
Bittner et al. (2014)	Some concerns	High	Low	Low	Low	Low	High
Burger et al. (2019)	Low	Low	Low	Low	Low	Low	Low
*Challacombe et al. (2017)	Low	Low	Low	Low	Low	Low	Low
Green et al. (2020)	Low	Low	Low	Low	Some concerns	Low	Some concerns
Guardino et al. (2014)	Low	Some concerns	Low	Low	Low	Low	Some concerns
Karamoozian et al. (2015)	Low	Some concerns	High	High	Low	Some concerns	High
Lilliecreutz et al. (2010)	Some concerns	Some concerns	High	Low	Low	Low	High
Loughnan et al. (2019c)	Low	Low	Low	Low	Low	Low	Low
Loughnan et al. (2019a)	Low	Low	Low	Low	Low	Low	Low
*Milgrom et al. (2011)	Low	Low	Low	Low	Low	Low	Low
Misri et al. (2004)	Low	Low	Low	Low	Low	Low	Low
Salehi et al. (2016)	Low	Some concerns	Low	Some concerns	Low	Low	Some concerns
*Shulman et al. (2018)	Some concerns	Some concerns	Low	Low	Low	Low	Some concerns
Yang et al. (2019)	Low	Low	High	Low	Low	Low	High
Zemestani and Fazeli Nikoo (2019)	Low	Low	Low	Low	Low	Low	Low

\*Note: Studies excluded from meta-analysis

#### 4. Discussion

The current meta-analysis aimed to systematically review and assess the evidence for the effectiveness of psychological interventions for anxiety in the perinatal period. Overall results indicated that psychological interventions were more effective than control conditions in reducing symptoms of perinatal anxiety with a medium post treatment effect size. Using a larger, and methodologically rigorous, sample this result extends previous review evidence (Maguire et al., 2018). It is also in line with narrative reviews of the effectiveness of psychological interventions for perinatal anxiety (Loughnan et al., 2018; Marchesi et al., 2016) and consistent with results for treatment of anxiety in the general population (Newby et al., 2015; Watts et al., 2015).

The meta-analysis included a small number of studies (n=12) with high levels of heterogeneity; therefore, results should be considered with a degree of caution. Moderator analyses also indicated a number of methodological aspects contributing to the effect size for anxiety reduction. Analyses

indicated that no one outcome measure was superior in capturing anxiety scores, however, this result was based on small sample sizes. Of note, most studies used general measures of anxiety, with only one study utilising a pregnancy specific anxiety measure as their primary outcome (Karamoozian and Askarizadeh, 2015). It has been suggested in the literature that pregnancy-related anxiety may be a distinct concept which might uniquely predict obstetric outcomes and postpartum mood disorders (Blackmore et al., 2016). Furthermore, pregnancy-specific measures account for anxiety related to health of the baby, impact of previous miscarriages/obstetric complications and first time versus experienced mothers (Blackmore et al., 2016). These pregnancy specific fears and worries have not yet been explored in treatment research, and their potentially transient nature may account for some reductions in symptomology as the pregnancy progresses (Blackmore et al., 2016). Previous literature has also suggested that the use of general measures may hinder the accurate identification of anxiety specific to the perinatal period (Loughnan et al., 2019b). The current review did not compare the use of general measures against pregnancy specific measures. Future studies could utilise a combination of measures to make comparisons across general and pregnancy specific anxiety, with implications for targeting and tailoring of interventions.

In addition, medium size effects were found for group-based and self-guided interventions, but no effect was found for individual interventions. Previous preliminary evidence suggested that individually delivered CBT was more effective than group CBT for women with perinatal anxiety (Maguire et al., 2018) and similar conclusions have been drawn for the treatment of perinatal depression (Sockol, 2015). However, previous research exploring individual versus group CBT for anxiety disorders in children and young people found no significant differences, suggesting that both were equally effective in the treatment of anxiety (Wergeland et al., 2014). A larger body of evidence has evaluated the use of individual CBT in the general population than for group CBT (Whitfield, 2010) and so it is unsurprising that close scrutiny of group versus individual CBT for perinatal anxiety has not yet been conducted. However, the result of the current meta-analysis suggests that both group and self-guided interventions are effective for this population, and that

individual treatment may not offer anything over and above them, this result warrants further investigation.

For mode of delivery, both face to face ( $d=-0.53$ ) and online ( $d=-0.74$ ) interventions showed medium effect sizes suggesting similar benefits. This is the first review to compare internet delivered interventions for perinatal anxiety with face to face interventions (Loughnan et al., 2019a). Although, a meta-analysis directly comparing the use of internet delivered CBT versus face to face CBT in the general adult population suggested the two formats are equally effective in the treatment of a range of psychiatric and somatic conditions, including various anxiety disorders (Carlbring et al., 2018). In addition, it has been highlighted that increasing the types of interventions and mode of delivery offered, such as group and internet based interventions, could have positive impacts on addressing treatment gaps and removing barriers to access (Kazdin, 2017). As such, exploring these factors for the perinatal population may be beneficial in determining the most effective and accessible treatments.

For therapeutic modality, the main therapeutic models utilised in the included papers were CBT and MBIs. Initially, CBT demonstrated a small effect ( $d=-0.36$ ) while MBIs demonstrated a large effect ( $-1.28$ ), suggesting the superiority of MBIs in the treatment of perinatal anxiety. However, this result may be subject to bias as the removal of an outlier reduced the effect size for MBIs to small ( $d=-0.34$ ), suggesting that CBT and MBIs may be equally effective in the treatment of perinatal anxiety. There have been no previous reviews directly comparing therapeutic modality for the treatment of perinatal anxiety. Moreover, there is a paucity of research exploring the direct comparison between CBT and MBIs in the treatment of anxiety in the general adult population. However, in the treatment of depression, accounting for anxiety reduction as a secondary outcome, CBT and MBCT have demonstrated equal effectiveness (Manicavasgar et al., 2011). In addition, both CBT and MBSR have been shown to have equal effects in the treatment of anxiety and depression in individuals with autism spectrum conditions (Sizoo and Kuiper, 2017). The results of our analysis are in line with those conducted for these different populations, therefore, suggesting the applicability of both

interventions in the treatment of anxiety, and comorbid anxiety and depression, in the perinatal period.

Of the 12 studies included, only two were conducted in the postnatal period, while eight were conducted in the antenatal period and two spanned both. Therefore, it was not possible to directly compare the effectiveness of interventions delivered antenatally versus postnatally. Subgroup analysis of the effect of intervention on symptoms of anxiety in the antenatal period found a medium effect, suggesting that psychological interventions are more effective for reducing anxiety symptoms in this period than control conditions. Existing literature highlights that antenatal anxiety is a strong predictor of postpartum mood disorders (such as depression; Loughnan et al., 2019b), therefore, this result supports the notion that delivering effective antenatal interventions may confer positive benefits for both mother and baby. This supports previous research which argues that early intervention antenatally can improve later outcomes for women and their infants (Thomas et al., 2014). However, further research is needed to establish the longer-term benefits of interventions offered antenatally and to evaluate treatments for postpartum anxiety. The delivery of interventions in the postpartum period may differ significantly from those delivered antenatally due to conflicting demands on new mothers (i.e., breastfeeding/childcare) and other factors, such as the impact of disrupted sleep.

This study also aimed to explore the secondary outcomes reported in the selected studies. A number of secondary outcomes were explored within the research, including perceived stress, worry, infant temperament, child behaviour, postpartum bonding and depression. The only secondary outcome consistently reported across studies, however, was depression and so this was the only one which could be statistically scrutinised. It is perhaps unsurprising that depression was measured in the majority of included studies (n=11) given the high rates of comorbidity reported between anxiety and depression in this population (Falah-Hassani et al., 2017). The results indicated that psychological interventions were more effective at reducing symptoms of depression than control conditions, demonstrating a medium effect. This is an interesting finding as it suggests that even

interventions targeted specifically at the treatment of anxiety will have a positive effect on depression. This supports research that suggests transdiagnostic interventions targeting both symptoms of depression and anxiety, tailored to the perinatal period, may be more beneficial than disorder specific interventions (Green et al., 2020; Loughnan et al., 2019a). Further research is needed to explore the impact of interventions for anxiety on infant outcomes.

#### 4.1 Limitations

The current study had a number of limitations. First, inclusion criteria for the review were broadly defined, this was purposeful in order to capture the wide range of anxiety symptomology, however, did not allow differentiation between specific anxiety disorder diagnoses. This means that the current review is unable to draw any conclusions about what works (i.e. therapeutic modality/delivery) for whom (i.e. specific diagnoses). This reflects the heterogeneity in the research evidence. Further research may consider whether interventions tailored to overall symptom reduction are sensitive enough to account for the broad range of presentations of anxiety. Future trials could utilise clinical diagnostic tools in order to draw conclusions about this, however, it is important to consider whether this risks excluding those who do not meet diagnostic criteria but still experience elevated anxiety and would still benefit from psychological intervention. Alternatively, future findings may point to the value of transdiagnostic interventions for perinatal anxiety (Loughnan et al., 2019a).

There are a number of pregnancy and birth related factors that may contribute to increased anxiety in the perinatal period, including hyperemesis gravidarum (severe vomiting; McCormack et al., 2011), preeclampsia (Asghari et al., 2016), significant health concerns for the infant (Gorayeb et al., 2013), pregnancy loss (Markin and McCarthy, 2019) and birth trauma (Weinreb et al., 2018).

Interventions aimed at treating anxiety within the context of these complex factors lay beyond the scope of the review. This review also does not include any studies exploring the use of psychological interventions to treat fear of childbirth or post-traumatic stress disorder (PTSD) in relation to birth trauma. This was due to the fact these papers did not meet inclusion criteria. Both, however, have

strong conceptual links with perinatal anxiety (Nieminen et al., 2016; Saisto et al., 2006) and so their exclusion may represent a significant limitation to the generalisability of the current findings and suggest a gap in the current literature which warrants further investigation.

Due to the small sample of represented studies, and the variance in time points of follow up data, this review was unable to draw conclusions about the long-term effects of psychological interventions for this population. Robust evaluation of treatment effects at follow up are imperative in order to effectively demonstrate the value of these interventions. It is important that these effects are systematically evaluated as previous research has suggested that anxiety symptoms may decrease naturally in the first six months following birth (Vismara et al., 2016) and so this phenomenon needs to be accounted for when exploring intervention effects. The included papers also did not consistently explore long term impacts on the mother-infant relationship and child development. Future research should consider how these factors can be evaluated considering the current evidence to suggest untreated perinatal anxiety is detrimental to both mother and infant (Glover, 2014; Loughnan et al., 2018).

The papers included in this review were all published in the English language and in peer reviewed journals, this may have introduced potential bias towards positive findings. Risk of bias in studies also varied significantly, with factors indicating high risk of methodological bias in a number of studies. It may be important for future intervention research to demonstrate rigorous delivery and treatment adherence by ensuring treatments are delivered by more than one trained facilitator, that treatment adherence is appropriately assessed (i.e. through use of recordings) and that therapist competence is independently rated (Shi and MacBeth, 2017). These measures need to be transparently outlined so appropriate risk of bias assessments can be undertaken. However, limitations based on study quality reflect challenges faced across the spectrum of health-service based treatment research in perinatal and infant mental health due to the nature of the population (Macbeth et al., 2015).

#### 4.2 Directions for future research

In order to draw firmer conclusions, future RCTs need to compare psychological interventions for perinatal anxiety with alternative psychological interventions and modes of delivery, the current research relies too heavily on treatment as usual and waitlist controls. The current research base is also limited to the use of CBT and MBIs, it has been suggested that other treatment modalities such as Interpersonal Psychotherapy (IPT; Sockol, 2018), Acceptance and Commitment Therapy (ACT; Bonacquisti et al., 2017) and Compassion Focused Therapy (CFT; Cree, 2010) may have utility in the treatment of common perinatal mental health conditions, however, these have not received adequate research attention. The bias in the literature towards CBT may be reflective of current NICE guidelines which advocate its use in this population (National Institute of Health and Care Excellence, 2014). The current study also does not explore the differences in clinician delivering the interventions, this may be an important factor to consider as this may influence the intensity of the intervention (i.e., primary care vs. specialist services), the accessibility (i.e., availability of adequately trained therapists and supervisors), integration into existing care pathways and cost-effectiveness. This is especially relevant in low resource settings where access to specialist services, practitioners and financial resources are limited (Clarke et al., 2013).

#### 4.3 Conclusion

This is the most comprehensive and up to date review of the available evidence base of the effectiveness of psychological interventions for perinatal anxiety. This review demonstrates that psychological interventions, including CBT and MBIs, are effective in reducing symptoms of both anxiety and comorbid anxiety and depression in the antenatal and postnatal periods. Given the negative consequences of untreated antenatal anxiety on postpartum outcomes, and women's preferences for psychological over pharmacological interventions, the current review advocates for the availability and use of these interventions in pregnancy, as well as postnatally. In addition, the results support a wide variety of intervention methods and modes of delivery, including face to face,

online, group and self-guided, suggesting that psychological interventions can be tailored to meet the individual and perinatal-specific needs of women in this period.



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***Journal Article 2: Empirical Project***

***Breaking down the barriers: A qualitative exploration of community healthcare professionals' experiences of working with women experiencing perinatal mental health difficulties in the North of Scotland***

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**Abstract**

The current study aimed to explore the experiences of community-based healthcare professionals (HCPs) working with women experiencing perinatal mental health difficulties (PMHDs). Individual semi-structured interviews were conducted with 13 HCPs from across primary and secondary care services. These interviews were analysed using Interpretative Phenomenological Analysis (IPA) from which superordinate and subordinate themes emerged. The main superordinate themes included: navigating a complex system; two lives to care for; “working at the coalface”; “it’s okay to talk about it”; and needs-led interventions. The results indicate that delivering care to women experiencing PMHDs is common across professions, but mental health needs in this period are considered complex and there are a number of individual and systemic barriers to delivering effective, needs-led care and treatment.

**Keywords**

Perinatal mental health; healthcare professionals; care delivery; Interpretative Phenomenological Analysis

## **Introduction**

Perinatal mental health (PMH) is a significant public health concern (Howard et al., 2014; McConachie & Whitford, 2009). Up to 20% of women will experience mental health difficulties during the perinatal period (conception to one-year post childbirth; Griffiths et al., 2019; Jones et al., 2014). PMHDs can have a significant and detrimental impact on women, their infants and their families (Silverwood et al., 2019; Stein et al., 2014). The consequences of unrecognised and untreated PMH can be widespread, in some cases increasing the risk of maternal suicide and infanticide (Galloway & Hogg, 2015; Spinelli, 2004; MBRRACE-UK, 2018). The long-term cost of poor PMH to society is five times the cost of improving services, with a significant proportion of this cost relating to infant outcomes (Royal College of Midwives, 2019). Therefore, the inadequate provision of PMH care across the UK has drawn heavy criticism (Smith et al., 2019). Consequently, improvement in the identification, assessment, and treatment of PMHDs has been highlighted as a public health priority (The NHS Mental Health Taskforce, 2016; Mental Health Strategy: Scottish Government, 2017).

The majority of PMH research has focused on common mental health problems, though, PMH is also complex and multifaceted (Khan, 2015; Rush, 2012; Judd et al., 2018). PMH can be influenced by: previous mental health; trauma; social factors, such as financial pressures and relationship breakdown; and perinatal loss, such as miscarriage and neonatal death (Gandino et al., 2019; Judd et al., 2018). The presenting difficulties women experience may also range from mild-moderate to more severe and enduring mental health problems, such as post-traumatic stress disorder (PTSD; Baas et al., 2017), puerperal psychosis (Spinelli, 2009) and obsessive-compulsive disorder (OCD; Challacombe et al., 2019). It is, therefore, imperative that HCPs, from all backgrounds, in contact with women during the perinatal period, have an awareness and understanding of the complexity of PMH (Higgins et al., 2018; Smith et al., 2019). This knowledge should include an understanding of mental health, parent-infant relationships, and child development, as well as effective treatment options (Perinatal Mental Health Network Scotland, 2019).

### Overview of the literature

National guidelines (e.g., SIGN 127; 2012; NICE; 2014) advise that all pregnant women are asked about their personal and family history of postpartum psychosis and severe mental illness, to improve risk assessment. Effective treatments, including Cognitive Behavioural Therapy (CBT), should be available for those who screen positive for PMHDs. SIGN recommend that psychological therapies be available in primary care for women during pregnancy and postpartum and that access to such services be prioritised; whilst NICE recommend an integrated care plan, outlining the roles and responsibilities of different professionals in the coordination of care, monitoring change and identifying and/or providing appropriate treatments. NICE also advocate the use of psychological interventions for PMHDs either as a standalone treatment or in combination with medication. The implementation of these recommendations, however, remains inconsistent across the UK (Cantwell, 2016; Galloway & Hogg, 2015).

During the perinatal period, women access a range of healthcare services including general practice, maternity, and health visiting services. This offers increased opportunities for the identification of, and early intervention for, those at risk of, or experiencing, mental health difficulties (Noonan, Doody, et al., 2017a). However, less than 50% of women experiencing PMHDs are identified by services (Bauer et al., 2016; Higgins et al., 2018; Howard et al., 2014). Of those who are identified in pregnancy, only 10-15% are offered appropriate and effective interventions (Goodman & Tyer-Viola, 2010; Woolhouse et al., 2009). Individual and systemic barriers may influence the under-recognition and treatment of PMHDs. These include limitations to service provision, staff continuity, time constraints, lack of training, awareness and confidence among professionals, poor relations between practitioner and client, and women's reluctance to seek help due to feelings of fear, shame, and mental health stigma (Bayrampour et al., 2018; Nagle & Farrelly, 2018; Noonan et al., 2018; Viveiros & Darling, 2018).

Integrated working between primary care, maternity, health visiting, and secondary care mental health services may improve PMH care delivery (SIGN 127, 2012; Myors et al., 2013). Pathways and

links between services are, however, not routinely well established, often leading to fragmented care provision (Silverwood et al., 2019). Communication between HCPs may also be poor, subsequently impacting on the risks associated with PMH (Royal College of Obstetrics and Gynaecology, 2004) and increasing delays in the delivery of adequate and effective interventions (Bauer et al., 2016; Gentile, 2017).

The capacity to provide effective PMH care is also hindered by the inconsistent training across several key professions (Galloway & Hogg, 2015). In Scotland, under the Getting it Right for Every Child (GIRFEC) principles, the midwife is the lead professional up to 28 days postnatal, and the health visitor (HV) from 28 days postnatal until the infant attends school (Scottish Government, 2013).

These professionals are, therefore, in an ideal position to screen for PMHDs, offer support and signpost to appropriate services for treatment but many studies show they do not have the training and confidence to do so (Ashford et al., 2017; Hauck et al., 2015; Rothera & Oates, 2011). Training inconsistencies, such as disparities in addressing PMH within undergraduate nursing and General Practitioner (GP) training, may also impact upon prevention, early intervention and management of PMHDs (Rush, 2012). In addition, in the absence of specialist PMH services in some areas, there is a reliance on generic services. For instance, in Scotland, only four out of 14 NHS health boards offer specialist community input (Perinatal Mental Health Network Scotland, 2019). It is, therefore, vital that those in generic services receive appropriate training to deliver PMH care and treatment.

The importance of continuity of care and communication between professionals has been highlighted by women receiving PMH care in the UK (Megnin-Viggars et al., 2015). Women suggest having one key professional throughout pregnancy is beneficial but in many cases this is not routinely available (Raymond, 2009). Women appreciate having time and space to discuss their mental health, yet, in several studies it has been found that they often experience professionals as too busy or reluctant to discuss and address these concerns (Megnin-Viggars et al., 2015; Nagle & Farrelly, 2018). For some women, GP's and HV's were perceived to be too focused on physical health, often seeming to dismiss emotional distress (Chew-Graham et al., 2009; Raymond, 2009).

Concerns were also raised that professionals lacked the knowledge and confidence to manage complex PMH needs, some stating that conversations about mental health felt like a “tick box” exercise (Nagle & Farrelly, 2018; Reddish, 2018). The research demonstrates women’s experiences of disjointed and disconnected care, often adding to feelings of isolation and increasing reluctance to seek help for PMH (Megnin-Viggars et al., 2015; Raymond, 2009).

There are gaps in the understanding of professionals’ experiences of working with women with PMHDs, with only one previous study exploring the experience of mental health professionals (McConachie & Whitford, 2009). Most available evidence is related to the experience of midwives, HVs, and to a lesser extent GPs and obstetricians (Silverwood et al., 2019). For midwives and HVs, working with women experiencing PMHDs is common and forms part of their core activity (Ashford et al., 2017; Higgins et al., 2018; Noonan, Doody, et al., 2017a; Noonan, Galvin, et al., 2017). In both roles, however, it has been identified that there are numerous obstacles to providing consistent care. Midwives have reported feeling under-equipped to address women’s mental health needs due to lack of training and organisational support (Bayrampour et al., 2018; Noonan, Doody, et al., 2017a). The training midwives and HVs receive is often limited to understanding post-natal depression and fails to address the broad spectrum of PMHDs and the complex factors that can influence their development. This can hinder their confidence and competence in addressing the range of issues that may present (Ashford et al., 2017; Higgins et al., 2018; Silverwood et al., 2019). For generic mental health nurses, it was limited experience and training in managing the mother-infant relationship that caused the most anxiety and uncertainty; they lacked confidence in their ability to care for the infant and assess parenting skills (McConachie & Whitford, 2009). In addition, across professions, the fragmentation of service provision and difficulties in interprofessional communication presented challenges to the delivery of care (McConachie & Whitford, 2009; Silverwood et al., 2019).



### The current study

Given the importance of PMH, and the lack of evidence relating to the experiences and understanding of mental health professionals, the current study sought to explore the attitudes and experiences of community-based HCPs from across primary and secondary care services in providing care to women with PMHDs. Therefore, a multi-professional sample was sought (including midwifery, health visiting, and community mental health teams (CMHTs)). The current study also focused on the unique experiences of professionals working in generic services, with limited or no access to specialist care, across both rural and urban communities.

## **Method**

### Design

A qualitative cross-sectional design was used, based on the principles of IPA.

### Ethics

This study received full ethical approval from the University of Edinburgh Health and Social Science Ethics Committee (Appendices 4 & 5) and R&D management approval from the three included NHS health boards (Appendices 6, 7, 8 & 9).

### Sample

Recruitment took place across three NHS health boards in Scotland. The project was advertised via posters circulated by email around relevant groups and displayed in relevant clinical settings. The project was discussed at CMHT and regional perinatal meetings and with service managers. Participants were eligible to take part if they were a community-based healthcare professional, currently employed by the participating NHS boards, with experience of working with women experiencing PMHDs, and able to give informed consent. Participants were excluded if they were not employed by the participating boards or did not have community-based experience with this population. Those who expressed interest in the project were given the participant information sheet (PIS; Appendix 10) and invited to take part. A total of 21 people expressed interest in participating; of those, three did not respond after being given the PIS, two did not respond to dates given for interview, one withdrew prior to interview, one was not an NHS employee and one did not

work in a community-based role. A total of n=13 participants, from across two health boards, consented to take part. All interviews were conducted within NHS facilities.

### Data Collection

Participants completed the consent form (Appendix 11), a demographics questionnaire (Appendix 12) and took part in a semi-structured, individual interview. Interviews were conducted following the principles of IPA outlined in Smith et al. (2009). Interviews were conducted by the researcher, either face to face (n=12) or via telephone (n=1). An interview schedule (Appendix 13) was created to support the dialogue between the interviewer and participant. As IPA is an interactive process, this schedule evolved as data collection proceeded to incorporate important ideas and concepts that were raised by participants. The interview schedule was applied in an open and flexible way, as IPA suggests the main content of the interviews should be guided by the participant and their personal experience. Participants were made aware that the interviewer was primarily interested in their individual experience. Participants were also made aware that they could choose not to answer any of the questions asked. Interviews lasted between 33-83 minutes (average = 57). Each interview was audio-recorded and transcribed verbatim. All identifiable information was removed from transcripts to protect confidentiality.

### Analysis

Verbatim transcripts were analysed using IPA which enabled detailed exploration of participants' personal experiences and interpretation of the meaning that participants gave to their experiences. The sample size of the current study was kept small to facilitate detailed case-by-case analysis, according to the principles set out by Smith et al. (2009). Each transcript was first read in full, one at a time. The researcher then engaged in a process of 'free coding' during which initial ideas and reflections were noted down (Larkin & Thompson, 2011). This process allowed the researcher to be open and curious, and become aware of, and reflect on, any personal biases in their thinking and perceptions. During these initial readings, close attention was paid to the experiences being described, the language being used, and the sense being made by the participants. Following initial

readings, a process of line-by-line coding was undertaken. During this process close attention was paid to the 'objects of concern' (things that matter to the participant) and the 'experiential claims' made by participants (linguistic and narrative clues about meaning of the things that matter; Larkin & Thompson, 2011). The researcher then began to identify emerging themes, first for individual participants and then patterns across all transcripts. These emergent themes were treated tentatively, identifying clusters of terms and phrases to describe the complexity of the subject matter and avoid narrowing or fixing the analysis too quickly. This process of interpretation remained grounded in the original transcripts by continually re-reading to create a dialogue between the researcher and the coded data. This in-depth process led to the identification of superordinate and subordinate themes representing the patterns and meaning across the data.

#### Credibility and rigour

Action was taken to establish the credibility and rigour of the analysis, while acknowledging that there is no agreed approach to undertaking this process (Fossey et al., 2002; Rolfe, 2006). The research supervisor close read and reviewed initial coding for three transcripts. The research supervisor also engaged in the process of coding one transcript and considering emerging themes. This was then compared with the researcher's emerging themes for the same transcript and consensus agreement was established. Superordinate and subordinate themes tables were also provided to the supervisor for comment.

#### Reflexivity

In IPA, it is acknowledged that the process of analysis is influenced by the researcher's own beliefs, personal experiences, perceptions, and biases (Langdridge, 2007). These influences may shape the researcher's construction of the meaning taken from the participants' accounts and, therefore, it is imperative that the researcher engages in reflexivity throughout. The process of reflexivity involves the researcher paying attention to the way their own experiences and biases may influence the way they engage with the participants' data and the research (Finlay & Gough, 2003). To engage fully in the process of reflexivity, the researcher kept a personal, reflexive journal throughout the data

collection, analysis and final write-up; the aim being to ensure that the researcher maintained an open and curious position when exploring the data, noticing when strong judgements or feelings emerged. Excerpts from this journal can be found in Appendix 14.

## **Results**

### Participant Characteristics

Participant characteristics are provided in groupings to protect anonymity. Of the 13 participants, 12 identified as female (92%) and one identified as male (8%). Most participants were aged 50+ (n=9) accounting for 70% of the sample, with two participants in the range of 30-40 (15%) and two in the range of 40-50 (15%). The sample represents the broad range of professions involved in the delivery of PMH care including mental health nursing (n=4), midwifery (n=2), clinical psychology/psychological therapy (n=2), psychiatry (n=2) and health visiting (n=3). The number of years qualified ranged from; less than 10 years (n=1), 10-20 years (n=5), 20-30 years (n=3) and 30-40 years (n=4). Most participants had no post-qualification training in PMH (n=9, 70%) and no post-qualification training in psychological therapies (n=8, 62%).

In-depth analysis revealed five superordinate themes related to the experiences of community-based HCPs working with women experiencing PMHDs. The main superordinate themes will be presented and discussed, the subordinate themes will be highlighted in text (*italics and underlined*). Direct excerpts from interview transcripts are used to demonstrate each theme, ellipses (...) are used to omit less relevant material within these quotations, and square brackets [] are used to remove identifiable information. All superordinate and subordinate themes are shown in Figure 1. Each superordinate theme with a selection of demonstrative quotes is shown in Table 1.

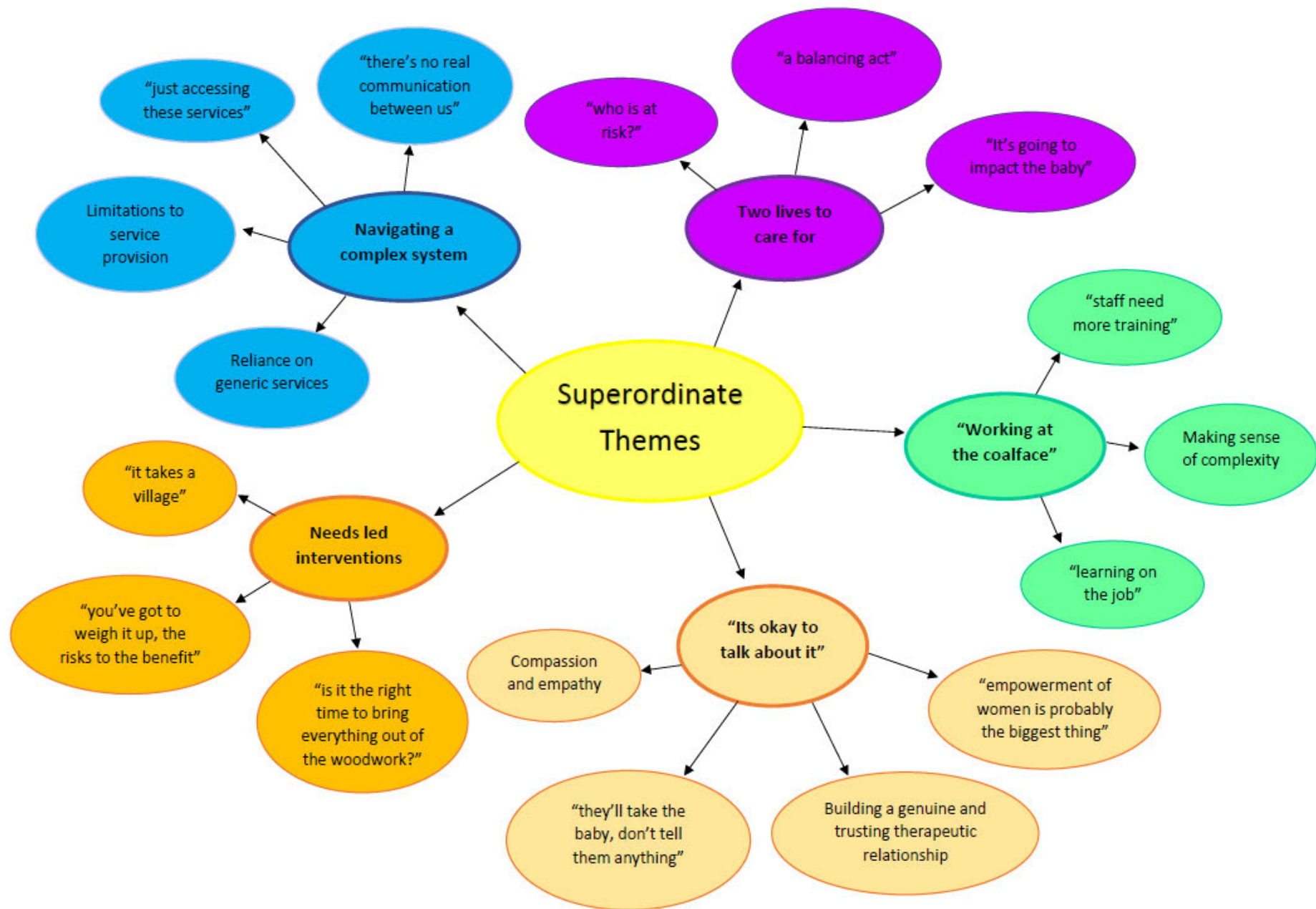


Figure 1: Summary of superordinate and subordinate themes

**Table 1: Superordinate themes with demonstrative quotes**

<b><i>Superordinate Theme</i></b>	<b><i>Demonstrative Quotes</i></b>
<b>Navigating a complex system</b>	<p>“...and just access to these services... having to attend another town for things, it’s not far if you do have a car or you don’t have any other problems, but yeah it’s a big thing to get through to the next village and to get a bus and its only about 3-4 miles away, but you know, if you are relying on public transport that’s pretty rubbish, the times of it and everything...”</p> <p>“...I’m having to do... perinatal mental health plans, in terms of pre-birth, birth, post-birth and stuff and I’m like, oh, not really sure what I’m doing here and then trying to kinda liaise with the midwife ...I’m the one writing it but I don’t...I’m not really sure what, what is available and what’s realistic...”</p> <p>“...I think that’s one of the issues is lack of communication, so whether that is em, down to us or down to them I’m not sure, I think probably a bit of both, that there isn’t any, sort of, dialog between us, there’s no real communication at all between us...”</p>
<b>Two lives to care for</b>	<p>“...so, it was a balancing act between what is right for baby...and what is right for mum...”</p> <p>“... she was too scared to bath the baby, so the baby went weeks...without being washed...she loved the baby, but she had this massive fear that she would drop baby...”</p>
<b>“Working at the coalface”</b>	<p>“I think having a baby... the midwives are always the first one that people will think about... but post-natal depression is more common...so health visitors have got a really important, big role in that...”</p> <p>“...I would say more education for midwives, just working at the coal face with it, because we see a lot of the, the kind of low tariff cases, em, our midwives work with these women and family’s day in day out...”</p> <p>“...if the expectation is that... adult mental health teams are taking on that role, because of course there needs to be somebody that looks after these women, that there is more training... for people like myself to look after them in the best way that they deserve to be looked after...”</p>
<b>“It’s okay to talk about it”</b>	<p>“...that’s one of the things I say about an assessment meeting, I’m assessing your problems and you’re assessing whether you want to work with me or not... I guess levelling things off a bit as far as possible, levelling off the power relationship is important...”</p> <p>“...the most important aspect of that therapy was giving her permission to feel... both to feel negative, unfashionable, politically incorrect and I think, above all, complex feelings. She learnt how to feel two or three different, often contradictory things at the same time, such as... loving and hating her husband...and realising that other women did the same...”</p>
<b>Needs-led intervention</b>	<p>“...so, when people are pregnant...sometimes I would have done something like EMDR, but I didn’t want to, it’s not established what the raising of cortisol would do for the baby... So, there’s times when you think we could do 3 or 4 sessions of EMDR for a previous trauma...and make something a lot better and she would be in a much better place when the baby comes, but nobody knows the effect of that on the baby...”</p> <p>“I also encourage... mums to use their resources as well, whether that be friends, family... anybody that’s out there... whether its mum come up...or its friends...I try and tease out...what they’ve got...in there, kind of, circle...”</p>

### Theme one: Navigating a complex system

All participants spoke of the complexities of navigating the system in order to provide effective care to women experiencing PMHDs. A number of participants discussed the difficulties of "just accessing these services", particularly, when discussing the referral pathway and availability of services. Some participants talked about their frustrations regarding the inability for them to refer directly into CMHTs. In many circumstances the GP was the gatekeeper for onward referral to mental health services and this raised several issues and concerns. For example, it was indicated that this created delays as the referral needed to be made by the GP when often it was the midwife or HV who had developed a therapeutic alliance with the woman, and gained a greater understanding of the problem:

"...I think the most significant challenges are, for health visiting and midwifery, it's probably them being able to engage with psychiatry...there's still some services that will only take a referral from a GP, which is a bit of a waste, you know, you're wasting time, when the person that knows this lady's circumstances best..."

It was perceived that the GPs knowledge and understanding was sometimes dependent on their own interest in mental health, which could lead to unhelpful responses when women did seek help:

"Very variable... unfortunately they don't always get the same response by the GP...and naturally in any kind of profession I guess, there is some GPs will have a, will have an interest in that thing, that side of things and there will be other GPs that are maybe not so...focused on that, so depending on which GP they see will depend very much on how they feel the appointment went..."

Access to, and availability of, GPs could also be inconsistent, especially in rural areas relying on locum practitioners, meaning some women were seen by several different GPs making it difficult for their PMH needs to be fully addressed and supported:

“...they are struggling to get GPs so it’s very much locum GPs there... we’ve got a mum just now...who has been to see a different, has had a different GP every time she went for postnatal depression and its really difficult for her, so... it’s not fair on this mum, having to go and tell her story every time she goes to see a GP, because it’s a different GP every time...”

Perspectives on access to services were more varied around referral criteria and eligibility. With some participants reporting that, in their experience, there were times when the CMHTs threshold criteria were too high, meaning that some women did not receive the support they needed. This made it difficult for these participants to access or offer appropriate support, and it seems this increased the pressure they felt was on them, especially if they perceived a woman’s mental health to be deteriorating:

“...so sometimes the thresholds are quite high, and actually when mums that we’ve identified that we have concerns with, it can be quite some time before they get to the process of seeing the CPN...and we’re the ones really, I suppose, supporting them, in that interim... which can be challenging if...you see a mum deteriorating...”

This seemed to be the case for more complex cases, such as mothers diagnosed with personality disorders, one participant reflected on the stigma associated with this diagnosis. They expressed frustration that the generic service may exclude those with more complex presentations when a specialist perinatal team would accept such a referral:

“...but there’s [not] a huge amount of support there for mums like that...I think it’s probably stigmatised... personality disorders ...I think they don’t always fulfil the criteria, but yet perinatal mental health teams would have seen all parents ...with a mental, with a personality disorder, they would have fulfilled the criteria...to see the psychiatrists, whereas the community teams will not pick up mums with personality disorder ...unless they’ve got a current mental illness...”



In contrast, other participants suggested that the thresholds for perinatal cases being accepted into CMHTs were lower than for non-perinatal cases. This could indicate differences between processes in different teams or localities but may also reflect different levels of understanding and awareness of PMHDs among professionals:

“...I can’t speak for other teams, but certainly in our team, I mean as soon as I hear any perinatal, to me they warrant an assessment, you just don’t, you know, somebody else, if it came through as a depressive episode or whatever you don’t class it as the same as perinatal, for me if its perinatal its priority, they have got to be seen quickly...and it’s not batted back to the GP...”

The need for, and lack of, a structured multidisciplinary team (MDT) approach was identified by several participants in the subtheme *“there’s no real communication between us”*. It was clear that participants regarded relationships and communication between professionals as important features of an effective, integrated, MDT approach to PMH care. There were, however, several barriers to developing such an approach.

Physical barriers, such as working base, proximity, and lack of face-to-face contact between professionals seemed to be key factors in the development of relationships and effective communication. Comparisons were made between urban and rural services. In rural communities it was seen as more likely that different professional groups would be “under one roof” aiding opportunities for informal contact and closer working relationships with colleagues:

“...but I suppose that the beauty of again working in a small community is that you know people, you can see them face to face, it’s not like you’re speaking to somebody you’ve never met before, so from your mental health, health visiting, that wider team, are co-located where I am, so you know exactly where to find people...”

Whereas, in the city it was noted that services are more spread out, meaning this type of informal contact was less common, likely impeding effective communication:

“...here, we’ve got psychiatry here, midwifery over there, you know, it’s just so spread out, and everybody is so busy they don’t easily talk to each other...”

For one participant these challenges were further compounded by the fact they were not aware of where their mental health colleagues were physically based, demonstrating a considerable disconnect between professionals and services. This participant compared their experience to a previous service they worked in where these relations were much better, allowing for a more joined-up approach:

“...we used to do joint visits... I would do joint visits with the CPN, we had quite a good relationship, ... but here... I don’t even know where they are, I think they are downstairs somewhere, I’m not sure where they are based... as I say I have spoken to one on the phone, but it would be nice to have a better relationship with them, that’s maybe something to work on...”

Uncertainties about the roles and expectations of other professionals involved, as well as the fact there are no standardised processes for care delivery also created challenges for effective communication:

“...it’s really difficult, I mean the midwives are just next door... but we don’t have like any formal meetings... so I would say...that its quite poor, the communication, we would perhaps get it in the discharge, when we get emailed the discharge, there might be something in there about it but not very often... we’re not aware... that somebody’s maybe... sort of additional during pregnancy due to mental health...”

Some felt that their role was underestimated or missed because of misconceptions about what they do. It seemed this meant that, at times, they were left out of the conversation, leaving a sense of

feeling undervalued, and potentially leading to a fragmented approach to care if a key figure is overlooked:

“...people don’t know what a health visitor does ...it’s that, lack of understanding of the role ... we’re seen as weighing babies and giving immunisations and that’s the kind of perception that some people have, and I mean I think probably that’s been a barrier... to us being involved in a lot of the conversations as well...”

For one participant, it was felt that despite their attempts to clarify their role and responsibilities with colleagues, there remained substantial pressure to take on inappropriate cases. This participant also reported there was limited communication about these decisions before these referrals were made. This represents the impact of limited referral options available to professionals, further reflecting the disconnect between services and demonstrating the pressure placed on limited resources. For this participant it was also clear that this lack of understanding and pressure had taken its toll and left them feeling disheartened, alone and questioning whether they want to continue this work:

“...I just don’t know if I really want to do that anymore...I feel really supported and midwives and health visitors... but mental health... it’s just like I’m here, they’ll just send to [], just send to []...everything is fine as long as it goes okay... but such is life, everybody is so busy with their own stuff and, they just don’t really understand what I do anyway...”

For other participants, the lack of standard processes further complicated their ability to engage in effective communication. It meant they were often unsure what other professionals wanted or needed from them, meaning that they just had to “muddle through”. This increased the potential for important information to be missed, especially with regards to risk, and left participants feeling uncomfortable. This further highlights the challenges of fragmented care provision. It seemed participants felt that care delivery could be much improved by clearer communication:

“...I guess you just try and get on with it and do the best job you can, but I think, it could be much better...that’s when it becomes more risky, where there isn’t that communication, you’re just trying to muddle through, like it shouldn’t be like that, you shouldn’t just have to be muddling through... with these cases where there’s babies involved and mums involved... it just doesn’t, it’s just not right...”

“...you know yourself, that when our cases don’t go well... and we look at where we failed along the way, it’s always communication, breakdown of, somebody failed to pass that on to somebody else, so that’s always at the forefront of my mind...”

Several participants thought that a specialised MDT team would be beneficial in improving professional relationships and communication, and ultimately patient care. It was acknowledged that often PMH cases are complex and so a structured team approach is needed, which for many participants was not their current experience of care delivery. It was suggested that having an identified group of professionals would be helpful so that they could then get to know and understand each other better, aiding effective care and communication, and an increased awareness of others’ expectations and responsibilities:

“...that’s why it’s so important for us all to be working together and in something like perinatal... it’s really important, I think, to identify a group of people who can manage that subset of patients and understand each other’s discipline better.”

“...it really just depends on who you’re working with, and I guess in some ways we’re relying on them telling us some of the things and vice versa, I suppose...it doesn’t feel the greatest, that, it would be much better if there was some sort of pathway and everybody kind of knew what they were doing, what their responsibilities were...”

In the absence of a dedicated PMH team, it was clear that *reliance on generic services* and *limitations to service provision* further increased the challenges of navigating an already complex system. With limited access to specialist services, it is generic mental health services that provide

PMH care. However, it was discussed that this was an expectation that had been placed upon participants in these services without additional training or support being offered to manage such cases:

“...it’s something that I’ve not had additional training for, but we’re still... I guess expected kind of, to look after these cases...”

For one participant, this seemed to feel like an inevitable process, that often adult mental health becomes the “catch all” when specialist resources are unavailable, an experience that seemed to cause frustration and a sense of obligation:

“...at the end of the day when perinatal services were removed ...I still see them...so we’ve all just absorbed that, general adult psychiatrists have just taken that back on again...So I guess if you, if resources are down here then it just has to be general adult doing everything...”

At times, generic services are under pressure to cater for many different client groups, meaning staff do not have time to prioritise learning for perinatal specific issues and instead follow the same protocols as for generic mental health:

“...but we’re expected to cover lots and lots of stuff, you know, veterans, whatever, you know, there’s just not time to prioritise all that CPD for perinatal.”

One participant expressed significant frustration at what was felt to be a lack of understanding of the requirements and nuances of PMH by those in generic adult mental health settings. They indicated that uptake for training and consultancy opportunities was low amongst their mental health colleagues. The participant explained that in practice this lack of knowledge was sometimes extremely evident, despite repeated efforts to establish training opportunities:

“... the midwives... were concerned that this lady would...become a psychiatric emergency overnight... the CPN actually said, but we know when she’s becoming unwell and it usually

takes a couple of days, so I had to step in and say no, this is different, she can become unwell within a matter of hours, this could be a very dangerous situation for the staff and the lady...”

“...that’s just one example of...knock your head off a brick wall because there’s so many practitioners that think they know all about perinatal mental health and then you find out they don’t.”

*Limitations to service provision* were emphasised by those participants working in rural communities.

It was highlighted that service provision, by way of local community resources, was limited in some areas and women are required to travel significant distances to access services, further serving to isolate those who cannot travel easily, especially given reduced transport links in some rural communities, and indicating a need for more community-based initiatives. This is especially true if women have had a caesarean section and are unable to drive for the first six weeks:

“...because of the rurality here, that there’s got to be services local...we’ve got mums who have had caesarean sections for instance that won’t be driving for at least the first 6 weeks...so can’t be independent at getting themselves to an appointment...so that’s a huge barrier...”

Concerns regarding the significant distances women must travel to access services were raised by nearly all participants, with access to the regional Mother and Baby Unit (MBU) being mentioned as a major issue. There is no capacity to admit mothers with their babies to psychiatric facilities locally and so there is a choice women have to make between accessing a specialist unit, where they can remain with their baby but at a significant distance from their families and other support networks, or be admitted locally but without their baby, in an environment that is not designed to meet their specialist needs, but where they remain as close to home as possible. This was regarded as a hugely difficult dilemma for families:

“...if they do need an inpatient admission, it’s Mother and Baby unit 1, so that puts a lot of strain on families, on mothers... they don’t have the same supports down there... like I’m saying, we’ve got somebody in the ward just now that doesn’t want to go there because of the travel, it would mean more isolation, less contact with the children she already has...”

One participant called it a “Hobson’s choice”, meaning that really, they get no choice at all:

“...well, they do get an option but it’s not, it’s a Hobson’s choice option, it’s if you want the Rolls Royce service, you’re going to have to go a long, long way away...it’s not only distance in miles, it’s you’re going to have to be cared for by a different team who you don’t know...”

It seemed that developing and improving service provision for PMH had also been impeded by organisational challenges. Several participants commented that difficulties recruiting a specialist psychiatrist in PMH had significantly impacted service development:

“I think the problem just now is there’s not any leadership in it here locally, because we can’t get anyone to do that... you need leadership, you need vision...it’s got to be somebody’s pet subject, and we don’t have that, there’s [multiple] vacancies across Scotland for consultant psychiatrists, it’s not going to happen quickly.”

### Theme two: Two lives to care for

All participants reported feeling they had two lives to care for in providing PMH care, and that it was always necessary to carefully consider and balance the needs of both the mother and the infant. Many participants discussed feeling increased pressure and responsibility due to the risk of harm to mother and infant, leading them to question *“who is at risk?”*. The risks were considered complex and included fear that a mother may cause direct harm to her infant or indirect harm through neglecting her baby’s physical or emotional needs. Two participants discussed their fears around both suicide and infanticide; the emotive language used gives a clear indication of the significance of these risks, the need for clarity around professional responsibility and importance of robust and clear service processes:

“...all psychiatrists live in fear of suicide...homicide, but infanticide is your biggest nightmare ...it’s absolutely the thing you want to get to the end of your career...and not have someone kill their baby...”

“...I have never had any suicides [knocks on table] or infanticides...that’s why I had to touch wood there, I would carry that around with me...”

The participants commented on the fact that managing such risks was further complicated by the differing views and perspectives between professionals involved and the lack of a shared approach and understanding. The way risks were perceived, and reacted to, seemed to differ particularly between those in mental health and non-mental health professions. It is possible that this related to different training backgrounds and experience of managing increased levels of risk. This seemed to create tension between professionals, especially when some perceived others as responding in a potentially ‘unhelpful’ manner. It is possible, however, that what was perceived by some as ‘unhelpful’ was a response to the emotional burden of shouldering such risk and managing the uncertainty caused by these situations. In circumstances where there is not a clear MDT approach to risk, some may feel they have limited control over decision making. For one participant, they felt increased anxiety and personal responsibility in these circumstances:

“...there was a lot of responsibility put back to her family to care for her at home...so I really struggled with it... I felt completely responsible... and it wasn’t my decision, but I just felt because I was her lead professional in her pregnancy that if anything had happened to her, I would have felt that we had failed her... although my mental health colleagues reassured me that this is their day job, they work with client groups that express that on a daily basis...for me as a midwife it was not a usual thing for me to know that there was somebody at home with these thoughts and making plans to see it through... differing perspectives completely, and regardless of how many times I spoke to the mental health colleagues, it still never made me feel at ease at all...”



It is possible that without robust and well-established relationships being in place, with an awareness of the point of view of each other, different professional groups are unlikely to be able to support each other to effectively manage the emotional demands of holding such risk.

The short- and long-term impact of PMH on the infant and child development was also discussed by most participants and captured in the subtheme *“it’s going to impact on the baby”*. Concerns were raised regarding the impact of PMHDs on early bonding and interaction with the infant. Some participants discussed that they felt that a mother with depression was less likely to engage with her baby using a range of dynamic facial expressions and it was feared that this could impact on the baby’s social and neuro development. Participants also reflected that mothers were usually able to engage in the practical aspects of their caring role but may have struggled to attend to the infant’s emotional needs which caused concerns for infant mental health. These difficulties may be subtle and require practitioners to have a framework for understanding infant psychology and development. Hence, developing skills, knowledge and confidence in these areas to aid understanding; the identification of potential difficulties; and the offering of correct support, are needed for all practitioners working with women in the perinatal period, and not just for those in specialist services:

“...two people to care for...right away, you’ve not just got one...you’ve got...the needs of... the baby, cos it’s one thing mum not looking after herself, but mum not looking after baby...and that could be everything...from emotional to... practical...your assessing as well of just that engagement with baby...are they giving baby eye contact, are they looking after baby...because a depressed mum, it’s so easy for them to do the jobs, but there not actually engaging with baby, you know, just the ‘goo goo’s’, the ‘ga ga’s’, that sort of thing...to a lot of mums it’s, it comes quite natural...but to a depressed mum it doesn’t...”

“... so for me it’s about that interaction between the baby and the mum as well, if you’ve got a mum with a very low mood, very flat...features, the baby’s not going to get that

feedback...the baby's not going to get that... you know she'll attend to the babies basic needs...but it's the other stuff... round the baby's development and we know so much more about the interactions...between the mum and baby's brain development... so if you've got a mum that's very flat and not got that dynamic face...it's going to impact on the baby and that can be quite...alarming."

The subtheme "*a balancing act*" highlighted another important aspect of care provision, balancing the needs of mother and baby. This could be challenging, especially when these needs did not necessarily align. An example of this was given by a participant discussing the impact of having an eating disorder on a mother's ability to breastfeed effectively, while the woman had a desire to breastfeed the participant had to ensure that the baby's nutritional needs were met:

"...I was checking baby's weight gain for instance...and also checking that baby was...getting enough milk and that the milk was good enough quality...for the baby to survive...so it was a balancing act between what is right for baby... and what is right for mum..."

Within this subtheme there was divergence between participants, with one participant discussing that, while balancing the needs of both mother and child, their primary focus is on the health and wellbeing of the infant, and another stating that their focus is primarily on the mother and commenting that it can be unhelpful to focus purely on the infant. This likely reflects the different professional backgrounds of these participants and, therefore, the perspective and role they take:

"...we are always keeping the child in the centre of our assessments and naturally, part of that process involves parenting and how well parents are managing...or health-wise, there could be physical illness or mental illness, so parents' health is always encompassed in that assessment... but because our focus is always on how does this impact the life of the child...then it's a huge thing when there is an identified mental illness..."

"I always, always focus on the woman... I don't think that you can prioritise the baby whether they're born or unborn and still be therapeutic... towards the woman, and it can

even be counter-productive...it's so easy for the patient to feel like she's only valued as the vehicle for this baby..."

This may further demonstrate the need for an MDT approach to ensure a careful balance is struck, holding in mind the needs of both mother and infant. It is likely that the need to ensure that a woman feels heard, contained, cared for and acknowledged, while also ensuring the safety and wellbeing of the infant, will be essential in the delivery of care during this vulnerable period.

### Theme three: "Working at the coalface"

Participants from both mental health and non-mental health settings described working with women experiencing PMHDs, suggesting that every professional has a role to play in the active delivery of care. For those in non-mental health settings, it was felt that women presenting with low-level, mild to moderate difficulties was a common, shared experience for them and part of routine care:

"...I would touch on it at most opportunities during pregnancy...I think we've moved away, as midwives, from just doing blood pressures...and checking tummies, cos it's the whole gamma of their being, their wider world...that you're discussing now...it's just...part of routine care..."

Even though all participants discussed their experiences of delivering care to women experiencing PMHDs, many highlighted that they had had no formal training in PMH and several described only "learning on the job". A number of participants across both mental health and non-mental health settings discussed that they received no PMH input during their core professional training:

"...there was no perinatal mental health training throughout health visiting, from the university point of view, things that I learnt while I was on placement, from the practice teachers that I was working alongside... so I very much learnt from their knowledge..."

“...I don’t even remember having any...that’s not to say, we might have had one presentation, no it was minimal, it was minimal...in fact I don’t, I couldn’t be sure we had any perinatal training at all...”

With one participant explaining that students are ‘sheltered’ from the more difficult side of the work:

“I think you’re sheltered from it... anything from... still births... early loss, that type of thing, you really don’t get experience of that until you’re qualified, so in terms of your question about training, as a student, no, the serious stuff you start learning once you’re qualified...”

It seemed that the view that learning is based on experiences and the knowledge of those in senior positions was common. This means it is possible that there are inconsistencies in the knowledge base across individuals in these key professions, which is dependent on exposure to these situations. It is, therefore, unsurprising that all 13 participants indicated that *“staff need more training”* in relation to this client group. In particular, the need to increase training to support professionals to have difficult conversations with women about more complex issues, such as experiences of trauma and suicidal thoughts, was raised. Concerns were highlighted that some professionals may be misinformed about these issues, leading them to avoid important conversations:

“...there was a health visitor who said to me, ‘I just don’t ask question ten in the Edinburgh Postnatal Depression scale’, which is about harming yourself... she was like ‘oh I just don’t ask that’, and I said, ‘why, you’re opening up a conversation’ and she says, ‘oh I’ll just put it into their heads to do it’, and I was really quite shocked with that, but apparently it was quite a common thought, that if you speak about it I’ll make them do it...”

It was suggested that the issue may be that professionals lack the confidence and training to have these discussions:

“...probably confidence, I think that not having that training... if you’ve not had that training... everybody speaks about, we all go into visits and we talk about domestic abuse

because we've had that training, so we routinely ask... about domestic abuse at certain visits because we know that... but we don't routinely ask about mental health, we will go in and say how are you...and they say they're fine, 'Oh I'm fine', and that's it..."

It was felt that increasing professionals' awareness and understanding would help to make PMH 'everyone's business', further integrating PMH into routine services and encouraging mothers to seek help:

"...I think that more awareness... of perinatal mental health...that needs to be more, I know we talk more about mental health now... but I think it's very generic...there should be more focus on perinatal mental health, I think that professionals, as well, when they come in to the midwifery service, when they do their booking that it should be, kind of, intertwined into all of their appointments..."

In many cases, participants described a complex interplay of psychological, social, environmental, biological and historical factors which could influence the development of PMHDs. Therefore, it would seem that a large part of a professional's role is *making sense of complexity*, which may be a difficult task when you consider the reported lack of specific, PMH training opportunities. Those delivering care discussed supporting women experiencing a range of difficulties and emotions in relation to the transition to motherhood, including the impact of loss of identity and how this affected a woman's confidence, leading her to question her ability to be a mother:

"...her view of herself had been entirely robbed by no longer being...totally confident and good at everything... she said herself that she felt more like a dependent little child and of course, the attachment to her husband, to me, to her mother... was not at all what she had been used to and she was starting to worry about how she would actually be the mother..."

As well as the common feelings women have of not being good enough, and the expectation that they "should" know what they are doing and be able to cope:

“...I think... they feel a sense of failure... that sort of, they shouldn't be feeling like this, this should be a happy time, I shouldn't be feeling, I should love this baby, I should...and it's like, guilt I think, guilt and failure...”

At times, it is possible that these types of experiences may influence whether a woman seeks help for her mental health and so it was considered important that professionals working with women experiencing PMH have an awareness and understanding of these factors and are able to confidently raise as part of their discussions with women in a normalising and validating way.

A history of mental health problems, adversity and trauma were also discussed as vulnerability factors for developing PMHDs. One participant discussed some of the complex issues they came across in their work as a midwife, including women who have had previous baby loss or who have experienced sexual violence. It was reflected that these can be difficult issues to hear and talk about and, at times, being expected to know what to do to support women in those circumstances felt overwhelming. Another participant reflected on the increased levels of complexity if someone has a history of trauma and adversity, coupled with a traumatic birth:

“I have thought that more latterly, it seems the, you know, asking someone about how their mood is postnatally, or a little bit antenatally is almost, in comparison to now, some of the things women are actually telling us is... oh I know all about that, I know how to deal with this side of things...but it's all these other huge things...”

“...that group are more difficult to deal with, childhood adversity often... abusive relationships... and then a problem, a real problem with childbirth...”

It was expressed across participants that managing these complex factors, understanding how they can influence both the development of PMH and the mother-infant attachment was challenging due to the limitations to service provision, access to services and lack of training opportunities already discussed. In addition, practitioners at the 'coal face' are further expected to hold in mind other possible factors including hormonal changes, adjusting to breastfeeding, sleep disturbance, and

social contributors such as poor housing and poverty, which may further complicate assessment and decision making as to whether a woman needs further mental health support, and if so, what pathways are available in their locality.

Theme four: "It's okay to talk about it"

In delivering care to women in the perinatal period the importance developing a compassionate and empathetic therapeutic relationship which allows women to feel safe to talk about their mental health, was highlighted across all transcripts. The importance of *building a genuine and trusting therapeutic relationship* was discussed by most participants. It was highlighted that getting to know the women and building these relationships facilitated difficult conversations and created a safe space for women to open up about how they were feeling. It was reflected that once this relationship was in place, conversations about mental health happened more naturally. An example was given that establishing a relationship allowed one woman to disclose traumatic experiences for the first time, aiding referral to the appropriate service. For this participant, it seemed that being that trusted person was a great privilege, and it demonstrated that this was a rewarding aspect of their role:

"...because we built up a relationship, she was able to start talking about two terminations that she'd had... it's something she had never spoken to anyone about, so I was really quite privileged with that, I was then able to refer her on to... birth trauma work..."

The importance of taking time to listen to a woman's experience and understand all the factors contributing to distress was emphasised. This indicates that participants are thoughtful about how they engage with women to help them feel validated and understood:

"...I find that on my first contact with mum, if I give them time to describe to me how their labour and delivery went... and given them time to ask me questions as well...so often my first visit is quite a lengthy visit...and if I get that right... if we manage to have time to have a

good conversation I think going on from that point it can be much more positive...in relationship building..."

In the subtheme "*they'll take the baby, don't tell them anything*" the majority of participants discussed the importance of recognising women's fears about discussing mental health. This awareness allowed them to ensure they approached conversations about mental health and risk gently and thoughtfully. Participants discussed fears women had which they perceived influenced help-seeking including fear of judgement and fear that their baby would be taken away. Sometimes these fears meant that women were reluctant to attend community groups that were considered helpful. This seemed to cause some disappointment for one participant because of their awareness that these are not uncommon feelings and that it could be beneficial for clients to attend such groups and gain peer support:

"I think it's the fear that they're not managing and they're going to go into a group of super mums... we know that's not the case, as I say 90% of them are probably struggling, to some degree, but for some reason... you think everybody else is a super mum but you're not, so it's like putting yourself into the lion's den isn't it...so to try and get somebody there is, that's a feat on its own..."

Participants discussed their perceived role in addressing these barriers to seeking care, it was clear they were passionate about this responsibility:

"...we can look at all the symptoms, the sleep, the feelings of guilt, the not wanting to go out ...it's just generating that discussion around their mental health and trying to cut down... break down the barriers..."

"...but we've still got that taboo... how do we shift that... as a midwife working with women...I have a responsibility to... kinda, thingmy that taboo to women, and reassure them..."



Compassion and empathy were seen as invaluable qualities in engaging women, building relationships and facilitating their journey through the perinatal period. Several participants reflected on how the experience of being a mother themselves increased their capacity for compassion and empathy:

“...I think now I’m a mum myself...that potentially makes it easier... I was quite young when I qualified... without really any experience of being a mother, what that was like, and then on top of that to have a mental illness as well and trying to bond with your baby and, all the other things that come with that, I guess I didn’t really appreciate...I suppose I’ve got a different perspective on it...now that I’m a mum myself...”

For two participants their personal lived experience of PMHDs has likely helped them to further understand the complexities of what their clients experience. Through training as a midwife, one participant was able to start to recognise some of difficulties they had opening up about how they were feeling after having their first child, which perhaps gives a unique perspective for supporting other mothers:

“...becoming a midwife, I identified feelings within myself, when I had my first child that... was a big similar thing... looking back on it, you’re trying to do the best that you can at the time, but looking back you can see that, there were issues, and as much as health professionals, we’re wanting to help, it would have helped if I had opened up, but I just didn’t feel like I could and just wanted to get on with it and do that...”

A significant number of participants felt that empowering women to ensure their voices are heard and that they have all the information they need to make informed decisions and choices about their care was an essential part of their role, demonstrated in the subtheme “empowerment of women is probably the biggest thing”. This was discussed within the context of childbirth. It was raised that if women feel listened to, heard, and respected during their birth they are less likely to experience the birth as traumatic even when it does not go to plan. The long-term impacts of women feeling they

were not listened to during this process, a time when they are exceptionally vulnerable, were discussed:

“...one lady who had a very difficult birth... felt that she had said no to a procedure that the consultant gave her...and that that was ignored...it got very complicated and the baby got whisked away... while they were still kind of sorting out mum, she didn't know what had happened to the baby... so it's had huge knock-on effects for her...”

In contrast, another participant discussed a woman's difficult birth experience within the context of her feeling empowered and respected:

“I had a lady who had a failed ventouse, a failed forceps and an emergency section and she'd come to the class and I thought oh my goodness that book is going to get thrown at me... she's going to say stuff your hypnobirthing and when I went in she said 'I would have a baby again tomorrow, that was amazing' and she said... that one of the doctors came in and said, 'you are doing this hypnobirthing', so they acknowledged that, they didn't make fun of it, didn't belittle it or anything, acknowledged that she was doing it...”

“...he said 'we have time, this is what we can do', and he actually gave her options and she chose the ventouse, then she chose the forceps and then she chose the emergency section, she said it was the most empowering situation she had ever been in because she had been given that choice...”

#### Theme five: Needs-led interventions

All participants discussed a range of informal and formal support and treatment options they felt would be beneficial for women with PMHDs. They spoke of both the facilitators and barriers for women accessing such interventions.

“Is it the right time to bring everything out of the woodwork?”: All participants discussed the role of psychological therapy as an intervention for women with PMHDs. However, there were mixed opinions around its use in the perinatal period, with some advocating its utility and benefits, and

frustrated by the barriers to access, and others encouraging caution. For some, it seemed frustration came from a feeling that the decisions around offering therapy were not always needs-led, and that often they were based on service factors, such as generic services not prioritising perinatal women and long waiting lists, or individual practitioner factors, such as beliefs or assumptions about therapy:

“...I like to follow the SIGN 127, the national guideline...but one thing is, perinatal women should be prioritised by psychological services...but they don't do that...they tend to want to wait until after the baby is born...when actually a lot of the work could be done prior to the birth of the baby in preparation...”

“... we all know that that would be a benefit to women but we, again, there's never a kind of opening for that to happen... I don't know if I've ever saw a mum actually get talking treatments...I think often the perception...is that they're not in a position to do these, some of these more intensive...therapies... so they're probably not referred at that time...”

Several participants commented that there seemed to be a reluctance to offer therapy in pregnancy, and a preference to wait until the postnatal period. This seemed to stem from the unknown impact therapy would have on the fetus or assumptions about a woman's ability to engage:

“...the worry is people become very anxious during therapy... so the concern would be... that surge in stress hormones from the mother, is that transmitted to the baby...does that have any long term effect, and the argument... is, if she is having flashbacks, she's getting that effect anyway and if the treatment is relatively brief, and its effective, then probably the balance is in favour of, this is beneficial, especially, if it gives her some resilience for the birth...”

For some, it was felt that this was a missed opportunity for early intervention, to engage in preparatory work to help women cope better when the baby arrives:

“I think a lot of the time, the difficulties mums are having... often stems from previous experience...of how they were parented for instance...and becoming a mum can often bring things back to when they were a child and how their parents interacted with them, so I think that’s a really important thing to focus on at the same time...so you can deal with that and support them in making it different for their own child...so I would feel that that, kind of, joint approach would be more beneficial, rather than waiting...”

It was argued that therapy could be adapted to meet the woman’s needs, focusing on what was most important to her at the current time and not confronting anything she was not ready for. Ultimately, the aim was to improve quality of life and build resilience for the transition to motherhood:

“...if we decide that there’s nothing to process, or its inappropriate to do any processing, then we will work on what, what gives the woman more resilience... and more peace of mind, because I think that, I mean the over-riding thing is, can you improve the quality of their life...so that trauma confrontation is not... desirable for everyone...”

On the other hand, some participants expressed more caution, perhaps feeling that the perinatal period is not the right time for therapy due to the conflicting demands on a mother’s time, and other factors, such sleep deprivation and childcare arrangements, which may impact ability to engage. For some it was a feeling that it was too much of a time commitment, especially if it was longer-term therapeutic work, and for others there was a worry that therapy might place increased pressure on a woman already struggling to manage:

“...I know that certain...psychotherapy and things like that, I guess you’ve got to think about the timing for the person...after having a baby and things, is that the right time to be doing therapy? Is always the question isn’t it, is that appropriate, are they going to manage that? Because there’s so much else going on... is that an added pressure that’s too much...”

It was clear from the debate around psychological therapy that all professionals wanted to do what they felt was best for their clients, but, the lack of perinatal-specific therapeutic options, tailored to meet the particular needs of women in the perinatal period, may have influenced their opinions.

There seemed to be a set idea of what therapy “should be”, perhaps undervaluing the benefits of a psychologically informed approach and illustrating that the system, and so the available options, is fixed and inflexible:

“...sometimes it is about supporting them while they’re waiting and until they’re ready, there’s an awful lot going on isn’t there, hormonal stuff going on, lack of sleep, lack of money if they’re, if they’ve stopped working... changes in relationships, other kids, you know there’s an awful lot going on, it’s hard to come and do 10 sessions of CBT for social phobia or something...”

Further demonstrating this, one participant spoke specifically of the unmet needs of a select client group, women with a diagnosis of a personality disorder, and that perhaps services were limited for those with complex needs in the perinatal period, echoing comments made earlier around access to services:

“...the best treatment for personality disorders is talking therapy and pregnancy is not the time to do it, immediately post-natal is not the time to do it either... I think it’s often the time commitment... I think if you present when you’re 5 months pregnant...to say right I want you to go and have an assessment and think about attending a group for the next 6 months they can’t do it... they just can’t do it... is it the right time to bring everything out of the woodwork? I’m not entirely sure it is, I think when your hormones go through the roof, it’s not the best time...”

The use of medication in pregnancy and breastfeeding were discussed in the subtheme *“you’ve got to weigh it up, the risk to the benefit”*. It was considered an essential aspect of needs-led interventions to be able to offer women all the information they needed to make informed choices

about medication. Many participants indicated that women were cautious in their approach to medication, and that at times they are reluctant to take medication, namely because of the unknown impacts on the fetus and infant. Participants themselves accepted that some of the risks of medication are unknown, but they argued that the risks of not taking medication might be much greater, in terms of the impact of untreated mental health on both the woman and her infant, and so they felt it was an important part of their role to help them weigh up the pros and cons:

“...there’s not a lot of evidence base of medications, how safe they are, and the baby, because you can’t obviously test pregnant mums, but the evidence base is... a depressed mum is more damaging than any medications ever going to be...”

In one case though, it was felt that they had no option other than to offer medication as a “quick fix” in the face of having limited alternative options, it was clear that this participant often found themselves in a deeply difficult and challenging dilemma:

“The waiting list is about 18 months just now and it’s like, their child will be going to nursery, all the damage will have been done, when we look at infant mental health... it would be brilliant if we could get some talking therapies as early as possible, possibly in the pregnancy itself, which again they tend not to... it’s a shame but so often we have to resort to the quickest fix, which is medication... with no counselling or...support during that time and that would be the time to do it, when the woman is feeling as well as possible on the medication, but I need a quick fix, and I need a quick fix for the infant’s mental health, so we’ve got the eye contact and all these little pathways being laid down...”

The need for good quality formal and informal community, peer, and family support were highlighted in the subtheme *“it takes a village”*. The real emphasis from participants was that not only should interventions be needs-led, but there should also be a range of options available locally. The lack of local early intervention and support options for mild to moderate difficulties was raised, with the implication that often women get to “breaking point” before they seek help and

highlighting a major gap in terms community-based initiatives at the lower tiers. This is hugely concerning given the fact that prevention and early intervention could mean better outcomes for women and families:

“...usually a lot of people have gone quite far down the line before they’ve sought help...which is such a shame because if it was caught earlier it might not even involve medication...it could involve a few sessions of just normalisation...with somebody, of this is okay...to feel like this, it’s okay to be tired, it’s okay to think thank goodness you’re in bed...cos the guilt is just massive...”

As part of this, education and awareness seemed important, particularly ensuring that partners and other family members are aware of the signs of PMHDs, helping them to support the woman and be aware of when to seek help:

“...I will say to, to partners when I do, when I talk to them about mental health, I’ll say you’re probably the one that will notice the change before...she does, the mum does...you may notice she’s becoming...more emotional, or maybe more snappy or she’s maybe...just a wee bit of change in personality, it’s just not her...and that would be maybe a red flag for you...”

The participants discussed that, at times, formal interventions from mental health services may not be what a woman or family needs. However, due to limitations to service capacity, providing education and awareness to women and their wider families was not routinely, or consistently offered across the workplaces of the participants sampled. It was clear that the lack of available community and peer support options made delivering needs-led care all the more difficult.

## **Discussion**

The current study emphasises that, from the practitioner perspective, providing care to women experiencing PMHDs is complex, both in terms of understanding and caring for the individual and navigating the wider system. Participants raised several facilitators and barriers to providing care and treatment to women experiencing PMHDs in non-specialist services. In line with previous

research exploring the views of HCPs and perinatal women, these included a variety of individual professional, patient, team and organisational factors (Ford et al., 2019; Smith et al., 2019; Viveiros & Darling, 2018).

The system within which care was provided emerged as a key barrier. These systemic barriers included limitations to referral pathways and service provision, reliance on generic services and fragmented communication between services. In the current study, midwives and HVs inability to refer directly to mental health services highlighted a disconnect between key services delivering care, seeming to delay timely referral to appropriate services. This type of 'broken referral pathway' was also seen to impede access to PMH care in previous research (Viveiros & Darling, 2018). The view that services are disjointed and fragmented when it comes to the delivery of PMH care was supported by previous literature (Bayrampour et al., 2018; Silverwood et al., 2019; Smith et al., 2019; Sword et al., 2008). A recent survey identified organisational factors, such as lack of specialist PMH services, absence of care pathways, heavy workloads and lack of time, as the greatest barriers to the delivery of PMH care (Higgins et al., 2017). The lack of clearly-defined care pathways, limited resources and access to appropriate interventions were frequently raised barriers in the current study and existing literature, making it difficult for professionals to know how to respond when PMHDs were identified, especially in primary care services (Jomeen et al., 2013; Noonan, Doody, et al., 2018).

Participants within the study recognised that quality PMH care requires an integrated, MDT approach. It was acknowledged that this approach was influenced by relationships and communication between professionals. In cases where these were lacking, this was a significant obstacle to the provision of safe and effective care. Where these were positive, they were regarded as facilitators to the provision of care. The barriers to building relationships and engaging in effective communication included a lack of physical proximity, limited face-to-face contact, and limited awareness and understanding of the roles and expectations of other professionals. There was a sense that participants felt they were 'just muddling through' and that the need for improved



communication was of the utmost importance, especially within the context of risk. This finding supports previous research identifying that inadequate communication and information sharing hinders care provision, and lack of proximity compromises opportunities for joint working (Silverwood et al., 2019). A recent review found that poor interdisciplinary communication and confusion over professional roles impedes access to mental health services, as women receive conflicting advice about whom to approach with concerns (Smith et al., 2019). In midwifery settings, the lack of awareness and understanding of the roles of other professionals was reported among more than 160 midwives (Bayrampour et al., 2018).

The provision, availability, and accessibility of services for women with PMHDs was also affected by geography. Participants were clear that the provision of locally based, community initiatives was limited and that women usually had to travel significant distances to access appropriate care. This was true of access to specialist MBUs owing to the lack of local capacity for appropriate inpatient psychiatric admission for women and their babies. Participants described women and families having to make difficult choices between being admitted locally to a general adult acute ward without their baby or being in a distant specialist environment with their babies, but without their wider family, social network, or care team.

In the UK it is considered best practice to admit perinatal women with their babies to specialist MBUs, although limited provision across many areas means this is not always possible (Griffiths et al., 2019). Griffiths et al. (2019) explored women and staff's experiences of MBU admission compared with admission to generic psychiatric wards. The MBU environment was perceived as more appropriate than a generic ward as it provides perinatal-specific, family-focused care and is equipped to meet the needs of both women and their infants. Women also reported that the experience of being separated from their babies was often traumatic and negatively impacted their recovery (Griffiths et al., 2019). It was beyond the scope of this study to explore the impact of these decisions on women, families, and care providers. Future research may be needed to explore the

experiences of women who have been offered or accessed admissions to the MBUs vs general acute wards from both urban and rural areas of Scotland.

PMH was regarded as complex, influenced by several inter-related biopsychosocial and historical factors, with having two lives to care for further adding to the complexity of care delivery. The need to carefully balance the needs of both mother and infant and assess the risks of short- and long-term harm, was highlighted. While participants in the current study considered the delivery of PMH care to be a common and routine part of their role, many of them highlighted the fact they had received no specialist PMH training during their core professional or post-qualification training. There was a common theme that the expectation was you 'learn on the job', however, it was clear that this impacted on professionals' awareness, knowledge and confidence, particularly in addressing more difficult subjects, such as trauma, pregnancy loss and suicidal ideation. The lack of specialist PMH training in both core and post-qualification training for key professionals providing PMH care has been widely documented (Ashford et al., 2017; Bayrampour et al., 2018; McConachie & Whitford, 2009; Noonan, Galvin, et al., 2017; Silverwood et al., 2019), as have the negative consequences of this from the perspectives of women receiving care (Megnin-Viggars et al., 2015; Reddish, 2018).

Despite the many obstacles and barriers, the results also identify several facilitators of good quality care for women with PMHDs. It was widely acknowledged among participants that building a genuine and trusting therapeutic relationship and creating a safe space facilitated conversations about PMH. Several factors aided the development of this relationship, including taking time to listen to women and acknowledge their fears, and being compassionate and empathetic. Evidence suggests women value supportive opportunities to raise their worries and concerns with HCPs and that this is easier within the context of a positive relationship (Nagle & Farrelly, 2018; Sword et al., 2008). The importance of creating these spaces was also emphasised in a review by Smith et al. (2019) which indicated that women may delay or avoid seeking help if they perceive professionals as judgemental or anticipate negative responses to disclosure. Many participants in the current study raised the issue that women and families fear losing their baby if they disclose concerns about their

mental health, this fear is a common factor in delaying or avoiding seeking help in previous research (Nagle & Farrelly, 2018; Patel et al., 2013). This indicates that raising awareness and understanding of PMH and the role of services continues to be of the utmost importance.

The importance of empowering women, ensuring that they feel heard and respected, as well as able to make informed decisions, was seen as an essential part of the delivery of care to women with PMHDs. Some examples of this were given in the context of the experience of childbirth. Participants thought that women who felt they were given time to consider their options, and have their opinions considered as part of a joined-up approach, felt much more in control, meaning that, even if their delivery didn't go as expected, it was still a positive experience. In contrast, for those who had traumatic deliveries within the context of feeling powerless or helpless, the long term, negative psychological impacts could be significant. This perspective of the importance of empowerment during childbirth is supported in the literature (Schmied et al., 2014; Thomson & Downe, 2010). Women who feel listened to, are provided with adequate information, and supported to engage in decision making, feel more in control and can subsequently experience a positive birth irrespective of how or where their baby is born (Thomson & Downe, 2010). In contrast, women's experiences of dehumanising or disrespectful care during labour and birth, by either the action or inaction of HCPs, can lead to feeling out of control, inadequate and helpless (Schmied et al., 2014). It has also been suggested that sometimes HCPs can find it difficult to understand that something they see as a 'routine procedure' may be perceived as traumatic by the woman, possibly leading to further dismissal of a woman's concerns and impacting on the likelihood of future help seeking (Schmied et al., 2014). Empowerment and woman centred care, promoting choice, respect, autonomy, information sharing and partnership in decision making, are considered to be beneficial for women's psychological wellbeing and resilience, and it is argued promoting this approach should be prioritised by services (Garcia & Yim, 2017; Hunter et al., 2017; Nieuwenhuijze & Leahy-Warren, 2019).

Participants discussed several interventions for women experiencing PMHDs which should be available on a needs-led basis. However, issues around service provision meant that access and availability of these interventions limited the extent to which these can be considered needs led. Medication appeared more easily accessible than psychological interventions. Indeed, medication was sometimes considered to be 'quicker' than waiting for access to, or completion of, psychological therapies. There were also differing opinions as to whether the perinatal period was the 'right time' for psychological therapy. This conflicts with the substantial evidence demonstrating the effectiveness of low and high intensity psychological interventions in the treatment of PMHDs (Loughnan et al., 2019; Shi & MacBeth, 2017; Sockol, 2015, 2018). The current findings suggest that specific, tailored psychological interventions in the perinatal period are not widespread, and reliance on generic mental health services presents challenges for prioritisation and delivery of psychological interventions in this period.

#### Limitations

There are several limitations to the study. The study utilised a small, purposive sample limiting generalisability to wider populations of community-based HCPs working with women with PMHDs. The participants were also likely to have a self-identified special interest in PMH which potentially motivated them to participate. Hence, this study does not capture the views of those professionals who may have less interest and awareness of PMH. While the sample was reasonably representative of the range of professionals involved in the delivery of PMH care, there was no GP representative, despite previous literature identifying GPs' significant role in the provision of PMH care (Noonan, Doody, et al., 2018). It was also beyond the scope of this research to explore issues associated with diversity and the cultural needs of women in the perinatal period, thus further research in this area is warranted.

#### Clinical Implications

It was repeatedly raised that professionals felt they had not received sufficient training to care for women experiencing PMHDs. It is important that the training requirements of all professionals

caring for women in the perinatal period are addressed to ensure that mental health needs are identified and assessed and that appropriate treatments are offered in a timely manner. Training should include the range of complex factors associated with PMH and be addressed in both core professional training programmes and made available post-qualification. There is also a need to address the awareness and understanding of PMH across services, ensuring that women are receiving accurate and up to date information. It may be important to consider whether standard processes for discussing mental health with women and families in the perinatal period could be established, alongside establishing effective pathways of communication between services.

The availability and accessibility of mental health services for perinatal women also needs to be improved, especially around clearer referral pathways for generic mental health teams. It may also be important to review the restrictions on who can make such referrals as, in perinatal cases, the HV and midwife may be in an equally relevant position to make such referrals as the GP. Women with PMHDs should also be offered timely access to psychological therapies in line with national guidelines (NICE, 2014; Matrix, 2015; SIGN 127, 2012).

### Conclusion

This qualitative analysis explores detailed accounts of community-based HCPs experiences of working with women experiencing PMHDs. These accounts offer insight into the facilitators and barriers to delivering effective care and suggest several improvements that could be made. PMH is a complex, and yet common, issue that professionals experience in both the routine delivery of antenatal/postnatal care and in generic mental health services. There was a clear theme indicating that organisational and systemic challenges impacted on the delivery of care. It is, therefore, important that health systems are organised and integrated to provide optimal conditions for continuity of care for women with PMHDs, especially within the context of significant access issues. Individual factors, including those related to women themselves (reluctance to seek help due to fear, shame, or stigma) and practitioners (awareness, knowledge and understanding), also impact on the provision of care. Finally, the rurality of the NHS health boards from which participants were

sampled gave a unique perspective. Service access issues remained a clear and significant concern across participants, highlighting the question of what should practitioners do when there is limited or no access to specialist PMH teams? Therefore, these organisational, individual, and demographic factors need to be addressed to create the most effective conditions to deliver PMH care.

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## Appendices

### Appendix 1: Submission guidelines for the Journal of Affective Disorders

#### GUIDE FOR AUTHORS

##### **Description**

*The Journal of Affective Disorders* publishes papers concerned with **affective disorders** in the widest sense: **depression, mania, anxiety and panic**. It is interdisciplinary and aims to bring together different approaches for a diverse readership. High quality papers will be accepted dealing with any aspect of affective disorders, including biochemistry, pharmacology, endocrinology, genetics, statistics, epidemiology, psychodynamics, classification, clinical studies and studies of all types of treatment.

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Please submit math equations as editable text and not as images. Present simple formulae in line with normal text where possible and use the solidus (/) instead of a horizontal line for small fractional terms, e.g., X/Y. In principle, variables are to be presented in italics. Powers of e are often more conveniently denoted by exp. Number consecutively any equations that have to be displayed separately from the text (if referred to explicitly in the text).

#### *Footnotes*

Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

#### **Artwork**

##### *Electronic artwork*

##### *General points*

- Make sure you use uniform lettering and sizing of your original artwork.
- Embed the used fonts if the application provides that option.
- Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
- Size the illustrations close to the desired dimensions of the published version.
- Submit each illustration as a separate file.
- Ensure that color images are accessible to all, including those with impaired color vision.

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**You are urged to visit this site; some excerpts from the detailed information are given here.**

##### *Formats*

If your electronic artwork is created in a Microsoft Office application (Word, PowerPoint, Excel) then please supply 'as is' in the native document format. Regardless of the application used other than Microsoft Office, when your electronic artwork is finalized, please 'Save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):

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TIFF (or JPEG): Color or grayscale photographs (halftones), keep to a minimum of 300 dpi.  
TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.  
TIFF (or JPEG): Combinations bitmapped line/half-tone (color or grayscale), keep to a minimum of 500 dpi.

**Please do not:**

- Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); these typically have a low number of pixels and limited set of colors;
- Supply files that are too low in resolution;
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Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

**References**

*Citation in text*

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

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### *Reference style*

*Text:* All citations in the text should refer to:

1. *Single author:* the author's name (without initials, unless there is ambiguity) and the year of publication;
2. *Two authors:* both authors' names and the year of publication;
3. *Three or more authors:* first author's name followed by 'et al.' and the year of publication.

Citations may be made directly (or parenthetically). Groups of references can be listed either first alphabetically, then chronologically, or vice versa. Examples: 'as demonstrated (Allan, 2000a, 2000b, 1999; Allan and Jones, 1999).... Or, as demonstrated (Jones, 1999; Allan, 2000)... Kramer et al. (2010) have recently shown ...'

*List:* References should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

### *Examples:*

Reference to a journal publication: Van der Geer, J., Hanraads, J.A.J., Lupton, R.A., 2010. The art of writing a scientific article. *J. Sci. Commun.* 163, 51–59. <https://doi.org/10.1016/j.Sc.2010.00372>.

Reference to a journal publication with an article number: Van der Geer, J., Hanraads, J.A.J., Lupton, R.A., 2018. The art of writing a scientific article. *Heliyon.* 19, e00205. <https://doi.org/10.1016/j.heliyon.2018.e00205>.

Reference to a book: Strunk Jr., W., White, E.B., 2000. *The Elements of Style*, fourth ed. Longman, New York. Reference to a chapter in an edited book: Mettam, G.R., Adams, L.B., 2009. How to prepare an electronic version of your article, in: Jones, B.S., Smith, R.Z. (Eds.), *Introduction to the Electronic Age*. E-Publishing Inc., New York, pp. 281–304.

Reference to a website: Cancer Research UK, 1975. Cancer statistics reports for the UK. <http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/> (accessed 13 March 2003).

Reference to a dataset: [dataset] Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T., 2015. Mortality data for Japanese oak wilt disease and surrounding forest compositions. Mendeley Data, v1. <https://doi.org/10.17632/xwj98nb39r.1>.

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*Data statement*

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Appendix 2: Revised Cochrane risk-of-bias tool for randomised trials (RoB-2) template

Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)  
TEMPLATE FOR COMPLETION

Edited by Julian PT Higgins, Jelena Savović, Matthew J Page, Jonathan AC Sterne  
on behalf of the RoB2 Development Group

**Version of 22 August 2019**

The development of the RoB 2 tool was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/2- N61), with the support of the host MRC ConDuCT-II Hub (Collaboration and innovation for Difficult and Complex randomised controlled Trials In Invasive procedures - MR/K025643/1), by MRC research grant MR/M025209/1, and by a grant from The Cochrane Collaboration.



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### Study details

#### Reference

### Study design

- Individually-randomized parallel-group trial
- Cluster-randomized parallel-group trial
- Individually randomized cross-over (or other matched) trial

### For the purposes of this assessment, the interventions being compared are defined as

Experimental:  Comparator:

### Specify which outcome is being assessed for risk of bias

**Specify the numerical result being assessed.** In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

### Is the review team's aim for this result...?

- to assess the effect of *assignment to intervention* (the 'intention-to-treat' effect)
- to assess the effect of *adhering to intervention* (the 'per-protocol' effect)

**If the aim is to assess the effect of *adhering to intervention***, select the deviations from intended intervention that should be addressed (at least one must be checked):

- occurrence of non-protocol interventions

- failures in implementing the intervention that could have affected the outcome
- non-adherence to their assigned intervention by trial participants

**Which of the following sources were obtained to help inform the risk-of-bias assessment? (tick as many as apply)**

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER or Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

## Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

### Domain 1: Risk of bias arising from the randomization process

Signalling questions	Comments	Response options
1.1 Was the allocation sequence random?		<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?		<u>Y</u> / <u>PY</u> / <b>PN</b> / <b>N</b> / NI
1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?		<b>Y</b> / <b>PY</b> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias arising from the randomization process?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of assignment to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / <u>PN / N</u> / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / <u>PN / N</u> / NI
2.3. If <u>Y/PY/NI</u> to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?		NA / Y / PY / <u>PN / N</u> / NI
2.4 If <u>Y/PY</u> to 2.3: Were these deviations likely to have affected the outcome?		NA / Y / PY / <u>PN / N</u> / NI
2.5. If <u>Y/PY/NI</u> to 2.4: Were these deviations from intended intervention balanced between groups?		NA / <u>Y / PY</u> / PN / N / NI
2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?		<u>Y / PY</u> / PN / N / NI
2.7 If <u>N/PN/NI</u> to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?		NA / Y / PY / <u>PN / N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 2: Risk of bias due to deviations from the intended interventions (*effect of adhering to intervention*)

Signalling questions	Comments	Response options
2.1. Were participants aware of their assigned intervention during the trial?		Y / PY / <u>PN / N</u> / NI
2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?		Y / PY / <u>PN / N</u> / NI
2.3. [If applicable:] <u>If Y/PY/NI to 2.1 or 2.2:</u> Were important non-protocol interventions balanced across intervention groups?		NA / <u>Y / PY</u> / PN / N / NI
2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?		NA / Y / PY / <u>PN / N</u> / NI
2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?		NA / Y / PY / <u>PN / N</u> / NI
2.6. <u>If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5:</u> Was an appropriate analysis used to estimate the effect of adhering to the intervention?		NA / <u>Y / PY</u> / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable



Domain 3: Missing outcome data

Signalling questions	Comments	Response options
3.1 Were data for this outcome available for all, or nearly all, participants randomized?		<u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
3.2 If <u>N/PN/NI</u> to 3.1: Is there evidence that the result was not biased by missing outcome data?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u>
3.3 If <u>N/PN</u> to 3.2: Could missingness in the outcome depend on its true value?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
3.4 If <u>Y/PY/NI</u> to 3.3: Is it likely that missingness in the outcome depended on its true value?		NA / <u>Y</u> / <u>PY</u> / <u>PN</u> / <u>N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to missing outcome data?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 4: Risk of bias in measurement of the outcome

Signalling questions	Comments	Response options
4.1 Was the method of measuring the outcome inappropriate?		Y / PY / <u>PN / N</u> / NI
4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?		Y / PY / <u>PN / N</u> / NI
4.3 If <u>N/PN/NI</u> to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?		NA / Y / PY / <u>PN / N</u> / NI
4.4 If <u>Y/PY/NI</u> to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?		NA / Y / PY / <u>PN / N</u> / NI
4.5 If <u>Y/PY/NI</u> to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?		NA / Y / PY / <u>PN / N</u> / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias in measurement of the outcome?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Domain 5: Risk of bias in selection of the reported result

Signalling questions	Comments	Response options
5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?		Y / PY / PN / N / NI
Is the numerical result being assessed likely to have been selected, on the basis of the results, from...		
5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?		Y / PY / PN / N / NI
5.3 ... multiple eligible analyses of the data?		Y / PY / PN / N / NI
Risk-of-bias judgement		Low / High / Some concerns
Optional: What is the predicted direction of bias due to selection of the reported result?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

Overall risk of bias

<b>Risk-of-bias judgement</b>		Low / High / Some concerns
Optional: What is the overall predicted direction of bias for this outcome?		NA / Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable



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## Appendix 3: Submission guidelines for Qualitative Health Research

### Manuscript Submission Guidelines: Qualitative Health Research

This Journal is a member of the Committee on Publication Ethics

This Journal recommends that authors follow the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals formulated by the International Committee of Medical Journal Editors (ICMJE).

Please read the guidelines below then visit the Journal's submission site <https://mc.manuscriptcentral.com/qhr> to upload your manuscript. Please note that manuscripts not conforming to these guidelines may be returned. Remember you can log in to the submission site at any time to check on the progress of your paper through the peer review process.

Only manuscripts of sufficient quality that meet the aims and scope of Qualitative Health Research will be reviewed.

There are no fees payable to submit or publish in this journal.

As part of the submission process you will be required to warrant that you are submitting your original work, that you have the rights in the work, and that you have obtained and can supply all necessary permissions for the reproduction of any copyright works not owned by you, that you are submitting the work for first publication in the Journal and that it is not being considered for publication elsewhere and has not already been published elsewhere. Please see our guidelines on prior publication and note that Qualitative Health Research may accept submissions of papers that have been posted on pre-print servers; please alert the Editorial Office when submitting (contact details are at the end of these guidelines) and include the DOI for the preprint in the designated field in the manuscript submission system. Authors should not post an updated version of their paper on the preprint server while it is being peer reviewed for possible publication in the journal. If the article is accepted for publication, the author may re-use their work according to the journal's author archiving policy. If your paper is accepted, you must include a link on your preprint to the final version of your paper.

#### 1. What do we publish?

##### 1.1 Aims & Scope

##### 1.2 Article types

##### 1.3 Writing your paper

#### 2. Editorial policies

##### 2.1 Peer review policy

##### 2.2 Authorship

##### 2.3 Acknowledgements

##### 2.4 Funding

##### 2.5 Declaration of conflicting interests

##### 2.6 Research ethics and patient consent

##### 2.7 Clinical trials

- 2.8 Reporting guidelines
- 2.9 Research Data
- 3. Publishing polices
  - 3.1 Publication ethics
  - 3.2 Contributor’s publishing agreement
  - 3.3 Open access and author archiving
- 4. Preparing your manuscript
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  - 4.5 English language editing services
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- 5. Submitting your manuscript
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  - 5.2 Information required for completing your submission
  - 5.3 Permissions
- 6. On acceptance and publication
  - 6.1 SAGE Production
  - 6.2 Online First publication
  - 6.3 Access to your published article
  - 6.4 Promoting your article
- 7. Further information
  - 1. What do we publish?
    - 1.1 Aims & Scope
 

Before submitting your manuscript to Qualitative Health Research, please ensure you have read the Aims & Scope.
    - 1.2 Article types Each issue of Qualitative Health Research provides readers with a wealth of information —, commentaries on conceptual, theoretical, methodological and ethical issues pertaining to qualitative inquiry as well as articles covering research, theory and methods.
      - 1.2.1 What types of articles will QHR accept?

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- Note the sections: General articles, critical reviews, articles addressing qualitative methods, commentaries on conceptual, theoretical, methodological, and ethical issues pertaining to qualitative inquiry.
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- Articles in QHR provide an array of timely topics such as: experiencing illness, giving care, institutionalization, substance abuse, food, feeding and nutrition, living with disabilities, milestones and maturation, monitoring health, and children's perspectives on health and illness.
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### 1.3 Writing your paper

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1.3.1 Make your article discoverable For information and guidance on how to make your article more discoverable, visit our Gateway page on How to Help Readers Find Your Article Online

## 2. Editorial policies

2.1 Peer review policy Qualitative Health Research strongly endorses the value and importance of peer review in scholarly journals publishing. All papers submitted to the journal will be subject to comment and external review. All manuscripts are initially reviewed by the Editors and only those papers that meet the scientific and editorial standards of the journal, and fit within the aims and scope of the journal, will be sent for outside review.

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As part of the submission process you may provide the names of peers who could be called upon to review your manuscript. Recommended reviewers should be experts in their fields and should be able to provide an objective assessment of the manuscript. Please be aware of any conflicts of interest when recommending reviewers. Examples of conflicts of interest include (but are not limited to) the below:

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2.2 Authorship Papers should only be submitted for consideration once consent is given by all contributing authors. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors. The list of authors should include all those who can legitimately claim authorship. This is all those who:

- (i) Made a substantial contribution to the concept or design of the work; or acquisition, analysis or interpretation of data,
- (ii) Drafted the article or revised it critically for important intellectual content,
- (iii) Approved the version to be published,
- (iv) Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Authors should meet the conditions of all of the points above. When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section. Please refer to the International Committee of Medical Journal Editors (ICMJE) authorship guidelines for more information on authorship.



## 2.3 Acknowledgements

All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support. Please do not upload or include the acknowledgments during the initial submission and review. IF your article is going to be accepted, you will be instructed to “unblind” the manuscript, and then you may add this section to your document.

### 2.3.1 Writing assistance

Individuals who provided writing assistance, e.g. from a specialist communications company, do not qualify as authors and so should be included in the Acknowledgements section. Authors must disclose any writing assistance – including the individual’s name, company and level of input – and identify the entity that paid for this assistance. It is not necessary to disclose use of language polishing services.

## 2.4 Funding

Qualitative Health Research requires all authors to acknowledge their funding in a consistent fashion under a separate heading. Please visit the Funding Acknowledgements page on the SAGE Journal Author Gateway to confirm the format of the acknowledgment text in the event of funding, or state that: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

## 2.5 Declaration of conflicting interests

It is the policy of Qualitative Health Research to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please ensure that a ‘Declaration of Conflicting Interests’ statement is included at the end of your manuscript, after any acknowledgements and prior to the references. If no conflict exists, please state that ‘The Author(s) declare(s) that there is no conflict of interest’. For guidance on conflict of interest statements, please see the ICMJE recommendations [here](#)

## 2.6 Research ethics and patient consent

Medical research involving human subjects must be conducted according to the World Medical Association Declaration of Helsinki

Submitted manuscripts should conform to the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals:

- All papers reporting animal and/or human studies must state in the methods section that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you blinded the name and institution of the review committee until such time as your article has been accepted. The Editor will request authors to replace the name and add the approval number once the article review has been completed
- For research articles, authors are also required to state in the methods section whether participants provided informed consent and whether the consent was written or verbal.

Information on informed consent to report individual cases or case series should be included in the manuscript text. A statement is required regarding whether written informed consent for patient

information and images to be published was provided by the patient(s) or a legally authorized representative. Please do not submit the patient's actual written informed consent with your article, as this in itself breaches the patient's confidentiality. The Journal requests that you confirm to us, in writing, that you have obtained written informed consent but the written consent itself should be held by the authors/investigators themselves, for example in a patient's hospital record. Please also refer to the ICMJE Recommendations for the Protection of Research Participants

## 2.7 Clinical trials

Qualitative Health Research conforms to the ICMJE requirement that clinical trials are registered in a WHO approved public trials registry at or before the time of first patient enrolment as a condition of consideration for publication. The trial registry name and URL, and registration number must be included at the end of the abstract.

## 2.8 Reporting guidelines

The relevant EQUATOR Network reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed CONSORT flow chart as a cited figure and the completed CONSORT checklist should be uploaded with your submission as a supplementary file. Systematic reviews and meta-analyses should include the completed PRISMA flow chart as a cited figure and the completed PRISMA checklist should be uploaded with your submission as a supplementary file. The EQUATOR wizard can help you identify the appropriate guideline. Other resources can be found at NLM's Research Reporting Guidelines and Initiatives

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## 3. Publishing Policies

### 3.1 Publication ethics

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#### 3.1.1 Plagiarism

Qualitative Health Research and SAGE take issues of copyright infringement, plagiarism or other breaches of best practice in publication very seriously. We seek to protect the rights of our authors and we always investigate claims of plagiarism or misuse of published articles. Equally, we seek to protect the reputation of the journal against malpractice. Submitted articles may be checked with duplication-checking software. Where an article, for example, is found to have plagiarized other work or included third-party copyright material without permission or with insufficient acknowledgement, or where the authorship of the article is contested, we reserve the right to take action including, but not limited to: publishing an erratum or corrigendum (correction); retracting

the article; taking up the matter with the head of department or dean of the author's institution and/or relevant academic bodies or societies; or taking appropriate legal action.

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## 4. Preparing your manuscript

### 4.1 Article Format (see previously published articles in QHR for style):

- Title page: Title should be succinct; list all authors and their affiliation; keywords. Please upload the title page separately from the main document.
- Blinding: Do not include any author identifying information in your manuscript, including author's own citations. Do not include acknowledgements until your article is accepted and unblinded.
- Abstract: Unstructured, 150 words. This should be the first page of the main manuscript, and it should be on its own page.
- Length: QHR does not have a word or page count limit. Manuscripts should be as tight as possible, preferably less than 30 pages including references. Longer manuscripts, if exceptional, will be considered.
- Methods: QHR readership is sophisticated; excessive details not required.
- Ethics: Include a statement of IRB approval and participant consent. Present demographics as a group, not listed as individuals. Do not link quotations to particular individuals unless essential (as in case studies) as this threatens anonymity.
- Results: Rich and descriptive; theoretical; linked to practice if possible.
- Discussion: Link your findings with research and theory in literature, including other geographical areas and quantitative research.
- References: APA format. Use pertinent references only. References should be on a separate page. Additional Editor's Preferences:

- Please do not refer to your manuscript as a “paper;” you are submitting an “article.”
- The word “data” is plural. 4.2 Word processing formats Preferred formats for the text and tables of your manuscript are Word DOC or PDF. The text should be double-spaced throughout with standard 1 inch margins (APA formatting). Text should be standard font (i.e., Times New Roman) 12 point. 4.3 Artwork, figures and other graphics
- Figures: Should clarify text.
- Include figures, charts, and tables created in MS Word in the main text rather than at the end of the document.
- Figures, tables, and other files created outside of Word should be submitted separately. Indicate where table should be inserted within manuscript (i.e. INSERT TABLE 1 HERE).
- Photographs: Should have permission to reprint and faces should be concealed using mosaic patches – unless permission has been given by the individual to use their identity. This permission must be forwarded to QHR’s Managing Editor.
  - o TIFF, JPED, or common picture formats accepted.
 The preferred format for graphs and line art is EPS.
  - o Resolution: Rasterized based files (i.e. with .tiff or .jpeg extension) require a resolution of at least 300 dpi (dots per inch). Line art should be supplied with a minimum resolution of 800 dpi.
  - o Dimension: Check that the artworks supplied match or exceed the dimensions of the journal. Images cannot be scaled up after origination.
- Figures supplied in color will appear in color online regardless of whether or not these illustrations are reproduced in color in the printed version. For specifically requested color reproduction in print, you will receive information regarding the costs from SAGE after receipt of your accepted article.

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Qualitative Health Research is hosted on SAGE Track, a web based online submission and peer review system powered by ScholarOne™ Manuscripts. Visit <https://mc.manuscriptcentral.com/qhr> to login and submit your article online. IMPORTANT: Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne Online Help.

### 5.1 ORCID

As part of our commitment to ensuring an ethical, transparent and fair peer review process SAGE is a supporting member of ORCID, the Open Researcher and Contributor ID. ORCID provides a unique and persistent digital identifier that distinguishes researchers from every other researcher, even those who share the same name, and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between researchers and their professional activities, ensuring that their work is recognized. The collection of ORCID IDs from corresponding authors is now part of the submission process of this journal. If you already have an ORCID ID you will be asked to associate that to your submission during the online submission process. We also strongly encourage all co-authors to link their ORCID ID to their accounts in our online peer review platforms. It takes seconds to do: click the link when prompted, sign into your ORCID account and our systems are automatically updated. Your ORCID ID will become part of your accepted publication’s metadata, making your work attributable to you and only you. Your ORCID ID is published with your article so that fellow researchers reading your work can link to your ORCID

profile and from there link to your other publications. If you do not already have an ORCID ID please follow this link to create one or visit our ORCID homepage to learn more.

## 5.2 Information required for completing your submission

You will be asked to provide contact details and academic affiliations for all co-authors via the submission system and identify who is to be the corresponding author. These details must match what appears on your manuscript. The affiliation listed in the manuscript should be the institution where the research was conducted. If an author has moved to a new institution since completing the research, the new affiliation can be included in a manuscript note at the end of the paper. At this stage please ensure you have included all the required statements and declarations and uploaded any additional supplementary files (including reporting guidelines where relevant).

## 5.3 Permissions

Please also ensure that you have obtained any necessary permission from copyright holders for reproducing any illustrations, tables, figures or lengthy quotations previously published elsewhere. For further information including guidance on fair dealing for criticism and review, please see the Copyright and Permissions page on the SAGE Author Gateway

## 6. On acceptance and publication

### 6.1 SAGE Production

Your SAGE Production Editor will keep you informed as to your article's progress throughout the production process. Proofs will be made available to the corresponding author via our editing portal SAGE Edit or by email, and corrections should be made directly or notified to us promptly. Authors are reminded to check their proofs carefully to confirm that all author information, including names, affiliations, sequence and contact details are correct, and that Funding and Conflict of Interest statements, if any, are accurate. Please note that if there are any changes to the author list at this stage all authors will be required to complete and sign a form authorizing the change.

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7. Further information Any correspondence, queries or additional requests for information on the manuscript submission process should be sent to the Qualitative Health Research editorial office as follows: Vanessa Shannon, Managing Editor Email:

**Appendix 4: University of Edinburgh Level 2 Ethical Approval Confirmation Letter**



SCHOOL of HEALTH IN SOCIAL SCIENCE  
CLINICAL AND HEALTH PSYCHOLOGY

The University of Edinburgh  
Medical School  
Doorway 6, Teviot Place  
Edinburgh EH8 9AG

Telephone 0131 651 3969  
Fax 0131 650 3891  
Email [submitting.ethics@ed.ac.uk](mailto:submitting.ethics@ed.ac.uk)

Natalie Clinkscales  
Trainee Clinical Psychologist  
School of Health in Social Science  
University of Edinburgh

08 February 2019

Dear Natalie,

**Application for Level 2 Approval**

**Reference:** CLIN556

**Project Title:** A qualitative exploration of community healthcare professionals'  
experiences of working with women with Perinatal Mental Health difficulties

**Academic Supervisor:** Angus MacBeth

Thank you for submitting the above research project for review by the Department of Clinical and Health Psychology Ethics Research Panel. I can confirm that the submission has been independently reviewed and was approved on the 5<sup>th</sup> February 2019.

Should there be any change to the research protocol it is important that you alert us to this as this may necessitate further review.

Yours sincerely,

Kirsty Gardner  
Administrative Secretary  
Clinical Psychology

## Appendix 5: Approved Amendment to Ethics Application

CPA University of Edinburgh, School of Health in Social Science

### RESEARCH ETHICS APPLICATION (REA)



The forms required when seeking ethical approval in the School of Health and Social Sciences have now been merged into this single electronic document. The sections you are required to complete will depend on the nature of your application. Please start to complete the form from the beginning and proceed as guided. On completion the *entire* document should be submitted electronically to your section's ethics administrator using the email addresses detailed on the final page.

FORM OVERVIEW	
FORM	COMPLETION
Project registration form	: Compulsory for all applications
Document checklist	: Compulsory for all applications
Level 1 Self Audit form	: To be completed for all research studies that are not subject to review by an external UK based ethical committee.
Level 2 /3 ethical review form	: To be completed when indicated by responses on the Level 1 form.
Level 4 ethical review form	: applies to research which is potentially problematic in that it may incorporate an inherent physical or emotional risk to researchers or participants, or involve covert surveillance or covert data collection.

### PROJECT REGISTRATION FORM

This form is the first stage in applying for University ethical approval and should be completed prior to the commencement of any research project. Applications submitted without appropriate documentation will be returned.

Ethical approval is required for all projects by staff or students conducting research, or similar. Applicants should familiarise themselves with the School's Research Ethics Policy prior to completion.

PR <sup>1</sup> Name of Applicant: Natalie Clinkscales
PR <sup>2</sup> Name of Supervisor <sup>1</sup> : Angus MacBeth
PR <sup>3</sup> Project Title: A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties.
PR <sup>4</sup> Subject Area (section of school): Clinical Psychology
PR <sup>5</sup> If student, type of assessed work that this application relates to: Doctoral Thesis
PR <sup>6</sup> Planned date of project submission: May 2020
PR <sup>7</sup> Date ethics application submitted: 07/12/18
PR <sup>8</sup> (Date complete information submitted if different):
PR <sup>9</sup> IRAS Approval Number if applicable:
<i>The following to be completed by ethics administrator</i>
PR <sup>10</sup> Date of initial response to applicant:
PR <sup>11</sup> Date of final approval:
PR <sup>12</sup> Amendments Requested Date:

<sup>1</sup> Not applicable to staff members.

PR13	Amendments Approved Date:
PR14	Reviewer 1
PR15	Reviewer 2 Level 2/3/4 only
DOCUMENTATION CHECKLIST	

1) <sup>DC1</sup> Does your research project require extraction or collection of data abroad? (✓)

<input checked="" type="checkbox"/>	No	If 'No' Skip to Q2	
<input type="checkbox"/>	Yes	Local Ethical review needed, please confirm (✓) electronic attachment of: Application to ethical review panel in country of data collection (in English) + copy of letter of approval	

2) <sup>DC2</sup> For the purposes of this research study, will you access identifiable<sup>2</sup> information on any NHS patient? (✓)

<input checked="" type="checkbox"/>	No	If 'No' Skip to Q3	
<input type="checkbox"/>	Yes	Please confirm (✓) electronic attachment of:	Caldicott Guardian approval for use of NHS data (or confirmation that it is not required)

3) <sup>DC3</sup> Does the project require ethical review by an external UK committee e.g. NHS REC or Social Work?

<input checked="" type="checkbox"/>	No	If 'No' Skip to Q4	
<input type="checkbox"/>	Yes	Please confirm (✓) electronic attachment of:	NHS REC (IRAS) /other application form + copy of letter of approval
<b>NOTE:</b> You are <u>not</u> required to complete University ethical review forms. Skip to Q6			

4) <sup>DC4</sup> Unless you answered 'yes' to 3, you must also obtain ethical approval through the University of Edinburgh process. Please submit a Level 1 form (with 'Methods' summary) and, if indicated, a level 2/3/4 form as well.

	SHSS Ethics paperwork	Forms: level 1	2/3/4	Summary of 'Methods'
Please indicate the SHSS Ethics forms completed herewith (✓):			X	

5) <sup>DC5</sup> If you have completed the Level 2/3/4 form please list any additional documentation provided in support of your application (E.g. Disclosure, consent form, participant information, GP letters etc., Data Storage Plan)

Documentation Name <small>These should reflect content</small>	(✓)	Documentation Name	(✓)
Participant Information Sheet	✓	Study Protocol	✓
Consent Form	✓	Recruitment Poster	✓
Debrief	✓		

<sup>2</sup> 'Identifiable information' refers to information that would allow you to know, or be able to deduce, the identity of a patient. The most common examples of this would be accessing medical records or similar, or accessing a database that includes patients' names.



6) Signatures

\_\_\_\_ Natalie Clinkscales \_\_\_\_\_ 10.12.18  
 Applicant's Name Applicant's Signature Date signed

\_\_\_\_ Angus MacBeth \_\_\_\_\_ 6.12.18  
 Supervisor<sup>3</sup> Name Supervisor's Signature Date signed

*Please return an electronic copy of your UoE HSS Ethics Application Form (in its entirety) to your Section's Ethics Officer, accompanied by electronic copies of additional documents indicated above. We do not accept paper documentation; please scan all documents into electronic formats. Please keep a copy of all documentation for your records.*

**LEVEL 1 SELF AUDIT FORM**

The audit is to be conducted by all staff and students conducting any type of empirical investigation, including research, audit or service evaluation.

The form should be completed by the principal investigator and, with the exception of staff, signed by a University supervisor.

<sup>5A1</sup>Primary Research Question:

Please tick	What type of research are you planning to do?
	Study of a novel intervention or randomised clinical trial to compare interventions in clinical practice
X	Study utilising questionnaires, interviews or measures, including auto-ethnographic data.
	Study limited to working with routinely collected clinical data.
	Meta-analysis or systematic review.
	Research database containing non-identifiable information.

<sup>5A2</sup>Please provide a brief summary of your proposed study. Our interest is in areas of your methodology where ethical issues may arise so please focus your detail on areas such as recruitment, consent, describing your participants and the nature of their involvement, and data handling.

**Project Summary:**

The current study aims to explore the attitudes and experiences of community healthcare staff (including those working in primary care and secondary mental health care) working with women experiencing mental health difficulties during the perinatal period (conception to one-year post childbirth). The study will use an exploratory, cross sectional, qualitative design in order to explore participants personal understanding and experiences of working with women w mental health difficulties during the perinatal period.

*Participants*

The participants will be community-based healthcare professionals (I.e. mental health nurses, health visitors, midwives, psychologists, psychiatrists) working within three local NHS health boards (Tayside, Grampian and Highland). **Recruitment:** The study will utilise a convenience sample; participants will be invited to take part through local primary care teams/

<sup>3</sup>Not required for staff applications.

community mental health teams (CMHTs) and the northern branch of the Managed Clinical Network (MCN) for PMH. Posters advertising the study will be placed in the office locations of these professionals as well as the researcher presenting and discussing the research project at local team meetings where appropriate.

**Procedure**

Participants will be asked to express their interest in taking part in the study and will be given a participant information sheet (See appendix 1). Informed consent will be gathered from those who agree to take part (See appendix 2). Each participant will be given a demographics questionnaire, this will gather basic information such as; age, gender, profession, years qualified, and specific information related to participants experience of post-qualification training in PMH or psychological therapies. Individual semi-structured interviews will be conducted in order to collect qualitative information about participants personal experiences, knowledge and ideas. A semi-structured interview schedule will be developed; broad topic areas that will be covered during the interview include:

- **Participants experiences of working with women with Perinatal Mental Health Problems (PMHPs)** (Example questions: How did it feel to work with someone experiencing PMHPs? What type of support did you offer? Were there any challenges related to this work?)
- **Participants attitudes towards PMHPs** (What comes to mind when you think of PMHPs? What factors might impact on the development of PMHPs? Do you think stigma has an impact on women seeking help?)
- **Experience of communication between professionals/services** (Have you experienced making/receiving a referral to generic mental health services? What processes were involved in deciding whether to make/accept a referral?)
- **Participants perceptions of diagnosis and risk in this period** (Could you give examples of times when diagnosis has been helpful or less helpful for women with PMHPs? In your experience did factors relating to risk influence the decision about support offered? In what way did this occur?)
- **Knowledge of psychological approaches to PMH** (What psychological approaches could be helpful? Are there circumstances when psychological approaches might be less helpful?)

Interviews will be conducted face to face and will last approximately 45-60 minutes. The interviews will be audio-recorded using encrypted equipment, and the data will be transcribed verbatim. All identifiable information will be removed. All data will be stored securely as per GDPR and University guidelines and procedures. Participants will be given debrief information at the end of the study (See Appendix 3); this will include links to NHS Education for Scotland (NES) training modules in Perinatal Mental Health.

Please circle your answer as appropriate:

ETHICAL ISSUES			
SA3	<b>Bringing the University into disrepute</b> Is there any aspect of the proposed research which might bring the University into disrepute? For example, could any aspect of the research be considered controversial or prejudiced?	No	YES
SA4	<b>Protection of research subject confidentiality</b> <i>Will you make every effort to protect research subject confidentiality by conforming to the University of Edinburgh's guidance on data security, protection and confidentiality as specified in: <a href="http://www.ed.ac.uk/information-services/research-support/data-library/research-data-mgmt">www.ed.ac.uk/information-services/research-support/data-library/research-data-mgmt</a></i> <i>For example, there are mutually understood agreements about:</i> (a) non-attribution of individual responses; (b) Individuals, and organisations where necessary, being anonymised in stored data, publications and presentations; (c) publication and feedback to participants and collaborators; (d) With respect to auto-ethnographic work it is recognised that the subject's anonymity cannot be maintained but the confidentiality of significant others must be addressed.	NO	Yes

S45	<p><b>Data protection and consent</b></p> <p><i>Will you make every effort to ensure the confidentiality of any data arising from the project by complying with the University of Edinburgh's Data Protection procedures (see <a href="http://www.ed.ac.uk/information-services/research-support/data-library/research-data-mgmt">http://www.ed.ac.uk/information-services/research-support/data-library/research-data-mgmt</a>).</i></p> <p>For example</p> <ul style="list-style-type: none"> <li>(a) Ensuring any participants recruited give consent regarding data collection, storage, archiving and destruction as appropriate;</li> <li>(c) Identifying information<sup>4</sup>, (e.g. consent forms) is held separately from data and is only accessible by the chief investigator and their supervisors;</li> <li>(e) There are no other special issues arising regarding confidentiality/consent.</li> <li>(f) That where NHS data is being accessed Caldicott Guardian approval has been obtained.</li> </ul> <p><b>IT IS NECESSARY TO GIVE THE HEAD OF SCHOOL'S NAME AS THE CONTACT PERSON IN CASE OF ANY COMPLAINT. PLEASE MAKE SURE THAT THIS LINK IS PROVIDED on any Information sheet/consent form:</b> (<a href="http://www.ed.ac.uk/files/imports/fileManager/WEB%20Complaint%20Form.pdf">http://www.ed.ac.uk/files/imports/fileManager/WEB%20Complaint%20Form.pdf</a>)</p>	NO	<input checked="" type="radio"/> YES
S46	<p><b>Duty to disseminate research findings</b></p> <p>Are there issues which will prevent all participants and relevant stakeholders having access to a clear, understandable and accurate summary of the research findings should they wish?</p>	<input checked="" type="radio"/> NO	YES
S47	<p><b>Moral issues and Researcher/Institutional Conflicts of Interest</b></p> <p><i>Are there any SPECIAL MORAL ISSUES/CONFLICTS OF INTEREST?</i></p> <p>Examples include, but are not limited to:</p> <ul style="list-style-type: none"> <li>(a) Where the purposes of research are concealed;</li> <li>(b) Where respondents are unable to provide informed consent</li> <li>(c) Where there is financial or non-financial benefit for <i>anyone</i> involved in the research, or for their relative or friend.</li> <li>(d) Where research findings could impinge negatively or differentially upon participants or stakeholders (for example when selecting an unrepresentative sample of a larger population).</li> <li>(e) Where there is a dual relationship between the researcher and subject? E.g. Where the researcher is also the subject's practitioner or clinician.</li> <li>(f) Where research involves covert surveillance or covert data collection.</li> <li>(g) Where routinely collected data is used for research alongside novel data.</li> </ul> <p><b>NOVEL DATA COLLECTION SHOULD NOT BE CONFLATED WITH ROUTINELY COLLECTED DATA. WHERE BOTH ARE BEING USED THIS NEEDS TO BE MADE CLEAR IN ANY COVERING LETTER, PARTICIPANT INFORMATION SHEET AND CONSENT FORM IN ORDER FOR INFORMED CONSENT TO BE POSSIBLE.</b></p>	No	<input checked="" type="radio"/> YES

<sup>4</sup> 'Identifiable information' refers to information that would allow you to know, or be able to deduce, the identity of a patient. The most common examples of this would be accessing medical records or similar, or accessing a database that includes patients' names.

SAB	<p><b>Potential physical or psychological harm, discomfort or stress</b></p> <p>Is there any foreseeable potential for:</p> <p>(a) significant psychological harm or stress for participants  (b) significant physical harm or discomfort for participants?  (c) significant risk to the researcher?</p> <p>Examples of issues/ topics that have the potential to cause psychological harm, discomfort or distress and should lead you to answer 'yes' to this question include, but are not limited to:  <i>Relationship breakdown; bullying; bereavement; mental health difficulties; trauma / PTSD; Violence or sexual violence; physical, sexual or emotional abuse in either children or adults; feedback of results from the project's assessments.</i></p>	No	YES
SAB	<p><b>Vulnerable participants</b></p> <p>Will you be <i>recruiting</i> any participants or interviewees who could be considered vulnerable?</p> <p>Examples of vulnerable groups, the inclusion of which should lead you to answer yes to this question include, but are not limited to:  Clients or patients of either the researcher OR the person recruiting subjects; Children &amp; young people; people who are in custody or care for example, offenders, looked after children or nursing home resident; persons with mental health difficulties including those accessing self-help groups; auto-ethnographic researchers examining distressing topics.</p>	NO	YES

**Assessment outcome:**

<sup>SAB10</sup> Have you circled any answers in **BOLD** typescript? Please tick as appropriate

- No  (i) Your responses on the completed self-audit confirm the ABSENCE OF REASONABLY FORESEEABLE ETHICAL RISKS.  
(ii) Please now read the guidance below and provide the required signatures.  
(iii) You are NOT REQUIRED to complete a level 2/3/4 application form.  
(iv) Please submit the UoE HSS Ethics Application Form electronic document (in its entirety) along with ALL additional required documentation, failure to do so will mean that your form is returned to you.
- Yes  (i) Your responses on the completed self-audit indicate that we require further information to consider your application.  
(ii) Read the Guidance below and provide the required signatures.  
(ii) You **ARE REQUIRED** to complete a level 2/3/4 application form.  
(III) Please continue to the next part of this document where you will find the level 2/3/4 form

Subsequent to submission of this form, any alterations in the proposed methodology of the project should be reviewed by both the applicant and their supervisor. If the change to methodology results in a change to any answer on the form, then a resubmission to the Ethics subgroup is required.

The principal investigator is responsible for ensuring compliance with any additional ethical requirements that might apply, and/or for compliance with any additional requirements for review by external bodies.



CONFIDENTIALITY AND HANDLING OF DATA	
<b>ER1</b> What information about participants'/subjects' data will you collect and use?	
	Demographic Information: Age, gender, profession, years qualified, and specific information related to participants experience of post-qualification training in PMH or psychological therapies  Qualitative Interviews: Participants experiences of, and attitudes towards, working with women experiencing perinatal mental health problems
<b>ER2</b> What is the risk category of the information? (See definitions contained in <a href="https://www.ed.ac.uk/infosec/how-to-protect/encrypting/use-cases/short-definition-of-sensitive-data">https://www.ed.ac.uk/infosec/how-to-protect/encrypting/use-cases/short-definition-of-sensitive-data</a> )	
	Low risk – the data will be anonymised
<b>ER3</b> Will the information include any of the following:	
	(a) racial or ethnic origin (b) political opinions (c) religious beliefs (d) trades union membership (e) physical or mental health (f) sexual life (g) commission of offences or alleged offences
	no
<b>ER4</b> Who will have access to the raw data?	
	Lead investigator and supervisor
<b>ER5</b> What training will staff receive on their responsibilities for the safe handling of the data?	
	n/a
<b>ER6</b> How will the confidentiality of the data, including the identity of participants, be ensured? Is there a strategy in place to replace disclosive identifiers of an individual or entity from the data?	

<ul style="list-style-type: none"> <li>• All identifiable data will be removed from verbatim transcripts (i.e. names, NHS health board, name of workplace). The name of each participant will be anonymised during discussion in write up – i.e. a pseudo name/number will be given to each participant. This name/number will coincide with each consent form, so participants can be identified by the researcher in the event that they would want to withdraw from participation in the study.</li> <li>• Consent forms will be stored separately from verbatim transcripts.</li> <li>• Consent forms containing identifiable information will be stored securely in a locked cabinet on NHS premises.</li> <li>• All data will be stored securely in line with NHS, university and GDPR protocols</li> </ul>
<p><b>ER7</b> Will the information be transferred to, shared with, supported by, or otherwise available to third parties outside the University?</p>
<p><b>NO</b> If yes, explain why the third party needs to have access to the information and how the transfer of the information will be made secure. Attach a copy of the agreement you will use to regulate the transfer and use of data.</p>
<p>The data will not be shared with any third parties – the results of the research will be written up for publication.</p>
<p><b>ER8</b> Describe the physical and IT security arrangements you will put in place for the data.</p>
<p>Paper based consent forms and demographic questionnaires will be stored in a lockable cabinet on NHS Grampian Premises.</p> <p>Interview recordings will be downloaded from encrypted recording device to an NHS Grampian computer/server. Recordings will be deleted from recording device. Recordings will be typed out verbatim and all identifiable participant information will be removed. Anonymised verbatim transcripts will be stored on the NHS Grampian server and transferred securely to the University of Edinburgh VPN for analysis.</p>
<p><b>ER9</b> Does the system have a security code of practice under the University's Information Security Policy? (see <a href="http://www.ed.ac.uk/information-services/about/policies-and-regulations/security-policies/security-policy">http://www.ed.ac.uk/information-services/about/policies-and-regulations/security-policies/security-policy</a>)</p> <p><b>YES</b></p>
<p><b>ER10</b> Will the data be used, accessed or stored away from the University premises?</p>
<p><b>YES</b> If YES, describe the arrangements you have put in place to safeguard the data from accidental or deliberate access, amendment or deletion when it is not on University premises, including when it is in transit.</p>
<p>Raw Data will be stored on NHS Grampian premises.</p> <p>Anonymised data will be accessed through the University of Edinburgh VPN for analysis to take place.</p>

<p><b>ER<sup>11</sup></b> Specify where the data files/audio/videotapes etc. will be retained after the study, how long they will be retained and how they eventually will be disposed of?</p>	
<p>Following completion of the research the interview transcript data will be transferred securely to the University of Edinburgh and kept for up to 5 years as per university protocol. Consent forms will remain in a lockable cabinet on NHS Grampian premises for 3-6 months after study completion, following this they will be shredded and disposed of in confidential waste. Audio recordings will be stored securely on the NHS Grampian server for 6 months following completion of the research.</p>	
<p><b>ER<sup>12</sup></b> How do you intend for the results of the research to be used?</p>	
<ul style="list-style-type: none"> <li>• To inform future service development and provision</li> <li>• To highlight current service and staff training needs</li> <li>• To add to the literature base in perinatal mental health and inform future research</li> </ul>	
<p><b>ER<sup>13</sup></b> Will feedback of findings be given to participants/subjects?</p>	
<p><b>YES</b></p>	<p>If yes, how will this feedback be provided?</p>
<p>Participants will be given the option of providing their email address upon data collection to receive a summary of the research results. The intention of the researcher is to publish the results of the research and these would also be circulated via the Perinatal Mental Health Managed Clinical Network.</p>	
<p><b>ER<sup>14</sup></b> Using secondary data: N/A</p>	
<p>YES/NO</p>	<p>(a) Is this reuse compatible with what the data subjects were originally told about the use of their data? (e.g. were they told that it would be destroyed at the end of the study?)</p>
<p>YES/NO</p>	<p>(b) Is it likely that someone could be identified from this data? (It is extremely difficult to make something totally anonymous, so even with secondary data there may be a need to apply security and access restrictions to it).</p>
<p>For more information regarding data linkage in evaluating interventions for the benefit of the population's health, please see: <a href="http://www.gov.scot/Topics/Statistics/datalinkageframework">http://www.gov.scot/Topics/Statistics/datalinkageframework</a></p> <p>Your application at this level is likely to require additional documentation, for example a Data Storage Plan, consent forms or participant information sheets. Please return to the Documentation Checklist on page 2 to list your supporting documentation.</p>	
<p>SECURITY-SENSITIVE MATERIAL</p>	



**ER15** Does your research fit into any of the following security-sensitive categories? If so, indicate which.

- NO            Commissioned by the military
- NO            Commissioned under an EU security call
- NO            Involve the acquisition of security clearances
- NO            Concern groups which may be construed as terrorist or extremist

**IF YOU HAVE ANSWERED YES TO ANY OF THESE CONTINUE TO ER16. IF YOU HAVE ANSWERED NO TO ALL OF THESE QUESTIONS MOVE TO ER21.**

**ER16** The Terrorism Act (2006) outlaws the dissemination of records, statements and other documents that can be interpreted as promoting or endorsing terrorist acts.

- NO            Does your research involve the storage on a computer of such records, statements and other documents?
- NO            Might your research involve the electronic transmission (e.g. as an email attachment) of records or statements?

**IF YOU ANSWERED YES TO ANY OF THESE YOU ARE ADVISED TO STORE THE RELEVANT RECORDS OR STATEMENTS ELECTRONICALLY ON A SECURE UNIVERSITY FILE STORE. THE SAME APPLIES TO PAPER DOCUMENTS WITH THE SAME SORT OF CONTENT. THESE SHOULD BE SCANNED AND UPLOADED.**

**ACCESS TO THIS FILE STORE WILL BE PROTECTED BY A PASSWORD UNIQUE TO YOU AND YOUR SCHOOL RESEARCH ETHICS OFFICER. PLEASE INDICATE THAT YOU AGREE TO STORE ALL DOCUMENTS RELEVANT TO THESE QUESTIONS ON THAT FILE STORE: N/A**

**ER17** Please indicate that you agree not to transmit electronically to any third party documents in the document store:

N/A

**ER18** Will your research involve visits to websites that might be associated with extreme or terrorist organisations?

NO

**ER19** If you answer YES to ER18 you are advised that such sites may be subject to surveillance by the police. Accessing those sites from University IP addresses might lead to police enquiries. Please acknowledge that you understand this risk:

N/A

<sup>ER20</sup> By submitting to the research ethics process, you accept that your School Research Ethics Officer and the convenor of the University's Compliance Group will have access to a list of titles of documents (but not the content of documents) in your document store. Please acknowledge that you accept this.

YES

Countersigned by supervisor/manager:

Name: Angus MacBeth

Date: 06/12/18

**RISKS TO, AND SAFETY OF, RESEARCHERS NAMED IN THIS APPLICATION**

<sup>ER21</sup> Do any of those conducting the research named above need appropriate training to enable them to conduct the proposed research safely and in accordance with the ethical principles set out by the College?

NO

<sup>ER22</sup> Are any of the researchers likely to be sent or go to any areas where their safety may be compromised, or they may need support to deal with difficult issues?

NO

<sup>ER23</sup> Could researchers have any conflicts of interest?

NO

**RISKS TO, AND SAFETY OF, PARTICIPANTS**

<sup>ER24</sup> Are any of your participants children or protected adults (protected adults are those in receipt of registered care, health, community care or welfare services. Anyone who will have contact with children or protected adults requires approval from Disclosure Scotland at <http://www.disclosurescotland.co.uk/>

Do any of the researchers taking part in this study require Disclosure Scotland approval? (v)

Not applicable	X
Relevant researcher/s has current Disclosure Scotland approval through a current NHS employment contract	
Yes*	

\*Ethical approval will be subject to documentation confirming Disclosure Scotland approval with this form.

<sup>ER25</sup> Could the research induce any psychological stress or discomfort?

YES
ER26 Does the research involve any physically invasive or potentially physically harmful procedures?
NO
ER27 Could this research adversely affect participants in any other way?
NO
<b>RESEARCH DESIGN</b>
ER28 Does the research involves living human subjects specifically recruited for this research project <i>If 'no', go to section 6</i>
YES
ER29 How many participants will be involved in the study?
12 – 20 (approx.)
ER30 What criteria will be used in deciding on inclusion/exclusion of participants?
<ul style="list-style-type: none"> <li>• Employed by NHS Grampian, Tayside or Highland</li> <li>• Working in a community-based health profession (i.e. GP, Health Visitor, Nurse, Psychologist, Midwife, Occupational Therapist etc.)</li> <li>• Registered with appropriate regulatory body (E.g. HCPC, GMC, NMC)</li> <li>• Over the age of 18</li> <li>• Able to provide informed consent to take part</li> </ul>
ER31 How will the sample be recruited? ( E.g. posters, letters, a direct approach- specify by whom.)
<ul style="list-style-type: none"> <li>• Advertisement through the Northern Branch of the Managed Clinical Network for Perinatal Mental Health</li> <li>• Poster advertisements in local GP practices, primary care teams and CMHT office spaces</li> <li>• Presentation and discussion of project at local team meetings</li> <li>• Word of mouth</li> </ul>
ER32 Will the study involve groups or individuals who are in custody or care, such as students at school, self-help groups, residents of nursing home?
NO
ER33 Will there be a control group?
NO
ER34 What information will be provided to participants prior to their consent? (e.g. information leaflet, briefing session)
Participant information sheet
ER35 Participants have a right to withdraw from the study at any time. Please tick to confirm that participants will be advised of their rights, including the right to continue receiving services if they withdraw from the study. <input checked="" type="checkbox"/>

ER36 Will it be necessary for participants to take part in the study without their knowledge and consent? (e.g. covert observation of people in non-public places)
NO
ER37 Where consent is obtained, what steps will be taken to ensure that a written record is maintained?
Paper based consent forms will be used and stored as per NHS and university guidelines
ER38 In the case of participants whose first language is not English, what arrangements are being made to ensure informed consent?
n/a
ER39 Will participants receive any financial or other benefit from their participation?
NO
ER40 Are any of the participants likely to be particularly vulnerable, such as elderly or disabled people, adults with incapacity, your own students, members of ethnic minorities, or in a professional or client relationship with the researcher?
NO
ER41 Will any of the participants be under 16 years of age?
NO
ER42 Will any of the participants be interviewed in situations which will compromise their ability to give informed consent, such as in prison, residential care, or the care of the local authority?
NO
<b>BRINGING THE UNIVERSITY INTO DISREPUTE</b>
ER43 If on the level one form you have answered YES that some aspect of the proposed research "might bring the University into disrepute", please elaborate alongside how this might arise, and what steps will be taken by the researcher to mitigate and/or manage this, to minimise adverse consequences to the University.

Subsequent to submission of this form, **both the applicant and their supervisor should review any alterations in the proposed methodology of the project.** If the change to methodology results in a change to any answer on the form, then a resubmission to the Ethics subgroup is required.

The principal investigator is responsible for ensuring compliance with any additional ethical requirements that might apply, and/or for compliance with any additional requirements for review by external bodies.

ALL forms should be submitted in electronic format. Digital signatures or scanned in originals are acceptable. The applicant should keep a copy of all forms for inclusion in their thesis.

\_\_\_\_ Natalie Clinkscales \_\_\_\_\_ 10.12.18  
 Applicant's Name Applicant's Signature Date

\_\_\_\_ \_\_\_\_\_ Angus MacBeth \_\_\_\_\_ 06/12/18 \_\_\_\_\_  
 \*Supervisor Signature<sup>6</sup> Supervisor Name Date

\*NOTE to Supervisor: Ethical review will be based only on the information contained in this form. If countersigning this check-list as truly warranting all 'No' answers, you are taking responsibility, on behalf of the HSS and UoE, that the research proposed truly poses no ethical risks.

ER44 ISSUES ARISING FROM THE PROPOSAL	
<p>I can confirm that the above application has been reviewed by two independent reviewers. It is their opinion that:</p> <p>a) Ethical issues have been satisfactorily addressed and no further response from the applicant is necessary,  OR</p> <p>b) The ethical issues listed below arise or require clarification:</p> <p>The following areas of ethical concern require either further clarification or consideration:</p> <p>ER2. Although the data will be pseudo-anonymised, consideration needs to be given of the identifiable data that will be stored until transcription is complete. The fact that data will be linkable to consent forms with names included also means these are not fully anonymous.</p> <p>ER5. Training is not n/a in this case as data will be sensitive until the completion of transcription.</p> <p>ER11. Please can you check with with Rena Gertz whether consent forms should be stored as long as the data are stored.</p> <p>ER25. In the information sheet and protocol it is made clear that the interviews could induce distress. This should be made explicit on the application form.</p> <p>ER27. It would be helpful to consider management of disclosures of potential malpractice (as above, this is noted in the protocol but not here on this form).</p> <p>ER40. There are specific ethical challenges of recruiting one's own work colleagues into the study.</p> <p>The applicant should respond to these comments in section 8 below.</p> <p>Signature:</p> <p>Position: Chair SREC</p> <p>Date: 19.01.19</p>	
ER45 APPLICANT'S RESPONSE (if required)	

<sup>6</sup> Not required for staff applications

Thank you for the feedback. Responses are given below:

**ER2. Although the data will be pseudo-anonymised, consideration needs to be given of the identifiable data that will be stored until transcription is complete. The fact that data will be linkable to consent forms with names included also means these are not fully anonymous.**

Low risk – all identifiable information (i.e. paper-based consent forms and demographics) will be stored securely on NHS Grampian premises. This information will be stored separately from all encrypted audio data and from verbatim pseudo-anonymised transcripts which will be stored securely on the NHS Grampian server. Data collected for this study will only be accessible to the lead researchers and supervisors. Pseudo-anonymised transcripts may be linked back to the original participant only in circumstances where they withdraw participation, and only by the lead researcher or supervisors, in which case appropriate protocol will be followed.

**ER5. Training is not n/a in this case as data will be sensitive until the completion of transcription.**

The researcher has undertaken all mandatory information governance and data protection training within their NHS health board as part of their role. In addition, the researcher will follow good practice guidelines of both the University of Edinburgh and NHS Grampian.

**ER11. Please can you check with with Rena Gertz whether consent forms should be stored as long as the data are stored.**

Dr Rena Gertz has advised that consent forms should be kept for up to three years following completion of the study. Consent forms will be stored securely on NHS Grampian premises for up to three years following study completion.

**ER25. In the information sheet and protocol it is made clear that the interviews could induce distress. This should be made explicit on the application form.**

It is not anticipated that this research will cause any distress to participants, however, participants will be asked about their experience of working with women who have experienced perinatal mental health difficulties, therefore this could be an emotive topic and may bring up issues that are potentially sensitive for individual participants. Any concerns can be discussed at the time of the interview and in addition all participants will be made aware of confidentiality protocols, their right to withdraw from the study at any time and they will be offered debriefing information. Any issues that arise will be discussed in supervision and appropriate action will be taken.

**ER27. It would be helpful to consider management of disclosures of potential malpractice (as above, this is noted in the protocol but not here on this form).**

As this study involves exploring staff attitudes and experiences it is possible that participants may disclose aspects of their practice that may concern the researcher. All participants will be informed that their information will be kept confidential except in instances where there may be a risk of harm to themselves or others. In addition, participants will be made aware that their anonymised information will be discussed in supervision. Any concerns will be discussed in supervision. Any identification of potential malpractice will be managed using appropriate protocols for individual health boards.

**ER40. There are specific ethical challenges of recruiting one's own work colleagues into the study.**

Some of the participants within this study may be healthcare professionals working within the same health board as the researcher, however, these professionals will be recruited from a vast variety of services across three health boards. Therefore, it is unlikely that the lead researcher, as a trainee clinical psychologist only exposed to a small number of services in NHS Grampian, will have a close professional relationship with any of the participants. If this does arise or there appear to be any conflicts of interest affecting recruitment or participation in the study this will be addressed in supervision and appropriate action will be taken.

Signature:

Date: 30.01.19

ER.06 CONCLUSION TO ETHICAL REVIEW (if required)

The applicant's response to our request for further clarification or amendments has now satisfied the requirements for ethical practice and the application has therefore been approved.

Signature:

Position: Lecturer

Date: 02/02/2019

<sup>ER47</sup> AMENDMENT/S: REQUEST FOR APPROVAL

Subsequent to receipt of ethical approval above, I, the applicant, would like to request the following amendment/s to my original proposal.

To conduct interviews via telephone and video conferencing, as appropriate, for participants in rural locations to which travel is not feasible due to time and financial constraints.

Signature:

Date: 20.09.19

<sup>ER48</sup> CONCLUSION TO ETHICAL REVIEW OF AMENDMENT

I can confirm that the above amendment has been reviewed:

- a. Ethical issues have been satisfactorily addressed and no further response from the applicant is necessary,

Signature:

Position:  
Ethics and  
Integrity  
Lead

Date:  
24/09/19

Acronyms / Terms Used

NHS: National Health Service

SHSS: School of Health in Social Science



25 March 2019

Miss Natalie Clinkscapes  
Trainee Clinical Psychologist  
Royal Cornhill Hospital  
Aberdeen  
AB25 2ZH

Dear Miss Clinkscapes,

**R&D MANAGEMENT APPROVAL – TAYSIDE**

**Title: A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties.**

**Chief Investigator: Miss Natalie Clinkscapes**

**Principal Investigator/Local Collaborator: Miss Natalie Clinkscapes**

**Tayside Ref: 2018MH05      NRS Ref: NRS18/253719      IRAS ID: 253719**

**REC Ref: CLIN556**

**Sponsor: University of Edinburgh**

**Funder: Unfunded**

Many thanks for your application to carry out the above project here in NHS Tayside. I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in Tayside.

Approval is granted on the following conditions:-

- ALL Research must be carried out in compliance with the Research Governance Framework for Health & Community Care, Health & Safety Regulations, data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).
- All amendments to be notified to TASC R&D Office via the correct amendment pathway. Either direct to the R&D Office or via the Lead Co-ordinating Centre depending on how the study is set up.
- All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS Tayside where required (<http://www.nihr.ac.uk/about-us/CCF/policy-and-standards/research-passports.htm>).
- TASC R&D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally.



- Notification to TASC R&D Office of any change in funding or an extension to study timelines.
- As well as any obligations to your Sponsor, you are required to notify [TASCGovernance@dundee.ac.uk](mailto:TASCGovernance@dundee.ac.uk) of all serious breaches of GCP and Serious Unexpected Serious Adverse Reactions (SUSARs) for Hosted Clinical Trials of Investigational Medicinal Products (CTIMPs).
- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.
- All eligible and adopted studies will be added to the Central Portfolio Management System (CPMS). Recruitment figures for eligible and adopted studies must be recorded onto the Portfolio every month. This is the responsibility of the lead UK site. If you are the lead, or only UK site, we can provide help or advice with this. For information, contact the local Portfolio team at [tascportfolio.tayside@nhs.net](mailto:tascportfolio.tayside@nhs.net).
- Annual reports are required to be submitted to TASC R&D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.
- Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to TASC R&D Office.
- You may be required to assist with and provide information in regard to audit and monitoring of study.

**Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.**

#### Approved Documents

Document	Version	Date
<b>Ethics - Department of Clinical and Health Psychology Ethics Research Panel Approval Letter</b>		08/02/19
<b>Participant Information Sheet</b>	2	07/12/18
<b>Consent Form</b>	1	08/11/18
<b>Recruitment Poster</b>		
<b>Study Protocol</b>	1	19/10/18
<b>CV – Natalie Clinkscales</b>		
<b>CV – Angus MacBeth</b>		

May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact TASC R&D Office should you require further assistance.

Yours sincerely

Elizabeth Coote  
Head of Non-Commercial Research Services

## Appendix 7: Research and Development Approval NHS Grampian

**Research and Development** Foresterhill House Annexe  
Foresterhill  
ABERDEEN  
AB25 2ZB



Miss Natalie Clinkscales	Date	8/03/2019
NHS Grampian	Project No	2018MH005
Block A		
Block D, Royal Cornhill Hospital	Enquiries to	Louise
Aberdeen	Extension	53846
AB252ZH	Direct Line	01224 553846
	Email	grampian.randdpermissions@nhs.net

Dear Miss Clinkscales

### **Management Permission for Non-Commercial Research**

**STUDY TITLE:** A qualitative exploration of community healthcare professionals experiences of working with women with Perinatal Mental Health difficulties.  
**PROTOCOL NO:** v1, 19/10/18  
**REC REF:** N/A  
**NRS REF:** NRS18/253719

Thank you very much for sending all relevant documentation. I am pleased to confirm that the project is now registered with the NHS Grampian Research & Development Office. The project now has R & D Management Permission to proceed locally. This is based on the documents received from yourself and the relevant Approvals being in place.

All research with an NHS element is subject to the UK Policy Framework for Health and Social Care Research (2017 v3), and as Chief or Principal Investigator you should be fully committed to your responsibilities associated with this.

**R&D Permission is granted on condition that:**

- 1) The R&D Office will be notified and any relevant documents forwarded to us if any of the following occur:
  - Any Serious Breaches in Grampian (Please forward to [pharmaco@abdn.ac.uk](mailto:pharmaco@abdn.ac.uk)).
  - A change of Principal Investigator in Grampian or Chief Investigator.
  - Any change to funding or any additional funding
- 2) When the study ends, the R&D Office will be notified of the study end-date.
- 3) The Sponsor will notify all amendments to the relevant National Co-ordinating centre. For single centre studies, amendments should be notified to the R&D office directly.

We hope the project goes well, and if you need any help or advice relating to your R&D Management Permission, please do not hesitate to contact the office.

Yours sincerely

**Susan Ridge**  
**Non-Commercial Manager**

cc: CI/Sponsor  
Research Monitor

**Sponsor:** University of Edinburgh

## Appendix 8: Research and Development Approval NHS Highland

Professor Angus Watson  
Research, Development & Innovation Director  
Research, Development & Innovation Division  
NHS Highland  
Centre for Health Science  
Old Perth Road  
Inverness  
IV2 3JH



Tel: 01463 255822  
Fax: 01463 255838  
E-mail: [REDACTED]

11<sup>th</sup> March 2019

NHS Highland R&D ID: **Highland 1474**  
NRSPCC ID: **NRS18/253719**

Natalie Clinkscales  
Trainee Clinical Psychologist  
NHS Grampian  
Royal Cornhill Hospital  
Aberdeen

[REDACTED]  
Dear Ms N Clinkscales,

### Management Approval for Non-Commercial Research

I am pleased to tell you that you now have Management Approval for the research project entitled: **'A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties'**.  
(Protocol V1 21/06/18)

I acknowledge that:

- The project is sponsored by **University of Edinburgh**.
- The project has **no external funding**.
- Research Ethics **approval is not required** (staff only study).
- The project is **Site-Specific Assessment exempt**.

The following conditions apply:

- The responsibility for monitoring and auditing this project lies with **University of Edinburgh**.
- This study will be subject to ongoing monitoring for Research Governance purposes and may be audited to ensure compliance with the UK Policy Framework for Health and Social Care Research (2018, V3.3 07/11/17), however prior written notice of audit will be given.



**Headquarters:**  
NHS Highland, Assynt House, Beechwood Park, Inverness, IV2 3HG

Chairman: David Alston  
Chief Executive: Elaine Mead

- Any researchers coming into NHS Highland for the purposes of carrying out research with patients will require a Letter of Access before starting the study at this site. Please contact Anna McIver ([anna.mciver@nhs.net](mailto:anna.mciver@nhs.net)) for further assistance, if this is required.
- You are reminded that all amendments (minor or substantial) to the protocol and associated study documents or to the REC application should be copied to the NHS Highland Research and Development Office to obtain a R&D amendment approval letter. Guidance can be found at <https://www.nhsresearchscotland.org.uk/services/permissions-co-ordinating-centre/permissions>
- The paperwork concerning all incidents, adverse events and serious adverse events, thought to be attributable to participant's involvement in this project should be copied to the NHS Highland R&D Office. Please email documents to Anna McIver, RD&I Facilitator ([anna.mciver@nhs.net](mailto:anna.mciver@nhs.net)).
- If applicable, monthly recruitment rates should be notified to the NHS Highland Research and Development Office, detailing date of recruitment and the participant trial ID number. This should be done by e-mail on the first week of the following month, to Debbie McDonald, RD&I Data Manager ([debbie.mcdonald@nhs.net](mailto:debbie.mcdonald@nhs.net)).
- Please report any other changes in resources used, or staff involved in the project, to the NHS Highland Research and Development Manager, Frances Hines (01463 255822, [frances.hines@nhs.net](mailto:frances.hines@nhs.net)).


*Please quote your RD&I Highland reference number (Highland 1474).*

Yours sincerely,



Frances Hines  
RD&I Manager

cc [Frances Hines](#), R&D Manager, NHS Highland Research, Development & Innovation Division, Phase 3, The Centre for Health Science, Old Perth Road, Inverness, IV2 3JH.

[Angus Macbeth](#), Dept of Clinical and Health Psychology, School of Health in Social Science, The University of Edinburgh, EH8 9AG. 

## Appendix 9: Acknowledgment of Amendment NHS Highland

### **NHS Highland**

R&D Ref No: **1474**  
REC Ref No: **NA**  
NRS Ref No: **NRS18/253719**  
EudraCT Ref No: **NA**  
MHRA Ref No: **NA**  
Today's Date: **29/10/2019**

Frances Hines  
Research, Development & Innovation Manager  
NHS Highland Research, Development &  
Innovation Department  
Centre for Health Science  
Old Perth Road  
Inverness  
IV2 3JH  
Tel: 01463 255821  
E-mail: frances.hines@nhs.net  
www.nhshighland.scot.nhs.uk



Ms. Natalie Clinkscales  
Trainee Clinical Psychologist  
NHS Grampian  
Royal Cornhill Hospital  
Aberdeen  
By email:

Dear Ms Clinkscales,

#### **LETTER OF ACKNOWLEDGEMENT OF YOUR RESEARCH PROJECT AMENDMENT**

**PROJECT TITLE:** A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties

**REC:** NA  
**NHS Highland R&D Ref Number:** 1474

<b>Amendment Type:</b>	<b>Substantial (SA)</b>	
	<b>Modified SA</b>	
	<b>Non-substantial (NSA)</b>	√
<b>Amendment No:</b>	<b>NSA 01</b>	
<b>Amendment Date:</b>	<b>26.09.19</b>	
<b>Current Protocol Version No:</b>	<b>V2 Dated 20.09.19</b>	

(R)\Common\Management\Research Governance\Management Approval Letters\2019 Management Approval



Headquarters: Assynt House, Beechwood Park, INVERNESS IV2 3BW

Interim Chair: Professor Boyd Robertson  
Chief Executive: Iain Stewart



We have been notified of the above amendment to your research project and have received the following documents:

- Notification of Non-Substantial Amendment form.
- Amended documents corresponding with those itemised in the above form.
- REC Approval was not requested in this instance.

The **RD&I Division**, NHS Highland, is happy to **acknowledge** this amendment as it is within the scope of the original Management Approval Letter (11.03.19).

Yours sincerely,

Frances Hines  
NHS Highland Research, Development & Innovation Manager



## Participant Information Sheet



You are invited to take part in the following research project: ***A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties***

Before you decide to take part, it is important you understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

### What is the study about?

The aim of this study is to explore community-based healthcare professionals' experiences of working with women who have perinatal mental health difficulties (during pregnancy or up to one year following childbirth). It is hoped that by understanding the personal experiences and attitudes of the people working with these women (such as yourself) we can identify service or training needs and improve service provision for women experiencing perinatal mental health difficulties.

### Why have I been asked to take part?

You have been asked to take part as you are a community-based healthcare professional with experience of working with women with perinatal mental health difficulties.

### Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect your employment or your legal rights.

### What will taking part involve?

Taking part in this study will involve participating in an interview with the researcher which will last approximately 45-60 minutes and be conducted face to face, via telephone or via video conferencing. Modality of interview will be dependent on your location and preference as well as availability of facilities. The interviews will take place at a location convenient to you, within your health board and at a time that is suitable for you. When we meet, we will discuss further what taking part involves and you will be able to decide whether you still want to participate. Once you have given your consent we will begin the interview. I will ask you some questions about your experiences of working with women with perinatal mental health difficulties. I will record each interview using a digital recorder.

### Will my taking part in the study be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. After the interview is finished, I will download



and store the digital recordings securely on an NHS Grampian computer. Each interview will be typed out exactly as it has been recorded and all identifiable information will be kept secure on an NHS Grampian computer. I will remove your personal information (e.g. your name, health board etc.) from the typed-out transcripts so the information will be anonymous. Anonymised data from your interview will only be accessed by the research team. Direct quotes from your interview may be used in the write up of the research, however, these will be anonymised, and your personal information will be kept confidential. The only circumstance where I would need to breach confidentiality would be if you told me something that would cause me concern about your own or someone else's safety, in which case I would discuss this with you prior to acting.

NHS Grampian will use your name, and contact details to contact you about the research study. Individuals from the University of Edinburgh may look at your research records to check the accuracy of the research study. The only people in the University of Edinburgh who will have access to information that identifies you will be people who need to contact you to discuss your participation or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

NHS Grampian will keep identifiable information about you (i.e. your signed consent form) from this study for 3-6 months after the completion of this research.

#### What are the possible benefits of taking part?

There are no direct benefits, but it is hoped that gaining an understanding of the experiences of those providing care to women with perinatal mental health difficulties will help inform the future development of specialist perinatal mental health services across Scotland.

#### What are the possible disadvantages and risk of taking part?

There are no known risks to taking part in this research, however, this may be an emotive topic and may bring up issues that are sensitive to you. If you have any concerns these can be discussed with the researcher at the time of your interview. You will also be given debrief information at the end of the research with access to further information. The study will also require you to volunteer your time (approximately 1.5 hours).

#### What if I want to withdraw from the study?

Agreeing to participate in this project does not oblige you to remain in the study nor have any further obligation to this study. If, at any stage, you no longer want to be part of the study, please inform the Lead Researcher (Natalie Clinkscales; Natalie.clinkscales@nhs.net). You should note that your data may be used in the production of formal research outputs (e.g. journal articles, conference papers, theses and reports) prior to your withdrawal and so you are advised to contact the research team at the earliest opportunity should you wish to withdraw from the study. On specific request we will destroy all your identifiable answers, but we will need to use the data collected and analysed prior to your withdrawal, and to maintain our records of your consenting participation.

#### What will happen with the information collected?

Information from all interviews conducted will be used to establish any common themes or similarities between people's experiences. The analysis of the research will be written up and discussed in relation to previous research in this area. I will include anonymised direct quotes from interviews as part of my analysis, however, I will not include any personally identifiable information within the write up of

the research. The results of this study may be summarised in published articles, reports and presentations. If you would like a copy of the results please provide your email address to the researcher.

All data collected during this research will be stored securely and in line with data protection guidelines. Consent forms will be stored for approximately 3-6 months. Interview transcripts and demographic questionnaires will be stored for 5 years after the end of the study. These may be used for future ethically approved research. ***When you agree to take part in a research study, the information you provided to researchers may be provided to researchers running other research studies in this organisation and other organisations. These organisations may be universities, NHS organisations or companies involved in health and social care research. Your information will only be used to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and social care research and cannot be used to contact you or affect your employment.*** You can find more about how we use your information and our legal basis for doing so in our Privacy Notice at [www.nhsforthvalley.com/privacy-policy](http://www.nhsforthvalley.com/privacy-policy)

#### Who is organising the research and why?

The lead researcher is a Trainee Clinical Psychologist completing their Doctorate level training in Clinical Psychology at the University of Edinburgh in conjunction with NHS Grampian. This research is being conducted as part of a thesis project which is an essential component of this training.

The University of Edinburgh is the sponsor for this study based in Scotland. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information <https://www.ed.ac.uk/records-management/data-protection> or by contacting the data protection officer on the details below.

#### Who has reviewed the study?

The study proposal has been reviewed by Dr Angus MacBeth (Research Supervisor) and Charlotte Smith (Research Governance Officer). A favourable ethical opinion has been obtained from the University of Edinburgh. In addition, appropriate approvals have been sought from the NHS Research and Development committee.

**If you are interested in taking part, or would like more information please contact Natalie Clinkscales (Lead Researcher):** \_\_\_\_\_

If you would like to discuss this research with someone independent of the study team please contact:

Dr Helen Griffiths  
Programme Director: Doctorate in Clinical Psychology  
Department of Clinical and Health Psychology  
School of Health in Social Science  
University of Edinburgh

Teviot Place  
EH8 9AG  
Tel no: 0131 6503482  
helen.griffiths@ed.ac.uk

If you wish to make a complaint about the study please contact NHS Grampian:

NHS Grampian Feedback Service  
Summerfield House  
2 Eday Road  
Aberdeen  
AB15 6RE  
Tel: 0345 337 6338; E-mail [nhsgrampian.feedback@nhs.net](mailto:nhsgrampian.feedback@nhs.net)

If you wish to raise a complaint on how we have handled your personal data you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at <https://ico.org.uk/>

Data Protection Officer contact information:

University of Edinburgh  
Data Protection Officer  
Governance and Strategic Planning  
University of Edinburgh  
Old College  
Edinburgh  
EH8 9YL  
Tel: 0131 651 4114; Email:

**Consent Form**

***A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties***

This form is aimed at providing you with the additional information you need to decide whether you wish to consent to take part in this study. Please take some time to consider the participant information sheet before agreeing to take part. If you have any further questions before signing this consent form, please discuss these with the researcher.

Once you have had the opportunity to read the information please **initial the boxes** if you agree with the statements and wish to participate in the study.

Please Initial  
as appropriate

***I confirm that I have read and understood the information sheet (Version 3, 20 September 2019) and have had the opportunity to consider this information and have any questions answered to my satisfaction.***

***I understand that my participation in this study is voluntary and that I have the right to withdraw any time without giving a reason and this will not affect my future employment or legal rights.***

***I understand that I have the right to choose not to answer any questions that are asked or not to provide information as I wish to.***

***I understand that my anonymised data will be stored for a minimum of 5 years and may be used in future ethically approved research.***

***I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor (the University of Edinburgh) or from the/other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records***

***I agree to take part in the above study***

Name of person giving consent

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Name of person taking consent

Date

Signature

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Original (x1) to be retained in site file. Copy (x1) to be retained by the participant.

Appendix 12: Demographics Questionnaire

**Demographics Questionnaire**

<b>Age</b>	
<b>Gender</b>	
<b>Profession</b>	
<b>Years Qualified</b>	
<b>Location</b>	
<b>Service worked in</b>	
<b>Post-Qualification training in Perinatal Mental Health (Please give detail)</b>	
<b>Post-Qualification training in Psychological Therapies (Please give detail)</b>	

Would you like to receive a summary of results via email following the end of the study?

Please tick one box: Yes:  No:

## Interview schedule

### *A qualitative exploration of community healthcare professionals' experiences of working with women with Perinatal Mental Health difficulties*

To be used as points for discussion rather than direct questions, to be guided by what the participant says - not all questions will be required for all participants depending on what they bring to the interview. Prompts to be used where appropriate as per IPA interview methodology.

1. Can you tell me about the experiences that prompted you to participate in this research?

Follow up:

- Could you tell me about a typical case or presentation that comes to mind when you think about PMH?
- How did you feel working with this client group? Did you experience any challenges?
- How do you feel about the way PMH was addressed within your professional training?

2. What were the signals that alerted you to the possibility that a woman was experiencing PMH problems?

Follow up:

- I'm wondering whether diagnosis played a role in your decision making?
- How do you think this may have shaped the process for the woman?
- Were there any concerns relating to risk?

3. What factors do you think might be involved in the development of perinatal mental health problems?

Follow up:

- What do you think influences a woman's decision to seek help?
- What information about PMH is given during the ante-natal period?

4. Can you tell me about the types of support or treatments that were considered or offered to the women you were working with?

Follow up:

- What treatments were available and were they effective? – talking therapy, medication?
- Were treatment options discussed with the woman?
- Did the woman request any specific treatment approaches?
- What role do non-professionals play?

5. Can you tell me about your experience of accessing support/advice from your colleagues either formally or informally during this work?

Follow up:

- Did you make/receive a referral to/from another service?
- What processes were involved in deciding to make/accept this referral?
- How did you find the process of referring a woman on to further services?
- Tell me about any opportunities you have had to engage in formal consultation or training in PMH?

6. What do you think are the unique needs of women experiencing PMH in your area?

Follow up:

- What do you think needs to change or develop in the delivery of perinatal mental health services in your area?

7. Do you think there are any broader changes that need to happen to improve perinatal mental health? – I.e. public health, education, societal understanding

#### Appendix 14: Excerpts from researchers' reflective journal

Entries written during early stages of analysis:

“The code 'superiority of mental health' may not quite capture what I am looking to capture and may also be quite jarring. However, I am trying to outline a feeling that those working in mental health seem to be far better supported than those working in primary care (maternity/health visiting and probably GPs) when it comes to perinatal mental health... while they still don't have the 'specialist' training that is perhaps needed they do have mental health training which in some ways gives them the confidence to manage these cases even when they are more challenging, they also have access to a team of mental health professionals for additional support and guidance, as well as the likelihood of some form of supervision, in some cases generic and in others more specialist... whereas primary care staff don't have that level of background training or easy access to mental health colleagues which leaves them feeling underconfident, anxious and unsupported? This is then potentially misunderstood by MH colleagues because they are in a 'superior' place of knowledge and experience and are unable to see from another's perspective?”

“This is interesting because for this participant the view of psychology seems to be as only being able to offer psychological therapy, and so the question becomes about a woman's readiness for therapy and whether it's the appropriate time etc... which seems to be a commonly held view... why is the role of psychology not broader? Why is it not considered to be part of an MDT approach? This seems problematic, especially when psychological awareness and understanding is so important.”